Adverse Drug Reactions Monitoring System (ADRMS) User Manual

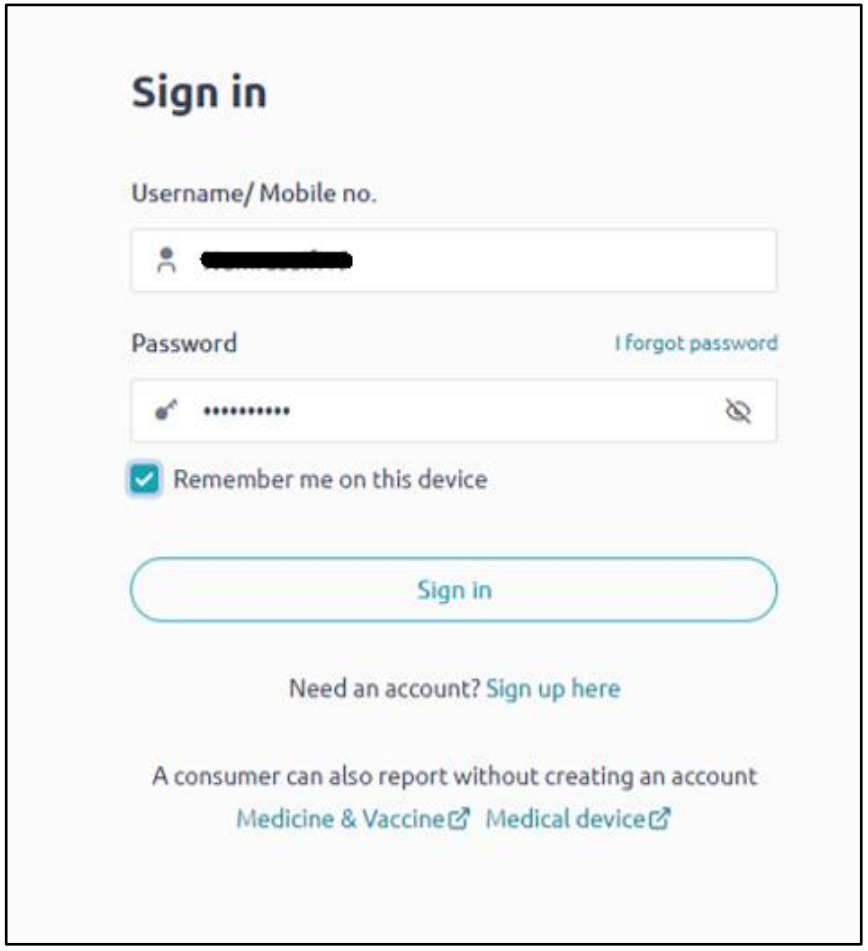
URL: https://adrmsipc.in/adrms/index.html

How to report Medical Device Adverse Event?

Programme Coordinator

Index

How to Sign In?

