16th EBF Open Symposium
Science - Winning the Race

Hyatt Regency Tower (Barcelona) 15-17 November 2023

Program at a glance

Day 1: 15 November 2023

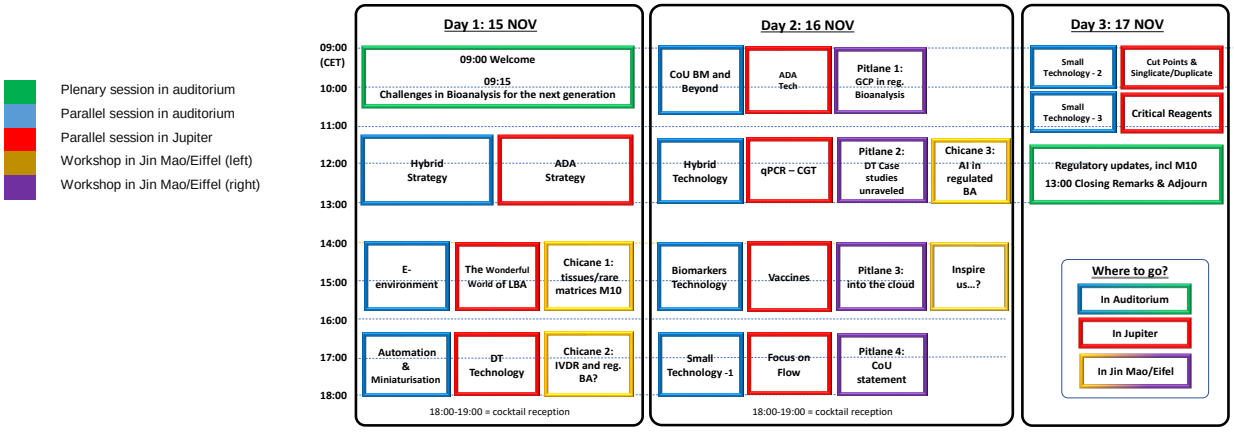
9:15	9:30	Welcome
9:30	10:30	Session 1: Challenges in Bioanalysis for the Next Generation
11:10	12:50	Session 2: Hybrid Assays - Strategy
		Session 3: ADA - Strategy (Parallel with session 2)
14:00	15:40	Session 4: E-environment
		Session 5: The Wonderful World of LBA (Parallel with session 4)
		In the chicane 1: is everything said on tissues/rare matrices after M10? (Parallel with session 4)
16:20	18:00	Session 6: Automation & Miniaturisation
		Session 7: Drug Tolerance - Technology (Parallel with session 6)
		In the chicane 2: IVDR, what is the role for reg. BA? - (Parallel)

Day 2: 16 November 2023

9:00	10:40	Session 8: CoU Strategy - Biomarkers and beyond…
		Session 9: ADA Technology (Parallel with session 8)
		Pitlane 1: GCP (Parallel with session 8)
		In the chicane 3: is there a place for AI in regulated bioanalysis? (Parallel with session 8)
11:20	13:00	Session 10: Hybrid Assays - Technology and Applications
		Session 11: qPCR (Parallel with session 10)
		Pitlane 2: Drug Tolerance case studies unravelled (Parallel with session 10)
14:00	15:40	Session 12: Biomarkers - Technology
		Session 13: Vaccines (Parallel with session 12)
		Pitlane 3: into the cloud (Parallel with session 12)
		Racing for the Future: inspire us….
16:20	18:00	Session 14: Small molecules - Technology
		Session 15: Focus on Flow (Parallel with session 14)
		Pitlane 4: Context of Use (Parallel with session 14)

Day 3: 17 November 2023

9:00	10:30	Session 16: Small Molecules away from Mainstream
		Session 17: Cut Points & Singlicate/Duplicate (Parallel with session 16)
10:10	11:10	Session 18: Small Molecules - technology
		Session 19: Critical Reagents (Parallel with session 18)
11:40	12:50	Session 20: Regulatory Updates & Future of Bioanalysis
12:50	13:00	Closing remarks - Adjourn



Program details (v.12SEP2023)

Day 1 - Wednesday 15 NOV 2023

9:15 9:30 Welcome

9:30 10:30 Session 1: Challenges in Bioanalysis for the Next Generation (PLENARY)

