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STRENGTHENING ETHICAL AND REGULATORY FRAMEWORKS FOR CLINICAL TRIALS IN LUSOPHONE AFRICA: INSIGHTS FROM THE CT-LUSO PROJECT

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Abstract: The CT-Luso Project is an ethical and regulatory capacity-building iniciative in clinical trials, funded by the EDCTP3 Programme, with support from the European Union. Its main goal is to strenghten the legal Framework for biomedical research in the five Portuguese-speaking African countries (PALOP): Angola, Cape Verde, Guinea-Bissau, Mozambique and São Tomé and Príncipe.

Given the growing expansion of clinical research in low/middle-income countries, it is essential to ensure robust regulatory systems that protect participants, retain research benefits locally and allign with international standards, such as Good Clinical Practice and EU

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Regulation No. 536/2014. A comparative legal analysis of the PALOP revealed significant regulatory heterogeneity and differing levels of development. Based on these findings, CT-Luso proposed a roadmap to align national legislation with international best practices and harmonize legal frameworks across partner countries, establishing the foundation for a PALOP clinical trials hub supported by a robust Policy Strategic Action Plan.

Keywords: Clinical Trials; International Good Research and Clinical Practices (BPC/GCP); Portuguese-speaking African Countries; Harmonization.

1. Introduction: Objectives and Methodologies of an Ambitious Project

CT-Luso[1] is an ethical and regulatory capacity-building project in the field of clinical trials in Portuguese-speaking African countries (PALOPs). It is approved and funded by the EDCTP3 Programme – the European and Developing Countries Clinical Trials Partnership, with the support of the European Commission. The project involves the active participation of the five PALOPs - Angola, Cape Verde, Guinea-Bissau, Mozambique, and São Tomé and Príncipe - through their Medicines Regulatory Authorities (MRAs), Research Ethics Committees (RECs), universities, national health institutes, research centres, and other relevant national institutions in the field.

The project's main objective is to promote the convergence of national legislation with international good research and clinical practices (BPC/GCP), complying with the ethical requirements and, second, to promote the harmonization between the legislation of the five partner countries as a fundamental and indispensable foundation for the establishment of a Portuguese-speaking African hub for clinical trials. In fact, the most ambitious goal is to establish a Portuguese-speaking research hub that is both, scientifically competitive and ethically grounded, thus becoming capable of attracting international collaborations, while ensuring the protection of participants, the retention of benefits at the national level, and the development of high-quality healthcare and research focused on locally relevant diseases.

As part of these broader objectives, a legislative international workstream was

1 CT-Luso <https://ct-luso.com/>, accessed 10 November 2025.

undertaken to support the establishment and strengthening of national ethical and legal frameworks for clinical research composed by nine legal experts: four members of the Centre for Biomedical Law (Portugal) and one legal expert appointed by the Ministry of Health of each PALOP. This study is based on their work and specifically aims to: (1) present the existing legislative and regulatory frameworks governing biomedical and clinical research in each country; (2) conduct a comparative analysis against international standards and best practices; (3) identify potential regulatory and ethical gaps; (4) and provide recommendations to promote alignment with global guidance and regional harmonisation within the PALOPs.

All five countries share a common language and, in some way, a legal heritage rooted in the Portuguese legal tradition, typical of continental Europe. This legal model is characterised by a codified system of law in which legislation constitutes the primary source, while judicial decisions play a complementary role. The Civil Codes of these countries exhibit significant similarities, particularly regarding the protection of personality and fundamental rights, since the general part and law of obligations are the same as in Portugal – enacted in 1966, still during the colonial period.[2] Over recent decades, the constitutional frameworks of the PALOPs have evolved to emphasise fundamental rights such as the right to life, moral and physical integrity, the right to health, and the right to to access to, participate in and benefiting from scientific research, reflecting a growing commitment to human dignity and social justice.

The overarching purpose of the CT-Luso project is therefore to strengthen and empower national systems in order to foster an ethically driven, sustainable, and collaborative research ecosystem within the Portuguese-speaking African community and open to the international realm. This strengthening is essential to prevent situations where the lack of an adequate legal framework compromises the evaluation, approval and monitoring of clinical trial protocols, highlighting regulatory gaps.[3]

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2 Fernando Dias Simões, 'Portuguese-speaking Africa and the Lusophone legal system: All in the family?' (2017), 76(1) African Studies <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2920891>, accessed 20 December 2025.

3 In Cabo Verde, a clinical trial proposal submitted in 2019 did not proceed due to unmet conditions, highlighting structural constraints in the national research systems. At the time, the absence of a specific legal Framework governing clinical trials was identified as a key barrier, illustrating how regulatory gaps can hinder the development and implemen-

Through initiatives like CT-Luso, the Portuguese-speaking African countries can thus consolidate their institutional frameworks, reduce dependence on external regulatory expertise, and progressively assert a stronger, autonomous role in the governance and conduct of clinical research in Africa. Furthermore, strengthening ethical and regulatory frameworks for clinical research in Portuguese-speaking African countries is not only a regional priority but also a matter of global health law. As clinical trials increasingly expand into low- and middle-income countries, ensuring robust, transparent and harmonized governance systems becomes essential to safeguard patients, ensure data integrity and support equitable international research collaborations.

In this context, this work, by addressing legal and ethical gaps in clinical research governance, has broader implications beyong Lusophone Africa and contributes to ongoing global efforts to promote ethical consistency, regulatory harmonization, and capacity building in clinical research, which are central to advancing global health equity and strengthening trust in international research collaborations. It highlights the challenges of regulatory fragmentation, capacity constraints, and legal gaps, offering insights into how context-sensitive approaches can support the development of effective and accountable research governance frameworks. The meaningful participation of these countries in global clinical research is essential to ensure that study populations are diverse and that research findings are generalizable across differente settings. At the same time, strengthening national regulatory systems is a prerequisite for equitable partnerships, preventing exploitative practices and ensuring that local population benefit from research conducted in their contexts.

