

Evaluation of Outsourcing Models

Strategic partnerships fact or fiction?

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Gilead Sciences

Disclaimer

- The opinions expressed are my own and not representative of my Company and blah, blah blah...the usual stuff

Agenda

- Why outsource
- Sourcing models
- The relationship continuum
- Partnerships in Other Industries
- Early examples in Pharma
- Where's the data – Tufts, Avoca
- A view from both sides of the fence
- What are the challenges
- “Vested Outsourcing”

Why Outsource

Access to expertise, new technology, geographies

Staff augmentation to respond to peak and troughs

Switch fixed to variable costs

Cost savings

Focus on core competencies

Sourcing Models

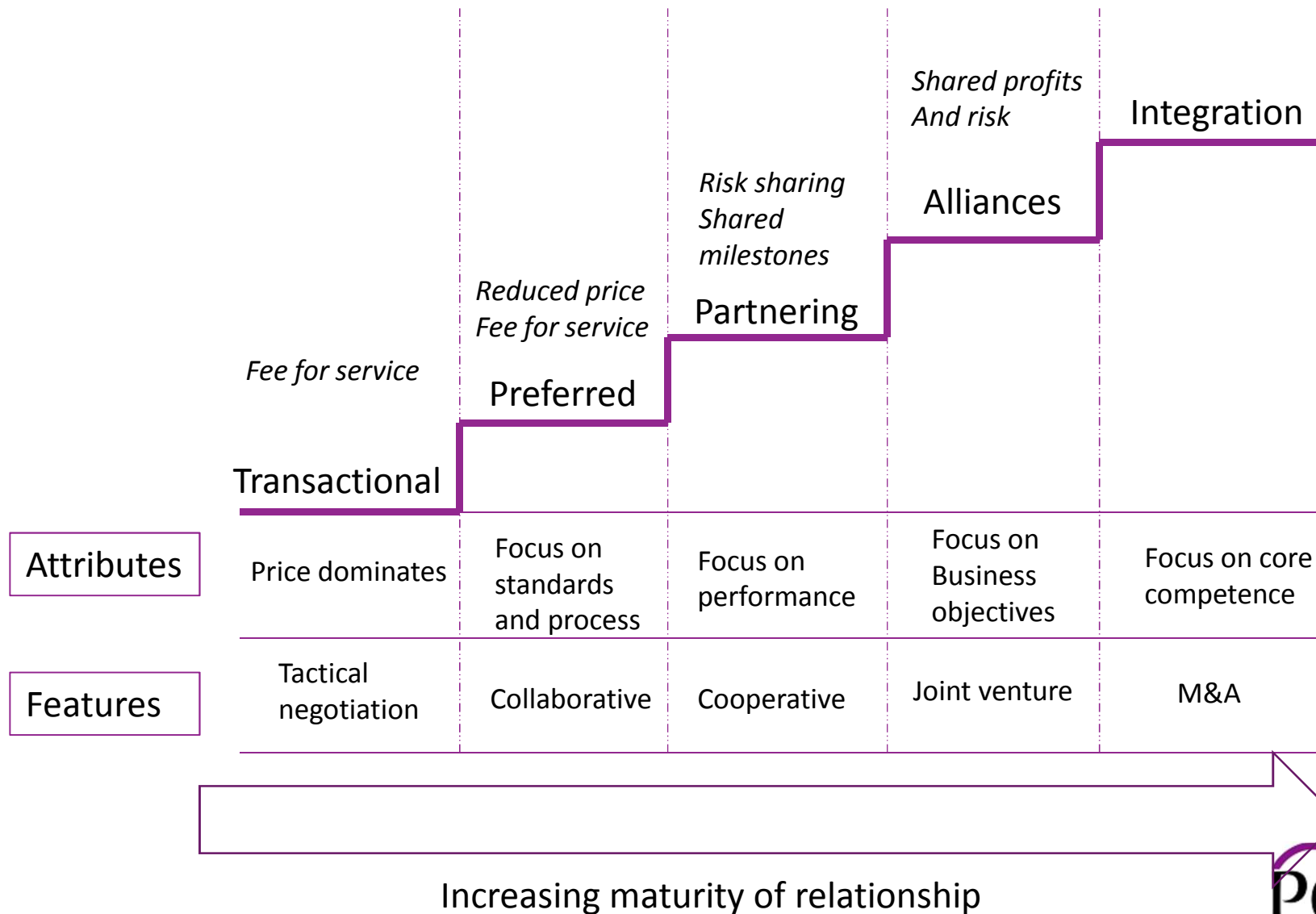
Full service outsourcing

Functional service provider

Insourcing

Hybrids

The Relationship Continuum



Partnerships in Other industries

- Late 1980's Chrysler used outsourcing to improve non core functions
- In early 1990s US Department of Defence began competing internal activities against external market place to generate savings (on average 20%)
- General motors outsourced accounts and payroll and realised 20% cost reductions

Early examples in the Pharma Industry

- Quintiles – HMR (1999)
 - Hoechst Marion Roussel divested Research facility and staff to Quintiles in return for guaranteed revenues over a 5 year period
- Wyeth – Accenture (2004)
 - Wyeth outsourced all data management activities in ground breaking deal to Accenture with detailed operating level and service level agreements for performance.

Embargo : October 14, 2004 at 8:30 AM

**NOVEL AGREEMENT WITH QUINTILES/PHARMABIO
DEVELOPMENT ACCELERATES THROUGHPUT
OF SOLVAY PHARMACEUTICALS R&D PIPELINE**

Clinical development specialist endorses SOLVAY'S R&D Portfolio

SOLVAY PHARMACEUTICALS and QUINTILES today announce, with immediate effect, a novel agreement that will effectively double the capacity to process SOLVAY'S early clinical projects.

Under the agreement, PHARMABIO DEVELOPMENT, QUINTILES' partnering affiliate, will provide \$25m of QUINTILES' development services for selected SOLVAY PHARMACEUTICALS clinical phase-two projects, thereby bearing around 50% of the normal costs and the uncertainties of the outcomes for these projects. In return, PHARMABIO will receive a milestone payment from SOLVAY PHARMACEUTICALS for each of the compounds reaching positive clinical proof-of-principle and moving into further development. Following on from previously announced deals between SOLVAY PHARMACEUTICALS and LUNDBECK and WYETH for schizophrenia treatments, and SOLVAY and BRISTOL-MYERS SQUIBB for obesity treatments, this agreement with QUINTILES constitutes further third-party interest in the potential of SOLVAY PHARMACEUTICALS' pipeline.



