efpia

European Federation of Pharmaceutical Industries and Associations

Critical impacts of IVDR implementation on patient access to clinical trials






CDDF webinar

7 September 2023

CONTENT of the SLIDES

- Background In Vitro Diagnostics Directive (IVDD) – IVD Regulation (IVDR)
- Unforeseen impact of IVDR
- EFPIA survey results
- EFPIA proposed complementary solutions
- COMBINE project
- Q&A

Background – In vitro Diagnostics Regulation (IVDR)

IVDR significantly increased requirements compared to IVDD – entered into force since May 2022

- IVDR adopted to improve public health and protect patients
- different classification system for IVDs
- **notified bodies** (NBs) have oversight role for many more IVDs
- life-cycle approach to **safety**
- increased scrutiny, control and monitoring by **regulators**
- **improved traceability** for IVDs with EUDAMED
- **more transparency**

Critical negative impact of IVDR implementation to clinical trials

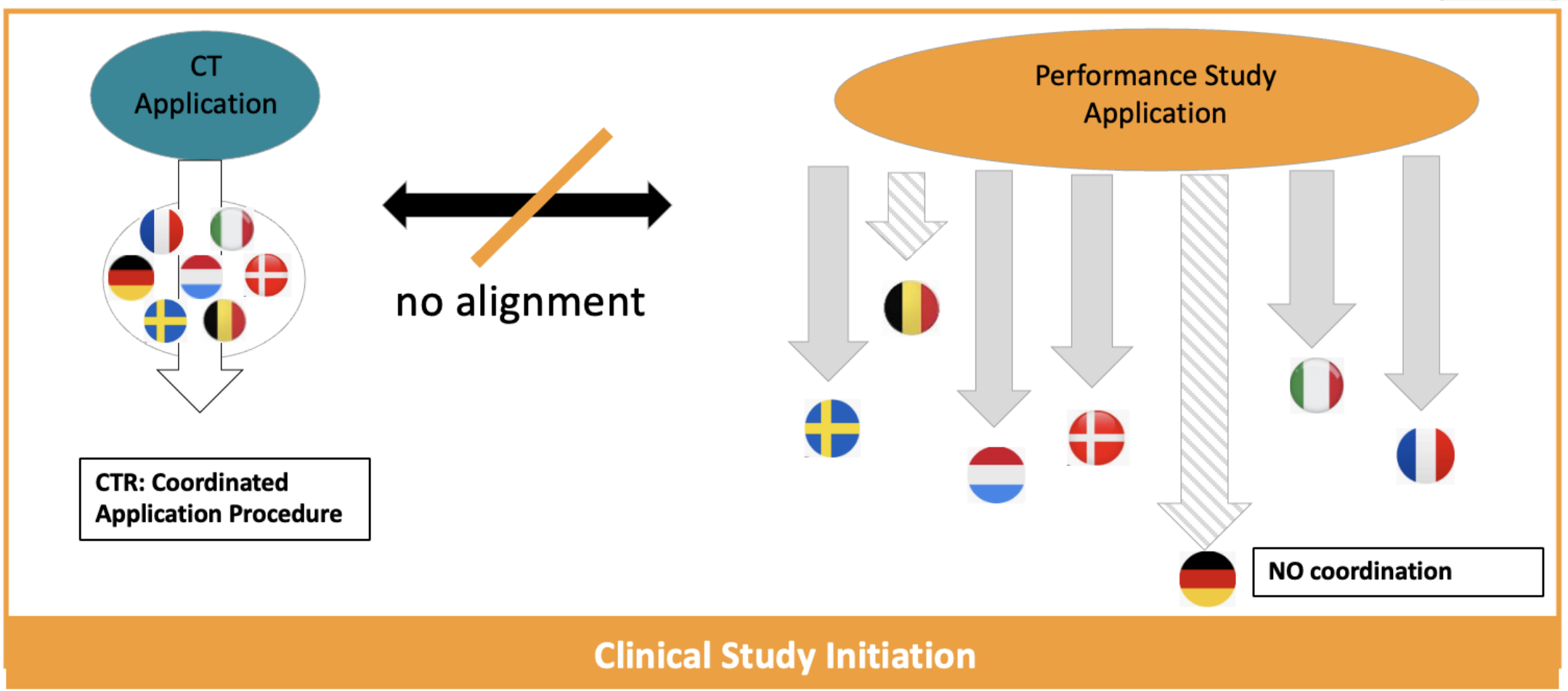
EFPIA fully supports the IVD Regulation aiming at ensuring a high level of public health and patient safety in Europe

However, complex Performance Study Application process leads to:

- **Delayed clinical study initiation and delayed clinical trial launch (6-12 months)**
- **Reduction in access to clinical trials for European patients**
- **Delayed access to novel therapies for European citizens**
- **Adverse impact on other initiatives** e.g. Europe's Beating Cancer Plan, Accelerating Clinical Trials in the EU (ACT-EU)

Ability to initiate clinical trials in Europe is severely impacted!

