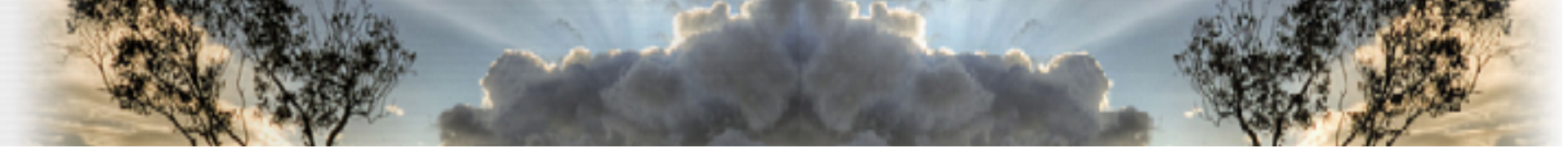


EBF Open Symposium

N° 13 From Cyberspace - Staying Connected

17-20 November 2020

A recap of EBF discussions and recommendations on Pharma-CRO partnership best practices for Method Development

Rachel Green, on behalf of the EBF

How did we get here?

EBF - Focus Workshop

Optimizing the Pharma - CRO interface in bioanalysis

12-13 March 2015, NH Sablon Hotel, Brussels, Belgium.

Thursday 12 March 2015

15:00 **Registration desk opens**

18.00 – 19.00 **Welcome drink**

19.00 – 19.45 **Appetizing presentations** – (5-8 minutes each)

- Welcome and introduction: why this workshop?
  Philip Timmerman, Janssen R&D for EBF
- Challenges of today's paradigm from an Pharma perspective with increasing outsourcing in earlier development
  Matt Barfield, GlaxoSmithKline
- Challenges of today's paradigm from a Pharma with full outsourcing
  Cecilia Sparr Eskilsson, Leo Pharma A/S
- Challenges of today's paradigm from a CRO perspective in support of Friday morning workshop: The Scientific challenge: who will be driving innovation in the future?
  Clare Kingsley, LGC

8th EBF Open Symposium

Into New Territories

Explore, Learn and Apply

Registration will close on November 3rd

EBF 10th Open Meeting: 10 - A New Journey begins

EBF 4th YSS will be organized as a stand-alone meeting in 1Q2018

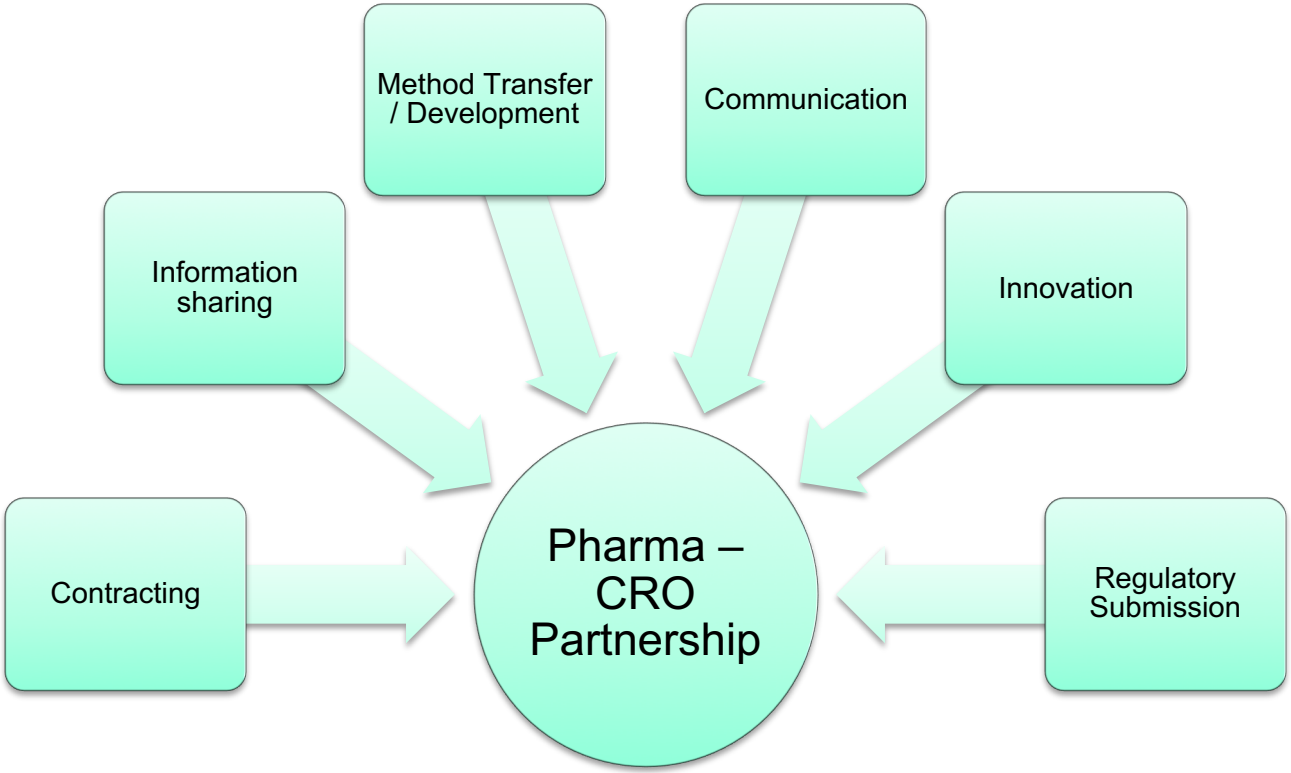
Hotel NH Collection Barcelona
Barcelona, Spain
November 15-17, 2017

