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स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

File No. EoI/MISC/2023/MD **dated: 13/05/2024**

Division of Communicable Diseases

Notification

This is to notify that due to inadequate number of response received during the previous call for Expression of Interest (No. EoI/MISC/2023/MD dated 01.03.2024) published on the ICMR website with a closing date of 31.03.2024, the competent authority has decided to reopen the call for Expression of Interest for joint collaboration in R&D, manufacturing, and commercialization of broad specificity Salmonella vaccine useful, against typhoid and paratyphoid fever and Salmonella Typhimurium gastroenteritis.

2. Details of EoI call for reopening-
   i. EoI No. EoI/MISC/2023/MD
   ii. Date of re-publication: 13.05.2024
   iii. Closing date for submission: 12.07.2024

3. Interested vaccine manufacturers/ pharma companies/ R&D Institutions are encouraged to submit their interest as per the instruction given in the EoI document.

4. Industries/companies which had already submitted the proposal/application during the previous call, need not submit again. Their earlier proposal shall be considered during the process of current evaluation.

13/05/2024

(Mr. Ved Prakash)
Administrative Officer

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं. 4911,
अंसारी नगर, नई दिल्ली - 110 029, भारत
V. Ramalingaswami Bhawan, P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110 029, India

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EoI No. EoI/MISC/2023/MD **Dated: 13/05/2024**

Expression of Interest (EoI)

For

joint collaboration in R&D, manufacturing, and commercialization of broad specificity *Salmonella* vaccine useful against typhoid and paratyphoid fever and *Salmonella* Typhimurium gastroenteritis

By ICMR-Hqrs

Indian Council of Medical Research
(Department of Health Research, GoI)
V. Ramalingaswami Bhawan, P.O. Box No. 4911, Ansari Nagar,
New Delhi - 110029, India

CONTENTS

Letter of Invitation

1. Invitation of expression of interest

Indian Council of Medical Research (ICMR), New Delhi, invites Expression of Interest (EoI) from experienced Indian agencies for '**Joint development and commercialization of a broad specificity glycoconjugate vaccine against *Salmonella* Typhi, *Salmonella* Paratyphi and *Salmonella* Typhimurium'**

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	**EoI No. EoI/MISC/2023/MD**
Date of re-publication	**13/05/2024**
Last date/Time of submission	**12/07/2024**

Note:

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

MDMS Unit (New Building 2nd Floor)
Indian Council of Medical Research,
V. Ramalingaswami Bhawan,
P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110029, India.

EoI Document No. **"EoI/MISC/2023/MD"** along with the title of the EOI as **"EoI for Technology Transfer/ Joint Development"** in **Bold** and complete address as above must be clearly mentioned on the sealed envelope. Only shortlisted firm(s)/organization(s) will be invited to participate in the Request for Proposal (RFP).

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-National Institute of Cholera and Enteric Diseases (ICMR-NICED), Kolkata, one of the constituent institutes of the Indian Council of Medical Research (ICMR), has developed a new technology entitled "A glycoconjugate vaccine formulation of *Salmonella* Typhi and Paratyphi outer membrane protein T2544 and *Salmonella* Typhimurium O-specific polysaccharide (OSP) as a novel vaccine candidate and broad specificity *Salmonella* vaccine formulation and ICMR-NICED has technical-know-how of process to prepare thereof" (hereinafter) referred to as **"Technology".**

ICMR is lawfully entitled to enter into any form of **non-exclusive agreements** with experienced manufacturing companies hereinafter referred to as the **"Company"/ "licensee"** through a defined agreement for Licensing/Commercialization of *Salmonella* glycoconjugate vaccine, hereinafter referred to as the **'Product'** which shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority**.**

3. Objective: Objectives intended under this joint collaboration are as follows:

- **i.** To validate the technology "**broad specificity glycoconjugate vaccine against *Salmonella* Typhi, *Salmonella* Paratyphi and *Salmonella* Typhimurium**" developed at ICMR-NICED, Kolkata
- **ii.** To develop the product "**broad specificity glycoconjugate vaccine against *Salmonella* Typhi, *Salmonella* Paratyphi and *Salmonella* Typhimurium**" with proper regulatory compliances and it's commercialization & marketing.

