



831458 – Trials@Home

Center of Excellence – Remote Decentralised  
Clinical Trials

**WP6 – PROMS**

## D6.6 Final version of sustainability plan

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### Document History

Version	Date	Description
V1.0	27-11-2025	Final version of sustainability plan

## Abstract

Trials@Home is a research project funded by EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2; Trials@Home grant n° 831458) which focuses on decentralisation of clinical trials. The project created a lot of knowledge which is shared via tangible project outputs. To ensure the maintenance of these results beyond the duration of the funding period, a sustainability plan has been developed. This plan summarizes the outputs of Trials@Home and indicates for each type of result whether and how these will be maintained after the project end, as well as how Trials@Home as a network will continue in the future.

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## 1. Introduction

The IMI Trials@Home project is a project supported by EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2; Trials@Home grant n° 831458). Since its start in September 2019, the public and private project partners have worked together to explore the opportunities of moving clinical trials from the traditional clinic setting to the participant's immediate surroundings. These so-called Decentralised Clinical Trials (DCTs) make use of new, digital innovations and enable participants to visit a clinical trial centre less frequently, if at all.

A lot of research was performed during the project's timespan of six years and three months. The primary outputs of the project are the recommendations on the further implementation of DCTs in Europe that follow from the analyses on best practices in DCTs, the technological options, as well as the legal, regulatory, ethical and psychosocial aspects, as implemented in the proof-of-concept study (RADIAL) comparing traditional approaches to (hybrid) DCTs. These recommendations and other materials including scientific papers, deliverable reports, research data, and course materials, are made available to a broad audience in pursuit of broad adoption to allow more efficient DCT deployments for trials where relevant.

To ensure the financial and institutional sustainability of all project outputs after the project formally ends in November 2025, a sustainability plan has been developed. This plan summarizes the results of Trials@Home and indicates for each type of result whether and how these will be maintained after the project end, bearing in mind the overall aim of effective dissemination to achieving a high impact on the stakeholders including scientists, industry, and the European society.

In addition to describing the plan for existing outputs, the sustainability plan describes how Trials@Home as a network will continue in the future. The project was set up as a public-private collaboration, where academic partners, Small and Medium-sized Enterprises (SMEs), private foundations, and EFPIA partners work together with other stakeholders from across the medical, technological, regulatory, ethical and social aspects of DCTs, with a common goal to develop concrete and practical recommendations regarding the implementation of DCTs in Europe. This expertise and network are an important asset of Trials@Home which should not be dissolved when the funded period ends.

Definition of 'sustainability' as defined in the IMI Scientific Committee Recommendation *Sustainability solutions are important criteria determining project quality and output in IMI*: Sustainability refers to the maintenance of outputs or deliverables from IMI-funded research programmes beyond the duration of the funding when it is conceived that this would benefit the EU public health and/or industry.

[https://www.ih.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/SC\\_Sustainability\\_June2018.pdf](https://www.ih.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/SC_Sustainability_June2018.pdf)

## 2. The Trials@Home recommendations website

The main result of Trials@Home are the recommendations for running Decentralised Clinical Trials (DCTs) or trials with decentralised elements. DCT development is learning by doing, which is why the learnings from Trials@Home are so valuable as they provide deep insights about the implementation of DCT elements for future trials. As described in the appendix, a recommendations working group was set up, and in collaboration with WP5 CODE, a new version of the website was designed that is centred around the Trials@Home recommendations.

The project legacy website was launched in October 2025: <https://trialsathome.com/>

For the website, it is important that it is easily discoverable and that it is an accessible knowledge hub. Items should be easy to find for all stakeholders, including the research community, patient associations, industry, regulators, and more. Therefore, the main recommendations are formulated as one-liners and placed at the centre of the landing page, where they can be expanded to get a bit more context.

Based on six years of multistakeholder scientific research on opportunities and challenges of decentralised clinical trials (DCTs), the Trials@Home consortium has developed a set of main recommendations covering the methodological, regulatory, ethical, operational and social aspects of DCTs. By nature, these main recommendations are high level, and we encourage users to go to the different content pages for more practical, detailed recommendations.

### Main recommendations

- ▶ Engage stakeholders during trial design to identify activities to decentralise
  - ▶ Assess and communicate clearly what is expected from participants to support engagement and fair compensation
  - ▶ Evaluate decentralised elements and advocate for ethical and regulatory acceptability
  - ▶ Assess site capabilities and provide tailored training, support and compensation
  - ▶ Select and test technologies early, and embed robust support and governance systems
- ▶ Establish participant-centred communication platforms and provide responsive support
  - ▶ Plan and test decentralised logistics to mitigate risks and ensure operational readiness
  - ▶ Define roles and responsibilities clearly and ensure oversight mechanisms are in place


Ensure additional specificity around roles and responsibilities because data collection, biological sample collection, and other procedures may be performed through non-traditional routes and involve participants and third-party vendors as the actors more often. Sites need to have access to all data required to maintain oversight and roles and responsibilities. Communication channels also need to be clearly defined before start of the trial.

