



# *e-Newsletter*

**VOL 4 | ISSUE 3 | 2022**

## **Materiovigilance Programme of India**

**Published by :**

**National Coordination Centre - Materiovigilance Programme of India**

**Indian Pharmacopoeia Commission**

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



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# New MDMCs

## Medical Device Adverse Event Monitoring Centres (MDMCs)

1. Sri Venkateswara Institute of Medical Sciences Alipiri Road, Tirupati Urban, Andhra Pradesh-517507
2. PES Institute of Medical Sciences & Research, Kuppam, Chittar District, Andhra Pradesh-517425
3. Sentini Hospital, 54-15-5 B&C Ring Road, Beside Vinayak Theatre, Vijayawada, Andhra Pradesh- 520008
4. Nagarjuna Hospital, Kanuru Road, Autonagar, Vijayawada, Andhra Pradesh -520007
5. HCG Curie City Cancer Centre, 44-1-1/3, Padavalarevu, Machavaram Down, Gunadala, Vijayawada- 520004
6. Silchar Medical College, Ghungoor, Silchar, Assam- 788014
7. Apollo Hospital (Unit: International Hospital) Lotus Tower, G.S. Road, Guwahati, Assam - 781005
8. Parikh Superspeciality Hospital, Police Station, Sardar Patel Ring Road, Opposite- Nikol, Beside Cricket Ground, Ahmedabad, Gujarat- 382350
9. Medeor Hospital Limited, Plot No. 2, Sector 5, IMT Manesar, Gurugram, Haryana -122052
10. Healing Touch Super Speciality Hospital, Ambala-Chandigarh Highway Ambala/Haryana, Ambala, Haryana- 134003
11. Guru Nanak Hospital, Railway Station Road, Khota Temple, Camp Market Palwal, Palwal, Haryana- 121102
12. Supreme Hospital, Eros Garden, Charmwood Village, Suraj Kund Road, Faridabad, Haryana- 121009
13. Sarvodaya Multispecialty and Cancer Hospital, Opposite, Red Cross Bhawan, Delhi Road, Hisar, Haryana- 125001
14. Nidaan Hospital, Murthal Road, Maharaja Hospital, Jeevan Vihar, Sonipat, Haryana- 131001
15. Shri Balaji Aarogyam Hospital, Behind Old Bus Stand, Kurukshetra, Haryana- 136118
16. Government Medical College Baramulla, Kanth Bagh, Baramulla, Jammu and Kashmir- 193101
17. Tata Main Hospital, C Road West, Northern Town Bistupur, Jamshedpur, Jharkhand- 831001
18. MS Ramaiah Medical College, MSR Nagar, Bangalore, Karnataka- 560054
19. Cytecure Hospital Pvt Ltd, Venkata, Near Bagalur Cross, Yelahanka, Bengaluru Karnataka- 560064
20. EK Nayanar Memorial Govt. Women and Children Hospital, Mangattuparamba, Kannur, Kerala- 670563
21. General Hospital, Kanjirappally, Kottayam, Kanjirappally, Kottayam, Kerala- 686507
22. Taluk Head Quarters Hospital, Near Boat Jetty Vaikom, Kottayam, Kerala- 686141
23. AA Rahim Memorial Govt District Hospital Kollam, Kerala- 691001



24. District Hospital Aluva KSRTC Bus Stand, Aluva, Ernakulam, Kerala- 683101
25. Government District Hospital, Kanhangad P.O, Bella Chemmattamvayal, Kasaragod, Kerala- 671531
26. District Hospital Mananthavady, Mananthavady, Wayanad, Kerala- 670645
27. District Hospital Palakkad, Palghat, Kerala- 678001
28. District Hospital, Kumarkuller, Ottupara, Kodungallur, Wadackanchery, Kerala -680582
29. Institute of Child Health, Medical College Hospital, Amalagiri P.O, Kottayam, Kerala- 686561
30. General Hospital, Irinjalakuda, Tana Junction, Thrissur, Kerala- 680121
31. General Hospital Muvattupuzha, Kerala - 686661
32. General Hospital, Pala, Kottayam, Kerala- 686575
33. General Hospital, Thalassery Taluk Library 1, Main Road, Thalassery, Kerala- 670101
34. Government Medical College, Konni, Pathanamthitta, Kerala- 689691
35. Government Taluk Hospital Kuthuparamba, Kannur, Kerala- 670643
36. Government Taluk Hospital, Panoor, Kerala- 670692
37. Government General Hospital, Kainatty, Kalpetta, Wayanad, Kerala- 673122
38. General Hospital, Changanacherry, Changanassery, Kottayam- 686101
39. Taluk Head Quarters Hospital Sasthamcotta, Kollam, Kerala- 650521
40. Taluk Headquarters Hospital Kuravilangad, Kerala- 686633
41. Taluk Head Quarters Hospital, Vythiri, Wayanad, Kerala- 673576
42. District Hospital Kozhencherry, Pathanamthitta, Kerala- 689641
43. District Hospital Nedumangad Trivandrum, Kerala- 695541
44. General Hospital, Adoor P.O, Pathanamthitta, Kerala- 691523
45. Government General Hospital, Kozhikode Beach Lighthouse, Beach Rd, Vellayil, Kozhikode, Kerala- 673032
46. Government District Hospital Vatakara, Badagara, Kerala- 673101
47. Government T D Medical College, Vandanam, Alappuzha, Kerala- 688005
48. Government Medical College Hospital, Gandhinagar Kottayam, Kerala- 686008
49. Govt. Medical College, Manjeri, Malappuram District Kerala- 676121
50. Taluk Head Quarters Hospital, Parassala, Trivandrum, Kerala- 695002
51. General Hospital Neyyatunkara, Kerala- 695121
52. Taluk Head Quarters Hospital Chavakkad, Hospital Road, Chavakkad, Kerala- 680506
53. Taluk Head Quarters Hospital, Karunagappally, Kollam, Kerala- 690518
54. VPS Lakeshore Hospital, NH-47 By-Pass, Maradu, Kochi, Kerala- 682040



