IVD Regulation – Regulatory consequences for Laboratories

Prague, 2 October 2015

Jesús Rueda Rodríguez
International Affairs Director, EDMA

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Overview of IVD Regulation

- Timeline
- In House Assays
- Genetic Tests
- Services delivered through information technologies
- Clinical Evidence

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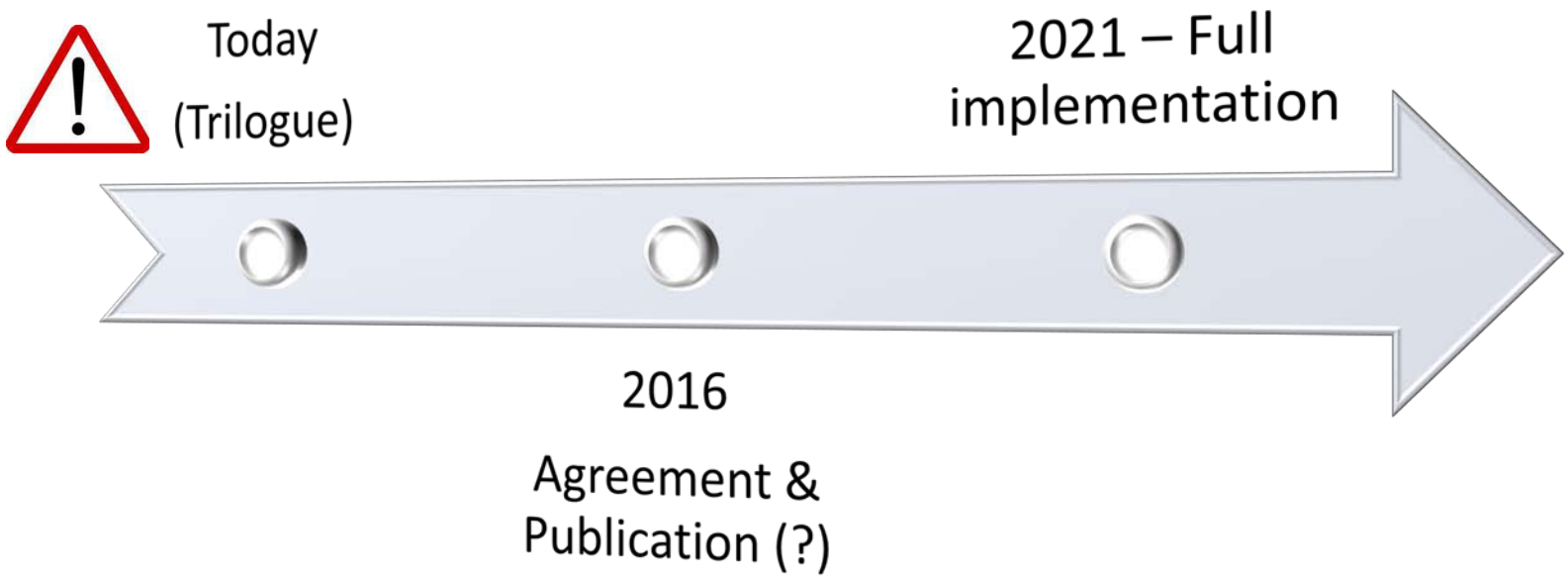
Timeline


Today
(Trilogue)
2021 – Full implementation
2016
Agreement & Publication (?)

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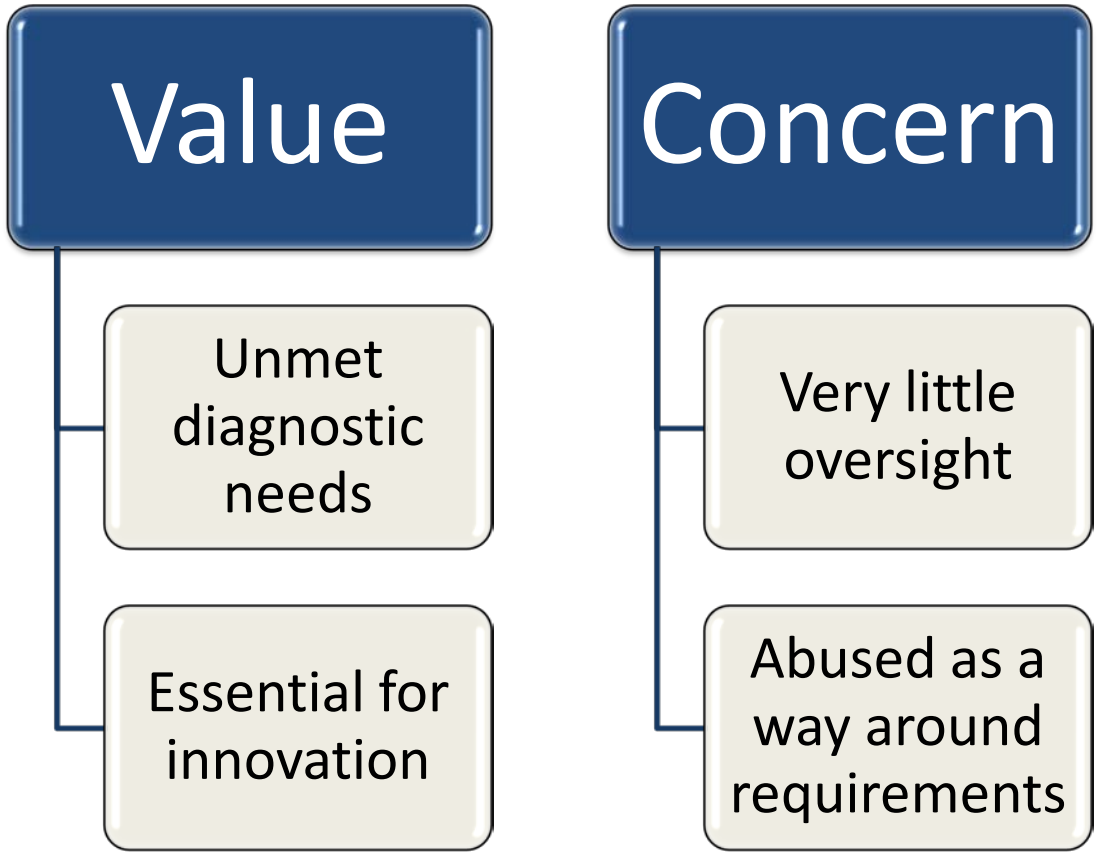
In house assays - concepts



