Viksit Bharat@2047: Transforming India from pharmacy of the world to pharma powerhouse to the world

November 2024

OPPI

भारत के लिए

Organisation of Pharmaceutical Producers of India

EY Parthenon

Shape the future with confidence

Fore word

As we look toward India's centennial in 2047, our healthcare and pharmaceutical sectors stand at a defining moment, ready to lead India into an era of unprecedented progress and health equity. This report, **Viksit Bharat@2047: Transforming India from pharmacy of the world to pharma powerhouse to the world**, serves as a blueprint for the role our industry will play in realizing this vision, brought to life through the collaboration between the Organisation of Pharmaceutical Producers of India (OPPI) and EY. It reflects our collective commitment to a future where India's healthcare system is not only self-reliant but also deeply interconnected with global advancements and innovation.

The journey ahead, marked by Amrit Kaal, symbolizes an auspicious era—one that demands resilience, responsibility and foresight. In alignment with India's ambitions to become a developed nation. This period calls for us to extend our reach and impact, ensuring that quality healthcare is both accessible and affordable across the nation. The concept of Kartavya Kaal reminds us that our duty goes beyond our borders; it spans global health needs and our capacity to lead in medicine, technology and equitable healthcare solutions.

The report's vision addresses critical areas of our success: pioneering innovation in research and development, securing a position in the global pharma supply chain, and reinforcing sustainable practices that prioritize equitable healthcare access. By achieving these goals, we are positioning India's healthcare ecosystem as a model of inclusivity and resilience, where every stakeholder—policymakers, providers, pharmaceutical companies, and patient advocates—plays a definitive role in elevating patient care and outcomes.

I am honored to present this forward-looking report as OPPI's President, and I am optimistic about the direction we are taking. This document is not only a guide to navigating emerging challenges but also a celebration of the opportunities within our grasp. We are deeply grateful to EY for their invaluable partnership and to all those who contributed their expertise to shaping this vision for 2047.

It is my hope that this report will inspire every individual and organization involved in India's healthcare sector to embrace this journey with determination and vision. Together, we are charting a path toward a future where India's pharmaceutical and healthcare industries are recognized as pillars of global health and innovation. Let us commit ourselves to this path with the conviction that India's best healthcare era lies ahead, as a beacon of hope, access and progress for all.

Mr. Bhushan Akshikar

President, Organisation of Pharmaceutical Producers of India (OPPI)

As India strides towards its 100th year of independence in 2047, we find ourselves at a historic juncture—a time to redefine the future of our healthcare and pharmaceutical sector. The "**Viksit Bharat@2047: Transforming India from pharmacy of the world to pharma powerhouse to the world**" report is both an ambitious roadmap and a call to action, developed through the collaboration of the Organisation of Pharmaceutical Producers of India (OPPI) and EY-Parthenon. This document offers a vision that aligns with India's broader aspirations under the Amrit Kaal, as introduced during the nation's 75th Independence Day celebrations. Amrit Kaal marks a period of auspicious transformation, encouraging us to set new standards of prosperity while embracing our responsibilities during this pivotal Kartavya Kaal.

Our pharmaceutical industry, already a leader in global healthcare, is uniquely positioned to drive forward this vision. As we face a rapidly evolving landscape, India has the opportunity to solidify its role as a comprehensive provider of healthcare solutions. The challenge is not merely to supply the world with medicines but to advance to a fully integrated approach, from the discovery of molecules to the manufacturing of APIs, intermediates, and cutting-edge therapies. By 2047, our goal is to move beyond formulation dependency, ensuring that India becomes a self-sufficient, innovation-led pharma powerhouse for the world, capable of addressing global health challenges with agility and foresight.

This report highlights critical themes that will define our journey: the potential of value-driven research and high-impact innovation, the creation of a seamless global pharma supply chain, and the pursuit of sustainable and equitable access to healthcare. Each of these areas is pivotal in shaping an ecosystem where patient outcomes are prioritized, and all stakeholders—healthcare providers, pharma companies, policymakers, and payers—work collaboratively within clearly defined roles to deliver accessible, high-quality care across the nation.

As the Director General of OPPI, I am proud to present this report. It captures not only the challenges we face but also the unprecedented opportunities that lie ahead. Viksit Bharat 2047 offers a detailed framework for navigating the next two decades, outlining the enablers and collaborative efforts needed to unlock the full potential of India's pharmaceutical and healthcare sectors. We appreciate the inputs of EY and the many contributors whose insights have made this report a robust guide for an industry on the cusp of transformative growth.

Together, we embark on this journey with a shared commitment to making India a global beacon of health and well-being. Let us ensure that our sector not only thrives but also serves as a catalyst for the future we envision—an India where healthcare is innovative, accessible, and equitable for all.

Anil Matai
Director General - OPPI India

Embarking on a journey toward a new era in India's pharmaceutical landscape, "**Viksit Bharat@2047: Transforming India from pharmacy of the world to pharma powerhouse to the world**" offers a thought-provoking exploration and a visionary glimpse into the transformative trajectory the Indian pharmaceutical industry is poised to undertake over the next quarter-century. The vision of Viksit Bharat@2047 is not merely aspirational but represents a carefully crafted roadmap to position India as a global leader in healthcare innovation and accessibility.

With a projected growth to a staggering US$450 billion market by 2047, India's pharmaceutical landscape is evolving with an unprecedented focus on self-reliance, innovation, consolidation and sustainability. The report also delves into the burgeoning advancements in the production of Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs), and cutting-edge therapies that are poised to redefine India's position as a Global Life Sciences leader. Further, It underscores the pivotal role of digital technologies and India's renowned IT acumen in propelling into innovation and services viz Contract Research and Manufacturing Services (CRDMOs) to new heights, while also emphasizing the significance of quality and compliance in establishing India as an attractive hub for biopharmaceutical investments.

As we delve into this forward-looking report, we encounter a future where the Indian pharmaceutical industry is not just a commercial giant but a beacon of universal healthcare. Initiatives such as Ayushman Bharat and ABDM reflect a deep-seated commitment to making healthcare accessible to the most remote corners of the nation, leveraging the power of digital advancements like telemedicine and beyond the pill applications to offer personalized care.

The vision laid out in this report is one of inclusivity and balance, where the pursuit of technological and industrial growth goes hand in hand with the mission to provide healthcare without disparity. It challenges us to reimagine the healthcare ecosystem as one that is integrally connected to the very fabric of society, ensuring that every individual, irrespective of their socioeconomic status, has access to the care they need. The report is not just a reflection of aspirations but a blueprint of focus areas for the entire healthcare and life sciences ecosystem- industry leaders, healthcare providers, policymakers, investors, startups, academia, to work collaboratively towards achieving the Viksit Bharat ambition.

With this foreword, I invite readers to embark on this journey through the pages that follow, to explore the contours of an industry in metamorphosis, and to envision the future state of India as a leader in pharmaceutical innovation and production on the global stage.

Suresh Subramanian
Partner,
National Life Sciences Leader,
EY India

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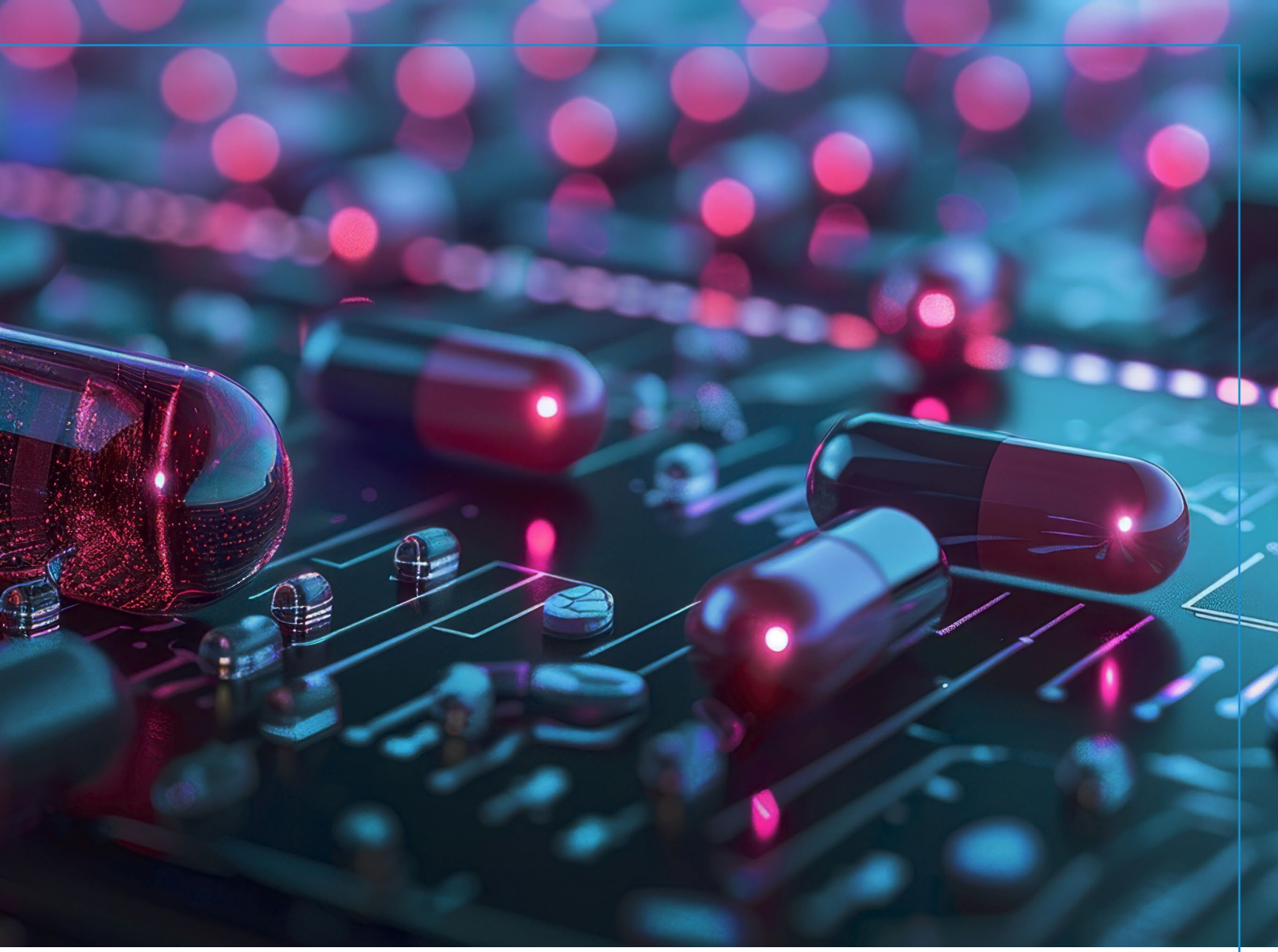
Executive summary

Viksit Bharat envisions a future India where universal healthcare access is a fundamental right for all citizens. This vision aims to ensure that individuals receive the right care at the right time, regardless of geographic or financial constraints. The pharmaceutical and healthcare sectors play a crucial role in realizing this vision.

To achieve the ambitious goal of a healthy nation and establish India as a global pharma and healthcare hub, self-reliance and innovation are critical. The nation aims to become self-reliant in Active Pharmaceutical Ingredients and Key Starting Materials while simultaneously accelerating efforts to move up the innovation value chain. This report discusses how the industry, supported by the government, and in collaboration with startups and academia is innovating in the API/KSM manufacturing space and establishing capabilities to becoming not only self-reliant, but to also expand exports. The expansion of the Contract Research and Manufacturing (CRDM) Organization, geopolitical shifts, diversification of supply chains, global pharma's pivot towards an asset-light model, and impending patent expiries of numerous biologics, are all significant forces that are driving the opportunity in the sector.

To identify the future direction of the industry and develop concrete action items, OPPI and EY conducted primary research with CXOs of leading Indian and global multinational pharma companies, CRDMOs, academic institutions and other organizations to understand their perspective about the pivotal growth areas for the pharma and healthcare sectors in the country. A key finding was the need for a shared vision for innovation as a nation and then collaboratively as a robust ecosystem strive to achieve it by defining key milestones and goals. In addition, quality and talent are pivotal forces for future growth. While quality has been identified as a key focus area across the entire value chain of the industry, essential for moving up the value chain, talent is the most critical enabler of growth, requiring a concerted effort to develop talent equipped to drive innovation and sustain growth.



The report also delves into areas of focus to improve healthcare access and affordability. Several government measures are already in place, and digital technologies can play a vital role as enablers across the value chain. The Ayushman Bharat Digital Mission (ABDM), supported by an ecosystem of startups and health-tech players, can significantly improve access, even in remote areas and will facilitate interconnected data and patient information flow, leading to informed, preventive and predictive care. To further improve affordability, the report also discusses scenarios like improving insurance coverage/penetration and new innovative financing mechanisms that allow patients to get access to the right treatment at the right time. These mechanisms can potentially reduce the overall cost of treatment while improving long-term outcomes.

The pharmaceutical and healthcare sectors are at the cusp of a transformative era, paving the way for a brighter tomorrow. The industry's potential is boundless, transcending borders and establishing a global footprint. Looking ahead, the pharmaceutical and healthcare landscape will be characterized by enhanced connectivity, groundbreaking innovation and an unwavering focus on patient-centric care. To summarize, India's journey towards pharmaceutical pre-eminence necessitates a deliberate fusion of digital innovation, an entrenched culture of quality, and unwavering change from a generic to an innovation mindset. By prioritizing these domains, India is poised to ascend as a dominant force in the global pharmaceutical landscape.

Introduction

Viksit Bharat@2047: A peep into the future state of pharma and healthcare

India's aspiration to become global pharma powerhouse and provide integrated accessible healthcare to every citizen in the country

Viksit Bharat

India becomes the global pharma powerhouse

Innovation-led pharma powerhouse of the world

- India would boast of robust Innovation clusters/ecosystem akin to those found in San Francisco and Boston
- Improved disease understanding will lead to more effective treatment modalities that cure the disease
- We would have potentially launched a few end-to-end indigenously researched and developed next-gen therapy blockbusters in domestic and global markets

Self-reliant API and KSM* industry

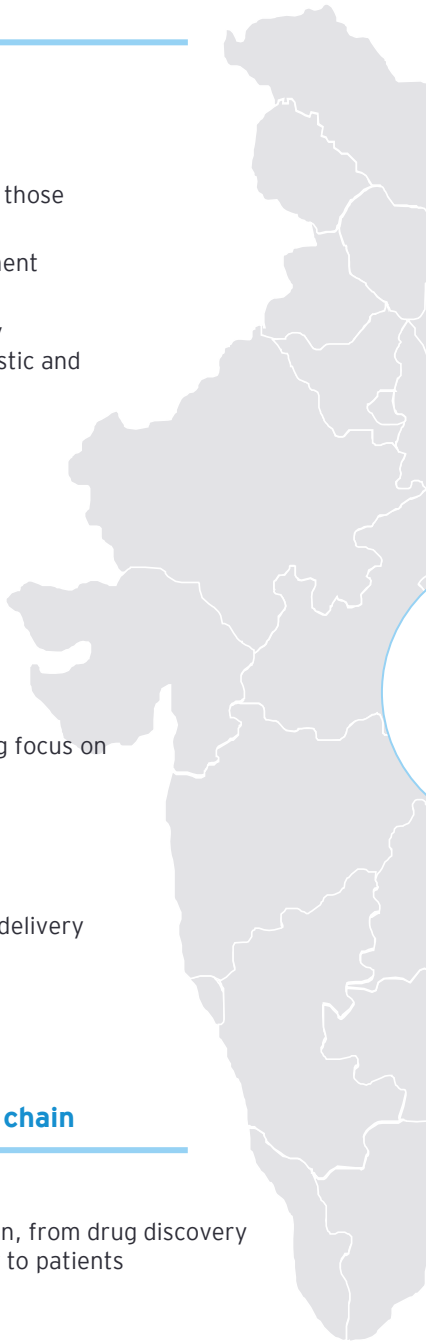
- We would not only be self-reliant, but will be a large global exporter of APIs and KSMs
- Sustainability will be at the core of our growth

Indian CRDMOs: Leading the global charge

- We will emerge as global leaders in the CRDMO space with a strong focus on biologics and novel therapies

Patient-centered quality standards

- India will be known for the quality of its medicines and healthcare delivery
- Fully harmonized quality on par with global standards



Confluence of digital across pharma and healthcare value chain

- Technology will be integral across pharma and healthcare
- Seamless digital integration across the entire healthcare value chain, from drug discovery and clinical trials to manufacturing, commercialization and delivery to patients

*API: Active Pharmaceutical Ingredients
KPI: Key Starting Material

@2047

Integrated healthcare accessible to every citizen in the country

100% universal healthcare coverage

- Everyone will have healthcare coverage. No one will be left behind
- Healthcare coverage will offer all essential services to keep individuals healthy or help patients manage their conditions while maintaining a high quality of life
- Health and wellness, and prevention will be the drivers of healthcare, and not just treating diseases
- Everyone will have access to innovative medicines that are required for their condition, and cost will no longer be the barrier to getting the right care

Connected and integrated healthcare

- Integrated digital infrastructure and ecosystem – anywhere anytime healthcare
- Inter-connected data, seamless flow of patient information resulting in evidence based preventive and predictive care

Individuals will be healthy and live longer

Informed and empowered individuals/patients

- Individuals are aware and have the means to live a healthy life
- They have access to their health data and the right to share it for their care
- Patients have full awareness of all the available clinical options and associated financial implications
- Individual/patient becomes a partner in taking care of their health and wellbeing in real sense

Robust healthcare infrastructure

- We will meet the WHO recommendations for the healthcare infrastructure, including Tier-2/ Tier-3 cities and remote areas

> By the time India celebrates a century of independence in 2047, we should be firmly established as the true pharmacy of the world. This means moving beyond mere formulation, where we currently rely on intermediates and starting materials from other countries to a fully integrated approach in delivering drugs globally. With the anticipated surge in medicine usage due to increased longevity worldwide, India's role in the pharmaceutical industry is set to expand significantly. We will see a profound transformation not just in formulation but across CDMO operations, GCCs, and the manufacturing of APIs and intermediates. The Indian pharma landscape is on the cusp of a golden age, poised to make a monumental impact on the global stage.
>
> Executive Chairperson, leading Indian pharmaceutical company

> We dream of a day when India discovers molecules that benefit the entire world. The goal is to foster genuine innovation and high-value contributions from India. With the right government policies and industry collaboration, this vision is well within our reach.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> To achieve the shift towards a more innovative pharmaceutical industry, we must adopt a radically different approach to our current methods. Transformation does not occur spontaneously; it requires a concerted effort and a well-thought-out strategy. India must commit to a long-term vision and action plan to realize this change.
>
> Chief Quality Officer, leading Indian CRDMO company

> Viksit Bharat will have a comprehensive integrated healthcare ecosystem with clear patient care pathways. All ecosystem stakeholders—providers, physicians, pharma companies, payers, policymakers—will have clearly defined roles with the sole objective of improving patient outcomes. This ecosystem will provide equitable access to consistent, high-quality care nationwide.
>
> Executive Chairperson, leading Indian pharmaceutical company

> In Viksit Bharat, no one will be left behind due to their location, financial capacity, or lack of information. Every citizen of the country will have universal health coverage with all the necessary components, empowering patients to select the most suitable medicines and services that are best suited for their unique situations.
>
> CEO, leading Indian NGO

> We have 23 years to realize our Viksit Bharat vision, and we cannot rely on the trajectory of the past 23 years. It is imperative to identify where changes to our strategy are required and what are the enablers and facilitators for the next wave of growth. Collaborative working of all stakeholders is critical for shaping the future we envision. It is time to chart a new path and work together to ensure our goals become a reality.
>
> Director General, Organisation of Pharmaceutical Producers of India (OPPI)

Chapter 1

The innovation imperative

India's path to pharma leadership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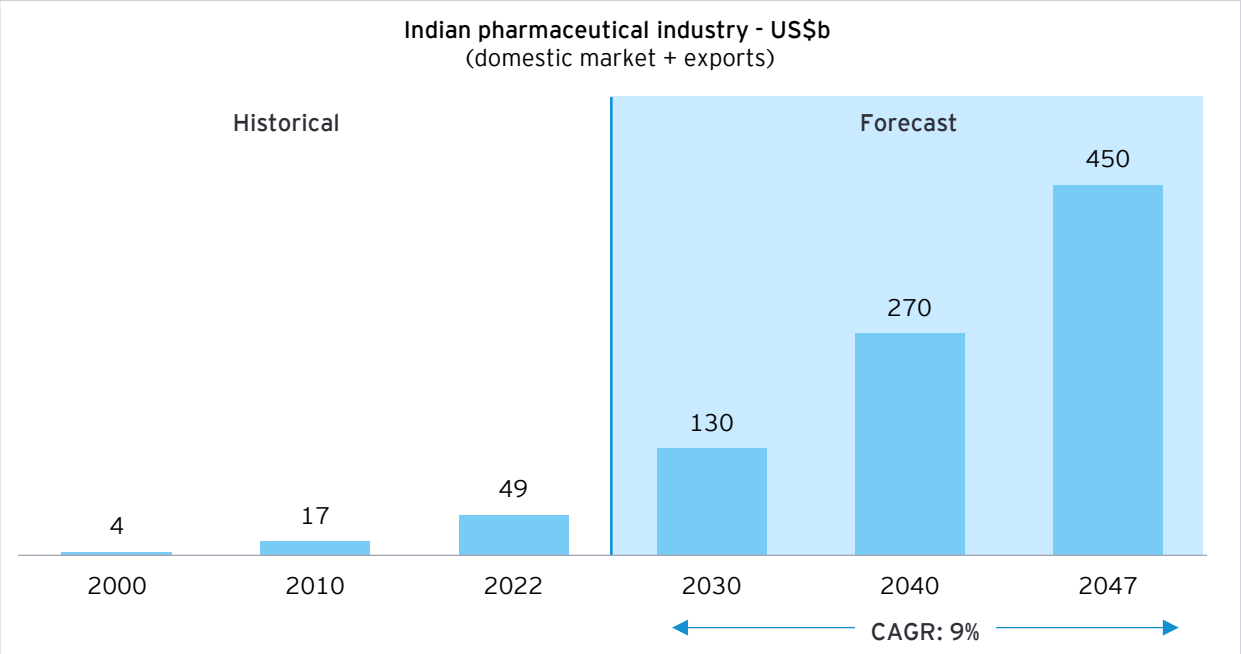


Sources: EY analysis, EY FICCI report, India pharma industry 2022, IBEF

The Indian pharmaceutical industry has grown from strength to strength in the last few decades, expanding from around US$4 billion in 2000 to approximately US$50 billion in 2023. The industry is further estimated to grow at a CAGR of 9% to US$450 billion between 2030 and 2047.[1] As discussed in our last year's report, *Reimagining pharma and healthcare for India@100*,[2] several factors are expected to drive this growth, including but not limited to:

- Expansion of domestic market driven by the strengthening of the Indian economy and an increase in per capita GDP
- Continuous expansion of healthcare coverage through Ayushman Bharat and other private insurance schemes
- Accessibility and service uptake expansion through ABDM platform and emerging digital native ecosystem
- Value driven innovation boosting exports, with a focus on complex generics, biosimilars, new chemical entities (NCEs), new biological entities (NBEs), next-generation therapeutics (antibody drug conjugates, cell and gene therapy, DNA/RNA therapies, etc.)

In addition, the COVID-19 pandemic and recent geopolitical shifts have underscored the critical need for supply chain diversification, prompting companies worldwide to reassess their sourcing strategies. This re-evaluation is not just a reactive measure, but a strategic move to enhance resilience and mitigate future disruptions. In particular, legislative developments such as the US BIOSECURE Act, which seeks to reduce the American biopharmaceutical sector's dependence on China, are poised to catalyze industry-wide changes. Such policy initiatives are expected to open new avenues for countries like India, presenting substantial opportunities to strengthen their position in the global market.

While these growth drivers and geopolitical shifts present a window of opportunity, India must strategically position itself to seize these prospects amid competition from other nations. It is imperative for India to bolster its research and development (R&D) capabilities, foster innovation, attain self-reliance in Active Pharmaceutical Ingredients (APIs) and Key Starting Material (KSMs), and reinforce quality and compliance commitments to not only attract but also sustain global partnerships and investments. India needs a proactive and coordinated approach to capitalize on these emerging opportunities and cement its status as a leading global destination for pharmaceutical innovation and manufacturing.

[1] IBEF - pharmaceutical-india

[2] EY-re-imagining-pharma-and-healthcare-for-india-100-report.pdf

The US BIOSECURE Act
(enacted on 9 September 2024)

What it means: Decoupling from China

- Prohibits US federal agencies and recipients of federal funds from contracting with or procuring services and biotechnology equipment from "Chinese biotechnology companies of concern*"
- Will extend to companies that source or utilize equipment or services from the listed companies

Window of opportunity for India's pharma industry

Why is India a contender?

- Opportunity for the growth of India's CRDMO industry as India supplies **40%-50% of all generic drugs in the US**
- India houses the most FDA-approved pharmaceutical manufacturing units outside the US
- Highly skilled workforce, relatively low manufacturing cost

Key focus areas for harnessing opportunity

Increase focus on quality
Need to build quality culture and strengthen audit mechanisms

Critical to achieve self-sufficiency in APIs
The act would extend to foreign entities associated with "biotechnology companies of concern" suggesting that India's API sourcing from China could be flagged

Become cost competitive
Building scale (bio-manufacturing capacity as well as capability in novel modalities) and efficiencies

**BGI Genomics, MGI tech, Complete Genomics, WuXi AppTec, and WuXi Biologics*

Sources: USFDA approved plants in India, US BIOSECURE Act, India-generic drug supplier, CNBC, Ropes & Gray, BIOSECURE Act (Congress.Gov)

Policy pillars: Government support for pharmaceutical sector advancement

Government continues to launch various schemes and programs to support the growth of the pharma industry. Several initiatives, including the 'National Policy on Research & Development and Innovation in the Pharma MedTech Sector', the Scheme for 'Promotion of Research and Innovation in Pharma MedTech Sector (PRIP)', and 'Research linked incentive' scheme for Pharma and MedTech sector, have been discussed in our last report.

In August 2024, the government launched 'Biotechnology for Economy, Environment, and Employment' (BioE3)[3] policy with an aim to foster high performance biomanufacturing, innovation-driven support to R&D, and acceleration of technology development and commercialization by establishing 'Biomanufacturing & Bio-AI hubs and Biofoundry'.

Similar to BioE3, Indigenisation of Biologics (InBx)[4] was launched in August 2024 under the aegis of Centre for Cellular and Molecular Platforms (C-CAMP). This program is dedicated to accelerating the development and production of biotherapeutics, including enzymes, monoclonal antibodies, and recombinant proteins. It adopts a public-private partnership model to provide comprehensive support to Indian MSMEs, start-ups, and researchers, guiding them from product development to market launch.

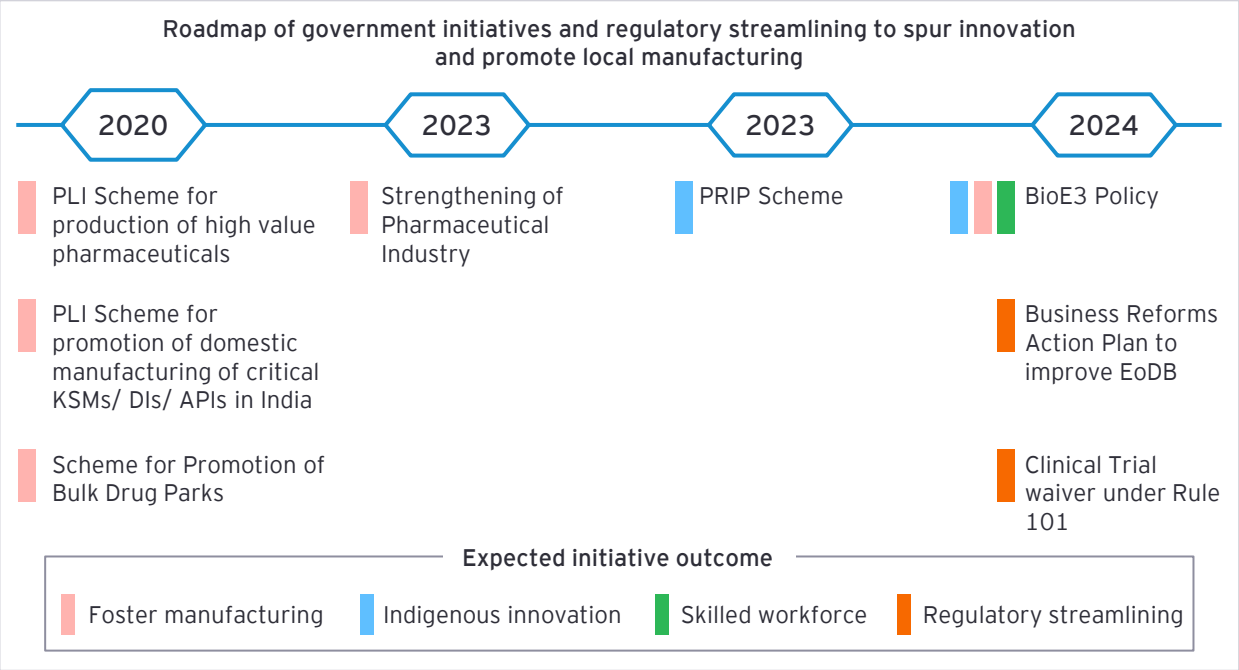
In addition, for regulatory streamlining, in February 2024, the Department for Promotion of Industry and Internal Trade (DPIIT) launched Business Reforms Action Plan (BRAP) aiming to create a more conducive business environment and improve Ease of Doing Business (EoDB) in India.[5] DPIIT is leading the way in reforming regulations across states and union territories by evaluating single window systems, online permissions, and labor reforms. Their goal is to simplify existing processes, eliminate unnecessary requirements, and make it easier to do business.

In August 2024, under the Rule 101 of New Drugs and Clinical Trials Rules 2019, the Government waived the requirement for clinical trials for certain

[3] Home | Department of Biotechnology
[4] CCAMP: inbx-national-biologics-catapult
[5] Press Release: Press Information Bureau

categories of drugs in India if they are approved in the US, the UK, Japan, Australia, Canada and the European Union. This will expedite launch of many new life saving innovative medicines in India, which currently might take a couple of years after the first global launch.[6,7]

The policies and schemes serve as a significant catalyst for fostering indigenous innovation and boosting local manufacturing.



Non-exhaustive

PLI: Production Linked Incentive
PRIP: Promotion of Research and Innovation in Pharma MedTech Sector
BioE3: Biotechnology for Economy, Environment, and Employment
EoDB: Ease of Doing Business

Sources: Department of Pharmaceutical (2023-24), BioE3 policy, US BIOSECURE Act, EoDB, CT waiver

Financial catalysts: PE and VC investments in Indian pharma

Aligned with the growth and the opportunities, the sector has attracted significant interest from Private Equity (PE) firms, who see the potential for growth and innovation in the market. The pharmaceutical industry has attracted over US$12 billion of PE and Venture capital (VC) investments since 2018 up to August 2024.[8] The investments peaked in 2020, driven by the COVID-19 pandemic, and the figures have continued to surpass pre-pandemic levels in subsequent years.

