Poster 866

ATTD 2025

March 19–22
AMSTERDAM, NL

RADIAL STUDY: A EUROPEAN INNOVATIVE MEDICINES INITIATIVE ASSESSING A DECENTRALIZED CLINICAL TRIAL APPROACH IN PEOPLE WITH TYPE 2 DIABETES TREATED WITH BASAL INSULIN

Melanie Davies[1], Fernando Gomez-Peralta[2], Emanuela Setola[3], Jacob Volmer Stidsen[4], Anna Siegel[5], Megan Heath[6], Valerie Pilorget[7], Mireille Bonnemaire[7], Mira Zuidgeest[8]

[1]Diabetes Research Centre, University of Leicester, Leicester, United Kingdom; [2]Head of Endocrinology and Nutrition Unit Segovia General Hospital, Segovia, Spain; [3]Cardio-Metabolic and Clinical Trials Unit, Internal Medicine Department, Italy; [4]Steno Diabetes Center Odense, Odense University Hospital, Odense, Denmark; [5]Pratia Medical Center, Katowice, Poland; [6]Sanofi, Reading, United Kingdom; [7]Sanofi, Paris, France; [8]Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, The Netherlands

To download e-poster and/or to listen to author summary scan the QR code

Summary

E-poster

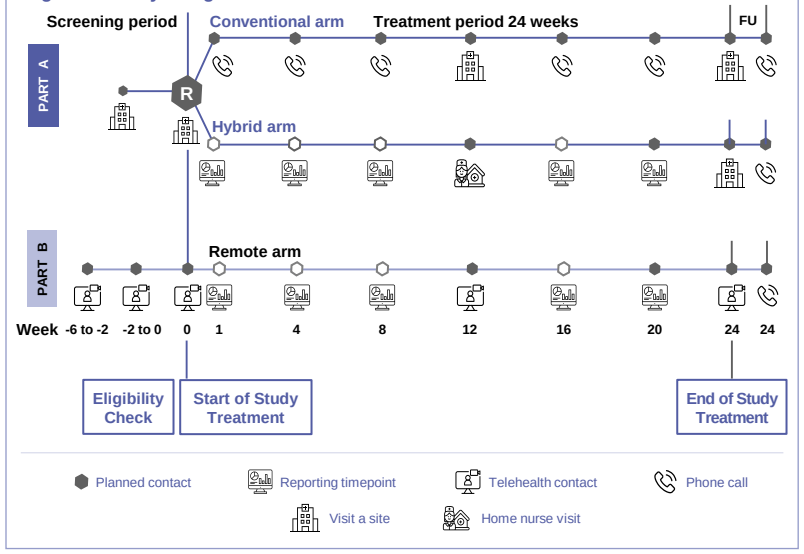
BACKGROUND AND RATIONALE

- Traditionally, clinical trials took place in research sites, requiring face-to-face visits and relying on physician networks, and in-person recruitment due to limited digital infrastructure.
  - Slow patient recruitment, low retention, and selective participation affects both the efficiency and the generalizability of the findings to clinical practice.
- The growing body of evidence supports using new digital technologies to conduct telehealth interactions and improve the monitoring and management of clinical trial participants.
- Decentralized clinical trials (DCT) are expected to make clinical trials more accessible to participants by moving activities to participants' homes or local settings, often by using technology, reducing the need for physical visits and easing the burden on participants.
- Additionally, decentralized approaches may accommodate more diverse population, and increased data collection in a real-world setting.
- Type 2 diabetes mellitus (T2DM) was selected for RADIAL study because of its high prevalence and using digital tools for disease monitoring and treatment.

OBJECTIVE

This proof-of-concept RADIAL study is designed to compare the scientific quality and operational feasibility of fully decentralized and hybrid approaches versus conventional approaches to provide insights to regulatory agencies and other stakeholders.

Figure 1: Study design



- RADIAL is a parallel-group, open-label, multi-center study which aims to compare three operational trial approaches (fully decentralized, hybrid and conventional) for their scientific and operational quality (**Figure 1**).
- People with T2DM with glycated hemoglobin (HbA1c) between 7%–10% and treated with basal insulin were enrolled from Denmark, UK, Spain, Italy, Germany and Poland (**Figure 2**)
- The scheduled frequency and timing of visits/reporting timepoints, as well as the collection of information, were consistent across all arms.

