BY ROBIN ROBINSON

PHASE III: Market Preparation

An important step during Phase III is preparing the market for eventual adoption.

How the brand begins to be positioned across the spectrum of medical communications — specifically how the science behind the brand and trial results begin to be discussed at global and local congresses, from interactive and traditional exhibit stands to symposia, from posters to special social events — starts in earnest during Phase III trials, according to Mario Nacinovich Jr., managing director of Axon.

With solid Phase III data, public relations efforts can bolster momentum as the brand begins to place great importance on bridging the gap between corporate and stakeholder interests, whether that involves patient advocacy, professional communications, or government relations, he says.

According to various research, marketing and communications budgets are known to increase 400% to 500% when drugs enter Phase III trials, then jump an additional 300% to 400% at launch, Mr. Nacinovich says.

"This is when all agencies need to be aligned and all egos checked at the door," he says. "It is critical for launch success that the brand leaders do not treat activities as individual tactics but as a comprehensive multichannel, integrated communications program. This is when all of the strategic partners need to interact and build from the lessons learned from each other and each part of the program at every step along the way."

Phase III: Market Readiness

During Phase III trials is when traditional market research efforts can be expanded with the assistance of MSLs to add information from the thought leaders, institutions, and centers of excellence, and companies can begin to reach beyond basic disease state knowledge and learn more about local current treatment dynamics, patient needs, and challenges, says Robin Winter-Sperry, M.D., president and CEO of Scientific Advantage and Science Oriented Solutions (SOS).

"One question to ask is what are the unmet patient needs that this new agent can satisfy?" she says. "It's also important to determine who the medical movers and shakers are and which healthcare provider segment — doctors, nurses, and pharmacists — is going to be most critical in the provision of the treatment. Market research should also help define potential hurdles and what the current and future competitive landscape looks like."

DR. MARTHA FELLER ■ *i3 Research*

The recruiting strategy should consider how patients collect and share information, as well as how they use the information to make decisions."

Efficiencies can also be improved by including investigators and center of excellence sites that can become speakers and authors who will have educational impact and influence in the medical community.

"MSLs are often the experts who provide recommendations of potential sites and investigators with an understanding of their clinical capabilities and potential commercialization impact," Dr. Winter-Sperry says.

The best time to engage key opinion leaders in Phase III is when the size of the study increases across the globe and the regional KOL teams can provide their perception on safety and efficacy data and market conditions, says Nagaraja Srivatsan, VP and head of life sciences, North America, Cognizant.

Dr. Winter-Sperry agrees: "KOLs should be used strategically to assist in providing guidance to the company regarding the therapeutic agent, how it will help to improve patient outcomes, where it will fit in their armamentarium, and educate others from a practitioner's perspective."

MARIO NACINOVICH JR. ■ *Axon*

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At this point the brand needs to enhance the communication exchange with opinion leaders, and it should not be overlooked that there is a need to create a platform for sustainable conversations between clinical trials, advisory boards, and other activities, Dr. Winter-Sperry says.

"In this prelaunch stage, preparation must be made to determine which of these opinion leaders are best suited to assist in facilitation or presentation skills training to ensure communication objectives are achieved," she says.

In allocating late-stage budgets closer to launch, a rigorous dialogue needs to emerge with KOLs through advisory boards and steering committees, and serious consideration needs to be made regarding establishing an online closed community that will fuse innovation with practicality of ongoing communication.

"These KOLs help ensure that program educational objectives are achieved and help in the development of all materials," Mr. Nacinovich says.

Phase III: New Strategies for Recruitment

Preparing the market also involves making sure the right patients were recruited into clinical studies, particularly late-stage trials.

DR. ROBIN WINTER-SPERRY ■ *Scientific Advantage*

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"There are two ways to look at contingencies to ensure recruitment," says Stuart Young, executive VP, clinical monitoring, at Chiltern. "One is to have the option to open additional sites based on predefined recruitment criteria. The other, my preference, is to budget additional funds up front and utilize the contingencies immediately."

