



Positioning India as a Pharmaceutical Innovation Hub

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Foreword



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India's pharmaceutical industry, currently valued at USD 50 billion, is one of the fastest-growing sectors in our economy. With projections indicating a rise to USD 130 billion by 2030, our industry is on an impressive trajectory. However, as we celebrate these advancements, it is vital to address the challenges that could hinder our ascent to becoming a global pharmaceutical leader.

Despite our progress in manufacturing and exporting generic drugs, India continues to rely heavily on imports for Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs). This dependency emphasizes a critical issue: our sector's investment in Research and Development (R&D) remains insufficient. Currently, India's expenditure on R&D stands at a mere 0.8% of GDP, a stark contrast to the 3-4% seen in developed countries. This shortfall in investment is a barrier to fully realizing our sector's potential and achieving sustained global leadership.

Our Annual Pharma Summit 2024, themed "Positioning India as the Pharmaceutical Innovation Hub," aims to address these concerns. This summit will serve as a platform to explore the full spectrum of challenges and opportunities within the industry, with a particular focus on enhancing R&D capabilities, leveraging technology, bridging the talent gap, and refining government policies.

We are pleased to present to you this pivotal white paper, "Positioning India as the Pharmaceutical Innovation Hub," prepared by Deloitte, and launched at ASSOCHAM's 'Annual Pharma Summit 2024'. We hope this document helps the stakeholders navigate the future of India's pharmaceutical sector, which stands poised for unprecedented growth.

This white paper delves into the current landscape of India's pharmaceutical sector, identifying key obstacles and outlining actionable items for overcoming them. It offers a comprehensive analysis of how India can transform these challenges into opportunities, positioning ourselves as a dominant player on the global stage by 2030.

Foreword



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The Indian pharmaceutical industry has witnessed remarkable growth, establishing itself as the world's largest provider of generic medicines through product and process innovations. Today, the industry has achieved significant scale and reach in the global market. No longer just the "Pharmacy of the World," India is rapidly emerging as a hub of pharmaceutical innovation and digitization. With immense growth potential, the industry is poised to elevate its position on the value chain by delivering affordable, quality-assured medicines and addressing the unmet needs of patients worldwide.

In recent years, Indian pharmaceutical companies have gained expertise and enhanced capabilities in areas such as chemical synthesis, especially for complex products, injectables and fermentation.

India's growing technological expertise in advanced analytics, AI/ML, and AR/VR has spurred more pharma services players to offer these solutions and encouraged the creation of technology "innovation hubs" by India-based global capability centers (GCCs) of international companies.

Significant strides are being made in the development and manufacturing of innovative biopharmaceuticals and biosimilars. These high-value drugs have an expanding market, and Indian companies are investing heavily in research and development in this sector. Investments in clinical trials are gaining pace as India is seen as a cost-effective location for conducting them. Indian pharmaceutical companies are increasingly focusing on innovation and developing novel drugs rather than just manufacturing generics.

Continuous regulatory reforms, robust innovation funding, industry-academia collaboration, and innovation infrastructure with a strong emphasis on patient-centricity, will serve as the key drivers for the Indian pharma sector to become a true innovation hub.

Foreword



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The future of the pharmaceutical industry in India looks exceptionally promising, marked by a dynamic blend of innovation and expansion. As the sector continues to leverage cutting-edge technologies such as artificial intelligence, machine learning, and advanced analytics, it is poised to drive significant breakthroughs in drug development and personalized medicine. India's burgeoning focus on biopharmaceuticals and biosimilars, coupled with a growing emphasis on research and development, is set to position the country as a global leader in these fields.

The rise of digital health solutions and increasing investments in clinical trials highlight India's role as a hub for innovative medical research. Moreover, ongoing regulatory reforms and robust industry-academia partnerships are creating an environment conducive to rapid advancements.

As Indian pharmaceutical companies shift from traditional generic manufacturing to pioneering novel drugs and high-tech solutions, the sector is not only enhancing its global presence but also contributing significantly to improving patient outcomes worldwide.

Foreword



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The Indian pharmaceutical industry has played a crucial role in shaping global health outcomes. During the COVID-19 pandemic, the industry ensured an uninterrupted supply of medicines to patients around the world. The Indian Pharmaceutical Industry is poised for a big leap in terms of its upward movement in value chain. The industry operates in diverse and very complex technological areas in ever evolving science based regulated environment.

Expanding into the Innovation space is key to achieving the Indian pharma industry's aspiration to grow to USD 120-130 Bn by 2030 and increase its global relevance. India's increasing expertise in biotechnology, bioinformatics and clinical testing provides a distinct advantage. Several overseas companies have outsourced research and clinical trials to Indian Clinical Research Organisations, while others have entered into collaborative R&D arrangements to supplement their R&D productivity.

Some of the critical interventions required for further growth of the industry would be the regulatory reforms, capacity building of CDSCO, Research enabling ecosystem, and pragmatic pricing mechanism.

The above interventions will move Indian pharmaceutical industry from volume to value leadership.

Foreword



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The pharmaceutical industry in India has come a long way from being a country that could produce a few affordable generics medicines, to being THE pharmaceutical and vaccine manufacturing hub for the world. India is one of the few countries that caters domestically as well as globally to the whole spectrum of the pharmaceutical value chain from drug discovery services to contract research and development to manufacturing of APIs, generics, branded formulations and complex biologics. And the best is yet to come.

Having firmly established itself as a sizeable and responsible supplier of various pharmaceutical services and products, it is only right that all the necessary steps are conceptualised and undertaken to achieve the foremost position in the world of medicines, in terms of quality, reliability and value. Undoubtedly, the pharmaceutical industry is complex and ever evolving, given the thrust on innovation, research and development, and the constant pursuit of better clinical outcomes sometimes even for hitherto non-existent therapies of currently known diseases and even those not yet discovered or explored.

Drawing parallels from some of the most iconic companies of the world, India has the potential to create the Google or Microsoft of the pharmaceutical world, which would require a lot of focus, especially on R&D and a determined thrust on investments. The gamut of areas requiring research and focus are many – to name a few but not limited to – AI / ML /GenAI-powered scientific and business processes, data science driven analytics, cell and gene therapies, regenerative medicines, higher efficiency in drug discovery and clinical trials, enhanced speed to market, etc. These are cutting edge areas where scientific knowledge and technological expertise continue to evolve and converge, and the industry must discover and pave its own paths, in order to come up with viable, affordable and consistently reliable solutions. A good case study is Genome Valley near Hyderabad, where many global innovator pharma companies have set up their R&D and Innovation centres which is fast becoming a drug discovery hotspot in our country.

What is clear is that India has the chance to make a lasting and purposeful impact in this golden age of scientific advancements in medicine, biology, biochemistry, and all related subjects, across most therapeutic areas. We have the talent, the intent, the ecosystem, and the environment, and we recognise the opportunity very well indeed. What is needed are investments, sound strategy, regulatory clarity, and support from all stakeholders, to make it happen.

