EOI No. VU/9/2022/ECD

Expression of Interest (EOI)

Indian Council of Medical Research, New Delhi

invites EoI for

Joint collaboration for development of vaccine against Kyasanur Forest Disease (KFD)

Indian Council of Medical Research
(Department of Health Research, GoI)
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P.O. Box No. 4911, Ansari Nagar,
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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 vaccine manufacturer/ pharma companies/ R&D Institutions etc. for undertaking R&D activities using KFDV isolate for development of vaccine against KFD and its manufacturing/commercialization etc.

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	**VU/9/2022/ECD**
Date of Publication	**Date: 23.02.2023**
Last date of submission	**Date: 17.03.2023**

Note: The EOI may be submitted through email to jitendra.narayan@gov.in. Shortlisted firm(s)/organization(s) shall only be contacted for the further process.

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 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.

Kyasanur Forest Disease (KFD) is a highly infectious viral illness transmitted by infected ticks through contact with monkeys and other wild animals. Till date there is no definite treatment available for KFD. Hence, vaccination is considered to be an important public health intervention to control KFD. Intramuscular administration of formalin inactivated indigenous KFD vaccine to the susceptible population has been found to drastically reduce the percentage of incidences. As the vaccine-induced immunity is short-lived, the first booster dose is recommended in about 6–9 months after the primary vaccination; thereafter, administration of annual booster dose is recommended for five years after the last confirmed case in the area. However, recent data show recurrence of KFD cases even in the vaccinated subjects, which may probably be due to the sub-optimal efficacy of the current vaccine or vaccination protocol. Additionally, the vaccine-associated side effects, such as pain, and administration of booster doses for five years are also believed to be some of the potential discouraging factors that might affect the vaccine acceptability. To overcome this problem, ICMR took the farsighted initiative for development of a new vaccine candidate which is intended to have higher efficacy and safety of the recipients. ICMR NIV Pune has isolated and characterized KFDV isolates from the recent outbreaks of KFDV held in Karnataka State. The genomic analysis was carried out with the 48 whole genomes of KFDV reported during 1957–2017, that indicated overall highly conserved genome2.24% and 0.75% divergence at nt/aa level.

Currently, there are no treatment options available and the inactivated whole virus vaccine is not sufficiently efficacious to control KFDV infection and to reduce the burden on India's public health system. KFDV outbreaks are very often in recent years highlighting the need for more potent countermeasures including more effective vaccines.

In a study done by Kasabi et al.,(2013), reported the effectiveness of KFD vaccine administered during the period from 2005-2010 , found that, vaccine was 62.4% effective among those who received two doses and 82.9% effective in those who received two doses followed by a booster dose, as compared to unvaccinated individuals.

The seed virus used for the current KFD vaccine P9605 was isolated in 1965 and has undergone several passages in mice. The current vaccine is a formalin inactivated and does not have the WHO approval. Also the current vaccine that was developed based on the strain isolated in early 1970s and not seem effective against the current circulating strain of KFD. There are reports of 2.24% diversity in the currently circulating strains of KFD virus in contrast to the strain used for vaccine preparation which was isolated in 1957. Therefore, it may be appropriate to develop a new and future ready KFD vaccine candidate using new isolates and advance technologies.

3. Intellectual Property Rights

ICMR National Institute of Virology (NIV), Pune one of the constituent Institutes of the Indian Council of Medical Research (ICMR), New Delhi, has isolated recent and useful **KFDV isolates** and is the owner of said TECHNOLOGY including any underlying Intellectual Property(ies) and Commercialization rights. By virtue of financial support and research endeavor provided by 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) on the invention(s) arising out of such endeavors, and/or ICMR is lawfully entitled to enter into any form of non-exclusive license agreements with selected vaccine manufacturer(s) including transfer of the TECHNOLOGY through suitable agreement..

4. Objective

To make available Kyasanur Forest virus (KFDV) isolates for undertaking R&D as well as manufacturing activities using characterized isolates of KFDV for development of vaccine candidate against Kyasanur Forest disease.

