BIOMARKER COMMERCIALIZATION

Interreg Baltic Sea Region

EUROPEAN UNION

EUROPEAN REGIONAL DEVELOPMENT FUND

BiC Bridge - Introduction to regulatory tools

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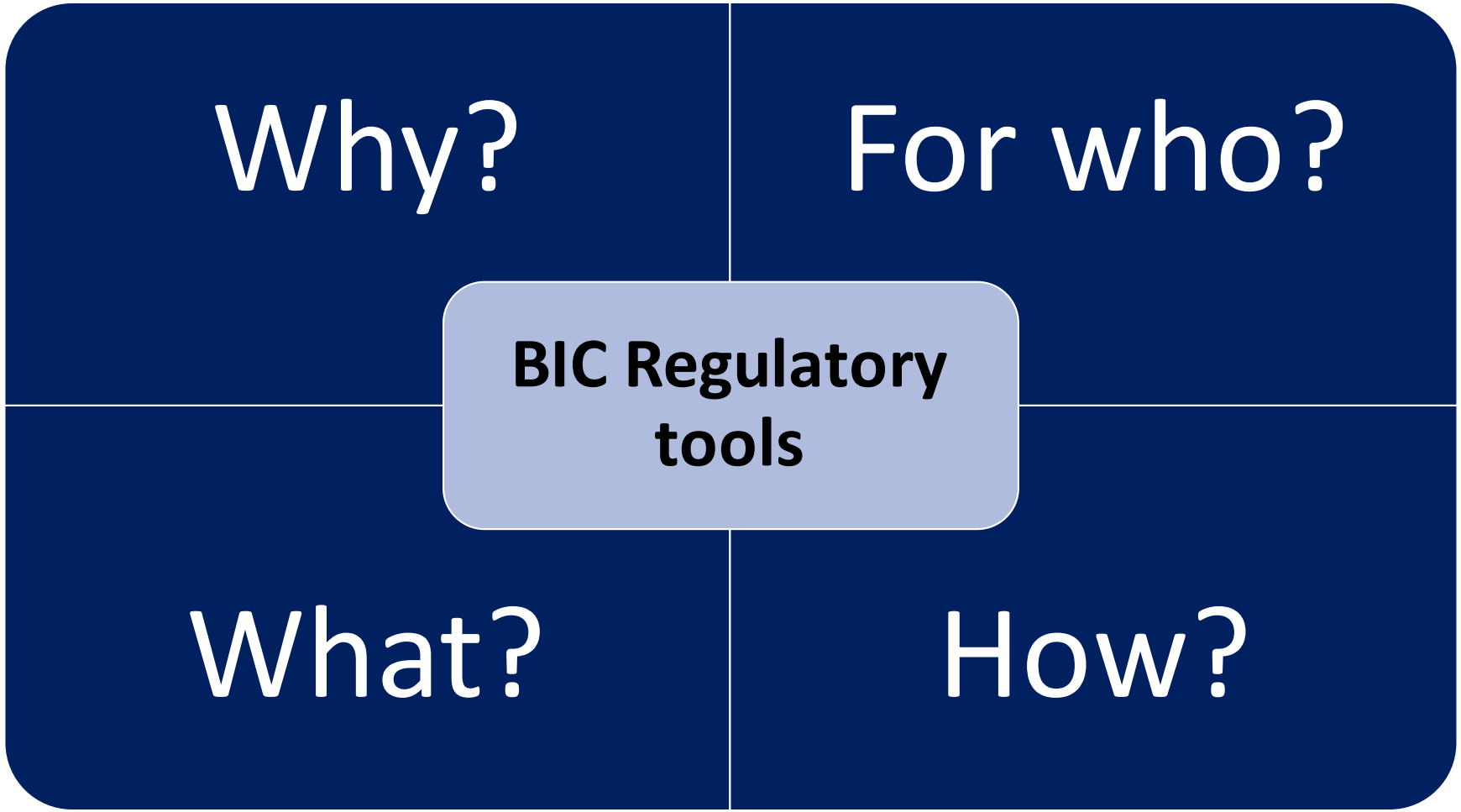
11.05.2021, Codex4SMEs & BIC The European In Vitro Diagnostics Regulation webinar

Plan of presentation



Why IVDR Guide & IVDR flowchart have been developed?

