

## **Day 1 – Wednesday 20 NOV 2019**

**08:45 09:00 Welcome**

### **09:00 10:40 Plenary session Day 1-01 (Implement): Ready for Launch**

- 09:00 09:20 Philip Timmerman, EBF  
*Imagine: from Apollo 8 to bioanalysis today*
- 09:20 09:40 Nils Boehm, Abbvie  
*Automation in a regulated bioanalytical lab – experience from a five-year journey from a manual to a 100% automated workflow*
- 09:40 10:00 Arundhuti Sen, GlaxoSmithKline  
*Automated workflows for ligand-binding assays: strategies for streamlined method development and rapid sample processing*
- 10:00 10:20 Michael Wright, LGC  
*Automation in a CRO environment: the challenge to invest, implement and integrate*
- 10:20 10:40 Michael Gröschl, Celerion  
*Implementation of laboratory automation in a CRO environment – from basic steps to advanced solutions*

### **10:40 11:30 Coffee break – General Poster Session**

### **11:30 12:50 Plenary session Day 1-02 (Influence): New (draft) Regulations – (potential) Areas of Biggest Impact**

- 11:30 11:50 Tom Verhaeghe, on behalf of EBF  
*ICH M10 cross validation & documentation: what now?*
- 11:50 12:10 Steve White, on behalf of EBF  
*ICH – other areas of biggest impact*
- 12:10 12:30 Rob Nelson, on behalf of EBF  
*Did the FDA BMV change our view of biomarker validations?*
- 12:30 12:50 Jason Wakelin-Smith, MHRA  
*MHRA Feedback on Regulated Bioanalysis*

### **12:50 14:00 Lunch break**

### **14:00 15:50 Plenary session Day 1-03 (Innovate): Patient Centric Sampling**

- 14:00 14:20 Kevin Bateman, MSD  
*From Innovation to Implementation: Overcoming Challenges in Patient Centric Sampling in Clinical Trials*
- 14:20 14:40 Lieve Dillen, Janssen R&D  
*The journey of microsampling in preclinical and clinical development*
- 14:40 15:00 Remco Koster, PRA Health Sciences  
*Volumetric absorptive microsampling in a hospital setting: are we there yet?*
- 15:00 15:20 Michele Protti, University of Bologna  
*Microsampling for the therapeutic drug monitoring of eating disorder patients under antidepressant treatment*
- 15:20 15:40 Neil Spooner, on behalf of AAPS  
*An Update from the Community on Microsampling and Patient Centric Sampling – Turning Imagination into Reality*

### **14:00 15:00 (NEW): EBF Satellite session Day 1-04 Aquila (Inspire): CRO – Pharma Collaboration**

- 14:00 14:20 Debbie McManus, LGC  
*Challenges in standardizations and collaborations for CROs: understanding the lifecycles of evolving immunogenicity assays*

14:20	14:40	Maria Heijer, AstraZeneca <i>Continued Strides to “Get it Right”—Further Tales of True Collaboration in Bioanalysis in the Covance Laboratory Partnership</i>
14:40	15:00	Emmanuel Desmartin, Eurofins Amatsi Analytics <i>A CRO perspective of the Pharma-CRO relationship</i>
<b>15:40</b>	<b>16:40</b>	<b>Coffee break – Poster Focus 1</b>
<b>16:40</b>	<b>18:00</b>	<b>(NEW) Launch Pad sessions:</b> Capitalising on the theme of the conference, we have included 3 strategic parallel discussion sessions. In each of the sessions, we start with a keynote speaker. From there we will engage the audience around some key questions on the challenges our industry faces today.
		<b>Session 1 – Innovate: Enhancing scientific collaborations in industry – the journey has only just begun</b> In this session we will focus on innovation as a result of interaction/collaborations between Pharma/CRO and academia/vendors Introduction: Matthew Barfield, on behalf of the EBF Keynote presenter: John Smeraglia, UCB Biopharma
		<b>Session 2 – Imagine: Value of doing things differently</b> In this session we will on the risk/value of doing things differently, with focus on risk-based approaches applicable to Bioanalysis Introduction: Magnus Knutsson, on behalf of the EBF Keynote presenter: Anja Gilis, Janssen R&D
		<b>Session 3 – Inspire: Biomarker assay validation – are we ready for launch?</b> In this session, we will continue the discussion from the recent Autumn Focus Workshop on managing Biomarker Assay Validation Introduction: Kyra Cowan, on behalf of the EBF Keynote presenters: Lars Karlsson, Ferring and John Allinson, Immunologixlabs
<b>18:00</b>	<b>19:00</b>	<b>Complementary Cocktail Reception</b>

