Pink Sheet

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EU Remote Trials Project Gets Moving

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By Vibha Sharma

THE COVID-19 PANDEMIC HAS GIVEN A fresh impetus to the ongoing EU project on remote decentralized trials with more appetite for innovative approaches.

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An EU project that is looking to develop standards and tools for remote decentralized clinical trials (RDCTs) has decided on diabetes as the ideal therapeutic area for a pan-EU pilot that will compare traditional clinical trials to fully and hybrid RDCT approaches.

The pilot is a key part of the Trials@Home project that is expected to result in concrete and practical recommendations in 2024 on how drug companies can use digital technologies to move clinical trials from the traditional clinic setting to the trial participant's immediate surroundings.

Trials@Home is being funded by the Innovative Medicines Initiative - a public private partnership between the EU (through its Horizon 2020 R&D innovation program) and the European pharmaceutical industry body EFPIA. The project involves exploring approaches that allow the widespread acceptance and use of RDCTs, thus reducing the need for a trial participant to visit a clinical trial centre, if at all. *(Also see "Remote Decentralized Clinical Trials Could Solve RCT Problems" - Pink Sheet, 21 Nov, 2019.)*

The five-year project started in September 2019, but has taken on new importance given COVID-19's impact of shuttering nearly the entire global clinical trial infrastructure due to restrictions on free movement. "In all our work, we are incorporating the fast-changing clinical trial landscape" due to the coronavirus pandemic and will "ensure that our [final] recommendations have value for the 'new normal situations' in the future," said Mira Zuidgeest, project lead for Trials@Home at a webinar on 24 June.

The impact of COVID-19 on Trials@Home has been

such that "in a way everything is accelerating," according to project coordinator Diederick Grobbee.

There were many regulatory and quality-related barriers and restrictions when the team first looked into the RDCT context, said Grobbee, who is professor of clinical epidemiology at the University Medical Center Utrecht (UMCU) and also chief scientific officer at the contract research organization, Julius Clinical. "Clearly, the COVID-19 epidemic is affecting that, and we assume that we will enter a situation where there is more room for innovation. There is a lot of appetite for that."

Diabetes Pilot

At the heart of Trials@Home is a pilot in which three groups of patients will be asked to participate in a diabetes trial. One group will have the conventional clinical trial experience with regular clinic visits, the second group will participate completely remotely, and the third group will follow a hybrid (partly conventional/partly RDCT) approach. The results of the pilot will be used to identify which approaches are best for patient satisfaction, data quality and other parameters.

While the pilot will concentrate on a diabetes trial, the overall project will continue to have a broad focus.

Zuidgeest explained that diabetes came out as the "first choice" for the pilot study as it fitted several predefined scientific and operational criteria. In making

its choice, the project team looked at factors such as which therapeutic area could really benefit from RDCT approaches, whether the results from the study could be generalized to other therapeutic areas, and ensuring that there was a clear clinical benefit for the subjects participating in the trial.

Other factors worked in favor of diabetes, said Zuidgeest, an assistant professor at UMCU who works with Grobbee at Julius Clinical. "It has a high disease burden, it involves a large and broad patient population, there are a lot of unanswered research questions still [in this field] and there is a lot of value in doing remote [clinical trial] approaches for this therapeutic area."

On the pilot study's design, the endpoints have not yet been decided. Zuidgeest explained that the main focus of the design will be on comparing operational traditional and RDCT approaches. "We will be looking at key performance indicators as some of the most important endpoints... The quality of data and safety data [from RDCTs] will have to be as good as conventional trials," she said.

Safety concerns and adverse events, for example, will have to be as detectable as they are in a conventional trial setting. Grobbee suggested that some remote technologies, such as wearables, "might even be better in detecting signals" as they are "more sensitive than the conventional methods that we rely on."

The pilot will also explore whether there is any truth in the many claims made by RDCTs in terms of improved patient recruitment and retention levels. On top of these aspects, the pilot study "will have a clinical improvement strategy with a clinical endpoint," Zuidgeest said.

The number of patients to be recruited to the diabetes study will be decided when the endpoints are finalized. "I guess it will be a couple of hundred in each arm," Grobbee said. No decision has been made on which EU member states will be involved, but at least five states are expected to participate in the study.

Best Practices And Other Work Packages

The pan-EU pilot is one of the six interconnected work packages in the Trials@Home project. Before the trial begins, the project will issue recommendations on best practices for RDCTs. The draft recommendations are due to be published this August and these will be updated based on case studies that would run in parallel to the pilot.

To facilitate the pilot, the project team is currently requesting information from companies/vendors on all existing as well as diabetes-oriented technologies that can be deployed in RDCT approaches. "We will take all solutions into account, rate them and hopefully get the best software for our pilot project," said Jeroen De Bruin, senior lecturer at Austria's FH JOANNEUM university and co-lead of the project's tech work package.

The project will also assess the regulatory, ethical, good clinical practice and legal aspects of the current EU environment relevant to RDCTs and identify challenges and solutions. Also RDCT approaches will be discussed with patients, regulators, payers, health technology assessment bodies and ethics bodies to ensure that the project outcomes can be implemented in the EU.

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