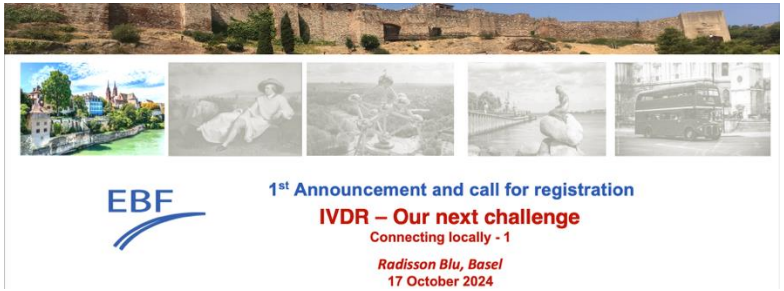
IVDR – connecting locally

Antwerp/Basel – 20/23 OCT 2025

Start of the meeting = 10:30 (coffee) and 11:00 (actual start)
Lunch and (quick) coffee around 12:30 and 15:00
End of the meeting = 16:00

1. **Introduction** on IVDR and the Journey of the EBF since 2020 (ca. 45 min), incl. Feedback and take-home messages
   a. Philip Timmerman, EBF
   b. Matthew Barfield, on behalf of the EBF
   c. Learnings from previous roadshows and EBF interactions with regulators
2. **Case studies**
   a. Two Case studies, providing a representative example of the challenges
3. **Discussion** (integrated in the discussion of the case study) & actions

Round 1

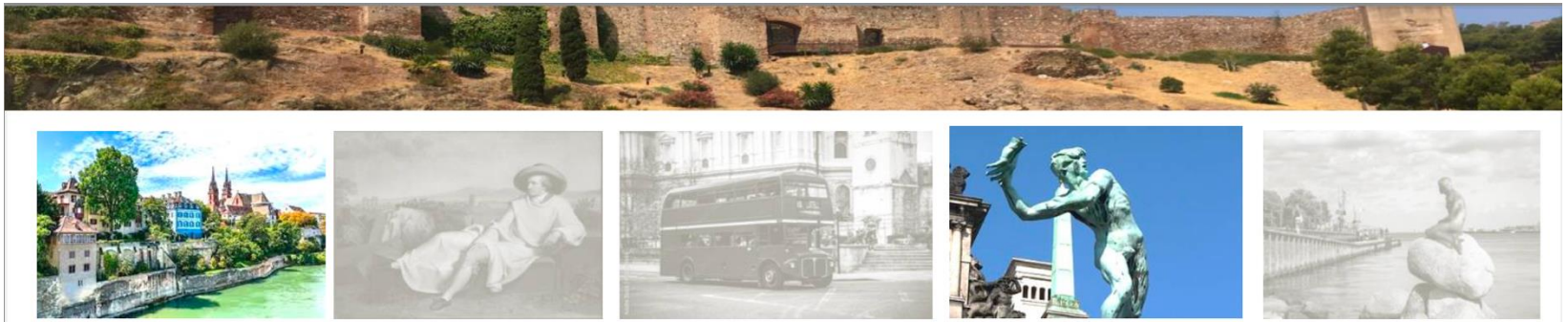

EBF
1st Announcement and call for registration
IVDR – Our next challenge
Connecting locally - 1
Radisson Blu, Basel
17 October 2024


EBF
1st Announcement and call for registration
IVDR – Our next challenge
Connecting locally – 2
NH Collection Frankfurt Spin Tower, Frankfurt am Main
18 October 2024


EBF
1st Announcement and call for registration
IVDR – Our next challenge
Connecting locally - 3
Woburn House, 20 Tavistock Square, London
24 February 2025


EBF
1st Announcement and call for registration
IVDR – Our next challenge
Connecting locally - 5
Radisson Blu Scandinavia, Copenhagen, Denmark
28 March 2025

