Trials@Home final recommendations

Kim Hawkins &
Mira Zuidgeest

#TrialsAtHome

Photographer: Jelle Verhoeks

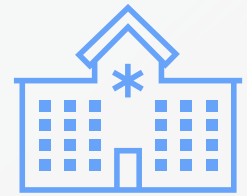
The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

The Trials@Home journey… the goal

To provide recommendations on Decentralised Clinical Trial (DCT) approaches in Europe

"operational model in which trial activities are designed to take place at or in the vicinity of the participant's home"

"rather than at a traditional clinical site"



"This approach may make use of technologies and other innovative operational approaches to facilitate data collection"

Santa-Ana-Tellez et al. Decentralised, patient-centric, site-less, virtual, and digital clinical trials? From confusion to consensus. https://doi.org/10.1016/j.drudis.2023.103520

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 Trials@Home journey… the consortium

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 Trials@Home journey… the approach

1. BEST
Best practices in RDCT's

2. TECH
Technologies - barries, enablers and data management

3. PILOT
Pan-EU RDCT pilot

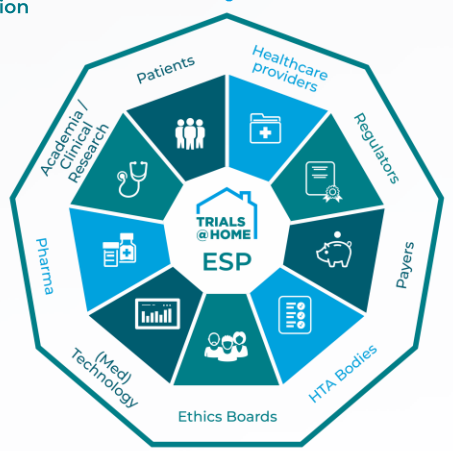
4. EAGLE
Ethical, regulAtory, Gcp and LEgal aspects

5. CODE
Communication, dissemination & stake-holder engagement

6

6. PROMS
PROject Management and Synthesis

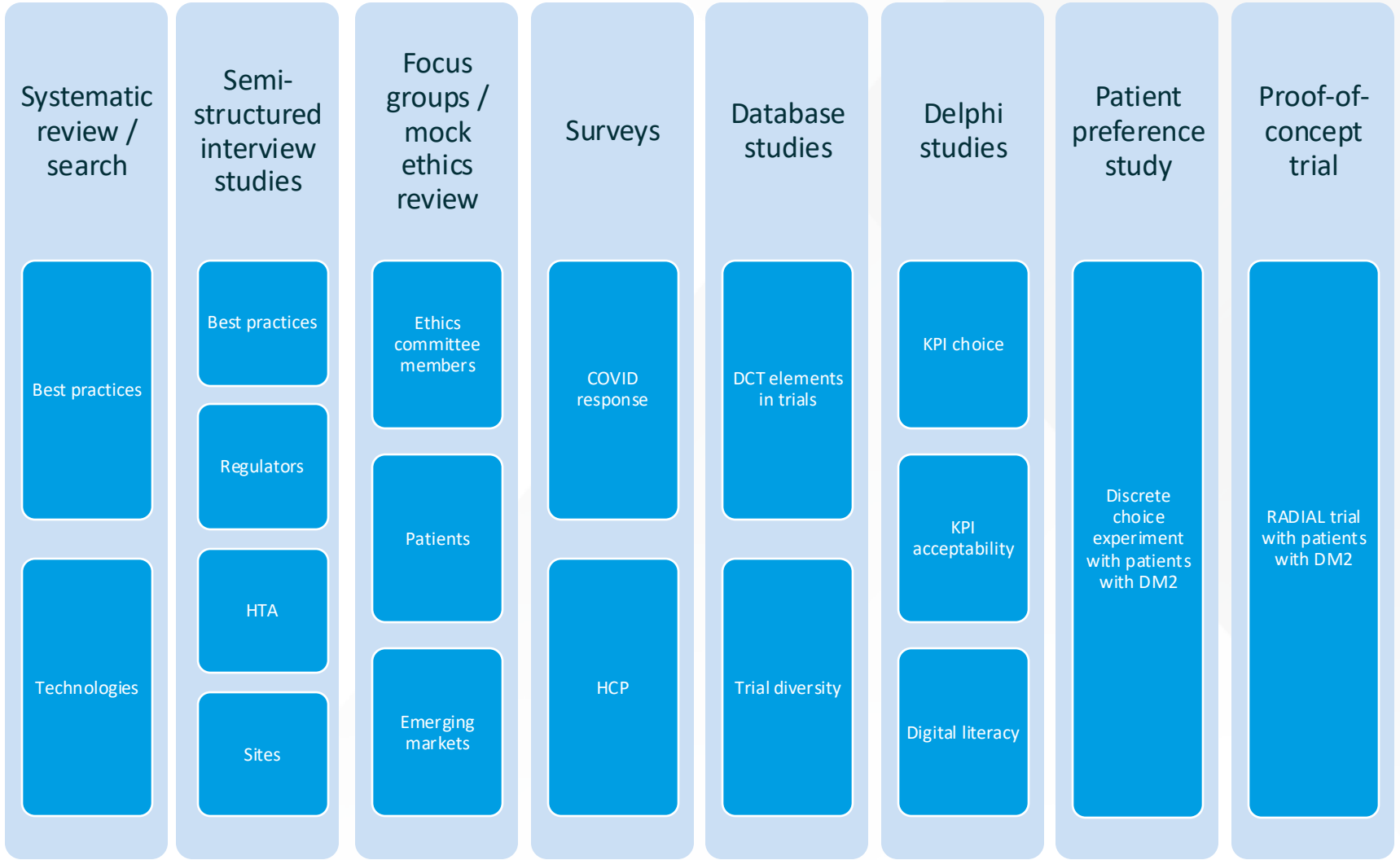
Recommendations and tools for RDCT in Europe:
- Technology
- Compliance
- PsychoSocial
- Organisational



