

Enhancing the Pharma-CRO relationship with a focus on method transfer



Chris Jones, Client Manager, Drug Development Services, LGC

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Science
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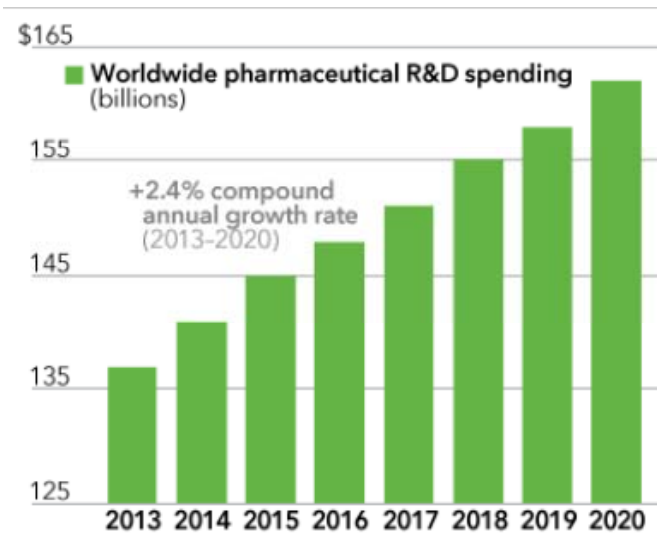


Overview

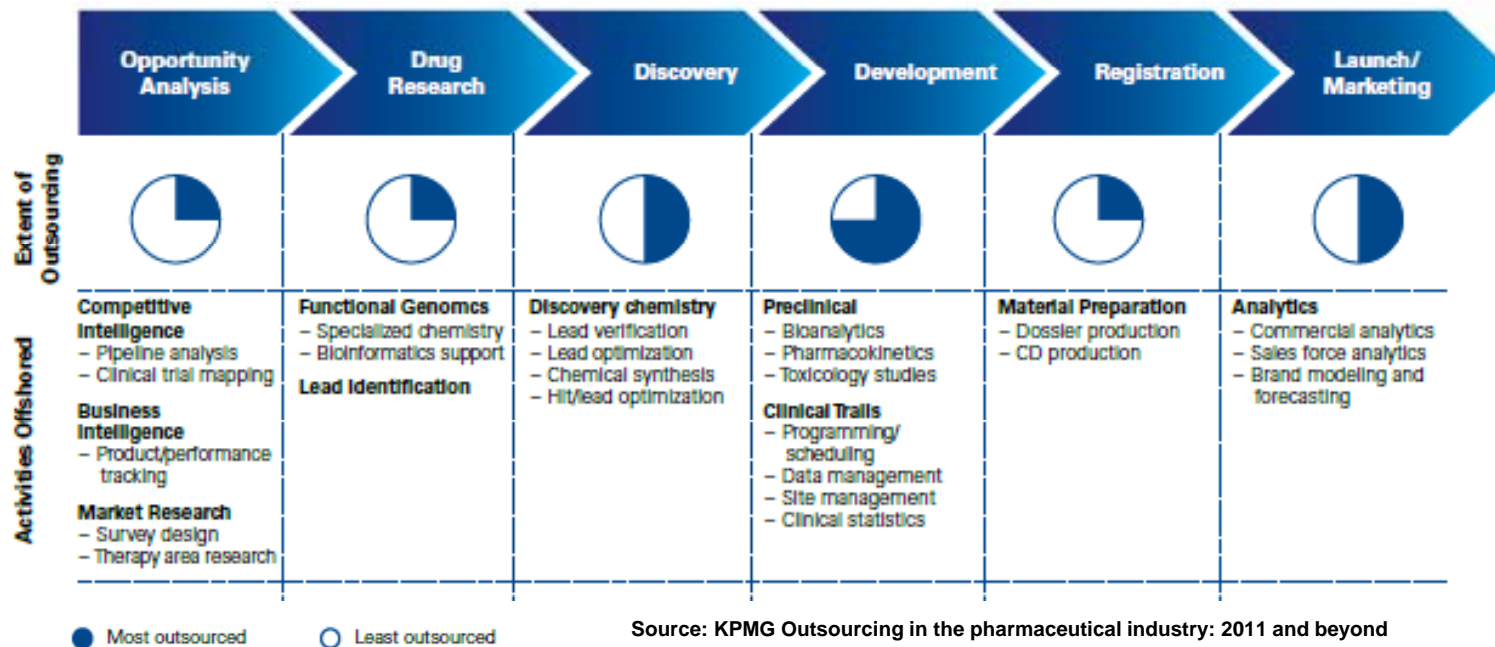


- **Introduction**
- **Our perspective on the Pharma – CRO relationship**
- **Case Study and Governance Structure**
- **Relationships in practice - Method Transfers**

