RISK MANAGEMENT OF INVESTMENT IN MEDICAL DEVICE SECTOR

Study conducted by Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

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1. INTRODUCTION

1.1. Overview of Medical Device Sector in India

The medical device sector in India is on a robust growth trajectory, fuelled by increasing healthcare demands, technological advancements, and strong government support. As per the latest report of Indian Brand Equity Foundation (IBEF)of May, 2025, the Indian medical device market was estimated to be valued at approximately $12 billion in FY of 2024. Projections indicate that the India medical device industry is growing at a robust rate of 15% compound annual growth rate (CAGR) over the past three years and is projected to reach $ 50 billion by FY 2030.

The market encompasses a diverse range of products, including diagnostic equipment, surgical instruments, orthopaedic devices, and wearable technologies. This diversity not only showcases the sector's breadth but also highlights its critical role in addressing various healthcare needs across the country. With a burgeoning market and a favourable investment climate, the sector presents significant opportunities for both domestic and international stakeholders. The combination of a growing population, rising health awareness, and supportive government policies positions India as a key player in the global medical device market. By capitalizing on these trends and fostering a culture of innovation, India can establish itself as a leader in medical technology and contribute significantly to global health outcomes. As we look to the future, the ongoing evolution of this sector will undoubtedly bring about transformative changes in healthcare delivery and patient outcomes.

Some of the emerging trends which have been fueling the Indian Medical Device Industry are:

- **Increased Demand for Advanced Technologies**

One of the most significant trends shaping the medical device landscape is the rising demand for advanced technologies. The emergence of telemedicine, remote monitoring solutions, and sophisticated diagnostic tools has significantly accelerated the need for innovative medical devices. The COVID-19 pandemic has further catalysed this shift, as healthcare providers and patients increasingly turn to virtual solutions for consultations and monitoring. Wearable health technologies, such as fitness trackers and smartwatches, along with point-of-care diagnostic devices, are gaining popularity due to their convenience and ability to empower patients with real-time health data. This trend is driven by changing consumer preferences, heightened health awareness, and a desire for more personalized healthcare solutions.

- **Growing Aging Population**

India's demographic landscape is shifting, with a substantial portion of the population aging. This demographic shift is accompanied by an increase in chronic diseases, such as diabetes, cardiovascular conditions, and respiratory ailments. As a result, there is a heightened need for advanced medical devices that can aid in the management and treatment of these conditions. Devices that offer continuous monitoring, such as glucose meters and heart rate monitors, are becoming increasingly vital

for patients and healthcare providers alike. This growing need presents significant opportunities for companies that focus on developing innovative solutions tailored to the unique requirements of an aging population.

- **Shift Towards Preventive Healthcare**

There is a noticeable shift in focus towards preventive healthcare in India, driven by increasing health awareness and government initiatives aimed at promoting early disease detection. This shift is leading to a higher demand for diagnostic devices and health monitoring solutions. Technologies that facilitate early diagnosis, such as imaging devices and biomarker tests, are becoming crucial in the fight against diseases. Furthermore, public health campaigns that emphasize the importance of regular health check-ups and screenings are contributing to the rising adoption of these technologies.

- **Digital Health Integration**

The integration of digital health solutions into the medical device ecosystem is transforming the landscape in unprecedented ways. Mobile health applications, electronic health records (EHRs), and telehealth platforms are enhancing the patient experience by enabling better engagement, communication, and data management. These digital tools allow for more streamlined workflows, improved access to health information, and enhanced patient monitoring. The convergence of digital health and medical devices is fostering a more holistic approach to healthcare delivery, making it more efficient and patient-centred.

- **Investment Landscape**

The investment landscape for the medical device sector in India has become increasingly attractive to both domestic and international investors. As per a latest EY report of November, 2024, the medical device sector in India has attracted significant interest from Private Equity (PE) firms, who see the potential for growth and innovation in the market. The healthcare devices and supplies had already attracted over US$1.2 billion of PE and Venture capital (VC) investments till August 2024, highest in the last five years. This influx of capital is indicative of the sector's potential and the confidence investors have in its growth trajectory. As the industry continues to evolve, innovative financing models and strategic partnerships will play a critical role in shaping its future.

1.2 Study Objective, Definition and Assumptions

Study Objective: The objective of this assessment study was to identify the current investment landscape and the funding gaps in Medical Device Sector in India and explore interventions needed from Government side. It also aims to explore ways for creating an ecosystem for risk based/risk adjusted financing.

Study Definition: The assessment study titled "Risk Management for investment in Medical Device Sector" encompassed the following key components:

- To identify the current investment landscape in India and funding gaps for the Medical Device Sector.

- To identify the effective facilitation environment for risk-based / risk adjusted financing and new financing models, such as blended finance that will broaden the financing options available in the Medical Device Sector.
- To identify the risk adjusted measures, risk mitigation tools in both public and private sector, that can foster investment in the Medical Device Sector.
- To find out the factors that will promote seed capital and series of funding from venture capitalists in Medical Device Sector, helping the Startup to incubate.
- To submit case studies of successful financial models in Medical Device Sector in various countries.
- Suggest interventions needed from the Government side to encourage private investments and external resource funding in the Medical Device Sector.

Study Assumptions: The study assumed that the information available on various secondary data sources like reputed research reports, study and annual reports and websites of Department of Pharmaceutical, DPIIT, DGFT, Startup India, Medical Device Associations is accurate and reliable. The study also assumed that in spite of early success in medical device sector, there is a long way ahead for the medical device sector and Indian Government is willing to support the sector in all the possible ways. The study was carried out assuming that access to sufficient and relevant data related to current state of investments in medical device sector and best practices of investment risk management in medical device sector were available for analysis and the recommendations were made on the basis of analysis of the data which was realistic, feasible, and aligned with the capabilities and resources of Indian medical device ecosystem.

1.3 Base Estimate and Working Approach

Duration: The study was conducted over a period of 4 months.

Resources: The study required a team of researchers, analysts, and subject matter experts with expertise in the medical device industry, sector specific investments, market research and analysis. The team allocated by BHPL included experienced individuals in the above-mentioned areas along with skills in data analysis, research methodology, and report writing in Medical Device Sector.

Data Sources: Robust and comprehensive questionnaires were used for the primary data collection of pharmaceutical and research & development companies during the study. The Semi-Structured and In-Depth Interviews with medical device industry experts, manufacturers, investors, regulators, policymakers, and key stakeholders were conducted to gather qualitative insights and opinions during the onsite visits of institutions. Reputable and reliable sources of information relevant to the research objectives were identified and utilized in secondary data collection. Systematic literature review was conducted to gather relevant academic articles, research studies, case studies related to medical device sector investments and associated financial risk management.

These sources included were not limited to:

Industry reports: Reports published by market research firms, industry associations, or consulting agencies that provide insights on the Indian medical device industry, latest market trends, investment trends, research and development funding etc.

Government publications: Reports and publications from governmental bodies such as Department of Pharmaceutical, DST, DPIIT, Startup India, BIRAC, NIPERS Government funded medical device incubator to provide insights into government initiatives.

1.4 Data Triangulation, Insight Generation and Working Approach

Data Triangulation

The data was validated by cross-referencing the information obtained from different sources. The quantitative and qualitative data gathered from various sources, including primary and secondary sources was combined to enhance the robustness of the analysis. Data was checked for consistency and coherence in the findings across the sources and converging evidence for consistent overarching trends, themes and patterns in the data. As a result of this holistic understanding of the data, the key insights were derived from the triangulation process.

Insight Generation

The key findings were interpreted within the broader context of the risk management of investments in medical device sector, regulatory consideration, market dynamics and relevant socioeconomic factors to synthesize insights. The generated insights were validated by checking their alignment with the data, analysis, and research objectives. It was ensured that the generated insights were logical, supported by evidence, and consistent across different sources and methods used in the study.

Working Approach: The study employed a combination of quantitative and qualitative research methods, including, literature review, online questionnaires, stakeholder interviews and expert opinions. Before distributing the online questionnaires to the target respondents, a pilot test was conducted within the BHPL team and a small group of respondents to identify the potential issues with the survey design, question clarity and other technical problems. After the data collection was completed, the data was cleaned and analyzed to summarize the responses and examine key patterns and trends. Further the survey findings were interpreted in the context of the given research objectives and existing literature and industry reports to provide a comprehensive understanding of the project.

1.5 Target Respondents and Sample Size:

Purposive sampling was employed to ensure representation of key stakeholders during the primary data collection. The primary data of 23 Medical device Manufacturing companies,10 promoters, 2 medical device incubators and 3 venture capital investing firms were collected using the questionnaires and interviews. **Table 1** has the list of the medical device manufacturers who participated in the survey and provided the feedback related to their understanding of risk management of investments and expectations from the Government for improvement of sector.

Table 1

Participant Companies in Survey	Scope of Manufacturing of Participant companies
Prahas Healthcare LLP	Manufacturer of diagnostic test strips, biosensors, and biochips
Shah Eye Care Private Limited	Manufacturer of ophthalmic microsurgical knives
Apple Suture Invent	Surgical suture manufacturing company
Ostwal Rehabilitation Aid	Orthopaedic support and rehabilitation manufacturing
Huwel Lifesciences Pvt Ltd	Molecular diagnostic RT PCR Kits, NAT Devices
Leelawathy Medical Devices Company	Manufacturer and global supplier of 100% Silicone Foley Catheters
Panacea Medical Technologies Pvt Ltd	Manufactures medical equipment for radiotherapy and radiology centers
3B BlackBio Dx Limited	PCR based Molecular Diagnostic kits, PCR Enzymes & PCR Reagents
Amrad Medical Equipments	Manufacturers of High/Line frequency X-ray systems, LED X-Ray View Box, Lead Sheet, Lead Glass and Lead Protection Barrier
AKAS Medical Equipment	Manufacturer of infusions pump and high-quality pumps syringes
Transasia Bio-Medicals Ltd.	In-vitro Diagnostic Company and offers solutions and products in Biochemistry, Hematology, Coagulation, ESR, Immunology
Inbios India	Manufacturer and PCR Kits Suppliers
Health Cubed India Pvt Ltd	Designs and manufactures point-of-care diagnostic devices to enhance the quality of primary care in diverse settings
Premium Healthcare Disposables Pvt Ltd	Manufacturers and exporters of surgical products, surgical disposables, medicated products
CM Flowmeters (India) Pvt Ltd	Manufacturer, Supplier and Exporter of Medical Rotameter, Industrial Rotameter & Laboratory Rotameter
Surgeine Healthcare India Private Limited	Manufacturer of surgical gowns, drapes, and custom procedure packs
Orthotech India Pvt Ltd	Manufacturer of Orthopedics implants and instrument
Molbio Diagnostics Pvt Ltd	Manufacturers of Portable devices and kits in POCT settings
Datt Medi Products Pvt Ltd	Medical textile and advance wound care products
Ramja Genosensor Pvt Ltd	State-of-the-art technology for infection detection and AMR
Innovative Ortho Surgicals Pvt Ltd	Manufacturer of Orthopaedic Implants, maxillofacial and Instrument
Vero Group	Manufacturer and supplier of latex surgical gloves
AVI Healthcare Private Limited	Manufacturers of ICU Ventilators, Bubble CPAP units, HFNC units, Infant Warmers, Phototherapy units, Transport Incubators, etc.

2. EXECUTIVE SUMMARY

The medical device sector is experiencing significant growth, driven by factors such as an aging population, higher healthcare spending, and a growing demand for personalized care. This rapid expansion has led to the development of a wide range of technologies, including medical devices, implants, diagnostics, imaging software, and robotic surgery. These innovations are helping meet the changing needs of both healthcare providers and patients.

Venture capital (VC) and private equity (PE) investments are key drivers of success for MedTech companies, offering the financial support necessary for growth and adaptation. However, despite advancements, the industry faces challenges, such as inflation, higher interest rates, and a frozen IPO market, which have slowed VC and PE investments. As per a recent article by BW healthcare, in the year 2022, the value of VC deals dropped from $9.7 billion in 2021 to $8.7 billion, with some areas like nonsurgical medical treatments and surgical robotics still attracting significant funding. The Indian medical devices sector is seeing a surge in private equity (PE) investments, driven by promising opportunities and a rapidly expanding market. Since 2017, there have been about 59 PE transactions in this space, with deals increasing by three times compared to pre-COVID-19 levels.

Prominent transactions in the medical devices space include investments such as Warburg Pincus's $210 million investment in Meril Life Sciences, Samara Capital's $150 million funding in stent manufacturer SMT, and KKR's acquisition of Hema from Apax Funds, valued at over $800 million. Indian companies concentrated their deal activity on medical consumables and mid-range equipment. This includes single-use products like syringes and higher-end equipment, such as stents and ventilators, produced by a growing number of Indian manufacturers.

Investment risk is an inherent to any financial venture, where the potential for profit is often accompanied by the possibility of loss. In the realm of medical device investment, this risk can be particularly pronounced due to the industry's complexity, regulatory hurdles, and the high rate of failure among startups. However, seasoned investors understand that risk is not something to be avoided but managed. They rely on the effective risk management that involves carefully assessing opportunities, diversifying portfolios, and making informed decisions based on thorough research and due diligence.

The goal is not to eliminate risk entirely, but to understand it and implement strategies that maximize the potential for positive returns while minimizing exposure to loss.

In the context of medical device investment, risks can stem from various factors such as regulatory approvals, technological challenges, market dynamics, and competition. These risks are compounded by long development timelines and high upfront costs, especially for innovative products that require extensive clinical trials. However, experienced investors use several tools and strategies to manage these risks. This includes understanding the lifecycle of the investment, identifying companies with a strong innovation pipeline, and leveraging partnerships with established entities to reduce uncertainty. Additionally, diversifying investments and focusing on companies with robust intellectual property portfolios can provide a safety net to medical device investors. Ultimately, a balanced approach that combines strategic foresight, market analysis, and risk mitigation is key to succeeding in the medical device sector.

On the other side, medical technology entrepreneurs often face the challenges of securing investment capital. Prolonged product development cycles, combined with supply chain delays create significant uncertainty about product cost and time-to-revenue. They also bring a greater risk of changing market conditions, which could adversely impact product viability, competitiveness, and profitability. While none of these factors can be completely removed, there are several ways in which medical device companies can mitigate these risks to ease investor apprehension. Proactively addressing these concerns can also help medical device companies stretch their raised capital to meet development milestones and reduce the risk of running out of runway.

Investors rely on detailed financial analysis involving gathering of all pertinent financial information into one place and then using that risk related data to analyze the feasibility of a particular investment. The data will help identify the estimated incremental cash flows related to the investment (the additional expenses and revenues that will result from the investment), which can show how a particular investment will improve overall business performance rather than just whether a particular investment will make a profit on its own.

Medical device venture capital investing has changed significantly since the onset of the economic downturn. Private equity firms and other investors tend to gravitate toward companies with existing revenue streams, seeing them as safer bets and more likely to be acquired, as they often contribute positively to the acquirer’s bottom line within a short time frame. Fundamental concepts and premises, such as capital intensity, company stage

at exit, the degree of difficulty in obtaining regulatory approval and exit valuations, are undergoing major shifts. These shifts are likely to have a considerable effect on the medical device venture capital ecosystem. This declining VC investment reduces the likelihood of innovative medical devices from small companies reaching patients. The last few years have seen a significant drop in small to mid-cap VC funds, which may delay or cause a standstill in financing for ideas and therapies. Only a fraction of VC money is getting committed to high risk, early-stage funding of medical device innovation, which may take decades to develop.

As the medical device industry adapts to a shifting health financing landscape, investors are pursuing innovative financial approaches to manage the risks.

Risk mitigation tools play a crucial role in fostering a conducive environment for investment, especially in sectors like medical devices. In the public sector, these tools help address a variety of challenges, from regulatory uncertainties to financial risks. By creating a stable framework that reduces investment volatility, governments can encourage both local and international stakeholders to invest in medical device development, manufacturing, and distribution. Effective risk mitigation strategies—such as insurance schemes, risk-sharing models, and clear regulatory pathways—instil confidence in investors, enabling them to navigate the complexities of the medical device industry with greater ease. These tools not only protect investors but also ensure that the medical device sector remains robust and competitive on the global stage.

For the medical device sector, public sector risk mitigation initiatives can further drive innovation and growth by offering targeted incentives such as tax breaks, grants, and funding for research and development. Public-private partnerships (PPPs) also play a pivotal role in sharing both financial and operational risks, facilitating the entry of cutting-edge technologies into the market. Additionally, streamlining regulatory processes through transparent guidelines and faster approval mechanisms can reduce the time-to-market for new medical devices, making the sector more attractive to investors. By integrating these risk mitigation tools into national and regional healthcare strategies, governments can not only improve the healthcare ecosystem but also stimulate long-term investment in the medical device sector, ultimately benefiting the economy and society.

Milestone-based financing in the medical device industry is one of the funding approaches where capital is allocated to medical device startups in stages, with each stage tied to achieving specific development milestones. This structured method reduces risk for investors by ensuring that funds are released only as the company meets key objectives,

aligning progress with capital infusions. Careful up-front planning to create a financing plan linked to key milestones and risk reduction has the best chance of attracting investment, minimizing dilution, and optimizing value creation. The optimal capital structure determines the amounts and potential sources of financing required during various milestone-based funding tranches.

