



e-Newsletter

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Ministry of Health and Family Welfare (MoHFW) Government of India

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MEDICAL DEVICE ADVERSE EVENT MONITORING CENTRES (MDMCS)

S. No.	State	MDMC Name & Address	Status
1.	Assam	All India Institute of Medical Sciences Guwahati (AIIMS Guwahati), Silbharal Changsari, Guwahati, Assam-781101	Government
2.	Delhi	Maharaja Agrasen Hospital West Punjabi Bagh, New Delhi-110026	Non-Government
3.	Gujarat	Government (CL & SC) Spine Institute and Physiotherapy College Civil Hospital Campus, Asarwa, Ahmedabad, Gujarat-380016	Government
4.		Sterling Hospital Plot No.251, Police Station, 150 Feet Ring Rd, Opp. Gandhigram, Dharam Nagar, Rajkot, Gujarat-360007	Non-Government
5.		Synergy Superspeciality Hospital Synergy Circle, Nr Gokulmathura Apartment, Ayodhya Chowk BRTS Stand, 150 Feet Ring Rd, Rajkot, Gujarat-360005	Non-Government
6.		Smt. Nathiba Hargovandas Lakhmichand Muncipal Medical College Ellis Bridge, Ahmedabad, Gujarat-380006	Government
7.	Haryana	Amrita Institute of Medical Sciences and Research Centre Mata Amritanandmayi Marg, Sector - 88, Faridabad, Haryana -121002	Non-Government
8.		Arpana Hospital Arpana Trust, Madhuban, Karnal, Haryana-132037	Non-Government
9.		Asian Institute of Medical Science (A Unit of Blue Sapphire Healthcare Private Limited), Badkal Flyover, Road, Sector 21A, Faridabad, Haryana-121001	Non-Government
10.	Jharkhand	Raj Hospitals Complex Mahatma Gandhi Main Road, Behind Central, Ranchi, Jharkhand-834001	Non-Government
11.		Bhagwan Mahavir Medica Superspecialty Hospital Near, Bariatu Road P.H.E.D Colony, Booty More Rd, Jai Prakash Nagar, Ranchi, Jharkhand-834010	Non-Government
12.	Karnataka	Koppal Institute of Medical Sciences Gangavathi Rd, Kiddidal Gate, Bhagyanagar, Karnataka-583231	Government
13.		ESIC -Medical College & PGIMER Academic Block 3 rd Block, Rajajinagar, Bangaluru, Karnataka- 560010	Government
14.		First Neuro Brain & Spine Super Speciality Hospital Mangalore, Kannur Village, Padil Post, Mangalore, Karnataka-575007	Non-Government
15.		Apollo Speciality Hospital New No.2, Old no. 21/2, 14 th Cross 3 rd Block, Jayanat Bangalore, Karnataka-560011	Non-Government

Medical Device Adverse Event Monitoring Centres (MDMCs)

16.	Karnataka	Sapthagiri Institute of Medical Sciences & Research Centre No.15, Hesaraghatta Main Road, Chikkabanavara, Bangalore, Karnataka-560090	Non-Government
17.		Motherhood Hospital (A unit of Healthcare Private Limited) Bangalore, Karanataka-560103	Non-Government
18.		Motherhood Hospital 4, 30 th Main Rd, Opp. Kempegowda Institute of Medical Science, Kaveri Nagar, Banagirinagara, Banashankari 3 rd Stage, Banashankari, Bengaluru, Karnataka-560085	Non-Government
19.		Motherhood Hospital (A Unit of Rhea Healthcare Private Limited) 50/C Yadav Giri, Karnataka-570020	Non-Government
20.	Kerala	KIMS Bellerose Institute of Medical Sciences Private Limited Kudamaloor, Kottayam, Kerala-686017	Non-Government
21.		Cosmopolitan Hospital Private Limited Pottakuzhy Rd, Pattom, Thiruvananthapuram, Kerala-695004	Non-Government
22.		KMCT Medical College Hospital Manassery PO Mukkam, Calicut, Kerala-673602	Non-Government
23.		Mitera Hospital Private Limited H 1, Thellakom, Ettumanoor, Kerala-686630	Non-Government
24.		Muthoot Health Care Private Limited College Road, Kozhencherry, Kerala-689641	Non-Government
25.		Caritas Hospital and Institute of Health Sciences Thellakam PO, Kottayam, Kerala-686630	Non-Government
26.	Maharashtra	Sadhu Vaswani Mission's Medical Complex 7-9, Koregaon Park, Pune, Maharastra-411 001	Non-Government
27.	Punjab	Guru Nanak Dev Super Speciality Hospital Goinowal Road, Tarn Taran, Punjab-143401	Non-Government
28.	Rajasthan	Healthcare Global Enterprises Shipra Path, Mansarovar Sector 5, Mansarovar, Jaipur, Rajasthan-302020	Non-Government
29.	Tamil Nadu	The Government Medical College The Nilgiris Udhagamandalam, Tamil Nadu-643001	Government
30.		Thanjavur Medical College Hospital Thanjavur, Tamil Nadu-613004	Government
31.		Government Medical College Hospital Tamil Nadu -626001	Government
32.		Government Thiruvapur Medical College Hospital Master Collectorate Office Campus, Thandalai, Thiruvapur, Tamil Nadu-610 004.	Government

