



**Capture and record the information while reporting MDAE in ADRMS**

**1.0 OBJECTIVE**

- 1.1 To lay down a procedure to capture and record the information while reporting Medical Device Adverse Event (MDAE) in Adverse Drug Reactions Monitoring System (ADRMS).

**2.0 SCOPE**

- 2.1 This document shall be applicable to National Coordination Centre (NCC) and all Medical Device Adverse Event Monitoring Centre (MDMC) under Materiovigilance Programme of India (MvPI).

**3.0 PROCEDURE**

- 3.1 Access the ADRMS portal using the link - <https://adrmsipc.in/adrms/index.html>
- 3.2 Login into your registered account.
- 3.3 To report any MDAE, refer to Annexure-I.
- 3.4 For troubleshooting, changing password or to update personal information etc. refer to Annexure-II.
- 3.5 Report any ADRMS crash or bug by capturing a short video/ screenshot and emailing it to [mvpi-ipc@gov.in](mailto:mvpi-ipc@gov.in)

**4.0 SAFETY AND PRECAUTIONS**

- 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	NCC	:	National Coordination Centre
6.2	MvPI	:	Materiovigilance Programme of India
6.3	SOP	:	Standard Operating Procedure
6.4	ADRMS	:	Adverse Drug Reactions Monitoring System
6.5	IPC	:	Indian Pharmacopoeia Commission
6.6	MDAE	:	Medical Device Adverse Event
6.7	MDMC	:	Medical Device Adverse Event Monitoring Centre
6.8	MvA	:	Materiovigilance Associate

## 7.0 ANNEXURE(s)

7.1	Annexure I	:	How to report in ADRMS
7.2	Annexure II	:	How to update personal information in ADRMS

REVISION LOG		
Version	Description of Change	Release Date
00	New document for posting on IPC's website	03-FEB-2026

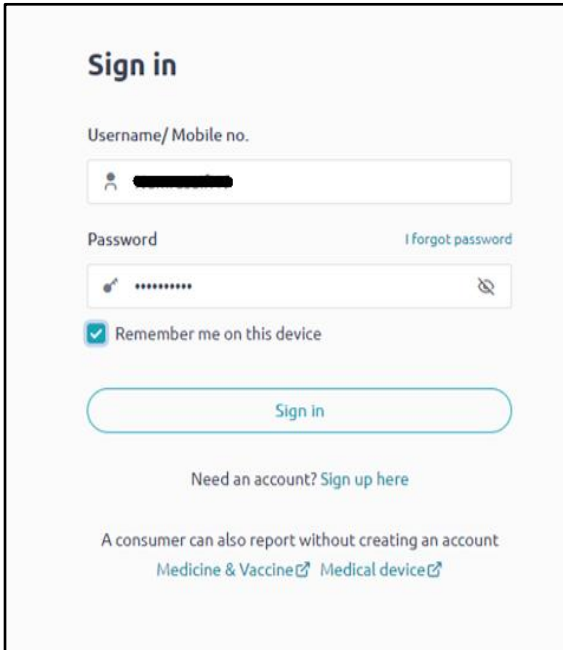
## Annexure-I

### How to report in ADRMS

Format No: IPC/MvPI/013/00/FMT/01

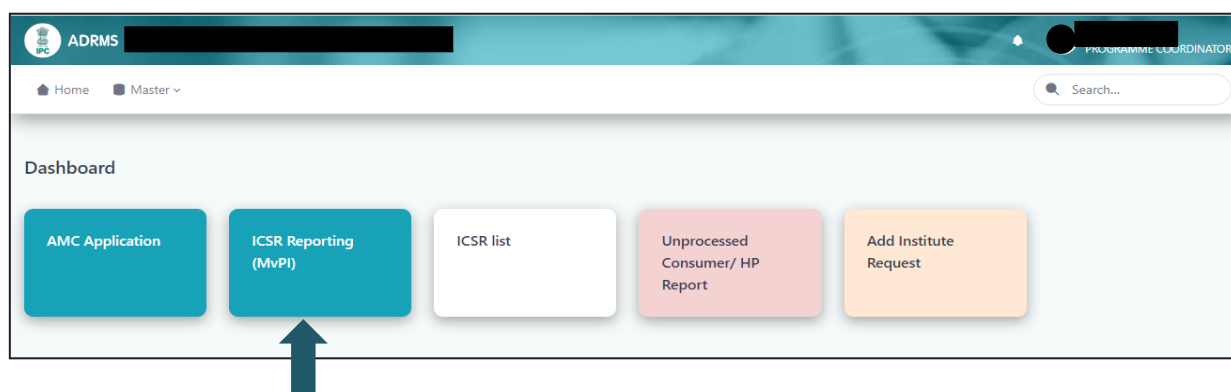
#### How to Sign in?