4. Scope of Work

i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for undertaking validation, joint development and commercialization of Product i.e. broad specificity

Salmonella Vaccine, in two phases:

Phase I: Independent validation of the broad specificity Salmonella vaccine developed by ICMR-NICED Kolkata.

Phase II: Joint R&D and co-development of the broad specificity Salmonella vaccine candidate for further scaleup, and regulatory permissions, clinical trial, commercialization, and marketing etc

ii. Company would be granted rights to undertake scientific/technical validation of the 'Technology' as a Phase-I, only after signing of a non-disclosure agreement (NDA)

iii. On successful completion of Phase-I with satisfactory results, the Company would be granted rights to undertake further research & development for scaleup, obtaining regulatory clearances, clinical trials, manufacturing, and commercialize the broad specificity Salmonella Vaccine.

iv. An Agreement following EoI and RFP is proposed to be executed on Non-exclusive basis with single/multiple companies to enable wider outreach of the broad specificity Salmonella Vaccine 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.

v. ICMR-NICED Institute has expertise in various techniques, methods, information, technical-know-how relating to aforesaid technology which could be used for the co-development of broad specificity Salmonella Vaccine.

Role of ICMR

i. ICMR-NICED Institute shall provide the company selected through the EoI with the 'Technology' after signing a non-disclosure agreement (NDA) for independent validation of the 'Technology' during phase-I.

ii. If the Phase-I is successful, ICMR-NICED Institute will provide expert guidance & technical support for the co-development of broad specificity Salmonella Vaccine, in all phases. Such technical oversight by ICMR-NICED Institute would accelerate the development of the Product and its commercialization.

iii. 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.

iv. 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.

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

Role of company

i. The Company shall have to undertake the technical/scientific validation of the technology as a Phase-I of this joint collaboration, and shall share the data generated after the validation to the ICMR.

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

iii. The Company shall have provisions to undertake the scale-up as required, manufacturing and commercialization of the broad specificity Salmonella Vaccine, in a set milestone.

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

v. 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.

vi. 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

Interested companies/manufacturers are invited to join hands with ICMR for co-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. 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 ICMR Guidelines for Technology Transfer and Revenue Sharing, as amended from time to time. 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, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay the Royalty, subject to approval as provided under ICMR Guidelines for Technology Transfer and Revenue Sharing.

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.

9. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, scope of work forexecution & requirements with respect to technical capabilities for submission of interest, subject for verification by ICMR.

Documents to be furnished are as follows:

a. Declaration - Expression of Interest (Format – 1)
b. Authorization Letter (Format – 2)
c. Undertaking with regard to Blacklisting (Format-3)
d. Undertaking with regard to Non-Litigation (Format – 4)
e. EoI document with each page duly stamped and signed by the Authorized signatory.
f. Undertaking with regard to laboratory facility (Format – 5)
g. Production Capacity Undertaking (Format-6)
h. Supporting documents, as mentioned in Format-1
i. MSME Certificate (if applicable)
j. 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)
k. Non-disclosure agreement (NDA) for the Phase I of the EoI
l. 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 aclarification 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 as per requirements.
iv. Received after the expiry of due date and time.
v. All relevant supporting documents are not furnished with the PQC.
vi. The proposal shall be substantially responsive without any material deviation, failingwhich 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. Only shortlisted proponents shall be provided with

RFP.

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 ten 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,	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized

	(applicable on commercial firms/organizations only).	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 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 Agreement	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
8	GMP/ quality certification (ISO or approved Indian certification for standards) 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)

13. Disclaimer

i. ICMR shall not be responsible for any late receipt of applications for any reason whatsoever.

ii. ICMR reserves the right to reject all applications without assigning any reasons thereof.

iii. ICMR may relax or waive any of the conditions stipulated in this document as deemednecessary 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

Any dispute and/ or any part of the dispute that 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 in New Delhi will have exclusive jurisdiction.

15. Contacts

In case any clarification is required, please contact:

For scientific issues

Director, NIOH, email santasabujdas@yahoo.com; director-nioh@gov.in

For Administrative issues

Dr. Suchita Markan, MDMS Division, ICMR Hq, Email: suchita.markan@icmr.gov.

