भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और 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: Phase-1/EoI/2023/BMS **Date: 22-05-2023**

First Expression of Interest (EoI) on "Novel candidates for Phase I studies"

Background:

Early steps in the development of a new safe and effective medicine include experiments to carefully assess its potential effects in preclinical models of disease, while also exploring its safety and tolerability in animals, so that a safe dose range can be reliably selected for further development. Promising candidates are then taken up for first-in-human phase I studies that are expected to yield critical insights into the safety and expected effective dose range of the new chemical entity for potential human use. Phase I studies often contain multiple objectives and endpoints that crucially determine whether a compound will survive to the next step in the drug development process.

ICMR is establishing phase I clinical trial infrastructure in the country to support drug discovery and development. These centers for advanced research and excellence (CARE) will be national assets to be made available to researchers working in drug discovery and development in therapeutic areas of national priority. To utilize this infrastructure, ICMR would like to invite Indian researchers working in drug discovery and development to respond to this call with details of their products that are ready for phase I clinical trials.

Statement of purpose:

The goal of this EoI is to support proposals from Indian researchers having healthcare products ready for **First in Human (FIH)** phase I clinical trials in healthy volunteers, or patients in special scenarios. Healthcare products may include drugs, biologics, devices, or vaccines for further development.

Scope:

- Researchers working in India on discovery/ development of drugs/ biologics/ devices/ vaccines having promising lead candidates (with necessary preclinical efficacy and GLP safety data as per regulatory requirements) that are ready to be taken up for phase I studies are encouraged to apply.
- Innovative modifications of existing products (improved formulation, new route

of administration, new indication, etc) with cogent rationale and preclinical proof of concept or evidence of therapeutic advantage will also be considered.

- Applicants should preferably be the inventor, having a new candidate product with demonstrated preclinical efficacy and GLP safety data, as per regulatory requirements.
- Start-ups and industry applicants must have identified a suitable academic partner.
- Applications that have scope for co-funding by another funding agency, investor, or partner must indicate the same. Co-development proposals/ matched funding models can be explored and need to be clearly mentioned in the EoI if the applicant wishes such models to be considered.

Review of EoIs

All EoIs for FIH phase I studies received up to June 30, 2023 will be reviewed in accordance with the timelines given below (see "Timelines" section). EoIs received subsequent to June 30, 2023 will be reviewed in subsequent review cycles to be scheduled periodically. The review will be carried out by the Healthcare Product Selection Committee (HPSC), constituted by the Inter-Ministerial Steering Committee. The HPSC will review the applications based on the following criteria and the data/ evidence submitted in support of the same:

1. Novelty – whether the candidate is innovative
2. Need for the product – comparative advantage over existing standard of care
3. Likely impact on disease burden – national priority
4. Need for the product – comparative PK-PD advantage over existing standard of care,
5. Market evaluation – whether the candidate will have a reasonable marketable relevance

Approval from the competent authority will be final.

Specific points for submission of EoI:

- Investigators should mention if they currently own or are likely to own intellectual property from their study.
- Data sharing policy and agreements of the data generated through the proposed clinical trial
- The summary of pre-clinical data on efficacy and GLP safety (preferably with published literature) should be submitted along with the EoI.
- Applicant should describe their plan for GMP manufacturing. If the applicant has not identified a GMP manufacturing facility, it needs to be indicated.
- If required, ICMR can leverage its expertise to collaborate with the applicant in

developing the necessary study protocols and regulatory dossiers. Such requirements must be indicated in the EoI.

- Applications with incomplete details will not be considered.

Timelines:

Release of call	Interactive webinar	Application receipt deadline	Evaluation of EoI by HPSC
5th June 2023	10h June 2023 11:00 a.m. https://echo.zoom.us/j/82249702591	25th July 2023 5:00 p.m.	25th September, 2023

Exclusions:

This EoI excludes-

- Candidates with insufficient preclinical data to support its efficacy and safety (GLP data) for FIH phase I studies
- Diagnostic products
- Health products from alternate systems of medicine
- Candidates that are not FIH phase I clinical trials, but for BA-BE studies/ special PK-PD studies/ interaction studies, etc.

Who Can Submit EoI:

The EoI should be submitted for financial support though ONLINE MODE ONLY (application format attached) (www.icmr.gov.in) by Indian scientists/ professionals working in medical institutes/ research institutes/ universities/ colleges/ recognized research & development laboratories/ government and semi-government organizations, or NGOs. Start-ups and industry applications must have identified a suitable academic partner as the primary applicant.

