EoINo.ICMR/EoI/09-MDMS/2024/Hb device

Invitation for Expression of Interest (EoI)

For

Participation of companies having 'Make in India' Non-Invasive/Minimally invasive Hemoglobinometer devices for validation by ICMR for effective screening of Anaemia

By ICMR-Hqrs

Indian Council of Medical Research
(Department of Health Research, GoI)
V. RamalingaswamiBhawan,
P.O. Box No. 4911, Ansari Nagar,
New Delhi - 110029, India

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Letter of Invitation

1. Invitation for Expression of Interest

Indian Council of Medical Research ((ICMR), New Delhi invites Expression of Interest (EoI) from the eligible organizations/companies/start-upsmanufacturing **'Non-invasive/ Minimally invasive hemoglobinometer'**hereinafter referred to as '**Product**', useful in effective screening of anaemia, as per national health priority.

The EoI document containing the details of qualification criteria, submission details, brief objective & scope of work and evaluation criteria etc. can be downloaded from the ICMR website (https://www.icmr.gov.in).

Schedule for the Proponents is as under:

EoI Document Number	ICMR/EoI/09-MDMS/2024/Hb device
Date of Publication	Date: 06/09/2024
Last date of submission	Date: 30/10/2024

Note:
Interested applicants may please send their proposals in a sealed envelope to the following address:

MDMS Unit (New Building 2nd Floor)
Indian Council of Medical Research,
V. RamalingaswamiBhawan,
P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110029, India.

EoI Document No. "ICMR/EoI/08-MDMS/2023/Hb device" along with the title of the EOI as "**EoI for Non-Invasive Hemoglobinometer device**" (for non –invasive devices) or "**EoI for Minimal invasive Hemoglobinometer device**" (for minimally invasive devices) in **Bold** and complete address as above must be clearly mentioned on the sealed envelope.

Only shortlisted firm(s)/organization(s) through this EoI will be requested to provide 5-6 non-invasive/Minimally invasive hemoglobinometer devices for validation by ICMR.

ICMR reserves the right to cancel this EoI and/ or invite afresh with or without amendments, without liability or any obligation for such EoI and without assigning any reason. Information provided at this stage is indicative and ICMR reserves the right to amend/add any further details in the EoI, as may be desired by the Competent Authority

ICMR and duly notified on its website.

2. Background

Anaemia continues to be a major public health problem in the country despite rigorous efforts of the Government and comprehensive AnaemiaMukt Bharat (AMB) programme, as a National Health Programme, being in operation. The prevalence of anaemia among six groups as per the National Family Health Survey 5 (2019-21) is 25.0% in men (15-49 years), 57.0% in women (15-49 years), 31.1% in adolescent boys (15-19 yrs), 59.1 % in adolescent girls, 52.2 % in pregnant women (15-49 years) and 67.1% in children (6-59 months)[1].

AMB programme adopts preventive and curative mechanisms through a 6X6X6 strategy including six target beneficiaries, six interventions and six institutional mechanisms for all stakeholders to implement the strategy. Testing and treatment of anaemia, using digital methods and point of care treatment, with special focus on pregnant women and school-going adolescents is one of the key AnaemiaMukt Bharat strategic interventions. The test and treat strategy, for its effective implementation, requires a simple, easy to use non-invasive/ Minimally invasive hemoglobinometer which will be acceptable to all, especially young children. Over the past few years, several 'Make in India' non-invasive/ Minimally invasive hemoglobinometer devices have become available. However, these devices need to be validated to establish its accuracy, bias, and precision of the noninvasive point-of-care methods before their use can be recommended in the programme.

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address the growing demands of scientific advances in biomedical research on the one hand and the need of finding practical solutions to the health problems of the country, on the other.

Research on interventions for mitigation/detection of anaemia is, therefore, ICMR's health research priority. Considering its national importance,ICMR intends to carry out a validationstudy of such non-invasive/ Minimally invasivehemoglobinometerdevices followed by health technology assessment for evaluating its suitability for the AMB programme.

