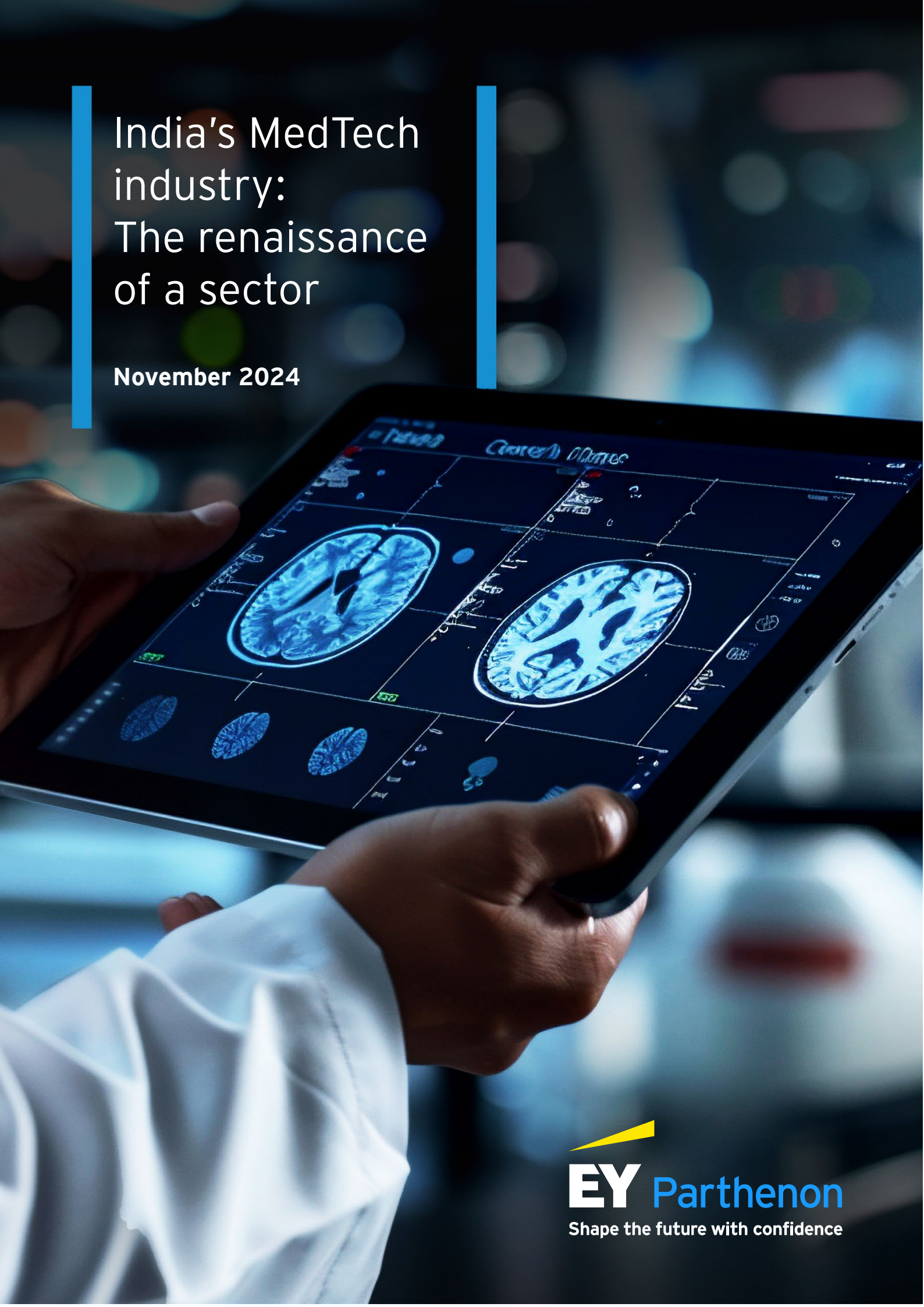
India's MedTech industry: The renaissance of a sector

November 2024



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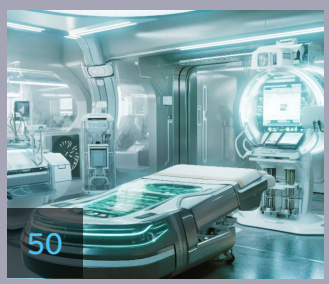

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Paving the way: Ascending the value chain with digital led innovation and start-up momentum

Foreword

Rajiv Nath
Managing Director

Hindustan Syringes & Medical Devices Ltd &

Forum Coordinator

Association of Indian Medical Device Industry (AiMeD)

We appreciate the endeavor of EY—***Shape the future with confidence***. The insights and quality services you provide help foster trust and confidence in capital markets and economies globally.

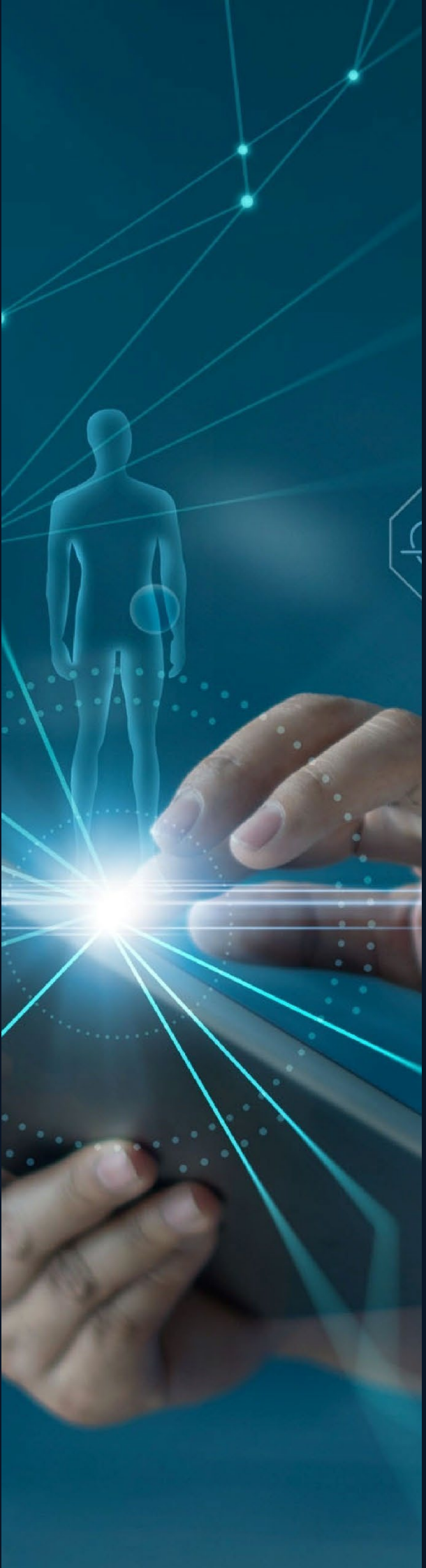
Congratulations to EY for publishing the Medical Devices Report, which maps the growth of this sector and outlines key drivers for positioning India as a leading manufacturing hub of medical devices, while providing a forward-looking perspective.

It is a timely follow up on the National Medical Device Policy of 2023, capturing the Government of India's 'Make in India' and 'Develop in India' initiatives. It conveys valuable feedback from medical device manufacturers eager to collaborate with the Government of India and the Department of Pharmaceuticals to achieve the vision of India as a top-five global medical device manufacturing hub. With appropriate policies and strategies, this sector has the potential to increase exports from the current level of INR32,000 crore to INR100,000 crore in the next five to seven years.

We wish to offer our gratitude to Mr. Suresh Subramanian, Ms. Rajni Sadana and the EY team @ EY for their sincere efforts as thought leaders, helping to guide and support the advancement of India's Medical Device Sector.

With best wishes,

Rajiv Nath



Foreword

Probir Das

Director, MTaI (Medical Technology Association of India)

Medical technology is 'miracle' technology. In the last century, it has repeatedly evolved to improve quality of life, reduce pain and extend lifespan. Over the past three decades, the rapid expansion of the Indian healthcare sector has significantly increased medical technology uptake in the country. This growing demand is set to continue, while India is also becoming a global hub of the MedTech supply.

India's ability to deliver global quality at an efficient cost is making it a go-to destination for innovation and manufacturing, attracting both established global corporations and emerging Indian players. The MedTech industry thrives on its ability to create high-quality therapeutic impact, agility in innovation, and a culture of relentless improvement. India has much to offer across these three pillars.

Over the past three and a half decades, I have been fortunate to work with global corporations that bet on 'Make in India' or 'Innovate in India' strategies well ahead of the curve, helping to build India's MedTech manufacturing ecosystem in India, and enhance therapy adoption to improve physician skills and patient care.

Looking ahead, I see the Indian MedTech opportunity multiply to US$50 billion by 2030 on the basis of three key growth drivers:

- **Precision engineering R&D and manufacturing**: India's well-developed supply side ecosystem in automotive, aerospace, defense, telecom and consumer electronics offers top-class talent, capability and scale.
- **Improved policy framework**: The combination of PLI, MedTech parks and regulatory strengthening makes Indian manufacturing more and more competitive globally.
- **Growth funding**: Aggressive interest of PEs, top domestic pharma, and public markets in scaling India's MedTech will add significant tailwind over and above MNC investments in India.

As a country, we must pursue the path of high quality, global standardization, and an efficiency-enhanced value chain to secure India's place on the global MedTech map permanently.

Foreword

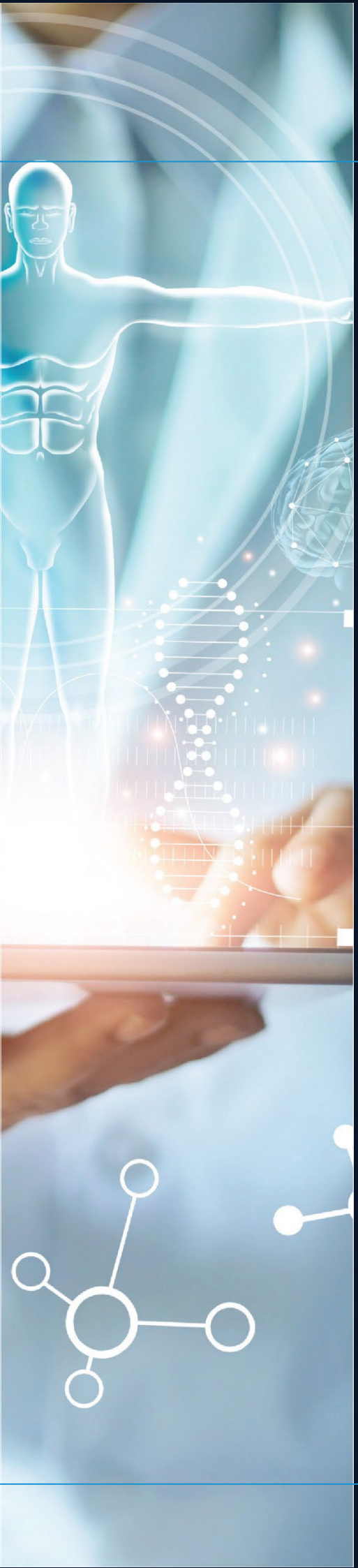
Suresh Subramanian
Partner, National Life Sciences Leader, EY India

As we witness the dawn of a new era in healthcare innovation, India's MedTech sector stands at a historic inflection point. The journey from a US$12 billion industry in 2023-24 to a projected US$50 billion powerhouse by 2030 represents more than just numbers; it symbolizes India's transformation from a major importer to a global hub of medical technology innovation and manufacturing. This transformation aligns perfectly with the global MedTech market's trajectory toward US$897 billion by 2028, positioning India as a crucial player in the worldwide healthcare technology landscape.

This report explores the sector's dual potential of harnessing rising domestic demand and tapping into global markets with innovative medical devices. Key drivers that will propel the MedTech sector's growth include shifting disease patterns and healthcare delivery trends, demographic and socioeconomic factors, and the evolving MedTech ecosystem. Increasing preventive healthcare awareness and the rising prevalence of chronic conditions are creating an unprecedented demand for advanced medical solutions. Rising income levels, growing healthcare infrastructure and the expanded reach of Pradhan Mantri Jan Arogya Yojana (PM-JAY) insurance, along with innovative digital platforms like Ayushman Bharat Digital Mission (ABDM), are democratizing access to advanced medical technologies nationwide. Growing medical tourism is generating parallel demand streams for both affordable and innovative medical devices.

Alongside the expanding MedTech segment, the convergence of pharma and MedTech presents new opportunities for innovation in complex medical devices, digital therapeutics, and solutions for healthcare providers, paving the way for integrated healthcare advancements.

The government's strategic vision has been instrumental in catalyzing this transformation. Key policy initiatives, including the Medical Device Rules and the National Medical Devices Policy, coupled with innovative schemes like the Production Linked Incentive (PLI) program and the establishment of medical device parks, have created a robust foundation for growth. India's recent inclusion in the International Medical Device Regulators Forum (IMDRF) marks a significant milestone, underscoring the country's commitment to global quality standards and opening new avenues for international collaboration.



Confidence from the investment community in this transformation is evident: medical devices have attracted over US$1.2 billion in PE/VC investments by August 2024, the highest in five years. The sector has also seen significant FDI inflow, with US$425 million invested in the first half of 2023-24 alone.

What makes India's MedTech story particularly compelling is the emergence of a sophisticated ecosystem where domestic innovation meets global excellence. Indian MedTech companies are charting growth through four strategic approaches: actively targeting import-dependent segments for local production, pursuing product lines with lower focus from global MNCs, establishing dominance in price-sensitive markets, and expanding their portfolios through global collaborations. This indigenous innovation is complemented by global MedTech MNCs strengthening their presence in India through strategic partnerships, localized manufacturing and product digitalization. The growing establishment of Global Capability Centers (GCCs) and the rise of Contract Research Development and Manufacturing Organizations (CRDMOs) further solidify India's position as a comprehensive ecosystem for innovation and manufacturing.

Our propitiatory analysis of established companies and start-ups shows that innovation is flourishing across subsegments, from therapeutic devices to diagnostic imaging and consumables. Companies are focusing on improving safety, enhancing efficacy, increasing accessibility and affordability, and optimizing efficiency. Digital innovations such as AI and data analytics remain at the core of these advancements, driving sophisticated, connected healthcare and enabling a shift towards an integrated healthcare landscape.

This report highlights five future growth areas the industry needs to shape its path toward becoming a global manufacturing hub: 'Enhancing manufacturing competitiveness', 'Strengthening the entire supply chain', 'Harnessing India's IT and digital prowess', 'Elevating commitment to quality excellence' and 'Embracing value-driven market access'. Various initiatives are already underway, setting the foundation for sustained progress.

The path ahead is both exciting and challenging, demanding a sustained focus on quality, continuous innovation and unwavering commitment to global standards. Yet, with the strong foundation we have built and the collective expertise of our industry, I am confident in our ability to achieve and exceed our ambitious goals.

Here's to the future of Indian MedTech – a future that promises to redefine global healthcare through indigenous innovation, inclusive access and unwavering excellence. Together, we stand at the threshold of creating a new benchmark in medical technology, poised to impact billions of lives globally through accessible, innovative healthcare solutions.

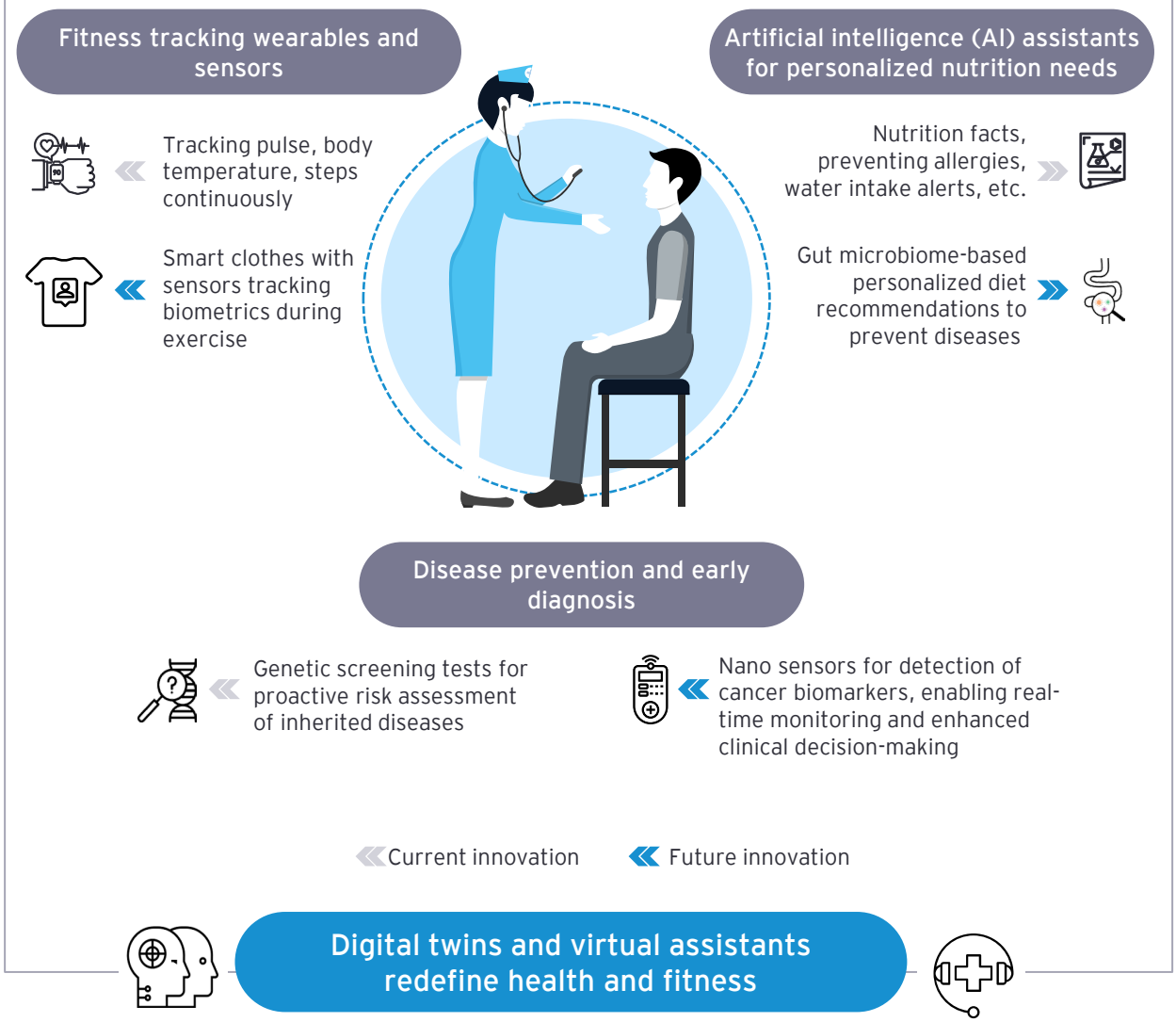
Introduction

Advancing healthcare through MedTech innovation for personalized and predictive healing

Medical device sector is advancing at an unprecedented pace. From Class A wearables to Class D surgical robotics, advanced technologies and the strategic integration of digital and data in devices are redefining healthcare. This spectrum of innovation, including advanced diagnostics, biomarkers, point-of-care solutions, and smart implants and prosthetics, is driving a strategic evolution towards personalized, preventive and predictive healthcare. This shift is completely redefining how we maintain our health, and the way diseases are diagnosed, treated, monitored and managed.

Here is a glimpse into the future of medical devices and how it continues to transform healthcare experience across the patient journey.

Staying ahead of illness: Nurturing lifelong health



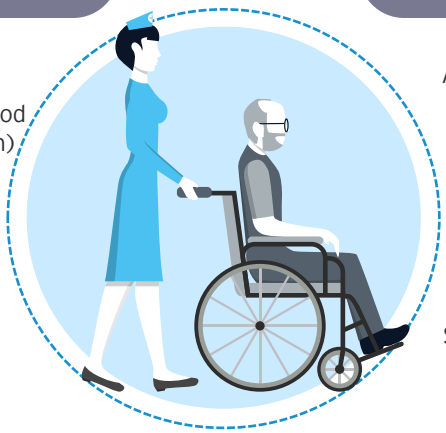
Ageless autonomy: Reinventing senior care and independence

Continuous monitoring of vitals with wearables

- Wearables tracking physiological (e.g., electrocardiogram, blood pressure, blood oxygen) and biochemical parameters (e.g., glucose, cortisol, electrolytes)
- Wearables tracking onset of brain disorders, e.g., wrist band tracking amyloid in brain for detecting potential onset of Alzheimer

Connected home surveillance and alerts

- AI-based surveillance for fall detection at home; alerts to family and caregivers
- Sensor network in entire home monitoring behavior, posture and movement of elders



Home diagnosis

- Home diagnostic kits for rapid health status assessment
- Smart diagnostic toilets with integrated biosensors to enable everyday health monitoring and continuous tracking

Current innovation Future innovation

Robotic assistants and AI tools revolutionize aging in place

Improving quality of life: Proactive approach to lifestyle diseases, e.g., Diabetes

Non-invasive continuous glucose monitoring (CGM)

- CGM wearables with trend analysis to understand glucose patterns
- Smart contact lenses that measure glucose levels in tears
- Wearables with hypo- and hyper-glycaemia alerts

Intelligent insulin delivery

- AI-based smart insulin pens that tailor dosages in response to real-time glucose readings
- More integrated and accurate artificial pancreas systems that deliver tailored insulin dose based on real-time glucose monitoring data

Use of Software-as-medical-device (SaMD) for personalized care and management

- Software that uses historical data to predict the risk of diabetes-related complications, prompting early intervention
- SaMD integrating real-time data from multiple sources, including wearables, health records, and patient-reported outcomes, enables multidisciplinary teams to deliver connected and predictive care

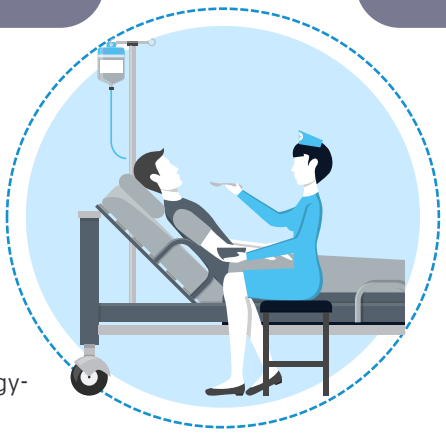
Current innovation Future innovation

Digital and data breakthroughs enabling non-invasive, personalized, real-time and predictive management

Enduring hope: Advances in chronic disease care, e.g., Cancer

Early diagnosis and monitoring

- AI-enabled imaging devices for earlier and more precise detection
- Non-invasive blood tests (liquid biopsies) to identify and monitor cancer at its earliest stages
- Microfluidic technology-based point-of-care (POC) diagnostics providing instantaneous diagnosis



Advanced treatment modalities

- Improved imaging, targeted radiation delivery, robotic surgery enhancing patient outcomes
- Advanced modalities (e.g., FLASH radiotherapy, ultrasound waves, tumor treating fields) with fewer side effects and potential to cure the disease

Convergence of drugs and devices

- Personalized medicine and biomarkers with companion diagnostics
- Advanced genome sequencing and gene editing techniques for targeted therapies
- Advanced drug device combinations for localized delivery and improved outcomes, e.g., nanoparticle-based radio enhancers, magnetic drug targeting, thermosensitive liposomes)

Current innovation Future innovation

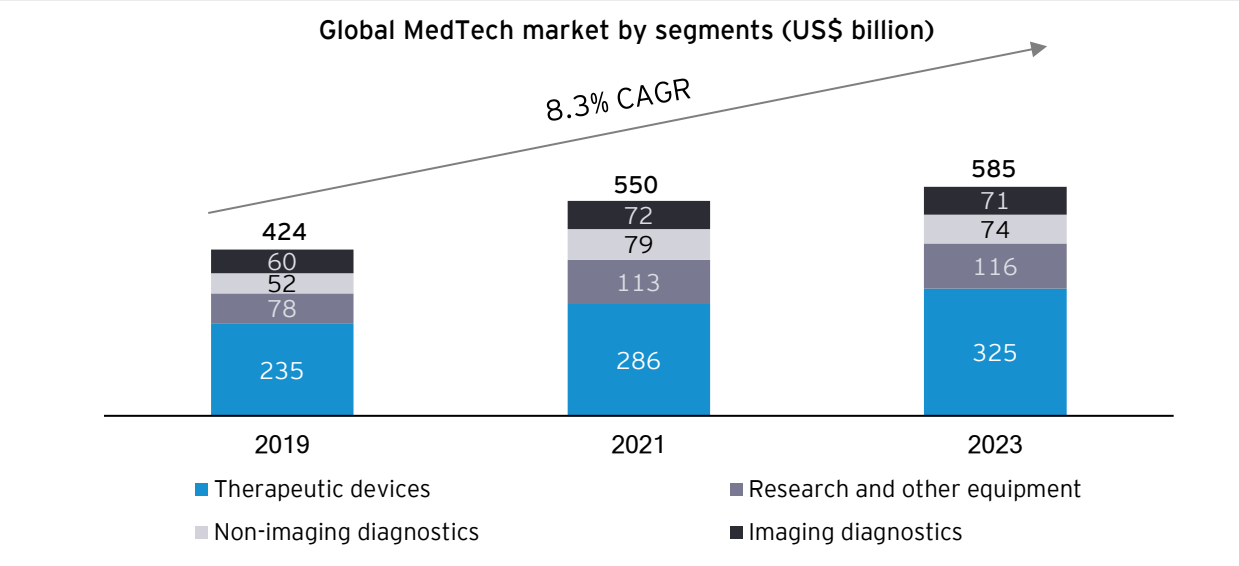
Advanced planning, management and connected care platforms to revolutionize cancer care

01 MedTech mosaic: Mapping the growth of the Indian and global MedTech industry

Global MedTech industry overview

Market size and growth drivers

According to the 'Pulse of the MedTech Industry' report by EY, the global MedTech industry was valued at US$587.6 billion in 2023, growing at a compound annual growth rate (CAGR) of ~8.3% in the four-year period from 2019 to 2023. [1] The industry is expected to continue the growth trajectory and is projected to reach US$897 billion by 2028. [2] This growth will be driven by a combination of factors, including transformations in the healthcare sector, changing disease patterns, and the swift adoption of digital technologies.



Notes:

Data shown in this chart is for the US and European public companies only

Some sales are attributed to 'others' segment, which is not highlighted in the chart. In 2023, the 'others' segment contributed approximately US$2b, bringing total market size to US$587.6b. The CAGR calculation includes sales from 'other' segment.

Source: EY analysis, Capital IQ, company financial reporting

Global MedTech industry: Split by segments

The global medical devices market consists of four major segments: 'therapeutic devices', 'research and other equipment', 'non-imaging diagnostics' and 'imaging diagnostics'.

Therapeutic devices: This is the largest medical device segment. It comprises a wide array of devices and implants for the treatment and prevention of diseases across therapy areas. Within therapeutic devices, notable sub-segments include cardiology, orthopedics, oncology, dental and hearing aids. Emerging trends in this segment include the launch of smart devices and implants, robotic-assisted surgery systems for precision procedures, and minimally invasive techniques that enhance patient safety, convenience, and health outcomes.

Additionally, the use of AI (Artificial Intelligence) and ML (Machine Learning) algorithms, whether embedded in devices or as independent solutions, is gaining traction for clinical decision support and for improved workflow.

Research and other equipment: This segment encompasses a diverse range of life science tools and analytical devices. Its growth is expected to be driven by the surging demand for research and manufacturing of advanced next generation therapeutics, such as cell and gene therapies and complex biologics.

Non-imaging diagnostics (in-vitro diagnostics): This category includes, for example, molecular diagnostics for genetic testing and infectious disease diagnosis, POC testing devices, and immunoassays. The growth in the segment is anticipated to be

[1] Pulse of the MedTech Industry Report 2024

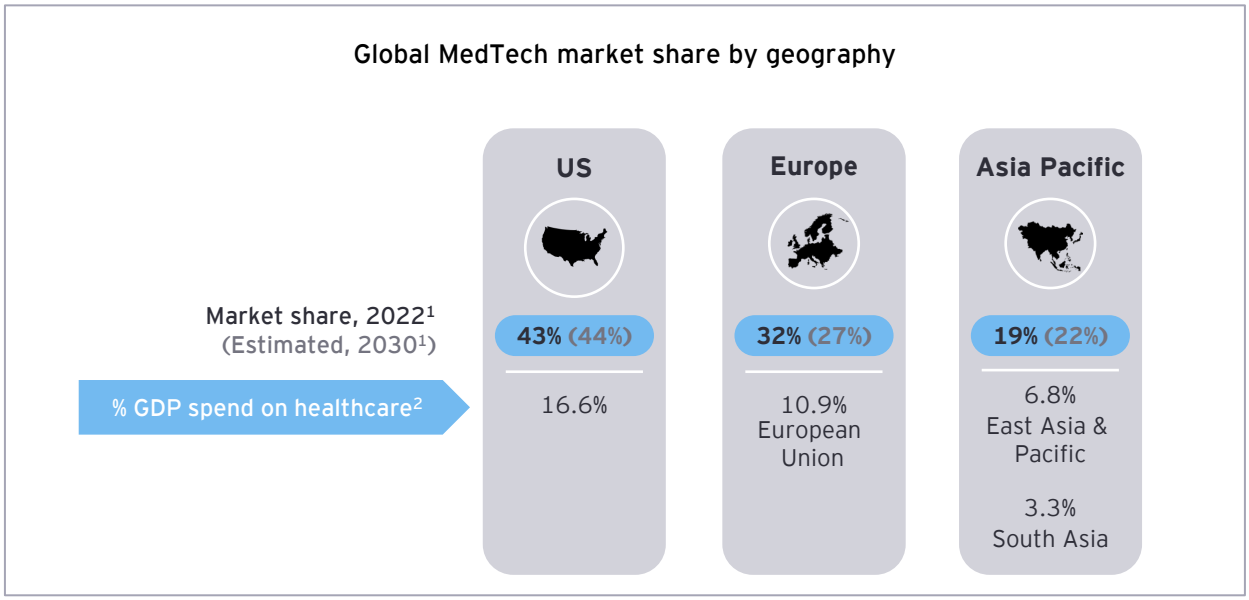
[2] Analysis from Evaluate medical device market size report (accessed on 17 Sep'24)

propelled by the broadening array of home diagnostics including non-invasive self-tests and continuous glucose monitoring (CGM) devices, and the emergence of digital solutions, such as digital pathology and image analysis, cloud-based sample management, and integrated laboratory software solutions.

Imaging diagnostics: This segment encompasses in-vivo imaging technologies such as MRI (Magnetic Resonance Imaging), CT (Computed Tomography) scans, X-Rays, ultrasound imaging, and PET (Positron Emission Tomography) scans. The growth in the segment is expected to be driven by the enhancement of diagnostics and surgical imaging equipment, particularly with the integration of AI/ML applications. Additionally, the introduction of portable diagnostic equipment (e.g., handheld ultrasound devices) and sustainable, energy-efficient devices (e.g., helium free MRI systems, power-saving dual source CT scanners) are anticipated to enhance accessibility and affordability.

Global MedTech industry: Split by regions

The United States (US) drives the global MedTech industry, hosting about 60% of the top 30 MedTech companies[3] and holding roughly 43% of the market share. This dominance reflects the country's advanced healthcare infrastructure and high healthcare spending. Europe and the Asia-Pacific region follow with market shares of roughly 32% and 19%, respectively, while the rest of the world (RoW) accounts for the remaining 6%.[4] By 2030, the US and RoW markets are forecasted to retain the share. Europe is expected to lose some market share to the Asia-Pacific region which is anticipated to register highest growth during the period driven by improving healthcare infrastructure, government initiatives, and the increasing prevalence of chronic diseases.



Sources: 1. Market Research Future report "Global medical devices market research report forecast to 2030" (published in 2022), 2. Current health expenditure (% of GDP), Worldbank.org (website accessed on 17 Sep'24),

[3] Final Boosting of Medical Devices Industry - Report - 2023.pdf (pharmaceuticals.gov.in)

[4] Market Research Future report "GLOBAL MEDICAL DEVICES MARKET RESEARCH REPORT FORECAST TO 2030", 2022

Indian MedTech industry overview

Market size

The medical device sector, recognized as a sunrise industry in India, played a crucial role during the COVID-19 pandemic. It swiftly manufactured and exported vital supplies, including ventilators, Rapid Antigen Test kits, RT-PCR kits, infrared thermometers, PPE kits, and N-95 masks.

According to the Association of Indian Medical Device Industry (AIMED), the Indian medical device market was valued at approximately US$12 billion in 2023-24. The market is expected to grow to US$50 billion by 2030. At present, the market ranks among the top 20 countries globally, with a market share of 1.65%. [5] This share is expected to rise between 10% and 12% within the next 25 years. [6]

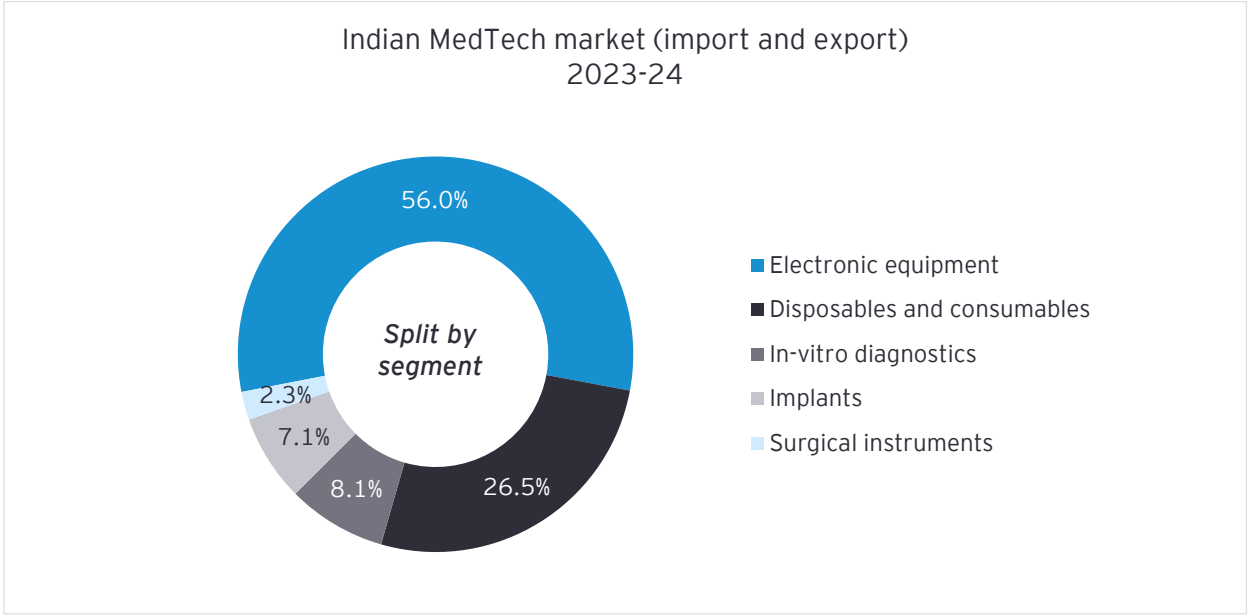
Key growth drivers

The Indian MedTech industry shares some of the global growth drivers, such as the rising incidence of chronic illnesses, an aging population, and a growing focus on preventive healthcare. In addition, India's MedTech sector is driven by various socioeconomic and demographic influences, along with a rapidly evolving industry landscape bolstered by favorable policies. Chapter 2 of this report will delve into these drivers in detail.

Indian MedTech market: Split by segment

In India, the medical device sector is categorized into five primary segments: 'electronic equipment,' 'in-vitro diagnostics,' 'disposables and consumables,' 'surgical instruments,' and 'implants.' The trade dynamics section of this chapter delves into the various types of devices spanning these segments. Digital technology plays a transformative role within each segment, enhancing the precision, functionality, and effectiveness of medical devices. Such digital solutions, including Software as a Medical Device (SaMD), are discussed in depth in Chapter 4 of the report.

The industry is primarily dominated by the 'electronic equipment' and 'disposables and consumables' categories, which together constituted 82.5% of the combined import and export market in 2023-2024. [7] Of this significant portion, 'electronic equipment' commands the majority with a 56% share, and 'disposables and consumables' contribute 26.5%. The remaining 17.5% of the market is shared among 'in-vitro diagnostics' at 8.1%, 'implants' at 7.1%, and 'surgical instruments' at 2.3%.



