Clinical Trial Opportunities in India

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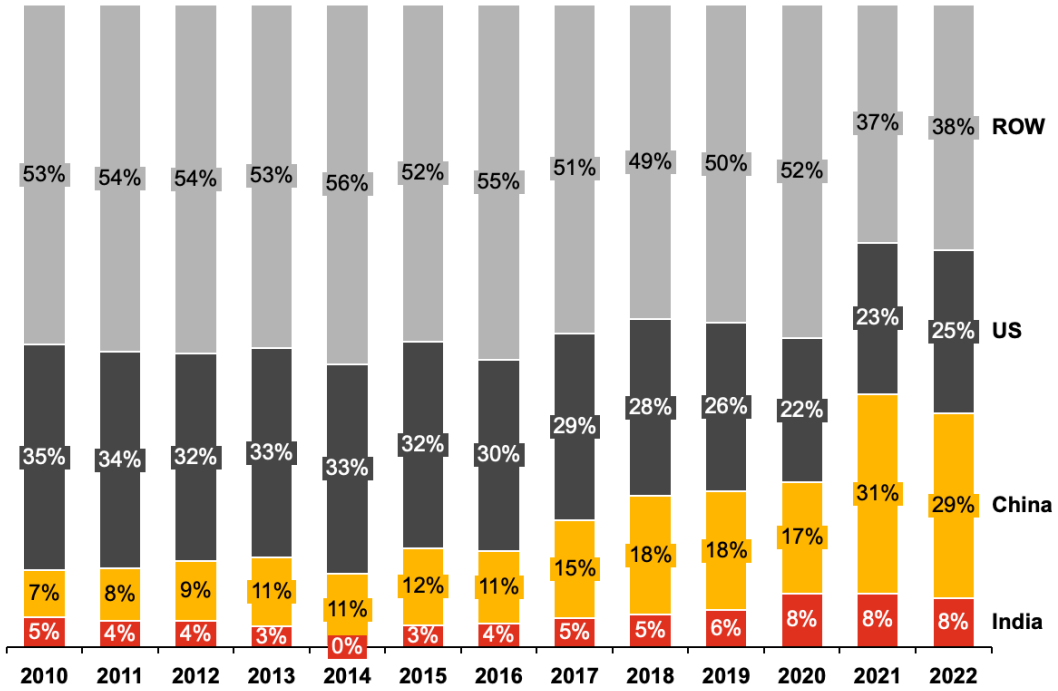
Despite India's position as the most populous country, the global clinical trial participation has been significantly low as compared to other countries

Key takeaway: While India's contribution to the global clinical trials has been ~4% in the last decade, top 20 pharma activity has increased by 10% since 2013

Trial Initiations, Top 20 Pharma Sponsored Trials
(India, China, US; 2010-2022)



1. Contribution to the global clinical trials

4% Despite of its large population, India's contribution to the global clinical trials has averaged at ~4% per year from 2010 to 2022

10% Top 20 pharma sponsored trials in India has increased by 10% since 2013 following multiple regulatory reforms

2. Trial participation

3% Of all the trial participants globally, India's contribution is only 3% as compared to 30% in the US

3. Industry sponsored trials

Top 5 Amongst the top 20 pharma, AstraZeneca, Novartis, Eli Lilly, Pfizer, and J&J are the top sponsors of clinical trials in India

Source: PwC Analyses, TrialTrove, December 2022; FDA Global Clinical Trial Participation

There are a number of historical perceptions about conducting trials in India; the current climate may present more opportunity

	Myths	Reality
01	**Long delays** in approvals to conduct clinical trials and manufacturing of drugs	Regulatory reforms post 2013 and the seminal **New Drugs and Clinical Trial Rules of 2019** have streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials
02	**Lack of disease-specific trial policies**, relaxations, provisions, or incentives	Several **relaxations and exemptions to conduct clinical trials for diseases that target life-threatening conditions**, including exemptions from phase III and phase IV trials
03	**Targeting tier-2 and tier-3 cities** as sites for clinical trials can result in higher access to patients and investigators	**Disease prevalence, density of investigators, and number of patients accessing healthcare is significantly higher in tier-1 cities**. In addition, majority of public and private sector tertiary care hospitals are located in tier-1 cities.
04	**Partnerships with private sector is not productive** as they lack access to patients and predominantly follow a commercial model, not focused on research and innovation	Hospitals in the **private healthcare sector represent 60% of all the hospitals in India**. Located primarily in the tier-1 cities, private hospitals provide 87% of all services, 80% of all doctors, higher bed capacity, advanced infrastructure, and access to patients
05	**Lack of awareness amongst patients and training of investigators** and ethical committee members	The overall **awareness and training of investigators and ethical committee members for clinical trials is growing**, led primarily by several initiatives from the government. Also, COVID-19 served as an inflection point to increase awareness on the significance of clinical trials in India

