

Clinical Trial Opportunities in India

February 2023



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01

Executive Summary

Overview of global clinical trial challenges and myths and reality of conducting trials in India



Overview

Introduction

Despite a large population, clinical trial activity in India has been historically low. However, the current climate may represent opportunities to mitigate the mounting challenges of conducting global clinical trials

- Current Industry perspectives around clinical trials: The COVID-19 pandemic has pushed industry players to adapt and address traditional trial challenges
- Despite India's position as the second most populous country, the global clinical trial participation has been significantly low as compared to other countries
- There are a number of historical perceptions about conducting trials in India; the current climate may present more opportunity

Enablers of Innovation

Key enablers of innovation, population dynamics, and rising investment, can unlock new opportunities for top pharma and CROs to conduct trials in India

- Prioritizing heterogeneity in clinical trial patient population can help bridge the trial diversity gap seen historically
- Trial recruitment challenges given current geopolitical environment: sponsors can consider India
- Shared value creation through collaboration with private sector hospitals and government research institutes

Clinical Trial Activity

Clinical trial activity has been increasing steadily since 2014 due to several key regulatory reforms

- Clinical trial activity was historically low until 2014 due to non-favorable regulations; since 2014 India witnessed a reversal of historical decline
- Regulatory reforms since 2014 have been aimed towards global harmonization, enabling open access to clinical trials in India
- Top biopharma can leverage the conducive ecosystem of industry, academia, and government partnerships in India to overcome the existing challenges

Infrastructure & Access

Realigning the clinical trial strategy towards tier-1 cities

- Large untapped patient population across the top therapy areas represents a growth opportunity for the top 20 pharma
- Disease prevalence by region aligns with locations with emerging clinical trial infrastructure, suggesting a potential approach to target tier-1 cities for trials

Emerging Private Sector Growth

Leveraging complementarities in partnerships to overcome the existing gaps

- Biopharma can benefit from the critical enablers of innovation in the private healthcare system in India and leverage the rapidly expanding healthcare infrastructure
- Several examples of successful partnerships with private sector demonstrate the availability of advanced trial infrastructure and clinical expertise

Current Industry Perspectives around Clinical Trials: The COVID-19 Pandemic has pushed industry players to adapt and address traditional trial challenges

Historical clinical trial challenges...

Timelines are increasing, driven by recruitment challenges

6.8 months

increase in mean clinical phase timelines between 2010-2020 while approval time ↓ 1.9 months



48% of clinical

trial sites fail to meet enrollment goals and fail to engage diverse patient populations.



87% of patients

are interested in participating, however > **70% of patients live 2+ hours from a site** deterring patients from enrolling

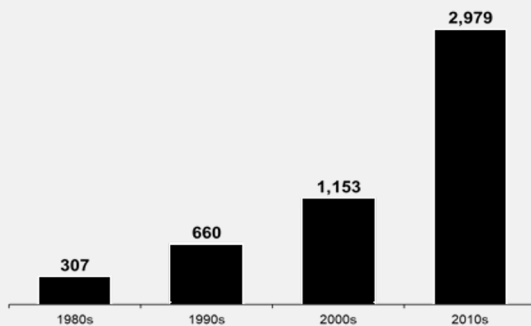


Racial and ethnic

minorities makeup **40%** of the U.S. population, but only **20%** of clinical trial participants

Costs of developing drugs is increasing rapidly, specially for orphan drugs

FDA Orphan Drug Designation by Decade



Cost of Developing Orphan Drugs

	2010	2019	CAGR
Average cost to develop an orphan drug	\$290M	\$504M	6%
Median cost per patient enrolled in orphan drug trial	\$26,000	\$93,000	15%

Source: PwC Analyses; Miller et al., Orphanet J Rare Dis 2021; Evaluate Pharma Orphan Drug Report 2020

What's being done...

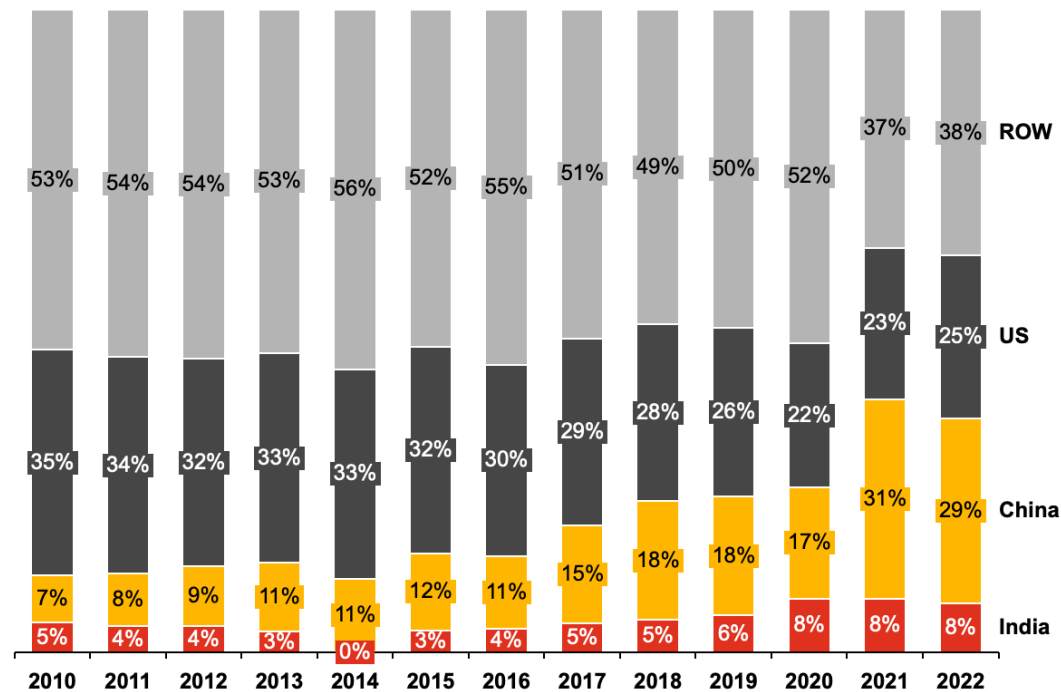
- **Biopharmaceutical Sponsors** reconsidered traditional approaches for delivery of trials during the COVID-19 pandemic to **mitigate risk of future disruptions** due to global events
- **Global regulatory** agencies and sponsors have increased appetite for change which has awoken service **providers, retailers, and technology companies** to establish formidable offerings



Despite India's position as the second 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 rare diseases and 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

