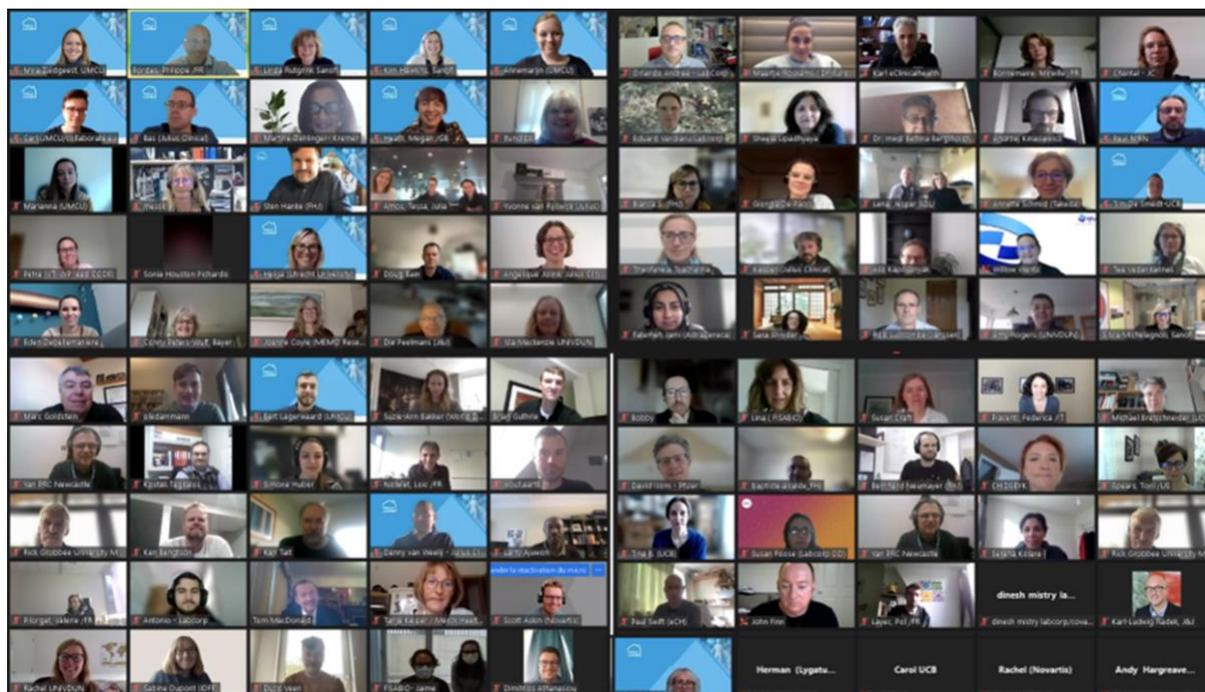


Trials@Home Annual Meeting – 2 & 3 November



On November 2 and 3, Trials@Home organised, in virtual format, its major annual event. More than 150 public and private partners and stakeholders came together to move the project forward, contribute to the larger landscape, and improve the access to clinical trials for patients. The meeting was held over two days, chaired by **Rick Grobbee**, **Kim Hawkins** and **Mira Zuidgeest**, the Trials@Home overall project leads, and included work packages updates and a series of scientific sessions. In short: a great opportunity to listen, engage, and contribute to the discussion and plans.