Blended finance is another of such approach whereby blended investments from various stakeholders with other sources of funding, primarily loans from multilateral development banks can take a combined leverage financing to achieve more impact in the development of needed medical devices and diagnostics. Blended finance is being recognized nationally and internationally as an important approach to unlock greater commercial investments to supplement public resources. For instance - The recent G20 framework has emphasized the use and need for Blended Financing structures as a catalyst to bridge the financing gap in the SDGs, especially in developing and underdeveloped nations. Blended finance in medical device sector is poised for an upward trajectory with recent interest and fundraising efforts in the space. While there is significant room to grow, it also points to the need for a more extensive portfolio of tools apart from blended finance. Despite the benefits, blended finance is yet to provide a proof of concept for truly unlocking healthcare for the lowest-income segments of the population. While blended finance is expected to play only a transitory role, the period of transition may be longer than anticipated. In the above light, grants continue to hold an important role. Grants remain essential for fostering product innovation in medical device sector through funding disruptive technologies and service models, providing technical assistance, or funding other models where the risk/financial return profiles may not be at market levels.

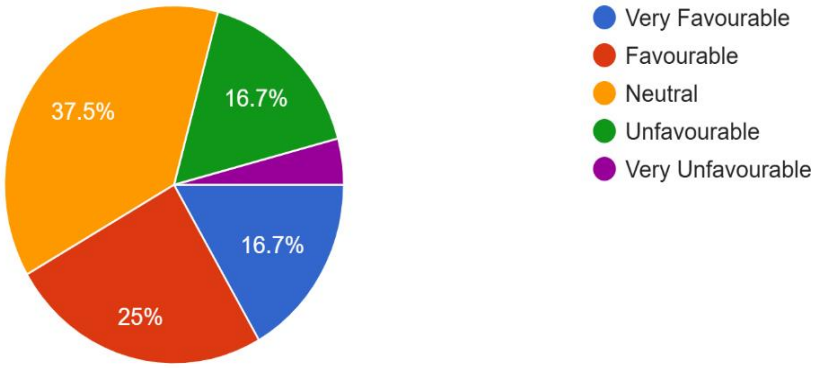
Furthermore, initiatives like single-window regulatory clearances, establishment of medical device parks, and provision of shared testing facilities significantly lower operational risks. By aligning national policies with global regulatory standards, governments can ensure a streamlined approval process, reducing the time and cost associated with bringing new devices to market. Such risk-adjusted measures are essential for building a robust and competitive medical device ecosystem, ultimately driving innovation, increasing accessibility, and improving healthcare outcomes.

3. KEY FINDINGS OF SURVEY

Key Finding of the Survey

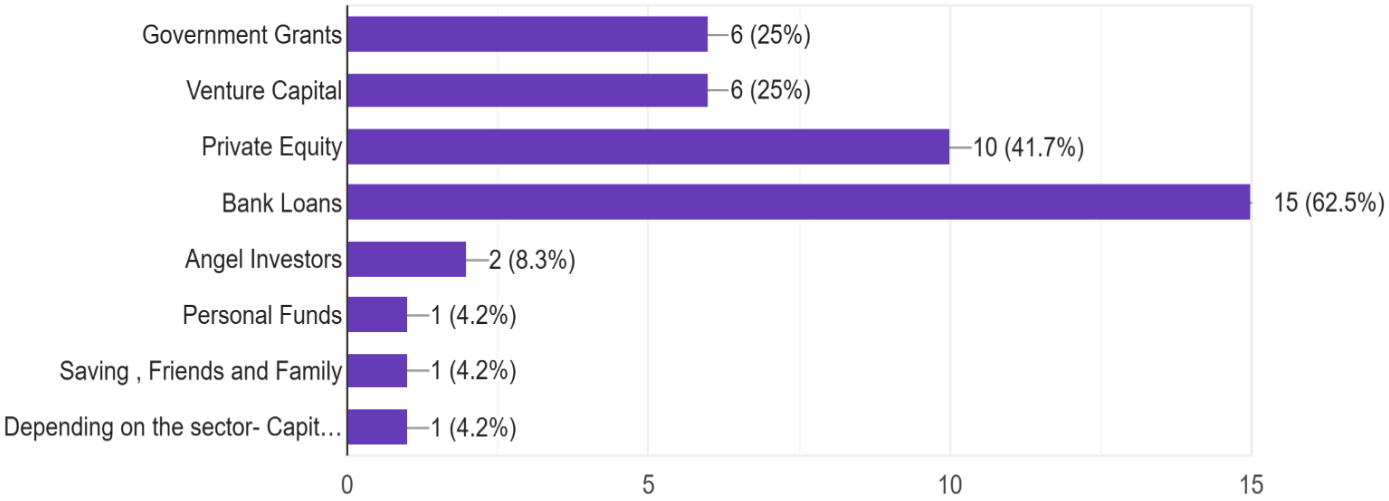
1. How would you rate the current investment climate for the Medical Device sector in India?

24 responses



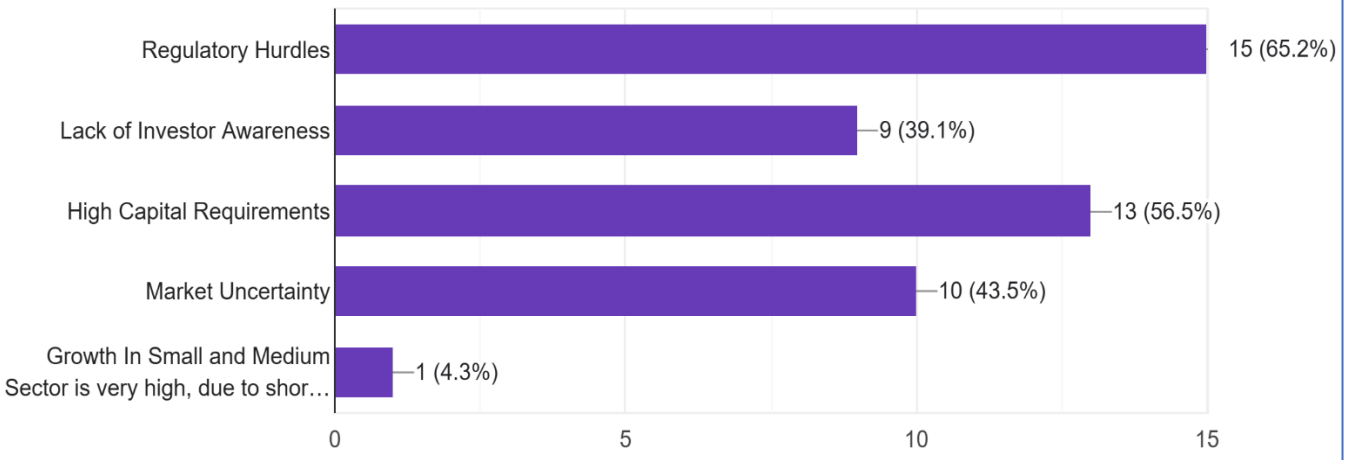
2. What are the primary sources of funding for medical device companies like yours in India? (Select all that apply)

24 responses



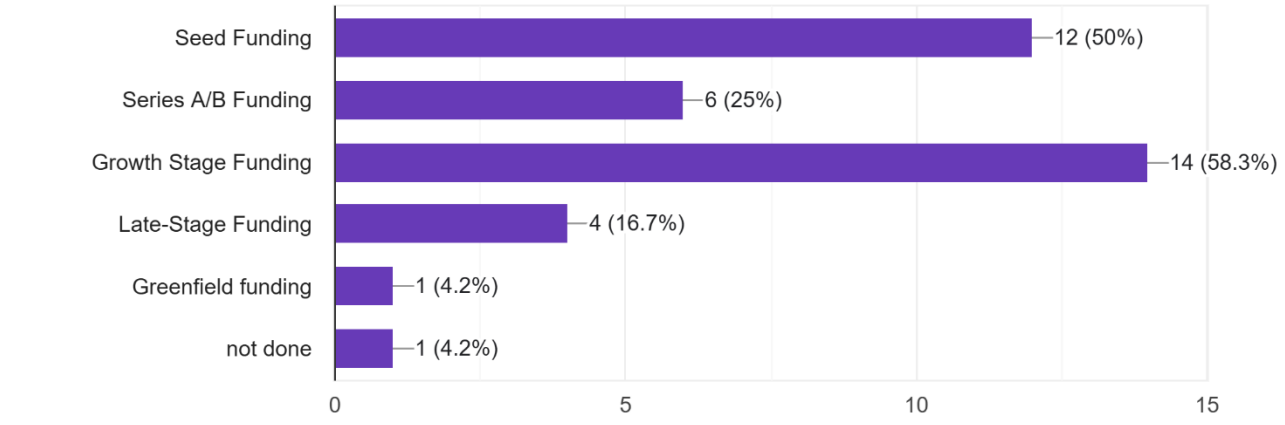
3. What challenges do you face in accessing funding for medical device projects?

23 responses



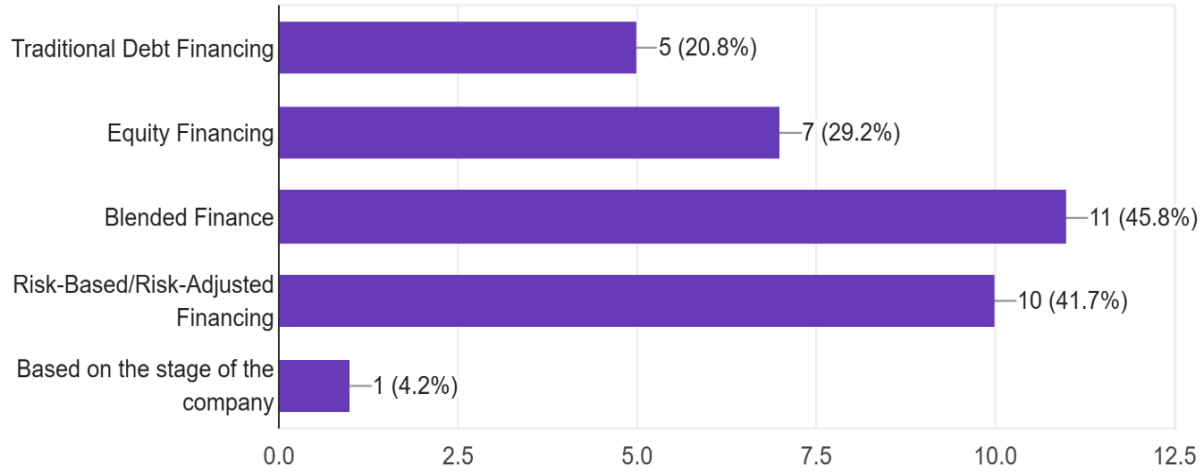
4. Which stages of funding are most challenging for medical device companies to secure? (Select all that apply)

24 responses



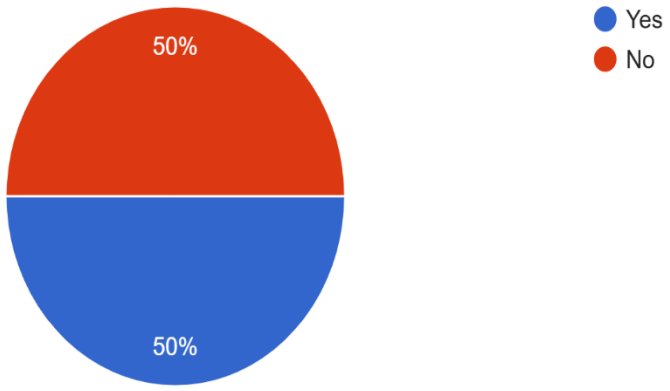
5. What types of financing models do you believe would be most beneficial for the Medical Device sector?

24 responses



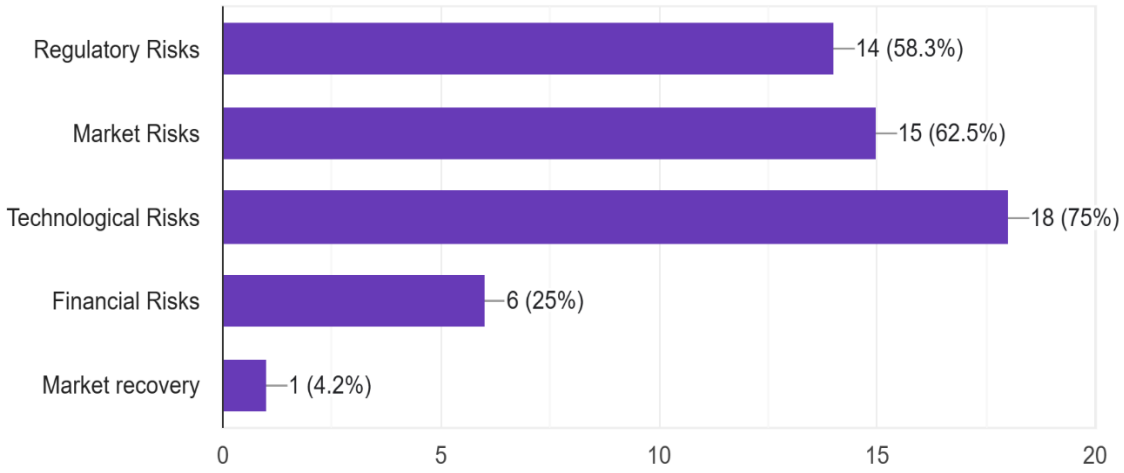
6. Are you familiar with risk-based or risk-adjusted financing models?

24 responses



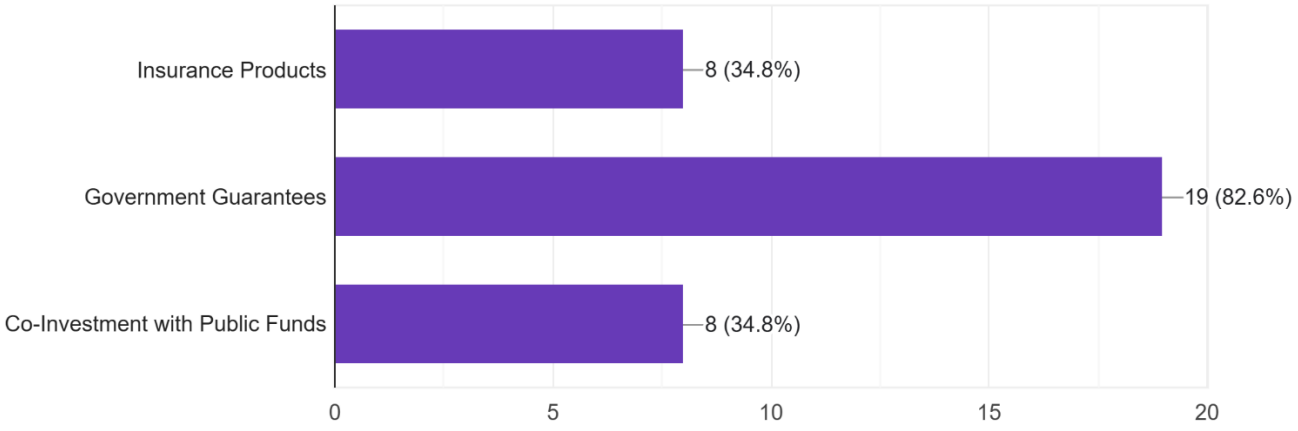
7. What are the main risks that affect investment in the Medical Device sector? (Select all that apply)

24 responses



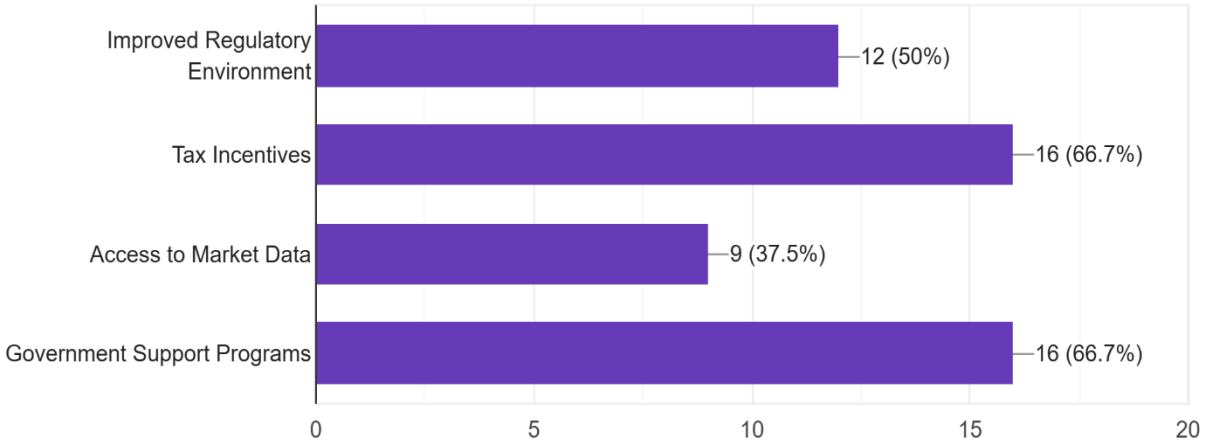
8. What risk mitigation tools do you believe are necessary to foster investment in the sector? (Select all that apply)

23 responses



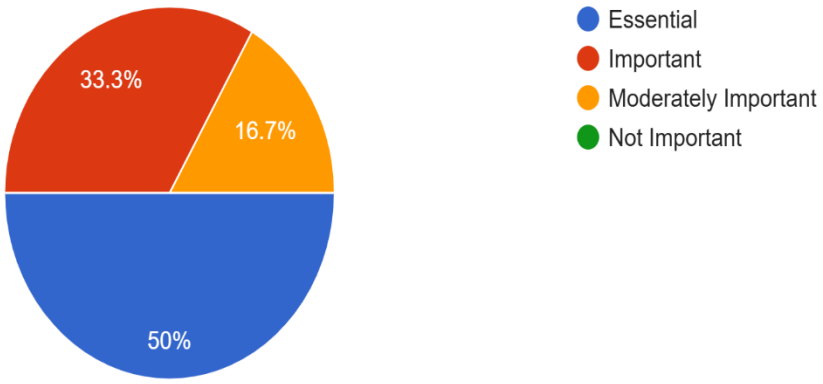
9. What factors would promote increased seed capital and series funding from venture capitalists in the Medical Device sector?

