Improving Trials with Technology

▶ Technology is taking center stage as a way to mitigate clinical challenges and improve patient outcomes.

The clinical trials market is massive and continues to grow. According to a report from Grand View Research, the global clinical trials market will be worth $65.2 billion by 2025. At the same time, clinical trials are costly, with many trial failures and difficulties with patient recruitment.

To help mitigate these challenges and improve outcomes, there has been a growing focus on adopting technologies, such as electronic data capture, electronic clinical outcome assessment, electronic informed consent, and, increasingly, digital platforms and mobile devices. Technology use is growing at a CAGR of 22% to 23%, with the global R&D technology market predicted to be worth $49.3 billion by 2023.

The Drive for Better Patient Recruitment

The demand for digital tools to help recruit patients and reach out to potential clinical trial participants has increased, leading to an increase in clinical trial management tools. One such platform is ClinOne, which aims to help sponsors and research sites to recruit potential patients to clinical trials. The tool can also be used to manage the clinical trial workflow and collect data from remote monitoring sensors. The tool received $3.6 million in Series A funding in March 2020.

Many other similar platforms have been developed with the goal of connecting patients to clinical trials. Natural language processing (NLP), a branch of artificial intelligence, for example, may be applied to search through doctors' notes and pathology reports to assess potentially eligible trial subjects. And to help hospitals search patient databases for eligible patients, an open source web tool called Criteria2Query translates data into a standardized, coded query format so researchers can search databases.

In a pilot study carried out by Mayo Clinic, the average enrollment time for breast cancer trials decreased by 80% by using IBM's Watson for Clinical Trial Matching system. Another AI platform that seeks to match patients to appropriate clinical trials is Viper, from Deep Lens, which combines AI, deep learning, and computer vision to rapidly identify difficult tumor sub-types/stages in real-time with very high accuracy. The tool can also find and match information associated with trials through real-time diagnosis enhancing coordination among research teams, care teams, and patients.

Meanwhile, COVID-19 is proving a significant catalyst for improved clinical trial solutions. One public health solution called World Without COVID from Clara Health is seeking to get patients into clinical trials more rapidly to advance research into the virus.

And as clinical trials for other conditions battle to continue during the COVID-19 pandemic, finding innovative ways to keep trials on track has become more and more important. Using tools that enable in-home clinical services, direct-to-patient support, and remote monitoring can help to keep clinical trials running during the crisis.

In March, the FDA published guidance on managing clinical trials during COVID-19, including carrying out assessments via phone or virtual visits and offering additional safety monitoring for clinical trial participants who can no longer access an investigational product or site.

Tools that can assist with siteless studies include wearables and other devices that enable companies to gather data without having to bring patients into trial centers. One example is a trial for acne treatment that used a proprietary mobile technology to capture real-time data from patients at their homes.

It's not only sponsors and sites that are eager to adopt clinical trial tools. According to one survey that described hypothetical mobile clinical trial and traditional clinical trial scenarios, a majority of patients would prefer to take part in a trial that uses mobile technology due to the convenience, fewer in-person clinic visits, and improved data accuracy.

Improving Data Collection

Another key benefit of mobile technologies with clinical trials is the ability to continuously collect outcome measures from trial participants as they go about their day-to-day lives while also reducing the burden on patients.

Technologies can help to make the trial process more flexible and efficient by bringing about greater standardization and continuity in how data is collected, exchanged, treated, and stored.

While mobile technologies bring benefits to sponsors, trial researchers, and patients there are challenges to overcome. These include concerns over choosing the most appropriate technologies; issues with collecting and analyzing data; ensuring protocols are adapted to accommodate mobile technologies; and concerns over data authenticity, integrity, and confidentiality.

To help address these issues Clinical Trials Transformation Initiative (CTTI) put together recommendations and created resources to assist with the appropriate use of mobile technologies. Among the recommendations are: know what you want to measure before selecting the mobile technology; ensure the selection process is justified through verification and validation processes; and carry out feasibility studies before full implementation, especially with large studies. (See sidebar for details.)

Designs on AI

Aside from mobile, another important technology innovation for helping with clinical trials is artificial intelligence (AI). Al-

CCTI Recommendations on Using Mobile Technologies

MOBILE TECHNOLOGY SELECTION

- Know what you want to measure before selecting the mobile technology
- Mobile technology selection should be specification-driven and collaborative
- Don't focus on a technology's regulatory status as the sole driver in decisions
- Carry out a verification and validation process when selecting mobile technologies
- Carry out feasibility studies before full implementation to reduce risk in large studies

DATA COLLECTION, ANALYSIS, AND INTERPRETATION

- Biostatisticians and data scientists, as appropriate, should be involved in all decisions regarding protocol design, data collection, analysis, and interpretation
- Collect the minimum data set necessary to address the study endpoints
- Include appropriate strategies for monitoring and optimizing data quality
- Address data attribution proactively with patient input
- Identify acceptable ranges and mitigate variability in endpoint values collected via mobile technologies
- Minimize missing data
- Plan appropriately for the statistical analysis of data captured using mobile technologies
- Establish industry-wide standards to drive the successful scaling and more rapid acceptance of clinical trials using mobile technologies for data capture.

DATA MANAGEMENT

- Ensure the authenticity, integrity, and confidentiality of data over its entire lifecycle
- Optimize data accessibility while preventing data access from unauthorized users
- Ensure that access to data meets your needs before contracting an electronic service vendor
- Apply an end-to-end, risk-based approach to data security
- Monitor the quality of data captured by mobile technologies centrally through automated processes
- Ensure that site investigators have access to data generated by their participants.

PROTOCOL DESIGN AND EXECUTION

- Data sharing decisions should be driven by safety and trial integrity
- Communication and transparency with participants regarding safety monitoring is critical
- Define and test processes for the implementation, operation, and maintenance of mobile technologies in the field before launching the trial
- Have a plan in place for mobile technology failure
- The considerations that inform adaptive designs in a trial using mobile are the same as for traditional studies

FDA SUBMISSION AND INSPECTION

- Ensure that trials conducted using mobile technologies for data capture can be readily reconstructed (i.e., end-to-end traceability)
- Source data should be the primary resource provided to FDA during inspection
- Be prepared to provide supporting material for mobile-based claims to FDA as part of any marketing appplication

Source: Clinical Trials Transformation Initiative, ctti-clinicaltrials.org

though AI hasn't been widely applied to clinical trials, it does have huge potential to create safer, faster, and less costly trials.

For example, using AI, researchers can quickly process information from comparable studies, clinical data, and regulatory information in the study design. Furthermore, AI makes it possible to collate far more data than a human being would be able to do.

Strict medication adherence is also a critical element in clinical trials. Some companies, such as AiCure, are developing platforms that allow patients to video themselves taking medication using their smartphones. Using AI algorithms, the software identifies the person and pill to confirm whether the medication was taken. Studies so far have shown higher adherence rates.

AI can also help with site selection by helping sponsor companies identify locations, the right investigators, and candidates, as well as collect evidence needed to show that the trial complies with Good Clinical Practice guidelines.

Digital technologies can help to advance and transform the clinical trial landscape, engaging patients, simplifying the process of gathering and analyzing data, and improving the entire communication process with all stakeholders. PV