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 Trials@Home journey… the science

- **Eight different types of research methods**
- **Involving all stakeholders in the field, including regulators, trial personnel, patient representatives, HTA, sponsors, vendors**
- **Leading to 27 scientific publications to date**
- **With >60 unique authors providing their expertise**



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.

BJCP British Journal of Clinical Pharmacology

ORIGINAL ARTICLE | Open Access

Direct-to-participant inv
in clinical trials in Europ
sponsors, site staff and

Amos J. de Jong, Yared Santa-Ana-Tellez,
Anthonius de Boer, Helga Gardarsdottir

First published: 12 July 2023 | https://d

UBU link

trialsathome.com.
Funding information: This work has rec
Joint Undertaking Trials@Home (grant No
be accessed through the following link: w
conducted as part of the Trials@Home co
stated authors and neither IMI nor the Eu
for any use that may be made of the info

Opportunities a
Regulators' Pers

Amos J. de Jong, Tess
Jaime Fons-Martínez,
the Trials@Home Consortium

First published: 30 April 2022
https://doi.org/10.1002/cpt.2628
Citations: 77

- **With >60 unique author**
  providing their expertis

Clinical Pharmacology & Therapeutics

Tutorial | Open Access

Selecting and Preparing Clinical Site
Conduct of Decentralized Clinical Tri
From the Trials@Home RADIAL Proo

Katarzyna Lipinska, Danny van Weelij, Bart Lagerwaard, Linda
Lina Pérez-Breva, Paul Bodfish, Megan Heath, Yvonne van Rij

First published: 01 October 2025 | https://doi.org/10.1002/

UBU link

These authors contributed equally to this work.

SECTIONS

ASCPT American Society for Clinical Pharmacology & Therapeutics

Member Se

Drug Discovery Today
Volume 28, Issue 4, April 2023, 103520

Journals > CTS > Translational Bytes > Why do Diabetic Participants Enroll in Clinical Trials?

Why do Diabetic Participants Enroll in Clinical Trials?

