Concept Note on Assessment of Health Innovation Product

Ministry of Health & Family Welfare

2025

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Background

1. The medical device sector in India is growing at a fast pace. Considering the diversity and multidisciplinary nature of the medical device sector, the regulations, skilling trade promotions of medical device industry are spread over several government departments both at the centre and state levels. The National Medical Devices Policy, 2023 is expected to facilitate and fuel innovations in the country and also orderly growth of the medical device sector to meet the public health objectives of equity, access, affordability, quality and innovation.

2. India is emerging as a global leader in Innovation and technology, making rapid strides in rising in the Global Innovation Index rankings. India ranks 38th globally in the Global Innovation Index (GII) 2025, maintaining its leadership in the Central and Southern Asia region. India's innovation ecosystem is supported by government policies, investment in research & development and a collaborative environment for startups and industries.

3. India has the third largest start-up economy in the world. Several Govt of India initiatives such as Make-in-India, Start-up India, Skill India aim to promote innovative technology development, skill development and foster indigenous manufacturing of technology to decrease import dependency of India. These innovative solutions not only cater to the healthcare needs specific to the Indian scenario but also facilitate cost-effective programmatic interventions leading to improved health outcomes.

4. Innovation is a broad concept encompassing (i) healthcare products which include devices or diagnostic products (ii) healthcare services and (iii) software/mobile apps. The standard course for MedTech innovation is to be superseded by more sophisticated, advanced and user-friendly technology.

5. **The National Health Policy (NHP) 2017**, emphasized on role of innovation to boost efficiency, accessibility and service delivery. It sets vision for Universal Health Coverage (UHC), preventive care, and reducing out-of-pocket expenses, pushing for technology adoption (EHRs, telemedicine) and better infrastructure

and provide tools to meet policy goals, fostering new solutions for accessibility, efficiency, and disease management.

6. Health Technology Assessment in India (HTAIn) is an institutional mechanism established by the Government of India to support evidence-based decision-making in the health sector. HTAIn aims to systematically evaluate the clinical effectiveness, cost-effectiveness, safety, and broader social and ethical implications of health technologies including drugs, medical devices, diagnostics, procedures, and public health interventions to inform policy decisions related to pricing, procurement, reimbursement, and adoption within public health programmes.

7. HTAIn functions through a structured, multi-stakeholder framework. The HTAIn Secretariat, housed within DHR, coordinates HTA activities and oversees the prioritisation of topics based on national health priorities and policy relevance. Technical assessments are carried out through a network of designated Technical Partners, including institutions such as the National Health Systems Resource Centre (NHSRC), academic institutions, and research organisations with domain expertise.

8. There is a need to systematically identify innovations and good practices in the country which can have high impact to address morbidity & mortality and to facilitate their prompt uptake and scale up through a platform, which can provide repository, learnings, information on enabling milieu and cross-learning.

9. The Ministry of Health and Family Welfare (MoHFW), Government of India, has been organising the National Summit on Good, Replicable Practices and Innovations in Public Healthcare Systems in India since 2013 to recognise, showcase, and document best practices and innovative initiatives by States and Union Territories to address public health challenges and improve health outcomes through effective implementation of programmes under the National Health Mission. These summits aim to promote cross-learning and knowledge exchange among State Governments, non-governmental organisations, healthcare institutions, academic bodies, and other stakeholders, enabling collaborative

efforts towards achieving national public health goals.

Healthcare Innovation

10. Innovation, in its modern meaning, is "a new idea, creative thought, new imagination in the form of device or method." Innovation requires collaboration, ideation, implementation and value creation. A technological innovation is a new or improved product or process whose technological characteristics are significantly different from before. Implemented technological product innovations are new products (product innovations) or processes in application (process innovations) that have been brought to market.

11. The World Health Organization (WHO) explains that 'health innovation' improves efficiency, effectiveness, quality, sustainability, safety, and/or affordability of healthcare. This definition includes 'new or improved' health policies, practices, systems, products and technologies, services, and delivery methods that result in improved healthcare.

12. The three conditions that must be met by health technologies to be classified as innovative:

(a) **The novelty condition:** the technology must display "innovative characteristics or be of an "innovative nature".

(b) **The substantial benefits condition**: the innovative nature of the technology must bring substantial health benefits to the patient, also referred to as a "'step-change' in the management of the condition".

(c) **The demonstrable and distinctive condition**: the substantial benefits brought by the innovative characteristics of the health technology must be captured in the incremental cost-effectiveness ratio (ICER) calculation of the technology under scrutiny and they must be "demonstrable and distinctive" benefit.

13. Access to innovations in health technologies is one of the pillars of the universal health coverage (UHC) strategy. Health innovation aims to develop or deliver new or enhanced health policies, systems, products, technologies, services, and delivery methods to improve the health of community at large. Recent advancements in the field of In-vitro diagnostics (IVDs), point-of- care devices,

artificial intelligence (AI), the internet of things (IoT), and robotics are changing the technology landscape in the country.

14. The investments in the healthcare sector are being steadily enhanced to strengthen public health systems, improve quality of care, and ensure equitable access to essential health services. MoHFW is prioritising increased funding for health infrastructure, human resources, medical equipment, diagnostics, and digital health platforms under flagship programmes such as the National Health Mission, Ayushman Bharat, PM–Ayushman Bharat Health Infrastructure Mission (PM ABHIM), and the Ayushman Bharat Digital Mission (ABDM). Focused investments are being made to expand and upgrade primary healthcare through Ayushman Arogya Mandirs, strengthen referral networks, and integrate technology-enabled solutions including telemedicine and health information systems.

15. Platforms such as e-Sanjeevani have enabled patients in rural and hard-to-reach regions to consult qualified doctors located in urban centres without the need for physical travel, thereby reducing out-of-pocket expenditure and delays in care. By integrating tele-medicine with primary healthcare facilities, Health and Wellness Centres, and national digital health initiatives, India is advancing more equitable, affordable, and accessible healthcare delivery while strengthening the overall resilience of the health system.

