



Meeting Agenda v08SEP2022



15th EBF Open Symposium

The Bioanalytical Compass - Navigating to our True North

16-18 November 2022 - Barcelona (Spain)

Meeting updates, travel and registration: <https://bcn.e-b-f.eu>

Sponsors: <https://bcn.e-b-f.eu/sponsors/>

Program @ a glance

	16 NOV	17 NOV	18 NOV
09:00 (CET)	Welcome	CGT Applications	Smaller, Higher, Lower, Faster... Pier 1: Challenges in Patient Centric Trials
10:00	Microsampling/patient centric	When It's Neither Large nor Small	Microsampling and Academia: Pier 2: WS on e-Environment
11:00	Biomarkers CoU / Strategy	Interesting Challenges in Clinical Studies and Beyond	Biomarkers Techn Pier 3: WS on 3R
12:00		Immunogenicity Tech - interference focus	Protein MS Pier 4: GCP Workshop
13:00 End			
14:00	Immunogenicity - Strategy	The e-Environment	
15:00	CGT and Beyond - Strategy	Microsampling / Clinical & Patient Centric Considerations	
16:00			
17:00			
18:00			

Day 1 - Wednesday 16 NOV 2022

- 09:15 09:30 Welcome (Plenary)
- 09:30 10:40 Starting Big on Small (Plenary)
- 11:20 13:00 Biomarkers CoU - Strategy
- 14:00 15:40 Immunogenicity - Strategy in parallel with The e-Environment
- 16:20 18:00 CGT and Beyond - Strategy in parallel with Microsampling / Clinical & Patient Centric Considerations

Day 2 - Thursday 17 NOV 2022

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

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" in parallel with Immunogenicity Tech
- 10:10 11:00 Regulatory updates (Plenary)
- 11:00 12:50 Challenges for the Future Landscape (Plenary)

Covid restrictions allowing, there will be complementary cocktail receptions in the evening of Day 1 and Day 2 from 18:00 to 19:00

Meeting organisation: Cecilia Arvidsson (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 (GlaxoSmithKline) and Philip Timmerman (EBF)

Details of the sessions

Day 1 - Wednesday 16 NOV 2022

09:15 09:30 Welcome

09:30 10:40 Starting Big on Small (Plenary)

09:30 09:40 **EBF - Introduction to the Session**

EBF next plans on Small

09:40 10:00 **Kevin Bateman, MSD (Merck & Co., Inc.)**

Patient Centric Sampling and Multi-Omics for Biomarkers in Clinical Development

10:00 10:20 **Helen Prior, NC3Rs**

Current use, 3Rs benefits and barriers for microsampling

10:20 10:40 **Liselotte Björsson, AstraZeneca**

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

10:40 11:20 Coffee break

11:20 13:00 Biomarkers CoU - Strategy (Plenary)

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 **Amanda Hays, 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 Immunogenicity - Strategy (Parallel)

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 **Janka Ryding, on behalf of 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 **Phillip Bartlett, Crescendo Biologics**

Detection of Anti-Ig light chains as an immunogenicity assay strategy for novel therapeutic proteins.

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

14:00 15:40 The e-Environment (Parallel)

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 **Gideon de Boer or other team member, 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.

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

A complete Method e-Validation process for all molecules

15:00 15:20 **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

15:20 15:40 **Panel Discussion on Vendor Neutral Data Transfers - Challenges & Opportunities**

15:40 16:20 Coffee break

16:20 18:00 CGT and Beyond - Strategy (Parallel)

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 - Alliancepharma**

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**
- 16:20 18:00 Microsampling / Clinical & Patient Centric Considerations (Parallel)**
- 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 Matviykviv, Novartis**
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 in a pediatric study
- 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
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Day 2 - Thursday 17 NOV 2022

- 09:00 10:20 CGT - Applications (Parallel)**
- 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 **Open slot**
to be assigned
- 09:40 10:00 **Zhe Liu, Labcorp Drug Development**
Detection of Antibodies to AAVs using Gyrolab
- 10:00 10:20 **Open slot**
to be assigned
- 09:00 10:20 Smaller, Lower, Higher, Faster, More, Less....Just Better (Parallel)**
- 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 - Alliancepharma**
Exploring the Benefits and Challenges of Universal Automated Methods.
- 10:00 10:20 **Open slot**
to be assigned
- 09:00 10:20 Pier 1: Workshop on Challenges in Patient Centric Trials (Parallel)**
Hosted by the EBF.
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 12:40 When it's Neither Large nor Small (Parallel)**
- 11:00 11:20 **Mohammed Abrar, BioApp Solutions Limited**
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
- 12:20 12:40 **Open slot**
to be assigned
- 11:00 12:40 Microsampling and Academia: Where New Ideas are Born (Parallel)**
- 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 **Daniel Owens, University of Southampton**

