Digital Technology Changing the Face of Clinical Trials

▶ The clinical trial industry is both changing and growing at a significant rate.

Greater investment in R&D and a growing number of clinical trials combined with accelerated demand for automated solutions are contributing to a rapidly expanding contract research organization (CRO) market and changing the face of clinical trials. According to some estimates, the CRO market will reach $59.42 billion by 2020, growing at a CAGR of 9.8% between 2015 and 2020. Certainly, investment in R&D is helping to accelerate growth in the CRO market. According to Evaluate, worldwide pharmaceutical R&D spending is expected to grow by 2.4% (CAGR) to $181 billion in 2022. A growing percentage of that spend is focused on the orphan drug market, which is expected to almost double between 2016 and 2022, reaching $209 billion by 2022.

Delivery of Clinical Trial Solutions

While a large number of clinical trials remain paper-based, that is starting to change with more companies moving to electronic methods to capture data, such as case report form data, as well as the rise of wearable and mobile health data, and increased use of genomics data.

Cloud-based technologies are now more than a trend. With the need to not only reduce costs but also have access to real-time data analytics, more companies are adopting cloud-based solutions. Cloud-accessible research platforms make it possible to collate data from electronic health records as well as harmonize trial design and improve relevant recruitment.

The pressure for better analytics to improve the quality of clinical trial practice is leading to innovation on analytics platforms. Pfizer, for example, is using predictive models to monitor studies for good clinical practice risk. The pressure is on companies to invest time and resources in supporting real-time analysis of clinical trial data from new sources and use analytics to identify performance issues.

Having clinical trial technologies based in the cloud confers many benefits. Real-time reporting and checking is important to ensuring a study's chances of success, and cloud computing allows information to be generated from a central system. Having access to real-time data speeds up decision-making, for example, in response to notifications of serious adverse events. Cloud computing also gives clinical trial managers greater control over the study and allows data to be accessed from any device or location. Cost efficiencies are another benefit of cloud computing since companies don't need storage space for servers. Cloud-based technologies are also spurring advances in the virtual trials movement.

Another important benefit of the cloud for clinical trial technologies is the increasing need for data security, particularly in light of the new European General Data Protection Regulation (GDPR) as well as HIPAA and other requirements.

The emergence of workflow automation in clinical trial applications, enabling automated study tracking and removing the need for manually prepared status reports and check-lists is another key trend. Automated workflows can help to direct study teams through various requirements, provide role management, as well as alerts for upcoming tasks.

AI and robotic process automation are also seen as opportunities to improve clinical trial productivity, and at the same time derive insights from the large volume of data generated from clinical trials, electronic health records, claims, and other sources.

Beyond the Site

The end of the blockbuster model and the growing emphasis on personalized medicine will affect the clinical trial model. There are expectations that rather than requiring participants to go to a specific site location, the study will be brought to the participant at times and places convenient to the patient.

Solutions have been developed to enable participation beyond the site. An example is Apple's ResearchKit platform, which was designed to make it easier to enroll patients and conduct studies. It allows information to be gathered daily, providing researchers with more frequent data, and patients don't have to attend study sites to complete tasks or fill out questionnaires.

Telemedicine solutions, such as Science 37's NORA platform, are enabling trials to be conducted without the need for a central trial site. Using mobile devices and telemedicine services, the platform enables clinical trial participation from home. In March 2018, the company signed an agreement with Novartis to support development of decentralized clinical trial offerings.

The use of smartphone apps and other mobile resources can enable better engagement with patients, such as reminding them to take their meds, recording health data, and responding to questions in real time.

Power to the Patient

As digital technologies evolve and the emphasis on patient-centric trials continues to grow, it will be important for companies to ensure they focus on patient trust. Some technologies have the potential to improve the patient journey, including embedded blockchain to improve safety and traceability, and gamification both for patient engagement and health literacy.

Biopharma companies are taking new steps to enable patient-centricity with clinical trials. For example, Genentech has a five-year agreement with PatientsLikeMe for a number of initiatives, including providing access to PatientsLikeMe's clinical trial awareness tool, which allows patients to learn about clinical trials. The company has also adopted a patient-centric approach to recruitment and enrollment, where patients are recruited through their physicians' and local networks' digital platforms, and, if interested, the approval process is handled by their local healthcare system rather than the traditional site-first approach.

