EoI No.ICMR/EoI/PM/05/Malaria vaccine (AdFalciVax)/2025

Invitation for Expression of Interest (EoI)

For

Transfer of Technology

of
A recombinant multi-stage malaria vaccine
(Vaccine Candidate)

ICMR-HQ

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 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 **'Transfer of Technology'**for commercialization of **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"**useful in **Preventing*Plasmodium falciparum* infection in humans and minimizing its community transmission**.

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/PM/05/Malaria vaccine (AdFalciVax)/2025
Date of Publication	Date: 17/07/ 2025
Last date of submission	Date: 17/08/ 2025

Note:

Interested applicants are invited to submit their Expression of Interest (EoI) through the Medical Innovation Patent Mitra portal (https://patentmitra.icmr.org.in/company-eoi-registration/).Applicants must first register by providing requisite company information, including details of the authorized representative. Upon successful registration, applicants are required to complete and submit the e-EoI form available on the portal.

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 demand 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-Regional Medical Research Centre, Bhubaneswar (ICMR-RMRCBB) one of the

constituent institutes of the Indian Council of Medical Research (ICMR), New Delhi has leddevelopment of a technology entitled **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparu*m**" consisting of full-length PfCSP (a pre-erythrocytic target for preventing infections in humans) in fusion with PfsPro6C (constituted of subdomains from two transmission blocking antigens Pfs230 and Pfs48/45).

This vaccine development study has been funded by the Biotechnology Industry Research Assistance Council-National Biopharma Mission (BIRAC-NBM), New Delhi. The ICMR-RMRCBB has technical-know-how of process to produce this recombinant chimeric multi-stage malaria vaccine in *Lactococcuslactis* thereof" (hereinafter) referred to as "**Technology**". The pre-clinical validation of this technology has been conducted in collaboration with ICMR-National Institute of Malaria Research (ICMR-NIMR), another constituent institutes of ICMR and National Institute of Immunology (NII), New Delhi, an autonomous research institute of the Department of Biotechnology, Government of India.

ICMR is lawfully entitled to enter into any form of **exclusive/non-exclusive agreements** with experienced manufacturing companies hereinafter referred to as the "**Company**"/ "licensee" through a defined agreement for Licensing/Commercialization of "**A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"**, hereinafter referred to as the '**Product**' which shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

3. Objective

To license the 'Technology' for "**A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"** useful in **Preventing *Plasmodium falciparum* infection in humans and minimizing its community transmission**, for commercialization and marketing activities.

4. Scope of Work

i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for undertaking transfer of technology for commercialization of **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*".**

ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology/Product entitled **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"**.

iii. An Agreement following EoI is proposed to be executed on a Non-Exclusive basis with single/multiple companies to enable wider outreach of **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"** (Technology/Product) for societal benefit and public health use. All the related issues shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

iv. ICMR- Regional Medical Research Center, Bhubaneswar, has expertise in various techniques, methods and information relating to aforesaid technology which could be used for the production of the **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"**.

Role of ICMR

i. **ICMR- Regional Medical Research Center Bhubaneswar (RMRCBB)** will provide expert guidance & technical support for the production of **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"**, in all phases. Such technical oversight by **ICMR- Regional Medical Research Center Bhubaneswar (RMRCBB)** would accelerate the development of the Product and its commercialization.

ii. ICMR would provide technical support through its team of experienced scientists in study planning, product development, development of study protocol, results/data analysis, outcome assessment, safety & efficacy 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, which will be decided later under the Agreement.

iv. ICMR would provide technical support in development of technology/ product and will also facilitate the validation, if required, as per the terms & conditions of the Agreement.

v. 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/ validation/ scale-up either directly or otherwise.

ii. The Company shall have provisions to undertake the scale-up as required, manufacturing and commercialization of **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"**, in a set milestone.

iii. The Company agrees to share the technical data with ICMR 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 to visit the designated lab/ production facility as and when required, as envisaged under this EoI and subsequent Agreement.

v. 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.

5. Intellectual Property Rights

It is submitted that in case of transfer of Technology, ICMR 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.

ICMR 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), and/or ICMR is lawfully entitled to enter into any form of non-exclusive License Agreements with selected companies including transfer of the Technology through suitable Agreement(s).

In case of collaboration between ICMR and the Company for the Joint development of the Technology/ Product, Background Intellectual Property ("BGIP") shall always remain the sole and Non-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, as revised and approved by the Competent Authority.

6. Process involved in Partnership/Collaboration/Technology Transfer

Interested companies/manufacturers are invited to join hands with ICMR for co-development/ further development & commercialization of the Technology/ 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 partnership/collaboration/technology transfer, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay the Royalty @ 2% on Net sales, as applicable, according to the ICMR Guidelines for Technology Development Collaboration.

