EBF

14th EBF Open Symposium

Science – Our Universal Language

BM and CoU –
where are we today and where are we going?

Philip Timmerman, EBF

24-26 November 2021, Barcelona

Our challenge…

Getting in right

EBF and BM - A 10y Journey

2011:
EBF Biomarker team formed

2011:
Presented @ 4th EBF OS

2012:
- Presented 5th EBF OS
- Biomarker recommendation published in 2 journals

2013 - 2018:
- *Presented @ JBF, CBF, stakeholders meetings…*

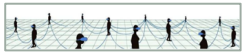
2015:
- *CC-VI*

2016 FW

2019:
Refocus on 2012 Recommendation

2019 FW & OS

2020 FW & OS



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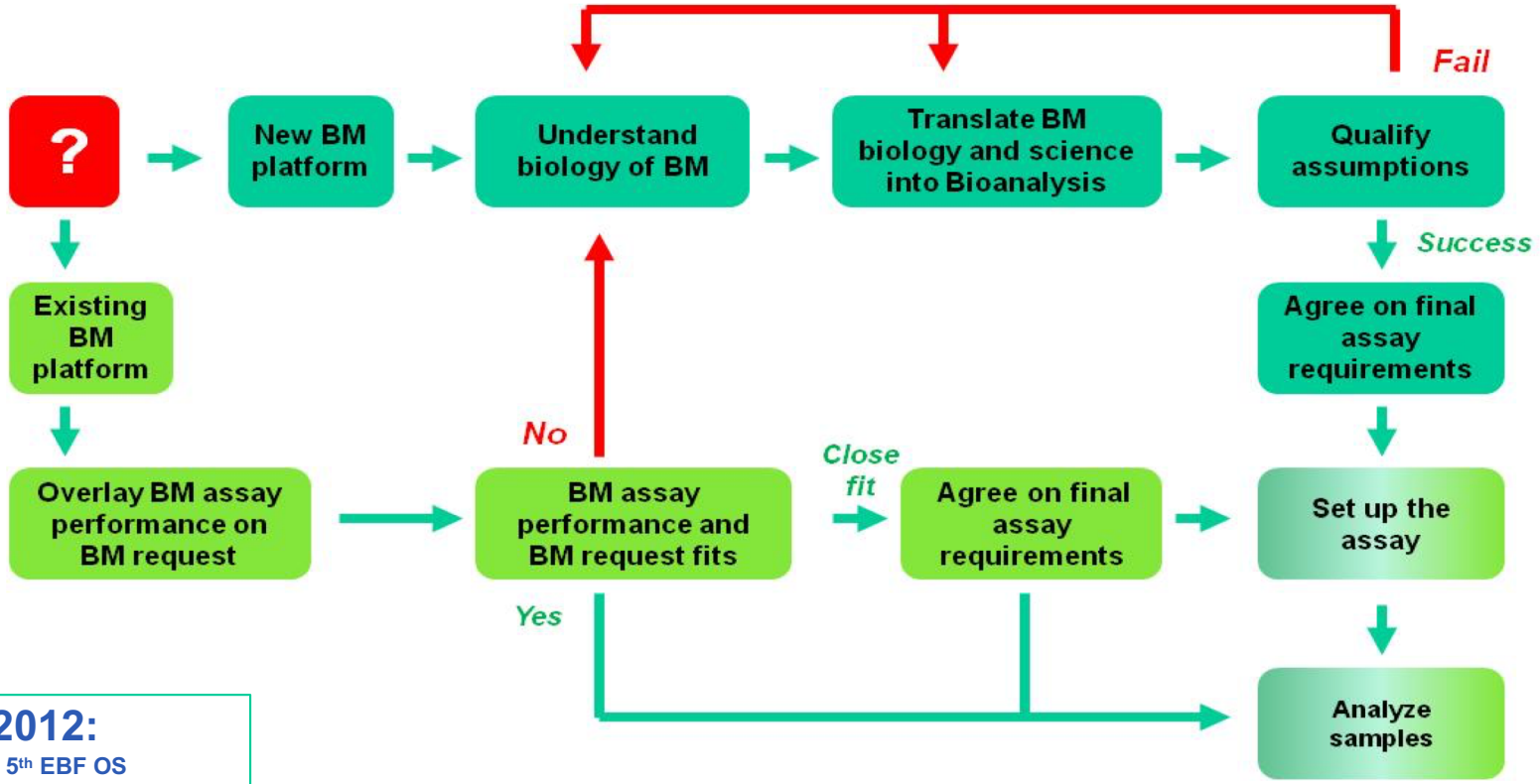