Foreword



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At the crossroads of global healthcare and pharmaceutical innovation, India is emerging as a key player in shaping the future of medicine. The country's rich and growing scientific talent, a robust regulatory framework, and a rapidly evolving technology landscape are guiding it to become a leading pharmaceutical innovation hub.

India has made remarkable strides in drug development and manufacturing in recent years. With a strong emphasis on biopharmaceuticals and biosimilars, Indian companies have not only made healthcare more accessible globally but have also established themselves as trusted collaborators in improving global healthcare systems. The rise of Contract Research Organisations (CROs) and Contract Development and Manufacturing Organisations (CDMOs) further strengthens the industry, allowing for more efficient and scalable drug development and production processes. Additionally, the market for generics continues to expand, positioning India as a vital player in affordable medicine. Clinical trials are also gaining momentum, supported by a diverse patient population and regulatory improvements, facilitating quicker and more reliable data collection. Global pharmaceutical giants are setting up Global Capability Centres (GCCs) in India to use the country's R&D potential, driving deeper investments in research and development for breakthroughs in healthcare.

By harnessing advancements in biotechnology, AI, and data analytics, Indian pharmaceutical companies can enhance their capabilities and focus on advanced therapeutic solutions. Collaborative efforts among academia, industry and government will be crucial in cultivating an ecosystem that encourages innovation while addressing global health challenges. This publication explores India's potential as a pharmaceutical innovation hub, offering insights into strategic pathways that can drive the sector forward and create a sustainable impact on health landscapes, both domestically and globally.

Introduction

India's pharmaceutical R&D ecosystem is at a pivotal juncture, marked by significant advancements poised to drive substantial growth. The market is estimated to expand to US\$130 billion by 2030.¹ India exports pharmaceutical products to over 200 countries, covers 50 percent of Africa and 40 percent generic demand of the United States and supplies 25 percent of the UK's medicine requirements. As the third-largest global producer of drugs by volume and 14th by value, India produces over 60,000 brands across 60 therapeutic categories and more than 500 APIs. India is also the leading global producer of generic drugs, offering some of the most affordable medications due to its cost-efficient manufacturing processes. The country hosts over 3,000 drug companies and 10,000+ manufacturing units.² Investment in R&D, especially in biotechnology, is on the rise. According to research conducted by the Department of Pharmaceuticals and Ministry of Chemicals and Fertilisers, Government of India (GOI), the Contract Research and Manufacturing Services (CRAMS), Contract Manufacturing Organisations (CMO) and Contract Research Organisation (CRO) industries have been growing at a CAGR of 10.75 percent and are expected to reach US\$2.5 billion by 2030.³ India is among the top 12 biotechnology destinations globally and the third largest in the Asia-Pacific region.⁴

Global pharmaceutical corporations increasingly invest and expand their R&D operations in India, drawn by the country's growing talent pool and burgeoning innovation potential. Noteworthy examples include Merck's establishment of a new R&D centre and Bristol-Myers Squibb's US\$100 million investment in Hyderabad's science and technology centre, employing 1,500 individuals.⁵ Pfizer has established its Global Drug Development (GDD) centre at IIT Madras.⁶ Additionally, collaborations with Indian public entities are on the rise, as seen in the collaboration between Johnson & Johnson and CSIR for drug discovery and development. These initiatives emphasize the role of fostering innovation and providing opportunities for the local talent pool to contribute to cutting-edge research and development. Also, the Government has taken measures to improve transparency and

accountability for regulating clinical trials and new drugs, including cell & stem cell-derived products, gene therapeutics products and xenografts for human use. Indian Council of Medical Research (ICMR) is also expanding the Indian Clinical Trial and Education Network (INTENT) beyond the current network of 47 institutes nationwide to increase participation and contribution.⁷ India's adherence to globally compliant standards is reflected in its approximately 1,700+ clinical trial sites, supported by around 4,200+ investigators trained in the ICH-GCP guidelines.⁸ These standards position India as a credible and reliable global pharmaceutical research and development destination.

Despite this promising growth trajectory, crucial levers of change must be addressed to realise its potential over the coming years.

India's AI-driven drug discovery and development market is on a promising trajectory, driven by the increased adoption of advanced technologies such as AI-enabled healthcare solutions, tools for cell and gene therapy and industry-academia collaborations. However, the sector faces challenges that must be addressed for sustained growth. Limited funding from venture capital and private equity firms constrains financial resources for R&D efforts. Additionally, there is a need to build trust in technology, which requires regulatory enhancements and a patient-centric approach. The industry experiences a shortage of specialised AI and data science skills, compounded by complex regulations that do not fully accommodate technology-specific advancements. Data privacy and cybersecurity concerns persist, with many Indian organisations not fully meeting protection standards. Despite these challenges, there is a positive trend in the form of strategic collaborations that are driving innovation. Notable collaborations include MedGenome's with US-based Emmes,⁹ Glenmark's alliance with APC Therapeutics for cancer drug development¹⁰ and AstraZeneca's work with Qure.ai to improve early lung cancer detection.¹¹ Merck's Uptune Programme in India, which supports early-stage start-ups, further emphasizes the industry's commitment to fostering innovation and overcoming obstacles through collaboration.¹²

There is an increase in attrition rates within the pharmaceutical sector, accompanied by a shortage of niche skills. The Indian pharmaceutical sector sees a significant imbalance between the growing pool of advanced degree holders and the specific expertise required by the industry exacerbated by high attrition rates that reached approximately 35 percent in 2024 along with brain drain.¹³ Efforts to address gaps in employability have been undertaken. Key initiatives include Excelra's collaboration with IIT Kharagpur to advance drug repurposing through Natural Language Processing and Machine Learning,¹⁴ Merck's collaboration with CSIR-IMTECH to establish a High-Tech Skill Development Centre,¹⁵ and GSK's joint venture with the Regional Centre for Biotechnology to develop a PhD programme.¹⁶ Additionally, global university collaborations, such as Virginia Tech's with NMIMS for a coordinated analytics programme,¹⁷ highlight the growing trend of cross-border academic engagements. There also has been an increase in collaborations between academia and industry aimed at elevating the quality of research and acting as an incentive to retain niche skills.

