EoI No. CSCR/EOI/BE/01/2026
Dated 14/06/2026

Invitation for Expression of Interest (EoI)

For

Early Phase-I Co-development, Regulatory Translation, and Progressing towards Licensing

of

Base-Edited Hematopoietic Stem and Progenitor Cells for the Treatment of Transfusion-Dependent Beta-Thalassemia

By
Centre for Stem Cell Research (A unit of BRIC-inStem),
Located at Christian Medical College Vellore.

Centre for Stem Cell Research (A unit of BRIC-inStem),
Located at Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India.

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Letter of Invitation

1. Invitation for Expression of Interest

Centre for Stem Cell Research (hereinafter CSCR), a unit of BRIC-inStem, located at Christian Medical College Vellore invites Expression of Interest (EoI) from eligible organizations, companies, and manufacturers for undertaking the Early Phase I co-development, regulatory translation, and progressing towards licensing of Base-Edited Hematopoietic Stem and Progenitor Cells for the Treatment of Transfusion-Dependent Beta-Thalassemia.

The EoI document containing the details of qualification criteria, submission details, brief objective & scope of work, and evaluation criteria can be downloaded from the Centre for Stem Cell Research website (https://www.cscr.res.in).

Schedule for the Proponents is as under:

EoI Document Number	CSCR/EOI/BE/01/2026 dated 14/06/2026
Date of Publication	Date: 03/07/2026
Last date of submission	Date: 31/07/2026

Note: Interested applicants are invited to submit their Expression of Interest (EoI) in a sealed envelope to the address mentioned below. In addition, a soft copy of the Expression of Interest (EoI) should also be submitted via email to: cscrhead@cmcvellore.ac.in and cscr@cmcvellore.ac.in

Address:

The Head
Centre for Stem Cell Research (A Unit of BRIC-inStem)
Christian Medical College Campus
Bagayam, Vellore – 632002
Tamil Nadu, India

Landline: +91 416 228 5101

It is hereby informed that CSCR 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. Any information provided at this stage is purely indicative in nature and CSCR reserves the right to amend/add any further details in the EoI, as it may deem fit.

2. Background

Centre for Stem Cell Research (CSCR) is the translational unit of the BRIC Institute for Stem Cell Science and Regenerative Medicine (BRIC-inStem), Bengaluru, established in collaboration with Christian Medical College (CMC) Vellore, an institution of eminence in healthcare.

Scientists at CSCR have developed a novel therapeutic approach utilizing base-editing

technology to modify Hematopoietic Stem and Progenitor Cells (HSPCs) for the treatment of transfusion-dependent beta-thalassemia. This technology aims to provide a one-time, curative treatment option for patients suffering from this severe inherited blood disorder.

For the aforementioned purpose, CSCR may enter into agreements with eligible manufacturing companies (hereinafter referred to as the "Company") through a defined agreement for Early Phase-I Co-development, Regulatory Translation, and Progressing towards Licensing of "Base-Edited Hematopoietic Stem and Progenitor Cells for the Treatment of Transfusion-Dependent Beta-Thalassemia", hereinafter referred to as the 'Product', which shall be governed by the institutional IP policies.

3. Objective

To undertake co-development, translation, and progressing towards licensing of the 'Technology' for Base-Edited Hematopoietic Stem and Progenitor Cells, useful in the treatment of transfusion-dependent beta-thalassemia, for further development, commercialization, and marketing activities.

4. Scope of Work

i. The selected Company shall participate from the beginning of Phase-I clinical development as a co-development partner and shall support regulatory translation, including preparation and submission of required applications to CDSCO/DCGI, GMP readiness, CMC development, scale-up, and subsequent commercialization. The Phase-I clinical trial shall remain under CSCR/CMC scientific oversight.

ii. An Agreement (in case of joint development or licensing) following EoI is proposed to be executed with single/multiple companies to enable wider outreach of the Technology/product for societal benefit and public health use.

iii. CSCR has the expertise in various techniques, methods, and information relating to the aforesaid technology which could be used for the production of the Technology/product.

