USING TECHNOLOGY TO IMPROVE TRIAL CANDIDATE CONVERSION RATES

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INTRODUCTION

Sponsors, contract research organizations (CROs) and investigative sites all share the burden of fulfilling patient recruitment requirements for clinical trials. As the industry investigates progressively rarer diseases with increasingly complex studies, the task is becoming more and more challenging and unproductive. Currently, the inability to meet patient enrollment deadlines is the primary cause of trial delays and terminations. Each day a program is delayed costs the sponsor hundreds of thousands to millions of dollars in operational and lost opportunity costs.[1]

It is not surprising that investigative sites, CROs and sponsors are exploring alternative methods to meet their enrollment goals or that digital recruitment programs have become the go-to solution. Digital's wide reach and flexibility make it ideal for attracting and enrolling study candidates. Nearly nine of every 10 U.S. adults use the internet, and nearly three-quarters of U.S. internet users look for health information online.[2]

Using a digital approach requires careful planning but allows trial stakeholders to target specific patient populations, gather immediate feedback and make adjustments. Digital methods may also reduce costs and speed up enrollment timelines. But perhaps the most important advantage is that they allow stakeholders to quickly implement contingency plans when milestones are not being met as predicted.

As enrollment complications rise, it is important we do all we can to convert the existing study candidate pool to active trial participants. Digital recruitment methods have the greatest potential for helping reach these goals, but, without proper coordination, the risk of referring unqualified participants or missing out on qualified candidates is immense, and, without proper support, the risk of losing existing study participants is high as well. In the absence of clear communication between all stakeholders, the conversion of digitally identified study candidates to valid study participants can be a major challenge.

Adding a technology partner to your digital recruitment strategy has been shown to boost enrollment success beyond what individual sites and traditional digital methods are capable of. We interviewed several thought leaders about the use of technologies such as Clinpal, eClinicalHealth's patient-centered clinical trial engagement platform, and technology's role in mitigating the risk of losing study participants during the handoff to investigational sites. Throughout this paper you will read their thoughts on recruitment challenges, technology partners and best practices for enrolling as many qualified patients into your trial as possible.

"The digital space remains an area full of potential for clinical trial enrollment. As technologies advance, our ability to present clinical trials as a care option to a wider variety of patients increases and in turn clinical research is benefiting. It's an exciting time for bringing new therapies to market."

— ***Bernadette Tosti,*** *senior director, head of patient recruitment programs, Quintiles*

FIND PATIENTS ONLINE BUT ALSO DETERMINE IF THEY ARE LIKELY TO PARTICIPATE

As the number of people who can access the internet at home approaches 3.5 billion,[3] more and more patients are seeking information online. In fact, those with rare, chronic and serious conditions have formed web communities where they share experiences and advice with others like them. According to a 2012 Pew Internet & American Life Project survey, one in three Americans performed a health-related online search for themselves, a family member or friend within the previous year.[4]

With so many people online, the health care community is finding success recruiting trial participants through electronic means. But even when digital recruitment methods drive large numbers of prescreened candidates to investigative sites, qualified candidates do not always participate. To ensure sites are not overburdened, it is important then to send sites only those qualified candidates most likely to participate.

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A candidate's willingness to enroll can frequently be predicted by his or her behavior after the initial touchpoint. For example, qualified, prescreened applicants who do not return secondary screening phone calls and study candidates with negative perceptions about clinical trial conduct are often less likely to agree to participate or skip their first appointment. Consequently, one of the biggest opportunities for improvement in conversion numbers is at the early stage of participant engagement.

HOW CAN A TECHNOLOGY COMPANY HELP?

Working with a technology partner has helped trial sponsors maximize their study-candidate-to-study-participant conversion rates and get the best return on their trial recruitment programs. In general, technology companies seek to support investigative sites throughout the enrollment process by sharing information about the trial with patients and allowing them to answer questions remotely before their first visit. Providing this information digitally aligns with candidate preferences for information consumption and gives candidates a more comfortable, less rushed setting to read or watch and more fully understand the trial.

