Trials@Home – Where are we two years down the road?

1 December 2021

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Kim Hawkins

Accomplishments & Case Study

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Two years as a T@H team

First scientific T@H publications, many T@H presentations and more to come :-)

Clinical Pharmacology & Therapeutics

Article | Open Access

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

Amos Jochanan de Jong, Yared Santa-Ana-Tellez, Ghislaine José Madeleine Wilhelmien van Thiel, Mira Gerta Petra Zuidgeest, Satu Johanna Siiskonen, Dinesh Mistry, Anthonius de Boer ... See all authors

First published: 05 March 2021 | https://doi.org/10.1002/cpt.2225 | Citations: 1

BJCP British Journal of Clinical Pharmacology

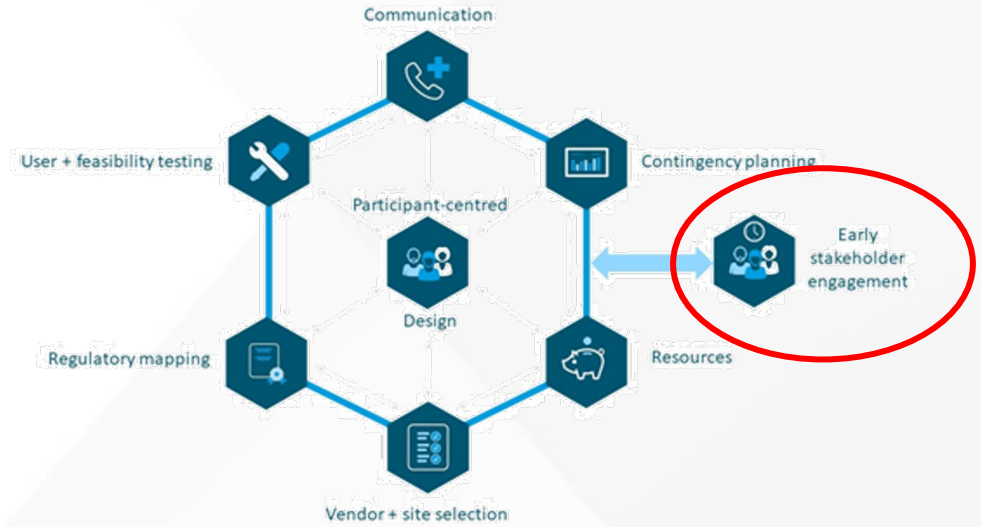
ORIGINAL ARTICLE | Open Access

Learning from remote decentralised clinical trial experiences: A qualitative analysis of interviews with trial personnel, patient representatives and other stakeholders

Joanne Coyle, Amy Rogers, Rachel Copland, Giorgia De Paoli, Thomas M. MacDonald, Isla S. Mackenzie, on behalf of the Trials@Home Consortium

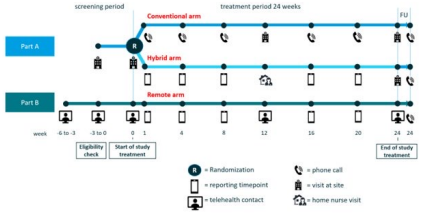
First published: 23 July 2021 | https://doi.org/10.1111/bcp.15003

Extensive stakeholder engagement (reg, patients, HCPs etc.)



Pan-EU pilot study has got a name, face, hands and feet....

