14th EBF Open Symposium
Science - Our Universal Language
Program

Day 1 – Wednesday 24 NOV 2021

10:00	**10:20**	**Welcome**
10:20	**12.10**	**Session 1: Biomarkers – Organisational design driving CoU (Plenary)**
10:20	10:30	*Philip Timmerman, on behalf of the EBF* BM and CoU – where are we today and where are we going?
10:30	10:50	*Kyra Cowan, on behalf of the EBF* Organisational design driving/preventing CoU – a challenge or an opportunity – a stakeholder perspective – a Pharma/Sponsor perspective
10:50	11:10	*Michaela Golob, on behalf of the EBF* Organisational design driving/preventing CoU – a challenge or an opportunity – a stakeholder perspective – a CRO/vendor perspective
11:10	11:30	*Peter Groenen, Idorsia* Organisational design driving/preventing CoU – a challenge or an opportunity – a stakeholder perspective
11:30	11:50	*Anna Laurén, Novo Nordisk* Updating the organisational process and responsibility split for translational work with biomarkers and CoU – a pharma perspective
11:50	**12.10**	**Q&A and Introduction to the workshop (Parallel to Session 5)**
12.10	**13.40**	**Lunch Break**
		Poster viewing – click on link to see poster list **Day 1 Poster session requests authors of pasters 1-20 at their poster**
13.40	**15:20**	**Session 2: NCE/Chromatography (in parallel with session 3)**
13:40	14:00	*Nico van de Merbel, ICON* A tiered approach to method validation for the support of a bioequivalence trial with ibuprofen
14.00	14:20	*Petra Lewits, Merck KGaA* Advances of Monolithic silica columns for the rapid, sensitive, and highly efficient separation of Biomolecules
14:20	14:40	*Cathy Lane, Sciex* Sub ng/mL quantification and characterization of oligonucleotides in plasma using microflow LC coupled to a novel QTOF mass spectrometer
14:40	15:00	*Heike Wiese, Nuvisan* Enzyme activity assays using LC-MS
15:00	15:20	*Delphine Maux, Syneos Health* Non liquid matrix analysis: challenge and approaches
14:00	**15:20**	**Session 3: New Modalities (in parallel with session 2)**
14:00	14:20	*Anna Laurén, on behalf of the EBF*

		Applying Context-of-Use to qPCR Method Validation and Analysis: A Recommendation from EBF
14:20	14:40	*Marianne Scheel Fjording, BioAgilytix* Bioanalytical assay strategies for immunogenicity assessment of new modalities
14:40	15:00	*Niels Nijstad, QPS* The development of a hybridization ECLIA assay for the determination of the payload of a oligonucleotide-antibody conjugate
15:00	15:20	*Johannes Stanta, on behalf of the EBF C&GT team* EBF Feedback on ICH S12
15:00	**16:20**	**Coffee break**
16:00	**18:00**	**Session 4: Workshop – Remote inspections by Health Authorities – experiences and challenges (in parallel with session 5)**
16:00	16:20	*Tsvetelina Ivanova, on behalf of the EBF* Regulatory framework for Remote HA inspection: an overview
16:20	16:40	*Robert Nelson, on behalf of the EBF* Practical considerations and challenges from industry
16:40	17:00	*Iain Love, Charles River Laboratories* 1.5y into remote HA inspections – learning together
17:00	17:20	Martijn Baeten, Sciensano (Belgian Institute for Health) On: Experience and learnings from remote inspections.
17:20	17:50	Workshop discussion – building on a pre-meeting survey to all delegates Preparing for best practices breakout – the Rosetta Stone for remote inspections by health authorities
17:50	18:00	Wrap up – preparing to continue the discussion at the December Workshop
16:20	**18:10**	**Session 5: Workshop – Biomarkers – Organisational design driving CoU (in parallel with session 4)**
16:20	16:40	*Kyra Cowan, on behalf of the EBF* Organisational design driving CoU – feedback from pre-meeting survey
16:40	18:00	Workshop discussion, incl. organisational design Case studies. Company perspectives from: 16:40 – 16:50 Laetitia Sordé, Sobi 16:50 – 17:00 Ulrich Kunz, Boehringer Ingelheim 17:00 – 18:00 Panel discussion
18:00	**18:10**	**Wrap up**

