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THE WAY TO RESCUE CLINICAL RESEARCH IS VIA...

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THE WAY TO RESCUE
CLINICAL RESEARCH IS VIA...

CAN MARKETING TECHNIQUES SAVE CLINICAL TRIALS?

Participants aren't sold on the merits. Recruiters can't find the candidates they need. No crucial area in pharma is more desperately in need of a fix — or more stubbornly resistant to change.

By Larry Dobrow

There are a great many things about which factions in and around pharma disagree. While there is broad consensus on the need to address the pharma industry's only-percentage-points-ahead-of-Congress reputation among the general public, good luck finding anything resembling a plan to address it. For a laugh, see if you can find common ground on their vision for pricing policy.

However, what just about everybody agrees upon is an urgent need for innovation within the realm of clinical research. In the era of smart science and smarter patients, clinical-trial units continue to struggle with a range of recruitment and access issues. Nobody's saying the system is broken beyond repair — most trials eventually get enrolled — but there's widespread agreement the space is in desperate need of new thinking and tactics.

"The process of clinical research is still not well known or well understood by most people," says Joe Kim, senior adviser, clinical innovation and optimization at Eli Lilly. "At best, it's considered a risk, kind of like rolling the dice with your health. At worst, there's still that human-guinea-pig idea out there."

Health-tech entrepreneur Fabio Gratton, CEO of clinical-trial awareness and recruitment facilitator CureClick, agrees that perception remains a major concern, adding, "Nobody is ever specifically looking to be a part of a clinical trial. People sign up because somebody recommends they participate, or sometimes because they feel it's their last resort."

Adds Tom Krohn, chief development officer of clinical research facilitator Antidote and formerly director, clinical open innovation at Eli Lilly, "Patients are a very scarce resource, and most of them are either not aware or not interested. There is a lot of wishful thinking."

Or put aside the perceptual and logistical concerns, and focus on the financial ones. Per the KMR Group's thorough Clinical Trial Cost Study, conducted in 2016, a Phase I trial for patients costs $3.4 million. A Phase II trial costs $8.6 million, while a Phase III trial costs $21.4 million. Additionally, every month tacked on to a Phase III trial costs another $671,000. Shwen Gwee, head of digital strategy, global clinical operations at Biogen, declines to weigh in on specific figures, but acknowledges "it becomes a big and expensive problem if you can't recruit on time."

Indeed, the word "crisis" is getting thrown around way too often for most people. It varies widely from one therapeutic category to the next, with trials for drugs that treat rare diseases pinched the most. "You know what they say: 'Flooding is only a problem if you're in the flood zone,'" notes Brian Loew, cofounder and CEO of online patient community Inspire.

But there's an industrywide recognition that the current state of affairs is unsustainable. Is it time for clinical groups to turn their attention toward marketing techniques?

TRIALS AND ERRORS

The problem is marketing strategies and tactics can only serve as so much of a balm for what ails recruiters and organizers of clinical trials. Take the issue of geography, which has been a pharma research bugaboo since the advent of the developmental regulatory system. During his Lilly

RECRUITMENT

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ENCY FROM MEDIA MIX

"IT WAS REAL ART REFLECTING ON THE HUMAN CONDITION. I REMEMBER THINKING, 'WHOEVER CREATED THIS KNOWS SOMETHING ABOUT HUMAN SUFFERING.'"

JOE KIM ELI LILLY

tenure, Krohn and his team devoted considerable energy to decoupling clinical studies from a single fixed location. "Maybe it could be a lab visit — you could do the lab work at Walgreens or CVS or LabCorp — but the system is slow to change. It was then, and it is now," he says.

John Reites, chief product officer and partner at Thread, which has created a well-regarded remote patient-research platform, similarly wonders why research remains geographically bound. "In every other industry, people are engaging and contributing data remotely. You see it when they shop, when they bank, when they help their kids with their homework. How are we the only ones who can't figure out how to get this right? As an industry, this should be a requirement."

There also remains a sizable knowledge deficit within the clinical arms of pharma companies, specifically in terms of digital techniques. One worry: As the Facebooks of the world push more aggressively into the realms of health and research, they'll poach the industry's comparatively few A-listers. Similarly, at some point Apple's ResearchKit will evolve into more than an infrequently tapped curio on the iPhone screen. If this occurs soon, those clinical groups that lack a defined digital center of excellence, which is most of them, are likely to find themselves playing catch-up.

"Forget [clinical organizations within big companies], the majority of people in pharma still aren't fully fluent in digital. In every other industry, you don't even get in the door without that digital ability, yet pharma is still hiring agencies to handle this work," Gwee explains.