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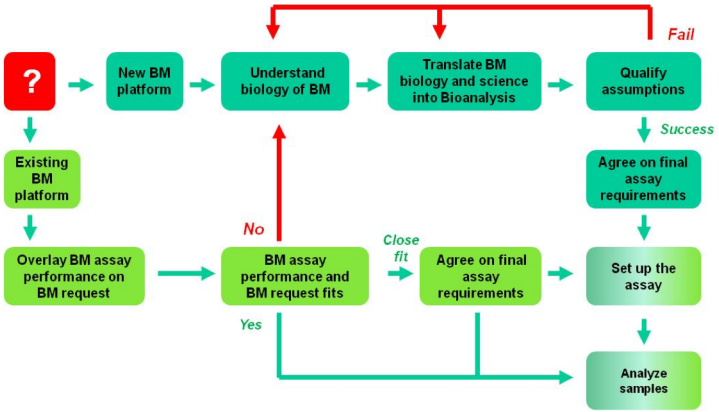

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EBF recommendation – 4 pillars

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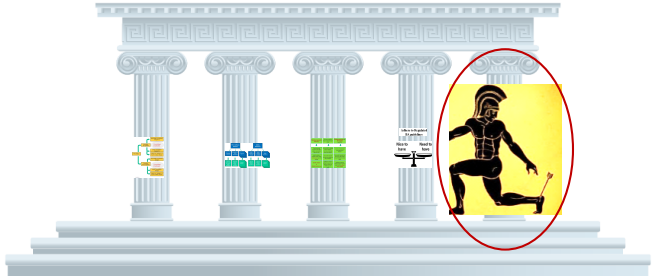

The 5th pillar - COMMUNICATION

Communicate, communicate, communicate:

- To understand the biology, pharmacological effect... of the BM
- To understand what the data will be used for
  - Scientific decisions taken
  - Safety decisions taken
  - Other?
- To share what is possible from a BA perspective (can be more or less)
- To share what is not realistic from a BA perspective
- To ensure optimal cost/benefit

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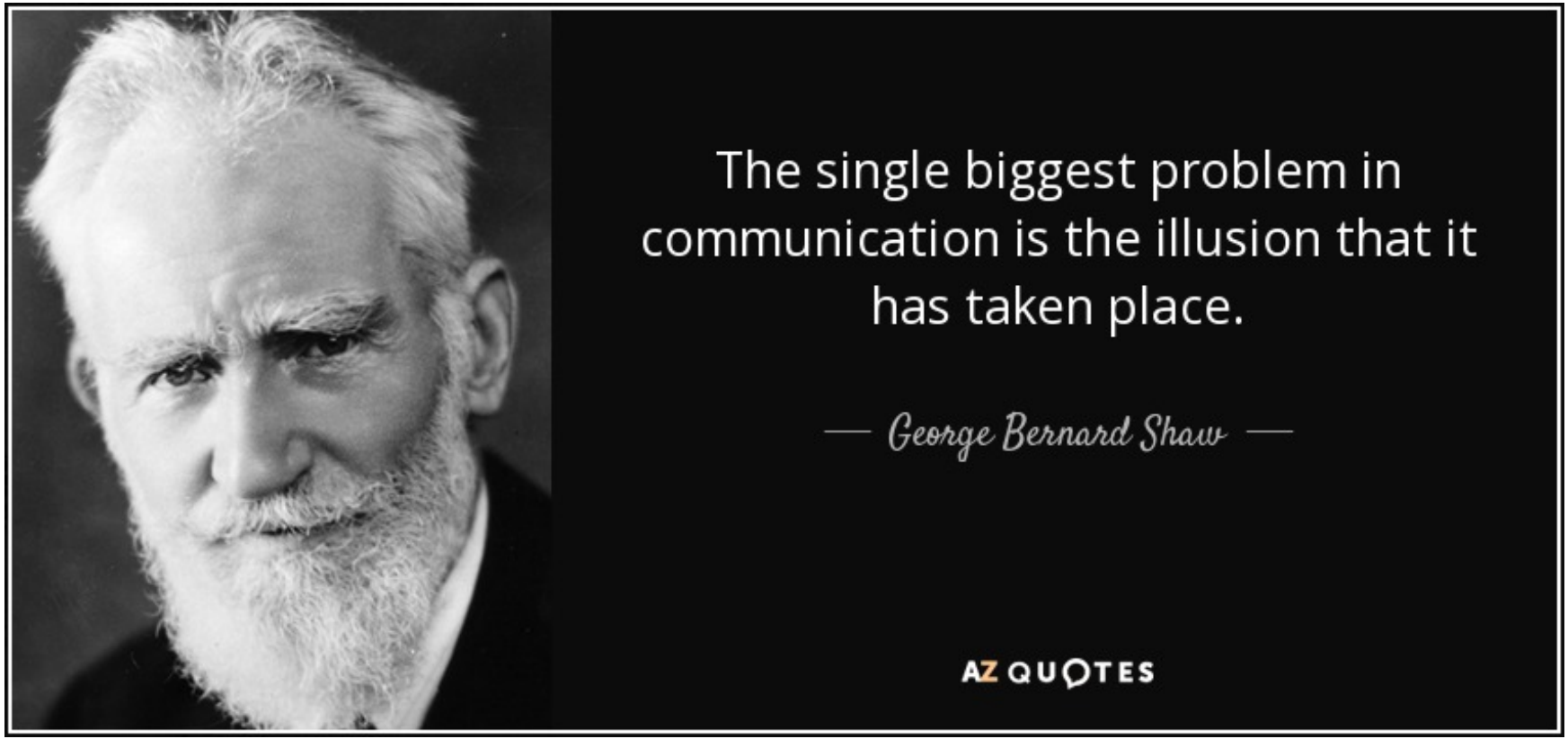
= CoU in 2012 language


