The Changing Face of Clinical Trial Solutions

▶ Clinical trials have undergone significant change over the past year amid concerns over patient safety during the pandemic.

According to a survey across biopharmaceutical companies, medical devices companies and clinical research organizations, 76% have sped up the move to virtual in the wake of COVID-19.

The cost of delaying clinical trials is significant to companies, which is prompting many to adopt digital solutions. In response, experienced market players are developing more sophisticated and adaptable solutions that will allow CROs, clinical trials solutions companies, and sponsors to achieve trial objectives more quickly and easily.

According to the survey conducted by Informa Pharma Intelligence on behalf of Oracle Health Sciences, a majority of respondents are adopting patient-facing technologies or alternatives (64%) and protocol redesign (63%), while many are also embracing investigator-facing technologies or alternatives (53%).

Finding Patients and Keeping Patients: A Digital Imperative

As sponsors and CROs look to attract patients to clinical trials, more are turning to digital outreach. According to reports, digital outreach has led to greater interest from clinical trial patients with one organization reporting a 20% increase in click through rate for digital ads for trial recruitment, a 13% increase in engagement rate, and a massive 80% increase in registration rate.

To simplify engagement for people in clinical trials, more companies are adopting wearables, remote patient monitoring, and remote data collection solutions. For example, the Oracle survey finds that 67% of respondents have adopted remote data collection in their trials through the use of patient apps (57%), ePRO (49%), and wearables/devices (45%).

These solutions do, however, add some challenges for organizations, specifically with regard to adopting new approaches to review, manage, and interpret data (something 49% of surveyed organizations noted were a concern) as well as expense (a concern for 46%), and regulatory considerations (42%). Data quality from remote collection is a concern for 57%, according to the Oracle survey, while data protection and lack of standardization of data were also raised (40% and 36%, respectively).

Nevertheless, there is awareness that wearables and remote monitoring technologies will make it easier for patients to participate (64%), enable organizations to leverage real-time data (52%), and help companies achieve cost savings (45%).

Technology to the Rescue

As more trials become virtual, technology solutions that support collaboration and ensure accurate datasets are provided to sponsors are becoming an imperative. Clinical trial management systems (CTMS) and eClinical solutions are two key capabilities companies have adopted or are adopting to support adaptive and remote trials.

To better organize data from clinical trials, improve cost-effectiveness, and increase visibility, companies are adopting electronic trial master file (eTMF) solutions. The advantages of eTMFs are that they provide a single source of truth and users can access the information from any device. According to data, the eTMF market was valued at $938.32 million in 2019 and is expected to grow at a CAGR of 16.5% from 2019 to 2027 to reach $3.16 billion by 2027.

Some organizations are looking toward aggregating all relevant clinical trial management information in a single platform, including consolidating CTMS and the eTMF for more effective clinical trial management. Unifying trial management capabilities allows organizations to aggregate information about the study, patients, contracts, payments, documentation, and monitoring, thereby improving productivity.

To address concerns over privacy and security, some organizations are looking to the promise of blockchain, which uses a distributed computer network platform that enables databases to store time-stamped transaction records and documents. Each server within

Virtual Trials: A Growing Market

The global virtual clinical trials market is expected to reach $10 billion by 2026, rising at a market growth of 6.5% CAGR during the forecast period. The virtual clinical trials (VCT) market, also known as remote or decentralized trials, is being driven by growth in R&D activities, the growing digitization in healthcare, and the adoption of telehealth.

Moreover, advances in technology and collaborations between clinical research companies, biotechnology companies, and pharmaceutical and support initiatives from governments are expected to boost the market.

VCTs abolish limitations presented by conventional clinical trials, such as time-taking procedures and delay in recruitment of patients, and that has pushed the demand for the VCT market.

Additionally, advances in technology in healthcare infrastructure and partnerships between pharmaceutical, biotechnology, and clinical research companies are expected to propel VCT market development in the coming years.

The rise in costs, combined with a higher rate of trial failures and an expansion in patient-centric trials, has resulted in a rise in demand to adopt technology in clinical trials.

Source: Reportlinker.com

the network processes and verifies each data entry, and archives and provides a trail of every transaction. In so doing, the data is stored intact. The certainty this provides has led Pfizer, Amgen, and Sanofi to work together to look at how blockchain technology can be used to store information and speed up clinical trials.

One organization, ConsilX, has developed a blockchain-based patient data and event management platform for clinical trials that conducts event-tracking and time-stamping of patient activity as well as encrypting data storage. Smart contracts manage cryptographic patient identities and enforce rules management for regulatory compliance.

