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.

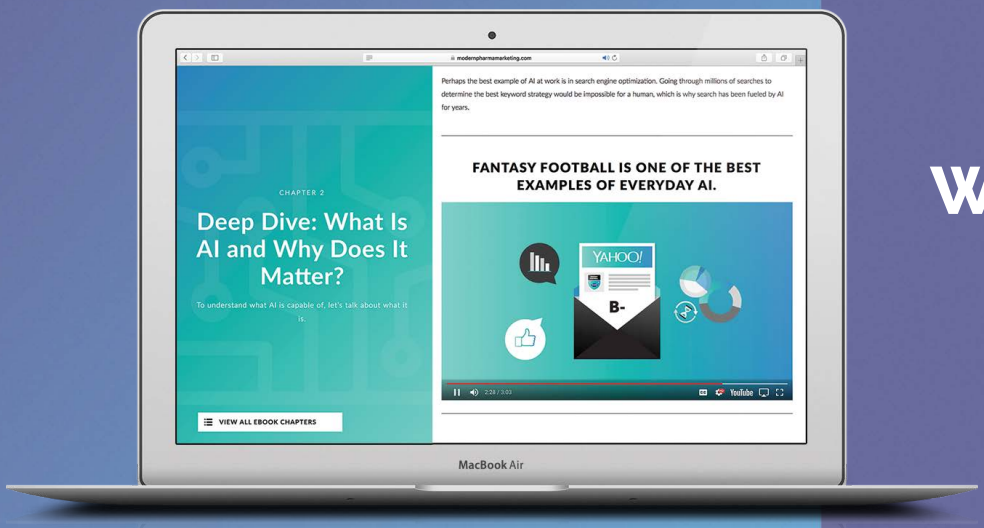
Adherence to the protocol is another problem that researchers have identified. One company noted that blood samples during monitoring showed that up to 40% of patients don't take the drug as required, often skipping the drug for up to two weeks.

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.



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AI algorithms can also offer predictive data on a number of important issues — whether the drug will have a positive or negative outcome for the patient, the likelihood of patient dropout, and the likely success of the trial. Technology has been an important driver in advancing the clinical trials market. Next-generation solutions are integral in improving and expanding clinical trial capabilities. PV

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Julie Ross
President
Advanced Clinical

Blockchain Technology Offers Many Advantages

Blockchain technology will provide secure, real-time access to unamendable clinical trial data and documentation while ensuring the accuracy and validity of: Enrolled patient's health records, clinical research stakeholder qualifications, remote patient monitoring data protecting privacy and authenticity, adverse event data and case processing and study reporting, and supply chain and drug monitoring data. Pilots of these blockchains are currently under way by the FDA, pharma/CROs, and in collaboration with large technology players and over time will gain much momentum.

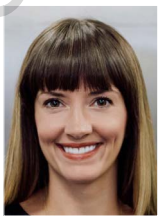
A Technology Evolution

In the next five to 10 years, clinical trials will see significant evolution in the areas of AI/ML, blockchain, mobile apps, and wearable data collection tools. The main driver is to successfully develop investigational products in significantly less time, with less money and resources. Much work is beginning with AI/ML to fine-tune the appropriate subject population that best matches the IP profile thereby decreasing the number of patients needed for a given trial and improving the success rate for meeting primary and secondary endpoints. All of the technologies play a key role in improving the speed to enroll patients, gain access to patient/subject data, ensure privacy, and decrease the overall cost and time while informing stakeholders at the right time with the right information throughout the clinical trial conduct.

Meredith Frank-Molnia
Senior Director, Clinical Management
Axiom Real-Time Metrics

Patient-Focus Driving Innovation

A focus on patients will continue to drive innovation of clinical trial solutions. Patients will have access to more advanced technology options directly from their own homes, which will increase compliance and will allow sponsors to collect reliable patient data (e.g. ePRO, vitals) in an efficient and cost-effective way. This technology will allow compliance with the regulatory requirements (ICH E6 R2) and allow data review to be more tailored to the key data end points.