Majority of investment in the last five-year period within the segment was in the formulations and API/ Intermediates space (45% and 40% investments respectively). In specific, APIs / intermediates have witnessed tremendous growth in investments with a CAGR of 45% from 2018 to 2023. The largest PE investment during the analysis period was Advent International Corporation buyout of Suven Pharmaceutical (API/ intermediates) with 50.10% stake in the company in December 2022 for ~US$770 million.[9] There has been an increase in investment toward Contract Development and Manufacturing Organizations (CDMOs) as well as the biotechnology sector, which accounted for ~8% share each of the total private equity investments during the period.

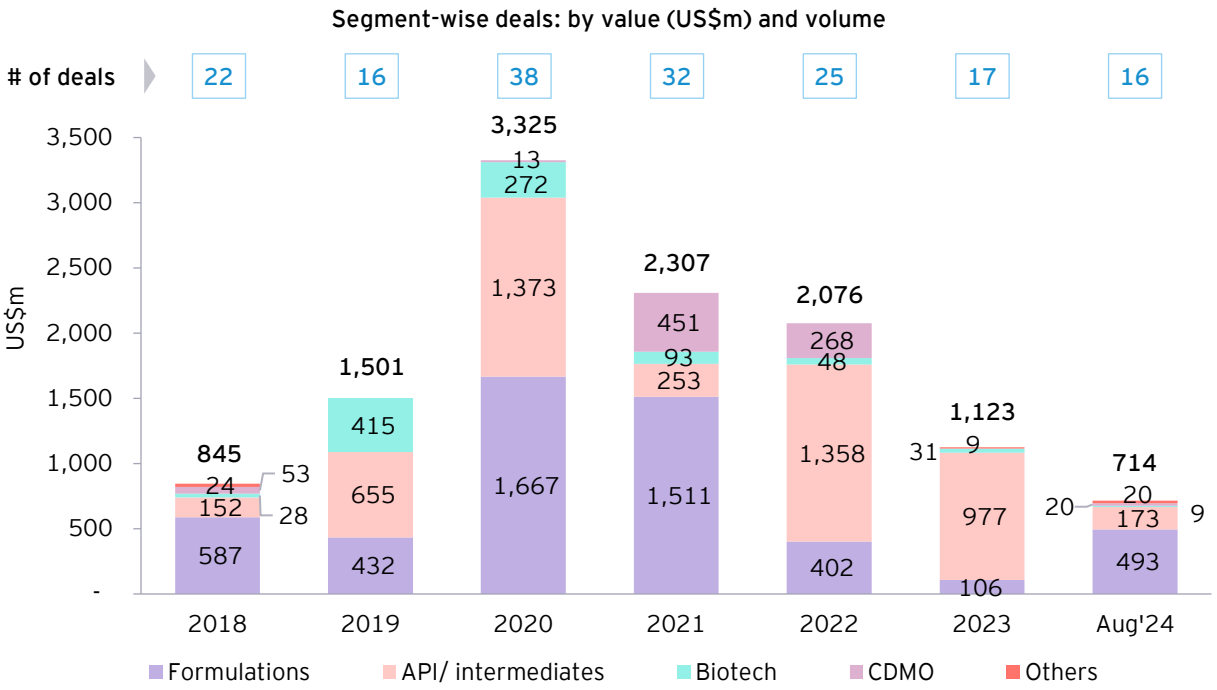
[6] Government waives clinical trial requirement for several drugs approved in select countries | India News - The Indian Express

[7] Clinical trials no longer needed for approval of international drugs in India - India Today

[8] EY analysis, VCC Edge Data

[9] Health.economictimes.indiatimes

Pharmaceutical PE investment deals (2018 – YTD August 2024)



Top five pharmaceutical PE investments: January 2018 to August 2024

Investor-target	Deal type	Year	Deal value (US$m)	Sub-sector
Advent Int. Corp- Suven Pharma	50% buyout	2022	770	API/ intermediates
New Mountain- Aurobindo Pharma, Natrol (US Unit)	100% buyout	2020	550	API/ intermediates
Unison Capital- Kyowa Pharma	100% buyout	2019	524	API/ intermediates
KKR- JB Chemicals	65% buyout	2020	495	Formulations
Carlyle- Piramal Pharma	20% growth investment	2020	490	Formulations

Sources: EY analysis, VCC Edge database, Advent-Suven, New Mountain- Aurobindo Pharma, Natrol, Unison Capital- Kyowa Pharma, KKR- JB Chemicals, Carlyle and Piramal Pharma

Pharma's path to becoming a global powerhouse: Key strategic pillars of growth

During September and October 2023, OPPI and EY conducted primary research with the CXOs of the leading Indian and global multinational pharma companies, contract research development and manufacturing outsourcing organizations (CRDMOs), leading start-ups, patient advocacy groups, academic institutions and other organizations to understand their perspective about the pivotal growth areas for the pharma and healthcare sectors in the country. From these discussions, three critical focus areas consistently emerged as essential for the industry to seize emerging opportunities and fulfill its aspiration of becoming a pharma powerhouse of the world, in line with the Viksit Bharat@2047 vision.

Let us delve deeper into each of these strategic growth drivers.

India's resurgence in KSMs and APIs: Building a foundation for self-reliance and innovation

India produces over 500 APIs and is the third-largest producer globally, holding an 8% share of the API industry by value.[10] Despite this, it relies on imports for approximately 35% of its API needs. In 2023-24, India imported APIs and bulk drugs valued at ~US$4.56 billion, with imports from China constituting roughly 70% of this amount. [11,12] This dependence is particularly high for many of the low-value, high-volume, off-patent essential medicines widely used in India. Additionally, India's substantial export of generic medicines is indirectly reliant on Chinese raw materials. In certain categories, such as life-saving medicines, dependency on Chinese imports reaches 80% to 100%. Fermentation-based APIs, including penicillin and erythromycin, show near-total reliance on China, with nearly 100% of imports sourced from Chinese suppliers.

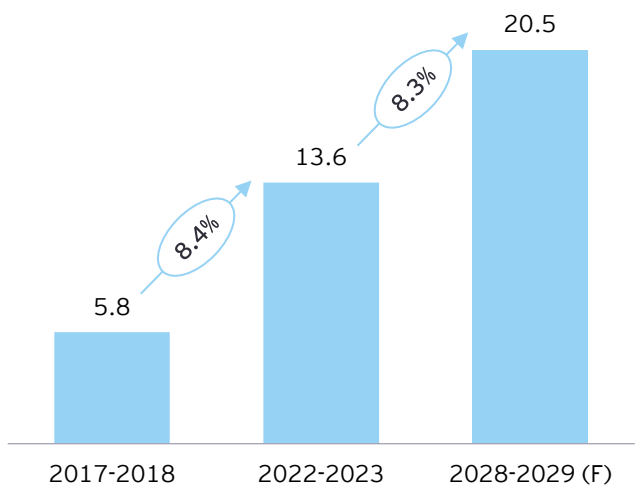
The cost advantages with the Chinese API industry and the volatility in the prices of APIs have made domestic production of certain APIs unviable for Indian manufacturers, resulting in continued dependence on China over the years. Even where APIs are manufactured locally, some of the KSMs are primarily sourced from China. The Chinese API industry, which caters to ~40% of the global requirement,[13] is supported by higher economies of scale, subsidies, and fiscal incentives offered by the Chinese Government, along with lower power, fuel and borrowing costs.

In the recent past, the Indian pharma industry has faced considerable instability in the availability of APIs and KSMs. The disruption caused by the COVID-19 pandemic, coupled with geopolitical shifts, has underscored the strategic imperative for India to secure its API and KSM supply chains. To fortify our pharmaceutical industry and safeguard against future disruptions, India must invest in the domestic production of APIs and KSMs. This is not only an opportunity to assert our autonomy in the global pharmaceutical landscape, but a matter of national security. By bolstering our capabilities in this sector, we can reduce import dependencies, stabilize drug pricing, and ensure uninterrupted access to essential medicines for our population. Moreover, self-reliance in APIs and KSMs will catalyze innovation, allowing for the development of proprietary processes and products that can command a premium in the international market.

[10] India's API Potential: Fueling Global Pharma Growth
[11] Can India Reclaim API Throne from China? (biospectrumindia.com)
[12] Business-standard
[13] ICRA-Research

Indian API industry

Indian API industry – market size (US$b)



Key initiatives towards self-reliance

Government:

- PLI scheme for bulk drugs and drug intermediates incentivizing companies to manufacture KSMs/APIs
- Establishment of bulk drug parks

Academia:

- Actively researching cost-efficient, clean, and scalable synthesis routes to support indigenous production

Industry:

- Capacity expansion / dedicated subsidiary
- Vertical integration to secure supply chain and maintain cost-competitiveness

Sources: EY analysis, Indian API Industry, ICRA , API market in India, Fortune India, Pharmabiz

Securing autonomy: India's roadmap to self-reliance in APIs and KSMs

The Indian API Industry has grown at a CAGR of 8.4% between 2017 and 2023[14] and is expected to grow at the same rate by 2029, driven by the nation-wide push for self-reliance. The journey towards self-reliance will require concerted efforts across policy reform and synergistic collaboration among the ecosystem players. It is a journey that holds the promise of economic growth, healthcare security, and enhanced global standing for India.

Government impetus for API and KSM self-reliance

APIs have been identified as one of the 13 pivotal categories under the Atmanirbhar Bharat Abhiyan, which was inaugurated in 2020 to foster self-reliance and reduce dependency on international imports. To catalyze the domestic production of essential KSMs, Drug Intermediates (DIs) and APIs in India, the Government of India introduced the Production Linked Incentive (PLI) Scheme.[15] The scheme has garnered significant momentum, with production of 35 of the 41 selected APIs already underway.[16] There has also been a notable decrease in API prices. For instance, the cost of the paracetamol API, which had surged to INR900 per kg during the COVID-19 pandemic, has now receded to INR250 per kg as of April 2024[17].

State governments are also complementing the central government's efforts. Several states have tailored their policies to support the central PLI scheme, providing additional incentives to spur investment in the manufacturing of KSMs and APIs. For instance, Gujarat has extended benefits such as capital subsidies, interest subsidies, and exemptions on stamp duty for the establishment of KSM/API production facilities.[18,19,20] A bulk drug park has also been proposed in the state. Similarly, Himachal Pradesh offers a suite of subsidies for land, power and water, coupled with tax advantages to the manufacturers of KSMs and APIs.[21]

[14] ICRA Limited

[15] Press Release: PIB

[16] Press Release: Press Information Bureau (pib.gov.in)

[17] Relief for pharma companies as API prices see a sharp fall - The Economic Times

[18] Gujarat, India's Pharma Hub - GUJARAT PHARMA 2020

[19] Gujarat government

[20] MCA

[21] Himachal Pradesh

Government initiatives to promote domestic manufacturing of critical KSMs, DIs and APIs

PLI scheme

Description

Financial outlay: INR6,940 crore (~US$930 million) between 2020-21 to 2029-30

Target products: 41 critical APIs, KSMs and DIs identified (among the 53 APIs for which India has 90% or more import dependence)

Incentives:

- Fermentation based bulk drugs @20% for first four years, 15% for fifth year, and 5% for sixth year on eligible sales
- Chemical synthesis based bulk drugs @10% for six years on the eligible sales

Current status (as of August 2024)

Projects approved: 249 applications received, of which 48 projects have been approved, with an investment of INR4,024 crore (62% of total investment)

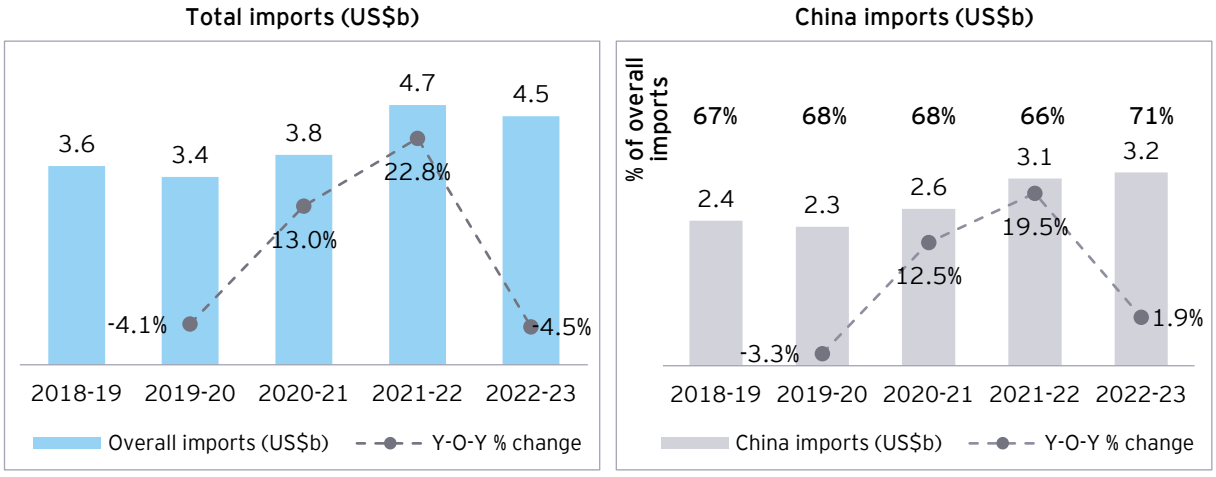
- Nine approvals for fermentation-based products and 39 for chemical synthesis products
- 32 projects have been completed with a cumulative installed capacity of 56,679 MT per annum, catering to 35 products out of the 41 identified products

Bulk drug parks

- Provide easy access to world class Common Infrastructure Facilities (CIF)
- Three bulk drug parks in development with a financial outlay of INR3,000 crore

Impact till date and future direction

India import dynamics (2018-2023): Bulk drugs (APIs) and intermediates



While the total imports, and imports from China, continue to grow, the growth rate declined in the last year. Experts in the CXO survey highlight that it would take at least five to seven years to see tangible results and reduced import dependence specifically from China.

Sources: EY analysis, PLI Scheme, PIB.gov, Indian API industry, Indian API industry-PLI scheme, PLI scheme-projects approved, PLI scheme-products approved, Bulk drug parks, PLI scheme effect

Synergizing efforts: Industry and academia's push for self-reliance

In sync with national policy measures, Indian pharmaceutical companies are also actively undertaking a range of initiatives to amplify the domestic production of KSMs and APIs. Companies are channeling investments to enhance their manufacturing capacities and pursuing R&D to innovate more efficient and economical production processes. Through diverse approaches, including vertical integration and the creation of specialized subsidiaries, these companies aim to meet their own requirements, and also to expand their footprint in global exports. For instance, Aurobindo is one of the largest vertically integrated pharmaceutical companies producing ~51% of its APIs in-house,[22] which underscores its commitment to self-reliance and market expansion. Government research institutions and academia are also focusing on innovations for cleaner, cost effective and scalable manufacturing.

Strategies adopted by Indian pharma companies to secure supply chain and reduce import dependence for APIs and KSMs

	Industry examples	
Vertical/backward integration	**Lupin** Established subsidiary 'Lupin Manufacturing Solutions Ltd.' to undertake business of manufacture, sale, export and import of all types of APIs, intermediates, fermentation activities	**Sun Pharma** Has 14 state-of-the-art API facilities to manufacture diverse portfolio of ~380 APIs, for complex formulations
Capacity expansion in dedicated KSM/API facilities	**Aurobindo Pharma** Established four state-of-the-art manufacturing facilities for Penicillin-G, 6-Amino Penicillanic Acid (6-APA), Injectable products, and Granulation	**Laurus Labs** Increasing its commercial API fermentation capacity from 190 kilolitre to 2 million litres
	Divis Laboratories Invested INR650-INR700 crore to expand capacity at API manufacturing plant (expected to be operational from Jan 2027)	**Rusan Pharma** Invested INR300 crore to set up a new manufacturing plant to boost its manufacturing capacity from 40 metric tons to 400 metric tons (10x increase)
Strategic shift towards high value KSMs/APIs	Lupin opened a new R&D facility, Lupin Research Park, in Pune dedicated to fermentation and Enzymatic research for development of innovative APIs and KSMs	

Non-exhaustive

Sources: Company reports (Lupin, Sun Pharma, Laurus Labs), Aurobindo, Divi's lab, Divi's lab-future, Rusan pharma, Lupin-new R&D facility

[22] AurobindoPharmaLimited-AnnualReport2023-24.pdf

Innovation strategies for efficient, economical and clean manufacturing

1 Re-engineering manufacturing process: Environment friendly and economical alternative synthesis route

Research institutions and academia

Council of Scientific & Industrial Research (CSIR), in collaboration with other laboratories, has developed **cost-effective** technologies using locally available chemicals to **produce APIs**

- **CSIR-CDRI**: Developed a non-infringing synthesis route for the API Centhaquin; engaging with Cipla for technology transfer (patent filed)
- **CSIR-CSMCRI**: developed a **clean, cost-competitive, and scalable process** for two key intermediates of Camostat Mesylate, with comparable yields and purity (patent filed)

NIPERs: started developing process for **18 KSMs/APIs;** filed three patents:

- **NIPER Kolkata**: developed a new, affordable process for **Clopidogrel:** adhered to green chemistry principles and avoided the formation of strong acid HBr; reduced one step compared to the classical process
- **NIPER SAS Nagar:** developed a new telescopic **affordable process for Carbamazepin**

Pharma companies

Aarti Drugs developed:

- an alternate route with eco-friendly solvent technology for metformin production; enhanced yield and quality while reducing impurities and hazardous waste; expected to be commercialized soon
- an alternate process using dichloro fluro benzoyl chloride (DCFBCl) as the starting raw material for Norfloxacin to reduce manufacturing costs and enhance supply chain resilience

2 Adoption of advanced manufacturing technologies for efficiency gains

Aurobindo Pharma

Invested in **process chemistry to** establish cost-effective and **sustainable processes for API characterization and preparation**

Cipla

Implemented **continuous manufacturing** at its Kurkumbh facility, which primarily focuses on API production.

The process is more sustainable than batch processing

Aarti Drugs

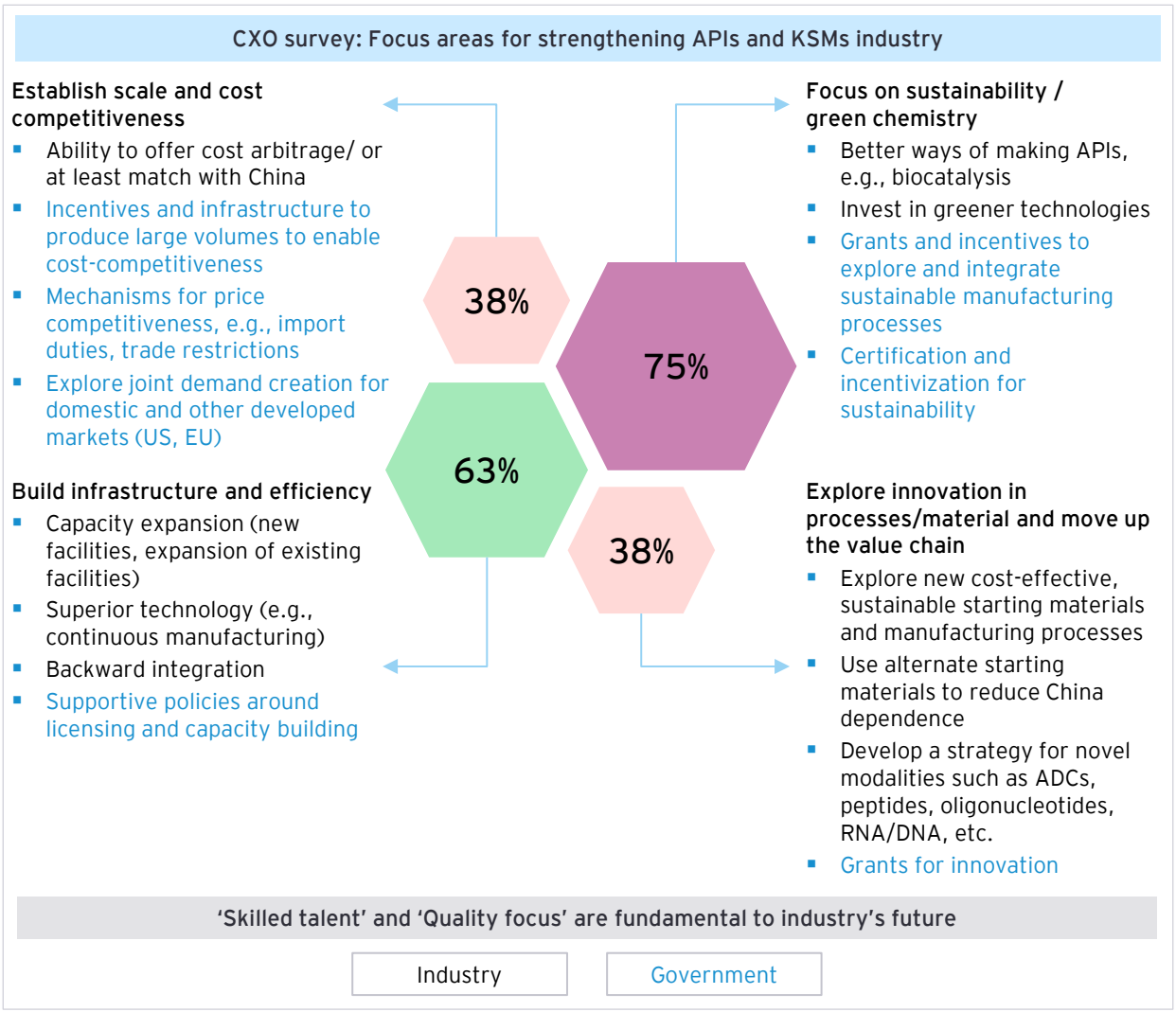
Developed a **continuous manufacturing process** for Ciprofloxacin HCl

Non-exhaustive

**CDRI: Central Drug Research Institute, CSMCRI: Central Salt & Marine Chemicals Research Institute*

Source: DoP India report, company reports (Aarti Drugs, Aurobindo Pharma), Cipla

The path ahead: Shaping the trajectory of India's API and KSM market



The CXO survey revealed a consensus among experts: India has significantly advanced its journey toward self-reliance in APIs and KSMs over the past years. They emphasized that the future of India's API industry lies in embracing sustainable practices, considering that the industry is capital and resource intensive with a significant amount of environmental pollution. Prioritizing cost efficiency through scaling operations and enhancing productivity is also crucial for the industry's growth and competitiveness.

To achieve these goals, substantial investment is needed to fuel innovation in manufacturing processes and materials. The focus must be on developing methods that reduce costs, improve productivity and minimize environmental impact, aligning with global sustainability trends. Advanced manufacturing technologies, such as continuous manufacturing, should also be adopted. Government should proactively provide subsidies to increase competitiveness and enable environment friendly manufacturing and waste disposal processes.

The industry experts have identified the aggressive dumping practices of China as a significant challenge for India's API manufacturers. To combat this, they propose a controlled market pricing mechanism, where the government plays a pivotal role in ensuring Indian manufacturers remain competitive. Furthermore, experts suggest that India should not navigate this landscape in isolation but seek collaboration with Europe and the US to consolidate demand and counteract China's pricing strategies.

Beyond the aforementioned priorities, experts underscored that 'Quality' and a 'skilled workforce' are fundamental for the industry's future. These topics will be explored comprehensively in subsequent sections of this report.

> India moved forward compared to all other parts of the world. Just after COVID, we announced the PLI scheme. We are going to start the production of penicillin. Atorvastatin has started. We lost an advantage last 30 years and it cannot be recovered in one year's time. It would take us a few years, but we have certainly moved forward in that agenda.
>
> Secretary General, Indian Pharmaceutical Alliance

> I have no doubts about India's capabilities in generating APIs. I believe India excels in this area. However, I think the industry needs to focus on creating a competitive advantage and positioning for APIs locally and globally, and the government needs to provide essential support for that.
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

> It is often discussed that India imports a significant number of APIs and KSMs from China, but I want to clarify that this is not due to our (India) inability to produce them, including fermentation-based APIs, which are a major import segment. The reality is rooted in economics and history—how China became a dominant player in manufacturing supported by its government, and how India's environment became less conducive for API production, leading to a loss of competitiveness in this area.
>
> Head of Strategy and Portfolio Management, leading Indian CRDMO company

> Green chemistry is the future, and we do not want to be left behind.
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

> Adoption of green chemistry is not just environmentally beneficial but also cost-effective. For instance, converting a five-step reaction synthesis into a single-step process through biocatalysis can significantly reduce labor and energy costs. However, the pharmaceutical industry's highly regulated nature means that changes in synthesis routes must be meticulously documented and approved. Variations must be filed, and customers must be onboarded for any new processes. While regulatory hurdles exist, sustainable practices must be incorporated into strategic planning for long-term benefits.
>
> Head of Strategy and Portfolio Management, leading Indian CRDMO company

> It is imperative that we adopt a balanced approach. Expansion in API/KSMs manufacturing cannot be at the cost of environmental pollution. We need to innovate and invest in green manufacturing processes and technologies that enhance throughput.
>
> Vice President - R&D, leading Indian pharmaceutical company

> The government can play a pivotal role in enhancing the environmental sustainability of the API industry, particularly in waste management. Given the substantial input materials required to produce just 1 kg of API, the resulting waste and carbon footprint are considerable. Government support in the form of subsidies and partnerships with the industry for technologies like solvent recycling can aid the industry in efficient waste disposal and reducing the carbon footprint of production. As India aims to capture a large share of the global API market, proactive measures are needed to manage the environmental impact of increased production.
>
> Head of Strategy and Portfolio Management, leading Indian CRDMO company

> I think we need to start being an innovation hub. We should not replicate traditional processes, but should focus on pioneering new innovations in APIs, exploring novel materials and manufacturing processes.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> Emerging technologies present Indian companies with the opportunity to lead the way, particularly in the ADCs, where a surge of new drugs is expected. With only a handful of companies globally handling the complete ADC value chain, there is potential for India to gain an early mover advantage by building capabilities. Similarly, peptides and oligonucleotides offer promising prospects, with their adjacency to small molecules providing a strategic edge. Although the journey into biologics manufacturing may take some time, these areas present a near-term opportunity for growth.
>
> Head of Strategy and Portfolio Management, leading Indian CRDMO company

India's potential in the API and KSM sector is immense. With the right mix of policy support and industry commitment to sustainability, quality, innovation, and cost-effective production, India is poised to attain not only self-reliance but also global prominence.

India's leap into next-generation therapeutics: Improving access to innovative medicine

India has established itself as the leader in the generics space. It constitutes ~20% of the global generics supply by volume[23], and continues to dominate with ~46% of all ANDA approvals in 2023[24].

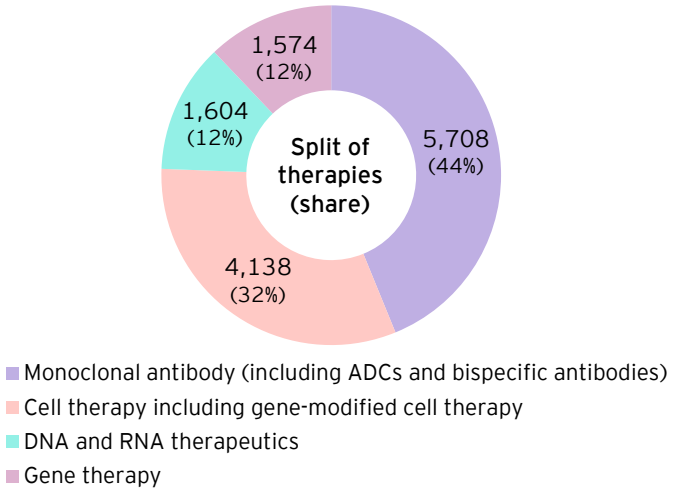
For last over two decades, research and development (R&D) in generics has been the traditional focus area for most India-based pharma companies. However, it is critical for India to transition from incremental to transformative innovation for the next wave of growth and to achieve its future ambition.

Global innovation landscape

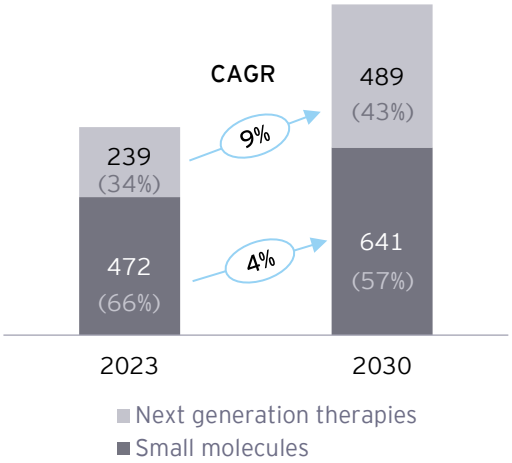
Globally, the pharmaceutical sector is undergoing a transformative shift towards next-generation therapeutic modalities, including cell and gene therapies (C&GT), monoclonal antibodies (mAb), antibody-drug conjugates (ADC), DNA and RNA therapies, and peptide therapies. There are ~13,000 such next-generation therapies in various stages of clinical development (discovery, pre-clinical, phase I to phase III and filed). These are projected to represent ~43% of the global pharmaceutical market in 2030 by value, a significant increase from 34% in 2023.

Transitioning towards next generation therapies

~13,000 next generation therapies in clinical development globally* (as of Sep 2024)



~Sales split: Next generation therapies vs. conventional small molecules (US$b)



Includes filed, phase I - III, preclinical and research projects

Source: Evaluate Pharma reports, accessed on 18 Sep 2024

Aligned with the trend, the majority of the global bio-pharmaceutical companies are reorienting their portfolios to include a substantial proportion of next-generation therapies. During 2020 to H1 2023, ~34% of >US$200 million deals executed by global pharmaceutical companies were focused on new modalities.

[23] PIB

[24] THE ANDA BOOST (pharmabiz.com)

Indian innovation landscape

Over the last few years, Indian pharmaceutical companies have also increased their investments into advanced therapies. For instance, Sun Pharma Advanced Research Company Ltd (SPARC) entered into a licensing agreement with Biomodifying (2021) to acquire exclusive rights for novel treatment modalities, including bi-specific antibodies and ADCs for cancer and other diseases.[25,26] Cipla invested in the German mRNA biotech, Ethris (June 2024), to fast-track innovative mRNA-based therapies for respiratory diseases.[27]

Likewise, Indian contract research development and manufacturing organizations (CRDMOs) are also strengthening their capabilities in the novel treatments. For instance, Aurobindo Pharma signed service agreement with Merck Sharp & Dohme (MSD), Singapore, for contract manufacturing of biologicals for supply to domestic and international markets. This is the first sizeable biologics manufacturing contract awarded to an Indian company by a large pharmaceutical corporation. To build scale, Aurobindo is investing ~INR1,000 crore to establish a manufacturing facility with end-to-end services, from drugceptions to drug product manufacturing.[28, 29]

The following section dives deep into the innovation landscape of India within the novel therapies including the advancements in cell and gene therapy, antibody drug conjugates (ADCs), DNA and RNA therapies and Proteolysis Targeting Chimeras (PROTACs). We will also discuss the growing role of CRDMOs/ CDMOs in the space of novel modalities.