Clinical trial recruitment companies are also making greater use of lab services and logistic partners to support testing and the collection of diagnostic data.

Integral to the recruitment process is informed consent, which typically is done in person. With the move to decentralized trials and the need to protect patients by avoiding unnecessary face-to-face interactions, there is a growing focus on e-consent. However, it's important that study population demographics are well-considered in any approach to ensure adherence to regulatory and ICH-GCP requirements.

Once a virtual trial gets underway, sponsors and CROs need to ensure patients receive the study medication safely and securely. Delivery solutions need to ensure that medicines are delivered in temperature-controlled vehicles, that delivery status updates are provided to the sender and recipient, and that there are

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Tom Mueller

Chief Commercial Officer
ACM Global Laboratories

Adoption of RWD Accelerates

With new technology and tools available, we're seeing a shift toward hybrid trials, remote clinical sites, and a larger inclusion of real-world data (RWD) into the overall protocol design and patient targeting efforts. There is little doubt that this will continue to expand over the next five to 10 years, and we will see drastic improvement of technological solutions as Moore's Law evolves the industry. I think that we will see the greatest advancements in "how" that data is used and the incorporation of RWD to be used more and more as evidence in submission of novel therapies and indications. As fast as the inclusion of RWD will continue to accelerate, for clinical trials specifically, the industry will need to balance this with patient access. In other words, we need to ensure that this inclusion is additive to the clinical trial process and not a direct replacement. The risk to the industry is exclusion of emerging markets and potentially creating inequity in patient population participation due to economic burden or lack of technology access.

Pivoting at Scale

Currently, there is a shift from everyone contributing to find a solution to the COVID-19 pandemic with the development of novel therapies and vaccines back to their portfolio of pipeline therapies. It is a challenge to pivot at scale from one to another, and a lot of trials were put on "pause" due to COVID. As we have seen the introduction of vaccines into the market, the shift back has caused many companies try to get back on track to their original pre-COVID timelines. If we look at the entire clinical trial ecosystem, the supply chain of supplies and reagents also took a pause as we adjusted to the new normal of COVID a year ago. At ACM, we are aware of this downstream effect and are taking special precautions and foresight to look at the entire supply chain and study duration when bidding on a study to reduce any disruption as much as possible and partner with the CRO/sponsor to ensure a successful trial.

Jason Casarella

Executive VP of Marketing and Business Development
Advanced Clinical

Adaptability and Collaboration

The clinical trial industry showed incredible adaptability in 2020. According to The Lancet, the average vaccine development timeline is 10 years, but thanks to collaborative efforts within our industry and government, we now have three approved vaccines to address the global pandemic. The past year also forced the adoption of decentralized and hybrid clinical trials. Today, our research community has stronger partnerships, better technologies, and proof that innovation can produce results that were never before imagined.

Optimizing Clinical Trials

While the clinical research industry continues to be positioned for growth and innovation, we will likely see the impact of additional M&As. With the rapid development of vaccines, there will be greater emphasis on real-world data as longer-term effects are studied. Explosive growth has created immense demand and a crowded market, so the competition will need to adapt to truly optimize clinical trials in the future.

Rama Rao

Cofounder and CEO
Bloqcube Inc.

Trial Operations Key to Success

Nature had an article recently that argued in the conclusion that "researchers have registered more than 2,900 clinical trials related to COVID-19,

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but the majority are too small or poorly designed to be of much use." How do we avoid that in the future? While trial design is key, trial operations are no less so. Post COVID-19, the impact will be in multiple areas. Vaccine trials are likely to continue — both effectiveness against new variants and creation of new vaccines for the new variants. Next will be the urgent need to unblock all the trials paused/suspended for various reasons during the lockdown phase. Additionally, a need to enhance our focus on patient-centric, decentralized trials to protect the patients and the site personnel is likely to stay. Even more important is to return to the sanctity of clinical trials for evidence-based medicine. Multiple systems may not be the answer — cumbersome, siloed, inefficient — but systems that deliver multiple capabilities via unified platforms with immutable data like in Bloqcube could be the answer. What we surely need to avoid is the conclusion quoted in Nature.

Technology's Impact on Trials for Tomorrow

The patient journey should be far more decentralized. Consequently, fully decentralized systems, and especially those running on a distributed ledger, would be key as they deliver data with trust and governance. Long neglected are payment efficiencies to key stakeholders in a trial. Smart contract-driven algorithms coupled with current e-commerce payment systems will be key to rectifying the payment asymmetries. Enhanced governance and trust provided by blockchain systems would anchor these changes, and software solutions like Bloqcube, the first fully decentralized CTMFS running on an iPad/cloud/distributed ledger, could be a key force for change.