Author: Julia Kopanz, Bart Lagerwaard, PhD, and Mira Zuidgeest, PhD on January 28, 2025

sed, patient-centric, site-less,
l digital clinical trials? From
o consensus

, Bart Lagerwaard [2], Amos J. de Jong [1], Helga Gardarsdottir [1 3 4],
Kimberly Hawkins [5], Megan Heath [6], Mira G.P. Zuidgeest [2],
m [7]

Share Cite

dis.2023.103520 Get rights and content

license Open access

s with trial personnel,
stakeholders

Paoli, Thomas M. MacDonald, Isla S. Mackenzie,

BMJ Journals

BMJ Open

Home / Archive / Volume 12, Issue 8

Article Text
Article info
Citation Tools
Share
Rapid Responses

Patient-centred medicine
Original research

Which decentralised trial activitie
protocols of drug trials initiated i
study in ClinicalTrials.gov

Amos J de Jong [1], Renske J Grupstra [1], Yared Santa-A
Gardarsdottir [1, 4, 5] On behalf of Trials@Home consortium
Correspondence to Helga Gardarsdottir; h.gardarsdottir@uu.nl

Abstract

Objectives Decentralised clinical trial activities—such a
wearables and direct-to-participant investigational med
trials (CTs) are conducted and with that to reduce the pa
investigated the decentralised and on-site conduct of tr
2020.

COVID-19 and the Em
Clinical Trials in the E

Amos Jochanan de Jong, Yared Sant
Mira Gerta Petra Zuidgeest, Satu Jo

First published: 05 March 2021 | h

BJCP British Journal of Clinical Pharmacology

ORIGINAL ARTICLE | Open Access

A systematic review of methods used to conduct decentralised clinical trials

Amy Rogers, Giorgia De Paoli, Selvarani Subbarayan, Rachel Copland, Kate Harwood, Joanne Coyle, Lyn Mitchell, Thomas M. MacDonald, Isla S. Mackenzie, Trials@Home Consortium

First published: 27 December 2021 | https://doi.org/10.1111/bcp.15205 | Citations: 57

Clinical Pharmacology & Therapeutics

Tutorial | Open Access

Bringing Trial Activities to Participants—The Trials@Home RADIAL Proof-of-Concept Trial Investigating Decentralization of Trials

Mira G.P. Zuidgeest, Megan Heath, Bart Lagerwaard, Danny R. van Weelij, Linda Rutgrink, Sten Hanke, Tea Vedenkannas, Taru Kosonen, Stefania Collamati, Jaime Fons-Martínez ... See all authors

First published: 01 September 2025 | https://doi.org/10.1002/cpt.70025 | Citations: 4

UBU link

SECTIONS PDF TOOLS SHARE

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

https://trialsathome.com/

Recommendation:

Evaluate a site's previous DCT experience and capacity to identify any training needs, support or gaps to be addressed prior to implementation, as well as tailored, just-in-time training particularly for novel digital tools and centralised support infrastructures (e.g., help desks and oversight teams during trial conduct).

Statement:

To ensure data quality and participant oversight we should only include sites with previous experience and already established processes and tools for DCT activities in trials with multiple decentralized elements.

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.

Recommendation:

Each decentralised element under consideration for inclusion in a trial should be individually assessed to ensure it is permitted in the participating countries, suitable and acceptable for the target study population and trial sites, and technically feasible given existing infrastructure and operational requirements (e.g., continuous broadband internet access).

Statement:

To ensure simplicity for patients and clinical research sites, the number of DCT elements being incorporated into a clinical trial should be limited to 1 or 2.