2. Mapping National Realities and Pathways to Harmonisation

Africa has a significantly lower number of clinical trials than any other continent: 845, which corresponds to around 1,1% of the 76.331 clinical trials iniciated globally in 2023. Between 1999 and 2023, in the five Portuguese-speaking African countries, only 420 of the 17.425 clinical trials conducted across the African continent were carried out. During this period, these countries recorded figures below the African average (17 clinical trials), with an average of just 8 clinical trials conducted. Individually, during these years,

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tation of clinical research. Expresso das Ilhas, 'Cabo Verde recebeu pedido para ensaio clínico que não chegou a avançar' (17 February 2020) <https://expressodasilhas.cv/pais/2020/02/17/cabo-verde-recebeu-um-pedido-para-ensaio-clinico-que-nao-chegou-a-avancar/68023>, acessed 20 December 2025.

Angola accounted for 47 clinical trials, Cape Verde conducted 24, Guinea-Bissau 98, Mozambique 229 and São Tomé and Príncipe 22.[4]

The pursuit of regulatory harmonisation in clinical research across Lusophone Africa must begin with an understanding of each country's distinct historical, institutional, and socio-political realities. While the overarching objective is to achieve convergence around shared scientific, ethical, and legal standards, the starting points are markedly diverse. Each national system reflects a unique trajectory shaped by legacies, legal and cultural traditions, administrative capacity, political ideology and stability and the evolving influence of international and regional organisations. Recognising these contextual differences is essential to designing feasible and inclusive pathways toward harmonisation that respect national sovereignty while complying with high international standards of good clinical practice.[5] Therefore, legislative convergence with international best practices and legislative harmonisation among the five Portuguese-speaking African countries, should not be conceived as an external procedure of uniformization imposed, but rather as a gradual and dialogical process of alignment, built upon the reinforcement of national capacities, the permeability of international norms to local contexts, and the promotion of regional cooperation.[6] The balancing between national and supranational realities determines the success of any effort to strengthen ethical and regulatory frameworks for biomedical research. Understanding these dynamics allows for the development of context-sensitive roadmaps —

4 Carla Barbosa and others, 'CT-Luso: para uma harmonização ética e regulatória dos ensaios clínicos nos países africanos de língua portuguesa' (2025) 14(4) Cadernos Ibero-Americanos de Direito Sanitário 14 <https://doi.org/10.17566/ciads.v14i4.1398>, accessed 20 March 2026.

5 Namely Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance); and the WMA Helsinki Declaration – Ethical Principles for medical research involving human subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964.

6 Justyna Bandola-Gill and others, 'Harmonising Global Public Policy: Producing Global Standards, Local Data and Statistical Capacity Development' in Governing the Sustainable Development Goals: Quantification in Global Public Policy (Springer International Publishing 2022) 44 <https://link.springer.com/chapter/10.1007/978-3-031-03938-6_3> accessed 20 December 2025; Ilia Diedushev and Nadiia Morhun, 'The balance between unification and adaptation in legislative harmonisation: a case study of institutional support for the budget process at the local level' (2025) 15(1) Law Journal of the National Academy of Internal Affairs 27-47 <https://elar.navs.edu.ua/server/api/core/bitstreams/28d3e9bc-6552-4995-bc81-15516569e37b/content>, accessed 21 November 2025.

such as the one proposed by the CT-Luso project — that link national reforms to broader regional and global strategies for ethical, safe, and scientifically sound clinical research.

2.1. *Angola*

Angola is a country on the western coast of Southern Africa with a population exceeding 36 million inhabitants[7] and has been independent since 11 November 1975. In 2023, its Human Development Index (HDI) stood at 0.616.[8] The national legislative framework governing health research is currently undergoing a phase of consolidation. The Constitution of the Republic of Angola recognises the State's duty to promote the development of biomedical research, a principle further reinforced by the Basic Law of the National Health System,[9] which enshrines the protection of life as the supreme value.

More recently, the Law on Clinical and Biomedical Research (Law No. 7/25 of 24 July) entered into force, reflecting significant efforts to establish a robust and coherent legal framework for the conduct of clinical trials in the country.[10] This law is complemented by other relevant legal instruments, including the Personal Data Protection Law[11] and several presidential decrees that define national health policies, pharmacovigilance mechanisms and the operational framework of regulatory institutions, namely the Regulatory Agency for Medicines and Health Technologies (ARMED)[12] and the National Institute for Health Research (INIS).[13] Angola is also in the process of developing

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7 Instituto Nacional de Estatística, Resultados Definitivos do recenseamento geral da população e habitação 2024 (2025) 33 <https://www.ine.gov.ao/Arquivos/arquivosCarregados//Carregados/Publicacao_638996687409619846.pdf>, accessed 21 November 2025.

8 Programa das Nações Unidas para o Desenvolvimento, Relatório sobre o Desenvolvimento Humano 2025: uma questão de escolha (2025) 30 <https://www.undp.org/pt/angola/publications/relatorio-do-desenvolvimento-humano-2025>, accessed 21 November 2025.

9 Law No. 21-B/92, of 28 August.

10 Breaches of ethical and regulatory requirements may entail ethical-professional, administrative, civil and criminal liability, these include the suspension or termination of clinical trials for protocol violations, criminal penalties for conducting research withour prior approval, and liability under general criminal law in cases involving harm to participants, including imprisonment. Less severe infringements may constitute administrative offences subject to financial penalties (Articles 42 to 46 of Law No. 7/25 of 24 July).

11 Law No. 22/11, of 27 June.

12 Presidential Decree No. 136/21, of June 1st (Organic Statute of the Regulatory Agency for Medicines and Health Technologies – ARMED).

13 Presidential Decree No. 177/19, of 22 May (Organic Statute of the National Health Re-

supplementary regulations and strengthening institutional and technical cooperation to ensure that clinical trials are conducted in an ethical and safe manner, in accordance with international best practices.

