



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre (NCC) - Materiovigilance Programme of India (MvPI)
MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA
SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.

Tel No: 0120- 2783392, 2783400, 2783401 Fax: 0120-2783311
e-mail: mvpi.ipcindia@gmail.com, Web: www.ipc.gov.in

Format No. IPC/MvPI/QA/021-F01-00

LETTER OF INTENT

Date:

I. Institutional Information:

- a. Name of the Institution/ Hospital:
- b. Name of the hospital attached:
- c. Govt. /Non Govt. (Please Specify):
 - c1. Registration number:
(if registered under clinical establishment act)
 - c2. Type of registration (Trust act, society act, company act etc.).....
- d. Distance between attached hospital & institution:
- e. No. of beds in the hospital:
- f. Patient statistics (Inpatient/ outpatient) year wise for the past 3 years:
- g. Name of the departments in the hospital:
- h. Total number and asset value of medical device in the hospital (Capital expenditure on Medical device):
- i. Approximate annual purchase value of implantable medical device, consumables and reagents:

II. Logistic/ infrastructural facilities to function as Medical Device Adverse Event Monitoring Centre (MDMC) under MvPI:

- a. Name of department to function as an MDMC:
-
- b. Total no. of faculties in the department:
-
- c. Whether workplace is allocated for MvPI (YES/No):
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- d. Whether computer & logistic facilities available for MvPI (YES/No):
-

III. Technical Information:

- a. Details of the Proposed Coordinator (Preferably Bio-Medical Engineer):
Name:
- Designation:
- Qualification:
- Total Experience:
-
- b. Details of the Proposed Deputy Coordinator (Preferably Bio-Medical Engineer):
Name:
- Designation:
- Qualification:
- Total Experience:
-
- c. Experience of Proposed Coordinator/Deputy Coordinator in Materiovigilance:
Coordinator:
-

Deputy Coordinator:

.....
(Additional sheet may be used)

- d. Details of training / CME or continued professional development on Medical devices/ Materiovigilance/ Pharmacovigilance attended by Coordinator / Deputy Coordinator in last 2 years:

.....
(Additional sheet may be used)

- e. Details of Medical Device Adverse Event (MDAE) reported during last 1 year (to be furnished as per the details in Annexure-I).

IV. Contact Details:

Sr. No.	Designation	Name	Phone no. (extension no. if any)	Mobile no.	Email Id
1.	Principal / Dean / Medical Superintendent/Incharge (Please tick)				
2.	Coordinator				
3.	Deputy Coordinator				
4.	Others (if any)				

Complete Postal Address of Proposed MDMC:

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State..... **Pin code**.....

Terms of Reference (TOR):

- a) All the above fields are mandatory to be filled otherwise the proposal shall be rejected.
- b) If the proposed centre is accepted as a Medical Device Adverse Event Monitoring Centre (MDMC), it's essential to function with own logistic/infrastructural facilities.
- c) List of logistics required to setup MDMC under MvPI:
Dedicated area/ Room for MvPI to carry out the Materiovigilance activities, Computer system with Internet connection, Printer with Scanner, Telephone, Computer table/ chair, Almira, Stationary and Notice board etc.
- d) NCC-MvPI, IPC may provide the trained manpower if the centres performance is found satisfactory.
- e) Your proposal may be accepted based on the significant track record on Materiovigilance.
- f) The acceptance of your centre as MDMC is based on the quality, quantity & frequency of Medical Device Adverse Event reporting.
- g) The competent authority /committee of MvPI reserve all the rights to accept/reject the proposal.
- h) The HOD/Dean/Principal of the proposed centre shall be responsible to establish/implement MvPI activities in the centre.
- i) The HOD/Dean/Principal of the institute shall be responsible to identify new Coordinator & Deputy Coordinator and to intimate NCC-MvPI in case of any change (transfer/ superannuation etc) immediately.
- j) If your centre is accepted as MDMC, NCC-MvPI will provide regular training, skill development & technical support to the personnel engaged in MvPI activities.

We have undergone the terms of reference and are interested to undertake the responsibility of Medical Device Adverse Event Monitoring Centre (MDMC) under the Materiovigilance Programme of India (MvPI). Our institute may be considered for the same.

Signature
Proposed Coordinator/ Incharge of MvPI

Signature
Head of Institution

*If your centre is approved, you will be sent with the detailed terms & conditions along with roles and responsibilities.

"Let us join hands with MvPI to ensure patients safety"
MDAE Reporting Help line (Toll Free): 1800-180-3024

(ANNEXURE- I)
Details of MDAEs reported during last 1 year

Sr. No.	Patient details		MDAE Report	Committee and professional details of members constituted for analyzing MDAE	Suspected Medical Device	Date of Event	Details of Reporter	Date of Reporting	Name of the MDMC/NCC-MvPI where report submitted
	AGE	SEX							
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									

Separate sheet may be used if the numbers are more.

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