



Operational Learnings from the RADIAL Trial

Webinar

Trials@Home

Interest Network

30 March 2026



Presenters



- **Kim Hawkins**
- Global Head of Clinical Project Operations
- Sanofi

Disclaimer

- **Megan Heath**
- Head of Clinical Studies Units European Region
- Sanofi

- **Mira Zuidgeest**
- Associate Professor
- University Medical Center Utrecht

- **Sten Hanke**
- Scientific Stakeholder Manager
- BBMRI-ERIC

- **Amos de Jong**
- Postdoctoral researcher
- University Medical Center Utrecht

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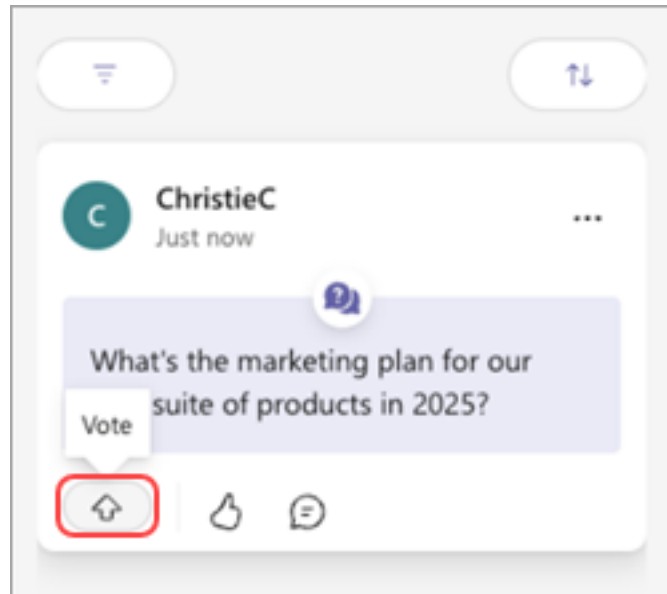
Agenda

16:30-16:40	Introduction webinar and RADIAL trial	Kim Hawkins & Megan Heath
16:40-16:50	Highlighting some operational learnings	Mira Zuidgeest
16:50-17:00	Technology learnings from the RADIAL Trial	Sten Hanke
17:00-17:15	Quality and safety of DCTS	Amos de Jong
17:15-17:30	Q&A	Kim Hawkins & Mira Zuidgeest

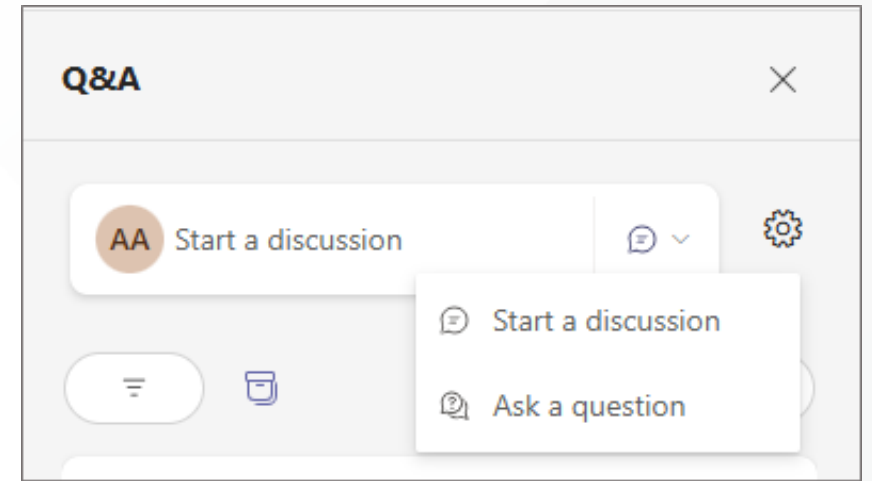
Q&A and comments



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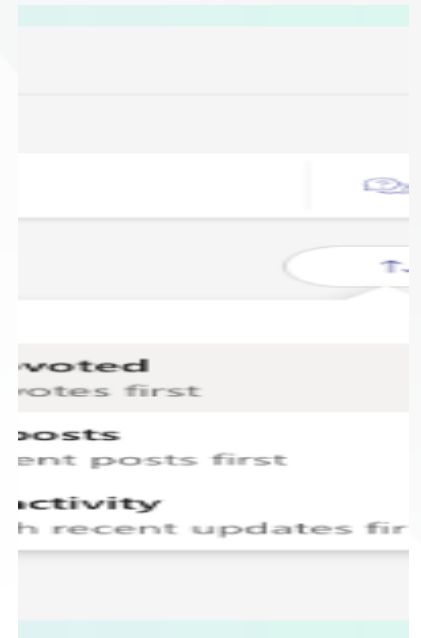


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The Trials@Home Interest Network

- Exchange understanding, experience, and implementation practices of DCT approaches.
- Discuss policy, methodological and operational questions related to DCTs and identify knowledge gaps and best practices.
- Continue to communicate, disseminate, and educate on DCT recommendations to enhance the field of DCTs.

Including....

Education

Webinars
Podcasts
Digests

Network meetings

Sharing best practices
Gathering insights for
ACT-EU
Surfacing gaps

Future opportunities

Research / funding
proposals
Focused workstreams

Trials@Home Interest Network

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We are happy to welcome new members.