24 responses



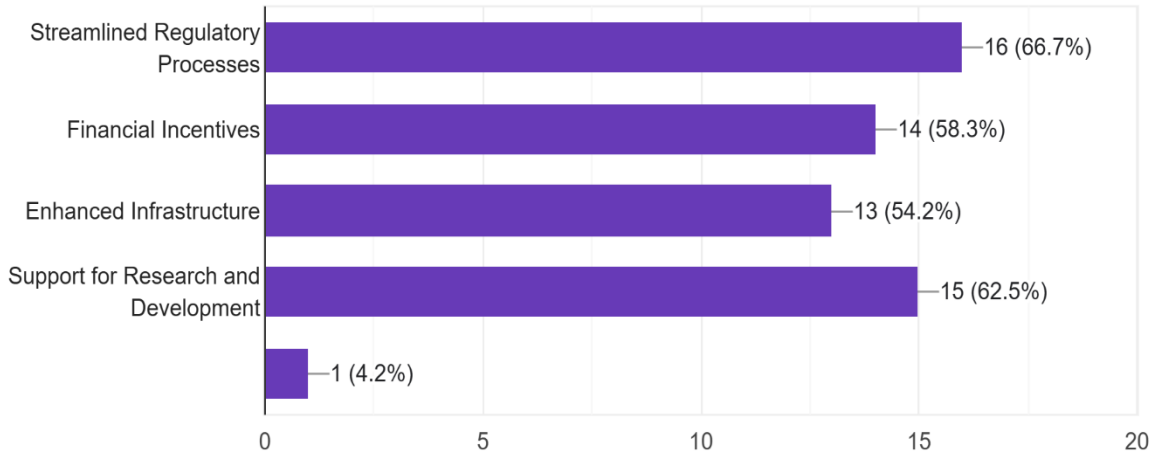
10. What role do you see for incubators and accelerators in supporting startups in the Medical Device sector?

24 responses



11. What interventions do you believe are needed from the Government to encourage private investments in the Medical Device sector? (Select all that apply)

24 responses



Comments or suggestion to improve investments in medical device Sector in India:

1. Improvement in Regulatory compliances such as certification for Medical Devices as per Indian MDR, lesser regulatory hurdles for innovative devices, stricter regulations for pre-use medical devices and control over fake certification bodies.

2. Government should promote initial 10-20 MVP validate in their government setup, which will give product validation for other customers and revenue and regulatory Avenue for Startup.

3. Increase of professionals & experts in the field.

4. Easier access to regulatory processes, Finances for technology acquisition, Easy finance options for capital investment.

5. Purchases from Govt. Organisations should be guaranteed.

6. Financial Support, Support in R & D, having tie up with research institutions.

7. Streamlined Regulatory Process.

8. Huge import substitution and innovations are possible in medical device sector.

9. Need to implement the drug rule for medical device in bottom line. the user is buying medical device product without asking for the manufacturers licence copy.

10. Develop Good Infrastructure for Research and Development including test sites. Also Focus on Skill Development of people to make them suitable for Medical Device Field

11. The Small and Medium Enterprises have all capabilities to move up the ladder. The machinery that are imported which doesn't have domestic manufacturer encourage high duty. Moreover, the finance options or support from government to give encouragement to this sector are all hypes and doesn't have ground level working which is very essential for this sector. Government should encourage giving incentive for this sector.

12. High GST rates and unwarranted regulation for this sector especially for category A medical Devices should be minimized.

13. The Entrepreneurs in this sector should have regular interaction with industry peers to give regular guidance's and how they can increase international market share by offering their products.

14. A regular buyers-sellers meet should be organised and encouraged by the government and medical tours to be conducted funded by government for these sectors.

4. CURRENT INVESTMENT LANDSCAPE IN INDIA

4.1. Overview of Medical Device Market

4.1.1 Market Size and Growth Projections

As per the latest report of Precedence research, the global medical devices market size was USD 604.20 billion in 2023, calculated at USD 640.45 billion in 2024 and is expected to reach around USD 1,146.95 billion by 2034, expanding at a CAGR of 6% from 2024 to 2034. The U.S. medical devices market size is estimated to the biggest among all at USD 169.51 billion in 2023 and is predicted to be worth around USD 328.65 billion by 2034, at a CAGR of 6.2% from 2024 to 2034. Further going by the latest report of Indian Brand Equity Foundation (IBEF) of May, 2025, the Indian medical device market was estimated to be valued at approximately $12 billion in FY of 2024. Projections indicate that the India medical device industry is growing at a robust rate of 15% compound annual growth rate (CAGR) over the past three years and is projected to reach $ 50 billion by FY 2030. India is the 4th largest Asian medical devices market after Japan, China, and South Korea, and among the top 20 medical devices markets globally.

The Indian medical device market share in the global market is estimated to be 1.65%. This share is expected to rise between 10 per cent and 12 per cent within the next 25 years. The Indian Government has identified the medical devices as a priority sector for the flagship 'Make in India' program and is committed to strengthen the manufacturing ecosystem. India is the fourth largest medical devices market in Asia. Currently, the Indian market has high reliance on imports but in recent times the

exports have seen a surged. 'Atma Nirbhar' Bharat mission is providing an impetus to India's vision of becoming a global manufacturing hub for medical devices

4.1.2 Key Players and Stakeholders in Indian Medical Device Sector Investments:

The Indian medical devices market comprises more than 800 manufacturers, of which 65% companies have a turnover of < (US$ 1.5 million), 25% companies have a turnover of US$ 1.5-6 million), and 2% companies have a turnover of >Rs. 500 crore (US$ 73 million). Some of the prominent Indian Medical device companies which have been able to attract major investments in recent time are mentioned in **Table 2 (Source: Crunchbase)**

Table 2

Name of the Company	Location	Products	Total Funding	Type Of Funding	Last Funding Round	Main Investors
Sahajanand Medical Technologies	Surat, Gujarat, India	Minimally invasive coronary stent systems	$48.19 Million	Secondary Market	9-Jan-23	StepStone Group, Unigestion, Axiom Asia Private Capital, TR Capital, Morgan Stanley, Samara Capital
Noccarc Robotics	Pune, Maharashtra, India	ICU Ventilators	$3.97 Million	Seed	13-Feb-24	Technology Development Board, Sunil Kant Munjal, IAN Group, Indian Institute of Technology Kanpur, Sunn91 Ventures, SIDBI Venture Capital, Technology Development Board, IAN Fund
Genworks	Bangalore, Karnataka, India	Neonatal Ventilators	$28.7 Million	Venture - Series Unknown	8-Aug-24	Evolvence India Fund, Ramesh K Sivaraman, Somerset Indus Capital Partners, Kasiraman swaminathan, BlackSoil, Morgan Stanley, Wipro GE Healthcare Pvt. Ltd
Translumina Therapeutics	New Delhi, Delhi, India	Cardiovascular medical devices	$60.24 Million	Private Equity	27-Aug-19	Everstone
Prodancy	Bangalore, Karnataka, India	Medical Device Designing	$257.83 K	Seed	27-Nov-24	Campus Angels Network, Atal Incubation Centre - Center for Cellular

						and Molecular Biology, Keiretsu Chennai
Sayre Therapeutics	Bangalore, Karnataka, India	Molecular diagnostics Oncology	$9 Million	Venture - Series Unknown	4-Sep-17	Accel, Aarin Capital, InnoVen Capital
Ezerx Health Tech	Bhubaneswar Orissa, India	Medical devices and innovative solutions	$3.46 Million	Corporate Round	5-Oct-23	Sun Pharmaceutical Industries
Relisys	Hyderabad, Andhra Pradesh, India	Cardiovascular Stents, Catheters and Structural Heart devices	$5.06 Million	Private Equity	1-Sep-21	Siguler Guff & Company, India Life Sciences Fund II
Medtel Healthcare	Bhubaneswar, Orissa, India	Aggregator for Digital Health Clinics	$ 643.3 K	Seed	14-May-21	Innovative Ventures and Technologies for Development (INVENT), Bharat Petroleum Corp., Startup Odisha
Poly Medicure	New Delhi, Delhi, India	Manufacturer of Medical devices	$120.48 Million	Post-IPO Equity	23-Aug-24	Kotak Life Insurance, quant Mutual Fund, Nomura Funds Ireland, ICICI Prudential Life Insurance, Lighthouse Funds, Max Life insurance, SBI Mutual Fund
InnAccel	Bangalore, Karnataka, India	Medical Technology Innovation Platform	$1.5 Million	Seed	20-Oct-20	Siraj Dhanani, Mount Judi Ventures
Chayagraphics	Bengaluru, Karnataka, India	Medical imaging consumables distribution	$361.45 K	Venture - Series Unknown	1-Sep-15	Somerset Indus Capital Partners
Innaumation	Bengaluru, Karnataka, India	AUM Voice Prosthesis Accessories Kit	$6.02 K	Grant	6-Oct-20	Department for Promotion of Industry and Internal Trade
UnivLabs	Gurgaon, Haryana, India	Medical devices in field of Endoscopy, Urology and Diabetic care	Information not available	Non-equity Assistance	1-Jan-23	Eurasante

Sensacore Medical Instruments Pvt Ltd	Hyderabad, Andhra Pradesh, India	Manufactures analytical and diagnostic analyzers, point of care devices, test strips reagents.	Information not available	Debt Financing	31-Oct-17	Axis Bank
Fontierz	Pune, Maharashtra, India	Medical equipment that is inexpensive, achieve patient outcomes, and help emerging economies	Information not available	Seed	13-Jun-23	Venture Center, Atal Incubation Centre - Shiv Nadar University
Stemtech Medical Devices	Mumbai, Maharashtra, India	Eva Scalp Cooling System to address side effect of chemotherapy-induced hair	Information not available	Seed	1-Jan-22	Venture Center
EffecMed	Mumbai, Maharashtra, India	Medical equipment manufacturer that delivers economical biomaterials-based medical devices for bone repair and regeneration	Information not available	Seed	1-Jan-23	Society for Innovation and Entrepreneurship
Rural Surgery Innovations	Kohima, Nagaland, India	Surgical Camps in rural areas, Online and Onsite Training, and medical devices	Information not available	Seed	1-Jan-23	Society for Innovation and Entrepreneurship
Meukron Technologies	Belgami, Karnataka, India	Machinery Manufacturing firm that helps Medical Devices manufacturing firm with their Product Development Cycle	Information not available	Pre-Seed	1-Jan-24	SIDBI Innovation & Incubation Centre (SIIC)

RayMedis	Hyderabad, Andhra Pradesh, India	Medical devices, including X-ray systems and dental equipments	Information not available	Seed	1-Jan-23	Dlabs
Phraction Scientifics	Thiruvanantha puram, Kerala, India	Medical devices to improve public health care	Information not available	Pre-Seed	1-Jan-20	SIDBI Innovation & Incubation Centre (SIIC)
Ezercon Medtech	Thane, Maharashtra, India	Medical devices with assistive technology that will help disable patients	Information not available	Seed	1-Jan-24	Society for Innovation and Entrepreneurship

4.2 Types of Investments in Medical Device Sector in India

4.2.1. Venture Capital

Venture capital is the most common source of funding for medical device startups globally. Venture Capital firms invest in high-risk medical device companies that don't qualify for conventional business financing. Venture capital plays a critical role in driving advancements in medical device innovations through its investment in early-stage companies. VC firms manage significant capital, with some investing in early-stage companies with high growth potential. Many of the VC firms also invest established small to medium size medical device companies which have limited resources to prioritize internal innovation. Translating a concept into a marketable innovative medical device typically takes between 5 and 15 years, with costs ranging from $100 million to $1 billion. Venture Capital accelerates the steps like enterprise creation, intellectual property licensing, proof of concept, and proof of safety. VC backed companies usually aim for exits (acquisition or initial public offering) in 3-5 years; however, it can take about 10 years for some cardiovascular devices needing outcomes trials to achieve global regulatory approvals. In addition, Venture Capital firms also accelerate clinical and regulatory development; use their networks to help companies; often serve on start-up boards; and focus on value-creating milestones, increased valuation, talent attraction and acquiring interest. Venture Capital backed companies aim for exits by focusing primarily on value-creating milestones.

It is estimated that medical device start-ups raised $8.8 billion (USD) in venture capital in 2023, falling nearly 62% since 2020. Several factors, including high interest rates, inflation, global economic slowdown and ongoing international conflicts, have contributed to a

decrease in both the number and value of VC deals. These declining investment trends in medical device sector stifle innovation and jeopardize the timely development of life-saving technologies, highlighting the urgent need for increased funding support. Some of the Prominent Venture Capital Firms operating in India and the details of the medical device companies in which they have invested are mentioned in **Table 3** (Source: Crunchbase)

Table 3

Name of the Organisation	Location	Investment In Medical Device Sector/Companies
Peak XV Partners	Bengaluru, Karnataka, India	Akumentis Healthcare, HealthKart
Blume Ventures	Mumbai, Maharashtra, India	BeatO, Ultrahuman, TriCog, Health Assure
Kalaari Capital	Bengaluru, Karnataka, India	HealthPlix, PhableCare, Connected, Healthium Medtech
India Chiratae Ventures	Bengaluru, Karnataka, India	Aether Biomedical, Alpha Digital Health Pvt Ltd, WeInnovate Biosolutions
100X.VC	Mumbai, Maharashtra, India	Hummsa Biotech, iSafe, Swaas Healthcare
ah! Ventures	Mumbai, Maharashtra, India	Punar Rehab Solutions, Helo Health, Quali55care
Omidyar Network India	Mumbai, Maharashtra, India	HealthKart, Axio Biosolutions, Healofy, HexaHealth
Saama Capital	Bengaluru, Karnataka, India	Sahajanand Medical Technologies Pvt Ltd., Wellthy Therapeutics, Medi Buddy, Fittr
Eight Capital	Mumbai, Maharashtra, India	Poly Medicure, Spectrum Electrical, Hemant Surgical Industries, Centenial Surgical, Shree Pacetronix, Immuneel Therapeutics
Kae Capital	Mumbai, Maharashtra, India	healthkart.com, Tata 1MG, Zyla Health
Orios Venture Partners	Mumbai, Maharashtra, India	Kenko Health, Le Travenues Technology, BeatO, Wipro GE Healthcare
Fireside Ventures	Bengaluru, Karnataka, India	Evelabs Technologies, Inito
BlackSoil	Mumbai, Maharashtra, India	GenWorks Health, Meddo, Medall Healthcare
VenturEast	Hyderabad, Andhra Pradesh, India	OneBreath, DiabetOmics, Portea Medical, Mardil Medical
SIDBI Venture Capital	Mumbai, Maharashtra, India	Poly Medicure Limited, Healthium Medtech Limited, Transasia Bio-Medicals Limited
Unicorn India Ventures	Mumbai, Maharashtra, India	Sascan Meditech, QubeHealth, Piscium
Ankur Capital	Mumbai, Maharashtra, India	Niramai, D-NOME
India Gemba Capital	Bangalore, Karnataka, India	Trivitron Healthcare, Prevest DenPro, Ge Healthcare Private Limited, DHR Holding India Private Limited, 3M India Limited, Baxter India Private Limited
Rebright Partners	Bengaluru, Karnataka, India	Medikabazaar, Medibuddy
1Crowd	Mumbai, Maharashtra, India	Poly Medicure Ltd., Cardinal Health Inc, Trivitron Healthcare

All In Capital	Delhi, Delhi, India	Meril Life Sciences, Sahajanand Medical Technologies, Molbio Diagnostics, Redcliffe Genetics, BeatO
Smile Group	Gurgaon, Haryana, India	Rovers Medical Devices, Bigfoot Biomedical
QI Ventures	Bangalore, Karnataka, India	Larkai Healthcare
GVFL	Ahmedabad, Gujarat, India	Allied Medical Limited, Arcatron Mobility, Sahajanand Medical Technologies
IAN Fund	New Delhi, Delhi, India	Consure Medical, Noccarc
Evolvence India Fund	Mumbai, Maharashtra, India	Health Care Global, GenWorks Health
Pi Ventures	Bangalore, Karnataka, India	Theranautilus, ten3T
Tata Capital	Mumbai, Maharashtra, India	Apex Kidney Care, Linux Laboratories, Sakar Healthcare, Atulaya Healthcare, Anderson Diagnostics
Aarin Capital	Bangalore, Karnataka, India	Insightra Medical, Vyome Biosciences, Invictus Oncology
Lighthouse Funds	Mumbai, Maharashtra, India	Suraksha Diagnostic, Poly Medicure, Tynor Orthotics
India Iron Pillar	Mumbai, Maharashtra, India	Healthium Medtech, Stasis Labs, Lenek Technologies, ShanMukha Innovations, Lifespark Technologies
Sun91 Ventures	Hyderabad, Andhra Pradesh, India	IDG Ventures
Bharat Innovation Fund	Ahmedabad, Gujarat, India	Nayam Innovations Pvt Ltd
Sharrp Ventures	Mumbai, Maharashtra, India	Hindustan Syringes & Medical Devices Ltd. (HMD)
HealthQuad	New Delhi, Delhi, India	AINU, THB, Impact Guru, Qure.ai, and Stanplus
ITI Growth Opportunities Fund	Mumbai, Maharashtra, India	Apollo Hospitals Enterprise Ltd.
Arali Ventures	Bangalore, Karnataka, India	Unbox Robotics, Oivi AS
Refex Capital Fund	Chennai, Tamil Nadu, India	CURA Healthcare, Adonis & 3i Medical Technologies
Karnataka Information Technology Venture Capital Fund	Bangalore, Karnataka, India	Fibroheal Wound care Pvt Ltd., Nesa Medtech, Jiva Sciences, Pandorum
Culture Cap	New Delhi, Delhi, India	Poly Medicure Limited,
Core91 Fund	Mumbai, Maharashtra, India	Johnson & Johnson
Capital 2B	Delhi, Delhi, India	Channel Medsystems
Enzia Ventures	Bengaluru, Karnataka, India	ZenOnco.io's, Circle Health (Healthcare Technology Systems)
Forward Slash Capital	Bangalore, Karnataka, India	Poly Medicure, Prevest Denpro, Nureca Ltd., Yash Optics & Lens Ltd., Hemant Surgical Industries Ltd.
RPG Ventures	Worli, Maharashtra, India	Juno Clinic, Medsonway, and Shieldsquare
N+1 Capital	Delhi, Delhi, India	Karma Healthcare, Transcell Biologics
quant Mutual Fund	Mumbai, Maharashtra, India	Wrig Nanosystems, FlexifyMe, BeatO
Jupiter Capital	Bangalore, Karnataka, India	Medsource Ozone Biomedicals India