Negative impact of IVDR on clinical trials using an IVD: Lack of coordinated process & clarity for Performance Studies



Ability to initiate clinical trials in Europe is severely impacted!

IVDR Related Roadblocks Delaying Start of Clinical Trials

SPONSORS assessing need for PSA

Roadblocks

e.g.: no published PSA-IVDR submission guidance, test awaiting CE Marking may require PSA

SPONSORS preparing PSA

Roadblocks

e.g.:no feedback from Ethic Com; high variability of docs required

SUBMISSION of PSA to NCAs

Roadblocks

e.g.:unstable submission portal; request for certified translations; EthC specific local forms

Roadblocks in review of PSA

Roadblocks

e.g.:delays due to EthC review; request PSA for left-over samples

Start of Clinical Trial

Roadblocks legend:

Orange = **Infrastructure** challenge

Blue = **Lack of clear guidance**

Yellow = **Lack of alignment/harmonized** approach

EFPIA Survey on Impact of IVDR on Clinical Trials

EFPIA surveyed Members anonymously to gather data on the impact of IVDR on clinical trials and delayed patient access to those trials

- More than 2/3 of EFPIA large member companies responded
  - Data gleaned from 21 of 32 large Member companies
- Results represent a **conservative estimate of impact** (more EFPIA & non EFPIA Members)

EFPIA Survey on Impact of IVDR – Trial Delays

82-160 Trials currently delayed

238-420 Trials potentially delayed over next 3 years

6-12 months Most frequently reported length of delay

43% of companies estimated **6-12 months delay** *currently*

48% estimate potential **6-12 months delay** *over next 3 years*

Responses from 21 of 32 EFPIA large Member Companies
Range of numerical responses provided by respondents

EFPIA Survey on Impact of IVDR – Patient Impact

Estimated impact over next three years:

33,815 - 42,200 Patients impacted (patients enrolled, not patients screened)

16,812 - 27,400 Cancer patients impacted

228 - 410 Trials that may enroll fewer EU patients

Responses from 21 of 32 EFPIA large Member Companies
Range of numerical responses provided by respondents

EFPIA Survey on Impact of IVDR - Impact on clinical research in Europe

Impact to Trial Sites

4,984

Number of European sites anticipated to be involved in these trials in the next 3 years

67%

Percentage of EFPIA Members that would consider reducing the number of EU trial sites if IVDR requirements remain the same

Impact to Patients

50,014 to 65,860

Number of European patients anticipated to be enrolled in these trials in the next 3 years

