



From Volume to Value

Fostering research and
innovation in India's
medical device
industry

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Foreword

As we stand on the cusp of a transformative era in healthcare, the journey of India's medical device sector is a compelling story of ingenuity and potential. This whitepaper serves to highlight the current landscape of innovation in the sector and the areas that need to be addressed for charting the course ahead.

The Indian medical devices industry is poised to touch USD50 billion by 2030, a testament to its potential. Notably, a focus to promote research and development investments, coupled with increasing demand for high-end devices, has propelled India to the forefront of this vital sector.

Yet, this journey is not without its challenges. The industry today has a great opportunity to tap given the underpenetrated insurance coverage, coupled with new quality assurance standards and infrastructural upgrades as these are essential to promote innovation. Also the industry requires enhanced collaboration between academia, research institutions, and the private sector to bolster indigenous R&D capabilities.

In this context, it is imperative for all stakeholders - industry leaders, academia, healthcare practitioners, and policymakers - to converge with a shared vision. The path forward requires a holistic approach, one that harmonises innovation with quality assurance, market access, and affordability.

The government, as the custodian of public health, holds a pivotal role in this endeavour. Strategic interventions, such as incentivising R&D initiatives, creating a conducive regulatory environment, and fostering collaborative platforms, are essential. Investment in skill development and infrastructure will be instrumental in nurturing a robust ecosystem for medical device innovation. Over the last decade, the government has taken steps in the right direction to promote innovation across the sector. The focus has been to transition from a cost-based to a value-based and innovation-based industry.

As we embark on this journey, stakeholders of the medical device ecosystem can work together to help India's healthcare sector to realise its potential. Medical device manufacturers that understand this and adapt, will play a major role in India's innovation journey.



As India takes strides towards a healthier future, medical device sector is poised to play a dominant role. Partnerships between stakeholders - industry, academia, and government will be central in pivoting innovation efforts towards breakthrough research and commercialisation of high-end devices.



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In India, there is consistently an emphasis on reducing costs. While this is essential, the focus on cost should not impede the adoption of technology. Advanced technologies deliver superior outcomes, expedite patient recovery, and provide enhanced comfort.



Shishir Agarwal

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Executive Summary

Fast forward to a case study in 2040 — a patient in rural India exhibits symptoms of gastrointestinal disorder. For diagnosis, an ingestible pill is prescribed that gives the doctor an internal view of the patient's body. Intriguingly enough, this ingestible has been innovated and manufactured in India.

This case study gives us a glimpse into the enormous potential India holds in the medical device sector. It now stands at the cross-roads — either it can continue being a producer of low-end medical devices and consumables or it can develop and improve infrastructure to stimulate research and innovation required to manufacture high-end devices. India, however, is aiming to embark on innovation and evolve as a global medical device powerhouse.

India has the potential to become a global leader in the medical device sector. There is a strong focus on promoting self-reliance in medical device manufacturing, encouraging indigenous innovation and ensuring accessibility and affordability of medical devices for all. Initiatives such as the Medical Technology Assessment Board (MTAB) have been instituted to streamline regulatory processes and support innovative projects. Incubation centres and innovation hubs similar to the Biotechnology Industry

Research Assistance Council (BIRAC), are expected to foster an environment conducive for start-ups and encourage cross-collaborations between academia and the industry. Going forward, collaboration between manufacturers, regulatory bodies, and healthcare providers will be key to developing products suitable for the Indian patient population. Advanced technologies such as IoT, 5G, Generative AI (GenAI), and 3D printing among others will help manufacturers to identify patient points and customise innovative solutions.

The report highlights the policies and initiatives taken by the government to promote innovation in Indian medical device sector. Furthermore, it highlights the gaps that exist and provides recommendations for the stakeholders to address. As we chart the future course, it is imperative that we build upon the momentum of innovation, address existing challenges and seize opportunities. This thought leadership is an attempt to guide stakeholders to navigate through this exciting journey of transformation, making healthcare in India more efficient, accessible and patient centric.

As India marches towards a transformative healthcare system, there is a greater role the medical device sector can play. To help India move up the value chain, government will need to ensure implementation of policies specific to the medical device sector. Successful governance is key to promote R&D and innovation in India.

Sagar Pawar

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1

Current state of medical device innovation in India

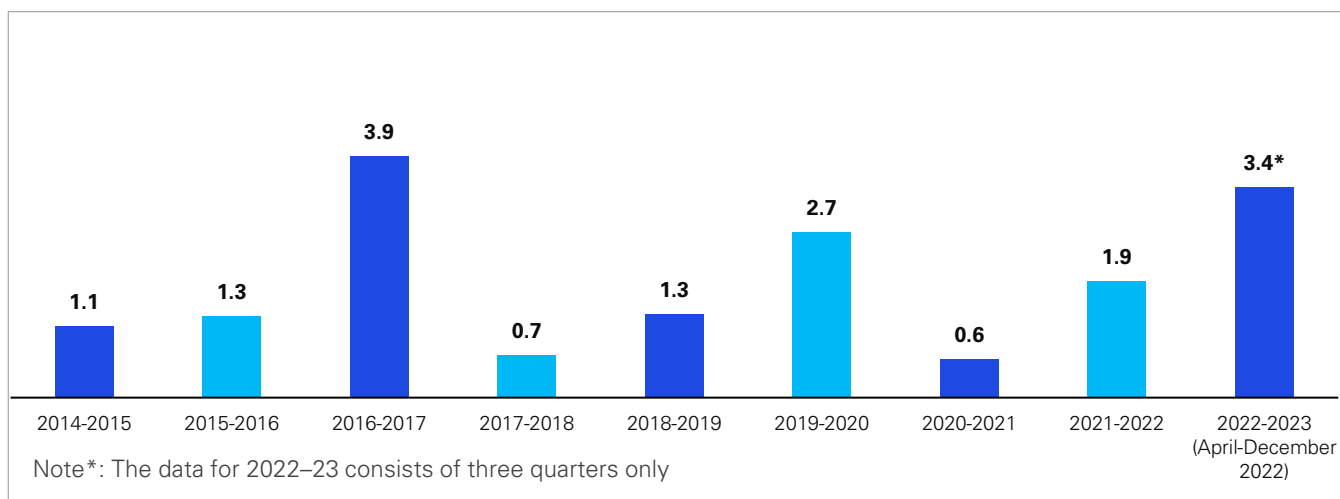
A sector with potential to grow

In April 2022, we published the ‘Enabling growth and innovation in the Indian medical device sector’ report, which underscored the importance of investment, manufacturing, and research and development (R&D) initiatives in the Indian medical device sector. This report, though subsequently worked upon, will act as a precursor and highlight India’s journey to move up the value chain in the medical device sector.

The Indian medical device market has been identified as a sunrise sector by the Government of India (GOI). The medical device sector was valued at USD11 billion in 2022 and is anticipated to reach USD50 billion by 2030¹. This growth can be attributed to increasing income levels, investments by the private sector in healthcare, a rising elderly population, rise of chronic diseases, increase awareness of health among people, popularity of medical tourism and supporting government policies. As part of the global

medical device sector, India accounted for 1.5 per cent of the market share in 2020². Indian medical device sector is at a nascent stage with most of the domestic manufacturing focused on consumables and disposables. In 2020-21, the medical devices sector contributed to 51 per cent of the total export³. During 2018–19, of the total import of medical devices USD4.7 billion (INR388.8 billion) only 16 per cent was accounted for consumables and disposables⁴. However, the overall import of medical devices witnessed an upsurge of 41 per cent during FY21–22, reflecting continued reliance on global markets for complex and high value medical devices. However, initiatives are being taken to drive indigenous manufacturing of medical devices through Production Linked Incentive (PLI), encouraging 100 per cent foreign direct investment (FDI) inflow in the country and other schemes.

Figure 1: FDI inflow in medical device industry in India (USD million)⁵



Note: Values have been converted from INR to USD at the currency exchange rate as on 18 July 2023 (USD1 = INR82.08), Oanda

1. National Medical Device Policy 2023, Drishti IAS, May 2023
2. Indian medical devices industry has potential to reach \$50 billion by 2030: Mansukh Mandaviya, Business today, September 2022

3. The Indian Opportunity: Pharmaceuticals & Medical devices, Invest India, April 2023
4. BT Buzz: Make in India flops for medical devices; domestic firms shutting shops to import, Business Today, July 2019
5. Report on Final Boosting of Medical Devices Industry, Department of Pharmaceuticals, August 2023

Need of the hour: Innovation

In the Indian context, innovation in medical devices can be defined as one that identifies specific patient challenges and provides affordable and sustainable care solutions to patients using new products and techniques without compromising on quality. The sector faces an interesting dichotomy with growing demand for innovative and latest technologies on one hand and the need to make them affordable on the other. Innovative health technologies can help enhance the quality of the healthcare delivery by reducing the overall healthcare cost, reduced hospital stays and real-time diagnosis of medical conditions.

Additionally, increase in patient population with non-communicable diseases (NCDs) is driving the need for affordable care solutions. In 2022, NCDs were responsible for 66 per cent of total deaths in India⁶. Innovation is required for developing high-end devices across areas such as cardiovascular diseases that have long been an epidemic, with an estimated 4.8 million deaths in India in 2020^{7,8}. Global medical device companies view India as an important growth market not only with respect to the domestic demand but also to cater to global markets. To ensure business expansion and diversifying portfolio, companies are boosting R&D initiatives in India. For instance, the Siemens Healthineers' new R&D centre in Bengaluru develops products for markets in South-East Asia, Africa, Eastern Europe, and South America⁹.

Another factor driving the need for innovation is competition. The medical device sector is highly fragmented in India, with players focused on manufacturing low-priced high-volume devices where the competition is intense. To improve margins, market players need to innovate and start addressing the patient challenges for medical devices.

Take on global innovation trends in the Indian context

Few of the global trends having implications for India are mentioned below:

- **Deglobalisation and reshoring to support high-tech manufacturing**

In recent times, geopolitical issues have impacted nations across the globe, which can be correlated to

the decreased global trade-to-GDP ratio from 61 per cent in 2008 to 57 per cent in 2021¹⁰. These issues have negatively impacted commodity costs, manufacturing costs and production timelines. This has underlined the importance of countries having sufficient stock of raw materials and critical components as well as having a diversified supplier base. Governments and market players are demonstrating willingness to resort to 'near-shoring' and 'friend-shoring' at a global level.¹¹ This could encourage manufacturers and researchers to localise their production, supply chain and research initiatives within the country. With additional incentives provided by government, this will lead to investments in research and innovation by manufacturers to drive efficiency and thereby providing room for innovation.

- **Rapid adoption of advanced technologies**

Advanced technologies such as 3D printing and robotics are being rapidly adopted globally in the medical device sector. The global market for medical robots is forecasted to reach USD35 billion by 2030 from USD10.6 billion in 2021, growing at a CAGR of 14.2 per cent¹². This is driven by growing investments in robotic surgery companies¹³. Further, increasing requirements in R&D of medical devices such as rapid prototyping, rapid production of personalised medical devices and designing of advanced products have led to an increasing requirement of 3D printing^{14,15}. Similarly, AI has wide applicability in the medical device sector, including remote surgery, clinical trials, assistance for diagnostic and therapeutic procedures. India has also witnessed adoption of technologies such as 3D printing in line with the global trend. In March 2021, the Andhra Pradesh MedTech Zone (AMTZ), inaugurated a 3D bioprinting facility for the development of artificial organs under the Bio Harmonised Aids for Rehabilitation and Treatment (BHARAT) programme to encourage diagnostics and therapy¹⁶. Accelerated adoption of advanced technologies is set to fuel innovation of high-end devices in the sector.