For more information and the sign-up sheet, please visit

<https://trialsathome.com/trialshome-interest-network/>



The RADIAL trial

Megan Heath
Sanofi



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

Approved proof-of-concept study

Methodological objective: KPIs as main outcomes

Low intervention phase IV trial

Compound[®] used within market authorization label

Population familiar with insulin use

People with DM2 treated with basal insulin with HbA1c 7-10%

Explore potential benefits: participant retention, recruitment, diversity, cost, site & patient satisfaction

Evaluate acceptability: safety oversight, data quality & treatment adherence

Decentralised elements in RADIAL



Online recruitment & Pre-screening



Remote consent



Remote trial visits



Direct-to-patient shipments of IMP & study materials



Data collection using sensors & wearables



Self-reporting of events & ePROs



At-home collection of biological samples

The conduct of RADIAL

- Total of 108 participants included
 - 100 Part A (53 hybrid, 47 Conventional)
 - 8 Part B (remote)
- Seven decentralised activities were possible
- Many learnings during set-up, regulatory submission, and conduct

Participating countries



Key operational learnings

Mira Zuidgeest

UMCU



RADIAL paper series on operational learnings



1. **Introduction** into DCTs and the RADIAL trial
2. **Regulatory** advice, interactions and approval
3. **Site** selection and training for DCT
4. **Recruiting** and **consenting** decentralised trial participants
5. Supply of **investigational medicinal product** and **study** to decentralised trial participants
6. **Technological** solutions for DCTS



RADIAL part B consent - Participant Experience

Recommendations

- Standardise informed consent requirements across countries
- Ensure equitable accessibility of remote eConsent
- Develop backup procedures for eConsent
- Invest in comprehensive training and ongoing support for site staff
- Implement long-term validity and storage solutions

DtP IMP delivery in RADIAL

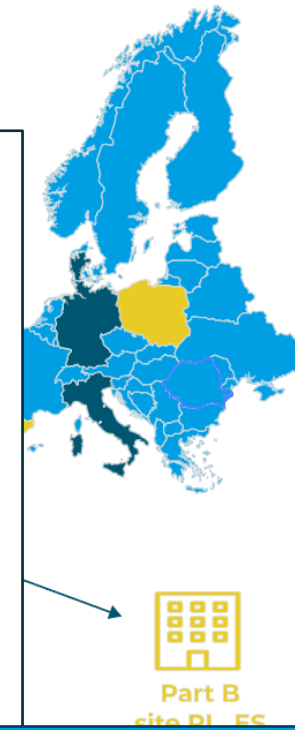
> Br J Clin Pharmacol. 2023 Dec;89(12):3512-3522. doi: 10.1111/bcp.15850. Epub 2023 Jul 29.

Direct-to-participant investigational medicinal product supply in clinical trials in Europe: Exploring the experiences of sponsors, site staff and couriers

Amos J de Jong¹, Yared Santa-Ana-Tellez¹, Mira G P Zuidgeest², Renske J Grupstra¹, Fatemeh Jami³, Anthonius de Boer^{1 4}, Helga Gardarsdottir^{1 5 6}; Trials@Home Consortium

Affiliations + expand

PMID: 37438875 DOI: 10.1111/bcp.15850



Be clear on what you're talking about → 4 models with difference in acceptance in different countries:

1. Site (pharmacy) – courier – participant
2. Central pharmacy – courier – participant
3. Sponsor – courier – participant → not in RADIAL
4. Local pharmacy – courier – participant → not in RADIAL

Participant

Hybrid Participant (V6 visit)



