Redefining the Clinical Trial SOLUTION LANDSCAPE

As the pharmaceutical industry has moved toward increased outsourcing of clinical trial processes, innovative clinical trial solutions are helping to redefine the landscape. Such solutions are playing an integral part in helping to reduce the time and cost involved in conducting clinical trials by accelerating data collection and analysis.

Clinical trial solutions bring together technology, product, and services to automate and better manage the clinical trial process. In addition to helping to reduce time and cost, clinical trial solutions are also vital for improving data management and in integrating data from different trials for clearer analysis.

Clinical trial solutions typically include electronic data capture (EDC) solutions, clinical trial management systems (CTMS), electronic patient reported outcome (ePRO) solutions, electronic clinical outcome assessment (eCOA), electronic trial master files, randomization and trial supply management systems (RTMS), interactive voice response systems (IVRS), and interactive response technology (IRT).

Segmentation of the clinical trial solutions market is based on type, component (software, service, etc.), mode of delivery (point solutions, licensed on-premise solutions, and cloud or as-a-service platforms), and end-user, reports note.

Clinical Trial Solution Stakeholders

- Healthcare IT service providers
- eClinical solution vendors
- Clinical research organizations
- Pharmaceutical/biopharmaceutical companies
- Research and development (R&D) companies
- Business research and consulting service providers
- Medical research laboratories
- Academic medical centers/universities/hospitals

Source: Marketsandmarkets

The pharmaceutical industry is the largest end-user of clinical trial solutions, followed by clinical research organizations (CROs), but increasingly hospitals and other healthcare providers are requiring some type of clinical trial solution.

From a regional perspective, the four key markets are North America, Europe, Asia-Pacific, and the rest of the world (ROW).

Market Growth

The eClinical solutions market over the forecast period of 2017 to 2022 is expected to grow to $7.61 billion by 2022, a CAGR of 12.4%, during the forecast period.

North America was the largest regional segment in the global eClinical solutions market in 2016, followed by Europe. The Asia-Pacific market is expected to grow at the highest CAGR from 2017 to 2022. A number of factors, including increasing government funding to support clinical trials, presence of less stringent regulatory guidelines compared to developed nations, availability of a large patient base and faster patient recruitment for clinical trials, and growing number of pharmaceutical companies and CROs are stimulating the growth of the eClinical solutions market in the Asia-Pacific region.

Demand for solutions has grown thanks to advances in technology, the geographic spread of clinical trials, and the benefits solutions offer: cost reduction, greater accuracy and efficiency, and enhanced compliance.

New growth opportunities are also propelled by the increased use of CROs and greater access to cost-effective solutions. At the same time, analysts warn that the clinical trials solutions market is hampered by the high cost of implementation, a shortage of skilled research professionals, and a lack of awareness among the research community.

To further bolster the market, global and local providers are developing partnerships and collaborations, M&As, geographic expansion into new markets, as well as new product developments and product enhancements.

GLOBAL INDUSTRY ANALYSTS PREDICT THAT THE MARKET FOR ECLINICAL SOLUTIONS WILL REACH $7.61 BILLION BY 2022, A CAGR OF 12.4%.

In terms of market dynamics, growth is being driven by the demand for more clinical trials to validate safety and efficacy of products, an increasing number of post-marketing clinical trials, and moves to replace paper-based processes with electronic data collection in order to automate data processing.

There are, however, constraints on the clinical trial solutions market, led by a scarcity of skilled professionals to operate advanced CTMS solutions, as well as budget constraints faced by pharmaceutical and biotech companies as well as many smaller CROs. Talent shortage, however, is driving increased demand for skills both internally and externally.

While there are an extensive range of clinical trial solutions, they can largely be segmented in high-level categories of management solutions, patient data solutions, and trial preparation and supply solutions. The details below explore these three categories in greater depth.

Clinical Trial Solutions by Segment

CTMS

CTMS solutions are designed to define and manage all of the activities involved in the clinical trial process. The solution helps to manage planning, performance, and reporting, and ensuring the milestones and deadlines are met.

CTMS solutions are used by pharmaceutical companies, clinical research centers, and

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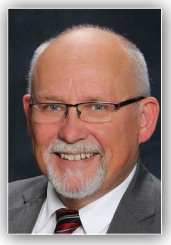

ROBERT CARLSON, M.D.
VP, Medical Affairs, ACM Global Laboratories

THE POSITIVE IMPACT OF DIGITAL PATHOLOGY

When it comes to incorporating computer image analysis into a pathologist's diagnostic tool set, digital pathology offers many advantages to clinical trials testing. Because the images produced are digital, critical areas of the slides themselves can be documented within the diagnostic report and included as part of the data set to provide important additional information.

DIGITAL PATHOLOGY BENEFITING PATIENTS

In addition to being able to directly incorporate critical images into a study dataset and providing access to an extended network of skilled pathologists, digital pathology facilitates more efficient collaboration and consensus development. This collaboration is achieved by enabling specialists and scientists involved in the study to quickly share images and consult with one another on difficult cases.

DONNA HANSON
Manager of Proposal Development, Advanced Clinical

PATIENT-CENTRICITY AND TRIAL DESIGN

We are finally seeing patient-centricity at the heart of decision-making around clinical trial design and execution. As a result, new solutions and technologies, including wearables, virtual visits, remote lab collection, are growing in utilization. Anything that can make the clinical trial experience the least invasive and most comfortable for patients and caregivers is prioritized — this is paramount when working in rare disease, paediatrics, and other critically ill indications.

JULIE ROSS
President, Advanced Clinical

THE CRITICAL SPONSOR/CRO PARTNERSHIP

Building a win-win partnership starts with trust, which requires time and effort up front. The strongest partnerships are created when a comfortable environment is established early on. Sponsors and CROs not only need to track performance and deliverables as usual, they need to create an open working environment — one that is rooted in trust and vulnerability because true success is measured beyond contract deliverables

PAUL BISHOP
CEO, Atlantic Research Group

COLLABORATION IN RARE DISEASE

Rare disease trials are often a journey of discovery that requires innovative thinking and extraordinary support for inexperienced investigators. As a result, success in rare disease is largely determined by a group of partners — e.g., sponsors, investigators, and CROs — each expert in their respective disciplines. Therefore, it is crucial that they work collaboratively to ask the right questions that anticipate unique problems and generate appropriate solutions.

COMBINE PATIENT-CENTRICITY WITH CRA-CENTRICITY

Although patient-centricity is critical in trial design and execution, often left out of discussions during contract negotiations with CROs are the institutional and cultural aspects that cause high CRA turnover, which can negatively impact a trial's success. As the study's face to investigators, CRAs who are empowered by CRA-centric policies that motivates them to think and act as partners, ensure continuity in trials by keeping every site and patient enrolled.

WENDY FIANDER
Director, Clinical Operations, Axiom Real-Time Metrics

REAL-TIME TECHNOLOGY

Unified eClinical platforms such as Axiom Fusion have greatly enabled a stronger collaboration between the sponsor and the CRO, among other parties. Real-time technology and related reporting tools have made conversations around study issues easier to dive into and solve. We see that faster,

even hospitals, all of which require better methods for managing the data generated.

The global clinical trial management system market is valued at an estimated $534 million in 2016, and is projected to grow at a CAGR of 11.5% during the forecast period of 2016 to 2021. Factors such as increasing R&D expenditure of life-science and clinical research industries, rising number of clinical trials, and increasing adoption of CTMS solutions are driving the growth of the global market. On the other hand, factors such as lack of skilled professionals to operate advanced CTMS solutions and budget constraints of small- and medium-sized pharmaceutical and biotechnology companies and small CROs are restraining the growth of the global market. Other important factors bolstering the CTMS market include, competition to be first to market, government-based clinical studies, and generally increased outsourcing of clinical trial activities.

The hospital market is another key driver for CTMS demand, a report from Persistence Market Research finds, specifically as the rise in chronic diseases results in demand for better data management, documentation, and access to hospital data across medical organizations. More healthcare providers and rising patient demands place further pressure on the need for CTMS-type capabilities.