16. Through these strategic investments, MoHFW seeks to reduce urban–rural disparities, enhance service delivery efficiency, and advance the goal of universal health coverage in a sustainable and inclusive manner. The MoHFW is increasingly leveraging tele-medicine to improve the access and availability of specialist care, diagnostics, and follow-up services in underserved and remote areas.

17. The technology innovation has proven to significantly impact by reducing preventable deaths in the country. Adoption of newer and emerging diagnostic technologies, such as wearable biosensors, microfluidics, lab-on-a-chip technologies, patient-centric mobile apps, remote monitoring solutions, digital platform integration, surgical robotic tools, smaller implants, AI, and 3D printing,

shall provide the necessary impetus towards achieving the vision of a connected healthcare ecosystem.

Health Technology Assessment (HTA)

18. Health Technology Assessment (HTA) is defined by the WHO as the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a novel health innovation or health technology. The main purpose of conducting an assessment is to inform a policy decision making.

19. Most HTA systems evaluate features of innovation that consider the impact of a product from the perspective of current patients (Therapeutic benefit, unmet need, safety, administration) or current budget holders (Cost), also called the static perspective. HTA systems less frequently explicitly consider the dynamic consequences or incentives created by a decision to adopt or not to adopt new technology in the direction of future Research & Development (R&D) and ultimately, further innovations. These terms overlap to some extent with the idea of the source of innovation being 'Pulled by Demand' or 'Pushed by Supply' or entrepreneurship.

Medical Device Classification & Categories of Innovation

20. The Medical Devices Rules, 2017 (MDR- 2017) were notified under the **Drugs and Cosmetics Act, 1940** and came into effect on **1 January 2018** to create a dedicated regulatory framework for medical devices and in vitro diagnostics (IVDs) in India. The goal was to ensure safety, performance, quality and patient protection through a risk-based regulatory approach.

21. Medical devices including in-vitro diagnostic devices (IVDs) are regulated using a **risk-based classification system**, wherein the level of regulatory control increases with the potential risk posed to patients and users. Under India's Medical Devices Rules, 2017, devices are classified into four classes—A, B, C, and D—based on factors such as intended use, degree of invasiveness, duration

of contact with the body, and potential impact on human health.The risk-based classification is listed below:

Classes of Medical Device	Risk Level	Example of Medical Devices	Example of IVDs
Class A	Low	Thermometers, tongue depressors, non-sterile bandages	Lab culture media, specimen containers, clinical chemistry analyzer
Class B	Low-moderate	Hypodermic needles, suction equipment, blood pressure monitor	Controls & Calibrators for IVDs, urine strop test, blood glucose monitor
Class C	High-moderate	Ventilator, orthopedic implants, infusion pump	Dengue, Malaria, Hepatitis B& C diagnostic kits, PSA test kits
Class D	High	Heart Valves, pacemaker, Surgically invasive catheters	HIV screening kit, HBsAg blood screening kit, blood grouping reagents

22. The Medical Devices Rules, 2017 demonstrates a significant regulatory reform in India's healthcare ecosystem by establishing a dedicated, risk-based framework for the regulation of medical devices and in vitro diagnostic (IVD) devices. The framework further empowers regulators to issue guidance documents and update risk classifications as required, thereby facilitating adaptive and responsive regulation in line with evolving technological advancements.

23. MDR-2017 provides regulatory space for novel and emerging technologies, including digital health and software-based medical devices, point-of-care diagnostics, and AI-enabled and smart medical devices. The Rules play a critical role in enabling, supporting, and scaling healthcare innovation while ensuring

patient safety, performance, and product quality. The framework allows regulators to issue guidance documents and classification updates, enabling adaptive regulation for evolving technologies.

24. The health technology startups/innovations can be broadly categorized as mentioned below. In India, startups are operating in one of these verticals and are using AI/ML, predictive analysis, data analytics and other modern digital tools to improve access, affordability and quality of health care.

Sl. No.	Sector	Description
1.	Medical Devices	Diagnostic, therapeutic, monitoring, assistive, medical devices
2.	Software as Medical Device (SaMD)	Technology integration to enable self-diagnosis of diseases & help in decision making. AI enabled remote diagnosis. IoT enabled remote fault diagnosis and improved utilization
3.	Personal Health management	Health advisory content aggregators and personal health tracking apps
4.	Fitness & wellness	Enablers of fitness & wellness services such as gym, yoga and mental wellbeing, health counselling
5.	Telemedicine	Enables doctor consultations virtually through apps or web-based videos, chats and voice guidance
6.	Diagnostics	Use of newer technologies like lab on chip-based diagnostics, microfluids, paper-based assays etc. to speed up diagnosis of diseases(PoC devices and IVDs).
7.	Assistive Technologies	Technology related to assistive, adaptive and rehabilitative devices for people with disabilities and elderly population.
8.	Immunization, maternal & child	Technologies related to immunization or RMNCH-A+

	health	
9.	Healthcare IT	Healthcare related IT dashboards, portals, professional registries, unique ID and electronic health records.
10.	Infection prevention and control	Technologies related to infection prevention and control.

25. **Product Innovation:** Innovative Health Products includes medical devices, Innovative technologies including Healthcare IT, m-health, and tele-health/e-health rapid diagnostics, point of care devices. New vaccines and Drugs follow other regulatory routes and usually get well identified and incorporated. However, medical technology innovations tend to remain unidentified due to inadequate system support.

26. **Software as Medical Device** (SaMD) refers to software intended to be used for one or more medical purposes that performs these purposes **without being part of a hardware medical device**. In India, SaMD is regulated by the **CDSCO** under the **MDR-2017. Software is considered SaMD if is:**

- Has a medical intent (as claimed by the manufacturer), and
- Functions independently of a physical medical device
- Software meant only for general wellness, lifestyle management, data storage, or administrative purposes, without a medical claim, is not regulated as SaMD.