Accessing trial information electronically allows the candidate to discuss concerns with family in private and do their own research before agreeing to participate. Some companies offer candidates the option to

fully or partially consent to a trial online. Both models increase patient convenience and reduce site burden. Then, when applicants are face to face with investigators at the trial site, they are able to complete the consent and screening procedures more efficiently and focus on any remaining questions regarding study participation.

When used correctly, technology companies can be the secret to meeting your enrollment deadlines or finishing early. Once individuals are identified as candidates, their journey can be tracked within the system. Not only does this allow stakeholders to track their progress toward enrollment goals, but it also allows them to examine their workflow for inefficiencies. For example, the analytics within Clinpal can break down conversion rates per tactic, enabling each outreach campaign to be optimized for minimum cost and maximum candidate-to-participant conversion.

A recent study by eClinicalHealth Limited and Sanofi on a remote trial called VERKKO reported an 81 percent conversion of study candidates to study participants. Although this high of a conversion rate is not typical — especially for larger trials — it is a testament to the power technology companies provide and the difference they can make compared to the best recruitment company metrics. In this study, 61 of the 76 people who signed up were enrolled, patient compliance was increased by 18 percent and timelines were reduced by 22 percent when compared to a previous study conducted with a similar protocol but without the Clinpal technology.[5]

COMMUNICATE THE ENROLLMENT STRATEGY EARLY

The kinds of improvements from the example above are possible only if all trial stakeholders are on board from the very beginning. In order to build a successful program, strong communication is key. As soon as the sites are selected, the sponsor or the CRO should be prepared to lay out specific recruitment plans and expectations and communicate early and often. One option for training multiple sites simultaneously is to conduct a group webinar, then provide online access to tutorials.

However, it is most important to communicate in a way that allows back and forth collaboration and to continue the conversations until everyone has a clear understanding of the plan. Some systems make that easier than others. Clinpal, for example, has a secure messaging system and access to approved recruitment support materials that promote easy study-related communication to reduce the burden for everyone involved — sites, CROs, sponsors and participants.

"By the time I get detailed recruitment plans from study sponsors or study CROs, I have already had to make my plans for purchasing recruitment media and sometimes that means I have to place very generic advertisements for our site. Ads that include specific study information are demonstrably more successful but are often delayed beyond usefulness due to the IRB approval process."

— ***Alan Powell,*** *COO, Sirius Clinical Research*

Share this information at the beginning of each trial:

- Your chosen recruiting method
- Technology training tools
- Deadlines for training and implementation
- Number of participants desired
- Enrollment responsibilities and expectations
- Timelines, including dates enrollment periods start, close and first-patient-in
- Roles and responsibilities of key stakeholders, including:
  - Site staff
  - CRO team
  - Sponsor team
  - Technology partner
  - Patient recruitment team
  - Call centers
  - Study candidates
- Location of online resources and support
- Advertising responsibilities and budgets
- Your ongoing communication plan

During the initial informational meeting, seek input and feedback from your sites. Your sites will have valuable information to offer about recruiting in their area. Knowing this information early will help optimize your study budget and create appropriate contingency plans. Setting the stage for strong communications with your sites at the beginning will jump-start open collaboration that can continue throughout the length of the trial.

Before choosing a technology partner, check to see that its site training platform facilitates this ease of communication with the right tools. The best site training modules are user-friendly and easy to access with built-in systems to ensure learning objectives are met and training records are in order. When your investigative sites are engaged with these programs, your study will benefit from higher candidate conversion rates and active study participants.

SUPPORT YOUR SITES

As mentioned above, when digital recruitment methods are used, a larger volume of leads may flow into sites, which can overwhelm their processing capacity — many are simply understaffed and struggle to keep up.

As a general practice, sites should reach out to prequalified candidates within 48 hours or the candidate's likelihood to participate significantly drops — by up to half. Ensuring sites are set up to do this successfully will allow you to track study candidates' conversion in real time. The best systems allow you to see how many have converted, how quickly they have done so and the reasons they may not be converting.

