



EBF Cyberconnect Events:
Focus Workshop: Biomarkers/CoU – Case Studies Dissected
 27-28 April 2021

Day 2: 27 April 2021

12:30	12:45	Coming online
12:45	13:00	Getting started - Welcome Philip Timmerman - EBF
13:00	14:00	Day 1 - Session 1: Setting the stage Session Chair: Philip Timmerman, EBF - Question moderator: Robert Nelson, Covance
13:00	13:15	Philip Timmerman, EBF <i>Is there appetite for CoU? - Feedback from a recent survey on CoU</i>
13:10	13:30	Kyra Cowan, on behalf of the EBF <i>Context of Use, removing the appetite for PK-criteria and practice for BM - the basic revisited</i>
13:30	13:40	Jo Goodman, on behalf of the EBF <i>The current (assumed) regulatory landscape on Biomarker Assays</i>
13:40	14:00	Lauren Stevenson, Immunologix labs <i>The blind leading the clear-sighted – undermining the science of COU</i>
14:00	14:30	Break
14:30	18:00	Day 1 - Session 2: case studies Session Chair: Robert Nelson, Covance - Question moderator: Kyra Cowan, Merck KGaA (part 1)
14:30	14:35	Robert Nelson, on behalf of the EBF <i>Introduction in the case studies sessions</i>
14:35	15:00	Wietske Lambert, PRA-HS <i>Enzymatic activity by LCMS - to assess enzyme inhibition</i>
15:00	15:25	Snezhana Kirmaz - Comac Medical <i>Strategizing and overcoming milestones during a phase II clinical trial for two renal biomarkers by direct scientific team-to-Sponsor line of communication</i>
15:25	15:50	Jean-Christophe Genin, F. Hoffmann-La Roche <i>Case study : The importance of collaboration with stakeholders in order to define the appropriate BA strategy</i>
15:50	16:00	Remaining questions from the session
16:00	16:20	Short Break
		Day 1 - Session 2: case studies, cntd Session Chair: Robert Nelson, Covance - Question moderator: Michaela Golob, Nuvisan (part 2)
16:20	16:45	Sabine Lennarz, Novartis <i>The brave new world of biomarker development in early clinical trials – defining a fit-for-purpose assay validation strategy on an emerging platform</i>
16:45	17:10	Claire Seal, F-Star <i>A case study on successful development and validation of a serum biomarker assay – the important of good communication</i>
17:10	17:35	Léa Costes, Sanquin <i>Biomarker assays and context of use: two stories, one success</i>

17:35	18:00	John Allinson, Immunologix labs <i>Scientific and financial risks when COU is MIA</i>
18:00	18:15	Remaining questions from the session
18:15	19:00	Zoom session remains open to allow 1/1 chat interactions
19:00		Zoom closes

Day 2: 28 April 2021

12:45	13:00	Coming online
13:00	15:30	Day 2 - Session 3: Organisational design influencing CoU practices Session Chair: Ulrich Kunz, Boehringer-Ingelheim - Question moderator: Jo Goodman, AstraZeneca
13:00	13:10	Ulrich Kunz, on behalf of the EBF <i>Introduction to the session</i>
13:10	13:30	Anna Laurén, NovoNordisk <i>Learnings from past projects to form new strategies for Biomarker validation and sample analysis</i>
13:30	13:55	Mark Ma, Alexion <i>Improve reliability and efficiency in biomarker research</i>
13:55	14:00	Logistic break - going into smaller groups
14:00	15:00	Breakout discussions - round tables - 3 themes around optimising organisational design - identifying hurdles and suggestion of optimisation for: 1. <i>The BioA lab (Q1)</i> 2. <i>Stakeholder management (Q2)</i> 3. <i>Management/QA interactions (Q3)</i>
15:00	15:40	Break
15:40	17:30	Day 2 - Session 4: And what about regulations? Session Chair: Kyra Cowan, Merck KGaA - Question moderator: Ulrich Kunz, , Boehringer-Ingelheim
15:40	16:10	Michaela Golob, Robert Nelson, Jo Goodman, on behalf of the EBF <i>Feedback from the breakouts</i>
16:10	17:00	Panel discussion: value and risk of a regulatory guideline for Biomarker Assays <i>Based on Pre-meeting survey question to delegates</i> <i>Including polling on who had issues and wants to share them?</i>
17:00	17:30	Final Q&A, next steps and adjourn
17:30		Adjourn
17:30	18:00	Zoom session remains open to allow 1/1 chat interactions
18:00		Zoom closes



Organising Committee:

Michaela Golob (Nuvisan), Joanne Goodman (AstraZeneca), Robert Nelson (Covance),
Kyra Cowan (Merck KGaA), Ulrich Kunz (Boehringer Ingelheim) and Philip Timmerman (EBF)