9:30 9:50 Session under construction by the EBF

9:50 10:10

10:10 10:30

10:30 11:10 Coffee break and Poster Discussion/Viewing

11:10 12:50 Session 2: Hybrid Assays - Strategy - (Parallel)

11:10 11:30 ***EBF team presentation***
title tbc

11:30 11:50 ***Alexandra Tavernier, Sanofi***
Protein vs peptide immunocapture: the case study of the quantitation of sBCMA

11:50 12:10 ***Nico van de Merbel, U. of Groningen***
Simultaneous quantification of protein biomarker isoforms by dual immunocapture and LC-MS/MS

12:10 12:30 ***John Perkins, KCAS Bioanalytical & Biomarker Services***
Using the Flexibility of Hybrid LC-MS/MS to Address Typical Challenges in Quantitation of Large Molecules

12:30 12:50 ***Shashank Gorityala, BioAgilytix***
Strategies and Case Studies on the Bioanalysis of Protein Therapeutics and Biomarkers by Immunoaffinity LC-MS/MS

11:10 12:50 Session 3: ADA - Strategy - (Parallel)

11:10 11:30 ***EBF team presentation***
title tbc

11:30 11:50 ***Presenter tbc***
title tbc

11:50 12:10 ***Hanna Widmaier, Nuvisan***
Cut-Point Limbo - low cut-points and their challenges

12:10 12:30 ***Claire Seal, invoX Pharma***
Case Study of a Neutralising Antibody Assay for FS118, an anti-PD-L1/LAG-3 Bispecific, Tetravalent Antibody

12:30 12:50 ***Nick White, AstraZeneca***
To analyse or not to analyse; that is the question? Changing the Immunogenicity Testing Strategy; Should it be Mandatory, or would a Risk-based Approach be More Appropriate?

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

14:00 15:40 Session 4: E-environment - (Parallel)

14:00 14:20 ***EBF team presentation***
title tbc

14:20 14:40 ***Michael Gröschl, Celerion***
Introducing Laboratory Automation to regulated bioanalysis: Integration of Liquid Handlers to a paperless laboratory

14:40 15:00 ***Bianca Komoll, Labware***
Archiving in GxP Process, Requirements and Pitfalls

15:00 15:20 ***Norbert Bittner, up to data***
Case study on the implementation of a regulatory compliant data platform for planning and execution, collaboration, review and reporting of bioanalytical studies.

15:20 15:40 ***David Pekar, Lablytica Life Science***
Experiences from 7 years of a paperless laboratory and archiving system under OECD GLP

14:00 15:40 Session 5 - The Wonderful World of LBA - (Parallel)

14:00 14:20 ***Gregor Jordan, Roche Diagnostics***
How to find the “optimal” assay for bioanalytical purposes – can we do better than using the conventional “QC-based” way of assay development and validation?

14:20 14:40 ***Sarah Childs, GSK***

Challenges in human tear analysis: Development of a fit-for-purpose qualitative immunoassay to detect biopharmaceutical exposure in rare matrices.

14:40 15:00 ***Yongzhong Zhao, Frontage Laboratories***
Mechanistic and Statistic Partitioning the Technical Variability of Ligand Binding Assays in Distinct Formats

15:00 15:20 ***Karien Bloem, Sanquin***
Cross-reactivity of anti-drug antibodies against anti-CD20 therapeutic monoclonal antibodies with other anti-CD20 antibodies

15:20 15:40 ***Aparna Kasinath, Syngene***
Risk Assessment and Mitigation Strategy for Clinical Bioanalysis: The Grand Prix of Endurance!

14:00 15:40 In the chicane 1: is everything said on tissues/rare matrices after M10? - (Parallel)
Small discussion forum under construction by the EBF

15:40 16:30 Coffee break and Poster Discussion/Viewing

16:20 18:00 Session 6: Automation & Miniaturisation - (Parallel)

16:20 16:40 ***Mike Wright, GSK***
Small steps, Big advances: unleashing the power of miniaturisation and automation for bioanalytical workflows

16:40 17:00 ***David Pekar, Lablytica Life Science***
Simple automation of 384well plate PPT assays using Liquid Handling Robot.

