

Impact of Startups on Transforming Clinical Research Practices

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In the dynamic landscape of healthcare, where clinical trials represent the cornerstone of medical progress, startups have emerged as key drivers of change. The clinical trials market in India was estimated to be valued at \$2.07 billion in 2022, and it is expected to expand at a compound annual growth rate (CAGR) of 8.2 per cent from 2022 to 2030, reaching \$3.88 billion by 2030. This exponential growth not only reflects the country's evolving medical infrastructure but also underscores the pivotal role of innovative startups in redefining the healthcare landscape.

Despite India's status as Asia's fourth-largest medical equipment manufacturer and its 8 per cent share in the global medtech research and development workforce, the country accounts for only 1.5 per cent of the global medical devices market. In response to these challenges, startups have begun offering disruptive technologies and innovative approaches that revolutionise clinical trial practices, paving the way for a more inclusive and patient-centric research environment.

India: A Global Hub for Clinical Trials

India is poised to re-emerge as a global hub for clinical trials in years to come, underpinned by a confluence of compelling factors. With a diverse patient population, a wealth of experienced investigators, cost-efficient research infrastructure, and forward-thinking regulatory reforms, India offers a promising environment for conducting clinical research. Despite having upwards of 15 per cent of the most high-prevalence diseases globally, (e.g. cardiovascular diseases, diabetes, respiratory infections, cervical cancer) India contributes to a meagre 3 per cent of the overall global clinical trials.

Challenges in Clinical Trials

At the heart of successful clinical trial programmes lies the imperative to achieve patient enrolment within budget, uphold data quality standards, and adhere to stringent timelines. Yet, these goals have become increasingly elusive in the face of mounting complexities and evolving regulatory requirements. The pressure to expedite therapy development and commercialisation underscores the urgent need for strategies and technologies that streamline the process while ensuring

patient safety and determination of unequivocal efficacy of the new medicine/device/vaccine/diagnostic.

Patient-Centric Innovations

Central to the success of clinical trials is the participation of patients, whose engagement and involvement are crucial for the timely completion of studies and the validation of therapeutic interventions. However, traditional recruitment methods often fall short in attracting diverse patient populations, particularly those from underserved communities or geographically remote areas. The concentration of trial sites in urban centres exacerbates this challenge, as patients from peripheral regions face barriers like travel distance, transportation costs, arranging for a caregiver to travel and/or stay with them and other logistical constraints.

Startups are slowly emerging as champions of patient-centricity, pioneering decentralised trial solutions that transcend geographic boundaries and empower patients to participate in research. Direct-to-patient shipment of investigational products, remote monitoring through wearable devices, and virtual consultations with healthcare providers are just a few examples of the innovative approaches that startups have accelerated to enhance patient access and engagement in clinical trials.

Democratising Access to Clinical Research

Startups have been instrumental in democratising access to clinical research by leveraging digital health technologies to reach populations traditionally excluded from traditional trial sites. By harnessing the power of telemedicine, mobile health apps, and electronic informed consent platforms, startups are breaking down barriers to entry and expanding the pool of eligible participants, thereby ensuring greater diversity and representation in clinical trials.

Regulatory Support and Collaboration

However, startups' success hinges on a supportive regulatory environment that fosters innovation and facilitates rapid novel technology deployment. Regulatory bodies play a critical role in ensuring patient safety and data integrity while fostering an environment conducive to innovation and experimentation.

Collaboration between startups, industry stakeholders, and regulatory agencies is essential for addressing emerging technology's unique challenges and opportunities. By fostering a culture of collaboration and knowledge sharing, regulatory bodies can help startups navigate the complex regulatory landscape and accelerate the development and adoption of innovative solutions that transform clinical research practices.

Tech Advancements and Data Management

Startups prioritise patient-centricity, embrace and leverage decentralised trial methodologies, breaking down barriers to participation and democratising access to clinical research. One area where startups have demonstrated remarkable prowess is in leveraging artificial intelligence (AI) and machine learning (ML) to streamline various aspects of clinical trials. From optimising patient recruitment through predictive analytics to automating data collection and analysis, AI/ML solutions offer unprecedented opportunities to enhance efficiency, reduce costs, and improve data quality. By harnessing the power of these cutting-edge technologies, startups are at the forefront of transforming the clinical trial landscape, enabling faster and more accurate decision-making while minimising human error and bias.

Furthermore, startups are pioneering innovative approaches to data management and security, addressing the critical challenges of ensuring patient privacy and data integrity in an increasingly digitised research environment. By employing advanced encryption techniques, blockchain technologies, and secure cloud-based platforms, startups are paving the way for robust and compliant data management solutions that instill confidence in stakeholders and facilitate seamless collaboration across diverse research networks.

Cultural Shift and Patient Engagement

The impact of startups in the clinical trial space extends beyond technological innovations. These agile organisations are also challenging conventional wisdom and fostering a culture of continuous learning and improvement. Through their willingness to embrace unconventional methodologies, startups are driving a mindset shift within the industry, encouraging stakeholders to question long-held assumptions and embrace novel approaches that prioritise patient needs and accelerate the pace of scientific discovery.

Moreover, startups are actively engaging with patient advocacy groups and community organisations, fostering a collaborative ecosystem that empowers patients and amplifies their voices in the research process. By involving patients as active participants rather than mere subjects, startups are reshaping the clinical trial landscape, ensuring that research efforts are aligned with the needs and preferences of those they ultimately serve.

As the healthcare industry continues to evolve, the role of startups in transforming clinical research practices will become increasingly pivotal due to their agility, innovative mindset, and unwavering commitment to patient-centricity. These disruptive forces are poised to catalyse a paradigm shift that will redefine the boundaries of what is possible in the realm of clinical trials, ultimately paving the way for more efficient, inclusive, and impactful medical breakthroughs.

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