

सं. / No. 31026/65/2024-MD  
भारत सरकार / Government of India  
रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals and Fertilizers  
औषध विभाग / Department of Pharmaceuticals

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Udyog Bhawan, New Delhi-110011  
Date: 23<sup>rd</sup> February, 2026

**CORRIGENDUM / ADDENDUM**

Subject : Modification in the operational guidelines of sub-scheme "**Medical Device Clinical Studies Support Scheme**" under the scheme "**Strengthening of Medical Device Industry**"-regarding.

Department of Pharmaceuticals issued Operational Guidelines of sub-scheme "**Medical Device Clinical Studies Support Scheme**" under the scheme "**Strengthening of Medical Device Industry**" on 8.11.2024.

2. Based on the decision taken in the Scheme Steering Committee (SSC) meeting held on 21<sup>st</sup> November 2025, amendments have been made to paragraphs 5.4 and 5.11 of the Scheme Guidelines for the sub-scheme *Medical Device Clinical Studies Support Scheme*.

3. This issues with the approval of the Competent Authority.

Encl. as above.

(Rakesh Kumar)  
Under Secretary to the Government of India  
Tel. No. 23389693

To

- i. Director, NIC, DoP- with a request to upload the same in the Department of Pharmaceuticals website.
- ii. CEO, LSSSDC-PMA of the scheme- for information and necessary action.

## **Annexure**

### **CHAPTER-V**

#### **5. Medical Device Clinical Studies Support Scheme**

##### **5.1 Objective**

To support the medical device industry by fostering development of devices supported by clinical evidence and generation of clinical data that demonstrates the safety and efficacy of the devices manufactured in India. This will promote manufacturing of quality products with better efficacy and safety. It will also enhance credibility of domestic manufacturers to produce high quality products, opening up opportunities for them in markets outside the country.

##### **5.2 Intended Beneficiaries**

- (i) Medical device manufacturers, having manufacturing facility in India, intending to generate pre-clinical data by means of animal studies to demonstrate safety and performance of an investigational medical device in animal models.
- (ii) Medical device manufacturers, having manufacturing facility in India, intending to conduct clinical investigation on human subjects to generate clinical evidence to demonstrate safety and performance of an investigational medical device.
- (iii) Medical device manufacturers, having manufacturing facility in India, intending to conduct Post Market Clinical Follow-up (PMCF) studies on human subjects to generate clinical evidence to demonstrate safety and performance of a medical device.
- (iv) In-vitro diagnostics manufacturers, having manufacturing facility in India, intending to conduct clinical performance evaluation on clinical samples to generate clinical evidence to demonstrate clinical performance of a new in-vitro diagnostic medical device.
- (v) Institutes of national importance like NIPERs, IISER, IITs, AIIMS, IISc, etc., and other reputed Central Institutes or Laboratories involved in design and development, or in pre-clinical evaluation, or in the clinical investigation or clinical performance evaluation of medical devices or IVDs.

##### **5.3 Eligibility Criteria**

- (i) Medical device manufacturers, having manufacturing facility in India, involved in design and development of an investigational medical device are eligible to apply to conduct animal studies as part of pre-clinical study. Applicant should be holding a test licence issued under the provisions of the Medical Devices Rules, 2017.

**OR**

- (ii) Medical device or in-vitro diagnostic manufacturers, having manufacturing facility in India, involved in design, development and manufacturing of an investigational medical device or a new in-vitro diagnostic medical device, are eligible to apply to conduct clinical investigation or clinical performance evaluation, as the case may be. Applicant should be holding permission to conduct clinical investigation or clinical performance evaluation issued under the provisions of the Medical Devices Rules 2017.

**OR**

(iii) Medical device manufacturers, having manufacturing facility in India, involved in manufacturing of class C and class D medical devices are eligible to apply to conduct Post Market Clinical Follow-up studies. Applicant should be holding permission to conduct such study, as per regulatory norms, if any.

OR

(iv) Institutes of national importance like NIPERs, IISER, IITs, AIIMS, IISC etc. and other reputed Central Institutes or Laboratories may conduct the clinical investigation / clinical performance evaluation themselves or through any Clinical Research Organization approved by the Regulatory Authority. The Startups working in the Incubation Centres under these Institutes may also apply through these institutes.

