Reimagining pharma and healthcare for India@100

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November 2023

OPPI
Organisation of Pharmaceutical Producers of India

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EY Parthenon
Building a better working world


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Foreword

Suresh Pattathil
President OPPI

In the pursuit of India@100, a vision that encapsulates prosperity, progress, and inclusivity, the pharmaceutical and healthcare sector emerges as critical components for transformative change. As President of the Organisation of Pharmaceutical Producers of India (OPPI), it is with great optimism and enthusiasm I present this report that seeks to reimagine the future of our industry within the ambit of 'Amrit Kaal'.

Amrit Kaal, denoting a propitious era in our nation's journey, sets the stage for us to propel India into global leadership by 2047. This report serves as a compass, guiding our industry through the intricate challenges and promising opportunities that lie ahead. It is a testament to our commitment to realizing the ideals laid out by the honorable Prime Minister, Shri Narendra Modi, during India's 75th Independence Day celebrations.

The Indian pharmaceutical industry, often celebrated as the 'pharmacy of the world,' has been a steadfast contributor to the nation's economic growth. Our industry, characterized as the "archetype of affordable healthcare," has not only bolstered the country's GDP but has also played a crucial role in improving public health outcomes globally.

This report meticulously explores the industry's potential to become an integral part of the global pharma supply chain, fostering innovation, and ensuring sustainable and equitable healthcare access for all. As we navigate the complexities of a rapidly evolving landscape, the insights presented herein will serve as a strategic roadmap for industry leaders, policymakers, and stakeholders alike.

I extend my sincere appreciation to EY for their collaboration in crafting this comprehensive report and commend the dedication of all contributors who have enriched it with their valuable perspectives. As we embrace the responsibilities outlined in "Kartavya Kaal," let us collectively work towards a future where the pharmaceutical and healthcare sector not only meets the demands of the present but becomes a driving force for India's holistic development.

Foreword

Anil Matai
Director General OPPI

As we stand on the cusp of transformative change, the pharmaceutical and healthcare sector in India is poised to play a pivotal role in shaping the nation's destiny. The India@100 report, a collaborative effort by the Organisation of Pharmaceutical Producers of India (OPPI) and EY, charts an ambitious course for the pharmaceutical and healthcare industry, aligning with the visionary goals set forth during India's 75th Independence Day celebrations through the concept of "Amrit Kaal."

Amrit Kaal, symbolizing an auspicious era, beckons us to ascend to new heights of prosperity, embracing the responsibilities outlined during the "Kartavya Kaal." It is within this transformative period that the pharmaceutical and healthcare sector must rise to the occasion, becoming a beacon of innovation, quality, and accessibility for all citizens.

The Indian pharmaceutical industry, recognized as a key player on the global stage, has made significant contributions to advancing worldwide healthcare. Amid the challenges posed by a rapidly changing global landscape, our industry has demonstrated resilience and an unwavering dedication to fostering innovation, conducting cutting-edge research, and establishing valuable global partnerships.

The report delves into key themes such as unleashing the value-driven research and innovation potential, integrating seamlessly into the global pharma supply chain, and achieving sustainable and equitable healthcare access. These pillars align with our shared vision for a future where the pharmaceutical and healthcare sector becomes an integral force in realizing the aspirations of Amrit Kaal.

As the Director General of OPPI, I am proud to present this report, which not only outlines the challenges and opportunities but also provides a roadmap for our industry to thrive in the decades to come. I extend my gratitude to EY for their collaboration and to all stakeholders who have contributed their insights to make this report a comprehensive guide for navigating the evolving landscape of pharma and healthcare in India.

Together, let us embark on this transformative journey, ensuring that the pharmaceutical and healthcare sector become a cornerstone of India's progress and a catalyst for global health and well-being.

Foreword

Suresh Subramanian
Partner, National Life Sciences Leader,
EY India

As we stand on the cusp of a new era, reflecting upon India's journey over the past decade invokes a sense of awe and admiration. India's journey has been nothing less than exceptional, catapulting the country from its previous position as the tenth largest economy to its current status as the fifth largest on the global stage. This remarkable trajectory, marked by unwavering resilience and determined progress, has positioned India as the fastest growing major economy for the third consecutive year. But what lies ahead for the Indian economy, and what is getting global attention, is the potential to achieve US$26 trillion by 2047.

In tandem with this journey, the Prime Minister of India unveiled the ambitious roadmap of Amrit Kaal, charting the course for India's ascent to global leadership by 2047. This vision serves as the guiding light for our collective endeavors, forging a path where India not only sustains its upward economic momentum but also emerges as a beacon of innovation and progress.

The pharmaceutical industry is poised to play a crucial role within this landscape of transformative growth. Fueled by a commitment to transformative innovation and bolstered by government initiatives toward universal health coverage, the industry aspires to surpass the US$450 billion mark by 2047.

This report attempts to navigate the pharmaceutical industry's journey towards excellence. The narrative unfolds against the backdrop of three pivotal themes – focus on transformative innovation, fortification of manufacturing and quality standards, and pursuit of sustainable and equitable healthcare. Embellished by green shoots of great beginnings in the ecosystem and case studies, future imperatives shared by several industry leaders make it a compelling story.

I extend my sincere thanks to the Organisation of Pharmaceutical Producers of India (OPPI) and my colleagues at EY. In presenting this report, we aspire for it to serve as a catalyst and a guiding document for all stakeholders. With unwavering conviction, we express our faith in our collective ability to realize the vision encapsulated in Amrit Kaal. The journey ahead is both promising and challenging, but with determination and collaboration, we are poised to script a new chapter in India's narrative of success.

Here is to the next 25 years of Indian Pharma and Healthcare. A phenomenon that the world will watch unfold and connive to make it happen.

Amrit Kaal: toward a heady ambition for India

Amrit Kaal: toward a heady ambition for India

Over the last decade, India's position has grown from the tenth largest economy to the fifth largest. The global economy is facing strong recessionary impulses, multi-decade high inflation, record levels of public debt and the squeezing of real household incomes. Amid all this, India has been the fastest growing major economy for the third year in a row—a bright spot in a global economy. Looking over the next few decades, the country presents a major growth opportunity.

In 2021, during India's 75th Independence Day celebrations, honorable Prime Minister Shri Narendra Modi introduced "*Amrit Kaal*".

> *The goal of 'Amrit Kaal' is to ascend to new heights of prosperity for India and the citizens of India.*[1]

A term drawn from Vedic inspiration, which means a uniquely auspicious period, 'Amrit Kaal' sets the foundation for transforming India into a developed nation by 2047. The next two decades form the period of "*Kartavya Kaal*" where every citizen should prioritize their duties and work toward the goals of this transformative period.

The ambition of Amrit Kaal is to empower India, bridge the urban-rural development gap, and embrace the latest advancements in technology. According to a recent EY report[2], India has the potential to be a US$26 trillion economy in market exchange rate terms by 2047-48. This transformation is rooted in our nation's strategic strengths, including geo-political significance, pool of highly skilled talent, remarkable pace of infrastructure development, and a thriving ecosystem of advanced technology and service capabilities. These strengths are poised to catalyze a seismic shift across various sectors, ultimately propelling the nation toward the envisioned prosperity of the Amrit Kaal era.

India GDP will be **US$26 trillion** in market exchange rate terms by 2047–48	**India's per capita income** would exceed **US$15,000** by 2047–48, putting it among the ranks of developed economies	In the medium term, India would remain **the fastest growing large economy**

[1] "Our Amrit Kaal", The Statesman, Sep'23

[2] "India@100-realizing the potential of a US$26 trillion economy", EY report

Pharmaceutical and healthcare sector: current state and ambition for India@100

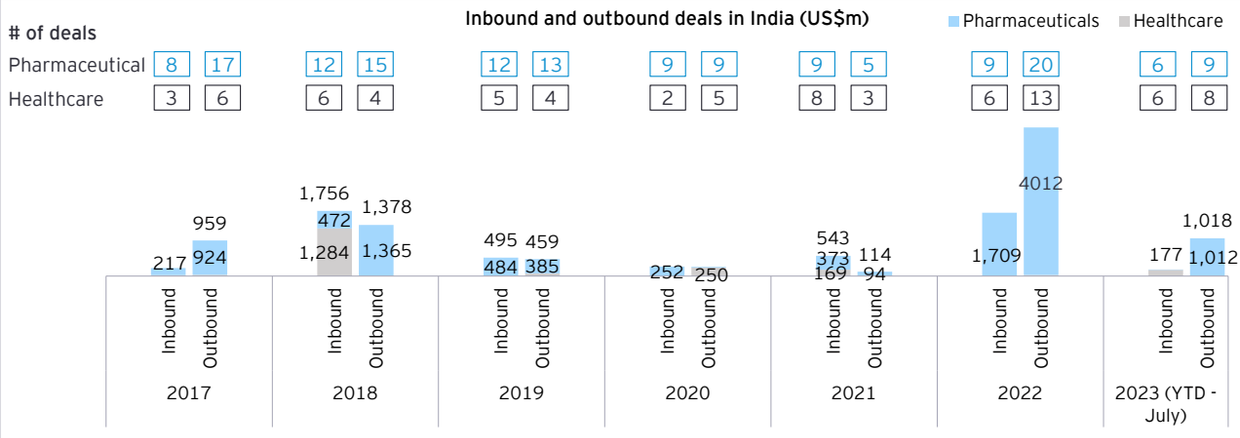
Indian pharmaceutical industry: today's pharmacy of the world

Indian pharma industry has been known as 'pharmacy of the world' for decades. Widely recognized for its leadership in the global generics sector, the industry represents over 20% of the global generics supply by volume and caters to approximately 60% of the global demand for vaccines.

The Indian pharma industry is contributing substantially to country's economic growth. It contributed ~1.72%[3] to the country's GDP in 2021 (does not include 'pharma service industry' and 'contract drug research, development, and manufacturing outsourcing organizations'). The industry is one of the top ten sectors in attracting Foreign Direct Investment (FDI). It generated cumulative FDI of US$21.46 billion between April 2000 to March 2023, constituting ~3.3% of the total FDI inflow in the country[4]. Over 2.7 million people are either directly or indirectly employed by the industry[5].

Popularly called the "archetype of affordable healthcare," the industry has significantly contributed toward improving public health outcome, both in India and across the globe.

Aligned with the strength of the healthcare and pharma sector, there has been a significant surge in the outbound and inbound deals in the recent years. Majority of the top five outbound and inbound deals by value in the last five-year period were in the pharma sector. The largest outbound deal during the analysis period was Biocon's acquisition of Viatris biosimilar business accounting for >80% of the total value of outbound deals in 2022. The largest inbound deal was the acquisition of India's Sterling Biotech by California based Perfect Day in 2022. The acquisition will help Perfect Day to scale up its precision-fermented protein production[6].



Top 5 outbound deals: 2017-2023 (YTD)

Acquirer-target (year)	Deal value (US$m)
Biocon Biologics – Viatris (2022)	3,335
Aurobindo Pharma – Sandoz (2018)	1,000
Sun Pharma – Concert Pharma (2023)	569
Sun Pharma – Taro Pharmaceuticals (2023)*	307
Acrotech biopharma LLC – Spectrum Pharmaceuticals (2019)	300

Top 5 inbound deals: 2017-2023 (YTD)

Acquirer-target (year)	Deal value (US$m)
Perfect Day – Sterling Biotech (2022)	1,104
Northern TK Venture – Fortis Healthcare (2018)	1,073
Viatris Inc – Famy Lifesciences Ltd (2022)	300
Procter and Gamble India - Merck Ltd (2018)	295
Apotex – Arrow Pharmaceuticals (2019)	282

*Additional stake acquisition

Sources: EY analysis, VCC Edge Database, Merger Market

[3] Sector Highlights: Pharmaceuticals | Make In India

[4] Invest India website

[5] "Indian pharmaceutical industry – pillar of India's growth", The Times of India, Aug'22

[6] Perfect Day Expands Global Footprint and Owned Manufacturing Capacity in India

Healthcare in India: current state

India has made significant strides in the healthcare space since independence. Consistent decline in communicable diseases, eradication of a few deadly diseases, and increase in life expectancy are a few positive indications. The per person disease burden, measured as DALY rate (Disability Adjusted Life Years lost per 100,000 population) dropped in India by 36% from 1990 to 2016, but there are major inequalities among the states[7]. India's current DALY rate stands at ~35,000[8], while the best in the world is ~10,000. India's out-of-pocket (OOP) expenditure as a percentage of total health expenditure is ~47%[9].

COVID-19 pandemic: India response and leadership

Public health consistently remains at the forefront of every country's agenda. The COVID-19 pandemic has further emphasized how public health transcends mere well-being and transforms into an economic and national security concern for a nation. To protect its citizens from COVID-19, India embarked on an ambitious program in January 2021, aimed at inoculating its entire population. Remarkably, within just one year, the country successfully administered an astonishing 1.56 billion vaccine doses, with 93% of adult population receiving the first dose and 70% achieving full vaccination[10]. This achievement not only marked one of the world's swiftest vaccination campaigns, but also showcased India's prowess as the architect of the world's largest digital vaccination initiative. This was enabled by the innovative CoWIN platform developed by the government to facilitate registration, immunizations and appointments, and issue digital vaccine certificates, enabling traction of the effort much ahead of its counterparts in the west.

India not only protected its own citizens but also supplied approximately 174 million vaccine doses to nearly 96 countries and various United Nation (UN) agencies within 15 months of initiating the program[11] (a total of ~300 million vaccine doses to 101 countries and various UN agencies as of 15 June 2023)[12]. This solidified India's status as the world's "vaccine capital".

Undoubtedly, the COVID-19 crisis has cemented India's position as a preferred global healthcare destination—a major player capable of delivering healthcare services at both scale and quality. This transformation underscores India's agility, expertise, and expansive capabilities in the healthcare arena.

That being said, the COVID-19 pandemic has also heightened awareness regarding the capability and scalability needed in the medical devices sector. The government has set ambitious targets to boost the growth of the medical devices industry in India, aiming to elevate it from its current US$11 billion valuation to US$50 billion by 2030[13]. To support this growth, the government has launched a scheme for four MedTech parks with an investment of INR400 crore[14]. The government also introduced a Production Linked Incentive (PLI) Scheme, offering financial incentives amounting to INR3,420 Crore (approximately US$400 million)[15]. This substantial commitment underscores the government's determination to make a significant impact in this sector.

[7] Disease burden initiative in India (healthdata.org)

[8] Frontiers | Lessons for Developing Countries From Outlier Country Health Systems (frontiersin.org)

[9] National Health Accounts Estimates

[10] COVID-19 vaccination, Jammu and Kashmir, CoWIN app (who.int)

[11] Why the world preferred India's Covid vaccines - The Hindu Business Line

[12] Vaccine Supply (mea.gov.in)

[13] India Medical Devices to become $50billion industry soon by Govt holistic approach: ET HealthWorld (indiatimes.com)

[14] Press Information Bureau (pib.gov.in)

[15] PLI Scheme for Medical Devices: Unleashing the Potential for Make in India, Make for the World (investindia.gov.in)

Government healthcare programs to improve coverage, accessibility, and outcomes

Several ambitious national level initiatives have been launched, signifying the Indian government's firm dedication to deliver healthcare to all. The launch of **'Ayushman Bharat' in 2018**[16] aligned with the Sustainable Development Goal 3 (Target 3.8 to achieve universal health coverage), further underscored this commitment. The flagship public health initiative has been internationally recognized as a significant step toward achieving universal coverage in the country.

Ayushman Bharat Digital Mission (ABDM) was launched in 2021[17] with the goal of establishing the foundation necessary to support the integrated digital health infrastructure. The aim of this initiative is to provide a unique health ID to every citizen, enable digital storage of health records, and facilitate seamless digital healthcare services. Ayushman Bharat Health Account or ABHA under ABDM is a digital account associated with the unique health ID of an individual. The ABHA provides a comprehensive view of an individual's health history, treatments, medications, and more. The goal is to give every citizen of India a health account where they can securely store and access their medical records.

Over 486 million Indian citizens had Ayushman Bharat Health Account (ABHA) (as of 18 Nov 2023)[18]. This Unified Health Record, stored in ABHA account of an individual, enables interoperability in the ABDM platform and can be shared among different healthcare providers, treatment centers, ensuring continuity of care and reducing repetitive tests and diagnostics. Also, with the digitized health records, services like telemedicine consultations, e-prescriptions and online pharmacy services become more streamlined and allow discoverability and access, enabling an increase in potential use of services.

This has the potential to expand the reach of medical treatment to millions who were previously underserved. This, in turn, is poised to drive increased consumption of pharmaceuticals, healthcare products, and services, ultimately benefitting both the healthcare sector and the individuals it serves.

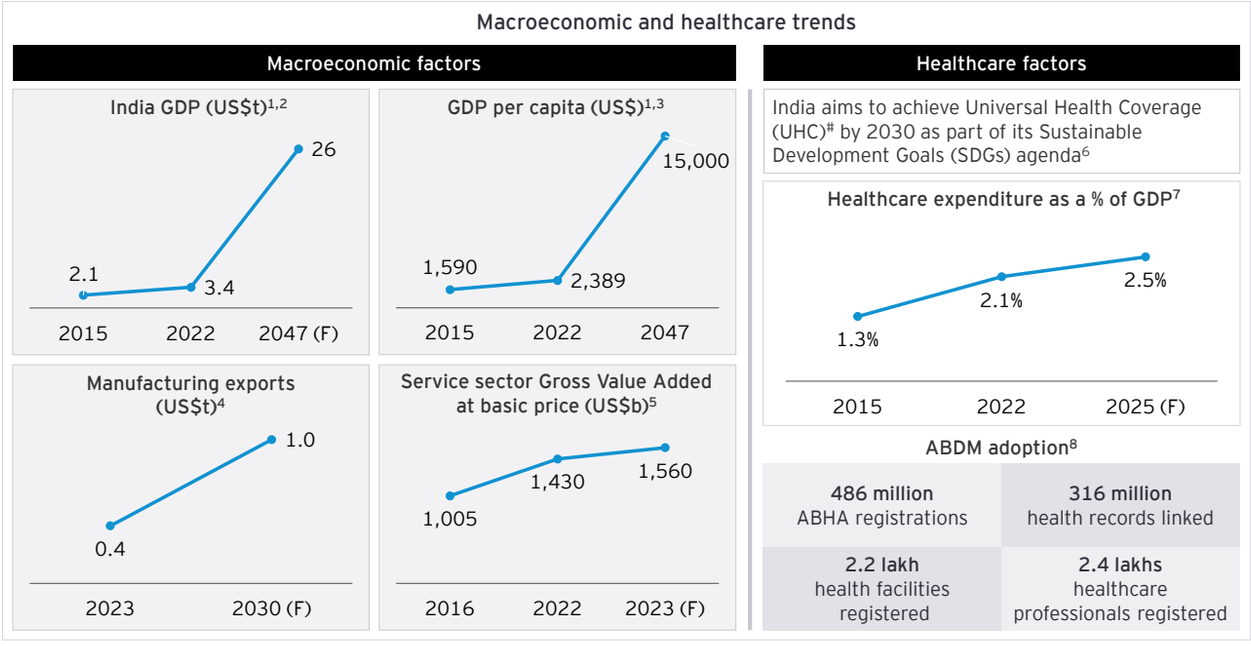
[16] Ayushman Bharat health scheme: All you need to know | India News - Times of India (indiatimes.com)

[17] NHA | Official website Ayushman Bharat Digital Mission (abdm.gov.in)

[18] ABDM-Insights

India@100: pharma and healthcare ambition

As briefly touched upon earlier, India finds itself at the brink of an inspiring economic metamorphosis, poised to surge to a staggering US$26 trillion economy in market exchange rate terms by 2047–48. This transformation is not just about macroeconomic growth, it is also set to empower citizens of the country with a projected per capita GDP that is over sixfold higher than its current level. Concurrently, the healthcare sector is experiencing a remarkable transformation, evident in the substantial increase in healthcare expenditure as a percentage of GDP. In 2015, this figure stood at 1.3%, and it is projected to almost double to an estimated 2.5% by 2025[19], reflecting our nation's commitment to improving public health and well-being.



#Achieving UHC means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship

Sources: EY analysis, 1. India@100 (EY analysis),2.GDP (current US$) - India | Data (worldbank.org), 3. GDP per capita (current US$) - India | Data (worldbank.org), 4. IBEF – Manufacturing industry, 5. IBEF – Services industry, 6. UHC ambition, 7.Healthcare expenditure, 8. ABDM Insights

Aligned with the macroeconomic growth trends and healthcare imperatives, the pharma industry is driven by an ambition to overshoot US$450 billion.

Concurrently, the healthcare sector should aspire to achieve a 'DALY rate of 10,000' and 'out-of-pocket expenditure' of 10% by 2047.

India@100: pharma sector ambition

"According to recent reports, the industry is heading towards an ambition of US$130 billion by 2030 and US$450 billion market by 2047."