Ed Seguine
CEO
Clinical Ink

Focus on Patient Data in Totality

Our industry constantly invents narrow solutions to very specific challenges — most platforms of today are merely aggregations of point solutions that evolved over time. Tomorrow's platforms must focus on patient data in totality — eliminate the distinctions between EDC, ePRO, ClinRo, eConsent, EMR, etc. — and capture data from patients wherever — on-site/at home — and however through mobile, web, or sensors. To do that requires fundamentally different platform architecture and data models, not just adding more new "features."

Simplifying the Complexity of Protocols

The complexity of protocol designs — not the science but the execution complexity — is a big trend. The dramatic growth of decentralized trials was primarily driven by simple study designs. We are seeing a resurgence of much higher complexity protocols. This doesn't mean more procedures or more visits; it means more options, iterative assessments, complex reports, even patient-specific options. This complexity is going to be permanent and creating platform capabilities to simplify this complexity will be critical.

Matthew McCarty
VP of Integrated Customer Solutions
ERT

The Promise of Clinical Trials

While the novel technologies, such as AI or voice, are attractive, and certainly have use cases, the promise of clinical trials continues to require high standards of evidence collection and global regulatory rigor. The greatest impact will, therefore, come from solutions that can humanize technology to reduce patient burden and increase patient choice, access, and diversity while enabling patients to be good stewards of their data and ensuring quality and compliance.

Cynthia Verst
President, Design and Delivery Innovation for Research & Development Solutions
IQVIA

DE&I in Clinical Trials

The biggest trend we have been seeing is the renewed interest of diversity and inclusion within clinical trials. We see increased investment in this space not only within IQVIA but across our sponsor partnerships and within the FDA as well. Within the COVID trials, the FDA mandated that the study population include a diverse and representative population. In order to achieve this goal, sponsors are thinking critically in the planning stage as to how they will

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run the study — altering site selection strategies and patient recruitment tactics. We have seen that if you wait until a study is underway, it becomes significantly more difficult to catch up to the desired inclusivity.

Transformative Technologies

Technologies that bring the journey to the individual will have a transformative impact on the patient experience. Applying voice-activated engagement technologies such as Alexa and Siri will allow hands-free access to trials. The use of speech biomarkers to identify and track disease progression will continue to evolve and provide additional opportunities for evaluation without travel outside the home. On-request access to medical records and the ability to augment that data with feeds from wearables, fitness devices, and environmental monitors will provide a clearer path to a personal wellness journey.

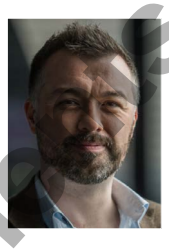
Amanda Wright
VP, Partnership Development
Javara Inc.

Lessons Learned Create a Lasting Paradigm Shift

Lessons learned as a result of the pandemic have the potential to create a lasting paradigm shift for our industry that supports better outcomes. Provisions for creativity and flexibility ensured trials could continue and proved that it was possible without compromising data. Our ability to remain steadfast and not revert to our prior methodologies will enhance participation rates and the patient experience.

The Importance of the CRAACO Movement

The transparency and magnitude of information and data in the public domain as a result of COVID-19 has raised awareness and expectation for clinical trials overall. Recognizing the importance of an inclusive patient engagement strategy that enables the trusted physician relationship, along with caregiver and community influences to positively impact the clinical research narrative, is critical to the decision-making process — reinforcing the importance of the CRAACO or "Clinical Research As A Care Option," movement.



Jonathan Burr
Senior VP, Clinical Platform Strategy
Saama Technologies

Going to the Intelligent Clinical Cloud

Though COVID-19 derailed the industry, it also catapulted it to new heights through accelerated vaccine development. The world will not accept a default to pre-pandemic drug development timelines. Leveraging the newly emerging category of purpose-built and intelligent infrastructure known as "Intelligent Clinical Cloud" will bring sustainable transformation for accelerated drug development. These AI-based clinical insights platforms will empower the industry to achieve scale, acceleration, and repeatability across therapeutic areas.

Rewriting the Playbook

The trend toward patient-centric decentralized clinical trials will continue, but we must rewrite the playbook. True patient-centered trials should be ones in which we give as much to the patient as we take from them in terms of data. AI-based trials will enable us to change the patient experience through precision medicine and the ability to provide patients with insights about their own health, as well as using individual insight to inform population health.

