Uncover the Hidden Benefits of eCOA

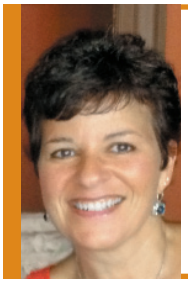
Use a mix of features in your eCOA solution to improve the patient experience, as well as their engagement

The next transformation in clinical research is taking shape through the convergence of the culture of digital patients and technological advances that enable automation, continuous monitoring and large volume data analysis. On a daily basis, digital consumers use the internet and mobile apps to check the weather, make purchases, perform banking transactions, communicate with others, play games and track personal health. In turn, digital patients who participate in clinical trials expect a similar user experience. Digital patients demand better engagement, transparent communication and relevant information from clinical trial sponsors. Central to digital patients' clinical trial experience is the sense they are an active contributor to new medicine as opposed to participating as a passive research subject. eClinical solutions that bring together efficient data capture technology and effective user experiences can deliver on today's expectations of patient engagement.

Electronic clinical outcomes assessment (eCOA) solutions, which incorporate electronic patient-reported outcomes (ePRO), clinician-reported outcomes (ClinRo), observer-reported outcomes (ObsRO), and performance reported outcomes (PerfRo), offer known benefits such as secure, and high-quality data collection. However, eCOA technology can also offer additional, under-utilized benefits that don't require next-generation technology or a big budget. An eCOA solution can promote patient engagement through a mix of features that provide study information, reminders, gamification and other features that ultimately make it easier for the patient to comply with study requirements.

As part of trial participation, many trials capture patient-reported outcome (PRO) data via patient diaries and questionnaires. Extrapolating from data summarized in a retrospective review of PRO measures used in clinical trials; over the past decade, the percentage of clinical trials using one or more PRO measures has doubled from 14% to nearly 30%, and is expected to steadily increase.[1]

For studies collecting patient self-reported data, electronic collection of this data is well-established and fits elegantly into the digital patient's lifestyle. It is widely accepted that–depending on how the data will be used in the study–electronic collection may be necessary.[2] According to Ari Gnanasakthy, Principal Scientist at RTI Health Solutions, "ePRO data collection also offers the sponsor greater flexibility in data collection. For example, in most clinical trials there is no reason why data cannot be collected the day before the study visits to lessen burden to patients as well as site staff. In oncology studies, especially with new oral anticancer medicines, patients can report treatment interruptions and low-grade toxicity from the comfort of their home, which can vastly improve the analysis of PRO data."



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Data are collected using an electronic device, typically a smartphone, supported by proprietary software provided by an eCOA vendor. Historically, this software has been hard coded and installed on each device. ePRO solutions have since evolved from hard-coded devices to app-based technology that offers flexibility, while simultaneously offering the sponsor benefits such as efficiencies in time and cost. The app-based ePRO solution fits well for any modality selected by the sponsor, whether a provisioned device or in a bring- your-own-device (BYOD) model. In a device provisioning scenario, the patient is provided with a smartphone during screening or after randomization into the clinical trial, whereas with BYOD the patient uses his or her own smartphone. Whether a provisioned smartphone, or personal smartphone, patients can quickly understand and use an app-based ePRO solution, since they are accustomed to using many apps in their life as a digital consumer.

Maximize ROI with configurable patient engagement features

Using ePRO in a trial presents an opportunity to maximize return on investment by designing the technology application to multitask in the trial by adding features the patient is accustomed to seeing and using in consumer apps, increasing usability, usefulness and fun. Therefore, without adding additional interfaces or systems which add burden to site staff and study staff, and for little additional cost, the ePRO solution becomes an engagement solution. This results in a patient who is better informed and educated, more engaged and more likely to be compliant with the rigors of protocol compliance.

There are many features that can be designed into the ePRO app to promote engagement. As a basic feature, a frequently-asked-questions (FAQ) section allows patients to easily share information about the study with friends or family members. Other basics include a contact link, allowing the patient to simply click to call, text or email the site with questions, while a similar link provides click access to a 24/7/365 helpdesk. Scheduling study visits can be simplified through an integrated calendar that syncs with a personal calendar. A visit schedule provides relevant information about the duration of the study, frequency and timing of visits, along with information on how to prepare and what to expect at each visit.

Pre-configured reminders can help ensure patients remember to bring study medications or laboratory samples, arrive with an empty stomach, or comply with any other requirements necessary for the visit. Patient results, including laboratory results and overall study results, can be communicated in an app. Countless patient research findings and industry publications suggest simple features like these can go a long way towards keeping the patient interested and engaged in the study.