India@100: healthcare sector ambition

"Given India's unique advantages on Human Resources side and on pharma side, the country should aspire to achieve a 'DALY rate of 10,000*' and 'out-of-pocket (OOP) expenditure of 10%'."

Nachiket Mor
Visiting Scientist, Banyan Academy of Leadership in Mental Health

*DALY: disability adjusted life years lost per 100,000 population

Source: Pharma industry: R&D efforts to boost India's global standing | Policy Circle

[19] Aiming to touch spending in healthcare at 2.5% of GDP by 2025: Mansukh Mandaviya (moneycontrol.com)

CXO survey findings

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), start-ups, patient advocacy groups, and other organizations to understand their perspective about the potential ambition for the pharma and healthcare sectors in the country for India@100[20]. Three goals unanimously emerged:

> *If we are able to establish credibility and can sell indigenously developed new modalities in the global markets, Indian companies can also achieve US$60 to US$70 billion annual turnover.*
>
> **Chief Technical Officer**
> leading Indian pharma company

> *Right to life guaranteed in the Indian constitution requires that every child, every adult, no matter where they are, should have equal access to basic health care services. Today, that is not true for India, particularly in some states.*
>
> **Visiting Scientist**
> Banyan Academy of Leadership in Mental Health

The next few chapters delineate key focus areas for achieving the Indian pharma industry's potential and country's healthcare ambition.

[20] Survey details: approximately 40 industry leaders (details at the end of the report)

Key highlights

Amrit Kaal (India@100)

- The goal of Amrit Kaal is to empower India, bridge the urban-rural development gap, and embrace innovative technology. It is a 25-year roadmap charting the course for India's ascent to global leadership by 2047.

India's economic growth

- Over the last decade, India has risen from the tenth largest economy to the fifth largest.
- India has the potential to become a US$26 trillion economy in market exchange rate terms by 2047-48, driven by its strategic strengths and technological advancements.

Indian pharmaceutical industry

- Indian pharma industry, also known as the "pharmacy of the world", plays an important role in improving public health outcomes in India and globally.
- The industry also contributes significantly to the country's economic growth.

Healthcare in India

- India has made significant strides in the healthcare space since independence.
- Government of India has launched several nation-wide programs such as Ayushman Bharat, Ayushman Bharat Digital Mission (ABDM), to provide access to healthcare to all
- With its ability to connect individual identities to treatment centers and other healthcare facilities, ABDM has the potential to expand the reach of medical treatment to millions who were previously underserved.

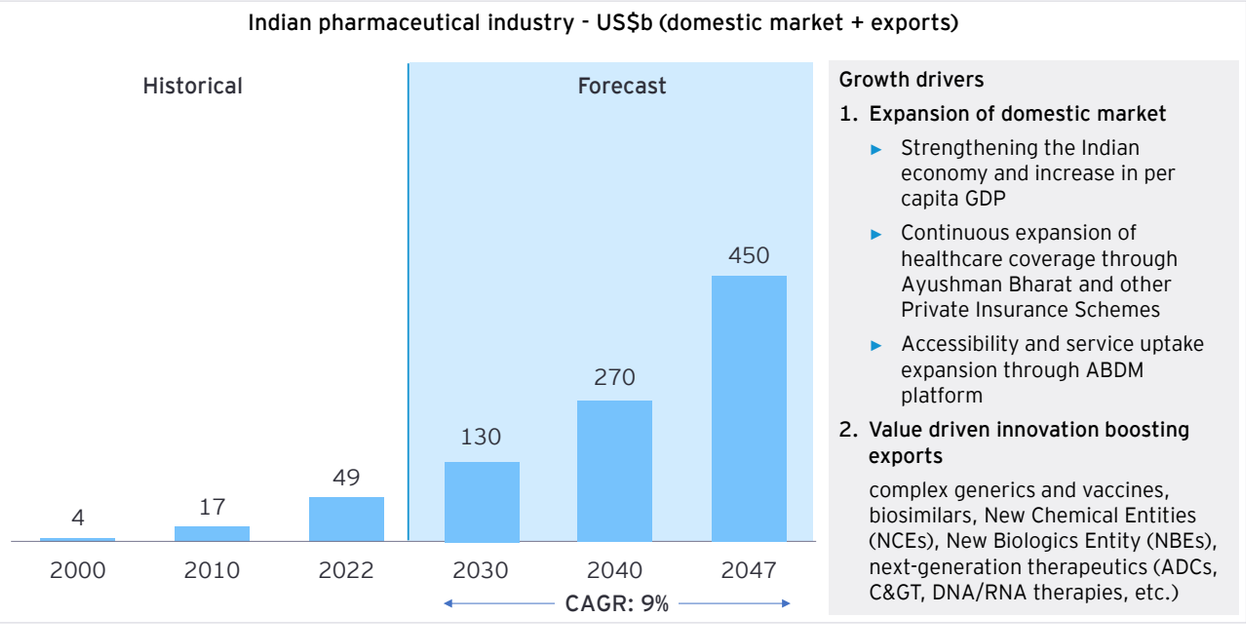
India@100: pharma and healthcare ambitions

- The pharma industry is driven by an ambition to achieve US$450 billion market.
- The healthcare sector should aspire to achieve a ‘DALY rate of 10,000’ and ‘out-of-pocket expenditure of 10%’.

Unleashing Indian pharma's value-driven research and innovation potential

Unleashing Indian pharma's value-driven research and innovation potential

Roadmap to become the innovation powerhouse of the world by 2047



#The above analysis does not include Global Capability Centers (GCCs) and Contract Research Development and Manufacturing Outsourcing organizations (CRDMOs)

NCEs: New Chemical Entities; NBEs: New Biologics Entities; ADCs: Antibody-drug conjugates; C&GT: Cell & Gene Therapies

Sources: EY analysis, EY FICCI report, India pharma industry 2022, Policy Circle

The Indian pharmaceutical industry has grown from strength to strength in the last few decades. Increase in coverage by PMJAY insurance, low cost of healthcare delivery enabled by ABDM, and overall macroeconomic growth and rise in per capita productivity will further improve access. Consequently, there will be an expansion and increase in consumption of health care services.

With this favorable momentum, the Indian pharmaceutical industry has the potential not only to meet expectations but to transcend with a deliberate emphasis on strategic investments and value-driven transformative innovation.

Country's key strengths – manufacturing prowess, low costs, skilled workforce – have enabled India to become the pharmacy of the world. According to reports published recently, the Indian pharma industry has the potential and bold ambition of achieving the target of US$130 billion by 2030 and US$450 billion by 2047[21]. With the transformation of the domestic market driven by initiatives such as the ABDM and digital native systems that reduce cost of delivery and enable access to millions currently not in the treatment pool, and value driven innovation which will boost exports, this goal has the potential to be surpassed. However, the speed of reforms and how these two levers play out will determine the progress in the Amrit Kaal period.

[21] Pharma industry: R&D efforts to boost India's global standing | Policy Circle

Research and development: Indian pharma journey and current focus

For last over two decades, research and development (R&D) in generics has been the traditional focus area for most India-based pharma companies. Our country has established itself as the leader in the generics space. It constitutes ~20% of the global generics supply by volume[22], and continues to dominate with ~48% of all ANDA approvals in 2022[23].

As the competition and pricing challenges in the generics market continue to grow, some Indian companies have started venturing into the lesser crowded complex generics space. Biosimilars are also increasingly becoming a focal point for India. With ~98 biosimilars approved in the country (as of Sep 2019)[24], India holds the highest number of domestic biosimilar approvals across all regions. However, only a handful of Indian companies have managed to successfully enter the US and Europe. Biocon's acquisition of Viatris in 2022 for US$3.3 billion[25] will help the company in expanding its presence significantly in the global biosimilars markets.

Continued endeavors are underway in the realms of new chemical entities (NCEs) and new biological entities (NBEs). In 2013, Zydus became the first Indian company to launch an indigenously developed NCE, Lipaglyn (saroglitazar)[26]. In 2021, Alembic Pharma's associate Rhizen received US Food and Drug Administration (FDA) approval for first NCE discovered by Indian scientists[27]. Biocon was the first company to launch indigenously developed novel biologics in India. The company launched BIOMab EGFR for head and neck cancer treatment in 2006[28], and Alzumab (itolizumab) for psoriasis treatment in 2013. Both these novel monoclonal antibodies have been launched in several countries in collaboration with global companies.

Now, if we look at the global pharma industry, biologics entered the market ~45 years back. The industry is moving swiftly toward next-generation therapies that are predicted to drive the next wave of growth. During the span of last six years (2015-2021), cell and gene therapies (C&GT) and DNA/ RNA therapies have seen a growth of 30% and 46%, respectively[29].

Evolution of pharma industry: small molecules to next-generation therapeutics

	Small molecules (1950s)	Biologics and targeted therapies (1980s)	Next-gen therapeutics (new modalities) (2000s) Cell and gene therapies (CGTs)	(2015+) Antibody-drug conjugates (ADCs)	(2020+) DNA & RNA based therapies (mRNA, RNAi)
Global trends	▸ Constitute ~50% of global pharma sales[1] ▸ High competition and pricing challenges could limit potential value growth	▸ Biologics constitute only ~2% of total prescriptions in the US market, however, they account for ~40% of total drug spending in the country[2]	Maximum potential for driving future value sales ▸ New modalities expected be a key driver of value growth for the biopharma industry over the next decade. ▸ In 2023, four of the six top-selling biopharma products are based on new modalities. In 2028, that will be true for all top six products[3]		
India trends	▸ Largest generics provider globally (20% share in global generics supply by volume) ▸ Exploring opportunities in the complex generics sector and new chemical entity (NCE) development	▸ Highest number of domestic biosimilar approvals (~98) across all regions; however, global reach is currently limited ▸ Exploring opportunities in the new biologics entity (NBE) development	**India is at a nascent stage in the next-gen therapeutics space** ▸ First indigenously developed CAR-T therapy got Central Drugs Standard Control Organisation (CDSCO) approval in India in Oct 2023[4] ▸ Efforts to develop gene therapy are now also in progress		

Sources: 1. Torreya – Pharma 1000 (2021), 2. FDA statement, 3. Global Data

[22] Invest India website

[23] Express Pharma

[24] Knowledge Paper (birac.nic.in)

[25] Biocon Biologics Completes Acquisition of Viatris' Global Biosimilars Business - Biocon

[26] The first approved agent in the Glitazar's Class: Saroglitazar

[27] First new chemical entity discovered by Indian scientists gets USFDA approval - BusinessToday

[28] Nimotuzumab - Biocon

[29] The Pharma 1000 - Torreya 2021

With the evolving global innovation landscape and country's ambition for 2047, the next frontier for India is to focus on transformative innovation.

In Oct 2023, the Central Drugs Standard Control Organization (CDSCO) approved India's first indigenously developed CAR-T cell therapy, NexCAR19. The drug from ImmunoACT has shown an excellent safety and efficacy profile. It is also expected to bring down the cost of treatment by more than 10 times. CAR-T cell therapy costs around US$400K or over INR3.3 crore per patient in the US[30]. NexCAR19 therapy will be accessible at 20 Indian government and private hospitals treating cancer across major cities at around INR30 to INR35 lakh per patient[31]. Efforts to develop gene therapy are now also in progress[32].

This success is a brilliant example of collaboration between academia, hospital, pharma[33]:

- IIT-Bombay designed and developed the drug
- Tata Memorial Hospital conducted clinical investigations and translational studies
- Laurus Labs has been the early-stage backer of ImmunoACT; invested over US$18 million to support R&D and commercialization efforts

Immuneel, a clinical stage cell and gene therapy start-up working on CAR-T therapy for cancer, has completed phase 2 clinical trial in India for its first product, which is under regulatory approval. The company was founded in Dec 2018 by the chairperson of leading Indian Pharma company Biocon, managing partner of Boston-based 5AM Ventures, and Pulitzer Prize-winning US-based cancer physician and researcher[34] (more details in the next section).

This is a big step ahead for India in the right direction. The need is now to increase the overall pace and scale of innovation. Most new modalities are available at very high prices globally. The increasing pricing pressures and new pricing regulations are coming up across all regions. With its dual strength of 'quality with affordability', India has the potential to become the next bright spot in the 'next generation therapeutics space', and potentially emerge as a frontrunner similar to how it became generics leader of the world.

As numerous Indian companies embark on their journeys into the realms of ADCs, DNA and RNA-based vaccines and therapies, and cell and gene therapy, India is poised to undergo a transformative shift, progressing toward its Discovery 1.0 phase.

The industry aligns with the need to shift from incremental innovation to transformative innovation, and that too at a fast pace

"While we are the third largest by volume, we continue to be 14th by value. We must transform into a research-driven nation with a focus on innovation - that is the path to sustainable growth now."
Chief Quality Officer, leading Indian pharma company

"While we have excelled in the generics sector, we have yet to fully tap into our innovation potential. Moreover, we are not advancing at the pace necessary to keep up with current demands."
VP & Head, Pharma Technology Center, leading Indian pharma company

"Defining true innovation is important. True innovation entails the entire journey, commencing with the discovery of a molecule through fundamental research and culminating in its global reach. It is imperative to shift our focus away from the periphery of innovation to the heart of the innovation."
Managing Director, India, of a leading global pharma company

"Innovation primarily means the ability to bring out medicines, which are new or first-in-class and serve unmet medical needs."
Managing Director, India, of a leading global pharma company

[30] CAR-T Therapies Cost Prohibitive for Diffuse Large B-Cell Lymphoma Treatment (managedhealthcareexecutive.com)

[31] Cancer treatment breakthrough: India's homegrown CAR-T cell therapy, a form of immunotherapy, gets market authorisation (downtoearth.org.in)

[32] Made-in-india Car-t Cells 'safe', Have Low Toxicity: Clinical Trial | Mumbai News - Times of India (indiatimes.com)

[33] CDSCO approves ImmunoACT's CAR-T cell therapy - The Hindu

[34] Primary research

Way forward: focusing on transformative research and innovation to achieve growth ambition

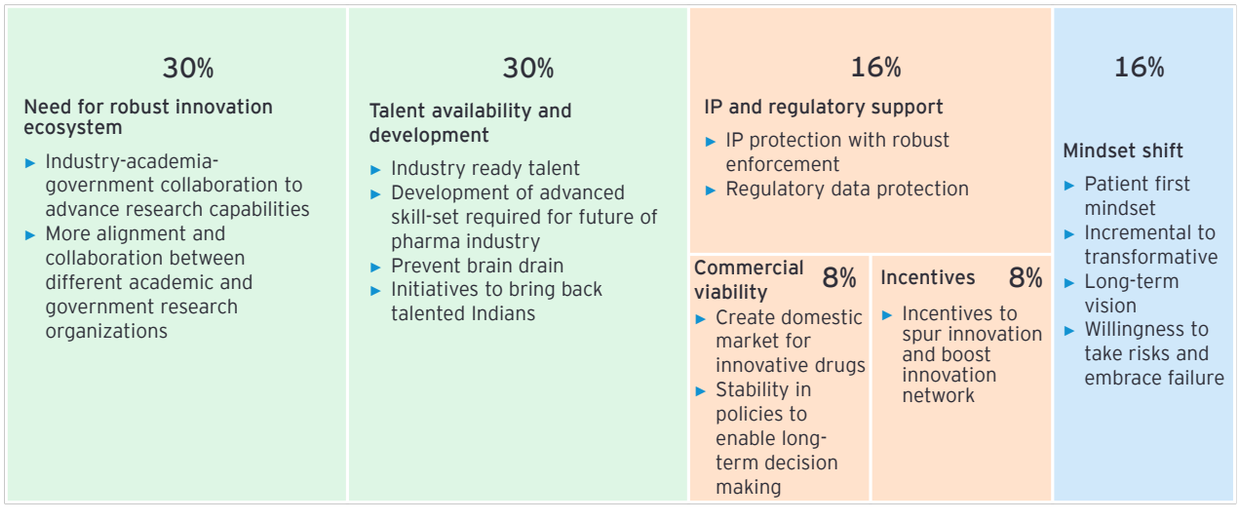
While novel drug development promises high returns, it also requires a high investment of time and resources. In the OPPI-EY CXO survey, the need for substantial investments over an extended gestation period, coupled with high risk of failure, emerged as the foremost barriers impeding the industry's advancement in the realm of innovation.

In order to advance further, the majority of leaders stressed the necessity of strengthening the innovation ecosystem and nurturing talent. They also emphasized the necessity of a mindset shift toward innovation within pharmaceutical companies.

Government support in the form of incentives, robust intellectual property protection, and a thriving domestic market for innovative drugs were underscored as pivotal factors. These elements play a crucial role in providing the necessary impetus during the initial stages, gradually paving the way for a self-sustaining ecosystem.

> *We need a strong innovation ecosystem and infrastructure. India has abundant talent, and with the establishment of an enabling ecosystem, we have the potential to even attract the Indian diaspora to return to our country.*
>
> **Chief Quality Officer**
> leading Indian CRDMO company

CXO survey results: research and innovation enablers for value-driven innovation



It is crucial to have a robust Intellectual Property protection policy. Equally important is ensuring rigorous enforcement and timely patent issuance.

Country Division Head and Managing Director, India
leading global pharma company

During COVID-19, India had the mindset to deliver the vaccines to the entire population – we innovated, we delivered. We have to have a similar mindset for transformative innovation. We have to innovate new drugs for the patients who need the therapy. That mindset can help India move up the value chain.

Executive Vice President
Clinical Logistics & Safety Services, leading Clinical Research Organisation

Much of the progress in China can be attributed to government support and innovation-focused subsidies. Over time, this enables the industry to become self-sustaining.

Chief Technical Officer
leading Indian pharma company

We need to have a short-term and a long-term vision to become the global innovation hub.

Executive Vice President
Clinical Logistics & Safety Services, leading Clinical Research Organization

Need for Intellectual Property and Regulatory Data protection

India needs to establish a comprehensive regulatory data protection framework and bolster the IP environment and enforcement. This will have a profound positive impact on India's innovation ecosystem and enhance patients' access to cutting-edge treatments by stimulating, for example:

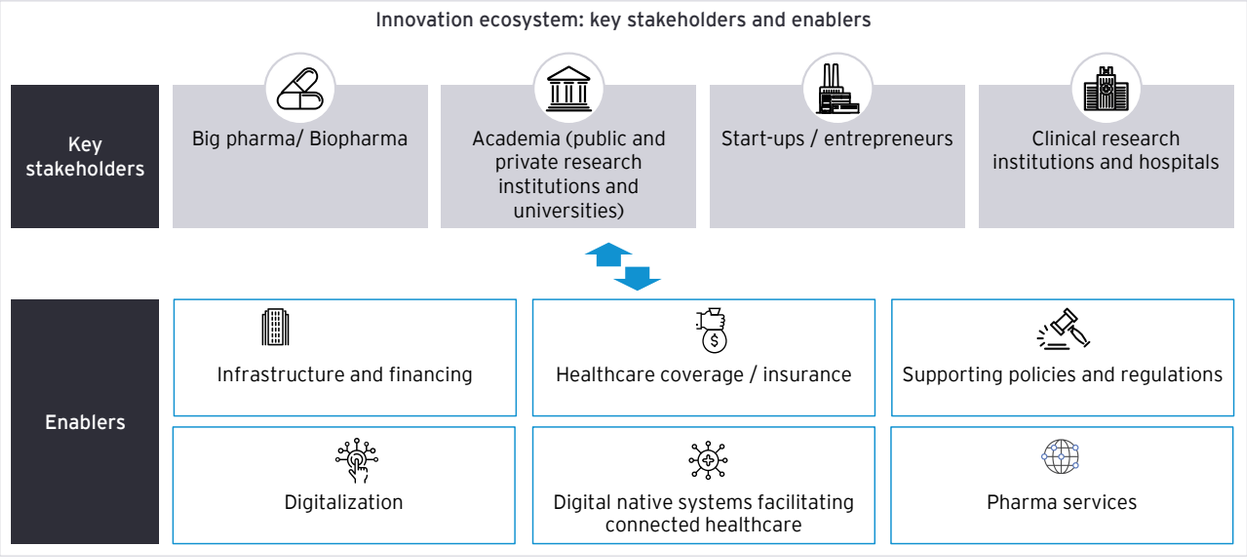
- the introduction of globally available innovative drugs and devices into the Indian market.
- increased research and manufacturing collaborations within the pharmaceutical industry, encompassing both domestic and global players.
- the conduct of more clinical trials in the country, given the significant disease burden and patient diversity. This will improve access to new therapies for the patients.
- the growth of the global capability centers established by the global pharma companies in India
- the confidence of Indian innovators and investors to undertake bold initiatives and invest their time and resources on disruptive innovation.