Majority of Indian medical device manufacturers specialize in the 'disposables and consumables' segment, mostly catering to the local consumption. Multinational corporations (MNCs) lead the high-tech

[5] Medical Devices Industry in India – Market Share, Reports, Growth & Scope | IBEF (accessed on 17 Sep'24)

[6] Medical Device Industry: Invest India (accessed on 17 Sep'24)
[7] Association of Indian Medical Device Industry (AIMED)

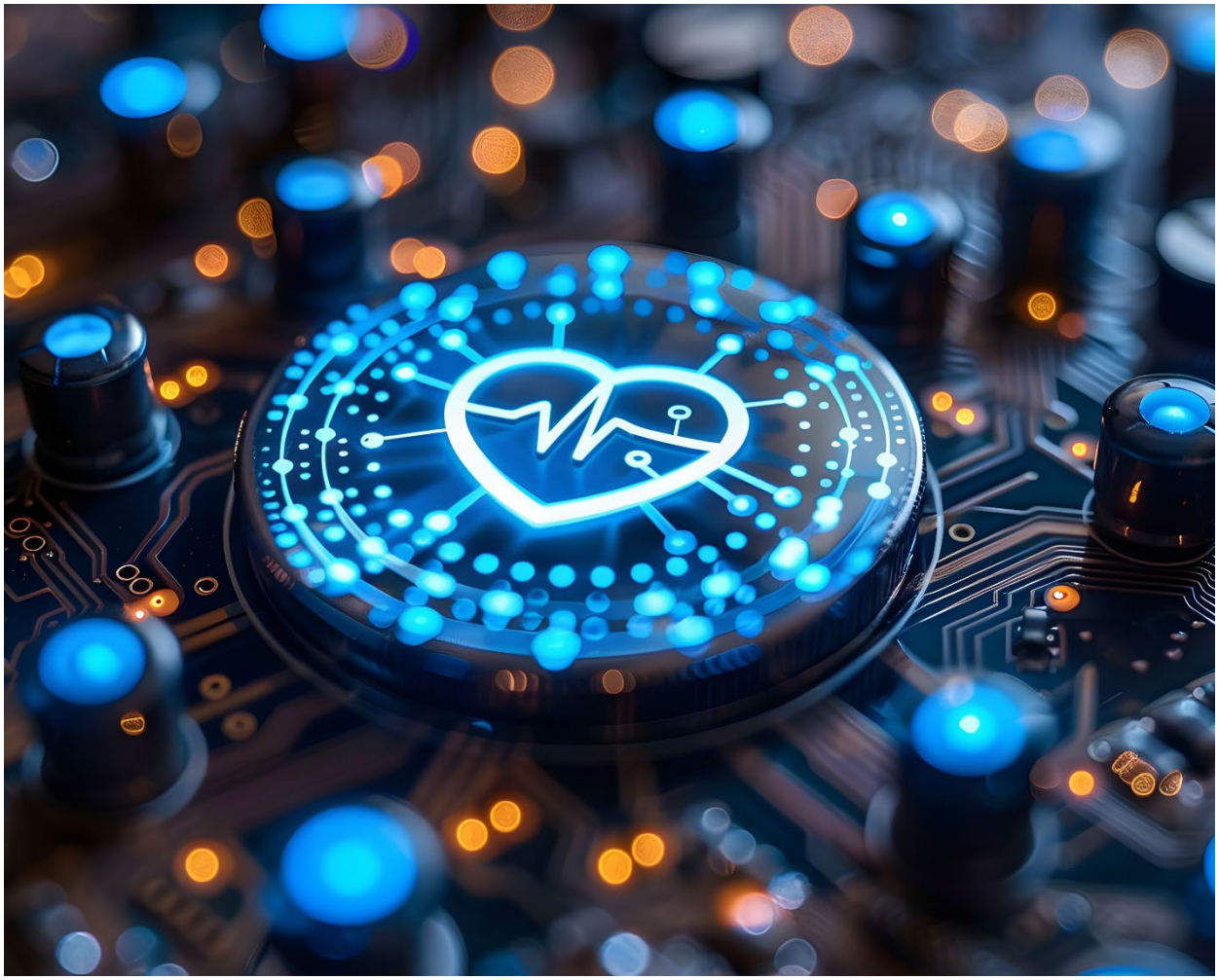
segment of the medical devices market with extensive service networks. [8]

Trade dynamics

Export trends: Key export destinations and leading product categories

India has achieved notable expansion in the export of medical devices, achieving a CAGR of around 14% from FY2019-20 to FY2023-24. In the FY 2023-24 alone, the country's medical device exports were valued at US$3.8 billion, reflecting a 13.5% increase from the year before. The United States stood as the top export market, receiving 18% of India's medical device exports. This was followed by Germany at 5.4%, China at 4.5%, Netherlands at 3.8% and Brazil at 2.4%. Together, these five countries constituted approximately 34% of India's total medical device exports. [9]

India's export portfolio includes products across various segments, such as PPE, diagnostic kits, sanitizers, surgical gloves, X-Ray tubes and implants. In 2023-24, the 'disposables and consumables' category represented nearly half of India's medical device exports driven by India's competitive edge in producing high-volume, low-cost medical devices within this segment. The 'electronic equipment' segment was the next largest, comprising 38% of the total medical device exports.



[8] Study on evaluation for the scheme of domestic promotion and publicity (dpp)" (pharmaceuticals.gov.in)

[9] Association of Indian Medical Device Industry (AIMED), Currency conversion rate (as of 3 Sep'24): 1 INR = 0.01192 USD

India's MedTech industry: Import and export dynamics (2023-2024)

Top five import sources
(% share)

US	18%
China	17%
Germany	11%
Singapore	10%
Netherland	6%

Top five export destinations
(% share)

US	18%
Germany	5%
China	5%
Netherland	4%
Brazil	2%

Import

US$8.2 billion
+13% y-o-y growth

Export

US$3.8 billion
+13.5% y-o-y growth

Key devices imported (non exhaustive)	% share of segment in total import	Segments	% share of segment in total export	Key devices exported (non exhaustive)
► Robotic navigation solutions ► X-Ray film viewer ► Chromatograph and electrophoresis instruments ► Oxygen therapy apparatus ► Gas analysis apparatus ► MRI machines	64%	**Electronic equipment**	38%	► X-Ray equipment, X-Ray tubes ► Electrocardiographs ► Endoscopes ► Electroencephalogram ► MRI machines ► Radiation-generation units
► Syringes and needles ► Opacifiers for X-Rays ► Diagnostic reagents for patient administration ► Surgical gloves	17%	**Disposables and consumables**	48%	► Cannula ► Fabric garments ► Contraceptives ► Hand sanitizers ► Surgical gloves ► Blood collection tubes, I.V. Sets
► Diagnostic reagent kits ► Lab chemicals for blood analyser ► Blood analyzers	9%	**In-vitro diagnostics**	5%	► Reagents ► Kits ► Calibrators
► Artificial joints ► Artificial teeth and other dental fittings ► Defibrillators	7%	**Implants**	7%	► Spectacle lenses ► Intraocular lenses ► Ophthalmic implants ► Artificial joints ► Artificial teeth ► Defibrillators
► Skin Stapler, ► Tourniquet electronic ► Trocar	3%	**Surgical instruments**	2%	► Surgical knives ► Scissors ► Blade

Note: Currency conversion rate used: INR1=US$0.01192 (as on 3 Sep'24)

Import trends: Continued import dependence

Despite growing export capabilities, India remains a net importer of medical devices, relying on imports for 80% to 85% of its domestic requirements[10]. In FY2023-24, India's medical device imports reached US$8.2 billion, marking a 13% increase from the previous year. This figure was more than twice the value of its total exports[11]. The surge in imports is attributed to the growth of top-tier hospital chains such as Max, Hinduja Group, Fortis, Manipal, Calcutta Medical Research Institute (CMRI) and Apollo, which are investing in advanced infrastructure. Additionally, the burgeoning medical tourism industry in India is driving demand for sophisticated medical devices.

India imports primarily from the US, China, Germany, Singapore and Netherlands, which constituted ~18%, 17%, 11%, 10% and 6% of total imports, respectively, in 2023-24. 'Electronic equipment' segment constituted the bulk of imports with 64% share and a growth of 14.5% compared to the previous year. The second most significant category was 'disposables and consumables', accounting for 16.7% of imports and experiencing a notable growth rate of 11.5% compared to the previous year.[11] The imported devices are typically high-value, low-volume items such as hematology analyzers, gas analysis apparatus, immunoassay processors, and treatment planning and robotic navigation solutions.[12, 13, 14]

While India is currently a significant importer of medical devices, it has the potential to emerge as a key exporter and a global MedTech industry leader. This shift would be driven by India's strategic strengths, which include a skilled workforce, cost competitiveness, technology edge, and government initiatives that promote domestic manufacturing and innovation. With these strengths harmoniously converging, India stands on the cusp of redefining its role in the international MedTech arena, not merely as a market participant but as a frontrunner steering the industry's future direction.

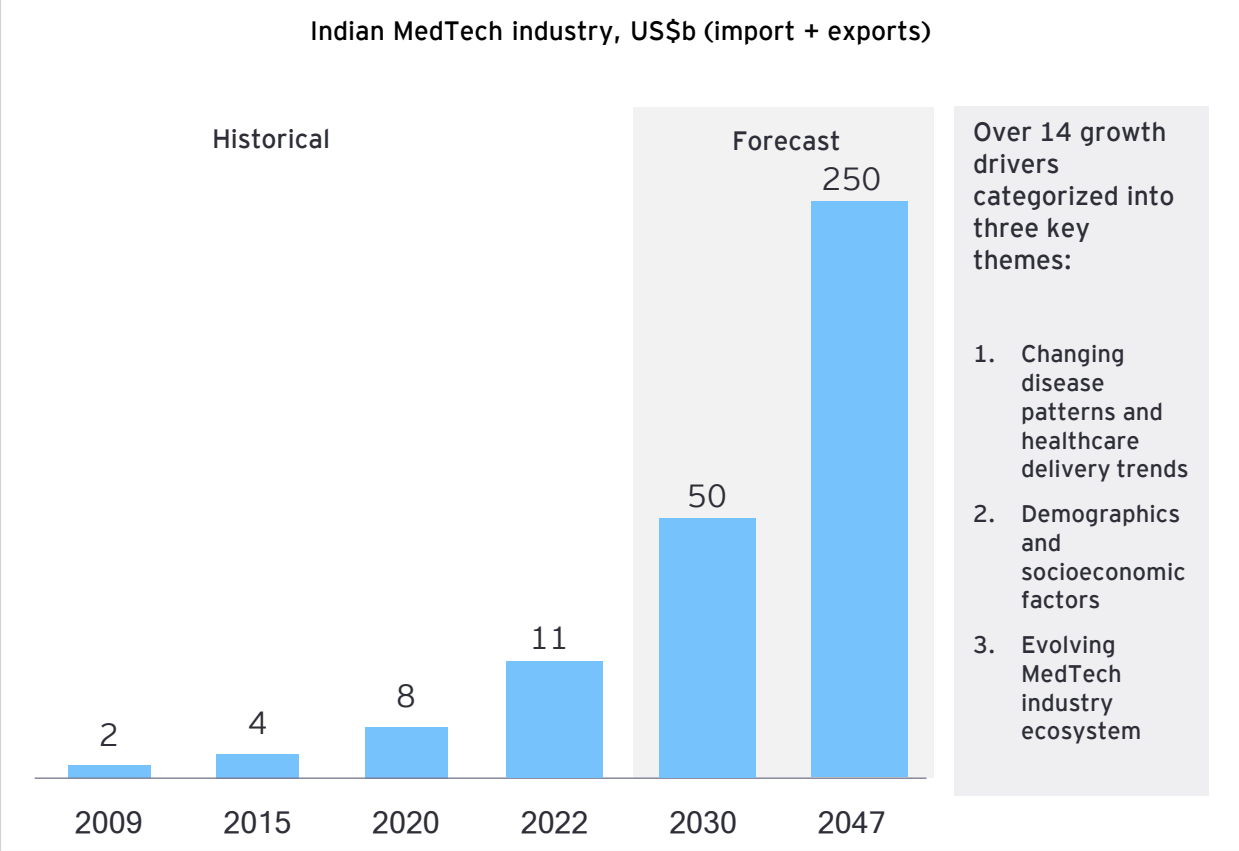
[10] Imports of medical devices rise 21% till October to Rs 61,262.84 cr | News - Business Standard (business-standard.com)
[11] Association of Indian Medical Device Industry (AIMED), Currency conversion rate (as on 3 Sep'24): 1 INR = 0.01192 USD
[12] Final Boosting of Medical Devices Industry - Report - 2023.pdf (pharmaceuticals.gov.in)
[13] Study on evaluation for the scheme of domestic promotion and publicity (dpp), 2023" (pharmaceuticals.gov.in)
[14] Supercharging India's Medical Device Industry Growth, GTRI report, Aug 2023

02 Charting the course: Indian MedTech market outlook and key growth drivers


TREATMENT
MEDICAL
HEALTHCARE

Targeting a US$50 billion ambition by 2030

Indian MedTech industry is expected to grow to US$50 billion by 2030. The Indian government introduced the National Medical Devices Policy in April 2023 aiming to boost the industry's growth and achieve this ambition. [15, 16] In addition, several factors and catalysts are expected to drive this growth. This chapter discusses these growth catalysts, grouped into three overarching themes, each representing a distinct set of strategic imperatives.



Sources: Historical, 2009 – 2020: Medical device manufacturing in India-a sunrise sector (pharmaceuticals.gov.in)
Historical, 2022: Annual Report 2022-23, Department of pharmaceuticals
Forecast, 2030 and 2047: 'Indian medical device industry is projected to reach US$50 billion by 2030', ET HealthWorld (indiatimes.com)

The Indian MedTech sector is brimming with potential across segments. With appropriate investments, breakthrough innovations and supportive government policies, the industry is poised for considerable and enduring growth. This progress could not only enhance healthcare services in India but also have a global impact in the future.

To understand the industry's viewpoint, we conducted primary research with industry experts from leading Indian and global MedTech corporations, and forward-thinking start-ups

[15] Policy for the Medical Devices Sector (pib.gov.in)

[16] 'Indian medical device industry is projected to reach US$50 billion by 2030' (indiatimes.com)

Primary research insights

The goal of reaching a US$50 billion market in the MedTech sector by 2030 elicited varied responses. Some experts consider it a readily attainable objective, while others view it as a conservative estimate of India's true potential, especially in light of robust initiatives aimed at fostering self-reliance and boosting exports, and numerous domestic growth drivers.

Nonetheless, there is a unanimous agreement among experts on the urgency for significant improvements in both infrastructure and systems. Such advancements are deemed critical for propelling the industry's growth rate beyond its present course.

> The projected figures (reference to US$50 billion by 2030) may seem ambitious, but they likely fall short of India's true potential in the MedTech space. The initiatives such as Make in India, the drive towards self-reliance, and a shift towards becoming a net exporter set a strong foundation for growth. Factors such as increased out-of-pocket healthcare spending, the rise of digital healthcare post-COVID, and other observable market trends all suggest that India's potential in this domain is not just achievable but likely to surpass expectations.
>
> *Co-founder, Indian medical device start-up company*

> Theoretically, it (ambition of US$50 billion by 2030) is achievable. But for that we will have to work on a few aspects. If nothing is fundamentally changing in terms of basic infrastructure and basic system to accelerate the growth, then the industry should be expected to grow at the same CAGR during the next five years as its growth in the last five years.
>
> *Forum Coordinator, Association of Indian Medical Device Industry (AiMeD)*

> The current global geopolitical climate has created a small window of unique opportunity for India. To be able to quickly catch on to that window, we must act with strategic intelligence and adopt pragmatic approaches that will position us for success.
>
> *Director, MTaI (Medical Technology Association of India)*

Let us delve into the details of the growth drivers and comprehend the opportunities they present for the medical devices industry.

Driving progress: Three key themes accelerating India's MedTech growth towards 2030 ambition

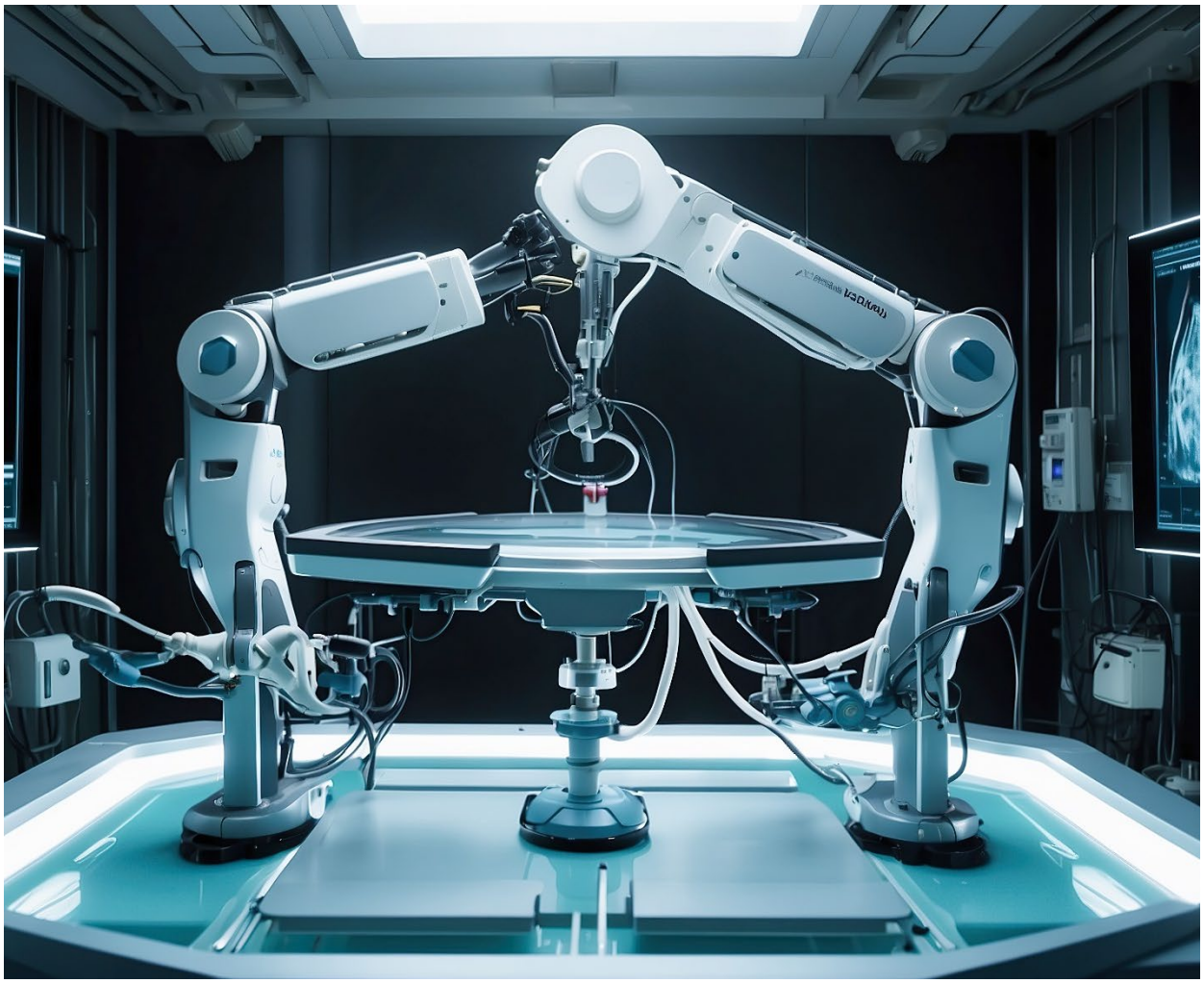
The growth drivers for the MedTech sector can be broadly classified under the following three overarching themes:

A) Changing disease patterns and healthcare delivery trends

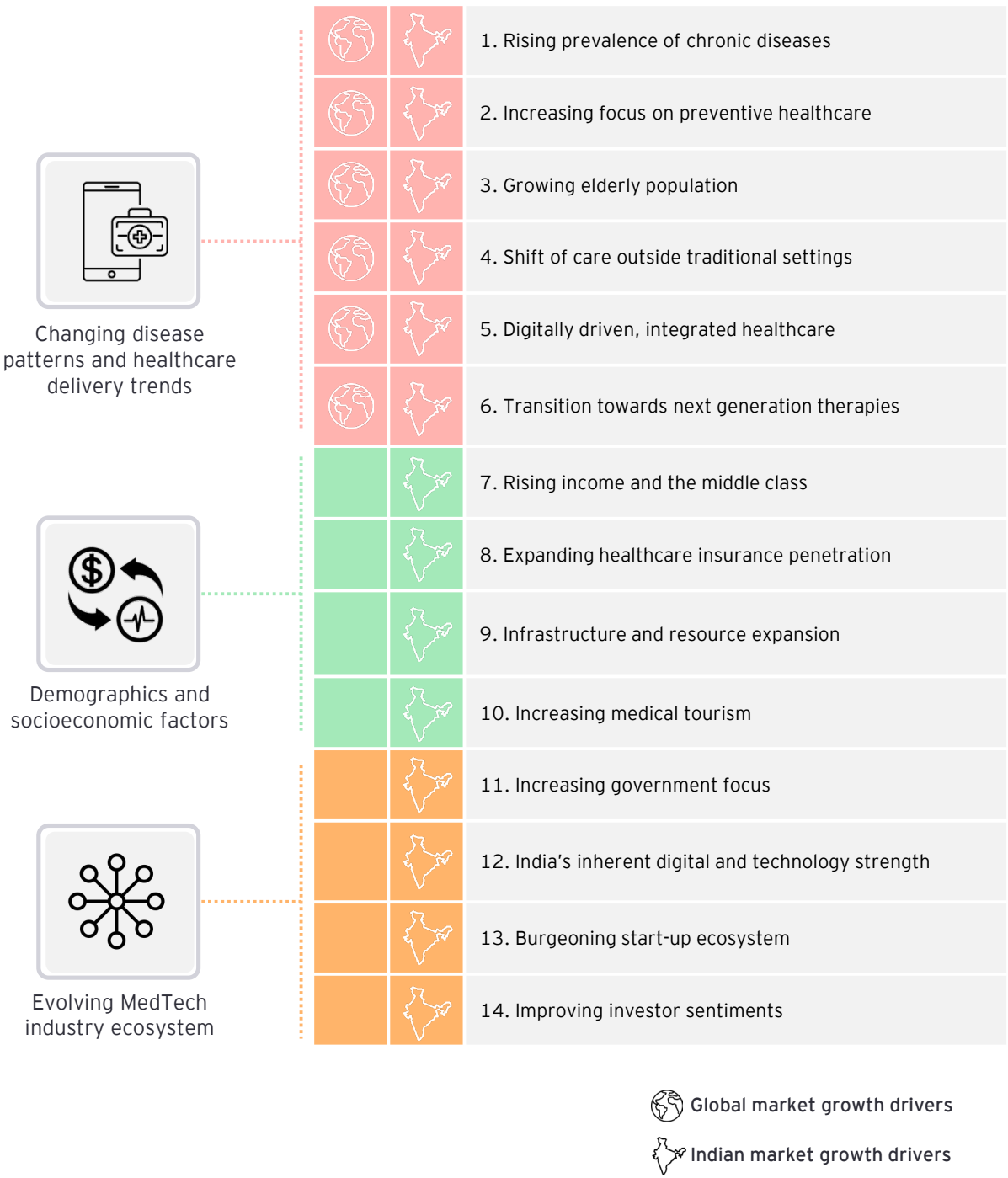
B) Demographics and socioeconomic factors

C) Evolving MedTech industry ecosystem

The subsequent section provides an in-depth analysis of the pivotal growth factors within each theme and their implications for the MedTech sector.



MedTech industry: Key growth drivers



Sources: EY analysis

A. Changing disease patterns and evolving industry trends

1. Rising prevalence of chronic diseases

The World Health Organization reports that chronic conditions such as heart diseases, cancer, diabetes and respiratory disorders lead to 41 million deaths worldwide each year. [17] In India as well, these conditions are also linked to significant economic output losses, projected to reach US$3.55 trillion between 2012 and 2030. [18] In addition to their inherent lethality, chronic conditions can serve as "comorbid factors", elevating the risk of individuals developing other serious illnesses.

Chronic diseases are responsible for 66% of deaths each year and are the primary drivers of substantial out-of-pocket expenditure on health in India. [19] Further, chronic diseases are increasingly being diagnosed in younger populations, indicating that individuals may live with these conditions for several decades. A 2017 survey by ASSOCHAM (The Associated Chambers of Commerce and Industry of India) revealed that two-thirds of those with chronic diseases in India are between 26 and 59 years old, a prime working age. This shift has profound effects on the well-being of patients and carries broader social and economic consequences. [20]

Rising prevalence of chronic diseases patients

Impact on healthcare

66% of all deaths associated with chronic diseases in India (6 million); increased ~10pp since 2010

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

2030
is the global deadline for achieving the Sustainable Development Goal (SDG) target to reduce premature mortality from chronic diseases by one-third

Impact on economy

US$3.55 trillion
of expected lost economic output in India due to the chronic diseases between 2012-2030

~11% Increased likelihood of work limitation in people with chronic diseases

~5 million
of YLDs (Years of healthy life lost due to disability per 100,000 population) due to diabetes and other endocrine disease in 2017 in India

Medical devices, diagnostics, and digital health solutions across chronic disease care continuum

Early diagnosis
- Point of care diagnostics
- Portable devices

Continuous monitoring
- CGMs and insulin pumps
- Smart spirometer

Personalized intervention
- Targeted radiation therapy devices

Personalized management
- Medication adherence reminder tools

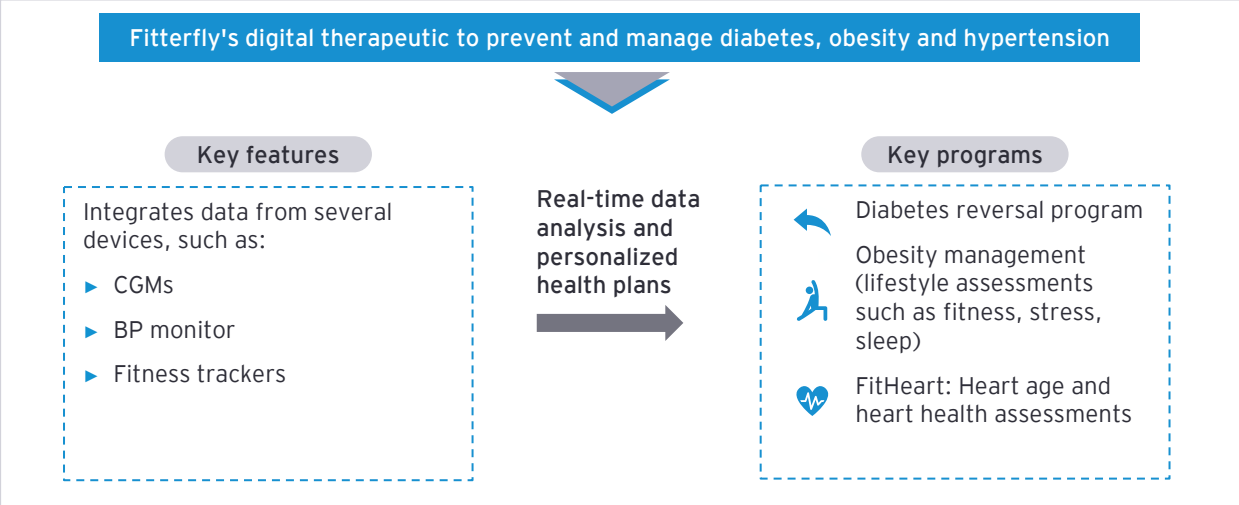
Sources: WHO NCD portal (India), CNBC, The Wire , iipsindia.ac.in, lancet.com, livemint.com

[17] Noncommunicable diseases (who.int)
[18] Non-communicable diseases to cost India around US$3.6 trillion by 2030 | Today News (livemint.com)
[19] India-noncommunicable-disease-deaths-who-report (thewire.in)
[20] NCD Report 2017, tari.co.in

To effectively manage and control these diseases, a holistic and personalized approach to care is required, including prevention and early detection, targeted treatment, continuous monitoring, and sustained management. By leveraging medical technology at each stage—from prevention to management—patients can receive more personalized care, healthcare providers can make more informed decisions, and the overall burden of chronic diseases on the healthcare system can be reduced.

Role of medical devices and diagnostics in the treatment and management of chronic diseases

Role of medical devices in the treatment and management of chronic diseases such as diabetes, cardiovascular conditions, and cancer is both transformative and expanding. For diabetes management, CGMs and insulin pumps have revolutionized patient care, allowing for real-time blood sugar monitoring and automated insulin delivery, thus improving glycemic control and patient autonomy. Smart spirometer helps patients with asthma, chronic obstructive pulmonary disease (COPD) to monitor lung health at home, and avoid attacks and hospital visits. Collectively, these medical devices are not only extending the lives of patients with chronic conditions but are also improving their daily quality of life (QoL), signifying a profound impact on public health outcomes. Additionally, mobile applications and smart devices for tracking symptoms and providing personalized health tips, checking medication adherence, among others, empower patients and promote better health outcomes. A good example is Fitterfly – a HealthTech firm using digital therapeutics and analytics to prevent and manage diabetes, obesity, and hypertension - an example of how HealthTech entrepreneurship and MedTech work in tandem to deliver healthcare.



Source: Fitterfly.com

This trend represents a substantial opportunity for the medical device sector to fulfill the growing need for comprehensive, integrated, and personalized care for individuals living with chronic conditions.

As technology advances, nanomedicine, bioelectronics, and advanced prosthetics have the potential to radically transform the treatment of chronic diseases. In the future, we can expect to see even more innovative solutions that will further enhance the quality of life for chronic disease patients and lead to a new era of treatment where chronic diseases are managed not just symptomatically, but at their root causes.

2. Increasing focus on preventive healthcare

The adage "An ounce of prevention is worth a pound of cure", is the fundamental principle that underpins the field of preventive healthcare. This approach to health emphasizes the importance of proactive measures to protect, promote, and maintain well-being, rather than solely focusing on the treatment of diseases after they occur. Preventive healthcare encompasses a broad spectrum of activities, including identifying the disease early through screening, mitigating disease risk factors, delaying the onset of illness at both individual and community levels, and improving the course of an existing disease.

Benefits of preventive healthcare*

For individuals	Enhanced quality of life	Reduced out of pocket expenses	Prolonged lifespan	Reduced risk of disease complications
For healthcare ecosystems	Reduced strain on resources	Cost efficiency	Improved patient outcomes	Data collection for public health research
For the government	Reduced healthcare cost	Improved public health	Improved GDP	National security

*not exhaustive

Medical devices, diagnostics and digital health solutions for disease prevention

Staying healthy
- Wearable fitness trackers
- AI-based personalized nutrition coaches

Routine diagnostics and screening
- Mammograms and colonoscopy
- At-home genetic kits

Early detection
- Gut microbiome analysis to detect disease biomarkers

AI and data for population patterns
- AI-powered analysis of retinal images or ECG data

Preventive healthcare can significantly reduce the incidence and severity of chronic diseases, leading to a better patient outcome and lower healthcare expenses than end stage disease management. In India, over 70% of cancer cases are diagnosed at an advanced stage, leading to drastically reduced survival rates. Early detection could dramatically increase the chances of cure, for instance there is 85% survival rate if cancer is diagnosed in the Stage 1, compared to less than 30% at Stage 3.[21] Preventive care offers not only immediate health benefits but also long-term economic advantages that can positively impact individuals, healthcare systems, society, and the entire nation.

Since the COVID-19 pandemic, there has been a marked increase in public awareness and focus on preventive healthcare. According to a survey, ~ 40% of respondents strongly preferred preventive health measures.[22] The Indian government has also intensified its focus on this area, as evidenced by the launch of the FIT INDIA Movement by the Prime Minister in August 2019. Establishment of preventive health and screening outpatient department in hospitals, making 'preventive and promotive health' a priority in National Medical Devices Policy, and the focus on National Digital Health Mission are some indicators of shift towards preventive healthcare.

Over the past decades, we have witnessed an increase in life expectancy. The goal now is to not only prolong life but also to enhance the quality of life or 'health span' of individuals, ensuring that everyone can perform at their maximum potential.

[21] World Cancer day: Early diagnosis is crucial for improving chances of survival - The Economic Times (indiatimes.com)

[22] Preventive Healthcare in India (IBEF.org)

Role of medical devices and diagnostics in disease prevention

Medical devices and diagnostics play an instrumental role in preventing or delaying the onset of diseases by promoting wellness, enabling early screening, and facilitating early detection.

Wearable technology has become a cornerstone in the pursuit of maintaining good health. Devices such as fitness trackers, smartwatches, and wearable ECG monitors encourage individuals to make informed lifestyle choices. Smart scales not only measure weight but also provide insights into body composition, such as body fat percentage and muscle mass, which can be crucial for preventing obesity-related chronic diseases. Similarly, home-based blood pressure cuffs and cholesterol testing kits allow individuals to monitor vital health markers that can indicate the risk of cardiovascular diseases. At-home genetic kits can identify genetic predispositions to certain chronic diseases, allowing for early lifestyle interventions. When patients can follow their own progress and see how certain choices directly impact their health, they are more likely to adhere to treatment plans, engage in their healthcare, and change their behavior.

Routine diagnostic and screening devices are indispensable for early disease detection. Tests such as mammograms and colonoscopy can predict and detect cancers at stages when they are most treatable. According to CDC, ~99% women diagnosed with breast cancer at an earlier stage have a better five-year survival rate compared to 32% of those diagnosed at an advanced stage. [23] According to studies, regular mammograms reduce the risk of dying from breast cancer by more than 65%. [24]

The integration of AI with diagnostic devices allows data integration and analysis from various sources to predict potential health issues, allowing for timely interventions. For example, machine learning models can analyze ECG data to detect atrial fibrillation, and AI-enhanced retinal screening can predict with 70% to 80% accuracy if patients are at risk of a heart attack over the next year. [25] We can see several preventive programs and solutions coming up in India as well, for example, Apollo's ProHealth program designed based on data from 22 million health checks and iiV Health's FootPlus for early screening and detection of Peripheral Arterial Disease.

Digitalization revolutionizing preventive healthcare by leveraging data-driven insights and personalized intervention

Apollo's ProHealth

India's first AI-driven personalized, predictive and preventive health check program

Based on data from 22 million health checks

The 24/7 platform allows integration of patient data from several sources into one digital health record to provide:

- Personalized health risk assessments (HRA)
- AI-powered predictive risk scores (cardiac, pre-diabetes, chronic obstructive pulmonary disease)
- Personalized guidance and care continuum

iiV Health Solutions

Preventive HealthTech start-up in India developing AI/ML-based screening devices

Developed FootPlus, an AI/ML-based smart, non-invasive device that early screens and monitors peripheral artery diseases

- Detects capillary/peripheral blood flow using thermal exchange technology in under nine minutes
- Portable and Bluetooth-enabled remote diagnostics
- Does not require trained medical personnel

Sources: Apollo247.com, iivhealth.com

[23] Health and Economic Benefits of Breast Cancer Interventions | National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), (cdc.gov)

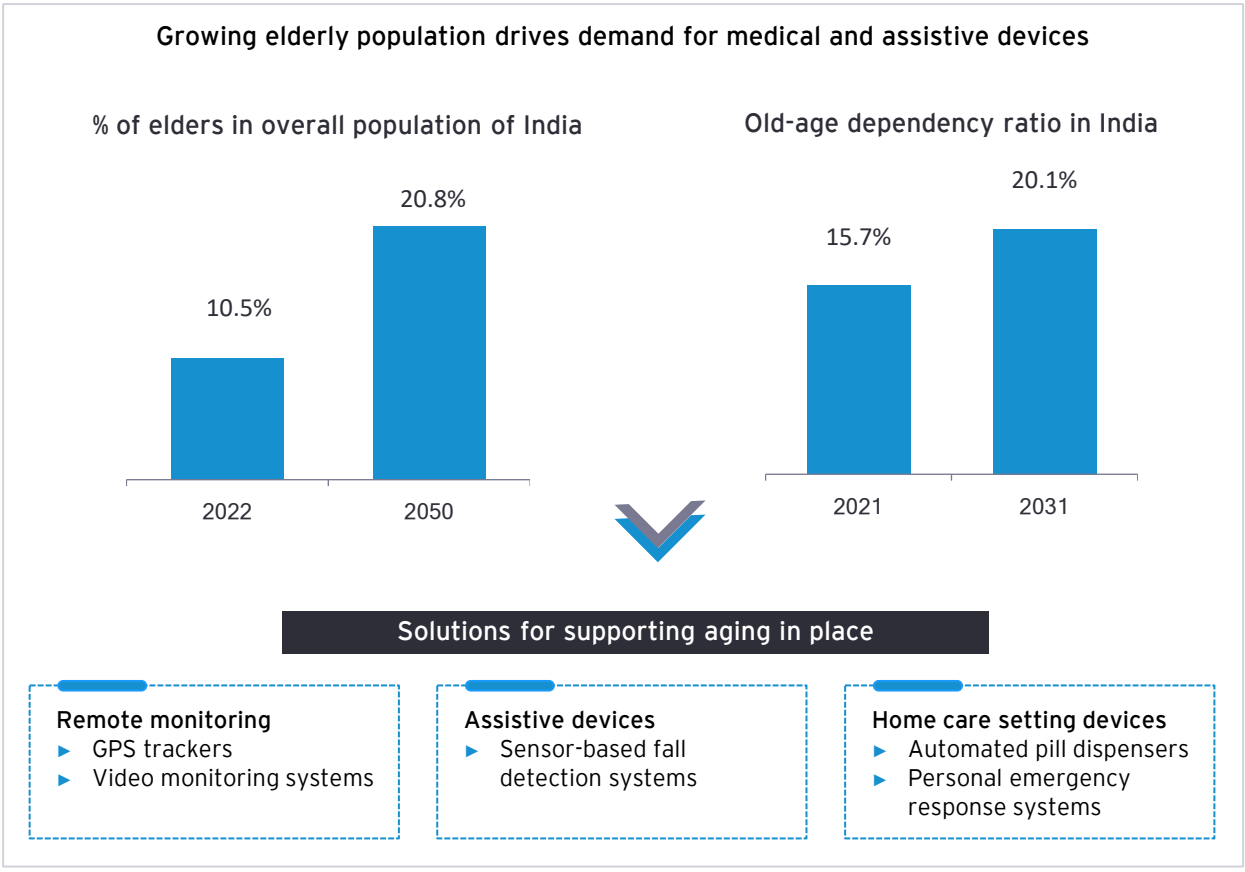
[24] Regular Mammograms Reduce Breast Cancer Deaths (breastcancer.org)

[25] Artificial Intelligence Can Analyze Eye Scans To Identify Patients at High Risk of Heart Attack (scitechdaily.com)

The proliferation of digital health solutions is generating an unprecedented volume of health data. This wealth of information, when harnessed by digitally integrated medical devices, digital therapeutics and AI-driven diagnostics, is not only enhancing current medical device capabilities but also fueling the creation of novel digital health interventions. This synergy is establishing a vicious cycle of innovation, where data informs development, leading to more advanced devices and solutions that, in turn, generate further data for continuous improvement and breakthroughs in patient care. The entrepreneurship that arises as a result of this marriage between HealthTech and MedTech cannot be understated.

