CT•LUSO CLINICAL TRIALS IN PORTUGUESE-SPEAKING AFRICAN COUNTRIES

CT-Luso

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

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

Deliverable 3.3 – Legislative Recommendations

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1. Introduction

CT-Luso is a Capacity-Building Project in Ethics and Regulation in the field of Clinical Trials in the Portuguese-Speaking African Countries (PSAC) – Angola, Cape Verde, Guinea-Bissau, Mozambique, and São Tomé and Príncipe – implemented in partnership with Portugal, approved and funded by the European and Developing Countries Clinical Trials Partnership (EDCTP3) with the support of the European Union (EU). The project runs from September 2024 to December 2027.

Its main objective is to strengthen ethical and regulatory capacities in each of the PSAC through a partnership between African and Portuguese institutions specialised in ethics, research regulation, and clinical trials. The initiative aims to harmonise legislative frameworks and implement international best practices in the field of biomedical research, particularly in relation to clinical trials, thereby promoting improvements in the quality and safety of research processes.

Work Package 3 (WP3) plays a key role, focusing on the legislative and regulatory analysis of the CT-Luso partner countries. It identifies potential gaps in relation to international best practices, as well as challenges and opportunities within the existing regulatory landscape. Recommendations are also formulated to ensure the creation and implementation of a robust and harmonised legislative and institutional framework across the PSAC, aligned with international best practices, enabling safer and more effective development of biomedical research and clinical trials.

In addition to technical capacity building, CT-Luso brings substantial benefits to the modernisation and structuring of health and research policies within the PSAC. The project aims to contribute significantly to the enhancement of quality and trust in the conduct of clinical trials, both nationally and internationally. By strengthening the ethical and regulatory frameworks of biomedical research, CT-Luso not only reinforces the scientific capacity of partner countries but also promotes greater transparency and safety in clinical trial processes, ensuring alignment with international best practices through the work of the National Research Ethics Committees and National Regulatory Authorities.

Within the scope of WP3, this deliverable has been produced with the main purpose of putting forward specific recommendations to support the harmonisation of legislative frameworks governing clinical trials in the PSAC. The proposal includes a brief

contextual overview of the current situation in each partner country, allowing for the identification of weaknesses and the formulation of measures capable of addressing them. Furthermore, it is essential to identify and plan future steps for the consolidation of the recommendations issued by CT-Luso.

To achieve this objective, WP3 adopted a methodology based on a rigorous and detailed analysis of the legal instruments currently in force, as well as those under legislative review, as provided by the National Research Ethics Committees and National Regulatory Authorities of the PSAC. Following this thorough analysis, WP3 identified gaps in ethical requirements when compared with international best practices and proposed suitable and clear solutions to address them. The analysis was conducted in a structured, collaborative, and continuous manner, with the active participation of national and international legal experts representing all partner countries[1], thereby ensuring a comprehensive, contextualised, and updated understanding of the legal and legislative needs.

The methodology employed-based on close collaboration among all stakeholders, and drawing on the Workshop and Symposium held on 24 and 25 September, which brought together the legal experts appointed by the Ministries of Health of all partner countries along with the leaders of the National Research Ethics Committees and National Regulatory Authorities – ensured clarification of the progress achieved since the beginning of the project and of the most effective actions for strengthening the legal framework in the PSAC. This approach guarantees the robustness and effectiveness of the assessment, enabling gaps and opportunities to be properly identified and addressed with recommendations that consider the specific circumstances of each country.

[1] https://ct-luso.com/mod/page/view.php?id=21

2. Current context

2.1. Angola

In general terms, Angola presents a medium-to-high level of legislative consolidation regarding clinical research and clinical trials, as it possesses a relevant normative structure and key legal instruments currently under review, such as the Medicines Law, whose proposal is ongoing. In addition, the Clinical and Biomedical Research Law – Law No. 7/25 of 24 July – was recently published, with regulatory development expected soon. This Law is complemented by other relevant instruments, including the Personal Data Protection Law and several presidential decrees establishing health policies, pharmacovigilance frameworks and the functioning of regulatory institutions – the National Regulatory Authority for Medicines and Health Technologies (ARMED) and the National Institute of Health Research (INIS). Nevertheless, a detailed analysis of Angola's current legislative framework reveals several significant gaps when compared with the European landscape, which undermine regulatory effectiveness and the adequate protection of participants. The legislative proposals that follow aim to address these weaknesses by recommending alignment of the Angolan legal framework with international best practices, thereby ensuring more robust, transparent, and ethical oversight of health research.

(1) It is noted that certain fundamental concepts – such as "study centre", "clinical study dissemination", and "manufacturer" – are absent or insufficiently defined, hindering interpretative clarity and consistent application of the law. The absence of these definitions compromises the identification of responsible entities and transparent scientific communication; their introduction and normative clarification are therefore recommended.

(2) Regarding data protection and public health, although confidentiality is referenced, there is no explicit provision for the disclosure of data when necessary for safeguarding public health. This omission may limit effective responses in contexts of collective risk, justifying the introduction of a safeguard clause balancing confidentiality with the protection of the public interest.

(3) With regard to provisions concerning the inclusion of minors and adults who lack capacity in clinical studies, the current legislation in Angola does not provide any specific rules. This absence of clear criteria for the participation of such individuals

exposes them to ethical risks, making it advisable to address these cases separately and to adopt cumulative conditions for their involvement.

(4) No specific regulation exists regarding conflicts of interest, which may compromise the impartiality of studies and participants' trust. Accordingly, mandatory declaration and assessment of such situations by the Research Ethics Committee should be required.

(5) Law No. 7/25 of 24 July refers only to the use of electronic websites for the limited disclosure of information. The absence of a public and systematised database undermines transparency and makes it more difficult for investigators, health professionals and the public to access research information. Establishing such a database would enable more rigorous and accessible monitoring of clinical trials conducted in Angola.

(6) The law does not provide for any mechanism for the clinical follow-up of participants after the conclusion of studies. This omission compromises continuity of care and the assessment of late-onset effects, making the intervention of the Research Ethics Committee essential at this stage.

(7) Addressing the absence of specific provisions requiring sponsors and investigators to adopt immediate measures in the face of emerging risks, as well as to ensure prompt notification to the competent authorities, would strengthen participant protection and bring national practice into alignment with international standards.

(8) Finally, the absence of a clear and distinct structure differentiating the various types of clinical studies (e.g., those involving medicinal products, medical devices, etc.) limits the specificity and applicability of the legal provisions. The proposed thematic separation would reinforce normative coherence and facilitate practical implementation.

In summary, the recommendations presented – further elaborated in section 3.1 – are intended to remedy the structural and operational gaps in Angola's current legislative framework, ensuring clearer and more effective regulation aligned with the ethical principles of modern scientific research, while also contributing to harmonisation across the PSAC.

2.2. Cape Verde

In general terms, Cape Verde demonstrates a medium level of legislative consolidation, as it already possesses foundational norms in force and strategic documents currently under review – such as the draft legislative package on medical devices.[2] The analysis of the country's legal instruments shows that, despite identifiable gaps in the area of clinical trials that may undermine normative robustness and the effectiveness of practical implementation, efforts have been made to address these shortcomings. This is reflected in the Draft Health Research Law and the documents relating to the National Health Ethics Council (CNES) and the Independent Health Regulatory Authority (ERIS).

The following assessments aim to address the identified weaknesses by proposing the alignment of Cape Verde's legal framework with international health research standards.

(1) First, in the Draft Health Research Law, the assessment of risks and benefits in clinical studies is addressed only superficially, with no clarification regarding its continuous re-evaluation throughout the study. This normative insufficiency compromises participant safety and research quality. A clearer and more robust formulation is therefore recommended, ensuring continuous oversight by the Independent Health Regulatory Authority (ERIS) and the National Health Ethics Council (CNES), allowing for revisions based on new evidence.

(2) There is also a lack of essential technical definitions, including those relating to clinical studies involving medical devices, cosmetic products and research centres. The absence of these definitions compromises uniform interpretation and practical application of the legislation.

