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RISING INDIAN CLINICAL TRIALS INDUSTRY AND CAREER OPPORTUNITIES

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ABSTRACT
The Indian clinical trials industry has seen stable growth over the past decades and especially since 2014 there has been a significant rise. With the current expected market growth rate, India has the potential to become one of the largest clinical trial hubs. The ministry of health had a very positive outlook towards the growth of the Indian clinical trial market; with the constant reformation of the regulatory guidance, the confidence of pharma companies to do trials in India is growing. The Covid-19 pandemic has caused mass public awareness about clinical trials and drug development process, this will increase acceptance and help to further promote the industry. This article provides an insight into the various drivers for the fast growth of the Indian clinical trials industry and at the same time discusses the numerous career opportunities the industry offers.

INTRODUCTION

It has been almost one and a half years since the COVID-19 hit the world and changed our lives in early 2020. Many practices that were previously considered to be the norm have been overturned; from remote-working, online schooling to accelerating digital transformation across different sectors. As the focus shifted to research and development of new drugs and vaccines to treat and prevent COVID-19, clinical trials received enormous attention. The pandemic had a huge impact on the way clinical trials are managed and conducted in the world including India. Usually, it takes around a decade for a certain drug to reach patients and the majority of this time (approximately 6-8 years) is spent in the clinical development process alone, but the pandemic has turned the marathon into a sprint. Having said we have already witnessed India's first fully indigenous COVID-19 vaccine got developed in less than a year [1].

India is one of the preferred destinations to conduct global clinical trials. According to GlobalData, India has accounted for

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an 8.3% share of the global clinical trials activity in 2020, registering an increase when compared with the last ten-year average of a 6.2% share. The trend is expected to continue and India's clinical trials market size is expected to reach USD 3.15 billion by 2025, it is projected to register a CAGR of 8.7% over the forecast period [2]. There are multiple advantages why conducting a clinical trial in India is preferable and on top of those now the urgent need for the development of COVID-19 cure will further boost that. As the clinical trial market is growing in India at the same time the job opportunities in this sector is also on the rise. The industry offers various job roles within the clinical trial lifecycle and provides a rewarding career.

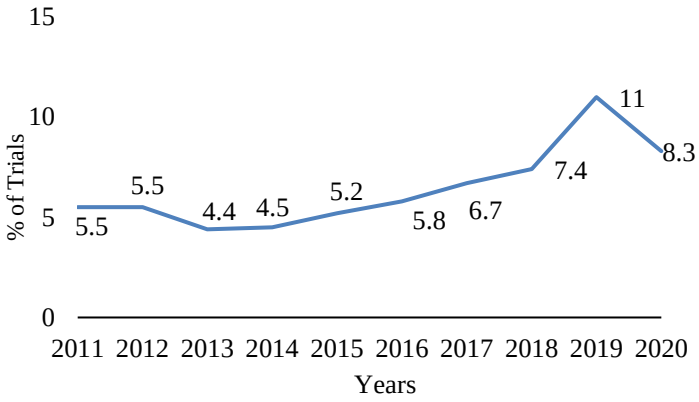

Figure 1: Clinical Trial in India: ten-year trend [2]

Advantages of Conducting Clinical Trials in India

India is an attractive destination to conduct global clinical trials because of several reasons. The major contributors have been discussed below:

1. Medical Infrastructure

Clinical trials are conducted in hospitals or medical institutes or any other clinical establishment having the required facilities to conduct a clinical trial. India has a total of 43,486 private hospitals with 1.18 million beds and 25,778 public hospitals with 713,986 beds [3]. Many of these hospitals that have the required equipment and infrastructure, can serve as ideal sites for multi-centered clinical trials.

Also in India, there are more than 1332 NABL (National Accreditation Board for Testing and Calibration Laboratories) accredited diagnostic laboratories which are helpful in the conduct of trials requiring standard local laboratory [4].

