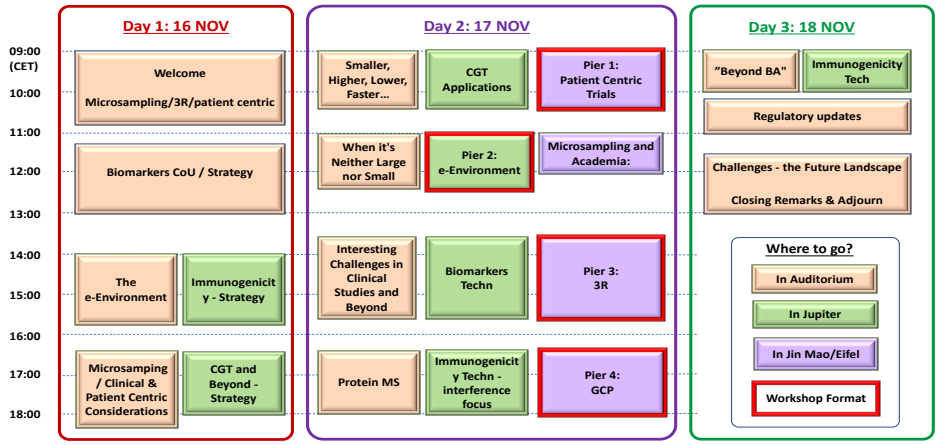
15th EBF Open Symposium

The Bioanalytical Compass

Navigating to our True North

16-18 November 2022 - Barcelona (Spain)

Program @ a glance



Day 1 - Wednesday 16 NOV 2022

09:00 09:20 Welcome (Plenary)
09:20 10:40 Starting Big on Small (Plenary) - incl. Introduction to Pier 1-4 Workshops
11:20 13:00 Biomarkers CoU - Strategy
14:00 15:40 The e-Environment *parallel with* **Immunogenicity - Strategy**
16:20 18:00 Microsamping / Clinical & Patient Centric Consideration (ends 18:20) *parallel with* **CGT and Beyond - Strategy**

Day 2 - Thursday 17 NOV 2022

09:00 10:20 Smaller, Lower, Higher, Faster, More, Less….Just Better *parallel with* **CGT - Applications**
11:00 12:20 Microsampling and Academia: Where New Ideas are Born *parallel with* **When it's Neither Large nor Small**
14:00 16:00 Interesting Challenges in Clinical Studies and Beyond *parallel with* **Biomarkers Tech**
16:40 18:00 Protein MS *parallel with* **Immunogenicity Technology - interference focus**

Parallel Workshops in the Harbour
09:00 10:20 Pier 1: Challenges in Patient Centric Trials
11:00 12:40 Pier 2: e-Environment Workshop
14:00 16:00 Pier 3: 3R Workshop
16:40 18:00 Pier 4: GCP Workshop

Day 3 - Friday 18 NOV 2022

09:00 10:00 "Beyond BA" *parallel with* **Immunogenicity Tech**
10:10 11:00 Regulatory updates (Plenary)
11:00 13:00 Challenges for the Future Landscape (Plenary)

Details of the sessions

Day 1 - Wednesday 16 NOV 2022

09:00 09:20 Welcome

09:20 10:00 Starting Big on Small (Plenary) - Auditorium
Session chair: Steve White, GSK
09:20 09:40 ***Kevin Bateman, MSD (Merck & Co., Inc.)***
Patient Centric Sampling and Multi-Omics for Biomarkers in Clinical Development
09:40 10:00 ***Liselotte Björsson, AstraZeneca***

Microsampling and Singlicate Analysis for Large Molecules delivering Scientific, Ethical and Cost Benefits

10:00 10:20 ***Neil Spooner, Patient Centric Sampling Interest Group and University of Hertfordshire***
An Overview of Patient Centric Sampling – Overcoming the Hurdles to Implementation

10:20 10:40 **We meet at the Pier? - Auditorium**
Short 5-min introduction to the 4 workshops on day 2 by the moderators (all on behalf of the EBF) to introduce the plans and anticipated deliverables
Pier 1: Challenges in Patient Centric Trials - Matthew Barfield
Pier 2: e-Environment Workshop - Cecilia Arfvidsson
Pier 3: 3R Workshop - Amanda Wilson (in collaboration with NCR3s)
Pier 4: GCP Workshop - Tsvetelina Ivanova

10:40 11:20 Coffee break

11:20 13:00 Biomarkers CoU - Strategy (Plenary) - Auditorium
Session chair: Michaela Golob, Nuvisan

11:20 11:40 ***Nico van de Merbel, ICON plc & U. Groningen***
Inspiration from another world; validation of LC-MS/MS assays for protein biomarkers in clinical chemistry

11:40 12:00 ***Carmen Fernandez-Metzler, on behalf of the AAPS***
Does ISR apply for Biomarker Assays?

12:00 12:20 ***Kyra Gelderman, Sanquin Diagnostic Services***
Complement biomarkers; challenges and solutions around complement measurements.

12:20 12:40 ***Kyra Cowan, on behalf of the EBF***
Past current and future of EBF discussions, challenges and recommendations on Biomarker/CoU

12:40 13:00 ***Panel Discussion***

13:00 14:00 Lunch break

14:00 15:40 The e-Environment (Parallel) - Auditorium
Session chair: Cecilia Arfvidsson, AstraZeneca

14:00 14:20 ***Cecilia Arfvidsson, on behalf of the EBF***
Past, current and future of EBF discussions, challenges and recommendations on secure data transfer

14:20 14:40 ***Norbert Bittner, up to data***
Applying Software as a Service (SaaS) to Enhance Productivity and Compliance in the End-to-End Workflows of Bioanalytical Labs

14:40 15:00 ***Federico Pastori, Labware***
A complete Method e-Validation process for all molecules

15:00 15:40 ***Burkhard Schäfer, on behalf of the data transfer vendor consortium***
The product pathway; a vendor-neutral secure data transfer process between LIMS/ELN and LC-MS/MS instruments for bioanalysis.
Followed by Panel Discussion on Vendor Neutral Data Transfers - Challenges & Opportunities

14:00 15:40 Immunogenicity - Strategy (Parallel) - Jupiter
Session chair: Robert Nelson, Labcorp Drug Development

14:00 14:20 ***Robert Nelson, on behalf of the EBF***
Past, current and future of EBF discussions and recommendations on Immunogenicity

14:20 14:40 ***Amanda Hays, on behalf od the AAPS Nab team***
Neutralizing Anti-drug Antibody Validation Testing and Reporting Harmonization: Status Update from AAPS

14:40 15:00 ***Dorte Kornerup Ditlevsen, H. Lundbeck A/S***
A new structured approach to working cross-functionally with immunogenicity

15:00 15:20 ***Jo Goodman, on behalf of the EBF***
Past, current and future of EBF discussions and recommendations on Cut Points

15:20 15:40 ***Panel Discussion***

15:40 16:20 Coffee break

16:20 18:20 Microsamping / Clinical & Patient Centric Considerations (Parallel) - Auditorium
Session chair: Matthew Barfield, F. Hoffmann La Roche

16:20 16:40 ***Ryan Lutz, MSD (Merck & Co., Inc.)***
Evaluation of a Novel Microsampling Device - Tasso-M20 in Support of Clinical PK Studies

16:40 17:00 ***Sofiya Matviykiv, Novartis*** ***(Not released for publication)***
Evaluation of a Tasso blood microsampling device for clinical trial sample collection and biomarker analysis

17:00 17:20 ***Heike Wiese, Nuvisan***
Comparability of PK data obtained from plasma and whole blood collected with VAMS devices

17:20 17:40 ***Hans Stieltjes, Janssen R&D***
Practical and Logistical Challenges for Bioanalysis with Dried Patient Centric Sampling devices
17:40 18:00 ***Maurice Steenhuis, Sanquin Diagnostic services***
Towards the use of fingerprick blood sampling for therapeutic drug monitoring
18:00 18:20 ***Richard Hughes, Drug Development Solutions – Part of Alliance Pharma***
Micro-managing: exploring the potential to use microsampling technology for quantitation of large molecules