Round 2



1st Announcement and call for registration

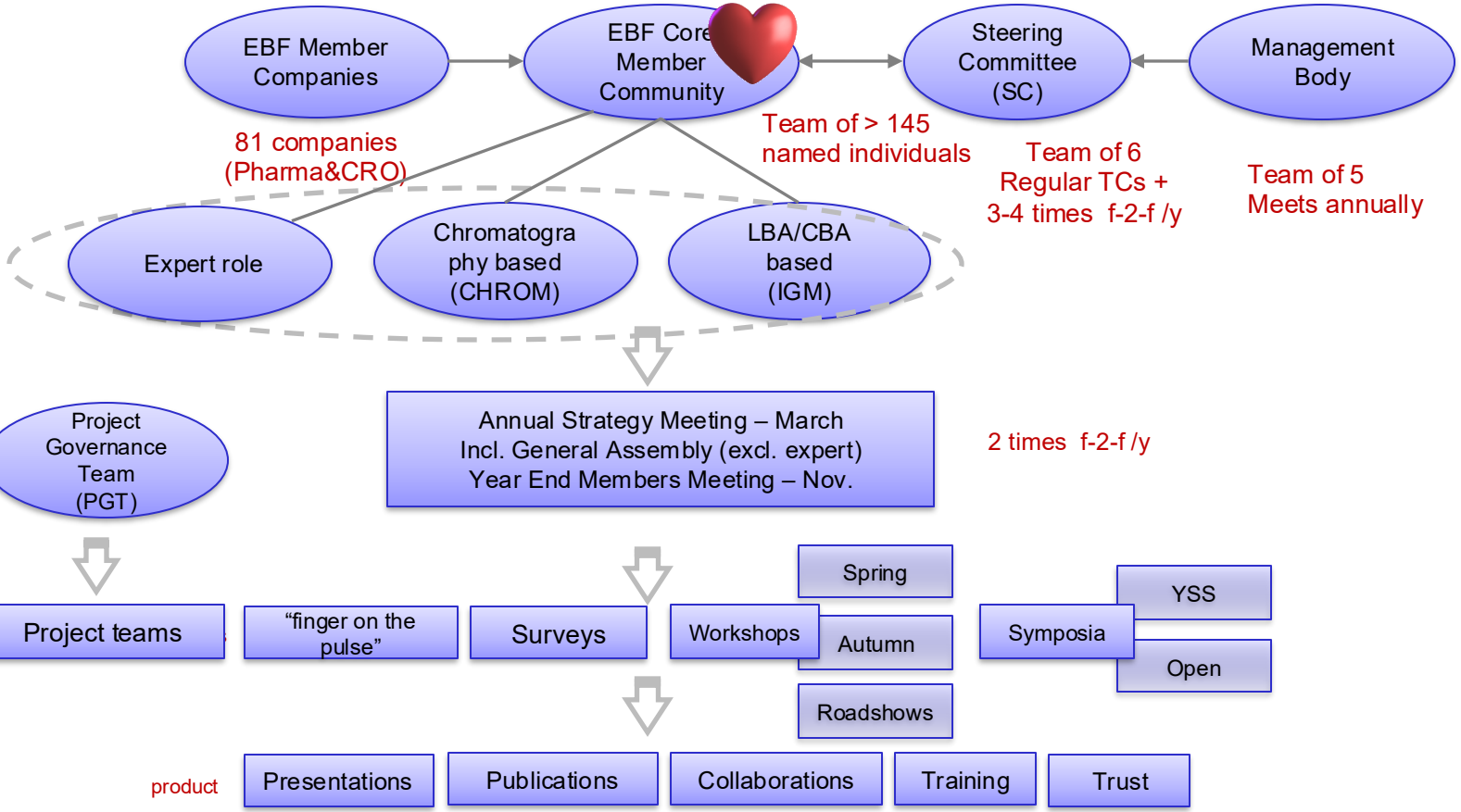
IVDR (II) – Our next challenge

Connecting locally – series 2

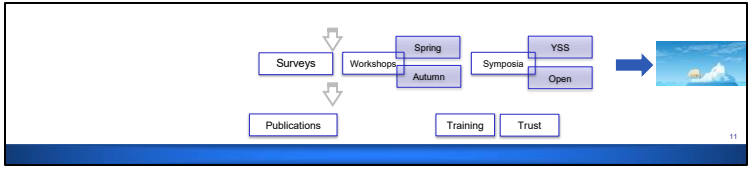
NH Antwerp, Belgium - 20 OCT 2025
Radisson Blu, Basel, Switzerland - 23 OCT 2025


EBF

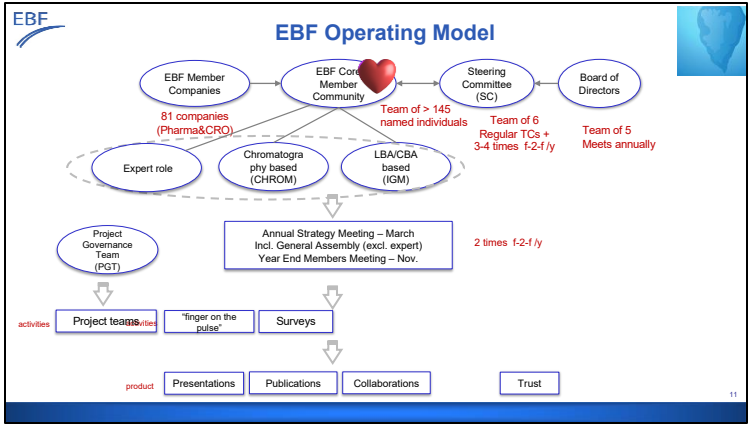
EBF Operating Model

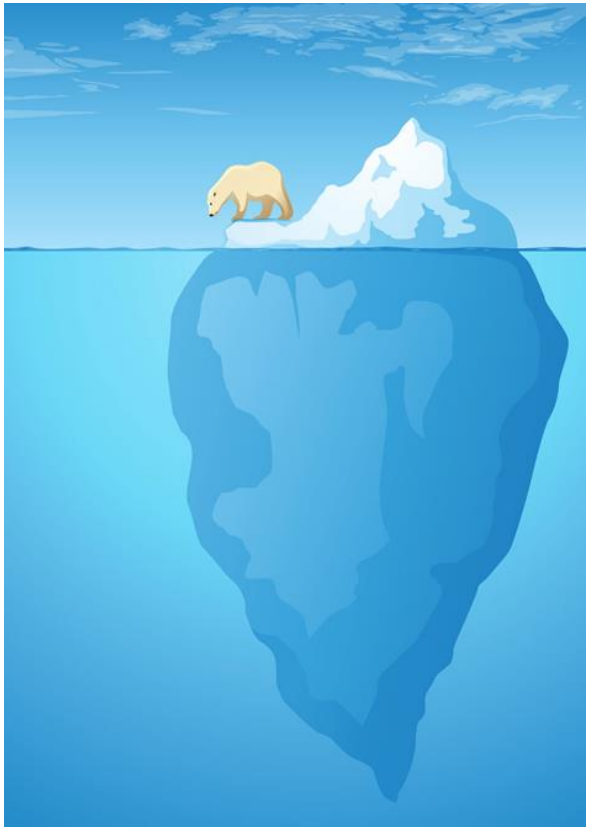


The (very) visible Open Symposium, Focus Workshops, Training Days, YSS



The (less) visible: internal discussions





EBF Operating Model

EBF Member Companies

EBF Core Member Community

Steering Committee (SC)

Management Body

81 companies (Pharma&CRO)

Team of ca. 150 named individuals

Team of 6 Regular TCs + 3-4 times f-2-f /y

Team of 5 Meets annually

Expert role

Chromatography based (CHROM)

LBA/CBA based (IGM)

Project Governance Team (PGT)

Annual Strategy Meeting – March
Incl. General Assembly (excl. expert)
Year End Members Meeting – Nov.

