No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025 dated 17.01.2025

Invitation for Expression of Interest (EoI)

For `

Development and Manufacturing of a Lateral Flow based Point of Care device for serum ferritin quantification

By ICMR-Hqrs

Indian Council of Medical Research
(Department of Health Research, GoI)
V. Ramalingaswami Bhawan,
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, manufacturers for undertaking **'Development and Manufacturing'** of a Lateral Flow based Point of Care device for serum ferritin quantification. Ferritin is an important biomarker of iron status in the blood, indicating iron deficiency anemia when levels are low.

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	**No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025**
Date of Publication	**17-01-2025**
Last date of submission	**28-02-2025**

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

Dr. Tanica Lyngdoh,
Scientist-E, RCN Division
Indian Council of Medical Research,
V. Ramalingaswami Bhawan,
P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110029, India.

A soft copy of the same is also to be sent to the following email id:
icmr.adm@gmail.com

EoI Document "**No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025 dated 17.01.2025**" along with the title of the EOI as "**EoI for developing and manufacturing of a Lateral Flow based Point of Care device for serum ferritin quantification**" in **Bold** and complete address as above must be clearly mentioned on the sealed envelope.

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

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.

The Centre for Technology Licensing (CTL) is Cornell University's technology transfer office, tasked with translating the University's scientific research, technological innovations, and medical breakthroughs into tangible products for public benefit. CTL also plays a key role in fostering new ventures and supporting economic development. One such innovation developed at Cornell is a technology called AnemiaPhone, a device designed for assessing iron deficiency by measuring the serum ferritin levels at the point of care (referred to hereafter as "the Technology"). This technology will be developed for deploying/distribution in the National program and cannot be commercialized.

Cornell University intends to share this Technology and related information with the ICMR to facilitate the developing and manufacturing of this device in India. This collaboration will support the Indian Government's Anemia Mukt Bharat initiative and other public health efforts aimed at reducing anemia across the country.

Under this arrangement, ICMR will receive detailed technical data, including designs, drawings, schematics, specifications, parts lists, instructions, procedures, documentation, publications and other materials related to the design, construction, manufacture, and operation of the Technology. This information will be provided to selected local manufacturers who will adapt the Technology to suit the Indian context, with the goal of producing a device specifically for iron deficiency assessment.

3. Objective

To undertake development and manufacturing of a **Lateral Flow based Point of Care device for serum ferritin quantification** (Device)

4. Scope of Work

i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for undertaking development and manufacturing of Product/Device based on

AnemiaPhone technology for assessing ferritin levels and iron deficiency at point of care.

ii. The Company will be granted the rights to undertake development, after which the 'Product' will undergo independent validation in an external setting. Upon receiving approval and successfully completing the validation process, the Company may be engaged for large-scale manufacturing of the "**Lateral Flow based Point of Care device for serum ferritin quantification**.

iii. Cornell University has expertise in techniques, methods and information relating to aforesaid technology which could be used for the production of the device used for assessing anemia

Role of ICMR:

i. ICMR along with Cornell University will provide expert guidance & technical support for the development of **Lateral Flow based Point of Care device for serum ferritin quantification**, in all phases. Such technical oversight by them would accelerate the development and manufacturing of the Product.

ii. ICMR will also facilitate the validation, if required, as per the terms & conditions of the Agreement.

iii. ICMR shall have no financial implications unless otherwise specified.

Role of Company

i. The Company shall have valid provisions to provide all necessary infrastructure/ material/ manpower required for product development and manufacturing/ validation/ scale-up either directly or otherwise.

ii. The Company shall have provisions to undertake the development and manufacturing as required, of the "**Lateral Flow based Point of Care device for serum ferritin quantification**" in a set milestone.

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

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

5. Intellectual Property Rights

It is submitted that in case of transfer of Technology, Cornell University is the sole owner of the said Technology, including any underlying Intellectual Property (ies) and commercialization 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.