REGISTER NOW

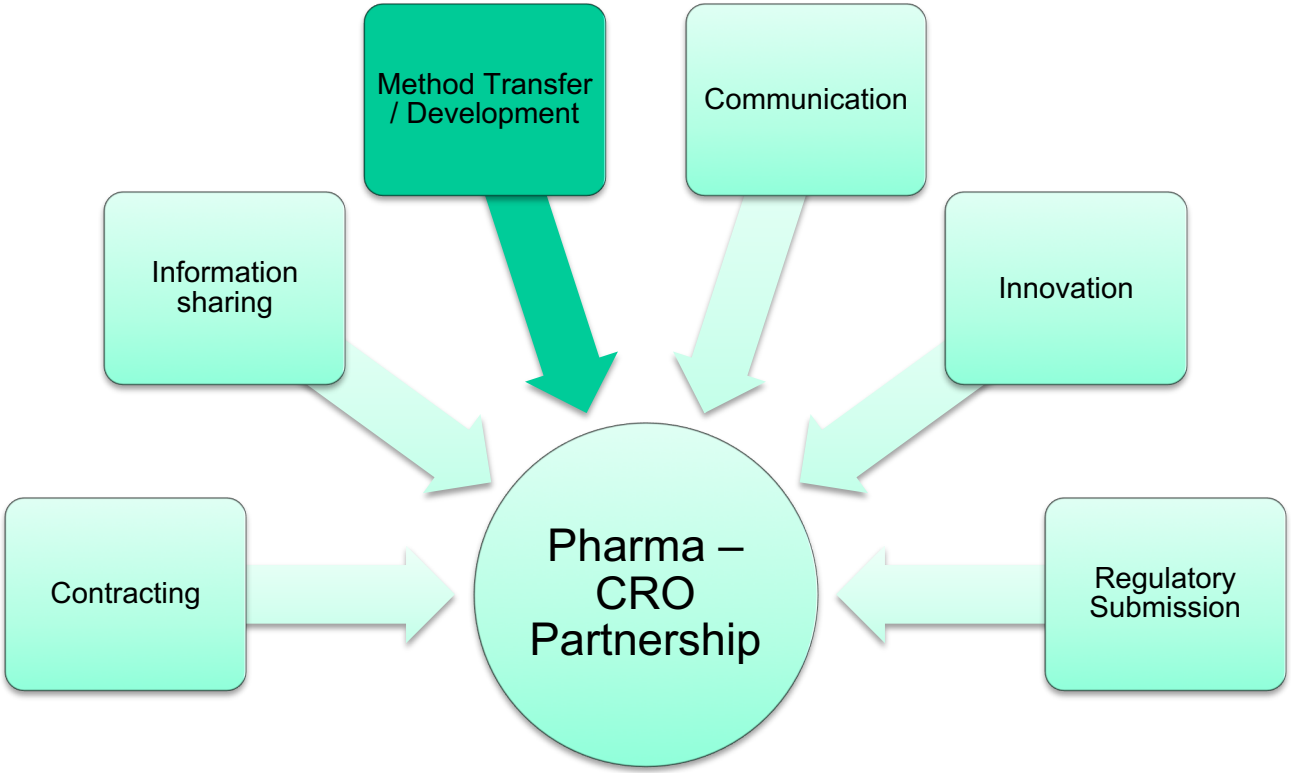
What do Pharma want to see?

