

17th Open Symposium

Taking the Temperature of Bioanalysis

20-22 November 2024 - Barcelona, Spain



Program at a glance

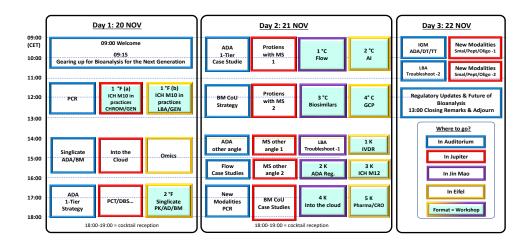
Day 1: 20 November 2024

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	18:00	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	Novembe	er 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: Al
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 M12validation of in vitro 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

Day 0. 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 Eiffel/Sears/Pisa (= left when walking to the Auditorium)

Workshop in Jin Mao/Petronals/Liberty (right when walking to the Auditorium)

Program details (v.06-SEP-2024)

Note: Abstracts can still be submitted for open slots in workshop Fahrenheit 1a/1b (day 1), sessions 9a, 12b and 18a.

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
09:15	10:30	Session 1: Turning up the Heat for the Next Generation (Plenary) 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
		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)
11:10	11:20	Robert Nelson, on behalf of the EBF Update on progress of the EBF PCR Team
11:20	11:40	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
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	Tracy Iles, Labcorp
40.00	10.10	Considerations and Challenges of Multiplex PCRs
12:20	12:40	Annick de Vries, Sanquin Diagnostic Services B-cell counts in small volume, remotely sampled capillary blood; a ddPCR approach.
		b cell counts in small volume, remotely sampled capillary blood, a duff of approach.
11:10	12:40	Fahrenheit Workshop 1a: ICH M10 on the radar - CHROM/General (parallel session) Workshop/round table Hosted by the EBF.
		Moderators: Lee Goodwin, Tom Verhaeghe, Neil Adcock and Robert Wheller on behalf of the EBF CHROM community
		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 310CT2024) and we will try to consider it in the session.
		you can send it to open e-b-i.ed (before 310012024) 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/round table Hosted by the EBF.
		Moderators: tbd, on behalf of the EBF IGM Community
		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 witih 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 310CT2024) 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)
17.00	13.40	incl. introduction of Fahrenheit Workshop 2: Singlicate analysis singlicate PK/ADA/BM
		2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2

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
14:40	15:00	Bioanalysis James Beecroft, F. Hoffmann-La Roche The Transition to Singlinate Biomerica: Analysis: Betrapperties and Brosperties Insights
15:00	15:20	The Transition to Singlicate Biomarker Analysis: Retrospective and Prospective Insights Stephanie Vauleon, F. Hoffmann-La Roche ADA analysis in duplicates versus singlicates: retrospective data evaluation and impact of singlicate analysis
15:20	15:40	on validation and toxicity study data 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) Incl. introduction of Celsius Workshop 4
14:00	14:20	Cecilia Arfvidsson, 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
15:00	15:20	Computerized LIMS System Validation in Cloud Deployments with IoT implementations 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)
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
14:40	15:00	Metabolomics enables larger-scale and real-world drug metabolism studies 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 16:20	18:00 16:40	Session 6: ADA 1-Tier strategy (parallel session) 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
17:40	18:00	A review of the bioanalytical strategy for immunogenicity assessment of cotadutide Q&A - Panel discussion
16:20	18:00	Session 7: Patient Centric Trials (PCT) & DBS technology (parallel session)
16:20	16:40	Joleen T White, Bill & Melinda Gates MRI Bioanalytical Strategies for Therapeutic Antibody Clinical Development in Low and Middle Income Countries
		Sofiya Matviykiv, Novartis
16:40	17:00	Operational aspects for implementing home-based digital assessments in people living with Amyotrophic
16:40 17:00	17:00 17:20	

17:20	17:40	Kevin Vandenbroucke, Ghent University Tackling the preanalytical instability of dihydropyrimidine dehydrogenase phenotyping via dried blood microsampling
17:40	18:00	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) 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	19:00	Complementary Cocktail Reception End of day 1

Day 2: 21 November 2024

09:00	10:40	Session 8: ADA 1-Tier - case studies (parallel session)
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, 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
		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)
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, Resolian
		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	Open slot
		if you have a contribution that fits, please contact open@e-b-f.eu
09:00	10:40	Celsius Workshop 1: Flow Cytometry in (regulated) Bioanalysis (parallel session)
		Hosted by the EBFFlow 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.

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: Al

Hosted by the EBF AI-Team

Moderated by a.o. Katja Zeiser, Connor Walker, on behalf of the EBF.

Includes 2 presenrations:

Connor Walker, F.Hoffmann-La Roche

Bioanalysis 2.0: Navigating the Al frontier.

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)
11:20	11:40	Kyra Cowan, on behalf the EBF
11.20	11.40	EBF's continued involvement in CoU for BM - a little bit of the past, connecting with present, but more importantlythe 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
12:20	12:40	Technical challenges encountered in the long-term assessment of biomarkers in clinical programs 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)
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
40.00	40.40	Accelerating the discovery of Fc-based biotherapeutics: simultaneous LC-MS bioanalysis of PK and PD invivo markers in preclinical samples
12:20	12:40	Frank Schalk, ICON
40.40	40.00	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)
		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)
		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)
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)
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
0	50	Connecting BioA with speciation to characterise the kinetics of Darinaparsin, a novel arsenical compound
14:30	14:50	
14.30	14.50	Robert Plumb, Waters

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

13:50	14:50	Session 13: Troubleshooting LBA -1: reagents/Matrices
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)
		Hosted by the EBF IVDR-Team Moderated by Matthew Barfield, on behalf of the 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.
14:50	15:10	small logistic break
15:10	16:10	Session 14: Flow Cytometry in (regulated) Bioanalysis - case studies (parallel session)
15:10	15:30	Teona Roschupkina, Resolian
45.00	45.50	Stabilizing Flow: Overcoming Logistics Challenge by "Split Processing"
15:30	15:50	Hanna Widmaier, Nuvisan
15:50	16:10	How precise is precise enough? Lessons learned from ex-vivo neutrophil activation assay Henko Tadema, ICON
10.00	10.10	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)
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	Open Slot
		If you have a contribution that fits, please contact open @e-b-f.eu
15:10	16:10	Kelvin Workshop 2: ADA - challenging the current testing paradigm (parallel session)
		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 M12validation of <i>in vitro</i> assays (parallel session) 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
46.75	40.55	
16:40	18:00	Session 15: New modalities - Focus on PCR (parallel session)
16:40	17:00	Otilia Cheregi, TATAA Biocenter 2-Tailed PCR for small RNA analysis in biodistribution and shedding
17:00	17:20	2-Tailed PCR for small RNA analysis in blodistribution and snedding Eric Lachacz, AstraZeneca
	20	Cell Therapy Clinical Bioanalysis: approaches, complexities, and challenges through the lens of CAR-T
47.00	47.40	global clinical studies
17:20	17:40	Presenter identified Avaiting approval of abstract
17:40	18:00	Awaiting approval of abstract Panel discussion
17.40	10.00	i and viscussion

16:40	18:20	Session 16: BM in practice (parallel session)
16:40	17:00	Jelena Popov-Čeleketić, Genmab
17:00	17:20	Development and Qualification of Free and Total Soluble Target Assays Tailored to Context of Use Alireza Maarouf, Sanofi
17:20	17:40	Ultrasensitive platforms for IL-13 measurement: Cross-platform comparison for IL-13 quantification Daniel Creed, Resolian
17:40	18:00	Overcoming the Hurdles of a PAD Enzymatic Endpoint Assay: A Demanding Development Florian Bernet, Celerion
18:00	18:20	Singlicate Biomarker Assay: enhancing assay performance by surrogate matrix optimization 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) Hosted by the EBF e-environment team
		Moderated by Cecilia Arfvidsson, on behalf of EBF, incl. Presentation: Upscaling of the archivist role and the archiving activities when transforming into a paperless and cloud based lab – workshop
		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) 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)
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	
	00.10	Gregor Jordan, Roche Diagnostics Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric
00.40		Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target
09:40	10:00	Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric
09:40 09:00		Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel
	10:00	Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel session) Luca Ferrari, on behalf of EBF
09:00	10:00 10:00	Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel session) Luca Ferrari, on behalf of EBF Update from Project #16: Peptides, Oligos, New Modalities Alexandra Bushby, Labcorp
09:00 09:00	10:00 10:00 09:20	Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel session) Luca Ferrari, on behalf of EBF Update from Project #16: Peptides, Oligos, New Modalities Alexandra Bushby, Labcorp Hybridization LC-MS for Bioanalysis of Oligonucleotides, including case studies Aihua Liu, Resolian
09:00 09:00 09:20	10:00 10:00 09:20 09:40	Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel session) Luca Ferrari, on behalf of EBF Update from Project #16: Peptides, Oligos, New Modalities Alexandra Bushby, Labcorp Hybridization LC-MS for Bioanalysis of Oligonucleotides, including case studies
09:00 09:00 09:20	10:00 10:00 09:20 09:40	Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel session) Luca Ferrari, on behalf of EBF Update from Project #16: Peptides, Oligos, New Modalities Alexandra Bushby, Labcorp Hybridization LC-MS for Bioanalysis of Oligonucleotides, including case studies Aihua Liu, Resolian The Challenges and Solutions in Developing Ultra-Sensitive Bioanalytical Assays for Oligonucleotide
09:00 09:00 09:20 09:40	10:00 10:00 09:20 09:40 10:00	Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel session) Luca Ferrari, on behalf of EBF Update from Project #16: Peptides, Oligos, New Modalities Alexandra Bushby, Labcorp Hybridization LC-MS for Bioanalysis of Oligonucleotides, including case studies Aihua Liu, Resolian The Challenges and Solutions in Developing Ultra-Sensitive Bioanalytical Assays for Oligonucleotide Therapeutics Using a Hybridization LCMS Platform
09:00 09:00 09:20 09:40	10:00 10:00 09:20 09:40 10:00	Immunogenicity assessment for antiviral medications: generic mitigation of the impact of the multimeric target Leroy Schreuder, ICON Improving drug tolerance of non-cell based neutralizing antibody assays with SPEAD Session 18a: New modalities - Focus on small molecules, peptides and oligos - analytical (parallel session) Luca Ferrari, on behalf of EBF Update from Project #16: Peptides, Oligos, New Modalities Alexandra Bushby, Labcorp Hybridization LC-MS for Bioanalysis of Oligonucleotides, including case studies Aihua Liu, Resolian The Challenges and Solutions in Developing Ultra-Sensitive Bioanalytical Assays for Oligonucleotide Therapeutics Using a Hybridization LCMS Platform Short logisitc break

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	Christopher Tiedje, 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	Open Slot If you have a contribution that fits, please contact open@e-b-f.eu
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. We plan to cover to cover the most relevant discussions with respect to regulatory challenges, challenges and opportunities for BioA
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 Arfvidsson, AstraZeneca; Mike Wright, GSK; Michaela Golob, Nuvisan; Matthew Barfield, F. Hoffmann- La Roche, Nico van de Merbel, ICON and Philip Timmerman, EBF

Meeting email: open@e-b-f.eu

<u>Sponsor Relations & related Logistics</u>: Christina Smith, Bavalan Bioconference SARL – email: <u>sponsors@e-b-f.eu</u>

<u>Meeting administration:</u> Veerle Philippaerts - email: <u>admin@e-b-f.eu</u>

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 and conference sponsors.