



NATIONAL INSTITUTE OF BIOMEDICAL GENOMICS

(A premier Autonomous Institute of Dept. of Biotechnology, Ministry of Science & Technology, Govt. of India)

EOI DOCUMENT

EOI No. NIBMG/Gene Panel/2024-25/021

Date : 03-10-2024

Expression of Interest for Joint development and Commercialization of Gene Panel/Diagnostic kit for
Early Oral Cancer Detection

Vendors who have already responded to the earlier EOI No. NIBMG/Gene Panel/2024-25/012 Dated
08.07.2024 (Tender ID: 2024_NIBMG_763254_1) and NIBMG/Gene Panel/2024-25/013 Dated. 13-08-2024
(2024_NIBMG_767890_1) do not need to re-apply.

October'2024

CRITICAL DATE SHEET

EOI No. NIBMG/Gene Panel/2024-25/021

Date : 03-10-2024

Published Date	03-10-2024 [06:00 PM]
Bid Document Download / Sale Start Date	04-10-2024 [09:00 AM]
Clarification Start Date	04-08-2024 [09:00 AM]
Clarification End Date	17-10-2024 [02:00 PM]
Bid Submission Start Date	04-10-2024 [09:00 AM]
Bid Submission End Date	23-10-2024 [04:00PM]
Bid Opening Date	24-10-2024 [04:30PM]

Expression of Interest for Joint development and Commercialization of Gene Panel/Diagnostic kit for Early Oral Cancer Detection

BRIC- National Institute of Biomedical Genomics (NIBMG) is a BRIC Institute, under the aegis of the Department of Biotechnology, Ministry of Science and Technology, in the year 2009. BRIC-NIBMG is explicitly devoted to research, training, translation & service and capacity-building in biomedical genomics. Based on deep genomic data and knowledge obtained from analysis of over 500 patients, scientists at BRIC-NIBMG have devised a gene panel for early oral cancer detection. Expression of Interest (EOI) is invited on behalf of the Director, BRIC-NIBMG, Kalyani for joint development and commercialization of gene panel/diagnostic kit for early Oral cancer detection.

1) Definitions

“Product” means the gene panel/detection kit for early Oral cancer detection.

“Bidder” means any firm making a formal proposal for licensing, further development and commercialization of the product. The word when used after the award of the contract shall mean the licensee with whom BRIC- NIBMG signs the agreement

“Document” means any embodiment of any text or image or any other electronic documents as per IT Act 2000

EoI Document Number	EoI No. NIBMG/Gene Panel/2024-25/021
Date of Publication	Date: 03-10-2024
Last date of submission	Date: 23-10-2024

2) Scope of work:

Joint Development and commercialization of a gene panel/diagnostic kit which will be used for Genomics based detection of very early oral cancer precursor lesions. Partners are sought who can lead the product through

- The gene panel/diagnostic kit should exhibit exceptional sensitivity and specificity for the detection of early oral cancer lesions based on the genomics markers obtained from a large number (>500) of patient samples.
- It should be possible to use the proposed gene panel/diagnostic kit in a clinical setting (like laboratories/district hospitals).
- The proposed gene panel/diagnostic kit should have a fast turnaround time, do rapid analysis and reporting, thereby enabling prompt diagnosis and timely treatment decisions.
- It should be cost-effective and affordable and give unambiguous results.
- The proposed gene panel/diagnostic kit can use any state-of-the-art technologies (for example genomics platform (sequencing, multiplex PCR, qPCR) and/or CRISPR and/or 3D printing to detect single nucleotide changes in the target genes/gene products.

BRIC-NIBMG commits to the co-development of the proposed the proposed gene panel /diagnostic kit to refine and expand the capabilities of the proposed gene panel /diagnostic kit.

The Company shall have valid provisions to provide all necessary infrastructure/ material/ manpower required for product development/ validation/ scale-up either directly or otherwise. The Company shall have provisions to undertake the scale-up as required, manufacturing and commercialization of the product, in a set milestone. 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.

2) Pre-qualification criteria: The following preconditions must be fulfilled by the bidder and supported by documentary evidence. Claims without documentary evidence will not be considered.