For any clinical trial to be conducted in any hospital/institute a clearance from the local/institutional ethics committee is mandatory. Currently, in India, there are 1236 ethics committees registered under CDSCO [5]. This makes the process of scientific and ethical review of study protocols at the clinical trial center very smooth.

2. Strong availability of patients across major disease areas

India accounts for 17.7% of the world's urban population. As per the technical group on population projections of the National Commission on Population (NCP), by 2036, India's population will be 1.52 billion, with a 70% increase in urban areas [6]. With lower government support and per capita spend on healthcare, participation in clinical trials is seen as an opportunity to avail of innovative therapies.

India has a large and diverse genetic pool of patients who need treatment and they are a potential population for clinical trials. The emergence of chronic diseases like cancer, diabetes, cardiovascular system (CVS), and central nervous system (CNS) disorders may drive demand for newer therapies. With the highest disease burden among all countries, India specifically offers a tremendous opportunity in contributing data for various disease areas.

3. Availability of skilled talent

India offers an abundant and growing pool of skilled, talented, and experienced medical professionals, and is the second-largest English speaking country in the world after the US. The country already has more than 12.5 lakh registered doctors and with over 12.8 lakh medical, paramedical, pharmaceutical, and life science graduates passed every year, India is surely the talent hub of the world [7, 8].

4. Favorable Regulatory Environment

Medicinal products globally are subject to stringent regulations to ensure quality, safety, and efficacy for consumers. Every country has its regulatory authority, which is responsible to enforce the rules and issue guidelines to regulate the pharmaceutical sector. Clinical trials in India are conducted in four phases with each phase beginning upon the successful completion of the previous phase. Permission from the CDSCO is required before beginning each phase of the clinical trial. Since 2013, India has undergone a significant regulatory transformation regarding clinical trials. Clinical trials are an important component of innovation and the government has been trying to streamline the norms and rules. The CDSCO-DCGI office is taking all necessary steps to promote clinical

research in the country via a transparent & faster approvals process.

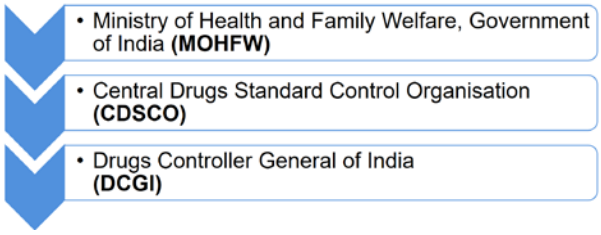

Figure 2: Indian regulatory authority-simplified organization chart [9]

During the pandemic, the DCGI showed immense flexibility and logical thinking to review the clinical trial proposals and often provided useful guidance on the planning and conduct of the trial. The trend of the number of new clinical trial approvals in the past 5 years is very encouraging and reflects the positive impact of the favorable regulatory environment. Even during the 1st year of the pandemic, between Mar 2020 till Mar 2021, 198 new clinical trials were approved by the DCGI [10].

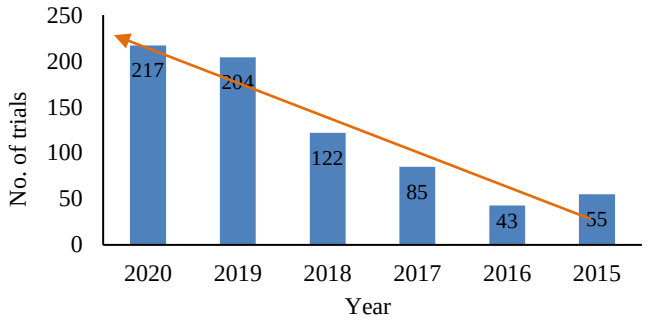

Figure 3: Trend of number of clinical trials being approved CDSCO in India in past 5 years [10]

5. Cost Competitiveness

The cost of conducting trials in India is lower by 50% to 75%, as compared to the United States or the European Union and it is possible to conduct both new drug discovery research and novel drug delivery system programs at competitive rates [11].

