CT-Luso

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

Project 101145790

WP8 - Communication, Dissemination, Exploitation of results and building a knowledge community

Deliverable 8.8 – Stewardship Plan

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1. Introduction

The CT-Luso project is an ethical and regulatory capacity-building project in the field of Clinical Trials (CT) in the Portuguese-speaking African Countries (PSAC) – Angola, Cape Verde, Guinea-Bissau, Mozambique and São Tomé and Príncipe – in partnership with Portugal. It was approved and funded by the Global Health European and Developing Countries Clinical Trials Partnership 3 (GH EDCTP3), with the support of the European Union (EU), and runs from September 2024 to December 2027.

Its overall objective is to contribute to the ethical and regulatory capacity-building of CTs in the PSAC, through three main specific objectives designed across different timeframes to ensure the long-term and sustainable replication of the project:

- (short-term) To strengthen and harmonise the ethical and legal framework for the conduct of CTs, the operational procedures of the competent institutions responsible for monitoring their lifecycle, and the training of professionals involved in managing the process, in support of the international validation of research;
- (medium-term) To establish a community of practice through the engagement of multiple stakeholders, promoting scientific research in view of its impact on scientific culture and socioeconomic development, as well as its integration into broad and credible international networks;
- (long-term) To build solid foundations for the establishment of a Lusophone CT cluster, enabling the submission of research protocols for implementation across the five PSAC, thereby attracting international investment, streamlining processes, optimising resources, and strengthening both the scope and quality of research.

CT-Luso is structured into eight Work Packages (WP): Coordination and management (WP1), Scientific leadership (WP2), Analysis of Legislative Gaps and Recommendations for Scientific Research Policies and Public Policies Implementation (WP3), Specialised professional training (WPs 4, 5, 6 and 7), and Communication, Dissemination, Exploitation of Results, and Community Building (WP8).

The project operates through an integrated approach across three complementary dimensions – legislative, institutional and professional – aimed at addressing the main constraints identified in the PSAC for the safe implementation of CTs in their respective

countries. In this context, the different WPs were designed to encompass these three dimensions and to establish the best possible conditions for their balanced development, ensuring a coherent and coordinated approach between: the analysis of legislative and institutional frameworks, with specific recommendations for strengthening the former and reinforcing the latter; and the training of qualified human resources.

The Stewardship Plan of the CT-Luso project aims to describe how the results achieved and the networks established throughout the project will be maintained, managed and used sustainably after its completion.

This plan seeks to ensure the continuation of training activities and the reproducibility of acquired competencies, the uptake of results by partner institutions and by the national public policy systems (particularly in health and science) of the PSAC, as well as ensuring broad access to and reuse of the materials produced. It also aims to define principles of responsible governance for the future management of these resources.

Additionally, the plan seeks to contribute to the consolidation of an active community of practice capable not only of sustaining the collaborative dynamics established during the project, but also of strengthening, in the medium and long term, the capacity of the participating countries to host and manage clinical trials, as well as to design and lead national and international projects.

Finally, the objective is for the five partner countries to become a unified hub for engagement with international clinical trial consortia. In other words, these countries, with their diverse geographical, climatic and ethnic realities, are expected to position themselves as a harmonised space – at legislative level (robust), institutional level (streamlined and agile), and professional level (competent) – for the conduct of clinical trials, a highly relevant factor in attracting external investment in this field.

2. Expected Results of the CT-Luso Project

The CT-Luso project will generate a set of results reflecting its action across the legislative, institutional and professional dimensions in the PSAC.

At the legislative level, the project includes:

- the completion of an in-depth analysis of the ethical and legal framework of the partner countries – D3.1 Legislation Dossier and D3.2 Organograms for each PSAC showing the relations between NRA and REC;
- the identification of gaps, challenges and opportunities in relation to international best practices in the field of biomedical research, as well as the formulation of recommendations aimed at supporting the development of a more robust legislative and institutional framework – D3.3 Legislative Recommendations.

These activities have already been completed and have enabled the proposal of harmonised approaches across the PSAC aligned with international best practices, contributing to a safer and more efficient environment for biomedical research and for clinical trials during their implementation. Throughout this process, different stakeholders were engaged and progressively integrated into the emerging community, ranging from Ambassadors to professionals and researchers, in addition to the institutional partners.