17:00 17:20 ***Laura Boffel, Ghent University***
Near-infrared-based hematocrit prediction using volumetric absorptive microsampling devices: an in-depth evaluation

17:20 17:40 ***Open slot***
EBF still welcomes your scientific contribution (contact open@e-b-f.eu before 15 Oct2023)

17:40 18:00 ***Federico Pastori, ERBC***
Hormones Monitoring in Preclinical Development:

16:20 18:00 Session 7: Drug Tolerance - Technology - (Parallel)

16:20 16:40 ***Jean-Christophe Genin, F. Hoffmann-La Roche***
Let the Biology guide our choices - Case study : Decoding immunogenicity assay performance for reliable ADA data delivery

16:40 17:00 ***Foka Venema, Ardena***
Adequate neutralization steps are essential for the development of sensitive, robust and highly drug tolerant anti-drug antibody screening and confirmatory assays

17:00 17:20 ***Gregor Jordan, Roche Diagnostics***
Improving drug tolerance: “An assay perspective”

17:20 17:40 ***Lili Liao, Frontage Laboratories***
Strategies for Improving Drug Tolerance in Immunogenicity Assay

17:40 18:00 ***Ortwin Van de Vyver, Sanofi***
PandA-monium: are we too tolerant in ADA method development?

16:20 18:00 In the chicane 2: IVDR, what is the role for reg. BA? - (Parallel)
Small discussion forum under construction by the EBF

18:00 19:00 Complementary Cocktail Reception
19:00 End of day 1

Day 2: 16 November 2023

9:00 10:40 Session 8: CoU Strategy - Biomarkers and beyond…

9:00 9:20 ***EBF team presentation - BM, qPCR, ADA…CoU is everywhere...***
title tbc

9:20 9:40 ***Nanda Gruben, ICON***
Case studies for testing stabilities for biomarker assays

9:40 10:00 ***Heike Wiese, Nuvisan***
Metabolomics screening kits for use in clinical trials – fit for purpose?

10:00 10:20 ***Presentation from UCB-Biopharma, presenter tbc***
A biomarker assay validation approach tailored to the context of use and bioanalytical platform

10:20 10:40 ***Richard Hughes, Resolian***
Presentation title tbc

9:00 10:40 Session 9: ADA Technology - (Parallel)

9:00 9:20 ***Valeria Castagna, Merck KGaA***
Generic ADA Assay: how to speed up early phase and preclinical immunogenicity testing.

9:20 9:40 ***Sijranke Post, Ardena***
The challenges to overcome when developing a synthetic peptide Anti-Drug Antibody assay

9:40 10:00 ***Christopher Tiedje, BioAgilytix***
Application of Different Approaches to ADA Domain Specificity Characterization

10:00 10:20 ***Anna Vlachodimou, Genmab***
Novel approach of immunogenicity testing in support of multi-specific antibody drugs

10:20 10:40 ***Sandra Henkelman, QPS***
Challenges during ADA assay development

9:00 10:40 Pitlane 1: GCP - (Parallel)
Workshop under construction by the EBF GCP team

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

11:20 13:00 Session 10: Hybrid Assays - Technology and Applications - (Parallel)

11:20 11:40 ***Barry Jones, Crinetics Pharmaceuticals***
Quantitation of Adrenocorticotropic Hormone (ACTH) using a Novel Reagent-Free LCMS Assay and Correlation Study to a Clinical Immunoassay

11:40 12:00 ***Abde El Galai, Fox BIOSYSTEMS***
Development of new FO-SPR technology to tackle new challenges with EV and hybrid assay applications. Fox BIOSYSTEMS EIC-project progress

12:00 12:20 ***Michael Blackburn, Quotient Sciences***
Hybrid extraction versus physicochemical methods for large peptides: some comparative data and observations

12:20 12:40 ***Linzhi Chen, Boehringer Ingelheim***
Development of ELISA plate-based immunocapture for LC/MS/MS analysis of therapeutic proteins

12:40 13:00 ***Presenter identified***
Title identified - awaiting final approval

11:20 13:00 Session 11: qPCR - (Parallel)

11:20 11:40 ***Amanda Hays, on behalf of AAPS***
qPCR Support of Cell and Gene Therapies - What to Measure and How

11:40 12:00 ***Lara Duchstein, BioAgilytix***
Development and validation of a multiplex qPCR assay for RCL monitoring

12:00 12:20 ***Neil Henderson, AstraZeneca***
CRISPR and Applications of Genome Editing: Bioanalytical Strategies & Challenges

12:20 12:40 ***Johannes Stanta, Celerion***
AAV8 shedding assay to support gene therapy clinical trials