How to apply:

1. Open the ICMR Electronics Project Management System (e-PMS) portal http://epms.icmr.org.in. The user manual of e-PMS (under Guidelines → e-PMS manual) is available at the portal.

2. EoI submission is a 3-step process in e-PMS:
   - Step 1: PI registration/ Login
   - Step 2: Verify email ID and complete/ update PI profile
   - Step 3: EoI submission

3. Click on "LOGIN" and select "Register" for new registration OR if already registered, provide details to login and enter into e-PMS portal.

4. Verify your registered email and complete the PI profile.

5. After completing the mandatory section of PI profile, click on "EoI submission → Submit".

EoI submission related query (Email: po.epms@icmr.gov.in)

1) Dr Pulkit Sharma
2) Mrs. Iqbal Kaur

Program related query (Email: icmrphase1centre@gmail.com)

1) Dr. Jerin Jose Cherian, Scientist-D (Med)
2) Dr. Monika Pahuja, Scientist-D
3) Dr Saibal Das, Scientist-D (Med)

Annexure - Format for EoI on Novel candidates for Phase I studies

1) Details of investigator/ inventor to EoI (including name, designation and affiliation of researcher(s) working in India)
2) Contact details – phone & email
3) Summary of product (in less than 250 words)
4) Type of lead novel candidate: Drug/ biological/ vaccine/ device/ other
    a. Please describe if any other
    b. Is it a health products from alternate systems of medicine - Y/ N?
    c. Is it a diagnostic - Y/ N?
5) Proposed indication(s) –
6) Is the lead novel candidate suitable for a FIH clinical trial – Y/ N/ Don't know
7) Meets all requirements for IND regulatory submission for FIH clinical trial – Y/ N// Don't know
8) GLP preclinical safety and efficacy data available as per regulatory standards– Y/ N/ Partially/ Don't know
    a. If available, give details (should not exceed 250 words pages)
    b. Details (as per D&C Act) – Hyperlink to one single PDF submission page (Annexure-1)
9) Inputs on each of the review criteria (upto 500 words each)
    a. Need for the product – comparative PK-PD advantage over existing standard of care,
    b. Novelty – whether the candidate is innovative, and whether a patent is granted or applied for (give details under item 18 below),
    c. Impact on health – National priority
    d. Market evaluation – whether the candidate will have a reasonable marketable relevance
10) In case of EoI from academia/ NGO, please share details of potential technology transfer agreements being planned (in less than 100 words)
11) Describe the future plans for possible product development lifecycle/ clinical development plans (in less than 250 words)
12) Have you identified a GMP manufacturing facility GMP – Y/ N
    a. If available, provide a brief summary (in less than 100 words)
13) In case of EoI from start-ups and industry, please share details of potential academic partner(s), and roles and responsibilities thereof each.
14) Study design/ regulatory expertise available – Y/ N
    a. If available, please mention the details of the team and strengths
15) Valid DSIR certificate available – Y/ N
    a. Funding requirements from ICMR – Summary of budget requirements (in less than 100 words)
16) Current & immediate intellectual property status/ plans including discussion on potential for technology transfer (upto 250 words)

Annexure 1 - The summary of pre-clinical data on efficacy and GLP safety

1. **Pharmaceutical Quality - Chemistry, Manufacturing & Controls Data**
    i. Characterization (Adequate level of quality characterisation required including heterogeneity, degradation profile)
    ii. Manufacturing process development and comparability (Process-related impurities)
    iii. Specifications (Particular attention to impurities that could be pharmaceutically active/toxic Methods for characterization should be suitable and qualified)
    iv. Stability and shelf-life
    v. Other Details (Manufacturing changes – have product characteristics changed? Assurance that product safety has not altered).
2. **Animal Pharmacological Data**
    i. Summary
    ii. Specific pharmacological actions
    iii. General pharmacological actions
    iv. Follow-up and Supplemental Safety Pharmacology Studies
    v. Pharmacokinetics: absorption, distribution; metabolism; excretion
    vi. Any other details
3. **Animal Toxicity Data**
    i. Systemic Toxicity studies
        a. Single dose toxicity
        b. Repeated dose toxicity
        c. Male fertility study
        d. Female reproduction and developmental toxicity studies
    ii. Local toxicity studies
        a. Dermal toxicity
        b. Ocular toxicity
        c. Inhalation toxicity
        d. Vaginal toxicity
        e. Photo allergy or dermal photo toxicity
        f. Rectal tolerance test
    iii. Genotoxicity
    iv. Allergenicity/Hypersensitivity
    v. Carcinogenicity
    vi. Any other details