



Deliverable N. D2.2_2023

Data Management Plan

WP2 - Task 2.1



Document Summary

Deliverable Number	D2.2_2023
Deliverable Name	Data Management Plan
Type	Report
Dissemination level	Public
Work Package	2 – Task 2.1
Lead Beneficiary	IT MOH
Contractual delivery date	30/06/2023
Actual delivery date	14/12/2023
Grant Agreement Number	101095654
Project name	European Partnership on Transforming Health and Care Systems
Acronym	THCS
Start date of the project:	01/01/2023
Duration	84 months

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DISCLAIMER

Funded by the European Union under the Horizon Europe Framework Programme - Grant Agreement N°: 101095654.

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Executive Summary

The THCS Data Management Plan (DMP) describes the data management principles and strategies, tools and data that will be produced as part of the THCS Partnership activities and thus included in this DMP. Should the Partnership published papers and articles, open access sources will be considered.

The DMP is a living document to be updated and revised as the implementation of THCS progresses and when significant changes and improvement will occur.

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Glossary/List of acronyms

ACRONYM	DESCRIPTION
CC BY	Creative Commons Attribution International Public License
CC 0	Creative Commons Public Domain Dedication
CSO	Citizen Science Organisations
DI	Data Infrastructures
DMP	Data Management Plan
DSP	Data Service Providers
EOSC	European Open Science Cloud
FAIR	Findable, Accessible, Interoperable, Reusable
IIS	Individuals in Science
JTC	Joint Transnational Call
NLI	National-Level Initiatives
PC	Project Coordinator
PID	Persistent Identifier
RI	Research Communities and Infrastructures
RFO	Research Funding Organisation
RPO	Research-Performing Organisation
SRIA	Strategic Research and Innovation Agenda
SS&A	Scientific Societies and Academies
THCS	Transforming Health and Care Systems

1 Objectives

The Data Management Plan (DMP) describes the data management life cycle for the data to be collected, processed and/or generated, stored and published by the THCS Partnership.

These data may derive from and/or be linked to research outputs of funded projects from the THCS' Joint Transnational Calls (JTCs), THCS dissemination and communication activities, WPs activities, engagement activities and other means depicted in the present deliverable. The DMP includes an overview of the type of data that will be generated and how the sharing, archiving, and storage of these data will be guaranteed throughout the lifetime of THCS and beyond. The DMP includes information on data ethics and data protection. The DMP aims at defining the management strategy of data generated during the Partnership with the purpose of making data findable, accessible, interoperable and reusable (FAIR). The deliverable is intended to be a living document and thus its content will be updated and described in more detail as THCS progresses, in order to reflect adaptations and changes with respect to its first version. The update of the DMP is due at M42.

Data Summary

The European Partnership on Transforming Health and Care Systems (THCS) represents a unique strategic opportunity to bring together stakeholders, create synergies, coordinate Research and Innovation actions, facilitate the digitization of Health and Care Services and support the transformation of Health and Care Systems with innovative solutions driven by knowledge and evidence.

The general objective of THCS is to contribute to the transition towards more sustainable, efficient, resilient, inclusive, innovative, high-quality, equally accessible and people-centred Health and Care systems. For this purpose, THCS aims not only at creating new knowledge and scientific evidence but also at co-designing new solutions and supporting their transfer and scale-up across countries and regions while fostering capacity building.

The approach for a successful and smooth implementation of THCS will focus on three main work streams:

- 1) Filling the knowledge gaps with research actions aiming at providing the necessary evidence;
- 2) Implementation and transfer aiming at supporting actions focusing on the testing of existing solutions and adaptability in different national and regional contexts;
- 3) Boosting Health and Care Systems through dedicated activities (capacity building and training, study visits, technical assistance, twinning, networking) involving different Health and Care stakeholders.

To address these three work streams, THCS is built around four pillars that group different types of activities addressing different types of stakeholders of the Health and Care sector. The activities are organised in ten Work Packages, clustered into these four Pillars, working closely together to achieve the objectives of the Partnership.

THCS Partnership will collect and manage different types of data.

Datasets will be collected through surveys, interviews, workshops, funded projects, and project activities. These datasets are collections of standard material produced by the funded research projects, partnership deliverables, dissemination material, etc.

The data collected are intended to be useful for (Meta)Data Service Providers (DSP) including repository and PID services, National-Level Initiatives (NLI), Research Communities and Infrastructures (RI), Research-Performing Organisations (RPOs), Individuals in Science (IIS), Research-Funding Organisations (RFOs), policymakers, publishers, Data Infrastructures beyond research (DI), the THCS ecosystem, Citizen Science Organisations (CSOs), and Scientific Societies and Academies (SS&A).

Specifically, the following activities will lead to data collection, analysis, storage, and publication:

- Organisation of workshops, aiming at establishing and maintaining the dialogue for collaboration and harmonisation of efforts between THCS and other related initiatives.
- Dissemination of activities and results of research projects funded through THCS' JTCs.
- Registration through the THCS website for events and other participatory activities.
- Meetings and teleconferences of the partners.

The estimated volume of the data that will be archived and published is less than 100 GB. This consists of the following:

<i>Content /Origin</i>	<i>Retention</i>	<i>Format</i>	<i>Personal information</i>	<i>Dissemination level</i>	<i>Comments</i>
Surveys run on the THCS website	THCS website database	SQL database, html, xls	Available to data processors only	Anonymised survey results will be made public	
Surveys on third-party tools (Sli.do or similar) during dissemination activities (workshops, conferences, etc.)	The results are downloaded, shared with data processors, published on THCS website and stored in OwnCloud when needed	csv/xls, pdf/a, ppt	In principle, no personal information will be collected. In case personal information is included, the results will be anonymised before publication	Anonymised survey results will be made public	
Results of the JTCs	The name of the successful applicant organization, title of the projects, lay summaries, coordinator's contact emails, partners of the research consortia information will be shared through project reports, THCS website, Funding Organizations and National stakeholders' websites and stored in OwnCloud. Personal Data processed for Applications will be	SQL database; pdf/a; xls	Applicants' name, role, organisation and email address will be collected when applying to the JTC. Successful applicant organisations will be made public via the THCS website	The name of the successful applicant organisation will be publicly shared through project reports and the website	Contact details may need to be retained only for as long as the project finances need to be retained in case of audit. The organisational information will be made public through our reports.

	kept for up to 15 years, according to THCS privacy policy.				
THCS results (deliverables, milestone reports, etc.)	In the case of public deliverables, the final non-approved version is published on THCS website with the relevant disclaimer. It is replaced by the final version once approved by the EC. The milestones are marked as achieved in the European Commission's Funding & Tenders portal and they are accompanied by short reports for internal use	pdf/a	Authors information, (name, affiliation)	All deliverables, apart from those marked as sensitive, will be made public on THCS website. Deliverables marked as sensitive will be available for the project consortium, reviewers and European Commission only.	
Scientific publications	OpenAIRE ORE, THCS Knowledge Hub, Other venues		Authors information (name, affiliation)	All scientific publications of the funded projects or of THCS will be in open access.	Open access is provided under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights; for monographs and other long-text formats, the licence may exclude commercial uses and derivative works (e.g. CC BY-NC, CC BY-ND)
Recording of webinars, workshops, GARR recordings	YouTube THCS website	mp4	Users will give consent for publication of recordings in the registration form	Recordings will be publicly available on YouTube and THCS website upon participants' and speakers' consent	Cross-link using PIDs and include slides

Workshop and online webinar materials other than recordings	THCS website	pdf/a, csv	Users will give consent for publication of photos in the registration form	Presentations, photos and other materials will be publicly available on THCS website upon participants' and speakers' consent	Make sure PPTx are converted to PDF and that extra materials (e.g., sample codes) are included in the upload.
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The file formats are open and comply with good practices and sustainability preferences of the repositories where the data are published. Proper funding attribution will be provided at all times.

