JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 10, No. 5, May 2014 "Happy Trials to You"

Site Perspectives on Clinical Supply

By Pat Larrabee, Samantha Carmichael, Marisa Co, Mary Costello, James Denmark, Mary Jo Lamberti, Diane Orino, Ana Sanseau, Kathy Stoddard, and Amy Musolino

Clinical supply is seldom mentioned as an issue in clinical research, but it frequently causes problems for research sites. If study sponsors consulted more often with sites prior to the start of a study about practical issues like clinical supply, study conduct would be faster and more efficient.

In an effort to identify clinical supply issues and generate practical solutions, 10 site representatives and other clinical research professionals from around the world joined together to create the Investigator Site Panel on Clinical Supplies.

Survey of Investigator Sites

In 2013, the Panel conducted a worldwide survey of investigator sites. More than 300 individuals completed the survey, representing sites in North, South and Central America; Central, Eastern and Western Europe; Asia and Africa.

Four primary areas of site concern emerged:

- **Drug availability.** Thirty-five percent of respondents called drug availability their greatest clinical supply challenge. Many likened the issue to "feast or famine," with some sites overburdened by excess inventory and others depending on "just-in-time" deliveries that sometimes arrive late.
- **Storage.** Twenty-four percent of respondents said they lacked storage space for excess study supplies, particularly those requiring refrigeration.
- **Pre-shipment notifications.** Nineteen percent of respondents indicated that not knowing when to expect shipments prevented proper preparation and delayed participant enrollment and visits.
- **Drug receipt and dispensing.** Respondents identified problems throughout the process.

Recommendations

One survey question asked respondents: "If you could make one recommendation to a sponsor, CRO or clinical supply vendor, that would most benefit your site from a clinical supplies perspective, what would it be?" Responses are categorized in Table 1.

Based on this data, other survey data, and personal experience, the panel makes the following recommendations for study sponsors:

- Engage sites earlier during the protocol development process and actively communicate with them throughout the trial. Ask for their input.
- Employ a push/pull model for supplying investigator sites, based on a tiered approach. Evaluate site enrollment levels to ensure that the highest enrolling sites can pull inventory outside of the preset IRT (interactive response technology) limits.
- Engage a clinical supply expert with close alignment to sites early on to help design the packaging.

- Use the smallest possible packaging. Utilize recyclable packaging or "white glove site services," where logistics carriers reclaim and dispose of empty packaging.
- Indicate the protocol number on exterior packaging, with high visibility, so it can be found quickly.
- Increase the font size on labels and find ways to highlight the key information for participants and site staff. For example, color code labels to draw attention to key data.
- Send out pre-shipment alerts so sites know when shipments will arrive. Verify prior to study start up that these alerts are going to the correct individual at the site, rather than the principal investigator or site monitor.
- Employ technology to help avoid errors and minimize time-consuming manual tasks, such as checking off hard-copy lists of numbers. For example, bar code scanners could eliminate manual data entry during receipt.
- Replace or supplement paper lists with Excel spreadsheets sorted in numerical order.

Table 1. Respondent Recommendations

Provide pre-shipment notifications	19%
Improve communication	12%
Better manage inventory	12%
Develop compact packaging	11%
Ensure drug availability	7%
Improve labels	7%
Improve packaging	6%
Make labels easier to read	5%
Facilitate automatic resupply	5%
Let sites order drugs	4%
Use correct recipient and shipping address	3%
Ship in bulk	2%
Enhance IVRS	2%
Include QP data in shipment	2%
Standardize paperwork processes	2%

Supplies as a Priority

Clinical supply might seem less important than participant enrollment, but it is just as essential. Late deliveries, lost deliveries, early deliveries, bulky packaging, inscrutable labels, long check-off lists, etc., waste time and space, delay study visits, and can lead to medication errors. To be clear, these are common problems that interfere with many studies.

Study sponsors should involve sites in the clinical supply planning process to answer questions like the following:

- How big should the shipments be?
- How do sites quickly obtain additional shipments, and how long will it take?
- What type of user packaging would best suit the target patient population?
- What type of external packaging is best?
- To whom and to where should pre-shipment notifications and deliveries be directed?

Some of these questions apply to multiple sites and others to individual sites.

About the Investigator Site Panel on Clinical Supplies

The Investigator Site Panel on Clinical Supplies was formed in 2011. It is comprised of investigator site representatives and clinical supply professionals in the United States, Europe and South America. The panel's mission is to identify best practices, raise awareness, and drive change to the clinical supply system, thereby clinical research conduct and the participant experience.

Authors

Pat Larrabee, RN, CCRC NP, Chief Executive Officer and Founder, Rochester Clinical Research, Inc. Contact her at 1.585.288.0890 or plarrabee@rcrclinical.com.

Samantha Carmichael, Lead Pharmacist, Clinical Trials, National Health Service Greater Glasgow and Clyde, UK

Marisa Co, Former President, National Research Institute

Mary Costello, Global Director, Strategic Marketing, Fisher Clinical Services

James Denmark, Founder and Chief Executive Officer, myClin Clinical Research

Mary Jo Lamberti, PhD, Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University

Amy Musolino, Program Director, New Service Development, Fisher Clinical Services

Diane Orino, Certified Clinical Research Coordinator, ActivMed Practices & Research

Ana Sanseau, Principal Investigator, Estudios Multicentricos, Instituto de la Vision

Kathy Stoddard, Vice President, Benchmark Research

