Features

Clinical Trial Supply Chain Management

Making the leap from commercial to clinical

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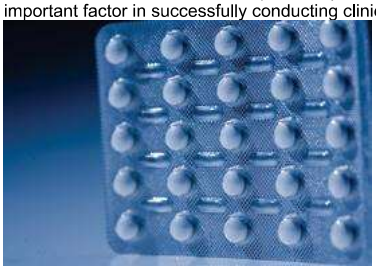
Making the leap from commercial to clinical

By RS Kumar

It is no secret that clinical development represents the longest and most cumbersome aspect of launching new drugs into the global marketplace. Product development challenges ha important factor in successfully conducting clinical studies is the efficient management of clinical trial supplies, particularly for those complex studies requiring detailed monitoring, pre



BearingPoint and AMR Research recently conducted a benchmarking study on the clinical supply chain. This highlighted the increasingly complex environment in which life sciences compa effective and efficient supply chain than currently exists. However, the focus needs to expand beyond the commercial supply chain to encompass the clinical supply chain. Only then will co

Our research showed that the number of trials is increasing (nearly 50% of companies will have more than 20 studies per year by 2010), more adaptive trials are planned (39% of these cor trials). Inefficient clinical supply chains will increasingly put these complex global trials at risk. The success of these studies is heavily dependent on providing study supplies to often large r result in patients being disqualified, potentially jeopardizing the entire study. However, forecasting of trial stock requirements is difficult, particularly with the rise of adaptive trials. Patient rec

Ease and expense of patient recruitment is one reason why companies are looking further afield to perform studies (only 38% of our respondents' trials will be administered within North Am product between sites, delay delivery of supplies to sites (a particular issue when there are short expiration dates) and even potentially un-blind trial supplies. Repeat infringement of trade r regulatory requirements keep regulatory compliance as a top-two concern for more than half of our European Union respondents.

Clinical Trial Supply Challenges

At the outset of any clinical trial, the enterprise uses a standard formula -- the number of participating patients at each site, multiplied by the number of doses administered daily, multiplied b patients for the length of the trial.

If everything worked beautifully, that would be the end of the story, as far as planning goes. But things generally aren't that simple. Let us take a closer look at the three key challenges in cl

Planning

Effective clinical trials depend heavily on providing study supplies to various sites so that prescribed drugs are administered at the correct times throughout the study. If supplies run out (kn supply stock-outs is difficult for a variety of reasons.

Patient recruitment can proceed at different speeds in the different study sites, resulting in "staggered" enrollment, with a fraction of the planned participants entering the study one week, a period of time.

Additionally, participants often drop out before the treatment is complete. As a result, some sites may enroll significantly more participants than others. However, regulatory restrictions som

Expiration dating also has an impact on supply management. Often, clinical supplies must be manufactured prior to the availability of medium- to long-term stability data. Clinical supplies m of replacement materials. Delays or extensions in the clinical study may also result in expired supplies -- again resulting in re-labeling or additional manufacturing campaigns.

Manufacturing

The production of clinical supplies in most ways mirrors the production of commercial drug products. All operations and processes must be fully compliant with current Good Manufacturing

Clinical supply manufacture faces a number of additional challenges that do not impact commercial drug supply chain operations to the same degree. These challenges include:

- The lack of adequate supply of the active pharmaceutical ingredient (API).
- The necessity to manufacture numerous small lots of the drug product.
- The reduced expiry dating due to lack of medium- or long-term stability data.
- The manufacture of numerous dosage strengths, placebos and comparator products that all need to look alike but must be controlled as unique entities throughout the supply chain.
- An enhanced complexity in primary and secondary packaging.

- The coordination of manufacturing, which may occur in a pilot plant or development laboratory, contract manufacturer site, and/or the commercial manufacturing site

Distribution

Compliant shipment of the drug to many trial sites, which are often scattered in different countries, may seem simple, but it is difficult to achieve because of the need to co

Another challenge is tracking the drug throughout the value chain. In fact, it is essential to have a reliable and efficient accountability process in place so that unused drugs may be reconcil

How Technology Helps

Technology may significantly streamline and improve the forecasting, manufacturing and distribution of clinical trial supplies. Clinical trial demand is defined as the number of doses of the tr be placed at the testing sites, in defined time periods, and this demand is then aggregated to a regional distribution point. The aggregated demand forecast should be developed at this dist

By using this approach, the manufacturer can allow for distribution flexibility to meet requirement changes and also help commit materials to testing sites in the appropriate amounts on the recent demand placed at the distribution point. This commitment to planned demand supports just-in-time (JIT) packaging and labeling of bulk product to add flexibility in the supply chain.

Demand-planning applications aid greatly in the initial forecasting as well as subsequent adjustments and distribution planning. Once created, the forecast is passed to a component applic

Supply chain planning applications evaluate demand requirements, taking into account the on-hand inventory, and create planned orders to cover the net clinical trial requirement. The outp of the clinical trial materials to the various distribution points.

Sourcing of clinical trial materials can be either fixed (using a single source) or dynamic (using multiple sources). The use of dynamic sourcing will select a feasible sourcing plan that includ fluctuations in patient participation at the testing sites. The advanced planning systems may also be used to perform safety-stock planning to ensure reasonable levels of availability.

Any last-minute demand changes are updated in the planning process and resolved using interactive planning to create a new demand-supply scenario. Rough-cut capacity planning helps end of the planning cycle, the clinical trial planned orders and requisitions are committed to an enterprise resource planning (ERP) system for execution.

Manufacturing execution systems (MES) may be effectively used to manage the manufacturing, packaging, labeling and shipping activities to help maintain both product integrity and tracea into three major categories:

1. Advanced planning and scheduling (APS) systems that perform forecasting and supply chain planning.
2. ERP systems that manage the manufacturing and distribution of the clinical trial materials.
3. Clinical trial management systems that perform these specific business processes:

- Study management,
- Site management and collaboration,
- Packaging and labeling,
- Batch records management, and
- Interactive voice recognition systems (IVRS).

Some functions, such as forecasting, may be performed by some or all three application categories. APS and ERP, for example, perform batch control and tracking. Other functions are uni

It is clear that no single technology solution can manage clinical trial processes completely and effectively by itself. More advantageous than a single vendor solution would be a combinatic management.

Systems Alone Are Not the Solution

Systems are merely tools to facilitate the clinical trial operation. The underlying business processes must be evaluated, improved and aligned. For example, if a company accurately foreca is gong to fix that underlying problem. By evaluating the underlying issues and redesigning the clinical supplies processes, the business can then use automated tools and systems to furth

- Clarify the goals of clinical trial management.
- Determine the core business processes required to reach these goals.

Based on the business requirements of the processes, enterprise business management may evaluate applications and systems and decide which technology would best support -- and er and responsibilities for each person and group involved in the clinical trial supply processes and with clear timeframes and metrics to verify that the procedures are followed. Additionally, th organization on a path of continuous improvement.

The current roadmap for clinical trials contains numerous time-consuming regulatory requirements, and over time we expect additional regulations will make the process even more comple the pharmaceutical enterprise can be prepared to deliver breakthrough drugs more efficiently and cost-effectively.

RS Kumar is a senior manager in BearingPoint's Life Sciences Practice. He leads the company's solution work for clinical trials supply chain management, and played a leading role in AMI

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