R&D spending is low and stagnant (less than 1 percent of GDP compared with 3–4 percent in developed countries).¹⁸ There are ongoing issues in intellectual property protection, such as stricter bars, additional tests, the linkage between marketing, patent approvals and a lack of incentives for industry-wide investment. A clear intent is to catalyse R&D through regulatory and policy reforms to address these issues. The National Policy on Research and Development and Innovation in the Pharma-MeDiTech sector is focused on streamlining approval processes, enhancing funding, improving infrastructure and fostering industry-academia collaboration and was launched in 2023.¹⁹ This policy draws on best practices from global regulatory agencies and includes Research Linked Incentives (RLI) scheme to incentivise R&D. Recent announcements have allocated budget for regulatory body capacity building and have proposed the use of ICMR labs for both public and private research by industry and academia. ICMR is in the process of implementing a new programme to promote research and innovation through collaborating Centres of Excellence (CoEs) and ICMR labs, along with reforms in clinical trial norms and increased support for R&D through funding and infrastructure. Further, the 'Pharma & Medical Devices Startup Grand Challenge,' the 'Biotechnology Ignition Grant,' and the 'Biotechnology Industry Partnership Programme drive innovation and support start-up growth. Upcoming reforms include the establishment of an interdepartmental research committee and the creation of multidisciplinary innovation hubs designed to facilitate collaboration among industry, academia and start-ups, accelerating advancements in biotechnology and related fields.





Pharma R&D innovation

Overview of the pharma R&D innovation landscape

The pharmaceutical innovation landscape in India is evolving, bolstered by a rising focus on developing new therapies and an increasing number of early-stage clinical trials focused on advancing healthcare solutions and improving patient outcomes. This emphasizes the potential for future growth in pharmaceutical R&D innovation in India, with increased research by Indian companies and start-ups, government initiatives and advancement in digital technologies.

Innovation in various therapeutic areas is nascent and is gradually gaining maturity. In candidate

selection, gene therapy and gene editing are still in early development, with most start-ups yet to initiate clinical trials in this domain. The Indian government and private sector are investing in improving infrastructure to support these advancements. Cells and tissue therapy and stem cell applications are more established, capitalising on India's large patient population and healthcare infrastructure. In contrast, Chimeric Antigen Receptor-T cell therapies remain in early development. In the drug delivery system, Nano drug delivery is advancing steadily in India, supported by the Nano Mission Programme—a research centre and programme set up by the

Government of India²⁰ and the development of innovative technologies by various companies, reflecting a medium level of maturity in this area. Companion Diagnostics (CDx) is in its early stage of maturity due to the rising interest in personalised medicine and improved patient outcomes, driven by the expansion of middle-class healthcare facilities and the availability of skilled clinicians.

The number of early-stage clinical trials conducted in India has increased significantly in recent years, and the momentum continues to demonstrate a healthy growth rate across all phases, with Indian institutions and pharmaceutical companies leading as the primary sponsors. This can be attributed to streamlined processes, enhanced research outcomes, significant regulatory and policy landscape improvements, and advancements in capabilities, talent acquisition and infrastructure.²¹ Notably, top Indian institutions and pharmaceutical corporations such as Zydus Lifesciences, Intas Pharmaceuticals, PGIMER, Sun Pharmaceutical and Viatris are the top sponsors of this spike, highlighting India's growing prominence in the world's clinical research arena.

India has witnessed a substantial increase in clinical trials within new therapy areas, with Indian

institutions and pharmaceutical companies leading as the primary sponsors. Cell and gene therapy has seen remarkable growth, with clinical studies in this area expanding significantly over recent years. The surge in cell and gene therapy trials in India aligns with global trends, underscoring the country's growing prominence in innovative therapeutic research. This resurgence highlights the sector's resilience and the growing commitment to advancing innovative therapies, driven by the continuous efforts of key stakeholders in the industry.

This increasing trend in trials also mirrors India's growing prominence in frontier fields such as platform-based genetic vaccines, where many trials were centred around these cutting-edge technologies during this time. This development highlights India's increasingly pivotal role in driving innovation in the global therapeutic landscape. By supporting these early-stage trials, Indian academic institutions and pharmaceutical corporations demonstrate their leadership in the country's clinical research environment. The top 5 sponsors include Stempeptic Research, PGIMER, ICMR, Reliance Life Science and AIIMS.

Industry challenges in pharma R&D innovation

The pharmaceutical industry in India faces significant challenges in terms of limited research funding for researchers in conducting large-scale clinical trials for innovative therapies. Moreover, a weak intellectual property environment discourages investments due to inadequate protection of innovators' rights. The lack of adequate infrastructure and database resources is evident, with limited genomic labs in India compared with global standards. Out of

approximately 100,000 pathology labs in India, only 500 to 1,000 conduct genome sequencing. In India, CSIR has completed 1,008 whole genome sequencing projects, to expand this to 20,000 in the next few years. On the other hand, Genomics England has completed sequencing 100,000 genomes and plans to increase this number to 500,000 over the next five years.²²

Drivers for change

Government initiatives

Government of India has implemented several initiatives to drive innovation in this space. Stem cell research laboratories have been established at 40 research institutions, while the National Biopharma Mission is advancing the development of a vector manufacturing facility and expanding CAR T-cell manufacturing capabilities to two additional organisations. The ICMR and Department of Health Research have established “Centres of Excellence” at 7 IITs to promote MedTech innovations. ICMR also operates 63 Next Generation Sequencing (NGS) facilities in 84 institutes spread across 24 states and 3 union territories.²³ The Open-Source

Drug Discovery (OSDD) initiative, led by CSIR, is a transitional platform targeting novel therapies for neglected tropical diseases such as tuberculosis, malaria and leishmaniasis. The GOI has allocated US\$46 million to the OSDD project, with US\$12 million disbursed.²⁴ Key contributors to this initiative involve CSIR laboratories (Institute of Genomics and Integrative Biology, Indian Institute of Integrative Medicine, NIPER Mohali, Central Drug Research Institute), academic institutions (IIT Madras, IIT Bombay, IIT Delhi) and industry/private partners (AstraZeneca, TCG Lifesciences, Infosys and HP).

Ecosystem players and pharmaceutical companies

Immunoact is advancing research in novel humanised CAR-T cell therapy, specifically H-CAR T-19, designed to treat certain types of blood cancer and has shown promising results within one week of administration. The treatment cost in India is approximately INR40 lakh per patient, significantly lower than INR4 crore abroad.²⁵ Intas Pharmaceuticals is establishing a Centre of Cell and Gene Therapy dedicated to developing next-generation gene and cell-based therapeutics. This initiative addresses various conditions, including blood disorders, blindness, muscular dystrophy

and various cancers. Meanwhile, 4Basecare and AstraZeneca are developing liquid biopsy panels using cfDNA (cell-free DNA) technology, providing comprehensive insights into tumour biology.²⁶ The Serum Institute of India has developed the Covishield vaccine, a recombinant chimpanzee adenovirus vector vaccine, through technology transfer from AstraZeneca and Oxford University. Additionally, Cipla has invested in Ethris, a leader in delivering mRNA directly to the respiratory system, to support the development of m-RNA-based inhalation treatments.²⁷

Future outlook

Indian pharmaceutical companies are significantly increasing their investments to maintain a competitive edge and drive innovation in research and development. At the same time, the Government of India is boosting support for the sector with

increased funding and infrastructure investments, particularly in cell and gene therapies. These developments are expected to create a more dynamic and collaborative research environment.

