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THE UNIQUE LANGUAGE CHALLENGES OF IVDs AND THE EU IVDR

In vitro diagnostic medical devices (IVDs) are a subsegment of medical devices that have their own unique terminologies outside the vernacular. IVD manufacturers wanting to place their products on the EU market after 26 May 2022 (when the EU IVDR fully applies) will have to produce and translate increasing volumes of technical and plain language content throughout the life cycle of the devices. Even distributors and importers need to control their language activities and establish procedures under their quality management systems to ensure that translation of information is accurate and up-to-date (IVDR, Article 16).

Given the complexity around terminology, content, and the user environment of IVDs, manufacturers and other economic operators cannot assume that any single translation agency or Language Service Provider (LSP) can support language activities across the life cycle of their IVD portfolio. An IVD product plan for design, manufacturing, conformity assessment, performance evaluation, marketing, and product surveillance should include a language strategy which is adapted and scaled to the specific device type, life cycle, risk classification, and markets in which the product is launched. In the EU in particular, launch markets and language aspects play a prominent role because of the multilingual nature of this region.

In this publication, we explore IVDs and the unique language challenges they bring to the medical device value chain. Terminology and communication challenges within IVDs are anchored not only in the enormous diversity of products, services, applications, and technologies of these devices, but also in the complex infrastructure, workflows, and user environments for processing and analyzing these tests. Our point of departure is the new EU IVDR; however, language aspects are universal across all markets.

EU IVDR triggers more content and translations throughout the IVD life cycle.

