Ministry of Foreign Affairs

Technology and Innovation Opportunities for India-Netherlands Collaboration in the Medical Devices Sector

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Technology and Innovation Opportunities for India-Netherlands Collaboration in the Medical Devices Sector

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Kingdom of the Netherlands

Disclaimer

This report has been drafted under the responsibility of the Embassy of the Kingdom of the Netherlands in New Delhi, India, commissioned by the ministry of Health, Welfare and Sport and the Ministry of Economic Affairs of the Netherlands. We are thankful to PwC in India for collaborating with us in preparing the report.

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Contents

Abbreviations

ABDM	Ayushman Bharat Digital Mission
ABHA	Ayushman Bharat Health Account
ABHIM	Ayushman Bharat Health Infrastructure Mission
AcE	Accelerating Entrepreneurs
AI	Artificial Intelligence
AIF	Alternative Investment Funds
AIIMS	All India Institute of Medical Sciences
AMR	Antimicrobial Resistance
AMR-Global	Antimicrobial Resistance Global
AMTZ	Andhra Pradesh Medtech Zone
ANRF	Anusandhan National Research Foundation
ASEAN	Association of Southeast Asian Nations
BETiC	Biomedical Engineering Technology Innovation Centre
BIG	Biotechnology Ignition Grant
BioNEST	Bioincubators Nurturing Entrepreneurship for Scaling Technologies
BIPP	Biotechnology Industry Partnership Programme
BIRAC	Biotechnology Industry Research Assistance Council
BIS	Bureau of Indian Standards
CAGR	Compound Annual Growth Rate
CAR-T	Chimeric Antigen Receptor T-cell
CBME	Centre for Biomedical Engineering, IIT Delhi
C-CAMP	Centre for Cellular and Molecular Platforms
CCMB	Centre for Cellular and Molecular Biology

CDSCO	Central Drug Standard Control Organization
CE	Conformité Européenne (European Conformity)
CFI	Centre for Innovation, IIT Madras
CHC	Community Health Centre
CORE	Co-Innovation and Research
CRS	Contract Research Scheme
CSIR	Council of Scientific & Industrial Research
CT	Computed Tomography
DBT	Department of Biotechnology (India)
DGHS	Directorate General of Health Services
DHR	Department of Health Research (India)
DoP	Department of Pharmaceuticals (India)
DPDP	Digital Personal Data Protection Act
DPIIT	Department for Promotion of Industry and Internal Trade (India)
DSS	Decision Support System
DST	Department of Science and Technology (India)
ECG	Electrocardiogram
EHR	Electronic Health Records
ESIC	Employee's State Insurance Corporation (India)
EU	European Union
EU MDR	EU Medical Device Regulations
EV	Electric Vehicle
FDA	Food and Drug Administration
FDI	Foreign Direct Investment

FFS	Fund of Funds for Startups
FHIR	Fast Healthcare Interoperability Resources
FITT	Foundation for Innovation and Technology Transfer, IIT Delhi
FSID	Foundation for Science Innovation and Development, IISc
FTA	Free Trade Agreement
FY	Finanical Year
GCC	Global Capability Center
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GINSERV	Global INcubation SERVices
HFR	Health Facility Registry
HIHI	Health Innovation Hub Ireland
HIPAA	Health Insurance Portability and Accountability Act
HPR	Healthcare Professionals Registry
HTA	Health Technology Assessment
HTIC	Healthcare Technology Innovation Center, IIT Madras
HWC	Health and Wellness Centre
ICMR	Indian Council of Medical Research
iCreate	International Centre for Entrepreneurship and Technology
ICU	Intensive Care Unit
IEC	International Electrotechnical Commission
IISc	Indian Institute of Science
IISER	Indian Institute of Science Education and Research
IIT	Indian Institute of Technology
IoT	Internet of Things

IP	Intellectual Property
ISO	International Organization of Standards
IVD	In-vitro Diagnostic Devices
JNCASR	Jawaharlal Nehru Centre for Advanced Scientific Research
KIC	Knowledge and Innovation Covenant
KYA	Know-Your-Approvals
LEAP	Launching Entrepreneurial Driven Affordable Products
LLP	Limited Liability Partnership
MAI	Market Access Initiative
MDR	Medical Device Rules (India)
MeitY	Ministry of Electronics and Information Technology (India)
ML	Machine Learning
MoE	Ministry of Education (India)
MoHFW	Ministry of Health and Family Welfare (India)
MoU	Memorandum of Understanding
MRI	Magnetic Resonance Imaging
MSDP	Medical Device Sector Development Program
MSME	Micro, Small and Medium Enterprises
MUMC	Maastricht University Medical Centre
NADP	Netherlands Antibiotic Development Platform
NCD	Non-Communicable Disease
NDHM	National Digital Health Mission (India)
NGO	Non-Governmental Organization
NIDHI	National Initiative for Developing and Harnessing Innovations (India)
NIMHANS	National Institute of Mental Health and Neurosciences

NIPER	National Institute of Pharmaceutical Education and Research (India)
NIRF	National Institutional Ranking Framework (India)
NITI	National Institution for Transforming India
NMDP	National Medical Devices Policy (India)
NMDPC	National Medical Device Promotion Council (India)
NSWS	National Single Window System
NTS	National Technology Strategy (Netherlands)
NWO	Dutch Research Council
OOPE	Out-of-pocket Expenditure
PACE	Promoting Academic Research Conversion to Enterprise
PE	Private Equity
PHC	Primary Health Centre
PHT	Personal Health Train
PLI	Production Linked Incentive
POC	Point of Care
PPP	Public-Private Partnership
PRIP	Promotion of Research and Innovation in Pharma-Medtech
R&D	Research and Development
RPM	Remote Patient Monitoring
RTA	Regional Trade Agreement
RVO	Netherlands Enterprise Agency
S&T	Science and Technology
SAARC	South Asian Association for Regional Cooperation
SAMRIDH	Startup Accelerators of MeitY for Product Innovation, Development, and Growth
SBIRI	Small Business Innovation Research Initiative

SCALE	Steering Committee on Advancing Local value-add & Exports
SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences and Technology
SEBI	Securities and Exchange Board of India
SEED	Sustainable Entrepreneurship and Enterprise Development
SIDBI	Small Industries Development Bank of India
SINE	Society for Innovation and Entrepreneurship, IIT Bombay
SJRI	St. John's Research Institute
SME	Small and Medium Enterprises
SNBNCBS	S N Bose National for Basic Sciences
SSMI	Strategic Sector Manufacturing Initiative
STEM	Science, Technology, Engineering, and Mathematics
STI	Science, Technology, and Innovation
STIP	Science, Technology, and Innovation Policy
TANSEED	Tamil Nadu Startup Seed Grant Fund
TAT	Turnaround Time
TCTD	Tata Centre for Technology and Design, IIT Bombay
TIDE	Technology Incubation and Development of Entrepreneurs
TIFR	Tata Institute for Fundamental Research
TRL	Technology Readiness Level
TTI	Technology Translation and Innovation
TTO	Technology Transfer Office
UMCG	University Medical Center Groningen
VC	Venture Capital

VWS	Ministry of Health, Welfare, and Sport (Netherlands)
WAH!	Water, Agriculture, and Health
WHO	World Health Organization

Introduction

About the Report

In the context of providing appropriate care[1] and creating long-term economic opportunities, the Dutch government is actively looking for international opportunities to collaborate in the field of medical devices[2].

This study aims to provide Dutch stakeholders, including government, industry, academia, and the Netherlands diplomatic network in India, with a clear picture and analysis of the short-, medium- and long-term scope of opportunities in the medical devices industry in India. The report aims to evaluate and provide recommendations and insights around the following four objectives:

1

Map out Indian labour-saving technological solutions

- Technological solutions in India that simplify and accelerate healthcare operations or increase patient self-sufficiency

2

Identify cross-border research and innovation opportunities

- Indian institutions and incubators with potential for collaboration

3

Strengthen the economic position of Dutch companies in India

- Healthcare landscape in India
- Challenges and opportunities faced by Dutch companies when entering the Indian market

4

Potential Areas for bilateral G2G collaboration

- Recommendations for government-to-government collaborations

The study offers insights into these areas and recommendations to help stakeholders navigate and capitalize on the opportunities in the medical devices sector.

[1] This refers to genuine transformation of healthcare by stimulating intensive cooperation between different parties. By doing so, unnecessarily expensive care or even unnecessary care can be avoided, the point-of-care can be shifted, care can be around patients by providing alternative types of care, such as e-health, domotics or also social support.
[2] A medical device is defined as any instrument, apparatus, appliance, software, material, or other article intended for use in humans for a medical purpose, encompassing diagnosis, prevention, monitoring, treatment, or alleviation of disease, injury, or handicap.

Executive Summary

Executive Summary

Introduction and Background

The Netherlands is recognized as a leader in medical device innovation, characterized by its quadruple helix model, which includes a robust network of patients, industry players, research institutions, and universities. The Dutch medical device ecosystem benefits from high levels of investment in R&D, advanced technological infrastructure, and a focus on addressing critical healthcare issues.

The Dutch government is proactively pursuing international collaborations in the medical devices sector with the aim of improving healthcare delivery and fostering long-term economic growth. In light of the significant increase in healthcare costs and the escalating shortage of healthcare personnel, the Netherlands acknowledges the necessity of global innovation partnerships to strengthen its medical device industry. These collaborations prioritize labor-saving technological solutions and patient empowerment. Addressing the increasing shortage of healthcare professionals by minimizing administrative burdens is crucial to allocate more time for direct patient care.

Therefore, it is necessary to pursue tech and innovation collaborations with rapidly growing countries like India. Identifying opportunities and formulating a multi-annual strategic approach for such alliances is crucial. The collaboration between India and the Netherlands is particularly advantageous, leveraging India's strong production capabilities and the Netherlands' extensive healthcare expertise. This partnership can facilitate a mutually beneficial exchange of technology and knowledge, advancing healthcare delivery and innovation to meet the growing global demand for medical innovations. Collaborating with India presents exciting opportunities. Increased stakeholders meetings can foster better understanding between India and the Netherlands, enhancing mutual growth. Aligning policies through stronger government-to-government collaboration can create synergies. There is great potential for expansion in medical technology, science, and innovation, promising fruitful advancements beyond current collaborations.
Over the years, the collaboration between India and the Netherlands has strengthened, particularly in healthcare and innovation. This partnership has been facilitated by various trade missions, with Dutch and Indian SMEs actively engaging in sectors such as digital health, MedTech, vaccines, and hospital-based solutions. The focus on MedTech has been particularly significant, with the 2023 mission led by Prime Minister Rutte highlighting the importance of this sector.

The National Technology Strategy (NTS) of the Netherlands is essential for preserving the Netherlands' competitive advantage amid rising global technological competition. Future collaborations should build on this strong foundation, addressing critical workforce shortages in healthcare delivery while enhancing patient self-sufficiency through innovation in medical technology. Promotion of cross-border research expanded market access, and utilization of existing funding opportunities will be key in creating a robust and scalable collaboration framework. Such initiatives will not only enhance healthcare delivery in both countries but also contribute to global goals of innovation, sustainability, and improved health outcomes.

This study aims to offer Dutch stakeholders—including government, industry, academia, and the Netherlands diplomatic network in India—a thorough analysis of labor-saving technological

opportunities in India that could be implemented in the Netherlands. It also formulates strategic approaches for collaboration. The report provides recommendations and insights to help stakeholders navigate and capitalize on these opportunities.

Overview of India’s Medical device industry

India's medical devices industry is rapidly growing, driven by increasing healthcare demand, technological advancements, and supportive government policies. Key policies include the Medical Device Rules 2017 and initiatives like MedTech Mitra and the PRIP scheme, which aim to enhance R&D capabilities and support innovation.

Currently valued at approximately €12.8 billion, the industry is projected to reach around €29 billion by 2030, with a compound annual growth rate of 12%. Despite this growth, high imports pose strategic and financial challenges, increasing dependence on international suppliers and burdening the national healthcare budget.

To address these issues, the Indian government has prioritized the development of medical device parks and clusters, fostering domestic manufacturing and innovation. Recent trade data shows export growth from €1.6 billion to €2.9 billion between 2018 and 2023, with large domestic conglomerates investing in the sector.

Government initiatives like the National Medical Devices Policy and the Market Access Initiative aim to boost local production and international competitiveness. However, the industry still faces challenges such as regulatory complexities and a fragmented market landscape. By leveraging low-cost manufacturing capabilities and fostering international collaborations, India has the potential to become a global hub for medical device innovation and manufacturing.

India and the Netherlands can collaborate to address shared challenges in import dependency and regulatory complexities. By combining their strengths, the Netherlands can utilize India's cost-effective production capabilities and emerging technologies, while India can benefit from the Netherlands' advanced R&D infrastructure and expertise in medical devices to improve its healthcare ecosystem. This collaboration could result in the development of affordable, high-quality medical devices and solutions for critical healthcare needs in both countries. Furthermore, the expanding markets in both nations and a solid government-to-government (G2G) collaboration provide a strong foundation for this partnership.

Methodology, Key Findings & Recommendations

This study aims to offer Dutch stakeholders—government, industry, and academia—a comprehensive analysis of the opportunities in India's medical devices industry over the short, medium, and long term. The report focuses on four main objectives:

1) Mapping Indian labor-saving technological solutions that enhance healthcare operations and patient self-sufficiency,
2) Identifying cross-border research and innovation opportunities with Indian institutions and incubators,
3) Strengthening the economic position of Dutch companies in India by analyzing the healthcare landscape and market entry challenges and
4) Recommending potential areas for bilateral government-to-government (G2G) collaborations.

Pillar 1: Technological Solutions: Map out Indian Labour-Saving Medical Devices

- **Mapping process followed:**
    - **Comprehensive long list of innovative solutions:** Identified 20 key sources, including leading companies, incubator/accelerator networks, PE/VC investments, and funding bodies.
    - **Methodology:** Primary and secondary research followed by discussions with key stakeholders (e.g., medical device companies, institutions, and incubators).
    - **Solution Review:** Reviewed over 1,000 solutions, shortlisting 140+ based on relevance. Conducted an in-depth analysis of the 49 shortlisted solutions basis the contextual relevance, novel technology and stage of development. These high-priority solutions were then mapped into three cohorts:
        - **Cohort 1 – Commercialized with EU Compliance** (low-risk, high-impact opportunities for immediate deployment)
        - **Cohort 2 – Commercialized with Other Relevant Compliances** (medium-term opportunities for investment and adaptation)
        - **Cohort 3 – At Pilot Stage** (long-term potential, joint R&D opportunities)
- **Key Recommendations**
    - **Commercializing Ready-to-Deploy Solutions (Cohort 1):** Facilitate dialogue between Indian companies and Dutch stakeholders to validate mutual interest and readiness, establish a monitoring program, and provide guidance on navigating the Dutch healthcare system.
    - **Regulatory Enablement for Cohort 2:** Establish Dutch-led regulatory mentorship, CE certification support, and leverage Dutch startup accelerators to facilitate compliance and commercialization.
    - **Co-development of Emerging Cohort 3 Innovations:** Invest in cross-border medical device innovation through bilateral R&D programs, venture capital, and co-funded pilot initiatives.
    - **Inviting Indian Start-ups to Start-up Challenge Programs:** Conduct bilateral workshops and seminars and initiate a bilateral startup challenge program to invite and shortlist key medical technologies.

Pillar 2: Collaborative Research & Innovation Opportunities

- **Process followed:**
    - **Policy Review:** Conducted a review of India's innovation policies (STIP), including the Medical Device Policy, central & regional level initiatives for medical devices

- **Collaboration Areas:** Identified key areas for India-Netherlands collaboration in research and innovation based on stakeholder feedback.
- **Program Leverage:** Outlined existing Indo-Netherlands programs and how they can support new initiatives.

- **Methodology:** Interviews with key stakeholders from India and the Netherlands and discussion at the Indo-Dutch Tech Summit 2025, with prominent speakers from leading IITs (Delhi, Kanpur, Hyderabad, Meerut), Department of Science and Technology, BIRAC, AMTZ, and private medical device players, such as Niramai Health. Evaluated over 260 central, state, and private universities in India through secondary research, along with public and private incubators, and identified the top 5 institutions and 5 incubators for collaboration with Dutch stakeholders.
- **Recommendations:** In the Dutch NTS framework, significant opportunities exist for the medical device sector, particularly in biomolecular and cell technologies, imaging technologies, and artificial intelligence. Indian institutions and incubators have made notable progress in these areas, offering a strong potential for collaboration with Dutch counterparts to co-develop health solutions that address healthcare challenges in both contexts.

  To capitalize on these opportunities, the following actions are recommended:

  - **Engage with Leading Institutions:** Explore collaboration opportunities with top Indian institutes (IISc, IIT Kanpur, IIT Bombay, IIT Delhi, IIT Madras) known for their innovations and cross-border collaborations in healthcare.
  - **Form Partnerships with Research Hubs:** Establish comprehensive collaborations with research hubs like the IITs and IISc in biomolecular and cell technology, medical imaging, and AI solutions.
  - **Collaborate with Leading Indian Incubators:** Partner with prominent Indian incubators (C-CAMP, BioNEST) to support companies developing products for the Dutch market, providing specialized programs and mentorship.
  - **Leverage the T-Bridge Program:** T-Hub incubator in Hyderabad, Telangana hosts the T-Bridge program to facilitate the seamless entry and establishment of startups from the foreign countries into the Indian market, and vice versa.

Pillar 3: Strengthening the Position of Dutch Companies in India

- **Process followed:**
  - **Primary Interviews:** Conducted a series of primary interviews with Dutch stakeholders to identify opportunities & barriers to market entry in India.
- **Insights from Interviews:** Feedback from Dutch stakeholders were analyzed and incorporated into our final recommendations for Pillar 4.

Pillar 4: Potential Areas for Bilateral G2G Collaboration

The following are the recommendations aimed to leverage existing G2G frameworks and foster collaboration, enhancing healthcare delivery and innovation in both countries.

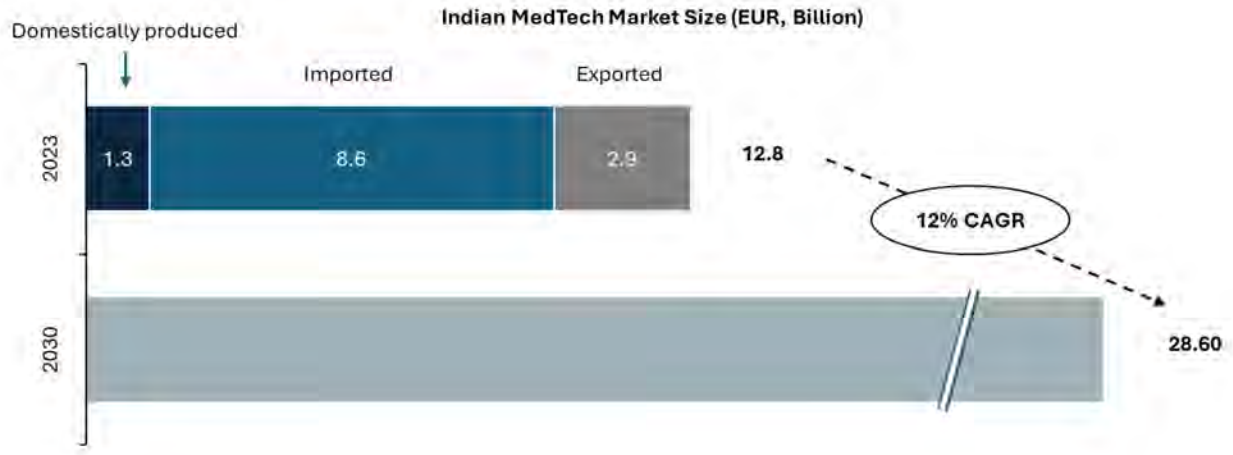
- **Co-Funding and Grants**: Establish bilateral funding programs under existing India-Netherlands healthcare initiatives, expand joint venture opportunities between Indian research hubs and Dutch research institutions, and provide incentivized grants to startups focused on labor-saving, patient-empowering, and cost-effective healthcare solutions.
- **Cross-Border Research and Knowledge Exchange**: Collaborate on research in AI, imaging, and biomolecular and cell technology, enable research exchange programs between Indian and Dutch institutions, and initiate a bilateral startup challenge program to invite and shortlist key medical technologies.
- **Technology Transfer**: Connect Indian and Dutch Technology Transfer Offices (TTOs) to accelerate the commercialization of research discoveries and act as a bridge between academia and industry in both countries.
- **Market Access and Regulatory Support**: Institutionalize the bilateral cooperation between Department of Pharmaceuticals and Ministry of Health, Welfare and Sport on medical devices focused on joint research, regulatory alignment and facilitate market access.
- **Awareness Initiatives**: Facilitate dialogue between companies and Dutch stakeholders to validate mutual interest and readiness and establish a monitoring program to assist startups in navigating regulatory landscapes.
- **Funding Opportunities**: Utilize programs like Globalstar, EU Horizon Europe, and the Dutch Research Council (NWO) for research funding, and access startup funding through BIRAC and MeitY schemes. Create a platform for Netherlands VC/PEs to evaluate and fund medical device startups with potential to enter the Indian market.

