

Transforming Clinical Trials: A Decade of Change and a Future of Innovation

Clinical trials play a pivotal role in advancing medical research and improving patient care. They are essential for new drug development, which is why they are constantly evolving.

In recent years, technological advancements, regulatory shifts and a growing focus on the needs and experiences of patients have been the main driving forces behind the significant changes in clinical trials. The Covid-19 pandemic has also significantly accelerated these trends, demonstrating the remarkable potential for rapid market deployment. While these changes have reshaped the conduct, regulation, and perception of clinical trials, the industry must remain aware of the possibilities and leverage the lessons learned to build on the successes achieved during the Covid-19 pandemic.

These changes have set the stage for potential significant advancements in the future. But first, let's take a closer look at the current shifts shaping clinical trials today before diving into predictions for what lies ahead.

Current Trends in Clinical Trials

One of the most prominent recent developments in clinical trials is the increasing use of real-world evidence (RWE). RWE uses data from various sources, such as electronic health records, insurance claims and wearable devices. For example, data from wearable devices can provide continuous health monitoring, offering valuable insights into how patients respond to treatments in their daily lives. This method allows researchers to gather data beyond traditional clinical trial settings, providing a more comprehensive view of a treatment's effectiveness and safety, with the additional advantages of optimising approval timelines and maximising cost efficiencies.

The pandemic has also driven the adoption of remote and decentralised clinical trials, known as virtual, at-home or site-less trials. These make use of telemedicine and home-based monitoring. Patients can participate from the comfort of their homes, eliminating the need to travel to specific sites. This approach has shown increased patient participation and study effectiveness, ultimately speeding up the time it takes to bring new drugs to market.

In addition, there is a growing emphasis on making clinical trials more patient-centric. Regulatory agencies and sponsors now actively involve patients in the trial design process to align research with their needs and preferences. This enhances the relevance of trials and improves patient recruitment and retention rates.

Regulatory Updates Around the World

Countries around the world are adapting their clinical trial regulations to the evolving landscape. In India, the Ministry of Health and Family Welfare updated the New Drugs and Clinical Trials Rules back in 2019. These updated rules set new time limits for responses to clinical trial applications, making the regulatory process simpler and more efficient.

More recently, in the United States, the FDA released a draft guidance in June 2023 titled "E6(R3) Good Clinical Practice (GCP)". This guidance encourages innovation and quality in clinical trials and supports the use of digital health technologies like wearable sensors to improve the efficiency of data collection.

Meanwhile, the European Union implemented the Clinical Trials Regulation in early 2023. This new regulation simplifies approval processes, harmonises trial designs and establishes a single portal for trial submissions across member states. These changes aim to reduce administrative burdens and increase the competitiveness of EU clinical research.

The United Kingdom has also introduced new measures. In October 2023, the Medicines and Healthcare products Regulatory Agency announced a more streamlined and flexible framework for clinical trial approvals. This new framework supports diverse trial designs, including decentralised trials, and aims to speed up approvals without compromising safety.

These regulatory changes across different regions reflect a global effort to make clinical trials more efficient and patient-focused. Going forward, we can expect regulatory agencies to collaborate with the pharmaceutical industry even more closely and adopt more flexible approaches.

This will improve the clinical trial landscape and enable faster responses to emerging health crises. For example, during a sudden outbreak of a new disease, regulatory bodies might expedite the trial approval process for promising treatments. This will allow faster deployment of critical medications while maintaining safety standards.

What the Future Holds

As the landscape of clinical trials continues to evolve, several key trends, driven by technological advancements, will shape the industry in the coming years.

One major trend is the integration of advanced data analytics. Artificial intelligence (AI) and machine learning is already being used to transform data analysis in clinical trials, however future developments in this technology will advance this even further. Predictive modelling, data mining and real-time monitoring is enabling more efficient trial designs, better patient selection and early identification of safety concerns.

For example, AI has the potential to analyse patient data to predict which individuals are most likely to benefit from a specific treatment. This can make trials more precise. It can also reduce costs and speed up the time to market for new drugs.

Transport/Logistics Outlook

The trend of decentralised and remote trials will expand and make trial participation more convenient for patients. The cold chain logistics industry plays a crucial role in this expansion by safely transporting temperature-sensitive medications to patients. This maintains the integrity and efficacy of treatments during virtual



trials. With the support of reliable logistics, virtual check-ins with healthcare providers and clear regulations, more people will be able to join these trials, leading to better overall outcomes.

At the same time, clinical trials will adapt to consider individual genetic profiles and treatment responses. This shift is driven by advances in genomics and biomarker discovery, which are paving the way for targeted therapies. We will see the rise of innovative trial designs and methodologies that meet the unique needs of personalised medicine. For instance, a clinical trial for a cancer treatment might stratify participants based on their genetic mutations and test the new therapy on the most relevant patient groups. Similarly, single patient samples and specimens will increasingly be transported for clinical trials, highlighting the critical role of effective, safe and rapid cold chain logistics.

A New Era for Clinical Trials

The world of clinical trials is hardly recognisable from what it was a decade ago. There is now a strong focus on real-world evidence, patient-centric approaches and streamlined regulatory processes. These changes have made clinical trials more efficient, user-friendly and more globally connected. The future looks even more promising with advancements in data analytics, decentralised trials, global harmonisation and the rise of personalised medicine.

With this advancement comes increasing pressure on the cold chain industry to respond to the demand for safe, secure and swift transport of medicines and clinical samples. For example, as remote and decentralised trials become more common, there will be increased demand for innovative packaging solutions. Packaging suppliers will need to develop materials and containers that maintain the integrity and efficacy of medications during transport to patient homes and remote locations. This includes meeting stricter temperature requirements and regulations for new drugs and ensuring secure transportation systems.

This progress will result in safer and more effective treatments, reducing the time spent in the trial phase and significantly benefiting those in need. The evolution of clinical trials will not only impact pharmaceutical companies and patients but also drive innovation across the supply chain, including packaging and logistics providers who will be continually challenged to handle increased volumes more rapidly and with reduced risk.

RESOURCES

1. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r3-good-clinical-practice-gcp>
2. <https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/clinical-trials-human-medicines/clinical-trials-regulation>
3. https://ijper.org/sites/default/files/IndJPhaEdRes_53_4s_451_0.pdf
4. <https://www.europeanpharmaceuticalreview.com/news/187569/mhra-regulation-overhaul-new-scheme-for-lowest-risk-uk-clinical-trials/>

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