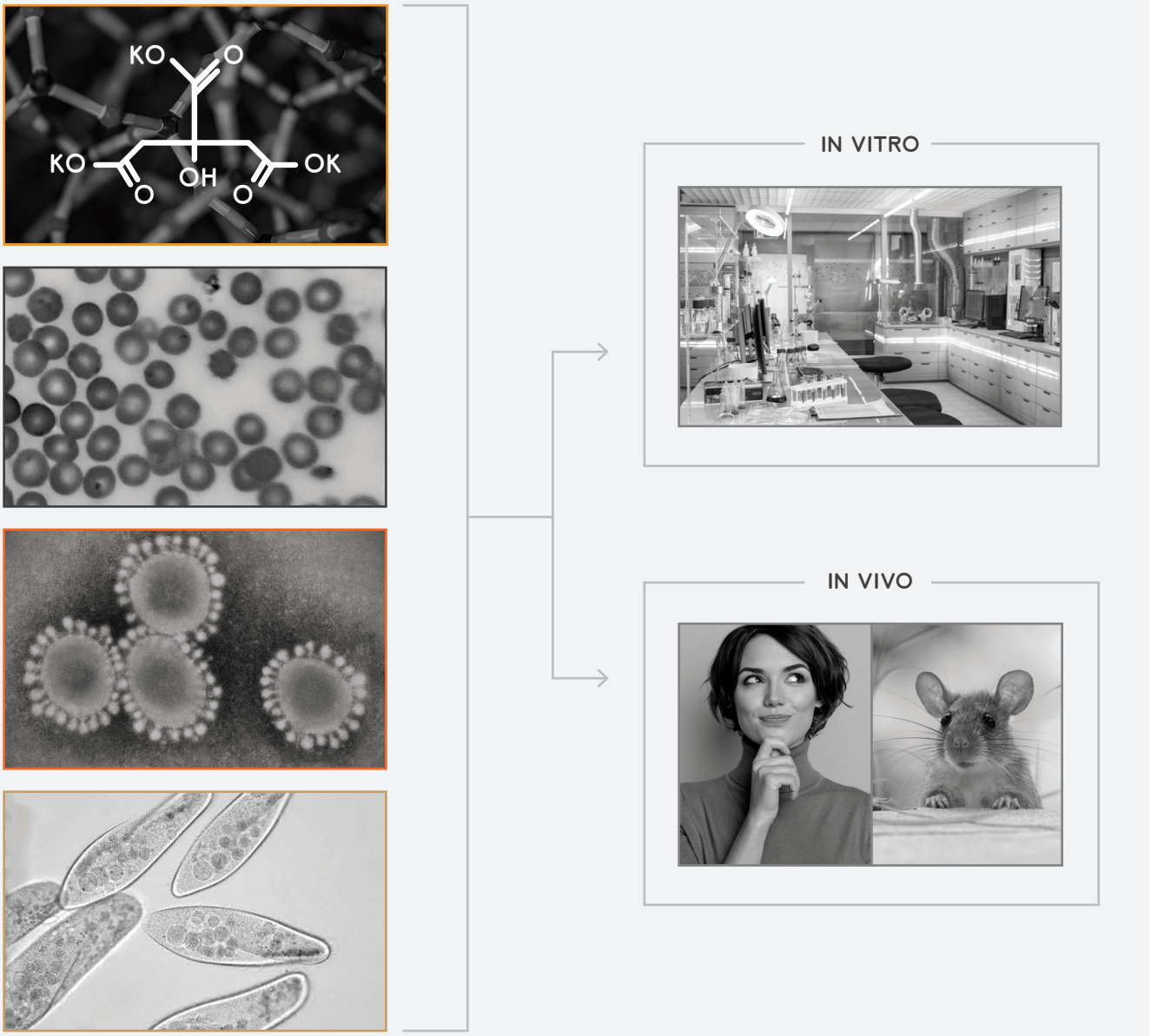
PLAIN AND TECHNICAL LANGUAGE AND CONTENT ASSETS

PRE-MARKET	PLACING ON THE MARKET	POST-MARKET
Translation of technical documentation and correspondence for conformity assessment	CE marking	Incident reporting/field safety notices (FSNs)
Draft labeling/IFUs/ packaging	Certificates of conformity	Product changes (IFUs, re-labeling/packaging, CE marking, etc.)
Summaries of Safety and Performance (SSP) for NB validation	Labeling/IFUs/packaging	Periodic Safety Update Reports (PSUR)
Translation of clinical documentation for performance evaluation	User interfaces (hardware/ software workstations)	Post-Market Clinical Follow-up (PMCF)
MDDTs for clinical device studies	EUDAMED content for public disclosure	
	Translations supporting IVD symbols	
	Registration of devices	
	Translation of Summaries of Safety and Performance (SSP)	

IVDs are "a subset of medical devices, defined as devices which, whether used alone or in combination, are intended by the manufacturer for the examination in vitro of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring, or compatibility purposes. They included reagents, calibrators, control material, and test kits." (Source: First WHO Model List of Essential In Vitro Diagnostics, 2017)

From Natural to Artificial Environments

IVDs are different from therapeutic medical devices because they are based on human specimens extracted from their natural human environment (in vivo) and then processed in an artificial laboratory/clinical environment (in vitro). In vitro is Latin for "within a glass" whereas in vivo means "within the living body". Achieving predictable and reproducible results from IVDs relies heavily on proper control of this artificial environment. Such control includes technical and supply chain workflows as well as the complex interaction between different human resources or skill sets involved in their processing and interpretation. The impact of clear communication, training, and language for IVDs is at least as important as it is for non-IVDs, if not moreso.



Criticality and Diversity of IVDs

IVDs are critical in today's healthcare and help drive healthcare decisions by taking biological samples (e.g., urine, tissues, or blood) and then processing and analyzing these samples to arrive at a diagnosis, prognosis or other outcome depending on their intended purposes. The value of IVDs is to provide diagnostic information to healthcare professionals and sometimes to patients, rather than directly treating a symptom or disease.

According to Value of Diagnostic Information (VODI): MedTech Europe, the results of in vitro testing influence 70% of clinical decisions today. IVDs employ different techniques including immunoassays (based on antibodies), clinical chemistry (based on bodily fluids such as blood or urine), molecular diagnostics (based on genetic material, DNA or RNA), microbiology (based on microscopic organisms; bacteria, viruses), and hematology (based on blood and its components). They include multiple different types of diagnostic tests with different intended purposes, different processing requirements, and different intended users. An IVD may be a simple self-testing device used in the home-setting (such as the well-known SARS-CoV-2 rapid antigen tests) or an advanced diagnostic test solution (such as cancer diagnostic or companion diagnostic test) performed in specialized hospitals and/or accredited laboratories.

