19th EBF Open Symposium

Fearless Science

Driven by Curiosity – Guided by Data

Barcelona, Spain 17-19 November 2026

19th EBF Open Symposium | Programme (v. 15SEP2026)

Day 1 - Tuesday 17 NOV 2026

Plenary Session

09:15	**09:30**	**Welcome**	
09:30	**10:30**	**Session 1: Introduction Session**	
		As in previous years, this session will be developed by the EBF, focusing on the conference objectives and strategic priorities emerging from recent EBF discussions and publications.	
10:30	**11:10**	**Coffee break and Poster Discussion/Viewing**	

Parallel Sessions

11:10	**12:50**	**Session 2: Smarter Workflows: From Implementation to Scientific Confidence**	
11:10	11:30	**Emma van Groesen, Genmab**	Implementation of an End-to-End Automated Bioanalysis Workflow
11:30	11:50	**Eginhard Schick, F. Hoffmann-La Roche**	Clinical Speed meets GLP Rigor: Upgrading an IVD Immunoanalyzer for High-Throughput PK/PD Analysis in a Bioanalytical Laboratory - Lessons Learnt
11:50	12:10	**Janett Schwarz, BioAgilytix Laboratories**	Fit-for-Purpose Implementation of a Generic Preclinical PK Assay: Lessons from Platform Transfer and Troubleshooting
12:10	12:30	**Joseph Ling, GSK**	Automation Innovations Drive Efficiencies in Flow Cytometry Clinical Sample Testing
12:30	12:50	**Matthew Andisik, Regeneron Pharmaceuticals**	One Well, Full Confidence: Automation-Enabled Singlicate Analysis for Regulated Bioanalysis

11:10	**12:50**	**Session 3: Vaccines**	
11:10	11:30	**Stefanie Siegert, AC Immune**	Active immunotherapy responder determination in a population with potential pre-existing antibodies
11:30	11:50	**Minke Bekker, Synexa Life Sciences**	When One Calibration Source Must Fit Eight Antigens: Lessons from Convalescent and Vaccinated Serum to Evaluate Vaccine-Induced Antibody Responses
11:50	12:10	**Foka Venema, Ardena**	Vaccine Ligand-Binding Assays for Clinical Sample Analysis: Qualification vs. Validation - A Fit-for-Purpose Approach to Dilution Series and Cut-Point Selection
12:10	12:30	**Matthieu Carriere, Charles River Laboratories**	Harmonizing Validation of Vaccine Immunogenicity Assays: A Fit-for-Purpose Framework for Quantitative and Semi-Quantitative Methods
12:30	12:50	**Anna Laurén, MinervaX**	Strategies for validating functional titre based vaccine assays versus concentration based multiplex vaccine immunoassays for a multicomponent bacterial vaccine

11:10	**12:50**	**WS 01: AI**	
		Workshop: AI	

		Building on the outcomes of the recent EBF AI Focus Workshop in Málaga, this workshop will translate key insights into practical next steps for bioanalysis. Participants will explore how AI can be applied responsibly, identify remaining scientific, regulatory and organisational challenges, and help define priorities for future EBF activities in this rapidly evolving area.	

