

*“Stay Ahead of the Game:
Transformation in Clinical Trials
in the Age of Artificial Intelligence.”*

**ANNUAL
CLINICAL TRIALS SYMPOSIUM**

November 8th, 2024

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Patient-Centricity and Decentralised Trials

Initial learnings from RADIAL, a pan-European, decentralised and hybrid proof-of-concept trial

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Disclaimer

The research leading to these results was conducted as part of the Trials@Home consortium. This presentation only reflects the personal view of the stated authors and neither IMI nor the European Union, EFPIA, or any Associated Partners are responsible for any use that may be made of the information contained herein.

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Trials@Home project

The aim

Provide recommendations on Decentralised Clinical Trials (DCTs) in Europe

Project start September 1, 2019, due to end August 31, 2024

The consortium



Content

1. Patient Centricity & Decentralised Trial Elements
2. RADIAL, *a decentralised proof of concept trial*
3. Patient Centricity Learnings from RADIAL

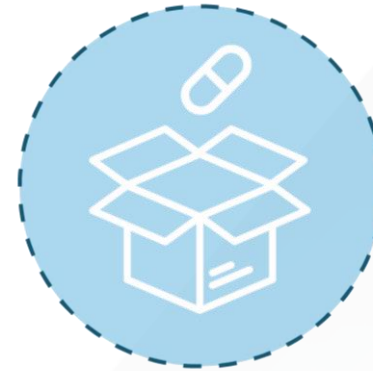
Part 1

Patient Centricity & DCT Elements



Decentralised clinical trials (DCTs)

Moving trials away from 'the centre', towards the participants' direct surroundings



Decentralised clinical trials (DCTs)

Moving trials away from 'the centre', towards the participants' direct surroundings



Patient-Centric Trials


Prioritises/Considers the needs, preferences and experiences of patients throughout the clinical trial.



Decentralised Trial = Patient-Centric Trials?

One is the goal and one is the (possible) means





How can we most effectively use decentralised trial elements to support patient-centricity in clinical research?

