

# Trials@Home Annual Meeting #3 Wuppertal 26 & 27 September

The 2022 Trials@Home Annual Meeting took place in Bayer's facilities in Wuppertal, where we had two full days of meetings, presentations, and networking. The project thanks Bayer for allowing use of their space for this meeting and for their support in the meeting organisation. The project also thanks the members from the Scientific Advisory Board (SAB), External Stakeholder Platform (ESP) and Patient Expert Panel (PEP) for their invaluable contributions so far.

With about 60 people in the room and 40 online attendees, we had a great time with a lot of inspiring and thought-provoking sessions. Some highlights are presented below.



## Overall progress

An important part of the meeting was the presentation on Work Package progress. The [draft recommendations with best practices for Decentralised Clinical Trials \(DCTs\)](#) are still standing today but WP BEST is working on updating this through follow-up interviews and new case studies. WP TECH and WP PILOT and WP EAGLE are working hard on preparations for RADIAL, the Trials@Home proof-of-concept study. RADIAL updates will be discussed in more detail in the next section. Besides this, WP PILOT is executing a Patient Preference Study for which they are currently setting up focus groups in various EU countries, as well as a Digital Literacy study and a Physical Examination project. WP EAGLE is focusing on the regulatory and ethical aspects of DCTs. WP CODE is continuing their work on communication and dissemination and hosted a session at this meeting on the importance and practicalities around the project's communication. WP PROMS is responsible for project management and is also working on the sustainability plan for Trials@Home.

Trials@Home was the main topic in more than 25 presentations during the past year, with five new published manuscripts. The manuscripts can be accessed via <https://trialsathome.com/peer-reviews-and-research-outputs/>. And you can find the posters here: <https://trialsathome.com/posters/>