Background - Pharma R&D spend



Source: World Preview 2014, Outlook to 2020, June 2014, EvaluatePharma



Source: KPMG Outsourcing in the pharmaceutical industry: 2011 and beyond

Outsource: obtain goods or a service by a contract from an outside supplier



Sponsor



CRO

Definitions are pretty cold.....

so how do we get the most from outsourcing?

Make the most of CRO capabilities



Core competencies

Expertise

Technical

- Analytical experts**
- ✓ Method development
- ✓ Method validation
- ✓ Visibility of industry trends
- ✓ Breadth of experience
- ✓ Track record
- ✓ Active in community

Regulatory

- Quality Systems**
- ✓ GLP
- ✓ GCP
- ✓ GMP

- ✓ CITES experience

Study Management

- ✓ Communication
- ✓ Planning
- ✓ Timelines
- ✓ Budget
- ✓ Flexibility
- ✓ Experience – track record?

Infrastructure

- ✓ Resource
- ✓ Instrumentation
- ✓ Sample Management
- ✓ Logistics
- ✓ Flexibility

The vital component is:



Building a **high quality** relationship

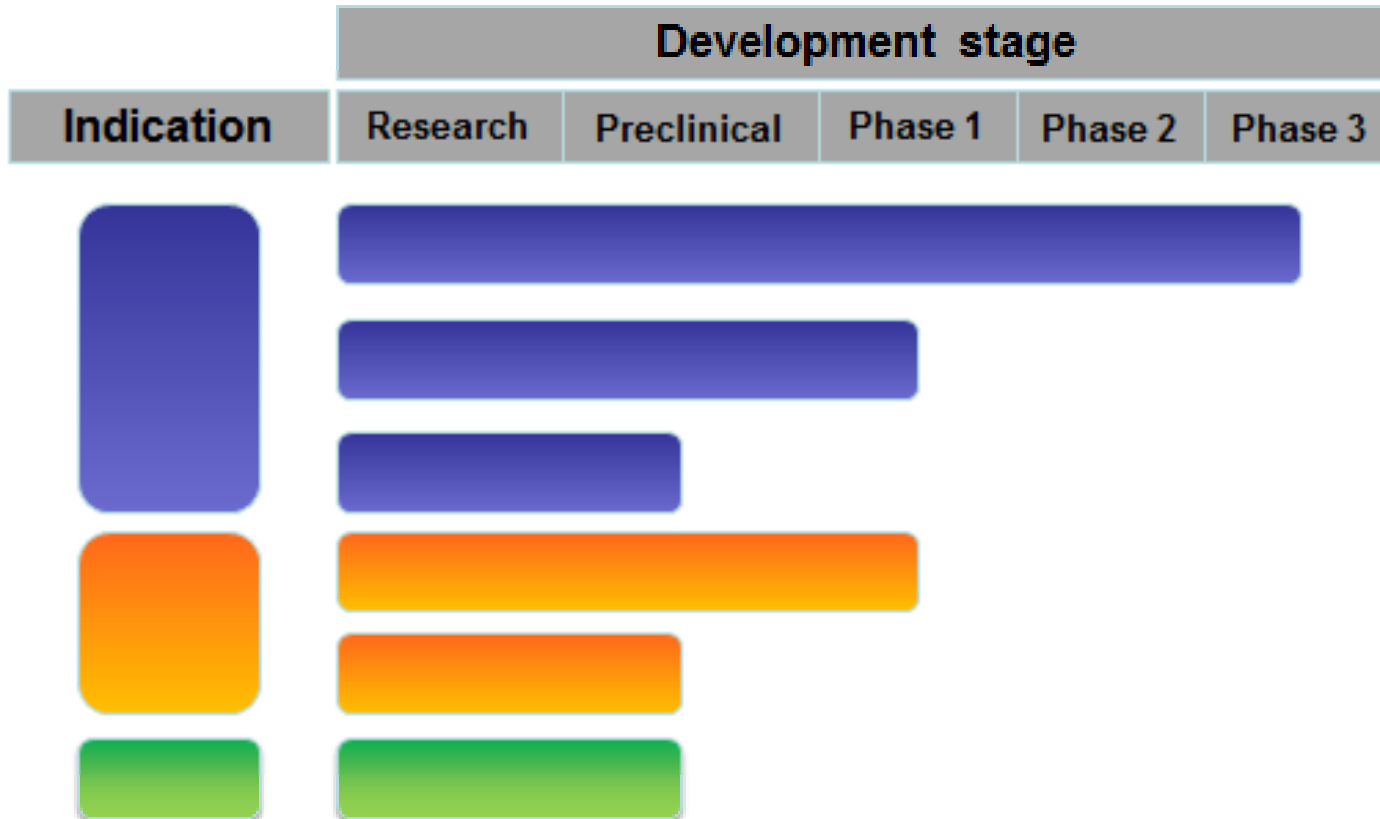
- **Teamwork and trust**
 - **Shared vision**
 - **Good communication**
- **Good personal relationship**
- **Understanding perspective**
 - **Mutual respect**