Part 2

RADIAL

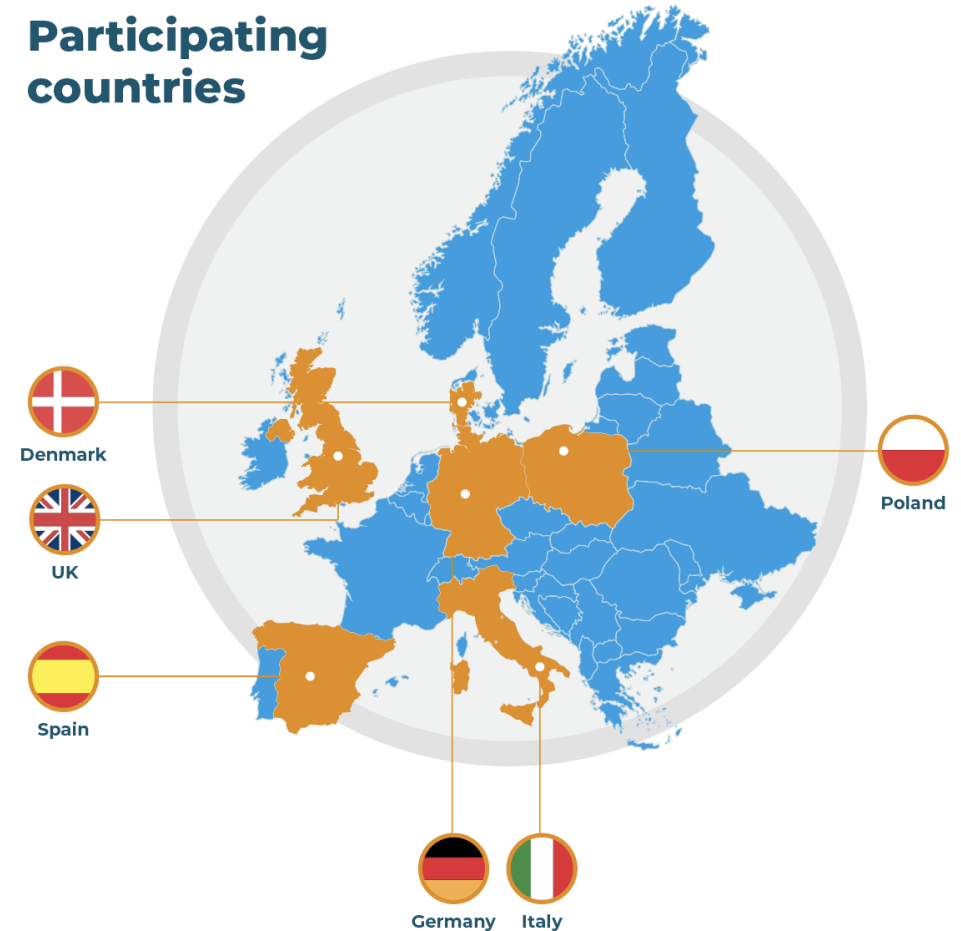
a decentralised proof of concept trial



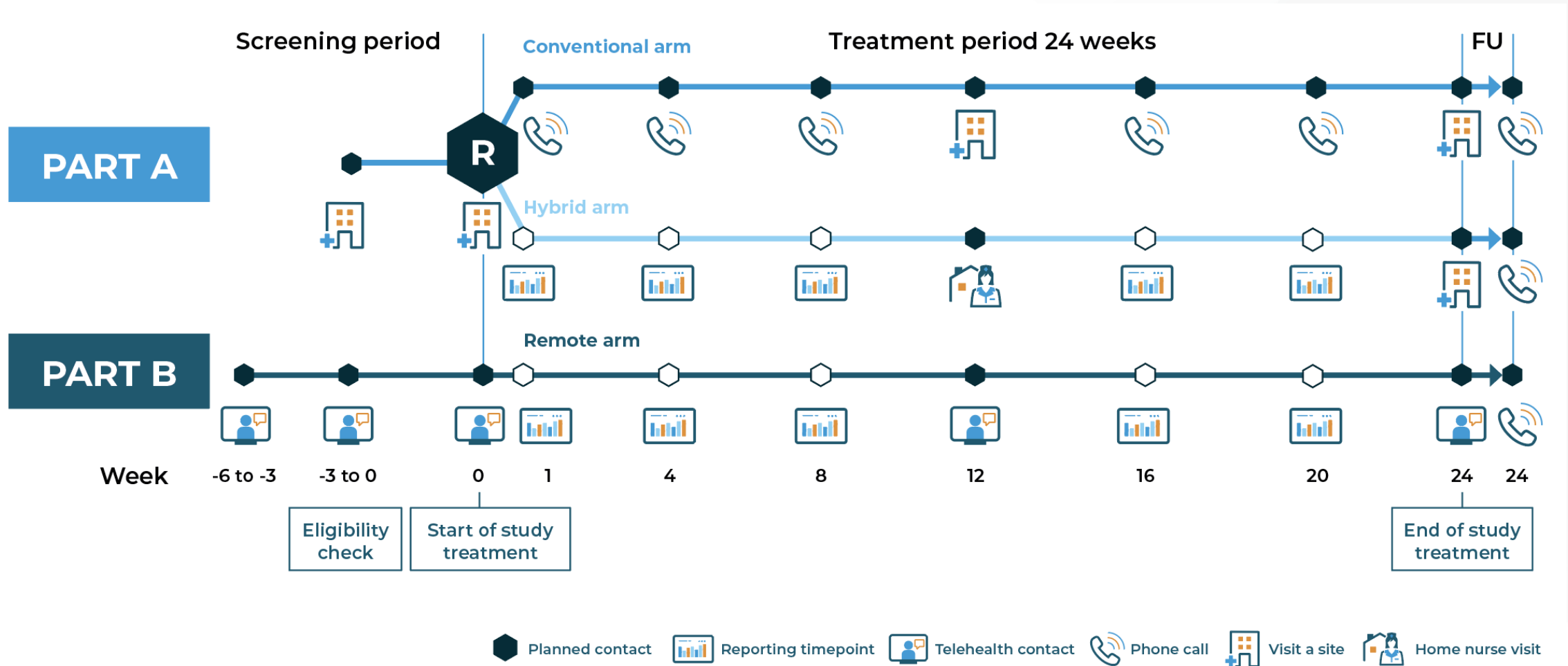
The *what* of the T@H RADIAL proof-of-concept study

