

Trials@Home Semi-Annual Meeting

7-8 June 2022, Brussels



On June 7 and 8, nearly two and a half years since the kickoff meeting in Paris, Trials@Home hosted a hybrid event with more than 100 delegates from public and private partners and stakeholders coming together in Brussels/Anderlecht (44) and virtually (61).

The meeting was hosted by UCB and held over two days allowing for maximum participation and time each morning for RADIAL and other work groups to meet. The meeting was chaired by **Annemarijn Douwes, Kim Hawkins, Mira Zuidgeest, and Rick Grobbee**.

DAY 1

A warm welcome was given by **Hans Van Tricht** (UCB) who signaled the start of the event by reminding the attendees that clinical research stands at the edge of a revolution and Trials@Home is here to demonstrate how we can improve the clinical trial experience and access to patients.

Mira Zuidgeest who was live on site welcomed the members of the three external boards: Patient Expert Panel (PEP), External Stakeholder Platform (ESP), and Scientific Advisory Board (SAB). Next she introduced Hamidou Traore who has recently joined as Work Package EALGE co-lead, and reminded the audience that even through COVID, at halfway through the project we have managed to do so much together. Rick Grobbee welcomed us from the Netherlands, and Kim Hawkins welcomed us from the United States with a fun quiz to set the mood. Two of the questions included, “What would be your superpower?” and “Where do you work most frequently from at home?”. Annemarijn who was on site set straight with the practicalities and welcomed the work package representatives to provide briefs on progress and deliverables.



WP1 BEST

Isla Mackenzie, University of Dundee
Kim Hawkins, Sanofi

Semi-annual meeting
June 2022



The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking [H2020-JTI-MI2] Trials@Home grant n° 831458. 7

WP1 BEST – **Isla Mackenzie** joined from Scotland to announce that the BEST team is conducting follow-up interviews from some of the original 20 case studies and 8 new case studies and has made a plea for additional new case studies. She prompted the team to read the [two articles published in BJCP](#) and to look forward to another coming publication.

WP2 TECH – **Sten Hanke** highlighted many significant achievements including the first integrations with technology partners, and the fast-approaching release of the RADIAL study app from eClinicalHealth. The User Acceptance Test (UAT) Working Group is in careful planning of the Dry Run which will run through October.



Update WP TECH

Rebecca Jackson, Sten Hanke, Kari Landert, Tanja Keiper, Lampros Mpaltadoros



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WP3 PILOT

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WP3 PILOT – **Mira Zuidgeest** confirmed the exciting news that the clinical trial was submitted in CTIS and feedback is expected soon. She also highlighted 4 new sub-projects that will kick off shortly. Sadly, we learned with Bas Nieuwenhuis will say goodbye to the project, while Ton Scheer will be joining the Trials@Home family.

WP4 EAGLE – **Helga Gardarsdottir** highlighted [EAGLEs newest publications](#) and showed off another 4 papers that have been submitted or are nearing submission. She also validated the importance of supporting RADIAL and an upcoming SWOT analysis.



WP4 EAGLE Update

Helga Gardarsdottir (UU) & Hamidou Traore (UCB)

T@H semi annual meeting
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WP5 CODE – **Petra Naster** painted a nice picture of the many communication activities, and promoted the use of [Trials@Home website](#), [Twitter](#), and [LinkedIn](#) to share across the industry and beyond. She also emphasized the collaborations with ESP, SAP, and other stakeholders to support not only CODE activities but a majority of Trials@Home activities.

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WP6 PROM – **Philippe Bordes** showed the work that has taken place since the previous meeting, including the Annual report. Next up will be a consortium climate assessment, midterm review by IMI at the end of 2022, and excitingly a Face-to-Face Annual meeting 26 & 27 September 2022.



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The highly anticipated RADIAL update was presented by **Bart Lagerwaard** and **Bas Nieuwenhuis** who were both lucky enough to be in Brussels. Bart provided the protocol overview noting that RADIAL is a Pan-EU, Parallel-group, Open-label, multi-center study that will be conducted in 6 countries. Results from the RADIAL study will allow us to further identify benefits and challenges of decentralized elements and drive the formulation of recommendations regarding the adoption of decentralized clinical trial approaches. Emphasizing the many workgroups that have been developing study elements, strategizing and problem solving, Bart noted that “now is the time to fit the puzzle pieces together”.

Bas provided an operational update noting that the biggest upcoming milestone is First Patient In (FPI), planned for Q4 2022. In preparation for FPI there have been 60 site selection visits with 44 conventional sites and 6 fully remote sites selected. Bas provided a visual of the ongoing vendor contracting and set-up as well as the key activities to complete before FPI. As Bas said, “teamwork makes the consortium work”.



Day 1 ended with the panel, **‘DCTs – Improving public trust and engagement in research’**.

The panelists included: **Kim Hawkins, Rick Grobbee, Craig Lipset (ESP, DTRA rep), Gergely Vertes (UCB Innovation Lead), Elin Haf Davies (Aparito), Ken Tait (patient expert) & Kostas Tagkalos (patient expert)**. Moderated by **Duane Schulthess**, the panelists were asked their opinions, experiences, expectations, and hopes for the future of RADIAL and all clinical trials.

