

Call for Proposal for

“Strategic Prioritization of Medical Technologies for the “MAHA MedTech Mission”

Mission for Advancement in High-Impact Areas (MAHA) - MedTech Mission

Anusandhan National Research Foundation (ANRF)

In collaboration with Indian Council of Medical Research and Gates Foundation.

Vision: Equitable access to high quality, affordable and innovative medical technologies to improve healthcare

Objectives:

- A. To support development and commercialization of indigenous, high-quality, affordable and innovative medical technologies with established proof-of-concept
- B. To foster indigenous development of high priority, high-cost, imported medical technologies to promote self-reliance and adaptation for Indian population

The primary focus of the mission will be supporting the development and commercialization of high-quality, affordable, and innovative medical technologies. Additionally, efforts will be directed towards fostering indigenous development of high priority, high-cost, imported medical technologies to promote self-reliance and adaptation for Indian population (for low-resource settings). Further, the mission may strengthen the existing infrastructure for medical device development at the government supported Institutions/ CoEs as special funds in case some technologies are ready for production.

Scheme Overview

Total duration of the Mission: 5 Years

Total Outlay: ₹750 Crores

Funding per Project: ₹5 Cr to ₹25 Cr; in exceptional cases upto ₹50 Cr (Milestone linked disbursement). Each project may be split into sub-projects with objectives specific for any of the three stages of product development viz., "Bio engineering", "preclinical/clinical development" and "industry/startup support" to be aligned with appropriate funding sources (ANRF, ICMR, GF). The participation is open to

Industry/MSME/Start-ups with T and C on a case-to-case basis as decided by the Technical Advisory Group for cost-sharing (eg. BIRAC guidelines, generally with a minimum of 30% private cost-share), IP owned by grantee, with clauses for affordable access.

Project Duration: 2-5 years depending on the current and proposed technology readiness level

Total Projects to be funded: Approximately 50 in 5 years

Technology Areas: Innovative medical devices and IVD (In vitro diagnostics) including High-end Frontier Technologies (Deep Tech like Imaging, Radiotherapy equipment, Robotics, minimal invasive technologies, implants, AI/ML enabled platforms & devices etc.) aligned with National Health Missions/Priorities/ICMR Priority List.

Therapeutics and vaccines are not an immediate focus of the current call and may be focused upon the subsequent calls.

Eligibility for the CFP:

1. Innovative technologies with established proof-of-concept (TRL-3 or above).
2. Indigeneous, high-quality, technologies targeting replacement of high-cost imported health technologies with at least 3- to 5- fold cost reduction.

Inter-Institutional (Bio-Medical and Engineering Institutes, Laboratories, Hospitals), Industry-Academia collaborations (Academia, Start-ups registered with DPIIT, MSMEs registered with Udyam, Industries with valid DSIR certification or proven track record in biomedical product development or production) are strongly encouraged. Each partner is allocated well-defined sub- deliverables and timeline as per the committed milestones.

Target Outcome

- A. Innovative/affordable MedTech Products to commercialization, with quality standards fulfilling international regulatory requirements (WHO pre-qualification, CE, US-FDA)

B. Establishment and strengthening of a Culture of collaboration between academia (engineering & medical) and industry (Public Private Partnership) for MedTech.

Information to be provided for CFP (Concept Note) – Please Refer Annexure 1

Submission Instructions

CFP will be received through www.anrfonline.in and evaluated through the evaluation procedures of ANRF, by following the implementation strategies identified for this CFP.

Timelines: The opening of online submission will be updated soon.

| | |
|-------------------------------------------|---------------------------------|
| Activities | |
| CFP for Concept Note | 15 th September 2025 |
| Closure of the CFP for Concept Note | 31 st October 2025 |
| Release of invitation for full proposal | 1 st December 2025 |
| Closure of CFP for full proposal | 31 st December 2025 |
| Tentative date of announcement of results | First week of February 2026 |

Disclaimer

This CFP (Concept Note) is issued by the Anusandhan National Research Foundation (ANRF), in collaboration with Indian Council of Medical Research (ICMR), Department of Health Research, Government of India, Gates Foundation to gather inputs from interested entities for the MAHA MedTech Mission.