Next Orbit Ventures Fund-I	Mumbai, Maharashtra, India	Janitri, Ameliorate Biotech, Thinkphi Healthcare, BioNEST Catalyst Centre
CDM Capital	Mumbai, Maharashtra, India	Neuranics, Navanc, Ikure, Lebencare
Investo Monk	Bangalore, Karnataka, India	Aether Biomedical, Alpha Digital Health Pvt Ltd, WeInnovate Biosolutions
RNT Capital	Mumbai, Maharashtra, India	Punar Rehab Solutions, Helo Health, Quali55care
Uniqorn Ventures	Mumbai, Maharashtra, India	Evelabs Technologies, Comofi Medtech, AADAR, Remedico, Greencure.co, Tablt, S3V Vascular Technologies
Cholamandalam	Chennai, Tamil Nadu, India	Lotus Surgicals, Iora Health
Merisis Advisors	Mumbai, Maharashtra, India	OneBreath, DiabetOmics, Portea Medical, Mardil Medical
TrueScale Capital	Mumbai, Maharashtra, India	Aarna Biomedical Products Private Limited, Agastya Buoyant Private Limited, Arogya MedTech Pvt Ltd, Cutting Edge Medical Devices, Monosha Biotech Private Limited, Mother Diagnostics
India Innovation Fund	Bangalore, Karnataka, India	Rovers Medical Devices, Bigfoot Biomedical

The decline in VC funding is concerning, yet select VC firms continue to fund early-stage companies that address genuine market needs and operate with a capital-efficient business model. Collaboration among VCs, health care professionals, university foundations, pension funds, and regulatory bodies is essential for overcoming challenges and ensuring the development of ethical, sustainable, and patient-centric health care solutions for our patients and our providers.

4.2.2 Private Equity

Private Equity (PE) is playing an increasingly important role in the sector. Over the past decade, PE firms have sponsored 924 medical devices and supplies companies in the US, investing more than $280 billion in the process. PE firms help strengthen a spectrum of medical device companies. Their goal is to make those companies more efficient, more innovative, and better at serving their ultimate customers: their patients. That is important for an expensive health care system that needs to care for an aging baby boom generation. The demand for safe, cost-efficient, and innovative medical devices will continue to increase, and PE firms are able to help the industry across all fronts.

The Indian medical devices sector stands at a pivotal moment, with private equity seeing robust growth potential fueled by favourable market conditions and government support. Over the next decade, the sector is expected to expand its footprint both domestically and internationally, with increased R&D and innovation. As Indian firms enhance their product

portfolios and quality standards, the industry's global standing is set to rise, potentially positioning India as a major player in the global medical devices market. Prominent Private Equity players operating in India are mentioned in Table 2 (Source: Crunchbase)

When PE-sponsored medical device companies get eventually sold to larger medical device manufacturers, substantial returns are delivered to shareholders but more importantly PE exits become an important source of innovation. That is important for patients because hospitals and other operators will be able to buy and use those products at a scale the smaller company would not have been able to match. Unsurprisingly, strategic players are enthusiastic beneficiaries of PE-sponsored companies because the PE-sponsored companies have worked for years to improve their technologies.

Currently, India excels in consumables and products used in non-complex procedures. However, experts anticipate a gradual move into high-tech manufacturing. This shift is contingent on an increase in domestic consumption and market share from multinational competitors, along with scaling innovation in more advanced medical devices. Some of the Prominent Private Equity Firms operating in India and the details of the medical device companies in which they have invested are mentioned in **Table 4** (Source: Crunchbase)

Table 4

Name of the PE Investor	**Location**	**Investment In Medical Device Sector/Companies**
Premji Invest	Bengaluru, Karnataka, India	Lotus Surgicals, Iora Health
True North	Mumbai, Maharashtra, India	Actis-BPEP Medical Devices,
Motilal Oswal Private Equity	Mumbai, Maharashtra, India	Pan Healthcare, Pathkind Diagnostics,
Evolvence India Fund	Mumbai, Maharashtra, India	Health Care Global, GenWorks Health
Tata Capital	Mumbai, Maharashtra, India	Apex Kidney Care, Orbicular Pharmaceutical Technologies, Linux Laboratories, Sakar Healthcare, Atulaya Healthcare, Anderson Diagnostics
Ascent Capital	Bangalore, Karnataka, India	Skanray Technologies, Transasia Bio-Medicals Ltd.
Lighthouse Funds	Mumbai, Maharashtra, India	Suraksha Diagnostic, Poly Medicure, Tynor Orthotics

Sharrp Ventures	Mumbai, Maharashtra, India	Hindustan Syringes & Medical Devices Ltd. (HMD)
Eight Roads Ventures India	Bangalore, Karnataka, India	Oziva, eKincare, Toothsi
InvAscent	Hyderabad, Andhra Pradesh, India	Maiva Pharma, Arcatron Mobility, Innaumation Medical Devices LLP
Culture Cap	New Delhi, Delhi, India	Poly Medicure Limited,
Kotak Alternate Asset Managers	Mumbai, Maharashtra, India	Biorad, Medisys.
CX Partners	New Delhi, Delhi, India	Healthium Medtech Pvt Ltd, Sutures India
Samridhi Fund	Mumbai, Maharashtra, India	ColMed, Glocal Healthcare Systems Private Limited
Samara Capital	Mumbai, Maharashtra, India	Sahajanand Medical Technologies
Tata Capital Healthcare Fund	Mumbai, Maharashtra, India	Sakar Healthcare, , Atulaya Healthcare, Anderson Diagnostics,
Xponentia Capital Partner	Mumbai, Maharashtra, India	Medsource Ozone Biomedicals India
Sabre Partners	Mumbai, Maharashtra, India	ekincare, Veeda Clinical Research, Portea
Fulcrum Venture India	Chennai, Tamil Nadu, India	Richfeel, Shield Healthcare
quant Mutual Fund	Mumbai, Maharashtra, India	Wrig Nanosystems, FlexifyMe, BeatO
Jupiter Capital	Bangalore, Karnataka, India	Medsource Ozone Biomedicals India
Stakeboat Capital	Bangalore, Karnataka, India	ZenOnco.io's, Circle Health (Healthcare Technology Systems)
Next Orbit Ventures Fund-I	Mumbai, Maharashtra, India	Janitri, Ameliorate Biotech, Thinkphi Healthcare, BioNEST Catalyst Centre
Creaegis	Bangalore, Karnataka, India	HealthPlix, PhableCare, ConnectedH, Healthium Medtech
Investo Monk	Bangalore, Karnataka, India	Aether Biomedical, Alpha Digital Health Pvt Ltd, HealthifyMe, WeInnovate Biosolutions

Asian Healthcare Fund	New Delhi, Delhi, India	healthkart.com, Tata 1MG, Zyla Health
Avenue Venture	Mumbai, Maharashtra, India	Poly Medicure Limited, Trivitron Healthcare
Merisis Advisors	Mumbai, Maharashtra, India	OneBreath, DiabetOmics, Portea Medical, Mardil Medical
JCurve Investment	New Delhi, Delhi, India	Niramai
Jashvik Capital	Mumbai, Maharashtra, India	Trivitron Healthcare, Prevest DenPro, Ge Healthcare Private Limited, DHR Holding India Private Limited, 3M India Limited, Baxter India Private Limited

4.2.3 Foreign Direct Investment (FDI)

Recognizing the importance of the sector, medical devices were included in the Make in India campaign and 100% FDI on the automatic route was allowed in Medical Devices in 2014. Over the next five years (2015-2020), India received US$ 600 million with key investments from countries such as Singapore, United States, Europe and Japan. After the year 2020, the Indian medical devices sector's contribution has become even more prominent as India supported the global battle against COVID-19 pandemic through the production of medical devices & diagnostic kits, e.g., Ventilators, RT-PCR kits, IR Thermometers, PPE Kits & N-95 masks.

On the policy front, the Indian Government is undertaking deep structural and sustained reforms to strengthen the healthcare sector; it has also announced conducive policies for encouraging Foreign Direct Investment (FDI). In fact, India's FDI regime has been liberalized extensively. Currently, FDI is permitted up to 100% under the automatic route (i.e., the nonresident investor or Indian company does not require approval from the Government of India for the investment) in the hospital sector and in the manufacture of medical devices. In the pharmaceutical sector, FDI is permitted up to 100% in greenfield projects and 74% in brownfield projects under the automatic route. India has emerged as one of the fastest-growing emerging economies over the last two decades, receiving large FDI inflows, which have grown from USD 2.5 Billion in 2000-01 to USD 50 Billion in 2019-20. The healthcare sector, in particular, has received heightened interest from investors over the last few years, with the transaction value increasing from USD 94 Million (2011)

to USD 1,275 Million (2016) – a jump of over 13.5 times. All of these factors together create several opportunities for investment in India's healthcare industry.

India's FDI regime has been liberalized extensively. Currently, FDI is permitted up to 100% under the automatic route (i.e., the non-resident investor or Indian company does not require approval from the Government of India for the investment) in the manufacturing of medical devices. This has made India one of the most attractive destinations for foreign investments in healthcare. However, there is still a lot of ground to be covered as compared to countries like Germany which was recognized as the leading destination market for greenfield medical device FDI, and the United States which emerged has been top source market for investments in the medical device sector.

Overall, the US and Germany dominated the global medical device FDI, representing 33% of global FDI inflows and 39% of outflows in 2019-2020. However, the Covid-19 pandemic has changed the landscape, and the future of medical device investments may shift in the post- Covid era to countries like India.

4.2.4 Government Support

The Indian medical devices sector is on a growth track and has an enormous potential to become self-reliant and to contribute towards the goal of universal health care. The Government of India has already initiated implementation of PLI Scheme for medical devices and support for setting up of Medical devices Parks in the States of Madhya Pradesh, Tamil Nadu and Uttar Pradesh. Under the PLI scheme for Medical Devices, till now, a total of 26 projects have been approved, with a committed investment of Rs.1206 Cr and out of this, so far, an investment of Rs.714 Cr has been achieved. Under the PLI scheme, total of 14 projects producing 37 products have been commissioned and domestic manufacturing of high-end medical devices has started which include Linear Accelerator, MRI Scan, CT-Scan, Mammogram, C-Arm, MRI Coils, high end X-ray tubes, etc. Remaining 12 products will be commissioned in near future. Five projects out of total 26 projects have been approved recently, under Category B, for domestic manufacturing of 87 products / product components.

While various Departments of the Government have undertaken programmatic interventions to encourage the sector, the current policy aims to put in place a comprehensive set of focus areas for growth of the sector in a coordinated manner.

Secondly, in view of the diversity and multi-disciplinary nature of the sector, the regulations, skilling trade promotion of medical device industry are spread over several departments in the Government both at the Centre and State levels. There is a need to bring together the range of interventions in a coherent manner that would facilitate focused and efficient support and facilitation for the sector by the respective agencies.

The National Medical Devices Policy, 2023 is expected to facilitate an orderly growth of the medical device sector to meet the public health objectives of access, affordability, quality and innovation. This sector is expected to realize its full potential, with the strategies viz, building an enabling ecosystem for manufacturing along with a focus on innovation, creating a robust and streamlined regulatory framework, providing support in training and capacity building programs and promoting higher education to foster talent and skilled resources in line with the industry requirements. Encouraging domestic investments and production of medical devices complements the Government's 'Atmanirbhar Bharat' and 'Make in India' programs. Some of the Initiatives taken by government are:

- **BIRAC-Industry Innovation Programme on Medical Electronics (IIPME): I**ndustry Innovation Programme on Medical Electronics (IIPME) was a collaborative project between the Ministry of Electronics and Information Technology (MeitY) and Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Ministry of Science and Technology, Government of India. The project goal was to fund a portfolio of Indian led pilot projects targeting innovations in multidisciplinary areas comprising of electronics, engineering, medical devices, healthcare, software, algorithms & information technology, to help medical electronics fraternity and to bring in fast pace research and development in this area. The idea was to provide funding support to applicants for testing their bold ideas, mentorship from various subject matter experts, networking platforms and an opportunity to scale up their technology. Under this project support will be provided at Seed, Early transition and transitions to scale stages. A mix of grant & loans for a period of 24 - 36 months was generally proposed. The project cost was matched equally by Government Funds and the industry.

- **AMTZ Financial Assistance**: In 2019, Andhra Pradesh MedTech Zone (AMTZ) received ₹25 crore for a superconducting magnetic coils project. The Andhra Pradesh MedTech Zone Limited, Vishakhapatnam, is the first one to be started by

the Government of Andhra Pradesh with support from various departments of the government of India. Such an industrial setup enhances production, advancement in research and development, and funding from both government and private sector. Such industrial units will target the Indian population, especially the low-resource segment. This will decrease the cost of the device and generate local employment.

- **ICMR MedTech Mitra program:** Launched on December 25, 2023, jointly by Indian Council of Medical Research (ICMR) and Central Drugs Standard Control Organization (CDSCO) under the guidance of NITI Aayog, the MedTech Mitra initiative aims to empower MedTech innovators and advance healthcare solutions by providing crucial support for clinical evaluation, regulatory facilitation, and the uptake of new products. The platform fosters collaboration among stakeholders, breaking silos and catalysing growth, ultimately strengthening India's commitment to Universal Health Coverage. The initiative aims to address the various challenges faced by innovators, including regulatory hurdles and production complexities, thus fostering an ecosystem that enables the seamless development of medical devices and diagnostics. Since its launch, MedTech Mitra has garnered significant attention from innovators across India, receiving widespread feedback for its strategic handholding support. The new initiatives aim to facilitate the indigenous development of affordable and quality MedTech devices and diagnostics, significantly reducing the sector's reliance on imports. By ensuring ease of innovation and conducting R&D, they provide emerging start-ups with end-to-end guidance, streamlining their journey from concept to product. The platform addresses critical gaps by supporting animal and clinical trials and fostering partnerships between engineers, scientists, and clinicians, which were previously lacking in the sector.

- **Department of Pharma Schemes for Medical Devices**: The Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical devices has been notified to boost domestic manufacturing and attract large investments in the industry. The scheme has a total outlay of about INR 3420 Cr Under the scheme, 5% incentive will be provided on incremental sales (over Base Year: FY 2019-20) of medical devices manufactured in India. The incentives under the scheme will be offered for a period of 5 years from FY 2020-21 to FY 2025-26. The Ministry of Chemicals & Fertilizers Department of Pharmaceuticals has also issued the Guidelines for the Scheme for "Assistance to Medical Device Clusters for

Common Facilities (AMD-CF)" on May 9 ,2023 with a proposed financial outlay of Rs. 300 crores. AMD-CF Scheme aims to strengthen the existing and new medical device clusters by providing financial assistance for setting up new testing laboratories for medical devices ensuring quality and sustainable growth for the sector. The Scheme further intends to support Central or State Government/s or Institutions or Organization to establish or strengthen the Testing Laboratories for Medical Devices to meet the needs arising due to roll out of the licensing regime of the MDR, 2017 and ensuring availability of more testing facilities for evaluation of Medical Devices on behalf of the manufacturers, as mandated under MDR, 2017 or as per the amendment thereon, from time to time. The Scheme would be implemented in a Public Private Partnership (PPP) mode through one time grant-in-aid for creation of infrastructure and common facilities.

- **Regulatory Risk Mitigation Tools - Single-Window Clearance:** India has launched the National Single Window System (NSWS) to simplify and speed up the process of obtaining approvals for medical devices. This new system acts as a one-stop portal where investors can apply for all necessary approvals, such as certificates of registration, manufacturing licenses, and permissions for clinical investigations and testing. Developed by Tata Consultancy Services (TCS), the NSWS will replace the older portals and provide a more streamlined and efficient way for businesses to interact with regulatory bodies. By bringing multiple authorities and approval processes under one platform, it eliminates the need to visit different agencies or websites, thus making it easier to do business in India. The NSWS is part of India's broader effort to attract investment into the medical device sector, which is expected to grow significantly in the coming years. This initiative is designed to reduce delays, lower administrative burdens, and improve transparency in the approval process. However, for the system to be fully effective, it is important that all relevant ministries and regulators are integrated into the platform. Industry experts believe that the success of NSWS will depend on seamless communication between regulators and the establishment of clear guidelines for approvals, ensuring faster, more efficient processes for both domestic and international medical device manufacturers.