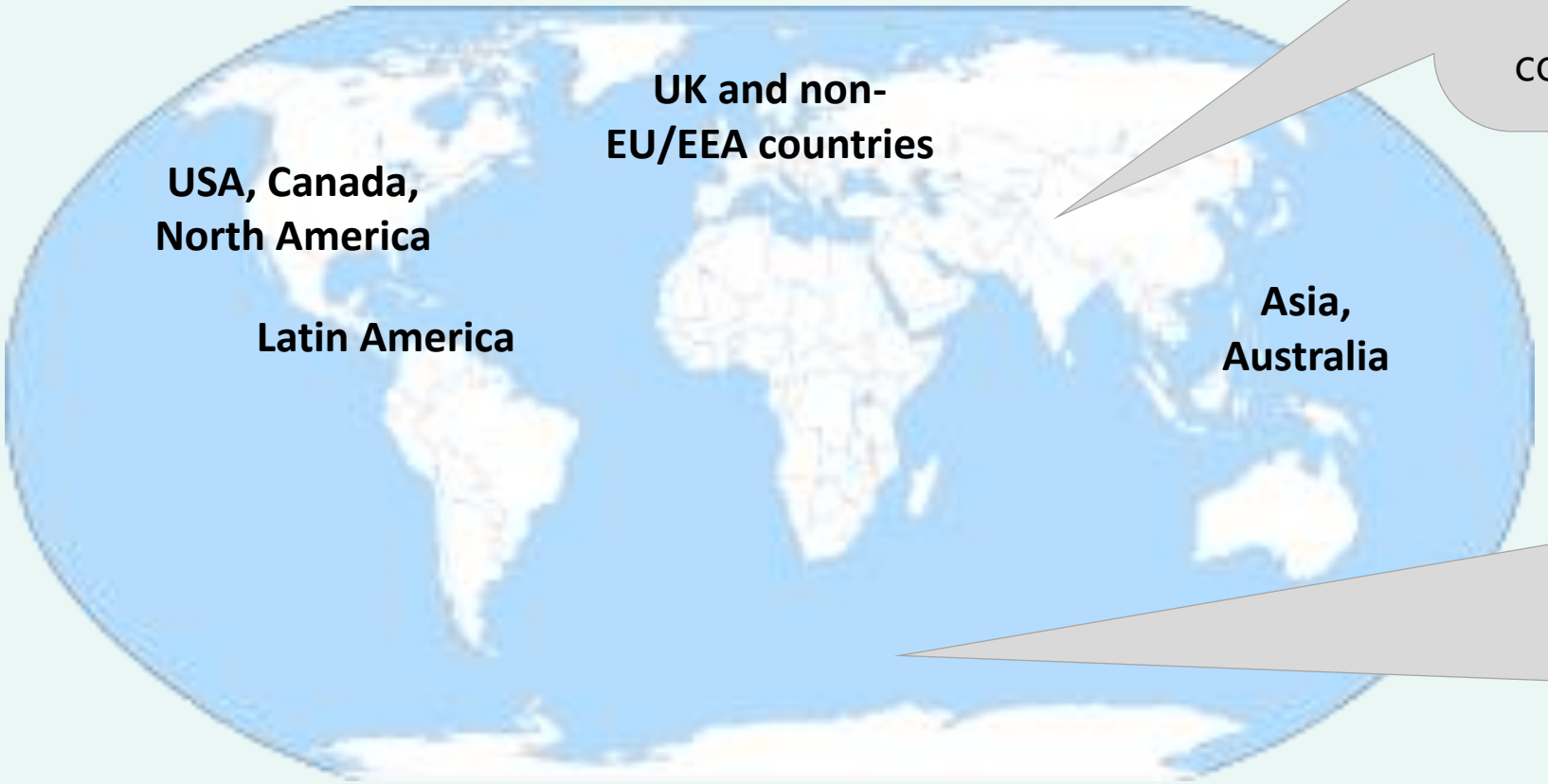
71%

Percentage of EFPIA Members that would consider reducing the percentage or number of EU patients if IVDR requirements remain the same

Responses from 21 of 32 EFPIA large Member Companies

EFPIA Survey on Impact of IVDR
Impact on Clinical Research in Europe

Where will the trials be conducted instead of European sites?

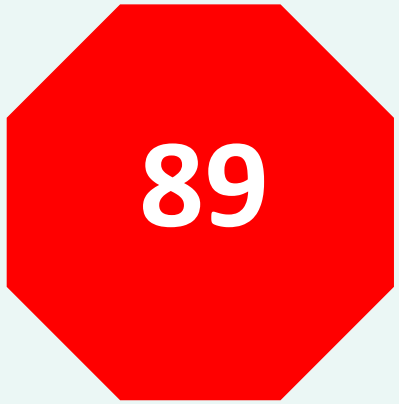


"**It is already occurring** now that trials are shifted away from Europe to US and Asia. This movement will be getting stronger upon the experience with IVDR adding more complexity to CTAs in Europe."

"The regulatory burden under the IVDR is large and **in rare disease**, the low testing volume could be challenging for clinical trials in the EU. The process as it currently stands is putting access to novel medicines for EU patients at risk."

EFPIA Survey on Impact of IVDR - Impact on Access to Innovative Medicines in Europe

Therapies that could face delayed launch in Europe if clinical trials are delayed…