"Get your sites' buy-in from the very beginning. Let them know that you are willing to support them with the resources they need to follow up with every lead and help them find patients."

— ***Lindsay Jackson,*** *account director, Merge, LLC*

With access to this kind of information, sponsors and CROs can try new methods to ensure their sites are prepared to convert prequalified study leads. Here are a few ideas:

- Involve third-party call processing and patient scheduling services
- Obtain consent to contact candidates' general practitioners to further qualify patients
- Share in advance the questions being asked in the prescreening tool
- Estimate the number of candidates being handed off
- Understand how interested the incoming leads will be
- Invest in sites that embrace technology-enabled patient recruitment and retention processes

See appendix for more site and patient best practices.

Again, technology partners can help implement all of these items listed above. Most partners have the capability to manage prescreening questions and understand basic candidate flow. The premiere technology partners, however, allow you to answer important questions regarding the patient experience, including: Was the candidate contacted within 48 hours? Did the candidate receive and review the information he or she was sent? When is the follow-up appointment scheduled?

Analytics suites allow the sponsor and CRO to see the study participants' entire journey but still protect patient privacy. Using secure technologies like Clinpal, stakeholders only have access to the information they need to make adjustments for future success. For example, sponsors can use conversion rates to implement site engagement programs that motivate and reward investigational sites for contacting and successfully enrolling prescreened candidates. Detailed analytics can also be used to further boost advertising campaigns around the highest performing sites.

REDUCE SITE BURDEN WITH THE ONLINE PRESCREENING TOOL

Optimizing the content of the online prescreening tool will ensure your sites are only sent the most qualified candidates for a trial. The goal is to ask as many questions as possible, but not overwhelm the applicants.

Ultimately, the details of the prescreener depend on the trial protocol, but there is an art to finding balance in the questions that should be asked digitally and those that should be asked during a follow-up phone call.

"The quality of the screener is paramount. If the screening questions are too general, sites may get a lot of referrals that aren't appropriate, which results in wasted time and frustration. If the questions are too specific or the screener too lengthy, you run the risk of potential candidates either being intimidated by, or unwilling to complete, the screening process. Optimizing the questions to be specific while limiting the length of the questionnaire is key."

— ***Cheryl Fiedler,*** *consultant*

Many technology partners help manage online prescreening questions, but you may be stuck with a rigid set. The most modern systems, like Clinpal, allow sponsors and sites to control how the prescreening tool behaves — breaking the questionnaire into more than one section or including both optional and mandatory responses. When using these types of systems, stakeholders gain dynamic information useful for the study in question and also for future patient engagement. For example, smart systems use an online site locator to allow interested study candidates to select the study site closest to them.

Perhaps one of the most successful approaches is to begin your prescreening with only basic questions. These should be questions that the candidate can readily answer. When candidates are forced to look up information or to move away from their computer, tablet or phone, chances are greater they will end their session.

The best questions are straightforward: age, gender, approximate date of diagnosis and location. If the trial requires online prescreening questions to branch out beyond the basics, it is beneficial to have a technology partner that provides additional features like online FAQs and term definitions. These resources can prepare candidates to answer a question more accurately, reducing the chances unqualified individuals make it into the participant pool and thus increasing conversion rates and reducing site burden. Advanced technology partners will have avatars that speak predetermined languages and offer visual appeal.

The analytics provided by your technology partner will help you understand the performance of your prescreening questions. The most helpful systems capture information about when and where patients are dropping out in the prescreening process. You can then use this information to make immediate adjustments. Also be sure your technology partner is compliant with 21 CFR Part 11, privacy regulations and local laws. You will want to be able to trust that its systems and processes always capture and handle participant data within the appropriate regulations.

For greater success with your prescreening tool, try these best practices as you are setting up and reviewing your questions:

- Ask simple questions based on inclusion and exclusion criteria of the study
- Ask only the critical questions in the prescreener, then invite respondents to opt in to further communications
- Include online resources to enable candidates to better understand their condition as well as to better comprehend more difficult questions; this may include term definitions, examples and FAQs
- Post the questionnaire on the trial website

"You need to keep the digital prescreener questions to just a few, simple questions that help determine minimally if a patient could qualify. The next step should be follow-up phone screening (still not yet by the investigative site), by a medical professional to ask the more difficult prescreening questions."