55. Meitra Hospital, Building No. 38/2208-B, Karaparamba – Kunduparamba Mini Bypass Road, Edakkad Post, Calicut, Kerala- 673005,
56. General Hospital Rd, Anantha Narayanapuram, Alappuzha, Kerala- 688011
57. Taluk Head Quarters Hospital, Cherthala, Police Station Road, Oppo. Govt. Boys Higher Secondary School, Cherthala, Kerala- 688524
58. Taluk Head Quarters Hospital, National Highway 47, Haripad, Karthikapally, Kerala- 690514
59. Atreya Hospital, Guruvayur Road, Near Pipeline Junction, East Fort, Thrissur, Kerala- 680005
60. Government Taluk Head Quarters Hospital, Karimbam (P.O.), Taliparamba, Kannur District, Kerala- 670142
61. Taluk Head Quarter Varkala, Temple Road, Varkala (PO) Kerala- 695141
62. Malabar Hospitals Private Limited, Door No.16/45A, Rajeev Gandhi Bypass Road, Karuvambram PO, Manjeri, Malappuram, Kerala- 676123
63. THQH Bedadka PO-Kasaragod, Kerala- 671541
64. Women and Children Hospital, Alappuzha, Kerala- 688012
65. Taluk Head Quarters Hospital Mangalpady, Nayabazar, Uppala PO- 680307
66. Taluk Head Quarters Hospital, Pulincunnu, P.O, Alappuzha, Kerala- 688504
67. Taluk Headquarters Hospital, Kollam- Chenkotta Road, Kottarakkara, Kerala-691506
68. Government Taluk Head Quarters Hospital Nileshtar PO, Percle, Near Village Office, Kerala- 671314
69. Government Taluk Head Quarters Hospital, Thrikkaripur, Kasaragod, Kerala- 671310
70. Taluk Hospital, Fort, Fort PO, Thiruvananthapuram, Kerala- 695023
71. District Hospital Chengannur, Alappuzha District, Kerala- 689121
72. Thaluk Hospital Poodamkallu, Rajapuram, Kerala- 671532
73. Asian Noble Hospital Private Limited, Shirdi Manmad Road, Chowk, Opp. Premdan, Savedi, Ahmednagar, Maharashtra - 414003
74. Saideep Healthcare and Research Private Limited, Viraj Colony, Plot NO 11, S NO 104/A2, 104/A2/1, Behind Yashwant Colony, Tarakpur, Ahmednagar, Maharashtra- 414003
75. Saifee Hospital,15/17, Maharshi Karve Marg, Mumbai, Maharashtra- 400004
76. Shree Pragati Foundation's Hira Mongi Navneet Hospital, Near Lions Club of Mulund Pavalion, Near SMPR High School, Valji Ladha Road, Mumbai, Maharashtra- 400080
77. Bhaktivedanta Hospital & Research Institute, Shrishti Complex, Bhaktivedanta Swami Marg, Mira Road (East), Thane, Maharashtra- 401107
78. D Y Patil Hospital, Sector -5, Nerul, Navi Mumbai, Maharashtra- 400706
79. Dr. Balabhai Nanavati Hospital, Mumbai, S.V. Road, Vile Parle (West) Mumbai, Maharashtra- 400056