(3) Regarding data protection and confidentiality, the draft provisions seek to guarantee the secure and appropriate handling of personal data, even after the individuals involved have ceased their functions, while simultaneously safeguarding the public interest and ensuring compliance with legal obligations by the competent authorities. Nonetheless, the current text remains vague.

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[2] It contains one order concerning items of negligible value and items subject to mandatory reporting; another concerning the access regime for commercial representatives in healthcare establishments and services; and a further one concerning medical devices.

(4) Additionally, the absence of clear provisions regarding civil liability should be noted, making it necessary to clarify that the law does not exempt sponsors, investigators or institutions from disciplinary, civil or criminal liability in the context of research activities.

(5) From an organisational perspective, the legislation does not include key roles such as monitors and auditors, which are essential to ensuring compliance with good clinical practice and the integrity of data. Their inclusion is recommended to strengthen internal control mechanisms within studies.

(6) Another critical issue is the absence of a national database of clinical studies. Simply publishing studies does not guarantee transparency nor allow effective oversight. The proposed creation of a national database under the responsibility of ERIS addresses this gap, contributing to increased traceability, safety and structured information sharing.

(7) Structurally, the Draft Health Research Law also lacks a dedicated section for studies involving medical devices, cosmetics and personal hygiene products. Although referred to throughout the text, these areas require specific regulation, as provided for in other benchmark legislation (e.g., Portugal's Law No. 21/2014).

(8) Finally, regarding the preliminary draft relating to CNES, there is no mention of collaboration with other ethical and bioethical bodies, nor of the possibility for citizens or participants to request opinions or clarifications. This limits the ethical scope of the institution. Recommendations therefore include widening access, increasing transparency and strengthening institutional cooperation. A clearer internal organisation of the legislation is also advisable, particularly through the separation of the rights and duties of CNES members, which are currently dispersed and difficult to consult and apply.

In summary, the proposed recommendations aim to make Cape Verde's legislation clearer, more comprehensive and more closely aligned with international best practices, thereby promoting participant protection and the quality of health research in accordance with international standards.

2.3. Guinea-Bissau

An analysis of the national landscape in Guinea-Bissau – with several legal instruments currently under legislative review, including the Statute of the National

Committee for Ethics in Health Research (CNEPS), the decree establishing the CNEPS, and the Draft Code of Ethics – reveals commendable efforts aimed at defining a legislative framework for clinical trials. The Draft Code of Ethics is particularly relevant in this regard, as it seeks to regulate scientific health research in the country. At the same time, several normative and structural gaps significantly undermine the country's effectiveness in this area and its alignment with international best practices, particularly given the absence of a biomedical research law. Nevertheless, relevant institutions exist, such as the National Institute of Public Health (INASA), the National Regulatory Authority of Pharmacies and Medicines (ARFAME), and the National Committee for Ethics in Health Research (CNEPS), all of which play central roles in the coordination and ethical oversight of research. Overall, Guinea-Bissau demonstrates a low level of legislative consolidation, with a fragile legal system and fundamental norms still under development, highlighting the need for substantial support to establish a basic regulatory framework.

The legislative proposals set out below aim to help build the country's capacity in biomedical research, in alignment with international standards.

(1) The Draft Code of Ethics defines only a limited number of concepts – such as "biomedical research" and "research in traditional medicine" – but omits essential notions including "sponsor" and "researcher". These omissions hinder interpretative and operational clarity. It is therefore recommended that an article establishing comprehensive definitions be introduced, in line with international legislative models.

(2) The ethical principles are insufficiently developed, as illustrated by the principle of human dignity, which is mentioned only briefly and indirectly. The lack of a robust and explicit formulation compromises participant protection. A clearer and stronger articulation affirming the primacy of participants' rights over scientific or societal interests is therefore advised.

(3) Regarding the assessment of risks and benefits, the draft merely states that benefits must outweigh risks, without providing for a formal prior evaluation mechanism. As such assessment is fundamental to any ethical research system, it is proposed that a formal and continuous process be institutionalised, overseen by bodies such as the CNEPS and ARFAME.

(4) Provisions on informed consent are dispersed throughout the document and insufficiently detailed, as are those concerning data confidentiality. It is recommended that specific and comprehensive sections be introduced on both matters, thereby strengthening participant protection.

(5) The drafts currently under consideration fail to address conflicts of interest involving sponsors and investigators. It is therefore recommended that CNEPS require mandatory declaration and prior assessment of such conflicts, as well as their public disclosure, consistent with international transparency standards.

(6) There are no clear provisions regarding systems for monitoring and auditing clinical trials, underscoring the need for norms on safety and oversight, including inspections, and for the creation of a national clinical trials database that enables the registration, tracking and sharing of information on studies conducted in the country.

(7) The drafts also lack explicit recognition and enforcement of good clinical practice, making it essential to establish binding standards and to designate ARFAME as the entity responsible for their oversight.

(8) Procedures for the authorisation of clinical studies are absent, as are mechanisms for responding to imminent risks to participant safety. It is therefore proposed that timeframes, criteria and mandatory documentation for authorisation requests be defined, along with emergency response measures.

(9) The roles of the sponsor, researcher, monitor and auditor are addressed only superficially. Clearer and consolidated definitions of these roles within the legislative text would strengthen accountabilities for all parties involved.

(10) Both the ARFAME and CNEPS statutes reveal institutional gaps, including the absence of specialised technical committees (e.g., inspection and licensing), insufficient cooperation with other national and international bodies, and omission of critical responsibilities such as the registration of clinical studies or an explicit safeguard of human dignity. The recommendations therefore propose expanding competencies and establishing appropriate committees.

Guinea-Bissau also occupies a distinctive strategic position in the Lusophone context as a member of the West African Economic and Monetary Union (UEMOA). This regional affiliation is particularly relevant for the future development of clinical trial

regulation, as UEMOA has made significant progress in harmonising pharmaceutical and clinical research frameworks among its Member States. UEMOA's regulatory instruments – notably Regulation No. 02/2010/CM/UEMOA on clinical trials of medicinal products for human use – establish common standards for the authorisation, conduct and supervision of clinical trials, fostering convergence and mutual recognition of regulatory decisions.

This regional alignment presents a valuable opportunity for Guinea-Bissau to strengthen its national regulatory capacity through cooperation, technical support and shared oversight mechanisms, while benefiting from harmonised procedures that reduce duplication and enhance transparency. Integrating UEMOA's regulatory developments into the national legal framework may help to address existing legislative gaps, enhance regulatory predictability and ensure that future biomedical research governance in Guinea-Bissau is both internationally credible and regionally coherent.

Beyond technical efficiency, participation within UEMOA represents an important driver of capacity-building and scientific sovereignty. By adhering to a regional system based on shared standards and collaborative governance, Guinea-Bissau can strengthen its institutional legitimacy and play a more active role in regional decision-making processes concerning research ethics, pharmaceutical regulation and innovation policy. Harmonisation within UEMOA thus functions not as an external imposition, but as a platform for solidarity and collective action, enabling Member States – particularly smaller or resource-constrained ones – to assert their priorities and ensure that clinical research serves national and regional public health interests.

Ultimately, aligning Guinea-Bissau's evolving biomedical research legislation with UEMOA's harmonised framework, which itself reflects international best practices, will not only enhance regulatory quality and participant protection but will also contribute to strengthening the country's health governance structures. This alignment will promote an ethically grounded, scientifically credible and regionally integrated research environment, and support the harmonisation of Guinea-Bissau's legislation with that of the other PSAC and with international best practices – the core objective of this project.

2.4. Mozambique

An analysis of Mozambique's current legal framework on clinical trials – supported by several regulations already in force – reveals a high level of consolidation, with robust and detailed legislation, including specific regulations on clinical trials, good clinical practice, and clearly defined statutes governing the roles of regulatory authorities. Notably, this framework includes Law No. 6/2023 of 8 June, which establishes the foundations for research in human health, regulated by Decree No. 53/2024 of 18 July and complemented by Decree No. 17/2023 of 27 April, which sets out the rules for conducting clinical trials. The mandates of the main institutions – the National Institute of Health (INS), the National Bioethics Committee for Health (CNBS), the National Medicines Regulatory Authority, IP (ANARME, IP), and the Multi-Institutional Committee for the Oversight of Research in Human Health (CFISH) – are clearly defined, ensuring the ethical protection of participants and the scientific quality of studies.

