



Moving from Task In-Sourcing to Comprehensive Outsourcing with CROs

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Session Purposes

- Share thoughts about the kinds of value that more collaborative relationships between sponsors and providers might be able to achieve
- Discuss some key barriers to such
- Consider how both sponsors and providers might work to overcome the barriers
- Be fairly prescriptive in terms of some processes to consider implementing to support sponsor - provider collaboration and joint value creation
- Have some fun (hopefully)

About Vantage Partners

- Mission: Drive measurable business results by transforming the way companies negotiate with, and manage relationships with, key business partners
- Practice Areas: Strategic Alliances, Sourcing and Supplier Management, Outsourcing Governance and Relationship Management, Key Account Management
- Spin-off of the Harvard Negotiation Project
- Faculty at Harvard University, the Tuck School of Business at Dartmouth, and the US Military Academy at West Point
- Leaders in international conflict resolution through CMG (now part of Mercy Corps)



Vantage Partners Writing



Quick questions...

- Sponsor? Provider?
- How many in fairly
 - ▶ Collaborative relationships?
 - ▶ Adversarial relationships?
 - ▶ Too often painful and not achieving the kind of value that we had hoped for kinds of relationships?
- Why are you here? What are some of the big questions that you have about
 - ▶ sponsor – cro relationships and / or
 - ▶ value maximizing relationship management



A possible context...?

- PharmaCo about to implement a new model for clinical development. Central to this model is a shift from “project outsourcing” – the traditional model in the pharmaceutical industry – to “functional outsourcing” – the standard outsourcing model in other industries.
- The new model will entail interdependent, long-term relationships with a very small number (two?) of CROs.
- The new model will also entail utilization of other suppliers with specialized expertise and capabilities.
- To be successful, PharmaCo will need to overcome an engrained cultural legacy of “doing everything ourselves” and / or treating Providers like “vendors” - and will need to help individuals make the transition from doing things, to managing external partners to get things done – in a manner that respects and values supplier expertise and capabilities



Context (continued)

- Efficient and effective execution of complex projects (like clinical development) ultimately depends on the ability of individuals to collaborate effectively – to make decisions, diagnose and solve problems, resolve conflicts, etc.
- Central to the success of PharmaCo's new outsourcing model will be the ability of retained staff, “re-badged” staff, and legacy CRO staff (and in certain situations, staff from other suppliers) to collaborate seamlessly – as if they were members of the same organization.
- Success will also require a balance between building and sustaining trusting, highly collaborative partnerships with CROs, and at the same time, holding suppliers accountable for performance, and guarding against supplier complacency (a risk inherent in the kinds relationships into which PharmaCo is entering.)



How a [Insert your choice of company] employee bakes a potato

1. Instruct an Idaho potato supplier to preheat the oven to 350° F.
2. Demand that the supplier show you how he turned the dial to reach 350° F, and have supplier come up with documentation from the oven manufacturer proving that it was calibrated properly.
3. Review documentation, then have supplier check the temperature using a sophisticated temperature probe.
4. Direct supplier to insert potato and set timer for 45 minutes.
5. Have supplier open oven to prove potato has been installed correctly, and request a free study proving that 45 minutes is the ideal time to bake a potato of this size and variability due to orientation within the oven.



How a [Company] employee bakes a potato (cont.)

6. Request a Six Sigma Study showing variable cook times for various potato sizes and orientations.
7. Check potato for doneness after 10 minutes.
8. Check potato for doneness after 11 minutes.
9. Check potato for doneness after 12 minutes.
10. Become impatient with supplier (Why is this simple potato taking so long to bake?). Demand status reports every five minutes.
11. Check potato for doneness after 15 minutes.

How a [Company] employee bakes a potato (cont.)

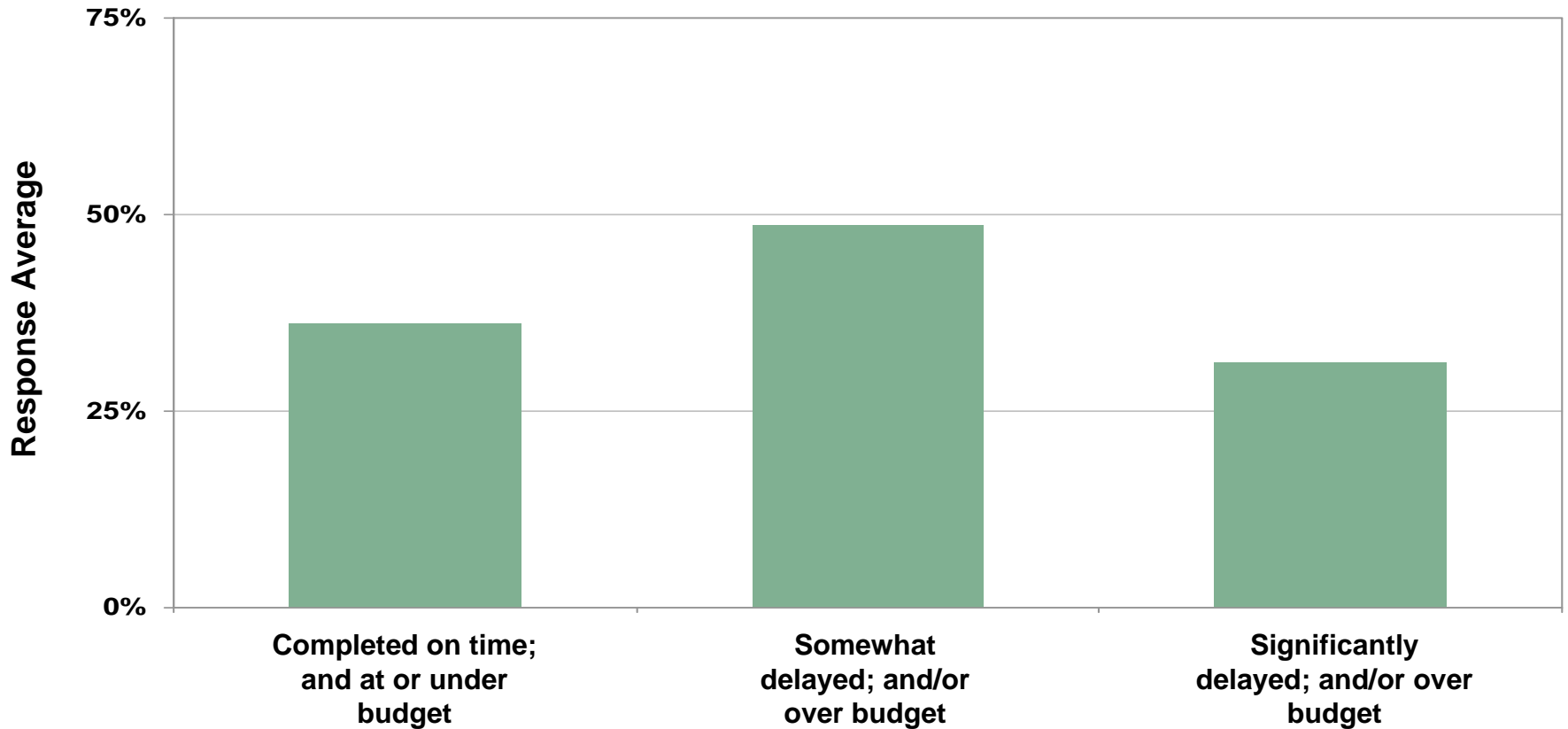
12. After 35 minutes, conclude that potato is nearing completion. Pass through Gate Review reporting all Green status.
13. Congratulate supplier, then update your boss on all the great work you've done, despite having to work with such an uncooperative supplier.
14. Remove potato from oven after 40 minutes of baking, as a cost save without loss of function or quality vs. the original 45-minute baking time.
15. Serve potato.
16. Wonder aloud what on earth those Japanese folks are doing over there to make such good, low-cost baked potatoes that people seem to like better than [Company] potatoes.



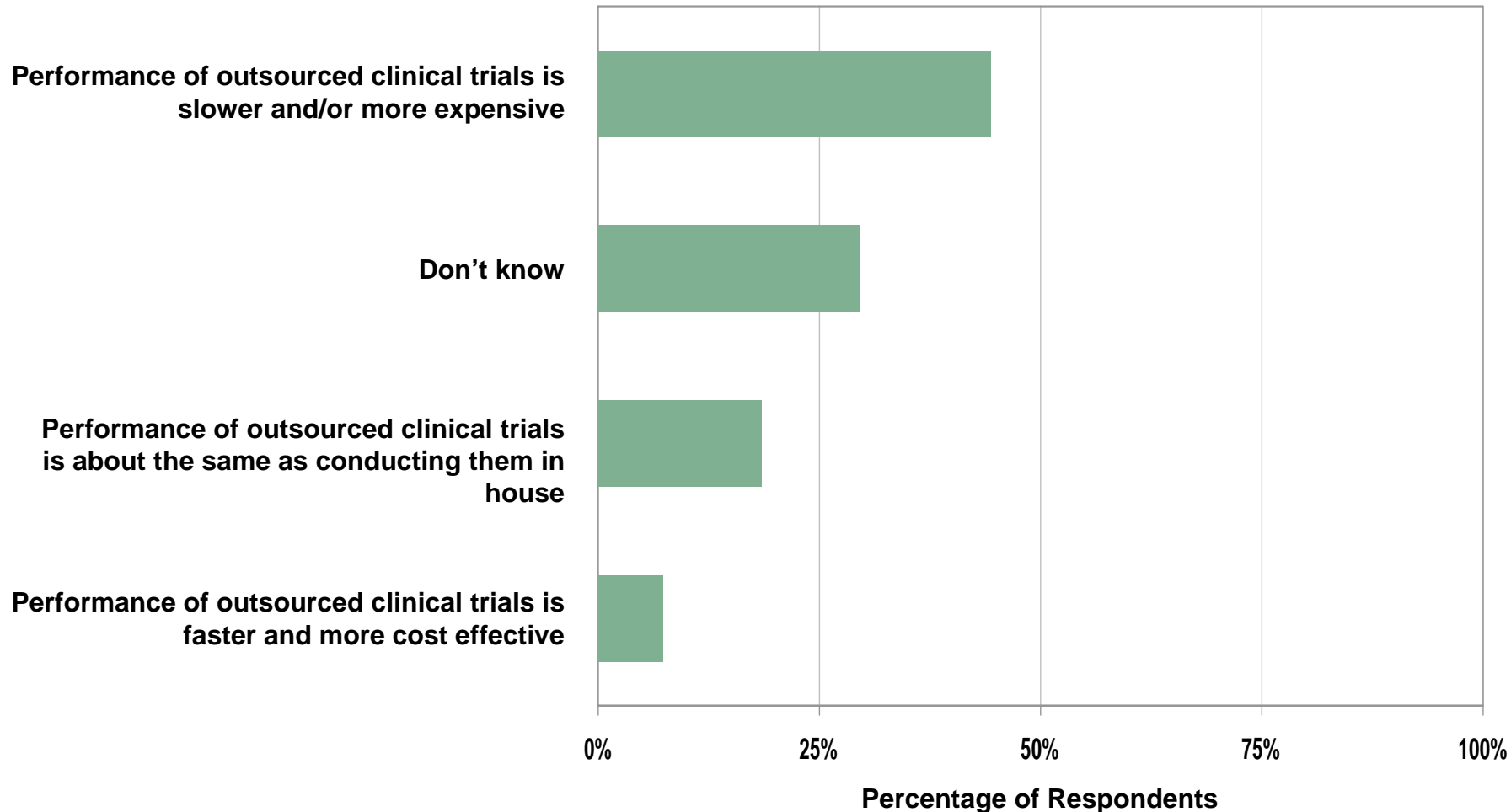
The Challenges to, and the Hope of, Collaboration



