Research highlights

Moderated by Bart Lagerwaard and Hamidou Traore

#TrialsAtHome

Photographer: Jelle Verhoeks

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.

Block 2 – Trials@Home research highlights

Short presentations by Trials@Home highlighting in-depth research results from the full scope of Trials@Home

Bart Lagerwaard

Assistant Professor

University Medical Center Utrecht

Scientific coordination RADIAL

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UCB Pharma, Brussels

Regulatory, Legal, Ethics, and GCP WP co-lead

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Block 2 – Trials@Home research highlights

Short presentations by Trials@Home highlighting in-depth research results from the full scope of Trials@Home

8 short lighting presentations by our own experienced researchers

3 minutes to dive in a topic

1 Q&A

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Overview of presentations in this session

Title	Presenter
Opportunities and challenges for DCTs in emerging markets	Pepijn Al (University Medical Center Utrecht)
Do people prefer to participate in a clinical trial from home or at the trial site?	Julia Kopanz (University Medical Center Utrecht)
Ethics and diversity in Decentralized clinical trials	Tessa van Rijssel (University Medical Center Utrecht)
Bringing the Trial to the Patient: Direct-to-Participant (DtP) IMP Supply in Europe	Helga Gardarsdottir (Utrecht University)
Greener trials? Evaluating the carbon impact of decentralisation in the RADIAL trial	Rebecca Barr (University of Dundee)
A Technology Helpdesk System for Multi-Vendor Decentralized Clinical Trials	Theresa Weitlaner and Sten Hanke (FH Joanneum, BBMRI-ERIC)
How to effectively involve lived experience representatives in public-private consortia	Erik Werson (T2D representative, Patient Expert Panel)
Economic insights into decentralised and hybrid clinical trials	Aniek Schouten (University Medical Center Utrecht)

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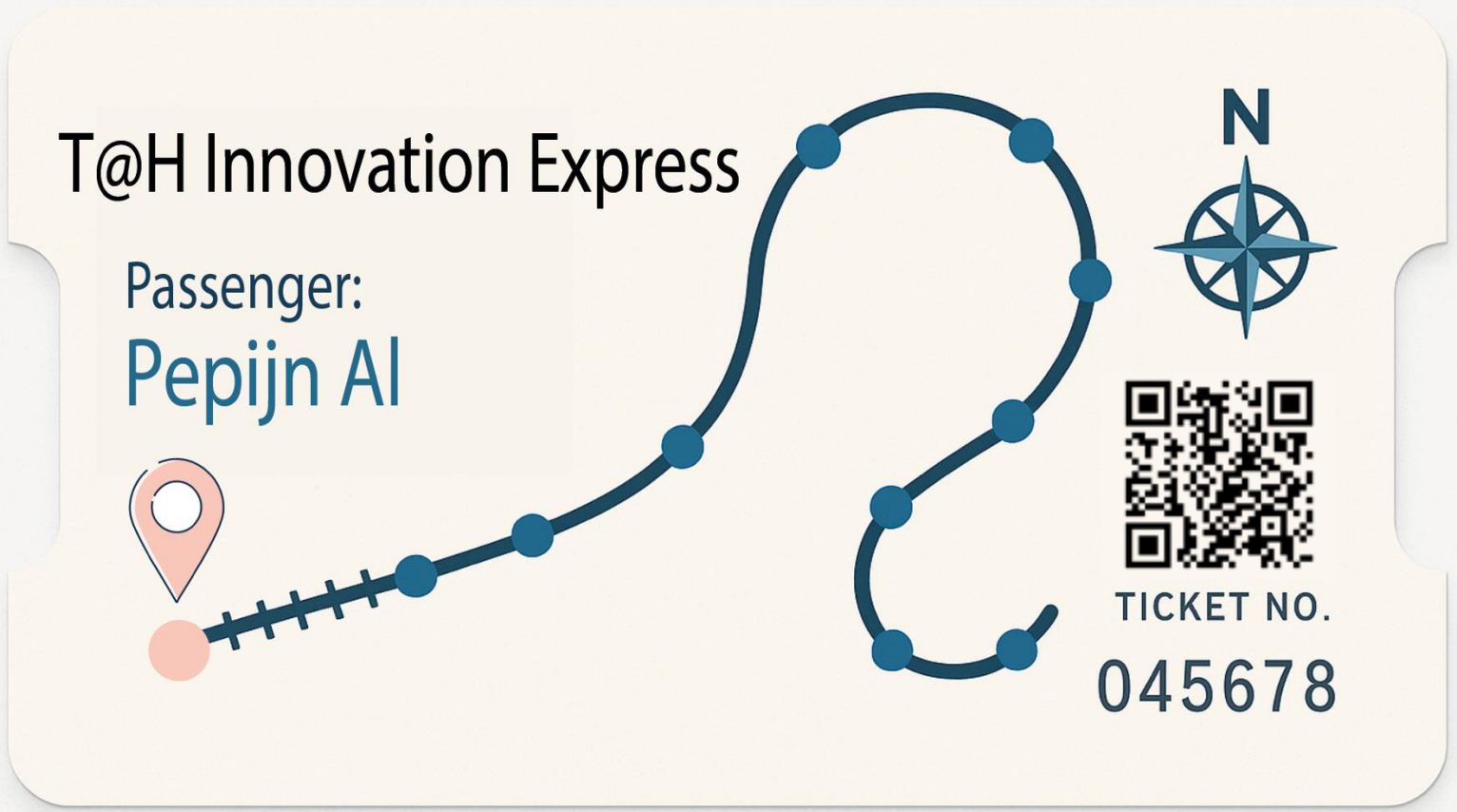

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Opportunities and challenges for DCTs in emerging markets

Pepijn Al, PhD

Postdoctoral researcher

UMCU

Photographer: Jelle Verhoeks

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Rationale and methodology

- **Research question**
  - **To describe challenges and opportunities for DCTs in two leading emerging markets for clinical research in their region (South Africa, and Brazil)**
  - DCT (elements) have the potential to improve trial efficiency, retention, and participant representation.
  - To a lesser degree, triangulate or extend learnings from similar work in the European context.
- Focus group discussions stratified by stakeholder group
  - 4 in Brazil; 2 with trial **participants**, 1 with trial **personnel**, 1 with trial **sponsors and regulators**
  - 5 in South-Africa; 2 with trial **participants**, 2 with trial **personnel**, 1 with trial **sponsors and regulators**
- Transcripts translated (where applicable) and inductively coded in NVIVO

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Preliminary themes

- Comfortable to perform actions
- Convenience vs. Burdens
- Data quality and trustworthiness
- Attitudes
- Digital literacy skills and problems with devices
- System-level benefits
- Home environment and personal circumstances
- Relationships and trust
- Support and Safety

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Conveniences and burdens

- There are clear conveniences for participants, trialists, and the trial system
  - Participants: less travel time
  - Trialists: easy, continous data collection
  - System: reaching a broader population
- But participants also expected some challenges
  - Participants: protecting privacy with at-home visits and deliveries
  - Trialists: increased travel time and potential no-shows
  - System: Handeling of medication during travel

"No, because all this is the beginning, right? What we're doing here is something that's just beginning. But surely, with time, we can improve everything; we can get tools, right, we can find ways for the process itself to be carried out, the whole process."

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Acknowledgement

- Team NL (UMCU)
  - Mira Zuidgeest
  - Bart Lagerwaard
  - Pepijn Al
  - Rieke van der Graaf
  - Martin Heine
- Team Brazil (Fiocruz / Sanofi)
  - Edson Moreira
  - Victor Fonseca
  - Sandra Moreira
  - Viviane Rezende
  - Carolina Borges
  - Adriana Ferreira
- Team South Africa (Ezintsha)
  - Samanta Lalla-Edward
  - Athini Nyatela
  - Siphamandla Gumede