#### 5.4 Incentive under the scheme

The department will provide financial support in conducting clinical investigation/clinical performance evaluation/Post Market Follow-up Study/animal studies to the eligible applicants as referred to in clause 5.3, in the form of grant on re-imburement basis as per the following criteria:

- Pre-Clinical Studies - Rs. 2.0 crore or 25% of the expenditure incurred, whichever is less;
- Clinical Investigations – Rs. 5.0 crore or 25% of the expenditure incurred, whichever is less; [provided that in case of an applicant who has an average turnover of not more than Rs. 10 crore in the preceding two financial years, it shall be Rs. 5 crore or 70% of the expenditure incurred, whichever is less;]<sup>1</sup>
- Post Market Clinical Follow-up – Rs. 1 crore or 25% of the expenditure incurred, whichever is less;
- Performance Evaluation of new IVDs – Rs. 1 crore or 25% of the expenditure incurred, whichever is less;

#### 5.5 Terms for disbursement of incentive

- The cost of project should include cost of conducting single or multi sites clinical investigation/PMCF. Expenditure incurred for subject enrolment, principal investigator fee, etc. may be claimed for re-imburement. *The expenditure incurred for manufacturing the devices/new IVD samples used during study will not be eligible for re-imburement.*
- Escalation in the cost of project over and above the sanctioned amount, due to any reason will be borne by the applicant. The department will not accept any financial liability arising due to delay in conducting/completion of clinical studies covered under these guidelines.
- The applicant shall be responsible for obtaining all necessary statutory clearances in a timely manner.
- The incentive under the scheme shall be disbursed on reimbursement basis on submission of statutory auditor certificate for the expenditure incurred during study and proof of publication of clinical study results. In case where applicant is an Institute of national importance like NIPERs, IISER, IITs, AIIMS, IISc, etc., or any other reputed Central Institute or Laboratory, the expenditure incurred shall be certified by their respective finance/account wing.
- Mere approval of the proposal by the Scheme Steering Committee for consideration of the support does not guarantee disbursement of grant to the applicant. Disbursement of the grant will be subject to fulfilment of conditions under which approval is granted and its verification by the Project Management Agency up to the satisfaction of the SSC.
- The applicant will be required to sign undertaking/agreement as may be approved by the SSC.
- The applicant shall make available all records which may be sought by PMA for purpose of verification, allow PMA access to facilities which have been used in the study and individuals/authorities who may have been involved in the project.

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<sup>1</sup> Inserted *vide* amendment approved in the first meeting of the Scheme Steering Committee of this sub-scheme, held on 21.11.2025

viii. Re-imbusement of expenditure incurred will be restricted to Clinical Studies conducted within India.

## 5.6 Eligible Activities

A list of eligible activities, under this Scheme is as under:

- i. Clinical investigation of an investigational medical device.
- ii. Clinical performance evaluation of the new in-vitro diagnostic medical devices.
- iii. Conduct of animal studies as part of pre-clinical activity for investigational medical devices.
- iv. Conduct of Post Market Clinical Follow-up studies for the devices approved under provisions of Medical Devices Rules 2017.

## 5.7 Project Proposal and its components

Project proposal should have the following details:

- a. Detailed process of conducting Clinical Investigations or Pre-Clinical animal studies for medical device or Clinical Performance Evaluation of new IVDs.
- b. Expected gains from the clinical investigation / clinical performance evaluation.
- c. Complete cost estimates for the proposed study and other activities till rolling out of the project.
- d. Expected number of patients who will be benefitted in the study.
- e. Expected overseas regulatory approvals for market authorization of the product with the help of clinical data generated from the study.
- f. Approved Protocol by CDSCO for conducting clinical investigation/clinical performance evaluation/PMCF study.
- g. Permission to conduct clinical investigation/clinical performance evaluation/PMCF study issued under provisions of Medical Devices Rules 2017.
- h. Identification of impediments and bottlenecks.
- i. Implementation schedule in the Action Plan to contain:
  1. Activity-wise time schedule
  2. Milestone for payments
  3. Expected date of Commissioning
  4. Delay and expected Risk
  5. Monitorable quantified targets for reporting outcomes.

## 5.8 Implementation Process & Timelines

- i. Eligible applicants should submit complete proposal for conducting Clinical Investigations/PMCF or Pre-Clinical animal studies for medical device or Clinical Performance Evaluation of new IVDs
- ii. PMA will scrutinize the proposals and submit its appraisal report with recommendations to the Technical Committee constituted for the evaluation of the proposals within one month.
- iii. PMA shall submit the proposals, complete in all aspects, along with the recommendation of the Technical Committee to SSC for final approval.

