GLOBAL Patient Recruitment

Robin Robinson

Social media, regulations, and outsourcing are shaping global trial recruitment models.

FAST FACT

ACCORDING TO A RECENT CEI SURVEY, MORE THAN 20% OF RESPONDING COMPANIES USE TEXT MESSAGING FOR PATIENT VISIT REMINDERS IN PHASE I THROUGH PHASE III.

Source: Cutting Edge Information

As is true in almost every sector of the world, social media and the use of the Internet is poised to significantly change the nature of global trial recruitment. As the emerging trend gains traction, the industry is struggling to determine how best to take advantage of its power.

One pharmaceutical company, Lundbeck, has just recently started using social media and the Internet to attract and retain patients to its clinical trials.

"Definitely the advent of social media has had an impact on patient recruitment," says Dorte Arnbjerg, divisional director, global study management, Lundbeck. "It's a new era for the company to be using the Internet and the social networks for recruitment to our clinical studies."

Ms. Arnbjerg says Lundbeck is in the first phases of change, exploring all of the new possibilities, but also weighing any new risks that may be involved with interactive Internet sites and social networks.

According to Elizabeth Moench, president and founder, MediciGlobal, the industry is experiencing a revolutionary shift in patient recruitment.

"There's recently been a real shift from using social media and networks to push out information to thinking more about how they can be used to build relationships with patients," she says.

However, much of the industry still views social media networks and digital technologies as media for managing information, but the reality is they should be used more as media to manage relationships, she adds.

According to Casey Ferrell, research analyst at Cutting Edge Information, clinical trial operations and recruitment is one space in which social media can play a role. While there is a lack of a clear regulatory environment surrounding the use of social media in prescription drug promotion, the development side of the industry presents a comparatively safe place to implement social media tools.

"A common example of how companies leverage social media in clinical development is in patient recruitment," Mr. Ferrell says. "Companies will use existing online communities organized around specific disease states to identify potential patient populations."

Companies realize that social media and digital communications in general have the potential to transform the landscape on the development side, and they are actively implementing digital and social tools to improve trial efficiency, patient recruitment, and data collection. A notable example, Mr. Ferrell says, is the REMOTE trial that Pfizer is conducting, in which everything from patient recruitment to treatment delivery to outcomes reporting is done remotely via an array of digital channels.

"This trial-in-a-box is exploratory, and Pfizer wisely chose a postmarketing trial for the methodology's test run," he says. "What comes out of it will likely inform future digital trial initiatives by the company and others, but it hints at a tantalizing future in which some clinical trials could be carried out entirely digitally."

Pfizer's digital clinical trial pilot is commendable and will hopefully pave the way for more companies, however fear of the unknown is a major detractor, Ms. Moench says.

"Some companies have overcome these concerns by forming digital media or social media taskforces, and they are working with them to move forward using social media for the patient recruitment process," Ms. Moench says. "To be successful in optimizing the benefits of social media, more companies will have to address their fears and move on."

Ms. Arnbjerg has concerns regarding the use of social media, in particular the challenge of effectively managing pharmacovigilance activities on the Internet.

"In traditional clinical studies, we have received ethics and regulatory approval of the advertisements we're using in different countries," she says. "Suddenly, that mechanism is put to sleep, you could say, when we work with the Internet. I have to be sure that I have my risks under control, which I can. I can design the initiative so that I prevent any risks from a pharmacovigilance nature, or any risks in terms of having unapproved advertisements on the Internet."

According to Ms. Moench, the responsibility for monitoring patient recruitment efforts is no more risky in the digital space than it is in the print-only arena; it requires having the right software and people in place to closely watch the context of the information.

Drilling down from social media, mobile is another channel that pharma should explore in terms of improving clinical development.

Methods and Activities to Improve Global Patient Recruitment

Cutting Edge Information has identified four key categories of activities to improve global patient recruitment. Each activity provides advantages and disadvantages, including cost effectiveness, time to execute, level of investment, and the number of people who must be involved.

Site/Patient Evaluation

- Perform site and investigator evaluation
- Conduct patient demographic/population research
- Work with advocacy groups
- Organize health fairs and community outreach initiatives

Site Development

- Recruit at point of care
- Train site staff/investigators
- Provide site support materials
- Manage online patient resources

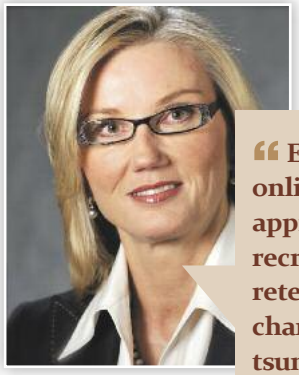
Direct-to-Patient Mass Media Marketing

- Newspaper/print
- Radio
- Television
- Web-based

External Support

- Use medical science liaisons
- Manage call centers
- Contact other physicians for referrals
- Contact patient referrals

Source: Cutting Edge Information.
For more information, visit cuttingedgeinfo.com.