In conclusion, the shift towards preventive healthcare is a transformative movement that promises to reshape the landscape of health and wellness. Medical devices and HealthTech are at the forefront of this revolution, offering innovative solutions for disease prevention and early detection.

3. Growing elderly population



Source: unfpa.org, mospi.gov.in

As life expectancy is increasing and birth rates are declining, the proportion of the global population aged 60 and above is expanding more rapidly than the overall population. In India, the elderly accounted for 10.5% of the population in 2022, and projections from the Longitudinal Ageing Study in India (LASI) suggest this figure will climb to 20.8% by 2050.[26] Consequently, the old-age dependency ratio – the ratio of individuals aged 60 and above to every 100 people of working age (15 to 59 years) – is set to rise. According to the government report, this ratio is anticipated to grow from 15.7% in 2021 to 20.1% in 2031.[27] This increase in the elderly population and dependency ratio signal an escalating need for the younger generation to provide care and address the social needs of older adults.

In addition to the demographic shift towards an aging population, the extension of average lifespans is also leading to a rise in the number of seniors dealing with chronic and acute health conditions. Consequently, the development of services, devices, and solutions specifically designed for the elderly is

[26] India Ageing Report 2023, UNFPA

[27] Elderly India 2021, mospi.gov.in

emerging as an essential public health priority. In response to this growing need, dedicated healthcare facilities are also comping up. For instance, in Sep 2024, Safdarjung Hospital in New Delhi inaugurated a geriatric care ward, which is the second such facility in Delhi. This facility provides senior-friendly infrastructure and offers a range of services tailored for the elderly, including specialized care for age-related conditions, physiotherapy, occupational therapy, and mental health support. [28]

Additionally, several home healthcare service providers in India are stepping up to make quality healthcare more accessible and convenient for the elderly. For instance, Health Care at Home (HCAH) acquired 'Seniority', a geriatric-centric digital platform in 2022, [29] to develop a geriatric-focused vertical and provide end-to-end senior care services. Another example is of Portea, a consumer healthcare provider, that launched a new healthcare service called 'Portea Health Prime', for elders aged 65 and above to address their comprehensive health monitoring needs. [30]

Acting as a further tailwind to this trend, in Sep 2024, the government extended insurance coverage under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) to senior citizens aged 70 and above, providing a much-needed boost to the accessibility and affordability of healthcare services for the elderly population.

Role of medical devices and diagnostics supporting ageing in place

Medical devices and diagnostics are crucial in empowering seniors to age in place, offering them the tools to preserve their autonomy, manage chronic diseases, and enhance their safety. For instance, wearable technologies such as GPS trackers safeguard the well-being of the elderly, especially those with Alzheimer's, dementia, or other cognitive issues that may cause them to wander or become disoriented. Sensor-based fall detection systems employ sophisticated algorithms and a range of sensors, like accelerometers and gyroscopes, to track movement and identify unusual patterns that could signal a fall. When a fall is detected, these systems promptly notify caregivers or emergency services, aiding in swift response and potentially mitigating the impact of severe injuries. Additionally, medication adherence is a notable challenge among the elderly. Automated pill dispensers equipped with alerts and reminders assist in ensuring that medications are taken correctly and on time, decreasing the likelihood of medication-related adverse events.

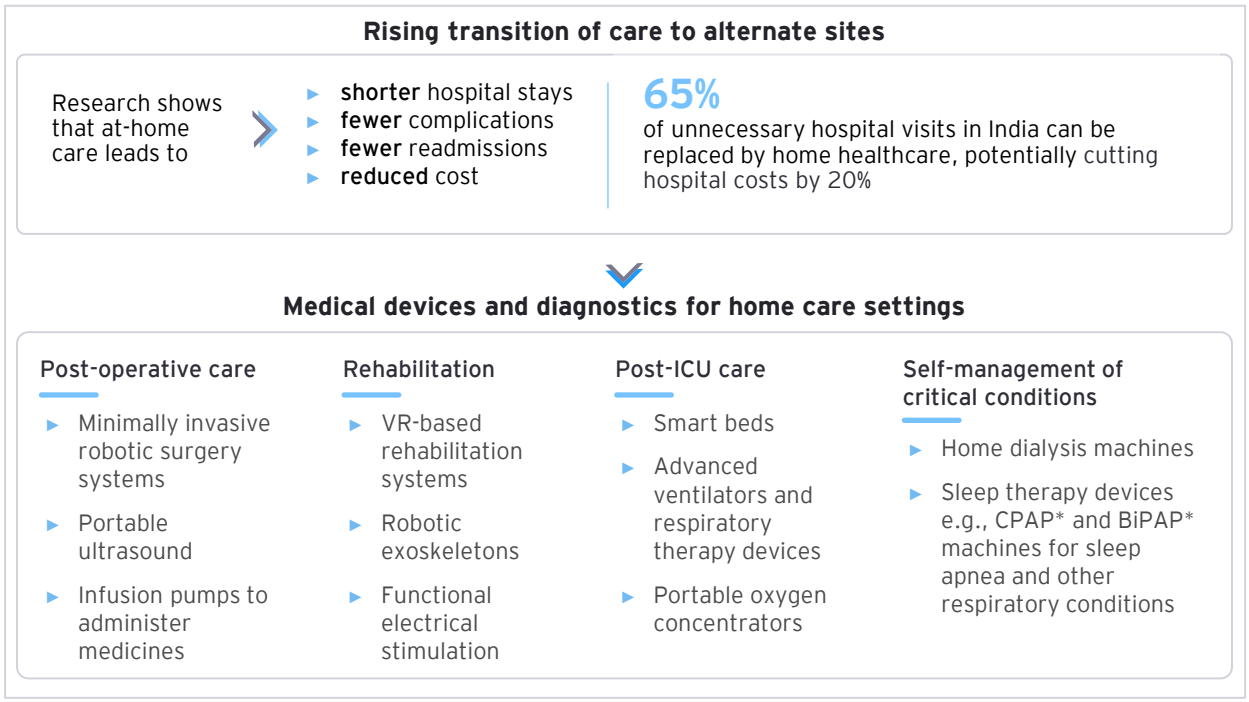
Leveraging these technologies can enhance the quality of life for the elderly, reduce healthcare costs, and create a sustainable model for aging societies.

4. Shift of care outside of traditional hospital settings

Traditionally, hospitals have been the cornerstone of healthcare, centralizing diagnosis, treatment, and recovery. However, this model has faced challenges, including rising costs, capacity constraints, risk of hospital-acquired infections, and a rise in consumer-driven healthcare demands. In response, the healthcare industry is witnessing a paradigm shift towards alternate sites of care that promise greater efficiency, accessibility, and patient-centeredness. The traditional model of hospital-centric care is being complemented—and in some cases, replaced—by a variety of out-of-hospital care or alternate sites of care.

Alternate sites of care refer to healthcare services provided outside of traditional hospital settings. These include home healthcare (e.g., home testing, tele consultations, home nursing and physiotherapy services, home medical devices and equipment), ambulatory surgery centers, transition care centers, urgent care clinics, and retail health clinics. Each setting offers a unique approach to care, tailored to meet the needs of patients in different contexts. While hospitalization is unavoidable for people with acute illnesses or injuries, alternative sites can significantly reduce hospital stay duration and outpatient visits. Additionally, alternative care sites can greatly enhance medical care accessibility for rural communities that are typically underserved, ensuring that a larger number of individuals receive timely and appropriate care.

[28] Safdarjung Hospital inaugurates new geriatric care ward, Health News, ET HealthWorld (indiatimes.com)
[29] HCAH acquires 100% stake in Seniority to expand its presence in India's geriatric health market, financialexpress.com
[30] portea-launches-healthcare-service-for-above-65-years-age (expresshealthcare.in)



*CPAP: continuous positive airway pressure; BiPAP: bilevel positive airway pressure
Sources: Nih.gov , Niti.gov.in

Medical devices and diagnostics are at the heart of the transition of care outside traditional hospital settings

Medical devices play a crucial role in post-surgical care, rehabilitation, ICU recovery, and self-management of critical conditions such as pneumonia, sleep apnea, open-and-closed wounds, kidney failure, and infection. These devices support recovery, enhance quality of life and ease healthcare facility burden. For instance, home dialysis setup helps patients avoid several trips per week to a dialysis clinic. Innovations in microfluidics have led to the development of home testing kits for a range of illnesses, such as kidney and celiac diseases. Beyond testing kits, medical imaging is also transitioning to home use.

Globally and in India, companies are innovating to produce medical devices and launching new services that meet the varied needs of patients in non-hospital settings. Concurrently, insurance offerings are also evolving to extend more comprehensive coverage for these services and solutions.

The shift to alternate sites of care represents a significant evolution in healthcare delivery, driven by economic, technological, and societal factors. Medical devices are central to this change, benefiting the entire healthcare spectrum.

As the industry continues to adapt and technology advances, we can expect an even greater proliferation of medical devices designed for use in alternate care settings, further revolutionizing the way healthcare is delivered and managed.

5. Digitally driven, integrated healthcare: Rapid digital HealthTech advancement and uptake

The global digital health market was valued at approximately US$211 billion in 2022 and is anticipated to expand at a CAGR of 18.6% between 2023 and 2030. Within this landscape, India's digital health market is anticipated to expand from US$12.2 billion in 2023 to US$25.64 billion by 2027, demonstrating a robust CAGR of 20.4% [31]

Digital health enhances efficiency, accessibility, personalization, and effectiveness of healthcare through the strategic application of data and technology. Patients gain greater control over their health with convenient access to care. Physicians are equipped with real-time data that supports early disease detection and enhances data-driven decision-making. Healthcare systems benefit from optimization and cost reductions.

[31] Digital health: trends, opportunities and challenges in medical devices, pharma and bio-technology - PMC (nih.gov)

Benefits of digital health across stakeholder groups

Patients

Improved and affordable access
- Anytime, anywhere care through telehealth, remote monitoring, etc.
- Healthcare access in rural areas

Enhanced engagement and experience
- Control over their health data
- Disease management tools
- Better compliance/adherence

Better health outcomes
- Earlier and more accurate diagnosis
- Personalized treatment

Physicians

Increased efficiency
- Streamlined workflows
- Automation of admin activities

Data-driven decision making
- Real-time data-driven analysis
- Clinical decision support tools for diagnosis and treatment

Advanced learning
- AR/VR-based self and patient learning modules

Healthcare system

Cost reduction
- Savings through virtual care
- Better resource utilization

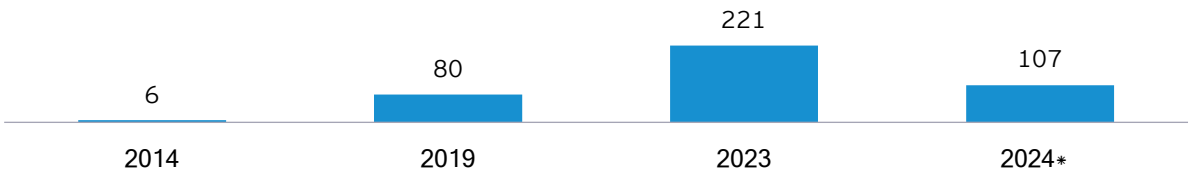
Improved public health
- Early disease detection enabling proactive interventions and reduced hospital admissions

Optimized healthcare delivery
- Large dataset to analyze health trends and optimize resource allocation

Digital health opportunities for the MedTech industry

The digital health landscape offers a transformative opportunity for the MedTech industry to innovate and redefine its value proposition. Some examples of such advancement include digitally enabled smart devices, sensor-based connected wearables, remote patient monitoring systems, telemedicine devices, and intelligent drug delivery systems such as smart inhalers. The integration of advanced technologies such as AI, Internet of Things (IoT) and big data analytics is enabling the development of sophisticated medical devices and services to deliver integrated care with improved efficiency, efficacy, and safety. Furthermore, digital therapeutics (DTx) are being developed as both standalone treatments as well as complementary therapies to current standard-of-care for conditions such as sleep disorders, schizophrenia, and chronic pain, bringing further opportunity for MedTech industry.

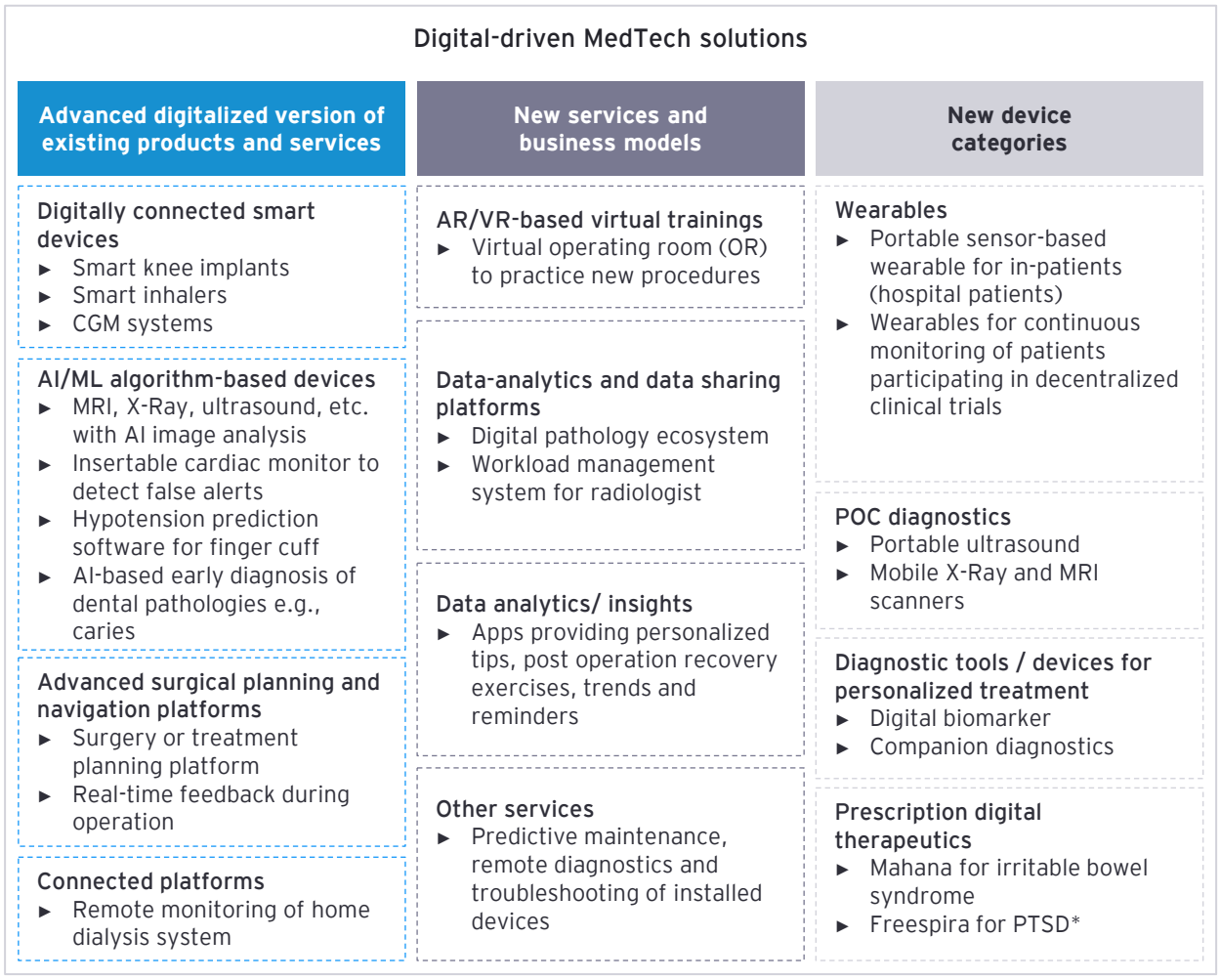
FDA approval of AI-enabled medical devices



Sources: EY analysis, FDA data.
*2024 data complete to November 19, 2024.

The exponential growth in FDA approvals for AI-enabled medical devices, which rose by over 176% from 80 in 2019 to 221 in 2023, demonstrates the rapid integration of digital technology in medical devices.[32] Chapter 4 of this report will discuss numerous examples of digital enhancements in MedTech devices across various segments.

[32] Pulse of the MedTech Industry Report 2024



Source: EY analysis

*PTSD: posttraumatic stress disorder

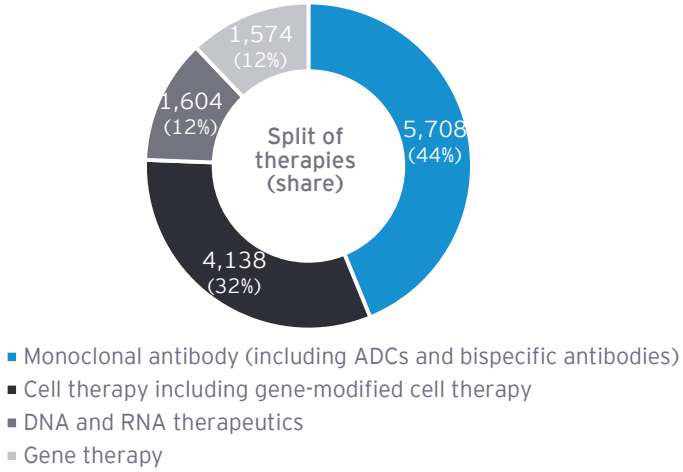
6. Transition towards next-generation therapies: creating a new ecosystem for medical devices and health technology

The pharmaceutical sector is undergoing a transformative shift towards next-generation therapeutic modalities, including cell and gene therapies (CGT), monoclonal antibodies (mAb), antibody-drug conjugates (ADC), and DNA and RNA therapies. Globally, around 13,000 of these therapies are in various stages of development, ranging from research and preclinical phases to clinical trials and regulatory review. These are projected to represent about 43% (by value) of the global pharmaceutical market by 2030, a significant increase from 34% in 2023. [33]

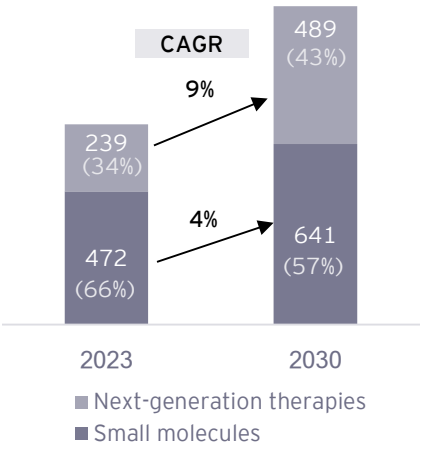
[33] Evaluate pharma database, accessed on 18 Sep'24

Transition towards next-generation therapies

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



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



Devices supporting R&D, manufacturing and delivery of next-generation therapies

Research and development
- High-throughput screening systems
- CRISPR – gene editing

Clinical trials
- Genetic screening tests
- Wearables for hybrid trials

Manufacturing
- Advanced bioreactors
- Cryopreservation equipment

Treatment
- Companion diagnostics
- Specialized drug delivery devices
- Drug device combinations

Post- treatment
- Wearable devices for monitoring
- In-vitro diagnostics for assessing therapy effectiveness

*Includes following development phases: research project, preclinical, phase I to phase III and filed (under regulatory review)

Source: Evaluate Pharma reports, accessed on 18 Sep'24

Role of medical devices and diagnostics across the value chain of next-generation therapies

Medical devices and diagnostics play an integral role throughout the life cycle of next-generation therapies, starting from R&D to patient administration and monitoring.

During the R&D phase, devices such as high-throughput screening systems and sophisticated imaging technologies allow for the rapid evaluation of numerous compounds or genetic sequences. Advanced bioreactors and cell culture systems are critical for developing cell and gene therapy (C&GT) production processes. Precision gene editing tools, such as CRISPR-Cas9, are vital for accurate genetic alterations.

In clinical trials, diagnostics are crucial for patient selection and stratification. Genetic testing, for instance, helps identify individuals likely to respond to specific gene therapies or are at risk for adverse effects. Given the specialized nature of next-generation therapy targets, clinical trials often require a hybrid approach to recruit enough participants, blending traditional site-based activities with remote elements. This necessitates increased use of wearables for continuous monitoring, remote

patient management systems, and point-of-care diagnostics.

Manufacturing next-generation therapies demands specialized devices capable of meeting strict quality and regulatory standards. This includes closed-system bioreactors, advanced aseptic manufacturing systems, cryopreservation equipment, and modular production systems that allow for continuous and agile manufacturing of these advanced therapies at scale while maintaining high-quality standards.

As the next-generation therapies are designed to be highly targeted, companion diagnostics play an important role in identifying the patients who will benefit from the treatment through assessment of one or more biomarkers. At the point of care, medical devices ensure the safe and precise administration of therapies. This includes infusion pumps, cell infusion systems, and specialized delivery devices.

After treatment, wearable devices are increasingly being utilized to continuously monitor health indicators, aiding in the early identification of possible side effects, such as cytokine release syndrome following CAR-T therapy. Additionally, in vitro diagnostic instruments are employed to assess biomarkers, providing insights into the effectiveness of the therapy.

Pharma and MedTech are driving the development of devices for the delivery of novel therapies

Collaboration for innovative delivery device

Roche + Enable Injections

Roche collaborated with Enable injections to leverage Enable's wearable drug delivery device, enFuse with its research projects

- enFuse wearable drug delivery device is designed to deliver large volumes of small molecule and biologic medications subcutaneously
  - Provides alternative to inconvenient and time-consuming IV infusions
  - At home self-administration, bring efficiency and value to the entire spectrum of healthcare

Collaboration for post treatment monitoring devices

Bristol Myers Squibb (BMS) + Voluntis

BMS partnered with Voluntis to develop a digital cancer companion app, 'Theraxium Oncology' utilizing Voluntis's core platform for digital therapeutics

- 'Theraxium Oncology' is powered by evidence-based algorithms to provide patients with real-time recommendations for self-management of symptoms

Potential of delivery devices for novel biologic therapies

Becton Dickinson (BD)

- Biologic therapies account for >40% of the BD's total 'pharmaceutical systems' business unit revenue
- With the growing clinical potential of GLP-1 biologics, BD plans to capitalize by supplying prefilled syringes to pharmaceutical companies
  - BD estimates the delivery devices market for these GLP1 biologics to reach ~US$1 billion by 2030

Sources: Enable Injections Expands Strategic Partnership with Roche, Bristol Myers Squibb - Voluntis, BD expects to surf GLP-1 wav, (fiercebiotech.com)

To sum up, the biopharmaceutical sector is advancing towards an era where cutting-edge therapies are becoming fundamental to treatment strategies.

As the sector progresses, there will be a corresponding evolution in medical devices and diagnostics throughout the entire value chain.

B. Demographics and socioeconomic factors

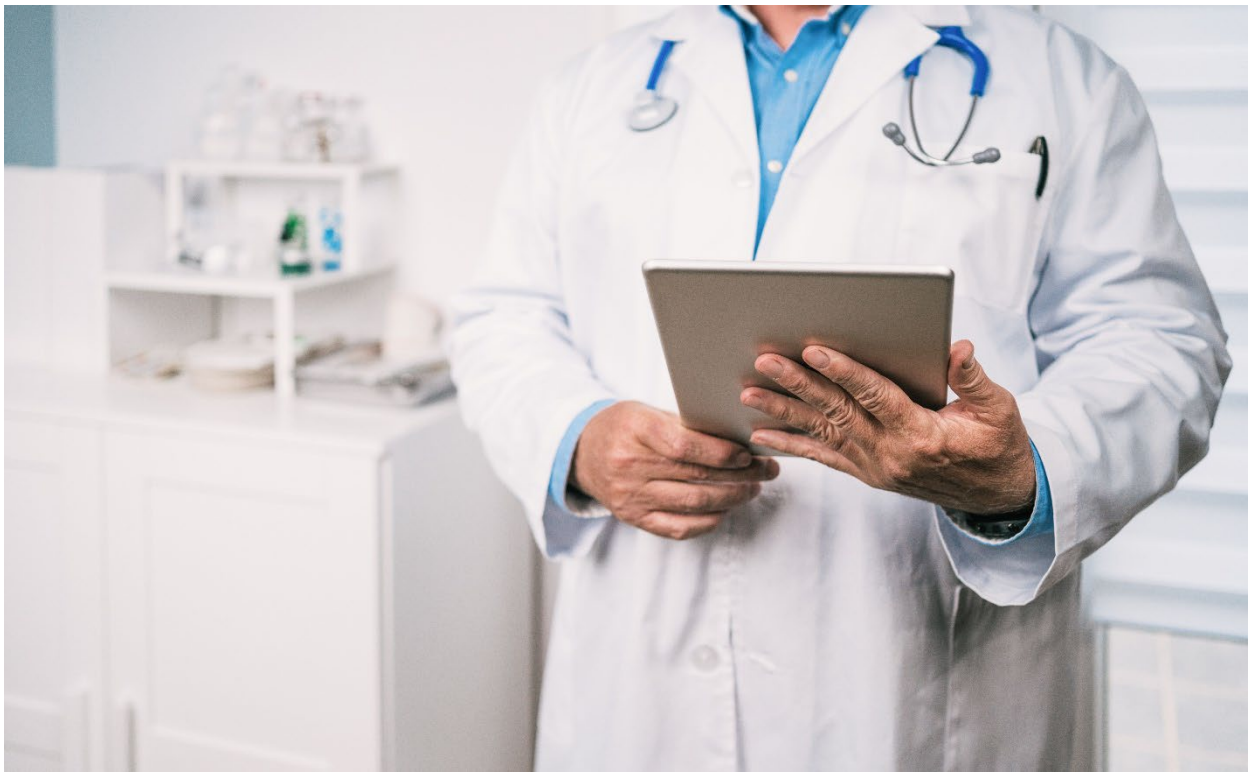
7. Rising income and the middle class

India's meteoric rise as one of the fastest-growing economies globally is a narrative of transformation and opportunity. With projections placing it as the world's third-largest economy by 2027 with a GDP of US$5 trillion, [34] the nation stands on the cusp of a significant economic milestone. This growth trajectory is reflecting a profound change in the socio-economic fabric of the country, particularly the burgeoning middle class.

The expansion of the middle class in India is a phenomenon that cuts across the rural-urban divide, reshaping the economic landscape. The Indian government's 2022-23 Household Consumption Expenditure survey reveals a steady increase in nominal household consumption expenditure, indicating the growing financial muscle of the Indian middle class. Rural households have seen an annual growth rate of 1.02% from 2011-12 to 2022-23, while urban counterparts have experienced a slightly higher rate of 1.12%. [35]

The expanding middle class, armed with increased purchasing power, is becoming more health-conscious and demanding higher standards of healthcare. This demand is not just for basic medical services but extends to high quality and more sophisticated healthcare solutions.

For the MedTech sector, this is an invitation to innovate, expand and deliver healthcare solutions that meet the aspirations of a new India that is healthier, wealthier and more discerning than ever before.

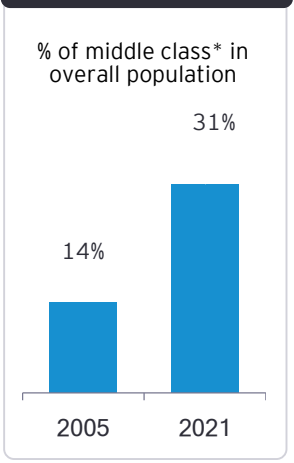


[34] India to become third largest economy with GDP of US$5 trillion in three years: Finance Ministry - The Hindu

[35] Understanding-India's-evolving-middle-class (East Asia forum.org)

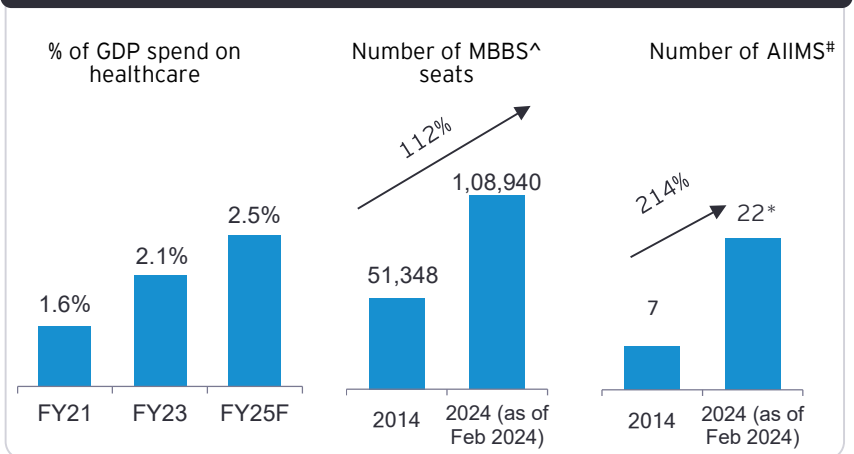
Demographics and socioeconomic factors in India driving the growth of the MedTech industry

Rising income and the middle class



*Considering the daily income of US$17-100

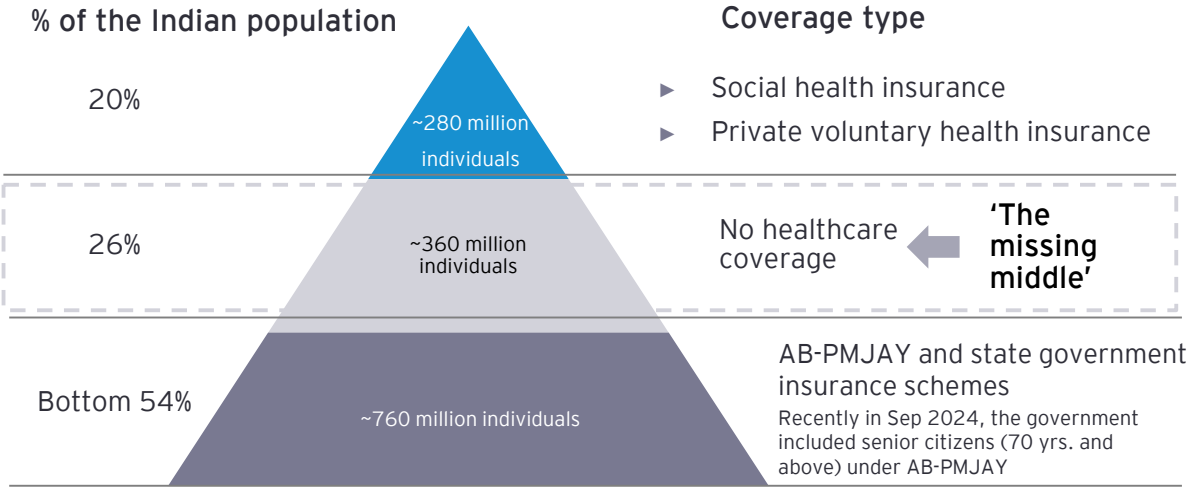
Infrastructure and resource expansion



*of the 22 AIIMS, six are fully operational and 16 are under different stages of development/function

^MBBS: Bachelor of Medicine and Bachelor of Surgery; #AIIMS: All India Institute of Medical Sciences

Expanding healthcare insurance penetration



Increasing medical tourism: key growth drivers

World class medical facilities
- 1600 NABH accredited hospitals
- 55 JCI accredited hospitals

Low cost
- 60% to 80% lower cost than in the US and UK

No language barrier
- Ease of communication in English language

Less waiting
- Little/no waiting time for diagnostic, surgeries, and treatment

Sources: Rising income and middle class- East Asia Forum.com

Expanding healthcare infrastructure and resources- Indiatimes.com, Economic Survey 2023, moneycontrol.com, Pib.gov.in, Progress in Medical Education, pib.gov.in

Growing coverage of healthcare insurance- Niti Aayog report, Indian population (as of 1 July 2023), Press Information Bureau (pib.gov.in)| Ayushman Bharat Becomes Bigger

8. Expanding healthcare insurance penetration

Healthcare coverage in India has been steadily improving. According to our earlier analysis, featured in last year's report, around 20% of the Indian population was covered by social or private insurance, and about 50% was covered by government schemes such as AB-PMJAY and state initiatives, leaving approximately 30% uninsured, often referred to as the 'Missing Middle'.[36] In September 2024, the government extended AB-PMJAY to senior citizens aged 70 years and above. This shift brought an estimated 60 million seniors—around 4% of the total population—into the government-covered category, reducing the size of the uninsured 'Missing Middle'.[37]

Increased insurance coverage translates to an increased healthcare utilization, leading to a rise in demand for medical devices and technologies. As more patients seek treatment, healthcare facilities must equip themselves with an array of medical devices, from basic diagnostic tools to advanced surgical instruments. This demand acts as a stimulus for both the production and innovation within the MedTech sector.

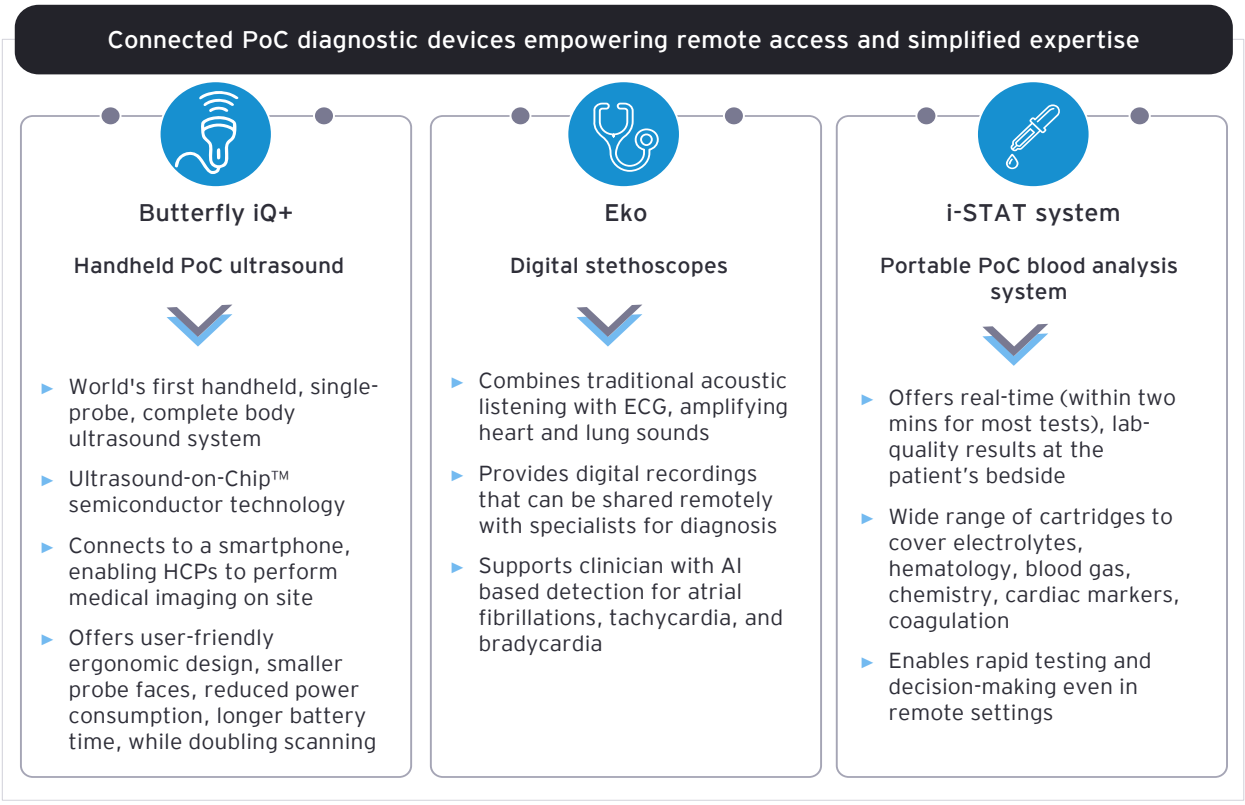
In addition, the substantial 'Missing Middle' from both rural and urban areas, which comprise a significant portion of the population, also creates unique innovation opportunities for various types of medical devices and diagnostics. By delivering innovative devices, supporting healthcare workers with digital health platforms and clinical tools, and expanding telehealth and remote surgery, MedTech can make quality healthcare a universal right, not just a privilege for urban populations.

Compact, portable, and energy-efficient advanced imaging diagnostics specifically designed for smaller facilities in rural areas are a cornerstone of MedTech's approach to rural healthcare. Devices such as the handheld ultrasound Butterfly iQ and the digital Eko stethoscope enable on-site diagnostics. Point-of-care testing (POCT) devices, such as the i-STAT system, offer immediate blood analysis. These diagnostics enable rapid testing and decision-making in remote settings, resulting in timely diagnoses and treatments that are critical for patient outcomes and disease control. Furthermore, virtual reality (VR) and augmented reality (AR) technologies are being used for training and simulation, providing healthcare workers with a safe and controlled environment to practice procedures and improve their skills without the stress of a live clinical setting.

In conclusion, the MedTech industry should continue to innovate to cater to the diverse needs of the Indian populace and democratize healthcare.