Despite these recent advances, an analysis of the existing legislative framework reveals some shortcomings and areas for improvement when compared with international standards. We briefly outline the key areas where a revision of the law could add value, with a view to addressing gaps in international requirements and strengthening elements that could be further developed. Here are some suggestions:

a. Article 3 of Law No. 7/25, which sets out the legal definitions, chould expressly include the concept of disclosure of clinical studies, in line with internationally recognised best practices;

b. Furthermore, although referenced in presidential decrees,[14] the role of the manufacturer lacks a clear legal definition. It is therefore recommended that the Law on Clinical and Biomedical Research incorporate a definition of manufacturer as "the natural or legal person responsible for the design, manufacture, packaging and labelling of a medical device with a view to placing it on the market under its own name, irrespective of whether these operations are carried out by that person or by third parties acting on its behalf";

c. Regarding data protection, Article 16 of the Law on Clinical and Biomedical Research could be strengthened by expanding the safeguards applicable to personal data and by clarifying the conditions under which information may be disclosed to protect public health. A possible legislative solution would be to establish that all information transmitted under the law is confidential and that all individuals who become aware of such information are subject to a duty of confidentiality. This obligation would then apply without prejudice to the disclosure of information strictly necessary to safeguard public health;

d. Moreover, it whould be ensured that, even after the termination of

search Institute – INIS).

14 Presidential decree no. 180/10, of 18 August (General Basics of the National Pharmaceutical Policy) and presidential decree no. 191/10, of 1 September (Regulation on the practice of pharmaceutical activity).

their duties, all individuals who have participated in clinical studies or have otherwise become aware of their conduct remain bound by a duty of confidentiality regarding any personal data accessed. In addition, the current legal framework does not provide for the appointment of a data protection officer, an essential safeguard required under Article 38 of the General Data Protection Regulation.[15]

e. Several additional elements required by international best practices could be incorporated to address the identified weaknesses, namely, concerning conflicts of interest. Although the Law on Clinical and Biomedical Research refers to transparency, the applicable rules could be further reinforced. In particular, the Ethics Committee of the Ministry of Health[16] – responsible for assessing the ethical aspects of studies involving human subjects, based on international norms (the Declaration of Helsinki and World Health Organization recommendations) – should be required to assess any conflicts of interest involving the sponsor or investigator of a clinical study;[17]

f. Furthermore, all publications arising from clinical studies should explicitly disclose any conflicts of interest relating to the investigator, sponsor or study centre;

g. Another significant gap is the absence of a national clinical trials database, a key requirement under international good clinical practice standards.[18] It is therefore recommended that such a database be established, preferably under the responsibility of ARMED. This

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15 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance).

16 It comprises a Coordinator, a Deputy Coordinator, eleven full members (two with distinguished expertise in the field of research ethics, six with experience in health or specialist research, and three members from different fields of knowledge, including lawyers, theologians or similar professionals and representatives of civil society, with an interest in research) and a Secretariat. The Ethics Committee of the Ministery of Health is established by a decree appointing its members, issued by the Minister of Health. The Coordinator, Deputy Coordinator, members and Secretariat are proposed by the appointed members.

17 If necessary, the Ethics Committee of the Ministry of Health may consult other Institutional Ethics Committees (IECs) whenever it deems it necessary, or refer the project to the National Research Ethics Committee (CNEI).

18 Angola is planning on implementing a national clinical trials database in 2026.

database should include detailed records derived from authorisation applications, inspections conducted to verify compliance with good clinical practice, reports of suspected serious unexpected adverse reactions or serious adverse events, and justifications for the inclusion of personal data that identify or allow the identification of participants, in strict compliance with confidentiality principles;

h. Regarding post-trial monitoring, Law No. 7/25 merely refers to the "right to medical support during and after the study, if necessary", without further clarification. It is proposed that the Ministry of Health's Ethics Committee be granted explicit authority to assess and determine the conditions for clinical follow-up of participants after the conclusion of a clinical study, where justified;

i. Finally, as a fundamental component of clinical trial governance, the legal framework should clearly provide for urgent safety measures. Sponsors and investigators should be required to take all appropriate immediate actions to protect participants from any direct risk to their safety, particularly those arising from events related to the conduct of the clinical trial, the investigational medicinal product, the medical device under investigation or any other intervention. Additionally, sponsors should be obliged to promptly notify the Ethics Committee of the Ministry of Health, ARMED and other competent authorities of any identified risks and measures adopted to mitigate them.

2.2. *Cape Verde*

The archipelago of Cape Verde is located on a volcanic archipelago near the northwest coast of Africa, has an estimated population of approximately 525,000 inhabitants[19] and become independet on 5 July 1975. In 2023, the country recorded a HDI of 0.668.[20] Cape Verde is currently engaged in a process of consolidating its legislative framework for clinical and biomedical research. Although the country has several foundational instruments in place – such as the Basic Law of the National Health System and the National Health

19 World Bank Group, 'Population, total – Cabo Verde' <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=CV> accessed 22 November 2025.

20 Programa das Nações Unidas para o Desenvolvimento, Relatório sobre o Desenvolvimento Humano 2025: uma questão de escolha (2025) 30 <https://www.undp.org/pt/angola/publications/relatorio-do-desenvolvimento-humano-2025>, accessed 22 November 2025.

Policy[21] – as well as key institutions - including the National Institute of Public Health (INSP),[22] the Independent Health Regulatory Authority (ERIS)[23] and the National Committee for Health Research Ethics (CNEPS),[24] - those responsible for biomedical research have long been alerting political authorities to the need for a specific legal framework governing health research, particularly clinical trials.

It was in this context that the National Coordination and Monitoring Commission (CNCA) was established in 2021, with the mandate to draft a Health Research Act and a law creating the National Health Ethics Council[25] (CNES), which is intended to restructure and regulate the activities of the current CNEPS. The Draft Health Research Act, completed in 2022, sets out universal ethical principles, strengthens the responsibilities of researchers and establishes clearer mechanisms for the authorisation, supervision and oversight of clinical trials. To date, its approval is still pending and is expected by 2026. In parallel, the Government intends to enhance the technical capacity of relevant institutions and to ensure that health research conducted in the country is aligned with internationally recognised ethical and scientific standards.

