EOI No.

Expression of Interest (EoI)

Indian Council of Medical Research, New Delhi

invites EoI for

Joint collaboration for production and supply of candidate antigens and monoclonal antibodies for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme

Indian Council of Medical Research
(Department of Health Research, GoI)
V. Ramalingaswami Bhawan,

P.O. Box No. 4911, Ansari Nagar, New Delhi - 110029, India

CONTENTS

Letter of Invitation

1. INVITATION OF EXPRESSION OF INTEREST

Indian Council of Medical Research, New Delhi, invites Expression of Interest (EoI) through email from experienced diagnostic manufacturers/pharma companies for undertaking production and supply of recombinant antigens of the lymphatic filarial parasite, *Wuchereria bancrofti*, and highly antigen specific monoclonal antibodies with high affinity for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme (details provided in Schedule A), **on a work for hire basis.**

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/**LFD.rAgs**/2023dated 13/04/2023
Date of Publication	Date: 13/04/2023

Note: The EoI may be submitted through email to Mrs. T. Shankari (Technical Officer – C), sankari.t@icmr.gov.in /sankarithirumal@gmail.com and to ICMR Nodal officer Dr. Manju Rahi (Scientist-F) manjurahi.hq@icmr.gov.in / drmanjurahi@gmail.com. Shortlisted firm(s)/organization(s) shall only be contacted for the further process of finalization of the agreement.

ICMR reserves the right to cancel this EOI and/ or invite a fresh 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 at 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 to the need of finding practical solutions to the health problems of the country, on the other.

ICMR-Vector Control Research Centre (ICMR-VCRC), Puducherry, one of the constituent institutes of the Indian Council of Medical Research (ICMR), New Delhi. The Centre has cloned twelve well characterized antigens of lymphatic filarial parasite, *Wuchereria bancrofti*, expressed and purified the recombinant antigens. In-house direct ELISA were developed using these antigens and preliminary evaluation of the diagnostic potential of these recombinant antigens based ELISAs showed them to be promising.

ICMR reserves all the Intellectual Property Rights and Commercialization rights on the recombinant antigens of *W. bancrofti*. ICMR is lawfully entitled to enter into any form of nonexclusive agreements with experienced immune-diagnostics manufacturers through defined agreement for undertaking production and supply of recombinant antigens of the lymphatic filarial parasite, *W. bancrofti*, and monoclonal antibodies, hereinafter referred to as the 'Product(s)'.

3. Intellectual Property Rights

ICMR Vector Control Research Centre (VCRC), Puducherry, one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi, has **recombinant antigens of lymphatic filarial parasite, *Wuchereria bancrofti*** and is the owner of the said ANTIGENS including any underlying Intellectual Property(ies) and Commercialization rights.

4. Objective

To make available the **recombinant antigens of lymphatic filarial parasite, *Wuchereria bancrofti*, and monoclonal antibodies**, to greatly accelerate the development of diagnostics.

5. Broad Scope of Work

i. ICMR is willing to collaborate with experienced diagnostics manufacturers on fixed term contract condition for undertaking the production and supply of recombinant antigens and highly antigen specific monoclonal antibodies with high affinity for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme etc.

ii. The firm(s)/organization(s) would be granted rights to undertake the production and supply of recombinant antigens and monoclonal antibodies for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme, after signing the **Non-Disclosure-Agreement (NDA)**.

iii. The Agreement, following EoI is proposed to be executed on "Non-Exclusive" basis with single/multiple firms.

iv. ICMR-VCRC has in its possession of **recombinant antigens of lymphatic filarial parasite, *Wuchereria bancrofti*** useful for the development of diagnostics for monitoring the lymphatic filariasis elimination programme. ICMR-VCRC has expertise in various techniques, methods and information relating to these antigens, which could be used for development of diagnostics for monitoring the lymphatic filariasis elimination programme, and other R&D activities etc. ICMR-VCRC will provide expert guidance & technical support on the R&D and product development, in all phases. Such technical oversight by ICMR-VCRC would accelerate the development of the Product.

v. The process developed by ICMR-VCRC during the course of development of the Product encompassing IP, shall be owned by ICMR. 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; and shall include without limitation, the Technology, Licensed Patents and Licensed Trademarks, developed/ created pursuant to this EoI.

vi. ICMR-VCRC would provide technical support through team of experienced scientist in study planning, product development, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, and other, if deemed fit upon the mutual understanding between ICMR-VCRC and collaborative company.

vii. The Company will undertake the production and supply of recombinant antigens of the lymphatic filarial parasite, *Wuchereria bancrofti*, and highly antigen specific monoclonal antibodies with high affinity for use in the development of diagnostics.

viii. The partnering company shall the provide necessary infrastructure and depute experienced/skilled manpower.