Despite this, some gaps remain that compromise the full protection of participants and the robustness of regulatory processes. The recommendations set out below aim to address these omissions, while ensuring continued alignment of Mozambique's legislation with international ethical standards.

(1) The Law on Research in Human Health – Law No. 6/2023 of 8 June – opted to include an annexed glossary rather than a dedicated article consolidating key legal definitions used throughout the text. This approach may hinder uniform interpretation of the law. A more systematic organisation of these definitions is therefore recommended, to facilitate clearer application by researchers, ethics committees, and regulatory bodies.

(2) Mozambique's legislation lacks detailed provisions on monitoring systems, inspections, and risk-management processes. The introduction of rules on continuous oversight, urgent safety measures, and mandatory notification to the competent authorities (including ANARME and the CNBS) is therefore essential to ensure appropriate and robust protection of participants throughout the duration of a study.

(3) The legal framework does not clearly foresee the establishment of a database enabling the centralisation and sharing of information on ongoing and completed clinical trials. The proposed creation of such a database, under the responsibility of ARMED and with appropriate safeguards for confidentiality, aims to increase transparency, strengthen oversight, and promote public trust.

(4) Current legislation does not address the limits and obligations relating to public communication of studies and their results. This highlights the need to regulate the matter in order to ensure that any information disclosed is accurate, ethical, and scientifically substantiated.

(5) Finally, regarding the functioning of the National Bioethics Committee for Health, it is recommended that a provision be introduced to legitimise and clarify requests for opinions, statements, and recommendations from the Committee by institutions, researchers, participants, and their representatives, thereby promoting greater accessibility and transparency in the process.

2.5. São Tomé and Príncipe

An analysis of the current legal framework of São Tomé and Príncipe in the field of health research reveals significant progress, particularly regarding the legislation already approved on the Medicines Authority, the Ethics Committee, and the Basic Health Law. There are also several legislative proposals pending promulgation, namely: the Draft Decree-Law on the Statute of Medicines and Health Technologies, Introduction, Marketing and Manufacture of Medicines and Health Technologies; the Draft Internal Regulation of the Health Ethics Committee for Scientific Research (CESIC); the Draft Decree-Law establishing the Central Procurement Agency for Medicines and Health Products (CAME); the Draft Legal Regime of Community Pharmacies and Medicines Outlets; and the Draft Decree-Law establishing the Regulatory Authority for Pharmacy, Medicines and Health Technologies and its respective Statute. Pending the approval of these instruments, São Tomé and Príncipe maintains a low to medium level of legislative consolidation.

Nevertheless, the country possesses a relatively robust legislative basis for regulating the activities of the national medicines authorities, ensuring mechanisms for quality control, authorisation, and supervision of the marketing of pharmaceutical products. Likewise, there are clear provisions concerning the establishment and functioning of ethics committees, with norms designed to safeguard the rights, safety, and well-being of participants in clinical research.

However, a major gap is evident in the legislative landscape: the absence of a specific legal framework dedicated to health research. At present, no draft legislation

exists that comprehensively regulates clinical trials, covering aspects such as the primacy of the human being, informed consent (particularly for persons lacking capacity), data confidentiality, conflicts of interest, the responsibilities of the sponsor, investigator, monitor, and auditor, the creation of a clinical studies database, the oversight of good clinical practice and the manufacture of investigational medicinal products, post-trial monitoring of participants, urgent safety measures, disclosure of clinical studies, and non-discrimination.

This legislative gap undermines the creation of a clear and predictable regulatory environment for the promotion of health research and hinders alignment with international best practices and the ethical principles underpinning them. It also limits the country's ability to attract regional and international collaborations in the field of clinical trials, given the weak explicit legal guarantees regarding applicable procedures and standards.

It is therefore imperative to develop a dedicated legal instrument on health research, complementing the existing framework and contributing to the strengthening of the national research system, in line with the health-sector development objectives of São Tomé and Príncipe.

3. Specific Recommendations

3.1. Angola

Following the contextualisation of the situation in Angola, it is now necessary to elaborate the proposals aimed at ensuring robustness, clarity, respect for international standards, and harmonisation of the regulatory frameworks of the PSAC in the field of clinical trials and health research.

Beginning with the Clinical and Biomedical Research Law – Law No. 7/25 of 24 July – Article 3, which sets out definitions, the concept of a clinical study centre, mentioned in Article 11[3], could be expressly defined, in a manner like subparagraph (h)

[3] "Article 11 (Research Sites): 1 – Clinical and biomedical research shall be carried out in study centres, namely hospital and laboratory establishments, and higher education institutions in the health sciences or similar fields, equipped with appropriate material and human resources for this purpose. 2 – The study centres referred to in the preceding paragraph must have Institutional Ethics Committees, in accordance with the legislation in force. (…)"

of Article 2 of Law No. 21/2014 of 16 April[4]. Accordingly, it is proposed that a legislative solution be considered in the following terms: “Clinical study centre: an entity that conducts the clinical study and has the appropriate material and human resources, irrespective of whether it is part of a public or private health establishment, laboratory or other institution, and irrespective of whether or not it is located within national territory.”

Still within the provision on definitions, the concept of dissemination of clinical studies is not provided for. It is therefore suggested that the following wording be added, for example: “Dissemination of clinical studies: any form of communication which has as its object or effect the provision of information on the conduct of a clinical study, which may include observations made in the context of the study, interpretation of results and conclusions thereof to the public, to health professionals, to the media, in general or scientific publications regardless of their target audience, and in advertising material for medicinal products, medical devices or any other means of health intervention” (as in subparagraph (m) of Article 2 and Article 40 of Law No. 21/2014 of 16 April).

Although the figure of the manufacturer is mentioned throughout Presidential Decree No. 180/10 of 18 August and Presidential Decree No. 191/10 of 1 September[5], no definition is provided – nor in the Clinical and Biomedical Research Law. It is therefore recommended that the following legislative solution be adopted: “Manufacturer: 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, regardless of whether these operations are carried out by that person or by third parties on its behalf” (similar to subparagraph (v) of Article 2 of Law No. 21/2014 of 16 April).

Regarding data protection, the safeguards in Article 16 of the Clinical and Biomedical Research Law could be further developed, and a provision added to allow for the disclosure of information necessary for the protection of public health. A possible legislative solution would be: “Information transmitted under this Law shall be confidential, and all those who become aware of it shall be bound by a duty of secrecy, without prejudice to the disclosure of information necessary for the protection of public health. The above shall not affect the fulfilment of the obligations of the competent authority and notified bodies as regards reciprocal information and the issuing of

[4] Enacts the Clinical Research Law.
[5] In this legal instrument, reference is made only to the “pharmaceutical factory or laboratory: any company or body engaged in the manufacture of medicines, products, or objects referred to in Article 3 of this instrument” (Article 44(1)(a)).

warnings. All those who, in any capacity, take part in clinical studies or who, in any way, become aware that they are being conducted, shall be bound by the duty of secrecy in respect of any personal data to which they have access, even after the termination of their functions." (similar to Article 51 of Law No. 21/2014 of 16 April).

Still within the sphere of data protection, the position of Data Protection Officer is not foreseen, despite its essential role. A provision similar to Article 38 of Regulation (EU) 2016/679 (General Data Protection Regulation) should therefore be incorporated.

With regard to the protection of vulnerable subjects, it is recommended that minors and adults lacking capacity to provide informed consent[6] be regulated in autonomous provisions, establishing cumulative conditions under which clinical studies involving such participants may be conducted, in line with Articles 7 and 8 of Law No. 21/2014 of 16 April.