Role of Centre for Stem Cell Research

i. CSCR will provide expert guidance & technical support for the development and production of the Technology/product in all the Phases.

ii. CSCR would provide technical support through its team of experienced scientists in study planning, product development, protocol development, data analysis, outcome assessment, safety & efficacy assessment, product improvement, etc., if deemed fit upon mutual understanding.

iii. CSCR BRIC-inStem and Christian Medical College Vellore shall have no financial implications unless otherwise specified.

Role of Company

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

ii. Based on the outcome from the Phase-I study the Company shall have provisions to undertake

the scale-up as required, further phase-II and Phase-III studies, manufacturing, and commercialization of the Technology/Product in a set milestone.

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

iv. The Company agrees to allow authorized personnel/scientist/team of CSCR to visit the designated lab/production facility as and when required, as envisaged under this EoI and subsequent Agreement.

v. 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 after the Phase-I.

5. Intellectual Property Rights

It is submitted that in case of transfer of Technology, inStem and CMC Vellore shall remain the owners of the said Background Technology, including any underlying Intellectual Property(ies) and associated 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.

inStem and CMC Vellore legally possess the joint 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 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 CSCR and the Company for the Joint development of the Technology/ Product, Background Intellectual Property ("BGIP") shall always remain the sole and exclusive property of the Party generating the BGIP. Any IP, if generated during the course of collaboration, including any improvement thereof, shall be governed and allocated between the Parties in accordance with terms to be mutually agreed in the definitive agreement, in accordance with the IP Policies of inStem and CMC Vellore.

6. Process involved in Partnership/Collaboration/Technology Transfer

Interested companies/manufacturers are invited to join hands with CSCR for co-development, co-translation, and progressing towards licensing 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. Qualified companies/manufacturers will only be contacted for further discussions and 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, as applicable.

7. Publication

Based on the contribution in the study from the industry partner, the acknowledgment/other credits (as applicable) will be given and in accordance with guidelines of International Committee of Medical Journal Editors (ICMJE.org).

Support of ICMR and CSCR, inStem and CMC must be duly acknowledged in all publications by the parties.

CSCR Scientists shall be given due advantage of authorship in the publications arising out of Licensing and/or co-development subject to protection of Intellectual Property

8. Data Rights

i. Data rights shall be jointly owned by CSCR/inStem/CMC Vellore and the Licensee/Co-developer, in case of joint funding.

ii. Data rights in cases where Artificial Intelligence is involved shall be governed as per mutually agreed terms in a separate agreement.

iii. Licensee/ Company to ensure that data is anonymized, kept confidential and strictly

iv. Abide by the provisions of Information Technology Act, 2000 and any other applicable regulations 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 for execution & requirements with respect to technical capabilities for submission of interest, subject to verification by ICMR.

i. Documents to be furnished are as follows:
ii. Declaration - Expression of Interest (Format – 1)
iii. Authorization Letter (Format – 2)
iv. Undertaking with regard to Blacklisting (Format-3)
v. Undertaking with regard to Non-Conviction (Format – 4)
vi. EoI document with each page duly stamped and signed by the Authorized signatory.
vii. Undertaking with regard to laboratory facility (Format – 5)
viii. Production Capacity Undertaking (Format-6)
ix. Supporting documents, as mentioned in Format-1
x. MSME Certificate (if applicable)
xi. 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)
xii. Any other information which proponent may wish to provide to support the EoI

CSCR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification becomes necessary for proper judgement 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.

iv. Received after the expiry of due date and time.

v. All relevant supporting documents are not furnished with the Pre-Qualification Criteria (PQC).

vi. The proposal shall be substantially responsive without any material deviation, failing which 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.

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 and shall have more than 51% of Company stakes by promoters from 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	Research paper/Pamphlet / brochure of the product/DCGI License for existing

	with manufacturing during the last three years, either in-house or through agreed collaboration and must have marketed same/similar products in the past with a good track record.	product. Supporting documents for collaboration, if any.
4	The proponent shall be a profitable entity 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 a good track record and should not have been previously and/or currently black-listed/ barred by any Central / State Government/ Public Sector Undertaking, Govt. of India, (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 manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
7	The proponent and its promoters should not have been convicted for any offence in India by any competent court or judicial body during the past 3 years.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)
8	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/necessary certifications for R & D	Copies of Certificates
9	The proponent and its promoters shall disclose any actual or potential conflict of interest including any relationships with personnel, prior or ongoing relationships with the institutions involved or involvement in competing technologies. CSCR reserves the right to disqualify any bidder where a conflict is identified that may compromise the integrity of the process.	Relevant documents
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)

NOTE- For MSMEs and Start-ups, Start-Up-India, Make-in-India and other relevant guidelines of Government of India shall be applicable

13. Disclaimer

i. CSCR shall not be responsible for any late receipt of applications for any reasons whatsoever.

ii. CSCR reserves the right to cancel the call for EoI without assigning any reasons thereof.

iii. CSCR may relax or waive any of the conditions stipulated in this document as deemed necessary in its best interest 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

That any dispute and/ or any part of the dispute which 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 Chennai and the courts at Chennai shall have exclusive jurisdiction.

15. Contacts for enquiry

In case any clarifications required, please contact:

For scientific issues-
The Head,
Centre for Stem Cell Research (A unit of BRIC-inStem),
Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India

Email: cscrhead@cmcvellore.ac.in, Landline No.: 416 228 5101

For EOI related Technical issues-
The Head,
Centre for Stem Cell Research (A unit of BRIC-inStem),
Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India

Email: cscrhead@cmcvellore.ac.in, Landline No.: 416 228 5101

Format-1

Expression of Interest

(To be submitted on Company's Letter Head)

To,

The Head,
Centre for Stem Cell Research (A unit of BRIC-inStem),
Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India

Email: cscrhead@cmcvellore.ac.in,

Subject: Submission of Expression of Interest (EoI) for Co-development, Co-translation, and Progressing towards Licensing of the Technology entitled "Base-Edited Hematopoietic Stem and Progenitor Cells for the Treatment of Transfusion-Dependent Beta-Thalassemia" and manufacturing, commercialization of therapeutic agent(s) useful in treatment of transfusion-dependent beta-thalassemia

Ref: CSCR/EOI/BE/01/2026 dated 14/06/2026

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining to your co-development, co-translation, and progressing towards licensing 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:

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 last 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 any)		
11	Business Plan	A brief concept note on planning & execution, 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-2

Authorization Letter

(To be submitted on Company's Letter Head)

To,

The Head,
Centre for Stem Cell Research (A unit of BRIC-inStem),
Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India.

Subject: Letter for Authorized Signatory

Ref: CSCR/EOI/BE/01/2026 dated 14/06/2026

Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for Co-development, Co-translation, and Progressing towards Licensing of Technology entitled "Base-Edited Hematopoietic Stem and Progenitor Cells for the Treatment of Transfusion-Dependent Beta-Thalassemia" and commercialization of therapeutic agent(s) useful in treatment of transfusion-dependent beta-thalassemia.

Mr./Ms./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

Undertaking with regard to blacklisting

(To be submitted on Company's Letter Head)

To,

The Head,
Centre for Stem Cell Research (A unit of BRIC-inStem),
Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India.

Subject: Undertaking regarding Blacklisting / Non-Debarment.

Ref: CSCR/EOI/BE/01/2026 dated 14/06/2026

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:
Place:

Format-4

Undertaking with regard to Non-Conviction

(To be submitted on Company's Letter Head)

To,

The Head,
Centre for Stem Cell Research (A unit of BRIC-inStem),
Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India.

Subject: Undertaking regarding Non-Conviction.

Ref: CSCR/EOI/BE/01/2026 dated 14/06/2026

Sir,

It is hereby confirmed and declared that M/s.....(Company Name) and owner of the firm / board of directors, have not been convicted for any offence in India by any competent court or judicial body during the past 3 years.

Yours faithfully,

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

Format-5

Undertaking with regard to laboratory facility

(To be submitted on Company's Letter Head)

To,

The Head,
Centre for Stem Cell Research (A unit of BRIC-inStem),
Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India.