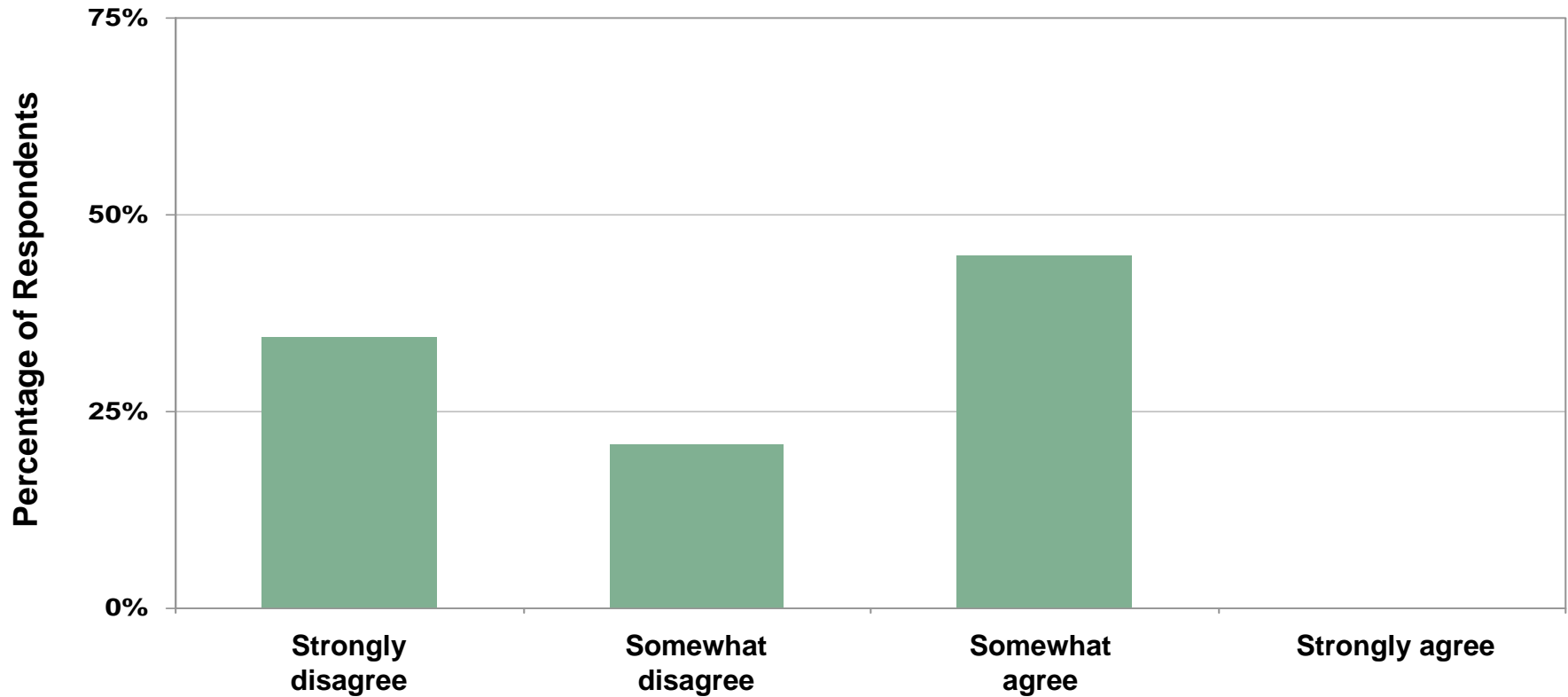
Sponsor scope of clinical trials



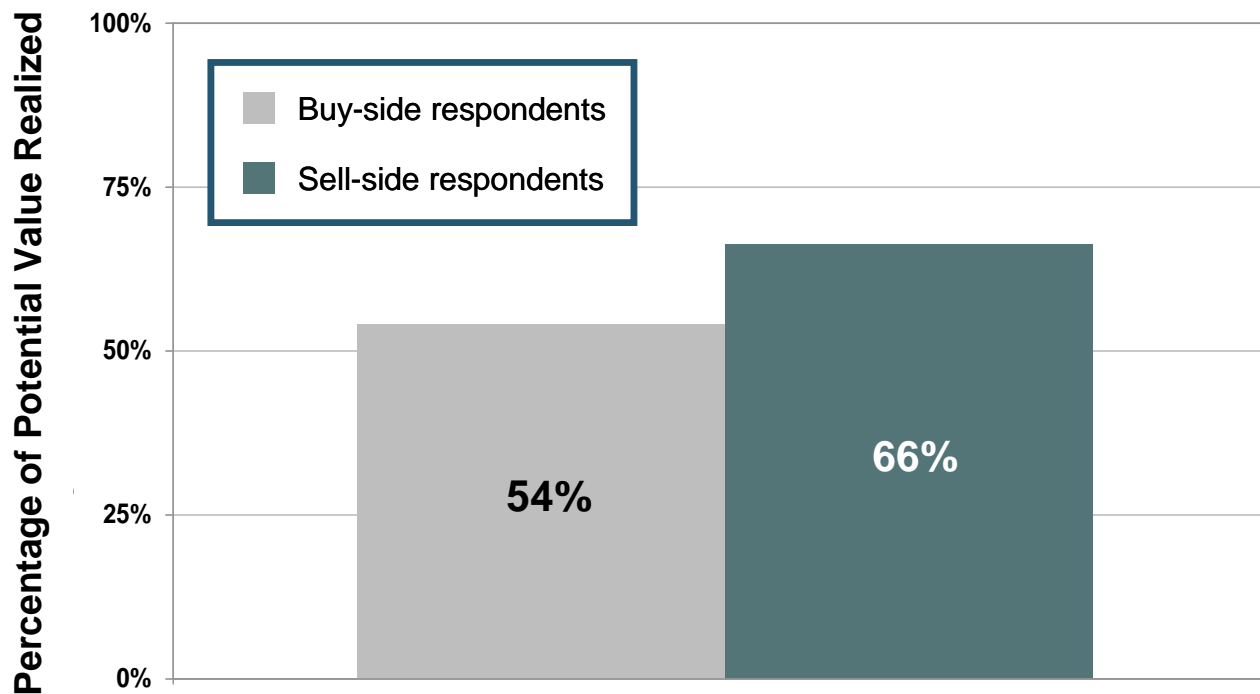
Which response best characterizes the performance of your outsourced clinical trials vs. the performance of your in house clinical R&D?



Extent to which CROs deliver significant innovation (in terms of protocol design, patient recruitment and monitoring, data analysis, etc.)



Percentage of contract value actually realized during implementation



Data from 2008-2009 study conducted by Vantage Partners involving over 500 companies



Major areas of value leakage

For customers

- **Expected innovation does not materialize**
- **Scope changes lead to additional costs**
- **Off-contract purchasing undermines expected savings**
- **Project delays due to supplier**
- **Quality problems**

For suppliers

- **Expected volumes do not materialize**
- **Changes in requirements lead to increased & unrecoverable costs**
- **Customer does not provide committed resources**
- **Project delays due to customer**