Several additional aspects required by international good practice are entirely absent. Regarding conflicts of interest – and although Law No. 7/25 of 24 July refers to the principle of transparency – it remains necessary to specify that the Ethics Committee of the Ministry of Health must *necessarily* assess any conflicts of interest involving the sponsor or investigator, and that the dissemination of clinical studies must identify any such conflicts on the part of the investigator, sponsor or clinical study centre. Accordingly, the following wording is proposed: "The Ethics Committee of the Ministry of Health shall be required to assess any conflict-of-interest situations involving the sponsor or the investigator in a clinical study," and "the dissemination of clinical studies must indicate any conflicts of interest on the part of those responsible for the conduct of the study, namely the investigator, sponsor and clinical study centre, where applicable," mirroring Article 16(6)(h) of Law No. 21/2014 of 16 April.

Regarding the database on clinical trials and clinical studies, which is essential and required by international best practices, Article 9 refers only to the website of the Ethics Committee of the Ministry of Health and other publicly accessible websites legally permitted. It is therefore suggested that a database be created, similar to that in force in Portugal (Article 38 of Law No. 21/2014 of 16 April). The following legislative solution is proposed: "ARMED shall be responsible for creating a database on clinical trials and

[6] In Article 15(5) of Law No. 7/25 of 24 July, the only reference made is the following: "the investigator, or the professional designated by him or her, must provide full information to the research subject or their legal representative regarding the relevant aspects of the research."

clinical studies involving medical devices conducted in clinical study centres located within national territory. This database shall include detailed records of: data extracted from authorisation requests; inspections carried out to verify compliance with good clinical practice; data relating to suspected unexpected serious adverse reactions or serious adverse events; and the justification for the need to include personal data identifying or making it possible to identify participants." It should further state that "the database and any exchange of data contained therein must fully respect the principle of confidentiality."

Regarding post-trial follow-up of participants, Law No. 7/25 of 24 July merely mentions the "right to medical support during and after the study, where necessary".[7] It is therefore proposed that the law expressly provide: "The Ethics Committee of the Ministry of Health shall assess the conditions for clinical follow-up of participants after the conclusion of the clinical study, where justified," as per subparagraph (i) of Article 16(6) and subparagraph (g) of Article 36 of Law No. 21/2014 of 16 April.

As a fundamental element of clinical trials, urgent safety measures should explicitly state that: "The sponsor and investigator shall adopt all urgent measures necessary to protect participants from any immediate risk to their safety, particularly arising from the emergence of any fact related to the conduct of the clinical study involving an intervention or the development of the investigational medicinal product, the device under investigation or any other intervention." It should also be stated that "The sponsor shall promptly notify the Ethics Committee of the Ministry of Health (CEMS), the Regulatory Authority for Medicines and Health Technologies (ARMED), and all other competent authorities of any risk-related findings and measures adopted."

Concerning the Organic Statute of the Regulatory Authority for Medicines and Health Technologies (ARMED), Article 15 ("Department for Quality Control of Medicines and Health Technologies") should be expanded with additional functions, following the model of INFARMED's Department for Risk Management of Medicines (Article 4 of Ordinance No. 267/2012 of 31 August[8]). Suggested additions include: "Ensuring the safety monitoring of medicines through periodic safety update reports; Ensuring safety monitoring through risk-management plans; Promoting and conducting epidemiological

[7] Article 20 (Rights of participants), paragraph 2(j) of Law No. 7/25 of 24 July.
[8] Approves the statutes of INFARMED – the National Authority of Medicines and Health Products, I.P.

studies; Collaborating with national and international bodies in promoting and conducting research in the field of pharmaceutical epidemiology; Exercising oversight of clinical trials through the collection, recording and assessment of adverse events; Assessing causal relationships between medicines and adverse reactions; Ensuring early identification of safety concerns relating to medicinal product use; Evaluating and issuing opinions on periodic safety reports and safety studies; Evaluating and issuing opinions on risk-management plans within the scope of pharmacovigilance."

Finally, regarding the internal regulation of the CEMS, it is recommended that a provision be introduced to guarantee appropriate infrastructure and support, such as: "The logistical, administrative and financial support necessary for the operation of the CEMS shall be ensured by the respective institutions, which shall provide a dedicated secretariat, IT support, and suitable premises for meetings and document archiving," as reflected in Article 13 of Decree-Law No. 80/2018 of 15 October.[9]

3.2. Cape Verde

In the Draft Health Research Law presented by Cape Verde, references to the risk/benefit assessment appear only briefly (in Article 7(1)(e) and Article 8(1)(b)), and it is not clear whether such assessment may be reviewed during the course of the clinical study. It is therefore suggested that the following legislative solution be considered: "The conduct of clinical studies shall depend on a prior assessment concluding that the potential benefits, whether present or future, outweigh the foreseeable risks and inconveniences. The CNES and ERIS shall be responsible for deliberating on the assessment and conclusion referred to in the preceding paragraph, within their respective areas of competence. The CNES and ERIS shall supervise the conduct of the clinical study and the maintenance of the conditions evaluated, within their respective areas of competence. The assessment described may be reviewed at any time during the clinical study in the event of new evidence or interim analyses of the study itself." (similar to Article 5 of Law No. 21/2014 of 16 April[10]).

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[9] Establishes the principles and rules applicable to ethics committees operating within healthcare institutions, higher education institutions, and biomedical research centres that conduct clinical research.
[10] Enacts the Clinical Research Law.

Although the draft already contains several relevant definitions, additional concepts considered essential in this domain could be included, such as the clinical study of a medical device: "Any study involving medical devices or their accessories falling within the scope of the legislation on medical devices, whose purpose includes: verifying the performance level of the device; determining potential undesirable side effects under normal conditions of use and assessing whether they constitute risks in light of the intended use of the device according to the *legis artis*; or conducting post-marketing clinical follow-up." (as in subparagraph (r) of Article 2 of Law No. 21/2014 of 16 April).

Another important definition is that of a clinical study involving cosmetic and personal hygiene products, which could be introduced using wording such as: "A study involving the use of any substance or mixture intended to be placed in contact with the various external parts of the human body – namely the epidermis, hair system and scalp, nails, lips and external genital organs – or with the teeth and the oral mucosa, with the exclusive or principal purpose of cleaning, perfuming, altering their appearance, protecting them, keeping them in good condition or correcting body odours." (as in subparagraph (s) of Article 2 of Law No. 14/2014 of 16 April).

The definition of research centre could also be expanded, as: "An entity where research is conducted, endowed with the appropriate material and human resources, irrespective of whether it is part of a public or private health establishment, laboratory or other institution, and irrespective of whether or not it is located within national territory." (cf. subparagraph (f) of Article 2 of Law No. 14/2014 of 16 April).

With regard to the protection and confidentiality of data, Article 19(1)[11] could be reformulated as follows: "All members of the research team, as well as all those who have access to data relating to the research, including personal data, shall be bound by a duty of confidentiality, under the terms and with the consequences established by law, even after the termination of their functions." It is further proposed that the following wording be added: "Information transmitted under this Law is confidential, and all those who become aware of it shall be subject to a duty of secrecy, without prejudice to the disclosure of information necessary for the protection of public health. The foregoing shall not affect compliance with the obligations of the competent authority and notified

[11]Article 19 (Duty of Secrecy and Confidentiality): 1 – All members of the research team, as well as all those who have access to data relating to the research, including personal data, are bound by a duty of secrecy, under the terms and with the consequences established by law.

bodies as regards reciprocal information and the issuing of warnings." (similar to Article 51 of Law No. 21/2014 of 16 April).

In Article 21 – "Civil liability and insurance" – it is proposed to add a paragraph providing that: "The provisions of this Law shall not constitute grounds for exempting the sponsor, investigator, members of the respective research team or the research centre from disciplinary, civil, administrative or criminal liability." (as set out in Article 15(5) of Law No. 21/2014 of 16 April).