Biologics and Biosimilars landscape and how it can be a game changer for the Indian pharma industry

India has emerged as a prominent biosimilar ecosystem compared with other countries in the last decade. This trend has been supported by government initiatives that include streamlined policies and incentives to encourage industry expansion. India is expected to enhance its position in the biosimilar sector in the next 5 years. With ongoing governmental support and a strengthening industry base, India is likely to become a significant competitor in the global biosimilar market, challenging established Western players.

Market attractiveness

The BioPharma market, of which Biosimilars and Biologics occupy a significant portion, is expected to grow to US\$63 billion by 2025. The biosimilar market is expected to grow at a healthy rate of 30 percent until 2047, provided good government reforms are implemented effectively.²⁸ Treatments for Cancer,

Autoimmune Diseases and Diabetes primarily drive it. In the antibody biotherapeutic landscape, immune disease indications currently dominate. However, recent trends in clinical development indicate that oncology applications are increasingly taking the lead in active development efforts.

This is because of the following factors

Per Deloitte analysis, by 2030, biologic products valued at approximately US\$100 billion will lose their patent protection globally, creating a significant opportunity for Indian biopharma companies to expand their portfolio of biosimilar products.

In India, where innovator biologics can be expensive and less accessible to the general population, biosimilar companies have a significant opportunity to contribute to indigenous drug development. This can enhance the affordability and availability of life-saving treatments. India already leads with 95 approved biosimilars in the domestic market, surpassing any other country.²⁹



Key emerging themes in biosimilars

The biosimilar ecosystem in India is flourishing compared with other countries, driven by a growing demand for safer biologics and effective biosimilars.

This growth is supported by advancements in technology and manufacturing, rising deal activity and favourable government policies and support.

High demand from chronic and unmet clinical needs



- In addition to being effective and safe, biosimilars, by targeting the prevalent chronic diseases that are increasing rapidly, play a crucial role in enhancing the quality of life for millions of patients and, thus, saving billions of dollars for the healthcare system every year.
- Biosimilars will also play a positive role in drug pricing, making the market more competitive.
- Biologics and biosimilars have also treated rare diseases and addressed unmet needs and conditions. Current treatments face challenges of safety, efficacy, convenience or other factors.

Biosimilars are driving innovation in BioTechnology



- Unlike generics with simpler manufacturing procedures, biosimilars are produced using living cells through intricate and multistep processes. This has driven significant advancements and innovations in biotechnology and chemical analytics. These innovations include sophisticated gene cloning processes, higher-yielding host cells, improved and efficient bioreactor technology and tighter manufacturing to minimise structural variation in biologics.
- Prominent names in this industry include Reliance Life Science Group, USV, Inbiopro, BioGenomics and Biocon, with several biologics in their pipelines, which have either been launched or are in the development stage.

Increasing licensing deals and collaborations



Biosimilar manufacturers are maintaining their competitive advantage through joint ventures and other collaborations. There have been numerous such collaborations between Indian players and their global counterparts:

- With the acquisition of Viatrix, Biocon Biologics emerged as the world's leading biosimilar player with eight commercialised products.³⁰
- Biocon Biologics has out-licensed two Biosimilar assets to Yoshindo for commercialisation in Japan.³¹
- Dr. Reddy's has collaborated with Prestige BioPharm to commercialise a trastuzumab biosimilar in select Latin American and Southeast Asian countries.³²

Government of India initiatives



- The revised Guidelines on Similar Biologics released by the Central Drugs Standard Control Organisation (CDSCO) and Department of Biotechnology (DBT) have provided a simplified, efficient and well-defined pathway for manufacturing processes assuring safety and efficacy.²⁹
- DBT, the Biotechnology Industry Research Assistance Council (BIRAC), and the Indian government are working to establish India as a leading hub for biotechnology innovation and research. This collaboration involves policy initiatives and investments, promoting industry-institute collaborations, creating entrepreneurship cells to support biotech start-ups and advancing skill development.
 - The Indian Government also supports the development of in-house biological drugs through “Make in India” by providing skill development platforms and research grants.
 - BIRAC-led “National Bio-Pharma Mission,” which is a collaboration between DBT and the World Bank, with a funding allocation of US\$250 million to boost research and development of biopharmaceuticals.²⁹
 - BIRAC is supporting 300–500 start-ups every year, creating a conducive environment for biotech start-ups in the country and the number of start-ups is projected to reach 10,000 by 2025.²⁹

The biosimilar market in India is rapidly expanding and is projected to sustain this growth through 2030. Key players are fortifying their market positions through strategic collaborations, while new entrants are benefiting from strong government support to enhance healthcare affordability and accessibility. With ongoing innovation and collaborations, India is set to solidify its global presence in the biosimilar sector.





Digital Innovation

Overview of digital innovation in the Indian context

India is undergoing a transformative drug discovery and development phase, propelled by integrating advanced digital technologies. Digital innovation, while still in its early stages, is proving to be a key enabler and potential disruptor in this sector. Technologies such as AI, Deep Learning (DL) and data analytics are becoming essential tools for optimising various stages of the drug discovery process, offering significant improvements in time, cost and overall efficiency. The adoption and maturity of digital use cases in the drug development lifecycle in India are growing rapidly, showcasing immense potential for tangible impact. However, despite these promising advancements, several growth-phase challenges must be addressed to make the most of these

technologies. These include gaps in funding, the need for clearer regulatory frameworks, concerns around data privacy and cybersecurity and a shortage of specialised skills in AI and data science. Overcoming these obstacles is crucial to unlock the significant cost and time efficiencies that digital technologies promise. The growing expenditure on healthcare AI, the surge in AI-driven patent activity and the increasing collaboration among pharmaceutical companies, government bodies and academia through grants and awards indicate India's potential to become a leader in digital drug discovery and development, provided these challenges are effectively managed.

Growth-phase hurdles

While the adoption of digital technologies in India is increasing, several limitations must be addressed to use their potential in the pharmaceutical sector. One of the primary challenges is the limited funding from venture capital and private equity firms, which constrains the pace of innovation. Additionally, there is a need to enhance regulatory capacity to understand and embrace technology, mainly through an ethical and patient-centric approach. Data privacy and cybersecurity concerns also pose significant challenges, as many Indian organisations

fall short in data protection, raising privacy concerns. Furthermore, the shortage of specialised skills in AI and data science presents another hurdle, limiting the adoption of advanced technologies. The convoluted and non-standardised regulatory framework, which often fails to account for technology-specific components, further complicates the landscape and creates barriers to innovation. Addressing these challenges is crucial to unlocking the full potential of digital transformation in India's pharmaceutical industry.

