

## CT-Luso

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

Project 101145790

WP1 - Project coordination, management and reporting

### **Deliverable 1.2 - Data Management Plan**

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## Data Management Plan

The Data Management Plan (DMP) aims to describe how data will be collected, organised, stored, shared and preserved during the life cycle of the CT-Luso project, in order to guarantee its security, confidentiality and quality and its translation into results.

The DMP follows the guidelines of the funding bodies, Global Health EDCTP3 (GH EDCTP3) and the European Union (EU), as well as the provisions contained in the Grant Agreement<sup>1</sup>, ensuring that data is managed transparently, efficiently and in accordance with good practices for data management, as well as ensuring compliance with the European Union's General Data Protection Regulation (GDPR) (EU 2016/679<sup>2</sup> and national legislation regarding the five Portuguese-speaking African countries (PALOPs).

The goals of this DMP are therefore:

- i. Organisation and structuring: establishing how data will be collected, organised and stored, and ensuring that all those involved in generating the data have a clear and structured plan to follow;
- ii. Security and Privacy: defining security measures to protect data from unauthorised access and ensuring that personal data is processed in accordance with applicable data protection laws;
- iii. Accessibility: ensuring that data is accessible to project stakeholders when needed, facilitating collaboration and informed decision-making;
- iv. Preservation and archiving: determining how data will be preserved in the long term and archived correctly for future use or audits;
- v. Quality: implementing processes to ensure that data is accurate, complete and consistent throughout the project lifecycle;
- vi. Transparency: establishing measures aimed at transparency, clearly recording and documenting all the stages of data management.

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<sup>1</sup> Annex 5 of Project Agreement No. 101145790, which details the specific rules for managing data and results.

<sup>2</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, available at: <http://data.europa.eu/eli/reg/2016/679/oj>

## 1. Data

### 1.1 Data reuse

Regarding the legislative and institutional study of the PALOP countries, the project envisages the reuse of already available data generated by the BERC-Luso project – predecessor of CT-Luso - and the generation of new data resulting from a new legislative survey.

No re-use of existing data is envisaged for the remaining activities.

### 1.2 Type of data

CT-Luso will generate different types of data throughout its activities, namely:

- Personal data - data on project partners, teachers, guests and trainees who take part in the various levels of training and other activities (workshops, conferences, meetings).
- Quantitative data - number of graduates, certifications, teachers, events, participants, evaluation results, quantitative responses to questionnaires.
- Qualitative data - open-ended responses to questionnaires evaluating training and other project activities, suggestions for improvement.
- Databases - sets of data built up from questionnaires and other quantitative collections carried out during the project, such as the contacts of project partners and the list of trainees.
- Sound and/or image data - recordings of training sessions and monthly meetings with partners, as well as photographs of the various events/meetings held throughout the project and the people involved.

The data obtained and/or produced will have various formats such as CSV, Open XML (docx, xlsx, pptx), JPEG and PNG in the case of images, and mp4 in the case of session recordings.

### 1.3 Usefulness of the data

Data will be collected and produced during the project in order to develop the proposed activities, monitor their success and assess whether their objectives have been met.

This will be done by collecting and analysing data on participation in the activities, measuring the trainees' knowledge, evaluating the activities carried out and making improvements.

The data generated under the project and its results will be useful to all partners at two main levels:

- i. ethical-legal, as there will be a detailed analysis of the legislation related to biomedical research and the drug regulatory bodies and ethics committees, as well as the identification of gaps and the discussion of these aspects with the representatives of each country.
- ii. The data generated will be useful for the countries involved, allowing participants to become trainers in their countries, continuing the work carried out during the project and fostering the creation of a Portuguese-speaking network for conducting clinical trials.

Some of the data generated during CT-Luso will also be useful outside the project, constituting a public source of information, particularly relevant for national and international clinical research organisations, since it will reflect the ethical, legal, professional and institutional reality of the PALOP countries in terms of their ability to carry out biomedical research, particularly clinical trials.

## 2. Principles of data management

The data generated by CT-Luso and its results will be managed in accordance with the FAIR principles (Findable, Accessible, Interoperable, Reusable)<sup>3</sup>, in order to guarantee their usefulness and reproducibility.

The FAIR principles indicate that the data should be:

- findable, the data has to 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 standardised communication protocol even if the data is no longer accessible;

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<sup>3</sup> 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/sdata.2016.18>

- interoperable, (meta)data necessarily uses a formal, accessible, shared and widely applicable language for the representation of knowledge;
- reusable, (meta)data associated with its provenance, is rendered available with a clear and accessible licence to use the data.

### 2.1. Findable data

The data generated will be supplemented with detailed metadata, i.e. metadata will be used to describe and contextualise the data collected. In the case of project participants, metadata will be collected such as the country to which they belong, location, profession, institutional affiliation and email address, telephone contact. Regarding training materials and scientific publications, metadata will be collected such as the author, the date of publication and the authors' affiliation.

Standardised formats will be used to make it easier to locate the data, except when it proves totally impossible for reasons beyond the control of the project.

