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ANSWERING THE CHALLENGE OF CLINICAL TRIAL RECRUITMENT

Disruptive technology fosters new connections between patient, physician, and research facility to eliminate the recruitment bottleneck

INNOVATIVE SOLUTION TRANSFORMS THE PATIENT RECRUITMENT LANDSCAPE

Outcome Health leverages its digital platform to connect with patients and drive recruitment results

BY ROBIN EILEEN BERNSTEIN

Patient recruitment for clinical trials is not a new challenge. In fact, one of the leading causes of the high cost of drug development is the age-old bottleneck in clinical trial recruitment.

One industry study of several hundred global clinical trials found that biopharmaceutical companies must typically double the planned enrollment period to give their investigative sites enough time to recruit study volunteers and complete a given clinical trial. Even with extended trial durations, more than 11% of investigative sites, on average, in any multi-center global clinical trial will fail to enroll a single patient, and 39% will under-enroll.

The problem is more acute than ever due to several factors. R&D is on the upswing — ultimately a positive development — which is putting increasing pressure on the patient pool. Meanwhile, recruitment criteria have grown more restrictive, making it even more difficult to find and identify eligible patients.

And with the advent of big data, another recent wrinkle has emerged: the fear among patients taking part in clinical trials that their data will be compromised or used for purposes other than the one they signed up for.

Not surprisingly, there is a growing demand in the pharmaceutical industry for solutions that more efficiently and purposefully engage physician and patient as partners in decisions about clinical trial participation, while keeping patients data secure.

An innovative new solution from Outcome Health — leveraging the company's proven digital platform in physicians' offices — meets this need. Outcome Health's unique Clinical Research Solutions enables a never-before-available opportunity for doctor and patient to learn about, discuss, and prescreen for clinical trial participation during private moments of care.

The disruptive technology offered by Outcome Health, in a platform that is patient-centric, delivers the right clinical trial content to the right place at the right time.

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In 2016, about $60 billion was spent on clinical trials in the U.S., but only 22 drugs were approved for use by the FDA

A PERSISTENT BOTTLENECK

Pharmaceutical drug development is growing by leaps and bounds. According to the Tufts Center for the Study of Drug Development (CSDD), total U.S. clinical trial grant spending for both federal and industry trials saw an annual growth rate of 7.5% from 2000 to 2012, increasing from $5.4 billion to $12.8 billion.

In the past 17 years, the number of registered studies ballooned from just more than 5,600 in 2000 to nearly 250,000 in 2017. In the past decade, the number of new entities in the R&D pipeline has been rising 6% each year and exceeds 10,000 active drug candidates, according to a CSDD 2015 white paper.

Yet that same study reports the already low success rate in bringing a drug from discovery through to commercialization is on the decline. Only 11.3% of drugs that enter clinical testing will be approved in the U.S., down from 16.4% 10 years ago. It takes an average of $2.6 billion and 15 years to develop and win approval for a new drug. The average clinical phase duration is 6.8 years, an increase of 15% during the past decade.

"Bringing new drugs to market is expensive and risky," said Don Butler, SVP, Clinical Research Solutions at Outcome Health. "In 2016, roughly $60 billion was spent on clinical trials in the U.S., yet only 22 drugs received FDA approval."

GETTING COMPLEX

One reason for the rising cost and duration of drug development activity is the increasing complexity of protocol design. For example, eligibility criteria have grown more restrictive, requiring more targeted patient populations and ever-larger pools of prescreened prospects.

A survey of stakeholders by the Clinical Trials Transformation Initiative, a partnership focused in part on identifying barriers in clinical trial recruitment, found the barrier rated by the most respondents as very or somewhat significant was finding patients who meet eligibility criteria (81%).

The end result is what is widely acknowledged as the persistent bottleneck in drug development: the difficulty in recruiting a sufficient number of patients to complete clinical trials in a timely manner.

