# Accelerating Health Tech Innovations in India: Government Strategies and ICMR's Role in Strengthening Healthcare Ecosystem

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**Medical Device and Diagnostics Mission Secretariat (MDMS), Development Research, ICMR**

# Evolution of India in the Field of Innovation



*"All government departments have played a pivotal role in enriching the National Innovation Ecosystem." – NITI Aayog*

# Ecosystem Requirements - Innovation to Impact

**Enabling Policies**

**Infrastructure advancements**

**HTA & Market Access**

**Funding Opportunities**

**Evidence based Research and Validation Mechanism**

# Role of ICMR in MedTech Ecosystem

*To promote "Global Affordable Need Driven Healthcare Innovation" (GANDHI) approach*

## Enabling Policies

- **ICMR-DHR policy Biomedical Innovation and Entrepreneurship policy**
- **Clinical Trial Registry of India**
- **Bioethics Guidelines: 2017**
- **Registration Portal: NAITIK**
- **Guidelines for Technology Transfer and Revenue Sharing**
- **Ethical Guidelines for AI – Biomedical Research & Healthcare**

## Infrastructure Development

- **ICMR-LAHF at AMTZ**
- **ICMR-NARFBR**
- **ICMR-DHR Centers of Excellence (CoEs) at IITs & Medical Institutes**
- **ICMR Centres for Advanced Research (CAR)**
- **ICMR-DHR-Medtech Product Development and Acceleration Gateway of India (mPRAGATI)**

## Funding Opportunity

### Fellowship Schemes
- **ICMR supporting JRF/ SRF/ PhD/ RA/ Post-Doctoral/ Biodesign ICMR – CLiMB/ Startup**

### Extramural Funding Schemes
- **Investigator Initiated Small – upto ₹ 2 Cr. /Intermediate Grant – upto ₹ 2-8 Cr.**
- **Centre for Advanced Research (CAR) - upto ₹ 15 Cr.**
- **Research on National Health Priorities – upto ₹ 20-25 Cr.**

### Intramural Funding Schemes
- **Seed Grant to Scientists at ICMR Institutes**

## Evidence based Research & Disease Surveillance

- **Advance Center for Evidence-Based Child Health (CAR EBCH)**
- **Polio surveillance system led to Oral Polio Vaccine in National Health Programme**
- **Antimicrobial Resistance Network**
- **Foodborne Pathogen Survey Network (ICMR-FoodNet)**

## Preclinical & Clinical Evaluation and Validation Support

- **ICMR-NARFBR (Pre-clinical study)**

**Clinical study**

- **ICMR-CSTU (National Clinical Trial Network)**
- **ICMR-LAHF at AMTZ**
- **ICMR-NARI**
- **ICMR-NIV**
- **ICMR-NIRRCH**
- **ICMR-NICED**
- **ICMR-NIIH**
- **ICMR-NIE**
- **ICMR-NIOP**
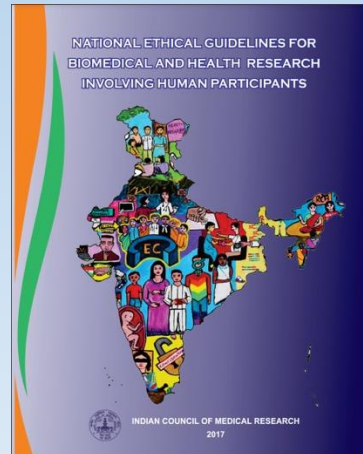- **ICMR-Institute of Cytology and Preventive Oncology**
- **ICMR-RMRC**

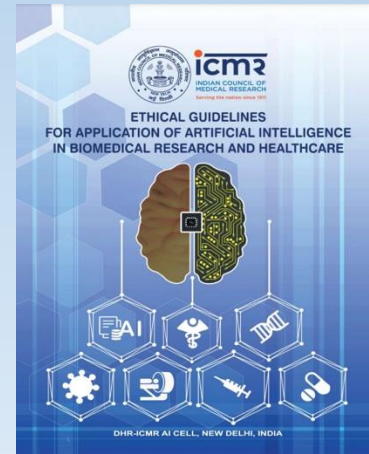## Health Technology Assessment

**DHR (HTAIn)**

# Enabling Policies

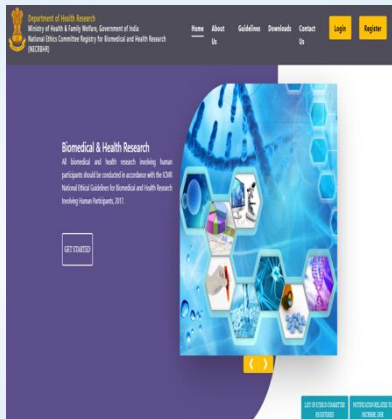**Entrepreneurship policy- Medical Professionals**

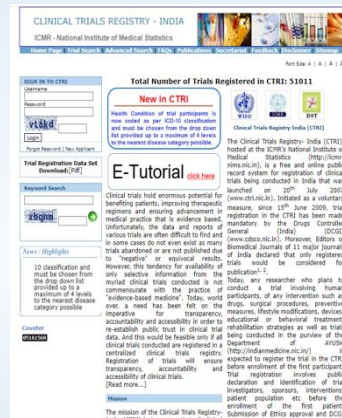**Bioethics Guidelines: 2017**

**Ethical Guidelines for Application of AI in Biomedical Research & Healthcare**

**Guidelines for Good Clinical Laboratory Practices**

**Registration Portal: NAITIK**

**Clinical Trial Registry of India**
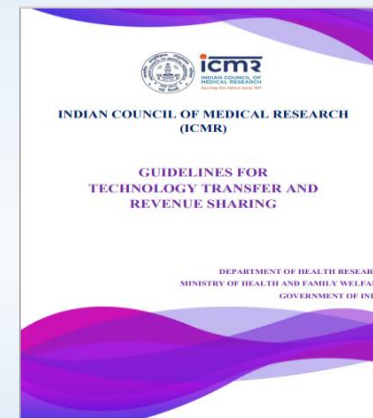
**Guidelines for Technology Transfer and Revenue Sharing**
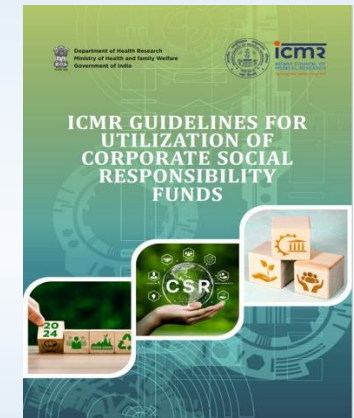
**Guidelines for Utilization of Corporate Social Responsibility Funds**

# Infrastructure Development



**Legend:**
- ICMR-DHR-CoE
- Testing Facility
- Pre-clinical Research Facility
- ICMR Clinical Trail Network (INTENT)
- Health Technology Assessment

**Doctors-Engineers collaboration**

**Testing**

**Preclinical & Clinical**

**Validation & HTA**

# Medical Device and Diagnostics Mission Secretariat (MDMS)

*A stepping stone towards "Atmanirbhar Bharat" by fostering "Make-in-India" for Medical Device and Diagnostics*