ICMR, therefore, invites EOIs proposals from Indian industry/start-up manufacturers that address the below-mentioned research goal:

Priority research goal

Expanding the effective screening network of Anaemia in different age populations across India.

[1]https://main.mohfw.gov.in/sites/default/files/NFHS-5_Phase-II_0.pdf

3. Objective

To independently validate the 'Product' foreffective/accurate diagnosis of anaemia, for addressing national health priority.

4. Scope of Work

ICMR is willing to collaborate with eligible organizations/companies to engage with ICMR by providing 'Make in India'non-invasive/Minimally invasive hemoglobinometer devices for effective screening of anaemia.

Following the Expression of Interest (EoI), the single/multiple companies qualifying the Pre-Qualification Criteria (PQC outlined in Section 12) shall make available the non-invasive/minimally invasivehemoglobinometers (the Product) to enable the independent validation study by ICMR at its validation centers/ hospitals to enable evaluation of the devices/products for their suitability for public use.

Role of ICMR:

i. ICMR would conduct a hospital based clinical study to validate the promising non-invasive/ Minimally invasive hemoglobinometer devices against gold standard method of hemoglobin measurement.

ii. ICMR would provide technical support through its team of experienced scientists in study planning, product validation, development of study protocol, results/data analysis, outcome assessment, product improvement, etc., if deemed fit upon the mutual understanding between ICMR and collaborative company.

iii. ICMR through its Institutes would provide support and facilitation to conduct the R&D/clinical study of new technology/ product in India through its Affiliates/ Institutes, in collaboration with the company/institutions in a professional and mutually agreed-upon manner and timelines.

iv. ICMR would provide technical support in the validation of new technology/ product through its Affiliates/ Institutes.

v. ICMR would return the productto the company after completion of the proposed validation study.

Role of Company

i. The Company shall provideProduct and allnecessary documents with essential regulatory approvals (as applicable) required to conduct validation of the Productby ICMR either directly or otherwise.

ii. The Company shall have valid provisions to provide all necessary infrastructure/material/manpower required, if any, for validation either directly or indirectly.

iii. The Company shall have provisions to undertake the scale-up as required, manufacturing and commercialization of the product, in a set milestone.

iv. The Company agrees to share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.

v. The Company agrees to allow authorized personnel/scientist/team of ICMR to visit the designated lab/ production facility as and when required, as envisaged under this EoI.

vi. The Company shall be responsible for obtaining all the regulatory approvals required for commercialization or starting from R&D for product development to its commercialization.

vii. The Company shall provide free-of-cost 5-6 devices,tentatively, depending upon the study population size and the number of sites, selected by ICMR to effectively undertake the study

viii. The Company shall have no financial implications unless otherwise specified

5. Intellectual Property Rights

Intellectual Property (IP) shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents.

In case of collaboration between ICMR and the Company for the validation of the Product, Background Intellectual Property ("BGIP") shall always remain the sole and exclusive property of the Party generating the BGIP. Any IP, if generated during the course of

collaboration, including any improvement thereof, shall be jointly owned by ICMR and the Company. All such provisions related to intellectual property rights shall be governed by ICMR IP Policy.

6. Process involved in Validation

Interested companies/manufacturers are invited to join hands with ICMR for validation of their Product(s). Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical requirements will be shortlisted based on their R&D plan, facilities and capabilities. On shortlisting, the qualified companies/manufacturers will only be contacted for making available required number of devices for conducting independent validation of the Product by ICMR. Suchcompanies/manufacturers shall be responsible to provide the Product along with all the necessary documents and essential regulatory approvals.

7. Publication

i. In case of Co-development, the Parties shall have equal rights on the manuscripts/scientific publications (joint publication/acknowledgment /other credits as applicable) and in accordance with guidelines of International Committee of Medical Journal Editors (ICMJE.org).
ii. Support of ICMR must be duly acknowledged in all publications by the Company.
iii. ICMR Scientists/ Clinicians involved in independent validation can be given due advantage of authorships in the publications arising out of such studies.