6. Share of deaths from non-communicable diseases in India in 2022, Statista, July 2023

7. Cardiovascular diseases, WHO India, November 2019

8. Impending epidemic of cardiovascular diseases among lower socioeconomic groups in India, The Lancet, June 2021

9. Siemens Healthineers invests in the growth market India and drives digitalization of healthcare by setting up an innovation hub in Bengaluru, Siemens Healthineers, October 2020

10. Trade (% of GDP), The World Bank, August 2023

11. Ten MedTech Trends to Watch in 2023, IQVIA, January 2023

12. Medical Robots Market Size And Forecast, Verified market research, April 2022

13. MedTech trends and challenges in 2023, Kyotu Technology, February 2023

14. 3D printing applications for healthcare research and development, ScienceDirect, December 2022

15. Guide to 3D Printing Medical Devices: From Prototyping to Commercialization, Formlabs, August 2023

16. Andhra Pradesh MedTech Zone (AMTZ) to Develop Artificial Organs through 3D Bioprinting, Manufactur3D Magazine, April 2021

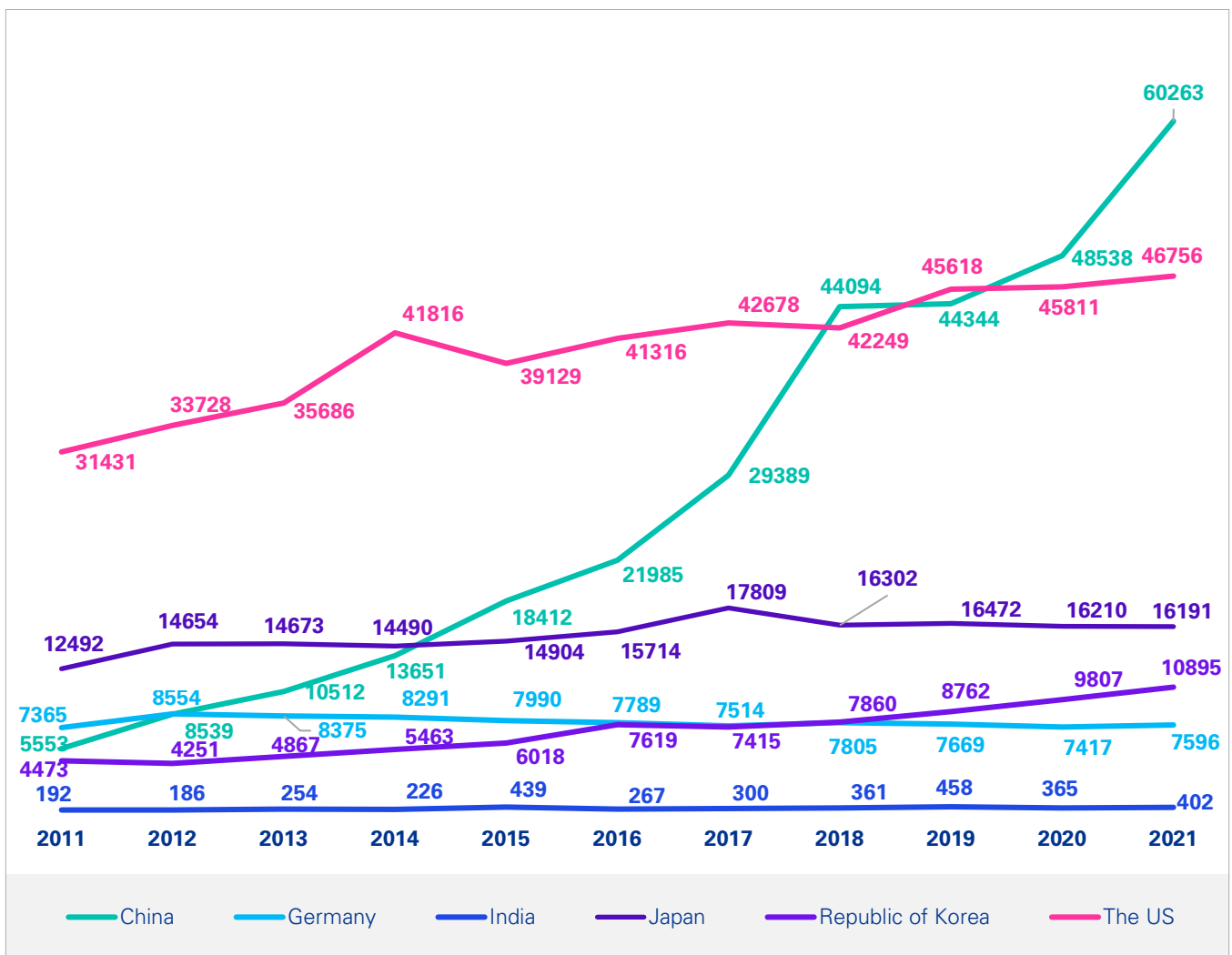
• **Affordable and accessible care**

It is estimated that half of the world’s population (3.5 billion) does not have access to healthcare services¹⁷. To address this issue, governments are trying to adopt universal health coverage (UHC) and are focused on promoting innovation across sectors including medical device. In India, it is reported that 30 per cent of the population do not have health insurance¹⁸. Also, high out-of-pocket expenditure (OOPE) is associated with the Indian healthcare system. The National Health Accounts (NHA) estimated, OOPE as a percentage of total health care cost to be 47.1 per cent in 2019–20¹⁹. This is an opportunity for medical devices sector to develop innovative solutions for patients.

• **Focus on intellectual property (IP)**

The number of patents filed in the medical device technology sector by countries across the globe has seen exponential growth for certain nations (figure 2). China, the US, and Japan are the top three countries to have the maximum number of patents filed in the year 2021. China has filed patents at a CAGR of 27 per cent between 2011-21 as compared to 2.7 per cent in Japan and 4 per cent in the US²⁰. India has the least number of patents filed during the same period as compared to US, Japan and China. This is a concern but an opportunity for India to promote innovation and climbing up the value chain.

Figure 2: The patents filed in medical technology sector by different countries and India²¹

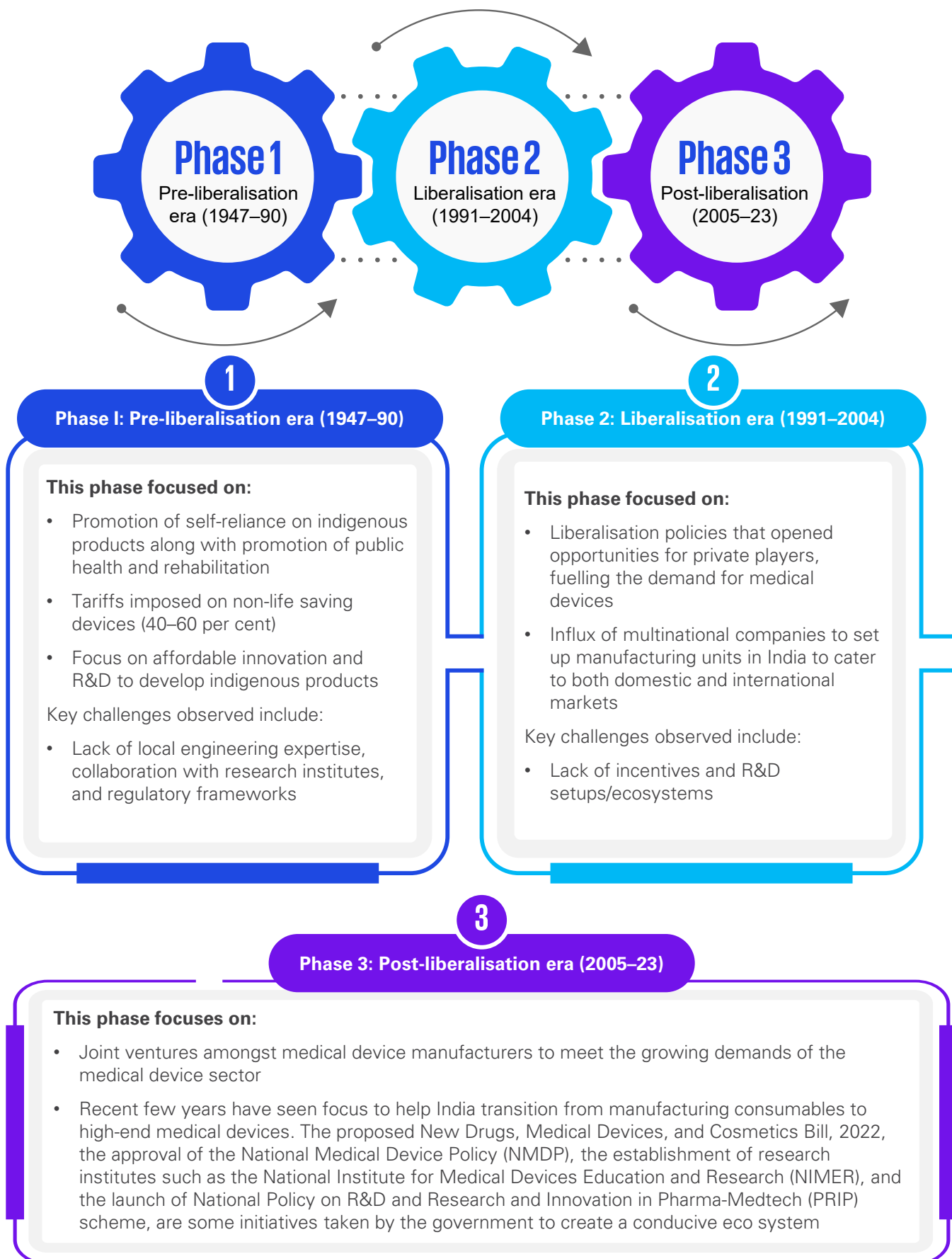


17. Here’s how to improve access to healthcare around the world, WEF, January 2020
 18. Nearly 30% of Indian population don’t have any health insurance: Survey, Economic times, October 2021
 19. National Health Accounts Estimates for India (2019-20) released, Ministry of Health and Family Welfare, April 2023

20. Report on Final Boosting of Medical Devices Industry, Department of Pharmaceuticals, August 2023
 21. Report on Final Boosting of Medical Devices Industry, Department of Pharmaceuticals, August 2023

Evolution of medical device innovation in India

The innovation landscape in Indian medical devices sector can be divided into three phases^{22'23'24'25}.



22. Indian Medical Device Industry: Legal and Tax Overview, Corpbiz, February 2023

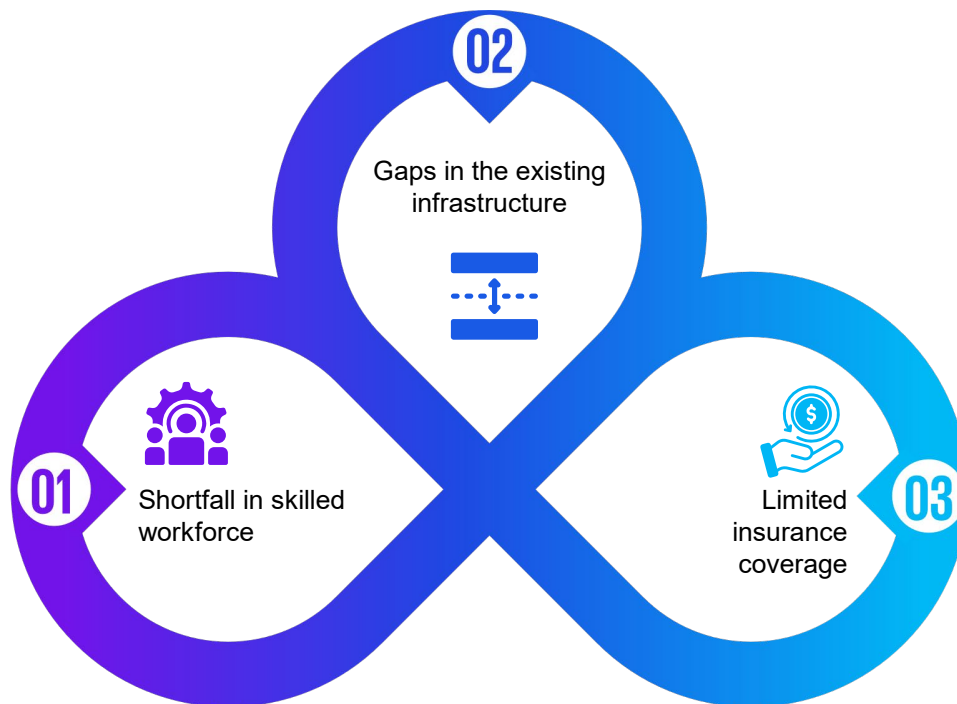
23. Medical devices industry in India, Local manufacturing and trade, Research and Information System for Developing Countries, April 2020

24. Mind the gap: Investigating the role of collective action in the evolution of Indian medical device regulation, The Open University, March 2019

25. India: Medical Devices Regulation In India: Tracing Its Evolution To Gets Cues On Its Future Development, Mondaq, January 2021

Existing gaps that hinder India's innovation journey

For medical device manufacturers, the path from concept to commercialisation is not an easy one. Some of the prominent gaps in the journey are mentioned below:



• Shortfall in skilled workforce

According to 2023 survey of industry leaders, 80 per cent of respondents conveyed the burgeoning need for skill development. The skill requirement was high for manufacturers developing medical devices such as implants, surgical instruments, and electronics and equipment as compared to the ones producing disposables, consumables and IVDs²⁶. Medical device industry requires diverse skills compared to other sectors owing to the diverse nature of roles within the industry. For instance, the product development team of a medical device company needs to have strong working knowledge across hardware (optics,

robotics, and manufacturing), software (engineering and data science) and even in R&D (microfluidics and other related latest technologies)²⁷.

Even though India produces one of the highest numbers of STEM graduates, including engineers, it continues to experience lack of coordination between biomedical education and engineering disciplines²⁸. Presently, the total number of colleges providing biomedical engineering courses are 218, of which 75 are government colleges according to an education sector-tracking portal²⁹. Additionally, the number of courses related to biotechnology engineering in India are low³⁰.

26. Report on Final Boosting of Medical Devices Industry, Department of Pharmaceuticals, August 2023

27. Career advice on skillset requirements in the MedTech space, The Times of India, October 2022

28. Why India is lacking in medical device manufacturing despite being one of fastest growing healthcare markets? Financial express, August 2022

29. List of Top Biomedical Engineering Colleges In India based on 2023 Ranking, Collegedunia, September 2023

30. Public notice and approach paper on draft NMDP 2022, Department of Pharmaceuticals, March 2022

- **Gaps in the existing infrastructure**

India's supply chain network has limited rural access. The current gaps include longer lead times for patient reach and the cost associated with transporting specialised products that have cold chain requirements. With focus on developing high-end devices, it is important to develop a robust infrastructure that helps deliver products in cost effective and timely manner. Also, investments in state-of-the-art research facilities such as medical device parks and clusters is a recent phenomenon and is limited to a few states. Greater focus to create state-of-the art facilities across the country to promote innovation is the need of the hour. Ability to innovate requires access to early-stage funding. This has been a challenge for start-ups. A recent survey conducted in 2020 by the National Venture Capital Association highlight a steady decline in the percentage of medical device companies receiving early stage (first-round) funding from 8.4 per cent in 2008 to 3.6 per cent in 2019³¹.

