Adverse Drug Reactions Monitoring System (ADRMS)

User Manual for Stakeholders

Materiovigilance Programme of India (MvPI)

2026

National Coordination Centre - Materiovigilance Programme of India
Indian Pharmacopoeia Commission
Ministry of Health and Family Welfare (MoHFW), Government of India
Sector-23, Raj Nagar, Ghaziabad - 201002
Tel. : 0120-2783400, 2783401, 2783392 Fax : 0120-2783311 Website: www.ipc.gov.in

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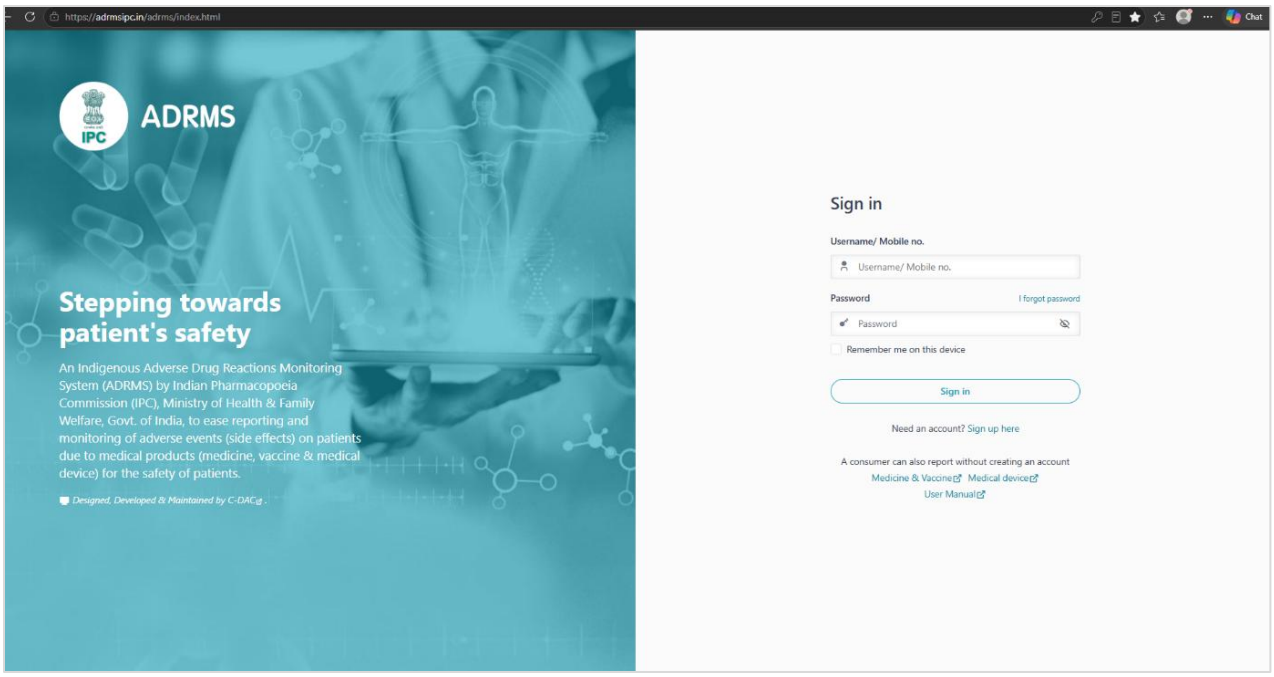
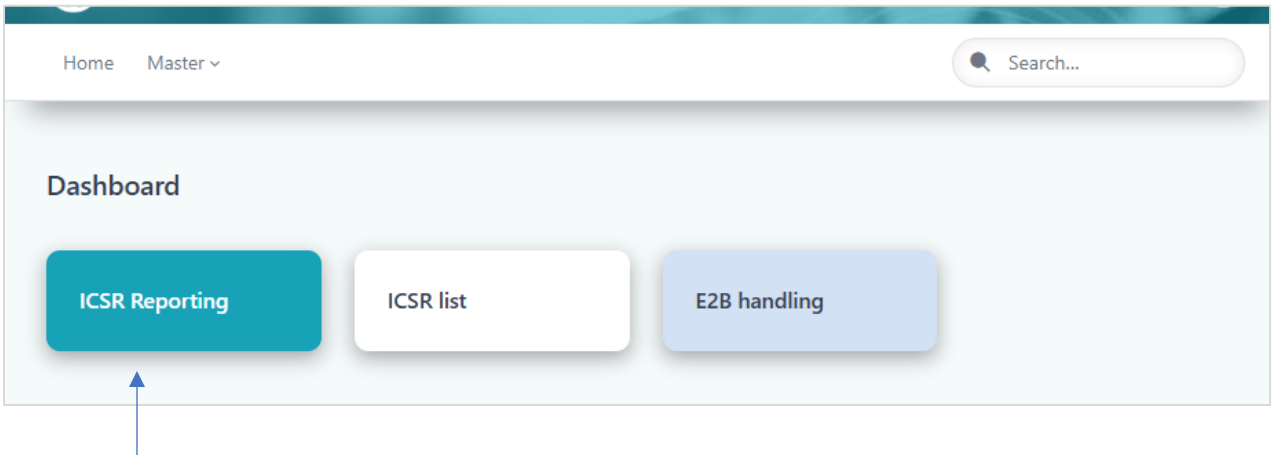


- Enter your username or registered mobile number, input the password and click on "Sign in."

After signing in, the dashboard will be displayed. Click on 'ICSR reporting' to proceed.



Click here to report MDAE

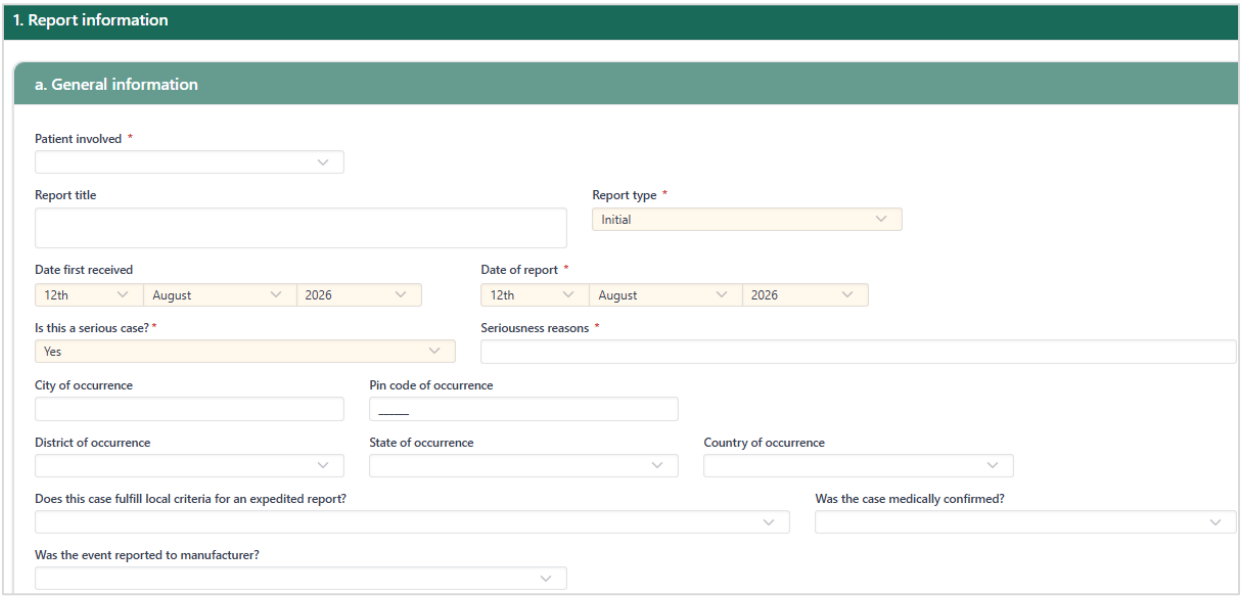
How to fill the MDAE form: The MDAE reporting form will open, comprising 09 sections including report information, medical device details and usage, event details, patient details, medical and past drug, hospitalization/death, result of tests/procedures and causality assessment. The MDAE reporting is segregated into the following sections. Fill details and proceed accordingly.