— Terri Roberson, *senior pharma consultant*

- Pay attention to the points at which people exit the survey early to spot trends that indicate questionnaire is too lengthy or too complicated
- Use technology that allows you to understand how digitally prescreened patients are enrolling and adjust your strategy as needed
- Be willing to make changes based on what you learn works and does not work

After a candidate completes an online prescreener, recruiting specialists can call the candidate to ascertain other necessary information — such as previous and current medications, medical history and other health conditions. Progress and outcomes of this secondary prescreening should be stored in a technology partner platform in order to get a full picture of the workflow and eventual outcome.

COMMUNICATE WITH PRESCREENED PATIENTS

Over the past decade, the number of applicants screened for a trial has increased significantly. However, the number who complete a trial has nearly dropped in half.[6] It may simply be the case that while digital methods draw more candidates, they also attract candidates who initially agree to participate on a whim or half-heartedly. After all, clicking on a button or filling out an online form requires less commitment and consideration than person-to-person communication. While automated prescreeners are an efficient tool for screening large volumes of interested candidates, those candidates can be harder to qualify when compared to methods that include an examination of health records and in-person patient visits.

What is important to learn from this is how critical it is to increase the candidate's level of commitment as soon as possible. That requires good communication. Enlisting a good technology partner to facilitate the handoff after a prescreener is completed can help fulfill the patient communication need by delivering additional information and pushing out reminders.

A few ways to open up communication between stakeholders and participants include:

- Asking participants how they prefer to be contacted (via phone, email, etc.)
- Reaching out with varied, frequent communications — include study details, reminders and next steps

"There is a natural funnel from how many candidates click to the website and how many actually go through the questionnaire. Some volunteers will just drop out — even those that you speak to in person may learn more and not want to participate."

— ***Tom Hoggan,*** *senior patient recruitment specialist, PAREXEL*

- Ensuring the candidates fully understand what is being studied, what the ultimate objective is and how their participation contributes to that goal
- Addressing known clinical research myths and barriers to participation early on in the process

There are several known barriers to patient retention.[6] One of the most prevalent barriers — misinformed or under-informed subjects — can be addressed and improved during the consent process using a technology partner. Clinpal, for example, allows the release of information to patients depending on their status, so they will always have easy-to-access, easy-to-understand information at the right time. Providing candidates with the right information up front, even as early as that first online questionnaire, allows patients the opportunity to weigh the commitment against their availability.

Sites also have an important role in answering any remaining questions. Conveniently, recruitment technologies can facilitate this dialogue and allow it to take place remotely. By weeding unqualified or unwilling candidates out before their first visit, site burden is lessened, saving time and money and providing sites better quality patient visits. The right technology can facilitate this communication and ensure that the study candidates are connected with their preferred site as soon as possible.

The most comprehensive technology partners can help facilitate the delivery of study information and communication by providing participants access to the technology platform with educational materials, references and specific information related to the trial. This direct access to information and supporting communications help build trust among participants, and these tools are often used as a go-to resource during the trial.

"The industry is starting to accept the fact that individuals want to have immediate information. There's a host of new tools out there to try and some of them are very successful in bringing candidates into a trial."

— ***Melynda Geurts,*** *vice president, operations, DAC Patient Recruitment Services*

"This industry is a numbers game. You need to keep the new patients coming in and that means being willing to try new things to get them in the door."

— ***Adam Larrabee,*** *president, Rochester Clinical Research, Inc.*

ADJUST AND ADAPT YOUR STRATEGY

While conducting today's clinical trials, sponsors, CROs and sites are not only dealing with an influx of people to screen but also an influx of data. Technology partners can help take control of this information while also providing unique opportunities for trial sponsors and sites to improve their relationships with their study candidates. Proper evaluation of your potential partner is key when you are seeking the highest possible conversion of online study candidates to study participants.

