EBF Spring Focus Workshop

IVDR: our next Challenge?

6-7 June 2024 - NH Malaga, Spain

Thursday 06-June-2024

9:30 10:00 Welcome coffee

10:00 10:30 Welcome & Why this meeting?
10:00 10:30 *Philip Timmerman, EBF*

10:30 12:30 Setting the Scene
10:30 11:00 *Matthew Barfield, on behalf of the EBF*
Is IVDR impacting drug development beyond the intention of the regulations?
11:00 11:30 *Lee Monk, UCB-Pharma*
When Pharma incorporates IVDs: a dynamic unification
11:30 12:00 *Fabian Iltzsche, Boehringer Ingelheim*
Impact of IVDR on patient enrichment in ongoing trials
12:00 12:30 *Gauging the audience on experience with IVDR - incl. 5-min pitches*
Feedback from pre-meeting survey to delegates
Opportunity for the delegates to share experience

12:30 13:30 Lunch break

13:30 14:30 A bit of technology…
13:30 13:50 *Ivonne Bernal, BioAgilytix*
Challenges and Learnings from Validation of AAV Neutralising Antibody (NAb) Assays under IVDR
13:50 14:10 *Toralf Roch, CheckImmune*
Proximity Extension Assay (PEA) as novel technology for pharmacodynamic assessments and CDx?
14:10 14:30 *Open slot*
you can still submit an abstract in scope of the session - https://meetings.e-b-f.eu/springfocus/

14:30 15:00 Coffee break

15:00 16:20 IVDR impacting the choice of lab you work with

15:00 15:20 *Cecilie Freja Dalby Kjelgaard, Novo Nordisk*
Genotyping for allocation of study participants
15:20 15:40 *Claire Seal, invoX Pharma*
Impact of the IVDR on Vendor Selection and Project Strategy: Two Case Studies
15:40 16:00 *Open slot*
you can still submit an abstract in scope of the session - https://meetings.e-b-f.eu/springfocus/

16:00 16:20 *Jennifer Russell, A4P Bio*
Health Institution Exemption – the easy way out?

16:20 16:30 Short logisitic break

16:30 17:00 Preparing the two round tables for day 2

17:00 Day 1 close out

Friday 07-June-2024

9:00	**10:30**	**Case studies impacting the lab activities**
9:00	9:20	*Tracy Iles, Labcorp Drug Development* IVDR regulations and consideration or application to VCN and vector shedding assays
9:20	9:40	*Marco Klinge, BioAgilytix* Roads to IVDR Compliance – Requirements and Strategies Following the In-House Test Approach
9:40	10:00	*Kyra A. Gelderman, Sanquin Diagnostic Services* Complement functional assays to support clinical studies: under IVDR or not?
10:00	10:20	*Pratiksha Gulati, F. Hoffmann - La Roche* IVDR and its implications on biomarker strategy in clinical studies – examples from Case studies
10:20	10:30	*Getting ready for round table 1*
10:30	**11:00**	**Coffee break**
11:00	**12:30**	**Round table discussion 1**
11:00	12:30	*Impact of IVDR on lab activities* Delegates will be grouped into tables of maximum 10 (incl. moderator and note taker). The discussions will be moderated around questions related to **the impact of IVDR on lab activities** prepared on day 1
12:30	**13:20**	**Lunch**
13:20	**15:00**	**Case studies impacting clinical programs**
13:20	13:40	*Diana Steinbuesch, F. Hoffmann - La Roche* Impact of IVDR on Patients, Clinical Development and Healthcare costs
13:40	14:00	*Jason Simon, Regeneron Pharmaceutical* Contradicting advice from national competent authorities when seeking clarity on use of lab tests in clinical trials; A case study
14:00	14:20	*Lien Dejager, Argenx* Sailing through uncharted IVD waters
14:20	14:30	Getting ready for round table 2
14:30	**15:00**	**Coffee break**
15:00	**16:30**	**Round table discussion 2**
15:00	16:30	*IVDR impacting clinical programs* Delegates will be grouped into tables of maximum 10 (incl. moderator and note taker). The discussions will be moderated around questions related to **IVDR impacting clinical programs** prepared on day 1
16:30	**16:45**	**Summarising the workshop, next steps and adjourn**

Organising Committee: Robert Nelson (BioAgilytix), Lee Monk (UCB Biopharma), Matthew Barfield (F. Hoffmann - La Roche) 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.