The clinical trial workforce contributes to around 30 to 35% of the overall trial cost. This makes manpower rates for clinical research a key parameter to consider. Equipment rental, IT and other operational costs are also very competitive in India [12].

6. Access to the fastest-growing clinical trial and pharmaceutical market in the world

India's economy shows signs of robust growth, and increased spending on healthcare needs is expected to drive revenue growth for pharma companies. The Indian pharma industry today is the third-largest market globally in terms of volume and 14th largest by value. According to reports by various market research organizations, the domestic pharma market is expected to grow at a CAGR of 11 to 12 percent annually to be a USD 120 – 130 billion market by 2030 [13].

With a 12 to 13 percent year-on-year growth, the Indian pharma industry is rapidly achieving a distinctive position in the global pharma space with contract research services and clinical trials. The industry is witnessing a paradigm shift as the focus is shifting from the manufacturing of generic drugs to drug discovery and development where many Indian pharma companies had applied for conducting clinical trials on numerous new drugs.

7. Advanced IT Support:

When it comes to the methods of delivery, India has a scalable IT infrastructure to facilitate new-age clinical research. Hybrid clinical trials that incorporate traditional methods with digital technologies like artificial intelligence and machine learning to provide real-time data on patient outcomes. This could streamline the development process and increase the speed with which drugs can be brought to market. With the increasing penetration of mobile and internet services, India is poised to lead the way in implementing tech-driven clinical trials. Remote-based, decentralized trials with patients participating in clinical trials from the comfort of his/her home would also be a big advantage in a country like India and in 2020, we have seen the regulators and the Ethics Committees agreeing with this approach. We are hopeful that this will continue in the future too.

Career Options and Opportunities in Clinical Research:

The clinical trial industry offers a great job opportunity across the globe for medical, paramedical, pharmaceutical, and life science graduates. Looking at it purely as a professional sector, it is creating more jobs, attracting more students for a future career. With the easing of regulatory guidelines, more international pharma companies and CROs are interested in India for their studies and research.

The entry-level positions, which are generally called the first level / first opportunity to enter the field of Clinical Research, have been listed below. The below list is inclusive but not an exhaustive list of all job roles/titles offered within the clinical trial industry.

1. Clinical Research Associate (CRA) is the most commonly available clinical research position. A CRA acts as a contact between the clinical trial sponsor and the clinical sites that are enrolling patients. The main responsibilities are clinical monitoring, overseeing the progress of the clinical trial at the site, and ensuring that it is being conducted appropriately. The daily focus is on protocol and regulatory compliance, data reliability, and the proper care, treatment, and safety of patients. Typical CRA roles are for on-site monitoring which involves a lot of traveling, however there also in-house CRA positions available who do risk-based remote monitoring.