4.2.5 Prevalent Investor Exit Strategies in the Indian Medical Device Sector

Exit strategies are a key consideration for Venture Capital (VC), Private Equity (PE) and strategic investors in the medical device sector. The average holding period for VC/PE in India's medical device sector ranges from 4 to 7 years but it may extend to 8–10 years for

companies with longer regulatory pathways (e.g., Class C/D devices requiring extensive clinical validation). Early exits (3–5 years) are possible for companies with revenue traction, robust product-market fit or if strategic buyers are actively pursuing acquisitions in the space. For startups still navigating regulatory approvals or those with capital-intensive R&D cycles, exit timelines tend to be longer.

Attainment of regulatory approvals like US FDA and EU CE significantly enhances the company value serving as a validation of product safety, efficacy, and export readiness. Evidence of product market fit like strong clinical adoption, repeat buyers (hospitals, clinics) and positive user feedback demonstrate product relevance make the companies more attractive acquisition target. Other factors like Predictable and growing revenue streams, scalability, strong intellectual property. healthy gross margins and a robust order book drive valuation multiple. An attractive and achievable exit increases the appeal of the medical device sector and drives deal flow. The Indian medical device sector's maturing investment landscape has plenty of exit strategies which now mirror global best practices. Key valuation drivers for exit remain robust regulatory credentials, demonstrated revenue growth, clear product-market fit, and sustainable margins. Startups and established companies should align business strategies to these investor expectations to unlock value and facilitate successful investment exits. Some of typical exit routes for Investors prevalent in India are:

- **Trade Sale (Mergers & Acquisitions):** The most frequent exit strategy for VC and PE investors in Indian medical device companies is a sale to a strategic buyer—usually a larger domestic or multinational healthcare/MedTech company. This route is preferred due to the sector's consolidation by multinational players looking to expand market share, add innovative product lines, or localize manufacturing. Zydus' acquisition of Amplitude Surgical (France) exemplifies Indian companies strategically acquiring overseas firms or being acquired by multinationals. This type of deal supports consolidation and product portfolio augmentation.
- **Initial Public Offering (IPO):** IPOs though less frequent compared to Mergers and Acquisitions do occur, especially for well-established, revenue-generating companies with a differentiated product portfolio and utmost compliance with regulatory standards. Notable medical device companies such as Poly Medicure

and Transasia Bio-Medicals have explored public listing as an exit option in India have been quite successful.

- **Secondary Sale:** Existing VC/PE investors often exit by selling their equity to other private equity funds, growth-focused investors, or strategic buyers, occasionally as part of a larger funding round or recapitalization. For example, Samara Capital invested $150 million in stent manufacturer Sahajanand Medical Technologies ,a major player in the minimally invasive coronary stent system segment. Such significant investment and growth positioned SMT for subsequent funding rounds and strategic expansion, providing Samara Capital with a profitable exit through secondary sales and strategic transactions. In an another prominent deals , global private equity firm Warburg Pincus invested $210 million in Meril Life Sciences, a leading manufacturer of medical devices and cardiovascular solutions. The investment facilitated the company's scale-up and led to eventual exit opportunities as the company attracted follow-on strategic interest and other secondary transactions.
- **Promoter/Management Buyback:** In select cases, founders or company management may buy back investor stakes, particularly if they want to regain control or if strategic priorities change.
- **Distress/Write-off:** If milestones are not achieved and product-market fit remains elusive, early-stage investors may exit with a write-off. It is more common among high-risk early-stage investments. While large publicly documented examples of write-off exits are not published generally due sensitive nature of failure disclosure, many early-stage investors write off losses on startups that miss milestones or fail market adoption.

5. FUNDING GAPS IN MEDICAL DEVICE SECTOR IN INDIA

5.1. Identification of Critical Funding Shortfalls in Medical Device Sector

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector. The Indian medical devices sector's contribution has become even more prominent as India supported the domestic and global battle against COVID-19

pandemic through the large-scale production of medical devices & diagnostic kits, such as Ventilators, Rapid Antigen Test kits, Real-Rime Reverse Transcription Polymerase Chain Reaction (RT-PCR) kits, Infrared (IR) Thermometers, Personal Protective Equipment (PPE) Kits & N-95 masks.

Challenges and Competitive Landscape

Despite growth, the Medical Device sector in India suffers from a considerable cost of innovation and manufacturing disability vis-a-vis competing economies like China, which is seen as a decade ahead in medical device technology and scale of manufacturing. Multinational corporations still dominate higher-tech sectors, which make up about 80-90 per cent of the market share for specialized devices and high-end surgical accessories. Other challenges faced by Indian manufacturers on account of lack of adequate infrastructure, domestic supply chain and logistics, high cost of finance, inadequate availability of power, limited design capabilities and low focus on research and development (R&D) and skill development etc.

- **Decreased venture capital** -
  Venture capital (VC) plays a crucial role in advancing medical device innovations and translating scientific knowledge into therapies. VCs often provide guidance and expertise to help start-ups navigate the complex regulatory and commercial landscape of the medical device industry. However, there has been a trend of decreasing interest from VC funds in investing in medical devices over a decade for several reasons. Medical device start-ups raised $8.8 billion (USD) in venture capital in 2023, falling nearly 62% since 2020. Several factors, including high interest rates, inflation, and ongoing international conflicts, have contributed to a decrease in both the number and value of VC deals.

- **Supply chain disruptions** Encouraging and supporting local production of healthcare equipment and gadgets will be important in 2022 to meet the goal of boosting healthcare spending to 3% of the country's GDP. Additionally, disruptions in the global supply chain have created chances for large-scale manufacturing in India. When a country relies heavily on imported medical devices, it becomes vulnerable to disruptions in the global supply chain. Events like trade disputes,

natural disasters, or pandemics can limit access to necessary products, making investors wary of investing in a market that is so dependent on external sources.

- **Uncertain Regulatory and Reimbursement systems:**
  Regulatory and reimbursement policies have a profound impact on the amount of capital and the types of life science projects that investors pursue. Medical device reimbursement involves navigating regulatory requirements such as approval by the regulatory authorities and securing coverage from payors (e.g., insurance companies or government programs). Reimbursement is the primary issue on every investor's mind, and it is one of the first things healthcare companies think about when developing new products or medical devices.
    - Reimbursement decisions covering - whether a device or procedure is covered as reimbursable, and at what amount, can have a significant impact on a provider's ability to access a particular technology, as well a manufacturer's ability (or willingness) to provide it. Uncertainties typically concern:
    - Safety and relative clinical effectiveness of a technology in a specified patient population, measured by short- and long-term outcomes that are relevant for patients,
    - Value for money of a technology and the question whether its reimbursement is considered an efficient use of available resources
    - the adoption and diffusion of a technology, such as the rate of uptake, disease areas in which the technology may be used, possible off-label use, and number of patients who may benefit from the technology.
    - the budget impact following adoption, i.e. the financial impact on the healthcare system, including additional costs and cost savings associated with reimbursing the technology.

These uncertainties may be considerable, especially when coverage and reimbursement decisions are taken close to the time of product approval and when they are inextricably linked to the characteristics of the technology, If coverage is uncertain, it is difficult for the manufacturer to predict whether an investment in a new technology will provide sufficient returns. This lack of predictability is an obvious barrier to securing venture funding. Moreover, it compromises innovation and limits patient access to advanced

technologies and solutions. In a nutshell, reimbursement and payer's coverage can make or break a device.

- **Slowing revenue growth** - Coming out of the COVID-19 pandemic, medical device companies experienced revenue growth as patients began to return for procedures. That growth slowed in subsequent years, however, leading industry watchers wondering what to expect in the future. In 2022, medical device revenues increased by 3.5% to $573 billion, compared to the 16% growth reported in 2021. The slowdown continued in the first half of 2023, with revenues for large MedTech firms "essentially flat" compared to the prior year period.

- **Research and Development Deficiency**
  Investment in medical devices R&D is far much smaller than for pharmaceutical sectors. On average, medical device firms invested 7.5 percent of sales in R&D, and it appears that this percentage has remained relatively stable over the last few years. Differences in R&D investment can be observed to depend on the size of the firm, and the particular type of device under development. For example, small firms invest almost double the industry average. The medical device industry requires more funding for research and development (R&D). India's ecosystem lacks the same level of investment in MedTech R&D, which is essential for developing innovative, home-grown solutions.

5.2. Global trends in Medical Device Sector

- **Mergers and Acquisitions Trends in Medical Device Sector: (2019–2024)**
  After three years of challenging elective surgery volume, it now appears to be climbing past pre pandemic levels. That means optimism among medical device companies may begin to rise and Mergers and Acquisitions could recover from low levels in 2023. Innovations in cardiology, robotic surgery, internet-connected wearable devices, and other areas may also spur deal making in 2024. Innovation across robotics, AI, machine learning, and IOT are driving advancement in this field. Dealmaking in medical devices may rebound in the coming year as elective surgery

volumes surge and innovation in cardiology, robotic surgery, AI-supported surgery, and other areas motivates industry leaders to bolster and reshape their portfolios, and, in some cases, to divest non-core assets. The large medical device competitors vary in their overall financial health coming out of COVID-19. Some are still recovering from the challenges COVID-19 created for their business. It is anticipated that in 2024 some of these companies will become more focused, considering carve out opportunities to improve their capital positions and enable them to focus on mergers and acquisitions in new and higher-growth areas. Overall, between divestitures and acquisition activity, we expect this industry segment to rebound in 2024. The slow pace of 2023 deal making in the medical device subsector, with the number of transactions almost 20 percent below 2022's numbers, is likely to give way to a more active 2024. Industry revenues are expected to rebound as the post-COVID-19 return of elective surgeries continues to accelerate, and companies that already have strong margin performance emphasize both technological advantages and building scale in selected areas. At the same time, companies in lower-margin sectors will likely look to expand into new procedure and device categories. Advances in devices that allow for remote patient monitoring, further improvements in diabetic care and cardiology, and an expansion of robotic surgery all could lead to increased mergers and acquisitions activity in 2024. AI-supported devices and services will continue to be an investment theme across the medical device landscape, and we expect increased numbers of deals as companies look to compete for both capabilities and talent.

- **Automation and AI in manufacturing** - Accelerating advances with AI and machine learning - Companies are incorporating robotics and other technologies to reduce costs and relieve workforce shortages. AI has rapidly entered mainstream awareness, significantly impacting the medical device industry. According to Grand View Research, the healthcare AI market is expected to grow from $15.4 billion in 2022 to $208.2 billion by 2030, driven by technologies in diagnostics and robotic-assisted surgery. Companies that effectively integrate AI and machine learning into their products stand to gain a competitive edge. Machine learning algorithms enable manufacturers to analyze data more accurately and quickly, enhancing both products and processes. Preparation for evolving regulations and market demands will be crucial for success. AI and machine learning have also facilitated personalized healthcare, improving medical decision-making and procedure

planning. When combined with advancements like 3D printing, the potential for individualized treatments is vast.

- **Emergence of Resilient Supply Chains** - Global supply chain challenges have become a significant concern, especially in medical device sector, where shortages of critical medical equipment can be life-threatening. Proactive solutions and strong partnerships are critical for manufacturers aiming to build resilient supply chains in the future. In response, healthcare and life sciences companies are prioritizing supply chain resiliency through several key strategies:

    1. **Multi-Sourcing**: Manufacturers are diversifying their component sources to avoid the risks of relying on a single supplier. While some core components may be difficult to multi-source without redesigns and FDA approvals, building strong relationships with key suppliers is essential.
    2. **Reshoring and Nearshoring**: Medical Device Companies are examining their supply chains to source parts from more stable locations, reducing risks associated with overseas manufacturing, particularly in the Asia Pacific region.
    3. **Design for Supply Chain**: Manufacturers are integrating supply chain considerations into the early design stages of products, allowing for more resilient sourcing decisions.

5.3. Successful MedTech Case Studies from other Countries

Japan:

Japan is at the forefront of medical device innovation, driven by its status as the world's third-largest economy and a robust healthcare system that accounted for 10.9% of its GDP in 2017, the highest in the Asia-Pacific region. The Japanese government has strategically fostered the Medtech sector through initiatives like the Future Investment Strategy under the Society 5.0 vision, incorporating IoT, big data, and AI to create a smart society. It has established networks for R&D, simplified regulatory frameworks for medical devices, and introduced pathways for approving software as stand-alone medical solutions. Trade shows like MedTech Japan and Medical Japan further facilitate global engagement, showcasing innovations and creating business opportunities. Organizations like JETRO actively support foreign companies entering the Japanese market through networking events, market-entry consulting, and business matchmaking services.

India can draw inspiration from Japan's structured approach by creating a similar ecosystem to attract investment in its growing medical devices sector. Key steps include simplifying regulatory frameworks, fostering R&D hubs, offering clinical trial support, and hosting international trade shows to showcase India's potential. Collaboration with international organizations and providing market entry facilitation, akin to JETRO, could bridge gaps and build trust with global investors. By prioritizing innovation, quality standards, and export readiness, India can position itself as a global manufacturing hub and reduce dependency on imports, aligning with its 'Make in India' vision.

China

China has positioned itself as a global leader in the medical device sector by establishing dedicated industrial hubs like the Suzhou Industrial Park (SIP) and Zhangjiang Hi-Tech Park, offering tax incentives, advanced infrastructure, and a supportive business environment. SIP alone has attracted over 5,100 foreign-funded projects, including 174 from Fortune 500 companies, reflecting China's strategic vision for integrating global investment with local innovation. These industrial parks not only foster R&D and manufacturing excellence but also serve as models of how to attract and retain multinational corporations in a highly competitive market.

India can emulate China’s success by enhancing its Special Economic Zones (SEZs) and Medtech parks to offer similar benefits, such as tax breaks, state-of-the-art infrastructure, and streamlined regulatory processes. Creating globally attractive industrial hubs dedicated to the medical device sector, combined with incentives for foreign direct investment, could transform India into a preferred destination for global Medtech manufacturers. By replicating best practices and promoting India’s capabilities on the global stage, India can accelerate investment inflows, foster innovation, and strengthen its position in the medical device industry.

United States of America

USA is a global leader in the medical device sector, driven by a strong innovation ecosystem, extensive R&D investment, and a regulatory environment that fosters product development and market entry. Post-COVID-19, U.S. medical device companies have increasingly sought partnerships with Indian manufacturers due to India's favorable manufacturing landscape. India offers cost-optimized production, skilled workforce availability, and robust government initiatives like the "Make in India" campaign, which mandates a minimum of 25% local manufacturing for government tenders. These policies have positioned India as Asia's fourth-largest medical device market, making it an attractive destination for U.S. companies seeking to expand and optimize operations. India can further encourage investment in its medical device sector through Public-Private Partnerships (PPP). By collaborating with private players to develop infrastructure, R&D hubs, and MedTech parks, India can emulate the U.S.'s success in fostering innovation. For U.S. medical device developers, partnering with Indian manufacturers offers strategic benefits, including access to a rapidly growing market, reduced production costs, streamlined regulatory support, and scalability. India's geographically advantageous location and advanced medical device parks ensure efficient supply chain management and production scalability. By aligning with Indian manufacturers, U.S. companies can strengthen their global footprint, improve cost efficiency, and capitalize on India's emerging role as a Medtech manufacturing hub. This mutually beneficial collaboration can drive innovation and make healthcare solutions more accessible worldwide.

Germany:

Germany has a more established and predictable regulatory framework, providing investors with greater confidence. Baden-Württemberg is one of the strongest Medtech locations in Germany. One fifth of all German employees in the Medtech sector work in Baden-Württemberg and achieve around 25% of the sector's total turnover in Germany. The Baden-Württemberg Medtech sector is dominated by small- and medium-sized companies: 568 of the 603 medtech companies listed in BIOPRO Baden-Württemberg's company database have less than 250 employees. The sector receives input from the diverse and well-structured research environment in Baden-Württemberg, including nineteen universities, four university hospitals and a large number of economically oriented research institutions and highly innovative biotechnology companies. Baden-Württemberg has a long tradition in the manufacture and development of surgical instruments; a large number of specialised companies have settled in the Tuttlingen area. Other Baden-Württemberg medtech areas focus on regenerative medicine, dental technology and diagnostics/molecular medicine.. Another German initiative is the DIGInostik innovation network, which focuses on developing improved diagnostic solutions through digital technologies and artificial intelligence (AI). This network is part of the ZIM program (Central Innovation Program for SMEs), supported by Germany's Federal Ministry for Economic Affairs and Climate Action (BMWK). The DIGInostik network connects various stakeholders like doctors, patients, clinics, laboratories, and developers from both the industry and academia. It fosters cooperation between research institutions, small and medium-sized enterprises (SMEs), and other relevant sectors to drive innovation. The network aims to enhance diagnostic solutions through digital tools and AI to improve healthcare delivery, from diagnosis to therapy. This includes using AI to analyze medical data and develop individualized treatment plans for patients. The

network is designed to boost the competitiveness of small and medium enterprises (SMEs) by linking them with research, development, and production. It provides access to funding programs and research collaborations that accelerate the development of new technologies. Since its launch, the program has submitted 12 projects with a total value of €14.5 million to federal and state funding programs, some of which have been approved. India can create platforms or networks that bring together small and medium-sized companies, universities, and research institutions in the healthcare sector. This would enable them to collaborate on innovations, share resources, and improve the development and commercialization of medical devices and diagnostics. India can launch a program similar to the DIGInostik network, which focuses on digital health technologies, including the use of artificial intelligence (AI) and machine learning to improve diagnostics, personalized treatments, and patient care.

