18th EBF Open Symposium

Tune in to Tomorrow
Science in High Definition

Opening Roadshows to the Wider Community

What are EBF roadshows?

- Small, focused scientific meetings organised by the EBF
- Hosted where bioanalytical activity is concentrated (Pharma clusters, CRO hubs, innovation centres)
- Built around one or two topics that need deeper community discussion and where input from and dialogue with non-BioA stakeholders is essential
- Designed for interactive exchange, not conference-style presentations
- Small meetings, limited to 25 people (mix BioA and stakeholders),

Bottom line:

- Roadshows bring EBF discussions to the doorstep of the community.

Why They Matter?

- Not everyone can travel to the Bioanalytical conferences
- Many scientific discussions need a smaller room to mature
- Roadshows give earlier visibility to emerging challenges
- They help identify gaps, needs, and divergent practices before they escalate
- They strengthen alignment between Pharma, CROs and platforms at operational level

Highlight:

- They ensure that the right scientific conversations happen earlier and involving the input from all, not only from our little silo.

Opening Roadshows to the Wider Community

- Originally intended for EBF member companies only
- From 2026 onwards: Roadshows will be open to all organisations
- Openness is essential to increase breadth of experience and perspectives
- Participation remains non-commercial and science-driven
- Delegates must bring practical expertise as stakeholders

Who Are Roadshows For?

- Bioanalytical scientists as the anchor group.
- Stakeholders listed only as examples, not an exhaustive list.
- “Depending on the theme” PK, PD, RA, pharmacology, clinical experts…

I.o.w…Roadshows are for people who can **shape decisions**, not just listen to them.

A Place Where Regulators and Industry Can Meet as Peers? (1/2)

Traditional conference formats put regulators “on a podium”, often creating one-directional messaging with disclaimers

- This can/has unintentionally lead/led to regulatory creep:
- interpretations or opinions become “requirements”, flexibility gets lost

A Place Where Regulators and Industry Can Meet as Peers? (2/2)

Roadshows create small, technical, neutral rooms where:

- regulators and industry speak with each other, not at each other
- scientific reasoning can be challenged and refined
- gain a clearer understanding of what is required, what is flexible, and what is simply habit

Roadshows help regulators and industry listen, question and learn together, without the constraints of a podium.

EBF Roadshows to Date (2023 – 2025)

- Basel: IVDR & Biomarker Context-of-Use
- Brussels: & Biomarker CoU
- Antwerp: IVDR
- Copenhagen: IVDR & Biomarker CoU
- London: IVDR & Biomarker CoU
- Frankfurt: Biomarker CoU

EBF Roadshows on the radar

- Basel: Pharma/CRO, BM CoU
- Copenhagen: IVDR, Pharma/CRO & Biomarker CoU
- London (or ‘UK’): IVDR, Pharma/CRO & Biomarker CoU

Being realistic, in the onset, we may move from 5 to 3 regions

- May not be the same 3 per theme, so current hubs remain but not all themes may go to all hubs

Choosing New Roadshow Themes?

- Topics where early scientific alignment is needed across Pharma, CROs and platforms
- Themes that require two-way interaction, not podium presentations
- Areas where key stakeholders input is essential and are not present at regular bioanalytical meetings
- Subjects that risk regulatory creep or divergence if not openly discussed
- Areas where community experience is fragmented and needs consolidation
- Topics with clear impact on decision-making
- Themes where regulators and industry benefit from peer-level dialogue

Bottom line:

- Roadshows focus on areas where the community needs to talk with each other in smaller forums, not just listen.

How do you see further enhancements?

How do you see contributions from your organisation?

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After three days, where are we now?

Where do we go from here?

Program at a glance

Day 1: 18 November 2025

09:15	09:30	Welcome and introduction to the 18th OS
09:30	10:30	Session 1: Setting the scene
11:10	12:50	Session 2: Biomarkers - Context-of-Use in High Definition
		Session 3: The Wonderful world of NBE - applications
		Session 4: Singlicate beyond PK in Prime Time (ends at 12:40)
14:00	15:40	Session 5: Multiplexing
		Session 6: LC-MS in Wide Screen
14:00	18:00	WS 1: AI ...where no man has gone before
16:20	18:20	Session 7: Automation - session moderated by the EBF-YSS
		Session 8: New modalities
		Session 9: PCR Unplugged: Amplifying What Matters

Day 2: 19 November 2025

09:00	10:40	Session 10: Non-standard matrices-analytes / CHROM
		Session 11: General ADA/Nab
		WS 2: GCP Sample Reconciliation
		Session 12: Mini-Omics session
11:20	13:00	Session 13: Pharma/CRO: in co-production
		WS 3: Kits and Reagent Bridging
		Session 14: ADC
		Session 15: Flow Cytometry: from Black & White to Technicolor
14:00	15:40	WS 4: IVDR - and what if the assay is in scope?
		WS 5: Singlicate/Duplicate - the Workshop
		WS 6: The Green Reel: Bioanalysis in 3R Motion
		WS 7: PCR - The Workshop
16:20	18:00	WS 8: WS - ICH M10/CoU/SV - re-interpreted for LBA?
		WS 9: ADA for ASO and Peptides
		WS 10: X-Validation for CHROM
		WS 11: Flow Cytometry - the Workshop