- It is a preparatory, non-binding exercise aimed at priority setting and screening of potential technologies. Some of these will be further evaluated for financial support following full proposal submission.
- Submissions are voluntary, non-mandatory, and will be treated confidentially.
- This (Concept Note) does not constitute an offer, commitment, or entitlement and creates no obligations on the Government of India and Gates Foundation.
- The ANRF reserves the right to modify or withdraw the (Concept Note) at any time without notice.
- Participation does not guarantee future engagement or funding, which will follow formal evaluation processes under the Mission's operational guidelines.

For further details, please contact:

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Anusandhan National Research Foundation

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Suggested changes for information to be provided for CFP (Concept Note)

Section A: Project/Technology Overview

1. Name and intended use of the Product/Technology

Input box for characters - (max 20 words)

2. Principal Investigator (PI) affiliation

Dropdown with the following options: (Select all applicable)

- Academic and research institutions
- Startups registered with DPIIT
- MSMEs registered with Udyam
- Hospitals/Medical College Hospitals
- Pharma/MedTech companies
- Others

3. Does your organization hold a valid DSIR (Department of Scientific and Industrial Research) certification? Note: DSIR certification is encouraged but it is not mandatory

Dropdown with the following options: (Select only one as applicable)

- Yes
- No

4. Project Technology Type:

Dropdown with the following options: (Select only one as applicable)

- Medical Equipment (e.g., Diagnostic, Therapeutic and Advanced Systems)
- Implants and Assistive Devices
- Medical Consumables
- In Vitro Diagnostics
- Software as a Medical Device
- Others

5. Does the medical device/technology have a predicate?

Dropdown with the following two options: (Select only one as applicable)

- Yes
- No

6. TRL Stage (**Please see Annexure II**)

Dropdown with the following 7 options: (Select only one as applicable)

- TRL 3: Early-stage proof of concept
- TRL 4: Advanced proof of concept
- TRL 5: Test-batch Evaluation
- TRL 6: Pilot CI / CPE studies / Clinical evaluation for predicate-based devices
- TRL 7: Pivotal CI / CPE studies / Clinical evaluation for predicate-based devices
- TRL 8: Pre-commercialization
- TRL 9: Commercialization and Post Market Studies

7. Select the risk classification of your product or technology, as defined by CDSCO

Dropdown with the following 4 options: (Select only one as applicable)

- Class A (Low-Risk)
- Class B (Low-Moderate Risk)
- Class C (Moderate-High Risk)
- Class D (High Risk)

8. IP Status & Ownership

Dropdown with the following options: (Select all options that are applicable)

- Patent filed in India
- Patent filed in countries outside India
- Patent granted in India
- Patent granted in countries outside India
- Freedom to operate study conducted
- Core IP licensed from third party
- **None of the above**

9. Regulatory status (CDSCO)

Dropdown with the following options: (Select all options that are applicable)

- No submission yet made to CDSCO
- Application submitted for Test License (Form MD-12/MD-16)
- Permission obtained for Test License (Form MD-13/MD-17)
- Application submitted for Clinical Investigation (Form MD-22) or for Import/Manufacture of Investigational Medical Device (Form MD-26)
- Permission granted for Clinical Investigation (Form MD-23) or for Import/Manufacture of Investigational Medical Device (Form MD- 27)
- Application submitted for Manufacturing or Import License for Commercialization (Form MD-3/MD-4/MD-7/MD-8/MD-14)
- Permission granted for Manufacturing or Import License for Commercialization (Form MD-5/MD-6/MD-9/MD-10/MD-15)

10. Provide the Collaborating Team Details, if any

Optional question.

Provide a two-field/column row to answer:

1. Entity Name – *Input box for words (max 20 words)*
2. Affiliation Type *Provide dropdown (select all as applicable)*

Drop-down values for field 2:

- Academic and research institutions
- Startups registered with DPIIT
- MSMEs registered with Udyam
- Hospitals/Medical College Hospitals
- Pharma/MedTech companies
- Others

Provide max of five such rows here.

11. Disease Area/National Health Priority Alignment -

Dropdown with the following options: (Select all options that are applicable)

- Communicable Diseases - *If selected, open second level dropdown*
- Non-communicable Diseases - *If selected, open second level dropdown*

- Woman and Child Health and Nutrition - *If selected, open second level dropdown*
- Primary Health Care
- Acute Ambulatory Care
- Oral Health
- AI in Health Care
- Cell and Gene Therapy (Rare genetic diseases)

Provide the following dropdown for communicable diseases – (select all applicable)

- Tuberculosis
- Vector-borne disease
- AMR
- Neglected Tropical Diseases
- Epidemic and Pandemic Readiness
- Other communicable diseases

Provide the following dropdown for non-communicable diseases – (select all applicable)

- Cancer
- Mental Health
- Ambulatory care
- Other non-communicable diseases

Provide the following dropdown for Woman and Child Health and Nutrition – (select all applicable)

- Anemia
- Childhood malnutrition
- Neonatal Care (including neonatal respiratory distress, neonatal support technologies and broader neonatal care continuum)
- Maternal Health (including antenatal, intrapartum and postpartum care)
- Women's Health

12. Provide a brief overview of your product/technology. What is the intended purpose of the device? Please briefly explain the technology. What are the key features of this product?

Input box for words - (max 150 words)

13. What is the rationale for your project? Describe how the product/technology addresses critical barriers in technical capability or healthcare delivery and its relevance to local, national or international context.

Input box for words - (max 100 words)

14. What is innovative/novel about your proposed solution? Select the dimensions in which the product / technology to be developed in this project is superior to the current standard of care and please describe why.

Dropdown with the following options: (Select all options that are applicable, Upto Maximum of 3)

- Higher sensitivity and specificity
- Better patient outcomes vs standard of care
- Easier to use / better ergonomics
- Better tolerability and safety
- More cost effective
- Portable or miniaturized
- Higher speed / lower latency
- Lower power consumption
- Others

Input box for words - (Max 150 words): Mandatory Box along with the dropdown above.

15. Market opportunity

15.1 Please describe the geographies where you believe your product can be commercialized

Input box for words - (max 50 words)

15.2 Number of patients/consumers **in India** that can benefit from the project output (lakhs/year)

Input box for numbers – (No Negative entries, Set a Positive Limit)

15.3 TAM: Total Addressable Market **in India** (INR Cr/year)

Input box for numbers – (No Negative entries, Set a Positive Limit)

16. Projected Sales Price per unit at Commercialization (in INR)

Input box for numbers – (No Negative entries, Set a Positive Limit)

17. Expected Impact on Public health (please describe who the intended users are and how this product/technology will impact national health priorities)

Input box for words – (Max 150 words)

18. Potential to reduce import dependence, if any (please provide details of the imported device that this product can replace including the HSN code, cost, market description and size)

Input box for words - (Max 100 words)

19. Does the product require any critical components that are import-dependent? If so, please provide details of the top 5 most critical or high-cost components

Provide three-field row:

1. Name of imported component – *Input box for words (Max 20 words)*

2. HSN code of component – *Input box for numbers (No negatives, Max – Digit limit)*

3. Cost of imported component (INR) – *Input box for numbers (No negatives, Max – Digit limits)*

Provide maximum of five rows, all optional

20. Describe the strength and expertise of the project team, including the Principal Investigator (PI) and key team members. Highlight products that the team has successfully commercialized, and the collective amount of funding that has been raised from PE/VC investors.

Input box for words (max 150 words)

21. Describe the documents or evidence available to substantiate your current TRL stage

Input box for words - (Max 50 words)

22. Upload supporting documentation that validates your declared TRL stage

Upload button to upload a document (Max size 20MB, 1 file only allowed).

Section B: Prior Financial Support

23. Provide the Total grant/support/investment/self-funds committed to the project to date (in INR Cr)

Input box for numbers – (No Negative entries, Set a Positive Limit)

24. Provide the Total grant/support/investment/self-funds utilized to achieve current TRL (in INR Cr)

Input box for numbers – (No Negative entries, Set a Positive Limit)

25. Provide the following details of the Top 5 major funding sources

Provide a two field/column row to answer:

1. Funding source (e.g. Self-funded, Industry, Start-up, Investors, DBT, DST, ICMR, DoP, BIRAC, MeitY, etc.) – *Input box for words (Max 20 words)*

2. Funding amount received (INR Cr) – *Input box for numbers – (No Negative entries, Set a Positive Limit)*

Provide Max of 5 rows.

First row is mandatory, others after first row (max 4 more) are optional.