What do CROs want to see?

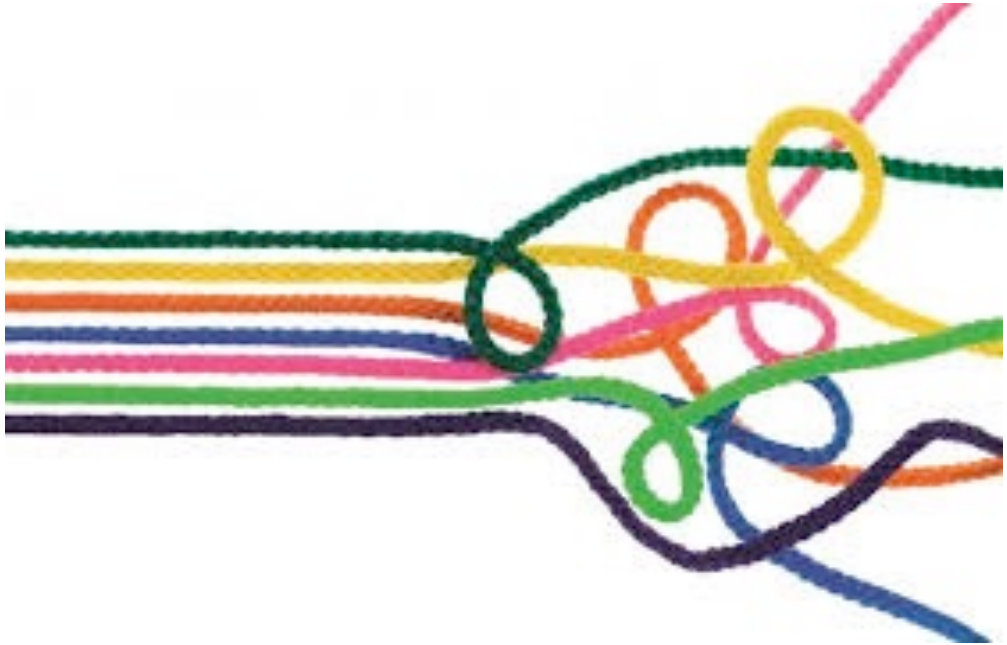
Topics covered in earlier discussions



Topics raised in earlier discussions



Moving from a controlled environment…



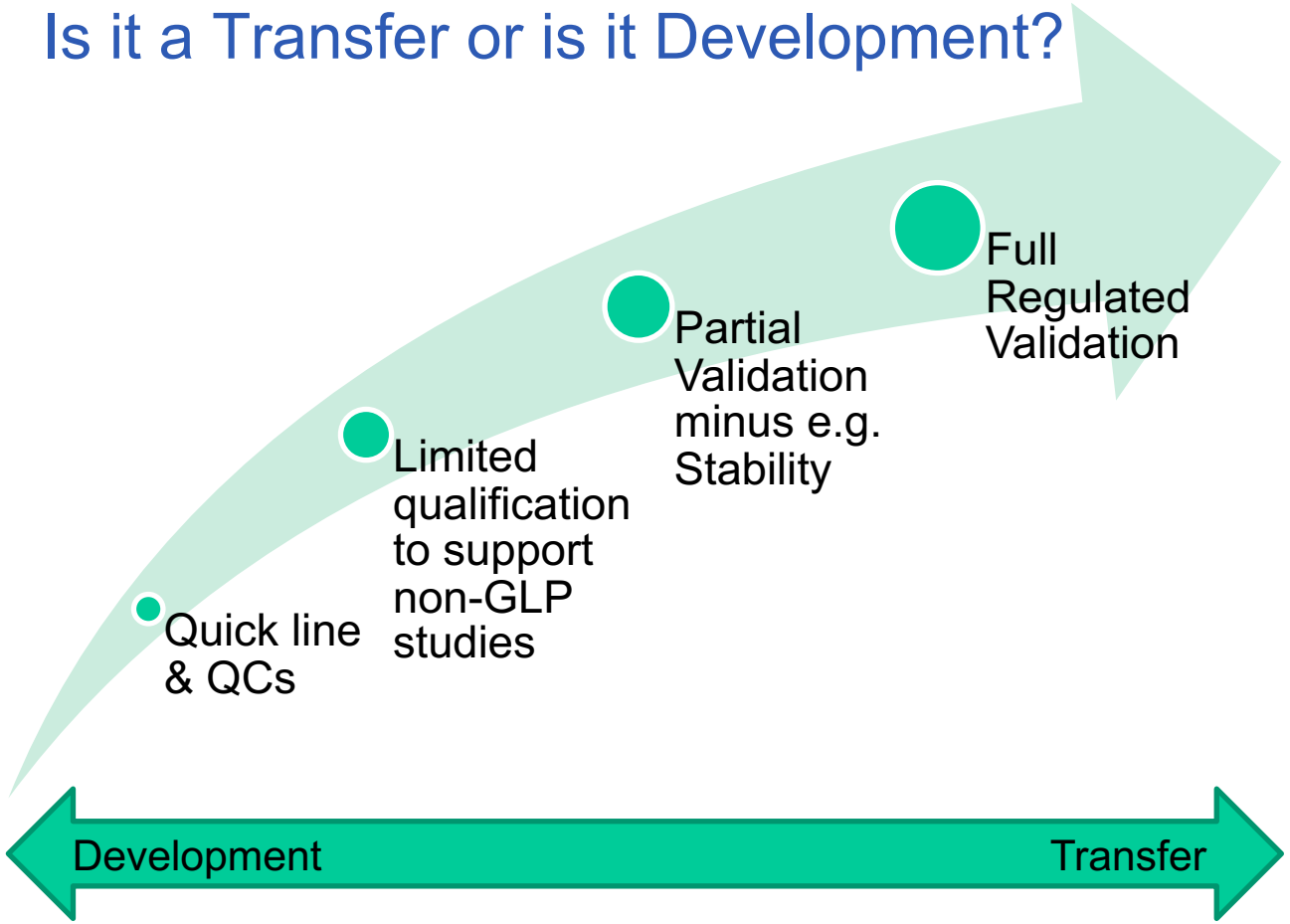
Develop methods with **robustness** and flexibility in mind

- Design of Experiment (DoE) approach in development
- Understand what are the critical parameters
- Robustness testing
  - Multiple instruments
  - Multiple analysts
  - Different sources/batches of reagents & materials
  - Stress test benchtop stability
- Avoid unnecessarily complicated methods

Develop methods with robustness and **flexibility** in mind

- Think about the potential method lifecycle from the start
- Aim to reduce the likelihood of a significant re-development
- Consider the technology available in the CRO lab
- New species? New patient populations? New dose route/formulation?
- What do we know about metabolism?
- Could changes in sample collection have an impact?

Is it a Transfer or is it Development?



Contracting

Considerations

- CROs would like to fully understand the scope of work when setting up contracts.
- Method development/transfer is typically the most difficult phase to contract accurately. Often a standard default e.g. 5 days is used.
- Competitive bidding situations can lead to CROs pricing too low and then under-resourcing the project.
- Scheduling can be problematic. Project timelines and CRO lead times shift between draft contract going out and finalisation.