Medical Device Adverse Event Monitoring Centres (MDMCs)

33.	Tamil Nadu	Government Medical College Hospital Krishnagiri, Tamil Nadu-635115	Government
34.		KAP Viswanathan Government Medical College Mahatma Gandhi Memorial Government Hospital EVR Rd, Puthur, Thillai Nagar, Tiruchirappalli, Tamil Nadu-620001	Government
35.		Government Thoothukudi Medical College Thoothukudi, Tamil Nadu-628008	Government
36.		Government Medical College Pudukkottai, Tamil Nadu-622004	Government
37.		Kanyakumari Government Medical College Asaripallam, Kanyakumari, Nagercoil, Tamil Nadu-629001	Government
38.		Government Medical College & ESI Hospital Coimbatore-15, Tamil Nadu-641015	Government
39.		Government Viluppuram Medical College Hospital Mundiampakkam, Village, Viluppuram, Tamil Nadu-605601	Government
40.		Government Medical College Hospital Gandhigramam, Karur, Tamil Nadu-639004	Government
41.		Government Vellore Medical College Munjurpet Road, Post, Sapthalipuram, Pennathur, Adukkamparai, Tamil Nadu-632011	Government
42.		Government Nagapattinam Medical College Hospital, Nagapattinam Opposite New Bus Stand, Velipalayam, Nagapattinam, Tamil Nadu-611001	Government
43.		Government General Hospital Karaikal, Puducherry-609602	Government
44.		Government Stanley Medical College and Hospital Old Jail Road, Chennai, Tamil Nadu-600001	Government
45.		Government Medical college Hospital Mohanur - Namakkal Rd, Thillaiapuram, Namakkal, Tamil Nadu-637001	Government
46.		Mehta Multispeciality Hospitals India Private Limited No. 50, Poonamallee High Road, Velappanchavadi, Tamil Nadu-600077	Non-Government
47.		MGM Healthcare Private Limited New No 72, Old, No 54, Nelson Manickam Road, Aminjikarai, Chennai, Tamil Nadu-600029	Non-Government
48.		Sir Ivan Stedeford Hospital 7, Madras Thiruvallur High Rd, Shobha Nagar, OT, Ambattur, Chennai, Tamil Nadu-600053	Non-Government
49.		Apollo Speciality Hospitals O M R, 5/639, Rajiv Gandhi Salai, Tirumalai Nagar, Perungudi, Chennai, Tamil Nadu-600096	Non-Government

Medical Device Adverse Event Monitoring Centres (MDMCs)