  - ▶ Implement rigorous data protection strategies and ensure secure digital infrastructures

From this page, you can navigate to subpages with more details on the recommendations based on the research performed by Trials@Home. In addition, the course materials are available on the website and there are several pages dedicated to explaining the basics of Trials@Home and DCTs as well as a page with all Trials@Home outputs at a glance.


## In-depth recommendations per theme

Explore our in-depth recommendations for decentralising specific trial activities, divided into themes.




Activities & Operations

More




Impact & KPIs

More




Patient Considerations & Involvement

More




Assessment & Approval

More



Oversight & Clinical Management

More



Technology & Support

More




The recommendations are supported by publications in prominent peer-reviewed journals, where the research is described in more detail. Therefore, each webpage that describes Trials@Home recommendations has a section with further reading, where the related articles are referenced. This section also contains references to deliverables, videos, posters and other materials created by Trials@Home.

### Further reading

#### Publications

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COVID-19 and the Emerging Regulatory Guidance for Ongoing Clinical Trials in the European Union.

 de Jong, et al  Clinical Pharmacology & Therapeutics  2021

Read now

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Opportunities and Challenges for Decentralized Clinical Trials: European Regulators' Perspective.

 de Jong, et al  Clinical Pharmacology & Therapeutics  2022


Read now

View poster

#### Deliverables

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Map of the EU legislation on DCTs including legal, regulatory, ethical and stakeholder recommendations for conduct of the pan-EU pilot.

 WP EAGLE, 2022

Read now

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Final EAGLE report.

 WP EAGLE, 2025

Read now

The website is hosted on the Vital Transformation server and website updates are managed by Vital Transformation. Vital Transformation will keep the website up and running for at least two years after the end of the project (until November 2027). At that time, the Trials@Home Interest Network (chapter 4) will review the need for maintaining the website. The consortium does not foresee major updates to the website content in that period. If there is an unforeseen need which does require a significant amount of time, there will be a request to the members of the Trials@Home Interest Network for funding.

### 3. Sustainability of the Trials@Home project outputs

Trials@Home has delivered many valuable outputs, focusing on developing standards, recommendations, and tools for implementing DCTs across Europe, addressing methodological, regulatory, ethical, operational, and social dimensions. A key achievement was the RADIAL proof-of-concept trial, a pan-European study comparing decentralised approaches with conventional trial models to evaluate feasibility, scientific integrity, and participant experience. The project produced a comprehensive set of recommendations for DCT implementation, emphasizing stakeholder engagement, patient-centric design, regulatory harmonization, and technology integration. It also generated numerous peer-reviewed publications, practical guidelines, and educational resources, including insights on recruitment, consent, supply chain logistics, technology deployment, and data management in decentralised settings.

#### Dissemination and collaboration

Dissemination of the materials has taken place via social media, newsletters and other sources, with the aim to reach as many people interested in the results as possible, as this directly contributes to the impact of the outputs in the DCT field.

To further stimulate the uptake of the Trials@Home recommendations and results, the consortium has also explored the options for collaboration with established entities, who can disseminate the materials in their network, build upon the work of Trials@Home and expand it.

For example, the patient-focused course materials created by Trials@Home will become part of an online academy for patient advocates and conversations are ongoing with several other patient organisations who are interested in embedding the Trials@Home materials on DCTs in their online course environments as well.

In addition, the Trials@Home results are published in the Decentralized Trials and Research Alliance's Resource Library - A Comprehensive Collection of DTRA Content and Resources Supporting the Adoption of DCTs (<https://www.dtra.org/dtra-resources>).

The press release around the launch of the project's recommendations has been circulated to international press channels as well as to all organisations in the field which were identified as potential collaborators. Several of these have further circulated it in their network via internal and/or external communication.

The Trials@Home Closing Event also featured speakers representing organisations in the field: EMA, CCMO, CTCG, EUPATI, ICON, EUCROF, FutureMeds, and DEEP. The event attracted approximately 120 attendees in-person and another 100 online. This provides a ground for future collaboration and all attendees were directly invited to join the Trials@Home Interest Network (chapter 4).

#### Long-term maintenance of the Trials@Home outputs

The table at the end of this chapter shows how the Trials@Home materials are maintained after the end of the project. Results are categorized as knowledge-sharing output, research data, RADIAL-specific outputs, and consortium management materials.

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).

#### Trials@Home website

🔗 <https://trialsathome.com/>

The main source of information about the Trials@Home project outputs is the legacy website, which can be accessed via <https://trialsathome.com>. Here, the content is presented in a coherent way, with references to further reading material where relevant.

#### Journal websites

As key resources for scientific research, the peer-reviewed articles will be maintained by their publishers and will have a lifespan beyond the project. The protocol of RADIAL is published and as such included in this category, and several publications include an appendix with the research data.

#### DTRA library

🔗 <https://www.dtra.org/dtra-resource-library>

The Decentralized Trials and Research Alliance (DTRA) offers a library of DCT-related resources on their website, including white papers and articles. The Trials@Home scientific papers are included to improve findability of the Trials@Home results.

#### Patient advocate courses

🔗 <https://openacademy.eurordis.org/courses/the-trialshome-course-on-decentralised-clinical-trials/>

The Trials@Home course on decentralised clinical trials is available on the EURORDIS Open Academy, which accompanies patient advocates by offering rare disease-specific comprehensive training programmes that empower advocates with the knowledge, skills and confidence they need to engage with different stakeholders as equal partners. In addition, the course materials will be made available by EUPATI and potentially other patient organisations or patient advocacy groups.

#### CTIS and clinicaltrials.gov

🔗 <https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en> (search for trial title: 'RADIAL')

🔗 <https://clinicaltrials.gov>

The RADIAL trial was registered with identifier NCT05780151 in clinicaltrials.gov and under 2022-500,449-26-00 in the Clinical Trials Information System (CTIS) clinical trial database.

#### CORDIS

🔗 <https://cordis.europa.eu/project/id/831458/results>

CORDIS is the database with results of EU-funded research. The project deliverables and scientific articles are available on the Trials@Home page.

#### Online repositories

As set out in the Grant Agreement, all Trials@Home peer-reviewed scientific publications must be open access and a copy of the manuscript must be deposited in a repository. Which repository is used depends on the standard practice of the institution of the first author. The following repositories contain Trials@Home publications:

- <https://dspace.library.uu.nl>
- <https://discovery.dundee.ac.uk>
- <https://netherlands.openaire.eu>
- <https://zenodo.org>

#### DataverseNL

🔗 <https://dataverse.nl>

The Clinical Study Report (CSR) for RADIAL has been prepared by the consortium and will become available in 2025 on DataverseNL, along with the protocol.

#### Available upon request

Although the consortium aimed to make research data available as much as possible, this was not always feasible. For example for interview studies, where there was no consent by the participants to share their responses. In some cases, the data can be shared upon request.

#### Archived at UMCU or owner of the output

UMCU as coordinator will archive most of the project materials. In some cases, the materials remain with the creator and owner of the materials, for example in the case of datasets of papers primarily performed at the institution of another consortium partner.

Output	T@H website	Journal websites	DTRA library	Patient advocate course	CTIS and clinicaltrials.gov	CORDIS	Repository / DataverseNL	Available upon request	Archived at UMCU or owner
<b>Knowledge-sharing outputs</b>									
Deliverable reports (confidential)	x	x	x	x	x	x	x	x	✓
Deliverable reports (public)	✓	x	x	x	x	✓	x	x	✓
Scientific articles	✓	✓	✓	x	x	✓	✓	x	✓
• Laymen summaries	✓	x	x	x	x	x	x	x	✓
Research posters	✓	x	x	x	x	x	x	x	✓
• Laymen summaries	✓	x	x	x	x	x	x	x	✓
• Video commentaries	✓	x	x	x	x	x	x	x	✓
Research videos	✓	x	x	x	x	x	x	x	✓
Podcasts	✓	x	x	x	x	x	x	x	✓
Training videos and infographics	✓	x	x	x	x	x	x	x	✓
Course materials	✓	x	x	✓	x	x	x	x	✓
Glossary	✓	x	x	x	x	x	x	x	✓
<b>Research data</b>									
Transcripts from interviews and focus groups	x	x	x	x	x	x	x	(✓)	✓
Raw data surveys	(✓)	x	x	x	x	(✓)	x	(✓)	✓
Raw data discrete choice experiment	x	x	x	x	x	x	x	✓	✓
Literature research	x	(✓)	x	x	(✓)	x	(✓)	✓	✓
<b>RADIAL-specific outputs</b>									
Study data	x	x	x	x	x	x	✓	✓	✓
Protocol	x	x	x	x	x	x	✓	x	✓
Patient-facing materials	x	x	x	x	✓	x	x	x	✓
Recruitment website	x	x	x	x	x	x	x	x	✓
Confidential materials	x	x	x	x	x	x	x	x	✓
<b>Consortium management materials</b>									
All confidential consortium materials	x	x	x	x	x	x	x	x	✓

## **Social media**

During the project period, Trials@Home has been active on Twitter (now: X), Facebook, and LinkedIn.

LinkedIn is the main social media platform for Trials@Home, where we have over 1,000 followers. This page will be kept active also beyond the end of the funding period for Trials@Home. It will be used by the Trials@Home Interest Network (chapter 4). In addition, there is a closed LinkedIn group which will also be used by the Network. There are no direct costs related to maintaining these channels. Content for public posts will be created by the Interest Network Steering Committee, with input from the Network's members where relevant.