RADIAL



PEP PATIENT EXPERT PANEL

up and running

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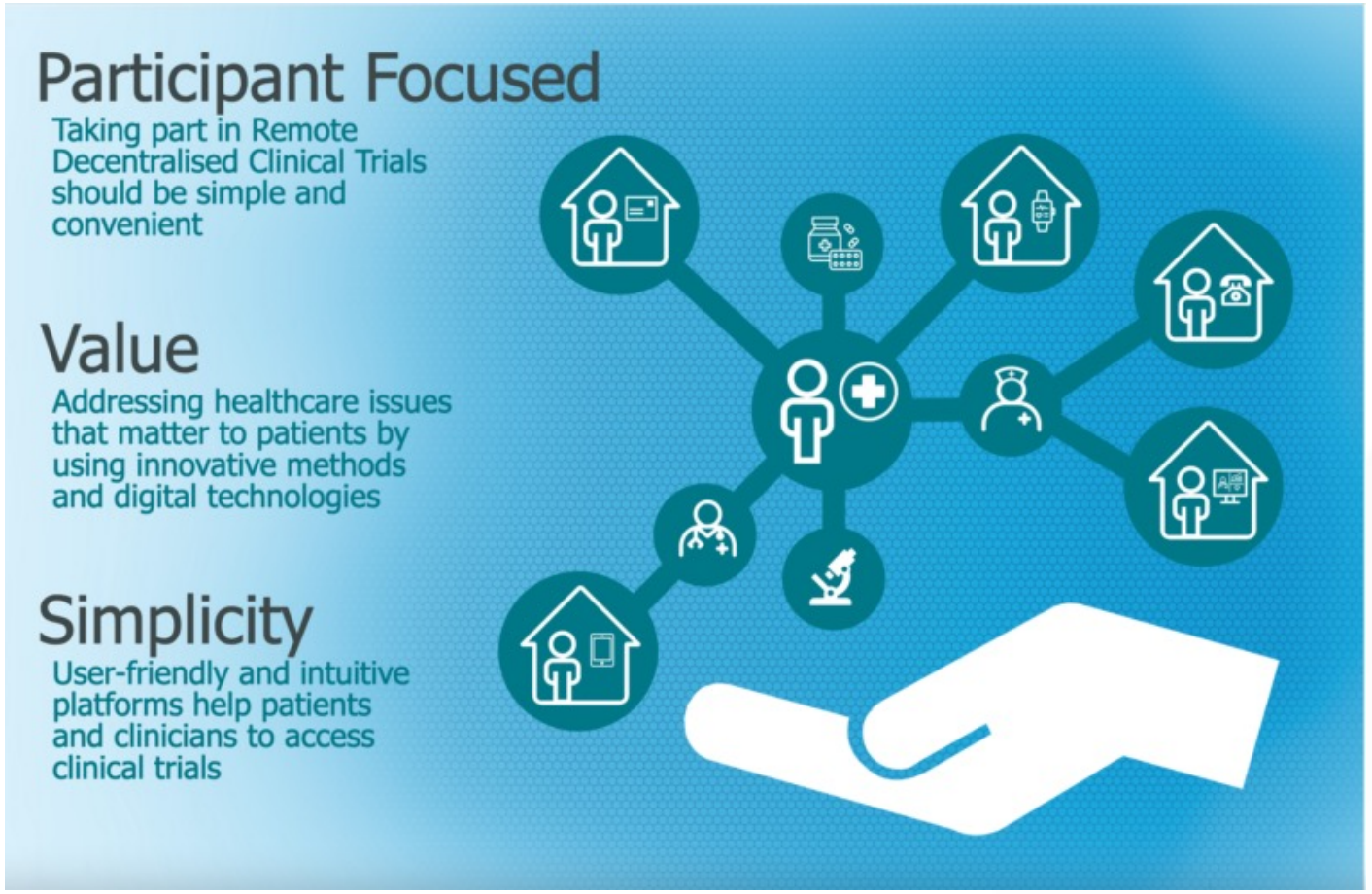
Initial Recommendations - DCTs



These draft recommendations are based on in-depth research, conducted over a 12-month period, into decentralised clinical trial methods. They apply to all aspects of DCTs from design, planning and set-up to close-out and reporting.