50.	Tamil Nadu	Chennai Noble Hospitals Private Limited M.Ct.M. School Basket Ball Court, (44, 4, Audiappa St, Near Lauders Gate, Opposite. Lady, Purasaiwakkam, Chennai, Tamil Nadu-600084	Non-Government
51.		Public Health Centre 174 Lake View Road, Ramakrishnapuram, West Mambabm, Chennai, Tamil Nadu-600033	Non-Government
52.		T.N.K.H.N.U Charity Fund Hospital No. 23, NRT Road, Theni, Tamil Nadu-625531	Non-Government
53.		Madurai Kidney Centre and Transplantation Research Institute 6 B-2, Sivaganga Rd, Managiri, Madurai, Tamil Nadu-625020	Non-Government
54.		St. Isabel's Hospital No: 49, Oliver Road, Chennai, Tamil Nadu-600004	Non-Government
55.		Apollo Hospital No.645, 646 T.H Road Tondiarpet, Chennai, Tamil Nadu-600081	Non-Government
56.		Sri Kauvery Medical Care India LTD. 110E/20/1, North Bypass Road, Vannarpettai Tirunelveli, Tamil Nadu-627003	Non-Government
57.		Apollo Proton Cancer Centre 4/661, Dr. Vikram Sarabai Instronic Estate 7 th St, Dr. Vasi Estate, Phase II, Tharamani, Chennai, Tamil Nadu-600041	Non-Government
58.		Apollo First Med Hospital No.154, Poonamallee High Road, Kilpauk, Chennai, Tamil Nadu-600010	Non-Government
59.		Apollo Speciality Hospital Nandanam 320, Anna Salai, Padma Complex, Mount Road, Teyanampet, Chennai, Tamil Nadu-600035	Non-Government
60.	Telangana	Usha Mullapudi Cardiac Centre Gajularamaram Rd, Shapur Nagar, Indira Nagar, Gajularamaram, Hyderabad, Telangana-500055	Non-Government
61.	Uttar Pradesh	Government Institute of Medical Sciences Greater Noida, Gautam Buddha Nagar, Uttar Pradesh-201310	Government
62.		Kailash Hospital and Heart Institute H-33, Shaheed Arjun Sardana Marg, H Block, Pocket H, Sector 27, Noida, Uttar Pradesh-201301	Non-Government
63.		All India Institute of Medical Sciences Gorakhpur, Kunraghat Gorakhpur, Uttar Pradesh-273008	Government
64.	West Bengal	All India Institute of Medical Sciences Kalyani NH -345 Connector, Basantapur, Saguna, Nadia, West Bengal -741245	Government

TRAINING & EDUCATION



Training Programme on Medical Device Adverse Event Reporting Tools & Uses

National Coordination Centre – Materiovigilance Programme of India (NCC-MvPI), in association with Tata Memorial Centre Cancer Research Institute, conducted a training programme on October 5, 2023, at Tata Memorial Centre Cancer Research Institute, Mumbai. Mr. Surya Pratap Yadav, Jr. Materiovigilance Associate, MvPI delivered a session on "Medical device adverse event reporting tools & uses: A case study discussion".



MvPI Participation in 78th Training Programme on "Celebrity Endorsements- Are we still being duped"

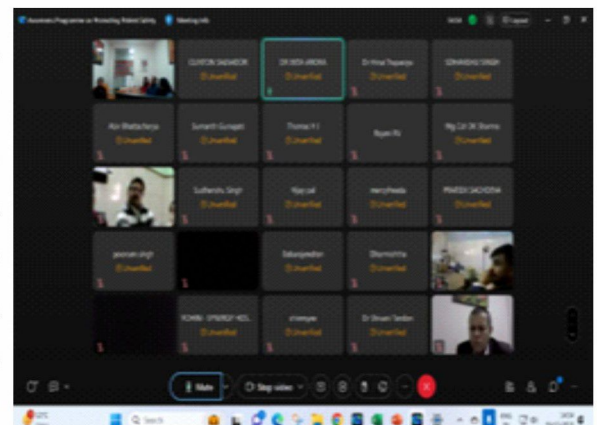


Training Programme on "Celebrity Endorsements - Are we still being duped" 78th Programme in Consumer Series was organized on October 7, 2023, at India Habitat Centre, New Delhi. Ms. Numra Saifi & Ms. Krishna, Junior Materiovigilance Associates, MvPI attended the said training programme and enhanced their knowledge regarding consumer awareness.



Webinar on "Promoting Patient Safety" for Healthcare Professionals

NCC-MvPI, IPC organized a webinar entitled "Awareness Programme on Promoting Patient Safety: A comprehensive MvPI Training for Healthcare Professionals" on December 19, 2023, via digital/virtual platform. Mr. Surya Pratap, Ms. Krishna & Ms. Numra Saifi, Jr. Materiovigilance Associates presented the session on the Overview of the Materiovigilance programme & modalities and ADRMS software to report medical device adverse events, respectively.





81st Programme in Consumer Series on "Truth about Cholesterol and Lipids"

81st programme in the Consumer Series on 'Truth about Cholesterol and Lipids' was organized on February 6, 2024, at India Habitat Centre, New Delhi. Dr. V. Kalaiselvan, Senior Principal Scientific Officer, Mr. Surya Pratap Yadav & Ms. Krishna, Junior Materiovigilance Associates, MvPI attended the said training programme and enhanced their knowledge regarding consumer awareness and discussed the opportunities, to have such sessions on Materiovigilance Programme of India (MvPI) in future.

