

EXPRESSION OF INTEREST (EOI)
for
Selection of partners for the licensing and development of gene therapy
products
For CSCR-inStem
Located at CMC-Vellore



Institute for Stem Cell Science
and Regenerative Medicine (DBT- inStem)

Issued By

Institute for Stem Cell Science and Regenerative Medicine(inStem),
GKVK Campus,
Bellary Road,
Bangalore 560065

Selection of partners for the licensing and development of gene therapy product developed by CSCR-inStem located at CMC-Vellore

Last for the submission of the EOI in sealed cover: 10-06-2024 till 1700 Hrs

Pre-Bid Meeting Scheduled on 03-06-2024 at 1430 Hrs

1. Introduction

The Institute for Stem Cell Science and Regenerative Medicine (inStem), an autonomous institute of the Department of Biotechnology, Government of India is dedicated to research in the area of stem cells and regeneration in the context of development and disease. inStem is a state-of-the-art research institute in Bangalore, India, dedicated to the study of stem cells and regenerative biology with translational emphasis.

The Centre for Stem Cell Research (CSCR-inStem), is the translational unit of DBT-inStem, Bengaluru, established in collaboration with the Christian Medical College (CMC), Vellore, an institution of eminence in healthcare, and is located at the CMC Campus, Bagayam, Vellore.

Scientists at CSCR-inStem and CMC, Vellore have developed novel product concepts for the gene therapy of inherited blood disorders. Further details of the technologies and related publications are noted under 'Scope of Work' below and are available on the CSCR website (www.cscr.res.in).

inStem / CMC invite expression of interest (EOI) for licensing and further product development of "Lentiviral vector - transduced autologous haematopoietic stem cell-based gene therapy for severe Hemophilia A (FVIII deficiency)" which is currently in Phase I clinical trials.

1.1 Definition of Terms

1.1.1 "Bidder" means any firm making a formal proposal for licensing and further development of one or more of these product concepts. The word when used after award of the Contract shall mean the Licensee with whom inStem signs the licensing and development agreement.

1.1.2 "Contract" is used synonymously with Agreement

1.1.3 "Document" means any embodiment of any text or image or any other electronic documents as per IT Act 2000.

1.1.4 "inStem" refers to the Institute for Stem Cell Science and Regenerative Medicine

1.1.5 "Licensee" means the bidder that has been awarded the Contract.

1.1.6 "Scope of Work" means all deliverables to be provided by the Licensee after award of Contract.

S. No	Particulars	Details
1	Document ID	INS-CSCR/EOI/01/2024
2	Release Date	08-05-2024
3	Shortlisting Method	As per Clause 2 and 3 of the EOI document
4	Name of the Inviting Authority	Director, Institute for Stem Cell Science and Regenerative Medicine(inStem), GKVK Campus, Bellary Road, Bangalore 560065
5	EOI issued by	inStem (On behalf of inStem and CMC)
6	Availability of EOI	EOI can be downloaded from: i) inStem website

		https://www.instem.res.in/tenders ii) Central Public Procurement Portal (CPPP) www.eprocure.gov.in EPublishing
7	Last Date of Submission of the EOI	Proposals must be submitted in a sealed cover on or before 10-06-2024 till 1700 Hrs

2. Pre-qualification Criteria (Shortlisting criteria under the EOI)

Following criteria prescribed as the Pre-Qualification criteria for bidder interested in undertaking the project shall be applicable. The bidder shall fulfil all the following preconditions and must submit documentary evidence in support of fulfilment of these conditions while submitting the bid. Claims without documentary evidence will not be considered.

S. No	Parameter.	Eligibility Criteria	Supporting Document/s
1	CP & OS	Company Profile & Organisation Structure	Company Profile and Organisation structure on letter head to be submitted
2	Legal Entity	i. An Organisation incorporated in India under the Companies Act, 1956, 2013 and subsequent amendments thereto/Firm/LLP/ Govt./PSU. ii. Should have GST Number iii. Should have a valid PAN Number	i. Copy of Certificate of Incorporation and Copy of Memorandum of Associations (MOA), Articles of Association (AOA) ii. GST Registration Copy iii. PAN Card copy
3	Financial Strength	Bidder should have positive Net Worth and demonstrated ability to raise funds necessary for development of product for which bid is being submitted.	Certificate from the Chartered Accountant for Positive Net Worth and a submission from management on ability to raise the necessary funds for product development and commercialization.
4	Related experience and capabilities	Demonstrated capabilities in developing gene therapies and other advanced medicinal therapies from laboratory proof-of-concept stage to commercialization.	Summary of product development and commercialization experience for similar products to be provided. Experience from multiple products can combined to demonstrate organizational capabilities.
5	Infrastructure	State-of-the art laboratory and cGMP manufacturing facilities for gene therapies and other advanced medicinal therapies.	Facility approval documents and detailed plans showing lab and manufacturing area layouts.
6	Non-Blacklisting	The Bidder should not be under a declaration of ineligibility for corrupt or fraudulent practices or Blacklisted.	Self—Declaration Letter duly signed by authorized signatory on company letter head as per format given

Note: The provisions related to Startups registered with DPIIT shall apply and if eligible for consideration, the relevant documents are to be submitted along with the EOI.