Recent advancements in novel modalities in India

India is making significant strides in the cell and gene therapy (CGT) arena. In Oct 2023, the Central Drugs Standard Control Organization (CDSCO) approved India's first indigenously developed CAR-T cell therapy, NexCAR19, from ImmunoACT for the treatment of B-cell lymphomas. Besides NexCAR19, we see a pipeline of CAR-T assets in various stages of development from several companies such as Immuneel Therapeutics, Dr. Reddy's Laboratories, and Intas Pharmaceuticals.

Development efforts for gene therapy are currently underway, with most projects in the discovery phase being spearheaded by academic and research institutions. Collaborative endeavors within the ecosystem are emerging to advance these therapies in India. For instance, IIT Kanpur has licensed gene therapy technology to Reliance Life Sciences, paving the way for the latter to further develop it into a homegrown product.[30]

[25] Biomodifying_press_release_03_dec.pdf (sparc.life)

[26] R&D Pipeline - Sparc Life

[27] Cipla investment

[28] Aurobindo Pharma signs pact with MSD

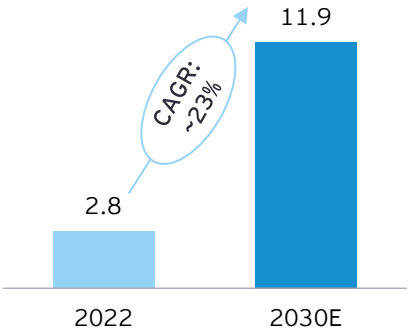
[29] Aurobindo Pharma subsidiary partners with MSD for biologics manufacturing - CNBC TV18

[30] IIT Kanpur licenses gene therapy for hereditary eye diseases to Reliance Life Sciences - The Hindu BusinessLine

Chimeric Antigen Receptor T-Cell therapy (CAR-T therapy): Global and Indian landscape overview

Global CAR-T landscape

Global CAR-T market size (US$b)



Six autologous therapies launched globally till date

Future focus areas

- Cell therapies for solid tumors
- Next-gen CAR-T manufacturing platforms
- Allogenic / off-the shelf therapies
- CAR-T beyond oncology for e.g., autoimmune disorders

India CAR-T landscape

ImmunoACT's first indigenously developed CAR-T

2023 → 2024 → 2024+

Approval and launch	Scaling up operations	
Oct 2023 ▪ **NexCAR19** approval ▪ Priced 10x less than the average cost globally for CAR-T therapy	**Expanding access within India** ▪ Engaging with the **oncology community** - broadened network through **partnerships with ~30 leading oncology hospitals** in India ▪ Strategically positioned in the north, west, south and east zones for **nationwide patient accessibility**	**Expanding access in other emerging markets** ▪ MOU signed with Govt of Mexico (Ph1 is yet to be approved) ▪ **Plans to expand** to countries in Eastern Europe, the Middle East and South Africa by establishing joint ventures / out-licensing

Impact	▪ *Vein-to vein time: 19 days per patient* ▪ *150 successful infusions since launch (as of Oct'2024)*
Future plans (India)	▪ *Treat **400-500 patients** in 2024* ▪ *Treat **~2,000 patients in 2025***

Pipeline advances in CAR-T

ImmunoACT
Three products in pipeline (pre-clinical) with expectations to complete pivotal trials by 2026-2028

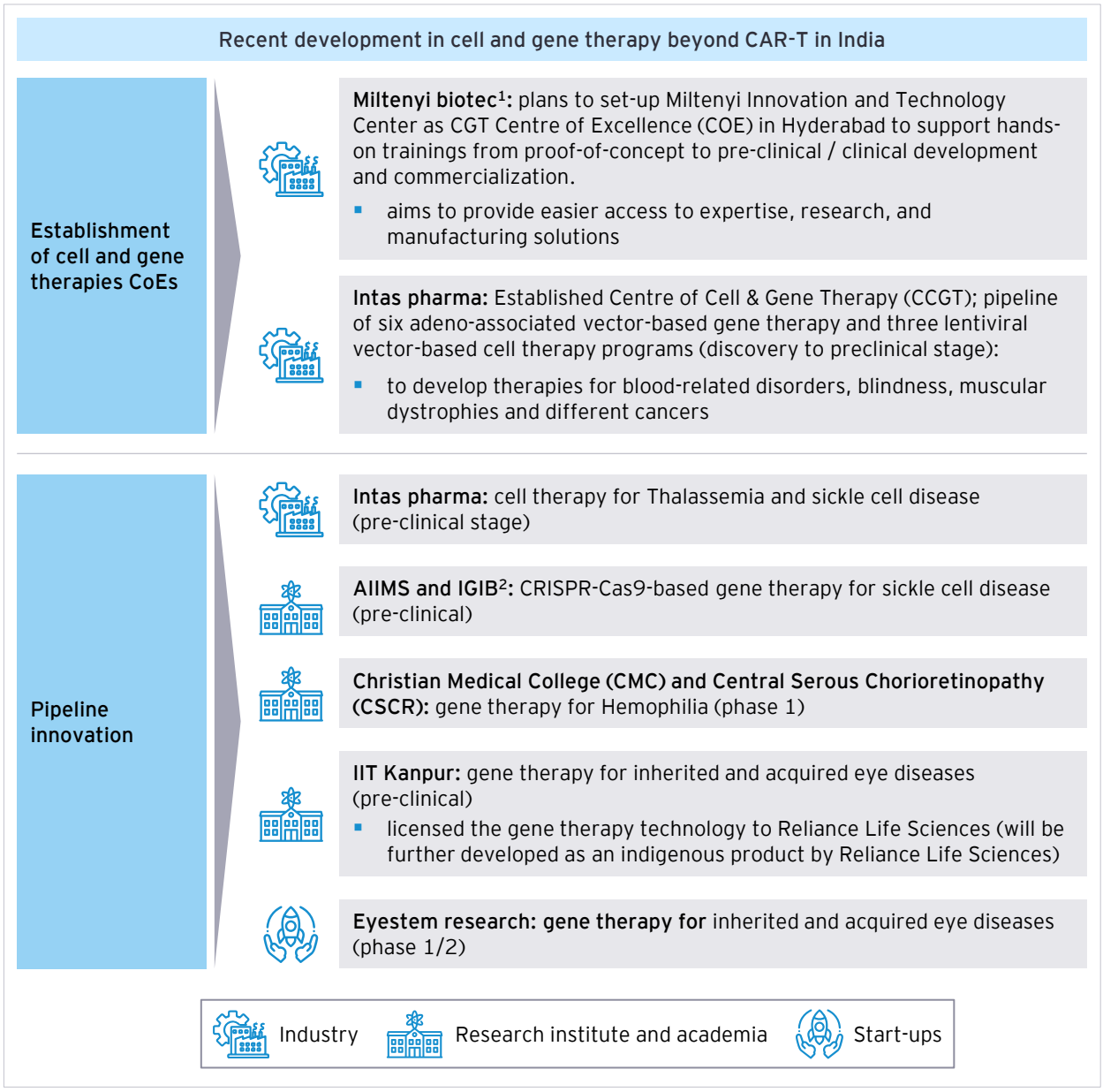
Immuneel:
CAR-T cell therapy in development; Three in pre-clinical phase and 1 in discovery phase)

Dr. Reddy's Laboratories (DRL)
Exclusive licensing agreement with China's Shenzhen Pregene Biopharma for PRG1801 to commercialize in India
- DRL will be responsible for further development, including clinical trials

Intas Pharma
Four autologous CAR-T therapies in pipeline (discovery to pre-clinical stages)

**(single-domain antibody-based anti-BCMA CAR-T cell therapy injection for multiple myeloma*

Sources: Grand View research: CAR-T market, Mordor Intelligence: CAR-T forecast, Citeline, company website (ImmunoACT, Immuneel, Intas Pharma, DRL) accessed on 5 November 2024



[1] *Global provider of products and services that empower biomedical discovery and advance cellular therapy.*

[2] *Institute Of Genomics And Integrative Biology*

Source: Miltenyi Biotec: CGT CoE, AIIMS-IGIB, CSCR, IIT Kanpur - Reliance Life Sciences, Eyestem research

India is still in its early stages of exploring other novel modalities such as ADCs, bi-specific antibodies, DNA/mRNA therapies, and PROTAC. A few companies are pursuing R&D in these domains. For instance, Sun Pharma's Subsidiary, Sun Pharma Advanced Research Company Ltd. (SPARC), expects its novel ADC asset SBO-154 to be in human trials in Q1 2025.[31] Zydus has developed a biosimilar to Roche's first ADC blockbuster Kadcyla.[32] Cipla has made an investment in German mRNA biotech Ethris to fast-track innovative mRNA-based treatments.[33]

[31] SPARC

[32] Zydus MD On Quest For Novel ADCs, Antibodies Amid Shifting Modalities | Insights (citeline.com)

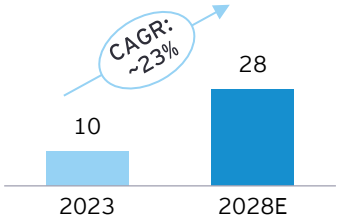
[33] Cipla EU to invest an additional EUR 3 million in Ethris | Cipla

Innovation landscape of next-generation therapeutics (global vs. India)

Antibody-drug conjugates (ADCs)

Global landscape

Market size (US$b)



Current assets

- 12 ADCs launched globally (as of Nov 2024)
- ~150 pipeline assets

Recent deals

- Pfizer acquired Seagen for US$43b (2023)
- Genmab acquired ProfoundBio for US$1.8b (2024)

Indian landscape

Industry

- **Sun Pharma (SPARC)**
  - Developing **novel ADC asset SBO-154**, plan to initiate clinical trials in FY25
- **Zydus**
  - Developed a biosimilar for Roche's first ADC blockbuster Kadcyla

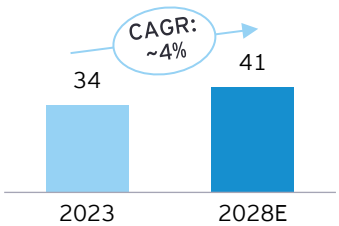
Academia

- **Institute of Science Education and Research (IISER), Bhopal**
  - Developed a technology named 'BHoPAL' for attaching chemical tags to proteins without compromising its function

mRNA/RNA therapies

Global landscape

Market size (US$b)



Current assets

- 2 mRNA therapies launched globally (as of Nov 2024)
- ~450 pipeline assets

Recent deals

- Bayer + NextRNA Therapeutics collaboration to develop lncRNA (US$500m, 2024)
- Novo Nordisk acquired Cardior Pharma for US$1.1b (2024)

Indian landscape

Industry

- **Cipla:** invested in the German mRNA biotech, Ethris, to fast-track innovative mRNA-based therapies
- **Gennova Biopharmaceuticals:** developed first indigenously developed mRNA COVID vaccine

Academia

- **Serum Institute of India (SII)**
  - Partnered with Univercells, a Belgian biotech innovator, to develop a cancer treatment using mRNA with Serum's rBCG vaccine candidate (VPM1002)
  - First in-human trial is expected in 2025

Proteolysis targeting chimera (PROTAC)

Global landscape

PROTACs oncology market to reach US$3.7b by 2030

Current assets

- 1st PROTAC drug is expected to enter market by 2027
- ~90 pipeline assets

Recent deals

- Novartis acquisition of Arvinas's phase III asset worth US$150m (2024)
- Pfizer + Arvinas collaboration worth US$350m to develop ARV-471 (2021)

Indian landscape

Currently, there are limited or no research and development initiatives in this field

Source: ADC market size, Citeline: ADC, BioSpectrum: IISER Bhopal, Pfizer-Seagen, Genmab-ProfoundBio, ETPharma: PROTAC Oncology, FT: Novo Nordisk-Cardior acquisition, Bayer-NextRNA, Cipla-Ethris GmbH, SII-Univercells, Citeline, GlobalNewswire: mRNA market, Fierce BioTeach: Novartis-Aravinas deal, GlobalNewswire: PROTAC market, GlobalNewswire: PROTAC pipeline

SPARC Life: Sun Pharma's dedicated subsidiary for advanced research

Company overview

- *Clinical-stage biopharmaceutical company, focussed on novel treatments*
- *350+ scientists across four research centers with US$500m+ invested to date*
- *79% of the portfolio comprises New Chemical Entity*
- *43% of the pipeline has 'best-in-class' and 57% has 'first-in-class' positioning*

Strategic focus

Innovative therapeutic focus	*Large proportion of programs focus on novel biology*	**Focus therapy areas:** Neurology, Oncology and Immunology Focus platforms: modular **immune-fusions and ADCs**
Strategic partnership with global players	*Plugged into global Innovation ecosystem*	Global research collaborations with tier 1 academic research institutions, e.g., **UK Dementia Research institute: to fund vital research into the mechanisms underlying neurodegeneration** *(2023)*
Active portfolio churn	*Rigorous review and prioritization*	Kill early, kill cheap and kill completely

Pipeline

- Three clinical stage programs targeting unmet needs
- **10+ NCE/NBE programs** (including ADC programs): US$20b+ peak sales potential in six indications
- Initiated first-in-human Phase 1 studies for SCD-153 in FY24
- Planning to initiate clinical trials for SBO-154 during FY25

Digital-driven efficiency

- Adopted innovative technologies and therapeutic approaches that utilize antibodies for multi-modal tumor targeting, aligning with international advancements

Future focus

- **Continue to build new competencies that are aligned with the broader portfolio strategy**
- **Continue to collaborate** with academic institutions to introduce additional early-stage research initiatives

Source: NDTV: SPARC high risk approach, company report (SPARC NSE report, JP Morgan health conference, pipeline update, pipeline transcript), SPARC-UKRI, SPARC-Tripoint; accessed as of Nov 5, 2024

Indian start-up innovation landscape

The last three years (2021-2023) have seen an exponential growth in pharmaceutical start-ups focusing on novel drug discovery (NCEs, NBEs), innovative formulations and drug delivery systems. The Government of India has implemented several schemes to fund and encourage start-ups, such as Startup India initiative, BIRAC funding schemes. In addition to government initiatives, strategic partnerships between pharma companies, PE investors, and start-ups are needed to provide early-stage funding and mentorship.

Indian pharmaceutical start-ups

Exponential growth in the number of pharmaceutical start-ups

As of June 2024, the Department for Promotion of Industry and Internal Trade (DPIIT) has recognized **2,127 start-ups (2% of the total start-ups)** in the pharmaceutical sector

2021	2022	2023
283 new start-ups	451 new start-ups	663 new start-ups

*The last three years have seen the setting up of **1,397** start-ups in the pharmaceutical sector*

Focus on innovation

Pharma start-ups are focusing on novel drug discovery, innovative formulations and drug delivery systems

New Chemical Entities (NCEs)	Zumutor has developed a fully human proprietary mAb technology platform (INABLR™) for rapid identification of selective and potent mAbs with potential to enhance antibody-dependent cellular cytotoxicity (ADCC) activity	
New Biological Entities (NBEs)	Genext Genomics, life science research start-up and CRO, is developing recombinant proteins and monoclonal antibodies, aiming to develop a mAb-based drug for TB	Eyestem, a cell therapy company, is developing scalable cell replacement therapies to treat incurable diseases like age-related macular degeneration
Drug delivery systems	Sekkei Bio is developing a peptide editing platform to specifically deliver peptide drugs orally	
AI in drug discovery	ImmunitoAI, an antibody therapeutics company, is developing an AI-platform for discovering and developing novel biologics with pre-defined drug properties entirely using AI	

Government support and initiatives

BIRAC
- **Funding initiatives:** BIG, SEED and LEAP schemes[1]
- Promotes innovation and research in biotechnology through the i4 and the PACE program[2,3]
- Takeda announced partnership with BIRAC to foster healthcare innovation *(Dec 2023)*

Startup India Initiative
- Launched on Jan 2016
- Promotes innovation and investment
- Initiative includes three flagship schemes, e.g., Fund of Funds for Startups; Startup India Seed Fund Scheme; and Credit Guarantee Scheme for Startups

Promotion of Research and Innovation in Pharma-MedTech sector (PRIP)
- Launched by Ministry of Chemicals and Fertilizers
- To create an ecosystem of skills and capacities including the academia and the private sectors, and give impetus to new talent among the youth through start-ups

Examples are non-exhaustive

[1]BIG: Biotechnology Ignition Grant, SEED: Sustainable Entrepreneurship and Enterprise Development, LEAP: Launching Entrepreneurial Driven Affordable Products

[2]i4 program: Intensifying the Impact of Industrial Innovation program to support biotechnological product/ technology development by strengthening R&D capabilities of start-ups/companies/ LLPs

[3]PACE program: Promoting Academic Research Conversion to Enterprise program to encourage/support academia to develop technology/product (up to PoC stage)

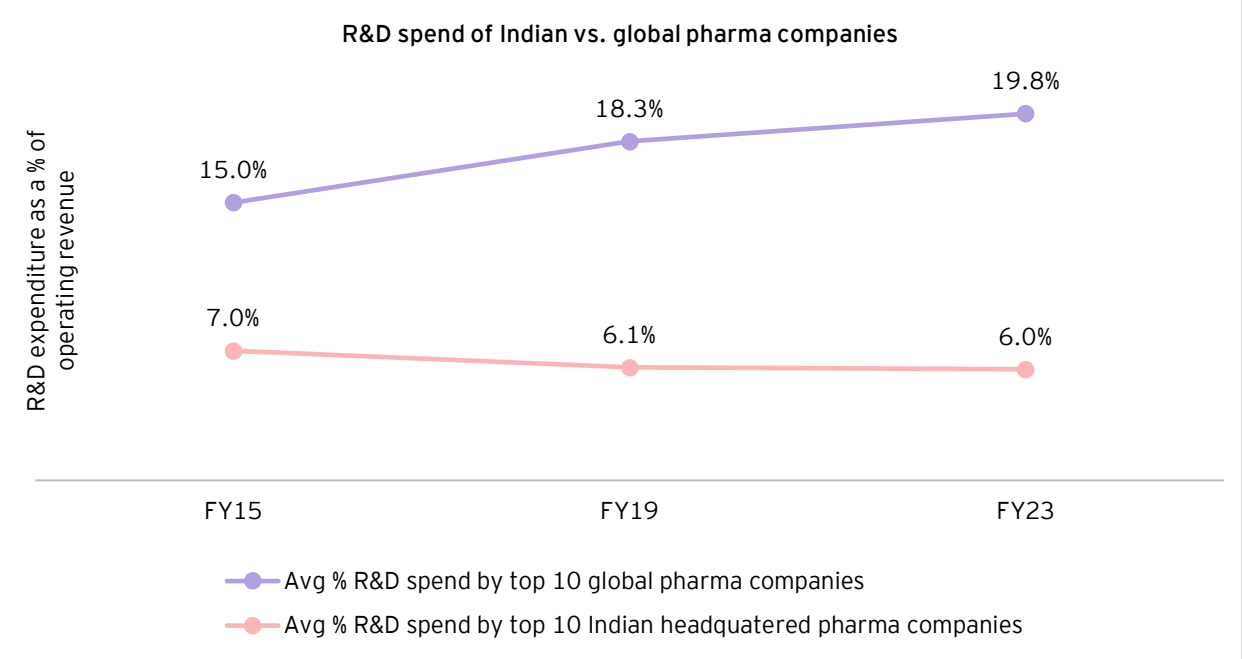
Source: Pharma startups, Zumutor, Genext Genomics, Eyestem, Sekkei Bio, ImmunitoAI, Government support and initiatives, BIRAC-Takeda, i4 program, PACE

Approach to innovation – Global best practices

Increase R&D spending

Securing investments for R&D funding remains a formidable challenge due to the extensive financial commitments required over an extended period and the high risk of failure. India's gross expenditure on R&D and innovation (GERD) is relatively low with the country allocating merely about 0.7% of its GDP to research, trailing behind the developed and also some of the emerging economies such as the US (3.5%), Sweden (3.4%), Germany (3%), Israel (5.6%), and South Korea (5%) (as of 2021).[34] To accelerate and amplify the scope of innovation in India, it is imperative to increase the percentage of GDP spend on the R&D.

The Indian pharma companies also need to substantially increase R&D investment (internal innovation). The R&D spending trend by the top 10 global pharma companies has increased by about 5% in the last decade, while the R&D spend by the top 10 Indian pharma companies has in fact reduced slightly. In 2023, the cumulative R&D spending as a percentage of revenue by the top 10 global biopharma companies was around 20% compared to only about 6% by the top 10 Indian headquartered pharma companies.[35,36] To venture into the innovation space, Indian companies must increase overall R&D investment, and specifically in the upcoming next generation therapeutics.



Top 10 Indian headquartered pharma companies: Sun Pharma, Dr. Reddy's Laboratories, Cipla, Aurobindo Pharmaceuticals, Lupin, Alkem, Glenmark, Mankind, Zydus Lifesciences, Torrent

Top 10 Global pharma companies: Johnson & Johnson, Roche, Merck & Co., Pfizer, Abbvie, Sanofi, AstraZeneca, Novartis, Bristol Myers Squibb, GSK

Source: Capital IQ and annual reports of Indian pharma companies

[34] UNESCO

[35] Indian pharma industry

[36] Capital IQ and company reports

Strong innovation ecosystem is a must

The success of the global innovation hubs underscores the necessity for India to cultivate a dynamic and robust innovation ecosystem. In such an ecosystem, every stakeholder — biotech start-ups, academia, financing institutions, policymaker, regulator, pharmaceutical giants — plays a vital role and collaborates towards a shared vision for innovation. A recent EY analysis revealed that smaller biotechs were responsible for 55% of all new NME approvals by the USFDA from 2015 to 2019.[37] Large biopharma companies secured the remaining 45%. Notably, 60% of these NMEs were sourced externally through collaborations, acquisitions, deals/in-licensing, investments, or partnerships with smaller biotechs and academia.

The significance of such collaborations is further illustrated by the development of the first two COVID-19 vaccines approved by the USFDA, which originated from small biotechs – vaccines from Pfizer-BioNTech and Moderna-National Institute of Allergy and Infectious Diseases.

In India, the successful launch of the first indigenous CAR-T cell therapy exemplifies the power of public-private partnerships, uniting academia, hospitals and pharma. This model of cooperation must become the standard for future innovation.

Experts interviewed for this report emphasize the importance of aligning the efforts of pharma companies, academia, research institutions and biotechs to foster a conducive environment for innovation. They advocate for a communication platform that facilitates idea exchange and partnership formation on mutual interests.

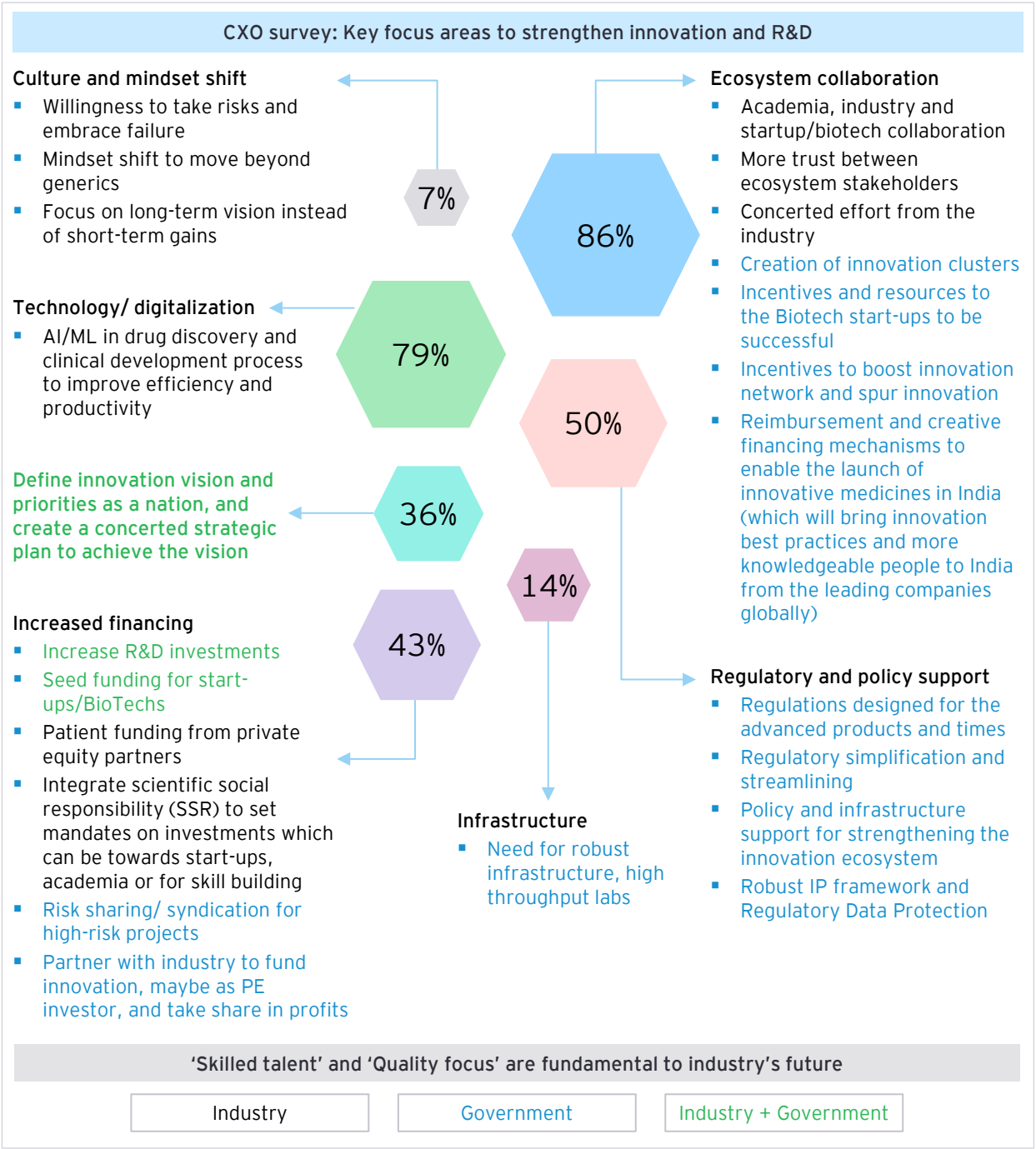
> India has primarily focused on small molecules and some biologics, but we must embrace a broader range of treatments. This requires collaborative ownership. Academia should focus on exploratory research, determining which diseases to study, the most effective mechanisms and modalities to treat diseases. Biotechs should come in for establishing proof of concept, and then industry should play their part to take it forward. The regulator's role is to be open to new ideas and offer feedback, allowing for iterative development.
>
> Government should enable a formal channel of communication where pharma companies must actively collaborate with start-ups, assigning them specific projects or problems, a practice common in the West but less so in India. It is essential for larger pharma entities to say, 'Develop this system for us, and we'll advance it together,' creating mutual benefits for both the biotechs and industry giants. Without this synergy, the gap widens, and start-ups grow disillusioned. Such a model can help us achieve self-reliance more swiftly.
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

[37] EY FICCI Report

> Innovation must be a collaborative endeavor. Synergy and trust between industry and academia are crucial. We envision companies opening labs in academic settings of their choice, where government-funded support for academic research is abundant. There should be some platform where large pharma organizations should give challenges to the PhD students on real-world problems, and foster new, innovative ideas that propel the industry forward. The platform should also enable academia to propose interesting research ideas to identify interested pharma companies with similar interests to partner. This change is imperative for innovation to flourish.
>
> The pharma sector has the potential to transform its Corporate Social Responsibility (CSR) initiatives by adopting a concept of Scientific Social Responsibility (SSR). By embracing the SSR approach, the pharma companies could concentrate on enhancing health outcomes and driving scientific progress through actions like funding innovative start-ups, bolstering educational institutions, and creating internship opportunities. By making SSR a mandatory aspect of investment, pharmaceutical companies can play a pivotal role in advancing science and healthcare, setting new standards for social impact and community engagement.
>
> Director, leading Indian pharmaceutical academic and research institute

As India's ecosystem players fortify their collaborative efforts in novel therapy areas, the country is on the brink of a significant transformation. Considering that the majority of next-generation therapies have been approved and commercialized within the last five to six years, there remains a window of opportunity and potential for India to emerge as a prominent force in the 'next generation therapeutics space'.

Cultivating cures: India's journey to becoming a pharma innovation powerhouse



A key takeaway from the primary research is the diverse perspectives on India's innovation potential and vision. Some experts believe that with all elements in place, by 2047, India could potentially launch a few blockbuster drugs, while others suggest that establishing the right ecosystem by then would be a significant achievement. Some argue that given the current pace, priorities and infrastructure, disruptive innovation may be out of reach, advising a focus on other opportunities instead. Experts agreed that it is crucial for the industry and the nation to articulate a clear vision for next-generation innovation by 2047. To realize this vision, stakeholders – academia, financiers, government, regulators, industry, and start-ups – must unite, each with clearly defined roles and KPIs, to work cohesively rather than in silos.

> We keep talking about the need to shift to innovation driven research. But it is important to define priorities and then make short- and long-term plan to achieve our goal.
>
> Director, leading Indian pharmaceutical academic and research institute

> As a nation, we must reach a consensus on our priorities and align our vision for innovation. Each stakeholder, including the private sector, academia, regulators, and funding agencies, must have a clearly defined role in achieving this vision. At present, divergent agendas among these groups hinder our progress. Establishing a national consensus is essential for functioning as a unified ecosystem and propelling collective advancement.
>
> Independent Director and Senior Advisor, leading Indian pharmaceutical company

The insights from the CXO survey emphasize the need to establish a robust innovation ecosystem as one of the most pressing needs to make progress in the innovation of novel therapies. The nation's robust pharmaceutical and CRDMO sector, IT expertise, good hospitals, and youthful population are significant assets that, if synergized effectively, can propel innovation forward. Experts suggest adopting a collaborative approach within the industry, and also between academia and government institutions such as the Council of Scientific & Industrial Research (CSIR), the Indian Council of Medical Research (ICMR), and the National Institutes of Pharmaceutical Education and Research (NIPER). Industry and academia synergistic partnership was called out as critical to develop basic research and skilled talent. We will discuss this in detail in the Chapter 3 of this report.

Innovation clusters, similar to those in San Francisco and Boston, should offer the essential environment for foundational research, advanced laboratory infrastructure, and a collaborative ecosystem where scientists can drive innovation alongside academia and industry. Regulatory frameworks must also adapt to support the rapid advancements in technology, ensuring that guidelines facilitate innovation.

