Enhancing the Patient Experience

In an effort to strengthen patient satisfaction and engagement in clinical trials, new technological advances should be utilised by study sponsors and CROs to improve and modernise patient engagement strategies.

The opportunities to strengthen patient engagement across all phases of clinical development have never been greater. We can now apply technology in creative ways to collect meaningful data from patients without increasing their burden as trial participants.

At the same time, empowered patients have high expectations of their health-related experiences in general, with clinical trial participation being no exception. As savvy consumers, patients expect technology to be both easy and enjoyable to use. Therefore, study sponsors and CROs should look to take advantage of the latest tools to ensure that a patient’s involvement meets their expectations, fits into their daily lives to the greatest extent possible, and is, overall, a rewarding experience.

There are well-established methods for overcoming privacy concerns in the way we collect, store, and transmit data; we are able to send information directly to patients and maintain patient data without exposing personally identifiable information. These new creative applications can improve patient communications and deepen their commitment to the trial.

Indeed, progressive sponsor teams are now dedicated to ensuring that they follow the recently articulated recommendations of industry groups, such as the Clinical Trial Transformation Initiative, to set patient expectations, protect privacy, return individual data, enhance interactions between participants and sites, and provide technical support (1).

The Basics of Patient Engagement

On average, nearly 30% of trial participants drop out prior to completing a study (2). Thus, finding ways to increase patient retention rates is a critical success factor for completing trials on time and budget and to usher investigational products through development efficiently and cost-effectively. The following are the building blocks of a sound approach to patient engagement.

Motivational and Educational Messaging

Patients respond well to dynamic, visual feedback and context-sensitive messaging about the trial itself. They require information on the protocol to understand the value of the study, as well as clear instructions on what they need to do and when they need to do it. Training is essential in helping them understand their trial responsibilities and providing on-device context with quick reference guides, videos, and FAQs.

Educational Information

One survey of trial participants found that more than a quarter of them were motivated to participate by the promise of receiving information about their condition (3).

Feedback on Trial Outcomes and Condition

Patients are eager to know the outcome of the trial or broader clinical program to which they have volunteered their time. In some therapy areas, this requires sponsors to maintain a relationship with patients over a number of years. As well as this, most patients appreciate seeing a graphical summary of their symptom data so they can see how it changes over time. However, presenting such feedback to patients during the trial could unblind them to their treatment group or bias their future responses. Therefore, it may only be appropriate to share this information with patients at the end of a trial. Patients also appreciate seeing a summary of their reporting compliance as compared to an average or target compliance – information that can motivate them to stay on track in completing their diaries.

Acknowledgement

A survey conducted by the Avoca Quality Consortium found that more than 69% of trial participants did so for “the opportunity to contribute to science” (4). This selflessness should be supported with frequent communication that reinforces the fact their participation is valued and worthwhile.

Digital Engagement Today

Patients are discerning and sophisticated consumers of technology and expect that any trial technology will be easy to use and will provide a rich and seamless experience. Sponsors and CROs who subscribe to a comprehensive digital trial philosophy will reap the benefits of making it easier and more satisfying for patients to participate (see Figure 1). An effective digital strategy should emphasise:
• Collecting more data directly from patients
• Increasing the dialogue with patients throughout the study
• Automating workflows for easier navigation across touchpoints
• Leveraging artificial intelligence and data science to make participation easier

Fortunately, advances in digital technology have opened new avenues for collecting data less obtrusively from within the context of a patient’s own environment and supporting patients throughout the trial. The bring-your-own-device approach to electronic clinical outcome assessment (eCOA) gives patients the ability to use the device of their choice to provide data and receive trial information. It is well established that patients prefer digital collection over paper/manual means, and, when they can use their own devices, data collection fits more easily into their daily lives. Today, patient engagement is bolstered through the following approaches.

**eConsent**
Informing potential trial participants of their trial rights and the expectations that will be had of them can easily be overwhelming for patients when presented in typical legal language. Incorporating eConsent tools that do not necessarily involve a visit to trial sites and that take advantage of multimedia to educate patients alleviate some of the burden from patients and can increase their understanding of why their ongoing participation is important.

**Wearable Sensors**
Wearable sensors and biomonitors are being used to collect data on primary and secondary endpoints. For example, many Trials have already used glucometers, activity meters, heart rate monitors, sleep monitors, and peak flow meters successfully.

**SMS 2.0 Text Messaging**
Text messaging has been used for some time to remind patients to take their medication, attend a scheduled visit, or complete their diary. The advent of SMS 2.0 allows for much richer content and has changed the landscape of what is possible. This medium can now be used to provide education, instruction, and encouragement rather than mere reminders and alerts. Links to other media, such as information leaflets and instructional videos, can also be imbedded. Many companies now create escalation pathways so that if a patient fails to respond/comply based on a text message, they are automatically reached through another form of communication.

**Gamification**
By borrowing elements from digital games, pharma and biotech sponsors can enrich the experience for patients and even make elements of participation fun. Components of gaming, such as competition, progressing through levels of tasks, and earning points or rewards, can guide patients through the stages of a trial and motivate them to complete their responsibilities. While this approach should not be reserved for paediatric populations only, the elements of the game must be designed for the target patient demographics.