- **Limited insurance coverage**

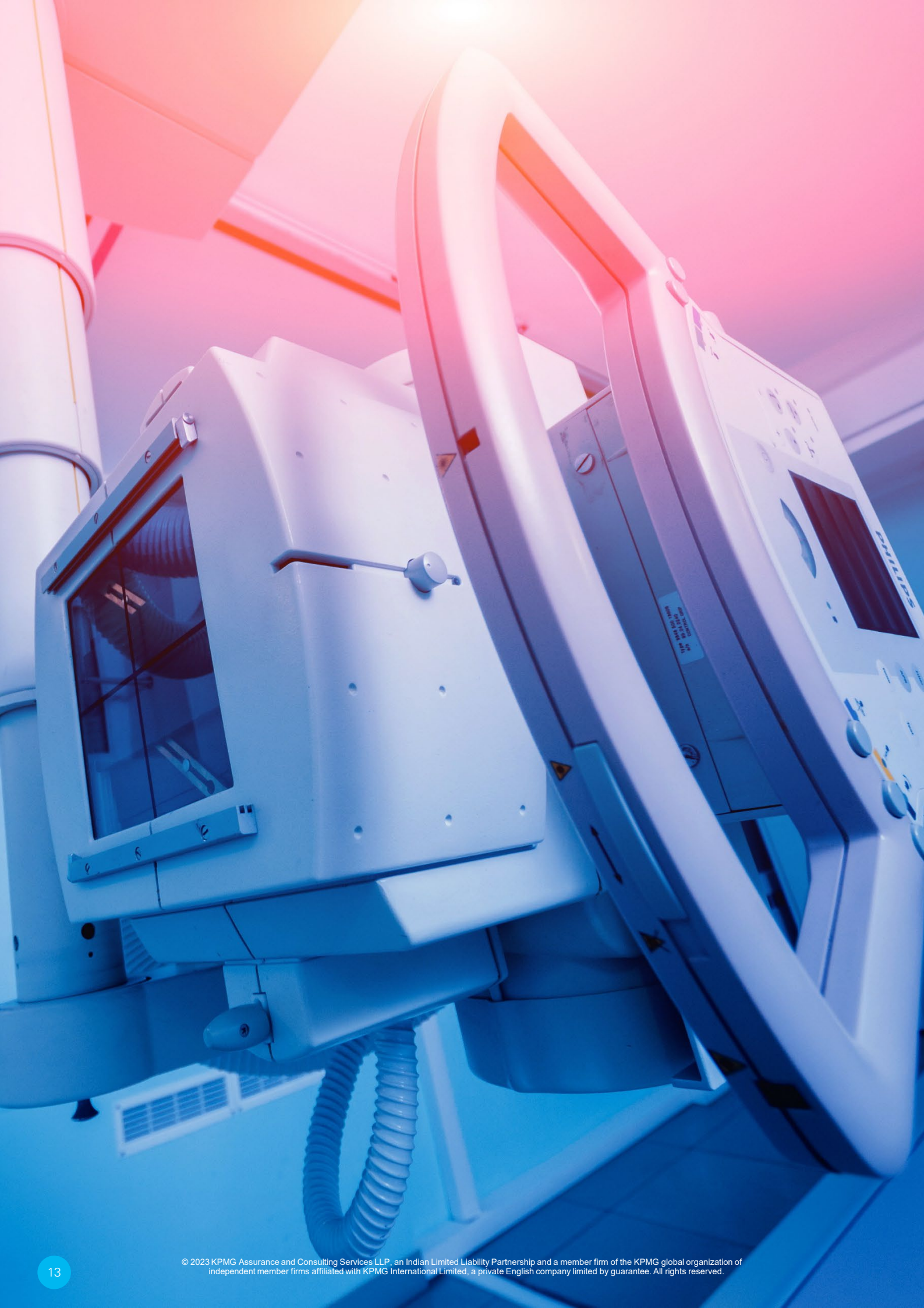
Apart from private investments, medical device companies rely on reimbursement from insurance

companies and government programmes to fund their R&D efforts. The reimbursement rates for medical devices under the Ayushman Bharat Scheme are often lower than the actual cost of the devices. This discourages healthcare providers from adopting innovative technologies and limits the financial resources available to medical device companies which may result in sub-optimal outcomes. Lack of insurance coverage could result in lower access to high end devices. In 2021, only 37% of the Indian population had some form of health insurance, resulting in limited access to high-end medical treatments. This is notably lower than the US, where nearly 90 per cent of the population has comprehensive healthcare coverage through private or government-funded insurance programmes^{32,33}. Additionally, shorter shelf life of medical device puts pressure on investors to focus on returns which could be one of the reasons for start-ups finding it difficult to secure early-stage funding. Greater insurance coverage can improve access to affordable healthcare thereby resulting in better health outcomes, and also increasing the demand for medical equipment, enabling domestic and foreign investors to introduce leading medical technologies.

31. Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary, NVCA, November 2020
32. Top Health Insurance Statistics Of 2023, Forbes, July 2023

33. Independent market report on surgical devices & medical consumables market in select geographies, Healthium Medtech, September 2021







2 Initiatives to help India achieve its innovation potential

Role of the government in catalysing R&D and innovation

The Union budget of 2023 touched upon nuances of R&D and innovation including upskilling of workforce through multidisciplinary courses and promoting cross-functional research through ICMRs³⁴. NMDP, launched by the government in 2023, provides a vision for addressing shortfalls across the entire medical device value chain with a strong focus on promoting R&D and innovation. Table 1 summarises the key initiatives and respective focus area of each scheme. It is important to collectively view the government policies as opposed to looking at them in isolation since no one policy can address the gaps.

Current policies and initiatives to bolster sector capabilities and promote innovation

Table 1: Government initiatives for medical device sector

Initiative	Manufacturing of high-end devices	R&D promotion	Workforce development	Regulatory reform
Policy on R&D and Innovation	✓	✓		✓
PRIP		✓		
NMDP	✓	✓	✓	✓
NRF Bill		✓		
AMD-CF	✓	✓		
PLI	✓			
Medical device parks	✓	✓		

Note: Promotion of Research and Innovation in Pharma-Medtech (PRIP), National Medical Device Policy (NMDP), National Research Foundation (NRF) Bill, Assistance to Medical Device Clusters for Common Facilities (AMD-CF), and Production Linked Incentives (PLI)

34. Union Budget 2023-24: Multidisciplinary courses for medical devices well receive, Economic Times, February 2023

National Policy on Research and Development and Innovation in Pharma-MedTech Sector

The National Policy on Research and Development and Innovation in Pharma-Medtech Sector was launched in September 2023. The policy aims to encourage R&D in pharmaceuticals and medical devices (domestic and international) and creating an ecosystem for innovation across the sector. There are the three main areas the policy focuses at:

- Creating a regulatory environment that promotes innovation and research in product development while improving the traditional regulatory objectives of quality and safety.
- Incentivising public and private investments within the sector through a mix of non-fiscal and fiscal measures.
- Building an ecosystem that is supportive of innovation and cross-sectoral research as a strong pillar for sustainable growth in the sector.

The policy also proposes to establish an Indian Council of Pharmaceuticals and Medtech Research and Development which promotes collaboration between industry, academia, and research institutes across departments³⁵.

Promotion of Research and Innovation in Pharma-Medtech (PRIP)

The Department of Pharmaceuticals (DoP) has launched the PRIP scheme to catalyse pharmaceutical and medical device research in the country. The scheme has two main components:

Note: Values have been converted from INR to USD at the currency exchange rate as on 18 July 2023 (USD1 = INR82.08), Oanda

35. Dr Mansukh Mandaviya launches National Policy on Research and Development and Innovation in Pharma-MedTech Sector in India and Scheme for promotion of Research and Innovation in Pharma MedTech Sector (PRIP), Ministry of Chemicals and Fertilizers, September 2023

- The first component focuses on boosting research infrastructure through the establishment of seven centres of excellence (CoE) at NIPERs. The goal of CoE is to strengthen research capabilities of medical device sector by providing advanced facilities and leveraging industry academia partnership.
- The second component focuses on provision of financial incentives for companies undertaking research initiatives in-house or in collaboration with government institutes across six moon-shot areas which includes - AI/ML based medical devices with software development, Software as Medical Device (SaMD), and Software in Medical Device (SiMD); medical diagnostics and screening devices with genetic engineering technology; robotic devices for surgery; and medical devices with telemedicine facilities. The duration of the scheme is for five years (FY23-24 to FY27-28) with a budget outlay of USD609 million (INR50 billion)³⁶. PRIP marks a major step towards incentivisation of research and with proper implementation.

National Medical Device Policy (NMDP)

NMDP, approved in April 2023, provides a holistic policy framework for accelerating innovation in the medical device sector³⁷. The policy defines a set of focus areas that would be key to propelling capabilities of the sector. It focuses on six key areas highlighted below:

36. PRIP launch brochure, August 2023

37. Cabinet approves the Policy for the Medical Devices Sector, Ministry of Chemicals and Fertilizer, April 2023



01

Regulatory streamlining

Creation of a 'Single Window Clearance System' for licensing of medical devices, developing a coherent pricing regulation and enhancing the role of Bureau of Indian Standards (BIS)

02

Enabling infrastructure

Establishing new and bolstering existing medical device parks/clusters. New medical device parks are envisioned to be in proximity to economic zones and would be equipped with requisite logistics connectivity as proposed in the 'National Logistics Policy' and the 'National Industrial Corridor Program'

03

Facilitating innovation

Establishing centres of excellence in academic and research institutions as well as introducing 'plug and play' infrastructure for supporting start-ups and innovation hubs

04

Attracting investments

Encourages private investments, funding from venture capitalists and public-private partnerships

05

Workforce development

The policy envisages the following measures for promoting skilled workforce:

- Leveraging resources available with the Ministry of Skill Development and Entrepreneurship for skilling, re-skilling and up-skilling of medical device professionals
- Supporting the creation of multidisciplinary courses for medical devices
- Developing partnerships with foreign academic and industry organisations for collaborating on medical technologies

06

Brand positioning and awareness

Creation of a dedicated medical device Export Promotion Council that will address issues pertaining to market access by:

- Studying global best practices of manufacturing and skilling systems
- Promoting knowledge sharing and building stronger networks across the sector through forums



Assistance to Medical Device Clusters for Common Facilities (AMD-CF)

Through AMD-CF, the government will provide financial assistance for building common infrastructure facilities at existing medical device clusters. With a total outlay of USD36.5 million (INR3 billion), the scheme would support building of 12 common facilities and 12 testing labs between FY23–24 and FY26–27³⁸. By supporting the creation of labs, the scheme will play a key role in advancing R&D capabilities of current and upcoming medical device clusters in the country.

National Research Foundation (NRF) Bill^{39,40}

In June 2023, introduction of the NRF bill in the parliament was approved by the Union Cabinet. Through NRF, the government aims to catalyse cross-functional and collaborative research. The Department of Science and Technology (DST) will function as the administrative arm of NRF and the total outlay of funds under NRF is expected to be USD6.1 billion (INR500 billion), which will be shared by the government and private sector over the course of the next five years (2023–28).

NRF's introduction compliments India's vision for collaborative research across the medical device ecosystem as stated in Budget 2023. The aim is to forge collaborations/partnerships across industry, government and academia. NRF will focus on building a policy framework and introduce regulatory processes that promote R&D spending and collaboration by players in the industry. However, it is important to consider that NRF will operate across the broader domain of scientific research. Provided that benefits of NRF reach stakeholders in the medical device sector, it will play a crucial role in medical device innovation by augmenting research across all models—government, private and collaborative.

Production Linked Incentives (PLI) scheme: The PLI scheme for medical devices was launched by the government in 2020 to promote domestic manufacturing of devices. The scheme extends an

incentive of 5 per cent on incremental sales of medical devices manufactured in India covered under the target segments. Total incentive outlay of the scheme is USD416 million (INR34.2 billion) and as of April 2023, manufacturing of 37 high-end medical devices have been commissioned including linear accelerators, MRI and CT-scan devices, mammogram, C-Arm and high-end X-ray tubes amongst others⁴¹.

The PLI scheme is playing a key role in the larger innovation eco-system by providing a platform for affordable high-end medical devices in India.

Promotion of medical device parks scheme: The scheme launched in 2020 aimed at strengthening the manufacturing and R&D ecosystem of medical devices in the country. The central government aims to provide financial assistance to select state governments for establishing medical device parks, to provide access to standard testing and advanced infrastructure facilities. The total financial outlay of the scheme is USD48.7 million (INR4 billion), and four states (Himachal Pradesh, Tamil Nadu, Madhya Pradesh, and Uttar Pradesh) have been granted an 'in-principle' approval to set up medical device parks⁴².

In addition to the medical device park scheme run by the central government, state governments have taken initiatives for establishing medical device parks either independently or in partnership with the central government. The medical device park set up by the Telangana government is a notable example of an independent initiative taken by a state government.