Access the Adverse Drug Reactions Monitoring System (ADRMS) portal using the link - <https://adrmsipc.in/adrms/index.html>



- Enter Username/Mobile no.
- Enter Password
- Click on 'Sign in'

To report any Medical Device Adverse Event (MDAE), click on 'ICSR Reporting MvPI' in the Dashboard:



Click here to report MDAE

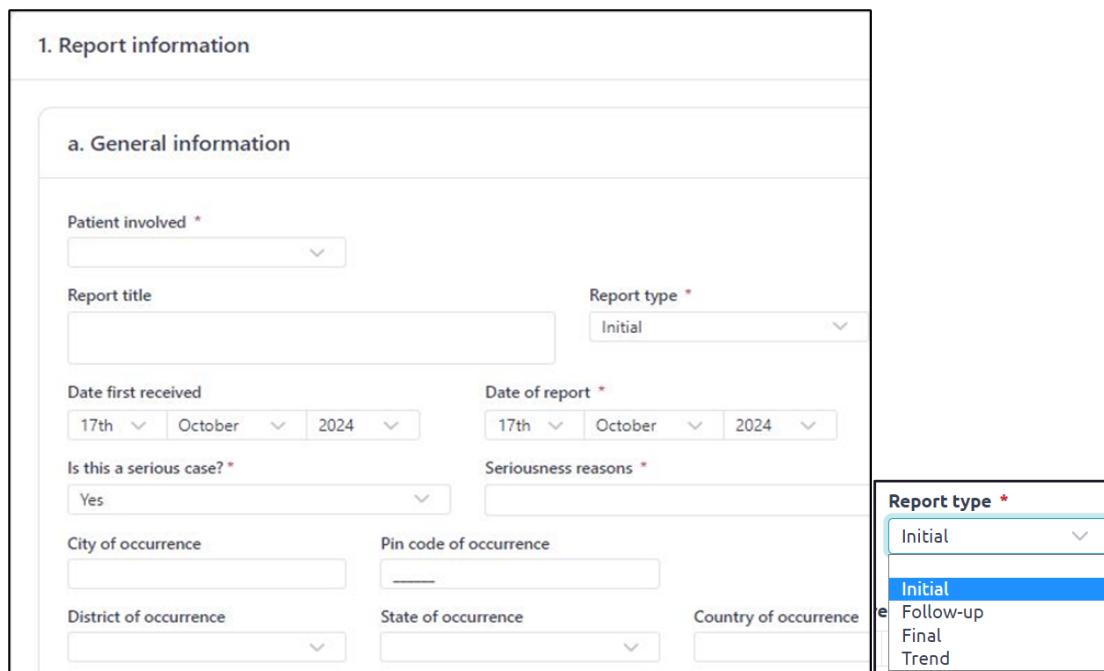
The MDAE reporting form consists of various sections such as report information, medical device details and usage, event details, patient details, medical and past drug/ medical device history, hospitalization/ death, tests and procedures which are applicable to all.

Note: Fields marked with \* are mandatory.

## 1. REPORT INFORMATION

### a. General Information

This section of the form covers:



- **Patient involved\*** – Was the patient involved? Select Yes/ No from the dropdown.
- **Report title** – Provide a brief title for the report that includes the report type, seriousness, device name, and adverse event, in the format:  
[Type of Report][Serious/Non-Serious][Device Name][Adverse Event]  
Example: Initial\_Serious\_IUD\_Expulsion
- **Report type\*** – Select the appropriate type of report (Initial/ Follow-up/ Final/ Trend) by ticking the checkbox in the dropdown menu.
  - Initial: The first report that the reporter is submitting about an adverse event.

- Follow up: Additional information provided subsequent to a previous report (either initial or follow-up report). If you are submitting a follow-up to a previously submitted report, please select the report type as 'follow-up', enter the original report number, and then proceed to update the relevant details within the existing report.

Report type *	Report No.	
Follow-up		Get

- Final: The last report that the reporter intends to submit about an adverse event. An initial report can also serve as the final report if the reporter possesses all the necessary information about the event.
- Trend: The manufacturers/importer/distributors/ healthcare professionals are required to monitor trends in the significant increase of any similar adverse events with any medical device. Any notable changes in the frequency or severity of events associated with devices must be reported. These reports are referred to as "trend" reports.
- **Date first received** – Enter the date when the adverse event was initially received by the reporter. This may be the same as the 'date of report' in case the adverse event was received and reported on the same day by reporter.
- **Date of report\*** – Enter the current date (the date on which reporter is filling the MDAE on ADRMS).
- **Is this a serious case\*?** – Determine whether the adverse event qualifies as a serious case and select Yes or No from the dropdown menu. If yes, then choose the Seriousness reasons\*(such as results in death, disability, life threatening, etc.).
- **City/ Pin code/ District/ State/ Country of occurrence** – Write the city, pin code, district, state and country of occurrence of the adverse event.
- **Does this case fulfil local criteria for an expedited report?** – An expedited report refers to a rapid reporting process used primarily in clinical settings to inform regulators and investigators about new, significant information regarding serious reactions or adverse events. Expedited

report typically require submission within 15 days. Select Yes/ No from the dropdown depending on whether the report is an expedited report or not.

- **Was the case medically confirmed?** – Select Yes/ No from the dropdown basis on whether the adverse event was medically confirmed by a healthcare professional or not.
- **Was the event reported to manufacturer?** – Select Yes/ No from the dropdown depending on whether the adverse event was reported or conveyed to manufacturer or not.
- **Other Report id tab** – Use this tab to reference a previously submitted related report.

Report ID → Enter the report ID of the previous case you want to cross-reference.

Source → Specify the origin of the referred report (e.g., MAH, MDMC).

Click the '+' (plus) icon next to 'Tab' to add multiple report id entries.

Other report id	Link report	Documents
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Tab +

Report id

Source

- **Link Report tab** – Use this tab to link this report to another related case.

Link Report → Select or enter the related report ID to link.

Reason → Mention why the reports are being linked (e.g., same batch, similar device malfunction).

Click the '+' (plus) icon next to 'Tab' to add multiple link report entries.

Other report id	Link report	Documents
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Tab +

Link report

Reason

- **Documents tab** – Use this tab to upload supporting files for the case.