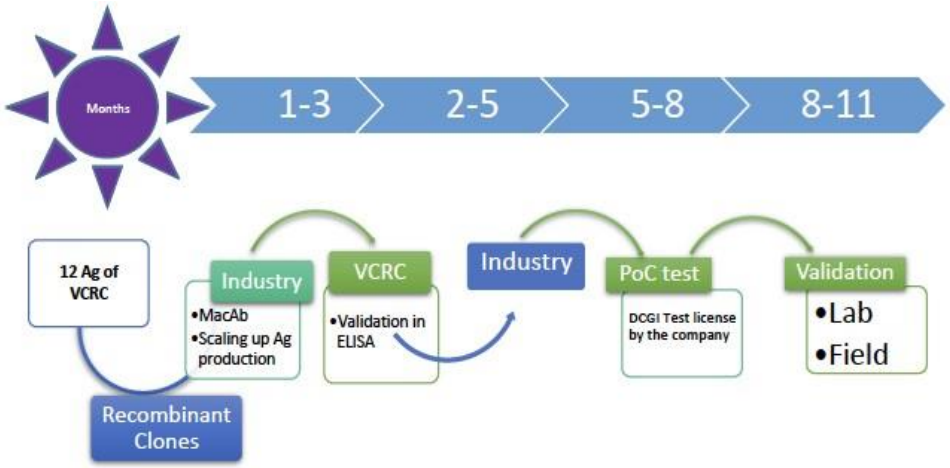
ix. The company will share the processes, details, and technical data of the production of antigens and monoclonal antibodies and their hybridoma clones with ICMR. The company shall participate in all discussions in a professional and mutually agreed-upon manner.

x. The company will allow authorized personnel/scientist/team of ICMR to participate in R&D activities if necessary and to carry out specific project activities.

6. Process involved in Partnership/Collaboration

i. Interested companies/manufacturers with demonstrated capabilities in the production and supply of recombinant antigens of *W. bancrofti*, and monoclonal antibodies for use in the development of diagnostics are invited to join hands with ICMR for of the said antigens

and monoclonal antibodies. Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical needs will be shortlisted based on their R&D facilities, capabilities, and demonstrated experience in the production of candidate antigens and monoclonal antibodies. Qualified potential companies/manufacturer will be then requested for partnership/collaboration through MoA/MoU on mutually agreed terms. The MoU/MoA shall have a **definite timeline line** for the production and supply of candidate antigens of *W. bancrofti*, and highly antigen specific monoclonal antibodies with high affinity for use in the development of diagnostics, which is as below:



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ii. The Agreement shall be valid from the EFFECTIVE DATE and subject to covenants and conditions herein contained and shall remain in force for a specific period which shall be decided mutually with the approval of competent authority.

7. 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/financial capabilities for acceptance and submission of documents for verification by ICMR.

Documents to be furnished are:
i. Authorization Letter (Format – 1) ii. Declaration - Expression of Interest (Format – 2) iii. Undertaking with regard to Blacklisting (Format-3) iv. Undertaking with regard to laboratory facilities (Format – 4) v. Undertaking with regard to Non-Litigation (Format – 5) vi. Production Capacity Undertaking (Format-6) vii. EoI document with each page duly stamped and signed by the Authorized signatory. viii. Supporting documents, as mentioned in Format-2 ix. MSME Certificate (if applicable) x. Concept note on business plan xi. Any other information which proponent may like to provide.

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.

8. Rejection Criteria

The application is liable to be rejected if:

- The proposal is not submitted as per the requirements indicated in the EOI.
- Not in the prescribed format.
- Not properly stamped and signed as per requirements.
- Received after the expiry of due date and time.
- All relevant supporting documents are not furnished with the Pre-Qualification criteria.
- The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.

9. 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. Only shortlisted proponents shall be contacted for execution of the License agreement.

- On shortlisting of technically suitable candidates, one Request for Proposal (RFP) will be shared with the shortlisted candidates. At the RFP stages, technically suitable candidates will be required to provide complete technical details. The selection of candidates will be decided on the basis of their offers at the RFP stage.