New product launches, partnerships, and agreements are strategies adopted by CTMS developers to further strengthen their position.

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earlier discussions are leading to solutions about study elements, and operational enhancements are coming to the surface from better real-time information.

ANDREW SCHACHTER
CEO and Founder, Axiom Real-Time Metrics

THE EVOLVING IMPACT OF PATIENT-CENTRICITY

The movement toward enabling the subject to be directly involved in various data streams such as diary and health-tracking information continues to evolve. For example, direct health activity data such as Fitbit information is a growing source of adjunct study information driven directly by subject participation. As technology sources get better and easier, we expect to see far more diverse data options provided directly from subjects through various mobile and other technologies.

SCOTT GRAY
CEO, Clincierge

COMMUNICATION KEY TO PARTNERSHIP

Effective communication is at the heart of all successful collaborations. It's important that both sides clearly understand from an early point the objectives of a particular trial and details of what will be involved, as well as obstacles encountered in the past that could be potential stumbling blocks to good trial performance. It also helps to know up front what criteria will be used to measure success and to provide frequent feedback on performance.

PATIENT-CENTRIC TRIALS

We are seeing an enormous increase in sponsors and CROs considering patient-centricity when designing trials. They are increasingly reaching out to unique service providers to help improve the patient experience and respond to specific family needs, and in doing so, improve trial performance overall. Patient-centric services have enabled improvements in recruitment and retention, as well as increased trial diversity, and even helped to rescue trials when sites unexpectedly shut down.

HUGO STEPHENSON, M.D.
Executive Chairman and Principal Investigator, DrugDev

ECONSENT HELPS WITH COMPLEXITY

New initiatives and technologies are moving the clinical landscape more and more toward patient convenience, which is great. As an investigator, I see eConsent as a great example of technology that is helping patients. Patients often have difficulty understanding the consent forms or certain aspects of the trial. When completing the consent process electronically the text is narrated, trouble spots are identified, and videos and graphics illustrate complex concepts and processes. eConsent helps patients understand what they are committing to and the protocol.

ELISA CASCADE
President, Data Solutions, DrugDev

LANGUAGE CONSISTENCY

To improve the efficiency of clinical trials, sponsors and CROs need to speak the same language both with the technology they use and the terminology they share. As sponsors and CROs rely on multiple technology providers, care must be taken to select partners that can integrate easily across multiple solutions. While no one expects everyone to use the same system, both the sponsor and CRO must select technologies that can "speak to each other." Furthermore, establishing common terminology and standards is a crucial step to speed up data management and decision-making.

BRION REGAN
Product Manager, ERT

OVERSIGHT AND INTEGRATION

Sponsors and CROs are working toward common objectives, but the processes and tools driving studies can at times appear to be working against one another. By leveraging solutions that promote oversight and integrate with operational systems, sponsors and CROs can foster better collaboration, spend less time on tactical issues, and focus on consistent quality metrics that enable them to quickly identify if they are meeting their shared objectives of

EDCs and ePROs/eCOAs

The main purpose of an EDC system is to store patient data that is collected during clinical trials. The purpose of ePROs/eCOAs is to replace paper diary data with patient data that are captured electronically directly from patients. An eCOA solution measures the patient symptoms and overall state of health and ePROs detect future adverse conditions of patients in advance.

Crucially, such solutions have helped to substantially reduce transcription errors. Both EDC and ePRO solutions ensure that data is provided within the appropriate range as defined in the study protocol. This helps to save time in data transcription and query.

Given the global nature of clinical trials, one of the biggest benefits to EDC and ePROs/eCOAs is that data can be shared and viewed anywhere in real time.

A survey of more than 160 industry professionals by ISR found that while paper CRFs are preferred by a small number of users, EDCs and ePROs/eCOAs have become the preferred tools to capture, review, and present data gathered during the course of a clinical trial. In fact, EDC preference has grown from 77% in 2013 to 91% in 2015.