Section C: Development Status

26. Provide details of Verifiable Outputs or achievements from your project to date (e.g., published data, patent/IP, IEC/IAEC approvals, RCGM approval, regulatory submission- CDSCO approvals)

Input box for words - (max 150 words)

27. Describe the key technical, regulatory, or scale-up barriers encountered so far in your project

Input box for words - (max 150 words)

28. Outline the critical next milestones planned for your project and the major challenges anticipated in achieving them

Input box for words - (max 150 words)

Section D: Support Needed from MAHA MedTech Mission

29. Indicate the total funding required over the 5-year tenure of MAHA MedTech Mission (INR Cr)

Input box for numbers – (No Negative entries, Set a Positive Limit)

30. Indicate how funding requirements are split across the three key stages of development (INR Cr values for each stage):

- Stage I – Proof of Concept (PoC)
- Stage II – Validation (Preclinical/Clinical Development)
- Stage III – Commercialization Support

30.1 Funding requirement for Stage I – Proof of Concept (PoC) (INR Cr)

Input box for numbers – (No Negative entries, Set a Positive Limit)

30.2 Funding requirement for Stage II – Validation (Preclinical/Clinical Development) (INR Cr)

Input box for numbers – (No Negative entries, Set a Positive Limit)

30.3 Funding requirement for Stage III – Commercialization Support (INR Cr)

Input box for numbers – (No Negative entries, Set a Positive Limit)

(Ensure to put a check that: Sum of values in question 30 should equal the answered value in question 29.

Give an alert to the user to input again if the check is not passed)

Technology Readiness Levels (TRLs) for ‘Investigational Medical Devices’ and ‘New In-vitro Diagnostic Medical Device’ (which do not have a predicate*)

| Stage | TRL | TRL achieved once milestones complete |
|--------------------------------------------------|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ideation | TRL 1 | Problem statement/unmet need defined and documented. Selection of the idea for a device for the intended application |
| Proof of Principle | TRL 2 | Preliminary device design selected and technical product specifications defined. Applicable technical standards identified. Freedom to operate (FTO) search completed & market analysis done. Suppliers and design partners identified. Establish preliminary “Intended Use Statement”. |
| Early-stage Proof of Concept | TRL 3 | In-house-prototype designed, In-house analytical performance tested. |
| Advanced Proof of Concept (Design freeze) | TRL 4 | In-house-prototype safety and efficacy analysed, Design finalised after iterations, device class identified, test-quantity and protocol defined, framed Instructions for use (IFU), submission of application for the Test license (MD-12) |
| Test-batch Evaluation | TRL 5 | MD-13 (Test License) obtained. Test-batches manufactured in compliance with schedule V, and evaluated by applying bench testing, simulated testing, analytical performance, stability, in compliance with device-specific standards. Submission of data for undertaking -clinical investigation (CI) of medical device (MD-22)/-clinical performance evaluation (CPE) of In-vitro Diagnostic medical device (MD-24) |
| Pilot CI/CPE studies | TRL 6 | MD-23 (Permission for clinical investigation (CI) of Medical device), / MD-25 (Permission for clinical performance evaluation (CPE) of IVD), obtained. Submission of Safety and efficacy data of Pilot clinical study along with fee to pursue pivotal study. |
| Pivotal CI/CPE studies | TRL 7 | Safety and efficacy data from Pivotal clinical study; Submission of data for permission to manufacture of medical device (MD-26)/IVD (MD- 28) |
| Pre-commercialization | TRL 8 | MD-27 (Mfg Licence for medical device) /MD-29 (Mfg Licence for IVD), MD-29. ISO 13485-compliant manufacturing line established. Packaging and labelling completed. |
| Commercialization and Post Market Studies | TRL 9 | Product launched with Post-Market Surveillance (PMS) system in place. User feedback system operational. |

***(For more details, please refer to MDR 2017, CDSCO and some relevant definitions derived from MDR 2017, CDSCO provided below)**

Technology Readiness Levels (TRLs) for ‘Medical Devices’ and ‘In-vitro Diagnostic Medical Devices’ (having a predicate*)