10. Pre-Qualification Criteria (PQC)

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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**	**Supporting copy of documents required** (All documents must be self-attested by the authorized person of the proponent)
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India.	Registration of firm/ organization/ Company Incorporation Certificate from 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 prior experience in R&D and manufacturing of diagnostics for any infectious disease and must have marketed such products in three (3) immediate preceding years.	Research paper/Pamphlet / brochure of the product/DCGI License for existing product
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 not black-listed by any Central / State Government / Public Sector Undertaking, Govt. of India, at least in three (3) immediate preceding Years. (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 registered office, manufacturing unit in India	Registration copies of both, and also copy of the DSIR Certificate
7	a. The proponent should have functional laboratory to carryout R&D for the product development. b. History of having produced large quantity of antigen and Monoclonal antibody in brief time (3 months). c. Regulatory approved manufacturing facility to produce 1-2 gram of antigen and Monoclonal antibody. d. Possess patent and publication in the areas of antibody development. e. Experience of having produced products that are regulatory approved and commercialized. f. Experience of developing lateral flow diagnostic systems.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)

	g. In-house capability to develop and validate ELISA based methods.	
8	The proponent should not be involved in any major litigation that may have an impact of affecting or compromising the conditions required under this EOI and in the MoU.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
9	GMP and ISO Certification (applicable on commercial firms/organizations only)	Registration copies of both
10	Capacity to produce at least one lakh tests per week	Undertaking (As per format – 6)
11	Business Plan	A brief concept note on planning & execution, product development, clinical trials, regulatory affairs, production, marketing etc. (not more than 5 pages)

11. Disclaimer

- ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
- ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.
- 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.
- To include any other item in the Scope of work at any time after consultation with proponents or otherwise.

12. Contacts

In case of any clarification required, please contact:

For scientific issues-

Dr. Ashwani Kumar Director, ICMR-VCRC, Puducherry, Email: - director.vcrc@icmr.gov.in

For Administrative issues

Dr. R. Lakshminarayanan, DDG (Admin), ICMR HQ, New Delhi
Email: - lakshminarayanan.r@icmr.gov.in

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Format-1

Authorization Letter

(To be submitted on Agency's Letter Head)

To,

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

Subject: Letter for Authorized Signatory
Ref: EOI No. ICMR/EoI/ /**LFD.Ags** /2023 dated

Sir,

This has reference to your above-mentioned Expression of Interest (EOI) for undertaking the production and supply of candidate antigens of *W. bancrofti*, and highly antigen specific monoclonal antibodies with high affinity for use in the development of diagnostics for LF.

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

(Specimen Signature of Representative)

Date: Place:

Yours faithfully,

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

Format-2

Expression of Interest

(To be submitted on Agency's Letter Head)

To,

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

Subject: Submission of Expression of Interest (EOI) for joint collaboration for the production and supply of recombinant antigens of *W. bancrofti,* and highly antigen specific monoclonal antibodies with high affinity for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme.

Ref: ICMR/EoI/ **LFD.Ags**/2023 dated

Sir,

The undersigned having read and examined in detail all the EOI documents pertaining to your technology, and do hereby express an interest to undertake the production and supply of recombinant antigens of *W. bancrofti,* and highly antigen specific monoclonal antibodies with high affinity for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme, 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, and DSIR Certificate		
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6	GMP and ISO Certification. Registration copies of both		
7	Authorization Letter	As per format – 1	
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	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory	As per format – 5	
11	Undertaking for declaring capacity to produce at least one lakh doses per week	As per format – 6	
12	MSME Certificate (if have any)		
13	Business Plan	A brief concept note on planning & execution, product development, clinical trials, regulatory affairs, 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:

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Format-3

Undertaking with regard to blacklisting (To be submitted on Agency'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/ **DLF.Ags**/2023 dated

Sir,

It is hereby confirmed and declared that M/s……has not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other agency 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 laboratory facility (To be submitted on Agency's Letter Head)

To,

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

Subject: Undertaking regarding laboratory infrastructure.
Ref: ICMR/EoI/OS/**DLF.Ags** /2023 dated

Sir,

It is hereby confirmed and declared that M/s…..... do have adequate laboratory infrastructure (CGAMP facility) and experienced staff/skilled manpower to undertake the production and supply of recombinant antigens and highly antigen specific monoclonal antibodies with high affinity for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme., as defined in the EoI.