3 Key Recommendations

1. Answer an important research question
2. Keep the focus on participants
3. 3. Simplify the participant experience whilst maintaining quality and scientific rigour

https://trialsathome.com/first-set-of-recommendations-for-rdcts-d1-1/

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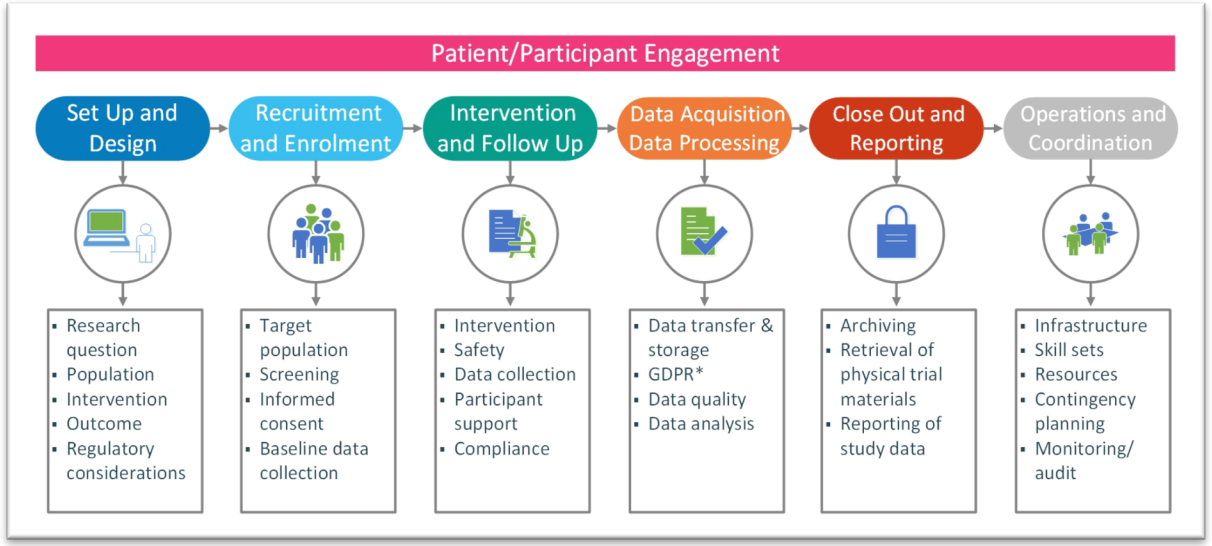
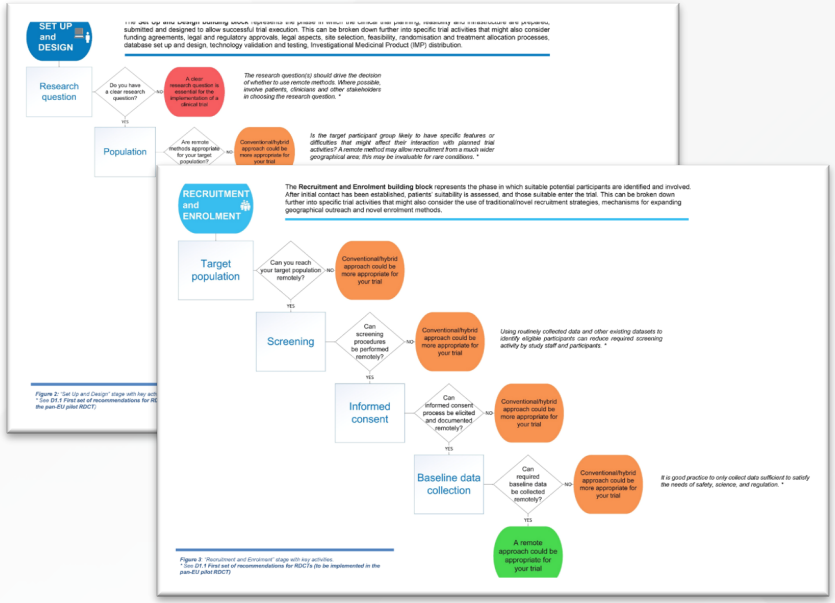
Criteria for selection of appropriate trials

https://trialsathome.com/criteria-for-selection-of-appropriate-trials-d1-2/





- Trial activities and processes to consider when planning a potential DCT
- Step-by-step decision aids for each trial stage