Conclusions: The collaboration between India and the Netherlands presents a strategic opportunity to address global healthcare challenges through innovative, cost-effective medical devices and solutions.

Overview of the Indian Medical Devices Landscape

Overview of the Indian Medical Devices Landscape

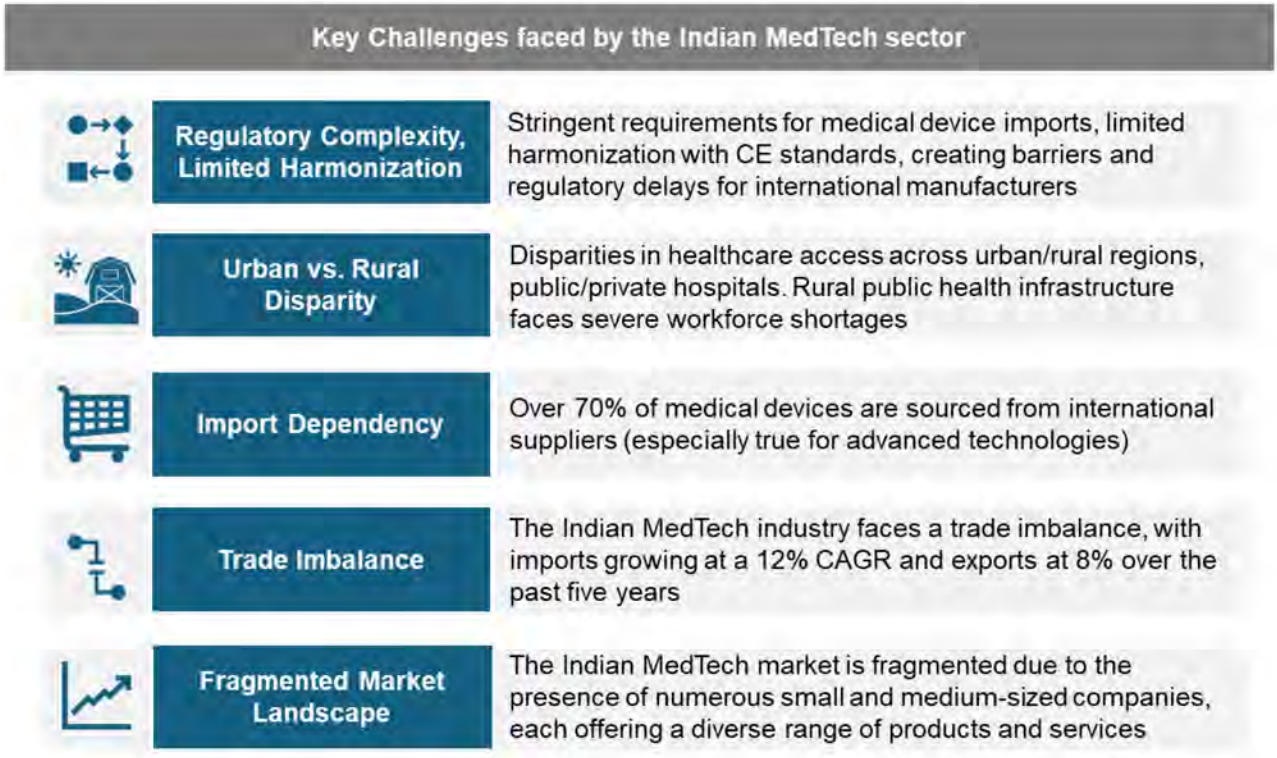
India's medical devices industry is experiencing rapid growth, fueled by increasing healthcare demand, technological advancements, and supportive government policies. India's central policies on medical device include the Medical Device Rules 2017, enforced on January 1, 2018, which regulate the safety and performance of medical devices. MedTech Mitra, a collaborative initiative by NITI Aayog, ICMR, and CDSCO, provides strategic support to medical device innovators. The Promotion of Research and Innovation in Pharma MedTech (PRIP) scheme, launched in 2023, focuses on enhancing R&D capabilities with a financial outlay of ~ €550 million. These policies leverage international standards and instruments like ISO certifications and WHO guidelines. The government's vision is to make India a global hub for medical device innovation, ensuring access, affordability, and quality healthcare. Currently valued at approximately €12.8 billion, it is projected to reach around €29 billion by 2030, with a compound annual growth rate of 12%.



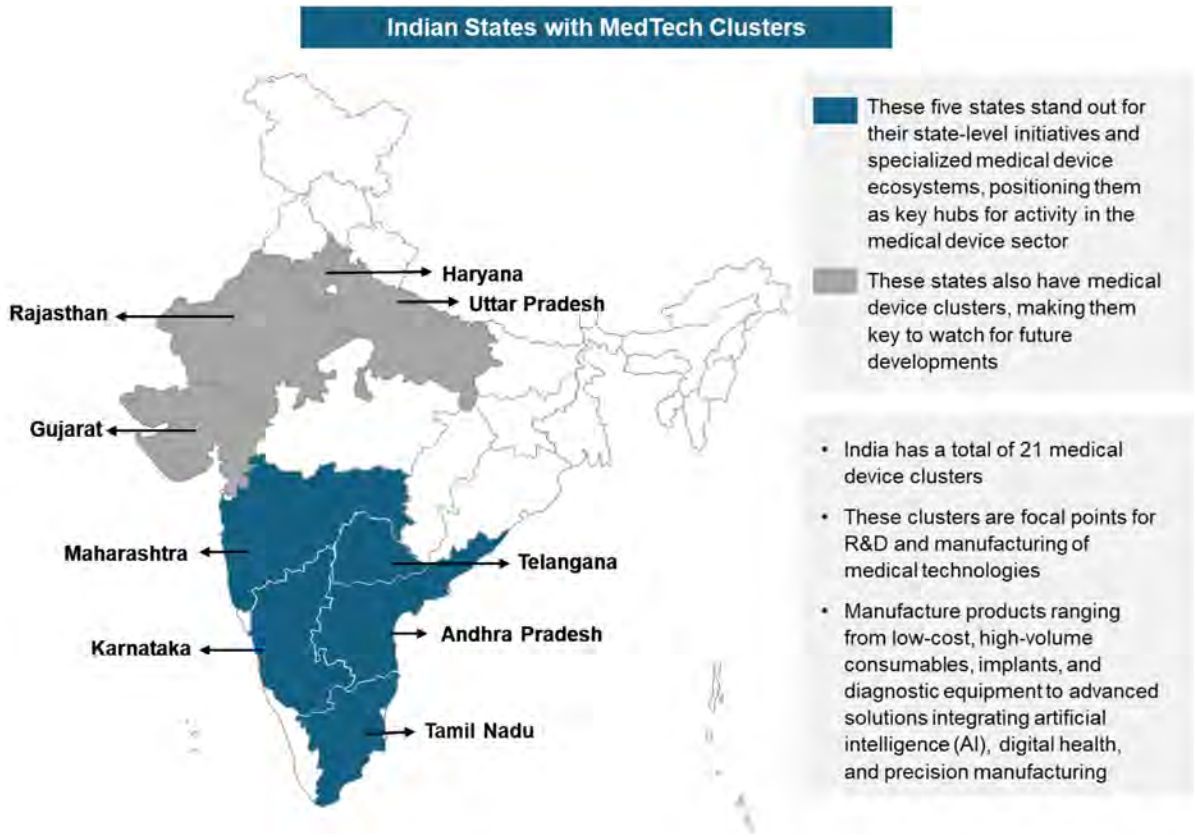
Source: Trademap.org, PwC analysis
The above market size includes imports, domestic & export sales for respective years and we have multiplied import value with 1.4 factor to reflect the realization achieved by manufacturers

Indian medical device imports have increased from €4.8 billion to €8.6 billion between 2018 and 2023, with a majority (i.e., ~52%) of imports coming from the United States, China, and Germany. High imports of medical devices poses both strategic and financial challenges for India by increasing dependence on international suppliers, which can result in supply chain disruptions during global crises. This reliance also hampers the development of the domestic medical device industry, limiting both innovation and employment opportunities. Additionally, the substantial import costs place a burden on the national healthcare budget, complicating efforts to deliver affordable healthcare to all citizens. Therefore, given India's population, geographical diversity, and disease demographics, the focus has been on making medical devices both accessible and affordable. However, with technological advancements, there is a growing demand for innovative medical devices specifically designed for remote patient monitoring and AI/ML-based diagnostic systems. Leveraging its low-cost manufacturing capabilities and extensive production facilities, India has the potential to become a hub for medical device innovation and manufacturing. This potential can be realized by fostering collaborations

between local manufacturers and international firms to share expertise and advanced technologies.



The government has set certain strategic priorities to address some of these challenges. Accordingly, it has undertaken multiple enabling initiatives and formulated policies.



Source: India Briefing

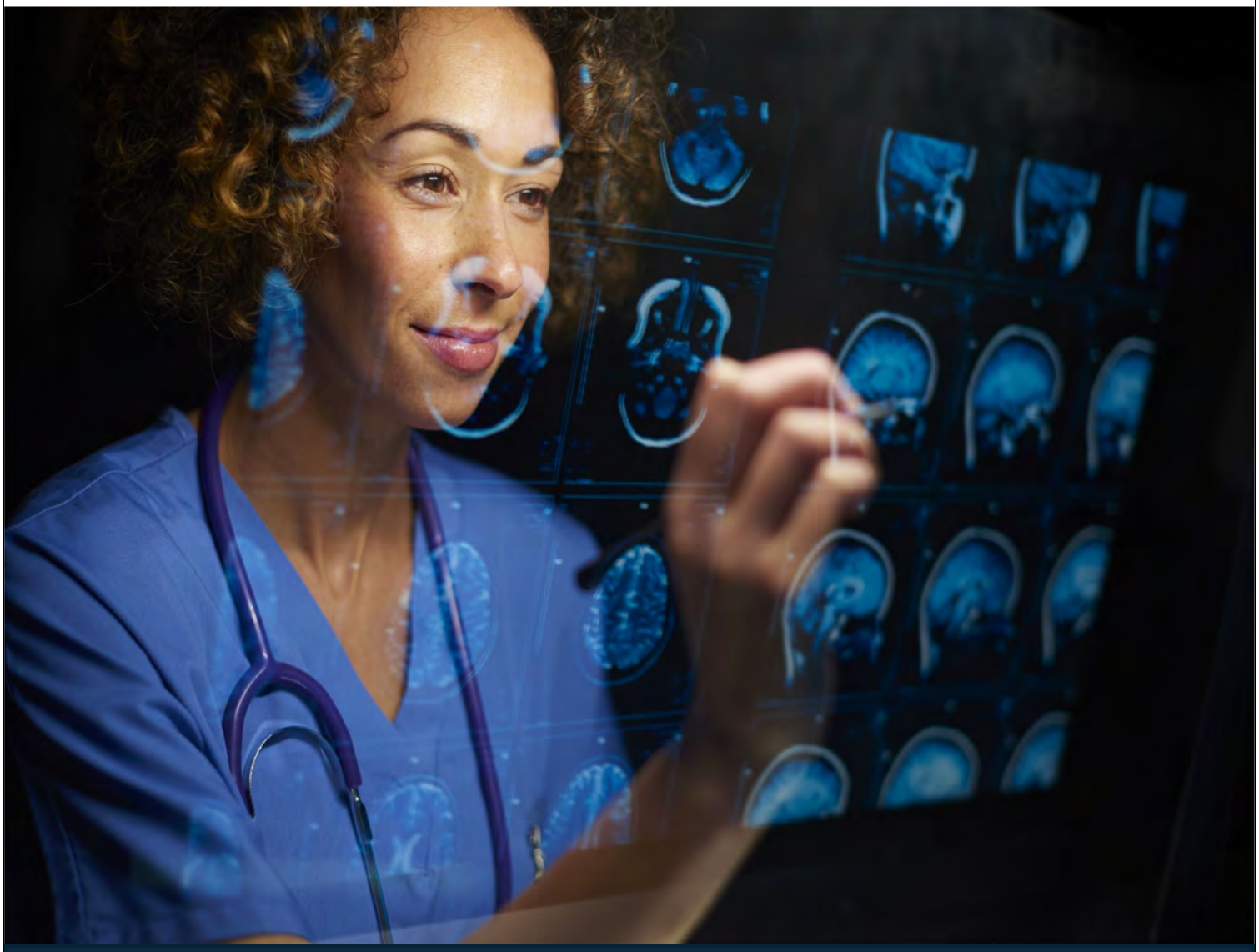
The central and state governments have been actively encouraging the development of medical device parks and clusters, recognizing them as significant drivers of economic growth.

India's medical devices industry is experiencing rapid expansion, driven by rising healthcare expenditure, increasing disposable incomes among the middle class, and a growing prevalence of chronic diseases. In addition, India has the capability to produce medical devices in high volumes. Recognizing these opportunities, India has focused on boosting its medical device industry. Recent trade data shows export growth from €1.6 billion to €2.9 billion between 2018 and 2023. Large domestic conglomerates, traditionally engaged in sectors like automotive and aerospace, are now investing in medical device manufacturing, leveraging their expertise in precision engineering to improve product quality and scalability.

Government initiatives, such as the National Medical Devices Policy[4] and the Market Access Initiative, have been instrumental in fostering domestic manufacturing, promoting exports, and enhancing market access. These policies also stimulate innovation and collaboration, aligning with India's broader strategy to establish itself as a global medical devices hub, enhancing both local production capabilities and international competitiveness.

While these advancements signal a shift towards self-reliance and international market penetration, the Indian medical devices industry still faces structural challenges. These include regulatory complexities, a fragmented market landscape, and a heavy reliance on imports for advanced technologies.

[4] National Medical Device Policy, Indian Ministry of Chemicals & Fertilizers, 2023



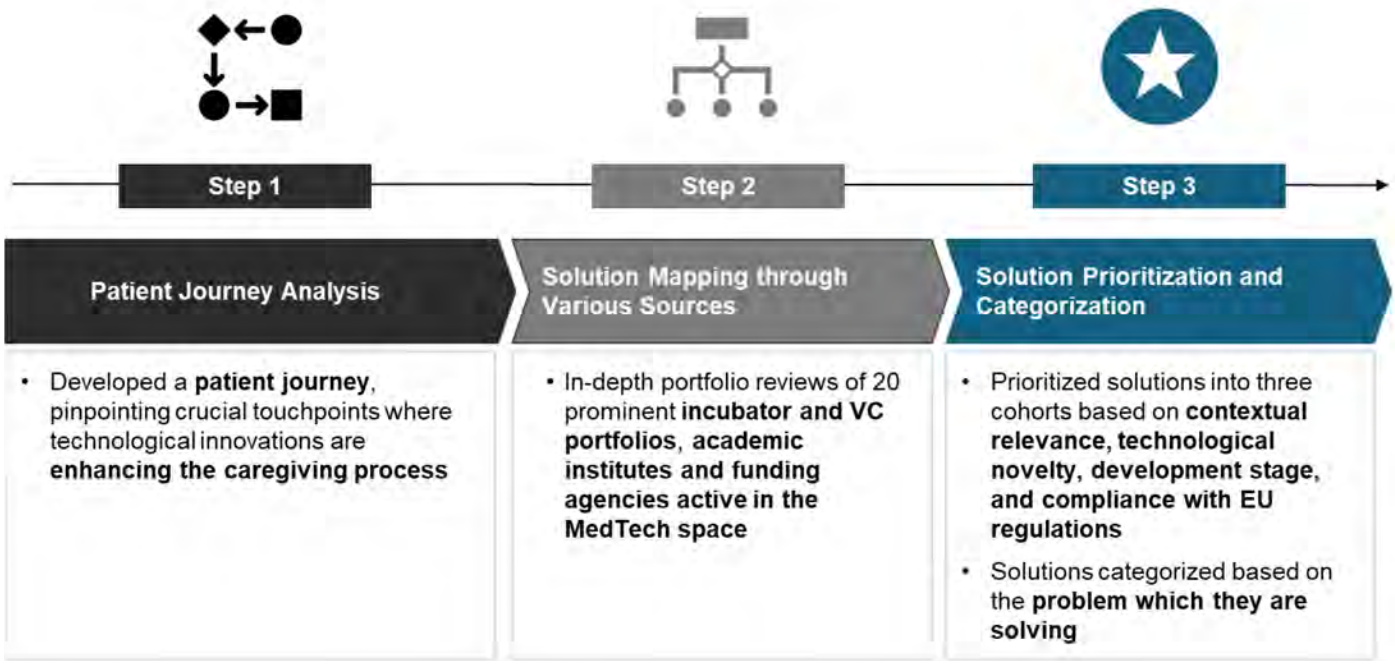
Technological Solutions: Labour-Saving Medical Devices

Mapping of Labour-Saving Medical Device Solutions

Abstract

This section analyzes labour-saving medical device solutions in India that could be relevant to the Netherlands. The process involved identifying 144 labour-saving solutions across the patient journey from over 1,000 solutions reviewed; these were sourced from incubator/accelerator portfolios, private equity/venture capital investments, web searches, public, academic, and research institutions, and team expertise. These 144 solutions were shortlisted into a list of 49 priority solutions based on relevance to the Dutch healthcare system, novelty, development stage, and regulatory compliance. The section also explores particularly relevant solutions and provides key recommendations for leveraging Indian labour-saving technological solutions to address Dutch healthcare challenges.