- The limit of detection of medications in whole blood using ATR-FTIR spectroscopy*
- 12:00 12:20 **Laura Boffel, Ghent University**
In-depth evaluation of automated non-contact reflectance-based hematocrit prediction of dried blood spots
- 12:20 12:40 **Open slot**
to be assigned
- 11:00 12:40 Pier 2: e-Environment Workshop (Parallel)**
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.
- 12:40 13:40 Lunch break**
- 13:40 15:40 Interesting challenges in clinical studies and beyond (Parallel)**
- 13:40 14:00 **Roland Staack, Roche Diagnostics GmbH**
Evaluation of free drug/target concentrations by bioanalysis or M&S – do we apply double standards?
- 14:00 14:20 **John Chappell, Gyros**
Development of an assay to measure free IgE as a solution for PK/PD assessment of Omalizumab
- 14:20 14:40 **Gareth Whitaker, Quotient Sciences**
Interim PK analysis and decision making in Translational Pharmaceuticals programs
- 14:40 15:00 **Aparna Kasinath, Syngene International Limited**
A simple complex: GLP/GCLP PK, PD and Immunogenicity analysis for GCP clinical studies
- 15:00 15:20 **Floris Loeff, Sanquin Diagnostic Services**
TDM of biologics reassures clinicians in personalised dosing
- 15:20 15:40 **Bioanalysis Zone BRSA Winner 2022**
will be announced soon...
- 13:40 15:40 Biomarkers technical (Parallel)**
- 13:40 14:00 **Ulrich Kunz, Boehringer Ingelheim**
Equilibrium (MSD) versus kinetic (Gyrolab) immunoassay in the quantification of a free soluble target – it makes a difference.
- 14:00 14:20 **Katja Zeiser, Nuvisan**
Diving deeper into data: investigation of a CV% issue during a biomarker study using Gyrolab
- 14:20 14:40 **Elena Vicentini, Aptuit (Verona) Srl, an Evotec Company**
High-sensitivity immunoassays for biomarkers of Huntington's disease
- 14:40 15:00 **Yerrib Hathout, Binghamton University**
Blood accessible biomarkers for Duchenne muscular dystrophy.
- 15:00 15:20 **Lars Elmann Larsen, ICON plc**
Challenges and opportunities for determining the dynamics of an unstable cell-membrane marker on a rare cell population by flow cytometry.
- 15:20 15:40 **Open slot**
to be assigned
- 13:40 15:40 Pier 3: 3R Workshop (Parallel)**
Hosted by the EBF in collaboration with the NC3Rs.
The discussions will focus on identifying opportunities and solutions to minimise usage of experimental animals in relation to in vivo tox/PK studies (we plan to engage with the stakeholders running these studies to identify continued hurdles) and how the BA community can reduce usage of blank (rodent) matrices after ICH M10 implementation.
- 15:40 16:20 Coffee Break**
- 16:20 18:00 Immunogenicity Technology - Interference Focus (Parallel)**
- 16:20 16:40 **Marnix Wieffer, ICON plc**
Insights from the development of a stable and sensitive anti-PEG antibody assay
- 16:40 17:00 **Nick White, AstraZeneca**
An Old Dog with New Tricks? Resurrection, Reoptimisation and Refinement to Render Drug and Target Interference Redundant
- 17:00 17:20 **Pallavi Hajela, Lambda Therapeutic Research**
Ligand Tolerance: new tool for more reliable immunogenicity data
- 17:20 17:40 **Laura Geary, Drug Development Solutions - Alliancepharma**
Pushing the Limits of Immunogenicity Assay Drug Tolerance
- 17:40 18:00 **Open slot or Panel Discussion**
to be assigned
- 16:20 18:00 Protein MS (Parallel)**
- 16:20 16:40 **EBF presenter, tbc**
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**
Calibration of clinical ELISAs to evaluate immune response by quantitative MS
- 17:40 18:00 **Ana Villar Garea, Sanofi**
Comparison of ligand-binding assays and hybrid LC-MS (intact protein) bioanalytical strategies for small therapeutic proteins
- 16:20 18:00 Pier 4: GCP Workshop (Parallel)**
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.

Day 3 - Friday 18 NOV 2022

- 09:00 10:00 "Beyond BA" (Parallel)**
- 09:00 09:20 **Claire Szuster, Drug Development Solutions - Alliance pharma**
Plasma Protein Binding: On RED alert!
- 09:20 09:40 **Humaira Naseer, AstraZeneca**
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 GmbH**
How can the BA expert assist in improving data interpretation and contribute holistically to project support?
- 09:00 10:00 Immunogenicity Tech (Parallel)**
- 09:00 09:20 **Sara Ongay, HEXAL AG (Sandoz a Novartis division)**
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 **Sarah Geen, Anapharm Bioanalytics**
Challenges in the Development and Validation of a Method for the Detection of Anti-PEGylated-aptamer Antibodies
- 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)**
- 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 10:30 Coffee Break**
- 11:00 12:50 Challenges for the Future Landscape (Plenary)**
- 11:00 11:50 **Foka Venema, Ardena**
The impact of COVID-19 on bioanalysis: 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 12:20 **Philip Timmerman, EBF**
Can YSS help fuel for our future?
- 12:20 12:35 **Presenter tbc, NovoNordisk**
On: "Challenges and Opportunities for future BA scientists", presentation title tbc
- 12:35 12:50 **Matthew Barfield, on behalf of the EBF**
View on the changing world and future challenges for the bioanalytical community
- 12:50 13:00 Closing Remarks & Adjourn**

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