It is important to introduce several additional aspects, including the concept of the monitor, as a figure responsible for ensuring that data are correctly recorded and that the storage, distribution, return and documentation of materials comply with good clinical practice. The following legislative formulation is proposed: "A professional with the necessary scientific or clinical competence, appointed by the sponsor to oversee the clinical study, to keep the sponsor permanently informed, to report on its progress and to verify the information and data collected." (as in subparagraph (aa) of Article 2 of Law No. 21/2014 of 16 April).

In addition, the definition of auditor should be included, as the professional who ensures that data are recorded, analysed and reported accurately through systematic examination of the activities and documents relating to the clinical study. The following wording is suggested: "A professional with the required technical competence, experience and independence, appointed by the sponsor to conduct audits of clinical studies." (cf. Article 2(c) of Law No. 73/2015 of 27 July).

It is also essential to establish a database of clinical studies, given that the draft currently refers only to the publication of studies in journals. In this respect, a legislative solution similar to Articles 38 and 39 of Law No. 21/2014 of 16 April is proposed: "ERIS shall be responsible for creating a database on clinical trials and clinical studies involving medical devices conducted in clinical study centres located within national territory. This database shall include detailed records of: data extracted from authorisation requests; inspections carried out to verify compliance with good clinical practice; data relating to suspected unexpected serious adverse reactions or serious adverse events; and the justification for the need to include personal data identifying or making it possible to identify participants." It should also be provided that: "The database and the exchange of data contained therein shall strictly comply with the principle of confidentiality."

Finally, as regards the structure of the draft instrument, although clinical studies involving medical devices, cosmetic products and personal hygiene products are mentioned throughout the document, they would benefit from a dedicated section, similar to Section III of Law No. 21/2014 of 16 April.

In the Draft Statute of the National Health Ethics Council (CNES), there is no mention of collaboration with other relevant bodies in the field of ethics and bioethics for the purpose of sharing best practices. It is therefore suggested that the following provision be added: "To collaborate, at regional, national and international level, with other relevant bodies in the field of ethics and bioethics, with a view to sharing best practices." (as in subparagraph (d) of Article 3 of Decree-Law No. 80/2018 of 15 October[12]).

Regarding those who may request opinions, additional information could be included concerning requests for information and statements. The following formulation could be added: "Any participant or potential participant in clinical research studies to be conducted at the institution, as well as users of the institution, their representatives or family members, who demonstrate an objective interest affecting the exercise of their rights before the institution." (as in Article 5 of Decree-Law No. 80/2018 of 15 October).

It is also recommended that the rights and duties of CNES members be set out in a dedicated section, rather than in Article 8 concerning organisational matters, in line with Articles 10 and 11 of Decree-Law No. 80/2018 of 15 October.

3.3. Guinea-Bissau

In the Draft Code of Ethics for Health Research, an article setting out the various definitions of concepts used throughout the document could be included (similar to Article 2 of Law No. 21/2014 of 16 April, which approves the Clinical Research Law). At present, only the definitions of biomedical research, research in traditional medicine, research in health systems and research in the social sciences are provided (cf. Article 4). It would therefore be advisable to add, for example, the definitions of *sponsor* and *researcher*.

[12] Establishes the principles and rules applicable to ethics committees operating in healthcare institutions, higher education institutions, and biomedical research centres that carry out clinical research.

The principle of the primacy of the human person is mentioned only briefly in a single subparagraph (Article 7(2): “respect for human dignity and for human rights”). It is therefore suggested that a legislative solution be adopted along the following lines: “Clinical studies shall be conducted in strict compliance with the principle of respect for the dignity of the human person and their fundamental rights. The rights of participants in clinical studies shall always prevail over the interests of science and society. In the conduct of clinical studies, all precautions shall be taken to respect the individual’s privacy and to minimise any potential harm to their personal rights and to their physical and mental integrity.” (cf. Article 3 of Law No. 21/2014 of 16 April).

Regarding the assessment of risks and benefits, the draft merely states that: “All biomedical research involving humans must provide the persons involved with a benefit far greater than the foreseeable risk incurred” (Article 21) but makes no mention of a prior assessment underpinning such a conclusion (in contrast with Article 5 of Law No. 21/2014). The following legislative solution is therefore proposed: “The conduct of clinical studies shall depend on a prior assessment concluding that the potential benefits, whether present or future, outweigh the foreseeable risks and inconveniences. The CNEPS and ARFAME, IP shall be responsible for deliberating on the assessment and the conclusion referred to in the article establishing the principles of good clinical practice, within their respective areas of competence. The CNEPS and ARFAME, IP shall supervise the conduct of the clinical study and the maintenance of the conditions assessed, within their respective areas of competence. The assessment described may be reviewed at any time during the clinical study in the event of new evidence or interim analyses of the study itself.”

Regarding informed consent, the references in the draft are exceedingly brief compared with Articles 7 and 8 of Law No. 21/2014, and the relevant provisions are dispersed across different articles (Article 8, Article 22, Article 23). A suitable legislative solution would therefore involve organising the information within a dedicated section on informed consent, including the informed consent of vulnerable subjects, in line with Articles 7 and 8 of Law No. 21/2014 of 16 April.

The confidentiality of data could be further developed, beyond the existing reference to “respect for privacy and confidentiality” (Article 7(12)). The following solution is proposed: “Information transmitted under this Law is confidential, and all those who become aware of it shall be subject to a duty of secrecy, without prejudice to the

disclosure of information necessary for the protection of public health. All those who, in any capacity, take part in clinical studies or who, by any means, become aware of their conduct shall be bound by a duty of secrecy concerning any personal data to which they have access, even after the termination of their functions." (cf. Article 51 of Law No. 21/2014 of 16 April). Furthermore, the position of the Data Protection Officer is not provided for, despite being essential to guaranteeing compliance in this domain. A provision similar to Article 38 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation) should therefore be added.

Certain aspects that are essential to good clinical practice should also be introduced, notably the matter of conflicts of interest, using wording such as: "The National Health Research Ethics Committee shall issue a mandatory opinion on situations of conflict of interest on the part of the sponsor or researcher involved in the health research study." and: "The dissemination of health research shall indicate any situations of conflict of interest of those responsible for conducting the study, namely the researcher and the sponsor, where such conflicts exist." (similar to Article 16(6)(h) of Law No. 21/2014 of 16 April).

With respect to safety and oversight, it is recommended that a provision be introduced in the following terms: "To establish and maintain a system of safety and surveillance of the clinical study through monitoring carried out under the responsibility of a qualified professional," as set out in Article 9(1)(g) of Law No. 21/2014 of 16 April. Oversight is further linked to inspection, defined as: "The activity consisting of the official control of documents, facilities, records, quality assurance systems and any other elements deemed relevant to the research." (cf. subparagraph (x) of Article 2 of Law No. 21/2014 of 16 April).

As there is currently no database of clinical studies, a legislative solution is proposed in the following terms: "ARFAME, IP shall be responsible for creating a database on clinical trials and clinical studies involving medical devices conducted in clinical study centres located within national territory. This database shall include detailed records of: data extracted from authorisation requests; inspections carried out to verify compliance with good clinical practice; data relating to suspected unexpected serious adverse reactions or serious adverse events; and the justification for the need to include personal data identifying or making it possible to identify participants." It should also be

added that: “The database and the exchange of the data contained therein shall strictly comply with the principle of confidentiality.” (cf. Article 38 of Law No. 21/2014 of 16 April).

There should also be explicit reference to good clinical practice, in the following terms: “All clinical studies shall be designed, conducted, recorded and reported, and their results reviewed and disseminated in accordance with the principles of good clinical practice applicable to research involving human subjects.” (cf. Article 4 of Law No. 21/2014 of 16 July). Similarly, reference should be made to the oversight of good clinical practice, along the following lines: “ARFAME, IP shall be the competent authority, for the purposes of this Law, in the fields of biomedical research and traditional medicine research, and shall also be responsible for overseeing compliance with good practice in such studies, whether in the context of research or otherwise. Its responsibilities shall include overseeing all matters relating to the research, including: the specific sites where the study is carried out; the analytical laboratories used for the research; the facilities of the sponsor; and any other establishment related to the research whose inspection is considered necessary.” (similar to Article 44 of Law No. 21/2014 of 16 April).