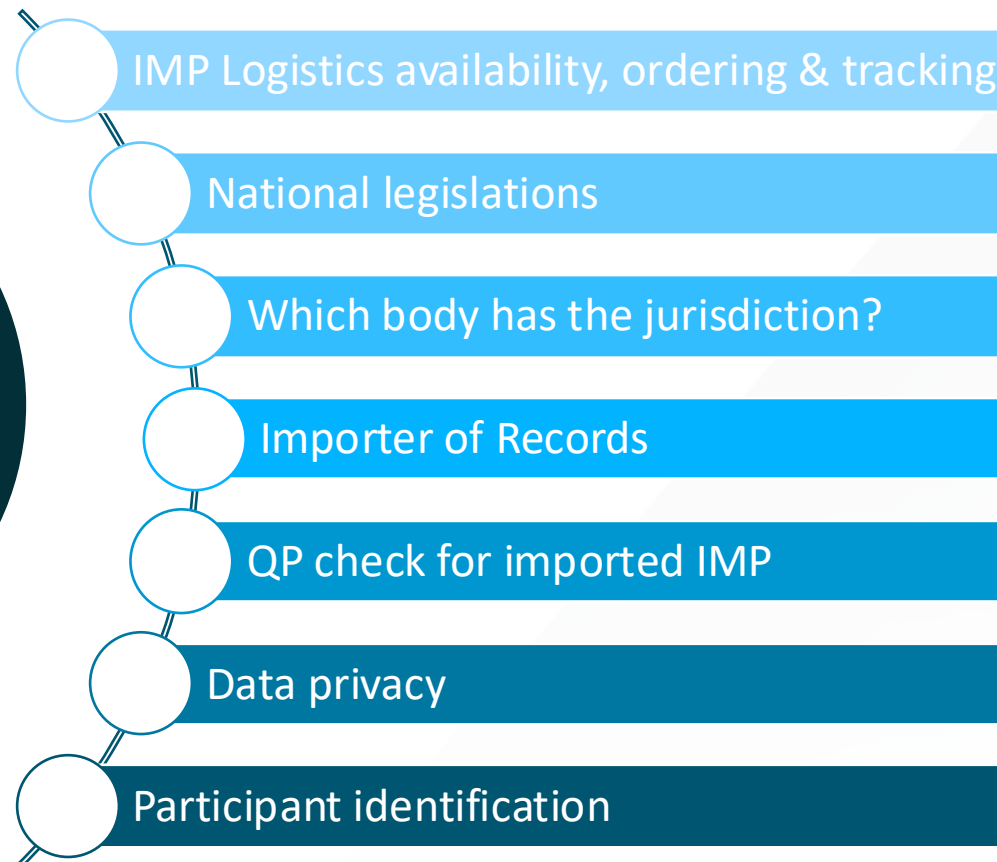
Part B site

DtP IMP delivery in RADIAL

Protocol approved in CTIS based on one general DtP IMP description

**Operationalizing
DtP IMP**

**The devil is in
the details**



Site satisfaction & perceptions in RADIAL

Recommendations

- Change reimbursement for site activities
- Assess site readiness for DCT elements
- Consider digital literacy of site personnel
- Ensure timely site contracting

- Sites preferred hands-on, live demonstrations and test systems for device usage and app navigation.
- Many interviewees emphasised that a responsive and knowledgeable helpdesk is crucial

“Multiple IT platforms had been quite a learning curve, I think being provided with a 'dummy' patient would have helped with learning.”





Technology Learnings from the RADIAL Trial

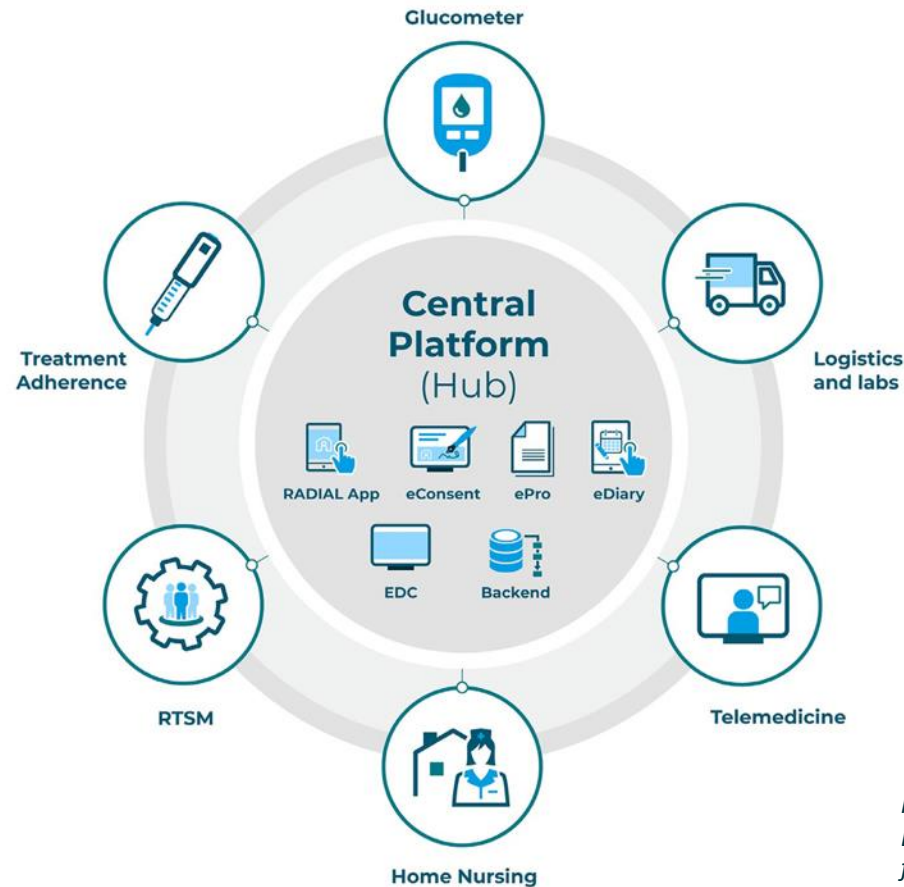
Sten Hanke

BBMRI-ERIC

WP TECH Scientific Lead



Multi-Vendor Hub-and-Spoke Architecture



Hanke, S., Giannikopoulos, D., Neumayer, B., Vedenkannas, T., Davey, R., Mpaltadoros, L., Guthrie, B., Jackson, R., Lagerwaard, B., Zuidgeest, M. and the Trials@Home consortium (2025), Operationalizing Decentralized Clinical Trials: Technology Insights from the Trials@Home RADIAL Proof-of-Concept Trial. *Clin Pharmacol Ther*, 118: 1090-1099. <https://doi.org/10.1002/cpt.70070>

Technology Components & Integration Strategy

Component	Integration Approach	Level
eConsent	Integrated with central platform	Full
Telemedicine	Secure SSO-like link; API link, no data transfer	Partial
Glucometer	App-based Bluetooth + API data transfer	Full
Smart Injector	Deep link to vendor app + weekly API data sync	Partial
Central Lab	Barcode scanning via study app	Partial
Recruitment Portal	External landing page → core platform pre-screener	Partial
RTSM	Manual entry by site staff	None
Shipment / Logistics	Managed via user access roles only	None
Home Nursing	Handled externally to central platform	None

BYOD: Flexibility vs. Real-World Complexity

RADIAL used participants' own smartphones for app use and Bluetooth device connectivity — offering flexibility but introducing significant real-world variability.