| Stage | TRL | TRL achieved once milestones complete |
|--------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ideation | TRL 1 | Problem statement/unmet need defined and documented. Selection of the idea for a device for the intended application |
| Proof of Principle | TRL 2 | Preliminary device design selected and technical product specifications defined. Applicable technical standards identified. Freedom to operate (FTO) search completed & market analysis done. Suppliers and design partners identified. Establish preliminary “Intended Use Statement”. |
| Early-stage Proof of Concept | TRL 3 | In-house-prototype designed, In-house analytical performance tested. |
| Advanced Proof of Concept (Design freeze) | TRL 4 | In-house-prototype safety and efficacy analysed, Design finalised after iterations, device class identified, test-quantity and protocol defined, framed Instructions for use (IFU), submission of application for the Test license (MD-12) |
| Test-batch Evaluation | TRL 5 | MD-13 (Test License) obtained. Test-batches manufactured in compliance with schedule V, and evaluated by applying bench testing, simulated testing, analytical performance, stability, in compliance with device-specific standards. |
| Clinical evidence including Substantial - equivalence to the predicate device | TRL 6-7 | Clinical evaluation for Medical Device and Performance evaluation for IVD. Established substantial equivalence to the predicate. Application submitted for Manufacturing license (MD-3 for Medical Devices Class A/B, MD-7 for Medical Devices Class C/D). |
| Pre-commercialization | TRL 8 | Manufacturing license obtained (MD-3 for Medical Devices of Class A/B, MD-7 for Medical Devices of Class C/D). ISO 13485-compliant manufacturing line established. Packaging and labelling completed. |
| Commercialization and Post Market Studies | TRL 9 | Product launched with Post-Market Surveillance (PMS) system in place. User feedback system operational. |

***(For more details, please refer to MDR 2017, CDSCO and some relevant definitions derived from MDR 2017, CDSCO provided below)**

Some relevant definitions derived from MDR 2017:

(For more clarity, please refer to MDR 2017)

1. "Investigational medical device" means a medical device
 - (i) which does not have its predicate device; or
 - (ii) which claims for new intended use or new population or new material or major design change; and is being assessed for safety or performance or effectiveness in a clinical investigation.
2. "New in-vitro diagnostic medical device" means any medical device used for in vitro diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto, including details of technology and procedure required;
3. A device shall be deemed to substantially equivalent in comparison to predicate device, if it has
 - (i) the same intended use and technological characteristics; or
 - (ii) same intended use and different technological characteristics, and demonstrate that the device is as safe and effective as the predicate device.

A claim of substantial equivalence does not mean that the proposed medical device and predicate device are identical. Substantial equivalence shall be established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

Checklist for comparing your device with a predicate

Product Details
Intended Use
Indications Materials
Design Characteristics
Mode of Action
Contraindications
Biocompatibility
Product Specification
Storage
Packaging and Labeling
Advantages
Disadvantages

4. An application for grant of permission to conduct,- a pilot clinical investigation on an investigational medical device as referred to in sub-rule (1) shall be accompanied with a fee as specified in the Second Schedule along with information as specified in the Seventh Schedule. Explanation - For the purposes of these rules, the pilot clinical investigation means clinical investigation to be carried out for the first time in human participants;
5. A pivotal clinical investigation on an investigational medical device shall be made on the basis of data emerging from pilot clinical investigation, accompanied with a fee as specified in the Second Schedule: Provided that no fee shall be payable by any institute, organisation, hospital run or funded by the Central Government or the State Government, as the case may be, for conduct of clinical investigation.

Frequently Asked Questions (FAQs)

Updated as of 7-October 2025

This document provides answers to frequently asked questions (FAQs) regarding the **महा MedTech Mission**. This document will be updated periodically based on queries received, ensuring that all interested entities have access to relevant and up-to-date information.

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Disclaimer:

This FAQ document is intended solely for guidance and informational purposes. In the event of any discrepancy, the **Operational Guidelines of the Mission**, to be formally issued at a later stage, will take precedence and serve as the final authoritative document.

A. Scheme Overview

1. What is the **महा** MedTech Mission?

The Government of India, through the Anusandhan National Research Foundation (ANRF) in collaboration with the Indian Council of Medical Research (ICMR) and the Gates Foundation, has launched the Mission for Advancement in High-Impact Areas (MAHA) MedTech Mission. The Mission has a total budgeted financial outlay of ₹750 crore over 5 years.

This Mission is designed to enable the development and commercialization of high-quality, affordable, and innovative medical technologies. It aims to spur innovation, reduce dependence on high-cost imports, and promote equitable access to high quality, affordable and innovative medical technologies to improve healthcare outcomes.

2. What are the Mission's core objectives?

The mission's objectives are three-fold:

- **Public health impact:** To back technologies that address national priority disease areas and improve access to care.
- **Affordability & access:** To support solutions that materially lower costs compared to imported alternatives.
- **Self-reliance & competitiveness:** To catalyze indigenous development and manufacturing, with stronger industry-academia collaboration to steer India towards self-reliance in MedTech.

3. What should I do if I have queries that are not covered in this FAQ?

If you have additional questions or require further clarification you may reach out to the Mission team at: pk-prasad@anrf.gov.in or mahamedtechmission@gmail.com

B. Applicant Eligibility

4. What kind of entities are eligible to apply?

Applications are open to a wide range of entities, including:

- Academic and research institutions (both public and private)
- Startups (registered with DPIIT)
- MSMEs (registered with Udyam)
- Hospitals/Medical colleges hospitals
- Pharma/MedTech companies
- Other MedTech businesses and non-profits with no restrictions on legal entity (e.g., companies, proprietorships, partnerships, Section 8, trust, and others)

The Lead Applicant must be an entity incorporated or established in India under applicable laws, with majority ownership and beneficial ownership vested in Indian citizens and/or Indian entities and having its principal place of business and key management located in India.

Applicants with DSIR certification will be given preference.

5. Can foreign nationals participate in the Mission?

Foreign nationals (including OCI and PIO) may participate if employed by an eligible institution in India, as a Principal Investigator (PI) with an Indian Co-PI, or as a co-PI with an Indian PI, provided they have sufficient residual official service in India (project duration +1 year).

6. Can multiple organizations submit a joint application?

Yes, the Mission encourages joint applications involving collaborations across institutions. For example:

- **Inter-institutional collaborations:** e.g., collaborations between biomedical and engineering institutes, laboratories, and hospitals
- **Industry-academia collaborations:** e.g., academia working with startups, MSMEs, MedTech companies

Collaborating partners should be listed in the application details. Each partner must be allocated well-defined sub-deliverables with timelines as per the committed milestones.

The Lead Applicant must be an entity incorporated or established in India under applicable laws, with majority ownership and beneficial ownership vested in Indian citizens and/or Indian entities and having its principal place of business and key management located in India. Funding under the scheme will be disbursed only to Indian entities as described above.

The Lead Applicant must be primarily responsible for project milestones.

7. Can projects that have currently or in the past been funded by other government schemes apply?

Yes, the scheme allows any project that has currently or in the past been funded by any government scheme to apply for funding, subject to the condition that funds made available under the scheme are for augmentation and there is no duplication in expenditures booked under the two schemes.

8. Can projects that are applying to DOP PRIP Scheme also apply to महॉ MedTech Mission?

Yes, projects that are eligible for both महॉ MedTech Mission and PRIP are encouraged to apply to both schemes simultaneously.

9. Can the same entity submit more than one application in a call?

There is no restriction on number of applications from an eligible entity.

10. Can the same Principal Investigator (PI) submit more than one application in a call?

An individual can be concurrently involved in at most one project proposal as a PI and at most one project as a Co-PI, to ensure adequate project focus and accountability.

C. Project/Technology Eligibility

11. What TRL (technology readiness level) stages are eligible under this Mission?

This Mission will fund innovative technologies with established proof-of-concept (TRL-3 or above), with TRLs as defined in Annexure II.

Projects that have reached TRL 3 will have:

- An in-house prototype that has been designed, and
- The prototype's analytical performance has been tested in a lab setting.

Such projects, as well as projects that have progressed further, will be eligible for funding.

12. If the project is currently at TRL-2 stage, is it eligible to apply for funding under the mission?

Projects that are only at **TRL-2** stage of development are **not eligible** to apply for the mission. Similarly, projects that are only at TRL-1 stage of development are also not eligible.

- **TRL-1 (Ideation):** Projects that have only identified the problem statement/unmet need, and documented or selected the idea for a device.
- **TRL-2 (Proof of Principle):** Projects that have completed preliminary design selection, defined basic technical specifications, or undertaken FTO/market analysis – but no prototype has yet been built or tested.

Since these stages do not include designing an in-house prototype and testing its analytical performance in a lab setting (the requirements for TRL-3), such projects do not qualify for this scheme.

TRL-based eligibility is a strict criterion, and no exceptions will be made to the same.

13. What kinds of medical technologies are in scope for this call?

The Mission will support a broad spectrum of innovative medical devices that address India's national health priorities. These include, but are not limited to:

- In vitro diagnostics (IVD)
- Equipment (diagnostic, therapeutic, other advanced systems), including but not limited to point-of-care diagnostics, imaging, robotics, etc.
- Implants and assistive devices
- Consumables
- Surgical tools
- Software as a medical device, including AI/ML tools that support clinical diagnosis, treatment or care delivery
- Critical subcomponents

Out of scope:

- Therapeutics and vaccines are not an immediate focus of the current call and may be focused upon in subsequent calls.
- Broader digital health applications, including applications that support wellness, lifestyle, or administrative activities, are out of scope.