International training programme on Materiovigilance for Bhutan Food & Drug Authority Officials at Punakha, Bhutan



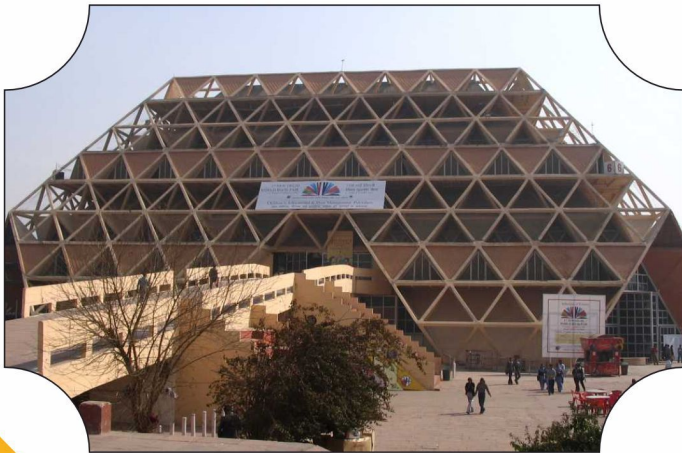
Based on the invitation for materiovigilance training received from Bhutan FDA, Ministry of Health, Royal Government of Bhutan, IPC officials i.e. Dr. Vivekanandan Kalaiselvan, & Dr. Shatrunajay Shukla along with Sh. Aseem Sahu, DDC from CDSCO imparted materiovigilance training from February 26, 2024 to March 01, 2024 at Punakha Bhutan. IPC officials sensitized the officials of Bhutan Food & Drug Authority & healthcare staff of different Government hospitals on Materiovigilance

and provided hand-holding support to establish a system for monitoring the quality of medical devices and promote safety of the citizens in Bhutan.

World Standards Day 2023



The Bureau of Indian Standards celebrated the "World Standards Day 2023" at Bharat Mandapam with the theme "Shared Vision for a Better World". Among the participants were Mr. Surya Pratap Yadav and Ms. Krishna, Junior Materiovigilance Associate from MvPI, who actively participated in the celebration.



MvPI Participation in "34th Edition Medical (B2B Medical Equipment) Exhibition 2023"

34th Edition Medical Exhibition India's largest B2B Medical Equipment, 2023 from October 7-9, 2023 was organized at Pragati Maidan, New Delhi. Ms. Shweta Wachaspati, Pharmacopeial Associate and Ms. Krishna, Jr. Materiovigilance Associate from NCC-MvPI set up a stall at the said expo and showcased the resource material related to the Materiovigilance Programme of India (MvPI).





Materiovigilance Conference: Safety of Medicines & Society of Pharmacovigilance's 21st Annual Conference

MvPI Participation in International Conference on Safety of Medicines & 21st Annual Conference of Society of Pharmacovigilance held on 10-11 February 2024 at Jawaharlal Nehru Medical College Hospital Aligarh Muslim University, Aligarh, Uttar Pradesh-202002.

Dr. V. Kalaiselvan, Senior Principal Scientific Officer, IPC chaired an insightful session on "Medical Device Safety Surveillance Systems in India: Materiovigilance Programme of India". He highlighted the key aspects of the Materiovigilance Programme of India and its role in ensuring the safety of medical devices in the country.

Dr. Shatrúnajay Shukla, Scientific Assistant, IPC efficiently managed activities related to the conference, ensuring smooth coordination and execution of various sessions and events.

Mr. Surya Pratap Yadav, Jr . Materiovigilance Associate, IPC played a crucial role in setting up the stall to spread awareness about the Materiovigilance Programme of India. The stall attracted a significant number of attendees and helped in disseminating important information about the programme.

Ms. Krishna, Jr Materiovigilance Associate, IPC delivered a session focusing on the Materiovigilance Programme of India, highlighting its significance and impact on ensuring the safety of medical devices in the country.



Initiative for Extending MvPI Program to Clinical Institutions in Karnataka



Implementation of MvPI in Karnataka with Commissioner, Commissionerate of Health & Family Welfare GOK, Mr. V. Hari Haran, Senior Materiovigilance Associate at MvPI, conducted a program aimed at extending the MvPI program to clinical institutions other than medical colleges. This initiative was undertaken under the DME NCC-MvPI, in collaboration with RTC-MvPI and NIMHANS at the Commissionerate H&FW GOK on 26-10-2023.