2 times f-2-f /y

activities

Project teams

"finger on the pulse"

Surveys

Workshops

Spring FW

Autumn FW

Roadshows

Symposia

YSS

Open

product

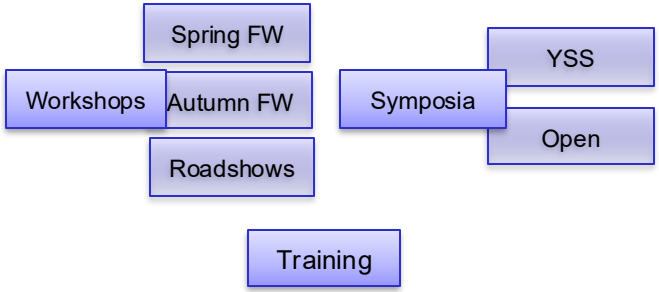
Presentations

Publications

Collaborations

Training

Trust


Spring FW
Workshops
Autumn FW
Roadshows
Symposia
YSS
Open
Training

EBF

Spring

- 2024 Focus Workshop: IVDR – Our next Challenge
  Malaga, Spain
- 2023 Focus Workshop: Challenging the Current Paradigm for ADA Testing
  Malaga, Spain
- Focus Workshop:
  Scientific, Regulatory and Technology Challenges
  in the Development of Oligonucleotide and Peptide Drugs
  Malaga, Spain
- 2022 Focus Workshop: Biomarkers/CoU – Sharing Experience through Examples
  Malaga, Spain
- Focus Workshop: Managing GCP in Regulated Bioanalysis
  Malaga, Spain
- Focus Workshop: Points to Consider on Cut Points
  Cyberspace
- 2021 Focus Workshop: Peptide/Protein Analysis with LC-MS/MS
  Cyberspace
- Focus Workshop: Spotlight on (Ligand Binding
  & cell-based Assays and Automation) TECHNOLOGY
  Cyberspace
- Focus Workshop: Biomarkers/CoU – Case Studies Dissected
  Cyberspace
- 2020 Cell & Gene Therapy Training Day
  Cyberspace
- Biomarkers in Pharma R&D – A roadmap from Context of Use to Using the data
  Cyberspace
- 2019 Biomarker Assay Validation – Bringing Context of Use into practice
  Malaga, Spain
- ICH M10 – Public consultation & Industry Feedback
  Towards a Science based Global Bioanalytical Guidline
  Barcelona, Spain
- 2018 Today's challenges and solutions in assessing immunogenicity in patients
  Lisbon, Portugal
- New Modalities and Novel Concepts in Bioanalysis
  Lisbon, Portugal
- 2017 Industry input into ICH M10:
  Experimental data as the cornerstone for a science driven bioanalytical guideline
  Lisbon, Portugal
- Bioanalytical Strategies for Large Molecules in Modern Drug Development:
  LBA and LC-MS united
  Lisbon, Portugal
- 2016 Current analysis of immunogenicity – Best Practices and Regulatory Hurdles
  Lisbon, Portugal
- Bringing Assay Validation and Analysis of Biomarkers into Practice
  Lisbon, Portugal
- 2015 The 'W4' of Metabolite profiling and quantification strategies in drug R&D:
  When, What, Why and Who?
  Brussels, Belgium
- Optimizing the Pharma CRO scientific interface in bioanalysis
  Brussels, Belgium
- 2012 Hatching
  Brussels, Belgium
- 2011 Large meets Small
  Brussels, Belgium
- 2010 Connecting Strategies on Dried Blood Spots
  Brussels, Belgium

Autumn

YSS

- 10th YSS OPEN UP – Explore, Transform, Inovate
  16-17 May 2024
- 9th YSS It's the New Dawn
  11-12 May 2023
- 8th YSS Into the Roaring Twenties
  18-19 May 2022
- 7th YSS Reconnecting after quarentine
  10-11 June 2021
- 6th YSS Future-proofing Bioanalysis – Contributing to a sustainable world
  24-25 September 2020
- 5th YSS To Bioanalysis and Beyond!
  21-22 March 2019
- 4th YSS The BioA Brain: Embracing new ideas
  15-16 March 2018
- 3rd YSS In Unity Lies Power; Building a Better Bioanalytical World Togethe
  15-Dec-16
- 2nd YSS Future of Bioanalysis… A Bridge between Industry and Academia
  17-Nov-15
- 1st YSS Unleashing the future
  18-Nov-14

Open

- 16th OS Science – Winning the Race
  15-17 November 2023
- ICH M10 Workshop One year into ICH M10
  14-Nov-23
- 15th OS The Bioanalytical Compass – Navigating to our True North
  16-18 November 2022
- ICH M10 Workshop Towards harmonised implementation of the ICH M10 Guideline
  15-Nov-22
- 14th OS Science – Our Universal Language
  24-26 November 2021
- 13th OS Cyberspace – Staying Connected
  17-20 November 2020
- 12th OS Imagine! – A New Bioanalytical Earthrise
  20-22 November 2019
- 11th OS Raise the Anchor – Set Sail for Science
  21-23 November 2018
- 10th OS 10 – A New Journey begins
  15-17 November 2017
- 9th OS Reaching Utopia – The Kaleidoscope of Bioanalysis
  16-18 November 2016
- 8th OS Into New Territories – Explore, Learn and Apply
  18-20 November 2015
- 7th OS Beyond the Horizon – Painting a new landscape
  19-21 November 2014
- 6th OS Moving Forward Together
  20-22 November 2013
- 5th OS Old Battles and New Horizons
  14-16 November 2012
- 4th OS Less is More
  16-18 November 2011
- 3rd OS From Challenges to Solutions
  1-3 December 2010
- 2nd OS The Broadening Scope of Validation
  2-4 December 2009
- 1st OS Burning issues in Bioanalysis
  1-2 December 2008

