BFI NAMAH
Nailwal MedTech Acceleration Hub
VENTURE CENTER

MedTech Translation Programme

BFI NAMAH AT VENTURE CENTER INNOVATOR HANDBOOK

Supporting innovators across design, validation, & regulatory readiness toward deployable medical technologies

CONTENTS

FOREWORD

India has always possessed immense potential in biomedical and MedTech innovation. The raw talent, the engineering brilliance, and the sheer grit required to solve complex healthcare challenges are all right here. Yet, for too long, I have watched truly great ideas fail — not because the science was flawed, but because innovators are left to navigate fragmented, complex systems completely on their own.

Coming from a background where I witnessed the stark realities of unequal access, and having spent my career building scalable global technologies, I learned a fundamental truth: a lack of infrastructure should never be the barrier that stops talent. Technology is the greatest equalizer we have, but its true value is only realized when it actively serves society and reaches the most vulnerable among us.

We built Blockchain for Impact (BFI) out of a stark realization: capital alone is fundamentally insufficient to unlock India's true scientific potential. We need systems that prioritize seamless execution over procedural friction. We need to stop building in isolation. The Nailwal MedTech Acceleration Hub (BFI NAMAH) at Venture Center is the embodiment of this vision. It serves as the vital anchor of our Innovation Full Stack — a comprehensive, end-to- end national platform designed to help you move from a brilliant lab concept to a market-relevant, globally deployable product.

This handbook is an innovator's gateway into that ecosystem. We are bringing together academia, clinical networks, and regulatory systems so that innovators can move forward with clarity, confidence, and continuity. The work they are doing today holds the power to democratize healthcare for India and the broader Global South. We are incredibly proud to back their vision.

Sandeep Nailwal

FOUNDER, BFI

Dr. Gaurav Singh

CHIEF EXECUTIVE OFFICER, BFI

PREFACE

Every year, countless biomedical research projects are initiated across India, resulting in brilliant discoveries and published papers. But we must ask ourselves a critical question: how many of these breakthroughs actually translate into real-world products that benefit the public?

If a solution remains confined to a laboratory, its impact is unrealized. At Blockchain for Impact (BFI), we recognized early on that a major reason we lag in translating deep-tech biomedical research is that the ecosystem operates in silos. The stark disconnect between academic research, clinical validation, and industry requirements creates a treacherous “valley of death.” Projects that have the potential to become tangible, life-saving products are in dire need of translational infrastructure and structural support.

This is the precise operational gap that the Nailwal MedTech Acceleration Hub (BFI NAMAH) is designed to close. By anchoring this hub at Venture Center and strategically synergizing with the deep translational frameworks of the Venture Center , we are dismantling these silos. We are not just funding research; we are providing a “full-stack” ecosystem to bridge the gap between bench and bedside.

This handbook is an operational blueprint for navigating that ecosystem. It details how BFI NAMAH combines rigorous engineering design, the early implementation of Quality Management Systems (QMS), and authoritative regulatory guidance to ensure that indigenous innovations are built to global standards. It is designed to help streamline the critical pathway through CDSCO regulations and clinical testing.

Our commitment is to handle the structural and regulatory complexities of medical device development so that founders and researchers can focus entirely on pioneering the next generation of healthcare technologies. We welcome all innovators to BFI NAMAH at Venture Center, and we look forward to accelerating their journey from a visionary concept to a clinical reality.

BFI INNOVATION FULL STACK

Innovation Full Stack is the flagship initiative of BFI, designed as an end-to-end platform that connects ideation, prototyping, validation, and market adoption to accelerate clinically validated healthcare innovations. Rather than addressing isolated stages, Innovation Full Stack anchors a cohesive enabling ecosystem that brings together all stakeholders across the medtech innovation pathway, spanning Technology Readiness Levels (TRLs) 1–9. In doing so, it supports the seamless progression of innovations from concept to real-world scale in an efficient and time-bound manner.

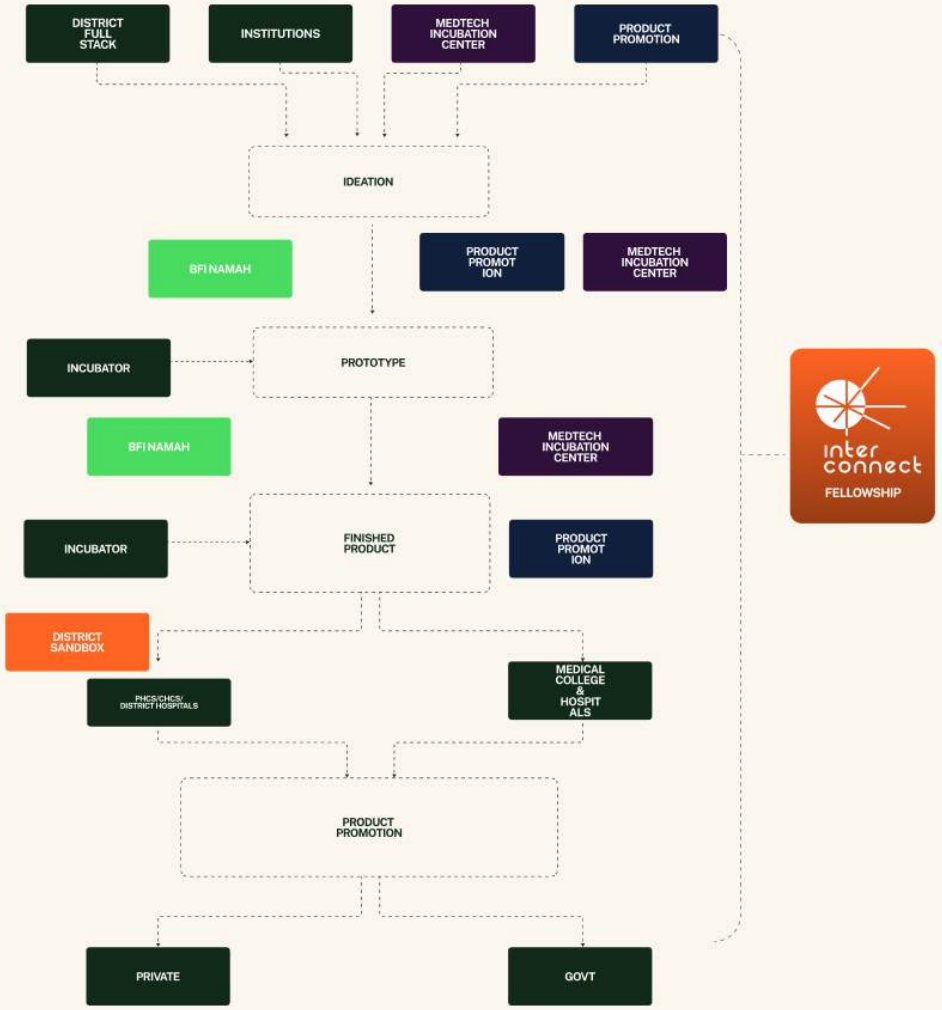
The program leverages a robust network of partnerships with research institutions, technology business incubators, and state-of-the-art infrastructure facilities (prototyping labs, design expertise, testing centres, etc.), medical colleges, district-level public healthcare systems (PHCs/CHCs), and central and state government agencies. Together, these collaborations create an integrated and expedited pathway for medtech innovators and startups.

