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

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EBF Open Symposium, 18th November 2015
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

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

Accountability

- Oversight from top level management
- Review and management of KPI’s
- Long-term visibility
Governance structure - Science

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

Science

- Operations
- Commercial

© CBS
Governance structure - Ops

- **Accountability**
  - 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

Open dialogue is vital
### Case Studies

<table>
<thead>
<tr>
<th>PD</th>
<th>ADA</th>
<th>PK</th>
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</thead>
<tbody>
<tr>
<td><strong>Challenge:</strong></td>
<td><strong>Challenge:</strong></td>
<td><strong>Challenge:</strong></td>
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<tr>
<td>Poor precision and variable background.</td>
<td>Poor sensitivity with selected positive control</td>
<td>Variable backgrounds observed impacting the LLoQ</td>
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<tr>
<td><strong>Problem identified:</strong></td>
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<tr>
<td>Analyte susceptible to environmental factors - open-plan lab identified as cause.</td>
<td>Change in drug batch. Assay developed prior to availability of clinical batch.</td>
<td>Method intolerant of certain type of PBS.</td>
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<tr>
<td><strong>Solution:</strong></td>
<td><strong>Solution:</strong></td>
<td><strong>Solution:</strong></td>
</tr>
<tr>
<td>Refurbished a dedicated clean-lab for the assay</td>
<td>Assay re-optimised around the new critical reagents</td>
<td>Defined a named PBS in the method work instruction</td>
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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

PK  PD  ADA
Summary

• 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
• Zafar Alam

• Our Sponsors
Thank you

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