Site use of EDC systems is growing, and on average sites are using 3.4 EDC systems and are expected to be using 4.5 systems within the next year or two.

In addition, the number of preferred pro-

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improving operational efficiency, ensuring patient safety, and monitoring regulatory compliance.

GAVIN BIRCHNALL
Senior Product Manager, ERT

DIGITIZATION IMPROVES TRIAL DESIGN

The patient-centricity movement is bringing new factors for consideration during clinical trial design. Although the core design will always focus on primary study objectives, the ability to digitize communications enables remote touch points to be integrated into trial design. This means patients can complete many trial actions such as assessments, questionnaires, and medical device readings from home, reducing the burden of participation and integrating activities into their everyday lives.

DR. PHIL BIRCH
VP, Strategic Alliance Management, ICON

SITE COLLABORATION KEY

Effective collaborations between sponsor companies and CROs drive productive relationships, which in turn deliver clinical programs more efficiently. Improvements can be made in two key areas: early engagement and stronger collaboration with sites. Early engagement refers to the pooling of sponsor/CRO expertise to optimize study protocols. The second area refers to developing three-way partnership with sites to help reduce site burden and deliver stronger relationships with investigators and site staff.

MAKING TRIALS EASY FOR PATIENTS

Identifying the right patient to enroll in a trial has become a major challenge. Increasing patient awareness and the desire to participate are key success criteria. Two factors that can help are involving patients to assess if protocols can be operationalized particularly with reference to patient/care burden and considering if the study design should be decentralized to reduce the number of conventional site visits and make participation easier for patients.

KEVIN DUFFY
Global VP, Global Solutions, Life Science & Healthcare, KellyOCG

CLINICAL TALENT NEEDED FOR FUTURE SUCCESS

Digitization is having a profound effect on talent acquisition in the clinical drug development sector. A growing number of companies are leveraging technology in biotech, biopharma, biomed, genetics, and molecular biology. On the operational side, they're undergoing digital transformation to become more streamlined while taking advantage of new technologies and expanding operations. As a result, tech companies are entering the industry either independently or as partners 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 talent to develop new methods of patient care.

MHEALTH SOLUTIONS

To effectively accommodate the changing needs and expectations of individuals enrolling in trials, life-sciences companies are developing mHealth (mobile health) solutions that provide patients constant access to their healthcare providers. Thanks to the ability to record and analyze patients' data remotely — wearable diagnostics — there's also a growing focus on precision medicine.

SIMON GRIFFIN
CEO, Lifelines Neurodiagnostic Systems

CLOUD-BASED EEG

Interactive, cloud-based EEG with video recordings are cutting-edge in the field of neurodiagnostics. With live-streaming of encrypted, secure EEG and video data to the cloud, patients can be monitored 24/7, from anywhere in the world, in real time by experts. This oversight provides assistance in fixing electrode and other technical problems and elevates recording quality. These solutions result in significantly improved, standardized recordings, and they eliminate screen failures due to technical EEG issues.

vider agreements in place at CROs and with sponsors is increasing.

Integration of systems between EDC and ePRO/eCOA is becoming a priority with users going forward. Increasingly, pharmaceutical sponsors and contract research organizations are looking for greater control over the systems used rather than relying simply going through their CROs for the EDC component, with the ISR report finding that the percentage of sponsors looking to contract directly with an EDC provider is expected to increase from 43% to 52%. The growth in use of these clinical trial solutions is being driven by greater ease of use, improved data accuracy, and the ability to access data instantly making it possible to make quick clinical decisions and improve compliance with protocol requirements.

RTMS

A $750 million to $1 billion industry, RTMS has become another key clinical trial solution, and is used to dispense treatment to sites and assign medication more rapidly and efficiently. Randomization is a crucial part of clinical trials, ensuring treatment balance and removing the risk of selection bias.