The BFI Nailwal Medtech Acceleration Hub (NAMAH), a core program under Innovation Full Stack, focuses on advancing innovations from prototype development through regulatory preparedness. It enables innovators to become ready for clinical validation under the Medical College Incubation Center program, followed by real world testing and pilot deployment through the District Sandbox across public health systems (PHCs/CHCs). The journey culminates in market readiness and adoption, supported by a dedicated Product Promotion program, ensuring that promising innovations reach and benefit the communities they are designed to serve.

Dr. Sanchita Chaudhary

PROGRAM DIRECTOR, BFI NAMAH

BFI INNOVATION FULL STACK



SCOPE

The Nailwal MedTech Acceleration Hub (BFI NAMAH) at Venture Center, supported by Blockchain for Impact (BFI), is dedicated to bridging the critical gap between early-stage academic research and clinical deployment. The primary scope of BFI NAMAH encompasses the comprehensive acceleration of medical device development, strategically leveraging the infrastructure and translational frameworks of the **Venture Center.**

By synergizing BFI NAMAH's acceleration capabilities with Venture Center's established deep-tech ecosystem, the hub provides a "full-stack" pathway for product realization. The operational scope of BFI NAMAH is defined by the following core focus areas:

- **Translational Engineering & Quality Management:** Facilitating the transition of lab-scale prototypes into market-ready, clinical-grade medical devices. This includes the implementation of rigorous design controls and the integration of ISO 13485 Quality Management Systems (QMS) from the early development phases, utilizing Venture Center's established engineering frameworks.
- **Regulatory Strategy & Compliance Pathway:** Providing structured, authoritative guidance to navigate India's complex medical device regulatory landscape. The scope includes assisting projects in aligning with Central Drugs Standard Control Organisation (CDSCO) guidelines, Medical Devices Rules (MDR) 2017 compliance, and necessary ethical approval processes to drastically reduce time-to-market.
- **Clinical Validation & Standardized Testing**: Enabling access to a mature ecosystem of standardized testing facilities and rigorous clinical validation protocols. The hub facilitates vital connections with clinical partners and medical experts to ensure technologies meet real-world clinical demands and safety standards.
- **Ecosystem Synergy & Deployment Support:** Acting as a central, national-level node that connects researchers, engineers, regulatory bodies, and industry stakeholders. This collaborative network is designed to bypass traditional developmental hurdles and build a streamlined pipeline for indigenous healthcare innovations.

Rajesh Kr. Sagar

PROGRAM PRINCIPAL, BFI NAMAH

VENTURE CENTER TEAM MEMBERS

SUJAYA INGALE

Head - Scientific Initiatives
Entrepreneurship Development Center, Venture Center

Advancing medtech innovations into practical healthcare solutions requires addressing engineering performance, clinical relevance, regulatory compliance, manufacturability, and real-world usability. By integrating multidisciplinary expertise across engineering, medicine, design, and quality systems, BFI NAMAH provides a structured, milestone-driven product realization framework.
The program creates a unique, national platform to accelerate translation of high-impact Indian MedTech innovations into clinically validated, regulatory-compliant, and market-ready products.

ANJAN KUMAR N

Manager | Head Engg Design, Prototyping & Testing
Entrepreneurship Development Center, Venture Center

Transforming healthcare ideas into market-ready medical technologies requires strong integration of engineering, prototyping, validation, and regulatory readiness.

BFI NAMAH supports the development of clinically relevant and scalable indigenous healthcare innovations by leveraging advanced engineering prototyping facilities that enable rapid design iterations, faster validation cycles, quality focused and accelerated product development.


NAMAH
Nailwal MedTech Acceleration Hub

ABOUT US

01

01. ABOUT US

1.1 PROGRAMME INTRODUCTION

BFI-NAMAH at Venture Center is a one year end-to-end product realization accelerator program, designed to systematically bridge the lab-to-market gap. Implemented by India's leading deep-tech and MedTech-focused incubator, it will support multiple cohorts of early-stage MedTech startups through structured, milestone-driven product realization — culminating in regulatory approval, market launch, and post-market surveillance.

By integrating certified infrastructure, regulatory and clinical expertise, IP and commercialization support, venture development, fundraising support and strong governance, BFI-NAMAH at Venture Center will create a unique, national platform for translating high-impact Indian MedTech innovations into safe, affordable, and globally competitive healthcare products.

This initiative is envisioned as a flagship, legacy-defining program aligned with the philanthropic vision of Mr. Sandeep Nailwal, contributing to national healthcare self-reliance and global health impact.

1.2 VENTURE CENTER

Established in 2007 under the aegis of CSIR and hosted by CSIR–NCL, Pune, Venture Center is one of India's most impactful technology business incubators.

Located within the 11-acre CSIR–NCL Innovation Park, Venture Center offers a comprehensive innovation ecosystem comprising plug-and-play laboratories, shared prototyping & scientific facilities, clean rooms, incubation offices, and IP, regulatory, and tech transfer advisory. It also operates multiple accelerator programs, seed funding mechanisms, and global mentoring networks, connecting startups to investors, corporates, and policymakers.

Venture Center has a strong and demonstrated track record in medtech incubation, with a portfolio of successful startups that have translated innovative technologies into commercially viable products.

Venture Center has developed specialized capabilities to support startups across the healthcare value chain, including:

- Therapeutics and biopharma
- Medical devices
- Diagnostics and point-of-care devices
- Implants, biomaterials, surgical and interventional tools
- Preventives, nutraceuticals, and wellness solutions
- Rehabilitation and assistive technologies

To enable translation and validation of biomedical technologies, Venture Center hosts specialized facilities such as Protoshop: a rapid prototyping workshop for MedTech and diagnostics device development and MedTech Cleanroom (ISO 13485 certified): for fabrication, packaging and sterilization of implants, wound-care, and medical devices.

By combining state-of-the-art infrastructure, scientific depth, and strong networks, Venture Center serves as a national hub for MedTech and healthcare innovation, accelerating the journey and catalyzing the growth of deep-science startups aligned with India's health and biomedical priorities.

VENTURE CENTER MEDTECH ACCELERATION FACILITY

- The BFI NAMAH programme will be operationally anchored at Venture Center, which offers:
- ISO 13485–compliant trial manufacturing facilities
- Expertise in regulatory documentation and quality management systems
- ISO 17025 accredited testing lab
- Testing, validation, sterilisation, and packaging infrastructure
- Proven experience with MD-13 licenses, clinical partnerships, and deployment-ready MedTech solutions

VENTURE CENTER

70+ TEAM MEMBERS

ISO 13485–COMPLIANT TRIAL MANUFACTURING FACILITIES

ISO 17025 ACCREDITED TESTING LAB

ENABLING MEDTECH ECOSYSTEM

1.3 BLOCKCHAIN FOR IMPACT (BFI)

Blockchain For Impact (BFI) was established during the second wave of COVID-19 pandemic in India, with a mission to enhance healthcare capabilities of the country. What began as a voluntary emergency response system has now evolved into a network that is changing the MedTech ecosystem through programmatic interventions at both the micro and macro levels in biomedical research and innovation. BFI aims to contribute to the development of inclusive health systems for the future. Utilising cross-sector partnerships, our goal is to leverage expertise, dedication, and technology to tackle health-related issues and anticipated gaps.

