Understanding the Continuum of Clinical Collaboration:

Maximizing Partner Relationships and Unlocking Greater Value

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As biopharma companies evaluate strategies to advance their products to market, they are increasingly doing so with new options for partnership. Contract Research Organization (CRO) or vendor partners are invited to solve challenges of capacity, quality, expertise and infrastructure – but not necessarily all at the same time. For one clinical team, short-term monitoring capacity in Asia is needed where the group has none; for another, in an established geography, more medical expertise in a newly-acquired therapy area will improve critical site relationships; in a third part of the same organization, drug safety leaders tackle fluctuating volumes that stress their ability to remain compliant. All of this under corporate pressure to raise research productivity without sacrificing quality.

Different challenges require different approaches, including different models and different partners. This is not new. Many Sponsor companies are employing a mixed-model strategy in which a functional service provider (FSP) exists alongside traditional project-based outsourcing or programmatic preferred providers.

One of the key trends of the last decade has been the consolidation of vendors, reducing the length of the right-tail distribution and increasing the concentration of work done by a smaller number of larger companies. Niche services remain critical, but taken as a whole fewer vendors perform a larger share of the outsourced work. That means that vendor-selection processes tilt towards finding as broad and deep a fit as possible, the better to capture the efficiencies from scale and repeatability that those moves are intended to deliver. It results in a "model of best fit" approach, which serves the greatest volume of need to the greatest possible extent. It can be an effective strategy, but as Sponsors pursue a reduced number of vendors in a dominant delivery model philosophy, it can raise the probability that the 'best fit' will leave capability cracks through which critical requirements can fall.

It can frequently be difficult to gain agreement on the definition of delivery models, but for the purposes of this discussion Figure 1 outlines simple descriptions of each.

Model	Description	Systems and Processes
Resource Augmentation	Insourcing functions or activities, with support from a vendor to provide capacity	Sponsor
Functional Service Provider	Outsourcing specific functions or activities	Sponsor
Programmatic	Outsourcing complete programs or trials; may involve outsourcing of entire function for one program or therapeutic area	Vendor
Traditional (aka Full Service)	Outsourcing projects or functions on a study-by-study basis	Vendor

Figure 1: Traditional Models of Outsourcing – Establishing a Vocabulary

However, the components of these mixed-models exist as distinct, separate compartments. They are like different terminals in an airport: built at different times, with different design ideas, different controls and different definitions of service and quality. It can be a disorienting experience, with too much time and effort spent navigating the obstacles and not enough focused on the destination.

The answer is not necessarily to force harmonization. One model may not fit all needs, at all times. As Ihrig and MacMillan have explained, each unit in a large company operates in its own ecosystem, with its own internal and external customers and partners.[1] Each makes its own decisions to best advance its own desired outcomes. The answer is to recognize the different needs and assemble an ecosystem that delivers maximum value.

> "[A hybrid approach] can be a route to maximizing partner relationships and unlocking greater value."

Many companies choose a dominant path based on their view of value, defined by the challenge they are addressing. For some, FSP-type models offer the best solution as the Sponsor retains control and, defines the process and partners connect seamlessly like interchangeable components. For others, a fully outsourced ("full-service") model with the implied higher accountability and lower oversight better serves their purpose.

Decisions on which model to use were made through an analysis of what was considered "core"

[1] *Martin Ihrig and Ian MacMillan, "How to Get Ecosystem Buy-In," Harvard Business Review, March/April 2017.*

and “non-core” to the organization. Underpinning these decisions was a calculation based upon variables of capacity, cost and control:

- What should the Sponsor do? *Over what should we retain control?*
- What should the Partner do? *What has less strategic criticality? What can be done at lower cost?*

Broadly, a function or task is classified into one bucket or another, and talk of “hybrid” approaches – using more than one model at the same time – sounds like a strategic compromise. In fact, it can be a route to maximizing partner relationships and unlocking greater value. Definitions of value are changing just as quickly as the business is. Increasingly, industry leaders are looking again at the core/non-core dynamic, this time with greater focus on the site and patient experience, and establishing brand recognition and strategic relationships with investigators. Rather than a task-based classification, the emphasis is now on core relationships and outcomes, with patients and sites correctly at the top of the list. That introduces a new dynamic into the “control” and value dilemma.