What would we like from this?



Partnership and collaboration



Engaging with your pipeline and your therapeutics is a massive motivator



Case Study – putting it into practice

Case study



2012

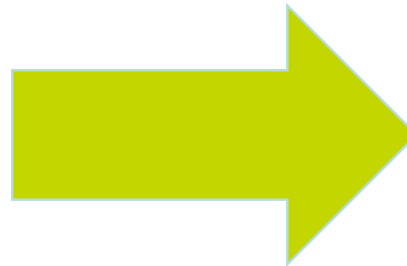
- **First contracts awarded**

2013

- **Invited to tender for preferred supplier status**

2014

- **Preferred supplier status awarded**



Governance structure

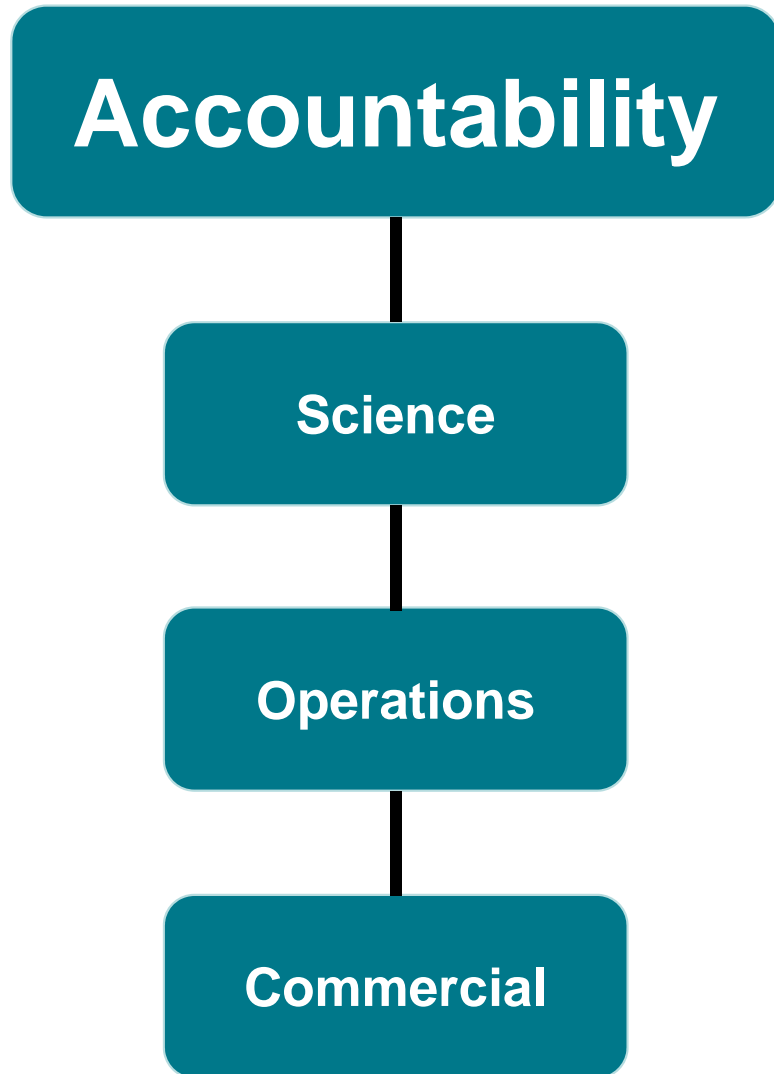
Accountability

Science

Operations

Commercial

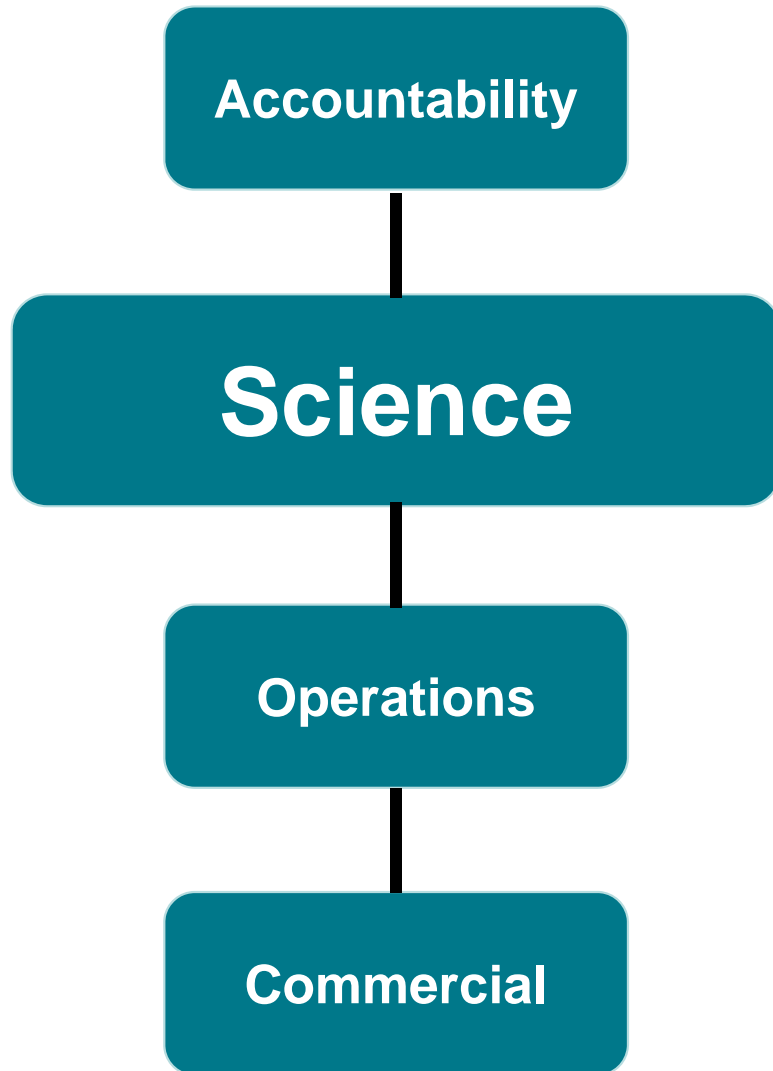
Governance structure - Accountability



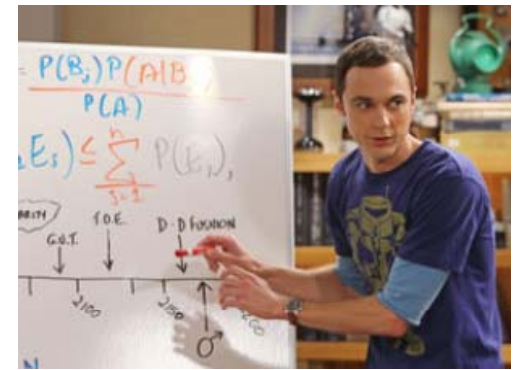
- Oversight from top level management
- Review and management of KPI's
- Long-term visibility