8. Data Rights

i. Data rights shall be jointly owned by ICMR and the Company.
ii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.
iii. Company to ensure that data is anonymized, kept confidential and strictly abide by the provisions of Information Technology Act, 2000 while dealing with such data

9. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical capabilities for submission of interest, subject for verification by ICMR.

Documents to be furnished are as follows:

i. Declaration - Expression of Interest (Format – 1)
ii. Authorization Letter (Format – 2)

iii. Undertaking with regard to Blacklisting (Format-3)
iv. Undertaking with regard to Non-Conviction (Format – 4)
v. EoI document with each page duly stamped and signed by the Authorized signatory.
vi. Undertaking with regard to laboratory facility (Format – 5)
vii. Production Capacity Undertaking (Format-6)
viii. Supporting documents, as mentioned in Format-1
ix. MSME Certificate (if applicable)
x. Concept note on the Product claimed for validation- A brief concept note on R&D, clinical studies, regulatory approvals and any other process involved etc. (not more than 5 pages)
xi. Any other information which proponent may wish to provide to support the EoI.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgment in evaluation.

10. Rejection Criteria

The application is liable to be rejected if:

i. The proposal is not submitted as per the requirements indicated in the EoI.
ii. Not in the prescribed format.
iii. Not properly stamped and signed.
iv. Received after the expiry of due date and time.
v. All relevant supporting documents are not furnished with the Pre-Qualification Criteria (PQC).
vi. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.
vii. Applications not fulfilling the terms of the document will be summarily rejected.
viii. Any other non-compliance.

11. Evaluation Methodology

Screening of EoIs shall be carried out as per Pre-Qualification criteria mentioned in the EoI document and based on verification of documents submitted. The EOIs received in response to this call will be reviewed and shortlisted by a committee of experts. The shortlisted Companies will only be contacted.

12. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	Pre-Qualification Criteria (General)	**Supporting copy of documents required** (All documents must be self-attested by the authorized person of the proponent)
General Criteria		
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India and shall have more than 51% of Company stakes by promoters from India..	Registration of firm/ organization/Company Incorporation Certificate from Registrar of Companies (ROC) /Partnership deed etc. whichever is applicable
2	The proponent must be registered in India with taxation and other administrative authorities.	GST Registration or GST exemption certificate/ PAN Card
3	The proponent should have proven prior experience of manufacturing and/or R&D with manufacturing during the last three years, either in-house or through agreed collaboration and must have marketed same/similar products in the past with a good track record.	Research paper/Pamphlet / brochure of the product/DCGI License for existing product. Supporting documents for collaboration, if any.
4	The proponent has to be profitable and should not have incurred overall loss in past three (3) years. (applicable on commercial firms/organizations only)	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.
5	The proponent should have good track record and currently not black-listed/ barred by any Central / State Government / Public Sector Undertaking, Govt. of India, (applicable on commercial firms/organizations only).	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).
6	The proponent should have a manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
7	The proponent and its promoters should not have been convicted for any offence in India by any competent court or judicial body during the past 3 years.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)
8	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
Specific Criteria (Based on the nature of the Proposal)		
9.	The proponent should have functional laboratory to carryout R&D for the product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
10.	Capacity to produce at	Undertaking (As per format – 6)

	least……(quantity) per week	

NOTE- For MSMEs and Start-ups, Start-Up-India, Make-in-India and other relevant guidelines of Government of India shall be applicable.

13. Disclaimer

i. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
ii. ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.
iii. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.
iv. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.

14. Arbitration

That any dispute and/ or any part of the dispute which couldn't be resolved through mutual consultation, the same shall be referred to the sole arbitrator as per the Arbitration & Conciliation Act, 1996 and any amendment thereafter. The Venue and Seat of the arbitration proceedings shall be New Delhi and the courts at New Delhi will have exclusive jurisdiction.