As authorisation procedures are not mentioned, the following legislative solution is recommended: The application for authorisation to conduct a clinical trial shall be submitted to ARFAME, IP by the sponsor and shall include the following documents: the protocol; the investigator’s brochure; full identification of the sponsor of the clinical trial and of the investigator or principal investigator; identification and qualifications of all members of the research team involved in the clinical trial; identification of the clinical study centres involved, together with a statement issued by the director of each centre indicating the terms of its participation; identification of the competent authorities concerned; and the investigational medicinal product dossier, in the case of a clinical trial involving an investigational medicinal product. ARFAME, IP shall issue a decision on the authorisation request within a maximum period of 30 days. During this period, ARFAME, I.P may request, once only, supplementary information or documentation, and the deadline shall be suspended until such elements are received.
Where ARFAME, I.P raises duly justified objections, the sponsor may, within the time limit set for that purpose, amend the content of the authorisation request once only, and the 30-day period shall be suspended until the amendment is submitted. Failure to amend the request in accordance with the foregoing shall result in its rejection, and the clinical trial may not be conducted.” (cf. Article 26 of Law No. 21/2014 of 16 April).

With regard to urgent safety measures, it is suggested that the following wording be introduced: “The sponsor and the investigator shall take all urgent measures necessary to protect participants against any immediate risk to their safety, particularly arising from any supervening fact related to the conduct of the interventional clinical study or to the development of the investigational medicinal product, the device under investigation or any other intervention.” (cf. Article 20 of Law No. 21/2014 of 16 April). It should also be stated that: “The sponsor shall, without delay, provide the CNEPS, ARFAME, IP and other competent authorities with the information on the identified risks and the measures adopted.”

Concerning dissemination of clinical studies, the following formulation should be added: “Any form of communication intended to inform or having the effect of informing about the conduct of a clinical study, which may include observations made in the context of the study, interpretation of results and conclusions thereof to the public, to health professionals, to the media, in general or scientific publications regardless of their target audience, and in advertising material for medicinal products, medical devices or any other means of health intervention.” (as in subparagraph (m) of Article 2 and Article 40 of Law No. 21/2014 of 16 April).

The functions of the sponsor (Article 5) require further elaboration. The following wording is recommended: “The sponsor shall, in particular: submit a request for an opinion to the CNEPS; request authorisation to conduct health research; propose the researcher and verify the latter’s scientific qualifications and professional competence, ensuring that the research is conducted in compliance with applicable legal and regulatory requirements; establish and maintain a safety and surveillance system for the clinical study through monitoring carried out under the responsibility of a qualified professional; ensure that audits are conducted when necessary in accordance with good clinical practice; inform the competent authorities of any requests or opinions issued by ethics committees regarding the same research or its variants; ensure compliance with the notification, communication and information obligations established under this Law; and notify the completion of the research.” (cf. Article 9 of Law No. 21/2014 of 16 April).

The functions of the researcher (Article 6) likewise require development. The following wording is proposed: “The researcher shall, in particular: conduct the clinical study in accordance with good clinical practice and applicable legal and regulatory requirements; comply with duties relating to the collection, recording and notification of

reactions; propose amendments to the protocol to the sponsor, as well as suspension of the studies were justified; ensure that clinical information collected during the study is recorded in the case report forms and prepare a final report of the clinical study; and guarantee confidentiality during the preparation, conduct and conclusion of the clinical study, as well as regarding information relating to research participants." (cf. Article 10 of Law No. 21/2014 of 16 April).

As regards the auditor, to ensure that data are recorded, analysed and reported accurately through systematic examination of activities and documents related to the clinical study, the following wording is suggested: "A professional with the necessary technical competence, experience and independence, appointed by the sponsor to conduct audits of clinical studies." (cf. Article 2(c) of Law No. 21/2014 of 16 April).

The monitor should also be added as a key figure responsible for ensuring that data are properly recorded and that storage, distribution, return and documentation of materials comply with good clinical practice: "A professional with the necessary scientific or clinical competence, appointed by the sponsor to oversee the clinical study, to keep the sponsor permanently informed, to report its progress and to verify the information and data collected." (cf. subparagraph (cc) of Article 2 of Law No. 21/2014 of 16 April).

In the statutes of the Regulatory Authority for Pharmacy, Laboratory, Medicines and Other Health Products (ARFAME, IP), several specialised technical committees are listed: the Medicines Evaluation Committee, Medical Devices Committee, Cosmetology Committee, Traditional Supplements Committee, Pharmacovigilance Committee, Medicines and Health Products Promotion and Advertising Committee, and the Therapeutic and Economic Evaluation Committee. It would be beneficial to introduce additional committees related to medicines risk management, inspection and licensing, quality verification and information systems and technologies (similar to the structure of INFARMED, IP).

As for the statutes of the National Committee for Ethics in Health Research (CNEPS), there is no reference to collaboration with other relevant national or international bodies in the field of ethics and bioethics for the purpose of sharing best practices (only collaboration to promote community training is mentioned – Article 4(2)(k)). Nor is there mention of issuing guidance or recommendations in situations that generate or may generate ethical conflicts arising from clinical practice. It is therefore proposed that the following be added to the current wording: "To collaborate, at regional,

national and international level, with other relevant bodies in the field of ethics and bioethics, with a view to sharing best practices; to prepare guidance and recommendations in cases and situations that generate or may generate ethical conflicts arising from clinical practice." (similar to Article 3(d) of Decree-Law No. 80/2018 of 15 October).

The document contains no reference to any registry of clinical studies, an important element in this area, which would align with the creation of the database mentioned above.

Finally, it should be noted that there is only a brief reference in the draft to the principle of the dignity and integrity of the human person: "recommending that researchers submit projects in accordance with ethical principles"[13]. It is therefore proposed that, in the article on competences, the following be added: "It shall be the general competence of the CNEPS to ensure, within the functioning of the institution, compliance with ethical standards, safeguarding the principle of the dignity and integrity of the human person."

3.4. Mozambique

The Human Health Research Law opted to annex a glossary rather than include an article consolidating all definitions of the concepts used throughout the legal text – as previously noted.

In Article 6 – "Primacy and rights of participants in human health research" – a subparagraph concerning informed consent should be added, using wording such as: "The participant, or their representative, may revoke informed consent at any time without incurring any form of liability," as provided in Article 6(4) of Law No. 21/2014 of 16 April.

There are several aspects whose inclusion is essential. Concerning the database of clinical studies, and to harmonise the regulatory frameworks of the PSAC, it is essential to provide clear legislative provisions[14], for example: "ARMED shall be

[13] Article 4(2)(d)
[14] "At present, this database is grounded in the interaction between Article 11(2)(j) of the Health Research Law and Article 17 of Decree-Law No. 53/2024 of 18 July, which approves the regulation of the Human Health Research Law."

responsible for creating a database on clinical trials and clinical studies involving medical devices conducted in clinical study centres located within national territory. This database shall include detailed records of: data extracted from authorisation requests; inspections carried out to verify compliance with good clinical practice; data relating to suspected unexpected serious adverse reactions or serious adverse events; and the justification for the need to include personal data identifying or making it possible to identify participants." It should also be stipulated that: "The database and the exchange of the data contained therein shall strictly comply with the principle of confidentiality." (similar to Article 38 of Law No. 21/2014 of 16 April).

It is also necessary to introduce a definition of dissemination of clinical studies, such as: "Any form of communication intended to inform or having the effect of informing about the conduct of a clinical study, which may include observations made in the context of the study, interpretation of results and conclusions thereof to the public, to health professionals, to the media, in general or scientific publications regardless of their target audience, and in advertising material for medicinal products, medical devices or any other means of health intervention." (as in subparagraph (m) of Article 2 and Article 40 of Law No. 21/2014 of 16 April).

Regarding post-trial monitoring of participants, which is referenced in the draft ethics regulation, a more detailed legislative provision is recommended: "The Ethics Committee shall be responsible for assessing the conditions for the clinical follow-up of participants after the conclusion of the clinical study, where justified." (as set out in Article 16(6)(i) and Article 36(g) of Law No. 21/2014 of 16 April).