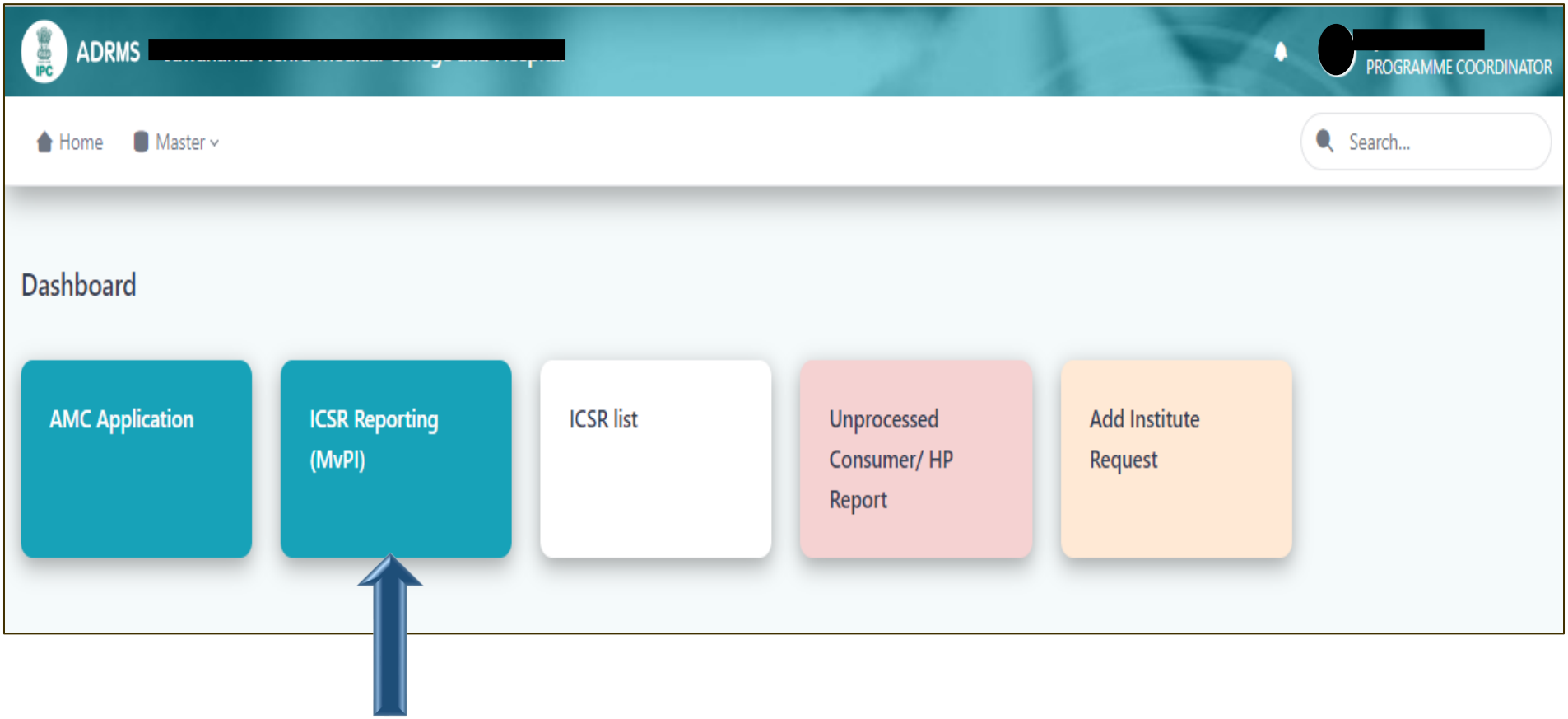


Enter Username/Mobile No.

Enter Password

Click on 'Sign in'

Reporting MDAE
Programme Coordinator Dashboard

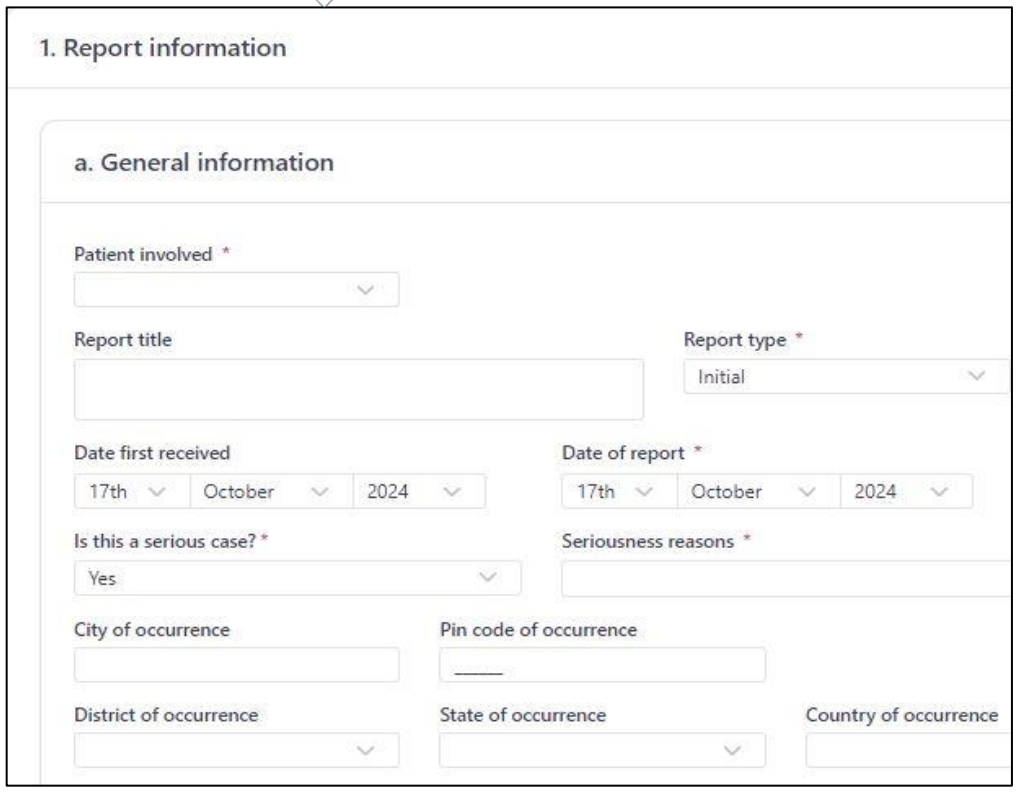


Click Here to report Medical Device Adverse Event (MDAE)

Reporting MDAE contd.