- Pan-EU, Parallel-group, open-label, multi-centre study
- People with type 2 diabetes (with Hb1Ac 7-10%)
 - Switch basal insulin
 - Phase IV study
- Low-interventional trial
- Academic sponsor, but Consortium-initiated trial

Participating countries



The *how* of the T@H RADIAL proof-of-concept study



Decentralised elements in RADIAL

PART B



eConsenting and eSignature

PART B



Telemedicine

PART B



Online recruitment and pre-screening

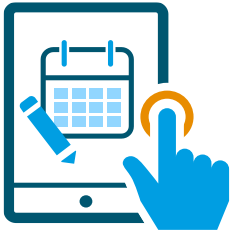
PART A



Home nurse visits



Remote monitoring IMP adherence



Study app for reporting (S)AEs and ePROs



Direct to patient shipment of IMP



At home sample collection

The *why* of the T@H RADIAL proof-of-concept study



aims to assess the scientific and operational quality of a fully decentralised and hybrid trial approach compared to a conventional trial approach

Evaluate the acceptability of DCTs in terms of safety, data quality and medical endpoints

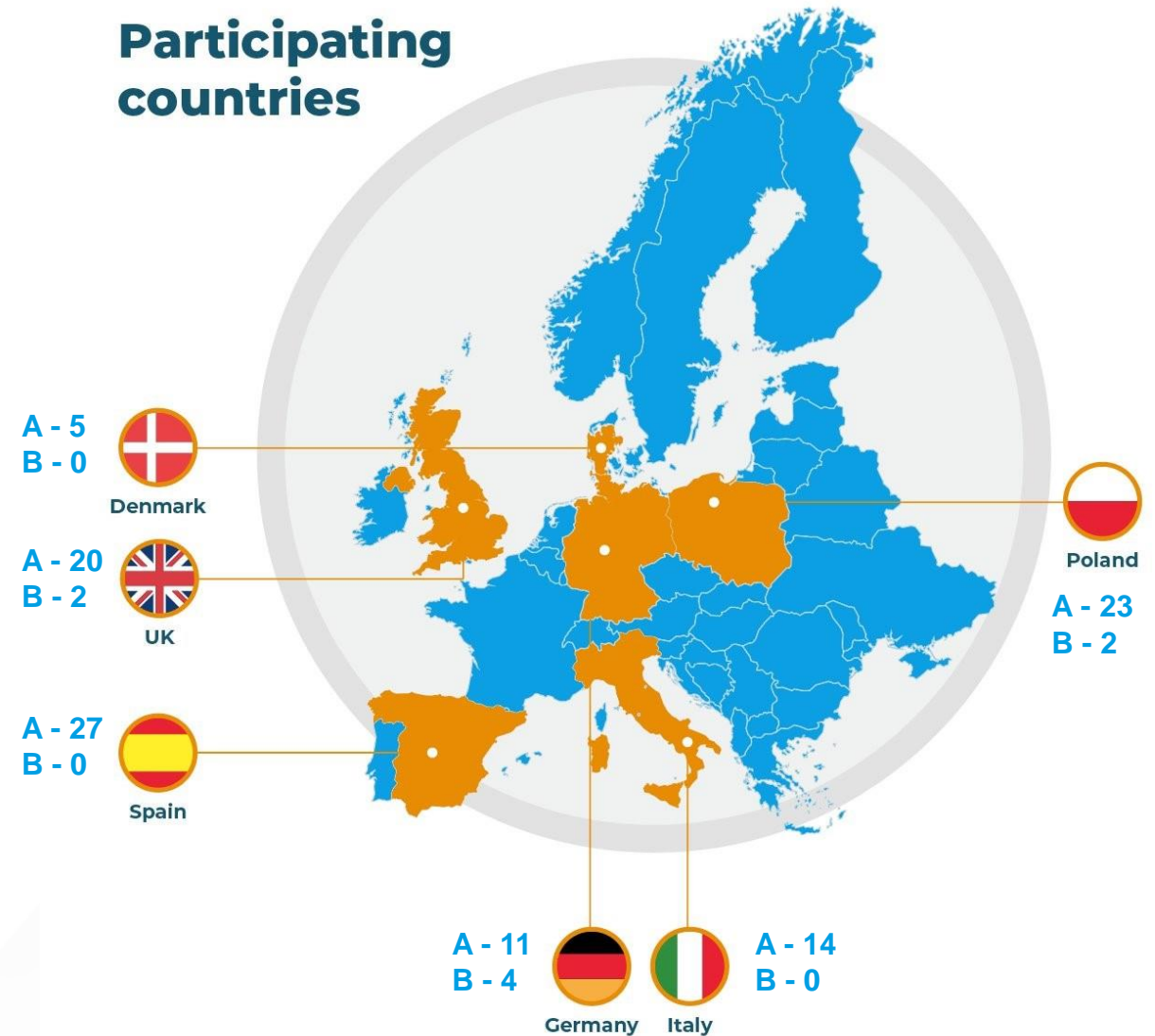
(i.e., can we responsibly move to decentralized clinical trial approach?)