16:20 18:00 CGT and Beyond - Strategy (Parallel) - Jupiter
Session chair: Anna Laurén, Novo Nordisk
16:20 16:40 ***Johannes Stanta, on behalf of the EBF CGT team***
Past, current and future of EBF discussions, challenges related to CGT
16:40 17:00 ***Amanda Hays, on behalf of the AAPS qPCR team***
qPCR in Regulated Bioanalysis- current discussions in the industry
17:00 17:20 ***Teona Roschupkina, Drug Development Solutions – Part of Alliance Pharma***
Gate that cell: Requirement for analysing Flow Cytometry Data reflection on H62 document
17:20 17:40 ***Anna Laurén, on behalf of the EBF***
Applying context of use to qPCR method validation and analysis - a progress update.
17:40 18:00 ***Panel Discussion***

Day 2 - Thursday 17 NOV 2022

09:00 10:00 Smaller, Lower, Higher, Faster, More, Less….Just Better (Parallel) - Auditorium
Session chair: Tsvetelina Ivanova, Comac Medical
09:00 09:20 ***Egidijus Machtejevas, Merck KGaA***
Analysis of Biomacromolecules by LC-MS Utilizing Novel, Narrow-bore, Wide Pore Monolithic and Superficially Porous Stationary Phases
09:20 09:40 ***Cathy Lane, Sciex***
Achieve sensitive quantification of complex peptides with disulfide bridging in rat plasma using a high-end triple quadrupole mass spectrometer
09:40 10:00 ***George Walters, Drug Development Solutions – Part of Alliance Pharma***
Exploring the Benefits and Challenges of Universal Automated Methods.

09:00 10:20 CGT - Applications (Parallel) - Jupiter
Session chair: Anna Laurén, Novo Nordisk
09:00 09:20 ***Michael Schwenkert, SVAR***
Development of an iLite® Reporter Cell Platform for the Quantification of Anti-AAV Neutralizing Antibodies.
09:20 09:40 ***Lydia Michaut, Tataa***
Beyond genetic medicine quantification in plasma: validating PCR assays for biodistribution and pharmacodynamic biomarkers
09:40 10:00 ***Zhe Liu, Labcorp Drug Development***
Detection of Antibodies to AAVs using Gyrolab
10:00 10:20 ***Axel Meyer, Abbvie***
From quantitative to digital: Validation of a droplet digital (dd)PCR assay

09:00 10:20 Pier 1: Workshop on Challenges in Patient Centric Trials (Parallel) - Eiffel/Jin Mao
Workshop moderator: Matthew Barfield
Short presentations and discussions to discuss the 'non-lab' related issues, i.e. focus on logistic challenges and opportunities for patient centric sampling/trials

10:20 11:00 Coffee break

11:00 12:20 Microsampling and Academia: Where New Ideas are Born (Parallel). - Eiffel/Jin Mao
Session chair: Steve White, GSK
11:00 11:20 ***Dries Vloemans, KU Leuven***
Novel self-powered microfluidic platform for advanced remote microsampling applications
11:20 11:40 ***Michele Protti, Unibo***
Exploring the cannabinoid space with second-generation blood microsampling
11:40 12:00 ***Laura Boffel, Ghent Universitiy***
In-depth evaluation of automated non-contact reflectance-based hematocrit prediction of dried blood spots
12:00 12:20 ***Open Forum: Microsampling in acadamia supporting technology development and new applications***

11:00 12:20 When it's Neither Large nor Small (Parallel) - Auditorium
Session chair: Anna Laurén, Novo Nordisk
11:00 11:20 ***Mohammed Abrar, BioApp Solutions Limited*** ***(Not released for publication)***
Bioanalysis of Inbetweeners- (Challenges & Solutions)

11:20 11:40 ***Frida Löthberg, Gyros***
Strategies for measuring oligonucleotides using a fully automated micro-fluidic immunoassay system

11:40 12:00 ***Michael Blackburn, Quotient Sciences***
Changing to a Physicochemical Format from Hybrid for a Large Peptide Assay: Pros and Cons

12:00 12:20 ***John Perkins, KCAS Bioanalytical & Biomarker Services***
Addressing the Impact of Structure on Bioanalysis of Polypeptides & Oligonucleotides

11:00 12:20 Pier 2: e-Environment Workshop (Parallel) - Jupiter
Workshop moderator: Cecilia Arfvidsson
Hosted by the EBF e-environment team. During the workshop, the discussion will focus on solutions for secure data transfer for the LBA toolbox and cloud based approaches for the (regulated) BA lab.