Telangana medical device park: In 2017, the government of Telangana established a medical device manufacturing and R&D park in Hyderabad. Since its inception, the Telangana medical device park has attracted investments from more than 50 companies, amounting to a total of more than USD182.7 million (INR15 billion). Following are the features that attract companies to the state and are responsible for the success of the park⁴³:

Note: Values have been converted from INR to USD at the currency exchange rate as on 18 July 2023 (USD1 = INR82.08), Qanda

38. Guidelines for the scheme for "Assistance to Medical Device Clusters for Common Facilities (AMD-CF)", Department of pharmaceuticals, May 2023

39. Cabinet approves Introduction of National Research Foundation Bill, 2023 in Parliament to strengthen research eco-system in the country, Ministry of Science & Technology, June 2023

40. No quick fix: On National Research Foundation Bill, The Hindu, July 2023

41. Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices, Invest India, May 2020

42. Scheme for "Promotion of Medical Device Parks", a key initiative to support the medical devices, notified, Ministry of Chemicals and Fertilizers, April 2023

43. Medical device parks, Telangana life sciences, July 2023

01

Talent pool

Strategic location gives it access to premier academic and research institutions

02

Strong supply chain

Telangana has more than 1,000 small and medium enterprises (SMEs) in the field of precision engineering and more than 6,000 plastic manufacturers

03

Robust infrastructure

- Rapid prototyping and tooling: 3D printing technologies, Computer Numerical Control (CNC) prototype machining
- Common facilities for medical device testing: Including sterility and toxicity testing, biocompatibility and biomaterial testing, electrical safety, and reliability testing
- Testing and certification labs: EMI-EMC testing capabilities and partnerships with global certification agencies
- Warehouse: 100,000 sq. ft. warehouse that is compliant with global standards

04

Promising incentives

- Up to 75 per cent reimbursement of state GST for seven years from commercial production
- 50 per cent subsidy on quality certification and patent registration
- 25 per cent subsidy on clean production measures



Research institutes are an important source of driving innovative solutions

The Indian Council of Medical Research (ICMR) is one of the oldest, globally recognised medical research institutes. It is the apex body for coordination, formulation, and promotion of R&D in the biomedical field. It helps conduct, coordinate, and implement research for the benefit of the society and translate medical innovations into products and processes. Along with 26 network institutes, ICMR is actively involved in the evaluation of new drugs and therapies for all diseases of national health priority along with neglected and regional ones. Similarly, Department of Pharmaceuticals (DoP) is playing a vital role to drive R&D in medical device sector. In the recently launched policy for R&D and innovation, DoP plans to setup a high-level task force to review and track implementation of the policy. Following are some of the notable initiatives taken by ICMR along with other government agencies to boost the medical device industry^{44,45}:

01

Indian Council of Medical Research-Department of Health Research (ICMR-DHR) policy

- The Health and Family Welfare Ministry and State Ministry launched the ICMR-DHR policy at medical, dental, para-medical institutes and colleges on 'Biomedical Entrepreneurship & Innovation' for medical professionals, scientists and technologists
- This policy is built with an aim to establish holistic innovation, multi-disciplinary collaboration and support entrepreneurship at the institute and college level by promoting Make-in-India, Atmanirbhar Bharat, and Start-up India initiatives
- The implementation of guidelines will help the institutes to collect a portion of the recurring revenue stream after the commercialisation of an invention, thus making the internal innovation process self-sustaining

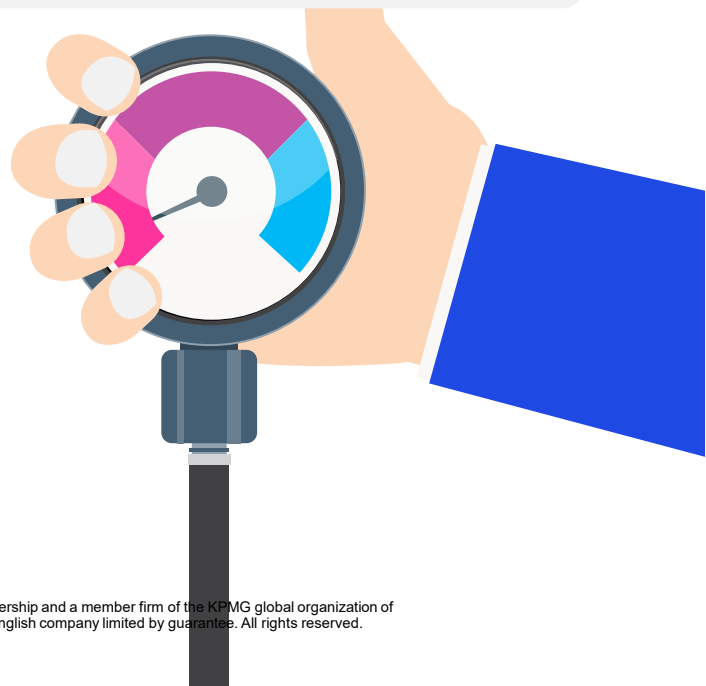
02

Medical Device and Diagnostic Mission Secretariat (MDMS)

- The MDMS under the division of Innovation and Translational Research (ITR) was launched with a vision to support and catalyse R&D and manufacturing of medical devices. The end goal is to decrease the import from other countries
- This initiative will incentivise and motivate local manufacturing in India and provide holistic support to the products or technologies approaching commercialisation
- The programme is based on a top-down and bottom-up approach to further create a pipeline of innovative medical device and start-up supporting programmes
- Some of the schemes in the pipeline under ICMR-MDMS are Catalysing and Leveraging Innovation in Medtech Biodesign (CLimB), Product Ignition and Development Enabler (mPRiDE), ICMR-Centre of Innovation and Bio design (CIBioD), and ICMR-DHR Centre of Excellence (CoE)

44. Annual Report 2020-21, ICMR, September 2023

45. A Complete Analysis Of ICMR For Medical Device, Corpbiz, November 2022



Working models that promote R&D in medical device sector

Academic research institutions are an important pillar that support and promote R&D in the country. These institutions are undertaking high-impact research individually and through collaborations. Cross-functional collaborative research undertaken by academic research institutions is a key step towards building a medical device research eco-system in the country that has operated in silos.

Industry-academia collaborations

Partnership for workforce upskilling: Boston Scientific in India collaborated with a leading academic institute in Ropar for developing a customised course for engineers at Boston Scientific. This initiative was first successfully piloted in 2021 and continued in successive years. Boston Scientific R&D plans to expand this effort to develop customised coursework in multiple disciplines across the domain of medical device design and development. Such collaborations focused on workforce upskilling will help companies to speed up the learning curve of employees while also helping academic institutes in developing industry ready talent.

Partnership for AI in medical imaging: Wipro GE Healthcare, in collaboration with a premier academic institute in Bengaluru, inaugurated a research centre focused on AI in medical and healthcare imaging in 2020. The research centre is developing deep learning-powered healthcare diagnostics solutions across therapeutic areas. Key areas of focus include deep learning models for classification and segmentation of COVID-19 lesions in lung ultrasound and CT images, classification of spectral domain optical coherence tomography images in ophthalmology, deep learning-powered medical image reconstruction and leveraging 3D volume data for reducing development and annotation costs⁴⁶.

Cross-functional academic collaborations

In 2023, a premier medical institute signed an MoU with another premier academic institute in Bhubaneswar for academic and research collaboration across health and technology. Through this collaboration, the institutions will advance research in the areas of biomedical engineering and technology, disease prediction modelling, AI and analytics, digital health, and tools for diagnostic and therapeutic purposes. They will partake in faculty and student exchange programme as well as offer joint academic programmes, reorientation, and training courses along with opportunities for cross-functional thesis work⁴⁷.

Foundations of breakthrough research: In 2022, Tata Memorial Centre in collaboration with a premier academic institute in Kharagpur launched the country's first cancer image-bank called 'CHAVI'. CHAVI is a repository of relational, de-identified and fully annotated cancer/oncological imaging data that will enable researchers to acquire requisite clinical information for research. The image-bank will allow evaluation of efficacy of current treatment protocols and development of new protocols to enhance patient outcomes⁴⁸.

Partnership for medical device and testing: In 2022, ICMR in collaboration with the Department of Health Research (DHR), established the MedTech Product Development Acceleration Gateway of India (mPRAGATI) at a premier academic institute in Delhi. mPRAGATI is an ISO certified medical device manufacturing and testing facility that will support the translation of medical products and technologies from proof-of-concept (TRL 3) stage to ready for clinical evaluation (TRL 7) stage. Additionally, the centre will facilitate workforce upskilling through bootcamps and training sessions for students, academicians and start-ups⁴⁹.

46. Wipro GE Healthcare and Indian Institute of Science partner to set up a Healthcare Innovation Lab, IISC, August 2023

47. AIIMS Bhubaneswar signs MoU with IIT Bhubaneswar on Artificial Intelligence (AI), PIB, April 2023

48. India gets its first oncology image bank, CHAVI to boost cancer research in the country, Financial express, September 2022

49. mPRAGATI, IIT Delhi, July 2022



Private sector contributions are critical for India to move up the value chain

Investment from private players will play a key role in embedding a culture of R&D in the industry along with providing a platform for upskilling and creating avenues for partnerships and collaborations. Below are some examples of R&D investments and partnerships of private players:



bioMérieux: In February 2022, bioMérieux launched its Antimicrobial Stewardship (AMS) Centres of Excellence (CoE) initiative in partnership with hospitals and laboratories worldwide, aiming to demonstrate the value of diagnostic solutions. As part of this initiative, bioMérieux is collaborating with Manipal Academy of Higher Education (MAHE) to establish a state-of-the-art laboratory at Kasturba Medical College in Manipal, India. Additionally, bioMérieux will emphasise the benefits of a global approach, including data and IT solutions, laboratory workflow optimisation, quality management support, and medical training through this initiative^{50,51}



Boston Scientific: In 2022, Boston Scientific strengthened its research efforts in India by launching a new R&D centre in Pune, making it the company's second R&D centre in the country after first one was setup in Gurugram in 2016. The combined R&D facility in India is now the second largest R&D footprints for Boston Scientific outside the Americas. The new R&D centre focuses on research initiatives across multiple therapeutic areas including interventional cardiology, peripheral interventions, and cardiac rhythm management. These R&D centres in Pune and Gurugram demonstrate the company's growing confidence in India's medical device R&D eco-system⁵²



Medtronic: Since 2020, Medtronic has invested more than USD500 million for expanding a Medtronic Engineering & Innovation Centre (MEIC) located in Hyderabad. Medtronic's investment of USD160 million in 2020 made MEIC the company's largest R&D centre outside the US. In 2023, Medtronic announced a further expansion of MEIC by committing an investment of USD350 million. The expansion will boost research across areas such as robotics, surgical technologies, implantable technologies and imaging technologies. This expansion is expected to increase MEIC's workforce from 800 to 1500, creating additional jobs. The expansion is a testament to Telangana and India's rising medical device ecosystem and sets a precedent for others⁵³



Siemens Healthineers: : In 2020, Siemens Healthineers announced that it will invest USD179.7 million (EUR160 million) between 2020 and 2025 for establishing an innovation hub in Bengaluru. The innovation hub will focus on design and development of entry-level products. The innovation hub will focus on digital competencies including data analytics, artificial intelligence, cybersecurity, and immersive technologies. For expanding digital capabilities, the company will hire up to 1,800 professionals in the coming years. This investment demonstrates India's importance as a growth market for the company⁵⁴



Stryker: In 2022, Stryker inaugurated a neurovascular research lab at Stryker's Global Technology Centre (SGTC) in Gurugram for developing innovative solutions for brain stroke. The new lab has three major components that include a neurovascular catheterisation lab equipped with imaging and communication equipment, a performance lab with neurovascular simulators along with 3D printing capabilities and a planned space for physician interaction. SGTC employs more than 1,000 employees and the new investment in SGTC reflects positively for India's medical device research eco-system. It demonstrates Stryker's continued interest in leveraging capabilities of the Indian medical device eco-system⁵⁵

Note: Values have been converted from EUR to USD at the currency exchange rate as on 18 July 2023 (USD1 = EUR0.89), Oanda

50. bioMérieux establishes Antimicrobial Stewardship Centres of Excellence (CoE) across the globe in partnership with hospitals, bioMérieux, September 2023

51. MAHE, bioMérieux to establish Centre of Excellence in Antimicrobial Resistance, Stewardship, Manipal Academy of Higher Education, February 2022

52. Boston Scientific launched second R&D centre in Pune, Economic Times, March 2022

53. Medtronic Bolsters Presence in India by Investing Approximately, Bloomberg, May 2023

54. Siemens Healthineers invests in the growth market India, Siemens Healthineers, March 2023

55. Stryker launches state-of-the-art Neurovascular R&D lab with advanced technology to accelerate stroke care innovation, Stryker, December 2022

Domestic manufacturers

Although homegrown enterprises in the sector have traditionally lagged in terms of innovation, in recent times, some have started to focus more on R&D and high-end devices. Some notable examples include:

- Skanray Technologies and Meril Life Sciences. The former is a Mysuru-based company founded in 2007. The company is focused on developing diagnostic X-Ray systems, surgical C-arms, ECG devices and patient monitoring systems. Skanray's focus on innovation is backed by more than 80 patents and more than 50 CE/FDA certified high-end medical devices⁵⁶.
- Meril Life Sciences founded in 2006 has a diverse portfolio of medical devices including vascular intervention, cardiac surgery, orthopaedic, endosurgical, ENT and diagnostic devices. The company has a strong focus on innovation and notably, in 2019, the company received the CE mark for 'Myval', its transcatheter heart valve⁵⁷.

