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Why India Is Most Preferred Clinical Trials Destination

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The ongoing reforms in the clinical trial regulatory landscape, the large patient pool, the clinical research technology and talent pools make India an attractive destination for clinical trials.

According to a February 2022 report by Research and Markets, the clinical trials market in India was estimated to be valued at $2.07 billion in 2022. It is expected to expand at a CAGR of 8.2 per cent from 2022 to 2030 and reach $3.88 billion by 2030.

The recent estimates from the United Nations Department of Economic and Social Affairs (UN DESA) indicate that India, with a population of 1.4 billion, has surpassed China to become the most populous nation in the world. Given the diverse geographical, environmental, cultural, and socio-economic variations across different states, India possesses a large population base characterised by diverse physical attributes and disease profiles.

Although the overall participation rate in clinical trials for the Indian population is around 3 per cent, it is worth noting that India bears 15 per cent of the global burden of the most highly prevalent diseases (e.g., respiratory infections, cardiovascular diseases, diabetes, cervical cancer, etc.). This observation underscores the immense potential for recruiting a sizable number of participants for clinical trials in the country.

Clinical trial footprint in India

Over the last decade, the clinical research and the pharmaceutical industry have proactively partnered and developed elective courses in clinical trial streams (such as Clinical Data Management, Pharmacovigilance, Regulatory Affairs, Medical Writing, etc.) as part of pharmacy curriculum or independent certification programmes to minimise the divide between industry and academic knowledge. This collaborative effort aims to foster a consistent pool of skilled professionals for the clinical trial industry in India.

Additionally, The Indian Society for Clinical Research (ISCR), founded in 2005, is a not-for-profit association of companies involved in the conduct of clinical trials with a focus on creating awareness about clinical research as a specialty in India, supporting the highest standards of quality and ethics in clinical trials. To drive this, ISCR conducts a variety of training, learning workshops, and programmes at the level of hospital sites and academic institutions to enhance capacity and competency building for sustaining high-quality clinical research in India.

The clinical trial industry is not limited to just the recruitment of patients at hospitals or clinics. Furthermore, it involves several specialised essential activities that are performed by multi-disciplinary experts during the trial planning, patient recruitment, and trial completion phases. These activities require in-depth knowledge of various guidelines, systems, and processes in specific functional domain areas such as Clinical Data Analytics, Medical Writing, Pharmacovigilance, Clinical Operations, Regulatory Submissions, Quality Assurance, etc. Completing these mandatory activities is critical to ensuring compliance with ethical and regulatory norms and facilitating marketing approval for a new drug.

Meanwhile, due to the large volume of clinical, physiological, behavioural, molecular and genomic data generated from clinical trials, several sophisticated technology systems and platforms are required to perform these tests and swiftly process the massive amount of complex data generated at scale and speed. These activities are performed by clinical research organisations (CROs) or IT-enabled service provider companies with consulting and business process services (BPS) capabilities in this specialised arena.

Technology companies with platform and services capabilities hold a sweet spot in the industry as they bring innovative technology solutions to the table, such as wearables, sensors, radio-frequency identification, remote monitoring systems, Generative artificial intelligence (AI), and Business Processes as a Service (BPaaS) models, to facilitate decentralised and home-based trials which grew intensely following the disruption caused by the COVID-19.

India accounted for around 8.3 per cent share of the global clinical trial activity in 2021, and almost a dozen top global pharmaceutical companies have built their Global Capability Centers (GCC) in India to perform the data processing activities at a high speed and a reasonable cost. Due to the growth of the clinical trial industry in India, many prestigious industry bodies, such as Clinical Data Interchange Standards Consortium (CDISC), PHUSE (The Global Healthcare Data Science Community), and Society for Clinical Data Management (SCDM), now hold events and conferences in India on a regular basis to engage with the Indian clinical trial workforce.

Enhancing the Clinical trial ecosystem in India

In order to provide early access to safe and effective medicines to the Indian population, the Government of India is working on strengthening the clinical trial and health regulations ecosystem and has issued various guidelines to provide clarity and impetus to the clinical trial industry.

The government amended the “New Drugs and Clinical Trials Rules, 2019” to include provisions for the registration of Ethics Committees and CROs. The National Ethics Committee Registry for Biomedical and Health Research (NECRBHR) has been set up to monitor the ethics committee activities and bring transparency & accountability in biomedical & health research.

The Central Drugs Standard Control Organisation (CDSCO) published the updated Medical Devices Amendment Rules in

March 2023 to ascertain the safety and effectiveness of medical devices before they are available in the market.

The National Medical Device Policy (2023) encourages innovation in the development of medical devices by using novel applications of nanotechnology, precision medicine, the Internet of Things (IoTs), and Artificial Intelligence.

In 2016, the government notified electronic Health Data standards for implementation by healthcare institutions to harness insights from the health data of Indian patients, which is valuable for the clinical trial industry for trial planning and execution.

The “New Digital Personal Data Protection Bill 2023” which is expected to be tabled in the Parliament in July 2023, will further provide a clear framework for processing of personal protected data of Indian people.

In addition to the above-mentioned steps, the government has done tremendous work in streamlining the clinical trial regulations through various initiatives, such as the launch of the Sugam Portal for online clinical trial applications, the clinical trial registry of India, and publishing of the National Guidelines for Gene Therapy Product (GTP) Development and Clinical Trials.

These initiatives have aided the execution of clinical trials leveraging the latest healthcare interventions in participants from India. One recent example of these initiatives is the Department of Biotechnology (DBT)-supported first CAR-T cell therapy trial initiated in 2021 at the Advanced Centre for Treatment Research and Education (ACTREC), Tata Memorial Hospital, Mumbai.

Challenges and Opportunities in Store for India in Future

Despite these reforms and encouraging developments, there are still a few opportunities in store for further streamlining the clinical trial landscape in India.

There are different committees required at the institutional level to enable regulatory compliance, such as Institutional Bio-Safety Committee (IBSC), Institutional Animal Ethics Committee (IAEC), and Institutional Committee for Stem Cell Research (IC-SCR).

Further, the following bodies under the aegis of government of India are there for regulatory oversight and for the review of proposals for advanced therapies.

RCGM: Review Committee on Genetic Manipulation under DBT
GTAEC: Gene Therapy Advisory and Evaluation Committee
HMSC: Health Ministry’s Screening Committee under The Indian Council of Medical Research (ICMR)

It is critical to establish detailed processes with checks and balances and have full-time expert staff on these panels. These could potentially help to demystify and streamline the approval pathways for different classes of products with predictable and consistent outcomes.

Further, it is important for the trial participants to learn about and understand the results of the clinical trials conducted in the past in order to make informed choices. Establishing a potential framework for public disclosure of clinical trial results in simple, everyday terms that a layperson can understand could help create public awareness about clinical trials and allow the clinical research industry to access a larger pool of trial participants and achieve faster patient recruitment in trials.

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