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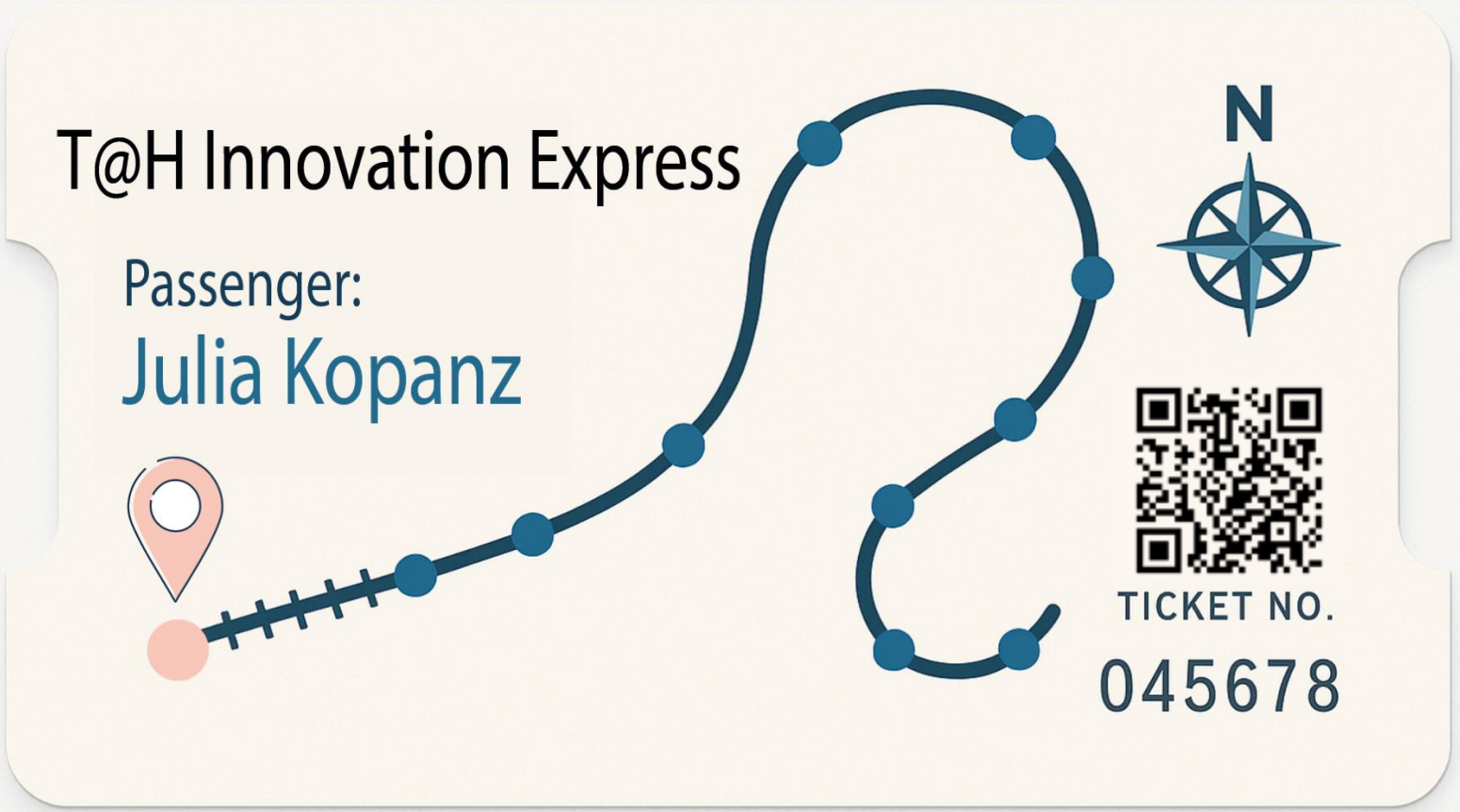

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TRIALS @HOME

Do people prefer to participate in a clinical trial from home or at the trial site?

Julia Kopanz

PhD candidate, UMCU

Photographer: Jelle Verhoeks

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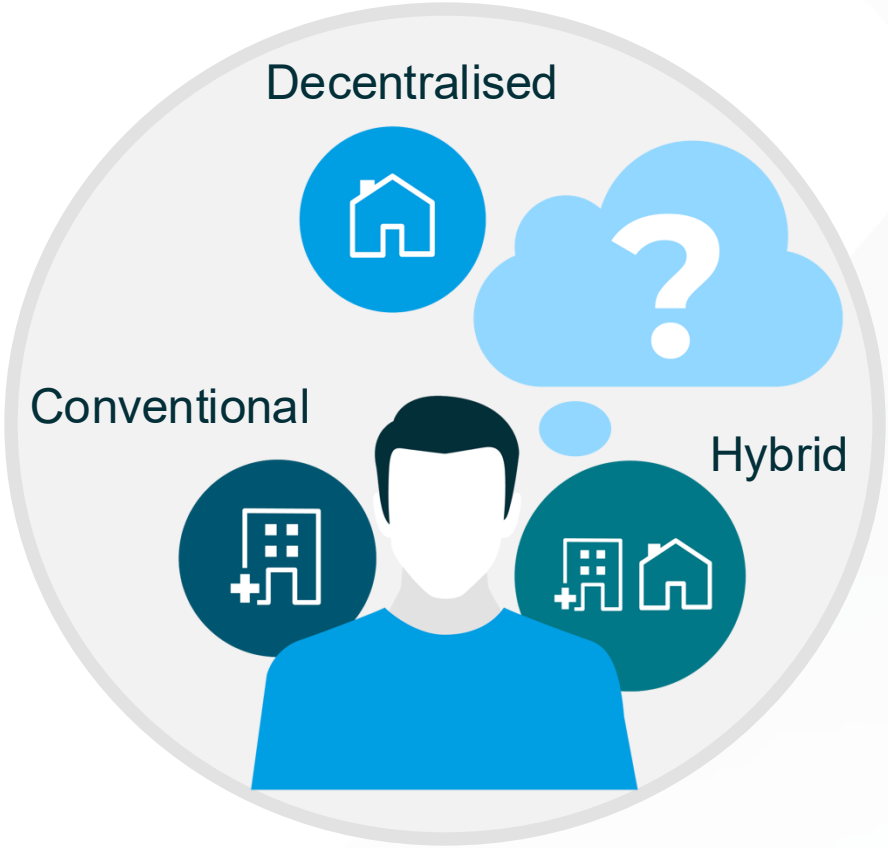
What trial designs do people prefer to participate in?



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Method: Discrete Choice Experiment (DCE)

DCE in three countries

🇳🇱 n=276

🇦🇹 n=265

🇩🇪 n=246

Data analyses

Mixed multinomial logit model

	Option A	Option B	Option C
Where and how you are in contact with the study team	At trial site at 30 minutes travel time	Home with no direct contact	Given these clinical trial options, I would not want to participate in either of the two presented trials.
Types of activities you need to do yourself	Drug, nutrition diary, health survey & simple measurements	Drug, nutrition diary, health survey	
Use of digital technologies	Communication technologies	Communication and measurement technologies	
Number of scheduled contact times	Once every three months	Once a month	
Duration of the clinical trial	3 years	1 year	
Safety and effectiveness of the drug.	There is little knowledge whether the drug is safe and whether the drug works	The drug is safe and works	
Which would you choose?	○	✓	○

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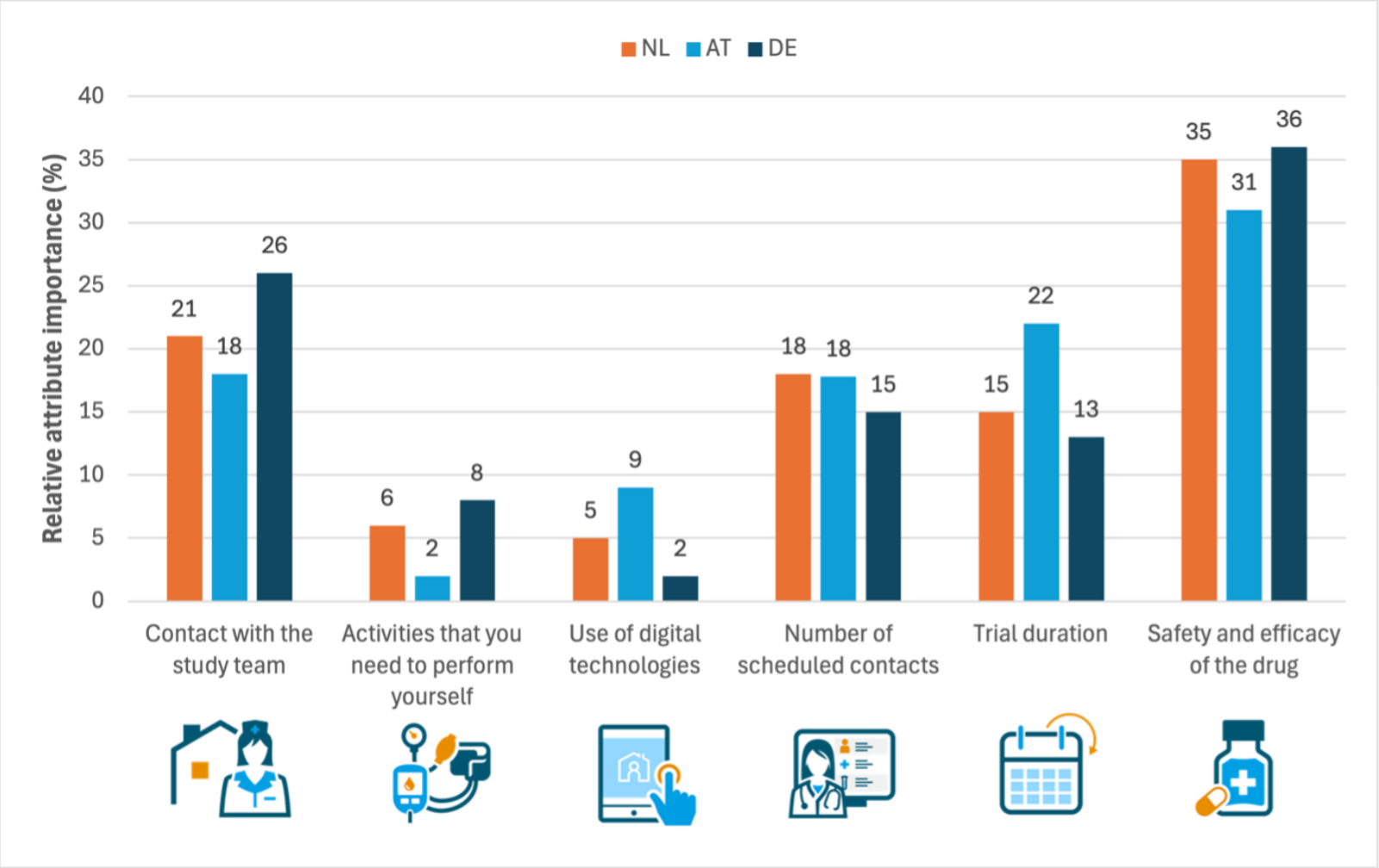
Results: Relative attribute importance



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Results: Trial participation probabilities

Different trial scenarios	Participation probability (%)		
	NL	AT	DE
 Baseline trial: Site at 30 minutes travel			
 Hybrid trial: Home and site at 30 minutes travel			
 DCT: Home visit			
 DCT: Home with video contact			

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Thank you!

