

# Adverse Drug Reactions Monitoring System (ADRMS) User Manual

URL: <https://adrmsipc.in/adrms/index.html>



How to report Medical  
Device Adverse Event?  
**Programme Coordinator**

 **ADRMS**

## Stepping towards patient's safety

An Indigenous Adverse Drug Reactions Monitoring System (ADRMS) by Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Govt. of India, to ease reporting and monitoring of adverse events (side effects) on patients due to medical products (medicine, vaccine & medical device) for the safety of patients.

 *Designed, Developed & Maintained by C-DAC*

# Index



<b>1) How to Sign In?</b> .....	Pg No.01
<b>2) Programme Coordinator Dash Board</b> .....	Pg No. 02
<b>3) Report Information</b>	
a)General Information.....	Pg No.3
b) Information on primary sources.....	Pg No.4
<b>4) Medical Device Information</b>	
a) Device category.....	Pg No. 5
b) Device details.....	Pg No. 6
c) Device usage.....	Pg No. 7
<b>5) Event Information</b>	
a)Event Description.....	Pg No. 8
b. Event outcome.....	Pg No. 9
<b>6) Patient Details</b>	
Patient information.....	Pg No. 10
<b>7) Medical and Past drug history</b>	
Medical history, Past drug history, Past medical device history.....	Pg No. 11
<b>8) Hospitalization/ Death Information</b>	
Hospitalization related information, Death related information.....	Pg No. 12
<b>9) Tests and Procedures</b>	
Results of tests and procedures.....	Pg No. 13
<b>10) Assessment</b>	
Causality assessment, Investigation & action taken .....	Pg No. 14
<b>11) Preview &amp; Save</b> .....	Pg No. 15

## How to Sign In?



### Sign in

Username/ Mobile no.

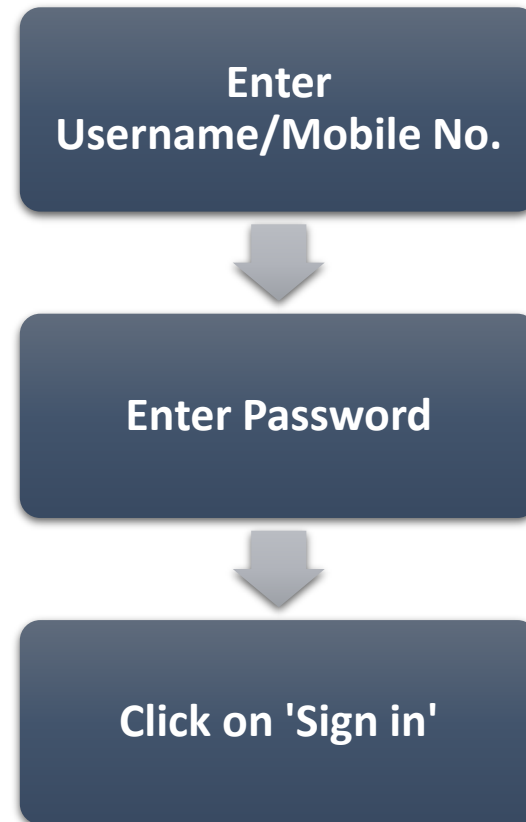
Password [I forgot password](#)

Remember me on this device

[Sign in](#)

Need an account? [Sign up here](#)

A consumer can also report without creating an account  
[Medicine & Vaccine](#) [Medical device](#)



# Reporting MDAE Programme Coordinator Dashboard



A screenshot of the ADRMS Programme Coordinator Dashboard. The header is teal and contains the ADRMS logo, a user profile icon, and the text 'PROGRAMME COORDINATOR'. Below the header is a white navigation bar with 'Home' and 'Master' menus, and a search box. The main content area is titled 'Dashboard' and contains five colored buttons: 'AMC Application' (teal), 'ICSR Reporting (MvPI)' (teal), 'ICSR list' (white), 'Unprocessed Consumer/ HP Report' (pink), and 'Add Institute Request' (orange). A blue arrow points to the 'ICSR Reporting (MvPI)' button.