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Enablers of Innovation

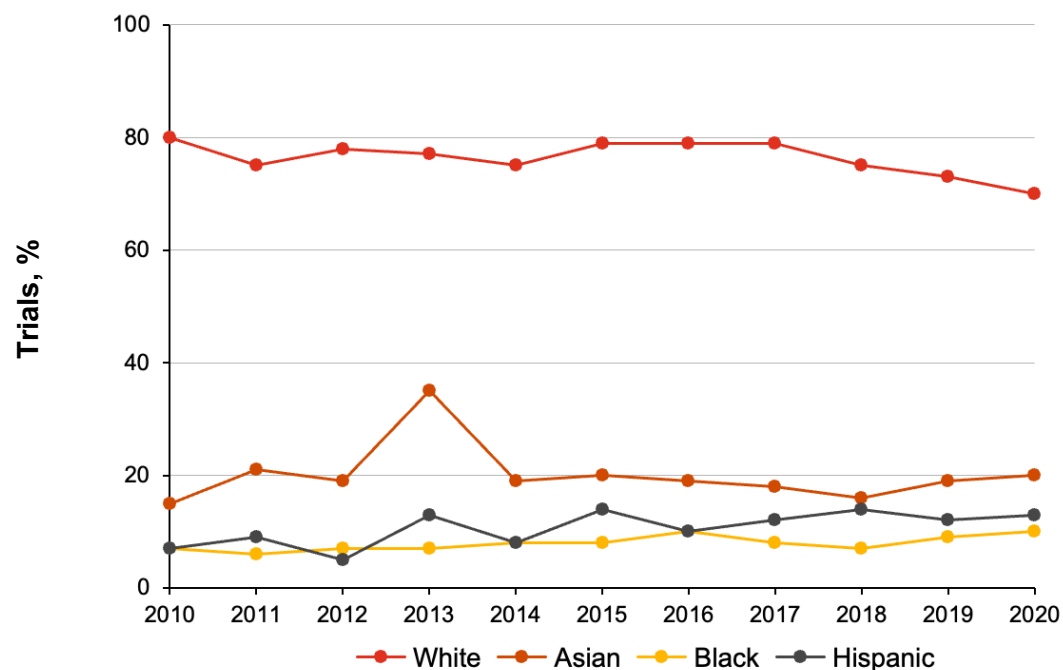
Prioritizing heterogeneity in trials, mitigation of rising geopolitical risk, and shared value creation ecosystem





Enablers of innovation: 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

Percentage of patients enrolled in FDA drug approval trials by race (% of Trials; 2010-2020)



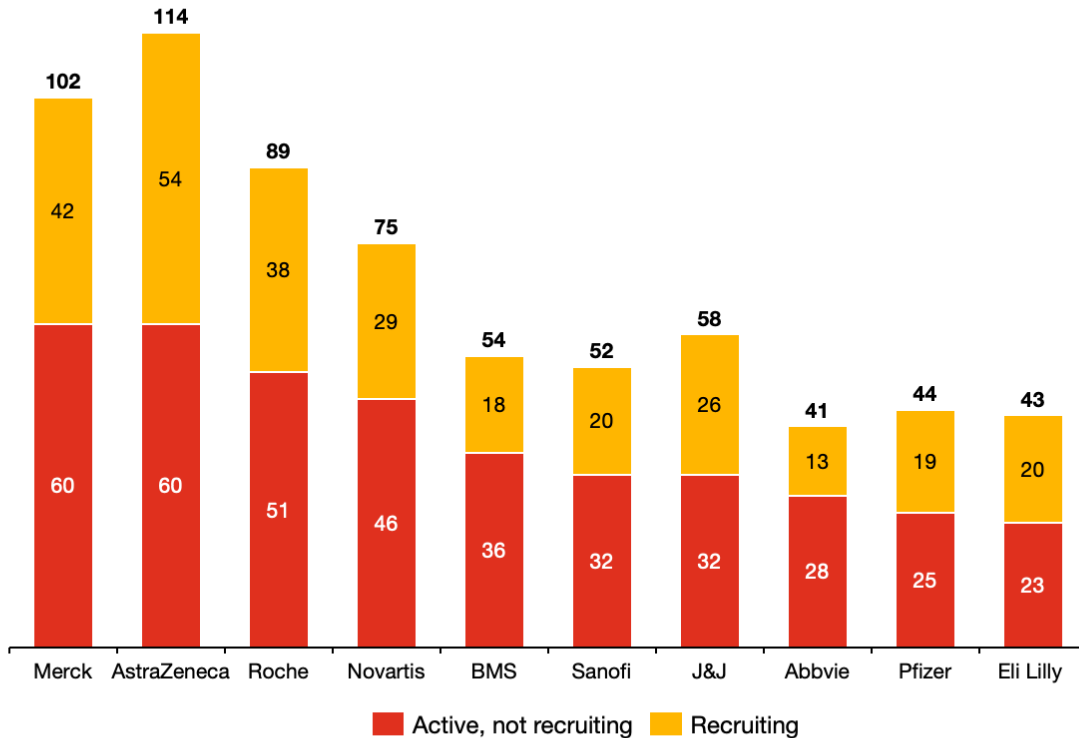
Source: PwC Analyses; JAMA 2020
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Pharmaceutical company	Therapy area	Challenge
	Oncology	FDA's Oncologic Drugs Advisory Committee did not accept Eli Lilly's clinical data based solely from trial in China and recommended Eli Lilly to conduct another trial for Sintilimab
	CNS	Roche was unable to recruit enough non-white patients for its lead candidate gantenerumab to treat Alzheimer's Given that non-white individuals have higher incidence of Alzheimer's, Roche could only identify 0.7% as Asian on race demographics, as compared to 96% of patients identified as white

Enablers of innovation: 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

Active clinical trials sponsored by big pharma with sites in Russia & Ukraine (Phase I-III)



*Includes only Phase I-III interventional trials
 **Top 10 pharma companies are listed based on the total number of trials in Russia

Source: PwC Analyses; ClinicalTrials.Gov (01/2023)

Key Insights

60% Majority of active trials (~60%) sponsored by the top 10 pharma are currently not recruiting patients

50% Most Phase I–III clinical trials (50%) sponsored by big pharma with sites in Russia & Ukraine are in Phase III

Top 5 NSCLC, breast cancer, multiple sclerosis, diabetes, and Crohn’s disease are the top 5 disease areas patient recruitment is halted

4 BMS, Merck, J&J, and Roche have officially announced halting the patient recruitment in Russia following the Russia-Ukraine war