At the institutional level, the project will promote the strengthening and consolidation of collaborative networks between the PSAC and Portugal, involving National Regulatory Authorities, Research institutions, Universities and other relevant stakeholders.

This network has been progressively built and expanded throughout the project through the implementation of training programmes and thematic webinars aimed at partner institutions and other professionals working in the field of clinical research in the partner countries. The project has already delivered:

- the training programme “The Ethical and Legal Requirements for the Development of Scientific and Clinical Research”, accredited by NOVA University Lisbon and the Faculty of Pharmacy of the University of Lisbon. The training was completed by 234 professionals from the PSAC, and the results are available in D4.2 – Results of the Training “The Ethical and Legal Requirements for the Development of Scientific and Clinical Research”;
- a complementary training webinar series aimed at developing and deepening some of the topics taught in the Training Programme and reinforcing the training delivered

through the selection of new related topics whose study may contribute to the educational qualification of participants – available in D4.3 Complementary Training Programme and on the project website.

Throughout these activities, professionals from various institutions and researchers specialised in several fields related to those prioritised by the project have been involved, thus expanding the emerging community. These networks will form the basis for the development of a sustainable community of practice, facilitating knowledge sharing, scientific cooperation and integration into international networks.

The project will also produce a set of scientific and technical deliverables resulting from activities carried out within the different work packages, contributing to knowledge production, decision-making support and the improvement of practices in the field of clinical trials.

The deliverables already produced by the project are available on the website, in both Portuguese and English, under open and free access. This ensures transparency regarding the results achieved and allows broad access to the content, methodologies and approaches adopted, facilitating their uptake and replication in similar contexts, thereby positioning them as a decisive factor in expanding the emerging community.

Future deliverables include:

- training materials resulting from the ongoing and forthcoming training programmes. These materials directly contribute to the reproducibility of the project from both training and institutional perspectives, strengthening and standardising existing procedures;
- strategic documents related to project sustainability, dissemination of results and communication activities throughout the project (monthly newsletters, posters and scientific communications). These documents ensure long-term planning that supports responsible management and the sustainability of the project.

In the field of professional capacity-building, four training programmes will be developed and implemented throughout the project, targeting the main stakeholders in clinical research in the partner countries, including members of National Regulatory Authorities and Research Ethics Committees, Researchers and Clinicians, Research project managers, Research centre administrators, University lecturers and other professionals.

These initiatives aim to strengthen the technical, ethical and regulatory competencies required for the conduct, evaluation and monitoring of CTs. The first training programme has already been completed and enabled the capacity-building of 234 professionals from the PSAC – D4.2 – Results of the Training "The Ethical and Legal Requirements for the Development of Scientific and Clinical Research".

Following the training programmes, training materials and resources adapted to different levels of specialisation will be produced, promoting a train-the-trainer approach in which trainees become trainers, thereby multiplying knowledge and enabling the continuation of training activities beyond the duration of the project.

The training programme already completed produced a set of training materials: D4.5 Training Programme Manual "The Ethical and Legal Requirements for the Development of Scientific and Clinical Research", D4.5 Infographic on the Informed Consent Form, D4.5 Infographic on the Submission and Evaluation Process of Research Projects, and templates – D4.4 Evaluation Templates Research Ethics Committees and National Regulatory Authorities. The remaining training programmes will generate additional training materials and templates of progressively more specific nature according to the relevant professional field and institution, adapted to the reality of each country.

Additionally, the project includes a strong dissemination component through the production of scientific articles, posters and presentations at national and international conferences.

The project has already been presented at international forums, namely:

- Mota-Filipe, H. et al., "CT-Luso Project" (oral communication). 82nd FIP World Congress of Pharmacy and Pharmaceutical Sciences, Cape Town, South Africa, 1 – 4 September 2024.
- Patrão Neves, M., Ribeiro, M. A., Mota-Filipe, H. et al., "CT-Luso - Ethics and Regulatory Capacity Building Partnership for Clinical Trials in Portuguese-speaking African Countries" (poster). 5th European Conference on Pharmaceutics, Porto, 24–25 March 2025.
- Patrão Neves, M., Mota-Filipe. H., Barbosa, C. et al., "CT-Luso - Ethics and Regulatory Capacity Building Partnership for Clinical Trials in Portuguese-speaking African Countries" (poster). 83th FIP World Congress of Pharmacy and Pharmaceutical Sciences, Copenhagen, Denmark, 31 August – 3 September 2025.

The project has already published some of its legislative results in the following articles:

- CT-Luso: para uma harmonização ética e regulatória dos ensaios clínicos nos países africanos de língua portuguesa. (2025). *Cadernos Ibero-Americanos De Direito Sanitário*, *14*(4), 12-27. https://doi.org/10.17566/ciads.v14i4.1398
- Strengthening Ethical and Regulatory Frameworks for Clinical Trials in Lusophone Africa: Insights from the CT-Luso Project – article submitted to Medicine and Law.

Regarding training outcomes, the article "Clinical trials in Lusophone Africa – results from a capacity building training initiative" (DOI: https://doi.org/10.21203/rs.3.rs-8065478/v1) has undergone peer review and was submitted to BMC Medical Education.

These activities will contribute to increasing the visibility of CT-Luso, promoting knowledge sharing and positioning the PSAC within the global clinical research landscape. At the same time, they provide an opportunity to generate scientific evidence on the topics addressed by the project, particularly in the areas of ethics, regulation and capacity-building in clinical trials, thereby strengthening the impact and credibility of the initiatives developed. These data will be important tools to support the creation of new projects and initiatives in these fields.

3. Stewardship Strategy

The stewardship strategy of the CT-Luso project aims to ensure the continuity, institutional ownership and sustainable use of the results achieved, ensuring that the benefits generated throughout the project endure beyond the funding period, within a logic of replication and multiplication. This strategy is based on the three pillars of the project already identified – legislative, institutional and professional – promoting their mutual consolidation within the national systems of the PSAC.

At the legislative and regulatory level, the sustainability of results will rely on promoting the adoption and implementation of the recommendations produced within the framework of the project, in coordination with the competent national authorities. The continuous involvement of these entities throughout the project, as has been fostered, will facilitate ownership of the results and increase the likelihood of integrating the proposed measures into national regulatory frameworks.

CT-Luso will continue to involve the PSAC Ambassadors accredited to Portugal, as well as the national representatives to the Community of Portuguese Language Countries (CPLP), who may support institutional dialogue and strengthen coordination with political decision-makers in their respective countries. This approach will contribute to the gradual harmonisation of regulatory systems in the PSAC and their alignment with international best practices.

The PSAC Ambassadors in Portugal have been involved since the beginning of the project, both through formal meetings and participation in public events. The project coordination team met with the Ambassadors and their respective representatives from all partner countries to present CT-Luso, promote close and agile contact between institutions, and share the project's results.

The project's public events have also included representation from the PSAC Ambassadors in Portugal and from the Ambassadors of Portuguese-speaking Countries to the CPLP, namely:

- Lusophone International Symposium "Lusophone regulatory and procedural harmonisation for clinical trials: is it possible?" – 25 September 2025, Portuguese Pharmaceutical Society, Lisbon;
- Lusophone Workshop "Legal and institutional recommendations for Lusophone harmonisation in the field of clinical trials" – 11 March 2026, Community of Portuguese Language Countries, Lisbon.

At the institutional level, the strategy is based on consolidating the collaborative networks established between the partner countries and Portugal. These have been developed mainly through the joint work carried out within the implementation of the project, but also through complementary initiatives such as participation in academic, scientific and professional events.

The project foresees the implementation of an in-person internship programme, which will allow 28 professionals from National Regulatory Authorities, Research Ethics Committees and Researchers from the PSAC to receive training with counterpart institutions in Portugal – National Authority of Medicines and Health Products (INFARMED, I.P.), Ethics Committee for Clinical Research (CEIC), NOVA University Lisbon and BlueClinical.

The sharing of experiences and the networks established between partner entities may also promote the engagement of African partners with other biomedical research projects led by members of the consortium.

These networks, which continue to expand and strengthen beyond the partnerships formally established within the project, will form the basis for the continuity of scientific and technical cooperation, promoting the sharing of experiences, the implementation of joint initiatives and integration into international consortia. The creation of an active community of practice will allow collaborative dynamics to continue beyond the project lifecycle.

In the field of capacity-building, sustainability will be ensured through the integration of training programmes into partner institutions, namely Universities, Research centres and National Regulatory Authorities. The adopted train-the-trainer approach will allow professionals trained within the project to become multipliers of knowledge, ensuring the continuity of training activities and the progressive expansion of the pool of qualified human resources in the field of clinical trials. The training materials and resources developed will be made freely accessible and made available in a structured manner, enabling their reuse for training activities, institutional capacity-building and support for the implementation of best practices in the field of clinical trials, while ensuring their adaptation to local needs and specificities.

Additionally, the continuous dissemination of project results through scientific publications, presentations and participation in international events will contribute to maintaining the visibility of CT-Luso and reinforcing its impact. These activities will not only disseminate the results achieved but also generate additional evidence and attract new opportunities for collaboration and funding.

Whenever public events are held, the project prepares press releases that are sent to national media outlets and to media in the partner countries. This has proven to be a particularly effective measure for disseminating project results and is intended to be maintained throughout the project, while encouraging its replication among partners. At the same time, the project operates in close coordination with the communication offices of partner institutions, the CPLP and institutions working within the Lusophone sphere. Partner countries are also encouraged to carry out local dissemination of results in forums and events related to the project themes.

The project will promote follow-up of the implementation of project activities and results after its completion through monitoring and knowledge-sharing mechanisms among partners. This process will make it possible to assess the continuity of actions, identify emerging needs and support the adaptation of initiatives to different national contexts.

3.1. Stewardship stategy of the partner institutions

The sustainability and stewardship of the CT-Luso project is a shared responsibility among the various partner institutions. The entities directly involved, namely National Regulatory Authorities, academic institutions and research centres in the PSAC, will be responsible for ensuring the continuity of actions within their respective national contexts, with the support of the Portuguese Pharmaceutical Society and the other Portuguese partners.

Coordination among partners will also be promoted through the institutional network established within the framework of CT-Luso, ensuring information sharing and strategic alignment. This strengthens local ownership of the results and contributes to their long-term sustainability.

For the preparation of this document, all partner institutions were invited to participate, contributing with the strategies they intend to adopt to ensure the stewardship of the project. Most partner institutions shared their contributions, and this document is the result of that cooperative effort.

3.1.1. Angola

Medicines and Health Technologies Regulatory Agency (ARMED)

To develop and ensure the sustainability of the results of the CT-Luso project, ARMED has included in its action plan the provision of training in the field of Clinical Trials. Currently, ARMED has seven senior technical staff benefiting from training on Good Clinical Practices – ICH-GCP(R3) Guidelines through CT-Luso, as a way of strengthening, building capacity and training the technical team responsible for the assessment of clinical trial dossiers at the level of the National Regulatory Authority.

Although ARMED does not have a dedicated Clinical Trials Support Office, it has a structured Clinical Trials area integrated within the Department of Pharmacovigilance,

Technovigilance and Clinical Trials of the National Regulatory Authority, which includes two technical officers and one legal adviser.

Regarding training activities in the field of clinical trials, the establishment of a content repository and follow-up mechanisms beyond the CT-Luso collaboration, ARMED is currently seeking to formalise partnerships to ensure the continuity of the results already achieved.

National Scientific Research Center of Angola (CNIC)

The CNIC is committed to ensuring the continuity of the results achieved through the operationalisation of the future Ethics Office, which will function as a permanent structure to support ethical review and the monitoring of scientific projects. It is also planned to maintain regular internal capacity-building activities for researchers and technical staff, making use of the knowledge acquired within the framework of CT-Luso and multiplying it among new institutional staff.

Additionally, CNIC intends to develop an institutional repository of technical documents, training materials and guidance produced during the project, facilitating continuous access to the resources created. Monitoring and follow-up mechanisms for supported projects will also be established, as well as strategic partnerships with other national and international institutions, to consolidate a sustainable network for scientific collaboration and ethics in research.

National Institute for Health Research (INIS)

To ensure the consolidation and sustainability of the achievements reached, the following strategies are proposed:

- The establishment of a Joint Technical Committee within the Lusophone framework, with responsibilities for supporting the supervision of clinical trials, promoting regulatory harmonisation and issuing joint opinions, under a rotating leadership model;
- The development of a shared repository of technical content, legislation, standards and guidelines, promoting access to information and the harmonisation of practices among partner countries;

- The institutionalisation of an Office for Training Support and Continuous Capacity-Building, focused on areas such as bioethics, health law, clinical trials and biomedical research;
- The formalisation of an interinstitutional commitment among partners, aimed at ensuring the continuity, maintenance and expansion of the results already achieved;
- The development of an advocacy and institutional mobilisation plan, aimed at raising awareness among the governments of partner countries of the strategic importance of the project and securing its funding and sustainability in the medium and long term.

3.1.2. Cape Verde

National Health Research Ethics Committee (CNEPS)

The ongoing legislative reform aims to transform the current National Health Research Ethics Committee (CNEPS) into the National Health Ethics Council (CNES), with an expanded composition and broader responsibilities. The proposed legislation provides that the CNES will have a support office composed of duly qualified and specialised technical staff, particularly in the fields of social sciences, pharmaceutical sciences, law and statistics, to ensure the effective fulfilment of its responsibilities and compliance with the deadlines established for its activities.

For CNES to operate fully and effectively, several conditions must be met, namely:

- The allocation of dedicated premises for its installation;
- The assignment of the necessary human resources to the CNES Secretariat so that it may fulfil the objectives and legal responsibilities entrusted to it;
- The preparation and implementation of a continuous training and capacity-building plan for CNES members, including a specific induction and training plan for new members joining the CNES as part of its expansion;
- The provision and budgeting of the financial resources necessary for the functioning of the CNES, as well as the establishment of partnerships aimed at ensuring the effective implementation of the training and capacity-building plan for its members;
- The furnishing of office facilities, namely the Chairperson’s office, meeting room and Secretariat office;

- The provision of IT resources to support the functioning of the Secretariat and the management of archives;
- The creation and implementation of a CNES website to enable the dissemination of information, guidelines and various forms, as well as to allow the online submission of research projects for CNES review and assessment.

Independent Health Regulatory Authority (ERIS)

ERIS will ensure the sustainability of the results of the CT-Luso project through the institutionalisation of permanent structures and mechanisms for technical support. In this context, following the approval of the biomedical research law, the creation of a technical support office is envisaged, dedicated to the consolidation and dissemination of the knowledge acquired, as well as to the coordination of subsequent activities.

At the same time, a digital content repository will be developed, containing manuals, procedures, training materials and technical guidelines produced within the framework of the project, ensuring continuous access to and preservation of institutional knowledge.

In addition, ERIS reaffirms its commitment to integrating technical capacity-building as a core component of its activities, promoting a continuous programme of internal training and professional development activities for its staff and institutional partners.

Monitoring and evaluation mechanisms will also be implemented, including performance indicators and periodic reports, to assess the practical application of the knowledge transferred and introduce continuous improvements.

Cooperation with reference institutions such as INFARMED, I.P., will be maintained as a strategic pillar to ensure continuous technical updating and alignment with international best practices.

National Institute of Public Health (INSP)

INSP has a set of institutional capacities, technical expertise and strategic partnerships which, combined with ongoing and planned initiatives, create favourable conditions to ensure the sustainability of the results of the CT-Luso project.

1. Institutional Integration and Strategic Alignment

INSP already has strategic and operational planning mechanisms that enable the incorporation of CT-Luso results into its regular activities. The integration of the tools, methodologies and approaches developed within the project into annual plans and national strategic instruments is foreseen, ensuring continuity and alignment with the priorities of the health sector.

2. Human Resources capacity-building

INSP has a multidisciplinary technical team with experience in epidemiological surveillance, applied research and public health, which has been further strengthened through training activities promoted within the framework of CT-Luso.

It is also essential to adopt a cascade training approach, allowing the knowledge and competencies acquired to be expanded at national level. In this regard, continued support from the CT-Luso project team will be highly valuable.

3. National and International Partnerships

INSP maintains well-established relationships with the Ministry of Health, academic and non-academic research institutions, as well as international partners, which can facilitate the continuity of the technical and scientific cooperation initiated under CT-Luso.

4. Financial Sustainability

To ensure the continuity of activities, INSP aims to rely on:

- the integration of priority activities into institutional and national budgets;
- the mobilisation of resources through new applications for international funding;
- the use of synergies with other ongoing projects.

5. Production and Use of Evidence

INSP has solid experience in the production of reports, studies and scientific evidence. The objective is to strengthen knowledge translation into public policies, ensuring that the results of CT-Luso continue to inform decision-making processes.

3.1.3. Guinea-Bissau

National Health Research Ethics Committee (CNEPS)

CNEPS and the Regulatory Authority for Pharmacy, Laboratory, Medicines and Other Health Products (ARFAME) of Guinea-Bissau, within the framework of the CT-Luso

project (2024 – 2027), are committed to local capacity-building, legislative harmonisation and the establishment of partnerships to ensure the sustainability of clinical trials and biomedical research in the country.

To ensure the effective implementation of these objectives, the main sustainability strategies and solutions should be structured as follows:

- Continuous training capacity: implementation of training programmes for local professionals, with a focus on competitive and regulated capacity-building.
- Legislation: Development of national legal and ethical regulatory frameworks for research, aligning them with international best practices and ensuring that the country does not continue to operate under conditions of persistent institutional legal uncertainty.
- Legal Formalisation of CNEPS: Strengthening CNEPS through the adoption of its legal statutes and the appointment of new members.
- Permanent Establishment of ARFAME: Creation of the necessary conditions for the legal establishment of ARFAME in accordance with its statutory mandate, making it fully functional and operational for the fulfilment of its strategic mission.
- Strategic and Institutional Partnerships: Cooperation with CPLP, specialised Portuguese institutions and other countries within the Lusophone community constitutes a fundamental basis for ensuring knowledge transfer and long-term institutional autonomy.
- Mobilisation of Funding Resources: Identification of new funding sources to ensure the functioning of CNEPS and ARFAME, as essential coordinating bodies required to overcome domestic limitations, mitigate risks associated with political instability in Guinea-Bissau, and position technical and institutional capacity as the main source of sustainability.

Bandim Health Project (PSB)

PSB has a solid foundation to ensure the sustainability of the results of the CT-Luso project, benefiting from its extensive experience in demographic surveillance and public health research, as well as from its integration with the National Institute of Public Health.

In this context, the consolidation of a Clinical Research Support Office is planned, which will function as a permanent structure for technical and methodological support, including

assistance with study design, data management, compliance with ethical and regulatory standards, and the preparation of funding applications.

At the same time, a continuous training offer will be maintained and expanded, based on the CT-Luso content, adapted to national needs and integrated into capacity-building programmes for health professionals and researchers.

Additionally, the project's digital repository of training content and technical resources will be used as a basis for continuous training and, above all, for the induction training of new PSB staff members. This repository should also be accessible to national partners, ensuring the continuity of knowledge transfer.

PSB also plans to implement monitoring and mentoring mechanisms, including alumni networks and supervision of research projects, to ensure the practical application of the competencies acquired.

Sustainability will be further strengthened through the integration of PSB into national and international clinical research networks and through the active promotion of new funding opportunities, ensuring the continuity and expansion of the activities initiated by CT-Luso.

3.1.4. Mozambique

National Bioethics Committee for Health (CNBS)

The Stewardship Plan of the CT-Luso project includes the following strategies:

- The organisation of sessions with Institutional Bioethics Committees (CIBS) to disseminate the tools and documents available through CT-Luso, promoting their consultation and possible replication;
- The inclusion of thematic areas and chapters developed within the CT-Luso project in training activities addressed to members of the CNBS, CIBS, and Researchers;
- The dissemination and promotion of the CT-Luso project website for consultation and use of the available materials and documentary resources;
- The establishment of monitoring and evaluation mechanisms for the use of CT-Luso tools and resources, in order to track their adoption, identify challenges and guide continuous improvement.

National Institute of Health (INS)

The activities that may be implemented by INS to enhance the impact of the CT-Luso project during and after its completion include:

- The integration and adaptation of the tools provided by CT-Luso for the implementation of clinical trials in the Mozambican context, through interdisciplinary working groups composed of relevant stakeholders (CNBS, INS, ANARME, FM-UEM);
- The organisation of sessions to disseminate key documents available on the CT-Luso website among existing research groups at national level;
- The promotion of broader participation in the training opportunities offered by CT-Luso, enabling the replication and dissemination of knowledge at all levels.

The Stewardship Plan of the CT-Luso project includes the following strategies:

- The incorporation of selected topics and materials developed within CT-Luso into existing institutional training programmes (GCP Course and Research Ethics Course);
- The establishment of an electronic repository within the Division of Health and Well-being Research, containing the tools and materials provided by CT-Luso, to ensure access for all interested stakeholders;
- The creation of a group of CT-Luso-trained staff members capable of replicating training activities whenever necessary.

