



Integrating and Interfacing

Johnathan Calderwood of Almac puts the spotlight on project management – the key to effective outsourcing relationships

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As the pressure to deliver new entities into the marketplace continues to grow, many sponsor companies now view their relationships with external suppliers as a critical business function. Most sponsor companies and their vendors are moving from a distant one-way relationship to effective partnerships with shared common objectives.

In the context of clinical trial supply and its integrated role within the drug development process, consistent delivery and a deeper mutual understanding between the sponsors and outsourcing partner provide new impetus to the marketplace. Time and cost as always are in the mix, but the day-to-day relationship "on the ground" can still hold sway in terms of long-term outsourcing strategies.

Time and time again, it is commented that effective project management is the number one factor in ensuring a sponsor company's continued selection of their clinical supplies partner. This article assesses the rationale to outsource the clinical supply chain and the value added to this by effective project management, all in the context of the clinical supply market. The typical client models that a clinical supply contractor has to deal with are also examined. Within these different sponsor company "types", there are inherent advantages and disadvantages and this is where skilled and experienced project managers can add true value to the relationship.

IN OR OUT?

Clinical supplies, their manufacture and distribution alongside IVR management systems are typically executed in-house or outsourced to a third party. Generally, the selected approach used depends on the company "type" and is either strategic or tactical in use. For instance, virtual or small pharma usually have little or no facilities of their own, so outsourcing is strategic and long term in nature. On the flip-side, larger pharma companies with extensive in-house research and development/manufacturing facilities that can handle the peak-and-trough nature of supply materials, and only require outsourcing for particular trial sizes or those that compete with commercial batches in-house.

OUTSOURCING MODELS

Once the decisions has been taken to outsource and an appropriate selection process completed, the contractor in question is generally presented with one of four sponsor company types:

Sponsor Company A:

Following a single sourced approach, in this context, all external activities are channelled through one clinical supply partner. By sharing expertise internally within the contract organization, and training staff in multiple disciplines, they can take on the burden of the different functions such as packaging, distribution and IVRS. With this approach, strain on the sponsor is reduced due to the limited contacts to be managed on a day-to-day basis.

Sponsor Company B:

On a multiple sourcing plan, the sponsor company maintains specific relationships for particular functional areas – such as manufacturing and distribution. This allows for gains in areas such as pricing or niche expertise, but may also be problematic in terms of segmenting the clinical supply chain and increasing workload due to maintenance of multiple relationships. Also information flow can prove difficult as multiple organizations are involved.

Sponsor Company C:

This is typical of medium and large sized pharma, where the outsourcing activities are controlled by both a clinical supply unit and a clinical research group. This approach can be of value by closely aligning the needs of each group to each functional area (IVR systems are built around information from the protocols developed by the clinical group). At times, the parallel development of trial supply and IVR strategy can result in incorrect assumptions that may become apparent after the "go-live" stage.

Sponsor Company D:

In such a situation all outsourced activities are assigned to the responsibilities of a specific CRO. This also can be a problematic set up in terms of defining the sponsor's requirements, as many decisions must be referred to the client from the contract organisations through the CRO, who are not necessarily experts in any of the functional areas. However, the expanded therapeutic expertise and patient management services may outweigh these challenges.

PROJECT MANAGEMENT

In terms of expectations of an outsourcing partner, the initial organizational type is of prime importance. This lets the skilled manager determine the remit and requirements expected from the client company. Often, this is not stated upfront. For instance – a virtual company who must rely on partners for most activities (type A) and who do not have a clinical supply function as such – they will rely heavily on the consulting aspect of the chosen provider. The project manager must act as a consultant for packaging design, inventory management and interpretation of the supply requirements from outline clinical protocols.

Alternatively, the project manager, working with company type C, may be part of a large and established international supply chain. The sponsor company will be interested in performance appraisal and monitoring – key performance indicators and regular business reviews. These clients generally experienced and well versed in clinical supply and IVR operations, so robust and formalized interactions are relevant.

RELATIONSHIPS ARE KEY TO SUCCESSFUL PROJECTS

The markets are awash with new production capacity offerings, technical tools and supply chain management systems. These are, of course, essential, but again the key to the correct clinical supplies delivered to the right place at the right time are the relationships forged by the sponsor company and their allocated project manager.