## Day 2 – Thursday 21 NOV 2019

<b>08:30</b>	<b>10:10</b>	<b>Breakout session Day 2-01 Auditorium (Implement): e-Environment</b>
08:30	08:50	Cecilia Arfvidsson, on behalf of EBF <i>EBF and the e-environment: The Journey Continues</i>
08:50	09:10	Jason Wakelin-Smith (MHRA) <i>The onward journey of your data</i>
09:10	09:30	Scott Davis, PPD <i>Data Integrity On Large Networks</i>
09:30	09:50	Willie van de Kerkhof, PRA Health Sciences <i>PRA’s Approach to Data Integrity – Scoring, Risks, Assessment and Implementation</i>
09:50	10:10	Carina Ekström, Ferring Pharmaceuticals <i>How to ensure long-term readability of your electronic data/records when you decommission your LC-MS system?</i>
<b>08:30</b>	<b>10:10</b>	<b>Breakout session Day 2-01 Jupiter (Innovate): Critical Reagents</b>
08:30	08:50	Susanne Pihl, on behalf of EBF <i>EBF Feedback on ADA critical reagents</i>

08:50	09:10	Matt Horsham, LGC <i>Positive Thinking: The Use of “Brain Power” in Positive Control Selection for ADA</i>
09:10	09:30	Chris Jones, AstraZeneca <i>Use of the Affinity Module on the Gyrolab Platform to Inform and Assess Critical Reagent Selection during Method Development and Beyond.</i>
09:30	09:50	Matt Johnson, Avacta Life Sciences <i>Improved PK and Drug Monitoring Tools with the Affimer® Platform</i>
09:50	10:10	Olivier Heudi, Novartis <i>Will plastic antibodies revolutionize the bioanalysis?</i>
<b>10:10</b>	<b>11:00</b>	<b>Coffee break – Poster Focus 2</b>
<b>11:00</b>	<b>12:40</b>	<b>Breakout session Day 2-02 Auditorium (Innovate): Taking Tech to the Moon and Back</b>
11:00	11:20	Jan Hellemans, Biogazelle (on behalf of Bio-Rad) <i>The potential of ddPCR for clinical research</i>
11:20	11:40	Gregor Jordan, Roche Diagnostics GmbH <i>Bioanalytical characterization of formed high molecular weight protein complexes to successfully support a clinical trial</i>
11:40	12:00	Philippe Ancian, Charles River Laboratories <i>Challenges in qPCR assay development and validation for biodistribution and shedding evaluation of Gene and Cell Therapies</i>
12:00	12:20	Patrick Brennecke, Celerion <i>Tracing Biomarkers with the top edge technologies Luminex, MSD and SIMOA</i>
12:20	12:40	Martine Broekema, PRA Health Sciences <i>Efficient set-up of a cell-based neutralizing antibody assay using a flow cytometry-based Receptor Occupancy assay format</i>
<b>11:00</b>	<b>12:40</b>	<b>Breakout session Day 2-02 Jupiter (Innovate/Inspire): Planet Immunogenicity</b>
11:00	11:20	Louise Jørgensen, Novo Nordisk <i>Anti-drug antibody analysis in non-clinical samples – a simplified strategy offering sufficient support for interpretation of toxicology studies</i>
11:20	11:40	Laure Querel, Covance Huntingdon <i>No Cut-point, no cry- Validating pre-clinical ADA assays without generating a statistical cut-point.</i>
11:40	12:00	Riejanne Bax-Seigers, PRA Health Sciences <i>A solution to overcome interference in a method to measure anti-drug antibodies</i>
12:00	12:20	Darshana Jani, Pfizer <i>Strategies for Clinical assessment of immunogenicity for Emerging Modalities including Multidomain Therapeutics, Oligonucleotides and Gene Therapy</i>
12:20	12:40	Anna Laurén, on behalf of EBF <i>Current and future considerations for Neutralising antibody assays</i>
<b>11:00</b>	<b>12:00</b>	<b>(NEW): EBF Satellite session Day 2-02 Aquila (Innovate): Microsampling Applications</b>
11:00	11:20	Elizabeth Osborne, LGC <i>Challenges with extensive sample pre-treatment in a microsampling study</i>
11:20	11:40	Annick de Vries, Sanquin Diagnostic Services <i>Support PK and ADA of biologics using finger prick sampling; a comparison of multiple devices which are on the market to sample capillary blood or serum</i>
11:40	12:00	Jeff Plomley, Altasciences