Spring

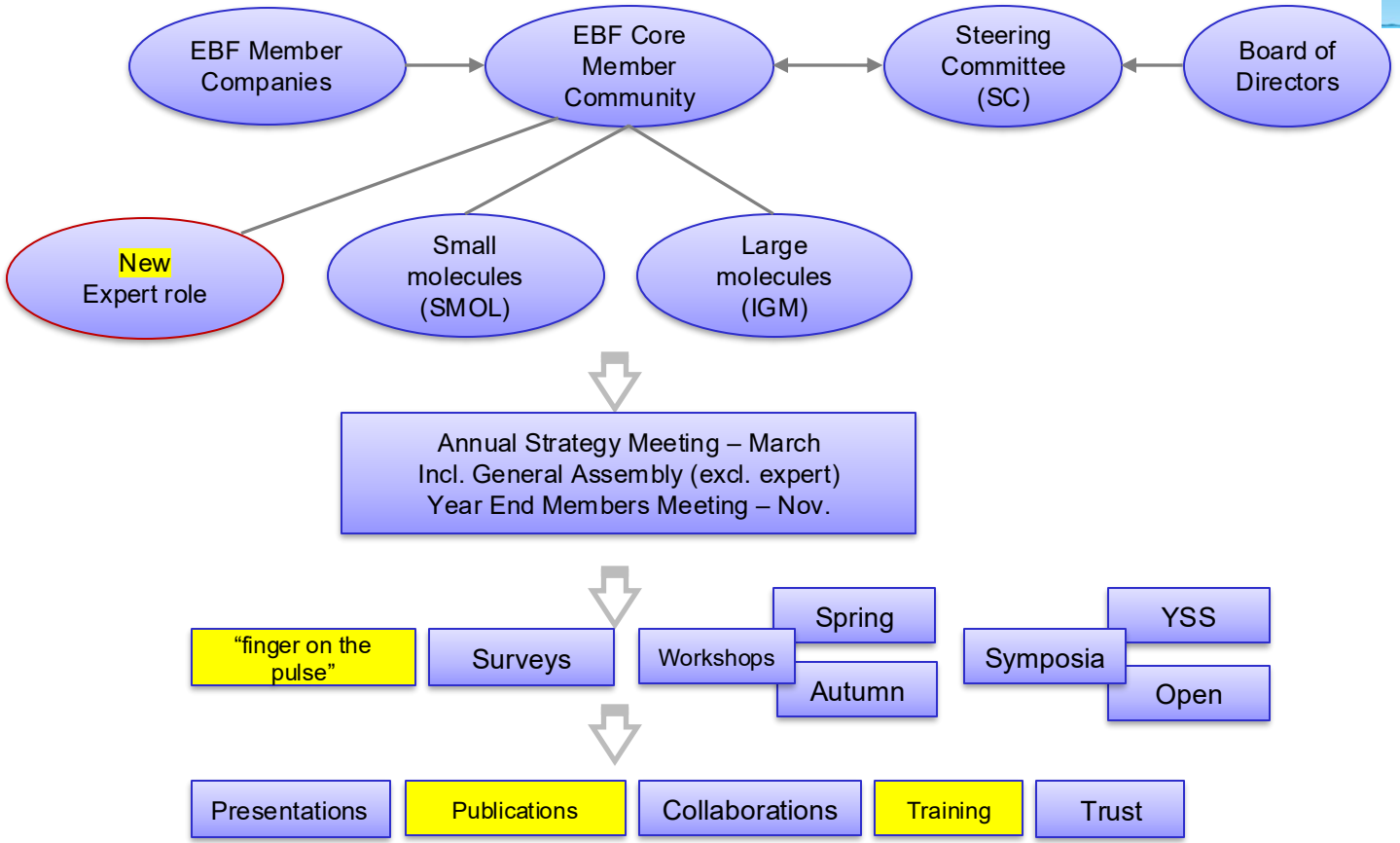
YSS

Autumn

Open

Training

- 2021 Training Day: managing the Practical Aspects of Immunogenicity
  Cyberspace
- 2018 Training day: Critical reagents for LBA
  Lisbon, Portugal
- 2017 Training day:
  Bringing ADC into Practice
  Lisbon, Portugal
- 2014 China Days – Meet the Dragon
  Berlin, Germany


EBF Member Companies
EBF Core Member Community
Steering Committee (SC)
Board of Directors
New Expert role
Small molecules (SMOL)
Large molecules (IGM)
Annual Strategy Meeting – March
Incl. General Assembly (excl. expert)
Year End Members Meeting – Nov.
“finger on the pulse”
Surveys
Workshops
Spring
Autumn
Symposia
YSS
Open
Presentations
Publications
Collaborations
Training
Trust

Publications

- Since 2009, the EBF has published over 100 papers covering virtually all strategic and scientific aspects of regulated bioanalysis.

- Often *ahead of the curve*, EBF publications have provided a safe, collaborative space for early discussions on topics such as harmonisation, CoU for biomarkers, microsampling, ADA and ISR, metabolite quantification, lean validation, and the e-environment for bioanalysis.