What are the Benefits to Solvay ?

- ▶ Access to people, processes and global core competencies from Quintiles.
- ▶ Reduced costs due to economies of scale.
- ▶ The capability to move faster – to issue “go” or “no go” decisions regarding new compounds.
- ▶ Access to patients and investigators – the most limited resource in clinical development.
- ▶ For each year saved in studies, Solvay gains one year of patent protected peak sales.
- ▶ Reduction in CRO contract management

FLEXIBILITY & SPEED

Mid size pharma with global large scale capabilities



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Solvay – Quintiles partnership

- ▶ In 2001 Solvay Pharmaceuticals and Quintiles signed an agreement to work together to bring new drugs to market.
- ▶ At that time this agreement was considered to be Breakthrough in Industry.
- ▶ The goal was to increase the value of Solvay' pipeline by processing more compounds and increasing speed of development projects.



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What are the Benefits to Quintiles?

- ▶ A more predictable revenue stream allows for more accurate long-term planning and growth.
- ▶ A shift from tactical transactional activities towards a true sharing relationship.
- ▶ Its vast global expertise can be used in a more efficient manner, which benefits both organizations.
- ▶ Quintiles has wanted to move more closely to the strategic decision making of drug development with customers.
- ▶ Can deliver strategic services to the customer (more value add)
- ▶ No cost for business development



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Pre Requisites

- ▶ Trust
- ▶ Commitment from all stakeholders
- ▶ **Invest in People issues**
- ▶ Redefinition of the business model in Pharma and CRO
- ▶ Accept Risk when changing the model and apply Risk mitigation



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Challenges

Plenty

Mostly related to People

- ▶ Model is against CRO nature. (billable hours, maximize profit per study, change order to the maximum, risk avoidance)
- ▶ Cooperation is difficult, in particular across company boundaries
- ▶ Pharma likes to be king and micromanage
- ▶ Pharma only knows best
- ▶ CRO staff turn over

✱ **Solution: Training, Training, Coaching, Management and Leadership**



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Conclusions

- ▶ It deliver results:
 - All pivotal studies were of good quality
 - Achieved 3 submissions in the 1st 5years of the alliance.
(On time, a bit above budget)
- ▶ Increased the value of our pipeline considerable
- ▶ It delivered large scale clinical operations capabilities to mid size Pharma
- ▶ **Biggest pay back is: reduction in time and value of the pipeline**



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Conclusions (2)

- ▶ Our relationship proves that it is possible to **successfully** change the paradigm between Client & CRO
- ▶ It is an **evolutionary** process
 - ▶ Everyday is a new learning experience for both Solvay & Quintiles and the Alliance
- ▶ It has **commitment** throughout BOTH organisations at ALL levels



It's Working!!



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Doing More with Less: A Novel Approach to Outsourcing Clinical Trials

November 6, 2007

Daniel J. Nardi
Executive Director
Research Procurement, Merck Global Procurement

6th Annual Partnerships in Clinical Trials

Amsterdam RAI, The Netherlands

PCMG CONSULTING GROUP



Key Outsourcing Learnings

Make the shift from "Doing the work" to "Oversight and Management of the work"

Build capability for efficient and effective outsourced activities, trials and programs

- Maximize communication and minimize hand-offs
- Utilize vendor systems and processes when possible and appropriate

Constantly challenge our assumptions about what must be done internally vs. externally

Internal governance structure and leadership commitment are success factors

Continuous Improvement

- Build processes on the ability to rapidly integrate best practices and respond to business changes

Establish performance metrics

- Ensure Supplier meets required service levels and continuous improvement

Two-Way Learning: leverage Merck's competitive advantage

- Merck has the fastest cycle time from Protocol Approval to LPE



10

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The Importance of Outsourcing in Our Future

Supports a lean and flexible business model

Reduces the need to expand our infrastructure as our clinical development portfolio grows

Allows Merck to strengthen its core capabilities and scientific leadership

Offers a competitive cost structure including the ability to leverage emerging market capabilities

Supports therapeutic areas and functions that are not core to Merck



8

Characteristics of a Partnership

Alignment of Merck and Partner culture and mission

Trust and collaboration

Pricing transparency

Benefit and risk sharing between partners

Executive-level governance and relationship management

Joint capacity planning and book of business review

Relationship is optimized across all business lines

Performance metrics that drive continuous improvement: speed and quality

New collaboration opportunities are assessed



18

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More recent examples

- PRA – Takeda
- Merck IQVIA
- Biogen IQVIA

Where's the data?

Assessing True CRO Usage and Identifying Actionable Steps to Optimize Team Effectiveness

Ken Getz, MBA

*Director, Sponsored Research Program, Associate Professor
CSDD, Tufts University Medical School*

