

IVDR Implementation– Industry perspective

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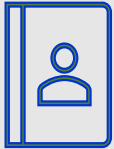
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ack IVDR March 2023



Short IVDR re-cap



New Changes introduced with IVDR in May 2022



Definition of Companion Diagnostics introduced



New risk-based classification system



Performance Evaluation/ Interventional clinical performance study introduced



Consultation procedure EMA-Notified Bodies



Transparency via EUDAMED for patients and caregivers

Requirement for CE certification: Performance evaluation



Scientific validity



Analytical performance



Clinical performance



Clinical evidence



This means that a performance Evaluation Study Submission under the IVDR is needed for all combined studies (drug + IVD) with any medical decision making in case

- a diagnostic test has no CE marking
- a diagnostic test is used outside the approved intended use.

This adds complexity: *EPFIA survey* showed that **approx. 42`000 pts** are negatively impacted in Europe by IVDR [link](#)

What are the key challenges



Classification- is the submission of a performance study required?

National Competent Authorities/ Ethic committees- different requirements

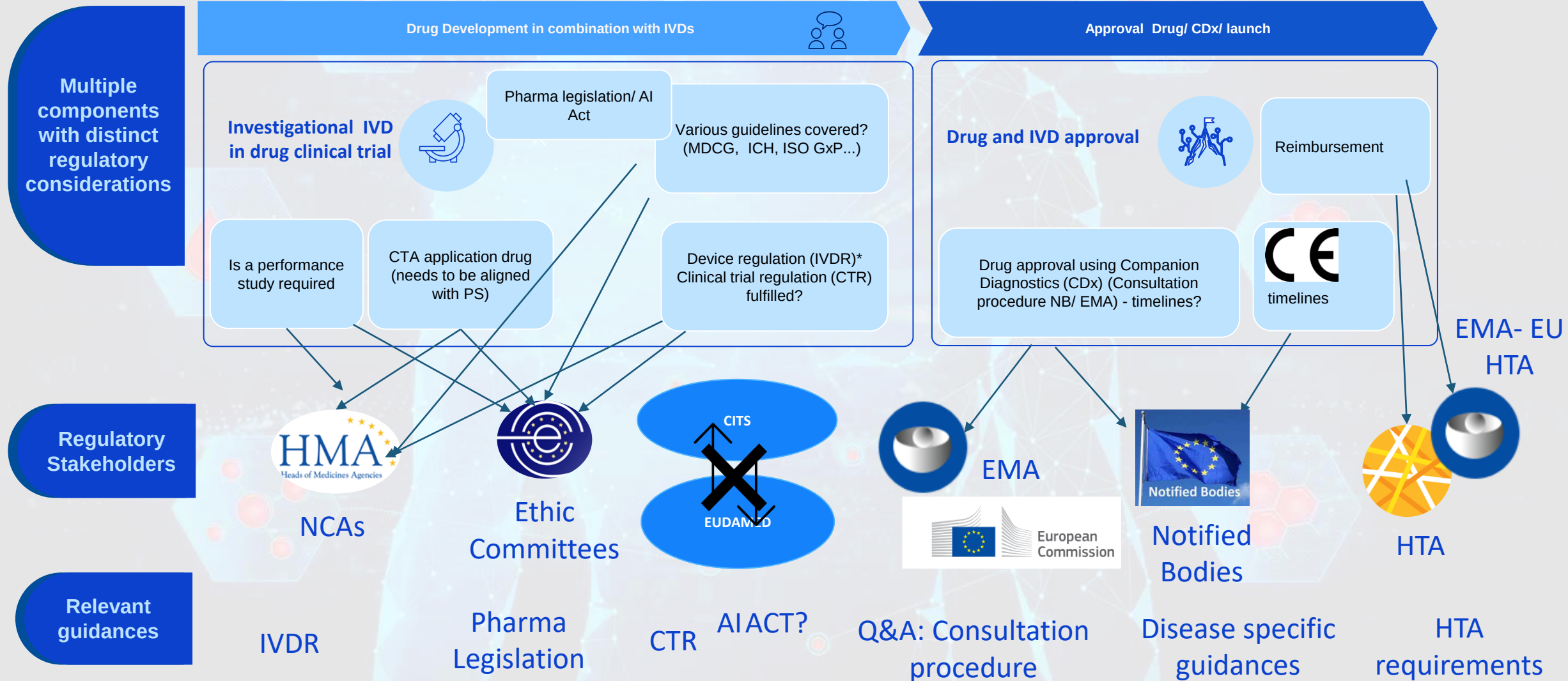
No harmonised approval process for performance studies –EUDAMED delayed

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

Use of Biomarkers- Points to consider



CTA = Clinical Trial application; AI = Artificial Intelligence; PS= Performance study; EC= Ethic Committees; EMA= European Medicines Agency; HTA= Health Technology Assessment Body; NCA= National Competent Authority

EFPIA proposed complementary solutions until coordinated process is in place

Proposal	Challenge(s) addressed	Impact level (H/M/L)	Timelines (short/long-term)	Lead
1. Postpone application of IVDR to clinical trials using an IVD	All – provides the opportunity to implement other solutions until coordinated process is available	H	Short term	European Commission
2. Voluntary Coordination Process across Member States	PSA submissions to each Member state, inconsistent process, timelines	H	Long term	HMA, MDCG
3. Common Set of Principles for Performance Study Submission and Review	Divergence & lack of clarity, inconsistency of approach Role & Responsibilities not clear	H	Medium term	MDCG (guidance drafted)
4. Risk-based Approach to Performance Studies	Infrastructure challenges; Burden of PSA	M	Long term	European Commission
5. Under Article 92: Temporarily Accept Non-conformity to PSA Requirements	PSA submissions to each MS in absence of needed infrastructure and coordination	M	Medium term	MDCG
6. Clarify Definitions of In-House Test to Broaden Scope	Burden of PSA, Enrolling early phase studies in Europe	M	Short term	MDCG

What is required?