> "Engaging patients online is a new approach in patient recruitment and retention that is changing things at a tsunami pace."
>
> **ELIZABETH MOENCH**
> MediciGlobal

> "Providing patients the opportunity to communicate through the Web with other trial subjects or with a nurse can keep them engaged in a study."
>
> **CASEY FERRELL** / Cutting Edge Information

"Given the gold rush to develop apps for the commercialized marketplace, there is an opportunity for the industry to shift its focus and look for innovative ways to use mobile technology to improve clinical development," Mr. Ferrell says. "Data from a recent CEI report show that on-market drugs are the focus of mobile support initiatives, while clinical development receives less attention the further a product gets from the market."

While some may think consumer mobile apps are a passing trend, when stakeholders, such as trial patients, physicians, investigators, and clinical development staff, experience the benefit of mobile technologies, their importance will be proven.

"From streamlining trial data collection and analysis to connecting potential trial patients with investigators, the clinical development space is an opportunity for pharma companies to differentiate themselves from the pack, find more value for their mobile investment and address clinical pipeline challenges that impact bottom lines," Mr. Ferrell says.

Fear of Social Media and Regulatory Risk

The industry has concerns around social media and regulatory reactions, but Ms. Moench says these fears are relatively unfounded.

"The challenge is that people are nervous about change and this is happening so fast that not a great deal of people understand how this technology works," she says.

Reminiscent of the early days of DTC, fear around regulatory risk manifests a desire within the industry to slow the change process down until people become comfortable with it, but unfortunately for the industry, social media is beyond its control.

"This is exactly what happened with direct-to-consumer advertising; people wanted to slow it down and put a moratorium in place," Ms. Moench says. "What's different with social media is that the industry isn't in control — patients are — and the dialogue is occurring."

Therefore, industry focus should not be on controlling social media, but rather on how to use it so it can be beneficial to patient recruitment, and to the patients within the trials once they have been recruited. The challenge lies not in fact, but in perception.

"We have given this world of online content new descriptive terms," Ms. Moench says. "So what we call a posting or a blog is actually no different from an article that's written in a newspaper or a magazine. But because it's in the digital space, the same content has a different name. If it is called a digital article, it's viewed differently."

When a press release is generated, the content must be fair balanced, truthful, and without claims, and function within the existing regulations. Once the press release is put on the wire, it goes viral all over the world by different media outlets. If the same information is posted online, with all the same elements of fair balance, etc., it works in exactly the same way.

"However, the industry perceives that it's different or maybe more dangerous," Ms. Moench says. "But if the information issued is well-constructed, accurate, with no claims, and no off-label promotion, the purpose is the same as a press release, but delivered in a different way, in a different world."

Engagement Brings Patient Voices to the Forefront

Using social media to recruit and retain patients for clinical trials has a beneficial outcome for patients — they become more prominent stakeholders in the process. Being more engaged keeps them compliant and more invested in the trial, improving the results, both clinically and financially. With patient dropout rates as high as 30% in certain therapeutic areas, the industry needs to use all the tools it can to retain patients, and building relationships through interaction is one of those tools.

"Engaging patients is an approach in the new world of patient recruitment and retention that is changing things at a tsunami pace," Ms. Moench says. "Success in clinical trials these days is all about engagement or building trust in the course of conversation with patients to get them interested in the clinical trial and retain them once they begin. The fundamental basis of the new retention model is all about engagement."

According to a CEI report, respondents stated that the No. 1 way to enhance patient retention is to make participants feel engaged with the site staff. In fact, one interviewee says that the best patient retention program is a good study coordinator who can give patients personal attention and make them feel like they are part of something bigger.

CROs are already using these types of strategies to avoid patient attrition, reports CEI. In fact, 67% of CROs use retention strategies.

"With such a high percentage of CROs employing patient retention strategies, drug manufacturers should follow suit to protect their recruitment efforts," Mr. Ferrell says.

Ms. Moench says she thinks the industry is beginning to recognize that social media and the patient voice are "too big to ignore." She has observed a shift from using only physicians as key opinion leaders, to including patients as KOLs.

"During the feasibility process, more often we are bringing the patient voice into clinical trials," she says. "We can actually break down a protocol and ask questions to patients to get an understanding of whether or not a protocol is even feasible."

Making sure that each and every patient completes the trial is a key to reducing costs. Recruiting patients after a trial has been completed because drop rates ran too high can crush a budget.

"With that in mind, it is shocking that 50% of all survey respondents choose not to practice patient retention strategies," Mr. Ferrell says.

Several interviewees of the study said reminding trial participants that they are not alone is another good way to boost retention. For example, a Web portal that provides patients with the ability to share their experiences with other participants can keep them engaged in the trial process.

Ms. Arnbjerg says successful patient retention relies mostly on properly designed protocols.

"I think patient retention is very much about the way we design our clinical studies — we must make the protocols the most appropriate for the question we're investigating, and try to strike the right balance between the scientific outcome and the burden on the patient for actually being in the studies."

Outsourcing and Regulations Challenges Remain

Although patient recruitment is tremendously important to any trial, many companies have not yet formed internal teams dedicated to this task. Only 15% of companies maintain a dedicated patient recruitment group. The majority of these are CROs, some of which specialize in patient recruitment activities.