Explore potential benefits of DCTs, in terms of subject retention, recruitment, diversity, cost, and site and patient satisfaction

Current status

- Recruitment close, LPLV end 2024
- Total of 110 participants included
 - 102 Part A (hybrid and Conventional)
 - 8 Part B (remote)
- Collecting all operational learnings and experiences.

Participating countries



Part 3

Patient Centricity & RADIAL

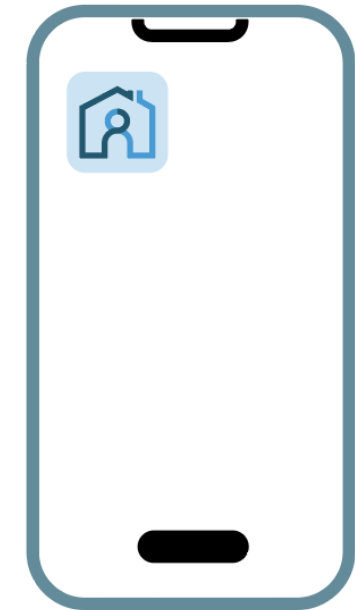




Bring your own device (BYOD) trial 1/2

RADIAL is a proof-of-concept; is the future of DCTs mostly BYOD?

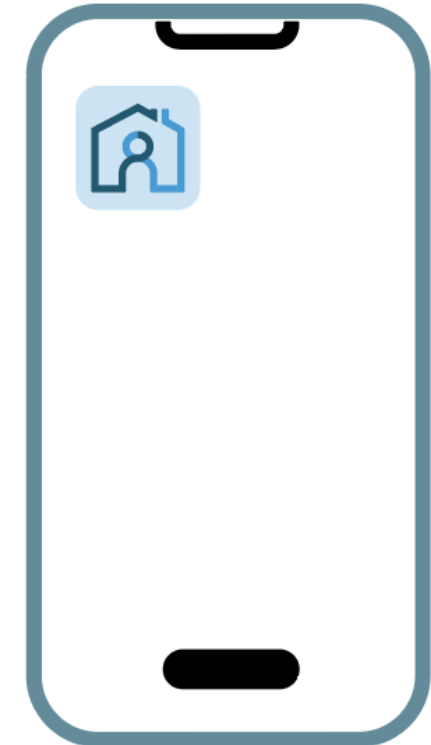
- Operationalisation of providing smartphones is challenging
 - Costs
 - Internet access, internet plan
 - Scalability
- Sustainability
- User experience
 - Using two devices?
 - Using a 'strange' device?