Reduce complexity-dialogue of all stakeholder is needed

Regulatory frameworks for diagnostics/ medical devices and medicinal products need to foster connections

Provide more guidance regarding combined development and approval pathways and ensure good collaboration between EMA, National Competent Authorities and Notified Bodies

Ensure fast qualification of novel methodologies

Positive examples

Focus Group Qualification

Ernst & Young Survey

Pilot Scientific Advice for Combination products & CDx

COMBINE Project

Combine Project:

analysing the regulatory landscape for
combined studies on the IVDR/MDR/CTR interface



Analysis phase - understanding challenges and obstacles

1

Issue List

Clarify problems that cause delays in combined studies in terms of 'scientific, procedural, legal' issues – with input from stakeholders.

3

Mapping of Relevant Activities

Mapping of work potentially related to the MDR/IVDR/CTR interface
(e.g. poss. update of Q&A on interface IVDR/CTR (DK)
devt of Q&A on performance studies (lead: SE), etc.)

2

Mapping of EU Landscape

Mapping of competent authority landscape for the different regulations on MS level and parameters relevant to the CT/PS/CI application processes.

4

Proposals for Solutions

Proposals for solutions that could address the issues identified, taking into account also the mapping of landscape and ongoing work

The outcome of the analysis phase will be a document describing the three analysis elements and the proposed solutions.



Combine Project: analysing the regulatory landscape for combined studies on the IVDR/MDR/CTR interface

High-level timeline



Conclusion: Reduce complexity



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

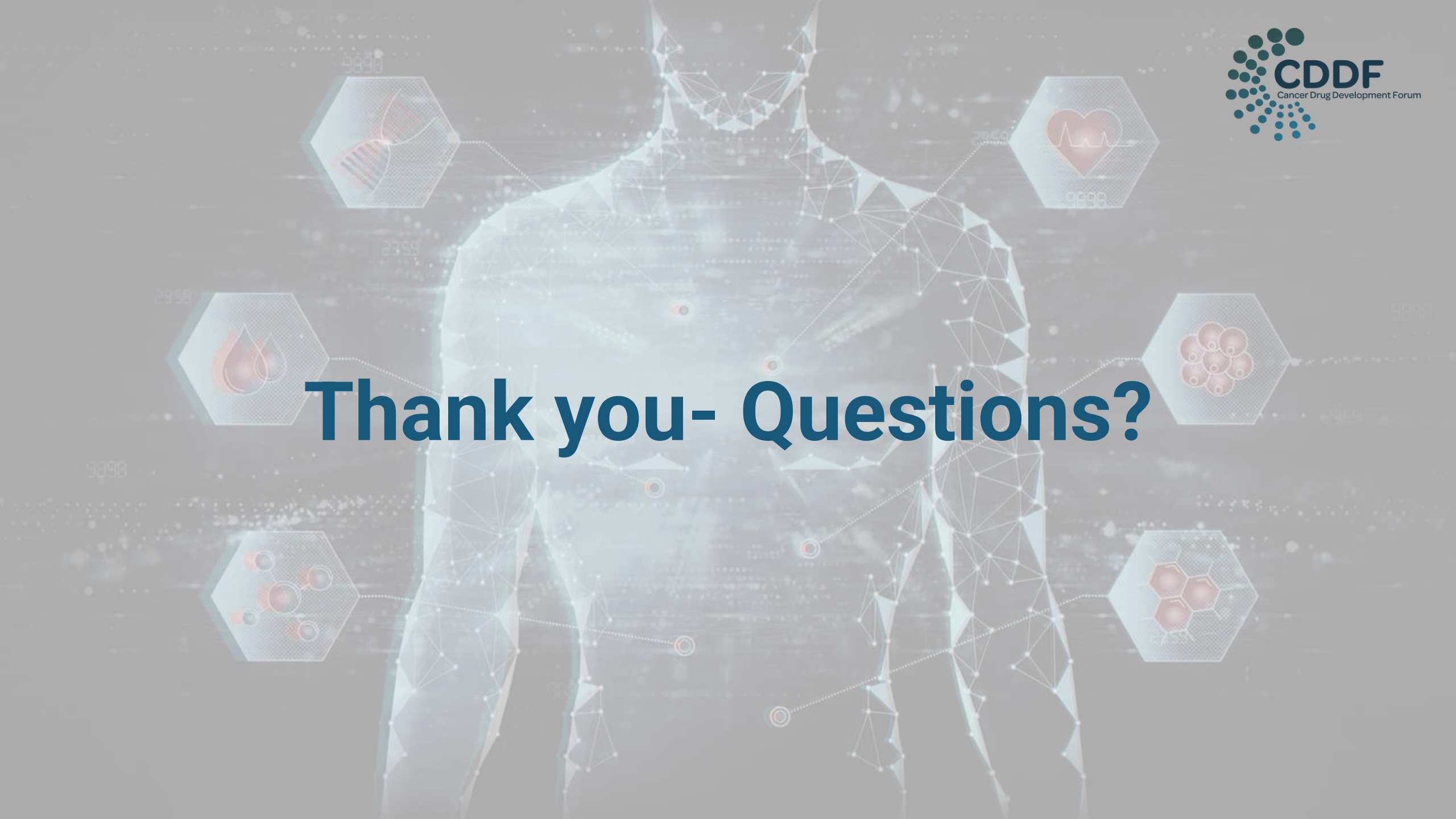
The IVDR increases complexity for

- 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 approval process for performance studies
- Focus on improved guidance for Health Authorities, Pharma & Academia

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



Thank you- Questions?