November 2015

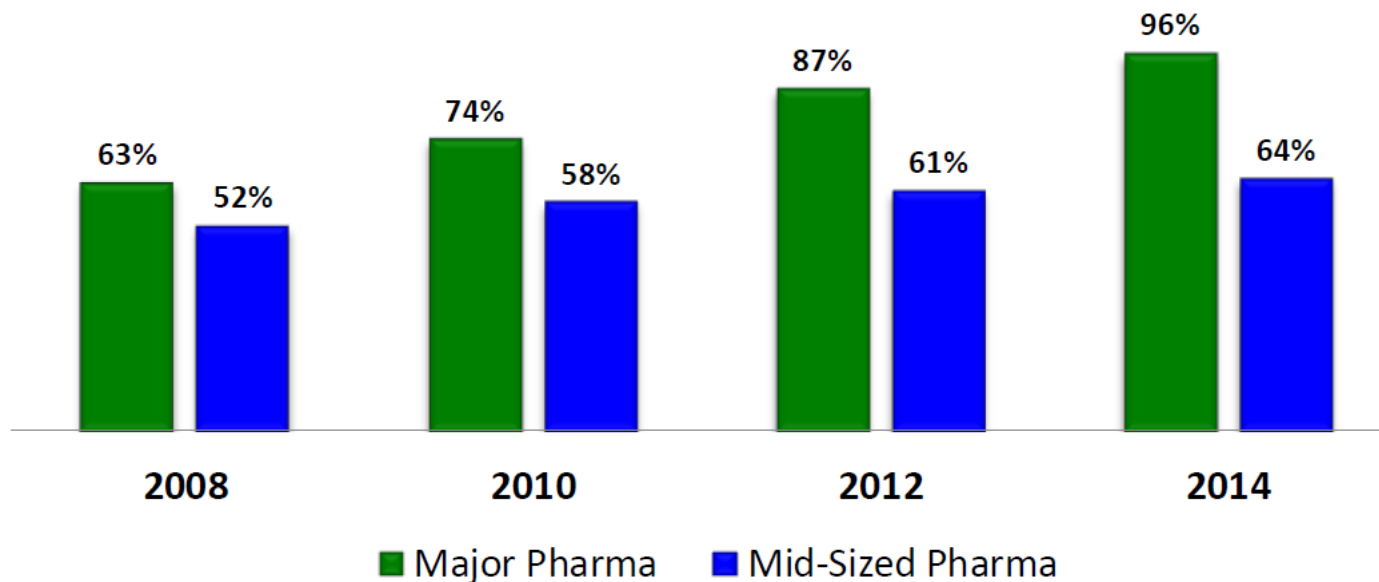


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Adoption of More Integrated Alliances

Proportion of Sponsors in at least One FSP or Integrated Alliance



Source: CenterWatch; N=~86 Sponsor Companies

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Tufts CSDD 2014 Study: **Outsourcing Models Used by 12 Sponsors on 43 phase II and III clinical trials**

Getz KA, Lamberti MJ, Kaitin KI. Taking the pulse of strategic outsourcing relationships. Clinical Therapeutics. 2014;36(10):1349-1355.

- **In no instance did a single CRO manage all functional areas supporting an individual phase II or III study. Sponsors vary the types of outsourcing relationship models that they use inconsistently, on a study-by-study basis.**
- **No statistically significant differences between relationship models across all but two performance and quality variables**
 - Integrated alliances had higher numbers of screen failure rates
 - Integrated alliances had lower frequencies of protocol amendments

Source: Tufts CSDD 2014; N=43 Phase II and III Studies.

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Study of Drug Development**
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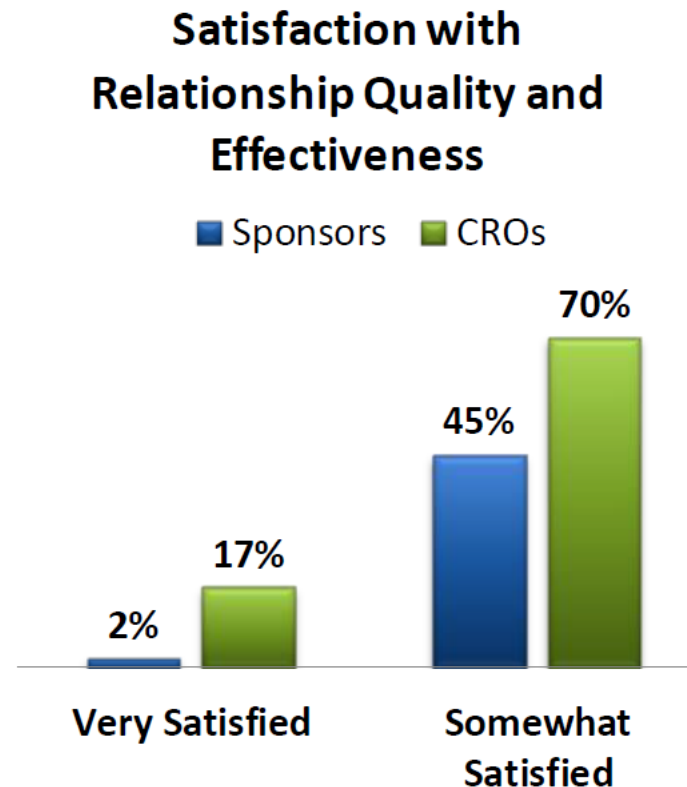
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Early Reports on Collaboration Promise

- **Tufts CSDD (2009) study** (N=116 Full Service vs. N=89 FSP/Alliance)
 - Significant start-up cycle time reduction
 - Significantly lower CRO staff turnover rates
- **Pfizer (2010)**
 - \$20 million net annual savings from consolidating management of 150 to 17 preferred vendors
 - 18-20% cost savings compared to prior outsourcing strategy
 - 26% enrollment cycle time improvements
 - 80% reduction in number of contracts delayed >120 days
- **Lilly (2011) on DM and Monitoring FSP Relationships**
 - 20% cost savings
 - 50% improvement in probability of site success
 - 38% cycle time improvements
 - 93% improvement in monthly patient enrollment volume

2011/12 Studies – More Mixed Reports

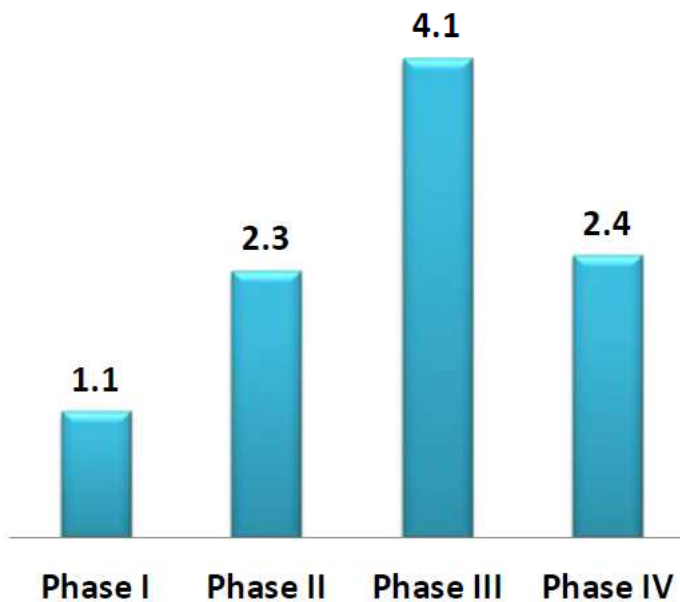
- 22% of 89 sponsors had terminated an integrated alliance
- 30% of 81 sponsors reported that alliances were failing to deliver expected cost and time savings
- 48% of 81 sponsors reported that CROs can't work collaboratively
 - 60% of 57 CROs said the same of their Sponsors