Examples include:

- Clinical decision support software for diagnosis or treatment planning
- Software for analysis of medical images or physiological signals
- Apps for disease risk prediction, monitoring, or prognosis

27. Classification of SaMD: SaMD in India is classified into Class A, B, C, or D based on the risk to patients and users, in line with the First Schedule of MDR-2017. Factors influencing classification include intended medical purpose, significance of

information provided for healthcare decisions, potential impact of incorrect output on patient safety, lower-risk SaMD falls under Class A/B, while higher-risk clinical decision-making software may fall under Class C/D.

28. **Regulatory requirements:** Depending on the class, manufacturers or importers of SaMD must:
    i. Obtain appropriate registration or licensing through the CDSCO online portal (SUGAM)
    ii. Comply with Quality Management System (QMS) requirements (e.g., ISO 13485)
    iii. Maintain technical documentation, including software description, risk management, clinical evaluation, and cybersecurity measures
    iv. Adhere to post-market surveillance and vigilance requirements

Dimensions of Innovation related to Medical Devices

29. The three broad dimensions of innovation related to medical devices are as follows:
    (a) Source of Innovation (demand or supply driven)
    (b) The degree of discontinuity introduced (Incremental or breakthrough)
    (c) Impact of the consequences of innovation (Measurable changes in terms of patients benefit, quality of service or costs).

30. Innovations require **prioritization** for identifying appropriate technology which are critical to improve health services and population health outcome. Factors like impact on SDG-3 goal, rural/tribal reach, cost effectiveness and alignment to Ayushman Arogya Mandir CP-CPHC services packages. The inclusion/exclusion criteria as enumerated below is based on identifying cost effective, indigenous and implementable solutions which can make significant impact on clinical/health outcome in primary healthcare setting.

Process flow for health innovation assessment

31. The process flow for the assessment of any health innovation generally involves a structured, multiphase approach, often linked to the broader health technology assessment (HTA) framework.

Phase I: Identification(Opportunity & Need assessment)

Phase II: Development (Design a prototyping)

Phase III: Implementation (Pilot testing & Scaling)

32. Key Assessment criteria- The key assessment criteria include the following

- Clinical Effectiveness & Safety
- Economic implications
- Organizational and workflow impact
- Social, legal and ethical issues
- Acceptability and usability

33. The inclusion and exclusion criteria for health technology assessment is discussed below:

(a) **Inclusion Criteria:**

i. The health product innovations that are relevant to existing health care needs of the population, especially those who are disadvantaged and marginalized.

ii. The product innovation that addresses locally endemic health problems and or diseases.

iii. The product innovation that facilitates better healthcare reach to people in terms of accessibility (geographies & population) affordability, including potential to reduce cost of care. Quality encompassing patient safety, and equity.

iv. The product innovation bridges a crucial specialized skill gap required in delivery of health services.

v. Innovations demonstrate effective health outcomes.

vi. Evidence of scalability into the large scale in the health systems.

vii. Practices/Interventions to achieve state specific SDG targets.

viii. Cost-effective intervention

ix. Interoperability with National digital health architecture (ABDM compliance)

x. Regulatory status for commercial use, Information on patent, availability in GeM/ local market

(b) **Exclusion Criteria:**

(i) Medical products that require **regulatory clearance.**

(ii) **Inadequate product profile:** for any innovation to be reviewed the document should include adequate information on process, human resource and infrastructure need, capacity building strategies, cost, challenges and lessons.

(iii) **Innovations that are at prototype stage.**

(iv) Innovations that are **not novel,** do not have demonstrable and distinctive substantial health benefit outcome or do not lead to any significant therapeutic benefit for the patient.

(v) Digital solutions without cybersecurity safeguards or privacy compliance-without CDSCO clearance

Criteria for Adopting Innovations in Health Systems

34. The criteria for adoption, innovations in the health systems include the innovations relative advantage over current practices, its compatibility with existing systems and routines and its perceived complexity. Additionally, practical factors like clinical safety, cost effectiveness, life cycle cost analysis, feasibility and the organization's capacity (resource and technology readiness) are critical for successful implementation. The criteria related to the adoption of innovation is as mentioned below:

(a) **Relative advantage:** The innovation must be perceived as having a clear benefit compared to existing methods

(b) **Compatibility:** It should align with the values, needs, and existing routines of the organisation and its staff

(c) **Complexity:** Innovations that are simpler to understand and implement are more likely to be adopted

(d) **Field-usability trial:** Field trial on a pilot scale can provide real time data and helps in reducing the uncertainty and generates evidence for adoption.

(e) **Observability:** The results or benefit of innovation should be visible and appreciable for others in accepting the product, thereby helping in diffusion.

(f) **Feasibility:** the practical ability to implement the innovation within the systems constraints, like availability of trained HR, spares, tech support and infrastructure is important for early adoption.

(g) **Acceptability:** The innovation needs to be acceptable to the key stakeholders, including clinicians and patients

(h) **Clinical safety and Effectiveness:** the innovation must be safe and improve clinical health outcomes

(i) **Cost effectiveness:** achieving a desired outcome at the lowest possible cost

Technology Readiness Levels (TRLs)

35. Technology readiness levels (TRLs) is a measure of estimating technology maturity of core technologies in a program during the selection process and in subsequent monitoring and evaluation phases until these technologies, or products utilizing them, attain market readiness. TRL scale is a metric with nine technology readiness levels for describing the maturity of a technology from ideation stage (TRL-1) to highest degree of application/commercial readiness (TRL-9).

