

831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP3 – PILOT

D3.8 Report on final evaluation of the Pan-EU pilot regarding KPI and learnings

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Abstract

The Trials@Home consortium investigated how clinical trials can transition from traditional site-based settings to participants' everyday environments. These Decentralized Clinical Trials (DCTs) leverage digital tools and operational innovations, reducing or even eliminating the need for participants to visit clinical trial centers. Our work included mapping and evaluating existing and emerging technologies for DCTs, alongside conducting a pan-European proof-of-concept study.

The RADIAL proof-of-concept trial assessed the scientific and operational feasibility of fully decentralized and hybrid trial designs compared to conventional site-based approaches. RADIAL was a three-arm, parallel-group, open-label, multi-center, low-intervention Phase IV trial involving people with Type 2 diabetes across six European countries (Germany, Denmark, Spain, Italy, Poland, and the UK).

Key Performance Indicators (KPIs) included recruitment, retention, diversity, site and participant satisfaction, cost, safety oversight, treatment adherence, and data quality. This report gives an overview of where the results of the analysis of KPIs and learnings can be found. The main source is scientific articles, and a series of six papers has been published on RADIAL. In addition, the Clinical Study Report is publicly available.

The RADIAL paper series

Findings and insights have been published in multiple scientific papers, including a dedicated series of six articles on RADIAL in *Clinical Pharmacology & Therapeutics*. An overview of these papers is provided below. In addition, more scientific articles are being published based on the data from RADIAL and experiences in Trials@Home. The full list of articles is available at <https://trialsathome.com>.

1. 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, Duco Veen, Helga Gardarsdottir, Isla S. Mackenzie, Sabine Dupont, Diederick E. Grobbee, on behalf of the Trials@Home consortium

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“The interest in trials in which activities are being moved to the participants' direct environment, that is, decentralized, has increased in recent years, but limited research has been conducted into the feasibility and acceptability of such approaches. The Trials@Home RADIAL proof-of-concept (PoC) trial aims to assess the scientific and operational feasibility and quality of a fully decentralized and hybrid trial approach compared to a conventional, site-based approach. RADIAL is a three-arm parallel-group, open-label, multi-center low-intervention phase IV trial conducted in people living with Type 2 diabetes mellitus in six European countries (DE, DK, ES, IT, PL, UK). The RADIAL trial compares three arms with the same clinical intervention (Insulin Glargine 300 U/mL) but differing degrees of decentralization (the methodological intervention), including online recruitment, remote consenting, remote visits, home-shipment of Investigational Medicinal Product and study materials, home-based biological sample collection, app-reported events/ePROs, and home-devices for data collection. Key Performance Indicators regarding recruitment, retention, diversity, site satisfaction, participant satisfaction, cost, safety oversight, treatment adherence, and data quality are the main outcomes of the trial. This paper discusses the set-up of RADIAL, describing the design, endpoint selection, and decentralized elements evaluated, as well as discussing insight from RADIAL for future PoC trials. This is the introductory paper in a series of six papers in which we share the lessons learned during set-up, regulatory submission, and conduct of RADIAL. By sharing these insights, we aim to support clinical trial designers, technology developers, and other stakeholders to successfully implement decentralized elements into clinical trials.”

2. Regulatory Interactions and Learnings—RADIAL the Trials@Home Proof-of-Concept Trial on Decentralization

Helga Gardarsdottir, Hamidou Traore, Kate Huntley, Dinesh Mistry, Amos J. de Jong, Agnes Legathe, Tim de Smedt, Scott Askin, Megan Heath, Solange Corriol-Rohou, Bart Lagerwaard, Mira G.P. Zuidgeest, on behalf of the IMI Trials@Home Consortium

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<https://doi.org/10.1002/cpt.70078>

“In this paper, insights from multiple formal regulatory interactions related to the RADIAL trial, conducted between 2021 and 2022, are presented. These interactions included (i) a consultation with the European Medicines Agency’s Innovation Task Force, (ii) a national Scientific Advice procedure, and (iii) the clinical trial application submission under the EU Clinical Trials Regulation (Regulation EU 536/2014). Given the novelty of the decentralized approach and lack of guidelines, many constructive comments and questions were received that supported the finalization of the protocol and conduct of the trial. It is important to acknowledge that clinical trials often span multiple countries and regulatory jurisdictions, creating complexity due to variations in complementary national legal and regulatory requirements. We conclude that early and continuous regulatory engagement is essential for the successful implementation of innovative trial designs. Although progress has been made in supporting decentralized clinical trials, persistent challenges related to legislative heterogeneity remain. Harmonized regulatory guidance and greater transparency through the sharing of regulatory experiences will be key to facilitating the broader adoption of decentralized approaches and advancing clinical trials in Europe.”

