The European In-Vitro Diagnostics Regulation

With the IVDR coming into force, manufacturers and developers of in vitro diagnostics and biomarkers must comply with the new regulatory requirements. Many companies, especially small and medium-sized enterprises, face major hurdles in this transition. With this condensed introduction to the IVDR, the two networks the Interreg North-West Europe Codex4SMEs and Interreg Baltic Sea BiC want to offer SMEs some guidance on how to get started. Attendees will receive an exclusive tutorial for the Biomarker Commercialization Guide and the IVDR Guide of the BIC project. To make new contacts, the event offers all participants the opportunity for one-to-one meetings during the networking session.

Agenda

Date: May 11th, 2021 at 15:00 – 17:00 CEST

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

- IVDR: introduction and new risk classification
- Performance evaluation: three pillars for clinical evidence
- Clinical performance studies: purpose and requirements
- Post-market surveillance: requirements and implementation

15:50 –16:05 **Networking Session** via Matchmaking Platform for Personalized Medicine

- As small and medium-sized enterprise find qualified experts and collaboration partners in 1:1 meetings
- As Research and Technology Organisation find new partners for technology transfer
- As product developer find partners to discuss new technology and innovative solutions
  - ✓ After registration, book virtual one-to-one meetings via this **link**.

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, Wroclaw Technology Park, Wroclaw, Poland

- Introduction to the BIC GUIDE, a support tool for commercialisation of biomarkers, from discovery to industrial launch of IVD based biomarkers
- The IVDR regulatory guide addressed to researchers and SMEs

16:35 - 17:00 Q&A

Click here for Registration>>

Speakers

Iweta Metzger, M.Sc.
Senior Consultant at novineon CRO GmbH, Tuebingen, Germany

Iweta Metzger is Senior Consultant at novineon CRO in Tuebingen. She studied molecular nutritional science with special focus on experimental research, genetics and molecular mechanisms at the **University of Hohenheim**. In a DFG-funded project, she conducted research on the aging-associated modification of intestinal homeostasis and barrier function and on metabolic liver diseases. During her research projects, she gained experience in various laboratory methods such as PCR, immunoassays, immunohistochemistry, cell culture and next generation sequencing. She specialized in the legal aspects of food law as well as pharmaceutical and medical technological regulations during her semester at the **University of Vienna**. Since February 2019, she has been working for novineon CRO. Her areas of competence are planning of and conducting clinical evaluations and performance evaluations as well as performance studies of in vitro diagnostics.

Marion Fehlker, Dr. rer. nat.
Director of Operations / authorized representative, novineon CRO GmbH, Tuebingen, Germany

Dr. rer. nat. Marion Fehlker, Director of Operations and authorized representative of novineon CRO, studied chemistry with biochemistry as a major subject at the University of Stuttgart. Subsequently, she did a doctorate in biology with focus on biochemistry/molecular biology at the Charité in Berlin. From 2005 – 2009 she worked as a post-doc in biomedical research at the Max-Delbrück-Centrum in Berlin, mainly studying the molecular biology of colorectal carcinoma. Since July 2010, Dr. Marion Fehlker is responsible for clinical evaluations at novineon CRO. Since 2013, she is certified "Manager Regulatory Affairs Medical Devices International". Dr. Marion Fehlker has been trained by CenTrial (Tuebingen) in the planning of clinical trials. Since 2016, she has been "Director of Operations" of the service division of novineon CRO.

Valérie Daussin Laurent
Team Leader Business Development, Aalborg University Hospital, Denmark
Project Leader BIC consortium

Valerie Daussin Laurent is Team Leader Business Development at Aalborg University Hospital in Denmark. She has 20 years of experience within innovation, patenting and technology transfer. With a background as legal adviser in Intellectual Property Rights, she assists researchers from the hospital from discovery to the industrial phase. The support includes patenting, fundraising as well as business development and negotiation with the partners. For the last 3 years, she has been project leader for the BIC consortium. BIC is an interreg program in the Baltic Sea Region that develops support tools for researchers, technology transfer offices and SMEs for a better and more successful commercialisation of biomarkers inventions.

Paweł Myszczyński
R&D projects specialist, Wroclaw Technology Park, Wroclaw, Poland

Paweł Myszczyński, R&D projects specialist in Wroclaw Technology Park. Until 2017 he is involved in implementation of Biomarker Commercialization project – BIC. He is an author of Regulatory Guide which comprises overview of new EU Regulation 2017/746 (IVDR). In the BIC BRIDGE project, which is a continuation of BIC, with cooperation with industry partners, he is working on regulatory roadmap for SMEs defining real-life regulatory pathways around IVDs.