TRL	Status
TRL - 1	Ideation
TRL - 2	Proof of Principle
TRL - 3	Proof of Concept demonstrated
TRL - 4	Proof of concept established
TRL – 5	Early-Stage Validation
TRL - 6	Clinical trials are conducted to demonstrate safety of medical device in controlled and intensely monitored clinical conditions
TRL - 7	Late-Stage Validation
TRL – 8	Pre-Commercialization
TRL - 9	Commercialization and Post Market Studies

Linkages with State Innovation Hubs/SHSRCs

36. At the National level, NHM has been encouraging states and UTs to come up with replicable and scalable innovations for improving health outcomes/parameters and have been supporting the initiatives by holding annual National Summit on Good, replicable, and innovative practices in public healthcare system in India since 2013. This summit have provided opportunities for learning from amongst states/UTs and exchange of ideas and adoption of experiments with good results taken up in a process of continued efforts to improve public healthcare system in India. Districts may face challenges in the implementation of the new health initiatives/products and at the same time, come up with innovative ideas to tackle them. Such situations may lead to missed opportunities.

37. National and State Health Systems Resource Centres serve as single-window technical support agencies under NHM, strengthening health systems through capacity building, problem identification, analysis, and solution-oriented implementation support.

38. NHM prioritizes the establishment of SHSRCs to provide knowledge management support for district planning, quality improvement, data analysis, information systems, and evidence-based decision making. SHSRCs are being equipped with the required infrastructure and human resources to develop context-specific strategies for better health system performance, financial management, and program delivery.

39. The list of active SHSRC is attached as **Appendix 'A'.** The field useability feedback form developed by NHSRC for field useability trials is placed as **Appendix 'B'**.

Institutional Structure

40. **Role of NHSRC**

i. NHSRC is the technical secretariat for MoHFW to receive proposals for innovative medical devices and undertake research for information gathering regarding usability, post market surveillance data, user feedback from states

implementing the technology, clinical effectiveness and safety parameters, spare management etc.

ii. To organize meetings/ workshops/ roundtable conferences for supporting States/UTs in technology assessment and its adoption.

iii. To formulate field assessment protocol in consultation with SHSRC nominated for the pilot trial.

iv. Organize appraisal by the central committee for shortlisting of innovations for adoption and diffusion in the health system.

v. To facilitate showcasing of shortlisted innovative health products in the annual National Summit on Good, Replicable Practices & Innovations in Public Healthcare Systems in India.

vi. Collate the HTAIn-DHR recommended technologies and other technologies related to healthcare having field data validated by ICMR and segregate HTA studies having adequate field data and studies not having adequate field data.

vii. NHSRC (HCT Division) will analyze the HTA report for review of evidence generated by HTA on clinical validation, sensitivity, specificity, NPV, PPV and limit of detection (LOD). The HTA study report should clearly bring out the economic evaluation outcome indicators like ICER and life years gained/QUALY/DALYs.

viii. NHSRC in collaboration with ICMR-DHR will develop the implementation protocol, operation and quality assurance framework, programmatic and budgetary impact analysis of the intervention and monitoring and evaluation framework.

41. **Role of SHSRC:** SHSRCs are mandated to undertake research and field evaluations to generate evidence for informed decision making and manage knowledge, introducing new ideas, best practices, and innovations into the State health ecosystem. Their effective functioning depends on adequate financial, technical, and administrative support. With evolving health priorities, SHSRCs now play an expanded role, including technical assistance for implementation and operational research under State NHM.

42. The field usability trial studies will be undertaken jointly by SHSRC in collaboration with nearby ICMR research centre. The list of ICMR- Research centres is placed as **Appendix 'C'**

43. A single window vertical for appraisal of mature technology (TRL 8/9) has been constituted at MoHFW under the chairmanship of JS(Policy). The central appraisal committee (CAC) helps in providing oversight, handholding support to the startups, integrating their technologies into the existing healthcare systems & appraise/ reviewing emerging technologies.

44. The composition of the '**Central Appraisal Committee'** at MoHFW is as follows:

Composition	Email Id	Remarks
Joint Secretary (Policy), MoHFW	jsadmn-mohfw@gov.in	Chairperson
Executive Director, NHSRC	ed-secretariat@nhsrcindia.org	Member
Nominee from ICMR/ DHR	secy-dhr@gov.in secy-dg@icmr.gov.in	Member
Nominee from NITI Aayog	ceo-niti@gov.in	Member
Nominee from CDSCO/ DCGI	dci@nic.in,	Member
Nominee from BIS	mhd.bis@nic.in	Member
Advisor, Healthcare Technology, NHSRC	hct@nhsrcindia.org	Member Secretary

45. The central appraisal committee (CAC) will appraise the innovative health products based on its potential public health impact, ease of use, acceptability, feasibility, clinical safety & efficacy, cost-effectiveness, scalability and availability in the Government e-Market place (GeM)/Local market. The scoring sheet for appraisal is placed as **Appendix 'D'.**

46. The shortlisted innovative health products will either require further field trials/user trials or direct uptake/adoption in the public health system, based on the programmatic need and cost-effectiveness. Innovative health products when found not undergone HTA will be recommended for HTA study by HTAIn, DHR-ICMR.

47. **National Healthcare Innovation Portal (NHInP)** serves as an online submission window for practitioners and innovators to submit their proposals. The web page is so designed that innovator/practitioners fill the mandatory fields including qualifying criteria. The web page enables submission of essential documents/reports/pictures and any other form of evidence online.

48. States/UTs governments have the option for submission of field validated innovative devices with evidence on improved patient outcome directly on the NHInP.

The steps for submitting such innovations to NHInP is as follows:

(a) Open the National Healthcare Innovation Portal (https://nhinp.org/) on any web browser.

(b) Scroll on 'Submit new innovation' and click on 'Health Product' to submit the innovation health product category.

(c) Click on 'New Registration' tab from the side menu and fill desired information.