[36] OPPI report : Reimagining pharma and healthcare (ey.com)

[37] Ayushman Bharat Pradhan Mantri Jan Arogya Yojana| National Portal of India



Sources: Butterfly.com, Eko Devices_medicaldevice-network.com, Ekohealth.com, Globalpointofcare.abbott

9. Infrastructure and resource expansion

The availability of healthcare infrastructure and resources is a major obstacle to accessing healthcare. Even developed nations are struggling with a shortage of facilities, equipment, and trained personnel. This problem is worsened by the uneven distribution of healthcare workers, leaving rural and remote areas underserved.

The Indian government has been actively working to strengthen healthcare services through various initiatives. In FY23, the government allocated ~ 2.1% of GDP to healthcare.[38] The government has also made several efforts to improve healthcare infrastructure and resources. For instance, the number of MBBS seats has increased by 112%, from ~ 51,000 in 2014 to ~108,000 in 2023, and the number of medical colleges has grown by 82%, from 387 in 2014 to 706 in 2023.[39] Furthermore, around 163,420 health and wellness centers, known as Ayushman Arogya Mandirs, have been established across the country till 15 Dec 2023. The government has sanctioned 16 new AIIMS in addition to the six already operating.[40] As more healthcare facilities and professionals become available, the demand for advanced medical technologies and devices will rise.

In addition, the MedTech industry is also rapidly innovating to create new devices and services designed to empower healthcare workers and reduce burnout. Robotic process automation (RPA) can handle administrative tasks such as appointment scheduling, billing, and data entry, freeing healthcare workers to concentrate on patient care. Telemedicine platforms enable healthcare workers to consult with patients virtually, expanding their reach and making care more accessible. Clinical decision support tools assist healthcare workers in diagnosing more efficiently and accurately, and in formulating personalized treatment plans.

As the healthcare landscape in India continues to evolve, the synergy between expanding infrastructure and innovative medical technologies will play a pivotal role in shaping the future of healthcare, ensuring that high-quality medical services are accessible to all.

[38] Health expenditure at 2.1% of GDP in FY23: Economic Survey (livemint.com)
[39] Press information Bureau (pib.gov.in), Progress achieved in medical education
[40] Press Information Bureau (pib.gov.in), Ministry of health and family welfare achievements in 2023

10. Increasing medical tourism

India's medical tourism sector has been on an upward trajectory, with the country becoming an attractive destination for patients across the globe seeking quality healthcare at affordable prices. India is now the second largest medical tourism hub in Asia. [41] In 2023, India hosted >500,000 international patients [42] and this figure is expected to rise to 3 million by the year 2030. [43] In the 2021 Medical Tourism Index, India was ranked 10th (of 46 destinations globally), underscoring its status as a hub of medical excellence. [44]

India's position as a leading Medical Value Travel (MVT) destination is driven by its advanced medical technology, skilled healthcare professionals, low waiting time for treatment, ease of communication in English language, and world-class infrastructure compliant with international quality standards, including Joint Commission International (JCI) and National Accreditation Board for Hospitals & Healthcare Providers (NABH). Medical procedures in India are over 60% to 80% less expensive than in developed countries. [45] For example, a cardiac procedure that costs ~ US$100,000 in the US or ~ US$40,000 (~£30,760) in the UK can be performed for merely ~ US$5,000 (~INR420,396) in India with similar clinical success. [46]

Recognizing the potential for medical tourism, the Government of India has implemented several measures to support its growth. For instance, 'Heal In India' initiative aims to promote India's medical facilities and infrastructure with plans to standardize processes and treatment packages for foreign nationals. The government has also eased visa restrictions to streamline the entry process for medical tourists. [47]

Patients from nations such as Afghanistan, Pakistan, Oman, Bangladesh, the Maldives, Nigeria, Kenya, and Iraq constitute a significant portion of India's medical tourists. Gradually, India is progressively drawing patients from more developed regions, including Europe and the Americas, encouraged by the government's active promotion of medical tourism and the esteemed standing of India's healthcare system.

This growth of medical tourism in India will create a demand for high-end equipment across different care sites, including hospitals, outpatient care settings, and home healthcare to cater to the diverse needs of international patients.

As India continues to attract medical tourists for its economical yet superior medical services, the MedTech sector will play a pivotal role in sustaining and enhancing this momentum.

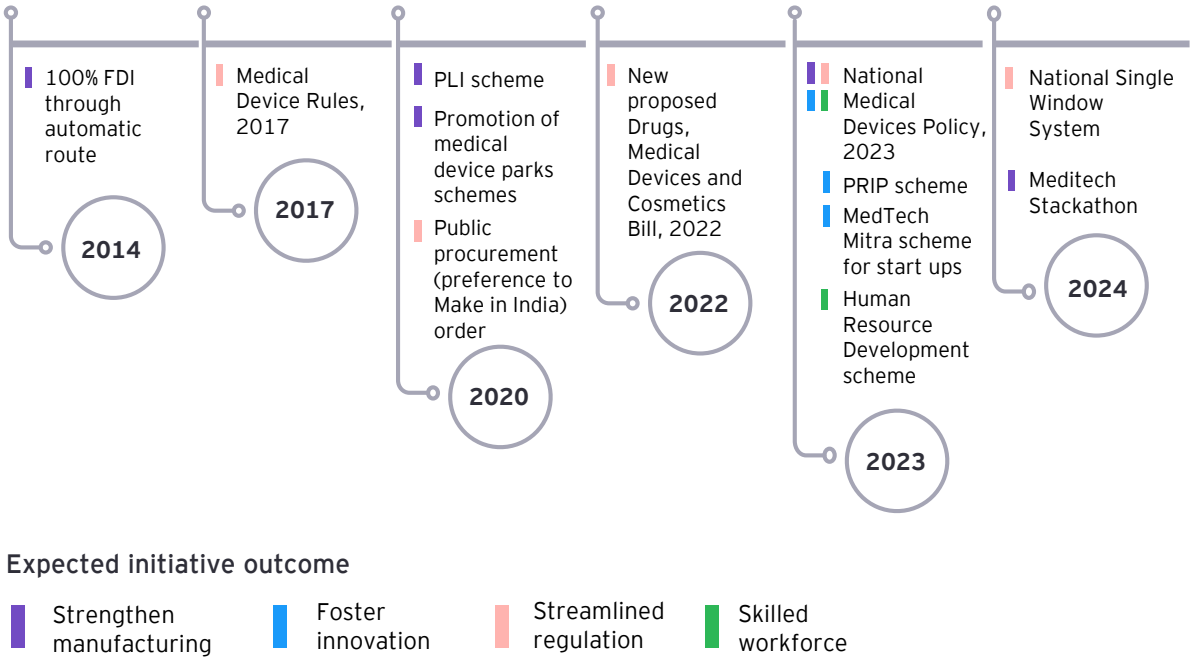
[41] The medical tourism industry takes off, albeit restricted to large cities, MedicalBuyer.co.in
[42] Development of Medical Tourism Hubs, Tourism.gov.in
[43] 2022—The Year of Indian Medical Tourism, Health News, ET HealthWorld (indiatimes.com)
[44] India ranked tenth in Medical Tourism Index for 2020-2021 (thestatesman.com)
[45] The medical tourism industry takes off, albeit restricted to large cities - Medical Buyer
[46] 2022—The Year of Indian Medical Tourism, Health News, ET HealthWorld (indiatimes.com)
[47] Team-india-blogs/heal-india-emergence-india-hub-medical-tourism (investindia.gov.in)

C. Evolving MedTech industry ecosystem

11. Increasing government focus

The Government of India has implemented a comprehensive set of innovative initiatives and supportive policies to reduce import dependence and boost exports. These efforts span across regulatory reforms (e.g., 'Medical device rules, 2017', 'National Medical device policy, 2023'), infrastructure development (e.g., Production Linked Incentive (PLI) scheme, promotion of medical device parks scheme), innovation promotion (e.g., MedTech Mitra platform for start-ups, Promotion of research and innovation in Pharma -MedTech sector (PRIP) scheme). Recently, on 3 Oct 2024, India has received membership in the International Medical Device Regulators Forum (IMDRF), highlighting its dedication to regulatory alignment with international norms and the production of medical devices that adhere to the most stringent global standards. [48] All these initiatives aim to foster a robust and competitive ecosystem for medical device manufacturing and innovation in India, with initial results already emerging.

Roadmap of government initiatives* for strengthening the MedTech sector



*Non-exhaustive

The PLI scheme for medical devices was launched in 2020 with the aim of reducing import dependence and enhancing the competitiveness of domestic manufacturers. It proposes financial incentives to boost domestic production and attract significant investment from both national and international companies. The scheme has successfully garnered the interest of prominent entities, such as Sahajanand Medical Technologies (SMT), Poly Medicure, Trivitron Healthcare, Wipro GE HealthCare, Siemens Healthineers and Panacea Medical Technologies, among others.

[48] India-becomes-affiliate-member-of-international-medical-device-regulators-forum (economictimes.indiatimes.com)

PLI scheme: The cornerstone of India's strategy to boost domestic manufacturing of medical devices

Scheme overview

- Total outlay of ~INR3,420 over a five-year period
  - 5% incentive on incremental sales of medical equipment over base year 2019-20
  - Minimum incremental sales requirement of INR60 crore in the first year, INR120 crore in the second year, and progressively INR280 crore by the fifth year.
- Four target segments (life-saving high-risk diseases):
  - Cancer care/radiotherapy
  - Radiology and imaging, nuclear imaging devices
  - Critical care devices (anesthesia, cardio-respiratory care, renal care)
  - All implants, including those containing implantable electronics

Achievements

- As of Apr 2024, **26 companies are approved under scheme** for manufacturing of **138 devices** including Linear accelerator, MRI machines, CT-Scan, Mammogram, C-Arm, MRI Coils, high end X-Ray tubes
- **13 factories** for medical devices inaugurated by March 2024
- **Actual production of ~INR5,889 crore** till April 30, 2024, offering employment to ~5,466 persons
- **High-end medical devices** being manufactured indigenously, some of them for the first time

Source: pharmaceuticals.gov.in , biovoicenews.com, pharmabiz.com, bwhealthcareworld.com

Establishment of medical device parks: The medical device parks are strategically designed to host a suite of world-class, common infrastructure facilities including testing and laboratory facilities, all centralized in one location. This arrangement significantly reduces manufacturing costs and fosters a strong ecosystem for medical device production. At present, India has nine medical device parks at different development stages, with two operational. In 2020, the government has introduced the 'Promotion of Medical Devices Parks Scheme'. Under this scheme, a grant of INR100 crore will be provided from 2020-21 to 2024-25 to establish common infrastructure facilities in medical device parks located in four states.

The National Medical Device Policy, approved in April 2023, aims at making India a global leader in medical device manufacturing and innovation by achieving a share between 10% and 12% in the expanding global market over the next 25 years. Six components of the policy are -streamlining the regulatory framework, enabling indigenous manufacturing, facilitating R&D and innovation, creating awareness and brand positioning, developing skilled workforce, and attracting investments.[49] Since the launch of this policy, the government has introduced a range of impactful initiatives aimed at driving its objectives.

[49] Press information Bureau (pib.gov.in)

Medical device parks in India

Medical device parks in India	District / city	Development status	Specialization / highlights
Andhra Pradesh MedTech Zone (AMTZ)	Visakhapatnam	Operational, launched in 2016	100+ companies working on R&D and production
Telangana	Hyderabad	Operational, launched in 2017	50+ companies working on production
Himachal Pradesh	Solan	Under development	► Medical electronic devices such as Ultrasound, C-arm, X-Ray machines, and automated lab analyzers ► Home-based devices such as glucometer, thermometer, and oximeters ► OT and ICU equipment ► Intraocular and orthopedic implants
Uttar Pradesh	Gautam Buddh Nagar	Under development	► Cancer care and radiology ► Imaging technologies ► Anesthetics ► Cardiorespiratory equipment ► Devices associated with pacemakers ► Cochlear implants
Tamil Nadu	Kancheepuram	Under development	► Preventive, diagnostic and therapeutic procedures ► Technical and application software ► IVD and reagents ► Artificial bio-devices
Madhya Pradesh	Ujjain	Under development	► Range of medical devices, including stents, implants, and diagnostic devices ► Investment proposal from 28 companies as of Apr 2024
Kerala (MedSpark)	Thiruvananthapuram	Under development	► High-risk medical device including medical implants and extracorporeal devices
Gujarat	Rajkot	Under development	► It is expected to facilitate research and development, testing, manufacturing, training, and incubation
Haryana	Panipat	Under development	► Proposed to provide CoE, research and development center, testing labs, etc.

Source: Pharmaceuticals.gov.in, amtz.in, lifesciences.telangana.gov.in, Uttar Pradesh (indiatimes.com), Indore (indiatimes.com), Kerala (newindianexpress.com), Gujarat (pharmabiz.com), Haryana (investharyana.in)

National Medical Devices Policy, 2023: Key components

Streamlining the regulatory framework
to enhance ease of doing research and business

Enabling indigenous manufacturing
through establishment and strengthening of large medical device parks and clusters

Facilitating R&D and innovation
to promote R&D and complement the proposed National Policy on R&D and Innovation in the Pharma-MedTech Sector

Creating awareness and brand positioning
through a dedicated Export Promotion Council (EPC) which will be an enabler to deal with market access issues

Developing skilled workforce
through skilling, reskilling and upskilling of professionals, and supporting multidisciplinary courses

Attracting investments
through Public-Private Partnership (PPP) and VC fundings

12. India's inherent digital and technology strength

The Indian Information Technology (IT) and software industry is a global powerhouse today, with significant impact across sectors. According to our analysis, discussed in detail in Chapter 4 of the report, digital integration is one of the core focus areas for innovation in medical devices globally. India's expanding digital ecosystem can be a powerful catalyst and give the Indian MedTech industry a differentiated edge in its pursuit of the next phase of innovation and transition into developers of advanced medical devices.

We see many collaborations between the Indian and global companies with the Indian tech firms. For instance, Indian company Mylab Discovery Solutions is partnering with Indian tech firm Qure.ai to integrate AI into its chest X-Ray screening tool for the early detection of tuberculosis (TB).[50] An Indian pure-play engineering services company, L&T technology, has a collaboration with global AI computing company, NVIDIA, to develop software-defined architectures for medical devices focused on endoscopy to enhance the image quality and scalability of products.[51]

[50] Mylab-partners-with-qure-ai-for-speedy-tb-diagnosis-through-ai-aided-x-ray (Indianexpress.com)

[51] L&T Technology Services Collaborates With NVIDIA to Unveil Gen AI and Advanced Software-Defined Architecture for Medical Devices - Press Release (ltts.com)

India's growing IT and digital landscape: Current state and future projections

~ 5.43 million individuals employed in the Indian IT industry in 2023-24[1]

India forecasted to become a trillion-dollar digital economy by 2025-26 (MeitY)[2]

By 2026, India's IT sector will need ~9.5 million professionals, including ~5.5 million in digital tech like AI and IoT [2]

Expanding digital talent

FutureSkills PRIME – digital skilling initiative[3,4]

- Launched in 2020 in partnership between MeitY and NASSCOM to make India a "Digital Talent Nation"
- Aims to create a re-skilling/up-skilling ecosystem in 10 emerging technologies, including IoT, AI/ML, GenAI, big data analytics, etc.
- Platform content to be created/curated directly by industry
- >2,000 courses and pathways
- >0.8 million candidates enrolled
- >0.6 million unique badge holders
- Presence in 710 Tier 2 and Tier 3 cities
- Partnerships with >2,000 academic institutions, >150 corporates

Tier 2 cities emerging as tech hubs[5,6,7,8]

Tier 2 cities are thriving in IT, driven by accessible talent, improved infrastructure, cost benefits, and government support

- **Talent pool:** ~11–15% of India's tech talent, with a significant number of STEM graduates
- **Start-up ecosystem:** Over 7,000 start-ups operating in tier 2 cities in fields from DeepTech to Business Process Management (BPM) services
- **Operational cost savings:** ~50% cost advantage over Tier 1 cities

Tier 2 cities are capitalizing on their unique strengths to carve out niches in specific services

- Mysuru positioning itself as a cybersecurity hub
- Ahmedabad developing strong capabilities in Banking, Financial Services and Insurance (BFSI), and Financial Technology (FinTech)
- Blockchain and Web 3.0 are gaining prominence in Mangaluru, Tiruchirappalli, and Visakhapatnam

Impact on the medical device industry

Increased development of AI-powered diagnostics and therapeutic devices

Growth in telemedicine and remote patient monitoring solutions

Advancements in data analytics for personalized medicine and population health management

Rise of Indian start-ups focusing on innovative digital health solutions

Sources: 1. IT/Software Sector | meity.gov.in , 2. Number of employees in IT (pib.gov.in) , 3. Futureskillsprime.in (assessed in Sep'24), 4.Future Skills Prime_indiatimes.com, 5. nasscom.in| Emerging Technology Hubs of India, 6. Indiabusinesstrade.in , 7. medium.com, 8. Starofmysore.com

13. Burgeoning start-up ecosystem

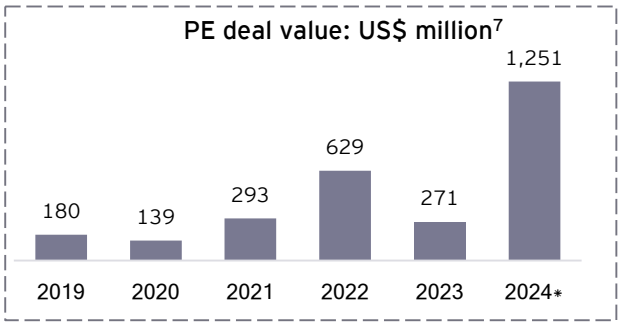
India has seen a surge in medical device start-ups in recent years, supported by the proliferation of incubation and acceleration programs at top academic institutions, government institutes, and global and Indian MNCs. These programs, such as the Center for Cellular and Molecular Platforms (C-CAMP) in Bangalore, [52] IIT Madras MedTech incubator, [53] and MedTech CoE in Software Technology Parks of India (STPI), Lucknow, provide start-ups with access to mentorship, funding, and technical resources to help them develop and scale their solutions. [54] These emerging enterprises are contributing fresh perspective and cutting-edge solutions across the MedTech segments, further propelling medical technology innovation. We will discuss innovation from start-ups in detail in Chapter 4 of the report.

14. Improving investor sentiments

The medical device sector in India has attracted significant interest from Private Equity (PE) firms, who see the potential for growth and innovation in the market. The healthcare devices and supplies had already attracted over US$1.2 billion of PE and Venture capital (VC) investments till August 2024, highest in the last five years. [55]

Growing investor interest in the MedTech industry

Drivers: Rising global demand for affordable, high-quality medical devices coupled with India's cost competitiveness and global export potential



*January to August 2024

- PE investment from Jan - Aug 2024 is already ~83% of the cumulative investment in the last five-year period (2019 to 2023)
- KKR's buyout of India's Healthium Medtech for US$839 million was the largest transaction in 2024 (till Aug) [1]
- Most deals during 2023 and 2024 focused on surgical devices and consumables, followed by IVD and cardiovascular devices

Top five deals in 2024 (till Aug'24)

Date	Investor	Investee	Deal value (US$ million)	Details
Jun'24	Jashvik Capital	Futura Surgicare	25	Futura Surgicare sells wound closure and surgical consumable products to 10,000+ hospitals in India across 26 states and 70+ countries globally[2]
May'24	KKR	Healthium Medtech	839	Healthium Medtech manufactures and sells surgical products in about 90 countries[3]
May'24	Kotak	Bioradmedisys	48	Bioradmedisys manufacturers orthopedic implants, surgical and consumables devices[4]
Apr'24	Warburg Pincus	Appaswamy Associates	300	Warburg Pincus, a US PE firm, secured its biggest Indian healthcare deal by acquiring a 65% stake in ophthalmic equipment producer, Appaswamy Associates[5]
Jan'24	360 One asset	AMPA Orthodontics	16	AMPA Orthodontics owns dental care brands, toothsi and makeO[6]

Sources: EY analysis

1. Reuters.com, 2. jashvikcapital.com, 3. livemint.com, 4. economictimes.indiatimes.com, 5. livemint.co | warburg-pincus, 6. vccircle.com, 7. medicalbuyer.co.in

[52] CCAMP
[53] Home – MedTech Incubator (iitm.ac.in)
[54] Centre-of-entrepreneurship_medtech (STPI.in)
[55] EY analysis

Additionally, **Foreign Direct Investment (FDI)** in the medical device sector is increasing over the years. In the first two quarters of 2023-24, India witnessed US$425 million in FDI in the MedTech sector, highest since 2019-20. [56] The liberalized FDI regime from government in 2014 i.e., allowing 100% FDI through the automatic route, has already led to increased interest from global medical device manufacturers in setting up production facilities in India. Recently, Medtronic announced its plan to expand its footprint in Hyderabad with INR3,000 crore investment in its R&D center. [57] Siemens Healthineers announced an investment of INR1,300 crore in Bengaluru innovation hub, which will combine R&D and manufacturing to make India a center of competence for the design and development of entry-level products. [58]

Seizing the future: Charting the course for realizing the potential

Amid all these powerful catalysts for growth, the Indian medical device industry stands at the cusp of two significant opportunities:

1. **Harnessing the vast untapped potential within the country to drive both 'India for India' and 'India for Global' strategies**
2. **Embracing the imperative for innovation in medical devices, both digital and non-digital,to meet evolving healthcare needs**

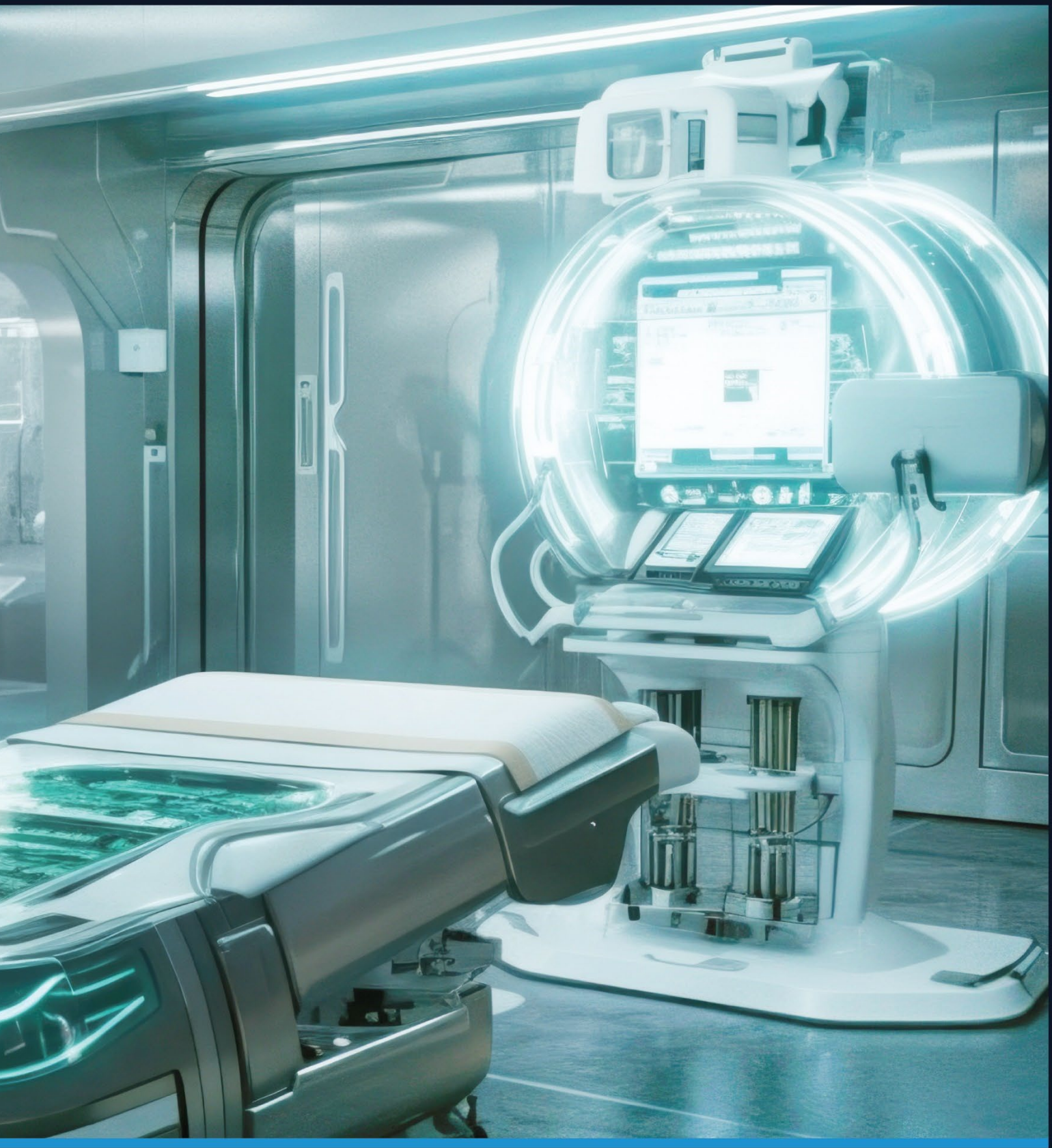
The subsequent chapters provide an in-depth analysis of the way forward in these two areas of opportunity as they form the foundation for India's emergence as a formidable force in the international MedTech market.

> The US$50 billion target is slightly underestimated. We are seeing more structure emerge, with significant advancements in innovation, the 'Make in India' initiative, and efforts toward self-reliance and becoming global exporters. Additionally, factors such as a rise in spending capacity and advancements in digital healthcare are driving growth. So, I believe that India has a higher potential.
>
> *Co-founder, Indian medical device start-up company*

> Continuous monitoring of the evolving medical landscape is essential. Currently, we are not setting industry trends; we are followers. Achieving a leadership position would significantly strengthen our standing.
>
> *Co-founder, Indian medical device start-up company*

[56] Health.economictimes.indiatimes.com|indias-medtech-witnesses-surge-of-464-million-in-fdi-investments-mtai
[57] Thehindu.com| medtronic-to-expand-rd-operations-in-hyderabad-with-3000-cr-investment
[58] Health.economictimes.indiatimes.com| siemens-healthineers-to-invest-inr-1300-cr-over-the-next-five-years

03 Shaping tomorrow: Strategic directions for the future of MedTech



For years, the Indian pharmaceutical industry has been a beacon of success, particularly renowned for its dominance in the global generics market. While the MedTech sector is still emerging, its rapid growth trajectory and projections suggest it has the potential to gain significant share in the global market.

With a robust CAGR and forward-looking forecasts, the MedTech industry is on a swift path to not just dominance but global preeminence. Recognizing the potential, some of the leading Indian pharma companies are also strategically diversifying into the MedTech space. This expansion reflects a keen awareness of the sector's dynamic growth prospects and the desire to harness the converging opportunities at the intersection of pharmaceuticals and medical technology.

India's MedTech revolution: Outpacing pharma growth and reshaping healthcare innovation

Sources: EY analysis, ficci.in

Beyond the pill: The confluence of opportunities for Pharma and MedTech

Pharmaceutical companies have acknowledged for a long time the significance of delivery devices in enhancing the effectiveness and convenience of drug delivery to patients. For instance, Cipla made an early entry with its Rotahaler, a transparent dry powder inhaler device introduced in 1997, while Biocon launched the INSUPen in 2011, a reusable insulin delivery pen. These developments underscore the pharma industry's dedication to holistic healthcare solutions, encompassing both drug development and delivery methods.

As the MedTech sector flourishes, pharma companies are increasingly delving into the core medical device arena. A prime example is Cipla's foray into Digital Therapeutics (DTx) in 2019, followed by the 2022 launch of Spirofy, a compact spirometer designed for respiratory conditions, and the 2023 debut of Cippoint, its first point-of-care diagnostic device. This strategic shift signifies Cipla's expansion beyond drug delivery systems to embrace more complex medical devices, signifying a pivotal transformation in its product strategy and portfolio.

India's leading pharma companies venturing into MedTech

Strategic partnerships and licensing agreements

Dr Reddy's

- Jan'23: Dr. Reddy's acquired exclusive marketing and distribution rights of Nerivio DTx in multiple markets from Theranica, an Israel-based prescribed DTx company
- Nerivio is an FDA approved and CE certified non-invasive wearable neuromodulation therapy for migraine
- Dr. Reddy's launched Nerivio in India in 2023, and further expanded to Germany, Spain, UK and South Africa in 2024

Hybrid approach: Strategic investments and in-house development

Cipla

DTx

- 2019: established partnerships with Wellthy Therapeutics and Brandmed

PoC

- 2022: Launched Spirofy, pneumotech-based wireless, portable device for lung function tests
- 2022: invested in Bengaluru based PoC testing company, Achira Labs
- 2023: launched Cippoint, a POC diagnostic device, to test conditions such as diabetes, infectious diseases, thyroid function, etc.

Diversification through dedicated subsidiaries

Lupin digital health

Lupin established its wholly owned subsidiary, 'Lupin Digital health', in 2021 with focus on developing digital therapeutics in cardiology

- 2023: introduced LYFE - cardiology Digital Therapeutics (DTx) platform
- Lyfe: AI-ML program provides doctors with real-time updates, and patients with personalized care pathways, emergency services, and educational resources to manage and recover at home after events such as angioplasty, bypass surgery, and heart failure
- Lyfe received class 3 (SaMD) medical device licence from CDSCO in 2024

Alkem medtech

Alkem established 'Alkem Medtech' in Mar 2024 as a wholly owned subsidiary with the objective of exploring medical device segment especially in cardiovascular and orthopedic therapeutic areas

- Aug '24: Alkem Medtech collaborated with the US-based MedTech company, Exactech to manufacture and market its knee and hip joint replacement implants in India

Direct investment in R&D and manufacturing

Zydus

In Jan'24, Zydus announced INR5,000 crore investment to develop next generation biotechnology products, **new medical device initiatives,** and hospitals for the healthcare sector

Sources: Dr Reddys (iTweb.com), drreddys.com, Economictimes.indiatimes.com, Cipla.com, Spirofy (cipla.com), Cippoint (indiatimes.com), Achira Labs (indiatimes.com), lyfe.in, Alkem Medtech (alkemlabs.com), Alkem Exactech (prnewswire.com), Zydus Group (indiatimes.com)

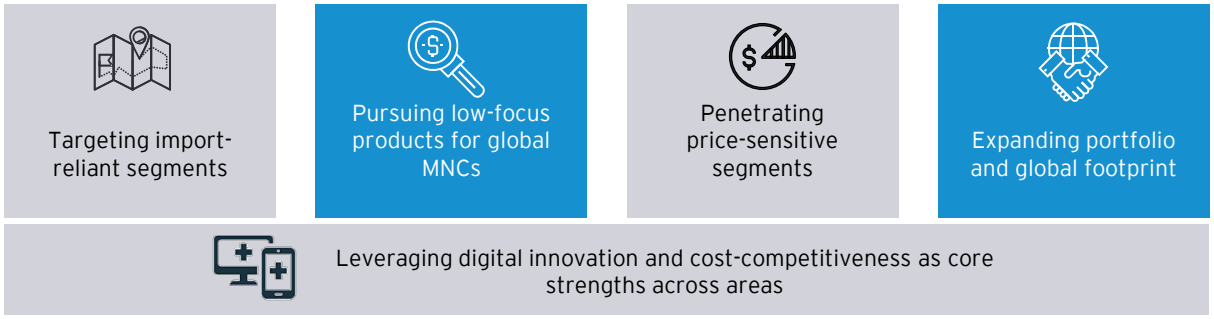
The rapid rise of the MedTech sector emphasizes strategic growth opportunities for both Indian and international MedTech corporations. Let us look into the key opportunity areas and strategic focus of some of the leading Indian and global MedTech MNCs.

Growth strategy of Indian MedTech MNCs

The pandemic served as a catalyst for Indian MedTech manufacturers, presenting an unforeseen opportunity to rise to the occasion and meet the surging medical devices' demand both at home and internationally. The expedited supply of critical devices, including ventilators, rapid antigen and RT-PCR test kits, infrared thermometers, PPE kits, and N-95 masks, not only accelerated the growth of India's MedTech sector but also significantly enhanced its capabilities. This surge in demand and supply has provided a substantial impetus to the industry, setting a robust foundation for continued strength and expansion in the post-pandemic era.

Based on our research and insights from industry experts, Indian MedTech MNCs are adopting four key strategies to drive growth.

Indian MedTech companies: Key growth strategies



One key area of focus is strategically targeting market segments that are heavily dependent on imports, aiming to localize production and reduce foreign dependency. At present, India's MedTech sector is nearly 80% to 85% reliant on imports, but there is a concerted effort to reduce this figure to below 50% by 2030. This drive towards self-sufficiency has already yielded tangible results, with approximately 150 medical devices that were previously imported now being produced domestically. Moreover, some of these locally manufactured products have begun to reach international markets, signaling a shift in the trade balance. [59]

The second strategy* Indian MedTech companies are adopting is the pursuit of product lines that have historically received less attention from global MNCs. This approach helps them target niche demands that bigger players have not served. Indian MedTech companies leverage their agile manufacturing capabilities to produce these niche products at a competitive cost and scale up rapidly in India and outside. Third area is dominating price-sensitive segments and markets. Indian MedTech companies are leveraging the country's cost-effective manufacturing environment and strength in value engineering to produce high-quality medical devices at lower costs, making them attractive to cost-sensitive markets. One such opportunity came up in 2017 when the government's intervention to cap stent prices disrupted the market dynamics. It fostered a more competitive environment and incentivized Indian producers to invest in research to enhance quality at a lower price. Previously dominated by international entities, the Indian stent market now features a mix of domestic and multinational firms. Prominent Indian manufacturers like Sahajanand Medical Technologies (SMT), Meril, and Translumina have made significant strides alongside global companies. Indian-made stents have earned trust and recognition, extending their reach to serve global markets. The impact is evident in the numbers: in 2017, Indian stent manufacturers accounted for 61% of total stent sales in India, up from 57% the previous year, marking a significant shift in the industry landscape. [60]

The fourth strategy is expanding portfolio and geographical reach by forming strategic collaborations with global entities for technology

*The number allocated to strategies does not follow any specific order of preference. Typically, companies employ a combination of these strategies, tailoring their approach to align with the specific segment and product category

[59] Govt, industry must work together to reduce import dependence: Pharma secy | News - Business Standard (business-standard.com)
[60] Indian stent makers: No more on the fringes of business - Express Healthcare

Indian MedTech MNCs: Examples of growth strategies

Leveraging domestic expertise of IT/digital technologies to develop advanced devices

Skanray

In 2024, partnered with Tata Elxsi, Bangalore based global design and technology services company, for advanced surgical imaging and healthcare innovation

- Develop new device families and modalities
  - Bring interoperability, compatibility and multi-modal functionality in all imaging, critical care and surgical systems; use AI and GenAI capabilities
  - Develop advanced analytics cloud platform

Expanding portfolio through strategic partnerships

SMT

In 2024, partnered with HeartX, a MedTech company focused on R&D for Congenital Heart Defect products

- Expand portfolio
- Transform congenital heart defect treatment with affordable products
- Bring domestic products to the global market

Enhancing geographical presence with strategic acquisition

Translumina

In 2023, acquired Munich-based interventional cardiology company, Lamed

- Enhance market penetration in Germany– getting access to major group purchasing organization (GPOs) and hospitals
- Broaden its vascular and cardiovascular product range

Expanding portfolio and global footprint with incremental innovation

HMD

The largest manufacturer of auto-disable syringes in the world

- Successful vertical integration, do not rely on other countries to procure raw materials
- 2024: Launched first-of-its kind single use syringes with safety needles to minimize needle stick injuries

Sources: Skanray (TataElxsi.com), SMT and HeartX (business-standard.com), translumina-acquires-lamed (cardiovascularnews.com) , hmdhealthcare.com, HMD (biospectrumindia.com)

No one strategy is better than the other, and companies usually adopt a combination of these strategies depending on the segment and product type. An excellent example is Meril's comprehensive strategy for its newly launched robotic surgery system.

Meril's strategy to democratize robotic surgery with 'Misso'

Misso: An indigenously developed advanced surgical robotic system for knee replacement procedures, launched in Jun'24

Key features

- **Compact design,** making the robot suitable for smaller operating rooms
- **AI integration** to reduce the pre-operative planning time by 83%, and improve personalization and precision
- **Real-time assistance** to doctors during knee replacement surgeries
- **Improved safety with** Bone Motion Monitor (BMM) that detects any slight movements during surgery
- **Sub-millimeter precision** in bone shaping, improving post-operative outcomes
- **Versatility,** technology is adaptable for potential use in other joint surgeries, indicating a future expansion in hip and spine

Key strategies to expand market share of robotic system

Key strategies

Cost leadership

Priced at INR2 crore, ~ 66% less than available alternatives in the Indian market

Accessibility

Expected to reduce the cost of knee replacement surgeries by 40% to 60%, making it accessible to a larger population

Market penetration

Smaller platform footprint makes it suitable for a broader market adoption, including smaller hospital rooms in Tier 2 and Tier 3 towns where cost is a significant factor in technology adoption

Establishing the ecosystem

Program in place to provide platform alongside an ecosystem of training and services support to surgeons and OT staff

Global expansion

- *Aim to sell ~ 100 units in the first year and scale up to 1,000 units in three years*
- *Plan to expand in overseas markets in Asia, Europe and the US*

Sources: merillife.com , business-standard.com, biovoicenews.com

Growth strategy of global MedTech MNCs

For decades, India has been a strategic market for most of the leading global MedTech MNCs, valued for its vast consumer base, skilled workforce, and growth potential across various healthcare segments. These companies have established a significant presence, adapting to local market dynamics and contributing to the healthcare ecosystem's evolution.

Based on our research and insights from industry experts, global MedTech MNCs are adopting three key strategies to drive growth in the Indian market.

