

# Best Practices in the Sponsor-Provider Partnership to Optimize the Clinical Trials Development Process

by Timothy S. Brewer

## Introduction

As the length, complexity, and global scale of clinical trials increase, the costs of clinical and investigational drug supplies have escalated disproportionately. Historically low priority areas for pharmaceutical and biotechnology companies, these areas now offer opportunities for optimizing the development process by introducing innovation through strategic partnerships between sponsors and providers.

In order to enact strategic practices, a great deal of trust and open communication must exist between both parties. The service provider can't over promise and under deliver; the sponsor can't manage the provider in the transactional, project-by-project manner in which they have in the past. Both need teams of individuals that are skilled at managing the relationship, communicating well, measuring the performance of the relationship, and leveraging that performance to help deliver the sponsor's goals for an investigational product.

This *Knowledge Brief* explains seven

best practices that can be adopted and adapted to drive improvements in the sponsor-provider relationship to optimize the development process and timeline.

1. *Involve the clinical logistics team in the planning and decision-making process, prior to site selection and patient enrollment.*

Involving clinical logistics professionals into the planning phase of a clinical protocol ensures that country selection and concerns about patient compliance or investigator populations can be addressed cost-effectively and within budget. With packaging designed for maximum patient compliance and product shelf life, as well as a review of each country's logistical issues, thoughtful solutions can be designed that best meet the needs of a clinical protocol. Solutions that consider the impact of volume, geography, and distribution across any number of investigational sites for packaging, multilingual labeling, process automation, storage, and distribution can prevent unplanned, costly changes that explode budgets.

*2. Use forecasting and planning tools and processes to manage rising drug and ancillary supply costs, not drive up cost by over-ordering and over-stocking investigator sites.*

By defining what is needed in a study, drug and supply waste can be minimized without compromising patient safety. Planning tools and processes help determine the specific amount of investigational product to manufacture, as well as allow for bulk purchasing of ancillary supplies at lower cost. Ongoing enrollment patterns are then used to predict inventory, determine when investigational products and ancillary supplies are needed, how much, and exactly what needs to go where by a specific time. With the flexibility to service new regions and previously underserved patient populations, choose technology solutions that allow individual product detail to be reviewed at specific locations, while ensuring a real-time comprehensive view.

*3. Consolidate and use fewer strategic outsourced partnerships, not coordinate the actions of hundreds of providers within specific timeframes.*

Size matters. Size equals capacity equals flexibility. Most internal structures require multiple resources in project management, outsourcing, procurement/purchasing, regulatory, clinical supplies, analytical chemistry, and specimen storage to either provide services or monitor the performance of outsourced providers on behalf of the clinical team to ensure quality and to meet study timelines. While risk was spread across multiple vendors with jobs competitively bid at their lowest task level, little to no focus was placed on creating a supply chain strategy that identified even greater value compared to the lower transactional costs.

Consolidating packaging over multiple protocols, leveraging project management resources, and proper utilization of Interactive Web Response (IWR) systems can help the sponsor realize the value of the truly integrated

supplier. As the sponsor begins to trust this relationship, costs are driven down internally as resources are no longer needed to manage each step.

Converting fixed costs to variable costs with a reliable outsourced provider can save time and reduce costs on routine processes and non-core services that would allow more capital to be re-invested in the core business and development pipeline. Reducing multiple vendors also eliminates layers of transactional errors in the supply chain and reduces overall management expense.

*4. Trim development time by completing complementary processes simultaneously.*

Many tactical activities happen sequentially creating a longer and more costly supply chain as information bounces back and forth between multiple providers. The result: escalating costs, extended development timelines, higher levels of drug supply wastage, and increasing risks to patient safety. The sponsor is best served when vendors are able to use their own systems and processes. There are many ways to gain efficiency and timeline improvement by funneling total project management responsibility to the vendor.

*5. Ensure proper planning for your investigational drug product requiring specified temperature and storage conditions, special handling requirements, and controlled substances.*

More and more, investigational products require customized handling that ensures supplies arrive at the right temperature to the site regardless of how remote the site is. Even one unexpected delay in transit can mean missing a treatment window, due to potency-destroying temperature fluctuations. For project critical scenarios, use a provider that leverages the latest technologies to preserve and monitor – in real-time – the conditions of clinical trials materials. All avenues must be defined and executed. The shippers must be validated, the

traffic lanes must be tried and true. It is essential to understand all regulatory requirements for all countries before planning a study start. Instituting a study plan using MS Project to identify all milestones of a shipment is also a helpful tracking tool. This would establish expected timelines for import licenses, number of days for transport, customs clearance, and other time critical items.