12:50	**14:00**	**Lunch break and Poster Discussion/Viewing**	
		Parallel Sessions	
14:00	**15:40**	**Session 4: Advancing the 3Rs: Smarter Sampling, Surrogate Matrices and Leaner Workflows**	
14:00	14:20	**Hayley Hawthorne, on behalf of the EBF**	EBF Project B-05 – 3Rs Cases Studies
14:20	14:40	**Cara Maguire, Charles River Laboratories**	Transition from Duplicate to Singlicate ADA Testing: A Retrospective Evaluation of Clinical Immunogenicity Data
14:40	15:00	**Emma Fagg, Labcorp**	From Collection to Analysis: Evaluating Patient-Centric Dried Blood Microsampling Technologies for Regulated Bioanalysis
15:00	15:20	**Ludovicus Staelens, UCB**	Routine use of surrogate matrix in regulated bioanalysis
15:20	15:40	**Ahmar Khan, U. Hertfordshire**	Development and Academia-to-Industry Transfer of a Patient-Centric Microsampling LC-MS/MS Assay for COPD Medication Monitoring
14:00	**15:40**	**Session 5: Expanding LC–MS Bioanalysis: New Modalities, Advanced Workflows and Multi-Omics**	
14:00	14:20	**Guangnong (Sunny) Zhang, NovoNordisk**	Beyond Plasma PK: Fit-for-Purpose Bioanalysis for Next-Generation siRNA and ASO Therapeutics
14:20	14:40	**Jessie Le, QPS**	M10 Compliant Quan–Qual Analysis of Parent Oligonucleotides and Metabolites Using a Next-Generation QTOF Platform
14:40	15:00	**Luca Ferrari, F. Hoffmann-La Roche**	LC-MS Bioanalysis of Lipid Conjugated siRNAs: Analytical Challenges and Novel Approaches
15:00	15:20	**Shane Needham, Veloxity Labs**	Comparative Quantitative Bioanalysis of Semaglutide, Tirzepatide and Retatrutide Using HRMS and Triple Quadrupole LC-MS/MS Workflows
15:20	15:40	**Robert Plumb, Waters**	Correlations between plasma concentrations of a tyrosine kinase inhibitor and its metabolites and changes in the lipid – proteome in the rat: A 3R's & Multi-Omics Study
14:00	**15:40**	**Session 6: Biosimilars**	
14:00	14:20	**Presenter, on behalf of the EBF**	Recommendations from the recent EBF Biosimilars PK-paper
14:20	14:40	**Presenter, on behalf of the EBF**	Work ahead: introducing the EBF dicsussions on ADA for Biosimilars
14:40	15:00	**Mia Wilkinson, Resolian**	Demonstrating Antigenic Equivalence Across Biosimilars and Reference Products: ADA and NAb Assay Validation Strategies Through Real-World Case Studies
15:00	15:20	**Corinne Petit-Frère, Fresenius-KabiSwissBioSim**	Root cause analysis of unexpected Denosumab Pharmacokinetic profile fluctuations in Study FKS518-001
15:20	15:40	**Panel discussion**	The evolving regulatory landscape forBiosimilars and the impact on the Bioanalytical Laboratory
15:40	**16:20**	**Coffee break and Poster Discussion/Viewing**	
		Parallel Sessions	
16:20	**18:20**	**Session 7: BM CoU in practice**	
16:20	16:40	**Fabian Gärtner, Nuvisan**	Target Engagement Biomarkers: Context-of-Use Driven Assay Selection
16:40	17:00	**Corinne Ramos, Aliri FRANCE**	When "How Much?" Is Not Enough: Adding the "Where" to Bioanalysis
17:00	17:20	**Sandra Henkelman, QPS**	Best Practices of Performing Parallelism in Biomarker Assays: A CRO Perspective
17:20	17:40	**Gregor Jordan, F. Hoffmann - La Roche**	Navigating Soluble Biomarker Complexity: Challenges, Assay Strategy, and Case Studies
17:40	18:00	**Sofie Martens, argenx**	From qualitative detection to quantitative insight: repurposing a diagnostic assay into a fit-for-purpose semi-quantitative titer assay as measure of treatment response

18:00	18:20	**Sylvia Lee, Genentech / Roche**	Establishing a Sustainable Analytical Strategy for Translational Kidney Safety Biomarkers

16:20	**18:00**	**Session 8: Pharma CRO**	
16:20	16:40	**Session introduction, on behalf of the EBF Pharma/CRO team**	Intoduction to the Session & Workshop
16:40	17:00	**Gareth Satchell, GSK**	Lessons Learned During In-Licensing
17:00	17:20	**Agnieszka Gruszka, Charles River Laboratories**	Analytical Challenges of Gas Shuttling Nanomedicine: A case study of Inter-CRO Transfer of a Bioanalytical Method for Complex Modalities
17:20	17:40	**Sofiya Matviykiv, Novartis Pharma**	Beyond the Pilot: Scaling a Centralized Sponsor Interface Model Across Strategic CRO Partnerships
17:40	18:00	**Taking questions form the audience for tomorrows Workshop**	