One key area of focus is strategic partnerships and joint ventures, which are a crucial aspect to tap into local knowledge and market presence. For instance, GE HealthCare's joint venture with Wipro has enhanced their ability to manufacture and distribute medical devices in India. Such collaborations enable MNCs to navigate the complex Indian healthcare landscape more effectively while sharing risks and resources.

The second strategy global MedTech companies are pursuing is localization of manufacturing and R&D. A notable example is Philips' launch of its made-in-India ultrasound and C-arm systems, which were specifically designed and manufactured for the Indian market. This localization effort not only reduces costs but also allows for customization to meet local healthcare needs and preferences, while supporting the government's 'Make in India' initiative.

The third strategy is driving growth through innovative digital solutions. For instance, Medtronic's comprehensive remote cardiac monitoring ecosystem and Philips' 'HealthSuite digital platform'. These digital services and data-driven products not only improve patient care but also generate additional revenue through B2B models.

Global MedTech companies: Key strategies for growth in India

Strategic partnerships

Localization of products

Digitalization of products and services

Joint ventures (JV) for long-term collaboration leveraging local expertise

Wipro GE HealthCare JV

Wipro Enterprises and GE Precision Healthcare formed Wipro GE HealthCare JV in 1990

- Invested over US$4 billion in R&D and manufacturing over three decades
- Fostered a strong local supplier ecosystem of MedTech component manufacturing – covering capabilities such as plastics, machining, castings, 3D printing, Electronics Manufacturing Services (EMS)

Increasing localization, bringing better patient outcomes at affordable cost

Philips

2020: launched first 'Make in India' Affiniti Ultrasound

The local production of the innovative Affiniti system ensures that Indian customers receive international quality products at:

- Standard delivery timelines
- Affordable price

2023: launched Zenition mobile C-arm - designed, developed and manufactured in India

Driving digitalization for growth

Philips

Offers connected cloud health applications

Philips HealthSuite Digital Platform (HSDP), cloud-based platform for connected care

- Collects and stores data from various sources, including medical devices, consumers and clinical data
- Analyzes and provides actionable insights for better health outcomes

Medtronic

Offers comprehensive remote monitoring solutions for cardiac patients

Mycarelink remote solutions:

- **Heart mobile app**: Allows patients to securely transmit data to their doctors
- **Smart patient monitor**: Portable device reader that connects to a smartphone; automatically sends cardiac device data to clinicians
- **Relay home communicator**: A bedside monitor that automatically connects to cardiac devices using Wi-Fi or cellular data while patients sleep

Sources: gehealthcare.in, philips.co.in, Zenition10, Philips healthcare innovation, medtronic.com

Wipro GE HealthCare: India as the key innovation and manufacturing hub

- **Wipro GE HealthCare is a joint venture**
  - **Established in 1990** between India's Wipro Enterprises Limited and the US-based GE Precision Healthcare LLC
  - **One of the longest-running JVs** with operations spread across India, Bangladesh, Sri Lanka, Nepal, Maldives and Bhutan
  - Invested over **US$4 billion** in R&D and manufacturing over three decades since inception

Investments and collaborations to drive innovation and growth

Pioneered the "Make in India - for India and the world" initiative

- In 2022, launched a new plant, Wipro GE Medical Device Manufacturing factory (MDM) under government PLI scheme to boost local manufacturing
  - CT machines, cathlab equipment, ultrasound scanners, patient monitoring solutions, ECG machines and ventilators
- In Mar'24, announced a ~US$1 billion investment to expand manufacturing and R&D facilities over the next five years
  - Aim to boost local manufacturing footprint to address the growing domestic and international market and build supply chain resiliency for the organization
  - 'Made in India' PET CT will be exported to 15 countries
  - 'Made in India' CT and MR coils will be manufactured 'In India for the World'

Recent collaborations

Indian Institute of Science (IISc), 2024

- To enhance industry-academia collaboration in key technologies such as precision care, robotics, cybersecurity, AI, and 5G to boost the innovation ecosystem and accelerate local manufacturing

> "The collaboration will emphasise combining science and engineering with translational & clinical research to epitomise "bench-to-bedside" innovation."
>
> **Govindan Rangarajan**
> Director, Indian Institute of Science (IISc)

Boston Scientific, 2022

- First-of-its-kind collaboration between the two MedTech companies in India to enhance interventional cardiac care
- Aim to support the training and education of healthcare professionals and raise consumer awareness

> "With our collaboration with Boston Scientific, we aim to unlock the potential of interventional cardiology, offer better heart care by building efficiency across the care pathway journey of the patient and deliver precision care."
>
> **Dr. Shravan Subramanyam**
> Managing Director, Wipro GE HealthCare

Future goals: aims to incrementally increase product localization from 50% to 70-80% annually

> "India is a high potential, high priority market for GE HealthCare globally. In fact, we are among the first MedTech companies to 'Make in India - for India and the World'. We will continue to invest in expanding India's domestic capabilities and its global footprint in MedTech manufacturing and R&D.
>
> *Peter J. Arduini*
> *President and CEO, GE HealthCare*

Sources: gehealthcare.in, gehealthcare.in (Investment), business-standard.com, gehealthcare.in (Boston Scientific), iisc.ac.in

India's ascent as a global MedTech innovation and manufacturing hub

Amid the shifting global landscape, global MNCs are now intensifying their focus on India not just as a key market, but as a critical hub for their "India for Global" strategy. This strategic pivot is driven by a confluence of factors: the pandemic-induced need for diversified and resilient supply chains, geopolitical realignments prompting a "China+1" approach, and the anticipation of the new Biosecure Act in the US, which may further indirectly influence global companies' partnership decisions.

In essence, the presence of global MedTech MNCs in India is evolving from a primarily sales-focused approach to a more integrated model, where India's contributions to R&D, manufacturing, and global strategy are becoming increasingly significant. This transition reflects a recognition of India's potential to enhance global MedTech operations, ensuring agility, innovation, and sustainability in a rapidly changing world.

By investing in local R&D facilities, global MedTech MNCs tap into India's pool of skilled scientists and engineers to drive innovation. These investments not only support the development of India-specific products but also contribute to the MNCs' global innovation pipeline.

India: The new nexus of global MedTech manufacturing and innovation

Boston Scientific

In 2022, expanded its footprint in India with the second R&D center in Pune; first in Gurugram (2014)

- First R&D center, established in 2014, has contributed to >100 patent fillings and innovation ideas
- The new R&D center in Pune to provide support in areas of mechanical design and analysis, software engineering, sustaining engineering, quality, and compliance

Siemens Healthineers

Manufacturing imaging systems in India for the world

- The Bengaluru factory is manufacturing entry-level C-arms and CT scanners, which are designed, developed, and made in India and are sold in South-East Asia, Africa, Eastern Europe, and South America
  - 2022: inaugurates CT scanner production line under Government's PLI scheme
  - 2023: inaugurates MRI facility under Government's PLI scheme
  - 2024: Announced to manufacture digital radiography X-Ray machine in India

Stryker

Inaugurated Neurovascular lab in 2022, within its Stryker's Global Technology Center (SGTC)

- Aims to accelerate stroke-related innovation in Asia Pacific
  - Has three core components:
  - A simulation catheterization lab,
  - A performance lab with neurovascular simulators and 3D printing capabilities
  - Area for physician interaction

Omron

Establishing its first Indian medical devices plant

- In 2023, initiated the establishment of a manufacturing plant for blood pressure monitors to produce locally-made devices to cater to the growing demand within the country
- Once operational, the plant will be an addition to its global network of production facilities spanning Japan, China, Vietnam, Italy, and Brazil

Sources: medicalbuyer.co.in, stryker.com, siemens-healthineers.com, siemens-healthineers.com, siemens-healthineers.com, indiatimes.com, newindianexpress.com

Additionally, the global MNCs are increasingly shifting their core capabilities and intellectual property (IP) development to Global Capability Centers (GCCs) in India. This strategic move allows companies to ensure tighter control over innovation, critical operations, and R&D processes, while leveraging India's cost efficiencies and skilled talent pool.

.

India: The new global hub for GCCs

India has become the preferred destination for GCCs with its unique combination of skilled expertise and cost-effectiveness. Accounting for over half of the world's GCCs, India is now the global hub for these operations across different sectors.

Since the early 2000s, many leading life sciences companies have set up GCCs in India. Several global MedTech MNCs are expanding their digital centers in India to utilize the exceptional talent pool and resources. For example, Roche inaugurated its Digital Centre of Excellence in Pune to create innovative digital healthcare solutions. Additionally, partnerships between global MedTech companies and Indian tech firms are emerging to enhance product development, such as HCLTech's dedicated product innovation center in Hyderabad (operational from July 2024) which will support Olympus' international operations. Based on comprehensive analysis of the GCCs of some of the leading global MedTech MNCs, GCCs have progressed from mere administrative functions in the past to become vital to the global strategies of the companies.

MedTech GCCs: Capabilities across the MedTech value chain

Company	Product development	Regulatory function	Commercial operations	Post market surveillance	Data and digital solutions
3M	■				
Cardinal health	■		■	■	■
Medtronic	■	■	■		■
Philips	■	■	■		■
Siemens Healthineers*	■		■		■
Stryker	■		■		■
Thermofisher	■				

Interesting facts

Medtronic

Medtronic Engineering and Information Center (MEIC)

- Company's **largest innovation** center outside of the US; will emerge as its **largest R&D site** globally by 2025, with around **1,500 engineers**

Siemens Healthineers*

- Announced investment of INR1300 crore in 2020 for innovation hub, largest investment in India so far
- Will be one of the four global innovation hubs (along with the US, Germany and China hubs)
- Plan to hire 1,800 skilled digital tech experts by 2030

*Planned as a part of their 2025 strategy

Global capability centers building technical capabilities and future skill-set

Medtronic

Medtronic Engineering and Innovation Center (MEIC), Hyderabad (Established in 2011)

Key capabilities across MedTech value chain

Product development

- Key contributor to Medtronic's global new product development
- In 2024, expanded their R&D facility in Hyderabad
- Supports ~15 Medtronic operating units globally with a focus on innovative software development, medical mobile apps, and engineering research

Regulatory function

- Operates globally, integrating various business units in product quality and regulatory domains
- Contributed to ~200 global patents and ~500 intellectual property disclosures

Commercial operations

- Supports global operations and supply chain

Post market surveillance

- Post-market quality check

Data and digital capabilities

Global IT Centre (GIT), Hyderabad

- In 2024, established GIT to enhance global technology capabilities
  - First large-scale IT capability center outside of the US
- Key technologies - cloud engineering, data platforms, digital health applications, hyper automation, AI/ML
- GIT will create 300 jobs over the next three to five years

Key facts

- MEIC is Medtronic's **largest innovation center** outside of the US
- **900+ engineers**, representing top STEM talent with diverse perspectives

Global relevance

> *Rapidly growing engineering and innovation center (MEIC) in Hyderabad will emerge as the largest R&D site globally by 2025 with around 1,500 engineers*
>
> *–Geoff Martha*
>
> *CEO, Medtronic*

> *India offers one of the best talent pools for IT. We look forward to leveraging the skillset to support the growth of healthcare technology, thereby positively impacting patient lives.*
>
> *–Rashmi Kumar*
>
> *SVP and CIO Global, Medtronic*

Global capability centers building technical capabilities and future skill-set

Key capabilities across MedTech value chain	Philips	Stryker
	Philips Healthcare Innovation Center (HIC), Pune (Established in 2011)	**Stryker's Global Technology Center (SGTC), Gurugram (Established in 2006)**
Product development	▸ End-to-end product development ▸ Smart manufacturing ▸ In 2024, announced new R&D center in Pune ▸ Will be operational in two years	▸ R&D center with SGTC provide engineering support to R&D functions in domestic and other emerging markets
Regulatory function	▸ Product quality and regulatory	
Commercial operations	**Philips Global Business Services, Chennai** ▸ Established in 2016 ▸ Supports human resources, finance, procurement, supply chain, and customer services etc.	▸ Supports sales and marketing
Data and digital capabilities	**Philips Innovation Campus, Bengaluru** ▸ In 2023, inaugurated innovation campus in Bengaluru ▸ Software and AI innovation	**SGTC Information Technology, Gurugram** ▸ In 2010, the Information Technology team commenced operations with focus on diverse enterprise platforms and services ▸ Key expertise include emerging technologies such as IoT, enterprise resource planning (ERP), salesforce, Business intelligence, analytics, and digital platforms
Key facts	▸ The new R&D center in Pune HIC will house 1900 employees	▸ With ~1,100 employees, R&D center in SGTC is one of the company's innovation hubs
Global relevance	"Company makes good use of the 'lot of talent' that is there in India. We will see more local manufacturing coming to India because the market is important and there is a good workforce." *-Van Houten* *CEO, Philips (2021)*	

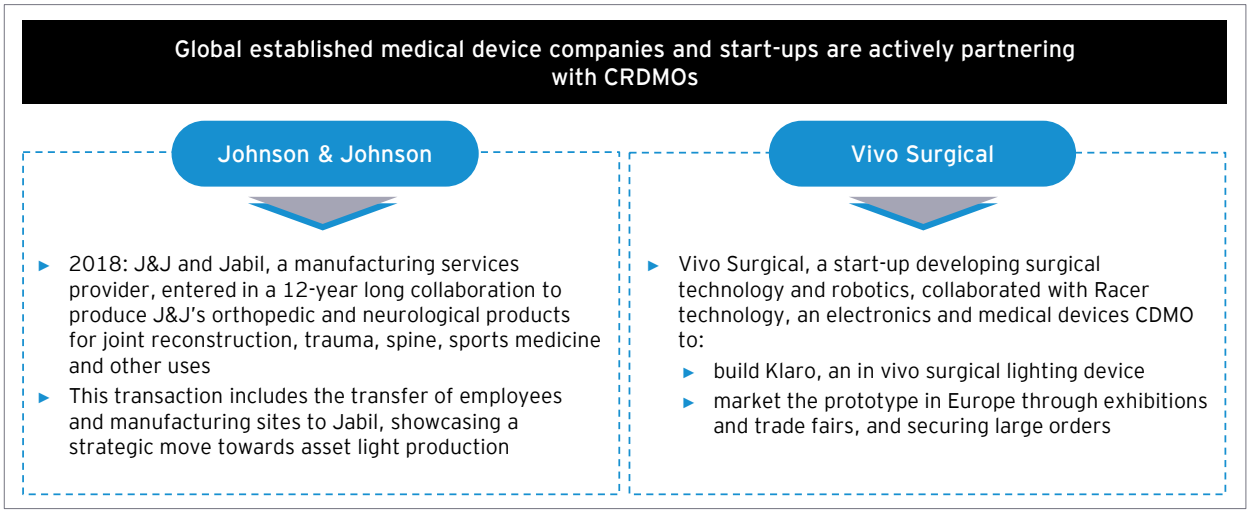
Growing opportunities for Contract Research Development and Manufacturing Organizations (CRDMOs) in the medical devices industry

Amid the growing complexities of the modern business landscape, several global trends are reshaping the way companies approach asset management and operational efficiency. As organizations strive to navigate the uncertain terrain of international markets, an asset-light strategy has become important to enhance flexibility and mitigate risks.

This approach is evident in the de-risking of global supply chains, where companies are not just diversifying their supplier base but also strategically relocating production facilities to safeguard against potential disruptions.

Another trend gaining momentum is the burgeoning partnership with CRDMOs. This collaboration represents a paradigm shift, allowing companies to concentrate on their primary competencies while tapping into the specialized skills and advanced capabilities of external entities for product development and manufacturing. This is exemplified by J&J and Jabil's collaboration to produce J&J's orthopedic and neurological products. [61]

This strategic orientation is not exclusive to established players; start-ups, too, are actively engaging with CRDMOs, starting from prototype development to product marketing, to amplify their product scale and expedite market entry.



Sources: J&J Annual report 2020.pdf , sginnovate.com

Reflecting on these global trends and the increasing focus on manufacturing within the Indian MedTech industry, it is anticipated that players in the MedTech sector will also seek such partnerships. These future-oriented collaborations are poised to become a cornerstone for Indian MedTech firms, enabling them to leverage expertise, accelerate product development, ensure regulatory compliance aligned with global standards, and achieve a more prominent footprint in the competitive landscape of medical technology.

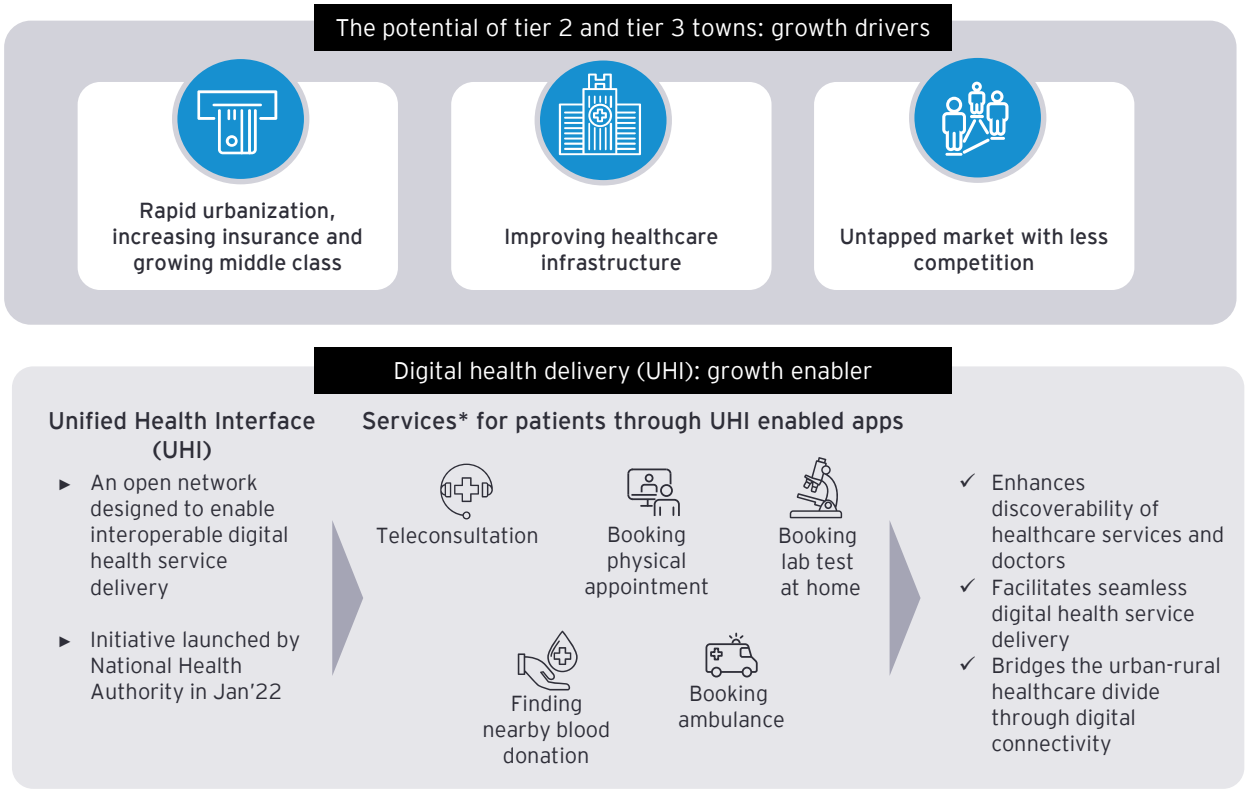
[61] J&J Annual report 2020.pdf

Evolving business models to expand into Tier 2 and Tier 3 towns

Along with the growth strategies adopted by the Indian and global MedTech companies discussed in the previous section, companies are adopting several shifts in their business models and adopting innovative approaches to capture the growing potential from Tier 2 and Tier 3 towns.

This expansion is strongly supported by key government initiatives and digital health enablers, such as the Unified Health Interface (UHI) under the Ayushman Bharat Digital Mission (ABDM), which streamlines digital health service delivery. UHI-enabled apps allow patients to seamlessly discover, book, avail, and pay for services from participating providers.[62] The increased accessibility of healthcare services, coupled with rising insurance penetration through PM-JAY and the rapid development of healthcare infrastructure in these towns, is driving the accelerated adoption of medical devices.

Indian MedTech industry: Unlocking the potential of Tier 2 and Tier 3 towns



*Non-exhaustive
Sources: pib.gov.in

[62] uhi.abdm.gov.in

By emphasizing affordability and accessibility as core features, companies are successfully entering tier 2 and 3 towns. They are also exploring drone delivery, implementing comprehensive training and customer support systems, and establishing unique distribution networks. The companies are embracing digital-native business strategies by leveraging e-commerce solutions, and the Open Network for Digital Commerce (ONDC), aiming to forge a more direct and efficient connection with end-users through home care services and direct-to-consumer tactics. In addition, companies are also adopting new financing models, considering the cost barriers related to the initial installation of expensive equipment.

Innovative strategies and initiatives adopted by companies to penetrate in Tier 2 and 3 towns

Distribution and support innovation

Comprehensive after-sales support and training	**Transasia Bio medicals** has a network of **350+ service engineers, 400+ sales and marketing teams**, that reach out to over **5,000 Tier 2-4 cities, towns, and villages,** including the farthest north-eastern regions in ~four to five hours.
Utilizing drones for delivery in hard-to-reach areas	**Redcliffe Labs** partnered with Skye Air to **pilot drone deliveries of diagnostic samples** in Uttarakhand's remote areas, reducing test sample transportation time from hours to minutes.

Digital-naive business models

Utilizing e-commerce platforms & ONDC	Various start-ups are leveraging e-commerce platforms to sell their products. For instance, 'Agatsa,' a maker of wearable cardiac monitoring devices, and 'Wehear,' a developer of hearing aids, **offer their products both through their official websites and platforms like Amazon.** Global MNCs such as Omron Healthcare India also use direct to customer channel through its website.
Digital health solutions	**GE healthCare** spun off a **healthcare delivery solutions** start-up, GenWorks, to create distribution network for its products in Tier 2 and Tier 3 cities; GenWorks currently offer **affordable digital solutions in 750+ districts in India.**

Innovative financial models

Pay-per-use payment options	Cyclops, domestic start-up, offers pay-per-use model for their diagnostic devices where **clinics and small hospital pay an initial fee and are then billed monthly** based on test volume.
Leasing medical equipment	GE HealthCare offers a provision of leasing medical equipment, allowing hospitals to access advanced tech without significant upfront investments.

Sources: erba.com, financialexpress.com, sanketlife.in, wehearglobal.com, indiatimes.com, genworkshealth.com, business-standard.com, omronbrandshop.com, medium.com

Vision 2030: Future aspiration and potential

India aspires to become a global manufacturing hub for medical devices, aiming to reduce import dependence from the current ~80% to below 50%[63] and boost exports from the current US$3.4 billion to US$18 billion by 2030.[64]

To realize this vision and foster a robust and competitive ecosystem for medical device manufacturing and innovation in India, the Government of India has implemented a comprehensive set of innovative initiatives and supportive policies. These efforts span across regulatory reforms, incentives, infrastructure development, skill development, and the creation of digital platforms (discussed in Chapter 2).

Based on our primary research, we identified five focus areas as important for the MedTech sector to achieve its ambition and to expedite the progress as it advances towards becoming an international nexus for medical device production. These five focus areas are 'Enhancing manufacturing competitiveness', 'Strengthening the entire supply chain', 'Harnessing India's IT and digital prowess', 'Elevating commitment to quality excellence' and 'Embracing value-driven market access'. The following visuals provide a detailed view of each of these five focus areas covering the achievements so far and future enhancements.

[63] Govt, industry must work together to reduce import dependence: Pharma secy | News - Business Standard (business-standard.com)

[64] Indian-medtech-industry-urges-govt-action-to-reduce-import-dependency (business-standard.com)

Key focus areas to propel growth of the industry (Indian MNCs, Global MNCs, start-ups)

1 Enhancing manufacturing competitiveness

Current state	Proposed potential future enhancements
▸ **Robust infrastructure:** ▸ PLI scheme for medical devices	*PLI scheme enhancement:* ▸ Simplify application and approval processes to ensure faster onboarding ▸ Expand coverage to include MSMEs and a wider range of products, especially in areas with high import reliance ▸ Establish more robust framework to facilitate technology transfer and collaboration between Indian and international firms ▸ Long-term policy stability to allow for strategic planning and sustained investment
▸ Promotion of Medical Devices Parks Scheme (2020)	*Enhancement of medical device parks:* ▸ Focus on specialization for each park to allow for more targeted and holistic infrastructure and services, e.g., technology focus (e.g., IVD) or therapy area focus (e.g., orthopedics) ▸ Establish incubation centres and on-site regulatory support hubs ▸ Integrate sustainability measures into parks' operations ▸ Introduce more forums to promote domestic and global partnerships ▸ Tailored incentives and programs for MSMEs, e.g., training centers for skill development
▸ **Regulatory reforms and policy** ▸ 'Medical Device Rules, 2017' (MDR) and 'National Medical Device Policy 2023' ▸ Waived medical devices approved by US, UK, Australia, Canada, Japan & EU authorities from clinical investigation requirements[1] ▸ Received membership in the International Medical Device Regulators Forum (IMDRF)[2]	*Regulatory roadmap* ▸ Synchronization of the regulatory frameworks with global standards ▸ Develop a comprehensive, predictable, incremental, and globally aligned regulatory roadmap for the next two to three years, allowing for industry input and adaptation ▸ Ensure long-term policy stability for enabling sustained investment
▸ **Skilled workforce** ▸ Scheme for Human Resource Development in Medical Device Sector' (2023)	*Strengthen vocational education for IT, Engineering, and Healthcare* ▸ Invest in education and enhancement of professionals who work at the confluence of IT, engineering, and healthcare ▸ Rejuvenate the appeal and applicability of vocational education in establishments such as Polytechnics and Industrial Training Institutes
▸ **Embrace sustainability** ▸ Companies are integrating eco-friendly practices across operations, from reducing waste to innovating biodegradable materials and energy-efficient technologies	*Fostering sustainability culture* ▸ Craft industry-specific sustainability guidelines and best practices ▸ Enforce achievable targets ▸ Launch certification program for sustainable manufacturing coupled with pricing or other incentives for certified products and processes

> Some regulations take too long a time, and then we do not know whether those are going to be implemented or not. Conversely, a few regulations might get implemented in an expedited manner without allowing the industry enough time to really contribute and adapt to the process. Industry would benefit immensely from a more balanced and predictable approach, at least for the foreseeable future.
>
> *- Forum Coordinator, Association of Indian Medical Device Industry (AiMeD)*

Sources: 1 ET HealthWorld (indiatimes.com), 2. Economictimes.indiatimes.com

Key focus areas to propel growth of the industry (Indian MNCs, Global MNCs, start-ups)

2 Strengthening the entire supply chain

Current state	Proposed potential future enhancements
▸ **Customs duty on raw material** ▸ Reduced custom duty on X-Ray tubes and flat panel detectors for use in medical X-ray machines (Jul'24)[1]	*Custom duty and tax rationalization* ▸ Reduce /eliminate customs duties on raw materials and components ▸ Lower GST on domestically produced medical devices *Streamlined quality control compliance* ▸ Simplify operational requirements for importing raw materials under Quality Control Orders (QCOs) *Export incentives* ▸ Implement an export credit system where companies can earn substantial tax credits proportional to their export value, encouraging them to expand internationally *Logistics optimization* ▸ Invest in modern logistics infrastructure (warehousing, IT systems) to streamline domestic distribution and international trade *Enhanced ancillary market development* ▸ Extend the PLI scheme to benefit raw material and component manufacturers ▸ Raise awareness among manufacturers about the diverse applications and potential of ancillary products for the MedTech industry

> It is crucial to strengthen the entire supply chain in India, particularly with tier 2 vendors capable of providing essential components such as power distribution units, electrical panels, and cables. This will enable us to not just assemble devices within India but also to procure critical components from local sources.
>
> One way to extend the PLI scheme to SMEs and component manufacturers is by allowing a PLI-certified entity to extend the benefits of certification to Tier 2 and Tier 3 vendors. Larger companies, already benefiting from PLI, could form consortia to qualify these smaller suppliers. Such an ecosystem would not only bolster finished goods manufacturers but also nurture component developers, which is precisely what our industry requires at this juncture
>
> *- Head of Imaging, South Asia, leading global medical device company.*

3 Harnessing India's IT and digital prowess

Current state	Proposed potential future enhancements
▸ **Ayushman Bharat Digital Mission (ABDM) to build a strong digital health infrastructure** ▸ As of Sep'24, 670+ millions Ayushman Bharat Health Accounts (ABHA) created[2]	**Digitalization of major hospitals across the country, such as AIIMS, to:** ▸ Improve access to clinical trials (virtual participation) ▸ Generate high-quality data for research and innovation

Sources: 1 indiatimes.com, 2. newsonair.gov.in

Key focus areas to propel growth of the industry (Indian MNCs, Global MNCs, start-ups)

4 Elevating commitment to quality excellence

Current state	Proposed potential future focus areas*
▸ **Robust quality standards** ‣ ~1,500 quality standards for medical devices by Bureau of Indian Standards (BIS) ‣ mandated compliance with BIS standards (May'24)	*Embrace 'Quality by Design' and 'Zero-defect' manufacturing culture* *Enhance the regulatory landscape* ‣ Provide robust post-market surveillance mechanism to monitor device performance ‣ Define clear pathway for licensing and certification of medical devices ‣ Maintain active engagement with stakeholders to refine the regulatory processes
▸ **High-caliber testing laboratories** ‣ Six central government laboratories, ‣ 39 CDSCO accredited private testing labs to conduct evaluation under the provisions of MDR (as of Sep'23)1	Reinforce the network of high-quality testing facilities ‣ Expand both the number of testing facilities and the range of devices which can be assessed, especially for state-of-the-art products ‣ Create a widespread network of government-operated or government-subsidized laboratories, optimally positioned in major industrial regions, offering a full spectrum of testing services spanning the entire value chain
▸ **Industry initiatives :** ‣ **'Quality by design' and 'Zero-defect' manufacturing culture;** e.g., Transasia receive ZED (Zero Defect Zero Effect) diamond quality certificate[2] ‣ **Extensive training for HCPs:** ‣ Meril Life Sciences has developed the 'Meril Academy'[3] ‣ Philips India has started 'MRI training schools'[4]	‣ Provide extensive training for HCPs for the effective use of medical devices

5 Embracing value-driven market access

Current state	Proposed potential future focus areas
▸ **Value-based care initiative** ‣ value-based care under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) (2023) ‣ Health Technology Assessment (HTA) through HTA in India (HTAIn) scheme (2017)	‣ *Prefer adopting value-based care models in India over price capping or flat pricing* ‣ *Adopt value-based procurement and strategic interventions, such as creating a centralized system for evaluating innovative healthcare technologies and establishing a clear market adoption pathway for start-up innovations* ‣ *Develop a robust validation and certification processes for value-added innovations, potentially coupled with government incentives like price advantages or preferential procurement policies for certified products.* ‣ *Establish evidence-based frameworks to assess value*

> Rather than adopting a one-size-fits-all models, such as flat pricing and price capping, it is essential to introduce options for affordable products across all categories to serve the entire spectrum of customers. Implementing a tiered or differential pricing strategy and value-based approach is vital, providing high-quality, value-added products to meet the demands of the quality-conscious and affluent middle and upper classes in India, as well as to support the burgeoning medical tourism industry in the country
> *– Managing Director, India, leading global medical device company.*

Sources: 1 pharmabiz.com, 2. BioVoiceNews.com, 3. merillife.com, 4. indiatimes.com

> Amid the shifting geopolitical landscape, India is in a very interesting position to start playing a bigger role in not just serving our own market, but also addressing global markets. We (global MNCs) are cognizant of this potential, and the future investments will be looked at in that light, not just 'in India for India', but 'in India for the World'. This paradigm shift is gradually taking root in the mindset of both local and international leadership. However, the journey ahead is substantial. To enhance competitiveness, it is crucial to amplify our engineering and production capabilities by creating a sizeable domestic market. It is also imperative to establish a comprehensive ecosystem of manufacturers and suppliers. The time is ripe for India to commit to 'Make in India for the world'
>
> *- Head of Imaging, South Asia, leading global medical device company*

04 Paving the way: Ascending the value chain with digital led innovation and start-up momentum

The global MedTech arena is rapidly evolving, with a clear trend toward valuing technological sophistication and specialized medical solutions. Innovation and moving up the value chain are pivotal for the Indian MedTech industry to unlock its US$50 billion potential by 2030.

As a first step in the innovation journey, it is important to understand the direction of innovation trends globally. To understand this, we conducted a detailed analysis of the innovation from leading global and Indian medical device companies for each MedTech segment.

> It is essential to perform ongoing assessments of the evolving medical landscape. Currently, we do not hold a leading role in setting industry trends at a national level; we tend to be followers rather than pioneers, and we need to change this.
>
> *- Co-founder, Indian medical device start-up company*

We conducted a detailed analysis of the new products, solutions and product extensions launched between Jan 2023 and July 2024 by five leading global companies in each of the following segments: 'Therapeutic devices (oncology, cardiovascular, orthopedic, dental and hearing aids)', 'Imaging diagnostics', 'IVDs' and 'disposables and consumables'.

Based on this analysis, we identified three distinct innovation archetypes:

- Incremental: small scale improvements to existing offerings to create competitive advantage
- Substantial: new, patentable product categories significantly altering the competitive landscape
- Breakthrough: redefining medical technology with the potential to transform medical practice

Each type of innovation is instrumental in propelling the field of medical technology forward, ranging from modest enhancements to revolutionary new approaches.

Our research revealed four prominent innovation themes across all MedTech segments: improved safety, enhanced efficacy, increased accessibility and optimized efficiency. These themes reflect the industry's focus on delivering better patient outcomes, expanding healthcare reach and optimizing resource utilization. Notably, digital solutions emerged as a significant enabler of innovation, either integrated into existing devices or as standalone offerings. These digital components are instrumental in enhancing device functionalities in several ways, such as improving data collection and analysis, facilitating remote monitoring, enabling more personalized patient care, improving outcomes and reducing healthcare resource requirement.

Innovation in the global MedTech industry: Analysis of new products, product extensions and solutions launched**

Innovation type: Incremental → Substantial → Breakthrough

Key innovation themes

- **Improved safety** — *Reduced risk to patients/ device users*
- **Enhanced efficacy** — *Better clinical outcomes, treatment precision and accuracy*
- **Increased accessibility** — *Wider availability (e.g., portable/remote access/ expanded patient group), and affordability*
- **Optimized efficiency** — *Optimized resource use (e.g., reduction in time/ reduced burnout/ no expert requirement/ reduced admin. work), and improved workflow*

Innovation examples*

	Improved safety	Enhanced efficacy	Increased accessibility	Optimized efficiency
Across segments	▸ Minimally invasive techniques ▸ Reduced device related complications	▸ AI-powered analysis ▸ Robotic-assisted surgical systems for precision	▸ Remote data access ▸ Reduced cost ▸ Portable device/smaller footprint ▸ Remote monitoring	▸ Workflow optimization ▸ Reduced procedure time ▸ User-friendly software ▸ AI-enhanced surgery planning
Oncology	▸ Precise tumor targeting ▸ Minimized radiation dose	▸ Improved adaptive treatment capabilities	▸ Data management solutions with remote access	▸ Oncology treatment planning platform
Cardiovascular	▸ MRI-compatible pacemakers	▸ Improved mapping/ablation ▸ Coordinated dual chamber pacing	▸ Expanded coverage of treatment for new patient groups (high risk/ inoperable/ younger patients) ▸ Outpatient procedures	▸ Simplified implant procedure with transcatheter valve technology ▸ Reduced procedure time
Orthopaedic	▸ intraoperative real-time feedback to surgeon ▸ Robotic assistance	▸ Smart implants ▸ Personalized 3D-printed prosthetics for better fit ▸ Comprehensive surgical planning solutions	▸ Devices with smaller footprint ▸ Reduced cost	▸ Robotic assistance
Dental	▸ Non-invasive alternatives to metal screw expanders ▸ Removable device supporting oral hygiene	▸ Reduced attachments for aligner activation ▸ Robotics for implant procedures with haptic guidance	▸ Platforms optimizing dentist and lab collaboration	▸ Automated 3D printing of dental products
Hearing aids	▸ MRI-compatible hearing aids	▸ Use of real-time AI / Deep Neural Network (AI / DNN) chip for speech-from-noise separation	▸ Appealing design to attract large segment of people ▸ Enhanced user experience (rechargeable battery, durable)	▸ Aids with self-replacement option reducing in-office visits
Imaging diagnostics	▸ Reduced radiation dose or exposure time ▸ Reduced procedural error	▸ AI enhanced imaging and workflow ▸ Advanced imaging technologies	▸ Energy efficient technology ▸ Helium-free MRIs and dual source CT scanner ▸ Broader patient group coverage	▸ AI enabled platform simplifying clinical and operational workflows ▸ Ergonomic design
IVD	▸ Decreased misdiagnosis ▸ Reduced contamination risk ▸ Predictive AI based CGM providing real-time insights	▸ Diverse pathogen detection ▸ Improved test sensitivity	▸ Multiple tests in one instrument ▸ Applicability for wider age group	▸ Reduced turnaround time ▸ Improved laboratory workflow
Disposables and consumables	▸ Minimized instrument contamination	▸ Needle free blood drawing		▸ Hair management drape improving patient preparation time ▸ Reduced instrument handoffs

Digital solutions (standalone or integrated) supporting innovation across the areas

* Non-exhaustive **Analysis of products launched between Jan 2023 and July 2024 by five global companies in each segment.