Subject: Undertaking regarding laboratory infrastructure.

Ref: CSCR/EOI/BE/01/2026 dated 14/06/2026

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 the Technology entitled "Base-Edited Hematopoietic Stem and Progenitor Cells for the Treatment of Transfusion-Dependent Beta-Thalassemia".

Yours faithfully,

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

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

Format-6

Undertaking with regard to production capacity

(To be submitted on Company's Letter Head)

To,

The Head,
Centre for Stem Cell Research (A unit of BRIC-inStem),
Christian Medical College Campus,
Bagayam, Vellore - 632002,
Tamil Nadu, India.

Subject: Undertaking with regard to production capacity.

Ref: CSCR/EOI/BE/01/2026 dated 14/06/2026

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

Yours faithfully,

(Signature of the Authorized signatory)

Name:
Designation:

Seal:
Place:

SCHEDULE-A
TECHNOLOGY DETAILS

i. **About the Technology/Product/Process:**

The proposed innovation is an autologous, ex vivo genome-edited hematopoietic stem and progenitor cell (HSPC)-based therapy for transfusion-dependent beta-thalassemia (TDT). Designed as a one-time treatment, the platform aims to achieve durable therapeutic benefit through sustained reactivation of endogenous fetal hemoglobin (HbF), with the potential to substantially reduce or eliminate transfusion dependence.

The technology integrates autologous stem cell transplantation with GMP-compliant cell processing and manufacturing workflows, and is being developed for clinical translation and scalable production. The programme seeks an industry partner for co-development, process scale-up, GMP manufacturing, regulatory support, and conduct of Phase I clinical trials, followed by Phase II/III clinical development.

The platform is based on proprietary intellectual property owned by the academic developer. Detailed technical information, including the genome-editing strategy and associated know-how, will be shared only with shortlisted partner(s) under appropriate confidentiality agreements.

Beyond beta-thalassemia, the platform may offer future applications in other hemoglobinopathies and selected monogenic disorders, while contributing to the development of indigenous advanced cell and gene therapy capabilities in India

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

Beta-thalassemia is among the most common inherited monogenic disorders in India, with a large number of patients requiring lifelong blood transfusions and iron chelation therapy. The disease is associated with substantial morbidity, reduced quality of life, premature mortality, and significant economic burden on affected families and the healthcare system.

Existing treatment options have important limitations, including donor availability and transplant-related risks associated with allogeneic stem cell transplantation, as well as the high cost and limited accessibility of currently available gene therapies. There remains a critical unmet need for affordable and durable curative therapies.

The proposed technology offers a potentially curative, autologous treatment approach with the potential to reduce or eliminate transfusion dependence, improve long-term clinical outcomes, and decrease disease-related complications. Development of an indigenous advanced cell therapy platform is expected to strengthen national capabilities in cell and gene therapy manufacturing, facilitate technology transfer and industry partnerships, and create opportunities for broader application in other hemoglobinopathies and selected monogenic disorders.

iii. **Validation Status and outcome:**

The technology has demonstrated promising proof-of-concept in laboratory and preclinical studies, including efficient genome modification, induction of therapeutic hemoglobin levels, and sustained therapeutic activity in relevant experimental models. These findings support further translational development.

Additional IND-enabling studies, GMP process development, safety evaluations, and clinical studies are planned to support regulatory submissions and progression to human clinical trials.

Additional Partnership Framework Clarification for Industry Participation

Purpose of the EoI:

This Expression of Interest is intended to identify an industry partner for early-stage co-development, clinical translation, regulatory facilitation, manufacturing readiness and commercialization of the Base-Edited Hematopoietic Stem and Progenitor Cell Therapy.

The selected industry partner shall be engaged from the beginning of Phase-I clinical development as a co-development partner and shall support regulatory strategy, preparation of regulatory dossiers, manufacturing scale-up, quality systems, clinical development planning and submission of applicable applications to CDSCO/DCGI and other competent regulatory authorities, as required under applicable Indian regulations and the respective roles and responsibilities of the Parties shall be defined in the definitive agreement.