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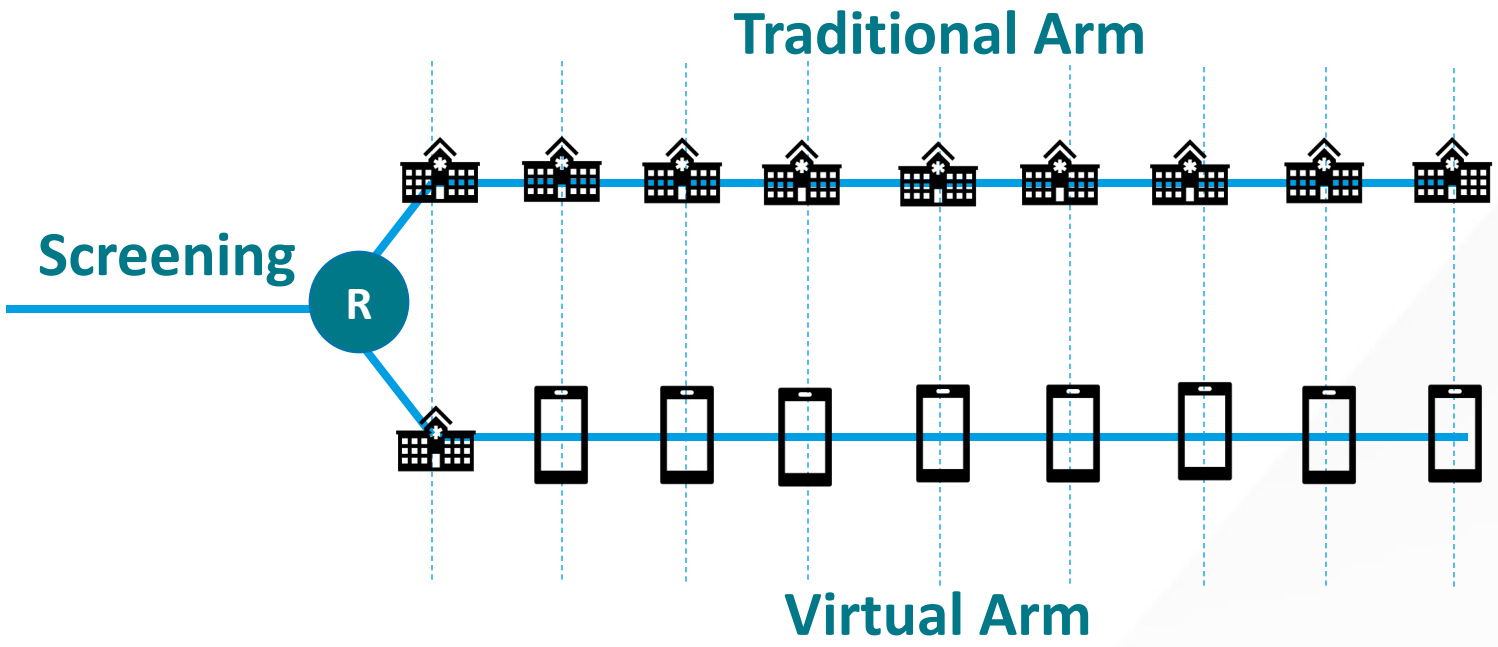
Example Case Study



- Remote versus traditional approach to glycaemic control using insulin glargine. The trial aimed to enrol 150 participants but was terminated early due to “prolonged low participant recruitment” (15 participants enrolled)
- Remote arm used eConsent, DTP IMP, DTP device shipment, eDiaries, direct data access for remote participants, ePROs, participant feedback, automatic data transfer, remote monitoring, and remote participant visits