2 FAIR data

Results should be clearly presented and based on evidence. Findings should address all the objectives. Findings on results should distinguish outputs, outcomes and impacts (where appropriate).

Gaps, limitations and unexpected findings (if any) should be discussed.

If the data reveals (or suggests) unusual or unexpected results, these should be highlighted and discussed in terms of their implications.

2.1 Making data findable, including provisions for metadata

THCS will not perform research activities itself, therefore there will be no collection of research data in the partnership. Particularly, no clinical information about human beings will be collected or stored.

Personal data and data from research projects funded under the JTCs, as well as other collected types of data (abovementioned), will be addressed confidentially within the partnership consortium, but they will not be anonymised, since detailed information is needed for the execution of the associated tasks (e.g., eligibility check of the proposals by the funding organisations). In case several data will be published, it will be only in an aggregated manner (e.g., report on survey outcomes).

Data from the applications and funded projects consortia under the JTCs can be published on the THCS website in an aggregated manner, e.g., as statistics. A determined dataset from the funded projects consortia (e.g., lay summaries, coordinators' contact emails, partners of the research consortia, etc.) can be published in the THCS website, National Funding Organizations' websites or other public documents (e.g., Newsletters), after consent of the funded coordinators on the dataset that will be made publicly available. Certain metadata will be associated with the

publication of the funded projects (e.g., Title of the project, coordinator, specific call, countries involved, etc.).

The list of the reviewers involved in the evaluation of proposals received under the JTCs can be published in an aggregated way on the THCS website, provided the concerned reviewers give their consent, but without reference to the proposal evaluated by each reviewer. This information will remain confidential and not available for the applicants.

Regarding the speakers of workshops or other events organised by THCS, the personal data provided during the registration process will be kept confidential (unless consent is provided), but their names and contributions to discussions can be published in the website reports and thus be findable and accessible.

No metadata standards will be generated. Metadata will be generated by impact analyses of THCS activities via success metrics to evaluate successes of funded research projects and their generated impacts (e.g., the number of publications, meetings, personnel exchange, patents, etc.). This data will be only published in an aggregated manner.

2.2 Making data accessible

The following data are made openly available on the THCS website:

- THCS funded projects information (names, affiliations, abstracts, keywords, etc.).
- Joint Transnational Calls statistics in aggregated manner (pdf format).
- Names of the reviewers per JTC upon consent, no reference to the reviewed proposals.
- Impact reports on finalized funded projects are made available for download in pdf format.
- Strategic documents (Strategic Research and Innovation Agenda, etc.).
- THCS Deliverables marked as not “confidential”.

In addition, specifically regarding the JTCs launched by the Partnership, data, both on the received proposals and on the projects selected for funding, will be transferred to the ERA-LEARN platform, according to the requested formats. Such data will be collected by ERA-LEARN and published on its [website](#).

2.3 Making data interoperable

The formats of the data used in THCS are standard Excel, Word, or pdf data. The files could be downloaded in interoperable formats (e.g., XML or CSV).

The produced data are publicly available, and they do not require interoperability.

Neither metadata vocabularies, standards nor methodologies are applied or necessary.

The section of the website informing about the THCS funded projects will operate with common keywords to enable users for the identification of topics, methodologies and technologies in already funded projects.

2.4 Increase data re-use

THCS is a partnership which foresees the participation of funding organisations with the aim of funding research projects. The resulting research is thus produced, published and stored by the funded projects consortia, and not by THCS.

For each JTC, THCS Partnership communicated to the applicants that all funded research projects must comply with the Horizon Europe standards for Open Access concerning their projects' outcomes and publications and adherence to the FAIR data principles.

In general, THCS will not produce data that could be licensed to permit the widest re-use possible. In general, the obtained data will not be made available or useable to or by third parties, not even after the end of the partnership, including those personal data mentioned in Paragraph 2, that are collected for conducting THCS activities, including the performance assessment of the JTCs.