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.

> **Report title**: Type of Report_Serious/Non-Serious_Device Name_Adverse Event
>
> **Example**: Initial_Serious_IUD_Expulsion

- ***Report type**** – Select the appropriate type of report by ticking the checkbox in the dropdown– initial, follow-up, final, trend.

> **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.
>
> **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".

- ***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 date on which the reporter completes and submits the ICSR.
- ***Is this a serious case*?* –** Determine whether the adverse event qualifies as a serious event and select Yes/No from the dropdown.

  If yes, then choose the seriousness reasons* from the dropdown - results in death, life-threatening, caused or prolonged hospitalization, disabling or incapacitating, congenital anomaly or birth defect, other medically important condition, required intervention to prevent permanent impairment.

Serious Adverse Event (SAE) as per MDR 2017: Serious Adverse Event means any untoward medical occurrence that leads to-

(i) a death; or

(ii) a serious deterioration in the health of the subject that either-

(A) resulted in a life-threatening illness or injury; or

(B) resulted in a permanent impairment of a body structure or a body function; or

(C) required in-patient hospitalisation or prolongation of existing hospitalization; or

(D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or

(iii) foetal distress, foetal death or a congenital abnormality or birth defect.

- ***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?*** **–** Select Yes/No from the dropdown depending on whether the report is an expedited report or not.

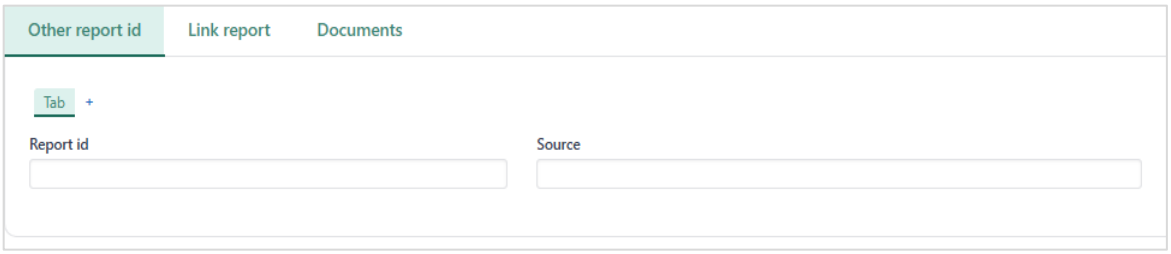
Expedited Report: According to the ICH E2D guideline (Post-Approval Safety Data Management by U.S. FDA), an expedited report is an ICSR that meets the requirements for reporting as soon as possible, but no later than 15 calendar days after day zero.

- ***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., Marketing Authorization Holder (MAH), Medical Device Adverse Event Monitoring Centre (MDMC).

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

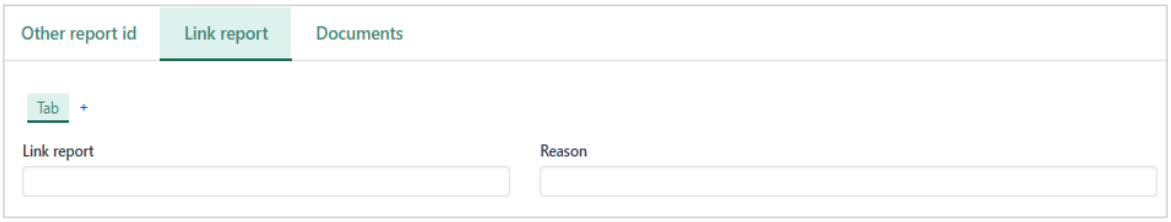


- ***Link Report tab*** – Use this tab to link this report to another related case.

  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.

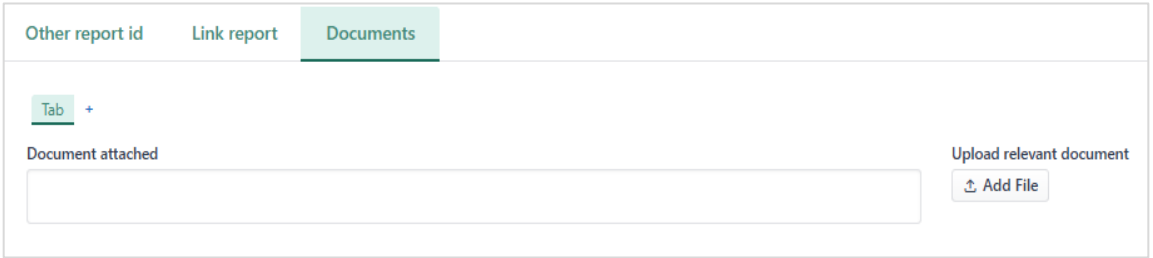


- ***Documents tab*** – Use this tab to upload supporting files for the case.

  Document held: Indicate whether relevant documents are available.

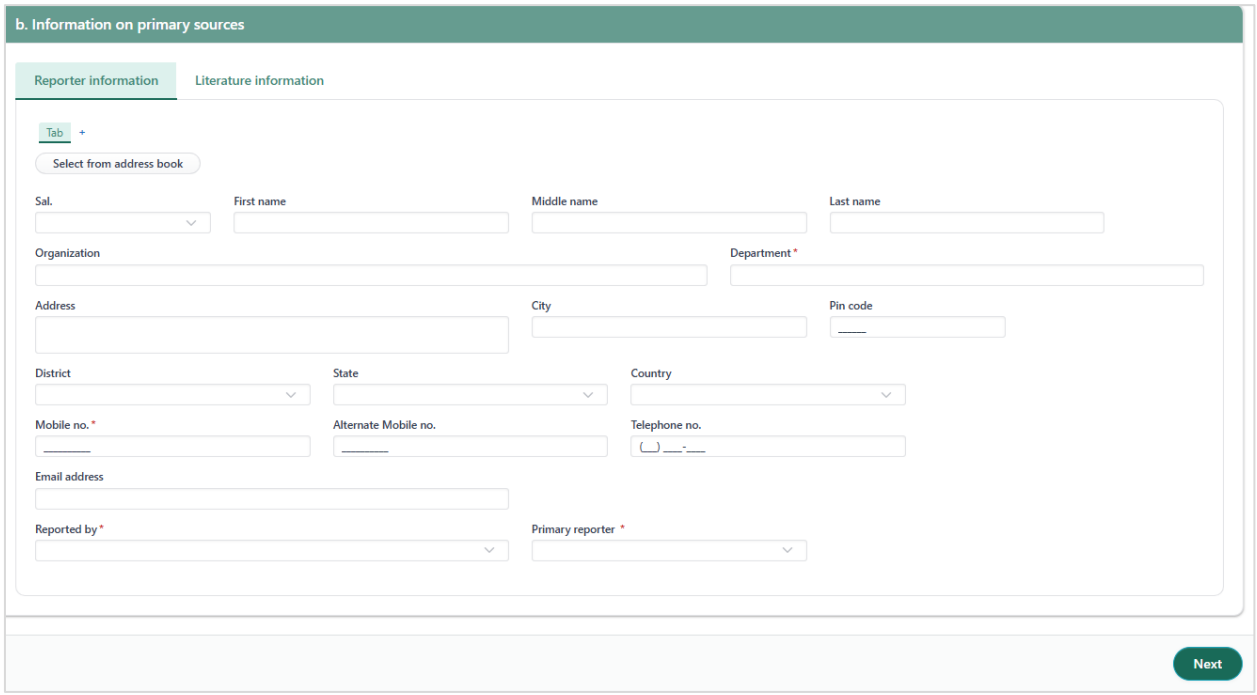
  Upload relevant document: Upload files (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 MB). Use 'browse' to select the file, then click 'upload' to attach the file or 'close' to exit.

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



b. Information on primary sources

This section of the form covers:



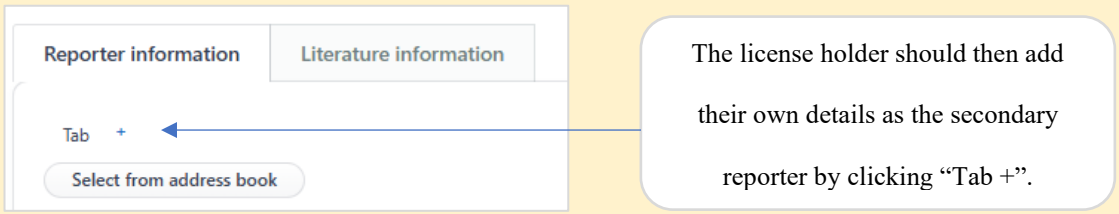
- ***Salutation (Sal.)*** – Select the appropriate salutation (Mr., Mrs., Ms., Dr., Prof.) from the dropdown.
- ***Enter reporter's full name*** – Fill in the first name, middle name (if any), and last name.
- ***Organization and department*** – Enter the name of the reporter's organization and their department*.
- ***Address and contact details*** – Fill the address, city, pin code, district, state, country*, mobile no.*, telephone no., and email address of the reporter.
- ***Reported by**** – Select the specific category of the person or organization submitting the report from the dropdown - Pharmaceutical Company, Regional Pharmacovigilance /Materiovigilance Centre, Health Professional, Patient /Consumer, Regulatory Authority, Other (e.g., Distributor, Study Sponsor, Contract Research Organization, or Non-Commercial Organization), Medical Device License Holder.

- ***Primary reporter****:* Select Yes/No based on whether the person or organization marked under "Reported by" is the primary reporter.

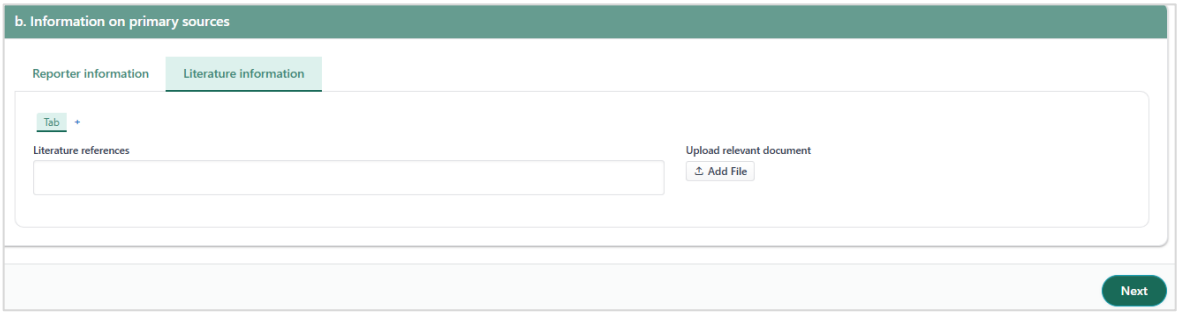
Primary reporter: Person who directly observed or was involved in the adverse event.

Note: If a hospital or patient shares an adverse event with a license holder who subsequently submits the report, the primary reporter must be the hospital's healthcare professional/consumer/user—not the license holder.

In such cases, enter the healthcare professional's details in the 'Reporter Information' section. The license holder should then add their own details as a secondary reporter by clicking "Tab +" and entering the required personal and organizational information.



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



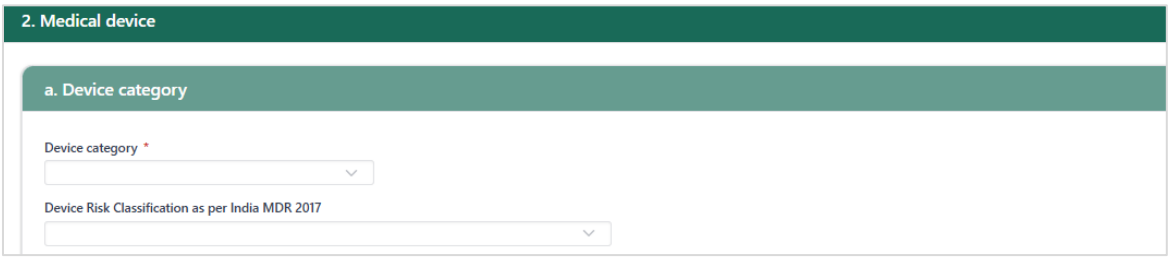
Click on '**Next**' to move on to the next section of the form.

2. MEDICAL DEVICE INFORMATION

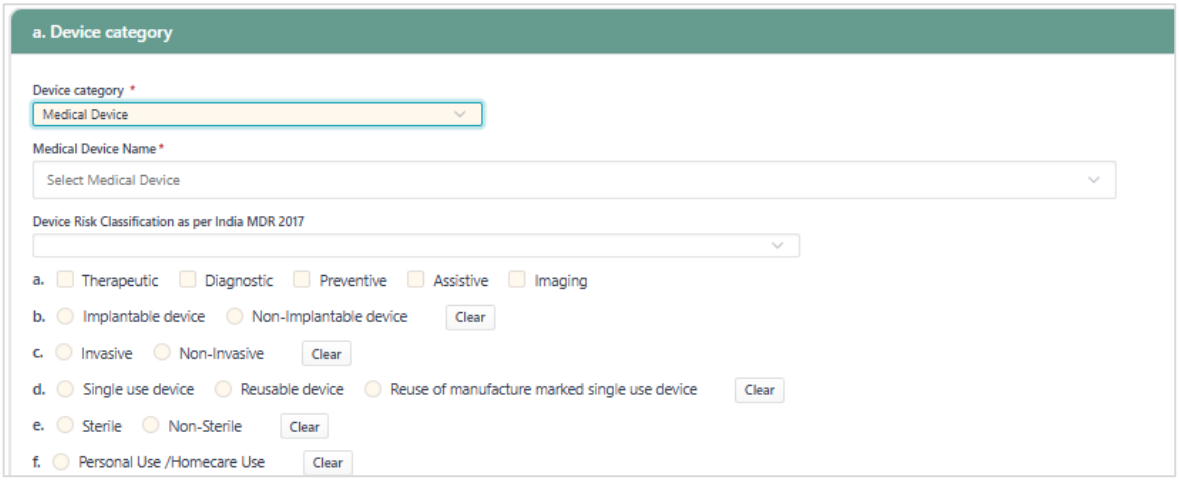
a. Device category

This section of the form covers:

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



- ***Medical device name**** – Enter the name of the medical device associated with the reported adverse event. Once the medical device name is entered (e.g., "Digital Thermometer"), the system will automatically fetch the corresponding device risk classification (e.g., "Low–Moderate Risk, Class B") as per the Medical Devices Rules (MDR), 2017 and medical device category. If the medical device is not available in the list, select "Others" and manually enter the specific name of the medical device along with the corresponding risk class, as per the MDR, 2017.



Medical Device (as per MDR 2017) — All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;

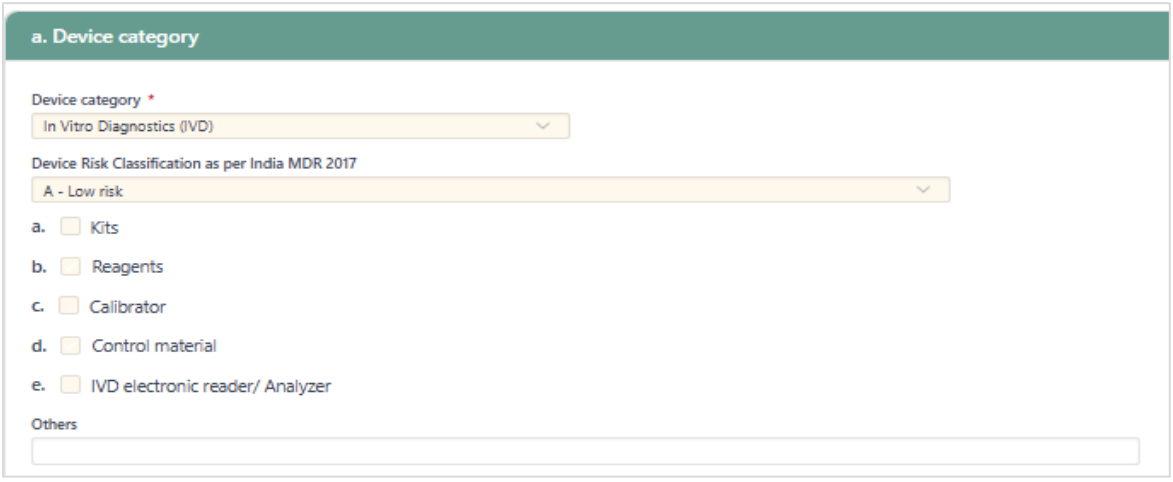
(iv) supporting or sustaining life;

(v) disinfection of medical devices; and

(vi) control of conception.

- ***In-Vitro Diagnostic device***– Select "In Vitro Diagnostics (IVD)" from the Medical Device Category dropdown if the suspected device is an IVD. Select the applicable risk classification according to MDR, 2017 and IVD sub-category (Kits, Reagents, Calibrator, Control Material, or IVD Electronic Reader/Analyzer) from the available options. The specific name of the IVD should be entered under the "Others" option.

In Vitro Diagnostics (IVD): A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.



- ***Device risk classification as per India MDR, 2017*** – Select the risk classification (A, B, C, D) from the dropdown.

Classification of medical devices (as per MDR 2017):

(1) Medical devices other than in vitro diagnostic medical devices shall be classified on the basis of parameters specified in Part I of the First Schedule of MDR, 2017, in the following classes:

(i) low risk - Class A;

(ii) low moderate risk- Class B;

(iii) moderate high risk- Class C;

(iv) high risk- Class D.

(2) *In vitro* diagnostic medical devices shall be classified on the basis of parameters specified in Part II of the First Schedule of MDR, 2017, in the following classes:

(i) low risk - Class A;

(ii) low moderate risk- Class B;

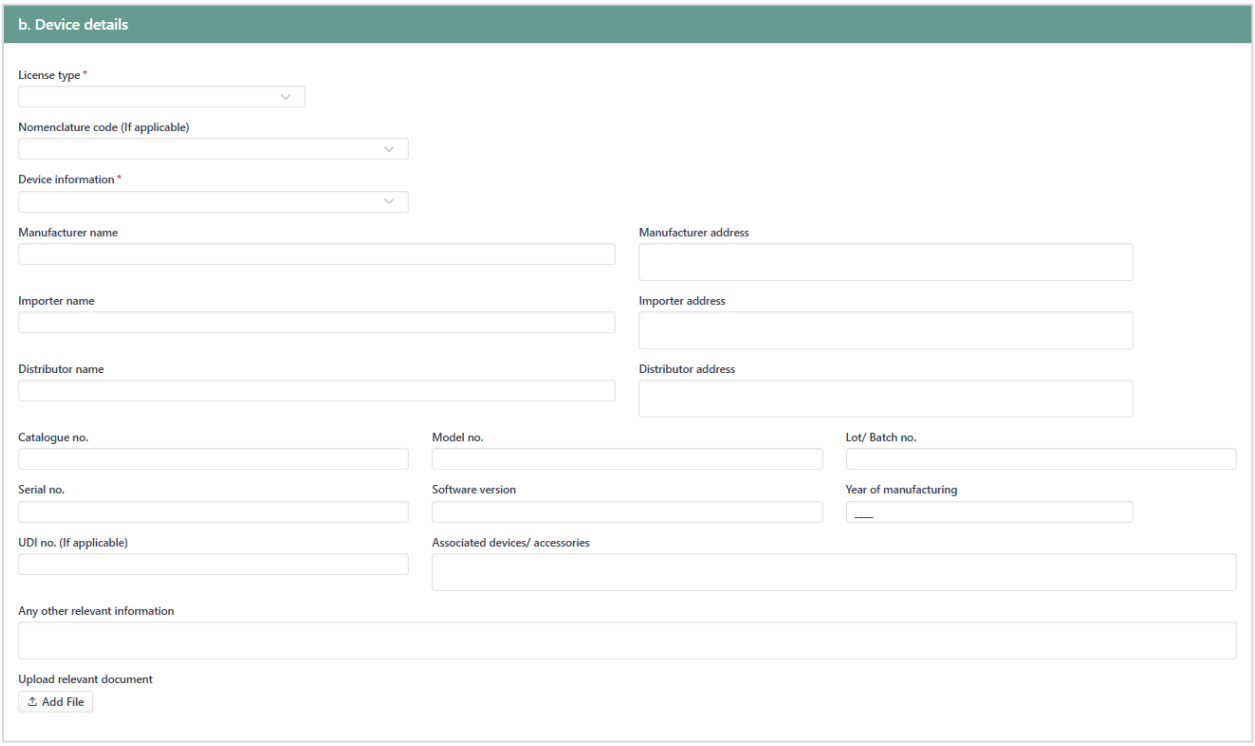
(iii) moderate high risk- Class C;

(iv) high risk- Class D.

Every device marketed in India is regulated and classified as per MDR 2017. Kindly visit www.cdsco.gov.in to see the classification of suspected medical device.

b. Device details

This section of the form covers:



- ***License type*** – Select the license type from the dropdown: Manufacture license or Import license. Write the license number after selecting the license type.
- ***Nomenclature code (If applicable)*** – Select the nomenclature code from the dropdown: Global Medical Device Nomenclature (GMDN) or Universal Medical Devices Nomenclature System (UMDNS). Write the code after selecting the nomenclature type.

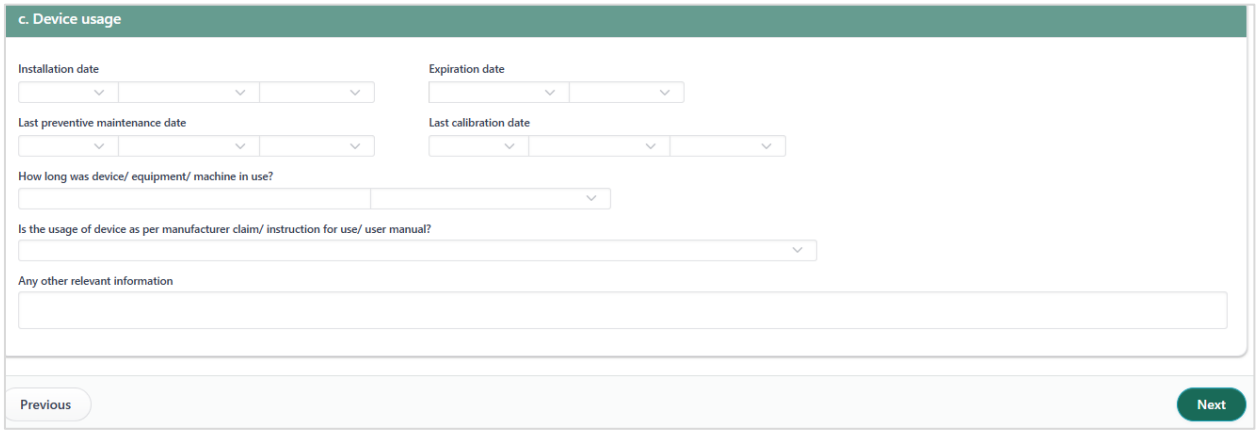
> Global Medical Device Nomenclature (**GMDN**) and Universal Medical Device Nomenclature System (**UMDNS**) are both systems used for classifying and identifying medical devices. These codes are the international naming and grouping convention used to identify and consistently describe medical device.

- ***Device information**** – Select whether you want to mention the device name/trade name/brand name from the dropdown.

- Provide details of Manufacturer/Importer/Distributor including name & address.
- ***Device identification details*:** Enter the catalogue no., model number, lot/batch number, serial number, software version (if applicable), year of manufacture, and UDI (Unique Device Identification) number (if applicable) of the medical device.
- ***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 (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 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:



- ***Installation date*** – Mention the date when the device was set up and made operational.
- ***Expiration date*** – Mention the expiry date of the device.

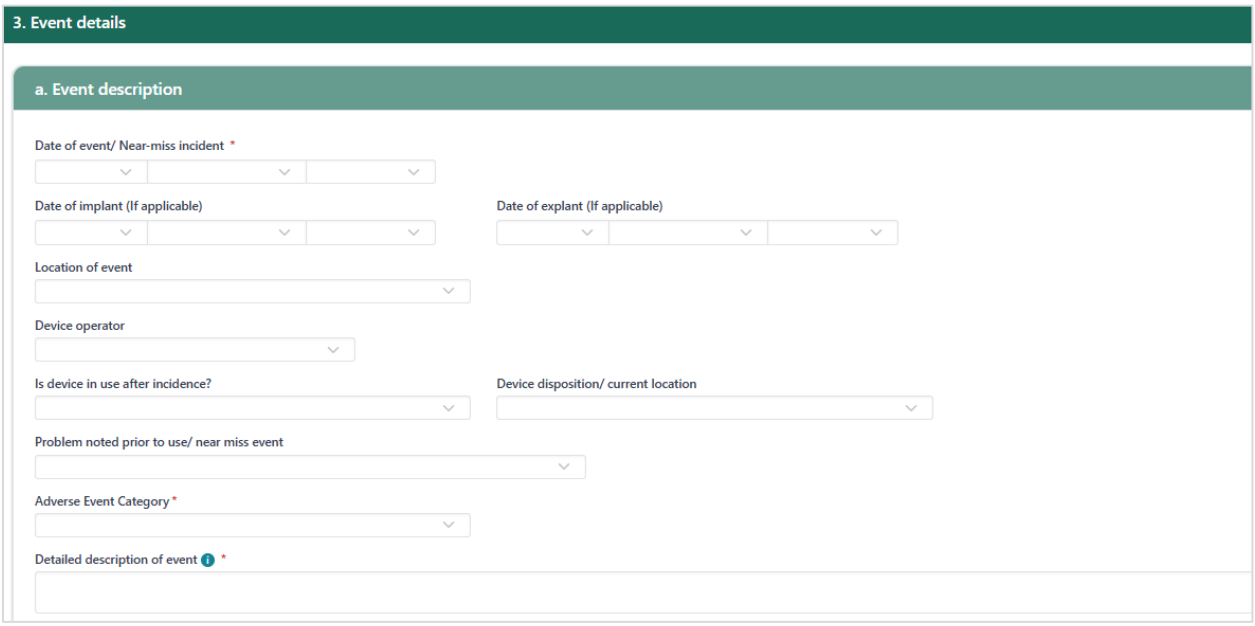
- ***Last preventive maintenance date*** – Mention the most recent date when the device underwent scheduled maintenance to ensure proper functioning.
- ***Last calibration date*** – Mention the most recent date when the device was calibrated to maintain accuracy and performance.
- ***How long was device/equipment/machine 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:



- ***Date of event/Near-miss incident**** – Mention the exact date when the event or near-miss incident occurred.

> **Near-miss incident**: A 'Near miss event' is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so.
>
> **Reference- Guidance Document: Materiovigilance Programme of India (version 1.2)**

- ***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 appropriate setting where the event occurred - hospital premise, manufacturer/distributor premise, home or others - and provide the full address of the location.

- ***Device operator*** – Select the appropriate option depending on who was operating the medical device when the event took place from the dropdown – healthcare professional, patient, others.
- ***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 current status of the device after the event- returned to company, remains implanted in patient, within the healthcare facility, at patient's home, destroyed, others.
- ***Problem noted prior to use/near miss event*** – Select Yes/No depending on whether the problem was noted prior to use/near miss event.
- ***Adverse event category**** – Select the adverse event category from the dropdown.
- ***Detailed description of event**** – Write a detailed description of the event, including what happened, how it occurred and any relevant circumstances or observations.

Description of event: The reporter should try to ensure that the event description captures all relevant details, including:

a. Date when patient joined or visit the hospital; b. Presenting symptoms; c. Medical device used; d. Adverse event observed; e. Patient outcome; f. Immediate action taken; g. Documents attached (Proof/Videos, if applicable)

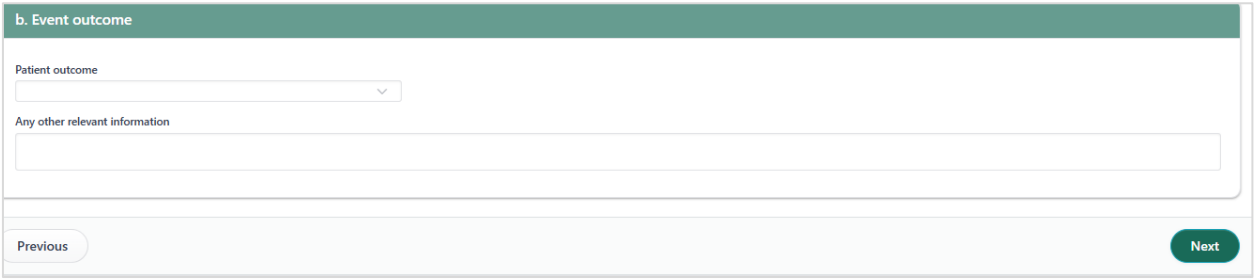
For ex: On 31/10/2025, patient 'X' visited the hospital with complaints of severe abdominal pain. The patient was administered IV medication using the 'XYZ Infusion Set'. During administration, it was observed that the set was faulty and the medicine was leaking. A new infusion set of the same (or different) brand was immediately used to continue the administration. The patient did not suffer any injury.

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

- ***Upload relevant document*** – Upload any relevant document (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 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:



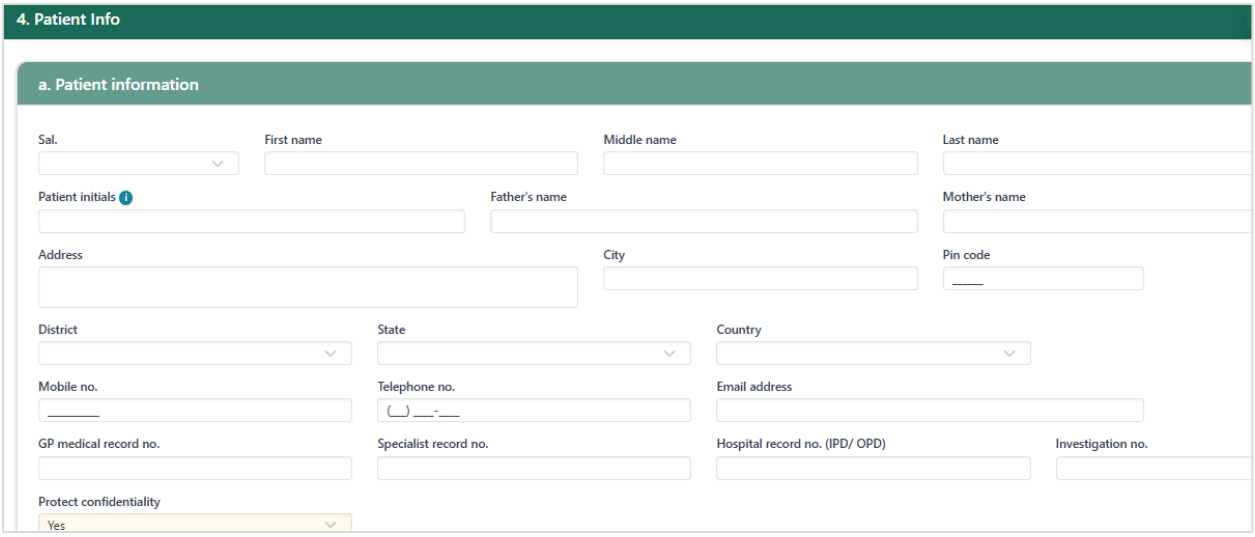
- ***Patient outcome***– Select the appropriate option from the dropdown to indicate the patient's status- recovered, not yet recovered, death, others, stable.
- ***Any other relevant information*** – Mention if there is any other relevant information available.