The single biggest problem in communication is the illusion that it has taken place.
— George Bernard Shaw —
AZ QUOTES

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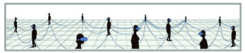

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B. Biomarkers

The recommendations in this guidance only pertain to the validation of assays to measure in vivo biomarker concentrations in biological matrices such as blood or urine. Considerable effort also goes into defining the biological function of biomarkers, and confusion may arise regarding terminology (e.g. biomarker method validation vs biomarker qualification).

Biomarkers are increasingly used to assess the effects of new drugs and therapeutic biological products in patient populations. Because of the important roles biomarkers can play in evaluating the safety, activity, or effectiveness of a new medical product, it is critical to ensure the integrity of the data generated by assays used to measure them. Biomarkers can be used for a wide variety of purposes during drug development; therefore, a FFP approach should be used when determining the appropriate extent of method validation. When biomarker data will be used to support a regulatory decision making, such as the pivotal determination of safety and/or effectiveness or to support dosing instructions in product labeling, the assay should be fully validated.

For assays intended to support early drug development (e.g., candidate selection, go-no-go decisions, proof-of-concept), the sponsor should incorporate the extent of method validation they deem appropriate.

Method validation for biomarker assays should address the same questions as method validation for drug assays. The accuracy, precision, sensitivity, selectivity, parallelism, range, reproducibility, and stability of a biomarker assay are important characteristics that define the method. The approach used for drug assays should be the starting point for validation of biomarker assays, although the FDA realizes that some characteristics may not apply or that different considerations may need to be addressed.

Together with AAPS-OSD #BeAScientist

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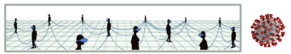