As previously mentioned, the publication of the collected information is foreseen only for certain activities. Should it be the case, Open Access will be ensured, and the re-use of data will be allowed where possible, except otherwise specified.

3 Other research outputs

n/a

4 Allocation of resources

Each WP leader is responsible for the data management within its specific WP, including updates and implementation according to the rules set out in this DMP. The Partnership Coordinator assumes responsibility for the overall data management in the context of the Partnership and for evaluating the implementation of the DMP. Evaluations and updates of this DMP will take place at M42 in alignment with the overall THCS management and progress reports.

Should a publication be released within the Partnership activities, costs for Open Access will be ensured, as the costs related to research data/output management can be eligible as part of the Horizon Europe grant if compliant with the Grant Agreement (GA) conditions.

Alternatively, Open Access platforms provided by the EC can as well be used (e.g., Open Research Europe and the European Open Science Cloud), which could be free of publication costs.

The remaining data made available through the THCS website (e.g., information on THCS funded projects, THCS public deliverables, public JTCs statistics, etc.) will not require extra costs, apart from the costs connected with the creation and maintenance of the website, which are already included in THCS budget.

5 Data security

Each organisation acting as Joint Call Secretariat for a given call implements its own data security measures. As submission tool, the CBIM software is used by all Joint Call Secretariats. This tool is secured by IT MoH measures (daily back-up, secure storage). Transfer of sensitive data occurs by the THCS Partner Portal where all THCS partners act as Joint Controllers.

All controllers involved will sign a Joint Controller Agreement (JCA) pursuant to Art. 26 GDPR Joint controllers in a transparent manner to determine which of them fulfils which obligation under this Regulation, in particular, regarding the exercise of rights of the Data Subject and who fulfils which information obligations pursuant to Articles 13 and 14 of the GDPR.

Those THCS partners that are situated in a country outside the European Economic Area (e.g., Israel, USA, Switzerland, UK, Iceland, Norway) will ensure compliance with the GDPR, by signing the EU Standard Contractual Clauses, as it is foreseen in the Joint Controller Agreement. Shared responsibility implies that upon requests from researchers or reviewers or speakers, all partners strive to support each other in the correct dealing with apparent problems or difficulties.

6 Ethics

THCS Partnership will not directly carry out biomedical research, but will fund research performed by third parties. The main THCS ethical concerns are the correct use of the personal data of participants, researchers and reviewers and the ethical issues that can arise in the funded Research and Innovation (R&I) projects. THCS will fulfil the ethical obligations included in Horizon Europe Regulation 2021/695 (articles 18 and 19), that would apply to the activities performed by the Partnership.

In paragraph 2, the personal data and other types of data that will be collected for the different activities of the Partnership are outlined with detail of means of collection, processing, storage and data management responsibility.

Raw ethnographic data with references to persons and organisations will be stored securely on approved platforms using institutional resources. OwnCloud will be used to ensure compliance with GDPR.

All partners collecting data for research purposes will follow their own institutional processes in securing ethical approval for the research they are conducting.

During the review process, personal data of reviewers are obtained and temporarily stored. Some personal data might be further processed to analyse the call statistics and to evaluate the quality of the procedure. When initial contact is established, reviewers are asked for consent to the storage of their personal data. If they participate in the further review process, they are asked for their consent. Upon completion of the process, all personal data are deleted unless consented otherwise.

Furthermore, the personal data of applying researchers are obtained and temporarily stored on CBIM might be further processed to provide JTCs statistics and to evaluate the quality of the procedure. Thus, the researchers will be asked for their consent. Upon completion of the process, all personal data are deleted from CBIM.

Regarding the protection of personal data (POPD), a Joint Controller Agreement (JCA) details the following points:

THCS partners, as Joint Controllers, will take all necessary technical and organisational measures to ensure that the rights of the data subjects, in particular in accordance with Articles 12 to 22 of the GDPR, can be or are guaranteed at all times within the statutory time limits, and observe the principle of data minimization within the meaning of the Article 5 (1) of the GDPR. They will ensure that security measures will be implemented to prevent unauthorised access to personal data.