"We can continue to do incremental innovation, such as process innovation, manufacturing innovation. But to drive true innovation, like the western world is doing, we need equally conducive Intellectual Patent protection regime and regulatory data protection."
Managing Director, India, of a leading global pharma company

"To encourage global companies to invest in the development of new medicines in India, it is imperative that we establish robust intellectual property (IP) protection and implement supportive policies concerning compulsory licensing. Another promising avenue is clinical trials. With a conducive environment, India has the potential to emerge as the central hub for clinical trials. This significant shift can greatly enhance patients' access to innovative medicines and lead to improved health outcomes."
Executive Director, Patient Access Advocacy Group, India

Establishing a robust innovation ecosystem

Pharmaceutical research and innovation necessitate collaborative efforts of several stakeholder groups, including big pharma/biopharma, start-ups and biotechs, academia, and clinical researchers. This ecosystem also requires growth enablers, including financing, infrastructure, and supporting policies and regulations.



Massachusetts Life Sciences innovation ecosystem is an excellent example of the power of investment in innovation ecosystem driving collaborative partnerships between government, academia, hospitals, and the private sector. The ecosystem contributes to significant healthcare and economic impact in the country.

In India, Telangana hosts one of the most extensive life sciences innovation ecosystems in the country. The state is equipped with several organizations dedicated to enabling and fostering innovation, including Technology Hub (T-Hub), Research and Innovation Circle of Hyderabad (RICH), Telangana State Innovation Cell (TSIC), Cybersecurity CoE, and more. It provides infrastructure and resources through Genome Valley, Biopharma Hub (B-hub), Pharma City, research and development institutes. The state's universities and colleges are sources of talent, complemented by the Telangana Academy for Skill and Knowledge (TASK). Furthermore, the state offers supportive polices and incentives[35].

These efforts have culminated in increased investments in the state. For instance, during the WEF Davos event in January 2023, the state attracted a noteworthy INR21,000 crores in investments[36]. The state will also host the World Economic Forum's (WEF) first life sciences and healthcare Centre for Fourth Industrial Revolution (C4IR) in India. C4IR Telangana will become the 18th center to join the WEF's Fourth Industrial Revolution (4IR) Network, spanning four continents. This center's mission is to facilitate, advance, and expedite the development and adoption of technologies in genomics, personalized medicine, and healthcare manufacturing. It places particular emphasis on the intersection of life sciences and technology, both within the region and globally[37].

With its four pillars of strength, the state aspires to witness the growth of a US$250 billion life sciences ecosystem by 2030, a significant leap from the US$80 billion in 2022. These pillars include[38]:

1) Enabling complex manufacturing at scale.
2) Focusing on research and development and fostering innovation.
3) Establishing high-end, cross-value chain global capability centers (GCCs).
4) Promoting the convergence of healthcare and technology.

[35] Telangana Life Sciences

[36] Telangana secures Rs 21,000 crore worth of investments during World Economic Forum in Davos - The Economic Times (indiatimes.com)

[37] World Economic Forum's Centre for Fourth Industrial Revolution in Hyderabad-Telangana Today

[38] Telangana pursuing multi-pronged strategy to accelerate Life Sciences industry growth - The Hindu

Telangana life sciences ecosystem

Innovation clusters

Genome Valley

Largest Life Sciences manufacturing cluster and innovation hotspot for R&D in India

- >2.5 mn sq. ft. of multi-tenanted laboratory facilities
- Houses >200 companies (global and Indian MNCs, incubation centers, CROs, vaccine manufacturers)
- Scientific workforce of ~15,000 professionals
- **Biopharma Hub (B-Hub):** end-to-end biopharma scaleup manufacturing facility lab space

Hyderabad pharma city

- Environmentally cleared integrated pharma cluster
- Pharma vendor and supplier ecosystem, including chemicals, solvents, industrial equipment, reactors, vessels, glass coating / lining, heat exchangers, packaging, etc.

Research and development institutes

- Top R&D institutions (Indian Institute of Chemical Technology, Institute of Life Sciences, Center for Stem Cell Sciences)

Talent (in the state)

Academia

- Rated among the top 5 locations for R&D/ Product Engineering Talent in India
- Three central universities, 17 state universities, 4,500+ engineering colleges, 350+ Pharmacy Colleges, 23 polytechnics, and 280 industrial training institutes
- >250,000 students in various graduation programs

Telangana Academy for Skill and Knowledge (TASK)

110+ programs offered

- 3,00,000+ students have been trained
- 2,50,000+ students graduated in various programs
- 80+ industry partnerships
- >17,000 skilled faculty

Investment incentives and support

- Time bound clearances within 15 to 30 days for approvals
- 50-75% reimbursement of State Goods and Services Tax for a period of seven years from commercial production
- 100% skilling / training costs borne by the government
- 50% Subsidy on the expenses incurred for quality certification/ patent registration
- Mega investors of greater than INR200 Crore (US$35m) get Special Policies/ Incentives
- INR one/unit power subsidy for a period of five years from commencement of commercial production
- 25% subsidy on specific cleaner production measures

C4IR WEF- Telangana: The Centre for Fourth Industrial Revolution Telangana (Feb 2023)

- Will facilitate, advance and accelerate development and adoption of newer technologies, including genomics, personalized medicine and healthcare manufacturing, with a focus on the interplay between life sciences and technology

Ecosystem enablers

T-Hub: innovation and business incubator hub - provides facility and investment

RICH: connects research institutions and academia with industry bodies and investors

TSIC: fosters an inclusive innovation ecosystem with state-as-a-whole-approach

Cybersecurity CoE: acts as a nerve centre to protect, uplift and build a strong Cybersecurity and Privacy ecosystem

Collaborative innovation ecosystem

Only state in the world with **214+ USFDA approved facilities**

20+ life sciences and Medtech incubators

Home to **four of the top 10 global pharmaceutical** companies

Accounts for **1/3rd** of global vaccine output and **~40%** of India's pharma production

Home to **~1,000+ pharma and biotech companies** with a **valuation of US$50 billion**

>US$3 billion investment in Life Sciences (since 2015)

Created >4.5 lakh jobs

Source: Telangana Life Sciences website (as of Oct'23); available at: https://lifesciences.telangana.gov.in/

Numerous state governments, including those of Karnataka and Tamil Nadu, among others, are formulating policies to facilitate integrated planning and strategic investments in the most pertinent areas. These dynamic ecosystems are attracting significant investments, nurturing collaborative opportunities within the ecosystem, and establishing a solid foundation for the development of entrepreneurs and the enhancement of skillsets.

National policy on Research and Development and Innovation in Pharma-MedTech sector

In Sep'23, the government launched the 'National Policy on Research and Development and Innovation in Pharma-MedTech Sector' in India and 'Scheme for promotion of Research and Innovation in Pharma MedTech Sector (PRIP)[39]'. The policy will help 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. It will also build synergies between various government institutions and agencies such as Pharma Department, Indian Council of Medical Research (ICMR), Department of Science and Technology (DST), Department of Biotechnology (DBT), National Institute of Pharmaceutical Education and Research (NIPER), etc. Three key focus areas include:

- Creating a regulatory environment that facilitates innovation and research in product development, expanding the traditional regulatory objectives of safety and quality.
- Incentivizing private and public investment in innovation through a mix of fiscal and non-fiscal measures
- Building an enabling ecosystem designed to support innovation and cross-sectoral research as a strong institutional foundation for sustainable growth in the sector.

Research linked incentive scheme for Pharma and MedTech sector

- Total Outlay of INR5,000 crore[40] over a period of five years (2023-24 to 2027-28)
- Component A: Setting up of Centres of Excellence at National Institute of Pharmaceutical Education & Research (NIPERs) (7 Institutes, INR700 Crore)
- Component B: Funding which is to be paid back later as royalty percentage on net sales after commercialization
  - Funding pharma research for companies that work in collaboration with government institutes (9 projects, INR1,125 Crore)
  - Funding projects with high commercial or societal value (30 projects, INR3,000 Crore)
  - Research in priority areas (125 projects, INR125 Crore)
    - NCE/ NBE / Phyto-pharmaceuticals
    - Complex generics including biosimilars
    - Precision medicine
    - Medical devices
    - Orphan drugs
    - Anti-microbial resistance

[39] Press Information Bureau (pib.gov.in)

[40] Centre rolls out Rs 5,000 crore RLI scheme for pharma, med-tech sectors (business-standard.com)

Roles of all stakeholders in the ecosystem

Large pharma/biopharma companies: growing emphasis on innovation driven by collaboration

The big pharma /biopharma companies play a pivotal role not only in drug research and development but also in unlocking the innovation potential originating from academia or start-ups and translating it into market reality. These firms bear the responsibility of advancing R&D through the promotion of both internal innovation (within their organizations) and external innovation (R&D projects in partnerships, funding external research projects, etc.). Pfizer and IIT Delhi Innovation and IP Program (PIIIP) and INDovation are good examples of company initiatives to boost the ecosystem[41].

Pfizer supporting healthcare innovations in India, for India and the World

Industry-Academia partnership for start-ups (support on commercialization and market access)

Phase I

PFIZER-IIT Delhi Innovation and IP Program (PIIIP)
Inception in 2015

- Collaboration with Foundation for Innovation and Technology Transfer (FITT) at IIT Delhi
- Funding: upto INR50 lakh for each innovator
- Incubation and IP support
  - physical infrastructure at the Biotechnology Business Incubator prototyping laboratory
  - funding support to take ideas to proof of concept/product prototyping and IP stage
  - opportunities to engage with venture capitalists and industry to take innovations into commercialization
  - mentoring support from IIT Delhi faculty and experts
  - mentoring support from Pfizer colleagues in India and US
- Focus areas: novel healthcare solutions with potential to prevent, diagnose or treat patients in India and across

Impact

- Incubated 34 healthcare innovators and supported 19 IP filings since inception in areas such as diagnostic innovations, drug delivery platforms, medical devices, medical simulation, and training of healthcare workers

Incubation accelerator initiative is in line with the government's priority of 'Start up India, Stand up India'

Industry-Academia-Government partnership

Phase II

INDovation Program
Inception in 2022

- Pan-India incubation support across IITs and other technology institutes in India
- Selected start-ups receive:
  - INR65 lakh each
  - support across product development, clinical validation and trials, regulatory pathways, funding, and product market launch
- Focus areas: Oncology and digital health (due to the increasing burden of cancer in India coupled with late intervention, which can be tackled by digital health solutions).

Collaboration with institutions

Atal Innovation Mission (AIM), NITI Aayog, Social Alpha, FITT, IIT-Delhi, AGNIi, UN Health Innovation Exchange (UNHIEX), PATH, Association of Healthcare Providers (AHPI), St Johns Research Institute, HCG Hospitals, Cytecare Hospitals, FICCI, Google for Startups, Design Alpha, Healthcare Information and Management Systems Society (HIMSS), Marico Innovation Foundation, and TenX2

INDovation supports healthcare innovations by start-ups in India, for India and the world.

Sources: Company reports

Academia: setting foundation of strong talent pool and research base

Academia provides the foundation for building the entire research and innovation pyramid in any country. Academia is the source of most critical resources for innovation: talent and basic research. To foster innovation spirit, topics on entrepreneurship and innovation mindset should be integrated in the curricula. Students should be encouraged to address significant unmet needs that demand innovation, rather than solely concentrating on degree completion.

Industry-academia collaboration is paramount for nurturing talent equipped with the skill set to address the current industry demands and prepare them for the innovation-driven future of the pharmaceutical sector. Global Capability Centers (GCCs) also make substantial contributions to the country's innovation ecosystem by fostering talent and skill development throughout the value chain, especially in intricate and strategic domains.

[41] INDovation: Healthcare innovations made in India | Pfizer India

Global capability centers: A testimony of India becoming a backbone to global pharma and a driver of India GDP

India continues to be the destination of choice for setting up a global capability center (GCC) because of the availability of quality talent in the country. In FY23, India had over 1,580 GCCs with more than 1.66 million employees, and generated over US$46 billion in revenue[42]. In addition to employment generation and economy boost, GCCs also contribute significantly to talent development.

Several leading global pharmaceutical companies have established their global capability centers in India, employing nearly half a million professionals[43]. Within these GCCs, Indian talent is engaged in a wide array of functions, spanning the complete R&D value chain, drug commercialization, manufacturing and supply chain, physician and patient engagement, business strategy, and digital operations. This has cultivated a rich talent pool in India, ready to contribute to the Indian pharmaceutical industry's transition into the innovative drug sector. Additionally, GCCs play a significant role in bolstering the country's innovation ecosystem, e.g., AstraZeneca GCC collaboration with Academia (Sastra university)[44] and NovoNordisk GCC collaboration with International Institute of Information Technology (IIIT) Bangalore and Manipal University for Higher Education (MAHE) to explore breakthrough innovations and efficiency gains across the pharma value chain and its application in the healthcare ecosystem[45].

Pharma GCCs: capabilities across the pharma value chain

Company	Drug development	Clinical research and trials	Manufacturing	Commercial operations	Post market surveillance	Data and digital capabilities
Novartis	■	■	■	■	■	
AstraZeneca		■	■	■	■	
Novo Nordisk		■	■	■	■	
Sanofi	■		■	■	■	
Merck	■		■	■	■	
Bayer	■	■	■			
Bristol Myers Squibb	■	■		■		
Pfizer	■	■	■			
Ferring		■	■	■		
GSK	■	■				
Roche		■				

Most of the GCCs have been awarded as "Top employers in India" and/ or "Best place to work in India" over the years

Interesting facts / key highlights

Roche Global Analytics and Technology Centre of Excellence (GATE)

Capabilities to create lean and scalable solutions: **aim to provide 2x benefit at half the cost to the healthcare system**

Bayer >60% of the healthcare products are manufactured in India

Local manufacturing partnerships for **production and entrepreneurship** in line with the government's Make in India plan

Bristol Myers Squibb

Establishing a state of-the-art site to expand its global drug development, digital innovation, and technology capabilities

AstraZeneca **Rebranded 'Global Technology Center' to 'Global Innovation and Technology Center (GITC)**

50% of global IT staff located in India; supports 50+ brands globally

Manufacturing and supply chain operations

Capabilities include predictive maintenance, designing and building smart factories, creating technology stack for future lights-out factories, predicting quality defects in production batches, developing technologies to manage operations remotely

Sources: EY analysis, primary research

[42] GCC 4.0 | INDIA REDEFINING THE GLOBALIZATION BLUEPRINT | nasscom

[43] Primary research

[44] AstraZeneca tieup with SASTRA University

[45] Novo Nordisk, IIIT Bangalore collaborate to drive industry-academia research opportunities and skill development - Education News | The Financial Express

Global capability centers building technical capabilities and future skill-set

AstraZeneca

Key capabilities across pharma value chain

Drug discovery

Global Innovation and Technology Centre (GITC, 2014)
- Simulations using digital twin technology for human cell modelling
- AI to shortlist drug candidates

Global Medicines Development – R&D (2017)
- Supports scientific capabilities such as medical chemistry, biometrics, clinical science

Clinical research/trials

Development Operations Office (2019)
- Clinical trial experts focused on core therapeutic areas (oncology, cardiovascular, renal and metabolism and respiratory)
- Data and evidence generation

Clinical Data and Insights division (2021)
- Clinical programs with an integrated end-to-end approach for clinical data, analytics, insights and risk management

Commercial operations

Global Innovation and Technology Centre (GITC, 2014)
- Global Experience Center (extended reality): visualization for patients on what to expect in clinical trial, or for physicians on how drug actually interacts or works within the body

Global Medicines Development – R&D (2017)
- Manage regulatory responses and health authority queries

Global commercial operations (GCO) under Global business services (2017)
- End-to-end commercial content management, marketing analytics, and reporting

Post market surveillance

Global Medicines Development – R&D (2017)
- Post-marketing safety surveillance
- Safety reporting, license renewals
- Patient risk management strategies, Post-Authorization Safety Studies (PASS), Environmental and Social Risk (ESR) studies

Data and digital capabilities

Global Innovation and Technology Centre (GITC, 2014)
- Supports global IT and digital innovation operations
- Visualisation, Data & Analytics, Hyperautomation, XR/VR – core capabilities

Key facts

>50% of company's global IT staff located in the GITC in India

The Global Medicines Development – R&D supports **>50** global brands

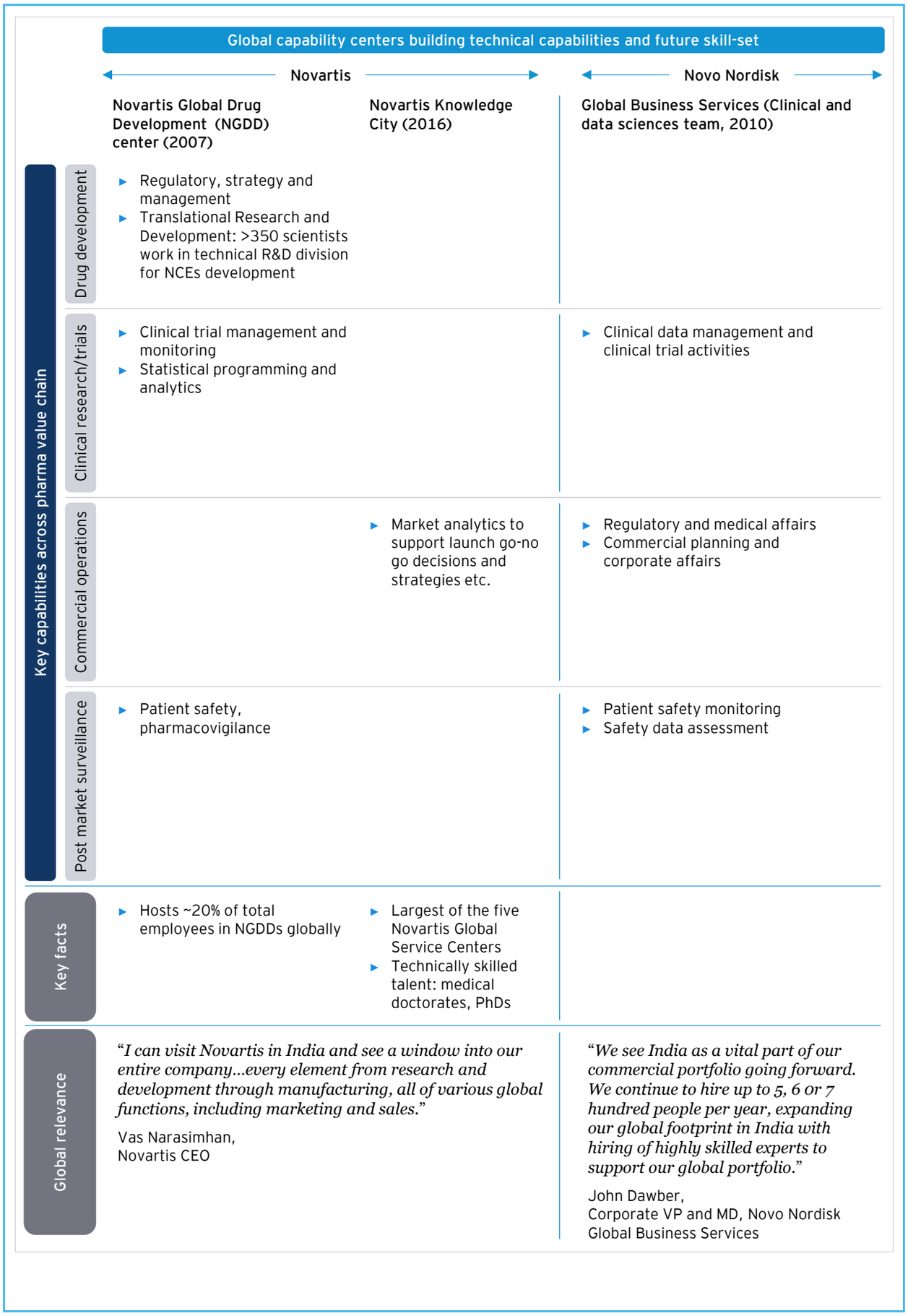
Global relevance

"*Role of GCCs in the overall growth of the parent organisation is witnessing a shift. Over the last decade, GCCs in India are undertaking more strategic and transformative work critical to the success of the organisation. Since its inception, our centers in India have supported the global organisation with various services spanning IT, Business Services and R&D.*"

Siva Padmanabhan,
Managing Director, AstraZeneca India Private Limited

"*Clinical data and insight solutions enable pharmaceutical organisations such as ours to gain in-depth visibility into the patient's journey by extracting actionable insights from disparate data sources.*"

Natalie Fishburn,
VP, Global Head of Clinical Data & Insights, AstraZeneca


Global capability centers building technical capabilities and future skill-set
Novartis
Novo Nordisk
Novartis Global Drug Development (NGDD) center (2007)
Novartis Knowledge City (2016)
Global Business Services (Clinical and data sciences team, 2010)
Key capabilities across pharma value chain
Drug development
Regulatory, strategy and management
Translational Research and Development: >350 scientists work in technical R&D division for NCEs development
Clinical research/trials
Clinical trial management and monitoring
Statistical programming and analytics
Clinical data management and clinical trial activities
Commercial operations
Market analytics to support launch go-no go decisions and strategies etc.
Regulatory and medical affairs
Commercial planning and corporate affairs
Post market surveillance
Patient safety, pharmacovigilance
Patient safety monitoring
Safety data assessment
Key facts
Hosts ~20% of total employees in NGDDs globally
Largest of the five Novartis Global Service Centers
Technically skilled talent: medical doctorates, PhDs
Global relevance
"I can visit Novartis in India and see a window into our entire company...every element from research and development through manufacturing, all of various global functions, including marketing and sales."
Vas Narasimhan, Novartis CEO
"We see India as a vital part of our commercial portfolio going forward. We continue to hire up to 5, 6 or 7 hundred people per year, expanding our global footprint in India with hiring of highly skilled experts to support our global portfolio."
John Dawber, Corporate VP and MD, Novo Nordisk Global Business Services

With increased government focus and support, GCCs hold the potential to evolve into a substantial growth opportunity for the Indian economy, a promising avenue for employment for the nation's young talent, and a significant contributor to the reinforcement of the innovation ecosystem.