…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%

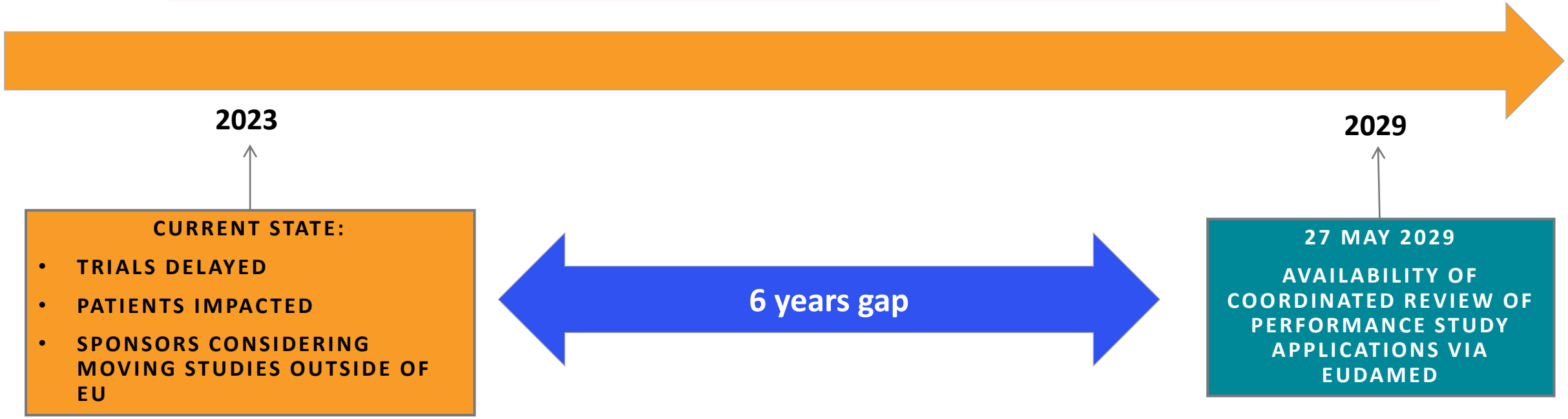
Challenges at Member State Level

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

Member States Cited by >25% of Respondents	Percentage of Respondents
Germany	74%
France	47%
Italy	32%
Czech Republic	32%
Spain	26%
Poland	26%
Austria	26%

How do we keep clinical research & innovation in Europe?

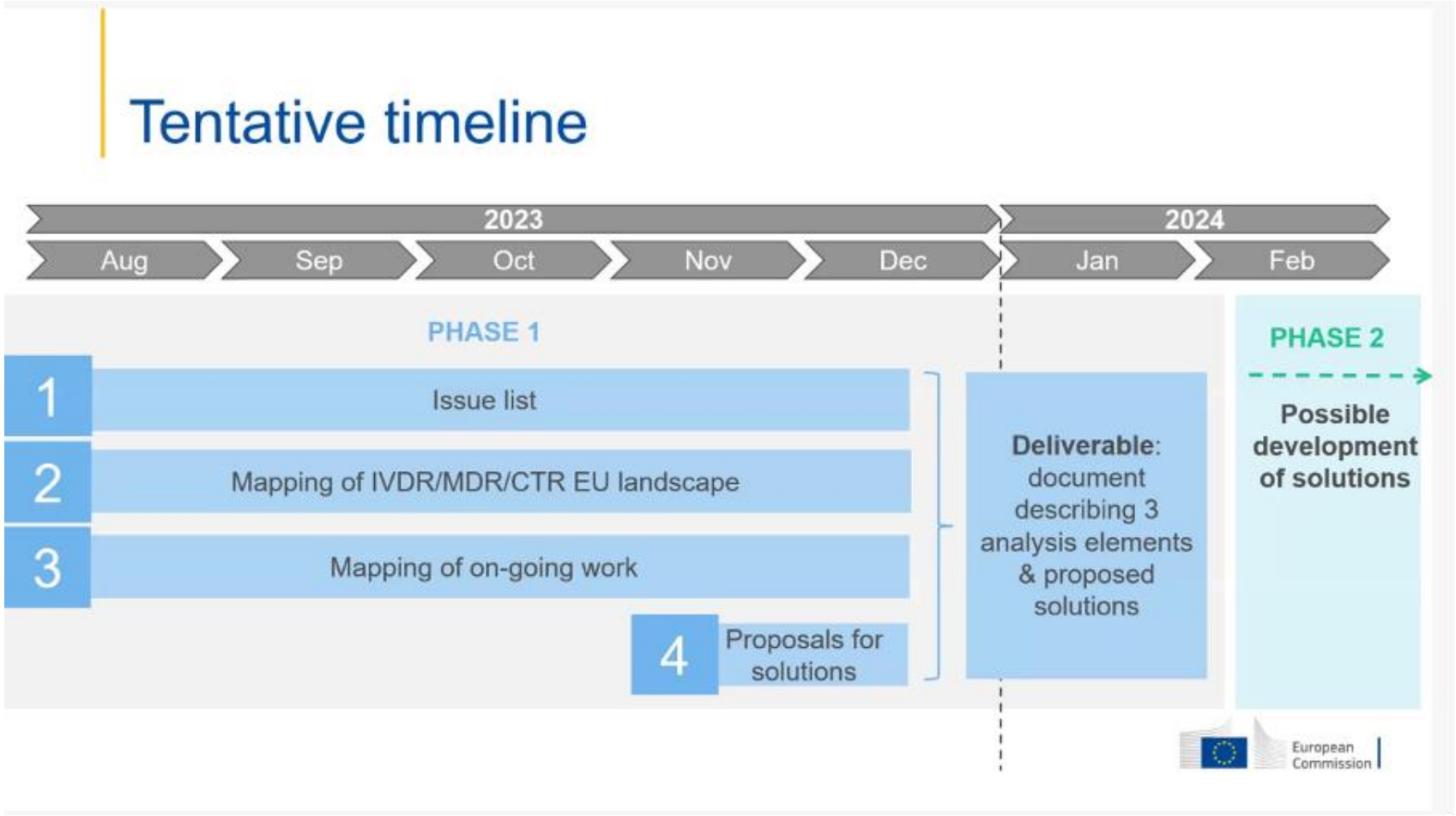
Further action is needed now
Combination of several proposed solutions implemented in parallel



