EOI No.ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022, dated 17.03.2022

Expression of Interest (EOI)

Indian Council of Medical Research, New Delhi

invitesEoI for

Joint collaboration for development of vaccine against COVID-19 (Omicron variant)

Indian Council of Medical Research
(Department of Health Research, GoI)
V. RamalingaswamiBhawan,
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 vaccine manufacturer/ pharma companies/ R&D Institutions etc.for undertaking R&D activities using SARS-CoV-2 Omicron variant for development of vaccine against COVID-19 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	ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022dated 17.03.2022
Date of Publication	Date: 17.03.2022
Last dateof submission	Date: 04.04.2022 IST 17:30

Note: Due to the current COVID-19 pandemic situation, 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 of finalization of agreement.

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.

ICMR-National Institute of Virology (ICMR-NIV), Pune, one of the Institutes of the Indian Council of Medical Research (ICMR), New Delhi had isolatedthe SARS-CoV-2 virus and its Omicron variant (including sub-lineages), which are being propagated on specific cell lines under the biosafety laboratory conditions. These isolates were further purified and characterized using the complete genome sequencing. Tissue culture infective dose (TCID50) has been estimated and bulk propagation of the virus stock has been achieved.

ICMR reserved all the Intellectual Property Rights and Commercialization rights on the SARS-CoV-2 Omicron variantvirus isolates. ICMR is lawfully entitled to enter into any form of non-exclusive agreements with experienced Drug/Pharma/Vaccinemanufacturers through defined agreement for undertaking R&D as well as manufacturing activities using characterized SARS-CoV-2 Omicron variant for development of vaccine against COVID-19, hereinafter referred to as the 'Product'.

3. Objective

To make available SARS-CoV-2 Omicron variantfor undertaking R&D as well as manufacturing activities using characterized SARS-CoV-2 Omicron variants for development of vaccine against COVID-19.

4. Broad Scope of Work

- **i.** ICMR is willing tocollaborate with experienced vaccine manufacturer on**Royalty**basis on fixed termcontract condition forundertaking R&D as well as manufacturing activities using characterized SARS-CoV-2 Omicron variants for development of vaccine against COVID-19.
- **ii.** The firm(s)/organization(s) wouldbe granted rightsto undertake further R&D, manufacture, sell, and commercializethe end products 'vaccine candidate' against the COVID-19.

iii. The MoU/MoA, following EoI is proposed to be executed on "Non-Exclusive" basis with single/multiple firms, due to the extensive demand of SARS-CoV-2 strain isolateswhich is being envisaged to develop vaccine candidates.

iv. ICMR-NIV has in its possession of SARS-CoV-2 Omicron strain(s) useful for development a vaccine against COVID-19. 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. against COVID pandemic. ICMR-NIV will provide expert guidance&technical supporton 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 EoIthrough ICMR support;

5. 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 a new and useful SARS –CoV-2 Omicron strain and is the owner of said TECHNOLOGY including any underlying Intellectual Property(ies) and Commercialization rights. By virtue of financial support and research endeavour 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 endeavours, and/or ICMR is lawfully entitled to enter into any form of non-exclusive license agreements with selected R&D/academic institution(s) and manufacturer(s) including transfer of

the TECHNOLOGY through suitable agreement to any other interested firm/organization/companies etc.

6. Revenue upon Technology Rights

Interested companies/manufacturerswith demonstrated capabilities in vaccine manufacturing are invited to join hands with ICMR for further development & validation of product.

The manufacturers/companies interested in this collaboration may quote **Royalty** not less than 5% (five percent) on **Net Sales** of the ENDPRODUCT on half yearly basis as entered in the books of account maintained by Company/Manufacturer, up to 31st March and up to 30th September respectively every year regularly and punctually and in any event not later than the last day of April and last day of October immediately following in every such year provided that the liability of the Company/Manufacturer to pay royalty shall accrue upon the commencement of the commercial sale of the Product **("Royalty")** manufactured at the plant, as per the terms of ICMR-Technology Transfer and Revenue Sharing Guidelines 2021 and as per the amendments approved by the competent authority from time to time.