The activities on Facebook were solely intended for patient recruitment related to a specific Trials@Home subproject. After this subproject finished, the profile on Facebook was taken offline.

The activities on Twitter / X were mostly relevant in the first stage of the project. In more recent years, we have seen a move towards LinkedIn. The Interest Network will therefore not continue using this channel and it will be taken offline after November 30, 2025.

## 4. The future of Trials@Home: the Trials@Home Interest Network

The Trials@Home consortium was a major European initiative aimed at transforming the way clinical trials are designed and conducted by advancing decentralised clinical trials (DCTs). Over six years, the consortium brought together academic institutions, pharmaceutical companies, technology providers, and patient representatives to explore how trial activities could be shifted from traditional clinical sites to participants' homes or local settings.

The main outcomes of Trials@Home were the recommendations, which were launched in October 2025 and the underlying knowledge base of scientific publications and other research outputs. These recommendations address the implementation of DCT elements in clinical trials, covering methodological, regulatory, ethical, operational, technological and social aspects. They aim to serve as guiding principles for many stakeholders involved in clinical trial design and execution, including academic researchers, methodologists, industry, regulatory authorities, ethical bodies, technology providers, and patient organisations, among others.

To stimulate short-term and long-term uptake of the recommendations and to leverage the network, expertise and experience gained during the project to continue the advancement of the field of DCTs, the Trials@Home consortium continues as the Trials@Home Interest Network.

The Trials@Home Interest Network is a voluntary community of individuals interested in the field of decentralised clinical trials (DCTs). The Network is devoted to the advancement of the field of DCTs and provides a forum for discussing questions and sharing best practices in a non-competitive environment.

The initial members of the Network are all individuals who were part of the Trials@Home consortium or its advisory bodies. Other individuals interested in the field of DCTs can sign up to join the Network in 2026. A contact list has been created and attendees at the Closing Event have been invited to join this list. It has also been communicated via social media. There will also be a contact page on the Trials@Home website where new members can sign up. For questions, the Network management team is available via [trialsathome@umcutrecht.nl](mailto:trialsathome@umcutrecht.nl)

The members will build upon the experience and expertise gained during the Trials@Home project and the preparation, execution, and analysis of the RADIAL proof-of-concept trial, and they can also bring in new experience from their organisations or ongoing research. The Network allows the identification of knowledge gaps which may result in collaborative activities between several members of the Network.

Besides this, the Network aims to increase the implementation of the Trials@Home recommendations and learnings by stakeholders. This requires continued communication and dissemination of the recommendations and underlying scientific outputs, as well as other outputs created by the consortium such as the course materials for people with lived experience.

**The primary objectives of the Trials@Home Interest Network are to:**

- **Exchange understanding, experience, and implementation practices of DCT approaches.**
- **Discuss policy, methodological and operational questions related to DCTs and identify knowledge gaps and best practices.**
- **Continue to communicate, disseminate, and educate on DCT**

### **recommendations and best practices to enhance the field of DCTs.**

The Trials@Home Interest Network offers several possibilities for engagement and contribution towards these objectives:

- Three plenary online meetings per year, with in-depth presentations and discussion.
- Closed LinkedIn group for ad hoc sharing updates and requests for information exchange.
- If the Network members identify a knowledge gap on which some of the members would like to work together, they can set up a Workstream. Workstreams are small groups focusing on specific topics that are of shared interest, which they wish to discuss in more detail than is possible in the plenary meetings.

There will be a Steering Committee, which has the responsibility to ensure overall progress towards the agreed objectives, including organising regular meetings and workstreams oversight as well as coordinating internal and external communication.

The Trials@Home Interest Network will not work in isolation but will collaborate with other initiatives in the field of DCTs and, where applicable, will seek advice and input from stakeholders including patients, health care providers and regulators. These stakeholders can join the Network as members or provide input on an ad hoc basis.