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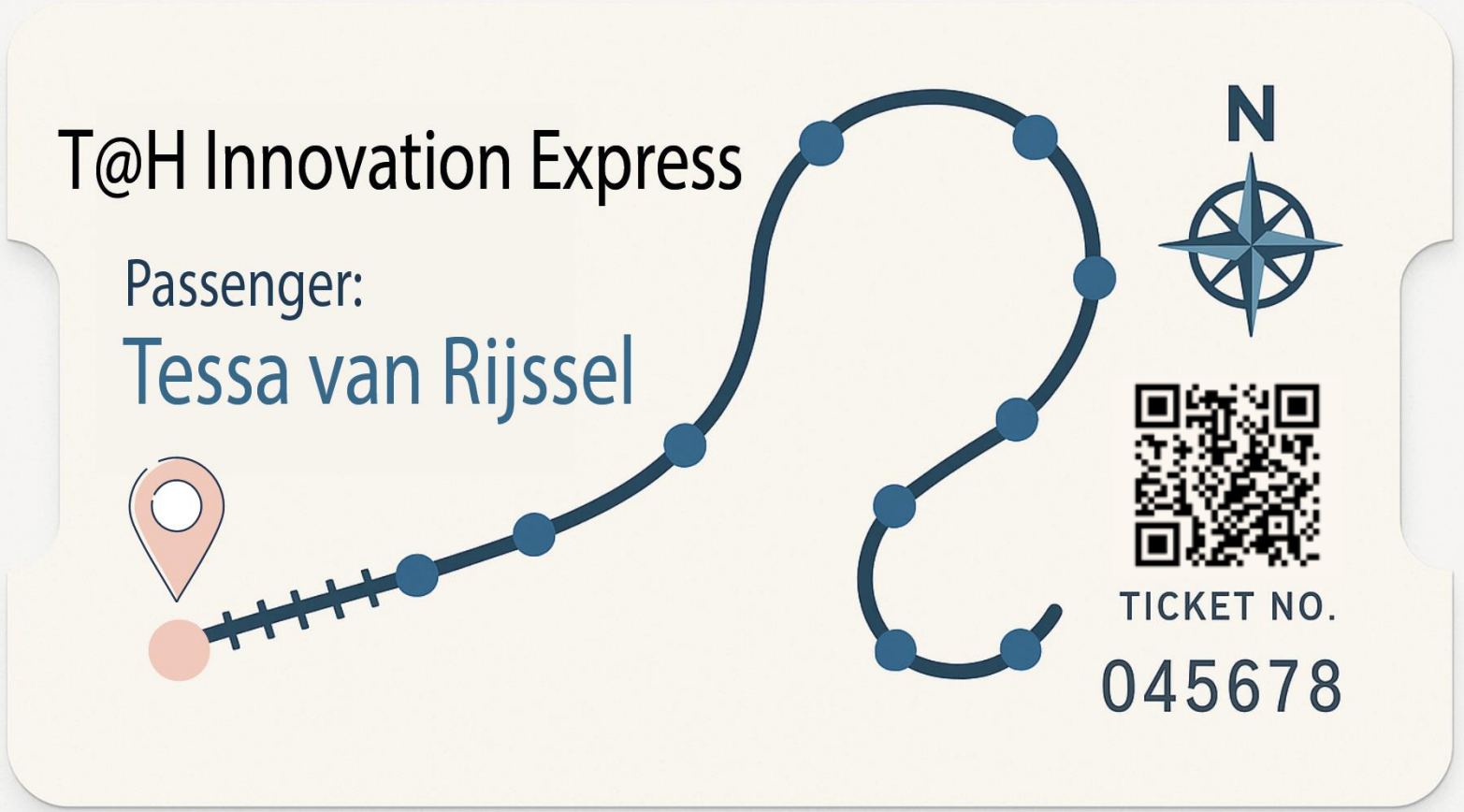

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Ethics and diversity in Decentralized clinical trials

Tessa van Rijssel

Photographer: Jelle Verhoeks

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.

PhD project Ethics and decentralized trials

"Bringing clinical research to patients: Ethical aspects of decentralized clinical trials"

Tessa van Rijssel

- Empirical qualitative research
- Normative reflection on informed consent, risk-benefit assessments and **diversity** in DCTs

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DCTs' promises for diversity

Increased accessibility for…

- Patients living further from research sites
- Patients for whom it is more difficult to travel (e.g., elderly patients, patients with comorbidities)

Digital environment enables…

- Better understanding (e.g., diverse formats and languages)
- Broader inclusion through online recruitment methods
- Increased anonymity when participating

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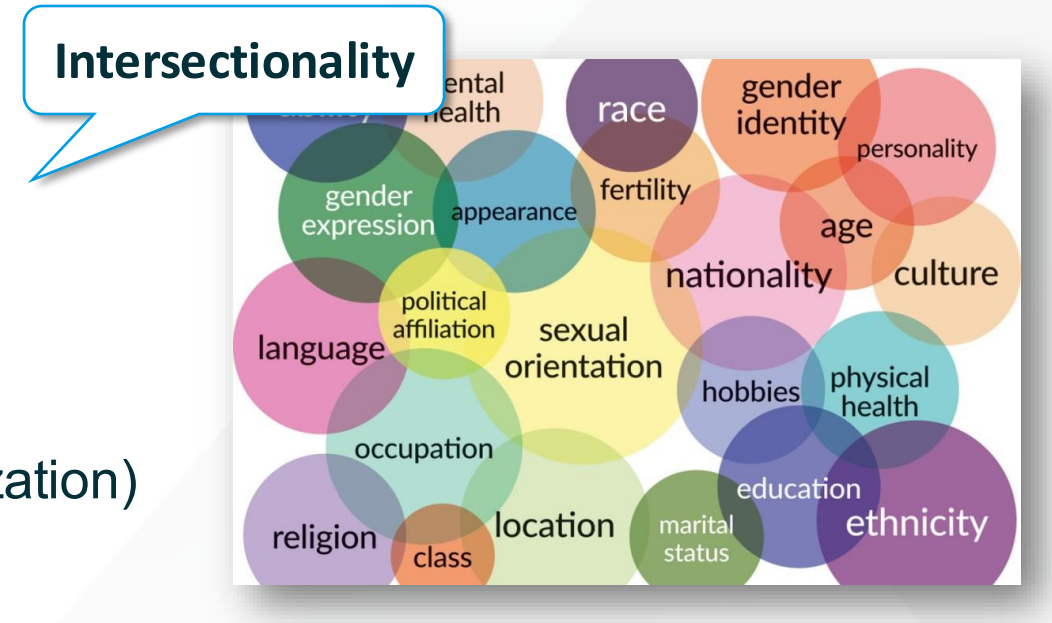
… But still many questions

- Also potential barriers
- Many different conceptualizatons of diverisity
- Many different groups and characteristics
- Harmful effects of classification (e.g., stigmatization)



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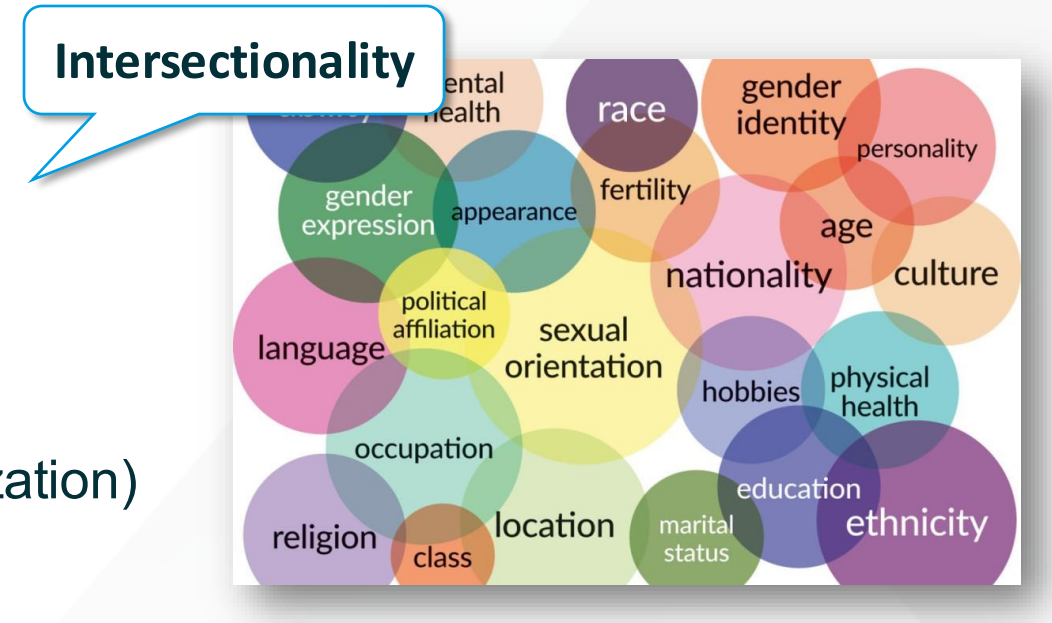

Aim of increasing diversity in clinical trials requires clear, careful, and well-substantiated specification