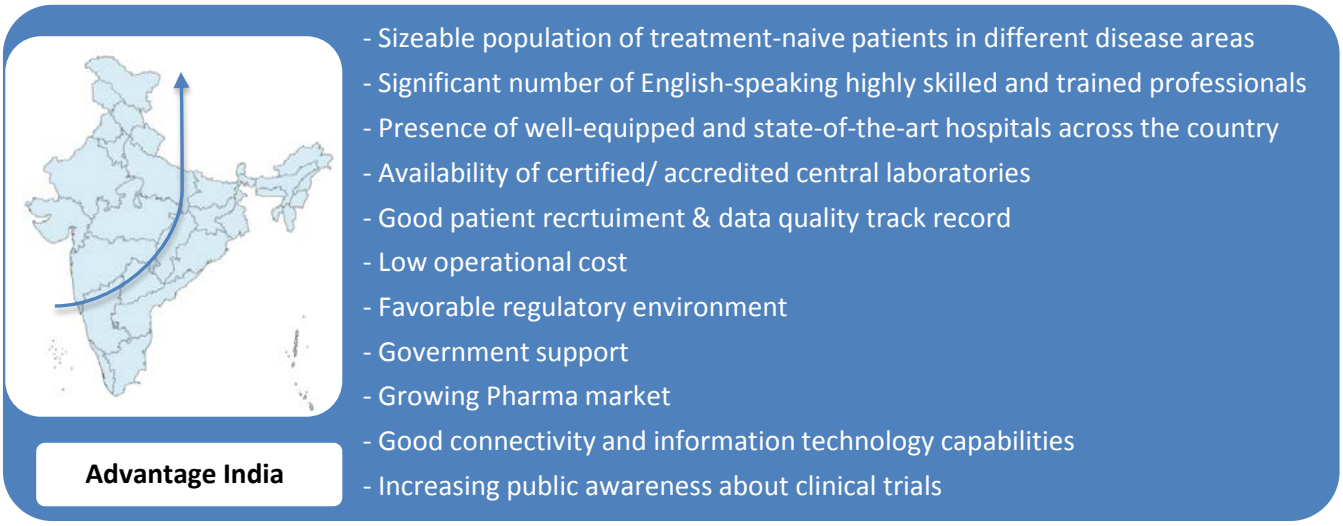

Figure 4: India's advantages as a destination for clinical trials

2. Clinical Research Coordinator (CRC) works under the direction of a principal investigator (PI) at a clinical site to coordinate and facilitate the daily clinical research activities, including screening and recruiting patients, collecting and recording data, and maintaining study documentation.

3. Clinical Trial Assistant (CTA) primarily manages the administrative aspects of a clinical trial at every stage of the process and closely with CRAs, as well as Clinical Project Managers. A CTA will be responsible for maintaining the complete documentation for the study as per the requirements, tracking many aspects of trial management, including vendor oversight, patient enrollment, regulatory documentation, and oversight of the trial master file (TMF).

4. Regulatory Affairs (RA) Associate is responsible for compiling, submitting, and maintaining documents to the national or international regulatory authorities as per the requirements.

5. Clinical Data Manager (CDM) is the architect of systems that captures the clinical trial data. They work along with the database developers/programmers and SAS programmers to design the data entry system as per the study protocol requirements. Once a trial is ongoing, the group reviews incoming data and maintains its database, ensuring that everyone is following the rules, then hands off the data to the biostatisticians for review.

6. Biostatistician is involved in every step of clinical research including trial design, protocol development, data management, monitoring, data analysis, and clinical trial reporting. When the trial data is available the biostatistician performed the statistical analysis to find out if the treatment effect is statistically significant or not. Preparing summaries and reports is another role of a biostatistician.

7. Clinical Quality Assurance (CQA) Associate/Auditors inspect all documents and processes for a study to ensure that they all comply with good clinical practice (GCP) guidelines, regulatory requirements and standard operating procedures (SOPs).

8. Drug Safety Associate (DSA) is responsible for monitoring, coding, organizing, and tracking adverse events that occur during a trial. Also, the DSA prepares the safety reports/periodic updates as required by the regulatory authorities.

9. The Medical/Scientific Writers can write various documents or sections in a document based upon the need of the role. It can be the clinical trial protocol, safety report, final study report, clinical overview, literature summaries, or publications of the trial data.

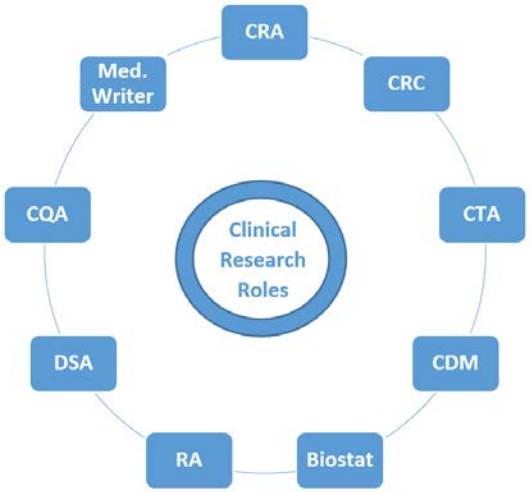

Figure 5: Different entry-level clinical research career options

These job roles are offered by various companies in India like:

1. Contract Research Organizations (CRO): Global CROs like Labcorp Drug Development (previously Covance), ICON, IQVIA, Paraxel, PPD, PRA, Syneos etc. have a very strong presence in India. They offer various services to the sponsor institute/pharma companies. Regional CROs have an equally strong presence, due to their local expertise. Key regional players like Syngene, Lambda, Navitas, Veeda, Siro Clinpharm, Accutest CRO have a good market share and have partnered with big pharma companies in their conduct of clinical trials.

2. Pharmaceutical companies: Almost all major pharma companies are doing clinical trials in India. Just to mention a few like AstraZeneca, Eli Lilly, GSK, J&J, Novartis, Novo Nordisk, Pfizer, Sanofi Aventis, DRL, Nicholas Piramal, Biocon, Cipla, Lupin etc.

3. Outsourcing organizations: Some of the top IT Companies having a presence in the health care and clinical domains are Accenture, Cognizant, Infosys, Wipro, and TCS.

4. Hospitals: Many private and government hospitals have their clinical research department and they do a lot of investigator initiates trials and also trials sponsored by pharma companies.

Figure 6: Multiple sectors offering clinical research jobs

5 Practical Pieces of Advice for the Entry-Level Candidates: While the behaviors and skills expected for an entry-level position in clinical research are similar to those that would be expected of any professional candidate. However, due to the high importance of patient safety, ever-changing regulatory environment and complexity of operations, one must be a fast learner, adaptable, flexible and a good communicator. For those who have not had any formal training in clinical research, here are 5 insights that would have been helpful at the beginning of our careers.

1. Be passionate about making a difference in the patient's lives. Clinical research saving peoples' lives or improving their quality of life. Learn about the different roles available within the field of clinical research and see what role excites you the most.

2. As a minimum become familiar with the good clinical practice (GCP) guidelines. ICH-GCP guidelines are considered the 'bible' of clinical trials and followed globally to safeguard the rights, safety and wellbeing of the clinical trial patients. Also keep learning about the drug discovery and development process, other clinical research regulations and guidelines. There are plenty of free resources available online.

3. Invest in additional learning if you feel a need for that to fill the knowledge/skill gap. Formal training in clinical research is not mandatory but it can provide an advantage. One can consider doing a certification from a credible and prestigious training institute. This adds a few extra points to your CV.

4. Look for internship opportunities in different pharma companies/CROs/hospitals for a clinical trial-related role. This is a great way to gain practical experience.

5. Write a good resume, apply for relevant positions and prepare well for your interview.

CONCLUSION

Over the last two decades, India has established its place in the global clinical trial market. It started with India being an economically attractive destination to conduct trials but the constant regulatory reformations, increasing disease burden in the country, growing pharma market, and India's capability to deliver high-quality trial data put India into a more strategic advantage position. India's highly skilled talent pool also attracted a lot of companies to open their global offices in India.

The current COVID-19 pandemic has further accelerated the growth in India, because of India's capabilities to quickly adapt to the newer technologies and support by the government. It's expected the Indian clinical trial industry to have more investments from top pharma companies and we will also witness unique collaborative approaches between companies. This accelerated growth will continue in 2021 and beyond and this will create further job opportunities for students. Finally, the pandemic has caused wide-scale awareness amongst the general public about the importance of clinical trials to prove the safety and efficacy of drugs and vaccines. With this India now has all strategic and enabling pillars to rise to new heights.

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Nil

CONFLICT OF INTEREST

The author declare no conflict of interest.

AUTHOR CONTRIBUTION

Arghya Biswas conceived the presented idea, performed the literature review, collected the data, created data visualizations and prepared the manuscript including any corrections/revisions.

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