Industry Voices

“We had about 60 to 70 studies running in Ukraine at the point of the invasion and so we are now looking as a company about how we move that book of work elsewhere around the world”

- Peter Ronco, Head of Global Development, Janssen R&D, J&J

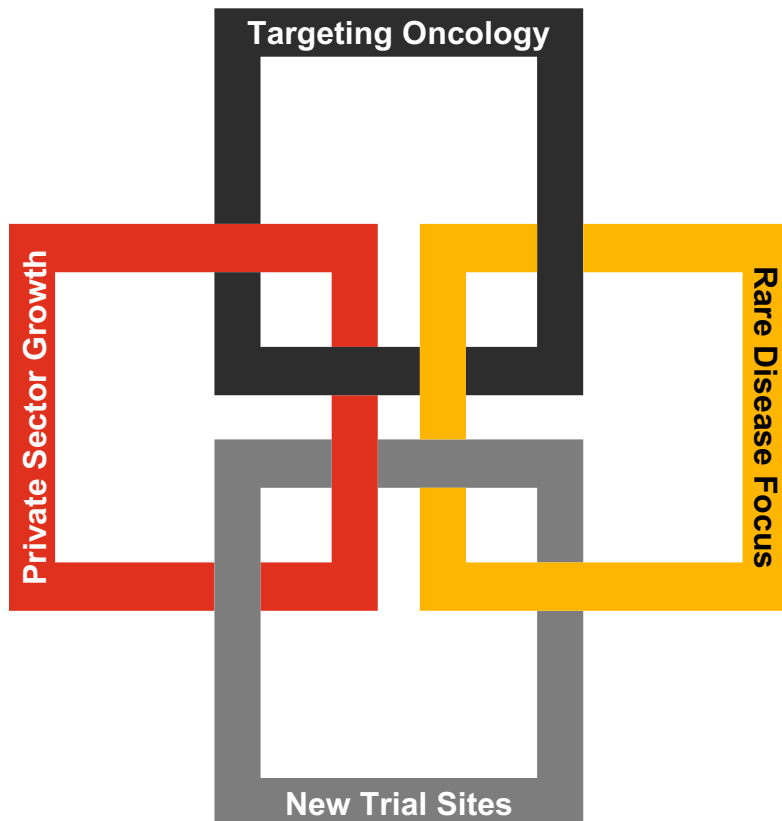
“We are mitigating the risk [Russia-Ukraine situation]. We do think, though, it opens the door in terms of opportunities for India”

- Peyton Howell, Chief Operating and Growth Officer, Parexel

Enablers of innovation: 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

Shared Value Creation Ecosystem



Private Sector Growth

- **Apollo Hospitals:** Single largest site solution organization in India with 200 investigators, 15 sites, and 80 certified and experienced clinical research coordinators. ~80% of all trials conducted at site are global multicentre trials
- **Medanta Hospitals:** Partnered with Duke to establish the Medanta Duke Research Institute as a joint venture for the creation of early phase clinical research facility at Medanta

Targeting Oncology

- **Haematolymphoid cancers:** Given that the incidence of cancer is highest in North East region, Government of India has invested in \$18M USD in 2021 to establish a dedicated services center for the management of paediatric and adult haematolymphoid cancers

Rare Diseases Focus

- **Rare Disease CoEs:** As part of the National Policy of Rare Diseases, India has established 11 CoEs across 7 states to increase diagnosis and provide treatment to patients with rare diseases
- **National Registry for Rare Diseases:** Indian Council of Medical Research has created a hospital-based 'National Registry for Rare Diseases' to overcome the dearth of epidemiological data for rare diseases in India

New Trial Sites

- **Phase I centers:** As per India's financial budget 2023, Indian Council of Medical Research (ICMR) has initiated plans to offer their lab and research facilities to be used by the private sector
- **Designations to foster growth in trial activity:** Several institutes and hospitals across India Advanced Centre for Clinical Trial; Regional Clinical Trial Unit; ICMR-Centre for Clinical Trial; Specialty Centre for Clinical Trial; Knowledge Partner for Clinical Trials
- **Clinical Trial Networks Initiative:** Launched by the National Biopharma Mission to strengthen the capacity to conduct clinical trials in India in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology (CHOORD) across 5 specialty networks of 36 organizations (hospitals, research institutes) in 18 states

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Clinical Trial Activity

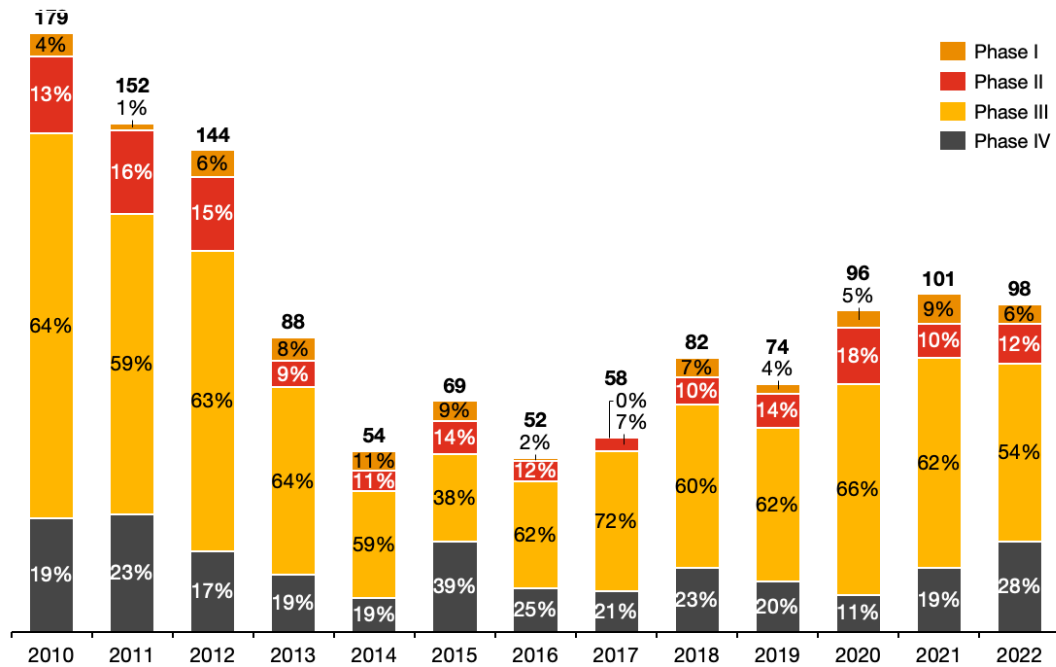
Current status of trial activity in India, challenges and potential strategies