RTMS can have multiple purposes including managing randomization and allocation of therapy, automated resupply of products to sites and depots, centralized patient recruitment, managing the expiry date of products, and drug reconciliation. Through RTMS ca-

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CALL FOR NEURODIAGNOSTIC EXPERTS

Engaging specialist suppliers early when developing study protocol can provide significant support for CROs and sponsors. For example, EEG is a complex procedure, and recording standards vary greatly around the world. Neurodiagnostic experts can assist in study design and site selection, and can provide technical recommendations and considerations. Experienced EEG providers can also provide technical guidance and education to recording sites, reducing costly errors made when selected sites are not capable of producing quality data.

MIKE CAPONE
Chief Operating Officer, Medidata

UPTICK OF MACHINE LEARNING

The clinical development landscape is starting to see a surge in machine-learning technologies that take advantage of existing data pools to mine for new insight. Our industry has generated an enormous amount of study data to date, with the Medidata platform alone collecting more than 1 million data points per day. If managed and shared properly, that data offers a near-endless supply of patient data rich for discovery and clinical strategy.

SHIFT TO PERSONALIZED MEDICINE

Patient-centricity's biggest impact resides within the shift to personalized medicine; nothing represents patient-centricity more than finding the right therapies for the right patients. Genomic sequencing and mobile health technologies — those that capture objective and continuous data previously inaccessible to researchers — are reshaping how we design clinical trials, and the industry must be prepared for the inundation of patient data that comes along with new tools targeted at individualized treatments.

TODD MEYERS
VP, Business Development, Medpace

THE ETHICS AND REGULATIONS OF TECHNOLOGY

Cutting-edge technologies are impacting the clinical landscape in ethical and regulatory considerations. Ethical concerns with non-therapeutic use of these technologies could potentially steer the future of clinical trials. With rapid technology advances, regulators will need to stay up to date on new therapies, and pathways to market will need to be flexible and allow timely patient access. Current regulations may need to drastically change to keep up with the advances we're seeing every day.

PATIENT INPUT AS EARLY AS POSSIBLE

Patient-centricity affects all parts of a clinical trial. By placing patients at the center of study planning and throughout the lifespan of the program, it encourages them to be engaged in the study. This results in greater satisfaction and a more successful outcome for study delivery. With clinical programs and new translational therapies it is now seen as very important to have patient input as early as possible to ensure protocol success and patient participation.

RONALD WAIFE
President, Waife & Associates

VENDOR OVERSIGHT

The critical challenge for research sponsors, in light of regulatory pressures and after decades of outsourcing, is to improve their oversight of their vendors. Years of outsourcing have led to a serious decline in operational expertise within sponsors, yet both sponsors and CROs need the benefits of informed, well-trained supervision. A second issue is that the success of outsourcing is tied entirely to the skills of the individual CRO project manager, not to the CRO brand name. How can sponsors build a long-term relationship with such inherent variability?

REDISCOVERING PURPOSE

I don't think patient-centricity is a movement, in the sense of novelty, but rather a re-discovery of our purpose as clinical researchers. The jargon is not the cause of protocols being more patient-friendly, but rather the effect, and the extent to which that effect is happening, we would hope to see wider use of technology close to the patient — eCOA, mobile collection — and greater respect for the role of investigative sites' relationships with patients.

pabilities, enabled by IRT, CROs and sponsors are able to manage randomization and management of the clinical trial supply chain, oversee real-time recruitment, tackle issues around emergency unblinding, and ensure dosage accuracy.

The RTMS market dates back to the mid-90s when simple solutions became available — typically making use of IVRS, and by the 2000s more advanced solutions became available.

Today and going into the future, RTMS solutions are tapping into mobile capabilities. Data that are collected remotely, such as apps to support tracking of clinical trial supplies or eLabels to assess patient compliance, can be fed back into an RTMS solution to provide greater control of the clinical trial supply chain.

RTMS solutions continue to adapt to changing clinical trial needs with the goal of enabling faster and simpler trial design, implementation, and management.

Solution Overview

The market and range of clinical trial solutions continue to grow and adapt to changing needs and capabilities, including mobile technologies and cloud deployment. The continued pressure to bring products to market faster and to reduce the cost of clinical trials, while improving recruitment and data collection, will drive greater uptake of advanced clinical trial solutions. PV

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