(d) On clicking the 'Submit Tab' a verification OTP is sent on the registered email and mobile number.

(e) Authenticate by submitting the OTP to proceed ahead.

(f) Enter the innovation details with all supporting documents and upload the corresponding document.

(g) Successful submission will be acknowledged by the system with a confirmation mail and message in the mobile with a unique registration ID.

49. MedTech Mitra (https://medtechmitra.icmr.org.in) was launched on 25 December 2023 jointly by Indian Council of Medical Research (ICMR) and Central Drugs Standard Control Organization (CDSCO) under the guidance of NITI Aayog, it aims to empower MedTech innovators and advance healthcare solutions by providing crucial support for clinical evaluation, regulatory facilitation, and the uptake of new products.

50. MedTech Mitra portal has the provision for submission of innovative health technologies by the innovator/start-up which is then appraised by the Medical Device and Diagnostics Mission Secretariat (MDMS), ICMR. The MDMS under the

Division of Development Research at ICMR HQs, foster development of affordable and accessible indigenous medical devices/ In-vitro diagnostics.

51. It is designed to provide strategic handholding support to MedTech innovators with assessing clinical viability, regulatory facilitation, and adopting new products. An applicant innovator / startup fills in online details of the product and stage of its development, and requests guidance. The various stages where the expert bodies (CDSCO, from product inception to maturity) facilitate the development of the technical readiness level of a health product and cross the valley of death is depicted below:

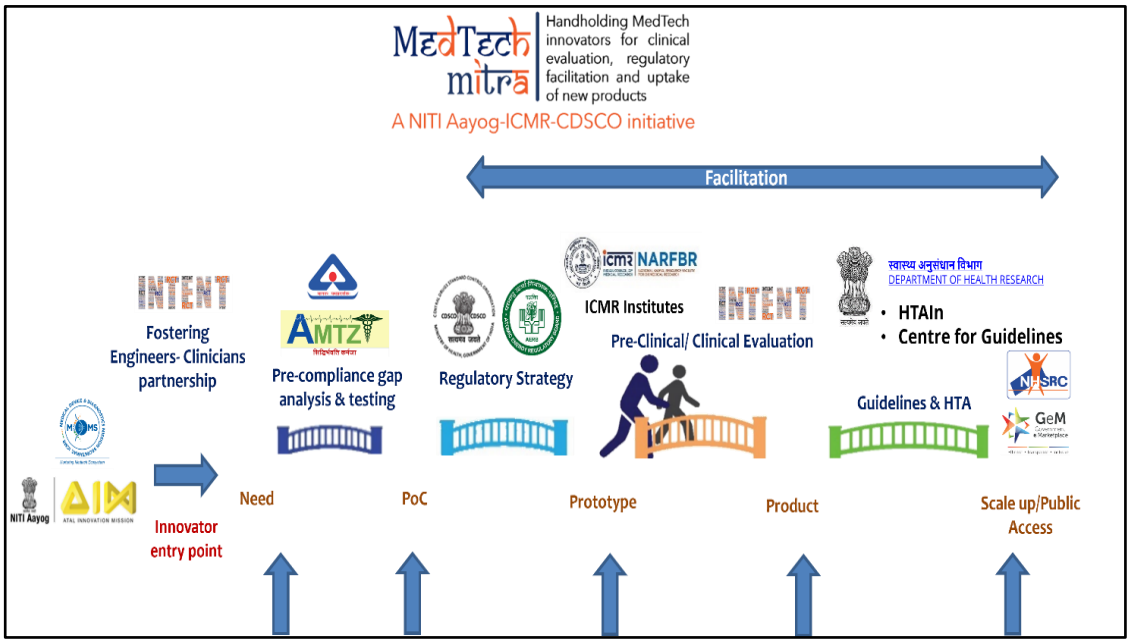

Figure: Handholding support provided to the innovator at various stages of technological readiness level (TRL)

52. The technologies having adequate field data backed up by the complimentary HTA report and user's feedback will be presented to the central committee for adoption and diffusion in primary healthcare settings.

53. For technologies where field data is inadequate or sample size studied in HTA report is inconclusive, NHSRC will undertake usability field trials of medical devices and IVDs where license are available from CDSCO with the support of ICMR- DHR and SHSRC.

Diffusion and Adoption of Product Innovation

54. The innovative health products recommended by Department of Health Research, ICMR for adoption will be apprised by the central appraisal committee (CAC) for the reviewing the available evidence and the relevance of the field data used in the study. This will be done subsequent to joint assessment by NHSRC HCT Division and DHR,ICMR.

55. CAC members will score the innovative technologies independently as recommended for further field trial/HTA study. A score of 10 will be considered as shortlisted innovation for uptake. The scoring sheet is placed as **Appendix 'D'**.

56. Intellectual Property Rights (IPR) play a critical role in encouraging innovation while ensuring public health interests are safeguarded. For innovative health technologies considered for adoption and diffusion in the public health system, the ownership of intellectual property, including patents, copyrights, design rights, and proprietary software, shall remain with the innovator or rightful owner, unless otherwise specified through a mutually agreed formal arrangement.

57. States/UTs will be financially supported to undertake the implementation research in alignment with the MoHFW approved Implementation Research-Health Systems Strengthening (IR-HSS) framework in collaboration with NHSRC.

58. The field usability trial and development of technical specifications will be completed preferably within six months. The field usability report along with the technical specifications will be sent to MoHFW for approval.