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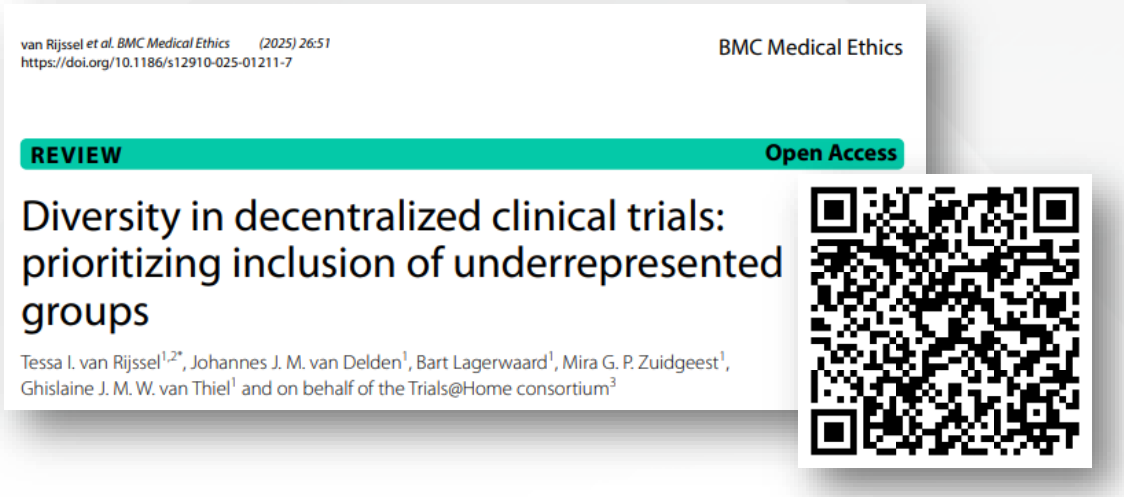
Our argument

- Analysis of **concept of diversity** and ethical requirements for **fair participant selection** to facilitate translating the aim of increasing diversity with DCTs to more specific and actionable objectives for recruitment and inclusion
- Considering history of **exclusion** and **underrepresentation** in research



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Thank you!

Contact: tessa.vanrijssel@radboudumc.nl

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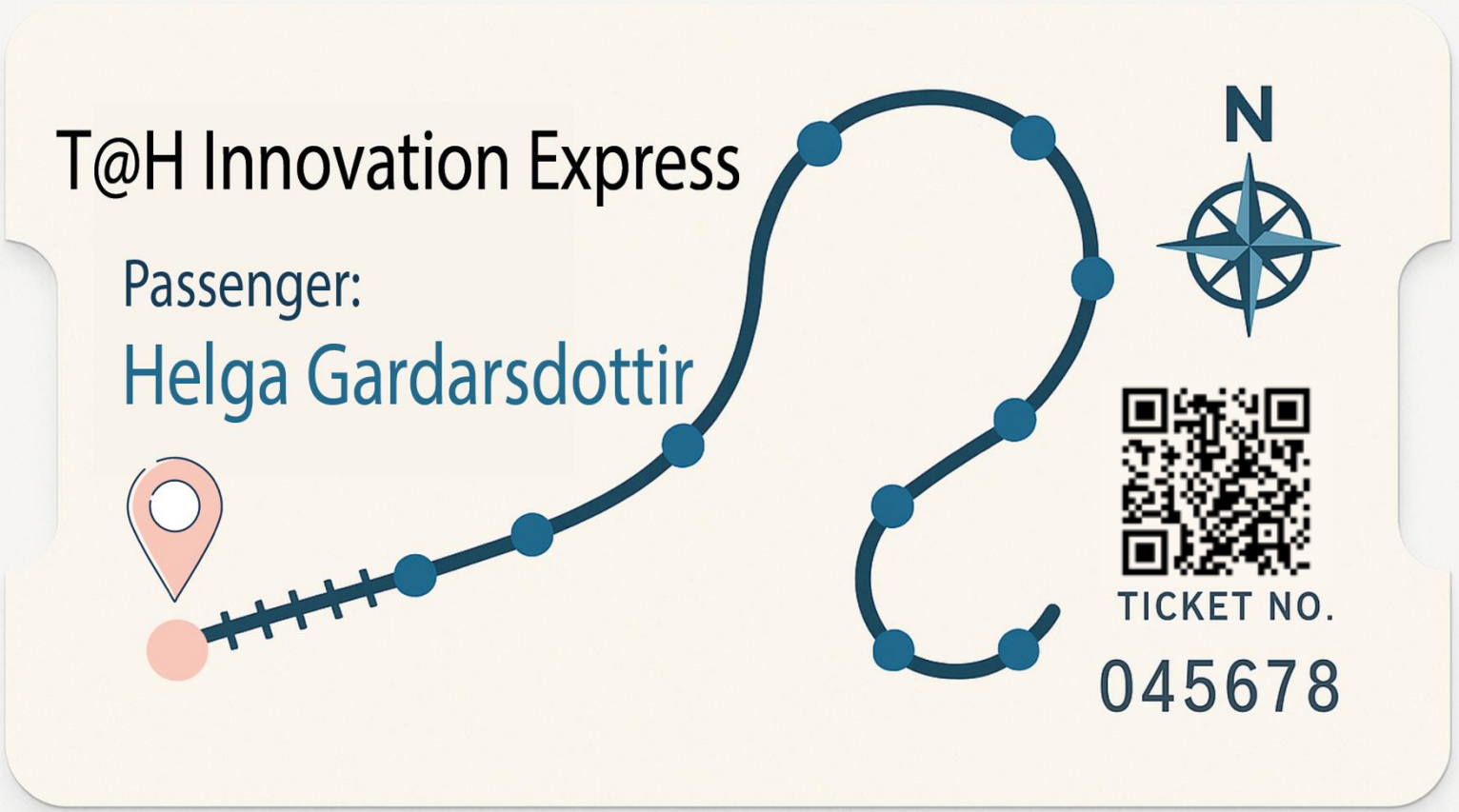

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Bringing the Trial to the Patient: Direct-to-Participant (DtP) IMP Supply in Europe

Helga Gardarsdottir

(on behalf of Amos de Jong)

Utrecht University

Photographer: Jelle Verhoeks

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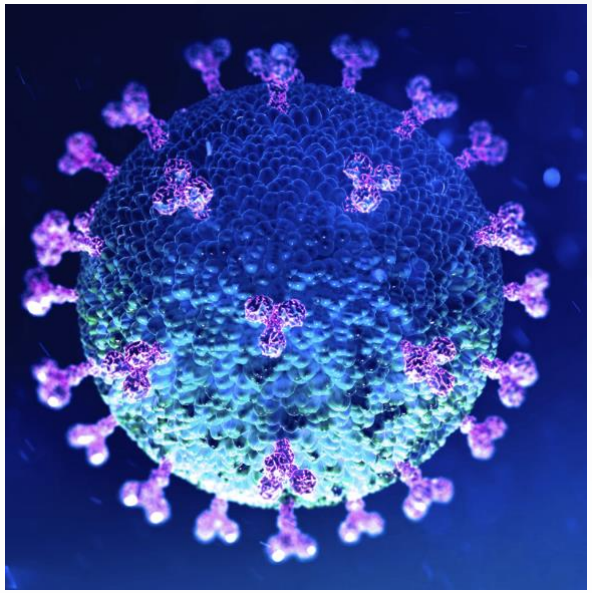
Early Trials@home days ...

2019/2020 landscape

EU	
Belgium	
Czech Republic	
Denmark	
France	
Germany	
Italy	
Polland	
Romania	
Spain	
Sweden	
The Netherlands	

Regulatory guidance during COVID-19



de Jong *et al*. CPT 2021; de Jong *et al.* BMJ Open. 2022;

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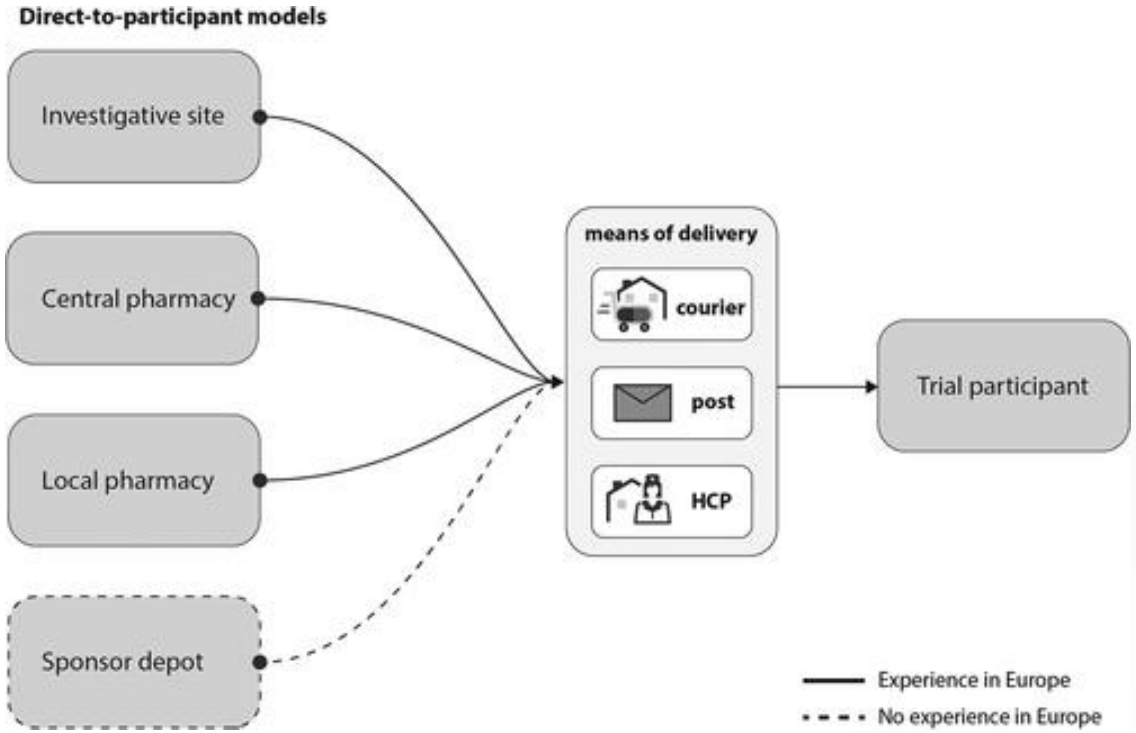
Experiences of sponsors, site staff and couriers