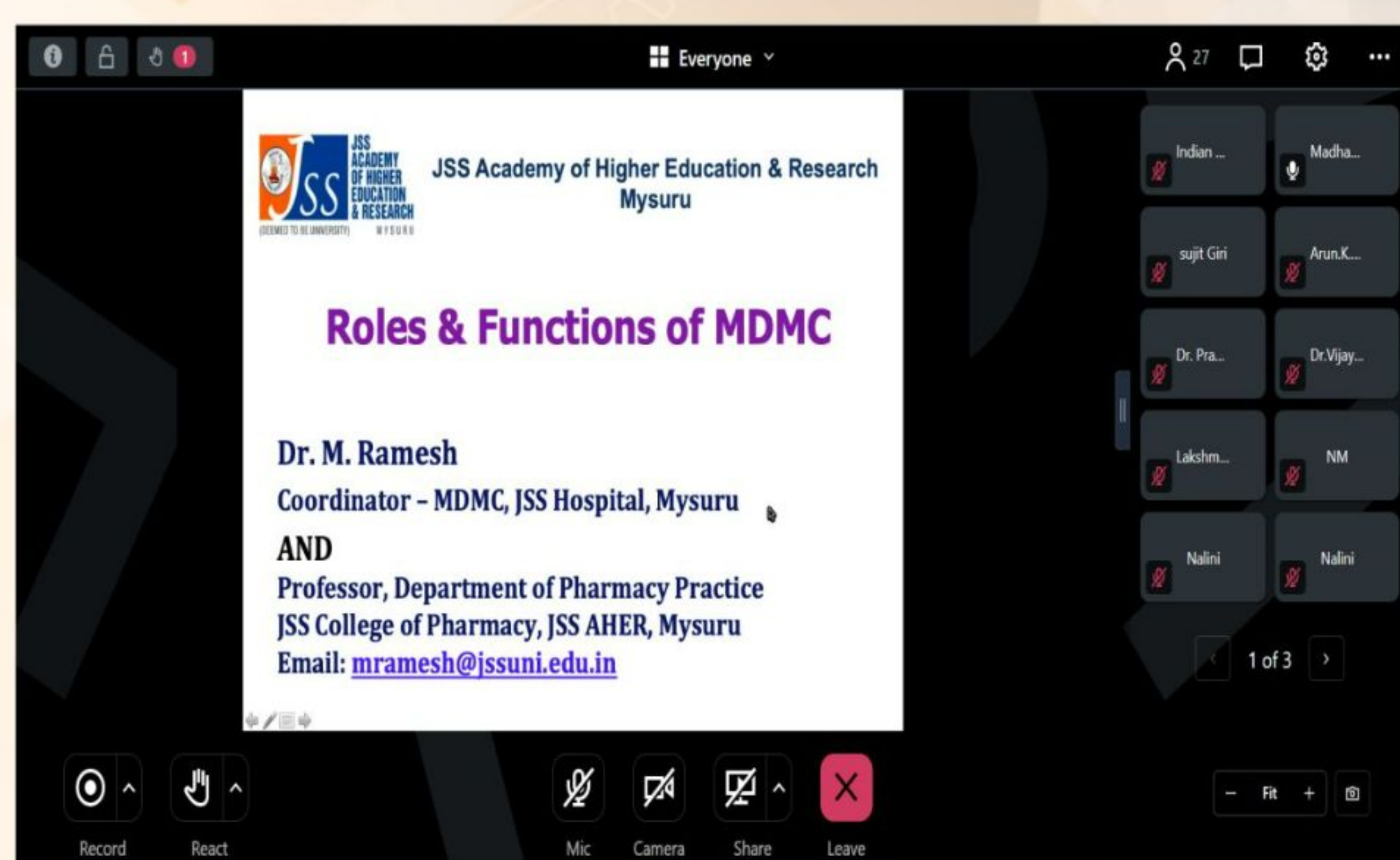
80. Jaslok Hospital and Research Centre, Biomedical Dept. 15, Pedder Rd, IT Colony, Tardeo, Mumbai, Maharashtra- 400026
81. Holy Spirit Hospital, Mahakali Caves Rd, Sher E Punjab Colony, Andheri East, Mumbai, Maharashtra- 400093
82. Nazareth Hospital, Arbuthnot Road, Near Police Point, Nongkynrih, Laitumkhrah, Shillong, Meghalaya- 793003
83. Vallabhbhai Patel Chest Institute, University of Delhi, Vijay Nagar Marg, Art Faculty, University Enclave, New Delhi-110007
84. Indraprastha Apollo Hospitals, Sarita Vihar, Delhi Mathura Road, New Delhi- 110076
85. Khandelwal Hospital & Urology Centre Private Limited, B-15, 16, Main Road, East Krishna Nagar Delhi- 110051
86. Moolchand Hospital, Lajpat Nagar III, Near Moolchand Metro Station, New Delhi-110024
87. Rathi Hospital, 2,3,4 Pratap Vihar, Ranhola Nangloi- Najafgarh Road, New Delhi-110041
88. Park Hospital, 12 Meera Enclave (Chowkhandi) Outer Ring Road, New Delhi-110018
89. RLKC Hospital, Pandav Nagar, Naraina Road, Near Shadipur Metro Station, New Patel Nagar, Shadipur, New Delhi- 110008
90. Bhima Bhoi Medical College and Hospital, Balangir, Odisha, Balangir- 767002
91. Sun Hospital, Sri Vihar Colony, Kanika Chakk, Tulsipur, Cuttack, Odisha- 753008
92. Abrol Medical Centre Super Speciality Hospital, Kailash Enclave, Batala Road, Gurdaspur, Punjab Region- 143521
93. Arora Neuro Centre, 120, The Mall, Civil Lines, Next to Narayana Group of Schools, Ludhiana, Punjab- 141001
94. Neelam Hospital, NH-7, Chandigarh-Rajpura Highway, Opp. Chitkara University, Patiala, Punjab- 140401
95. Orison Hospitals, Opp. Grand Walk Mall, Barewal Road, Ludhiana, Punjab-141012
96. Moga Medicity Hospital, Barnala - Amritsar Bye Pass, Moga, Punjab-142001
97. S.R. Kalla Memorial Gastro & General Hospital, 78-79, Dhuleshwar Garden, Sardar Patel Marg, C Scheme, Jaipur, Rajasthan-302001
98. American International Institute of Medical Sciences, Near, Airport Rd, Bedwas, Transport Nagar, Udaipur, Rajasthan-313001
99. Dhanwantri Hospital and Research Centre, Bus Stand, New Sanganer Rd, Near Madara, Ward 27, Mansarovar Sector 6, Mansarovar, Jaipur, Rajasthan- 302020
100. S N Super Speciality Hospital Private Limited, Murraba No- 60, Chak 2ML, Hanumangarh- Suratgarh Bypass Road Nathwala, Sriganga Nagar, Rajasthan- 335001



