



Program at a glance

Day 1: 20 November 2024

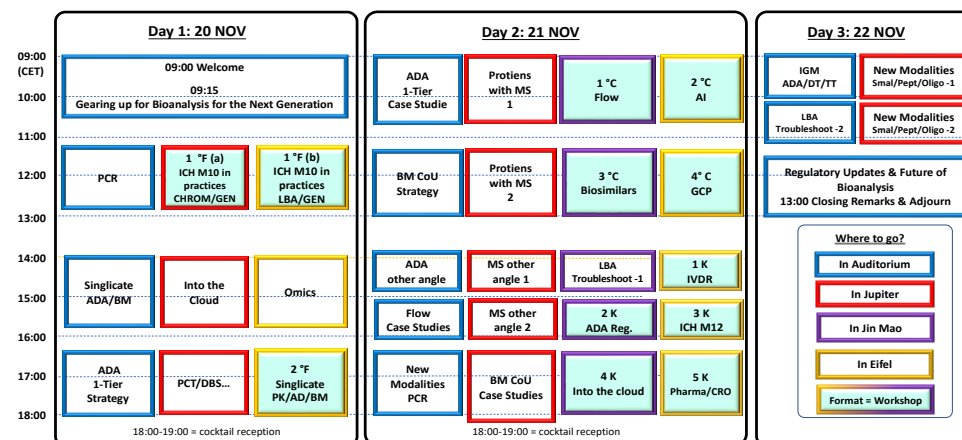
09:00	09:15	Welcome
09:15	10:30	Session 1: Turning up the Heat for the Next Generation (Plenary)
11:10	12:40	Session 2: Focus on PCR Fahrenheit Workshop 1a: ICH M10 on the radar - CHROM/General Fahrenheit Workshop 1b: ICH M10 on the radar - IGM/General
14:00	15:40	Session 3: Singlicate analysis beyond PK Session 4: Into the Cloud Session 5: OMICS
16:20	18:20	Session 6: ADA 1-Tier strategy Session 7: Patient Centric Trials (PCT) & DBS technology Fahrenheit Workshop 2: Singlicate analysis for PK/ADA/BM

Day 2: 21 November 2024

09:00	10:40	Session 8: ADA 1-Tier - case studies Session 9a: Proteins with LC-MS Celsius Workshop 1: Flow Cytometry in (regulated) Bioanalysis Celsius Workshop 2: AI
11:20	13:00	Session 10: BM CoU strategy Session 9b: Proteins with LC-MS (cntd) Celsius Workshop 3: Biosimilar bioanalysis Celsius Workshop 4: GCP
13:50	14:50	Session 11: Immunogenicity from another angle Session 12a: MS from another angle Session 13: troubleshooting LBA -1: reagents/Matrices Kelvin Workshop 1: IVDR
15:10	16:10	Session 14: Flow Cytometry in (regulated) Bioanalysis - case studies Session 12b: MS from another angle Kelvin Workshop 2: ADA - Challenging the current testing paradigm Kelvin Workshop 3: ICH M12...validation of <i>in vitro</i> assays
16:40	18:00	Session 15: New modalities - Focus on PCR Session 16: BM in practice (ends 18:20) Kelvin Workshop 4: Into the cloud Kelvin Workshop 5: The Pharma/CRO Interface (parallel session)

Day 3: 22 November 2024

09:00	10:00	Session 17: IGM - ADA Drug Tolerance / target tolerance Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical
10:10	11:10	Session 19: Troubleshooting LBA -2: PK/ADA Session 18b: New modalities - Focus on small molecules, peptides and oligo's - analytical (cntd)
11:40	12:50	Session 20: Regulatory Updates & Future of Bioanalysis
12:50	13:00	Closing remarks - Adjourn - Auditorium



- Plenary or Parallel session in auditorium
- Parallel session in Jupiter
- Workshop in Eifel/Sears/Pisa (= left when walking to the Auditorium)
- Workshop in Jin Mao/Petronals/Liberty (right when walking to the Auditorium)

Program details (v.30-SEP-2024)