**A Sense of Community**
Participants can join online communities where they can share their trial experiences, find resources such as support groups and healthcare professionals, and access tips and training. These communities can be maintained after the study to keep patients informed of study outcomes and promote future adherence.

**Coming Innovations**
Advances in technology are moving rapidly, and it is only a matter of time before they are commonly applied to the challenges of patient engagement. We foresee the growing use of multiple sensors and internet-connected devices for ‘never-off’ data capture. Technologies that fit into patients’ daily lives will reduce the burden and increase their participation and retention.

The following innovations are largely experimental at the moment, but show great promise.

**Voice Assistance (VA) Technology**
Conversational interfaces, such as Amazon’s Alexa and Google Plus, are becoming ubiquitous in consumers’ lives. Indeed, enabled smart speakers are expected to become the most common form of our interaction with technology in the near future. Comscore predicts that, by 2020, half of all online searches will be voice activated (5). It is likely that this technology will be a game changer for the industry, and is
already being used in patient support programs as well as Phase 3 trials to collect exploratory endpoints.

For example, VA that has been interacting with a patient all day could, at the appointed time, announce, ‘it is time to record your blood pressure. Please confirm that this is a good time for you’. Thus prompted, the patient would take his or her blood pressure using a monitor and then read out the results to the voice assistant. The program would then automatically transmit the results to the trial’s electronic data capture system.

One clear benefit is that VA technology gives patients hands-free access to study information and uploading data. Patients can respond while doing other things, and, more importantly, it can expand the pool of patients to include those with manual dexterity problems, such as those with advanced arthritis and Parkinson’s disease. If using traditional paper-and-pencil or electronic devices for data entry, these patients might otherwise have difficulty reporting data or fail to enter their responses regularly, eventually becoming noncompliant or entirely disengaged with the study.

The Next Generation of Sensors
Sensors are opening up new possibilities for collecting objective data from patients beyond heart rate monitors, pulse oximeters, and activity monitors. This world of possibilities includes:

- Biopatches revealing detailed muscle capabilities
- Sensors in clothing to provide respiratory, cardiac, and perspiration data
- Shoe inserts to track gait and steps
- Jewellery that provides sleep data
- Pill sensors
- In-home sensors that record how often patients perform certain activities such as leaving the house or taking a shower

Objective data gathered from sensors can confirm patient-reported outcomes data or give it meaningful context. For example, entries in an electronic patient diary might explain an incidence of elevated heart rate picked up by a monitor.

Biometrics
The security of applications used for patient reported outcomes could be improved in the future by allowing access to devices through fingerprints or facial recognition.

Adapting Technology Wisely
Deploying technology should be viewed as part of a holistic engagement strategy that is spelled out in a customised communication plan for each study. The plan can extend from simple medication and visit reminders to a more fully developed motivational, educational, and support program.

Any software used should be designed specifically for the patient population, appropriate for the protocol, and compliant with regulations. For this reason, proposed approaches must be vetted with sample patients prior to adoption, similar to the increasingly common practice of involving patients in the protocol creation. This will help ensure that the tools reduce, rather than add to, the patient’s burden of participation.

The best solutions will be simple to use, have an intuitive interface, and be easy to integrate into patients’ everyday lives. Separate components such as an eDiary or sensor should be connected seamlessly from the patient’s point of view. Also, simple features can make a big difference in patient satisfaction, such as a progress bar to indicate how far along a patient is in completing an eDiary. Nevertheless, sponsors should be prepared to provide training to patients on devices and assessments to improve their compliance.

In addition to testing engagement tools with patients, sponsors should discuss their ideas with regulators to ensure they are acceptable, and investigators must also be brought into the loop on the sponsor’s selected approach. Investigators can make or break any engagement strategy, and a strategy that does not include site engagement will go from being a well-planned patient engagement experience to a poorly executed one.

Finally, once a technology is selected, it should be used in a small substudy as a pilot before it is widely adopted across a clinical program.
Today’s clinical trial participants have different expectations from those of even a decade ago. Patients who are very active in their own healthcare decision-making expect to understand the value of their trial participation, to be informed of trial results, and to be able to rely on technology to make their participation as easy as possible. When sponsors and CROs deliver on these expectations as part of a holistic approach to addressing patient needs, they can improve patient engagement in the trial. Technology advances are moving rapidly, and there are some very exciting new tools in use today as well as on the horizon.

References

James Munz is a product expert who has been solving business problems with cutting edge analytical and technical solutions for close to 20 years. As Vice President of eCOA Product Management, James is responsible for building and executing ERT’s market-driven strategy for the eCOA product line. Prior to ERT, he was Vice President of Product at Opera Solutions where he was responsible for the development of a Big Data analytics platform used across supply chain, financial services, marketing, healthcare, and telecommunications industries. Additionally, he led one of the first products to leverage the Amazon Cloud.

Chris Watson PhD is a Product Strategist with 20 years’ experience in the delivery of business and consumer-based solutions, the last 10 of which have been within the clinical technology industry. He has extensive knowledge of product and software development processes and is responsible for implementing the product strategy for ERT’s digital patient business. Chris earned his PhD in Behavioural Neurosciences from the University of Nottingham, UK, and a BSc in pharmacology and toxicology, with honours, from the University of Bradford, UK.