Securing investments continues to be a significant hurdle, given the substantial financial commitment required over a period of several years and the inherent high risk of failure. Experts suggested the need to establish industry consortiums and explore partnerships with PE firms that can provide patient funding. The government's role in incentivizing and supporting the industry is crucial, with models such as risk syndication being suggested to alleviate the high risks involved in developing advanced therapies.

Experts also feel that there is a need to develop appetite and foster a cultural shift necessary to embrace the risk inherent in pioneering new therapies. In the West, failure is often seen as a stepping stone to success, a sentiment that needs to be cultivated in India to encourage innovation and experimentation.

> We have a disparate and fragmented ecosystem today. We need to integrate all our strengths to advance R&D and innovation. Leveraging the combined strength of our IT prowess, robust pharmaceutical and CRDMO industries, youthful demographic, and existing hospital infrastructure is crucial.
>
> We must also synergize the innovative efforts of government institutions like CSIR and ICMR with the capabilities of NIPERs, and foster a partnership between industry and academia to fully leverage these collective assets and expertise.
>
> Secretary General, Indian Pharmaceutical Alliance

> Indian pharmaceutical industry has laid a strong foundation in the last around two decades as the pharmacy to the world. We need to build upon this foundation and move up the value chain. We have been talking about this for a few years – we must significantly ramp up our investments in research and innovation. This requires not just investment but also enabling support from the government, including incentivization for exports and a robust intellectual property protection framework, ensuring that the crores of rupees invested in research are well-protected and yield the value they deserve.
>
> Director General, Organisation of Pharmaceutical Producers of India

> In India, we are trying to be as safe as possible. That never happens when you are looking at all these diseases and treating them with cutting edge technology –it always comes with a risk, but it is worth taking that risk.
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

> In terms of newer areas and technology, the investment is definitely a problem, for any company to come up with an NCE, we will have to spend at least a US$1 billion to US$1.5 billion, and a time frame of about 10 to 12 years to get a drug into the market. This kind of investment is not possible for most of the Indian companies. This is going to be a deterrent in terms of innovation in new drugs. We need some form of partnerships for financial backup and muscle power.
>
> Vice President - R&D, leading Indian pharmaceutical company

> The real challenge lies in the willingness to invest. Currently, many Indian pharma companies and investors seek immediate returns, but patience is key in novel technologies. Firms must seek private equity partners who understand the long-term nature of these investments and are not looking for a quick exit. Valuations will eventually materialize. We must also accept that not every experiment will succeed and should be prepared to embrace failure. Yet, as technology progresses, the frequency of breakthroughs is bound to increase.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> Advanced technologies, such as quantum physics and artificial intelligence, can be deployed to pre-emptively determine the interactions within the human proteome during drug development. By employing machine algorithms, a drug's safety, efficacy, and success ratio can be predicted much earlier in the drug research and development process. These kinds of advanced digital technologies can re-define R&D and improve efficiency and success rates.
>
> President of Safety & Logistics and Country Head, leading global CRO company

The CRDMO wave: India's strategic position and prospects

Global CRDMO landscape and India potential

The global CRDMO industry has grown at a rate of over 9% from 2018 to 2023,[38] and is expected to continue growing in the next five years. This momentum is mainly due to pharmaceutical companies' strategic pivot towards an asset-light model with the objective of concentrating on their key competencies – innovation and commercialization. Other factors driving outsourcing include the need to mitigate risk across portfolios, expedite the drug-to-market journey, and manage the intricacies of specialty and complex medicine production. Pharma companies are increasingly preferring end-to-end service providers, resulting in the rise of the CRDMOs that now act as strategic 'partners' rather than mere 'service providers.' Additionally, the emergence of smaller biotech firms lacking extensive infrastructure, and the impending patent expiries of numerous biologics are other significant growth opportunities for the CRDMO sector.

In this evolving landscape, India's CRDMO sector has made remarkable strides, transforming from a local player to global contenders. Their capacity to deliver cost-effective solutions, backed by a pool of qualified and skilled scientists and researchers, has positioned them at the forefront of the industry.

The diversification of supply chains, spurred by the COVID-19 pandemic and geopolitical shifts, has become a strategic imperative for pharma companies globally. The US BIOSECURE Act*,[39] which seeks to diminish the US companies' reliance on foreign biopharmaceutical sources, especially from China, is further set to catalyze a pivotal realignment within the CRDMO sector.

Majority of the top 10 pharmaceutical companies and numerous large biotech firms today already outsource a portion of their preclinical and clinical research to India.[40] As companies worldwide search for secure and reliable R&D and manufacturing partners, with its strong foundation in pharmaceutical manufacturing and a growing emphasis on quality and compliance, India is well-positioned to capitalize on the shifts and position itself as the leader in the global landscape.

**The Act aims to reduce US biopharmaceutical reliance on China and restrict technology transfer. Specifically targeting five Chinese giants—WuXi Apptec, Wuxi Biologics, BGI, MGI, and Complete Genomics—the Act bars firms collaborating with these companies from receiving US government grants, loans, or contracts, though existing contracts may be honored for up to eight years.*

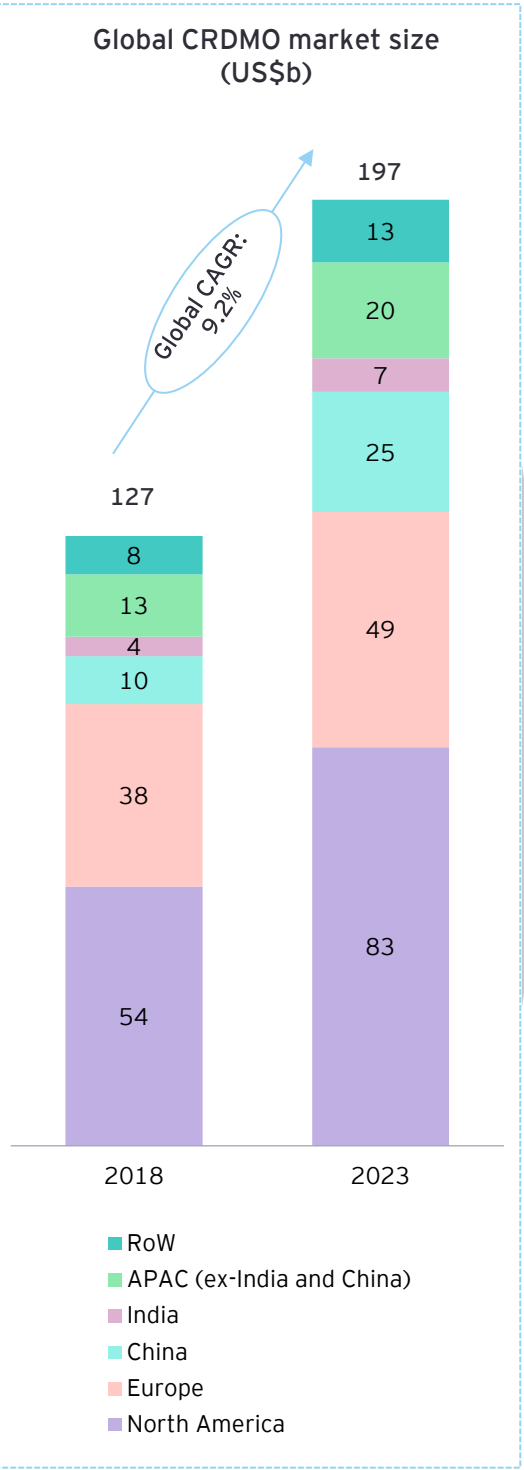
[38] Frost-sullivan-industry-report.pdf

[39] 118th congress house bill

[40] CROs CDMOs

CRDMO market size and growth drivers for India

The global CRDMO industry has experienced robust growth with a CAGR exceeding 9% from 2018 to 2023



Emergence of industry trends boosting CRDMOs

Creation of end-to-end services by integration of CROs and CDMOs, resulting in the rise of CRDMOs that act as 'partners'

Pharma companies' shift towards asset light model

Focus on their core activities of innovation and commercialization, and for optimizing cost

Growing dependence on CRDMOs to address complexity

~70% of the ADC manufacturing is outsourced owing to manufacturing complexity, augmenting the role of CRDMOs

Portfolio de-risking

Pharma companies are outsourcing very high-risk or very low-risk projects to specialized service providers and improve efficiency

Shorter time to market

Outsourcing enables pharma companies to run parallel activities and bring new drugs to market quickly

Biosimilars surge from biologics patent expiry

Patent cliffs in the US/EU over the next 5-10 years are set to boost the CRDMO biosimilar market

Emergence of small/virtual BioTechs

Limited in-house resources and high dependence on technology (in-silico, AI/ML driven research) leading to heavy outsourcing

India's position and opportunities

Supply chain de-risking – China +1 strategy

Changing dynamics due to geopolitical and macroeconomic shifts, the US BIOSECURE Act, gives an opportunity for Indian CRDMOs to establish as a reliable outsourcing option

Continued government support

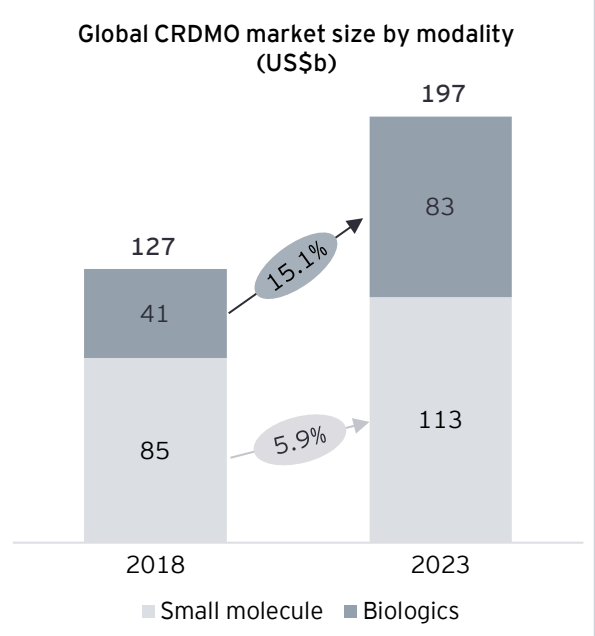
Initiatives such as the BioE3 policy, PRIP and PLI schemes to bolster Indian CRDMOs' capabilities and enhance global competitiveness

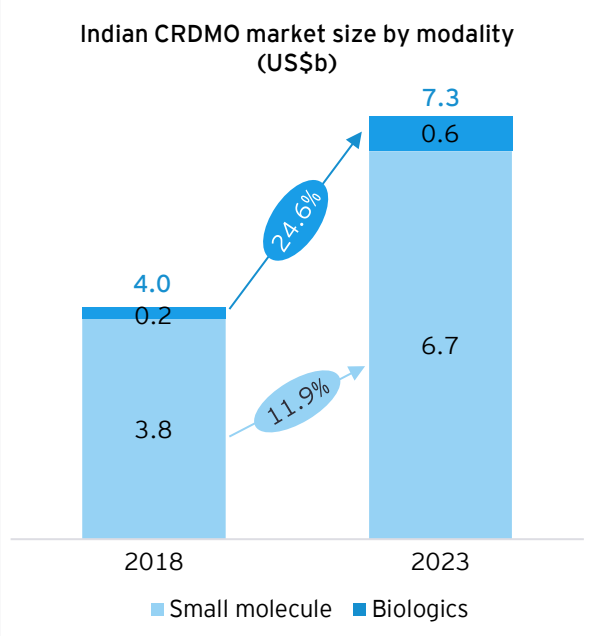
Availability of **skilled personnel, lower production cost, and lower capex spend,** large number of WHO-GMP certified plants serves as the key driver

Source: Sailife CRDMO report

Indian CRDMOs building scale and capabilities

Global CRDMO market is experiencing a paradigm shift towards large molecules, with their share increasing from 35% in 2018 to approximately 42% in 2023.[41] This trend is expected to persist, propelled by the increasing shift towards next-generation therapeutics, as also discussed in the previous section of this chapter. Conversely, the Indian CRDMO industry has traditionally been skewed towards small molecules, which accounted for over 90% of the market in 2023.





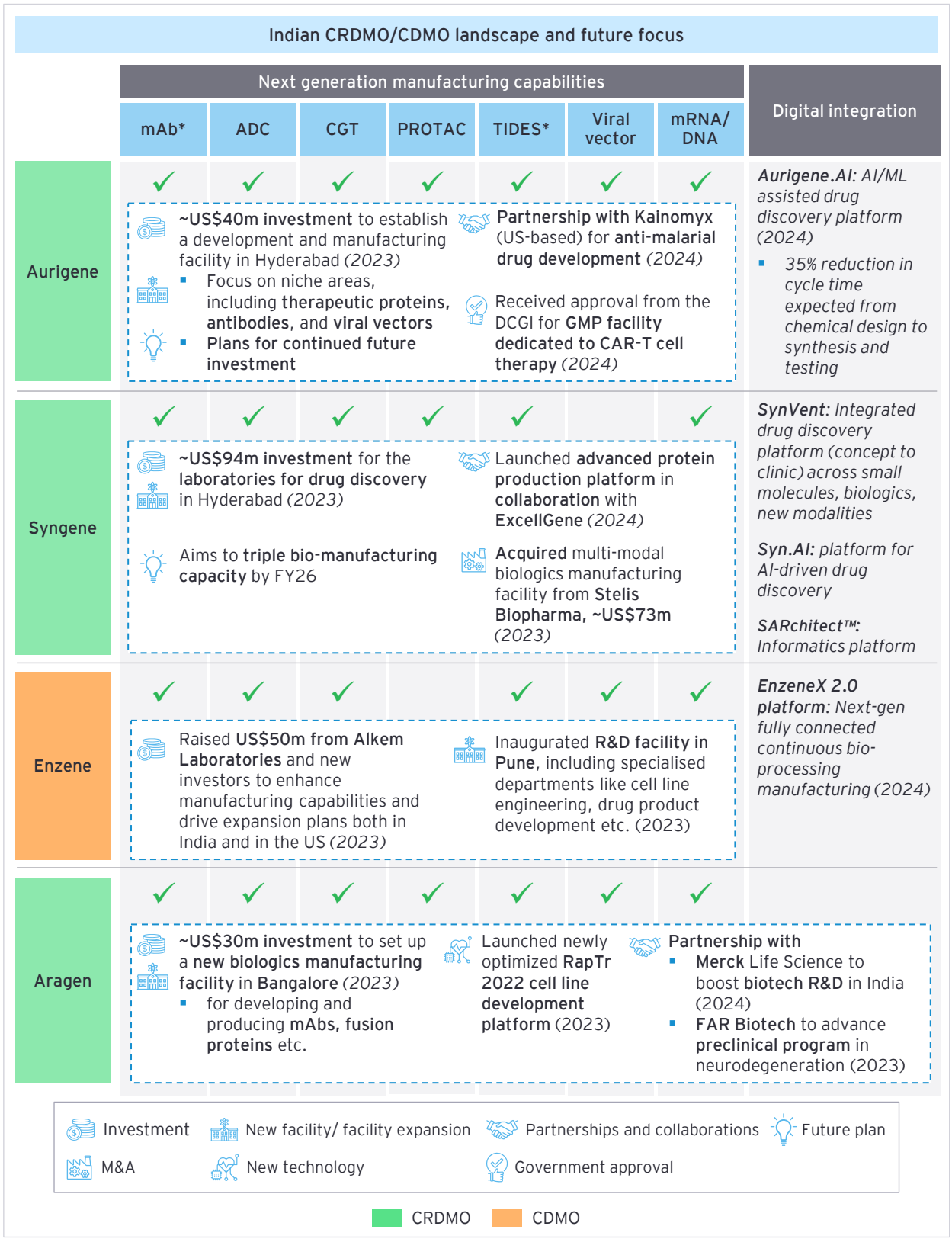
Source: Sailife CRDMO report

However, recognizing the growth potential in the global CRDMO industry and the strategic China+1 opportunities, leading Indian companies are recalibrating their strategies to broaden their scope in this sector. Companies are channeling substantial investments to enhance their manufacturing capabilities beyond generics or small molecules. They also aim to become comprehensive service providers and offer one-stop-shop from "concept to commercialization". For instance, Syngene International's investment of US$98 million in a new biologic manufacturing facility, inclusive of microbial cGMP and mammalian cell manufacturing capabilities[42], and its acquisition of Stelis Biopharma's multi-modal biologics manufacturing facility in 2023,[43] are indicative of this strategic shift. Similarly, Aurigene Pharmaceutical Services planned US$40 million investment for a facility specializing in therapeutic proteins, antibodies, and viral vectors in Hyderabad underscores the industry's direction.[44]

The sector's expansion is further evidenced by significant moves from major domestic pharmaceutical players. Aurobindo's joint venture with MSD to establish a biologic facility,[45] Alkem's Enzene Biosciences' inauguration of its first manufacturing site in the United States,[46] and Gland Pharma's acquisition of the French-based CDMO Cenexi,[47] all signal the increasing significance of the CRDMO/CDMO sector. These developments not only reflect the industry's growth but also its readiness to embrace more complex biologic and large molecule projects, positioning India as a competitive force in the global CRDMO landscape.

Alongside industry effort, government is also providing support through initiatives such as the BioE3 policy, PRIP, and PLI scheme discussed earlier in this chapter.

[41] Frost-sullivan-industry-report.pdf
[42] Syngene
[43] Stelis_Syngene
[44] Aurigene biologics
[45] Aurobindo Pharma
[46] Enzene Biosciences launches its first manufacturing base in the US | Enzene Biosciences Ltd.
[47] Gland pharma

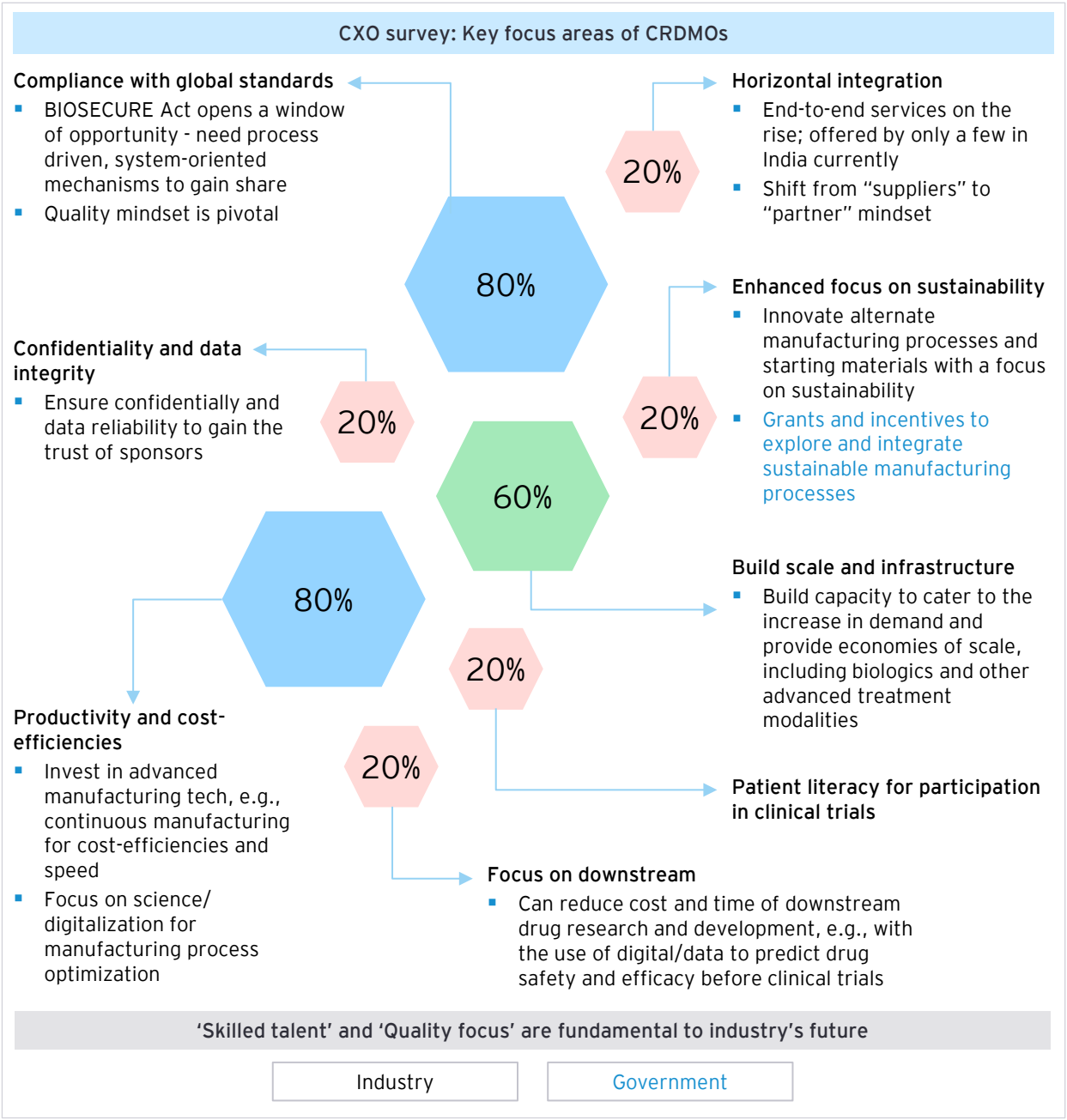


Non-exhaustive

**mAb: monoclonal antibodies; TIDES: Oligonucleotide and Peptide Therapeutics*

Source: Aurigene-investment, Aurigene-Kainomyx, Aurigene-GMP facility approval, Aurigene.AI, Syngene-investment, Syngene-FY26 aim, Syngene-ExcellGene, Syngene-Stelis Biopharma, SynVent, Syn.AI & SARchitect™, Aragen-investment, Aragen-Merck, Aragen-FAR Biotech, Aragen-RapTr, Aragen-digital platform, Aragen-Xlrate, Enzene-Alkem, Enzene-R&D facility, EnzeneX Technology, EnzeneX 2.0

Strategic imperatives for Indian CRDMO market dominance



The future of India's CRDMO industry hinges on several pivotal themes, as revealed in the CXO survey. Experts unanimously agreed that while enactment of the US BIOSECURE Act could redirect business from China, yet India must assess its capacity to absorb such a shift. To grab a large part of this business, the Indian industry must elevate its scale and efficiency to match global leaders. This includes enhancing quality, reliability, and compliance with international standards to attract and retain multinational clients. Specific focus is required to strengthen capabilities in the biologics space to capture the large market that would open up with the upcoming patent expiry of some of the big blockbusters.

Availability of a skilled talent pool was highlighted as a critical concern. With fewer students entering scientific fields, there is an urgent need for initiatives that promote careers in science and pharmacy. There also need to be initiatives to ensure that the students coming out of the colleges are appropriately skilled to be absorbed by the industry for the numerous upcoming roles. The talent agenda has been discussed in detail in the later part of this report.

Confidentiality and sustainability are also key considerations. Indian CRDMOs must demonstrate their commitment to protecting intellectual property and adhering to sustainable practices to gain the trust of potential partners. Moreover, the industry must focus on advanced manufacturing techniques, such as continuous manufacturing, to improve cost efficiency and productivity.

The concept of horizontal integration, where companies offer end-to-end services from clinical research to market release, is gaining traction. Additionally, focusing on the downstream aspects of drug development can enhance the process's speed and predictability, potentially leading to quicker market entry and a lower risk of failure.

Patient education was also highlighted as being important for the industry's growth. With only a small fraction of India's population participating in clinical trials, there is a vast untapped potential for India to become a clinical trial hub. By educating patients about the drug development process and the importance of clinical trials, India can increase participation rates and expedite the introduction of new therapies. **The integration of digital technologies and innovative tools is essential in driving progress in these key areas.**

> BIOSECURE Act has come in as a favorable tailwind for India. Companies are looking for an alternative for supply chain security – China+1. This is an opportunity for Indian CRDMO companies to showcase and deliver global standards. There is this window of opportunity that is emerging. If we build the capability and the talent pool, and deliver the desired cost and speed, this industry will grow to glory.
>
> Executive Chairperson, leading Indian pharmaceutical company

> With the BIOSECURE Act, a lot of companies will try to come out of China. The CRDMO industry can benefit immensely, provided the productivity levels go up. India needs to have scale and efficiency with which it operates with a strong focus on quality and compliance. A lot of upgrades will have to be applied by the Indian CRDMOs to capture the bulk of the work coming from China.
>
> Chief Quality Officer, leading Indian CRDMO company

> Just by the BIOSECURE Act, the business will not come to India. To enhance India's CRDMO sector, following focus areas are important: first, building the talent base is very important. Second, adopt advanced manufacturing techniques like continuous manufacturing to drive cost efficiency. Third, focus on building scale and providing robust infrastructure, which is essential to attract companies. And last but not the least, prioritize data reliability and quality, embedding these values deeply into our industry's mindset, as they are critical for establishing trust and credibility in the global market.
>
> Secretary General, Indian Pharmaceutical Alliance

> A significant challenge in the CRDMO sector today is the scarcity of talent – we require a robust pool of scientists, project managers, and other skilled professionals.
>
> Executive Chairperson, leading Indian pharmaceutical company

> The BIOSECURE Act could indeed prompt a shift away from China, but the question remains: is India prepared to match the scale and efficiency of giants like Wuxi? ...To benefit from this opportunity, we must elevate our standards, particularly in productivity and quality. We need to make significant upgrades to our infrastructure and a commitment to world-class standards to seize the bulk of this opportunity.
>
> Chief Quality Officer, leading Indian CRDMO company

> Investment in skill development and talent expansion is critical. India is home to the largest pool of skilled talent, but we must bridge the gap between academic output and industry needs. We need initiatives that cultivate industry-ready clinical researchers, data scientists, and healthcare professionals. Current courses, while theoretically sound, often lack practical industry relevance.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> We face a significant challenge in sourcing both manpower and quality talent. As professionals and government entities, we must inspire the next generation to pursue these critical fields. It is imperative that we act now to develop strategies that attract and retain talent within the pharmaceutical industry. Without intervention, we may face a future where skilled pharmacists and scientists are scarce.
>
> Vice President - R&D, leading Indian pharmaceutical company

> I believe more Indian companies should consider horizontal integration to form CRDMOs. These cover the entire journey of clinical research and manufacturing services on an end-to-end basis, which is preferred by global multinationals these days as it eases out the burden of having to go to multitude of providers.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> Patient education is a cornerstone for expanding India's role in the global drug development process. Despite being a vast market for pharmaceuticals, only about a very small percentage of India's population engages in clinical trials. We need to dispel myths and build trust by educating the population on compliance standards and the drug discovery and development process. If we can enhance patient understanding and confidence, India has the potential to become a world leader in clinical trials, surpassing the current market share held by China and others.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> CRDMOs will have to start thinking not just from the molecule manufacturing perspective, but what else can they do on the upstream and the downstream through the entire lifecycle of the drug development in a much more cost effective yet compliant manner. I think the one area that most of the time the CRDMOs focus on is the upstream, for instance, improving the chemical composition of the product, more efficient product manufacturing. We also now need to evolve on the downstream – how effectively are we able to get more innovative ways to do the drug research, identify the patients, recruit them more effectively, and get the drug faster into the market. Ability to predict the safety and efficacy, and probability of success of the drugs even before the first-in-human study happens. Digital and data platforms for predictive analytics can play an important role and increase our trust with the sponsors.
>
> President of Safety & Logistics and Country Head, leading global CRO company

The digital infusion: Enhancing the pharma R&D value chain

Digital technology, data analytics and artificial intelligence (AI)/machine learning (ML) hold the potential to revolutionize the entire R&D value chain, spanning from drug discovery to clinical development. This transformation can enhance efficiency and productivity, reduce cost and timelines, and improve patient access and diversity.

Numerous start-ups are emerging to offer R&D platforms and solutions, some of which have already achieved initial success such as Sravathi AI that developed 100 new chemical entities (NCEs) customized for curing COVID-19 using AI and other advanced computing techniques.[48] Some of the Indian companies are also getting into this field. For instance, TCS recently launched its ADD Connected Clinical Trials[49,50] a comprehensive platform for patient-centric clinical trials. This cloud-based interface streamlines operations by connecting patients, sites, and sponsors with features for tracking, digital labeling, adherence monitoring, electronic diaries, outcomes assessments, consent, and tele visits. It supports automated data collection and remote monitoring for handling large volumes of data efficiently. IIT Madras Researchers[51,52] have developed an AI-based tool, 'PIVOT', that can predict cancer-causing genes in an individual which can be crucial for patient stratification/ selection for clinical trials based on their genetic profile and likelihood of response and/ or devising personalized cancer treatment strategy.

