

# ThreeWire: Marketing Meets Patient Recruiting for Device Trials

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**Summary:** Regulatory requirements for devices are becoming more demanding, making clinical trials more complex and costly. ThreeWire's marketing-based approach looks to speed patient recruitment, a benefit for start-ups since, in clinical studies, time is definitely money.

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## ThreeWire: Marketing Meets Patient Recruiting for Device Trials

**Regulatory requirements for devices are becoming more demanding, making clinical trials more complex and costly. ThreeWire's marketing-based approach looks to speed patient recruitment, a benefit for start-ups since, in clinical studies, time is definitely money.**

by Stephen Levin

For medical device companies, the bar has never been higher in terms of the importance of clinical trials, and the standard keeps going up. Yet, as trials keep getting larger and their usage extends to more clinical specialties, many industry executives complain that the clinical trials process, particularly recruiting patients, continues to be done on a business-as-usual basis. This means often relying on an inefficient, advertising-based program that can increase both the time and expense of the study, while ultimately incurring an even greater cost: delaying a product's eventual commercialization.

**ThreeWire Inc.** CEO and co-founder Mark Summers believes his company has a better approach to patient recruitment: "We emphasize the importance of thinking of patient recruitment as a marketing program," he explains. "That's anathema to many clinical affairs people, but the truth is you need to think in terms of marketing a clinical study in the same way that you go about marketing a product."

The era of evidence-based medicine and its emphasis on clinical trials' data is no longer confined to interventional cardiology, the specialty in which this trend really took hold and grew. Increasingly, data from clinical studies in many therapeutic areas is being used not only by the FDA in determining when devices become commercially available, but also by physician customers to make product adoption decisions and by payors to determine reimbursement coverage policies. As a result, device companies with products in therapeutic areas that previously eschewed the need for clinical studies are now feeling the pressure to gather solid data.

The increasing size, complexity, and cost of this new generation of studies, already a burden for larger companies, can be crushing for start-ups. For small companies, the situation is a catch-22: they can't commercialize their product without conducting the studies necessary to provide the supporting data, yet it can be difficult to fund the studies without the revenue from having a product on the market. Gone are the days of getting a device approved with minimal clinical data and then conducting additional studies once the device is generating sales to drive adoption.

When ThreeWire was founded in 1999, these changes in the device clinical trials landscape were still in their early stages. Indeed, the company, located in the Minneapolis area, didn't initially focus on clinical trials recruitment. Summers says the company initially launched as a "direct-to-patient," which he prefers over the term "direct-to-consumer," marketing firm primarily for medical device companies.

Summers started the company after working for more than 20 years in sales and marketing for device companies, including American Hospital Supply, Alcon, and Sulzer Spine-Tech. "I realized that the medical device marketing model was really a value-added reseller marketing model where physicians were being asked basically to be resellers for our products, amounting to what I would call supply-side marketing," he explains. "Companies were not thinking much in terms of demand-side marketing, which entails going directly to the patients." That was the idea behind the launch of ThreeWire, which was funded with founders' and angel money. (The company's name is a naval term for a perfect aircraft carrier landing, going back to Summers' previous career as a naval flight officer.)

For the first five years, the company focused exclusively on marketing projects from a wide range of clinical specialties. ThreeWire's early clients included Kyphon Inc. (spinal compression fracture devices, recently

acquired by **Medtronic Inc.** [W#200710114]), **Rita Medical Systems Inc.** (radiofrequency ablation system for liver cancer; now part of **AngioDynamics Corp.**), and **American Medical Systems Holdings Inc.** (penile implants). The type of services varied from building simple web sites to creating call centers, but all of ThreeWire's work was focused on creating interest in a particular device among a targeted patient population. All three companies eventually took these programs in-house, and Mark Summers takes pride in the fact that all of these programs remain ongoing.

Direct-to-patient marketing is a tricky proposition in medical devices. More than one company has been burned when it was not adequately prepared for the challenges that this approach can present. The biggest obstacle lies in making sure that the target physician population is sufficiently well-informed about a device so that enough doctors are both familiar with and supportive of the technology. Nothing is more harmful to a company's and product's reputation than placing a prospective physician customer in the position of having a patient come to his or her office and ask about a device with which the doctor is either unfamiliar or unwilling to use. "It damages the physician-patient relationship," Summers suggests.

That was the problem that ThreeWire addressed with Kyphon, its first client, Mark Summers recalls. "Patients were going to their primary care physicians and asking about Kyphon's product, but these doctors didn't know anything about vertebral compression fractures," he notes. ThreeWire worked with Kyphon to develop a marketing campaign to educate primary care physicians about compression fractures and create a physician referral program so that the PCPs could refer patients to spine specialists who would perform Kyphon's procedure.

Through their work with Kyphon, ThreeWire developed a series of four elements that, in Summers' view, are necessary for a successful direct-to-patient marketing program. First is the need to identify a targeted patient population and engage those patients with a specific call to action, such as urging them to see their physician for a particular condition. Next is the need to be able to connect those patients with a specific clinician in their geographic area. Third is the need to conduct some type of screening process to ensure that only qualified patients contact physicians, which is essential in order to avoid having doctors feel like their time is being wasted. The final element is the need to track these programs to a detailed level. "Medical device companies, unlike big pharmaceutical companies, don't have a lot of money to spend on these marketing campaigns, so it is essential to track these programs both to make adjustments and to calculate a company's return on its investment," Summers says.

