CHALLENGES OF TODAY’S PARADIGM FROM A CRO PERSPECTIVE. THE CHANGING BUSINESS RELATIONSHIPS: ARE CONTRACTS LIMITING SCIENTIFIC FREEDOM?

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Traditionally, a CRO offers ‘bioanalytical services’ to the customer, made up of technical skill, facilities, instruments, resource and knowledge.

The customers traditionally see the CRO as ‘a service provider’.
Changing Landscape

• Changing Business Drivers; FIPCO vs FIPNET
• Variety of clients; virtual, small, mid, large, consultants and other CROs
• Variety of CRO types; ‘Full Service’ vs. ‘Niche’

Different outsourcing models;

• Transactional
• FTE (dedicated headcount agreements)
• Preferred Partner
• Alliance
Pharma / CRO interface; understanding your needs

CRO Performance vs Importance in CRO selection

- Geographic Coverage
- Communication
- Method Development
- On-time data Delivery
- Assay Development
- Quality (vs regulatory inspection)
- Technical Expertise
- Cost

Importance in CRO selection
Pharma and CRO Interface; Contracts

Legally binding commercial contract defines Scope of Work.

Limits liabilities

But can limit freedom for rapid change in direction (driven by science)

Both Pharma and CRO need creativity and flexibility to adapt to change and meet shared goals.
Understanding each other

Bioanalysis is science
- Science takes time
- Quality takes time
- The path may change!

Need creativity and flexibility, which may be contrary to established processes (change)

Clear communication is a key requirement
Outsourcing any bioanalysis requires trust
First steps….

‘The true sign of intelligence is not knowledge but imagination’

(Albert Einstein)

Let us imagine different ways of working between Pharma and CRO