Clinical trial activity was historically low until 2014 due to non-favorable regulations; since 2014 India witnessed a reversal of historical decline

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, by phase
(Top 20 Pharma Sponsored Trials; India; 2010-2022*)



Actual annual trial initiation count may differ because not all trials were reported with phase distribution
*2022 trial initiation counts are provisional and updated on December 15, 2022

Source: PwC Analyses, TrialTrove, December 2022

1. Growth recovery

- 4%** While bulk of the sponsored trials are Phase III, Phase IV trials have grown at 4% annually over the last decade
- 40%** Following the new regulations, the number of sites increased by 40% between 2014 and 2022




2. Catalysts of growth

- 10+** Since 2013, 10+ regulatory updates (e.g., NDCT 2019, online platform, relaxation on approval processes) have catalyzed the growth in trial activity
- 2019** The 2019 NDCT** Rules established the principles and practices for clinical trials, including the continuous evaluation of data to achieve safety

**NDCT: New Drug & Clinical Trial Rules, 2019

Regulatory reforms since 2014 have been aimed towards global harmonization, enabling open access to clinical trials in India...(1 of 2)




Key takeaway: Reforms targeting EC and CDSCO now allow for accelerated approvals, relaxation for certain drugs, and improved access to sites and patients

 Myth	 Perception	 Reality
Delays in the the approval to initiate clinical trials	Long clinical trial approval timeline of 120 days	Central Drugs Standard Control Organisation (CDSCO) now has 90 days to decide whether to approve global clinical trial applications
No relaxation on conducting trials for drugs already approved in other countries	Mandatory phase III clinical trials, irrespective of prior approval in other countries	Pharmaceutical companies that want to sell a new drug no longer have to conduct a phase III clinical trial in the Indian population, if it has been approved for sale in the EU, UK, US, Australia, Canada, or Japan
Trial could not be conducted at a site with no EC	Targeting sites without EC is not productive	If a site does not having an EC of its own, the study can still be conducted at such sites after obtaining EC approval from another site , provided that such approving EC shall be responsible for the study and it is located within 50 km radius from the clinical trial site
No incentive for conducting orphan drug trials	No trial regulations for orphan drugs	Orphan drug trials can be exempted , which treat conditions affecting less than 500,000 Indians, from both phase III and IV clinical trials
No provisions for conducting trials targeting life-threatening conditions	Mandatory phase III clinical trials, irrespective of the severity of disease / condition	Efficacy observed in Phase II for the investigational new drug may be considered for granting the marketing approval if it is intended for the treatment where available therapy is inadequate
Long delays in approval for manufacturing limits the commercialization potential	Approval timeline of 180 days for manufacturing of drugs	Revised timeline for approval to manufacture new drugs in India has been reduced to 90 days
Commercial IRBs cannot be hired for clinical trials	Use of commercial IRBs restricted to bioequivalence studies	CDSCO now allows the pharmaceutical companies to use commercial IRBs to oversee drug development across all types of clinical studies
Short validity of EC leads to long trial delays	Delays due to re-registration as the validity of registration is only for 3 years	Validity of registration of the EC has been increased to 5 years, thus the reducing the overall trial delays

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











...however, lack of training and slow progress in the implementation of reforms continue to create a negative impact on the biopharma activity in India (2 of 2)

Key takeaway: Reforms targeting EC and CDSCO now allow for accelerated approvals, relaxation for certain drugs, and improved access to sites and patients

 Reforms	 Roadblocks	 Impact for Biopharma
Fast-track decision making through approval from one main designated ethics committee	<ul style="list-style-type: none"> Individual hospital ethics committees rarely accept previous review by the central ethics committee Example: Among the 42 sites participating in the COVID-19 trials coordinated by the George Institute for Global Health, only 3 accepted central ethics committee approval 	<ul style="list-style-type: none"> Delays due to redundancy in making additional applications for separate ethics committee approval
Separate ethics committee for academic-led and industry-led trials	<ul style="list-style-type: none"> Many ethics committees unable to differentiate between academic-led and industry-led trials due to lack of training and awareness of the new guidelines 	<ul style="list-style-type: none"> Delays in approval from the ethics committee
Common template for submissions to receive ethical approval	<ul style="list-style-type: none"> Despite the existence of a common forms template from the ICMR for submissions for ethical approval, most sites insist on receiving applications in their respective templates, adding to delays in approval 	<ul style="list-style-type: none"> Delays due to redundancy in making separate applications for each site
Training of ethics committee members	<ul style="list-style-type: none"> While the new rules mandate the training of ethics committee members, the regulator has made no recommendations about the contents, nature, or frequency of training nor has it identified any organization / institute who is authorized to impart the training 	<ul style="list-style-type: none"> Delays in approval from the ethics committee Negative impact on the quality of research

Top biopharma can leverage the conducive ecosystem of industry, academia, and government partnerships in India to overcome the existing challenges

Key takeaway: Complexity of trial processes and low trial participation rate continues to exist. Pharmaceutical companies can leverage new and existing partnerships to build awareness and provide training to facilitate their access to patients and sites

 Challenges	 Roadblocks	 Impact for Biopharma
Complex & time-consuming regulatory processes to initiate and conduct trials	<ul style="list-style-type: none"> Partnership with CROs specifically engaged in streamlining the country-specific regulatory processes 	<ul style="list-style-type: none"> Trials run in partnership with the top 5 CROs* represented ~70% of all the active, industry sponsored trials with sites in India
Low trial participation	<ul style="list-style-type: none"> Launch patient awareness initiatives to participate in trials Use of digital, data-driven patients to trial matchmaking services 	 <ul style="list-style-type: none"> Partnered with Tata Trusts to launch Pfizer Cancer Care initiative for community outreach and setting-up health and wellness service kiosks  <ul style="list-style-type: none"> Launched Avacare Clinical Research Network that uses AI to help sites in the India and the U.S. to match patients to clinical trials faster and more effectively
Difficulty in conducting trials for rare diseases	<ul style="list-style-type: none"> Access patients to improve patient enrolment through accessing disease-specific and rare-disease not-for-profit organizations 	 <ul style="list-style-type: none"> Partnered with CureSMA Foundation of India for improving access to its drug for SMA  <ul style="list-style-type: none"> Partnered with Indian Academy of Medical Genetics for capacity building in the field of genetics and rare diseases
Lack of trained healthcare personnel	<ul style="list-style-type: none"> Collaborate with tertiary care hospitals / institutes to train healthcare personnel to recognize risk factors, causes, pathophysiology, screening methods, diagnostic tests 	 <ul style="list-style-type: none"> Partnered with AIIMS Jodhpur as part of the India-Sweden Healthcare Innovation Centre to launch an e-learning Upskilling Program in Diabetes Management for nurses  <ul style="list-style-type: none"> Partnered with CSIR-Institute of Microbial Technology to train and develop a high-quality skilled workforce to drive R&D and manufacturing activities
Availability of a network of clinical research sites	<ul style="list-style-type: none"> Partnership with hospitals that have multi-city presence and can support additional trial-related logistical and clinical testing 	 <ul style="list-style-type: none"> Apollo Hospital is located in 48 cities and has network of 3,400 pharmacies, 90 primary care clinics, and 150 diagnostic centers across India