Another essential aspect requiring further detail concerns urgent safety measures, for which a legislative solution is proposed in the following terms: "The sponsor and the investigator shall take all urgent measures necessary to protect participants against any immediate risk to their safety, particularly arising from any supervening fact related to the conduct of the interventional clinical study or to the development of the investigational medicinal product, the device under investigation or any other intervention." (similar to Article 20 of Law No. 21/2014 of 16 April). It should also be stated that: "The sponsor shall, without delay, provide the National Research Ethics Committee for Health, ANARME and other competent authorities with the information on the identified risks and the measures adopted."

As regards safety and oversight, a strengthened legislative formulation is recommended: “To establish and maintain a system of safety and surveillance of the clinical study through monitoring carried out under the responsibility of a qualified professional,” similar to Article 9(1)(g) of Law No. 21/2014 of 16 April. Oversight relates to inspection, defined as: “The activity consisting of the official control of documents, facilities, records, quality assurance systems, and any other elements deemed relevant to the research.” (subparagraph (x) of Article 2 of Law No. 21/2014 of 16 April).

It is recommended that the introduction and strengthening of these ethical requirements be integrated through an amendment to Good Practice Resolution No. 5/2023 of 8 November, as this is likely to constitute the most efficient legislative route.

Regarding the internal regulation of the National Research Ethics Committee for Health, it is proposed that an article be included concerning requests for opinions, information and statements, in the following terms: “The following may request the issuance of opinions, reports, recommendations and other documents from the National Research Ethics Committee for Health: the highest governing body of the institution or intermediate management bodies; any professional of the institution; any researcher intending to conduct clinical research studies within the institution; any participant or potential participant in clinical research studies conducted within the institution; users of the institution, their representatives or family members who demonstrate an objective interest affecting the exercise of their rights in relation to the institution.” (cf. Article 5 of Decree-Law No. 80/2018 of 15 October).

3.5. São Tomé e Príncipe

Following an analysis of the legislative framework of São Tomé and Príncipe, and noting the robustness of the instruments currently under consideration – namely the internal regulation of the Health Ethics Committee for Scientific Research, the Health Framework Law, the draft Decree-Law establishing the Regulatory Authority for Pharmacy, Medicines and Health Technologies and approving its Statute – it is

recommended that a specific legal instrument[15] dedicated to clinical research be developed, incorporating all currently omitted requirements.

Accordingly, it is suggested that a provision be introduced setting out the definitions to be used throughout the instrument, including the concepts of auditor, manufacturer, monitor, participant, sponsor, good clinical practice, informed consent, and clinical trial, similar to Article 2 of Law No. 21/2014 of 16 April. This provision should be followed by the enshrinement of the principles relating to the human person and good clinical practice, in line with Articles 3 and 4 of the aforementioned Law.

The assessment of risks and benefits is essential in this field; therefore, the following legislative wording is proposed: "1 – The conduct of clinical studies shall depend on a prior assessment concluding that the potential benefits, whether present or future, outweigh the foreseeable risks and inconveniences. 2 – The Health Ethics Committee for Scientific Research (CESIC) and the Regulatory Authority for Pharmacy, Medicines and Health Technologies (ARFAMED) shall be responsible for deliberating on the assessment and the conclusion referred to in the preceding paragraph, within their respective areas of competence. 3 – CESIC and ARFAMED shall supervise the conduct of the clinical study and the maintenance of the evaluated conditions, within their respective areas of competence. 4 – The assessment described may be reviewed at any time during the clinical study in the event of new evidence or interim analyses of the study itself." (cf. Article 5 of Law No. 21/2014 of 16 April).

Informed consent, as a fundamental pillar of clinical research, must be strengthened, particularly through the inclusion of provisions safeguarding minor participants and adults incapable of providing informed consent, similar to Articles 6, 7 and 8 of Law No. 21/2014 of 16 April.

With regard to data protection, São Tomé and Príncipe has in force Law No. 03/2016 of 10 May, which regulates the protection of personal data. While this Law is detailed, it does not address information processed within the context of clinical trials. Accordingly, it is proposed that a future health research law incorporate a provision along the following lines: "Information transmitted under this Law is confidential, and all those who become aware of it shall be subject to a duty of secrecy, without prejudice to the

[15] At the CT-Luso Workshop held on 24 September 2025, the legal expert from São Tomé and Príncipe clarified that the Minister's adviser would be responsible for developing the draft Decree-Law (which would be essential, as it constitutes a faster legislative route) or Law.

disclosure of information necessary for the protection of public health. The foregoing shall not affect compliance with the obligations of the competent authority and notified bodies as regards reciprocal information and the issuing of warnings. All those who, in any capacity, take part in clinical studies or who, by any means, become aware of their conduct shall be bound by a duty of secrecy concerning any personal data to which they have access, even after the termination of their functions.” (similar to Article 51 of Law No. 21/2014 of 16 April). Moreover, Law No. 03/2016 of 10 May[16] does not provide for the role of a Data Protection Officer, an essential element in ensuring compliance. A provision equivalent to Article 38 of Regulation (EU) 2016/679 (General Data Protection Regulation) should therefore be added.

Regarding conflicts of interest, the following wording is recommended: “The Health Ethics Committee for Scientific Research must issue a mandatory opinion on any situations of conflict of interest involving the sponsor or the investigator participating in the clinical study” and “the disclosure of clinical studies must indicate any conflicts of interest of those responsible for conducting the study, namely the investigator, the sponsor, and the clinical study site, where such conflicts exist,” in line with Article 16(6)(h) of Law No. 21/2014 of 16 April.

With regard to the database on clinical trials and clinical studies, the creation of a database similar to that in force in Portugal (Article 38 of Law No. 21/2014 of 16 April) is recommended. Accordingly, the following legislative solution is proposed: “ARFAMED shall be responsible for creating a database on clinical trials and clinical studies involving medical devices carried out at clinical study centres located within the national territory. This database must include detailed records of: data extracted from authorisation requests; inspections carried out to verify compliance with good clinical practice; data relating to suspected unexpected serious adverse reactions or serious adverse events; and the justification for the need to include personal data identifying or allowing the identification of participants.” It should also be added that “the database and the exchange of the data contained therein shall strictly comply with the principle of confidentiality.”

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[16] “Only the following reference is made in Article 23: ‘Requests for an opinion or for authorisation, as well as notifications, submitted to the National Personal Data Protection Agency must contain the following information: (…) (e) the entity responsible for processing the information, if different from the data controller.”

Regarding the post-trial follow-up of participants, the following legislative provision is proposed: "The Health Ethics Committee for Scientific Research shall assess the conditions for clinical follow-up of participants after the completion of the clinical study, in cases where such follow-up is justified" (cf. Article 16(6)(i) and Article 36(g) of Law No. 21/2014 of 16 April).

As an essential component of clinical trials, urgent safety measures should be provided for, namely that "the sponsor and the investigator shall take all urgent measures deemed appropriate to protect participants against any immediate risk to their safety, including any newly arising facts related to the conduct of the clinical study involving intervention, or to the development of the investigational medicinal product, the device under investigation, or any other intervention" (cf. Article 20 of Law No. 21/2014 of 16 April). It should also be stated that "the sponsor shall promptly submit to the CESIC, ARFAMED, and all other competent authorities the relevant risk information and the measures adopted."

The inclusion of civil liability provisions is also necessary in this domain, with a clause similar to Article 15 of Law No. 21/2014 of 16 April being recommended.

A specific section should be devoted to the fundamental aspects of clinical trials, including the authorisation procedure, similar to Article 26 of Law No. 21/2014 of 16 April, as well as provisions on investigational medicinal products (cf. Subsection II). Finally, reference should be made to the existing authorities, in order to harmonise the legal instruments already in force or under legislative review in São Tomé and Príncipe, thereby strengthening the proposed framework to be developed.