"Ninety percent of clinical trials fail to complete enrollment within the period of time anticipated, with an average delay of six weeks," said Butler. "Nearly half of all trial sites fail to reach established enrollment goals. This is despite roughly $1.2 billion spent annually on patient recruitment, which at 32% of trial budgets is the largest single driver of clinical costs."

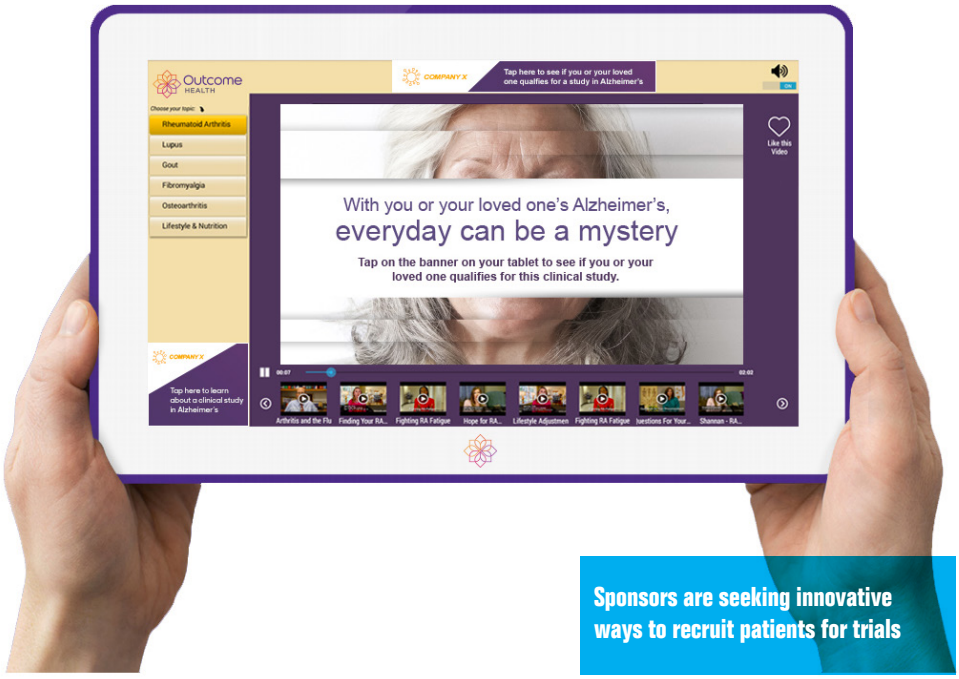
EXTRA TIME ISN'T ENOUGH

A CSDD study of several hundred global clinical trials drives this point home, noting that biopharmaceutical companies must typically double the planned enrollment period to give their investigative sites enough time to recruit study volunteers and complete a given clinical trial.

Even with extended trial durations, 11% of investigative sites, on average, in any multi-center global clinical trial will fail to enroll a single patient, and 39% will under-enroll. Likewise, the average number of randomized patients per trial per site has been dropping, from 6.6 in 2003, to 5.3 in 2008, to 3.7 in 2013. Also decreasing is the aggregate patient recruitment success rate from screen to completion, from 49% (1999-2003) to 29% (2004-2008) to 25% (2009-2013).

Ken Getz, associate professor and director of sponsored research at Tufts CSDD, has noted that patient recruitment is one of the greatest challenges facing the clinical research enterprise and is a major cause of drug development delays, especially in this era of precision medicines that require sites to recruit from more narrowly defined populations.

DEMAND GROWS FOR BETTER SOLUTIONS



Sponsors are seeking innovative ways to recruit patients for trials

More needs to be done, and the good news is the industry is rising to the challenge, propelling a sea change in the patient recruitment landscape. Meeting recruitment milestones on time and on budget has become a key measure of success. In order to succeed, patient involvement and education is key.