The importance of collaboration

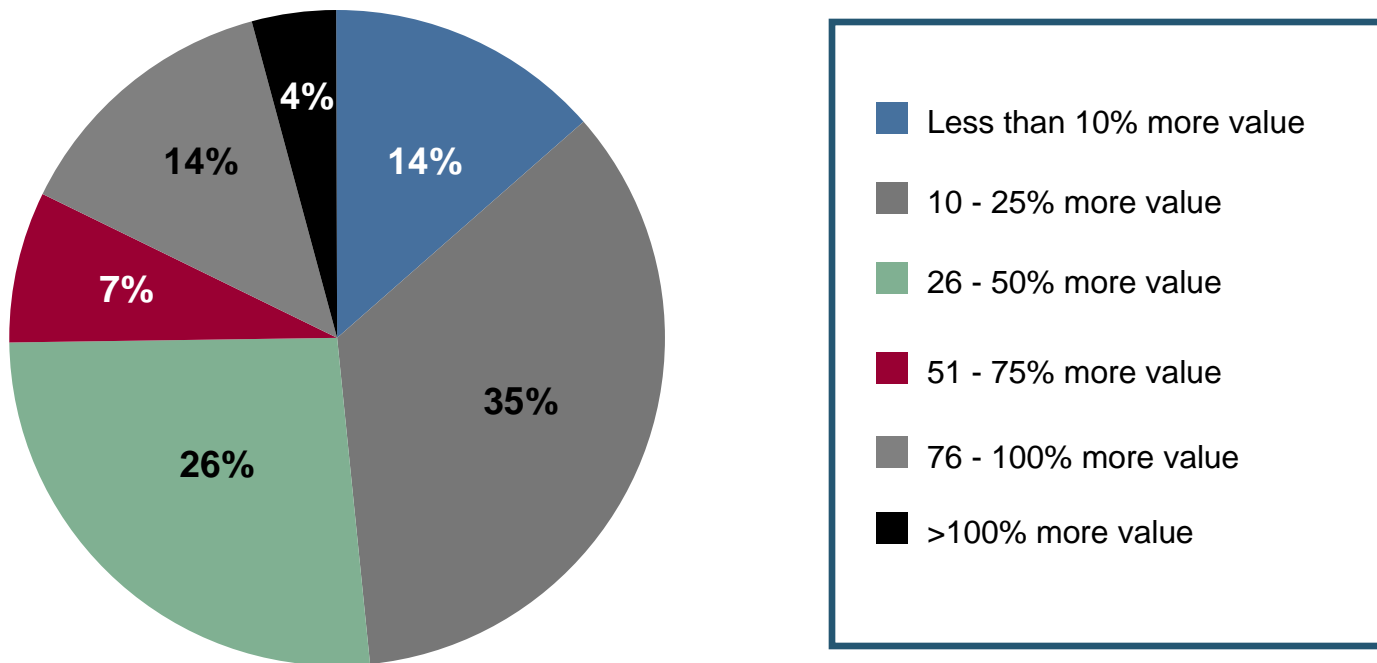
62% of purchasing executives in a 2005 Industry Week value chain survey stated that supplier collaboration was the most effective means by which to (further) reduce costs and improve profitability – substantially more than the number who named global sourcing, and nearly twice the number that named spend analysis.

Study conducted in collaboration with IBM Business Consulting Services, with assistance from APQC



Additional value generated through collaborative relationships – according to customers

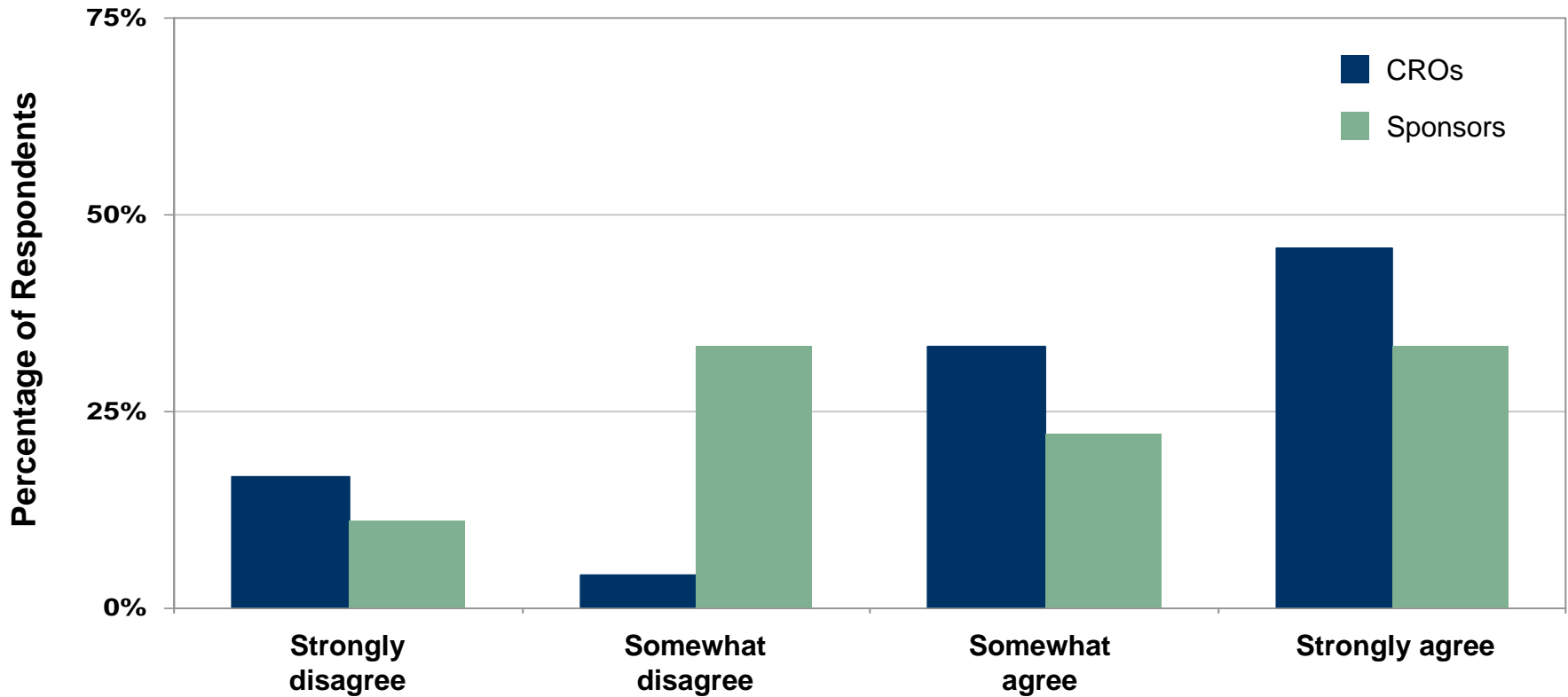
Customers report realizing an average of **40% more value** from their ***most collaborative key suppliers*** compared to their ***least collaborative key suppliers***



The challenge



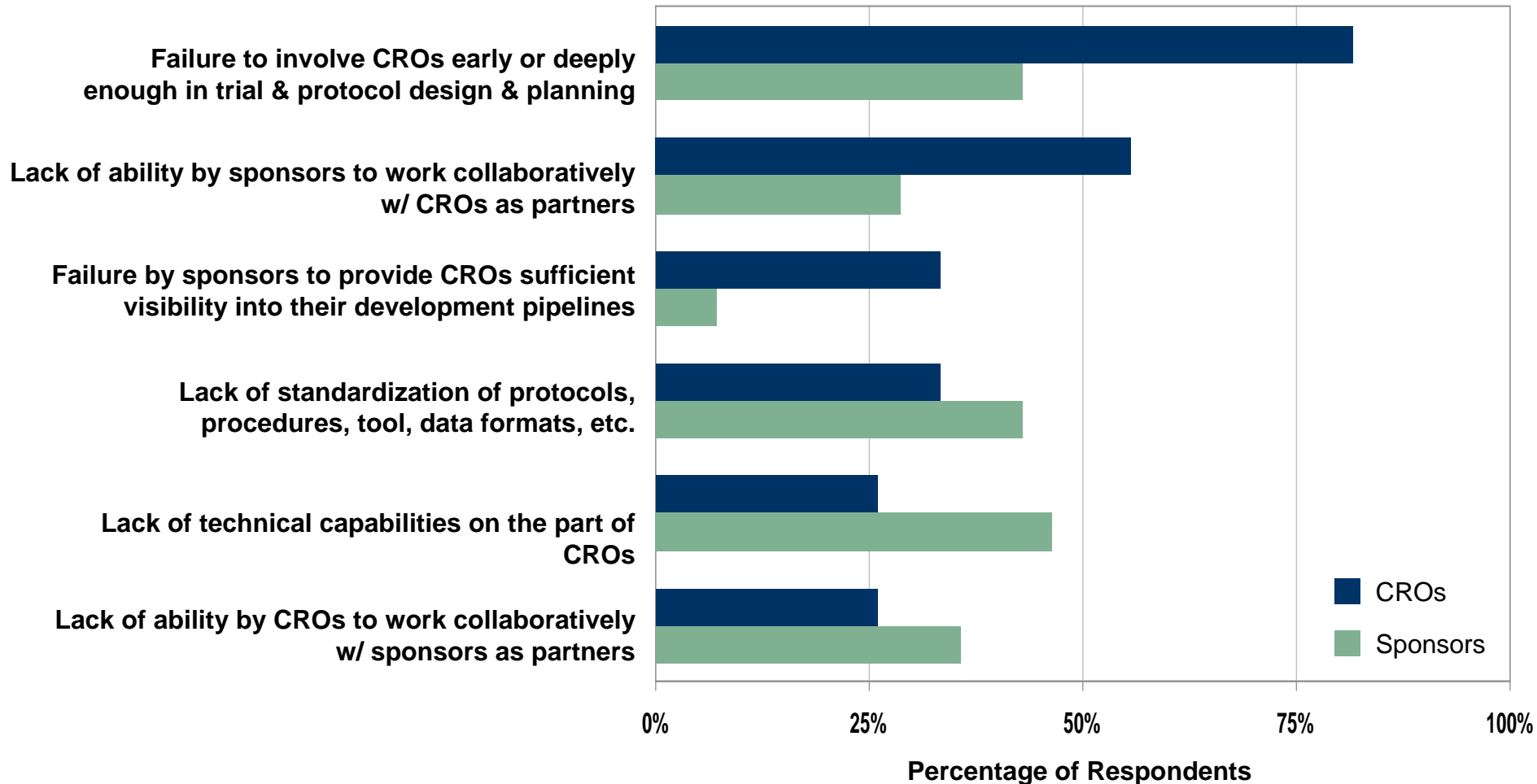
Extent to which close partnerships between sponsors and CROs are a better means of managing costs and maximizing value for sponsors than competitive bidding of individual trials