Problems

- Varying smartphone models & OS versions
- Outdated systems caused Bluetooth failures
- connection with Smart insulin injector cap
- Generated high support ticket volume

Mitigations

- Mid-study manual glucose entry added
- Video-based troubleshooting support
- Server-side diagnostics recommended

Recommendations

- **Tech Compatibility:** Define strict hardware/software specs for study apps and BYOD (Bring Your Own Device) integration.
- **Diverse Field Testing:** Conduct early-stage pilot tests across global regions using participant-owned hardware.
- **Remote Diagnostics:** Implement server-side logging to enable real-time troubleshooting of remote devices.
- **Agile Fallbacks:** Design "no-update" workflows (e.g., manual entry) to bypass immediate system failures.
- **Hybrid Provisioning:** Provide study-issued devices to participants failing tech specs, while accounting for "dual-device" burden.
- **Run-in Validation:** Use a pre-enrollment phase to verify stable data flow and connectivity before formal entry.

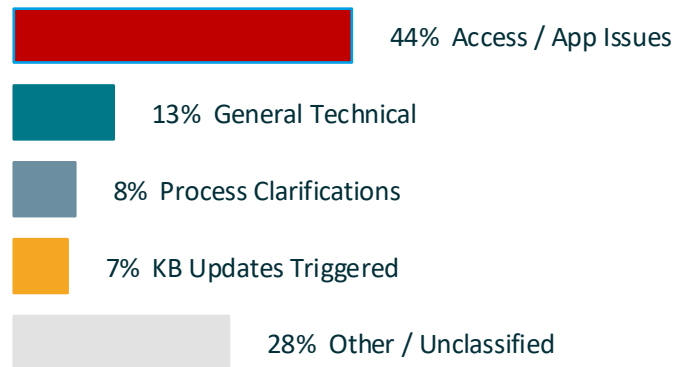
Lesson: Define BYOD requirements early, conduct diverse device testing, and build fallback workflows before go-live.

Technology Support System: Centralized & Multilingual

170

Support
Tickets
Handled

Ticket Distribution



Key Insight

80% of tickets bypassed CRAs — sites contacted support directly.

Ticketing System

Centralized escalation from sites → CRAs → tech support, with external vendor coordination.

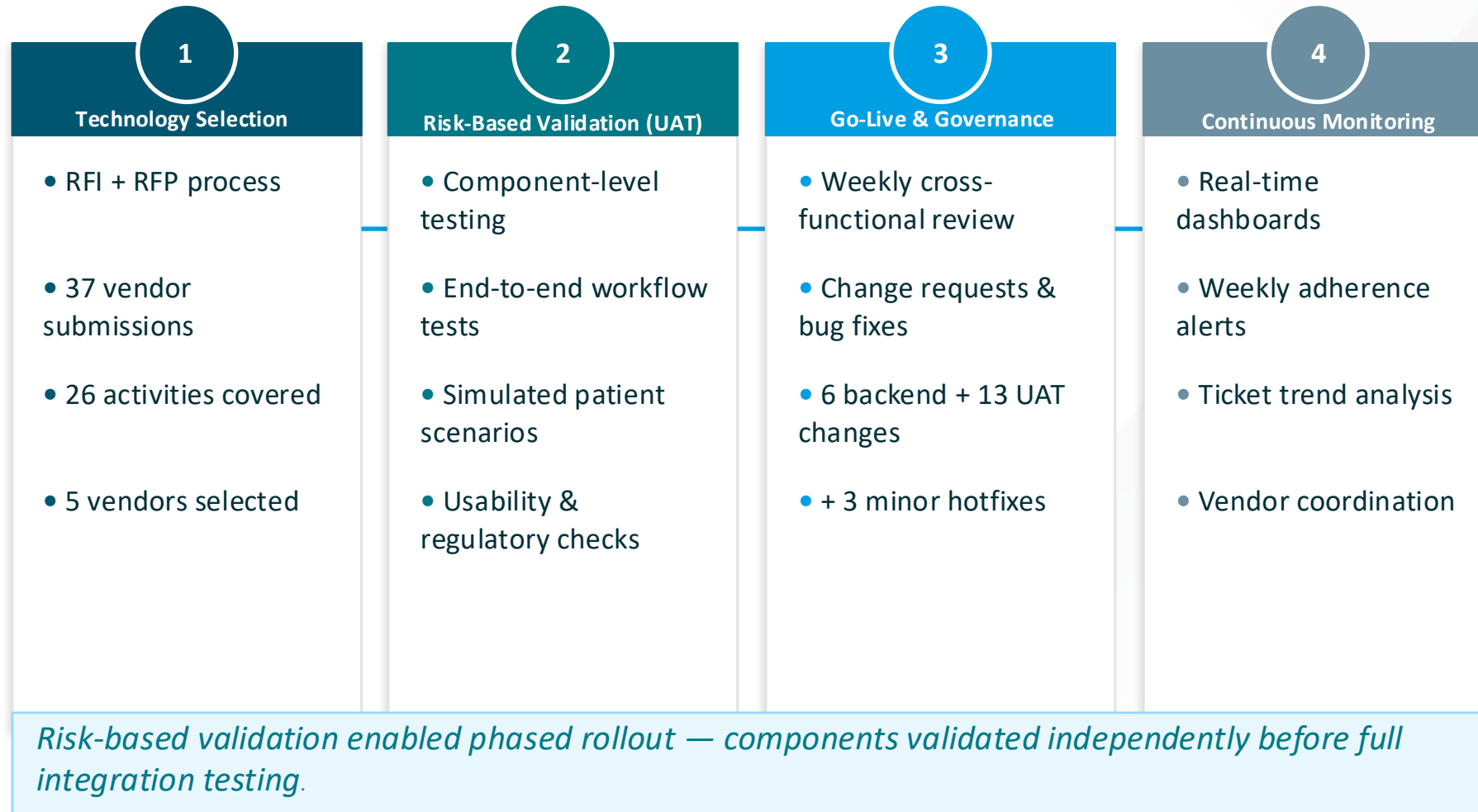
Knowledge Base (KB)