Note: Once the winner of the Bioanalysis Rising Star Award (BRSA) is announced, the presentation will be included in the agenda

Day 1 - Wednesday 20 NOV 2024

09:00	09:15	Welcome - Philip Timmerman
09:15	10:30	Session 1: Turning up the Heat for the Next Generation (Plenary) Session Chair: Philip Timmerman <i>In this opening session, it is our plan to discuss ideas on where drug development is going in the next decades, and how BioA should prepare themselves. What does the future hold? Is it real or a faraway Fata Morgana?... Can we see beyond "New Modalities" or incremental technology changes and are our systems, tools and regulations ready for a shift...</i> Philip Timmerman, EBF: Short introduction to the session Key Note speakers are being identified
10:30	11:10	Coffee break and Poster Discussion/Viewing
11:10	12:40	Session 2: Focus on PCR (parallel session) Session Chair: Robert Nelson Robert Nelson, on behalf of the EBF Update on progress of the EBF PCR Team Tracy Iles, Labcorp Considerations and Challenges of Multiplex PCRs Lara Duchstein, BioAgilytix Applying Context of Use to the development and validation of a RT-qPCR assay for detecting gene knock-down Foka Venema, Ardena Bioanalysis Adequate computerized system and assay validation are essential for the development of sensitive, precise and robust qPCR assays in a regulated environment Annick de Vries, Sanquin Diagnostic Services B-cell counts in small volume, remotely sampled capillary blood; a ddPCR approach.
11:10	12:40	Fahrenheit Workshop 1a: ICH M10 on the radar - CHROM/General (parallel session) Workshop Moderators: Lee Goodwin, Nico van de merbel, Tom Verhaeghe, Neil Adcock and Stuart McDougall Workshop/round table Hosted by the EBF. In this workshop feedback will be given on issues, feedback from HA and ambiguities we have captured within the EBF community related to the interpretation of the ICH M10 Guideline. Different delegates will give feedback on one specific case study after which these can be discussed in round table/panel format Case studies are being collected with the EBF. We currently have > 10 Listed. If you have a case study and can summarise it in 3 slides (5-min presentation), you can send it to open@e-b-f.eu (before 31OCT2024) and we will try to consider it in the session.
11:10	12:40	Fahrenheit Workshop 1b: ICH M10 on the radar - IGM/General (parallel session) Workshop Moderators: Richard Hughes, Mike Wright and Michaela Golob Workshop/round table Hosted by the EBF. In this workshop feedback will be given on issues, feedback from HA and ambiguities we have captured within the EBF community related to the interpretation of the ICH M10 Guideline. Different delegates will give feedback on one specific case study after which these can be discussed in round table/panel format Case studies are being collected with the EBF. We currently have > 10 Listed. If you have a case study and can summarise it in 3 slides (5-min presentation), you can send it to open@e-b-f.eu (before 31OCT2024) and we will try to consider it in the session.

12:40 14:00 Lunch break and Poster Discussion/Viewing

14:00 15:40 **Session 3: Singlicate analysis beyond PK (parallel session)**
incl. introduction of **Fahrenheit Workshop 2: Singlicate analysis singlicate PK/ADA/BM**
Session Chair: Mike Wright

14:00 14:20 **Gareth Satchell, GSK**

Why Can't We – A Different Mindset for Singlicate Analysis

14:20 14:40 **Janine Micheli, PPD, a part of ThermoFisher**

Exploring Singlicate Analysis: Feasibility, Implementation, and Real-World Applications in Immunoassay Bioanalysis

14:40 15:00 **James Beecroft, F. Hoffmann-La Roche**

The Transition to Singlicate Biomarker Analysis: Retrospective and Prospective Insights

15:00 15:20 **Stephanie Vauleon, F. Hoffmann-La Roche**

ADA analysis in duplicates versus singlicates: retrospective data evaluation and impact of singlicate analysis on validation and toxicity study data

15:20 15:40 **Emma Rankka, Mercodia**

Evaluating Singlicate vs. Duplicate Testing in Biomarker Assays: Insights from a Case Study

