# CT-Luso

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

Project 101145790

WP1 – Project coordination, management and reporting

**Deliverable 1.3 – Updated Data Management Plan**

Version 2

28/02/2026

## Index

## Updated Data Management Plan

The Data Management Plan (DMP) describes the procedures adopted for the collection, organisation, storage, sharing, protection and preservation of data generated throughout the lifecycle of the CT-Luso project, ensuring their quality, security, confidentiality and appropriate use in the production of scientific, technical and training outputs.

The DMP follows the guidelines of the funding bodies, Global Health EDCTP3 (GH EDCTP3) and the European Union (EU), as well as the provisions set out in the *Grant Agreement*[1], ensuring that data are managed in a transparent and efficient manner and in accordance with good data management practices, while also guaranteeing compliance with the European Union General Data Protection Regulation (GDPR) (EU 2016/679)[2] and national legislation applicable to the five Portuguese-Speaking African Countries (PSAC).

Accordingly, the objectives of this DMP are:

i. organisation and structuring: to establish how data will be collected, organised and stored, and to ensure that all stakeholders responsible for data management follow a clear and structured plan;
ii. security and privacy: to define security measures to protect data against unauthorised access and to ensure that personal data are processed in accordance with applicable data protection laws;
iii. accessibility: to ensure that data are accessible to project stakeholders when required, thereby facilitating collaboration and informed decision-making;
iv. preservation and archiving: to determine how data will be preserved in the long term and properly archived for future use or audits;
v. quality: to implement processes ensuring that data remain accurate, complete and consistent throughout the project lifecycle;
vi. transparency: to establish measures aimed at transparency by clearly recording and documenting all data management stages.

The first version of the DMP, submitted in February 2025, defined the planned data management strategy for the project, including the types of data to be collected, storage

[1] Annex 5 of Project Agreement No. 101145790, which details the specific rules for managing data and results.
[2] 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

procedures, security and privacy measures, as well as the accessibility, preservation, quality and transparency principles to be applied.

Following more than one year of project implementation, this updated document reconfirms the objectives previously presented and, reflecting the practical experience gained, includes the data already produced, the solutions implemented and the methodological and operational improvements introduced, thereby ensuring the continued suitability of the DMP to the project's needs, partners' expectations and applicable regulatory requirements.

## 1. Data

### 1.1. Data reuse

With regard to the legislative and institutional study in the PSAC, the project foresees the reuse of already available data generated by the BERC-Luso project – the predecessor of CT-Luso – alongside the generation of new data resulting from an updated legislative review. No reuse of existing data is envisaged within the scope of the remaining activities.

The previously defined data reuse strategy remains in place, particularly concerning the use of information produced by the predecessor project BERC-Luso, which constitutes a relevant source of legislative, institutional and comparative background for the partner countries.

During the project implementation period, BERC-Luso data were used as a starting point for the legislative and institutional analysis activities carried out under CT-Luso and were complemented by updated data collection and the production of new data. These included the conduct of a country-specific legislative and institutional analysis for each partner country (Deliverables 3.1 and 3.2) and the development of legislative recommendations in the area of clinical trials (Deliverable 3.3).

BERC-Luso is expected to continue to be used as a reference throughout the project, together with data from partner institutions in the development of training materials (templates, checklists, procedures) and data from the legislative and regulatory repository to produce comparative legislative and institutional studies. However, as new data are generated within CT-Luso, these also constitute an autonomous knowledge base, enabling comparative analyses, progress monitoring and assessment of the evolution of the ethical-legal and institutional contexts of the partner countries.

For the remaining project activities, no reuse of external data is foreseen, with data being predominantly generated through primary collection during the implementation of project actions.

### 1.2. Type of data

The CT-Luso project has generated, as planned, different types of data throughout its activities, with the initially identified categories remaining appropriate and comprehensive.

Personal data (including name, email address, country, age, profession, affiliation, among others) are collected and processed in relation to project partners, trainers, invited speakers, trainees and other participants in training activities, meetings, workshops and events. This collection is expected to continue throughout the project strictly for management, monitoring, evaluation, reporting and dissemination purposes, in compliance with applicable legal requirements on data protection. Personal data are always collected with the data subjects' consent.

The project also produces:

- quantitative data – including numbers of participants in activities, certifications, events delivered, performance indicators and closed responses to evaluation questionnaires;
- qualitative data – namely open responses, comments and suggestions collected through evaluation tools used for training and other activities;
- databases, resulting from the consolidation of information collected through questionnaires and administrative records, including participant lists and institutional contact information;
- audio and/or image data – corresponding to recordings of training sessions, technical meetings and photographic records of events.

File formats remain those defined in the initial plan, prioritising open or widely used formats such as CSV, Open XML (docx, xlsx, pptx), JPEG, PNG and MP4, thereby ensuring interoperability, accessibility and long-term preservation of data.