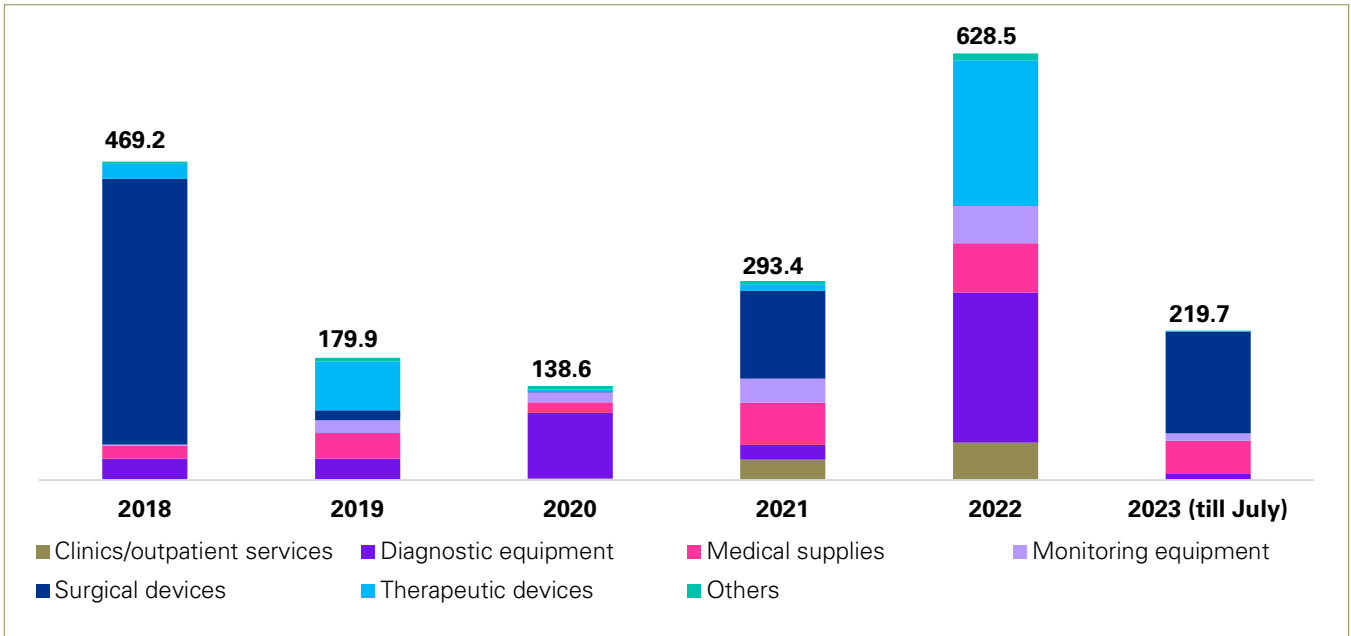
Recognising the role of start-ups and investors

India houses more than 250 start-ups in the field of medical devices and allied technology⁵⁸. In recent years, start-ups have picked up momentum in domestic as well as international markets. Strong backing of venture capital (VC)/private equity (PE) has been an important catalyst in catapulting the growth of start-ups. Medical robotics, medical imaging, and AI-powered diagnostics are some of the prominent focus areas of Indian start-ups in the sector.

Diagnostic and therapeutic devices have been the focus of investors

In the last few years, there has been a major focus on digital therapeutics and wellness solutions with diabetes and cardiovascular diseases being the prominent therapeutic areas. Investments in the sector picked up significantly, especially in the last two years and has continued a positive trajectory into 2023. Notably, 2022 proved to be a significant year with the sector securing more than USD600 million in PE/VC investments. Private investments in 2023 are already exceeding pre-pandemic levels with a renewed interest in surgical devices, molecular diagnostics and cardiovascular devices⁵⁹.

Figure 3: Deal value of PE/VC investments in healthcare devices and supplies in India (USD million) 2018–23 (YTD)



56. About Us, Skanray Technologies, August 2023

57. Meril Life Sciences Gains CE Mark for Aortic Heart Valve, FDA News, June 2019

58. Medical devices sector, Invest India, October 2023

59. KPMG analysis of Pitchbook data as of July 17, 2023

Table 2: Notable PE/VC medical device deals in 2022 and 2023⁶⁰

In India's innovation journey, emergence of start-ups will be a major catalyst to help the sector move up the value chain. Some of the most notable deals in the past year are highlighted in table 2:

Company	Company type	Focus area of company	Deal description	Deal size (USD million)	Investment till date (USD million)
Meril Life Sciences	SME	Vascular, interventional, orthopaedic, IVD and endo-surgery devices	PE growth/expansion capital from Warburg Pincus	210.0	213.2
Sahajanand Medical Technologies	SME	Molecular diagnostics	Continuation fund through leveraged buyout by Samara Capital	150.0	177.8 (estimated)
Molbio Diagnostics	Start-up	Molecular diagnostics	Development capital from Temasek Holdings and Oswal Alternates	85.0	118.4
Redcliffe Genetics	Start-up	Molecular diagnostics	Series B funding led by Leapfrog Investments	61.0	94.6
BeatO	Start-up	Glucose monitoring device	Late-stage venture funding deal led by Lightrock	32.8	46.1
Tricog	Start-up	Ai-based cardiac monitoring device	Series B2 venture funding led by Sony Innovation Fund	8.5	30.6
Rivaara Labs	Start-up	Molecular diagnostics	PE growth/expansion capital from Amicus Capital and others	7.3	7.3
Dozee	Start-up	Remote patient monitoring	Series A2 venture funding led by State Bank of India	6.0	26.3

60. KPMG analysis of Pitchbook data as of July 17, 2023



3

India's vision of medical device innovation



With India expected to become a USD10 trillion economy by 2035⁶¹, medical device sector is expected to play major role to help realise its aspiration. While India can keep playing the volume game, providing affordable and high-quality care to masses can happen through focusing on research and innovation. Just like the impetus given to 'Make in India,' there is rising focus on 'Innovate in India,' which could enable India to become a desirable destination for R&D in the medical device domain. The vision can be accomplished by developing a strategy and subsequently a roadmap for enhancing the India's innovation quotient. We could expect the government to focus on implementing policies that provide financial incentives to manufacturers, incentivising private players for investments in R&D, and adoption of advanced technologies to develop high-end medical devices. Greater focus needs to be on developing collaborations between manufacturers, hospitals and academic institutes. Also, promoting growth of start-ups will fuel the innovation engine, which needs to be sustained by a skilled workforce.

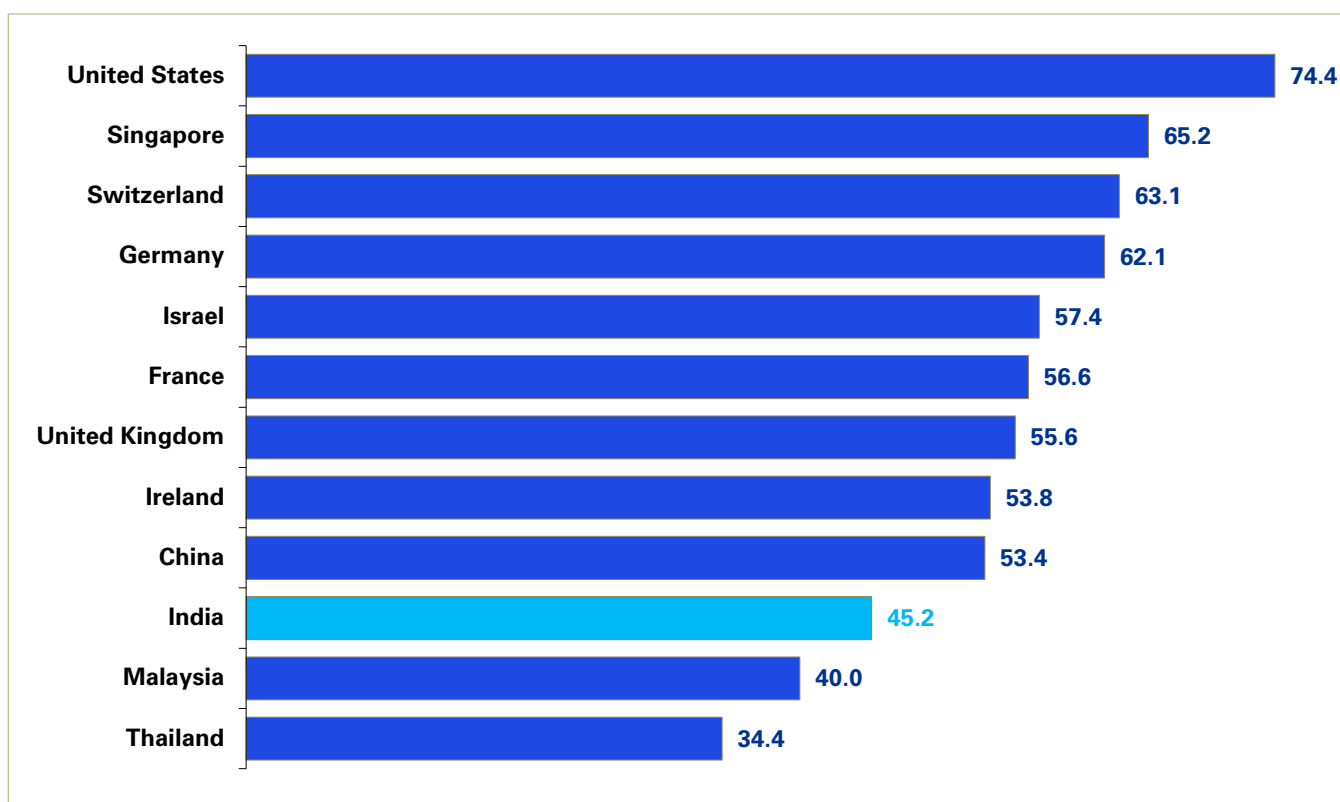
Medical device Innovation Index – India compared to global nations

The Indian medical device sector lags its global counterparts when it comes to ground-breaking innovation. India was ranked 40th on the global innovation index in 2022. The index measures countries in terms of political environment, education, infrastructure and knowledge creation of each economy. However, in the same index, it was first amongst the 36 lower-middle-income group economies and among the top 10 economies in Central and Southern Asia⁶². This highlights the potential that India holds and reaffirms its larger

aspirations. The index highlights areas where India lags which include high capital investment, new technology adoption, upskilling of professionals, a conducive ecosystem and innovation cycle⁶³.

To understand the state of innovation in the medical device sector, we conducted a comparative analysis of 12 countries (figure 4) to develop a medical device innovation index. We identified a set of key themes and parameters to score the countries on a scale of 0 to 100. Basis the score, selected countries featuring in top 50 of the global innovation index were ranked. A detailed description of key parameters for each of the themes can be found in the appendix.

Figure 4: Medical device innovation index, KPMG Analysis



61. India's growing strides towards 10 trillion-dollar economy, Invest India, January 2023

62. Global Innovation Index, WIPO, July 2023

63. Equitable Access to Medical devices, Public Health Foundation of India (PHFI), March 2023

Based on our analysis, some of the key observations are:

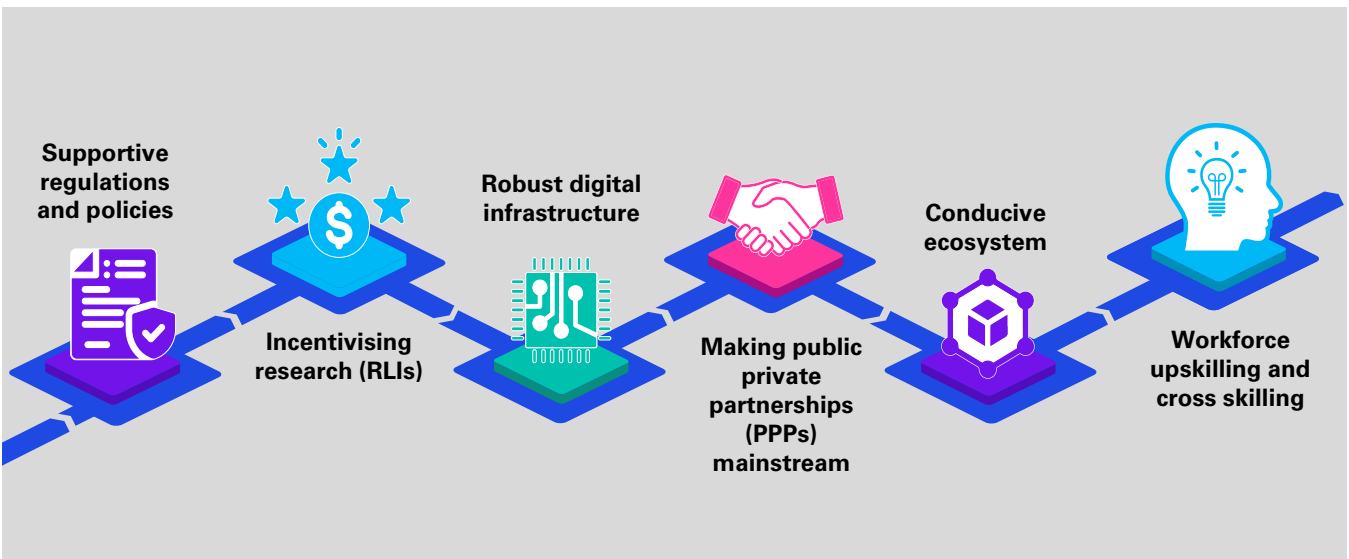
- The US leads medical device innovation index (74.4), followed by Singapore and Switzerland.
 - The high scores observed for the US medical device sector can be attributed to strong, demonstrated capabilities such as high number of medical equipment companies in the country, high export value of medical devices, large number of biomedical engineers, availability of investment capital and a strong government commitment to innovation.
- In the southeast Asian region, Singapore (65.2) ranks highest. India ranks 10th with an overall innovation score of 45.2 and is above countries such as Malaysia (40.0) and Thailand (34.4).
 - Higher score for Singapore can be attributed to parameters such as better health infrastructure, export of medical devices, PE/VC funding in the medical device sector, lower unemployment rate, and higher global innovation index score.