59. Technologies recommended by MedTech Mitra, DHR validated innovations (HTA completed studies), MoHFW (PDs) and independent NHInP submission will be done by NHSRC, and the products will be reviewed by the Central Appraisal Committee (CAC), as above. The convergence & process workflow for undertaking user trial in a schematic flowchart is placed as **Appendix 'E'.**

Appendix A

LIST OF SHSRC IN STATES/UTS

S. No	Name of States	SHSRC Address	Contact Details
1	Maharashtra	564, Raja Bahadur Mil Road, Railway Officers Colony, Sangamwadi, Pune, 4111001	Phone No. : 020-26057510, Email ID:shsrc.gom@gmail.com
2	Chhattisgarh	State Health Resource Centre Chhattisgarh, Bijli Office Chowk, Kalibadi, Raipur, Chhattisgarh, India.492001	Phone No. : 0771-4247444 Email ID: shrc.cg@gmail.com
3	Haryana	State Health resource Centre, Haryana, SIHFW Campus, Opposite Hansraj Public School, Sector 6, Panchkula, Haryana, 134109	Email ID: edhshrc@gmail.com
4	Kerala	State Health Systems Resorce Centre, KSIHFW, Thycaud, Thiruvananthapuram, Kerala, PIN 695 014	Phone No.:+91-471-2323223, 2323213 Email ID: shsrckerala@gmail.com

5	Madhya Pradesh	SHRC, Atal Bihari Vajpayee Institute of Good Governance and Policy Analysis, Sushasan Bhavan, Bhadbhada Chouraha, T.T. Nagar, Bhopal- 462003	Phone No. : 0755-2770765 Email: aiggpa@mp.gov.in Website: www.aiggpa.mp.gov.in
6	Tamil Nadu	359, Anna Salai, 5th Floor, DMS Annex Building, DMS Complex, Teynampet, Chennai 600006	Phone No. : 044-29510300 Email: rchpcni@nic.in Website: www.nhm.tn.gov.in
7	Karnataka	SHSRC, Arogya Soudha, 1st Floor, East Wing, Magadi Road, Bengaluru-5600023	Email: pakarshsrc@gmail.com Website: www.kshsrc.org
8	Odisha	Annex Building of SIHFW, Unit 8, Nayapalli, Bhubaneshwar 751012	Phone No. : 0674-2392480 Email: tlshsrcnhm@gmail.com Website: www.nhmorrisa.gov.in
9	Punjab	SHSRC, NHM Punjab, 5th Floor, Prayaas Building, sector 38-B, Chandigarh 160036	Email ID: ed.shsrc.nhm@punjab.gov.in

10	Gujarat	SHSRC, 1st Floor, NHM Bhavan, Civil Hospital Campus, opp. Pathikashram, Sector 12 B , Gandhinagar 382012	Email ID: shsrc.gujarat@gmail.com
11	West Bengal	SPSRC Branch, 4th Floor, 'B' wing, Swasthya Bhawan, GN-29, Sector-V, Salt Lake City, Kolkata 700091	Phone No. : 033233300609/0655/0633/0136 Email: spsrcwb2019@gmail.com, spsrc.ppp@gmail.com Website: www.wbhealth.gov.in

Appendix B

FIELD ASSESSMENT & FEEDBACK REPORT

State: ……..

Facility Name: ……..

Name of the In-Charge: ……..

Contact details: ……..

1. Respondent Profile & Service Context

- **Role:** ☐ Frontline Worker (ASHA/ANM) ☐ Staff Nurse ☐ Medical Officer ☐ Program Manager ☐ Public Health Specialist ☐ Community User ☐ Other: _____
- **Health Facility/Service Setting:** ☐ AAM-Sub-Center ☐ AAM-PHC ☐ CHC ☐ District Hospital ☐ Tertiary Facility ☐ Community/Household ☐ Mobile/Outreach Camp
- **Population Type Served:** ☐ Urban ☐ Rural ☐ Tribal ☐ High-risk ☐ Hard-to-reach
- **Average daily beneficiary load for relevant services:** _____

2. Technology Description & Intended Public Health Use

- **Technology Name/Model:** _____
- **Primary Public Health Function:**
    - ☐ Screening
    - ☐ Diagnosis
    - ☐ Treatment/Management
    - ☐ Monitoring/Surveillance
    - ☐ Supply Chain/Logistics

- **Level of Care Targeted:** ☐ Community ☐ Primary ☐ Secondary
- **Was the technology appropriate for the local health system capacity?** ☐ Yes ☐ Partially ☐ No

3. Accessibility, Acceptability & Equity

- **Ease of Adoption by Health Staff:** ☐ Very Easy ☐ Easy ☐ Moderate ☐ Difficult
- **Ease of Use for Beneficiaries:** ☐ Very High ☐ High ☐ Moderate ☐ Low
- **Did beneficiaries understand the purpose of the technology?** ☐ Yes ☐ Partially ☐ No
- **Language/Usability Barriers:** ☐ None ☐ Minor ☐ Significant
- **Did the technology improve access among vulnerable populations (women, elderly, remote communities)?** ☐ Yes ☐ Somewhat ☐ No

4. Impact on Service Delivery & Health Outcomes

- **Did the technology reduce waiting time or improve service efficiency?** ☐ Yes, significantly ☐ Somewhat ☐ No
- **Improvement in early detection/screening coverage:** ☐ High ☐ Moderate ☐ Low ☐ None ☐ Not Applicable
- **Improvement in treatment adherence or follow-up:** ☐ High ☐ Moderate ☐ Low ☐ None ☐ Not Applicable
- **Impact on data quality/reporting:** ☐ Significant improvement ☐ Moderate ☐ No change ☐ Worsened
- **Contribution to public health outcomes (e.g., reduced disease burden, better monitoring):**
    - ☐ Strong impact
    - ☐ Moderate impact
    - ☐ Minimal impact
    - ☐ No observable impact

5. Integration With Health Systems

- **Was the technology compatible with existing workflows?** ☐ Fully ☐ Partially ☐ Not at all
- **Interoperability with HMIS/other digital systems:** ☐ Full ☐ Partial ☐ None ☐ Not Required
- **Human resource readiness to operate the technology:** ☐ Adequate ☐ Needs strengthening ☐ Inadequate
- **Supply chain/logistics feasibility:** ☐ Feasible ☐ Challenging ☐ Not feasible
- **Maintenance & sustainability requirements manageable?** ☐ Yes ☐ Somewhat ☐ No

