Agenda 14th EBF Open Symposium (Cyberspace sessions 1-3 DEC 2021)

01 DECEMBER – DAY 1 – CET Morning Sessions

(afternoon sessions are identical to the morning session)

09:30	**09:40**	**Introduction to the Cybermeeting**
09:40	**11:50**	**ADA Strategies**
09:40	09:50	Welcome – Introduction to the session – Michaela Golob, Nuvisan
09:50	10:10	Michaela Golob, on behalf of the EBF Immunogenicity Strategies: cross-industry, cross-functional approaches to understand immunogenicity potential from discovery through launch – incl. FB from 14th OS panel discussion
10:10	10:30	Kyra Cowan, Merck KGaA Immunogenicity Strategies - Cross-functional collaborations
10:30	10:50	Yvonne Katterle, Bayer How immunogenicity risk assessment can translate into an immunogenicity testing strategy
10:50	11:20	Daniel Kramer (Sanofi) - morinng presenter Michael Partridge (Regeneron) - afternoon presenter on: Risk Based Approaches to Immunogenicity - Progress since the March EBF Training Day
11:20	11:50	Panel discussion Panelist: Session presenters
12:30	**14:30**	**Regulatory updates and emerging challenges**
12:30	12:40	Welcome – Introduction to the session – Philip Timmerman, EBF
12:40	13:00	Anna Laurén, on behalf of the EBF qPCR team EBF recommendation on applying CoU principles for qPCR
13:00	13:20	Eric Woolf, representing the AAPS China BA Support Discussion Group Bioanalytical Support for Studies in China
13:20	13:45	Tom Verhaeghe, on behalf of the EBF team EBF feedback to industry and FDA on FDA Bioanalytical Method Template
13:45	14:10	Faye Vazvaei, representing the AAPS Discussion Group AAPS feedback to industry and FDA on FDA Bioanalytical Method Template
14:10	14:30	Q&A – discussion

02 DECEMBER – DAY 2 – CET Morning Sessions

09:15		**Coming Online**
09:30	**11:30**	**Data integrity & E-Data**
09:30	09:40	Welcome – Introduction to the session – Cecilia Arfvidsson, AstraZeneca
09:40	10:00	Tsvetelina Ivanova, on behalf of the EBF

		Updates on Data integrity requirements in (emerging/draft/new) regulatory Guidelines
10:00	10:20	Cecilia Arfvidsson, on behalf of the EBF Status update on EBF e-team progress (Chromatography & LBA tools)
10:20	10:35	Ranbir Mannu, Labcorp Case study 1 – day to day data integrity challenges in the LBA workflow
10:35	10:50	Harm Buddiger, Genmab Case study 2 – day to day data integrity challenges in the LBA workflow
10:50	11:30	Panel discussion – dialogue (based on pre-meeting survey and in-meeting polls) From Challenges in data integrity challenges in the LBA workflow to solutions for end users and instrument vendors
11:30		Wrap up – Adjourn
12:00	**14:20**	**Strategies on nAb – parallel**
12:00	12:10	Welcome – Introduction to the session – Robert Nelson, Labcorp
12:10	12:30	Robert Nelson, on behalf of the EBF NAb team Feedback from EBF discussion on NAb strategies
12:30	12:50	Nicoline Videbæk, NovoNordisk Recent Developments in the PK, PD, ADA Integrated Approach versus in vitro NAb Assay, New Case Studies and Evolving Trends
12:50	13:10	Weifeng Xu, MSD Novel idea to overcome Drug Interference in Immunogenicity Testing with Much Reduced Acid Treatment and Biotin-conjugated Drug Usage
13:10	13:30	Todd Lester/Heather Myler – AAPS FB from AAPS nAb team
13:30	13:50	Joao Pedras-Vasconcelos, FDA-CDER A regulatory perspective
13:50	14:20	Panel discussion Panelist: Session presenters
12:30	**14:30**	**The future of BA – our responsibility to the community – parallel**
12:30	12:40	Welcome – Introduction to the session – Jo Goodman, AstraZeneca
12:40	13:00	Connor Walker, on behalf of the EBF-YSS community Sustainable Bioanalysis: Where are we now, where are we going?
13:00	13:20	Coral Munday, on behalf of the EBF-YSS community How Covid-19 impacted our day to day work – learnings for the future
13:20	14:20	Brain storm and panel discussion on future challenges for the Bioanalytical community Moderator: Philip Timmerman, EBF Panel: SMEs from 14th OS organising committee

		Themes include, New modalities, old modalities, 3R, Is every patient/volunteer sample needed? Learnings from Covid-19
14:20	14:30	Wrap up

03 DECEMBER – DAY 3 – CET Morning Sessions

10:00	**12:00**	**Remote HA audits: Opportunity or threat?**
10:00	10:10	Welcome – Introduction to the session – Philip Timmerman, EBF
10:10	10:30	Tsvetelina Ivanova, on behalf of the EBF Regulatory framework for and challenges for industry with remote HA audits
10:30	10:50	Robert Nelson, on behalf of the EBF Feedback from the EBF on experiences with remote HA inspections
10:50	11:00	Martijn Baeten, Sciensano (Belgian Institute for Health) On: Experience and learnings from remote inspections.
11:00	11:10	Lee Monk, UCB Biopharma 1-2-6: A Tale of 1 Analytical Method, 2 FDA Inspections, 6 years apart
11:10	11:50	Round table discussion discussing outcome of pre-meeting survey to delegates and EBF members Panellist: Session presenters
11:50	12:00	Wrap up
12:30	**14:30**	**The global challenge of Biomarker assay validations**
12:30	12:40	Welcome – Introduction to the session – Kyra Cowan, Merck KGaA
12:40	13:00	Peter Groenen, Idorsia A stakeholder perspective
13:00	13:20	Arvind Kinhikar, AAPS Biomarker and Precision Medicine Community Clinical Biomarker Assay Validation: The Power of Western Blotting……Thinking Outside the Box!
13:20	13:40	Kyra Cowan, on behalf of the EBF Feedback from 14th EBF Open Symposium & Recent EBF discussions
13:40	14:00	Lauren Stevenson, Immunologix/AAPS-OSD Biomarkers Require Reason, not Rules. #BeAScientist
14:00	14:10	Philip Timmerman, EBF CoU: a new Tower of Babel? – introduction to the panel discsuon
14:10	14:30	Panel discussion Panellist: Session presenters
14:30		**Adjourn**