## Mandate

To adopt a multipronged approach for fostering holistic development of Medical Device & Diagnostic sector in India in a mission mode.
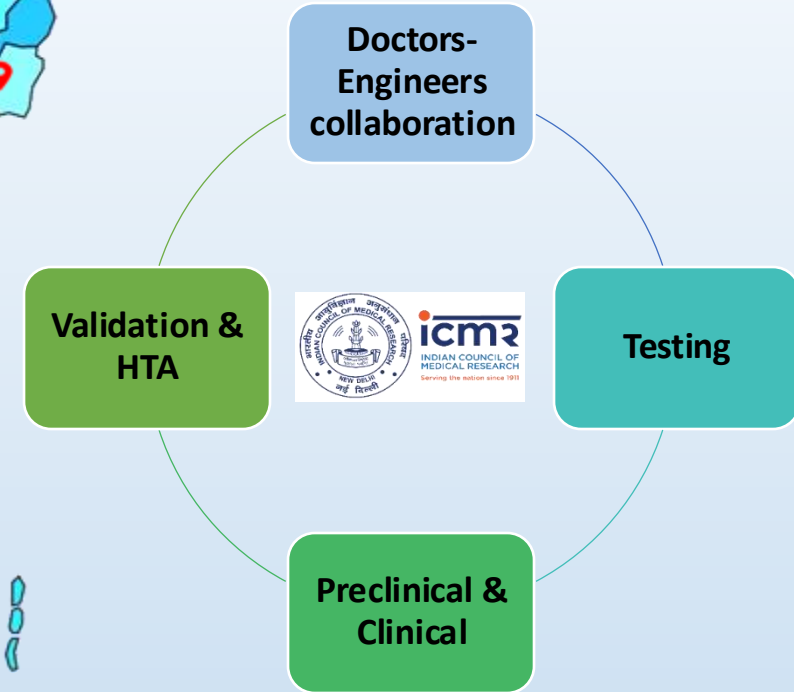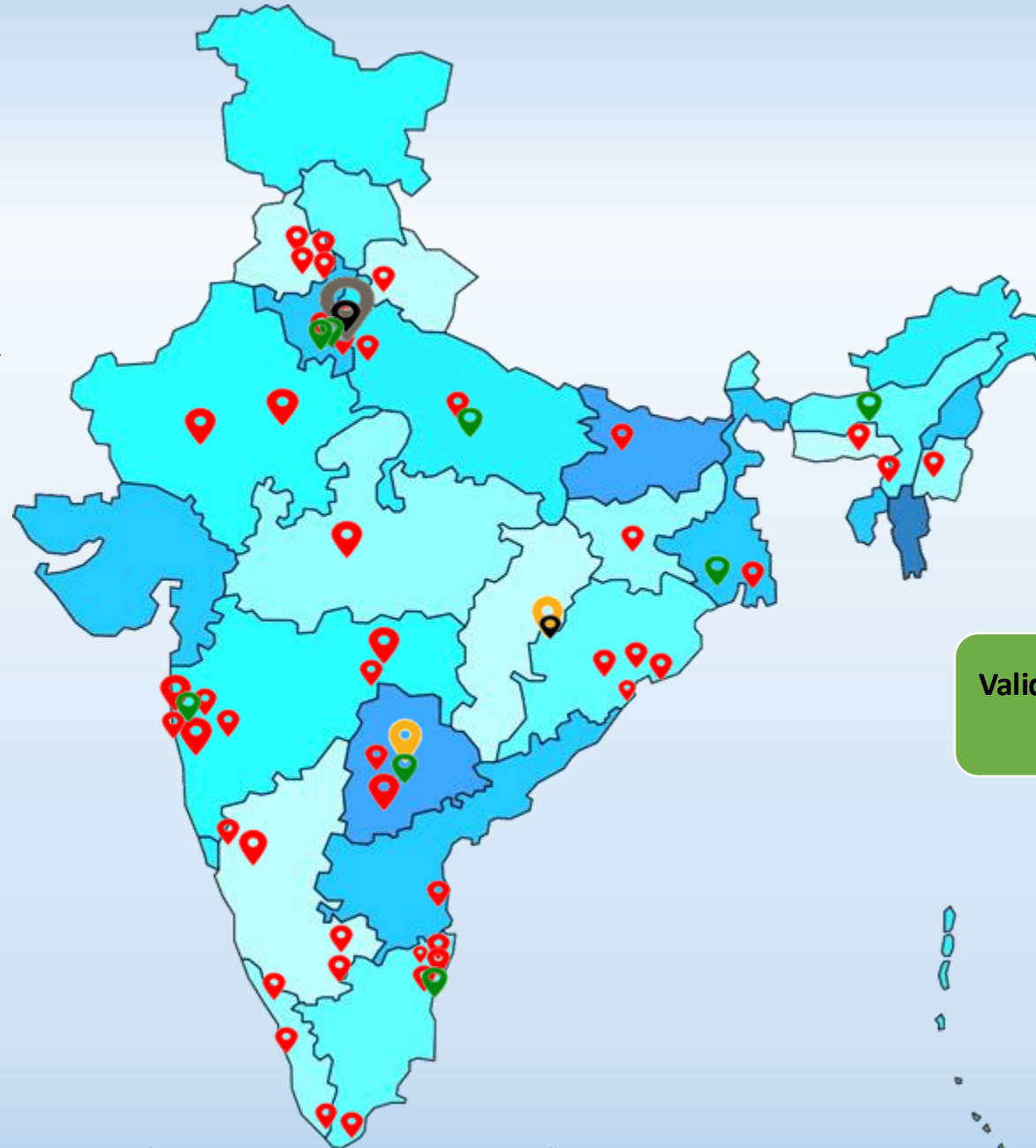
## Vision

To support and catalyze research, development, and indigenous manufacturing of robust and cost-effective medical devices to strengthen healthcare sector in India and reduce import dependency through a Mission Mode Consortia Approach.



Medical device journey

| TRL1 | TRL2 | TRL3 | TRL4 | TRL5 | TRL6 | TRL7 | TRL8 | TRL9 |

Idea — Proof of concept — Clinical evaluation — Commercialization

MAKE IN INDIA

## Objectives

- Technology Development & Commercialization
- Start-ups Handholding
- Strengthening Infrastructure
- Advisory on Market Facilitation
- **MDMS**
- Skill Development and Capacity Building
- Animal Studies (Small & Large)
- Clinical Validation and Regulatory Support
- Policy Analysis and Advocacy support HTA

# ICMR-MDMS- Funding Schemes

## MDMS Schemes/Programs

- ICMR-DHR Centre of Excellence (ICMR-DHR CoE) at IITs
- Medtech Product Development and Acceleration Gateway of India (mPRAGATI)
- Product Ignition and Development Enabler Program (mPRiDE)