Primary research insights

> India must drive innovation throughout its product range, encompassing both high-volume, low-value items and low-volume, high-value, technologically sophisticated equipment. The path to future growth lies in concentrating on adding value and enhancing competitiveness across the spectrum.
>
> *-Forum Coordinator, Association of Indian Medical Device Industry (AiMeD)*

> There is huge focus globally on digital therapeutics and connected/data-driven medical devices. With its strength and global recognition in the IT space, India is poised to be at the forefront of this innovation wave. We have already witnessed several start-ups developing digital therapeutics, such as those for diabetes that are designed specifically for the Indian population.
>
> *- Co-founder, Indian medical device start-up company*

> We were behind on the whole medical device innovation, but our strength in the IT sector will push us to the forefront, much like the UPI revolution that placed us on an equal footing globally. With the advent of the Ayushman Bharat Digital Mission, we are on the cusp of a new wave of innovation that promises to elevate our standing on the international stage, leveraging our comprehensive infrastructure in this domain.
>
> *- Co-founder, Indian medical device start-up company*

Let us look at the innovation deep dive for each MedTech segment. Our in-depth analysis for each segment is structured into two parts:

1. **Portfolio insights and innovation patterns of global MedTech majors** covers portfolio mapping, and digital and MedTech technology specific innovation trends of five leading global companies across key sub-segments (Note: innovation trends of leading global start-ups have been covered later in the Start-up analysis section of this chapter).

2. **Trends and trailblazers in Indian MedTech** cover portfolio mapping, and digital and MedTech technology specific innovation trends of leading Indian MNCs and start-ups.

The innovation spectrum: A comprehensive exploration of emerging trends across segments

A. Therapeutic devices

1. Oncology therapeutic devices

Portfolio insights and innovation patterns of global MedTech majors

The landscape of cancer treatment is rapidly evolving, shifting the perception of cancer from a terminal illness to a chronic condition that can be managed. This shift demands therapies that are fast, cost-effective, safe, precise and accessible to all patients. Companies are working on innovations across all these areas. Leading global companies such as Varian, Elekta, Accuray, NovoCure and Ion Beam Applications (IBA) offer diverse portfolios across subsegments, specializing in various treatment niches from radiation therapy to electric field therapy.

Global oncology therapeutic device companies: Portfolio mapping across sub segments*

Company	Revenue US$ m, FY23	Radiation therapy				Thermal ablation	Electric fields therapy/ Tumor Treating Fields (TTF)	Quality assurance (QA) tools	Others
		External beam radiation			Internal radiation				
		X-Rays *(e.g., Linear accelera-tors/ LINAC)*	Gamma rays *(e.g., gamma knife system)*	Proton beam therapy systems	Brachy-therapy				
Varian	3,978	✓		✓	✓	✓		✓	✓
Elekta	1,656	✓	✓		✓				
NovoCure	509						✓		
Ion Beam Applicati ons (IBA)	473			✓				✓	✓
Accuray	448	✓							

Sources: Company annual reports (for revenues), company websites (for portfolio mapping)
Notes: Currency conversion rate (as on 28 Aug'24): 1 EUR = 1.11701 USD; 1 SEK = 0.09816 USD
*The information is sourced from publicly available domains and may not be comprehensive.

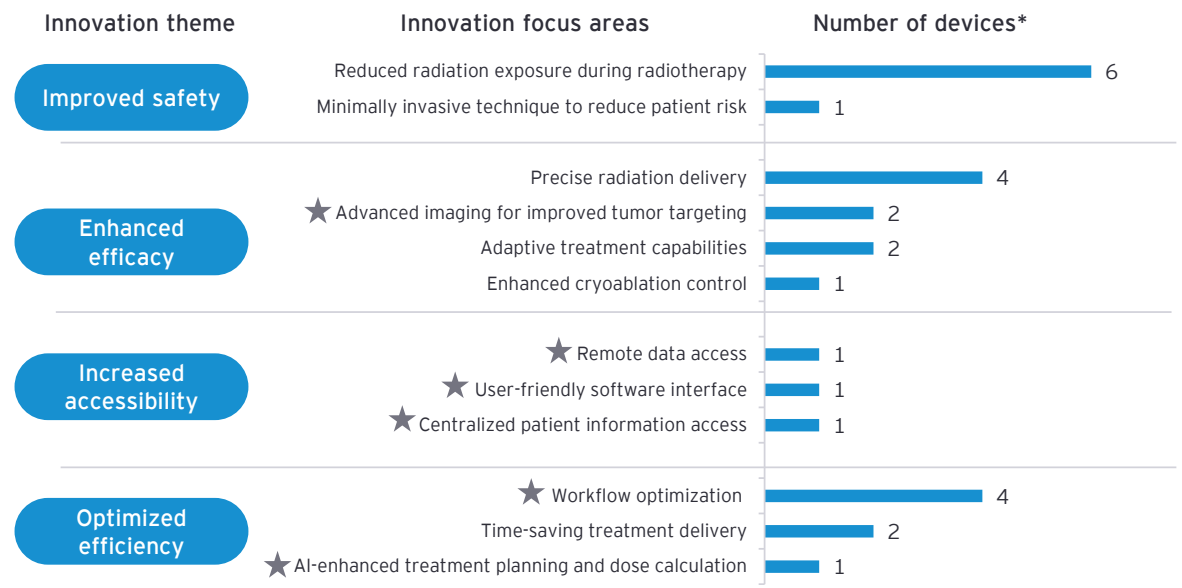
Based on our analysis of these companies, innovations in recent launches are centered around enhancing precision in tumor targeting, adaptive planning and surface-guided radiation therapy. Within the robotic-assisted devices space, the primary emphasis is on the advancement of imaging technologies to improve accuracy and enhance patient outcomes. In addition, there are some breakthrough treatment modalities such as FLASH therapy, TTF and histotripsy that focus on minimizing adverse effects and improving efficacy compared to traditional cancer therapies.

Another significant observation is the promising intersection of Biotech and MedTech in the field of oncology. Some breakthroughs include nanomaterial-based radio enhancers.

Innovation landscape in oncology therapeutic device segment

Innovation focus areas

*Analysis based on new products, product extensions, and solutions launched between Jan'23 and Jul'24 by global five companies**



*devices are overlapping and not unique (i.e., all innovations related to a device are captured within each relevant innovation theme. For instance, if a device improves both safety and efficacy, it is counted under both themes)

★ *Integration of digital solutions* *Not-exhaustive

Innovations in key sub segments

Key sub segments	Sub segment description	Key innovations within sub segment (leading examples)[1]
Radiation therapy	Employs high-energy radiation to damage cancer cells	► Precision in tumor targeting and adaptive planning (e.g., Accuray's Synchrony) ► Surface-guided radiation therapy enabling real-time and continuous motion management (e.g., Varian's IDENTIFY system)
Surgical devices	Range from traditional instruments to advanced robotic systems	► Advancements in robotic-assisted devices for improved precision and better patient outcomes (e.g., Accuray's CyberKnife)
Quality assurance (QA) tools	Software and equipment for ensuring consistent, accurate, and safe performance of oncology devices	► QA and dosimetry software integrating data across departments and sites (e.g., IBA's myQA Platform)
Other cancer care devices	Includes radiation protection tools, drug delivery systems, pain management devices, and supportive care equipment	► Nanoparticle-based radioenhancers (e.g., J&J and Nanobiotix's NBTXR3)

Key breakthroughs

FLASH Therapy

- Ultra-high radiation doses are delivered in extremely short pulses (under one second), reducing the traditional 25 to 30 treatment sessions to just one to five sessions
- Potential to reduce toxicity and spare healthy tissue[2]

Histotripsy

- Using ultrasound waves to destroy cancer cell
- Non-invasive treatment with the potential to eliminate side effects of radiation and chemotherapy, and offer quicker recovery[3]

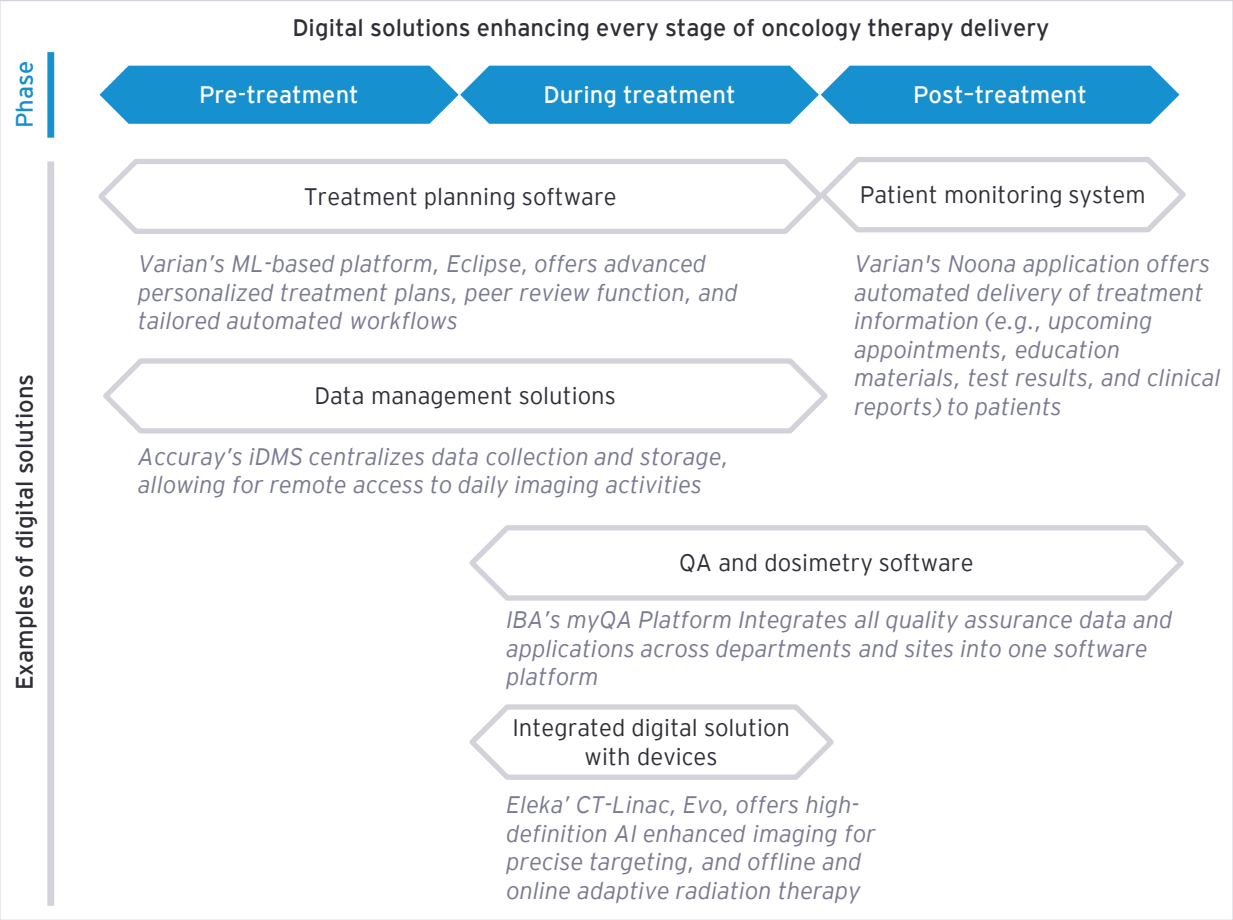
TTFs

- Non-invasive cancer treatment that uses electric fields to inhibit cancer cell division
- Being tested for other solid tumors after promising outcomes in glioblastoma[4]

Sources: 1. Company websites 2. Varian.com, 3. Histosonics.com, 4. Novocure.com

Oncology therapeutic device segment: Digital and data disruption

Digital solutions are being developed across all stages of cancer treatment, from the initial pre-treatment planning phase to post-treatment patient monitoring. These solutions are empowering clinicians to deliver effective and efficient patient care.



Sources: Company websites

Trends and trailblazers in Indian MedTech

India's oncology therapeutic device landscape is undergoing a transformation driven by the innovative efforts of leading domestic manufacturers, such as Panacea Medical Technologies and Trivitron Healthcare. Panacea's EU and USFDA approved Stereotactic Body Radiation Therapy (SBRT) enabled LINAC system, Siddharth II, with precise treatment delivery for multiple types of surgeries, is an example of India's developments in sophisticated cancer treatment technologies.

Indian oncology therapeutic device companies: Portfolio mapping across sub segments*									
Companies name	Revenue US$m, FY23	Radiation therapy				Thermal ablation	Electric fields therapy/ Tumor Treating Fields (TTF)	Quality assurance (QA) tools	Others
		External beam radiation			Internal radiation				
		X rays *(e.g., Linear accelera-tors/ LINAC)*	Gamma rays *(e.g., gamma knife system)*	Proton beam therapy systems	Brachy-therapy				
Trivitron Healthcare	71^								✓
Panacea Medical Technolo-gies	11	✓						✓	✓

Sources: EMIS company database, accessed on 28 Aug'24 (for revenues), company websites (for portfolio mapping)
Notes: Revenues for full business, not specific to any segment
^FY22 revenue
*The information is sourced from publicly available domains and may not be comprehensive.

Government initiatives and research institutions are also supporting the development of advanced devices. For instance, the collaboration of MeitY with the Society for Applied Microwave Electronics Engineering & Research (SAMEER) has yielded developments such as the 6 MEV LINAC.[65] Another good example is the collaboration between the government and Panacea to indigenously develop high-powered Magnetron technology for cancer radiation therapy.[66]

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

[66] Govt to support high-powered Magnetron tech used in cancer radiation therapy - BusinessToday

Sascan's Oralscan: An affordable and accessible handheld oral cancer imaging diagnostic

Current challenge in oral cancer diagnosis

- Traditional clinical practices rely on visual inspections using torchlight and biopsies
- These screening methods not only cause patient discomfort, but are also unreliable for diagnosing oral, potentially malignant lesions (OPMLs) in the early stages

Oralscan imaging diagnostic

- Handheld imaging device that uses a highly sensitive intraoral camera combined with fluorescence technology to accurately detect OPMLs
- This approach not only improves diagnostic accuracy but also identifies the optimal biopsy site, reducing patient discomfort

Advantages

- **Cost-effective:** affordable compared to traditional methods
- **Accessible**: portable and user-friendly
- **Innovative**: patented technology in India and filed in the US

Value add and Impact

- ISO 13485 and CE certified
- Validated via multi-centric trials

Innovative financing model

- Pay per use scheme
- Monthly rental

Quick facts

- **Founded in 2015** by Dr. Subhash Narayanan and Dr. Ruhi Agarwala
- **Incubated** at the Technology Business Incubator, Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST)
- **Support from Government schemes:** The National Initiative for Developing and Harnessing Innovations (NIDHI) and Kerala Start-Up Mission

Sources: sascan.in, Department Of Science & Technology (dst.gov.in)

Domestic start-ups spearheading oncology therapeutic devices innovation

India is witnessing a significant increase in medical devices and diagnostic start-ups developing innovative solutions to create access to appropriate cancer care for local populations. [67] Among these innovators is Sascan, a Kerala-based start-up that has developed OralScan, an innovative handheld diagnostic tool for the early detection of oral cancer. **SIAMAF Healthcare** is developing innovative magnetic nanotechnology and magnetic particle spectroscopy technologies to offer radiation-free affordable diagnosis and treatment. [68] **Onco.com** is transforming cancer care with its holistic care management platform, designed to support patients from diagnosis through treatment. [69] This patient-centric system provides relevant information to patients and their families, including treatment costs, outcomes and experts. It also facilitates online consultations with oncologists, continuous monitoring and personalized treatment planning, streamlining the entire care journey. [70]

[67] Emerging Business Models in Cancer Diagnostic Startups in India and Lessons for African Countries | SpringerLink
[68] SIAMAF Healthcare - Home
[69] Onco | Get The Right Cancer Treatment | Get Priority Appointments
[70] Five Indian Startups Taking On Cancer | Entrepreneur

2. Cardiovascular therapeutic devices

Portfolio insights and innovation patterns of global MedTech majors

The leading global cardiovascular therapeutic device companies include Medtronic, Abbott Laboratories, Boston Scientific, Johnson & Johnson (J&J) and Edwards Lifesciences. These companies offer a comprehensive product portfolio across sub-segments, from intervention and peripheral cardiovascular devices to surgical tools. Notably, all companies have a presence in the catheters and guide wires segment, underscoring its fundamental importance in cardiovascular interventions.

Global cardiovascular therapeutic device companies: Portfolio mapping across sub segments**

Company	Revenue* US$b, FY23	Intervention and peripheral cardiovascular devices		Rhythm management and electrophysiology devices			Heart assist devices	Structural heart disease devices		Surgical tools and other devices
		Catheters and guide wires	Stents	Defibrilla-tors	Pace-makers	Ablation and mapping system	Ventri-cular assist devices, artificial hearts etc.	Trans-catheter valves	Surgical valves and devices for structural intervention	Minimally invasive surgical tools; devices for vascular closure, thrombectomy, embolic protection, cardiac monitoring, etc.
Medtronic	11.6	✓	✓	✓	✓	✓	✓	✓	✓	✓
Abbott Laborator-ies	10.2	✓	✓	✓	✓	✓	✓	✓	✓	✓
Boston Scientific	8.8	✓	✓	✓	✓	✓		✓		✓
Johnson & Johnson	6.4	✓				✓	✓			✓
Edwards Lifes-ciences	5.1	✓						✓	✓	✓

Sources: Company annual reports (for revenues), company websites (for portfolio mapping)

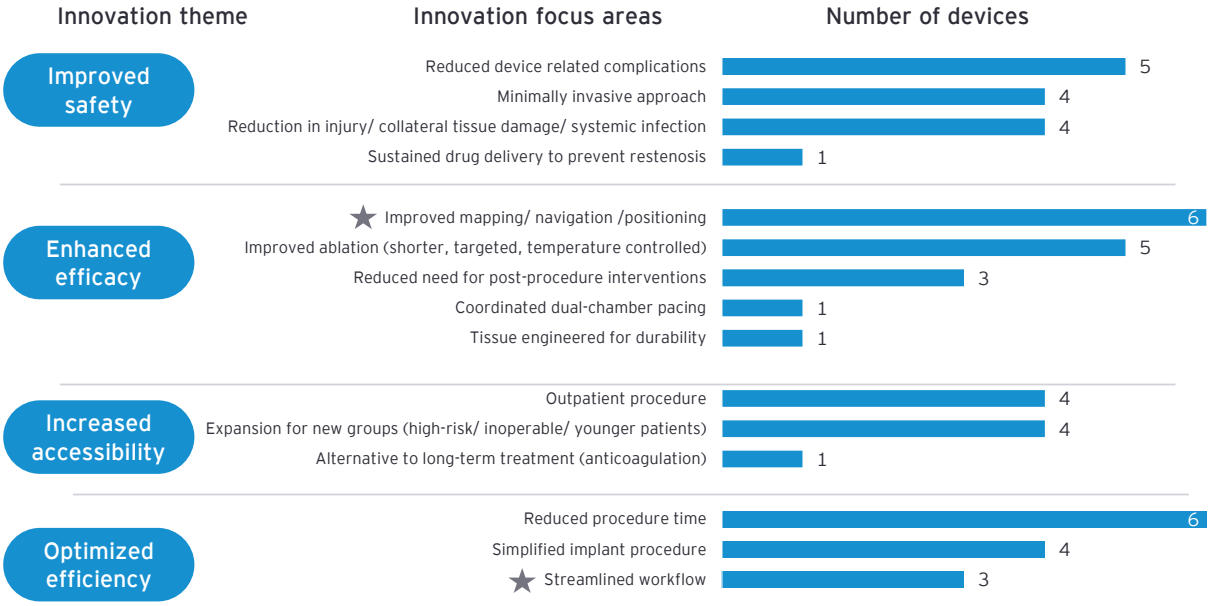
*Represent revenues of specific segment (Medtronic: Cardiovascular; Abbott Laboratories: Medical devices (rhythm management, electrophysiology, heart failure, vascular and structural heart); Boston Scientific: Cardiovascular; Johnson & Johnson: Interventional solutions; Edwards Lifesciences: Transcatheter aortic valve replacement, transcatheter mitral and tricuspid therapies and surgical heart valve therapy)
**The information is sourced from publicly available domains and may not be comprehensive.

Our analysis of recent launches reveals that the innovations in the cardiovascular therapy area focus on enhancing procedural precision, improving durability and long-term outcomes, and expanding treatment options for previously underserved patient groups. Innovations in the structural heart space include advancements in transcatheter therapies, particularly for aortic and tricuspid valves, with a focus on durability and ease of implantation. The cardiac rhythm management field is witnessing a revolution with the introduction of leadless pacemaker systems, significantly reducing procedural complications and improving patient comfort.

Innovation landscape in cardiovascular therapeutic device segment

Innovation focus areas

*Analysis based on new products, product extensions, and solutions launched between Jan'23 and Jul'24 by global five companies**



*devices are overlapping and not unique (i.e., all innovations related to a device are captured within each relevant innovation theme. For instance, if a device improves both safety and efficacy, it is counted under both themes)

★ *Integration of digital solutions* *Not-exhaustive

Innovations in key sub segments

Key sub segments	Sub segment description	Key innovations within sub segment (leading examples)
Cardiac rhythm management devices	Pacemakers and implantable cardioverter-defibrillators (ICDs) to regulate heart rhythms	▸ **First dual-chamber leadless pacemaker** (e.g., Abbott's Aveir DR with i2i technology enabling synchronized communication between pacemakers) 💡 ▸ **Novel extravascular approach for defibrillation** (e.g., Medtronic's Aurora EV-ICD) 💡
Electrophysiology devices	Mapping systems and ablation catheters for heart rhythm disorders	▸ **Pulse field ablation (PFA) technique:** use of non-thermal electric fields to ablate cardiac tissue, potentially reducing the risk of collateral damage compared to traditional thermal-based methods (e.g., Medtronic's PulseSelect, Boston Scientific's Farapulse and J&J's Varipulse) 💡 ▸ **Integrated PFA, radiofrequency, and high-density mapping catheter**, providing real-time feedback (e.g., Medtronic's Affera) ▸ **High density fixed array mapping catheter** (e.g., J&J OPTRELL Mapping Catheter with TRUEref technology covering largest area in a fixed matrix format and supporting physicians effectively map in a shorter time)
Structural heart devices	Transcatheter and surgical valves; Heart assist devices such as ventricular assist devices (VADs) and artificial hearts	▸ **Tricuspid valve replacement system** (e.g., Edwards Lifesciences' EVOQUE, the first dedicated transcatheter solution for severe tricuspid regurgitation, addressing a previously unmet clinical need) 💡 ▸ **Innovative anti-calcification technique,** which prolongs valve lifespan and reduces structural deterioration (e.g., Edwards' SAPIEN 3 Ultra RESILIA) ▸ **Treatment to repair leaky tricuspid heart valve** (e.g., Abbott's TriClip TEER, first minimally invasive option for tricuspid valve repair)

💡 Key breakthroughs

Sources: Company websites

Additionally, breakthrough treatment modalities, such as pulsed field ablation (PFA) for atrial fibrillation and extravascular defibrillation, are emerging, which minimize adverse effects and have higher efficacy compared to traditional approaches.

There is a significant trend of integrating digital technologies into the cardiovascular device landscape. This trend focuses on improving cardiac diagnostics and patient monitoring. For example, artificial intelligence and machine learning are used to analyze ECGs, while AI-powered smartwatches monitor the heart rate. Digital advancements are also being made in mapping systems for cardiac therapeutic devices. J&J has upgraded its CARTO™ 3 System with an AI algorithm that generates detailed maps of the left atrial anatomy. This reduces procedure time and improves precision. Overall, these digital integrations streamline workflows and enable personalized care.

Trends and trailblazers in Indian MedTech

The leading Indian cardiovascular therapeutic device companies include Meril, Sahajanand Medical Technologies (SMT) and Relisys Medical Devices, offering a range of products in three major sub-segments: interventional and peripheral devices, structural heart disease devices and surgical tools.

Indian cardiovascular therapeutic device companies: Portfolio mapping across sub segments*

Company	Revenue US$m, FY23	Intervention and peripheral cardiovascular devices		Rhythm management and electrophysiology devices			Heart assist devices	Structural heart disease devices		Surgical tools and other devices
		Catheters and guide wires	Stents	Defibrilla-tors	Pace-makers	Ablation and mapping system	Ventri-cular assist devices, artificial hearts etc.	Trans-catheter valves	Surgical valves and devices for structural interven-tion	Minimally invasive surgical tools; devices for vascular closure, thrombectom y, embolic protection, cardiac monitoring, etc.
Meril	101	✓	✓					✓	✓	✓
Sahajanand Medical Techno-logies (SMT)	99	✓	✓					✓	✓	✓
Relisys medical devices	20	✓	✓					✓		✓

Sources: EMIS company database, accessed on 28 Aug'24 (for revenues), company websites (for portfolio mapping)
Notes: Revenues for full business, not specific to any segment
*The information is sourced from publicly available domains and may not be comprehensive.

The cardiovascular devices industry in India is experiencing significant innovation and growth, driven by both established domestic companies and dynamic start-ups. Leading domestic companies are developing cost-effective alternatives and products tailored to local needs.

Meril, one of these leading innovators, brought a notable advancement to stents with the launch of the first indigenously researched and developed bioabsorbable stent, MeRes100.[71] This 100-micron "bio-resorbable scaffold" (BRS), a non-metallic mesh, removes blocks in the coronary artery and is naturally reabsorbed within two to three years,

[71] Meril Life Sciences launches indigenously developed bioresorbable scaffold - The Economic Times (indiatimes.com)

potentially reducing long-term complications from permanent implants. Meril launched MeRes100 in India in 2021, and by October 2023, it had already been used in over 2,500 surgeries. The company is now planning to expand its access at the district level in India. [72] The company also received EU approval in 2019.

In addition to stent, Meril launched the first indigenously designed and manufactured Transcatheter heart valve (THV), 'Myval', in 2018, [73] which was subsequently given a CE mark in 2019. [74] Myval comes in a wide range of sizes, making it more accessible to a broader population. In a recent trial, published by Meril in Lancet, 'Myval' is found to be non-inferior, safe and effective as compared to contemporary THVs - Sapien series and Evolut series. [75]

Domestic start-ups revolutionizing cardiovascular care with affordable and accessible innovations

Indian start-ups are driving significant innovations in the cardiovascular device segment, addressing unique challenges in the country's healthcare landscape. Start-ups such as **Cardiac Design Labs and Agasta** have developed cardiac monitoring devices that provide continuous and real-time diagnosis. [76] Another start-up, **Cardiobionic,** is innovating heart failure treatment with a cost-effective bi-ventricular assist pump, designed to serve a wider patient base, including children and improve upon the limitations of existing, costlier pumps. [77]

[72] Meril pushes ahead on growth plans in the country and abroad - The Hindu BusinessLine
[73] Myval: India's First Artificial Heart Valve Technology Launched (ndtv.com)
[74] Myval: A Novel Transcatheter Heart Valve for the Treatment of Severe Aortic Stenosis - PMC (nih.gov)
[75] Meril's MYVAL Transcatheter heart valve series trial research published in Lancet (indiatimes.com)
[76] Cardiacdesignlabs.com
[77] From napkin scribbles to heart pumps, a life-saving breakthrough from casual dinner talk - The Economic Times (indiatimes.com)

Agatsa: Revolutionizing cardiac care with portable, affordable and connected ECG technology

Agatsa, founded in 2014, has developed the world's smallest touch-based 12-lead ECG device, SanketLife

Quick facts*

- **36+** Awards
- **1 million+** ECGs taken
- **1 lakh+** lives saved
- **25,000+** devices sold
- ✓ CDSCO approved
- ✓ Plan of US approval

SanketLife 2: Key benefits

- **Affordable and portable, key chain sized compact design**
- **Real-time insights with >98% accuracy**
- **Instant ECG report on mobile app,** sharable via WhatsApp and email
- **Early detection of 100+ cardiac conditions**

For patients
- ✓ 24x7 monitoring
- ✓ Reduced hospital visits
- ✓ Progress tracking

For medical professionals
- ✓ Real-time patient insights
- ✓ Enhanced remote monitoring with AI

For young adults
- ✓ Proactive health monitoring
- ✓ Consultation with cardiologists

Key business models

E-commerce
- ► Direct buy from official website
- ► Products available on e-commerce platforms like Amazon, Flipkart

B2B model

Multiple customer groups with customized pricing models, including:
- ► Hospitals and HCPs
- ► Geriatric centers
- ► Insurance providers
- ► Educational institutes
- ► Gyms and fitness centers
- ► Corporate gifting

Health kiosks
- ► Planned walk-in kiosks, where people can check vitals and get services, such as virtual doctor consultation, e-pharmacy and ambulance services

ECG as a service/tele-consultation: Offers ECG report interpretation by a doctor within 10 mins.

* Not specific for SanketLife 2.0, the company also offers other variants such as 'SanketLife ProPlus' (both touch-based and lead-based ECG devices for doctors and professional) and 'Health360' (all-in-one device for tracking ECG, vital signs such as BP, SpO2, temperature)

Sources: agatsa.com, sanketlife.in, agatsa.com, health.economictimes.indiatimes.com, yourstory.com

3. Orthopedic therapeutic devices

Portfolio insights and innovation patterns of global MedTech majors

Some of the key global orthopedic therapeutic device companies include J&J, Medtronic, Stryker, Smith & Nephew and Zimmer Biomet. Most companies maintain a strong presence in core areas, such as joint reconstruction, trauma fixation and sports medicine. All five companies are focusing on advanced surgical instruments, including navigation and robotic systems, indicating a trend towards precision and technology-driven solutions in orthopedic procedures. Additionally, companies are entering the emerging field of orthobiologics, focusing on innovations like bone grafts, cell therapies and growth factors to promote the healing and regeneration of musculoskeletal tissues.

Global orthopedic therapeutic device companies: Portfolio mapping across sub segments**

Company	Revenue^ US$b, FY23	Joint recons-truction	Spine devices	Cranio-maxillo facial (CMF) devices	Trauma fixation	Sports medicine	Surgical instru-ments*	Ortho-biologics
Johnson & Johnson	8.9	✓	✓	✓	✓	✓	✓	✓
Stryker	8.7	✓	✓	✓	✓	✓	✓	✓
Zimmer Biomet	7.4	✓		✓	✓	✓	✓	✓
Medtronic	4.4		✓		✓	✓	✓	✓
Smith+Nephew	3.7	✓			✓	✓	✓	

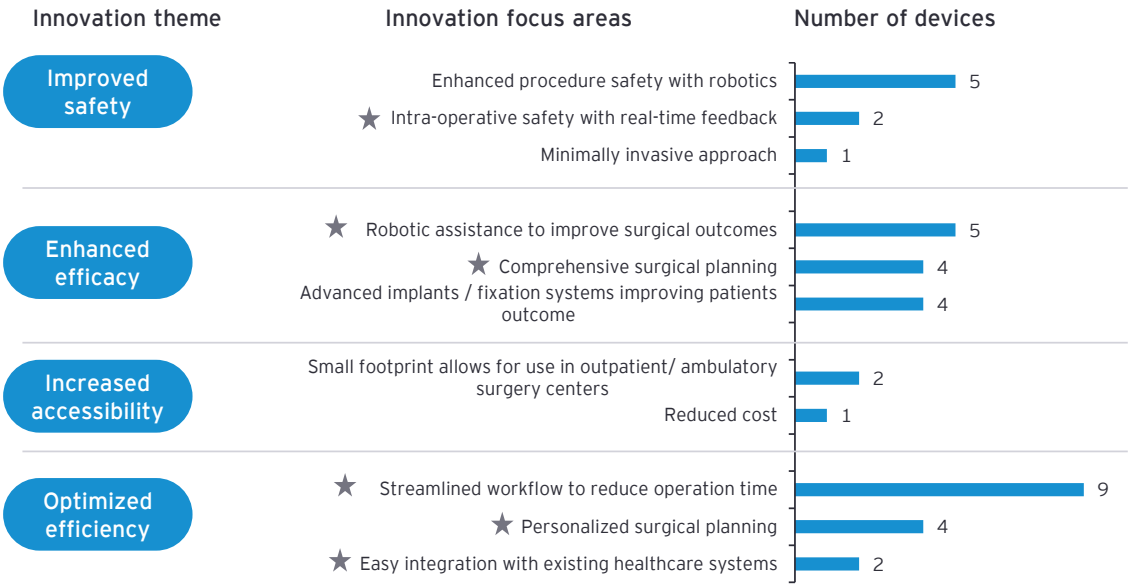
Sources: Company annual reports (for revenues), company websites (for portfolio mapping)
^Represent revenues of a specific segment (Stryker: orthopedics and spine; Johnson & Johnson: orthopedics; Medtronic: cranial and spinal technologies; Smith+Nephew: orthopedics and sports medicine)
*Portfolio includes surgical navigation and/or robotic systems
**The information is sourced from publicly available domains and may not be comprehensive.

Based on our analysis of recent product launches, innovation in the orthopedic device industry is focused on advancements that enhance surgical precision, improve long-term patient outcomes and offer more personalized treatment options. Innovations in joint reconstruction include improved implant designs that cater to individual patient anatomy and biomechanics. In spine and craniomaxillofacial devices segment, significant strides are being made in surgical planning and navigation systems, utilizing AI to increase the predictability and repeatability of complex procedures. The trauma fixation segment is moving towards minimally invasive approaches that aim to reduce tissue trauma and expedite recovery. Additionally, the integration of robotic surgical assistance is transforming intra-operative workflow to achieve greater accuracy.

Innovation landscape in orthopedic therapeutic device segment

Innovation focus areas

*Analysis based on new products, product extensions, and solutions launched between Jan'23 and Jul'24 by global five companies**



*devices are overlapping and not unique (i.e., all innovations related to a device are captured within each relevant innovation theme. For instance, if a device improves both safety and efficacy, it is counted under both themes)

★ *Integration of digital solutions* *Not-exhaustive

Innovations in key sub segments

Key sub segments	Sub segment description	Key innovations (leading examples)
Joint reconstruction devices	Implants and prostheses for hip, knee, shoulder, elbow, and ankle replacements	▸ **Improved implant designs,** for e.g., Smith & Nephew's OR3O dual mobility system with enhanced biomechanical stability and material innovation which reduces dislocation risk
Spine and Craniomaxillofacial devices	Spinal fusion devices (e.g., interbody cages) and non-fusion devices (e.g., artificial discs)	▸ **Enhanced surgical planning and navigation,** for e.g., Medtronic's UNiD ASI uses AI to enhance precision in spine surgery
Craniomaxillofacial devices	Plate and screw fixation devices, flap fixation devices, temporomandibular joint replacement devices, etc., for skull and facial injuries	▸ **Enhanced surgical planning and navigation,** for e.g., Stryker's Cranial surgery planning and navigation software, with its hybrid optical tracking and algorithmic processing, simplifies complex surgical tasks
Surgical instruments	Power tools for orthopedic procedures like drills and saws, and advanced navigation and robotics systems	▸ **Advanced robotic surgical assistance to improve intra-operative and post-operative outcomes,** for e.g., Zimmer Biomet's ROSA® system (world's first robotic system for shoulder surgery)

Sources: Company websites

Digital revolution transforming orthopedic care

The orthopedic market is experiencing a digital revolution, with innovations spanning across various aspects of patient journey, from surgery planning to post-operative management. These solutions are transforming patient care and surgical outcomes.

Digital innovations transforming orthopedic care

Preoperative planning

Solutions for developing personalized surgical models

- **J&J VELYS enabling technology portfolio provides surgeons with a range of tools, including:**
  - **Robotic-assisted solution**: supports precise implant positioning
  - **Hip navigation' software**: assists in pre-operative planning and intraoperative execution
  - **'Patient Path' platform and app**: facilitates personalized care by connecting surgeons, care teams, and patients throughout the journey from surgery preparation to recovery
  - **Cloud-based portal- 'Insights'**: captures and analyses intraoperative data to support decision-making

Intraoperative decision

Solutions offering real-time, actionable insights during surgeries

Postoperative care

Solutions enabling real-time monitoring and progress tracking

- **Zimmer Biomet's Persona IQ** is a smart implant that collects key kinematic data metrics, offering
  - Long-term access to patient-specific data for ~10 years
  - Intuitive interface for both patients and physicians through 'mymobility care' platform
- **Stryker's MotionSense with OrthoLogIQ:** wearable device for knee replacement recovery
  - continuous progress tracking of metrics such as pain scores, range of motion, wound image, daily steps
  - cloud-based platform, OrthoLogIQ, for surgeon and care team interaction

Source: Jnjmedtech.com, zimmerbiomet.com, stryker.com

Trends and trailblazers in Indian MedTech

Some of the key domestic orthopedic device companies include Meril, Sharma Orthopedics, Biorad Medisys, Auxein and GPC Medical. All companies contribute significantly to the domestic market, offering a range of products across various segments of joint reconstruction, spine, trauma, sports devices. Meril has expanded into advanced technologies and robotics, launching its indigenously developed surgical robotic system, MISSO, in June 2024. MISSO offers real-time assistance to doctors during knee replacement surgeries, enhancing precision and support in the operating room. [78]

[78] Meril launches indigenously developed knee-replacement robotic system (business-standard.com)

Indian orthopedic therapeutic device companies: Portfolio mapping across sub segments**								
Company	Revenue US$m, FY23	Joint reconstruc-tion	Spine devices	Cranio-maxillo facial (CMF) devices	Trauma fixation	Sports medicine	Surgical instru-ments	Ortho-biologics
Meril	101	✓	✓		✓	✓	✓*	
Biorad Medisys	29	✓				✓	✓	
Auxein	14	✓	✓	✓	✓	✓	✓	
GPC Medical	6^	✓	✓	✓	✓	✓	✓	
Sharma Orthopedics	6	✓	✓	✓	✓		✓	

Sources: EMIS company database, accessed on 28 Aug'24 (for revenues), company websites (for portfolio mapping)

Notes: Revenues for full business, not specific to any segment

^FY21 revenue

*Portfolio includes surgical navigation and/or robotic systems

**The information is sourced from publicly available domains and may not be comprehensive.

Start-ups are making remarkable progress in the orthopedic MedTech space. Piltover Technologies, for example, has developed the world's most functional mechanical prosthetic hand for differently abled individuals at an affordable price. [79] Another start-up, Ortho Regenics, in collaboration with IIT Kanpur, is pioneering bone regeneration technology with innovative porous composite scaffolds designed to reconstruct irregular bone defects and bridge substantial gaps. [80] Additionally, AlgoSurg is leading in digital innovation, developing AI solutions for next-generation surgical applications, including robotic surgeries, AR-based navigation and training, and cloud-based 3D surgery planning. [81]

4. Dental therapeutic devices

Portfolio insights and innovation patterns of global MedTech majors

The leading dental therapeutic device companies worldwide are Dentsply, Straumann, Envista, Align technology and Ivoclar. They specialize in different areas of dental care, from orthodontics to digital imaging. Dentsply Sirona, Ivoclar and Envista offer a wide range of dental solutions and digital solutions. Align technology is known for its clear aligner technology and imaging systems.

