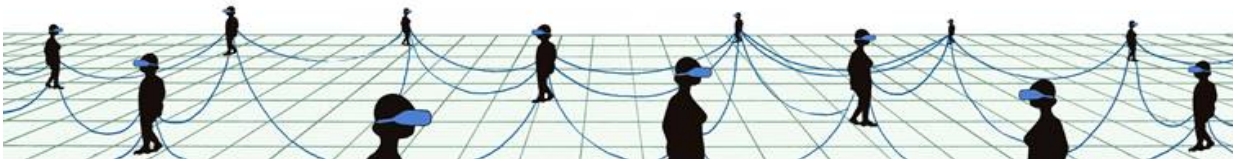
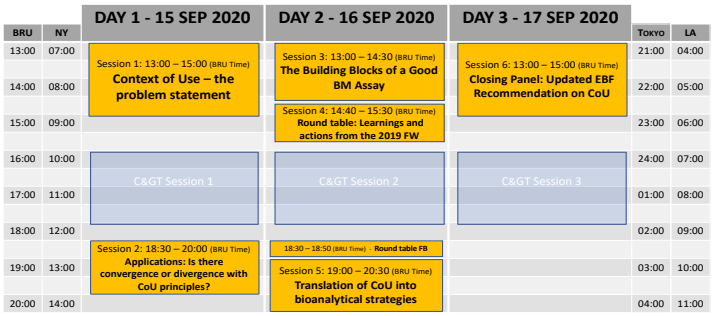


Agenda – EBF Focus Workshop

in collaboration with the *Biomarker and Precision Medicine Community* (AAPS), CBF and JBF

Biomarkers in Pharma R&D

A roadmap from *Context of Use* to *Using the data*



timezone = CET (Brussels time zone)

Day 1 - 15 SEP 2020

13:00 – 13:10 Coming online – Welcome – Meeting dynamics

13:10 – 15:00 Session 1 – Context of Use – the problem statement

13:10 – 13:30 Wrong Data – Wrong Decisions: the CoU Problem Statement
Jo Goodman, AstraZeneca

13:30 – 13:50 Are we informed – have we informed ? The end user's voice
Tova Landström, Ferring Pharmaceuticals

13:50 – 14:10 Be Specific – Putting Biomarker Assay Validation in context
Lauren Stevenson – Immunologix

14:10 – 14:30 Current understanding of COU and its impact – Results from the 2020 AAPS Survey
Yan Ni, Passagebio

14:30 – 14:50 LC-MS/MS Biomarker Assay Validation Considerations from the New Guidance: Discussion of the Upcoming AAPS Whitepaper Recommendations
Carmen Fernandez-Metzler – PharmaCadence

14:50 – 15:00 Q&A

15:00 – 18:30 Break – for C&GT TD delegates, go to session 1 of the C&GT TD (16:00 – 18:00)

18:30 – 20:00 Session 2 – Applications: Is there convergence or divergence with CoU principles?

18:30 – 18:40 Coming online

18:40 – 19:00 Biomarker assay development: Translation from research into clinical trials
Tobias Marquardt, Bayer

19:00 – 19:20 Biomarker Assay Validation and Context of Use: A CRO's Perspective From Discovery through Clinical Drug Development
Sophie Cotton, Charles River Laboratories

19:20 – 19:40 Biomarker assays in a bioanalytical environment – a case study
Dorte Kornerup Ditlevsen – Lundbeck

19:40 – 20:00 The Influence of Context of Use (CoU) on Biomarker Method Development and Validation
Krystal Alligood – BioAgilytix

20:00 End of day 1

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Day 2 - 16 SEP 2020

13:00 – 14:30	**Session 3 – The Building Blocks of a Good BM Assay**
13:00 – 13:10	Introduction to the session *John Allinson/Lauren Stevenson – Immunologix*
13:10 – 13:30	Considerations on matrix sources for biomarker assays *Radboud van Trigt, PRAHS*
13:30 – 13:50	EBF feedback for critical reagents in LBA biomarker assays *Susanne Pihl, on behalf of the EBF*
13:50 – 14:10	Parallelism Acceptance Criteria: Driven by Context of Use *Marc-Olivier Pepin, Charles River Laboratories*
14:10 – 14:30	Navigating through the composite source of BM assay variability *Sofia Stinchi, Merck KGaA*
14:40 – 15:30	**Session 4 – Learnings and actions from the 2019 EBF FW**
14:40 – 14:50	Introduction to the session – Interactive round table *Michaela Golob, on behalf of the EBF*
14:50 – 14:55	Logisitic break Connecting to virtual breakout tables
14:55 – 15:30	Round table: we will engage with the delegates around the key challenges related to understand CoU. * hurdles in connecting outside of BA / inside BA * asking the rigth questions * understanding the questions asked * sense and nonsense of aligning CoU with development stage
15:30 – 18:30	**Break – for C&GT TD delegates, go to session 2 of the C&GT TD (16:00 – 18:00)**
18:30 – 18:50	**Session 4 (cntd) – Feedback from the round tables** Plenary feedback from the round table discussions
19:00 – 20:30	**Session 5 – Translation of CoU into bioanalytical strategies**
19:00 – 19:10	Coming online
19:10 – 19:30	Staging Biomarker Development *Devangi Mehta – Immunologix*
19:30– 19:50	Cytokines as Biomarkers of Immunotoxicity in Preclinical Safety Assessment: Navigating “Context of Use” *Amy Reeves – Covance*
19:50– 20:10	Understanding the Biomarker Strategy of Antisense Oligonucleotide (ASO) Drugs from Non-Clinical and Clinical Studies *Nick White – AstraZeneca*
20:10– 20:30	The chemokine MCP-1/CCL2 is a key biomarker for respiratory diseases and lung tissue harm *Marita Zoma – Celerion*
20:30	End of day 2

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Day 3 - 17 SEP 2020

13:00 – 14:30	**Session 6 – Closing Panel : Updated EBF Recommendation on CoU**
13:00 – 13:10	Introduction to the Closing Panel Discussion:
13:20 – 13:40	Facilitate fast trial/project decisions and confirmation of context of use based on early PK and biomarker data – The VISTA Approach *Thomas Arnhold – Boehringer-Ingelheim*
13:40 – 14:00	EBF recommendation refining CoU requirements for the Biomarker assay community *Philip Timmerman, on behalf of the EBF*
14:00 – 14:20	Practical aspect of CoU – a deeper dive into the EBF recommendation *Kyra Cowan/Jo Goodman, on behalf of the EBF*
14:20 – 14:50	Closing Panel Discussion All
14:50 – 15:00	**Adjourn**
16:00	**For C&GT TD delegates, go to session 3 of the C&GT TD (16:00 – 18:30)**

Meeting Organisation

Focus Workshop: *Ulrich Kunz (Boehringer-Ingelheim), Linda Terry (GlaxoSmithKline), Lars Karlsson (Ferring), Robert Nelson (Covance), Kyra Cowan (Merck KGaA), Joanne Goodman (AstraZeneca), Michaela Golob (Nuvisan) and Philip Timmerman (EBF).*

Training Day*: Johannes Stanta (Covance) and Chris Cox (PisOxus)*

Cybermeeting logistics*: Magnus Knusson (for EBF)*

With collaboration from the AAPS, JBF and CBF