



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



European Regional Development Fund

- 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.
- If you cannot hear the speaker please inform us via CHAT. Alternatively, use the dial-in number:





European Regional Development Fund

Interreg NWE Project Codex4SMEs Introduction

Codex4SMEs project introduction



Codex4SMEs

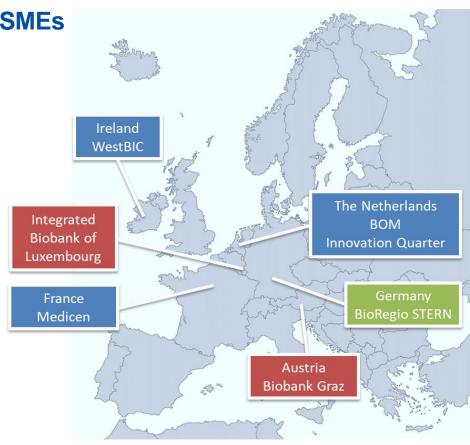
= Companion diagnostics expedited for SMEs

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

Discovery & Development Pre-clinical / Clinical Research Market Knowledge Sample Business **Market Analyses** Roadshows Access Transfer Modelling Codex4SMEs ★ Support • Drugs/products in pipeline • Free sample access Free services by Analysis of current Roadshows to by Biobank Graz Biobank Graz: development state venture capital Approved drugs (limitations apply) of individual SME: companies Webinars · Status of clinical trials Roadshows to large On request: Business model Courses Potential clients and competitors Fee-based sample pharma companies Market Guided tours • Demographic health information access via other Compliance Direct consulting • Reimbursement systems all over cooperating Risk factors and counselling the world institutions Codex4SMEs Access to expert insights and to Companion Diagnostics (Cdx) ecosystems across Europe Network Online Map **Networking and Business** Personal 1h Webinars Matchmaking of Cdx Information development Approach **Ecosystems** Events contacts via EATRIS

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



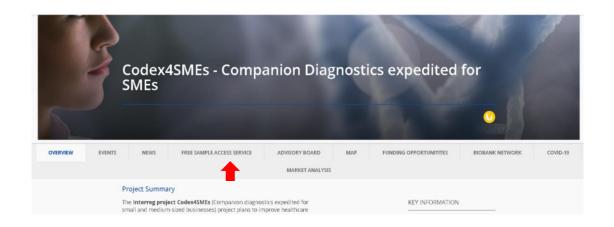




Access to both support schemes is limited!

Important: first come first serve!

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





Contact Information:

Dr. Margot Jehle

E-Mail: jehle@bioregio-stern.de

Project Website:

www.nweurope.eu/codex4smes



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.































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 commecialization?
- 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