## 1.3. Data utility

Data collection and production within the CT-Luso project continue to pursue the objectives defined in the initial DMP, namely supporting the implementation of planned activities, monitoring their performance and assessing the degree of achievement of established objectives. The data generated within the project are useful for partners, particularly in the following areas:

i. ethical-legal, through the detailed analysis of legislative and institutional frameworks related to biomedical research and the development of legislative recommendations in the field of clinical trials, reflected in Deliverables 3.1, 3.2 and 3.3;
ii. training, through the systematic collection of information on participation, performance and evaluation of capacity-building activities, supporting the development of educational materials, continuous improvement of training programmes and consolidation of local competencies. These outcomes are reflected in Deliverables 4.1 to 4.5. During subsequent training programmes, additional training-related data will continue to be produced and collected, culminating in educational materials and technical documents tailored to PSAC contexts, with the resulting outcomes reflected in the deliverables expected from these training programmes.

The data produced have therefore contributed to strengthening institutional and technical capacities in the participating countries, promoting training-of-trainers approaches and the creation of a Lusophone collaborative network in the field of clinical trials.

The collection and production of this type of data are expected to continue in subsequent project phases, namely within the next training programmes planned under Work Packages 5, 6 and 7, ensuring continuous activity monitoring, impact assessment and consolidation of achieved results.

Additionally, beyond project management purposes, the generated data and results will constitute a relevant source of information for national and international stakeholders in the field of clinical research, reflecting the evolution of the ethical-legal, professional and institutional contexts of PSAC in the domain of biomedical research and clinical trials. The data generated may also support public policy development and strengthen ethical-legal systems in PSAC in the area of 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*)[3], in order to guarantee their usefulness and reproducibility.

The FAIR principles indicate that the data should 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 standardised communication protocol even if the data is no longer accessible;
- 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 generated data are complemented with detailed metadata that describe and contextualise the collected data. For project participants, metadata collected include country of origin, location, profession, institutional affiliation, email address and telephone contact. With regard to training materials and scientific publications, metadata such as author, publication date and authors' affiliations are collected.

Standardised formats are used to facilitate data discovery, except where this proves entirely impossible due to reasons beyond the project's control.

The datasets and documents produced to date are organised in institutional repositories and structured folders, with standardised nomenclature and clear identification by work package and activity. Descriptive metadata (date, source, version) have also been associated, helping to describe and contextualise the collected data and facilitating their search, identification and retrieval by project partners.

[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/sdata.2016.18

The use of standardised formats remains in place, and no significant limitations to the application of this principle have been identified during the analysed implementation period.

## 2.2. Acessible data

Data accessibility is managed by the project coordination and management team across two domains/repositories:

- public – data made available through the project website and social media channels, as well as data reported to the funding bodies, are openly accessible;
- private – data made available through the e-learning platform established for training activities conducted throughout the project, where access is restricted and granted through the provision of user-specific credentials.

To ensure accessibility to different target audiences, data are made available in two languages, Portuguese and English.

## 2.3. Interoperable data

The strategy defined at project outset regarding the use of open and widely recognised formats for storing produced information has proven appropriate. Generated data have been stored, where applicable, in formats such as CSV and Open XML (docx, xlsx, pptx), as well as JPEG and PNG for images and MP4 for audiovisual content, thereby ensuring compatibility across different platforms, systems and IT tools.

Systematic production of metadata describing, categorising and indexing project data and documents has also been observed. These elements facilitate information search, retrieval and traceability, as well as its correct interpretation and potential reuse by different partners.

Whenever possible, common models and structures are used for information organisation, including templates shared among partners and, where applicable, models recommended by the funding bodies, thereby promoting consistency, harmonisation and integration of content produced across the different work packages.

Data and metadata are managed in accordance with principles of integrity, quality (reliability, accuracy, relevance and consistency), security and privacy. Measures have been implemented to verify the accuracy and relevance of information, as well as version

control mechanisms. In cases involving sensitive or personal data, coding and anonymisation practices are adopted in compliance with applicable legal and ethical requirements.

These practices will be maintained throughout subsequent project phases, and no need for substantial revision of the initially defined approach has been identified.

### 2.4. Reusable data

Non-sensitive data, namely technical reports, legislative analyses, recommendations and training materials, are made available through the project's public channels, promoting knowledge sharing and reuse by partners. These contents are accompanied by contextual information supporting their correct interpretation.

The accuracy and integrity of the data produced have been ensured throughout the various project phases, in alignment with internal quality assurance procedures, including internal reviews, information validation and version control.

The planned adoption of appropriate data sharing and reuse models is maintained, notably using Creative Commons licences or equivalent schemes for content to be made openly accessible in subsequent project phases, in accordance with funding bodies' guidance and in compliance with applicable legal limitations.

Overall, the categories and procedures defined in the initial DMP remain appropriate, and no significant limitations to the application of the FAIR principles have been identified. These will continue to guide data management throughout the subsequent phases of the project.