14:00 15:40 **Session 4: Into the Cloud (parallel session)**

Session Chair: Cecilia Arvidsson

14:00 14:20 **Cecilia Arvidsson, on behalf of EBF**

Regulated bioanalysis into the cloud – this is what you need to consider

14:20 14:40 **Norbert Bittner, Up to data**

Enhancing Bioanalytical Study Oversight: Cloud-Based Collaboration between CROs and Sponsors

14:40 15:00 **Federico Pastori, LabWare**

Computerized LIMS System Validation in Cloud Deployments with IoT implementations

15:00 15:20 **Robert Peverley, Labcorp**

Integrating Electronic Laboratory Workbooks into Regulatory Bioanalysis LC/MS Method Validation: Challenges and Opportunities

15:20 15:40 **Jack Hodges, Resolian**

Agile development and Risk-Based validation of bespoke LIMS – Laboratory innovation in a post GAMP 5 Second Edition era

14:00 15:40 **Session 5: OMICS (parallel session)**

Session Chair: Nico van de Merbel

14:00 14:20 **Amy Bartlett, Waters**

Investigating off target pharmacology and metabolism of methapyrilene using metabolomics, lipidomics and MS imaging: A case study

14:20 14:40 **Frank Klont, U. Groningen**

Metabolomics enables larger-scale and real-world drug metabolism studies

14:40 15:00 **David Bonnel, Aliri FRANCE SAS**

Integrating Mass Spectrometry Imaging and Spatial Transcriptomics for Clinical Insights into Disease Complexity and Drug Response

15:00 15:20 **Jacqueline Wendering, CheckImmune**

Advancing Precision Medicine by Multiomic Single-Cell RNA Sequencing for Cellular Insights and Clinical Applications

15:20 15:40 **Panel Discussion - role of Omics in Bioanalysis/Drug Development**

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

16:20 18:00 **Session 6: ADA 1-Tier strategy (parallel session)**

Session Chair: Kyra Cowan

16:20 16:40 **Kyra Cowan, on behalf of the EBF**

Update on current discussions on ADA related themes in the EBF (1-Tier, DT, CoU beyond BM...)

16:40 17:00 **Annelies Coddens, argenx**

Impact of changing the 3-tiered ADA testing into a 1 or 2 tiered approach on reporting of clinical immunogenicity data.

17:00 17:20 **Lauren Stevenson, Immunologix Laboratories**

What's all the noise? How cut points confound clarity of signal.

17:20 17:40 **Chris Jones, AstraZeneca**

A review of the bioanalytical strategy for immunogenicity assessment of cotadutide

17:40 18:00 **Presenter identified**

Awaiting final abstract approval

18:00 18:20 **Q&A - Panel discussion**

- 16:20 18:00 Session 7: Patient Centric Trials (PCT) & DBS technology (parallel session)**
Session Chair: Steve White
- 16:20 16:40 **Ruchika Sachdev, Novartis**
 Re-imagining blood sampling: measuring biomarkers (Neurofilament Light & C-Reactive Protein) at patients'
- 16:40 17:00 **Joleen T White, Bill & Melinda Gates MRI**
 Bioanalytical Strategies for Therapeutic Antibody Clinical Development in Low and Middle Income Countries
- 17:00 17:20 **Sofiya Matviyukiv, Novartis**
 Operational aspects for implementing home-based digital assessments in people living with Amyotrophic Lateral Sclerosis
- 17:20 17:40 **Neil Spooner, PCSIG**
 Overcoming the challenges for incorporating patient centric sampling approaches into multicentre clinical trials for pharmaceutical drug development
- 17:40 18:00 **Kevin Vandenbroucke, Ghent University**
 Tackling the preanalytical instability of dihydropyrimidine dehydrogenase phenotyping via dried blood microsampling
- 18:00 18:20 **Cristine Steen-Louws, Genmab**
 Principles of 3R in the BioA lab - Application of microsampling in exploratory studies
- 16:20 18:00 Fahrenheit Workshop 2: Singlicate analysis for PK/ADA/BM (parallel session)**
Moderators: Mike Wright and Matthew Barfield
 Workshop/round table Hosted by the EBF team
Scientific discussion & CRO/Pharma partnership discussion
- More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.
- 18:00 19:00 Complementary Cocktail Reception**
19:00 End of day 1

