

831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP3 – PILOT

D3.9 Report on status of posting results

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Document History

Version	Date	Description
V1.0	27 November 2025	First version

The Trials@Home project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 831458. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA. <http://www.ih.europa.eu/>

The research leading to these results was conducted as part of the Trials@Home consortium. This paper 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.

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).

The results of the trial are available through CTIS.

Results

This trial was registered with identifier NCT05780151 in clinicaltrials.gov and under 2022-500,449-26-00 in the Clinical Trials Information System (CTIS) clinical trial database.

The protocol will become available in DataverseNL in 2025 (<https://dataverse.nl/>).

The clinical trial summary results information has been submitted to MHRA on 18/11/2025 and the synopsis of the Clinical Study Report (CSR) as well as the (translated) lay summaries were submitted to CTIS on 24/11/2025.

The CSR will also become available in DataverseNL in 2025 (<https://dataverse.nl/>).