1st Announcement and Call for Abstracts

IVDR – our Next Challenge?

6-7 June 2024

NH Málaga, Spain

INTRODUCTION & AIM OF THE WORKSHOP

With the EU In Vitro Diagnostic Medical Devices Regulation (IVDR) becoming applicable in May 2022, the European Bioanalysis Forum, as many others, is looking at the impact of this regulation on (bio)pharmaceutical drug research and development. Already, we observe a growing concern of the industry on potential scope creep of the IVDR into early clinical studies for assets where it is believed the regulations were not intended for. Consequently, cost and timelines are under pressure for these (mostly early clinical development) studies.
More and more, we see the regulated BioA lab and the Biomarker Assay lab getting pulled into the IVDR discussions. Hence, as a regulated BioA community we hope to bring the stakeholders together at the workshop and try/help to ensure the IVDR stays within its intended scope, that assays truly in scope follow the required pathway and people understand the substantial associated requirements, and those assays not in scope are not unnecessarily burdened.

CALL FOR ABSTRACTS

For this Focus Workshop, we look forward to your contributions, which should fit with the areas we plan to include in the workshop:

- Case studies of (potential) out of scope interpretation of the IVDR and the consequences for patient enrollment, timelines and cost of the studies impacted.
- Case studies of the in-scope interpretation of the IVDR and its value for the patient
- Although the main focus of the Workshop is on understanding the interpretation of the IVDR in clinical studies, we also want to include a technology session on CDx development and the scientific challenges, to illustrate the complexity of a CDx (re-)development under IVDR, its related cost and value for the patient.

You can submit your abstract **before 15-MAR-2024** using the attached form or via https://springfocus.e-b-f.eu/submit-an-abstract/ (website is being updated). Inclusion into the program will be evaluated by the organising committee and is based on its fit with the meeting goals. We will communicate acceptance of your abstract before 25-MAR-2024.

MEETING AGENDA & FORMAT

The agenda will include (i) presentations submitted via this call for abstract and (ii) case studies and (project/regulatory) experience from the EBF (stakeholder) community. The agenda will become available on the website around mid-April.
The meeting format will be a mix of round table discussions and plenary presentations for optimised interaction.
For your travel planning, the meeting will start at 10:00 CET on June 6th and will end around 16:00 CET on June 7th.

WHO SHOULD ATTEND?

Bioanalytical Scientists, Clinical PK/Ops experts impacted by the IVDR, Biomarkers and IVD-CDx experts from Pharma R&D, CRO and academia, and Health Authorities involved in the challenges related to IVDR in (early) drug development.

HOW TO REGISTER

- Registration fee: 565 Euro. There will be no early bird rate nor 1-day passes.
- For maximum interaction, the meeting attendance is capped to 60 delegates and 3 delegates per organisation (excluding presenters, for which the registration fee will be waived)
- To register: https://springfocus.e-b-f.eu/registration/ (registration opens on 15-JAN-2024)
- The meeting will be at NH, Málaga (Spain). Hotel reservations are independent from the EBF and not included as part of the meeting registration. More info in travel and lodging: https://springfocus.e-b-f.eu/travel-lodging/

MEETING ORGANISATION

Matthew Barfield (Roche), Robert Nelson (BioAgilytix) + 2 or 3 more from the EBF-IVDR team and Philip Timmerman (EBF)

EBF Focus workshops are organised by the EBF vzw as non-sponsored non-profit events and are independent from EBF member companies.