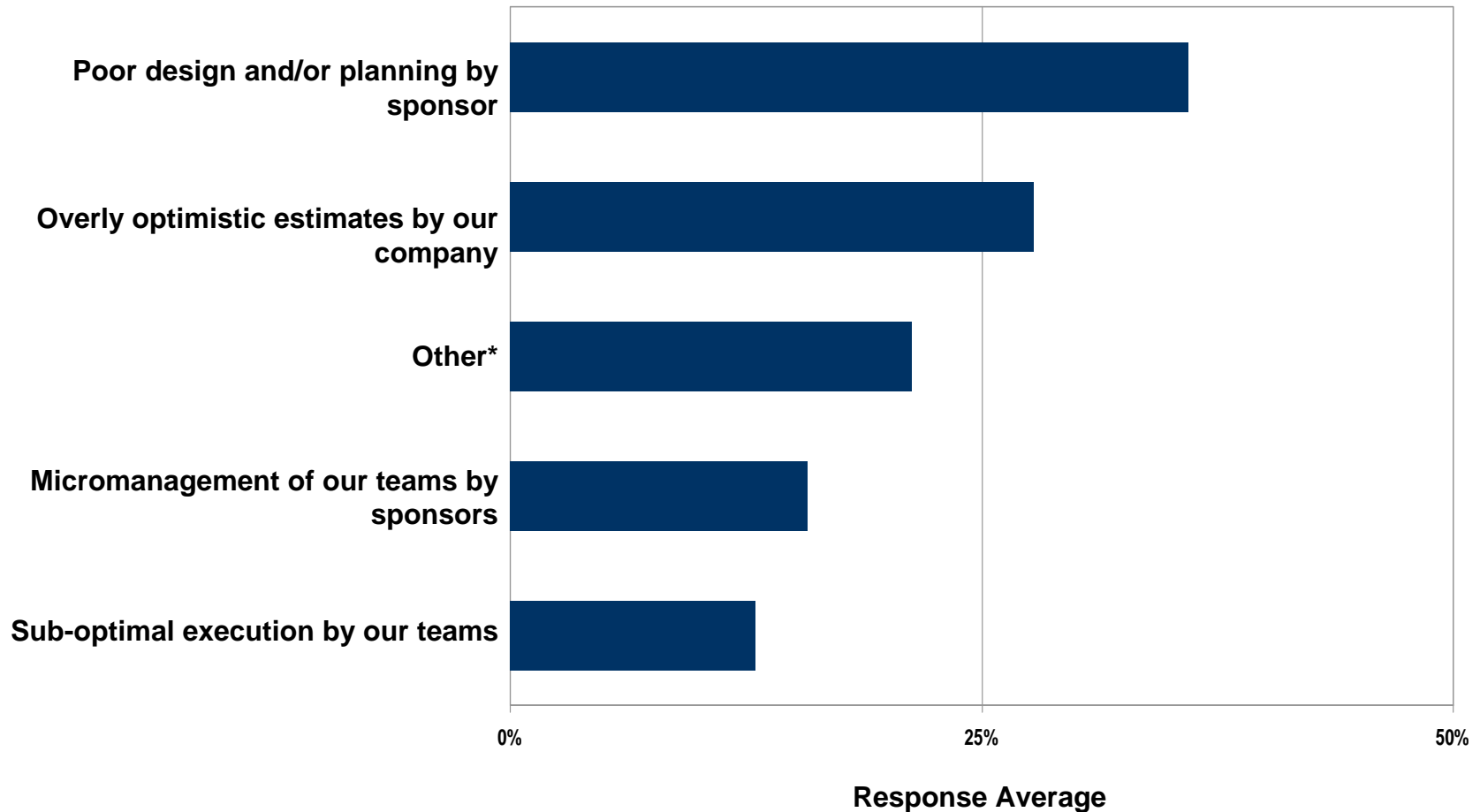
Small Group Discussion

- Do you think that more or less value is likely to be achieved for both CROs and Sponsors in relationships that are more collaborative than not?
- What kinds (categories) of value might be created, for CROs and Sponsors, by closer, more integrated, more collaborative, kinds of relationships?
- What big barriers exist to achieving such?

Top reported barriers to maximizing the efficiency and total value delivered through the outsourcing of clinical trials



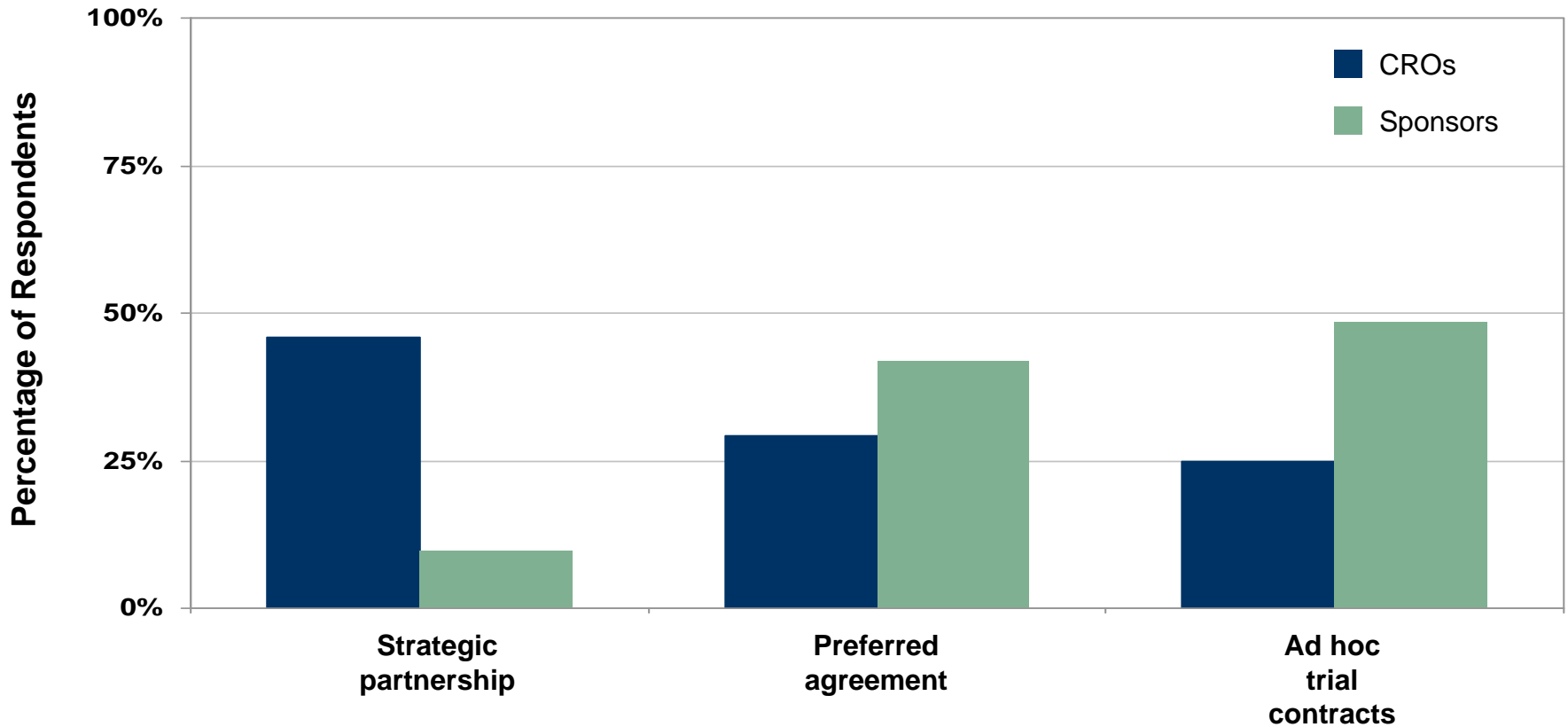
Reported causes for delayed or over budgeted clinical trials according to CROs



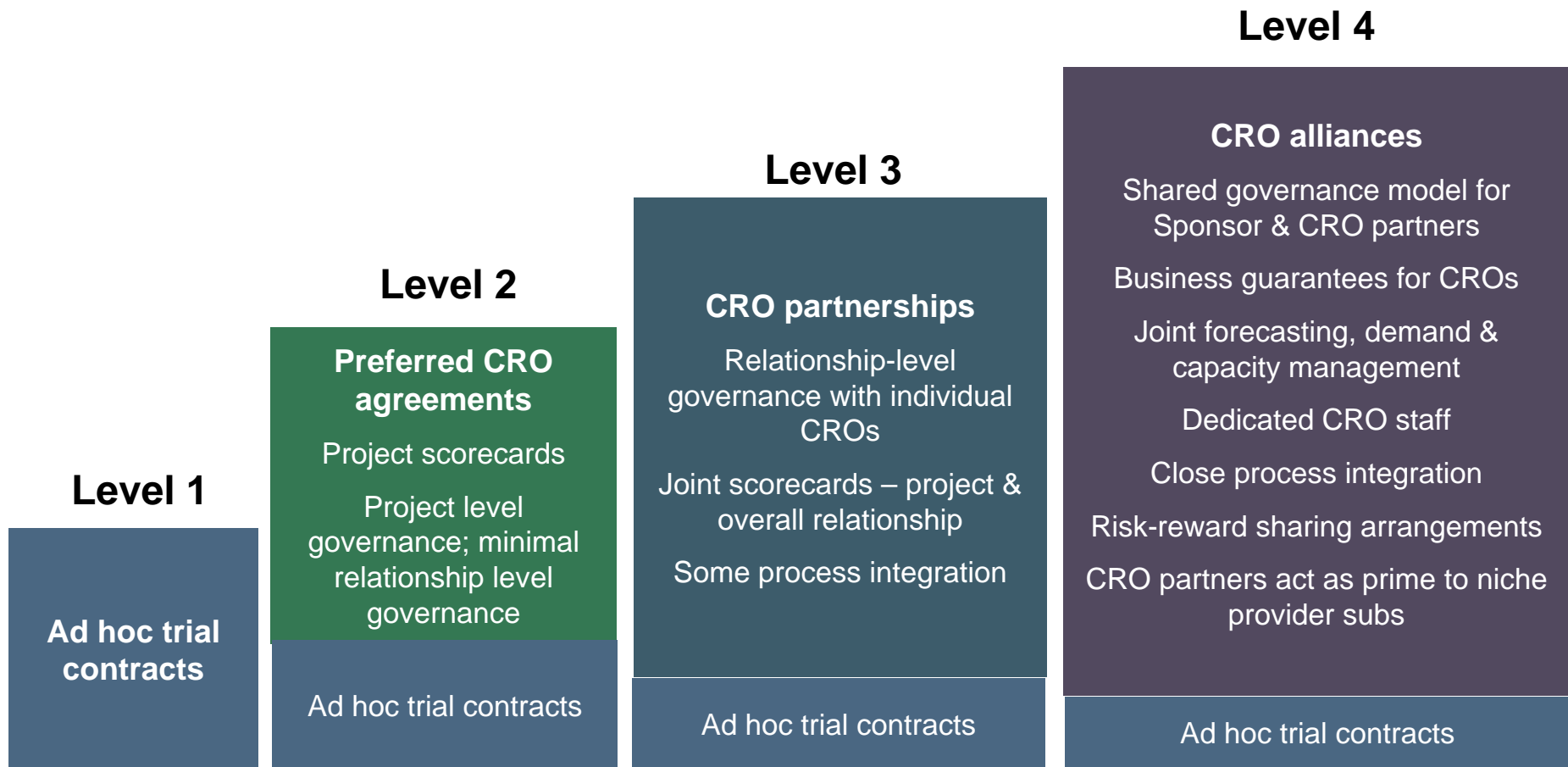
*Other responses included: failure to enlist the patients; additional service requests from the sponsor; macroeconomic challenges; new resources; changes in management; unexpected system and database issues