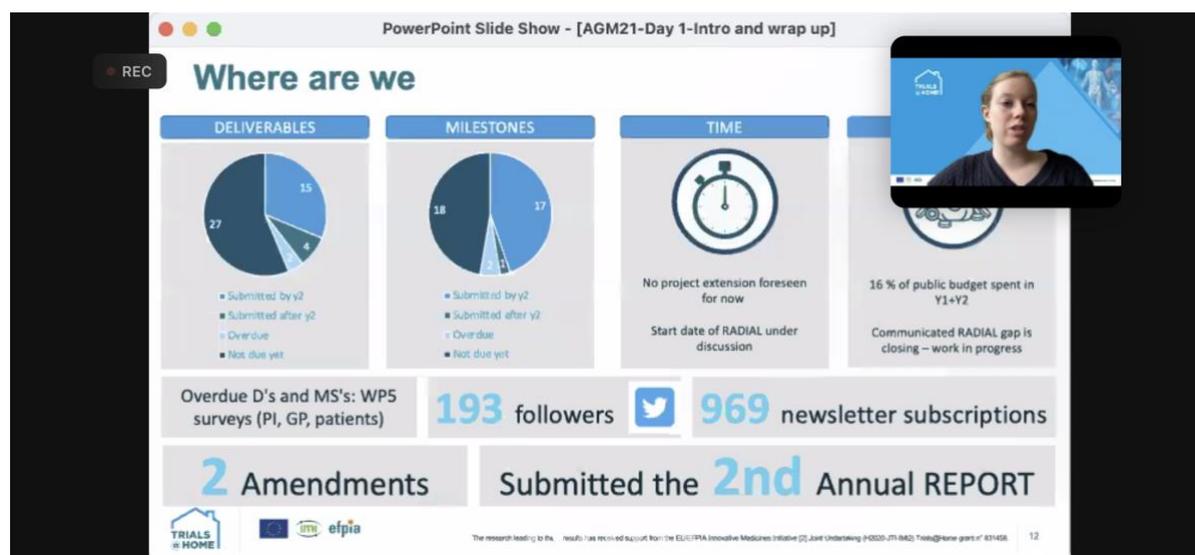
DAY 1



The meeting kicked off with a quick “how are you feeling today”. Attendees voted on their actual and desired work routine (back to the office, hybrid, remote), which session they are looking forward to the most and the best strategy to keep sharp during long online meetings.

Right after this, the management team made a positive review of the two years of Trials@Home which included an update on the project results and their dissemination which have resulted in [two scientific publications](#). Also, the project's efforts in stakeholder engagement and the progress made within the RADIAL pan-EU pilot study.

The last part of this block was, presented by project manager [Annemarijn Douwes](#) (UMCU), dedicated to present a project overview of "Trials@Home in numbers", with figures on how many people were involved in the project, newsletter subscriptions and twitter followers, annual reports and amendments submitted, etc. Bringing attendees up to date with the project developments!



Several Trials@Home babies were born in the past six months and the team took a moment to welcome them.

WP Updates (I)

The next block was dedicated to work package (WP) updates, where representatives of each WP briefed the attendees on their research's developments. Three of them were introduced on Day 1 and the remaining three were allocated to Day 2.



First up was WP1, presented by [Isla Mackenzie](#) (University of Dundee) on behalf of herself and Kim Hawkins (Sanofi). She explained that the first set of [recommendations for Decentralised Clinical Trials](#) (DCTs) were available at the end of the first year of project. Also, she informed that the systematic review of methods used to conduct DCTs had resulted in

a manuscript which will soon be released and that an additional manuscript on stakeholder experience from 20 original DCT case studies has been [published](#).

A third manuscript about the follow up interviews with researchers working on ongoing DCTs is in preparation and the original DCT case studies are being upgraded. To finish,

Mackenzie informed that the team is reviewing new case studies and that 5 have been identified so far.

Sten Hanke (FH JOANNEUM), WP2 TECH lead along with Rebecca Jackson (Janssen), informed on the concluded tasks. A major milestone of the past year was the conduct of the Request for Proposals and the selection of technology partners. He also provided updates on the ongoing activities, such as the design, assembly and testing of the technology pack for RADIAL. Information on deliverables publications and milestones was also shared. The WP leader also presented the different actors within RADIAL including technology systems and other companies and updated on what has the [glossary](#) working group been doing.



Last but not least was WP3 PILOT. **Megan Heath** (Sanofi) explained that the team has been working on two manuscripts on COVID and on KPI methodology. Regarding RADIAL, the team updated the consortium on achieved milestones, including the selection of the therapeutic area, definition of key objectives and drafting the protocol for the

study. And “as there is life outside the RADIAL”, Heath said, “we are working to address possible impact areas of DCTs such as participant diversity, participant preferences, and Real World Data collection and pragmatic trials”.

Next up was the RADIAL update by **Mira Zuidgeest** (UMCU) and **Tim de Smedt** (UCB). “We have already moved on from a study within a work package to an actual clinical trial where a lot of creative thinking and lot of work was put to get where we are now. Despite (of this progress) there is much work still ahead of us, we can now show more details about the study and share with you the feedback obtained from stakeholders”, said Mira Zuidgeest, overall project lead, together with Rick Grobbee (UMCU) and Kim Hawkins (Sanofi) and WP3 PILOT lead along with Megan Heath (Sanofi).



During this session WP3 and WP4 presented the latest version of the RADIAL protocol and the feedback that was collected on various consultations, such as the External Stakeholder Panel (Sept 2021) and the EMA ITF and the Scientific Advice with National Health Authority

DAY 2



The starting signal of the meeting was given by IMI officer **Colm Carroll** who oversaw Day 2's welcome and introduction. "Take advantage of the expertise you have both at public and private level, which is a real strength, to drive your project forward to the outcomes people are waiting for.", said Carroll.

Colm Carrol talked about the importance of maximising long-term impact and to scale-up the project results including the sustainability of the project and access to data after the project funding period is over. The officer informed the team about how to face the midterm review and stressed the importance of future public-private partnership (a unique part of IMI projects with relation to other funded initiatives).

WP Updates (II)

The next block was dedicated to the three remaining WP updates of WP4, 5 and 6. First up was WP4 EAGLE leader **Helga Gardarsdottir** and Tim De Smedt. The main highlights introduced were the surveys



conducted among consortium members and regulators to understand the regulatory/legal/ethical barriers and opportunities for DCTs and the mock ethics review of the RADIAL remote arm with 26 stakeholders from ethics committees. Also, the team informed on the [published](#) (1) and planned (6) publications along with an overview of the tasks performed (e.g., mapping of legislation).



