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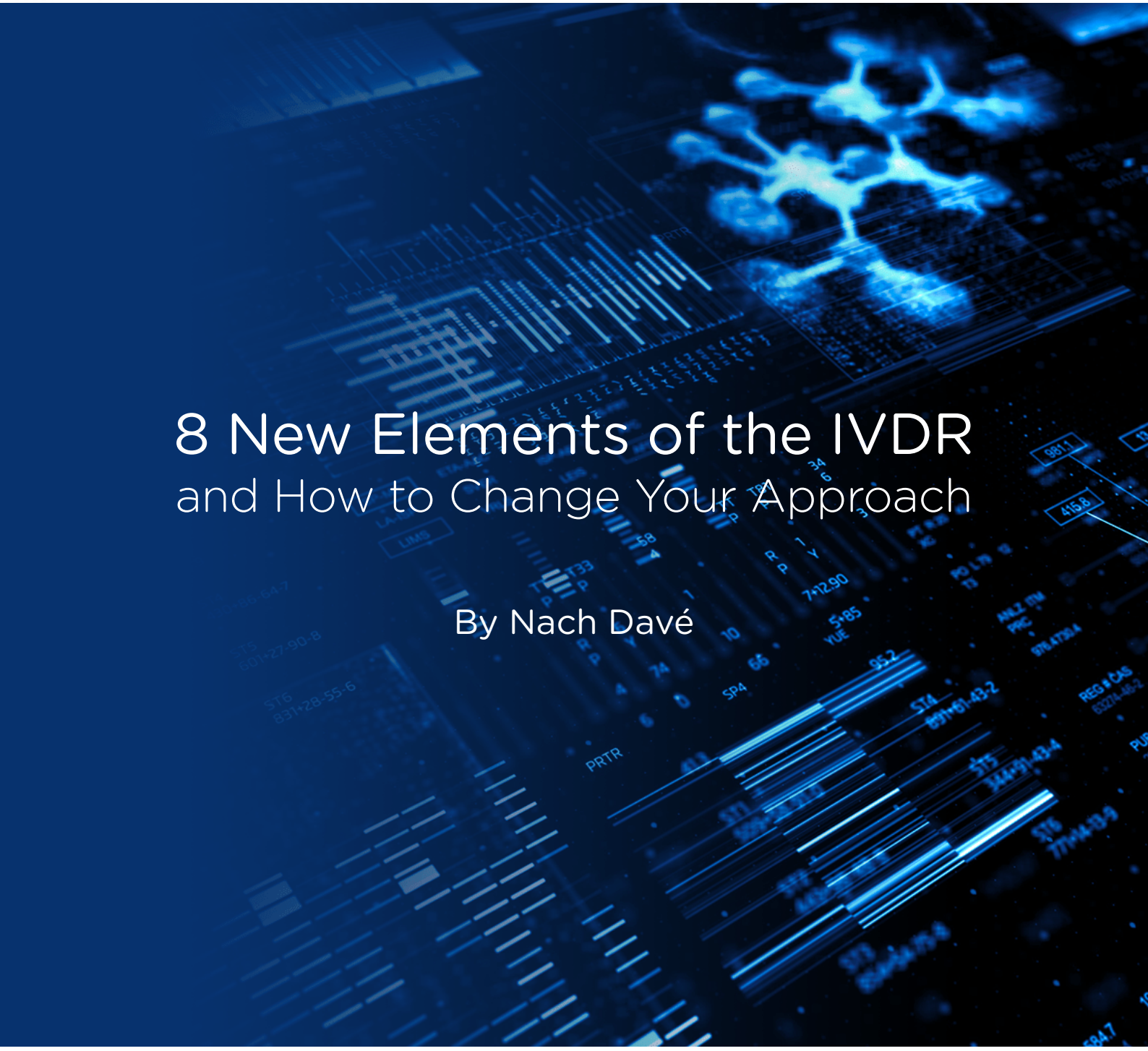

8 New Elements of the IVDR
and How to Change Your Approach

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8 New Elements of the IVDR — and How to Change Your Approach

If you develop or manufacture in-vitro diagnostic products, you know the May 2022 roll-out date for the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) is just around the corner. But what, exactly, does that mean?

Many of our sponsors have been approaching us with questions, such as:

- What aspects of the IVDR apply to my business?
- What types of data generation need to be in place?
- Does any grace period apply, given the December progressive rollout update?
- Who can I work with to ensure there are no gaps in my understanding of compliance?

The answers, tiny details that could make or break in vitro diagnostic (IVD) approval, lie buried within an extensive document. Fortunately, we at Premier have done the digging — so you don't have to.

In this blog post, our regulatory experts highlight eight new concepts in the published document and point out new ways to think about IVD approvals to help you prepare for the switch to IVDR.

