

831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP6 – PROMS

D6.8 Final version of Data management plan

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Document History

Version	Date	Description
V1.0	09 Jun 2020	D6.3 First version of Data Management Plan
V2.0	15 Jun 2023	D6.11 Updated Data Management Plan
V3.0	27 Nov 2025	D6.8 Final version of Data Management Plan

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1. Data summary

The Trials@Home consortium explored the opportunities of moving clinical trials from the traditional clinic setting to the participant's immediate surroundings. These Decentralised Clinical Trials (DCTs) make use of digital and operational innovations, enabling participants to visit a clinical trial centre less frequently, if at all. The research conducted by Trials@Home includes an inventory and evaluation of existing and new techniques for use in DCTs as well as a pan-European proof-of-concept study.

Overall, the Data Management Plan (DMP) provides a description of the data management that is applied in the Trials@Home project including:

- A description of the data repositories, who is able to access the data, and who owns the data.
- The main DMP elements for each of the studies contributing (or sharing) data.
- The time period for which data must be stored.
- The standards for data collection, validation and evaluation.
- The possibilities of and conditions for sharing data.
- The implementation of data protection requirements.

The Trials@Home project has identified 2 main types of data that will be collected during the time of the action:

“Clinical Data” means any and all unprocessed information or raw data, including but not limited to any and all serological data, metabolic or genetic data, collected for each human subject involved in a Clinical Trial carried out as part of the Action. Clinical Data to which another Party may have access to in the framework of the Consortium Agreement shall be pseudonymised or anonymised. Clinical Data remain under the sole management, custody and responsibility of the Sponsor and constitute Results under the Consortium Agreement.

“Clinical Trial Metadata” means any and all metadata obtained in a Clinical Trial, that provide information about the design, conduct, performance and compliance of a Clinical Trial, including but not limited to: user preferences (patient, site, sponsor, other stakeholders), interview notes, transcripts or recordings, performance metrics and model relevant KPI's (throughput, recruitment, retention, ...), feedback from regulatory authorities and ethical committees, observed incidents and support issues, user satisfaction, and/or cost-benefit results. Individual patient data will be anonymised by the data owner or Sponsor before sharing with any other party.

2. Data repositories

The research conducted by Trials@Home includes an inventory and evaluation of existing and new techniques for use in DCTs as well as a pan-European proof-of-concept study. The results are published in scientific journals and the data supporting the research is stored at the data owners, which are generally the institutes leading the research.

This DMP gives guidance and provides an oversight of general data management, while each study has specific data management information including access rules. These are summarized in the text and table below. The data in the table is related to studies based on a specific dataset, known on November 30, 2025. For the other research performed by the project, the publications are available via the project website <https://trialsathome.com>, and related data can be requested to the corresponding author of the publication.

A detailed data management plan, specific for the pan EU proof-of-concept study RADIAL, is developed by WP2 TECH (Deliverable D2.5). This is a confidential document.

- Literature research data: the data used for literature research is normally fully disclosed in the publication via citations or in a separate supporting data file. In exceptional cases where not all data is available in the publication, the data are available from the corresponding author upon reasonable request.
- Interview data, including focus groups: audio recordings will be made of all interviews. These will be transcribed and pseudonymised. All data will be stored in a secure database at the data owner, with limited access to research team only. All data will be handled and stored in accordance with local information governance SOPs (Standard Operating Procedures). Participants will not be individually identified in any publications but nonetheless may be identifiable by role to those with knowledge of the case studies being presented. In some cases, excerpts from anonymized transcripts can be made available upon request. Participants do have a right to withdraw their consent to participation at any time. However, rights to access, change or remove their data may be limited if data have already been analysed and/or incorporated into study results. If participants do withdraw from the study they will be informed as to what data has been collected and if it can be removed.
- Survey data: survey results will be pseudonymised and stored in a secure database at the data owner, with limited access to research team only. All data will be handled and stored in accordance with local information governance SOPs (Standard Operating

Procedures). Participants will not be individually identified in any publications but nonetheless may be identifiable by role to those with knowledge of the case studies being presented.