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 can be given due to advantage of authorships in the publications arising out of Licensing/co-development.

8. Data Rights

i. Data rights shall be jointly owned by ICMR and Licensee/Co-developer.

ii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.

iii. Licensee/ 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.

iv. Rights will be exclusively with ICMR, if ICMR provide 100% funding.

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-Litigation (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 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.

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.	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 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:

For scientific issues –
Dr. Susheel Singh, PhD,
Scientist-D
Bio-molecular Engineering Division
ICMR-Regional Medical Research Centre,
Nalco Square, Chandrasekharpur, Bhubaneswar, Odisha-751023
Cell/WhatsApp: +91-6370400680
Email: skbaghel@gmail.com; susheel.13@icmr.gov.in

Dr. Subhash Singh, PhD,
Project manager
Bio-molecular Engineering Division
ICMR-Regional Medical Research Centre,
Nalco Square, Chandrasekharpur, Bhubaneswar, Odisha-751023
Cell/WhatsApp: +91-9419125539
Email: subhash0974@gmail.com;

For Technical issues –
Medical Innovations Patent Mitra Team,
Email: patentmitra.hq@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 Transfer of Technologyof "**A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"**and manufacturing, commercialization of Vaccine candidate, useful in in **Preventing *Plasmodium falciparum* infection in humans and minimizing community transmission**.

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Ref:ICMR/EoI/PM/05/Malaria vaccine (AdFalciVax)/2025 dated …….

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: EoI No. ICMR/EoI/PM/05/Malaria vaccine (AdFalciVax)/2025 dated …….

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for 'Transfer of Technology of **"A recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*"**and commercialization of vaccine candidate, useful in **preventing infection in humans and for minimizing community transmission.**

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:……..

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/PM/05/Malaria vaccine (AdFalciVax)/2025 dated……..

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/PM/05/Malaria vaccine (AdFalciVax)/2025 dated ……..

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/PM/05/Malaria vaccine (AdFalciVax)/2025 dated……..

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 recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against Plasmodium falciparum".**

Yours faithfully,

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

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

*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/PM/05/Malaria vaccine (AdFalciVax)/2025 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 manufacturing of …… (Name ofTechnology/ 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:**

-A recombinant chimeric multi-stage malaria vaccine against *Plasmodium falciparum* for preventing infection in humans and for minimizing community transmission.

- Process for expression in *Lactococcuslactis* and purification of novel recombinant chimeric multi-stage malaria vaccine (AdFalciVax) against *Plasmodium falciparum*.

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

Malaria continues to pose serious challenges to public health and economies, particularly in the tropical and subtropical regions around the world. Globally in 2023, there were almost 263 million estimated malaria cases in 83 malaria-endemic countries, an increase of 11 million cases compared with 2022. India accounted for half of all estimated malaria cases in the South-East Asia region in 2023. The introduction and rollout of malaria vaccines, such as RTS,S and R21/Matrix-M, have shown promise in reducing disease incidence, particularly among young children in high-burden areas. While significant progress has been made in combating malaria, the global burden remains substantial. In order to address the goal of malaria elimination, an improved vaccine with better efficacy needs to induce protection against infection in human hosts as well as block or reduce transmission to the mosquito vector. It has been hypothesized that a combination of Pre-erythrocytic/Anti-Infection Vaccines (AIV) with Transmission-blocking Vaccines (TBV) will reduce the force of infection and be more efficacious than an AIV, like RTS,S or R21/Matrix-M alone. In this proposed technology, we developed a process for the production of *P. falciparum* recombinant chimeric malaria antigen (AdFalciVax) consisting of full-length CSP together with PfsPro.6C (consisting of subdomains from Pfs230 & Pfs48/45, both leading transmission-blocking antigens) and have tested it for improved immunogenicity with different adjuvant formulations (alum or spray-dried alum-based microparticle formulation).

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

TLR-4 (Third party validation ongoing)

iv. **Validation Status and outcome:**

In-house validation for expression, purification and characterization of therecombinant chimeric multi-stage malaria vaccine (AdFalciVax) in *Lactococcuslactis* (technology) has been completed at ICMR-RMRCBB.The pre-clinical validation of this technology has been conducted in collaboration with ICMR-National Institute of Malaria Research (ICMR-NIMR), another constituent institutes of ICMR and National Institute of

Immunology (NII), New Delhi, an autonomous research institute of Department of Biotechnology, Government of India. Further third-party validation for Standard Membrane feeding assay (SMFA) for transmission blocking is being carried out at TropIQ Health Sciences, Nijmegen, the Netherlands.

v. **IP Filing Status/Publications**

Application number: 202411095679

Title: Producing a chimeric recombinant multi-stage vaccine for preventing *Plasmodium falciparum* infection and its community transmission

Date of filing: December 04, 2024

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