6. Cost, Efficiency & Sustainability

- **Operational cost per user/service:** ☐ Very Low ☐ Low ☐ Moderate ☐ High ☐ Very High
- **Resource savings achieved (time, manpower, consumables):** ☐ Significant ☐ Moderate ☐ Minimal ☐ None
- **Is continued scaling financially viable for the program?** ☐ Yes ☐ Partially ☐ No
- **Community/health worker willingness to continue use without external support:** ☐ High ☐ Moderate ☐ Low

7. Safety, Ethics & Community Trust

- **Any privacy/data protection concerns:** ☐ None ☐ Minor ☐ Major
- **Was informed consent clearly understood and obtained?** ☐ Yes ☐ Partially ☐ No
- **Any adverse events or safety concerns reported?** ☐ No ☐ Yes (describe): _____
- **Community trust in technology:** ☐ Very High ☐ High ☐ Moderate ☐ Low

8. Public Health Recommendations & Insights

- **Key public health benefits/impact observed:**

  _____

- **Challenges affecting population-level impact:**

  _____

- **Suggestions to improve equity, uptake, or community acceptance:**

  _____

- **Any additional programmatic/public health insights:**

  _____

9. Clinical Effectiveness

Accuracy	True Negative	False positive	True positive	False negative

10. Regulatory Compliance & Availability

- CDSCO License ☐Available ☐ Not available
- Availability in GeM/ Local market ☐Available ☐ Not available
- Post market surveillance report ☐Available ☐ Not available
- Software as Medical Device CDSCO license (where applicable) ☐Available ☐ Not available

11. Usability Data

- Ease of use: ☐ Very Easy ☐ Easy ☐ Moderate ☐ Difficult
- Durability: ☐Yes ☐ No
- Ease of Maintenance: ☐Very Easy ☐ Easy ☐ Moderate ☐ Difficult
- Local access to technical support: ☐Available ☐ Not available
- Training of human resource: ☐Available ☐ Not available

Appendix C

LIST OF ICMR RESEARCH CENTRE

S.No	ICMR Institute	Director Name	Designation	Email Address	Ph. No
1	ICMR-National JALMA Institute for Leprosy & Other Mycobacterial Diseases, Agra	Dr. Anup Anvikar	Scientist G & Director in-charge	director-jalma@icmr.gov.in	+91-562-2331751
2	ICMR-National Institute of Occupational Health, Ahmedabad	Dr. Bhavesh Modi	Scientist G & Director	director-nioh@gov.in	+91-79-22688711, 22686142
3	ICMR-National Centre for Disease Informatics and Research, Bengaluru	Dr. Prashant Mathur	Scientist G & Director	director-ncdir@icmr.gov.in	+91-80-22176400
4	ICMR-Bhopal Memorial Hospital & Research Center, Bhopal	Dr. Manisha Srivastava	Scientist G & Director-in-charge	directoroffice-bmhrc@icmr.gov.in; bmhrcbhopal@gmail.com	+91-9425017316
5	ICMR-National Institute for Research in Environmental Health, Bhopal	Dr. Rajnarayan Tiwari	Scientist G & Director	tiwari.rr@gov.in	+91-9479787480
6	ICMR-National Institute of Epidemiology, Chennai	Dr. Manoj Vasant Murhekar	Scientist G & Director	director.nie@icmr.gov.in	+91-44-26136204
7	ICMR-National Institute for Research in Tuberculosis, Chennai	Dr. Manoj Vasant Murhekar	Scientist G & Additional Charge of Director	directornirt@nirt.res.in	+91-44-28369600

8	ICMR-National Institute for Research in Tribal Health, Jabalpur	Dr. Rajnarayan Tiwari	Scientist G & Additional Charge of Director	director@nirth.res.in	+91-761-2370800; +91-9968074889
9	ICMR-National Institute of Nutrition, Hyderabad	Dr. Bharti Kulkarni	Scientist G & Director	director.nin@icmr.gov.in; kulkarni.bharati@icmr.gov.in	+91-40-27197297
10	ICMR-National Animal Resource Facility for Biomedical Research, Hyderabad	Prof. Mukesh Kumar Gupta	Scientist G & Director	director-narfbr@icmr.gov.in	+91-40-27197201
11	ICMR-National Institute of Bacterial Infections, Kolkata	Dr. Santasabuj Das	Scientist G & Director	director-niced@icmr.gov.in	+91-33-23633373, 23701176
12	ICMR-National Institute for Research in Reproductive & Child Health, Mumbai	Dr. Geetanjali Sachdeva	Scientist G & Director	dir@nirrh.res.in	+91-22-24192002
13	ICMR-National Institute of Immunohaematology, Mumbai	Dr. Manisha Madkaikar	Scientist G & Director	director@niih.org.in; directorniih@gmail.com	+91-22-24132928, 24138518
14	ICMR-National Institute of Malaria Research, New Delhi	Dr. Anup Anvikar	Scientist G & Director	anvikar.anup.nimr@gov.in; director-nimr@icmr.gov.in	+91-11-25307103-105
15	ICMR-National Institute of Child Health and Development Research, New Delhi	Dr. Sanghamitra Pati	Additional Director & Director-in-charge	director-nip@icmr.gov.in	+91-11-26198402
16	ICMR-National Institute for Research	Dr. Mona Duggal	Scientist-G & Director	nims.director@icmr.gov.in	+91-11-26588803