There's been a paradigm shift in thinking about IVD

A renewed focus on safety and accountability has brought about a fundamental change in how an IVD will be regulated. As a manufacturer or developer, what are the additional items you need to pay attention to when the new regulation takes effect?

The following is a shortlist of essential updated concepts everyone should be aware of. Some items are completely new, compared to the former In Vitro Diagnostic Medical Device Directive (IVDD), such as single-use device and the falsified device. Others clarify previous grey areas; for example, genetic testing is now unequivocally covered by the new IVDR. With more clarity in these definitions — such as what the EMA considers a companion device — both manufacturers and regulators will have far greater certainty as to what rules apply to a given device.

New and Revised Concepts Presented in the IVDR

Definitions (Article 2)

01 GENETIC TESTING

Although with some bending of rules, these tests are currently overseen by the IVDD, they will now be formally defined as IVDs, falling under "concerning the predisposition to a medical condition or a disease" (Definition 2c) and listed specifically as Class C (Annex VIII, Classification rules 2.3).

In addition, for genetic testing and counseling, IVDR requires the Member States to establish measures that ensure the provision of adequate information to patients. Manufacturers of in-house tests may face additional requirements in the specific Member States. (Article 4)

02 DEVICES FOR NEAR-PATIENT TESTING

Intended for testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional. Self-testing is excluded. (Definition 6)

03 COMPANION DIAGNOSTIC

A device that is essential for the safe and effective use of a corresponding medicinal product (e.g., identifying potential users, and identifying patients likely to suffer adverse reactions). (Definition 7)

04 SINGLE-USE DEVICE

Intended to be used during a single procedure. The concept of single-use devices has already been introduced in the MDD but is new for IVDs. This particular condition only impacts user information and registration of the device, as thisinformation must be mentioned on the label, in the IFU, and the registration information for the IVD's unique device identifier (UDI). (Definition 9)

05 FALSIFIED DEVICE

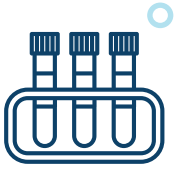
A false presentation of identity, source, and/or CE marking certificate. However, unintentional noncompliance or infringements of intellectual property are not in the scope of this definition. This particular product status is important because it obligates distributors and importers to report falsifications and enables authorities to take appropriate action. (Definition 10)

06 KIT

A set of components packaged together and intended to be used to perform a specific examination of a part thereof. This definition codifies the interpretation in MEDDEV 2.14/1 and will help determine borderline cases where devices work together in an IVD procedure. (Definition 11)

07 CLINICAL EVIDENCE

A set of definitions to facilitate understanding of the requirements for clinical evidence. (Definitions 36-62)



08 COMMON SPECIFICATIONS (CS)

Technical and/or clinical requirements that provide a means to comply with the requirements applicable to a device, process, or system. (In the IVDD, Common Technical Specifications (CTS) were intended to apply to Annex II List A or Annex II List B, but in reality, only CTS for Annex II List A IVDs were ever published. The new CS complete the requirements for List B.) (Definition 74; also, Article 9)

You are expected to comply with IVDR - within reason

The EMA regulators expect everyone will be compliant. At the same time, they're realistic and understand that while some companies will be completely buttoned up, most will be lacking something. While it may not be practical for everyone to understand every regulation and be 100 percent compliant right at the outset, discussions with the notified body or the regulators will be much more satisfactory if you can demonstrate A concerted and documented effort to be compliant. Be sure to demonstrate you've made a good-faith effort toward compliance and document the progress. Premier Research diagnostic experts can perform a gap analysis to help you understand where your deficiencies are, prioritize them and propose reasonable remediation services to help you reach compliance within an acceptable time frame.

Even if the above eight regulations don't apply, others will

Some sponsors may find that none of the regulations listed here apply to them or that they have already made the necessary adjustments. However, additional guidance may still be beneficial. We've listed the top eight issues that stand out to us, but obviously, there's much more detail within the requirements. If you have concerns at all about where you may be falling on the spectrum of compliance, let's have a conversation. Our gap analysis will go well beyond the eight factors we've called out for the purposes of our blog.

The upside: globally relevant regulations

While these regulations apply in the EU, they are now more globally relevant and better harmonized with FDA regulations. So as a European client, you will likely find a faster pathway through the FDA or other regions when you are compliant with the IVDR.

This way, if you want to take your product into Asia or the Middle East, the regulatory pathway can be more optimized as these other regulatory bodies largely rely on having regulatory compliance to the European the U.S. regulations.

Our expertise is your peace of mind for IVDR

Adapting to IVDR is a challenge, with a variety of possible interpretations, steps and processes. However, with a reasoned approach, it is very doable — and Premier can help you navigate. We are deeply familiar with the new in vitro device regulations and will help you with gap analyses and planning your approach to compliance. Learn more about our services for medical device development, FIH to post-market surveillance, including our expertise in product development and regulatory consulting.