Day 2: 21 November 2024

- 09:00 10:40 Session 8: ADA 1-Tier - case studies (parallel session)**
Session Chair: Kyra Cowan
- 09:00 09:20 **Karien Bloem, Sanquin Diagnostic Services**
 Data from real-life patient cohorts for adalimumab and certolizumab show similar anti-drug antibody (ADA) incidence, whether tested in a 1-tier or 3-tier assay.
- 09:20 09:40 **Laura Geary, Resoliant**
 Evaluating the Tiered Approach in an ADA Gene Therapy Assay
- 09:40 10:00 **Marco Klinge, BioAgilytix**
 Evaluating the utility of the multi-tiered immunogenicity testing paradigm
- 10:00 10:20 **Ben Leatherdale, ADCT**
 Evaluation of a 1-tier vs 3-tier approach for ADA testing in clinical trial for an ADC where low incidence of immunogenicity is observed.
- 10:20 10:40 **Hannah Higgins, Labcorp**
 Are we doing too much? Clinical Case Studies to assess the opportunity for a 1-Tiered Approach
- 09:00 10:40 Session 9a: Proteins with LC-MS (parallel session)**
Session Chair: Nico van de Merbel
- 09:00 09:20 **Nico van de Merbel, on behalf of the EBF**
 Update on discussions in the EBF on protein LC-MS
- 09:20 09:40 **Katrin Schroeter, Sanofi**
 Bioanalytical Strategy: A requirement for complex protein therapeutic projects
- 09:40 10:00 **Dawn Dufield, KCAS Bio**
 Hybrid LC-MS/MS Technology Becoming Increasingly Valuable in the Bioanalysis of Antibody Drug Conjugates – Bioanalytical strategy Illustrated by Case Studies
- 10:00 10:20 **Ashley Phillips, Resoliant**
 Upstream without a PAD-dle: Challenges and their Resolution in the Development of a Hybrid LC-MS Assay for PAD2 and PAD4
- 10:20 10:40 **Paul Boersema (Byondis)**
 LBA vs LC-MS: Choosing the Right Tool for Reliable Total Antibody Quantification in ADCs
- 09:00 10:40 Celsius Workshop 1: Flow Cytometry in (regulated) Bioanalysis (parallel session)**
Workshop Moderator: Anna Laurén and Richard Hughes
 Hosted by the EBF Flow Cytometry team

Moderated by Anna Laurén, on behalf of EBF

More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.

09:00 10:40 Celsius Workshop 2: AI
Workshop Moderators: Matthew Barfield, Katja Zeiser (Nuvisan), Connor Walker (F. Hoffmann-La Roche) and Philip Timmerman
Hosted by the EBF AI-Team

09:10 09:25 **Connor Walker, F.Hoffmann-La Roche**
Bioanalysis 2.0: Navigating the AI frontier.

09:25 09:40 **Katja Zeiser, Nuvisan**
Nuvisan ChatGPT – artificial intelligence in a (regulated) bioanalytical laboratory of a CRO

Panel discussion / Round table - sharing experiences on where is AI going (or should not be going (yet)) in (regulated) bioanalysis

Discussion will build on an extensive survey which is currently being held in EBF and may serve as the stepstone for the upcoming EBF Spring Focus Workshop in June 2025

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

11:20 13:00 Session 10: BM CoU strategy (parallel session)
Session Chair: Kyra Cowan

11:20 11:40 **Kyra Cowan, on behalf the EBF**
EBF's continued involvement in CoU for BM - a little bit of the past, connecting with present, but more importantly...the future

11:40 12:00 **Philip De Decker, argenx**
The COU challenge: A case study on biomarker assay validation agility

12:00 12:20 **Pratiksha Gulati, F. Hoffmann-La Roche**
Technical challenges encountered in the long-term assessment of biomarkers in clinical programs

12:20 12:40 **Debbie McManus, Intertek**
Recombinant Biomarkers, are they Fit-for-Purpose for every Context of Use?

12:40 13:00 **Radboud van Trigt, ICON**
Tools for practical implementation of biomarker methods in a bioanalytical laboratory

11:20 13:00 Session 9b: Proteins with LC-MS (cntd) (parallel session)
Session Chair: Nico van de Merbel

11:20 11:40 **Mathieu Dupré, Sanofi**
Development of innovative bioanalytical methods using LC-MS for ultrasensitive quantification of a fusion protein in tissues to support in vivo preclinical studies

11:40 12:00 **Joe Palandra, Takeda**
Use of Hybrid LC-MS to help mitigate ADA Interference in PK assays

12:00 12:20 **Ana Villar Garea, Sanofi**
Accelerating the discovery of Fc-based biotherapeutics: simultaneous LC-MS bioanalysis of PK and PD in-vivo markers in preclinical samples

12:20 12:40 **Frank Schalk, ICON**
Simultaneous isotyping and semi-quantitation of anti-drug antibodies to a monoclonal IgG1 biotherapeutic using hybrid LBA-LC-MS/MS

12:40 13:00 **Emmanuel Njumbe Ediage, J&J IM**
LC-MS/MS assay for Pegasys (pegylated interferon alpha 2a) provides indirect insights on anti-drug antibody titer and prevalence in NHP serum samples

11:20 13:00 Celsius Workshop 3: Biosimilar bioanalysis (parallel session)
Workshop Moderator: Michaela Golob and Robert Nelson

Hosted by the EBF Biosimilar Team

Moderated by Michaela Golob, on behalf of EBF

More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.

11:20 13:00 Celsius Workshop 4: GCP (parallel session)
Workshop Moderator: Tsvetelina Ivanova and Steve White

Hosted by the EBF GCP Team

Moderated by Tsvetelina Ivanova, on behalf of EBF

More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.

13:00 13:50 Lunch break and Poster Discussion/Viewing

13:50 14:50 **Session 11: Immunogenicity from another angle (parallel session)**

Session Chair: Anna Laurén

13:50 14:10 **Liang Zhu, Moderna**

Characterization of Immune Response to mRNA-1230 (Influenza, RSV, and SARS-CoV-2) Vaccine Candidate: a Case Study

14:10 14:30 **Federico Riccardi Sirtori, Merck KGaA**

In-vitro immunogenicity strategy in the development of novel NBEs and ADCs

14:30 14:50 **Yvonne Katterle, on behalf of ARDAT**

Strengths and weaknesses of different ligand binding assay formats for the determination of anti-AAV9 antibodies

13:50 14:50 **Session 12a: MS from another angle (parallel session)**

Session Chair: Lee Goodwin

13:50 14:10 **Cathy Lane, SCIEX**

Breakthrough workflow for identification of targeted protein degrader (TPD) metabolites

14:10 14:30 **Michael Blackburn, Quotient Sciences**

Connecting BioA with speciation to characterise the kinetics of Darinaparsin, a novel arsenical compound

14:30 14:50 **Robert Plumb, Waters**

Comparison of the Pharmacokinetics, drug metabolism and lipid dysregulation of gefitinib and PROTAC – gefitinib-3 in the rat

13:50 14:50 **Session 13: Troubleshooting LBA -1: reagents/Matrices**

Session Chair: Richard Hughes

13:50 14:10 **Duco Schriemer, QPS Netherlands**

Case studies of free drug assays with their own challenges and assay designs

14:10 14:30 **Elena Vicentini, Aptuit (an Evotec company)**

Day to day challenges in the use of validated biomarker assays with commercially available kits, throughout the lifecycle of sample analysis phase.

14:30 14:50 **Alex Mulvanny, Medicines Evaluation Unit**

Sputum Supernatant Cytokine Measurements – Assay Validation, Clinical Application and Repeatability

13:50 14:50 **Kelvin Workshop 1: IVDR (parallel session)**

Workshop Moderator: Matthew Barfield and Robert Nelson

Hosted by the EBF IVDR-Team

More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.