Document held → Indicate whether relevant documents are available.

Upload relevant document → Upload files in JPG/PNG/PDF format (max size: 10 MB). Use 'browse' to select the file, then click 'upload' to attach the file or 'close' to exit.

Click the '+' (plus) icon next to 'Tab' to add multiple document entries.

Other report id	Link report	Documents
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Tab +
 

Document held

Upload relevant document  
 Add File

## b. Information on primary sources

This section of the form covers:

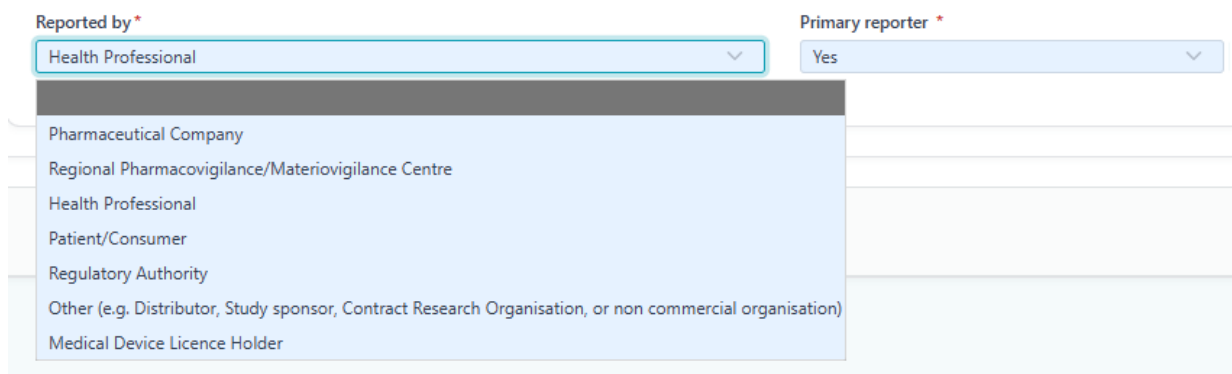
b. Information on primary sources
 

Reporter information
 Literature information

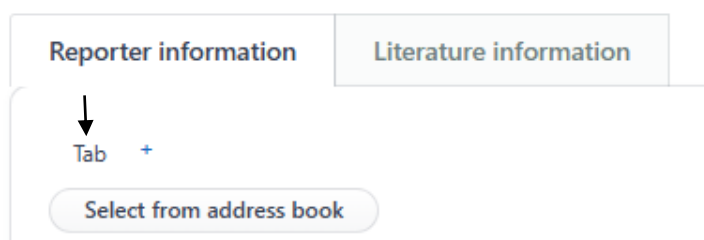
Tab +
 Select from address book
 Sal.
 First name
 Middle name
 Last name
 Organization
 Department
 Address
 City
 Pin code
 District
 State
 Country
 Mobile no.
 Telephone no.
 Email address
 Reported by \*
 Primary reporter \*

- **Salutation (Sal.)** – Select the appropriate salutation (Mr., Mrs., Ms., Dr., Prof.) from the dropdown.
- **Enter reporter's full name** – Fill in the first name, middle name (if any), and last name.
- **Organization and department** – Enter the name of the reporter's organization and their department.
- **Address and contact details** – Fill the address, city, district, state, country, mobile no., telephone no., and email address of the reporter.

- **Reported by\*** – If the person reporting (e.g. health professional) is the primary reporter of the MDAE, then select ‘Yes’ in the dropdown of primary reporter.



If the person reporting (eg. healthcare professional) is not the primary reporter of the MDAE, add new tab and then add the details of secondary reporter.



- **Literature Information** – Navigate to the 'literature information' tab to add any literature references.

Literature references → Enter the literature reference.

Upload relevant document → Click the ‘add file’ button to upload a supporting document related to the literature reference. Upload files in JPG/ PNG/ PDF format (max size: 10 MB). Use ‘browse’ to select the file, then click ‘upload’ to attach the file or ‘close’ to exit.

Click the ‘+’ (plus) icon next to 'Tab' to add multiple literature entries.



**b. Information on primary sources**

Reporter information

Literature information

Tab +

Literature references

Upload relevant document

[Add File](#)

[Next](#)

Click on ‘Next’ to move on to the next section of the form.

## 2. MEDICAL DEVICE INFORMATION

### a. Device category

This section of the form covers:

**2. Medical device**

**a. Device category**

Device Risk Classification as per India MDR 2017

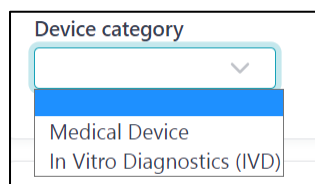
Device category

Device Risk Classification as per India MDR 2017

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

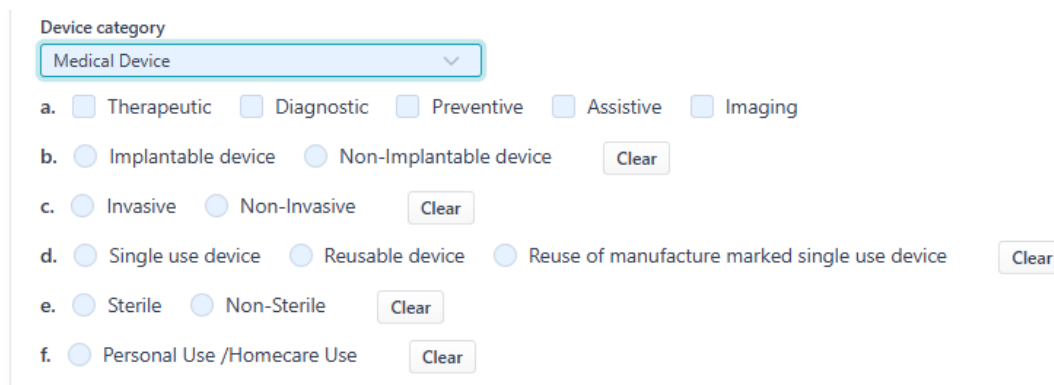
• **Device risk classification as per India MDR 2017** – Select the risk classification (A, B, C, D) of the medical device from the dropdown menu. Every device marketed in India is regulated and classified as per MDR 2017. Kindly visit [www.cdsc.gov.in](http://www.cdsc.gov.in) to see the classification of suspected medical device.

• **Device category** – Select the category of the medical device from the dropdown menu: Medical Device or In Vitro Diagnostics (IVD).



Medical Device category: Select the medical device categories from the options in dropdown:

- Therapeutic, Diagnostic, Preventive, Assistive, Imaging
- Implantable Device, Non-Implantable Device
- Invasive, Non-Invasive
- Single Use Device, Reusable Device, Reuse of manufacturer marked single use device
- Sterile, non-sterile



In Vitro Diagnostics (IVD) category: Select the IVD categories from the options in dropdown:

- Kits
- Reagent
- Calibrator
- Control Material

➤ IVD electronic reader/Analyzer

➤ Others (specify)

Device category

In Vitro Diagnostics (IVD)

a. ☐ Kits

b. ☐ Reagents

c. ☐ Calibrator

d. ☐ Control material

e. ☐ IVD electronic reader/ Analyzer

## b. Device details

This section of the form covers:

**b. Device details**

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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?

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

**License type** – Select the license type from the dropdown: Manufacture license or Import license. Write the license number after selecting the license type. The official number granted to a manufacturer or importer authorizing them to manufacture or import medical devices is the license number.

**License type**

▼

Manufacture license

Import license

▼

- **Nomenclature code (If applicable)** – Select the nomenclature code from the dropdown: Medical Device Nomenclature (GMDN) or Universal Medical Devices Nomenclature System (UMDNS). These codes are the international naming and grouping convention used to identify and consistently describe medical device. Write the code after selecting the nomenclature type.

**Nomenclature code (If applicable)**

▼

GMDN code

UMDNS code

- **Device information\*** – Select whether you want to mention the device name/trade name/ brand name from the dropdown menu. Trade name/ brand name - name given to a product by its manufacturer or marketer, used for branding and commercial purposes.

**Device information \***

▼

Device name

Trade name

Brand name

- Provide details of Manufacturer/ Importer/ Distributor including name & address.
- **Is the device notified/ regulated in India?** – Select Yes/ No from the dropdown depending on whether the medical device in question is notified or regulated in India or not.

- **Catalogue no.** – Mention the catalogue no. of the medical device. Catalogue no. is a unique number used in product catalogues to identify and order specific medical devices.
- **Model no.** – Mention the model no. of the medical device. A model number is a unique identifier assigned to each product by its manufacturer.
- **Lot/ Batch no.** – Mention the lot/ batch no of the medical device. The identifier for a specific production batch of devices, used for tracking and quality control.
- **Serial no.** – Mention the serial no. of the medical device. Serial no. is a unique number assigned to an individual device for identification and traceability.
- **Software version** – Mention the software version of the medical device. The specific version of software installed on a medical device, if the device includes software components.
- **Year of manufacturing** – Mention the year when the device was manufactured.
- **UDI no. (If applicable)** – Mention the UDI no. of the device if applicable. Unique Device Identification number (UDI no.) is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard enabling better traceability and enhanced patient safety.
- **Associated devices/ accessories** – Mention if any additional equipment or components were used in conjunction with the primary medical device.
- **Any other relevant information** – Mention if any other relevant information is available for the medical device.
- **Upload relevant document** – Upload any relevant document in JPG/ PNG/ PDF format (max size: 10 MB). Use 'browse' to select the file, then click 'upload' to attach the file or 'close' to exit.

### c. Device usage

This section of the form covers:

**c. Device usage**

<b>Installation date</b> <input type="text"/>	<b>Expiration date</b> <input type="text"/>
<b>Last preventive maintenance date</b> <input type="text"/>	<b>Last calibration date</b> <input type="text"/>
<b>How long was device/ equipment/ machine in use?</b> <input type="text"/>	
<b>Is the usage of device as per manufacturer claim/ instruction for use/ user manual?</b> <input type="text"/>	
<b>Any other relevant information</b> <input type="text"/>	

Previous
Next

- **Installation date** – Mention the date when the device was set up and made operational.
  - **Expiration date** – Mention the expiry date. The date beyond which the device or its components should not be used.
  - **Last preventive maintenance date** – Mention the most recent date when the device underwent scheduled maintenance to ensure proper functioning.
  - **Last calibration date** – Mention the most recent date when the device was calibrated to maintain accuracy and performance.
  - **How long was device/ equipment/ machine in use?** – Mention the total time period that the device/equipment/machine has been in use.
  - **Is the usage of device as per manufacturer claim/ instruction for use/ user manual?** – Select Yes/ No depending on whether the device was used according to the manufacturer's guidelines and instructions provided in the user manual. If no, specify the usage.
  - **Any other relevant information** – Mention if there is any other relevant information available.
- Click on 'Next' to move on to the next section of the form.

### 3. EVENT DETAILS

#### a. Event description

This section of the form covers:

**3. Event details**

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**a. Event description**

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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 \*

- **Date of event/ Near-miss incident\*** – Mention the exact date when the event or near-miss incident occurred. This date is crucial for tracking and addressing occurrences that might affect safety, quality, or operations.
- **Date of implant (If applicable)** – Mention the date (DD/MM/YYYY) when the implantable device was initially inserted into the patient body or body orifice (for implantable medical devices only).
- **Date of explant (If applicable)** – Mention the date (DD/MM/YYYY) when the implantable device was removed from the patient body or body orifice (for implantable medical devices only).
- **Location of event** – Select the location where the event occurred from the dropdown menu:
  - Hospital premise: Select when the event took place within a hospital.

- Manufacturer/Distributor premises: Select if the event occurred at the location of the manufacturer or distributor.
- Home: Select if the event happened at the patient's home
- Others: Select if the location is not listed in the above options.

Then mention the exact address of the location selected.

Location of event

Hospital premise

Hospital premise

Manufacture/ Distributor premise

Home

Others

Location address

Device disposition/ current location

- **Device operator** – Select the appropriate option from the dropdown depending on who was operating the medical device when the event took place.
  - Healthcare professional: Select if a medical worker operated the device.
  - Patient: Select if the person receiving the treatment used the device.
  - Others: Any other individual or entity involved, with a space to specify who they are.
- **Is device in use after incidence?** – Select Yes/ No from the dropdown depending on whether the device is still being used after the reported incident.
- **Device disposition/ current location** – Select the device's current location from the dropdown after the event has happened.
  - Returned to company: Select if the device was sent back to the manufacturer, further mention the date of return.
  - Remains implanted in patient: Select if the device is still inside the patient.
  - Within the healthcare facility: Select if the device is still at the healthcare facility where it was used.
  - At patient home: Select if the device is with the patient at their home.
  - Destroyed: Select if the device has been disposed of or destroyed.
  - Others (specify): Any other status or location not listed above.



- **Problem noted prior to use/ near miss event** – Select Yes/ No depending on whether the event was a near miss event or not. A Near miss event is an unplanned event in which patient/user was not involved and that did not result in injury, illness, or damage – but had the potential to do so.
- **Adverse Event Category\*** – Select the adverse event category from the dropdown menu.
- **Detailed description of event\*** – Write a detailed description of the event, including what happened, how it occurred, and any relevant circumstances or observations. This section captures a focused, factual, and clear account of the case, including exact words or short phrases used by the reporter.
- **Frequency of occurrence of similar adverse event in India in past 3 years** – Mention details of similar adverse events in India in the past 3 years, including the number of similar events, total no. of devices supplied, and frequency of occurrence (%).

Frequency of occurrence of similar Adverse Event in India in past 3 years			
2022	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2023	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2024	No. of similar events	Total no. supplied	Frequency of Occurrence(%)

- **Frequency of occurrence of similar adverse event globally in past 3 years** – Mention details of similar adverse events globally in the past 3 years, including the number of similar events, total no. of devices supplied, and frequency of occurrence (%).

Frequency of occurrence of similar Adverse Event in globally in past 3 years			
2022	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2023	No. of similar events	Total no. supplied	Frequency of Occurrence(%)
2024	No. of similar events	Total no. supplied	Frequency of Occurrence(%)

- **Upload relevant document** – Upload any relevant document in JPG/ PNG/ PDF format (max size: 10 MB). Use ‘browse’ to select the file, then click ‘upload’ to attach the file or ‘close’ to exit.

## b. Event outcome

This section of the form covers event outcome:

- **Patient outcome\*** – Select the appropriate option from the dropdown menu to indicate the patient's status.

- Recovered: Select if the patient has fully recovered from the event with no ongoing symptoms or complications.
- Not yet recovered: Select if the patient is still experiencing symptoms or is under treatment and has not returned to their normal health status.
- Death: Select if the patient passed away as a result of the incident or during the course of the related condition.
- Others: Select if the patient outcome does not fall under the listed categories. Further details should be provided if this option is selected.
- Stable: Select if the patient is in a stable condition, with no immediate life-threatening concerns, but may not be fully recovered yet.

b. Event outcome

Patient outcome \*

Any other relevant information

Previous
Next

- **Any other relevant information** – Mention if there is any other relevant information available.

Click on '**Next**' to move on to the next section of the form.

#### 4. PATIENT DETAILS

##### a. Patient information

This section of the form covers:

4. Patient Info
IN-IPC-MD31242 [PDF](#)

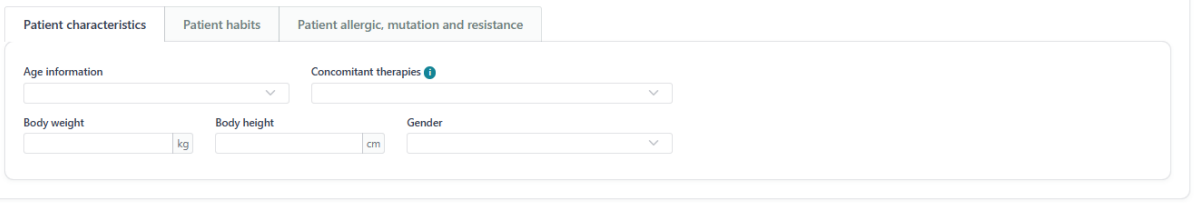
**a. Patient information**

Sal. <input type="text"/>	First name <input type="text"/>	Middle name <input type="text"/>	Last name <input type="text"/>
Patient initials <span style="color: blue;">?</span> <input type="text"/>	Father's name <input type="text"/>		Mother's name <input type="text"/>
Address <input type="text"/>		City <input type="text"/>	Pin code <input type="text"/>
District <input type="text"/>	State <input type="text"/>	Country <input type="text"/>	
Mobile no. <input type="text"/>	Telephone no. <input type="text"/>	Email address <input type="text"/>	
GP medical record no. <input type="text"/>	Specialist record no. <input type="text"/>	Hospital record no. (IPD/ OPD) <input type="text"/>	Investigation no. <input type="text"/>
Protect confidentiality <input type="text"/>			

- **Salutation (Sal.)** – Select the appropriate salutation (Mr., Mrs., Ms., Dr., Prof.) from the dropdown for the patient.
- **Enter patient's full name** – Fill in the first name, middle name (if any), and last name of the patient.
- **Patient initials** – Enter patient's name or initials.
- **Father's name** – Enter patient's father's name.
- **Mother's name** – Enter patient's mother's name.
- **Address and contact details** – Enter the address, city, pin code, district, state, country, mobile no., telephone no., and email address of the patient.
- **GP medical record no.** – Enter the patient's general practitioner (GP) record number.
- **Specialist record no.** – Enter the patient's specialist consultation record number.
- **Hospital record no. (IPD/ OPD)** – Enter the Inpatient Department (IPD) or Outpatient Department (OPD) hospital record number.
- **Investigation no.** – Enter the laboratory or radiology investigation reference number.
- **Protect confidentiality** – Select Yes/ No from the dropdown to protect confidentiality or not.

• **Patient characteristics** – Select the option from the dropdown of the ‘age information’ to provide details about the age of the patient.

- Date of birth: Mention the date of birth of the patient.
- Age at onset of reaction: Mention the age of patient at the onset of reaction/ adverse event.
- Age group: Select the appropriate age group of the patient from the dropdown menu: foetus/ neonate (preterm and term newborns)/ infant/ child/ adolescent/ adult/ elderly.



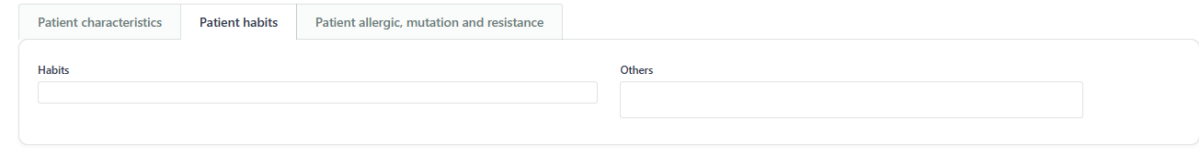
Concomitant therapies: Select Yes/ No from the dropdown depending on whether at the time of reaction there were concomitant therapies or not.

Body weight: Mention the body weight of the patient in kg.

Body height: Mention the body height of the patient in cm.

Gender: Select the gender of the patient from the dropdown: female/ male/ transgender/ unknown.

• **Patient habits** – Select the patient's habits from the dropdown menu. Multiple options can be selected: alcohol/ abuse/ contraceptives/ drug abuse/ nicotine use/ special diet. If the patient has any other habits not listed, please specify them under the 'others' option.



• **Patient allergic, mutation and resistance**

Allergic to drug: Select Yes/ No from the dropdown depending on whether there is any Fixed Drug Combination (FDC) or not. Enter the drug name (WHO Drug) in the provided text box. Click on the “+” button if you need to add more than one drug allergy.

Allergic to food: Mention any known food allergies into the "allergic to food" text field.

Mutation: Mention any known genetic mutations relevant to the patient's medical history in the "mutation" text field.

Resistance: Mention any known resistance (e.g., antimicrobial or drug resistance) into the "resistance" text field.

Patient characteristics

Patient habits

Patient allergic, mutation and resistance

**Allergic to drug**

Tab +

Fixed drug combination (FDC)

Drug name (WHODrug)

Allergic to food

Mutation

Resistance

Previous
Next

Click on ‘**Next**’ to move on to the next section of the form.

## 5. MEDICAL AND PAST DRUG HISTORY

### a. Medical history

This section of the form covers:

5. Medical and past drug history

IN-IPC-MD31283
PDF

**a. Medical history**

Tab +

Relevant medical history (MedDRA)

Start date

▼

▼

▼

Continuing ⓘ

▼

Comment ⓘ

Family history ⓘ

Relevant medical history ⓘ

- **Relevant medical history (MedDRA)** – Write the relevant medical history of the patient according to the Medical Dictionary for Regulatory Activities (MedDRA) codes. MedDRA is an internationally recognized set of terms used to facilitate the regulation of medical products for humans, including biopharmaceuticals, medical devices and vaccines.
- **Start date** – Select the date when the condition began using the calendar popup or manual entry.
- **Continuing** – Choose Yes/ No from the dropdown depending if the ‘medical condition’ provided is still present at the time of the report or not.
- **Comment** – Write any additional relevant information about the ‘medical condition’ provided that could not be captured otherwise.
- **Family history** – Select Yes/ No depending on whether the ‘medical condition’ provided is reported also to be present in another family member (such as hereditary diseases.)
- **Relevant medical history** – Write any other medical history that could not be coded in the above section.

