

## **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 - Intellectual Property Rights**

## Intellectual Property Rights (IPR)

Intellectual property, within the scope of the CT-Luso project, refers exclusively to Copyright, i.e. the property rights of those who have produced the diversity of material that, for different purposes, according to the various objectives, are produced within the scope of the project.

### 1. Assignment of Intellectual Property Rights

The authorship policy for scientific publications produced within the scope of CT-Luso will comply with the European Code of Conduct for Research Integrity<sup>1</sup>. All publications will include a statement on the corresponding contribution of each author, justifying their inclusion as an author and their position in relation to the other authors.

All publications are open access.

### 2. Intellectual Property Rights Management

The intellectual property of the various contents and materials of the project naturally differs not only according to their authors, but also according to their nature, specifically the legislative and institutional study in the PALOPs, the training contents and the e-learning platform.

#### 2.1. Legislative and institutional study in the PALOP

The (1) analysis of the legislation, in force or in process, on biomedical research in each of the Portuguese-speaking African countries (PALOPs), the identification of the respective gaps using International Good Practices as a standard model, the drafting of recommendations for updating and revising them, along with the (2) analysis of the structure of the Medicines Authorities and the Research Ethics Committees, as well as the relationship between the two institutions in the partner countries, and (3) the reports and publications which will be produced in this context will be authored by the international team of jurists - made up of members of the Biomedical Law Centre of the

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<sup>1</sup> ALLEA, European Code of Conduct for Research Integrity, 3<sup>rd</sup> edition, 2023.

University of Coimbra and the jurists designated by the Ministries of Health of each of the PALOPs - and the members of the coordinating team who have actively participated in the work in question.

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## 2.2. Training content

### 2.2.1 Property rights

The extensive and intense training provided by CT-Luso generates a significant diversity of training content. The ownership of these materials belongs to the respective trainers who produced them as part of the activities set out in Work Packages 4, 5, 6 and 7. Most of the CT-Luso trainers are affiliated with the project partner organizations, which make up the project consortium, namely institutions related to biomedical research, specifically clinical trials, universities and private institutions and academic CROs in Portugal and the PALOP countries.

CT-Luso also relies on the collaboration of trainers from outside the consortium, who are invited as experts on specific topics. In these cases, ownership of the content belongs to the creator of the material.

In every case, all materials produced within the scope of CT-Luso are open access, but their use requires prior authorization from the authors as defined by them.

### 2.2.2 Division of rights

Intellectual property will be shared between members of the consortium, a Portuguese institution, responsible for creating the training content, and one or more African institutions leading the local adaptation and implementation.

### 2.2.3 Licensing

The material produced by CT-Luso will be licensed under a Creative Commons license (or any other appropriate license), where suitable, thus allowing its wide distribution for free access in the PALOPs and favouring its use by health professionals, researchers, regulators and academics from these countries.

### 3. E-learning platform

The e-learning platform is developed by the entities that make up the project consortium and it is constantly updated with new training content, activities and resources. The production of the software and the architecture of the platform, as well as its management, is of the responsibility of the company providing the service, Ed-Rom, and it is owned by CT-Luso.

Access to the platform will be rendered available to project partners free of charge, with the conditions of use clearly defined in terms of licensing, to ensure that the content and platform can be updated and used without restriction during the project. For this to happen, the annual licensing fee for the platform will be paid by the institution responsible for the project financial management, the Ordem dos Farmacêuticos (Portuguese Pharmaceutical Society).