United Kingdom:

The UK is attracting significant investment in its medical device sector through a groundbreaking £400 million public-private collaboration aimed at boosting clinical trials and enhancing healthcare infrastructure. This investment is part of the Voluntary Scheme for Branded Medicine Pricing, Access, and Growth (VPAG) program, which supports faster access to innovative treatments and strengthens the UK's life sciences sector.

The funding will be used to create 18 new Commercial Research Delivery Centres (CRDCs) across the UK to accelerate clinical trials, improving patient access to cutting-edge treatments. A substantial portion of the investment will go towards expanding the UK's capacity for commercial clinical trials, enhancing research delivery and patient recruitment through improved infrastructure, technology, and resources. This collaboration between the UK government and the healthcare industry aligns with the nation's goals to strengthen its global competitiveness in the life sciences sector, foster

economic growth, and make the NHS more efficient. By attracting investments from both public and private sectors, the UK is positioning itself as a leader in health innovation, which is likely to draw further global investments in the future.

Singapore:

Singapore tapped into its established expertise in electronics, precision engineering, and biomedical sciences, creating a seamless ecosystem for MedTech innovation. These sectors work in synergy, allowing efficient development of high-quality, advanced medical devices. The Singapore-Stanford Biodesign Programme partnered with global leaders to train the next generation of MedTech innovators, blending academic excellence with entrepreneurial expertise. Programs like the Biomedical Engineering Programme foster collaboration among clinicians, engineers, and scientists, addressing clinical needs directly.

6. FACILITATORY ENVIRONMENT FOR RISK BASED FINANCING

6.1. Overview of Conventional Risk based/Adjusted Financing Models

6.1.1 Convertible Debt: Convertible debt (also called convertible notes) is a form of financing that is often used by high-growth early-stage companies.

Convertible debt is a financing tool often used in the medical device sector, especially by startups and early-stage companies seeking capital for development. It functions as a loan from investors that can later be converted into equity. This structure allows medical device companies to secure funding without immediately determining the company's valuation, which can be challenging in the early stages of product development. Investors lend money with the agreement that the loan will convert into equity at a future financing round, typically at a discounted rate or with a valuation cap. This provides flexibility to both parties while giving the company immediate access to funds for research, regulatory approval, or market entry.

In the medical device industry, where product development is capital-intensive and timelines are long, convertible debt is particularly advantageous. It allows companies to defer valuation discussions until they have achieved significant milestones, such as clinical trial results or regulatory clearance, which can enhance valuation accuracy. For investors, convertible debt offers an opportunity to benefit from future equity at a discount while mitigating initial risks. Additionally, the interest accrued on the debt until conversion provides a level of security. This financing model bridges the gap between early-stage innovation and later equity investment, helping medical device companies advance critical healthcare technologies.

For investors, convertible debt presents an attractive opportunity to invest in early-stage medical device companies with reduced risk. The conversion feature allows investors to eventually convert their debt into equity at a discounted rate or a capped valuation, offering them upside potential once the company's valuation becomes clearer and more established. Additionally, the interest accrued on the debt provides a return during the waiting period, further adding to the appeal of the investment. This financing method also allows investors to participate in the growth of a potentially high-reward industry, like medical devices, with less exposure to the early-stage uncertainties of equity investments.

6.1.2 Milestone-Based Financing

Milestone-based pricing introduces a novel strategy for medical device development. The concept behind milestone-based pricing is to create a symbiotic relationship between the success of the service provider and the client. By setting a fixed cost for reaching predefined milestones, both parties are incentivized to work efficiently and collaboratively toward the successful and timely completion of the project. This approach establishes a mutual commitment to the project's success and fosters lasting partnerships. With projects lasting many months and even years, this model of fixed-cost pricing was initially greeted with scepticism. When embraced by medical device companies and their product development partners, milestone-based pricing has resulted in significant benefits contributing to lower project risk and accelerated path to commercialization.

Milestone-based pricing offers an added layer of financial transparency and control, eliminating the concern over unexpected expenses. This model contrasts sharply with traditional hourly billing systems, which can lead to projects spiralling out of control, causing inflated costs and extended timelines. The fund allocation is milestone based and shall be released in instalments based on review of the milestones achieved.

For medical device startups, the Milestone-based financing is crucial, particularly for early and mid-stage startups to de-risk product development and ensure disciplined use of capital. Securing proper funding to reach key milestones in medical device development like prototype completion, initial clinical testing, regulatory submission and market launch is very important. For example, in Indian context, for any new medical device following the Indian Medical device regulations regulatory path requires funding for legal expenses, patents and early engineering. Therefore; the seed round should necessarily cover design, development, verification, regulatory compliance and pre-commercial strategic manufacturing. Each achieved milestone can lend credence to the product for investors and serves as a trigger for subsequent funding rounds, helping to maintain financial momentum and support ongoing development efforts

Established Manufacturers may use milestone financing selectively for expansion projects, new product lines, or entering new markets. However, they more commonly prefer traditional finance for large-scale, low-risk expansions.

Investors assess the risk-reward at each TRL stage, with lower TRLs seen as much higher risk. It is generally observed that Seed and Angel Investors typically invest at early TRLs (TRL 2–4), focusing on early product concepts, proof-of-concept, and prototyping while Venture Capitalist invests at TRL 4–7, expecting functional prototypes, early

animal/human data, and regulatory planning. Growth and Expansion Funds are typically preferred for late-stage companies (TRL 7–9) with regulatory clearance, initial sales and scaling potential at global level. Below mentioned table illustrates various types of milestones relevant to financing and development in the medical devices, categorizing the typical examples of milestones, the common bottlenecks or challenges faced at each stage, the Technology Readiness Level (TRL) associated with those milestones and the types of organizations for which these milestones are most suitable. It provides a clear overview of how the development process is broken down into technical, regulatory, clinical, commercial, organizational, and intellectual property (IP) milestones:

Milestone Type	**Examples**	**Bottlenecks**	**TRL Stage**	**Suitability**
Technical Milestones	Prototype development, proof of concept	Technical hurdles, incomplete prototype	TRL 2–4	Startups
Regulatory Milestones	Regulatory submission and approvals	Regulatory uncertainty, documentation delays	TRL 6–7	Startups, SMEs, Established Companies
Clinical Milestones	Preclinical/clinical trials completion	High trial costs, recruitment delays	TRL 4–7	Startups, SMEs
Commercial Milestones	Product launch, first sales	Market access, reimbursement challenges	TRL 8–9	Scaling start-ups, Established Companies
IP Milestones	Patent grants, freedom-to-operate	Patent disputes, weak IP	Various	Both

Milestone-based financing can effectively address several bottlenecks faced by medical device companies during their development and commercialization journey by structuring funding releases around the achievement of specific, critical milestones. Below are some the bottle necks that can be addressed by the milestone-based financing model:

1. Regulatory Complexity

- **Challenge:** Regulatory processes and requirements from bodies like CDSCO or FDA can be complex, change over time, or have unclear guidelines, causing delays in approvals.
- **How milestone financing helps:** By tying funding disbursements to regulatory milestones—such as achieving specific documentation, submissions, or preliminary approvals—companies are incentivized to prioritize and allocate resources efficiently toward meeting regulatory requirements. This ensures focused progression and builds investor confidence by demonstrating regulatory compliance step-by-step, reducing uncertainty around changing rules.

2. Clinical Trial Costs

- **Challenge:** Clinical trials involve significant expenses and often experience delays due to recruitment issues or operational challenges.
- **How milestone financing helps:** Clinical trial milestones (e.g., trial initiation, patient enrollment targets, data collection completion) are linked to tranche releases, allowing companies to manage cash flow aligned to trial progress. This reduces financial strain by ensuring funds are expended strictly for trial advancement, encouraging timely execution and reducing wasted resources on stalled or prolonged trials.

3. Intellectual Property Risks

- **Challenge:** Patent disputes or reliance on unproven IP can stall progress or expose the company to legal and commercial risks.
- **How milestone financing helps:** Releasing funds upon achieving IP-related milestones such as patent filing, patent grants, or freedom-to-operate analyses encourages early mitigation of IP risks. This structured approach ensures that critical IP protections are secured before further capital is committed, protecting investor interests while supporting solid IP foundations.

4. Reimbursement Challenges

- **Challenge:** Difficulty securing insurance coverage or reimbursement listings can limit product adoption and market success.
- **How milestone financing helps:** Milestones may include obtaining preliminary reimbursement assessments or agreements with payors. Funding contingent on these milestones helps companies prioritize engaging with reimbursement pathways early in development, reducing the risk of market rejection and aligning product development with payer requirements.

5. Market Access Issues

- **Challenge:** Slow adoption by clinicians or hospitals, and complicated procurement processes can delay product uptake.
- **How milestone financing helps:** Commercial milestones tied to market access—such as securing first purchase orders, partnership agreements, or distribution deals—focus company efforts on overcoming adoption barriers. Funding linked to such milestones helps ensure resources are actively directed to marketing, partnerships, and customer engagement, accelerating market penetration.

6. Funding Gaps

- **Challenge:** If milestones are not reached, future funding can become uncertain or cease entirely, creating a risk of development halt.
- **How milestone financing helps:** This model inherently manages investor risk by disbursing capital only after successful milestone completion, thus incentivizing efficient use of funds. It ensures continued investor support is contingent on demonstrable progress, reducing exposure to failure, and providing transparency on investment value. Startups and investors can plan funding rounds realistically and avoid overextension.

6.1.3. Net Present Value with Risk-adjustment

Based on the concept that money now and money in the future cannot be directly compared with one another, the net-present-value analysis subtracts the value of what all the cash coming in from the investment would be worth today from the value of what all the costs and expenses of the investment would be worth today and shows how the potential investment would compare to the rate of return of some alternative investment. This type of analysis helps the investors to decide which investment would provide the most value in the future. It is important to further analyze this data with a break-even analysis, a payback analysis, and a net-present-value analysis. These analyses can show the short- and long-term financial implications of the investment and the length of time it will take for the investment to pay itself off. Such analyses are useful in sectors where there is an initial lump sum investment at the beginning of a project followed by a stream of revenue over a period of years in the future, as is the case with some of the conventional and me-too medical device manufacturing sectors.

For the innovative MedTech products, however Risk-adjusted net present value (rNPV) is a method used to value future cash flows of a product, adjusted for the probability of success at various stages before discounting them with a risk rate. If the rNPV is negative, it suggests that the product may result in a financial loss and should not proceed. However, rNPV can vary significantly based on the data inputs and given the high costs (many times in billions of USD) of bringing an innovation to market without guaranteed

reimbursement, the financial risk is substantial. Complex and invasive devices generally require substantial clinical trials and assessment before approval for market launch is granted, whereas non-invasive and low-risk devices face minimal regulatory hurdles before they can be marketed. Risk adjustment models help account for these uncertainties by incorporating the likelihood of regulatory approval into financial projections. A reconfiguration of approaches could offer more value by considering real-world data, updated clinical success rates, and evolving reimbursement models, particularly in the later stages of product development.

6.1.4. Revenue-Based Financing (RBF) :

Revenue-based financing is a method of raising capital for a business from investors who receive a percentage of the enterprise's ongoing gross revenues in exchange for the money they invested. In an RBF investment, investors receive a regular share of the businesses' income until a predetermined amount has been paid. Typically, this predetermined amount is a multiple of the principal investment. For medical device startups, which often face extended regulatory timelines and delayed revenue streams, RBF provides non-dilutive funding that aligns well with their growth and cash flow cycles.

This model is appealing for companies aiming to retain ownership while scaling sales and reaching the commercialization stage. With RBF, the repayment structure is flexible and payments increase or decrease based on the company’s revenue flow, making it more manageable during periods of fluctuating sales.

6.2 Blended Financing Approach

Blended financing in the medical device sector refers to the strategic combination of public and private investment to fund the development and commercialization of medical technologies. This approach aims to reduce financial risks for private investors by leveraging public or philanthropic funds, thus encouraging more investment into high-risk, high-reward innovative medical devices. The blended finance model hits serves two purposes- it uses development finance and philanthropic funds to attract private capital into deals and the private investors receive financial returns which are in line with market expectations. In doing so, it not only helps reduce the dependency of start-ups on government funding but also accelerates the building of commercially viable social impact projects.

By combining grants, debt and equity, blended finance allows medical device companies to scale operations while ensuring financial sustainability. It can help the SMEs of medical device sector integrate cutting-edge technologies into device manufacturing and delivery systems, capacity-building efforts, market validation and demand generation thereby; paving the way for widespread adoption of medical innovations.

6.3. Global Examples of Blended Financing & Applicability to India

6.3.1 Global Fund:

The Global Fund is a worldwide partnership to defeat deadly infectious diseases like HIV, tuberculosis (TB) and malaria and strengthen health systems of most effected countries. It raises and invests more than US$5 billion a year and is a perfect example that demonstrates that by working hand-in-hand with civil society, governments, private sector partners, philanthropists, technical partners and communities affected by the diseases, society can save lives and dramatically change the course of HIV, TB and malaria.

It works closely with countries to identify and deliver blended finance opportunities as a complement to traditional grants. For example, to enhance domestic funding for TB, the Global Fund is executing blended finance transactions with partners like the World Bank. The Global Fund reduces the cost of the loan to the country, and in exchange, the country commits to using the proceeds to strengthen its TB programs. Looking ahead, countries are also leveraging integrated platforms to provide TB services, including lab sample transport and community service delivery platforms.

The Global Fund supports countries to ensure the effectiveness, efficiency and equity of our investments whilst ensuring that inputs are achieved at lowest possible cost, to maximize value for money. In the last grant cycle (2021-2023), the Global Fund supported almost 50 countries in the costing of national strategic plans for HIV, TB or malaria, and in improving efficiency in service delivery. The Global Fund will continue to explore the ways by which value for money can be optimized.

6.3.2 MedAccess (UK)

MedAccess is a social finance company, wholly owned by the UK's CDC Group. With a mission to make global healthcare markets work for everyone, it applies blended finance to make diagnostic devices, like rapid HIV and malaria test kits, more accessible in underserved areas. Its work is funded by UK aid through the Foreign, Commonwealth & Development Office. MedAccess offer volume guarantees that reduce commercial risk and allow medical manufacturers to accelerate supplies into new markets at affordable and sustainable prices. In this way, medical diagnostic tests and medical devices can reach patients far sooner than existing market forces would allow. During the peak covid times, MedAccess announced support for UNICEF to secure vital COVID-19 medical products, including diagnostic tests and clinical management supplies, for low- and middle-income countries. MedAccess, provided a guarantee of up to US$ 50 million enabling UNICEF to secure essential products from suppliers in the fight against the virus.

6.3.3 FIND (Switzerland)

FIND seeks to ensure equitable access to reliable diagnosis around the world. FIND connects countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. Founded in Geneva, Switzerland, in 2003, FIND has regional hubs in Kenya, India, South Africa and Viet Nam. FIND Diagnostics and VIA Global Health partnered recently to expand access to quality diagnostics in low- and middle-income countries. FIND and VIA Global Health have signed an agreement that will provide new routes to market for regional and global manufacturers of high-quality diagnostic tests The agreement brings together VIA Global Health, a leading online marketplace that delivers medical products to over 80 countries, and the DxConnect Marketplace, conceived by FIND to directly connect buyers with approved test suppliers to serve market segments that cannot access quality products through other procurement mechanisms . In the first instance, rapid diagnostic tests from Premier Medical Corporation in India will be made available to purchase from VIA Global Health by buyers for low- and middle-income markets

6.3.4 Samridh Healthcare Blended Finance Facility, India

The SAMRIDH Healthcare Blended Finance Facility is taking the measures to overcome some of the challenges associated with adopting blended finance to achieve scale. Supported by the United States Agency for International Development (USAID) in collaboration with Atal Innovation Mission & Women Entrepreneurship Platform, NITI Aayog, Principal Scientific Advisor to the Government of India, the National Health Authority, Indian Institute of Technology, Rockefeller Foundation, Axis Bank, IndusInd Bank, HDFC Bank, Caspian Debt, and Centre for Cellular and Molecular Platforms, SAMRIDH is managed by IPE Global to advocate the regulatory changes required to scale up the adoption of the blended finance solutions across the healthcare ecosystem.

To mitigate the challenges concerning mobilization of private capital and fostering strategic partnerships to implement multi-stakeholder models, the SAMRIDH facility is leveraging philanthropic capital to partner with financial institutions, including Banks and NBFCs. Through this experience, important learning have emerged that acknowledge gaps in donors' expectations versus private funders. The win-win solution is to create social success notes or partial risk guarantees, which provide capital to for-profit enterprises with a social impact mindset. These structures provide a much-needed impact on philanthropic capital and commercial returns to private capital. In addition, SAMRIDH assesses the commercial viability and technical robustness of the solutions to impact the most vulnerable populations and provides technical assistance to social enterprises. Since its launch in 2020, SAMRIDH has made significant advancements toward strengthening the access, quality, and responsiveness of healthcare delivery in India.

Key achievements include:

- Recognition among ‘India’s top 50 COVID-19 last mile responders’ by the World Economic Forum.
- Mobilized a capital pool of $300 million to offer both grant and debt financing provisions to healthcare enterprises and innovators, augmenting their capacity for the production and supply of high-impact health solutions.
- Winning the P3 Impact Award 2022, led by the U.S. State Department’s Office of Global Partnerships, the University of Virginia Darden School of Business Institute for Business in Society, and Concordia.