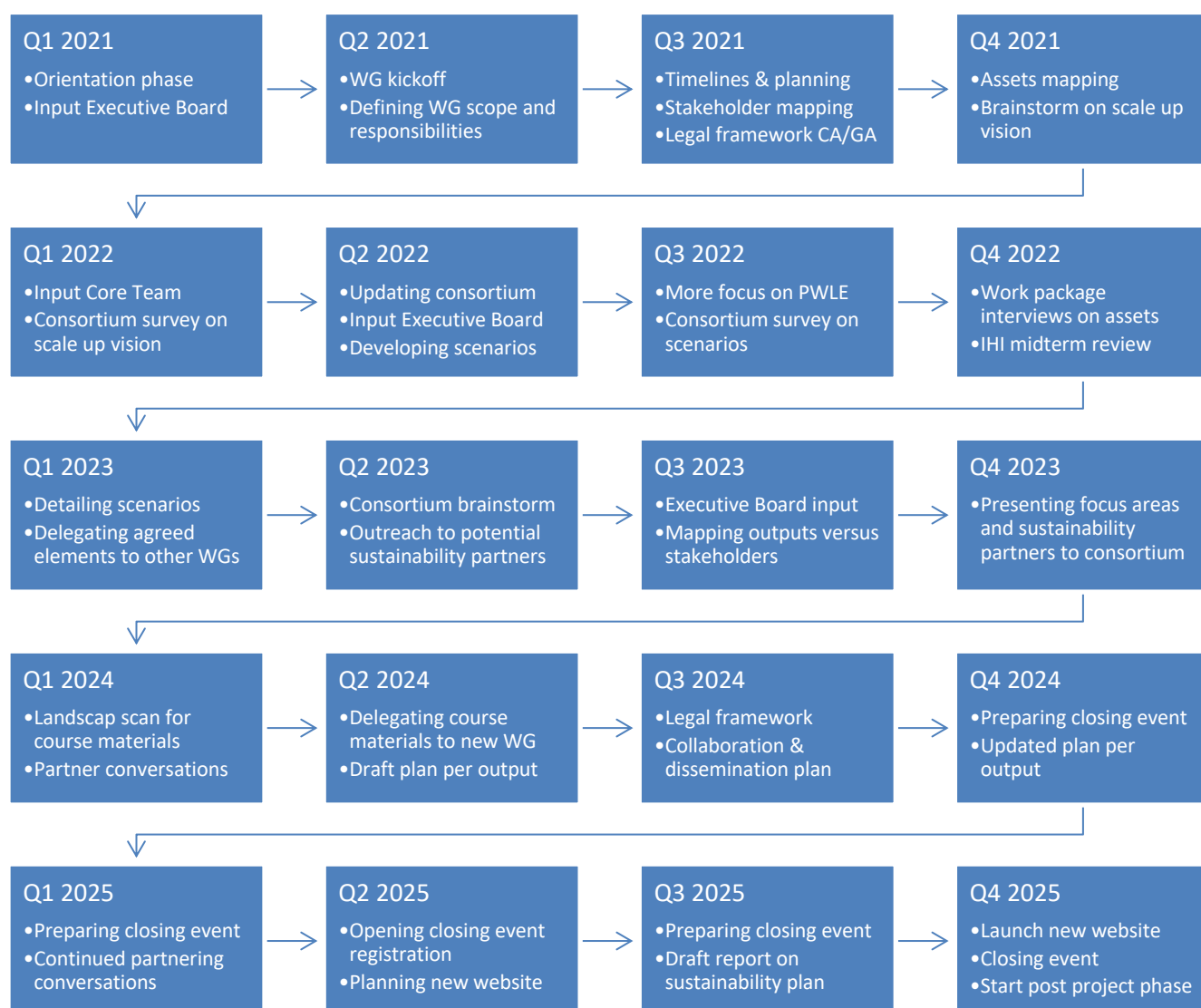
The Trials@Home Interest Network is a voluntary network. There is no membership fee, and there is no central budget for activities. When a group of Network members agrees to work on a research topic together, it may be possible that the work gets funded via one of the organisations that these members are affiliated with. In such case, there will be stand-alone contracts to describe the roles and responsibilities as well as the funding structure.

## Appendix 1. Methods of the Sustainability Working Group

There are a lot of possibilities when it comes to the sustainability of funded research projects. The Trials@Home Sustainability Working Group (SWG), led by UMCU as project coordinator, was therefore launched early in the project. The group kicked off in May 2021 with the overall aim to map the possibilities, collect consortium input, and to lead the consortium discussion towards deciding the best route forward. In practice, the group's aims were to identify all sustainable project outputs and to consider how these can reach our stakeholders most effectively after the project end, in order to facilitate and stimulate the acceptance and implementation of DCTs and hybrid approaches in the global clinical trial landscape when relevant. The main challenges that were identified included the quick changing of the DCT landscape (especially since COVID-19), the costs related to activities after the funding period ends, and ensuring compliance with the legal contracts including the Grant Agreement.

To a large extent, the SWG followed “Scaling innovations emerging from public-private partnerships – A field manual” provided by EFPIA and IMI. This involved mapping the project's assets and stakeholders, defining a scale up vision, and performing a landscape scan.

The SWG took the following steps:



- *Legal framework*

As one of the first steps, the SWG summarized the legal framework from the Grant Agreement and Consortium Agreement. The agreements on IP ownership, access rights after completion of the project, depositing of research data, FAIR requirements, open access requirements and obligation for exploitation and dissemination were summarized in a clear way to serve as reference throughout the rest of the project.