Governance structure - Science



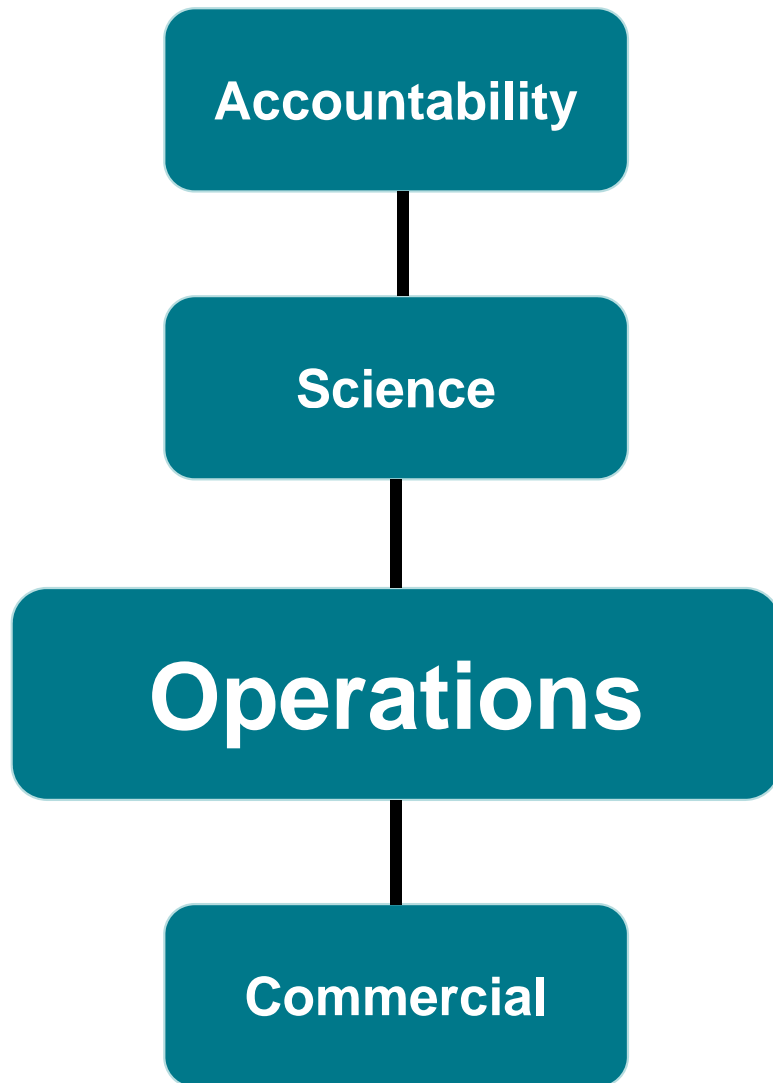
- **Point of contact**
 - **Science Leads**
- **Scientific challenges**
- **Knowledge sharing**
- **Conference downloads**
- **White papers and regulations**
- **Emerging technologies**



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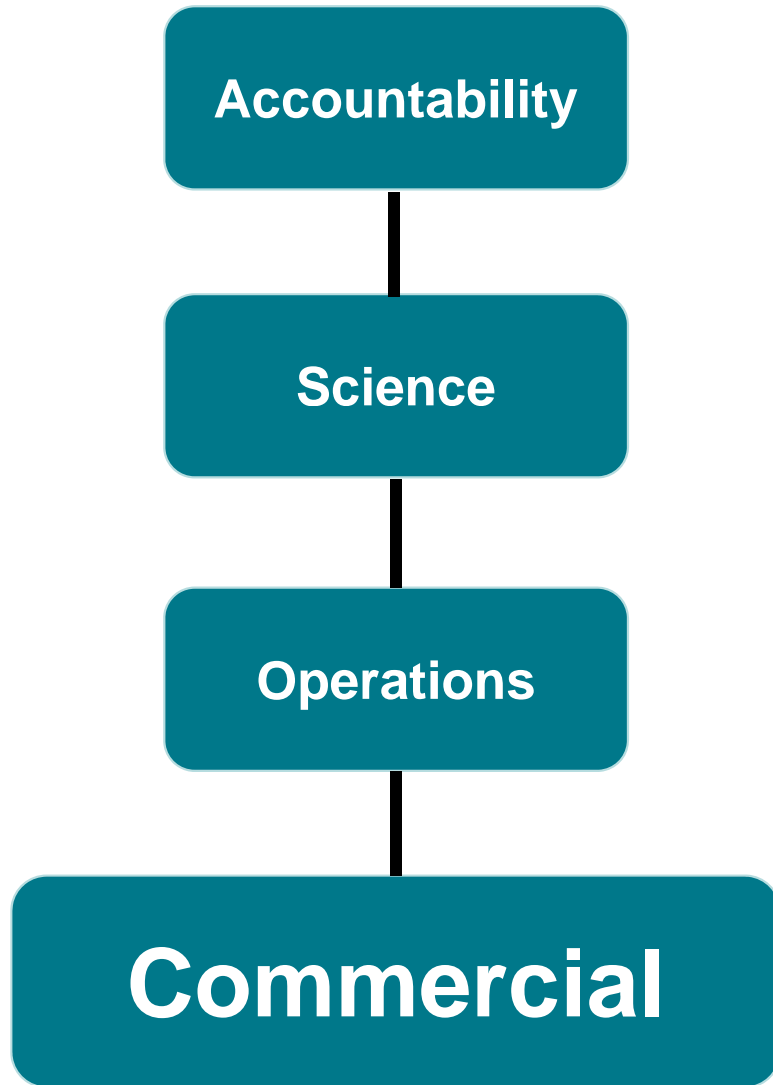
Governance structure - Ops