Respondent definitions of CRO-sponsor relationships



Sponsor-CRO relationship maturity...where we are and potential...



Some differences between focus of strategic sourcing and supplier relationship management

Strategic Sourcing

Emphasis on cost savings

Suppliers are segmented hierarchically as more or less important, based on amount of spend and switching costs

Emphasis on leverage over suppliers

Focus on activities up to the point of signing the contract

Supplier Relationship Management

Emphasis on total value and contribution to competitive advantage

Suppliers are segmented based on amount, and type, of value that can be realized

Emphasis on collaboration with suppliers

Focus on activities after the contract is signed



Two views of suppliers

Traditional View of Suppliers

- Suppliers are companies from whom we purchase goods and services
- Our interactions with suppliers are fundamentally zero sum
- Leverage over suppliers is the key to value
- Contracts are the primary tool by which we manage interactions with suppliers

Alternate View of Suppliers

- Suppliers are a source of knowledge, expertise, and assets that we can leverage to gain competitive advantage
- In a world of competing supply chains, our success is tied to that of our suppliers
- Collaboration with suppliers is the key to value
- Complex supplier relationships require formalized governance and relationship management



Attributes of more and less collaborative relationships

Attributes of *least* collaborative relationships

- Low level of trust; significant fear of opportunistic behavior by partner
- Relatively little information (about plans, priorities, capabilities, etc.) is shared
- Focus (as evidenced by metrics, decision-making, etc.) is on maximizing short term, unilateral value
- Differences (in goals, expertise, strategies, etc.) produce friction and undermine trust
- Conflicts are resolved on the basis of who has most leverage at any given point in time

Attributes of *most* collaborative relationships

- High level of trust; confidence that a company's actions will be fair and take partner interests into account
- High degree of transparency about plans, priorities, capabilities, etc.
- Focus is on maximizing long-term value, and ensuring success of partner
- Differences are respected and leveraged as a source of innovation and value creation
- Conflicts are resolved "on the merits;" partners search out (or create) and apply, objective criteria aimed at producing fair and reasonable outcomes



Two approaches to relationship management

Model One

- Maximize unilateral control
- Maximize leverage
- Maximize winning; minimize losing
- Unilaterally define and implement approach to relationship management
- Focus on narrow measures of short-term value
- Focus on automating interactions
- Strategy drives relationship management

Model Two

- Shared decision-making on the merits
- Maximize collaboration; balance leverage
- Maximize legitimacy; commitment to mutual success
- Jointly define and implement approach to relationship management
- Focus on broad measures of long-term value
- Focus on enabling effectiveness of interpersonal interactions
- Key relationships help to shape strategy

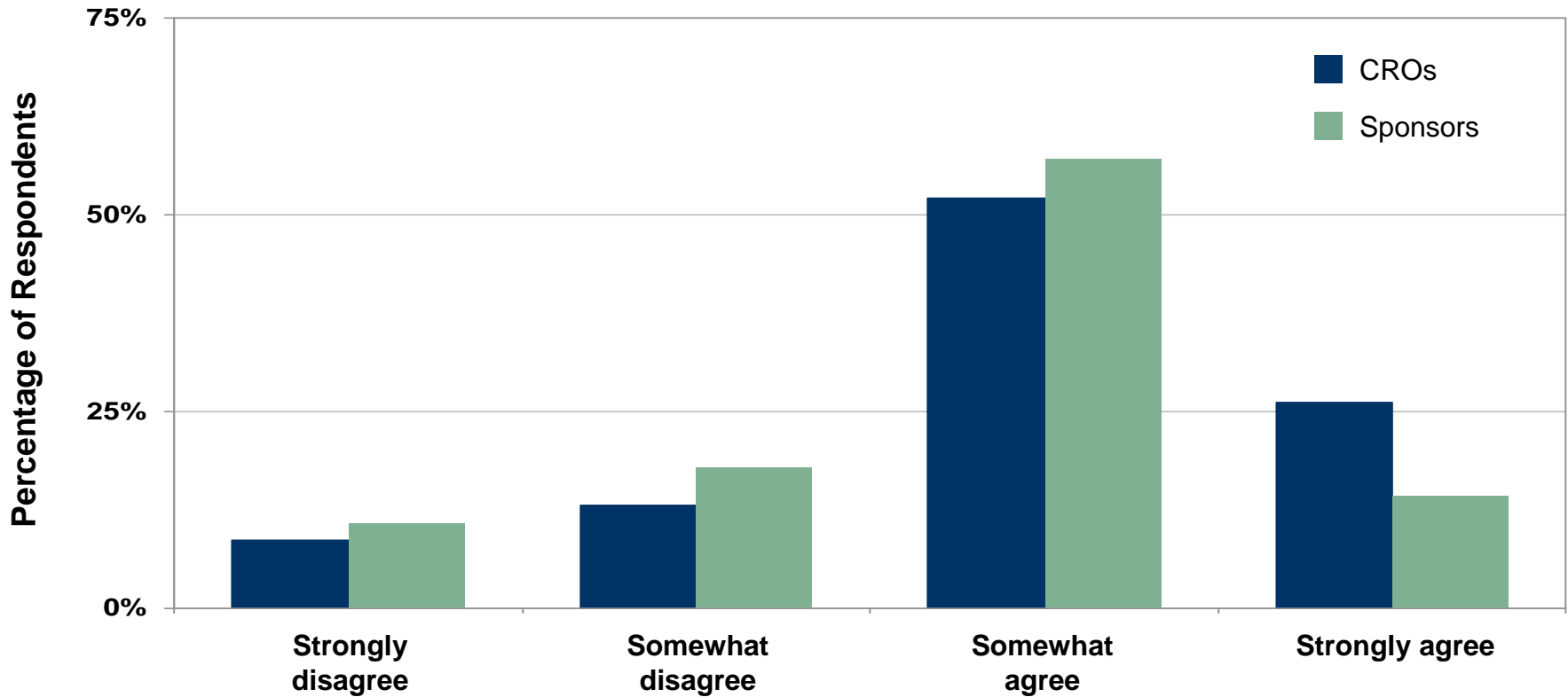


Key risks of, and barriers to, increased supplier collaboration

- **Reduced leverage:** With fewer, more interdependent, supplier relationships, switching costs are higher, and hence customers have a smaller stick for use in negotiating and managing performance
- **Competitive risks:** Sharing more strategic and/or proprietary information with suppliers creates risk of leakage to competitors, or of helping suppliers to become competitors
- **Short term cost pressures:** Many companies prioritize short term cost reduction at the expense of larger long term savings and other value
- **Lack of internal alignment:** Different customer functional groups and business units are not aligned around priorities for what they want from suppliers
- **Lack of capabilities:** Most companies are not equipped to collaborate effectively with suppliers (or other business partners)

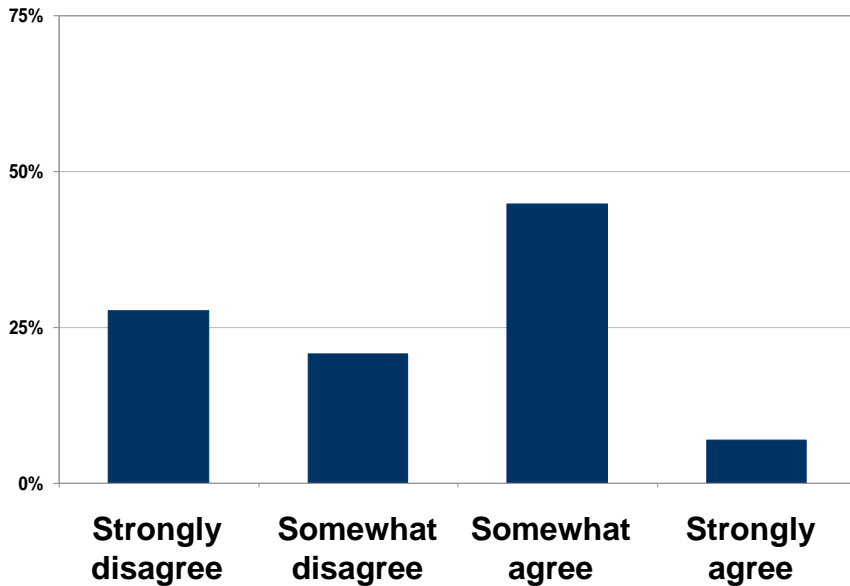


Extent to which individuals collaborate seamlessly – as if they were members of the same organization