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Example Case Study

Key Challenges:

- Frequent technical challenges with participant app led to frustration e.g., errors with data synchronisation, video conferencing not working, etc.
- Staff approaching trial planning and regulatory procedures in differing ways due to specialised area of expertise.
- Selecting suitable technologies/tech vendors not experts in clinical trials
- Ensuring validity of home data collection

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Mira Zuidgeest

The RADIAL study

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RADIAL: rationale & design

RADIAL (**R**emote **A**nd **D**ecentralised **I**nnovative **A**pproaches to Clinical Tria**l**s)

Protocol Title:
Pan-European pilot study comparing Decentralised Clinical Trial (DCT) and hybrid approaches to a conventional clinical trial approach in patients with Type 2 diabetes treated with Toujeo.

Rationale: The proposed study has been designed to compare the scientific and operational quality of fully decentralized and hybrid approaches to a conventional clinical trial approach and evaluate the feasibility of such approaches

Overall Design:

- Parallel-group, open-label, multicenter study in Europe
- People with type 2 diabetes (T2D) insufficiently controlled on their previous glucose-lowering treatment
- 2 parts with 3 different arms:
  - Part A (*site-based recruitment, randomisation 1:1*)
    - Conventional arm *(~200 participants)*
    - Hybrid arm *(~200 participants)*
  - Part B (*recruitment performed remotely, no randomisation*)
    - Remote Arm *(~400 participants)*

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RADIAL: pan-EUR proof-of-concept study

8 countries selected

11 KPIs selected

The RADIAL study will focus on the characterisation and evaluation of recognised **Key Performance Indicators (KPIs) which reflect scientific and operational quality of clinical trials**

To explore potential benefits of DCT approaches on subject retention, recruitment, diversity, cost, site and patient satisfaction

To evaluate acceptability of DCT approaches by measuring variables related to data quality, safety oversight and treatment compliance

