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Decentralized Clinical Trials: EU To Demystify Differences Between Member States

by Vibha Sharma

A compilation of the differences and similarities in regulatory requirements for decentralized trials across the EU member states could help sponsors better understand the nuances per country.

Efforts are under way to make it easier for study sponsors to navigate the EU's fragmented regulatory landscape relating to decentralized clinical trials (DCTs).

Members of the EU's DCT project are preparing a report that highlights the differences and similarities in regulatory requirements among EU member states with respect to such trials.

The DCT project was established in March 2022 building on EU's earlier experience with DCTs, which allow certain trial activities to be conducted remotely and in, or near, the homes of study participants. Such trials started becoming more commonplace during the COVID-19 pandemic when social distancing and travel restrictions made it difficult or impossible to conduct trials in the traditional manner.

The DCT project seeks to provide the European medicines regulatory network with a harmonized and transparent approach for the use of DCT elements in clinical trials. Its members comprise, amongst others, clinical trial authorization experts, ethical experts and good clinical practice (GCP) inspectors across the member states.

The report on the differences and similarities in DCT requirements is expected to be published by the end of 2022. It should come as a relief to trial sponsors, who have repeatedly highlighted that they find it difficult to introduce decentralized elements in clinical trials in the EU because there is no common approach to DCTs in the bloc. Sponsors have been asking for help to understand the nuances per country. (Also see "*Is It Tougher To Conduct Decentralized Trials In The EU? 'Don't*

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Fall Prey To Negative Narrative'" - Pink Sheet, 11 May, 2022.)

The report aims to outline the differences in member state requirements regarding the deployment of decentralized elements in clinical trials caused by, for instance, differences in national legislation and infrastructure. It should also help to "find a harmonised way to conduct decentralised clinical trials" in the EU, the European Commission's Expert Group on Clinical Trials (CTEG) noted at its 6 July meeting, the *minutes* of which were published on 15 September.

A first draft of the report, following an internal consultation process, was to be shared among CTEG members this month, according to the meeting minutes. The CTEG provides the commission with advice and expertise on clinical trials in relation to the preparation and implementation of legislation and policy initiatives.

Ethical experts from the CTEG are part of the EU DCT project team, which also includes experts from the EU Heads of Medicines Agencies' Clinical Trials Coordination Group and inspectors from the European Medicines Agency's GCP Inspectors Working Group.

EU DCT Guidance Coming Soon

Other work under way by the EU DCT project team includes the development of a much-anticipated recommendation paper on the use of decentralized elements in clinical trials. This paper is to be discussed at a multistakeholder workshop that the EMA is due to host on 4 October.

At the workshop, stakeholders from different areas of the research community will get an opportunity to provide feedback on the DCT recommendation paper, which is planned for publication in Q4 2022. (Also see "*Plans Press On To Harmonize Decentralized Clinical Trial Requirements In EU*" - Pink Sheet, 8 Aug, 2022.)

The event will also allow the EU DCT project group to present an update on how the European medicines regulatory network has supported DCTs through collaborative initiatives. The DCT project was *established* as part of the priority actions listed in the Accelerating Clinical Trials in the EU (ACT EU) initiative. (Also see "*New EU Clinical Trials Transformation Initiative Gets Underway*" - Pink Sheet, 17 Jan, 2022.)

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