Semi-structured interviews with 16 respondents, conducted between May and Sept 2021



Stakeholder group

Industry sponsor	5 (31%)
Site study staff	3 (19%)
Courier-service provider	8 (50%)

Years of experience

0-5 years	3 (19%)
6-10 years	4 (25%)
≥10 years	9 (56%)

de Jong *et al.* Br J Clin Pharmacol 2023

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Conclusions and learnings

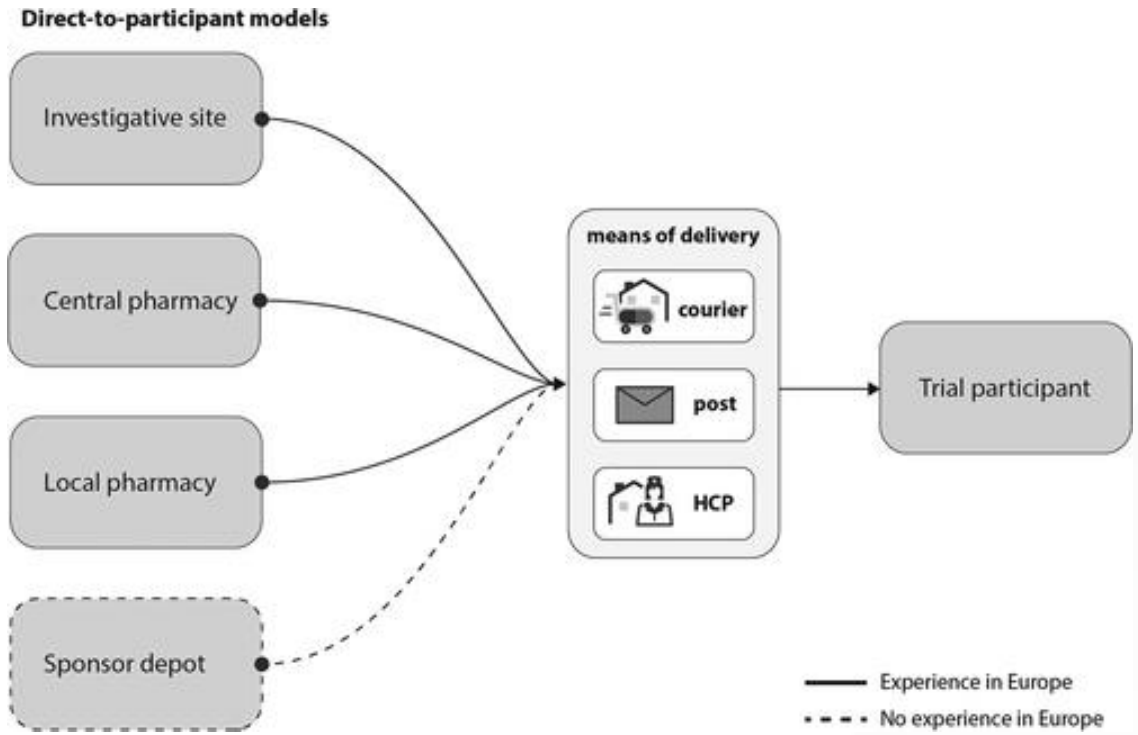
Several supply models are implemented in the EU, each with their benefits and barriers

81%

44%

13%

0%



✅ Few regulatory barriers
❌ Increased burden for site staff

✅ Reduced IMP spillage and cost
✅ Enabling DtP, but with stringent stability requirements
❌ Increased distance between site staff/pharmacist and study participant
❌ Not accepted in all EU countries
✅ Enabling low-intervention trials with authorised IMP
❌ Increased burden for local pharmacists

de Jong *et al.* Br J Clin Pharmacol 2023

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Questions?

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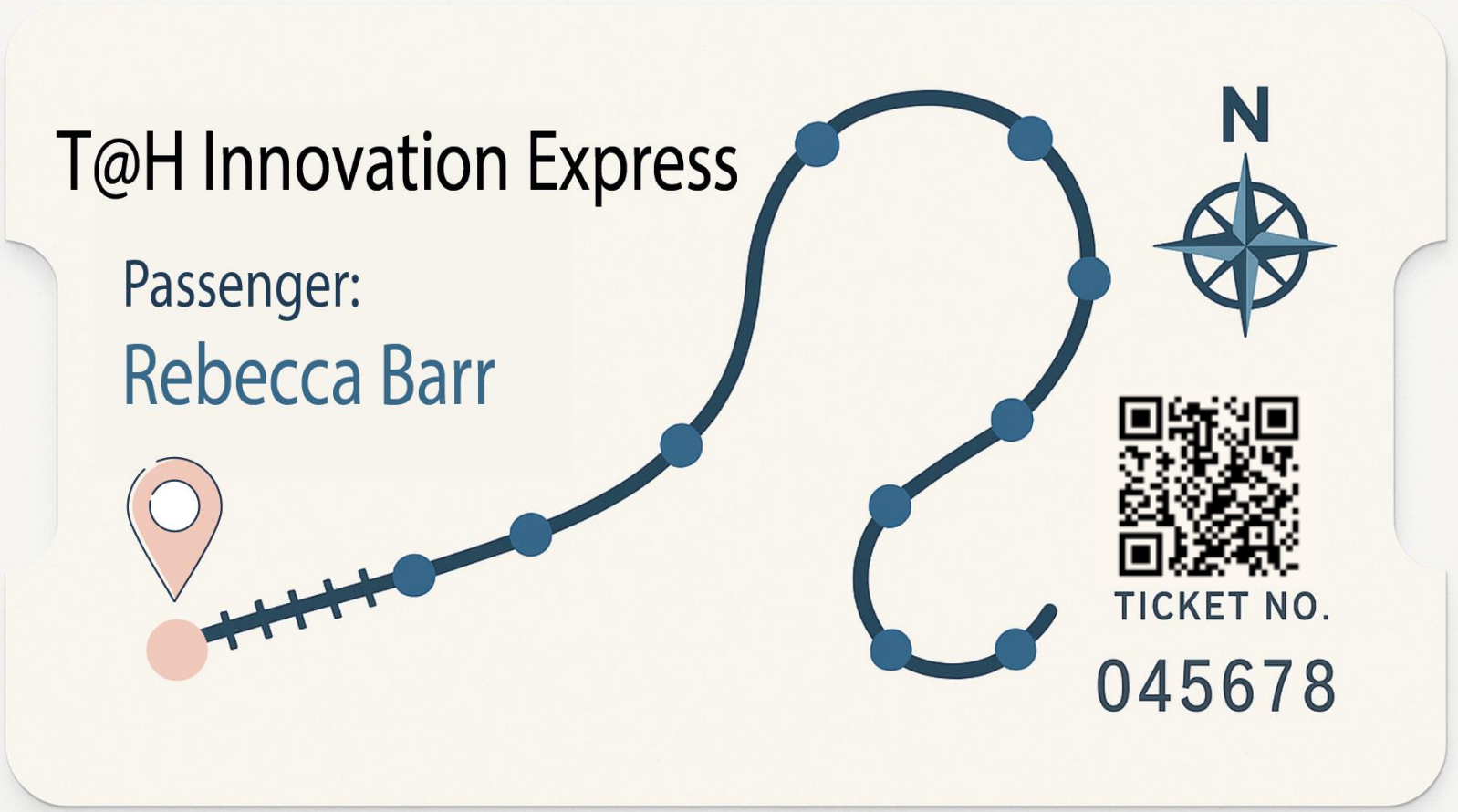

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Greener trials? Evaluating the carbon impact of decentralisation in the RADIAL trial

Rebecca Barr
University of Dundee

Photographer: Jelle Verhoeks

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The slides are not yet publicly available because this research has not yet been published in a manuscript

