EBF

14th EBF Open Symposium

Science – Our Universal Language

Organisational design driving/preventing CoU - a challenge or an opportunity

- a stakeholder perspective - a CRO perspective

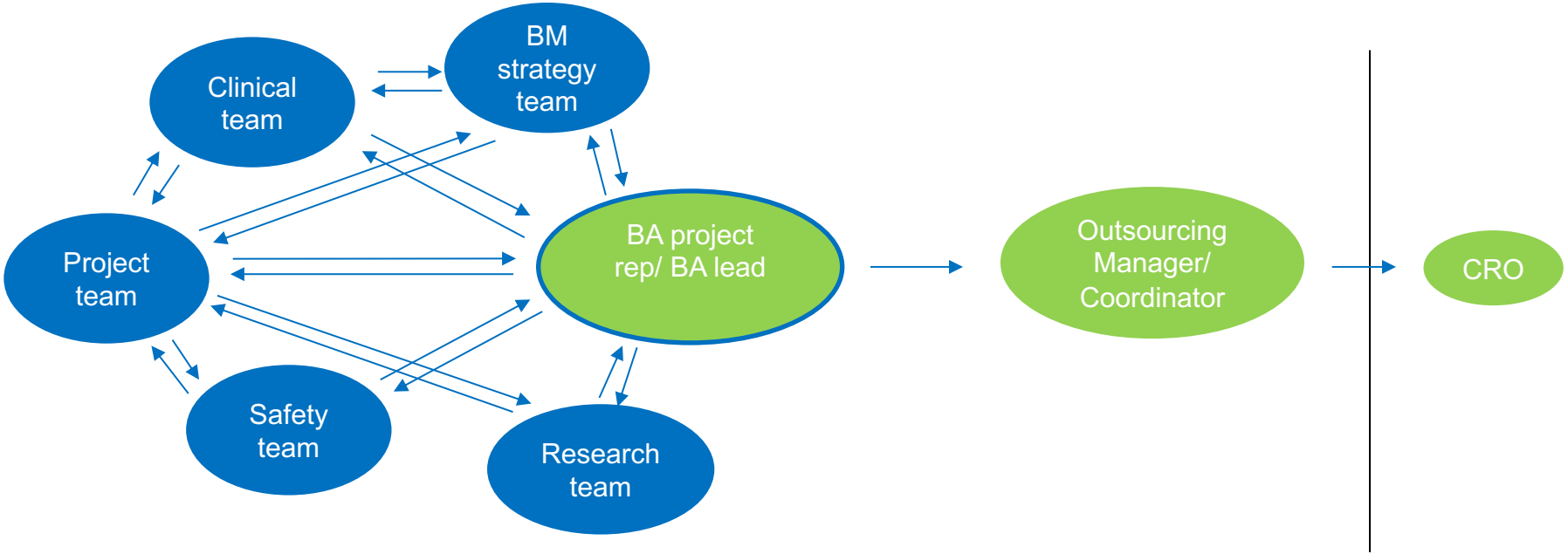
Michaela Golob, on behalf of the EBF

24-26 November 2021, Barcelona

BM- CoU (Context of Use) | What is key

"Communication is key"

….and this is often already one of the biggest issues within pharma/sponsor companies:



BM- CoU| Mindset

Lars Karlsson (Ferring)

"BM work should not be driven by technology but by CoU"

EBF WS 2017

Issue:
Many companies have separated BA in groups for small and large molecules
=> Within these groups same analysts for PK and BM

BM- CoU| How it should be

Expected procedure based on state-of-the-art BA community discussion/ agreement

Sponsor

Sponsor/ Sponsor & CRO/ CRO

Discussion on BM - Definition of CoU

Selection of analytical technology to answer specific question

Definition of Fit-for-Purpose validation parameters

Analytical work at the CRO

BM- CoU| Reality

Expected procedure based on state-of-the-art BA community discussion/ agreement

Sponsor

Sponsor/Sponsor & CRO/CRO

Discussion on BM - Definition of CoU

Selection of analytical technology to answer specific question

Definition of Fit-for-Purpose validation parameters based on CoU

BM- CoU| Reality

Expected procedure based on state-of-the-art BA community discussion/ agreement

Sponsor

Sponsor/Sponsor & CRO/CRO

Discussion on BM - Definition of CoU

Selection of analytical technology to answer specific question

?

Maybe internally in Pharma – often no info to CRO

Definition of Fit-for-Purpose validation parameters based on CoU

Reality

Large / Small Molecule BM?

"There should be a commercial LBA kit available"

"your standard LCMS"

Full Validation "to be on the safe side"

BM- CoU| Reality

Expected procedure based on state-of-the-art BA community discussion/ agreement

Sponsor

Discussion on BM - Definition of CoU

?

Maybe internally in Pharma – often no info to CRO

Sponsor/Sponsor & CRO/CRO

Selection of analytical technology to answer specific question

Definition of Fit-for-Purpose validation parameters based on CoU

Reality

Large / Small Molecule BM?

