



EBF Autumn Focus Workshop - 2
Biomarkers/CoU
Sharing Experience through Examples
29-30 September 2022 - NH Malaga, Spain

Final Agenda

Thursday 29-Sep-2022

09:15 09:30 Introduction to the Focus Workshop (FW)

09:30 10:30 Session 1: Updates from the EBF BM team

09:30 10:00 *Kyra Cowan, on behalf of the EBF*

FB from BM team discussions on organisational design driving CoU principles

10:00 10:15 *Peter Groenen, on behalf of the EBF*

Context of Useit depends on who you ask.

10:15 10:30 *Richard Hughes, on behalf of the EBF*

The BM toolbox...did you know there is more in life than LBA & LC/MS?

Sessions 2 - 7: Case studies

11:00 13:00 Session 2: Getting an appetite to discuss case studies 1, 2 and 3

11:00 11:40 *Ulrich Kunz - Boehringer Ingelheim*

Case Study 1: An explorative physiological response pd biomarker - from CoU to measurement using a commercial ELISA kit

11:40 12:20 *Case Study 2: Lien Dejager - UCB Biopharma (not released for publication)*

Importance of cross-functional interactions to define, align and understand CoU

12:20 13:00 *Case Study 3: James Lawrence - F-Star Therapeutics*

Context of Use? It's Just Exploratory!

**14:40 16:20 Session 3: Understand the principles of CoU - do we understand the same?
& Case studies 4, 5 and 6**

14:40 15:00 *Peter Groenen - Idorsia*

Case Study 4: CoU, from Babylonian confusion to patient benefit: how to be accurate and precise.

15:00 15:40 *Philip De Decker (not released for publication)*

Case study 5: CoU as guide for the bioanalytical assay objectives for a phase I dose escalation study

15:40 16:20 *Daniel Thwaites - Labcorp drug development*

Case study 6: An Evolving CoU Culture on Biomarker Assay Validation – Applications from LBA to ELISpot in Supporting Immunotoxicology Safety Assessments

16:20 17:00 Coffee break

17:00 19:00 Session 4: A stakeholders perspective & Case studies 7 and 8

17:00 17:40 *Luise Gram Schleiss - NovoNordisk*

A Translational Medicine stakeholder perspective on cross-functional communication for

17:40 18:20 *James Beecroft - F. Hoffmann La Roche*

Case Study 7: Implementing COU statements for the first time - the importance of stakeholder discussions

- 18:20 19:00 *Anna Laurén - NovoNordisk*
Case Study 8: Cross-functional collaboration to form the assay strategy for Target engagement and potential CDx biomarkers
- 19:00 **Anticipated End of day 1**

Friday 30-Sep-2022

- 09:00 09:05 **Introduction to day 2**
- 09:05 10:40 **Session 5: Different technologies - Different challenges? & Case studies 9 and 10**
- 09:05 09:20 *Philip Timmerman, EBF (not released for publication)*
Themed presentation - BMs amenable to Chromatographic assays: are the challenges different?
- 09:20 10:00 *Mathias Gebauer - Merck KGaA*
Case Study 9: Identification of pathways represented in liquid biopsy samples from osteoarthritis and autoimmune disease patients by microRNA biomarker profiling which could be used for patient stratification in clinical trials
- 10:00 10:40 *Axel Meyer - Abbvie*
Case study 10: Validation of a ddPCR Assay According to its Context-of-Use
- 11:20 13:00 **Session 6: BM and regulatory expectations & Case studies 11 and 12**
- 11:20 11:40 *Anna Laurén, on behalf of the EBF*
Themed presentation: Spotlight on CLIA and recent IVDR – when is it relevant for biomarkers and
- 11:40 12:20 *Laetitia Sordé - Sobi*
Case study 11: IVD, fit for purpose...somewhere in between
- 12:20 13:00 *Ulrich Kunz - Boehringer Ingelheim*
Case Study 12: A total soluble target ELISA - translating CoU into an analytical strategy and a validation plan
- 14:00 15:20 **Session 7: The challenges for CROs on CoU and Case studies 13 and 14**
- 14:00 14:20 *Michaela Golob/Robert Nelson, on behalf of the EBF*
Themed presentation: The challenges for CROs on CoU
- 14:20 14:50 *Richard Hughes - Drug Development Solutions, part of Alliance Pharma Inc*
Case Study 13: Off-the-shelf “validated” biomarker assays – fitting a square peg into a round hole
- 14:50 15:20 *Manuel Daldin - IRBM (not released for publication)*
Case Study 14: Novel and ultrasensitive SMC assay for the measurements of polyglutamine length-independent huntingtin protein, a pharmacodynamic biomarker in human CSF
- 16:00 17:00 **Close out session: Summary session on all case studies**
Learnings, take home messages and conclusions from the presented case studies (3-5 min recap/case study).
Agreeing on recommendations from the FW
- 17:00 **Adjourn**



Meeting Organisation: Kyra Cowan (Merck KGaA), Anna Laurén (NovoNordisk), Joanne Goodman (AstraZeneca), Ulrich Kunz (Boehringer-Ingelheim), Michaela Golob (Nuvisan) and Philip Timmerman (EBF)

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