Sponsors and clinical research organizations (CROs) are seeking innovative ways to recruit for trials and are exploring new channels to reach, educate, and engage patients. This groundswell of recognition by drug developers of the need to improve R&D efficiency is stimulating new strategies and transforming the way clinical trials are approached. For example, the concept of patient-centricity is stimulating new ways to use technology to connect with patients more effectively.

For years, the typical patient recruitment model emphasized conventional strategies such as TV, radio, and print advertising. More recently, it involves database-driven direct mail and email, social media, and digital marketing. These latter strategies make use of big data, which is raising concerns about how healthcare data is shared.

Recent critical news coverage about its use in clinical trial recruitment focuses on privacy and ethical issues, and it raises important considerations about the sharing of private information.

A survey about privacy concerns regarding the use of big data in clinical trials, conducted in partnership with CenterWatch, found the public preferred their healthcare data be kept separate from social media posts or online shopping history. Patients said they most often turned to their physician for guidance about trial participation, which highlights the trusted role doctors play in the recruitment process.

It also lends support to viewing recruitment less as a strategy of identifying patients — especially if there are privacy implications — and more as a private decision between patient and physician. This insight makes it all the more surprising that one key group has been neglected in this equation: the primary and specialty healthcare provider.

"The genesis of clinical trial recruitment was in direct-to-patient advertising, on assumption the patient will make the final decision to participate," explained Bill Abbott, senior director of Clinical Research Solutions at Outcome Health. "Doctors weren't on the sponsor's radar, therefore prior efforts at physician outreach weren't comprehensive enough."

CHANGING WITH THE TIMES

Under this old model, communication about drug research to the healthcare community was haphazard. Doctors learned about the availability of clinical trials at annual meetings or from peers, medical science liaisons, and patient advocacy groups. Patients today are more informed and technology-driven. They invest time online to learn about their disease, treatment options, and clinical trial availability.

"Doctors have little time to keep up with the burgeoning number of trials. Patients may ask their doctor about a trial and he or she may or may not know about it," Abbott said. "Yet research

indicates patients want to hear about trials from their doctors. Doctors are the missing piece of the equation and must be part of the solution."

IT'S NOT A SECRET

Experts have long known of this weak link. More than 10 years ago, a CenterWatch survey found that although more than three quarters of the public viewed medical professionals as the most trusted source of information, fewer than 20% learned about clinical trials from them.

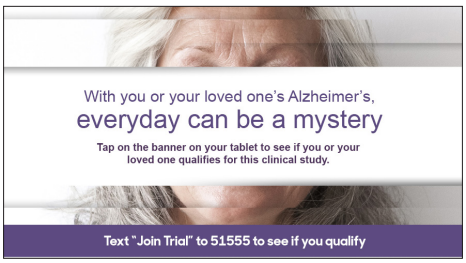
A Harris-Interactive survey in 2004 found even lower rates: 14% from primary care physicians (PCP) and 11% from specialty care physicians (SCP). Fewer than half of all physicians reported referring patients to a clinical trial and the average referral rate was less than one patient per year. Physicians said it wasn't fear of liability or patient loss that stopped them, it's not having enough time and not knowing where to find the information they needed to give them confidence to make the referral.

A CenterWatch physician survey in 2012 reported similar findings. More than half (58%) said they lacked information about the study, nearly a third (30%) lacked time to evaluate the study, and more than one in four (28%) were unsure where to refer patients.

Fast forward to today and not much has changed. A study released earlier this year by the CSDD found that although nearly all physicians (91%) and the majority of nurses (72%) were comfortable discussing clinical trials, they referred only a fraction of their patients (less than 0.2%).

This reflects, in part, a failure by sponsors, CROs, and investigative site staff to engage healthcare providers in the clinical research process. As in the decade-old CenterWatch survey, they cited the inability to access information and insufficient information and time as key reasons for not referring patients, which underscores the critical need to leverage healthcare providers in engaging patients about clinical trials.