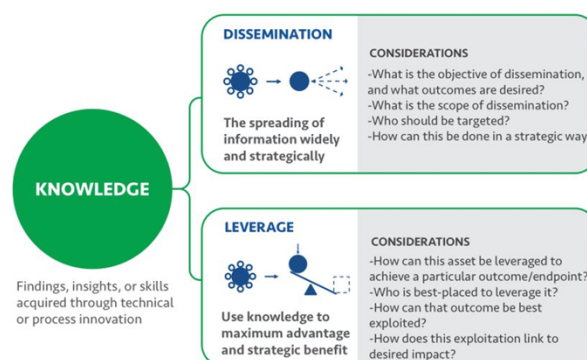
In 2024, this was elaborated with what is allowed for the data of the clinical trial, RADIAL, as set out in the ICF, DMP, CDAs and other study specific contracts. In addition, the consequences of the European Health Data Space (EHDS) were mapped. In March 2025, the EHDS came into force, setting multiple transition periods including for secondary use of data. The options (several data holders in their role of controller, or a joint platform formed by the data holders as defined under the EHDS and an open access platform) were weighed against the background of the FAIR principles and plans were made for the transition period from the end date of the Consortium.

- *Scale up vision*

The members of the SWG held several brainstorm sessions on the question “What could success look like after the project’s end date?”. This was an open conversation with many creative ideas, which helped get a clearer view on what the most valuable assets of the project were expected to be.

Next, the consortium was consulted via an online survey, which probed them on what ongoing success could look like for Trials@Home, what the core activities or resources are that need to be sustained, what tangible outcomes are envisioned for successful sustainability, what the core values and purpose are of these tangible outcomes, and whether they would be interested in providing ongoing input after the end of the project. The survey was conducted between 18 February and 01 April 2022. 26 of the 31 consortium organisations responded to the survey.

From the survey, it became clear that Trials@Home’s most important type of asset is knowledge, rather than a specific product or platform. The aim was to share this knowledge via scientific articles, deliverables, speaking engagements and the recommendations, towards the overall aim to increase awareness of DCTs and to ensure that DCTs can be implemented across Europe in a compliant, predictable and smart way to accelerate clinical research for the benefit of patients and society.



*Figure 1 Knowledge as an asset, figure from “Scaling innovations emerging from public-private partnerships – A field manual”.*

Several organisations indicated their willingness to participate in activities beyond the end of the project. Although this survey was conducted early in the project and the activities after the end of the project were not yet clearly defined, this input did provide insight in how organisations envisioned their own role in the sustainability activities.

- *Sustainability scenarios*

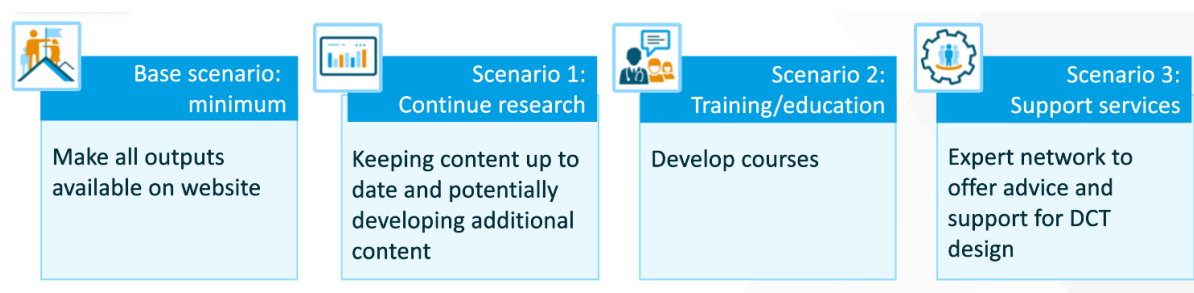
Based on the consortium survey in Q1 2022 and discussions with the Executive Board, multiple ideas for continued development of the project’s outputs were prioritised. These boiled down to the following four base scenarios, which could be combined or implemented

individually:

1. Create a legacy website where all public outputs will be available. This serves as a library of the project recommendations and the supporting materials including publications, deliverables, and other assets developed by Trials@Home.
2. Continue research activities beyond the end of the project by keeping existing project materials up to date and potentially developing additional content.
3. Developing course materials for one or more stakeholder groups which can be sustained after the end of the project.
4. Set up support services as expert network to support the design of DCTs.

At the annual meeting of 2022, the SWG presented these to the consortium, and it was agreed that scenario 1 would be implemented in any case. For scenario 2, 3, and 4, the consortium members were asked to rate whether they think it is currently missing in the field, whether it is interesting for potential clients, and whether Trials@Home has what it takes to implement this. There was room for comments and for identifying which organisations could play a driving role, as well as room for additional suggestions.

