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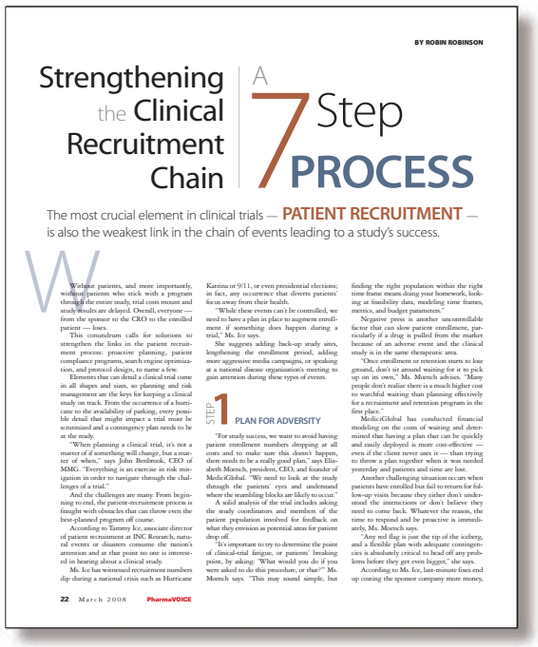

BY ROBIN ROBINSON

Strengthening the Clinical Recruitment Chain

A 7 Step PROCESS

The most crucial element in clinical trials — PATIENT RECRUITMENT — is also the weakest link in the chain of events leading to a study's success.

Without patients, and more importantly, without patients who stick with a program through the entire study, trial costs mount and study results are delayed. Overall, everyone — from the sponsor to the CRO to the enrolled patient — loses.

This conundrum calls for solutions to strengthen the links in the patient recruitment process: proactive planning, patient compliance programs, search engine optimization, and protocol design, to name a few.

Elements that can derail a clinical trial come in all shapes and sizes, so planning and risk management are the keys for keeping a clinical study on track. From the occurrence of a hurricane to the availability of parking, every possible detail that might impact a trial must be scrutinized and a contingency plan needs to be at the ready.

"When planning a clinical trial, it's not a matter of if something will change, but a matter of when," says John Benbrook, CEO of MMG. "Everything is an uncertainty in risk mitigation in order to navigate through the challenges of a trial."

And the challenges are many. From beginning to end, the patient-recruitment process is fraught with obstacles that can throw even the best-planned program off course.

According to Tammy Ice, associate director of patient recruitment at INC Research, natural events or disasters consume the nation's attention and at that point no one is interested in hearing about a clinical study.

Ms. Ice has witnessed recruitment numbers dip during a national crisis such as Hurricane Katrina or 9/11, or even presidential elections; in fact, any occurrence that diverts patients' focus away from their health.

"While these events can't be controlled, we need to have a plan in place to augment enrollment if something does happen during a trial," Ms. Ice says.

She suggests adding back-up study sites, lengthening the enrollment period, adding more aggressive media campaigns, or speaking at a national disease organization's meeting to gain attention during these types of events.

STEP 1 PLAN FOR ADVERSITY

"For study success, we want to avoid having patient enrollment numbers dropping at all costs and to make sure this doesn't happen, there needs to be a really good plan," says Elizabeth Moench, president, CEO, and founder of MediciGlobal. "We need to look at the study through the patients' eyes and understand where the stumbling blocks are likely to occur."

A solid analysis of the trial includes asking the study coordinators and members of the patient population involved for feedback on what they envision as potential areas for patient drop-off.

"It's important to try to determine the point of clinical-trial fatigue, or patients' breaking point, by asking: 'What would you do if you were asked to do this procedure, or that?'" Ms. Moench says. "This may sound simple, but finding the right population within the right time frame means doing your homework, looking at feasibility data, modeling time frames, metrics, and budget parameters."

Negative press is another uncontrollable factor that can slow patient enrollment, particularly if a drug is pulled from the market because of an adverse event and the clinical study is in the same therapeutic area.

"Once enrollment or retention starts to lose ground, don't sit around waiting for it to pick up on its own," Ms. Moench advises. "Many people don't realize there is a much higher cost to watchful waiting than planning effectively for a recruitment and retention program in the first place."

MediciGlobal has conducted financial modeling on the costs of waiting and determined that having a plan that can be quickly and easily deployed is more cost-effective — even if the client never uses it — than trying to throw a plan together when it was needed yesterday and patients and time are lost.