Examples of IVD test purposes in the patient care continuum

SCREENING	DIAGNOSIS	PROGNOSIS	STAGING	MONITORING
Detect a disease or condition	Confirm a disease or condition Preclude or confirm diagnosis in select population	Predict likelihood of developing a disease or condition	Categorize patients with confirmed disease or condition into groups for choice of therapy Predict outcomes/ responses to therapy	Monitor progress or response to treatment or to monitor the treatment itself

(Source: First WHO Model List of Essential In Vitro Diagnostics, 2017)

IVDR Classification Drives Content and Translation Volumes

Under the EU IVDR, IVDs will be classified according to a new system. Generally, this system is based on the risk of an incorrect result from the assays and their perceived risk to individuals or the public. The risk classification determines whether an IVD will require conformity assessment by a Notified Body and which level of regulatory control and quality management system said IVD will be subject to pre- and post-market.

From a content and language perspective, there is a positive correlation between the risk classification of an IVD and the target markets, and the volume of content and translations that an IVD manufacturer must produce under the IVDR. Manufacturers of medium to high risk IVDs will generally be required to conduct more clinical investigations for performance evaluation and to deliver more/more frequent post-market safety and performance reporting for safety and transparency purposes.

In addition, they may voluntarily seek to obtain more clinical experience with their devices outside of the regulatory safety and performance requirements during post market clinical follow up. IVD manufacturers will need to provide a Summary of Safety and Performance (SSP, Article 29 in the EU IVDR) which is equivalent to the Summary of Safety and Clinical Performance (SSCP) under the EU MDR. The summary may contain a plain language part intended for patients in addition to the technical part intended for professionals. Some of these new content elements required under the IVDR must be uploaded to the EUDAMED database and be publicly available in local language.