#### **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)

- **Relevant past drug name (WHO Drug)** – Write the name of the relevant past drug as per WHO.
- **Relevant past drug name** – Write the name of the drug/ medicinal product as used by the reporter.
- **Start date** – Select the date when the patient began using the drug.
- **End date** – Select the date when the patient stopped using the drug.
- **Indication (MedDRA)** – Write the indication of the drug as MedDRA.

- **Reaction (MedDRA)** – Write the reaction of the drug as MedDRA.

**c. Past medical device history**

c. Past medical device history

Relevant past medical device history

Previous
Next

- **Relevant past medical device history**–Write any relevant past medical device history.

Click on ‘Next’ to move on to the next section of the form.

## 6. HOSPITALIZATION/ DEATH INFORMATION

**a. Hospitalization related information**

This section of the form covers:

6. Hospitalization / Death

a. Hospitalization related information

Hospitalization date
Discharge date

Treatment details

Upload discharged summary
Add File

- **Hospitalization date** – Select the date of hospitalization of the patient in case the patient was hospitalized.
- **Discharge date** – Select the discharge date in case of hospitalization.
- **Treatment details** – Write the details of the treatment given to the patient.
- **Upload discharged summary** – Upload the discharge summary documents. Upload any relevant document in JPG/ PNG/ PDF format (max size: 10 MB). Use ‘browse’ to select the file, then click ‘upload’ to attach the file or ‘close’ to exit.

## b. Death related information

b. Death related information

Death date

Death time

Tab

+

Death cause (MedDRA)

Death cause

Autopsy performed?

Upload relevant document

Add File

Previous

Next

- **Death date** – Select the date of death of the patient.
- **Death time** – Select the time of death of the patient.
- **Death cause (MedDRA)** – Write the cause of the death of the patient according to MedDRA.
- **Death cause** – Mention the original reporter's words and/ or short phrases used to describe the use of death of the patient.
- **Autopsy performed?** – Select Yes/ No/ Unknown from the dropdown depending on whether the autopsy was performed or not or is unknown to the reporter.
- **Upload relevant document** – Upload any relevant document in JPG/ PNG/ PDF format (max size: 10 MB). Use 'browse' to select the file, then click 'upload' to attach the file or 'close' to exit.

Click on '**Next**' to move on to the next section of the form.



## 7. TESTS AND PROCEDURES

### a. Results of tests and procedures

This section of the form covers:

7. Tests and procedures IN-IPC-MD31433 PDF

**a. Results of tests and procedures**

Tab +

Test date

Test name (MedDRA)

Test name

Test result  Test result (code)  Low range  High range

Result

Comments

Upload relevant document

- **Test date** – Select the date of test done for the patient.
- **Test name (MedDRA)** – Write the name of the test as per MedDRA.
- **Test name** – Write the name of the test.
- **Test result** – Write the result of the test in units (as g, g/l, bq). Select the unit from the dropdown menu. If you could not find the required unit in the dropdown then select others from the dropdown, a text field will appear, enter the required unit there.
- **Test result (code)** – Select the result code of the test from the dropdown- positive/ negative/ borderline/ inconclusive.
- **Low range** – Mention the low range.
- **High range** – Mention the high range.
- **Result** – Write the result of the test.
- **Comments** – Write any relevant comments (by the reporter) for the test.


- **Upload relevant document** – Upload any relevant document in JPG/ PNG/ PDF format (max size: 10 MB). Use ‘browse’ to select the file, then click ‘upload’ to attach the file or ‘close’ to exit.

Click on ‘Next’ to move on to the next section of the form.

## 8. ASSESSMENT

### a. Causality assessment

This section of the form covers:



- **Reporter's comments** – Reporter can write his comments on the diagnosis, causality assessment or other issues considered relevant.
- **Sender's diagnosis (MedDRA)** – Write if there are any sender's diagnosis as per MedDRA.
- **Sender's comments** – Write if there are any sender's comments for the assessment of the case or any disagreement with, and/ or alternatives to the diagnosis given by the reporter. Also, in case of multiple ICSRs, the reason should be provided in these comments.
- **Investigation action taken** – Write the specific actions taken during an investigation and the corresponding dates or deadlines when these actions were carried out or completed.
- **Root cause of problem** – Mention the root cause of the event.

**b. Investigation & action taken**

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

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Manufacturer/ Authorized representative device risk analysis report

Corrective/ Preventive action taken

Device history review

Previous
Next

This section is specifically for the medical device license holders.

- **Manufacturer/ Authorized representative device risk analysis report** – Manufacturer/ Authorized representative is requested to write about the device risk analysis report summary.
- **Corrective/ Preventive action taken** – Write the measures implemented to address and rectify the identified issue (i.e. corrective action) and to prevent its recurrence in the future (i.e. preventive action).
- **Device history review** – Write about the device history (such as quality tests etc.).

Click on ‘**Next**’ to move on to the next section of the form.

## 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
------------------	-----------------------

**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
-----------------	-------------------

**4. Patient**

Protect confidentiality ☒ Yes

**Patient Characteristics**


Age information	
Gender	Female

**6. Tests and procedures**

**7. Assessment**

**a. Assessment Information**

Previous Save

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

## Annexure-II


### How to update personal information in ADRMS


Format No: IPC/MvPI/013/00/FMT/02

#### How to change password?

Account information

ACCOUNT TYPE	Programme Coordinator Materiovigilance Programme Of India
USERNAME	██████████
PASSWORD	.....