2020:
Update of 2012 Recommendation

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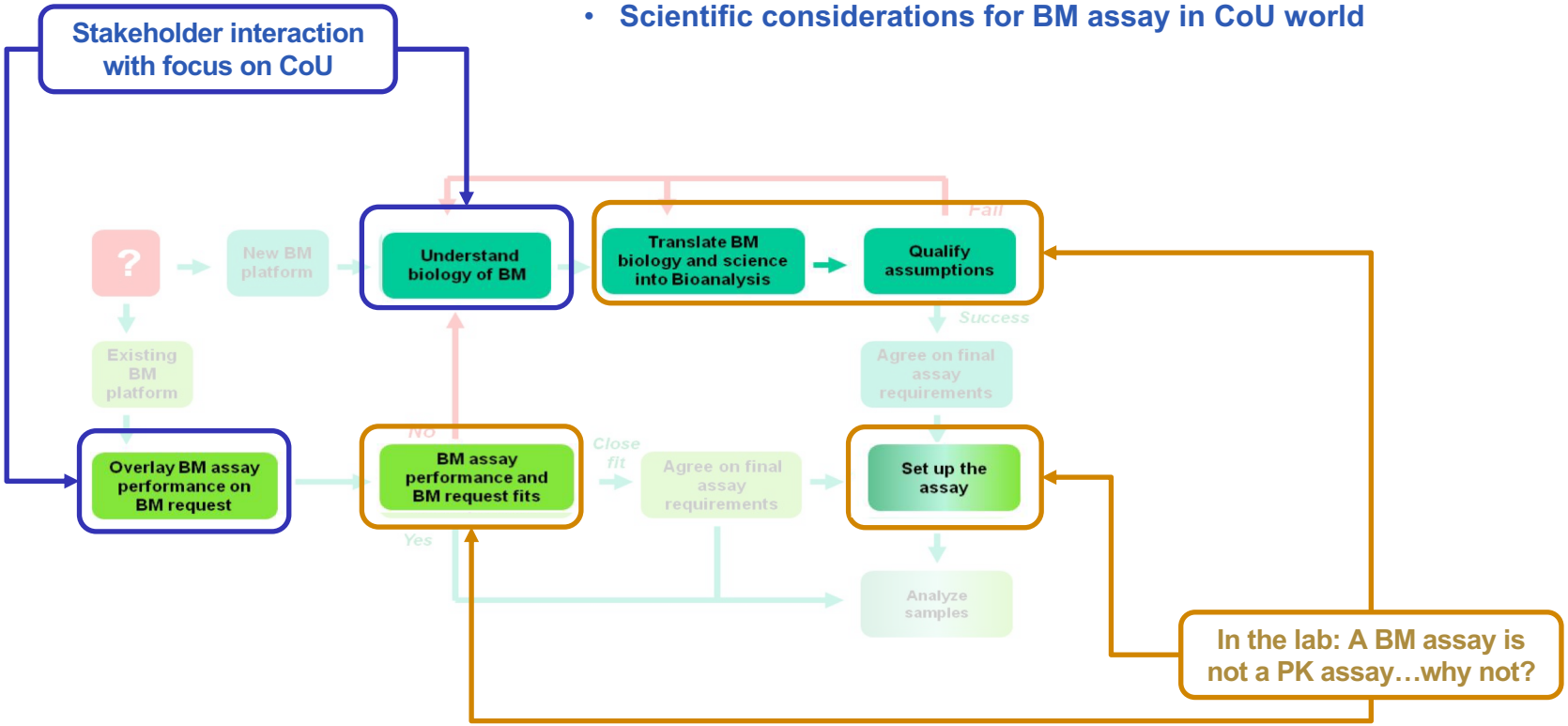
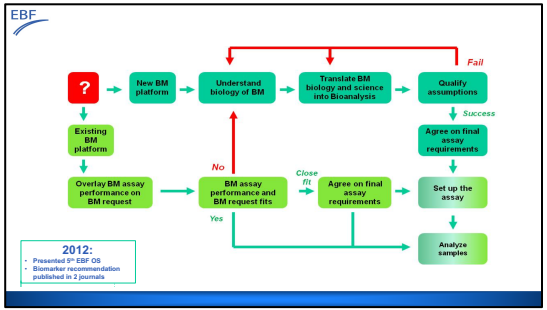
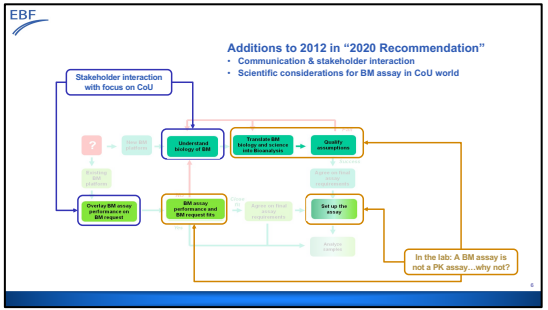
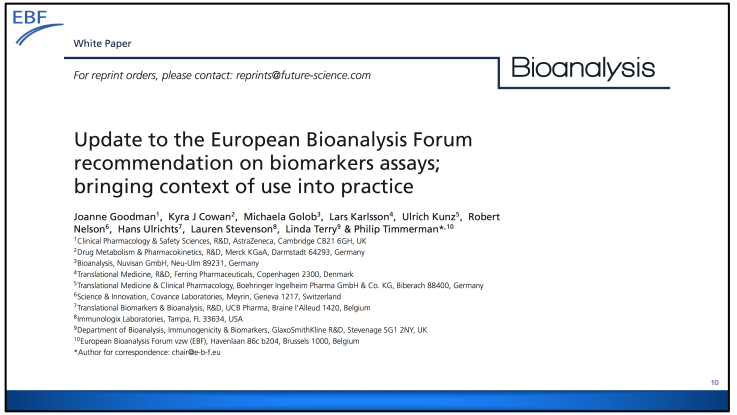
Additions to 2012 in “2020 Recommendation”