Alignment with health priorities:

- This call for proposal encourages (but is not limited to) technologies that are aligned with India's national health priorities (refer Annexure I). We welcome technologies that impact public health and health outcomes beyond those listed here.
- For direct financial support to private sector companies, MSMEs, and startups, the Mission will prioritize technologies that impact communicable diseases, and woman and child health and nutrition (sections A and C in Annexure I)

14. How is it determined whether a medical device has a predicate or not?

A device is considered to have a predicate if it can be shown to be substantially equivalent to an already approved device. Substantial equivalence means the new device has:

- The same intended use and technological characteristics; or
- The same intended use but different technological characteristics, provided it can be demonstrated that the device is as safe and effective as the predicate.

Importantly, a claim of substantial equivalence does not mean the devices are identical. Substantial equivalence shall be established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility, and relevant standards. Refer to Annexure II for more detail.

D. Funding Scope and Limits

15. How much funding can a project receive?

Projects will receive funding support in the range of ₹5 crore to ₹25 crore, depending on the scope, scale, and stage of development of the project. In exceptional cases, funding support of up to ₹50 crore may be considered.

16. What is the typical project duration that can be supported?

Projects under the Mission will typically be supported for a duration of 2 to 5 years, depending on the stage of development, scope of work, and milestones proposed. The exact duration will be finalized during evaluation and grant agreement.

Projects that are expected to reach commercialization beyond this timeframe are eligible to apply by defining milestones achievable within the Mission's support period.

17. How are projects divided into sub-projects under the Mission, and what does this mean for funding and support?

A project may be divided into sub-projects based on its stage of development:

- Stage I – Proof of Concept
- Stage II – Validation (Preclinical/Clinical Development)
- Stage III – Commercialization Support

This structure ensures that funding and support are customized to each stage, with the right form of engagement defined across ANRF, ICMR, and the Gates Foundation. By splitting projects in this manner, applicants receive stage-appropriate funding, mentorship, and partnerships, making support more focused and effective.

For the initial concept note, a single application is sufficient.

E. Funding Terms and Utilization

18. What are the key funding terms and conditions that applicants should be aware of?

Cost sharing:

- Cost-share requirements:
 - Private sector players (e.g. MedTech companies, MSMEs, etc.) are required to contribute to total project cost from their own resources. The specific terms of the cost-share will be determined by the Technical Advisory Group on a case-to-case basis (generally with a minimum of 30% private cost-share). The balance (i.e., ₹5-25 crore) will be funded through the scheme.
- Cost-share exemptions:
 - Academic/research institutes and start-ups will be exempt from cost-share requirements.
 - Projects that deal with national health priorities (see Annexure I) will be exempt from cost-share requirements.
 - The Technical Advisory Group will make the final determination on whether a project qualifies for these exemptions
- Specific terms of the cost-share will be determined by the Technical Advisory Group on a case-to-case basis.
- In case of collaborations/joint applications by multiple types of entities: The portion of the grant allocated to private sector entities will be subject to cost sharing as determined by the Technical Advisory Group.

Acceptable sources of cost sharing include (but are not limited to):

- Internal budget allocation/Self-funding
- Funding from domestic individuals or institutional investors
- Funding from foreign institutional investors
- Funding from other grants/government schemes, subject to the condition that funds made available under the scheme is for augmentation and there is no duplication in expenditures booked under the two schemes

Benefit sharing:

The scheme provides a grant with no requirement of benefit or equity sharing.

IP ownership:

The intellectual property (IP) generated under the **महल MedTech Mission** will be owned by the grantee itself.

Milestone-linked payments: Disbursements will be tied to the achievement of approved technical and developmental milestones, with subsequent tranches released once satisfactory progress is demonstrated against the agreed roadmap.

19. How can funding be used?

Funding under the Mission may be used for legitimate R&D, manufacturing and commercialization activities aligned to the approved project plan. Broadly:

Grant funding can cover:

Recurring expenses including:

- Personnel directly involved in the project
- Consumables
- Project related travel
- Field work
- Contingencies related to project execution
- Other costs (e.g., cloud compute credits, software licenses, publication costs, annual maintenance charges, short-term facility access)

Non-recurring expenses including:

- Equipment
- Software Purchase
- Long-term purchase of cloud or remote facility access
- Pre-clinical and clinical trials (excluding CROs)
- Regulatory processes and patent filings

Funding cannot cover:

- CROs
- Civil infrastructure and rental expenses
- Costs already incurred prior to grant sanction (no retrospective reimbursement)
- General corporate overheads or unrelated expenses
- Activities not connected to the approved milestones or scope of the project

Cost-share can be applied across activities without any restriction.