In Cape Verde, breaches of ethical and regulatory requirements may constitute administrative offences, Including conducting research without prior authorisation or ethics approval, failure to obtain informed consent, continuation of suspended studies, or non-compliance with safety obligations.[26] Notwithstanding these positive developments, the draft legislation presents

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21 Law No. 41/IV/2004, of 5 April.
22 Regulatory Decree No. 12/2024, of 27 September.
23 Decree-Law No. 3/2019, of 10 January (Independent Health Regulatory Authority – ERIS).
24 Decree-Law No. 26/2007, of 30 July (National Committee on Health Research Ethics – CNEPS).
25 The CNES oversees the ethical compliance of health research in relation to the health research projects submitted to it, based on internationally recognised ethical principles, established on the Declaration of Helsinki. It comprises a section with specific responsibility for the evaluation of clinical trials involving medicinal products and research into medical devices, cosmetics and personal care products, and a section with specific responsibility for the evaluation of all health-related research not covered by the former. Its members are individuals of recognised merit and integrity, chosen for their competence and professional experience in their respective fields, preferably with expertise in ethics, bioethics and health research. The members of the CNES are appointed by order of the Government member responsible for health, published in the Official Gazette.
26 These violations can result in administrative sanctions, without prejudice to potential civil, disciplinary or criminal liability.

some weaknesses that could be addressed significantly improving the law in terms of its convergence with international best practices. We highlight here the most relevant aspects:

1. References to risk–benefit assessment are brief,27 and it remains unclear whether such assessments may be reviewed during a clinical study. It would be advisable that a legislative solution be adopted granting CNES and ERIS, within their respective areas of competence, the authority to assess and reassess the risk–benefit balance at any stage of the clinical trial, to draw conclusions based on that assessment, and to supervise the conduct of the trial and the maintenance of the approved conditions;

2. Although the draft act includes some important definitions, there is still possibility to improvement, introducing other essential concepts in this field. For example, it would be advisable to add a definition of a clinical study involving a medical device, covering any investigation involving medical devices or their accessories that fall within the scope of medical device legislation. The objectives of such studies would include, *inter alia*, verifying the performance of the device; identifying any undesirable side effects under normal conditions of use and assessing whether they pose risks in relation to the intended use in accordance with the *leges artis*; and conducting post-marketing clinical follow-up;

3. Furthermore, given that clinical trials involving cosmetic and personal hygiene products are repeatedly referenced throughout the text, a specific definition of such trials should also be introduced;

4. In addition, the concept of a research centre could be clarified and defined as an entity where research is conducted and which is equipped with adequate material and human resources, whether integrated into a public or private healthcare establishment, laboratory or other facility, and regardless of its location within national or international territory;

27 Articles 7/1/e) and 8/1/b).

5. Regarding data protection and confidentiality, the draft does not explicitly establish that all individuals who, in any capacity, have access to information relating to health research are subject to a duty of confidentiality, without prejudice to the disclosure of information strictly necessary to safeguard public health;

6. It would also be worthwhile introducing additional roles that are standard under international good clinical practice, in particular, the role of the monitor defined as a function responsible for ensuring that data are accurately recorded and that the storage, distribution, return and documentation of investigational products and materials comply with applicable standards. Similarly, the concept of an auditor could be incorporated and defined as the individual responsible for verifying that data is accurately recorded, analysed and reported through systematic and independent reviews of activities and documents related to the clinical study;

7. Moreover, the establishment of a national database for clinical studies should be considered a priority. The current draft refers only to the publication of study results in scientific journals, which is considered insufficient under international best practices. A legislative provision could therefore be introduced assigning ERIS responsibility for creating and maintaining a database of clinical trials and clinical studies involving medical devices conducted in research centres located within national territory, in strict compliance with data confidentiality principles. This database should include detailed records derived from authorisation applications, inspections undertaken to verify compliance with good clinical practice, reports of suspected serious unexpected adverse reactions or serious adverse events, and justifications for the inclusion of personal data that identify or allow the identification of participants;

8. Finally, from a structural perspective, although clinical studies involving medical devices, cosmetic products and personal hygiene products are addressed throughout the draft, the legal framework would benefit from the establishment of distinct and dedicated sections for each category, to clarify the specific requirements and regulatory expectations applicable to each type of study.

2.3. *Guinea-Bissau*

Guinea-Bissau is situated in West Africa and is independent since 24 September 1973. It has a population of approximately 2.2 million inhabitants.[28] In 2023, the country recorded a HDI of 0.514.[29] Guinea-Bissau, despite being a small country with a largely impoverished and low-educated population and marked political instability is among the analysed countries with a comparatively high number of clinical studies.[30]

The country is currently in the process of strengthening its legal and institutional framework in the health sector. The Constitution of the Republic recognises public health as a fundamental right and assigns the State responsibility for promoting the physical and mental well-being of the population,[31] guided by principles of prevention and the progressive socialisation of medicine. Nevertheless, Guinea-Bissau still lacks a specific legal framework governing biomedical research, creating a strategic regulatory vacuum with implications for participant protection and the oversight of health research activities.

However, there are several key institutions play important roles in the coordination and ethical supervision of research, namely the National Institute of Public Health of Guinea-Bissau (INASA), the National Regulatory Authority for Pharmacies and Medicines (ARFAME, I.P.),[32] and the National Ethics Committee for Health Research (CNEPS). The national strategic plan foresees the adoption of legislation on scientific and biomedical research,[33] the establishment of research databases and study registration systems (leading to the creation of a National Register of Scientific Studies in Health), and the strengthening of the technical and regulatory capacity of these institutions by 2026. In parallel, efforts are underway to finalise and technically validate the regulatory and legal framework of the National Ethics Committee (CNEPS),

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28 World Health Organization, 'Guinea-Bissau' <https://www.afro.who.int/pt/countries/guinea-bissau>, accessed 22 November 2025.

29 Programa das Nações Unidas para o Desenvolvimento, 'Relatório sobre o Desenvolvimento Humano 2025' (n 17) 30.

30 World Health Organization, 'Number of clinical trials by year, country, WHO region and income group (1999-2022)' (2024) <https://www.who.int/observatories/global-observatoryon-health-research-anddevelopment/monitoring/number-of-clinical-trials-byyear-country-who-region-and-income-group>, accessed 22 November 2025.