Most patients want to hear about clinical trials from their doctors, but many physicians lack the information to refer their patients

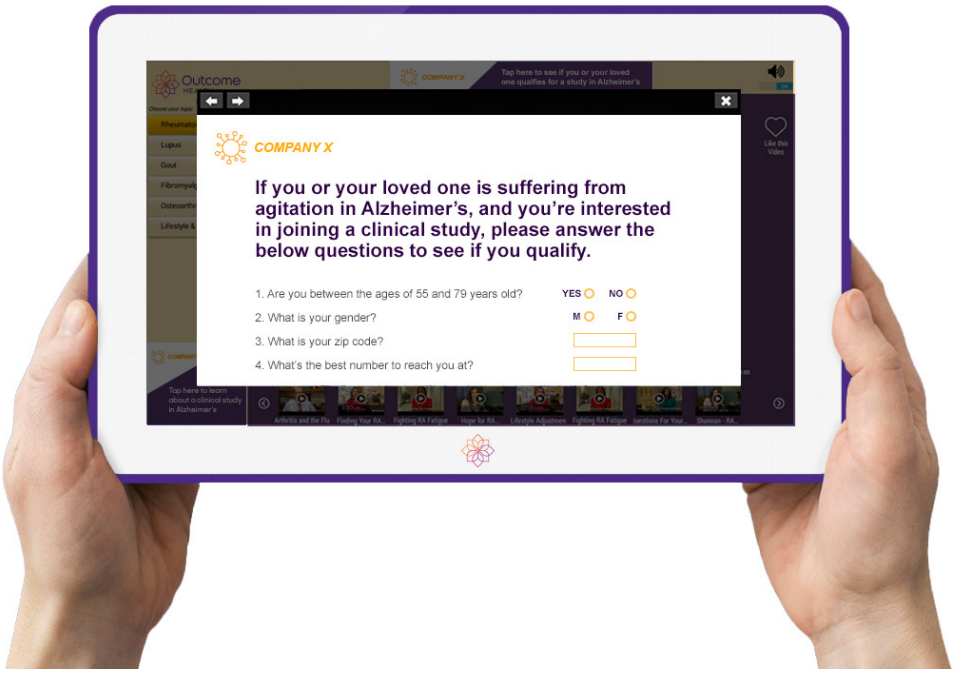


Indeed, more must be done to improve outreach to referring physicians, as 82% of them would be more willing to refer patients if they developed a working relationship with a clinical trial investigator.

Likewise, patients want their doctors to engage with them about clinical trials, according to the CISCRP 2015 Perceptions & Insights survey, the largest global assessment of attitudes, perceptions, behaviors, and experiences toward clinical research among the public and patients:

"Doctors have little time to keep up with the burgeoning number of trials. Yet research indicates patients want to hear about trials from them. Doctors are the missing piece of the equation"

Bill Abbott
Outcome Health



- While most respondents preferred to receive clinical research information from their PCP (51%) or research study staff (44%), far fewer actually got information from them (23%)
- Respondents preferred learning about trials from information in a doctor's office over such sources as online patient communities, social media, pharmaceutical company websites, or, least preferred, TV and newspaper ads
- Top factors most likely to influence participation were if a study would help (86%) or offer a cure (84%), a doctor recommendation (83%), and if there was no risk (82%)
- When asked whom they'd speak with before participating in a trial, 71% of respondents said a PCP or SCP, which was more than any other source including investigative site staff (59%), family or friends (40%), and pharmacists (20%). This increased with age and disease severity
- More than half of respondents (58%) said they never or not very often considered research as an option when speaking with their doctor, and while most (85%) were comfortable presenting their doctor with clinical research opportunities, only 17% had done so. Yet among those respondents who did, the majority (63%) ended up joining the study

The Clinical Trials Transformation Initiative stakeholder survey proposed several solutions, one of which was increased education of patients and physicians about research. Many felt that building relationships and referral programs with trusted clinicians was crucial, and some suggested that a research presence be established in waiting rooms or via electronic alerts. Responses to a question about emerging recruitment methods emphasized the use of technology, with respondents noting its power to create efficiencies.

