When Outsourcing Stops Making Sense

A Case Study To Help You Consider Your Options

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Where you can get these slides

www.cytel.com
What You Will Learn

1. Outsourcing is a fact of life because it offers important benefits: 1. Cost savings, 2. More labor flexibility, 3. Access to specialized skills

2. Offshore-outsourcing for cost alone is risky because the short-run benefits may be reversed quicker than it takes to realize true gains

3. Simple ROI calculations and auction-style bidding, which may accompany the drive to reduce costs, do not provide an adequate picture nor a good way to choose an outsourced clinical partner

4. Offshore-outsourcing works in many situations – several of these will be indicated
What’s Driving Outsourcing?

Big-pharma’s urgent need of flexibility in structural costs:

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>2012 Rx Sales</th>
<th>R&amp;D spend</th>
<th>R&amp;D/% of Sales</th>
<th>2011 Rx Sales</th>
<th>R&amp;D spend</th>
<th>R&amp;D/% of Sales</th>
<th>Change in Rx Sales</th>
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<tr>
<td>1</td>
<td>Pfizer</td>
<td>$47.4bn</td>
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<td>$57.7bn</td>
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<td>$54.0bn</td>
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<td>23.0%</td>
<td>($3.4bn)</td>
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</table>

Source Pharma Executive, Top 50 Pharmaceutical Companies in 2012
Why do sponsors say they outsource?

1. Reduced costs (53%)
2. Improved quality (43%)
3. Improved efficiency in use of internal staff (43%)
4. Access to operational expertise (43%)
5. Process improvement (30%)\(^1\)

Offshoring: does it work most of the time?

59% of sponsors said after 3yrs they were getting worse quality than in-house \(^1\)

Maybe We Have it Backwards?

1. Access to highly specialized capabilities\(^1\)
2. Remove non-core activities and increase focus on core
3. Increase flexibility of workload peaks & troughs
4. Short-run gross margin incentives
5. Avoidance of regulations, taxes, energy costs, labor benefits
6. Lower cost of labor

\(^1\) Such as clinicians, patients, monitors, advanced skills such as adaptive trial simulation, DMC experience
Quality is a constant companion of outsourcing

Rework and quality: 22% of sponsor companies surveyed by Avoca reported having discontinued strategic relationships ... because of poor quality of deliverables,

http://www2.theavocagroup.com/

Avoid the Problems & Reap the Benefits

DO

- Outsource for increased workload flexibility
- Outsource to gain skills you do not have
- Outsource to increase home-team’s focus on work you cannot outsource
- Set expectations appropriately
  - Plan start-up time realistically
  - Expect significant cultural, communication issues, know what they are and train
  - Do transfers between partner and offshore staff
- Carefully select a partner with experience and reputation in your field
- Set up KPI’s & monitor closely
- Adjust early and often
Avoid the Problems & Reap the Benefits

DON’T

- Outsource for short-term cost savings
- Select your partner on price alone
- Outsource if it would result in depletion of core competencies
- Expect immediate gains
- Don’t expect your IT provider to do your statistical programming offshoring
- Expect outsourcing to solve your workflow or business process problems
Increased constraints in labor flow: fewer H1B’s

**Reduced** constraints on movement of capital and goods
- Reduced banking regulations, increasingly global flow of electronic funds
- Increased ease, decreased costs of transportation

**Radically decreasing** communication costs
- These act to reduce geographic concentration of industrial development
- And lower the cost to spread ideas & practice which results in improved coordination and efficiency within corporations across countries

**Increased** technology enables more tasks to be offshored
- A SAS program written in Massachusetts can run trial analysis in India

**Increased** educational investment & social incentives in developing south for technical & scientific capability vs developed north

**Wage Convergence** is probably not an issue yet
- Monetary policy and politics could change that quickly
Increasingly constrained labor flows
Immigration Reforms

1. Current USA Immigration Reform proposals\(^1\) will affect offshore business
2. Restrictions on the placement H-1B employees at the client’s location increases costs & puts offshore model at risk
3. Indian outsourcing providers are looking at US acquisitions and larger presence in smaller US cities

\(^1\)“This bill negatively affects many of the largest companies in the US who use our services because of the shortage of science, technology, engineering, maths graduates in the USA,” said R Chandrasekaran, group chief executive at Cognizant

Publication: The Economic Times Mumbai; Date: May 13, 2013;
Less Regulation on movement of capital & goods, radically decreased communications costs, massive increase in availability of computational power …