Quinn Zarubick
Associate Director, Clinical Operations
Axiom Real-Time Metrics

Unifying Technology for Increased Efficiency

As studies become more complex, sponsors are looking to utilize technology to increase their efficiency when managing their clinical programs. Sponsors are increasing their technology footprint leveraging ePRO, clinical supply management, and data monitoring tools for increased efficiency to monitor data trends, GCP compliance, patient retention, and to optimize study costs. They can do this more easily as technology becomes increasingly unified and specialized applications allow for integration.

Mike Nolte
CEO
CRF Bracket

Software Driving Transformation

When you look at clinical research, the technology used directly in drug discovery is often leading edge and the software solutions that manage the drug development process itself are still at the front end of the adoption curve. On one hand, it is compelling and exciting to talk about big data, artificial intelligence, or a host of other innovative solutions. The current state, though, is that workflow, communication, assessments, analysis, approvals, consenting, and a significant amount of other data collection still depend on manual process supported by file storage and spreadsheets. Data and machine learning offer promise for the future, but today's reality is that there is plenty of opportunity for established software solutions to replace manual processes, improve data reliability, eliminate human error, and streamline clinical operations.

It is encouraging that eCOA adoption continues to rise and that there are breakthroughs made every day in the use of remote devices to collect or augment endpoint data. There is even growing recognition that manual data entry into EDC systems and the verification that goes along with it would benefit from more aggressive ▶

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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.

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Prakriteswar Santikary, Ph.D.
VP and Global Chief Data Officer
ERT

AI and Machine Learning Require Solid Infrastructure

New technologies are driving clinical development advances at a rapid pace. We're seeing an expansion in the use of AI and machine learning for making clinical trials intelligent, optimizing patient recruitment and retention, and delivering greater insight for smarter decision-making.

In order to truly leverage the cost- and time-saving potential of these technologies, sponsors first need an infrastructure that keeps up with the exponential data growth happening in the life-sciences industry. Modern data platforms based on the cloud meet sponsors' data integration and quality needs and deliver scale, agility, and performance — enabling AI and machine learning to have a big impact in clinical development.

Tom O'Leary
Chief Information Officer
ICON

Digital and Mobile Health Technologies

Some of the biggest tech trends in the clinical trial area include digital and mobile health technologies. These capabilities are enabling the capture of drug efficacy and safety measures remotely within the bounds of clinical trials, which is driving improvements in patient safety, enabling virtual trial capabilities and easing the overall site burden in the conduct of clinical trials. These advances will lead to accelerated clinical trial times, resulting in better medicines being available to patients sooner.

Wearables and Predictive Analytics

Over the next five to 10 years, clinical trial solutions will be dominated by wearable technologies and predictive analytics capabilities. Wearable technologies will increasingly be used to monitor physiological and other indicators from blood pressure and glucose to heart rhythms and physical activity with that information being sent back to monitoring sites. Other electronic monitors will assess medication compliance, peak respiratory flows, weight, and even patient mood. Artificial intelligence, machine learning, and other predictive technologies will be further leveraged to derive value from big data in healthcare and enable more evidence-based insights to help guide drug development.

Richard Staub
President, Research & Development Solutions
IQVIA

Technology Expertise

Clinical development has gone through several innovation/evolution cycles from the adoption of electronic data capture, risk-based monitoring, and adaptive study designs, to the adoption of alternative delivery models such as virtual studies. All have had a significant impact in helping to improve trial performance in terms of cost, timelines, quality, and outcomes.

Technology alone won't transform clinical research — but it does provide the foundation to fundamentally change the way things have traditionally been done. Along with robust data and analytics, technology must be coupled with industry experts who understand the complex needs of clinical trials and how technology can be successfully integrated to address unique clinical research challenges.

The Next Transformative Revolution

We are on the cusp of the next transformative revolution in clinical trials — a digital transformation — and it has the potential to be significant. Digital transformation is complex and resource intensive, but the rewards of improved patient engagement, faster cycle times, and cost savings will be meaningful. Digital technologies — for example connected devices, mobile applications, artificial intelligence, machine learning — will help drive greater product and patient value that traditional approaches cannot. Adopting a digital strategy will likely become a business necessity to help move drug development forward.