*Top 5 CROs: IQVIA, ICON plc, Parexel, PPD, Labcorp
 Note: Only 22% of active, top 20 pharma sponsored trials in India are tagged with an associated CRO

Source: TrialTrove, Jan 2023; PwC Analyses

04

Infrastructure and Access

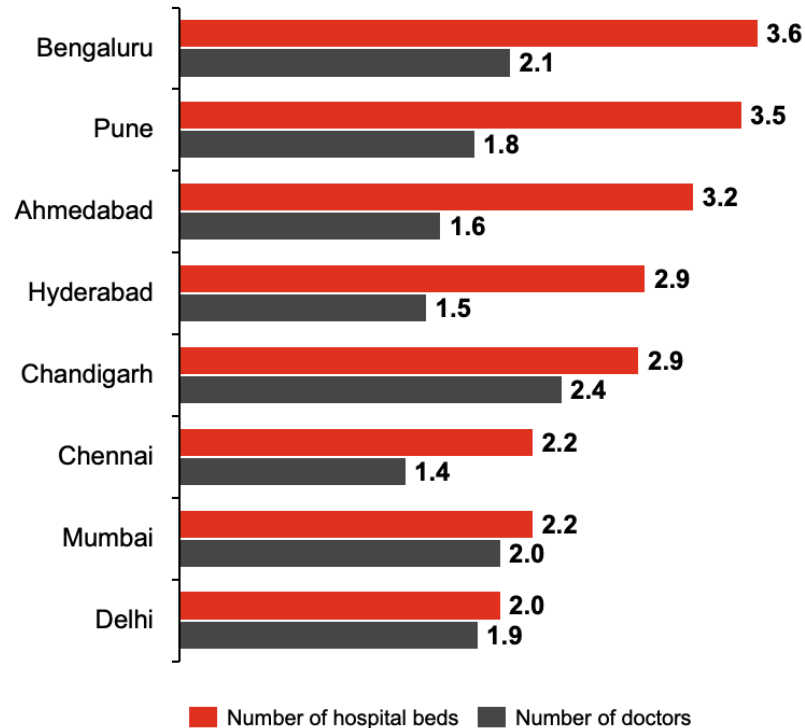
Realigning the clinical trial
strategy towards tier-1 cities



Infrastructure: Medical infrastructure in tier-1 cities in India is highly amenable to conducting clinical trials across different therapy areas

Key takeaway: 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

Number of hospital beds and medical doctors, by cities with most urban population (Per 1,000 population; 2020)



Higher bed capacity & # doctors in tier-1 cities

30 Although the average bed capacity at the country level is only 1.4, tier-1 cities have on average a bed capacity of 2.8

17 The average number of doctors per 1,000 population is 0.82, tier-1 cities have on average 1.8 doctors per 1,000 population

65% Private hospitals contribute 65-70% of total bed capacity in states with metro cities

51 Chandigarh has the highest bed (2.86) to doctor (2.38) ratio, where the government / public hospitals contribute 67% of the total bed capacity

7+ ~7 super-specialty hospitals with geographical presence in 3-5 tier-1 cities hold more opportunities for running multi-city clinical trials

Initiatives to increase infrastructure

1 ICMR to set-up new standalone facilities capable of executing phase I clinical trials

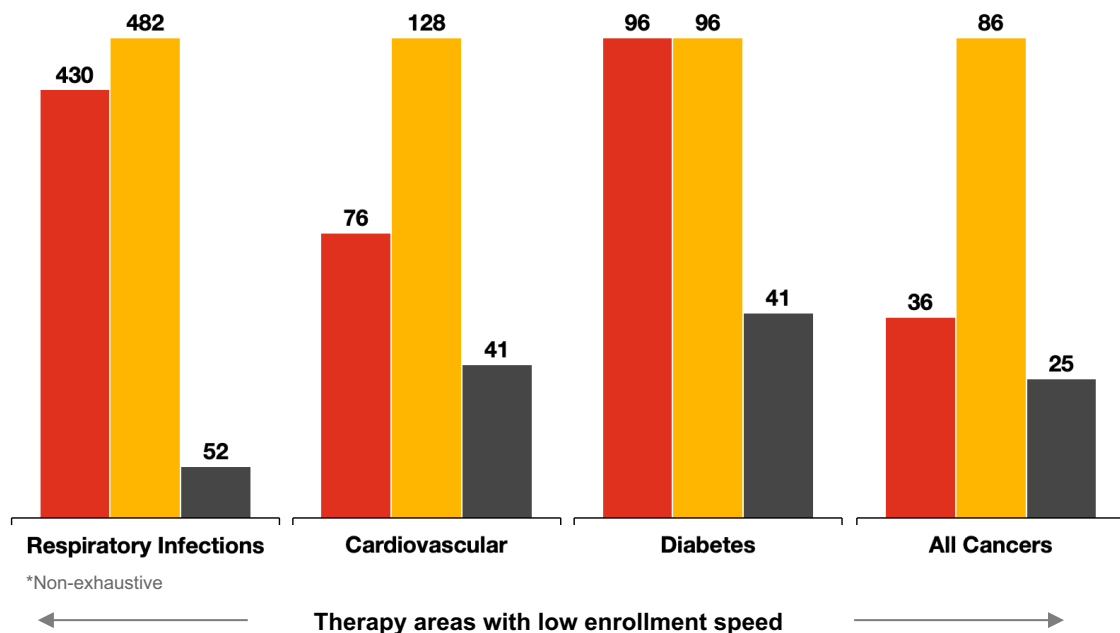
2 Ministry of Health has designated 8 tertiary-care hospitals as Centre of Excellence for treating rare diseases

Source: PwC Analyses; National Health Profile, MoHF&W, State Economic Survey, State Health and Family Welfare Department; TrialTrove, Dec 2022

Access: Higher disease prevalence and low clinical trial activity represents an untapped potential for conducting trials in India

Key takeaway: 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

Disease Prevalence, by country*
(Millions; 2021)



1. Low trial participation

3% Indian trial participants account only for 2.9% of the total clinical trial participants enrolled globally, compared to 30% in the U.S.