After the selection process (a subject to consider in itself), there must be an open and frank discussion to agree the way forward, such as:

- The needs and requirements of the sponsor company:
- The operational structure of the sponsor company:
- The expectations of the sponsor company
- Procedural aspects specific to the sponsor company
- The needs and requirements of the contractor (often overlooked)
- Development of trust and commitment

REPRESENTING THE INTERESTS OF THE SPONSOR COMPANY

There are many reference documents and publications related to specific aspects of the discipline of project management. However, the best laid plans, costing and resource allocation can account for nothing if communication is poor between the sponsor and contractor.

The project manager must consider themselves as the champion of their allocated company. This, in effect, means acting as the voice of their partner within the contract organisation – maintaining the interests of their clients, imparting the knowledge of the specific working practices and requirements. This, built on the foundation of planning, communication and resource management will take the relationship to the level of trust that is required, and reduces the risk to the clinical supply chain.

CHOOSING THE RIGHT APPROACH

As a substantial proportion of trials are now multinational, the clinical supply chain often spans multiple continents. Vendor companies should offer a range of management models to the sponsor – and let the best fit for the specific trial requirements dictate the management structure. For instance, client companies may conduct packaging and distribution activities in Europe and the US, so would choose a project manager for each region. Alternatively, a single point of contact may be chosen to report for both locations, perhaps due to time zone compliance, or a relationship already established with one location.

Complementary to the point of contact models, a global approach is essential in order to present a consistent and integrated project management structure, GMP documentation and operating culture. A sponsor company will not want to divide their already stretched resources to deal with multiple iterations of their outsourcing partner.

SETTING THE SCENE

A systematic, upfront approach to general supply agreements assists in plotting a course forward. All companies must agree and execute a standard master services agreement and

technical agreement. These are termed as umbrella agreements, generally not specific to one particular trial. A project management document is also of use and is generally project-specific in scope.

The master services agreement details all the legal and liability information in accordance with standard business operational procedures. The technical agreement, which must be agreed before any work can commence between partners, defines general operational procedures and processes. For instance, each stage of function related to processing of clinical supplies is covered, detailing general operating standards and processes. It is of note that this must be executed in compliance with the European Directive 2003/94/EC Article 12 for work contracted out.

The project management document – relating to a particular study or protocol, details agreed information on the provision of clinical trial supplies, outlining site responsibilities, kit list information, supply formats, quantities and shipping of trial materials to various countries to name but a few. When these documents are in place and agreed, the platform is available to operate on a longer term basis and develop understanding between the companies.

FORECASTING AND PLANNING

Aside from the routine communication over progressing projects and studies, it is important to set regular face-to-face meetings to look at longer term pipelines. This gives the contract company an advantage in terms of extending the window of visibility normally not available to them. Also, it allows the trial sponsor company to secure resources at the appropriate time and allow for extra if peaks are anticipated. This relates to both machinery and manpower.

DEVELOPING THE RELATIONSHIP-MONITORING AND PERFORMANCE

It may be useful to implement certain metrics or key performance indicators to help monitor and improve the operational relationship. These are by no means part of a blame game, but can be very useful in setting expectations and benchmarking performance. Typical indicators used include:

- Lead times for generation of clinical supply requirements
- Timelines for generation of batch documentation
- Timelines for receipt of material
- Documentation review and release metrics
- Quality incidents and close outs

It is important to ensure that correct business processes are measured and the agreed expectations are realistic. Also, the data produced must be reviewed and actions implemented as required – too often people are concerned with the day-to-day management and this is overlooked as a sideline issue. Monitoring and benchmarking can assist in highlighting weaker areas in the full relationship, and can help develop a deeper working relationship.

BENEFITS FOR SPONSOR COMPANIES

Competent project management between sponsor companies and their partners results in:

- Patients supplied correctly and on time

- Reliable and timely data from clinical trials
- Meeting of internal FPI dates
- Minimised waste and patient drop out
- A clearer view of the clinical supply chain, which saves time and money

CONCLUSION

The interface between a sponsor company and its clinical supply partner is a critical one. Relationships based on a deep knowledge of people and processes can be developed and monitored over time. A competent project manager can provide a huge contribution to the overall success of a clinical trial and be seen as a partner in the overall objectives of successful trial completion.

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