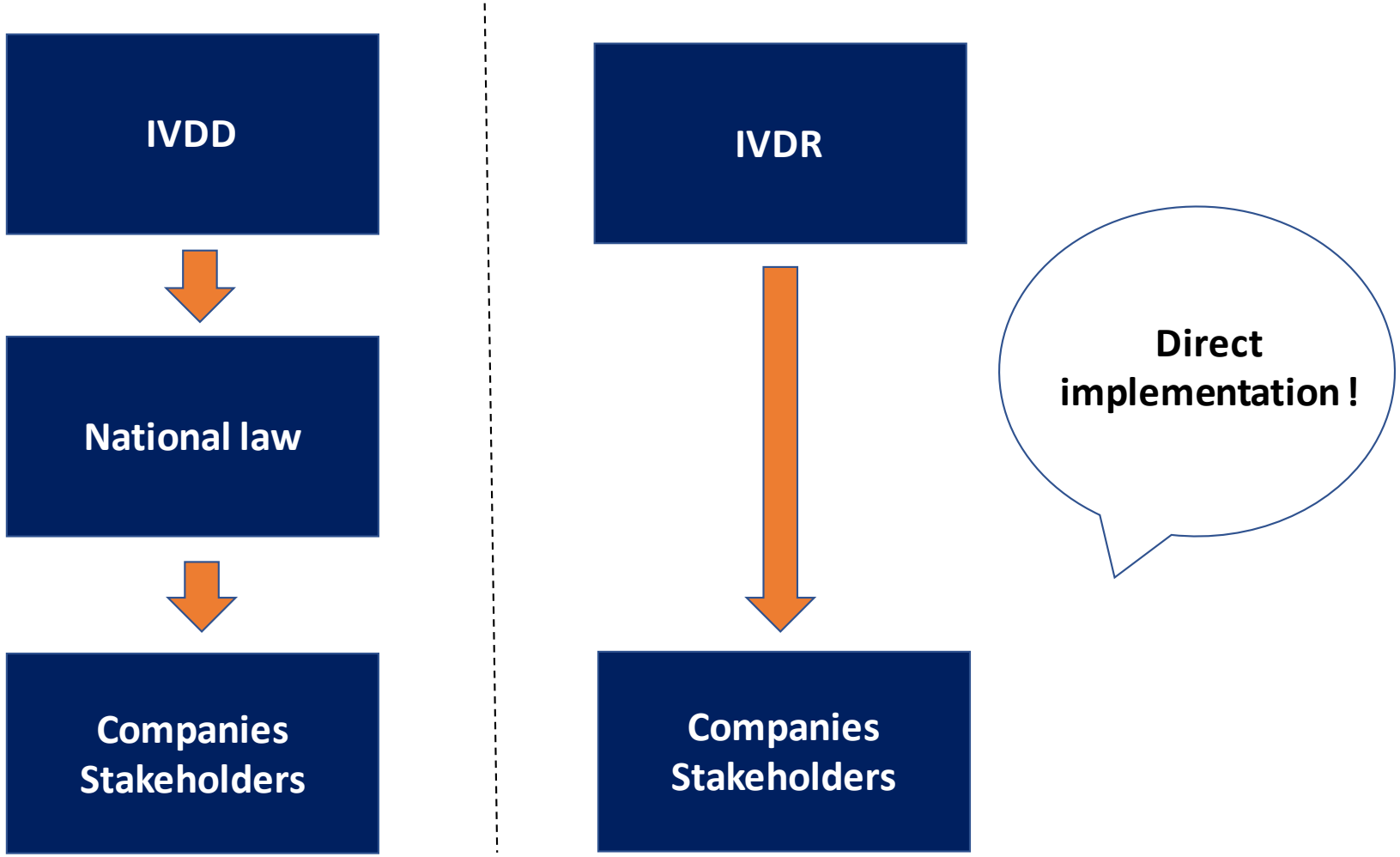
Transformation of regulatory environment

Need of standarization in commercializing biomarker inventions

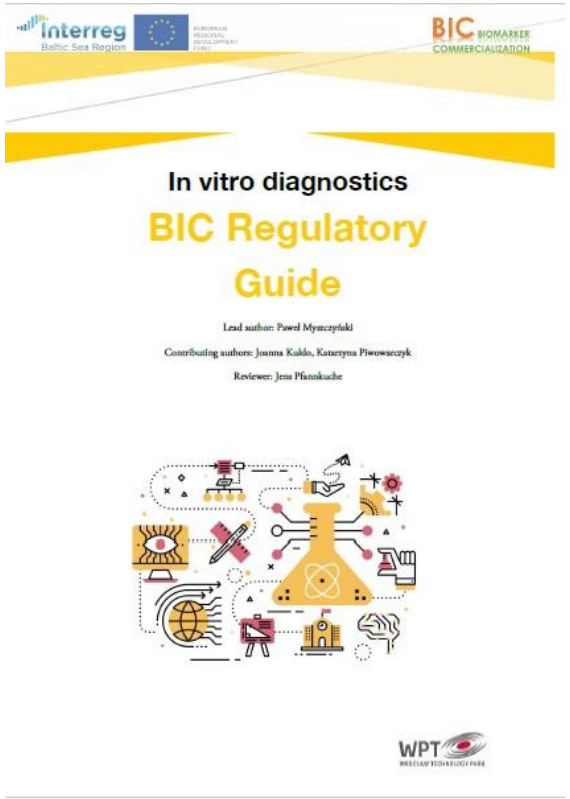
Poor understanding of regulatory process, especially within academic researchers