2. Untapped potential

20% India represents 20% of the global **respiratory infectious diseases** burden, but accounts for only 3% of respiratory infectious disease trials

14% India represents 14% of the global **cardiovascular disease (CVD)** burden, but accounts for only 4% of CVD trials

19% India represents 19% of the global **diabetes mellitus** burden, but accounts for only 8% of diabetes mellitus trials

8% India represents ~8% of the global **cancer** burden, but accounts for only 2% of cancer trials

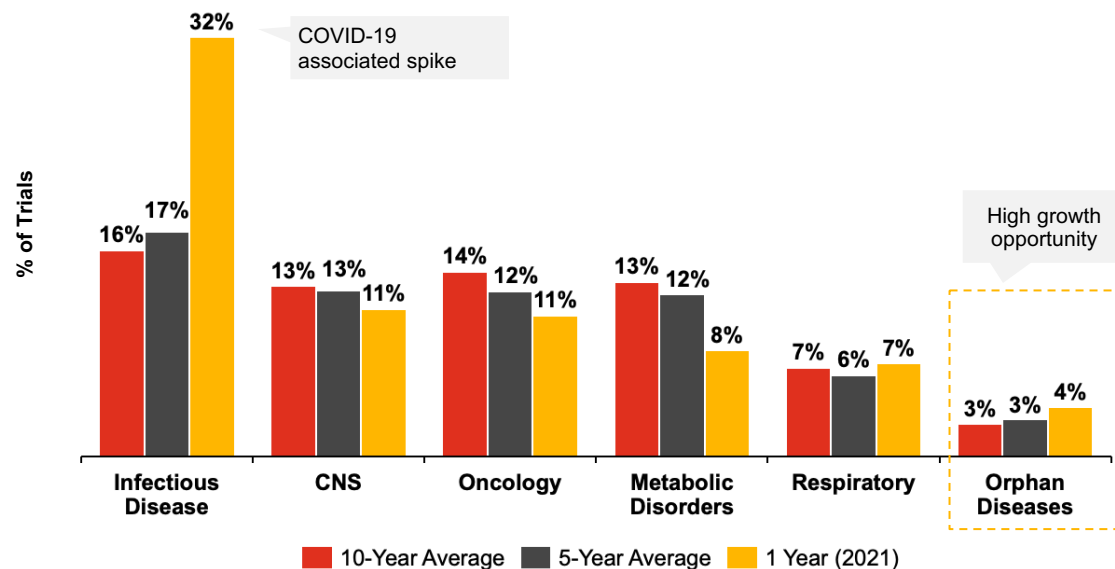
**Disease prevalence is based on estimates from Global Burden Disease, with 10-year growth rates used to extend the estimates beyond 2019. Enrollment speed was estimated based on patients / site / month data from TrialTrove

***Prevalence estimates for respiratory infections excludes the COVID-19

Access: Large untapped patient population across the top therapy areas represents a growth opportunity for the top 20 pharma

Key takeaway: 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 key diseases (e.g., pain, epilepsy, cervical cancer) and orphan diseases (β -thalassemia, Duchenne Muscular Dystrophy)

Top therapy areas for industry sponsored clinical trials in India
(% of Trials; 2010-2021)



1. Disease-level insights

- 6%** Infectious disease continue to be the top therapy class for top pharma in India (CAGR: 6%) due to higher incidence of TB, malaria, and HIV
- 7.5%** Within **CNS**, pain was the top disease target in India, accounting for 7.5% of top pharma sponsored trials in pain globally
- 3%** Within oncology, breast cancer was the top disease target in India, accounting for 3.3% of top pharma sponsored trials in breast cancer globally

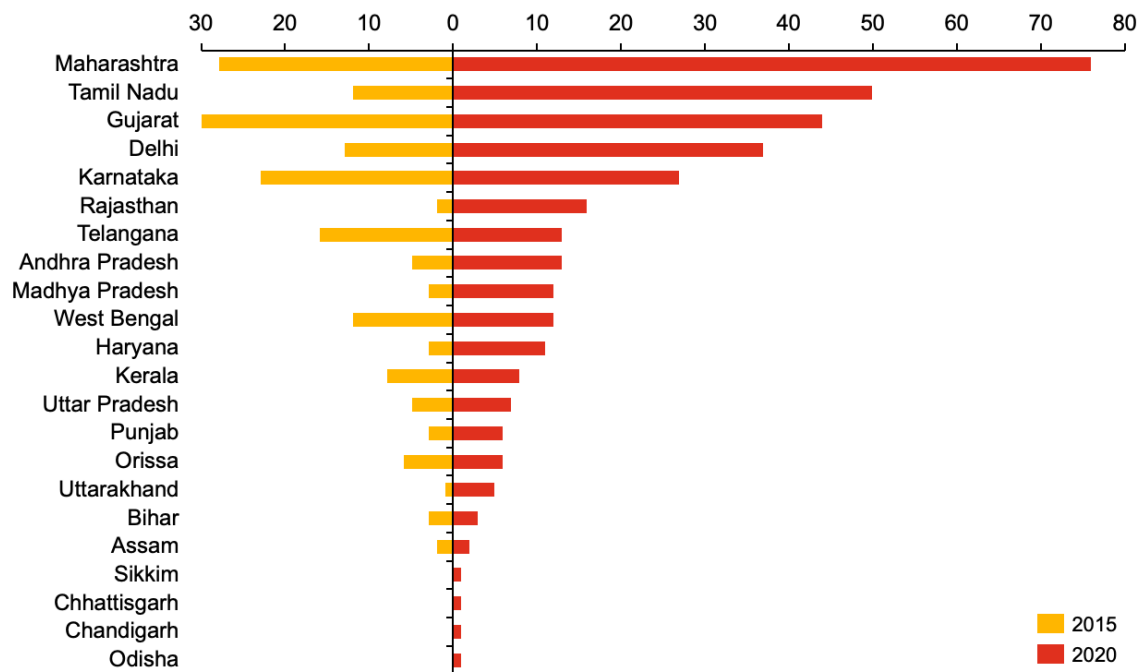
2. Growing potential for orphan diseases

- 4%** Top pharma sponsored trials for orphan disease has increased by 4% in India in the last decade (2010-21), primarily led by Novartis, Sanofi, and AZ
- 50%** Although India has a high prevalence of orphan disease (6-8% of population), total trial activity is only half (3%) of other top therapy areas (~7-9%)

Access: Availability of investigators has doubled between 2015 and 2020, supporting growth in trial activity across diverse therapy areas

Key takeaway: 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.