## ICMR Funding Schemes

- Centre for Advanced Research & Excellence (CAR) (upto $1.78 million)
- Research on National Health Priorities – upto $3 million
- Investigator Initiated Small Grant (upto $0.24 million)
- Investigator Initiated Intermediate Grant (upto $1 million)
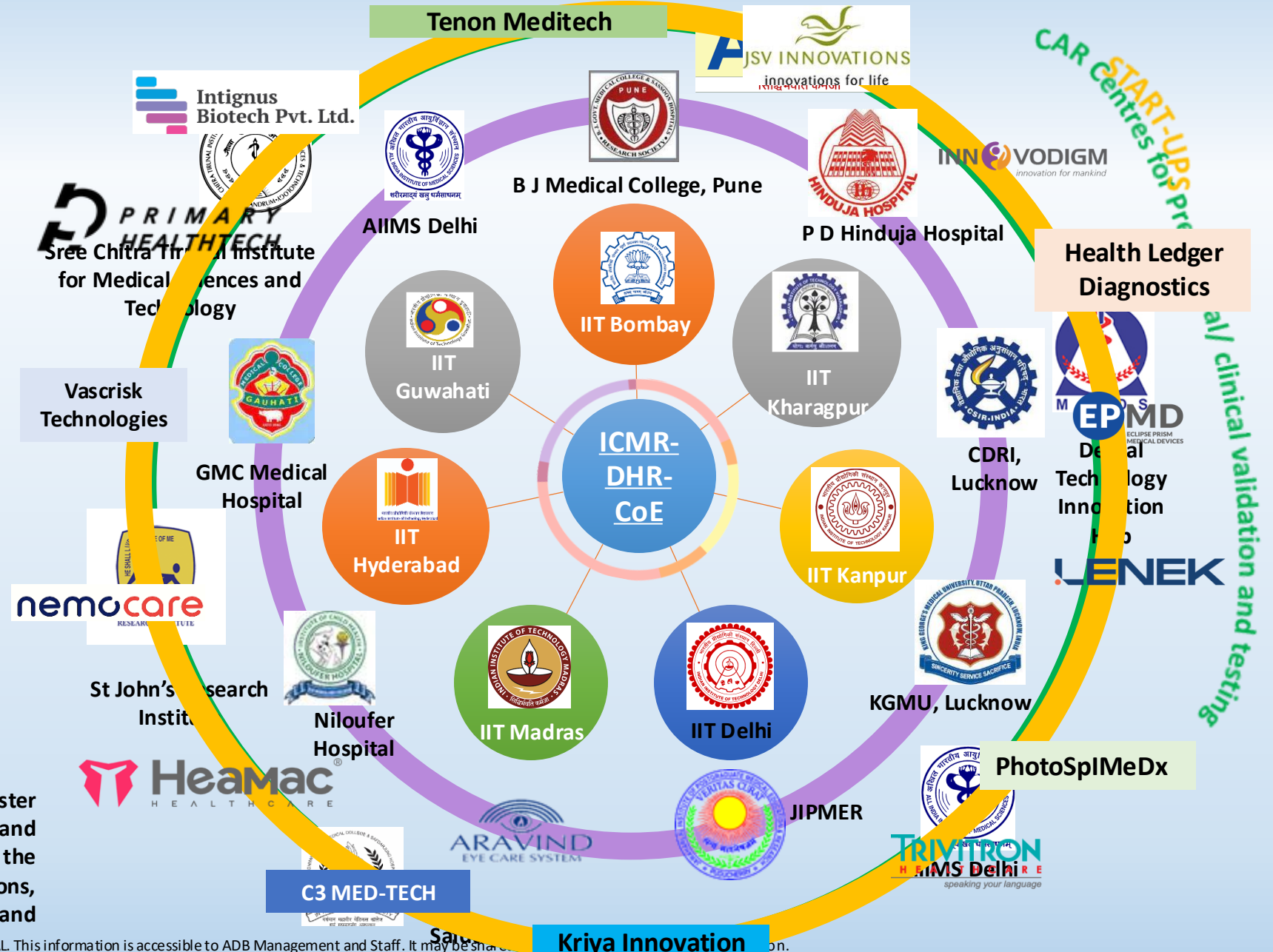
**To create a conducive ecosystem and to drive accessibility and affordability in Medtech Sector**

# ICMR Initiatives (ICMR-DHR-CoE) for Fostering inter disciplinary research for NHM oriented product development



**Academia**

**Government**

**Industry**
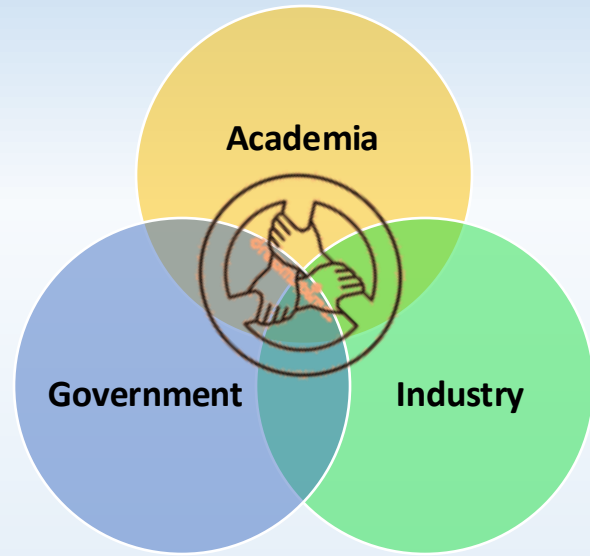
**Medical Institutes/Doctors & Engineering Institutes/Engineers (Start-ups)**

ICMR-DHR CoE at IITs/IIT like Institutes aim to foster strategic Make-in-India product development and their commercialization in synergies with the requirements of National Health Missions, Ayushman Bharat – Health and Wellness Centres and Public Health Programs of GoI

Tenon Meditech

JSV INNOVATIONS
innovations for life

Intignus Biotech Pvt. Ltd.

PRIMARY HEALTHTECH

Sree Chitra Tirunal Institute for Medical Sciences and Technology

AIIMS Delhi

B J Medical College, Pune

P D Hinduja Hospital

INNOVODIGM
innovation for mankind

Health Ledger Diagnostics

Vascrisk Technologies

GMC Medical Hospital

IIT Guwahati

IIT Bombay

IIT Kharagpur

CDRI, Lucknow

EPMD
ECLIPSE PRISM MEDICAL DEVICES

Dental Technology Innovation Hub

nemocare

IIT Hyderabad

ICMR-DHR-CoE

IIT Kanpur

LENEK

St John's Research Institute

Niloufer Hospital

IIT Madras

IIT Delhi

KGMU, Lucknow

PhotoSpIMeDx

HeaMac HEALTHCARE

ARAVIND EYE CARE SYSTEM

VERITAS

JIPMER

TRIVITRON HEALTHCARE
speaking your language

AIIMS Delhi

C3 MED-TECH

Kriya Innovation

CAR Centres for Pro

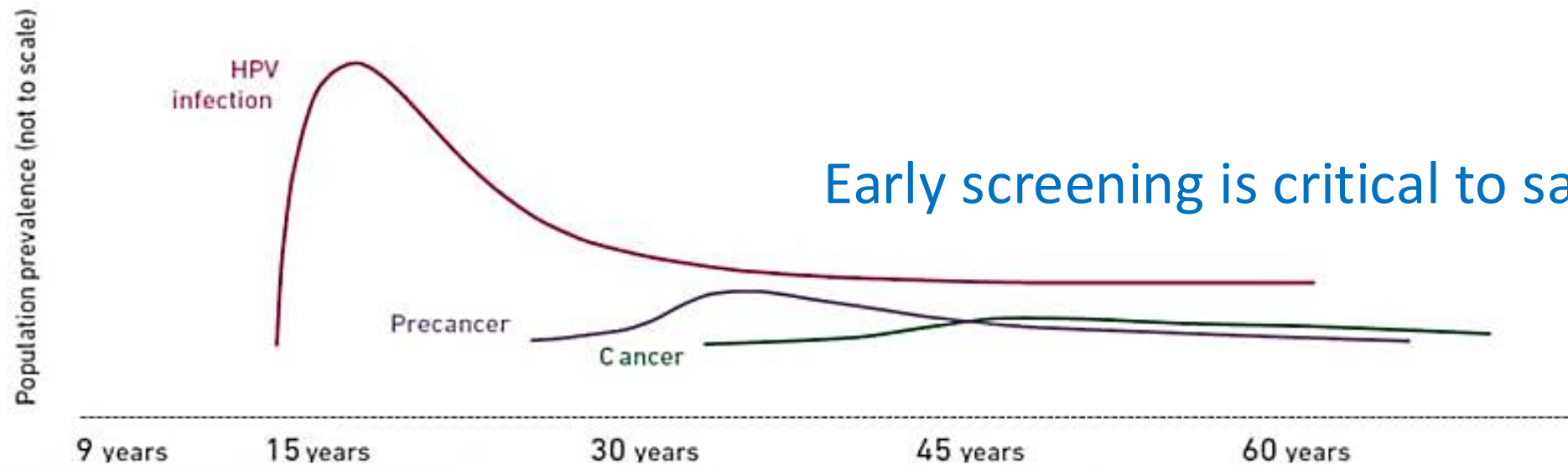START-UPS

al/ clinical validation and testing

# Case Studies on Devices and Diagnostics in reference to NCDs

**Autoscope (Automated AI assisted platform for cervical cancer diagnosis)**

# Autoscope
# (Automated AI assisted platform for cervical cancer) diagnosis



Early screening is critical to save life!

## Unmet need: Cervical cancer diagnosis

➢ 6.0 lakhs New cases in 2020 globally
➢ 56.6% mortality
➢ 1.25 lakhs cases in India
➢ ~ 2 crore people require screening every 5 years

## Current practice:

❖ Manual microscopy
❖ Skilled manpower
❖ Manual sample preparation
❖ Large number of images

# Autoscope
## (Automated AI assisted platform for cervical cancer diagnosis)



ICMR
INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI
Serving the nation since 1911

Designed for scalable manufacturing

**Autostain**, an automated sample preparation system, Process 4 slides at a time

~60 minutes per run for sputum sample
~20 minutes per run for pap sample

**Autoscope**, an automated digital imaging platform, Process 4 slides at time

TAT ~10 mins, including scanning and AI processing

# Autoscope – ICMR Hand holding

**ICMR - DHR MedTech Product Development Acceleration Gateway of India (mPragati)**

Prototype fabrication

Clinical utility assessment

Pre-clinical evaluation

ISO13485 QMS documentation

Clinical evaluation plan (CDSCO)

Clinical use process development (HTA)

**Clinical team**

Department of Obstetrics and Gynaecology, Department of Pathology, Safdarjung Hospital

National Institute of Cancer Prevention and Research, ICMR, Noida

**2**

# Mobilab™: A Portable Blood Testing Device

*"Affordable, Accessible and Accurate Point Of Care Testing"*

**NO - Early Symptoms**
Liver, Heart, Kidney and Pancreatic Diseases

**Diagnosed at last stage**

Primary to Tertiary
**Cost of Dialysis > ₹2 Lakhs**

**High-end Infrastructure**
1. High CapEx
2. High OpEx

**Lack of training**
1. Lack of trained technician
2. **>60%** Pre-analytical Errors

**Disconnected Healthcare**
1. Delay in result
2. High error
3. High Drop out rate

"Current healthcare diagnostic technologies are capital intensive and requires intensive training, leading to delays and several patients losing out on timely care."

# Mobilab™ : A Portable Blood Testing Device



**Mobi**lab™ **is a Port**able, **Afford**able, **Easy**-to-Use **Diag**nostic **Device for ear**ly **Detection o**f NCD diseases

**20x** Reduced Cost

**100%** Unlimited Storage

**21+** Indian Languages

**50x** Light Weight

**50x** Low Powered

ISO 9001:2015

CDSCO CDSCO

**Drugs License** D/OL/KMP/22934 & D/OL/KMP/22935

ISO 13485:2016

**3**

**HemoQR- Paper based point of care devices for blood haemoglobin level detection – Lab to market translation**

# HemoQR- Paper based point of care devices for blood haemoglobin level detection – Lab to market translation

HemoQR is a hemoglobin Detection Software System intended for in vitro diagnostic use in clinical setting / population-based screening as Point-of-care usage for the quantitative determination of hemoglobin with human blood

**Institute:** IIT Kharagpur
**Clinical Evaluation Site:** AIIMS - All India Institute of Medical Science, New Delhi
**Current Status:** Manufacturing License received
**NHM:** **Anaemia Mukt Bharat Mission**

Three steps easy-to-use hemoglobin detection kit.

Instant real-time hemoglobin results.

Regular tracking and monitoring of hemoglobin levels.
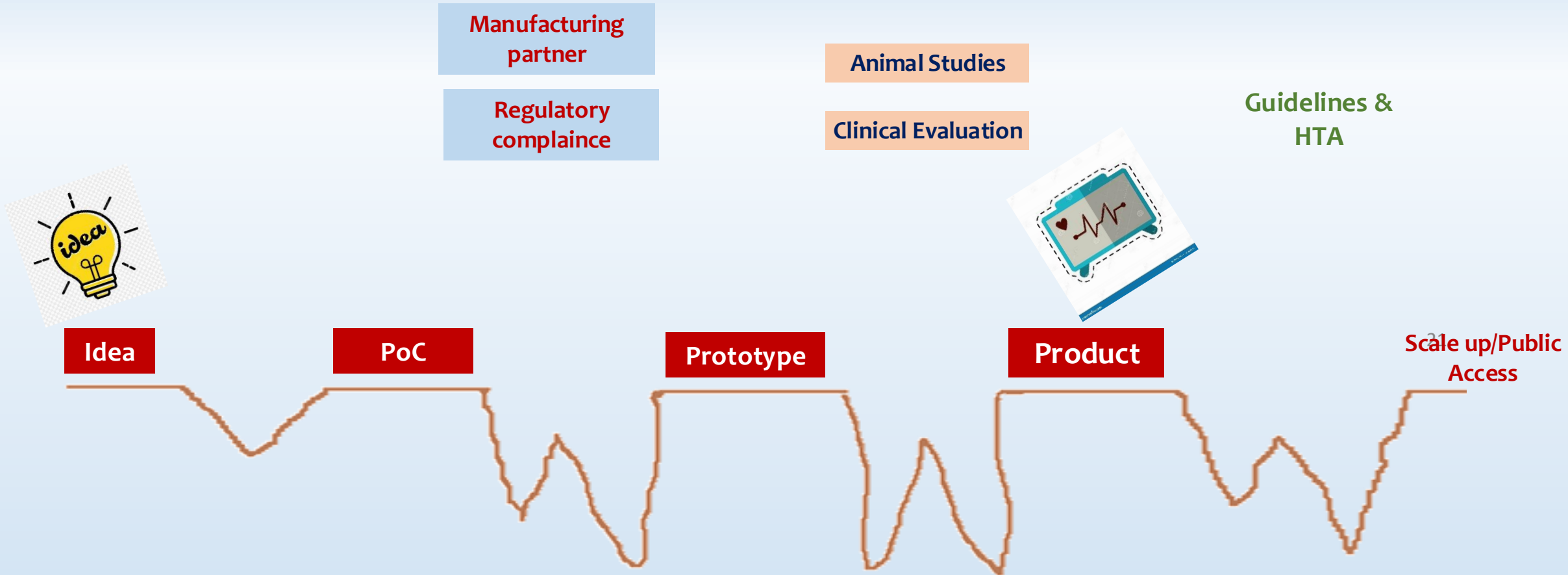
Self-testing kit for anemia screening.