Yours faithfully,

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

Place:

Format-5

Undertaking with regard to Non-Litigation (To be submitted on Agency's Letter Head)

To,

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

Subject: Undertaking regarding Litigation.
Ref: ICMR/EoI/**DLF.Ags**/2023 dated

Sir,

It is hereby confirmed and declared that M/s…..... and owner of the firm / board of directors, do not have any litigation / arbitration pending/under trial in court.

Yours faithfully,

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

Place:

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Format-6

Undertaking with regard to production capacity

(To be submitted on Agency'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/**DLF.Ags**/2023 dated

Sir,

It is hereby confirmed and declared that M/s…… does have the capacity in all mean (including infrastructure, fund, material, staff etc.) for the production and supply of 25 mg each of 12 recombinant antigens and 10 mg each of 12 monoclonal antibodies, within 3 and 6 months of time.

Yours faithfully,

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

Place:

SCHEDULE – (A)

Joint collaboration for production and supply of candidate antigens and monoclonal antibodies for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme

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

Lymphatic Filariasis (LF) caused by filarial parasites, *Wuchereria bancrofti, Brugia malayi* and *Brugia timori*, is a major public health problem leading to societal stigma besides causing huge burden of disability and economic loss in India and other tropical and subtropical countries. As a neglected tropical disease, it is therefore, identified as one of the six diseases that are targeted for elimination. One of the important requirements for this is more sensitive and specific diagnostic markers to measure the impact of preventive chemotherapybased intervention for stopping decision.

Therefore, a study was under taken and 12 antigen biomarkers have been identified based. These antigens have been cloned and expressed. The antigens were used for developing indirect ELISAs for detecting filariasis specific antibodies and antigens.

ii. **Need and utility of invention:**

Following the resolution of World Health Assembly, a '**Global Programme for Elimination of Lymphatic Filariasis (GPELF)'** was launched by the WHO in the year 2000, with the aim to eliminate LF by 2020. Mass Drug Administration (MDA) of a single dose of Diethylcarbamazine/Ivermectin and Albendazole combination for 5-6 years, repeated annually and morbidity management and disability prevention of chronic cases are the recommended strategies to achieve LF elimination. So far at least 17 out of 99 LF endemic countries have achieved elimination of LF and the MDA programme is being continued in the rest of the 72 endemic countries. With the recent NTD roadmap, the target for LF elimination is realigned and set as 2030. Triple drug regimen (Ivermectin, DEC and Albendazole - IDA) has been recommended as an alternate strategy to accelerate LF elimination by the WHO, based on the results of randomized and community control trials. Eleven countries are implementing this new strategy. This strategy requires only 2-3 rounds as IDA is known to inhibit the production of microfilaria, besides its clearance. Transmission Assessment Survey (TAS) is recommended as a decision tool to stop MDA and conduct postelimination surveillance. However, this tool is based on incidence of infection in children who are born after the introduction of MDA and hence not appropriate for IDA based strategy which requires only fewer rounds of MDA. Therefore, a new monitoring and evaluation protocol is required for IDA. One of the important requirements for this is more sensitive and specific diagnostic markers to measure the impact of preventive chemotherapy-based intervention for stopping decision. Further, such marker(s) will also be useful as a potential signal to detect early the risk of resurgence under low prevalence settings during postelimination phase.

iii. **Scope for collaboration:**

This collaboration will open up scope for production and supply of candidate antigens and antigen specific monoclonal antibodies for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme.

iv. **Role of ICMR through its institute (ICMR-VCRC)**

ICMR would provide technical support through team of experienced scientists for production and supply of candidate antigens and monoclonal antibodies for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme

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v. **Role of company**

a. The Company will undertake the production and supply of candidate antigens and monoclonal antibodies as per the terms of collaboration.

b. The partnering company should provide necessary infrastructure and depute experienced/skilled manpower.

c. The company will allow authorized personnel/scientist/team of ICMR to participate in undertaking the production and supply of candidate antigens and antigen specific monoclonal antibodies for use in the development of diagnostics for monitoring the lymphatic filariasis elimination programme, as envisaged under this EoI and subsequent Agreement.

d. The company shall be responsible for obtaining all the necessary approvals required for production of the said immunological reagents.

vi. **Methodology/process:**

ICMR-VCRC, Puducherry has cloned several well characterized antigens of lymphatic filarial parasite, *Wuchereria bancrofti*, expressed and purified the recombinant antigens. The detailed methodologies will be shared with the firm after the award of the work and signing of NDA.

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