14:50 15:10 small logistic break

15:10 16:10 **Session 14: Flow Cytometry in (regulated) Bioanalysis - case studies (parallel session)**

Session Chair: Anna Laurén

15:10 15:30 **Teona Roschupkina, Resolian**

Stabilizing Flow: Overcoming Logistics Challenge by "Split Processing"

15:30 15:50 **Hanna Widmaier, Nuvisan**

How precise is precise enough? Lessons learned from ex-vivo neutrophil activation assay

15:50 16:10 **Henko Tadema, ICON**

Fluorescent barcoding as a tool to increase quality and efficiency in clinical flow cytometry

15:10 16:10 **Session 12b: MS from another angle (cntd) (parallel session)**

Session Chair: Lee Goodwin

15:10 15:30 **John Perkins, KCAS Bio**

Refining Method Development & Validation Testing for Antibody Drug Conjugate Payloads

15:30 15:50 **Rob Vreeken, TNO**

The application of ¹⁴C-labeled substrates for efficacy measurements in drug development

15:50 16:10 **Presenter identified**

Awaiting final abstract approval

15:10 16:10 **Kelvin Workshop 2: ADA - challenging the current testing paradigm (parallel session)**

Workshop Moderators: Michaela Golob and Kyra Cowan

Hosted by the EBF IGM community

Open round table format to share experience and provide ideas to move forward in support of science driving the new approaches and regulatory thinking

More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.

15:10 16:10 Kelvin Workshop 3: ICH M12...validation of *in vitro* assays (parallel session)

Workshop Moderator: Steve White and Philip Timmerman

Hosted by the EBF

Open round table format to share experience and provide ideas to move forward in support of science driving the new approaches and regulatory thinking

More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.

16:10 16:40 Coffee break and Poster Discussion/Viewing

16:40 18:00 Session 15: New modalities - Focus on PCR (parallel session)

Session Chair: Robert Nelson

16:40 17:00 **Otilia Cheregi, TATAA Biocenter**

2-Tailed PCR for small RNA analysis in biodistribution and shedding

17:00 17:20 **Eric Lachacz, AstraZeneca**

Cell Therapy Clinical Bioanalysis: approaches, complexities, and challenges through the lens of CAR-T global clinical studies

17:20 17:40 **Presenter identified**

Awaiting approval of abstract

17:40 18:00 **Panel discussion**

16:40 18:20 Session 16: BM in practice (parallel session)

Session Chair: Kyra Cowan

16:40 17:00 **Jelena Popov-Čeleketić, Genmab**

Development and Qualification of Free and Total Soluble Target Assays Tailored to Context of Use

17:00 17:20 **Alireza Maarouf, Sanofi**

Ultrasensitive platforms for IL-13 measurement: Cross-platform comparison for IL-13 quantification

17:20 17:40 **Daniel Creed, Resolian**

Overcoming the Hurdles of a PAD Enzymatic Endpoint Assay: A Demanding Development

17:40 18:00 **Florian Bernet, Celerion**

Singlicate Biomarker Assay: enhancing assay performance by surrogate matrix optimization

18:00 18:20 **Sergio Menta, F. Hoffmann-La Roche**

Shaping a Biomarker Assay for an Endocannabinoid based on its evolving Context-of-Use in Drug Development.

16:20 18:00 Kelvin Workshop 4: Into the Cloud - Upscaling of the archivist role (parallel session)

Workshop Moderator: Cecilia Arfvidsson

Hosted by the EBF e-environment team

16:20 16:40 **Cecilia Arfvidsson, on behalf of EBF**

Upscaling of the archivist role and the archiving activities when transforming into a paperless and cloud based lab – workshop

16:40 18:00 **Continuation of panel/round table discussion**

More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.

16:40 18:00 Kelvin Workshop 5: The Pharma/CRO Interface (parallel session)

Session Chair: Matthew Barfield and Michaela Golob

Hosted by the EBF

Includes 2 short presentations:

16:40 16:55 **Eginhard Schick, F. Hoffmann-La Roche** - Optimizing Bioanalytical Outsourcing via Implementation of a Sponsor Key Performance Indicator System for CROs

16:55 17:10 **Petya Milusheva, Comac Medical** - Bridging the gap: navigating bioanalytical challenges in Pharma-CRO collaborations

17:10 18:00 **Workshop discussions planned to include:**

Issues in implementing singlicate, BM CoU <> SOP? IP sharing...