Sl. No.	Pre-Qualification Criteria (PQC)	Supporting copy of documents required (All documents must be self- attested by the authorized person of the bidder)
General Criteria		
1	The bidder 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 bidder must be registered in India with taxation and other administrative authorities.	GST Registration or GST exemption certificate/ PAN Card
3	The bidder should have proven prior experience of development 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 bidder 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 bidder should have good track record and currently not black-listed/ barred by any Central / State Government	Undertaking on the Letter Head of the bidder duly signed & stamped by Authorized Signatory (As per format in Annexure 1)
6	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
7	The bidder should have functional laboratory to carryout R&D for the product development	Undertaking on Bidder's Letter Head, duly signed and stamped by the Authorized Signatory (As per format in Annexure 2)

NOTE- The provisions related to Startups registered with DPIIT shall apply and if eligible for consideration, the relevant documents are to be submitted with the EOI

3) Evaluation of the EOI

Interested applicants may please send their EOI and supporting documents as specified in PQC in a sealed envelope to the following email address: eoiresearch@nibmg.ac.in

The subject should be “EoI for Technology Transfer/ Joint Development from (name of the bidder)”

- Bidder should include a concept note about planning and execution of the work. The note should also indicate the following:
 - (a) the approximate cost of making the prototype of the product
 - (b) the time frame required for the development of the gene panel
 - (c) the approximate cost of the product in market if launched
 - (d) the financial plan for development of the prototype
 - (e) the fees to be paid by bidder to BRIC-NIBMG for developing the prototype, if awarded the contract.
- All bids received within the last date specified in the advertisement for EOI will be screened and evaluated by BRIC-NIBMG.
- BRIC-NIBMG reserved the right to seek additional documentation or clarifications as and when required.
- 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 bidder(s) shall be called for further meetings and will be allowed to participate in the Global tender to be uploaded in the CPP portal.
- The proposal will be rejected if not properly stamped and signed or documents pertaining to the PQC are missing.
- Only the bidders who are qualified in the EOI will be allowed to take part in the normal tendering process via CPPP portal
- The decision of BRIC-NIBMG in evaluation of responses to the EOI will be final. BRIC-NIBMG reserves the right to reject any or all the EOI received or to close the process without assigning any reason.
- At the global tendering stage, if all the scientific evaluations are equal, NIBMG will enter into agreement with the bidder(s) who brings maximum financial benefit to the Institute.

Potential partners will be provided with non-exclusive license for commercialization and marketing of the gene-panel to enable wider public health benefits.

Annexure 1

Undertaking with regard to blacklisting
(To be submitted on Company's Letter Head)

To,
Director
BRIC-National Institute of Biomedical Genomics
P.O.: N.S.S.,
Kalyani 741251,
West-Bengal

Subject: Undertaking regarding Blacklisting / Non-Debarment.

Ref: NIBMG/Gene Panel/2024-25/021

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:

Place:

Seal:

Annexure 2

Undertaking with regard to laboratory facility
(To be submitted on Company's Letter Head)

To,
Director
BRIC-National Institute of Biomedical Genomics
P.O.: N.S.S.,
Kalyani 741251,
West-Bengal

Subject: Undertaking regarding Blacklisting / Non-Debarment.

Ref: NIBMG/Gene Panel/2024-25/021

Sir,

It is hereby confirmed and declared that M/s (Company Name) do have

- i. Adequate laboratory infrastructure (equipped laboratory facility; please specify the facilities) and
- ii. Adequate no. of experienced staff/skilled personnel to undertake manufacture/ research/ commercialization of gene panel/diagnostic kit for early oral cancer detection.

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Place:

Seal:

DETAILS OF TECHNOLOGY

Technology: Gene panel/Diagnostic kit for early oral cancer detection

Potential Impact:

Oral cancer is a significant health concern, with high mortality rates among males in India and is consistently among the top 5 causes of death among cancer patients in India in the last 2 decades. The proposed gene panel/diagnostic kit has the potential to early detection of oral cancer by targeting dysplastic lesions. Healthcare providers will benefit from the proposed gene panel/diagnostic kit as it will enable early detection and intervention of oral cancer, leading to better patient outcomes and reduced healthcare costs.

The proposed gene panel/diagnostic kit will offer an innovative tool for large-scale oral cancer screening, facilitating unbiased diagnosis and efficient testing workflows to Clinical Laboratories and public health providers/hospitals: