Lessons Learned from the Clinical Trial Trenches: How to Use Patient Engagement Technology Successfully

When Googled, "how to choose the right gift" returns 748 million results with articles written by Forbes, The Huffington Post, and more. This is with good reason. Whether it's a family member, a significant other, or a close friend, gift giving is an art that has the potential to take a good relationship to new heights or undercut its foundations. A good gift confirms your understanding of a person, their values, and their interests. A poor gift, on the other hand, can make the recipient question how well they really think you know them.

Taken within the context of clinical trials, patient engagement (PE) technology must be treated with the same reverence as gift giving. Put simply, organisations who don't consider their audience will upset patients and sites, while potentially harming their trial. Thus we have giftwrapped our findings from an early 2019 webinar in order to share some best practices with the industry.

Be Mindful of the Patient and Site Populations

Technology is great, but it can be a burden if not implemented correctly. You must consider the patient, and the site, and what's right for them. Thus, before choosing PE, organisations must first understand the types of populations their trial will need while also considering their own goals and organisational structure.

While these considerations may differ wildly across trials and companies, organisations should at least consider a population's age, location, country, familiarity level, demographics, language, psychographics, and more before thinking about PE. For instance, does the trial involve older populations? If so, it's important to note that while mobile uptake among older populations is lower compared to younger users, mobile technology may still be successful in certain trials, but additional care should be taken. People in this group typically prefer to be shown how to use the technology and have time to practise. They may do well with SMS reminders and emails but may be turned away by overengineered solutions that are complex to use.

Countries with very strict technology regulations, or places where technology is not yet prevalent, may require further evaluation. However, it's important to remember that PE does NOT need to be 100% deployed by a population in order to see important gains. Thus, if you have several countries where PE is a good fit, consider using it only in these areas.

When it comes to your clinical trial sites, it's important to try to work within the boundaries that they are already using. If sites are well-versed with existing tablets and phones, a "bring your own device" (BYOD) application of PE will fare much better than trying to force them to use yet another new tablet or phone. However, if they dislike the experience they are currently receiving with their devices, they may welcome a new start.

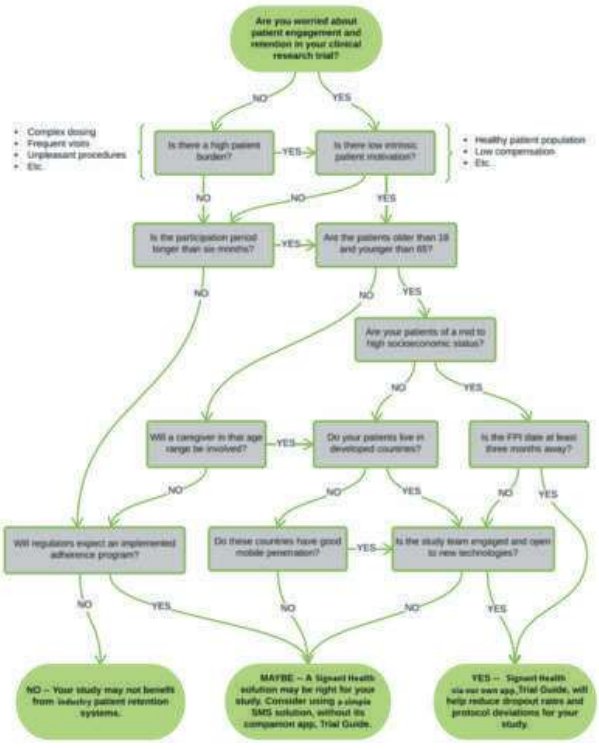
With all of these considerations at hand, it can be difficult for organisations to come to a solid conclusion about their patient and site populations. Thus, in order to make a well-educated decision, we recommend that organisations…

Create an Organisation-specific Decision Tree

While our example tree (pictured to the right) is a fantastic starting point, we recommend companies create a decision tree that follows the logic of their trials.

An honest look at the trial and its goals will reveal how to best start on a decision tree. For instance, is the protocol complex? Would patients benefit from understanding why they are asked to do specific tasks, and how it may impact their health or the study? Do you think patients will need reminders to stay on target? Is patient retention critical? Are diaries involved?

Organisations that have a firm understanding of their needs will find that a tree allows them to easily choose the PE path that's best for them. And, once they know the solution of best fit, they can begin to…



Pick the Right Partner Using Data
Organisations must find a trusted and experienced partner that:

1. Understands the trial,
2. has experience with the therapeutic area or patient population,
3. has experience with the countries where the trial will be conducted, and
4. has experience with similar studies.

In order to find the right partner who meets these needs, we recommend that organisations discuss proof points with their vendor, such as the ability to offer satisfaction surveys to patients and sites, reductions in protocol deviations, and increased patient retention rates.

When analysing data, it's important to make sure that organisations are looking at comparable data that highlights how patients using PE tools did versus patients who did not. In instances where vendors don't have an exact data match on your type of trial, look for something that's a close fit. For example, if you have a phase two oncology trial in South Korea, oncology metrics in Asian-Pacific countries may be a good reference point to evaluate patient engagement fit in that region.

How to Measure Success
Once in place, it's important to start measuring the current success of your trial and PE vendor. This can be accomplished using the feedback mechanisms available to your site and patient populations. Organisations who are using a low-touch SMS approach may elect to send a survey to patients, while those using full-fledged PE apps may prompt users to indicate their satisfaction within the application itself.

The primary goal of either of these approaches is to ensure that the patient has a "voice," and that the patient voice impacts the way current and future trials are conducted. Organisations should also use these same tactics to assess the sites' voice.

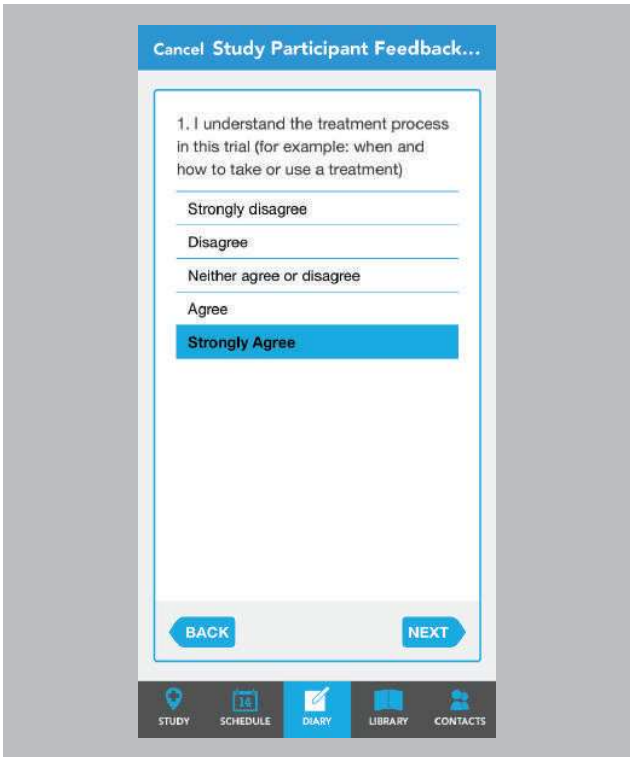
In addition to patient and site voice, organisations must ensure that they continually monitor:

1. Patient retention rates,
2. protocol deviations,
3. improved adherence to medication or procedures,
4. diary completion rates,
5. long-term follow-up, and
6. any other metric that is vital to the success of the study.

Typically, this is achieved through access to the vendor's system, a review of reports, governance meetings, or any other form of study check in. Regardless of the medium, it's important to establish a regular cadence for review.

How to Maximise the Number of Patients Using PE
Once the study is live and patients are enrolled, it's important to help steer as many patients as possible towards PE. The best way to do this is by integrating PE early, such as during study consent, and also through site reinforcement. Start early, at the investigator meeting and ensure that each site receives training on PE, how to talk about it, and the benefits it provides to them as well as patients.

From here, find site champions who are using PE well and share their success stories. Leverage the data you do have to show others what they are missing and take time to speak with sites who have a low percentage of enrolled patients.



For sites who are reluctant to engage, deploy the features of PE to give them a voice. Ask them how they feel about the trial, PE itself, and what else can help them better run the trial.

Make it a Gift to Remember
As stated earlier, technology is great, but it can be a burden if not implemented correctly. Thus, before implementing PE, organisations must consider the lives and experiences of their patients and sites.

That's because, above all else, PE is like a gift. Good gifts stay with us, shaping the way that we feel and interact with that person for years to come. But then again, so do the bad ones.

Mindy Gruba

Mindy Gruba is a Senior Product Manager at Signant Health, responsible for developing the product strategy and roadmap for TrialGuide, the company's mobile solution for patient engagement in global clinical trials. Mindy has worked with top 20 pharmaceutical companies and CROs to develop gamification, patient education, virtual trial and mobile engagement strategies for vaccine, rare disease, and oncology studies, leveraging her 10+ years of experience in mobile technology, product development, and behaviour change communication. Prior to Signant Health, she worked at J&J's Human Performance Institute and multiple health information technology start-ups, taking products from concept to market. Mindy has also spent time advancing her health research and communication strategies at the NIH, Peace Corps, and NASA's Kennedy Space Center. Mindy holds an MPH from The George Washington University and a BS from the University of Wisconsin-La Crosse.

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