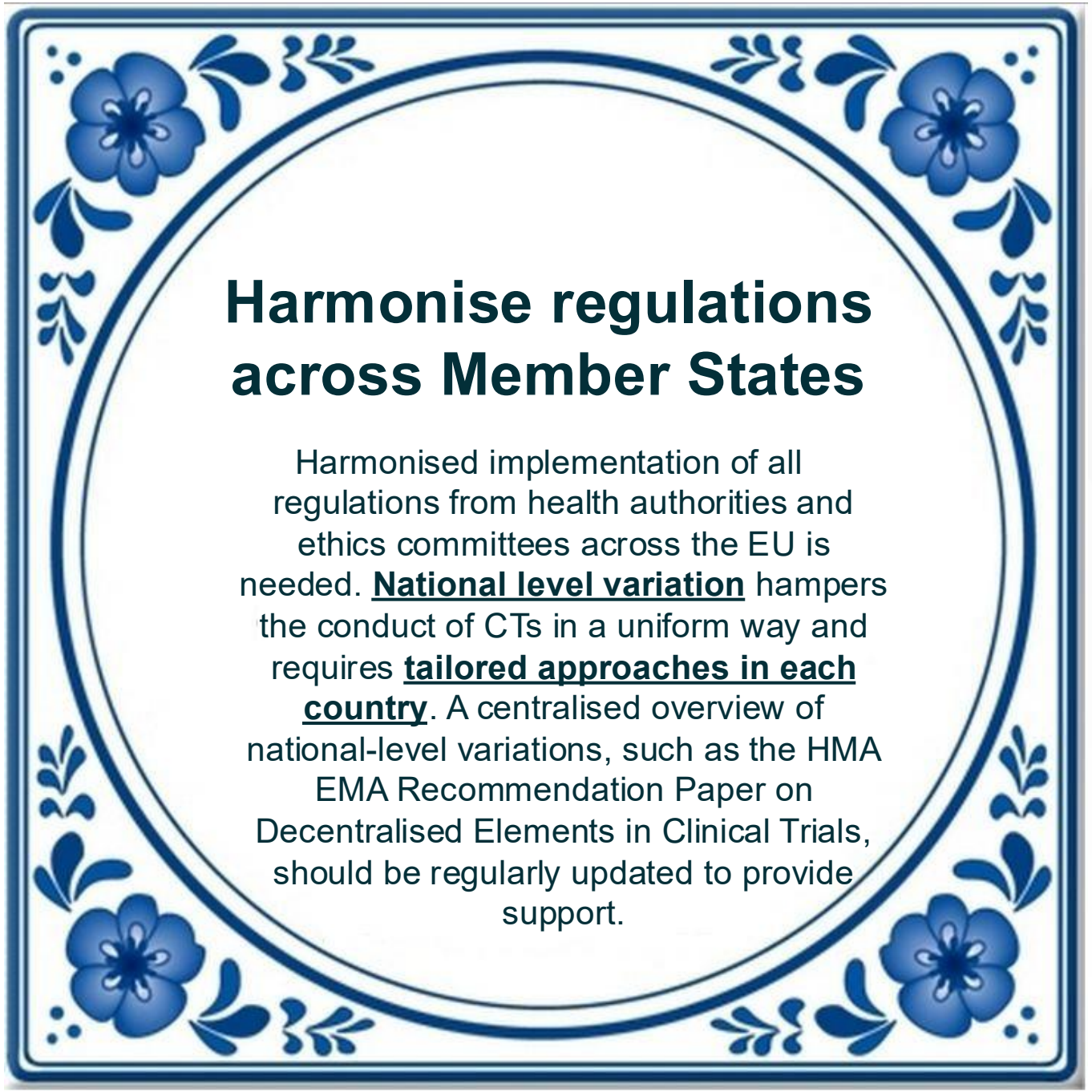
The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Questions?

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.

Panel discussion

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.



Helga Gardarsdottir

Equip study teams with foundational technical knowledge to effectively support site staff

Ensure study teams **recognise and anticipate common technical challenges**, and are trained to offer basic troubleshooting guidance. Define an **escalation process** to respective study team members can promptly refer complex technical issues to specialists. Include **trial-specific technology training for study team members** during pre-trial activities, enabling them to effectively assist and empower the primary stakeholders.

Sten Hanke

TRIALS @HOME

Agree on roles and responsibilities

Everyone involved in a DCT has a role, from participants remembering to complete questionnaires to the person responsible for ensuring that blood samples arrive in the laboratory on time. **Knowing who is responsible for what and when** ensures that tasks are not overlooked and that participants are kept safe

Isla Mackenzie

TRIALS @HOME

When using online recruitment, prioritise search engine advertisements

Our data suggest that paid search drove more pre-screener completions than performance max campaigns. Targeted keyword strategies in search advertising, aligned with condition-specific search behaviour, are essential to improve recruitment efforts. Future research should aim to **understand the search behaviour of potential participants** and further explore paid search to attract users actively searching for trial-related information.

Megan Heath

TRIALS @HOME

Incorporate patient preferences into future trial designs

We recommend clinical design teams to integrate patient preferences (and caregiver preferences in case of pediatric trials) for trial participation into the trial design. Teams should **also take into account possible differences in preferences** among people of, for example, different age or gender.

João Nabais

TRIALS @HOME

Advance clinical trial innovation through public-private partnerships

Trials@Home followed a co-creative, multi-stakeholder approach where academic partners, small and medium-sized enterprises (SMEs), private foundations, patient organisations and EFPIA partnersworked together with other stakeholders from across the medical, technological, regulatory, ethical and social fields of DCTs

Reamonn Madden

Q&A

#TrialsAtHome

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.