



# Challenges of today's paradigm from a Pharma with full outsourcing

EBF Focus Workshop

**Optimizing the Pharma - CRO interface in bioanalysis**

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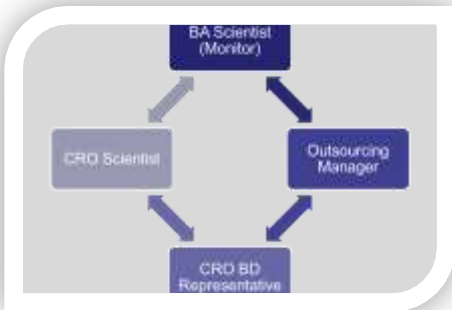
# Yes, we trust!



- 100% outsourced since 2008 - in house team of senior scientists
- Scientist dedicated to a certain project



- Preferred partners and Specialised CROs.
- Access to external experts and consultants.



- Strong internal collaboration
- Build long-term relationships (Scientist - CRO Scientist)

**Monitor visits**  
**Pro-active planning**  
**Openess**  
**Communication**  
**Issue resolution**



# Challenges



- Selection of CRO's (quality and expertise)
- Common understanding of "right" quality level
- Variety in deliverables, e.g. method validations
- CRO's SOPs vs. Sponsor SOPs/requirements
- Culture barriers
- Difficult to contribute to EBF surveys