16:20	**18:20**	**Session 9: New technologies and emerging modalities in Bioanalysis: PCR**	
16:20	16:40	**Guido Wisselink, ICON plc**	How to validate qPCR assays in rare matrix such as ocular epithelial cells
16:40	17:00	**Hala Ismael, J&J Innovative Medicine**	Automating qPCR Workflow: Investigation and Resolution of Over-Recovery from Low-Copy Numbers During Workflow Development
17:00	17:20	**Kyriel Pineault, UCB**	Overcoming tissue matrix interference in a droplet digital PCR analytical method for biodistribution assessment
17:20	17:40	**Rachael Dixon, Labcorp**	Measuring Biological Response Using RT-qPCR: A Bioanalytical Perspective on Relative Gene Expression
17:40	18:00	**Lara Duchstein, BioAgilytix**	Considering DNA & RNA Extraction for PCR-Based Assay Validations
18:00	18:20	**Maria Wisner, Kymos**	A Case Study in qPCR Bioanalysis of Viral vectors: Overcoming Matrix Effects and Extraction Challenges Using Automated Nucleic Acid Extraction

18:00	**19:00**	**Complimentary Cocktail Reception**

19:00		**End of day 1**

Day 2: 18 November 2026

Parallel Sessions

09:00	**10:40**	**Session 10: Bioanalysis Beyond Conventional Matrices**	
09:00	09:20	**Adnan Mohamed Abdi, F. Hoffmann-La Roche**	From First-in-Human to Multi-Site Trials: Practical Bioanalytical Strategies to Preserve CSF Pharmacokinetic Data for Highly Adsorptive Molecules
09:20	09:40	**Annabel Hood, Resolian**	Bioanalytical Challenges of PK Assessment in Nasal Mucosal Lining Fluid for a Novel Antiviral Therapeutic
09:40	10:00	**Audrey Noble, F. Hoffmann La Roche**	Operationalizing Unstable Biomarkers: How Biosample Operations and Bioanalysis Enable Successful Scale-Up from Single-Site to Multi-Site Clinical Trials
10:00	10:20	**Presenter tbc**	abstract under revision
10:20	10:40	**BRSA-winner**	

09:00	**10:40**	**Session 11: Rethinking ADA Assessment, Context, Evidence and Evolving Expectations - part 1**	
09:00	09:20	**Presenter, on behalf of the EBF**	EBF intro on Adaptive Tier
09:20	09:40	**Lauren Stevenson, Immunologix Laboratories**	Validation of Clinically Relevant ADA Assays Requires Context, not Convention
09:40	10:00	**Robert Nelson, on behalf of the EBF**	Pre-existing Drug-Reactive Antibodies: Revisiting the Challenges and Recommendations for a Changing Therapeutic Landscape

10:00	10:20	**Charlie Britten, ADC Therapeutics**	Clinical Relevance of ADC Immunogenicity: Are We Measuring What Matters?
10:20	10:40	**Diana Knapp-Buehle, Merck KGaA**	Never Too Old to Be Questioned: What a 20-Year-Old Product Taught Us About Immunogenicity Expectations

09:00	**10:40**	**Session 12: Assay life cycle**	
09:00	09:20	**Presenter, on behalf of the EBF**	EBF Perspective: From Method Validation to Lifecycle Stewardship
09:20	09:40	**Katja Heinig, F. Hoffmann-La Roche**	Assay Lifecycle in Practice: Strategic Stewardship, Change Control, and Revalidation Case Studies
09:40	10:00	**Duco Schriemer, QPS**	Challenges during implementation of new reagent lots
10:00	10:20	**Gabriele Conti, Celerion**	Beyond Reagent Continuity: A Strategic Approach to Assay Life Cycle Management and Method Evolution
10:20	10:40	**Annika Carlsson, Mercodia AB**	Lifecycle Management of a Clinical PK Assay Through Change Control, Investigation, Optimization and Revalidation

10:40 **11:20** **Coffee break and Poster Discussion/Viewing**

Parallel Sessions

11:20	**13:00**	**Session 13: BioA Clinic**	
11:20	11:40	**Arundhuti Sen, GSK**	It's not your assay, it's us: reappraising the CoU in response to extra-analytical factors
11:40	12:00	**Luca Genovesi, CellCarta**	Keeping It Soluble: A Quantitative Biomarker Comparison of BCMA and M-Protein by Mass Spectrometry in Multiple Myeloma
12:00	12:20	**Elena Mallat, Ardena**	Analytical Challenges in Sphingolipid Quantification: Enabling Biomarker Discovery in Lysosomal and Neurodegenerative Disorders
12:20	12:40	**Dave Beyerlein, BioAgilytix**	Cross-Platform Evaluation of Total Antibody and Total ADC PK: LBA versus LC-MS
12:40	13:00	**Presenter tbc**	Abstract under revision

11:20	**13:00**	**Session 14: Rethinking ADA Assessment, Context, Evidence and Evolving Expectations - part 2**	
11:20	11:40	**Debbie McManus, Intertek**	Did we get the context?
11:40	12:00	**Justine Collet, argenx**	A streamlined ADA testing strategy to assess the clinical immunogenicity of a biological drug entering clinical development
12:00	12:20	**Marie-Eve Lane, Charles River Laboratories**	Rethinking In-Study Cut Point Application for siRNA Immunogenicity Assessment When False Positive Rates Fall Outside the Conventional Range
12:20	12:40	**Yana Vandenbossche, Sanofi**	The Immunogenicity Nexus: Investigating the Predictive Relationship Between Early-Onset ADA Kinetics in NHP and Human Immune Responses
12:40	13:00	**Lysie Champion, Celerion**	PABAD in Action: Advancing Drug-Tolerant NAb Testing

11:20	**13:00**	**WS 2: emerging challenges in the e-environment**	
11:20	11:30	**Workshop prepared and hosted by the EBF e-environment team**	EBF intro for WS -4
11:30	11:50	**Bianca Komoll, LabWare**	Maintaining Predictive Validity Across the Assay Lifecycle: When Method Revalidation Triggers Model Revalidation
11:50	12:10	**Norbert Bittner, up to data**	Generative AI in Regulated Bioanalytical Reporting: A Two-Layer Validation Architecture for GxP-Compliant Deployment
12:10	12:30	**Norbert Zombori, Sanofi**	Rethinking the Discovery Bioanalytical Dataflow using a Bespoke End-to-End Digital Solution
12:30	13:00	**Panel Discusson**	

13:00 **14:00** **Lunch break and Poster Discussion/Viewing**

Parallel Sessions

14:00	**15:40**	**WS 3: Pharma/CRO**	

		Workshop hosted by the EBF- Pharma/CRO team	
		From Collaboration Compass to Community Guidance: Developing Practical Recommendations for Successful Sponsor-CRO Partnerships	

14:00	**15:40**	**WS 4: BM CoU Strategy**	
		Workshop hosted by the EBF-CoU team	
		Preparation is in progress and includes value and risk when using CoU for BM assays	

14:00	**15:40**	**WS 5: PCR**	
		Workshop hosted by the EBF PCR team	

14:00	**15:40**	**WS 06: New Modalites**	
		This workshop will explore the emerging immunogenicity challenges associated with new therapeutic modalities, where established approaches may no longer be sufficient. Through round-table discussion, participants will share experiences, identify common scientific and regulatory uncertainties, and define priority questions and practical areas where further alignment, guidance or collaborative EBF work is needed.	

15:40	**16:20**	**Coffee break and Poster Discussion/Viewing**	
		Parallel Sessions	

16:20	**18:00**	**WS 7: New Approach Methodologies - NAM**	
		Workshop hosted by the EBF	
		This workshop will explore whether, where and how bioanalysis can contribute to New Approach Methodologies (NAMs). Participants will consider the bioanalytical expertise, technologies and data interpretation needed to support human-relevant models, identify opportunities beyond traditional regulated bioanalysis, and define where the EBF and its community can add meaningful scientific value.	
16:20	16:35	**Introduction into NAM - FB from the Workshop**	
16:35	16:50	**Emilyanne Leonard, AstraZeneca**	Bioanalysis as a Scientific Partner in NAM Development: Advancing a Bone Marrow Microphysiological System from Characterisation to Translational Implementation
16:50	18:00	**Panel and round table discussion**	

16:20	**18:00**	**WS 8: Signal-to-Noise Approaches in Immunogenicity Assessment**	
		Workshop hosted by the EBF S/N-team	

16:20	**18:00**	**WS 9: Dose Formulation Analysis (DFA)**	
		Workshop hosted by the EBF-DFA team	

16:20	**18:00**	**WS 10: ADA - Adaptive Tier**	
		Workshop hosted by the EBF Adaptive Tier team	
16:20	16:40	**EBF intro for WS 10**	
16:40	17:00	**Issa Jyamubandi, Intertek**	Adaptive ADA Tiered approach: A Better Fit for Therapeutics with Pre-Existing Antibodies
17:00	17:20	**Roland F. Staack, F. Hoffmann-La Roche**	Overcoming the 3-Tier ADA Testing Paradigm via Mechanistic Assay Understanding
17:20	18:00	**Panel discussion**	

18:00	**19:00**	**Complimentary Cocktail Reception**	

19:00		**End of day 2**	

Day 3: 19 November 2026

Parallel Sessions

09:00	**10:20**	**Session 15: Flow**	
09:00	09:20	**Sarah Gailhac, Sanofi**	From Raw Data to Insights in Minutes: Development of an Automated Flow Cytometry Data Pipeline for Preclinical Studies
09:20	09:40	**Henko Tadema, ICON**	Implementation and validation of a 25-color immunophenotyping backbone with modular expansion toward 40-color spectral flow cytometry
09:40	10:00	**Thea Hogan, GSK**	Operationalising high-parameter flow cytometry for large-scale clinical research
10:00	10:20	**Christian Lubich, Institute Krems Bioanalytics**	Towards Harmonization of In Vitro T-Cell Assays: Lessons from the Development of a Naïve CD4+ T-Cell Proliferation Assay

09:00	**10:20**	**WS 11: ADC with focus on ADA**
		Workshop hosted by the EBF ADC team
		This workshop will examine the specific challenges of assessing anti-drug antibodies for ADCs and related conjugated modalities. Building on earlier EBF surveys and the June 2026 ADC Focus Workshop, participants will discuss current practices, unresolved scientific questions and opportunities for greater consistency, providing further input to the ongoing work of the EBF ADC team.

09:00	**10:20**	**Session 16: Protein MS tech 1**	
09:00	09:20	**Stephanie Keane, Resolian**	Extending the Sensitivity of a Hybrid LC-MS/MS Assay for PAD2 and PAD4 Through Microflow Chromatography
09:20	09:40	**Sergio Menta, F. Hoffmann-La Roche**	A Multiplexed LC-MS/MS Strategy for the Simultaneous Quantification of a Transgene Protein and its Endogenous Counterpart in a Gene Therapy Program.
09:40	10:00	**Bas Sleumer, ICON**	The use of multiple signature peptides for quantitative protein bioanalysis by digestion and LC-MS/MS
10:00	10:20	**Heike Wiese, Nuvisan**	Overcoming High Soluble Target Interference in Drug Quantification: A Hybrid Immunocapture LC-MS/MS Approach for Clinical Bioanalysis

09:00	**10:20**	**Session 17: placeholder for AMS**
		In this session, we plan to create a vendor-neutral space within the EBF Open Symposium to explore the scientific value, practical applications and limitations of AMS. In line with the EBF's goal and mission , we are working with the AMS community and PK/metabolism scientists to secure at least four case-study presentations from four different users, followed by a panel discussion.

10:20 **11:10** **Coffee break and Poster Discussion/Viewing**

Parallel Sessions

11:10	**12:50**	**Session 18: Connecting Metabolism, Exposure and Multi-Omics**	
11:10	11:30	**Ian D Wilson, Imperial College**	Integrating Multiomics and DMPK
11:30	11:50	**Stewart Jones, AstraZeneca**	From Tissue Microenvironments to Mechanism: Deploying LMD-Omics Across Drug Exposure, Toxicity and Disease Biology
11:50	12:10	**Heather Hughes, Sciex**	Comprehensive metabolite identification of liraglutide in rat S9 fractions using LC–HRMS with complementary fragmentation for improved metabolite coverage and structural elucidation
12:10	12:30	**Anastasiia Shevchuk, Nuvisan**	Challenges and prospects of targeted metabolomics kits validation
12:30	12:50	**Presenter tbc**	Abstract under revision

11:10	**12:50**	**Session 19: ADC Bioanalysis, From Community Recommendations to Complex PK Decisions**	
11:10	11:30	**Federico Riccardi Sirtori, On behalf of the EBF ADC Team**	Update on recent EBF recommendations on ADC
11:30	11:50	**Dominic Warrino, representing the AAPS team**	Updated Recommendations for the Bioanalysis of Antibody–Drug Conjugates (ADC) from the ADC working group of the AAPS Bioanalytical Community

11:50	12:10	**Ilse De Salve, Merck KGaA**	Hybrid Immunocapture (IC)/LC-MS methods for the simultaneous quantification of Total Antibody and Conjugated Payload across different species case studies.
12:10	12:30	**Jordane Biarc, Charles River Laboratories**	Decoding ADC Complexity: Bioanalytical LC-MS Approaches and application to preclinical and clinical studies
12:30	12:50	**Robin Woerdenweber, BioNTech SE**	Trust, but Verify: A Risk-Based Framework for Orthogonal LC-MS Investigation of Unexpected ADC Pharmacokinetic Profiles

11:10	**12:50**	**Session 20: Pushing the Limits of Sensitivity and Multiplexing in Bioanalysis**	
11:10	11:30	**Minh Dang, BioAgilytix**	Responding to Evolving Clinical Needs: A Collaborative Journey to an Ultra-Sensitive PK Assay
11:30	11:50	**Pratiksha Gulati, F. Hoffmann-La Roche**	Navigating High-Plex Profiling and Targeted Quantification in Drug Development
11:50	12:10	**Katharina Malinowsky, Microcoat Biotechnologie**	Next-Generation Ultrasensitive Biomarker Testing: Enabling Scalable Blood-Based Biomarker Strategies for Global Clinical Trials
12:10	12:30	**Vicentini Elena, Aptuit (Verona) Srl, an Evotec Company**	Next-Generation Ultrasensitive Protein Detection in Huntington's Disease: from SMC™ to NULISA™ Technology
12:30	12:50	**Christine Bain-Wendlinger, KCAS Bio**	Combining versatility and ultrasensitivity with the NULISA technology

12:50 14:00 Lunch break and Poster Discussion/Viewing

Parallel Sessions

14:00	**15:20**	**Session 21: Protein MS Tech 2**	
14:00	14:20	**Stéphane Muccio, Sanofi**	Generic Hybrid Immunocapture LC-MS/MS Approach for Integrity Assessment of Multispecific Antibodies in Clinical Studies: A Breakthrough Bioanalytical Strategy
14:20	14:40	**Mathieu Dupré, Sanofi**	Advanced LC-MS Strategies for In Vivo Bioanalysis of Next-Generation Biotherapeutics: From Method Development to Multi-Therapeutic Area Applications
14:40	15:00	**Tim Lijster, ICON**	Analytical aspects of LC-MS/MS-based neutralizing antibody testing
15:00	15:20	**Peter Blattmann, Idorsia**	Development and Clinical Application of a Fit-for-Purpose LC-MS/MS Assay for Quantification of CT-proET-1 in Human Plasma

14:00	**15:20**	**Session 22: Towards Harmonisation of ADA Guidelines: Surfacing the Challenges**	
		In this session, we will begin exploring where regional ADA expectations diverge, where guidance conflicts with scientific practice, and how these differences affect real development programmes. The discussion will identify and prioritise issues for deeper, case-based examination at the EBF Focus Workshop on harmonisation of ADA guidelines in June 2027 in Malaga. The session will be developed over the coming weeks and may include a pre-conference survey to gather your input.	

15:20 16:00 Coffee break and Poster Discussion/Viewing

Plenary Session

16:00	**17:30**	**Session 23: Closing Session - Towards ICH M10 (R1)**	
		Includes pitches from	
		Robert Neely, Immunologix Laboratories *Aligning Compliance with Science - Rethinking Bioanalytical Guidance for LBAs*	
		Stuart McDougall, on behalf of the EBF *Feedback from EBF community one year on from our publication of European Bioanalysis Forum recommendation on*	
		Case studies are being prepared	

17:30 Closing Remarks - Adjourn

Scientific Programming: Cecilia Arfvidsson, Matt Barfield, Michaela Golob, Lee Goodwin, Kyra Cowan, Rob Wheller and Steve White
Meeting management: Philip Timmerman (EBF)

The conference is organised as a non-profit event by the EBF vzw. The organisation of the conference is independent from all EBF member companies