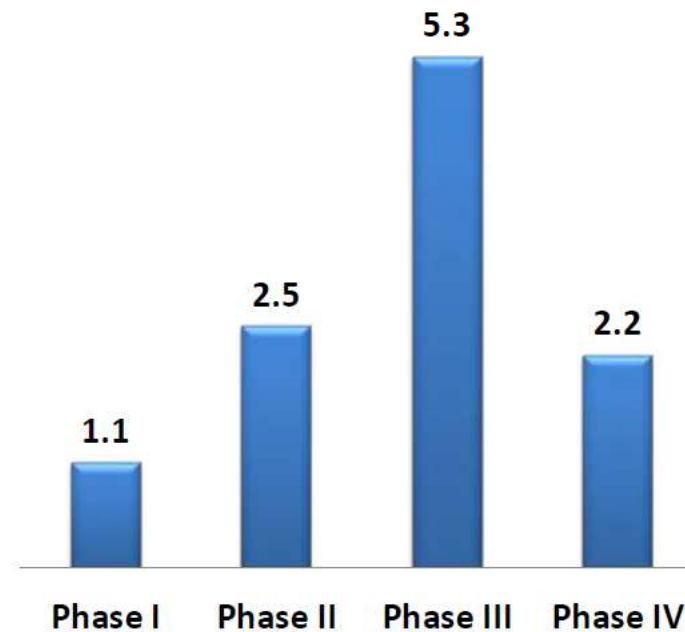
Sources: Vantage Partners, Avoca, TCSD

Tufts CSDD 2012 Study on Change Orders

Transactional Relationships (Average Number per Study)



Integrated Alliances (Average Number per Study)



Source: Tufts CSDD, 2012; N = 138 studies

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The 2016 Avoca Report

Strategic Partnerships Under Scrutiny:

A Renewed Look at the State of
Clinical Outsourcing

SPONSOR & PROVIDER
PERCEPTIONS

Avoca
THE AVOCA GROUP

October 2016

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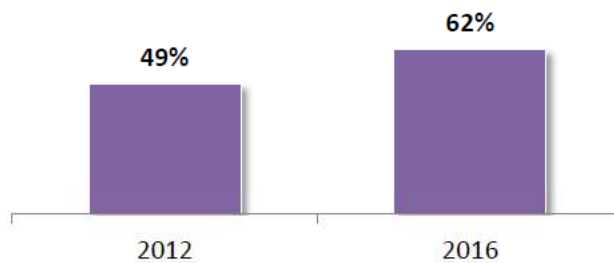


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Evolution of the Strategic Partnering Landscape

Strategic Partnering (SP), and the number of such relationships, is reported to have increased since 2012. Among those not engaging in SPs, lack of proper resources to establish and manage the partnership were top reasons.

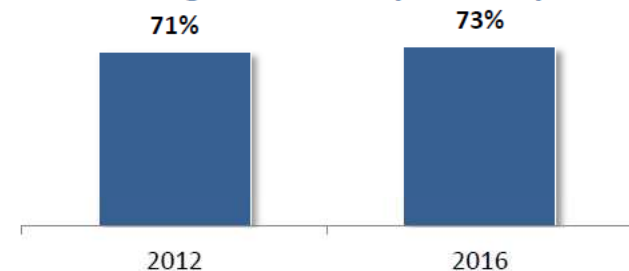
SPONSOR
% with Strategic Partnerships with Providers



Current Number of Strategic Partnerships



PROVIDER
% with Strategic Partnerships with Sponsors



Current Number of Strategic Partnerships



- Objectives
 - Sponsor reduced costs and increased efficiency
 - Provider business stability meeting customer needs

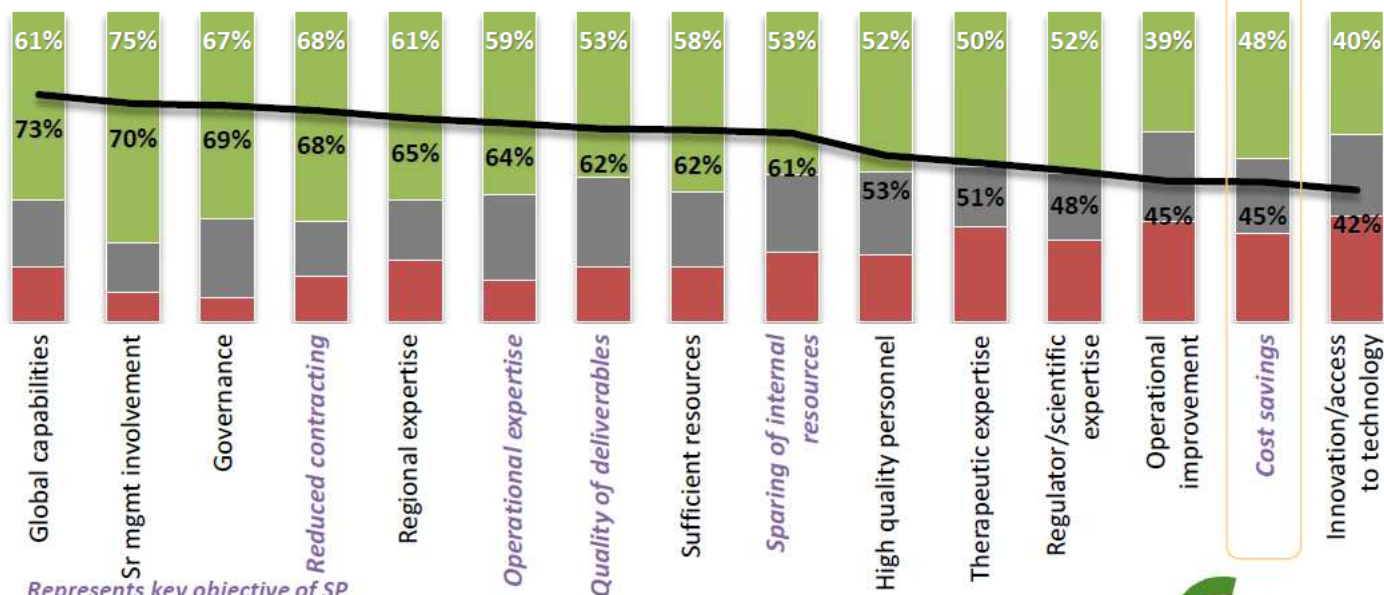
How are SPs Performing Against Objectives?

The more “functional” aspects of SPs (e.g., global capabilities, senior management involvement) are being realized more quickly and show greater satisfaction among Sponsors. Reduced costs, a key objective of SPs, is among the slowest to take hold, and is weakest with respect to meeting expectations.