Multilingual, searchable wiki covering FAQs, video tutorials, device guides — continuously updated.

Live Support

Native-language calls introduced mid-study to resolve complex device & access issues in real time.

Deployment, Validation & Post-Go-Live Governance



Key Lessons Learned

1 Prioritize Interoperability

Assess integration readiness & vendor API quality — not just technical feasibility. Lack of standards forced late-stage workarounds in RADIAL.

2 Adopt Modular, Risk-Based Deployment

Validate components independently before integrating. Phased rollout enables regulatory compliance and agility in multi-vendor setups.

3 Use Integration Selectively

'Fit-for-purpose' avoids over-engineering. Manual processes and role-based access were sufficient for low-risk, low-volume workflows.

4 Plan Thoroughly for BYOD

Define compatibility requirements upfront, conduct diverse device testing, enable fallback mechanisms, consider hybrid provisioning.

5 Automated Multichannel Notifications Work

Task-based SMS, email, and in-app alerts guided participant navigation, adherence, and coordinated decentralized workflows.

6 Invest in Cross-Functional Support Early

Centralized support teams, multilingual KB, and live assistance are essential. Site staff should not bear sole tech-support responsibility.

Conclusions & Future Outlook

- ▶ RADIAL confirmed that multi-vendor DCT components can be successfully operationalized across six countries under real-world conditions.
- ▶ The hub-and-spoke architecture enabled flexibility but requires shared data models, interface standards, and early cross-system testing.
- ▶ BYOD demands layered support, pre-defined fallback mechanisms, and rigorous technical screening before and during enrolment.
- ▶ Decentralisation must not shift burden to participants — equitable access and participant-centered design are non-negotiable.
- ▶ The technology support system (ticketing + KB + live support) proved essential; early team engagement and clear escalation paths are critical.

Hanke, S., Giannikopoulos, D., Neumayer, B., Vedenkannas, T., Davey, R., Mpaltadoros, L., Guthrie, B., Jackson, R., Lagerwaard, B., Zuidgeest, M. and the Trials@Home consortium (2025), Operationalizing Decentralized Clinical Trials: Technology Insights from the Trials@Home RADIAL Proof-of-Concept Trial. *Clin Pharmacol Ther*, 118: 1090-1099. <https://doi.org/10.1002/cpt.70070>

Quality and safety of decentralized clinical trials

Results from the RADIAL Proof-of-Concept trial

30 March 2026

Amos de Jong, PhD



Safety and quality outcomes

- Availability of adherence data
- Time to AE reporting
- Missing data
- Query rate

Final analyses are ongoing



Safety and quality outcomes

- Availability of adherence data
- Time to AE reporting
- Missing data
- Query rate



Flowchart

Part A

Assessed for eligibility (n = 175)

Excluded (n = 75)
♦ Not meeting inclusion criteria (n = 75)

Randomized (n = 100)

Allocation

Conventional arm (n = 47)
♦ Received allocated intervention (n = 47)

Hybrid arm (n = 53)
♦ Received allocated intervention (n = 53)

Follow-Up

Discontinued study (n = 4)
♦ Lost to follow-up (n = 2)
♦ Withdrawal by participant (n = 1)
♦ Other (n = 1)

Discontinued study (n = 6)
♦ Lost to follow-up (n = 2)
♦ Withdrawal by participant (n = 1)
♦ Physician decision (n = 2)
♦ Other (n = 1)

Analysis

Analysed (n = 47)

Analysed (n = 53)

Part B

Prescreened (n = 133)

Assessed for eligibility (n = 37)

Excluded (n = 29)
♦ Not meeting inclusion criteria (n = 21)
♦ Other reasons (n = 8)

Allocation

Remote arm (n = 8)
♦ Received allocated intervention (n = 8)

Follow-Up

Discontinued study (n = 2)
♦ Lost to follow-up (n = 1)
♦ Withdrawal by participant (n = 1)

Analysis

Analysed (n = 8)