15. Contacts

In case of any clarification required, please contact:

For scientific issues: (Pl contact)

Dr. Suchita Markan
Scientist E&Mission-in-charge,
Medical Device & Diagnostics Mission Secretariat,
ICMR Headquarters, New Delhi
Email: suchita.markan@icmr.gov.in

Format-1

Expression of Interest

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Submission of Expression of Interest (EoI) for ……
.

Ref: ICMR/EoI/…… /202X dated …….

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining to validation, and do hereby express the interest to provide the product as mentioned in the EoI document. The details of the Company and contact person are given below:

Name of the Proponent	
Address	
Name, designation & address of the person (to whom all communications shall be made)	
Telephone No. (with STD code)	
Mobile No. of the contact person	
Email ID of the contact person	

The following documents are enclosed:

Sl. No.	Documents required	Type of document attached	Page No.
1	Company Incorporation Certificate from ROC/Partnership deed etc.		

2	GST Registration or GST exemption certificate/ PAN Card.		
3	DCGI/CDSCO license for the product or any other regulatory approvals (as applicable).		
4	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for las three financial years, Income Tax return.		
5	Proof of a registered office and a manufacturing Unit in India. Including DSIR certificate		
6	GMP/ GLC and ISO Certification. Registration copies to be furnished (as applicable)		
7	Authorization Letter	As per format – 2	
8	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory.	As per format – 3	
9	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 4	
10	MSME Certificate (if have any)		
11	Business Plan	A brief concept note on planning & execution, production, marketing etc. (not more than 5 pages)	

I/we hereby declare that my/our EoI is made in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

(1)- Name of the Technology or name of the product
(2)- Commercial use of the Technology/ Product

Format-2

Authorization Letter

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Letter for Authorized Signatory
Ref: ICMR/EoI/09-MDMS/2024/Hb device dated 06 Sep, 2024.

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for ……(1)Device / Diagnostic assay/ Kit *(only tick whichever is applicable)* against ……..…. (2) disease.

Mr./Ms./Mrs./Dr…….is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s……. (Company Name) ……., who's signature is below.

(Specimen Signature of Representative)

Date:
Place:

Yours faithfully,

(Signature of the Authorized signatory)
Name:……..
Designation:……..
Seal:……..

(1)- Name of the Technology or name of the product
(2)- Commercial use of the Technology/ Product

Format-3

Undertaking with regard to blacklisting

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Blacklisting / Non-Debarment.
Ref:ICMR/EoI/09-MDMS/2024/Hb device dated 06 Sep, 2024

Sir,

It is hereby confirmed and declared that M/s……(Company Name) currentlyhas not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other company for which works/assignments/services have been executed / undertaken.

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-4

Undertaking with regard to Non-Conviction

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding Non-Conviction
Ref:ICMR/EoI/09-MDMS/2024/Hb device dated 06 Sep, 2024

Sir,

It is hereby confirmed and declared that M/s….....(Company Name) and owner of the firm / board of directors, have not been convicted for any offence in India by any competent court or judicial body during the past 3 years

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

Format-5

Undertaking with regard to laboratory facility

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding laboratory infrastructure.
Ref:ICMR/EoI/09-MDMS/2024/Hb device dated 06 Sep, 2024

Sir,

It is hereby confirmed and declared that M/s…..... (Company Name) do have

i. Adequate laboratory infrastructure (equipped laboratory facility). Please tick BSL-2/BSL-3/ABSL-3/GMP/GLP/ Other* (if other please specify) and

ii. Adequate no. of experienced staff/skilled manpower to undertake manufacture/ research/ commercialization of ……. (Product details).

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

*The Laboratory/ facility requirement will depend on the technology/ Product

Format-6

Undertaking with regard to production capacity

(To be submitted on Company's Letter Head)

To,

The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking with regard to production capacity.
Ref:ICMR/EoI/09-MDMS/2024/Hb device dated 06 Sep, 2024

Sir,

It is hereby confirmed and declared that M/s…… does have the capacity in all mean (including infrastructure, fund, material, staff etc.) for manufacturing of …… (Name ofTechnology/ Product), minimum……(mention the quantity per week/per month).

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:

Place: