CT-Luso

Ethical and Regulatory Training in Clinical Trials in Portuguese-speaking African Countries (PALOPs)

Project 101145790

WP1 - Project coordination, management and reporting

Deliverable 1.1 - Quality Management Plan

Version 1

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1. Introduction

The Quality Management Plan (QMP) aims to ensure all the activities planned under the CT-Luso project are carried out in accordance with the quality standards required by the Global Health EDCTP3 (GH EDCTP3) and the European Union (EU)[1] , ensuring that the goals of the project are met and all deliverables are planned and executed in accordance with strict quality criteria.

The QMP sets out how the project quality planning, execution, assurance and control will be carried out. This plan aims to outline the quality strategy of the project and identify those responsible for managing it and their corresponding roles. It also aims to define the project quality assurance and control activities and methodologies, as well as to identify the metrics and methods for assessing quality.

The QMP applies to all the activities of the project, with a special focus on strengthening and harmonizing the ethical-legal framework in Portuguese-speaking African countries (PALOPs) and training professionals who work in the field of biomedical research, especially clinical trials, in these countries.

1.1. Project Summary

CT-Luso is an ethical and regulatory training project in the area of clinical trials in the PALOP countries - Angola, Cape Verde, Guinea-Bissau, Mozambique and São Tomé and Príncipe - in partnership with Portugal, bringing together the main national institutions involved in biomedical research. The project aims to train local professionals involved in clinical trials, namely the Medicines Regulatory Authorities and Ethics Committees, so that their practice is based on the ethical and legal requirements demanded internationally.

The CT-Luso is divided into 8 Work Packages (Work Packages/WP). Its general goal will be pursued by reviewing the national ethical and legal framework (WP3) and organizing a training programme at various levels:

[1] European Union. HORIZON-JU-GH-EDCTP3-2023-01. Grant Agreement No. 101145790 - CT-Luso. 2023

- the first, interdisciplinary and thematically comprehensive, will be placed within the framework of internationally agreed ethical and legal principles (WP4);
- the second will focus on the ethical, legal and procedural requirements of clinical research (WP5);
- the third, of actual practice, will refer to training in the monitoring of the entire process of submission, approval and follow-up of clinical trials (WP6);
- the fourth will be dedicated to simulating situations in order to put into practice all the levels of training received (WP7).

Coordination and management will ensure the smooth running of the project (WP1), in cooperation with scientific supervision (WP2). The dissemination of results will be planned according to the various target audiences (WP8).

2. Quality management

Quality management aims to ensure that the project achieves the expected results efficiently and that the deliverables are delivered in accordance with the planned requirements and validated by all the partner entities. In addition to technical issues, quality management also encompasses financial issues, in order to guarantee the suitability of the expenses incurred and the correct allocation of the planned funds.

Quality management comprises the activities of identifying, planning, executing, monitoring and controlling the quality of the project.

The main goals of project quality are to ensure that:

- the quality characteristics of the project are defined, agreed and achieved throughout the project;
- quality assurance activities are carried out as planned;
- any non-conformity, or opportunity for quality improvement, is identified and implemented;
- the deliverables are accepted by the partners and the funding bodies;
- money is correctly applied and managed throughout the project, with a view to achieving their goals.

2.1. Quality management team

Quality management is carried out by the project coordination and management, the scientific supervision team and the project partner institutions (Figure1). From a financial point of view, quality management is carried out by the project financial advisor and external auditors.

Figure1 - Project organization chart

The **coordination and management of the project** - Work Package 1 - is of the responsibility of the Ordem dos Farmacêuticos (OF, Portugal), represented by Helder Mota Filipe, Maria do Céu Patrão Neves, project coordinators, and Catarina Sobrinho, project manager. This team is responsible for implementing and executing the project and supervising quality, as well as creating the QMP and implementing quality control mechanisms to ensure that the results and deliverables of the project meet the standards required by the funding bodies and that they are validated by the partners.

The **scientific supervision** team - Work Package 2 - is made up of Esperança Sevene, representing the National Bioethics Committee (CNBS, Mozambique) and the scientific consultant of the project, Maria Alexandra Ribeiro. Their duties are to ensure compliance with quality, scientific, technical, legal, regulatory and ethical requirements, in accordance with international standards, and to organize, plan and execute the goals of the different Work Packages, while also promoting the validation and credibility of the project conclusion.

The **scientific team** of the project, which comprises partner entities, is made up of specialists from various areas and key entities in the field of clinical trials in Portugal and the PALOP countries, namely Medicines Regulatory Authorities, Ethics Committees, Health Institutes and Universities. The Work Packages are led by one or more partner institutions, which ensure the implementation of the activities set out in each one and the delivery of the corresponding deliverables. The following institutions are responsible for leading the Work Packages:

- Work Package 1 – Ordem dos Farmacêuticos (Portuguese Pharmaceutical Society) (OF, Portugal);
- Work Package 2 - Comité Nacional de Bioética (National Bioethics Committee) (CNBS, Mozambique);
- Work Package 3 - Centro de Direito Biomédico da Universidade de Coimbra (Biomedical Law Centre of the University of Coimbra) (CDB, Portugal);
- Work Package 4 - Universidade Nova de Lisboa (Nova University of Lisbon) (UNL, Portugal), Faculdade de Medicina Eduardo Mondlane (Eduardo Mondlane Faculty of Medicine) (FAMED, Mozambique), Instituto Nacional de Saúde Doutor Ricardo Jorge (National Institute for Health Doutor Ricardo Jorge) (INSA, Portugal), Instituto Nacional de Saúde (National Institute for Health) (INS, Mozambique);
- Work Package 5 - Comissão de Ética para a Investigação Clínica (Ethics Committee for Clinical Research) (CEIC, Portugal) and Comité Nacional de Bioética (National Bioethics Committee) (CNBS, Mozambique);
- Work Package 6 - Autoridade Nacional do Medicamento e Produtos de Saúde, IP (National Authority for medicines and Health Products) (INFARMED, Portugal) and Autoridade Nacional Reguladora do Medicamento, IP (National Regulatory Authority for Medicines) (ANARME, Mozambique);
- Work Package 7 - Ethics Committee for Clinical Research (Ethics Committee for Clinical Research) (CEIC, Portugal);
- Work Package 8 - Ordem dos Farmacêuticos (Portuguese Pharmaceutical Society) (OF, Portugal).

Quality management of the financial aspects is of the responsibility of the **financial advisor** of the project, Eduardo Martins Pereira, who ensures and validates payments and expenses are made in compliance with the rules stipulated by the funding bodies. At the same time, the financial records of the project are scrutinized by an **external auditor**, Oliveira Reis e Associados - Sociedade de Revisores Oficiais de Contas, Lda.

(Chartered Accountants Firm), who analyses their compliance with the requirements of the institution responsible for managing its funds, the OF.

The financial quality of the project is also ensured by another **external auditor** (Oliveira Reis e Associados - Sociedade de Revisores Oficiais de Contas, Lda. (Chartered Accountants Firm)), which corresponds to one of the requirements imposed by the funding bodies. The external auditor is responsible for reviewing the financial documents of the project and ensuring compliance with the rules established by the funders and the integrity of the data, with the aim of obtaining legal certification of the accounts (Certificate on the financial statements - CFS).

3. Quality planning

Quality planning involves defining the key performance indicators (KPIs) of the project. These indicators are defined according to its goals and correspond to quantitative or qualitative metrics which provide relevant information about its performance.

The KPIs defined for the CT-Luso project, according to its Work Packages, are as follows:

Work Package(s)	KPI	Responsible
1	Submission of progress reports in August 2025 and December 2026, and submission of the final report in December 2027	OF
1	Obtaining legal certification of accounts (CFS)	OF
1 e 2	Holding at least 20 meetings with work package leaders and project partners	OF, CNBS and Scientific Advisor
1 e 2	Preparation of 100% of project deliverables	OF, CNBS and Scientific Advisor
3	Participation of at least 1 representative of the Medicines Regulatory Authority and 1 representative of the Ethics Committee of each country involved, in the workshops of work package 3	CDB
3	Submission, to political decision-makers, of new	OF and CDB

Work Package(s)	KPI	Responsible
	draft laws, or improvements to existing ones, in at least 3 of the countries involved, by the end of the project	
3	Writing at least 3 scientific articles in law, ethics or public health journals by the end of the project.	CDB
4	Number of candidates for the work package 4 training programme exceeds 120	OF and Work Package Leaders 4
4	70% pass rate in the training programme of Work Package 4	Work Package Leaders 4
4	60% participation rate in the online discussion forum following the training plan	OF and Work Package Leaders 4
4	Level of satisfaction with the training programme of 70% or more	OF and Work Package Leaders 4
5	Creation of 3 groups of trainees - regulators, members of ethics committees and research centres/researchers), with members from all PALOP countries.	OF and Work Package Leaders 5
5	Pass rate of at least 60% in each group of trainees	OF and Work Package Leaders 5
5	Level of satisfaction with the training programme of 70% or more	OF and Work Package Leader 5
6	Participation of at least 28 trainees in the training programme of Work Package 6	OF and Work Package Leaders 6
6	Participation of at least 28 trainees in the face-to-face activities of training programme of Work Package 6	OF and Work Package Leaders 6

Work Package(s)	KPI	Responsible
6	Level of satisfaction with the training programme of 70% or more	OF and Work Package Leader 6
7	Preparation of 1 report and 5 SWOT analyses, 1 per country, after completion of the activities of Work Package 7	OF and Work Package Leaders 7
7	Level of satisfaction with the training programme of 70% or more	OF and Work Package Leader 7
4, 5, 6 e 7	Making 100% of training materials available on the digital platform, no later than 3 days after the training has taken place, whenever it is not possible to share them in advance	OF and Leaders of Work Packages 4, 5, 6 and 7
8	Holding a project presentation meeting with the ambassador of each country in Portugal, in the first year of the project	OF
8	An event to disseminate the results in each partner country at the end of the project	OF
8	Sending 1 monthly newsletter to partners	OF and Communications Advisor
8	Monthly publication of 2 news items on the project website	OF and Communications Advisor
8	Annual increase of 30% in the number of the LinkedIn followers of the project	OF and Communications Advisor
8	30% annual increase in the number of views of the project website	OF and Communications Advisor
8	Annual participation in 2 scientific events to disseminate the project	OF and Communications