As a result, many of the people coordinating trial design and recruitment don't know what they don't know. They understand participation in clinical research is a hugely disruptive process. On the other, they don't seem to get why patients haven't seized on what they believe to be an opportunity to save or improve many lives.

Sandra Shpilberg, CEO and founder of research-recruitment specialist Seeker Health, takes that part of her mission very seriously. Over the summer, she participated in a trial for people who share a similar ancestry and thus may be prone to the development of neurodegenerative diseases such as Alzheimer's and Parkinson's. "You might think you know what patients go through, but you don't," she says flatly. "Anybody who pretends otherwise is going to have a hard time doing this in a way that patients respond to."

Eli Lilly's Hero's Journey Art was created to generate clinical-research awareness and celebrate trial participants

Reites agrees. "We come at people like healthcare always does, not like a consumer-facing brand does," he explains. "Whenever I speak about this, I routinely ask, 'Hey, how many of you have actually been a patient in a clinical trial?' The number of hands that goes up is small. We know how to manage a grocery store pretty well, but we haven't shopped in it. It's one thing to manage a process, it's another to be a part of the process."

So why hasn't the industry adopted marketing techniques to kick-start patient recruitment and access efforts? "Marketing" may be a dirty word within the clinical realm, owing to pharma's efforts to keep separate church and state, so to speak. On the other hand, Gwee notes that "what a lot of people in clinical organizations and groups don't appreciate is that applying these principles can help them do what they want to do, which is recruit better and better target the people they need. The end justifies the means."

Kim similarly scoffs at the idea that marketing techniques should be anathema to research groups. "It's a dirty phrase in our circles, but it doesn't have to be. Nobody's saying you do this with glitz and glam. You do it responsibly."

LILLY'S HERO'S JOURNEY

Judging by an informal survey of individuals hammering away at clinical-trial problems at big pharma companies, CROs, and elsewhere, Kim's 90-strong group at Lilly is the industry's gold standard (other vote-getters include units at Pfizer and Janssen). Not coincidentally, it happens to be one of the very few that has embraced marketing techniques.

When asked what differentiates Lilly's approach, Kim downplays the differences. "What some people forget is that we're not selling medicines," he explains. "We're activating a community to do something that's emotional and even artistic. You're not going to convince somebody to participate in a trial through logic alone."

Kim's words, particularly artistic, are carefully chosen. A few years ago, doctors at Philadelphia's Fox Chase Cancer Center corrected his misdiagnosis of stage-four cancer (Kim was actually suffering from an infection). When he later returned to meet with the facility's manager of academic programs and training about a summer science curriculum, he was struck by some of the sculptures showcased in the building's then-new women's wing.

Getty Images

Clinical trial recruiters used to rely on the carpet-bombing approach, placing ads on radio stations and in and around mass transit

"It didn't resemble anything you'd see in a hospital or hotel," Kim recalls. "It was real art reflecting on the human condition. It looked to me like waify, emaciated patients. I remember thinking, 'Whoever created this knows something about human suffering.'"

Kim's instincts proved spot-on. The sculptures had been created by artist John Magnan, whose wife was treated at Fox Chase. Kim cold-called Magnan, hoping to interest him in a project designed to generate awareness for clinical-research programs and celebrate trial participants. Magnan, a mathematician with the NSA in his first professional life, came on board.

The Hero's Journey Art sculptures he birthed were created from wood bricks sent to around 2,000 participants in Lilly clinical trials as well as Lilly researchers; the recipients customized the bricks with words or artwork, then returned them to Magnan. The first Hero's Journey sculpture was unveiled during this year's SXSW and is on exhibit at the Livestrong Foundation headquarters in Austin, while the other two sculptures will be displayed on Lilly's home turf in Indianapolis and in Winston-Salem, North Carolina.

"The idea was to raise awareness of research in an authentic way, but also to pay homage to the people participating," Kim says. "We sometimes forget how intense this is for them. You can be an expert patient in your condition, but when you come in for research there's another level you need to hit. Science demands it."

TRIAL BALLOONS

Of course, appeals to the heart only go so far. That's why individuals stationed all over the business — within big pharma, but also in the worlds of media and health tech — have dedicated themselves to fixing the awareness and access issues around clinical research.

Shifting the media mix to spur awareness of research opportunities and participation therein is a top priority. Media buying and strategizing still falls largely to pharma's agency partners, which presents a different problem: While most are adept at performing such tasks for regular branded and unbranded campaigns, many lack the know-how for doing so around research participation.

In years past, clinical trial recruiters relied on a carpet-bombing approach, placing ads on radio stations and in and around mass transit. This was nobody's idea of efficient, but it worked well enough for trials involving conditions with large patient populations, such as diabetes.