- As an independent, peer-driven forum, free from single-company or regulatory bias, the EBF ensures most papers are made freely available.
  👉 Full list: https://e-b-f.eu/wp-content/uploads/2024/10/EBF-publication-list-October-2024.pdf

Publications

Training

EBF has always been at the forefront of industry discussions…

- Value and place of DBS (2008)
- Challenge guideline-scope to focus on science and patient needs (2008)
- ADA guidelines (2009)
- Hybrid assays (2010)
- GCP for Bioanalysis (2011)
- Harmonisation of guidelines / ICH M10 (2011)
- BM Assay Validation & Contect of Use (2011)
- E-environment (2014)
- IVDR for Bioanalysis (2023, 2025)
- …

96 Moving into the cloud: a summary from a European Bioanalysis forum workshop on introducing cloud applications in bioanalytical laboratories

Cecilia Arfvidsson, Katja Zeiser, Lars-Ole Andresen, David Van Bedaf, Harm Buddiger, Christopher Jones, Werner Schauerte, Jens Sigh, Milan Vagaday & Philip Timmerman

Bioanalysis

Meeting Report | Published Online: 30 Oct 2024 | Views: 309

95 Perspective on LC-MS(/MS) for biotherapeutic and biomarker proteins in research and regulated Bioanalysis: a consolidation of more than a decade of experience across the European Bioanalysis Forum community (Part 1: "The What")

Amanda Wilson, Mark Jean Gnoth, Nico van de Merbel, Peter Blattmann, Benno Ingelse, Gregor Jordan, Fabrizia Fusetti, Michael Blackburn, Sune Hove Sporring, Iain Love, Stephane Muccio, Matthew Barfield, Rob

Bioanalysis

Comment | Published Online: 06 Nov 2024 | Views: 283

94 Perspective on LC-MS(/MS) for biotherapeutic and biomarker proteins in research and regulated Bioanalysis: a consolidation of more than a decade of experience across the European Bioanalysis Forum community (Part 2: "The How")

Nico van de Merbel, Mark Jean Gnoth, Amanda Wilson, Peter Blattmann, Benno Ingelse, Gregor Jordan, Fabrizia Fusetti, Michael Blackburn, Sune Hove Sporring, Iain Love, Stephane Muccio, Matthew Barfield, Rob

Bioanalysis

Comment | Published Online: 06 Nov 2024 | Views: 330

93 The use of surrogate matrices in bioanalytical preclinical safety testing using chromatographic methods: a recommendation from the European Bioanalysis forum

Lee Goodwin, Stuart McDougall, Mark Jean Gnoth, Daniel Mascher, Luca Ferrari, Robert Wheller, Hayley Hawthorne, Josep-Maria Jansat, Joerg Faber, Peter Huber, Alessandro Greco, Lars F Eggers, Matthias Sury, Jens-Jakob Karlsson, Sune Hove Sporring, Susanne Globig, Nico van de Merbel & Philip Timmerman

Bioanalysis

Editorial | Published Online: 20 Oct 2010 | Views: 3013 | Citations: 1

7 Best Practices in a Tiered Approach to Metabolite Quantification: Views and Recommendations of The European Bioanalysis Forum
Philip Timmerman, Morten Anders Kall, Ben Gordon, Sirpa Laakso, Achim Freisleben & Richard Hucker
Bioanalysis, Volume 2, 2010 - Issue 7
Discussion | Published Online: 13 Jul 2010 | Views: 4354 | Citations: 1

6 Request for Global Harmonization of the Guidance for Bioanalytical Method Validation and Sample Analysis
Philip Timmerman, Steve Lowes, Douglas M Fast & Fabio Garofolo
Bioanalysis, Volume 2, 2010 - Issue 4
Letter to the Editor | Published Online: 13 Apr 2010 | Views: 3011 | Citations: 4

5 Towards Harmonized Regulations for Bioanalysis: Moving Forward!
Peter van Amsterdam, Berthold Lausecker, Silke Luedtke, Philip Timmerman & Margarete Brudny-Kloeppel
Bioanalysis, Volume 2, 2010 - Issue 4
Editorial | Published Online: 13 Apr 2010 | Views: 2048 | Citations: 2

4 Conference Report: The Broadening Scope of Validation: Towards BestPractices in the World of Bioanalysis
Richard W Abbott
Bioanalysis, Volume 2, 2010 - Issue 4
News | Published Online: 13 Apr 2010 | Views: 2489 | Citations: 2

3 Incurred Sample Reproducibility: Views and Recommendations by the European Bioanalysis Forum
Philip Timmerman, Silke Luedtke, Peter van Amsterdam, Margarete Brudny-Kloeppel, Berthold Lausecker, Stephanie Fischmann, Susanne Globig, Carl-Johan Sennbro, Josep M Jansat, Hans Mulder, Elizabeth Thomas, Magnus Knutsson, Dirk Kasel, Stephen A White, Morten Anders Kall, Nathalie Mokrzycki-Issartel, Achim Freisleben, Fernando Romero, Michael Pilgård Andersen, Norbert Knebel, Marcel de Zwart, Sirpa Laakso, Richard S Hucker, Dietmar Schmidt, Ben Gordon, Richard Abbott & Pierre Boulanger
Bioanalysis, Volume 1, 2009 - Issue 6
Discussion | Published Online: 24 Sep 2009 | Views: 14119 | Citations: 7