Format-1

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 in R&D and manufacturing, commercialization of broad specificity *Salmonella* vaccine useful against typhoid and paratyphoid fever and *Salmonella* Typhimurium gastroenteritis**.

Ref: EoI/MISC/2023/MD dated 13.05.2024

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:

1	Name of the Proponent	
2	Address	
3	Name, designation & address of the person towhom all references shall be made	
4	Telephone No. (with STD code)	
5	Mobile No. of the contact person	
6	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 notes on planning & execution, production, marketing etc. (not more than 5 pages)	
12	Non-Disclosure Agreement (NDA)	NDA to receive the said technology for independent validation (Phase I)	

I/we hereby declare that my/our EoI is made in good faith and the information contained is true andcorrect to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Authorised signatory)

Name:

Designation:

Seal:

Date:

Place:

Format-2

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 SignatoryRef.

Ref: EoI No. **EoI/MISC/2023/MD dated 13.05.2024**

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for **joint collaboration in R&D and manufacturing, commercialization of broad specificity *Salmonella* vaccine useful against typhoid and paratyphoid fever and *Salmonella* Typhimurium gastroenteritis.**

Mr./Miss/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

U **Undertaking with regard to blacklisting**

n (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/MISC/2023/MD dated 13.05.2024

Sir,

It is hereby confirmed and declared that M/s…… (Company Name) currently has not been blacklisted / debarred by any Government Department / Public Sector Undertaking / or any other company for which works/assignments/services have been executed / undertaken.

Yours faithfully,
(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Date:
Place:

Format-4

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/MISC/2023/MD dated 13.05.2024

Sir,

It is hereby confirmed and declared that M/s….....(Company Name) 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:

Date:

Place:

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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/MISC/2023/MD dated 13.05.2024

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 **broad specificity *Salmonella* vaccine**.

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Date:

Place:

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

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/MISC/2023/MD dated 13.05.2024

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 any previously successful Vaccine (Name of Technology/ Product), minimum …..……. (mention the quantity per week/per month).

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Date:

Place:

SCHEDULE-A

TECHNOLOGY DETAILS

i. About the Technology/Product/Process:

- A glycoconjugate vaccine formulation of *Salmonella* Typhi and Paratyphi outer membrane protein T2544 and *Salmonella* Typhimurium O-specific polysaccharide (OSP) as a novel candidate vaccine has been developed by a team of scientists at ICMR-NICED Kolkata which is ready for validation.
- If the validation is experimentally satisfactory, then a Novel broad specificity *Salmonella* vaccine formulation and process optimization can be done for further product development, scale-up, manufacturing, and commercialization.

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

Human *Salmonella* infections pose significant public health challenges globally, primarily due to low diagnostic yield of systemic infections, emerging and expanding antibiotic resistance of both the typhoidal and non-typhoidal *Salmonella* strains and the development of asymptomatic carrier state that functions as a reservoir of infection in the community. The limited long-term efficacy of the currently licensed typhoid vaccines, especially in young children and non-availability of vaccines against *Salmonella* Paratyphi and non-typhoidal *Salmonella* serovars necessitate active research towards developing a multivalent vaccine with wider coverage of protection against pathogenic *Salmonella* serovars. The candidate glycoconjugate, OSP-T2544 comprises of O-specific polysaccharide (OSP) from *Salmonella* Typhimurium and the conserved outer membrane protein (T2544) of *Salmonella* Typhi/ Paratyphi. O-Antigen in OSP-T2544 will confer protection against *Salmonella* Typhimurium and cross-protection to *Salmonella* Enteritidis, whereas T2544 will protect against both *Salmonella* Typhi and *Salmonella* Paratyphi. It is an advancement in the field of *Salmonella* vaccine development because it provides the necessary broad spectrum protection needed to achieve a vaccine of global utility.

iii. Technology Readiness level (TRL)

TRL-4/5

iv. Validation Status and outcome:

In-house validation was completed by ICMR -NICED. Third party validation is pending and to be done under this EoI (Phase I).

v. IP Filing Status/Publications

Patent application filed on 16th Oct. 2023 (Application no. 202311070211).