- **Points of contact**
 - **CRO Client Manager**
 - **Bioanalytical Science Manager**
- **Responsibility for deliverables**
- **Ownership of specific projects**
- **Day to day operational activities**



Governance structure - Commercial



- **Points of contact**
 - **CRO Business Development Manager**
 - **Sponsor Commercial Lead**
- **Contractual agreements**
- **CDA's**





Relationships in action - method transfers

Method transfers



Crucial and potentially challenging area of the Sponsor – CRO relationship

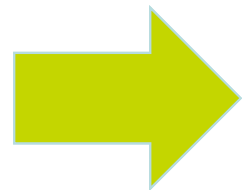
Early considerations:

What constitutes a transfer?

Availability of SOPs

Interpretation of method

Strategic approach



Generate data



Issues?



Probably!



Open dialogue is vital

Case Studies



PD

Challenge:

Poor precision and variable background.

Problem identified:

Analyte susceptible to environmental factors - open-plan lab identified as cause.

Solution:

Refurbished a dedicated clean-lab for the assay

ADA

Challenge:

Poor sensitivity with selected positive control

Problem identified:

Change in drug batch. Assay developed prior to availability of clinical batch.

Solution:

Assay re-optimised around the new critical reagents

PK

Challenge:

Variable backgrounds observed impacting the LLoQ

Problem identified:

Method intolerant of certain type of PBS.

Solution:

Defined a named PBS in the method work instruction

Learning points



- **Understand as much as possible about the assay**
 - What level of development has been performed?
 - SOPs, Method Work Instructions, Reports?

- **Visit the lab and perform the assay - understand the smaller details**

- **Details matter!**
 - Critical reagents
 - Reagent procurement
 - Labware and consumables
 - Lab equipment
 - Data

- **Share data – the scientist who developed the method may have seen comparable issues**

- **Define what a transfer is and understand the boundaries**
 - When does a transfer become a development project?

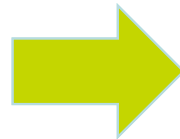
Transfer pack



Developed in conjunction with the Sponsor

Sponsor Transfer pack

- Full Protocols
- SOPs if required
- Full reagent list
- Validation Report



CRO Transfer process

- F2F visit
- Pre-defined experimental list

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Document Status: Draft

STANDARD OPERATING PROCEDURE
Method Transfer (Ligand Binding Assays)

Document Authorisation:

Owner	Andrew Roberts
Management	[Management Approver(s)]
Quality Assurance	[QA Approver(s)]

Changes Since Last Version:

Revision	Summary of Changes
1	Add a clear definition as to what constitutes a PK method transfer to LGC
2	Include reference to SOP0002 Critical Reagents Management
3.1	Change of wording to remove ambiguity of BUOON, limit of quantification samples and generally re-phrase to be concise in method transfer and to remove the requirement to use pooled samples from the sponsor
3.2.4	Remove the section on pooled samples as this will be required in method transfer
3.3.4	New section added to describe assay data assessment
3.3.8	New section about Critical Reagents
3.3.9	Remove the section on pooled samples as this will be required in method transfer
Appendix 1	No section detailing the plan/risk of the key experiments required for a method transfer

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PK



PD



ADA

- **Close Pharma-CRO relationships help get the most from outsourcing**
- **Case Study and Governance structure demonstrate example of shared commitment from both Sponsor and CRO**
- **Analytical projects will always encounter problems – managing problems and finding solutions as a team is crucial.**

Acknowledgements



- **Robin Longdin**
- **Andrew Roberts**
- **Clare Kingsley**
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- **Our Sponsors**



Thank you

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