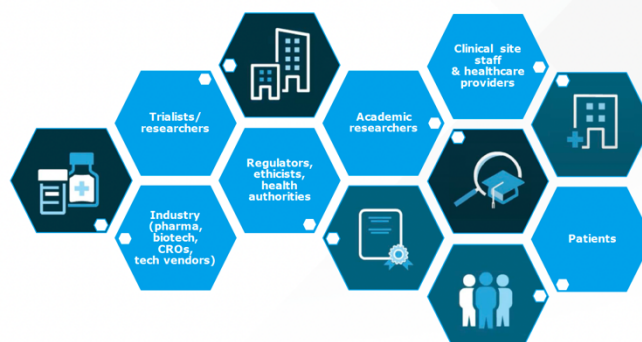
In general, the consortium was positive about all scenarios provided but for each scenario, questions were raised regarding feasibility (especially budget required and time dedication). Next steps included looking into a business plan and performing a landscape scan to identify which stakeholder groups should be addressed when developing additional project outputs such as course materials.



- *Stakeholder mapping*

The communication work package, WP5 CODE, had listed the stakeholders for Trials@Home as part of their plan for communication and dissemination. One of the initial activities of the SWG was to review and update this list and to categorize them as low interest versus high interest and low power versus high power. In addition, their influence and motivation were mapped. This exercise helped to get insight into the prioritisation of stakeholders when creating project outputs and disseminating them, and it provided a framework for the next steps of the sustainability plan to keep the stakeholders in mind at all phases.

### Trials@Home main stakeholders



- *Mapping sustainable project outputs*

To get an overview of all the assets of Trials@Home, the SWG listed all tangible outputs that were planned to be available at the project end. The starting point for this was the Description of Action, which was part of the Grant Agreement. To get more detailed insight and to make sure that the consortium members are all on the same page regarding expectations, the SWG held interviews with the work package leads in Q4 2022. This resulted in a complete list of outputs that would be available at the project end, including the target audience and the envisioned sustainability approach and what this would require.

At the semi-annual meeting of 2023, the progress was reported to the consortium, followed by an interactive brainstorm session. This session focused on the Trials@Home outputs and



where they can be hosted after the end of the project for increased impact and potentially continued development. Here, the consortium also provided any missing outputs on the list, after which the list could be completed. The full list and draft sustainability plan per output were shared with the consortium at the semi-annual meeting in 2024. An overview of the final sustainability plan per output type is provided in chapter 3.

- *Mapping project outputs versus stakeholders*

As a next exercise, the project's tangible materials were mapped for each of the stakeholder groups. This provided insight into which outputs were intended for which audience in the current planning, which allowed for subsequent adjustments. For example, what became clear from this overview is that the number of outputs that are directly suitable for people with lived experience or the general public, are limited.

Output – primary target audience	Trialists/ researchers	Academia	Pharma + tech	CROs (BD)	HCPs	Regulators + ethicists	Payer + HTA	Patients (orgs)	Public
Final recommendations <i>Depends on setup</i>	+	+	+	+	?	?	?	?	-
Reports: Scientific papers	+	+	+	+	+	+	+	-	-
Reports: Deliverables	+	+	+	+	-	+	+	-	-
Education: Webinars	+	+	+	+	+	+	-	+	-
Education: Awareness campaign	+	+	+	+	+	+	+	+	+
Education: Course materials <i>Depends on content</i>	?	?	?	?	?	?	?	?	?
Templates: WP5 surveys	+	+	+	+	-	-	-	+	-
Templates: DCE material	+	+	-	-	-	-	-	-	-
Other: Regulatory mapping	+	+	+	+	-	+	+	-	-
Other: Glossary	+	+	+	+	-	+	-	-	-
Other: RADIAL materials	+	+	+	+	-	-	-	-	-
Other: Consortium network	+	+	+	+	-	+	+	-	-
Other: Communication	+	+	+	+	+	+	+	+	+

- *Planning additional outputs*

At the different steps of mapping the sustainable project outputs, new ideas were shared to increase the project's impact and disseminate the generated knowledge in an effective way. Two of these ideas were: developing additional educational materials, and setting up support

services, which were also included in the scenarios. After more discussion on several occasions, it was agreed not to pursue the latter. Interest in the consortium was limited, and there were uncertainties regarding the operational feasibility. In addition, the number of service providers in the field of DCTs is already increasing, and Trials@Home experts can serve as advisors also without creating a commercial entity.

However, there was sufficient interest to pursue the development of education materials. The consortium provided input at the semi-annual meeting of 2023 and to balance impact of the output with the effort to create and maintain it, it was agreed not to develop a full accredited course hosted by Trials@Home, but to develop course materials which can be implemented by other course providers. As the mapping of outputs versus stakeholders showed that the materials for laymen (people with lived experience or the general public) were limited while this is an important stakeholder group, this was selected as the initial target audience. After a landscape scan of what is already available in the field and where the course materials could potentially be implemented, the SWG drafted a course outline, which was then handed over to the Training and Education working group in WP5 CODE. This working group wrote the actual course materials as one of the Trials@Home assets.