However, as the biotech world continues its shift away from blockbusters and toward products that treat rare diseases,

"YOU'RE NOT TOLD ANYTHING ABOUT THE TRIAL OR EVEN IF THERE'S GOING TO BE ONE NEAR YOU. WE'RE PUTTING A HUGE AMOUNT OF BURDEN ON THE PATIENT EVEN BEFORE THE ACTUAL RESEARCH STARTS."

FABIO GRATTON CURECLICK

the scattershot approach makes even less sense. Loew recalls a recent trip to New York City during which he saw a subway ad for an upcoming clinical trial. "It seemed like an act of desperation," he says.

Justin Freid, SVP, search, social, and emerging media at CMI/Compas, says clinical-trial units within pharma have only recently begun to tweak this approach. "Efforts to recruit for trials need different media plans and different tactics than those for traditional drugs," he explains.

That's another reason why research boosters single out Eli Lilly's 90-strong clinical innovation and optimization group. Hoping to appeal to audiences that likely haven't given research participation much thought, the company published "an explainer" on Buzzfeed in September 2016. Casual and even slightly irreverent in tone, "12 Things You Didn't Know About How Medicines Get Approved" surveyed a host of misconceptions about clinical trials, singling out the "over 2 million brave people" who participate every year and pointing interested readers toward its online Lilly TrialGuide.

"You see things like this when a corporate brand talks about its thought leadership around a certain disease state. What you don't see as much is somebody talking about a particular part of the development process the way [Lilly] did," Gwee notes. "I thought that was a very targeted play toward a younger generation that might not understand clinical trials, or might have the wrong information about them."

Alas, few of Lilly's big-pharma peers have adopted similar tactics or tonality in the year since. What we're left with are the usual scattershot media placements that borrow too liberally from the branded-advertising playbook.

"If your patient population is only 100,000, you're only going to be able to find so many people [for an upcoming trial] with display ads. I think you'll see companies turn to more of a direct-response model," Freid says.

Will this work? Freid thinks it's worth a shot. "Outside of pharma, there's a whole industry around optimizing the path to conversion — in this case, that means enrollments [in research]," he continues. "Look at the insurance business and how well they convert people to get a quote for home or auto insurance. That's a big area of opportunity for pharma and research."

It's one that might be at odds with another oft-stated goal: to simplify everything about clinical trials, especially recruitment. The typical online recruitment process starts with flagging down would-be participants, which is straightforward enough. But then the recruitment calls lead those individuals into a netherworld of microsites, questionnaires, screenings, and phone conversations. Frankly, given the number and different types of bars to clear, it's amazing that trials are able to enroll as many patients as they do.

"You have to answer 20 or 30 questions, most of which require having your entire medical history right next to you. You're not told anything about the trial or even if there's going to be one anywhere near you. We're putting a huge amount of burden on the patient even before the actual research starts," Gratton laments.

PATIENT-PHYSICIAN DISCONNECT

Meanwhile, clinical groups within pharma companies are actively ignoring patients' wishes by largely cutting physicians out of the informational loop. Just about every study of patients and clinical trials shows a continued receptivity to participate and a high degree of comfort and satisfaction with the experience. The disconnect seems to be related to physician relationships — specifically, that patients want to hear about research opportunities from their care providers, but are instead left to learn about them through the media or via internet research.

"The stakeholder we have not engaged well at all is that treating physician. Any outreach that doesn't make room for the conversation with the treating physician is extremely short-sighted," says Craig Lipset, head of clinical innovation in Pfizer's global product development group.

Indeed, for all the talk about how some combination of artificial intelligence and EHR functionality will revolutionize the identification of A-grade candidates for clinical research, there sure doesn't seem to be much effort directed toward supporting physicians or providing them with the most up-to-date information. Somebody has to engage with patients after the EHR notification dings, no?

"You hear all this talk about, 'Well, it's 2017, we have to be patient-centric.' I'd say that we're completely failing on that count with patients and clinical trials," Lipset continues. "Patients will hear about [a research opportunity] on their own and they'll go back to their treating physician and ask, 'What do you think?' But we're not giving those treating physicians a good enough reason to care about research participation — and we're not giving the patient materials and information to go to the treating physician with. For all intents and purposes, we're setting patients up for an uncomfortable conversation and then abandoning them."

Along these lines, Lipset is equally baffled that research organizations inside and outside pharma haven't worked more closely with large healthcare systems. "Why aren't we leveraging the Geisingers, the Sutters, the MedStars of the world? Why aren't we bringing investigators together with the leaders of health systems?" he asks. "Healthcare has changed in a way that should be good for this. Everyone wins — the patient, the system, the research sponsor, everyone."