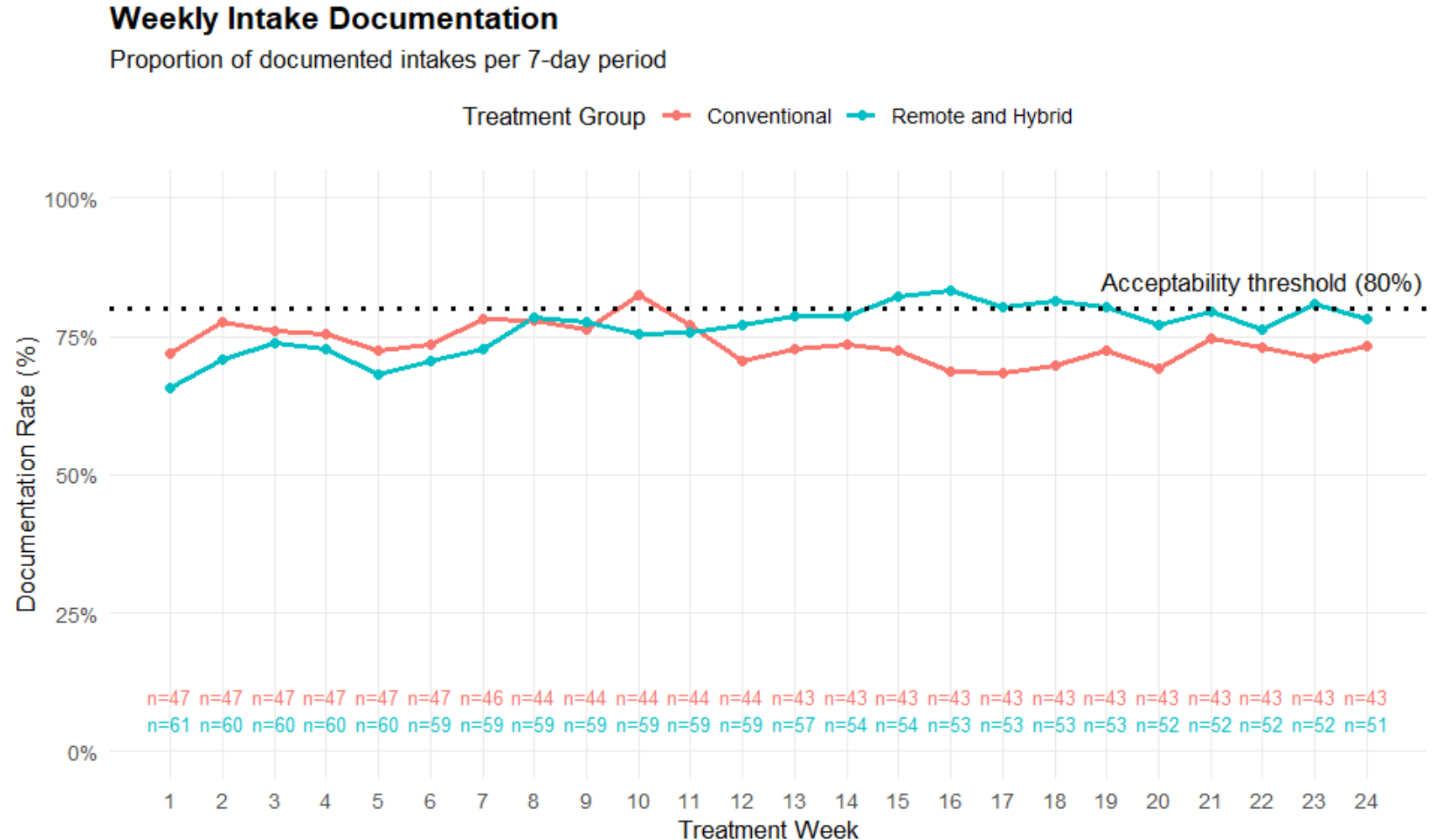
Participant characteristics

	Conventional (N=47)	Hybrid (N=53)	Remote (N=8)	Total (N=108)
Female sex, n (%)	13 (27.7)	17 (32.1)	3 (37.5)	33 (30.6)
Age, years (median, IQR)	64.0 (12.0)	66.0 (14.0)	62.0 (7.3)	64.0 (12.0)
Distance from site (km)				
Median (IQR)	8.1 (13.0)	8.7 (22.0)	58.0 (530.0)	8.6 (26.0)
Missing	1	4	0	5

Treatment adherence

Percentage of days with documented intake of study drug

- Smart cap and manual: hybrid and remote arm
- Manual: conventional arm
- Adherence acceptability threshold of 80%