Overview of Mapping Methodology



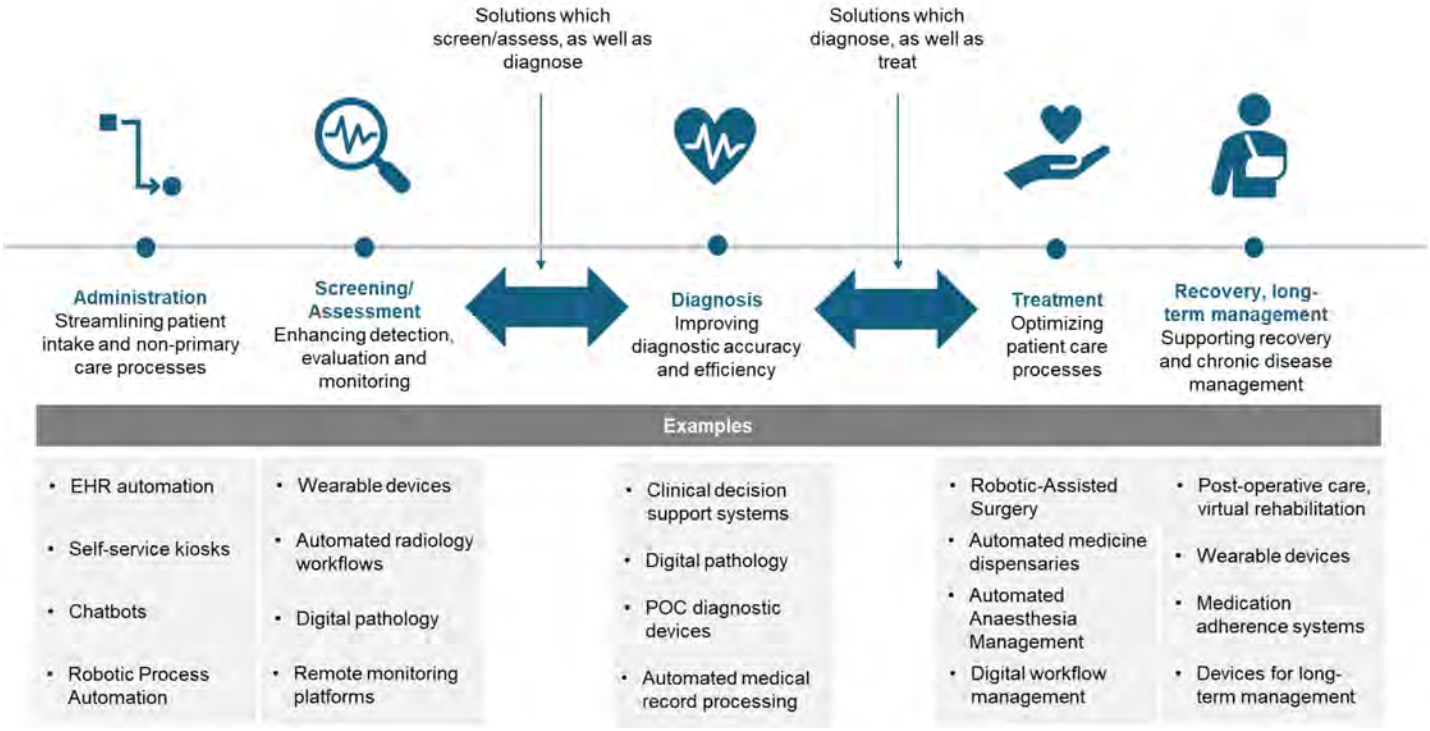
4.1 Solution Mapping Process

Mapping of Labour-saving Solutions Through Various Sources

To identify the most impactful labour-saving medical device solutions, an extensive review was conducted of over 1,000 innovations sourced from leading incubators, venture capital networks, academic institutions, and industry funding agencies. This review process involved in-depth evaluations of technology portfolios, web-based research, and direct engagements with firms. A full mapping of sources is available in Annexure A.

Patient Journey Analysis

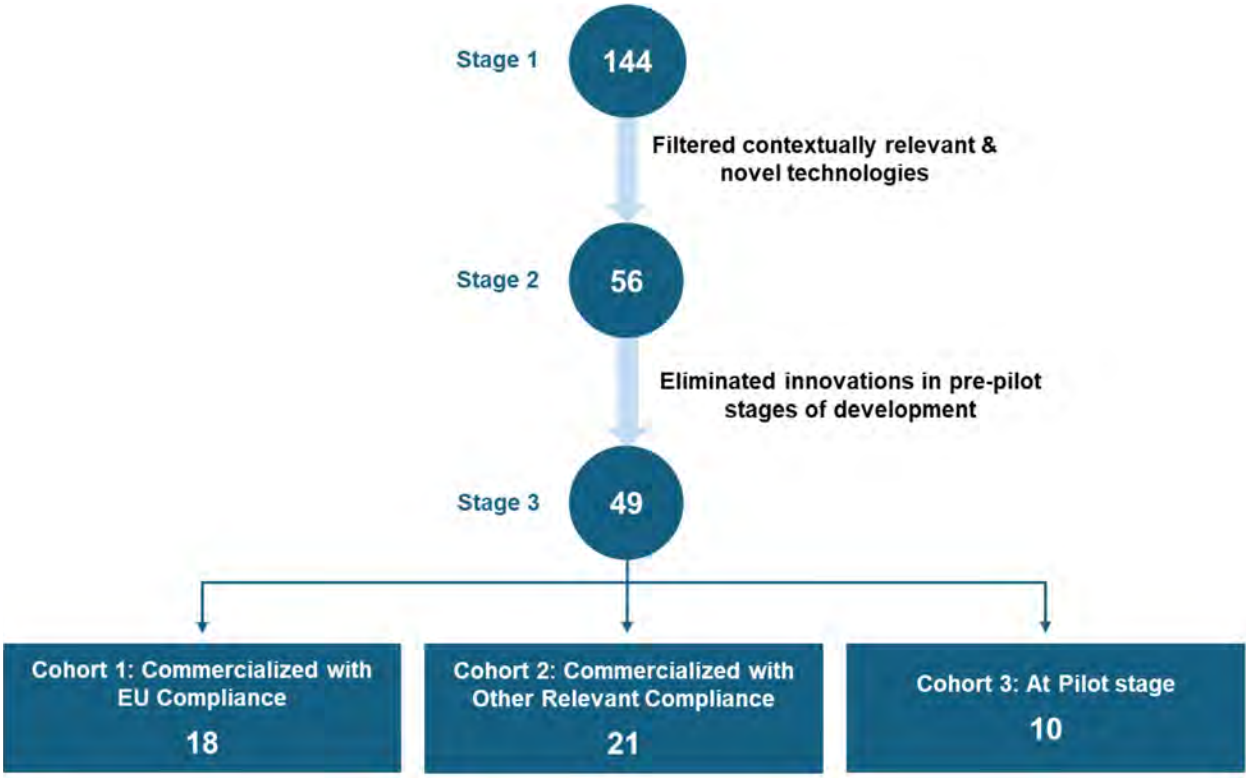
To systematically identify where labour-saving medical device solutions can provide the greatest impact, a patient journey was developed, outlining key touchpoints in the care pathway. This exercise pinpointed areas where technological solutions can actively streamline workflows, reduce caregiver burden, and improve patient outcomes.



4.2 Solution Prioritization and Categorization

Prioritization of Solutions

Of the 1,000 solutions reviewed, 144 companies offering relevant labour-saving solutions were identified. To pinpoint the most viable opportunities for introduction into the Dutch market, these 144 labour-saving medical device solutions were systematically filtered through a prioritization framework based on their relevance, technological maturity, and regulatory compliance.



The initial screening applied two primary criteria:

1. *Contextual relevance* – Solutions had to address disease and healthcare burdens significant in the Netherlands (i.e., primarily cardiovascular disease, cancer, maternal and fetal care, elder care, and chronic diseases) or demonstrate clear potential to reduce healthcare workforce strain.
2. *Technological novelty* – The solution had to introduce new or underrepresented innovations in the Dutch medical devices industry landscape.

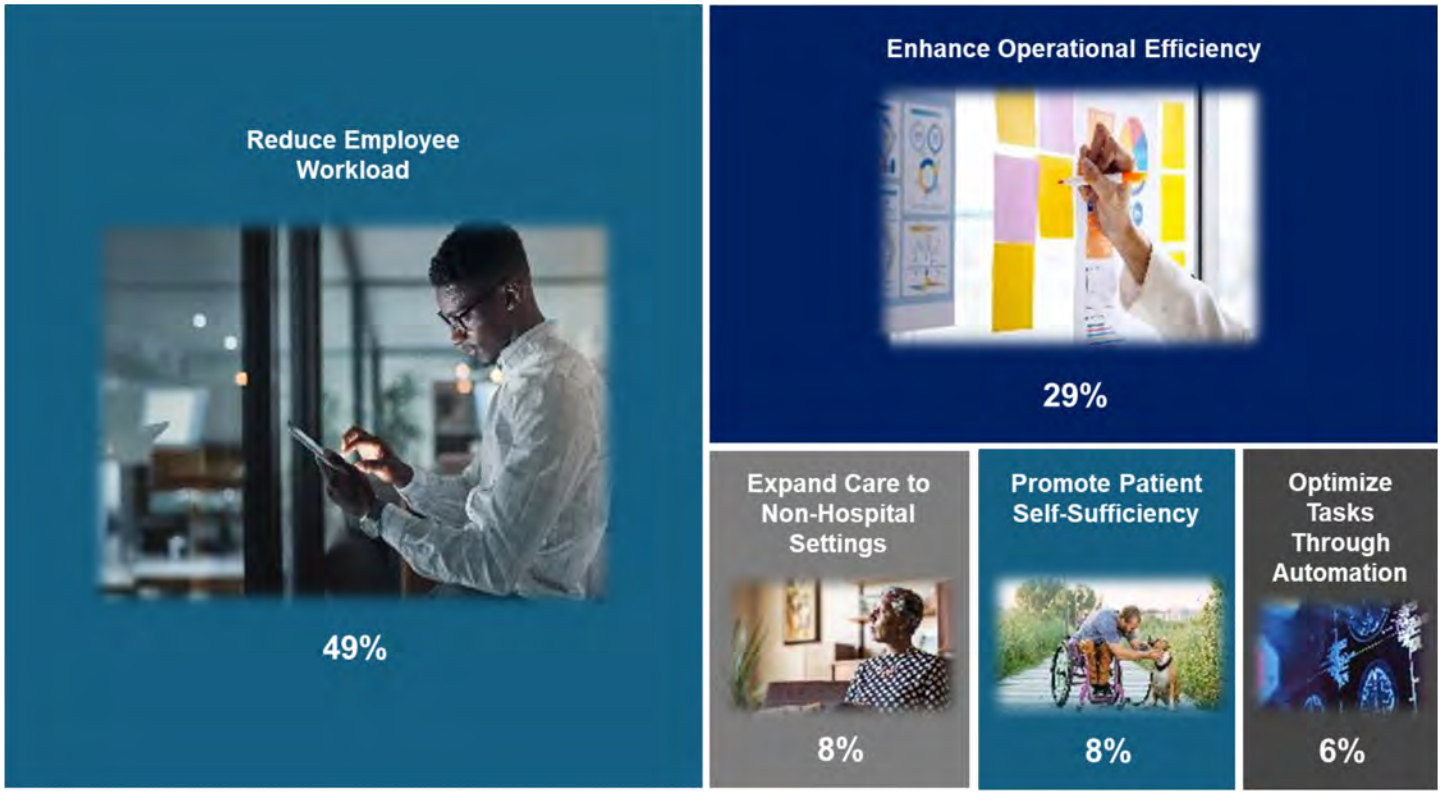
Filtering for technological novelty significantly reduced the number of eligible solutions, leaving 56 solutions for further evaluation. However, while the solutions eliminated were not considered novel, many may still hold competitive merit in terms of cost-effectiveness or scalability, which are key strengths of the Indian medical device industry.

After removing solutions still in pre-pilot development, the remaining 49 solutions were categorized into three cohorts based on their regulatory status and commercialization stage,

providing a structured approach to determine market readiness of the mapped solutions. These solutions will be explored in detail in a following section.

Five Categories Based on the Primary Problem Being Solved

The 49 solutions identified were also categorized into five distinct groups based on their primary labour-saving impact factor (i.e., the specific mechanism through which the solution creates labour savings). The five categories of solutions are as follows:



1. ***Reduce Employee Workload (n = 24, 49%):*** Simplifying complex tasks to reduce workload on healthcare professionals, speed up time-consuming tasks, increase productivity, prevent burnout, enhance turnaround time, and maintain quality of care.
    - *Examples:* Automated vitals measuring and monitoring systems, incontinence management systems, apnea management, AI/ML-driven diagnostics, radiology, and pathology interpretation.
2. ***Enhance Operational Efficiency (n = 14, 29%):*** Improve healthcare processes by streamlining workflows, reducing bottlenecks, and ensuring smooth and efficient operation of facilities, enabling greater throughput and more efficient use of labour.
    - *Examples*: Smart wards, physiotherapy biosensors, AI assistants for hospital management, surgery planning solutions, virtual nursing, and tele-ICUs.

3. ***Expand Care to Non-Hospital Settings (n = 4, 8%):*** Enabling healthcare delivery outside traditional hospital environments, particularly in patients' homes. Expanding care to non-hospital settings enables homecare, reduces hospital admissions, healthcare costs, and strain on hospital resources.
    - *Examples:* Wearable biosensors, movement rehabilitation platforms for elderly patients, integrated remote monitoring ecosystems, remote maternal and fetal monitoring.
4. ***Promote Patient Self-Sufficiency (n = 4, 8%):*** Empowering patients to manage their own health, reducing the need for frequent interactions with healthcare providers. These solutions provide patients with the resources they need to take an active role in their health, leading to increased patient satisfaction while reducing demand for healthcare resources.
    - *Examples:* Portable heart monitoring, fall detection systems, assistive devices for the visually impaired, at-home rehabilitation systems, and custom prosthetics.
5. ***Optimize Tasks Through Automation (n = 3, 6%):*** Automation of repetitive, time-consuming tasks that do not require human intervention, thereby freeing up healthcare workers for more complex primary care activities.
    - *Examples:* Health self-service kiosks, ventilator secretion management, automated neonatal therapy, medicine dispensaries, and ambulatory care.

Closer Examination of the Three Cohorts

1. ***Cohort 1 – Commercialized with EU compliance (n = 18, 37%):***
    - Solutions that have already obtained EU regulatory approvals (i.e., CE marking) and are commercially available. Some are currently available in the Netherlands, while others are available in other European markets (such as Sweden or Germany). They present low-risk, high-impact opportunities for immediate deployment into the Dutch market.

Category	*#*
Optimize tasks through automation	*2*
Reduce employee workload	*7*
Expand care to non-hospital settings	*1*
Promote patient self-sufficiency	*1*
Enhance operational efficiency	*7*

2. *Cohort 2 – Commercialized with Other Relevant Compliances (n = 21, 43%):*

- Commercially established solutions with non-EU but relevant regulatory approvals (e.g., US FDA, Indian CDSCO, global ISO/IEC). While they require additional certification and testing to enter the Dutch market, they represent medium-term opportunities for investment and adaptation.

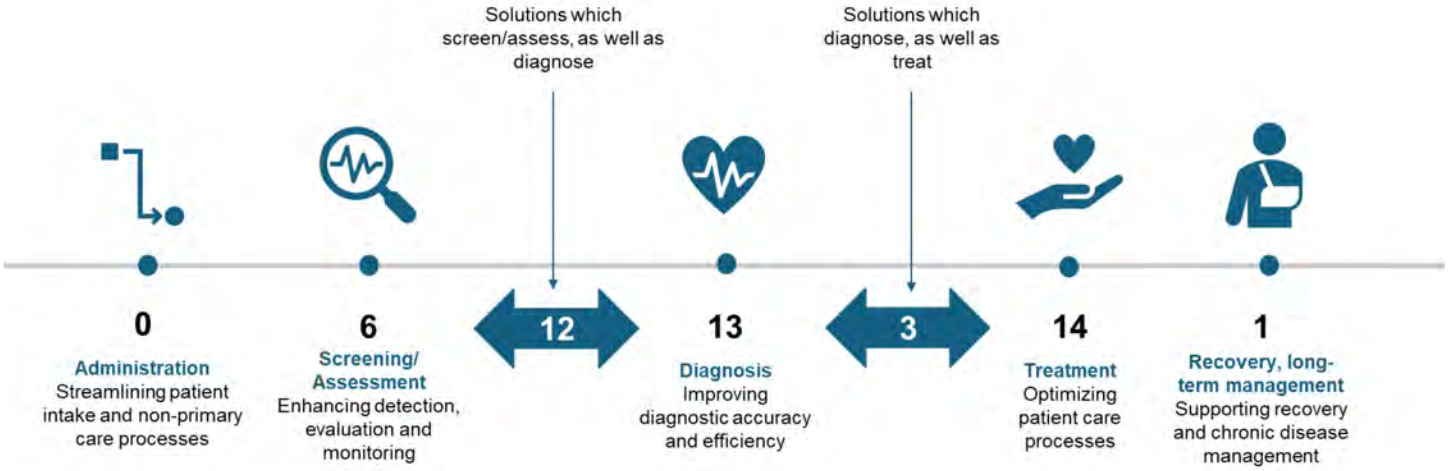
Category	#
Optimize tasks through automation	*1*
Reduce employee workload	*11*
Expand care to non-hospital settings	*1*
Promote patient self-sufficiency	*2*
Enhance operational efficiency	*6*

3. *Cohort 3 – At Pilot Stage (n = 10, 20%):*

- Primarily early-stage innovations that are relevant and novel but still in pilot phases. These solutions present long-term potential and may benefit from joint R&D collaborations.

Category	#
Optimize tasks through automation	*0*
Reduce employee workload	*6*
Expand care to non-hospital settings	*2*
Promote patient self-sufficiency	*1*
Enhance operational efficiency	*1*

The 49 prioritized solutions were also mapped across the identified patient journey touchpoints:



4.3 Exploration of Relevant Solutions

This section highlights a selection of solutions from Cohorts 1 and 2 chosen for deep dives based on their high priority, suitability, and readiness for the Dutch market.

Cohort 1 – Commercialized with EU compliance

1. Sunfox Spandan 4 – Portable ECG

Impact: Compact design offers a solution for expanding cardiac screening without increasing labour costs. By integrating AI-driven diagnostics with portability, Spandan 4 is transforming cardiovascular care, enabling rapid, remote heart monitoring across diverse clinical settings.

Need: ECG testing typically requires the patient to be at a healthcare facility and is done under the supervision of a trained technician, contributing to the burden on healthcare facilities and personnel. There is also a high cardiovascular disease burden in the Netherlands.

Category: Promote patient self-sufficiency

Product: Sunfox Spandan 4 is an ultra-portable, AI-powered ECG device that enables rapid cardiac screening while reducing the burden on healthcare professionals. Unlike traditional ECG machines requiring extensive setup and skilled technicians, Spandan 4 is a pocket-sized device that connects to a smartphone via Bluetooth. Its simple lead-based system aids in early

diagnosis of conditions like arrhythmias and ischemic changes. The ECG reports can also be shared with the clinician.

Presence: Deployed in 1,500+ medical facilities across 15+ countries, including the US and Germany, it has conducted 1 million+ ECGs, potentially saved 200,000 lives, while easing workforce shortages.

Regulatory Compliance: Spandan 4 is CE marked, FDA-approved, ISO 13485:2016 compliant, and available in European markets, such as Germany.

Source(s): Sunfox website, Research articles - European Journal of Cardiovascular Medicine, International Journal of Health Sciences

2. Qure.ai qXR – AI-Driven Lung Cancer Detection

Impact: AI-powered imaging accelerates lung cancer detection without adding to radiologist workloads. By offering solutions to automate analysis and standardize interpretation, Qure.ai enhances diagnostic efficiency, reducing bottlenecks in critical care pathways.

Need: Lung cancer is a significant contributor to the Dutch disease burden. In addition, interpretation and report writing for radiology images to diagnose these conditions is highly labour-intensive and time-consuming.

Category: Enhance operational efficiency

Product: Lung cancer is among the highest contributors to the Dutch disease burden, requiring rapid and accurate diagnosis for timely intervention. Qure.ai is a company building AI-driven radiology solutions including qXR, which enhances diagnostic efficiency by automating medical imaging interpretation. Its advanced algorithms analyze chest X-rays, enabling faster detection

of lung nodules and stroke-related abnormalities, reducing dependency on radiologists for initial assessments. In addition to qXR, Qure.ai also has other AI algorithms for different contexts, such as qER for stroke and brain injury detection.

Presence: Deployed in 2,700+ healthcare facilities across 90+ countries, including at Erasmus Medical Center in the Netherlands, Qure.ai provides a scalable, validated solution for healthcare systems.

Regulatory Compliance: With regulatory approvals such as CE, GDPR compliance, FDA clearance, as well as WHO evaluation, Qure.AI solutions are trusted tools for hospitals.

Source(s): Qure.ai website, Research Articles – Cureus Journal, Springer

3. Niramai Thermalytix – AI-Powered Breast Cancer Screening

Impact: Non-invasive AI screening enables early breast cancer detection without requiring radiologists or specialized imaging infrastructure. By leveraging thermal imaging and machine learning, Niramai expands access to preventive care while optimizing healthcare resources.

Need: Early and accurate breast cancer screening with minimal training requirements for healthcare workers – particularly for testing on women with dense breast tissue where traditional mammography is less effective.

Category: Reducing employee workload

Product: Traditional mammography is less effective for women with dense breast tissue, creating a need for more accurate, early-stage breast cancer detection. Niramai's Thermalytix offers a noninvasive, radiation-free, AI-driven screening technology that leverages thermal imaging to detect breast cancer at an early stage. By combining AI analytics with thermal scans, Niramai's solution reduces reliance on radiologists, automates risk assessment, and improves screening efficiency.

Presence: With implementation in over 200 hospitals and diagnostic centers, including Apollo Clinics, HCG, Narayana Health, etc., Niramai is a scalable, globally expanding solution. The

technology is commercially available in multiple countries, including the UAE, Kenya, Sweden, Bulgaria, and Turkey.

Regulatory Compliance: Niramai's technology is CE marked and holds 32 granted patents across the US, Japan, Europe, Singapore, China, and Canada.

Source(s): Primary interview with Dr. Jyotsna (Regional Head - International Business Development), Niramai website, Research Articles - BMJ Open journal, ASCO JCO Journal

4. YOLO Health's Health ATM

Impact: The fully automated Health ATM offers comprehensive services like body checkups, urine and blood tests, teleconsultations, instant health reports, and integrated medicine dispensers. By integrating AI-driven verification with self-service kiosks, it reduces pharmacy staff workload and ensures timely access to prescriptions, improving efficiency in high-demand settings.

Need: Overburdened healthcare professionals spend significant time on routine diagnostics and primary care consultations, reducing the availability for complex cases.

Category: Optimize tasks through automation

Product: Yolo Health's Health ATM is a self-service kiosk for checkups, diagnostics, teleconsultations, prescriptions, and medicine dispensing, reducing reliance on on-site medical staff.

Available as the standard version, wall-mounted variant, as well as mobile units, it streamlines healthcare delivery in workplaces, pharmacies, and public spaces. By automating diagnostics and consultations, it cuts staffing needs and administrative burdens. Health ATM can check up to 60 parameters in under 15 minutes.

Presence: With 750+ installations and partnerships with India's National Health Mission, Fortis Hospitals, and Tata 1mg, it has facilitated 4.4 million tests.

Regulatory Compliance: US FDA and CE certified, Health ATM offers a scalable, cost-effective solution to ease workforce pressures.

Source: YOLO Health website, Research Articles- International Journal of Advanced Research in Nursing, Primary research – Live demo of 'YOLO Health ATM' implemented at a diabetes clinic in Delhi.

5. Cyclops MedTech Postura – Balance Assessment and Movement Rehabilitation

Impact: Postura improves long-term care, especially for elderly patients, by enabling early detection of balance issues, reducing fall-related hospitalizations, and easing the workload on caregivers through automated, data-driven rehabilitation.

Need: With ageing populations, the Dutch healthcare system faces growing challenges in managing balance-related disorders and preventing falls, a leading cause of injury and hospitalization among the elderly. Traditional assessments require in-person supervision and lack continuous monitoring.

Category: Expanding care to non-hospital settings.

Product: Postura is a comprehensive balance assessment and rehabilitation platform integrating static posturography, smart sensors, and virtual reality. It offers advanced diagnostic protocols such as the Modified Clinical Test of Sensory Interaction and Balance, Limits of Stability, and the Balance Error Scoring System. It provides precise, data-driven evaluations of postural control. These assessments help detect early signs of balance deterioration, enabling proactive interventions to prevent falls.

Beyond diagnostics, Postura features interactive rehabilitation modules, including weight-shifting exercises and gamified balance training, improving patient engagement and adherence to therapy. Its portable design allows for use in hospitals, rehabilitation centers, and even home care settings, enabling long-term monitoring and remote supervision.

Presence: Postura is used in over 900 clinics and hospitals across 14 countries, conducting more than 1.5 million balance assessments and rehabilitation sessions. Integration into long-term care facilities demonstrates its potential to improve elder care outcomes while easing workload on caregivers and healthcare providers.

Regulatory Compliance: Postura meets international medical device standards, holding CE marking and ISO 13485:2016 certification, ensuring safety, reliability, and compliance with global healthcare regulations.

Source(s): Cyclops website.

Note that the solution deep dives above provide a select sample of Cohort 1 solutions. The list of the remaining prioritized solutions can be found in Annexure B.

Cohort 2 – Commercialized with Other Relevant Compliances

1. Dozee Smart Beds - Continuous Vitals Monitoring

Impact: Dozee exemplifies a scalable, technology-driven solution to workforce shortages, improving patient outcomes through automation and early intervention. Contactless vitals monitoring enables early detection of patient deterioration without adding to nurse workloads. By automating real-time health tracking, Dozee enhances patient safety and optimizes staff efficiency in high-acuity care settings.

Need: There is a need for continuous, real-time vitals monitoring for bedridden and ICU patients. However, manual vital sign monitoring is labour-intensive and time-consuming.

Category: Reducing employee workload

Product: Dozee's Smart Bed contactless monitoring system automates continuous vital sign tracking, reducing manual workload for healthcare professionals. A sensor sheet beneath the mattress captures micro-vibrations from heartbeats, respiration, and body movements, with AI-driven algorithms translating them into heart rate, respiratory rate, and oxygen saturation data. This non-invasive technology enables early detection of patient deterioration, ensuring timely interventions without manual monitoring.

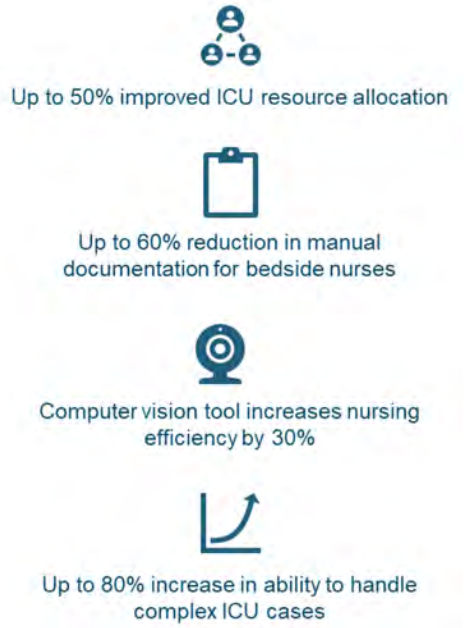
Presence: Deployed in over 200 Indian hospitals, as of date it has transformed 15,500+ beds into smart beds.

Regulatory Compliance: Regulatory approvals include US FDA clearance, ISO 13485:2016 certification, and CDSCO registration, ensuring compliance with international safety and quality standards.

Source(s): Dozee Website, Research articles – Cureus journal, IEE Xplore

2. Cloudphysician - Virtual Nursing Support

Impact: AI-driven virtual nursing support enhances patient monitoring without increasing staff requirements. By integrating remote clinical oversight with real-time alerts, Cloudphysician optimizes workforce efficiency while maintaining high standards of care.



Need: Due to limited workforce availability, there is an urgent need for efficient ICU management to reduce administrative burden, ensure continuous monitoring, and timely intervention, especially on overnight shifts.

Category: Enhance operational efficiency

Product: Cloudphysician's Virtual Nursing Support system combines automation and remote monitoring to ease hospital staff workloads while improving patient care. Integrating AI-driven clinical decision support with real-time virtual nursing, it allows nurses to remotely monitor multiple patients, triage cases, and provide timely interventions, ensuring continuous oversight without increasing on-site staffing demands.

Presence: Deployed in 280+ hospitals, it manages 2,000+ ICU beds and 130,000 patients, integrating India-based virtual nurses with US teams to strengthen night-shift coverage.

Regulatory Compliance: HIPAA- and ABDM-compliant, Cloudphysician enables a single remote nurse to monitor multiple patients across facilities, addressing staffing shortages without compromising care. Its AI-powered, scalable solution optimizes workforce efficiency while improving clinical outcomes.

Source(s): Cloudphysician website, Google Cloud case study, ISB Center for Learning and Management Practices

3. Consure Medical – Labour-Saving Incontinence Management

Impact: Automated incontinence management minimizes nursing intervention while improving patient hygiene and dignity. By reducing manual handling and streamlining waste management, Consure Medical's devices enhance efficiency in long-term and acute care settings.

Need: Manual stool and incontinence management of ICU, bedridden, or elderly patients is labour-intensive and time-consuming. It takes away time from primary care activities and poses infection risks for both the patient and caregiver.

Category: Reducing employee workload

Product: The Qoramatic Stool Management System by Consure Medical automates incontinence care for ICU and bedridden patients, reducing manual nursing intervention and infection risks. Its closed-loop design diverts waste, schedules flushing, and features a soft in-dwelling receptacle that minimizes tissue damage and rectal injuries.

Presence: Consure Medical extends automation to urine incontinence care as well, and has products deployed in 600+ ICUs (70-75% of sales are concentrated in the US).

Regulatory Compliance: CDSCO registered and widely available on online marketplaces such as Amazon India and USA.

Source(s): Consure Medical website, Research Articles: Biodesign Stanford, Indian Journal of Critical Care Medicine, BMJ Case Report

4. Synapsica: AI-Powered Radiology Analysis

Impact: AI-assisted radiology reporting accelerates diagnosis without increasing workforce burden. By automating image interpretation, Synapsica improves diagnostic accuracy and turnaround times, addressing workforce shortages in imaging departments.

Need: Growing demand for radiology services, coupled with a shortage of trained radiologists and the time-consuming nature of preparing radiology reports, leads to diagnostic delays and increased burden on existing staff.

Category: Reducing employee workload

Product: Radiologists face mounting workloads, particularly spinal MRI interpretation, leading to delays and diagnostic variability. Synapsica's AI-powered solutions, including RadioLENS, Spindle, and SpindleX, automate MRI and X-ray reporting, detect low-quality scans, and generate customized reports, reducing manual effort and errors. Synapsica also offers AI-backed teleradiology services for quick diagnosis or second reads.

By leveraging AI-driven automation, Synapsica enables radiologists to increase their productivity, with more cases processed per hour and improved turnaround times. Its quantitative analysis improves diagnostic accuracy and minimizes report-making time.

Presence: Synapsica streamlines radiology workflows globally, with over 500 installations across 15+ countries.

Regulatory Compliance: It complies with ISO 27001 (information security management), and US FDA approval for several of its solutions.

Source(s): Synapsica website, Research Articles - MGM Journal of Medical Sciences, NASSCOM Center of Excellence - IoT and AI

5. LifeSpark WALK – Assistive Device for Parkinson's Patients

Impact: Intelligent mobility assistance restores patient independence while reducing caregiver dependency. By integrating adaptive gait support, LifeSpark WALK enhances mobility, improving quality of life for individuals with Parkinson's disease and reducing the burden on caregivers.

Need: Prevalence for Parkinson’s disease increases significantly with age. Parkinson’s patients typically face difficulties in walking and have an increased risk of falls.

Category: Promote patient self-sufficiency

Product: WALK by LifeSpark is a wearable device that enhances mobility and prevents falls in individuals with Parkinson's disease. Using muscle stimulation and haptic vibrations, it improves coordination, reduces freezing of gait, and tracks symptoms to help users and caregivers monitor progression.

Regulatory Compliance: With CDSCO registration and its availability as a consumer product on online marketplaces like Amazon India and USA, WALK provides a scalable, cost-effective intervention for mobility support.

Source(s): LifeSpark website

Note that the solution deep dives above provide a select sample of Cohort 2 solutions. A list of the remaining prioritized solutions can be found in Annexure B.

4.3 Key Recommendations: Leveraging Indian Expertise to Address Dutch Challenges

India's medical devices industry is on a rapid growth trajectory, projected to reach €28 billion by 2030, with ~11,500 medical device startups being recognized by the Indian Ministry of Commerce and Industry since 2016. The industry's focus on AI-driven diagnostics, automation, and remote care aligns with Dutch focus on technologies to address labor shortages and improve patient self-sufficiency.

As part of the study, many companies were identified which could potentially address the problems discussed in this chapter. Currently, each of these companies has their own expansion plans and may not be actively considering the Netherlands market in the immediate future. To encourage and facilitate these companies to extend their offerings in the Netherlands market, following actions could be considered:

1. **Commercializing Ready-to-Deploy Solutions (Cohort 1):**
    a. **Align Two-way interest:**
    Mutual alignment discussions between representatives of the Indian companies and concerned stakeholders from the Netherlands (could be health insurers, large healthcare institutions, etc.) to validate suitability of their offerings in the Dutch context, mutual interest levels, and readiness.
    b. **Establish a monitoring program:**
    It is recommended to establish a monitoring program which should include facilitation, stakeholder meetings, bottleneck identification, process assistance, and periodic reviews to nudge relevant stakeholders as needed.
    c. **Guidance to start-ups in navigating the system:**
    Provide guidance through respective stakeholder ecosystems, on matters such as: i) conducting clinical trials and validation studies on Dutch patient demographics, particularly for AI/ML-powered diagnostics and imaging solutions, ii) guiding Indian firms with high-potential digital solutions on interoperability standards and EHRs utilized by Dutch healthcare facilities to ensure ease of integration.
2. **Regulatory Enablement for Cohort 2:**
    a. Establish Dutch-led regulatory mentorship, CE certification support, and pilot programs for high-potential Indian startups to support EU market entry.
    b. Leverage Dutch startup accelerators to facilitate compliance and commercialization of Indian startups in the Dutch market.
3. **Co-development of Emerging Innovations in Cohort 3:**
    a. Invest in cross-border medical device innovation through bilateral R&D programs, venture capital, and co-funded pilot initiatives.

4. **Inviting Indian start-ups to start-up challenge programs:**
   Objective would be leveraging the vibrant start-up eco-system in India to develop solutions targeted to address healthcare priorities in the Netherlands. Initiatives that can be considered:

   a. **Awareness Initiatives:**
      Conduct bilateral workshops and seminars that invite companies and startups, to enable alignment with the key objectives of the Dutch and Indian healthcare ecosystems.

   b. **Startup Challenge Program:**
      Initiate a bilateral startup challenge program to invite multiple startups based on current needs and shortlist key medical technologies.

Collaborative Research and Innovation Opportunities

Collaborative Research and Innovation Opportunities

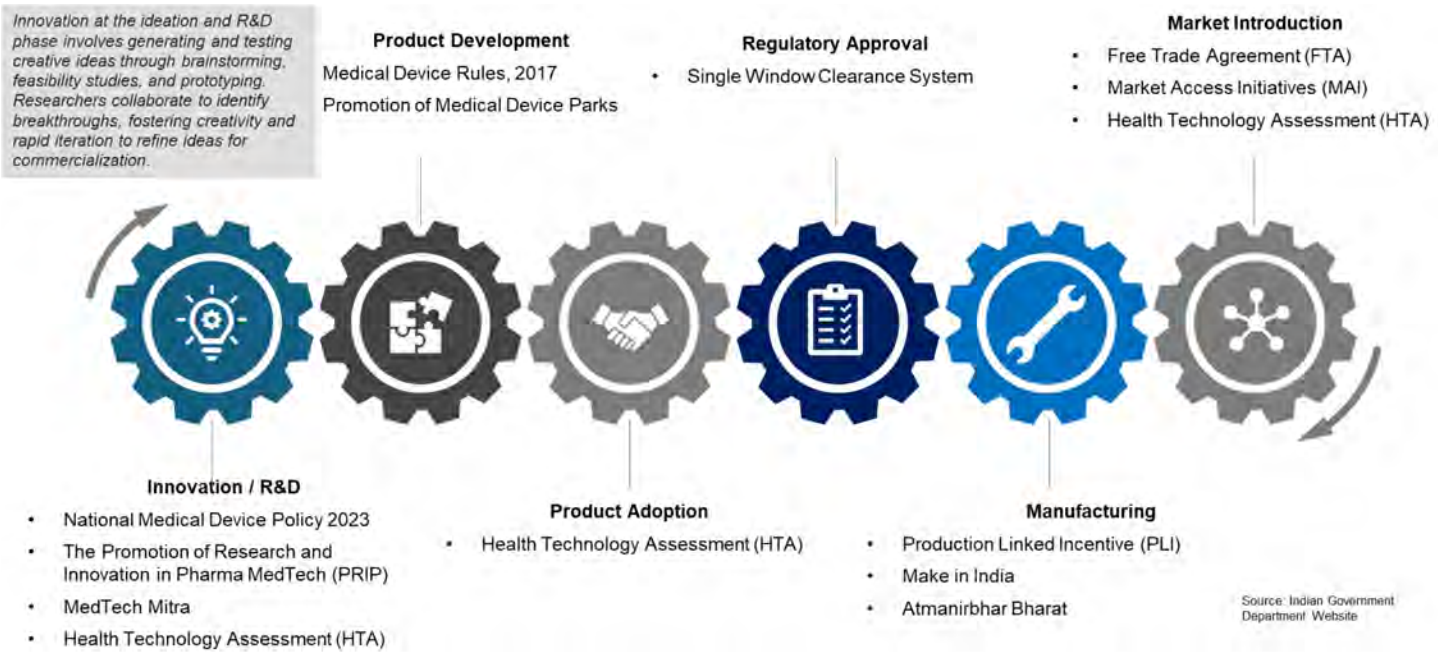
Abstract

This section explores various government policies and regulations applicable to the medical device sector. These regulations and policies not only safeguard the safety, efficacy, and quality of medical technologies but also foster advancements in science, technology, and innovation within the medical technology sector. The section also maps out key institutions, government bodies, and incubation hubs that are conducting medical device research in India and identifies the institutions that the Netherlands government and institutions can consider for collaboration, given the commonality of interest. It further explores and provides specific recommendations for enhancing collaboration.

5.1 Government Medical Device Policies and Initiatives

India imports 70% to 80% of its medical devices, which poses risks such as supply chain disruptions and increased costs. To address these challenges, promote self-sufficiency, and enhance the medical device ecosystem, the Indian government has developed extensive resources and strengths. India's medical device ecosystem is increasingly robust and dynamic, demonstrating significant capabilities. The country has made advancements in cutting-edge academic research, state-of-the-art incubation facilities, and comprehensive startup support. The Indian government offers substantial funding and policy assistance, creating a supportive environment from ideation to commercialization. This ecosystem is designed to enable rapid industry advancement. For more details, please refer to Annexure H.

Government policy mapped around Medical Device value chain Government



The Indian government is taking significant strides in fostering medical device innovation through various initiatives. The MedTech Mitra initiative is designed to boost domestic innovation by offering strategic support for clinical evaluation, regulatory facilitation, and commercialization, empowering local innovators and enhancing the medical device landscape in India. Transitioning the pharmaceutical and medical device sectors from cost-based operations to innovation-driven industries requires a robust R&D ecosystem.

The Promotion of Research and Innovation in the Pharma and Medical Device Sector (PRIP) scheme has been launched by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, with the goal of transforming India into a global powerhouse for R&D in the Pharma medical device sector. The scheme promotes industry-academia collaboration, establishes Centers of Excellence, and accelerates R&D investments, thereby enhancing global competitiveness.

Health Technology Assessment (HTA) systematically evaluates health technologies for clinical efficacy, cost-effectiveness, and safety, ensuring optimal resource allocation and the adoption of effective technologies for affordable and high-quality healthcare. Together, these initiatives are set to transform India's medical device sector into a globally competitive and self-reliant industry, with the government's commitment to innovation and support for local talent paving the way for a brighter future in healthcare technology.

