EoI No. INTENT/Vorinostat_DMD/01/2026

Invitation for Expression of Interest (EoI)
For
Development and Manufacturing of Vorinostat Formulation for Duchenne Muscular Dystrophy (DMD)

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

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Letter of Invitation

1. Invitation for Expression of Interest

Indian Council of Medical Research ((ICMR), New Delhi invites Expression of Interest (EoI) from the eligible organizations, companies, manufacturers for the **Development and Manufacturing of Vorinostat Formulation for Duchenne Muscular Dystrophy (DMD).**

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	INTENT/Vorinostat_DMD/01/2026
Date of Publication	26th November 2026
Last date of submission	24th December 2026

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

Dr. Aparna Mukherjee
Scientist F and Head,
Clinical Studies and Trial Unit
Division of Development Research,
Indian Council of Medical Research,
V. Ramalingaswami Bhawan,
P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110029, India

EoI Document No. INTENT/Vorinostat_DMD/01/2026 along with the title of the EOI as "EoI for Development and Manufacturing of Vorinostat Formulation for Duchenne Muscular Dystrophy (DMD)" in Bold and complete address as above must be clearly mentioned on the sealed envelope.

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

Duchenne Muscular Dystrophy (DMD) is a rare, severe, X-linked recessive neuromuscular disorder caused by pathogenic variants in the DMD gene, resulting in the absence or near absence of functional dystrophin protein. Dystrophin plays a critical role in maintaining the structural integrity and stability of skeletal and cardiac muscle fibers. Deficiency of dystrophin leads to progressive muscle degeneration, chronic inflammation, fibrosis, and irreversible loss of muscle function. Clinically, DMD is characterized by delayed motor milestones, progressive muscle weakness, difficulty in walking, frequent falls, loss of ambulation during adolescence, respiratory insufficiency, cardiomyopathy, and premature mortality. The disease imposes a substantial lifelong physical, psychological, and socioeconomic burden on affected individuals, their families, and healthcare systems.

Current standards of care include corticosteroids, supportive rehabilitation, respiratory and cardiac management, and mutation-specific therapies for a limited subset of patients. While corticosteroids remain the cornerstone of pharmacological management and have demonstrated benefits in slowing disease progression, their long-term use is associated with significant adverse effects, including growth retardation, obesity, osteoporosis, behavioural disturbances, hypertension, and glucose intolerance. Furthermore, currently available mutation-specific therapies are applicable only to selected genetic variants, are associated with high treatment costs, and remain inaccessible to the majority of patients in low- and middle-income countries.

Recently, Givinostat became the first histone deacetylase (HDAC) inhibitor to receive approval from the United States Food and Drug Administration (US FDA) in 2024 for the treatment of Duchenne Muscular Dystrophy in patients aged 6 years and older. While this represents a significant advancement in DMD therapeutics, its limited availability and high cost continue to restrict access for patients. Therefore, there remains a continued need to explore other HDAC inhibitors with established clinical safety profiles that may offer an affordable and accessible therapeutic alternative through drug repurposing.

Vorinostat, an orally administered histone deacetylase (HDAC) inhibitor approved for other clinical indications, is a promising candidate for drug repurposing in Duchenne Muscular Dystrophy. HDAC inhibition has been shown to modulate gene expression involved in muscle regeneration, reduce inflammation and fibrosis, enhance satellite cell function, and improve muscle repair. Preclinical studies in dystrophic animal models have demonstrated improvements in muscle histopathology, muscle strength, and functional performance following HDAC inhibition. In addition, Vorinostat possesses an established pharmacokinetic profile, well-characterized manufacturing processes, and extensive human safety data from its approved indication, making it a promising candidate for clinical evaluation in Duchenne Muscular Dystrophy.