*6. Use centralized, regional distribution centers for clinical trial materials.*

The pursuit of patients that have the illness for which a medical therapy is designed is driving more clinical trials to locations with “treatment-naïve” patients, or those who may not have been previously exposed to therapies. This dramatic shift is expanding clinical work into Asia, Latin America, India, and Sub-Saharan Africa – and introducing distribution and logistics challenges.

Bureaucracy is a huge hurdle to overcome in countries where jurisdictional disputes over paperwork can delay shipments (sometimes as much as a year). With complex tiers of policies and regulations that vary by national, regional, and local government, it pays to have people on the ground that understand the local language and regulations and can help shepherd the shipment through the process. Using a regionalized approach allows greater flexibility in shipping drugs to support actual trial enrollment. Drug product can be stored at a central, regional location for further distribution to the site. This helps to ensure that drug product will be in the country when needed for patient enrollment.

To help make the drug development more seamless means that both sponsor companies and service providers need to work in collaboration with regulatory bodies around the world to develop more common approaches. By using international organizations, such as ISPE, change is able to be effected so we can eliminate waste, assure patient protection, and streamline the ability to design and deploy a clinical trial globally in a much more effective way.

### 7. Ask for a recommendation, not just a quote.

Additional value comes through increased compliance, as monitored through a robust performance metrics program, exposure to technological solutions developed by industry-leading experts in supply chain processes, and access to data via custom-designed “dashboards” allowing views to multiple systems.

An outsourced provider that can design a study focused on operational effectiveness and reducing cost will yield significant savings through a collaborative planning process. With the implementation of these unique technologies, a sponsor could see a 20% reduction in waste and a shorter deployment window. The result is reduced project cost, enhanced quality assurance, simplified vendor interface, and expedited study delivery.

## Conclusion

There are best practices that can be learned from working with an outsourced provider that has worked with multiple sponsor companies on a wide-range of protocols and therapeutic areas. This exposure provides a higher level of experience and broader expertise to design the clinical supply chain for a trial that decreases turnaround times, ensures compliance with the latest regulatory changes around the world, and identifies new opportunities to acquire or build new service offerings to better meet needs.

## For Further Information

For more detailed information, the following ISPE resources are available:

### Publications:

- “External Sourcing of Clinical Trial Materials, Part 1: Process and Points to Consider,” by Charles F. Carney, *Pharmaceutical Engineering*, Sept/Oct 2004, Volume 24, Number 5, Clinical Trial Materials (CTM) Supplement, pp. 22-27.

- “External Sourcing of Clinical Trial Materials, Part 2: Impact of Electronic Automation on the Sourcing of Model for Clinical Supplies Preparation,” by Charles F. Carney, *Pharmaceutical Engineering*, Sept/Oct 2004, Volume 24, Number 5, Clinical Trial Materials (CTM) Supplement, pp. 28-31.
- “Considering Outsourcing? Risks and Benefits for FDA-Regulated Firms,” by Mukesh Kumar, *Pharmaceutical Engineering*, Jan/Feb 2009, Volume 29, Number 1, pp. 68-70.  
<http://www.ispe.org/pharmaceuticalengineering>

### Investigational Products (IP) Community of Practice (COP):

- Visit our IP COP on the ISPE Web site for the most current and up-to-the-minute discussions on the topic discussed in this *Knowledge Brief* and other related topics.  
<http://www.ispe.org/communitiesofpractice>

## About the Author

**Timothy S. Brewer** is Global Vice President, Logistics, at Fisher Clinical Services. Formerly Chief Executive Director of Clinical Trial Services (CTS), Brewer has more than 15 years of experience in the pharmaceutical industry. He established CTS, a pharmaceutical packaging firm, in December 1996 where he was responsible for providing executive leadership, managerial direction, and client development. Brewer attended the United States Military Academy at West Point where he majored in chemical engineering, and Alvernia College where he received a BS in business administration and management. He is a member of various professional organizations, including the Drug Information Association (DIA), Association of Clinical Research Professionals (ACRP), ISPE, AAPS, and others. ●