Cornell University legally possess the rights and authority to retain full or part of the 'Technology' by itself or to assign at its discretion full or part of the Technology including any patent(s) or intellectual property rights(s) or the invention(s).

6. Process involved in Partnership/Collaboration

Interested companies/manufacturers are invited to join hands with ICMR and Cornell University for development and manufacturing of the Product(s). Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical need will be shortlisted based on their R&D plan, facilities and capabilities. Qualified companies/manufacturers will only be contacted for execution of MoA/MoU/Agreement for development and manufacturing the Product(s).

7. Publication

i. Cornell and ICMR Scientists may be given due advantage of authorships in the publications (if any) arising out of work undertaken.

8. Data Rights

i. Data Rights will be exclusively with ICMR and Cornell University.
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 business plan- A brief concept note on R&D, clinical studies, planning & execution, production, marketing etc. with timeline (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 judgement 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.

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 development And manufacturing and/or R&D with development/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 least……(quantity) per week	Undertaking (As per format – 6)

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.
v. For International Clients, please note that EoI and other necessary correspondences shall be submitted in English only.

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:
icmr.adm@gmail.com

For scientific issues:
lyngdoh.t@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 development and manufacturing of a Lateral Flow based Point of Care device for serum ferritin quantification

Ref: No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025 dated 17.01.2025

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining to your transfer of technology, and do hereby express the interest to undertake the research & development/manufacture/ sale /commercialization of 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 existing products available in the market		
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 of both		
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:

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: No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025 dated 17.01.2025

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for development and manufacturing of a Lateral Flow based Point of Care device for serum ferritin quantification

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:
Place:

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: No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025 dated 17.01.2025

Sir,

It is hereby confirmed and declared that M/s…… (Company Name) currently has 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: No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025 dated 17.01.2025

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: No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025 dated 17.01.2025

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 a Device based on AnemiaPhone technology to develop a Point of Care device for serum ferritin quantification

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: No-5/7/10/ICMR-EOI/Serum Ferritin/RCN-2025 dated 17.01.2025

Sir,

It is hereby confirmed and declared that M/s…… does have the capacity in all mean (including infrastructure, fund, material, staff etc.) for development and manufacturing of a Lateral Flow based Point of Care device for serum ferritin quantification (Name of Technology/ Product), minimum …….(mention the quantity per week/per month).

Yours faithfully,

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

SCHEDULE-A

TECHNOLOGY DETAILS

i. **About the Technology/Product/Process:**

Anemia Phone deploys a minimally invasive, point-of-care, low-cost, non-infrastructure dependent, and highly portable point-of-care screening platform for iron status assessment based on quantification of serum ferritin (SF), soluble transferrin receptor (sTfR), and C-reactive protein (CRP). AnemiaPhone technology has been developed and tested in the laboratories of Professors Saurabh Mehta, David Erickson, and Julia Finkelstein at Cornell University and the technology will be transferred to the Indian Council of Medical Research for development, manufacturing and scale-up in India.

ii. **Need and utility of the Technology from Public health perspective:**

Iron deficiency (ID) represents a critical public health issue with severe consequences for maternal and child health. Unfortunately, limited access to healthcare and the high cost of testing often result in screening and diagnosis being restricted to hemoglobin levels, rather than more comprehensive diagnostic methods. India through its Anemia Mukt Bharat campaign is focusing on reducing and eliminating anemia to the extent possible. These efforts will be bolstered by a locally produced inexpensive iron deficiency test. Cornell University has agreed to give access to AnemiaPhone technology and certain rights in, the Technology in order to adapt it to the local context in India and work with local manufacturers to produce and scale the availability of diagnostic tests for iron deficiency, ensuring broader access to the Indian public.

i. **Technology Readiness level (TRL)**

…….

ii. **Validation Status and outcome:**

This technology has been developed and tested in the laboratories of Professors Saurabh Mehta, David Erickson, and Julia Finkelstein of Cornell University

iii. **IP Filing Status/Publications**

……...

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