Number of investigators in trials sponsored by the top pharma, by state
(# of investigators; 2015 and 2020)



1. Availability of investigators

2x

The number of investigators have doubled since 2015 in the top pharma sponsored trials in India

65%

Top 5 states (Maharashtra, Tamil Nadu, Gujarat, Delhi, Karnataka) account for 65% of all investigators in India

20%

20% of investigators specialize in Internal Medicine, followed by Oncology (11%), Endocrinology (7%), Gastroenterology (6%), and Cardiology (5%)

2. Availability of sites

Public

Top 5 trial sites in the public sector are AIIMS New Delhi, CMC Vellore, GMCH Hyderabad, GMCS, Surat, and SGRH, New Delhi

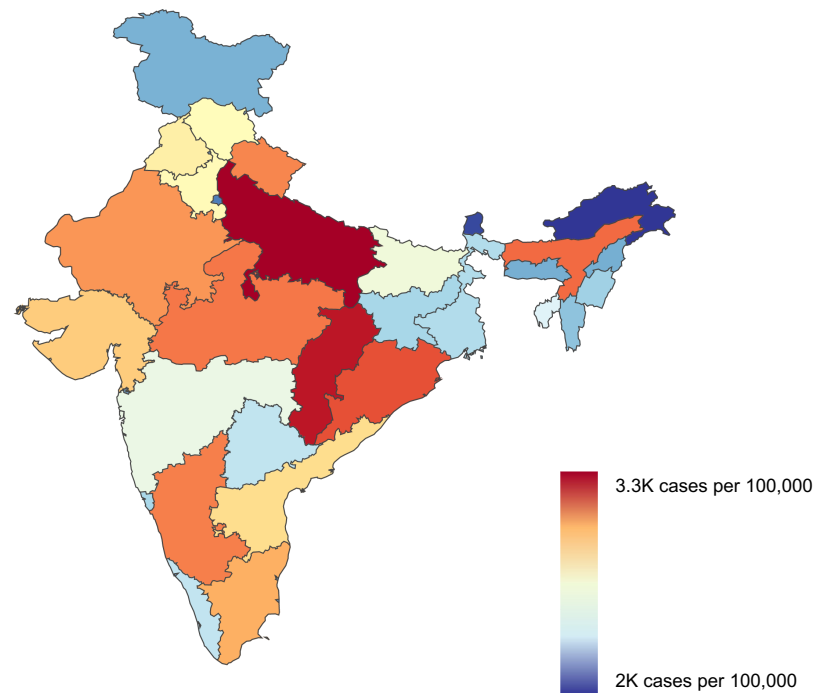
Private

Top 5 trial sites in the private sector are Tata Memorial Cancer Hospital, Apollo hospitals, Fortis Hospitals, Hinduja Hospital, and MAHE Manipal

Access: 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

Key takeaway: 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

Cancer Prevalence per 100,000 population
(Both sexes, All ages, 2021)



Stratification of a disease by states follows the trend in the availability of advanced medical infrastructure

01

States with high disease prevalence (e.g., Kerala, TN, Karnataka) are also the states with most number of tier-1 cities and availability of advanced medical infrastructure

02

Availability of tertiary care public and private hospitals in Tier-1 cities in states with high burden also act as nodal zones for neighboring tier-2 and tier-3 towns

03

Prevalence trends for most diseases follow these geographic trends **except few infectious diseases** (e.g., tuberculosis, malaria), which predominantly occur in tier-2 cities

04

Geographic variations across different states is also reflective of the **availability of investigators**, with higher number of investigators available in tier-1 cities

05

Capitalizing on the Emerging Private Sector Growth

Leveraging complementarities in
partnerships to overcome the
existing gaps

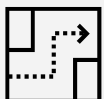


Biopharma can benefit from the critical enablers of innovation in the private healthcare system in India and leverage the rapidly expanding healthcare infrastructure

Key takeaway: Private sector is a well-suited channel for the top biopharma to conduct more efficient clinical trials with easier and faster access to investigators and patients



Enablers of Innovation



Transition from traditional commercially-oriented healthcare services towards **innovation**



Increase in the number of **super-specialty hospitals** due to growth in demand from rapidly expanding urban population



Infrastructure



Hospitals in the private sector provides **87% of all services**



Hospitals in the private sector represent **63% of all hospitals in India**



Partnerships with Microsoft, Amazon, and Google for advanced digital analytics, **virtual care services**, and **precision oncology**



Access



81% of all physicians are engaged in private sector, located predominantly in tier-1 cities


















Private sector offers access to **63% of the total bed capacity** in India



Private healthcare infrastructure represents **70% of all health infrastructure in tier-1 cities**, where there is higher prevalence of chronic diseases and density of investigators

Several examples of successful partnerships with private sector demonstrate the availability of advanced trial infrastructure and clinical expertise

Key takeaway: Developing strategic partnerships that leverages complementarities with private hospitals can overcome the existing gaps in patient access and trial operational delays

Private Hospital	Partners*	Category	Description
		Trial recruitment	Improve access to global clinical trials and support patient recruitment using real world data and evidence
		Site infrastructure	Trial for polyp detection using colonoscopy with real-time image processing coupled with AI-based high performance computing
		Patient access	Joint venture to improve access to advanced care for patients with diabetes
		Center of excellence	Joint venture to set up Medanta-Duke Research Institute and establish centers of excellence for conducting early phase clinical research
		Center of excellence	Establishing center of excellence for infectious disease research in India and training and scientific exchanges for Hinduja Hospital researchers by NIH
		Investigator training	Training for evidence generation and use of real world data and evidence in research and clinical practice
		Center of excellence	Collaborative research, Oncology Training Institute, and Centre of Excellence for Cancer equipped with imaging, molecular diagnostics, data analytics
		Site infrastructure	Enhancing paediatric liver transplant facilities and support towards research, diagnosis and treatment pathways for children recommended for liver transport
		Rare disease	Trial site for conducting phase I/II clinical trial evaluating the efficacy of investigational drug in adults with late-onset Pompe disease