3.1.5. Portugal

Centre for Biomedical Law (CDB) of the University of Coimbra

CDB of the University of Coimbra is committed to ensuring the sustainability of the results of the CT-Luso project through the consolidation of existing technical and scientific support structures, as well as through the development of new mechanisms aimed at the continuous capacity-building of partners.

Among the planned strategies, particular emphasis is placed on the provision of dedicated support with expertise in methodological guidance and knowledge transfer, as well as on the integration of the CDB's training offer with content developed within the framework of the project.

Additionally, the creation of hyperlinks to a digital repository of resources will be promoted, ensuring open and continuous access to materials, tools and best practices developed throughout the project.

At the same time, CDB foresees the implementation of monitoring mechanisms to assess the application and evolution of project results after its completion. These mechanisms will include collaborative networks among partners, follow-up initiatives and spaces for the exchange of experiences, strengthening the continuity of the dynamics created.

Through these actions, CDB aims not only to ensure the long-term sustainability of CT-Luso results, but also to strengthen institutional capacities and promote continuous innovation across the contexts involved.

Ethics Committee for Clinical Research (CEIC)

CEIC proposes the implementation of workshops and technical training focused on the tools and methodologies developed within the framework of the CT-Luso project, as well as the production of technical documentation, tutorials and user manuals, including templates and standard models, in order to ensure autonomy in the use of the project results.

The CEIC Support Office may also provide a dedicated helpdesk or direct support line for the clarification of questions and technical guidance, facilitating the effective use and long-term sustainability of the resources developed.

National Authority of Medicines and Health Products (INFARMED, I.P.).

INFARMED, as a partner institution of the CT-Luso project, aims to ensure that the results arising from the capacity-building of teams from the PSAC participating in the project are robust and remain consolidated after its completion.

In this regard, INFARMED remains available to support the needs of partners by sharing knowledge through its specialised experts, as well as by providing updated information resulting from the ongoing adaptation of the regulatory system in connection with the European regulatory ecosystem.

In addition to the contact point established through the CT-Luso project, INFARMED continuously develops a strategy of institutional collaboration with African medicines

regulatory agencies, thereby reinforcing its commitment to further strengthening the competencies developed.

Faculty of Pharmacy of the University of Lisbon (FFUL)

FFUL will ensure the continuity of capacity-building in partner African countries through the delivery of advanced training activities, short courses and other continuous professional development programmes aimed at professionals in the field of clinical research. In parallel, FFUL will strengthen the integration of professionals and students from the PSAC through the establishment of academic and scientific cooperation agreements with partner universities and institutions, promoting the training of new pharmacists.

Following the conclusion of the CT-Luso project, FFUL will continue to provide technical and scientific support through repositories of training content, pedagogical materials, templates and guidance developed throughout the project, ensuring their open access and future reuse. Coordination with other partner institutions will enable the consolidation of permanent cooperation networks and mechanisms for monitoring identified training and institutional needs.

FFUL will also seek to integrate CT-Luso partner institutions into future international project consortia in which it participates, promoting additional opportunities for funding, academic mobility and scientific cooperation.

These approaches will contribute to the progressive expansion of the network of qualified professionals in the field of clinical research in the PSAC, ensuring local ownership of results, strengthening institutional capacities and sustaining the project's impact beyond its funding period.

National Institute of Health Doutor Ricardo Jorge (INSA)

INSA, as a State Laboratory with a mission to promote public health, ensures the sustainability of the results of the CT-Luso project through a strategy centred on continuous capacity-building, the structured provision of knowledge and ethical support to research and public health practice.

In this context, particular emphasis is placed on its training offer, supported by a Training Office and specialised technical-scientific departments, enabling the development of initiatives in key areas such as public health planning, bioethics, research integrity and ethical-legal frameworks applied to clinical trials and biobanks. This training is delivered by experts with established experience, ensuring technically rigorous provision tailored to the needs of the project partners.

At the same time, INSA maintains an institutional repository of scientific outputs and technical-scientific content, as well as the Health Library, which constitute strategic instruments for the dissemination, preservation and continuous access to the knowledge generated within the framework of CT-Luso. These resources support autonomous learning and sustained capacity-building in partner countries.