**Click Here to report Medical Device Adverse Event (MDAE)**



# Reporting MDAE contd.

## Report Information

**a. General information**

1. Report information

a. General information

Patient involved \*

Report title

Report type \*

Date first received

Date of report \*

Is this a serious case? \*

Seriousness reasons \*

City of occurrence

Pin code of occurrence

District of occurrence

State of occurrence

Country of occurrence

This Section of the form Covers

- Report Type
- Date of Report
- Seriousness Criteria

Report type \*

Initial

Initial

Follow-up

Final

Trend



## Reporting MDAE contd.

### Reporter Information

#### b. Information on primary sources

b. Information on primary sources

Reporter information | Literature information

Tab +

Select from address book

Sal. First name Middle name Last name

Organization Department

Address City Pin code

District State Country

Mobile no. Telephone no. Email address

Reported by \* Primary reporter \*

Next

This Section of the form Covers the reporter details

- Name of Reporter
- Address of the Reporter

Reported by \* Primary reporter \*

Health Professional Yes

Pharmaceutical Company  
Regional Pharmacovigilance/Materiovigilance Centre  
Health Professional  
Patient/Consumer  
Regulatory Authority  
Other (e.g. Distributor, Study sponsor, Contract Research Organisation, or non commercial organisation)

Click "Next" → for the Next Page

## Reporting MDAE contd.

### Medical Device Information

#### a. Device category

2. Medical device

a. Device category

Device Risk Classification as per India MDR 2017

Device category

This Section of the form Covers the medical device details

- Device Category
- Device Classification

Device Risk Classification as per India MDR 2017

A - Low risk  
B - Low-moderate risk  
C - Moderate-high risk  
D - High risk

Device category

Medical Device  
In Vitro Diagnostics (IVD)

Device category

Medical Device

a.  Therapeutic  Diagnostic  Preventive  Assistive

b.  Implantable device  Non-Implantable device

c.  Invasive  Non-Invasive

d.  Single use device  Reusable device  Reuse of manufacture marked single use device

e.  Sterile  Non-Sterile

Device category

In Vitro Diagnostics (IVD)

a.  Kits

b.  Reagents

c.  Calibrator

d.  Control material

e.  IVD electronic reader/ Analyzer



## Reporting MDAE contd.

### Medical Device Information

#### b. Device details

b. Device details

License type

Nomenclature code (If applicable)

Device information \*

Manufacturer name

Manufacturer address

Importer name

Importer address

Distributor name

Distributor address

Is the device notified/ regulated in India?

This Section of the form Covers the device information

- **Manufacture Details**
- **Importer Details**
- **Distributor Details**

Device information \*

Device name

Trade name

Brand name

Catalogue no.

Model no.

Lot/ Batch no.

Serial no.

Software version

Year of manufacturing

UDI no. (If applicable)

Associated devices/ accessories

Any other relevant information

Upload relevant document

This Section of the form Covers the device information

- **Catalogue No.**
- **Model No.**
- **Lot/Batch No.**
- **Serial No.**
- **Year of Manufacturing**





## Reporting MDAE contd.

### Medical Device Information

#### c. Device usage

c. Device usage

Installation date    Expiration date

Last preventive maintenance date    Last calibration date

How long was device/ equipment/ machine in use?

Is the usage of device as per manufacturer claim/ instruction for use/ user manual?

Any other relevant information

Previous

This Section of the form Covers the device information

- Installation Date
- Expiration Date
- Last Preventive Maintenance Date
- Last Calibration Date

Click "Next" → for the Next Page

# Reporting MDAE contd.

## Event Information



### a. Event description

#### 3. Event details

##### a. Event description

Date of event/ Near-miss incident \*

Date of implant (If applicable)

Date of explant (If applicable)

Location of event

Device operator

Is device in use after incidence?

Device disposition/ current location

Problem noted prior to use/ near miss event

Detailed description of event **i** \*

This Section of the form Covers the device information

- Date of event/Near miss incident
- Date of implant
- Date of explant
- Location of event
- Device operator
- Device disposition/current location
- Detailed description of event



## Reporting MDAE contd.

### Event Information

#### b. Event outcome



b. Event outcome

Patient outcome

Any other relevant information

Previous Next

This Section of the form covers event outcome

- Patient outcome
- Any other relevant information

Click "Next" → for the Next Page

# Reporting MDAE contd.

## Patient Details



### a. Patient information

4, Patient IN-IPC-MD20990 PDF

a. Patient information

Sal.  First name  Middle name  Last name

Patient initials  Father's name  Mother's name

Address  City  Pin code

District  State  Country

Mobile no.  Telephone no.  Email address

GP medical record no.  Specialist record no.  Hospital record no. (IPD/ OPD)  Investigation no.