Some companies are also seeking patient feedback on trial design. One large pharma company set up a meeting with an experienced patient advocate and clinical development staff on the clinical trial protocol for a study into a targeted medicine in pediatric patients with a chronic myeloid leukemia (CML) with resistance or intolerance to other medicines. The advocate was sent the trial synopsis two weeks before the meeting and their notes were returned to trial staff two days before the meeting and then discussed. The input received led

to significant modifications in the trial protocol without delay to the development process.

Digital technologies have the potential to transform the entire clinical trial process — through automation, improved data storage and sharing, and better engagement with patients. How it is implemented and used, along with processes adopted to adjust to new solutions, will be key.

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Stacey Arrambide
VP, Biometrics
Advanced Clinical

Going Virtual Via the Cloud
Cloud-based technologies are a critical catalyst in the virtual trials movement because it allows for real-time data entry, data review, and analysis. The enhanced ability to dynamically unify, manage, control, and report on data from various sources results in multiple time efficiencies, including reducing time to database lock and resolving queries leading to better quality and increased overall value. As cloud-based transactions are aggregated, this becomes another big data analytics prize to learn from.

Ami DeBoer
Director of Recruitment
Advanced Clinical

Call for Remote-Based Talent
From my perspective in strategic resourcing, the demand is growing for remote-based workers to help identify and draw in top talent. Because clinical study complexities are rising, companies are looking for clinical research professionals who have demonstrated experience and more strategic skills in protocol development, vendor management, CRO and/or vendor oversight, data review, and the ability to provide direction in study start-up activities.

Barinder Marhok
Associate VP, Head of Life Sciences R&D Practice, and Venture Partner
Cognizant

New Models for Trial Success
Cloud-based technologies are the foundation for new CRO and sponsor business models, from centralized/remote monitoring to virtual clinical trials, which are driving effectiveness, efficiencies, and cost savings. We expect additional models to emerge and gain support, as newer disease interventions such as gene therapy are challenging some of the concepts that have shaped clinical trial execution over the last several decades.

Digitally Enhanced Clinical Products
Digital clinical products and services are delivering greater speed and scale to drug development. Wearable technologies, the Internet of Things, big data analytics, and artificial intelligence give us real-world evidence of the patient journey, which guide us to design the right protocol, predict and locate the right clinical trial participants, and continually enhance the patient experience during development and postapproval.

Rick Morrison
President
Comprehend Systems Inc.

Enhanced Transparency and Efficiency
Sponsors and CROs both benefit from greater information transparency among teams, and a common space to investigate issues, speed resolutions, and collaborate across studies, portfolios, and roles.
In recent surveys, more than 70% of sponsors claimed issues that prevented successful data aggregation, while 84% still used manual data reporting methods. By eliminating lag and risk in data integration, reporting, and insights, cloud solutions enable stakeholders to focus on accelerating timelines and achieving successful study results.

The Future of Fact-Based Views of Performance
In the coming years, both sponsors and vendors need to be prepared in three key areas: collaborative methods to enable real-time, shared views of harmonized clinical data; risk-based approaches to assess and monitor trial status and issues; and adaptive methods to flexibly identify and manage course corrections during study conduct due to protocol, enrollment or resource changes, and other concerns. The way forward is capitalizing on technology to deliver fact-based views of status and performance.

Elisa Cascade
Chief Product Officer
DrugDev, an IQVIA company

Clinical-Trial Operational Technology
Simplicity, efficiency, and transparency are the key advantages to cloud-based clinical trial operations technology. Rather than emailing documents, tracking progress in spreadsheets, and uploading final copies to the eTMF, for example, clinical trial operations technology drives the workflow, sends alerts/notifications when action is needed, tracks status, and files completed documents in the eTMF. By automating the process, we decrease cycle time, increase quality, and ▶

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enable transparency for all stakeholders — sponsors, CROs, sites — at every step of the workflow.
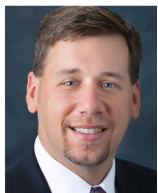
Brett Kleger
Chief Commercial Officer
DrugDev, an IQVIA company

Rapid Deployment

When clinical trial services work the way they should, trials are made easier. The rapid deployment of technology and sponsor/CRO service teams has helped simplify trials while providing valuable transparency and resources. Ultimately, this means that we have the potential to do more as an industry, at a quicker rate than before. But, it also means that we expect more of each other than ever before, raising the level of expectations for everyone involved.

Don Ragas
VP and Chief Technology Officer
ERT

To the Cloud

Cloud-based technologies help sponsors and CROs quickly and more easily integrate all clinical trial data points — both operational and clinical — to enable a multi-dimensional view at the patient-, site-, study-, and portfolio-level. Sponsors can better integrate legacy data stores with newer and emerging data sources to gain real-time insight into trial progress, so they can quickly adjust and prepare for what's coming next. Cloud technology also enhances sponsor and CRO collaborations so they can more effectively manage risk, which keeps development programs on track and on budget.

Real-Time Trial Management

Today's drug development processes are still heavily dependent on paper and manual data capture, but these bring inefficiencies and significant data quality problems. EDC solutions help mitigate some of these, but are not the ultimate endgame. As trials go fully digital, real-time management will enable sponsors to quickly identify and mitigate risks associated with patient enrollment and compliance, site and investigator performance, as well as adverse events and efficacy. This will enable sponsors to shut down sites and trials more quickly, if needed, to avoid unnecessary costs and delays.

Rose Kidd
Senior VP, Clinical Operations
ICON

Re-Imagining the Clinical Trial Process

I would say that clinical trial services are evolving and expanding to meet the demand of the changing drug development landscape. There is a hunger in the industry to drive change to improve R&D efficiency and although opinions may differ, pharma, biotech, and CROs are all involved in the conversation. Transforming the industry will mean transforming organizations, but the return on investment of time and resources will be more effective therapeutic products serving unmet patient needs. The clinical trial services needed for the future will require re-imagining of the entire clinical trial process using a combination of applied innovation and emerging technologies.

Taking a Holistic Approach to Transformation

A recent study by ICON-Pharma Intelligence shows that companies realize the need for a more holistic approach to achieve a data-driven organization and to navigate industry challenges — 62% of respondents have started or plan to start a holistic strategy to transform clinical trials. This will involve better collaboration both internally and between sites and sponsors. Internally, interdisciplinary collaboration will be a key element to success, in order to transform trials in a coordinated fashion. The associated needed skills will be strong strategic leadership to drive through challenges and lead in a dynamic industry. Change management, technical expertise, and data science and analysis will also be essential skills required.

Kevin Duffy
Global VP Life Science & Healthcare
KellyOCG

Addressing the Skills Shortage

It's important to note that the skills shortage is already adversely impacting life-sciences companies' ability to expand. Employers need to start fostering their human capital now in order to expand their capabilities as these trends further develop and mature. A growing number of companies are leveraging technology in biotech, biopharma, biomed, genetics, and molecular biology for everything from data analytics to manufacturing automation. On the operational side, they're undergoing digital transformation to become more streamlined and nimble while retaining the ability to take advantage of new technologies and expand their operations. As a result of this growing role of technology, tech companies are entering the industry either independently or as partners ▶

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to life-sciences companies. Employers will experience a growing need for R&D and clinical talent with high-level specialties such as biomechanics, molecular biology, and genetics. They'll also need talent with data management and analytics skills to process the growing amount of information, as well as specialized, multidisciplinary, and hybrid talent to develop new methods of patient care. To further exacerbate the situation, experts predict an average job growth of 10% in the U.S. life-sciences industry in the next 10 years. Scientists, computer occupations, and engineering occupations will experience the highest increase. The sectors that will experience the most growth will be medical equipment and supplies manufacturing, pharma and medicine manufacturing, and most importantly, R&D in biotechnology.

Nicola Goatman
Business Intelligence
Manager
Medical Research
Network

The Power of an Integrated Technology Approach

Emergence of new technologies and services such as eCOA, EDC, eSource, eConsent, EHR, telehealth, telemedicine, wearable devices, artificial intelligence, and home nursing will all fundamentally change the way clinical research is performed. eCOA, EDC, eSource, and eConsent present efficiencies in data integration. Telehealth, telemedicine, and wearable devices expand the type of data collected to incorporate remote, real-time, and patient-driven information. Home nursing changes the fundamental location of clinical research, no longer restricted to traditional research sites. Whilst all of these solutions have impact separately, the power comes in using the solutions together in an integrated approach and clearly defining when each solution has maximum benefit, not just one size fits all.