In addition, the INSA Ethics Committee plays a central role in supporting the implementation of best practices, providing guidance and oversight on ethical matters related to health research, thereby contributing to the robustness, accountability and sustainability of the activities developed.

NOVA University of Lisbon (UNL)

NOVA University Lisbon, through NOVA Medical School, ensures the sustainability of the results of the CT-Luso project through its structured training offer in the field of clinical research.

The Master's degree in Clinical Research Management (MEGIC) serves as the main vehicle for continuity, integrating on a permanent basis the content, methodologies and competencies developed within the framework of the project into its curriculum. Delivered in Portuguese, MEGIC ensures that the pedagogical resources produced and clinical trials literacy continue to reach professionals and students from Portuguese-speaking countries, strengthening the competencies of the communities that the project aimed to build capacity in.

NOVA Medical School also has complementary mechanisms that deepen this long-term impact, namely active interinstitutional partnerships with NOVA Information Management School, National School of Public Health and University of Aveiro, which expand the reach of training and promote an interdisciplinary approach to clinical research.

NOVA Medical School's training offer also includes the development of short courses aimed at professionals and institutions requiring specific and applied training in core areas of clinical trials, thus ensuring an agile and scalable response to the needs of partner countries and institutions.

The commitment of NOVA University Lisbon – NOVA Medical School is to ensure that the results of CT-Luso are translated into a robust Portuguese-language training ecosystem, capable of maintaining and deepening, at different levels, the competencies built throughout the project.

3.1.6. São Tomé and Príncipe

Health Ethics Committee for Scientific Research (CESIC)

CESIC already has:

- professionals trained in bioethical requirements, with strong ongoing support from the CT-Luso project through continuous training activities; however, it is essential that this capacity-building remains continuous and sustained;
- a locally developed guidance manual for users;
- updated protocol assessment and ethical review tools aligned with good practices.

CESIC still requires:

- the development of a practical strategy for the follow-up and monitoring of approved protocols;
- support for the development of an institutional policy on ethical research.

Ministry of Health of São Tomé and Príncipe – Pharmaceutical Department

The Ministry of Health of São Tomé and Príncipe recognises the importance of ensuring the sustainability of the results achieved through the CT-Luso project, with a view to consolidating national capacity in clinical trials.

In this regard, it is necessary to accelerate the formal establishment of the National Regulatory Authority for Medicines and Health Products (ARFAMED), as well as the development of regulatory instruments, the strengthening of the pharmacovigilance

system and the implementation of regulatory mechanisms aligned with international standards.

The Ministry/Pharmaceutical Department is committed to integrating the competencies developed within the framework of the project into its long-term health policies and programmes. This includes the creation of a communication platform between the Pharmaceutical Department and CESIC, which will function as a centre for the coordination, monitoring and promotion of clinical trials in the country. Its primary mission will be to provide technical and administrative support to researchers, as well as to ensure the regulatory and ethical compliance of all studies.

In addition, a digital repository of training content and reference documents will be established, accessible to all health professionals and researchers, ensuring the continuous dissemination of knowledge and the updating of best practices.

Beyond internal consolidation, mechanisms will be developed to monitor the ongoing impact of CT-Luso and identify emerging capacity-building needs. Sustainability will also be reinforced through the integration of CT-Luso legislative recommendations into the national legal framework, ensuring a favourable and predictable regulatory environment for clinical research.

Efforts will also be made to establish strategic partnerships with academic and research institutions, both nationally and internationally, in order to promote collaboration, knowledge exchange and the mobilisation of additional funding, ensuring that the benefits of the CT-Luso project continue to expand and contribute to the improvement of Public Health in São Tomé and Príncipe.

4. Conclusion

The CT-Luso project strengthens ethical, regulatory and institutional capacities in the field of clinical trials across the PSAC, promoting their integration into national systems and the consolidation of practices aligned with international standards. Through this Stewardship Plan, the continuity of the results achieved is ensured, underpinned by institutional ownership and the sustainable use of the resources developed.

Partner institutions play a central role in this process, assuming responsibility for the continuation of activities and for the implementation of strategies aimed at sustaining the project's impact within their respective national contexts.

The consolidation of legislative, institutional and professional capacities will create favourable conditions for attracting investment, fostering innovation and increasing participation in international clinical trials. This will contribute to positioning the PSAC as more competitive partners in global biomedical research, with lasting benefits for health systems and for society.