BFI is building a full-stack innovation ecosystem that empowers India's brightest minds to develop solutions rooted in local needs and realities. The mission is to create seamless pathways for indigenous technologies to move from idea to impact, enabling innovations to translate into global influence. Through this approach, BFI envisions an India that not only innovates for itself but also emerges as a global leader in biomedical research.

1.4 PROGRAMME OUTCOMES

Over a three-year period, BFI NAMAH will advance the MedTech products through a structured methodology of evaluation, execution including design, documentation, manufacturing, third party testing, pre-clinical and clinical studies. The measurable outcomes are:

- Enable 30+products to reach TRL 6–7
- Facilitate regulatory submissions as per MDR-2017 and clinical evaluations
- Strengthen India's MedTech manufacturing and regulatory ecosystem
- Create scalable, affordable solutions aligned with national health priorities

1.5 CORE OBJECTIVES

BFI NAMAH is guided by a comprehensive set of core objectives designed to drive structured MedTech translation, regulatory readiness, and sustainable ecosystem development:

1. To translate early-stage MedTech innovations from TRL 2–3 to near-market readiness (TRL 6–7) through structured technical, regulatory, and clinical support.
2. To enable regulatory-compliant design, pilot manufacturing, and clinical validation, thereby reducing time-to-market and translational risk.
3. To strengthen national capacity in MedTech product development, quality systems, and regulatory science, creating a sustainable ecosystem for innovation.

1.6 KEY PERFORMANCE INDICATORS (KPIs)

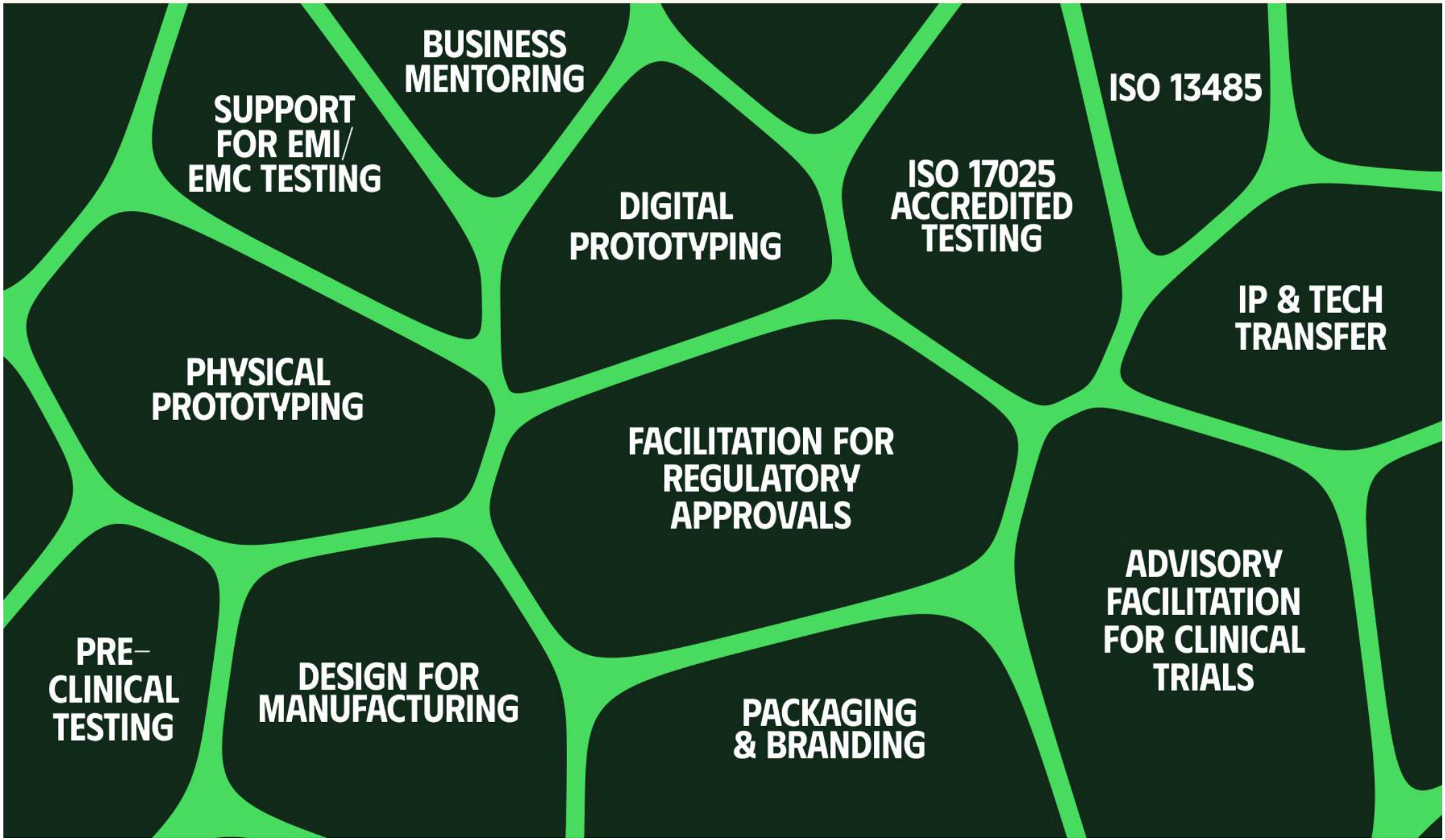
BFI NAMAH will track programme performance and translational impact through a defined set of key performance indicators (KPIs) including:

METRIC	TARGET (3 YEARS)
Devices reaching TRL ≥ 6	≥ 30
Regulatory submissions	≥ 30
Clinical evaluations completed	≥ 15
Startups / licences created	≥ 10

1.6 PROJECT DURATION

The Project is initially for a period of one (1) year, extendable for an additional period of two (2) years.

WHAT WE DO


BUSINESS MENTORING
SUPPORT FOR EMI/ EMC TESTING
DIGITAL PROTOTYPING
ISO 17025 ACCREDITED TESTING
ISO 13485
IP & TECH TRANSFER
PHYSICAL PROTOTYPING
FACILITATION FOR REGULATORY APPROVALS
ADVISORY FACILITATION FOR CLINICAL TRIALS
PRE-CLINICAL TESTING
DESIGN FOR MANUFACTURING
PACKAGING & BRANDING