This needs to be done hand-in-hand with a strict and open site closure policy where poor performing sites are closed early in the study cycle, thereby reducing ongoing costs and ensuring the best sites in the study are the ones going forward, giving the optimal opportunity to meet the protocol recruitment goals within agreed timelines, he adds.

Matching the investigator to the needs of the trial is also important, Mr. Srivatsan says.

"It's important to approach the right investigators who have access to the target patient population, a database of preidentified patients, and established referral programs," Mr. Srivatsan says. "Effective communication of study benefits as well as patient awareness programs and involvement of social networks will also increase recruitment and retention."

According to Martha Feller, Ph.D., global executive VP, operations, at i3 Research, a more sophisticated patient enrollment environment usually refers to a more knowledgeable patient population, combined with a busier-than-ever-before investigator site.

"A significant advance to patient recruitment includes recruitment messages when the patient is thinking about his or her health at additional points of care — at the pharmacy counter and on the Internet — while taking into consideration patient social behaviors," Dr. Feller says. "Simple, low-tech tactical examples include giving patients refer-a-friend cards or speaking at support group meetings."

New high-tech tactics include online communities for the study population, posting recruitment information on newsgroups, even posting trials with iPhone apps, she adds. The recruiting strategy should consider how patients collect and share information, as well as how they use the information to make decisions.

"As both additional points of care and networking strategies are used more frequently to reach patients, sponsors, and CROs will need to ensure that the information provided to patients is complete and easy to understand, and that it takes into account how patients are networking and learning in our fast-moving culture," she says.

Now more than ever, it is important for CROs and sponsors to develop new strategies to meet the challenges of a more crowded and sophisticated patient enrollment environment.

Our experts say a coordinated approach is required to achieve enrollment momentum in a crowded and competitive market.

This means a dual effort, according to John Benbrook, CEO of MMG.

"We need to work from the top down and the bottom up to create a tipping point where solid planning during the feasibility and site selection phase converges with a more targeted use of today's cutting-edge technologies," he says. "From the top, it's important to start with site selection based on informed sources: multiple information streams of independent data analyzed to find the right site mix. From the bottom up, the approach centers on using a more sophisticated communication channel that targets patients where they enter the information stream, whether that is through technology or their offline social networks.

"Today's patient has come to expect that information relevant to them will appear in their communication pathways from sources they can trust," Mr. Benbrook adds.

Phase III: Best Practices

Efficiency and effectiveness go hand-in-hand at this stage of clinical development and the key challenge is decreasing the time to market with clinical trial patient recruitment and retention, Mr. Nacinovich says.

"To improve efficiencies, companies need to invest in strategies and tactics that will accelerate the pace of trial patient recruitment including developing strategies to identify, target, and recruit patients first and then put the right strategies and materials in place to help keep the patient enrolled and motivated throughout the life of a trial," he says.

In many ways, trial efficiency has a direct correlation to the efficiency of the relationships that have been established with sites, CROs, and others, such as the recruitment partner.

"Relationships that have been established early, that take advantage of well-defined working practices, and are collaborative among all study stakeholders increase the efficiency of a trial exponentially," Mr. Benbrook says. "Coordinated communications across all service areas and the ability to tap a historical knowledge base about elements critical to seamless trial execution are musts. It's all about controlling the knowns, such as site quality and effective messaging to the target study population. If we can control the knowns, we control the most efficient pathway to last patient in."

Improving efficiency also comes from maintaining the quality of data through the life cycle, and that comes from having standards in place and adhering to them, says Dave Evans, chief information officer at Octagon Research Solutions.

"Unfortunately, if the methods and machinery are not standardized, the maintenance of high quality data comes at a price of increased time, resources, and cost," he says. "Ultimate efficiency is dependent upon a frictionless process of moving information through the machine." ✦