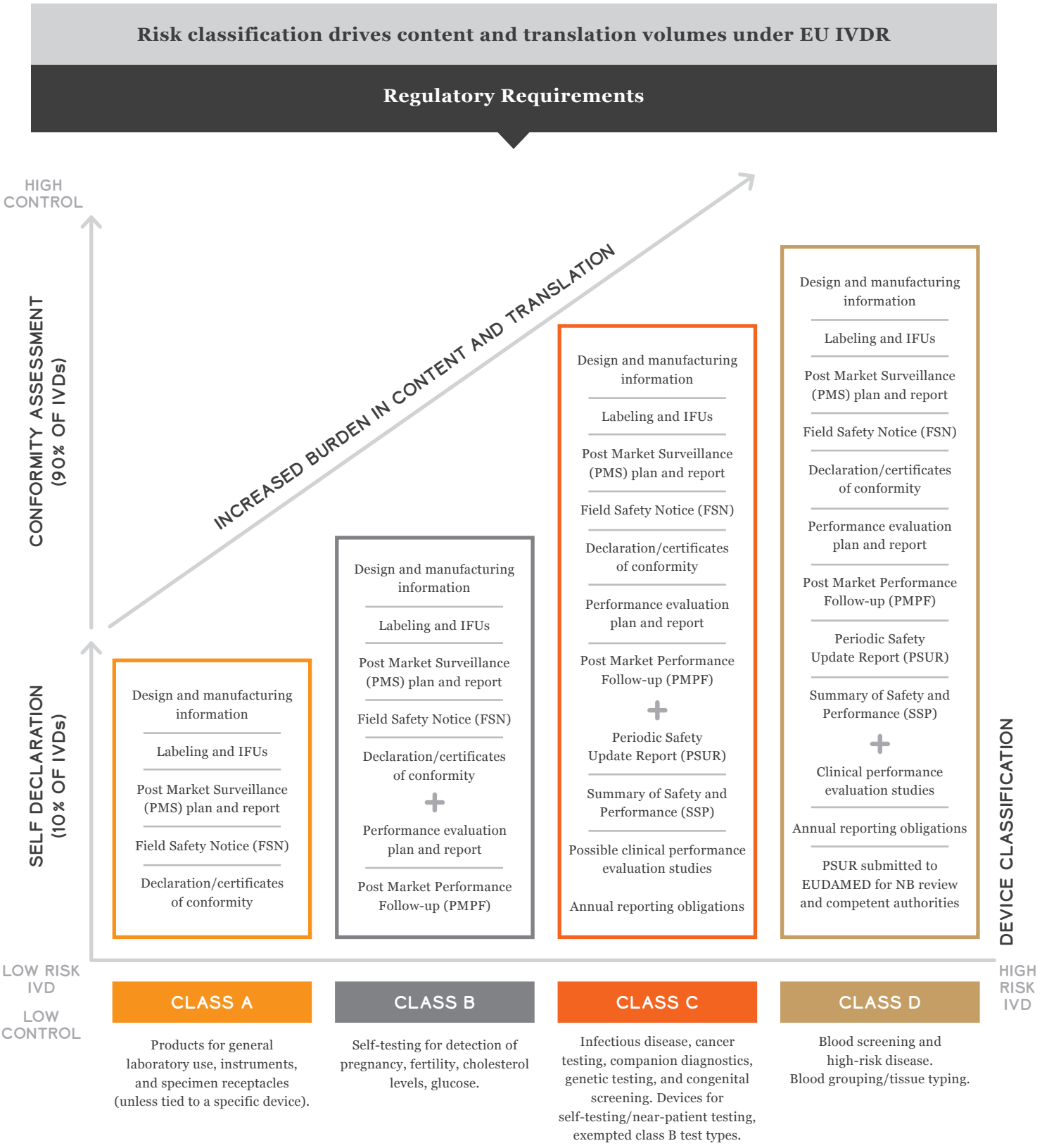
Content Boost Calls for Centralization

Given the explosion in regulated content required under the EU IVDR, manufacturers with a diverse portfolio of products will benefit from developing a centralized language strategy. The key determinants for this strategy are: risk classification of their medical device portfolio, their intended use(r)s, and launch territories. This recommendation applies for both therapeutic medical devices falling under the scope of the EU MDR and IVDs falling under the scope of EU IVDR.

The IVD classification system is similar to the one for therapeutic medical devices in that IVDs are also categorized under four different risk classes. Where therapeutic medical devices are classified as class I, IIa, IIb, and III, IVDs are classified as class A, B, C, and D, with A being low risk devices and D high risk devices.

As a rule of thumb, the higher the risk, the more content and translations the EU IVDR requires. This applies throughout the life cycle of the IVD. Because class C and D IVDs present a higher risk to patients, users, and the general public, IVD manufacturers will have increased obligations to provide evidence of the device safety and performance as well as increased reporting requirements.

The correlation between regulatory control, risk classifications, and the burden of content and translations under the EU IVDR is illustrated below.

