

Online Seminar

The European In-Vitro Diagnostics Regulation

15:00 – 15:10	Words of welcome and short Codex4SMEs and BiC project introductions
15:10 –15:50	The European In-Vitro-Diagnostics Regulation by Iweta Metzger & Marion Fehlker, novineon CRO GmbH, Tuebingen, Germany
15:50 –16:05	Q&A
16:05 – 16:35	The Biomarker Commercialization Guide and the IVDR Guide of the BiC project by Valérie Daussin Laurent, Aalborg University Hospital, Denmark Paweł Myszczyński, Wrocław Technology Park, Wrocław, Poland
16:35 - 17:00	Q&A

1. The online seminar will be recorded
2. Switch off your camera and your microphone.
3. During the whole webinar, only the speakers will be allowed to talk.
4. Ask questions via the CHAT.
5. **If you cannot hear the speaker please inform us via CHAT. Alternatively, use the dial-in number:**



Interreg NWE Project Codex4SMEs Introduction

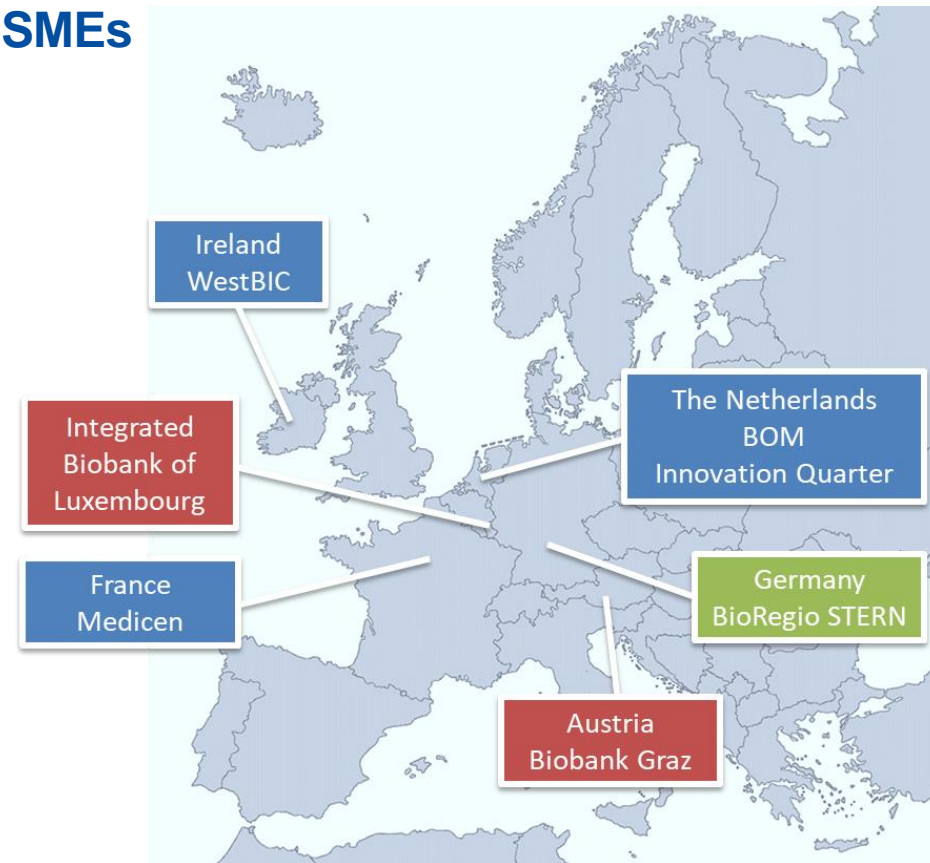
Codex4SMEs project introduction

Codex4SMEs
= **Companion diagnostics expedited for SMEs**

Total budget: 3 M €
ERDF budget: 2 M €
Project period: 51 months

Objective of the project:

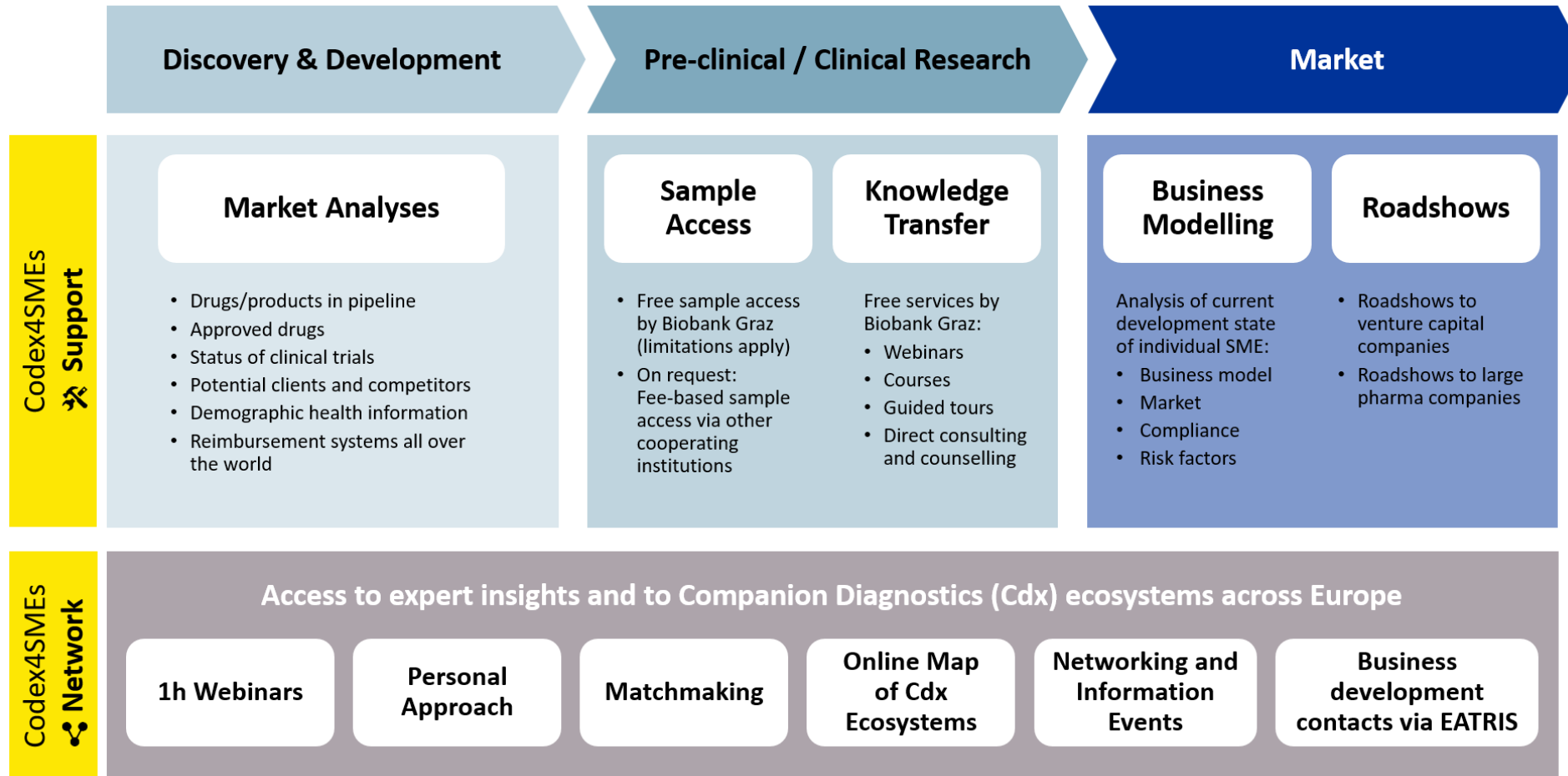
- Improve healthcare by enhanced adoption of Personalized Medicine
- Establishing a network which supports SMEs along the value chain of (Companion) diagnostics (Cdx) development



Codex4SMEs project introduction

What is in for you?

Our services for your path towards the market



As part of the **Interreg-NWE Codex4SMEs** project, Biobank Graz offers “sample access” and “knowledge transfer” for **small and medium-sized companies**.



Sample Access



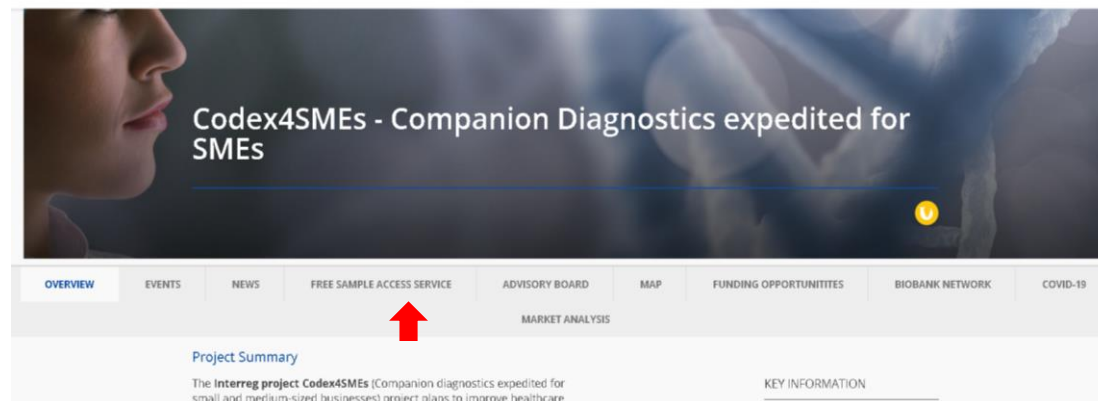
Knowledge Transfer



Access to both support schemes is limited!

Important: first come first serve!

👉 “Free Sample Access Service”: Guidelines & Application forms available on project website:
www.nweurope.eu/codex4smes



Contact Information:

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Project Website:

www.nweurope.eu/codex4smes



Tools for Biomarker Commercialization

The BIC and BIC BRIDGE
Project

Project Partners and Funding

- A transnational cooperation of 3 *research* and 5 *cluster* organizations in the Baltic Sea Region: **Denmark** (Coordination: Aalborg University Hospital), **Estonia**, **Finland**, **Germany**, **Lithuania**, **Poland**
- Project budget is EUR 2,55 million and it is co-financed by the European Regional Development Fund through the Interreg Baltic Sea Region Programme with EUR 1,96 million.



EUROPEAN
REGIONAL
DEVELOPMENT
FUND

EUROPEAN UNION



BIC – the challenges to be addressed

- How do you translate a biomarker discovery from lab to clinical setting?
- How to ensure efficient validation phase and generation of valid data?
- How to ensure that the researchers have adequate knowledge about the commercialization of biomarkers?
- How does a Technology Transfer Office (TTO) select the best biomarkers projects for commercialization?
- How to provide relevant documentation to industry or investors?

The BIC – Tools

- BIC Guide Tool for development and commercialisation from discovery to market launch
- A Best Practice Handbook, based on real life experiences
- A Review Tool for screening and selection addressed to TTOs
- The IVDR Guide: Guidelines for Regulatory Requirements
- An Educational Toolbox for research institutions- to use comprehending the process toward commercialisation