Source: Press search

*Non-exhaustive list of partnerships

Case Study: Novo Nordisk developed a long-term strategy to target R&D and commercialization efforts for diabetes treatment in India through partnerships and sustained investments

Key takeaway: Multi-stakeholder partnership and country investments are an imperative for increasing trial activity and improving commercialization potential of the drugs in development



Given the high prevalence for diabetes in India, Novo Nordisk moved 33% of its global diabetes R&D to India. Novo Nordisk collaborated with multiple stakeholders and made sustained investments towards the development and commercialization of its diabetes drug portfolio. **The total trial activity of Novo Nordisk for diabetes trials in India increased by ~60% between 2014 and 2020**

Objective

Activity

Partner

Raising Awareness

- Novo Nordisk Education Foundation and Roche Diabetes care partnered to provide **education and training** for doctors and nurses, and enhance awareness about diabetes and its management among children in India
- Launched “Changing Diabetes in Children” in India program and initiated awareness campaign for **17,000+ children and provided training for 7,000+ HCPs**,
- Launched “Break the Partnership” between diabetes and obesity campaign spread awareness across key stakeholders and **engage HCPs**



Improving R&D Infrastructure

- **Established 3 centres of excellence:** JIMS, Noida; Aligarh Muslim University, Aligarh; and, Gandhi Hospital, Hyderabad for R&D, training HCPs, and improving access to diabetes care
- Partnered with UNLEASH and the World Diabetes Foundation to **establish a Global Innovation Lab** with an objective of facilitating an R&D ecosystem for identifying and scaling innovations to treat diabetes



Manufacturing

- Expanded partnership with India-based Torrent Pharmaceutical to **improve the market share** of its drug portfolio for treatment of diabetes



06

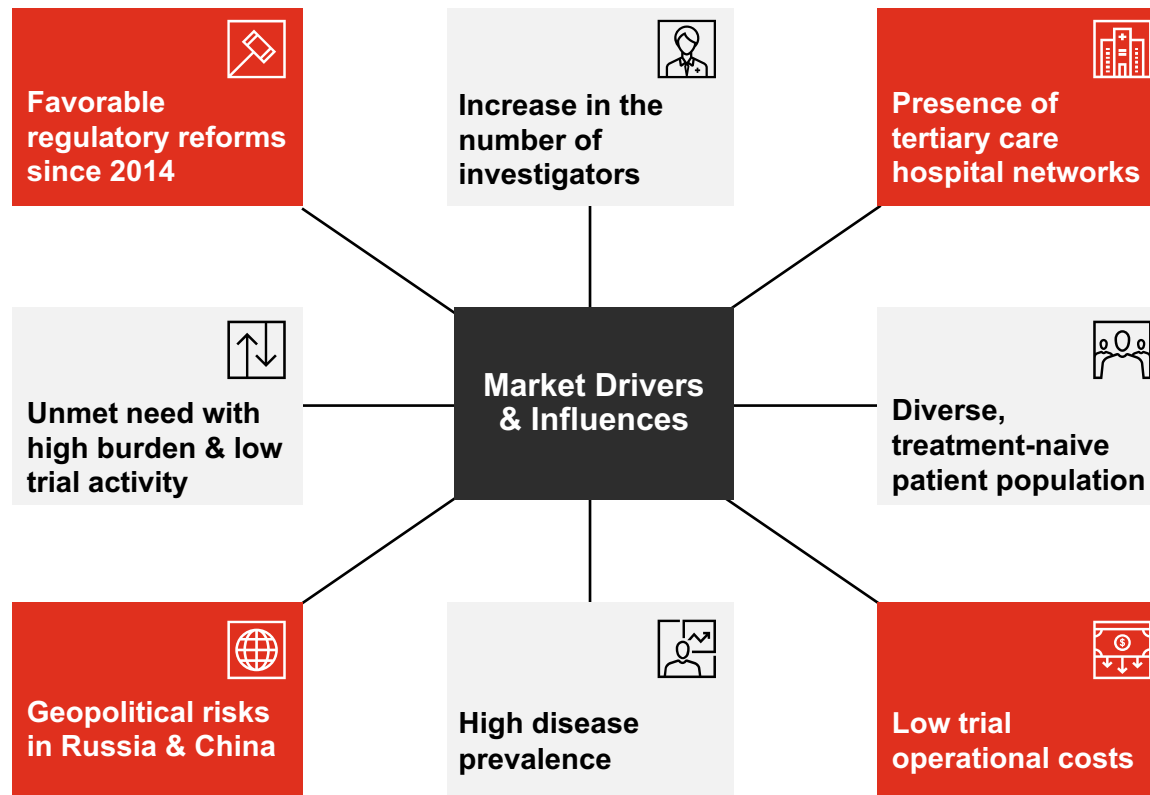
Seizing the Opportunity

Developing a long-term strategy that focuses on the key enablers of innovation and strategic partnerships



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 exist 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 rare disease patient pool and enabling ecosystem strengthened by the establishment of public and private sector CoEs for rare diseases treatment
- Derive economic advantage from recent regulations to fast-track orphan drug application, waiver of application fees, and exemption of orphan drugs from price controls

Appendix



Internal PwC documents drawn upon in this report

Vision 2025: Unlocking India's potential for leadership in pharmaceutical innovation	Sujay Shetty
Committed to India: Indian Pharma moving to a more R&D-focused industry	Sujay Shetty
India Pharma Inc. Changing landscape of the Indian pharma industry	Sujay Shetty
How retailers are disrupting the clinical trial delivery model	Anup Kharode, Brian Slizgi
India Pharma Inc. Gearing up for the next level of growth	Sujay Shetty
Uniquely understanding industry needs from a business perspective	Anup Kharode
Global pharma looks to India: Prospects for growth	Simon Friend, Steve Arlington, Michael Swanick, Sujay Shetty, Nisha Vishwakarma
Enabling Global Growth in Pharma: Why navigating local complexities is key to unlocking value	Karla Anderson, Thalita Marinho, Tom Southwell
Next in pharma: How can pharmaceutical companies drive value growth?	Glenn Hunzinger, Greg Rotz, Laura Robinette, Matthew Rich
Next in pharma: Thriving in 2023	Glenn Hunzinger, Greg Rotz, Laura Robinette, Matthew Rich, Roel Van Den Akker, Philip Sclafani

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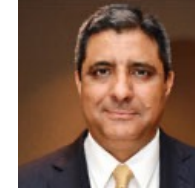
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