Consider whether the proposed technology partner provides the communication and analytical tools you need to be successful. The best programs will pinpoint where you stand to gain the most in your conversion efforts, enabling you to design more personalized

recruitment and engagement strategies. Stay on top of this information; use it to continually adjust your strategies for your current trial and to determine the best strategies for future studies. Only by being willing to adapt to meet the needs of your investigative sites and trial candidates will you be able to improve recruitment.

APPENDIX

Best Practices to Convert Interested Online Study Candidates to Active Study Participants

TECHNOLOGY PARTNER BEST PRACTICES

Process and Communications

1. Plan early for use of modern technology
2. Recognize your technology partner as a key accountable stakeholder in ensuring successful conversion of candidates
3. Require mandatory technology partner participation in kickoff meetings, investigator meetings and key team meetings
4. Plan for site feedback loop during both the setup stage and user acceptance testing of patient recruitment technology
5. Plan for prescreener adaption based on site feedback loop
6. Plan site user technology tutorials
7. Check and document site's retention of learnings and working practices to convert interested study candidates to study participants
8. Consider use of call center to support conversion
9. Align all stakeholders in agreed technology plan (site, sponsor, CRO, technology partner, recruitment partner, call center)
10. Use a technology partner that provides analytics about site throughput and reaction time and allows the capture of reasons for screening

Patient Engagement

1. Enlist a technology partner that offers a solution that is user-friendly
2. Provide easy access to study information by offering a patient-facing portal
3. Clearly identify study-specific FAQs, definition of terms, speech-enabled functionality and translations
4. Select a technology partner that functions as a trusted third party to ensure patient privacy is protected
5. Through the use of technology, allow interested study candidates to reach out to sites in the most convenient location
6. Offer communication options, such as phone, secure messaging and call center support
7. Offer flexible eConsent options to meet the needs of the study candidate
8. Utilize technology that allows collection of patient data on a variety of devices such as smartphones, tablets and laptops
9. Offer travel assistance and technology options to reduce the need for travel to the site

Site Engagement

1. Offer sites user-friendly technology training options (group webinars, online tutorials, investigator meetings trainings, long-term certifications)
2. Select sites that embrace the use of technology and modern methods of communication
3. Invite site feedback on the prescreener
4. Select a technology partner that offers an easy and secure site for patient communication
5. Use technology that brings forward more informed study candidates to diminish site burden
6. Select a technology partner that diminishes site workload with eConsent options
7. Diminish site burden by offering single sign-on options
8. Select a technology partner that reduces workload at the site by offering prescreener, e-learning, patient reminders, eConsent, collection of patient reported data and screening log maintenance through one technology platform
9. Use a technology partner that seamlessly integrates with call centers to deliver more prequalified study candidates
10. Provide the site a one-stop-shop for a multitude of approved study aids and documents.

ABOUT ECLINICALHEALTH LIMITED:

eClinicalHealth Limited, developers of the revolutionary Clinpal patient engagement platform, was founded in early 2012 to provide innovative clinical trial solutions. Headquartered in the United Kingdom, the company is committed to leading open and collaborative innovation discussions about remote clinical trial processes and technology with pharmaceutical companies, CROs and other service and technology providers. For more information, visit www.clinpal.com.

REFERENCES

1 Recruitment Infographic, blog post, March 18, 2016. http://www.clinpal.com/clinpal-blog/recruitment-infographic/

2 Health Fact Sheet, Pew Research Center. http://www.pewinternet.org/fact-sheets/health-fact-sheet/

3 Internet World Stats. http://www.internetworldstats.com/stats.htm

4 "Health Online 2013," Pew Research Center. http://www.pewinternet.org/2013/01/15/health-online-2013/

5 eClinicalHealth Limited press release, June 16, 2016. https://www.clinpal.com/clinpal-blog/eclinicalhealth-announces-successful-results-entirely-remote-online-clinical-trial-3/

6 "Subject Recruitment and Retention: Barriers to Success," Applied Clinical Trials, April 4, 2004. http://www.appliedclinicaltrialsonline.com/subject-recruitment-and-retention-barriers-success

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