1.8 NATIONAL CONTEXT

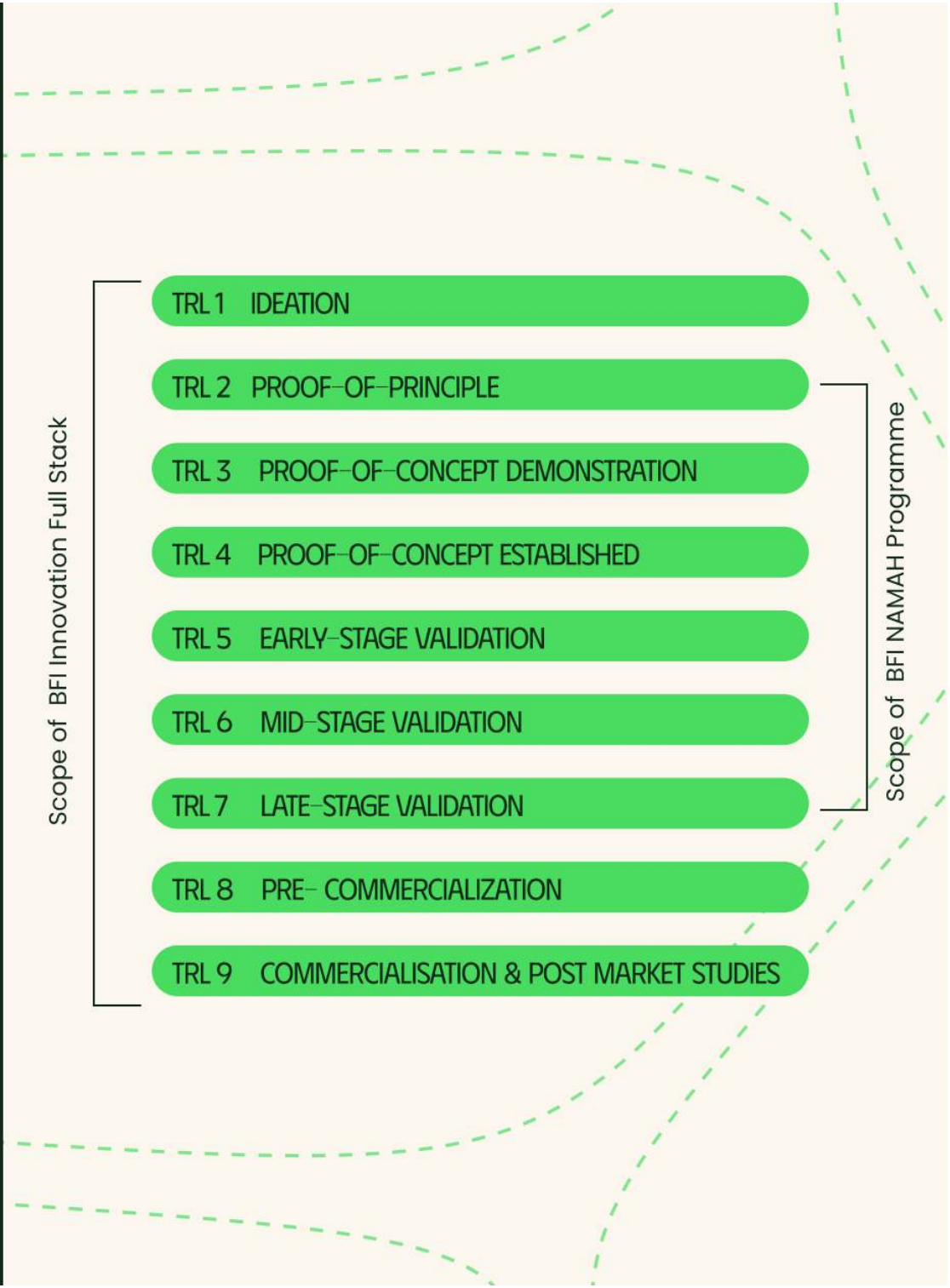
India's medical technology sector is at a critical inflection point. Despite a strong base of scientific research, clinical expertise, and entrepreneurial activity, the country continues to import nearly 70% of its medical devices by value, creating strategic dependency and cost pressures on the healthcare system. A major reason for this gap is the high attrition of innovations during the translation phase—nearly 80% of MedTech startups fail between Technology Readiness Levels (TRL) 3 and 6. This stage requires capabilities that are rarely available to individual innovators, including design for manufacturability, quality management systems, regulatory documentation, and access to clinical validation sites. Additionally, long and uncertain regulatory timelines, stringent compliance with global quality standards, and the complexity of generating credible clinical evidence further slow down product development and market entry. As a result, many promising technologies fail to reach patients, limiting both healthcare impact and industrial growth.

1.9 THE BFI NAMAH VALUE PROPOSITION

BFI NAMAH is conceived as a mission-driven MedTech translation and execution platform, distinct from conventional incubators or accelerators. It directly addresses the TRL 3–7 gap by systematically de-risking innovations from both technical and regulatory perspectives. Anchored in ISO 13485–compliant manufacturing and quality infrastructure, BFI NAMAH enables true end-to-end productisation—from prototype refinement and regulatory strategy to pilot manufacturing and clinical validation. The programme supports innovators from academia, startups, and hospitals, ensuring that clinically relevant ideas are transformed into deployable, compliant, and scalable medical technologies.

SCOPE OF BFI NAMAH PROGRAMME

Technology Readiness Levels (TRLs) define the progression of medical technologies from ideation to commercial deployment. The mid-TRL phase (TRL 2–7) is the most demanding, requiring design refinement, validation, regulatory readiness, and pilot manufacturing capabilities. BFI **NAMAH** operates across this critical span, systematically advancing innovations toward pre-commercialisation (TRL 8) and market entry, ensuring that promising concepts translate into safe, scalable, and deployable medical devices.



DELIVERY MODEL

02

2.1 BFI NAMAH Pathway

2.2 Stage Gated Process Flow

2.3 TRL - Based Stage-wise Innovation Readiness Checklist

2.1 BFI NAMAH PATHWAY

NATIONAL CALL FOR PROPOSAL BY BFI

TRL 1: BASIC PRINCIPLES OBSERVED 01
Scientific research begins to be translated into applied R&D.

- **Next Critical Steps :**
  Identify clinical need & potential technological solution.
- **Facility Support :**
  Nailwal Medtech Acceleration Hub at Venture Center
- **Regulatory & Licenses :**
  i. Initial Risk Classification determination (Class A, B, C, or D).
  ii. Intellectual Property (IP) search & strategy initiation.

TRL 2: TECHNOLOGY CONCEPT FORMULATED 02
Basic principles are observed & practical applications are identified.

Next Critical Steps :
Identify clinical need & potential technological solution.

Facility Support:
BFI NAMAH (Venture Center) Initial engineering consultation & DFM (Design for Manufacturing) strategy.

Regulatory & Licenses
ISO 13485 (QMS) planning. ISO 14971 (Risk Management) preliminary planning.

TRL 3: PROOF OF CONCEPT (POC) 03
Active R&D initiated. Analytical & laboratory studies

- **Next Critical Steps :**
  Demonstrate technical feasibility in a laboratory setting.
- **Facility Support :**
  BFI NAMAH (Venture Center) Prototyping & early-stage engineering validation.
- **Regulatory & Licenses :**
  Formalizing Design History File (DHF). Initial bench testing protocols.

TRL 4: COMPONENT/PROCESS VALIDATION 04
Design verification at laboratory scale.