### 2.2. Accessible data

Data accessibility will be controlled by the coordination and management of the project in two domains/repositories:

- Public - the data which is rendered available on the project website and social networks and reported to the funding organisations will be freely accessible;
- Private - the data which is rendered available on the e-learning platform, created for the training that takes place throughout the project, where access is restricted and takes place through the provision of specific credentials per user.

To ensure that the data is accessible to different target audiences, it will be made available in two languages, Portuguese and English.

### 2.3. Interoperable data

The data generated will preferably be stored in open, standardised formats, such as CSV and Open XML (docx, xlsx, pptx), JPEG and PNG (images) and mp4 (videos), so that they can be recognised by various platforms and systems.

Whenever possible, metadata will be produced in order to categorise and index the project data/documents, facilitating the search for and access to specific information and its reuse, as well as guaranteeing the traceability of the data/documents produced. The data may be associated with categories and/or attributes or relationships in order to guarantee their interoperability.

The data and metadata will also follow the principles of guaranteeing integrity and quality (reliability, accuracy, relevance and consistency), as well as security and privacy, through the coding/anonymization of sensitive data, and the monitoring and continuous improvement of the meta(data) produced.

#### 2.4. Reusable data

Whenever possible, the data will be made publicly available or in suitable repositories in order to guarantee the possibility of reuse, while respecting confidentiality restrictions. The accuracy and integrity of the data will be guaranteed during all phases of the project, in accordance with its Quality Management Plan.

An appropriate licensing regime will be defined, such as the Creative Commons licence (or another appropriate licence), where suitable, thus allowing the sharing and reuse of data.

### 3. Results

CT-Luso will produce a set of results from analysing and interpreting the data collected and stored throughout the project.

The results relate to statistical analyses, qualitative interpretations and conclusions or recommendations:

- Training documents - training materials developed and/or shared to train trainees (presentations and support documents);
- Scientific publications - scientific articles, posters;
- Dissemination, communication and exploring activities - publications in the media, newsletters, social networks (LinkedIn, whatsapp), emails, websites, scientific articles, progress reports for funding organisations;

- Audit reports.

#### **4. Allocation of resources and responsibility for data management**

Compliance with the DMP will be of the responsibility of the project coordination and management team and scientific supervision team. These elements are responsible for guaranteeing the integrity and quality of the data during the collection, analysis, disclosure and dissemination phases.

Responsibility for data management also lies with the project partner institutions, which, depending on their role, will be involved in data management tasks, particularly those leading the work packages of the project.

All parties involved in the management of CT-Luso project data are aware of the good practices applicable in this area, and of the personal data protection requirements contained in the GDPR and applicable PALOP national legislation.

Whenever necessary, the Data Protection Officer of the organisation responsible for managing the project, the Ordem dos Farmacêuticos (Portuguese Pharmaceutical Society), will be consulted.

#### **5. Data security**

##### **5.1. Data access and sharing policy**

Project data will be accessible to partners and third parties in accordance with the data protection laws of each partner country and in accordance with the GDPR.

The use of personal data will be made with the explicit consent of the data subjects participating in the project and access to the data will be restricted to team members and authorised partners, and protected against undue access.

##### **5.2. Storage and backup**

As far as storage is concerned, data will be kept on secure servers in the cloud or on designated platforms, with password-restricted access.

Sensitive data, such as participants' personal information, will be stored in places where access is restricted and controlled.

Data will be backed up on a monthly basis and stored in different locations to ensure security and recovery.

### 5.3. Archiving and data storage

Once the project has been completed, the data will be kept for the period laid down by law or regulation or, in the absence of this, for as long as it is necessary to fulfil the purpose for which it was collected and processed.

This period will last at least 5 years, in accordance with the guidelines of the funding organisations<sup>4</sup>, which state that:

- Records and supporting documents must be kept for at least 5 years in order to prove that the activities were carried out and to justify the amounts declared.
- Data must be kept for at least 5 years for confidentiality, record-keeping and impact assessment purposes and for at least 2 years for reviews and audits.

The Ordem dos Farmacêuticos de Portugal (Portuguese Pharmaceutical Society) may keep some of the data for longer periods, for statistical purposes, without prejudice to guaranteeing the fulfilment of the rights and freedoms of the data subject, under the terms of the legislation in force.

Data will be archived in open and common formats such as CSV, Open XML (docx, xlsx, pptx), JPEG and PNG for images and mp4 for videos.

## 6. Ethical aspects

The data collected in the course of the project will be processed in accordance with the GDPR and the data protection laws of each partner country, in particular those relating to:

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<sup>4</sup> Annex 5 of Project Agreement No. 101145790, which details the specific rules for managing data and results.

- Consent - All participants will be informed and asked to consent to the use of their data for the purposes of building databases and using it for statistical purposes, publicising and disseminating the results of the project. By continuing to fill in the questionnaires they consent to the collection, processing and storage of their data.
- Anonymization - Personal data will be anonymised, as far as possible, in order to minimise the risk of being traced and thus protect the identity of participants.
- Storage of Personal Data - Personal data will be kept in databases with restricted access, granted only to authorised people.

## **7. Monitoring and review**

The DMP will be reviewed and updated periodically, especially after each relevant phase/activity of the project (data collection, analysis, publication of results), with the aim of ensuring that all data management standards and best practices are being put into practice, namely compliance with the GDPR and the FAIR principles.