The Emergence of Strategic Outsourcing in CLINICAL SUPPLY CHAIN MANAGEMENT

Contributed by

ROBERT DUNLOP
President and Managing Director,
Almac Clinical Services

JIM MURPHY
President and Managing Director,
Almac Clinical Technologies

Ten years ago few biopharmaceutical industry professionals could have predicted how broadly the landscape for outsourcing would change by 2012. Most companies were outsourcing in a tactical, project-by-project manner and utilizing dozens of providers across functional areas. Some were moving to a "preferred provider" model in which five to 10 providers were being used for particular drug development tasks. Then financial and operational realities hit many companies. It proved too costly to identify, contract, and manage so many vendors, particularly in an era when revenue and margin growth, as well as stock prices and R&D productivity were declining. Facing such challenges, small, medium, and large firms alike began developing strategic outsourcing relationships with a handful of providers capable of providing a variety of services across phases of drug development and functional areas. Strategic outsourcing has changed the way service providers manage their businesses and interact with sponsors. In the area of clinical supply chain management, the changes have been dramatic.

Strategic Partnerships

One of the most recognizable trends in supply chain management has been the tendency of biopharmaceutical firms to outsource to a handful of market leaders that can provide a variety of supply chain services. Today it is becoming increasingly more common for biopharmaceutical companies to outsource aspects of drug manufacturing, analytical testing, storage and depot management, packaging and labeling, worldwide distribution and logistics, and Interactive Voice and Web Response technologies (IVR/IWR) to one company. One of the main benefits of forming strategic relationships for sponsors is to drive value in the long-term through innovation of the supply chain due to integrated delivery models. To be selected as an integrated services outsourcing partner, firms not only need to demonstrate high-quality output experience and expertise, as in the past, but also stability, longevity, and the ability to commit to long-term strategic relationships.

A Global Influence

It is no coincidence that the trend of strategic outsourcing has paralleled the growth of international drug development, particularly in Phases II and III. As the market for new drugs has grown considerably in emerging regions and the challenge of patient recruitment has intensified, sponsor firms have increased the volume of international trials, with the number of sites and patients abroad growing considerably over the past 10 years. Faced with the decision of making large investments to develop R&D footprints on a global level, many biopharmaceutical companies have opted to use global contract research organizations, contract drug manufacturers, and contract clinical supplies firms to manage such trials. Supply chain management suppliers, for example, are strengthening their overseas depots networks, multilingual IVR/IWR systems, and human resources that understand global regulatory guidelines.

Integration

These market dynamics have led to significant changes in how supply chain companies manage their business. Operationally, such trends have forced suppliers to integrate services in a logical way and deliver them seamlessly to clients. To do so requires more coordination between various departments across geographical locations of global firms. Hence, forward-thinking supply chain firms have invested in facilities that house integrated project management staff across supply chain and technology disciplines. By working together in integrated services departments, supply chain and technology professionals collaborate to efficiently deliver bundled services to sponsors while driving innovations that are not possible when each group operates in silos. In terms of sales and business development initiatives, strategic outsourcing has required suppliers to train sales people across drug development disciplines and sell to higher levels inside sponsor firms, as decisions on integrated service purchases are often made at the director, vice president, or C-Suite levels and supported by procurement professionals.

Strategic Relationships

The growth of strategic and integrated services outsourcing has also changed the na-

ture of the relationship between sponsors and suppliers. Strategic relationships involve nurturing cooperative efforts between the two parties to negotiate service level agreements, establish metrics to evaluate quality, and integrate technologies and processes between sponsors and supplier organizations. Today it is common to have joint committees that help assess, evaluate, as well as improve the quality of deliverables and the working relationship between suppliers and sponsors. Such committees typically exist on the operational, management and executive levels between firms. The goal is to better understand each other's needs, operational and financial realities, and find ways to develop a win-win relationship that results in higher quality drug development at a reduced cost.

The reduction of drug development costs is a factor that today is omnipresent in the relationship between sponsors and suppliers. Supply chain management suppliers, for example, are now working cooperatively with sponsors to figure out ways to drive down the costs of the supply chain. There are a number of ways in which this objective is being attained, the three most common being the purchase of integrated services, a strong emphasis on consultation and planning, and devising processes/practices to drive efficiencies across the supply chain. As the topic of integrated services purchasing has already been covered, we will focus now on how planning and efficiency programs are generating cost savings for sponsors.