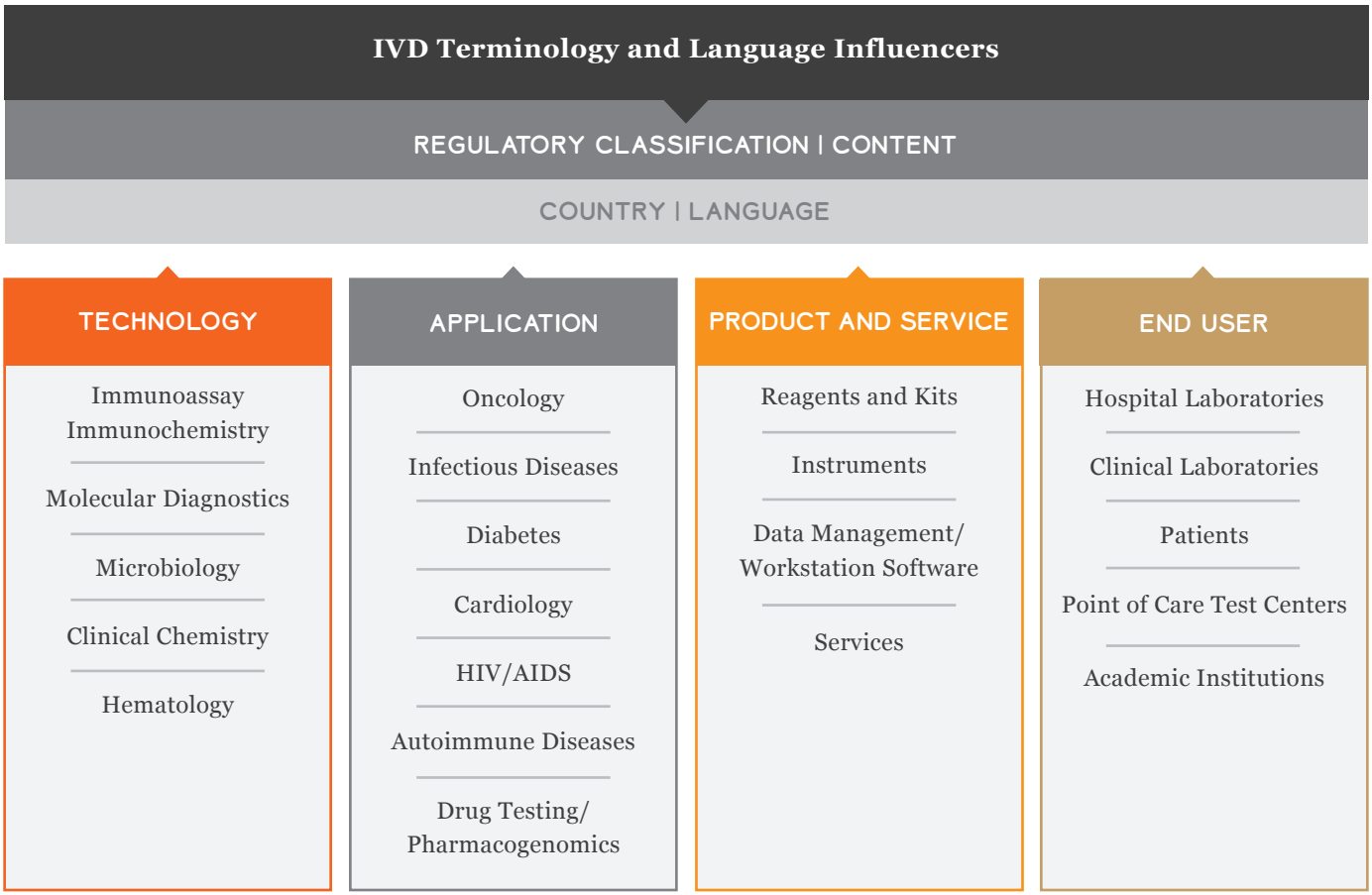


Human Factors and the User Enviroment

IVDs are a diverse and complicated type of medical devices because of the many environmental and human factors impacting their functionality and outcomes. As an example, the results of an IVD test used for diagnosis of a cancer relies very much on the laboratory and clinical environment in which it is processed and the interfaces between technology, clinicians, and laboratory staff. From the extraction and preservation of human tissue samples to their processing in the laboratory — which may involve a complicated mix of hardware, software, and reagents — to the interpretation of results by a pathologist, each touch point of IVD use can influence the outcome.

A myriad of potential misunderstandings or errors may occur in this complicated infrastructure and in the user environment around IVDs. This inevitability is one of the reasons that the regulatory requirements on human factors and usability engineering have become more strict under the EU MDR and the EU IVDR.

Usability engineering is about creating a safe environment around the use of a device by identifying and eliminating potential use errors where possible. Clarity in communication, training, and language are key elements for obtaining such a safe use environment. User interfaces may require translations depending on the operator's or user's language skills; without local language UIs, the risk of introducing errors increases. Laboratory operators and lay users of self-testing IVDs will have different jargon and language needs than clinicians, software engineers, or pathologists that work with technical or medical aspects of IVDs. Understanding the user profiles and their communication and training needs throughout the product value chain is therefore key.



