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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...assay validation of <i>in vitro</i> assays
16:40	18:00	Session 15: New modalities - Focus on PCR (ends 18:20) 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

Program details (v.10-DEC-2024)

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 the opening session, we aim to explore the future direction of drug development over the coming decades and how BioA can best position itself for what's ahead. What lies ahead for the industry? Is it within reach, or just a distant illusion? We want to look beyond "New Modalities" or incremental technological advances? And are our systems, tools, regulations and above all, our minds prepared for a transformative shift?</i>
09:15	09:40	Philip Timmerman, EBF (not released for sharing) Introduction to the 17th OS Taking the temperature of Bioanalysis - Challenges for BioA for the next decade
09:40	10:10	Keynote Speaker: Peter Groenen, cerebrumDAO (not released for sharing) Pills and Thrills: a trip into the future of biopharmaceutical innovation
10:10	10:30	Q&A / Comments and reflections from the audience

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
11:10	11:20	Robert Nelson, on behalf of the EBF Update on progress of the EBF PCR Team
11:20	11:40	Tracy Iles, Labcorp Considerations and Challenges of Multiplex PCRs
11:40	12:00	Lara Duchstein, BioAgilytix Applying Context of Use to the development and validation of a RT-qPCR assay for detecting gene knock-down
12:00	12:20	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
12:20	12:40	Annick de Vries, Sanquin Diagnostic Services (not released for sharing) 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, Robert Wheller and Stuart McDougall Workshop/round table Hosted by the EBF. P009 - Intro to the ICH M10 Chrom session - final P010 - ICH M10 session Chromatography pitches - final P011 - M10 matrix effects - Rob Wheller - final P01 - Slides discussed at the CHROM session - final 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. Delegates will give feedback on one specific case study after which these can be discussed in round table/panel format - feedback gathered from pre-conference survey to all delegates. Includes: EBF FB on surrogate matrix, co-med stability, matrix effects and others
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. P013 - ICH M10 session LBA pitches - final 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 - feedback gathered from pre-conference survey to all delegates.
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 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 Arfvidsson
14:00	14:20	Katja Zeiser, on behalf of the 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	Rebecca Sleigh, 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 (not released for sharing) 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	Q&A - Panel discussion P038 - Kyra Cowan, ADA 1-tier Panel Discussion - final
16:20	18:20	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' bedside"
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 Matviykv, 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 (not released for sharing) Tackling the preanalytical instability of dihydropyrimidine dehydrogenase phenotyping via dried blood microsampling
18:00	18:20	Cristine Steen-Louws, Genmab (not released for sharing) 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
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 (not released for sharing) 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 Creed, Resolian 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 (not presented) 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 **Dominic Warrino, 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 the EBF
P057 - Anna Laurén - Intro to the Flow Cytometry workshop - final
- 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
P058 - Intro to the AI workshop - Final
- 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 was held in EBF and will 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**
Context of Use Considerations and Technical Challenges in Long-Term Biomarker Assessment in Clinical Trials
- 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 (not released for sharing)**
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 Njumbé 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 the EBF
P072 - Michaela Golob, Intro to the Biosimilars workshop - Final
- 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 the EBF
P073 - Tsvetelina Ivanova, Intro to the GCP workshop - Final
- 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
P083 - Matthew Barfield - Intro to the IVDR workshop - Final
- 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 **Tomislav Caval, Regeneron (BRSA winner in 2024) (not released for sharing)**
 Unraveling O-glycosylation patterns with O-glycoproteases and mass spectrometry
- 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

P090 - Kyra Cowan, Intro to the ADA 1-tier workshop - Final

- 15:10 16:10 Kelvin Workshop 3: ICH M12...assay 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
P091 - Steve White, Intro to the ICH M12 workshop - Final
Feedback was gathered from pre-conference survey to all delegates.
More details on the workshop dynamics and goals will be shared during the conference or session introductions
- 16:10 16:40 Coffee break and Poster Discussion/Viewing**
- 16:40 18:20 Session 15: New modalities - Focus on PCR (parallel session)**
Session Chair: Robert Nelson
16:40 17:00 Otilia Cheregi, TATAA Biocenter (not released for sharing)
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 17:50 Panel Discussion - Moderated by Robert Nelson, on behalf of the EBF PCR team, incl. EBF PCR team feedback
P095 - Robert Nelson, EBF PCR Team feedback - final
EBF sub-team leads EBF PCR providing feedback from recent discussions and surveys on Stability, Calibration Curve & QCs, Cross- & Partial Validation, Replicate Analysis & Inhibition Testing, Nucleic Acid Extraction.
17:50 18:20 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 (not released for sharing)
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, Resoliant
Overcoming the Hurdles of a PAD Enzymatic Endpoint Assay: A Demanding Development
17:40 18:00 Wibke Lembke (replacing 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.
- 16:40 18:00 Kelvin Workshop 4: Into the Cloud - Upscaling of the archivist role (parallel session)**
Workshop Moderator: the EBF e-environment team
Hosted by the EBF e-environment team
16:40 17:00 Cecilia Arfvidsson, on behalf of the EBF
Upscaling of the archivist role and the archiving activities when transforming into a paperless and cloud based lab – workshop
17:00 18:00 Continuation of panel/round table discussion
More details on the workshop dynamics and goals will be shared during the conference or session introductions
In the meantime, the EBF team has diligently prepared 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 the conference or session introductions
- 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
P106 - Kyra Cowan, introduction to the ADA Drug Tolerance session - final
- 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 (not released for sharing)**
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 the 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 Hughes
- 10:10 10:30 **Valeria Castagna, Merck KGaA**
Complex troubleshooting of a clinical LBA assay
- 10:30 10:50 **Lucie Diouloufet, Sanofi (not released for sharing)**
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)**
Session Chair: Luca Ferrari
- 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 **Davindra Sanghera, 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) - for details, go to page 19**
- 11:40 12:00 **Fabian Gärtner - on behalf of the EBF-YSS community**
Future of BioA - a YSS perspective
- 12:00 12:50 **Moderated panel discussions, including a few 3-minute pitches**
Prepared questions from the EBF community on ICH M10 chapters 1,2, 5, 6, 7 (ex. 7.1) and 8
Prepared questions from the pre-conf. survey on ICH M10 chapters 1,2, 5, 6, 7 (ex. 7.1) and 8
P120 - Slides discussed @ the GENERAL session
Time allowing - Open questions from the audience
- 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

The conference is organised as a non-profit event by the EBF vzw.