The problem is that most of the solutions involve the use of technology – and there's already concern about overreliance on technology to goose clinical-trial participation. "Please don't call me with the message that you're using AI to find patients. AI can generate a heat map, but

you're going to have to rely on human intelligence to go that last mile," Lipset adds. "Matching and recruitment are two different things. 'My algorithm will match patients' only gets you so far."

On a less complicated level, pharma companies need to address the language they use in their outreach and awareness efforts. Clinical-research boosters have many, many things to say about ClinicalTrials.gov, the NIH-backed website that debuted in February 2000 to disseminate information about upcoming research opportunities (*see right, An opportunity missed*), but they're united in their belief that the site comes off as cold and clinical.

Compare this with AbbVie's Patients At Heart effort, designed to demystify clinical-trial participation to Canadian patients and the people in their support networks. The site features warm colors, welcoming imagery, and easy-to-parse language, including a FAQ component that offers abundant information about clinical research and AbbVie itself. Tonally and structurally, it's as close to a handcrafted invitation as pharma has ever attempted to deliver.

Then there's the push by Lilly and others to change the language associated with clinical research. For years, companies sought out "subjects." Later, they pursued "participants" and "patients." Today, the sharpest appeals are the ones that target "heroes" or "volunteers."

'OPTION ON THE MENU'

Will change come quickly? Gratton is skeptical. "There's a reason pharma is in this crisis in the first place: [Companies] know what they're doing with clinical trials isn't working, but there are very few who are willing to put in the effort to empower the clinical-trial people in their organization. You can't blame this one on regulations. It's pure fear."

Or maybe it's selfishness. "I was on the inside for 13 years. Pharma approaches clinical research with an attitude of, 'It's my study,' which is ridiculous." Krohn says. "Patients don't think about Lilly or Johns Hopkins. They think, 'What can help me or my mom feel better?' They don't care about the mechanism of action."

As with every push for change within pharma, there's likely going to be more than a bit of internal selling involved. When Krohn sought to enact changes big or small during his time at Lilly, he realized "woe is us" wasn't resonating among his colleagues.

What worked for him then, and what he recommends to trial-minded individuals embedded within pharma now, is discussing the need for change in the context of untapped opportunity.

"The way to present this is to say, 'Hey, look at all the value that's left on the table,'" Krohn explains. "Pharma is very successful, so the system is geared toward self-protection. You need an argument better than 'the way we do this isn't sustainable,' because the earning statements suggest otherwise."

Kim remains optimistic. "The awareness [of research opportunities] parallels the awareness of organic foods. They used to be just for hippies. But now, all things being even, people will buy organic over conventional," he says. "Once clinical research becomes an option on the menu at large health systems, that's when you'll know it has really arrived." ■

AN OPPORTUNITY MISSED

Getty Images

When the National Institutes of Health debuted the ClinicalTrials.gov website back in 2000, it was with the best of intentions. In the press release that heralded its arrival, the organization promised to provide "patients, families, and members of the public easy access to information about the location of clinical trials, their design and purpose, criteria for participation, and, in many cases, further information about the disease and treatment under study."

Prior to the rise of the empowered patient, there was reason to believe ClinicalTrials.gov would evolve into the type of resource that would help demystify the world of clinical research. However, more than 17 years later, patients and their support networks have changed — and ClinicalTrials.gov largely has not.

Even as the site started rolling out "a series of changes to improve usability for stakeholders" in June, it remains difficult to navigate and visually unappealing. More troubling is it continues to convey information in a way that's borderline unintelligible for those who lack a scientific background — in other words, many of the people it is designed to reach.

"The target is to frame the info on a sixth- to eighth-grade level, but you need between 20 and 28 years of education to understand what's on the site," says Tom Krohn, chief development officer of Antidote. "You need to be an MD or a Ph.D., because they wrote the material."

The most oft-cited reason for the site's unparsablility is that information within recruitment notices qualifies as competitive intelligence and thus it behooves research groups not to share too much.

In other corners of the research world, much improvement can be seen. For example, Bristol-Myers Squibb's Study Connect site not only delivers details about the company's own trials, but also easy-to-comprehend information about the importance of clinical research.

"In the past there may have been some recruitment sites done by companies, but there hasn't been much of 'here's our corporate attitude toward clinical trials in general.' Patients want that," explains Brian Loew, CEO of Inspire.

If there's any silver lining, it's that the industry isn't attempting to gloss over ClinicalTrials.gov's limitations. When clinical trial awareness and recruitment facilitator CureClick did research, it asked patients what they wanted from pharma. The most common response: more information about clinical trials.

"It wasn't 'more co-pay cards' or 'free medicine.' And it was across all therapeutic conditions," says CureClick CEO Fabio Gratton. "ClinicalTrials.gov doesn't quite cut it."