Impact of IVDR on Pharma, Patients and Clinical Development

Diana Steinbuesch, BioX Portfolio Lead, Oncology
F. Hoffmann La Roche, Basel

Key features and changes brought about

New Changes introduced with IVDR in May 2022

More stringent

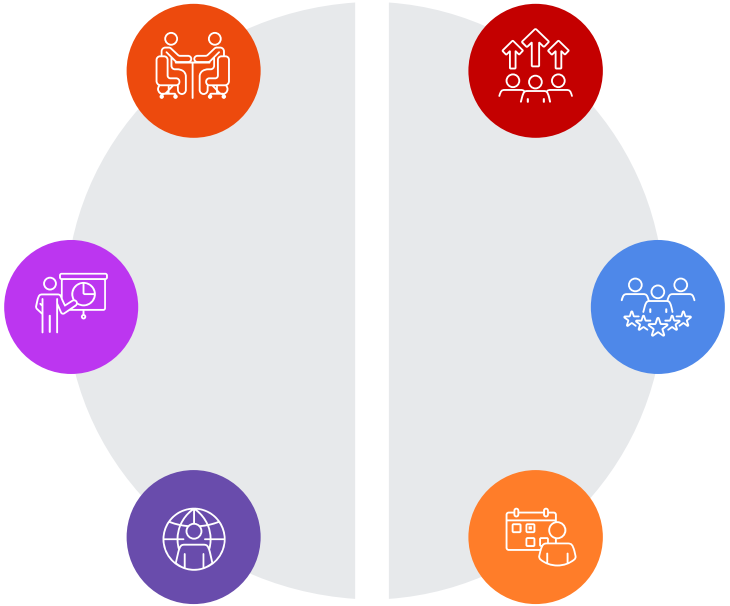
It aims to ensure improved safety, performance, and quality of IVD products, ultimately enhancing patient and public health outcomes.

Risk based Classification

This classification determines the conformity assessment routes and certification processes for manufacturers, ensuring appropriate scrutiny for higher-risk devices.

Enhanced Notified Body Oversight

IVDR imposes stricter requirements and assessments for notified bodies that approve IVD devices



Increased Transparency

EUDAMED registration enables public access to information on devices, manufacturers, economic operators, and clinical investigations, promoting traceability and market surveillance.

Patient Safety

IVDR mandates assigning a unique code to each IVD device. This enhances traceability throughout the supply chain, and faster response to adverse events

Impact on Manufactures

IVDR imposes stricter requirements on manufacturers to introduce quality management systems

What are the key challenges

- Classification - is the submission of a performance study required?
- National Competent Authorities/ Ethic committees- different requirements
- No harmonised approval process for performance studies –EUDAMED delayed
- Uncertainties regarding the consultation process and CDx label
- Timelines ? What to do if drug approval is faster than the CE mark approval ?
- No possibility for scientific consultation EMA/ Notified Bodies

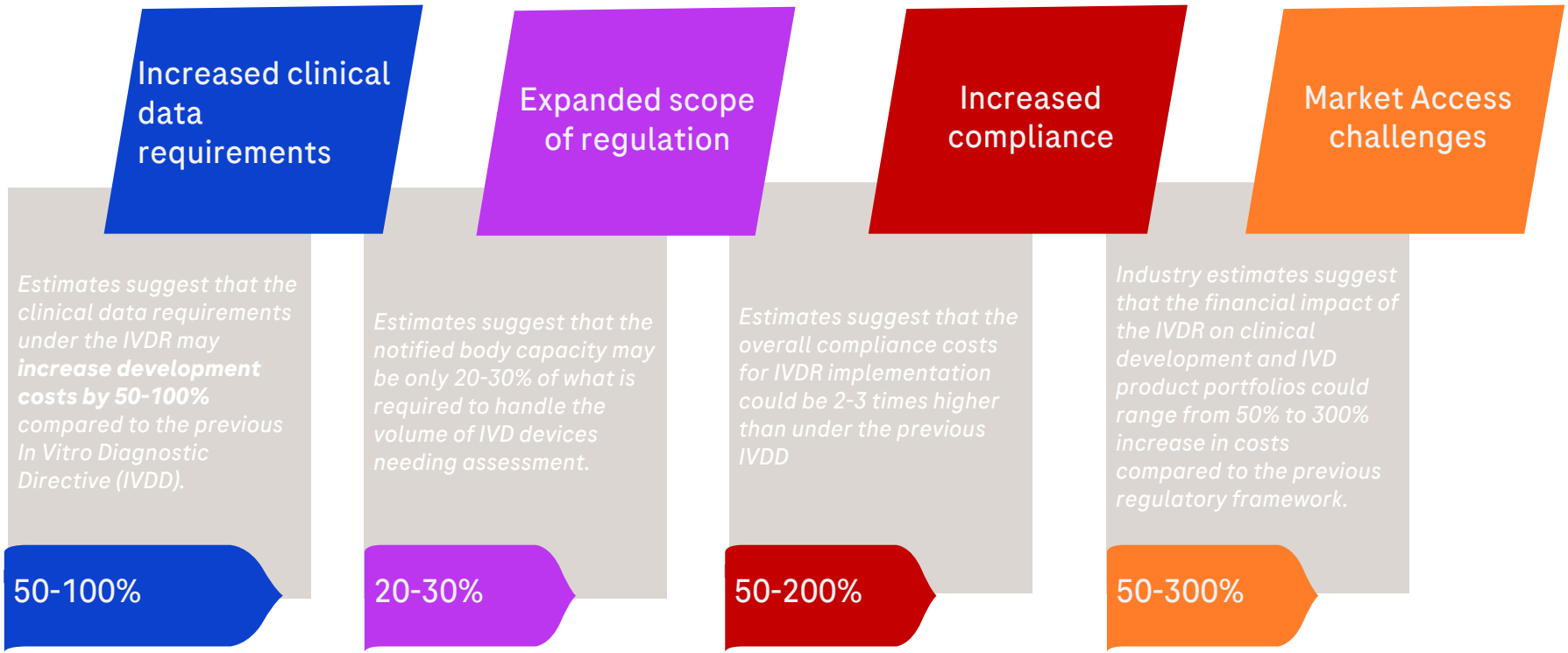
Impact on Pharma and CROs

- **Product Development** Impact:
  - Grey areas resulting in challenges in the setup of clinical trials
  - Increased time-to-market due to more comprehensive testing and stricter regulatory requirements

- **Compliance Costs**: related to adapting to IVDR standards.
  - upgrading infrastructure, and ensuring quality management systems meet IVDR requirements.
  - Investment in Training programs and upskilling of personnel

- **Resource Impact**
  - Increased demand for skilled personnel in regulatory affairs, quality assurance, and clinical development
  - Beaureaucratic burden and increase of administrative tasks to do a submission

Financial Impact | Estimates



Source: multiple industry sources

Impact to Clinical trials and Patients over next 3 years

Based on a survey conducted (Q4 2022) by the European Federation of Pharmaceutical Industries and Associations (EFPIA)

80-160 Studies Delayed in EU in early 2023

30000-45000 Pts impacted

Enrolled not screened

200-400 Trials delayed in the next 3 years (till 2026)

16000-27000 Cancer Pts

6-12 months of delay reported (early 2023)

200-400 trials enroll fewer EU patients

Responses from 21 of 32 EFPIA large Member Companies

Impact on Clinical Research in Europe

Based on a survey conducted by the European Federation of Pharmaceutical Industries and Associations (EFPIA)

300–600

Trials requiring IVDR submission in the next 3 years

200

No submission required in the next 3 years (non-registrational)

300

Trials to be regional where submissions are required in the next 3 years

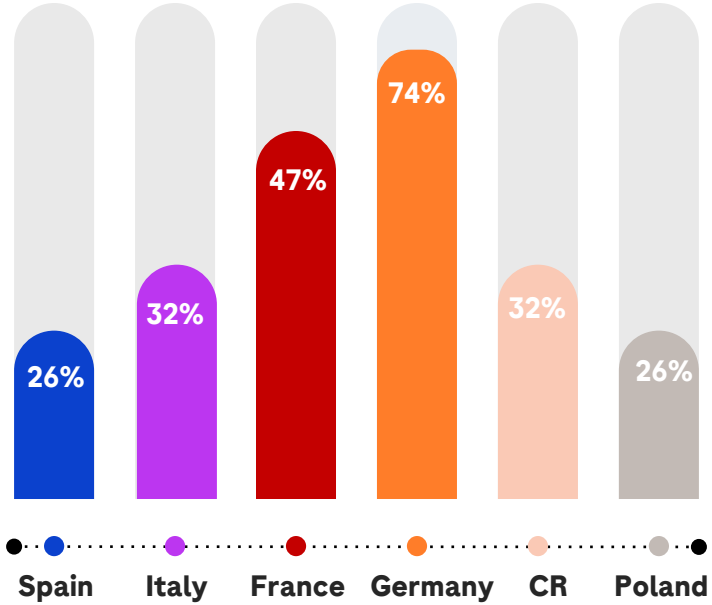
89 Therapies that could face delayed launch in Europe if clinical trials are delayed….in the following therapeutic areas:

…In the following therapeutic areas (Respondents asked to select all that apply)

Therapeutic Area	Percentage of Respondents
1. Oncology	84%
2. Rare Disease	58%
3. Neuroscience	42%
4. Inflammation	37%
5. Cell & Gene Therapy	32%
6. Pediatrics	26%
7. Cardiovascular	25%

Burden of Performance Study Applications (PSA)

Which EU Member States are Currently Posing or Expected to Pose the Most Challenges?



Responses from 21 of 32 EFPIA large Member Companies

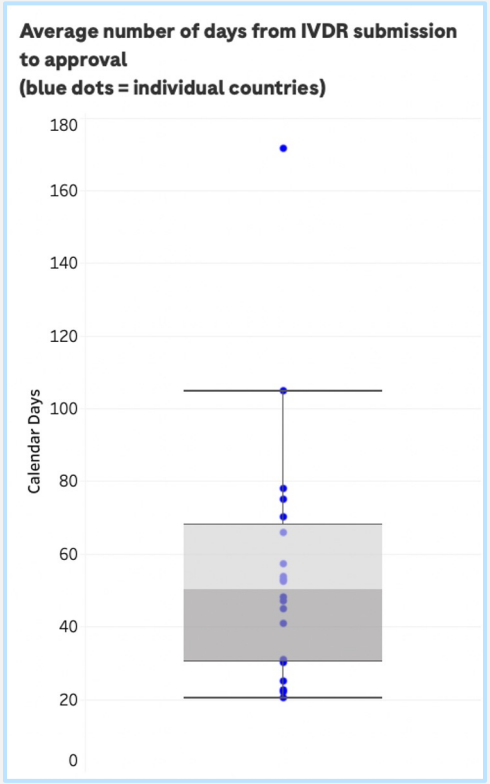
Roche IVDR overview and implementing as needed

100+ successful IVDR submissions in **23** countries...

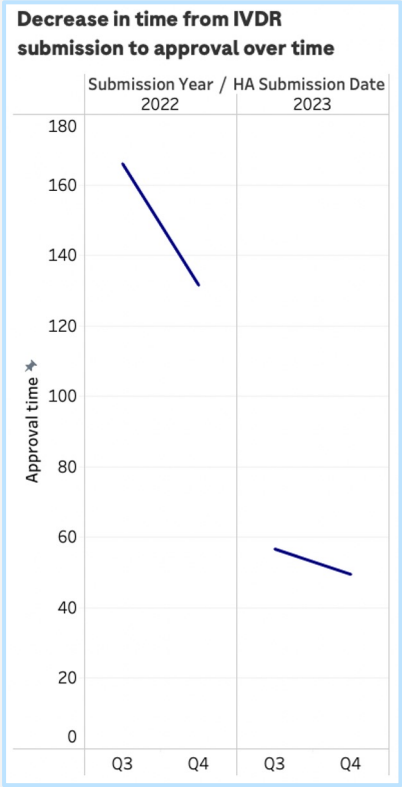
in collaboration with **5** diagnostic partners...

for **>12** in vitro diagnostic devices

Average of **~50** days from IVDR submission to approval



Trend towards a decrease in approval time



Conclusion: Reduce complexity

Biomarkers are widely used at every stage of drug discovery, drug development and in clinical care.

The IVDR increases complexity for
- clinical trials using IVDs (medical treatment decisions)
- and for CDx drug approvals.
How to cope with this?

- Close collaboration between all stakeholders is required

- Focus on simplification: e.g. ensure harmonised approaches

- Focus on improved guidance for Health Authorities, Pharma & CROs

Our common goal as outlined in the IVDR:
High standards of quality, safety and reliability to safeguard patients.


Má?aga

Doing now what patients need next

How to overcome the challenges and minimize expenses

- Explore collaborative opportunities between Pharma and CROs to share resources and expertise in navigating IVDR challenges.

- Joint ventures, partnerships, or outsourcing certain aspects of compliance activities:
  - Develop joint guidance on common set of principles for performance study submissions and reviews (in development by EFPIA)

- Strategic Planning Recommendations to minimize the cost expenses
  - Discuss mitigations for financial and resource challenges
  - Risk-based approach to Performance studies (IVDR submissions & compliance)
  - importance of early adaptation, continuous monitoring of regulatory updates, and agile business strategies.
  - Opportunity for Long-term Financial Benefits IVDR compliance → Enhanced product quality leading to improved market acceptance and reduced post-market surveillance costs
  - Temporary accept non-conformity (EFPIA proposed solution)

Additional suggestions

- Actions should include for **policy makers** to implement reforms to the system on the mid to longer term, to ensure continued availability of diagnostic and innovative tests
- Need for **special regulatory pathways** to facilitate the certification of rare/niche/orphan IVDs and breakthrough innovation, as exist in other (non-EU) regulatory systems. Pre/early certification access models should be developed, preferably in collaboration with academic diagnostic experts, the IVD Expert Panel, EU Reference Laboratories, the European Rare Disease networks (ERN), the European Commission, Competent Authorities and registered stakeholders in the Medical Devices Coordination Group (MDCG)
- Notified bodies need to **limit excessive bureaucratic load** by appropriate digitalisation and harmonisation, which will contribute to accelerated participation by manufacturers, particularly once EUDAMED is fully operational.
- There must be **additional support and provisions to assist laboratories in using IH-IVDs** and conforming with regulatory requirements. IH-IVDs already play an important role in the diagnostic sector
- **Clarify definitions of in-house test to broaden scope**

Source: https://www.biomedeurope.org/images/news/2024/Statement_prevention_shortage_IVDs_final_16.01.pdf