3. Selecting and Preparing Clinical Sites for the Successful Conduct of Decentralized Clinical Trial Activities—Findings From the Trials@Home RADIAL Proof-of-Concept Trial

Katarzyna Lipinska, Danny van Weelij, Bart Lagerwaard, Linda Rutgrink, Eduard Vardianu, Petra Naster, Lina Pérez-Breva, Paul Bodfish, Megan Heath, Yvonne van Rijswijk, Diederick E. Grobbee, Mira G.P. Zuidgeest, on behalf of the Trials@Home consortium

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“Decentralized clinical trials (DCTs) offer opportunities to improve trial accessibility, participant convenience, and efficiency, yet may pose significant operational challenges for clinical trial sites. This paper presents the operational insights gained from selecting, training, and supporting clinical sites within the RADIAL proof-of-concept trial, part of the Trials@Home project. RADIAL was a multicenter, low-intervention phase IV trial comparing conventional, hybrid, and fully decentralized approaches for individuals with type 2 diabetes mellitus across six European countries. Site selection involved detailed feasibility assessments evaluating operational capabilities, recruitment potential, technological readiness, and willingness to implement decentralized elements. Despite proactive training, including ongoing support via a centralized helpdesk, sites faced initial difficulties with technology management and participant onboarding. Contractual complexities were prominent, particularly regarding clearly delineating responsibilities and data handling in agreements involving third-party providers. Moreover, integrating third-party services necessitated meticulous oversight strategies and continuous stakeholder coordination to ensure regulatory compliance and efficient trial management. Our experiences underscore essential considerations for future DCT implementations: proactive stakeholder alignment; tailored, timely, and ongoing training and support; intuitive technology design informed by clinical user input; robust, centralized oversight structures; and clearly defined delegation frameworks for third-party engagements. Addressing these operational considerations will facilitate smoother transitions toward decentralized clinical research models, maximizing their potential benefits while managing associated complexities effectively—especially for clinical site staff.”

4. Recruiting and Consenting Decentralized Clinical Trial Participants—Learnings from the Trials@Home RADIAL Proof-of-Concept Trial

Bart Lagerwaard, Linda Rutgrink, Danny van Weelij, Katarzyna Lipinska, Tina Bornemann, Robert Davey, Jaime Fons-Martinez, Sabine Dupont, Diederick E. Grobbee, Mira G. P. Zuidgeest, on behalf of the Trials@Home Consortium

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“Clinical trials often face recruitment challenges. From the participant’s perspective, barriers such as time commitment, travel to sites, and logistical burden, like arranging care duties or time off work, can deter enrolment. Decentralized clinical trials (DCTs) aim to address these by shifting activities closer to participants’ homes and using online methods for recruitment and consent. This study explores recruitment strategies and remote eConsent implementation in a decentralized setting. The RADIAL trial, a three-arm, open-label, phase IV study in six European countries, enrolled participants with type 2 diabetes mellitus administering Insulin Glargine 300 U/ml. Recruitment strategies included online campaigns, search engine advertising, social media, and research database outreach. The remote consent process involved eConsent, telemedicine consultations, eidentification, and eSignatures. Online recruitment campaigns generated a lot of impressions but led to very few pre-screener completions or enrolments. In contrast, outreach through research databases proved more effective, accounting for 7 of the 8 enrolled participants in the decentralized arm. Major pre-screening drop-off occurred at the initial consent step, with 69% exiting before data collection. Eleven participants successfully completed eConsent; 4 others required remote paper-based consent due to eidentification issues. Implementing the multimedia-enhanced eConsent system was resource-intensive, complicated by country-specific layouts and differing regulatory requirements. Tailored recruitment strategies and simplified remote consent processes are needed to enhance the accessibility and efficiency of DCTs. Further research should optimize targeting and keyword use in online recruitment.”

