

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 - Open Science Strategy

Open Science Strategy (OSS)

The concept of "open science" refers to the practice of providing free online access to up-to-date scientific information. This practice allows information to be shared and, in turn, redistributed and reused, making investments in science more profitable and fostering the creation of collaborative work networks, while at the same time favouring the integration of countries/centres with fewer resources. Open science incorporates the principles of Transparency, Inclusion and Equity, in the assumption of the social responsibility of research.

CT-Luso adopts the European Union "open science strategy"¹, respecting the rules of open access to research data - including "open innovation" and "open to the world" - of the Horizon 2020 Program². This is a strategy that can have an impact of excellence on regulatory and clinical research institutions, society and patients in particular, and in each Portuguese-speaking African country (PALOP) in general.

1. Open Access

1.1. Production

In the course of its development, CT-Luso will produce studies, recommendations, guidelines, reports, various teaching materials, manuals, graphs, organizational charts, infographics and articles published in national and international journals. All the materials produced within the scope of the CT-Luso will be in Portuguese, and should be translated into English whenever necessary, taking into account the target audience. The goals of the priority given to the Portuguese language are:

- providing the African Portuguese-speaking community with access to excellent material to enhance ethical and regulatory training in Portuguese-speaking African countries (PALOPs);

- promoting the conversion of project trainees into future trainers, creating a replicating and multiplying effect;

¹ Open Science", *Research and Innovation - European Commission*, consulted on February 10th 2025, available at: https://rea.ec.europa.eu/open-science_en

² European Commission: Directorate-General for Research and Innovation, *Horizon Europe, open science - Early knowledge and data sharing, and open collaboration*, Publications Office of the European Union, 2021, <https://data.europa.eu/doi/10.2777/18252>

- expanding the education and training of professionals, making it possible for these materials to be used, for example, by institutions for higher education;

- building a "community of practitioners" in the PALOPs.

This "community of practitioners" must be increasingly integrated into international research networks, which will be a determining factor in the selection of materials produced by CT-Luso to be translated into English.

These works, as well as all the others produced as part of the project, will be freely accessible by rendering them available online.

The materials produced will be specifically shared with the community of ethics experts through existing networks, such as the European Network of Research Ethics Committees (EUREC) and the European Network for Research Ethics and Integrity (ENERI), and others which may be created during the course of the project. They will also be directly disseminated in researcher communities such as "The Embassy of Good Science", "International Reproducibility Networks" and "Open Science" communities.

1.2. The data

All the materials produced, as well as all the data deposited in CT-Luso, have "Creative Commons" licenses, meaning they can be shared, used and worked on by others, not just by their authors.

The results of the project will be made available in compliance with the FAIR principles³, i.e. they will be:

- findable, the data must be and remain findable, namely with a record or indexing of the (meta)data in a searchable resource;

- accessible, the (meta)data must be and remain accessible, even if the data is no longer accessible, e.g. be retrievable via its identifier, via a standardized communications protocol even if the data is no longer accessible;

³ Wilkinson, M., Dumontier, M., Aalbersberg, I. *et al.* The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data* 3, 160018 (2016). <https://doi.org/10.1038/s41598-016-0018-1>

- interoperable, (meta)data necessarily uses a formal, accessible, shared and widely applicable language for the representation of knowledge;

- (meta)data, associated with its provenance, is made available with a clear and accessible license to use the data.

In short: it must be possible to find the research data; there must be information on how to access it; it must be compatible with other data; and it must be possible to reuse it.

2. Peer review

All scientific articles will be published in peer-reviewed scientific journals, thus ensuring the quality of the work produced, as well as its international credibility. These journals will also be open access, making the research and actions developed by CT-Luso available to the public at no additional cost.