6.4. Successful Examples of Blended Financed Indian MedTech companies

6.4.1 Blackfrog Technologies:

A med-tech company specializing in the last mile delivery of medical supplies and biologicals. Their groundbreaking invention, EMVÓLIO, a portable, active cooling, battery-powered device facilitates safe last-mile delivery of COVID-19 vaccines across the country. The enterprise needed to raise funds to increase its manufacturing capacity and expand its presence to other geographies.

Investment Manager: IIT-Delhi, Caspian Debt & IPE Global

Developmental Funder: USAID and Rockefeller Foundation Launch Year: 2021

Total Investment Size: USD 200,000

Interest Subvention: 10% p.a. for 18 months | Returnable Grant: USD 71,000 Partial Risk Guarantee: USD 114,000

Challenges: Given the nascent stage of the enterprise, Blackfrog was experiencing a cashflow crunch triggered by long working capital cycles, high up-front costs, and limited manufacturing capacity. Combining returnable grants with a commercial loan from NBFC allowed the enterprise to scale up faster and achieve financial sustainability without relying heavily on the equity funds.

How Blended Finance Approach Helped Blackfrog Technologies Through the blended finance structure, Blackfrog was able to avail a loan from Caspian Debt, a leading NBFC. However, given the risk profile of the enterprise, there was a requirement for additional collateral to avail the loan and initial support to service the loan at market rates until entity achieves commercial sustainability. Given the future demand for the EMVÓLIO product and the order pipeline, the enterprise was a good fit to avail a blended investment for business expansion and long-term sustainability. Further, Blackfrog was provided with scale-up advisory support through technical assistance facility of USAID to enable access to international markets such as Africa.

6.4.2 AERBIOSYS INNOVATION

Aerobiosis Innovations Private Limited is a company focused on developing affordable life-saving medical equipment with advanced technologies for hospitals, medical institutions, and individual practitioners.

The company was co-founded in 2019 by two young Biodesign Innovation fellows (3rd Cohort) of the Center for Healthcare Entrepreneurship (CfHE) and incubated at the Indian Institute of Technology, Hyderabad.

Investment Manager: C-CAMP, DST and IIT Hyderabad

Developmental Funder: CSR (Corporate Social Responsibility) Funding

Total Investment Size: USD 88.5K

Challenges The high prevalence of respiratory diseases in India, especially in semi-urban and rural areas, highlighted a critical demand for affordable and accessible ventilators. However, the barriers included limited healthcare infrastructure, the absence of trained pulmonologists, and frequent power outages in primary healthcare centers (PHCs). Additionally, the economic burden on patients and families from rural areas needing ICU care in urban hospitals exacerbated the issue, as families incurred significant debts for transportation, treatment, and lodging

How Blended Finance Approach Helped Aerobiosys Innovation

SAMRIDH initiative, was instrumental in overcoming these challenges. This approach combined public funding, private investments, and philanthropic contributions to support Aerobiosys' mission. The funding enabled the development and deployment of Jeevan Lite, a cost-effective, IoT-enabled ventilator with unique features such as a cloud-based platform for real-time monitoring and telemedicine support. It also facilitated outreach to rural healthcare settings, ensuring scalability and sustainable impact.

6.4.3 CARDIAC DESIGN LABS

Cardiac Design Labs (CDL) is a healthcare technology company that develops innovative medical devices and software solutions. Cardiac Design Labs provides efficient cardiac monitoring and diagnosis by deploying intelligent systems that enable automatic remote reporting.

Investment Manager Unitus Seed Fund

Developmental Funder: BIRAC

Total Investment Size: USD 2.22 million

Challenges

The COVID-19 pandemic exacerbated these challenges and created a demand for reliable remote monitoring systems that would minimize the risk of exposure to the coronavirus and allow medical specialists to monitor multiple patients simultaneously from anywhere in the world. Padma Rhythms is a long-term cardiac monitoring device that helps diagnose cardiac rhythm problems earlier than they become acute. It is a five-day test that works by transmitting the data through the patient's phone and with the help of in-house developed algorithms, remote monitoring of the patient is achieved and with data analysis the hospitals find it convenient to scale it up, to address the COVID-19 challenges in India.

How Blended Finance Approach Helped Cardiac Design Labs

SAMRIDH's financial assistance enabled CDL to manufacture and deploy 2,500 Padma Vitals / Padma Rhythms devices at district level hospitals, community health centers, and primary health centers. The enhanced sales have helped CDL to generate the required cash flows to support its operations and manufacture additional devices that will be deployed in hospitals located in tier 2 and 3 cities. SAMRIDH has further been catalytic in augmenting CDL's business capabilities by strengthening its marketing and sales effort towards reaching out to potential partners and customers for demos and trials.

6.4.4 COLLATERAL MEDICAL

Collateral Medical is medical device marketing and distribution company that specializes in leveraging technology and partnerships for delivering quality. Collateral Medical Private Limited (ColMed), a distributor of medical equipment and devices in India, is enhancing the distribution of oxygen concentrators at affordable prices to plug the supply gaps in healthcare facilities.

Investment Manager Carpediem Capital, SIDBI Venture Capital and Caspian Debt

Developmental Funder: BIRAC

Total Investment Size: USD $3.5 Mn

Challenges

The sudden onset of the second wave of COVID-19 in India posed the challenge of meeting an unprecedented rise in demand for medical oxygen. Due to the complexities involved in safely transporting liquid oxygen and the bottlenecks in prevailing demand and supply, the shortage was felt more acutely in tier 2 and 3 cities.

How Blended Finance Approach Helped Collateral Medical

The support from SAMRIDH enabled ColMed to streamline the process of distributing oxygen concentrators and other similar devices at discounted rates to make it affordable and accessible to the public.

SAMRIDH has assisted Collateral Medical (ColMed) with operational cost for the distribution of importing 3000 oxygen concentrators, ventilators, BiPAP machines and other similar devices to help bridging the supply gap in hospitals and enabling better management of COVID-19 patients. Under the partnership, ColMEd provided oxygen concentrators and ventilators and BiPAP devices at subsidized rates to hospitals and COVID-19 care units serving vulnerable populations and tier 2 and tier 3 cities.

6.4.5 HEMEXDX

Hemex Health is a healthcare technology company that is dedicated to improving healthcare outcomes globally by providing innovative, accessible, and affordable medical tests. Hemex Health is working to empower the frontlines of healthcare with our inexpensive, portable, and easy-to-use diagnostic device - Gazelle®. Gazelle provides affordable, accurate testing to new populations at sites where it is needed most. Hemex designs products for the real world by listening to the needs of providers including those located in remote and challenging settings. Initial tests include sickle cell disease, beta thalassemia, and (soon to be released) ferritin. Hemex Health develops affordable medical tests with gold-standard accuracy for point-of-care.

Investment Manager National Heart, Lung and Blood Institute

Developmental Funder: Business Oregon

Total Investment Size: USD 9.9 million

Challenges Cultural barriers, lack of awareness, and stigmas surrounding genetic testing further hinder the adoption of diagnostic services. The absence of widespread newborn screening and premarital testing programs delays early intervention, exacerbating the disease burden. Scaling affordable diagnostics for economically disadvantaged communities while ensuring business sustainability remains a critical hurdle.

How Blended Finance Approach Helped HemexDx

Implementing the National Sickle Cell Anemia Elimination Mission (NSCEM) required coordinated efforts among central and state governments, NGOs, and private players, which can face misaligned priorities or delays. To overcome these challenges, HemexDx deployed innovative, portable diagnostic devices designed for resource-limited settings, collaborate with stakeholders for awareness and capacity-building initiatives, and leverage public-private partnerships to ensure sustainable financing for mass screening programs.

6.4.6 INACCEL

InnAccel Technologies' Saans is a groundbreaking, infrastructure independent, low-skill, and non-invasive neonatal Continuous Positive Airway Pressure (CPAP) device. Designed to offer short term breathing support for infants with respiratory distress syndrome (RDS), This device was conceptualized and developed in partnership with the Consortium of Affordable Medical Technologies (CAMTech) and the Department of Biotechnology, Government of India.

Investment Manager Mount Judi Ventures, Acunova Life Sciences and iTekniqs

Developmental Funder:

Total Investment Size: USD $6.06 million

Challenges

Respiratory Distress Syndrome (RDS) is a common breathing disorder among premature babies in India. 50,000 Babies die annually in India during transport to NICUs due to inadequate respiratory support. 1,50,000 Premature babies in India succumb annually to respiratory distress syndrome (RDS). To reduce these tragic losses, it is crucial to make CPAP therapy accessible in lower-level healthcare centers and suitable for transport to NICUs.

How Blended Finance Approach Helped InAccel.

Through this partnership, InnAccel Technologies, which was incubated at C-CAMP, received access to affordable finance and technical assistance to expand the production and distribution of SAANS, which was the world's first infrastructure-independent, easy-to-use, portable neonatal CPAP system that can provide lifesaving breathing support to infants in hospital settings, as well during transport. SAMRIDH's financial support has significantly boosted InnAccel's manufacturing capacity for Saans devices, ensuring wider availability.. InnAccel has leveraged SAMRIDH's support to raise further funding in the form of grants, and plan to raise equity, leading to a leverage of about 7x over SAMRIDH's support. SAMRIDH's blended financing approach promises to expand Saans' reach, enhancing neonatal care and saving lives across India.

6.4.7 JEEVTRONICS

Jeevtronics is known for developing the **SanMitra 1000 HCT and HCT EMS Biphasic Defibrillators**, the world's first dual-powered, ambulance-certified defibrillators. These devices are designed to address the critical need for reliable and affordable cardiac care solutions, particularly in resource-constrained settings. Jeevtronics' defibrillators can operate without electricity, thanks to their hand-cranked charging capability, making them ideal for deployment in rural hospitals and ambulances across India, where power outages are common.

Investment Manager Indian Institute of Management Calcutta, Tata Group, Venture Center, and IKP Knowledge Park

Developmental Funder: BIRAC, DBT grant

Total Investment Size: USD 47 million

Challenges

The journey of **Jeevtronics** is a clear example of how India is seeing a robust start-up ecosystem as enterprises come up with innovative solutions in the healthcare sector, especially with the COVID-19 pandemic unfolding. However, like any other new enterprise, it also lacked affordable capital and business advisory support to scale their solutions and reach out to vulnerable populations in hard-to-reach areas low-income or rural markets due to the high cost of development and distribution.

How Blended Finance Approach Helped Jeevtronics

Blended finance, facilitated by SAMRIDH and supported by USAID, played a pivotal role in overcoming Jeevtronics' challenges. Through financial and business advisory support, SAMRIDH enabled Jeevtronics to scale its innovation by expanding market presence, optimizing distribution, and securing affordable working capital loans. This support helped the company design a commercial strategy to ensure a steady flow of orders, enabling the widespread deployment of its dual-powered defibrillators in resource-constrained hospitals and ambulances across India. Blended finance also bolstered Jeevtronics' research and development efforts, allowing the company to enhance its product portfolio and pursue strategic partnerships for scaling up.

6.5 Recommendations for broadening the Financing Options in Medical Device Sector in India

6.5.1 Public Sector Initiatives

Governments play a crucial role in mitigating risks associated with the medical device sector by offering policies that encourage investment, innovation, and market access. These policies may include tax incentives, subsidies, and grants aimed at reducing the financial burden on companies developing innovative medical devices

Public sector initiatives for risk mitigation of investments in the medical device sector are essential to ensure safeguarding of long-term investments in medical devices while protecting the public health. These initiatives are led by government bodies and public health organizations to establish regulatory frameworks, provide guidelines, and monitor device performance. The real trouble the medical device manufacturers face is the capital expenditure. In order to set up a manufacturing unit, they need to invest huge capital. For addressing this issue, the Government can invest on the land, infrastructure and to an extent on machinery for scientific facilities. This can bring down the need of huge capital investment and several entrepreneurs or industrialists can come forward to set up their factories as the biggest problem is solved.

6.5.2. Investment in Research and Development (R&D) & Funding by Venture capital firms

Large and small medical device companies both play a role in the development of new medical devices. Small medical device companies are engaged primarily in developing new medical technologies, and typically their work is narrowly focused on a specific therapeutic area. These companies have traditionally been funded by venture capital firms that hope to profit if the companies develop promising products. The prospects for these companies are uncertain given the challenges of securing enough start-up funding, developing the new medical device itself, figuring out how to manufacture the device in a cost-effective manner, obtaining the necessary regulatory approvals, and marketing the device to providers such as hospitals and physicians. These companies typically spend a large share of their revenues on research and development and may be unprofitable for years before developing a viable product or going out of business.

6.5.3. Public-Private Partnerships

Public-Private Partnerships (PPPs) represent a strategic collaboration framework that plays a pivotal role in advancing the medical device industry in India. These partnerships harness the unique capabilities of both the public and private sectors, combining the regulatory expertise of the former with the innovation, efficiency, and technical prowess of the latter. This synergistic alliance is strategically tailored to address the critical requirements of the healthcare sector, with a specific focus on the development and deployment of cutting-edge medical technologies. At its core, the PPP model within the medical device industry is intricately designed to expedite innovation and enhance the delivery of healthcare services. This concept is firmly grounded in the recognition that when the public sector's expansive reach and regulatory oversight unite with the private sector's agility and resourcefulness, the potential for significant advancements in medical technology is magnified. These collaborative endeavours typically encompass a spectrum of activities, spanning research and development, manufacturing, and the distribution of medical devices.

An inherent characteristic of PPPs is the equitable sharing of risks. Through the equitable distribution of risks associated with innovation and market dynamics between public and private entities, these partnerships establish a more stable environment conducive to sustained investments in medical technology. PPPs streamline the transition from development to deployment, a critical aspect within a sector where the timely introduction of medical devices can significantly influence public health outcomes. PPPs within the medical device sector extend beyond mere financial and infrastructural collaborations. They encompass knowledge exchange, capacity enhancement, and policy formulation, thereby ensuring a comprehensive approach to healthcare innovation. This multifaceted partnership model is of particular relevance in a nation like India, characterized by diverse healthcare challenges mirroring its demographic and geographical diversity. The concept of Public-Private Partnerships in India's medical device industry embodies a collaborative approach that is indispensable for bridging the existing gaps in healthcare innovation and service delivery. By harnessing the strengths of both the public and private sectors, PPPs are purposefully engineered to foster a sustainable and impactful healthcare ecosystem that remains responsive to the ever-evolving needs of a diverse and burgeoning population.

India's medical device industry, characterized by its complexity and potential, is currently undergoing a significant transformation driven by the strategic collaboration between public and private sectors, known as Public-Private Partnerships (PPPs). In a nation where

healthcare demands are as diverse as its population, PPPs can emerge as a critical solution, offering a synergistic approach to address the unique challenges of medical device sector. In recent years, India has seen a significant uptick in the adoption of PPPs, particularly in the medical device domain. Through partnerships, companies can gain knowledge, garner financial support, and strengthen their pathway to market. These relationships generally involve groups such as local stakeholders, NGOs, private companies, and academic institutions. Andhra Pradesh Medtech Zone was first conceptualized in November 2015 as India's first medical device park on the PPP model. It is India's premier medical technology park, with common manufacturing & scientific facilities. Through its unique governance model, it has been able to stitch across government funding for facilities which are being operated by private companies, thereby making it viable for startups working on innovative products & research. The unique model where manufacturers and innovators can utilize the innovation value chain support created by AMTZ in the complete product development, technology upgradation and market access. Innovators focus on innovation while AMTZ aids in regulatory affairs, policy making and making the products commercially viable.

6.5.4. Establishing of Social Impact Bonds (SIBs): Social Impact bonds can be another innovative blended financing instrument that blends public, private, and philanthropic capital through performance-based contracts dedicated to creating social impact. In a SIB, a risk investor provides the initial capital to the social enterprise (implementation partner) to scale its work. An outcome funder(s) repays the risk investor if and when the project's target outcomes are achieved, and the on-ground impact has been generated. Social Impact Bonds can also be categorized as Pay-for-Performance instruments. They enable desired outcomes to be achieved, triggering success payments to implementers and repayment of principal to investors via outcome sponsors. Social Impact Bonds (SIBs) represent a new way to finance social service and health promotion programs whereby different types of investors provide an upfront investment of capital. If a given program meets predetermined criteria for a successful outcome, the government pays back investors with interest.

6.5.5. Microfinance : An Alternative Means of Healthcare Financing for the Poor

The success of a country’s start-up ecosystem is reflected by the entry of homegrown start-ups in international markets. Microfinance solutions and use of crowdfunding

platforms can be one of the important steps towards supporting the early-stage development of medical devices. These platforms can democratize access to capital by allowing small investors or the general public to contribute to the funding of innovative devices.

6.5.6 Industry-academia and stakeholder partnerships to bolster start-ups: With an increasing focus on industry-academia partnerships in India, as highlighted in Budget 2023 and the focus on implementation of New Medical Device Policy, the next imperative step for India can 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 recognized globally. Facilitating dialogue between hospitals, investors, regulators 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.

6.5.7. Government support Regulatory Frameworks and Standards

Risk management is also a regulatory requirement from the technical perspective. Investors need to be aware the of the Risk management principle associated with the safety and performance requirements of medical devices of their interest. Regulatory authorities globally demand the incorporation of risk management principles into the life cycle of medical devices. From the U.S. Food and Drug Administration (FDA) to Australia's Therapeutic Goods Administration (TGA), and the European Union's Medical Device Regulation (MDR), a solid risk management system is a prerequisite for market entry.