It is important to understand different areas where India can contribute potentially to the global innovation ecosystem. When considering R&D, we often focus on physical infrastructure, but a significant portion of investments in India are allocated to conducting clinical trials. Here, India can play a crucial role by establishing more centers that are well-versed in the globalized approach to clinical trials, data integrity, and related aspects.

Chief Quality Officer
leading Indian CRDMO company

Our GCC in India covers a wide spectrum of activities across the entire value chain. Here are some examples of the types of activities we engage in:

- *Research and development: we specialize in advanced clinical trial data analytics, managing safety events, preparing final submissions to regulatory bodies like the FDA, developing AI algorithms for drug discovery, conducting genomic analysis, and running simulations using digital twin technology for human cell modeling*
- *Manufacturing and supply chain operations: our capabilities include predictive maintenance, designing and building smart factories, creating technology stack for future lights-out factories, predicting quality defects in production batches, developing technologies to manage operations remotely.*
- *Commercialization: we provide omni-channel activities, extended reality-based solutions for experiences for physicians (e.g., how drug works within the body), patients (e.g., what to expect in a clinical trial), medical reps (e.g., 'empathy app' to understand the life of a patient)*

VP, Global IT Enterprise Capabilities & Solutions, & Managing Director
global pharma company, India

Pharma GCCs are growing at a fast pace in India because of the strong talent in the country. Many large biopharma companies have established their centers here, employing ~50,000 individuals. With the government's support and conducive environment in terms of tax and IP protection policies, there is an immense potential for sustained growth and further expansion.

VP, Global IT Enterprise Capabilities & Solutions, & Managing Director
global pharma company, India

Start-ups: boosting the innovation momentum

Start-ups in India are working across a range of innovative solutions covering the entire patient life cycle and product (pharma/biopharma drug) value chain. Funding, infrastructure, and mentoring are crucial factors in supporting start-ups to realize ground-breaking innovations. Sustained nurturing from the ecosystem, which encompasses academia, pharmaceutical firms, and government support, can significantly accelerate the introduction of these innovations to the market – the recent approval of the first indigenously developed CAR-T drug is a very good example.

Novartis Biome[46] serves as a good illustration of a platform that effectively brings together start-ups, academia, and health innovators. This initiative has yielded the development of several good proof of concepts.

Industry collaboration with startups

Novartis Biome (Innovation hub for start-ups (2020)

Asia's first Novartis Digital innovation hub: one of the four Novartis Biomes
(other three Biomes in San Francisco, Paris, and London)

Aim of the Novartis India Biome:

- Scale up, complement and boost the connection and interaction between Novartis and partners from across the digital ecosystem (start-ups, academia, health innovators)
- Act as a bridge to the external ecosystem, enabling teams to better discover, develop and transform innovative initiatives into impactful and scalable solutions for patients.
- Provide innovators access to the assets and expertise of the broader global Novartis portfolio, including:
  - Access to anonymized data
  - Customized residency programs
  - Personalized mentoring

"Proof-of-Concept (PoC)" and engagement success stories*

In Silico – PharmaFlow
- Use of predictive data analytics/AI/ML to accelerate generic drug development and increase probability of success

Digital Logistics Hub – POC in progress
- A digital logistics hub to enable a seamless flow of information, always having visibility and control, enabling real time planning and execution
- Innovative and intuitive options to transform material sourcing process and achieve operations benefits–reduced cost, lower inventory, better flexibility and agility and improved service reliability.

*not exhaustive

Sources: Company reports

[46] Novartis launches Biome India, a digital innovation hub in Hyderabad; first in Asia | Novartis India

Clinical research institutions and hospitals: augmenting clinical research capabilities

Globally, medical teaching institutions serve as the major hubs of biomedical research. The physicians, with their expertise and the availability of large amount of patient data in the institutions, can make a significant difference in the quality of research outcomes.

India can enhance clinical research capabilities by strengthening research training, incentivizing high impact research activities, and allocating appropriate funds. This will motivate more students to pursue research as a profession and enable them to carry out high-quality research activities.

Collaborations with the industry additionally contribute significantly to the development of overall capabilities. For example, Roche has started a new program to strengthen the capabilities of public health institutions to do clinical trials and drug research as per global standards with focus on innovative treatment and patient safety[47].

Industry collaboration with clinical research institutions	
Roche	**Clinical trial excellence project (2023)**
	In the first phase, Roche aims to partner with 10 government hospitals. Solutions include training of the research team on: ▸ Process development or enhancement, ▸ Digitization of dossier submission and review by Ethics Committee
	**Project objective:** ▸ Strengthen the capabilities of public health institutions/ infrastructure to do clinical trials and drug research as per global standards ▸ Enable government hospitals to become the Centers of Excellence for Clinical Research and move up the value chain ▸ Enable centers to lead high-quality clinical research ▸ Enhance skills and capabilities of healthcare professionals

Sources: Company reports

The achievements of India's COVID vaccines and CAR-T therapy can be credited to the productive and efficient collaboration across the entire ecosystem. Looking ahead, this well-established ecosystem can serve as a launching pad for the comprehensive indigenous development of next generation therapies, from inception to commercialization.

Mission Covid Suraksha: vaccine innovation

DBT BIRAC collaboration with industry partners

Company	Vaccine	Innovation
Bharat Biotech	Covaxin	India's first indigenous viral vector vaccine against Covid-19*
Bharat Biotech	iNCOVACC	World's first and India's indigenously developed **intranasal COVID-19 Vaccine**
Gennova	GERMCOVAC-19	India's first indigenously developed mRNA vaccine
Biological E. Limited	CORBEVAX	India's first protein sub-unit vaccine
Zydus	ZyCov-D	World's first and India's indigenously developed DNA Vaccine

*DBT supported manufacturing expansion
Sources: Company reports, PIB.gov

[47] Roche Pharma launches clinical trial excellence project in India - Express Pharma

CAR-T developments in India

Interplay between innovation ecosystem for India's first indigenously developed CAR-T cell therapy

Incubation (Academia)	Financing		Infrastructure	Academia
Incubated under the Society for Innovation and Entrepreneurship at IIT-B	**Laurus Labs:** invested over US$18 million to support R&D and commercialization efforts	**National Biopharma Mission:** INR19 crore funding for conducting a first-in-human phase-I/II clinical trial	**Tata Memorial Hospital:** conducted clinical investigations and translational studies	**National Cancer Institute:** collaborated as a knowledge partner and established a short-term scientist exchange program

NexCAR19 (CD19-targeted CAR-T cell therapy): India's first indigenously developed CAR-T cell therapy available at 10 times less cost compared to the therapy cost in the US; received CDSCO approval in Oct'23

Sources: Company reports

Immuneel (CGT start-up): collaborations, activities, and achievements

Ecosystem collaborations

Founders	▸ Kiran Mazumdar-Shaw (founder and chairperson of Biocon) ▸ Dr. Kush Parmar (managing partner at Boston-based 5AM Ventures) ▸ Dr. Siddhartha Mukherjee (Pulitzer Prize-winning cancer physician and researcher)
Scientific board	▸ Carl June (credited with the development of T-cell therapy for CAR-T) ▸ Bruce Levine (conducted first in-human adoptive immunotherapy trials using CAR-T cells) ▸ Noopur Raje, translational researcher, and Director, Center for Multiple Myeloma)
Investors	Raised around US$28 million (as of Jul'2023) from: ▸ Hospital groups such as Manipal, Apollo, Narayana Health ▸ Venture capitalists: Eight Roads Ventures, True North Fund VI LLP and F-Prime Capital, Kotak, Khosla Ventures
Hospitals	Narayana Health Bengaluru, Apollo Chennai & PGI Chandigarh for multi-center clinical trials

Achievements

- India's first **integrated and hospital based state-of-the-art cell therapy R&D, quality testing and manufacturing facility, including vector facility**
- IMAGINE study, India's **first Phase 2 multicentre and first industry-sponsored** CAR-T cell therapy trial
- Widely accepted and **presented data from IMAGINE study across the globe** – ASH: American Society of Hematology; EHA: European Hematology Association; ISCT: International Society for Cell & Gene Therapy; SIOP: International Society of Paediatric Oncology, Cellicon Valley
- **Robust pipeline** with 2 clinical assets
- **Winner of multiple recognitions in India & globally** – 'Biopharma's Most Promising Startups 2023' at the Endpoints 11, 'Most Promising Cell & Gene Therapy Startup in APAC' at the Asia Pacific Cell & Gene Therapy Excellence Awards 2023 & 'Innovation in Cell and Gene Therapy' at BioPharma Honours 2023
- Company plans to **invest in digital technology** to improve operational efficiency including track and trace to have a high degree of control (important component of CAR-T therapy)
- The digital framework **will help bring all of the elements of clinical manufacturing data together into an analytical platform**

Sources: Company reports

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 costs and timelines, and improve patient access and diversity. Globally, numerous start-ups are emerging to offer R&D platforms and solutions, some of which have already achieved initial success. Given India's robust IT capabilities, the country has a substantial opportunity not only to lead in this domain, but also to catalyze the innovation journey of the Indian pharmaceutical industry.

Digital, data, and artificial intelligence use cases across R&D value chain

Drug discovery		Clinical development		
Target identification: ▸ Enhance and accelerate identification of new molecular targets (genes or proteins) ▸ Identify novel rare variants for complex diseases ▸ Predict safety/toxicity and efficacy of compounds to improve probability of success	**Drug development:** ▸ 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 to design novel drug candidates and predict the potency of molecules for selected targets ▸ Drug repurposing to identify new uses for clinical stage molecules	**Clinical trials (CT) design:** ▸ Reduction in the size of control arms ▸ CT companion tool to optimize, automate and add intelligence into design, planning, and costing process ▸ Identify novel biomarkers and endpoints to predict patient outcomes	**Recruitment:** ▸ Improve diversity in CT patient population ▸ Accelerate patient recruitment ▸ Better detection of patient populations to accelerate and de-risk treatment development	**CT management and monitoring:** ▸ Faster data review ▸ Predict/alert about safety and tolerability signals for early action and improving trial success rate ▸ Clinical supply chain planning optimization ▸ Improve patient experience and retention ▸ AI-powered facial and image recognition algorithms to monitor drug adherence
Data-driven decision making has the potential to transform drug discovery by increasing efficiency and productivity, improving regulatory compliance, and reducing failure rates, cycle time, and overall costs.		Clinical trials (CT) are one of the most expensive and time-consuming elements of the R&D value chain; CTs can be significantly optimized using digital tools and AI across the value chain, starting from trial design, patient recruitment, to management and monitoring.		

Source: EY analysis

Key highlights

Indian pharma industry India@100 ambition

- The industry aims to achieve US$130 billion by 2030 and US$450 billion by 2047. This growth trajectory will be propelled by:
  - Expansion within the domestic market, spurred by the nation's economic growth and the heightened adoption of healthcare services, largely influenced by government initiatives like Ayushman Bharat and Ayushman Bharat Digital Mission.
  - The industry's strategic pivot toward innovation of next generation therapeutics resulting in an increase in global exports.

Research and development focus

- Traditionally, Indian pharma companies have focused on generic drugs dominating the global generics market.
- Some companies have ventured into complex generics, biosimilars, NCEs, and NBEs.
- Globally, the pharma industry is moving swiftly toward next-generation therapies, such as cell and gene therapies (C&GT), ADCs, and DNA/RNA therapies.
- With its first CAR-T therapy approved by CDSCO in Oct'23 and the next one in pipeline, India is already moving in the right direction – the need is to now increase the pace and scale of these endeavors.

Priorities for Indian pharma to shift toward disruptive innovation - CXO survey findings

- Majority of leaders emphasized the imperative to fortify the innovation ecosystem and cultivate talent.
- Need for mindset shift toward innovation within pharma companies was also highlighted.
- Government support in the form of incentives, robust intellectual property protection, and a thriving domestic market for innovative drugs were underscored as pivotal factors.

Establishing a robust innovation ecosystem

- A strong innovation ecosystem requires collaboration between various stakeholders, including big pharma, academia, start-ups, and clinical researchers.
- Government support, financing, infrastructure, and policies are crucial for building this ecosystem.
- Recent CAR-T innovations, as well as COVID-19 vaccines, are a result of effective collaboration between the different ecosystem stakeholders.
- Telangana hosts one of the most extensive life sciences innovation ecosystems in the country. Similar other setups are emerging in a few other Indian states as well.
- Global Capability Centers (GCCs) also contribute significantly to the innovation system with the developing of talent and skillset across the value chain in highly complex and strategic areas.

Digital and data analytics potential across the 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.
- Given India's robust IT capabilities, the country has a substantial opportunity not only to lead in this domain but also to catalyze the innovation journey of the Indian pharmaceutical industry.

Becoming an integral part of the futuristic global pharma supply chain

Becoming an integral part of the futuristic global pharma supply chain

Manufacturing and end-to-end supply chain management are pivotal components within the pharmaceutical industry. In today's competitive landscape, success hinges on the meticulous management of manufacturing operations and supply chain costs to optimize cost-to-serve ratios and minimize inventory levels, all while upholding the highest service standards. In addition to these three challenging variables that need to be delicately balanced, supply chain and manufacturing leaders in pharmaceutical companies are tasked with the additional responsibilities of overseeing product quality, ensuring compliance with relevant regulatory frameworks, and upholding the safety of products, assets, and personnel.

India has created a formidable infrastructure for manufacturing finished dosage forms. It has the distinction of having the largest number of U.S. Food and Drug Administration (USFDA) compliant pharma plants (more than 600 as of Oct'22)[48] outside of the US and has more than 2,000 World Health Organisation Good Manufacturing Practice (WHO-GMP) approved pharma plants. Staggering 10,500 plus pharmaceutical manufacturing facilities cater to demand from more than 150 countries in the world[49].

Emerging industry trends demand effective manufacturing and supply chain strategy

Over the past few years, several emerging trends have gained prominence in the industry. These include the rising pressures of pricing and inflation, the digitization of operations to enhance efficiency and ensure precision and compliance, and an increased focus on Environmental, Social, and Governance (ESG) factors to establish sustainable supply chains. Furthermore, the transition toward personalized medicine and next generation therapeutics (including the demand for just-in-time deliveries in cell and gene therapies), and innovative healthcare delivery models directly to patients are all compounding the complexities within manufacturing and supply chain operations. These trends serve as crucial catalysts, necessitating a shift in priorities and much needed transformation of the manufacturing sector.

These evolving industry trends, along with the macroeconomic variables, and geopolitical changes, position India at the forefront of the "China+1" opportunity. During the survey, industry leaders highlighted the following three areas of focus for the Indian industry to be able to leverage these opportunities and become an integral part of the global pharma supply chain:

CXO survey: key priorities for manufacturing and supply chain function

1. Advancement of manufacturing technologies, with a specific focus on automation and digitalization
2. Building credibility in the global market with an unwavering commitment to quality
3. Adopting sustainable practices

[48] Fiscal Year 2022 Report on the State of Pharmaceutical Quality (fda.gov)

[49] Most small drug makers aren't WHO-GMP certified | Mint (livemint.com)

Contract research, development and manufacturing outsourcing organizations (CRDMOs)

Indian CDMOs have undergone a remarkable transformation, evolving from regional service providers to international leaders in pharmaceutical development and manufacturing. Their ability to offer cost-effective solutions, along with qualified and skilled scientists and researchers, has propelled them to the forefront of the industry. Adoption of new technologies, rigorously robust quality standards, and supply chain and regulatory expertise also provide a competitive edge to these firms. CRDMOs in India are investing in expanding capacities and extending capabilities to offer one-stop shop from "concept to commercialization" spanning from generics to complex formulations, biologics, and even next-gen modalities[50].

Contract research, development and manufacturing outsourcing organizations (CRDMOs)

Core competencies		Core competencies
Experienced partners from early discovery to commercial supply	**CRDMO offerings:** ► **End to end integrated services:** concept to commercialization ► **Entire portfolio coverage:** APIs, formulations, bio-therapeutics (e.g., ADCs, mAbs, mRNAs, CAR-Ts), etc.	Operational efficiencies due to scale and digital adoption (AI/ ML in drug discovery
Global regulatory alignment: compliance with global standards		The highest standards of QMS, Project Management
Qualified and trained talent: PhDs, international experience		Strong focus on ESG and Health, Safety and Environment (HSE) protocols

Source: EY analysis

Many of the top 10 pharmaceutical companies and numerous large biotech firms today outsource a portion of their preclinical and clinical research to India. Increasingly, segments of the global pharmaceutical industry are adopting asset-light models for managing their product life cycles. A significant portion of manufacturing is expected to shift toward Contract Development and Manufacturing Organizations (CDMOs). For example, Syngene's 10-year contract with Zoetis to manufacture biologics exemplifies this trend[51]. This is also fanned by interest of private equity firms in funding and establishing CDMO platforms with a global focus. A recent example is Advent International, which launched Cohance Lifesciences as a new brand identity for its API and CDMO platform in 2022[52]. In the same year, the firm also acquired Suven Pharma, a listed CDMO based in Hyderabad[53].

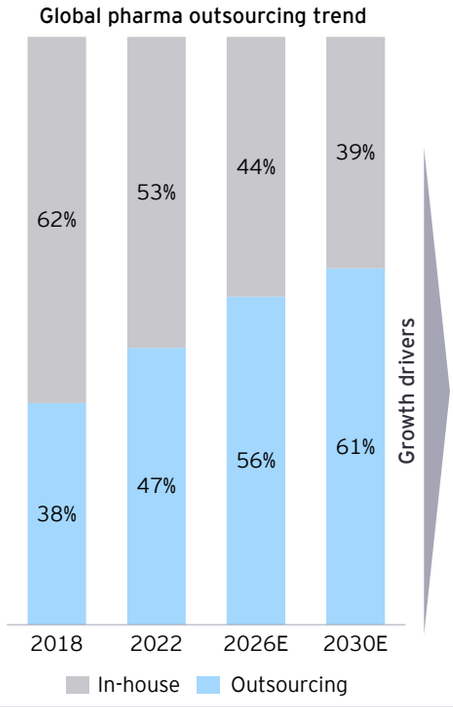
[50] Can partnerships with CRDMOs boost biosimilar manufacturing? - Pharma News | The Financial Express

[51] Press release_Zoetis_final_140722 (syngeneintl.com)

[52] Advent International launches Cohance Lifesciences, a new brand identity for its API platform - Advent International

[53] Suven: PE Advent completes acquisition of Suven Pharma, appoints new Board and management team - The Economic Times (indiatimes.com)

Outsourcing for drug research, development, and manufacturing is set to grow



Growth drivers

Focus on core competencies by pharma companies
Increasingly becoming marketing and sales organizations to maximize commercial potential of product and outsource services to CROs/CDMOs

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

Shorter time to market
Pharma companies aim to bring new drugs to market quickly, leading to parallel research work with multiple CROs

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

Integration of services by CROs and CDMOs
End-to-end solution makes the project management easier for pharma companies and provides them higher flexibility

Increasing share of complex projects
The complexity of new drugs (such as highly potent APIs (HPAPI)) is increasing and the shifting focus of research on reducing the failure rate

Sources: EY analysis, Frost and Sullivan research reports, secondary research and primary expert interactions

A multitude of prominent companies, including Syngene, Sai Life Sciences, Neuland, Aragen, Veeda, and several others, including the recent addition of PI Health Sciences, collectively signify a CRDMO landscape that holds great promise for delivering research, development, and manufacturing services on a global scale. Furthermore, government's recently launched Production Linked Incentives (PLI) schemes serve as a significant catalyst in improving resiliency and local manufacturing.