PK-Assay
PK-Assay
PK-Assay
PK-Assay
PK-Assay

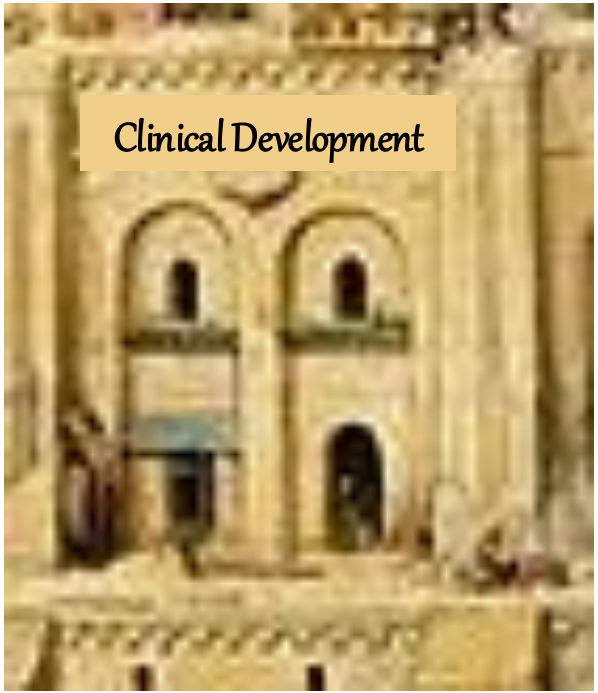
Context

Implementation of IVDR has led to **misclassification** of non-diagnostic PK, ADA, and BM-CoU assays used in early clinical research.

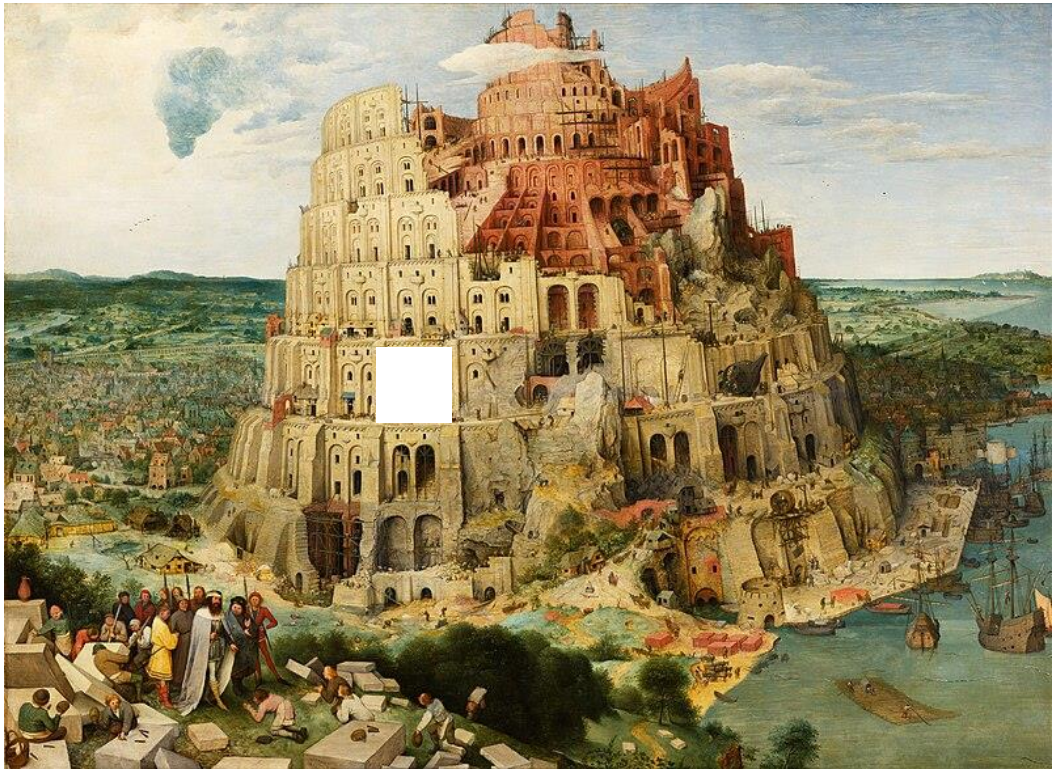
EBF has:

- **Published two papers**
  1. *Finding our way in the IVDR* (*2023, discussion paper*)
  2. *Navigating IVDR Challenges for PK, ADA, and BM assays…* (*2025, recommendation paper)*
- Conducted a **Focus Workshop (Málaga 2024)** and **Roadshows (2024–2025)** (Round 1: Copenhagen, London, Basel and Frankfurt)
- Identified **recurring pain points**, i.e. over-interpretation, protocol ambiguity, inconsistent national implementation, and unclear “health institution” definitions.

Us…or the area where we struggle



The others…for which IVDR may make sense?



Antwerp & Basel 2025 Roadshows

Aim: Move beyond discussion toward concrete case studies demonstrating why and how misinterpretation happens — and how it affects timelines, enrolment, and compliance.

Audience: ~20–25 participants — BioA, QA, Regulatory, Clinical Ops, Pharmacologists, CDx experts, and ideally **health authority** representatives.

Goal: Add *"more meat to the bone"* tangible evidence showing:

- Real examples of unintended IVDR scope inclusion,
- Quantified impact (delays, cost, resource load),
- and cross-functional misunderstanding in protocol design or RA handling.

Current EBF position

- IVDR intent = patient protection → *supported*.
- Issue = mis/over-interpretation → *not the regulation itself*.
- Proposal:
  - **Regulatory exemption** for early development non-diagnostic assays.
  - **Clearer guidance** on protocol language and health-institution scope.
  - **Education and harmonization** across EU member states.
  - Keep EBF as a **neutral, science-driven facilitator**.