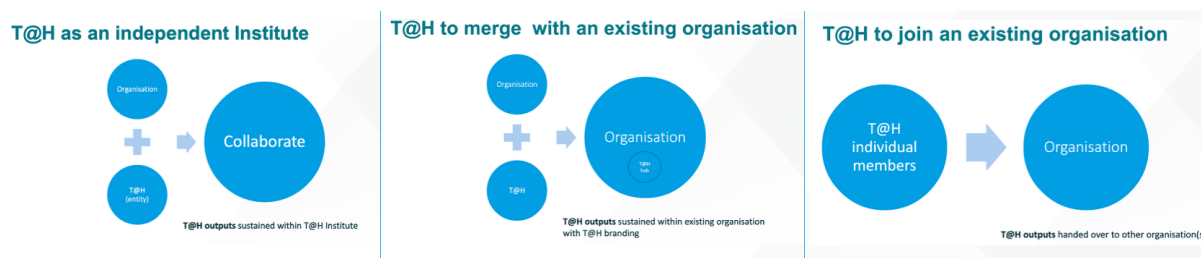
Besides the course materials, WP5 CODE took on an additional task to translate existing project materials into lay language to make them more easily understandable for the general public and people with lived experience.

- *Sustainability framework*

Besides focusing on specific outputs, the SWG discussed the overarching vision with the Executive Board. What are the possibilities to continue research activities beyond the end of the project? Should Trials@Home become a legal entity to continue some of the work after the end of the project, with its own business plan, or should there be primarily a focus on collaboration with existing organisations?

1. Consortium members could apply to potential future IHI-funded projects on the topic of DCTs which could address topics or angles that could not be covered in Trials@Home. Although this is a relevant activity, it falls outside of the scope of the Trials@Home sustainability plan.
2. Setting up a new legal entity would give the consortium full control in the design of this entity, and it can be fully tailored to the Trials@Home values. However, it is a complicated and long process, and it requires a solid business model while Trials@Home strives to make all outputs open access and available at no cost. Moreover, several organisations already exist in the field of DCTs. This option was therefore not considered the best solution from a cost-impact point of view.
3. Collaborating with existing entities. This is a promising option: we can achieve high impact through collaboration with well-established entities in the field of DCTs, which already have an existing network, a functioning funding model, and a proven track record. This partnership can be with one or more consortium organisations as well as with other projects, organisations or alliances outside of Trials@Home. It was agreed to focus on this option, along with the legacy website.

There are also multiple scenarios for collaboration with existing organisations:



- *Collaboration with existing organisations*

To explore the options for collaboration, a landscape scan was performed to identify relevant initiatives in the field and get an initial feeling for how they match Trials@Home. Consortium input was provided at the semi-annual meeting of 2023. With this consortium input, the SWG prepared a slide deck to support the conversations with potential sustainability partners. This slide deck was approved by the Partner Assembly.

In May-August 2023, the SWG had explorative conversations with several organisations to get more insight in the different options for collaboration. Three main options were discussed:

- Disseminating: spreading Trials@Home materials
- Sustaining: continue actively using Trials@Home output on the long term
- Expanding: expanding the work started by Trials@Home

This could include for example being a hub for the Trials@Home network, sharing Trials@Home learnings via their communication channels, incorporating Trials@Home results in their products, and continuing research initiated by Trials@Home.

The results of this exercise are described in chapter 3.



- *Dissemination and the legacy website*

The Trials@Home recommendations were identified as the most important project output. A lot of thought went into how to formulate these recommendations and how to disseminate them to reach the stakeholders. It was eventually decided that the legacy website, where all project outputs will be maintained after the project ends, should be designed around the recommendations. In 2023, a recommendations working group was set up, which had several shared members with the SWG to ensure alignment. The website is described in more detail in chapter 2.

Related to this, the communication and dissemination plan was updated towards the last project year, in collaboration with the SWG. This plan covered the active communication around expected outputs that would be released as part of Trials@Home, as well as collaboration with other organisations. Several organisations were approached to discuss whether and how they want to showcase or adopt the Trials@Home recommendations, or other project assets.

The key dissemination activity in the last year was the Closing Event. The SWG members formed a subgroup that focused specifically on the Closing Event preparations. The Closing Event took place shortly after the publication of the recommendations and provided a platform to highlight them and provide more context.

- *Maintaining the Trials@Home network*

In the 2022 consortium survey on the scale up vision, consortium members also suggested developing a community of practice to stay connected and maintain the knowledge obtained during the project, for strengthening future collaborations, and for enabling ongoing discussions. This was further discussed at the semi-annual meeting in 2023, where the consortium shared ideas on how the Trials@Home network can be maintained.

As the project advanced, the added value of the Trials@Home network became more and more evident. This was also confirmed at the Closing Event, where it was a recurring theme from both people inside and outside Trials@Home, who stressed the importance of maintaining the network and continuing the collaboration.

The plans for the future of the Trials@Home network are described in chapter 4.