[79] Piltover Technologies
[80] Signs MoU with Ortho Regenics (iitk.ac.in)
[81] AlgoSurg: AI for Surgeries

Global dental therapeutic device companies: Portfolio mapping across sub segments*									
Company	Revenue US$b, FY23	Restorative and prosthetics *(e.g., dental implants, prosthetics - crowns, bridges, and dentures)*	Dental material *(e.g., materials for restorations and impressions; biomaterials for bone grafts, haemostatics)*	Orthodontics *(devices for teeth alignment e.g., braces, clear aligner)*	Endodontic *(devices for root canal treatment)*	Imaging devices *(e.g., intraoral scanners, X-Ray systems, cone beam CT (CBCT) systems*	Dental laboratory products *(e.g., CAD/CAM^ systems, 3D printers)*	Surgical and other instruments *(e.g., dental lasers, handpieces, rotary instruments)*	Dental chairs and operating lights
Align Technology	3.8			✓		✓			
Dentsply Sirona	3.9	✓	✓	✓	✓	✓	✓	✓	✓
Straumann	2.8	✓	✓	✓		✓	✓	✓	
Envista	2.5	✓	✓	✓	✓	✓	✓	✓	
Ivoclar Vivadent	1.0	✓	✓		✓	✓	✓	✓	✓

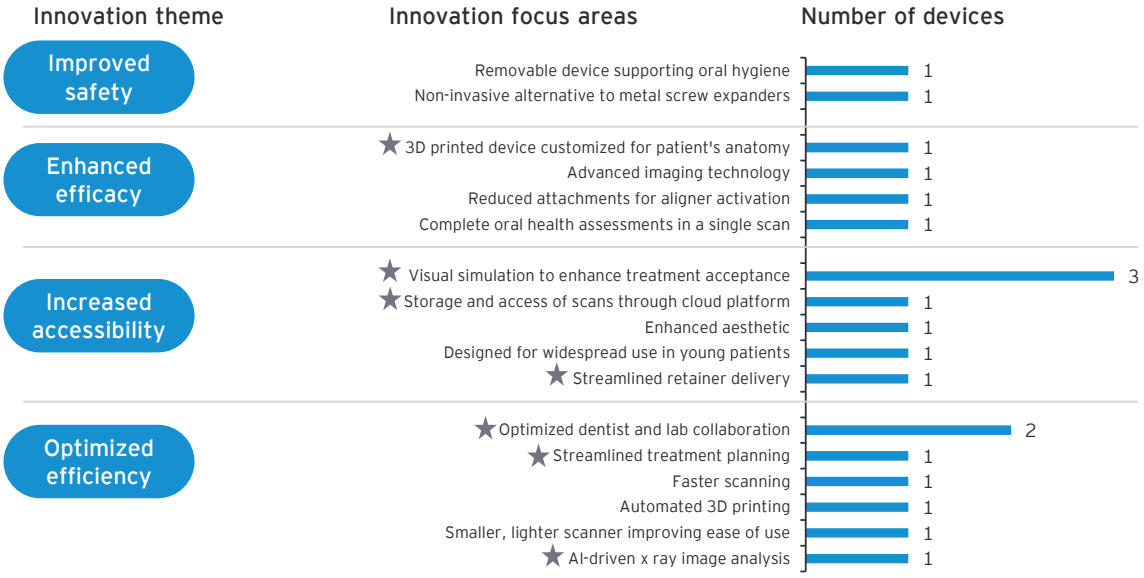
Sources: Company annual reports (for revenues), company websites (for portfolio mapping)
Notes: Currency conversion rate (as on 28 Aug'24): 1 CHF = 1.18347 USD
*The information is sourced from publicly available domains and may not be comprehensive.
^CAD: Computer-aided design, CAM: computer-aided manufacturing

Based on our analysis of recent product launches, innovation in the dental device segment is focused on improving treatment efficacy, enhancing patient comfort and streamlining dental procedures. In orthodontics, advancements in clear aligner technology aim to offer more precise and aesthetic treatment solutions. The dental imaging segment is advancing with innovative digital impression and intraoral scanning solutions that increase accuracy and improve patient experience. Additionally, advancement in 3D printing is transforming dental product manufacturing, enabling faster and more efficient production processes with higher precision. These developments are driving significant improvements across the dental care landscape.

Innovation landscape in dental therapeutic device segment

Innovation focus areas

*Analysis based on new products, product extensions and solutions launched between Jan'23 and Jul'24 by global five companies**



*devices are overlapping and not unique (i.e., all innovations related to a device are captured within each relevant innovation theme. For instance, if a device improves both safety and efficacy, it is counted under both themes)

★ *Integration of digital solutions* *Not-exhaustive

Innovations in key sub segments

Key sub segments	Sub segment description	Key innovations (leading examples)
Orthodontics	Products for correcting teeth alignment and jaw irregularities, e.g., metal braces, ceramic braces, clear aligners, etc.	▸ Expanding clear aligner principles to palatal expansion for e.g., Align technology's Invisalign palatal expander system offers direct 3D printed device with improved aesthetics, comfort and potentially more precise expansion compared to traditional metal expanders
Imaging and diagnostic devices	Intraoral and extraoral X-ray systems, cone beam computed tomography (CBCT) systems, intraoral cameras	▸ Faster and easier scanning processes with high accuracy and patient comfort compared to traditional impression methods. For e.g., Align Technology's Itero lumina intraoral scanner
Dental laboratory products	CAD/CAM systems for designing and manufacturing dental restorations, milling machines, and 3D printers, etc.	▸ Streamlined in-house production, from digital design to final product of various dental products with increased precision and efficiency and reduced manual efforts. For e.g., Dentsply Lucitone digital print denture system with primeprint solution

Breakthrough innovations from global start-ups

Robotic-assisted surgery

Neocis has developed **Yomi robotic system**, the first US FDA approved robotic device for dental implant procedures, providing haptic guidance to dental surgeons and improving the accuracy of implant placement[2]

AI-powered diagnosis

Overjet has developed **an AI-based platform for radiograph analysis** to detect and outline dental caries, quantify bone loss, and identify various dental pathologies with high accuracy[3]

Sources: 1. Company websites, 2. neocis.com 3. overjet.com

Digital technologies are increasingly shaping the future of dentistry. These innovative solutions are playing a crucial role in treatment planning, practice management and improving the patient experience throughout their dental journey.

Digital innovations transforming dental care

Treatment planning and customization	Practice management	Remote monitoring
'ClinCheck Pro' treatment planning software	**'DS Core' digital dentistry platform**	**'Invisalign virtual care AI' remote monitoring solution**
▸ **'3D control' tools**: To modify treatment plans directly on the dentition ▸ **Auto-generated 3D model:** Gives practitioners a comprehensive view for informed treatment planning ▸ **Interactive video simulation:** Offers patients a before-and-after visual representation of potential results	▸ Cloud platform to streamline workflow and enable effective communication between dentists and dental labs ▸ **sharing all necessary patient files** (X-Rays, intraoral scans and other records) on a single platform ▸ **Manage orders** in a single location, including messages, approvals and digital case files	▸ **Virtual clinical assessment** through photos captured by patients allows clinicians to remotely assess progress ▸ **Timely clinical support** using AI enables early detection ▸ **AI-assisted assessment** of photos to measure aligner spaces ▸ **Automated patient notifications** delivered in about an hour

Sources: invisalign.com, Dentsplysirona.com/en-in , invisalign.com

Trends and trailblazers in Indian MedTech

Key domestic dental therapeutic device companies include Skanray, S H Pitkar Orthotools, Narang Medical and Mediray. These companies offer products across multiple segments, such as restorative and prosthetics, dental materials, orthodontics and surgical instruments, reflecting a concentrated yet developing landscape in the Indian dental industry.

Indian dental therapeutic device companies: Portfolio mapping across sub segments*

Company	Revenue US$m, FY23	Restorative and prosthetics *(e.g., dental implants, prosthetics - crowns, bridges, and dentures)*	Dental material *(e.g., materials for restorations and impressions; biomaterials for bone grafts, haemo-statics)*	Ortho-dontics *(devices for teeth alignment e.g., braces, clear aligner)*	Endodontic *(devices for root canal treatment)*	Imaging devices *(e.g., intraoral scanners, X-Ray systems, cone beam CT (CBCT) systems*	Dental laboratory products *(e.g., CAD/CAM^ systems, 3D printers)*	Surgical and other instruments *(e.g., dental lasers, handpieces, rotary instruments)*	Dental chairs and operating lights
Skanray	31					✓		✓	✓
S H Pitkar Orthotools	7	✓		✓				✓	
Narang Medical	6	✓	✓	✓	✓		✓	✓	✓
Mediray	NA					✓		✓	✓

Sources: EMIS company database, accessed on 28 Aug'24 (for revenues), company websites (for portfolio mapping)
Note: Revenues for full business, not specific to any segment
*The information is sourced from publicly available domains and may not be comprehensive.
^CAD: Computer-aided design, CAM: computer-aided manufacturing

In addition, domestic start-ups are at the forefront of innovation, driving breakthroughs in various areas of healthcare. For instance, **Theranautilus** is pioneering oral healthcare with its innovative magnetic nanobots, offering a permanent solution for tooth hypersensitivity and promoting regeneration.[82] Another innovative start-up, **DENTRA** enhances dental care with its AI-driven intraoral 3D scanning platform where dentists scan and send 3D images to partner labs and receive final product, potentially reducing costs, improving efficiency and ensuring precise results.[83] Further **makeO** is advancing orthodontics with its 3D-printed clear aligners, leveraging robotic automation for faster production and consistent quality.

[82] Theranautilus.com

[83] Dentratech.com

makeO: Developing innovative clear aligners, Toothsi, to make orthodontic treatment more accessible and convenient for everyone

Toothsi clear aligners

- Custom-made clear aligner treatment to fix various teeth alignment issues
- Pan India presence, with over 2000+ partner clinics, 22+ experience centers
- Presence in five cities across Gulf Cooperation Council (GCC); acquired UAE-based Healthtech, Smileneo (as of 2023); aim to become the largest clinical beauty technology platform across both the Asian and MENA markets

Key features and technology

Affordable and convenient care

- **Affordable and accessible**: makeO's vertically integrated platform and in-house aligner manufacturing reduce the cost of aligners to INR50,000 to INR80,000 vs. industry average of INR1.5-4.0 lakh
- **Personalized and convenient care**: customized treatment plans for each patient, fewer clinic visits

Digital app enabled customer journey

First of its kind end-to-end digital platform for clinical makeover treatments accessible via mobile app

- **Book at-home scans** for in-person diagnosis
- **On-demand connect** with dentists and orthodontists
- **Remote monitoring** by sharing photos and videos to track progress

Largest 3D printing aligner facility

- Asia's largest US-FDA cleared **3D printing aligner manufacturing lab** in Mumbai
- Collaboration with automation companies from France, Sweden and Japan, to integrate **advanced robotic systems to automate manufacturing**

Sources: makeo.app/about-us, wamda.com, indiatimes.com, business-standard.com

5. Hearing aids

Portfolio insights and innovation patterns of global MedTech majors

Key global companies developing hearing aids include Sonova, Demant, WSAudiology, Cochlear and GN Store Nord (GN Hearing). These companies are developing comprehensive portfolios of hearing aid solutions to address a wide range of hearing loss severities and user preferences.

Our analysis of recent product launches shows that companies in the hearing aid segment are focusing on innovations that enhance sound quality, improve user experience and boost device connectivity. AI technology now drives real-time speech separation, providing a superior hearing experience in challenging environments. The industry is also pushing towards miniaturization, with manufacturers introducing smaller, more discreet devices without sacrificing performance. Connectivity is a key area of innovation, with many new devices incorporating Bluetooth and other technologies to seamlessly integrate with smartphones and audio devices. Additionally, advancements in battery technology offer rechargeable options, improving convenience for users.

Furthermore, the industry is expanding its focus to address diverse user needs, from over-the-counter solutions for mild hearing loss to sophisticated systems for severe-to-profound hearing impairment. These developments are driving significant improvements across the hearing care landscape, enhancing both the efficacy of hearing solutions and the quality of life for users.

Global innovation in hearing aid solutions

*Analysis based on new products, product extensions, and solutions launched between Jan'23 and Jul'24 by global five companies**

Innovation theme	Focus areas	Key innovations (leading examples)
Enhanced efficacy	Advanced technology (including AI) for improved sound quality	► **Use of real-time AI / Deep Neural Network (AI / DNN) chip** for speech-from-noise separation (e.g., Sonova's Audéo Sphere Infinio) ► **Hearing multiple speakers** in noisy group conversations clearly, enhancing speech and reducing background noise (e.g., WS Audiology's Integrated Xperience) ► Fast **detectors adjusting annoying and sudden sounds** for improved sound quality (e.g., 'Wind and handling stabilizer' and 'SuddenSound Stabilizer' features of William Demant's Oticon Real)
	Advanced user customization	► World's first hearing aid with **4D Sensor technology providing intention-based personalization;** it can capture a person's unique communication goal, improving speech comprehension by 15% (e.g., William Demant's Oticon Intent)
	Innovative design for improved performance	► **Innovative L-shaped design** that improves microphone angles to enhance directionality and speech targeting (e.g., WSAudiology's Widex SmartRIC)
	Improved connectivity	► **World's first hearing aid to connect with Auracast broadcast devices** (e.g., GN Store Nord's ReSound Nexia)
Increased accessibility	Miniaturization	► Over the counter aids featuring **a 'micro' design that is 25% smaller** than standard receiver-in-ear hearing aids (e.g., GN Store Nord's Jabra Enhance Select 500)
	Enhanced user experience	► **Aids with self-replacement option** reducing in-office visits (e.g., Sonova's Lyric device, which is 100% invisible and offers 24/7 wear) ► **Rechargeable battery** that can be charged for a full day in only one hour (e.g., William Demant's Encanta miniRITE) ► **Enhanced durability to handle the knock**, spills, and accidents in everyday life (e.g., WSAudiology's Rexton BiCore B-Li Rugged, featuring water resistance at a depth of 2 meters for up to 30 minutes)
	Focus on specific groups	► Aids designed for **children and teenagers**, prioritizing speech understanding in noisy classroom environment (e.g., Sonova's Sky L-M and SP) ► Bone conduction hearing solutions for **children aged five and older** (e.g., Cochlear's Osia System, first bone conduction system enabling MRI)
	Appealing design to attract large segment of people	► **Modern consumer earbud design to appeal** to hearing aid rejectors at an affordable price (e.g., Signia Active Pro IX)

Key breakthroughs

Sources: Company websites *Not-exhaustive

Trends and trailblazers in Indian MedTech

Leading domestic companies in the hearing aids segment include ALPS International and Arphi Electronics. Both companies offer comprehensive hearing aids portfolio including behind-the-ear (BTE), in-the-ear (ITE), receiver-in-the-canal (RIC) systems to accommodate all hearing loss needs. These companies are bringing innovative solutions. For instance, ALPS international has recently launched "NYLO" an innovative rechargeable hearing aid with Bluetooth connectivity for audio streaming from various media sources. Its Bluetooth low-energy technology allows for direct digital programming without external interfaces, and its mobile app enables users to customize their listening experience for different environments, enhancing audio quality and user convenience. [84]

Along with established companies, Indian start-ups are also coming up with innovations. For instance, **WeHear**, a Gujarat-based start-up, has launched products such as advanced bone conduction-based hearing aids and smart headphones with AI algorithm for personalized experience. Another start-up, **Sohum Innovation Labs**, while not strictly a hearing aid company, has developed a non-invasive device for early screening and diagnosis of hearing impairments in newborns, especially designed for mass screening in resource-constrained settings. [85]

[84] Indianexpress.com/article/news-today/alps-international-eyes-one-fourth-hearing-aid-market

[85] The Solution « Sohum Innovation Lab (sohumforall.com)

WeHear: An audio technology start-up, offering innovative 'Make in India' hearing solutions to the world

In-house product designing, electronics hardware and firmware development, software and mobile development, and electronics manufacturing

Quick facts

2017	26	6	17+
founded	member R&D team	product patents	countries reached

Innovative solutions for different hearing issues

HearNU BTE for partial hearing loss

- Behind the ear hearing aid with almost invisible design
- Advance programming tool with AI auto tuning feature
- Lightweight, Bluetooth connectivity, and rechargeable battery
- Mobile app-based customization

HearNU for physical ear hearing loss

- **World's first non-surgical solution for people with 100% conductive hearing loss and congenital anomalies**
- Based on bone conduction technology
- Features noise cancellation technology which removes whistling sound and unwanted noise
- Lightweight and rechargeable battery

- ~11,000+ devices sold since launch in 2021 to Apr'24
- INR5.5 crore revenue in FY 2023-24

WeHear OX smart headphones

- **India's first bone conduction open ear wireless earphones**
- Safe for prolonged usage, preventing any physical damage to ears
- 'WeHear OX App': inbuilt translator covering 72 languages; personal hearing intelligence (PHI) algorithm which analyzes a user's hearing patterns and gives personalized suggestions for health-friendly hearing

Key business models

E-commerce

- Direct buy from official website
- Products available in e-commerce platforms like Amazon, Flipkart

B2B projects

- Hearing solutions in defense applications

Sources: HearNU.com, wehearglobal.com, business-standard.com, thebetterindia.com, wehearglobal.com

B. Imaging diagnostic devices

Portfolio insights and innovation patterns of global MedTech majors

Leading global imaging diagnostic companies include Siemens Healthineers, Philips, GE HealthCare, Olympus and Canon. Siemens, Philips and GE HealthCare offer a broad portfolio of imaging solution and technologies across sub segments, while Olympus specializes in endoscopic solutions, and Canon in MRI, CT and ultrasound. In addition, companies are developing various digital solutions, including advanced visualization platforms, AI-powered decision support and solutions to optimize imaging operations.

Based on our analysis of recent product launches, innovations in diagnostic imaging are primarily focused on enhancing imaging precision, improving diagnostic accuracy, and reducing scan times and radiation exposure.

Digital integration is an important focus area across all sub-segments within the diagnostics space. Of all the products analyzed, ~60% featured some form of digital and data analytics integration.

In MRI, key advancements center around sustainability and AI driven image enhancement, enabling wider coverage of patients with more complex conditions. In CT, AI integration is improving imaging accuracy and reducing radiation dose. Ultrasound advancements include AI-enhanced imaging for faster and more precise diagnoses, especially in cardiovascular conditions. In surgical imaging, C-arm systems are improving intraoperative efficiency by digital automation and streamlined workflows.

Global diagnostic imaging device companies: Portfolio mapping across sub segments**

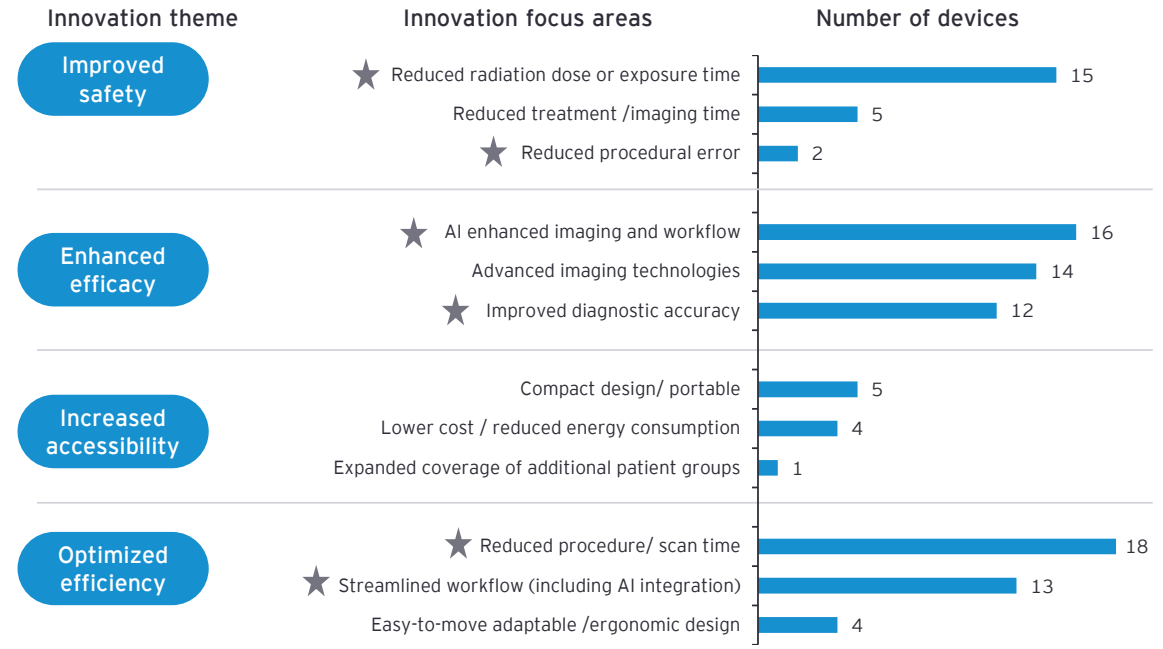
Company	Revenue* US$b, FY23	MRI imaging	Ultra-sound imaging	Radiology imaging						Nuclear imaging	Endo-scopic imaging
				X-Ray systems	CT scan	C Arm / Surgical imaging	Angio-graphy	Mammo-graphy	Fluoro-scopy		
GE HealthCare	14.0	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Siemens Healthineers	13.2	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Philips	9.8	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Canon	3.8	✓	✓		✓						
Olympus	3.8										✓

Sources: Company annual reports (for revenues), company websites (for portfolio mapping)
Notes: Currency conversion rate (as on 28 Aug'24): 1 EUR = 1.11701 USD; 1 JPY = 0.00692 USD
*Represent revenues of specific segment (GE HealthCare: Imaging and ultrasound; Siemens Healthineers: Imaging; Philips: Diagnosis & treatment; Canon: Medical business and Olympus: Endoscopic solutions)
**The information is sourced from publicly available domains and may not be comprehensive.

Innovation landscape in imaging diagnostics segment

Innovation focus areas

*Analysis based on new products, product extensions, and solutions launched between Jan'23 and Jul'24 by Global five companies**



*devices are overlapping and not unique (i.e., all innovations related to a device are captured within each relevant innovation theme. For instance, if a device improves both safety and efficacy, it is counted under both themes)

★ *Integration of digital solutions* *Not-exhaustive

Innovations across key sub segments

Key sub segments	Key innovations (leading examples)
MRI	► **Focus on sustainability** e.g., Siemens' Magnetom Flow, first 1.5 tesla MRI platform with virtually helium-free technology, efficient workflows and AI-enhanced imaging, reducing measurement times by up to 50% ► **Improved image quality and faster scan times** e.g., GE HealthCare's Sonic DL uses deep learning to acquire cardiac MRI images by up to 12x faster than conventional methods, expanding MRI eligibility to patients with arrhythmias or breath-holding challenges
CT scan	► **AI-based image analysis** e.g., Philips' CT 5300 features AI-based reconstruction for higher image quality and 80% lower radiation dose ► **Reduced radiation exposure** e.g., Canon's AI-based CT systems (revised Aquilion CT platform) enhance imaging quality, lower the dose, and offer simplified operation with automated workflows
Ultrasound	► **AI-based image analysis e.g.**, GE HealthCare's Voluson Signature 20 and 18 systems for women's reproductive health imaging use AI to enhance image quality and exam speed, enabling providers to make accurate diagnoses ► **Improved workflow efficiency e.g.,** Philips' AI-enabled cardiovascular ultrasound platform offers industry's first automated tools for segmental wall motion scoring and 3D quantification supporting clinicians make better-informed decisions for coronary artery disease or heart valve disease
Mammography	► **Faster and more accurate 3D breast imaging** e.g., Siemens' Mammomat B.brilliant offers high-speed 3D mammography with wide-angle tomosynthesis, providing 35% faster acquisition time
C-arm and surgical imaging	► **Enhanced image quality and workflow efficiency in intraoperative imaging e.g.,** Philips' Zenition 90 Motorized offers high-power imaging with fast controls and automated workflows; Siemens' Ciartic Move, an automated self-driving C-arm, reduces intraoperative imaging time by up to 55%
Nuclear imaging	► **Combined multiple imaging modalities to enhance diagnostic capabilities e.g.,** GE HealthCare's SIGNA PET/MR AIR system integrates: ► PET and MRI for prostate cancer and Alzheimer's diagnosis ► Deep learning to improve image quality and reduce scan times ► MotionFree Brain technology to address motion-related PET image degradation

Sources: Company websites

Trends and trailblazers in Indian MedTech

Key domestic companies in the imaging diagnostic segment include Allengers, Trivitron Healthcare, BPL Medical Technologies, Skanray and Panacea Medical Technologies. Unlike their global counterparts, which focus on a wide range of imaging technologies, portfolios of domestic companies are concentrated in specific areas, especially C-arms and X-Ray radiography (including digital radiography).

Indian diagnostic imaging device companies: Portfolio mapping across sub segments*

Company	Revenue US$m, FY23	MRI imaging	Ultra-sound imaging	Radiology imaging						Nuclear imaging	Endos-copic imaging
				X-Ray systems	CT scan	C Arm / Surgical imaging	Angio-graphy	Mammo-graphy	Fluoro-scopy		
Allengers	91			✓	✓	✓	✓	✓			
Trivitron Healthcare	71^		✓	✓		✓		✓			
BPL Medical Technologies	55		✓	✓		✓					
Skanray	31			✓		✓					
Panacea Medical Technologies	11							✓			

Sources: EMIS company database, accessed on 28 Aug'24 (for revenues), company websites (for portfolio mapping)
Notes: Revenues for full business, not specific to any segment
^FY22 revenue
*The information is sourced from publicly available domains and may not be comprehensive.

These companies are spearheading innovation by launching advanced imaging systems that offer enhanced usability, portability and multifunctional capabilities. For example, in a significant industry milestone, Allengers became the first Indian company to launch an indigenously developed CT scanner in 2020 in a joint collaboration with Japan's Canon.[86] Trivitron Healthcare has expanded its portfolio to include advanced ultrasound systems with 3D/4D imaging capabilities, digital C-arms featuring flat panel detector technology and portable digital X-Ray machines, addressing the growing demand for versatile and mobile imaging solutions. Skanray has developed C-arms with unique features that significantly enhance their functionality and adaptability across a wide spectrum of surgical environments, including orthopedics, neurosurgery, spinal procedures and gastroenterology.

Domestic start-ups driving cutting-edge innovation

Several Indian start-ups are working on some cutting-edge solutions in the imaging diagnostics space. For e.g., **VoxelGrids Innovations**, in collaboration with government, developed first indigenous affordable, lightweight, ultrafast, high field (1.5 Tesla), next generation MRI scanner in 2023, which is expected to reduce cost of MRI scanning in India.[87] **PlebC Innovations** has developed a teleoperated robotic ultrasound system where radiologists can operate ultrasound from multiple centers without changing their location.[88] **Qure.ai** is leveraging deep learning algorithms to automate the interpretation of radiology exams.[89] **Niramai** is revolutionizing breast cancer screening globally with its novel radiation-free AI assisted thermal imaging technology, enabling early and accurate breast cancer detection.[90]

[86] Allengers in association with Canon launch India's first Made in India 32 slice CT - Express Healthcare
[87] India launches first indigenously developed Magnetic Resonance Imaging (MRI) Scanner (biospectrumindia.com)
[88] Tele robotic ultrasound | PlebC
[89] Qure AI | AI assistance for Accelerated Healthcare
[90] Niramai – A Novel Breast Cancer Screening Solution

Qure.ai : Transforming radiology imaging interpretations with AI algorithms

Quick facts

2016 founded

24 patents as of Mar'23

~13 FDA approved AI-enabled solutions

90+ countries reached

Innovative AI-powered products* enabling more accurate and faster diagnosis

qXR: AI-based chest X-Ray automation and interpretation solution	**40% turnaround time** (TAT) reduction Available in **90+ countries**, 3,100+ sites
qTrack: AI-based end-to-end platform for Tuberculosis (TB) screening and case management	**99%** reduction in TAT to confirmed diagnosis (from three weeks to around two hrs) Available in **55+ countries** and 1,900+ sites
qMSK: AI-based trauma related musculoskeletal (MSK) X-rays interpretation	**<20 sec** processing time >0.9 sensitivity to detect signs of fracture
qER: AI solution for faster head CT interpretation	**179%** increase in proportion of stroke patients receiving early intervention in golden hour

Recent collaborations

Collaborating firm	Type of firm	Location	Collaboration focus
Strategic Radiology	Coalition of private radiology practices	US	To provide AI-powered medical imaging solutions to radiologists under coalition
AstraZeneca	BioTech	UK	Launch initiative to improve early diagnosis of lung cancer
Therapixel	Software	France	Improve access to breast cancer detection through AI
Fujifilm	MedTech	Nigeria	Accelerate TB screening in rural Nigerian communities
Telemedicine Clinic and Unilabs	Diagnostic service provider	UK	Triage chest X-Rays in the UK

Sources: Qure.ai, Qure.ai/news, Qure.ai FY22-23 impact report

*Selected examples, not-exhaustive

C. Invitro diagnostics devices

Portfolio insights and innovation patterns of global MedTech majors

Some of the key global IVD companies include Roche Diagnostics, Abbott Laboratories, Thermo Fisher Scientific, Siemens Healthineers and BioMérieux. These companies have a comprehensive portfolio spanning all major sub segments.

Global in-vitro diagnostics device companies: Portfolio mapping across sub segments**						
Company	Revenue* US$b, FY23	Molecular diagnostics *(e.g., PCR, NGS^)*	Immunoassay *(e.g., ELISA, RIA^)*	Haematology *(e.g., complete blood count, blood clotting)*	Point-of-Care testing *(Test providing rapid results)*	Clinical chemistry *(e.g., clinical chemical analyzer and reagents)*
Roche	16.7	✓	✓	✓	✓	✓
Abbott Laboratories	9.9	✓	✓	✓	✓	✓
Siemens Healthineers	5.1	✓	✓	✓	✓	✓
Thermo Fisher Scientific	4.4	✓	✓	✓	✓	✓
BioMérieux	4.1	✓	✓	✓	✓	✓

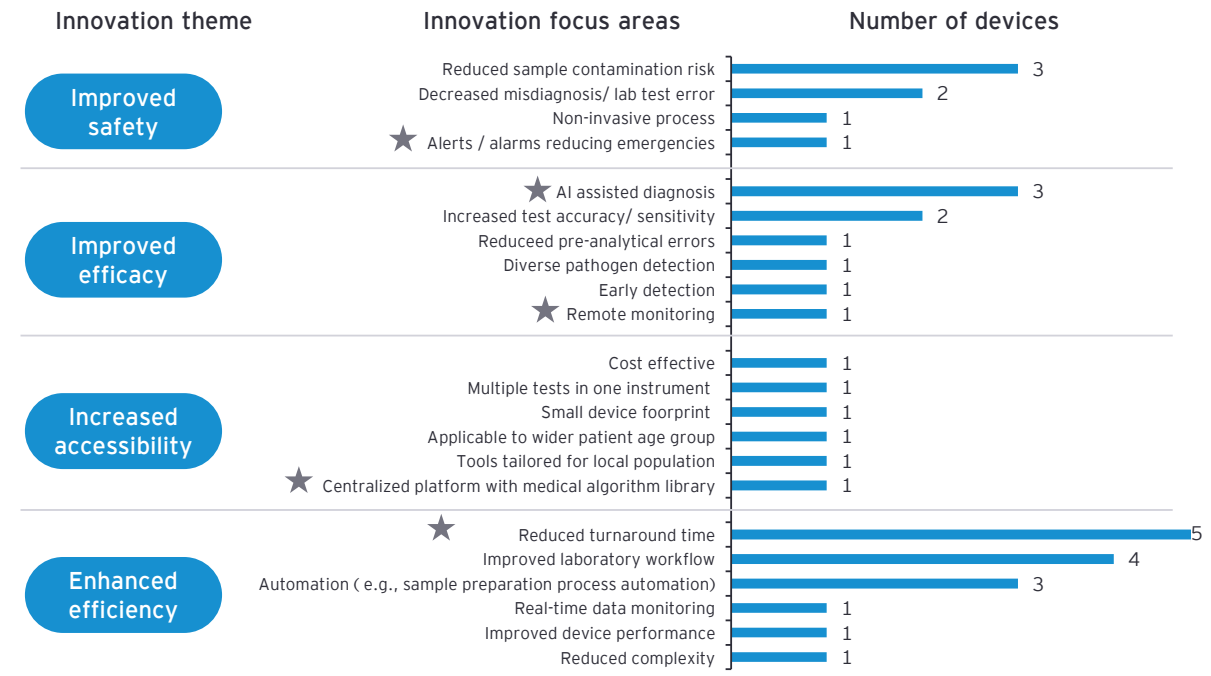
^PCR: Polymerase Chain Reaction, NGS: Next-generation Sequencing, ELISA: Enzyme-Linked Immunosorbent Assay, RIA: Radioimmunoassay
Sources: Company annual reports (for revenues), company websites (for portfolio mapping)
Notes: Currency conversion rate (as on 28 Aug'24): 1 CHF = 1.18347, USD, 1 EUR = 1.11701 USD
*Represent revenues of specific segment (Roche: Diagnostics; Abbott Laboratories: Diagnostics; Siemens Healthineers: Diagnostics and Thermo Fisher Scientific: Speciality diagnostics)
**The information is sourced from publicly available domains and may not be comprehensive.

Our analysis of recent product launches by leading global IVD companies shows that they are focusing their innovations on improving diagnostic accuracy, expanding testing capabilities, reducing the risk of sample contamination and misdiagnosis, and streamlining laboratory workflows. In molecular diagnostics, advancements offer faster and more reliable testing. Within PoC diagnostics, diabetes management has seen huge advancement with the integration of CGM systems that enable real-time insulin adjustments. In clinical chemistry, innovations include non-invasive diagnostic methods and compact systems designed for smaller laboratories, addressing specific medical needs. Additionally, the adoption of advanced laboratory automation solutions is enhancing sample tracking, reducing diagnostic result times and optimizing overall workflow efficiency.

Innovation landscape in in-vitro diagnostics segment

Innovation focus areas

*Analysis based on new products, product extensions, and solutions launched between Jan'23 and Jul'24 by global five companies**



*devices are overlapping and not unique (i.e., all innovations related to a device are captured within each relevant innovation theme. For instance, if a device improves both safety and efficacy, it is counted under both themes)

★ *Integration of digital solutions* *Not-exhaustive

Innovations across key sub segments

Key sub segments	Key innovations (leading examples)
Molecular diagnostics	▸ **Expanding testing capabilities,** e.g., Biomérieux's Biofire spotfire system offers small, scalable, multiplex PCR-based detection of common respiratory diseases, providing results in under 20 minutes, accommodating both large and small multiplex tests on a single platform ▸ **Integrated software improving efficiency,** e.g., Thermo Fisher's Diomni Enterprise Software unifies labs, instruments, assays, and laboratory information systems on a single platform, reducing qPCR diagnostic result time by over two hours
POC diagnostics	▸ **Advancements in continuous glucose monitoring (CGM):** ▸ **Hybrid closed-loop system that predicts glucose levels and automatically adjusts insulin delivery,** e.g., Abbott's 'FreeStyle Libre 2 and 3 sensors' integration with automated insulin delivery systems enables real-time insulin adjustments and offers extended wear times of up to 15 days. ▸ **AI-based real-time insights,** e.g., 'Accu-Chek SmartGuide CGM' with predictive AI real-time insights along with 14-day wear
Clinical chemistry	▸ **Non-invasive biomarker testing,** e.g., Thermo Fisher's 'CXCL10 Testing Service' offers a urine-based biomarker method for monitoring graft dysfunction in kidney transplant recipients, providing results in 24 hours ▸ **Compact space-efficient analyzers,** e.g., Siemens Healthineers' 'Atellica CI Analyzer' addresses the needs of smaller laboratories with a compact immunoassay and clinical chemistry testing system, offering high assay throughput and rapid results in ~14 minutes

Sources: Company website

Digital solutions and AI integration are increasingly shaping the IVD segment, improving diagnostic accuracy and reducing turnaround times. In pathology, AI tools enhance decision-making and improve productivity. Additionally, laboratory automation and unified platforms are driving faster diagnostics and greater efficiency in clinical labs.