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

4. PATIENT DETAILS

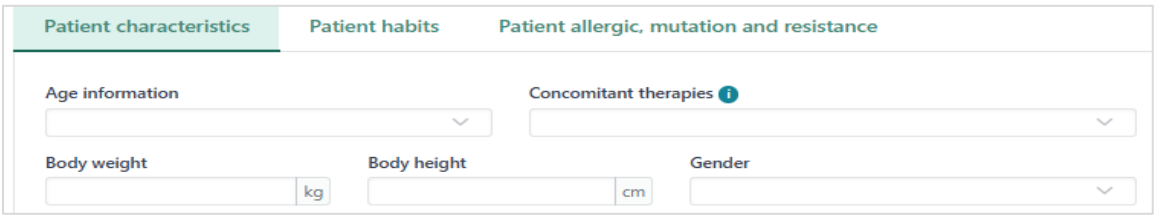
a. Patient information

This section of the form covers:

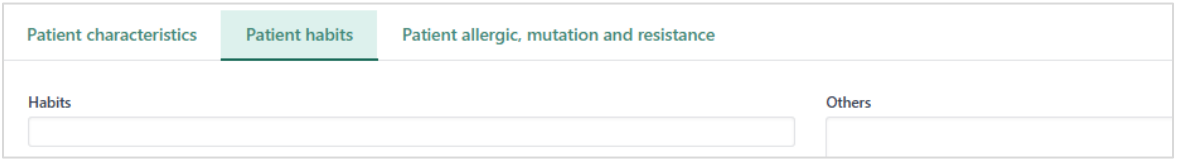


- ***Salutation (Sal.)*** – Select the appropriate salutation (Mr., Mrs., Ms., Dr., Prof.) from the dropdown for the patient.
- ***Patient details*** – Fill in the patient's name or initials.
- ***Father's name*** – Enter the patient's father's name.
- ***Mother's name*** – Enter the patient's mother's 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.

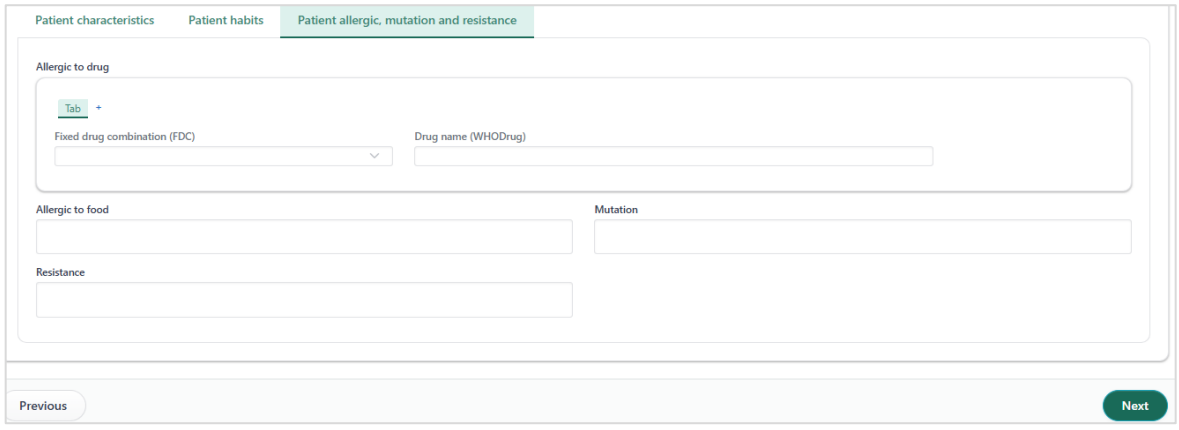
- ***Protect confidentiality*** – Select Yes/No from the dropdown to protect confidentiality or not.
- ***Patient characteristics*** – Enter the patient's age information, gender, body weight (kg), body height (cm), and indicate whether concomitant therapies were present at the time of the event.



- ***Patient habits*** – Select the patient's habits from the dropdown. Multiple options can be selected: alcohol/contraceptives/drug abuse/nicotine use/special diet.



- ***Patient allergic, mutation and resistance*** – Indicate whether the patient has any known drug allergies by selecting Yes or No from the dropdown and enter the drug name(s) in the text field; use the "+" button to add multiple entries if required. Mention any known food allergies, relevant genetic mutations, and documented resistance in the respective text fields.

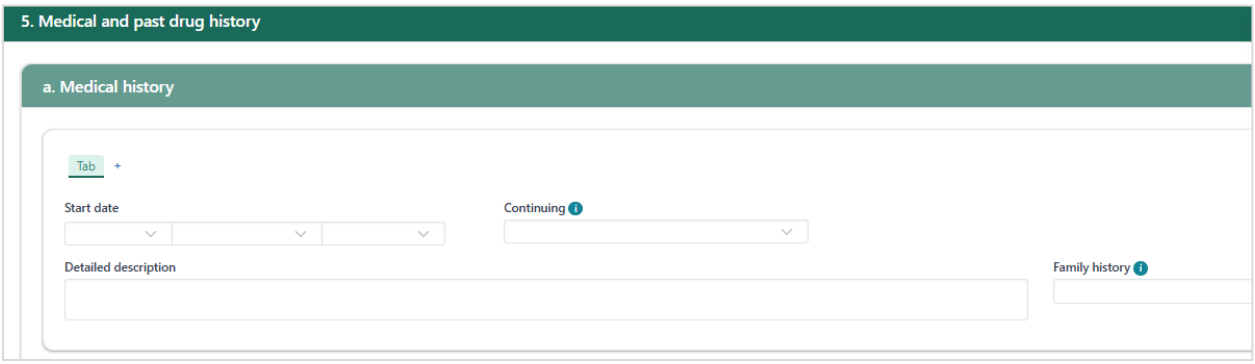


Click on '**Next**' to move on to the next section of the form.