Sponsor Ratings on Performance on SP Dimensions

Time to meet expectation/% SP has met/exceeded expectations

Never/not yet More than 1 year Within 1 year Generally meets/exceeds expectations



Represents key objective of SP

N: Sponsor=92-105

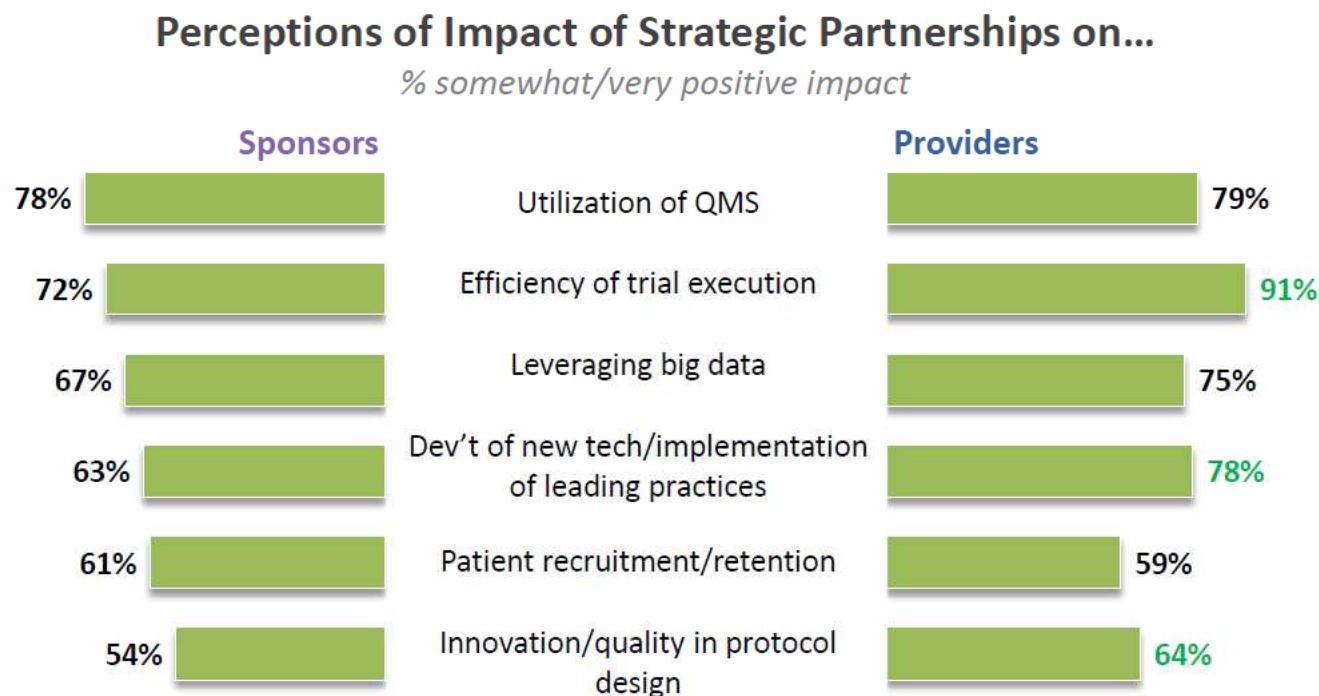
For each of the areas listed below, please indicate how long it took before the partnership “generally” met your expectations.

To date, please describe the extent to which this strategic partnership has met your expectations with respect to each of the following.



Impact of SPs on Aspects of Clinical Trial Execution

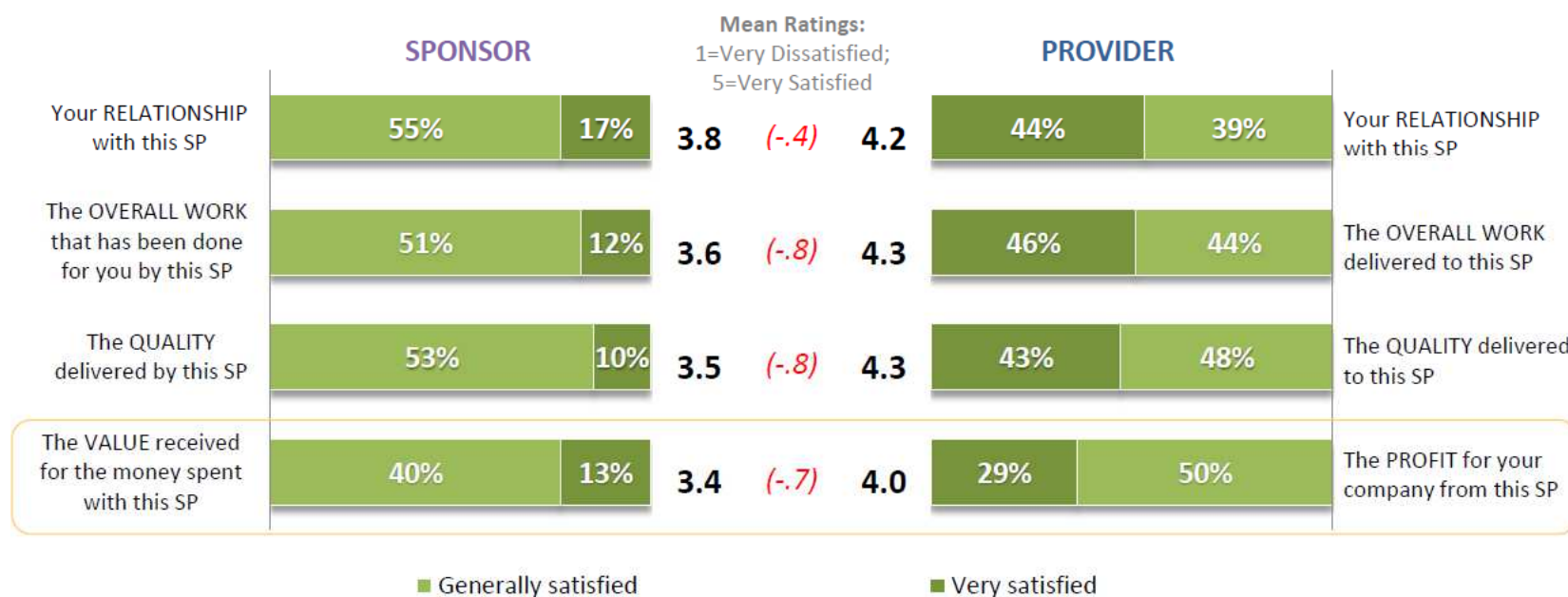
Both audiences believe that SPs have impact on key aspects of clinical trials, especially so for utilization of quality management systems and efficiency of trial execution. Providers show even greater favorability to the positive impact of SPs.