# Challenges faced by Innovators – Valley of Death

Manufacturing partner

Regulatory complaince

Animal Studies

Clinical Evaluation

Guidelines & HTA

Idea

PoC

Prototype

Product

Scale up/Public Access

Manufacturing partner

Regulatory compliance

Animal Studies

Clinical Evaluation

Guidelines & HTA

Idea

PoC

Prototype

Product

Scale up/Public Access

MedTech Mitra

MedTech Mitra

MedTech Mitra

MedTech Mitra

# MedTech Mitra: Empowering innovators to face the challenges in the development pathway

# "What"
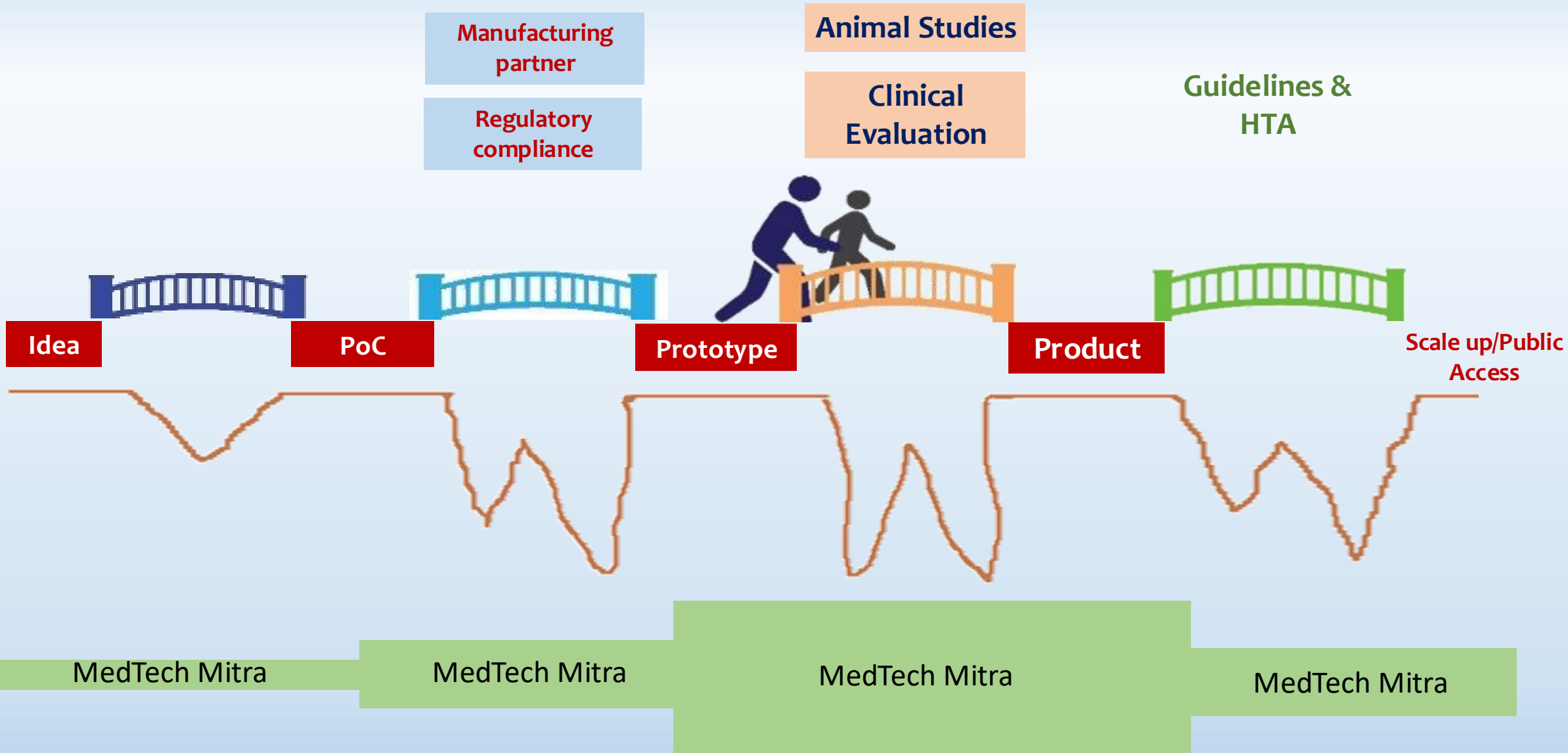## Medtech Mitra offers ??

# MedTech Mitra:Empowering MedTech Ecosystem



MedTech mitra
Handholding MedTech innovators for clinical evaluation, regulatory facilitation and uptake of new products
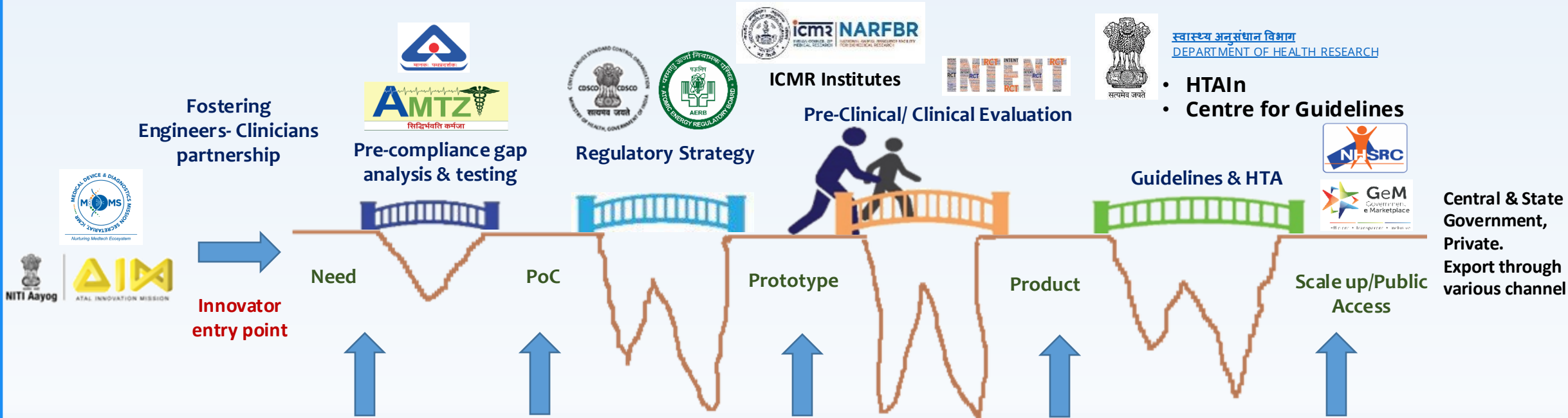A NITI Aayog-ICMR-CDSCO initiative

**Pillars of Strength for "MedTech Mitra"**

- ICMR-MDMS under the guidance of NITI Aayog-Atal Innovation Mission
- CDSCO
- AERB
- BIS
- KIHT/AMTZ
- ICMR-NARFBR
- ICMR-DHR-LAHF at AMTZ
- ICMR-INTENT
- DHR-HTAIn
- DHR-Centre of guidelines
- NHSRC
- GEM

Department of Health Research
Ministry of Health and Family Welfare
Government of India

# Scope of MedTech MITRA

MedTech mitra — Handholding MedTech innovators for clinical evaluation, regulatory facilitation and uptake of new products

A NITI Aayog-ICMR-CDSCO initiative

**Information Cell**

**ICMR Handholding for Pre-clinical/Clinical/HTA/Guidelines (GL)/Public Access**
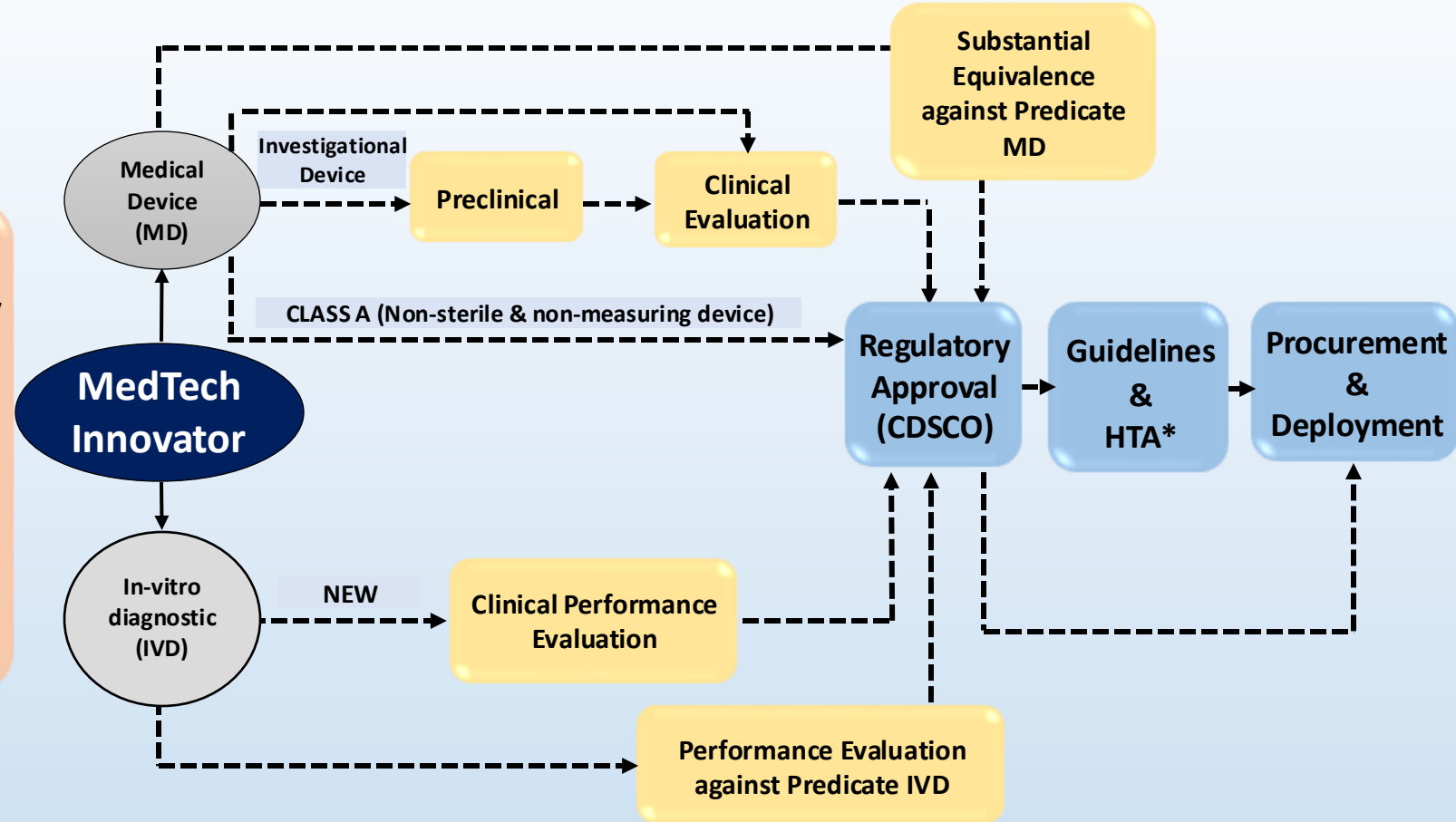
Fostering MedTech Product development through Engineers-Clinicians partnership