20. Will there be any non-financial support available beyond the grant?

In addition to financial support, the Mission will also provide support such as:

- Patent Support through **Patent Mitra**: Assistance with patent filing, protection, and technology transfer.
- Regulatory Support through **MedTech Mitra**: Guidance and facilitation for regulatory clearances and clinical evaluation.

- **Clinical Trial Support through the Intent Network:** Access to accredited sites and support for conducting pre-clinical and clinical trials.
- **Follow-on Funding Support:** Connections to private investors, venture capital, and other funding sources to help scale promising projects
- **Mentorship Support:** Guidance from industry leaders, domain experts, and business mentors on technology development, commercialization strategies, and navigating the MedTech ecosystem. Grantees have the option to bring on their own mentors, with honorariums/travel being funded if required.

F. Application Process and Timelines

21. How long will the Mission run, and when will grants be given?

The Mission will run for 5 years. The first call for applications will be in October - December 2025 with grants given in February/March 2026. The Mission expects to make two more funding calls, giving applicants multiple opportunities to apply.

22. What are the key dates and deadlines for the current call?

Refer to the ANRF website for timeline of closure of CFP for Concept Note. The CFP for the full proposal will open tentatively in December 2025, with results announced around February 2026.

23. Is it mandatory to submit a Concept Note, or can applicants directly submit a Full Proposal?

Submission of a Concept Note is mandatory. A subset of applicants from the Concept Note stage will be invited to submit a Full Proposal.

24. What types of evidence are acceptable to demonstrate the TRL stage of a project?

Applicants must provide evidence to substantiate the Technology Readiness Level (TRL) they are claiming. The following are indicative examples of acceptable proof at each TRL stage:

- **TRL 3 (Early-stage Proof of Concept):**
Peer reviewed publications or technical report/validation from a third party
- **TRL 4 (Advanced Proof of Concept / Design Freeze):**

MD-12: Submission acknowledgement of application for Test License

- **TRL 5 (Test-batch Evaluation):**

MD-13: Test License, and

MD-22: Submission acknowledgement of application for permission to conduct clinical investigation (CI) of medical devices

MD-24: Submission acknowledgement of application for permission to conduct clinical performance evaluation (CPE) of IVDs

- **TRL 6 (Pilot CI / CPE Studies – Phase I/Equivalence to predicate):**

MD-23: Permission for clinical investigation of medical device,

MD-25: Permission for clinical performance evaluation of IVD

- **TRL 7 (Pivotal CI / CPE Studies – Phase II/Equivalence to predicate):**

MD-3 / MD-7 (as applicable to the device class): Submission acknowledgement for obtaining Manufacturing License

MD-26/ MD-28(for IVDs): Submission acknowledgement of data for permission to import

- **TRL 8 (Pre-commercialization):**

MD-5 / MD-9 (as applicable to the device class): Manufacturing License

MD-27/ MD-29 (for IVDs): Import License

- **TRL 9 (Commercialization and Post-Market Studies):**

Post-Market Surveillance (PMS) reports

The Mission may request additional documents or clarifications during review.

G. Application Selection and Evaluation

25. What are the selection criteria for progressing from the Concept Note stage to the full application?

Concept Notes will be evaluated across several dimensions, including (but not limited to):

- Scientific/technical merit of the proposed solution
- Potential for public health impact, economic impact and self-reliance
- Strength of the development plan and potential for commercialization
- Strength of the applicant team and partnerships (e.g., industry–academia collaboration)

26. Will shortlisted applicants be asked to present or demonstrate?

No presentations or demonstrations will be required at the Concept Note stage.

27. If an applicant is not selected for funding, can they re-apply in future calls?

Applicants who are not selected will be given structured feedback on their submission and will be eligible to reapply in subsequent calls.

28. Will information in the Concept Note submission and the Full proposal submission be kept confidential?

All data and information submitted for the Concept Note or Full Proposal stage will be kept confidential. The evaluation committees will use this information only for assessment purposes.