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**

Positive developments – COMBINE project launched by EC to look at the interface between the IVDR/MDR/CTR



Positive developments – COMBINE project with MDCG, CTCG, CTEG, CTAG

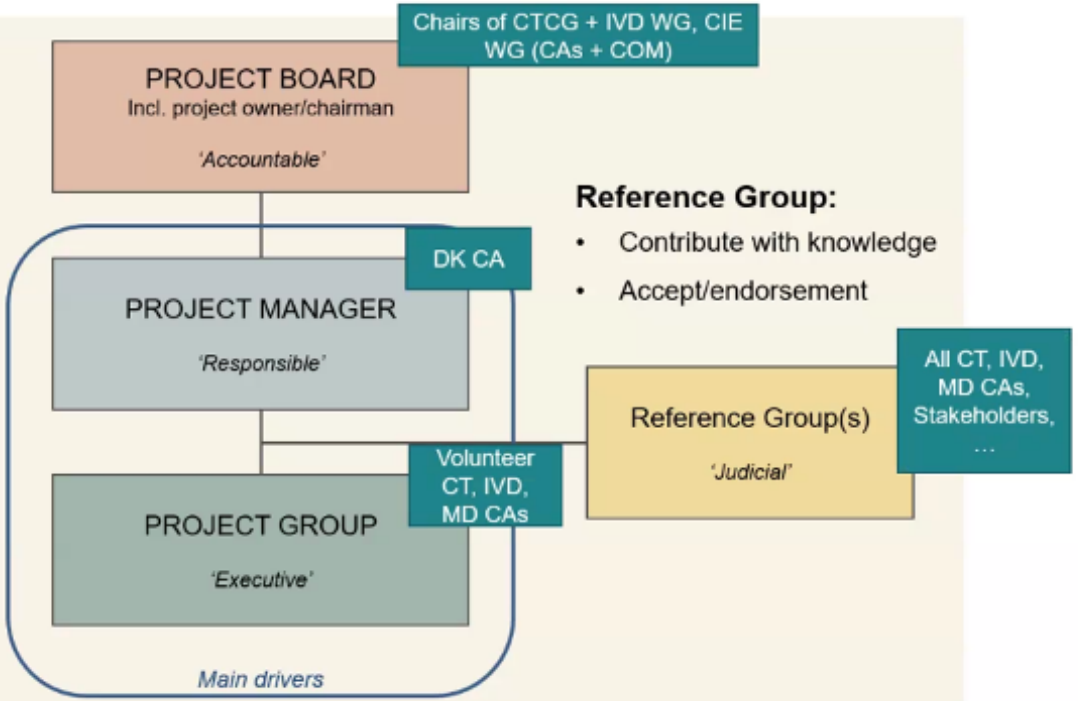
How will we work together? - Project management approach

Steering group/project owner:

- Decides on major issues
- Pays/provide resources
- Paves the way for the project

Project Manager and Project group:

- Develop solutions
- Delivers the agreed deliverables – in accordance with project plans



European Commission

Thank you for your attention !

European Federation of Pharmaceutical Industries and Associations






EFPIA Brussels Office
Leopold Plaza Building * Rue du Trône 108
B-1050 Brussels * Belgium