Participants do have a right to withdraw their consent to participation at any time. However, rights to access, change or remove their data may be limited if data have already been analysed and/or incorporated into study results. If participants do withdraw from the study they will be informed as to what data has been collected and if it can be removed.

Data collected for this project will not be used for automatic decision making or profiling.

Type of data	Access provisions	Data owner	Link to publication of results
Interview transcripts from interviews about case studies (WP1)	Access is restricted to the study team in accordance with the requirements of the ethical approval.	University of Dundee	<ul style="list-style-type: none"> • https://doi.org/10.1186/s13063-022-06521-4 • https://doi.org/10.1111/bcp.15003
Dataset from literature research on methods used for DCTs (WP1)	The data that support the findings of this study are available from the corresponding author upon reasonable request.	University of Dundee	<ul style="list-style-type: none"> • https://doi.org/10.1111/bcp.15205
Survey data on the early impact of COVID-19 on the update of DCT methods (WP3)	The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request.	University Medical Center Utrecht	<ul style="list-style-type: none"> • https://doi.org/10.1186/s13063-022-06706-x
Dataset from the pan-EU proof-of-concept study RADIAL (WP2, 3, 4)	The study protocol and CSR are available and serve as metadata for this dataset. Access requests are managed via https://dataverse.nl/ .	University Medical Center Utrecht, FH Joanneum, Sanofi, Julius Clinical, Utrecht University	<ul style="list-style-type: none"> • https://doi.org/10.1002/cpt.70025 • https://doi.org/10.1002/cpt.70070 • https://doi.org/10.1002/cpt.70042 • https://doi.org/10.1002/cpt.70072 • https://doi.org/10.1002/cpt.70075 • https://doi.org/10.1002/cpt.70078

Focus group transcripts from the focus groups on motivation of people living with T2DM for participation in DCTs (WP3)	The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request.	University Medical Center Utrecht	<ul style="list-style-type: none"> • https://doi.org/10.1111/cts.70070
Dataset from discrete choice experiment on participant preferences for DCTs (WP3)	The preference data of this study are available from the corresponding author on reasonable request.	University Medical Center Utrecht	<ul style="list-style-type: none"> • https://doi.org/10.1136/mjopen-2025-107737
Dataset from literature research on physical examinations in clinical trials (WP3)	The data that support the findings of this study are openly available in the ClinicalTrials.gov database at https://clinicaltrials.gov . The extracted data from the clinical trial protocols for this study are available from the corresponding author upon reasonable request.	University Medical Center Utrecht	<ul style="list-style-type: none"> • https://doi.org/10.1002/bcp.70258
Interview transcripts from interviews on physical examinations in clinical trials (WP3)	Until publication, the data is not accessible outside the research team.	University Medical Center Utrecht	<ul style="list-style-type: none"> • Manuscript in preparation
Dataset on carbon footprint analysis of RADIAL trial (WP3)	Until publication, the data is not accessible outside the research team.	University of Dundee	<ul style="list-style-type: none"> • Manuscript in preparation
Dataset from literature research on DCT activities reported in protocols (WP4)	Data are available in a public, open access repository. The data file has been made freely available and is accessible via doi.org/10.17632/9ns6gmtz3j.1 .	Utrecht University	<ul style="list-style-type: none"> • https://doi.org/10.1136/mjopen-2022-063236
Interview transcripts from interviews on EU regulatory perspective on DCTs (WP4)	Participants did not consent to make the transcripts publicly available. Supporting quotes are available in the results section of this paper. Excerpts from anonymized transcripts can be made available upon request. Please contact the corresponding author for more information.	Utrecht University	<ul style="list-style-type: none"> • https://doi.org/10.1002/cpt.2628
Interview transcripts from interviews on EU HTA perspective on DCTs (WP4)	Excerpts of transcripts available on request from corresponding author of paper. Full dataset cannot be made available due to conditions of informed consent and ethical approval.	Utrecht University	<ul style="list-style-type: none"> • https://doi.org/10.1016/j.jval.2023.11.006
Interview transcripts from interviews	Participants did not consent to make the	Utrecht University	<ul style="list-style-type: none"> • https://doi.org/10.1111/b