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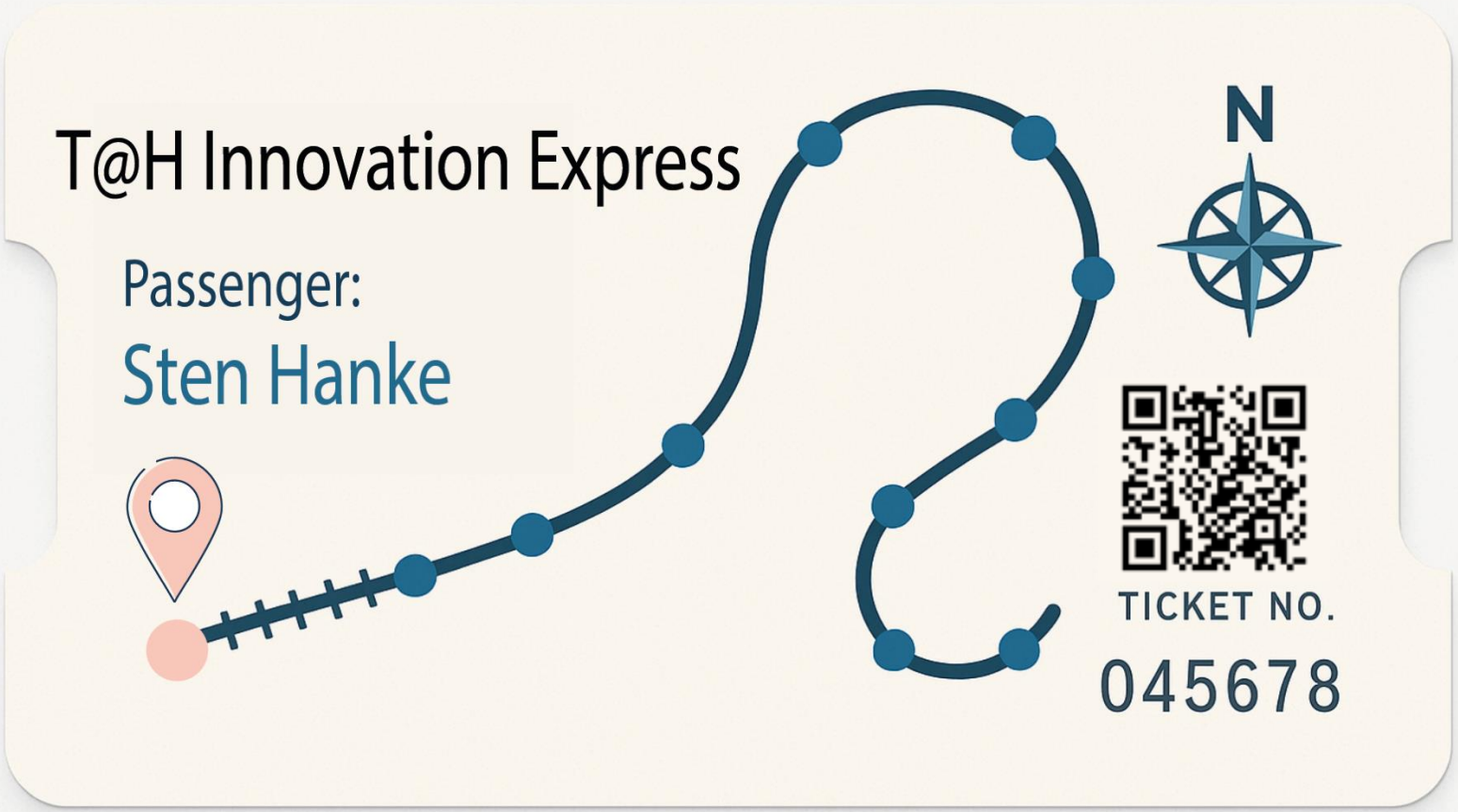

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A Technology Helpdesk System for Multi-Vendor Decentralized Clinical Trials

Theresa Weitlaner and

Sten Hanke

Photographer: Jelle Verhoeks

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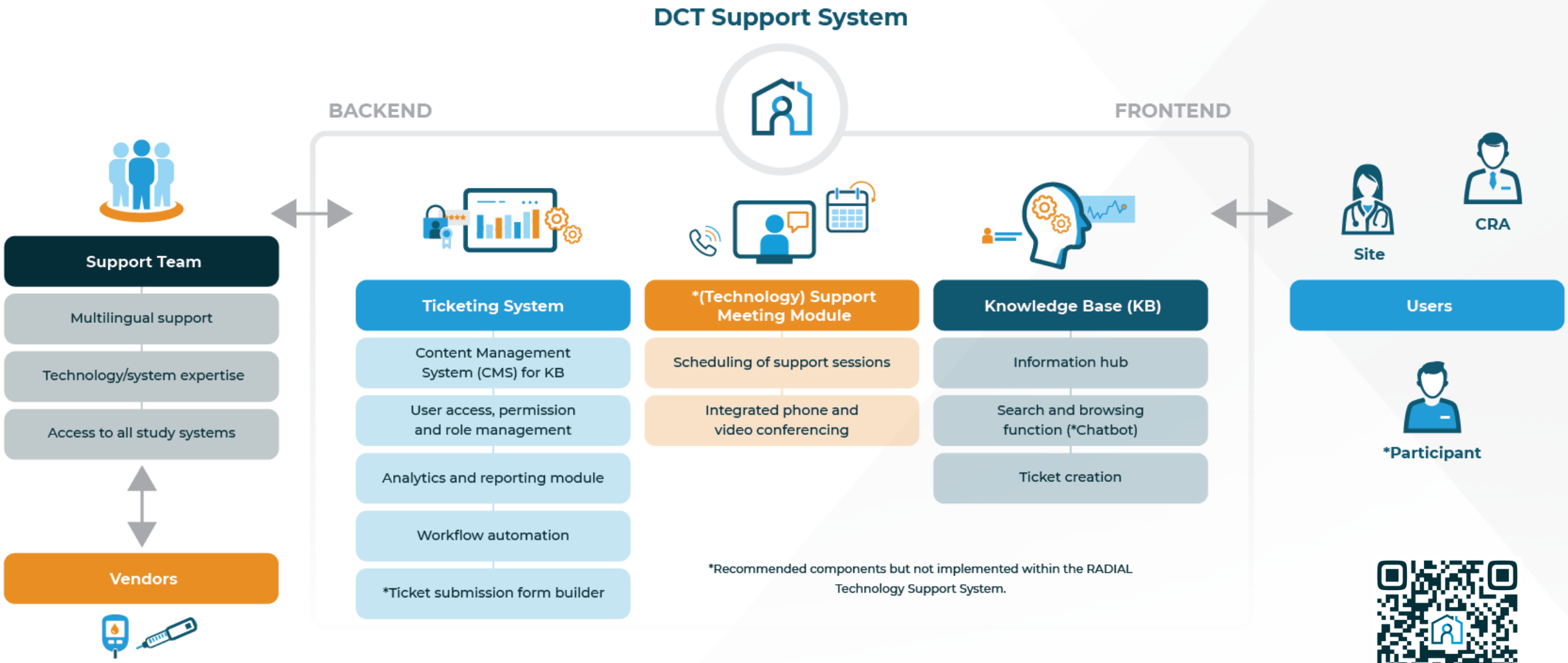
Technology Support System



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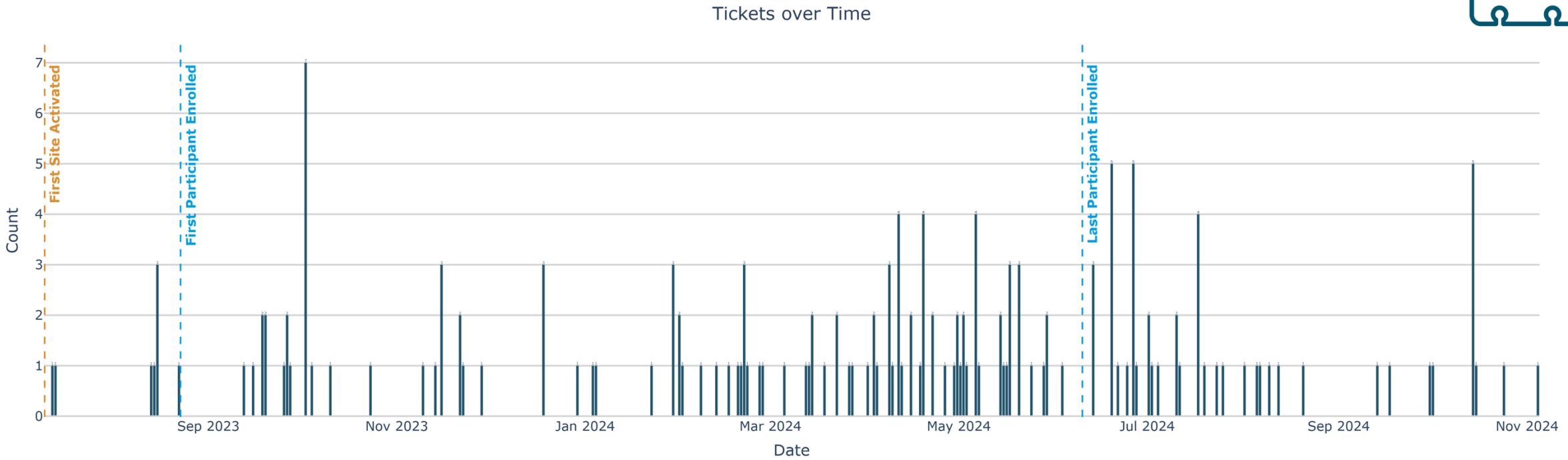
RADIAL Helpdesk Tickets



- **Total tickets submitted:** 169; across **29** of 38 participating sites
  - **90%** (*26 of 29*) of active sites engaged with the support system at least once
- **Ticket Resolution Time:** ranged from **a few hours to 140 days → Mean resolution time:** *14.6 days*
  - **23% (n = 39)** resolved within **24 hours**
  - **50% (n = 85)** resolved within **3 days**
- **Support Team Involvement: 13 agents** in total resolved or closed at least one ticket
  - **51% (n = 86)** of tickets resolved by a **single lead agent** serving throughout the study
  - **76% (n = 128)** resolved by **three long-term agents**

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RADIAL Helpdesk Tickets

Reporting period: 1 July 2023-1 December 2024

- Most **common ticket types**:
  - **Device-related issues** – *77 tickets (46%)*

    Pproblems with the glucometer, smart cap for insulin dosing, and their Bluetooth pairing with smartphones
  - **Study app-related issues** – *29 tickets (17.2%)*
  - **Requests for live support/standby** – 15 ticket (8.9%)
  - **Other issues** – 48 tickets (28.4%)
    - General support, study platform, telehealth, RTSM and logistics, account creation, onboarding

Group	Total Ticket Count	Number of Participants	Ticket per Participant
Clinical Operations / Support Team	27	N/A	N/A
Denmark	6	5	1.2
Germany	13	15	0.9
Italy	16	14	1.1
Poland	41	25	1.6
Spain	23	23	1
United Kingdom	43	21	2.1

Additional Notes

- Internal identifier used for tickets from clinical operations/support team not linked to a site
- Three sites without enrolled participants also submitted tickets
- Sites with participants submitted an **average of 1.3 tickets per participant**
- Sites that enrolled participants but submitted no tickets are not represented.
- Ticket type “Schedule Live Support Session” was introduced in February 2024.