31 Article 15.

32 Decree No. 13/2023, of 4 July.

33 In case of violation of ethical and regulatory provisions, the criminal law applies, according to the Articles 42 to 49 of the Draft Law on the Code of Ethics in Health Research.

followed by its approval by the Council of Ministers and subsequent promulgation, with support from the CT-Luso project and international partners.[34] Here are some legislative suggestions:

a. In this context, the Draft Law on the Code of Ethics in Health Research could benefit from the inclusion of a dedicated provision defining the key concepts used throughout the text, following, for example, the approach adopted in several European legal frameworks on clinical research. The current draft only briefly refers to the principle of primacy of the human being, underlining the need for a more explicit statment that the rights, safety and well-being of clinical trial participants must prevail over the interests of science and society. Such a framework should also ensure the implementation of adequate safeguards to protect individual privacy, as well as physical and mental integrity, throughout the conduct of clinical research;

b. On what concerns risk–benefit assessment - and pointing out here some fundamental aspects that could benefit from the attention of the competent national authorities -, the draft just states that "all biomedical research on humans must provide the people involved with a benefit that far outweighs the foreseeable risk incurred", without explicitly requiring a prior and documented assessment to support this conclusion. It would be, therefore, recommended that the law provides for a mandatory risk–benefit assessment prior to authorisation, as well as for its continuous reassessment throughout the clinical study. In addition, the respective competences of CNEPS and ARFAME, I.P. to deliberate on this matter, supervise the conduct of the clinical trial and ensure the maintenance of the approved conditions at any stage of the study should be clearly established;

c. Informed consent is rightly recognised as a cornerstone of biomedical research. However, the draft would benefit from a more detailed and structured treatment of this issue, particularly regarding vulnerable populations. The concept, scope and procedural requirements of informed consent could be further developed to ensure ethical rigour, legal clarity and comprehensive protection for all participants;

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34 Namely, UNESCO, WHO, organisations and researchers working in Guinea-Bissau, until the second trimester of 2026.

d. Although the draft acknowledges respect for privacy, its provisions on data confidentiality would benefit from further elaboration. All individuals who, in any capacity, have access to personal data should be bound by a duty of confidentiality, including after the termination of their functions, without prejudice to the disclosure of information strictly necessary for the protection of public health. Furthermore, the draft does not provide for the appointment of a data protection officer, an essential safeguard for ensuring effective compliance with data protection principles. The inclusion of a provision inspired by Article 38 of the General Data Protection Regulation would therefore be advisable;

e. The incorporation of some essential elements to good clinical practice could also improve significantly the current law, namely by expliciting rules on conflicts of interest, clarifying that CNEPS is responsible for assessing conflicts involving sponsors or investigators and ensuring that such conflicts are transparently disclosed;

f. In addition, to ensure participant safety and effective oversight, the law should establish a safety and surveillance system for clinical trials, based on monitoring activities conducted under the responsibility of appropriately qualified professionals;

g. The absence of a national clinical trials database constitutes another significant gap that is worthwhile to highlight.[35] A legislative solution should therefore designate ARFAME, I.P. as the authority responsible for creating and maintaining such a database, with the objective of ensuring comprehensive registration of all clinical trials conducted in the country. This database should include information relating to authorisation applications, inspections carried out to verify compliance with good clinical practice, and reports of suspected serious unexpected adverse reactions or serious adverse events;

35 Alemayehu Duga and others, 'Strengthening national regulatory authorities in Africa: a critical step towards enhancing local manufacturing of vaccines and health products' (2025) 13(6) Vaccines (Basel) 1-7 <https://pmc.ncbi.nlm.nih.gov/articles/PMC12197664/>, accessed 23 November 2025.

h. It is also essential that the legal framework clearly refers to good clinical practice standards and provide for their supervision by ARFAME, I.P., both within and outside the context of specific research activities. This supervisory competence should extend to all aspects of the research process, including trial sites, laboratories, sponsor facilities and any other establishments whose inspection is deemed necessary;

i. One of the weaknesses of the current regulatory framework concerns authorisation procedures for clinical trials. It would advisable that the law stipulates that authorisation applications are submitted to ARFAME, I.P. by the sponsor and must include, inter alia: the study protocol; full identification of the sponsor, investigator or principal investigator and research team; the clinical trial sites involved; and the relevant competent authorities. ARFAME, I.P. should also be required to decide on the application within a maximum period of 30 days and may, on a single occasion, request additional information, suspending the deadline until receipt. Failure to comply with such a request should result in rejection of the application, thereby prohibiting the conduct of the clinical trial – following best international good practices;

j. Safety measures are very needed and urgent. Therefore, the law should explicitly require sponsors and investigators to take immediately all due measures to protect participants from any direct risk to their safety. Sponsors should also be obliged to promptly notify CNEPS, ARFAME, I.P. and other competent authorities of any identified risks and the measures adopted in response;

k. The respective roles and responsibilities of the sponsor, investigator and auditor must be clearly defined to enhance transparency and facilitate cooperation with international research partners. In addition, the role of the monitor should be introduced as a key function responsible for ensuring accurate data recording and compliance with good clinical practice standards relating to the storage, distribution, return and documentation of materials, while keeping the sponsor continuously informed of the progress of the clinical study.

Finally, Guinea-Bissau occupies a strategically significant position within the Lusophone context due to its membership in the West African Economic and Monetary Union (UEMOA), which has made notable progress in harmonising pharmaceutical and clinical research regulatory frameworks across its member

states.[36] Instruments such as Regulation No. 02/2010/CM/UEMOA on clinical trials of medicinal products for human use establish common regional standards for the authorisation, conduct and supervision of clinical trials, thereby promoting regulatory convergence and fostering mutual recognition within the region.