3. Evaluation of EOI

3.1 General Instructions on Bid Submission

3.1.1 The EOI shall be submitted in a single sealed envelope superscripted with “Expression of Interest for Licensing and Development of gene therapy products developed by CSCR-inStem located at CMC-Vellore” and bidder’s name. This envelope should contain EOI proposal and one soft copy of the same in the form of CD/USB.

3.1.2 EOI proposal shall consist of supporting proofs and documents as defined in Section 2 — Pre- Qualification Criteria

3.1.3 Bidder shall submit all the required documents as mentioned

3.1.4 Envelope should indicate clearly the name, address, telephone number, and Email ID of the bidder.

3.1.5 The EOI proposal submitted by bidder should be a complete document and should be bound as a volume. The document should be page numbered, must contain the list of contents with page numbers and shall be signed by the Authorized Representative of the bidder.

3.1.6 EOI document submitted by the bidder should be concise and contain only relevant information as required.

3.1.7 The entire proposal shall be strictly as per the format specified in this Invitation for Expression of Interest and any deviation may result in the rejection of the EOI proposal.

3.1.8 Any proposal received by inStem after the submission deadline shall be rejected and returned unopened to the Bidder. inStem shall not be responsible for any postal delay or non-receipt/ non-delivery of the documents. No further correspondence on the subject will be entertained.

3.1.9 inStem will shortlist bidders who meet the Pre-Qualification criteria as mentioned in Section 2 of this document.

Interested companies meeting the eligibility criteria and other details as per the EOI Document, may submit their Expression of Interest (EOI) along with supporting documents in a sealed envelope to “The Registrar, Institute for Stem Cell Science and Regenerative Medicine (inStem), GKVK Campus, Bellary Road, Bangalore-560065 so as to reach this office on or before 10-06-2024 till 1700 Hrs. The Pre-Bid meeting will be held in the inStem premises/online (For online meeting, the interested bidders shall write an email to purchase@instem.res.in keeping cc to headadm@instem.res.in & sao@instem.res.in seeking the details of the online meeting). The information regarding the pre-bid meeting scheduled on 03.06.2024 at 1430 Hrs, either at inStem or online, would be updated on the inStem website's tenders page.

Note:

- 1) **inStem reserves the right to reject any or all EOI received or to close the process without assigning any reason**

3.2 Evaluation Process

3.2.1 inStem shall evaluate the responses to the EOI and all supporting documents/ documentary evidence. Inability to submit requisite supporting documents/ documentary evidence may lead to rejection of the EOI Proposal.

3.2.2 inStem may seek additional documents or clarifications as and when required from the bidders.

3.2.3 Each of the responses shall be evaluated to validate compliance of the applicant according to the Pre-Qualification Criteria, Forms and the supporting documents specified in this document.

3.2.4 The decision of inStem in the evaluation of responses to the Expression of Interest shall be final.

3.3 Notification of short-listed bidders

3.3.1 inStem shall notify the shortlisted bidders.

3.3.2 Only Shortlisted bidders will be called for further meeting and RFP.

4. Scope of Work

Partners are sought that can lead the product development post Phase I clinical trial through Phase II/III clinical trials, regulatory approval and commercialization. Bidders should have demonstrated capabilities in developing gene therapy or other advanced medicinal therapies to include, but not limited to:

- a. Early process and product development including pivotal in-vivo studies and regulatory toxicology studies
- b. Infrastructure and capabilities for manufacturing process development and cGMP manufacturing of advanced clinical stage products
- c. Conduct of late stage and approval-enabling clinical trials including handling of related regulatory matters with an emphasis on accelerated approvals in India
- d. Capabilities to build and commission commercial scale cGMP manufacturing facilities
- e. Ability to commercialize advanced medicinal therapies in resource-lean contexts

Further details of this technology and related publications are available through the CSCR website (cscr.res.in).

For and on behalf of
Institute for Stem Cell Science and Regenerative Medicine
Sr Admin Officer-Purchase

SELF-DECLARATION
NON-BLACKLISTING

To,
The Director,
Institute for Stem Cell Science and Regenerative Medicine(inStem),
GKVK Campus,
Bellary Road,
Bangalore 560065

Sir,

In response to the "Selection of partners for the Licensing and Development of gene therapy products developed by CSCR-inStem located at CMC-Vellore", We hereby declare that presently our Company/Service provider _____ is having unblemished record, and any of our related entities related to examination business in India is neither blacklisted nor debarred by any PSU or Any Regulatory Body /Deptt /Autonomous body of Government of India or State Government or any of its agencies for any reasons whatsoever for indulging in corrupt or fraudulent practices or for indulging in unfair trade practices. Further, we confirm that none of our employees has ever been convicted by any law and order agency.

If this declaration is found to be incorrect then without any prejudice action that may be taken against us, we may be disqualified to participate in the Bid/RFP and future tenders.

Thanking you,

Yours faithfully,

Name of the Bidder

Authorized Signatory

Seal of the Organization