Bring your own device (BYOD) trial 2/2

RADIAL is a proof-of-concept; is the future of DCTs mostly BYOD?

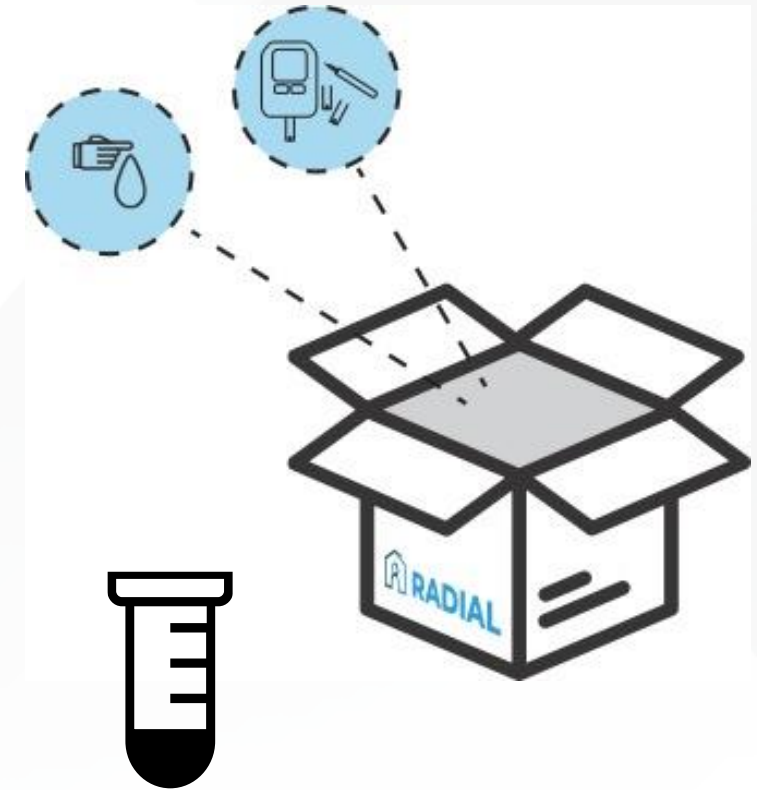
- Feedback from sites: exclusion of participants due to having a (up-to-date) phone
 - Remote monitoring a big advantage for sites.
- Some (older) phone models were not supported by the smart device on Insulin
 - Loss of data
 - Manual back-up



Home Deliveries and Sample Drop-offs

The trial on your doorstep?

- All study materials and IMP are delivered at the participant's house
- Blood samples taken by participant need to be brought to a drop-off point.
 - Reimbursement?
 - Not all participants were able to do this.
- Solutions: Pick-up, Home Nurse, etc



Overall observations & way forward



Observations

- **General interest** in possible benefits of DCT approaches and willingness to contribute to the trial.
- **Lessons** on how decentralised elements are implemented in practice and how these might affect patient centricity in trials.
- **Move forward;** how should we design future trials with decentralised elements?

How to get involved?

- **Looking for Regulators/Ethics** for participation in an Expert, **Delphi study** determining the acceptable levels of “performance” of Key Performance Indicators (KPIs) of trial (Adherence, Data Quality, Safety Oversight).
- **Exchange of Knowledge and Experiences**

Thank you!

Further information on T@H and RADIAL

- Project website www.trialsathome.com
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