… act to spread ideas & practice, improve coordination and efficiency within corporations across countries & create new competitive opportunities
Technology enables more tasks to be offshored

Chief economist with Morgan Stanley, Stephen Roach:

“The internet has forever changed the competitive climate for most white-collar knowledge workers. Courtesy of near-ubiquitous connectivity, the output of the knowledge worker can now be emailed to a desktop anywhere in the world. That brings low-cost, well-trained, highly-educated workers in Bangalore, Shanghai and Eastern and Central Europe into the global knowledge-worker pool.”
Economics: Wage Convergence

... wiping out the benefit of labor arbitrage-based outsourcing and with it the competitiveness and industrial base of the developed economies
Boosting EMD Serono’s Biostatistics & Programming with a Cytel “Extension Arm”

Sponsor’s Challenge
EMD Serono is conducting clinical studies in multiple therapeutic areas, including oncology and multiple sclerosis.

The company seeks a flexible, scalable resourcing model to meet additional R&D demands without raising head-count.

To increase their biostats and programming capacity, EMD Serono turns to Cytel.

The Cytel-staffed “extension arm” must:
• lower costs, yet deliver qualified clinical stats and SAS and R talent
• adhere to EMD Serono standards
• limit start-up disruptions
Creating the External Arm
Team-building for EMD Serono

Responses

Assemble qualified team - Cytel assembles a team of qualified biostatisticians and SAS and R programmers from our Indian offices.

Co-develop start-up strategy – together, construct a plan addressing typical outsourcing challenges – especially requisite skill level fulfillment and synchronizing distributed work centers.

Monitor and adapt - progress and quality of the extension team’s work is carefully monitored both by both Cytel and EMD Serono managers.
No Startup Disruptions

COMPLETELY SPECIFY PERFORMANCE CRITERIA FROM THE START:

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<td>Non-Solicitation of Employees</td>
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<td>Projects</td>
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<td>3.</td>
<td>SERVICE LEVELS AND CUSTOMER SATISFACTION</td>
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<td>3.1</td>
<td>General</td>
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<td>3.2</td>
<td>Service Level Failure</td>
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<td>3.3</td>
<td>Cooperation with Third Parties</td>
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<td>3.4</td>
<td>Excused Performance</td>
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<td>3.5</td>
<td>Periodic Reviews</td>
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<td>3.6</td>
<td>Measurement and Monitoring Tools</td>
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<td>3.7</td>
<td>Third Party Provider Performance Data</td>
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<td>3.8</td>
<td>Service Level Reporting</td>
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<td>Quarterly Reporting</td>
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<td>3.10</td>
<td>Customer Satisfaction Surveys</td>
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<td>4.</td>
<td>COVENANTS OF PROVIDER</td>
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<td>Maintenance</td>
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<td>4.2</td>
<td>Completion of Milestones and Deliverables</td>
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<td>4.3</td>
<td>Facilities and Space</td>
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<td>4.4</td>
<td>Dedicated Personnel</td>
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<td>Quality Assurance</td>
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<td>4.7</td>
<td>Conflicts</td>
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<td>4.8</td>
<td>Use of Third Party Intellectual Property</td>
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<td>4.9</td>
<td>Evidence of Compliance</td>
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<tr>
<td>4.10</td>
<td>Competitors</td>
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The EMD Serono project is a great example of setting expectations realistically and managing the delivery carefully ...

... with the result that cost savings are a consequence of the decision without compromising the quality and flexibility Serono demanded.

Outcomes
The extension team is now functionally integrated with EMD Serono’s own biostatisticians and statistical programmers in Europe and the US.

The additional resources also can flexibly scale to cope with future or resource bottlenecks anticipated or unforeseen.

Ajay Sathe
Chief Executive, Indian Operations
Cytel Inc.
Summary

1. The offshore/outsourcing model brings benefits that are here to stay:
   i) Cost savings, ii) More labor flexibility, and iii) Access to specialized skills

2. Don’t outsource for cost benefit alone because the short-run benefits may be reversed by economic or political challenges quicker than it takes to realize true gains

3. Don’t expect ROI calculations to tell the truth
   The realities of start-up costs, bridging the experience chasm, true managerial overhead, large relative regional productivity differences, rework or non-tangible drawbacks such as customer service, staff turn-over, cultural barriers .... are much more nuanced

4. Use a common-sense approach to balance outsourcing and offshoring that works for your situation
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Thank you.

Your comments or questions?

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