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Learnings and recommendations

- **Multilingual support is essential** - Non-English speaking sites showed lower engagement
- **Proactive training** - Most-viewed content was training materials
- **Live support options** - Added mid-trial due to demand
- **Single point of contact** - Centralized helpdesk prevented fragmented vendor communication

- Involve support team from trial design phase
- Ensure support staff have access to ALL trial systems
- Implement structured governance with weekly reviews
- Plan for BYOD complexity (device heterogeneity increases support needs)
- Use KPIs for continuous monitoring and predictive analytics

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Questions?

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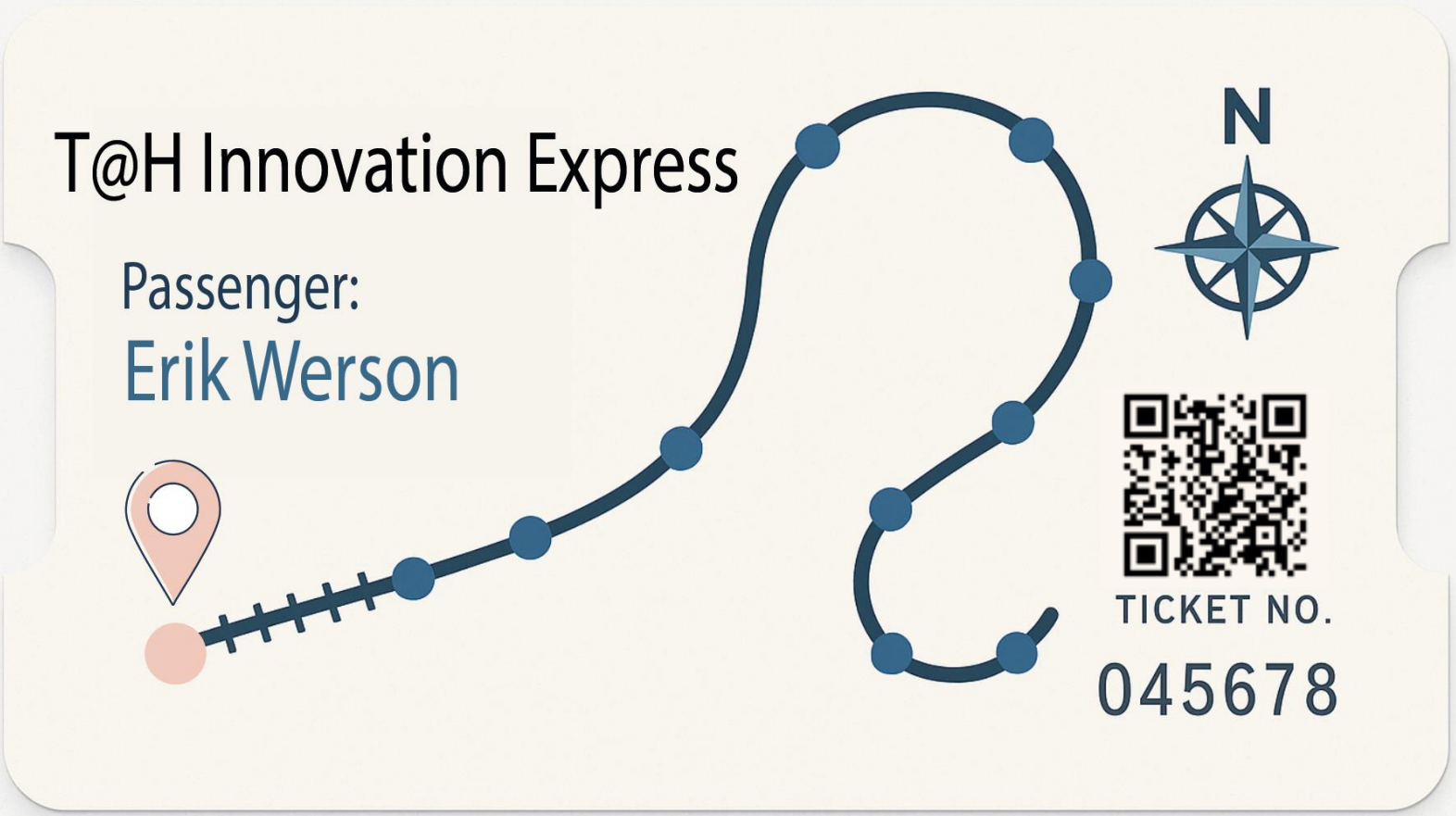

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How to effectively involve lived experience representatives in public-private consortia

Erik Werson, T2D advocate & Member of the T@H Patient Expert Panel

Photographer: Jelle Verhoeks

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.

The T@H patient engagement set-up

The T@H Patient Expert Panel (PEP)

- Seven People with Lived experience of Diabetes coordinated by IDF Europe
- PEP embedded as part of all Work Packages, Annual and Semi-Annual meetings as well as ad-hoc activities
- Promoting two-way communication

Mark Duman

João Valente Nabais

Cristina-Maria Petrut

Konstantinos Tagkalos

Ken Tait

Theophaneia Tsachalina

Erik Werson

Cameron Keighron

IDF Europe Coordination

PEP PATIENT EXPERT PANEL

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.

PEP core activities

RfP Vendor Pitch

Protocol Design & Review

Awareness Campaigns

Informed Consent

User Acceptance Testing

Discrete Choice Experiment

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Optimising the effectiveness of the engagement

Upcoming publication

Mixed method research:

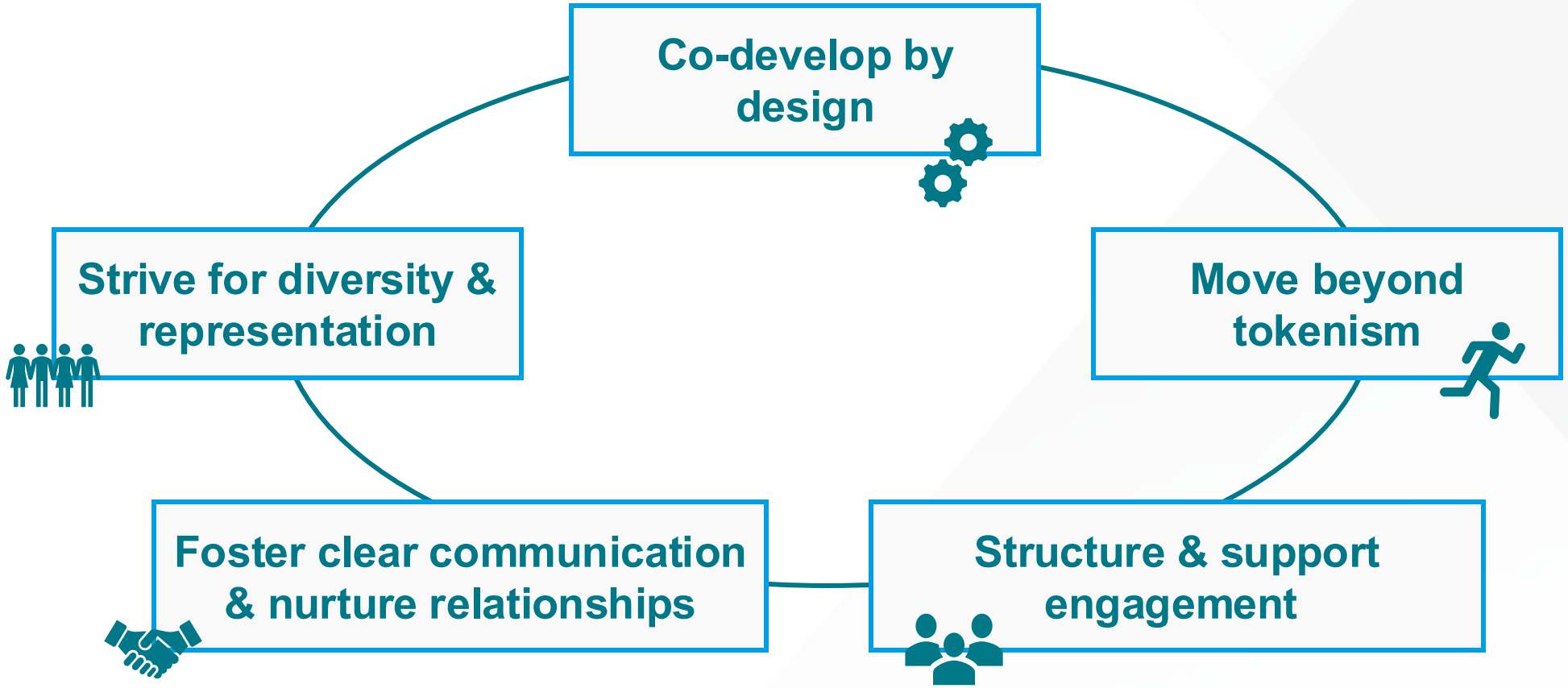
- **Survey** (55 respondents)
- **Qualitative interviews** (eight PEP and Consortium Members)

Objectives

- Assess the **PEP's impact** and **researchers' attitudes and values** towards Patient & Public Involvement & Engagement (**PPIE**)
- Identify which **PPIE practices** enabled a **stronger impact** of PEP engagement
- Publish research **results**
- Develop **how-to guidelines** for use in research projects on best practices and the sustainability of PPIE in large multistakeholder consortiums

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.

