

Don't Get Stopped Short by a Shortage of Study Drug

Good Project Management Can Keep Trials Running Smoothly



Timothy J. Noffke, VP Life Sciences

Managing a clinical trial can be a daunting endeavor; with significant factors such as study design, site selection, and patient recruitment to contend with. Even so, one of the most frequently underestimated tasks — with the potential to bring a trial to a grinding halt — is the manufacture and packaging of investigational drugs. Managing clinical supplies may appear to be a fairly simple task but in fact it is a complex logistical challenge. The challenge continues to mount as regulatory agencies demand more and larger trials and multiple variations of packaging and labeling to satisfy their requirements.

Effective clinical-supply management requires marrying the dynamic needs of the R&D organization with the quality, planning, and control of a manufacturing supply chain. For many, this is easier said than done. Making, labeling, packaging, and replenishing investigational product for on-time, accurate delivery to study sites presents a multivariable problem. If not managed proactively, the entire program can fall off track. Good project management can help anticipate and mitigate conflicting requirements to ensure a dependable supply of study drugs.

One of the most frequently underestimated tasks —
with the potential to bring a trial to a grinding halt — **is the**
manufacture and packaging of investigational drugs.

Align Expectations

The key to understanding potential schedule constraints starts with clearly defining the schedule requirements of all involved in the process. This can best be achieved by fostering a close collaboration between the clinical-development team and the clinical-supplies organizations. A constructive exchange about requirements and constraints is critical to getting everyone on the same page, and is a give-and-take process. It's important to determine which elements of the clinical program are "must haves" to provide pivotal data, and which elements are "nice-to-haves" to provide supplemental data. Participants should establish the flexibility and capacity of the supply chain, and how technology development and sourcing decisions can be accelerated to maintain a steady availability of clinical supplies. Agreement about which needs are absolute and which are variable can also empower productive contract negotiations with third-party partners, such as CMOs and CROs. The bottom line is that the earlier everyone defines the requirements, the greater the probability that the clinical supplies team will meet the study start date, with the right materials in the right place at the right time.

Plan for Success

Creating a solid framework for the time and effort it takes to effectively manage clinical supplies provides clarity to the clinical team and, of critical importance, protects the clinical supplies organizations from being expected to do the impossible. A robust integrated project plan details activity sequence, functional interdependencies, and resource commitments, as well as the risks and opportunities inherent in the process. Guided by a well-defined roadmap, emphasis can be placed on tracking activities and mitigating risks. Taking a few additional steps can further bolster a plan's effectiveness:

- Mapping the interdependencies of the supply chain from raw materials to final delivery greatly enhances planning and forecasting accuracy. A clear, and literal, picture of the process helps all stakeholders understand and manage the complexities of having supplies on time and at the right place.
- By establishing, when possible, a standard set of formulations and comparators across studies within a program, the clinical team can reduce risk of error while increasing efficiency.

- Creating a dynamic clinical-supply-versus-demand model enables real-time scenario analysis that can be used to help mitigate risk. Such a model is relatively easy to construct and provides a tool for quantifying how the team needs to react if the manufacturing yields aren't what was expected or the study is expanded or changed.

Execute, Execute, Execute

Even with all the ducks in a row, it's not yet time to rest. Diligent oversight is critical to success. The best on-paper process means nothing if on-the-ground execution falls short. That means closing the loop on every task, every day, whether ensuring proper performance of a planned activity or quickly solving a late-breaking problem, to keep the program on schedule.

A focused project-management approach to clinical-supplies management saves money, maximizes productivity, and delivers results that meet everyone's expectations. Reliable execution of clinical trials not only helps bring products to market faster, but also supports positive relationships among internal functions, external partners, trial investigators, and patients, laying the groundwork for current and future successes. ■

INTEGRATED PROJECT MANAGEMENT COMPANY INC., Burr Ridge, Ill., is a project-management firm with a specialty in the life sciences.

For more information, visit ipmcinc.com.