

Trials@Home Interest Network - Terms of Reference

Purpose

Trials@Home was a public-private partnership running from 1 September 2019 until 30 November 2025, which has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

The main outcomes of Trials@Home were the Final 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 final 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.

Objectives

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 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 final 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.

Scope

The Trials@Home Interest Network focuses on DCTs exchanging information and experience on DCTs in a non-competitive environment.

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 Network provides a community where questions can be discussed, best practices shared, and knowledge gaps can be identified. This may result in [new research proposals](#). Such new research proposals might lead to formal research collaborations which are established by some of the Members inside or outside of this Trials@Home Interest Network and following their own stand-alone contract agreement(s) and legal/ethical responsibilities. When the Network engages in new research that will result in [scientific publications](#), a research communication policy will be developed.

The Network members may be affiliated with [commercial organisations](#). To maintain the integrity and neutrality of this initiative, representatives from commercial organisations are welcome to contribute their expertise. However, they must refrain from using the Network for direct commercial promotion or sales activities. Participation that aligns with the consortium's objectives, including indirect commercial benefits such as knowledge exchange or innovation collaboration, is acceptable.

The Trials@Home Interest Network will not provide commercial consultancy services or engage in advocacy activities. However, the Steering Committee of the Network can decide to respond to requests for input, for example for input on regulatory guidelines related to DCTs. Such requests will be addressed on an ad-hoc basis.

Governance

There will be a [Steering Committee](#), which has the following responsibilities:

- Ensuring overall progress towards the agreed objectives
- Daily management of the Trials@Home Expert Interest Network, including acting as the first point of contact and taking operational decisions
- Defining the agenda for plenary Network meetings in collaboration with the Network members and chairing those meetings
- Workstreams oversight
- Coordinating internal and external communication
- General management of the Network, including updating the member list

At the start of the Network, in November 2025, the Steering Committee will be composed of Mira Zuidgeest (UMCU; academic lead of Trials@Home) together with Kim Hawkins (Sanofi; industry lead of Trials@Home) and will be supported by one or more project managers in the Network.

Steering Committee members can step out of their task as Steering Committee member by notifying the other Steering Committee members via email.

Replacements or new Steering Committee members need to be approved unanimously by the other Steering Committee members (quorate: 100%).

Membership

The Trials@Home Interest Network consists of individuals interested in the field of DCTs. Members are expected to [actively contribute](#) to the workstreams and/or the plenary meetings.

The initial members of the Network are all individuals who were part of the Trials@Home consortium or its advisory bodies, unless they opted out of becoming part of the Trials@Home Interest Network.

[New members](#) can join the Network upon request via e-mail to the project managers. In their message, they should indicate what their interest is. The project managers will update the Steering Committee on new membership applications as they come in. In principle, all membership requests will be granted. The entire Network will be updated of new memberships in advance of the plenary Network meetings. Prior to any participation in activities of the Network, the new member will receive this Terms of Reference. Membership may be discontinued if a member's conduct disrupts meetings or negatively affects the functioning of the group, following a warning and at the discretion of the Steering Committee.

If a member wishes to [end their membership](#), they can do so by notifying the Steering Committee via e-mail.

The supporting project managers are responsible for updating the list of members and informing all members of changes in members at the plenary meetings.

[Guests](#) may be invited to the Trials@Home Interest Network's plenary meetings, if there are no objections from the Steering Committee.

Operations

The Trials@Home Interest Network will share updates with the members. This will be done via [update emails](#) and via the [closed LinkedIn group](#). Key information from the Trials@Home Interest Network (e.g. new publications, announcements of training events & webinars) will also be posted on the [Trials@Home website](#). This website will also contain a contact form.

Three times per year, there will be [online plenary Network meetings](#). The duration of these meetings depends on the topics for discussion but is expected to be 60-90 minutes. The Steering Committee will decide per meeting whether this is members-only or open to anyone interested. Occasionally, the meetings may take place in-person. Such meetings can be financially sponsored or for example attached to a conference which many members attend. These plenary meetings will contain [in-depth presentations](#), and the agenda will be sent at least 14 days before the meeting. The Steering Committee is responsible for the selection of the topics and the preparation of the content, which they can delegate to a small group of members as appropriate. The Steering Committee project manager is responsible for the minutes, which will be shared after the meeting.

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. The workstreams can be set up by Network members after endorsement by the Steering Committee. The Workstreams each appoint a Workstream Lead. The Workstream Lead is responsible for monitoring the progress towards the overall goal of the Workstream, setting up monthly online meetings, taking minutes for these meetings, and informing the Steering Committee on progress. External communications on these Workstreams are coordinated by the Steering Committee.

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.

Members will continue to make [independent decisions](#) around all commercial, development and other competitive activities and will comply with all applicable laws and regulations.

[Proprietary and/or confidential information](#) concerning the participating members is excluded from discussions.

Changes to the Terms of Reference

All members will receive this Terms of Reference via e-mail. New members will receive this when they join the Network. It is the responsibility of the supporting project managers to ensure that all members receive the Terms of Reference.

If there is a need to [change these Terms of Reference](#), the changes will be discussed and agreed by the Trials@Home Interest Network members.

The decision on whether proposed changes will be integrated into the Terms of Reference will be taken by the Steering Committee (majority agreement, quorate 100%) and the Network members (majority agreement, quorate 50%, one vote per member).