101. Apollo Reach Hospital, Madurai Main Road, Managiri, Sivagangai District, Karaikkudi, Tamil Nadu- 630307
102. Vijaya Medical & Educational Trust, Old No. 180, New No. 434, N.S.K Salai, Vadapalani, Chennai, Tamil Nadu- 600026
103. Apollo Loha Hospital, Kawai Road, 163- Allwyn Nagar, Karur, Tamil Nadu- 639002.
104. Medway Heart Institute, (A Unit of United Allaince Healthcare Private Limited, No.9, 1st Nain Road, United India Colony, Kodambakkan, Tamil Nadu- 600024
105. Hindu Mission Hospital, 103, GST Road, Chennai, Tamil Nadu- 600045
106. Kauvery Hospital Hearticity A Unit of Sri Kauvery Medical Care India Limited, No-12/52, Alexanderia Road, Cantonment, Tiruchirappalli, Tamil Nadu- 620001
107. Continental Hospital Plot No 3, Rd Number 2, Financial District, Gachibowli, Nanakaramguda, Telangana- 500032
108. Prathima Hospital, 3/4/3 Station Road, Kachiguda, Hyderabad, Telangana- 500027
109. Olive Hospitals, Nanalnagar X Road, Mehdiapatnam, Hyderabad, Telangana- 500028
110. Landmark Hospitals (A unit of capital Health Services India Private Limited), MCK Block 22, Near JNTU Mero Station, Hydernagar, Telangana, Hyderabad- 500085
111. OMNI Hospitals, Kukatpally, Mumbai Hwy, Opp. Big Bazar, Balaji Nagar, Kukatpally, Hyderabad, Telangana- 500072
112. MIMHANS, Neurosciences Hospital, Meerut 281-283, Sector-1, Mangal Pandey Nagar, Opp. CCS University, Meerut, Uttar Pradesh- 250004
113. Ashutosh Hospital & Trauma Centre, 15/20, Opposite Kamla Nehru Hospital, Hashimpur Rd, Prayagraj, Uttar Pradesh- 211002
114. Ajay Pratima Hospital, Dharam Kanta, 57 Brijlok Colony, Near, Prem Nagar Bareilly, Uttar Pradesh- 243005
115. Max Super Speciality Hospital (A unit of Crosslay Remedies Ltd.) W-3, Sector -01, Vaishali, Ghaziabad, Uttar Pradesh- 201012
116. Regency Renal Sciences Center 113/104-A, Swaroop Nagar (OPP. Motidheel), Uttar Pradesh- 208002
117. Yatharth Super Speciality Hospital, Plot No. 1, Sector 110, Gautam Budh Nagar, Noida, Uttar Pradesh- 201304
118. B.P. Poddar Hospital & Medical Research 71/1 Humayun Kabir Sarani, New Alipore, Block G, Kolkata, West Bengal- 700053
119. Medica Super Speciality Hospital, 127 Mukundapur, E.M. Bypass, Kolkata, West Bengal -700099

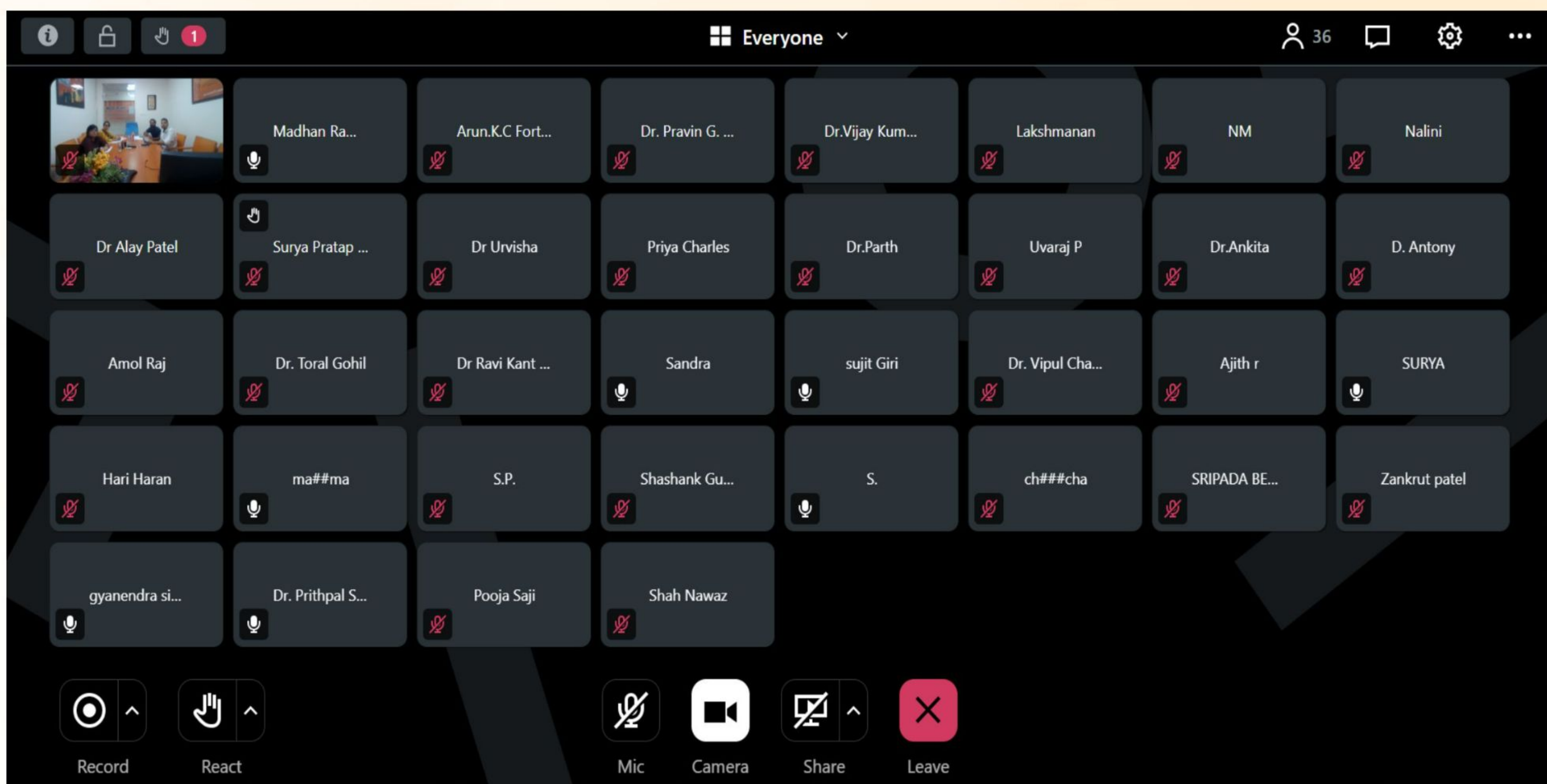


# Training & Education



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) organized an Induction-cum-training programme from June 23-24, 2022 via digital/virtual platform for newly identified coordinators, deputy coordinators and materiovigilance associates. During the indexed period, NCC-MvPI, IPC has recognized 24 new Medical Device Adverse Event Monitoring Centres (MDMCs) pan India. For the seamless functioning of materiovigilance programme at the newly

identified centres, NCC-MvPI organized an Induction-cum-training programme for newly identified coordinators, deputy coordinators and materiovigilance associates. The Induction-cum-training programme organized to develop the basic understanding of newly identified coordinators, deputy coordinators, Materiovigilance associates on Medical Device Rules, Materiovigilance Programme, Available tools for Reporting, Post-marketing surveillance and baseline Study of medical devices.