12:20 13:30 Lunch break

13:30 15:30 Interesting challenges in clinical studies and beyond (Parallel) - Auditorium
Session chair: Robert Nelson, Labcorp Drug Development

13:30 13:50 ***Roland Staack, Roche Diagnostics*** ***(Not released for publication)***
Evaluation of free drug/target concentrations by bioanalyis or M&S – do we apply double standards?

13:50 14:10 ***John Chappell, Gyros***
Development of an assay to measure free IgE as a solution for PK/PD assessment of Omalizumab

14:10 14:30 ***Gareth Whitaker, Quotient Sciences***
Interim PK analysis and decision making in Translational Pharmaceutics programs

14:30 14:50 ***Aparna Kasinath, Syngene International***
A simple complex: GLP/GCLP PK, PD and Immunogenicity analysis for GCP clinical studies

14:50 15:10 ***Floris Loeff, Sanquin Diagnostic Services***
TDM of biologics reassures clinicians in personalised dosing

15:10 15:30 ***Bioanalysis Zone BRSA Winner 2022: Shelby Barnett, Newcastle University (Newcastle, UK)***
Development of a national therapeutic drug monitoring programme in childhood cancer in the UK

13:30 15:30 Biomarkers technical (Parallel) - Jupiter
Session chair: Kyra Cowan, Merck KGaA

13:30 13:50 ***Ulrich Kunz, Boehringer Ingelheim***
Equilibrium (MSD) versus kinetic (Gyrolab) immunoassay in the quantification of a free soluble target – it makes a difference.

13:50 14:10 ***Katja Zeiser, Nuvisan***
Diving deeper into data: investigation of a CV% issue during a biomarker study using Gyrolab

14:10 14:30 ***Elena Vicentini, Aptuit (Verona) Srl, an Evotec Company***
High-sensitivity immunoassays for biomarkers of Huntington's disease

14:30 14:50 ***Yetrib Hathout, Binghamton University***
Blood accessible biomarkers for Duchenne muscular dystrophy.

14:50 15:10 ***Wikke Berg-Koopmans, ICON plc***
Challenges and opportunities for determining the dynamics of an unstable cell-membrane marker on a rare cell population by flow cytometry.

15:10 15:30 ***Peter Blattmann, Idorsia Pharmaceuticals***
Biologically active CXCL12α plasma concentrations increase after multiple-dose treatment with an ACKR3 antagonist in humans

13:30 15:30 Pier 3: 3R Workshop (Parallel) - Eiffel/Jin Mao
Workshop moderator: Amanda Wilson
The discussions will focus on identifying opportunities and solutions to minimise usage of experimental animals for in vivo tox/PK studies and how the BA community can reduce usage of blank (rodent) matrices after ICH M10 implementation.

15:30 16:20 Coffee Break

16:20 18:00 Protein MS (Parallel) - Auditorium
Session chair: Matthew Barfield, F. Hoffmann La Roche

16:20 16:40 ***Matthew Barfield, on behalf of the EBF***
Past, current and future of EBF discussions, challenges and recommendations on Protein MS

16:40 17:00 ***Szabolcs Szarka, Drug Development solutions***
Design of Experiment – a Powerful Tool to Optimise Sample Preparation in Bottom-up Targeted Protein LC-MS Workflows

17:00 17:20 ***Ilse De Salve, Merck KGaA***
Combined affinity capture LC-MS/MS method, for total antibody and conjugated payload quantitation from in-vivo and in-vitro ADC samples.