Recommendations for successful engagement



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Questions?

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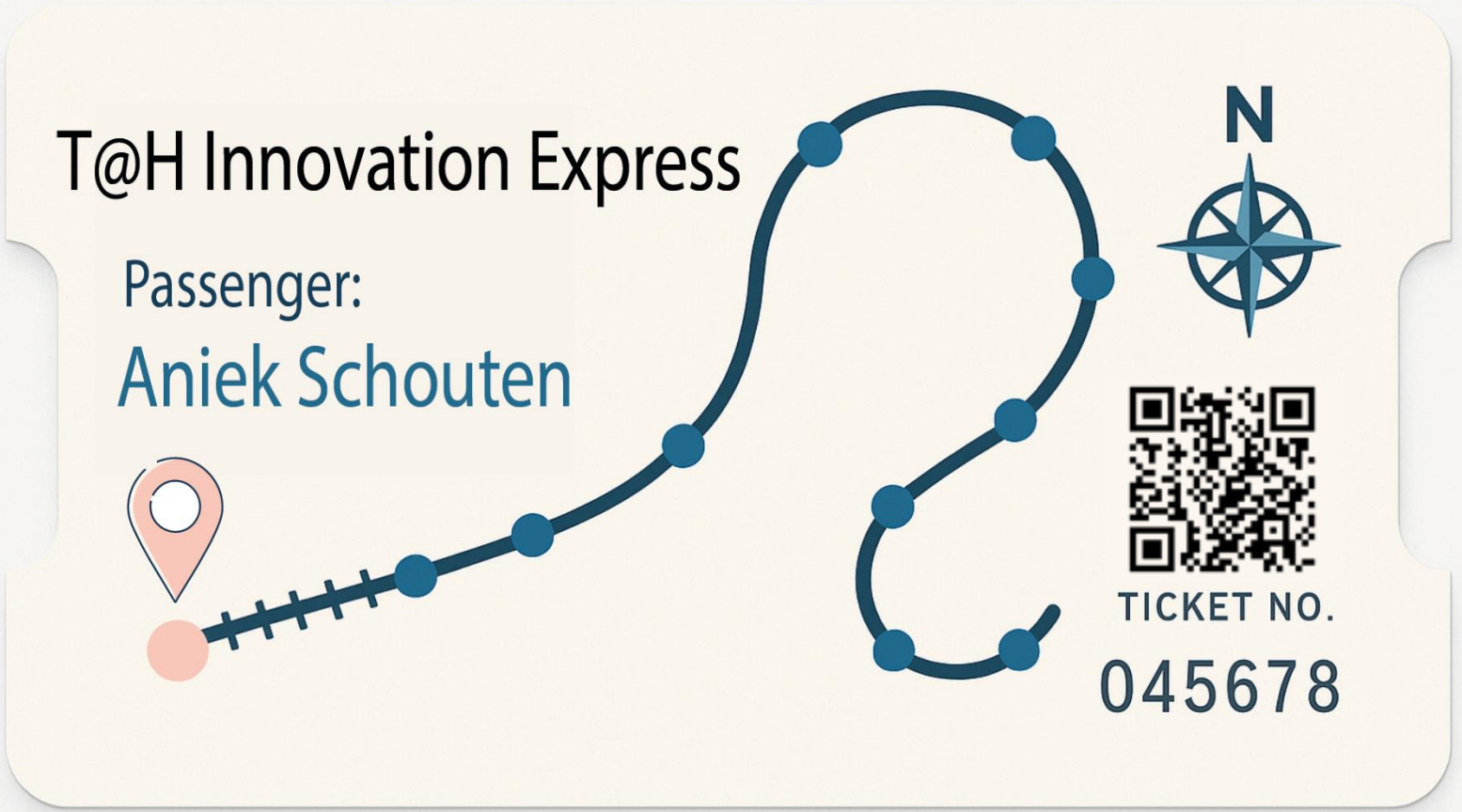

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Economic insights into decentralised and hybrid clinical trials

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Photographer: Jelle Verhoeks

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Background

Research Aim

Evaluate the economic impact of the decentralised elements introduced in the RADIAL trial

More specifically

Assess the costs for each of the trial arms associated with:

- Trial personnel costs
- Study site costs
- Third party service provider costs
- Other costs

Investigating the cost drivers of:

- Set-up
- Recruitment
- Follow-up

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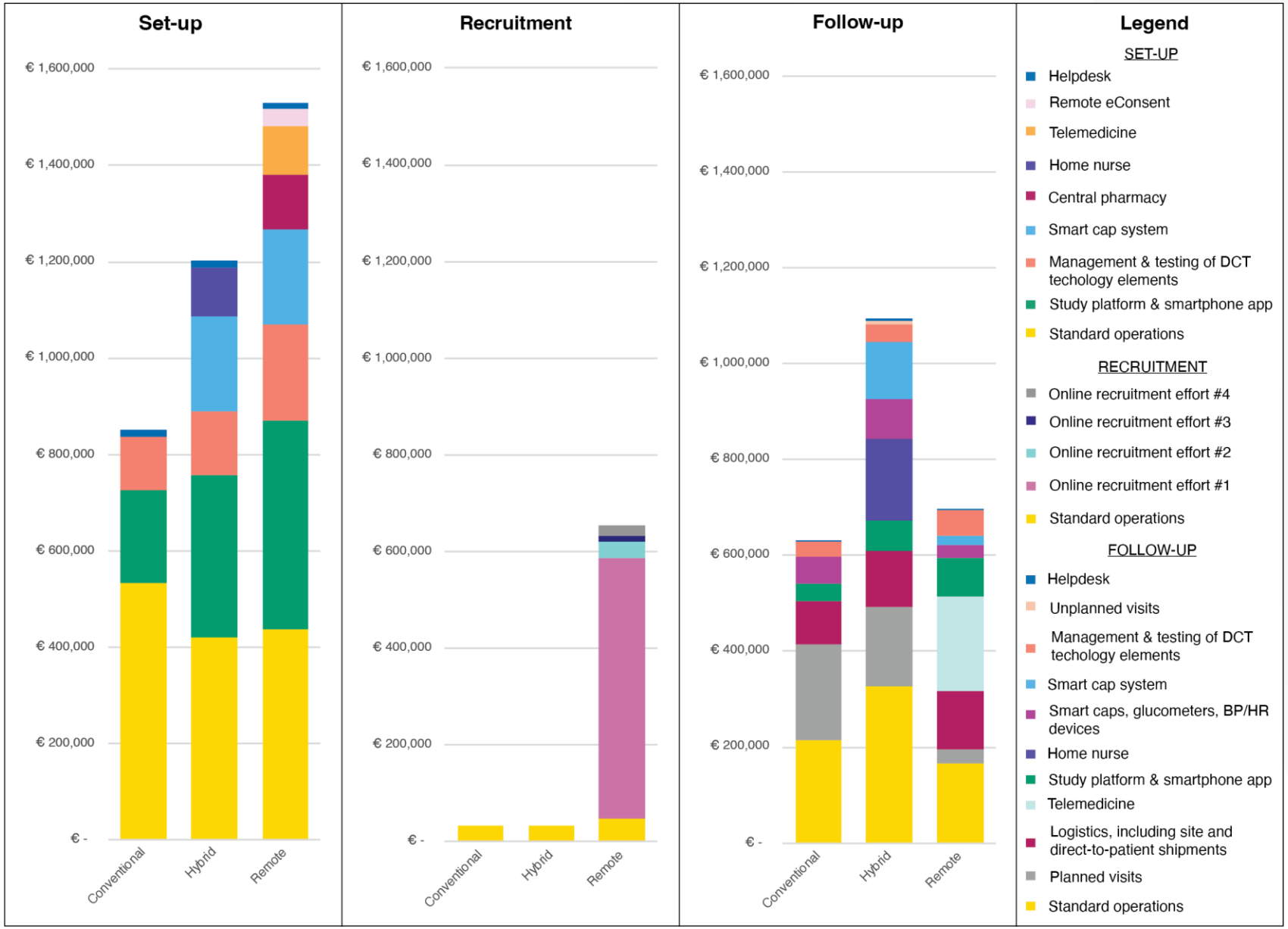
Results

Cost drivers:

- Development of a trial-specific central study platform and smartphone application
- Decentralised recruitment efforts



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Main takeaways

‘Reduce, reuse, and recycle’ technology

- Minimise complexity & costs (training & resources) of sites & participants
- Fewer vendors
- Re-use or adapt instead of new custom developments

Learning curve

- Experience with DCT elements will reduce study personnel costs

Evaluate the added value of DCT elements in relation to costs

- Feasibility and added value of the DCT elements should be considered in context of the study population.
- Relevant cost drivers to take into account are speed of enrolment, retention, overall trial timelines, and trial size.
- Trial size can be relevant: high upfront costs & scalability vs cost increases with participant numbers.

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Q&A

#TrialsAtHome

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