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Clinical Trial Solutions

Technology the Key to Improving Efficiencies and Retention in Clinical Trials

▶ The use of technology has become ubiquitous in clinical trials as the industry looks to streamline and improve processes.

Most pharmaceutical companies and contract research organizations have adopted technology solutions, including electronic data capture solutions and clinical trial management systems to increase efficiencies, reduce costs, and improve the patient experience. These solutions have been instrumental in improving clinical trial processes. Past reliance on paper records made for a cumbersome, time-consuming process by making data management highly complex. However, many of the biggest issues remain — in particular, recruitment and retention of patients.

Patient-Centric Trials

One of the big problems for clinical trials is the high rate of patient drop out. Improved retention calls for a more patient-centric approach and technology is integral to putting patients at the center.

The use of electronic clinical outcomes assessments (eCOAs) and electronic patient reported outcome (ePRO) solutions to capture patient data has been found to improve compliance levels. This is because electronic devices can be used to motivate and engage patients and because ePROs simplifies the questionnaire process for patients.

Gathering patient feedback on the overall experience is another key aspect to patient engagement. This can be done through social listening strategies to monitor online conversations. Social listening allows sponsors and CROs to learn what's being said about the trial and gives immediate insight into how patients are responding to information about the specific therapy, medication for a disease state in general, and new diagnoses for a disease state.

Digitization and the expansion of the market to start-ups, as well as technology giants, have led to an explosion of patient-centric technologies for clinical trials. Examples include:

- An app developed by a University at Buffalo researcher that lets patients quickly assess clinical trials, including the time involved, and if there is a study close to them.
- An app from Geospace that lets providers match patients to clinical trials in real time.

The use of wearables also allows clinical trial sponsors and CROs to gather data without requiring patients to visit the trial site every week. Perhaps the best-known wearable now is the Apple Watch, which received FDA approval in 2018 for two applications — an EKG and a pulse monitor.

A growing number of companies are offering apps and wearables to assist with clinical trials. For example, Novartis is working with Science 37, which designs decentralized clinical trial technology, to use digital technologies to enhance clinical trial participation. The technology allows some aspects of clinical trials to be conducted from the patient's home or from a local doctor's office.

Another company using technology to enable clinical trials to be done remotely is AOBiome, which also worked with Science 37 to conduct a study of patients with mild to moderate acne from their own homes. Patients were loaned an iPhone and given a data plan and connected to dermatology experts via a Network Oriented Research Assistant (NORA) platform.

Charting a New Course

It's well known that bringing drugs to market is expensive — as much as $2.9 billion according to the Tufts Center for the Study of Drug Development — and time-consuming. Complex clinical trials and difficulties in managing data and patients contribute to those costs. Today, advances in AI solutions play an integral role in taking cost out of clinical trials and improving efficiency. For example, AI can be used to better identify the right patients for a trial, which then enables companies to engage with those patients directly. This is made possible first by drawing on key data — from electronic medical records, from physician notes, data from images and scans, and other patient information — then assessing this data against the clinical trial criteria.

A common problem with clinical trials is the protocol design. AI can be deployed to compare large data sets from previous trials to determine similarities and areas of concern and use that information to improve the protocol design of the forthcoming trial.

Adherence to the protocol is another problem that researchers have identified. One company noted that blood samples during monitoring showed that up to 40% of patients don't take the drug as required, often skipping the drug for up to two weeks.

Facial recognition technologies from companies such as AiCure can determine if a patient has taken the drug. Alerts can be sent to investigators if the drug has not been taken.

For investigators and other site staff, the complexity of inputting data into many different sponsor and CRO systems adds further complexity. Technology that digitizes standard clinical assessment, automates data capture, and shares data across those many different systems vastly reduces the burden on busy site staff.

The use of cognitive technologies can create action steps for clinical staff based on specific protocol requirements, such as tests that a patient needs to carry out. They can also help with setting up patient visits and filling patient data into EDC systems.

And robotic technologies can automate repetitive tasks, which not only saves clinical staff time, but reduces errors. Such tasks include creating standardized contracts such as confidentiality agreements. Once a trial is under way, robotic technologies can be deployed to determine patient data points to be captured in line with the protocol, check for missing data, and highlight inconsistencies. Once the trial has been completed, natural language processing capabilities can be deployed to fill in standard information in the final study report.

EXECUTIVE VIEWPOINTS

adoption of technologies like risk-based monitoring (RBM). However, the stakeholders involved in complex, expensive research will likely remain (quite rightly) highly conservative. It is up to technology providers to deliver on the promise of valuable, accurate and reliable software.

Unfair or not, software tools are often most visible only when things are not going right and rarely highlighted as a part of why they are. A balanced view and real partnerships between technology and biopharma companies are crucial to accelerating adoption and eliminating inefficient tools and process. In fact, the best advertisements for effective use of technology are reliability and high value process innovation, perhaps supported by "small" data and "actual" intelligence.

Risk Tolerance Driving Evolution

The industry will continue to evolve at the pace of risk tolerance, not at the pace of technology evolution. Virtual, or more likely, hybrid trials promise to be the economic and social rationale to push technology even closer to patients. The breakthrough in solutions that support research will likely be the explicit connection to preserving capital. Every dollar not spent is a dollar that can be re-invested in more work and more potentially lifesaving therapies. If the patient experience is simpler and more convenient, if it requires less time spent engaged with a site or traveling to and from one, two things occur.

First, the "patient density" — or how many patients have to ultimately participate in some portion of the trial, including recruiting, for the trial to be successful — decreases.

Easier recruiting, easier participation, easier communication, easier engagement all mean fewer required participants, lower churn and better-quality data.

Second, technology, through devices, telemedicine, engagement solutions etc. potentially widens the population of potential participants. A larger audience not only enhances the patient density, it also creates a social good that gives access to more individual patients who might benefit from experimental medications. Reaching this potential may be a bit of a long movie, but how the movie ends seems relatively clear.

Fabio Gratton
CEO
CureClick

Mobilizing Data Collection

The dropping costs of "dumb sensors" combined with the remarkable computing power packed in everyday phones is making it possible to collect real-world data like never before — and this will assist not only with monitoring safety and efficacy during a trial, but will also help inform the design of future trials based on real-world evidence (RWE). In addition, the ability to efficiently and seamlessly capture patient reported outcomes (PROs) through mobile app interactions, text messages, and automated voice surveys will ensure that the total patient experience eventually becomes an integral component of all new drug applications.

The Power of Influencer-Powered Communications

Companies are constantly struggling to find patients for their trials. One of their biggest challenges they face is delivering targeted messages to the right patients, without violating laws and trust. We have personally witnessed the power of influencer-powered communications to reach trial candidates — and that is largely due to the fact that we are leveraging the trust inherent between people in those communities. Similarly, I believe blockchain technology can play a key role in protecting privacy while connecting patients to trials on a very large scale. It all starts with personal data ownership and transparent transactions between companies, data brokers, and patients.

David Elario
Executive VP and Product Line Executive, eCOA
ERT

eCOA Solutions Improve Trial Efficiency

Today's electronic Clinical Outcome Assessment (eCOA) solutions are continuously evolving to boost trial efficiencies and data quality. I expect we'll see further conversion from paper to more compliant, reliable electronic collection as regulatory bodies continue to recognize eCOA's benefits. In oncology, the FDA now recommends QoL endpoints beyond survivability, so patient-reported outcomes will expand further.

We'll see site personnel with one tablet for both clinician and patient outcomes, and eCOA systems will capture more data from new devices/sensors like activity trackers and fall indicators. BYOD will expand as more patients use their own cellphones in trials, as well as Siri, Alexa, and other VA devices — all providing greater data context, patient insights, compliance, and outcomes — fueling product differentiation in this competitive pharma market.