In the event of default in payment of royalty as above, interest @ 12% (twelve percentage) per annum on the Royalty due shall be charged for the first six months. If default persists for more than six months interest at similar rate will be charged on the accrued interest also from the due dates of payments till realization/recovery of such amounts by the ICMR. Taxes and levies, as made applicable by the Government, shall be charged at the time of payments made to ICMR over and above the payments that shall be applicable as per terms of specified license Agreement to be executed with selected companies.

"NET SALES"shall mean gross sales made by company/its sub-licensee/marketing partner/affiliates based on ex-factory sale price of the product excluding sales Tax & Excise Duty or any other tax, as applicable at the given point of time, on invoice price which is realized from the party as defined by the Indian Accounting Standards and duly certified by the Chartered Accountant.

7. Validity of contract

i. A MoU/MoA shall be executed with Company/Manufacturer to decide conditions for execution of this collaborative activity. The MoU/MoA shall have a defined time line, which will be decided mutually by both the parties, considering the R&D requirements for product development.

ii. The MoU/MoA 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 not be less the twenty (20) years or shall be decided mutually with the approval of competent authority, commencing from the accrual of Company's obligation to pay **Royalty** to ICMR, after the commercialization of the Product (the "Term"). After the end of LICENSE term, the product will be royalty free.

8. 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 / 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.** Royalty Offer (Format-7)
- **viii.** EOI document with each page duly stamped and signed by the Authorized signatory.
- **ix.** Supporting documents, as mentioned in Format-2
- **x.** MSME Certificate (if applicable)
- **xi.** Concept note on business plan
- **xii.** 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.

9. 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 PQC.
- The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.

10. 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.Shortlisted proponent shall be sent the License agreement, approved by the competent authority, ICMR for execution.

11. 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/ proprietorshipfirm underrespective acts in India.	Registration of firm/organization/Company Incorporation Certificate from ROC/Partnership deed etc. whichever is applicable
2	The proponent must be registeredin 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 notblack-listed by any Central /State Government / Public Sector Undertaking, Govt. of India, at least in three (3) immediate	Undertaking on the Letter Head ofthe Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).

	preceding Years. (applicable on commercial firms/organizations only)	
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 theMoU.	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	Royalty offer	(As per format – 7)
12	Business Plan	A brief concept note on planning & execution, product development, clinical trials, regulatory affairs, production, marketing etc. (not more than 5 pages)

12. Disclaimer

- ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
- ICMR reserves the right to reject all applications 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.

13. Contacts

In case of any clarification required, please contact:

For scientific issues-

Dr. Pragya Yadav, Scientist-E, ICMR-NIV, Pune, Email: -hellopragya22@gmail.com;

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. ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022 dated 17.03.2022

Sir,
This has reference to your above-mentioned Expression of Interest (EOI) for Collaborationfor R&D and development of vaccine against COVID-19.

Mr./Ms./Mrs./Dr……..is herebyauthorized 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 collaborationfor R&D and manufacturing, commercialization of vaccine against COVID-19.

Ref:ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022 dated 17.03.2022

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 theresearch &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 orGST 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 inIndia.		
6	GMP and ISO Certification. Registrationcopies ofboth		
7	Authorization Letter	As per format – 1	
8	Undertaking on theLetter Head of the Proponent duly signed& Stamped byAuthorized 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	Royalty Offer	As per format – 7	
13	MSME Certificate (if have any)		
14	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:

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: EOI No. ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022 dated 17.03.2022

Sir,

It is hereby confirmed and declared that M/s……has not been blacklisted/debarredbyanyGovernmentDepartment/PublicSectorUndertaking/oranyotheragency forwhichworks/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: EOI No. ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022 dated 17.03.2022

Sir,

It is hereby confirmed and declared that M/s……..... do have adequate laboratory infrastructure (equipped laboratory facility) and 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: EOI No. ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022 dated 17.03.2022

Sir,

It is hereby confirmed and declared that M/s…..... and owner of the firm/board of directors, donot 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: EOI No. ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022 dated 17.03.2022.

