



831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP3 – PILOT

D3.5 First study subject approvals package

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Document History

Version	Date	Description
V1.0	20-12-2022	Ethical approvals for RADIAL

Summary of the submission process

As part of Trials@Home, a clinical trial will be conducted. The acronym of this trial is RADIAL. RADIAL is a pan-European proof-of-concept study comparing Decentralised Clinical Trial (DCT) and hybrid approaches to conventional clinical trial approaches in patients with Type 2 diabetes mellitus treated with Toujeo®.

The clinical trial submission in the Clinical Trials Information System (CTIS) was initiated on the 28th of March 2022 for conduct in Denmark, Germany, Italy, Spain, and Poland. On the 14th of June, the consortium received the RFI for CTIS part I. The comments from the regulators have been addressed in the response document and, where required, also in the protocol. The new protocol and response document were submitted in CTIS on the 27th of June. The different versions of the protocol have been shared in Deliverable 3.4.

Approval for CTIS part I was received on the 18th of July, after which the documents for CTIS part II were submitted. The final approvals for Denmark, Germany, Italy, Spain, and Poland were received between the 2nd and 28th of November 2022. For the United Kingdom, the submission process was initiated on the 22nd of July after which we went through a round of RFI questions. Approvals were received on the 8th of November 2022.

The submission documents for CTIS, including the protocol, are publicly available through <https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en> (search for 'RADIAL'). The approvals will be retained in the Trial Master File. The submission documents for the UK are the same as for CTIS, with the addition of patient facing materials as used during the trial.

Approval for RADIAL in the United Kingdom

19 October 2022 – NHS HRA REC Ethical approval (available upon request)

8 November 2022 – NHS HRA and Health and Care Research Wales (HCRW) approval (available upon request)

16 November 2022 – MHRA acceptance of the amended request (available upon request)

Approval for RADIAL in Denmark, Germany, Italy, Spain, and Poland

Member state	Current status	Decision date
Denmark	Authorised	02/11/2022
Germany	Authorised	17/11/2022
Italy	Authorised	23/11/2022
Spain	Authorised	25/11/2022
Poland	Authorised	28/11/2022

This overview of the trial status as well as the decision documents are publicly available through <https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en> (search for 'RADIAL')