Pharmacovigilance and Materiovigilance Regional Training Centre (North Zone), Postgraduate Institute of Medical Education and Research (PGIMER) Chandigarh organized a symposium and workshop on Medical Devices for students and faculty members at National Institute of Pharmaceutical Education and Research (NIPER), Mohali on June 25, 2022. More than 40 participants including faculty members and students from various departments attended this sensitization programme. The symposium commenced with the welcome address by Prof. Dulal Panda and Prof. Arvind Bansal (Dean NIPER). Dr. Bikash Medhi, Professor, PGIMER, Chandigarh delivered a lecture on Introduction to Medical Devices: Regulations, preclinical studies, national and international perspective. Dr. Nitin James Peters (Associate Professor, Dept of Paediatric surgery, PGIMER) and Dr. Siddhartha Sharma (Associate Professor, Dept of Orthopaedics, PGIMER) presented their insights on medical device inputs from clinician's perspective. This was followed by a lecture on Sample size calculations for research studies by Dr. Ajay Prakash (Associate Professor, Department of Pharmacology, PGIMER). Then Materiovigilance Associate from IPC, Ms. Nikita Mishra delivered a brief talk on the Materiovigilance Programme of India (MvPI) way forward via virtual mode.





National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI) in association with National Institute of Medical Health and Neuro Sciences (NIMHANS), Bengaluru organized a National conference on July 09, 2022. Since 2017, NIMHANS is functioning as a medical device adverse event monitoring centre under MvPI. Distinguished speakers from Central Drugs Standard Control Organization (CDSCO), New Delhi, Bureau of Indian Standard, New Delhi, Sree Chitra Tirunal Institute of Medical Sciences & Technology,



Kerala and Andhra Pradesh MedTech Zone, Vishakhapatnam, Andhra Pradesh participated in the conference and enhanced the knowledge of participants. Approx. 200 participants participated in the national conference. Dr. V Kalaiselvan, Senior Principal Scientific Officer, IPC presented the session on "Materiovigilance Programme of India: An Overview" and Dr. Shatrunjay Shukla, Scientific Assistant, IPC presented the session on "Tools for reporting Medical Device Adverse Events and Case Study Discussion". In the panel discussion, a lot of queries from the participants were asked and the speakers responded and cleared their queries.