"There should be a commercial LBA kit available"

"your standard LCMS"

Full Validation "to be on the safe side"

BM- CoU| Responsibility

Details on request: “please use LCMS/any of the commercial kit assays, fully validate the assay and be prepared for clinical sample analysis”

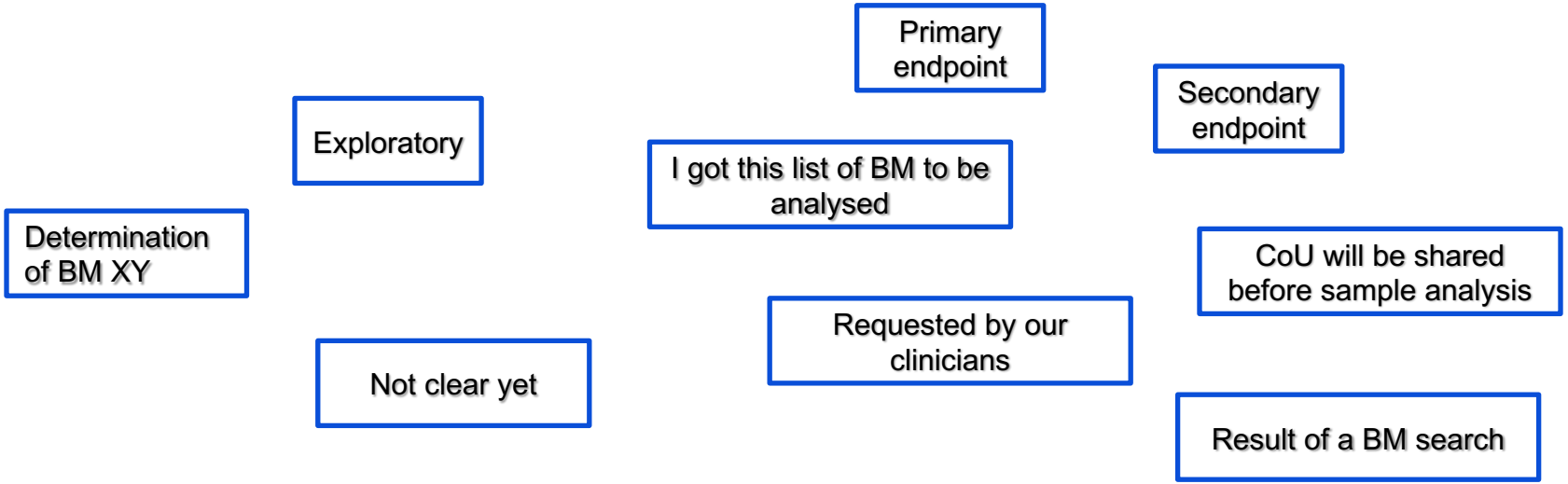
Some CROs:
Pharma should know what they ask for
=> my figures need to be super end of the month
=> I sell the max package = BMV according to PK guidelines

We all sit in the “pharma industry boat”, and we are all responsible for our data!
BMV guideline does not mean better assays/ results!

It is also our responsibility – as a CRO – to get the right information on the CoU – even if it is nasty – to produce the right data

BM- CoU| When we ask

What we get, if we ask first time for a CoU:



BM- CoU| How we react

No clear CoU
….in the BA teams – CRO & Sponsor:

"Why do you need a CoU, your BD mentioned you have analysed this BM before"

"Do I really need to ask back for CoU?"

"Perfect there is a commercial kit on the market, no need for any assay development/ transfer"

"It's a BM, let's widen up the acceptance criteria – we always did it like that"

"Full validation to be on the safe side"

"Come on, the request is "determination of BM xy" and we have the method up and running – no need for CoU discussion"

BM- CoU| Another way of trouble

BD-Info mail account:
Request for a BM assay validation and clinical sample analysis of a clinical study, please provide a Cost Proposal

↓

Proposal Team: creates a cost proposal based on “standard prize grid” for full validation and sample analysis

↓

Contract signed ….

↓

Transfer to operations who follow exactly what was agreed in the signed contract

BM- CoU| How it could be

Our idea of how it could/ should work at the CRO:

1. Getting the request for a proposal/service estimate
2. Please fill in our BM questionnaire
3. Selection of possible method (already clear or discussed)
4. Proposal of fit-for purpose validation parameters
5. Agreement on fit-for purpose validation parameters
6. Prep of proposal/service estimate for the client

Fear there is no time/ energy to go through this discussion and other CROs just do it

BM- CoU| What we need

Sponsor & CRO

We need to insist on a clear written rationale for any requested analysis

=> if a clear rational is not available, is there one at all?

- Memories are short, people leave or change companies
- How are the data going to be used?

Written statement on the CoU/ purpose of the data need to be documented at least in the validation/ study report.

Only when the CoU is clear the data fit the purpose

BM- CoU| Fully validated

"Fully validated" - what does this mean?

In the head of a regulated BA scientist this means immediately BMV guideline

"Discussion" with the sponsor: "should we do a full validation?" => "yes" => "ok we follow BMV"

Our own fault!

We need to be careful how we use and interpret this phrase

Real meaning is fully validated to its CoU and in case of CoU = PK there is a guideline to follow

BM- CoU| Change in mindset

Biggest issue:

Clear understanding of the CoU – be a scientist not a robot!
CoU concept needs a change in mindset in regulated BA - at the Sponsor and at the CRO!

BM are analysed within regulated BA groups, and it is easy and faster to just follow the PK guideline => “to be on the safe side” regulated BA guideline thinking – no link to the use of the BM data and the questions that should be answered by BM analysis

Finally: PK is a specific CoU => very clear focus, guidelines available
Immunogenicity is a specific CoU => guidelines available

Biomarker is a very broad and complex field with different biology, different effect ways…leading to different questions to be answered by different technologies and different ways of data needs/ interpretation… => different CoU (remember the shoes first presented by Lauren Stevenson ☺)

We **all in regulated bioanalysis** need to step out of our thinking pattern and change our perspective

Pharma and CRO
need to work together
for successful Biomarker science
to bring effective and safe medicine
to the patient

Acknowledgements

EBF BM team
EBF Community

Contact Information

Questions: info@e-b-f.eu

European Bioanalysis Forum vzw

www.e-b-f.eu