5. MEDICAL AND PAST DRUG HISTORY

a. Medical history

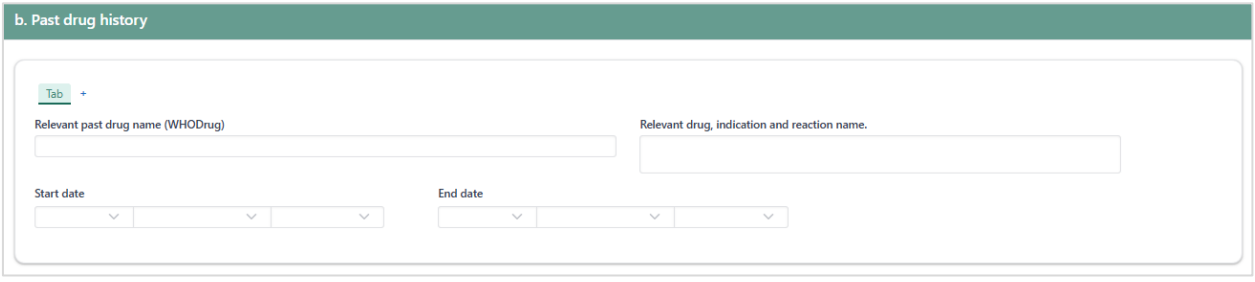
This section of the form covers:



- ***Start date*** – Select the date when the condition began.
- ***Continuing*** – Choose Yes/No/Unknown from the dropdown depending if the 'medical condition' provided is still present at the time of the report or not.
- ***Detailed description*** – Write detail description or any additional information about the 'medical condition' provided.
- ***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.)

b. Past drug history

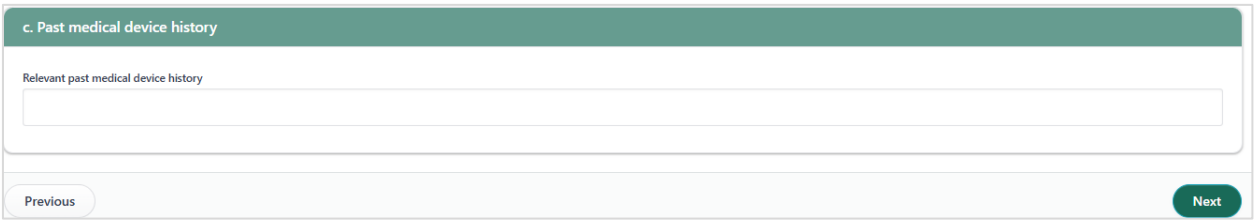
This section of the form covers:



- ***Relevant past drug name (WHO Drug)*** **–** Write the name of the relevant past drug.
- ***Relevant drug, indication and reaction name*** **–** Write the name of the drug, indication and reaction.
- ***Start date*** **–** Select the date when the patient began using the drug.
- ***End date*** **–** Select the date when the patient stopped using the drug.

c. Past medical device history

This section of the form covers:



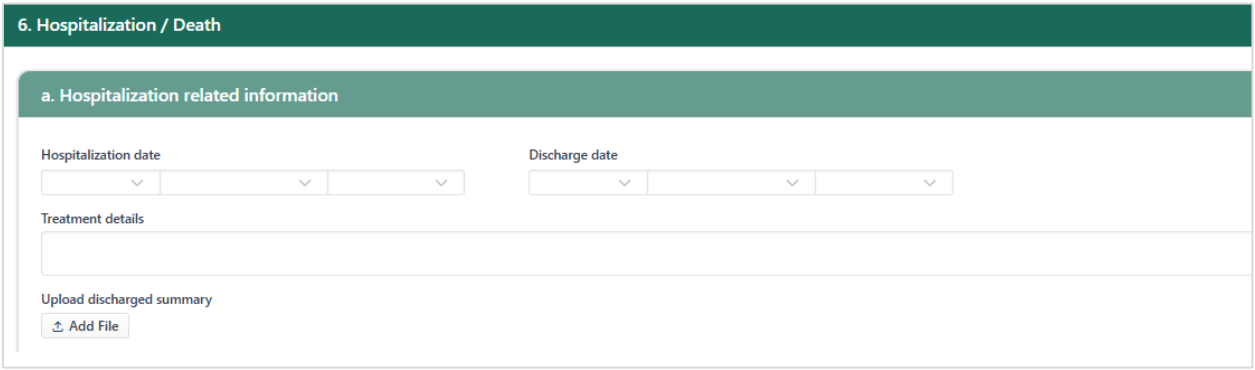
- ***Relevant past medical device history*** **–** Write any relevant past medical device history.

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

6. HOSPITALIZATION/DEATH INFORMATION

a. Hospitalization related information

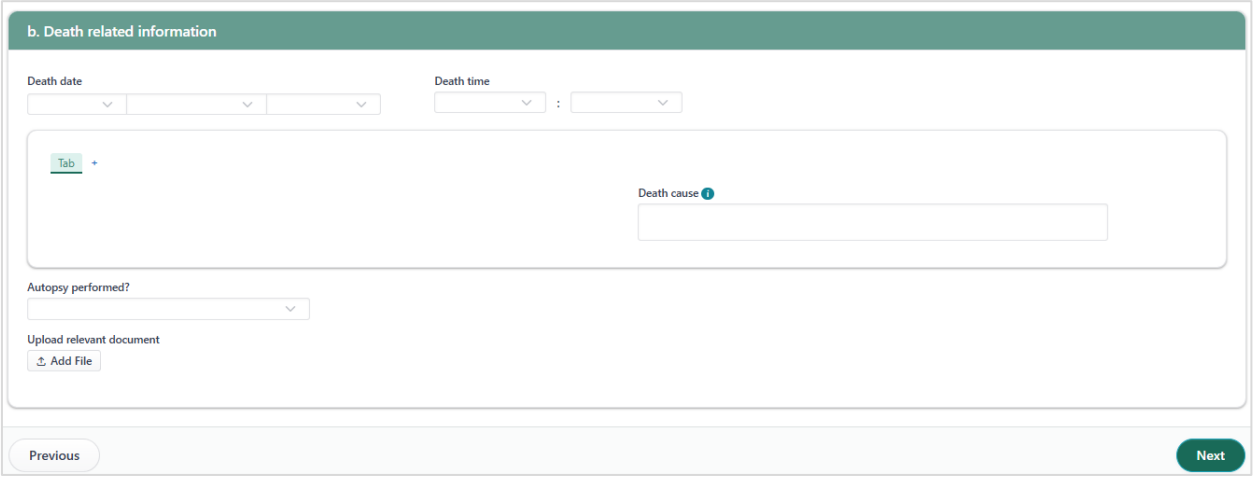
This section of the form covers:



- ***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 (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 MB). Use 'browse' to select the file, then click 'upload' to attach the file or 'close' to exit.

b. Death related information

This section of the form covers:



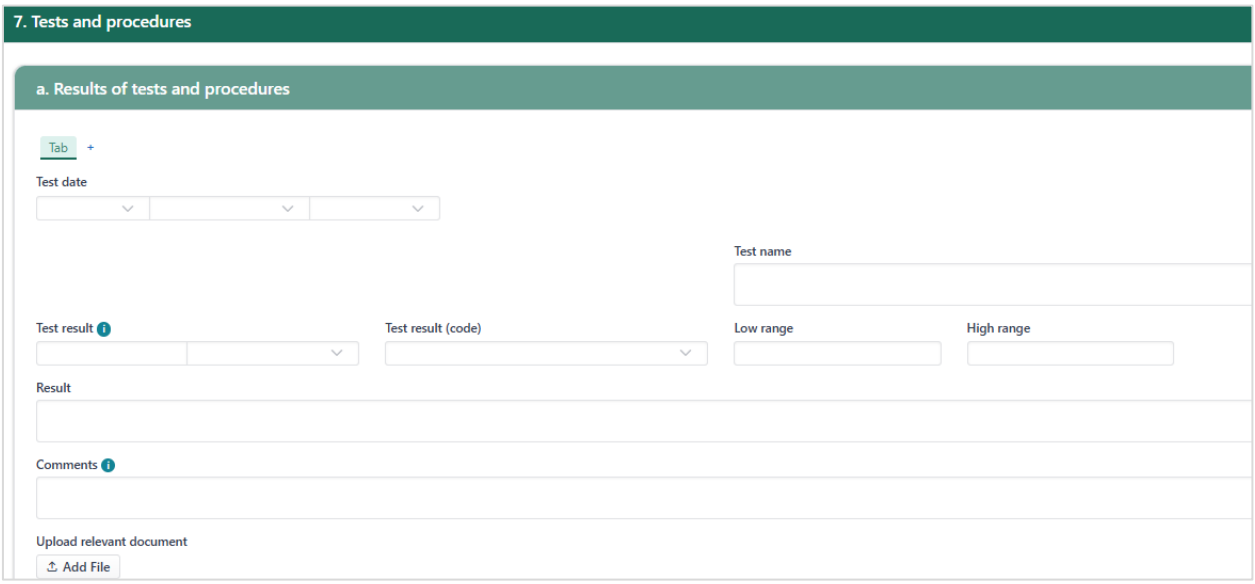
- ***Death date*** – Select the date of death of the patient.
- ***Death time*** – Select the time of death of the patient.
- ***Death cause*** – Write the cause of the death of the patient.
- ***Autopsy performed?*** – Select Yes/No/Unknown from the dropdown depending on whether the autopsy was performed or not or is unknown to the reporter.
- ***Upload relevant document*** – Upload any relevant document (image/video) in JPG/PNG/PDF/MP4 format (max size: 10 MB/25 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:



- ***Test date*** – Select the date of test done for the patient.
- ***Test name*** – Write the name of the test.
- ***Test result and code*** – Write the result of the test in units (as g, g/l, bq). Select the unit from the dropdown. 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. Select the result code of the test from the dropdown- positive/negative/borderline/inconclusive.
- ***Range*** – Mention the low and 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.