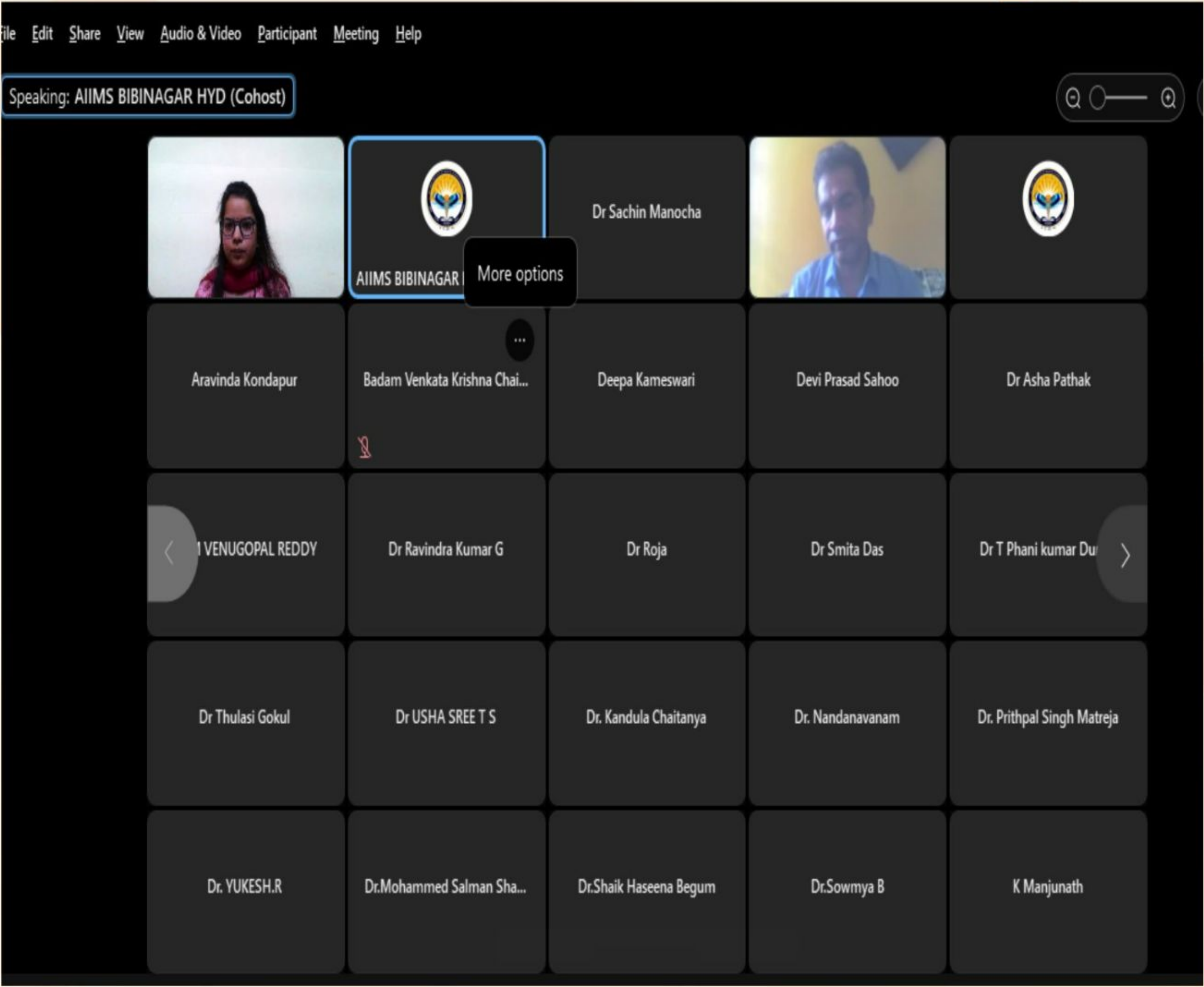


National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI) has conducted a workshop on "Key role of in-vitro diagnostic medical device stakeholders in Materiovigilance Programme of India" on July 22, 2022 at Indian Pharmacopoeia Commission, Ghaziabad. Workshop started with the welcome address of Dr. V. Kalaiselvan, Senior Principal Scientific, Officer, IPC followed by the remarks of Dr. Ranjan Kumar Choudhury, Advisor, Health Technology Division, National Health

Systems Resource Centre (NHSRC), New Delhi. Dr. Anup Anvikar, Director, National Institute of Biologicals (NIB), New Delhi presented the special remarks in the workshop. Dr. Adrien Inoubli, Regional Adviser for Medical Products Quality & Regulation, World Health Organization (WHO) was the Guest in the said workshop. In the workshop, eminent speakers from WHO, Central Drugs Standard Control Organization, NIB, Indian Pharmacopoeia Commission, SRL Diagnostics Private Limited, PGIMER, Chandigarh and Elli Lilly India Private Limited enlightened the participants with their rich experience and knowledge. In total, 50 stakeholders from different medical device industry participated in this workshop. Overall, this was an interactive workshop that welcomed many questions and queries from the participants. This workshop furnished all the attendees with knowledge of adverse events reporting, the current state of vigilance & regulation system in India and way forward. We have also taken participant's consultation for developing the training module on in-vitro diagnostics safety monitoring in India. The session was moderated by Dr. Bikash Medhi, Professor, PGIMER, Chandigarh.

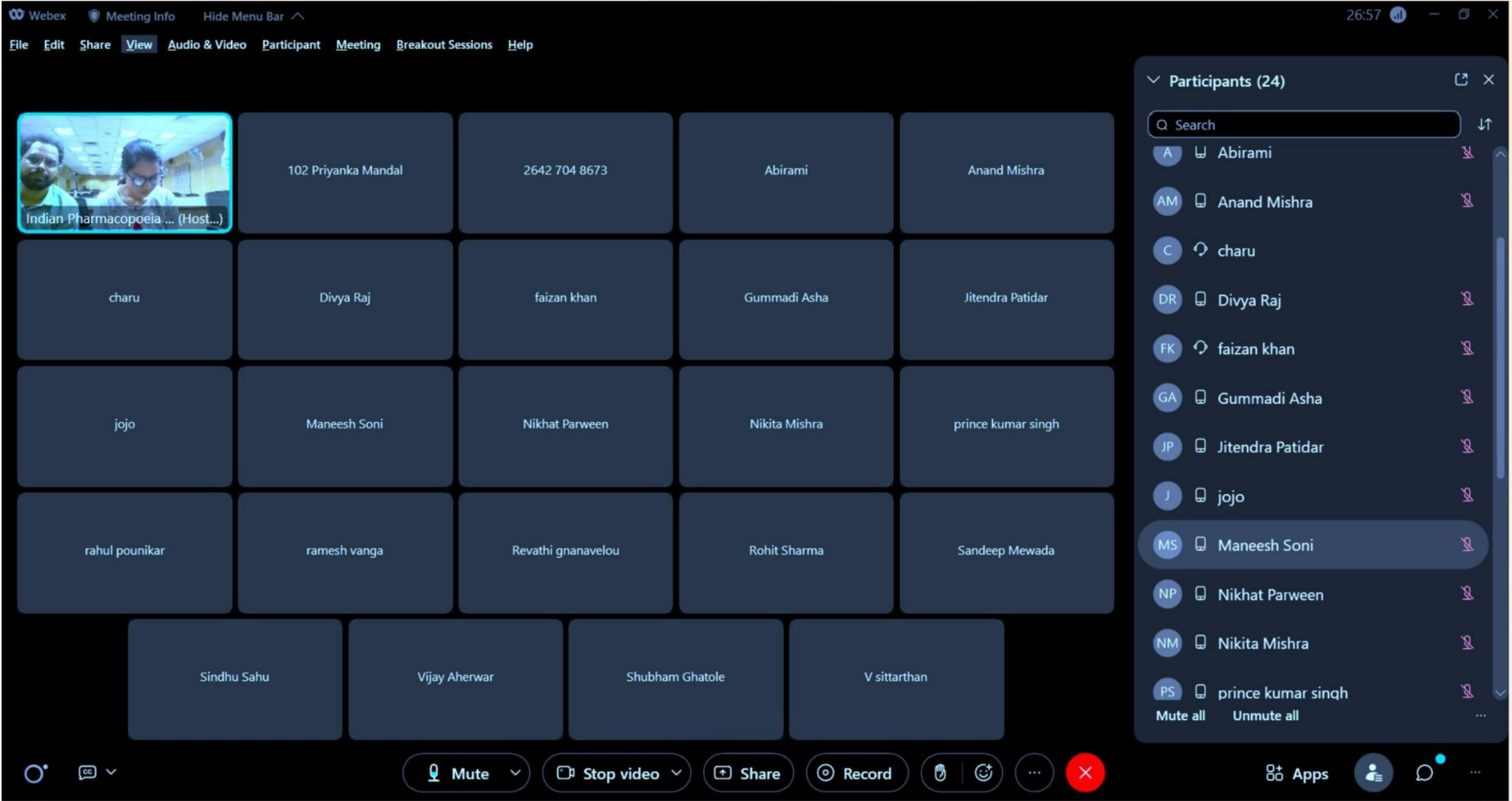






National Coordination Centre- Materiovigilance Programme of India (NCC-MvPI) in association with AIIMS, Bibinagar conducted a Hands-on workshop on Materiovigilance on July 16, 2022 via digital/virtual platform. Dr. V Kalaiselvan, Senior Principal Scientific, Officer encouraged the audience with his special remarks in the said workshop. Nikita Mishra, Materiovigilance Associate under MvPI presented a session on “Overview of Materiovigilance Programme” and also resolved the queries asked by the participants in the said workshop.