FINDING A PARTNER

To further improve the patient recruitment process, Outcome Health is partnering with The Center for Information and Study on Clinical Research Participation (CISCRP), a nonprofit dedicated to informing the public, patients, medical/research communities, and policymakers about clinical research, to produce educational content for use at clinical trial point-of-care campaigns.

"Our collaboration with Outcome Health stems from our shared commitment to engage patients as partners in the clinical research process," said Ken Getz, founder of CISCRP in addition to his role at CSDD. "Outcome Health's digital platform is an exciting way to apply this model directly to potential study volunteers at the point of care."

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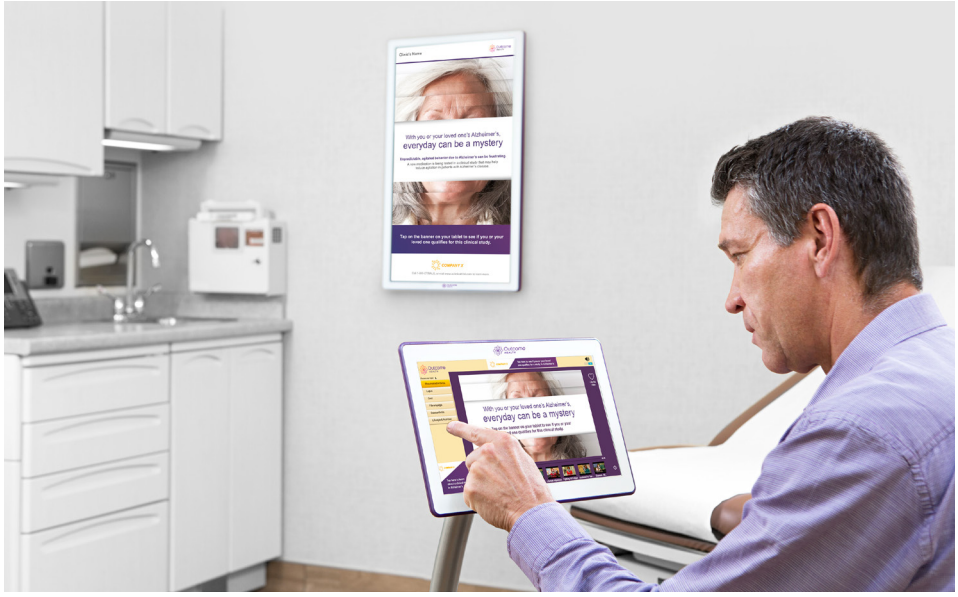
Ken Getz
CISCRP

INNOVATIVE CLINICAL TRIAL RECRUITMENT AT MOMENT OF CARE



Just as Uber now exists due to the evolved capability of mobile touchscreen technology, an innovative patient recruitment solution is now possible thanks to Outcome Health's leading digital platform, which delivers actionable medical intelligence via TV monitors, digital wallboards, and tablets in the waiting rooms, exam rooms, and infusion suites of physicians nationwide.

As the platform continues to grow, nearly 600 million patient visits a year are impacted in more than 21 therapeutic areas including cardiology, dermatology, endocrinology, gastroenterology, general health, infectious disease, neurology, OB/GYN, oncology, ophthalmology, optometry, pediatrics, psychiatry, and urology.

This marks the first time digital technology can be utilized proactively for patient recruitment in the doctor's office.

"Like any good disruption, Outcome Health is leveraging its proven digital platform to help unclog the age-old recruitment bottleneck," said Don Butler, SVP, Clinical Research Solutions at Outcome Health. "For the first time, sponsors and CROs can access a patient-centric, technology-at-scale platform to deliver the right clinical trial content to the right place at the right time, throughout the patient journey, from awareness through enrollment and beyond, which will prove a key contributor to the efficiency and positive outcomes of clinical research."