4. Next steps and objectives of each country

All countries are currently in a phase of consolidating and harmonising their legislation in relation to biomedical research and, in particular, clinical trials. In September, during the workshop dedicated to "Building Lusophone Regulatory and Procedural Harmonisation for Clinical Trials", the legal experts representing the five partner countries, together with the heads of their respective National Regulatory Authorities and National Research Ethics Committees, prepared proposals for legislative amendments and assumed commitments which were subsequently updated at the 14th

CT-Luso meeting held on 5 November 2025. At that meeting, the international legal experts reviewed the status of each commitment undertaken, noting progress since September.

The tables below present the commitments as of that date.

Objective	Strategy	Deadline	Status Update
Preparation of Clinical Trial Regulations, considering international best practices	Holding working sessions with the existing technical group	Until May 2026	
Creation of the National Bioethics Committee for Research Involving Humans and its regulation	Drafting the proposal for the establishment and regulation of the Committee	Until December 2025	
Development of a workflow for the processing, authorisation and management of clinical trial applications between ARMED and the Ethics Committee	Holding working sessions with the existing technical group	Until December 2025	A meeting is scheduled for mid-November.

Objective	Strategy	Deadline	Status Update
Training of Inspectors and Technical Staff	Preparation of a Training Plan	Until January 2026	
Creation of Clinical Study Databases	Acquisition of IT equipment and data-management software	Until February 2026	A meeting is scheduled for mid-November.
Improvement of laboratory infrastructure and technical capacity		Ongoing	

Legend: table presented by Angola.

Activity	Target	Deadline	Status Update
Promotion of a meeting between the entities and the Minister of Health	Advocacy for the remaining activities related to the approval of the legal instruments	October 2025	Completed: - meeting of the CNEPS with the Minister - meeting of ERIS with the Minister
Promotion of actions aimed at approving the draft law amending Decree-Law 26/2007	CNEIS operational and regulatory competences in research ethics strengthened	December 2025	The review work began on 5 November 2025 and will be concluded by 14 November. A meeting between the legal expert

Activity	Target	Deadline	Status Update
Promotion of actions aimed at approving the draft Clinical Research Law	New legal framework established for health research	December 2025	and the President of the CNES will follow. The draft instruments will then be sent to the Minister for approval by the Council of Ministers and subsequently submitted to Parliament.
Provision of a secretariat for the CNEIS, with the technical and administrative staff required to perform its functions	Improved technical and administrative working conditions	1st Quarter 2026	
Provision of a dedicated space for the CNEIS to carry out its activities.	Improved operating conditions and functionality	1st Quarter 2026	
Provision of resources for the creation and launch of a CNEIS website and the updating of the ERIS website	Improved communication conditions, especially with the public	1st Quarter 2026	
Training and capacity building for staff of CNEIS, ERIS and	Staff of the entities involved trained and capacitated	1st Quarter 2026	

Activity	Target	Deadline	Status Update
Institutional Ethics Committees			

Legend: table presented by Cape Verde.

Objetive	Action	Strategy	Deadline	Responsible Entity
Provide ARFAME and the CNEPS with a webpage	Design the webpage with financial support from ARFAME's revenue	Hire an IT consultant	By December 2025	ARFAME
Training new pharmacists to address the shortage of pharmaceutical professionals	Identification of training needs by ARFAME in coordination with the Pharmacy Council of Guinea-Bissau	Advocate with academic institutions in Guinea-Bissau, the Pharmacy Council of Guinea-Bissau, and the Portuguese Pharmaceutical Society	By December 2025	ARFAME/MINSAP
Provide the CNEPS with a legal and regulatory	Finalise and technically validate the normative and legal	Advocacy with the senior leadership of MINSAP	By December 2025	Members of CNEPS e o MINSAP

Objetive	Action	Strategy	Deadline	Responsible Entity
instrument for its functioning	documents (Laws, Statutes and Internal Regulations) and ensure their approval by the Council of Ministers and subsequent promulgation by the President of the Republic			
Create a more organised and robust information management mechanism	Create a database for the registration of submitted protocols and implement monitoring of approved studies	Take inspiration from the databases of other countries in the sub-region and the PSAC	By March 2026	Permanent Secretary of the CNEPS
Implement a national registration system for	Develop, validate and implement the National	Request support from CT-Luso;	By May 2026	Members of the CNEPS and MINSAP

Objetive	Action	Strategy	Deadline	Responsible Entity
scientific studies in health	Registration Form for scientific studies related to human health carried out in Guinea-Bissau	Request support from UNESCO; Request support from WHO; Advocacy with the senior leadership of MINSAP; Advocacy with entities and researchers conducting work in Guinea-Bissau.		
Provide the country with a national Scientific Research Law	Draft and adopt a Scientific Research Law at national level	Request support from CT-Luso; Request support from UNESCO; Request support from WHO; Advocacy with the senior leadership of MENES and MINSAP; Advocacy with entities and	1st Quarter of 2026	Members of the CNEPS, MENES and MINSAP

Objetive	Action	Strategy	Deadline	Responsible Entity
		researchers conducting work in Guinea-Bissau.		
Provide the country with a national Biomedical Research Law	Draft and adopt a Biomedical Research Law at national level	Request support from CT-Luso; Request support from UNESCO; Request support from WHO; Advocacy with the senior leadership of MENES and MINSAP; Advocacy with entities and researchers conducting work in Guinea-Bissau.	2nd Quarter of 2026	Members of the CNEPS, MENES and MINSAP

Legend: table presented by Guinea-Bissau.

Objective	Status Update
WHO GBT assessment for the National Regulatory Authority and Research Ethics	In progress. A formal GBT assessment by WHO inspectors is underway

Objective	Status Update
Committees (achievement of Maturity Level 3);	regarding the quality control laboratory. The Research Ethics Committee is progressing with normative documents; they have completed the WHO survey on the assessment of Research Ethics Committees and have received recommended documents, which are currently being shared. A meeting was held with ANARME to complete certain documents required for the assessment of clinical trials within the GBT evaluation. Support is being provided to ANARME to finalise these documents. Participation is planned in the WHO assessment visit taking place in Mozambique during the week of 24 November.
Digital transformation with computerised review processes;	At an advanced stage, with a company currently working on the digitalisation of all documents.
Addressing the gaps identified in the comparative legislative study among the PSAC (regulations on research involving medical devices, completion of SOPs for	Not yet initiated.

Objective	Status Update
each institution covered by the law, harmonisation of existing legislation);	
Continuous capacity-building and staff development;	Ongoing training with INFARMED.
Establishment of communication platforms and mechanisms for sharing experience and knowledge among institutions and among the PSAC;	
Joint assessments and supervision/inspections in Good Clinical Practice.	

Legend: table presented by Mozambique.

Strategic Pillars	Priority Actions	Responsible Entity	Deadline	Status update
1. Legal Framework	Develop the special legal framework for scientific research and clinical trials, aligned with international standards (including ethical requirements)	Ministry of Health	2026	
	Develop the special legal framework for	Ministry of Health	2025	The document is currently

Strategic Pillars	Priority Actions	Responsible Entity	Deadline	Status update
	the National Research Ethics Committee for Health and Clinical Research			with the Legal Office of the Ministry of Health for further progress, which will take place in 2025.
	Approve the Internal Regulation of the Ethics Committee through a normative act of the Government (Decree or Resolution of the Council of Ministers)	Ministry of Health	2026	
2. Submission and Evaluation Processes	Establish fees through a joint order signed by the ministers responsible for finance and health, in compliance with the legal procedures governing the State financial administration system.	Ministry of Health	2025	The document is currently with the Legal Office of the Ministry of Health for further progress, which will take place in 2025.

Strategic Pillars	Priority Actions	Responsible Entity	Deadline	Status update
3. Governance and Capacity-Building	Train the teams in Good Clinical Practice and regulatory assessment.	Ministry of Health	2026	
	Organise an integrated national symposium on scientific research and clinical trials (CT-Luso project)	Ministry of Health	2026 - annual	

Legend: table presented by São Tomé and Príncipe.