NCC-MvPI, IPC has conducted a training programme with selected trainees on “Overview of Materiovigilance Programme & Medical Device Adverse Event reporting” under MvPI on September 7-8, 2022 via digital platform. MvPI team sensitized the selected trainees on Materiovigilance programme and tools for reporting medical device adverse event.







National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI) in association with Mamata Academy of Medical Sciences, Hyderabad, Telangana conducted a workshop on "Importance of Materiovigilance programme of India & medical device adverse event reporting" on July 25, 2022 via digital/virtual platform. Dr. V Kalaiselvan, Senior Principal Scientific, Officer encouraged the audience with his special remarks and also resolved the queries asked by the participants in the said workshop. Nikita Mishra, Materiovigilance Associate under MvPI presented a session on "Overview of Materiovigilance Programme" in the said workshop. Participants also asked the questions related to the reporting in materiovigilance programme.



National Institute of Health & Family Welfare conducted a workshop on September 26, 2022 at Munirka, New Delhi. Dr. Shatrunjay Shukla, Scientific Assistant presented two sessions on "Materiovigilance Programme of India: An Overview" & "Tools for Reporting Medical device Adverse Event in the said conference.

Teerthanker Mahaveer Medical College and Research Center & MIT College of Pharmacy, Moradabad, Uttar Pradesh conducted a training programme on the occasion of National Pharmacovigilance Week on September 23 & 24, 2022. Mr. Maneesh Soni, Senior Materiovigilance Associate sensitized the audience on "Safety Surveillance System for Medical Products and their Adverse Events Reporting Tools".





# 2<sup>nd</sup> National Pharmacovigilance Week - 2022 (September 17 - 23, 2022)

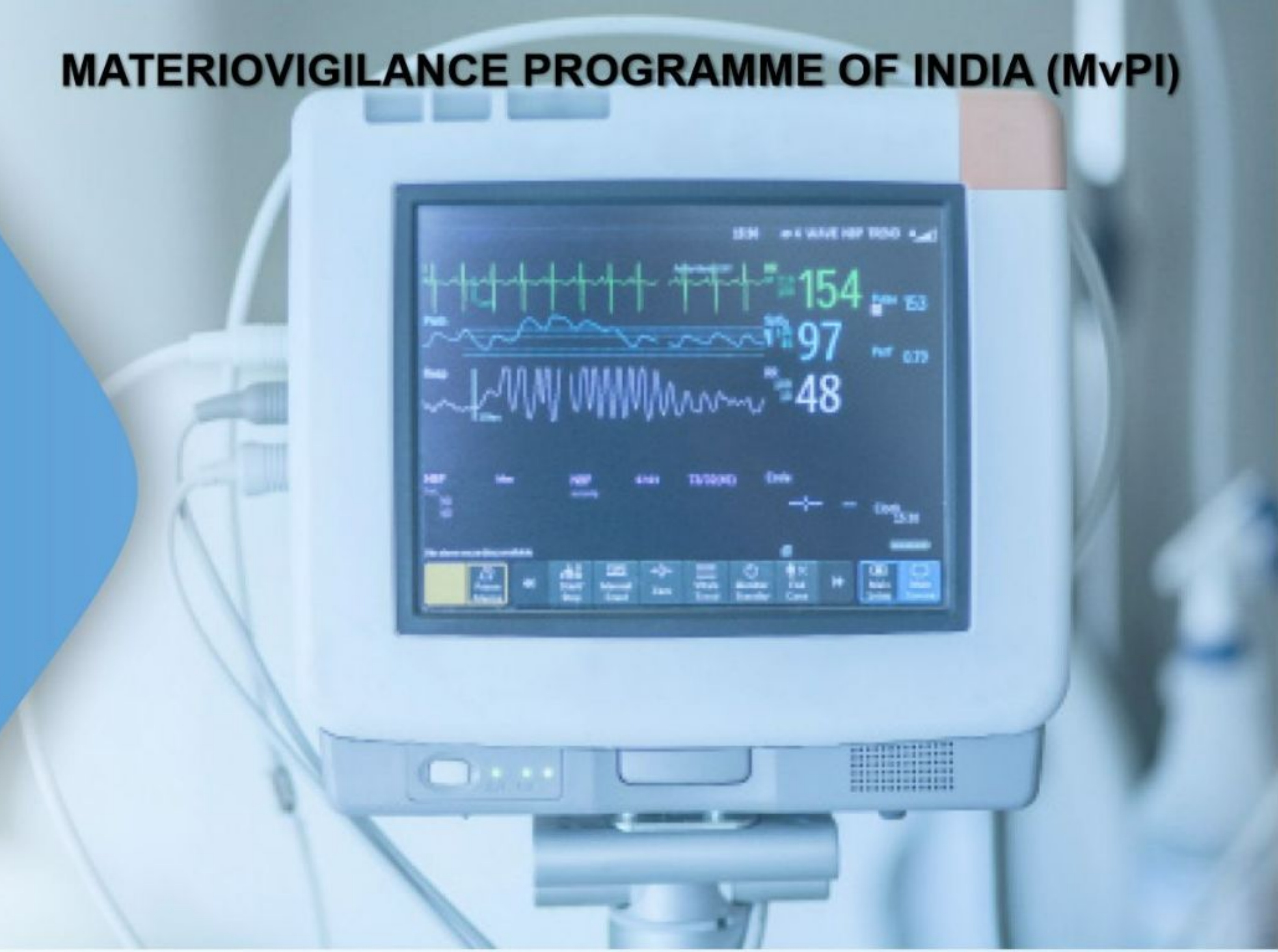
MvPI Team participated in "2<sup>nd</sup> National Pharmacovigilance Week" commenced from September 17-23, 2022 at Indian Pharmacopoeia Commission, Ghaziabad. The theme of this NPW 2022 was to encourage the adverse event reporting by the consumers. Various modes like workshops, conferences, pharmacovigilance walkathon, quiz competition, poster competition and skit were used during the entire week for creating the awareness at hospitals, medical colleges and academia across the country. During 2nd NPW, a walkathon in Ghaziabad has organized on September 20, 2022 to create awareness about the reporting of adverse events with the use of medical products and also distributed the pamphlets & resources materials prepared in Hindi and English to the public, hospitals and chemists.