Sir,

It is hereby confirmed and declared that M/s…… doeshave the capacity in all mean (includinginfrastructure, 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:

Format-7

Undertaking for Royalty
(To be submitted on Agency's Letter Head)

To,

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

Subject: Undertaking for Royalty.
Ref: EOI No. ICMR/EOI/OS/SARS-CoV-2 (OMICRON) Strain/2022 dated 17.03.2022

Sir,

It is hereby confirmed that M/s ……, agrees to pay a Royalty of **……. % (……. Percent)**to the ICMR to be calculated against the **Net Sales** done with respect to the product developed under this collaboration.

(As per the terms of ICMR-Technology Transfer and Revenue Sharing Conditions, the**"NET SALES"** shall mean gross sales made by company/its sub-licensee/marketing partner/affiliates based on ex-factory sale price of the product excluding sales Tax & Excise Duty or any other tax, as applicable at the given point of time, on invoice price which is realized from the party as defined by the Indian Accounting Standards and duly certified by the Chartered Accountant)

Yours faithfully,

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

SCHEDULE – (A)

Joint collaboration for development of vaccine against COVID-19 (Omicron variant)

i. About the Technology/Product/Process:

The ability of SARS-CoV-2 to rapidly mutate has been the biggest challenge the world has faced while responding to the pandemic. Omicron has posed a serious public health concern due to the mutations/deletions associated with increased binding affinity to ACE2 (S:Q498R, S:N501Y), increased transmissibility (S:H655Y, S:N679K, S:P681H), increased viral load (N:R203K, N:G204R), innate immune evasion (ORF1a:L3674-, ORF1a:S3675-, ORF1a:G3676), and S-gene target failure (S:H69-).

Corona viruses use spike proteins to attach to ACE-2 receptors on the surface of human cells and the omicron variant contains a new pattern of mutations in its spike protein. These changes could disrupt the ability of the antibodies induced by the current vaccines to bind to the spike protein. If that happens, the vaccines could be less effective at severe infections and death.

ICMR NIV Pune has isolated and characterized Omicron variant (Including sub-lineages) from COVID-19 positive human clinical specimens. The isolated Omicron strain would be useful in developing of newer vaccines.

ii. Need and utility of invention:

Studies conducted by ICMR-NIV and DBT-THSTI suggest that Omicron evades vaccine induced immunity and can lead to mild breakthrough infections in vaccinated individuals. Another study conducted by ICMR-NIV reports substantial immune response in individuals infected with Omicron. The neutralizing antibodies generated by breakthrough infections can effectively neutralize not only Omicron but other VOCs like delta, alpha and beta.This overall indicated the need for Omicron variant vaccine. Therefore, it may be opportune to develop an Omicron-specific vaccine candidates.

iii. Scope for collaboration:

This collaboration will open up scope for development of new vaccine candidates, improvement of existing vaccine, to fight against COVID-19 pandemic, collaborative research etc.

iv. Role of ICMR

a. 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.

b. ICMR through its institutes would provide support and facilitate to conduct the clinical trial of developed vaccine candidate in India through one or more of 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.

v. Role of company

a. The Company will undertake the research activities using SARS-CoV-2 Omicron variant for development, manufacturing and commercialization of COVID-19 vaccine.

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

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

d. The company will allow authorized personnel/scientist/team of ICMR to participate in R&D activities and to carry out specific project activities as envisaged under this EoI and subsequent MoA.

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

Methodology/process:

ICMR-NIV Pune has isolated Omicron variant (Including sub-lineages) strains using Vero CCL-81 cells. Confirmation of the isolates was performed using next generation sequencing. These isolates were further purified and characterized using the complete genome sequencing. Bulk preparation of the virus stock was undertaken and Tissue culture infective dose (TCID50) was estimated.

vi. Envisaged outcome:

Development of the Omicron variant vaccine or multi strain vaccine for the eliciting strong, durable, and broad immune responses for robust clinical protection against current and future SARS-CoV-2 variants and be a first step towards developing a pan-coronavirus vaccine.

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