*The Application of Impact-Assisted Extraction to Overcome Hematocrit Recovery Bias and Age-Related Extractability in Mitra® Volumetric Absorptive Microsampling: Towards a Universal Sample Preparation Approach*

**12:40 14:00 Lunch break**

**14:00 15:30** Again, we will host 5 parallel workshops. In each of these short workshops, the workshop moderators will prepare a discussion around themes relevant to our industry today. More details on the questions asked and anticipated deliverable for each of these workshops will be shared as we move closer to the meeting.

**WS 1: Practical application of FDA & EMA ADA Guidelines**

Moderators = Joanne Goodman (AstraZeneca) and Michaela Golob (Nuvisan)

Includes contribution from Joao Pedras-Vasconcelos (FDA-CDER) and Meenu Wadha (NIBSC)

Workshop includes following presentations:

– **Sebastien Boridy, Charles River Laboratories**

How low is too low: assessing cut points in anti-drug antibody assay validation based on recommendations in the Final FDA guidance

– **Floris Loeff, Sanquin Research**

Multi-tiered versus semi-quantitative single-tiered immunogenicity testing in real-life datasets

**WS 2: Microsampling: New Devices and Novel Challenges**

Moderators = Matthew Barfield (GlaxoSmithKline)/Kevin Bateman (MSD)

**WS 3: e- Environment WS on Data Integrity – Building Common Understanding for Future System Solutions**

Moderators = Cecilia Arfvidsson (AstraZeneca)/Magnus Knutsson (Ferring Pharmaceuticals)

**WS 4: Supporting Cell & Gene Therapies in the Bioanalytical Laboratory**

Moderators = Johannes Stanta (Covance) / Paula Miranda (UniQure)

**WS 5: qPCR in regulated bioanalysis**

Moderators = Chris Cox (PsiOxus)/Milena Blaga (Charles River Laboratories)/Robert Nelson (Novimmune)

**15:30 16:20 Coffee break break – Poster Focus 3**

**16:20 18:20 Breakout session Day 2-03 Auditorium (Influence/Inspire): Immunogenicity Strategies**

16:20 16:40 Heather Myler, on behalf of the AAPS  
*ADA Validation Testing and Reporting Harmonization Recommendations*

16:40 17:00 Joao Pedras-Vasconcelos, FDA-CDER  
The Harmonized ADA Assay Validation Template – an “Immunerdy’s “ Perspective from FDA’s Side of the Dance Floor

17:00 17:20 Anna Laurén, on behalf of EBF  
*Preclinical Immunogenicity Assessment – When to include and what to include?*

17:20 17:40 Omnia Ismaiel, PPD  
*Is ADA by LBA/LC–MS/MS Realistic for Routine Analysis? – “A Practical Rout for a Validated LCMS Assay“*

17:40 18:20 Panel Discussion

**16:20 18:20 Breakout session Day 2-03 Jupiter (Innovate/Implement): Other Tools to Reach the Moon**

- 16:20 16:40 David Rowe, University of Southampton  
*Optimising antimicrobial dosing with mid-infrared spectroscopy: a proof of concept study*
- 16:40 17:00 Michael Blackburn, ARCINOVA  
*New hybrid immuno-affinity mass spectrometric method for dosed or endogenous human insulin in clinical samples*
- 17:00 17:20 Moon Jung, Waters  
*A Systematic Approach for Improving the Recovery of Hydrophobic Peptides during LC-MS Analyses*
- 17:20 17:40 Steve Murphy, Agilent  
*Highly Selective Phosphopeptide Enrichment Workflow*
- 17:40 18:00 BSRA Rising star award winner – announced in Barcelona  
*Rising Star Award*
- 18:00 18:20 Esther van Duijn, TNO  
*AMS in drug development; The current situation within the regulatory space*