Day 2: 25 November 2021

10:00	**11:40**	**Session 6: Microsampling – recent technological developments – patient centric trials (in parallel with session 7)**
10:00	10:20	*Franck Saint-Marcoux, Limoges University Hospital – for Shimadzu* Measurement of tacrolimus in dried blood spots: a fully automated sample preparation and LCMS method
10:20	10:40	*Bryan van den Broek, Sanquin Diagnostiek* Home sampling as alternative to venepuncture: results, patient experience and implementation
10:40	11:00	*Remco Koster, ICON*

		Analytical evaluation of a device for volumetric absorptive microsampling for whole blood sampling from the upper arm
11:00	11:20	*Liesl Heughebaert, U-Ghent* Hematocrit prediction of DBS: current status and future outlook
11:20	11:40	*Michele Protti, U-Bologna* Advanced blood and tissue microsampling for biomarker investigation of neurodegenerative diseases
10:20	**12:00**	**Session 7: Immunogenicity Technology and Applications (in parallel with session 6)**
10:20	10:40	*Annelies Turksma, Sanquin Diagnostiek* Robust multi parameter immunomonitoring; Polyfunctional T cell analysis by FluoroSpot
10:40	11:00	*Samuel Pine, Ablynx, a Sanofi company* Accessible, adaptable and automated: having it all with an immunogenicity cut-point calculator
11:00	11:20	*Laura Geary, LGC* The importance of characterising critical reagents with a focus on bio-conjugated reagents
11:20	11:40	*Sam Willcox, Labcorp Drug Development* Development of an anti-PEG antibody assay for assessing immunogenicity of PEGylated proteins and lipid nanoparticles
11:40	12:00	*Issa Jyamubandi, LGC* Challenges of developing an ADA assay for Bispecific antibody therapeutic and further ADA characterisation
11:40	**13:40**	**Lunch break**
		Poster viewing – click on link to see poster list **Day 2 Poster session requests authors of pasters 21-40 at their poster**
13:40	**15:20**	**Session 8: Biomarker – Technology and Applications (in parallel with session 9)**
13:40	14:00	*Petia Doytcheva, Celerion* A fully automated method for CD34+ cells enumeration by flow cytometry in stabilized whole blood
14:00	14:20	*David Bettoun, Larimar Therapeutics* Development of NanoString Gene Expression Assays for Studying Frataxin-sensitive Gene Markers in Clinical Samples
14:20	14:40	*Kyra Gelderman, Sanquin Diagnostiek* Biomarker assays: a take on optimization and validation in a regulated bioanalysis lab
14:40	15:00	*Thomas Antoine, Ablynx, a Sanofi company* Trust but verify: optimization of a multiplex cytokine kit to monitor preclinical CRS
15:00	15:20	*Michael Blackburn, Quotient Sciences* Direct LC-ICP-MS / ICP-MS assay for measurement of Non-ceruloplasmin bound copper in Wilsons Disease (a biomarker) with confirmatory High Res MS proteomics

14:00	**15:40**	**Session 9: LBA/CBA – Technical Challenges (in parallel with session 8)**
14:00	14:20	*Martin Schaefer, F. Hoffmann – La Roche* One plate ahead of the unspecific binding: An innovative approach to solve obinutuzumab interference in a glofitamab-specific PK-Assay
14:20	14:40	*Sarah-Jane Kellmann, Bio-Rad Laboratories* Faster Generation of Anti-Drug Antibodies using SpyTag Technology
14:40	15:00	*Richard Hughes, LGC* Pushing the limits of PK analysis: can we meet BMV PK criteria with high sensitivity LBAs
15:00	15:20	*John Chappell, Gyros Protein Technologies* Advances in ADA, PK, and biomarker immunoassays to meet demands for assay speed and performance
15:20	15:40	*Birgitte Stoevring, SVAR Life Science* Functional potency assay feasibility of therapeutics and new modality drug candidate targeting the complement cascade.
15:20	**16:20**	**Coffee break**
16:20	**18:00**	**Session 10: Immunogenicity Strategies (in parallel with sessions 11 and 12)**
16:20	16:40	*Michaela Golob, on behalf of the EBF* Immunogenicity Strategies: cross-industry, cross-functional approaches to understand immunogenicity potential from discovery through launch
16:40	17:00	*Annelies Coddens, Argenx* Immunogenicity strategies across programs: risk-based approaches and challenges
17:00	17:20	*Yvonne Katterle, Bayer* How immunogenicity risk assessment can translate into an immunogenicity testing strategy
17:20	18:00	panel discussion
16:40	**18:20**	**Session 11: Protein MS – Applications and EBF update (in parallel with sessions 10 and 12)**
16:40	17:00	*Dominic Foley, Waters* Analysis of SARS-CoV-2 using LC-MS Peptide Enrichment for Clinical Research
17:00	17:20	*Alessandro Greco, Evotec (Aptuit, an Evotec company)* Quantification of two mAbs using both ELISA and LC-MS/MS generic methods. Comparison of in-vivo sample results
17:20	17:40	*Richard Lucey, LGC* Missed cleavages in bottom-up protein LC-MS workflows: 'Breaking Bad'-ly cleaved surrogate peptides
17:40	18:00	*Matthew Barfield, on behalf of the EBF* Status update from EBF Protein MS team
18:00	18:20	*Zhuo Chen – GllaxoSmithKline – 2021 2021 BRSA winner* The Versatility of Q-TOF HRMS in Bioanalysis: From Small Peptides Quantitation to Protein Complexes Characterization
16:20	**18:10**	**Session 12: Data (in parallel with sessions 10 and 11)**
16:20	16:40	*Gidion de Boer, on behalf of the vendor-neutral secure data transfer team*