Maximizing Clinical Collaboration with Hybrid Design

Effective solutions are therefore about taking the *BEST* approach (Blended Efficient Sustainable Team). What is BEST is what works, allowing for strategic needs that move faster than a current partner set-up can keep apace of. It does not reflect a failure of partner-sourcing decisions; on the contrary, it demonstrates that partnerships are established in pursuit of clear-eyed business objectives, rather than the reverse. BEST models integrate different partners as well as different models of delivery that range from resource augmentation, through project-based outsourcing to high accountability joint-investment partnerships.

The BEST approach in summary:

Blended

Mix of Sponsor and Partner, multiple delivery models and systems, adapting quickly to changing development needs of all stakeholders and regions.

Efficient

Achieving more with no more; it is more than a measure of operational productivity and cost, the critical factor is unlocked value.

Sustainable

Value created this year becomes the baseline for next year, the onward drive continues through investments in innovation, or the ecosystem’s ability to shift shape to increase the amount of challenge it addresses.

Team

Clarity that advances further than the usual notions of RACIs and task matrices to work aligned to value outcomes, made easier when some elements can still be delivered in Sponsor systems under Sponsor control.

To illustrate, here are two examples.

Example One: Supplementing a Programmatic Partnership in Asia

In a full-service preferred partnership, where a selected partner is chosen under the “best fit” approach, challenges may arise if the demands of a portfolio require a greater presence in Korea and China than were envisaged at annual portfolio planning. The model operates as a traditional full-service approach with feasibility, site selection, monitoring and project leadership under one umbrella. A BEST approach allows for insourced delivery of one or more functional lines, remaining under the project leadership of the chosen provider. The insourced staff is onboarded to Sponsor systems and processes, supplied by either a third party vendor on a flexible-capacity basis or, if of sufficient scale and duration, by a functional model.

Example Two: Supplementing a Functional Partnership with Therapeutic Leadership

In a functional partnership designed for Sponsor control and adherence to defined metrics, Partners can focus unduly on the ‘how’ rather than the ‘why’ of clinical outcomes. By taking a BEST approach, Sponsors can adapt Partner metrics to be more aligned with internal success milestones while maintaining control over the mode and method of operational delivery. Additionally, where new ideas or expertise are needed to enhance probability of success or to improve site comprehension of a difficult protocol, therapeutic and medical leadership can be inserted on a project-by-project basis without disrupting the scale and flow of an established functional partnership.

Breaking the Hub and Spoke: Planning for Success in a BEST Approach

There are three key factors to success if the BEST approach is to be fruitful:

1. Collaboration is King

It is no longer a requirement that a Sponsor be the governing hub at the center of multiple partnering spokes. Neither is it required, or desirable, that a Sponsor company is responsible for coordinating everyone’s place in the model. That dynamic is what drove the push for vendor consolidation, but it is passé. Effective partners work seamlessly in the BEST model, bringing their differing offerings to bear in pursuit of maximizing value and minimizing risk.

2. Articulate and Measure Desired Outcomes

For example, clinical monitoring leaders are concerned about high attrition. Attrition is not the problem; impact to site satisfaction and site data quality is the problem. Too much change of personnel at sites may reduce a site’s ability to be an effective part of a study. Similarly, emphasis on specific levels of experience comes with an

assumption that experience impacts performance. By articulating desired outcomes that encompass operational performance, site and patient experience, Sponsor companies can better blend operational models and retain control of what is of true value. In more advanced cases, this will extend to output-based performance and even shared risk.

3. Adaptation and Integration

Models and partners have their respective strengths, which drove their original selection. A BEST approach recognizes that a model of best fit may still address most challenges and a supplement is not a signal of failure. Depending on the scale and duration of any altered approach, some investment of time is critical, especially as internal teams migrate from one project to another, where delivery models are different. If satisfaction equals expectation minus delivery, deviation from what a team expected could be harmful, even if all are doing just what was contracted.

In conclusion, the biopharma industry has reached a new level of maturity in clinical collaboration. Where previously, vendor consolidation was a strategic end in itself, with this new maturity comes the ability to look afresh at challenges as opportunities and for partners to respond by helping to remold development operations in a way that delivers enhanced capacity, reliable quality, targeted expertise and customized infrastructure all at the same time, even if not through one vendor in one model.

About Mark Scullion

Mark Scullion is Senior Vice President, Global Alliance Management at inVentiv Health, where he leads partnership strategy, oversight of large-scale project design and delivery, process design and innovation. His work has included designing alternative approaches to clinical trial design and the creation of productivity and financial models to maximize the return on sponsor company assets. Mark holds an MBA from UNC Chapel Hill, an MS in European politics from the University of Liverpool and a B.S. with honors in French and Portuguese from the University of Leeds.

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