- Communication & stakeholder interaction
- Scientific considerations for BM assay in CoU world









And: https://e-b-f.eu/conferences/past-conferences-2/ for all slides ever presented

2019 FW & OS

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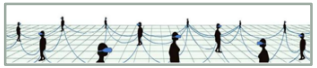

2021 FW & OS

Another Survey

To EBF Core

Jan 2021
A recent survey in the EBF

1. What are you still struggling with related to BM validation and analysis?
2. What are you still struggling with related to CoU specifically?
3. Pharma:
   - Who else (besides you?) is still struggling with CoU?
   - What are they still struggling with CoU?
4. CRO:
   - Who else (besides you?) is still struggling with CoU?
   - What are they still struggling with CoU?

4

To Delegates

Pre-meeting survey to delegates

Q1. I am relatively new in the BM field (< 1y) and my choice (personal or requested by my management) is to use the SOP I use for PK studies for the BM analysis

Q2. I am experienced in the BM field (> 1y) and my choice is to use the SOP I use for PK studies for the Biomarker analysis

Q3. I am experienced in the BM field (> 1y) and my management's choice is to use the SOP I use for PK studies for the BM analysis

Q4: (more than 1 answer is possible) I am aware of the CoU discussions and:

Q5: For me, the major hurdles to bring CoU into practice are:

Q6: Some suggestions to overcome major hurdles to bring CoU into practice

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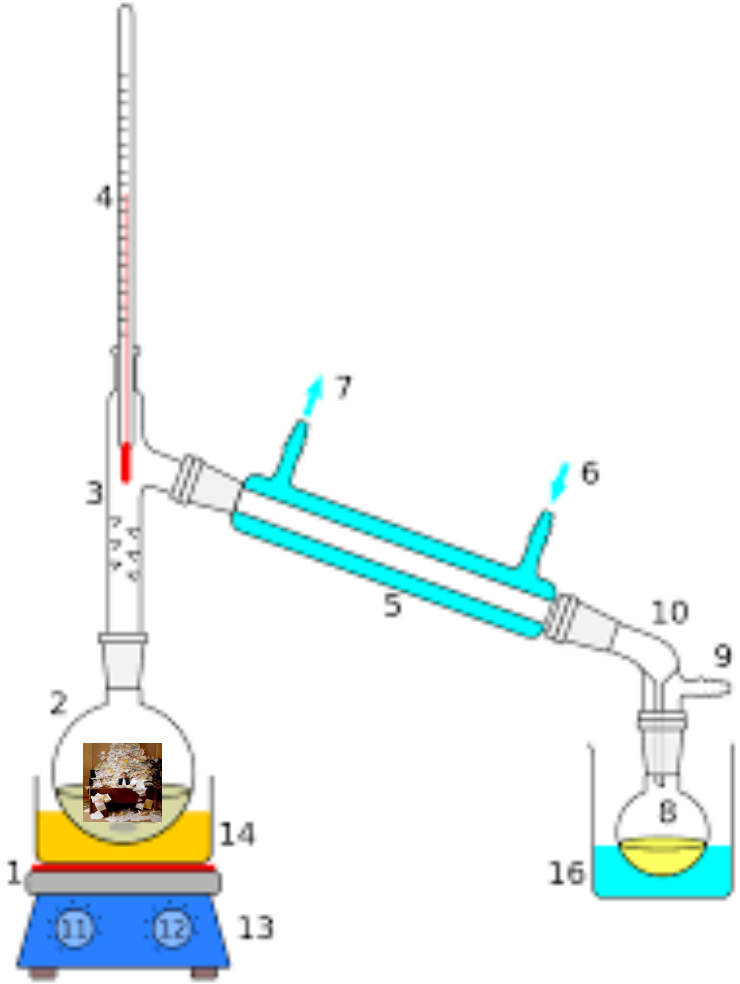

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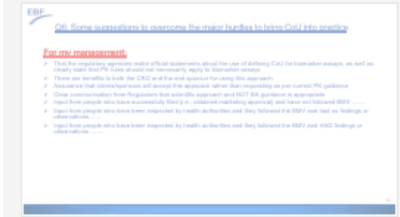

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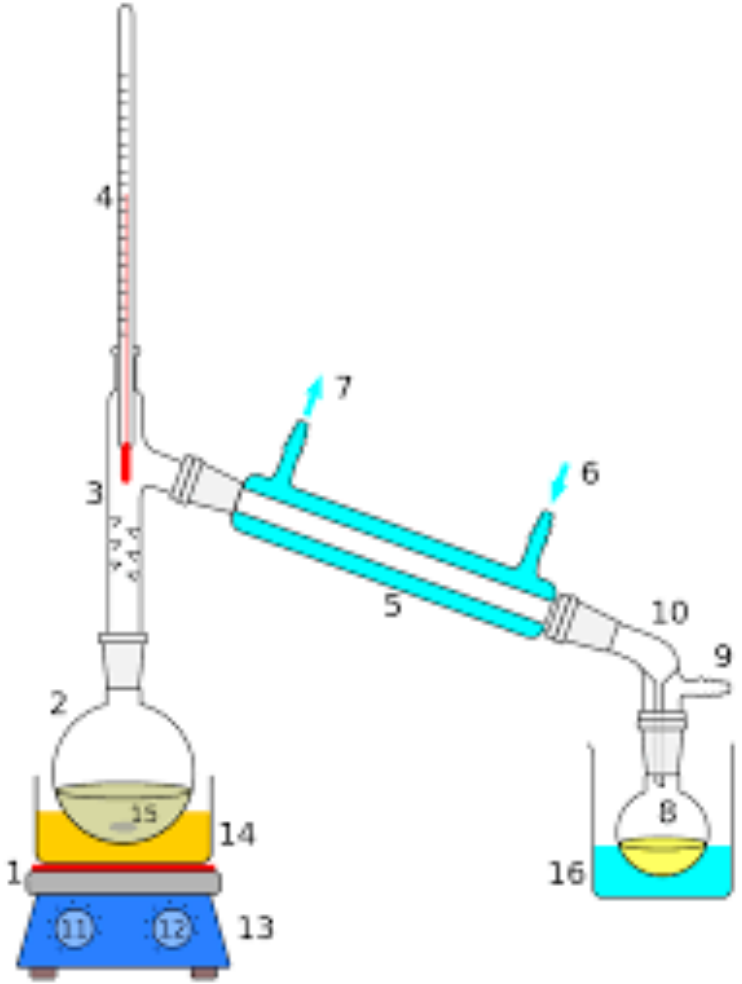

Is my organisation ready to apply CoU?

me
the BA lab
my management
the end user
QA

the health authorities

COSMOS

10:20 12.10 Session 1: Biomarkers - Organisational design driving CoU (Plenary)

Session Chair: Kyra Cowan (Merck KGaA)

Next

10:30 10:50 ***Kyra Cowan, on behalf of the EBF***

Organisational design driving/preventing CoU - a challenge or an opportunity - a stakeholder perspective - a Pharma/Sponsor perspective

10:50 11:10 ***Michaela Golob, on behalf of the EBF***

Organisational design driving/preventing CoU - a challenge or an opportunity - a stakeholder perspective - a CRO/vendor perspective

11:10 11:30 ***Peter Groenen, Idorsia***

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

11:30 11:50 ***Anna Laurén, Novo Nordisk***

Updating the organisational process and responsibility split for translational work with biomarkers and CoU – a pharma perspective

11:50 12.10 ***Q&A and Introduction to the Workshop (Session 5)***