- **Conventional arm:** Study visits were conducted in-person at the clinical site. During the study, participants received phone calls to collect data at scheduled timepoints and visited the clinical site during screening, at baseline, Week 12 and at end of treatment (EOT).
- **Hybrid arm:** In-person visits were scheduled at screening, baseline, and EOT. A home nurse visit was scheduled at Week 12.
- **Remote arm:** Enrolment and eligibility checks were conducted fully remote with telehealth contacts during screening, baseline, Week 12 and at EOT. This arm was fully decentralized from recruitment model, through intervention, up to data collection.
  - At scheduled reporting timepoints, participants received notifications via the RADIAL study app to confirm their eDiary data was complete and accurate for both **Hybrid** and **Remote** arm.

STUDY POPULATION

- Age ≥18 years; T2D for at least 1 year HbA1c: 7.0% to 10.0%
- Treated with basal insulin for at least 3 months
- Access to a tablet/smartphone that supports remote data entry and video conferencing
- Signed informed consent, and capable of performing daily activities with minimal assistance

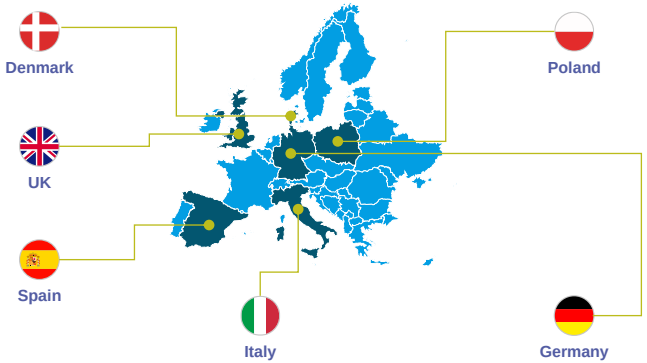
OBJECTIVE /ENDPOINTS

- The primary objective was to assess the potential benefits of a DCT approach on participant retention, recruitment, diversity, cost, site staff and participant satisfaction.
- The co-primary objective was to determine acceptability of a DCT approach by measuring variables related to safety oversight, treatment adherence and data quality (missing data and query rate) within arms that have a different degree of decentralization.
- The key secondary objective was to determine whether the efficacy of insulin glargine 300 U/mL fell within the accepted range across the arms with different degree of decentralization.
- All primary and secondary endpoints were analyzed using descriptive statistics, both the intent-to-treat and safety population sets.

STUDY ASSESSMENTS

- Early and ongoing feedback was collected using the Trials@Home Patient Expert Panel, patient consultations, and surveys.
- These efforts aimed to understand the life of people living with T2DM and what would attract them to participate in a clinical trial, identify potential hurdles for recruitment, adherence with the planned study procedures, and learn about patient and physician relationship.
- Based upon assignment, endpoint assessments were performed by clinical site personnel or study participants.
- Patient-reported outcome (PRO) questionnaires were prompted via automatic reminders and were filled out in the study app.
- The questionnaires needed to be completed independently, outside scheduled visits by the study participant within the allocated time window.

Figure 2: Participating countries in the RADIAL study



CONCLUSIONS

- Enrolment into this study has been closed and data are being analyzed.
- Outcomes of this RADIAL EU study is expected to provide insights into KPIs related to data quality, study feasibility, and PROs from both participants and investigators.

DISCLOUSRE

MD: Consultant/advisor and speaker: Eli Lilly, Novo Nordisk and Sanofi; Advisory boards: Amgen, AstraZeneca, Biomea Fusion, Carmot/Roche, Sanofi, Zealand Pharma, Regeneron and EktaH; Grants: AstraZeneca, NovoNordisk and Boehringer Ingelheim; Speaker: AstraZeneca and Boehringer Ingelheim.

FG: Advisory board: Insulcloud S.L., Abbott Diabetes, Novartis, Astra Zeneca, Sanofi and Novo Nordisk; Participated as principal investigator: Sanofi, Novo Nordisk, Boehringer Ingelheim, and Eli Lilly; Speaker: Abbott, Novartis, Sanofi, Novo Nordisk, Boehringer Ingelheim, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Co., and Eli Lilly.

ES: Research grant: Sanofi, Novo Nordisk, Eli Lilly, Novartis, Bayer, New Amsterdam, Amgen, Astra Zeneca; Advisory board: Boehringer Ingelheim

JVS, AS and MZ: declare no conflict of interest.

MH, VP and **MB** are employees of Sanofi and may hold shares and/or stock options in the company.

ACKNOWLEDGEMENT

Medical writing assistance was provided by Silpi Mishra, M. Pharma and Deepak Gade, Ph.D., of Sanofi.

STUDY SUPPORTED BY:

This work has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home (grant No 831458) (www.imi.europa.eu). As part of their agreed contribution to the consortium, Sanofi provided study drug- insulin glargine-300 U/mL. This communication reflects the views of the Trials@Home consortium and neither IMI nor the European Union and EFPIA are liable for any use that may be made of the information contained herein.