"What's revolutionary is that we're

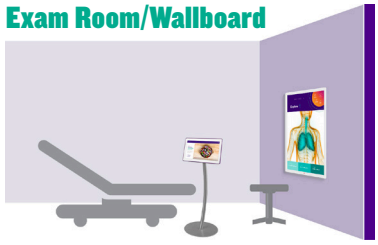
How the solution works

Consider a patient with lung cancer who has an appointment with her oncologist. The TV monitor in the waiting room offers general information about various types of cancer, along with messaging such as "ask your doctor about clinical trials for new cancer treatment therapies available in this area."

Waiting Room TV

Once she's in the exam room and waiting for the doctor, a touchscreen tablet on a mobile stand also offers information on various types of cancers, health, disease management education, tips for managing side effects, patient testimonials, and a tab to click for more information on available clinical trials. At this point she can request to have more information emailed or texted, or even answer some prescreening questions to see if she qualifies for the study.

Exam Room/Wallboard



During the examination, the oncologist uses a touchscreen consultation wallboard to show the patient 3-D anatomical models of her lungs, tumor, and progression. He can zoom in and rotate these diagrams to better explain lab results and the progression of the disease.

not only introducing clinical trials into a conversation where at best it was just an afterthought, but we're actually making it an integral part of that conversation," said Outcome Health's Bill Abbott.

"There's a fundamental awareness that this platform is enabling and creating an opportunity that didn't exist before. It's an unparalleled new connection between patient, physician, and research site."

The platform allows study sponsors and CROs to tailor their message for the moment of care. This is powerful and compelling because context matters.

For example, a national TV spot delivers broad reach but is blind to relevance. Likewise, telling physicians about clinical trials outside the treatment room increases the likelihood that the message will be lost or forgotten.

How much more effective and efficient is it for trial sponsors to tell their story in an exam room when they have both the physician and patient's attention and are in a treatment and decision mindset?

This provides an opportunity to deliver a highly tailored message at various moments of care between patient and physician. Being in the moment of care is a new frontier in recruitment that can lead to better patient and research outcomes, offering an opportunity to rethink the entire process in a purposeful way.

As point-of-care — a single doctor-patient encounter — evolves into myriad fluid moments of care comprising exam room consultations, texts, emails, phone calls, and even time in the waiting room, the Outcome Health digital platform provides the flexibility to tailor messages for those many pivotal moments of the healthcare decision-making journey.

Thus, appropriate meaningful information about active clinical trials can be made available at the moment it is most impactful — a capability previously unavailable in clinical trial recruitment.

The wallboard also presents clinical trials in this context that the oncologist can use to introduce clinical research and discuss a specific trial as a treatment option with the patient. He can email or text links to information on the trial to the patient and her family, so she can discuss it with them at home.

Infusion Tablet

After the consultation, the patient can once again use the tablet to complete a prescreening questionnaire assessing their qualification against the study inclusion and exclusion criteria, and to receive a referral to the oncologist office conducting the trial. The Outcome Health platform is able to engage potential study patients from this critical moment all the way through their screening visit, consent to participate, and enrollment.

Physicians who are in the Outcome Health network know how powerful this platform is.

"The communication starts even before I come into the room," said Kashif Ali, MD, an oncologist with Maryland Oncology Hematology. "The patients are looking at these wallboards and they're asking 'What should I be eating? What foods should I avoid? What clinical trials are available at this particular practice?'"

Outcome Health works with sponsors and CROs to define measurement and metrics for success. Physician and patient engagement with each device, prescreening, site referral, and all steps through enrollment can be measured in real-time.

Outcome HEALTH

Activating patient recruitment during the critical moments of care.

Innovative solutions to reach and recruit the right patient.

Activate Good.

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