Direction for Antwerp (20OCT2025)
"When Evidence Speaks"

Demonstrating the Real-World Impact of IVDR Misinterpretation

Objective

- Antwerp's meeting aims to move beyond discussion into evidence and data. Building on the Málaga workshop and 2024–2025 roadshows, the focus is to show why the problem exists, using real-world case studies that **reveal the practical impact of IVDR overinterpretation**.
- Present and discuss **concrete examples** of how PK, ADA, and BM-CoU assays became unintentionally classified under IVDR, highlighting the resulting procedural ambiguity, delays, and inconsistencies across EU member states.
- The outcome should be **actionable**: identify patterns, quantify impact, and provide **cross-functional validation** (QA, RA, Clinical) to strengthen the case for regulatory clarification.

Direction for Basel (230CT2025)
“When Words Bring Assays into Scope”

Theme: “– Preventing IVDR Misclassification through Protocol Clarity”

Objective

- Following Antwerp’s evidence-based session (“why we have the problem”), Basel aims to tackle the **“how to avoid the problem”** side — focusing on **protocol language, cross-functional awareness, and operational alignment** between BioA, QA, RA, and Clinical functions.

- The outcome should be practical: a set of **do’s and don’ts**, or a **guideline outline** for protocol authors, to reduce accidental IVDR triggers.

From Antwerp…

- New case studies were shared, shedding further light on the issues we face.
- We agreed to develop a catalogue of anonymised case studies to illustrate these challenges:
  - [1] Publication → reference on the EBF conference website, where case studies can be uploaded.
  - [2] Add a “Roadshow” link under Post-meetings.
  - Upload case studies or illustrative (“dummy”) examples to help regulators better understand the impact of the IVDR on early clinical development in the EU.
- We already touched on ‘protocol’ challenges, which remain the key topic of today’s discussion.

Bioanalysis. 2024 Feb;16(3):117-120. doi: 10.4155/bio-2023-0262. Epub 2024 Jan 10.

Finding our way in the *In Vitro* Diagnostic Medical Devices Regulation: a discussion paper from the European Bioanalysis Forum

Philip Timmerman [1], Anna Laurén [2], Robert Nelson [3], Matthew Barfield [4]

“If not in scope, don’t bring it in scope”

Leading to…

- An EBF IVDR Team preparing a Focus Workshop to gauge deeper..

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.

Discussions @ the FW…

Thursday 06-June-2024

09:30	**10:00**	**Welcome coffee**
10:00	**10:15**	**Welcome & Why this meeting?**
10:00	10:15	*Philip Timmerman, EBF*
10:15	**12:30**	**Setting the Scene**
10:15	10:30	*Matthew Barfield, on behalf of the EBF* Is IVDR impacting drug development beyond the intention of the regulations?
10:30	10:50	*Diana Steinbuesch, F. Hoffmann - La Roche* Impact of IVDR on Patients, Clinical Development and Healthcare costs
10:50	11:15	*Lee Monk, UCB-Pharma* When Pharma incorporates IVDs: a dynamic unification
11:15	11:40	*Fabian Iltzsche, Boehringer Ingelheim* Impact of IVDR on patient enrichment in ongoing trials
11:40	12:00	*Robert Nelson, on behalf of the EBF* IDE & LDT vs. IVDR - a next hurdle?
12:00	12:30	Q&A - discussion
12:30	**13:30**	**Lunch break**
13:30	**14:30**	**Preparing the two round tables for day 2 and Gauging the audience on experience with IVDR** incl. feedback from pre-meeting survey to delegates Opportunity for the delegates to share experience
14:30	**15:30**	**A bit of technology…**
14:30	14:50	*Ivonne Bernal, BioAgilytix* Challenges and Learnings from Validation of AAV Neutralising Antibody (NAb) Assays under IVDR
14:50	15:10	*Toralf Roch, CheckImmune* Proximity Extension Assay (PEA) as novel technology for pharmacodynamic assessments and CDx?
15:10	15:30	*Anne-Laure Bauchet, Sanofi* *IVDR challenges in Pathology/immunohistochemistry*
15:30	**16:10**	**Coffee break**
16:10	**17:10**	**IVDR impacting the choice of lab you work with**
16:10	16:30	*Jennifer Russell, A4P Bio* Health Institution Exemption – the easy way out?
16:30	16:50	*Cecilie Freja Dalby Kjelgaard, Novo Nordisk* In Vitro Diagnostic assay for genotyping of clinical study participants
16:50	17:10	*Claire Seal, invoX Pharma* Impact of the IVDR on Vendor Selection: a Case Studies
17:10	**17:15**	**Day 1 close out**

Day 2: Friday 07-June-2024

09:00	**10:30**	**Case studies impacting the lab activities**
09:00	09:20	*Tracy Iles, Labcorp Drug Development* IVDR regulations and consideration or application to VCN and vector shedding assays
09:20	09:40	*Marco Klinge, BioAgilytix* Roads to IVDR Compliance – Requirements and Strategies Following the In-House Test Approach
09:40	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* Impact of IVDR on biomarker assessments 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	**13:30**	**Lunch**
13:30	**15:00**	**Case studies impacting clinical programs**
13:30	13:50	*Claire Seal, invoX Pharma* Impact of the IVDR on Project Strategy: a Case Studies
13:50	14:10	*Jason Simon, Regeneron Pharmaceutical* Contradicting advice from national competent authorities when seeking clarity on use of lab tests in clinical trials; A case study
14:10	14:30	*Lien Dejager, Argenx* Sailing through uncharted IVD waters
14:30	14:40	Getting ready for round table 2
14:40	**15:10**	**Coffee break**
15:10	**16:40**	**Round table discussion 2**
15:10	16:40	*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
16:40	**16:50**	**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.