Another challenging situation occurs when patients have enrolled but fail to return for follow-up visits because they either don't understood the instructions or don't believe they need to come back. Whatever the reason, the time to respond and be proactive is immediately, Ms. Moench says.

"Any red flag is just the tip of the iceberg, and a flexible plan with adequate contingencies is absolutely critical to head off any problems before they get even bigger," she says.

According to Ms. Ice, last-minute fixes end up costing the sponsor company more money,

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A Missing Link

I just finished reading the March article, "Strengthening the Clinical Recruitment Chain," and it seems to me that you forgot a crucial first step in the process you describe. This would be the establishment of a sound protocol that makes scientific sense and benefits the subject. It's a lot easier to convince a subject to join a clinical trial when there is a tangible benefit to said subject (albeit only potential, because of the necessary use of placebo controls or standard of care comparators) rather than tailored by the need to prove to the FDA a slim, specific, sometimes rather obscure benefit vs. a competitor's drug. Even when well-intended, a badly designed study does not incite a coordinator's enthusiasm to keep subjects in the trial.

An added complication is that very few people volunteer for "the good of science" any more, especially when a current common perception is that "big pharma makes so much money, why should I volunteer for free, and put my life potentially at risk."

As much as I do agree with the body of the article, being a coordinator myself, I just wanted to underline those points.

Bruno Jubelin, Ph.D.
SC/REGULATORY
LRA INC.

Getting Better Acquainted

I thoroughly enjoyed reading the insights from several industry experts, most of whom were dead on with their analysis of social media and what it means to DTC marketing. The importance of collaboration between brand and legal teams must be stressed as it will take buy-in and cooperation from multiple stakeholders to communicate with agility and effectiveness in the Web 2.0 landscape. Education about how social media work, a plan for how employees and agents will interact online, and a little faith are all steps toward a robust social media strategy.

The one element of the article that I found puzzling was the title: "Controlling the Message in Cyber Space and Time." The power and essence of Web 2.0 is the complete lack of corporate control; this is the main reason it scares the living daylights out of so many regulatory/med/legal review teams. Consumers no longer have to rely on mainstream media to broadcast their messages; social media puts users in control. As marketers, there is a great opportunity to get proactive and become involved with social media by taking steps to allow users to participate in conversations regarding their healthcare outcomes. Marketers who open the door to two way communications and transparency will ultimately gain customer/patient loyalty, build community, trust and market leadership. We have a long way to go to test and trial these strategies, but it will be worth it in the long run. Marketers who insist on controlling the message will ultimately fail. Those who embrace transparency, dialogue, trust and above all create an unbeatable product will thrive in the user experience economy.

Scott Kiekbusch
DIRECTOR OF DIGITAL MARKETING SOLUTIONS
CRAMER

Pardon us ...

In the February issue of PharmaVOICE in the What's New department, we inadvertently cut off the end of the Guard Dog Brand Development LLC (GDBD) brief celebrating the agency's recent launch. Our apologies to Camille DeSantis, Copresident and Managing Partner, Brand Strategy and Client Service at GDBD, and Maria Casini, Copresident and Managing Partner, Strategic Brand Design at GDBD.

What you didn't get to read was: "Many people may not fully understand the distinction between brand development and branding," Ms. Casini says. "Brand development is the creation of a brand strategy and identity, both verbal and visual, and branding is the application of that brand identity across various mediums."

For more information about the New York agency, please visit guarddogbd.com.

Establishing a Sound Protocol

Even when well-intended, a badly designed study does not incite a coordinator's enthusiasm to keep subjects in the trial.

Bruno Jubelin, Ph.D.
SC/REGULATORY, LRA INC.

PharmaVOICE 100

Who Has Inspired You?

PharmaVOICE 100

The fourth annual PharmaVOICE 100 will be determined by the collective participation of you, our readers. This is your opportunity to recognize the people who inspire you and others; who are having the greatest influence on corporate leadership, research and development, technology, creativity, marketing, strategy, and more; and who are impacting the life-sciences industry through their actions.

These individuals should view industry trends as challenges not burdens, as opportunities not obstacles. They should embody panache and conviction. They should be leaders who plan for the future rather than respond to change. They should be innovative, creators of outside the box and breakthrough strategies, products, and services. They should be pioneering new paths and lifting their companies to new heights.

The deadline for submissions is May 1, 2008. To submit your nomination, please visit pharmavoice.com/100.