In case a Controller and/or its Processor(s) from the EU transfer(s) personal data in the scope of the execution of the THCS Agreement to a Controller and/or Processor and/or other entity situated in the third country that does not present adequate safeguards under the GDPR, they shall ensure that such transfer is possible and that it complies with the GDPR. Cross borders data flows are governed by Standard Contractual Clauses provided by the EU, and they must be signed by the relevant data importer(s) and the data exporter(s).

Regarding Non-EU countries (NEC): 'In case activities undertaken in non-EU countries raise ethics issues, the applicants must ensure that the research conducted outside the EU is legal in at least one EU Member State. This must be specified in the Grant Agreement.' Although THCS does not undertake its own research activities in non-EU countries, it will receive research grant proposals from JTCs for research projects.

Research proposals submitted for funding under THCS will potentially include the following activities that may cause ethical and data protection concerns:

- behavioural studies on human subjects,
- collection of biological samples from human individuals,
- interventions in human subjects, use of existing databases,
- use of stored biological samples, and/or animal experiments.

THCS will only fund research of the highest ethical standards complying with the European Directive and the relevant national/regional laws, rules, and regulations.

Therefore, applicants (including applicants from third countries that are included in the research consortia) are required to complete an ethics issues table and supply an ethical self-assessment, describing potential ethical aspects and applicable regulatory aspects of the work to be carried out, and the way they are dealt with according to relevant national and European rules and other relevant international guidelines.

Each consortium should explain how ethics issues will be treated in the proposed research project in the proposal form on ethics and legal issues and describe which participant(s) is/are responsible for the ethics issue. If an ethics permit is required, the applicants should include the status of the permit (not applied/under review/permit granted and date of submission/approval). This statement also pertains to data protection, human participation, and the use of animals.

In the framework of THCS, as mentioned in the Ethics chapter of the partnership, a specific procedure will be organised for the Ethics Review and Monitoring, including the Ethics & RRI.

As specified in THCS calls and in the Standard Operating Procedure Manual, an Ethical assessment and clearance process will be performed by Ethics experts to check that the research proposals that are selected for funding are aligned with ethical norms and regulations. The Ethics experts may put forward additional conditions that need to be fulfilled by applicants. Each applicant to a THCS call must comply with both THCS ethics considerations and the national/regional/local regulations.

Only those proposals approved by both the scientific evaluation and ethical assessment (complying with all central Horizon Europe and relevant regional/national ethical requirements) will be funded. The joint selection list of projects to be funded will be communicated to the EC, accompanied by the ethical review of the selected projects.

The ethical assessment performed in the framework of the THCS Calls does not substitute the national ethical boards and procedures, and additional ethical authorisations might be required by some funding organisations according to national regulations. The final ethical clearance of funded proposals should be fully approved after documented necessary improvements done.

To respect the high importance of ethical responsibility by funders, THCS will pay special attention to potential ethical issues (e.g., research on humans or animals, privacy of data and biomaterials, informed consent, gender balance, etc.). In the case of research proposals involving human embryonic stem cells (hESCs) or non-human primates, the EC must be immediately informed.

THCS will ensure a high level of transparency in all steps of the JTC procedure by:

- publishing the final results of the calls on the THCS website,

- publishing the reviewers' names upon consent on the THCS website after completion of the call,
- providing the anonymised reviewers' written comments and consented funding recommendation to the applicants.

Transparency is restricted in favour of personal data protection by keeping the reviewer assignments to proposals confidential.

In the review procedure, the reviewers invited to evaluate the submitted proposals will be instructed to review objectively, to safeguard confidentiality, and to state conflicts of interest (according to the THCS Guidelines for Reviewers, the Declaration of Impartiality and Confidentiality and the Declaration of Conflicts of Interests for reviewers).

7 Other issues

n/a