The Need for the Patient Voice

Involving patients in clinical trial design has many benefits. It adds a voice and perspective often missed when viewing a trial as simply from the physician's perspective. The science will be deeply affected by the FDA's deepening commitment to including patient experience outcomes in NDAs. Patient involvement in clinical research can span everything from focus areas for research, design of the trial, communicating results, and advising on additional support and care that would benefit the patient. However, it is still to be seen how deeply patients can impact the fundamental design of clinical trials and which parts should change — as opposed to can change — in order to benefit patients in the long run considering the important factors of safety, efficacy, and cost associated with getting a new drug to market.

Anthony Costello
VP, Mobile Health
Medidata

Consolidating Tools

Medidata Rave EDC is broadly used throughout the life-sciences industry to capture and

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Contact Kathy Deiuliis at kathy@pharmavoice.com

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manage research data. The rest of the products and services on the Medidata Clinical Cloud enables CROs and sponsors to consolidate vendors and features they previously outsourced in multiple directions, and move to a single, unified platform. Using multiple point solution providers creates a lot of integration points for data, a lot of confusion at sites, a lot of risk to data quality, and a lot of extra cost for most projects. For these reasons, we see a lot of our customers really evaluating the Rave and Edge family of tools and services to complement what they are already doing with Rave EDC.

The BYOD Movement
In the last couple of years, we've seen a serious bring-your-own-device (BYOD) movement in the eCOA market finally starting to take hold early in protocol design, we've seen eConsent starting to scale globally among big pharma and CROs, and partial hybrid to fully virtual trials are being piloted in the United States and Europe. All of these methods create more eSource-driven and accurate clinical data for researchers, and are significantly more convenient for patients than traditional methods.

James Streeter
VP, Life Sciences
Product Strategy
Oracle Health Sciences

New Levels of Collaboration
Aside from the traditional advantages of cloud technologies such as lowered hardware and software costs, other advantages include new levels of collaboration across departments, increased data transparency, innovative applications, and dramatically reduced

study setup and execution times. These benefits alone have the ability to drive growth for CROs and sponsors.

Technology-Focused Skills
New skills for sponsor and clinical trial service provider personnel should focus on technology as this is changing the way clinical trials are run. Clinical trials will require skills to manage data more efficiently and effectively using advanced business analytics and business intelligence in addition to skills in machine learning and AI.

Karim Damji
Senior VP, Product
Management and
Marketing
Saama Technologies

Changing the Game
Cloud-based clinical trial technologies are empowering CROs and sponsors to achieve significant efficiencies in site identification timelines and reduction in non-enrolling site costs. Furthermore, the flexibility of cloud-based platforms, in terms of algorithms, speeds up time-to-market by almost five times compared with standard platforms. Cloud-based solutions will produce game-changing results, allowing trial teams to focus on research and analysis versus data wrangling, opening up new possibilities for managing data in the life-sciences industry.

Natural Language Understanding
Natural Language Understanding (NLU) is opening doors in the life-sciences industry that, until recently, were bolted shut. The application of AI to NLU engines is creating a revolutionary paradigm shift for drug development, catapulting the traditional user experience (UX) on

an impersonalized dashboard to a conversational experience (CX) involving personalized analytics. This paradigm shift is transforming the conduct, speed and outcomes of clinical trials, shaving years and costs off the launch of new drugs.

Cheryl Murphy
Senior VP, Clinical
Development
Synteract

Driving the Evolution
Changes in drug development are actually driving the evolution in clinical trial services. For example, in oncology trials, patient assessments associated with personalized medicine drive the need for immediacy of data so patient specific investigational products can be developed. This necessitates complex logistics management services of samples for DNA testing. Another change is concierge services to support the needs of patients for transportation and housing so we don't lose a valuable subject due to lack of proximity to an investigative site.

Partnership and Transparency
The need to work in parallel to share and understand data-driven insights derived from clinical trials is increasingly important given the need to make faster go, no-go decisions. Working jointly instead of in silos, with the requisite communication skills continues to be critical to success. With GDPR legislation going into effect in May 2018, partnership and transparency across sponsors and CROs is of paramount importance. With pediatric development plans a requirement for all new medicines, an understanding of this vulnerable patient population will be a must. PV

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