**Key Information**

- Applicable Standards
- Testing Centres/ Manufacturing Facilities
- Funding Opportunities
- IP Advisory

**Advise for Regulatory Strategy**

- Classification
- Regulatory Pathway
- Test/ Manufacturing License Requirements

**MedTech Innovator**

Medical Device (MD)

Investigational Device

Preclinical → Clinical Evaluation

CLASS A (Non-sterile & non-measuring device)

Substantial Equivalence against Predicate MD

In-vitro diagnostic (IVD)

NEW → Clinical Performance Evaluation

Performance Evaluation against Predicate IVD

Regulatory Approval (CDSCO) → Guidelines & HTA* → Procurement & Deployment

*Health Technology Assessment

# "How"
## Medtech Mitra supports ??

Atal Innovation Mission (AIM) is the Government of India's initiative to promote a culture of innovation and entrepreneurship.
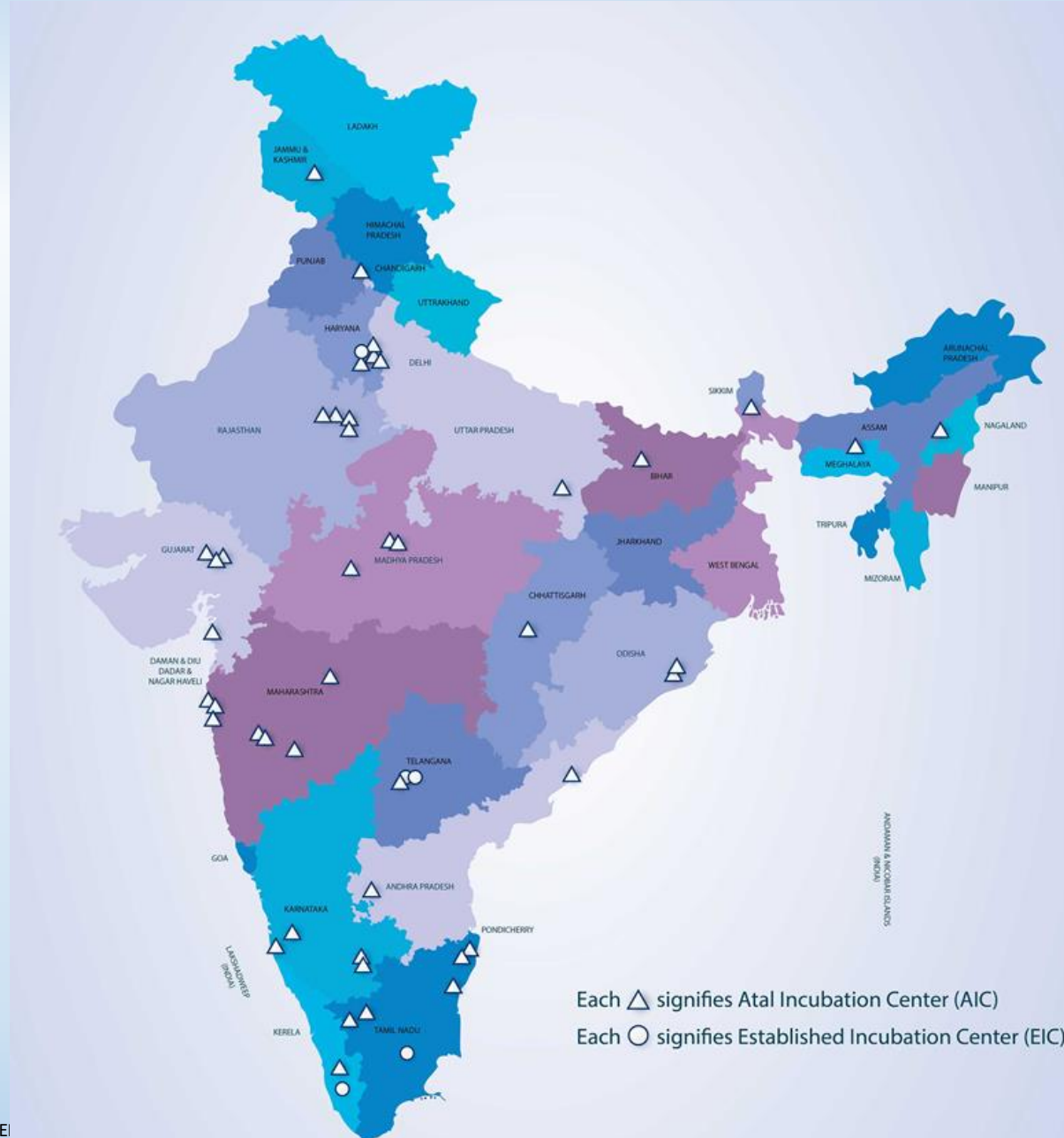
Atal Incubation Centres play a vital role in accelerating the development and deployment of innovative healthcare technologies.



Each △ signifies Atal Incubation Center (AIC)

Each ○ signifies Established Incubation Center (EIC)

MedTech mitra
Handholding MedTech innovators for clinical evaluation, regulatory facilitation and uptake of new products
A NITI Aayog-ICMR-CDSCO initiative

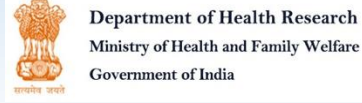# Pre-compliance gap analysis and Testing