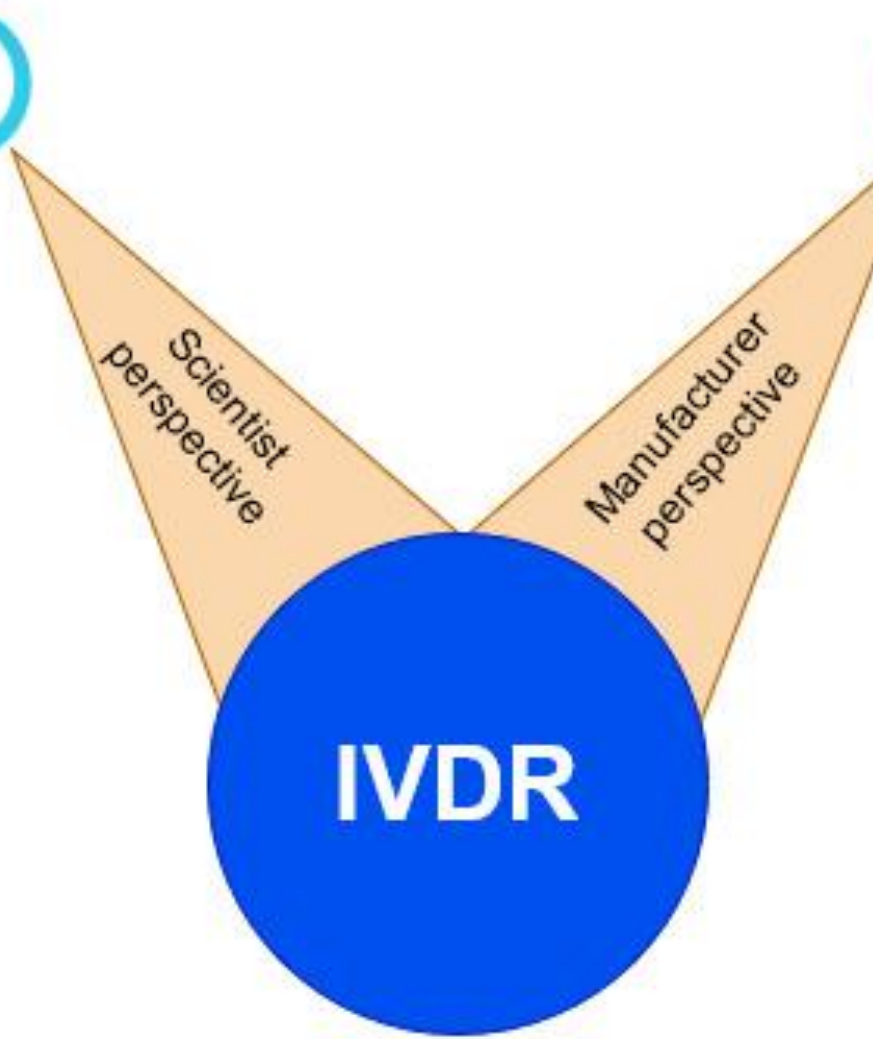
Encouragment of researchers to commercialization