## 3. Results

CT-Luso has generated a range of results arising from the analysis and interpretation of data collected and stored since the start of the project.

The results include statistical analyses, qualitative interpretations and recommendations, namely:

- training documents – training materials developed and/or shared within the scope of capacity-building activities for trainees (presentations and supporting documents);

- scientific publications – scientific articles and posters;
- dissemination, communication and exploitation activities – publications in media outlets, newsletters, social media (LinkedIn, WhatsApp), emails, websites, scientific articles and progress reports submitted to the funding bodies;
- audit reports foreseen for the final phases of the project, in accordance with applicable contractual obligations.

## 4. Resource allocation and responsibility for data management

The responsibility structure defined in the initial Data Management Plan remains in force and has been applied throughout project implementation.

Project coordination and management, together with the scientific supervision team, have ensured the implementation of data management practices, particularly regarding the collection, validation, storage, analysis, protection and dissemination of produced information. These actors regularly monitor compliance with established procedures, ensuring data integrity, consistency and quality.

Partner institutions also play an active role in data management, in line with the functions and responsibilities assigned within each work package, particularly those leading work packages, activities or deliverables. All parties involved in CT-Luso data management are aware of applicable good practices in this area and of personal data protection requirements contained in the GDPR and relevant national legislation in PSAC.

Whenever necessary, consultation of the Data Protection Officer of the Portuguese Pharmaceutical Society (Ordem dos Farmacêuticos), as the coordinating institution of the project, is possible. To date, no occurrences requiring significant corrective measures have been recorded.

## 5. Data security

### 5.1. Data access and sharing policy

The data access and sharing policy defined in the initial DMP has been applied. Access to information is granted to partners and, where applicable, to third parties, in accordance with data protection legislation in force in the partner countries and with the GDPR. Personal data are processed based on informed consent from participants, collected within the context of the various project activities.

The use of personal data is carried out based on explicit consent from participating data subjects, and access to data is restricted to authorised team members and partners and protected against unauthorised access. To date, no incidents of unauthorised access or security breaches related to project data have been recorded.

## 5.2. Storage and *backup*

Data are stored on secure institutional cloud-based servers, such as shared folders, and on platforms designated to support project activities, with password-protected restricted access and differentiated permission levels assigned according to each user's role.

Sensitive information, including participants' personal data, is stored in restricted and controlled access environments. Regular information protection procedures have been implemented, including periodic backups stored in separate locations, to prevent accidental loss and ensure data recovery when necessary.

No significant failures in storage or information recovery mechanisms have been identified.

## 5.3. Archiving and data storage

Following project completion, data will be preserved for the period established by applicable legal or regulatory provisions or, in their absence, for the duration necessary to fulfil the purposes underlying their collection and processing. Although the formal post-project archiving period has not yet commenced, partners have been informed of the retention obligations set out in the project Grant Agreement.

This period will have a minimum duration of five years, in accordance with funding bodies' guidelines[4], which establish that:

- records and supporting documentation must be retained for at least five years in order to demonstrate implementation of activities and justify declared costs;
- data must be retained for at least five years for confidentiality, record-keeping and impact assessment purposes and for a minimum of two years for reviews and audits.

[4] Annex 5 of Project Agreement No. 101145790, which details the specific rules for managing data and results.

The Portuguese Pharmaceutical Society (Ordem dos Farmacêuticos) may retain certain data for longer periods for statistical purposes, without prejudice to the safeguarding of data subjects' rights and freedoms under applicable legislation.

Data will be archived in open and commonly used formats, such as CSV, Open XML (docx, xlsx, pptx), JPEG and PNG for images, and MP4 for videos, ensuring future readability and reuse.

## 6. Ethical aspects

Data collected during the project are processed in accordance with the GDPR and data protection legislation of each partner country, as initially planned, notably with regard to:

- consent – all participants are informed and consent is requested for the use of their data for database construction and for statistical, dissemination and project results communication purposes. By proceeding with questionnaire completion, participants consent to the collection, processing and storage of their data;
- anonymisation – personal data are anonymised where possible to minimise the risk of traceability and thereby protect participants' identities;
- storage of personal data – personal data are maintained in databases with restricted access granted only to authorised individuals.

To date, no relevant ethical issues have been reported, nor requests from data subjects to exercise their rights that would require substantial changes to the defined procedures.

## 7. Monitoring and review

The DMP retains its dynamic nature and will be periodically reviewed and updated, particularly following each relevant project phase or activity (data collection, analysis, publication of results), with the aim of ensuring that all data management standards and good practices are being implemented, including compliance with the GDPR and FAIR principles.

The defined approach remains valid and operational, with no need identified for structural revision or substantial adaptation. Nevertheless, the DMP will continue to be updated whenever relevant changes occur in data collection, processing, sharing or preservation processes.