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

8. ASSESSMENT

a. Causality Assessment

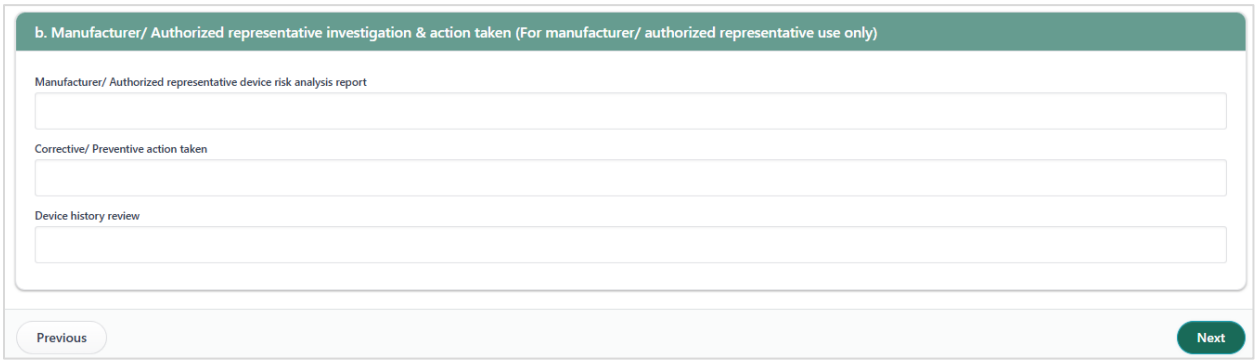
This section of the form covers:

- ***Reporter's comments*** – Reporter can write his comments on the diagnosis, causality assessment or other issues considered relevant.
- ***Sender's 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.
- ***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.

> **Root Cause Analysis:** RCA is a defined process that seeks to explore all of the possible factors associated with an incident by asking what happened, why it happened and what can be done to prevent it from happening again.

b. MAH Investigation & action taken

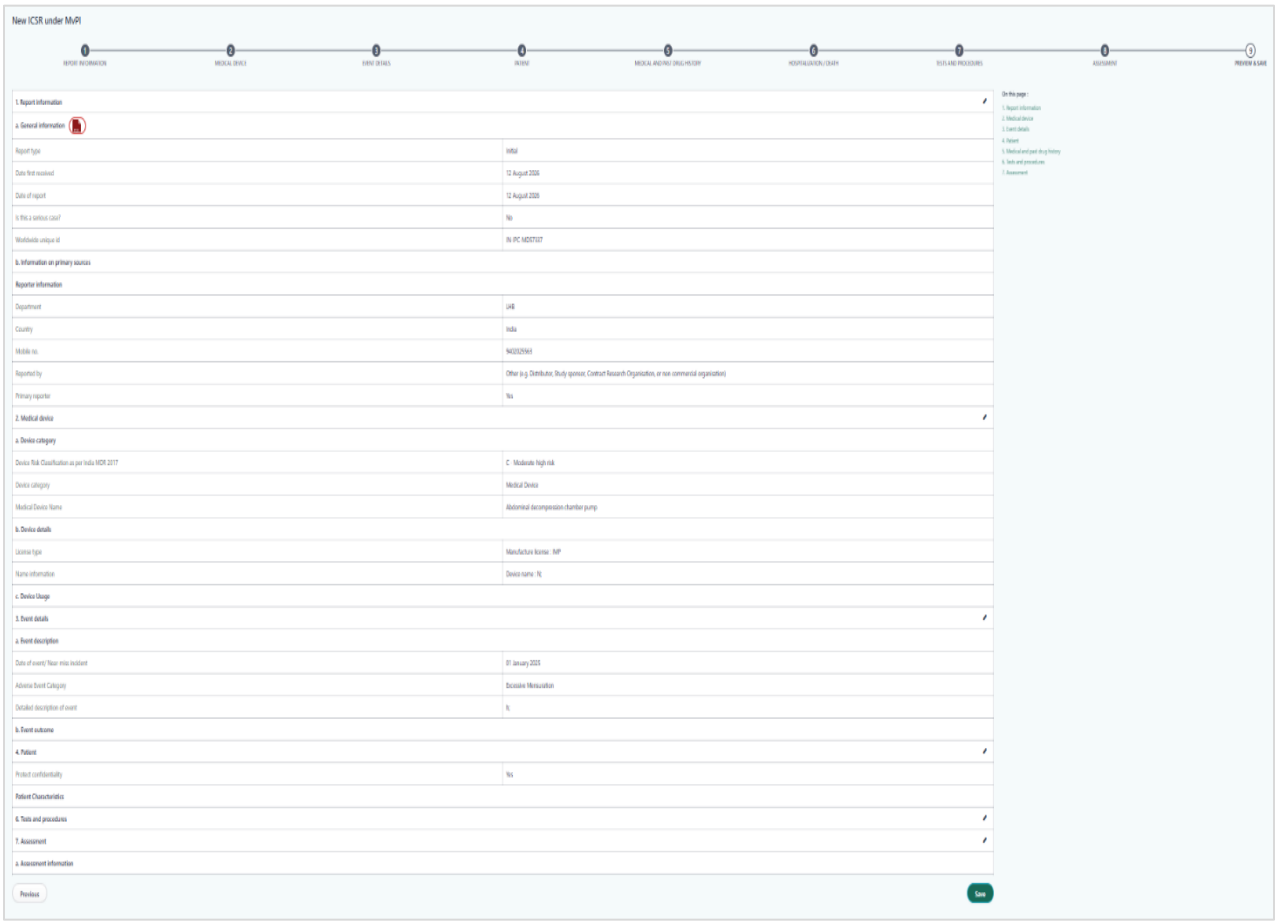
This section of the form covers:



- ***Manufacturer/Authorized representative device risk analysis report*** – MAH 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



Verify and edit the report details in the **Preview** section as required. Once all information has been confirmed, click "**Save**" to submit the MDAE report directly to NCC-MvPI, IPC.

ABBREVIATIONS

Abbreviation	Full Form
ADRMS	Adverse Drug Reactions Monitoring System
GMDN	Global Medical Device Nomenclature
GP	General Practitioner
ICSR	Individual Case Safety Report
IPC	Indian Pharmacopoeia Commission
IPD	Inpatient Department
IVD	In Vitro Diagnostics
MAH	Marketing Authorization Holder
MDAE	Medical Device Adverse Event
MDMC	Medical Device Adverse Event Monitoring Centre
MDR	Medical Devices Rules
MvPI	Materiovigilance Programme of India
NCC-MvPI	National Coordination Centre – Materiovigilance Programme of India
OPD	Out-Patient Department
UDI	Unique Device Identification
UMDNS	Universal Medical Devices Nomenclature System