12:40 13:00 ***Philippe Ancian, Charles River Laboratories***
The validation of a duplex qPCR assay to study biodistribution/Shedding of a dual gene therapy vector

11:20 13:00 Pitlane 2: Drug Tolerance case studies unravelled (15 min pitch/case studies) - (Parallel)

11:20 11:25 ***Martin Rieger, MorphoSys AG***
Case study: Regulatory interaction with regards to DT on a mAb

11:25 11:40 ***Morten Funch Carlsen, LEO Pharma***
Life Cycle Management of ADA and NAb Assays During Clinical Development of a Monoclonal Antibody with Focus on Drug Tolerance Improvement – Nice to Have or Must Have?

11:40 11:55 ***Laura Geary, Resolian***
Improving assay performance when complex sample pre-treatment is required – a CRO perspective

11:55 12:10 ***Daniel Dyer, Labcorp Drug Development***
Experience of a CRO: Drug Tolerance Case Studies

12:10 12:25 ***Arno Kromminga, BioNTech***
ADA Drug Tolerance – Why and when?

12:25 13:00 ***And now...unravel***
Panel discussion of the 5 case studies presented

11:10 12:50 In the chicane 3: is there a place for AI in regulated bioanalysis? - (Parallel)
Small discussion forum under construction by the EBF

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

14:00 15:40 Session 12: Biomarkers - Technology - (Parallel)

14:00 14:20 ***John Perkins, KCAS Bioanalytical & Biomarker Services***
Challenges of LC-MS/MS method development for the quantitation of a polar low molecular weight biomarker in biological fluids

14:20 14:40 ***Hongming Zhang, Frontage Laboratories***
Validation of an Ultra-sensitive Method for Phospho-Tau 217 (pTau-217) Quantitation in Human Plasma, Serum and CSF

14:40 15:00 ***Danilo La Terra, Quanterix***
Simoa technology enables ultrasensitive biomarker detection

15:00 15:20 ***Alessandro Greco, Aptuit - an Evotec company***
Development and validation of a bioanalytical microLC-MS/MS bottom-up approach method to quantify Semaphorin-3A protein in human plasma samples.

15:20 15:40 ***Panel discussion***

14:00 15:40 Session 13: Vaccines - (Parallel)

14:00 14:20 ***Stefanie Siegert, AC Immune***
Active immunotherapy in neurodegenerative disease: how to define antibody responses to the self-antigen following immunization?

14:20 14:40 ***Floris Loeff, Sanquin***
Afucosylated immunoglobulin G responses are a hallmark of enveloped virus infections and are efficiently quantified using the novel fucose-sensitive ELISA for Antigen-Specific IgG (FEASI) assay

14:40 15:00 ***Marijke W.A. Molenaar-de Backer, Sanquin***
Hijacking the Monocyte Activation Test from pyrogen test to support immunogenicity testing

15:00 15:20 ***Jason Pennucci, Moderna***
Bioanalytical challenges for LNP-mRNA vaccines

15:20 15:40 ***Aparna Kasinath, Syngene***
Immunogenicity Wanted: Differences between assays for biologics and vaccines

14:00 15:40 Pitlane 3: into the cloud - (Parallel)
Under construction by the EBF e-environment team

14:00 15:20 Racing for the Future: inspire us….
Parallel: small discussion booth - bring your ideas to the EBF for future focus

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

16:20 18:00 Session 14: Small molecules - Technology - (Parallel)

16:20 16:40 ***Esther van Duijn, TNO***
The metabolism of lufotrelvir, a prodrug for the treatment of SARS-COV2, in humans following intravenous administration

16:40 17:00 ***Bertram Nieland, Sciex***
Structural elucidation of conjugation drug metabolites by utilizing novel electron-activated dissociation (EAD)

17:00 17:20 ***Robert Plumb, Waters***
Doing more with less: Application of microsampling, LC/MS/MS and MS imaging for the measurement of drug….

17:20 17:40 ***Arne Egberts, Merck KGaA***
Enhancing Carbohydrate Metabolite and Glycan Analysis through Porous Graphitic Carbon HPLC Columns

17:40 18:00 ***Daniel Schulz-Jander, QPS Netherlands***
Oligonucleotide bioanalytical method development - triple quadrupole and high-resolution mass spectrometric detection - the benefits and challenges of selecting the technology.