on direct to participant shipment (WP4)	transcripts publicly available. Supporting quotes are available in the results section of this paper. Excerpts from anonymized transcripts can be made available upon request. Please contact the corresponding author for more information.		cp.15850
Dataset from literature research with trial participant characteristics of DCT participants, conventional trial participants and patients in daily practice (WP4)	Aggregated data from the referenced trials is publicly available. This study is based in part on data from the Clinical Practice Research Datalink. Analytical is available via GitHub (amosdejong/The-impact-of-operational-trial-approaches-on-representativeness).	Utrecht University	<ul style="list-style-type: none"> • https://doi.org/10.1016/j.drudis.2025.104304
Focus group transcripts from the focus groups on mock ethics review (WP4)	Data cannot be made available; participants did not consent to sharing.	University Medical Center Utrecht	<ul style="list-style-type: none"> • https://doi.org/10.1016/j.drudis.2022.07.011
Data from SWOT analysis (Delphi) on ethical legal and operational barriers and enablers for DCTs in the EU (WP4)	Part of the data is already published as appendices to D4.2. Until publication, the data is not accessible outside the research team.	FISABIO	<ul style="list-style-type: none"> • Deliverable 4.2 • Manuscript in preparation
Survey data on benefits and downsides of DCTs for PIs, patients, and GPs (WP5)	The anonymized survey data is shared as annexes to D5.4.	Vital Transformation	<ul style="list-style-type: none"> • Deliverable 5.3 and 5.4
Data from surveys and qualitative interviews on public patient involvement and engagement (WP6)	Until publication, the data is not accessible outside the research team.	IDF Europe	<ul style="list-style-type: none"> • Manuscript in preparation

3. FAIR data

2.1 Making data findable, including provisions for metadata

All publications are made publicly available in open repositories such as OpenAIRE (Netherlands Research Portal), Utrecht University Repository, Discovery (the University of Dundee Research Portal), and Zenodo. Datasets will also be made available in these repositories or in some cases in more targeted repositories such as DataverseNL in the case of the clinical trial data.

The availability of the data in these repositories makes this data both easily discoverable and identifiable from the outside (since they will be given a Digital Object Identifier (DOI)). In addition, they are available on the project's website and disseminated through other organisations, where they will also be discoverable.

Datasets that will be only used internally by project partners are stored on the closed project SharePoint repository, MyProjectPlaza, during the project duration. The datasets are internally discoverable and identifiable using simple queries with keywords or filters.

After the project end, the materials will be archived at University Medical Center Utrecht, where they are available for project partners upon reasonable request.

Data will be made discoverable in different ways depending on its utility for internal or external stakeholders. Versioning of data, whenever applicable, will be applied to all data (incl. documents, questionnaires) created and/or collected. Secondary data will be documented by carefully explaining terms, variable names, codes and abbreviations used.

Because of the interdisciplinary nature of the project, it is important to promote the use of common terminology within the project. The choice of terminology will be driven by the Trials@Home glossary.

Depending on the method of data publication chosen, version number will be made available. The templates created for the project deliverables will include the version numbers and details about the changes made.

For datasets that will be shared via open repositories, the metadata standards used by these repositories will be used.

2.2 Making data openly accessible

Although Trials@Home opted out from the Pilot on Open Access to Research Data, it does take into account the related Guidelines to make as much research data openly available as per consortium discretion, ensuring that where possible data will be findable, accessible, interoperable and reusable (FAIR), following the Guidelines on FAIR Data Management in Horizon 2020.

After completion of the project, third parties have the right to request access rights to the results for research use, as specified in the Consortium Agreement. Requests must be submitted as a written request directly to the owner of the results. Access rights will be granted subject to a separate written bilateral agreement between these parties, defining the appropriate conditions agreed between the consortium partner and the third party, including but not limited to ensuring that access rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

More specifically, there is also privately-owned data, usually collected by companies/institutions working with the patients, which was analysed by WP1. Such data (e.g. data for the patients' medication or interviews), provided to the project for research purposes, will be used internally by project partners after following the procedure defined in WP1 BEST. Aggregated and anonymised conclusions and abstractions obtained through the analysis of data may be publicly or confidentially shared if this promotes the project's goals. Personal information that may identify individuals will never be shared.