Day 3: 20 November 2025

09:20	10:20	Session 16: BioA supporting PK - non-standard approaches
09:00	10:20	Session 17: Immunogenicity - Technology
		WS 12: The Pharma-CRO Partnerships
		WS 13: e-data - 'the cloud'
11:10	12:50	Session 18: ICH M10 embracing CoU
		Session 19: 1-Tier Technology
		Session 20: Biosimilars
14:00	15:40	Session 21: More on Hybrid assays
		Session 22: 1-Tier: Strategic discussions
16:20	17:20	Session 23: Closing session - from Learnings to Action
17:20	17:30	Closing remarks - Adjourn

Red = Workshop format

From Openness to Reflection

What We Observed at the 18th OS

- Broad participation brought diverse scientific viewpoints
- More platforms, more technologies, more emerging modalities
- Strong alignment on scientific validation and CoU thinking
- And a clear observation across sessions…


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WS 9: WS - ICH M10/EU-CoU - re-interpreted for LBA?
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We place ICH M10 central to our scientific discussions, but
For only 12% of of the presentations, ICH M10 is truly relevant.

From Openness to Reflection

Many of you mention CoU

But equally so, many of you are trying to fit new technologies applied for new modalities into the ICH M10 narrative

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8

After all the science we discussed the last 3 days:

- ➢ Is ICH M10 really the anchor of everything we do in Bioanalysis?
- ➢ Many presentations focused on innovation, challenging health authority guidance, engaging proactively with regulators, and “friendly reminders”.
- ➢ So much focus on nuance, novel modalities, ongoing global transitions.

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8

ICH M10: No longer the Anchor of Bioanalysis

Designed for **PK**, not biomarkers, ADA, hybrid, or emerging platforms

- Increasing risk of **over-validation** of **incorrect focus** when misapplied
- Innovation (cell-based, PCR, multi-omics) is moving *beyond the scope* of M10
- Regulators emphasise **flexibility**, not replication of M10 across all endpoints

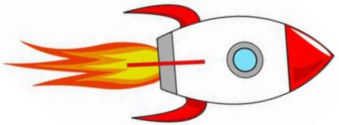

Program at a glance

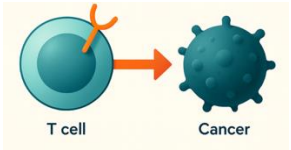
With Modern bioanalysis requiring a **CoU-driven design**, not template-driven checklists, **M10 should remain a guideline within its intended scope, not become an industry default**

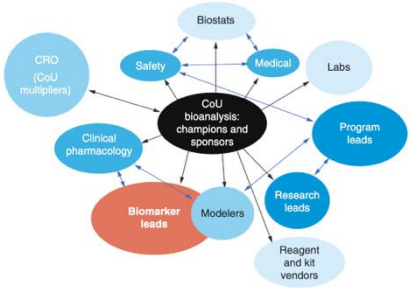
Our projects increasingly need flexibility in our science,
We need to show our professional adaptability…

Bringing Validation back to Science

The Bigger Picture: Our Responsibility as a Community







2025 **2035**

Questions:

1. Who decides the future of bioanalysis — guidelines or *us*?
2. Do we want flexibility based on science?
3. Are we willing to take ownership for defining that flexibility?

Your voice

1. Who or what defines the future of bioanalysis: guidelines or us?
2. What does “flexibility based on science” mean?
3. Who goes first…or, are we willing to take ownership for defining that flexibility?

The value of the community voice

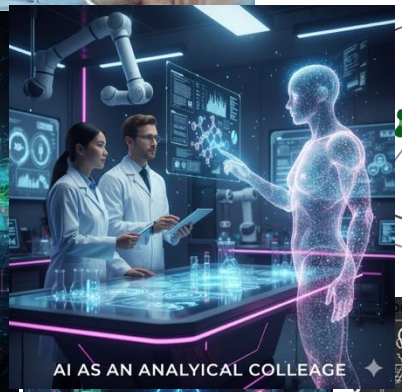
What can we (continue) to do?

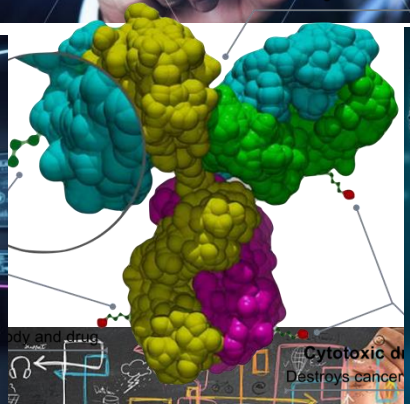
But also

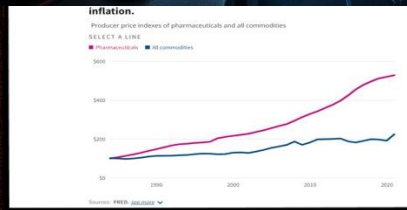
How can you support the neutral community voice and facilitate the necessary change?

Progress doesn’t happen by removing boundaries,
but by learning to cross
them together

Antibody
Targets cancer cells







- It’s the sponsor
- It’s the CRO
- We are not big enough to challenge
- We are too big to challenge
- It’s my management
- It’s the regulator/regulations

What if……

- I get a 483
- My molecule is delayed

We as humans are so good at thinking of reasons why not

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We as humans are so good at thinking of reasons why

Bioanalysis without borders is not a vision, it's a responsibility


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