Source: PwC Analyses; Dubey et al., IJPER 2019; Vaidyanathan Nature 2019; Bassi et al., Lancet Glob Health 2022

Enablers of Innovation: Prioritizing heterogeneity in trials, mitigation of rising geopolitical risk, and shared value creation ecosystem

Prioritizing heterogeneity in clinical trial patient population can help bridge the trial diversity gap created due to trials with primarily Caucasian study participants

Key Takeaway: Among new molecular entities and biologics approved in 2020, only 11% of participants were Hispanic, 8% were Black, and only 6% were Asian. Targeting India as the trial destination can enable top biopharma to conduct studies with diverse and representative clinical trial population

Trial recruitment challenges given **current geopolitical environment**: sponsors can consider India

Key Takeaway: A significant number of Phase I–III clinical trials sponsored by big pharma with sites in Russia and Ukraine are still not recruiting participants. India is a potential site for reallocation of trials as the country has high prevalence in the top disease areas where trial recruitment is halted

Shared value creation through collaboration with private sector hospitals and government research institutes

Key Takeaway: In addition to the regulatory reforms, India is setting up various collaborative centers for research and development across diseases of high burden. Collaborating with these centers can enable faster access to sites and patients for the top biopharma for diseases with high unmet need

Source: PwC Analyses; Press search

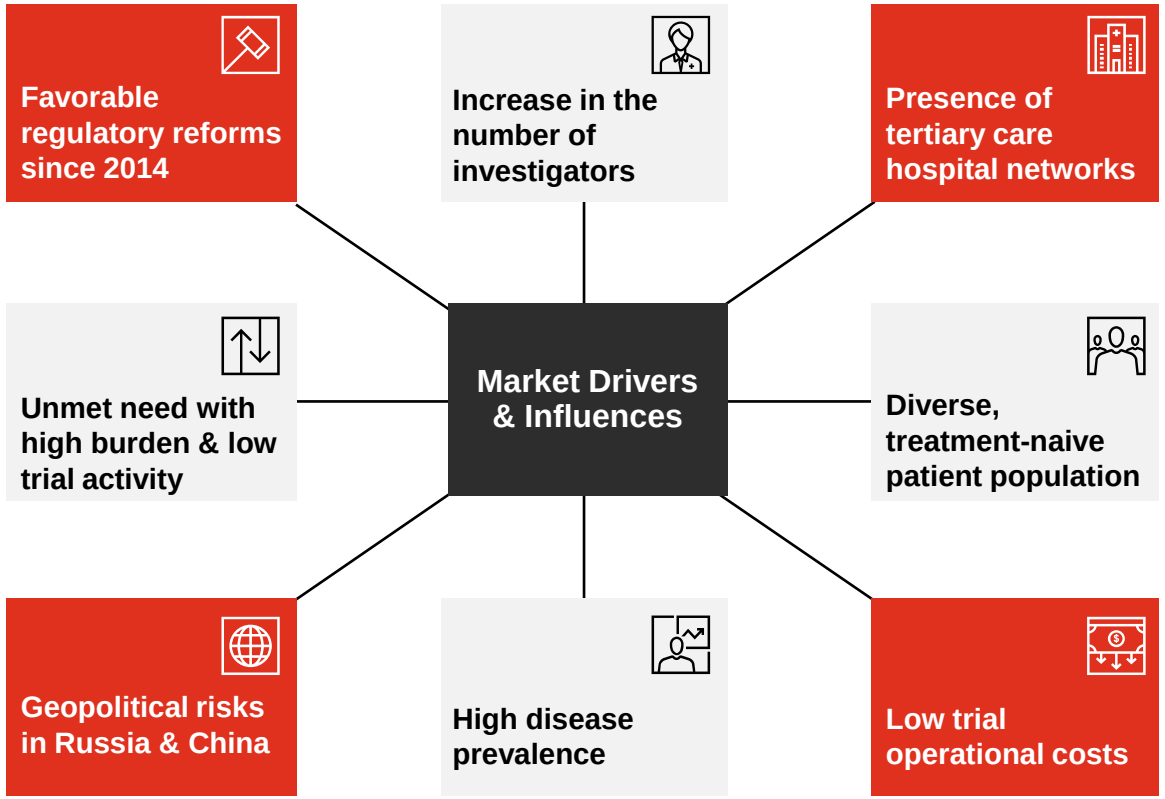
Infrastructure and Access

	Infrastructure and Access	Key Takeaway
01	Medical **infrastructure in tier-1 cities** in India is highly amenable to conducting clinical trials across different therapy areas	Top biopharma should align their strategy towards tier-1 cities (e.g., Mumbai, Delhi, Bengaluru, Chennai) where the higher bed capacity, number of doctors, and presence of tertiary care multi-city hospitals can support enablement efforts of running faster and more efficient clinical trials
02	**Higher disease prevalence and low clinical trial activity** represents an untapped potential for conducting trials in India	India has an overall clinical trial participation of ~3% but contributes upwards of 15% to the global burden of most high prevalent diseases (e.g., respiratory infections, cardiovascular, diabetes, cervical cancer), representing an untapped potential for top pharma
03	**Large untapped patient population** across the top therapy areas represents a growth opportunity for the top 20 pharma	While the top 20 pharma activity for the major therapy classes in India has remained largely constant in the last decade, growth opportunities exist across several key diseases (e.g., pain, epilepsy, cervical cancer)