3 pages of comments and suggestions

Topline summary on next slide

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12:30	**13:30**	**Lunch**
13:30	**15:00**	**Case studies impacting clinical programs**
13:30	13:50	*Claire Seal, invoX Pharma* Impact of the IVDR on Project Strategy: a Case Studies
13:50	14:10	*Jason Simon, Regeneron Pharmaceutical* Contradicting advice from national competent authorities when seeking clarity on use of lab tests in clinical trials; A case study
14:10	14:30	*Lien Dejager, Argenx* Sailing through uncharted IVD waters
14:30	14:40	Getting ready for round table 2
14:40	**15:10**	**Coffee break**
15:10	**16:40**	**Round table discussion 2**
15:10	16:40	*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
16:40	**16:50**	**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.

Discussion during the round tables –
Small groups of 6-8 moderated around targetted questions

Round table 1: Impact of IVDR on lab activities

Short description of the Issue	**Impact in the lab** e.g. on timelines, resources	**Resolution** e.g. suggest rewording of a paragraph in IVDR guideline, clarification via Q&A…	**Gain** Tangible gain in addition to cost savings. Impact on (patient) safety

Round table 2: Impact of IVDR on clinical programs

Short description of the Issue	**Impact in the lab** e.g. on timelines, resources	**Resolution** e.g. suggest rewording of a paragraph in IVDR guideline, clarification via Q&A…	**Gain** Tangible gain in addition to cost savings. Impact on (patient) safety

14 pages of comments and suggestions

Key Learnings – Málaga Focus Workshop (2024)

1. Ambiguous protocol language

2. Delays in clinical trials

3. Limited cross-functional awareness

4. Procedural uncertainty

5. Inconsistent national interpretation

Key Learnings – Málaga Focus Workshop (2024)

1 **Ambiguous protocol language**
→ Terms like “supporting clinical decisions” or “assessing eligibility” unintentionally suggest diagnostic intent, bringing assays into IVDR scope.

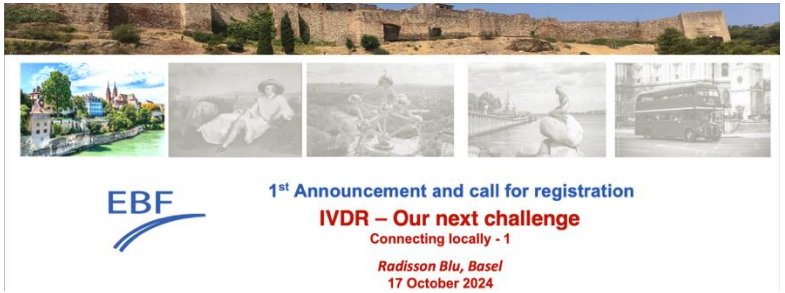
2 **Delays in clinical trials**
→ Misinterpretation of scope caused protocol revisions and slow study start-ups, especially in oncology and early development.

3 **Limited cross-functional awareness**
→ QA, RA, and clinical teams often misunderstood PK, ADA, and BM-CoU assays — assuming diagnostic or kit-based intent.

4 **Procedural uncertainty**
→ Even when assays were legitimately in scope, labs lacked clear guidance on how to align ICH M10 or immunogenicity frameworks with IVDR.

5 **Inconsistent national interpretation**
→ Divergent implementation across EU Member States created administrative burden and loss of harmonization.

Leading to EBF Roadshows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1st Announcement and call for registration
IVDR – Our next challenge
Connecting locally - 1
Radisson Blu, Basel
17 October 2024


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1st Announcement and call for registration
IVDR – Our next challenge
Connecting locally – 2
NH Collection Frankfurt Spin Tower, Frankfurt am Main
18 October 2024


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IVDR – Our next challenge
Connecting locally - 3
Woburn House, 20 Tavistock Square, London
24 February 2025


EBF
1st Announcement and call for registration
IVDR – Our next challenge
Connecting locally - 5
Radisson Blu Scandinavia, Copenhagen, Denmark
28 March 2025

Leading to Publication 2

Bioanalysis. 2025 Jul;17(14):889-892. doi: 10.1080/17576180.2025.2540187. Epub 2025 Aug 4.

Navigating IVDR challenges for pharmacokinetic, anti-drug antibodies, and biomarker assays in early clinical research: a recommendation from the European Bioanalysis Forum

Philip Timmerman [1], Matthew Barfield [2], Jon G Bartlet [3], Peter Blattmann [4], Nils Boehm [5], Louis Christodoulou [2], Cecilie Freja Dalby Kjelgaard [6], Tracy Iles [7], Fabian Iltzsche [8], Marco Klinge [9], Leslie Henderson [10], Lee Monk [11], Robert Nelson [9], Yang Liu [12]

EBF Roadshows – Turning Insight into Action (2024–2025)

1 Clarify scope through protocol awareness

→ Develop *cross-functional guidance* on wording and intent in clinical protocols.

→ Avoid language that implies patient-management or diagnostic use.

→ Plan a *hands-on workshop* (Basel) to translate these learnings into practical examples.

2 Engage regulators for proportional application

→ Advocate for a *regulatory exemption* for non-diagnostic PK, ADA, and BM-CoU assays used in early clinical development.

→ Promote *harmonized interpretation* across EU Member States.

→ Maintain dialogue with MDCG and national authorities to ensure alignment with IVDR's true intent.

Leading to Roadshows II

- Here we are…

Preserve patient protection while enabling efficient, science-based early clinical research.

More information on the EBF: **www.e-b-f.eu**

Contact us: **info@e-b-f.eu**