- India ranked higher in terms of the number of health-tech start-ups and bioengineering colleges. However, number of hospitals, medical device companies, researchers and patents are areas where India scored lower than other Asian countries.

Six themes that will drive India's innovation journey

India presents plentiful opportunities when it comes to innovation in life sciences, including the medical device sector. Private players, government agencies, care providers and other stakeholders are striving to find ways of enabling patient access to high-end medical devices at an affordable rate. Through our discussions with experts and research, we have identified six key themes which the stakeholders need to focus on (figure 5).

Figure 5: Key themes that will enable India to achieve its 'Innovate in India' vision



Supportive regulations and policies

Current state:

Medical devices in India have been classified as drugs and regulated under the Drugs and Cosmetics Act (DCA), 1940. While there are certain similarities that both deliver patient outcomes, the requirements for both are quite different and hence they need to be addressed separately. The government is drafting a new regulation which aims to address issues in the current legislation. The new draft bill called 'The Drugs, Medical Devices & Cosmetics Bill 2022' will be a collective legislation addressing pharmaceutical and cosmetic products along with medical devices.

The IP filing process can be further streamlined which should help reduce costs associated with obtaining and maintaining IP. Also, there is scope to improve awareness about patent filing processes which could encourage manufacturers to file IPs and further drive innovation. The interpretation of medical device patent laws is still at nascent stages in India which is a concern with respect to patentability of innovative devices. For instance, Section 3(i) of the Patents Act provides exclusion from patentability of certain devices that may get interpreted as treatment procedures⁶⁴. The lack of concrete laws could fuel issues such as patent infringement and counterfeit devices in the country.

India should strive for:

- **Enabling effective medical device regulation:** The upcoming Drugs, Medical Devices & Cosmetics Bill 2022 should view medical devices independently of pharmaceutical products and

should have provisions that can cater to the nuances of the medical device sector.

- **Harmonisation of Indian quality standards with global standards:** It is imperative that India aligns with global norms and standards, to position itself as a reliable and innovative hub for medical devices. India should consider regulatory reliance and convergence with other regulators and available international standards. Efforts are required for achieving greater alignment with global standards and for periodically refreshing the standards. To this effect, the Union Health Ministry has issued a draft notification proposing the recognition of American Standard Test Method (ASTM) as an acceptable standard for medical devices in India⁶⁵. Under the Medical Equipment and Hospital Planning department, 620 Indian standards have been published that are harmonised with international standards⁶⁶.
- **Innovation friendly IP laws and processes:** Simplification and streamlining of IP processes will not just save time/efforts of innovators but will also help in reducing costs associated with maintaining IP.
- **Robust implementation:** A strong monitoring mechanism needs to be in place to ensure policies and initiatives announced are being implemented on time. The recent launch of a national policy on R&D and innovation has provision of setting up a task force which will review the implementation of policy.

India can further accelerate on Innovation deliberately by improving R&D spend, better infrastructure, and increased institutional partnerships and provide easier processes and avenues for innovation.

Srinivas Peddi

Site Director, Becton Dickinson Technology Campus India

64. IP protection for medical devices in India increases, IP Stars, July 2019

65. Medical device industry in India, Nishith Desai Associates, April 2023

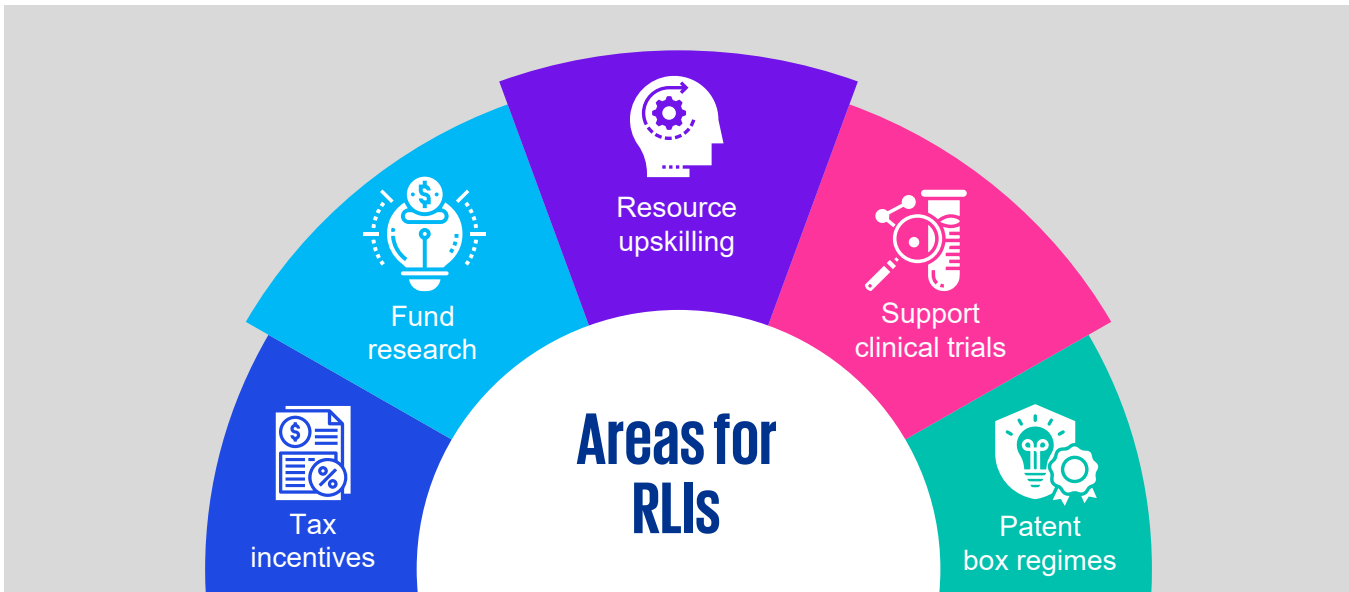
66. 146th report on action taken by government on the recommendations contained in the 138th report on the medical devices: regulation and control, Parliament of India, August 2023

Research-linked incentives (RLIs)

The government has launched the PRIP scheme which is focused on incentivising R&D across the medical device sector. Policymakers are taking steps to ensure RLIs are structured to promote innovation in the medical device sector along with the pharma sector – for companies working in pre-defined moon-shot or priority areas. Adoption of a RLI structure that is progressive and suit the Indian medical device ecosystem would go a long way to drive innovation. A few options for RLIs could be:

- Based on R&D expenditure.
- A different rate of maximum tax credit for large enterprises and SMEs.
- Companies without a corporation tax liability, to claim cash incentives especially for SMEs and start-ups.
- Innovative financial instruments such as returnable grant-in-aid from CSR or philanthropy to encourage innovators.

Some of the key areas that can be incentivised to promote research are highlighted below:



a. Tax incentives to promote innovation

- Out of the total 38 OECD countries, 34 countries (till 2021) provide some form tax incentives for innovation. Germany allows companies to get a tax credit based on R&D workforce expenditures⁶⁷. Of the total wages and salaries paid by companies to its research staff, 25 per cent is credited against the annual tax liability and any surplus amount is reimbursed.
- In the UK, tax credit is given to companies against the qualifying R&D expenditure, which includes costs associated with the workforce, software and consumables, and contracting/sub-contracting functions. The qualifying R&D expenditure for large companies (annual turnover above EUR50 million) is capped at 20 per cent while for small companies (annual turnover less than EUR50 million) it is 86 per cent⁶⁸. The provision of two different credit rates makes it suitable for both large and small companies. Taking inspiration from the UK, the RLI scheme in India can also be structured to suit large companies and SMEs.

b. Grants for undertaking research

- In the US, FDA's Centre for Devices and Radiological Health (CDRH) provides grants for small and upcoming medical device innovators under the national Small Business Innovation Research (SBIR) programme. The CDRH conducts innovation challenges in select areas of interests. In 2018, CDRH launched a challenge focused on medical devices for preventing and treating 'opioid use disorder'. The challenge was made open to both small and large companies and the selected applicants are working directly with the FDA for development of the device and expediting the review process⁶⁹.
- China launched three distinct incentive schemes for addressing various stages of prototyping and sample development of Class II and above medical devices (includes moderate and high-risk devices)⁷⁰.

67. Updates: R&D tax incentive - support for research and development, BDO Germany, October 2021

68. Research and Development (R&D) Tax reliefs – Reform, Government of UK, November 2022

69. CDRH Innovation, FDA, June 2023

70. Medical Device Classification Rules in China, Cris group, November 2019

c. Grants for workforce training and jobs created

In the US, the North Carolina government provides different types of performance-based incentives and funds to companies situated at the Research Triangle Park (RTP) to train resources. Some incentives and grants available to companies are⁷¹:

- **Job Development Investment Grant (JDIG):** Through JDIG, the government provides cash grants to new and expanding companies for reducing the cost of relocating or expanding in the state. Value of the grant is proportionate to the personal income tax withholdings associated with the new jobs.
- **Workforce grants:** Companies can use this grant for availing and reducing cost of on-the-job trainings that will aid in upskilling of employees in line with industry needs.

d. Funds and grants for clinical trials

- Australia has a government organisation to support a USD13.2 million (AUD19.8 million) programme called 'Clinical Translation and Commercialisation Medtech' (CTCM) for supporting the initial stages of clinical trials for selected innovative medical devices⁷². Such provisions can be crucial for supporting innovation initiatives of SMEs and start-ups in the country.

e. Patent box regimes

- Patent box regimes provide a preferential taxation rate for the income generated through patents and other IP.
- Switzerland provides tax relief of up to 90 per cent of patent income.
- Current Indian patent box regime allows taxation of income derived from patents at a rate of 10 per cent as opposed to the statutory corporate income tax rate.
- However, the current regime only applies to patents and does not include other types of IP.
- Given that software copyright will be an important element of medical device innovation, the inclusion of software copyright in the patent box regime will make it more beneficial for the sector⁷³.

Robust digital infrastructure

Current state:

- Ayushman Bharat Digital Mission (ABDM) has paved the way for creation of a digital health ecosystem.

- However, the issue of patient data security and privacy needs to be addressed, given the increasing threat of cyber-attacks.
- The introduction of Digital Information Security in Healthcare Act (DISHA) is a step in the right direction however, implementation and its effectiveness in real-world settings needs to be focused upon.
- Digital Personal Data Protection Act 2023 (DPDP) will foster accountable digital technologies.
- In terms of digital infrastructure, adoption of electronic health records (EHRs) is a key area and interoperability remains a major obstacle for promoting research efforts.
- Higher adoption of initiatives such as DigiLocker and Ayushman Bharat Health Account (ABHA) is required to ensure interoperability^{74,75}.
- Government agencies are working on development of common technical standards and protocols – initiatives from private and public sector hospitals as well as medical associations would ensure interoperable medical data which is ready for research^{76,77}.

India should strive for:

- **Adoption of DISHA and data privacy laws:** India must adopt a flexible approach for incorporating changes into DISHA and other data privacy laws, enabling the use of data for innovation without compromising on the safety of sensitive data.
- **AI and new-age technology:** Adaptation to advancements in digital health technologies, such as AI-driven diagnostics, telemedicine, and wearable devices and align with global developments and standards is imperative to chart an early path for the growth of the industry. The EU has proposed the AI Act for regulating AI technologies and ensuring conducive conditions for the development of AI-powered solutions⁷⁸.
- **Funds to enhance digital infrastructure:** India must ensure that the necessary funds are allocated for the maintenance of existing digital stack and expansion of digital capabilities. As highlighted by NMDP, investment in technologies such as 5G and Internet of Medical Things (IoMT) will be key in expanding the horizon of innovation in the country.

Note: Values have been converted from AUD to USD at the currency exchange rate as on 18 July 2023 (USD1 = AUD1.46), Qanda

71. Incentives & Grants, Research triangle regional partnership, August 2023

72. Clinical Translation and Commercialisation Medtech Program, MTPConnect, September 2023

73. Innovation tax incentives in Pharma, BioTech & MedTech, KPMG, May 2022

74. PIB, Government of India, November 2022

75. Adoption of electronic health records: Paths and pitfalls, Hindustan times, May 2023

76. Digital health adoption in India: Opportunities and challenges, Times of India, July 2023

77. National health digital mission, National Health Authority, July 2020

78. EU AI Act: first regulation on artificial intelligence, European Union, June 2023

Making PPPs mainstream

Current state:

- In India, PPPs are largely focused on collaborations between private sector healthcare providers, pharmaceutical companies and public sector academic/research institutions. Partnerships with private medical device players are limited except for a few instances as highlighted earlier. Additionally, collaborations between healthcare providers and medical device manufacturers are far lesser.

India should strive for:

- **Leverage PPPs:** Medical device manufacturers need to leverage PPPs frequently to drive innovation. They can leverage partnerships and drive synergies in areas where they lack expertise. In 2021, the Innovative Health Initiative (IHI), a PPP between the European Commission and private consortia including MedTech Europe, came into effect for supporting cross-sectoral innovation across medical technology, digital health and biotechnology. PPPs could drive innovation in tough financial environments where cost pressures are severe.