5. The Supply of Investigational Medicinal Product and Management of Study Materials for Decentralized Participants—Insights from the Trials@Home RADIAL Proof-of-Concept Trial

Megan Heath, Amos J. de Jong, Shaun Magorrian-Spence, Chao Jin, Danny R. van Weelij, Lucas Pagnier, Yvonne van Rijswick, Volker Haufe, Bart Lagerwaard, Mira G. P. Zuidgeest, on behalf of the Trials@Home Consortium

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“Decentralized clinical trials (DCTs), which move trial activities to participants’ homes or direct surroundings, offer potential advantages over conventional site-based trials through reduced participant burden and improved accessibility. The direct-to-participant (DtP) delivery of investigational medicinal products (IMPs) and other study materials and collection of biological samples requires careful planning and execution to ensure participant safety and data integrity. Here, we report operational experiences from the RADIAL proof-of-concept trial, a three-arm parallel-group study conducted across six European countries comparing conventional, hybrid, and fully decentralized approaches in type 2 diabetes patients. The study implemented two DtP IMP models: clinical trial site-to-participant and central pharmacy-to-participant delivery, with comprehensive logistics tracking and temperature monitoring. In RADIAL, 68 DtP IMP shipments were executed with a 94% successful delivery rate. Four shipments (6%) failed due to participant unavailability, temperature excursions, defective monitoring equipment, or courier loss. The central pharmacy model demonstrated inventory savings compared with conventional site-based distribution. Biological sample collection for HbA1c assessment was done through drop-off, which proved more challenging in the remote arm. Key challenges related to DCT logistics as experienced in RADIAL included unclear importer/exporter responsibilities, regulatory divergence across countries, participant material management, and sample drop-off reliability. DtP IMP delivery and biological sample collection are feasible in European DCTs but require enhanced planning, clear vendor responsibilities, and robust contingency procedures. Success depends on appropriate participant training, reliable courier services, temperature control systems, and accessible biological sample collection methods.”

6. Operationalizing Decentralized Clinical Trials: Technology Insights from the Trials@Home RADIAL Proof-of-Concept Trial

Sten Hanke, Dimitrios Giannikopoulos, Bernhard Neumayer, Tea Vedenkannas, Robert Davey, Lampros Mpaltadoros, Brian Guthrie, Rebecca Jackson, Bart Lagerwaard, Mira Zuidgeest, on behalf of the Trials@Home consortium

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“While decentralized clinical trials (DCTs) hold great promise for improving trial accessibility and efficiency, the effective deployment of DCT elements requires robust technological infrastructure and careful system integration. Although several innovative technologies are now available for implementing DCT elements, most existing setups integrate single-vendor solutions, which restrict the potential for tailored trial designs as well as seamless interoperability between different platforms and solutions. This paper presents operational learnings from the Trials@Home RADIAL proof-of-concept trial. RADIAL implemented a modular, multi-vendor technology package. RADIAL adopted a deliberate strategy to avoid a monolithic “one-vendor-for-all” solution, instead selecting technologies and integrating them only where it added clear value. Core systems—such as eConsent and Bluetooth glucometer—were fully integrated into the central platform, while other components were deliberately managed outside the core system. The aim was to implement and validate a multi-vendor technology setup and generate learnings that would help DCT trialists in designing DCTs, especially in terms of technology selection and integration. Key challenges arose from Bring Your Own Device (BYOD) variability, immature device technologies, and infrastructure limitations at clinical sites—particularly affecting components like telemedicine. The results emphasize the significance of investing in participant support infrastructure, as well as early cross-functional support, while automated, multichannel notifications seem to guide participant engagement. Finally, embedding compliance by planning early streamlines documentation through a clear governance model seemed to enhance agility and reduce burden.”

The Clinical Study Report (CSR)

The Clinical Study Report (CSR) for RADIAL has been prepared by the consortium and will become available in 2025 on DataverseNL (<https://dataverse.nl/>).