Leveraging its formidable IT prowess, India is well-positioned not just to excel in the digital domain but also to drive the innovation wave across its pharmaceutical industry. This encompasses R&D and the creation of next-generation therapeutics, attaining self-sufficiency in APIs and KSMs production, and establishing a dominant presence in the international CRDMO market. **Drawing on global precedents, Indian firms with strong IT capabilities have the potential to make significant strides and position India as a global nexus in the pharmaceutical sector.**

> "India is recognized as the global IT hub. We possess all the necessary ingredients to not just catch up but to leapfrog ahead, creating not just best practices, but next practices that others will emulate. Companies globally admire India's core strengths and look up to us for inspiration. With pride in our capabilities and the potential of AI and cloud computing, we can deliver world-class healthcare solutions to our patients and the global community."
>
> Independent Director and Senior Advisor, leading Indian pharmaceutical company

> "The latest that data science can contribute to research is in the area of natural language processing (NLP), machine learning and predictive analytics in clinical trials. Some of the outcomes that predictive analytics and machine learning algorithms have assisted clinical domains are designing better clinical trials, detecting adverse events by analyzing real-world evidence such as electronic health records and insurance claims data, predicting the side effects to medications, interaction prediction between drugs, predicting clinical trial enrolment and dropout rates."
>
> Managing Director, leading global pharma MNC

[48] Sravathi AI

[49] TCS ADD™ CCT: Digital Trials in a Connected World

[50] Clinical trial platform launched by TCS bags Indian pharma award (freepressjournal.in)

[51] IIT-M technology to play 'Pivot'al role in providing patients with cancer with individualised care (adda247.com)

[52] IIT Madras

Digital and data-driven drug discovery

Potential to transform drug discovery by increasing efficiency and productivity; improving regulatory compliance; and reducing failure rates, cycle time and overall costs

Global use cases*

Next-generation sequencing using AI/ML	Target identification and drug discovery	Drug development
▪ Generating multiple levels of genomic data for drug discovery, including transcriptome profiling and epigenetic modifications	▪ Enhance and accelerate identification of new molecular targets (genes or proteins) ▪ Predict safety/toxicity and efficacy of compounds to improve probability of success ▪ Next-generation sequencing: Generating multiple levels of genomic data for drug discovery, including transcriptome profiling and epigenetic modifications	▪ Reduction in overall time from novel target identification to preparing a drug for clinical trials ▪ Lower costs while increasing success rates (possibility to reduce time and money spent by up to 90%) ▪ Generative AI (GenAI) to design novel drug candidates and predict the potency of molecules for selected targets ▪ Drug repurposing to identify new uses for clinical stage molecules

Successful adoption in India*

MedGenome
AI/ML based tools for deep informatics transforming data into insights for bulk transcriptomics

Clevergene
Augmenting genomic discoveries, genetic diagnostics and precision medicine through DNA sequencing and **AI driven data interpretation**

Aurigene.AI
AI-assisted drug discovery platform

Syngene Syn.AI
platform for AI-driven drug discovery

IIT Madras
Developed an AI-based tool (PIVOT), to predict cancer-causing genes in an individual

Peptris
AI-driven drug development/discovery platform

Sravathi AI
Proprietary AI-based platform to generate novel compounds, identify and validate targets

ImmunitoAI
AI-platform for discovering and developing novel biologics with pre-defined drug properties

CRDMOs/CDMOs | Research institute and academia | Drug discovery start-ups | Bio-tech companies

Non-exhaustive

Source: Aurigene.AI, Syn.AI, Peptris, Sravathi AI, IIT Madras-PIVOT, Clevergene, Medgenome, Immunito AI

Digital and data-driven clinical trials

Clinical Trials (CT) can be significantly optimized using digital tools and AI across the value chain, starting from trial design and patient recruitment, to management and monitoring

Global use cases*

CT value chain

CT design	Recruitment	CT management and monitoring
▪ Reduction in the size of control arms ▪ Digital twin control arm to predict treatment progression/ outcome ▪ CT companion tool to optimize, automate and add intelligence into design, planning, and costing process ▪ Identify novel biomarkers and endpoints to predict patient outcomes ▪ Faster and accurate drug trial site selection	▪ Improve diversity in CT patient population ▪ Accelerate patient recruitment ▪ Better detection of patient populations to accelerate and de-risk treatment development ▪ Software platform to match patients with CT in near real-time	▪ Faster data review using Real World Evidence (RWE) / clinical evidence ▪ Predict/alert about safety and tolerability signals for early action and improving trial success rate ▪ Clinical supply chain planning and optimization ▪ Improved patient experience and retention ▪ AI-powered facial and image recognition algorithms to monitor drug adherence ▪ Automated production of key submission documents

Decentralized clinical trials

- Increases access and inclusivity, reduces geographical barriers and allows for greater participation from diverse populations
- Improves patient retention: remote monitoring, in-home visits, and virtual visits; eliminates the need for frequent in-person visits

Successful adoption in India*

Cloud based clinical trial management system

TCS ADD connected clinical trial platform

Connected Clinical Trial platform unified interface for patients and sites, and incorporates smart, intuitive, futuristic, cloud-based technologies

Clinevo Technologies

Cloud-based clinical trial management systems

AI/ML-driven digital biomarker repository

OncoStem Diagnostics

*Developed "**CanAssist Breast Biomarkers**" for cancer prognosis using ML algorithms*

Tata Medical Centre + IIT collaboration

Launched a de-identified cancer image bank to improve biomarker detection

Decentralised clinical trials

Advarra

Support decentralized clinical trials from study design to close-out

Anju Software

***TrialMaster Electronic Data Capture (EDC) suite** - enables management and scaling of even the most complex decentralized trials in record time*

Real word evidence/ clinical evidence using AI

THB

End-to-end support on evidence generation - RWE insights from over 1 billion+ clinical parameters

HealthTech company | Research institute and academia

Non-exhaustive

Source: Clinevo, TCS ADD, THB, Advarra, Business Standard: THB, Anju Software, Tata Medical centre and IIT, Oncostem

Need for robust Intellectual Property (IP) framework and regulatory data protection for ease of doing business

Access to innovative and affordable medicines is crucial for every country to maintain public health. Robust intellectual property framework plays a crucial role in safeguarding innovation. This is important for global companies to bring their innovation to India and also for the domestic companies to confidently make investment in R&D and innovation. Recognizing this, the Indian government has taken significant steps to foster a supportive environment for innovation by streamlining the IP framework as part of broader reforms to improve the ease of doing business.

Overview of recent Patents (Amendment) Rules:

The Government amended the Patents Rules in March 2024[53] as part of a broader effort to strengthen India's position in the global innovation landscape. By streamlining procedures to be more applicant-friendly and reducing administrative burdens, the new patent rules represent a significant milestone in the quest to promote innovation and economic growth.

In addition, industry experts also highlighted the need for Regulatory Data Protection (RDP) in India for biopharmaceutical companies seeking to safeguard their clinical trial data that they have generated with a lot of investment. Although India currently lacks RDP, the recent Trade and Economic Partnership Agreement (TEPA) signed with the European Free Trade Association in March 2024[54] includes provisions for "Protection of Intellectual Property on undisclosed information." This represents a potential first step towards data exclusivity and underscores India's commitment to addressing concerns about unfair practices.[55]

To further expedite the process and make it more efficient, experts emphasized establishing specialized bench led by judges who are well-versed in the scientific intricacies of drug innovation. Such a bench would ensure that legal decisions are informed by a deep understanding of the pharmaceutical domain.

India's commitment to transforming its IPR framework, as evidenced by the recent reforms and the TEPA agreement, reflects a broader vision of fostering a thriving innovation ecosystem. By addressing the remaining challenges and continuing to refine its IPR regime, India can further solidify its position as an attractive destination for investment and a global leader in innovation.

[53] Understanding 2024 amendment India patents rules

[54] PIB-Press release

[55] Express pharma

Summary of key amendments in Patents Rules 2024*

Before	Amendment	Impact
Commercial working statement (Form-27)		

Working statements required on an annual basis	▪ **Working statements to be submitted once in three years**
	▪ Simplified Form-27
	  ▪ No information needed on revenue/patent value
	  ▪ One Form-27 can be filed in respect of multiple patents, provided all are related patents and are granted to the same patentee(s)
	  ▪ One of the joint patentees can file single Form-27 on behalf of all the patentees
		▪ **Simplifies reporting requirements**

General extension of time and condonation of delay		
Extension of one month was allowed	**Up to 6 months extension** or condonation of delay for ▪ Patent Cooperation Treaty (PCT) national phase entry ▪ Request for examination ▪ Response to Office Action ▪ Written submission post hearing ▪ Procedural formalities such as Proof of Right, Power of Attorney, verified English translations, etc. **Request for an extension** of time or condonation of delay **can be made multiple times** within the six months' extended period	▪ **Relaxed and flexible timelines**
Pre-grant opposition		
	New screening process: ▪ Requires the Controllers to examine whether a pre-grant opposition holds merit at a preliminary level ▪ **Timelines of 1 month for processing oppositions** and to dismiss frivolous oppositions	▪ **Speedier pre-grant opposition proceedings** ▪ Acts as a deterrent for frivolous pre-grant oppositions or filing of proxy pre-grant oppositions
Timeline: Up to 3 months to file a reply statement	▪ Timeline has reduced to **two months**	
Official fee: no fee for filing pre-grant opposition	▪ **Introduction of fees** for filing pre-grant oppositions and attending hearings	
Post-grant opposition		
Time period of three months for the opposition board to provide their recommendation	▪ Timeline has reduced to **two months** ▪ **Increased fees** for filing post-grant oppositions and attending hearing	▪ **Speedier post-grant opposition proceedings** ▪ Acts as a deterrent for frivolous oppositions

Non-exhaustive

Source: EY analysis, Patent rule

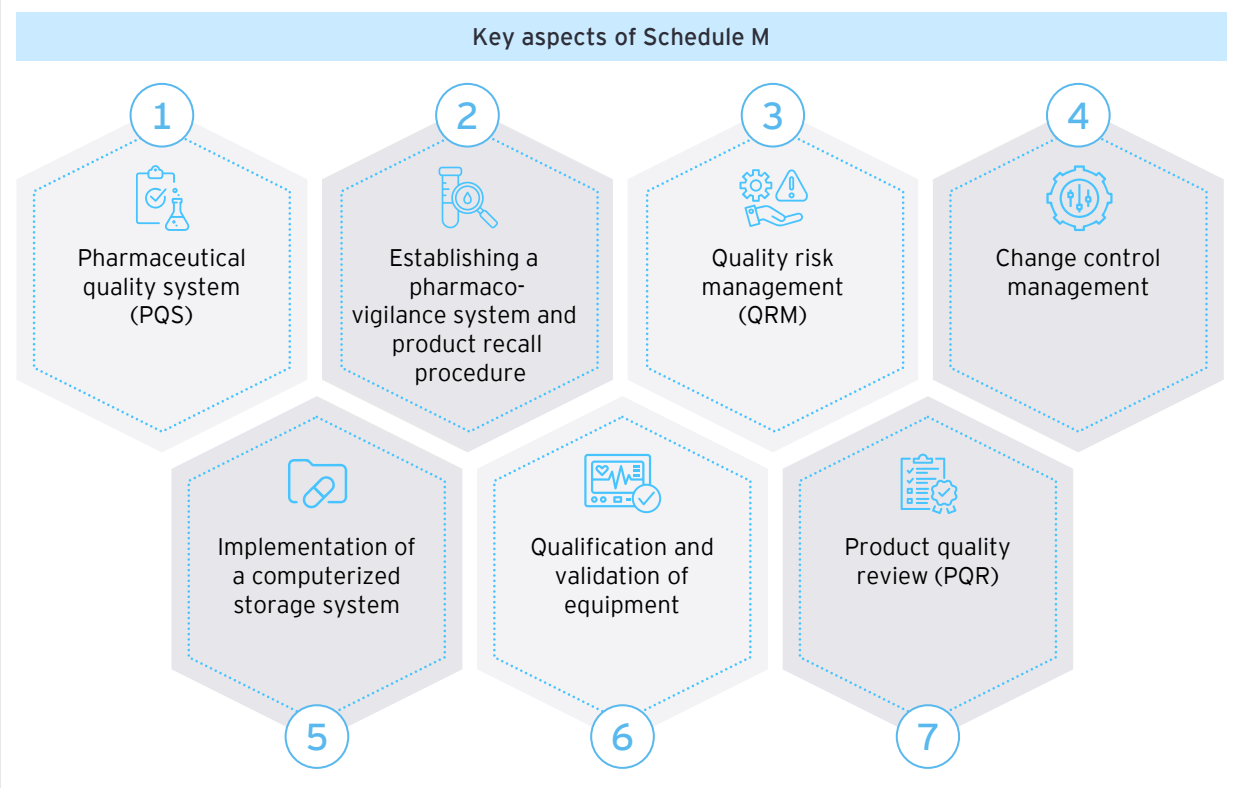
> Since 2005, this is the most remarkable change in the IP law that has happened. It kind of sends the right message that India is willing to look at some of the outstanding issues.
>
> Managing Partner, leading Indian law firm

> We have witnessed encouraging developments in the recent years with several changes enhancing our IP landscape, including progress in pre-grant opposition. On a scale of ten, we are halfway there, and there is some more ground to cover. Let us continue this positive momentum towards the journey of a fully robust IP system.
>
> Director General, Organisation of Pharmaceutical Producers of India (OPPI)

Quality focus: Building credibility and strengthening India's position in the global market

As Indian pharma companies, API manufacturers, and CRDMOs/CDMOs continue to expand their geographical footprint and build capabilities outside simple generics to gain global leadership, it is essential that quality and compliance are embedded as key element in the overall growth strategy. With numerous manufacturers in the country, there is a pressing need to ensure that all companies adhere to the required quality and compliance standards on par with the global standards.

To ensure this, all pharma manufacturing companies operating in the country have been directed to adopt mandatory Good Manufacturing Practice (GMP) standards under Schedule M notified in December 2023. Pharma manufacturing companies with annual turnover of >INR250 crore were to compulsorily follow GMP within six months (June 2024) while those with a turnover <INR250 crore were expected to do so over a 12-month period (December 2024). The government has placed special emphasis on manufacturing premises, risk management, self-inspection, qualification and validation of equipment, in addition to the existing GMP requirements.[56,57]



Source: Revised Schedule M

[56] Schedule M

[57] GMP-revised-guidelines

In October 2023 Indian Pharmacopoeia Commission (IPC) became a member of Pharmacopoeial Discussion Group (PDG),[58] that will bring together the US, European, Japan, and Indian Pharmacopoeia to harmonize global pharmacopeial standards.

IPC's membership in the PDG is one step forward towards promoting harmonization of pharmaceutical standards, improving regulatory compliance, facilitating international recognition, and is expected to play a substantial role in bolstering the export of pharmaceuticals manufactured in India.

In line with the growing focus on quality, India hosted the 19th International Conference of Drug Regulatory Authorities (ICDRA) for the first time, which brought together global regulators and industry leaders from over 194 WHO member states, to discuss critical issues affecting drug regulation. India highlighted Central Drugs Standard Control Organization (CDSCO) achievements such as the establishment of robust systems for the approval of safe and efficacious drugs, digitalization of over 95% of regulatory processes brining in transparency, implementation of QR codes on leading drug brands to strengthen the drug supply chain.

The conference also featured key discussions around various topics including smart regulations to streamline processes across countries; the need for stringent regulations of pharma products starting from their inception; and role of AI in improving regulatory oversight and addressing challenges related to data privacy and protection.[59]

[58] PIB-PressRelease

[59] PIB-PressRelease

Company initiatives

Fostering a culture of compliance with global best practices like Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) is crucial to ensure that manufacturing and distribution processes align with the necessary quality and safety regulations. To ensure quality compliance, companies are investing in robust quality management systems and conducting thorough risk assessments. For instance, Syngene has invested ~30% of its capex into development and manufacturing, including support infrastructure such as a quality control lab and a testing laboratory for biologics manufacturing, and has a fully digitalized quality management system.[60] Neuland Labs has a comprehensive Quality Assurance Management System (QAMS), and Laboratory Information Management System (LIMS) ensuring proactive defect prevention, data accuracy and integrity, and accessibility for informed decision-making.

At the heart of these efforts lies the adoption of a culture of quality. For instance, Aurobindo Pharma has instituted a Quality Marshal program and initiated specialized training led by industry experts. The company follows a three-tiered approach for internal quality audits and has made substantial investments in technology and automation.[61]

Syngene's tech-integrated Quality Management System

Digital and automation tools in the quality control laboratories optimize operational efficiency, and enable the highest standards of quality and traceability in the processes

Key technologies

Digitalization of quality processes	Integrated quality management system	Automation for enhanced efficiency and error reduction

▪ **Implemented Electronic Lab Notebooks (ELNs)** across all service divisions
  ▪ facilitates audits
  ▪ enables compliance with Good Practices (GLP, GMP, GRP) and ALCOA+ principles*
▪ **Electronic Batch Manufacturing Records (eBMR)**
▪ **Laboratory Information Management System:** to ensure data integrity, supporting quality control and regulatory compliance
	▪ **TrackWise system** for managing deviations, change controls, CAPAs*, and other quality events, ensuring compliance with regulatory standards
	▪ **Learning Management System (LMS)** to provide online training modules on various quality-related topics
		▪ **Automated liquid handling systems** and robotics in high-throughput screening and other processes
		  ▪ increased speed and regulated quality
		▪ **Paperless laboratory operations** by utilizing Electronic Document Management System (EDMS) and electronic forms

Impact

- **Improved speed, accuracy and quality control**
- **Robust quality management - enhanced data integrity, traceability and efficiency**

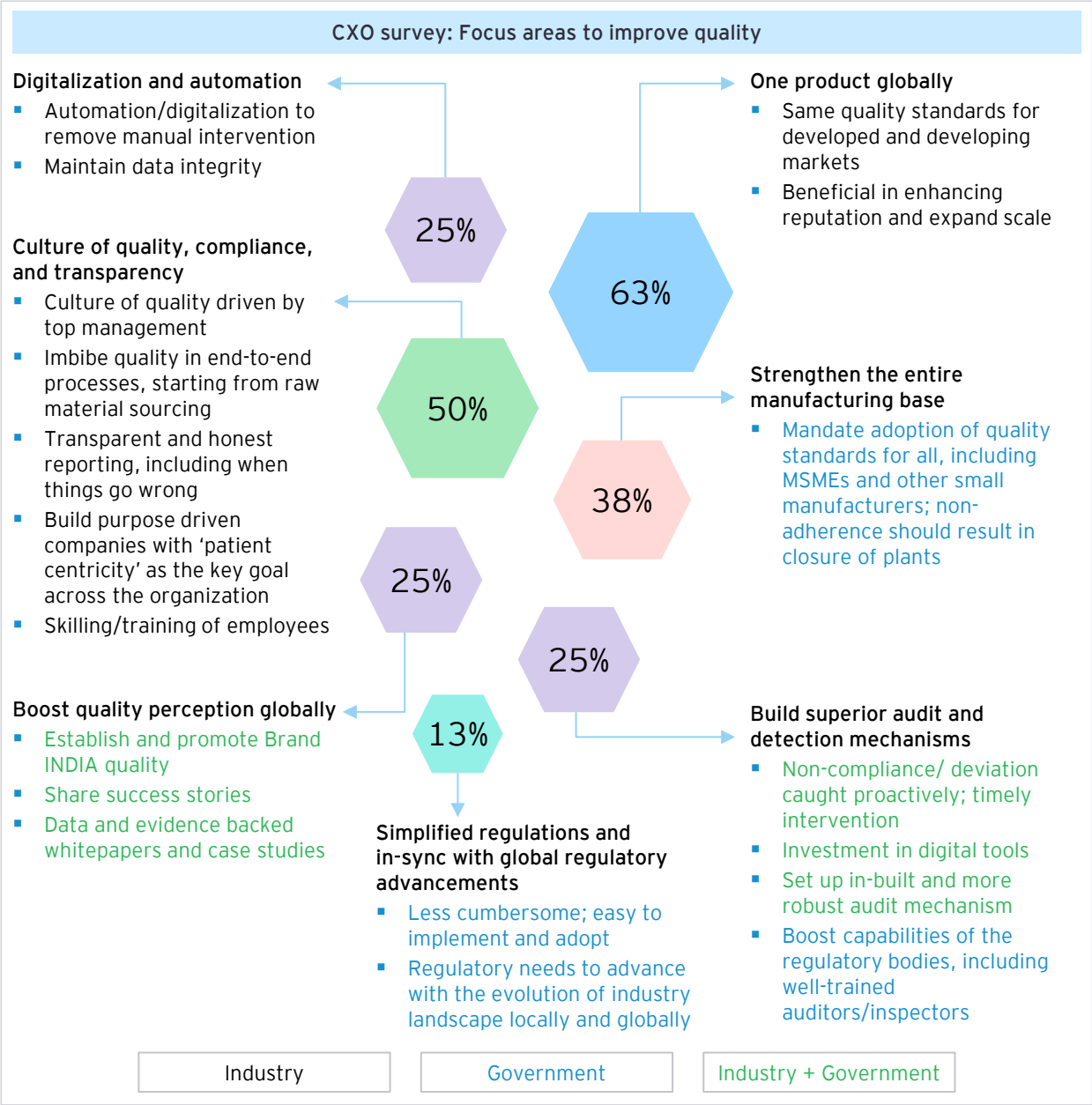
** ALCOA stands for Attributable, Legible, Contemporaneous, Original, Accurate; GLP: Good Laboratory Practice; GRP: Good regulatory practice; CAPA - Corrective and Preventive Action (CAPA)*

Source: Syngene, Quality management

[60] Syngene-Annual-Report-2023-24-main.pdf

[61] Aurobindo

Quality milestones transforming pharma for the future



The collective insights from industry experts outline a comprehensive strategy for India to elevate its pharmaceutical sector, emphasizing the importance of fostering a robust quality culture, enhancing detection mechanisms, and striving for global quality standards.

Digitalization and automation were called out as the way forward to ensure data integrity and compliance. Most large pharma companies and CDMOs have implemented advanced systems such as paperless QC labs, fully digitalized quality management systems. Yet, for India to truly lead in the pharmaceutical sector globally, there is a call for the entire industry to embrace digital transformation and automation.

Experts emphasized the importance of mandatory quality standards for all MSMEs and small pharmaceutical manufacturers, claiming this is crucial to strengthen the industry's foundation.

Quality perception is another focal point, with a recommendation to publish white papers that articulate the high standards followed by Indian pharma. These reports should be data and evidence-backed, serving to market India's commitment to quality to the international community. Furthermore, experts stress the importance of celebrating successes and building a positive image of India's pharma sector, as seen with the hosting of the international regulators conference by CDSCO.

By highlighting such achievements, India can construct a narrative that showcases its progress and potential.

There is a need for better mechanisms to detect non-compliance, shifting the focus from imposing heavy compliance to enhancing the efficiency of detection. This shift will ensure that regulations are not just on paper but are actively enforced and adhered to.

Culture of quality and compliance is critical to maintaining high standards, and this should be driven by the top. There should be transparency in all reporting. Experts also highlighted the need for a single global product standard, which would not only improve the quality of pharmaceuticals, but also streamline manufacturing processes and elevate compliance levels.

In summary, the path forward for India's pharmaceutical industry involves a strategic blend of digital innovation, culture of quality and transparency. By addressing these areas, India can not only meet the current challenges but also position itself as a leader in the global pharmaceutical landscape.

> Companies must be driven by purpose, and for pharma companies, that purpose is serving patients. Merely stating patient-centricity is not enough; it must be a value deeply rooted across all levels of the organization. The worker on the shop floor packing paracetamol should feel a sense of pride, knowing their work is part of a larger mission to save lives. It is the responsibility of senior leaders to instill this belief in every employee, to recognize the privilege we have in making a tangible difference in people's lives.
>
> Independent Director and Senior Advisor, leading Indian pharmaceutical company

> One product across the globe should be the goal, and India can achieve this milestone with concerted effort and a strategic plan. Serving the entire globe with a singular product will necessitate enhanced manufacturing conditions, elevating our compliance levels and quality to new heights. We could potentially also benefit from economies of scale.
>
> Vice President - R&D, leading Indian pharmaceutical company

> Undoubtedly, digitalization and automation are the future. These technologies can provide a safeguard against data integrity issues and non-compliance. Many digital solutions can be deployed. For instance, completely paperless QC labs, fully automated systems that eliminate manual data entry and physical Certificate of Analysis (COAs), fully digital quality management systems that are integrated with manufacturing with Manufacturing Execution Systems (MES). While leading pharma companies and CRDMOs are making strides in this area, the broader industry must accelerate its digital transformation to keep pace with these advancements.
>
> Chief Quality Officer, leading Indian CRDMO company

> There should be a culture of compliance, culture of quality – including the willingness to report failures.
>
> Chief Quality Officer, leading Indian CRDMO company

> It is about cultivating a mindset where quality is pivotal at every stage of production, from material sourcing to each step of the manufacturing process. Ensuring excellence throughout is crucial for our industry's global standing. In addition, it is also critical for the government regulatory bodies to boost infrastructure and competence for stringent audits.
>
> Head of Strategy and Portfolio Management, leading Indian CRDMO company

> MSMEs and smaller manufacturers constitute a significant part of India’s pharma manufacturing base. To strengthen quality, we need to strengthen the entire base.
>
> Chief Quality Officer, leading Indian CRDMO company

> To elevate India's pharma manufacturing, stringent standards must be established, ensuring that only those who meet these top-tier criteria can enter the industry.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> Similar to global practices, we need to implement more efficient detection mechanisms to identify non-compliance.
>
> Chief Quality Officer, leading Indian CRDMO company

> To elevate the global perception of India's quality standards, we must author and disseminate data-driven, evidence-backed whitepapers that showcase our adherence to excellence to the world.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> It is vital to celebrate our (pharma industry) successes and highlight our achievements. This is instrumental in constructing a positive image of India on the world stage.
>
> Secretary General, Indian Pharmaceutical Alliance

Emerging horizons: Capitalizing on the convergence of Pharma, Digital and MedTech

The convergence of digital technology, pharmaceuticals and medical technology is creating unprecedented opportunities for innovation and growth in the healthcare sector. This synergy is not only revolutionizing drug development and patient care but also opening up new avenues for personalized medicine and advanced treatment modalities.

Digital technology is the driving force behind this transformation, enabling the collection and analysis of vast amounts of data to inform decision-making and improve outcomes. AI and ML algorithms as a standalone or integrated with diagnostics are improving clinical decision making and enabling personalized treatment. Meanwhile, advancements in medical technology, such as wearable devices and telehealth platforms, are facilitating real-time monitoring and remote care, making healthcare more accessible and patient centric.

The pharmaceutical industry stands to benefit immensely from this integration. By leveraging digital tools and MedTech innovations, pharma companies can streamline their operations, from R&D to manufacturing and distribution. The ability to harness big data can lead to more targeted therapies, reduced time-to-market for new drugs, and more effective management of chronic diseases. We discussed some of these aspects in the earlier part of this chapter.

In addition, this evolving landscape also presents a wealth of opportunities for the pharmaceutical industry to add value for stakeholders across the entire ecosystem. This value creation is achieved through technology integration and the provision of services that extend beyond the traditional scope of drug offerings. The integration of medical and digital technology gives rise to the "Beyond the pill" concept, where patient management goes beyond mere medication to a holistic patient centered approach including lifestyle and disease management.

Improving outcomes through pharma + digital + medtech confluence

For patients

- Wearables
- Services facilitating diagnosis
- Support groups
- Information sources
- Patient adherence
- Doorstep medicine delivery

For doctors

- Discussions on therapeutic advancements
- KOL interactions
- Learning opportunities
- Assistance with patient education
- Learnings on global development
- Evidence-based practices

"Beyond the pill" interventions

Disease management solution

Lupin's LYFE: Evidence-based cardiac rehabilitation program for patients; disease management education modules for physicians

Sun Pharma's RespiTrack: Connects doctors and patients; enables complete monitoring of asthma attacks, symptoms and medications – increase compliance and better disease management

Wellthy Therapeutics' Wellthy CARE: Personalized care management platform for chronic diseases

Industry examples

Digital therapeutics (DTx)

Dr. Reddy's Nerivio DTx#: Drug free non-invasive wearable neuromodulation therapy for migraine

Point of Care (PoC) diagnosis

Cipla's in-house PoC, CipPoint, for NCDs and infectious diseases

Cipla and Achira Labs to develop innovative and affordable PoC solutions for **for early diagnosis and treatment**

Morepen Lab: glucometers, blood pressure monitors

Drug delivery system

Lupin's **Adhero**: first-of-its-kind connected smart device to track usage pattern of metered dose inhaler by patients (built-in sensors to track daily usage and consumption pattern)

Niveoli: Cipla's proprietary inhaler – hydrofluoroalkane propelled delivery of extra-fine particles

Remote care platforms for physicians

Eris Lifesciences + PlexusMD: AI-powered online learning platform for doctors, called *Saarthi*

Mankind Pharma's Docflix: OTT (over-the-top) platform for doctors: scientific content tailored to various practice needs

Patient Doctor

Non-exhaustive

#Dr. Reddy's entered into an exclusive agreement with Theranica, for the marketing and distribution of Nerivio® in India.

Sources: Lupin's LYFE, Wellthy CARE, Cipla-Achira Labs, Cipla's CipPoint, Morepen lab, Sun Pharma's RespiTrack, Dr.Reddy's+Theranica, Cipla-Niveoli, Lupin-Adhero, Eris lifesciences, Mankind-Docflix

Globally, pharmaceutical companies are evolving their business models to support patients not only with treatments but also with comprehensive solutions and services that span their entire healthcare journey. In this dynamic environment, pharma companies are positioned to be active partners with patients and healthcare providers, delivering drugs and solutions, tracking and measuring progress, and contributing to improved health outcomes. From doctors who need materials to keep up with the treatment updates, to patients who desire more information about diseases and treatment options, the landscape is transitioning from a 'nice to have' to an essential strategic component for pharma companies, emphasizing the need to offer targeted services beyond the medication itself.

By leveraging technology, pharmaceutical companies can influence various aspects of the patient journey, such as enhancing long-term treatment adherence through digital reminders and advanced drug delivery systems that simplify administration and reduce dosage frequency.

> Developing advanced drug delivery systems that are easy to administer and minimize the frequency of administration can revolutionize patient care. Imagine replacing daily insulin shots with weekly patches or biannual implants. Such advancements could significantly reduce the need for frequent doctor visits, making healthcare more accessible and manageable for those in remote locations. It's time to innovate and offer these life-altering delivery systems and solutions to enhance the quality of life for patients across India, and potentially globally.
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

Pharmaceutical companies can also collaborate with tech start-ups or medical device companies to offer user-friendly point-of-care diagnostics, remote monitoring solutions, mobile health apps, self-care programs, and disease management platforms. These innovations not only improve health outcomes but also provide competitive advantages. For example, Lupin Digital Health launched Lyfe, a digital therapeutic solution for comprehensive healthcare[62], while Cipla introduced "Cippoint," a point-of-care testing device, broadening its diagnostic product offerings. Such solutions can go a long way in improving accessibility and enhancing patient outcomes[63].

Furthermore, pharma companies are advancing digital services for doctors, facilitating information exchange through online resources. These platforms enable real-time medical discussions within the broader healthcare professional community. For instance, Eris Lifesciences' partnership with PlexusMD to create 'Saarthi,' an AI-powered learning platform for physicians[64], exemplifies this trend. This initiative aims to keep physicians abreast of global developments and promote evidence-based medicine.

The pharmaceutical industry is at the forefront of a transformative era, where the fusion of digital, pharma, and MedTech is reshaping the landscape. By embracing this confluence, pharma companies can deliver integrated healthcare solutions that transcend traditional drug therapies, positioning themselves as integral players in the patient care continuum. The future promises a more connected, efficient and patient-centric healthcare experience, with India poised to make significant contributions to this global evolution.

[62] Lupin lyfe

[63] Cipla Cippoint

[64] Eris-lifesciences

Chapter

2

Integrated healthcare

Improving access and affordability

In a Viksit Bharat vision, a robust healthcare system becomes indispensable. Such a system catalyzes socio-economic advancement by promoting equity in access to essential healthcare services, mitigating the burden of disease, and bolstering resilience against unforeseen health crises. It is a future where quality healthcare is readily accessible and affordable for every citizen, underpinning the nation's broader aspirations for prosperity and well-being.

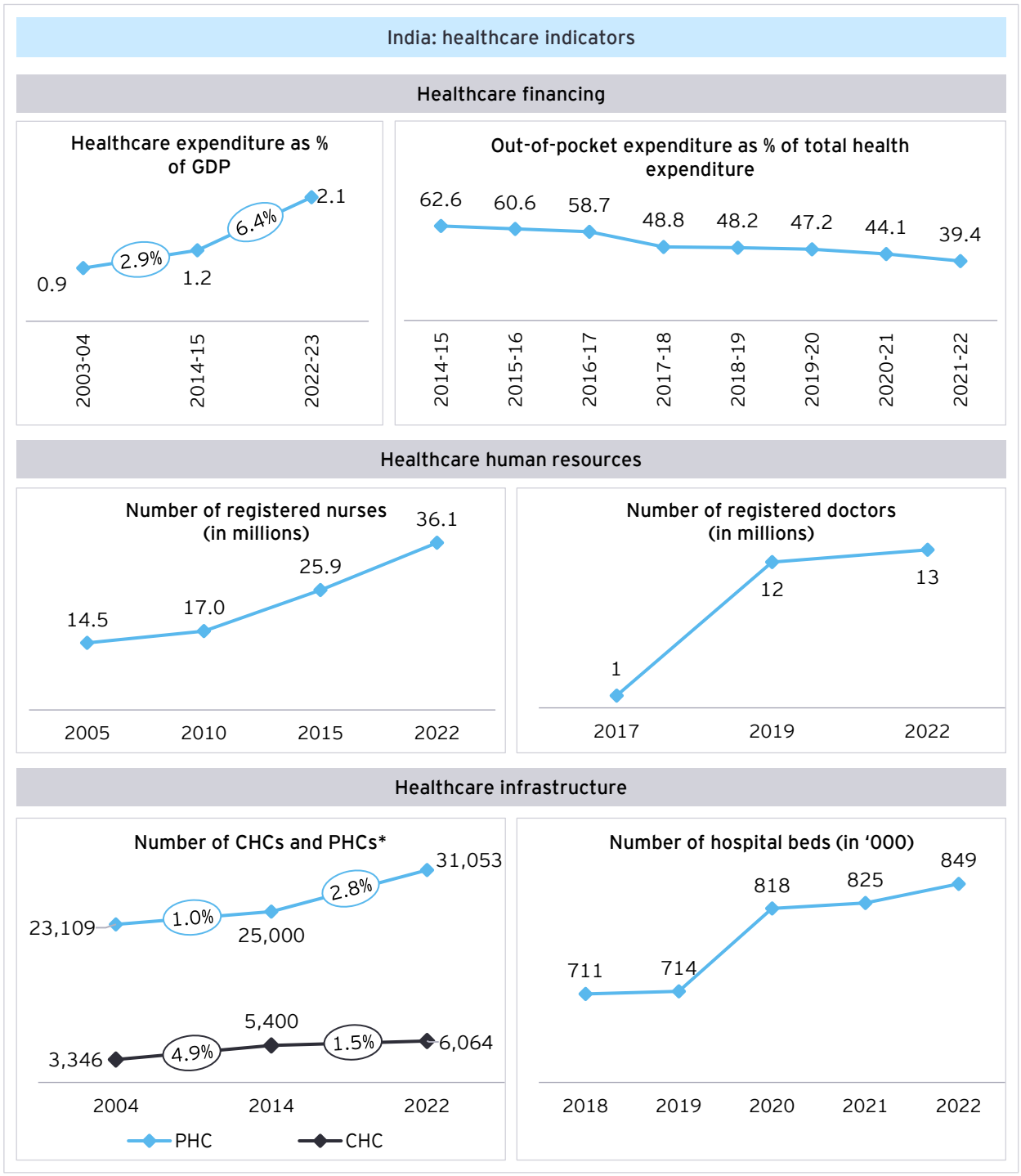
> In Viksit Bharat, universal healthcare access will transcend basic care, empowering patients with the freedom to select optimal services and innovative medicines tailored to their unique circumstances. In this future, neither affordability nor information asymmetry will dictate patient care, ensuring equitable and informed health choices for all.
>
> CEO, leading Indian NGO

India's healthcare landscape: Current snapshot

Of the 17 Sustainable Development Goals (SDGs), SDG 3 aims to ensure healthy lives and promote well-being for all at all ages. India's pursuit of Universal Health Coverage (UHC) by 2030 is a key component of its commitment to achieving this goal[65].

The healthcare sector in India is experiencing a remarkable transformation evident in the substantial increase in healthcare expenditure as a percentage of GDP, increase in the healthcare infrastructure in terms of facilities and professionals, and decrease in the out-of-pocket expenditure (OOPE).

[65] https://loksabhadocs.nic.in/Refinput/Research_notes/English/04122019_165108_102120495.pdf



CHCs: Community Health Centers, PHCs: Primary Health Centers

Source: Decoding India's healthcare landscape - EY, Registered doctors-2017, Registered doctors-2019, Registered doctors-2022, Number of hospital beds

Over the years, the Indian Government has played a critical role in strengthening the healthcare sector through the formation of numerous committees, the enactment of National Health Policies, the launch of various centrally sponsored and sector-specific schemes, as well as by establishing institutions focused on research and development. Ayushman Bharat launched in 2018 has significantly increased healthcare coverage and penetration with its two complementary schemes: 'Health and Wellness Centres (HWCs)' to deliver comprehensive primary healthcare services and 'Pradhan Mantri Jan Arogya Yojana (PMJAY)' to improve access to hospitalization services at secondary and tertiary level health facilities.

Recently, the Government of India has launched Ayushman Bhav, a comprehensive healthcare initiative to expand the reach of healthcare services under the Ayushman Bharat, to every intended beneficiary across every village and town in the country, including those in the last mile. [66,67]

Ayushman Bharat Yojana and Ayushman Bhav Campaign realizing India's vision of Universal Health Coverage

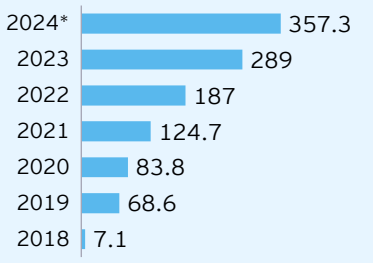
2018: Ayushman Bharat Yojana

Health and Wellness Centers (HWCs)

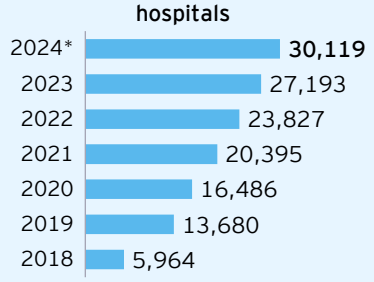
1,75,001 functional HWCs*

Pradhan Mantri Jan Arogya Yojana (PM-JAY)

357+ million Ayushman cards created*



68+ million authorized hospital admissions with **30,000+** empaneled hospitals*



as of 05 Nov 2024

A national campaign was launched to expand the reach of healthcare services established under Ayushman Bharat and to extend comprehensive healthcare coverage to every village and town

2023 (September): Ayushman Bhav

Collaborative effort by **Gram Panchayats in coordination with the Department of Health**, other government departments and local elected bodies in the rural and urban areas

Synergistic approach aims to **expand coverage of health services through its three components**

Ayushman Apke Dwar 3.0

- Boost Ayushman card penetration
- To **provide Ayushman cards to remaining eligible beneficiaries** enrolled under the PM-JAY scheme

Ayushman Melas at HWCs and CHCs

- Facilitates the creation of **ABHA IDs and issuance of Ayushman Bharat Cards**
- Offers **early diagnosis, comprehensive primary health care services**, tele consultation with specialists, and appropriate referrals
- Encourages health seeking behavior

Ayushman Sabhas

- Set up in every **village and Panchayat**
- Distributes **Ayushman cards,** generates **ABHA IDs**
- Raises awareness about health schemes and disease conditions, such as NCDs*, TB*, sickle cell disease

Impact (as of Dec 2023)

100+ million footfall in **1.2+ million** Ayushman Melas

170+ million people screened for diseases like TB, diabetes, cancer, etc.

43+ million ABHA (health ID) cards generated

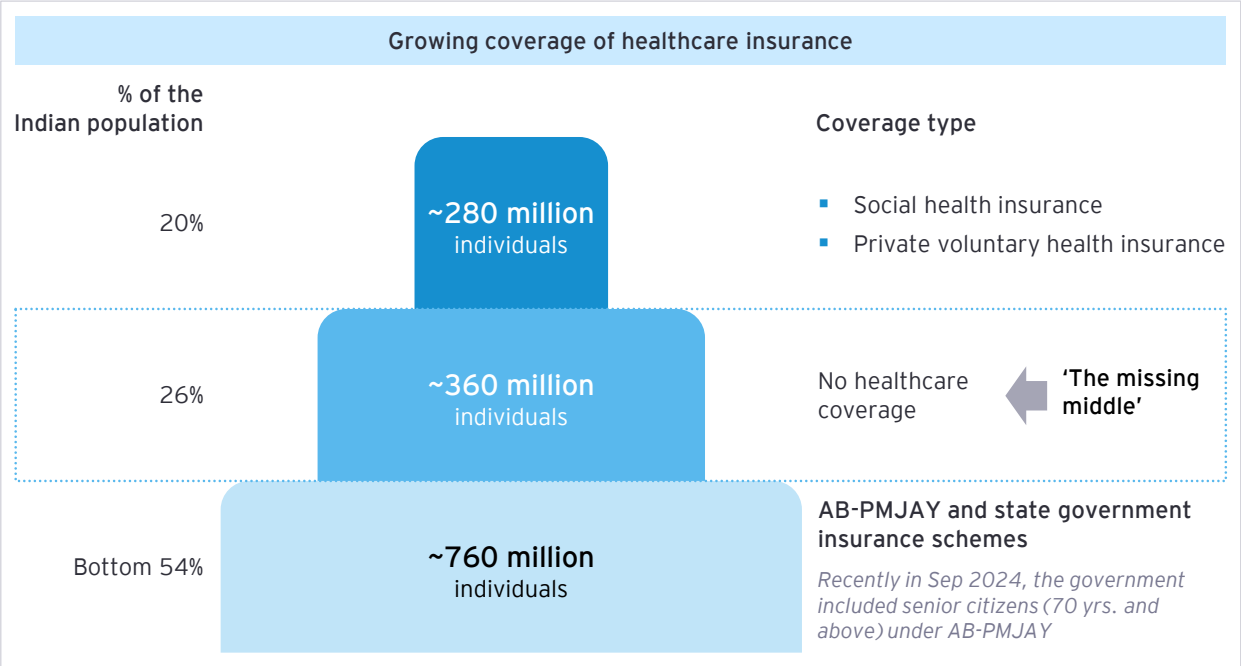
*NCDs - Non Communicable Diseases; TB - tuberclusois

Source: Ayushman Bharat; HWCs; Decoding India's healthcare landscape, PM-JAY; Tamil Nadu – PMJAY; PMJAY states; PMJAY dashboard; Ayushman Bhav; Ayushman Bhav-impact1; Impact2

[66] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1956673

[67] Press Release: Press Information Bureau

The Ayushman Bharat program provides an annual coverage of INR5 lakh per family per year to the country's population below poverty and has recently included senior citizens aged 70 and above[68]. Ayushman Bharat, together with the state government schemes, social health insurance, and private voluntary insurance, extends coverage to ~75% of the population. This leaves an estimated 26% in the 'Missing Middle' category without coverage. Moreover, because of the limited coverage, cutting-edge treatments that have the potential to greatly enhance disease outcomes, for instance, some of the novel cancer therapies remain inaccessible to a vast segment of the population. A significant hurdle remains the disparity between urban and rural healthcare, where roughly three-quarters of the population relies on a mere quarter of the available medical infrastructure. In terms of healthcare infrastructure as well, while we have made significant progress, India continues to be below the WHO recommendations for the number of physicians, nurses, and hospital beds per 10,000 people.



Sources: Niti Aayog report, Indian population (as of 1 July 2023), Press Information Bureau (pib.gov.in)| Ayushman Bharat Becomes Bigger

The Indian healthcare system is currently at a critical juncture, where it needs to overcome key challenges and progress towards the path of achieving universal health coverage (UHC) by 2047. UHC means providing affordable and accessible healthcare to all citizens, regardless of income or location. The next section explores critical factors and conditions that must be addressed to significantly advance the affordability and accessibility of healthcare across the country.

[68] https://www.india.gov.in/spotlight/ayushman-bharat-pradhan-mantri-jan-arogya-yojana

Elevating healthcare: Key strategies for affordability and access

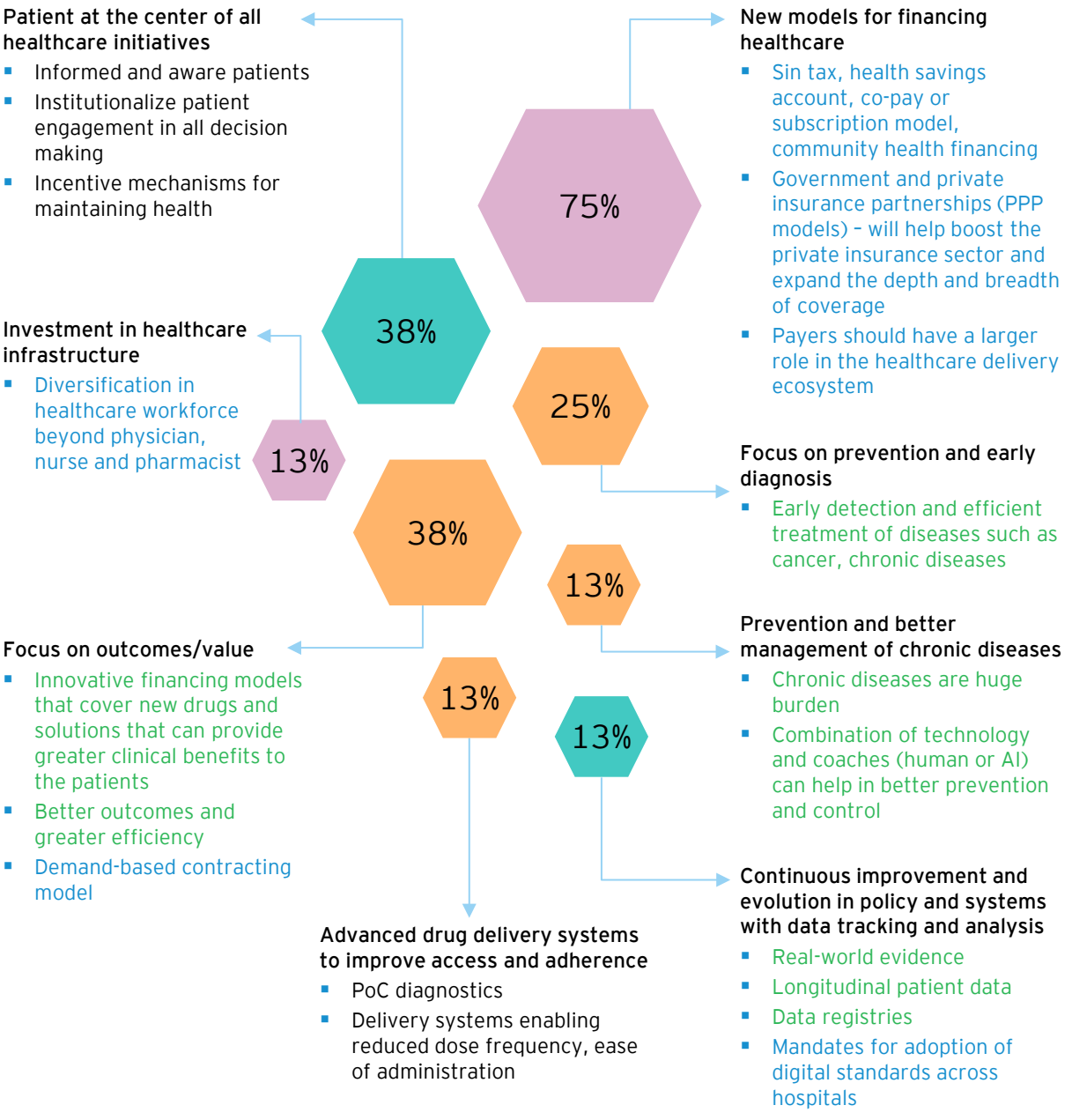
India's vast healthcare landscape requires a strategic balance of demand and supply to meet the needs of its diverse population. Insights from the CXO survey suggest adopting a multifaceted approach that prioritizes health and wellness, alongside preventive measures and early detection, emphasizing the sustainability of such an approach and its potential to alleviate the burden on curative services. In instances of illness, the focus should shift to outcome-driven treatments and effective disease management, with an emphasis on providing access to the most beneficial treatments without being hindered by cost considerations. This approach is key to enhancing patient outcomes and achieving long-term cost-effectiveness, benefiting patients, the healthcare system and the government alike.

Concurrently, there should be effort to increase healthcare infrastructure, both in terms of facilities and personnel, to deliver high-quality care. To expand the healthcare workforce, experts suggest including diversified roles such as case managers and community outreach workers and encourage educational institutions to adapt their curricula accordingly. Experts identified innovations in drug delivery systems, especially those simplifying administration and reducing the need for frequent dosing, as potential solutions to improve access and adherence, particularly in remote rural areas.

Experts also emphasize the need for new financing models and patient education. Furthermore, experts highlight the critical importance of disease registries and real-world evidence for continuously shaping and improving healthcare policies and managing diseases more effectively.

Digital transformation emerges as a key theme across all these areas, acting as an essential catalyst for enhancing healthcare delivery, patient engagement, and the overall efficiency of the healthcare system.

CXO survey: Key approaches to improve healthcare access and affordability



Digital and technology integration as a pivotal enabler across all the approaches

Industry | Government | Industry + Government

Solutions resulting in reduced demands | Increase supply and access | Enhanced healthcare experience and impact

> In the context of a Viksit Bharat, it is clear that with our vast population, relying solely on curative measures is not the answer. While Ayushman Bharat began with the noble goal of providing curative services to help many cope with severe health expenses, the future must pivot towards a more robust preventive healthcare. Curative care is sustainable only to an extent, as evidenced by the strain it places on even developed nations. With a stronger preventive approach, the demand for curative services will naturally diminish, leading to fewer complications and reduced healthcare spending.
>
> CEO, leading Indian NGO

> We should explore incentive mechanisms that reward citizens for maintaining their health, such as staying fit, avoiding illness, or managing chronic conditions like diabetes. These incentives could be implemented in workplaces, educational institutions, and beyond. Such a holistic approach to health and wellness is a key component of what Viksit Bharat stands to gain.
>
> CEO, leading Indian NGO

> There is a pressing need to expand our healthcare workforce beyond the traditional trio of doctors, pharmacists, and nurses. In developed countries, the healthcare workforce is much more diverse than what we currently see here. There is also a gap in task shifting. We lack a sufficient number of professionals who can provide patient counseling, manage cases, or conduct community outreach.
>
> CEO, leading Indian NGO

> Consider the profound impact advanced delivery systems could have in rural areas, where the reluctance to visit doctors is often due to the extensive travel required for simple treatments. Such options that reduce dose frequency can go a long way in improving adherence and accessibility.
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

The CXO survey clearly indicates that technology and digital integration are unanimously seen as fundamental across various strategies for tackling affordability and accessibility challenges in healthcare. Additionally, the survey identified 'innovative financing mechanisms and healthcare delivery models' as the second most crucial elements needed to close the gap between the current state and the desired state of healthcare. In the following section, we will delve deeper into these key areas.

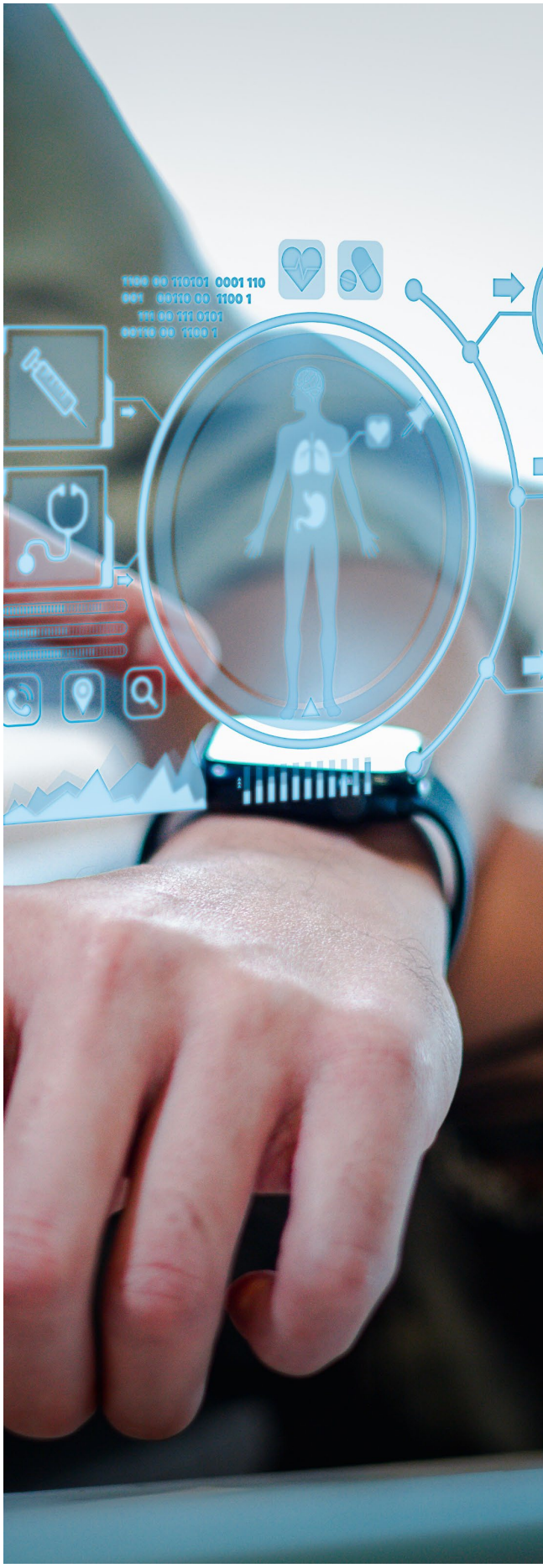
Digitally enabled healthcare: Bridging gaps, building connections and improving outcomes

Digital health refers to the use of digital technology and connected devices to optimize healthcare delivery, enhance patient experiences, and improve health outcomes. Globally, **digital health technology is transforming the traditional models of where and how care is delivered to a more connected model where patient is at the center, and the entire healthcare ecosystem is connected to deliver a better experience and health outcome.**

Digital solutions can play a critical role in improving health literacy of the individuals, empowering them with greater control over their health information, and enabling informed decision-making and self-management of their conditions. These platforms connect various stakeholders — care providers, hospitals, diagnostic centers — facilitating an integrated healthcare experience throughout the patient journey, thus optimizing care for improved outcomes. Key components of digital health impacting the patient journey include:

1. **Health personalization tools**: Wearables and mobile apps are revolutionizing patient care by tracking vital signs and lifestyle patterns, enabling proactive health management. The integration of genomics into these tools allows for treatments tailored to individual genetic profiles, ushering in an era of personalized medicine.
2. **Remote health and virtual care delivery**: Telehealth platforms are expanding access to care, remote monitoring systems are reducing the need for hospital visits, and e-pharmacies are simplifying medication procurement.
3. **AI/ML enhanced decision making and automation tools:** Electronic Health Records (EHR) and Electronic Medical Records (EMR), clinical decision support systems (CDSS), and e-diagnostics are leveraging artificial intelligence (AI) and machine learning (ML) to automate and improve clinical workflows and patient care. AI is also transforming data analysis for population health, identifying at-risk groups, and optimizing preventive care.
4. **Healthcare Software as a Service (SaaS)**: Cloud-based SaaS solutions are streamlining administrative tasks, allowing for seamless patient-provider interactions and collaborative care across healthcare systems.
5. **Digital therapeutics**: Digital therapeutics are providing new avenues for treatment, either as standalone or in combination with standard of care.

By embracing these digital health components, India can create a more efficient, patient-centered healthcare system that not only meets the current needs but also adapts to future challenges, paving the way for a truly Viksit Bharat.



Digital and data enabled patient journey (illustrative)

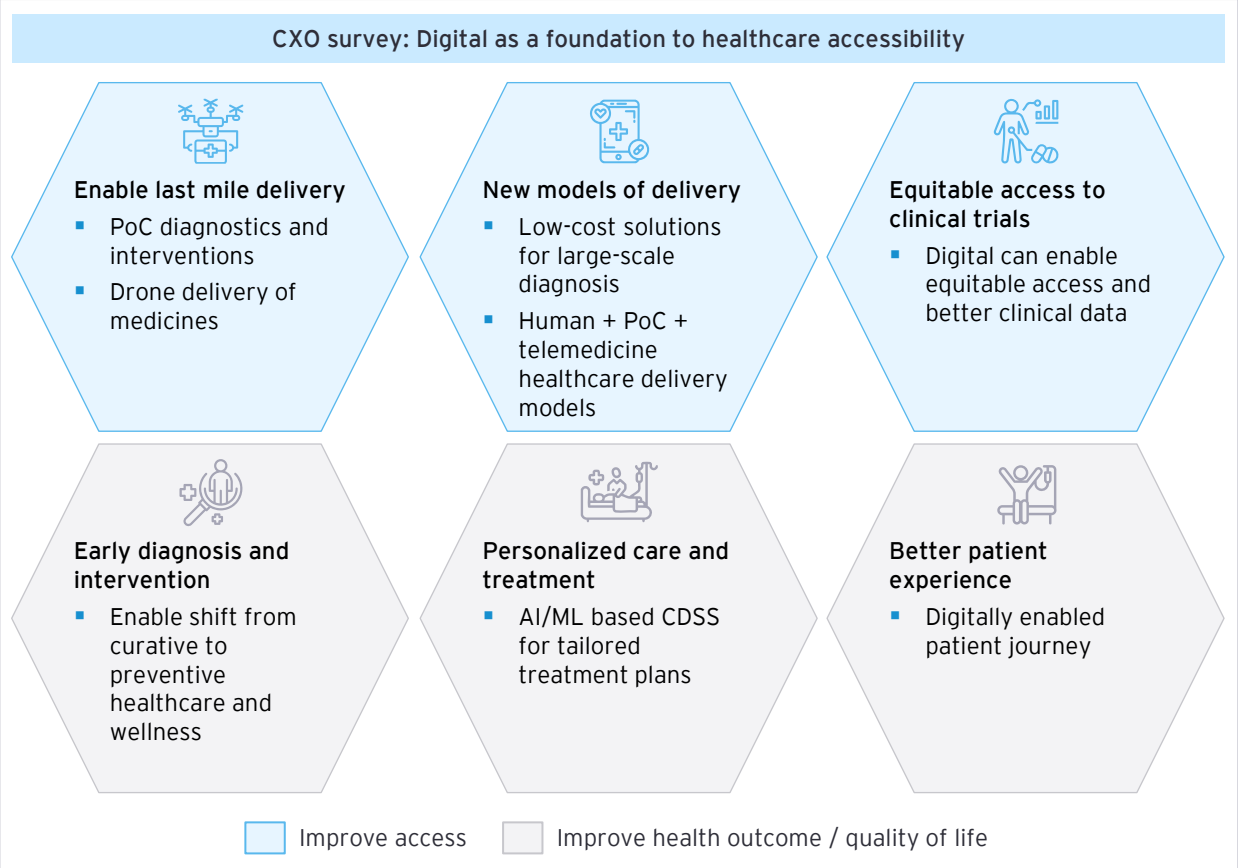
Emerging technologies have the potential to improve healthcare access, overcoming the barriers of inadequate health care infrastructure and shortage of medical professionals

Stage of patient journey	Digital interventions	Outcome achieved
Healthy individual	Fitness tracking devices, wearables, mobile apps	▪ Enable healthy living ▪ AI powered personalized health insights and alerts of any deviations early on, prompting symptom awareness and early intervention
Primary health consultation	Remote/virtual health tools, telemedicine, electronic health records (EHR)	▪ Convenient virtual appointment scheduling and tele consultation
Diagnosis	AI-powered e-diagnostic platforms	▪ Early and accurate detection, enabling timely and appropriate intervention
Treatment and management	CDSS, connected ambulance, remote ICU, digital twin, robotics	▪ Personalized treatment plan integrating medical records, drug history, genetics, etc. ▪ Real-time monitoring, evaluation, and intervention
Maintenance	Remote monitoring, telemedicine, medication adherence tools	▪ Digital therapeutics, personalized recovery plan ▪ Digitally enabled self-management ▪ Real-time remote monitoring and management

The insights from industry experts on digital healthcare in India further underscored the critical role of digital in transforming healthcare delivery and enhancing the patient outcomes. Some of the use cases shared by experts include the potential of digital health in revolutionizing last-mile delivery, making healthcare accessible even in the most remote areas. Clinical trials in India are predominantly driven by hospitals and investigators, with recruitment often limited to patients who seek care. Digital platforms could democratize access to clinical trials, offering more robust clinical data and

equitable enrolment opportunities. Additionally, the application of artificial intelligence in healthcare promises faster diagnostics and treatments.

Experts suggested that point-of-care devices are experiencing significant growth in India, presenting an opportunity to create low-cost, large-scale diagnostic solutions that could serve not only the domestic market but also the global community. The vision extends to personalized medicine, where AI and genetic mapping converge to tailor treatment protocols, particularly for conditions like cancer.



> Technology, especially AI, will play a crucial role in earlier and more accurate diagnosis and personalized treatments. Combined with genetic mapping and an enhanced comprehension of therapeutic pathways, these areas hold immense promise. I expect to see a lot more development in the next five to ten years in these areas.
>
> Chairperson and Non-Executive Director, leading Indian home healthcare company

> Technology will play a very big role, because everything will get online. This will increase visibility and transparency, resulting in consistent high-quality care across all healthcare delivery systems.
>
> Executive Chairperson, leading Indian pharmaceutical company

> One area where we have yet to reach our full potential is in optimizing clinical trials and broadening access to them. Currently, our approach is predominantly investigator or hospital-driven, with patient recruitment largely happening by chance upon hospital arrival. We lack a proactive, nationwide system for enrolling participants in clinical trials, an issue that could be addressed through digital means. This approach could not only provide more robust clinical data but also ensure fairer access to trial participation.
>
> CEO, leading Indian NGO

Ayushman Bharat Digital Mission: Future of integrated digital healthcare delivery in India

The Ayushman Bharat Digital Mission (ABDM), launched in 2021, is at the forefront of transforming the digital healthcare paradigm in India. It is aimed at laying the essential groundwork for a seamless integrated digital healthcare infrastructure in India. ABDM's mission is to optimize healthcare delivery by harnessing the power of digital technologies, with a strong emphasis on enhancing efficiency and efficacy. Through ABDM, patients have the option to avail healthcare services remotely via teleconsultation and e-pharmacies. They are able to access their medical records and conveniently share them with healthcare providers. Health professionals can securely access more comprehensive longitudinal patient medical histories, contingent on the patient's consent, and leverage clinical decision support tools, thereby enabling them to prescribe personalized treatments that are more effective. Policymakers and program managers can enjoy improved access to data, enabling more informed decision-making. Researchers can scrutinize and assess the efficacy of various healthcare programs and interventions. This will concurrently bolster transparency and reliability in healthcare.