Geoffrey Gill
President, Shimmer Americas
Shimmer Research Inc.

Remote Monitoring and Patient Safety

Wearables and other telehealth technologies will have the biggest impact on patients. They can significantly reduce or eliminate the need for clinic visits — one of the most burdensome elements of trials. Remote monitoring has the potential to identify some adverse events earlier, improving patient safety. Depending on how they are implemented, wearables may also provide direct feedback to patients on their own health status, improving engagement in the trial.

Wearables and the Future

Wearables will progress from being assessed in exploratory pilot studies to being relied upon to measure the primary endpoints for many trials. This will transform not only the operation

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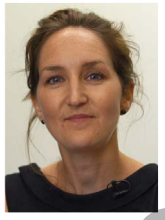
of the trial — think fewer clinic visits — but also improve the accuracy of the outcome assessment. Improved outcome assessment will drive shorter trials with fewer participants, significantly reshaping the economics of research.

Scott Scarola
VP, Operations Management
Syneos Health

Wearable Devices and Connections

Direct-to-patient advertising and landing pages, while not permitted globally, will allow patients to access clinic trials faster. In addition, wearable devices will allow quicker connections to patients in the absence of or in between visits. This represents a significant growth area with multiple options to suit a wide range of needs. Lastly, the ability for sharing data back to the patient will play a key role in empowering patients across their health journey.



Noolie Gregory
VP, Operations Management, Decentralized Solutions
Syneos Health

Landmark Changes to Healthcare

The application of decentralized solutions will become an industrywide change as the industry embraces new technologies. Patients will demand to access their care in new ways, and regulatory frameworks will be updated to reflect the technologies available. Healthcare systems will also become more tech-savvy. It will be interesting to see how large tech players such as Google, Apple, and Amazon will use their expertise and clout to make landmark changes to healthcare.

John Reites
CEO
THREAD

Taking an Omnichannel Approach

The mobile phone is still the most impactful technology in supporting the participant journey in clinical research. The ability to have one app that enables a participant to consider a clinical trial, consent, schedule visits, be reminded of activities, view their data, contribute data, and conduct visits via a mix of telehealth and in-clinic visits is the future. This single, comprehensive model that is available in an omnichannel approach — i.e. available via app, web, in-clinic visit, etc. — offers the biggest impact to making studies more comprehensive, inclusive, and efficient.

Expanding DCTs

We are contributing to and closely tracking the continued expansion of global hybrid decentralized trials. As the industry strives to improve recruitment, data collection, and retention, it will seek to enhance flexibility and visit options for patients. These focus areas will materialize in study designs as hybrid decentralized approaches that support global programs, meaning that technology-enabled clinical research with a more global focus will become a standard clinical design approach.

comprehensive instructions for the patient on how to administer the medication.

Technology Innovations

Adherence to clinical trial regulations mean companies are focused on developing optimal study designs to ensure all stakeholders can participate easily and achieve the best outcomes. Artificial intelligence is being leveraged to help optimize clinical trial protocols and develop patient-centric trial designs. Whether for remote or centralized trials, collection of real-world data is proving key to assisting with analysis and proving drug efficacy, so factoring in sources such as clinical registries, electronic health records, and post-authorization reports is important. Sponsors and CROs managing trials must therefore start to consider e-source technologies to support research, such as:

- AI/ML-based platforms that support enrollment of subjects in clinical trials
- AI-based medication and protocol adherence support
- Innovation in eCOA technology to facilitate a more patient-centered approach to trial design and administration
- Interoperability-enabling platforms
- Smart technologies that integrate data from various streams to expedite analysis and understanding of the data

The ability to capture, monitor, and analyze real-world patient-generated data and outcomes in trials is of increasing importance to sponsors and CROs, while the use of eCOAs can enable pharma R&D departments to improve the reliability of patient-reported data.

Patient Preferences

Visiting sites is a burden for many patients, with reports showing that around 70% of Americans live more than two hours away from study sites. Furthermore, a Center for Information and Study on Clinical Research Participation study of 12,000 participants found 60% considered physical location of a site very important when considering joining a study. The ability of sponsors, CROs, and sites to support virtual or DCTs is therefore important to drive better engagement. The use of new technology solutions will therefore be critical to successfully enabling virtual trials and helping organizations achieve greater efficiencies and reduce costs.

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Matt Lasmanis, Sage Therapeutics

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