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

16:20 18:00 Session 15: Focus on Flow - (Parallel)

16:20 16:40 ***Peter van Bommel, ICON***
Go with the flow? Ligand binding versus flow cytometry methods for the analysis of anti-drug antibodies in support of CAR-T cell trials

16:40 17:00 ***Levent Akyüz, CheckImmune***
Challenges in Validating Flow Cytometry Panels for Clinical Trials of Cryopreserved Blood Samples

17:00 17:20 ***Julian J. Freen-van Heeren, Sanquin***
Considerations for selecting the right flow-based read-out and experimental conditions for development of new antibodies

17:20 17:40 ***Petia Doytcheva, Celerion***
Sample stability assessments in flow cytometry assays: immunophenotyping case study and critical considerations

17:40 18:00 ***Johannes Stanta, Celerion***
Bringing unstable flow cytometry assays closer to the patient. Case study of an ex-vivo CD11b stimulation flow cytometry assay collected at external clinical site.

16:20 18:00 Pitlane 4: Context of Use - (Parallel)
Workshop under construction by the EBF BM/CoU team

18:00 19:00 Complementary Cocktail Reception
19:00 End of day 2

Day 3: 17 November 2023

9:00	**10:30**	**Session 16: Small Molecules away from Mainstream - (Parallel)**
9:00	9:20	***Tim Vale, Resolian*** Road to Recovery: Exploring the challenges in assessing recovery during the validation of an LC-MS method in a rare matrix
9:20	9:40	***Darren Spark, Charles River Laboratories*** Bioanalysis Supporting In-vitro Permeation Tests: Alternatives to Tick-Box Assay Validations
9:40	10:00	***Nico van de Merbel, Icon*** Experiences with development and validation of bioanalytical methods for prodrugs
9:00	**10:30**	**Session 17: Cut Points & Singlicate/Duplicate - (Parallel)**
9:00	9:20	***Jacomijn Dijksterhuis, ICON*** Singlicate analysis applied to pharmacokinetic ligand binding assays: case studies from a CRO perspective
9:20	9:40	***Issa Jyamubandi, Resolian*** A generic singlicate immunogenicity method to detect anti-PEG antibodies: Pre and post dose of pegylated therapies
9:40	10:00	***James Lawrence, Invox Pharma*** It's all relative, an alternative to the cutpoint approach to Pre-clinical immunogenicity assessment
10:00	**10:10**	**Short logisitc break**
10:10	**11:10**	**Session 18: Small Molecules - technology - (Parallel)**
10:10	10:30	***Szabolcs Szarka, Resolian*** Design of experiments and automation for the efficient protein LC-MS method development
10:30	10:50	***Hanna De Baets, Ghent University*** Capillary application of (volumetric) dried blood spot assays for tacrolimus and creatinine determination in stem cell transplant patients
10:50	11:10	***Open slot*** EBF still welcomes your scientific contribution (contact open@e-b-f.eu before 15 Oct2023)
10:00	**10:10**	**short Logistic break**
10:10	**11:10**	**Session 19: Critical Reagents - (Parallel)**
10:10	10:30	***Morgan Evans, Agilex Biolabs*** Can technology choice make your data SPARCL?
10:30	10:50	***Karien Bloem, Sanquin*** Understanding critical reagent and sample handling in the bioanalytical lab; examples around haemostasis biomarkers
10:50	11:10	***Paola Genevini, Bio-Rad*** Generation of Recombinant Tool Antibodies to Support Cell and Gene Therapy Development
11:10	**11:40**	**Coffee break**
11:40	**12:50**	**Session 20: Regulatory Updates & Future of Bioanalysis - (PLENARY)** Session under construction by the EBF
12:50	**13:00**	**Closing remarks - Adjourn**

Meeting Organisation: Cecilia Arfvidsson (AstraZeneca), Matthew Barfield (F. Hoffmann – La Roche), Kyra Cowan (Merck KGaA), Michaela Golob (Nuvisan), Jo Goodman (AstraZeneca), Anna Laurén (NovoNordisk), Robert Nelson (BioAgilytix), Steve White (GSK) and Philip Timmerman (EBF)

SPONSORS of the 16th OS: https://bcn.e-b-f.eu/sponsors/

MEETING UPDATES, AGENDA, TRAVEL: https://bcn.e-b-f.eu

REGISTER for the meeting: https://bcn.e-b-f.eu/registration/

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