Work Package(s)	KPI	Responsible
		Advisor
8	Identification of the network of experts from each country formed by the project after its conclusion	OF

4. Quality assurance

Project quality assurance consists of various activities to verify that the project complies with its objectives and with the guidelines laid down by the funding bodies.

The activities planned for quality assurance are as follows:

- Weekly meetings of the management support team;
- Monthly meetings of the coordination, management and scientific supervision teams to discuss the project work and identify risks and mitigation measures;
- Monthly meetings are held with the project partners, particularly with the leaders of the Work Packages, to ensure the progress of the work and communication between all those involved;
- Review of deliverables by partner organizations prior to submission to funding agencies;
- Monitoring of the results of the harmonization of each country's ethical and legal framework - validation of the planned deliverables on these matters; publication of scientific articles with the results obtained; meetings with the PALOP ambassadors;
- Monitoring of trainees' training results - results of assessment tests; number of certifications obtained; number of recovery assignments received; number and content of trainees' interactions during training sessions;
- Monitoring of the results of the activities carried out - results of the training evaluation questionnaires (teachers, content, structure), informal evaluation by the participants (interactions in chat, emails, interactions on social networks), number of people enrolled in the activities of the project; drafting of new bills in the countries based on the proposed changes; number of participations in scientific events to present the results obtained;

- Preparation of project progress reports in August 2025, December 2026 and December 2027;
- Sharing of improvement results identified by the partners and resulting from the audits carried out.

5. Quality control

Quality control of the project and its results will be carried out on an ongoing basis using various techniques, tools and monitoring of Key Performance Indicators (KPIs). A system for continuous improvement of the project will also be defined, with identification of potential risks and respective corrective actions, which will be updated throughout the project.

Quality control techniques will also include:

- Review of the deliverables by the partner entities and final validation by the coordination and management team and scientific supervision;
- Biannual external audits of the financial aspects of the organization responsible for the project, the OF. The first, an interim audit, takes place in June and the second, a final audit, in February/March.
- External audit to obtain legal certification of accounts (CFS), under the terms of the regulations;
- Project risk analysis;
- Evaluation of project performance by monitoring key performance indicators - KPIs.

The quality control tools of the project consist of:

- Progress checklists - identification of tasks by Work Package and their fulfilment;
- Progress documents - minutes of meetings, updates of project artefacts, namely the schedule and status reports;
- Activity evaluation questionnaires - training and workshops;
- Budget and expenditure control spreadsheets;

- EU Funding & Tenders Portal - platform used to submit the various documents proving the progress of the project. The quality of these documents is assessed by the Project Officer appointed by the funding bodies;
- Risk matrix.

5.1. Identification of risks and corrective actions

Quality control also involves the identification of risks which could jeopardize the quality of the project, as well as the consequent corrective actions.

The main risk is that most of the interactions between all the project partners are remote. It is therefore necessary for the coordination and management of the project to establish a close relationship with all those involved, based on frequent contact (meetings, phone calls and emails). This communication must be based on permanent updates on the project - status, number of people involved in activities and future activities.

As a result of the physical distance between countries, there is a dependence on digital communication, which is often unreliable. It will therefore be important to implement alternative, asynchronous means of communication, such as emails and WhatsApp and, as far as training is concerned, the creation of a digital platform, the recording of sessions and events and the availability of training material for deferred consultation.

The different socio-political and economic contexts in the five PALOP countries, as well as the different cultural realities and levels of institutional maturity, are another identified risk. Faced with this challenge, it is necessary to establish direct contact with each country's political entities and embassies and, indirectly, through partners, in an articulated manner.

Finally, the motivation and involvement of the partners throughout the project is a risk which can be mitigated by creating conditions for the parties to remain connected and interested, namely the frequent collection of suggestions for improvement and better adaptation to the reality of each country, the accreditation of the training provided and the issuing of certificates of participation and flexible working practices.

6. Conclusion

The QMP is a constantly updated document which must be reviewed and amended as the project progresses. Quality will be monitored on an ongoing basis, with the implementation of processes to guarantee and control it.

Periodic quality monitoring will enable coordination and management to assess the development of the project and report back to the funding bodies and all the partners.

Implementation of and compliance with the QMP is intended to ensure that all ethical and regulatory training activities in the area of clinical trials in the PALOP are carried out with the highest quality, in accordance with the established requirements and adapted to the reality of each country, thus ensuring the success of the project and the fulfilment of its goals.