An important part of ThreeWire's marketing business was its call center, which handles patient inquiries. To further distinguish the company from competitors, Mark Summers decided to staff the call center with experienced nurses, many with more than 20 years of experience. The call center attracted the attention of several pharmaceutical companies, and in 2004, ThreeWire was part of a short-lived program to build a registry for the antiplatelet drug, Plavix, which was co-marketed by **Bristol-Myers Squibb Co.** and Sanofi Synthelabo (now **Sanofi-Aventis**). [W#199320214]

Although the Plavix program was quickly discontinued, it proved valuable for ThreeWire because the company gained first-hand experience with the clinical trials process. "It was through that project that we saw that clinical trials had a lot in common with direct-to-patient marketing; the main difference was that you are marketing a study protocol instead of a product," Summers says. Patient recruitment was particularly attractive because the patient connection raised similarities with ThreeWire's DTP approach.

Summers studied the approaches other firms were taking in recruiting patients for drug studies. Most of this work was being done by former advertising agency people who would recruit by using media ads to get prospective patients to contact a call center, where they would be asked several questions, the results of which would determine if they meet the trial's inclusion criteria. "We thought we could do a better job by creating a system of interconnected interactions that would be measurable and predictable, based on the work we had done in DTP marketing," Summers explains.

Regulatory requirements for devices are becoming more demanding, making clinical trials more complex and costly. ThreeWire's marketing-based a

The result was what ThreeWire calls its FAST system, which stands for the four components of the company's patient recruitment process. Those components are: finding and engaging targeted patients; assessing them according to predetermined study inclusion and exclusion criteria; scheduling them with clinician investigators who are enrolling patients in the trial; and tracking and managing the patient throughout the process.

ThreeWire's first device client for patient recruitment was **Northstar Neuroscience Inc.**, a neurostimulation company. Northstar was in the process of recruiting patients for its pivotal EVEREST trial, which involved using its device to treat stroke rehabilitation patients. While ThreeWire had little previous patient recruiting experience, Nawzer Mehta, PhD, Northstar's VP of clinical affairs, liked the fact that the company would focus its efforts exclusively on recruitment, while other companies were more interested in providing a broader range of services. "With Northstar being a small company, I also was looking to forge a partnership with a company of a similar size that could understand the start-up mentality and that would provide me with easy access to senior executives," he explains.

Given the criticality of clinical trials particularly for start-ups, one of the key questions that device companies face is determining which parts of the process they will keep in-house and which components they will farm out. In Northstar's case, Nawzer Mehta acknowledges, "While every small company wants to be in control of its own destiny, I knew that I couldn't afford that luxury, and patient recruitment and setting up a call center are aspects of clinical trials that a small company should not do, primarily because we don't have the facilities or the experience and expertise to do it effectively."

Yet, it was important for Mehta to retain a certain amount of control over the process. "I knew that I didn't want to completely farm out recruitment to another company," he says. The result was that Northstar and ThreeWire devised what Mehta calls a "hybrid process" under which Northstar's in-house recruitment manager worked with ThreeWire's project manager to co-direct the process. "This allowed us to retain greater control over patient recruitment, including developing our own initiatives, and then working with ThreeWire to implement those steps," he explains. For Mehta, ThreeWire's willingness to adapt its approach to address Northstar's specific interests was a big plus. "I'm not sure I would have gotten that kind of flexibility from larger companies," he adds. The result: Northstar completed recruitment of 164 patients for its 21-center US trial in about 20 months, which Mehta says is fast for a neurology trial.

Another of ThreeWire's device clients, **CVRx Inc.**, which is developing a device to treat hypertension, took a similar perspective. ( See "Can Devices Succeed Where Drugs Fail in High Blood Pressure?," IN VIVO, September 2007 [A#2007800140] .) Nadim Yared, president and CEO of CVRx, saw using ThreeWire as a way to enhance his company's internal expertise. "Since we are a relatively unknown company with a new and unproven therapy, we knew that recruiting patients could be challenging, so we wanted to do whatever we could to make sure enrollment went as quickly and smoothly as possible, and using an outside firm like ThreeWire supplemented the expertise and resources that we have in-house," Yared explains.

Clinical trials now compose around two-thirds of ThreeWire's business, with 70% of its patient recruitment business coming from devices, but the company also handles biopharma projects. One such example being **Acadia Pharmaceuticals Inc.** in San Diego, which was doing a clinical trial on a drug to treat Parkinson's disease and, according to Mark Summers, had only enrolled 35 patients in 18 months with a goal of 60 patients. "We were able to work with them to enroll the remaining 25 patients in 60 days," he says.

ThreeWire basically employs three different patient recruitment models, depending on the client. These include a centralized system, a site-based system, and a combination of both. "Drug trials are better suited to a centralized approach where you often use a nationwide media campaign, whereas device trials, by their nature, almost have to be site-based because you are dealing with individual IRBs, whereas drug trial most often involve a centralized IRB," Summers explains.

Although the similarities between ThreeWire's original marketing mission and patient recruitment are what initially drew the company into the clinical trials business, Mark Summers also points out that the value propositions between a marketing program and a clinical study are very different. "In a marketing program, our product has to pay for itself through the incremental revenue we bring to the table," he says. "In a clinical trial, we're saving time."

The value of time saved in a clinical study for any device company is critical. Perhaps the most expensive examples are drug-eluting stent studies, where every month of delay in getting patients enrolled can cost a company upwards of \$50 million. For a start-up, clinical trial delay can mean the difference between success and failure in terms of when a product is commercialized and begins generating revenue. Device clinical trials are currently averaging from \$500,000 to \$1 million per month to run. "If a company is able to enroll patients eight or nine months earlier, as we have enabled our clients to do in some cases, that means they are getting their product launched that much earlier, so we help them monetize time and the value of that is huge," Summers says.