With an even greater nod to the digital consumer, gamification can provide a high level of engagement. Consider apps like Waze, Snapchat, and Todoist which all use gamification to engage and entertain the user, add motivation, and appeal to their competitive nature, while making the app more fun. An ePRO app can offer badges or other rewards earned for completing various tasks or meeting certain study milestones, including completion of daily assessments, adherence to study medication, and compliance with study visit attendance, among others. A current observational study, involving patients with hematological disease, awards points when participants complete daily patient diaries. Patients use their ePRO devices to track points. Site staff track completion through an online portal. Points can be redeemed at office visits for institutional review board (IRB) approved items, including a low-value digital gift card, or a charity donation.

Social network capabilities; reality and education

Social networks have become a staple in the lives of many digital consumers for their ability to keep them connected with relevant groups and communities.

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Using an ePRO app to create a social network for trial participants allows for shared experiences and provides a sense of community within the trial. While patients flock to online discussion communities organized by medical condition, like the ones provided by Inspire and PatientsLikeMe, clinical trial communities pose concerns for the sponsor. Chief among these concerns are patient safety, as patients may discuss adverse events online and not share the same events with the investigator. The risk for unblinding is high as patients may discuss the investigational product in a way that leads them to believe they know who is taking active product and who is taking placebo. Patient dropout is another concern, as patients who believe they are taking placebo may choose to leave the trial.

In spite of sponsor concerns about adverse event reporting, bias or unblinding through patient social interactions, there is a positive push towards using social communities to boost engagement. It's practically impossible to prevent this from happening, but online sharing of sensitive or safety-related information can be minimized through upfront patient education, explicit rules of engagement, frequent monitoring, and other risk management techniques. The Center for Information and Study on Clinical Research Participation (CISCRP) has developed patient education tools to educate participants about the effect of talking to others in the same study.[3]

Internet of things paves the way for device integration into eCOA

Another way to use ePRO to engage patients is through IoT (internet of things). IoT is "a system of interrelated computing devices, mechanical and digital machines, objects, animals or people that are provided with unique identifiers and the ability to transfer data over a network without requiring human-to-human or human-to-computer interaction."[4] For ePRO purposes, IoT includes integrating the eCOA app with medical and/or consumer devices, including wearables. Medical devices such as glucometers, weight scales, PEF meters and blood pressure machines have Bluetooth interfaces that allow for integration with the eCOA app, simplifying use for the patient, and streamlining data collection for the sponsor. As with the ePRO data, the integrity of the biometric data collected with this type of integration also meets FDA ALCOA standards (attributable, legible, contemporaneous, original, accurate).[5] There are many types of consumer wearables that track many aspects of health and fitness. Items such as smart watches, fitness trackers, smart clothing and smart jewelry collect massive amounts of data and can feed this into consumer apps such as Google Fit and Apple Health. An app-based ePRO solution can pull relevant data from these apps as needed for study participation. Hundreds of clinical trials use some type of wearable device to collect pa-

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transcription error involved with manual data entry of the final values into the database. Additionally, by removing human interaction, the portal is able to process multiple changes as approvals are obtained, thereby avoiding a backlog of DCFs pending implementation.

A full history of time-stamped conversations and user activity is available for review by study teams and inspectors in an easy-to-view format. "Original data are stored with data change requests, user roles and supporting context, and in chronological order. It's more of a structured history of data changes than a non-linear data dump," says Michael Hughes, Vice President, Operations and Development at YPrime. "Reports contain dates and times of conversation history, everyone who has interacted with the data, reasons for changes as well as rejected data changes."

The future

The expanding role of the patient's voice in drug development is a trend that will continue for years to come. As organizations such as the Patient-Centered Outcomes Research Institute, the European Patients' Academy (EUPATI) as well as initiatives such as the FDA's patient-focused drug development initiative and patient representative program continue to influence drug development programs, the pharmaceutical industry will not only expand the use of eCOA measures, but also their use as primary endpoints in clinical trials.

To meet the needs of this type of research and satisfy global regulatory requirements for data integrity and good documentation practices, eCOA technology will have to keep pace. Technology needs to be robust, flexible and capable of integration with new domains, in addition to enabling automation and providing a user-centric experience.

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tient data.[6] According to Fitbit's Fitabase, their devices have been used in over 400 research studies and clinical trials.[7] The most common conditions studied where these devices are in use are mental and brain related and body weight related.[8] While common functions measured by wearable devices include step count, gait, heart rate, and distance, wearable functionality is rapidly expanding to reduce invasive monitoring techniques for conditions involving diabetes, rheumatoid arthritis, respiratory diseases and Parkinson's Disease.[9]

Patients as consumers expect to use technologies that add convenience, create efficiency, promote a sense of belonging and add fun. Increasingly, consumers are accessing these technologies via mobile devices which can connect to other devices and the internet. Collecting PRO data electronically, whether on a provisioned device or the patient's personal smartphone, and doing it with a 21st century app-based solution, offers sponsors the chance to tap into the hidden benefits of eCOA-based patient engagement, thereby improving patient compliance and increasing their eClinical return on investment.

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