Central themes that emerged:

- Building trust and engagement throughout process (not a single point of contact)
- “Co-creation” of programs, platforms, materials with patients, sites, etc. Not a seat at our table, but a role in building.
- Start early and keep the patients involved and engaged throughout

DAY 2

Day 2 was kicked off with a welcome from **Annemarijn Douwes**, and a throwback to past meetings starting with our first and last fully in-person meeting November 2019. The team then joined in a group picture featuring all attendees in Brussels and on-line.



First presentation of the day was a DCT case studies highlight from **Amy Rogers** (WP 1) and guest speaker **Kazem Rahimi** (UOXF). Amy provided a review of the case studies (process, types, indications) that have been explored and analyzed by the WP1/BEST team. Amy brought to our attention that Oncology remains underserved/underrepresented therapeutic area within DCTs.

She also shared the key findings, 8 inter-related concepts including:

- Communications
- Contingency planning
- Early & sustained stakeholder engagement (pts, HCPs, regulators, etc)
- Adequate resourcing (having the right people, with the right skills)
- Vendor & site selection (experience, # of providers)
- Regulatory mapping (global, local is present), but one additional layer down was missing (medical licenses, telemedicine, home nursing, etc)
- Feasibility testing & mitigation planning
- Participant-centered Design

The WP1 BEST team is conducting follow up interviews on some of the original 20 case studies and exploring 8 new case studies across 6 therapeutic areas in the hope of learning more about DCT experiences. Kazem Rahimi joined us remotely from the University of Oxford to share the story of SupportHF, an implementation trial for home-based heart failure management (2014-2018). He also shared information about a new fully virtual hypertension trial providing validation of the Zeesta platform. In this trial, delivery of antihypertensive treatment is tracked using online pharmacy and it includes other DCT elements. Kazem reported a high level of satisfaction from patients and a high level of efficiencies using such a clinical trial platform.

Next, **Colm Carroll**, IHI scientific officer, conducted an introduction on the main differences between IMI and the new IHI. Innovative Health Initiative (IHI) is focused on the whole spectrum of health providers (beyond medicines) and places emphasis on delivery for the patients (always an evident pathway). The goal is to take a highly fragmented health care system – bring it to together to harness the benefits for the patients. Colm offered Trials@Home well-received motivation to go further with communication, informing scientific community and policy makers. Also, to focus on providing evidence to key stakeholder to influence guidelines, and provide learnings/best practices for the industry to use

Zachary Hallinan joined us virtually to share the updated set of DCT recommendations developed as part of Clinical Trials Transformation Initiative's (CTTI) Digital Health Trials Hub, a US based public-private consortia co-founded by Duke & FDA. There are three sets of recommendations that can be found on the CTTI website: 1. Planning Decentralized Trials; 2. Interacting with Regulators; 3. Supporting Sites. Zachary discussed 7 areas of work needed to clear a path for broad implementation of DCT and gave us a glimpse into CTTI's bold vision for how clinical trials should be done in 2030. [Transforming Trials 2030](#).

Keith Moore, Sustainable Healthcare Coalition (SHC), joined virtually as well to inform us on the topic Carbon footprint of clinical trials. Clinical trials need to be decarbonized and SHC has proposed a strategy for doing so, [published in the Lancet](#) in June 21 2021. SHC is part of a collaboration with funding from NIHR to develop, test, and disseminate an eco-design and guidance for clinical trials. The project will develop a bespoke eco-design tool to investigate the carbon footprint of trials, to encourage low carbon choices. What is next? Making the tool universal. <https://shcoalition.org/>

As the final presentation of the day, Trials@Home's own **Paul Bodfish** presented on behalf of the Trials@Home Sustainability Workgroup. The vision is facilitate DCT implementation beyond the funding period of Trials@Home. This group is challenged to determine how the identified outputs could be sustained after the project ends and how stakeholders can be reached with our outputs. The sustainability workgroup will eventually provide recommendations on an approach to the Executive Board.

In conclusion:

The 2022 IMI Trials@Home semi-annual meeting was an uplifting time for those who could be together in Brussels, and equally motivating for those attending virtually. The hybrid experience was interactive and beneficial for all who attended. According to **Kim Hawkins**, overall industry project lead and WP1 co-leader from Sanofi, ***"A key theme of the entire two days is making sure that we are engaging early and we're engaging with the right stakeholders- which is a very large group."*** Kim provided a clear summary of the two days and recognized that our publications, presentations at conferences, and social media presence is getting the Trials@Home message out there. She validated all members efforts noting that we are making very good progress and getting the necessary input to make a strong impact.

In a final closing moment, **Hans Van Tricht** (UCB) sent us off with these sentiments: ***"My sincere hope is that you will be able to launch soon a successful Trials@Home RADIAL study across multiple countries in Europe. I'm convinced it sits deep in all your hearts"***.

The entire consortium looks forward to an extremely well attended face to face Annual Meeting in September with more exciting news regarding RADIAL, and from the project teams.