# MEDICAL DEVICE UPDATES

MATERIOVIGILANCE PROGRAMME OF INDIA (MvPI)



File No.29/Misc/03/2022-DC(257)

F. No. 29/Misc/03/2022-DC (257)  
Central Drugs Standard Control Organisation  
Government of India  
Ministry of Health and Family Welfare

FDA Bhawan, New Delhi  
Dated the 30<sup>th</sup> September, 2022

## CIRCULAR

Subject: Regulation of all Class A & B Medical Devices under Licensing regime, w.e.f 01.10.2022, as per G.S.R. 102(E) dt 11.02.2020 - Regarding.

The Ministry of Health & Family Welfare (MoHFW) has published notification vide S.O. 648 (E) dated 11.02.2020 specifying all medical devices under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940, which is effective from 01.04.2020.

In order to regulate all the medical devices, MoHFW has published G.S.R. 102 (E) dated 11.02.2020 for regulation of such devices in phase wise manner. As per the said notification the Class A & B medical devices will be under licensing regime from 01.10.2022.

In the meantime, representations from various Associations and Stakeholders have been received by this office, requesting that the business continuity should not be disrupted due to the implementation of licensing regime w.e.f. 01.10.2022 for Class A & B medical devices.

In view of the above, it has been decided that, in case, if an existing importer/manufacture who is already importing /manufacturing any of Class A or Class B Medical Devices, has submitted application to Central Licensing Authority or State Licensing Authority on or before 30.09.2022, as the case may be, for grant of import /manufacturing licence in respect of the said device(s) under the provisions of MDR, 2017, the said application shall be deemed valid and the importer/manufacture can continue to import /manufacture the said device(s) up to 6 months from the date of issue of this order or till the time, the Central Licensing Authority or State Licensing Authority, as the case may be, takes a decision on the said application, whichever is earlier.

Digitally Signed by Dr. V G

Somani

Date: 30-09-2022 20:41:38

Reason: Approved

(Dr. V. G. Somani)

Drugs Controller General (I)

To

All Stakeholders/Associations.

Copies to:

1. All State Drugs Controllers.

2. All Zonal/Sub-Zonal offices of CDSCO

3. All Port offices.

**Regulation of all Class A & B  
Medical Devices under  
Licensing regime, w.e.f  
01.10.2022, as per G.S.R.  
102 (E) dated 11.02.2020.**

**Classification of non-sterile,  
non-powered, hand-held or  
hand-manipulated surgical  
instruments for general use  
intended to be used in various  
general surgical procedures  
under the provisions of  
Medical Device Rules, 2017.**

Drugs Controller General (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road, New Delhi

## Notice

09 SEP 2022

File No. 29/Misc./03/2022-DC (228)

Date:

Subject: Classification of non-sterile, non-powered, hand-held or hand-manipulated Surgical Instruments for general use intended to be used in various general surgical procedures under the provisions of Medical Devices Rules, 2017-Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018.

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classifying the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017.

Classification of non-sterile, non-powered, hand-held or hand-manipulated Surgical Instruments for general use intended to be used in various general surgical procedures placed at Appendix A subjected to the following:

1. General intended use given these devices is for guidance. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. V. G. Somani)  
Drugs Controller General (India)

To,

1. CDSCO Website



# Safety Alert



**NCC-MvPI, IPC has observed an adverse event report of Toxic anterior segment syndrome (TASS) associated with Implantable Collamer Lens which may lead to serious adverse event.**

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Implantable Collamer Lens	Toxic anterior segment syndrome

## 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 in medical device adverse event reporting form after the use of these devices to NCC-MvPI, IPC via e-mail: [shatrunjay.ipc@gov.in](mailto:shatrunjay.ipc@gov.in).

## Recommendation to Central Drugs Standard Control Organization (CDSCO)

National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI), IPC sent a recommendation to CDSCO on Invalid Result associated with HCG/Pregnancy Test Kit for information and necessary actions at their end.





# Publication

**N**CC-MvPI has published an article entitled *“Public Private Partnership in ensuring safe use of medicines: An Indian Experience”* in *Frontiers in Public Health* journal (Impact factor- 6.4).



[Front Public Health](#). 2022; 10: 930696.

PMCID: PMC9435468

Published online 2022 Aug 11. doi: [10.3389/fpubh.2022.930696](https://doi.org/10.3389/fpubh.2022.930696)

PMID: [36062131](https://pubmed.ncbi.nlm.nih.gov/36062131/)

Public-private partnership (3Ps) in ensuring safe use of medicines: An Indian experience

[Vivekanandan Kalaiselvan](#),<sup>1,\*</sup> [Shatrunajay Shukla](#),<sup>1</sup> [Shubhang Arora](#),<sup>2</sup> [Tarani Prakash Shrivastava](#),<sup>3</sup> and [Rajeev Singh Raghuvanshi](#)<sup>1</sup>

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