Drivers of growth

Industry collaborations

Collaborations among pharma tech players, the government and the industry are driving significant growth in India's pharmaceutical innovation ecosystem. Start-ups receive mentorship, financial assistance and access to advanced facilities. For instance, AstraZeneca's Innovation Challenge offers cross-country mentorship and access to the AIIMS Jodhpur incubation centre and AZ labs.³³ At the same time, Merck's Uptune programme provides up to €100k in financial assistance to start-ups in digital health, cell and gene therapy and other innovative technologies.¹² Additionally, Pfizer, in collaboration with public collaborators, has awarded grants totalling INR65 lakh through its INDOvation programme, along with mentorship and technical assistance to digital health and oncology start-ups.³⁴ Government-backed initiatives, such as the Society

for Innovation and Entrepreneurship (SINE) at IIT Bombay and the Healthcare Technology Innovation Centre (HTIC) at IIT-Madras, supported by BIRAC, also contribute to this growth.³⁵ These centres provide incubation support, prototyping grants, infrastructure, access to business support services and seed funds to MedTech start-ups, helping them scale and innovate. Prominent contributors to this ecosystem include the Department of Science & Technology, BIRAC, Startup India and Sanofi, among others, which support numerous start-ups such as Whiterabbit.ai, Clarity Bio Systems India, Haystack Analytics, Neos HealthTech, Ubiqare Health and Buzzark Simulations. These collaborations and initiatives are positioning India as a pharmaceutical innovation hub by nurturing a robust digital innovation ecosystem.

Government initiatives

Government-led initiatives such as the Start-up India Seed Fund and Aatmanirbhar Bharat App Innovation Challenge provide crucial support to start-ups and foster innovation in the sector. The Scheme for Promotion of Research and Innovation in the Pharma MedTech Sector (PRIP) has been launched to bolster research and innovation capabilities. This scheme aims to facilitate cutting-edge research in the pharmaceutical and medical technology sectors,³⁶ with a total outlay of INR5,000 crore (approximately US\$604.5 million) approved from 2023–2028. Critical

components of this scheme include grants for advanced research, support for technology transfer and the establishment of specialised research centres. Healthcare Technology Innovation Centre is a joint initiative by IIT-Madras and DBT, supported by BIRAC, which provides infrastructure, access to business support services, industrial interactions, mentoring, seed funds and training programmes to MedTech start-ups (Neos HealthTech, Ubiqare Health and Buzzark Simulations).³⁷

Rising patent activity

The increasing number of patents filed, particularly in AI-driven drug discovery, indicates a growing emphasis on innovation. The country is one of the largest markets globally for AI-driven drug discovery, reflecting its growing focus on using cutting-edge technologies for pharmaceutical innovation. Per Deloitte analysis, between 2016 and 2022, there has been a dramatic rise in patent activity, with the number of patent families alive and pending in India increasing 15-fold since 2016 and more than doubling in 2021 alone. This surge demonstrates the

significant advancements and investments in AI and ML technologies within the pharmaceutical sector. Examples of innovative patents include research from the Karunya Institute of Technology and Sciences on target protein prediction for infectious diseases and the Lloyd Institute of Engineering and Technology's AI system to direct drugs to faulty DNA sequences or tailor gene sequences. These advancements are pivotal in positioning India as a hub for pharmaceutical innovation, driven by its robust digital and AI capabilities.

Future outlook

The adoption of AI, data analytics and RWE is transforming drug discovery and development and driving sustained growth in patent activity in the pharmaceutical sector. There is also a trend towards inorganic growth, with companies increasingly acquiring or investing in smaller pharma tech players

to bolster their capabilities and innovation portfolios. As India matures in adopting digital innovation in drug discovery, the potential for unlocking tangible benefits is immense. The industry is poised for a future where AI, data analytics and RWE are central to driving efficiency and innovation.



Key technologies revolutionising drug discovery and development in India

Although several technologies have shown high impact potential in this sector, only a limited number have been most widely adopted in India:



Decentralised clinical trials: Reducing or eliminating the need to travel for study participation through trial hubs, home treatment, telemedicine, wearables, etc.
Successful adoption in India:

- **Anju Software:** Managed over 10,000 patients in a single study using TrialMaster electronic data capture
- **Advarra:** Improved protocol compliance and facilitated virtual visits with integrated decentralised clinical trial solutions
- **IQVIA:** Conducted 30+ decentralised trials across 75+ countries



AI and analytics-driven genomics: Enhancing cell and gene therapies using digital technologies
Successful adoption in India:

- **Strand:** GeneSpring software cited over 25 thousand times in Google Scholar for genomics analysis
- **MedGenome:** Sequenced over 250 thousand exomes and genomes, delivering zero false negatives in 40,000 Non-Invasive Prenatal Testing samples
- **Cleverage:** Processed over 90 thousand samples across over 2,600 projects, providing deep molecular insights



AI/ML-driven digital biomarkers: Objective, quantifiable, physiological and behavioural data collected and measured via digital devices
Successful adoption in India:

- **Innoplexus:** Identified drug leads using data from 95 percent of public life sciences sources
- **OncoStem Diagnostics:** Developed "CanAssist Breast Biomarkers" for cancer prognosis using ML algorithms
- **Tata Medical Centre and IIT:** Launched a de-identified cancer image bank to improve biomarker detection



Next-generation sequencing: Generating multiple levels of genomic data for drug discovery, including transcriptome profiling and epigenetic modifications.
Successful adoption in India:

- **Clevergene:** Enabled discovery of genetic variations with genome and RNA sequencing
- **4basecare:** Collaborated with AstraZeneca India for DNA and RNA NGS-based genetic testing
- **MedGenome:** Delivered single-cell NGS and bulk transcriptomics, sequencing over 250 thousand exomes and genomes



Analytics-driven drug development: Software/data-driven methods using data to create efficiencies in clinical trials and quality management processes
Successful adoption in India:

- **Excelra:** Reduced study timelines by 15 percent with data mining and bioinformatics services
- **Radiant Sage:** Centralised clinical trial management through SaaS solutions, improving resource efficiency by 25 percent
- **THB:** Provided end-to-end support with insights from over 1 billion clinical parameters



Data-driven drug discovery (Enabled by AI/ML): End-to-end drug discovery or accelerating part of discovery using AI (ML/NLP, knowledge graphs or any algorithms)
Successful adoption in India:

- **SPARC:** Collaborated with OneThree Biotech for AI-driven discovery of anticancer compounds
- **Peptris:** Used AI/ML to design neural network architectures, curating millions of biological data points
- **Sravathi AI:** Designed 250,000 molecules with AI, advancing the discovery of COVID-19 treatments



AI-driven pharmacology and toxicology in preclinical and clinical studies: Includes diagnostic and pathology services in preclinical and clinical studies.
Successful adoption in India:

- **Aira Matrix:** Improved preclinical toxicology efficiency with hybrid DL-based models
- **Qure.ai:** Enhanced treatment pathways with a 17 percent improvement in sensitivity using AI for chest X-rays
- **Farcast Biosciences:** Combined AI with human tumor microdynamics for precise treatment response biosignatures.