- iv. Approved clinical investigations/animal studies/clinical performance evaluation, shall be completed within 3 years or as per the approved timeline by the CDSCO. However, SSC can grant an extension of 1 year for delays due to reasons not in control of applicants.
- v. In case of any deviation from the approved project proposal or time line, approval of DoP must be sought for consideration of financial support to the project.
- vi. Financial support for clinical studies under this scheme may also be obtained along with support from Indian Clinical Trial and Education Network (In-TENT) initiatives of the ICMR. However, any duplication of financial support for the same purpose should be avoided.

## 5.9 Selection Criteria

- I. Project proposals will be considered by SSC based on category of medical devices/new IVDs for which clinical studies are being conducted.
- II. Preference in assistance will be given to those proposals which involve conduct of clinical investigation for investigational medical devices or for clinical performance evaluation for new in-vitro diagnostic medical devices or where the medical device under study is intended to be used for rare diseases, national health priorities and reducing dependence on import of high end medical devices.

## 5.10 Physical and Financial Outlay

Year	Physical Target (no.)	Financial Outlay (Rs. in crore)
	Support to pre-clinical studies, clinical investigation for medical device and clinical performance evaluation for in-vitro diagnostic medical device	Grant-in-aid
Year 1	0	0
Year 2	20-30	50
Year 3	30-60	50
Total	30-60	100

## 5.11 Schedule for release of Grant

The release of funds by the Department will be based on scrutiny and verification by the PMA with approval of the Scheme Steering Committee (SSC) in the following manner: -

Grant-in-Aid disbursement on reimbursement basis	Pre-requisites
<ul style="list-style-type: none"> <li>• Performance Evaluation of new IVDs – Rs. 1 crore or 25% of the expenditure incurred, whichever is less;</li> <li>• Pre-Clinical Studies - Rs. 2 crore or 25% of the expenditure incurred, whichever is less;</li> </ul>	<ul style="list-style-type: none"> <li>• Final approval of the project by SSC.</li> <li>• Verification of the records and documents by the PMA.</li> <li>• The expenditure incurred on new studies taken up after the date of approval by the SSC will only be considered.</li> <li>• Submission of Certificate from Statutory Auditor along with supporting documents such as receipts in respect of total</li> </ul>

<ul style="list-style-type: none"> <li>• Clinical Investigations – Rs. 5 crore or 25% of the expenditure incurred, whichever is less; [Provided that in case of an applicant who has an average turnover of not more than Rs. 10 crore in the preceding two financial years, it shall be Rs. 5 crore or 70% of the expenditure incurred, whichever is less;]<sup>2</sup></li> <li>• Post Market Clinical Follow-up – Rs. 1 crore or 25% of the expenditure incurred, whichever is less;</li> </ul>	<p>expenditure incurred by the applicants for conducting Clinical Investigations or Pre-clinical animal studies for medical device or Post Market Clinical Follow-up or Clinical Performance Evaluation of new IVDs. Publication of the clinical data of Clinical Investigation/Post Market Clinical Follow-up/</p> <ul style="list-style-type: none"> <li>• Clinical Performance Evaluation. Any other condition laid down by the SSC at the time of approval of the proposal.</li> <li>•</li> </ul>
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### 5.12 Maintenance and ownership of assets/data

- i. The assets/data acquired by the applicant out of government assistance shall not be encumbered or utilized for purposes other than for which the funds have been released.
- ii. The clinical data generated through the study shall be maintained by the applicant for a minimum of 20 years and such data shall be made available to any Government agency as and when asked.

### 5.13 Expected Benefits

- i. Improvement in quality standards of medical devices.
- ii. Improvement in regulatory compliance specified for medical device
- iii. Increase in export of Medical Devices based on Clinical Investigations or Pre-Clinical animal studies for medical device or Post Market Clinical Follow-up Clinical Performance Evaluation of new IVDs
- iv. Promotion of domestic Contract Development and Manufacturing Organizations (CDMOs) industry.

### 5.14 Monitoring

- i. The PMA/DoP shall carry out regular monitoring of the implementation of the scheme and each project approved thereunder. The PMA shall prepare Monitoring Reports in the frequency and format as decided by the SSC and assist the SSC and DoP in monitoring the Scheme.
- ii. PMA will provide full access to the scheme monitoring portal to Department of Pharmaceuticals and shall monitor approved projects through physical inspection, implementation schedule based on Critical Path Method / Gantt Chart and submit monthly & quarterly reports.
- iii. PMA shall identify potential delays and failure of projects to meet deadlines and propose corrective action as part of the monitoring process.

<sup>2</sup> Inserted *vide* amendment approved in the first meeting of the Scheme Steering Committee of this sub-scheme, held on 21.11.2025