Over INR25,000 crore outlay has been planned for the different Production Linked Incentive (PLI) schemes to improve resiliency and local manufacturing in the life sciences sector; >100 applicants shortlisted

PLIs introduced in the pharmaceutical sector

- **PLI scheme for production of high value pharmaceuticals**
  - Outlay of **INR15,000 crore** over a period of six years.[1,2]
  - As of May 2023, **55 applicants** were selected, including 20 MSMEs.[2]
  - Department of Pharmaceuticals had **ear-marked INR690 crore** as the budget outlay, with INR166 crore disbursed as of Feb'23 for FY23.[1,3]
- **PLI scheme for production of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs)**
  - Outlay of **INR6,940 crore** for 41 eligible products in six years.[1,3]
  - Incentive rates for fermentation-based products are 20% and chemical-based products are 10% for initial four years of the scheme.[1,3]
  - 48 applicants selected under the scheme as of Nov'23[4]

Production Linked Incentives

PLIs introduced in the medical devices sector

- **Scheme for promoting domestic manufacturing of medical devices**
  - The scheme has a total outlay of about **INR3,420 crore** over a period of five years.[1,3]
  - **5% incentive will be provided** on incremental sales (over Base Year: FY 2019-20) of medical devices manufactured in India.[5]
  - As of April 2023, **21 companies** have been shortlisted under this scheme.[3]

Impact

- Local production of the listed APIs/KSMs will increase, will help MNCs in the implementation of China + 1 sourcing strategies
- The PLI scheme for high-value pharmaceuticals will augment both local organizations and MNCs in their shift towards Complex Generics by achieving significant cost differentiation in the global markets
- Production of medium-high complexity medical devices will kick-start from the traditionally manufactured low-end products

Sources: EY analysis, 1. PLI scheme for pharmaceuticals, 2. calculated from Department of Pharmaceuticals – PLI schemes website, 3. PIB, 4. List of approved applicants Dated 06th November, 2023.pdf (pharmaceuticals.gov.in), 5. Invest India

1 Advancement of manufacturing technologies, with a specific focus on automation and digitalization

Adoption of cutting-edge digital technologies, including AI/ML, automation, and data analytics within manufacturing and supply chain functions, can wield a profound influence in cultivating a nimble, highly responsive, efficient, and top-quality operational framework. In addition, it also helps companies in meeting regulatory requirements, upholding quality standards, and embracing sustainable practices. Globally, the traditional manufacturing facilities are transitioning from conventional, isolated, and reactive systems to integrated and networked systems.

Future of integrated manufacturing and supply chain systems

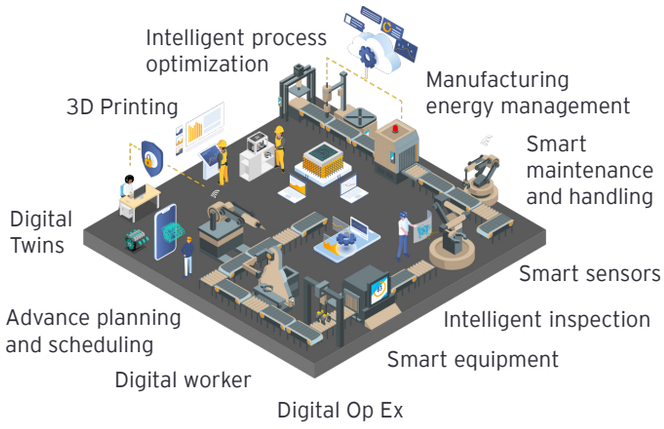
Traditional manufacturing facilities

Data stored in siloed systems
High reliance on manual methods to collect machine data or perform root-cause analysis

Reactive problem solving in case of process failure or downtime

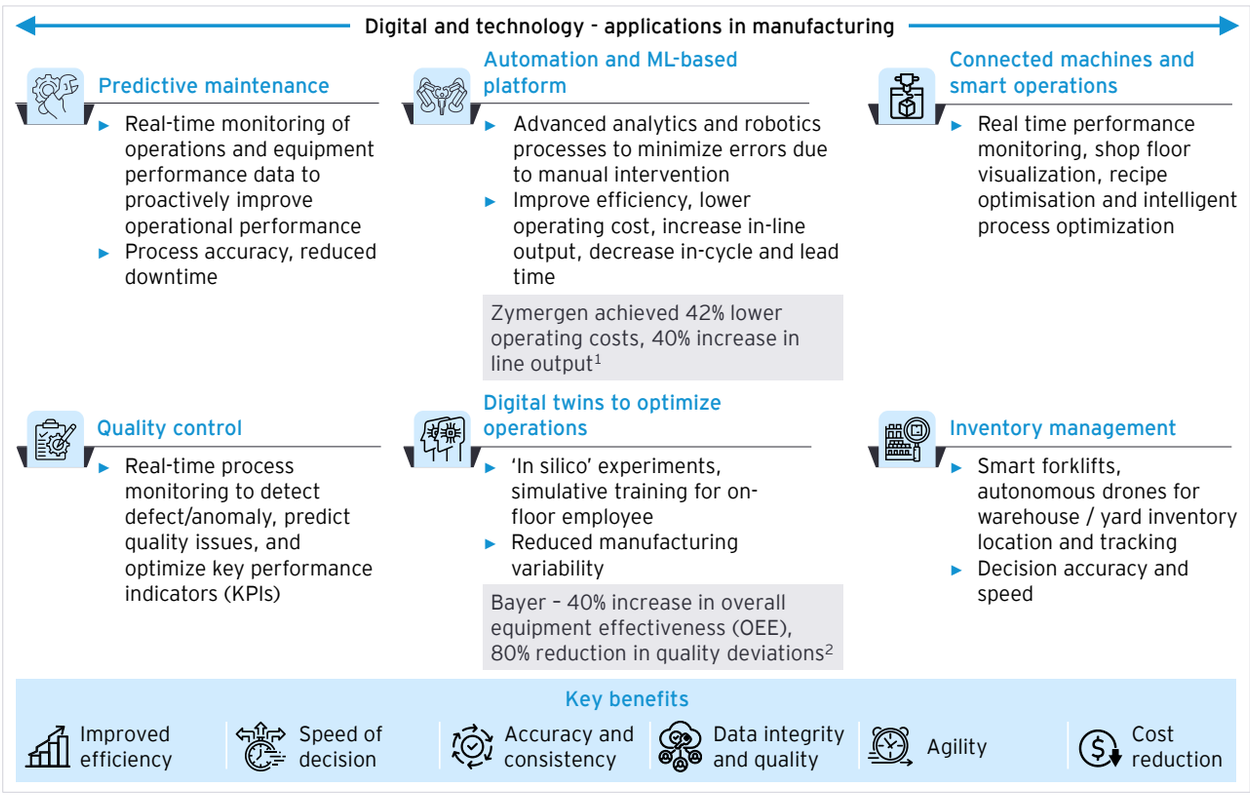
Distinct operations at shop floor and top floor

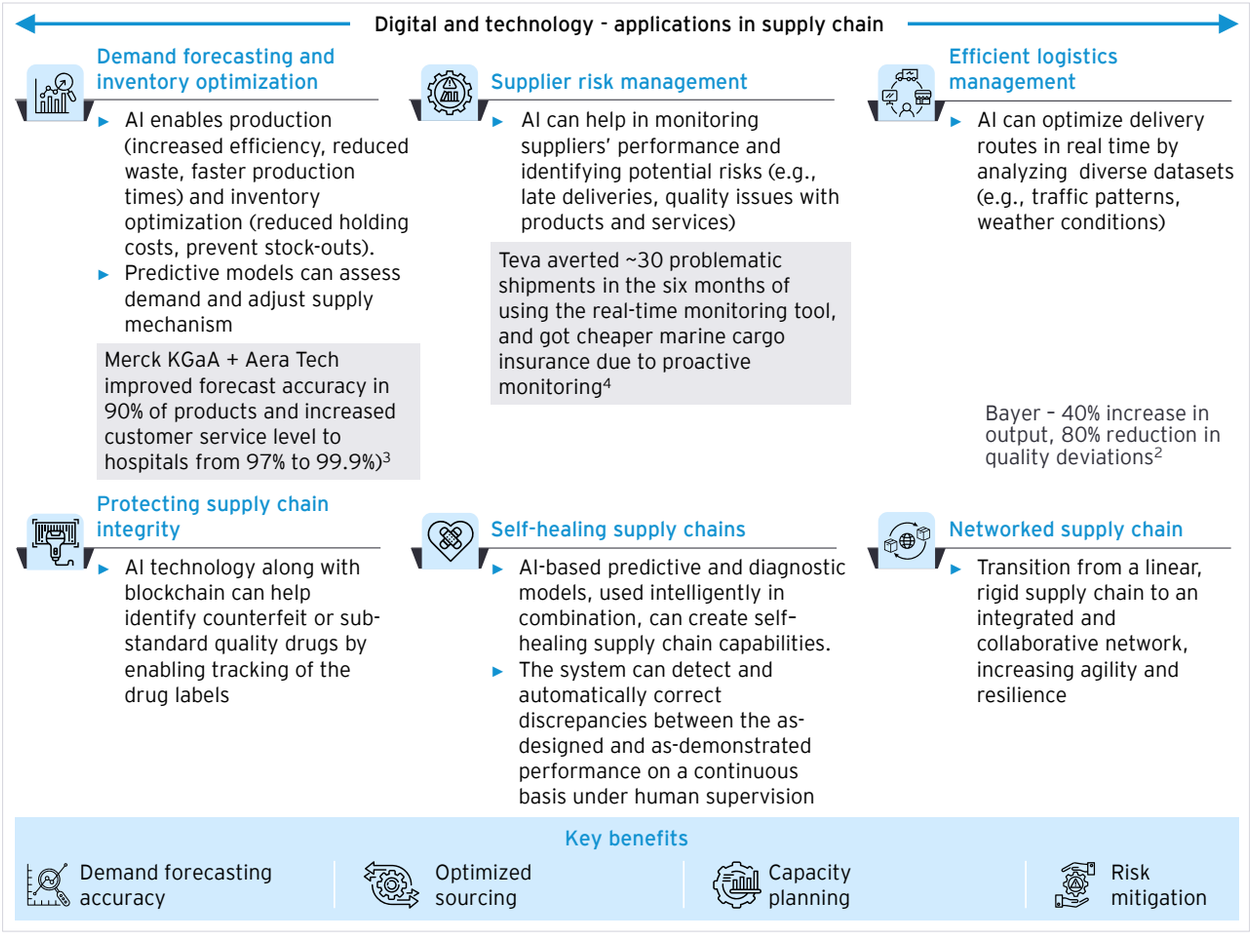
Evolution of smart manufacturing facilities, integrating advanced digital technologies and optimizing manufacturing operations and productivity



Source: EY analysis

Manufacturing and supply chain operation: digital technologies reduce cost and improve efficiency, agility, and quality





Sources: EY analysis, 1. Zymergen, 2. Bayer, 3. Merck KGaA + Aera Tech, 4. Teva,

Indian pharma companies are making rapid strides in their journey toward digitalizing manufacturing and supply chain operations. Over the years, they have implemented electronic lab notebooks (eLNBs), electronic quality management systems (eQMS), and Laboratory Information Management Systems (LIMS). SAP and Enterprise Resource Planning (ERP) systems have become integral component. The digitalization of procurement, production planning, and scheduling is also in progress.

> *Companies are in different stages of their journey of digital adoption, but the pace has been good. While earlier, digital adoption was a differentiator, today, being on digital platforms for manufacturing and quality operations is a bare minimum and a basic need.*
>
> **Chief Quality Officer**
> leading Indian CRDMO

This digital transformation is laying the foundation for improved efficiency, enhanced productivity, better regulatory compliance, and robust data protection. Additionally, it is aiding firms in achieving business growth, sustainability, and a competitive edge. Elimination of manual intervention and the streamlining of processes also instills a high level of confidence among the regulatory agencies. Another area of investment in technology is to achieve 24x7 audit readiness.

As next steps, companies are now moving toward end-to-end integrated planning, and adopting smarter systems to transition from a reactive approach to a predictive one. A good example is Cipla's journey to build a digital-native organization.

Cipla's re-imagination journey to build a digital-native organization

Cipla Indore's oral solid dosage (OSD) plant designated as an "Advanced Fourth Industrial Revolution (4IR) Lighthouse' by the WEF

- 'Digital Automation Analytics' deployed across a network of 22 Indian sites
- Adopted '**at-scale by design**', digital transformation approach

30+ 4IR use cases (spanning*)

- Industrial Internet of Things
- Advanced analytics
- Natural Language Processing (NLP)
- Robotic Process Automation
- Distributed control system
- Automated quality labs

26% ↑ Improvement in total cost

23% ↑ Rise in productivity

28% ↓ Decrease in specific greenhouse gas emissions

> *Aim at the organization level is to produce high-quality products which comply with sustainability goals, which are affordable and leave the planet safer. The **3 Rs of repeatability, reliability and resilience are its guiding force in this journey.***
>
> Geena Malhotra
> Global Chief Technology Officer, Cipla

Aspiration is to move from predictive to prescriptive in automation journey and be fully autonomous

*not-exhaustive

Sources: Cipla Lighthouse

Digitalization of the manufacturing, quality systems and supply chains, and sustainability and net-zero obligations are among the top three areas in which consultants get engaged in the pharma sector. More so, there is a sharp rise in demand for these services post the COVID pandemic. This surge is driven by the imperative to comply to the highest GxP standards, operate at scale, and drive efficiencies in a growing export footprint of US$25b, which is poised to increase exponentially in the coming years.

Partner, National Life Sciences Leader
EY India

Integrated digitalization (equipment, IT systems, instrumentation) is a great advantage because of the possibility to achieve highest level of transparency and reliability. This gives a lot of confidence to regulatory agencies and customers.

Executive Vice President
Clinical Logistics & Safety Services, leading Indian Clinical Research Organization

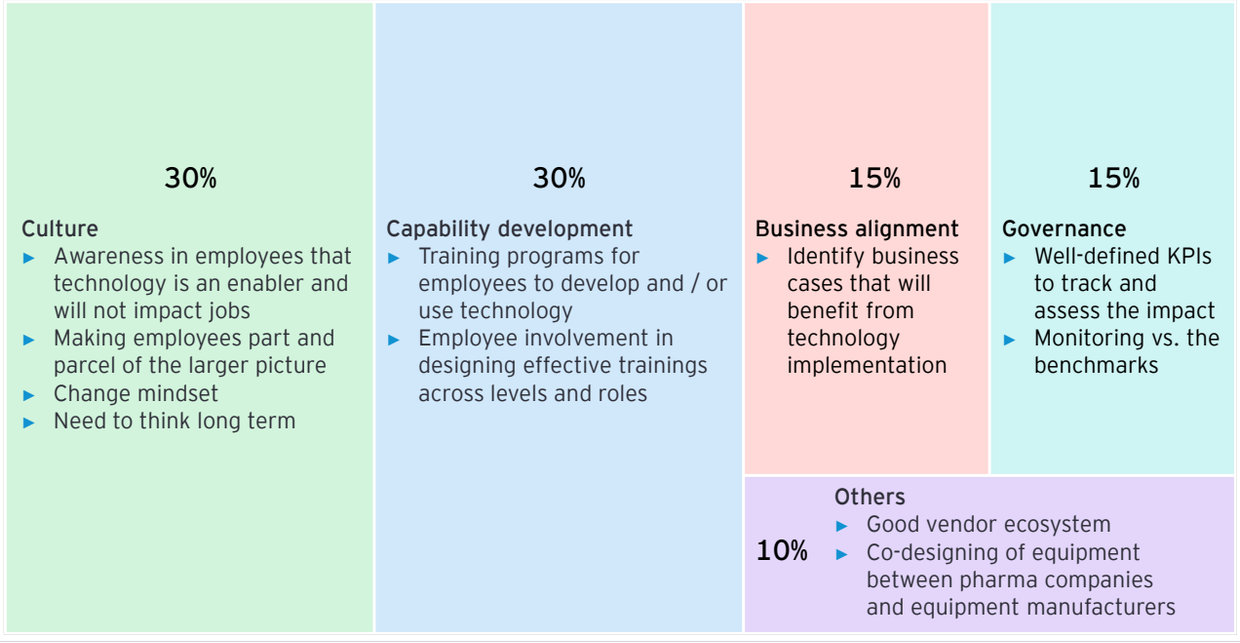
Supply chains are becoming more complex with the need to deal with a lot of countries, a lot of routes with a lot of dependencies, evolving geopolitical scenarios. But our supply chains are still very nascent and do not factor many things. They are not intelligent - many times the decisions are very human centric and not process driven.

Chief Quality Officer
leading Indian pharma company

Critical success factors for effective technology implementation and adoption

Technology or digitalization is not a standalone capability; rather, it serves as an incredibly potent tool to enhance and amplify existing capabilities and tools, making them more powerful and efficient. To fully reap the desired benefits, the implementation of digital and automation should be carried out with strategic precision. During the survey, Indian pharmaceutical industry leaders highlighted culture, capability development, business alignment, and robust governance as critical success factors for maximizing the Return on Investment (RoI) derived from the integration of advanced technologies.

Manufacturing and supply chain digitalization: a priority for Indian pharma
CXO survey: success factors for technology and digital implementation



2 Building credibility in the global market with an unwavering commitment to quality

Medicines are critical for saving lives of patients. Quality lapses by even one organization can set the perception for the whole industry, and even country.

Country Division Head and Managing Director, India
leading global pharma company

As Indian companies continue to expand their geographical footprint and their capabilities outside simple generics, it is essential that quality and compliance are embedded in the overall growth strategy. While the large number of manufacturers is a strength for Indian pharma industry, it also poses a few challenges. The country has a huge network of around 3,000 drug companies and about 10,500 manufacturing units. A significant disparity exists between established large-scale facilities and smaller local ones in terms of quality and compliance. Consequently, there is a pressing need to ensure that even smaller companies adhere to the required standards.

In the wake of quality deficiencies observed, all pharmaceutical companies operating in the country have been directed to adopt mandatory Good Manufacturing Practice (GMP) standards under Schedule M within six to twelve months beginning 1 August 2023, with the timeline varying based on the size of the companies. Among India's 10,500 pharmaceutical manufacturing facilities, a significant 8,500 fall under the Micro, Small, and Medium Enterprises (MSMEs) category[54]

It is paramount for pharmaceutical companies to prioritize both patient safety and product quality. To achieve this, companies are heavily investing in robust quality management systems and conducting thorough risk assessments. 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. Leveraging emerging technologies, such as AI / ML, Cloud computing/ Big Data Analytics, can significantly enhance transparency, traceability, and accountability throughout the supply chain. Additionally, continuous training and education of employees, and proactive monitoring of manufacturing processes are essential to help prevent issues and uphold high-quality standards. The sector must collectively work toward fortifying the ecosystem to ensure consistent delivery of high standards of quality.

[54] Health Ministry sets deadline for pharma industry to implement revised Schedule M - The Hindu.

Excerpts from the press meet with Robert M. Califf, M.D., Commissioner of Food and Drugs Administration (FDA), during his visit to India in Oct'23

"For the US, where more than nine out of 10 prescriptions dispensed are generic drugs, India is a critical partner, responsible for a substantial portion of these drugs."

"India's role in the medical product space represents both a unique opportunity and an important responsibility."

"The US, and indeed the world, is relying on Indian pharmaceutical companies to make safe, effective, high-quality drugs that can be trusted to have their intended effects and to remain consistently available."

"The FDA requires all manufacturers making products for the US, no matter where they are located, to abide by CGMPs. Beyond CGMP, manufacturers are encouraged to adopt a top-down, bottom-up culture of quality that allows for critical feedback from operator to manager on processes to ensure compliance as well as facilitate continuous improvement."

"The discussions on my trip reflected a continued willingness and enthusiasm from the Government of India and industry alike to work collaboratively with the FDA to ensure robust quality management for safe and effective drugs."

"Ensuring a secure, resilient, and high-quality pharmaceutical supply chain is a high priority for the FDA, and India remains a key partner in this critical effort."

Sources: FDA Voices

During his recent visit to India, the USFDA Commissioner underscored the vital role that India plays in global drug supply and the significant responsibility associated with it. Similar thoughts were shared by the industry leaders in the primary research. Need for strong regulatory reinforcement, a shift in mindset, capability development, and adoption of advanced technology were identified by the industry leaders as pivotal elements for meeting quality standards and establishing credibility. The need to provide training to the MSMEs on quality orientation and processes and systems for quality control was also highlighted. These will continue to be key drivers in the near and medium term for Indian Pharma.

CXO survey: key priorities for building credibility and quality

33%

Enforcement
- Compliance with rules and regulations
- Quality should be considered high priority
- Need for a strong regulatory and audit system

25%

Change in mindset
- Patient centric approach
- Purpose driven mindset
- Global thinking
- Proactive approach instead of reactive
- One quality, one standard approach
- Leadership to be at the forefront

21%

Capability development
- Training and upskilling of workers/operators
- Be up-to-date on market trends and regulatory updates in all markets

17%

Technology adoption
- Data integrity
- Shift from manual, people-dependent processes, to automated systems that minimize any unintentional human errors
- 24x7 audit readiness

4%

Policy intervention
- Need to recognize and encourage high-quality standards (e.g., in tender process)
- Guidelines for supply chain distribution quality

It is the mindset. It is how you talk about what you are doing. It is whether the cleaner on the floor knows that they are actually manufacturing a highly critical medicine for cancer, or even if it is paracetamol that helped with headache and fever associated with COVID. They need to know the purpose of what they are doing. We need to talk about the patient's benefit. It is also important to understand that quality is everyone's responsibly and not only of the quality team.