Clinical trial and design management: AI and data-led design of clinical studies and trial management, including patient monitoring, reporting and analysis
Successful adoption in India:

- **Innoplexus:** Accelerated clinical trial design by analysing data from over 100 databases
- **Clinevo technologies:** Achieved a 15 percent reduction in study timelines with cloud-based management systems
- **IQVIA:** Improved trial site identification by 46 percent using predictive modelling and real-world data



Data integration for clinical decision-making: Focuses on developing infrastructure to store, organise and access internal data to facilitate clinical development decision-making (e.g., Indication Strategy)
Successful adoption in India:

- **Strand Lifesciences:** Conducted over 132 trials, integrating AI and tech for clinical decision models
- **Elucidata:** Reduced analysis time by 70 percent with the ML-based platform 'Polly'
- **National Cancer Grid:** Established the Koita Centre for Digital Oncology to promote AI-assisted decision support tools

Source: Company Websites



Talent pool and industry-academia collaboration

Overview of talent and academia landscape

Talent availability

The Indian pharmaceutical sector is currently grappling with a significant imbalance between the growing pool of advanced degree holders and the specific expertise required by the industry. This disparity is evident as there is a decrease in PhD graduates from top pharmacy institutes between 2019 and 2024, signalling a shortfall in niche skills, particularly in emerging fields such as AI/ML

and computational biology. Additionally, in 2023, approximately 58 percent of B. Pharma graduates are deemed job-ready.³⁸ However, a substantial disconnect remains between industry requirements and the competencies provided by academia. This mismatch contributes to the ongoing challenges in filling specialised roles within the sector.

Research output

India's research output has gradually improved, particularly in its contribution to global pharmaceutical publications, which increased to 7.30 percent in 2024. This growth is primarily driven by the top pharmacy institutes, which account

for 56.64 percent of all publications.³⁹ Despite these challenges, there has been growth in the enrolment of PhD students in Indian pharmacy institutes, suggesting a gradual improvement in the development of research talent within the country.

Limitations

Skill gaps and attrition

Despite the increase in qualified professionals, the industry struggles with significant skill gaps, with high attrition rates of approximately 30 percent, well above the global average of 12 percent.⁴⁰ Brain drain remains a pressing issue, with highly skilled researchers increasingly seeking opportunities abroad due to better infrastructure, funding and career prospects. This outflow of talent is compounded by a lack of support for niche skills,

such as drug safety and regulatory affairs, leaving India with a talent gap that hampers its innovation potential. Surveys conducted by NASSCOM, IIM-A and NABP between 2018 and 2020 reveal that a small percentage of respondents reported strong skill availability in crucial areas such as data science, AI/ML, drug discovery, clinical trials and regulatory affairs.

Quality of research and industry-academia collaboration

While India's research output has grown, the quality of this output remains a concern. Indian pharmaceutical companies invest approximately 7 percent of their net sales in R&D, significantly lower than the 15-20 percent typically spent by global counterparts.⁴¹ This underinvestment reflects the declining ability to produce high-value patents and India's poor standing in global research rankings, with Indian research institutions ranking at 452 out

of 500 institutions in 2024, according to the SCIMAGO institutional rankings.⁴² Moreover, the effectiveness of industry-academia collaborations in India's pharmaceutical research sector has been limited, with few collaborations driving significant innovation. Five of the top 10 industry players have collaborated on fewer than four publications, underscoring the need for stronger collaborations to drive research and development.

Drivers of change

Government initiatives

Several emerging trends and initiatives offer hope for strengthening the talent pool and fostering industry-academia collaboration. Recent data indicates a notable increase in the number of Indian nationals returning to India for research and development purposes. The number of MS and PhD students enrolled has increased from 1,142 in 2021 to 1,525 in 2023 across the 7 NIPERs in the country.⁴³

Additionally, there has been a threefold increase in Indian MBBS graduates from international universities seeking to practice in India, equivalent to about 30 percent of total medical seats in the country. These trends indicate a growing interest in participating in India's research ecosystem, which could be used through stronger industry-academia collaborations.

Reverse brain-drain

The Department of Biotechnology introduced the Ramalingaswami Re-entry Fellowship to attract up to 75 foreign Indian Nationals to take up research positions annually. This fellowship has supported the return of over 500 scientists to India since 2007.⁴⁴ The Indian government is actively taking measures to make research in India more attractive. It has recognised the need to address the challenges of integrating academic research with industry needs and has implemented several strategic measures. These include enhancing the role of

ICMR labs in public-private-academic collaborations, expanding early-stage research facilities and establishing innovation hubs and centres of excellence. Additionally, the formation of inter-departmental research councils aims to promote cross-disciplinary cooperation, while the setup of patent and technology transfer offices (IPOs/TTOs) within academic institutions is designed to facilitate intellectual property management and technology commercialisation.

Future outlook

Private sector investment in industry-academia collaboration is expected to continue enhancing translation research and providing more PhD guidance from sector leaders. Additionally, government and industry-backed international collaborations and grants contribute to this effort. There is a growing emphasis on building capabilities and developing niche skills, including hiring professionals from tech backgrounds for data science roles and using talent pools returning from abroad. These combined efforts aim to strengthen the research ecosystem, fostering innovation and retaining specialised talent.



Notable industry collaborations

The effectiveness of industry-academia collaborations in India's pharmaceutical research sector has been limited, posing challenges to innovation and the commercialisation of research. Although India has seen a growing number of research publications, there is a notable lack of

collaboration between industry and academic institutions. Five of the top 10 industry players have collaborated on fewer than four publications. GSK and Bristol-Myers Squibb are among the few leading collaborators, highlighting the need for more robust collaborations to drive research and innovation.

<p>Dr. Reddy's Institute of Life Sciences and NIPER Hyderabad</p> <p>Aimed at fostering research and academic collaboration in pharmaceutical sciences, particularly process innovation, process analytical technologies and drug discovery programmes in infectious and rare diseases.</p>	<p>Zeon and NIPER Mohali</p> <p>Conduct collaborative research activities encompassing pharmaceutical technology, synthesis, analytical techniques and pharmacotherapeutics to examine the product formulation and its development and conduct joint clinical trials</p>	<p>GSK</p> <p>Developed PhD programmes with the Regional Centre for Biotech to cater to data and AI-driven pharma research demand</p>
<p>Pfizer</p> <p>Company's first Global Drug Development centre in Asia-set up in IIT-Madras research park</p>	<p>Excelra</p> <p>Advance drug repurposing using NLP/ML with IIT-Kharagpur</p>	<p>Merck</p> <p>"High-tech Skill Development Centre" set up with CSIR-IMTECH</p>





Regulatory and policy reform

Overview of the regulatory landscape in India

India's pharmaceutical ecosystem is transforming significantly, supported by comprehensive regulatory and policy reforms to foster innovation and growth. The regulatory framework, which governs drug discovery, development and commercialisation, is being actively enhanced to streamline approval processes, increase transparency and reduce barriers to entry for innovative products.