		Solution towards a vendor-neutral and secure transfer of data between LIMS and Instruments
16:40	17:00	*Norbert Bittner, up to data* Time to bring it all together: From data transfer to processing to full reporting under ICH M10 based on the EBF Data Integrity Initiative (LCMS)
17:00	17:20	*Oriol Peris, Charles River Laboratories* Impact of the data variability due to different patterns of bioanalytical bias – Pharmacokinetic assessment through simulation
17:20	17:40	*Luca Ferrari, on behalf of the EBF* EBF feedback to industry and FDA on FDA Bioanalytical Method Template
17:40	18:10	Panel Discussion on FDA Bioanalytical Method Template

Day 3: 26 November 2021

08:00	**10:00**	**Breakfast buffet in Conference Area**
09:40	**11:00**	**Session 13: the patient (in parallel with session 14)**
09:40	10:00	*Julian Freen-van Heeren, Sanquin Diagnostiek* Investigating antibody effector mechanisms: how to monitor (unwanted) effects of your therapeutic antibodies
10:00	10:20	*Katja Heinig, F. Hoffmann – La Roche* Overcoming bioanalytical challenges during the preclinical and clinical development of risdiplam (Evrysdi®) for the treatment of spinal muscular atrophy in children and adults
10:20	10:40	*Floris Loeff, Sanquin Diagnostiek* TDM of biologics reassures clinicians in personalised dosing
10:40	11:00	*Coral Munday, LGC* Cryoactivation, CRESS, and the Importance of Preanalytics
10:00	**11:20**	**Session 14: NAb – Strategies and applications (in parallel with session 13)**
10:00	10:20	*Maija Pfenniger, Celerion* How to deal with the challenges of NAb assays: case studies evaluated
10:20	10:40	*Johannes Stanta, Freeline therapeutics* Novel approaches for a neutralising anti-capsid assay to detect pre-existing antibodies
10:40	11:00	*Robert Nelson, on behalf of the EBF NAb team* Feedback from EBF discussion on NAb strategies (Note: the presentation includes an introduction in the feedback from AAPS, which will be provided in more detail by AAPS NAb leaders in the 01-03 December NAb session)
11:00	11:20	Q&A and sharing experience on NAb strategies by the audience
11:00	**12:00**	**Coffee break**
12:00	12:10	Feedback from Workshop Session 4: Remote HA inspections (Plenary)
12:10	12:20	Feedback from Workshop Session 5: Biomarkers – Organisational design driving CoU (Plenary)

12:20	**14:15**	**Session 15: The future of BA – our ethical responsibility to the community (Plenary)**
12:20	12:40	*Connor Walker, on behalf of the EBF-YSS community* Sustainable Bioanalysis: Where are we now, where are we going?
12:40	13:00	*Coral Munday, on behalf of the EBF-YSS community* How Covid-19 impacted our day to day work – learnings for the future
13:00	14:00	*All-delegates interactive brain storm and panel discussion on future challenges for the Bioanalytical community* *Moderator: Philip Timmerman, EBF* Panel: SMEs from 14th OS organising committee Themes at least include – New modalities, old modalities – Avoiding unnecessary experimental animal usage – Is every patient/volunteer sample needed? Learnings from Covid-19 Additional themes may be identified with input from a pre-meeting survey to EBF members and meeting delegates
14:00	**14:15**	**Closing remarks – Adjourn**