



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI)

Conducting research and project-based training of students/ research scholars in Materiovigilance at MDMC or NCC-MvPI, IPC

1.0 OBJECTIVE

- 1.1 To lay down a procedure for conducting research and project-based training of students/ research scholars in materiovigilance at Medical Device Adverse Event Monitoring Centre (MDMC) or National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), Indian Pharmacopoeia Commission (IPC).

2.0 SCOPE

- 2.1 This document is applicable to enroll research scholar/ project trainee for conducting research at MDMC/ NCC-MvPI, IPC.

3.0 PROCEDURE

- 3.1 **The research scholar/ project trainee who wish to apply for an internship opportunity at MDMCs/ NCC-MvPI shall be pursuing final year or completed any of the following courses:**
- 3.1.1 Pharmaceutical sciences such as B. Pharm., M. Pharm., Pharm. D., Ph.D.
 - 3.1.2 Medical sciences such as M.B.B.S., M.D., D.M.
 - 3.1.3 Dental sciences such as B.D.S, M.D.S, Ph.D.
 - 3.1.4 Engineering such as B.E./ M.E./ B. Tech./ M. Tech./ M.Sc./ M.S./ Ph.D. in biomedical, clinical, medical electronics, instrumentation & related courses.
 - 3.1.5 Nursing such as ANM, GNM, DNA, B.Sc./ M.Sc., Nursing.
 - 3.1.6 Allied health science courses.
- 3.2 The internship shall be offered for varying durations of 3 months, 6 months, and 1 year, with batches commencing in January, April, July, and October. Interested applicants are advised to visit the IPC website (www.ipc.gov.in) for details regarding internship opportunities, which are circulated 45 days prior to each month in which internship is starting.

NOTE: This is a paid internship. The fee structure is ₹3,000 for 3 months, ₹6,000 for 6 months, and ₹12,000 for 1 year. The applicable amount must be paid to NCC-MvPI, IPC prior to the commencement of the internship.

3.3 **Roles & responsibilities of NCC-MvPI:**

- 3.3.1 To send an email to all the existing MDMCs seeking their approval to allow interns at their centres and requesting the number of interns each MDMC is willing to accommodate. NCC-MvPI shall maintain the list of MDMCs allowing internships at their centre as per Annexure I;
- 3.3.2 Based on the responses received from the MDMCs, concerned personnel shall facilitate the enrollment process for research scholar/ project trainee into MDMC/ NCC-MvPI by circulating the internship application form through social media platforms such as IPC website, linkedIn, twitter, etc. for minimum 14 days;
- 3.3.3 Allocation of MDMC/ NCC-MvPI for research scholar/ project trainee shall be based on the availability of vacancies at the MDMC/ NCC-MvPI and the preferences of the research scholar/ project trainee;
- 3.3.4 To send an email to all the selected research scholar/ project trainee requesting them to complete and return the consent form (Annexure II) within a week;
- 3.3.5 To provide the relevant SOPs and other resource materials to the selected research scholar/ project trainee in order to ensure smooth functioning of assigned duties;
- 3.3.6 To provide proper induction training, guidance and hand holding support to research scholar/ project trainees. Induction training shall be conducted during the first week of joining for each batch;
- 3.3.7 Content for the induction training shall include but not limited to:
 - a. Overview of MvPI
 - b. Understanding Medical Device Adverse Events (MDAEs)
 - c. Introduction to the Adverse Drug Reaction Monitoring System (ADRMS)
 - d. Reporting modalities (offline and ADRMS portal)
 - e. Steps for reporting MDAEs



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- f. Causality assessment methodology
- g. Interns' roles, responsibilities, and expected deliverables
- 3.3.8 To collect 'Monthly Report' (Annexure III) from the research scholars/ project trainees;
- 3.3.9 To organize an 'E-Poster Competition' or any other suitable activities during the tenure of each internship batch;
- 3.3.10 To collect the duly signed 'MvPI Internship Report' (Annexure IV & VI) from the research scholars/ project trainees at the end of their internship tenure duly signed from the Coordinator/ Deputy Coordinator;
- 3.3.11 To maintain the number of reports submitted by research scholar/ project trainee as per Annexure V;
- 3.3.12 To provide the 'Certificate of Completion' after consultation with the respective Coordinator/ Deputy Coordinator to the research scholar/ project trainee once the following assigned duties shall be successfully completed:
 - a. Minimum 75% attendance;
 - b. Submission of internship report signed by Coordinator/ Deputy Coordinator;
 - c. Submission of ≥ 30 reports for a 3-month internship and ≥ 60 reports for a 6-month internship period;
- 3.3.13 To provide the 'Certificate of Excellence' to the research scholar/ project trainee with the approval of the Competent Authority of NCC-MvPI subject to fulfillment of the following criteria:
 - a. A minimum of 90% attendance (for interns at both MDMC and NCC-MvPI);
 - b. For interns posted at MDMC: Submission of more than 100 validated reports (3-month internship) or more than 200 validated reports (6-month internship), or completion of research work with communication/publication of a research paper;
 - c. For interns placed at NCC-MvPI: Completion of assigned research work along with communication/ publication of a research paper.

- 3.4 Roles & responsibilities of research scholar/ project trainee at NCC-MvPI, IPC:**
- 3.4.1 To actively participate in the quality review of Individual Case Safety Reports (ICSRs) and in signal detection activities;
- 3.4.2 To maintain a minimum attendance of 75% for obtaining the “Certificate of Completion” and to maintain a minimum attendance of 90%, along with completion of the assigned research work and communication/publication of a research paper, for obtaining the “Certificate of Excellence”;
- 3.4.3 To understand the functioning of MvPI and assist Materiovigilance Associates (MvAs) in their activities for better learning and practical hands-on exposure;
- 3.4.4 To carry out research work by selecting a suitable topic approved by the competent authority, NCC–MvPI shall make efforts to publish the work done under the guidance and supervision of the assigned Materiovigilance Associate (MvA) and submit ‘MvPI Internship Report’ as per Annexure VI;
- 3.4.5 To perform any other tasks or responsibilities assigned by the competent authority, as and when required.
- 3.5 Roles & responsibilities of research scholar/ project trainee at MDMC:**
- 3.5.1 To support the Coordinator of the MDMC & peripheral hospitals/ clinics in order to improve quality, quantity and frequency of adverse event reporting within the available resources of the institution;
- 3.5.2 To visit the hospital premises such as nursing station/ ward/ Intensive Care Unit (ICU)/ Operation Theatre (OT)/ lab & other clinical departments as and when required to collect the MDAEs as per prevailing norms and instruction from the Coordinator/ Deputy Coordinator;
- 3.5.3 To maintain a minimum attendance of 75% and submit ≥ 30 reports during 3-month internship or ≥ 60 reports during 6-month internship period for obtaining the ‘Certificate of Completion’;

- 3.5.4 To carry out/ assist awareness programs to healthcare professionals under the supervision of Coordinator/ Deputy Coordinator/ concerned authorities from MDMC, peripheral hospitals/ clinics & NCC-MvPI;
- 3.5.5 To maintain a cordial relationship with healthcare professionals as per the code of conduct of organization/ hospital/ MDMC and peripheral hospital/ clinic;
- 3.5.6 To submit 'Monthly Report' to NCC-MvPI as per Annexure III;
- 3.5.7 To submit 'MvPI Internship Report' (Annexure IV) to the Coordinator/ Deputy Coordinator for their review and signature and signed copy to NCC-MvPI;
- 3.5.8 To keep the data generated through research/ project confidential and shall not publish/ present in public meetings until prior approval from NCC-MvPI is obtained.

Note: The "Certificate of Excellence" shall be awarded to interns demonstrating outstanding reporting performance with attendance above 90%. Eligibility requires submission of more than 100 validated reports (for a 3-month internship) or more than 200 validated reports (for a 6-month internship), or completion of assigned research work along with communication/publication of research paper.

3.6 Roles & responsibilities of Coordinator/ Deputy Coordinator:

- 3.6.1 To provide administrative support such as ID card (if applicable), permission for collecting and reporting medical device adverse events from various departments and conducting awareness programmes in MDMC & peripheral hospitals;
- 3.6.2 To provide support & guidance to the research scholar/ project trainee to carry out the assigned duties;
- 3.6.3 To maintain a record of attendance of the trainees allotted at the centre and MDAE collected;
- 3.6.4 To maintain proper communication with NCC-MvPI & corresponding college/ institute about the progress and performance of the research scholar/ project trainee as and when required;
- 3.6.5 To check the authenticity, accuracy and quality of data generated through research/ project and ensure the transmission of data to NCC-MvPI;

3.6.6 To collect and sign the ‘MvPI Internship Report’ from research scholar/ project trainee as per Annexure IV and ensure submission of signed copies to NCC-MvPI.

4.0 SAFETY AND PRECAUTION

- 4.1 Do not use any SOP if it is not signed and issued by competent personnel or the authorized signatories.
- 4.2 Do not use adhesive tape or whitener on SOP.
- 4.3 Do not share the SOP information outside the organization.

5.0 REFERENCES

In-House

6.0 ABBREVIATIONS

6.1	ADRMS	:	Adverse Drug Reactions Monitoring System
6.2	ICSR	:	Individual Case Safety Report
6.3	ICU	:	Intensive Care Unit
6.4	IPC	:	Indian Pharmacopoeia Commission
6.5	MDAE	:	Medical Device Adverse Event
6.6	MDMC	:	Medical Device Adverse Event Monitoring Centre
6.7	MvA	:	Materiovigilance Associate
6.8	MvPI	:	Materiovigilance Programme of India
6.9	NA	:	Not Applicable
6.10	NCC	:	National Coordination Centre
6.11	OT	:	Operation Theatre
6.12	SOP	:	Standard Operating Procedure

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7.0 ANNEXURE(s)

- 7.1 Annexure I : List of Medical Device Adverse Event Monitoring Centre (MDMC) allowing internship at their centre
- 7.2 Annexure II : Consent Form
- 7.3 Annexure III : Monthly Internship Report of research scholar/ project trainee
- 7.4 Annexure IV : MvPI Internship Report (For interns at MDMC)
- 7.5 Annexure V : Record of MDAE reports received by research scholars/ project trainees per month
- 7.6 Annexure VI : MvPI Internship Report (For interns at NCC-MvPI, IPC)

REVISION LOG		
Version	Description of Change	Release Date
00	New document for posting on IPC's website	29-July-2026