Next was WP5 CODE, represented by **Petra Naster** on behalf of herself and Eduard Vardianu (Labcorp). Attendees received an overview of the activities in terms of communication that are happening now (website, Twitter, RFP process...) and those planned for the future (external newsletter, videos). Naster updated the team on the surveys to probe patients/Pis/GPs on DCT training needs.

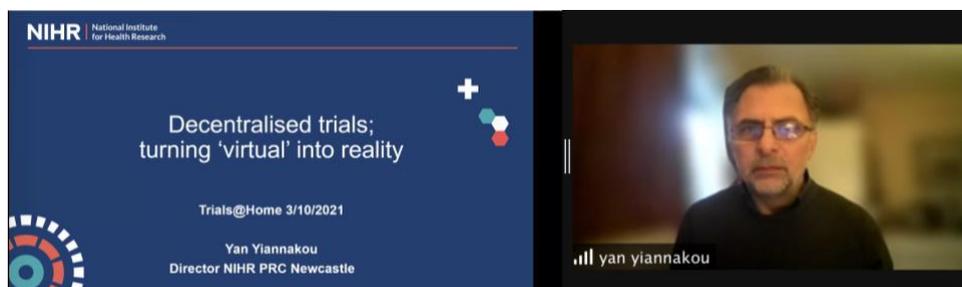
Last update session was dedicated to WP6 PROMS and was presented by **Philippe Bordes** (Sanofi). From a project management's perspective, he thanked the consortium for keeping up with the enthusiasm and efficient interaction within work packages despite the



current virtual circumstances. An update on the meetings and webinars organised. Also, the amendments and reports presented and the new team members. Next steps are to prepare the midterm review with IMI (June 2022) and develop collaborations with other consortia, Bordes said.

The next block was dedicated to remote sites organised by **Bart Lagerwaard** (UMCU) and moderated by **Isla Mackenzie** (University of Dundee). It was a valuable session to learn a lot from people who have real experience in remote trials. The guest speakers were **Yan Yiannakou**, consultant gastroenterologist in Durham and Clinical Director of the NIHR Patient Recruitment Centre (Newcastle) and **Bettina Bergtholdt**, managing partner of Emovis GmbH, a company that offers various patient-connected services in the area of clinical research such as dedicated research site for out-patient studies phases II-IV, a sleep lab, the department homecare visits as well as patient recruitment services.

Yiannakou described his experience as Clinical Investigator of a UK-based trial that was converted to a remote trial during the pandemic and the challenges and advantages that presented. “Remoted trials could potentially reduce burden of the activity and significantly reduce drop-outs”, he stated. As additional potential advantages of DCTs, he mentioned: faster recruitment (remove geographical exclusion), more generalizable population (real world), equity of access, and cost reduction.



On her side, **Bettina Bergtholdt** discussed her 10-year practical experience relating to remote trials and presented an example on how the conduct of homecare visits can be organized, discussing potential issues as well as potential solutions. Main concerns identified were how to deal with source documentation and storage/archive. Bettina stated that “e-source is the future according to my experience”, for training of nurse personnel and PI oversight throughout the process.



Next up was an interactive session on external engagements conducted by **Petra Naster** (Vital Transformation) and **Eduard Vardianu** (Labcorp).

The session started with a short presentation by **Giorgia Di Paoli** who presented the [REAL-hope project](#) (Real world Handling Of Protein drugs, Exploration, Evaluation and Education), a project which will monitor those stressor components recognized as possible threats to the stability of protein drug products. A collaboration with Trials@Home could be possible in the future. For Trials@Home, the benefit would be to understand if patients are adhering to storage instructions of this class of medications, and, if not, to open a dialogue with the participants themselves: what are the challenges faced when dealing with protein drug products, and what is the solution that some of them may have adopted to overcome these challenges?



After that, the team discussed the project's external communications including the planned engagement strategy. Petra and Eduard presented the Trials@Home Communication plan for 2021/2022 and new ideas planned for the future. Another key topic was the creation of a conference tracker, from which a working group emerged to develop a plan to keep the project participations traceable.

The final block, under the name "Ask Anyone Anything", was a unique opportunity to throw some questions or comments to the project leads, work package leads, or members of the Advisory Boards or any fellow consortium member. "What will a clinical trial look like in 2050?" and "Are there any ideas on how to improve our external communications?" are some of the questions asked during the discussion.

After a quick wrap up, the day ended with a new informal Viva Variety session in which attendees competed as a quiz took place.

Despite still working virtually for most of 2021 and having to meet again in an online setting, Trials@Home has been able to accomplish so much together. See you next year (hopefully in person)!