ABDM promotes adoption of open standards by all digital health stakeholders, including HealthTech start-ups. Government has set up ABDM sandbox to integrate these solutions to ABDM ecosystem. Government has also launched various initiatives like the Digital Health Incentive Scheme, Microsites[69], Ayushman Bhav, and collaboration with pharmacies and laboratories to accelerate adoption of digital health, particularly focused toward private sector including start-ups. Partnerships with academia are also being forged to improve digital literacy and create frameworks for future innovation. For instance, it collaborated with IIT Kanpur to use the data available under the ABDM to **create a public benchmark for AI models for quantifying and diagnosing diseases,** against which other AI models can be benchmarked[70]. It also signed MoU with the Maharashtra University of Health Sciences (MUHS) to integrate digital health in medical curricula to enhance digital skills of medical students and professionals, and building digital health awareness across all stakeholders in the health ecosystem.[71]

[69] https://www.thehindu.com/news/national/karnataka/project-for-improving-digitization-in-private-health-facilities-launched/article67817678.ece

[70] https://pib.gov.in/PressReleasePage.aspx?PRID=2053721

[71] NHA collaborates with MUHS to drive digital health education in India, ET Government

Ayushman Bharat Digital Mission

Progress (as of Nov 5, 2024)

679 million ABHA registrations	**444 million** health records linked	**0.34 million** health facilities registered	**0.50 million** healthcare professionals registered

Key initiatives (2022-2024)

ABHA based Scan and Share Service (Oct 2022)

Efficient and convenient paperless services for treatment delivery

- Patients can register for OPD appointments by scanning a QR code displayed at the OPD registration counter
- **Upcoming service:** 'Scan and Send' and 'Scan and Pay' to share health records and make payments

Benefit

- *Paperless services cutting the waiting time*
- *Enhanced patient experience*

AIIMS CDSS (Aug 2024)

Clinical decision support system (CDSS) for better diagnosis and personalized treatment

AIIMS, in collaboration with Centre for Chronic Disease Control (CCDC), developed a **digital health technology-based Clinical Decision Support System (CDSS)** for the public health system in India to help manage the non-communicable disease burden

Benefit

- *Generates personalized clinical management plans*
- *Identifies high-risk patients and assists in diagnosis*
- *Prompts optimal drug and dosage, drug escalation and down-titration*
- *Follow up prompts and alerts on contraindication*

NHA + IIT Kanpur MoU (Sep 2024)

Data and infrastructure for developing new digital solutions

- Will use the data available under the ABDM to **create a public benchmark for AI models for quantifying and diagnosing diseases** against which other AI models can be benchmarked
- Aims to provide an **open public benchmarking platform** for comparing and validating AI models

Benefit

- *Goal is to improve diagnosis and outcomes*
- *Accelerate the development of **AI-powered health solutions to strengthen digital public health infrastructure***

NHA + MUHS MoU (Sep 2024)

Resources for capacity building

- MoU between National Health Authority with Maharashtra University of Health Sciences (MUHS)
- MUHS will offer its digital health foundation course to NHA and co-develop digital health program

Benefit

- *Integration of digital health in medical curricula to enhance digital skills of medical students and professionals*
- *Build digital health awareness among all stakeholders in the health ecosystem – lays foundation for more connected and effective healthcare system*

AyushmanNHA WhatsApp Chatbot (Sep 2024)

Resources for capacity building

One stop platform, providing readily available training resources about ABDM and capacity building resources for doctors, hospitals, clinics and labs

Benefit

Will serve as a valuable resource for doctors, hospitals and clinics, diagnostic laboratories to onboard on ABDM

Doctor | Policymaker | Researcher | Lab representative | Patient | Student

Source: ABDM-ABHA, PIB-ABHA, CDSS, AIIMS-CDSS, NHA+IIT Kanpur, NHA+MUHS, AyushmanNHA chatbot

Practo, Paytm and several other private entities have already been integrated with ABDM. A host of start-ups and digital natives are emerging, providing services and solutions for patients, care providers and hospitals across the patient journey. Integrating all the HWCs, NCDs, district hospitals, medical college hospitals and the vast number of the digital natives and linking them to the ABHA identity is expected to facilitate access, reduce reach costs, improve healthcare delivery and profoundly impact patient health outcomes in a resource-constrained country.

Emerging ecosystem of start-ups/digital natives improving outcomes across the patient journey

	Digital health interventions	Platform examples*
Healthy individual	▪ Consolidate health data in one place ▪ Monitor body vitals regularly ▪ Personalized health insights and tips	▪ Personal Health Record (PHR) platform: Eka Care, HealthifyMe ▪ Wearable: e.g., smartwatches
Scheduling and primary health consultation	▪ Virtual scheduling ▪ Online doctor consultation ▪ Health-checks and tests	▪ AI-powered on-demand healthcare platform e.g., MFine, Practo
Diagnosis	▪ AI/ML powered screening, pathology, and diagnosis ▪ Microscopy through AI, digital, cloud computing ▪ Faster, earlier, and more accurate diagnosis	▪ Intelligent diagnosis platform: SigTuple, Qure.ai
Treatment	▪ Expert consultations ▪ Personalized treatments ▪ Real-time monitoring, alerts and notifications	▪ Clinical decision support system (5MinuteConsult); ▪ Remote ICUs and connected ambulance (INTeleICU, 5G ambulances)
Treatment maintenance and management	▪ AI/ML powered solutions and services for self-management of chronic diseases ▪ Medication adherence alerts and incentivization ▪ Online regular follow-ups	▪ Disease management platforms, such as BeatO (diabetes management); Wellthy Therapeutics ▪ Medication adherence app: Karma Dost app (by DawaaDost Pharma)

Non-exhaustive

Source: EY analysis, company websites

Global and Indian pharma companies are also leveraging technology in enhancing access, awareness and screening designed to assist early diagnosis and treatment options. For instance, Bayer had established phygital primary healthcare centers via telehealth that helps in expanding access.[72] Likewise, Cipla has enabled drone-delivery to provide critical medicine to rural and remote areas.[73] Companies are also partnering with ecosystem players to provide patient centric solutions such as mobile apps for personalized support and awareness programs, ultimately enhancing outcomes and quality of life.

[72] https://www.bayer.in/en/news/bayer-to-set-up-27-telemedicine-centres-across-8-states-in-the-country

[73] https://www.cipla.com/press-releases-statements/cipla-launches-drone-based-delivery-services-in-himachal-pradesh

Bayer: initiatives to expand access, awareness and screening

Expansion of healthcare facilities: Phygital PHCs to offer tele consultation and raise awareness

Objective:

Provide complete healthcare solutions via telehealth; conduct training and awareness sessions on health, hygiene and nutrition

- Plan to set-up **27 telemedicine centers** under **unique hub and spoke (nodal) model** in **12 districts** across **eight states** (2023-24)
- Offer 20 different medical specialties

Medical camps to create awareness for **breast cancer, diabetes, skin conditions**

Partnerships with **RxDx Healthcare** and **Piramal Swasthya**

RxDx

- Telemedicine command center in **Bengaluru**
- Caters to **14 phygital PHCs** in **Karnataka, Gujarat, Maharashtra and Madhya Pradesh**

Piramal Swasthya

Piramal Swasthya's hub (not-for-profit healthcare organisation) in Ranchi caters to **13 phygital centres** across **Bihar, Chhattisgarh, Jharkhand, and UP**

Benefits

Ensure timely access to quality healthcare	**Build local health capacities and support local innovations**	**Reduce the load on the health system, as well as OOPE for beneficiaries**	**Each centre to cater to ~25-35 villages and cover 35,000-50,000 beneficiaries**

Partnerships with ecosystem players to enhance cancer screening in India

- Partnered with Karkinos Healthcare (tech-led oncology platform) for early cancer detection and screening in **Mumbai and Puducherry** (2023)
- *Two-year program to **reach 100,000 individuals***
- **65 health professionals trained** in conducting risk assessment and screening

- ***Six health facilities** (4 PHC, 2 rural clinics) set up as of Aug 2023*
- ***26 awareness campaigns** arranged for **>2,000** people*
- ***>30,000** risk assessments carried out*

- **5-year initiative in partnership with AIIMS's National Cancer Institute (NCI)** to enhance cancer screening access in India's rural areas for prostate, head and neck, oral cancer (2021)
- NCI-AIIMS offers preventive, curative, and palliative care
- **Mobile technology** to deliver screening services to patients

- *Will enable screening of **~12,000 patients** in the geographical vicinity of NCI*

Company initiatives enabling awareness and education among masses

Bayer benefitted **4 million+ Indians** through various initiatives in the **last five years**

Andhra Pradesh DOHMFW + Bayer Zydus MoU (Mar 2024)	Health for all, Hunger for none initiative (as of 2023)
Aims to educate the public and HCPs about heavy menstrual bleeding and ill-effects of hysterectomy	**Aims** to target food security and health access in underserved areas for a fairer, sustainable world
100 gynecologists will be trained on medical management of heavy menstrual bleeding	**Focuses** on rural development, preventive health care and education and community engagement in India

Source: Telemedicine centers, Phygital telemedicine, Bayer+AIIMS, Initiatives enabling health, Ministry of health + Bayer Zydus MoU

Cipla: Initiatives to expand access, awareness and screening

Leveraging technology for improving healthcare access

Drone-based delivery services: *First among large Indian pharma companies to adopt drone-based deliveries*

- Launched **drone-powered deliveries** (Sep 2023) **for critical medicines** for **hospitals and pharmacies in Himachal Pradesh,** in partnership with **Skye Air Mobility**
- **On-time delivery** of medicines to chemists and clinics in **remote areas**
  - Minimizes delays, temperature excursions affecting cold chain products

- Plan to **scale the service** and expand market
- To **cover inaccessible and hilly terrains,** such as Uttarakhand and Northeast India

To Increase **penetration in underserved rural areas** of India and **address critical healthcare gaps** where pharmaceutical coverage is limited

Strategy to invest in "channels of the future"

Breathefree - Lung health app

Digital therapeutic platform promotes early diagnosis, adherence to therapy, and personalized support

Launched in 2022

Tailored program for individuals	Face and finger-based vitals screening
Medicine reminder for improved adherence	Doorstep delivery for enhanced accessibility
Events and live webinars for increasing awareness	Lung health diary for easy documentation and tracking

Investments in digital technology

GoApptiv (Dec 2023), in line with its strategy to invest in "channels of the future"*

To provide **patient-centric solutions** and enhance **healthcare access** by leveraging its **'phygital' model**

*Achira Labs** (Jun 2022)*

- PoC to bring **innovative, affordable,** and **quality diagnostic solutions** for all **for early diagnosis and treatment**
  - **Rapid identification of the bug** that would eventually help in choosing the appropriate antibiotic early in the treatment process

**GoApptiv is an end-to-end business services provider for healthcare companies in India with its 'phygital' model that provides quality healthcare access to extra-urban and rural India*

***Achira Labs is engaged in development and commercialisation of point of care (PoC) medical test kits in India*

Awareness program for asthma management

Berok Zindagi *one of the largest initiative to create awareness of asthma (launched in 2017)*

*Aims to **improve the quality of life** for Asthma patients, focuses on **educating asthmatics** about their condition and the importance of proper treatment; encourages **asthmatics to embrace the use of inhalers** without stigma*

Tuffies *campaign targeting children between 5 -10 yrs of age and their caregivers (launched in 2023)*

*Aims to **inform and entertain young audiences** through **comic books, educational videos, animated lessons** and **songs** to make them understand about respiratory care*

Source: Cipla-drone; Cipla-Goapptiv; Goapptiv; Breathefree; Cipla-Achira Labs; Berok-zindagi; Berok zindagi 2017; Tuffies; Tuffies 2023

Connected healthcare: Way forward

While India is renowned as an IT powerhouse, experts emphasized that the full potential of digital technology in healthcare remains untapped in India. For instance, the COVID-19 pandemic spurred a surge in telemedicine and telehealth, yet these advances have not been fully sustained post-pandemic. Experts highlighted the need for a systematic integration of digital solutions, such as point-of-care screening and medicine delivery, into the healthcare policy framework to ensure continuity and reach.

Data creation and utilization were identified as areas demanding significant focus. National registries are available for only a few diseases, and they remain mostly underutilized. A comprehensive epidemiological roadmap for non-communicable diseases is lacking. A robust data infrastructure is crucial for conducting in-depth analysis to comprehend disease patterns, which can inform the development of targeted prevention and management strategies, thereby reducing wastage and improving system efficiency.

Experts advocate for a sustained emphasis on the successful adoption of ABDM and the implementation of policies that mandate and enable digital adoption across both public and private healthcare sectors. This approach is seen as instrumental in strengthening India's integrated healthcare infrastructure. Enhancing digital literacy among all stakeholders, including healthcare professionals and patients, and ensuring that information is readily accessible, are identified as pivotal factors in driving the widespread adoption of digital health solutions.

> “The Ayushman Bharat Digital Mission (ABDM) holds tremendous potential. In an ideal scenario, with all stakeholders—providers, healthcare professionals, insurers, and beneficiaries—integrated on a single platform, the efficiency and effectiveness of healthcare delivery could be significantly enhanced. It is imperative that we expedite its penetration and adoption to fully realize the vision of a digitally empowered healthcare ecosystem.”
>
> Chairperson and Non-Executive Director, leading Indian home healthcare company

> “The absence of long-term health records is a significant gap in our current healthcare system, making it challenging for both patients and doctors to get a complete picture of one's health history, especially for caregivers of the elderly. Thankfully, emerging technologies can address this challenge of transforming how we manage health records, moving from isolated episodes to comprehensive, longitudinal data. AI, in particular, has the potential to revolutionize healthcare by digitizing and organizing past records, making them easily accessible and portable across different healthcare systems, whether locally or internationally.”
>
> Chairperson and Non-Executive Director, leading Indian home healthcare company

> “To truly enhance the patient's healthcare journey and streamline data capture, it is recommended that India establish a mandate for digital patient records. By recognizing the importance of digital documentation and actively promoting its adoption, we can ensure a more efficient and integrated healthcare system. The development and implementation of such technology should be accompanied by clear policies that underscore the necessity of this fundamental shift towards digital health.”
>
> Chairperson and Non-Executive Director, leading Indian home healthcare company

> Establishing comprehensive registries and collecting accurate data are essential for accurately assessing the disease burden in various areas. With a clear understanding of the epidemiological landscape, we can make informed decisions about the necessary investments for managing specific conditions. This includes not only curative measures but also preventive and promotive strategies to effectively address healthcare needs.
>
> CEO, leading Indian NGO

> Numerous digital initiatives are underway in both the private and public sectors, yet a cohesive integration of data remains elusive. The challenge lies in creating a system that facilitates this 'handshake' to enable data integration. We need to conduct more real-world evidence studies in India and harness the data to gauge outcomes from both clinical and patient perspectives. To drive the collection of real-world data, we need to involve patients, patient groups, and civil society organizations actively in the data-gathering process. This evidence is crucial for continued enhancement of healthcare delivery and improved patient outcomes.
>
> CEO, leading Indian NGO

In summary, digital health in India is at a pivotal point, with the potential to significantly improve patient experiences, streamline healthcare delivery, and foster a more inclusive and efficient healthcare system. The insights from industry leaders highlight the necessity for policy integration, infrastructure enhancement and a focus on training to harness the full power of digital health technologies.

Innovative healthcare financing mechanisms and paying for healthcare delivery

To expand healthcare access and integrate novel medical solutions for every citizen, it is imperative to explore steady and sustainable financing sources. The recent trend in healthcare financing has been toward innovative pooling methods like blended financing, impact funding and community health financing. These models are designed to bridge affordability gaps and enhance access to quality healthcare services. They distribute financial risk and bring together funds from public, private, and philanthropic sources to establish enduring financial structures tailored to the varied healthcare needs of India's population.

Community-based health insurance schemes are particularly suited to India's demographic diversity, offering affordable coverage that is invaluable for rural and informal sectors. By collectively managing risks and resources, these schemes not only facilitate healthcare access but also provide a safety net against devastating healthcare costs.

Public-Private Partnerships (PPPs) are evolving to include risk-sharing agreements and outcome-based financing. These innovative approaches encourage investment by offering shared risks and rewards, aligning the interests of public and private sectors toward common health goals.

Healthcare crowdfunding and philanthropic funding platforms enable individuals and organizations to raise funds for medical treatments, research, and health projects. This model democratizes healthcare financing by allowing the public to directly support causes they care about.

Moreover, flexible payment options like co-pay, micro-insurance, and health savings accounts are making healthcare more affordable for individuals. These models, coupled with incentives that promote healthy behaviors, are paving the way for a more proactive and preventive healthcare system.

Approaches for financing healthcare and expanding coverage	
Fund pooling model	
 **Healthcare blended financing**	**Catalytic funding from public and philanthropic sources is utilized** to mobilize private sector investment to realize social goals and outcomes ▪ ***SAMRIDH initiative:*** *a tri-sector collaboration between public, private and philanthropic resources (details in next page*
 **Social impact funding**	**Outcomes based funding**, where investors provide upfront capital for social services, and then are paid with a return ▪ ***Palladium group*** *with* ***UNDP*** *and* ***PCMC***[1] *designed* ***India's first social impact bond*** *in the healthcare sector; PCMC will only have to bear the costs if the project targets are met*
 **Developmental impact funding**	**Performance-based investment** used to finance development programs in **low-resourced countries** ▪ ***Utkrisht impact bond***[2]*, the first global maternal and newborn health bond to reduce the number of mother and baby deaths by* ***improving the quality of maternal care in Rajasthan***
 **Sin-tax/ Health tax**	**Tax from tobacco, alcohol, sugar sweetened beverages, foods high in fat, sugar or salt** that lead to health deterioration ▪ ***Philippines has used sin tax*** *to finance the expansion of UHC*
 **Community health financing**	**Community members** pooling funds to offset the cost of healthcare (usually voluntary); targeted to low-income people reducing out-of-pocket expenditure ▪ ***SEWA*** *offers health insurance to* ***self-employed women*** *in* ***Gujarat*** ▪ ***ACCORD offers health insurance to adivasi population, living in Gudalur, Tamil Nadu***
Flexible payment models for individuals	
 **Buy Now Pay Later (BNPL) / zero-cost EMI option**	Allows patients to **receive medical services immediately and pay for them over time** through installments without requiring upfront payment ▪ *Navia Life Care's* ***Aarogya Pay*** *offers* ***instant, interest-free loans*** *for medical treatments,* ***payable*** *in* ***three or six EMIs***
 **Health savings account (HSA)**	**Savings account for medical expenses,** including costs not covered in basic health insurance; can complement health insurance plans ▪ ***Fedo HSA***[3] *- India's* ***first-of-its kind HSA*** *provides a systematic way of planning for health needs* ▪ ***IDFC FIRST Bank*** *HSA; provides health insurance cover*[4] *without any pre-policy, medical examination*
 **Co-pay, microinsurance**	**Cost-sharing health plan**; tiered model with free insurance for below poverty section and co-pay for remaining population ▪ ***Niva Bupa's*** *copayment option: policyholders can choose plans with predetermined copayment percentages; allows lower premiums while sharing some costs with the insurer*

[1]*UNDP: United Nations Development Program; PCMC: Pimpri Chinchwad Municipal Cooperation*

[2]*Developed by USAID, Merck for Mothers, the UBS Optimus Foundation, Population Services International (PSI), Palladium, and Hindustan Latex Family Planning Promotion Trust (HLFPPT)*

[3]*AI driven HealthTech company, Fedo, launched Fedo HSA in collaboration with Asia's largest neo bank 'Open'*

[4]*The account covers all pre-hospitalization charges for 30 days and post-hospitalization charges for 60 days along with day care treatment*

Source: SAMRIDH, Impact funding, Utkrisht, Social impact, Sin tax, Sin-tax PH, Community health financing, SEWA ACCORD, ACCORD2, Aarogya pay; HSA; Fedo HSA; Co-pay; Community health financing

Blended finance model
Sustainable Access to Markets and Resources for Innovative Delivery of Healthcare (SAMRIDH)

USAID partnered with IPE Global and stakeholders from the Indian government, academia, and the private sector in 2020 to launch a blended finance facility, aiming to combine public and philanthropic funds with commercial capital to create and scale market-based health solutions

USAID + **IPE Global** + **Stakeholders** From the government, academia and private sector → **SAMRIDH**

SAMRIDH is a **tri-sector collaboration between public, private and philanthropic resources**
- It uses development finance and philanthropic funds to attract private capital into deals
- Private investors receive financial returns which are in line with market expectations

Impact
- Reduces the dependency on government debt
- Accelerates the building of commercially viable social impact projects
- Supports the immediate deployment of high-impact healthcare solutions

SAMRIDH business model

- **Mobilize grant support** as catalytic funding with an aim to get leverage of 5x-10x
- **Broker partnerships** with banks and debt funds to provide affordable debt capita
- **Provide business and technical advisory** to refine business models, make process and product improvements

Leads to growth financing

Structuring blended financing instruments, combining grant and debt capital

- Concessional capital
- Returnable grants
- Cash collaterals
- Market validation
- Assistance grants
- Partial/first loss guarantee
- Portfolio umbrella guarantee
- Social success notes

Improving healthcare services for vulnerable communities through high-impact health solution

Impact as of Oct 2024

- **US$24+ million** deployed
- **28 states** reached through healthcare services
- **45+ million** touchpoints with people
- **US$330+ million** leverage estimated
- **4,200+** health facilities reached
- **21+ million** people directly impacted
- **90+** high impact health solutions supported
- **38,000+** medical staff, nurses and community health workers trained

Source: SAMRIDH

In addition to pooling mechanisms and flexible options for expanding individual healthcare coverage, there is also a need to establish mechanisms to improve access to novel drugs. One such example is Mango Sciences, that enables affordable access to novel medicines by harnessing AI-driven clinical insights and value-based payment model. The Patient Benefit Program (PBP) allows access to loans at low interest rates and rebates the full amount in case the intended benefits are not achieved.[74]

India case study: Mango Sciences enables affordable access to novel cancer treatments

Innovative Patient Benefit Program linking cost to treatment outcome/benefit

Affordable access to novel medications by harnessing the power of AI-driven clinical insights and value-based payment model

Mango Sciences Querents' AI-driven clinical insights

- Utilize clinically detailed EHR data from hospitals and clinics to identify and administer the most effective treatments for patients at the optimal time
- Offer aggregated, population-level real-world insights to enable data-driven strategic decision making by healthcare administrators and doctors

Partnership with financing institutions, such as Arogya Finance and HDFC Bank

- Mango Sciences' Patient Benefit Program (PBP) allows access to loans at low rates of interest
- Treatment benefits are evaluated against set parameters; patients receive a **rebate from Mango if the full intended benefit is not achieved**

Source: Mango Sciences, Patient benefit program, Affordable access

> "Identifying effective methods to determine which patients would most benefit from hormonal or targeted therapies from the outset, and identifying means to provide access to such therapies could prevent the loss of many who commence chemotherapy but abandon it due to rapid cancer progression, and subsequently drop out of the healthcare system. This represents a loss of investment and resources, as neither the patient benefits nor does the government sees the desired clinical outcome from its financial input."
>
> CEO, leading Indian NGO

> "A health savings account is an excellent concept, especially for the middle class. Similar to a provident fund, individuals could contribute a certain amount to this account, which should be tax free. Currently, people spend out-of-pocket for healthcare every year. If that same amount were channeled into a premium, they could receive substantial coverage."
>
> Executive Chairperson, leading Indian pharmaceutical company

[74] Mango Sciences, Inc. – Welcome to our Official Site

> Coverage/package should provide for the required healthcare, including innovative medicines, that are needed for a patient in the given circumstances.
>
> Executive Chairperson, leading Indian pharmaceutical company

In addition to the several financing models, industry experts also emphasized that patients are willing to pay when they understand the value and potential outcomes of their healthcare expenditures.

Enhancing patient-provider communication is key, offering patients informed choices and fostering trust in the healthcare system.

> A significant portion of the population is ready to pay for healthcare if they understand the value and expected outcomes of the services they are purchasing. This requires a system where patients are explained the alternatives or the trade-offs between quality of life and longevity. For instance, some may prefer a better quality of life for a shorter duration over prolonged incapacitation. Yet, this choice is seldom presented to patients. We need to enhance this dialogue to make informed choices a standard part of patient care.
>
> CEO, leading Indian NGO

Incentivizing health and wellness behaviors through innovative financing models not only encourages a healthier populace but also reduces the long-term costs of healthcare. By embracing these diverse financing strategies, India can move closer to providing comprehensive healthcare coverage for all its citizens, ensuring that no one is left behind in the journey towards a healthier future.

Chapter 3

Nurturing talent

Skilling for a new era of pharma innovation and global leadership

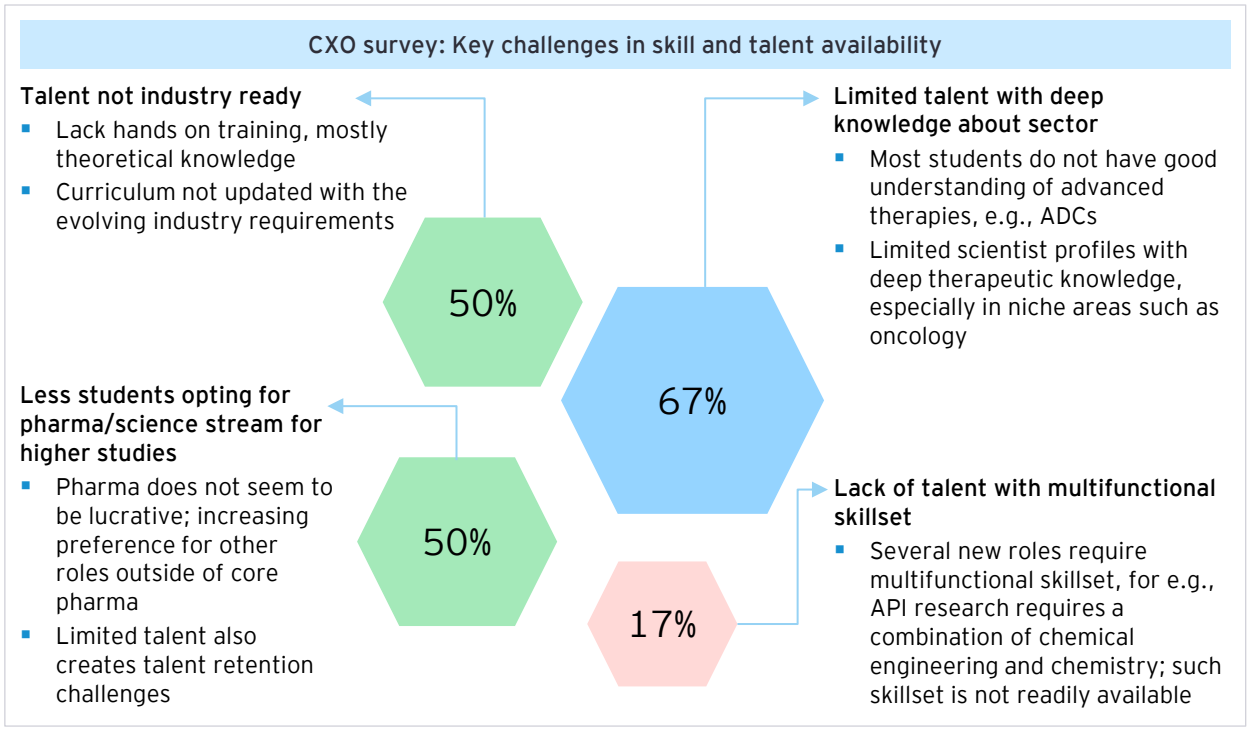
Present landscape of pharma workforce in India

India enjoys a demographic advantage that positions it uniquely in the global landscape. With a median age of just 28.4 years,[75] India is home to one of the world's youngest populations, with over 65% of its population below the age of 35.[76] Beyond sheer numbers, India is also emerging as a skills powerhouse. India's talent advantage is a cornerstone of the socioeconomic growth in the country over the years.

India's IT sector, a global leader, exemplifies the potential of India's skilled workforce. The country produces ~1.5 million engineering graduates annually.[77,78] Recognizing the talent pool benefit, global companies are strategically setting up their Global Capability Centers (GCCs) in India. With 1,700 GCCs as of September 24, India has become the 'GCC capital of the world'.[79]

However, despite India's vast talent pool, the concerns about employability are growing rapidly. The Economic Survey 2023-24 reveals that an estimated 51.25% of Indian graduates are considered employable by the industry. Although this marks a significant improvement from 34% in 2014, it still indicates that nearly half of the young population is under-prepared for the job market.[80] A large majority of graduates lack the practical skills and industry-specific knowledge required by the employers. Rapid pace of technological advancements and industry shifts are further exacerbating the skills gap. This disparity poses a significant challenge to the nation's economic growth and progress.[81]

The Ministry of Skill Development & Entrepreneurship, in its annual report for 2022-23,[82] has identified several hurdles in the skilling and entrepreneurship landscape. These include the fragmented skill development programs across various ministries lacking effective coordination, a mismatch between demand and supply at sector level, limited coverage and awareness of apprenticeship programs, outdated skill curricula, and the absence of a guaranteed wage premium for skilled individuals.



[75] India Population (2024) - Worldometer

[76] Economic Survey 2024: 65% of the population under 35, yet many lack skills for a modern economy - BusinessToday

[77] Business standard

[78] 52% Of GCCs Select India For Its Rich Talent Pool: CaptiveAide Study

[79] India GCCs: India's GCC count rises to 1,700 in FY24, revenue up 40% at $64.6 billion: report - The Economic Times

[80] Press Release:Press Information Bureau

[81] Business Standard

[82] MSDE.gov

The insights shared by industry experts shed light on the pressing challenges facing India's pharmaceutical talent landscape. A notable concern is the waning interest among students in pursuing careers in pharmaceuticals or science. Even those who enter these fields often seek opportunities outside core pharma roles or choose to work abroad, leading to a brain drain of top talent from India.

Experts also highlighted gap between academic training and industry requirements. Graduates, including those with bachelor's and master's degrees, frequently lack the hands-on experience that is critical for success in the pharmaceutical sector. Additionally, there is a knowledge deficit regarding emerging drug modalities, such as ADCs, which are becoming increasingly important as the industry progresses up the value chain.

Experts emphasize the necessity for a shift from producing generalists to cultivating specialists with deep therapeutic area expertise, capable of managing niche therapies and personalized medicines. The demand for talent with multifunctional skills is also growing; for example, green chemistry requires a unique blend of chemical engineering and chemistry skills to develop alternative synthesis routes. This specialized expertise is both scarce and highly sought after.