A key milestone in this transformation has been the implementation of the Clinical Trial Rules 2019, which have significantly reduced the approval timeline

for clinical trials to 90 days.⁴⁵ This acceleration has enhanced India's appeal as a preferred destination for clinical research. The National Single Window System, a digital platform, has also been introduced to simplify regulatory processes for medical devices in India.⁴⁶ Further, introducing the Pharmaceuticals Policy 2020 aims to encourage research and innovation, ensure quality standards, and make healthcare accessible and affordable. This policy is a comprehensive effort to promote the growth of the pharmaceutical sector by enhancing access to affordable medicines and fostering an environment conducive to innovation and quality manufacturing.

Policy impediments and challenges

Despite these advancements, several policy challenges continue to hinder the growth of India's pharmaceutical R&D sector, such as inadequate capacity for drug regulation, the need for advanced testing facilities and the lack of a strong framework for monitoring quality compliance in manufacturing units. There is scope for harmonisation between state and central policies to ensure a uniform regulatory environment across the country. There is also a lack of alignment among different regulatory bodies, resulting in overlapping jurisdictions and inconsistent regulatory outcomes. Additionally,

bureaucratic complexities within the regulatory framework led to extended timelines for drug approvals and clinical trials, making India less attractive for conducting high-quality clinical research. Another major challenge in this area includes the high cost of compliance with global standards, which can be particularly burdensome for Small and Medium-Sized Enterprises (SMEs). Addressing these specific impediments through streamlined processes and clearer regulations is essential for enhancing India's position in global pharmaceutical R&D.

Drivers of change

Strengthening intellectual property protections

Reforming the Intellectual Property (IP) landscape is another critical component of the regulatory changes to foster innovation. The government has recognised the need to reduce the pendency time for patent approvals, currently averaging 50 months—substantially higher than the global average.⁴⁷ By targeting a reduction to approximately 30 months, the government aims to align India's IP framework

more closely with global standards, enhancing its appeal to international pharmaceutical companies. Furthermore, introducing Patent Term Extension (PTE) and Data Exclusivity (DE) provisions is expected to provide additional incentives for pharmaceutical companies to invest in innovative drug development.

Incentives for innovation and collaboration

The Research Linked Incentive (RLI) Scheme represents a significant policy shift towards encouraging innovation in the pharmaceutical sector. This scheme offers financial incentives for early-stage research to reduce the financial risks associated with drug discovery and development. With a budget allocation of INR5,000 crore⁴⁸ (approximately US\$670 million) over the next five years, the RLI scheme is expected to support over 500 R&D projects, particularly in high-impact areas such as biosimilars, complex generics, orphan drugs, precision medicines, vaccines and antibiotics. Establishing Centres of Excellence (CoEs) in premier academic institutions aims to promote cutting-edge research in biotechnology, genomics and personalised medicine. These CoEs are projected to increase the number

of collaborative research projects, further bridging the gap between academic research and industrial application.

Additionally, the National Biopharma Mission, launched in June 2017, continues to play a vital role in promoting industry-academia collaboration to accelerate biopharmaceutical development in India.⁴⁹ The mission focuses on enhancing indigenous production capabilities and reducing import dependency. New initiatives under this mission include grants for translational research and Public-Private Partnerships (PPP) to expedite biotech innovations' commercialisation.

Addressing infrastructure and funding gaps

The government has introduced several initiatives to bridge the existing infrastructure and funding gaps, including the Strengthening of Pharmaceuticals Industry (SPI) scheme.⁵⁰ This scheme is designed to enhance the sector's competitiveness through financial support for infrastructure development, technological upgrades and the creation of common facilities. The SPI scheme includes three key sub-schemes:

- **Assistance to Pharmaceutical Industry for Common Facilities (APICF):** Provides grants up to INR20 crore per cluster to develop common facilities such as testing labs and effluent treatment plants⁵¹
- **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS):** Offers up to 5 percent per annum interest subvention or a 10 percent capital subsidy on loans for technology upgrade⁵²
- **Pharmaceutical and Medical Devices Promotion and Development Scheme (PMPDS):** Supports awareness programmes,

studies and infrastructure development to promote the pharmaceutical and medical device sectors⁵³

Additionally, the government has launched the Production Linked Incentive (PLI) Scheme for pharmaceuticals, with a budget of US\$2.04 billion (INR15,000 crore). This scheme is designed to boost domestic manufacturing capacity by providing financial incentives based on incremental sales of products under target segments such as critical bulk drugs and drug intermediates.⁵⁴ The PLI scheme has attracted significant interest, with several companies committing to setting up new manufacturing units and expanding their existing facilities.

The expansion of ICMR labs for collaborative research and initiatives such as supporting C-CAMP and BIRAC's Bio-NEST, which have commercialised over 800 products and filed more than 1,300 IPs, further enable PPPs and foster a more integrated research ecosystem.⁵⁵

Enhancing global collaboration and compliance

The government is committed to aligning India's regulatory framework with global best practices to enhance its competitiveness. Key initiatives include adopting adaptive trial designs, rolling submissions based on Real World Data, and Real World Evidence to make the regulatory process more flexible and responsive. Additionally, the draft policies propose increased collaboration with international regulatory agencies such as the US FDA and EMA to facilitate

faster drug approvals. These initiatives are expected to reduce the time-to-market for new drugs, aligning India more closely with global standards and enhancing its reputation as a hub for pharmaceutical innovation. The Government of India has also signed multiple bilateral agreements to promote mutual recognition of drug approvals, further streamlining the process for Indian pharmaceutical exports.

Focus on digital transformation in regulatory processes

Digital transformation is a cornerstone of the ongoing regulatory reforms. The development of a Digital Regulatory Platform (DRP) aims to create a single window for regulatory approvals, reducing the time and cost associated with the approval process. This platform, powered by blockchain technology, will ensure data integrity and security, enhancing transparency and trust in the regulatory process. Moreover, deploying AI-based tools to

assist in evaluating clinical trial data is expected to reduce review times by 30 percent and improve the accuracy of the evaluation process, making the regulatory framework more robust and efficient. The government's National Digital Health Mission also aligns with these objectives, focusing on creating a digital backbone for healthcare delivery, including pharmaceuticals.

Future outlook

To address existing challenges, the Indian government has introduced several new policies to enhance the pharmaceutical innovation landscape further. The "Draft Policy to Catalyse R&D and Innovation" aims to reduce drug approval timelines by 50 percent.⁵⁶ This policy includes establishing a National Research Development Corporation (NRDC) to oversee and coordinate research activities across sectors, ensuring a unified approach to innovation. Additionally, the policy proposes creating a Comprehensive Science Policy Platform (CSPP) to integrate efforts across various ministries and departments. These initiatives aim to increase India's share in the global R&D market from 2 to 5 percent by 2025, positioning the country as a significant player in pharmaceutical research.