Click on '  ' to edit password. A pop-up window will appear.

**Change password** ×

Current password \*

New password \*


Reenter new password \*

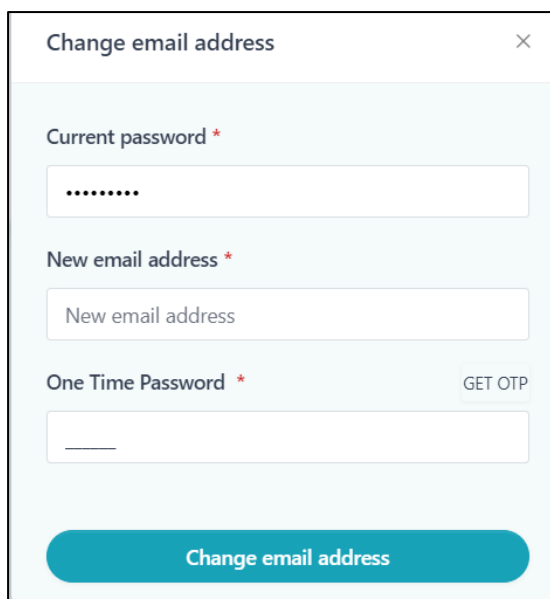
**Change password**

1. Enter the current password, new password, and re-enter new password.
2. New password must be 8-20 characters long, contain at least one lowercase letter, one uppercase letter, one number, and one special character (~!@#%^&\*()\_+?:.).
3. Must be different from previous passwords.

### How to change email address?



Click on ‘’ to edit email address. A pop-up window will appear.



1. Enter the current password, new email address you want to change to, and OTP (One Time Password) which is sent by ADRMS after clicking on GET OTP.
2. Enter a valid email address. This email address must not exist already in our system.
3. Verify your email by entering the following OTP. Please do not share this with anyone.

### How to change mobile number?

Contact information

EMAIL ADDRESS

MOBILE NO.

+

Click on ‘’ to edit mobile number. A pop-up window will appear.

Change mobile no.

Current password \*

Current password

New mobile no. \*



One Time Password \*

GET OTP

Change mobile no.

1. Enter current password.
2. Enter a valid mobile no., this mobile no. must not exist already in our system.
3. Please click on GET OTP link to receive an 8-digit long OTP on your email, enter that OTP here.


### How to change professional information of Programme Coordinator?

Professional information



INSTITUTE NAME

Click here to change the Institute name



Click on ‘’ to edit professional information. A pop-up window will appear.

Change professional information


Designation

Qualification

Total experience

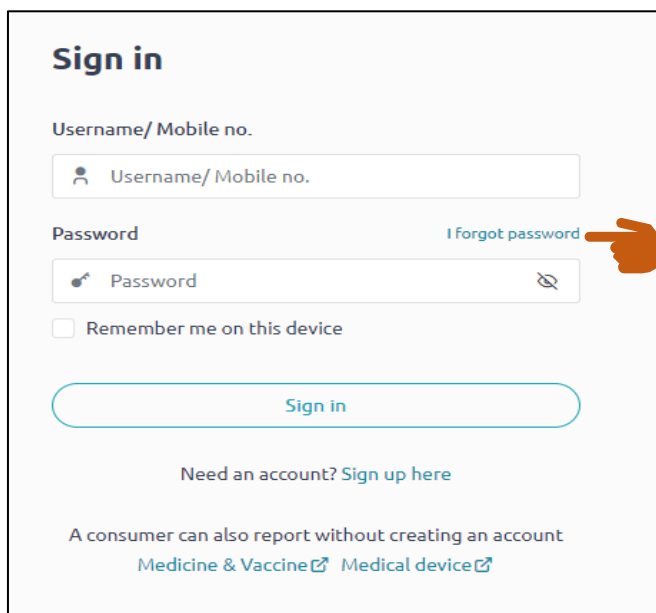
Year

Month


Change professional information

Enter designation, qualification, and select year and month of total experience of the Coordinator.



## How to reset password?



**Sign in**

Username/ Mobile no.

Password [I forgot password](#)

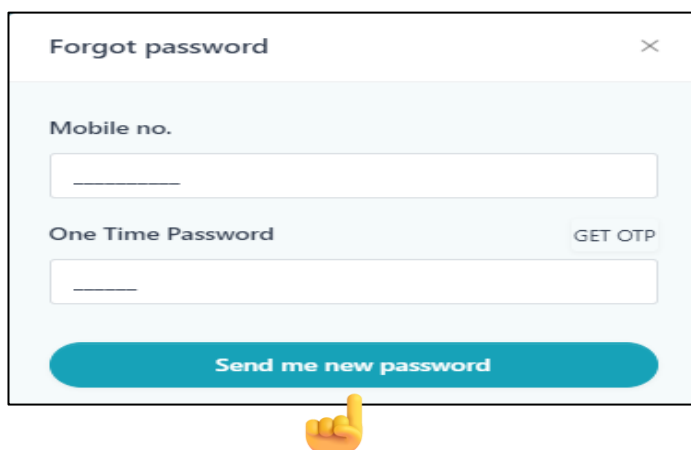
☐ Remember me on this device

[Sign in](#)

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

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

Click on “I forgot password” a new window appears.



**Forgot password** ×

Mobile no.

One Time Password [GET OTP](#)

[Send me new password](#)

1. Enter mobile number then click on ‘GET OTP’. Enter OTP.
2. Click on ‘send me new password’.
3. You will receive new password on your registered mobile number.