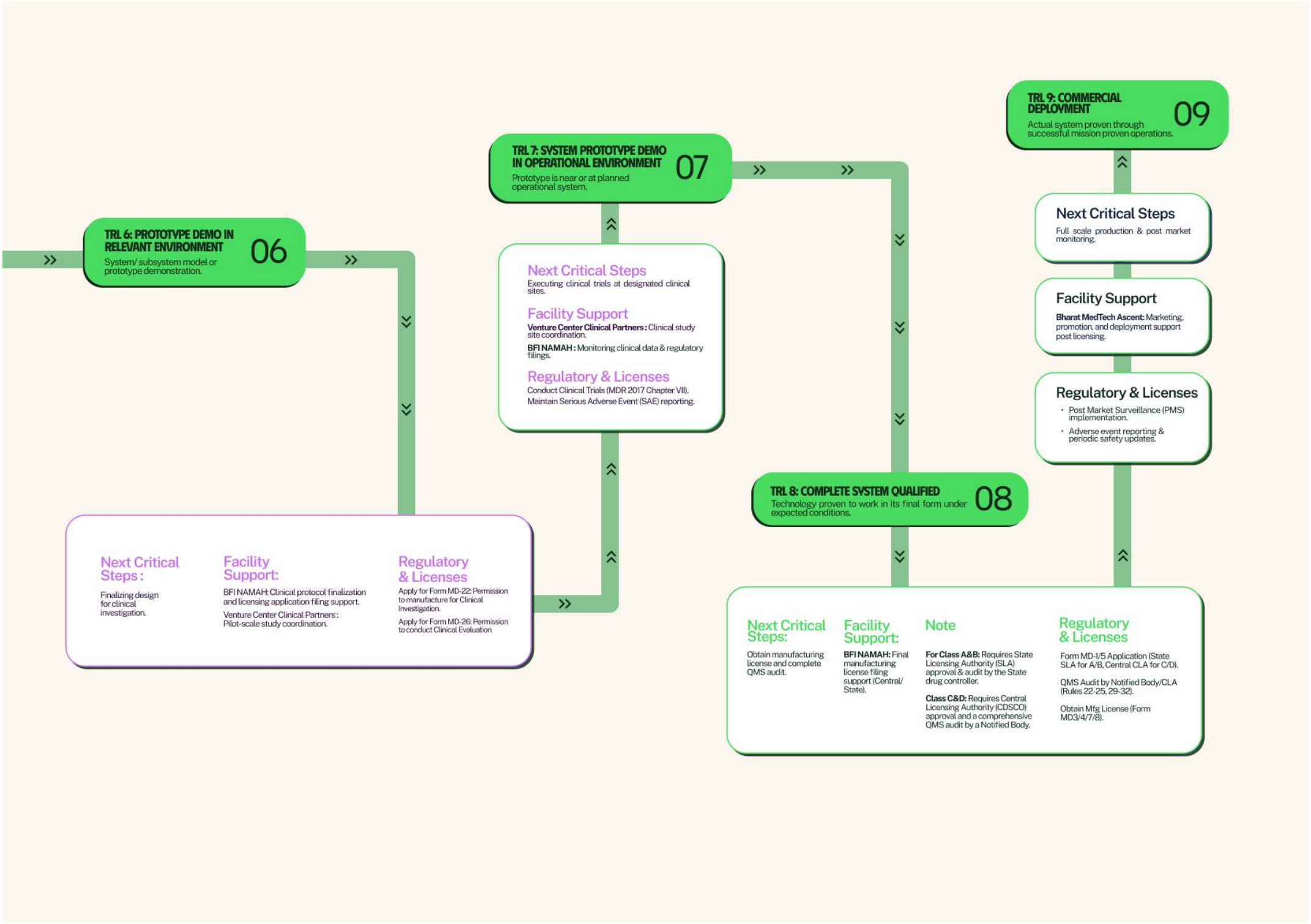
Next Critical Steps :
Alpha prototype assembly & bench testing.

Facility Support:
BFI NAMAH (Venture Center) Product readiness & advanced DFM & Protocol design for clinical / analytical studies.

Regulatory & Licenses :
Biocompatibility testing (ISO 10993) start. Software validation (IEC 62304) if applicable.

TRL 5: SYSTEM VALIDATION IN RELEVANT ENVIRONMENT 05
The technology is refined & tested in a simulated environment.

- **Next Critical Steps :**
  Beta prototype testing and pre-clinical verification.
- **Facility Support :**
  BFI NAMAH : EMI/EMC coordination with approved test centers.
  BFI Pre-Clinical Site : Location for specialized pre-clinical bench studies.
- **Regulatory & Licenses :**
  EMI/EMC Testing (IEC 60601-1-2). Finalizing QMS implementation for manufacturing site.


TRL 6: PROTOTYPE DEMO IN RELEVANT ENVIRONMENT
06
System/ subsystem model or prototype demonstration.
Next Critical Steps :
Finalizing design for clinical investigation.
Facility Support:
BFI NAMAH: Clinical protocol finalization and licensing application filing support.
Venture Center Clinical Partners : Pilot-scale study coordination.
Regulatory & Licenses
Apply for Form MD-22: Permission to manufacture for Clinical Investigation.
Apply for Form MD-26: Permission to conduct Clinical Evaluation
TRL 7: SYSTEM PROTOTYPE DEMO IN OPERATIONAL ENVIRONMENT
07
Prototype is near or at planned operational system.
Next Critical Steps
Executing clinical trials at designated clinical sites.
Facility Support
Venture Center Clinical Partners : Clinical study site coordination.
BFI NAMAH : Monitoring clinical data & regulatory filings.
Regulatory & Licenses
Conduct Clinical Trials (MDR 2017 Chapter VII).
Maintain Serious Adverse Event (SAE) reporting.
TRL 8: COMPLETE SYSTEM QUALIFIED
08
Technology proven to work in its final form under expected conditions.
Next Critical Steps:
Obtain manufacturing license and complete QMS audit.
Facility Support:
BFI NAMAH: Final manufacturing license filing support (Central/ State).
Note
For Class A&B: Requires State Licensing Authority (SLA) approval & audit by the State drug controller.
Class C&D: Requires Central Licensing Authority (CDSCO) approval and a comprehensive QMS audit by a Notified Body.
Regulatory & Licenses
Form MD-1/5 Application (State SLA for A/B, Central CLA for C/D).
QMS Audit by Notified Body/CLA (Rules 22-25, 29-32).
Obtain Mfg License (Form MD3/4/7/8).
TRL 9: COMMERCIAL DEPLOYMENT
09
Actual system proven through successful mission proven operations.
Next Critical Steps
Full scale production & post market monitoring.
Facility Support
Bharat MedTech Ascent: Marketing, promotion, and deployment support post licensing.
Regulatory & Licenses
Post Market Surveillance (PMS) implementation.
Adverse event reporting & periodic safety updates.

2.2 STAGE GATED PROCESS FLOW

2.1 MEDTECH INNOVATION & PRODUCT DEVELOPMENT

BFI NAMAH shall operate as a hands-on, execution-driven translation programme, where infrastructure, expert teams, and governance are tightly integrated to support innovators from concept to market. Each innovator is onboarded into a structured product journey, with defined milestones, access to facilities, and dedicated technical handholding.

STAGE 1. IDEATION & CLINICAL NEED IDENTIFICATION (TRL 2–3)

- Guide innovators to align innovations with real clinical needs through immersion and market research.
- Help draft clinical problem statements and refine them into viable product concepts.
- Advise on initial risk classification of devices under CDSCO.
- Advice and guide on early IP landscaping, prior-art searches, and patentability assessments.