In house assays - considerations

- Unmet need? – No equivalent CE marked assay
- Quality System – Required!
- Vigilance – need to report incidents
- Commercial laboratories vs health institutions

Outcome – in house assays

Scope

- Reduced number of assays
- Reduced number of laboratories

Controls

- Quality system requirements
- Additional (i.e vigilance) requirements

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Genetics – concepts

Policy	Vulnerable subjects	Access to Genetic tests
• High profile • Most controversial part of the regulation	• Protect minors • Protect incapacitated patients	• Control access of patients to genetic information • Prescription only?

Genetics – possible outcomes

- Tighter rules on consent in genetics
- Restricted access to tests – i.e. only through specialists or through prescription
- Guidance to different EU member states

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The Internet!

Internet has become a portal through which patients can access diagnostic services

Regulation will cover such services, even if physically labs are located outside the EU

Authorities will be given enforcement powers – effectiveness remains to be seen

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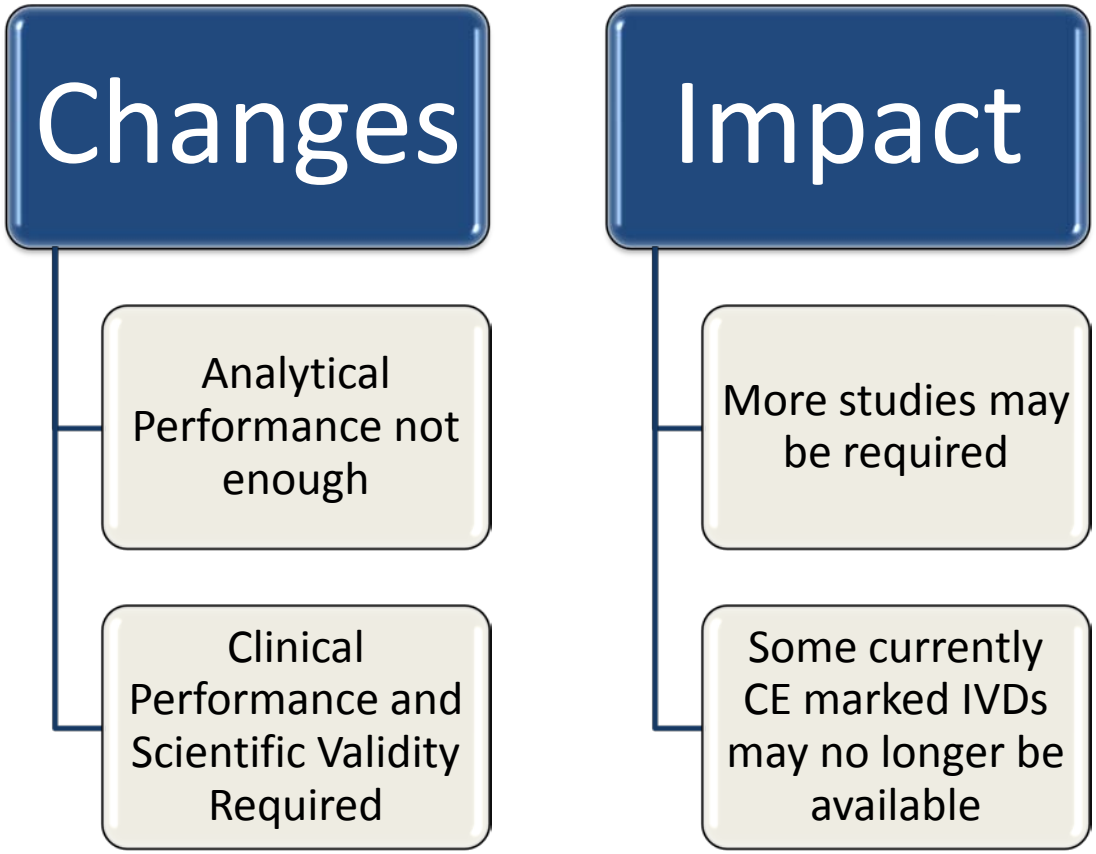
Clinical Evidence - concepts



How clinical evidence is gathered

performance of a device shall be demonstrated based on one or a combination of the following sources

- **clinical performance studies;**
- **literature;**
- **experience gained by routine diagnostic testing.**

Other considerations

UDI

Unique device identification will be required

- Can this be adapted effectively for other uses e.g. stock management?
- Data which becomes publicly available through UDI will it be of interest?

Transparency

Much greater transparency on IVDs

- Easier to see incidents and problems which have occurred
- How will that information be used? What impact will it have on assay selection?

Implementation

Many critical details will not be in the regulation

- How will the users of IVDs engage in the implementation process?

Thank you!

Questions?

Jesús Rueda Rodríguez
j.rueda@edma-ivd.eu