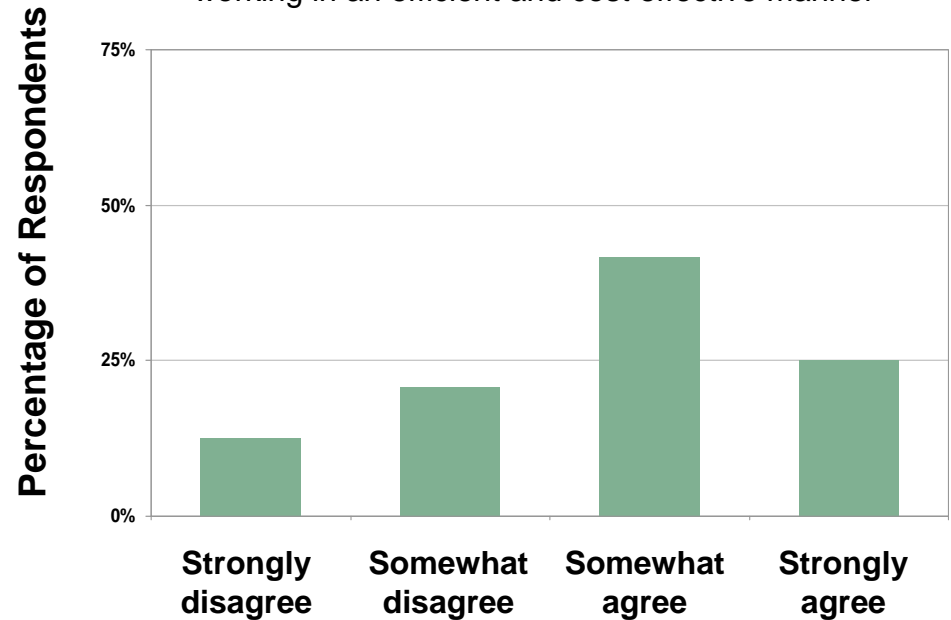
Transparency into development pipelines and future plans

Extent to which sponsors provide CROs with a high degree of transparency into development pipelines and future plans for clinical trials



According to CROs

Extent to which failure on the part of sponsors to provide sufficient visibility into their development pipelines & future plans is a significant barrier to working in an efficient and cost effective manner



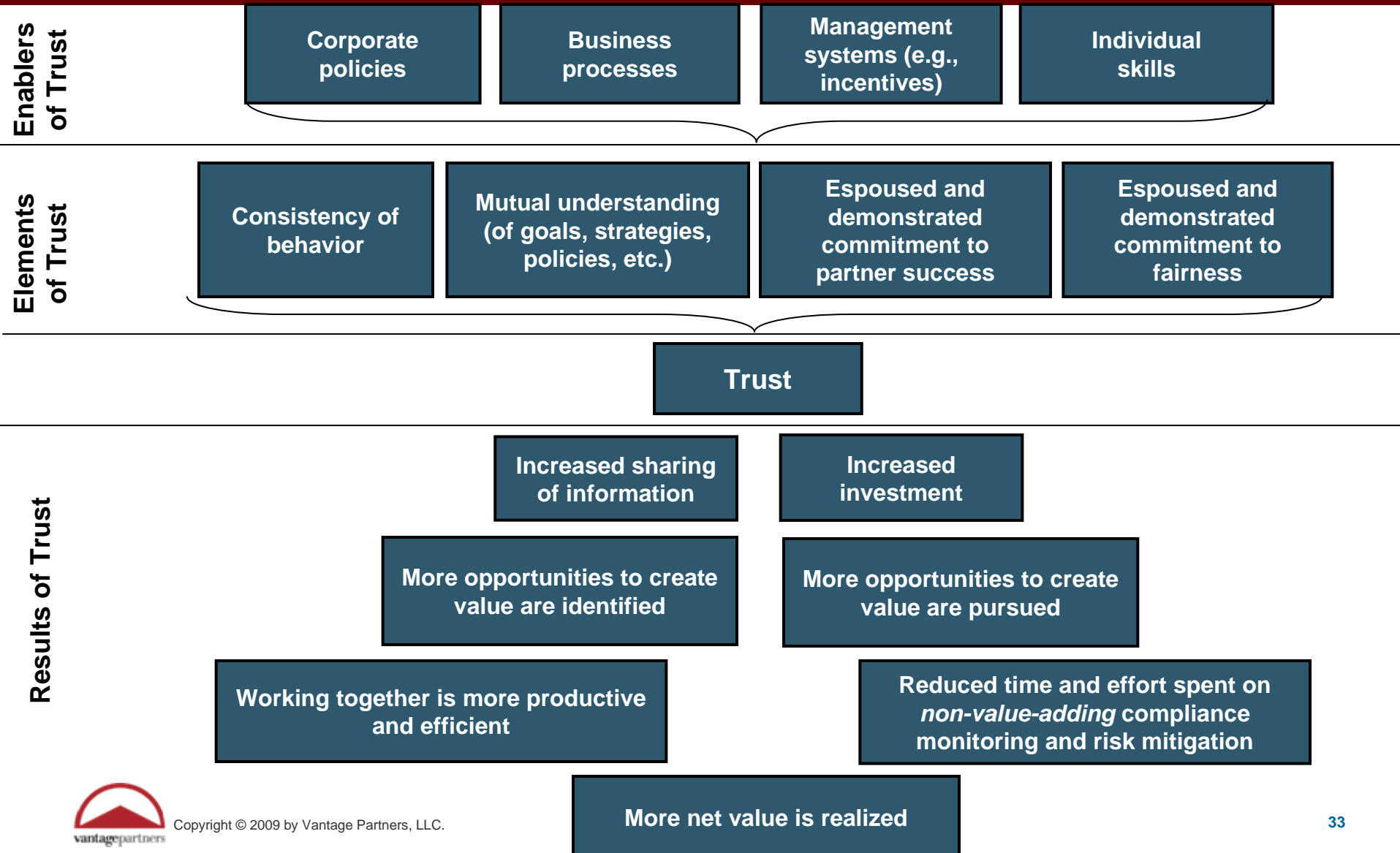
According to sponsors



Question:

- What do you think are likely to be best practices for creating significant value out of Sponsor – CRO relationships?

Trust: Mapping causes and effects



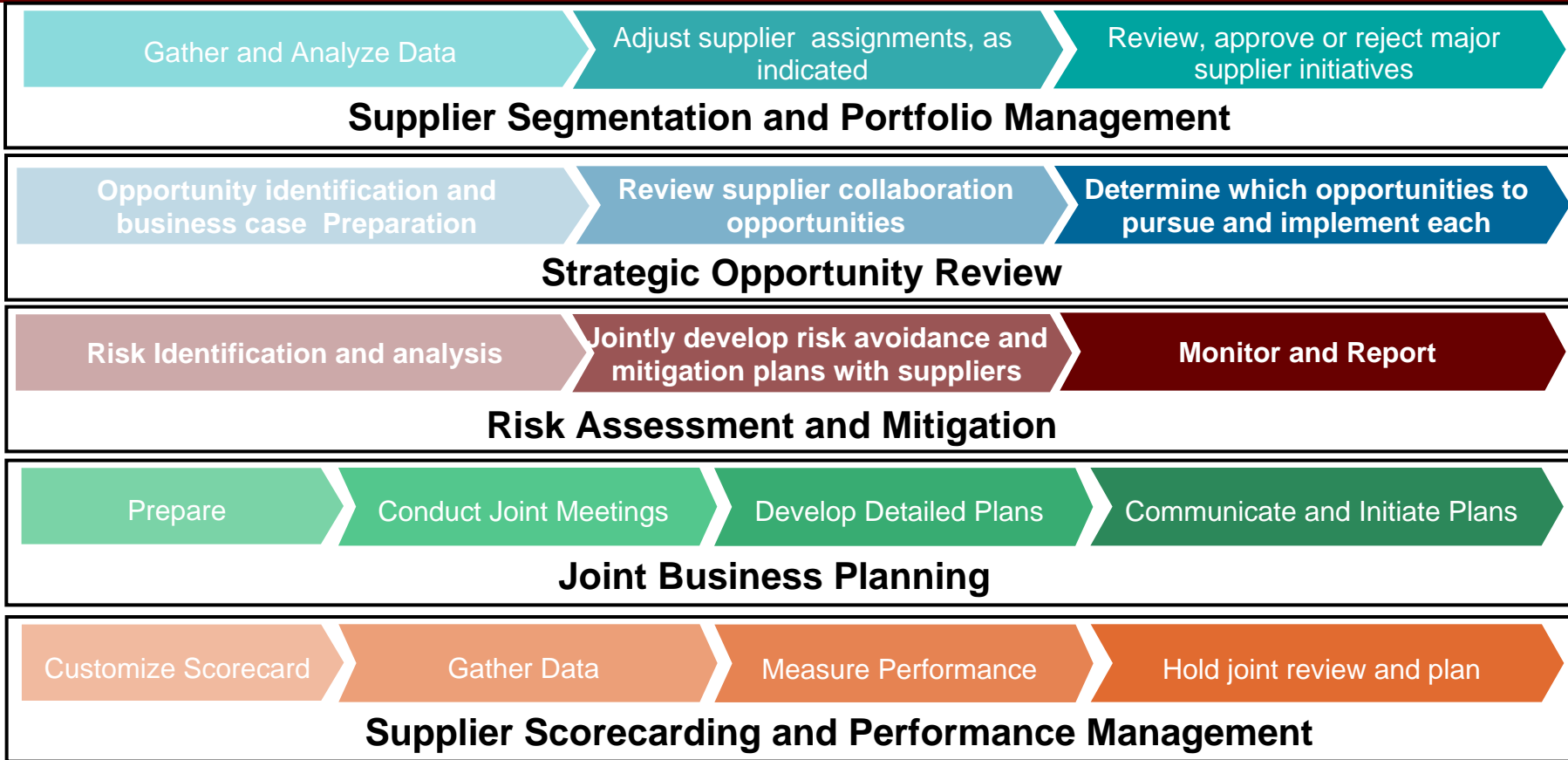
Overview of sponsor-CRO alliance best practices