In contrast to 10 years ago, sponsors are increasingly engaging suppliers in the planning process for clinical trials. It is now becoming common for sponsors to approach supply chain management firms early in the drug development process, often during the protocol development and planning stage with the goal of driving down costs through efficiency initiatives. Hence, supply chain experts from supplier firms are being asked to help forecast when drug products will actually be needed during the clinical trial. Upfront forecasting empowers sponsors to better manage product expiration dates, develop a consistent and rational plan for an integrated IVR/IWR and packaging/labeling strategy, reduce costs in analytical testing, and assure that biopharmaceuticals are available when patients need them during the trial.

Forecasting for Success

There are a variety of ways in which forecasting is conducted to deliver on the goals of reduced costs and improved efficiencies in the supply chain. Working jointly with supply chain management companies, sponsors are utilizing a variety of forecasting tools to more efficiently manage their supply chains. Such tools use sophisticated algorithms and supply parameters combined with inputs from simulated recruitment models to more accurately predict demand for supplies by sites. Moreover, supply chain firms that provide IVR/IWR services in addition to clinical supplies-related services (e.g., drug manufacturing, packaging, labeling, global logistics etc.) are boosting forecasting efforts by feeding live data from such systems into the forecast. This facilitates real-time adjustments to the forecast. In these ways, the demand for pharmaceutical products, particularly in large Phase III studies, can be better forecasted. This allows sponsors to better plan their packaging and labeling efforts, reduce storage costs and drug wastage, as well as decrease overproduction of drugs that eventually expire. Success in forecasting is particularly relevant to biological products, which are typically more expensive to manufacture than chemical entities, require cold chain storage, and often have shorter expiry windows.

In addition to forecasting, sponsors are attempting to drive down costs of drug development in the supply chain by taking advantage of the integrated data provided by large, global supply chain firms. When sponsors purchase clinical supplies and IVR/IWR separately, they tend to benefit less from the data that both firms collect because sharing and analysis of pooled information across companies proves too difficult. In contrast, when the services are purchased as part of an integrated bundle from one firm, sponsors can use integrated data and reporting to improve trial planning and management.

Supply Chain Management

Beyond providing improvements in planning through integrated data and reporting, global supply chain firms are assisting sponsors by effectively managing drug inventory and reducing shipping costs. Proactive management of supplies by experienced supply chain professionals, especially those armed with real time supply and demand data, allows them to actively manage the method of shipment and number of shipments to sites, hence saving sponsors considerable money on shipping costs. Such enlightened management of supplies also alleviates the burden on sites to store excess drug product in their facilities. After all, it is not just drug products that sites must maintain. They are also responsible for storage of central laboratories kits, diagnostic products, and other key supplies needed during the trial. Hence, alleviating the burden of managing excess clinical supplies makes life much easier and less costly for investigators and other site personnel who need to maintain space for supplies storage. Finally, reducing the volume of shipments also makes the tasks of the clinical research associates and site personnel much easier, as their efforts relating to inventory management (and the actual hand-counting of products on site shelves) can be reduced. One of the keys to achieving such efficiencies, however, is to have IVR/IWR systems integrated into supply chain management technologies, which is exactly what the market leaders are implementing on a global level today.

As relationships between sponsors and suppliers have become more strategic, the possibilities of slowing the growth or in some cases reducing the costs of drug development have become realities. However, strategic outsourcing requires innovative ways of thinking, behaving, and interacting between sponsors and suppliers. It necessitates a better understanding of each other's businesses, particularly financial, operational, and management issues. For supply chain suppliers it requires us to become more embedded in our sponsors' businesses, from the planning of trials through operational delivery. It also requires us to operate on a significant scale with the capacity to deliver integrated services including manufacturing, packaging, labeling, depot management, global logistics, and IVRS/IWRS technologies.

Such integrated supply chain solutions are necessary to manage mega studies and global trials that require high levels of expertise, international reach, and regulatory knowledge. Moreover, such levels of breadth in service offerings and niche domain expertise are required to become strategic partners with sponsor firms in an era of strategic outsourcing. PV