Digital solutions driving efficiency and precision in IVD

Solution type	Industry examples
Cloud-based sample management	Roche's 'Navify Sample Tracking' offers real-time tracking of patient samples, detecting errors before samples reach the lab, reducing pre-analytical mistakes
Digital pathology and image analysis	Roche's 'Navify Digital Pathology' software integrates AI-powered image analysis with digital pathology workflows, improves productivity and shortens turnaround time in pathology laboratories
Integrated laboratory software solutions	Thermo Fisher's 'Diomni Enterprise' software unifies labs, instruments, assays, and LIMS on a single platform, reducing qPCR diagnostic result time
AI in point-of-care diagnostics	Roche's 'Accu-Chek SmartGuide' CGM with AI offers proactive glucose management through real-time insights

Sources: Company websites

Trends and trailblazers in Indian MedTech

Some of the key Indian companies in the IVD sector include Transasia Bio-Medicals, Agappe Diagnostics and Molbio Diagnostics. These companies are driving innovation in the domestic IVD market by focusing on cost-effective solutions with improved accuracy and increased accessibility.

Indian in-vitro diagnostics device companies: Portfolio mapping across sub segments**						
Company	Revenue US$m, FY23	Molecular diagnostics *(e.g., PCR, NGS^)*	Immunoassay *(e.g., ELISA, RIA^)*	Haematology *(e.g., complete blood count, blood clotting)*	Point-of-Care testing *(Tests providing rapid results)*	Clinical chemistry *(e.g., clinical chemical analyzer and reagents)*
Transasia Bio-Medicals	138*	✓	✓	✓	✓	✓
Agappe Diagnostics	49	✓	✓	✓	✓	✓
Molbio Diagnostics	41	✓			✓	

^PCR: Polymerase Chain Reaction, NGS: Next-generation Sequencing, ELISA: Enzyme-Linked Immunosorbent Assay, RIA: Radioimmunoassay
Sources: EMIS company database, accessed on 28 Aug'24 (for revenues), company websites (for portfolio mapping)
Notes: Revenues for full business, not specific to any segment
*FY22 revenue
**The information is sourced from publicly available domains and may not be comprehensive.

Transasia Bio-Medicals has a diverse portfolio offering affordable and user-friendly diagnostic solutions. The company has introduced automated systems such as the ErbaLisa series for ELISA testing and cloud-based LIMS (Laboratory Information Management System). Agappe Diagnostics has made strides in automated analyzers, with products like the Mispa series of analyzers incorporating IoT and cloud connectivity. Additionally, their POC vein detecting system and hemoglobin analyzer offer enhanced remote care. Molbio's innovative Truenat platform, a portable, battery-operated real-time PCR system, allows rapid molecular testing for various diseases, including COVID-19, tuberculosis and HIV. This technology has been particularly impactful in resource-limited settings. The company is also developing an AI enabled POC test for various hematology applications.

Domestic start-ups driving cutting-edge innovation

Start-ups are at the forefront of driving innovation, making affordable POC and at-home diagnostic solutions. **Adsys** is developing an AI-powered device that delivers rapid Complete Blood Count (CBC) reports from a simple finger prick, enabling anywhere testing.[91] Similarly, **Primary Healthtech** has created Mobilab (to be launched by 2025-2026[92]), a portable diagnostic solution for HCPs offering accurate and instant test results in diverse settings, including remote locations. Mobilab analyzes 24 key blood parameters within just 10 minutes, providing a comprehensive digital report.[93] **TrueHb** has developed a compact, phone-sized device for convenient and affordable hemoglobin measurement at home, enabling efficient monitoring of conditions such as anemia, chronic kidney disease (CKD), inflammatory bowel disease (IBD), and supporting health management during pregnancy.[94] **Yolo Healthcare** has developed 'Health ATM' PoC devices- a one stop solution for overall health assessment ranging from basic to advanced tests. Company offers 'HealthATM' variants such as wall mount designs, standing model, portable and a desktop model, which can perform 35 to 100+ tests depending on the model.[95]

[91] Rapid Blood Diagnosis | Adsys
[92] Mobilab-market-launch-within-3-years (business-northeast.com)
[93] Products | Mobilab
[94] Best Hemoglobin Meter | TrueHb Hemoglobin Meter Price In India
[95] About - Yolo Healthcare

D. Disposables and consumables

Portfolio insights and innovation patterns of global MedTech majors

The leading global companies in the disposable and consumable sector include Cardinal Health, 3M, Becton Dickinson (BD), Molnlycke Health Care and Ansell. Cardinal Health, BD and 3M have broad-ranging portfolios. Molnlycke and Ansell concentrate on specialized segments such as surgical and wound care supplies.

Global disposables and consumables device companies: Portfolio mapping across sub segments*

Company	Revenue* US$m, FY23	Syringes and needles	Surgical supplies *(e.g., gloves, drapes, gowns, masks, sutures)*	Wound care products *(e.g., bandages, dressings)*	Infection control products *(e.g., PPE, disinfectant wipes, hand sanitizers)*	Infusion and fluid management devices *(e.g., IV catheters, tubing, infusion sets, cannula)*	Respiratory care supplies *(e.g., oxygen masks, nebulizer kits)*	Others *(e.g., drainage tubes/bags, pads/ napkins, diapers, hot & cold pack or bags)*
Cardinal Health	15,014	✓	✓	✓	✓	✓	✓	✓
Becton, Dickinson and Company (BD)	9,502	✓		✓		✓		✓
3M	4,625	✓	✓	✓	✓			✓
Molnlycke Health Care AB	2,149		✓	✓				
Ansell	904		✓		✓			

Sources: Company annual reports (for revenues), company websites (for portfolio mapping)

Notes: Currency conversion rate (as on 28 Aug'24): 1 EUR = 1.11701 USD

*Represent revenues of specific segment (Cardinal Health: Medical; BD: Medical ; 3M and Ansell: Medical solutions)

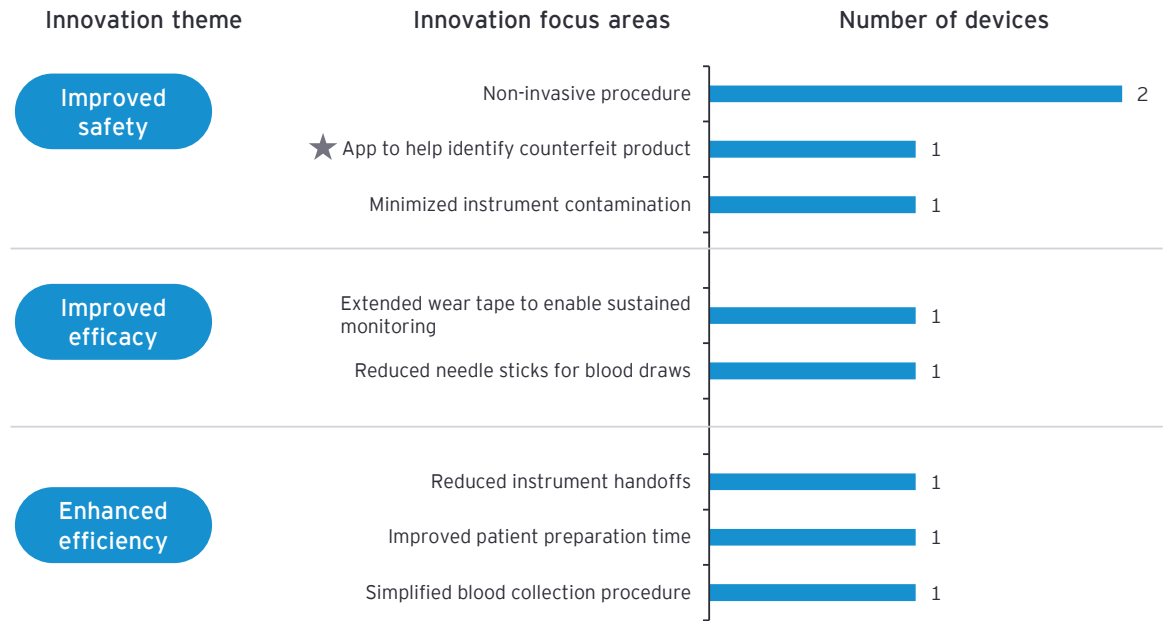
**The information is sourced from publicly available domains and may not be comprehensive.

Based on our analysis of the new product launches, we have observed advancements across various areas of medical care aimed at improving safety, enhancing efficiency and streamlining healthcare procedures. In **surgical supplies**, there is a focus on enhancing sterility and accessibility, with innovations aimed at streamlining procedures and reducing preparation time. **Patient safety** has also emerged as a priority, with advancements in blood collection technologies designed to improve comfort and reduce procedural risks. In the **medical adhesive** space, companies are focusing on long-term wear solutions, addressing issues like extended wear times, particularly for monitoring devices.

Innovation landscape in disposables and consumables segment

Innovation focus areas

*Analysis based on new products, product extensions, and solutions launched between Jan'23 and Jul'24 by global five companies**



*devices are overlapping and not unique (i.e., all innovations related to a device are captured within each relevant innovation theme. For instance, if a device improves both safety and efficacy, it is counted under both themes)

★ *Integration of digital solutions* *Not-exhaustive

Innovations across key sub segments

Key sub segment	Key innovations (leading examples)
Surgical supplies	▸ **Unique surgical gown designs,** for e.g., Cardinal health's SmartGown EDGE gown features built-in instrument pockets that provides easy access to instruments during procedures, promoting self-sufficiency for surgical teams and improves sterility maintenance ▸ **Drapes enhancing surgical site accessibility,** for e.g., Cardinal health's Stray Away hair management drape addresses specific challenges in craniofacial and neurosurgical procedures. This first-of-its-kind drape offers unique anchoring points for secure hair management, hence streamlining patient preparation
Infusion and fluid management devices	▸ **Needle-free blood draw technology,** for e.g., BD's PIVO Pro system, a needle free technique, compatible with long peripheral IV catheters. It reduces the need for additional needlesticks during a patient's hospital stay, preserves vessel health and improves overall patient comfort
Wound care products (dressings and bandages)	▸ **Extended wear medical tapes,** for e.g., 3M's Medical Tape 4578 offers up to 28 days of wear capacity, minimizing patient interruptions and enhancing long-term monitoring with various health monitors and wearables devices
Digital solutions	▸ **App to identify counterfeit products,** for e.g., 3M's Verify app addresses the crucial issue of counterfeit PPE. This app allows real-time authentication of 3M's PPE products through barcode scanning technology, enhancing worker safety

Sources: Company websites

Trends and trailblazers in Indian MedTech

Some of the key Indian companies in the disposables and consumables sector include Hindustan Syringes & Medical Devices Ltd (HMD), Poly Medicure and Romsons. These companies have been making significant strides in innovation and product development, catering to both domestic and international markets. HMD, renowned for its auto-disable syringes which prevent reuse, has been at the forefront of vaccination technology. HMD's recent innovations include the development of Dispojekt single use syringes with safety needles, designed to prevent needlestick injuries among health workers and reduce infection control costs. The company is also venturing into smart syringes, an advanced device that enhances safety by combining auto-disable technology with a protective needle cover to prevent both needlestick injuries and syringe reuse. [96, 97]

Indian disposables and consumables device companies: Portfolio mapping across sub segments*

Company	Revenue US$ m, FY23	Syringes and needles	Surgical supplies *(e.g., gloves, drapes, gowns, masks, sutures)*	Wound care products *(e.g., bandages, dressings)*	Infection control products *(e.g., PPE, disinfectant wipes, hand sanitizers)*	Infusion and fluid management devices *(e.g., IV catheters, tubing, infusion sets, cannula)*	Respiratory care supplies *(e.g., oxygen masks, nebulizer kits)*	Others *(e.g., drainage tubes/bags, pads/ napkins, diapers, hot& cold pack or bags)*
Poly Medicure	133	✓				✓	✓	✓
Hindustan Syringes & Medical Devices Ltd (HMD)	105	✓				✓		✓
Romsons	103	✓	✓			✓	✓	✓

Sources: EMIS company database, accessed on 28 Aug'24 (for revenues); Annual report 2023, Poly Medicure; company websites (for portfolio mapping)
Notes: Revenues for full business, not specific to any segment
Currency conversion rate (as on 28 Aug'24): 1 INR = 0.01191 USD
*The information is sourced from publicly available domains and may not be comprehensive.

Start-ups are also pivotal in this innovation drive. For instance, **Fibroheal Woundcare** has commercialized innovative silk protein-based wound management solutions that accelerate wound healing across acute, chronic, traumatic and post operative wounds. [98] **Axio Biosolutions** has made a mark with its patented hemostatic bandage, Axiostat, which stops bleeding within minutes of administration. [99]

[96] Indian firms ramp up syringe, vial production to meet global demand amid Covid-19 vaccine roll-outs | The Straits Times
[97] Revolutionizing healthcare safety: hindustan syringes' journey of innovation and impact | Hindustan Syringes & Medical Devices (Voiceofhealthcare)
[98] Silk Protein – Fibroheal
[99] Aaxiobio.com

Axio Biosolutions: Redefining hemostatic technology in emergency care

Axiostat: Innovative hemostatic dressing called stops bleeding within two to three minutes of application

Bioactive dressing

- **Rapid hemostasis:** controls moderate to severe bleeding within minutes
- **Biodegradable:** made from 100% chitosan, a natural biopolymer derived from shellfish

Patented 'protonated bioadhesive technology'

- unique charge-based mechanism of mucoadhesion which forms a mechanical barrier on the bleeding site
- successful even in patients taking the blood thinning medications

Wider application

- **Vascular surgeries** – control arterial bleeding from puncture sites
- **Military** – rapid bleeding control in battlefield injuries
- **Emergency and trauma care**
- **Others** - dental and nasal procedures, hemodialysis, etc.

From India to the world

- Available in 50+ countries, including the US and Europe
- First Indian hemostat to gain US FDA approval
- Manufacturing 1 million+ units per year

15+ awards

- Innovator of the year, Smart Bio awards, 2021
- MedTech Innovator Asia Pacific 2019

Sources: axiobio.com/technology, axiobio.com

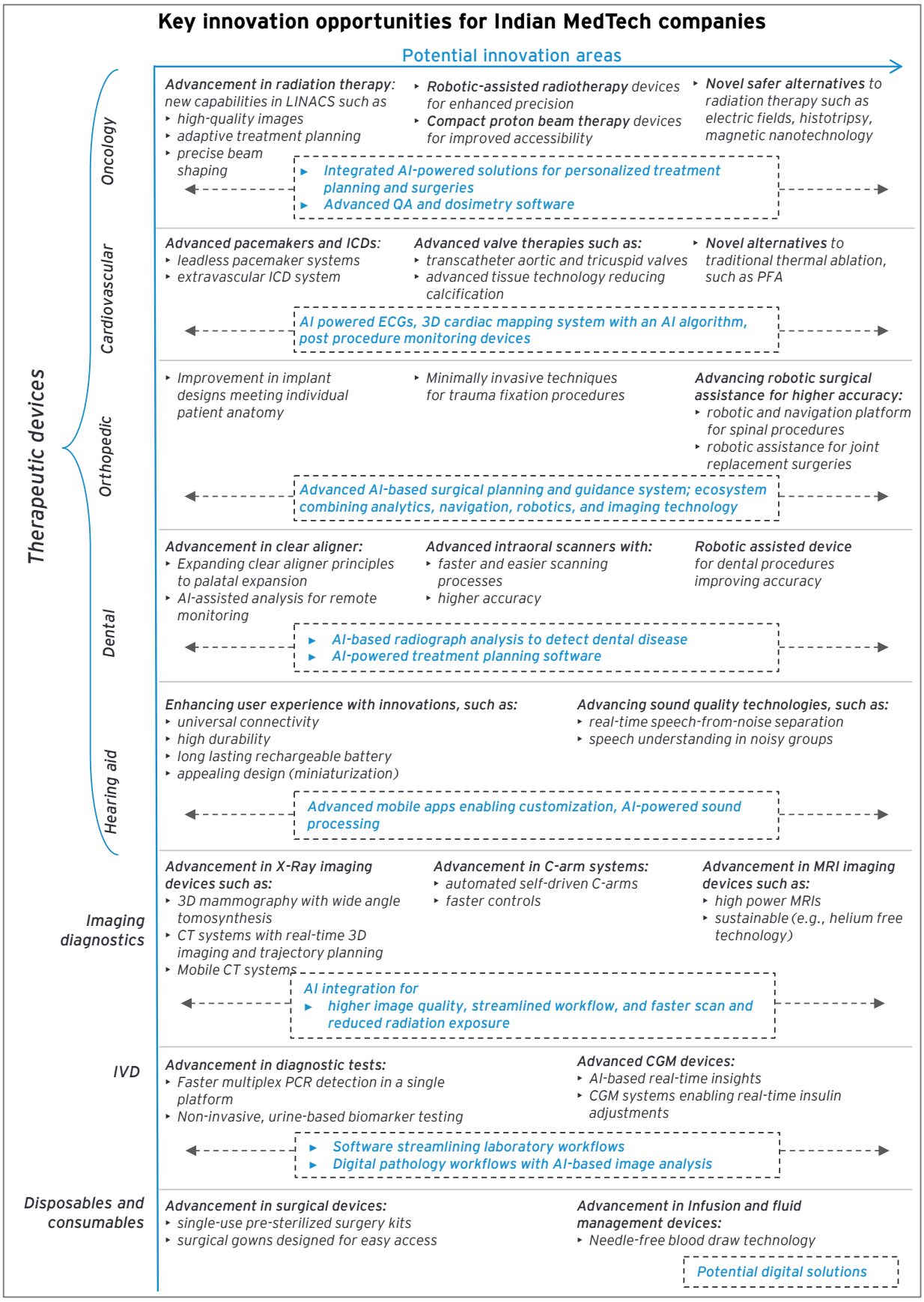
Emerging avenues for innovation in India's MedTech industry landscape

With this comprehensive analysis, it is evident that innovation in India's medical device industry is emerging. Both established entities and burgeoning start-ups are introducing innovative products that cater to local demands while aligning with international advancements.

Moving forward, it is imperative for Indian MedTech companies to intensify their innovation endeavors with even greater vigor. Strategic alignment with domestic needs and global prospects will be paramount. Innovation will be the cornerstone of growth, with an emphasis on crafting solutions that are not only affordable and accessible but also uphold the highest quality standards.

Our analysis reveals that companies exhibit varying degrees of innovation maturity, each charting a course in line with their envisioned future and growth strategies. Primary research indicates that experts advocate for innovation across the entire device spectrum, from basic to highly advanced technologies. The recommended approach begins with incremental innovation, prioritizing quality, affordability and accessibility. Subsequent phases should focus on enhancing user experience, operational efficiency and patient outcomes. The ultimate goal is to achieve groundbreaking innovations that redefine the industry.

Crucially, Indian companies must harness the nation's formidable IT prowess and data analytics capabilities, integrating these as central components of both existing and forthcoming products and services. Such integration will pave the way for more personalized and integrated healthcare solutions, optimizing patient outcomes and healthcare expenditure. Collaboration with academic institutions and cross-industry partnerships will be vital in nurturing an innovation-centric ecosystem and expediting the path from ideation to market introduction.



Source: EY analysis (indicative and not exhaustive)

Note: The key opportunities identified are based on the existing device landscape in India and global innovation

Global and Indian start-up landscape and innovation trends: EY analysis

The MedTech market is witnessing a surge of creativity and innovation from start-ups. These emerging enterprises are contributing fresh perspective and cutting-edge solutions across the segments, further propelling medical technology innovation.

To conduct an in-depth analysis of start-up innovation, we curated a comprehensive database encompassing 100 start-ups, with an equal distribution of 50 global and 50 Indian companies. Using this database, we examined and scrutinized a multitude of trends in the start-ups landscape, including the nature and scope of innovation and the extension of integration of pure medical technology with digital advancements.

Our assessment is built upon a variety of parameters that allow us to understand the innovation landscape. These parameters include medical device segments, focus therapy area and innovation outcomes. Furthermore, we delve into the breakthroughs achieved by some of these start-ups, which range from novel therapeutic approaches such as sensor-based implant, robotic surgery, bioabsorbable polymers, robotic exoskeletons, to cutting-edge digital health solutions including AI algorithms, automation.

Innovation highlights

MedTech start-ups globally and in India are revolutionizing healthcare through cutting-edge innovations focused on early disease detection, patient convenience with home-based solutions, improved treatment outcomes using advanced materials and minimally invasive techniques. While digital integration is a common theme globally, Indian start-ups demonstrate notably higher digital integration with the objective of democratizing healthcare. Technologies such as AI, IoT and cloud computing are being leveraged by Indian start-ups to improve accessibility through portable and user-friendly medical devices, remote patient monitoring tools and driving higher efficiency.

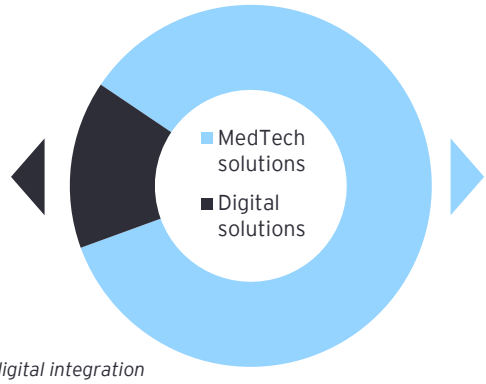
> Majority of innovations within India's MedTech start-up ecosystem are concentrated at the intersection of medical devices and software. While there is a significant focus on devices, particularly in diagnostics, the real drive is coming from advancements in software, with AI integration and data analytics playing a pivotal role.
>
> *- Head of Imaging, South Asia, leading global medical device company*

Innovation landscape: Global MedTech start-ups

Innovation split: MedTech solutions* vs. digital solutions

15%

of the innovation is propelled by purely digital solutions



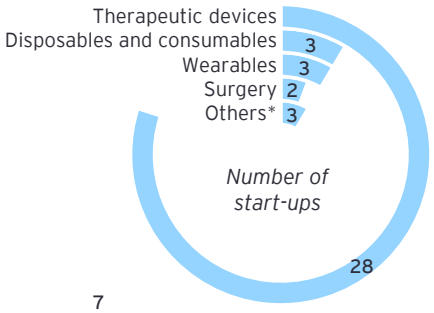
85%

of the innovation is driven by **medical technology solutions**. Of these **~50% solutions are digitally integrated**

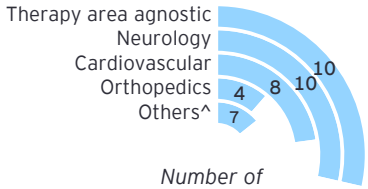
**includes medical solutions with digital integration*

MedTech Solutions

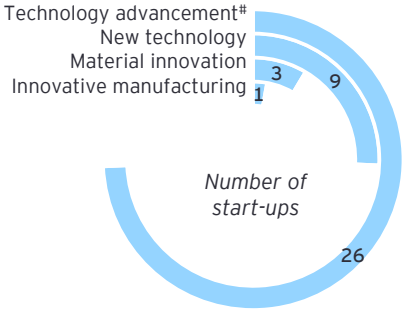
Innovation by segment



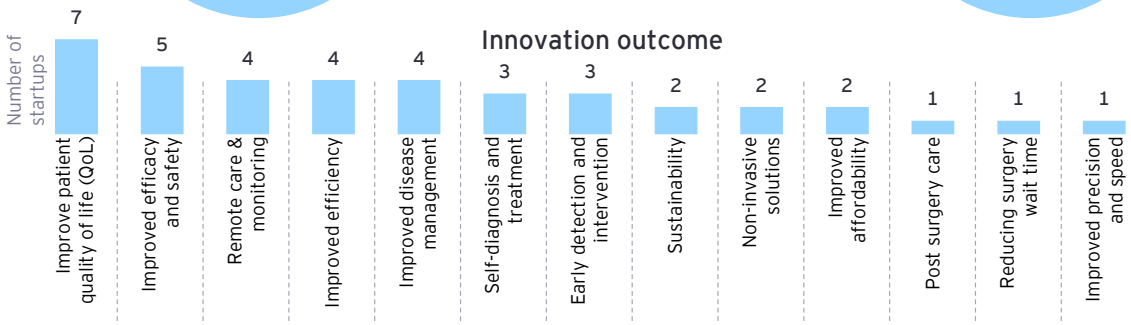
Therapy area focus



Innovation type



Innovation outcome



'Others':** includes portable real-time POC diagnostics, imaging diagnostics, remote care; ^'**Other' therapy areas:** includes oncology, respiratory, renal, diabetes. #'**Technology advancement**' innovation: includes but not limited to robotic surgery, bioelectronics, smart implants, robotic exoskeleton, deep transcranial magnetic stimulation, automation, saliva-based biosensors*

Key highlights

Advancements in early detection: AI algorithms to enhance physician decision-making and improve patient outcomes

Focus on patient convenience: Remote consultation tools, at-home testing kits, self-treatment at home, improved disease management tools developed to facilitate patient care without the need for clinic visits

Improvement in treatment outcomes: Solutions designed to minimize complications and improve treatment efficacy, such as biodegradable and bioabsorbable polymers, artificial vessels and valves, minimally invasive technique, surgical robots, pre-sterlized surgery kits, and image-guided surgery

Notable breakthroughs

Synchron is developing neurointerventional electrophysiology platform that will enable patients to control digital devices with their thoughts. It allows those with severe paralysis or degenerative diseases, such as amyotrophic lateral sclerosis, to regain communication abilities

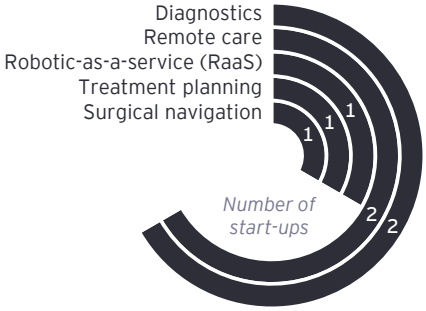
Garwood's BioPrax, a minimally invasive device designed to prevent biofilm infections on prosthetic knee implants by using electrodes to prevent microbe growth

Source: EY analysis

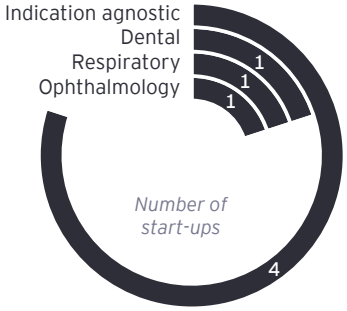
Innovation landscape: Global MedTech start-ups

Digital solution innovations

Innovation by segment

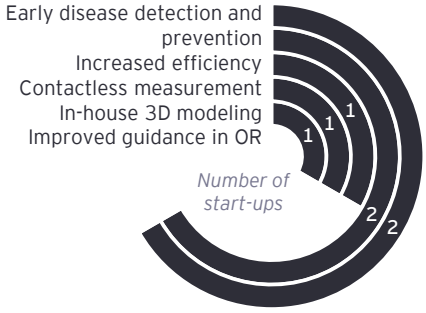


Therapy area focus



Innovation type

Innovation outcome



*'**Others':** includes surgical navigation and 3D printing*

Key highlights

Start-ups are leveraging AI, digital platforms, and robotics to drive innovations across healthcare, focusing on early disease detection, remote patient monitoring, cost-effective robotics, enhanced automation, and improved surgical precision, collectively transforming the efficiency and accessibility of medical care.

Notable breakthroughs

EyRIS, AI-driven algorithm called SELENA+ performs automated image analysis for eye diseases, implemented in Singapore's national health programs

Caducy uses contactless photoplethysmography (rPPG), signal analysis, and AI to detect pulse waves from the human face for contactless vital measurement

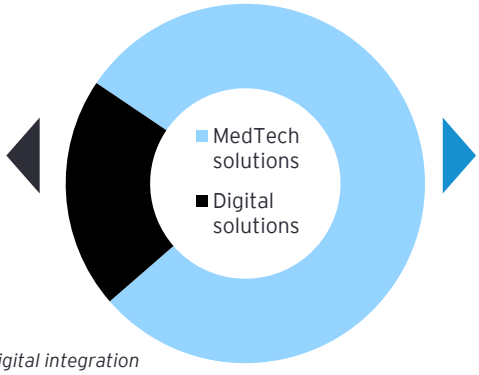
Source: EY analysis

Innovation landscape: Indian MedTech start-ups

Innovation split: MedTech solutions* vs. digital solutions

21%

of the innovation is propelled by purely digital solutions



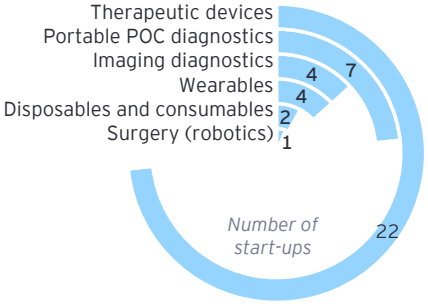
79%

of the innovation is driven by medical technology solutions. Of these, **~63% solutions are digitally integrated**

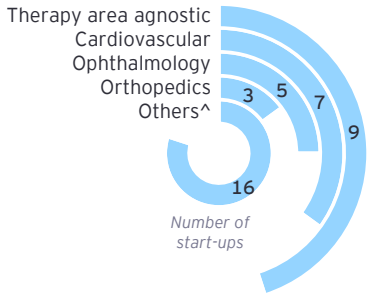
**includes medical solutions with digital integration*

MedTech Solutions

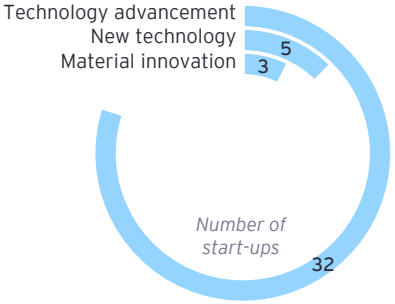
Innovation by segment



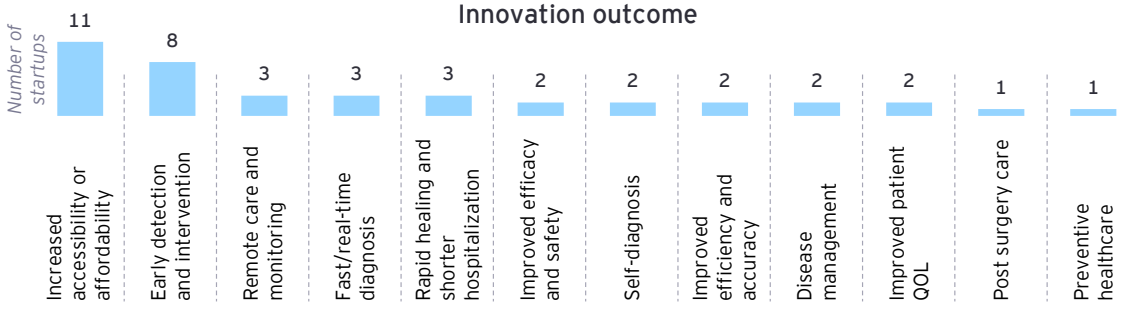
Therapy area focus



Innovation type



Innovation outcome



*^'**Others**' therapy areas: include oncology, dental, blood disorders, respiratory, wound care and neurology*
*#'**Technology advancement**' innovation: includes but not limited to portable screening and monitoring devices, sensor-based health screening, smartphone-enabled glucometer, AI-based image analysis, IoT-based ventilators*

Key highlights

Widespread integration of digital solutions: Extensive adoption of AI, IoT, cloud-based solutions and mobile apps for data analysis, remote monitoring and telemedicine

Democratization of healthcare: Portable, affordable, automated, and easy-to-use medical devices to increase accessibility to quality healthcare in remote and resource-limited settings

Technology advancements: Miniaturization of diagnostics and therapeutic devices, novel materials and nanotechnology applications, advanced imaging and sensing technologies (e.g., thermal imaging)

Notable breakthroughs

Pacify Medical: Developed a wireless, portable "Skin Spray Gun" device for rapid wound healing in burns and acid attacks, potentially reducing surgery time and hospital stays

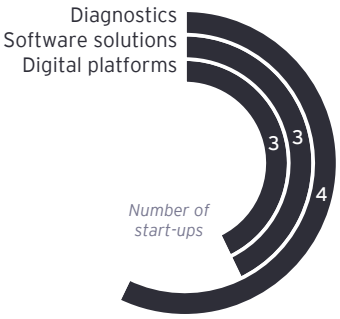
SS Innovations: Developed the SSi Mantra 3, an advanced surgical robotic system with five arms and a 3D HD headset for precise control. Its fingertip-sized incisions potentially reduce pain, blood loss, and scarring

Source: EY analysis

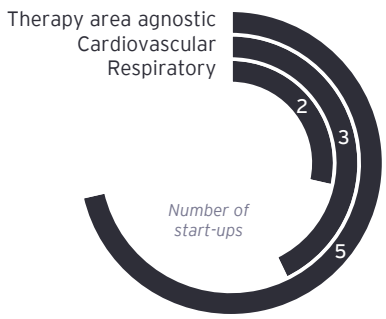
Innovation landscape: Indian MedTech start-ups

Digital solution innovations

Innovation by segment



Therapy area focus



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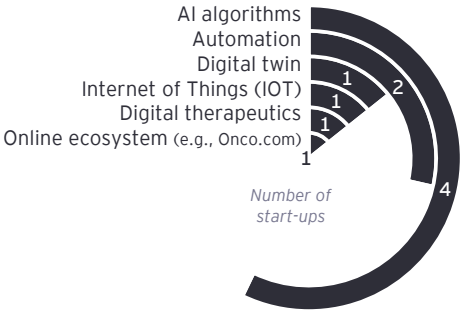
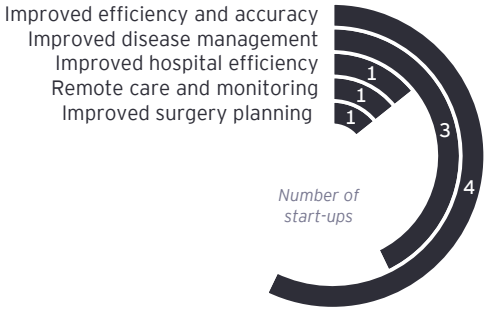


Innovation outcome



*'**Others':** includes surgical navigation and 3D printing*

Key highlights

Cloud-based remote monitoring and care management: solutions improving hospital efficiency and enabling real-time patient management

Advanced visualization and surgical planning: technologies, such as digital twins, 3D visualization, and AI are being used to enhance surgical planning and improve procedure outcome

Notable breakthroughs

Qure.ai: created deep-learning algorithms that can interpret radiology images (such as X-Rays, CT scans, and MRIs) within seconds, significantly speeding up the diagnostic process

AlgoSurg: developed AI solutions for various next-generation surgical applications ranging from robotics-surgeries, AR-based-navigation/training, cloud-based 3D surgery planning

Source: EY analysis

Innovative commercial models from Indian start-ups revolutionizing MedTech accessibility

In our research, we encountered a variety of innovative commercial models being trailed by start-ups, including rental agreements, subscription services and pay-per-use arrangements. We discussed one such case study in detail in the earlier section of this chapter. The exploration of these diverse models is driven not only by the challenge of affording the initial outlay for costly medical equipment but also by the intrinsic nature of the innovations within the devices themselves. Particularly, the incorporation of digital solutions that enable the remote monitoring of medical product usage is reshaping how these devices are marketed and monetized. This shift towards more flexible and usage-based pricing structures reflects a deeper understanding of customer financial constraints and a commitment to increasing accessibility to advanced medical technology.

> Budgetary constraints have undeniably presented us with opportunities to innovate. Now, we (start-ups) are pioneering creative approaches, transforming devices into services with rental and subscription models. These concepts, once novel in the medical device industry, have gained traction over the past few years and have now become mainstream models today. MNCs are also piloting it with a few of their products, which are built specifically for Indian context.
>
> *- Head of Imaging, South Asia, leading global medical device company*

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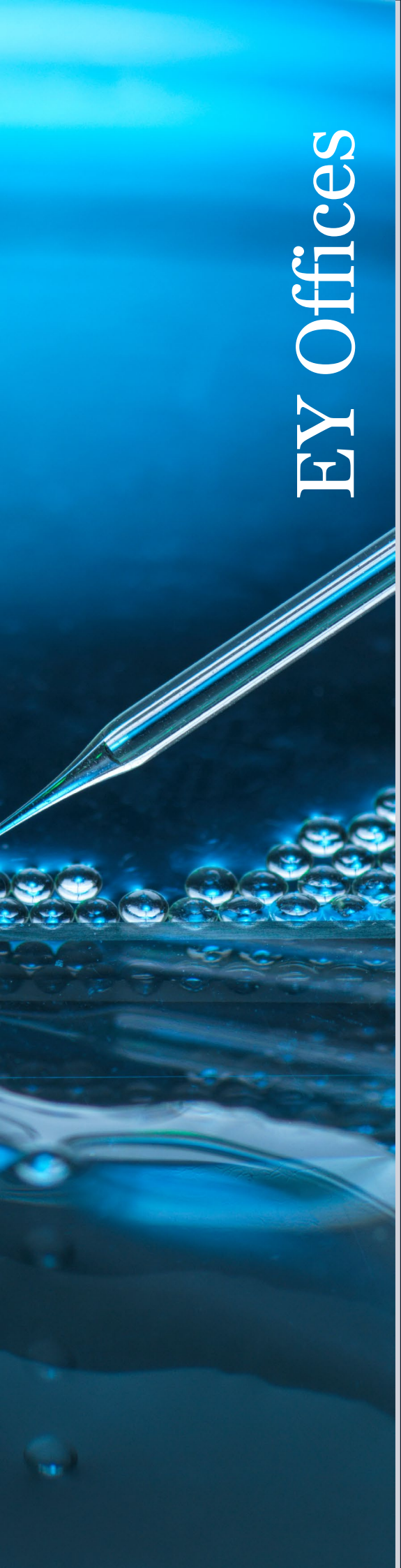

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