- Long-term agreements with clearly defined performance requirements
- Sponsor commits a percentage and/or base amount of business to CRO partners; CRO guarantees (some) dedicated staff to sponsor partners
- Clearly defined governance structures and processes
- Joint process for sponsor to share pipeline information with CRO partners, and CROs to share capacity information with sponsors
- Standard process for joint scope management
- Standard process for launching new projects with focus on jointly anticipating and planning for possible challenges and difficulties
- Joint scorecard and two way performance management process
- Standard process for capturing, codifying, and disseminating lessons learned and best practices across trials and CRO partners
- Joint training on collaboration skills for sponsor and CRO staff



Some key processes and enablers of realizing the potential of Sponsor – CRO collaboration

Core SRM Processes



Enablers



Illustrative collaboration supporting business processes



- **Supplier segmentation and portfolio management** - is the process by which sponsors regularly evaluate its supplier categorization and segmentation in alignment with its business strategies and ensures continuous improvement of the key CRO efforts

Illustrative collaboration supporting business processes



- **Strategic opportunity review process** - process by which sponsors engages its most key CRO partners to identify, internally assess, and implement new opportunities for collaboration, thereby generating significant new value for both through e.g., development of innovation opportunities, improvement of existing processes, or mitigation of relationship risks

Illustrative collaboration supporting business processes



- **Supplier risk assessment and planning process** – systematic process (both internal and jointly with suppliers) for identifying supplier risks, the probability of their occurrence, and the development of scenario-based plans for mitigating their likelihood and action plans should they occur

Illustrative collaboration supporting business processes



- **Joint business planning process** – annual process by which PharmaCo and its key CRO partners share their strategic direction and business objectives (both corporate and for the relationship), and plan key activities and projects for the year

Illustrative collaboration supporting business processes



- **Supplier scorecarding and performance management process** – process by which PharmaCo jointly and regularly assesses the supplier *and its* performance, the quality of the PharmaCo-supplier working relationship, and diagnoses areas of under-performance and relationship challenges to develop remediation plans

Four dimensions of supplier performance and value measurement

| Outcome Measures (Ends) | Strategic Value | Financial Value |
|--------------------------------|--|---|
| | <p>Innovation</p> <p>Access to specialized expertise/technology</p> <p>Effectiveness of joint planning</p> | <p>Accuracy of cost forecasting</p> <p>Actual cost</p> <p>Volume of business</p> <p>Value of strategic contributions</p> |
| Predictive Measures (Means) | Operational Performance | Relationship Quality |
| | <p>Adherence to contract</p> <p>Cycle times</p> <p>Quality</p> <p>Administrative processing</p> <p>Flexibility</p> <p>Administrative</p> | <p>Level of trust</p> <p>Degree of commitment</p> <p>Quality of problem-solving</p> <p>Quality of communication</p> <p>Degree of mutual understanding</p> |

Excerpt scorecard detail

Scorecard Structure

Dimension of Performance Measurement

Metric Category

Metric Subcategory

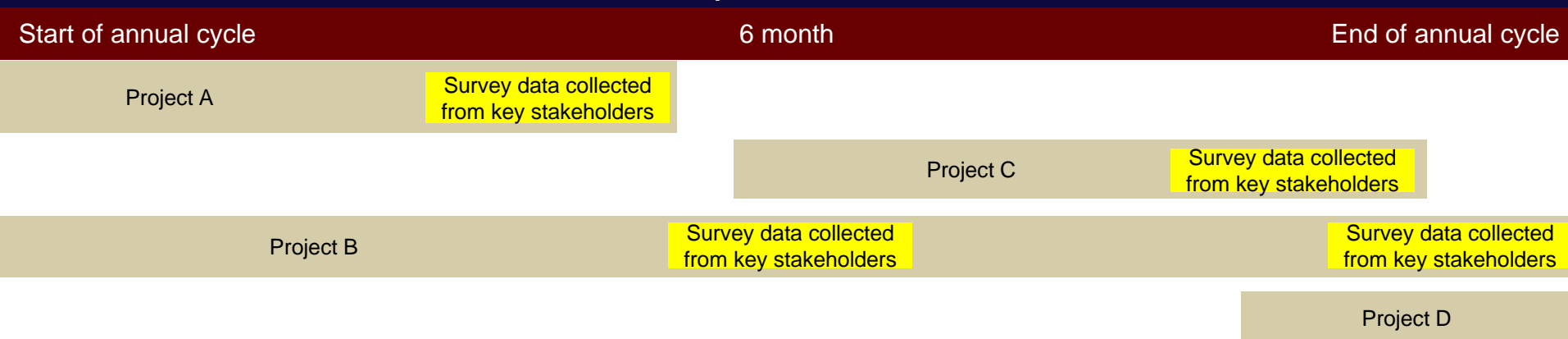
Metric

Scorecard Excerpt

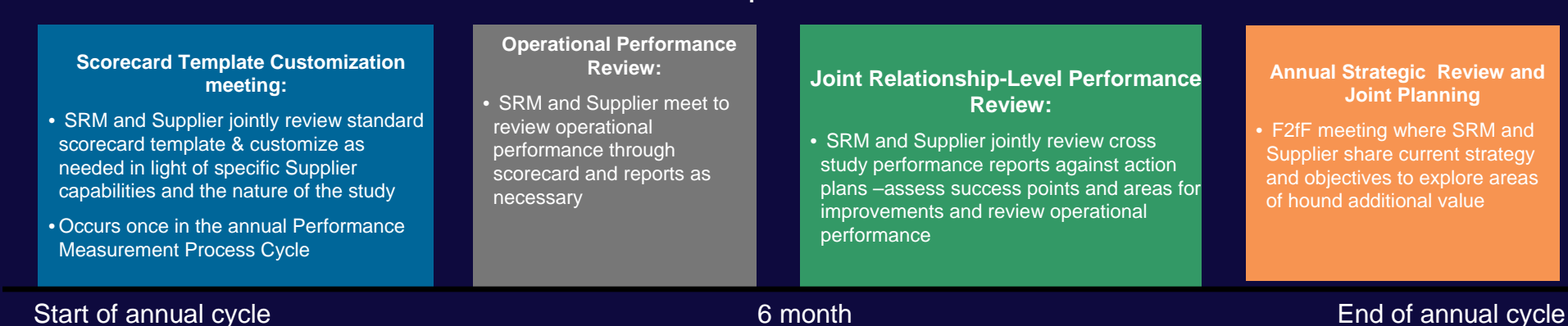
| STRATEGIC VALUE | | |
|-----------------|---|---|
| Categories | Sub Category | Metric (or survey question) |
| Innovation | Study Design | Has CRO contributed to innovative study design? |
| | Problem solving | If there is an issue our partner comes to us with options for resolution, not just problems |
| | Direction of new technology investments | Has there been CRO investment commitment based on research direction? |
| | Technology | \$ allocated for systems or technology improvement |
| | | Has there been CRO technology brought on-line to satisfy need? |
| | | Has there been CRO Capacity brought on-line to satisfy need? |

Illustrative joint performance management process (pharma clinical research services)