Protect confidentiality

Patient characteristics Patient habits Patient allergic, mutation and resistance

Age information  Concomitant therapies

Body weight  kg Body height  cm Gender

Previous Next

This section of the form covers Patient details

- Patient Name
- Patient Address
- Mobile no. of the patient

Click "Next" → for the Next Page

## Reporting MDAE contd.

### Medical and Past drug history

#### a. Medical history

5. Medical and past drug history

a. Medical history

Tab +

Relevant medical history (MedDRA)

Start date

Continuing

Comment

Family history

Relevant medical history

#### b. Past drug history

b. Past drug history

Tab +

Relevant past drug name (WHODrug)

Relevant past drug name

Start date

End date

Indication (MedDRA)

Reaction (MedDRA)

#### c. Past medical device history

c. Past medical device history

Relevant past medical device history

Previous

Next

This section of the form covers medical and past drug history of patient

- Medical history of patient
- Past drug history of patient
- Past medical device history of patient

Click "Next" → for the Next Page



## Reporting MDAE contd.

### Hospitalization/ Death Information

#### a. Hospitalization related information

6. Hospitalization / Death

a. Hospitalization related information

Hospitalization date:    Discharge date:

Treatment details:

Upload discharged summary:

This section of the form covers hospitalization and death related information

- Hospitalization date
- Discharge date
- Death date
- Death time
- Death cause

#### b. Death related information

b. Death related information

Death date:    Death time:  :

Tab +

Death cause (MedDRA):  Death cause:

Autopsy performed?:

Upload relevant document:

Previous

Click "Next"  for the Next Page



## Reporting MDAE contd.

### Tests and Procedures

#### a. Results of tests and procedures



7. Tests and procedures IN-IPC-MD28991 PDF

a. Results of tests and procedures

Tab +

Test date

Test name (MedDRA)

Test name

Test result <sup>i</sup>

Test result (code)

Low range

High range

Result

Comments <sup>i</sup>

Upload relevant document

Add File

Previous Next

This section of the form covers test and procedures related information

- Test date
- Test name
- Test result

Click "Next" → for the Next Page



## Reporting MDAE contd.

### Assessment

#### a. Causality assessment

8. Assessment

a. Causality assessment

Reporter's comments

Tab +

Sender's diagnosis (MedDRA)

Sender's comments

Investigation action taken

Root cause of problem

This section of the form covers assessment of medical device adverse event

- Causality assessment
- Manufacturer/ Authorized representative investigation & action taken

#### b. Investigation & action taken

b. Manufacturer/ Authorized representative investigation & action taken (For manufacturer/ authorized representative use only)

Manufacturer/ Authorized representative device risk analysis report

Corrective/ Preventive action taken

Device history review

Previous Next

Click "Next" → for the Next Page



# Reporting MDAE contd.

## Assessment



Preview & Save

New ICSR under MvPI

1 REPORT INFORMATION   2 MEDICAL DEVICE   3 EVENT DETAILS   4 PATIENT   5 MEDICAL AND PAST DRUG HISTORY   6 HOSPITALIZATION / DEATH   7 TESTS AND PROCEDURES

1. Report Information

a. General Information **PDF**

Report type	Initial
Date first received	04 July 2023
Date of report	04 July 2023
Is this a serious case?	No
Worldwide unique id	IN-IPC-MD10541

b. Information on primary sources

Reporter Information

Sal.	Ms.
First name	Nikita
Country	India
Reported by	Health Professional
Primary reporter	Yes

2. Medical device

b. Device details

Name information	Device name : Syringe
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c. Device Usage

3. Event details

a. Event description

Date of event/ Near-miss incident	July 2023
Detailed description of event	Syringe damage

b. Event outcome

Patient outcome	Not yet recovered
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4. Patient

Protect confidentiality

Protect confidentiality	Yes
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Patient Characteristics

Age Information

Gender	Female
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6. Tests and procedures

7. Assessment

a. Assessment Information

Previous Save

Click "Save" → to submit medical device adverse event report directly to NCC-MvPI