Key Government Initiatives

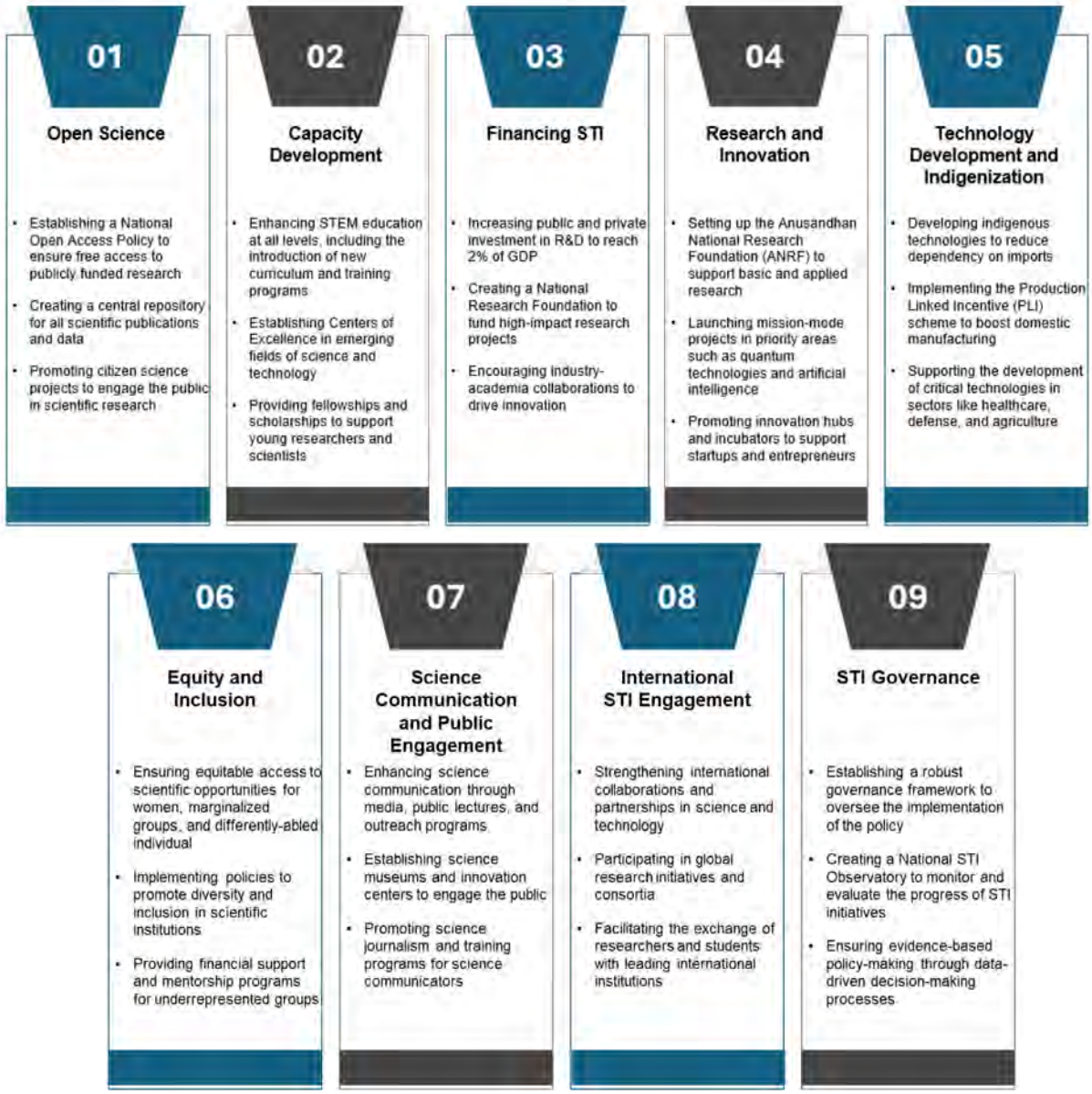
Initiatives	Objectives	Details
MedTech Mitra	MedTech Mitra is an online platform designed to support emerging talents in the field of medical technology. It helps in research, knowledge enhancement, and analytical reasoning, while also providing crucial support for securing regulatory approvals	• This initiative is under the NITI Aayog's Atal Innovation Mission, in collaboration with the Indian Council of Medical Research (ICMR) and the Central Drugs Standard Control Organization (CDSCO) • It offers tailored support and mentorship and helps innovators navigate complex regulatory landscapes. Ultimately, it strives to enhance healthcare outcomes and ensure timely access to life-saving medical device
Health Technology Assessment	HTA India (under the Department of Health Research, MoHFW) is entrusted with the responsibility to analyze health technologies viz. medicines, devices and health programmes for its cost-effectiveness, clinical-effectiveness and equity issues by means of Health Technology Assessment (HTA)	• HTA India collaborates with various stakeholders, including policymakers, healthcare providers, and researchers, to ensure comprehensive evaluations. This help in decision making for an efficient use of the limited health budget and provide people access to the quality health care reducing their out-of-pocket expenditures (OOPE) on health
Promotion of Medical Device Parks	The "Promotion of Medical Device Parks" scheme supports the medical devices industry under Atmanirbhar Bharat (Government of India national initiative). It aims to improve infrastructure, reduce costs, and enhance domestic availability of medical devices	• It has earmarked financial Assistance of €44 million for FY 2020-2025, covering up to 90% of project costs in certain states, with a €11 million cap per park • It targets four segments: cancer care/radiotherapy devices, radiology and imaging devices (ionizing and non-ionizing), anesthetics and cardio-respiratory devices, and all implants, including electronic • Currently, 19 greenfield projects have been launched, with production of 44 high-end devices like MRI machines and CT-Scans underway

Source: Indian Government Department Website

5.2 India’s Innovation Focus

India's STIP 2020 aims to foster innovation in medical devices through collaboration among academia, industry, and healthcare institutions. This policy is designed to create a conducive environment for technological advancements by establishing innovation hubs and leveraging emerging technologies. By increasing R&D investment, the policy seeks to drive significant progress in the medical devices sector. Additionally, STIP 2020 proposes various incentives such as tax benefits, funding programs, and regulatory reforms to facilitate quicker market access for new innovations. These measures are intended to streamline the development and commercialization process, making it easier for innovative solutions to reach the market and benefit the healthcare ecosystem.

Key Pillars of STIP 2020



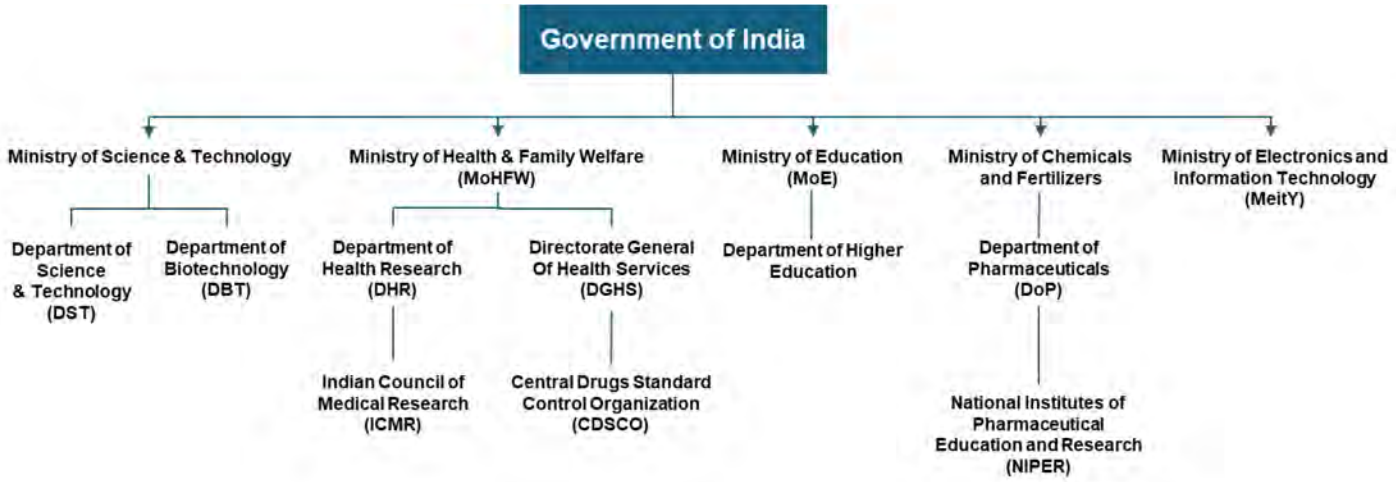
The National Technology Strategy (NTS) of the Netherlands is essential for preserving the Netherlands' competitive advantage amid rising global technological competition. It focuses on ten key enabling technologies that are pivotal for economic growth, tackling societal challenges, and safeguarding national security. The Dutch National Technology Strategy (NTS) emphasizes the importance of public-private partnerships and prioritizes ten key technologies, including AI, semiconductors, and quantum technologies, to address societal challenges. The NTS aims to harness these advanced technologies to solve global issues, thereby enhancing the quality of life and promoting sustainable development. By focusing on high-quality scientific research and fostering strong international relationships, the NTS aims to drive technological innovation. The strategy also highlights the need for a collaborative approach, involving various stakeholders from different sectors to drive technological progress and create impactful solutions.

Both policies focus on creating a robust innovation ecosystem by promoting cross-border collaborations and leveraging each country's strengths. The alignment between India's STIP and the Dutch NTS paves the way for joint initiatives that can drive technological advancements and address global healthcare challenges effectively. This synergy underscores the importance of public-private partnerships and international cooperation in enhancing the medical device sector. By working together, India and the Netherlands can combine their expertise and resources to develop innovative solutions that improve healthcare outcomes and contribute to global health and well-being. This collaborative approach not only strengthens the medical device ecosystem but also fosters a culture of innovation and continuous improvement.

5.3 Key Regulatory and Scientific Apex Bodies

Medical device regulation in India involves multiple government bodies working together to foster innovation, ensure safety, and promote commercialization. Key players include the Ministry of Science & Technology, Department of Biotechnology (DBT), Department of Science and Technology (DST), Biotechnology Industry Research Assistance Council (BIRAC), NITI Aayog, Ministry of Health & Family Welfare, Central Drugs Standard Control Organization (CDSCO), Indian Council of Medical Research (ICMR), and the Department of Pharmaceuticals. These organizations provide funding, formulate policies, ensure quality standards, support research and development in the medical device sector, and promote interdisciplinary research and startups. This holistic approach positions India as a global leader in science and technology, addressing societal challenges and boosting economic development. Detailed definitions of the Indian departments and sub-departments can be found in Annexure G.

Key Regulatory and Apex bodies



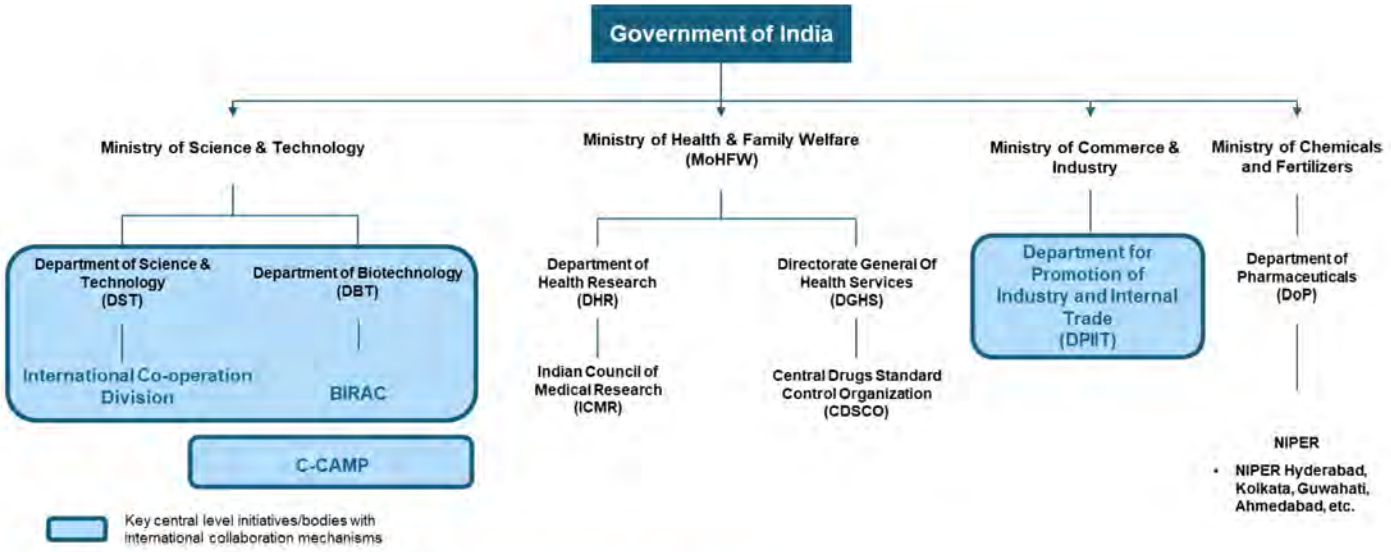
Department of Biotechnology (DBT)	The DBT is instrumental in the development and commercialization of biotechnology products. It provides grants and incentives for biotech startups, supports clinical trials, and facilitates the translation of research into market-ready medical technologies.
Biotechnology Industry Research Assistance Council (BIRAC)	BIRAC, a not-for-profit organization under the DBT, plays a pivotal role in nurturing the biotech ecosystem in India. It provides funding, mentorship, and incubation support to Medtech startups, helping them develop innovative medical technologies and bring them to market. BIRAC's initiatives, such as the BioNEST program, create a conducive environment for Medtech innovation and entrepreneurship.
Central Drugs Standard Control Organization (CDSCO)	CDSCO regulates the safety, efficacy, and quality of medical devices, pharmaceuticals, and cosmetics. It ensures that Medtech products meet stringent standards before they reach the market, safeguarding public health and promoting trust in medical innovations.
Indian Council of Medical Research (ICMR)	ICMR is the apex body for biomedical research in India. It conducts and supports research on various health issues, promotes the development of new medical technologies, and ensures that innovations are evidence-based and beneficial to public health.
The Department of Higher Education	The Department of Higher Education in India, under the Ministry of Education, is essential for overseeing the Indian Institutes of Technology (IITs). It formulates policies, provides funding, and ensures educational standards through quality assurance measures.
Department of Pharmaceuticals (DoP)	The Department of Pharmaceuticals focuses on the growth and development of the pharmaceutical sector. It supports the Medtech industry by facilitating the production of high-quality medical devices, encouraging innovation, and ensuring the availability of essential medical products. It also regulates institution like NIPER which play a crucial role in Medtech research and innovations.

Source: Indian Government Department Website

5.4 Government Initiatives to Foster Research and Innovation

Central Level Initiatives

India's central government has launched strategic programs to boost the medical device sector, offering collaboration opportunities for foreign governments, innovators, and startups. The National Policy on R&D and Innovation in Pharma and Medical Devices provides incentives for research and innovation. Key organizations include the International Cooperation Division, BIRAC (supporting over 474 startups with €4.68 million), C-CAMP (incubating around 450 startups with investments exceeding €5.50 million), and DPIIT (recognizing 1.57 lakh startups). These initiatives aim to attract international interest and investments, establishing India as a competitive global player in medical devices and fostering technological advancements and economic growth in healthcare. More details can be found in Annexure C.



01 International Co-operation Division

Bilateral S&T Cooperation Agreements: Facilitates research collaborations between Indian scientists and international counterparts through joint projects, workshops, and technology development programs.

02 BIRAC

Biotechnology Industry Partnership Programme (BIPP): De-risks company investments in R&D by sharing the risk through loans, equity, or grants.
BioNEST: Offers incubation facilities and supports bio-incubators.
BIG, PACE, SBIRI, CRS: Various schemes supporting biotech startups with funding, incubation, and research collaborations.

03 C-CAMP

WAH! Accelerator: Emphasizes on co-creation and co-development of new technologies in Water, Agriculture, Animal and Human health towards fulfilling the One Health approach to address Antimicrobial Resistance
Accelerator and Bio-Entrepreneurship programs: Support startups with mentorship and funding. Their Technology Development initiative offers access to advanced platforms for developing Medtech solutions.

04 Department for Promotion of Industry and Internal Trade

Indo-Dutch StartUpLink: Facilitates market entry for Dutch and Indian startups by providing access to networks, mentorship, and strategic contacts.
FDI Policy: Allows 100% Foreign Direct Investment in the manufacturing of medical devices through the automatic route.

Source: Indian Government Department Website

State Level Initiatives[5]

In addition to national initiatives, several Indian states are implementing targeted initiatives to enhance the medical device industry, paving the way for foreign startups and companies to thrive in India. Several Indian states are implementing targeted initiatives to enhance the medical device industry. Five states have been identified based on their facilities and specialized ecosystems for the medical device industry, Karnataka's new Industrial Policy emphasizes medical device investments and job creation. Telangana hosts the largest Medical Device Park in Hyderabad. Maharashtra is developing the Maharashtra Global Med Tech Zone to attract global healthcare leaders. Gujarat is establishing a medical device park in Nagalpar, Rajkot. Tamil Nadu supports medical device startups through incubation facilities. These state-level efforts complement central initiatives, fostering a robust ecosystem for growth and international collaboration in the medical device space. Details can be found in Annexure D.

1. Karnataka

Initiatives: Karnataka Global Capability Centre Policy and Global Innovation Alliance.
Key Features:

- **Global Capability Center Policy Draft (2024-2029)**: Aims to attract 500 new GCCs to Karnataka, generating economic output of ~€47.5 billion and creating 350,000 new jobs by 2029.
- **Global Innovation Districts**: Establishes three new technology parks to enhance connectivity and support innovation.
- **Centre of Excellence for AI**: Focuses on advancing artificial intelligence capabilities within GCCs.
- **Beyond Bengaluru Package**: Provides incentives for establishing GCCs in Tier-II and Tier-III cities.

2. Telangana

Initiatives: Hyderabad Pharma City and the establishment of the country's largest Medical Device Park.
Key Features:

- **Telangana Life Sciences Cluster**: Hosts 800+ life sciences companies valued at a combined €4000+ million, supporting 51,000 direct and 150,000 indirect jobs.
- **Medical Device Park**: Spread over 302 acres, it supports the manufacturing and R&D of medical devices, with over 55 companies setting up units.
- **Innovation Ecosystem**: Hyderabad's comprehensive ecosystem includes innovation centers, prototyping centers like T-Works, and a strong supplier network.

[5] State Government Websites for Karnataka, Telangana, Tamil Nadu, Maharashtra, and Gujarat

3. Tamil Nadu

Initiatives: TANSEED and MSDP programs.
Key Features:

- **TANSEED (Tamil Nadu Startup Seed Grant Fund)**: Provides early-stage financing grants of up to ~€11,000 to support innovative enterprises in sectors like agriculture, climate action, and livelihood.
- **MSDP (Medical Device Sector Development Program)**: Focuses on developing the medical device sector by creating a conducive environment for manufacturing and innovation, including infrastructure development, regulatory support, and R&D incentives.

4. Maharashtra

Initiatives: Innovative startup policies to attract investments and develop incubators.
Key Features:

- **Maharashtra State Innovative Startup Policy (2018)**: Aims to drive economic growth and job creation by encouraging entrepreneurs to design novel solutions in sectors like biotechnology, AI, and FinTech.
- **Support for Incubators**: Establishes and expands incubators to foster a culture of innovation and entrepreneurship.
- **Skill Development**: Emphasizes skill development and training programs to build a skilled workforce.

5. Gujarat

Initiatives: Biotechnology Policy and iCreate initiative.
Key Features:

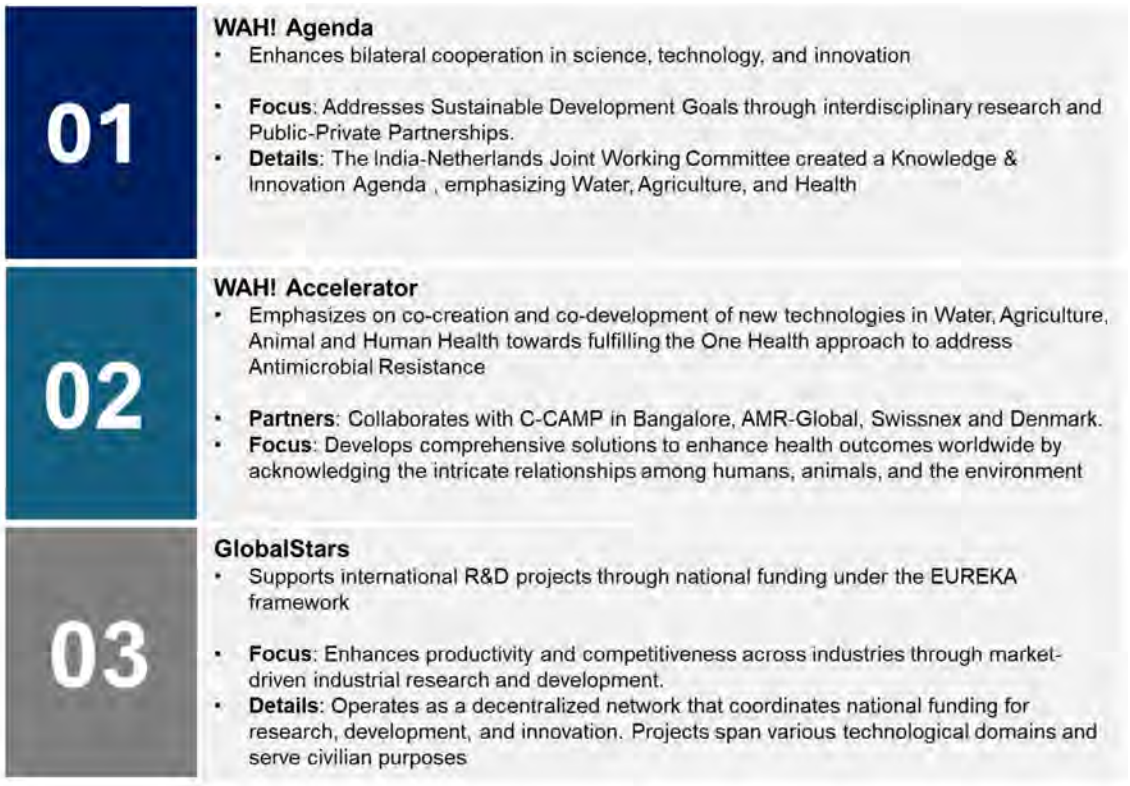
- **Biotechnology Policy (2022-2027)**: Aims to make Gujarat a globally competitive destination for biotechnology products, processes, and services by leveraging the state's industrial ecosystem.
- **iCreate (International Centre for Entrepreneurship and Technology)**: Provides a platform for startups to innovate and scale, offering incubation, mentorship, and funding support.
- **Support for Innovation**: Focuses on creating inter-sectoral synergy and promoting partnerships between various stakeholders, including local and state administrations, NGOs, and industry.

5.5 Existing India-Netherlands Collaboration

Bilateral Programs between India and the Netherlands

The partnership between India and the Netherlands has been instrumental in driving mutual growth and innovation, especially in research, medical technology, and innovation. By combining the Netherlands' cutting-edge infrastructure with India's technological expertise, they have addressed global challenges like climate change and universal healthcare access. This collaboration enhances bilateral trade and facilitates the exchange of ideas and sustainable practices, focusing on healthcare, medical devices, water management, agriculture, and renewable energy. The Netherlands and India have adopted a bilateral knowledge and innovation agenda named the WAH! Agenda, a mission-driven, interdisciplinary initiative targeting Water, Agriculture, and Health & Life Sciences, supported by key enabling technologies under the National Technology Strategy. Since 2008, the cooperative relationship has been formalized through a Memorandum of Understanding between the Netherlands' Ministry of Economic Affairs and India's Department of Science and Technology (DST). This includes the Joint Working Group involving the Department of Science and Technology (DST), Department of Biotechnology (DBT), Ministry of Electronics and Information Technology (MeitY), Indian Council of Medical Research (ICMR), and the Dutch Research Council (NWO), leading to numerous research programs, also in medical technologies. Such initiatives position India and the Netherlands to develop sustainable solutions benefiting both countries while prioritizing Science, Technology, and Innovation cooperation. Further details regarding Indian ministries can be found in Annexure G.

Examples of Innovation Instruments in Life Science and Health



The partnership between India and the Netherlands has continuously fostered advancements in healthcare technology. The 2017 joint call for sustainable healthcare technologies by the Netherlands Organization for Scientific Research (NWO) and the Department of Biotechnology (DBT) exemplifies the efficacy of this collaboration. This initiative, alongside numerous cooperative projects, capitalizes on the strengths of both countries. The achievements of these joint efforts highlight the significant potential for future collaborations in creating sophisticated and accessible healthcare solutions.

Examples of Life Science Health Research & Innovation

Joint Call on 'Technology for a Sustainable Healthcare: Minimally invasive techniques' between by NWO (ZonMw, Netherlands) and DBT (Department of Biotechnology, India) focuses on developing minimally invasive techniques to enhance sustainable healthcare. This initiative aims to foster collaboration between Dutch and Indian researchers to create innovative medical devices that improve patient outcomes while reducing healthcare costs. The program emphasizes less invasive treatments, early diagnosis, and personalized care.

Project - SMART surgical system , developed through a collaboration between Indian institutions (Dr Prashant Jha - AIIMS and IIT Delhi) and the Netherlands (Prof Jenny Dankelman - TU Delft), aims to revolutionize minimally invasive surgery. By providing high-quality medical devices, it makes advanced surgical techniques accessible even in low-resource settings. This innovation promises to enhance healthcare outcomes and bridge the gap in medical technology availability.

Project - IMAGING NEEDLES, developed through a collaboration between Indian institutes (Indian Institute of Science, National Institute of Mental Health and Neuroscience, and St. John's Research Institute) and Dutch institutions (University of Twente, TU Delft, and University Medical Center Groningen), are advanced needle probes designed for deep tissue multi-modal molecular imaging. These innovative probes enable precise imaging of molecular structures within deep tissues, enhancing diagnostic accuracy and treatment planning.

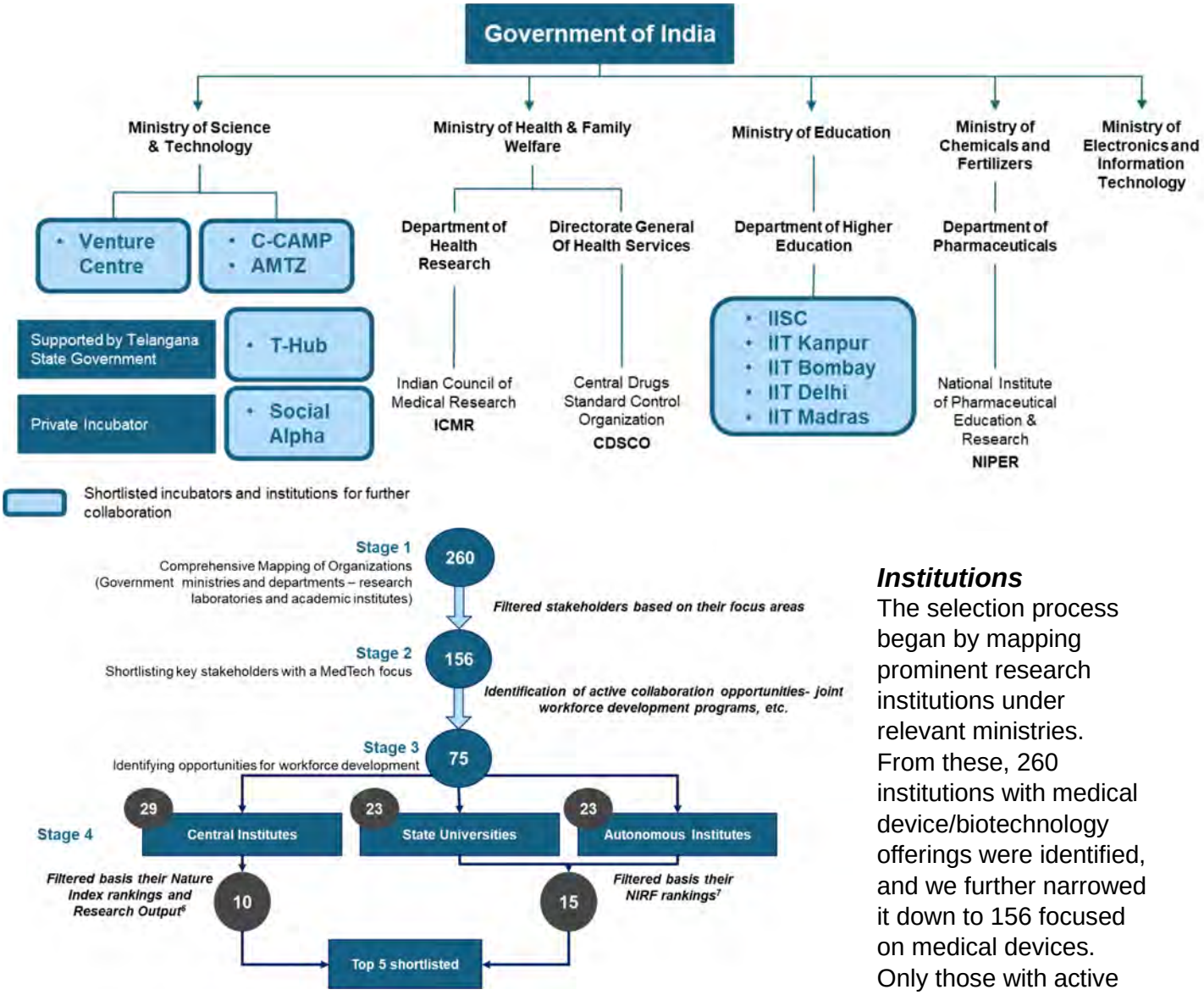
Project - Next-generation corneal crosslinking The collaboration between India and the Netherlands is pioneering the development of next-generation corneal crosslinking. By integrating artificial intelligence and biomechanical modeling, this partnership aims to enhance the precision and efficacy of treatments for corneal diseases. This innovative approach promises to significantly improve patient outcomes and advance the field of ophthalmology.

Project - Bionic is developing a bionic pancreas to advance diabetes management. In partnership with Tata Memorial Centre in Mumbai, India and Maastricht University Medical Centre (Netherlands), the project focuses on enhancing automated image analysis ('Radiomics') using a distributed framework and Semantic Web technology. These refined tools are deployed at both centers to improve decision support systems for cancer treatment.

Project - TRAIN aims to enhance cancer treatment through personalized healthcare solutions in radiation oncology. It involves academic, industrial, and clinical leaders from India (Centre for Development of Advanced Computing) and the Netherlands (Maastricht University), focusing on developing Decision Support Systems (DSSs) using the Personal Health Train (PHT) approach. The project applies machine learning to hospital data while ensuring privacy and data fairness, with clinical trials planned to validate the DSSs.

5.6 Potential Institutes and Incubators for Further Collaboration

This section outlines the institutions and incubators shortlisted to further strengthen the bond between India and Netherlands in medical device space.



Institutions

The selection process began by mapping prominent research institutions under relevant ministries. From these, 260 institutions with medical device/biotechnology offerings were identified, and we further narrowed it down to 156 focused on medical devices. Only those with active collaboration opportunities were considered. Institutions were categorized into central, state, and autonomous entities, with central institutions shortlisted based on their Nature index ranking and research output, while state and autonomous ones were assessed using NIRF scores, resulting in the final selection of five institutions. Find more details in Annexure F.

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[6] The Nature Index evaluates academic institutions according to their research contributions in the natural sciences. It employs the "Share" metric to quantify the extent of an institution's authorship in prestigious journals. This metric specifically assesses the proportion of authorship that an institution contributes to a research article

[7] The NIRF ranking evaluates Indian higher education institutions based on five key parameters: the quality of teaching and learning resources, research output and impact, student graduation outcomes, inclusivity and outreach, and the institution's reputation among peers. These criteria provide a comprehensive assessment of institutional performance, ‘‘helping to identify the top educational institutions in India’’

Top five institutions for collaboration

IISc Bangalore (Indian Institute of Science)

- **Location**: Bangalore, Karnataka
- **Focus Areas**: AI and robotics innovations in healthcare, biomedical engineering, and biotechnology.
- **Special Programs**: Foundation for Science Innovation and Development (FSID), Co-Innovation and Research (CORE Labs), and Deep Science Incubation (STEM Cell).
- **Additional Details**: IISc has partnered with Wipro GE Healthcare to set up a Healthcare Innovation Lab focused on AI in medical imaging. They also have a pioneering alliance with GE Healthcare to advance medical devices innovation, research, and technology development.

IIT Madras (Indian Institute of Technology, Madras)

- **Location**: Chennai, Tamil Nadu
- **Focus Areas**: Affordable healthcare, biomedical engineering, and global research collaborations.
- **Special Programs**: Centre for Innovation (CFI), Healthcare Technology Innovation Centre (HTIC).
- **Additional Details**: IIT Madras has incubated over 200 deep technology startups, including those focused on medical technology. The incubator supports startups developing innovative healthcare solutions.

IIT Delhi (Indian Institute of Technology, Delhi)

- **Location**: New Delhi, Delhi
- **Focus Areas**: Biotech, healthcare startups, and medical devices.
- **Special Programs**: Foundation for Innovation and Technology Transfer (FITT), Centre for Biomedical Engineering (CBME).
- **Additional Details**: IIT Delhi has incubated 147 startups and executed 271 international research collaborations. They have developed affordable COVID-19 diagnostics.

IIT Kanpur (Indian Institute of Technology, Kanpur)

- **Location**: Kanpur, Uttar Pradesh
- **Focus Areas**: Bio design innovation, biomedical research, and technology transfer.
- **Special Programs**: School of International Biodesign - SHInE Fellowship, Centre for Bioengineering and Biomedical Research.
- **Additional Details**: The DST NIDHI-Center of Excellence in MedTech Innovations at IIT Kanpur supports startups with technical mentorship, networking opportunities, and state-of-the-art infrastructure. They have developed innovations like the Sanjeevani oxygen concentrator.

IIT Bombay (Indian Institute of Technology, Bombay)

- **Location**: Mumbai, Maharashtra
- **Focus Areas**: Healthcare innovation, biomedical engineering, and technology transfer.
- **Special Programs**: Tata Centre for Technology and Design (TCTD), Biomedical Engineering and Technology (Innovation) Centre (BETiC).
- **Additional Details**: BETiC at IIT Bombay has developed 25 devices, incubated 16 startups, and licensed 14 products to local industry partners. They also have a collaboration with Samsung to propel AI and digital health innovation.

Incubators

The purpose of medical device incubators is to accelerate the growth of healthcare startups by providing tailored support and essential resources. They offer critical elements like expert mentorship, funding opportunities, and advanced incubation facilities, which are vital for developing innovative solutions. When selecting these incubators, emphasis was placed on their ability to connect startups with influential industry networks and VC connects for strategic partnerships and guidance. Additionally, their proven effectiveness in facilitating seamless commercialization ensures startups can successfully bring their innovations to the market. Refer to Annexure E for more details.

Startups can access BIRAC Funds like LEAF fund, SEED Fund, AcE Fund and other BIRAC schemes through affiliated incubators. A key eligibility criterion for startup is maintaining 51% Indian shareholding

C- Camp (Centre for Cellular and Molecular Platforms)

Location: Bangalore, Karnataka
Offerings: Provides a "plug & play" model with fully equipped lab spaces, basic and high-end equipment, and access to technology platform. This setup enables startups to initiate research projects without needing initial funding. Offers specialized programs for diagnostics, medical devices, and biotechnology startups.

T-Hub

Location: Hyderabad, Telangana
Offerings: Provides extensive mentorship, co-working spaces, and funding opportunities. Hosts the T-Bridge program, which facilitates international collaboration and market access for startups. Focuses on technology diplomacy with startup hubs/cities across the world to deepen and broaden collaboration. Offers personalized mentorship and networking opportunities with industry experts.

Venture Centre

Location: Pune, Maharashtra
Offerings: India's largest technology incubator with more than 56% of its resources allocated for health startups. Provides lab spaces, funding, and access to specialized equipment. Offers personalized

Bio Valley – AMTZ

Location: Visakhapatnam, Andhra Pradesh
Offerings: Provides plug-n-play facilities at the AMTZ campus, access to top-notch testing centers and fabrication labs, and networking opportunities with industry experts. Supports startups above TRL (Technology Readiness Level) 5. Offers financial support and specialized programs for diagnostic devices.

Social Alpha

Location: Multiple locations across India
Offerings: Partners with NIPER Ahmedabad for lab infrastructure and industry connections. Provides funding, mentorship, and access to specialized equipment. Dedicated program for diagnostic devices. Offers personalized mentorship and networking opportunities with industry experts.

5.7 Key Recommendations: India-Netherlands Research and Innovation Collaboration Opportunities

The National Technology Strategy (NTS) of the Netherlands emphasizes biomolecular and cell technologies, imaging technologies, and artificial intelligence (AI) for their transformative potential in healthcare. Cell technologies drive innovations in precision health, enabling personalized medical treatments and diagnostics. Imaging technologies enhance medical imaging equipment, facilitating early detection and effective treatments. AI integration further boosts these technologies, enabling advanced data analysis and improved decision-making in medical devices. The Netherlands aims to lead globally in the medical device sector by fostering innovation and collaboration to tackle healthcare challenges and enhance patient outcomes. This strategic focus aligns with India's advancements in these areas, offering a robust opportunity for collaboration between Dutch and Indian institutions to co-develop health solutions that address healthcare challenges in both countries.

1 Research Collaboration between Indian and Dutch Institutes

- **Engage with Leading Institutions:** Explore collaboration opportunities with the five institutes highlighted in the report (IISc, IIT Kanpur, IIT Bombay, IIT Delhi, IIT Madras), which are renowned for their innovations, research exchanges, and cross-border collaborations in healthcare.
- **Form Partnerships with Research Hubs:** Establish comprehensive collaborations with research hubs such as the IITs and IISc in the fields of biomolecular and cell technology, medical imaging, and AI solutions.

Few Examples for collaboration:

- **CAR-T Cell Therapy:** Indian institutions like IIT Bombay and Tata Memorial Hospital have developed indigenous CAR-T cell therapies with high success rates. Collaborating with Dutch research institutions can enhance these therapies and make them more accessible globally.
- **Bi-Specific CAR-T Cell Therapy:** Delhi-based Cellogen Therapeutics has pioneered bi-specific CAR-T cell therapies. Joint research and clinical trials with Dutch biotech firms can accelerate the development and commercialization of these advanced therapies.
- **Development of Diagnostic Imaging Equipment**: India is working on reducing its dependency on imported imaging equipment by developing core technologies and subcomponents. Collaboration with Dutch companies can lead to the co-development of cost-effective, high-quality imaging solutions tailored for both markets.
- **AI Integration in Imaging:** Indian advancements in AI for medical imaging can be combined with Dutch expertise to create innovative diagnostic tools that improve accuracy and efficiency.

2 Incubation and Partnership with Indian Incubators

Collaborate with Leading Indian Incubators: Partner with prominent Indian incubators to support companies developing products that meet the needs of the Dutch market. These incubators provide specialized programs, including plug-and-play facilities and personalized mentorship, which are crucial for medical device startups.

