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EU Project To Evaluate Delays To Drug Trials Conducted Alongside Studies For IVDs/Devices

by Vibha Sharma

The European Commission is steering a new member state-driven project that aims to get to the bottom of factors causing delays to trials that simultaneously investigate a drug product with an IVD or a medical device, and propose some solutions.

EU regulators have launched a project to address the challenges faced by sponsors in running so-called combined studies in which the clinical trial of an investigational medicinal product is combined with the performance study of an *in vitro* diagnostic or the clinical investigation of a non-IVD medical device.

The project is being driven by EU member states and will look at the interface of three EU Regulations: the Clinical Trials Regulation or CTR (536/2014) that came into effect on 31 January 2022, the IVD Regulation or IVDR (2017/746) that has been in effect since 26 May 2022, and the Medical Devices Regulation or MDR (2017/745) that became applicable on 26 May 2021.

It comes in response to criticism by pharmaceutical companies earlier this year that problems with implementing the IVDR were inadvertently delaying drug trials and blocking patient access to new treatments for conditions like cancer and rare diseases. (Also see "*Pharma Blames EU IVD Regulation For Clinical Trial Delays*" - Pink Sheet, 21 Mar, 2023.)

The CTR/IVDR/MDR interface project was shaped in spring/summer 2023 and is expected to conclude by early 2024. It was discussed at the June meeting of the EU's Clinical Trials coordination and Advisory Group (CTAG), the minutes of which were *published* last month. The project follows an iterative approach and is currently in its first stage, which comprises three strands of analysis focused on:

- Collecting and categorizing issues reported by various actors engaged in combination studies. This involves creating an “issue list” to clarify problems that cause delays in combined studies in terms of scientific, procedural and legal issues, and whether they pertain to a single legal framework or to the interface.

- Mapping relevant national processes in EU member states.

- Mapping ongoing work in this area. One example of this is a Q&A document on the interface between the CTR and the IVDR that was endorsed last year by the Medical Device Coordination Group (MDCG) and the Clinical Trials Expert Group (CTEG), which are the competent authority groups overseeing the implementation of the medical device and clinical trial legislation respectively. (Also see "*EU Clarifies Requirements On Use Of Assays In The Context Of Clinical Trial Regulation*" - Medtech Insight, 27 May, 2022.)

Based on data gathered, a fourth work strand on possible solutions to address the most important issues will be proposed. The subject and timing of the future phases of project will depend on the outcomes of the analysis phase.

The European Commission is the chair of the project board and has the role of steering the project. While volunteers from member state competent authorities will participate in the work strands in a project group, not all member states are represented.

However, the outcomes of the project will be presented for endorsement to the MDCG and relevant clinical trial groups of authorities, in which all member states are represented. The European Medicines Agency will also contribute to the project in line with its remit established by the CTR.

Industry representatives and other stakeholders, such as patient groups and clinical professional associations, have been invited (in connection with the ACT EU multi-stakeholder platform and stakeholders registered as observers to the MDCG) to form a reference group, which will provide input to the project.

ACT EU (Accelerating Clinical Trials in the EU) is a collaborative initiative involving the commission, the Heads of Medicines Agencies and the EMA. It seeks to transform how clinical trials are initiated, designed and run in the region. A key priority under the initiative is to establish a multi-stakeholder platform to discuss changes to the clinical trial landscape. (Also see "*Who Will Join Us? EU Regulators Seek Feedback On Proposed Clinical Trials Discussion Platform*" - Pink Sheet, 6 Feb, 2023.)