Moreover, the Interim Budget 2024–25 earmarked US\$120 million (INR 1,000 crore) for promoting bulk drug parks, a significant increase from the previous year, and allocated a total of US\$156.5 million (INR 1,300 crore) for the overall development of the pharmaceutical industry for FY25. The budget also includes US\$18 million (INR150 crore) for promoting medical device parks, further underlining the government's commitment to fostering a comprehensive ecosystem for the pharmaceutical and medical devices sectors.⁵⁷

In alignment with these policy reforms, India also uses its diverse industrial base to support pharmaceutical growth. Key states such as Gujarat, Maharashtra, Telangana and Andhra Pradesh have emerged as crucial hubs for pharmaceutical manufacturing, hosting major facilities for companies such as Cadila, Lupin and GSK. These states provide strategic advantages, including access to local infrastructure, skilled labour and state-specific incentives, fostering a conducive environment for R&D and large-scale production. By geographically diversifying these pharmaceutical ventures, the government not only enhances regional development but also strengthens the resilience and capacity of the country's pharmaceutical sector to meet global demands. This regional spread of manufacturing capabilities complements broader regulatory initiatives and reinforces India's commitment to becoming a global pharmaceutical innovation and production leader.

India's regulatory and policy reforms are crucial for shaping the future of pharmaceutical R&D by streamlining approval processes, strengthening IP protections and incentivising innovation. As India modernises its regulatory framework and enhances collaboration with global regulatory agencies, it is well-positioned to become a global leader in pharmaceutical innovation.





Future of India's pharmaceutical industry

In the next 5–6 years, India should capitalise on increasing investments in the pharmaceutical sector by making conscious efforts and focusing on key strategic areas. The country must upgrade its infrastructure and embrace advanced technologies such as AI and data analytics to transform drug

discovery and development. Strengthening collaboration between industry and academia, investing in talent and successfully implementing new policies aimed at accelerating R&D and streamlining processes will be vital to creating a vibrant innovation ecosystem.

We believe the recommendations below would help position India as a hub for pharmaceutical research and development, with a robust ecosystem capable of supporting global standards and driving innovative advancements.

01

The government should actively promote India as a leading hub for pharmaceutical discovery and preclinical and clinical research. Using its expanding CRO sector, cutting-edge research centres, cost efficiency and diverse patient base, India can position itself as an attractive collaborator for global pharmaceutical companies in these areas.

02

Currently, most government research grants are limited to institutions and academic centres, with few exceptions for private companies. The Department of Pharmaceuticals should introduce similar provisions for research grants, financial incentives and funding support to encourage private CROs to participate in early discovery and clinical research in India.

03

To attract FDI into the pharmaceutical sector, the government should invest in modern research infrastructure, including shared laboratories, advanced equipment and drug discovery facilities. This infrastructure should be accessible to private CROs and pharmaceutical companies on a "usage-based model" and managed by independent agencies to ensure efficiency.

04

The government and educational institutions should design and regularly update specialised courses for the pharmaceutical industry, emphasizing AI, data science and best practices. These programmes should be tailored to reflect current industry trends and provide comprehensive training in both core subjects and practical applications.

05

Ensuring patient data privacy and protection is crucial for maintaining confidentiality and building trust. While existing laws provide a foundation, they must be strengthened and aligned with international standards to attract global sponsorships for clinical trials.

06

There is a significant untapped patient population in tier 2 and tier 3 cities in India for pharmaceutical R&D across various therapeutic areas. To increase participation and engagement, educating people on the benefits of such research and addressing awareness-related issues is essential. Campaigns can play a crucial role in dispelling myths, building trust and enhancing understanding of the research process.

Abbreviations

S No.	Abbreviation	Full Form
1	AIIMS	All India Institute of Medical Sciences
2	CAGR	Compound Annual Growth Rate
3	CAR-T	Chimeric Antigen Receptor T cell
4	CMO	Contract Manufacturing Organisation
5	CRAM	Contract Research and Manufacturing Services
6	CRO	Contract Research Organisation
7	CSIR	Council of Scientific and Industrial Research
8	DCT	Direct Coombs Test
9	DNA	Deoxyribonucleic acid
10	EDC	Electronic Data Capture
11	EMA	European Medicines Agency
12	FDA	Food and Drug Administration
13	GDP	Gross Domestic Product
14	GOI	Government Of India
15	GSK	GlaxoSmithKline
16	ICH-GCP	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice
17	ICMR	Indian Council of Medical Research
18	IIM	Indian Institute of Management
19	IIT	Indian Institute of Technology
20	IP	Intellectual Property
21	MBBS	Bachelor of Medicine and Bachelor of Surgery
22	m-RNA	messenger-Ribonucleic Acid
23	MS	Master of Science
24	NAPB	National Association of Boards of Pharmacy
25	NASSCOM	National Association of Software and Services Companies
26	NIPER	National Institute of Pharmaceutical Education and Research
27	NIPT	Noninvasive Prenatal Testing
28	NLP	Natural Language Processing
29	PGIMER	Postgraduate Institute of Medical Education and Research
30	PhD	Doctor of Philosophy
31	RLI	Research Linked Incentive
32	RWD	Real World Data
33	RWE	Real World Evidence

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The Associated Chambers of Commerce & Industry of India (ASSOCHAM) is the country's oldest apex chamber. It brings in actionable insights to strengthen the Indian ecosystem, leveraging its network of more than 4,50,000 members, of which MSMEs represent a large segment. With a strong presence in states, and key cities globally, ASSOCHAM also has more than 400 associations, federations and regional chambers in its fold.

Aligned with the vision of creating a New India, ASSOCHAM works as a conduit between the industry and the Government. The Chamber is an agile and forward-looking institution, leading various initiatives to enhance the global competitiveness of the Indian industry, while strengthening the domestic ecosystem.

With more than 100 national and regional sector councils, ASSOCHAM is an impactful representative of the Indian industry. These Councils are led by well-known industry leaders, academicians, economists and independent professionals. The Chamber focuses on aligning critical needs and interests of the industry with the growth aspirations of the nation.

ASSOCHAM is driving four strategic priorities - Sustainability, Empowerment, Entrepreneurship and Digitisation. The Chamber believes that affirmative action in these areas would help drive an inclusive and sustainable socio-economic growth for the country.

ASSOCHAM is working hand in hand with the government, regulators and national and international think tanks to contribute to the policy making process and share vital feedback on implementation of decisions of far-reaching consequences. In line with its focus on being future-ready, the Chamber is building a strong network of knowledge architects. Thus, ASSOCHAM is all set to redefine the dynamics of growth and development in the technology-driven 'Knowledge-Based Economy'. The Chamber aims to empower stakeholders in the Indian economy by inculcating knowledge that will be the catalyst of growth in the dynamic global environment.

The Chamber also supports civil society through citizenship programmes, to drive inclusive development. ASSOCHAM's member network leads initiatives in various segments such as empowerment, healthcare, education and skilling, hygiene, affirmative action, road safety, livelihood, life skills, sustainability, to name a few.

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