Examples of Leading Indian Incubators:

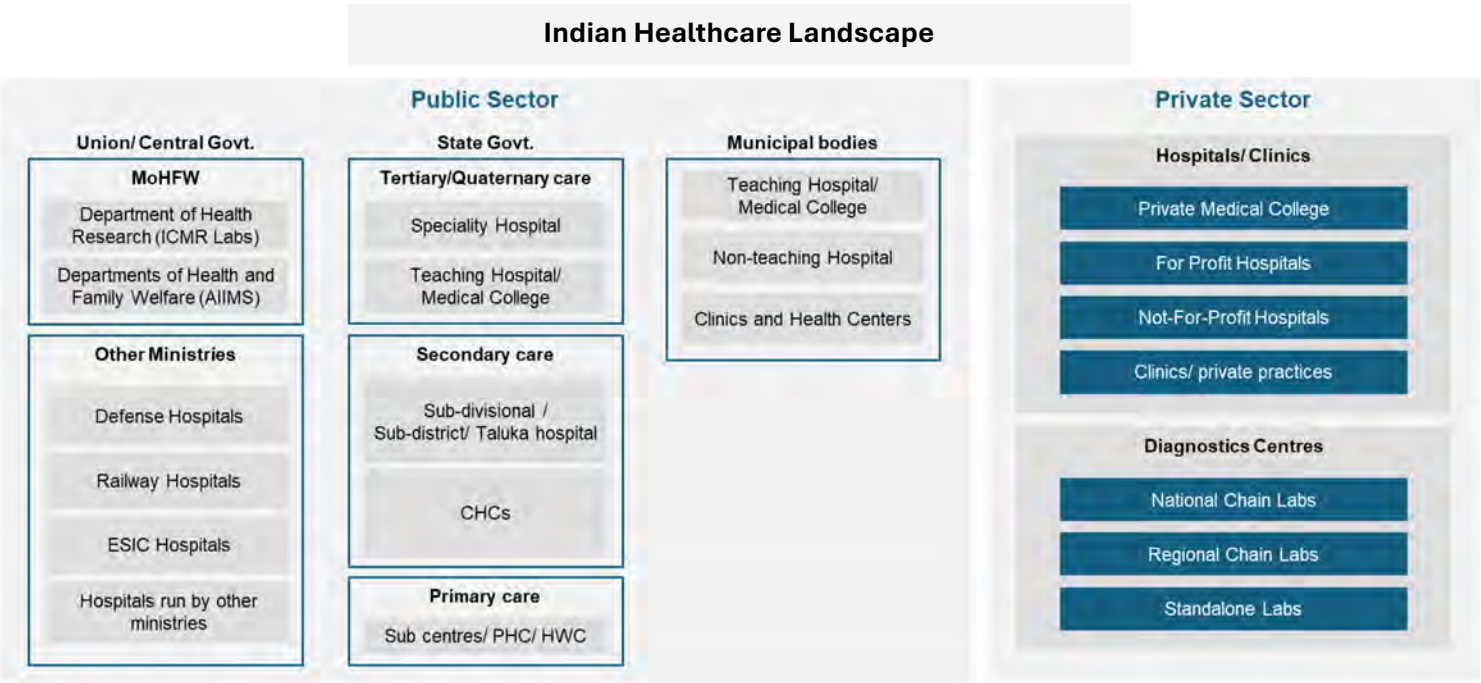
- **C-CAMP (Centre for Cellular and Molecular Platforms):** Known for its focus on life sciences and healthcare, C-CAMP provides incubation, funding, and mentorship to startups working on innovative medical technologies.
- **BioNEST (Bioincubators Nurturing Entrepreneurship for Scaling Technologies):** Incubators supported under BioNEST program of BIRAC offers incubation facilities and support to biotech startups across India.
- **Leverage the T-Bridge Program:** Utilize the T-Bridge program to facilitate the seamless entry and establishment of startups from the Netherlands into the Indian market, and vice versa. This program provides market access, mentorship, and networking opportunities for startups looking to expand internationally.

These collaborations can pave the way for the creation of groundbreaking medical devices and technologies, meticulously tailored to meet the unique needs of the Indian market while also possessing the versatility for adaptation and implementation in the Netherlands. This cross-border exchange of knowledge and technology will invigorate the Dutch healthcare sector with new solutions. By harnessing the collective expertise and ingenuity of both countries, we can usher in a new era of healthcare advancements that benefit patients and healthcare providers alike.

Strengthening the Position of Dutch Companies in India

Strengthening the Position of Dutch Companies in India

The Indian healthcare system is a vast and intricate network, serving over 1.4 billion people with a mix of public and private providers. This complexity is heightened by the diverse socio-economic landscape and varying health needs across regions. Foreign companies often struggle with navigating India's regulatory environment, which includes intricate laws and compliance requirements. Additionally, cultural differences and language barriers further complicate market entry and operations. The competitive landscape, with numerous established local players, adds another layer of challenge for foreign entrants.



CHC: Community Health Centre, PHC: Primary Health Centre, HWC: Health and Wellness Centre

In India, there is a market for every product, depending on which stakeholders the business targets.

India's manufacturing sector is poised for significant growth, driven by a combination of factors. The country's youthful and cost-effective workforce provides a strong foundation for industrial expansion. By adopting cutting-edge technologies such as Industry 4.0 and the Internet of Things (IoT), production processes have become more streamlined and efficient. As multinational corporations look to diversify their supply chains beyond China, India is becoming an attractive alternative. The nation's stable political environment, coupled with its vast resources and skilled professionals, further enhances its appeal. Additionally, the ease of foreign investments, particularly in sectors like medical devices, and improvements in the business climate, underscore India's potential as a global manufacturing hub.

India's offerings

Ease of Doing Business

India has significantly improved its ease of doing business, ranking 63rd in the World Bank's Doing Business Report 2020, up from 142nd in 2014.

Fund of Funds for Startups (FFS) Scheme

The Fund of Funds for Startups (FFS), overseen by the Department for Promotion of Industry and Internal Trade (DPIIT) and operated by the Small Industries Development Bank of India (SIDBI), is a €1.1 billion initiative to support startups. It invests in Securities and Exchange Board of India (SEBI)-registered Alternative Investment Funds (AIFs), which must invest at least double the FFS amount into government-recognized startups. By 2024, these AIFs had channeled approximately €2.2 billion into startups.

Industry 4.0 & IoT

Adoption of Industry 4.0 and IoT in asset maintenance and supply chain monitoring enhances production efficiency.

Skilled Workforce & Resources

India has a vast geography, rich resources, and a highly skilled workforce, making it a prime location for manufacturing and business.

FDI in Medical Devices

India allows 100% foreign direct investment (FDI) in its medical devices sector via the automatic route, facilitating easier investment for Dutch companies.

India supports foreign medical device companies through various initiatives, programs, and schemes. These efforts provide financial incentives, infrastructure development, and regulatory simplifications, creating a conducive environment for foreign medical device companies to thrive in India.

India's regulations and initiatives around medical devices

Medical Device Rules, 2017

The Medical Devices Rules, 2017, regulate the manufacturing, import, sale, and clinical investigation of medical devices in India, effective January 1, 2018. They cover in vitro diagnostics, surgical dressings, mechanical contraceptives, disinfectants, and other notified devices. Devices are classified into four risk categories: Class A (low risk), Class B (low moderate risk), Class C (moderate high risk), and Class D (high risk).

National Medical Device Policy 2023

The policy focuses on access, affordability, quality, and innovation, with metrics for impact assessment and guidelines for implementation to enhance competitiveness and self-reliance.

MedTech Mitra

MedTech Mitra is an online platform designed to support emerging talents in the field of medical technology. It helps in research, knowledge enhancement, and analytical reasoning, while also providing crucial support for securing regulatory approvals.

Single Window Clearance System

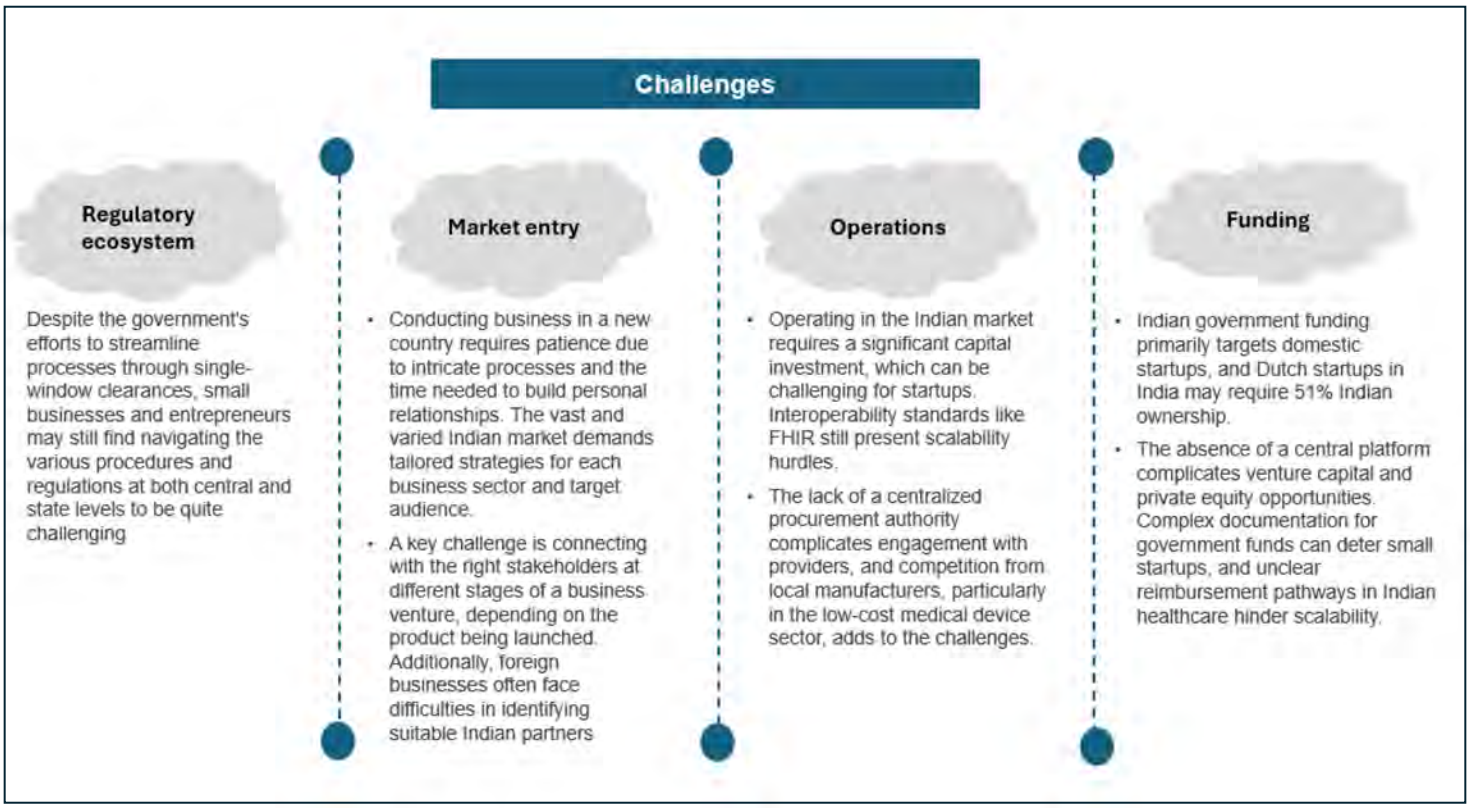
The National Single Window System (NSWS) is a digital platform to guide stakeholders in identifying and applying for approvals according to their business requirements. The Know Your Approvals (KYA) module includes guidance for 32 Central Departments and 34 States. It provides access to over 658 central approvals and 6,787 state approvals.

The Promotion of Research and Innovation in Pharma MedTech (PRIP)

The Scheme for Promotion of Medical Device Parks has been notified to develop common infrastructure facilities which in turn will reduce the production cost of medical devices manufactured in the country.

Potential Challenges and Opportunities for International Collaboration

Collaboration between the Indian and Dutch medical device industries presents both opportunities and challenges, influenced by differences in regulatory frameworks, funding structures, and market priorities. As part of the study, interactions were organized with Dutch entrepreneurs to explore their journeys, experiences, and the challenges they faced in the Indian market, as well as to identify potential support mechanisms. Addressing these barriers while leveraging opportunities requires a structured approach that facilitates knowledge exchange, regulatory alignment, and market access. By fostering collaboration, India and the Netherlands can create a more cohesive medical device ecosystem that addresses the challenges of both healthcare systems.



Moving forward, possible strategies for co-development, co-innovation, and test beds include:

- The expanding Indian economy, growing middle class, and increasing healthcare needs present opportunities for Dutch companies. **With an anticipated rise in disposable income and a burgeoning demand for quality healthcare services, Dutch companies can tap into a vast market by offering innovative healthcare solutions and products. It's crucial to understand the local consumer behavior and tailor offerings to meet the specific needs of the Indian population.**

- The Indian government can develop a unified platform to connect venture capital and private equity firms with startups, assisting with capital requirements and initial support for Dutch startups. **Such a platform would streamline the process of securing funding, providing a one-stop solution for financial support. It would also foster networking opportunities, mentorship, and guidance from experienced investors, enabling Dutch startups to navigate the Indian market efficiently.**
- The Netherlands Enterprise Agency (RVO) and the Netherlands Trade Network in India aid Dutch companies in navigating the regulatory ecosystem. **These agencies offer critical insights into local laws, regulations, and compliance requirements. They provide resources such as market research reports, legal advice, and connections to local industry experts, helping Dutch companies mitigate risks and establish a strong foothold in India.**
- Investments in healthcare research, AI, and imaging technologies align with Dutch competencies. **Dutch companies renowned for their expertise in medical technology and research can leverage this by focusing on developing advanced diagnostic tools, AI-driven healthcare solutions, and cutting-edge imaging technologies. Collaborating with Indian research institutions and hospitals can lead to co-created innovations that benefit both markets.**
- A dedicated single point of contact at the Embassy of the Netherlands in India can assist Dutch companies entering the Indian market. **This liaison officer would act as a bridge between Dutch businesses and Indian authorities, providing essential support in areas such as business setup, regulatory approvals, and market entry strategies. Having a reliable contact person can significantly simplify the establishment process and enhance bilateral trade relations.**
- Engaging in contract manufacturing allows Dutch companies to maintain a lean asset structure, reducing capital requirements and expediting business start-up. **By outsourcing production to local manufacturers, Dutch companies can minimize initial investment costs while benefiting from India's skilled labor force and cost-effective manufacturing capabilities. This approach enables faster market entry and scalability without heavy capital expenditure.**
- Startups can collaborate with ABDM-compliant hospitals and systems to focus on health record sharing, which addresses interoperability challenges for Dutch companies. **Working with hospitals that adhere to the Ayushman Bharat Digital Mission (ABDM) standards ensures seamless integration of health records. This collaboration can help Dutch companies develop interoperable solutions that improve patient care, streamline operations, and comply with Indian digital health regulations.**
- Private consultancy firms can help foreign startups set up businesses in India, guiding them from market entry to commercialization. **Consultancy firms provide end-to-end services, including market analysis, business registration, regulatory compliance, and go-to-market strategies. Their local expertise and strategic advice are invaluable for Dutch startups aiming to establish and grow their presence in India's competitive market.**

Potential Areas for Bilateral G2G Collaboration

Potential Areas for Bilateral G2G Collaboration

Life sciences and health have been identified as priority sectors for strategic investment, with growing market opportunities in India complementing the Netherlands' strengths in therapeutics, vaccines, diagnostics, medical devices, and E-health. Over the years, the collaboration between India and the Netherlands has strengthened, particularly in the areas of healthcare and innovation. This partnership has been facilitated by various trade missions, with Dutch and Indian SMEs actively engaging in sectors such as digital health, MedTech, vaccines, and hospital-based solutions. The focus on MedTech has been particularly significant, with the 2023 mission led by Prime Minister Rutte highlighting the importance of this sector.

Memorandum of Understanding (MoU) of 2014 between India's Ministry of Health and Family Welfare (MoHFW) and the Netherlands' Ministry of Health, Sports & Welfare has paved the way for deeper collaboration. The Task Force Healthcare (NL) and NatHealth strengthened their partnership by signing a Memorandum of Understanding (MoU) in 2015, which subsequently accelerated various initiatives in the healthcare sector.

The Netherlands has also supported Indian companies in navigating market access and regulatory frameworks, ensuring smoother collaboration. Medical centers from both countries have been working together on various initiatives, such as AI-based imaging systems, radiology, oncology, and cardiac monitoring. These collaborations serve as catalysts, addressing mutual societal challenges and fostering economic ties. With joint efforts in digital health, devices, diagnostics, and One Health/AMR, vaccines and therapeutics, India and the Netherlands are actively shaping the future of healthcare and medical technology, contributing to shared global goals of innovation and sustainability.

Future collaborations between India and the Netherlands in the medical devices sector should build on the strong foundation established through previous initiatives. These efforts should focus on addressing critical workforce shortages in healthcare delivery, while also enhancing patient self-sufficiency through innovation in medical technology. Cross-border research expanded market access, and the utilization of existing funding opportunities will be key in creating a robust and scalable collaboration framework. Such initiatives will not only enhance healthcare delivery in both countries but will also contribute to the global goals of innovation, sustainability, and improving health outcomes.

The following recommendations are designed to leverage existing India-Netherlands frameworks, which may not currently emphasize medical devices, to foster collaboration in this sector.

Joint R&D and Technology Co-Development	
Instrument of Collaboration	**Details**
Co-Funding and Grants	Establish medical device sector-specific bilateral funding programs under existing India-Netherlands collaborative healthcare initiatives, such as WAH! agenda, ensuring capital access for both early- and late-stage medical device innovations

	Expand joint venture opportunities between Indian biotech hubs (e.g., C-CAMP, Maharashtra's Medical Device Park) and Dutch research institutions and companies (e.g., Leiden Bio Science Park, Delft University of Technology)
	Provide incentivized grants to startups focused on creating labor-saving, patient-empowering and cost-effective healthcare solutions
Cross-Border Research and Knowledge Exchange	Collaborate on research in the medical application of technologies such as AI, imaging, or biomolecular and cell technology
	Enable research exchange programs between Indian engineering and medical colleges (e.g., IITs, AIIMS, NIPER) and Dutch counterparts (e.g., TU Delft, Utrecht University, Leiden Bio Science Park).
	Initiate a bilateral startup challenge program to invite multiple startups based on current needs and shortlist key medical technologies.
Technology Transfer	Connect Indian and Dutch Technology Transfer Offices (TTOs) to accelerate commercialization of research discoveries by enabling knowledge exchange and acts as a bridge between academia and industry in both countries
Market Access and Regulatory Support	
Instrument of Collaboration	**Details**
Bilateral Agreements and Policy Alignment	Institutionalize the bilateral cooperation between Department of Pharmaceuticals and Ministry of Health, Welfare and Sport on medical devices focused on joint research, regulatory alignment and facilitate market access.
	Establish close cooperation between DPIIT and the Ministry of Economic Affairs in the startup domain to provide guidance to startups in matters of regulatory affairs and connecting companies/startups with the right stakeholders.
	Collaborate in major conferences, such as Global Bio-India and BioAsia, to create awareness, showcase innovations, discuss regulatory frameworks, and identify areas for joint R&D.
Awareness Initiatives	Facilitate matchmaking in the form of innovation missions, trade missions, conferences, or virtual platforms to increase knowledge and connections between India and the Netherlands
	Host targeted networking events to connect Indian and Dutch stakeholders, including startups, researchers, incubators, and

	investors, to enable alignment with the key objectives of the Dutch and Indian healthcare ecosystems.
	Set up a dialogue between representatives of Indian companies and concerned stakeholders from the Netherlands (e.g., health insurers, large healthcare institutions, etc.) to validate suitability of the companies' offering in Dutch context, mutual interest levels, and readiness. This should be carried out in a fixed time frame and monitored at an appropriate level to ensure progress.
	Some shortlisted startups may need to navigate additional regulatory requirements. To support them, a monitoring program is recommended—developed in collaboration with incubators from both countries. This program should offer facilitation support, stakeholder engagement, bottleneck identification, process assistance, and periodic reviews to ensure timely interventions.
Funding Opportunities	
Instrument of Collaboration	**Details**
Research Funding	The multilateral GlobalStars program, in collaboration with the Department of Biotechnology (DBT), which could be utilized to fund international research collaborations.
	The EU Horizon Europe program can offer significant funding for bilateral and multilateral research and innovation to address healthcare challenges.
	The Dutch Research Council (NWO) can support bilateral funding under the WAH! Agenda through various bilateral programs with DST, DBT, and ICMR.
Startup Funding	Access financial support for funding through BIRAC funds, including the Launching Entrepreneurial Driven Affordable Products (LEAP) Fund, and Sustainable Entrepreneurship and Enterprise Development (SEED) Fund.
	Startup fund schemes provided by the Ministry of Electronics and Information Technology (MeitY) are also promising, such as the Technology Incubation and Development of Entrepreneurs (TIDE) 2.0 and the Startup Accelerators of MeitY for Product Innovation, Development, and Growth (SAMRIDH).
	Create a platform for Netherlands VC/PEs to evaluate the startups/MSMEs aligning with the key objective of Labour-

	saving technology and fund medical device startups with potential to enter the Indian market.