Recognizing this important unmet medical need, the Indian Council of Medical Research (ICMR) has proposed a multicentre Phase III clinical trial to evaluate the efficacy and safety of oral vorinostat in ambulatory boys with Duchenne Muscular Dystrophy. The proposed study is a randomized, double-blind, placebo-controlled, multicentre clinical trial designed to evaluate whether the addition of vorinostat to standard of care can slow disease progression and improve functional outcomes while maintaining an acceptable safety profile. The study is expected to

generate high-quality clinical evidence to support the potential repurposing of vorinostat for the management of Duchenne Muscular Dystrophy.

The Indian Council of Medical Research (ICMR), an autonomous organization under the Department of Health Research, Ministry of Health & Family Welfare, Government of India, is the apex body in the country for the formulation, coordination, and promotion of biomedical research. ICMR has consistently endeavored to address the growing demands of scientific advances in biomedical research while simultaneously developing practical solutions to the country's pressing healthcare challenges. As part of its commitment to strengthening research in rare diseases and promoting affordable therapeutic options through drug repurposing, ICMR has undertaken this initiative to generate robust indigenous evidence that may facilitate improved access to effective treatment for patients with Duchenne Muscular Dystrophy.

For implementation of the proposed trial, multiple tertiary care centers across India have been shortlisted as participating clinical sites based on their expertise in neuromuscular disorders, availability of multidisciplinary clinical teams, clinical research infrastructure, and access to an adequate number of eligible patients. Collectively, these centers possess the required expertise and facilities for successful conduct of the proposed multicenter Phase III clinical trial.

Successful execution of the study requires the availability of a Good Manufacturing Practice (GMP)-compliant investigational formulation of oral vorinostat and matched placebo suitable for clinical research and regulatory submission. Since the proposed study is intended to generate evidence for regulatory purposes, the investigational product must be manufactured in compliance with applicable Good Manufacturing Practices (GMP), Good Clinical Practice (GCP), and regulatory requirements, with appropriate quality control, stability data, packaging, labelling, documentation, and regulatory support. The manufacturer will also be expected to support the preparation of Chemistry, Manufacturing and Controls (CMC) documentation and other regulatory documents required for obtaining approvals from the Central Drugs Standard Control Organization (CDSCO) and other applicable regulatory authorities for conduct of the clinical trial.

Accordingly, ICMR invites Expressions of Interest (EoI) from eligible pharmaceutical manufacturers possessing the technical capability, manufacturing infrastructure, quality systems, and regulatory expertise to develop, manufacture, and support the regulatory approval of the investigational oral vorinostat formulation and matched placebo for use in the proposed multicentre Phase III clinical trial. The selected manufacturer will be expected to collaborate with ICMR in formulation development, manufacture, quality testing, packaging, labelling, documentation, preparation of regulatory dossiers, regulatory submissions, and timely supply of the investigational product in accordance with Good Manufacturing Practices (GMP), Good Clinical Practice (GCP), and applicable regulatory requirements.

3. Objective

To collaborate with eligible companies for the development and manufacturing of Vorinostat Formulation for Duchenne Muscular Dystrophy (DMD).

Weight based dosing is to be given in patients aged group 6 – 15 years

- 0.6 mg/kg/day vorinostat
- 1.2 mg/kg/day vorinostat
- 2.4 mg/kg/day vorinostat
- 3.6 mg/kg/day vorinostat
- Matching placebo

Proposed Clinical Development and Investigational Product Requirement

The proposed clinical development programme is a **multicentre, randomized, placebo-controlled Phase II/III clinical trial** to evaluate the safety, tolerability and efficacy of oral Vorinostat in **ambulatory boys aged 6–15 years with genetically confirmed Duchenne Muscular Dystrophy (DMD)** receiving standard of care (SOC).

The study will comprise a **Dose-Finding Stage (Part A)** followed by a **Confirmatory Phase (Part B)**. The Dose-Finding Stage and Confirmatory Phase will have separate participant enrolments.

Part A – Dose-Finding Stage

Phase	Participants	Duration
DFS – 0.6 mg/kg/day	20	48 weeks
DFS – 1.2 mg/kg/day	20	48 weeks
DFS – 2.4 mg/kg/day	20	48 weeks
DFS – 3.6 mg/kg/day	20	48 weeks
DFS – Placebo	20	48 weeks
OLE – RP3D	100	48 weeks

Part B – Confirmatory Phase

Phase	Participants	Duration
Vorinostat RP3D + SOC	183	48 weeks
Placebo + SOC	92	48 weeks
OLE – RP3D	275	48 weeks

Investigational Product Development Requirements

The company shall **develop, manufacture and supply Vorinostat and a matching placebo** suitable for use in the above clinical trial.

As the study involves **weight-based dosing in children aged 6–15 years**, the company is requested to propose the most appropriate **pediatric oral dosage form and formulation strength/concentration**.

A strength of 10 mg/ml or the final dosage form may be proposed by the manufacturer based on pharmaceutical development considerations.

The manufacturer should provide a **matching placebo of identical/suitably matched appearance, presentation and administration characteristics** to maintain study blinding.

An estimated quantity of 80 kg of API is required for the investigational product, including the applicable overage.

The manufacturer shall propose a suitable pediatric dosage form, strength/concentration, excipients, pack size and dosing device**, along with the** required quantity of Vorinostat and matching placebo, manufacturing batch size and number of batches, applicable overage, stability/shelf-life data and programme, and GMP-compliant manufacturing and quality-control/release specifications**.**

4. Scope of Work

i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for the **'Development and manufacturing of Vorinostat Formulation and matched plabeco for Duchenne Muscular Dystrophy (DMD)'.**
ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Product '**Vorinostat Formulation for Duchenne Muscular Dystrophy (DMD)'** or undertake further R&D and commercialize the end product(s).
iii. An Agreement (in case of joint development or licensing) following EoI is proposed to be executed on a "Exclusive/Non-Exclusive" basis with single/multiple companies to enable wider outreach of the **Vorinostat Formulation for Duchenne Muscular Dystrophy (DMD)** (Product) 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.

Role of ICMR:

i. ICMR will provide expert guidance & technical support in R&D for development of vorinostat formulation and matched placebo for Duchenne Muscular Dystrophy (DMD), in all phases. Such technical oversight by Scientist of ICMR would accelerate the development of the Technology/Product and its commercialization.
ii. 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.
iii. ICMR would provide support and facilitation to conduct the R&D/clinical study of new 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.
iv. ICMR 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. The Company shall have provisions to undertake the scale-up as required for the **Development and manufacturing of Vorinostat formulation for Duchenne Muscular Dystrophy (DMD),** in a set milestone.
iii. The Company agrees to share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.
iv. 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.
v. The Company shall be willing to act as the **sponsor of the product development programme** and shall be responsible for **preparation, submission, and management of all requisite regulatory submissions and approvals**, as applicable, from the R&D/product development stage through commercialization.

5. Intellectual Property 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 'Product' by itself or to assign at its discretion full or part of the Product 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 product through suitable Agreement(s).

In case of collaboration between ICMR and the Company for the Joint development of the 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 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/Product Transfer

Interested companies/manufacturers are invited to collaborate with ICMR for co-development & commercialization of the 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 execution of MoA/MoU/Agreement for partnership/collaboration/product transfer, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay the Royalty @ 1% or 2% on Net sales, as applicable, according to the ICMR Guidelines for Technology/Product Development Collaboration.

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 and vice versa.

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 will be exclusively with ICMR, if ICMR provide 100% funding in clinical trial.

ii. Data rights shall be jointly owned by ICMR and Licensee/Co-developer, in case of joint funding.

iii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.

iv. Licensee/ Company to ensure that data is anonymized, kept confidential and strictly abide by the provisions of Information Technology Act, 2000 and other applicable data protection laws and 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 for verification by ICMR.

Documents to be furnished are as follows:

i. Declaration - Expression of Interest (Format – 1)

ii. Authorization Letter (Format – 2)

iii. Undertaking with regard to Blacklisting (Format-3)

iv. Undertaking with regard to Non-Conviction (Format – 4)

v. EoI document with each page duly stamped and signed by the Authorized signatory.

vi. Undertaking with regard to Functional Manufacturing Facility and Quality Control Laboratory (Format – 5)

vii. Undertaking regarding Manufacturing Capacity (Format-6)

viii. Supporting documents, as mentioned in Format-1

ix. MSME Certificate (if applicable)

x. Undertaking regarding Uninterrupted Supply and Maintenance of Reserve Stock of the Investigational Product (As per format – 7)

xi. Supported evidence in form of research paper/articles published in peer reviewed journals, or detailed report containing Data pertaining to drug/product formulation developed

xii. Concept Proposal (Format-8)

xiii. Any other information which proponent may wish to provide to support the EoI.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become 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**	**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 a manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
4	The proponent should have not been Blacklisted by any of the government funding agency/department.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format –3)
5	The proponent and its promoters should have not 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)
Specific Criteria (Based on the nature of the Proposal)		
6	The proponent should have Functional Manufacturing Facility and Quality Control Laboratory to carryout R&D for the technology/product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
7	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
8	Proponents should have experience in the development of oral pharmaceutical formulations and should have established proof of capability for formulation development, GMP manufacturing, and regulatory support for investigational medicinal products.	Supported evidence in form of research paper/articles published in peer reviewed journals, or should submit detailed report containing Data of preclinical studies
10	The applicant should have adequate GMP-compliant manufacturing capacity to develop, manufacture, package, test, and supply the investigational oral vorinostat formulation and matched placebo in quantities sufficient to support the proposed multicentre Phase III clinical trial, including all enrolled participants throughout the study duration, with provision for replacement supplies, stability requirements, and contingency stock.	Undertaking (As per format – 6)
11	• Experience in manufacturing oral solid and/or liquid dosage forms under GMP.	Supported evidence in the form of research papers/articles published in peer-reviewed journals,

	• Experience in manufacturing investigational medicinal products (IMPs) for clinical trials. • Capability for blinding/placebo manufacture • Capability for multiple tablet/syrup strengths or weight-based dosing. • Experience in preparation of Chemistry, Manufacturing and Controls (CMC) documentation and other manufacturing-related regulatory documents for CDSCO/DCGI submissions. • Stability studies as per ICH guidelines. • Batch traceability and documentation. • Capacity for nationwide distribution to participating clinical trial sites. • Ability to supply study drug continuously for the entire study period.	technical reports, product dossiers, or documentary evidence demonstrating experience in formulation development, GMP manufacturing, and/or investigational medicinal products for clinical trials. and Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory Undertaking (As per format – 7)

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. Technology/Product rights will be owned by ICMR

ii. In case the agency/ company/ entity could not be able to continue the contract or wishes to break the contract, the technology/product rights will be given to any agency/ company/ entity that ICMR would specify.

iii. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.

iv. ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.

v. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.

vi. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.

vii. 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 New Delhi and the courts at New Delhi will have exclusive jurisdiction.

15. Contacts

In case of any clarification required, please contact:

Dr. Aparna Mukherjee
Scientist F and Head,
Clinical Studies and Trial Unit
Division of Development Research
Indian Council of Medical Research
Email ID: aparna.sinha.deb@icmr.gov.in

Dr Monika Pahuja
Scientist-E and Program Officer-Rare diseases
Discovery Research Division,
Indian Council of Medical Research
Email ID: pmonika@icmr.gov.in

Format-1
Expression of Interest
(To be submitted on Company's Letter Head)

To,
The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Submission of Expression of Interest (EoI) for development and manufacturing of Vorinostat Formulation and matched placebo for Duchenne Muscular Dystrophy (DMD)

Ref: No. _____ dated _____

Sir,

The undersigned having read and examined in detail all the EoI documents pertaining to the product, and do hereby express the interest to undertake the development and manufacture/ quality testing/ regulatory support/ 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	Authorization Letter	As per **Format–2**	
2	Company Incorporation Certificate/Certificate of Incorporation from ROC/Partnership Deed/LLP Registration, as applicable	Self-attested copy	
3	GST Registration Certificate or GST Exemption Certificate and PAN Card	Self-attested copy	
4	Valid DCGI/CDSCO Manufacturing License for existing products, wherever applicable	Self-attested copy	
5	Proof of Registered Office and Manufacturing Unit in India	Self-attested documentary evidence	
6	DSIR Recognition Certificate (if applicable)	Self-attested copy	

7	Undertaking regarding Blacklisting	As per **Format–3**	
8	Undertaking regarding Non-conviction	As per **Format–4**	
9	Undertaking regarding Functional Manufacturing Facility and Quality Control Laboratory	As per **Format–5**	
10	Valid GMP and/or GLP and/or ISO Certification	Copies of valid certificates	
11	Undertaking regarding Manufacturing Capacity	As per **Format–6**	
12	Undertaking regarding Uninterrupted Supply and Maintenance of Reserve Stock of the Investigational Product	As per **Format–7**	
13	Supporting evidence demonstrating formulation development/manufacturing capability, regulatory support proof-of-concept, or relevant research publications/technical reports	Research papers, technical reports, product dossiers, or equivalent evidence	
14	Proposal for Development, Manufacturing and Regulatory support of the Investigational Vorinostat Formulation and matching placebo	As per **Format–8**	
15	MSME or recognized start-up	Certificate (if have any)	

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 Director General
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Letter for Authorized Signatory

Ref: No. _____dated _____
Sir,

This has reference to your above-mentioned Expression of Interest (EoI) for the development and manufacture of the investigational oral vorinostat formulation and matching placebo for Duchenne Muscular Dystrophy (DMD).

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:
Place:

Format-3

Undertaking with regard to blacklisting

(To be submitted on Company's Letter Head)

To,

The Director General,

Indian Council of Medical Research,

Ansari Nagar, New Delhi.

Subject: Undertaking regarding Blacklisting / Non-Debarment.

Ref:

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 Director General,

Indian Council of Medical Research,

Ansari Nagar, New Delhi.

Subject: Undertaking regarding Non-Conviction.

Ref: No.

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 Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding laboratory infrastructure.

Ref:

Sir,

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

i. Adequate laboratory infrastructure (equipped laboratory facility) for formulation development, analytical testing, quality control, manufacturing and regulatory support of the investigational oral vorinostat formulation and matching placebo. Please tick GMP/GLP/Quality Control Laboratory/Formulation Development Laboratory/Other* (if other, please specify).

ii. Adequate no. of experienced staff/skilled manpower to undertake to undertake formulation development, analytical testing, manufacturing, quality assurance, quality control, regulatory support, packaging, and commercialization of the investigational oral vorinostat formulation and matching placebo.

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

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

Format-6

Undertaking with regard to production capacity

(To be submitted on Company's Letter Head)

To,

The Director General,

Indian Council of Medical Research,

Ansari Nagar, New Delhi.

Subject: Undertaking with regard to production capacity.

Ref:

Sir,

It is hereby confirmed and declared that **M/s. _____ (Company Name)_____** has the capacity in all respects (including infrastructure, funds, materials, equipment, and skilled manpower) for the development and manufacture of the investigational oral vorinosatat formulation and matching placebo, sufficient to meet the requirements of the proposed multicenter Phase III clinical trial.

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

Format-7

Undertaking regarding Uninterrupted Supply and Maintenance of Reserve Stock of the Investigational Product

(To be submitted on Company's Letter Head)

To,
The Director General,
Indian Council of Medical Research,
Ansari Nagar, New Delhi.

Subject: Undertaking regarding uninterrupted supply and maintenance of reserve stock of the investigational product.

Ref: EoI No. _____ dated _____

Sir,

It is hereby agreed and declared that M/s. _____ (Company Name)_____ shall ensure uninterrupted manufacture, supply, and maintenance of adequate reserve stock of the investigational oral vorinostat formulation and matching placebo required for the proposed multicentre Phase III clinical trial.

It is also agreed that M/s. _____ (Company Name)_____ shall manufacture and supply additional quantities of the investigational product, if required by ICMR during the conduct of the clinical trial, within the agreed timelines and in accordance with the applicable quality and regulatory requirements.

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

Format-8

Proposal for Development and Manufacture of the Investigational Oral Vorinostat Formulation and matching placebo

A. About the Product / Formulation

- Brief description of the proposed investigational oral vorinostat formulation and matching placebo.
- Proposed dosage form(s) (tablet/capsule or other oral dosage form), strength(s), and formulation approach.
- Manufacturing process and any novel formulation features, if applicable.
- Proposed packaging and labelling suitable for use in a multicentre clinical trial.
- Regulatory strategy, including the proposed approach for preparation of Chemistry, Manufacturing and Controls (CMC) documentation and support for obtaining regulatory approvals from CDSCO/DCGI for the proposed clinical trial.

B. Work Done So Far

- Experience in formulation development of oral solid dosage forms.
- Experience in manufacturing and regulatory support for vorinostat or similar pharmaceutical formulations.
- Analytical method development and validation experience.
- Stability studies and pilot/commercial batch manufacturing experience, if available.

C. Product Development Readiness

- Current stage of formulation development.
- Availability of formulation development data, analytical methods, and manufacturing process.
- Regulatory readiness, including experience in preparation of Chemistry, Manufacturing and Controls (CMC) documentation and other manufacturing-related documents required for regulatory submissions.
- Estimated timeline for development, validation, manufacturing, and supply of the investigational product.

D. Intellectual Property & Publications

- Status of patents, if any, related to the proposed formulation or manufacturing process.
    - Status of IP: patents filed/granted (national and international).
- Relevant publications or technical reports related to formulation development, manufacturing and regulatory support.

E. Company Profile & Experience

- Experience in formulation development and manufacturing of oral pharmaceutical products.

- Experience in manufacturing investigational medicinal products (IMPs) for clinical trials.
- Experience in regulatory support documentation and other manufacturing-related documents required for regulatory submissions or approvals obtained.
- Past collaborations with national or international health agencies (ICMR, DBT, WHO, CEPI, etc.).

F. Capacity and Infrastructure

- GMP-compliant manufacturing facilities.
- Formulation development, analytical, quality control, and quality assurance laboratories.
- Manufacturing capacity and batch size.
- Stability testing facilities.
- Packaging, labelling, storage, and distribution capabilities for clinical trial materials.

G. Analytical & Quality Control Capabilities

- Availability of validated analytical methods.
- Batch release testing facilities.
- Stability testing capability.
- Quality assurance and quality control systems.

H. Regulatory & Compliance Readiness

- Experience with CDSCO/DCGI regulatory requirements.
- Experience in manufacturing investigational medicinal products for clinical trials.
- GMP certifications and regulatory inspections.
- Ability to comply with applicable GCP, GMP, and regulatory requirements.

I. Timelines & Project Management

- Proposed timelines for formulation development, analytical method validation, manufacturing, packaging, and supply.
- Availability of dedicated technical and project management teams.
- Risk mitigation strategies to ensure uninterrupted supply.

J. Supply Chain & Resource Mobilization

- Availability of raw materials and supply chain management.
- Storage and transportation facilities.
- Availability of skilled manpower.
- Capacity to ensure uninterrupted manufacture and supply throughout the study period.

K. Support Required from ICMR

- Technical discussions regarding formulation requirements.
- Support related to the proposed multicentre clinical trial.

- Regulatory coordination, where applicable.
- Any other support required from ICMR.

L. Compliance & Declarations

- We have gone through the complete EoI document No. _____ dated _____ and have understood all the terms and conditions.
- We have understood the purpose and objectives of this EoI.
- We hereby declare that the information furnished in this proposal is true and correct.
- We will not be deviated from the any of the commitment proposed in this proposal.
- We agree to abide by the roles and responsibilities as outlined by ICMR in this EoI.
- We accept that ICMR reserves the sole right to accept or reject any proposal without assigning any reason thereof.

Authorized Signatory
(Name, Designation, Seal, Date)