	in Digital Health and Data Science, New Delhi				
17	ICMR-National Institute of Cancer Prevention and Research, Noida	Dr. Shalini Singh	Scientist G & Director	director.nicpr@icmr.gov.in	+91-120-2578837
18	ICMR-Rajendra Memorial Research Institute of Medical Sciences, Patna	Dr. Krishna Pandey	Scientist G & Director	pandey.krishna@icmr.gov.in; director-rmri@icmr.gov.in	+91-612-2631565
19	ICMR-Vector Control Research Centre, Puducherry	Dr. Manju Rahi	Scientist G & Director	director.vcrc@icmr.gov.in	+91-413-2272396
20	ICMR-National Institute of Virology, Pune	Dr. Naveen Kumar	Scientist G & Director	director.niv@icmr.gov.in	+91-20-25880982
21	ICMR-National Institute of Translational Virology and AIDS Research, Pune	Dr. Sheela Godbole	Scientist G & Director	sgodbole@nariindia.org; director@nariindia.org	+91-20-27331329, 23771200
22	ICMR-National Institute of Traditional Medicine, Belagavi	Dr. Subarna Roy	Scientist G & Director	roys@icmr.gov.in	+91-831-475477, 2475478
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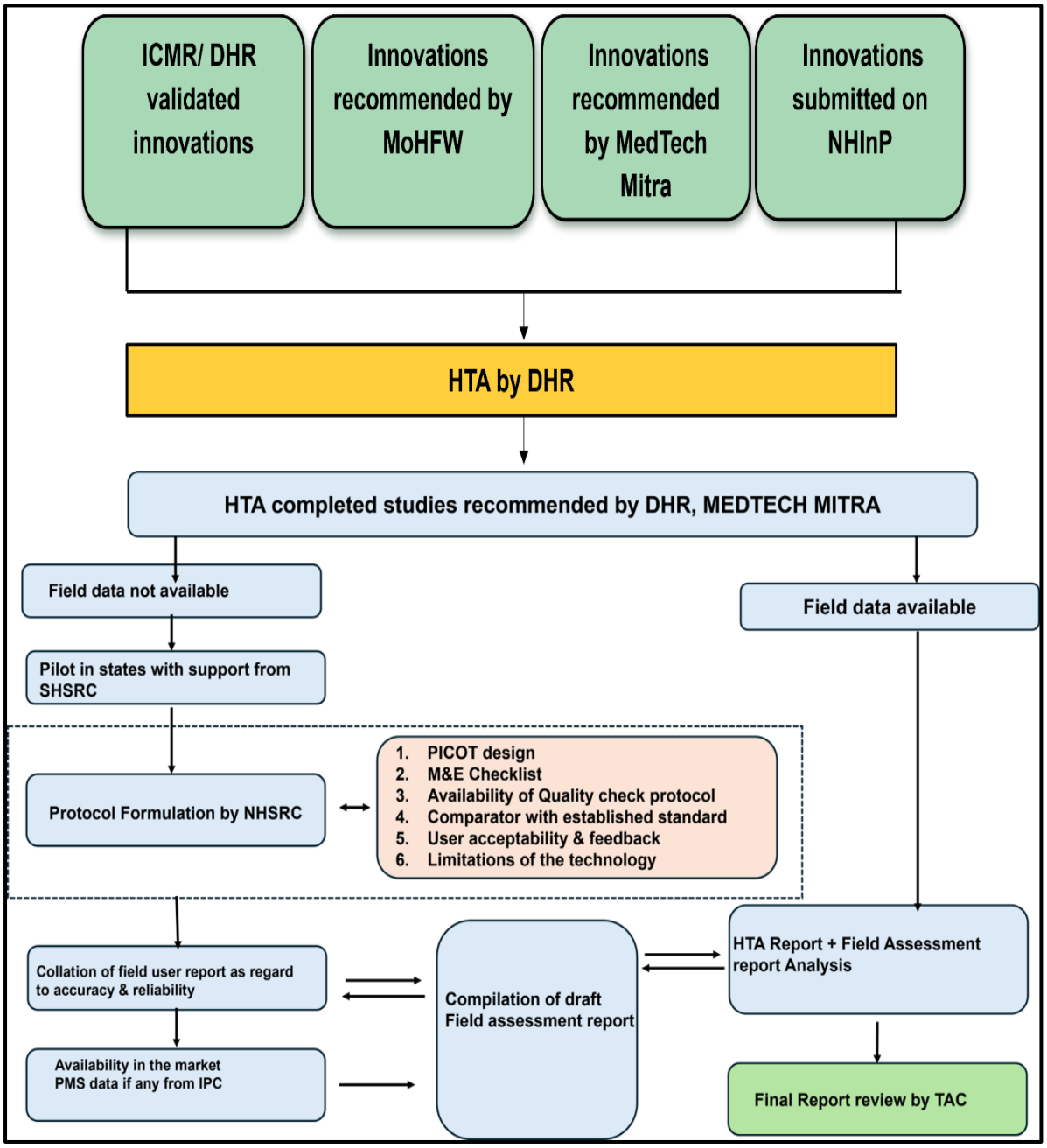
Appendix D

SCORING SHEET

Sr. No.	Question	Criteria	Max Score	Score Obtained
1	Does the technology address a well-defined and substantial public health problem	Yes	2	
		No	0	
2	Has the product undergone HTA backed up by adequate field data	Yes	2	
		No	0	
3	Is the product recommended by HTA to be clinically effective and cost effective	Yes	2	
		No	0	
4	Regulatory Compliance obtained CDSCO, AERB)	Yes	2	
		No	0	
5	Availability in GeM	Available	1	
		Not available	0	
6	Is the field user trial report complementary	Yes	1	
		No	0	
Total Score			**10**	
	Scoring Grade	10	Recommended for Uptake	
		7-9	Recommended for HTA/ Field useability trial	
		0-6	Not recommended	

Appendix – E

CONVERGENCE – NATIONAL HEALTH INNOVATIONS SUBMITTED ON DIFFERENT PORTALS



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5.	Dr. Nidhi Nigam	Sr. Consultant, MoHFW

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