Workshop: Stepping forward to promote the safety of medical devices

Royal Care Super Specialty Hospital (RCSSH), Coimbatore organized a workshop entitled "Stepping forward to promote the safety of medical devices: Materiovigilance Program of India". This workshop took place on February 16, 2024, at Gokulam Park, Coimbatore. The objective of this training programme was to create awareness about materiovigilance and medical device adverse event reporting among faculty members, medical device & textile industry officials, healthcare organizations, students and other HCPs. Around 280 participants participated in this workshop.



MEDICAL DEVICE UPDATES

IPC-MvPI's efforts to become a certification body for Indian Certification of Medical Devices (ICMED) Scheme under the Quality Council of India (QCI)



IPC-MvPI had submitted an application in July, 2023 to become a certification body under the Indian Certification of Medical Devices (ICMED) scheme, a collaborative effort between the Quality Council of India (QCI) and the Association of Indian Medical Device Industry (AIMED). This initiative aims to ensure the quality of medical devices and mitigate risks associated with poor quality of medical devices.

QCI auditors have conducted an office assessment on January 10-11, 2024, and found that IPC-MvPI has established an overall system and procedures in place. However, only two

non-conformities (1 Major, 1 Minor) were identified according to their guidelines. Subsequently, IPC-MvPI addressed those two nonconformities successfully and completed the necessary corrective actions. In response, QCI has accepted the proposed corrective actions & closed the Ncs.



Once approval is obtained, IPC-MvPI will join the select group of very few previously approved CBs for assessing the Quality Management System (QMS) of medical device stakeholders. This accreditation aims to enhance patient safety, ensure consumer protection, and significantly reduce the trade of sub-standard products or devices with questionable origins. Additionally, it will create opportunities for indigenous medical device manufacturers to compete more efficiently with international players.



Safety Alerts

NCC-MvPI, IPC has observed an adverse event report of IOL Breakage Post Implantation with the use of Intraocular Lens (IOL) which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Intraocular Lens (IOL)	IOL Breakage Post Implantation

NCC-MvPI, IPC has observed an adverse event report of Contamination with foreign particles (Pseudomonas aeruginosa) with the use of Ophthalmic Solution (pre-filled sterile syringe) which may lead to the serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Ophthalmic Solution (pre-filled sterile syringe)	Contamination with foreign particles

NCC-MvPI, IPC has observed an adverse event report of Contaminated with fungus, leaky with the use of Blood Administration Set which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Blood Administration Set	Contaminated with fungus, leaky

NCC-MvPI, IPC has observed an adverse event report of Poor Quality, Blockage, Plunger Breakage with the use of Hypodermic Syringe which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Hypodermic Syringe	Poor Quality, Blockage, Plunger Breakage

NOTE

You are requested to closely monitor the adverse events of these devices at your respective monitoring centre. If these devices are being used at your hospital. Kindly report all the suspected adverse events related to above mentioned medical devices, if any, using reporting form, available on www.ipc.gov.in and send via e-mail: shatrunjay.ipc@gov.in.

IMPORTANT MESSAGE

The content of this safety alert is highly confidential. It is strictly forbidden to share any part of the message with any third party/vendor or on public platforms such as social media, local newspapers/posters etc., without a written consent of the publisher. Your support in this regard is highly solicited.



PUBLICATIONS

NCC-MvPI has published an article entitled "Risk of pancreatitis and pancreatic carcinoma for anti-diabetic medications: findings from real-world safety data analysis and systematic review and meta-analysis of randomized controlled trials".

DOI: [10.1080/14740338.2023.2284992](https://doi.org/10.1080/14740338.2023.2284992)

Risk of pancreatitis and pancreatic carcinoma for anti-diabetic medications: findings from real-world safety data analysis and systematic review and meta-analysis of randomized controlled trials

Asif Muhammed, Christy Thomas, Vivekanandan Kalaiselvan & Krishna Undela 

NCC-MvPI has published an article entitled "Risk of serious skin and subcutaneous tissue disorders for nimesulide among the pediatric population: a jeopardy identified through the analysis of global individual case safety reports".