Role of CSCR/CMC/inStem:

CSCR/CMC/inStem shall continue to retain ownership and control of the background technology, scientific know-how, originating intellectual property, clinical innovation, process knowledge and technology platform developed prior to the collaboration.

The Phase-I clinical trial shall be conducted under the scientific and clinical leadership of CSCR/CMC as per approved regulatory requirements. The industry partner shall not have unilateral rights to modify scientific objectives, clinical protocols, product specifications or technology ownership.

Role of Industry Partner:

The selected industry partner shall contribute expertise and resources towards:

1. Regulatory development strategy and preparation/submission of applications to CDSCO for clinical evaluation and subsequent product development milestones.

2. GMP manufacturing readiness, analytical validation, quality systems, CMC documentation and scale-up planning.

3. Support for Phase-I and subsequent clinical development activities as mutually agreed.

4. Commercial manufacturing, market authorization, distribution and commercialization after successful development and regulatory approval.

Licensing and Commercial Rights:

Any licensing arrangement shall be governed through a mutually negotiated agreement between CSCR/CMC/inStem and the selected industry partner.

The collaboration shall follow a fair and transparent model wherein:

- Background Intellectual Property of CSCR/CMC/inStem remains protected and shall not be transferred or assigned merely by participation in the EoI process
- Industry partner shall receive appropriate commercialization rights/licence rights based on agreed milestones, investment, regulatory contribution and commercial commitments
- Any new intellectual property generated jointly shall be managed through mutually agreed terms consistent with institutional IP policies, Government of India guidelines and applicable regulatory frameworks.

The objective is to establish a balanced public-academic-industry partnership enabling successful translation of an indigenous advanced therapy while ensuring patient access, scientific integrity, protection of innovation and sustainable commercialization.

Enhanced Industry Partner Participation Framework

The industry partner is envisaged as a strategic co-development partner contributing expertise, resources and capabilities required for successful clinical translation and commercial availability of the technology. The partnership model is designed to ensure meaningful industry participation while maintaining scientific leadership, institutional ownership and public health objectives.

The selected industry partner shall have an active role from early Phase-I development, including:

1. Regulatory Development Partnership:

The industry partner shall support preparation of regulatory strategy, CMC packages, quality documentation, clinical development plans and regulatory submissions to CDSCO/ DCGI and other applicable authorities in accordance with prevailing regulatory requirements for advanced therapy medicinal products. The respective regulatory roles and responsibilities of the Parties shall be defined in the definitive agreement.

2. Manufacturing and CMC Development:

The industry partner shall contribute expertise in GMP-compliant manufacturing, process optimization, analytical method development, validation strategy, comparability assessment, quality management systems, technology scale-up and commercial readiness.

3. Clinical Translation Support:

The industry partner shall support clinical trial execution through agreed responsibilities including clinical operations, pharmacovigilance, regulatory compliance, product supply chain and post-development planning. Scientific and clinical decisions shall remain under the governance framework agreed with CSCR/CMC.

4. Commercial Development:

Following successful clinical development and regulatory approvals, the industry partner shall support manufacturing, market authorization, commercialization, accessibility planning and sustainable patient availability.

Balanced Partnership Principles:

- Participation in co-development activities shall not constitute transfer of ownership of CSCR/CMC/inStem background technology or associated intellectual property.
- The industry partner shall receive appropriate rights commensurate with its financial, technical, regulatory and commercial contribution through a mutually negotiated licence or commercialization agreement.
- CSCR/CMC/inStem shall retain scientific leadership and oversight of the technology, clinical strategy and core innovation.
- Decisions involving major scientific changes, clinical pathway, product identity, safety considerations and technology modifications shall be taken through mutually agreed governance mechanisms.

- Joint contributions by the industry partner towards regulatory, manufacturing and commercialization activities shall be appropriately recognized in agreements, including commercial rights, milestones, revenue sharing or other mutually acceptable mechanisms.

The objective of this partnership is to combine academic innovation with industrial development expertise to create a globally competitive, affordable and accessible indigenous advanced therapy while protecting institutional innovation and ensuring equitable benefit sharing among all stakeholders.