Generally, standard computer software and no developer skills will be required to access the data e.g. to download, and read them in Excel, CSV formats. However, different methods and software tools will be required to access data depending on the nature of data and means of publication e.g. website, wiki or API. That may include database management systems e.g. SQL, more sophisticated formats like JSON or standardised formats such as LinkedData etc.

Data to be openly shared will be deposited in open repositories such as OpenAIRE (Netherlands Research Portal), Utrecht University Repository, Discovery (the University of Dundee Research Portal), Zenodo, and DataverseNL. These are widely used repositories adopting standard and simple procedures to allow data sharing by researchers. No need for appropriate arrangements is foreseen. Real-time or data logs may be shared (via an API). Arrangements will be made by the partners participating in the current project. Finally, data shared on the project's website will be arranged by the consortium.

In the case of restricted use, access can be provided either through use of consent and anonymization, or by regulating and restricting access to external users. Access will be provided by the Data Access Committee of the data owner. The DAC will manage all requests from external parties, evaluate data, maintain inventory and review in-kind contributions.

Machine-readable licenses will be used for the data we plan to make openly available.

For the datasets we plan to share, open access will be granted. For the data that will be used only internally by project partners (which is stored on the project's platform), access control procedures are in place that define access rights and provide secure access with username/password credentials.

2.3 Making data interoperable

Interoperability of data is only relevant for the RADIAL dataset. This is described in a detailed data management plan specific for the pan EU-pilot, is developed by WP2 TECH (Deliverable D2.5). This is a confidential document.

2.4 Increase data re-use

Datasets that will be made publicly available will be uploaded in open repositories like OpenAIRE (Netherlands Research Portal), Utrecht University Repository, Discovery (the University of Dundee Research Portal), Zenodo, and DataverseNL, thus making this data easily re-usable by outside parties (since they will be given a DOI).

As per Grant Agreement and Consortium Agreement, consortium partners will take measures to aim for exploitation of project results for four years after the end of the project and keep records until five years after the final payment of the balance. Third parties can request access to project results for research use until 10 years after the end of the project (November 2025).

An important aspect of data reusability is the quality of the produced data. To ensure the quality of the datasets, several quality assurance processes are in place, each being the responsibility of the Work Package generating the data.

4. Allocation of resources

Open Access costs will be covered by project budget of the partner organisation for which the corresponding author is originating from. Cost for storage, collection and analysis of collected data will be covered by partner institutions responsible for the relevant materials.

Data Management (and all associated costs) for the pan-EU proof-of-concept study RADIAL is the responsibility of WP2 TECH, who set up a database and developed a detailed data management plan for RADIAL (available as Deliverable 2.5, see DoA (Description of Action), task 2.4).

5. Data security

Data security is the responsibility of the various partners generating data and should be monitored by each institution's DPO (Data Protection Officer).

Data transfer between partners

Trials@Home researchers commit to the highest standards of data security and protection to preserve the interests of the study participants. Data security when sending patient data between Trials@Home partners is ensured by using the facilities offered by the data generating institute. Data Protection Officers of the institutes will be consulted to find the appropriate solution, which in most cases will be an encrypted data transfer requiring licenses, such as e.g. ShareFile.

6. Ethical aspects

The research performed by Trials@Home was conducted in accordance with the principles of the Declaration of Helsinki, good scientific practice and the EU General Data Protection Regulation.

The research complies with ethical requirements. Although our research concerns medical scientific research, participants are not in all cases subjected to procedures or required to follow rules of behaviour and no burdensome or intimate questions were asked. Therefore, it was considered case by case whether an evaluation by a medical ethics committee was required or waived.

Where human subjects were involved, the research team considered case by case whether informed consent was required, and if so, in what form. Where informed consent was required, this was obtained from all participants at the start of their participation.

7. Other

A detailed data management plan, specific for the pan EU-pilot, is developed by WP2 TECH (Deliverable D2.5). This is a confidential document.