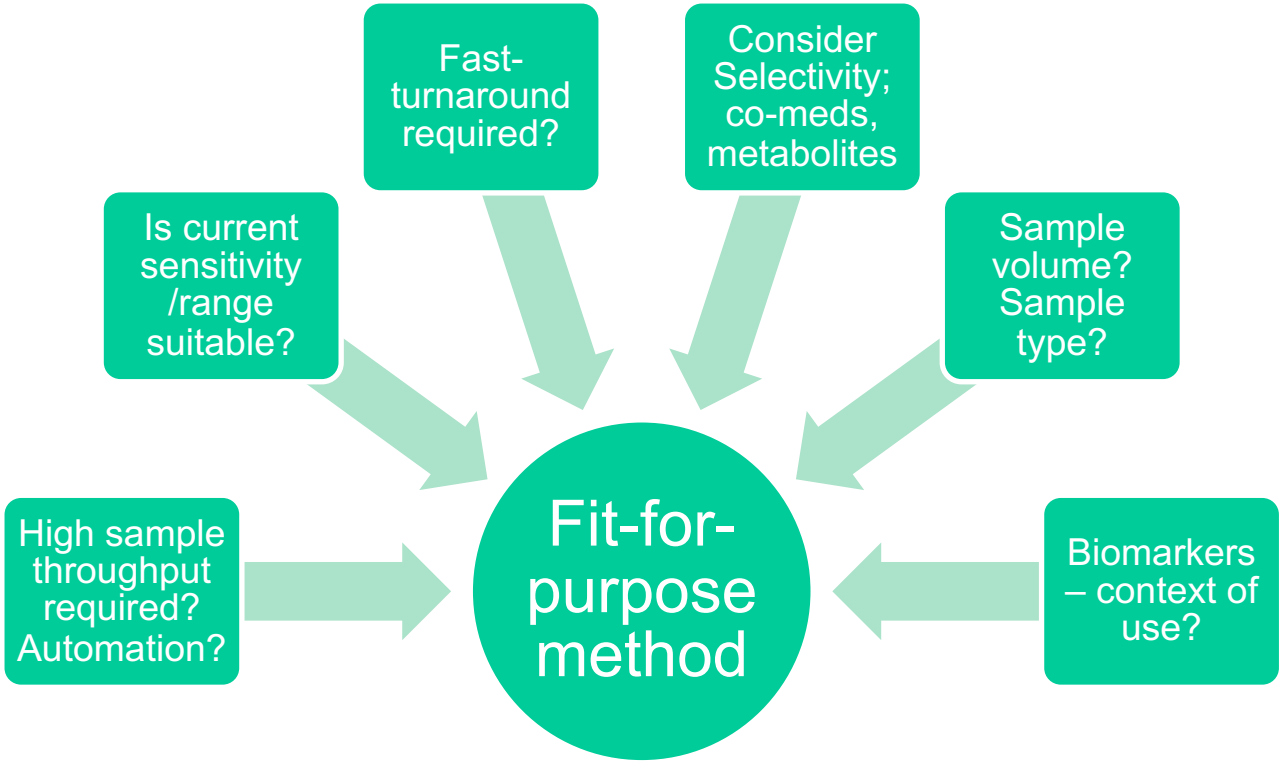
Recommendations

- Give the CRO the information they need up-front to properly scope the work.
- Aim to have as little change as possible to the contract once in progress. Avoid out-of-scopes which are an additional admin burden for both partners. Build flexibility into contracts.
- Maintain communication if there is a delay to finalising contracts so that scheduling can be updated.
- Consider value for money rather than absolute cost