> "India boasts the largest talent pool and possibly the highest number of pharmacy graduates. However, there remains a disconnect between the skill sets of our graduates and the actual needs of the industry."
>
> President of Safety & Logistics and Country Head, leading global CRO company

> "Our talent pool, particularly at the Master and Bachelor level, lacks the hands-on industry experience that is crucial for success."
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

> "In India today, the pharma industry often misses out on the key talent, as the most qualified individuals tend to opt for engineering or management courses, or pursue PhDs and careers abroad. This leaves a significant talent gap at the mid-level within the country. While there are people available, very few possess the cutting-edge knowledge required for specialized fields like ADCs."
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

> "Securing the necessary talent is a major challenge in green chemistry. Developing alternative synthesis routes requires a highly specialized skill set that blends chemical engineering with chemistry—a combination that is rare to find. For API production, this mix is crucial, and finding professionals who excel in both the intricate chemistry and the practical aspects of processing and unit operations is difficult."
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

> In global clinical studies, especially in oncology and hematology, sponsors often prefer specialists based in the US or Europe due to their extensive experience. India's specialists, while present, do not always meet these international standards. Intensive development of therapeutic expertise, not just generalists, is essential as we anticipate a rise in niche therapies, cell and gene therapies, and personalized medications. Driving this expertise, especially in fields beyond oncology and hematology, like rare diseases and cell and gene therapies, is critical.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> New technologies such as ADCs, peptides, oligonucleotides, these areas present a near-term opportunity for growth. However, the biggest challenge is lack of trained manpower and trained scientists who can synthesize these products.
>
> Head of Strategy and Portfolio Management, leading Indian CRDMO company

The talent imperative: Nurturing pharma's next-gen workforce

Right talent pool and skillset is indispensable to achieve the ambition of becoming a global leader in innovative and integrated pharma and healthcare industry – in fact, talent is the most important critical enabler of this growth.

For the growth of the pharma industry into a global innovation powerhouse, talent is required across different job roles. For instance, skilled workforce for manufacturing of high-quality advanced therapies, researchers and scientists to conduct R&D for pharma and CRDMOs. Furthermore, the rapid advancement of technology necessitates a future-ready workforce equipped with the latest skills to adapt to evolving industry demands and maintain a competitive edge.

Government initiative to empower India's skill landscape

The Indian government has intensified its focus on education, skill development, and innovation, aligning these efforts with the nation's Viksit Bharat vision. Recent years have seen a significant increase in initiatives designed to enhance the skill set of India's youth and bridge the employability gap.

Initiatives such as 'Skill India' (2015), 'National Apprenticeship Promotion Scheme' (2016), 'National Education Policy' (2020) and others aim at bolstering skill development and bridge the employability gap among India's young talent. In fact, the National Education Policy has the provision of no hard separation between arts and sciences that helps in building holistic skills for the current and the emerging industry needs. These efforts focus on vocational training and technical education, to align with the evolving demands of the market[83].

[83] Press Release:Press Information Bureau

Government initiatives to promote industry ready talent in the last decade

National Policy on Skill Development & Entrepreneurship (NPSDE) — 2015
Focuses on **bridging skill gaps**, improving industry engagement, and expanding apprenticeship opportunities

Pradhan Mantri Kaushal Vikas Yojana (PMKVY) — 2015
Enhances **skill development** by short-term training, up-skilling and re-skilling through recognition of prior learning

National Apprenticeship Promotion Scheme (NAPS) — 2016
Provides **financial support to industrial establishments** undertaking apprenticeship program

Samagra Shiksha' Scheme — 2018
Integrates **vocational education with general academic education** in all secondary/senior secondary schools; enhancing students' employability and entrepreneurial abilities

National Education Policy (NEP) — 2020
Integrates **vocational education and skill development with general education,** bridging the education-employment gap

Skill India Digital Hub platform — 2023
Facilitates **access to skilling and employment** through **AI/ ML;** enhancing accessibility to educational resources essential for vocational training

Skill India International Centers — 2024
Establishment of 30 Skill India International Centers# to promote the recognition of Indian qualifications and easy recruitment abroad

Skilling program announced under the Union Budget 2024-25 — 2024
Skilling program with a financial outlay of INR60,000 crore scheme to skill 20 lakh youth by 2029-30

Revised Skill Loan Scheme* — 2024
Provides **loans up to INR7.5 lakh** to **individuals pursuing advanced skill development courses,** with government-backed guarantee

Previously the loan amount was up to INR1.5 lakh; #announced in interim budget 2024-25

Impact (of certain initiatives)

PMKVY *(since inception to Sep 2024)*	NAPS *(since inception to Mar 2024)*
14.2 million individuals trained	**0.22 million** institutes registered, providing apprenticeship
11.3 million receive certification	**3,208.8 million** funds disbursed

Source: India's skill development, Skill India mission, NEP 2020, Vocational education, DBT-Biotechnology Industrial Training Program (BITP) Apprenticeship

The latest Union Budget 2024-2025 includes a comprehensive package for employment and skilling, emphasizing job-linked incentives for newcomers, expansive skilling schemes, and robust internship programs.

The following are the key highlights from major programs:

Union budget 2024-25: Skilling and internship scheme

Skilling scheme – key highlights

- Targets **skilling of 20 lakh youth** over a five-year period
- Total outlay of **INR60,000 crore**, in collaboration with the state governments (INR20,000 crore) and industry (INR10,000 crore)
- **Industry can utilize CSR funds** for funding their part for this scheme
- **Upgradation of 1,000 ITIs*** into hub (200 hubs) and spoke (800 spokes) model with a focus on outcome and quality of skilling
- **Redesign and review of existing courses** to align with industry's skill needs; introduction of new courses for emerging needs
- **Capacity augmentation of five national institutes** for training of trainers

Internship scheme – key highlights

- Aimed towards providing **practical work experience and skill development** opportunities
- **One crore youth to be skilled** by India's top companies in five years
- Twelve months **Prime Minister's Internship with monthly allowance of INR5,000**
- **Cost sharing model for government and industry**: Government as INR54,000 towards monthly allowance; Company as INR6,000 from CSR funds towards monthly allowance
- Minimum **50% of the period should be in actual working experience/job environment**
- **Companies to provide experience** themselves or in tie-ups with its forward or backward supply chain (e.g., suppliers or customers)

**ITIs: Industrial Training Institutes*

Source: Union budget 2024-25

Public-private synergy: The impact bond model

The success of any large-scale skilling initiative hinges on its connection with industry, ensuring that the training provided is relevant, and that there is sufficient demand to employ the newly skilled workforce. Recognizing this, the Skill India mission actively collaborates with the industry through the National Skill Development Council (NSDC)-driven partnerships for skill development, reskilling, and upskilling.

A notable endeavor is the launch of the Skill Impact Bond in 2021, a pioneering impact bond that brings together public and private partners, and public private partnership organization NSDC[84]. This program utilizes the Development Impact Bond model, an outcomes-based financing mechanism that draws private sector investment and expertise into skill development. It emphasizes job placements and retention, particularly for marginalized and underserved communities. The coalition has amassed a US$14.4 million fund with the goal of training 50,000 youth, ensuring a minimum of 60% female participation, through NSDC-affiliated training partners over a span of four years[85].

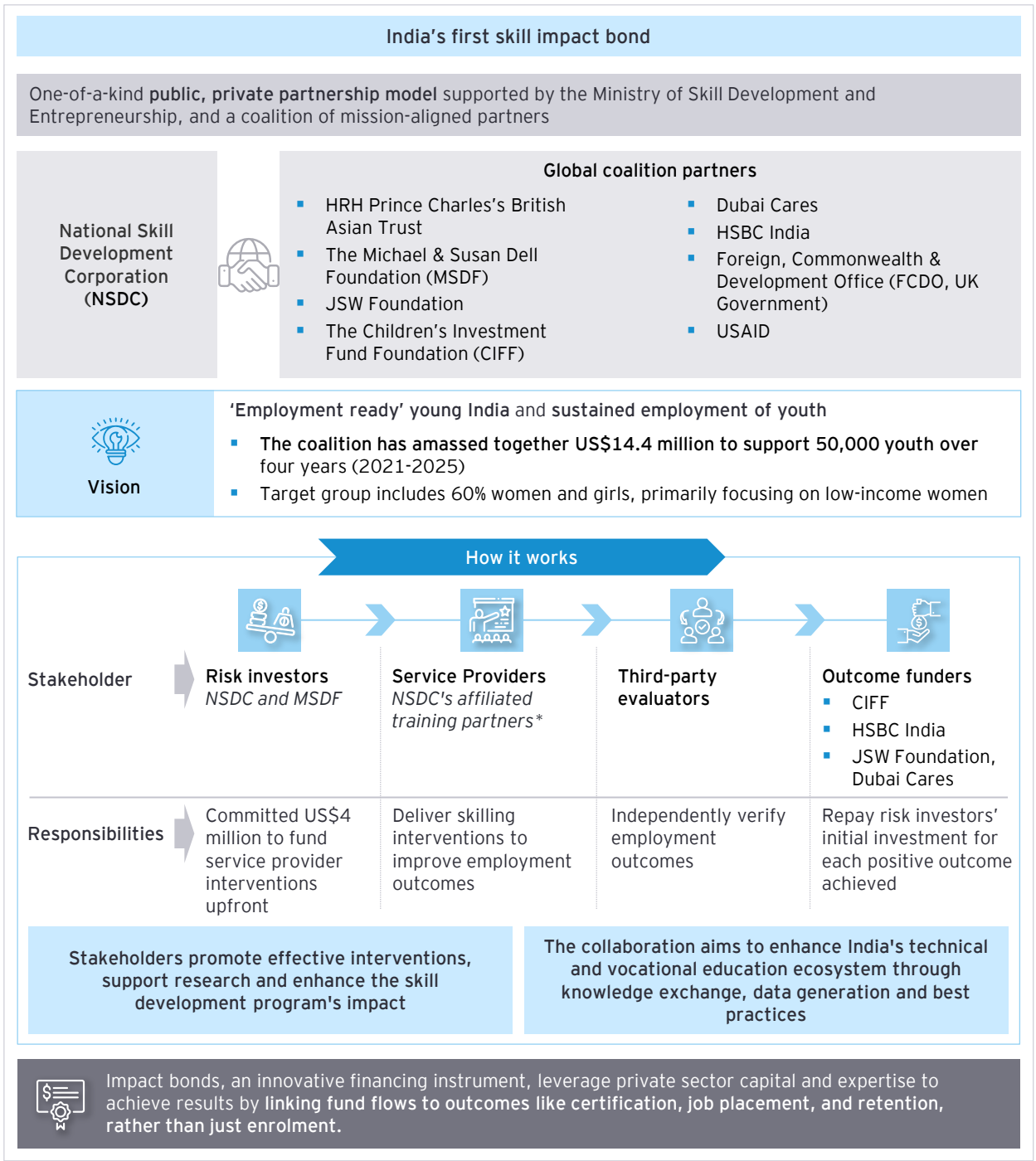
From November 2021 to March 2024, the program has made significant strides: enrolling 29,365+ candidates across five cohorts, certifying 23,464 individuals, placing 19,209 in jobs, and maintaining 13,853 in job retention[86]. Notably, the program has achieved a remarkable 74% female enrollment rate.

[84] | National Skill Development Corporation (NSDC)

[85] India's first 'Skill Impact Bond' launched, fund to benefit 50,000 youth | News on Markets - Business Standard

[86] https://pib.gov.in/PressReleasePage.aspx?PRID=2053796

These efforts by the Skill India mission underscore the critical role of industry collaboration and innovative financing models in developing a skilled future ready workforce.



Includes Apollo Medskills Ltd, Gram Tarang Employability Training Services Pvt Ltd, Learnet Skills Ltd, Magic Bus India Foundation and PanIIT Alumni Foundation

NSDC: National Skill Development Corporation

Source: Skill impact bond-NSDC, Impact of skill impact bond, Skill impact bond launch, Skill impact bond, Skill impact bond-women

Industry and academia collaboration initiatives in cultivating future-ready talent

Beyond government-led programs, the pharmaceutical industry itself is a pivotal force in shaping a skilled workforce, with initiatives that complement and enhance academic offerings. The industry's proactive engagement is essential for identifying future job skills and providing students with exposure to the practical demands of an evolving sector.

Leading Indian and global pharma companies, CRDMOs, and GCCs have launched several initiatives to develop industry-ready talent.

A notable example is AstraZeneca India's partnership with Sastra Deemed University in 2023 to design a specialized curriculum on clinical research and development. This three-year MoU aims to narrow the divide between academic theory and industry application. As part of this collaboration, Sastra University will launch a six-month elective course on clinical R&D covering a spectrum of topics, from applications of clinical sciences in drug discovery to various regulatory authorities and procedures governing clinical research.[87]

Roche's inauguration of its first Customer Experience Center in Chennai in August 2023 represents another innovative approach.[88] Powered by immersive and interactive healthcare content, the center will help stakeholders, including healthcare professionals and researchers, visualize disease pathways and drug mode of action to co-create better patient solutions. As a key aspect of this program, Roche has partnered with four tech-schools and universities to help co-create programs to foster the development of niche skills for immersive technologies and high-end data analytics.[89] Select students will be provided long-term internship opportunities with Roche on immersive media, real time engines, high end data analytics and artificial intelligence.

Moreover, in a first-of-its-kind public-private partnership, Merck in collaboration with CSIR-Institute of Microbial Technology (IMTECH) established academia-led High-Tech Skill Development Centre in Chandigarh to augment Government's "Skill India" initiative. The center will be equipped with advanced high-tech instruments, enabling researchers to gain hands-on experience and enhance their skills in areas such as cancer research and novel drug development, conducting real-time analysis on samples as part of workshops. This would help to develop a high-quality skilled workforce relevant to current and emerging employment market needs and will help support drive R&D and manufacturing activities in India.[90]

[87] AstraZeneca partners with Sastra University for course on clinical research & development - Times of India

[88] Roche Pharma India: Roche Launches Experience Centre In Chennai | Chennai News - Times of India

[89] Roche | Roche unveils its first ever Customer Experience Center in Chennai

[90] CSIR-IMTECH partners Merck to open a high-tech skill development centre - BioVoiceNews

Industry-academia collaborations and initiatives for skill and talent development

Curriculum and course design Public-private partnership	**Roche + Universities in Tamil Nadu*** *(Aug 2024)* Co-created course curriculum/programs for niche skills, such as immersive technologies and high end data analytics; select students get long-term internship opportunities with Roche **AstraZeneca + Sastra University** *(Jul 2023)* Developed curriculum on clinical research and development, bridging the gap between theory and practice **Aragen + CSIR-IICT + Kewaunee Labway** *(Mar 2023)* Course design and development in synthetic organic chemistry to develop industry ready talent; students get hands-on training on real problems
Hands on training Learn while earn	**Pfizer + Gandhi Institute of Technology and Management (GITAM) University** *(Oct 2023)* One-of-its kind women-only program to develop a multi-skilled workforce; offers Bachelors of Chemistry and three-year experience across pharma manufacturing while pursuing bachelor's degree **Lupin's "Learn and earn" program** Three-year paid program: students get Bachelor Vocational in Manufacturing Technology by TISS*, along with work experience and job in Lupin's manufacturing factory
STEM Education (Science, Technology, Engineering and Mathematics)	**GSK Scholars Program** Provides scholarship to meritorious and financially constrained MBBS students from government colleges to cover academic expenses **Syngene STEM scholarship** In collaboration with Research and Innovation Circle of Hyderabad (RICH) - offers scholarships and mentorship to women studying STEM subjects at tier-2 and 3 institutions

R&D | Manufacturing | Data analytics | Business Function agnostic

CRDMO | Pharma MNC | Indian pharma company | Pharma GCC

SASTRA Deemed University, Vellore Institute of Technology, Kumaraguru College Of Technology and Saveetha Institute of Medical and Technical Science, TISS - Tata Institute of Social Sciences

Source: EY analysis and company websites accessed as on Nov 5, 2024 (Pfizer, Lupin, Roche, AstraZeneca, Aragen, GSK, Syngene)

Academia and industry collaborations are synergistic with each other. The industry benefits from access to innovative research and talent. Academia benefits by getting the required funding, infrastructure and mentoring (technical and commercial) support for moving the ideas from the research stage towards commercialization. Laying the right foundation through skill-building at an early stage, these partnerships reduce future training costs. Collaboration in curriculum development and student internships can ensure graduates possess the specific skill sets. This fosters a talent pipeline that aligns with industry needs and creates a win-win scenario for all stakeholders involved.

While some companies have initiated such programs, scaling them up is essential for realizing the Viksit Bharat vision.

Skill synergy: The IT Industry's model for capability development

Some interesting skilling examples and best practices can be taken from India's IT industry that has ascended to global leadership. NASSCOM, the industry's apex body, has pioneered a tripartite ecosystem in collaboration with the IT industry and the Indian Government. A prime example of this is FutureSkills Prime,[91] a digital skilling initiative that arms learners with the latest technological competencies.

This initiative also features the Talent Connect Portal,[92] a platform that seamlessly connects businesses in search of digitally skilled talent with certified professionals seeking career advancement. It serves as a vital resource for upskilling and reskilling within the dynamic tech landscape, thereby boosting the employability of Indian talent. Such models exemplify how targeted skilling, continuous learning, and industry-government collaboration can elevate a workforce to meet the demands of a rapidly evolving industry.

[91] futureskillsprime.in

[92] https://talentconnect.sscnasscom.com/

NASSCOM: Building a future-ready digital talent nation

Spearheading India's digital supremacy with innovative initiatives aimed at equipping the youth with skills in emerging technologies and enhancing their employability opportunities

FutureSkills Prime
Digital skilling ecosystem backed by the IT industry, NASSCOM and the GoI

- Launched in 2021
- Joint initiative by MeitY and NASSCOM
- Bridging the industry skill gap **Up-skilling and re-skilling working professionals**

Key offerings:

1. **Courses and pathways** in the most in-demand skills
2. **Experiential project-based learning** for building industry-ready skills
3. **Hackathons and subject olympiads** with outcome-based assessments
4. **NASSCOM certifications** to enhance employability
5. **Talent connect portal** to bridge job scout-seeker gap
6. **Government of India incentives** on course completion

The pan-India network of C-DAC and NIELIT centers is being leveraged to extend the reach of this program in smaller towns and remote locations through blended learning programs

Key technologies

Artificial intelligence | Internet of Things | Blockchain | 3D-printing | Cybersecurity | Cloud computing | AR/VR

Impact (since inception to 2024)

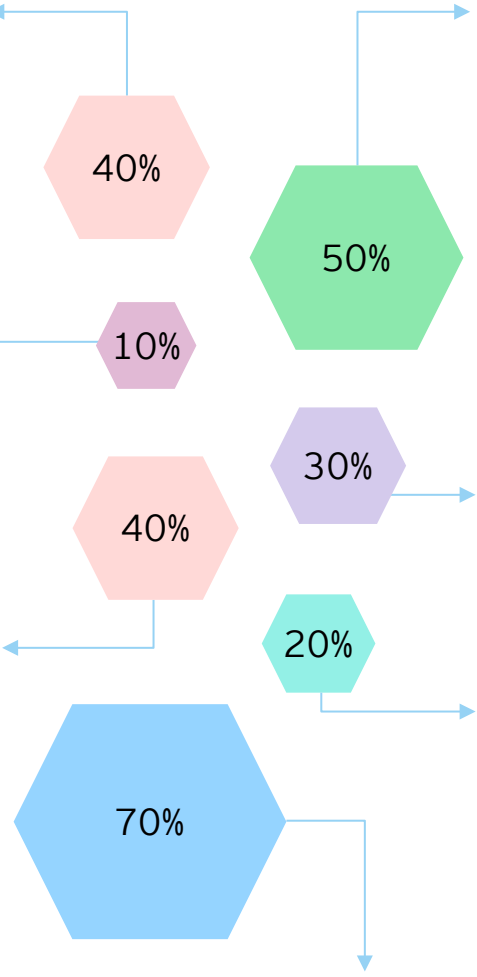
0.8+ million	15.7+ billion	2,000+	13	2,100+	160+
enrollments	learning hours	Courses and pathways	State government partnerships	Academic institution partnerships	Corporate partnerships

NASSCOM: National Association of Software and Service Companies
MeitY: Ministry of Electronics and Information Technology
AR/VR: Augmented Reality / Virtual Reality
C-DAC: Centre for Development of Advanced Computing
NIELIT: National Institute of Electronics and Information Technology

Source: FutureSkills Prime, Launch of FutureSkills Prime, Talent connect portal

Adopting similar strategies within the pharmaceutical sector could catalyze the development of a skilled talent pool capable of driving innovation and maintaining India's competitive edge. By emulating the IT industry's approach to capability development, the pharma sector can ensure its workforce is equipped to navigate the complexities of next-generation therapies, API/KSM self-reliance, and the expanding CRDMO industry.

CXO survey: Key solutions to build skill and talent availability



Bring back bright India talent from outside

- Incentivization and a supportive environment for good talent to come back to India; this can help in establishing the ecosystem that is required

Do more industry internships

- Programs by companies for hands on training and actual work experience
- Government + industry collaboration for internships. For e.g., the recent internship scheme
- Academia and industry collaborations to train and absorb students
- Industry should consider utilizing CSR funds for talent development and internships

Industry to be more aware about government and sector skill development programs

- Communication between the industry and sector skill development council to identify suitable skill/ talent programs

Provide good compensation and incentives

- Pharma industry should match the package given by other industries

Encourage students to pursue pharma/STEM

- Pharma companies should be purpose driven – this will attract young students motivated to make a difference in the lives of people
- Critical for industry, government and academia to come together and encourage students to pursue the pharma field to bridge supply-demand gap
- Create new roles for STEM students, e.g., roles in the tech transfer offices and IP offices
- Encourage more girls to take up this field as currently the proportion of girls is very less

Create an ecosystem and develop more infrastructure

- Good ecosystem will attract bright students
- Build infrastructure (universities, laboratories, etc.) in tier-2 universities to cater to the increasing manpower need

Revise curriculum and grading system aligned with industry needs

- The curriculum should be regularly revised with the evolving talent needs of the industry
- There should be options for specialization
- Focus on practical knowledge along with theoretical
- Industry and academia should partner to define talent needs and then work cohesively to develop the talent
- The grading system should be updated to reward right metrics
- Curriculum should include topics such as Design thinking, Entrepreneurship
- Mandatory adoption of National Education Policy 2020 for all colleges to enable multifunctional skill development

Industry | Government | Industry + Government

Primary research findings: Elevating India's pharma talent

Insights from the industry

The insights from industry experts underscore the urgent need for a robust talent development framework to support India's burgeoning pharmaceutical industry.

Experts suggested several approaches to address the talent supply-demand gap. Internships for students were highlighted as a crucial step towards bridging the gap between academia and the practical demands of the industry. The Prime Minister's internship program is a commendable step towards this goal, with the government's support in funding internships seen as a vital investment in the future workforce.

Industry and academia partnerships were highlighted as critical to nurturing industry-ready professionals. Aligning educational curricula with industry requirements ensures that the workforce is prepared to meet the demands of an industry increasingly focused on advanced therapies such ADCs, oligonucleotides, and CAR-T therapies. To address the talent shortage, industry must articulate their talent needs, collaborate with the government, academia, and skill development bodies, and create a blueprint for future-ready talent development.

Compensation emerged as a concern, with science and pharma graduates often earning less than their counterparts in other sectors, which makes it challenging for the field to attract top talent. To address this issue, the industry must offer better compensation packages. Additionally, organizations should find ways to actively encourage talent to pursue science and pharmaceuticals by exploring incentives that make these fields more appealing. One potential solution to address this is to create new roles for STEM graduates. For instance, involving individuals with degrees in chemistry and biology in collaboration with legal teams in tech transfer offices can increase process efficiency. Defining a clear company-wide purpose is essential, especially for the younger generation, who are motivated to make a positive impact in their surroundings and seek deeper connections with their work.

Boston's biopharmaceutical hub, with its significant Indian talent, serves as a model for what can be achieved in India. By incentivizing those with international experience to contribute to India's growth, the country can lead in innovation. Like China, which has successfully repatriated talent to bolster its domestic industries, India must create a strategy and environment that attracts and retains skilled professionals.

In summary, India's pharmaceutical industry is at a critical juncture, requiring a concerted effort to develop talent that is equipped to drive innovation and sustain growth. By implementing strategic initiatives that foster skill development, offer competitive compensation, and encourage industry-academia collaboration, India can secure its place as a global leader in pharmaceutical innovation and manufacturing.

> "We must acknowledge that the younger generation emerging today is incredibly purpose-driven. These young students are intelligent and eager to make a meaningful difference in the world. Pharma companies need to provide these students with a purpose, the purpose of making a difference in people's lives through life-saving medicines."
>
> Independent Director and Senior Advisor, leading Indian pharmaceutical company

> "The Prime Minister's internship initiative is commendable, and the government's role in funding and insisting on such programs is vital."
>
> Executive Chairperson, leading Indian pharmaceutical company

> To attract talent to scientific courses and careers, we must address the incentives that drive career choices. The pay packages in pharma, when compared to software or other industries, are less competitive, which naturally influences decisions. We need to reevaluate our compensation structures, ensuring they are on par with other industries. Beyond salaries, we should create an environment that motivates young talent to join the pharma sector. We must innovate with incentives that truly resonate with those considering a future in science or pharmaceuticals.
>
> Vice President - R&D, leading Indian pharmaceutical company

> The niche capabilities required for ADCs, oligonucleotides, and CAR-T therapies represent an area where India's ecosystem is still nascent. While the country excels in generics, APIs, and formulations, the biologics sector, particularly monoclonal antibodies (mAbs), is only a decade old. The challenge lies not in infrastructure or investment but in finding the talent to operate these sophisticated facilities. Even with significant financial resources, the question remains: from where will we source the skilled professionals to manage these advanced operations?
>
> Chief Quality Officer, leading Indian CRDMO company

> Internships within the industry are crucial. Without industry exposure, we risk losing this valuable resource. These internships not only provide practical experience but also guide career choices. While some progress has been made, scaling up these efforts is essential for achieving the Viksit Bharat vision.
>
> Executive Chairman & Managing Director, leading Indian pharmaceutical company

> Partnerships between industry and academia are essential to cultivate the next wave of clinical researchers, data scientists, and healthcare professionals who are truly industry-ready. Current courses often focus on theory at the expense of practical skills. There is a critical need to align educational curricula with the practical demands of the industry. This alignment would enable graduates to transition seamlessly into professional roles, reducing the need for extensive on-the-job training.
>
> President of Safety & Logistics and Country Head, leading global CRO company

> CRO industry expansion requires readily available and well-prepared talent. Government has a pivotal role in ensuring that universities provide industry-aligned education and practical exposure. Tier-2 universities must also be capable of producing industry-ready graduates to cater to the vast manpower need. India faces a pronounced talent gap in the biologics space as well, particularly at the senior level who can mentor and develop further talent. To fill this gap, government should attract Indian students from outside India who have pursued advanced degrees and postdocs in molecular biology and bio-manufacturing. Offering high positions within government universities and various programs can help get these experts back to India. This expertise is vital for training university faculty and developing a skilled workforce in biologics, both in manufacturing and bioanalytical roles, and will be critical for India to emerge as a biologics leader by 2047.
>
> Head of Strategy and Portfolio Management, leading Indian CRDMO company

> In addition to the multiple skilling initiatives from the central government, various states also have unique skilling initiatives tailored to the developmental needs of their youth. Sector skill councils play a pivotal role, serving as implementation partners for both central and state government schemes. The Life Sciences Sector Skill Development Council stands ready to facilitate industry requirements with consolidated list of available programs and initiatives, ensuring that industries can easily access and benefit from the full spectrum of skilling opportunities available.
>
> Chief Executive Officer, Indian vocational education awarding body

> With data becoming a precious asset to any company, roles in clinical data management have evolved significantly over the years. Some of the key roles include data analysts, data engineers, data architects, database designers, database administrators and data scientists We need to ensure that tailored university curriculum is developed to include core drug discovery, clinical data management and healthcare value chain–related courses. The curriculum should place a strong emphasis on statistics for clinical trials. Frequent connects through appropriate forums are required between industry and academia. This will help to bridge the gap on the industry needs and create talent pools.
>
> Managing Director, leading global pharma MNC

Insights from academia

The insights from academicians on the state of talent and skill development in India's pharmaceutical sector reveal a pressing need for reform and innovation. They suggested that in an attempt to set baseline standards for pharmacy education, we may inadvertently stifle innovation by enforcing a uniform curriculum across all institutions. Premier institutes with a track record of excellence, like NIPERs, should be granted autonomy to develop specialized domains and tailor their programs to foster expertise in specific fields. For research mindset, there is also a need to strengthen foundational skills such as design thinking and entrepreneurship.

Metrics in academia, such as the number of papers, citations, and patents, do not necessarily translate to real-world impact. For instance, patents that remain uncommercialized represent a missed opportunity and suggest a disconnect between research focus and market needs. True success lies not in numbers but in tangible solutions that address real-world challenges. This clearly establishes the need to revisit some of the current metrics to evaluate the performance of the students.

The traditional approach to higher education, which narrows focus as students advance, is evolving. The concept of T-shaped or V-shaped specialization encourages depth in one's primary field and complementary knowledge in adjacent areas. For example, a chemist with a deep understanding of biology could design drugs more effectively. This flexibility in education, allowing for dual specialization or a broader yet deep knowledge base, is essential for fostering innovation. We also need provisions for students who are good in life sciences and further want to gain better understanding of digital/technology – such options are limited currently. This will help nurture the futuristic talent at the confluence of life sciences, technology and digital.

In summary, India's pharmaceutical education system requires a paradigm shift to meet the industry's talent needs. Autonomy for leading institutions, innovative curriculum design, entrepreneurial training, and a focus on practical knowledge are the cornerstones of building a future-ready workforce.

> In academia, we often measure innovation and research success by the number of papers, citations, patents, and technology transfers. Yet, these metrics alone are not indicative of true impact. For instance, if an institute has several patents, but if none of those have been commercialized, then that suggests a disconnect. It is not about the quantity of output, but the quality and relevance. Metrics must reflect real-world applications and solutions, not just numbers. We need to focus on addressing the right problems and building trust to ensure that academic research translates into tangible benefits.
>
> Director, leading Indian pharmaceutical academic and research institute

> In the short term, deliberate programs and concerted efforts are needed to foster a confluence of technology and life sciences. Such initiatives can catalyze the collaboration of diverse minds, leading to greater innovation. Over time, adopting a more flexible education policy will be crucial, allowing students with an interest in crossing streams to gain the necessary exposure. For instance, a technocrat with a passion for life sciences should have clear pathways to pursue this interest academically. Making these options available is key to developing skilled professionals who are well-versed in both technology and life sciences, and who can significantly contribute to our industry. These are the steps we must consider while building a talent pool that will drive the sector forward. For instance, India's first CAR-T originated from IIT-Bombay.
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The Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, represents the research-based global pharmaceutical companies in India. OPPI has been an integral part of the healthcare journey of the country. We remain committed to supporting the nation's healthcare objectives, putting patients at the core of all decision making and collaborating with all stakeholders to find sustainable solutions to realize the collective vision of *Health for All*.

Our member companies have been serving the country's healthcare ecosystem since pre-independence and continue to remain committed to patient safety and providing quality care in the future as well. As an association, our advocacy decisions, patient commitment and work are always keeping the country first and we embody the spirit of working for *'Bharat Ke Liye'*; driven with innovation to find solutions for unmet medical needs, collaboration with government stakeholders, and co-creation with partners coming together to address the nation's healthcare challenges. We are committed to the Hon'ble Prime Minister Shri Narendra Modi-ji's clarion call of *'Jai Vigyan and Jai Anusandhan'*.