STAGE 2. PRODUCT DESIGN & PROTOTYPING (TRL 3–5)

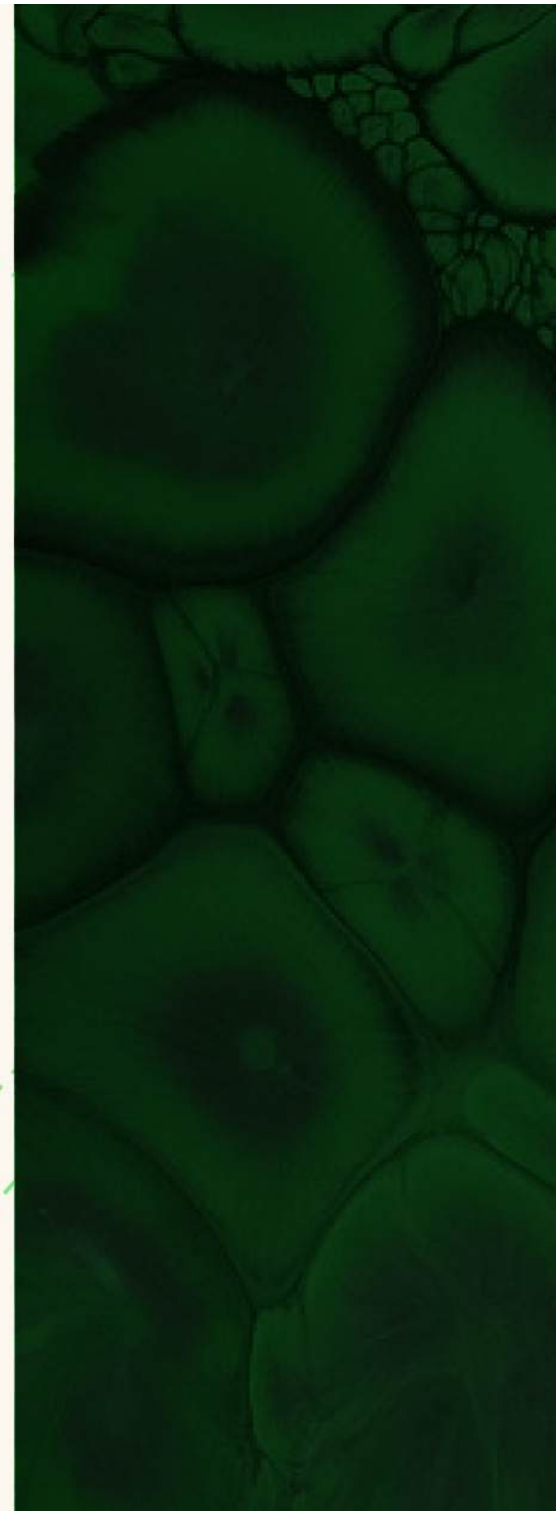
- Support design input documentation and creation of risk management files (ISO 14971).
- Advice on rapid prototyping (3D printing, PCB design, sensors, biomaterials).
- Train innovators on human factors engineering & usability standards (IEC 62366).
- Help maintain design history files (DHF) and device master records (DMR) for regulatory readiness.

STAGE 3. PRE-CLINICAL VALIDATION & REGULATORY PREPARATION (TRL 5-6)

- Guide innovators in building documentation for:
  i) ISO 13485 (Quality Management Systems for Medical Devices).
  ii) ISO 14971 (Risk Management).
  iii) ISO 10993 (Biocompatibility).
- Assist in pre-clinical validation, biocompatibility, and safety testing.
- Prepare innovators for CDSCO applications (MD-12, MD-13, clinical investigation approvals).

STAGE 4. MANUFACTURING READINESS (TRL 6-7)

- Guide innovators on Design for Manufacturing (DFM) and scaling from prototypes to batch production.
- Guide on setting up ISO 13485-compliant QMS at pilot manufacturing scale.
- Assist with Good Manufacturing Practices (GMP) documentation.
- Provide expertise for obtaining MD-13 licenses, ensuring facility and processes comply with CDSCO norms.
- Train teams on supply chain management and vendor qualification.



STAGE 5. CLINICAL EVALUATION & CERTIFICATION (TRL 7–8)

- Support certification processes:
  - i) NABL-accredited test labs (mechanical/electrical/biocompatibility testing).
  - ii) BIS certification (Indian standards).
  - iii) CE Marking conformity assessment.
- Assist in designing pilot and pivotal clinical evaluation.
- Guide in data management systems
- Provide guidance on post-market clinical follow-up (PMCF) and safety reporting.

STAGE 6. ECOSYSTEM BUILDING & KNOWLEDGE DEVELOPMENT

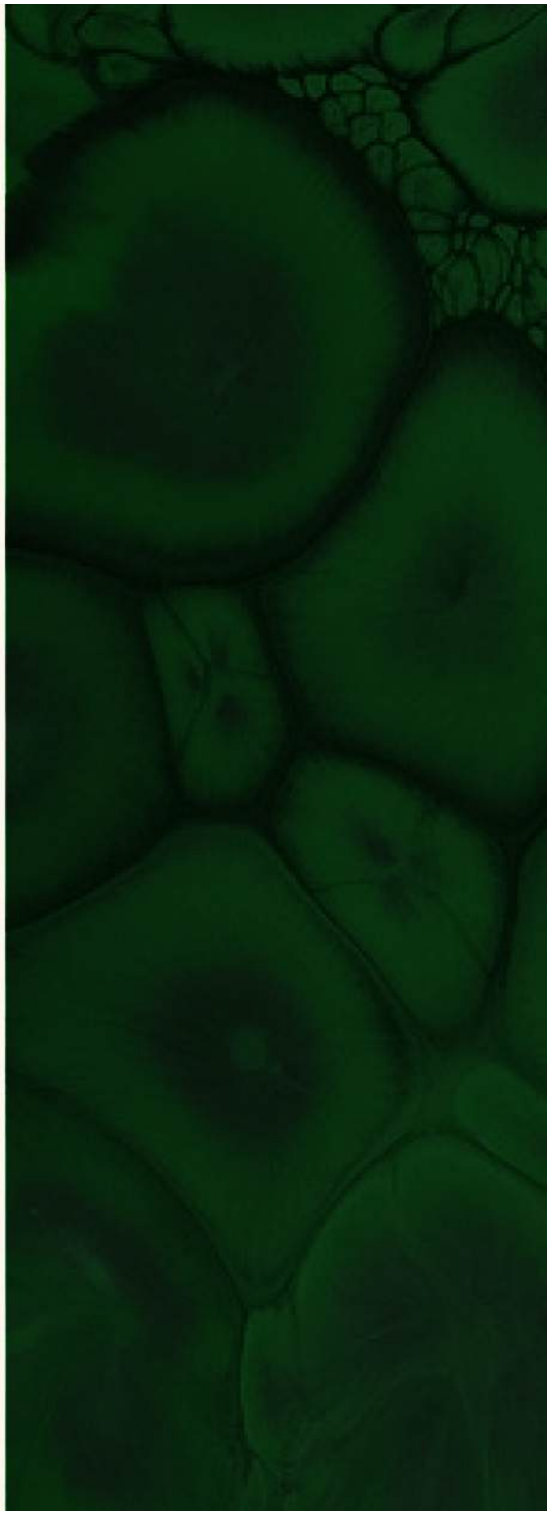
Beyond individual projects, BFI NAMAH will:

- Develop regulatory toolkits and templates
- Conduct training workshops on certification, compliance, and regulatory strategy.
- Act as a liaison with regulators and notified bodies
- Build a national repository of regulatory and translational resources

STAGE 6.1 INNOVATOR RESPONSIBILITIES & ACKNOWLEDGEMENT

Innovators supported under BFI NAMAH shall:

- Actively engage in milestone reviews
- Follow BFI NAMAH quality and compliance processes
- Acknowledge BFI, Venture Center and other contributors in all public disclosures, publications, and product documentation.