- **Dialogue amongst stakeholders:** The government needs to facilitate dialogue and promote partnerships between public sector academia, healthcare providers and private sector medical device players. For instance, in the US, the FDA's Centre for Devices and Radiological Health (CDRH) executed a memorandum of understanding with Medical Alley Association, a consortium of private companies to establish research collaborations in regulatory science⁷⁹.
- **Role of private organisations:** A recent successful example of innovation focused PPPs was seen in the pharmaceutical sector when Bharat Biotech and ICMR collaborated for developing Covaxin. Medical device companies can take a cue from this and focus on partnerships aimed to serve the domestic market⁸⁰.

In addition to Industry-hospital partnership, we need to have strong Industry-academia-hospital-government partnerships.

Divya P Joshi

Vice President & Site Leader, Medtronic Engineering & Innovation Center

79. Building research collaborations in regulatory science, MIDC, September 2023

80. Phase 3 Clinical Trial of COVAXIN, developed by ICMR & Bharat Biotech, shows 81% Efficacy, ICMR, March 2021

How Switzerland promoted R&D

Snapshot of the Switzerland medical device sector

1st



Global innovation index

8.87



Health infrastructure score (0-10)

1622



Number of medtech companies

USD24.2 billion

Medical technology industry revenue as of 2021



Key initiatives undertaken to foster innovation in the sector

Tax incentives

- Medical device companies can avail R&D tax credit of up to 50 per cent of company's taxable income for expenses pertaining to staff directly involved in R&D.
- Innovation activities such as design and development of autonomous diagnostic devices and new production processes for existing medical device products are eligible for the additional tax credit. It includes incentives to produce higher yield.
- Further, companies can also avail patent box schemes as part of this. Patent-related income used for tax calculation can be reduced by up to 90 per cent for Swiss, European & foreign patents.

Role of academia

- Premier academic and medical institutions undertake intensive R&D in the field of medical devices and technology.
- Notably, these institutes invest a significant proportion of their research budget across the entire spectrum of medical technology.

Conducive ecosystem

- Start-ups and newly established foreign enterprises are eligible to receive partial or full tax exemptions in certain cases and capital taxes for up to 10 years.
- Further, innovators collaborating with a Swiss institute, can avail funds for up to 50 per cent of the project from government authorities.
- The Sitem StartUp Club (SSC) offers an acceleration programme for early-stage medical technology start-ups.
- The programme offers a wide range of support including regulatory consultation, financing and networking for the start-ups located in Bern.

Regulatory support

- The government has recently passed a motion to allow US FDA approved medical devices to be marketed in Switzerland.
- The move will allow patients and physicians early access to innovative solutions that are yet to be approved in Switzerland or EU.
- The government has identified specific regions with skillsets that can promote innovation in medical device sector. One such example is the Jura region. The region known for manufacturing high quality and innovative watches, is passing on the same to medical devices. The region is home to thriving ecosystem of start-ups that provides opportunities to innovate.

Note: Values have been converted from CHF to USD at the currency exchange rate as on 18 July 2023 (USD1 = CHF0.86), Oanda

81. Switzerland as a medical technology hub, Switzerland Global Enterprise, November 2020

82. The MedTech Booster Program, Sitem StartUp Club, September 2023

83. Switzerland: US FDA's Medtech Can Bridge Innovation Gap Left By MDR, Medtech Insight, March 2023

84. Swiss medtech – bringing together traditional skills and high-tech industry, Medtech Innovation, August 2023

85. World talent ranking 2022, IMD, December 2022

86. Swiss medical technology industry sector study 2022, Swiss medtech, September 2022

87. KPMG analysis of Factiva data as of July 26, 2023

Conducive ecosystem

Current state:

India can develop a supporting ecosystem to drive innovation in medical devices. A few aspects that need emphasis include:

- R&D focused interaction and collaboration between stakeholders.
- mentorship and early-stage funding
- support of Indian academia and research institutions for small and large players
- clinical research organisations (CROs) for medical device trials

India should strive for:

- **Greater synergy among stakeholders:** Facilitating dialogue between hospitals, manufacturers, and start-ups could be imperative for growth in medical devices. In countries such as Singapore, focused innovation groups such as Health Technologies Consortium, plays a key role in increasing dialogue and exchange of ideas across stakeholders.
- **Industry-academia partnerships to bolster start-ups:** The success of a country's start-up ecosystem is reflected by the entry of homegrown start-ups in international markets. With an increasing focus on industry-academia partnerships in India, as highlighted in Budget 2023 and the NMDP, the next step for India would be to position academic and research institutions as the base to launch start-ups. Manufacturers need to collaborate with academic institutes to develop and nurture start-up ecosystem that is recognised globally.

- **Develop a strong infrastructure:** Government can take a structured approach when it comes to promoting infrastructure including medical device parks. With upcoming medical device parks in multiple states as highlighted in section 2, channelising resources of one medical device park in a specific area of medical technology will reduce the competition for investments. Also, it will strengthen and diversify India's capabilities across the overall medical device value chain.
- **Transparency and trust with customers:** To build trust with the consumers, manufacturers can emphasise on clinical evidence generated using medical device and increase user adoption by publishing the results in industry journals.
- **Funding support:** Given the pressure of shorter shelf life for innovative products, investors need to explore innovative funding models (risk-sharing). Start-ups could be provided with financing options to ensure early-stage funding. Investors could further help manufacturers access global markets and showcase capabilities to global investors, promote peer to peer learning, and leverage Indian family run businesses to fuel the innovation engine.
- **Support from hospitals and physicians:** Hospitals and physicians, can drive innovation by working closely with innovators for identifying patient needs, evaluating solutions, and providing design inputs. They can focus on adoption of digital tools to help innovators seamlessly integrate their offerings and create an interoperable ecosystem. Hospitals and diagnostic labs can offer testbeds to help validate innovative products which will help address patient needs in real-world settings.

At Medtronic, we view innovation as both a significant opportunity and a responsibility. It is core to multiple areas, from developing new technologies to improving existing products, devising newer ways of healthcare delivery & training and education of healthcare professionals on use of innovative technologies in patient care, thus making healthcare systems more efficient and more sustainable in the process.

Michael Blackwell

Vice President and Managing Director, Medtronic India

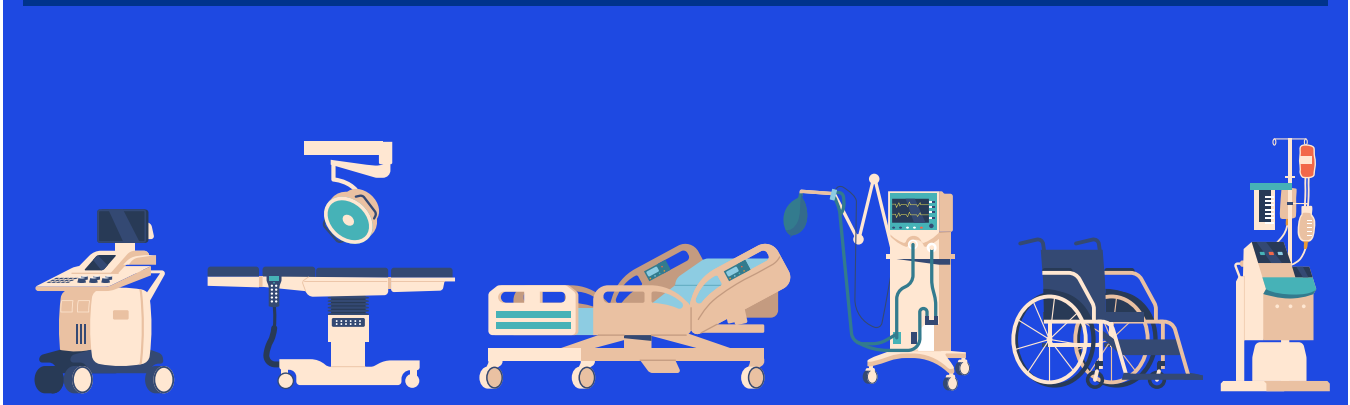
Israel is known as the hotbed of cutting-edge technology, boasting a thriving investment landscape and research institutions that foster the development of innovative medical technologies. This favourable environment has contributed to the country's growing medical device industry, which continues to reach new heights.

Government support for encouraging early-stage start-ups:

- The **'Yozma program'** is a venture capital fund established by the Israeli government in the early 1990s to support start-ups. It raised USD100 million in 1993 and USD250 million in 1996, attracting over 30 foreign venture capital firms to Israel. The programme provided 40 per cent of its capital to foreign investors, leveraging government funding and private sector expertise to support innovative companies.
- Israel's **'Seed Incentive Program'** is a programme run by a government body that encourages investments in early-stage start-ups and supports the growth of the country's entrepreneurial ecosystem. The programme provides grants covering up to 50 per cent of investment made in qualifying start-ups, with a maximum grant amount of USD1.5 million per project. It also offers tax benefits to investors, allowing them to deduct their investments from their taxable income. By offering such incentives, the programme aims to increase the availability of seed funding for start-ups, promote innovation, and create jobs. Offering grants or tax incentives to investors can encourage more investment in Indian start-ups, especially in the seed stage when they need it most, leading to increased innovation, job creation, and economic growth. Such a programme can also attract foreign investors, bringing in new expertise and resources.

Risk-sharing by fostering collaboration between MNCs and Israeli companies:

- The government's R&D Collaboration with Multinational Corporations (MNC) Program offers a unique opportunity for Israeli start-ups to collaborate with leading MNCs. Participating MNCs include Abbott, B. Braun, BD, Boston Scientific Corporation, Siemens, and others. This programme facilitates joint research and development projects, allowing start-ups and MNCs to share the risks and benefits of R&D investments. The government and Israel-based companies provide financing, while MNCs may invest in the project or offer resources and expertise, such as regulatory advice. IP rights can be arranged in three ways: sole ownership by the Israel-based company, non-exclusive licensing to the MNC while the Israel-based company owns the IP, or joint ownership between the two parties. This would require the government to play a proactive role in facilitating collaborations, providing funding and infrastructure support, as well as investments in education, and research that encourage innovation and risk-taking.



88. Israel: a medtech innovation hub for the world, Medical Device Network, June 2019
 89. Israel Innovation Authority: A More Mature Start-up Nation, Haaretz Labels, April 2023
 90. The government venture capital fund that boosted Israel's start-up economy, apolitical, June 2017

91. Seed Incentive Program, Israel Innovation Authority, September 2023
 92. R&D Collaboration with Multinational Corporations Program (MNC), Israel Innovation Authority, September 2023
 93. MNC, Israel Innovation Authority, September 2023

Workforce upskilling and cross skilling

Current state:

Workforce upskilling is a key requirement for the medical device sector to promote innovation and develop high-end devices. Currently, the workforce is trained to manufacture low-end medical devices and consumables.

India should strive for:

- **Industry academia collaboration:** One of the ways to upskill the workforce is to leverage collaborations between academia, hospitals, and manufacturers. For instance, in Australia, collaboration between Johnson and Johnson (J&J), start-up company Fusetec, and a leading south Australia university has led to effective trainings of surgeons. It has resulted in the development of 3D
- **Industry relevant training:** With the advent of technologies, organisations need to train their workforce on assembling high-end devices, learn about R&D, product life cycle management, and manufacturing while on the job. In a nutshell, employee's need to develop varied skills to add value in the innovation life cycle.
- **Conducive working environment:** Manufacturers need to ensure they build a conducive environment for the employees to grow and learn. This will help retain employees and build their skillset when they work for an organisation over a period. It also helps chart a dedicated career pathway for professionals.

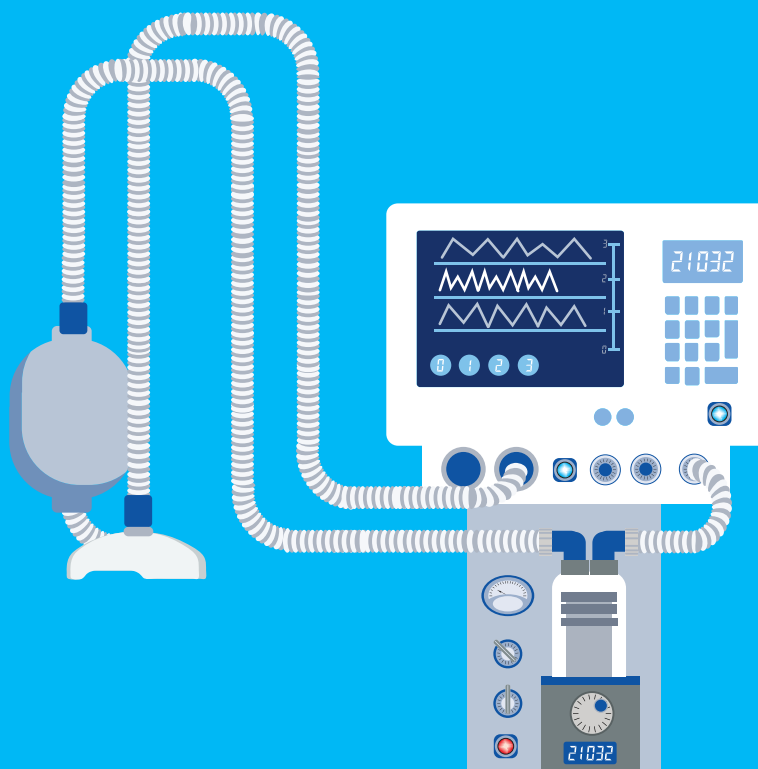
surgical training models for orthopaedic surgeries, preparing individuals to use advanced devices⁹⁴.

India's medical device sector has the potential to become a global powerhouse of manufacturing and innovation in the coming decades. Industry stakeholders need to ensure they contribute towards creating a sustainable ecosystem of innovation. This will require creation of a job-ready workforce and supportive regulations to improve ease of doing business and promote innovation in India.