Executive Vice President & Chief Operations Officer
leading Indian pharma company

We have to keep enhancing our own standards. We should have sites that are producing for all geographies, and not differentiate by India specific, or emerging markets specific, or US specific. This will also give better economies of scale.

Chief Technical Officer
leading Indian pharma company

In addition to improving the quality standards in our manufacturing processes, it is equally essential to instill quality criteria in our procurement practices. By incorporating quality as a qualifying criterion in the tender procurement process, the entire ecosystem can be steered toward achieving higher-quality outcomes.

Managing Director, India
leading global pharma company

The government's unwavering commitment, as outlined in the new Drugs, Medical Devices, and Cosmetics Bill of 2023[55], and rigorous enforcement of Schedule M, is directed toward ensuring that all MSMEs and other stakeholders adhere to the globally recognized WHO GMP standards within a specified timeframe. This move is anticipated to provide the essential momentum for enhancing quality and will play a substantial role in bolstering the export of pharmaceuticals manufactured in India.

Indian pharmaceutical companies are proactively adopting a blend of strategies to ensure regulatory compliance and attain high-quality standards. These strategies encompass various best practices, namely:

- Dr. Reddy's uses advanced analytics to help in yield optimization, create a golden tunnel for process parameters to generate better quality outcomes and digital dashboards for faster execution[56]
- Biocon has implemented a robust, targeted training program designed to foster synergy between quality and production teams, promoting effective learning, and practical application from the training sessions[57].
- Aurobindo Pharma has instituted a Quality Marshal program and developed specialized training initiatives led by industry experts. The company follows a three-tiered approach for internal quality audits and has made substantial investments in technology and automation[58].
- Sun Pharma has outlined a clear Quality Vision and adopted an integrated and comprehensive quality management approach to ensure high standards are maintained[59].

With significant emphasis on quality and compliance standards, the company has undertaken various initiatives:

Quality Marshal program	Quality-focused training programme	Three-tiered approach for internal audits	Automated controls and continuous process improvement

▸ Shop floor teams undergo 'Train the Trainer' program
▸ Post training, employees must impart 20 hours of learning to their team members regarding various quality scenarios to be certified as Quality Marshals.
  ▸ 180+ Quality Marshals as of 2021
  ▸ learnings to the tune of 1,900+ person hours across all formulation manufacturing units.
	▸ Specially designed training program for employees by industry experts on human-error reduction, airflow visualization studies using advanced visualization technology, preparing for USFDA inspections, communications, ethical conduct, and quality behaviors and protocols	▸ Internal audits are conducted by intra-departmental personnel, inter-departmental auditors, and by Corporate Internal Auditors every quarter
		▸ Improved quality metrics to make it more meaningful and well-structured to identify and flag emerging trends
		▸ Harmonized best practices
		▸ Automated rapid microbiology testing
			▸ Technology and automation to flag and pre-empt concerns, e.g., eLIMS, paperless laboratory
			▸ Software-based continued process verification program
			▸ Manufacturing process equipment up-gradation to derive real-time manufacturing data parameters
			▸ Automated vendor qualification processes

Sources: Aurbindo Pharma

These best practices exemplify the commitment of Indian pharmaceutical companies to upholding regulatory compliance, delivering quality products, and coming up to global standards. Several leading Indian pharmaceutical companies have embarked on digital transformation initiatives to enhance their operational efficiency and ensure compliance with quality standards. Notably, India boasts the highest number of USFDA-approved plants outside of the US (more than 600 as of Oct'22). Additionally, there are over 2,000 WHO GMP-approved facilities. Scaling up in terms of quality is a natural progression for the industry.

[55] Drugs, Medical Devices, and Cosmetics Bill of 2023
[56] Annual Report 2020 (drreddys.com)
[57] Biocon_ESG_Report_2022.pdf
[58] AUROPHARMA_04082020180445_LtrToSEsAGMNoticeAndAR201920.pdf (nseindia.com)
[59] Quality - Sun Pharmaceutical Industries Ltd.

3 Adopting sustainable practices

The pharmaceutical and healthcare industry plays a critical role in keeping people healthy, but it also significantly impacts the environment through its carbon footprint. From the extraction of raw materials to the disposal of drugs, the industry's chain of operations has a considerable carbon footprint. According to a recent report, healthcare[#] is accountable for ~4.4% of global net emissions[60]. Now, if we consider the pharmaceutical sector alone within the healthcare ecosystem, the sector itself is contributing 48.55 tons of CO_2e (carbon dioxide equivalent) per million dollars which is 55% more than the automotive sector[61].

Environmental challenges have never been more critical or more urgent than they are today. The imperative for sustainability in the pharmaceutical industry has become increasingly important as global apprehensions about climate change and environmental deterioration continue to escalate. Various nations, including India, are introducing regulations and mandatory reporting requirements. A growing proportion of investors are favoring companies that place sustainability goals at the forefront. Furthermore, consumers are displaying heightened awareness and a greater sense of responsibility for their environmental impact, which is influencing their purchasing decisions.

The entire pharmaceutical industry must undergo substantial reevaluation and resource reallocation to effectively prepare for this transition. Indian pharmaceutical companies have already commenced initiatives to mitigate their environmental footprint. In primary interviews, numerous industry leaders emphasized that sustainability ranks at the forefront of their leadership agenda. Significant efforts are in progress to render the entire manufacturing and supply chain processes more environment friendly. They also emphasized that, in the long term, these sustainability endeavors will not only yield cost savings but could also lead to competitive advantages and potentially open new revenue-generating opportunities.

> *Our boards are getting involved in driving many of these initiatives. We know that this is just a beginning and we have to travel a long distance, but the intent is there.*
>
> **Chief Quality Officer**
> leading Indian pharma company

> *Sustainability can be a big differentiating factor for the companies working with the global counterparts, including the CRDMOs. Global companies are increasingly emphasizing the adoption of sustainable practices, as our carbon footprint gets added to theirs. So a combination of scientific innovation and sustainability is critical for establishing a meaningful presence within the global supply chains.*
>
> **Chief Quality Officer**
> Leading CRDMO, India

[60] HealthCaresClimateFootprint_092319.pdf (noharm-global.org); [#]Health sector is defined as "all organizations, institutions, and resources that are devoted to producing health actions. A health action is defined as any effort, whether personal health care, public health service or inter-sectoral initiative, whose primary purpose is to improve health."

[61] McMaster University

Initiatives such as reducing raw material consumption, reducing energy consumption – these give competitive advantage by reducing operational costs, and are also environment friendly. Employing a strategy of incremental progress over an extended timeframe is prudent and effective.

Director
leading global pharma company

Sustainability practices in pharma manufacturing and supply chain

Most of the sustainability initiatives being adopted by pharma companies in the manufacturing and supply chain function can be broadly classified under three buckets: sustainable manufacturing and green chemistry, fostering supply chain sustainability, and reducing packaging waste. The visual below provides a view of the type of initiatives and company examples under these three buckets *(this is not comprehensive, and only indicative)**.

Sustainability initiatives by pharma companies#

Type of activities#	Company initiatives	Impact
Sustainable manufacturing and green chemistry ▸ Renewable energy (solar and wind power to meet energy needs) ▸ Reducing water consumption ▸ Waste management practices (zero waste to landfill sites)	**Indian Pharma 1** ▸ Replaced furnace oil to biomass-based boilers ▸ Adopted agro-waste based solid fuel and natural gas boilers ▸ Sensor-based water taps ▸ Rainwater harvesting ▸ Tertiary treatment using filters, nano-filters and reverse osmosis ▸ Active monitoring	38% of energy needs met from renewable sources ~86% of manufacturing facilities are Zero Liquid Discharge
Fostering supply chain sustainability ▸ Responsible sourcing of raw materials – supplier selection based on ethical and sustainable practices (e.g., sustainable farming and harvesting methods) ▸ Investments in localized manufacturing (reduction in carbon footprint associated with pharma distribution)	**Indian Pharma 2** ▸ Focus on sustainable supply chain through supplier engagement ▸ 603 local-based suppliers for manufacturing facilities globally ▸ Alternate Vendor Development strategy for sourcing APIs, promotes local manufacturing and reduces risks **Code of Conduct outlines the criticality of adhering to environmental and social parameters*	1,461 suppliers adopted the company's Supplier Code of Conduct* 62% of procurement budget spent on local sourcing De-risked products worth US$300m, with a saving of ~US$4m
Reducing packaging waste ▸ Sustainable packaging design (recycle, repurpose, or biodegradable) such as blister packs, reduction of paper waste	**Indian Pharma 3** ▸ **Primary packaging:** reduction of bottle sizes, removal of fillers (cotton, rayon, polyester oils), downsizing wall thickness of bottles, thermoform blisters in place of 3/4 layers of cold form blister ▸ **Secondary packaging:** replaced physical medication guides with electronic copy	60% Reduction in pack size 80% Reduction in material consumption

non-exhaustive

Sources: Company reports, EY analysis

As private equity investments grow and globalization expands for India to take a lead role in the China+1 opportunity, the Indian pharmaceutical industry will be compelled to take a leading role in adopting green and sustainable practices. This shift will not only be a responsible choice but also a competitive advantage that strengthens and solidifies its global presence.

Key highlights

India's manufacturing infrastructure

- India has the largest number of USFDA compliant pharma plants outside the US and over 2,000 World Health Organization - Good Manufacturing Practice (WHO-GMP) approved pharma plants.
- More than 10,500 pharmaceutical manufacturing facilities serve global demand.

Evolving industry trends

- Several emerging trends influence manufacturing and supply chain priorities. These include pricing pressures, digitalization, ESG considerations, shift toward personalized medicine, and innovative healthcare delivery models.
- This transformation positions India at the forefront of the "China +1" opportunity.

CRDMO is set to grow

- Indian CRDMOs have transformed from regional providers to international leaders in pharmaceutical development and manufacturing.
- Their cost-effective solutions, skilled scientists, supply chain and regulatory expertise, and adoption of new technologies and robust quality standards have propelled them to the forefront of the industry.
- They now offer comprehensive services from concept to commercialization.
- Many top pharmaceutical and biotech companies outsource R&D and manufacturing activities to India
- With the global pharmaceutical industry favoring asset-light models and increasing number of biotechs pursuing niche areas, CRDMOs are poised for further expansion.

Areas of focus for the Indian pharma industry – CXO survey findings

- Industry leaders highlighted three areas of focus to leverage opportunities and become integral to the global pharma supply chain.
- These areas include adoption of advanced manufacturing technologies, commitment to quality, and focus on sustainability.

Advanced manufacturing technologies

- Embracing innovative digital technologies, such as AI/ML, automation, and data analytics in manufacturing and supply chain functions can significantly enhance operational efficiency and quality.
- Digitalization also facilitates regulatory compliance, quality maintenance, and sustainability practices.
- Indian pharmaceutical companies are rapidly progressing in their digitalization efforts for manufacturing and supply chain operations.
- CXO survey findings identify following areas of focus to achieve favorable return on digital implementation i.e., cultural change, capability development, business alignment, and governance processes.

Quality and Compliance

- As Indian companies continue to expand their geographical footprint and their capabilities outside simple generics, it is essential that quality and compliance are embedded in the overall growth strategy.
- CXO survey suggests that to build credibility and quality, there is a need for a shift in mindset, capability building, technology adoption and policy intervention
- The survey also suggests that it is critical that all companies, including the MSMEs, mandatorily ensure compliance – government's mandatory enforcement of Schedule M will provide the essential momentum for enhancing quality.
- Indian pharmaceutical companies are proactively adopting a blend of strategies to ensure regulatory compliance and attain high-quality standards

Sustainability

- The pharmaceutical industry has a significant carbon footprint, necessitating a shift toward sustainability.
- In addition, the imperative to embrace sustainability is underscored by regulatory mandates, investor inclinations, consumer consciousness, and globalization.
- Pharma companies and CRDMOs are now increasingly adopting green and sustainable practices

Achieving sustainable and equitable healthcare access for all

Achieving sustainable and equitable healthcare access for all

Achieving equitable and sustainable healthcare access is a must for a country to achieve economic growth. Being the world's second most populous country, India faces unique opportunities and challenges in the healthcare space. In the Healthcare Access and Quality (HAQ) Index for the year 2016, India's ranking stood at 145 out of 195 countries[62].

The most pressing healthcare challenges are the escalating disease burden of non-communicable diseases (NCDs) and the substantial gap between healthcare supply and demand.

Surging Non-Communicable Diseases (NCDs)

Under the Sustainable Development Goal 3.4, the target is to reduce by one third premature mortality from NCDs by 2030 through prevention and treatment and promoting mental health and wellbeing[63]. Contribution of NCDs to total 'disability-adjusted life years' (DALYs) has almost doubled in the last three decades in India – from ~30% in 1990 to ~58% in 2019[64]. NCDs account for ~66% of deaths in India[65] and a lot of these deaths can be prevented if patients get the right care at the right time.

Non-communicable diseases: impact on healthcare and economy
High mortality: ~66% of all deaths in India
Economic growth: significant impact by limiting people's ability to work

66%
of all deaths associated with NCDs in India (60.1 lakh deaths); increased ~10pp since 2010

US$30t
global cost of productivity loss due to the four major NCDs between 2011-2030

22%
probability of premature mortality due to NCDs in India vs. global probability of 18%

2030
is the global deadline for achieving the Sustainable Development Goal target to reduce premature mortality from NCDs by 1/3rd

India: NCDs facts and figures

	Percentage of total deaths	Facts
Cardiovascular diseases	▸ 28% ▸ 58% of the deaths are under 70 years)	▸ ~86% of the deaths could have been prevented or delayed ▸ 63% people remain undiagnosed
Chronic respiratory diseases (CRDs)	▸ 12% (primarily due to COPD and Asthma) ▸ 37% of the deaths are under 70 years	▸ Proportion of deaths due to CRDs in India is highest globally
Cancer	▸ 10% ▸ 68% prevalence in people aged <70 years	▸ ~50% of the cancer deaths could have been prevented/ delayed
Diabetes	▸ 4% ▸ 54% of these are under 70 years	▸ Overweight and obesity are the primary risk factors

Obesity

- Continued increase in prevalence over time in adults (from 6% in 2020 to 9% in 2030)
- WHO projects that India will miss the global target of halting the rise of obesity by 2025
- Obesity is one of the leading risk factors for NGDs and cancer
- **During COVID, NCDs and obesity increased the risk of serious illness or death due to Covid-19. This is expected to be the case for future viral diseases and epidemics as well**

Sources: WHO NCD portal (India), CNBC, The Wire

[62] India 145th among 195 countries in healthcare access, quality: Lancet - The Hindu
[63] Noncommunicable diseases: Mortality (who.int)
[64] VizHub - GBD Compare (healthdata.org)
[65] More Than Half of Deaths in India Are Due to Cancer, Diabetes, Heart and Respiratory Diseases (thewire.in)

Continued large gap in healthcare demand and supply

Currently, India does not meet the WHO recommendations for the number of physicians, nurses and hospital beds per 10,000 people and lags other BRIC nations on these key performance indicators. The healthcare infrastructure availability gap is further widened due to urban-rural disparities. Less than 25% of the country's healthcare infrastructure is available to about 73% of the population living in rural areas.

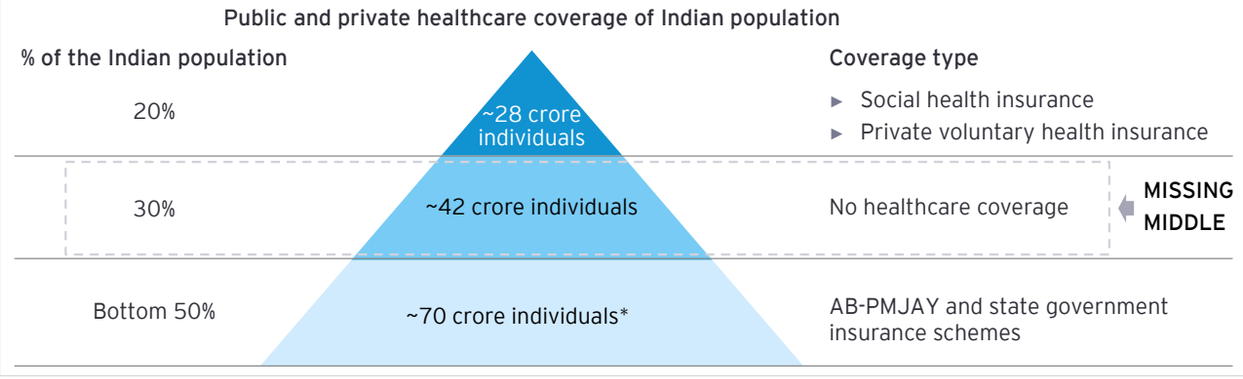
> *Right to life guaranteed in the Constitution requires that every child, every adult, no matter where they are, should have equal access to basic health care services – today that is not true for India, particularly in some states.*
>
> *We clearly have the basic infrastructure, money, and human resources. If we layer technology and modern tools to this, we should be able to provide world class primary, secondary, and tertiary care to every citizen of India, including the poorest and remotest villages in the next 10 to 15 years.*
>
> **Visiting Scientist**
> Banyan Academy of Leadership in Mental Health

Government programs to increase access to healthcare and improve health outcomes

Government has launched several initiatives to provide healthcare access to the population.

Ayushman Bharat launched in 2018[66] has two complementary schemes: 1) Health and Wellness Centres (HWCs) to deliver comprehensive Primary Healthcare (PHC) services, free essential drugs and diagnostic services to the entire population; and 2) Pradhan Mantri Jan Arogya Yojana (PMJAY) for improving access to hospitalization services at secondary and tertiary level health facilities for the bottom 50% of the population.

Besides bottom 50% who are covered under PMJAY, ~20% of the population is covered through social health insurance and private voluntary health insurance. The remaining 30% of the population is devoid of any health insurance or coverage. There should be some strategy for AB-PMJAY or some other program to provide coverage to the uncovered 30% of the population – the missing middle class. By expanding the coverage to include the middle class, the government will also get the benefit of scale in negotiating with hospitals. NITI Aayog is working on a strategy to extend the health coverage to this 'missing middle'.



Sources: Niti Aayog report, Indian population (as of July 1, 2023)

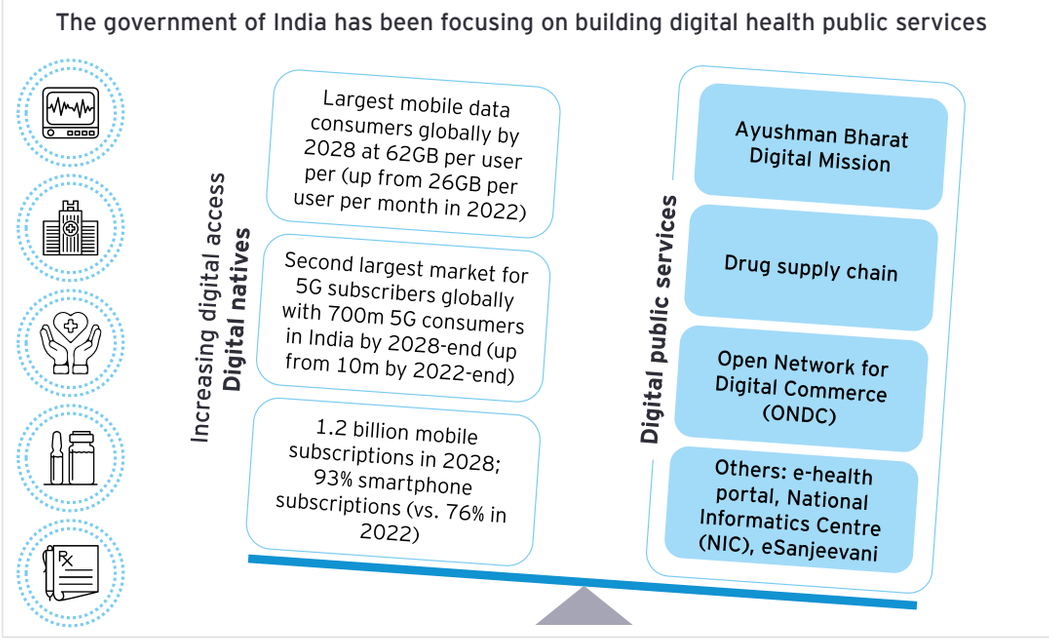
[66] About PM-JAY - National Health Authority | GOI (nha.gov.in)

In addition to Ayushman Bharat, there is also an increasing focus on managing NCDs. For example, NCD clinics have been set up at district hospitals, at taluks, and at community health center level as part of the National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)[67].