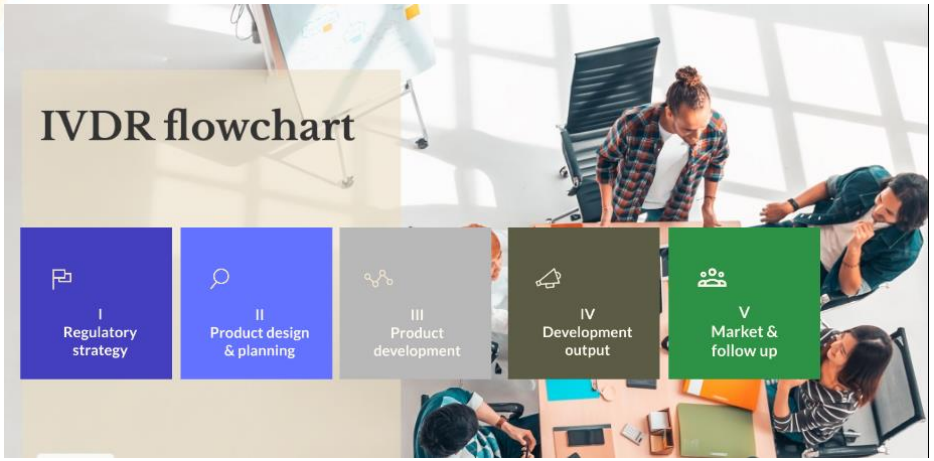
From IVDD to IVDR



BIC Regulatory tools







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Regulatory environment

CLSI guidelines

IEC 62304

ISO 13485

IEC 62366

IVDD

How to achieve regulatory compliance?

IVDR

ISO 14971

MEDDEV standards

ISO 20916

MANUFACTURER

MDCG guidelines

Characterization of tools

BIC Regulatory Guide

- Developed at the basis of IVDR and based on the commercialization model identified within the project
- Focused on early-stages
- Big picture of the process including stakeholders (and its potential role) from researcher perspective
- Include IVDR overview
- Regulatory activities are correlated with TRLs and commercialization stages
- In the form of the handbook

IVDR Roadmap

- Developed at the basis of IVDR and real-life experience of industrial partners
- Focused on CE-approval stages
- Regulatory process from SME perspective
- How to deal with obligations imposed by IVDR
- Regulatory issues introduced in the chronological manner illustrating manufacturer's real-life process
- In the form of user-friendly digital tool

Activities

1 Familiarize yourself
regulations

Familiarize yourself with the
definitions, obligations and r
by using the source documen
guidelines. ISO 18113 could
here, as well.

3 Identify the produ
applicable legislat

It is crucial to identify all appl
legislation for our further pro
Because of the variety of pro
medical device could be subje
different set of laws. Compli
MDR or IVDR could be not e
can consider services of a reg
professional.

Prezi

3.1. Commercialization process: Bi

The first stage of commercialization process, in re
the **discovery phase**. The main stakeholder involve

BACKGROUND:

Conducted BIC interviews indicate that researche
strictly scientific perspective and they are not awa
are not legally responsible for IVDR requirement
commercial potential, should be aware of the
accompanying biomarker projects. This knowledg
if they intend to exploit the commercial potential.
and adjusted to business, as well as to legal require
partners and its market value rises. However, first
document stringently each biomarker discovery as

The **researcher**, from the beginning of th
quality and relevant data (as input for further te
formity assessment further in the process.

In order to assure effectiveness of the com
principles (fig. 8).

Figure 8: Suggested principles for researchers

Implement data quality
assurance by working i
quality systems

Fulfil business requireme
related to biomarker proj
(corresponding to TTOs
requirements)

Secure intellectual prope

Source: BIC interviews

Figure 10: Regulatory tasks regarding discovery phase

Regulatory tasks regarding discovery phase

Regulatory tasks to fulfil within 1st commercialization stage	Good practices
❖ Familiarise with general information regarding the early stages of development from a regulatory perspective The stages of the IVD assay commercialization process that do not forecast the participation of enterprise (at the early stages of development) do not contain mandatory regulatory tasks regarding product placement on the market (required by IVDR). The researcher has to take into account a regulatory pathway that biomarker products have to go through, but he/she is not legally responsible for it. Therefore, tasks concerning regulatory aspects at the early stages were developed on the basis of good practices. Application of the practices would potentially improve the pace of industry assay development (fulfil legal enterprise obligations), and as a result place the product on the market. Link to IVDR: https://eur-lex.europa.eu/legal-con-	❖ Plan how you will compile your data and results From a regulatory point of view, the researcher, from the beginning of the biomarker project, is responsible for collecting good quality and relevant data (input for technical documentation). Well-structured raw data and availability, facilitate further comparisons, validation and reduce differences in re-tests. Research should be carry out in conformity with current standards and IVD methods. It's recommended to implement quality system and/or data management & stewardship system, e.g. GLP, FAIR. ❖ Work according to a quality system for non-clinical studies & familiarise with the "state of the art" of IVD development Be familiar with the popular standards: QPBR, GLP, FAIR (for scientific data management and stewardship). Consider if there are any specific rules that require the use of a system. GLP handbook by WHO can be found here: https://www.who.int/tdr/publications/documents/glp-handbook.pdf U.S. standards: CMS/CLIA, CLSI

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Thank you for attention!

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