17:20 17:40 ***Lieve Dillen, Janssen R&D*** ***(Not released for publication)***
Calibration of clinical ELISAs to evaluate immune response by quantitative MS

17:40 18:00 ***Ana Villar Garea, Sanofi*** ***(Not released for publication)***
Comparison of ligand-binding assays and hybrid LC-MS (intact protein) bioanalytical strategies for small therapeutic proteins

16:20 18:00 Immunogenicity Technology - Interference Focus (Parallel) - Jupiter
Session chair: Jo Goodman, AstraZeneca

16:20 16:40 ***Nick White, AstraZeneca***
An Old Dog with New Tricks? Resurrection, Reoptimisation and Refinement to Render Drug and Target Interference Redundant

16:40 17:00 ***Presentation cancelled by author***
cancelled

17:00 17:20 ***Laura Geary, Drug Development Solutions – Part of Alliance Pharma***
Pushing the Limits of Immunogenicity Assay Drug Tolerance

17:20 17:40 ***Karien Bloem, Sanquin Diagnostic Services***
Anti-drug antibody testing of therapeutic monoclonal antibodies, have we gone too far?

17:40 18:00 ***Panel Discussion***

16:20 18:00 Pier 4: GCP Workshop (Parallel) - Eiffel/Jin Mao
Workshop moderator: Tsvetelina Ivanova
Hosted by the EBF GCP team. During the workshop, we plan to focus on the learnings and Outcome of the GCP Focus Workshop (15-16 September 2022, Malaga) and design/refine recommendations on how to implement GCP requirements into the BA workflows.

09:00 10:00 "Beyond BA" (Parallel) - Auditorium
Session chair: Tsvetelina Ivanova, Comac Medical

09:00 09:20 ***Claire Szuster, Drug Development Solutions – Part of Alliance Pharma***
Plasma Protein Binding: On RED alert!

09:20 09:40 ***Humaira Naseer, AstraZeneca*** ***(Not released for publication)***
Overcoming the bioanalytical complexities of nucleotide based biotherapeutics and antibody drug conjugates in tissues derived from non-clinical PK/PD, biodistribution and safety studies

09:40 10:00 ***Gregor Jordan, Roche Diagnostics*** ***(Not released for publication)***
How can the BA expert assist in improving data interpretation and contribute holistically to project support?

09:00 10:00 Immunogenicity Tech (Parallel) - Jupiter
Session chair: Jo Goodman, AstraZeneca

09:00 09:20 ***Sara Ongay, HEXAL AG (Sandoz a Novartis division)*** ***(Not released for publication)***
Insights into some of the method capabilities and bottlenecks of hybrid LBA-LC-MS/MS for ADA analysis: a case study for a monoclonal antibody (IgG1)

09:20 09:40 ***Phillip Bartlett, Crescendo Biologics*** ***(Not released for publication)***
Detection of Anti-Ig light chains as an immunogenicity assay strategy for novel therapeutic proteins.

09:40 10:00 ***Elisa Bertotti, Merck KGaA***
Pre-Existing Anti-Drug Antibody evaluation: a standard workflow to support drug candidates selection

10:00 10:10 Logistic Break

10:10 11:00 Regulatory updates (Plenary) - Auditorium

10:10 11:00 *During the session, we will give an update on recent/upcoming regulatory requirements or challenges for the BA community. The session will build on a pre-meeting survey and ad hoc Q&A.*

11:00 11:30 Coffee Break

11:30 13:00 Challenges for the Future Landscape (Plenary) - Auditorium
Session chair: Kyra Cowan, Merck KGaA

11:30 11:50 ***Foka Venema, Ardena***
The impact of COVID-19 on BA: accelerating assay development without compromising quality

11:50 12:10 ***Radoiane Helbaj, F. Hoffmann La Roche***
Biosample Operation Specialist and Bioanalytical manager combined role

12:10 12:30 ***Mari Enoksson, NovoNordisk***
Challenges and Opportunities for future BA scientists

12:30 12:45 ***Matthew Barfield, on behalf of the EBF***
View on the changing world and future challenges for the bioanalytical community

12:45 13:00 ***Philip Timmerman, EBF***
The YSS fueling our future

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),Tsvetelina Ivanova (Comac-Medical), Anna Laurén (NovoNordisk), Robert Nelson (Labcorp), Steve White (GSK) and Philip Timmerman (EBF)*