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

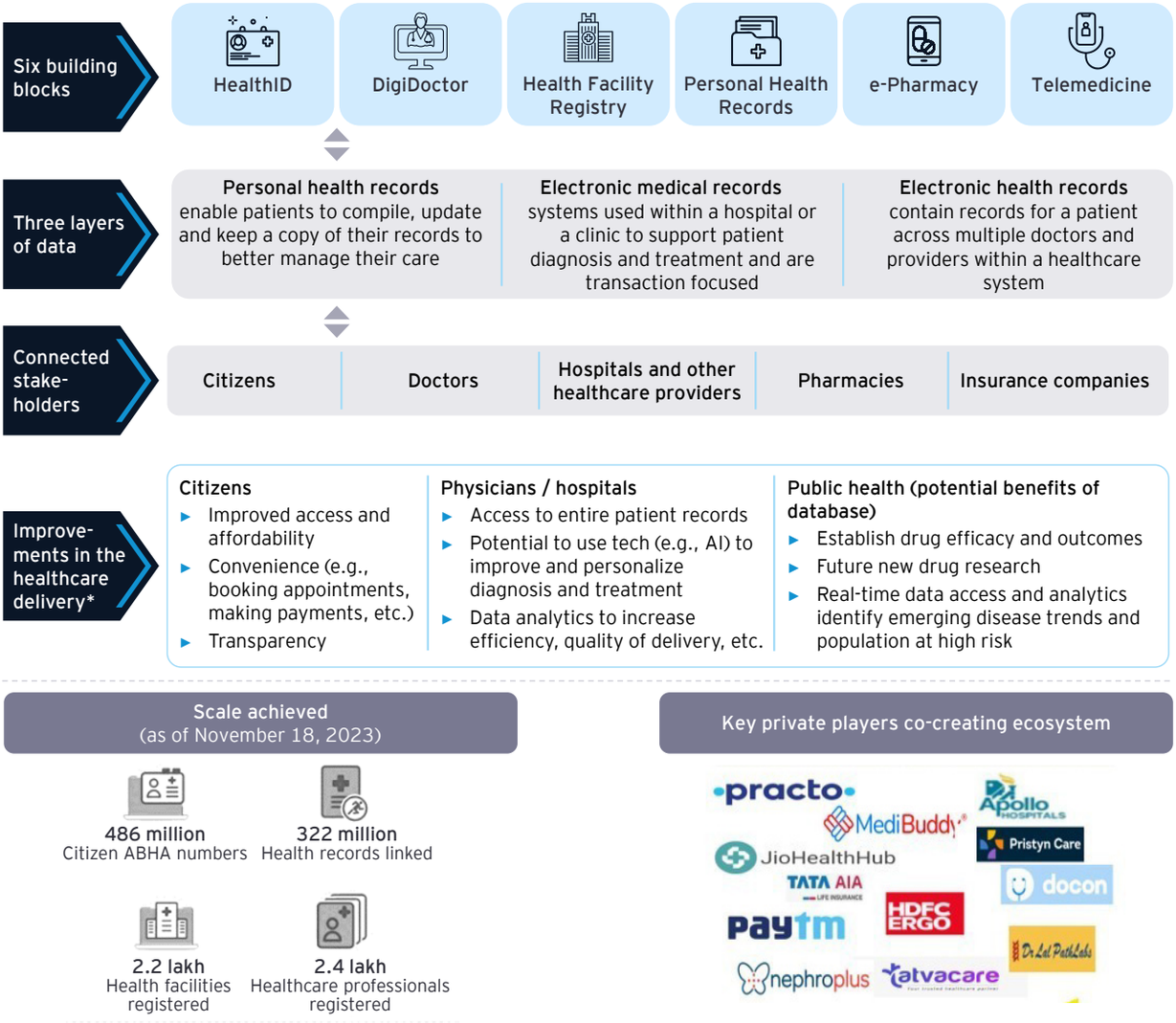
The Ayushman Bharat Digital Mission (ABDM), launched in 2021, is aimed at laying the essential groundwork for a seamless integrated digital healthcare infrastructure in India.

ABDM's mission is to optimize healthcare delivery in India by harnessing the power of digital technologies, with a strong emphasis on enhancing efficiency and efficacy. Through ABDM, patients will gain the capability to access their medical records and conveniently share them with healthcare providers. Furthermore, patients will have the option to avail healthcare services remotely via teleconsultation and e-pharmacies. Health professionals will be able to securely access more comprehensive patient medical histories, contingent on the patient's consent, thereby enabling them to prescribe treatments that are more effective. Policymakers and program managers will enjoy improved access to data, enabling more informed decision-making. Researchers will be empowered to scrutinize and assess the efficacy of various healthcare programs and interventions. This will concurrently bolster transparency and reliability in healthcare. With these myriad advantages, ABDM has the potential to spearhead a healthcare revolution in India.



[67] Press Information Bureau (pib.gov.in)

Ayushman Bharat Digital Mission Overview

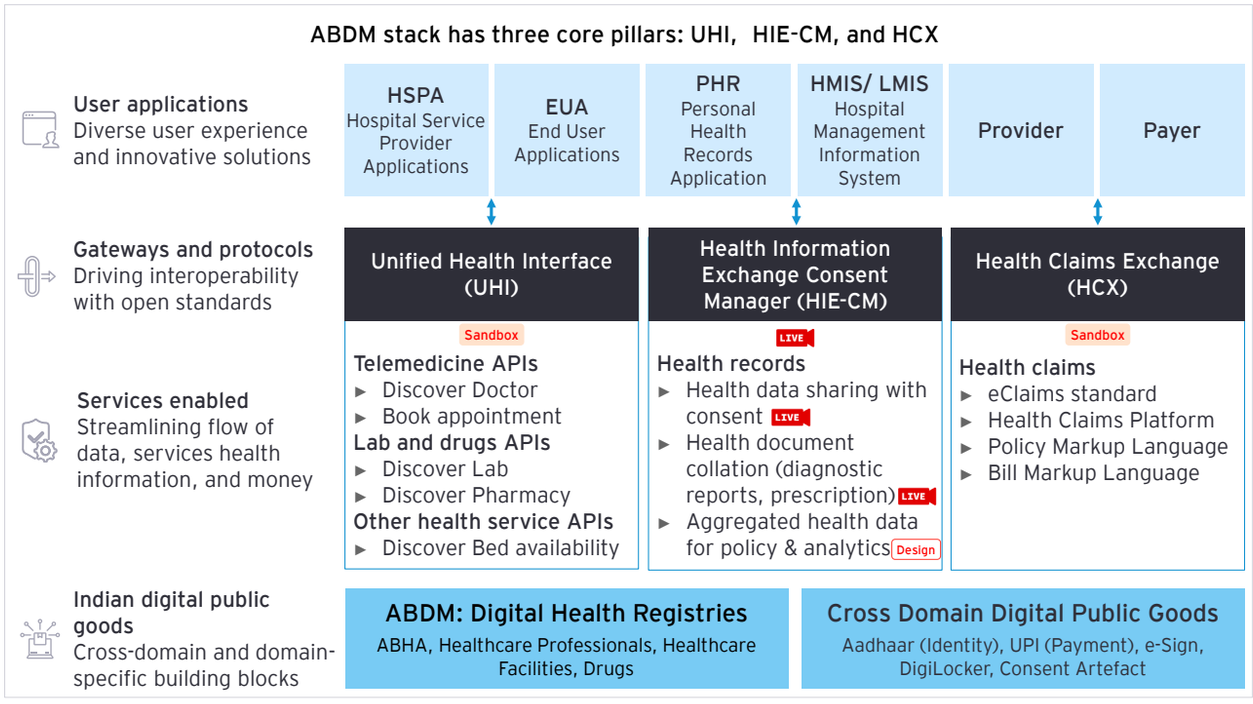


*The list is indicative and not exhaustive

Sources: EY analysis, ABDM Insights

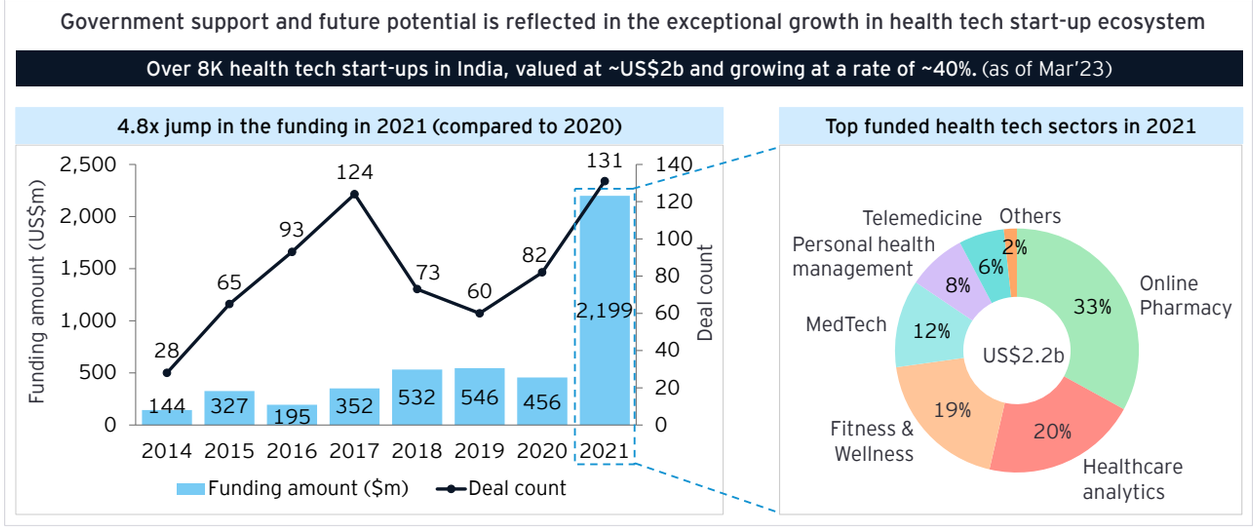
ABDM – potential to revolutionize healthcare delivery in India

Database repository and information flow	▸ Longitudinal health records ▸ Disease surveillance and data for public health management ▸ Anonymized large dataset for machine learning
Patient empowerment and convenience	▸ Patients will have access and rights to their data, with the ability to share data in a secure digital way with healthcare providers (HCPs) ▸ Patients can visit any hospital in any part of the country with anywhere, anytime access to their digital health records (paper-less health services) ▸ Interoperability across providers; reduced queues for insurance/ appointment/ payments
Improved quality of healthcare	▸ Better and early diagnosis ▸ Remote follow-ups to improve patient adherence ▸ Real world evidence trends for improving health outcomes



Sources: ABDM Sandbox, ABDM Building blocks

ABDM promotes adoption of open standards by all digital health stakeholders, including health tech start-ups. Government has set up an ABDM sandbox to integrate these solutions to ABDM ecosystem. Government has also launched various initiatives like the Digital Health Incentive Scheme, microsites, collaboration with pharmacies and laboratories to accelerate adoption of digital health, particularly focused toward private sector including start-ups[68]. Practo, Paytm and several other private entities have already been integrated with ABDM[69].



Sources: With 4 Unicorns & $2.2 Bn Funding, Healthtech Startup Funding Shoots Up (inc42.com), Health tech start-ups: New stars of India's healthcare ecosystem (indiatimes.com)

[68] Press Information Bureau (pib.gov.in)

[69] India's flagship health digitisation project will involve Paytm, Jio, and others (medianama.com)

Digital natives: a host of start-ups are emerging that provide services and solutions for patients, care providers, hospitals

Digital native players	Description	Engagement across patient journey*				Service platform (illustrative examples)
		Awareness and wellbeing	Screening and diagnosis	Treatment	Management	
Wellness and personal health	Fitness and healthy lifestyle solutions and services	✓				HealthifyMe, cure.fit
Deep tech diagnostics	Use of AI / ML in diagnostics and screening		✓			SigTuple, Qure.ai
Tele-consultation	Online doctor consultation (voice and video calling)			✓	✓	Practo, MFine, MediBuddy
B2B Tele-medicine	Tele-radiology services, remote ICU management, connected ambulance			✓	✓	INTELeICU, 5 Care Network
Healthcare at home	Medical equipment and trained nurses/technicians at home				✓	Portea, HCAH (Healthcare at home)
Clinical decision support system (CDSS)	Evidence-based recommendations to enable physicians in making appropriate diagnosis, treatment, and management decisions		✓	✓	✓	5MinuteConsult, Clinical Intelligence Engine (CIE by Apollo)
E-pharmacy/ E-labs	Online medicine retailing and home collection services		✓	✓	✓	PharmEasy, MedPlus, Tata 1mg
Disease Management	Disease management services, AI/ ML powered services for chronic disease	✓	✓	✓	✓	Wellthy Therapeutics, Beat Control

Healthcare delivery tools

healthcare data technology and analytics platforms
For patient acquisition/ engagement and retention

THB, Innovaccer

EHR/EMR
Electronic health/medical records software systems

DocOn, DocPulse

B2B marketplace
Tech enabled supply chain management (SCM) solutions, streamlining hospital procurement

Medikabazaar, Aknamed

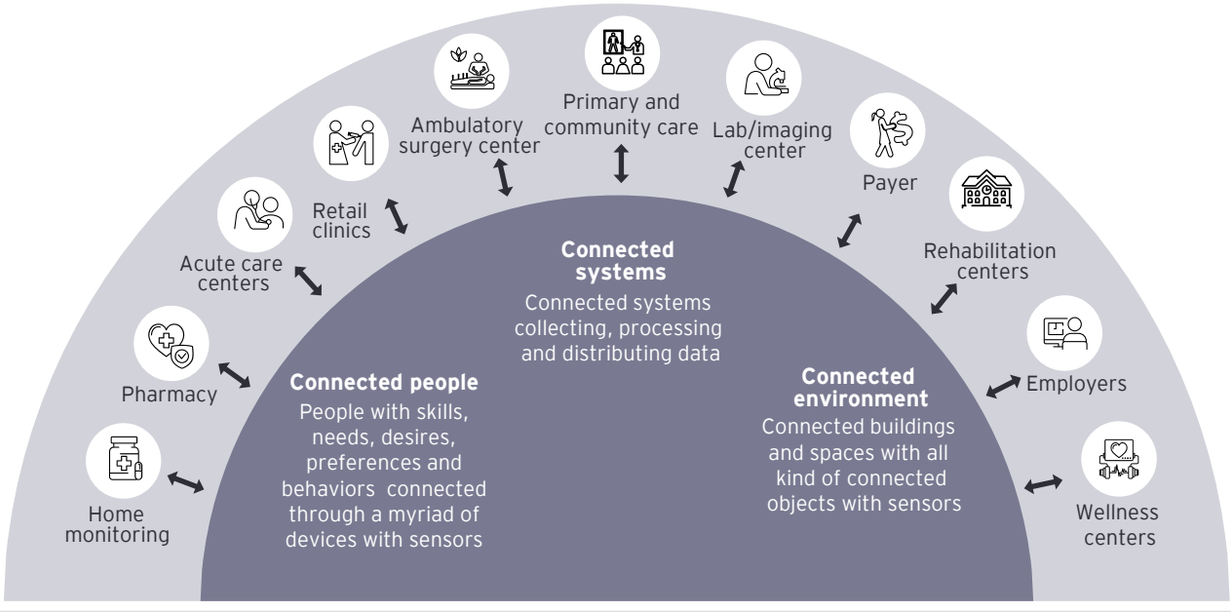
Hospital management systems
Cloud based system to track hospital activities, inventory, cost management

Insta (by practo), Lifetrenz, DocEngage

*Only key platform services are highlighted in the above analysis; these platforms might be providing some services in other parts of the patient journey as well

Integration of 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 have a profound impact on patient health outcomes in a resource-constrained country.

Going forward, digital health players will enable **hyper-connected healthcare systems** which will improve reach, cost to serve, and experience



Unified Health Interface (UHI) is on the cusp of revolutionizing healthcare much as (Unified Payment interface) UPI transformed finance, representing a pivotal inflection point for the entire healthcare ecosystem in India.

As the growing adoption of UHI and the Digital native models increasingly improves experience and reduces cost to serve, this will enable coverage of a large part of the currently underserved population, including the missing middle, and revolutionize access and healthcare delivery in the Amrit Kaal period.

Putting patients first: shifting from sick care to well being

In addition to the potential offered by various government initiatives, primary research underscored the necessity for enduring, comprehensive programs aimed at controlling and managing India's most prevalent non-communicable diseases (NCDs), including diabetes, cancer, cardiovascular diseases, and chronic respiratory diseases. Such programs promise a twofold advantage —they can enhance healthcare quality while simultaneously reducing the overall healthcare expenditure.

For instance, the World Health Organization (WHO) has reported that, based on studies in high-income countries, early cancer diagnosis has the potential to reduce the cost of cancer treatment by two to four times. The United Nations health agency emphasizes that early cancer diagnosis not only saves lives but also reduces treatment costs, particularly in developing countries where the majority of cancer cases are detected at advanced stages[70]. Similarly, there are studies on the increasing prevalence of diabetes in the younger population in India. In addition to the adverse health effects, this trend has a substantial economic impact due to productivity losses and premature deaths. However, the severity of diabetes, its resulting complications, and mortality can be significantly mitigated through proper disease management.

Health and economic impact of diabetes in India

- In India, diabetes is increasingly affecting younger individuals. In 2017, an estimated 54.4 million (7.6%) working-age individuals in India had diabetes.
- Diabetes-related premature deaths and comorbidities can lead to reduced labor force participation, reduced productivity from workdays lost to ill health, and decreased efficiency at work
- Resulting loss of productivity can impose a substantial economic burden on individuals, employers, and the government through reduced earnings, tax revenue, and gross domestic product (GDP)

Benefits of effective diabetes management

- Effective blood sugar management can reduce the risk of eye disease, kidney disease, and nerve disease by 40%.
- Blood pressure management can reduce the risk of heart disease and stroke by 33% to 50%.
- Regular eye exams and timely treatment could prevent up to 90% of diabetes-related blindness.
- Detecting and treating early diabetic kidney disease can reduce decline in kidney function by 33% to 37%.

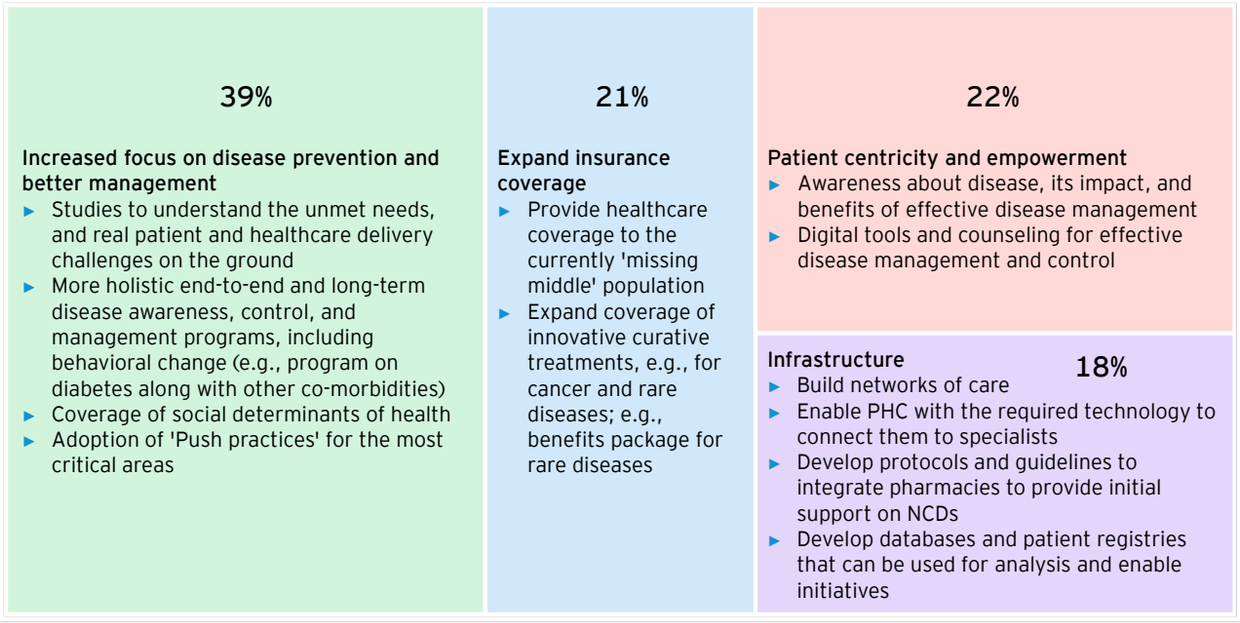
Sources: The Impact of Diabetes on Productivity in India | Diabetes Care | American Diabetes Association (diabetesjournals.org), CDC

Another critical finding during the primary research was the necessity for programs aimed at empowering patients and healthcare providers throughout their healthcare and disease journey. Both on a global scale and within India, there is a growing emphasis on patient-centric approaches. The shift from a "sick care" mentality to a true healthcare mindset requires involvement from the population, starting even before someone becomes ill. It is imperative to raise awareness among the masses about various diseases and underscore the significance of early diagnosis and appropriate disease management. Equally important is the empowerment of individuals with tools and data that enable them to assume a more significant role in their healthcare. This can be accomplished through a strategy that fosters patient empowerment throughout their healthcare journey.