This regional alignment provides Guinea-Bissau with an important opportunity — particularly in conjunction with the CT-Luso initiative — to strengthen its national regulatory capacity through cooperation, technical support, and shared oversight mechanisms. Such collaboration can help address existing legislative gaps, enhance regulatory predictability and ensure that biomedical research governance is both internationally credible and regionally coherent. Moreover, it enables Guinea-Bissau to participate more actively in regional decision-making processes, while ensuring that clinical research activities effectively serve national and regional public health priorities.

2.4. *Mozambique*

Mozambique is located in Southeast Africa and has been independent since 25 June 1975. The country has an estimated population of approximately 35.6 million inhabitants.[37] In 2023, it recorded a Human Development Index (HDI) of 0.493.[38] In recent years, Mozambique has made significant progress in consolidating a comprehensive legal and institutional framework for health research.

The legal basis for human health research in Mozambique is established by Law No. 6/2023 of 8 June, which was further regulated by Decree No. 53/2024 of 18 July and complemented by Decree No. 17/2023 of 27 April.[39] specifically governing the procedures and requirements applicable to clinical trials. This legislative framework clearly delineates the roles and responsibilities of the main institutions involved, namely the National Health Institute (INS), the

36 This is one of the reasons why it is possible to affirm the urgency of implementing the strategic plan developed by Guinea-Bissau.

37 World Population Review, 'Mozambique' <https://worldpopulationreview.com/countries/mozambique>, accessed 23 November 2025.

38 Programa das Nações Unidas para o Desenvolvimento, 'Relatório sobre o Desenvolvimento Humano 2025' (n 17) 30.

39 Conducting clinical trials with medicines, vacines and other biological and health products for human use.

National Bioethics Committee for Health (CNBS),[40] the National Medicines Authority (ANARME, I.P.)[41] and the Multi-Institutional Commission for the Oversight of Human Health Research (CFISH), thereby ensuring both the ethical protection of research participants and the scientific integrity of studies.

Despite these significant achievements,[42] some aspects of the legal framework require further refinement to achieve full alignment with international best practices that are desired to be implemented by 2026. To this end, Mozambique has developed a national implementation plan that includes continuous staff training and capacity-building iniciatives, the ongoing WHO GBT assessment of regulatory authorities and ethics committees, and a digital transformation process aimed at introducing computerized review systems. This strategic plan is designed to address the following recommendations:

a. Article 6 of the Human Health Research Act, entitled "Primacy and Rights of Participants in Human Health Research", would benefit from the inclusion of a dedicated provision on informed consent, given its status as a fundamental right of individuals participating in clinical trials. In its current form, the article does not adequately address situations involving individuals who are unable to provide informed consent. The absence of explicit references to minors and to adults lacking legal or factual capacity — together with the lack of corresponding safeguards — highlights the need for targeted legal measures to ensure both the ethical inclusion and the effective protection of vulnerable populations.Indeed, despite the overall robustness of the framework, challenges remain, particularly regarding the establishment of a national clinical trials database. Such a database is essential not only for transparency and oversight, but also for the harmonisation of regulatory approaches among the Portuguese-speaking African countries (PALOP), and international

40 Dispatch Rule No. 58/2017, of 31 August (Creation of the National Bioethics Committee for Health – CNBS).

41 Ministerial Diploma No. 20/2022, of 9 February; Decree No. 115/2020, of 31 December.

42 In Mozambique, the Human Health Research Act (Article 35) explains that breaches of clinical trial regulations may constitute administrative offences punishable by substantial fines, without prejudice to civil, criminal, or disciplinar liability. These include conducting trials without authorisation and ethical approval from ANARME, IP and CNBS, non-compliance with approved conditions, continuation of suspended studies, failure to obtain informed consent and violations of confidentiality and data protection.

best practices.[43] The legislation should therefore explicitly assign responsibility for the creation and management of this database and define the categories of data to be included, ensuring strict compliance with confidentiality and data protection principles;

b. Additional elements aligned with international ethical standards, regarding safety and oversight mechanisms, could also improve the current laws. A legislative solution would also be advisable to establish and maintain a comprehensive system for the safety monitoring and surveillance of clinical studies, with monitoring activities conducted under the responsibility of appropriately qualified professionals;

c. Furthermore, sponsors and investigators would be legally obliged to take all necessary immediate measures in response to any urgent risks to participants' safety. Sponsors should also be required to promptly notify the National Bioethics Committee for Health, ANARME, I.P., and other competent authorities of identified risks and the corrective actions implemented;

d. The legal framework should further address post-trial monitoring of participants, an aspect that is currently absent from the legislation. It should clearly assign responsibility to the Ethics Committee for assessing the conditions under which clinical follow-up is required after the completion of a trial, in accordance with ethical principles and participants' rights;

e. Finally, although the Human Health Research Act contains a glossary of definitions, it does not define the concept of clinical study disclosure, which it describes only as any form of communication intended to inform, or resulting in the informing of others, about the conduct of a clinical study. Incorporating a precise definition of this term would strengthen transparency and promote closer alignment with international best practices.

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43 Conselho das Organizações Internacionais de Ciências Médicas and Organização Mundial da Saúde, Diretrizes internacionais para pesquisas relacionadas com a saúde envolvendo seres humanos, (4th edn, 2016) 63-109 <https://ct-luso.com/pluginfile.php/729/mod_page/content/1/CIOMS%2C%20Diretrizes%20%C3%89ticas%20Internacionais%20para%20Pesquisas%20relacionadas%20com%20a%20sa%C3%BAde.pdf>, accessed 23 November 2025.

2.5. *São Tomé and Príncipe*

São Tomé and Príncipe is a country situated in the Gulf of Guinea and has been independent since 12 July 1975. It has an estimated population of approximately 241,000 inhabitants.[44] In 2023, the country recorded a Human Development Index (HDI) of 0.637. [45] São Tomé and Príncipe is currently in the process of developing, structuring, and strengthening its legislative framework for health research.