DOI: <https://doi.org/10.1080/14740338.2023.2274416>

Risk of serious skin and subcutaneous tissue disorders for nimesulide among the pediatric population: a jeopardy identified through the analysis of global individual case safety reports

Krishna Undela  , Vivekanandan Kalaiselvan, Sai Krishna Gudi, Subeesh K. Viswam & Syed Kashif Ali

NCC-MvPI has published an article entitled "Health-care professionals' perception toward medical device post market surveillance practices: A cross-sectional study in India". Indian Journal of Public Health.

Recommendations to Central Drugs Standard Control Organization (CDSCO)

- NCC-MvPI sent a recommendation to CDSCO on "Guidewire Breakage Inside the Body" associated with "Central Venous Catheter" for information and necessary actions at their end.
- NCC-MvPI sent a recommendation to CDSCO on "Foreign Particles Present/Leakage/Poor Quality" associated with "Hemodialysis Catheter" for information and necessary actions at their end.
- NCC-MvPI sent a recommendation to CDSCO on "Uncontrolled Flow/Poor Quality" associated with "Intra Venous Infusion Set" for information and necessary actions at their end.
- NCC-MvPI sent a recommendation to CDSCO on "Struck in Trachea" associated with "Nasogastric Tube" for information and necessary actions at their end.
- NCC-MvPI sent a recommendation to CDSCO on "Suture Break" associated with "Suture Mediated Closure System for Arterial and Venous Access" for information and necessary actions at their end.
- NCC-MvPI sent a recommendation to CDSCO on "Extractor not Opening" associated with "Stone Extractor" for information and necessary actions at their end.
- NCC-MvPI sent a recommendation to CDSCO on "IOL Breakage Post Implantation" associated with "Intra Ocular lens" for information and necessary actions at their end.
- NCC-MvPI sent a recommendation to CDSCO on "IOL Opacification Post Implantation" associated with "Intra Ocular lens" for information and necessary actions at their end.



It's truly commendable how MvPI has placed paramount importance on the safety of medical devices, setting up numerous medical device safety monitoring centers across various clinical settings in the country. This initiative has not only ushered in a new reporting culture regarding medical devices but has also significantly contributed to the betterment of patient care. The opportunities that have arisen from this drive are immense, and I am confident that MvPI will continue to provide valuable scientific evidence for the advancement of clinical practice. MvPI's dedication and commitment to ensuring the safety and efficacy of medical devices are invaluable to the healthcare community and the well-being of patients.



Dr. Dilip.C

*Principal
Alshifa College of Pharmacy
Malappuram, Kerala*

I, Aditya, appreciate the Materiovigilance Programme of India (MvPI) initiative in providing a platform for consumers to report adverse events related to medical devices. While the initiative is commendable, improvements in accessibility, simplification of the reporting process, and establishment of a feedback mechanism are necessary. Enhancing awareness through multiple channels, simplifying reporting forms, and providing timely updates on reported events would further empower consumers and enhance patient safety. I believe this programme would encourage more individuals to participate actively in reporting adverse events, ultimately benefiting public health.



Aditya

*Consumer
Haridwar, Uttarakhand*

I, Vishal Kumar, a MvPI trainee, enrolled in the Materiovigilance Programme of India, IPC Ghaziabad, a medical device adverse event monitoring center (MDMC) under MvPI, under the supervision of coordinator Dr. Pramod Kumar Manjhi of the All India Institute of Medical Science in Patna, Bihar, 801507. I express profound gratitude for the team's dedication to Materiovigilance. Your efforts have significantly enhanced healthcare outcomes through insightful analysis of adverse event reactions. The program's systematic approach to data acquisition and reporting has been remarkably effective. I am deeply impressed by your unwavering commitment to patient safety. Thank you for your outstanding contributions towards patient safety.



Vishal Kumar

*MvPI Trainee
All India Institute of
Medical Science
Patna, Bihar*

In my 9 months as an MvPI trainee at AIIMS-Rishikesh under Dr. Puneet Dhamija, I would like to appreciate the dedication and commitment of MvPI team towards the safety of medical device. Thanks to IPC-MvPI for this learning opportunity. AIIMS-Rishikesh having a stellar team of experienced doctors who impart invaluable knowledge, stressing the significance of even minor healthcare aspects. I've learned firsthand experience how substandard devices can jeopardize the patient well-being. It's crucial aspect to promote MvPI, to highlight the profound impact of device quality on patient safety.

Arohi Agarwal

*MvPI Trainee
All India Institute of
Medical Science
Rishikesh*





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ADR Mobile-app

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1800 180 3024



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www.ipc.gov.in

We have started a journey of Materiovigilance, for saving patient's lives