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“There needs to be a shift in communication and transparency around clinical trials”

01 June 2022 | Interviews

While we saw a large number of COVID-19 clinical trials conducted in India during the pandemic, clinical trials in other therapeutic areas slowed down on account of the lockdowns and related restrictions. However, we are beginning to see the situation improve over recent months. Jinu Jose, Vice President, Head – Sales and Clinical Operations, R&D Solutions, IQVIA India shares more in this regard

What is India's current hold in the global clinical trial market?

India’s share of global clinical trials, according to clinicaltrials.gov, is around 1.15 per cent which is hugely disproportionate to the disease burden and patient populations that exist in the country. According to estimates from Indian Society for Clinical Research (ISCR) and research & markets.com, the clinical trial market in India is estimated to reach $3.125 billion by 2025.

We are, however, optimistic that the situation will improve as we come out of the pandemic, which presents its own challenges for clinical trials.

Leveraging its expertise and experience during the pandemic, India will continue to remain a key destination for clinical trials in infectious diseases along with other therapeutic areas such as oncology, metabolic diseases, gastroenterology, rheumatology, ophthalmology, and respiratory disorders. India will also continue to leverage existing capabilities and lead in clinical trials for biosimilars and complex generics.

The introduction of the New Drugs and Clinical Trials Rules in 2019 was a significant milestone in the regulatory structure and will encourage more global clinical studies to be conducted in India, thus improving access to treatment for patients.

Which are the leading players in the Indian clinical trial market?

Over 150+ organisations are estimated to be currently conducting clinical trials in India. These include multinational pharma companies, Indian pharma, CROs, academic and teaching institutions and not for profit organisations.

The top 10 Indian pharmaceutical companies spend close to 7-8 per cent of revenue on R&D, contributing to the volume of trials being done in India and overseas.

Large multinational life sciences companies are also setting up hubs in India for services like clinical data management, centralised monitoring, pharmacovigilance, clinical data analytics, project management and many other centralised functions to support global clinical trials infrastructure.

What are the upcoming trends for top therapy areas of clinical trials in India?

COVID-19 and Respiratory: The past two years have been dominated by COVID-19 related clinical trials, including vaccines and other therapies. The trend is likely to continue in 2022 with new trials for COVID-19 vaccine boosters, mixing of various COVID-19 vaccines, self-testing kits and immunity boosters. Fueled by the successful use of mRNA vaccines in COVID -19, RNA therapeutics are expected to make large strides. Vaccines for other infections like seasonal influenza vaccine, pneumococcal vaccines, Hepatitis, RSV vaccines are also likely to undergo clinical trials.

We also foresee a resurgence in respiratory tract infection and respiratory tract inflammation clinical trials this year. In the generic market, clinical equivalence studies for respiratory diseases like COPD and Asthma are likely to demand a big space with several inhaler drugs going off-patent in the coming years.

Oncology: The top indications for oncology clinical trials include breast, lung, ovary, and colorectal carcinomas. Immunotherapy, targeted therapies, and personalised medicine have the largest interest, and these have been used for many solid and hematological cancers, including pediatrics.

Changes in treatment modalities towards targeted anti-cancer drugs due to resistance, refractoriness and survival benefits is the need of the hour, and this has led to a steady rise in novel therapeutic approaches. Many different targeted therapies have been approved but are being further evaluated as mono- and combined therapies for cancer treatment.

Immuno-oncology clinical trials with PD-1 and PD-L1 inhibitors have increasing interest by investigators due to their select availability to patients and high costs.

We also expect an increase in trials using biomarkers to stratify patients, indicative of personalised cancer treatments in the future.

Early Clinical Development (ECD): There is increasing interest in early clinical development from industry, academia and regulatory bodies and there has been an increased focus on awareness, resources, training, infrastructure, developing SOPs, and qualification of sites for ECD.

Cell & Gene Therapy: Another emerging area of focus is personalised medicines, including cell and gene therapies. With various research institutions developing CAR-T cell technology platforms and regulators providing a clear framework for CAGT studies, this could be a potential niche area of growth that will also address unmet medical needs, especially in rare diseases.

How do you foresee the sync between regulatory bodies and implementation of virtual clinical trials in the coming years?

The past couple of years have provided an excellent opportunity to leverage digital infrastructure and facilitate various aspects of clinical trials, from remote regulatory reviews (online IRB and SEC meetings) and remote monitoring to patient follow-up and safety oversight, positively impacting trial timelines and quality.

During the pandemic, the clinical trial industry worked very closely with regulators on innovative trial designs, improvised pathways for approvals, and use of digital health platforms in various aspects of the clinical trial continuum. We hope that these will continue beyond the pandemic to sustain the momentum and fast track the clinical trial application review process.

While these were short term measures, we are confident that this opens many possibilities to further improve the overall clinical trials process and leverage technology and automation to bring drugs to markets faster, while reducing the overall cost of development.

Some of the specific areas in virtual trials that require focus from a regulatory perspective include – IMP (Investigational Medicinal Product) Management, patient consent, use of digital platforms, documentation, and access to data.

We also believe that there are significant opportunities for the industry to proactively partner with regulators to drive continued innovations and faster adoption of newer ways of working.

Which factors might affect the competitive nature of the clinical trials market in India?

The following areas are key to ensure that we continue to advance the clinical trial ecosystem in India and improve overall access to healthcare.

Regulatory Environment – A vibrant clinical trials environment can only be encouraged if the clinical trial regulations are simple, interpreted consistently, pathways/timelines are well understood and there is focus on continuous improvement of processes. The environment is certainly more positive, but rebuilding trust and confidence is a slow process. What has been extremely encouraging is the inclusive approach adopted by the Indian regulators and we are confident that the momentum will continue.

Talent Availability & Industry-Academia Collaboration – Conducting a clinical trial requires expertise across multiple domains, including, pharmacology, statistics, chemistry and microbiology. The industry and academia must work together to ensure that these gaps are bridged, and we improve our research acumen and availability of talent at the grass roots.

Augmenting clinical research capabilities and quality of trial data – The leadership role that is played by the institutions/investigators during the clinical trial is immense. It is important that we continue to evolve and augment clinical research capabilities at these institutions so that we have the highest quality of data from the clinical trials.

Awareness and perceptions – Clinical trials are a much-debated topic and awareness in the public is quite low. Often, public perceptions about clinical trials are influenced by media/ social media that may not be providing an objective and complete view. COVID-19 has put product development and clinical trials firmly in the public domain and we believe that this will contribute towards a generally more informed patient community. Overall, there needs to be a shift in communication and transparency around clinical trials. Better public education around clinical trials must be the starting point.

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