**Bureau of Indian Standards (BIS)**

**Kalam Institute of Health Technology (KIHT)**

**Andhra Pradesh Medtech Zone Ltd. (AMTZ)**

**Animal House for Large Animal Testing- Medical devices**

# ICMR - Clinical Study Support

**Clinical Studies, Trials & Projection Unit (CSTU) – ICMR Hqrs**

**Indian Clinical Trail & Education Network (INTENT)**
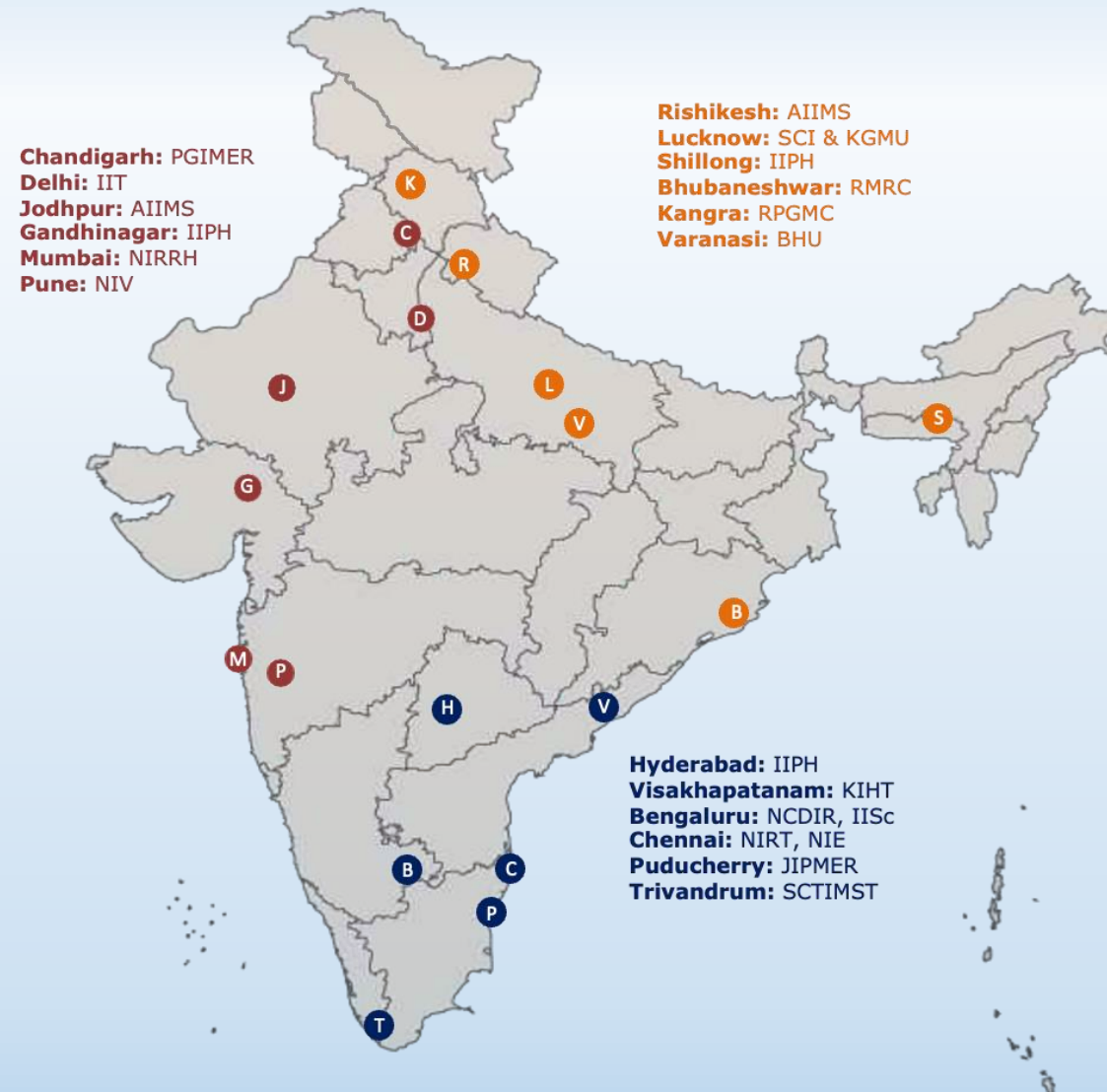
# HTA Support

## Mandate

To evaluate appropriateness and cost effectiveness of available and new health technologies in India.

## Purpose

To design and institutionalise Health Technology Assessment (HTA) that embodies modern best international practice which features transparent, inclusive, fair and evidence based decisions.

## HTAIn Resource Centres



**Chandigarh:** PGIMER
**Delhi:** IIT
**Jodhpur:** AIIMS
**Gandhinagar:** IIPH
**Mumbai:** NIRRH
**Pune:** NIV

**Rishikesh:** AIIMS
**Lucknow:** SCI & KGMU
**Shillong:** IIPH
**Bhubaneshwar:** RMRC
**Kangra:** RPGMC
**Varanasi:** BHU

**Hyderabad:** IIPH
**Visakhapatanam:** KIHT
**Bengaluru:** NCDIR, IISc
**Chennai:** NIRT, NIE
**Puducherry:** JIPMER
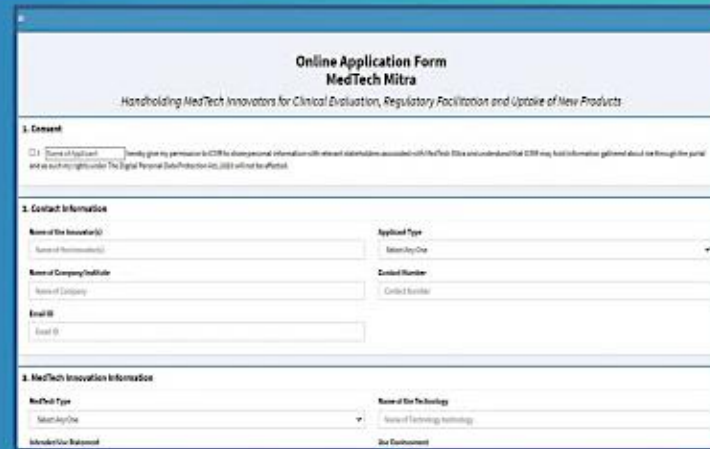**Trivandrum:** SCTIMST

**Resource Centres** have been established in Government research institutes **to conduct HTA** and other multi-centric studies allocated by HTAIn Secretariat.

# "How"
## to contact
## Medtech Mitra ??

# MedTech Mitra Portal



▶ Click on MedTech Mitra portal (medtechmitra. icmr. org.in)
which displays the Application form

Innovator submits the query by filling the MedTech Mitra application form

An email acknowledging the submission is sent to the Innovator

Additional info to be submitted by innovator, if required

Evaluation of adequacy of information for the query

MedTech Mitra and Innovator meeting scheduled to understand and address the query

Technical & Regulatory Advice to all the Innovators

Requisite information sought provided to all the innovators

Render handholding support and/or financial assistance to selected Innovators as recommended

Launch of MedTech Mitra
December 25, 2023

# Technical advisory Committee Meetings for MedTech Mitra to address the innovators' queries

**First Technical Advisory Committee**

**Second Technical Advisory Committee**
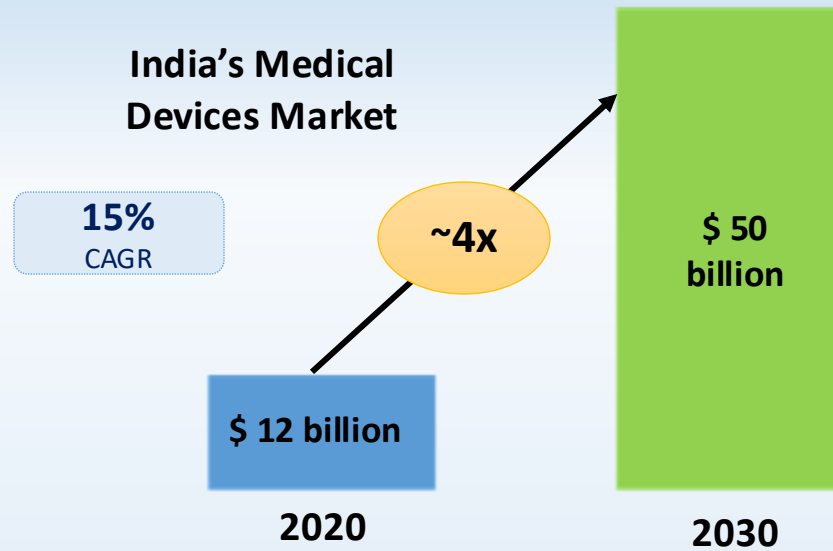
**Third Technical Advisory Committee**

**Fourth Technical Advisory Committee**

**Fifth Technical Advisory Committee**

# Way Forward - From Import Dependence to Atmanirbhar Bharat

**India's Medical Devices Market**

**15%** CAGR

**~4x**

**$ 50 billion**

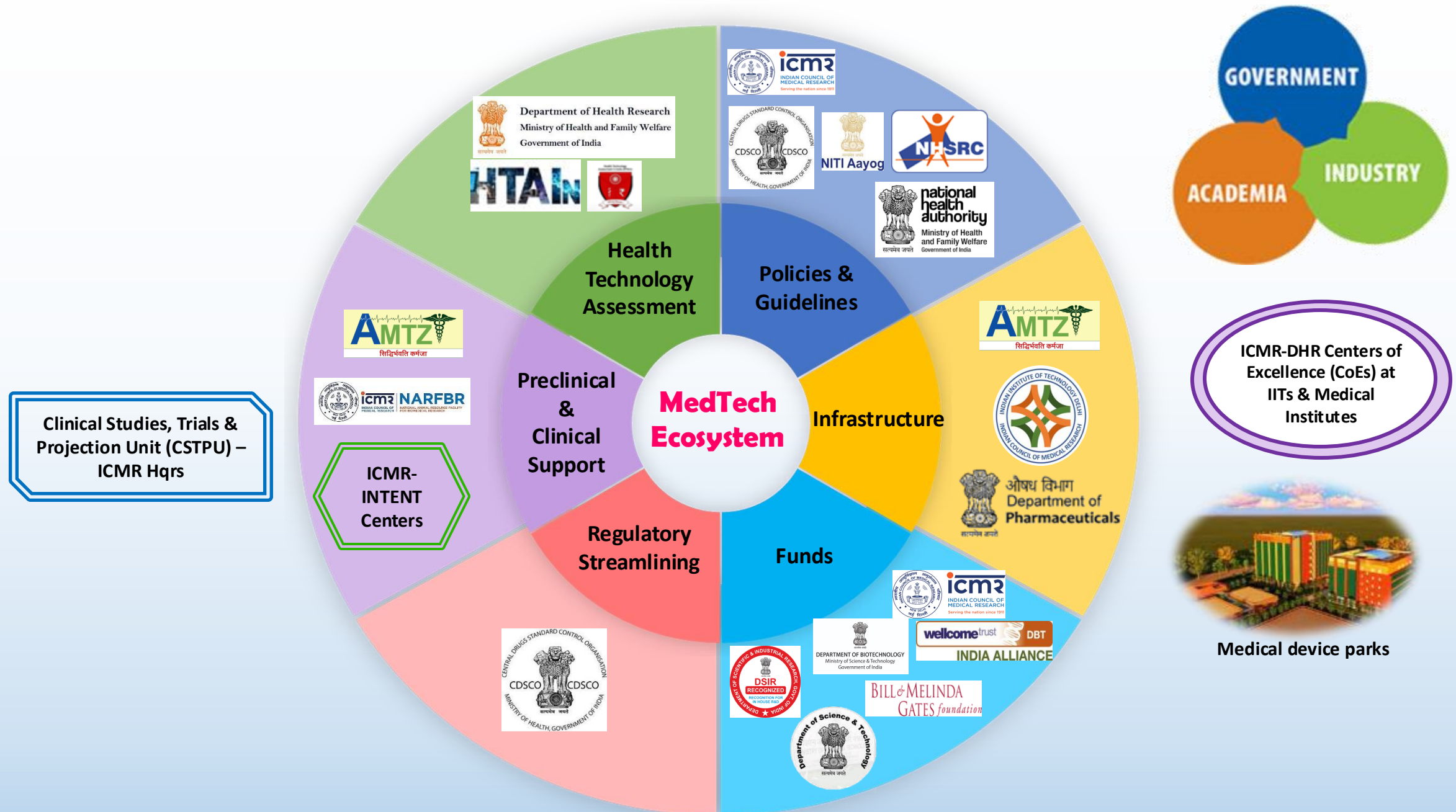**$ 12 billion**

**2020**

**2030**

**7%** CAGR

**Global Medical Device Market Growth Rate**

## MedTech mitra
Handholding MedTech innovators for clinical evaluation, regulatory facilitation and uptake of new products

A NITI Aayog-ICMR-CDSCO initiative

**MedTech Mitra has the potential to be a game-changer for India's MedTech Innovation Ecosystem and the make-in-India mission.**
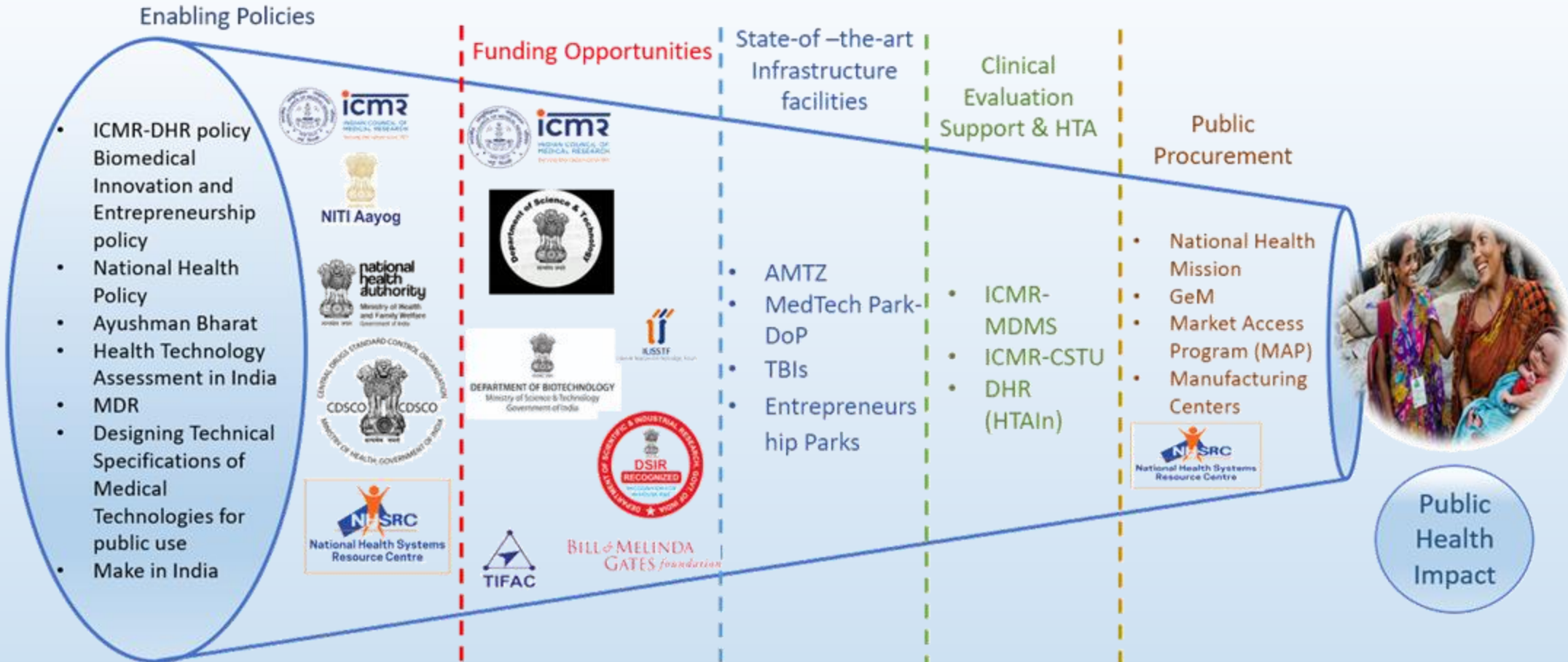
It aims to foster development of affordable and accessible indigenous Medical devices and In-vitro diagnostics by providing strategic holistic handholding to MedTech innovators for technology development, evaluation and HTA leading to uptake of new products.

# India - Innovation Ecosystem in MedTech

# Innovation to Impact - Enabling Medtech Ecosystem in INDIA



**Enabling Policies**

- ICMR-DHR policy Biomedical Innovation and Entrepreneurship policy
- National Health Policy
- Ayushman Bharat
- Health Technology Assessment in India
- MDR
- Designing Technical Specifications of Medical Technologies for public use
- Make in India

**Funding Opportunities**

**State-of –the-art Infrastructure facilities**

- AMTZ
- MedTech Park-DoP
- TBIs
- Entrepreneurship Parks

**Clinical Evaluation Support & HTA**

- ICMR-MDMS
- ICMR-CSTU
- DHR (HTAIn)

**Public Procurement**

- National Health Mission
- GeM
- Market Access Program (MAP)
- Manufacturing Centers

**Public Health Impact**

Thank You