Annexure

Annexure A – Sources used for Mapping Solutions

#	Source	Research/Innovation Focus	Stakeholder Type	# of Startups in Portfolio	# of Relevant Startups
1	Healthcare Technology Innovation Center (IIT Madras)	Healthcare and medical device	Incubator	50	14
2	BIRAC Biotech	Healthcare, Medical Devices, Diagnostics, Agriculture, Food tech, Industrial product, Bioprocesses, Biodegradable alternatives, Bio services, and others	Public Sector Enterprise	~500	21
3	VC Edge	List of VC/PE companies where investments have happened in medical device space over the last 14 years	VC / PE	300	23
4	SINE (IIT Bombay)	MedTech, Cleantech, FinTech, IoT, IT/ICT, and Others	Incubator	70	12
5	C-CAMP	Medical devices, AI, Diagnostics, Drug discovery and development, Agriculture, Nutraceuticals, and Industrial/Environmental Biotechnology	Incubator	96	14
6	MeitY - Centre for e Governance	Healthcare eGovernance	Government	20	2
8	IIT Kanpur's Startup Incubation and Innovation Center	Medical devices, Diagnostics, and Digital health technologies	Academia	60	5
9	Web search	NA	Web	NA	25
10	Venture Center	Health and Rehabilitation, Energy and Environment, Engineering and Automation, and Agriculture and Nutrition	Incubator	50	0
11	NIPER-Hyderabad Avishkaran/BioNest	Pharmaceutical sciences, digital health technologies	Academia	40	0
12	Social Alpha	Health and Wellness, Climate and Sustainability, Livelihoods and Prosperity	Incubator	20	3
13	Indian Angel Network	Healthtech, Health and Wellness, Agri tech, Bio Tech, Clean Tech, Consumer Brand & D2C, Deep Tech, EdTech, Electric Mobility, E-Commerce, FinTech	VC	~250	1
14	IIM Calcutta Innovation Park	50+ industries, including medical devices, Healthcare, Wellness	Academia	100	3
15	Mazumdar Shaw Medical Foundation (Narayana Health)	Personalized Medicine, Companion Diagnostics, Drug Discovery and Development, Translational	Medical	7	5

		Research, Academic and Hospital Collaborations			
16	Dr. Moopen's iNEST (Aster DM Healthcare)	Bioprinting, Digital Health, Blockchain, Personalized Medicine, Nutrition, Women's Health, Bioengineering, Medical Devices	Medical	17	3
17	Manipal Universal Technology Business Incubator (Manipal Hospitals)	Healthtech, Clean Tech, InfoTech, Agri Tech	Medical	44	1
18	Villgro Innovations Foundation	Healthcare, Agriculture, Climate Action, Inclusive Livelihoods	Incubator	13	4
19	Atal Incubation Centre - CCMB	Healthcare, biopharma, industrial biotech, agriculture and med-tech	Incubator	160	3
20	Personal connections & Networking	NA	Networking	NA	5
Total				1047	144

Annexure B – List of Remaining Prioritized Solutions (Cohorts 1, 2, and 3)

#	Solution	Cohort
1	ArtSens Plus	Cohort 1
2	TempWatch by Bempu	Cohort 1
3	Postura by Postura	Cohort 1
4	DeepTek Suite	Cohort 1
5	DRISTi by Artelus	Cohort 1
6	HealthCubed Ecosystem by HealthCube	Cohort 1
7	LifeSigns Smart Wards	Cohort 1
8	Medios DR by Remidio	Cohort 1
9	Oivi AS	Cohort 1
10	MAXIO, ROBIO EX, and NAVIOUS by Perfint Healthcare	Cohort 1
11	SpectralHT by Pramana	Cohort 1
12	Qure.aI Lung Cancer Care - qLC Suite	Cohort 1
13	Renalyx Dialysis Machines	Cohort 1
14	AI-Based Cardiovascular Diagnostic Tools by Acuradyne	Cohort 2
15	Fertility kit by Inito-fertility	Cohort 2
16	Aikenist Suite	Cohort 2
17	ApneBoot by Bempu	Cohort 2
18	Qivi - Female External Urine Management Device (FEC) by Consure Medical	Cohort 2
19	Qivi - Male External urine management device (MEC) by Consure Medical	Cohort 2
20	nLite 360 by Heamac Healthcare	Cohort 2
21	InstaECG and InstaEcho by Trigcog Health	Cohort 2
22	Revive by Sensivision	Cohort 2
23	Swaasa by Salcit Technologies	Cohort 2

24	SanMitra 1000 HCT EMS by JeevTronics	Cohort 2
25	Pheezee (Device, electrodes, and App) by Startoon Labs	Cohort 2
26	Stasis Lab by Unreasonable Group	Cohort 2
27	SWASAM by Caldor Health Technologies	Cohort 2
28	VELOX CARE by Yostra Labs	Cohort 2
29	WALK by LifeSpark	Cohort 2
30	A3rmt Modular Remote Monitoring Ecosystem	Cohort 3
31	AI100 by SigTuple	Cohort 3
32	AI-based Cloud Medical Diagnostic Software by PrediScan	Cohort 3
33	Dripo by Evelabs	Cohort 3
34	FracID AI Solution by Ezovion	Cohort 3
35	CanScan by Kozhnosys	Cohort 3
36	Micalys by Medprime Tech	Cohort 3
37	Mobile Eye Surgical Unit (MESU)	Cohort 3
38	Raksha by Nemo Care	Cohort 3
39	Savemom Toolkit	Cohort 3

Annexure C – List of Central Level Collaborative Initiatives

Ministry	Implementation Agency	Policy/Scheme	Description
Ministry of Commerce and Industry	Startup India	India-Netherlands #StartUpLink	The India-Netherlands #StartUpLink initiative is designed to open-up the Indian market to Dutch startups, and vice versa. The platform has been developed by Startup India in collaboration with the Embassy of the Netherlands provides access to information, relevant networks, pilot opportunities and a single point of contact for navigating through the Indian and Dutch startup ecosystems, respectively.
	Department for Promotion of Industry and Internal Trade (DPIIT)	Foreign direct Investment (FDI) Policy	FDI up to 100%, under the automatic route is permitted for manufacturing of medical devices.
DBT	C-CAMP	WAH! Accelerator	India-Netherlands bilateral collaboration will emphasize on co-creation and co-development of new technologies in Water, Agriculture, Animal and Human Health
	BIRAC	Biotechnology Industry Partnership Program	To be eligible, for the Company/LLP, minimum 51% shares of the Company should be held by Indian Citizens holding an Indian passport, Minimum half the persons who subscribed their names to the LLP document as its partners should be Indian citizens. For Public or Private institute, University, NGO, or Research Foundation, proper registration/accreditation from a government body is mandatory like certification, AICTE, CSIR/DSIR, SIRO certification. Funding at all stage – BIG, LEAP, BIPP, SBIRI, SEED, AcE, BioAngels
DST	International Cooperation Division	Science, Technology, and Innovation Agreements	Presently, India has bilateral S&T cooperation agreements with 83 countries with active cooperation with 44 countries. By and large, biomedical research/health sciences prominently figure in all bilateral agreements in the field of Science & Technology.

Annexure D – List of State Level Collaborative Initiatives

State	Offerings			
	Incubation & Mentorship	Funding & Innovation Networks	Partnerships	Details
Karnataka	GINSERV is a community-driven incubator helping tech business startups	Karnataka Startup Policy 2022-2027: Seeking to set up 50 new-age innovation networks in technology institutions in Tier-II and Tier-III cities.	Strong collaborations between academic and industry	Attract investments and generate employment in the state, including the medical technology sector. The policy includes the establishment of Global Innovation Districts and a Centre of Excellence for AI Technology diplomacy with startup hubs/cities across the world to deepen and broaden Karnataka's collaboration with these hubs.
Telangana	T-Hub in Hyderabad is one of the largest incubators providing extensive mentorship	Offers funding opportunities and a robust innovation network	Collaborates with academic institutions for research and development	Established the country's largest Medical Device Park spread over 302 acres in Hyderabad
Tamil Nadu	Offers incubation and mentorship through institutions like IIT Madras Research Park	Provides funding opportunities and innovation networks	Strong ties between academic institutions and industries	Provides seed funding, mentorship, and networking to early-stage startups in Tamil Nadu to support innovative ideas and scale operations. Focuses on developing the medical device sector by creating a conducive environment for manufacturing and innovation, including infrastructure development, regulatory support, and R&D incentives.
Maharashtra	Hosts several incubation centers and mentorship programs, including those at IIT Bombay	Strong presence of venture capital and innovation networks	Collaborations between academic institutions and industries in Mumbai and Pune	Attract angel and seed stage investment of €549.5 million. Develop at least 15 incubators in collaboration with industry and academia. Facilitate incorporation of at least 10,000 start-ups
Gujarat	Hosts incubation centers like iCreate, providing mentorship and support	Offers funding opportunities and a strong innovation network	Collaborates with academic institutions for research and development	Single Window Clearance Mechanism Plug and Play Facility Provide avenue for innovation and startup ecosystems between two countries to collaborate

Annexure E – Facilities provided by Incubators.

Incubators	Ideation	Proof of Principle	Proof of Concept demonstrated	Validation	Regulatory compliance	Pre commercialization	Commercialization and post market studies
C-CAMP	●	●	●	●	●	●	●

Venture Centre	●	●	●	●	●	●	●
T-Hub	●	●	●	●	●	●	●
Bio valley - AMTZ	Provides in case of exceptional circumstances			●	●	●	●
Atal Incubation Centre-CCMB	●	●	●	●	●	●	●
IIM Kolkata Innovation Park	●	●	●	●	●	●	●
SINE (IIT Bombay)	●	●	●	●	●	●	●
SIIC (IIT Kanpur)	●	●	●	●		●	●
Social Alpha	●	●	●	●	●	●	●
Health start					●	●	●
Indian Angel Network						●	●
Villgro Innovations	●	●	●	●	●	●	●

Annexure F - Shortlisted Institution based on NIRF and Nature ranking.

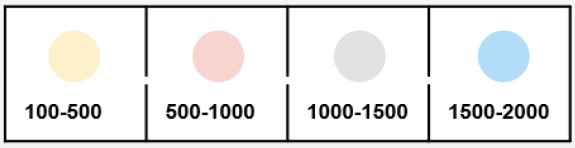
S.No.	Central Institution
1	Centre for Cellular & Molecular Biology (CCMB)
2	Central Electronics Engineering Research Institute (CSIR-CEERI)
3	Central Scientific Instruments Organisation (CSIR-CSIO)
4	Central Drug Research Institute (CSIR-CDRI)
5	Institute of Genomics and Integrative Biology (CSIR-IGIB)
6	Tata Institute for Fundamental Research (TIFR)
7	Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR)
8	S N Bose National for Basic Sciences (SNBNCBS)
9	Bose Institute

10	Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) (13) *

S.No.	State and Autonomous Institutions
1	IIT Madras
2	IISc Bengaluru
3	IIT Bombay
4	IIT Delhi
5	IIT Kanpur
6	IIT Kharagpur
7	IIT Roorkee
8	IIT Guwahati
9	Anna University
10	Bharathiar University
11	Banaras Hindu University
12	IIT Hyderabad
13	IIT Gandhinagar
14	IISER Pune
15	IIT Ropar

Legend

International Institute Ranking (Nature Index):



Annexure G – Definitions for Indian Departments and Sub-Departments

Departments/Organization	Definition
Ministry of Science & Technology	The Ministry of Science and Technology is the Indian government ministry charged with formulation and administration of the rules and regulations and laws relating to science and technology in India.
Department of Science & Technology	Department within the Ministry of Science and Technology, established to promote new areas of science and technology and to play the role of a nodal department for organizing, coordinating and promoting scientific and technological activities in the country.

Department of Biotechnology	Department under the Ministry of Science and Technology responsible for administrating development and commercialization in the field of modern biology and biotechnology in India.
National Science and Technology Entrepreneurship Technology Board	Established by the Department of Science & Technology as a means to support the promotion of knowledge-driven and technology-intensive enterprises. The Board, now under the Technology Translation and Innovation (TTI) Division, aims to encourage innovation and the startup ecosystem through Science, Technology & Innovation interventions.
BIRAC	Set up by Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.
BioNest	Bio-NEST was launched by BIRAC with a vision that focused on fostering the biotech innovation ecosystem in the country. Bio-NEST program provides support to establish bio-incubators either as a standalone entity or as a part of the academia.
Ministry of Health & Family Welfare	The Ministry of Health and Family Welfare, also known by its abbreviation MoHFW, is an Indian government ministry charged with health policy in India. It is also responsible for all government programs related to family planning in India.
Department of Health Research	Department of Health Research (DHR) was created as a separate Department within the Ministry of Health & Family Welfare. The aim of the DHR is to bring modern health technologies to the people through research and innovations related to diagnosis, treatment methods and vaccines for prevention.
Directorate General of Health Services	Directorate General of Health Services (DGHS) is an attached office of the Department of Health & Family welfare and has subordinate offices spread all over the country. The DGHS renders technical advice on all Medical and Public Health matters and is involved in the implementation of various Health Services.
ICMR	The Indian Council of Medical Research, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest and largest medical research bodies in the world.
CDSCO	The Central Drugs Standard Control Organization is India's national regulatory body for cosmetics, pharmaceuticals and medical devices. It serves a similar function to the Food and Drug Administration of the United States or the European Medicines Agency of the European Union.
Niti Aayog	National Institution for Transforming India, serves as a policy think tank for the Government of India, created to evolve a shared vision of national development priorities, sectors and strategies with the active involvement of States.
Atal Incubation Centre	Flagship initiative to promote the culture of innovation and entrepreneurship in India. It is an umbrella structure that has been mandated to promote innovation and revolutionize the entrepreneurial ecosystem in the country.
Ministry of Electronics and Information Technology	The Ministry of Electronics and Information Technology (MeitY), responsible for formulating and implementing national policies and programs aimed at enabling the continuous development of the electronics and IT industry.
Ministry of Chemicals and Fertilizers	Ministry of Chemicals and Fertilizers is the federal ministry entrusted with the responsibility of planning, development and regulations of the chemicals, petrochemicals and pharmaceutical industry sector.
Department of Pharmaceuticals	The Department of Pharmaceuticals was created under the Ministry of Chemicals & Fertilizers with the objective to give greater focus and thrust on the development of pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines.

NIPER	National Institute of Pharmaceutical Education and Research (NIPERs) are a group of national level institutes of pharmaceutical sciences in India. NIPER aims to foster excellence in the field of pharma education.

Annexure H – List of Relevant Government Medical Device Policies/Regulations in India

Policy/Initiative	Details
Ayushman Bharat Digital Mission (ABDM)	• The Ayushman Bharat Digital Mission (ABDM) aims to create a unified digital health ecosystem in India by integrating hospitals, healthcare providers, and patients through a secure and interoperable digital platform. Key components include the ABHA (Ayushman Bharat Health Account) ID, which allows individuals to access and share their health records digitally, and the Healthcare Professionals Registry (HPR) and Health Facility Registry (HFR) for streamlining healthcare services. ADBM enhances efficiency, accessibility, and data-driven decision-making in India's healthcare sector.
National Medical Device Policy 2023	• The "National Medical Devices Policy, 2023" aims to boost India's medical devices sector with a patient-centric, innovative, and globally competitive approach. Key strategies include regulatory streamlining with a 'Single Window Clearance System' for licensing. The policy focuses on access, affordability, quality, and innovation, with metrics for impact assessment and guidelines for implementation to enhance competitiveness and self-reliance
Medical Device Rules, 2017	• The Medical Devices Rules, 2017, regulate the manufacturing, import, sale, and clinical investigation of medical devices in India, effective January 1, 2018. They cover in vitro diagnostics, surgical dressings, mechanical contraceptives, disinfectants, and other notified devices. Devices are classified into four risk categories: Class A (low risk), Class B (low moderate risk), Class C (moderate high risk), and Class D (high risk). The Central Licensing Authority oversees classification and licensing, ensuring compliance with safety and performance standards. The rules mandate clinical investigations, ethical compliance, and post-marketing surveillance, including unique device identification and recall procedures. They provide a comprehensive framework to ensure the safety, efficacy, and quality of medical devices in India.
National Single Window System	• The National Single Window System (NSWS) is a digital platform to guide stakeholders in identifying and applying for approvals according to their business requirements. The Know Your Approvals (KYA) module includes guidance for 32 Central Departments and 34 States. It provides access over 658 central approvals and 6787 state approvals.
Public Health Research Initiative Program (PRIP)	• The Scheme for Promotion of Medical Device Parks has been notified to develop common infrastructure facilities which in turn will reduce production cost of medical devices manufactured in the country. • The scheme has a total outlay of about €550 Mn. • Under the scheme, financial assistance will be provided for the creation of CIFs in four medical device parks selected under the scheme. The assistance will be 90% of the project cost in northeastern states and hilly states while it will be 70% in other states. • The scheme will be valid for a period of 5 years from FY 2020-21 to FY 2024-25.
Make in India	• The "Make in India" initiative encompasses several critical areas, including: • Indigenous Manufacturing: Promotes local manufacturing and competitiveness with private investments and mixed financing models. • Public Procurement: Utilizes the Public Procurement (Make in India) Policy and Ayushman Bharat to boost domestic production. • Infrastructure: Develops medical device parks and clusters with top-tier facilities.

	• Phased Manufacturing: Supports gradual production of essential components for consistent device availability. • Investment Attraction: Proposes measures to draw investments, fostering a competitive manufacturing ecosystem
Atmanirbhar Bharat	• The Atmanirbhar campaign is set to create significant opportunities within the Indian business landscape. Some initiatives under this campaign specifically targeting the medical device industry include: • Streamlining Regulation: Single Window Clearance for licensing and stakeholder collaboration. • Infrastructure: Medical device parks under national programs. • Innovation: Centers of Excellence and start-up support. • Investment: Boosting private investment and partnerships. • Skills: Workforce development with global collaborations. • Branding: Export Promotion Council for market access and best practices.
Free Trade Agreement (FTA)	• A free trade agreement (FTA) is a treaty between two or more countries that reduces or removes trade barriers. The goal of an FTA is to increase trade between the countries involved • India has signed 13 Regional Trade Agreements (RTAs)/Free Trade Agreements (FTAs) with various countries/regions namely, Japan, South Korea, countries of ASEAN region and countries of South Asian Association for Regional Cooperation (SAARC) Mauritius, United Arab Emirates, Australia
Market Access Initiatives (MAI)	• The Market Access Initiative (MAI) Scheme is designed to boost India's exports by targeting specific products and markets. It offers financial assistance to various organizations, including export promotion and trade organizations, research institutions, and exporters. The scheme supports Marketing Projects Abroad, Capacity Building, Statutory Compliance Support, Market Studies, and Project Development
SCALE	• To boost local value addition, create employment opportunities, and strengthen India's manufacturing base in line with the goal of 'Atmanirbhar Bharat', a Steering Committee for Advancing Local Value-add and Exports (SCALE) was constituted under the aegis of the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry. SCALE plays a crucial role in driving the Government's initiatives for achieving self-reliance in key champion sectors • (i) Auto Components, (ii) Automobiles (including EVs), (iii) Capital Goods, (iv) Chemicals, (v) Drones, (vi) Electronics System Design and Manufacturing (vii) Medical Devices (viii) Aerospace & Defense, (ix) Leather & Footwear, (x) Textiles and (xi) Space.

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