Satisfaction with Key Relationship Indicators

Overall, Sponsors and Providers report disparity in satisfaction with service delivery across key quality and relationship health attributes. 'Value for Money,' a key driver of entering into SPs for Sponsors, received the weakest satisfaction rating among Sponsors.

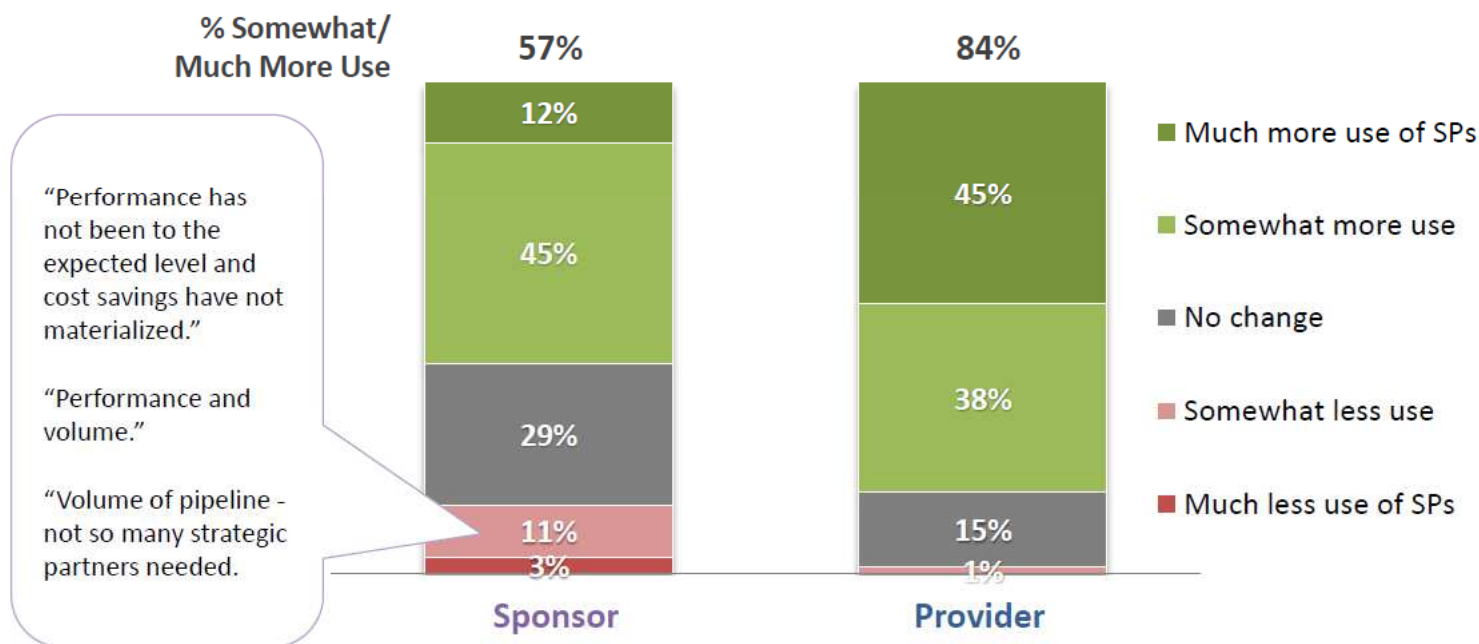
2016 Overall Assessment of Strategic Partnerships



Future Outlook on Strategic Partnering

Just over half of Sponsors who were surveyed said they anticipate greater usage of SPs in the near future; 84% of Providers reported the same. Among Sponsors who anticipate less usage, pipeline volume and performance were cited as key reasons.