04	**Availability of investigators has doubled** between 2015 and 2020, supporting growth in trial activity across diverse therapy areas	Total number of investigators has increased by 2x between 2015 and 2020, with majority of the increase occurring in the internal medicine and oncology specializations. However, the growth in the number of investigators is largely restricted to tier-1 and 2 cities
05	Disease prevalence by region aligns with locations with emerging clinical trial infrastructure, suggesting a **potential approach to target tier-1 cities for conducting clinical trials**	Indian states with high disease prevalence (e.g., cancer) also have the most number of tier-1 cities, with advanced medical infrastructure and availability of investigators. Targeting these states can provide biopharma companies with faster access to patients, sites, and investigators

Source: PwC Analyses; Dubey et al., IJPER 2019; Vaidyanathan Nature 2019; Bassi et al., Lancet Glob Health 2022

Through several key drivers, India is emerging as a favorable destination to conduct clinical trials; however, there are several challenges that need to be overcome

Enablers exists to drive the growth in clinical trial activity…



- Identified as a key driver of clinical trial activity

…but biopharma need to overcome few challenges to realize greater potential

Lack of trained healthcare personnel, trial investigators, and advanced trial sites

Complex and time-consuming regulatory processes to initiate and conduct trials

Low awareness of clinical trials and the regulatory reforms that impacts the access to the patients and sites

Streamlining the strategy to target tier-1 and tier-2 cities to access advanced tertiary care hospitals and investigators

Top biopharma can develop a long-term portfolio strategy targeting Indian sites and participants

01 Portfolio-based strategy

- Target therapy areas with high prevalence in India (e.g., diabetes, CVD, oncology) and low recruitment rates in the U.S.
- Develop an innovation strategy for the country by leveraging the vast pool of treatment-naive patient population for first-line therapies

02 Adopting a regional approach focused on tier-1 cities

- Realign the strategy towards tier-1 cities with advanced, tertiary care hospitals and higher availability of sites, investigators, and patients for non-communicable diseases

03 Build a network of partners

- Capitalize on the improving infrastructure of bed capacity, rise in tertiary multi-city network of hospitals in the public (e.g., AIIMS) as well as private sector (e.g., Apollo Hospitals)
- Invest in forming a therapeutic area-based network of partnerships and collaborations with public and private sector hospitals, research institutes, and advocacy organizations

04 Pursue “niche busters”

- Access India’s large disease patient pool and enabling ecosystem strengthened by the establishment of public and private sector CoEs for trials
- Derive economic advantage from recent regulations to fast-track application, waiver of application fees, and exemption of specific drugs from price controls

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