EBF

14th EBF Open Symposium

Science – Our Universal Language

FB from Workshop session 5

Kyra Cowan, on behalf of the EBF

24-26 November 2021, Barcelona

FB from Workshop

16:20	**18:10**	**Session 5: Workshop – Biomarkers – Organisational design driving CoU (in parallel with session 4)**
16:20	16:40	*Kyra Cowan, on behalf of the EBF* Organisational design driving CoU – feedback from pre-meeting survey
16:40	18:00	Workshop discussion, incl. organisational design Case studies. Company perspectives from: 16:40 – 16:50 Laetitia Sordé, Sobi 16:50 – 17:00 Ulrich Kunz, Boehringer Ingelheim 17:00 – 18:00 Panel discussion
18:00	**18:10**	**Wrap up**

QUESTIONS to the WS participants

Four Questions, 40 minutes:

1. In my company/organisation, we actively apply the principles of CoU for BM assays, with CoU summarised in one sentence as:

Building the BM assay on decision taken by the data, (i) having informed the end user of the data (stakeholder) of what the assay can do, and (ii) being informed by the end user of the data (stakeholder) what the assay should do to allow valid decision to be taken by the data. CoU is not copying PK-assay criteria (i.e. from BMV guideline) as a starting point for the assay performance

a. Yes
b. Partly: please comment of what you apply/don't apply:
c. No
d. I do not sufficiently understand CoU principles
e. I understand CoU differently: please comment

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a. **Yes: 12**
b. **Partly: please comment of what you apply/don't apply: 34**
c. **No: 6**
d. **I do not sufficiently understand CoU principles**
e. **I understand CoU differently: please comment**

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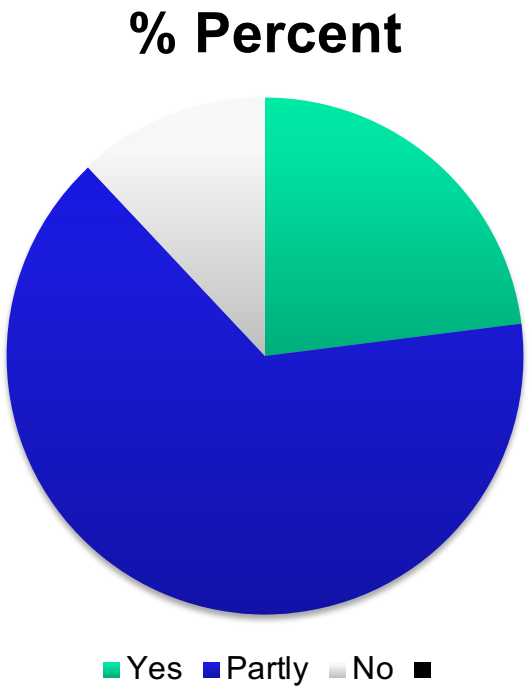

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a. **Yes: 12**
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- Project dependent. More and more people are more educated and understand what is COU. It is not totally completely documented. From CRO point of view, 80% of BM are validated as PK assay as no COU information available.
- For CRO's the stakeholder/client can be a limiting factor in the application of the CoU. CRO's are limited by the clients decision, the CRO can try and convince client to carefully consider the CoU but at the end the decision point is defined by the clients final decision making. This can be difficult especially with exploratory BM.
- Could help to send a questionnaire to client in order to achieve a good perspective on the CoU.
- Stakeholders are not fully aware of the criteria that should be applied.
- Can the CoU always be defined? This can be difficult for very early stage studies.
- Would be helpful for some guidance on developing an appropriate questionnaire.
- Partially, most delegates are still implementing CoU, as it's not always required (depends on the project). It does make sense – getting the right data to answer the question(s) sponsors have and agree on that up front. It also quite depend on sponsor wishes whether interpretation by partners/CROs is required, and the type of agreement/working relation between sponsor and partner/CRO.

QUESTIONS to the WS participants

2. What is the analytical process that your organisation applies for BM assays?
    a. BMV principles as per EMA/FDA Guideline, i.e. we use our PK SOP
    b. Diagnostic principles as for central labs (CLSI/CLIA)
    c. An internal guideline/SOP that defines in detail the validation strategy for Biomarkers, dependent on the analytical technology but independent from the CoU.
    d. I do not follow any guideline or SOP
    e. Other…

QUESTIONS to the WS participants

2. What is the analytical process that your organisation applies for BM assays?

a. **BMV principles as per EMA/FDA Guideline, i.e. we use our PK SOP: 20**
b. **Diagnostic principles as for central labs (CLSI/CLIA): 6**
c. **An internal guideline/SOP that defines in detail the validation strategy for Biomarkers, dependent on the analytical technology but independent from the CoU.: 19**
d. **I do not follow any guideline or SOP: 3**
e. **Other…**