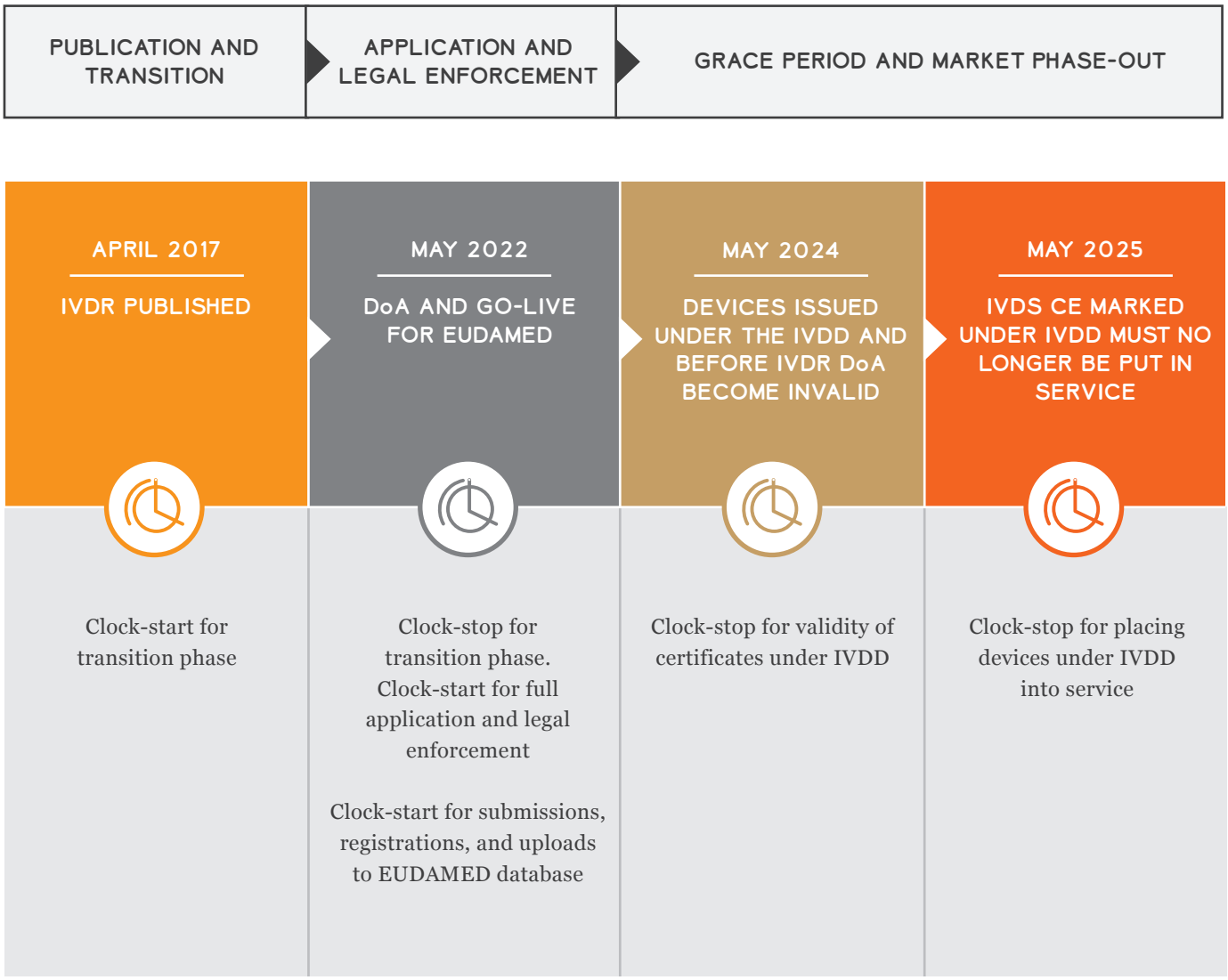
Having a LSP that understands the complicated environment around the development, conformity assessment, marketing, and post-market maintenance of your IVDs will help alleviate the burden of new content and language requirements under the EU IVDR. In a partnership model, Lionbridge can help build a language strategy for your IVD portfolio which takes into consideration the unique terminology and user environment for your devices.

A Short Recap of IVDR Timelines

The new IVDR will fully apply from 26 May 2022, the Date of Application (DoA). The DoA completes a five-year transition phase since the Regulation was officially published on 5 April 2017 in the Official Journal of the European Union.

Some requirements have gradually been implemented dependent on the device type and classification. In addition, some device certifications under the In Vitro Diagnostic Device Directive (IVDD) may still remain valid during a grace period until 27 May 2024 when all certificates granted under the IVDD become invalid.

The IVDR allows such devices to be put in service a further year until 27 May 2025 to allow sale of old stocks and continuity of care.



HOW LIONBRIDGE CAN HELP MANAGE YOUR LANGUAGE CHALLENGES

In a partnership model, Lionbridge will help you understand, implement, and manage language challenges in the EU and obtain efficiencies throughout the individual device life cycle or across your device portfolio. Our medical device language services include translations of technical as well as plain language content, user interface testing, readability testing and linguistic validation for COAs/eCOA used in medical device investigations.

To learn more about how Lionbridge can help with translation requirements for the new EU IVDR, reach out to our team today.

About Lionbridge

Lionbridge partners with brands to break barriers and build bridges all over the world. For 25 years, we have helped companies connect with their global customers and employees by delivering translation and localization solutions in 350+ languages. Through our world-class platform, we orchestrate a network of passionate experts across the globe who partner with brands to create culturally rich experiences. Relentless in our love of linguistics, we use the best of human and machine intelligence to forge understanding that resonates with our customers' customers. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 23 countries.

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