Project Timeline



Relationship-Level Timeline



Start of annual cycle

6 month

End of annual cycle



Illustrative enablers of effective sponsor – CRO collaboration

SRM Program Governance

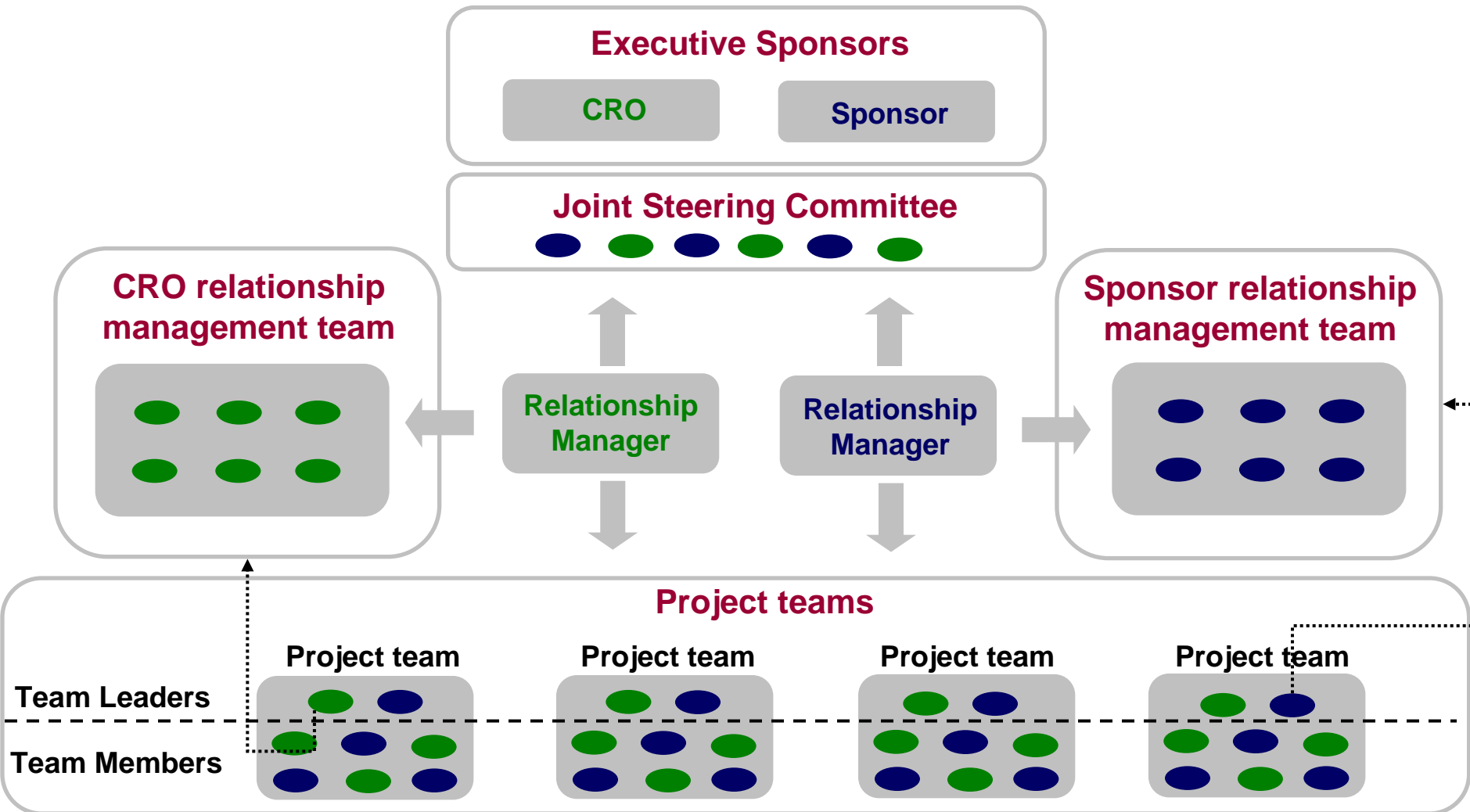
Individual Supplier Governance

IT Tools

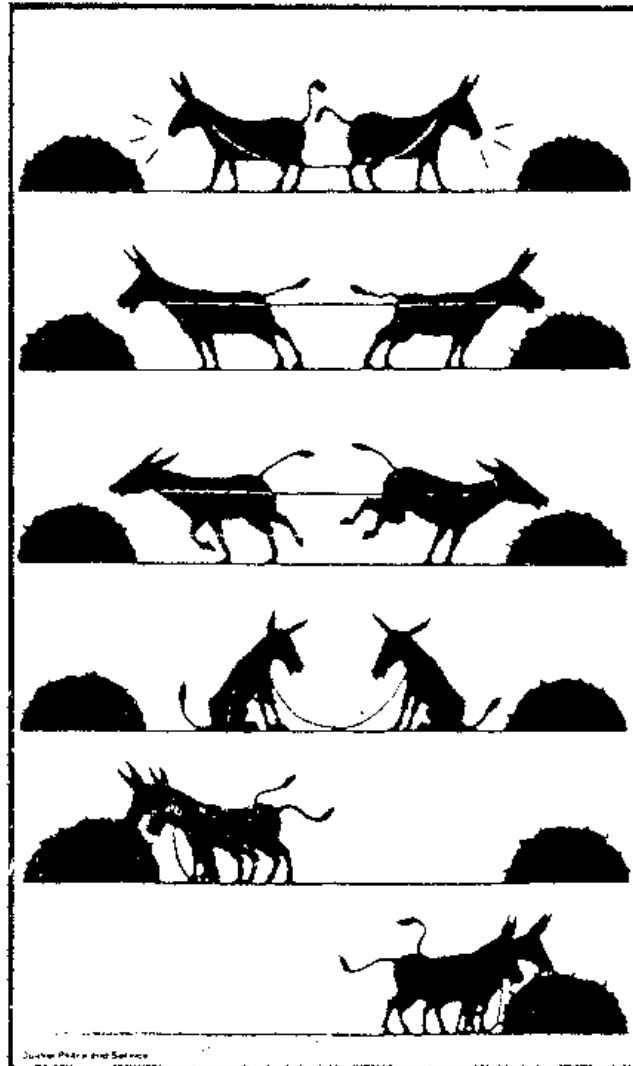
SRM Skills and Training

- **CRO collaboration Program Governance** – The process and structure by which PharmaCo oversees and coordinates all key CRO collaboration activities across the key supplier base and ensures their continuous improvement and refinement
- **Individual key CRO Governance** – The process and structure by which PharmaCo identifies and tracks the execution of key decisions and proactively manages the identification and resolution of conflicts and issues as they arise
- **IT Tools** – SRM-focused software which facilitates, standardizes, and increases the efficiency of gathering, analyzing and reporting supplier performance data, identifying and managing supply chain risks, and facilitating collaboration with suppliers
- **SRM Skills and Training** – Systematically equipping individuals who interact regularly with suppliers, with skills needed for effective relationship management (e.g., collaboration, negotiation, joint problem solving, and influence) and the processes by which PharmaCo intends to manage its supplier relationships

Illustrative governance structure for Sponsor-CRO alliances



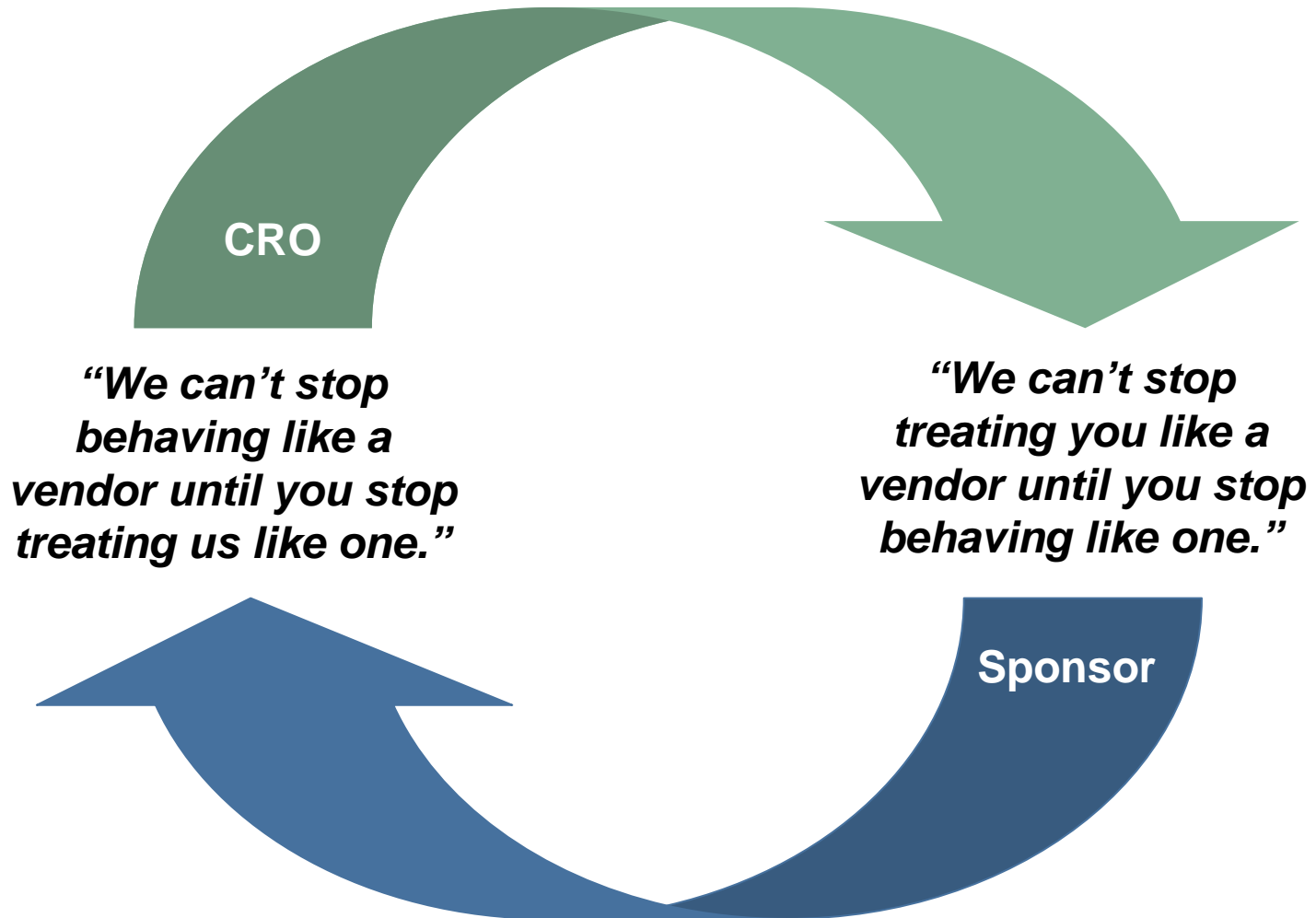
Ultimately, successful sponsor-CRO relationships depend on people



Overview of key skills required for success of sponsor-CRO alliances

- **Joint problem-solving** – including the ability to jointly conduct root cause diagnosis of problems without a dysfunctional emphasis on finger-pointing and attempting to assign (or defend against) blame
- **Effective communication** – specifically the ability to understand and learn from different ideas and perspectives
- **Scope management** – including the ability to plan and manage work within scope; and to manage/creatively and fairly resolve scope change requests
- **Commitment management** – including the ability to make clear requests for commitments; clarify and effectively respond to requests for commitment; hold colleagues (internal and external) accountable for commitments; and effectively deal with and learn from broken commitments
- **Conflict management** – specifically, the ability to creatively and collaboratively resolve disagreements

A difficult cycle to break



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Vantage Partners

A spin-off of the Harvard Negotiation Project, Vantage Partners helps companies achieve breakthrough business results by transforming the way they negotiate with, and manage relationships with, their suppliers, customers, and alliance partners.

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Appendix: MBC survey data



Survey demographics

- 88 individuals participated in the survey
- Illustrative list of participant titles included:
 - ▶ President and CEO
 - ▶ COO
 - ▶ Vice President
 - ▶ Directors of BD, Sourcing, Regulatory Affairs, Clinical Research, and Data Management
 - ▶ Managers of BD, Clinical Trials, Drug Development, Research, and Outsourcing
 - ▶ Project Manager
- Respondent average annual revenue was 725M
- 35 CROs participated in the survey; 51 sponsors participated in the survey

Clinical research outsourcing spectrum