tech pack selected

Contracting in process →
Stay tuned for update in next webinar

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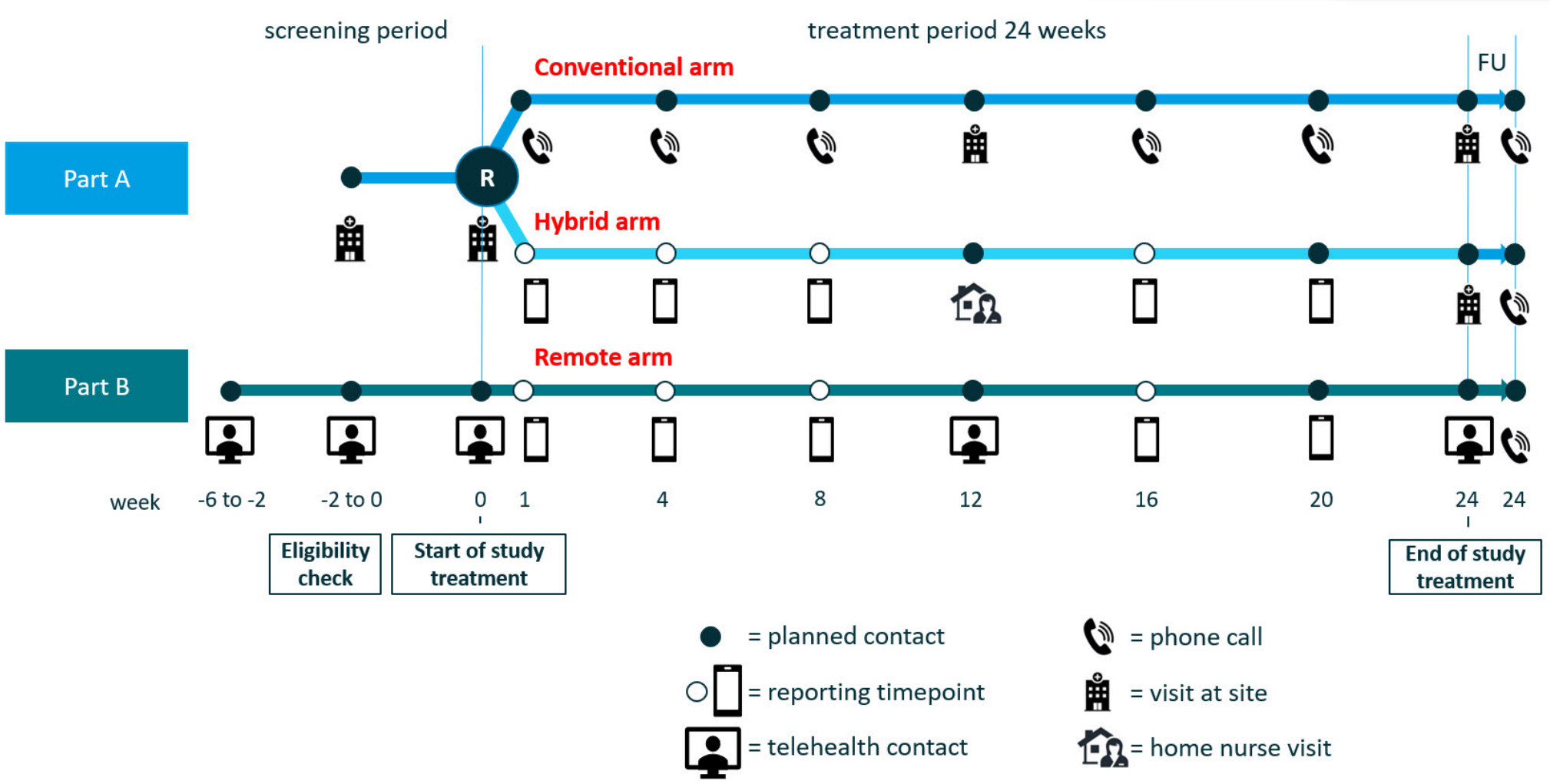
RADIAL: study schedule



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RADIAL: discussion

Strengths

Proof of concept study

- Direct comparison between the three operational arms
- Testing of fully decentralised approach

Limitations

One study, one population, one tech pack

- Patient preferences cannot be solicited in this design → Separate Discrete Choice Experiment
- Populations may differ between part A and B → both an important learning and something that has to be taken into account in the interpretation of the findings

Results

From the RADIAL study will…

- Allow us to further identify benefits and challenges of decentralized elements
- Drive the formulation of recommendations regarding the adoption of decentralised clinical trial approaches.

