INFO SHEET

Our approach to changes in EU IVDR regulation

Effective May 26, 2022, the European Union (EU) *In Vitro* Diagnostics Regulation (IVDR) replaced the *In Vitro* Diagnostics Directive. This regulation governs how *in vitro* diagnostics (IVDs) and lab-developed tests (LDTs) are regulated for diagnostic and EU/European Economic Area patient management purposes. In light of how these changes affect relevant assays, Labcorp has produced a comprehensive impact assessment. This assessment informs our strategic approach and recommendations to our sponsors, enabling us to strengthen our support of clinical research and development involving patients from this region.

What is the purpose of IVDR?

- Updates rules on EU market placement regarding IVD medical devices for human use and their accessories
- Outlines rules on conduct of performance studies that are carried out in the EU concerning IVD medical devices (or accessories)
- Introduces stricter procedures for conformity assessment (to ensure that unsafe or noncompliant devices do not end up on the market) and postmarket surveillance to boost patient safety[1]

How does IVDR impact clinical trials?

Labcorp Drug Development supports regulatory efforts that promote the safety and well-being of patients participating in clinical trials. In response to these regulatory changes, we created an EU IVDR Task Force to conduct a robust and thorough impact assessment. The IVDR Task Force included a highly experienced team of regulatory and operational subject matter experts throughout Labcorp, working in consultation with legal counsel. Our internal review of device classification helped determine whether affected assays were properly labeled and utilized for regulatory compliance. Through further insights gleaned from external consultation, we explored a variety of possible IVDR regulation exemptions. This additional measure helped ensure our decisions were guided through understandings of the most currently available information.

SOME LABCORP LDT ASSAYS AFFECTED

The *In Vitro* Diagnostics Regulation (IVDR) applies to *in vitro* diagnostics (IVDs) used for testing European Union (EU) patients where data will be used for medical decisions. Regardless of the testing location, in-house developed devices or lab-developed tests (LDTs) used for medical decisions or patient management are subject to the regulations.

WHAT TO DO NEXT

We recommend your team conduct an internal review and risk assessment to identify actionable items based on the specific needs of your study. Meet with your Labcorp key contact to discuss which LDTs being used in your clinical trial are affected and which LDT assays can continue to be used in your clinical trial.

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Many of the requirements set forth within the EU IVDR are already included in our standard processes for the quality and reliability of the results we provide. The IVDR applies to IVDs used for testing EU patients where data will be used for medical decisions in patient management. Regardless of the testing location, in-house developed devices, or lab-developed tests (LDTs), used for medical decision or patient management are subject to the regulations.

On May 25, 2022, the Medical Device Coordination Group (MDCG) issued MDCG 2022-10 to clarify the interface between the IVDR and the EU Clinical Trials Regulation, including the requirements for assays used in the context of clinical trials.[2] Labcorp LDTs are not CE-marked, and our interpretation based on current understanding of available guidance is that these assays may not be used for clinical diagnostic or patient management in clinical trials.

What additional actions can be taken?

We recognize that IVDR may prompt further questions from our sponsors. While continuing our commitment to support our sponsor's missions, we are enacting the following methodologies:

- We will continue to provide impacted assays in active running studies with no changes if deemed appropriate by the sponsor organization while emphasizing the focus on patient safety
- We will review the use of non-CE-marked LDT assays—existing or new—for upcoming clinical trials on a case-by-case basis
- We have explored finding IVDR-compliant alternative assays and are adopting those that are relevant. We will continue to seek CE-marked alternatives as we move forward
- We do not require further action from sponsors. However, we recommend each sponsor conduct an internal review and risk assessment to identify additional actions based on the specific circumstances of their study needs and applicability of IVDR requirements

We believe these actions are in the best interest of our sponsors at this time. We will continue to update our strategies to inform clinical decisions and optimally serve our partners as more information becomes available or regulatory standards are updated.

"The regulations clarify for the sponsor their responsibility to identify—within their registration submission—whether the assay is being used for patient management and that it is appropriately compliant with IVDR and/or CE-marked.

We partner with the sponsor to understand how they are utilizing the assay. We then confirm the regulatory status of the assay we are reviewing and determine next steps based on that information. It's wonderful to have the opportunity to partner with sponsors in this way because we are in this together."

Diane Corbett
Corporate and Vice President of Global Regulatory Compliance and Quality Assurance for Labcorp Drug Development, Central Labs and Companion Diagnostics

References

1. EUR-Lex. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on ***in vitro*** diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (text with EEA relevance.) Accessed August 2022. https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32017R0746&qid=1653054215022.
2. Medical Device Coordination Group; Clinical Trials Expert Group. Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR). May 25, 2022. https://health.ec.europa.eu/system/files/2022-05/mdcg_2022-10_en.pdf.

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