> *We need some push care. Identify cohorts of people, make an individual doctor or community health worker or case manager responsible for that. They track the risk of somebody going off treatment and take appropriate action to ensure proper management.*
>
> **Visiting Scientist**
> Banyan Academy of Leadership in Mental Health

[70] Early cancer diagnosis saves lives, cuts treatment costs (who.int)

CXO survey: priorities for improving healthcare access and patient outcomes



Diabetes, cancer, and cardiovascular diseases are increasingly affecting younger individuals in India. This trend has significant economic implications, given that India's youthful population and talent are among its primary assets. To address this, there is a pressing need for well-structured, long-term programs aimed at disease control and management in India.

Managing Director, India

leading global pharma company

As a common behavioral pattern, many individuals tend to postpone seeking medical attention until their conditions have significantly deteriorated, making the situation more challenging. For instance, early cancer screening is significantly underutilized in India, resulting in late-stage diagnosis that severely impacts the economic condition and quality of life of cancer patients.

It is important to change the health-seeking behavior. To address this issue, it is imperative to identify motivators specific to various communities and design programs tailored to their respective incentives, such as self-employed people, shopkeepers, rural residents, etc. The initial step involves education, followed by providing sustained support throughout the treatment and funding process.

Chairperson & MD

leading Home Healthcare company, India

Social determinants also play an important role in health outcomes. For example, we are providing chemotherapy to patients. However, after two to three cycles, patients do not turn up because they are not able to tolerate that chemotherapy since they do not have nutritional support.

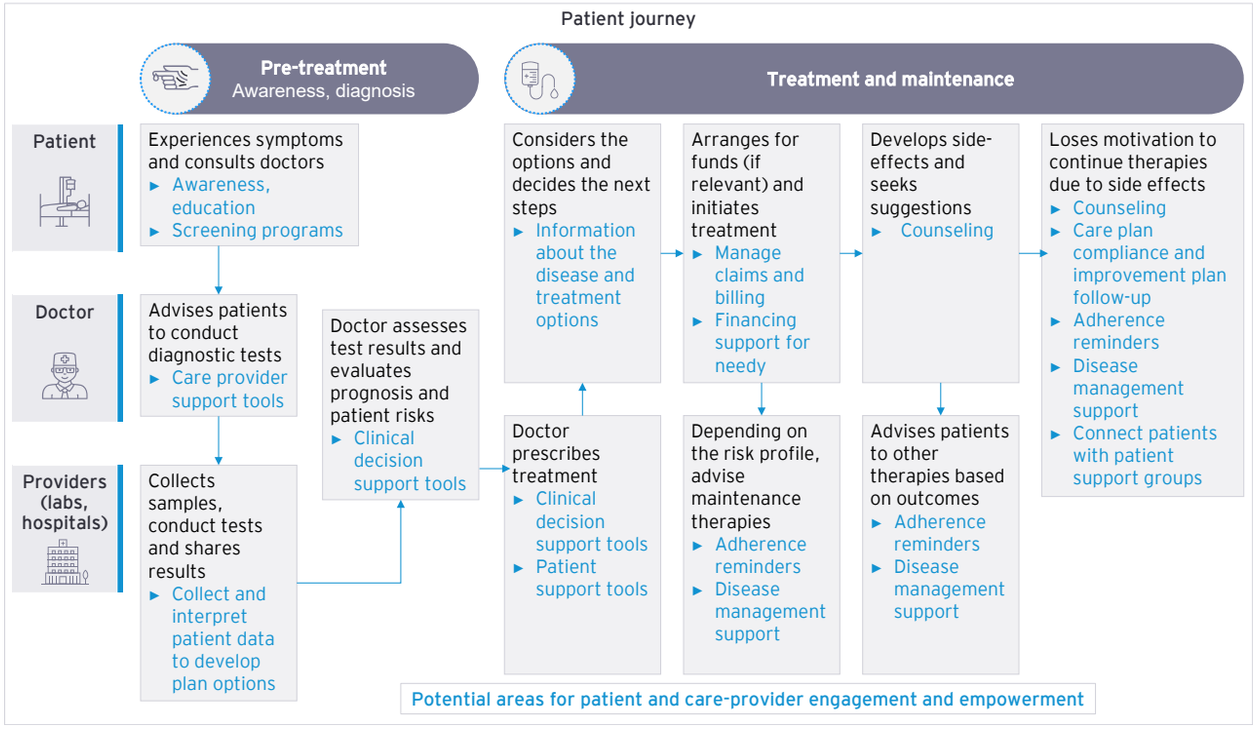
CEO
of a leading NGO, India

There is a need for field-based studies to actually understand and identify where the real challenges and unmet needs are. The primary health care should work as the eyes and ears of the government and hear from the patients. It is important to understand what is it that people require and then translate that into large scale public programs.

CEO
of a leading NGO, India

Patient journey: patient engagement and empowerment

A typical patient journey starts with the appearance of symptoms. The patient then takes some time to read about the symptoms, and finally goes to a doctor if the symptoms persist. The doctor suggests diagnostics. After the diagnostics come, the physician prescribes the treatment. Then starts the hard part of disease management, which includes adherence to medicines, lifestyle changes, timely follow-ups with the doctors, etc.



Sources: EY analysis

Pharma companies, in collaboration with government and other associations, are playing a very active role across the patient journey. Multiple instances of disease-specific programs exist, designed to assist patients and healthcare providers in enhancing their overall health outcomes. Below are some interesting examples:

Biocon oral cancer control program (2011) is a technology enabled (m-health, artificial intelligence), cost-effective, door-to-door oral cancer screening, diagnosis and treatment program. Since its inception, 4,000+ individuals have been screened, of which 25% have been diagnosed and treated for abnormal lesions[71].

Biocon: technology-enabled, cost-effective, sustainable national oral cancer control program

Cancer control program

- **Training for frontline healthcare workers (FHPs)** to use mHealth and effectively screen patients
- Frontline healthcare workers (FHPs) capture diagnostic data and images in mobile phone with clinical decision algorithm
- Patients monitored and counseled over call by FHP

- **Door-to-door oral cancer screening** along with counseling sessions
- **Dental camps** to screen and treat dental caries and periodontal diseases.
- Remote diagnostics and surveillance by specialists

Technology integration

- **Mobile-phone-based platform (mHealth)** for oral cancer screening and surveillance: evidence-based screening for every patient correlated with their habit, history, and clinically relevant photographs
- **AI device for automated and accurate diagnosis of pre-cancerous lesions**
- Device development: in partnership with Indian Institute of Science (IISc)
- AI algorithm development: in partnership with IIIT Hyderabad
- Image dataset collection for creation of algorithm: outpatient clinics of the Department of Oral Medicine, Radiology at KLE Society Institute of Dental Sciences, outreach programmes

Impact

Oral cancer screening (as of 18 Nov 2022)

4,000+	25%
individuals screened	diagnosed and treated for abnormal lesions

Dental camps

13,000+	19%
individuals screened	diagnosed and treated for dental problems

Sources: company reports

[71] BioconFoundationAnnualReport2021-22

Biocon - eLAJ smart clinic program Support primary healthcare system for non-communicable diseases (NCDs)

Program details

Technology enabled transformation of Primary Health Centres (PHCs) into comprehensive one-point treatment facilities with digitized clinical consultation, electronic medical records, advanced diagnostic services and screening for NCDs

- **Community outreach program**: Trained field health workers conduct regular household visits and free consultation programs to raise awareness and conduct population-based surveillance for **NCDs**

Program impact

Started in partnership with the Government of Karnataka (2016)

The program has been adopted at 20 government PHCs through a public-private partnership (PPP), and three clinics run by the Biocon Foundation (as of 18 Nov 2022)

71,000	46,000	22,000+
patient visits	patients benefited	hematology and biochemistry laboratory investigation

Sources: company reports

Roche Blue Tree Program (2015) helps patients and caregivers navigate the complexities of cancer, hemophilia, and other rare diseases' treatment. It addresses challenges like diagnosis, reimbursement, affordability, and adherence. The company introduced the Blue Tree 2.0 mobile app in 2022 to enhance the patient and healthcare professional experience by simplifying enrollment, providing convenient access to multiple support services, thereby increasing the scale and reach of the program to patients. More than 11,000 patients have benefitted from the program since launch. The program was showcased as an effective patient support program at the Unified General Assembly week[72].

The Blue Tree program - Pan-oncology patient support initiative launched in 2015

Support across patient journey for cancer, hemophilia, and rare disease

Blue Tree version 1

Disease awareness and testing

- Material provided by doctors in 9 languages across 5 different types of cancers (breast, lung, colorectal, ovarian, and cervical cancer).
- Biomarker testing support for patients who cannot afford, or do not have access to quality testing facilities

Funding solutions: helps eligible patients find funding from a range of sources, including government, local health authorities, charities, and preferential loans

Adherence support: program coordinators reach out to the patient at set frequency, especially before and after infusion cycles.

- Patients are additionally supported with patient access programmes for all key products
- Medicine is delivered to the patient's home in remote locations where access to treatment can be a challenge

Blue Tree 2.0 (2022): companion mobile app to simplify treatment journey and improve access

- Digital enrollment
- Requests for free drug assistance
- Doorstep delivery services of drugs, and a live order tracker
- Advance notifications to patients on their upcoming infusion schedules
- Free expert consultations on emotional wellbeing, physiotherapy, healthy eating, etc.
- Diagnostic support services
- 24*7 helpline, reminder and counselling

Impact *(as of November 8, 2023)*

11,000+	1,800+	750+ doctors	pan-India partnerships
patients benefitted across India	diagnostic tests conducted	300+ cancer care centers	

This integrated approach for patient support also empowers doctors to initiate therapy as early as possible, ensuring delivery of optimal outcomes

The Blue Tree Program was showcased as an effective and unique patient support program at the United General Assembly (UNGA) Week, as part of the 72nd session of the UNGA in Sep'2017

Sources: company reports, Impact

[72] Roche | The Blue Tree Program (rocheindia.com)

Sanofi's comprehensive diabetes programs are a well-integrated portfolio of care offerings tailored to both adults and children. Notably, their Saath 7 initiative stands out as one of the longest-running programs in the industry dedicated to diabetes management – the program was launched in 2003 and has continued since then making a difference in lives of more than 400,000 patients. The initiatives encompass a wide spectrum of activities, ranging from general diabetes awareness campaigns to specialized programs addressing behavioral aspects associated with diabetes.

The company has also initiated 'Diabetes with dignity' program for rural areas to assess feasibility and effectiveness of a model for enhanced care of adult diabetes with support from Accredited Social Health Activists (ASHA) workers. The pilot has been successful and the company plans to scale the program and share learnings for broader adoption[73],[74].

Sanofi – integrated care offerings in diabetes

Patient support programs

Saath 7

One of the industry's longest running patient support programs for diabetes in India (continuing since 2003)

- Daily, a team of nearly 100 counselors across 45 cities guides patients on their diet, exercise, and insulin administration.
- Unlimited on-demand calls with Clinical Nutritionist, Psychotherapist and Physiotherapist
- Personalised diabetes nutrition plan and healthy recipes

Diabetes with Dignity

Pilot program in a rural community of Pune district, Maharashtra to assess feasibility and effectiveness of a model for enhanced care of adult diabetes with support from ASHA workers.

- Educated Accredited Social Health Activists (ASHA workers)
- Built capacity of Auxiliary Nurse Midwife (ANM) and Multi-Purpose Workers (MPW) of sub centers
- Reoriented and educated medical officers at Primary Healthcare Centers
- Involved community-based organizations in raising awareness of diabetes and its complications

Partners: Chellaram Diabetes Institute; Public health foundation of India

Made a difference in the lives of >400,000 patients

- Sanofi will release a white paper on learnings and effectiveness to help scale-up and tackle diabetes burden in rural India.
- "Diabetes with Dignity" project showed that with the assistance of ASHA field workers, there is a direct improvement in HbA1c as well as qualitative aspects of life"

– Dr. UnniKrishnan, Chelledaram Diabetes Institute

Sources: company reports, Diabetes with dignity, Saath7

Type 1 diabetes (T1D) awareness programs

KiDS (Kids and Diabetes in Schools)

For children with type 1 diabetes (T1D)

Program objective:

Foster a culture of healthy lifestyle management in the school and communities. Included several behavior change activities:

- STEP challenge: cover 10K steps daily for three months
- Sakhar Free Shukrawar: students were taught recipes with healthy substitutes for sugar

Partners: International Diabetes Federation; Public Health of India

OneUp TREK

Program objective:

Demonstrated how people with T1D can take up any challenge if they regularly monitor their blood sugar, have carefully regulated meals, and scheduled insulin administration

Partners: International Diabetes Federation, Public Health of India; Udaan, Diabetes India

T1D challenge

Program objective:

A sporting activity brings together international team of T1D patients to raise awareness and encourage overall better diabetes management

Partners: World Diabetes Tour

- 1,50,000 students benefitted
- 2,400 participants in STEP challenge (1,200 parent-child teams)

23 young Indians successfully scaled Maharashtra's highest peak with OneUp TREK, India's first T1D challenge

Intolife.in – a diabetes dedicated website by Sanofi. Provides general information on diabetes, myths / facts, managing lifestyle, food and nutrition, diabetes risk score

Sources: company reports, KiDS

[73] Providing integrated care offerings in diabetes - Sanofi India

[74] IDF Kids

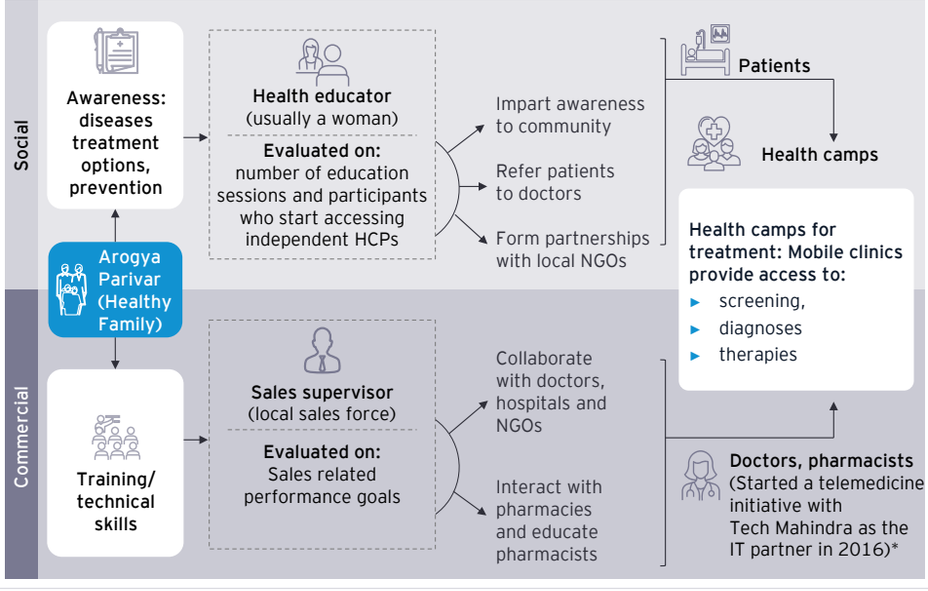
Digital apps from other companies for diabetes

Novo Nordisk	AstraZeneca	Cipla
Changing Diabetes® in Children	Beyond Sugar	Wellthy Care app

Sources: company reports

Novartis Healthy Family, also called Arogya Parivar Yojna (2007), is an initiative aimed at addressing the healthcare needs of underserved and rural communities. The Arogya Parivar Yojna combines a multi-faceted **approach**, including health awareness campaigns, the distribution of affordable and quality medicines, and the training of local health educators and pharmacists in an effort to bridge the healthcare gap and improve health outcomes for marginalized populations. The program is operational in 15+ states across India, covering more than 22,000 villages. The program achieved break even within 30 months of launch. Based on the success in India, the program has been extended to other countries such as Vietnam, Indonesia, and Kenya[75].

Case study: Novartis's Healthy Family (Arogya Parivar launched in 2007 in India)



Social Impact

- Operating in 15 states across India covering 22,000 villages
- 44,000 doctors covered to serve rural India
- 50+ million rural Indians impacted (as of November 8, 2023)

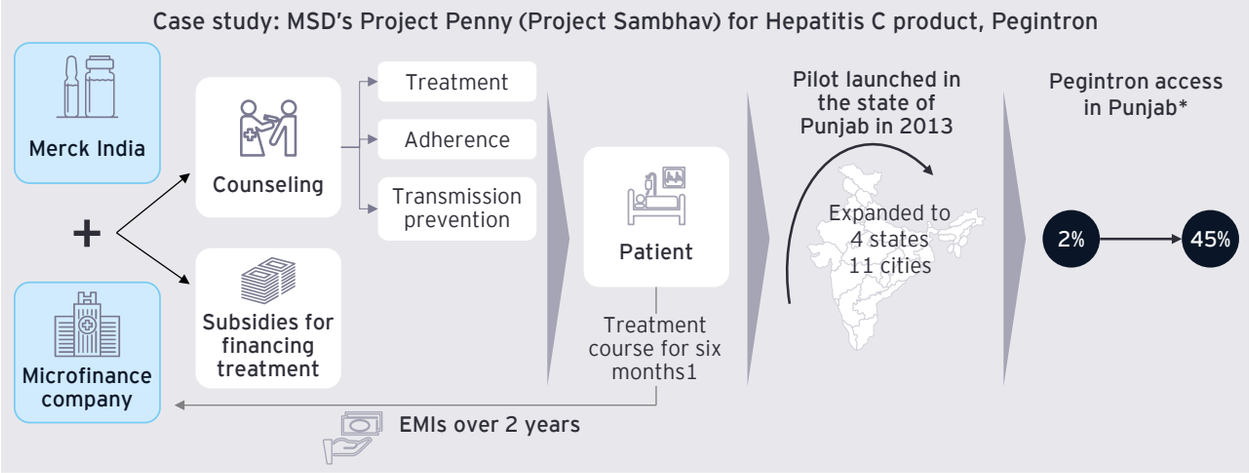
Business Impact

- Launched in Vietnam, Indonesia (2012) and Kenya (2013)
- Achieved break even within 30 months of launch
- As of 2017, the Healthy Family product portfolio in India, Vietnam and Kenya had grown to 51
- Increased sales by ~300 times in 10 years (as of 2017)

Sources: company reports, Novartis Health program

[75] Arogya Parivar | Novartis India

MSD's Project Penny (Project Sambhav - 2013) is a program for Hepatitis C awareness, prevention, treatment and adherence. Support is also offered for financing the treatment. Since launch first in Punjab, the **program** has been extended to several other states[76].



[1] Cost of treatment for the six-month period is ~ US$ 3750; average per capita income in India – US$ 1631
*Patients with limited or no insurance coverage
Source: https://www.iapo.org.uk/sites/default/files/files/IAPO%20PSD%20FACT%20SHEET%202.pdf (as of 2016)

In the future, it is crucial to foster greater collaboration among industry stakeholders, government entities, and start-ups to fully unlock the potential of patient initiatives and achieve enhanced outcomes.

[76] IAPO PSD FACT SHEET 2.pdf

Key highlights

Healthcare challenges in India:

- The most pressing healthcare challenges include escalating disease burden of non-communicable diseases (NCDs) and the substantial gap between healthcare supply and demand.
- NCDs account for ~66% of deaths in India.
- India falls short of WHO recommendations for healthcare professionals and infrastructure, with urban-rural disparities further widening the gap.

Government programs are expected to increase access to healthcare and improve health outcomes:

- **Ayushman Bharat:** the program has two components 1) Health and Wellness Centres (HWCs) to deliver comprehensive Primary Healthcare (PHC) services, free essential drugs and diagnostic services to the entire population; and 2) Pradhan Mantri Jan Arogya Yojana (PMJAY) for improving access to hospitalization services at secondary and tertiary level health facilities for bottom 50% of the population
- **Ayushman Bharat Digital Mission (ABDM)** was launched in 2021 with the goal to digitally connect various stakeholders within the healthcare ecosystem and facilitate the provision of digital healthcare services to the country's citizens, marking significant stride toward achieving integrated, affordable, efficient and inclusive healthcare.
  - ABDM strives to enhance the efficiency, efficacy, affordability, and accessibility of healthcare delivery in India.
  - Government has set up an ABDM sandbox to integrate digital solutions, including those from start-ups, to ABDM ecosystem
  - This integrated healthcare approach is expected to facilitate access, reduce reach costs, improve healthcare delivery, and have a profound impact on patient health outcomes in a resource-constrained country.

Focus on patient centricity and shift from sick care to well-being – CXO survey findings:

- CXO survey underscored the necessity for enduring, comprehensive programs aimed at early diagnosis and treatment of cancer, and for controlling and managing India's most prevalent non-communicable diseases (NCDs). Such programs promise a twofold advantage– they can enhance healthcare quality while simultaneously reducing the overall healthcare expenditure.
- To achieve this, it is necessary to have programs aimed at empowering patients and healthcare providers throughout their healthcare and disease journey.
- Many programs have been launched by global and domestic pharma companies in collaboration with government and other stakeholders for awareness, early diagnosis, disease management and treatment.
- In the future, it is crucial to foster greater collaboration among industry stakeholders, government entities, and start-ups to fully unlock the potential of patient initiatives and achieve enhanced outcomes

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Notes

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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'.

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