**16:20 17:20 (NEW): EBF Satellite session Day 2-03 Aquila (Inspire): Different Challenges**

- 16:20 16:40 James Howard, LGC  
*Development of a sensitive antibody drug conjugate free-payload methodology and its application within a preclinical micro-sampling study*
- 16:40 17:00 Urs Duthaler, Basel University  
*Pharmacokinetics and drug-drug interactions of ivermectin in yellow fever mosquitoes*
- 17:00 17:20 Lee Boyling, Arcinova on behalf of the Gadolinium Based Contrast Agent Consortium  
*Scientific Validation: A Case Study for Quantification of Gadolinium in Multiple Tissue Types Using One Tissue as the Calibration and QC Matrix*

**18:20 19:00 Complementary Cocktail Reception**

**Day 3 – Friday 22 NOV 2019**

**09:00 10:40 Breakout session Day 3-01 Auditorium (Innovate/Implement): Further Applications of Mass Spectrometry**

- 09:00 09:20 Julien Peltier, GlaxoSmithKline  
*An intact protein LC-MS assay for pharmacokinetic concentration determination of a mAb: validation experiments, sample results, and assay comparisons*
- 09:20 09:40 Jordane Biarc, Charles River-Saint Nazaire  
*Pembrolizumab method validation in human serum: Comparison of Triple quadrupole and High resolution instrument.*
- 09:40 10:00 Mohammed Abrar, BioApp Solutions Ltd  
*The Use of High-Resolution MS for Bioanalysis: – “Are we There Yet”?*
- 10:00 10:20 Michael Buonarati, Intertek Pharmaceutical Services  
*Development and Validation of a LC-MS/MS Hybrid Assay using nSMOL for Bevacizumab Quantification in Human Serum*
- 10:20 10:40 Naomi Teekamp, PRA Health Sciences  
*LC-MS/MS quantification of M254, a hyper-sialylated endogenous IgG biotherapeutic: analytical pitfalls and solutions*

**08:30 10:50 Breakout session Day 3-01 Jupiter (Inspire/Influence): Biosimilars**

- 08:30 08:50 René Anour, AGES  
*An introduction to Biosimilars – Basics and new developments*
- 08:50 09:10 Johann Poetzl, Sandoz

		<i>Learnings and emerging trends in bioanalytical assay development for Biosimilars</i>
09:10	09:30	Todd Lester, BioAgilytix <i>What the New AAPS White Paper Recommends for Development and Validation of ADA Assays in Support of Biosimilar Programs</i>
09:30	09:50	Janka Ryding, SVAR Life Science <i>Design of Biosimilar Bioanalytical Programs – Assay Strategy perspectives</i>
09:50	10:10	Joao Pedras-Vasconceles, FDA-CDER <i>FDA Regulatory Perspectives on Immunogenicity Testing for Biosimilars</i>
10:10	10:30	Essam Kerwash, MHRA <i>Biosimilar Pharmacokinetics Considerations</i>
10:30	10:50	Panel discussion (break starts at 10:50)
<b>10:40</b>	<b>11:30</b>	<b>Coffee break – Poster Focus 4</b>
<b>11:30</b>	<b>13:00</b>	<b>Plenary session Day 3-02 Auditorium (Innovate): Cell &amp; Gene Therapies</b>
11:30	11:50	Paula Miranda, UniQure <i>Bioanalytical strategies to support CGT: a stakeholder perspective</i>
11:50	12:10	Lisa Seavers, Covance Huntingdon <i>Immunogenicity strategies for gene therapies</i>
12:10	12:30	Fabrizia Fusetti, QPS <i>Bioanalytical monitoring of gene therapy trials: methodologies for PK-PD assessment and patient eligibility</i>
12:30	12:50	Johannes R Stanta, on behalf of EBF <i>CGT discussion points from EBF</i>
<b>12:50</b>	<b>13:00</b>	<b>Closing remarks: Safe Landing</b>
	<b>13:00</b>	<b>Adjourn</b>