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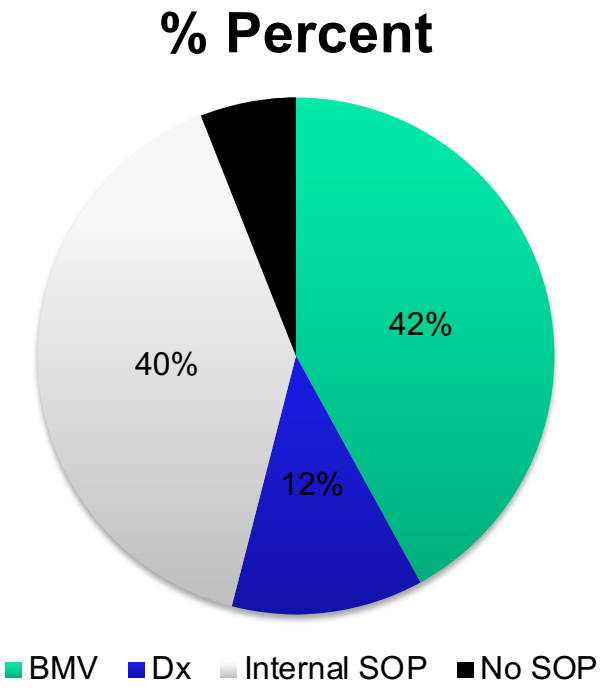

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- a : BMV and go down; BMV by default
- b : since extended activity to US and related to the COU ; if a diagnostic assay exists, will start from it for biomarker analysis
- B/C, in the past BMV was used but have been moving towards CoU.
- Qualification is performed “in the spirit” of the BMV
- It is very difficult to write an SOP for a BM, sometimes there is a process to map out the potential options. Another preference would be to make additional comments to the PK SOP stating of how the SOP can be differently applied to BM.

QUESTIONS to the WS participants

3. In my company/organisation, the team(s) involved in BM assay validation and analysis is organised within:

a. Same scientists also dealing with PK/ADA assays
b. Dedicated and Integrated in the bioanalytical department (PK/ADA)
c. Dedicated Biomarker team not involved in PK/ADA assays (e.g. part of pharmacology, translational medicines team,…but not a regulated BA team)
d. Other or if more answers apply: please specify.

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3. In my company/organisation, the team(s) involved in BM assay validation and analysis is organised within:

a. **Same scientists also dealing with PK/ADA assays: 34**
b. **Dedicated and Integrated in the bioanalytical department (PK/ADA): 10**
c. **Dedicated Biomarker team not involved in PK/ADA assays (e.g. part of pharmacology, translational medicines team,…but not a regulated BA team): 5**
d. **Other or if more answers apply: please specify.**

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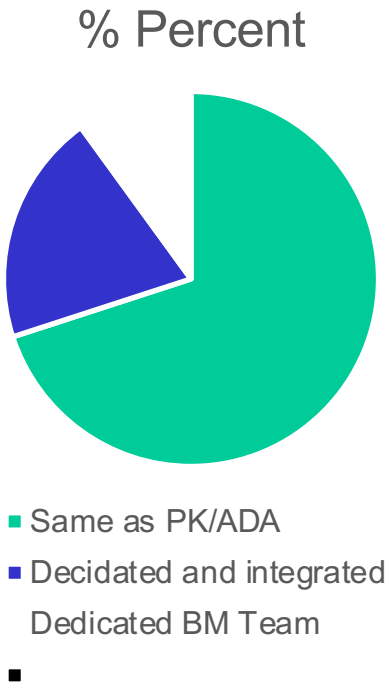

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- Not easy in small structures to have separate teams ; depends also on repartition of the activities

- In general, try to have analytical scientists who can do BM and PK/ADA, however not always possible. Having scientists who can do both allow for more flexibility and personal fulfillment for the scientists. One CRO has Client dedicated teams so means the scientists are responsible to the client itself, and hence should be able to cover both.
- Can be risky to only have single dedicated experts, is often limited by the size of the lab.
- If you want to really apply the CoU then you risk of falling into the 'PK criteria'.

QUESTIONS to the WS participants

4. Who should be responsible/accountable for the validity/usefulness of the requested Biomarker data?

a. The stakeholder/sponsor who requested the BM analysis in a particular trial/project (= end user of data)
b. The bioanalytical expert who selects the BM assay based on input from stakeholder and requests assay validation inhouse or external (CRO)
c. The Lab Head/Scientist of internal lab or CRO who performs assay validation/sample measurement according to a validation plan/analytical work plan
d. Someone else – please comment

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Question 4

Question 8: Bonus question Who should be responsible/accountable for the validity/usefulness of the requested Biomarker data?	
The stakeholder/sponsor who requested the BM analysis in a particular trial/project (= end user of data)	**Accountable – for "Usefulness"**
The bioanalytical expert who selects the BM assay based on input from stakeholder and requests assay validation inhouse or external (CRO)	**Responsible – for "Validity"**
The Lab Head/Scientist of internal lab or CRO who performs assay validation/sample measurement according to a validation plan/analytical work plan	**Responsible – for "Validity"**
Someone else – please comment	

Contact Information

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