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Pharma Blames EU IVD Regulation For Clinical Trial Delays

Lack Of Coordination On Performance Study Applications Negatively Affecting Drug Trials

by Vibha Sharma

The challenges posed by the implementation of the EU IVD Regulation are having a negative impact on medicine trials using diagnostics. Many of such studies are currently stalled and research-based drug companies are calling on all partners to engage in dialog to find an urgent solution.

Problems in implementing the EU In Vitro Diagnostics Regulation (IVDR) are unintentionally delaying drug clinical trials and blocking patient access to new treatments for conditions like cancer and rare diseases, says the European federation of research-based pharmaceutical companies, EFPIA.

Between 82 and 160 trials involving the use of IVDs to manage study participants are currently delayed in Europe and the situation is expected to get worse if no urgent action is taken, shows a *recent survey* undertaken by EFPIA to gather feedback from its member companies on the impact of the IVDR on clinical trials and delayed patient access to those trials.

The industry body said it launched the survey "after hearing concerns from numerous companies" on trial delays due to the IVDR, which came into effect in May 2022. The aim of the legislation was to improve public health and protect patients, but its implementation has been "challenged by a lack of infrastructure, guidance, and coordination, triggering a series of unintended consequences," noted EFPIA.

These trial-related delays are taking place because the IVDR requires that IVDs used in clinical studies must go through an assessment process (called the performance study application

process) when the diagnostic test result influences patient medical management.

However, as this process is "complex and uncoordinated," it results in "patients waiting longer to participate in clinical trials, or even not participating at all," EFPIA states. The survey includes feedback from more than two thirds of EFPIA's 31 large member companies and the results represent a "conservative estimate of impact" of the IVDR on drug research.

The survey showed that:

- If no effort is made to address the current situation, 238 to 420 trials are expected to be delayed over the next three years. This could result in 33,815 to 42,200 patients in Europe facing delays in accessing trials over the next three years, of whom around half (up to 27,400) would be cancer patients.

- The launch of 89 therapies could be delayed because of the IVDR in innovative therapeutic areas such as oncology and rare diseases.

- Up to 400 trials are expected to enroll fewer patients, meaning some people missing out on innovative new treatments. These include trials for cancer, rare disease, neuroscience, inflammation, cell and gene therapies, pediatrics and cardiovascular diseases.

- 43% of the surveyed companies expect delays of six to 12 months to current clinical trials, with 48% expecting six- to 12-month delays over the next three years.

- 67% of the surveyed companies would consider reducing the number of EU trial sites if the IVDR requirements remain the same, noting these trials would move to the US, Canada, UK and Asia, among other locations.

- The launch of novel therapies on the European market is also likely to be delayed. Many of these products are for patients with life-threatening diseases and those with unmet medical needs where no treatment is available.

EFPIA's director general Nathalie Moll said these figures were "extremely worrying" for patients with rare and life-threatening conditions, who "should be at the front of the queue, getting fast access to care, not having to wait due to complicated bureaucracy and a lack of coordination across Europe."

The current situation "is a real time example of how a lack of forward thinking in Europe could penalise patients and drive research out of the region," Moll said.

The trade body is urging all partners to enter talks to find solutions and mitigate the negative

unintended impact of the IVDR on clinical trials, which could force drug companies to omit European sites from their trials and divert the research to other jurisdictions. “Our members are telling us that this is already happening,” Moll added.

Performance Study Applications Under IVDR

A key hurdle faced by study sponsors in relation to the IVDR is the lack of a consistent process across EU member states for submitting performance study applications for the IVDs to be used in the drug trial.

Of the companies who responded to the EFPIA survey:

- 89% said there were inconsistent interpretations of which studies required performance study applications under the IVDR.
- 83% said performance study application documentation was not consistent across member states.
- 67% said the timing of ethics committee reviews was not consistent and posed challenges for planning.
- 61% said member states have inconsistent positions regarding the timing of performance study applications relative to clinical trial applications under the Clinical Trials Regulation.
- 61% said performance study application documentation expectations were too burdensome.
- 50% said the review of performance study applications was not meeting the IVDR timelines.

To address the issue, EFPIA wants all partners to enter into talks to find solutions. It is recommending that the European Commission should consider:

- Delaying the application of the IVDR for clinical trials using an IVD.
- Organizing voluntary coordination processes at member state level to improve the IVD assessment procedure.
- Developing new guidance clarifying the assessment process.
- Considering a risk-based approach to avoid assessing IVDs that are low risk for patients.
- Accepting on a case-by case basis, and with agreement of the member states involved, to not

conform with IVDR requirements if certain conditions are fulfilled.

- Clarifying the definition of in-house testing to broaden its scope.