Strategische Partnerschaften von Sponsoren und Dienstleistern in der klinischen Entwicklung – True Value?

PPH plus - IX. Interdisziplinäres Expertengespräch
Frankfurt, 16. Mai 2014
# Sourcing Decisions Algorithm

<table>
<thead>
<tr>
<th>Depth of Lilly’s TA experience</th>
<th>Project</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Weak</td>
</tr>
<tr>
<td></td>
<td>- No/limited expertise</td>
</tr>
<tr>
<td></td>
<td>- Limited KOL relationships</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trial resource intensity</th>
<th>Functional</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Strong</td>
</tr>
<tr>
<td></td>
<td>- Significant expertise</td>
</tr>
<tr>
<td></td>
<td>- Strong KOL relationships</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound novelty</th>
<th>Project</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Low novelty</td>
</tr>
<tr>
<td></td>
<td>- Second in-class</td>
</tr>
<tr>
<td></td>
<td>- Line extensions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Value proposition</th>
<th>Functional</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• More certain value proposition</td>
</tr>
<tr>
<td></td>
<td>- Placebo trials to prove differentiation</td>
</tr>
<tr>
<td></td>
<td>- Strong efficacy in prior trials</td>
</tr>
</tbody>
</table>

* Other considerations are placement of ongoing work, volume commitments, volume discount rates and supplier diversity initiatives.
## Sourcing Model Distinctions

<table>
<thead>
<tr>
<th>Quality</th>
<th>Role</th>
<th>Process</th>
<th>Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standards</td>
<td>Lilly</td>
<td>Lilly</td>
<td>Lilly</td>
</tr>
<tr>
<td>Procedures</td>
<td>Lilly</td>
<td>TPO</td>
<td>TPO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Work</th>
<th>Role</th>
<th>Process</th>
<th>Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment method</td>
<td>FTE rate</td>
<td>Activity or Deliverable unit pricing</td>
<td>Milestones</td>
</tr>
<tr>
<td>Forecast Volume</td>
<td>Lilly Function</td>
<td>Lilly Function</td>
<td>TPO</td>
</tr>
<tr>
<td>Resource Planning</td>
<td>Lilly</td>
<td>TPO</td>
<td>TPO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Integration</th>
<th>Role</th>
<th>Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM Accountability</td>
<td>Lilly</td>
<td>TPO – Process, Lilly - Project</td>
</tr>
<tr>
<td>Data Integration</td>
<td>Lilly</td>
<td>Lilly</td>
</tr>
</tbody>
</table>

TPO = Third Party Organisation
Lilly’s Transformation Makes Positive Impact

“...the agreements with Quintiles and i3 Statprobe... represent significant changes in Lilly’s drug development model and indicate a shift in how major pharmaceutical companies will work with CROs in the future.”

“The strategic partnership differs from a traditional staff augmentation model or tactical outsourcing agreement in many ways, beginning with the joint planning carried out between the two organizations.”

“...relationship design and relationship management issues will be key to the success of these deals and other strategic partnerships... the new job at Lilly is to make it work, not to shadow these companies or duplicate their activities”

“...this is a landmark announcement of a major pharma really looking to use CROs as strategic partners in a very different way from the usual purchase of services”
Clinical Operations Partner by Region

North American Operations - Supported by QUINTILES®

EU - Supported by ICON

AMERIT – Supported by QUINTILES®

Latin America – Supported by QUINTILES®

Asia Pacific - Supported by PAREXEL

AMERIT = Africa, Middle East, Russia, India, Turkey
Goals and Intent of Outsourcing

- **Cost** (fixed and total)
- **Complexity** (no. of CROs, CRO oversight)
- **Capability** (focus on sponsor/CRO core competencies)
- **Flexibility** (Idle capacity, allocate studies where patients are)
- **Speed** (cycle times)
- **Productivity** (e.g. use of CRO infrastructure)
- **Quality**
Guiding Principles

- Core capabilities (customer centricity) to be maintained by Lilly
- Continue to increase productivity strategically
- Maintain global quality standards
- Remain cost-competitive and efficient
- Reduce headcount
- Increase flexibility
- Deliverables-based pricing model for outsourced services
Single Global Business Model

Clinical Development Consultants

Relationship Management
- Establish and maintain inv. sites and clinical research leaders
- Study feasibility
- Site identification, evaluation and selection
- Enrollment plan dev. & mgmt
- Issue escalation/resolution

Study Start-up

Site Activation
- CA application
- ERB submission
- Contracts and Budgets Payments

Site Monitoring
- Monitoring Plan development & execution
- Site training
- Monitoring visit reporting
- Query resolution
- Issue resolution/escalation

Country Study Manager
- Country/Region level
- Study Management/ Feasibility
- Enrollment Readiness Training
- Country/Region Enrollment

*Rely on strategic partners for this Capability*
Results and Challenges

Results
• Delivery on the portfolio is reliable and improved (enrolment to plan)
• Since implementation of deliverables model, cost savings are exceeding the business case
• Proportion of non-enrolling sites has decreased
• Investigator feedback is positive
• Headcount reduction

Challenges
• Understanding of the model by external and internal stakeholders
• Understanding of expectations (accountability, pro-activity), inter-faces, and processes in both companies
• Agreeing on Key Performance Indicators/Metrics
• Technology (integration of databases, collaboration sites)
• Continuous communication needed
Summary – goal (blue arrows) vs actual (comment in red)

↓ Cost – only limited data available to make a statement, eventually
↓ Complexity - reduced
↑ Capability - improved
↑ Flexibility - increased
↑ Speed – slightly worsen
↑ Productivity - only limited data available to make a statement
← Quality - only limited data available to make a statement
Damit das Mögliche entsteht, muss immer wieder das Unmögliche versucht werden.

Hermann Hesse