6.5.8. Funding Options for Capital Expenditure and Operational Expenditure

Funding options across Capital Expenditure, Research & Development and Operational Expenditure are interdependent pillars that drive growth in the Indian medical device sector. Capital Expenditure funding empowers manufacturers to build robust domestic infrastructure, R&D funding spurs innovation and product development essential for competitive differentiation and Operational Expenditure funding sustains business operations, enabling commercialization and market expansion. Medical device manufacturers in India have multiple options to access the funding pathways for capital expenditures. Leading financial institutions (e.g., ICICI Bank, Bajaj Finserv etc.) offer

machinery and medical equipment finance with typical interest rates ranging from 9.7% to 14% per annum, depending on equipment type, applicant credit profile, and tenure. Their offered Loan sizes can go up to Rs. 30 crores with tenures as long as 10 years. The working capital lines/overdrafts at interest rates generally are within the same band (10–14%) applied for capex loans. Additionally, many governments of states like Haryana have come up with Haryana's Medical Devices Manufacturing Policy in year 2024 which provide capital subsidies ranging from 5% to 25% of eligible capital expenditure (up to Rs. 300 crore), reimbursed over ten years. Many VCs and PE firms are also increasingly financing scaling manufacturing operations.

7. PROMOTING SEED CAPITAL AND SERIES FUNDING

7.1. Strategies for attracting Seed Capital

7.1.1 Utilization of Crowdfunding Platforms - Crowdfunding is the practice of asking for money to fund a specific goal, generally through a website dedicated to crowdfunding, from the general public. Crowdfunding of medical devices is still a gray area for FDA as many in the industry question if the practice of crowdfunding with reward-based returns is considered 'preselling' or 'marketing' the device in advance of clearance or approval. FDA considers any products that are distributed (interstate commerce) prior to clearance or approval as 'adulterated'. Marketing activities prior to clearance without appropriate disclaimers (e.g., investigational or regulatory submission status) is considered misbranding and false or misleading labelling. Yet, several start-up companies have engaged in crowdfunding, using donation-based and reward-based methods, as a way to pay for the cost of developing medical devices and of conducting clinical or usability studies to support the remaining development activities and regulatory submission activities.

7.1.2 Leverage Incubators and Accelerators - Leveraging incubators and accelerators can significantly enhance a startup's ability to attract seed capital funding in the medical device sector. These programs provide startups with essential resources, mentorship, and networking opportunities that increase their credibility and appeal to potential investors. By participating in an incubator or accelerator, startups gain access to experienced mentors who can refine their business models, optimize product development, and develop compelling pitches, making them more attractive to investors. Additionally, these programs often facilitate connections with venture capitalists and angel investors who are specifically interested in health tech innovations. Furthermore, the structured support and resources provided by incubators and accelerators enable startups to demonstrate

progress and milestones more effectively, showcasing their potential for growth and scalability. This combination of expert guidance, networking opportunities, and enhanced credibility positions startups favorably in the eyes of investors, ultimately increasing their chances of securing the necessary seed capital to advance their medical device innovations.

7.1.3 Embracing the MVP approach -Minimum Viable Product (MVP) in Medical Device broadly refers to create a prototype. The concept of the Minimum Viable Product (MVP) applies to medical device startups as well involves using prototypes to streamline product development. Product development can be viewed in several phases, with each phase representing its own MVP. Initially, the development begins with an idea or concept, which might start as a simple sketch or screenshots—this serves as the first MVP.

The process includes building prototypes, learning from them, iterating, and repeating. As the development progresses, the next stage involves defining the intended use and engaging end-users. At this point, the MVP evolves into a proof-of-concept prototype. Creating proof-of-concept MVPs and involving end-users early in the process is crucial for refining the product. This iterative process continues as each MVP progresses closer to production. Including end-users in feedback sessions at each stage is essential, as these individuals will ultimately champion the product. Early and consistent engagement with end-users significantly enhances the chances of market success for the medical device.

7.2. Role of Incubators and Accelerators in supporting Startups

Incubators and accelerators stand as two essential pillars for fostering creativity and accelerating business expansion for early-stage entrepreneurs and innovators.

Incubators offer crucial resources including coaching, networking opportunities, and occasionally, finance, in a nurturing atmosphere for developing entrepreneurs. On the other hand, accelerators are meant to help organizations that currently have a defined product or minimum viable product (MVP) develops quickly. The accelerator experience offers connections, mentorship, and seed funding. This helps the startup achieve more growth in less time than they would on their own. A key difference for an accelerator is the company has proof of product-market fit. They have some customers and growth and now want to capitalize on that as soon as possible. In some accelerators, startups receive seed funding in return for a small stake in the company.

Incubators tend to attract founders and stakeholders from a local area. Accelerators attract entrepreneurs who may need to relocate to take part in the program. Accelerators may also provide office space, rather than an open co-working setting.

The relocation aspect is one reason why accelerators have fixed start and end dates. Unlike some incubators, you can't stay in an accelerator for an indefinite amount of time. Both the models offer extensive support, including financing, access infrastructure and resources, contacts to investors, and coaching. The significance of these programs is enhanced multi-fold in the MedTech industry considering the specialized infrastructure and mentoring requirements, compliance considerations, capital intensive-high risk investments and industry insights to drive innovations that potentially impact lives. Below are the main functions of Incubators and Accelerators:

- **Funding and Financial Support**:
  The funding might range from an investment in building prototypes, to investment for manufacturing and production, to funds for marketing and distribution. This funding may take the form of actual funds, or it may be provided through making manufacturing or research and development fasciitis available to medical device startups as part of the medical device accelerator and its agreement.
  .
- **Mentorship and Guidance**: Accelerators and incubators provide invaluable mentorship to startups in the medical device sector. Experienced mentors, often industry veterans or successful entrepreneurs, offer guidance on various aspects of business development, from refining product ideas to navigating market challenges. This mentorship helps startups avoid common pitfalls and accelerates their growth by providing tailored advice on technology development, business strategy, and market entry.

- **Access to Resources**: Startups in the medical device sector benefit from access to a wide range of resources offered by accelerators and incubators. This includes funding opportunities, physical workspace, and advanced laboratories equipped with necessary technology. Additionally, they may gain access to networks of investors, potential customers, and industry contacts, which are crucial for building partnerships and securing the necessary financial backing for their innovations.

- **Accelerated growth:** If the incubator's goal is to hatch the startup, then the accelerator is all about funding and flight. An accelerator helps a startup attract funding to grow more quickly. It is like flight school for a new venture that wants to fly further, faster.

- **Regulatory Assistance**: Navigating the complex regulatory landscape is a significant challenge for medical device startups. Accelerators and incubators often provide specialized support in this area, helping entrepreneurs understand the requirements for FDA approval or other regulatory clearances. They may offer workshops, resources, and expert advice on best practices for compliance, which can significantly shorten the time needed to bring a product to market and ensure that it meets safety and efficacy standards. Prominent MedTech Incubators and Accelerators of India are mentioned in Table 5 below (Source: Crunchbase)

TABLE 5

Name Of The Organisation	Location	Investment In Medical Device Companies
Venture Catalysts	Mumbai, Maharashtra, India	Sunfox Technologies, Aikenist
IIT Mandi Catalyst	Mandi, Himachal Pradesh, India	Janitri, Ameliorate Biotech, Thinkphi Healthcare, BioNEST Catalyst Centre
JioGenNext	Ghansoli, Maharashtra, India	Tvasta, HealthifyMe
India Accelerator	Gurgaon, Haryana, India	Aindra Systems, Virohan, Qure.ai, CureMetrix, MedBot
Villgro	Chennai, Tamil Nadu, India	Nayam Innovations, Yostra Labs, Tricog Health, Ten3T
Tlabs	Noida, Uttar Pradesh, India	Superdoc
IIM Calcutta Innovation Park	Kolkata, West Bengal, India	Aarna Biomedical Products Private Limited, Agastya Buoyant Private Limited, Arogya MedTech Pvt Ltd, Cutting Edge Medical Devices, Monosha Biotech Private Limited, Mother Diagnostics
Crescent Innovation and Incubation Council	Chennai, Tamil Nadu, India	OMG Labs
Venture Center	Pune, Maharashtra, India	Kozhnosys Pvt Ltd, Sensivision Health Technologies Pvt Ltd
Atal Incubation Centre - Shiv Nadar University	Noida, Uttar Pradesh, India	A2Z Medical: A healthcare/medtech startup, Soundclear, Sparcolife Digital Healthcare Technologies, Raytom Medical Systems

Forum for Innovation Incubation Research and Entrepreneurship	Margão, Goa, India	Ubiqare Technologies, Swaas Health Technologies, WellnessIQ
NRL iDeation	Guwahati, Assam, India	Arohan AgriSciences
IKP Knowledge Park	Secunderabad, Andhra Pradesh, India	Innaumation Medical Devices LLP
HealthStart	Noida, Uttar Pradesh, India	Yostra Labs, PregBuddy
RevvX Hardware / IOT Accelerator	Bangalore, Karnataka, India	Cyclops Medtech
RICH Research and Innovation Circle of Hyderabad	Hyderabad, Andhra Pradesh, India	Olympus, UnivLabs Technologies Pvt Ltd
Amrita TBI	Kollam, Kerala, India	ZenOnco.io's, Circle Health (Healthcare Technology Systems)
Startup Oasis	Jaipur, Rajasthan, India	Redcliffe Labs
Villgro USA	Chennai, Tamil Nadu, India	Sunfox Technologies Private Limited,
MN iHub	Medchal, Andhra Pradesh, India	
Atal Incubation Centre - Center for Cellular and Molecular Biology	Hyderabad, Andhra Pradesh, India	Meril Life Sciences, Sahajanand Medical Technologies, Molbio Diagnostics, Redcliffe Genetics, BeatO
Incubation Centre IIT Patna	Bihta, Bihar, India	Stempeutics

8. RECOMMENDATIONS

Despite India's $12 billion MedTech market and the country’s potential to become a global manufacturing hub, scaling businesses in the sector remains challenging. Experts attribute it to hurdles such as an underdeveloped supply chain, regulatory complexities, and talent gaps. Investing in the medical device sector presents a unique opportunity to enhance healthcare systems while driving economic growth. However, the sector is often characterized by high risks stemming from regulatory complexities, capital-intensive R&D, and market uncertainties. The main risks to investing in it relate to technological obsolescence and the impact of the shift to value-based healthcare systems, as well as product-specific risks that include failure, withdrawals and related legal liabilities. The public sector plays a pivotal role in mitigating these risks through targeted, risk-adjusted measures that attract and sustain investments. Public sector interventions, such as subsidies, tax incentives, and public-private partnerships (PPPs), act as powerful risk mitigation tools for investors. Public-Private Partnerships (PPPs) in India's medical device sector also represent a strategic synergy that unfolds various technical advantages instrumental in reshaping the healthcare ecosystem. The medical device sector necessitates substantial investments, often daunting for both public and private entities individually. PPPs bridge these resource gaps effectively by amalgamating public funding with private investment, mitigating the risks inherent in high-cost projects, particularly in pioneering technology R&D, rendering long-term investments feasible for both parties.

The synergy of PPPs can harness the public sector's regulatory strength and the private sector's agility in research and development (R&D). This collaboration can foster an environment conducive to groundbreaking innovations in medical devices. Particularly advantageous is the capacity to develop technologies tailored to the unique healthcare needs of India's diverse population. Multidisciplinary expertise from fields such as engineering, medicine, and technology converges, fostering a holistic approach critical for innovative medical device development.

By leveraging financial incentives, regulatory reforms, and infrastructure development, governments can create a supportive environment that reduces barriers to entry and promotes innovation. These measures not only encourage domestic and foreign investments but also foster the development of life-saving medical technologies that align with public health priorities. On the basis of the data collected from primary and secondary sources, BHPL would like to make the following recommendations to mitigate investment risks and enhance commercial scalability in medical device sector in India:

1. **Implement a Staged, Milestone-Linked Capital Architecture:** Manufacturers should move away from seeking "blanket funding" and instead structure investment rounds tied to specific Technical Readiness Levels (TRL). By anchoring capital tranches to hard milestones—such as the completion of a functional prototype (TRL 4), successful animal studies, or the filing of a Form MD-14 for clinical investigation—firms can significantly lower the "risk premium" demanded by investors. This disciplined approach prevents premature equity dilution and provides a transparent roadmap that builds institutional trust over the long term.

2. **Utilize Blended Finance and Performance-Based Instruments:** To bridge the "Valley of Death" between R&D and commercialization, medical device manufacturers should actively pursue Blended Finance models. This involves layering high-risk commercial equity with low-cost "patient capital" from impact investors or government grants (like DoP, BIRAC's BIG or SBIRI). Furthermore, exploring Social Impact Bonds (SIBs) allows manufacturers to transfer performance risk; under this model, repayment to investors is contingent on achieving verifiable public health outcomes, thereby aligning the financial success of the manufacturer with social impact.

3. **Mitigate CAPEX through Shared Infrastructure and Clusters:** High upfront capital expenditure for specialized testing and manufacturing is a primary cause of failure of medical device companies. Manufacturers should strategically locate operations within Medical Device Parks (e.g., AMTZ or Telangana MedTech Valley). Leveraging these "plug-and-play" ecosystems allows firms to access common scientific facilities, gamma radiation centres, and 3D prototyping labs on a pay-per-use basis. This converts high fixed costs into manageable variable costs, preserving the manufacturer's runway for critical R&D efforts.

4. **Adopt "Design-for-Compliance" to Shorten Regulatory Lead Times:** Regulatory lag is a major investment deterrent. Manufacturers should integrate regulatory experts at the design stage rather than as a post-development afterthought. Utilizing the National Single Window System (NSWS) for a unified application process across CDSCO and other agencies reduces administrative friction. Proactively seeking US FDA or EU CE certification early in the process—even for products intended for the Indian market—acts as a "global gold standard" validation that drastically increases company valuation during exit negotiations or Series B/C funding rounds.

5. **Build Supply Chain Resilience through Localization and PLI Benefits:** To insulate against global price volatility and trade wars, manufacturers should leverage the Production Linked Incentive (PLI) Scheme. This should be coupled with a "China Plus One" sourcing strategy, identifying local vendors for non-critical components to reduce import dependency. Until domestic self-sufficiency is achieved, manufacturers should actively utilize custom duty concessions on imported high-end components to offset the cost disabilities faced against global competitors. Balancing this with the 'Make in India' vision will allow manufacturers to maintain price competitiveness while scaling up their domestic manufacturing capabilities. By achieving a higher percentage of local value addition, manufacturers not only benefit from government incentives but also present a de-risked profile to investors concerned about foreign exchange fluctuations and global logistics disruptions.

6. **Operationalize Cluster-Based Backward Integration:** Manufacturers should strategically position themselves within specialized MedTech parks to facilitate

convergence with ancillary industries. This proximity allows for "backward integration"—sourcing critical components and testing services from neighbouring units within the cluster. This geographical concentration reduces logistics costs, ensures quality control of high-end components, and mitigates the supply chain risks associated with fragmented manufacturing.

7. **Establish Integrated "Clinical Test-Beds" Hospital Partnerships:** Clinical validation risk is a significant hurdle for PE/VC investors. Manufacturers should move beyond simple vendor relationships with hospitals to form deep, futuristic collaborations. By developing dedicated clinical test-bed facilities in partnership with academic medical centres, manufacturers can validate research in real-world patient populations early. These partnerships provide access to real-world patient data and clinician feedback during the iterative design phase. This ensures that the final product has a demonstrated "product-market fit," significantly reducing the risk of commercial rejection or post-market safety withdrawals. This further provides the "Generalizability of Results" that institutional investors require, significantly reducing the risk of commercial failure due to lack of product-market fit.

8. **Implement Robust Product Liability Insurance Safeguards:** To protect against the catastrophic financial risk of litigation, manufacturers must treat Product Liability Insurance as an essential operational safeguard. Comprehensive coverage for design, manufacturing, or labelling defects not only protects the company's balance sheet but also acts as a critical "due diligence" check-mark for PE/VC firms who are wary of legal exposure in the healthcare sector.

9. **Strategize IP Portfolios as Valuation Anchors:** Manufacturers should view Intellectual Property (IP) not just as legal protection, but as a primary risk-management tool. A strong patent portfolio creates market exclusivity and justifies premium pricing. By securing patents for unique design elements and manufacturing processes early, companies can guarantee higher margins and provide investors with a clear, defensible path to a superior Return on Investment (ROI).

10. **Prepare for Strategic Exit through M&A Readiness:** Manufacturers must operate with the "end in mind" by aligning their internal governance and IP portfolios with the requirements of global acquirers. This includes maintaining a robust Quality Management System (QMS) and a clean Intellectual Property (IP) trail. Demonstrating a clear path to a trade sale or a strategic merger with a multinational corporation provides the liquidity assurance that institutional investors require, making the manufacturer a far more attractive destination for growth capital.

11. **Leverage Blended Finance for Social Impact Innovations:** To support business models focusing on vulnerable communities or high-impact diagnostics that may not attract traditional VC capital, manufacturers should adopt Blended Finance. By layering philanthropic grants with commercial equity, manufacturers can tackle "new frontiers" in MedTech. This structure provides a financial cushion for high-uncertainty R&D while effectively using private sector expertise to execute developmental strategies.

12. **Institutionalize "MedTech Entrepreneurship" within Internal R&D:** Manufacturers should bridge the industry-academia gap by creating "Entrepreneurial Projects" for postgraduate researchers (e.g., in collaboration with NIPERs). By offering flexible curriculum options where students work on real-world commercialization challenges instead of traditional research, manufacturers can build a pipeline of "original thinking" talent that is business-ready, reducing the human capital risk of innovation.

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Double-stranded DNA