12th EBF Open Symposium
Introduction to Launch Pad 3: Biomarkers

Kyra Cowan, on behalf of the EBF

the Launchpad session

- Introduction (similar to today's intro)
  - EBF and Biomarkers
  - Survey data
  - Round table from Malaga
- Stakeholder view: Lars Karlsson, Ferring
- CoU Expert view: John Allinson, Immunologixlabs
- Question and discussion:
  - Introduction to the question
  - CoU in practice – can it really work for ALL assays?

BM: The challenges we face today

Analytical:

- Progress in technology opens a new world of options for analysis
- New and/or multiple assays platform for 1 BM
- BM-Assays ran by PK-assay experts

Scientific:

- Understanding the PD / Biology…IOW: the context

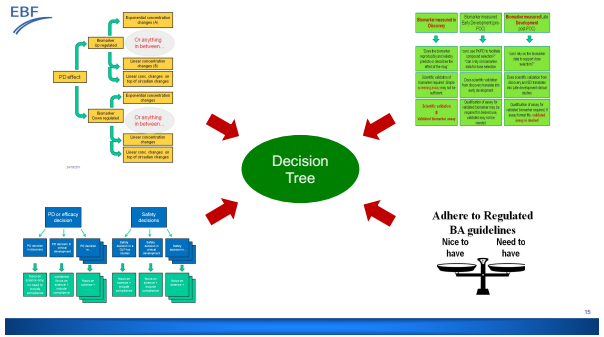
Communication:

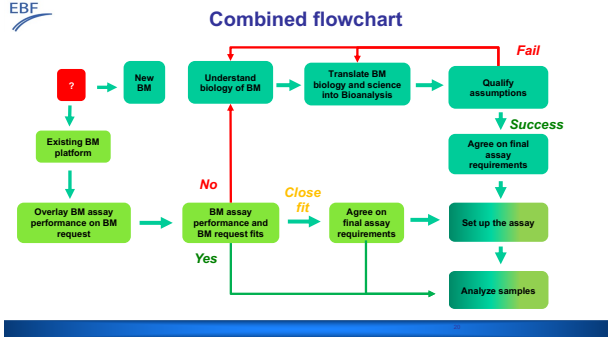
- Who talks, who listens? Who understands and who translates?

Regulatory:

- HA in learning mode too….
- In absence of a better idea, HA are raising the bar by off-track, sometimes irrelevant and unrealistic analytical requirements for the assay

EBF recommendation vs CoU





≅ CoU

communication

Key Messages from Autumn Focus Workshop - 1

From pre-FW the survey to core/delegates

Assays are validated towards “4-6-20 (15 for MS based)” as per PK SOP

- Interpretation of CoU gravitates to applying a version of Tiered Approach (*typically adding 5 or 10 % imprecision, but still in 4-6-XX paradigm*)

CoU ≠ Tiered Approach

Key Messages from Autumn Focus Workshop - 2

From pre-FW the survey to core/delegates

Assays are validated towards “4-6-20 (15 for MS based)” as per PK SOP

- Interpretation of CoU gravitates to applying a version of Tiered Approach (*typically adding 5 or 10 % imprecision, but still in 4-6-XX paradigm*)

From Round table at the meeting

around theme “We are applying the PK-SOP for BM BMV out of ignorance, fear for non-compliance or as a safe haven → see next slide

Autumn Round table questions and output

1. Do we actually want to leave the safe “PK SOP” haven? Why or why not?
   - Yes we want to leave just want to know how
   - We don’t want to as we are not comfortable (one pair of shoes)

   Main blockers/challenges: Fear, Process and harmonization, Outsourcing may not include the BM scientists, Regulatory experience and mindset may not be aligned globally, Not ready to take ownership

2. Who else (or maybe who really) do you need to convince to move away from *current practice* into what we believe is desired practice
   - Project teams: data users, modellers, biomarker groups, clinicians, etc.
   - Health authorities and internal regulatory colleagues, and sponsors (CRO), QA (CRO/Pharma)
   - Line Management
   - Ourselves

3. Where can EBF be of help?
   - Publish recommendation
   - Interact with authorities @ EBF level
   - Provide Training & Continue regular meetings as this one
   - Continue to connect with other cross industry groups

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But for today…. Context of Use

- Does this mean different criteria are required for each BM assay?
  - And how do we manage this?
- Or… can it mean that as a minimum requirement we would expect documented interaction with the end user of the data to understand the CoU of the data and take one of below steps:
  - Use existing ‘PK-SOP’ if this fits CoU enough (and what is enough?)
  - Define other criteria required by CoU (and how do we do this?)

  - 4 tables – 20 minutes (moderators = OC members Spring FW)
  - Each table 5 minutes FB