Anticipated Use of Strategic Partnerships in Next 5 Years

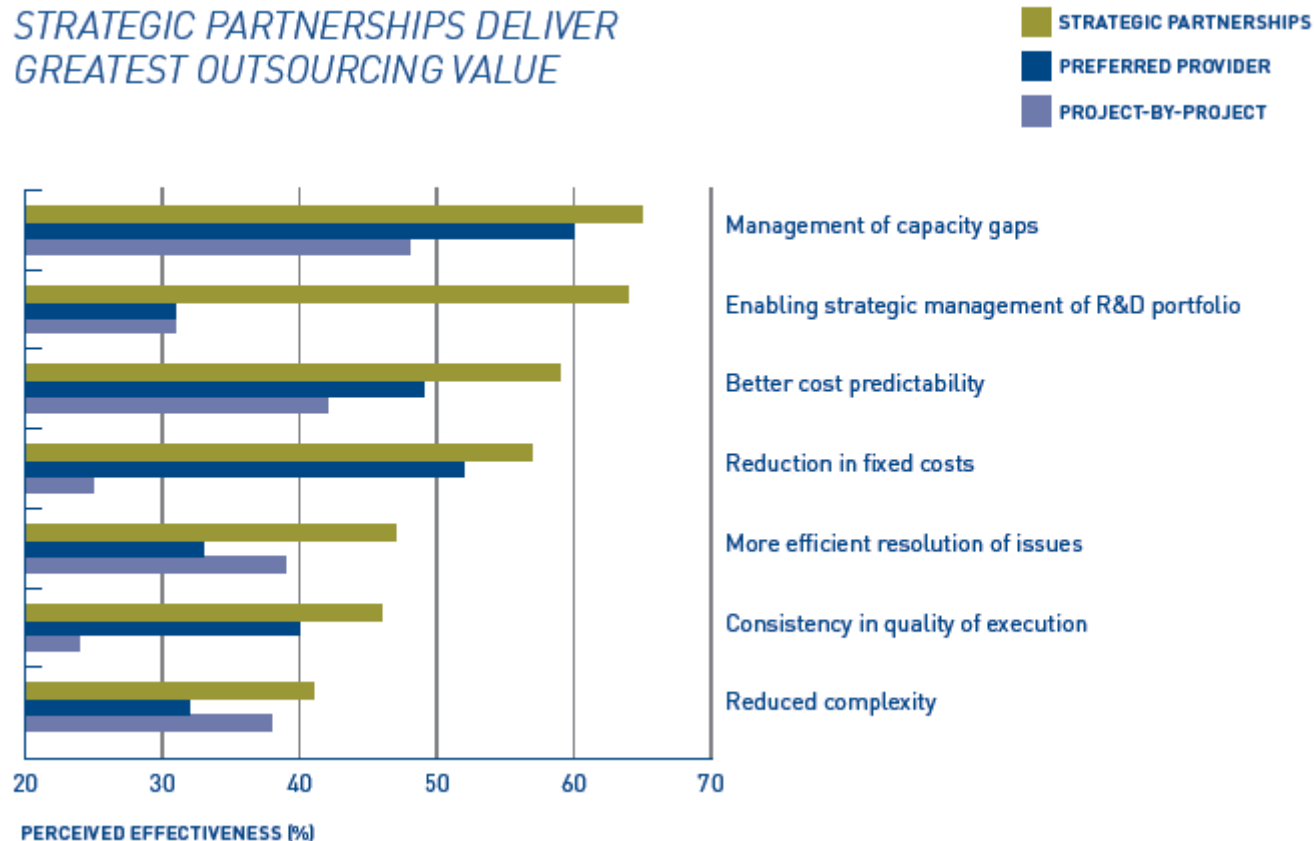


Parexel Strategic Relationships Report (2014)

- The Strategic Partnership model is perceived to be the most effective biopharmaceutical outsourcing approach in meeting a number of key sponsor needs
- Among biopharmaceutical companies surveyed, more than half now use a Strategic Partnership model.
- The Strategic Partnership model holds untapped potential to yield additional value and meet future biopharmaceutical industry needs.

STRATEGIC PARTNERSHIPS CONSIDERED MOST EFFECTIVE OUTSOURCING MODEL

STRATEGIC PARTNERSHIPS DELIVER GREATEST OUTSOURCING VALUE



“The Emperors new clothes”

- “...although the vision of Sponsor-CRO alliances...might sound appealingly noble, facts demonstrating real added value are hard to find and reasons to doubt are many.”
 - Long lasting relationship reduce flexibility, agility and competition
 - Governance is expensive
 - Integration introduces prohibitive exit costs

What are the challenges?

- Aligning objectives



What are the challenges?

- Commitment



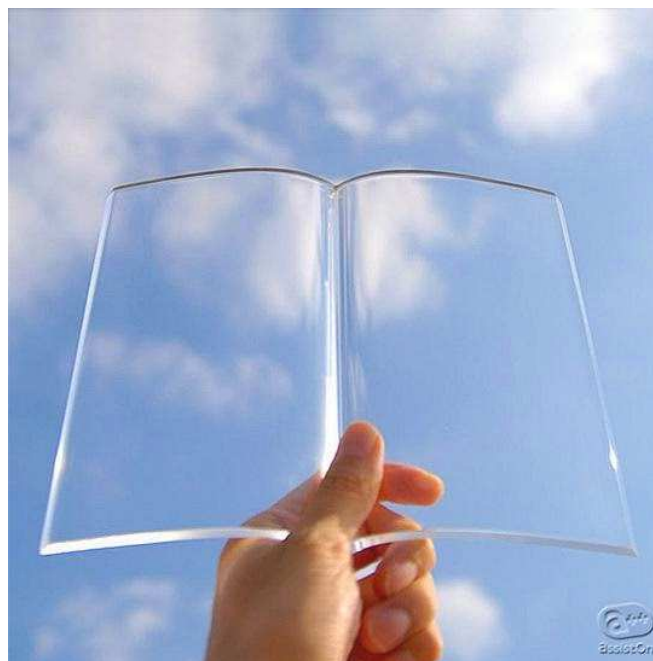
What are the challenges?

- Building the Infrastructure?



What are the challenges?

- Transparency



What are the challenges?

- Developing Trust



What are the challenges?

- Defining Core Competencies



What are the challenges?

- Managing performance



What are the challenges?

- Managing Risk



A few more practical considerations

- From “Change orders, necessary evil or avoidable pain?” Copestake and Webber PCMG Annual Conference June 2018

There is a spectrum of outsourcing approaches



Outsource for Capacity

- Sponsor manages and makes all decisions
- CRO commits to provide trained resources (FTEs)
- Sponsor manages all risk
- CRO follows Sponsor processes
- Contract scoped at high level, pay for FTEs

Outsource for Expertise

- CRO manages and makes all operational decisions (within parameters)
- Sponsor performs oversight
- CRO commits to deliver to project
- CRO manages risk within its control with agreed mitigation plans
- CRO follows own processes
- Contract scope focused on outcomes, pay for outcomes



In Practice there is a confusing mix

Outsource for Capacity

- Sponsor manages and makes all decisions
- CRO commits to provide trained resources (FTEs)
- Sponsor manages all project processes
- CRO follows Sponsor processes
- Accountable only for provision of resource
- Contract scope at highest level, pay for FTEs

- Sponsors need resources but consider they retain the expertise

- Sponsor makes most of the decisions
- Sponsor tries to hold the CRO accountable for delivery with limited success
- A mixture of sponsor and CRO processes are used
- Project scope is defined in great detail with frequent changes leading to large number of amendments and budget overruns
- There is little clarity around responsibility for risk management

Outsource for Expertise

- Sponsor manages and makes all operational decisions (within parameters)
- CRO commits to deliver to project
- CRO manages risk within its processes with agreed plans
- CRO follows own processes
- Accountable for delivery
- Contract scope focused on outcomes, pay for outcomes

In Practice there is a confusing mix (2)



Outsource for Capacity

- Sponsor manages and makes all decisions
- CRO commits to provide trained resources (FTEs)
- Sponsor manages all risk
- CRO follows Sponsor processes
- Accountable only for provision of resource
- Contract scope pay for FTEs

- CRO not given time to adequately prepare their bid
- CRO does not correctly assess the risks associated with project delivery
- A mixture of Sponsor and CRO processes are used
- Sponsors still insist on the project scope being defined in great detail
- Lack of transparency of CRO costs & profit models
- Poor alignment on how to agree on outcomes and assess project success

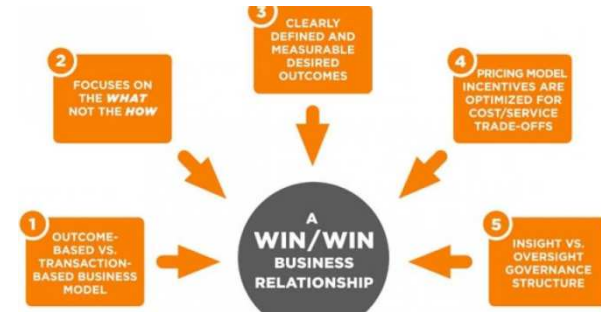
Outsource for Expertise

- CRO manages and makes all operational decisions (within parameters)
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- CRO follows own processes
- Accountable for delivery
- Contract scope focused on outcomes, pay for outcomes



“Vested outsourcing”

Based on research with University of Tennessee and United States Air Force.