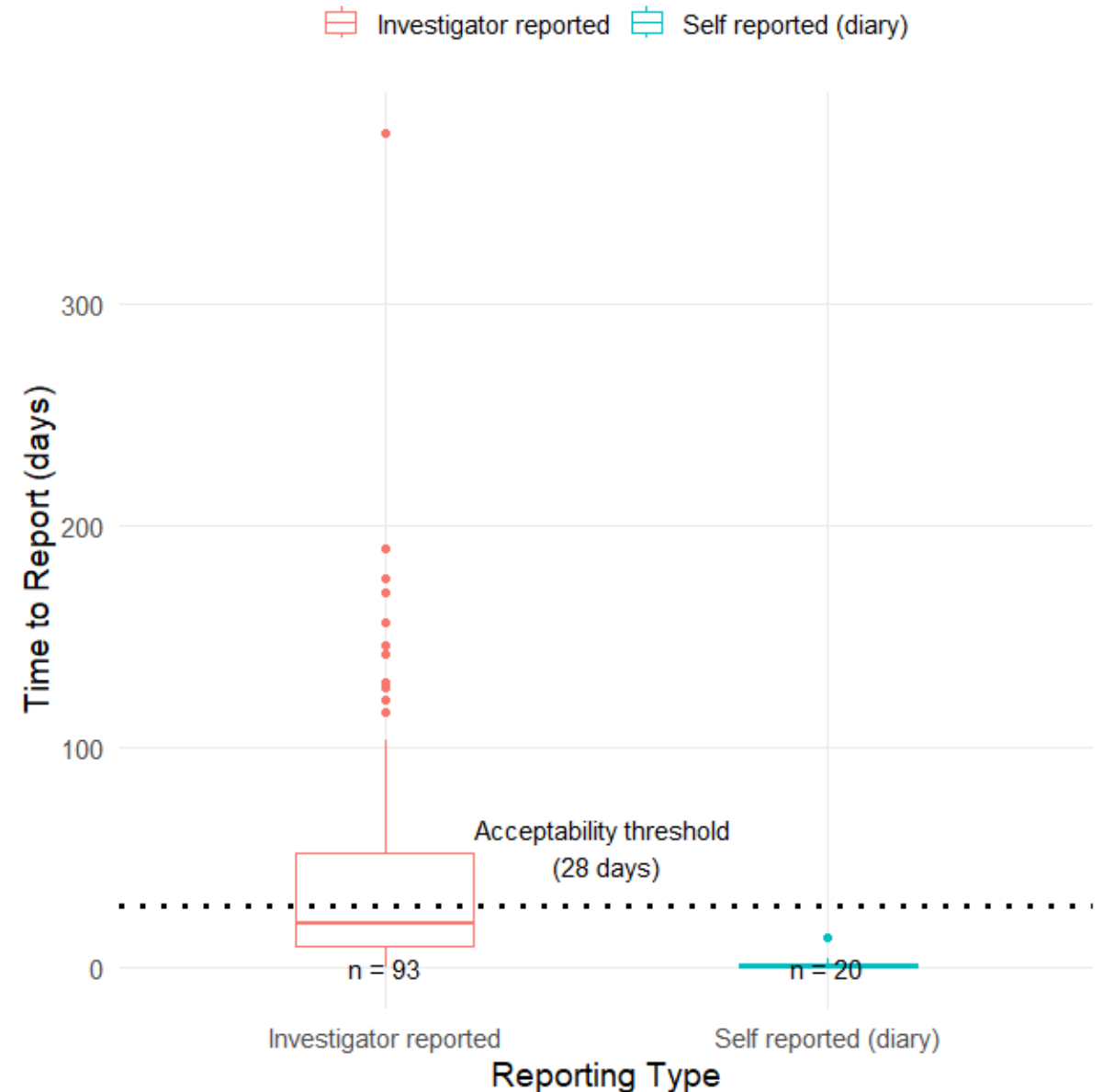
Time to AE reporting

- Hybrid and remote arms allowed for self-reporting
- Acceptability threshold: 28 days

	Self-reported (N = 20)	Investigator-reported (N=93)	
		Conventional (N = 42)	Hybrid and remote (N = 51)
Severity score, n (%)			
Mild	8 (40.0)	26 (61.9)	34 (66.7)
Moderate	7 (35.0)	16 (38.1)	17 (33.3)
Severe	5 (25.0)	0 (0.0)	0 (0.0)
Treatment given for event, n (%)			
	12 (60.0)	23 (54.7)	19 (37.3)

Time to Adverse Event Reporting

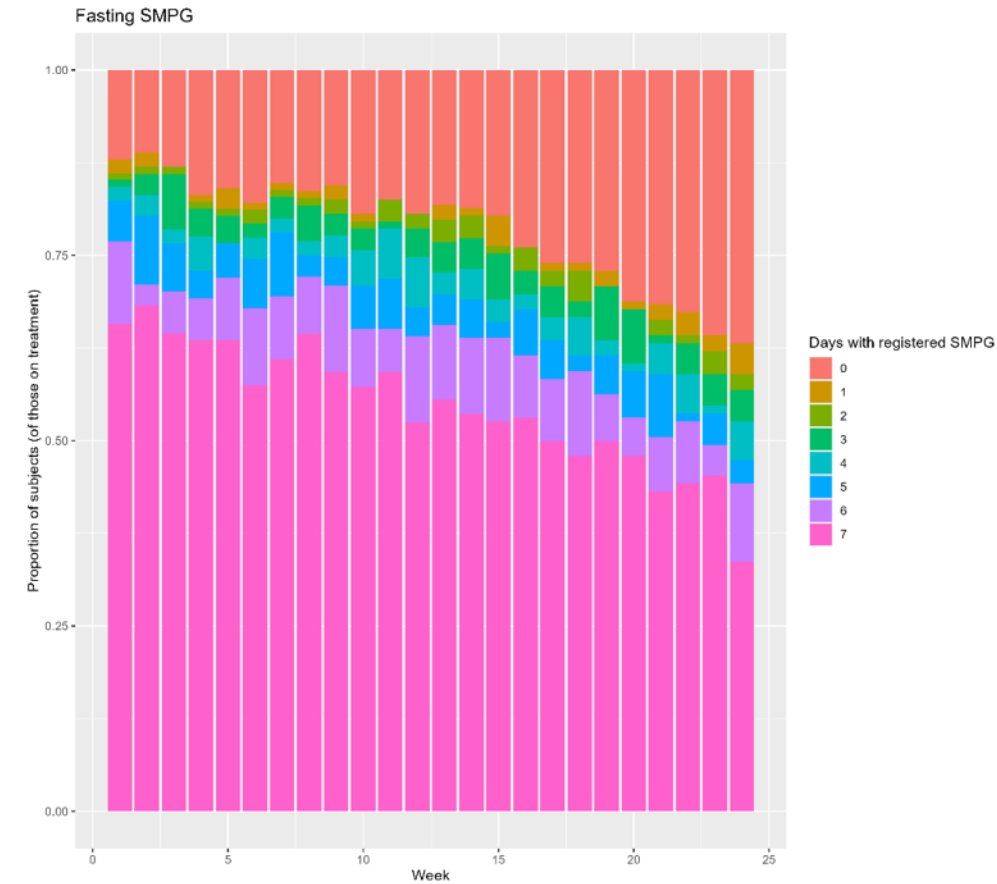
Comparison of Investigator-Reported vs Self-Reported Events