The country has established key regulatory and ethical oversight bodies, most notably the Regulatory Authority for Pharmacy, Medicines and Health Technologies (ARFAMED), which is responsible for implementing pharmaceutical policy and for regulating and supervising medicines and health products, including clinical trials. In addition, the Health Ethics Committee for Scientific Research (CESIC)[46] plays a central role in ensuring the ethical protection of research participants and in overseeing the conduct of researchers.[47] Despite the existence of these institutions, São Tomé and Príncipe does not yet have a specific legal framework governing clinical trials. For this reason, the implementation plan identifies as a priority the drafting of a specific legal framework for scientific research and clinical trials aligned with international standards, as well as the approval of the Ethics Committee's Internal Regulations in 2026.[48] Ethical and regulatory oversight is carried out by bodies such as ARFAMED and CESIC, whose authority stems from the broader health and administrative legal system. Even in the absence of explicit statutory powers tailored to clinical trials, these bodies hold the mandate to review, issue recommendations, and set conditions for the implementation of research activites. In practice, their opinions and approvals are required for the conduct of research, holding sufficient authority to both recommend and

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44 World Population Review, 'Sao Tome and Principe' <https://worldpopulationreview.com/countries/sao-tome-and-principe>, accessed 23 November 2025.

45 Programa das Nações Unidas para o Desenvolvimento, 'Relatório sobre o Desenvolvimento Humano 2025' (n 17) 30.

46 Ministerial Dispatch No. 59/2024.

47 CESIC is responsible for issuing ethical opinions on all scientific research in the field of health carried out within the national territory. It comprises nine members, representing the fields of health, biology, the humanities and the exact sciences, appointed by Ministerial Dispatch.

48 This country has also set the objective of training teams in good clinical practice and regulatory assessment, and of holding annual integrated national symposia on scientific research and clinical trials.

effectively implement standard governing clinical research. The development of dedicated legislation is therefore essential to ensure legal certainty, safeguard participant protection, and align national practices with international standards.

In this context, addressing existing gaps with respect to international requirements would be highly advantageous. Future legislation should include a provision establishing clear and comprehensive definitions of the key concepts used throughout the law — such as auditor, manufacturer, monitor, participant, sponsor, good clinical practice, informed consent, and clinical trial. These definitions should be complemented by the explicit articulation of foundational principles, including respect for human dignity and strict adherence to good clinical practice.

a. Given that informed consent constitutes one of the core pillars of clinical research, the legal framework should clearly regulate the conditions under which consent is obtained, documented, and verified. Specific provisions should further address the participation of minors and adults who lack the capacity to provide informed consent, ensuring the establishment of robust safeguards to protect these vulnerable populations;

b. Risk–benefit assessment is a structural component of ethical and scientific oversight in clinical research. It would therefore be advisable to introduce a regulatory mechanism requiring CESIC and ARFAMED, within their respective mandates, to evaluate and deliberate on the potential risks and anticipated benefits of clinical trials, as well as to supervise their implementation throughout the research process;

c. Regarding data protection, São Tomé and Príncipe currently applies Law No. 03/2016 of 10 May, which regulates the protection of personal data. Despite the comprehensive nature of this legislation, it does not expressly address the processing, transfer, or secondary use of data in the context of clinical trials. This gap could be effectively remedied in future biomedical research legislation, which should also provide for the mandatory appointment of a data protection officer as a key safeguard for confidentiality, data security, and regulatory compliance;

d. The Health Ethics Committee for Scientific Research should be explicitly mandated to assess potential conflicts of interest involving sponsors or investigators participating in clinical studies, ensuring impartiality and protecting the integrity of the research process;

e. As a fundamental component of clinical trial governance, the future legal framework would also benefit from the inclusion of provisions on urgent safety measures, requiring sponsors and investigators to take all necessary steps to protect participants from any immediate risk to their safety. Following the implementation of such measures, CESIC should be responsible for evaluating whether post-trial clinical follow-up of participants is required, based on an assessment of ethical, scientific, and medical considerations;

f. It would be highly beneficial for ARFAMED to establish a national clinical trials database, similar to those operating in various European jurisdictions. Such a database should contain detailed and systematically recorded information covering all stages of clinical trials, thereby enhancing transparency, strengthening regulatory oversight, and promoting alignment with international best practices;

g. Finally, it would be advisable to establish a comprehensive system that clearly defines the legal implications of breaching ethical and regulatory framework, including the imposition of administrative offense, for instance where a study is conducted without CESIC's approval or where a clinical trial continues despite its authorization having been suspended.

3. Discussion

Convergence of national legislation with internationally recognised good research and clinical practices (BPC/GCP), together with regulatory harmonisation across the five partner countries, constitutes a fundamental pillar for the development of ethically robust and operationally effective clinical research systems.

In many low- and middle-income countries, including those of Lusophone Africa, the absence of relevant legislation — or the incompleteness, fragmentation, and outdated nature of existing regulatory frameworks — continues to undermine the attractiveness of these settings to international research consortia and hinder the conduct of clinical trials that meet global quality standards. More broadly, shortcomings in national legislative frameworks not only delay access to scientific innovation and therapeutic advances but also perpetuate dependence on externally designed projects and guidelines, often preventing countries from fully benefiting from the most relevant scientific and health gains.

In this context, convergence and harmonisation emerge not merely as technical regulatory exercises but as strategic instruments for strengthening national and regional governance of biomedical research. They enable countries to establish predictable, transparent, and ethically sound environments capable of hosting high-quality clinical trials, while also enhancing regional cooperation, improving research equity, and contributing to long-term health system strengthening.

Harmonised regulatory frameworks enable the establishment of shared standards that safeguard participant safety, scientific integrity and transparency, ensuring that clinical research conducted across different jurisdictions complies with comparable ethical and legal requirements. Alignment with internationally recognised norms – such as the ICH Good Clinical Practice (GCP) guidelines, the Declaration of Helsinki and World Health Organization recommendations – enhances the global credibility of national oversight systems, while still allowing for contextual adaptation to local epidemiological, social and cultural realities. This balance between international alignment and contextualisation is essential to avoid uncritical regulatory transplantation and to foster genuine regulatory maturity.

