Agenda Outline v.20JUL2019

Wednesday 18-Sep-2019

08:45 09:00 Welcome and aim of the meeting

09:00 10:20 Session 1: Setting the Scene

09:00 09:20 *Philip Timmerman (EBF)*
A recap on the EBF Biomarker Recommendation
09:20 09:50 *Lars Karlsson (Ferring)*
Biomarker work should begin at the end - first why? then how?
09:50 10:20 *Lauren Stevenson (Immunologix Laboratories)*
No context, no assay - demanding Context of Use in a demanding world

10:20 11:00 Coffee break

11:00 12:20 Session 2: Limitations of the current analytical paradigm for Biomarker assays

11:00 11:20 *Kyra Cowan (Merck KgaA)*
Optimizing our Biomarker Interface
11:20 11:40 *Dave Fairman (GlaxoSmithKline)*
The importance of communication between PKPD modellers and bioanalytical scientists
11:40 12:00 *Sari Häkkinen (Orion Pharma)*
How to boost workflows on biomarker analytics between stakeholders in early research projects?

12:00 12:20 Philip Timmerman
Feedback from the survey and introduction into the Workshops

12:20 13:30 Lunch - connect around posters

13:30 15:00 Afternoon Parallel Breakout Sessions

13:30 15:00 Session 3a: Context of Use - Case studies - Focus on communication (Breakout)

13:30 13:50 *Anders Sjödin (SVAR)*
A Custom Approach to an Anti-cN-1A Assay as a Semi-quantitative Disease Activity Marker in Inclusion Body Myositis
13:50 14:10 *Liz Hickford (UCB Biopharma)*
Translating Context of Use into High Quality Fit-for-Purpose Biomarker Assays
14:10 14:30 *Sophie Cotton (Charles River Laboratories)*
Biomarkers assay development: Do you know your context of use?
14:30 14:50 *Stephanie Traub (Cancer Research UK)*
Context of Use - Case studies: What went wrong in context with Biology?
14:50 15:00 *Short break to move from breakout into plenary*

13:30 15:00 Session 3b: Context of Use - Case studies - Focus on the assay (Breakout)

13:30 13:50 *Devangi Mehta (Immunologix labs)*
Do you know what you are measuring? Developing biomarkers that have clinical impact
13:50 14:10 *Tim Townend (GlaxoSmithKline)*
Effective life cycle management of an assay: A case study
14:10 14:30 *Johannes Stanta (Covance)*
LC-MS-MS assay for cholestane-3,5,6-triol and 7-ketocholesterol to support a pivotal clinical trial

14:30 14:50 *Michael Wright (LGC)*
Demonstrating control over multiplexed biomarker methods - can the context of use save the day?
14:50 15:00 *Short break to move from breakout into plenary*

15:00 15:50 Plenary Panel discussion on sessions 3a/b: Context of Use - Learnings from Case studies

15:00 15:20 *Linda Terry (GlaxoSmithKline)*
It's good to talk: How communication gets us closer to the truth, a case study
15:20 15:50 Panel discussion

15:50 16:30 Coffee break - connect around posters

16:30 18:20 Session 4: Starting from a white page…preparation for Day-2 round tables

16:30 16:50 *Hans Ulrichts (UCB Biopharma)*
The changing COU of a biomarker within drug development: a case study
16:50 17:10 *Martin Gerl (Boehringer Ingelheim)*
Case Study: Aldosterone measurement outside the qualified diagnostic context of use in a phase-I trial – challenges to make the grade
17:10 17:30 *Radboud van Trigt (PRA-HS)*
Best practices for quality control and inter-laboratory standardization of biomarker results in the clinical chemistry laboratory
17:30 17:50 *John Allinson (Immunologix labs)*
What can we learn from clinical labs?
17:50 18:20 Panel discussion

Thursday 19-Sep-2019

08:30 09:00 Summary of day 1

09:00 10:20 Morning Parallel Breakout Sessions

09:00 10:20 Session 5a: Bioanalytical lab challenges (Breakout)

09:00 09:20 *Robert Nelson, on behalf of EBF*
EBF TT61 - Considerations on parallelism
09:20 09:40 *Hervé Farine (Idorsia)*
Scientific lab challenges: when reagents and technology matter to measure low abundant protein biomarkers.
09:40 10:00 *Agostinho Gomes Rocha (Syneos Health)*
The challenges in validating a biomarker assay for IKAP quantification in whole blood
10:00 10:20 *Michael Naughton (GlaxoSmithKline)*
Assessment of Parallelism in Biomarker Support: Strategies for application and real-life data interpretation.

09:00 10:20 Session 5b: Bioanalytical lab challenges (Breakout)

09:00 09:20 *Ulrich Kunz (Boehringer Ingelheim)*
How to assess long term stability of endogenous proteins in highly variable assays
09:20 09:40 *Rachel Hewitt (LGC)*
Case study of Coproporphyrins as a DDI marker: The importance of fresh endogenous plasma stability controls whilst keeping eyes on the prize
09:40 10:00 *Pia Davidsson (AstraZeneca)*

Validation of LC-MS/MS assays for Leukotriene B4 in human plasma and Leukotriene E4 in human urine

10:00 10:20 *Florian Neff (F. Hoffmann-La Roche)*
Assay Strategies And Technologies To Analyse - Soluble Targets Of New Antibody Therapeutics

10:20 11:00 Coffee break - connect around posters

11:00 13:00 Session 6: Focus Workshop Round tables
Workshop delegates will be assigned to discuss in a round tables format. Each (group of) tables will be tasked to develop (a part of) a sustainable Context of Use process considering the presentations and the discussions at the meeting.
Round table moderators: Organising Committee, extended with Liz Hickford, Linda Ingeman, Marrianne Scheel Fjording, Sari Häkkinen and Michaela Golob

13:00 14:15 Lunch

14:15 15:30 Summary from round tables - Closing Panel discussion - agree on next steps

15:30 16:30 Connect at Close out Coffee break - Adjourn