Missing data

Proportion of data available to what was expected

	Conventional	Hybrid	Remote
HbA1c	94.7	92.7	77.3
ePRO	86.5	81.8	77.3
SMPG	60.4	60.0	61.0



SMPG availability over time

Take home messages

- RADIAL results show that decentralized elements can be safely implemented in diabetes mellitus trials
- Remote participant monitoring using mobile applications reduces time between AE occurrence and reporting, and can complement investigator solicitation
- Technology should be extensively tested and mitigation strategies should be in place to limit missing data





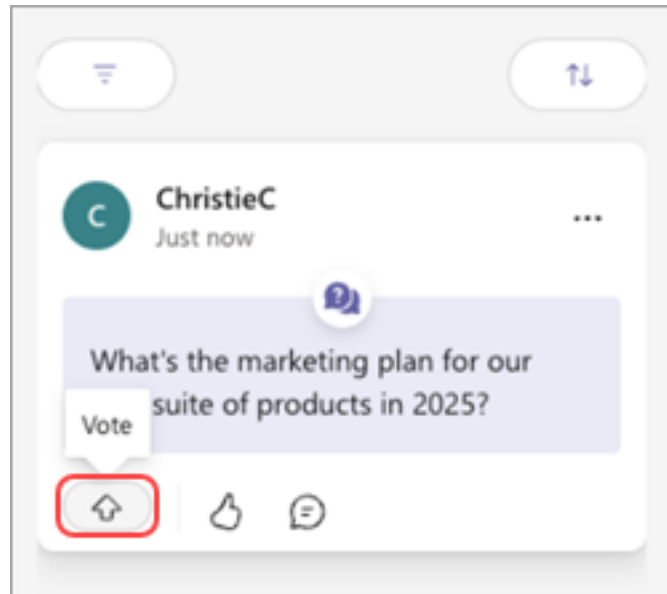
Q&A



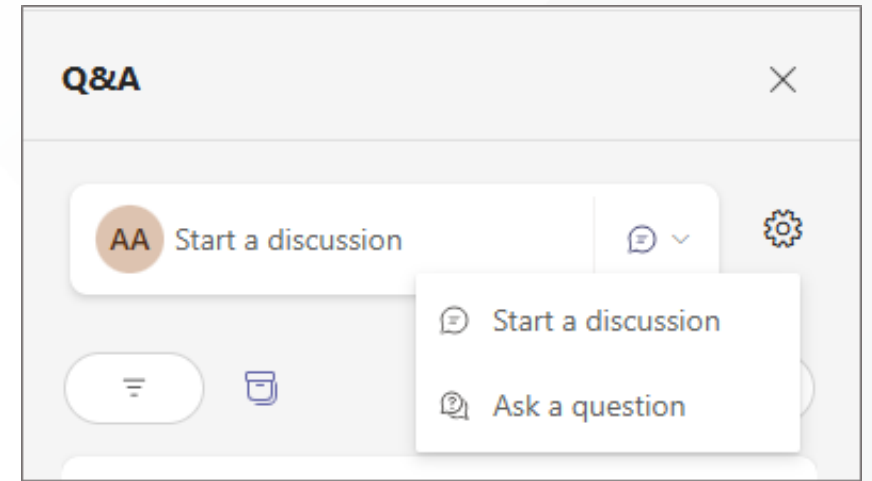
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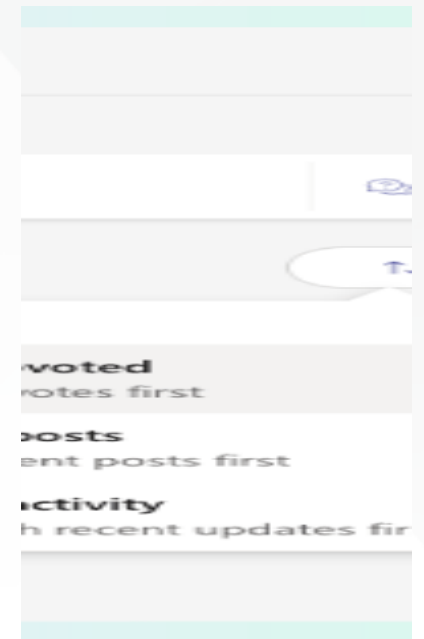


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In-depth recommendations per theme

Explore our in-depth recommendations for decentralising specific trial activities, divided into themes.



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Patient Considerations & Involvement

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Next webinar: ~June 2026

Patient preference & Participant Satisfaction with DCT approaches