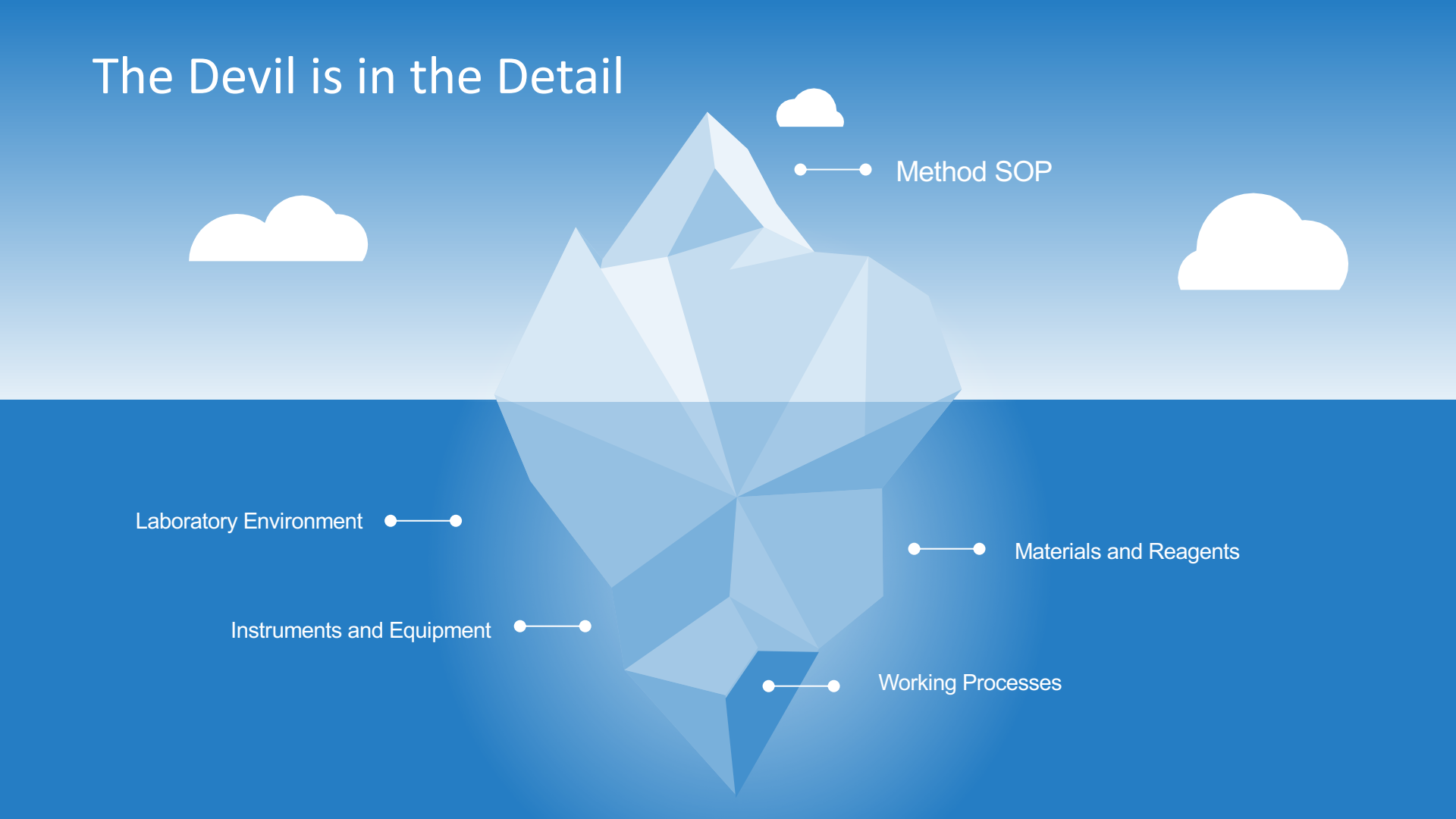
Information sharing

- A well-documented, well-understood method is essential for a successful transfer
- Method Transfer Information Pack
  - Method Validation Report, if available
  - Comprehensive Method Sheet or SOP
  - Immunogenicity risk assessment, if relevant
  - CRO questionnaire
  - Problems encountered and overcome
  - Tips and hints
- When details aren't fully specified they are open to interpretation
- What can be changed and what cannot?

What is the intended purpose of the method?



The Devil is in the Detail



Communication

Considerations

- Scientist to scientist communication important
- There can be a tendency for the CRO to try to fix the problem and avoid delivering bad news. Pharma sponsors need transparency. Good communication is critical.
- Cultural differences and language issues can hinder clear communication

Recommendations

- Agree a communication plan up-front
- Adjust regularity of communication depending on phase of work.
- Scientist to scientist communication important, preferably the person who developed the method is available
- Lab visit if necessary
- Vitally important for CROs to quickly communicate problems or delays.
- Open and honest communication = Trust

Communication

Considerations

- In big Pharma outsourcing typically done by a specific outsourcing/procurement team and separate from the bioanalytical scientists who understand the method well.
- Similarly in big CROs Proposals may be prepared by a team remote from the bioanalytical scientists.

Recommendations

- The interface between CRO Business Development and their Scientists needs to be strong to ensure a solid understanding of the scope.
- It is good practice for Pharma Procurement to set-up an MSA/pricing agreement with preferred partners so that aspect is in place, leaving the scientific discussions to bioanalytical expert outsourcers.

Documenting method development/transfer

- Understanding how and why scientific decisions on a MD/transfer were made is important to regulators
- FDA BMV 2018 guidance had increased emphasis on ensuring method evolution is fully documented
- Consider even though it's a non-regulated study inspectors will look at the method development data
- When a method is transferred to a CRO they should document any changes they make to the method and why
- Helpful for the CRO to understand the story of how the method evolved prior to transfer

What does success look like?

- Method validated successfully in the receiving lab
- Cross-validation type exercise to demonstrate comparability
- On-going monitoring of method performance
  - Batch failure rates
  - Data trending charts

Recommendations for Successful Method Transfer

- Methods should be developed with robustness in mind. Keep it simple.
- Consider equipment and working processes at the CRO
- Familiarity with each others labs and ways of working is helpful
- Full disclosure of drug and method information up-front
- Clarity on the intended purpose of the method
- Get the contracting right, allowing for flexibility
- Details matter!
- Set-up a clear communication structure, allowing scientist to scientist comms
- Allow enough time to investigate and resolve problems
- Mutual respect and trust

Acknowledgements

Everyone who has presented on the topic and contributed to workshop discussions at previous EBF meetings

Contact Information

Questions: info@e-b-f.eu

European Bioanalysis Forum vzw

www.e-b-f.eu