EBF

14th EBF Open Symposium

Science – Our Universal Language

Welcome

Introduction to the Session

Kyra Cowan, on behalf of the EBF

3 December 2021, Cyberlona

Biomarker Assay CoU: The Game-Changer for Many

- **Understand what it is**
- **Understand why it is critical**
- **Understand how to implement it, considering the many challenges**
  - Scientific
  - Analytical
  - Strategic: communication, stakeholder management, operational

What is Context-of-Use for BM Assays?

- Detailed definition of the purpose of the assay for each analyte
  - Understood and agreed upon by all stakeholders
  - Documented in method summaries, validation plans, validation reports

- What does it look like?:
  - 2-4 sentences defining biomarker to support assay needs.
- Key thoughts: To understand the biology, pharmacological effect; to understand what the data will be used for, eg. scientific or safety decisions taken, to then consider what is possible from a BA perspective; to understand biological, analytical variability…
- Ultimately: To ensure the appropriate interpretation of data to serve patients.

- What does it not look like?:
  - „To quantify the analyte“

Technology agnostic

Why is Documenting Context-of-Use for BM Assays Important?

- **The purpose of the assay may change from one study to the next**
  - The types of decisions being made based on the results may vary and should be communicated each time.
  - Without an agreed CoU there is a risk of implementing the wrong assay, with inappropriate characterizations and therefore validation.
  - Leads to incorrect data and decisions, negatively impacting patients.

- **Institutional knowledge may change:** new team members, people may leave.

Bottom Line: Bioanalytical scientist takes ownership and accountability to communicate with their stakeholders and provide adequate education.

EBF Recommendations on BM Assay Characterisation

- **CoU must first be defined and agreed upon by all stakeholders:**
  - **EBF recommends** this to fully understand what question(s) the biomarker data will address.

- **The identified questions would then address:**
  - **Type of assay** required (e.g. free or total, in-house assay, commercial kit, single analyte, multiplex, research use, diagnostic)
  - **Format** of the assay and critical reagents
  - **Technology** choice, with pros and cons
  - Access to appropriate **biomarker samples**

Quotes from Stakeholders:

- I believe that we understand and apply this principle to our development and degree of validation efforts, but I don't think the rest of the world is aligned to this.
- Often I feel that people cite CoU without understanding what boundaries are defined.
- There is a misunderstanding from high stakeholders on CoU.
- I guess I know what it is but not sure I fully understand what it involves.

Learnings from 2019, and 2020, and again in 2021:

- Workshops reconfirmed the community struggles to apply CoU.
- Hurdles haven't changed:
  - Difficult to identify or get stakeholder/end-user engaged
  - Fear for 483
  - Fear to leave the PK SOP-comfort zone

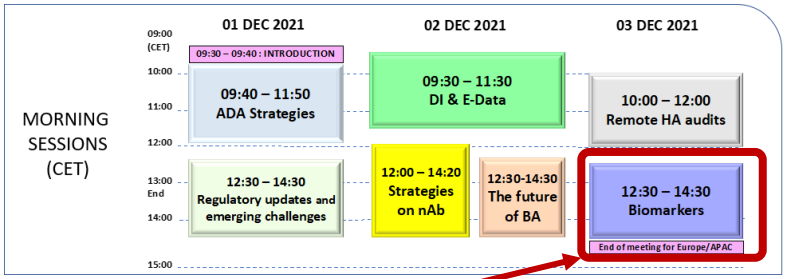
2021 bioanalytical community poll: still struggling…

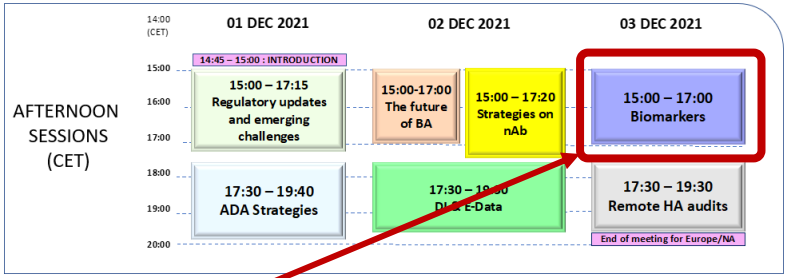
1. **No proper guidance available** to understand what is expected for the various use cases
2. **Convincing stakeholders of applying the COU** process and receiving the correct feedback from stakeholders
3. Sponsors tend to think in terms of **broad categories** (exploratory & primary and secondary end point).
4. The expectation is that an **off the shelf commercial kit or prior validated method will meet** the requirements of the biomarker measurement.

What we can do to change this…

2021 Objectives	Biomarker Strategy Subteam
Project Title:	Biomarker CoU: Implications for the assay
Team Leader:	Kyra Cowan, Merck KGaA
Team *(from organizing committee)*	Jo Goodman, AstraZeneca; Michaela Golob, Nuvisan; Anna Lauren, Novo Nordisk; Philip Timmerman, EBF
Team	Laetitia Sorde, Sobi; Peter Groenen, Idorsia; Ulrich Kunz, Boehringer-Ingelheim; James Lawrence, F-Star; Lien Dejager, UCB; Alessandra Vitaliti, Novartis; Laurent Vermet, Sanofi; Lene Andersen, Orphazyme; Marianne Fjording, Bioagilytix; Mario Richter, Abbvie; Matti Kimberg, Synexa; Mike Wright, GSK; Nicole Justies, Roche; Philip De Decker, argenx; Radboud van Trigt, PRAHS; Renaud Jasnowski, Active-Biomarkers;
Goals *(for this year)*	**First: battle for industry-wide implementation of CoU**

1- 3 December – “CYBERLONA”





<u>03 DECEMBER - DAY 3 - CET Morning Sessions - (repeated from 15:00 to 17:00)</u>

12:30	**14:30**	**The global challenge of Biomarker assay validations**
12:30	12:40	Welcome - Introduction to the session - Kyra Cowan, Merck KGaA
12:40	13:00	Peter Groenen, Idorsia *A stakeholder perspective*
13:00	13:20	Arvind Kinhikar, AAPS Biomarker and Precision Medicine Community *Clinical Biomarker Assay Validation: The Power of Western Blotting……Thinking Outside the Box!*
13:20	13:40	Kyra Cowan, on behalf of the EBF *Feedback from 14th EBF Open Symposium & Recent EBF discussions*
13:40	14:00	Lauren Stevenson, Immunologix/AAPS-OSD *#BeAScientist*
14:00	14:10	Philip Timmerman, EBF *CoU: a new Tower of Babel? - introduction to the panel discsuon*
14:10	14:30	Panel discussion *Panellist: Session presenters*

Contact Information

Questions: info@e-b-f.eu

European Bioanalysis Forum vzw

www.e-b-f.eu