Beyond procedural efficiency, regulatory harmonisation functions as a mechanism of institutional and political empowerment. By converging around shared frameworks, Lusophone African countries can engage in international research collaborations from more equitable positions, with greater capacity to define ethical expectations, negotiate research priorities and ensure fair benefit-sharing from studies conducted within their territories.[49] Harmonisation also facilitates the creation of regional mechanisms – such as joint ethics reviews, shared regulatory assessments and interoperable clinical trial databases – which strengthen institutional confidence, reduce duplication of efforts and diminish reliance on external validation.

Moreover, harmonisation promotes capacity-building and knowledge exchange among Lusophone countries, fostering a community of practice in which regulators, ethics committees and researchers can share expertise, training resources and regulatory experience. The existence of a shared linguistic and

49 Lenias Hwenda and others, 'The African Medicines Agency: the key to unlocking clinical research in Africa' (2022) 10(8) Lancet Glob Health 1088-1089 <https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(22)00243-1/fulltext>, accessed 24 November 2025.

cultural space provides a unique platform for sustained cooperation in areas such as professional training, digital infrastructure development and legislative reform. These elements are critical for the construction of autonomous, resilient and ethically grounded research governance systems.

In the long term, regulatory harmonisation contributes to the consolidation of national health research systems capable of actively participating in global clinical research, rather than remaining peripheral recipients of externally led initiatives. It strengthens institutional legitimacy, enhances transparency and accountability, and helps ensure that clinical trials address national and regional health priorities, respect local values, and contribute meaningfully to sustainable development.

Finally, it cannot be ignored that training is a critical component to ensure both compliance and effective implementation of ethical and regulatory requirements – an aspect that has been taken into account in each country's implementation plans. Capacity-building efforts should target members of ethics committees, regulatory authorities, and research teams, focusing on areas as Good Clinical Pratice (GCP) and research ethics. Continuous professional development and certification mechanisms may further enhance the quality and consistency of oversight.

4. Conclusion and Policy Strategic Action Plan (SAP)

The legislation of five Lusophone African countries analysed in this study – Angola, Cabo Verde, Guinea-Bissau, Mozambique and São Tomé and Príncipe – present different levels of regulatory development but share a common trajectory of convergence with international good research and clinical practices (BPC/GCP) and toward strengthening their legal frameworks for clinical and biomedical research.

Collectively, these countries are already embarking on a trajectory that will enable the emergence of a Portuguese-speaking African hub for the conduct of clinical trials, demonstrating significant potential to contribute to global clinical research while simultaneously addressing pressing national and regional health priorities. Realising this potential — and creating research ecosystems that are scientifically robust, ethically rigorous, and legally sound — requires targeted policy actions integrated into a coherent Strategic Action Plan (SAP), through a structured approach. This SAP – and each step – was developed by the international team of legal experts involved in the CT-Luso project,

comprising lawyers appointed by the Ministries of Health of each PALOP country and taking into consideration their respective national contexts.

The first policy initiative proposed under this SAP is the adoption — or consolidation — of comprehensive and specific legislation on clinical and biomedical research across all five countries. Such legislation should explicitly regulate clinical trials, medical devices, and other health-related interventions, thereby ensuring clarity and legal certainty. Moreover, the regulatory framework should be firmly grounded in human rights principles and aligned with internationally recognised standards, including the ICH Good Clinical Practice guidelines, the Declaration of Helsinki, and relevant World Health Organization guidance, while allowing for contextual adaptation to local realities.

Second, governments should prioritise the formalisation and clarification of institutional mandates for regulatory authorities and ethics committees.[50] Clear allocation of responsibilities for authorisation, ethical review, safety oversight, inspection and post-trial follow-up is essential to avoid regulatory overlap, ensure accountability and strengthen public trust in research governance. Legal frameworks would also explicitly define the roles of sponsors, investigators, monitors and auditors in accordance with good clinical practice.

Third policy action would be to establish national and interoperable clinical trials registries. These databases, ideally coordinated by national regulatory authorities, should ensure systematic registration of clinical studies, transparent reporting of results, and recording of safety data, while complying with data protection and confidentiality requirements. In the medium term, interoperability among Lusophone countries' registries would support regional oversight, research transparency and regulatory cooperation.

Fourth, ethical safeguards must be reinforced through robust provisions on informed consent, protection of vulnerable populations, conflict of interest management and post-trial access to care. Ethics committees should be legally empowered to conduct continuous risk–benefit assessments, supervise urgent safety measures and ensure that participants receive appropriate follow-up and care after trial completion when justified.

50 Barbosa and others (n 13) 24-25.

The fifth policy action is the institutionalization of capacity-building and professional training as a core component of research governance.[51] Policymakers should invest in continuous training programmes for regulators, ethics committee members and researchers, with particular emphasis on legal literacy, ethical review, pharmacovigilance and data protection. Ensuring that training materials and regulatory guidance are available in Portuguese is essential for accessibility and effective implementation.

The final step of the SAP would consist of advancing regulatory harmonisation across the Lusophone African region through structured cooperation mechanisms. This would include the development of shared ethical guidelines, mutual recognition procedures, joint inspection systems and collaborative review processes, drawing where appropriate on existing regional models. Such cooperation has the potential to reduce duplication of efforts, optimise the use of limited resources and strengthen the collective negotiating position of these countries in international research partnerships.

By implementing this proposed Strategic Action Plan, the Lusophone African countries could progress beyond fragmented regulatory reforms toward a coordinated and empowered model of clinical research governance. Such an approach would strengthen participant protection, enhance scientific quality, and ensure that clinical research conducted within these settings contributes meaningfully to national health systems, fosters regional integration, and supports global health innovation.

51 Organisation for Economic Co-operation and Development, Digital Government Studies – Promoting the digital transformation of African Portuguese-speaking countries and Timor-Leste (OECD Publishing 2018) 19-20 <https://www.oecd.org/content/dam/oecd/en/publications /reports/2018/11/promoting-the-digital-transformationof-african-portuguese-speaking-countries-and-timorleste_g1g97a19/9789264307131-en.pdf> accessed 24 November 2025; Duga and others (n 44) 1-7.