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Tim De Smedt

Stakeholder Feedback

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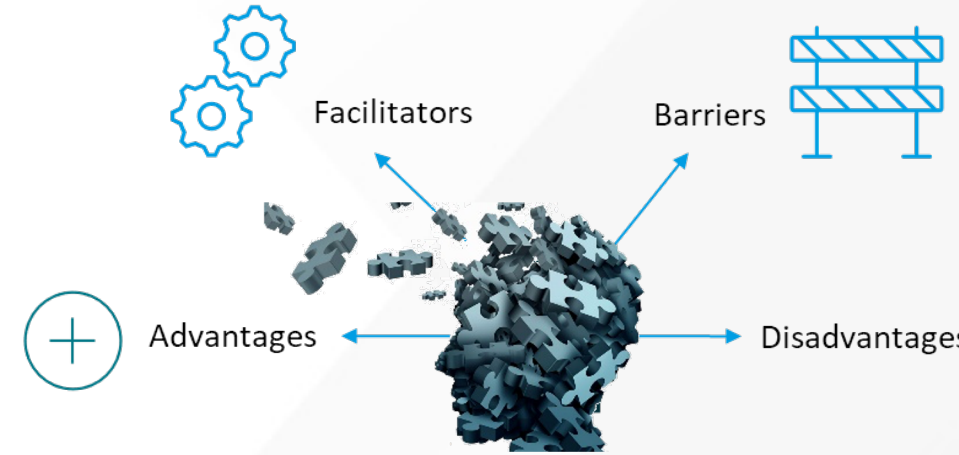
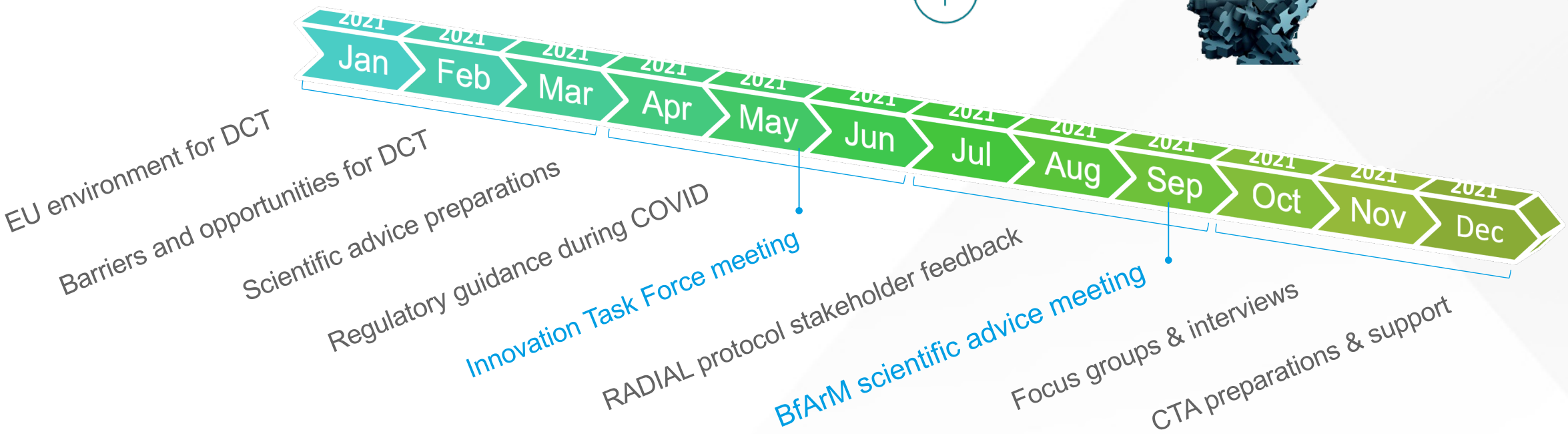
Never waste a good pandemic…





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Stakeholder interactions 2021

Aim was to discuss DCT and RADIAL, first high-level and later more focused on operational aspects

- Meeting with EMA's Innovation Task Force → Initiate early dialogue with EU Regulators
- Scientific Advice with BfArM (Germany) → Follow-up for in-depth advice on RADIAL protocol
- Patient Expert Panel → Introduce expert views from people living with diabetes
- External Stakeholder Panel → Align on relevance of the RADIAL approach with key stakeholders in DCT
- Scientific Advisory Board → Scientific & methodological feedback from independent panel
- Ethics focus groups → Obtain Ethics expert perspectives & advice

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Summary of key Regulatory considerations for DCT

Onboarding, training & consent

- Compliance with divergent national regulations in a heterogenous EU environment

Investigator responsibilities per ICH GCP

- Need to ensure adequate Investigator oversight of remote participants, personnel and procedures

Safety and efficacy

- Adverse event reporting in remote setting, comparability of assessments in clinic vs. at home

Data integrity, participant rights & privacy

- ID verification, appropriate data access & hosting, GCP compliance & inspections

If you want to join our consortium go to:

https://trialsathome.com/faqs/

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Thank you!

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