In fact, only 45% of companies surveyed by CEI had specific departments responsible for patient recruitment.

"Time is money in the clinical arena, as trial delays mean a later-than-expected product launch," Mr. Ferrell says. "Using CROs can often shorten the time required to complete enrollment."

The major driver behind using a CRO is not cost-savings, but rather a company's inexperience or lack of scope with clinical trials, a trial that is too large or geographically dispersed to be managed by internal staff, and inexperience handling patient recruitment. Upward of 38% of survey respondents report that patient recruitment is outside of their scope of expertise. When the clock is ticking, having an entire clinical group learning on the job can cost far more than outsourced assistance.

"The industry is starting to focus on how to use the Internet and social networks for patient recruitment."

DORTE ARNBJERG / Lundbeck

Lundbeck made the strategic decision about three years ago to outsource its clinical studies in Phase II and Phase III, which means all of the monitoring and the management of the managers is performed by global CROs. Ms. Arnbjerg says this was not for cost-savings purposes, but rather because the company wanted to be able to place the clinical trial activities in the areas where it was most optimal for it to conduct the clinical trials.

"We now have more resource flexibility in working in an outsource setup," she says.

Although the CRO works as an interface between Lundbeck and the investigator, the company puts high value on making sure that the studies are well-branded.

"It's very important to us that we brand

SOUND BITES FROM THE FIELD

Through social media, the patient's voice is becoming more prominent as a stakeholder in clinical trials. Industry thought leaders share best practices in moving toward a patient engagement model for clinical trial recruitment.

SCOTT CONNOR is VP, Marketing, at Acurian, a full-service provider of clinical trial patient enrollment and retention solutions. For more information visit acurian.com, or email scott.connor@acurian.com.

"Social media has created wonderful venues for patients to share experiences about managing and living with a variety of medical conditions. Tapping this therapeutic aggregation has become an important augment to traditional recruitment methods, but by no means is it a trial enrollment game changer by itself. Protocol designs and site geographies continue to significantly cut the available trial population, so any single-threaded approach to enrollment will fail for trials requiring significant volume."

GRETCHEN GOLLER is Senior Director of Therapeutic Expertise, at PRA International, an independent institute for research on the effect and operation of new drugs. For more information, visit praintl.com.

"Patients are engaged. Like modern medicine, patients have evolved. They are constantly seeking information about their disease state and are proactively involved in their healthcare. For these reasons, methods of finding patients have to evolve as well. We have to respond to this increased engagement by reaching patients where they are: on the Internet, in social media forums, on blogs, on advocacy group chats, etc. We can no longer rely on traditional methods of reaching patients who are using nontraditional ways to become stakeholders."

JUDITH TEALL is Director of Patient Recruitment, Exco InTouch, a provider of mobile communication solutions for patient recruitment, retention, compliance, ePRO, e-diary, and postmarketing studies. For more information, visit excointouch.com.

"Life-sciences companies must first listen and understand the full patient profile, taking into account what life is like with that condition, patients' symptoms, impact on lifestyle, typical responsibilities, and fundamentals such as demographics and geography. Once a company has a clear picture of all of this, it can then start to plan how to optimally engage with those patients through the most relevant media, using appropriate language and timing via supportive stakeholders."

the studies of the investigator sites, even though we work in a fully outsourced CRO model," Ms. Arnbjerg says.

An outsourcing model does not mean any loss of control over the study or any increased risk, she adds.

"I still maintain the sponsor responsibility and I have mechanisms in place for all the sites so that I don't run into any regulatory risks," Ms. Arnbjerg says.

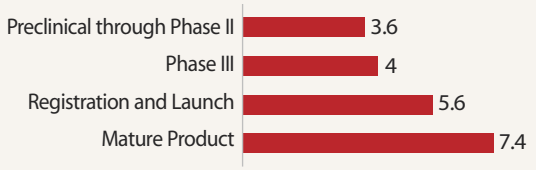
Mr. Ferrell adds another dimension to the regulatory argument.

"From what regulatory experts tell me, the risk of global trials boils down to the issue of the transferability of results from one patient population to the next," he says. "There is a fear that the rapid proliferation of global clinical trials is going to create an environment in which data collected from emerging market trial sites will be highly scrutinized by the FDA, EMA, and other agencies."

This may be true, but perhaps not for the reason that some would think, Mr. Ferrell adds. Virtually all companies and their CRO partners understand the imperative to establish good clinical practices (GCP) at every site from which trial data are collected, so this is generally not going to be the issue. Instead, it may be that applicability of results obtained in one human population to the next is a big regulatory sticking point.

"As drugs become more and more specialized, in terms of specific biomarkers, genetic characteristics, and other criteria, the question will be can a company successfully argue that its compound will be as effective in a U.S. population as it was for the Indonesian population in which trial data were obtained," he says. "This issue quickly gets scientifically complex, and will be a matter for those at the cutting edge of development to sort out." PV

Average Rating of Mobile Technology as a Support Tool, by Development Phase*



* On a scale of 1 to 10, with 10 representing high usage of mobile technology
Source: Cutting Edge Information. For more information, visit cuttingedgeinfo.com.

EXPERTS

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