5. Broad Scope of collaboration

- **i.** ICMR is willing to collaborate with experienced vaccine manufacturer for undertaking R&D as well as manufacturing activities using characterized KFDV isolates for development of potential vaccine candidate against Kyasanur Forest disease.
- **ii.** The firm(s)/organization(s) would be granted rights to undertake further R&D, manufacture, sell, and commercialize the end products 'vaccine candidate' against the Kyasanur Forest disease.
- **iii.** The MoU/MoA, following after all the processes, is proposed to be executed on "Non-Exclusive" basis with single/multiple firms, due to the extensive demand of KFDV isolates which is being envisaged to develop vaccine candidates.
- **iv.** ICMR-NIV has in its possession of **KFDV isolates** useful for development of a vaccine against Kyasanur Forest disease. ICMR-NIV has expertise in various techniques, methods and information relating to these strains which could be used for development of vaccine, drug, and other R&D activities etc. ICMR-NIV will provide expert guidance & technical support on the R&D and product development, in all phases. Such technical oversight by ICMR-NIV would accelerate the development of the Product.
- **v.** The process developed by firm(s)/organization(s) during the course of development of the Product encompassing IP, shall be owned jointly by ICMR and firm(s)/organization(s). 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 through ICMR support;
- **vi.** ICMR would provide technical support through team of experienced scientist in study planning, product development, development of clinical trial protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, and other, if deemed fit upon the mutual understanding between ICMR and collaborative company.
- **vii.** ICMR through its institutes would provide support and facilitate to conduct the clinical trial of new vaccine candidate in India through its Affiliates/ Institutes, in collaboration with company/institutions in a professional and mutually agreed-upon manner and timelines, which will be decided later under the MoA/MoU.
- **viii.** The Company will undertake the research & development, scale-up of vaccine candidate, manufacturing and commercialization of KFD vaccine.
- **ix.** The partnering company shall provide necessary infrastructure and depute experienced/skilled manpower.

x. The company will share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.

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

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

6. Process involved in Partnership/Collaboration/Technology Transfer

Interested companies/manufacturers with demonstrated capabilities in vaccine manufacturing are invited to join hands with ICMR for development & validation of vaccine candidate. 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, capabilities and demonstrated experience in vaccine manufacturing. On shortlisting of technically suitable companies, 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 along with their financial proposal w.r.t. upfront payment and royalty component, in line with the applicable revenue sharing policy of ICMR. Selection of candidates will be decided on the basis of their offers at the RFP stage. Qualified companies/manufacturers will only be contacted for execution of MoA/MoU/Agreement for partnership/collaboration/technology transfer.

7. Details of documents to be furnish

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical 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 further submission of proposal.

10. 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**	**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 vaccine/ drug/ pharma product 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
7	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 – 4)

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 doses per week	Undertaking (As per format – 6)
11	Scientific Plan	A brief concept note on planning & execution, product development, clinical trials, regulatory affairs, production, 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. Pragya Yadav, Scientist-F, ICMR-NIV, Pune, Email: - hellopragya22@gmail.com;
Dr. Jitendra Narayan, Scientist C, ICMR HQ, New Delhi Email: jitendra.narayan@gov.in

For Administrative issues

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

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. VU/9/2022/ECD dated 23.02.2023

Sir,
This has reference to your above-mentioned Expression of Interest (EOI) for Collaboration for R&D and development of vaccine against KFD.

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 R&D and manufacturing, commercialization of vaccine against Kyasanur Forest disease.
Ref: VU/9/2022/ECD dated 23.02.2023

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/ commercialization /manufacture/ sell 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.		
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 &	As per format – 3	

	Stamped by Authorized Signatory		
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 R&D 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:

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: VU/9/2022/ECD dated 23.02.2023

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: VU/9/2022/ECD dated 23.02.2023

Sir,

It is hereby confirmed and declared that M/s…..... do have adequate laboratory infrastructure. Please tick BSL-2/BSL-3/ABSL-3/GMP/Other (if other please specify)

2. Adequate no. of experienced staff/skilled manpower to undertake research on vaccine development.

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: VU/9/2022/ECD dated 23.02.2023

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:

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: VU/9/2022/ECD dated 23.02.2023

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 vaccine doses min. 01 (one) lakh unit per week.

Yours faithfully,

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