More details on the workshop dynamics and goals will be shared during regular agenda updates. In the meantime, the EBF team is diligently preparing the workshop.

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

Day 3: 22 November 2024

09:00	10:00	Session 17: IGM - ADA Drug Tolerance / target tolerance (parallel session) Session Chair: Kyra Cowan
09:00	09:20	Lysie Champion, Celerion The rollercoaster between free drug tolerance and target interference in the development of an antidrug antibody assay
09:20	09:40	Gregor Jordan, Roche Diagnostics Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target
09:40	10:00	Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD
09:00	10:00	Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel session) Session Chair: Luca Ferrari
09:00	09:20	Luca Ferrari, on behalf of EBF Update from EBF Project #16: Peptides, Oligos, New Modalities
09:20	09:40	Alexandra Bushby, Labcorp Hybridization LC-MS for Bioanalysis of Oligonucleotides, including case studies
09:40	10:00	Aihua Liu, Resolian The Challenges and Solutions in Developing Ultra-Sensitive Bioanalytical Assays for Oligonucleotide Therapeutics Using a Hybridization LCMS Platform
10:00	10:10	Short logisitc break
10:10	11:10	Session 19: Troubleshooting LBA -2: PK/ADA (parallel session) Session Chair: Richard HughesAnna
10:10	10:30	Valeria Castagna, Merck KGaA Complex troubleshooting of a clinical LBA assay
10:30	10:50	Lucie Diouloufet, Sanofi Strategy and development of ADA assays to support several clinical phases using Fab therapeutic targeting Achondroplasia disorders.
10:50	11:10	Matthias Reichel, BioAgilytix Fit-for-purpose non-clinical immunogenicity assessment to support PK data interpretation – a case study
10:10	11:10	Session 18b: New modalities - Focus on small molecules, peptides and oligo's - analytical (cntd) (parallel session)
10:10	10:30	Chris Williams, Charles River Laboratories Oligonucleotide bioanalysis using LC-MS/MS
10:30	10:50	Alessandro Greco, Aptuit (an Evotec company) Is the addition of cryoprotective agents to stabilise the encapsulated liposome sufficient for the quantification of the unencapsulated compound?
10:50	11:10	Enric Bertran, Moderna Expanding the Horizon of mRNA Technology: From Vaccines to Therapeutics and Bioanalytical Innovations
11:10	11:40	Coffee break
11:40	12:50	Session 20: Regulatory Updates & Future of Bioanalysis (plenary session) Session remains under construction by the EBF until close to the conference date. <i>We plan to cover to cover the most relevant discussions with respect to regulatory challenges, challenges and opportunities for BioA</i>
12:50	13:00	Closing remarks - Adjourn

MEETING ORGANISATION

Organising committee – the EBF Steering Committee:

Robert Nelson, BioAgilytix; Steve White, GSK; Kyra Cowan, Merck KGaA; Michaela Golob, Nuvisan; Matthew Barfield, F. Hoffmann- La Roche and Philip Timmerman, EBF

Scientific committee – the EBF Project Governance Team:

Luca Ferrari, F. Hoffmann- La Roche; Richard Hughes, Resolian; Stuart McDougall, Quotient Sciences; Robert Nelson, BioAgilytix; Anna Laurén, MinervaX; Tsvetelina Ivanova, Comac-Medical; Tom Verhaeghe, J&J IM; Lee Goodwin, Labcorp Drug Development; Steve White, GSK; Neil Adcock, Pharmaron-UK, Kyra Cowan, Merck KGaA; Cecilia Arvidsson, AstraZeneca; Mike Wright, GSK; Michaela Golob, Nuvisan; Matthew Barfield, F. Hoffmann- La Roche, Nico van de Merbel, ICON and Philip Timmerman, EBF

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The organisation of the conference is independent from all EBF member companies and conference sponsors.