2.3 TRL–BASED STAGE–WISE INNOVATION READINESS CHECKLIST

Each checklist captures critical activities, documentation needs, and compliance milestones across TRLs to enable structured advancement of MedTech innovations.

TO DO LIST (TRL 2–3): IDEATION & CLINICAL NEED IDENTIFICATION

Clinical Need Definition & Early Assessment: Establish clinical relevance, early regulatory direction, and innovation feasibility.

NO.	TO DO	COMPLETED		REMARKS
		YES	NO	
01	Define The Clinical Need Through Immersion & Market Research.			
02	Draft And Refine The Clinical Problem Statement.			
03	Assess The Innovation's Viability As A Product Concept.			
04	Identify Initial Device Risk Classification Under CDSCO.			
05	Conduct Early IP Landscaping And Prior-Art Review.			
06	Document Patentability Assessment Inputs.			

TO DO LIST (TRL 3–5): PRODUCT DESIGN & PROTOTYPING

Design Development & Prototype Readiness: Establish design controls, prototyping strategy, and regulatory documentation.

NO.	TO DO	COMPLETED		REMARKS
		YES	NO	
01	Define Design Inputs For Product Development.			
02	Prepare Risk Management Files Under ISO 14971.			
03	Identify Suitable Rapid Prototyping Methods (3D Printing, PCB, Sensors, Biomaterials).			
04	Apply Human Factors And Usability Requirements Under IEC 62366.			
05	Maintain Design History File (DHF) Documentation.			
06	Prepare Device Master Record (DMR) For Regulatory Readiness.			

TO DO LIST (TRL 5–6): PRE-CLINICAL VALIDATION & REGULATORY PREPARATION

Regulatory Documentation Development: Build required technical & quality documentation to support pre-clinical validation, safety testing, and regulatory submissions.

NO.	TO DO	COMPLETED		REMARKS
		YES	NO	
01	Define Documentation Requirements Under ISO 13485 For Device Quality Management.			
02	Prepare And Document Risk Management Files As Per ISO 14971.			
03	Identify Applicable Biocompatibility Evaluation Requirements Under ISO 10993			
04	Plan And Document Pre-Clinical Validation, Safety, And Performance Testing Protocols.			
05	Compile Test Reports And Technical Records For Regulatory Submission Readiness.			
06	Prepare Documentation For CDSCO Applications (MD-12 / MD-13 / Clinical Investigation Approvals.			

TO DO LIST (TRL 6–7): MANUFACTURING READINESS

Manufacturing Planning & Compliance: Define manufacturing scale-up requirements and establish quality systems for pilot production.

NO.	TO DO	COMPLETED		REMARKS
		YES	NO	
01	Define Design For Manufacturing (DFM) Requirements For Prototype-To-Batch Scale-Up.			
02	Establish ISO 13485-Compliant Quality Management Processes For Pilot Manufacturing.			
03	Prepare GMP Documentation For Manufacturing Activities.			
04	Assess Facility And Process Requirements For MD-13 Licensing Compliance.			
05	Identify Supply Chain And Vendor Qualification Criteria.			
06	Document Manufacturing Readiness For Pilot Batch Production.			

TO DO LIST (TRL 7–8): CLINICAL EVALUATION & CERTIFICATION

Clinical Evaluation & Certification: Plan certification pathways, clinical evaluation, and compliant data systems.

NO.	TO DO	COMPLETED		REMARKS
		YES	NO	
01	Identify Required Testing Through NABL-Accredited Laboratories.			
02	Define Applicable BIS Certification Requirements.			
03	Prepare Documentation For CE Conformity Assessment.			
04	Design Pilot And Pivotal Clinical Evaluation Protocols.			
05	Establish Compliant Clinical Data Management Systems.			
06	Document PMCF And Safety Reporting Requirements.			

TO DO LIST: INNOVATOR RESPONSIBILITIES & ACKNOWLEDGEMENT

Programme Participation & Compliance: Ensure active engagement & acknowledgement across project milestones.

NO.	TO DO	COMPLETED		REMARKS
		YES	NO	
01	Participate In Scheduled Milestone Reviews			
02	Maintain Adherence To NAMAH Quality Processes.			
03	Follow Defined Compliance And Documentation Requirements.			
04	Record Progress Against Agreed Deliverables.			
05	Acknowledge BFI And Venture Center In Outputs			
06	Ensure Contributor Recognition In Publications And Product Documentation.			

HEALTHCARE FOCUS AREAS & AVAILABLE INFRASTRUCTURE

03

3.1 Focus Areas

3.2 Selection Criteria

3.3 Selection Process & Best Practices

3.4 Facilities available for Innovators

3. HEALTHCARE FOCUS AREAS & AVAILABLE INFRASTRUCTURE

3.1 FOCUS AREAS

BFI NAMAH will focus on high impact medical technology domains where India has strong unmet clinical needs, high import dependence, and clear opportunities for translation and scale-up. The programme will prioritise technologies that can benefit from structured translational support and have the potential to achieve regulatory approval and deployment within a defined timeframe.

The priority technology domains under BFI NAMAH include:

- In-vitro diagnostics (IVD): Laboratory and point-of-care assays for infectious diseases, non-communicable diseases, and population screening.
- Imaging and optical diagnostics: Microscopy, imaging systems, and optical sensing technologies for diagnosis and clinical decision support.
- Point-of-care devices: Portable, rapid diagnostic and monitoring tools designed for decentralised and resource limited settings.
- Implants and active devices: Orthopedic, cardiovascular, and other implantable or electrically active medical devices requiring stringent quality and regulatory control.
- Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD): AI- and software driven diagnostic and therapeutic solutions integrated with hardware or operating independently.
- Assistive and rehabilitation technologies: Devices that support mobility, recovery, and long-term patient care, particularly for ageing populations and chronic conditions.

3.2 SELECTION CRITERIA

Projects will be evaluated using a structured and transparent framework based on the following criteria:

- **National health relevance:** Alignment with priority disease burdens and healthcare needs in India.
- **Import substitution potential:** Ability to reduce dependence on imported medical devices.
- **Regulatory feasibility:** Clarity of regulatory pathway and likelihood of approval within programme timelines.
- **Manufacturing scalability:** Potential for cost-effective, scalable manufacturing in India.
- **Clinical pull:** Demonstrated demand or endorsement from clinicians and healthcare providers.

3.3 SELECTION PROCESS AND BEST PRACTICES

To ensure fairness, quality, and diversity of innovation, BFI NAMAH will adopt a **two-pronged selection process**:

1. Nationwide Open Calls: Periodic calls for proposals will be issued by the BFI inviting applications from academia, startups, hospitals, and independent innovators across the country.
2. Strategic Nominations: Select projects may be nominated by the **BFI–Venture Center Project Committee**, based on strategic relevance, demonstrated clinical need, or exceptional translational potential.

All submissions will undergo **multi-stage evaluation**, including technical review, regulatory assessment, and clinical relevance screening. Selected projects will be onboarded through defined milestones, best-practice product development workflows, and stage-gated reviews to ensure timely progress and accountable use of resources.

3.4 Facilities available for Innovators

01 DESIGN & SIMULATION LAB

a. SolidWorks
b. ANSYS Simulation Suite
c. MATLAB & Simulink
d. PCB Design Tools

02 RAPID PROTOTYPING LAB

3D scanners

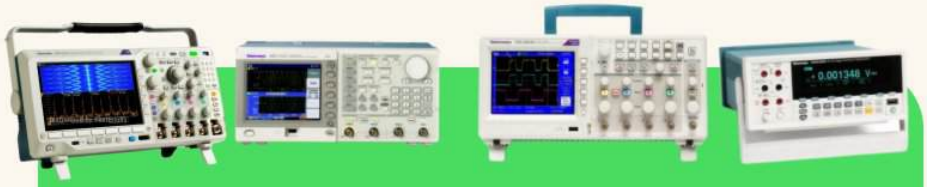
02 RAPID PROTOTYPING LAB

3D Printers

02 RAPID PROTOTYPING LAB

a. Laser cutter
b. Plotter cutter

3.4 Facilities available for Innovators



03 ELECTRONICS LAB

a. Spectrum Analyser Mixed Domain Oscilloscope
b. Arbitrary Function Generator
c. Digital Storage Oscilloscope
d. Digital Multimeter

03 ELECTRONICS LAB

a. Linear Power Supply
b. Printed Circuit Board Plotter
c. Solder Rework System
d. Potentiostat/Galvanostat/ Impedance Analyser

04 MECHANICAL FAB LAB

a. Vertical Machining Center
b. Lathe
c. CNC Router
d. Vertical Drill

05 PROCESSING LAB

a. Injection Molding Machine
b. Hydraulic Press
c. Two Roll Mill

3.4 Facilities available for Innovators

06 STERILIZATION & PACKAGING

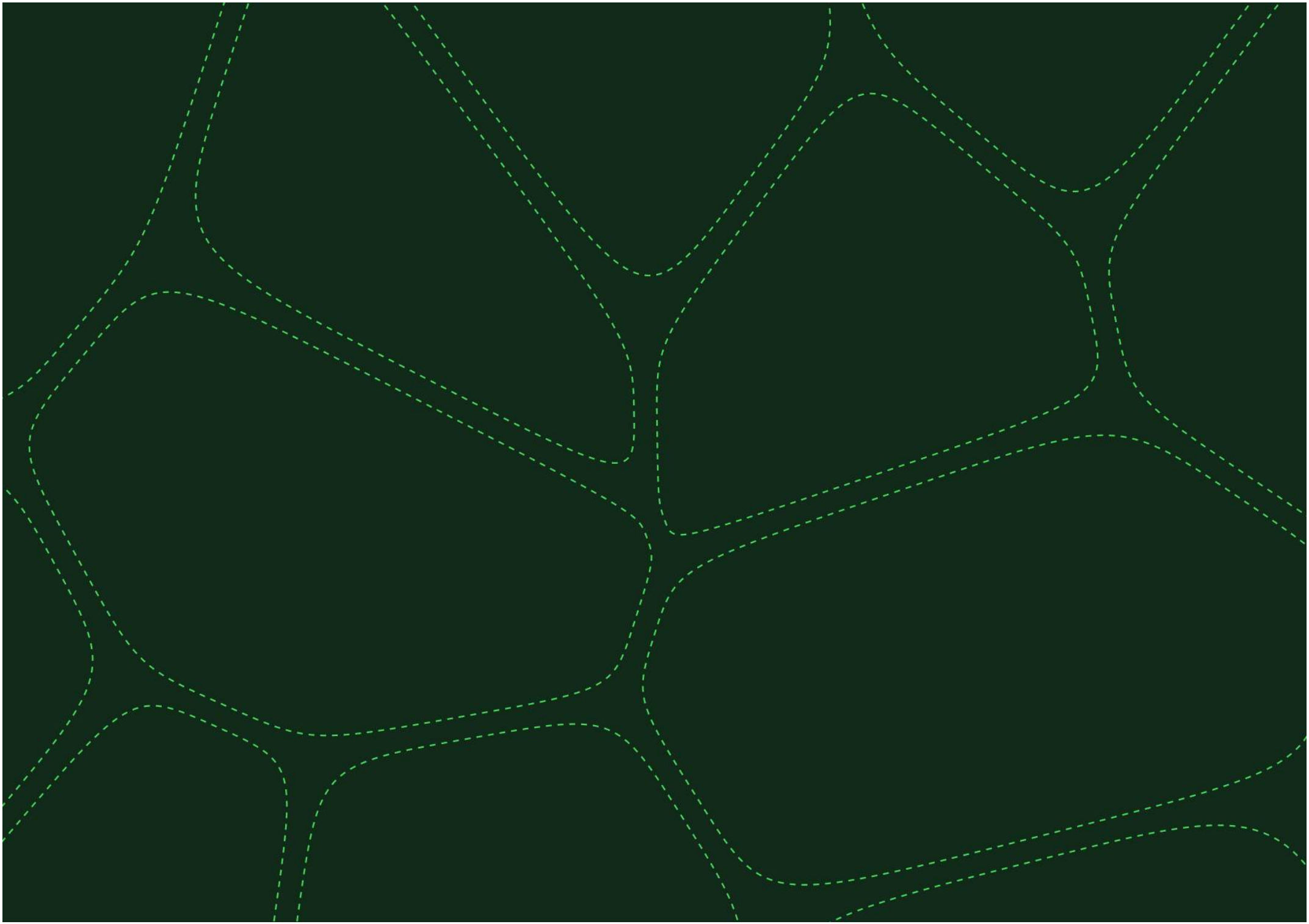
a. Ethylene Oxide Sterilizer
b. Cartolux Sealing Machine
c. Hawo Rotary Sealer

07 TENSILE TESTING to test the mechanical properties of new materials

08 POUCH BURST TESTING to assess the burst strength of pouches

09 ISO 13485 CERTIFIED TRIAL MANUFACTURING CLEAN ROOMS

A dedicated ISO 13485:2016 Quality Management System (QMS) certified cleanroom facility, designed to provide a controlled environment for the manufacturing and packaging of medical devices.



04

NATIONAL & GLOBAL IMPACT

IMPACT
NATIONAL AND GLOBAL

BFI NAMAH's National and Global Translational Impact

BFI NAMAH is envisioned as a mission-driven programme with significant national and global impact, addressing critical gaps in medical technology access, affordability, and innovation capacity. By enabling structured translation of MedTech innovations from early-stage research to regulated, deployable products, BFI NAMAH will accelerate the availability of high-quality, affordable medical technologies for India and other low- and middle-income countries (LMICs). This will directly contribute to improved health outcomes by expanding access to diagnostics, devices, and treatment solutions that are tailored to real-world clinical settings.

At the national level, BFI NAMAH will strengthen India's regulatory, manufacturing, and quality systems capacity by embedding best practices in design controls, regulatory science, and pilot manufacturing within the innovation ecosystem. This will create a skilled workforce capable of supporting advanced MedTech development and reduce systemic bottlenecks that currently delay market entry. By prioritising technologies with high import substitution potential, the programme will reduce India's dependence on imported medical devices, enhancing healthcare resilience and supply chain security.

Globally, BFI NAMAH will position India as a trusted hub for MedTech innovation, validation, and manufacturing, particularly for cost-sensitive and scalable solutions. Through international collaborations and compliant product development, BFI NAMAH-supported technologies will enable faster global outreach, reinforcing India's role as a contributor of impactful medical technologies to global health systems.

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