Katherine Vandebelt
Global Head of Clinical Innovation
Oracle Health Sciences

AI's Impact on AEs

One of the biggest trends we are seeing is around artificial intelligence (AI). Leveraging AI to help automate processes such as adverse events (AEs)/serious adverse events (SAEs) intake is one area where AI is making a significant impact. With AI, each source document can be processed in 12 to 18 seconds with 90% accuracy. Automating safety workflow with AI not only saves time and money, it also frees drug safety teams ▶

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to focus on other more critical tasks. We are confident the AI trend will continue to expand into other areas of clinical development.

Scalable Solutions

Over the next five to 10 years, clinical solutions will need to evolve to be scalable and flexible to handle the digital trial, which comes with more complex data from a wider breadth of sources both known today and those that are unforeseen in the future. Clinical technology will need to support genomics data and EHR data, which will improve patient recruitment, engagement, and retention. Data from devices, sensors, and apps will also need to be supported, so the technology must evolve with this in mind. With the increase in digital data, we will have more insights into the patient healthcare and clinical trial journey and predictive models for trial feasibility.

Crystal Black
Director of Marketing Programs
Saama Technologies

AI-Powered Analytics

Leveraging artificial intelligence (AI)-powered data analytics to ensure a patient-centric focus on clinical development is one of the biggest technology trends in the clinical arena. Machine learning and deep learning platforms are seamlessly integrating, curating, and animating unlimited sources of structured, unstructured and real-world data for more actionable insights across therapeutic areas. These insights are expediting clinical trials to bring new therapeutics to patients faster than ever before.

A Frictionless Experience

Ensuring a frictionless experience for clinical trial participants will inform the evolution of clinical trials over the next decade. Virtual trials, enabled by cloud-based technology and AI-powered data analytics will be one of the main drivers of this trend. Data analytics solutions will facilitate rapid clinical trial patient identification, targeted selection of optimal clinical trial sites, and easier, more efficient patient engagement, all of which will optimize and accelerate therapeutic development.

Aaron Berger
Senior Director, Safety Epidemiology Registries Risk Management
UBC

Healthcare Data Digitization

Healthcare data digitization sets the stage for patients to have greater access to and ownership of their healthcare records than ever before. The network effect of partnerships and data interoperability standards will catalyze the movement toward virtualized trial designs and fuel modernized approaches to patient identification, enrollment, engagement, and multi-modal collection of patient-generated data throughout the clinical trial lifecycle. The traditional approach of "bringing the patient to the study" at brick-and-mortar facilities will be augmented and replaced by tactics that "bring the study to the patient."

Paul Bloom
Senior Director, Software Engineering
UBC

Curated Data

Technologies that enable the realization of the vision set forth in the 21st Century Cures Act and FDA's RWE Framework will have the most significant impact in the clinical trial arena. Technologies that facilitate interoperability of high-quality data from disparate and unstructured sources to generate de-identified, research-grade datasets will bring transformative value to the clinical trial arena. These curated data assets will enable sophisticated hypothesis-generation, novel study designs, accelerated patient identification, enrichment of data, and unprecedented visibility into patient pathways.

Mark Hanley
CEO
VirTrial

A Virtual Trial Hybrid Model

One trend I see today is the drive for 100% virtual trials. Unfortunately, jumping straight into a fully virtual model has several fundamental issues. First, only a small number of studies can be designed as 100% virtual in their protocol. Second, by eliminating the intrinsic value of human-to-human relationships and requiring patients to learn new technology without support increases the likelihood of poor retention. I believe virtual trials will shift to a hybrid model based on necessity. The human element can never be fully replaced by technology and that will drive the need for hybrid virtual clinical trials where telemedicine providers work hand-in-hand with research sites to provide a combination of virtual and in-person visits, offering patients the best of both worlds. PV