Nikhil Patil

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94. The value of Medtech report, MTAA, June 2023



Best practices from global markets

India can adopt best practices from other countries to accelerate and promote innovation in the medical device sector.

Table 3: Global best practices

Theme	Developed markets	Emerging markets
Supportive regulations and policies	<ul style="list-style-type: none"> A leading government agency in Singapore provides consultation services and regulatory review during a medical device's development or pre-submission phase to accelerate the review process⁹⁵. 	<ul style="list-style-type: none"> The Thailand regulatory body laid down new measures to improve the medical device registration programme, which entails a third-party review system. It also allows resubmission of rejected applications and organising training courses to certify the competency of medical device registration applicants⁹⁶.
Research-linked incentives (RLIs)	<ul style="list-style-type: none"> The Australian government provides financial support to companies by covering cost of clinical trials. Support is provided to innovation-focused SMEs and start-ups in bringing products to market⁹⁷. Zentrales Innovationsprogramm Mittelstand or The Central Innovation Programme (ZIM) is a national-wide funding programme for supporting innovative solutions by SMEs in Germany⁹⁹. 	<ul style="list-style-type: none"> Government of Thailand offers eight years corporate income tax exemption (CIT) for projects involving R&D and innovation to manufacturers of high-risk or high-technology medical devices (such as CT scan machine and implants) or for medical devices commercialised from collaborative public-private sector or public sector research⁹⁸. China has implemented three schemes to provide funding for manufacturers. The first scheme provides incentives worth USD41,842 (RMB300,000) for laboratory stage development of medical device prototypes. Under the second scheme, medical device companies can avail a maximum subsidy of USD83,684 (RMB600,000) per project for developing the engineering prototype of Class II and above medical devices. The third scheme provides funding worth USD139,474 (RMB1 million) to medical device companies for clinical evaluation of devices¹⁰⁰.
Robust digital infrastructure	<ul style="list-style-type: none"> The EU General Data Protection Regulation (GDPR) has concrete laws pertaining to data security that are applicable across the globe¹⁰¹. 	<ul style="list-style-type: none"> China has developed public service platforms to improve its research capabilities in advanced medical equipment by providing technical support and industrial services. Industrialisation of advanced medical equipment and utilisation of big data services platforms have been actively supported¹⁰².

95. Consultation schemes, Health Science Authority, August 2022

96. Thai FDA improves medical device application process, Asia Actual, July 2023

97. Insight – Australia: A go-to destination for clinical trials, Austrade, May 2022

98. Medical device industry in Thailand, Thailand Board of Investment, September 2023

99. ZIM: Central Innovation Programme for SMEs, Vdivde-it, September 2023

100. Shanghai's New Incentive Policies on the Promotion of Biotech and Pharmaceutical Industry, Dentons, June 2023

101. What is GDPR, the EU's new data protection law?, GDPR.eu, November 2018

102. Key Risks and Development Strategies for China's High-End Medical Equipment Innovations, NIH, July 2021

Theme	Developed markets	Emerging markets
<p>Making PPPs mainstream</p>	<ul style="list-style-type: none"> A consortium in Singapore has developed a platform to collaborate and interact between industry and academic institutions for the development and translation of disruptive technological innovations in the health and wellness space. It focuses on software technologies, health and wellness, and hardware technologies (including therapeutic devices, diagnostic and imaging medical technologies, AR, VR, and MR along with others)¹⁰³. The US FDA CDRH has formed a partnership with a consortium of private companies for advancing regulatory science at an industry level¹⁰⁵. 	<ul style="list-style-type: none"> In Malaysia, a industrial research and technology organisation under the purview of the Ministry of Investment, Trade and Industry has established the Medical Device Innovation Centre (MDIC). MDIC aims to facilitate collaboration with partners including medical device manufacturers, the ministry and government agencies, global innovation centres and research institutes¹⁰⁴. The National Innovation Centre for Advanced Medical devices (NMED) in Shenzhen, Guangdong Province, is China’s first national innovation centre for medical equipment. NMED provides an open global platform for innovation, business and industrial integration, by effectively combining innovative resources from leading enterprises, research institutions and industry associations¹⁰⁶.
<p>Conducive ecosystem</p>	<ul style="list-style-type: none"> In Singapore, medical technology initiatives such as The Technology for Enterprise Capability Upgrading (T-UP) programme provides up to 70 per cent support for eligible costs to SMEs and start-ups, or 30 per cent support for large companies capped at USD250,000 per project. It also supports research projects outside the country, engages scientists and research engineers, and collaborates with R&D institutions for effective technology transfer¹⁰⁷. 	<ul style="list-style-type: none"> Thailand’s Eastern Economic Corridor (EEC) supports innovation areas for medical devices industry. Salaya start-up town is a leading innovation facility of EEC. The facility features ‘Maker Space’ - a Medical Robot Centre with an ecosystem for a healthcare platform that focuses on the use of AI technology for health examination tools and equipments such as surgical robotics and brainwave technologies^{108,109}.

103. SingHealth and A*STAR establish S\$8 million partnership to co-develop healthcare innovations, BioSpectrum, April 2023

104. Advancement of Medical Devices Industry, SIRIM, August 2023

105. Partnerships to Advance Innovation and Regulatory Science (PAIRS), FDA, July 2021

106. Innovation fires up medical devices, China Daily, January 2021

107. Technology for Enterprise Capability Upgrading (T-Up), Enterprise Singapore, August 2023

108. Innovation space for the medical device industry in Thailand, Swasdee Thailand, January 2023

109. Medical device industry in Thailand, Thailand board of investments, August 2023

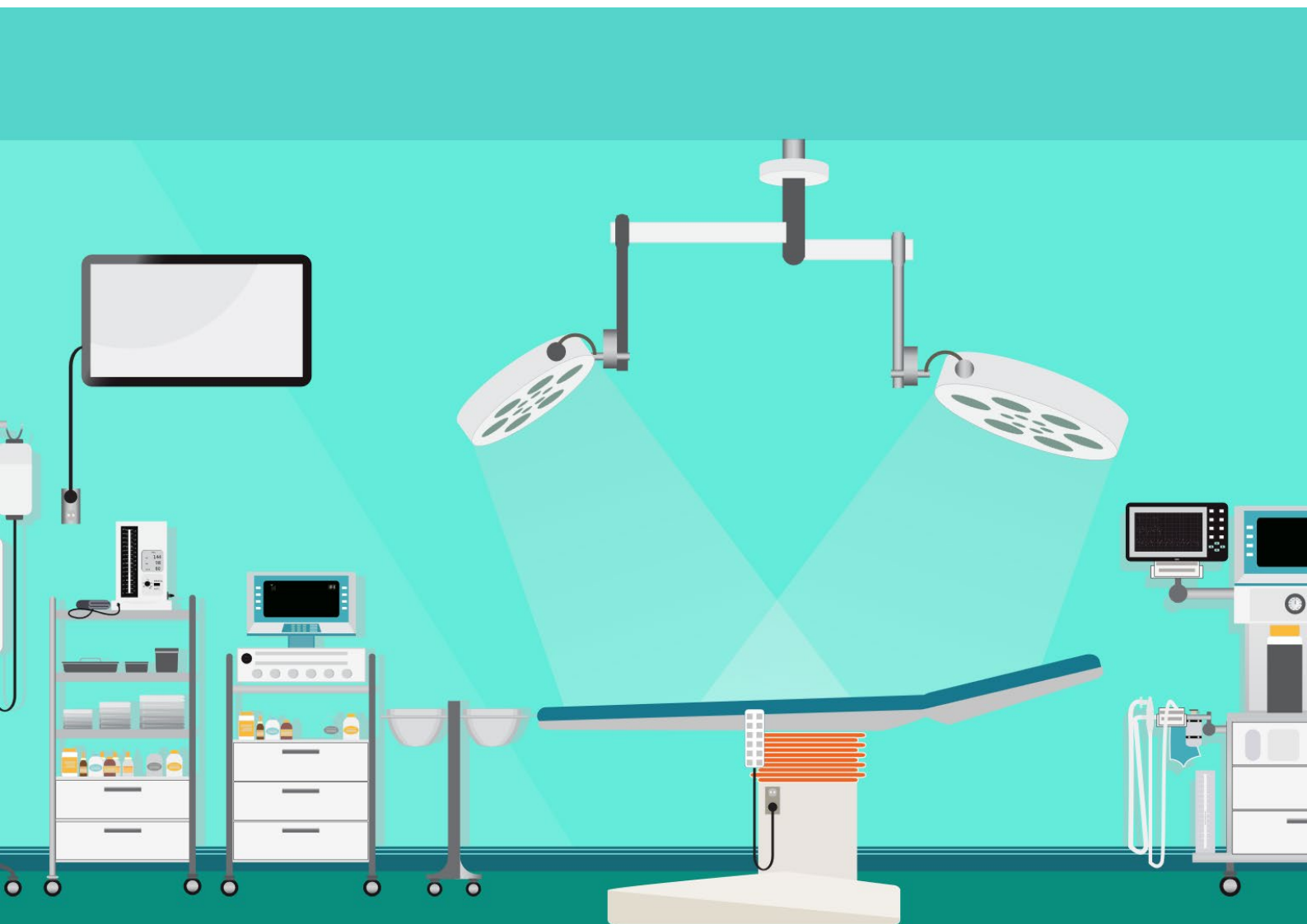


Theme	Developed markets	Emerging markets
Workforce upskilling and cross skilling	<ul style="list-style-type: none"> A government agency in Singapore through its Biomedical Engineering programme (BEP) collaborates with the Centre for Integration of Medicine and Innovative Technology in Boston, Massachusetts for training engineers and clinicians to collaborate in scaling cost-effective innovative medical products through research projects¹¹⁰. A research institute in Singapore provides training courses in medtech manufacturing including new product development and apply design thinking for product innovation¹¹². 	<ul style="list-style-type: none"> Thailand has established Thailand Plus Package, an initiative to catalyse investment in high-tech sectors. The package includes incentives for medical device enterprises involved in human resource development and building a skilled workforce. For instance, a 250 per cent tax deduction is offered for certified training courses, while 150 per cent tax deduction is given for hiring employees with advanced STEM knowledge¹¹¹.

110. Boosting the Indian Medical Devices Industry, Department of Pharmaceuticals, July 2023

111. STEMPlus: Workforce development platform for industry advancement, Office of National Higher Education Science Research and Innovation Policy Council (NXPO), August 2023

112. Modular Programmes, Singapore Institute of Manufacturing Technology (SIMTech), September 2023



Appendix

Our research

KPMG in India interviewed medical device sector experts from large MNCs and SMEs in August and September 2023. This was supplemented with secondary research and qualitative analysis of the PitchBook data to identify trends and draw out inferences.

Global medical device innovation index (methodology)

For conducting the global medical device innovation index analyses, five themes including – infrastructure, workforce and talent, macroeconomic data, regulatory and policy landscape, and market and investment landscape were identified. Each theme had key performance indicators (KPIs), against which the countries were scored. The data, qualitative and quantitative, for KPIs was sourced through secondary research. Subsequently, each of the themes and KPIs were assigned weightage based on criticality. Next, rating was assigned on a scale of 1–5, with 5 being the best. The scores were then consolidated for each theme basis the weightage. The sum of weighted scores for all the themes was capped at 100. Finally, each country was ranked basis the score out of 100. Please note, countries selected for the comparison was based on secondary research and discussions with industry experts. It was ensured that the data used for assessment of the country was most recent or on best availability basis and properly disclosed. The evaluation of the data for the selected countries was conducted to understand the significance of the data and score accordingly.

Approach

- The countries which are included in the assessment are India, China, Singapore, Malaysia, Thailand, Israel, France, Germany, the UK, Switzerland, Ireland, and the US.
- The KPIs considered for the evaluation under each theme are as follows:

- Infrastructure: Health infrastructure, hospital beds/1000 people, medical equipment company, 3D printing start-ups, healthtech start-ups, number of universities in QS world ranking, QS world university rankings by subject: Engineering & Technology, and number of universities having biomedical engineering.
- Workforce and talent: Biomedical engineers, researchers, FTE per million population, brain drain, graduates in science and engineering, unemployment rate, and digital or technological skills.
- Macroeconomic data: Import value of medical devices, export value of medical devices, expenditure on education as per cent of GDP, gross expenditure on R&D as per cent of GDP, and global innovation index.
- Regulatory and policy landscape: Patent publications in medical technology, patent grants in medical technology, intellectual property protection index, governments support to promote innovation in medtech sector, tax incentives for the creation of IP assets, and intellectual property rights.
- Market and investment landscape: Foreign direct investment, as per cent of GDP, PE/VC funding (Y-o-Y growth, six years), market size of medical devices, country credit rating, and venture capital.

Assumptions

- Innovation index assessment study provides an overview of the perceived differences between countries assessed. Please note that the rating or ranking of the assessed locations cannot be compared with any locations that were not included in this study.
- The tool will give a relative ranking based on the parameters selected and data used for analysis. However, the result needs to be considered with a range of other qualitative factors to determine the most appropriate answer for a particular situation.

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About Asia Pacific Medical Technology Association (APACMed)

Founded in 2014 and headquartered in Singapore, APACMed represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific.

Providing a unified voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of medical technology and promote regulatory harmonization. We strive to promote digital health innovation and impact policy that advances healthcare access for patients by engaging with medical device associations and companies in Asia Pacific.

APACMed is also host to the annual Asia Pacific MedTech Forum.

www.apacmed.org



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