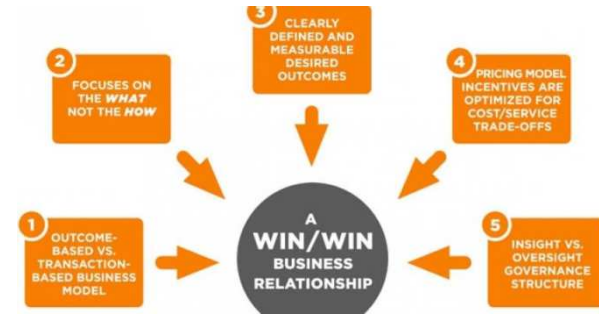


Key attributes:

- Focus on outcomes, not transactions
- Focus on the WHAT, not the HOW
- Agree on clearly defined and measurable outcomes
- Optimise pricing model incentives
- Governance provides insight not just oversight

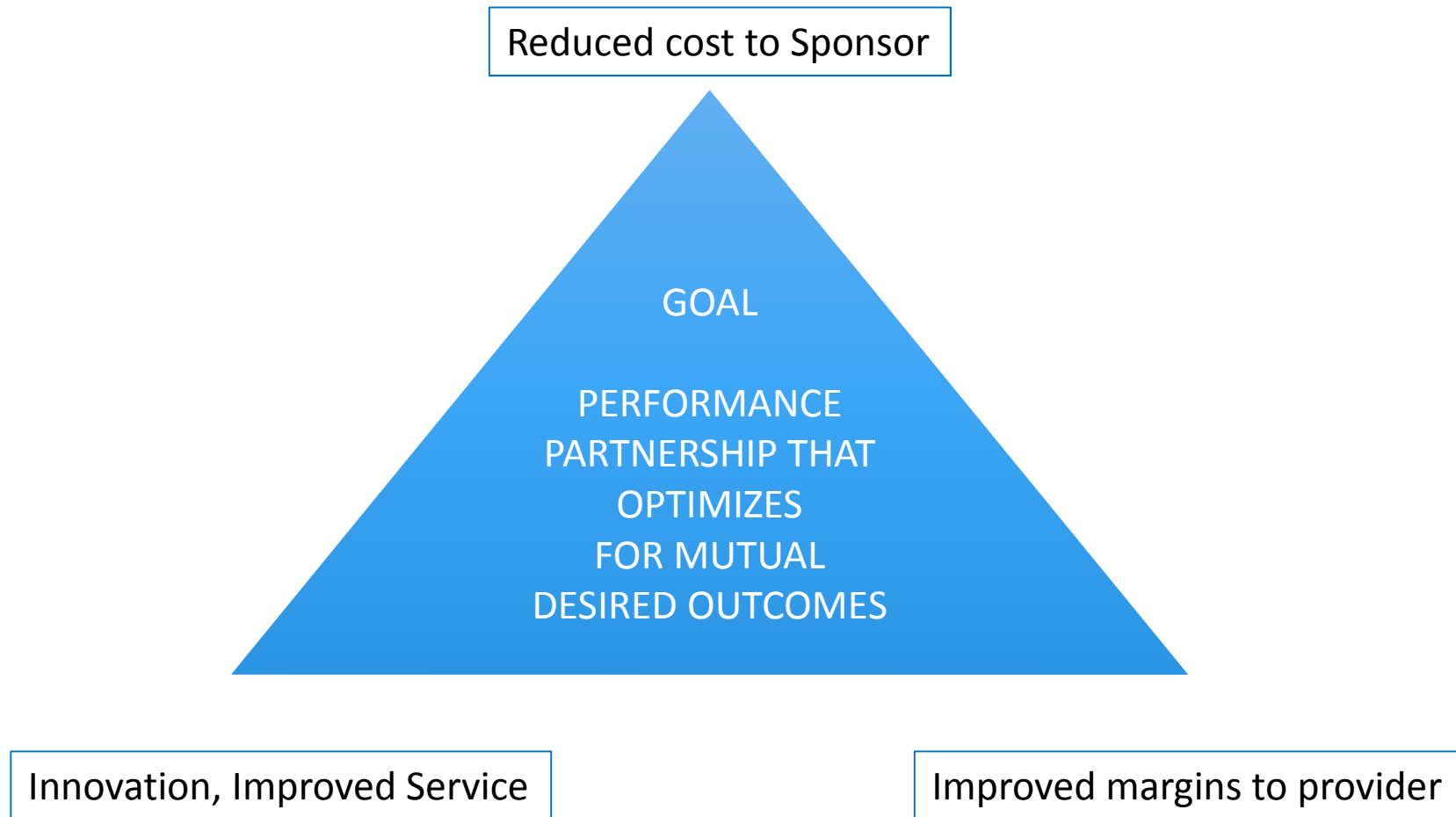
“Vested Outsourcing” – Kate Vitasek, Feb 2010

Top ten flaws



1. Penny wise pound foolish – too much focus on driving down costs
2. Outsourcing paradox – Sponsor dictates the how
3. Activity trap – Focus on tasks not deliverables
4. The junkyard dog – Duplication of effort by retaining internal staff
5. The honeymoon effect – Declining performance levels and satisfaction over time
6. Sandbagging – Holding back on performance to deliver frequent small improvements
7. The zero sum game – Looking to win, not for the win-win
8. Driving blind disease – Lack of performance management/governance
9. Measurement minutiae – Too many metrics
10. The Power of not doing – Not following up on red flags

Performance Pyramid



Reproduced from "Vested Outsourcing" K Vitasek, 2010

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Conclusions

- A wide range of outsourcing approaches in use that are often subject to change
- A paucity of robust, transparent data to evaluate the effectiveness of approaches
- Much talk of maturing relationships over the years impacted by a highly volatile ever changing environment

Questions?



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