**Trials@Home conference presence 2022** 

 **DIA EUROPE 2022**  
29-31 MARCH 2022  
BRUSSELS & VIRTUAL

 **FIGON & EUFEPS**  
EUROPEAN MEDICINES DAYS 2022  
1-3 June 2022 - Leiden, The Netherlands

 **informa**  
Benchmark with Cutting-Edge Case Studies Exploring Fully  
Decentralized and Hybrid Trials

 **phastar**  
Life Science  
Summit 2022

 A NETWORK POWERED BY PEERS  
**eClinical**  
forum

 **EFSPi** Statisticians

 **SCOPE EUROPE**  
SUMMIT FOR CLINICAL OPS EXECUTIVES

 **ANCEI** Ethics  
VIII CONGRESO  
CALERRE, 1-3 DE MAYO DE 2022

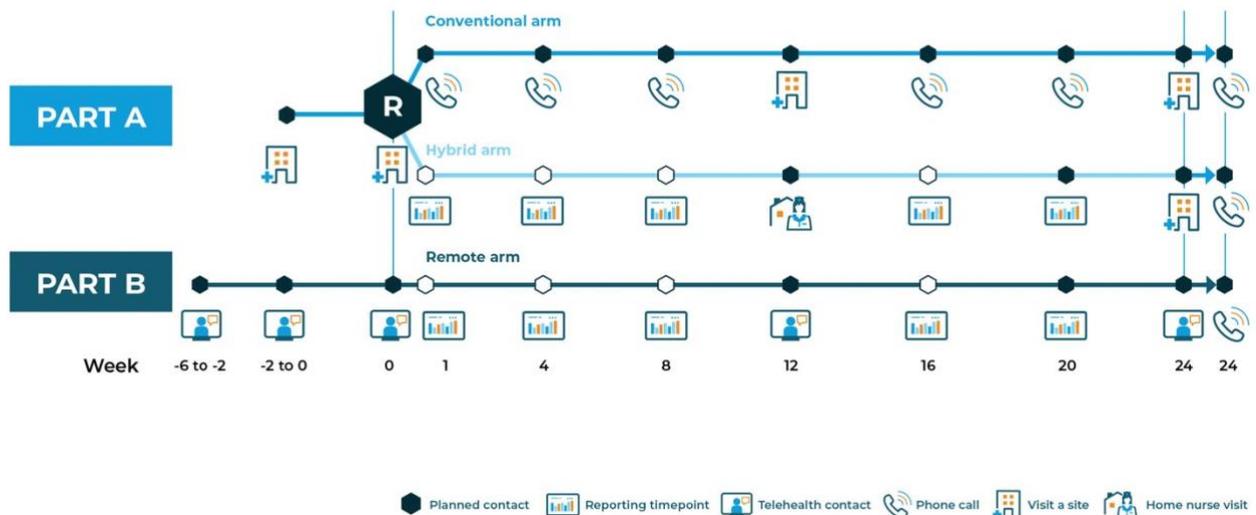
 **SCOPE**  
SUMMIT FOR CLINICAL OPS EXECUTIVES

**The International Rare Disease Showcase 2022**

## RADIAL, the Trials@Home proof-of-concept study

The preparations for RADIAL are in full swing. In this study, three treatment groups vary in the extent to which they are decentralised, for example the number of in person visits versus phone calls or virtual visits. The remote arm will have telehealth contacts and report data via the RADIAL study app, whereas the conventional arm will have study visits conducted in-person at the clinical site. The hybrid arm will contain elements of both methodologies. The full setup is explained in the image below. The project has now submitted the Clinical Trial Application via CTIS and has received positive feedback. The First Patient First Visit-milestone is expected for early 2023.

In the meantime, WP TECH is working on technology integration and implementation as well as User Acceptability Testing (UAT). WP PILOT is progressing on site contracting, development of all necessary materials, and the many other preparations that come with setting up a clinical trial. WP EAGLE is supporting in regulatory submissions and executing the Data Protection Impact Assessment (DPIA). At the annual meeting, we walked through the full RADIAL experience for a remote trial participant: the recruitment materials, RADIAL website (currently in development), enrolment process including pre-screening questionnaire, and the interface and functionalities of the app.



## Considerations with regard to Decentralised Clinical Trials

In an interactive session, a series of controversial statements related to DCTs were presented by various consortium members, often with comedic or artistic elements. Participants then moved to the designated red, yellow, or green zone of the room to indicate to what degree they agreed or disagreed with the statements. Online participants could participate as well by showing a red, yellow, or green object on screen to indicate their opinion. After each statement and the movement to show stance, there was an opportunity for discussion.



This session sparked a lot of stimulating discussion. For some statements the group was unanimous while for others, audience standpoints were diverse. But we did agree that these discussions need to continue beyond the annual meeting, so keep an eye on our [LinkedIn page](#).

Let's hope that our RADIAL trial will be able to provide further insights through the study data and our final recommendations.

We also had two panel sessions on the agenda. The first was the heavily debated topic "Return of Data to Patients". The discussion addressed a variety of related elements and raised also some new questions. To conclude this session, the final question to the panel and the audience was "Do you think we need to return RADIAL data to the patients?" A simple showing of hands indicated that the consortium all agreed this should be pursued.

The second panel discussed the regulatory feedback on DCT approaches. Topics such as "can we renounce in-person physical examination in clinical trials?", "What are the required digital literacy skills and assets needed for effective participation in DCTs? Can we define a set of skills needed to participate in DCTs and if so, who do we potentially exclude?", "How do we keep the regular healthcare provider in the loop?", and "How to ensure safety & SAE reporting in a DCT?" were discussed at large with the panel and the audience.

Interestingly, many comments about DCT methodology apply to all clinical trials. The audience was asked to consider whether this feedback comes from a place of apprehension over a new concept... Food for thought! Only the future will tell...

### All in all, ...

It was a fruitful Annual Meeting full of lively discussion, networking, and fun. The next meeting will be the Semi-Annual Meeting, taking place at the end of March 2023, in Valencia, Spain.

