EBF – Focus Workshop

Bringing Assay Validation and Analysis of Biomarkers into Practice

9-10 June 2016, Lisbon

The Altis Grand Hotel, Lisbon, Portugal

8-Jun-16

17:00 – 19:00	Registration desk opens

9-Jun-16

07:30	Registration desk opens
08.45 – 09.00	**Welcome and aim of the meeting - Plenary**
09:00 – 10.30	**A developing regulated environment for Biomarker Assay Validation – Plenary**
09:00 – 09:25	Overview and comparison of current approaches to Biomarker assay validations in drug development and diagnostics. *John Allinson, on behalf of the EBF*
09:25 – 09:50	Biomarker Assay Validation – a status update on the EBF Recommendation and discussions in Industry *Marianne Scheel Fjording, on behalf of the EBF*
09:50 – 10:10	Biomarker Assay validation – are we asking the right questions and can we optimize the scientific Pharma/CRO interface *Philip Timmerman, on behalf of the EBF*
10:10 – 10:30	Panel discussion: how to integrate the different expectations into solid regulatory strategy? *Moderators & Panelists: Begoña Barroso, John Smeraglia and Session presenters*
10:30 – 11:00	Coffee break

workshop sessions

Note: each 90 minute (breakout) session will consist of 4 parts:

- *Preparing for the analysis: Integrating project info, PK, PD, aspects of biology/pharmacology , link to healthy volunteers/target population (15 min.)*
- *Analytical challenges – assay criteria – Assay development & validation (15 min.)*
- *How have/will data be(en) used in the project (15 min.)*
- *Panel discussion: what would you have done differently, how and why? (45 min.)*

11:00 – 12:30 **Morning Workshop session - Plenary**

11:00 – 12:30 To spike or not to spike? The value of spiking recombinant proteins for the validation of biomarker methods
Liz Hickford, UCB BioPharma

12:30 – 13:30 Lunch

Presentation - Plenary

13:30 - 14:15 Biomarker driven early phase oncology clinical trials; challenges in the real world
Sidath Katugampola (CRUK Centre for Drug Development)

14:15 - 14:30 logistic break – change rooms to go into breakout

14:30 – 16:00 **Afternoon Workshop session - Breakout**

14:30 – 16:00 4 Beta hydroxycholesterol, an emerging biomarker on hepatic CYP3A4 activity with the potential of predicting Drug-Drug Interactions
Ulf Diczfalusy, Karolinska Institutet - Cecilia Arfvidsson, AstraZeneca and Hamza Kandoussi, BMS

14:30 – 16:00 Development of an early stage Biomarker within discovery: considerations for assay requirements
Adrian Freeman, Envigo

16:00 – 16:30 Tea break

16:30 – 18:00 **Afternoon Workshop session - Plenary**

16:30 – 18:00 Integrating an exploratory BM in an early clinical stage in Pharma R&D
Ulrich Kunz, Boehringer-Ingelheim

10-Jun-16

Morning Workshop - Plenary

09:00 – 10:30 Verification and validation of an efficacy biomarker during early clinical development
Robert Nelson, Novimmune

10:30 – 11:15	Coffee break
	Presentation - Plenary
11:15 – 12:00	Integrating Biomarker data into projects. Overcome Challenge and develop partnership to maximize value. *John Allinson, LGC*
12:00 – 12:30	feedback and summary from the workshop sessions (20 minutes) Introduction to the plenary closing panel discussion (10 minutes)
12:30 – 13:30	Lunch
13:30 – 15:00	**Closing Panel discussion - Plenary** Bringing Assay Validation and Analysis of Biomarkers into Practice – Development of biomarkers strategy/hypothesis, incl. • Interaction within discovery, preclinical and clinical colleagues to understand Mode of Action, PK/PD, and how effect translate into clinical • How understanding biology impacts sampling strategies and the assay validation criteria *Moderators: conference organizers and presenters*
15:00 – 15:30	Tea break
15:30 – 16:00	**Summary, conclusion and next steps**
16:00	**Adjourn**