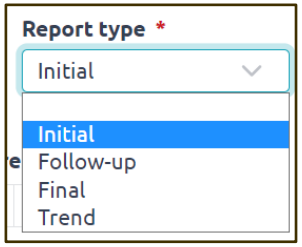
Report Information

a. General information



This Section of the form Covers

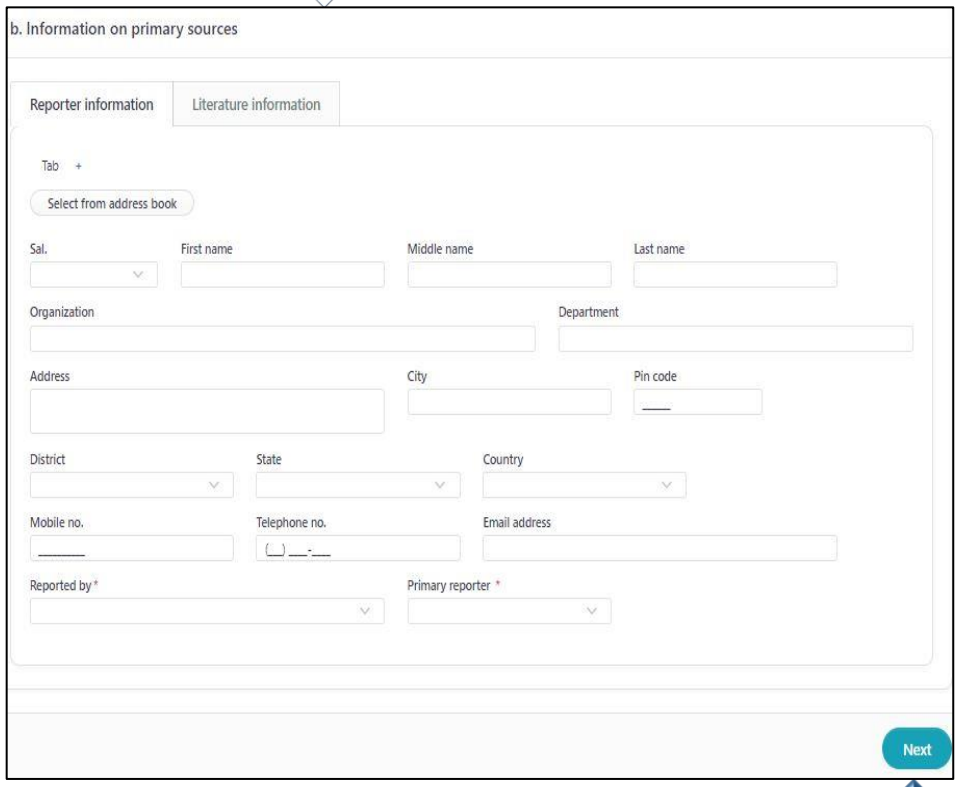
- **Report Type**
- **Date of Report**
- **Seriousness Criteria**



Reporting MDAE contd.

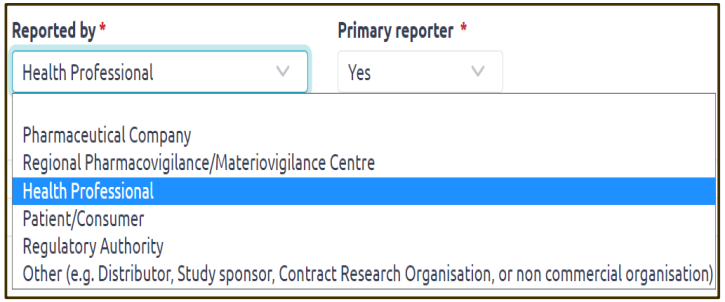
Reporter Information

b. Information on primary sources



This Section of the form Covers the reporter details

- **Name of Reporter**
- **Address of the Reporter**

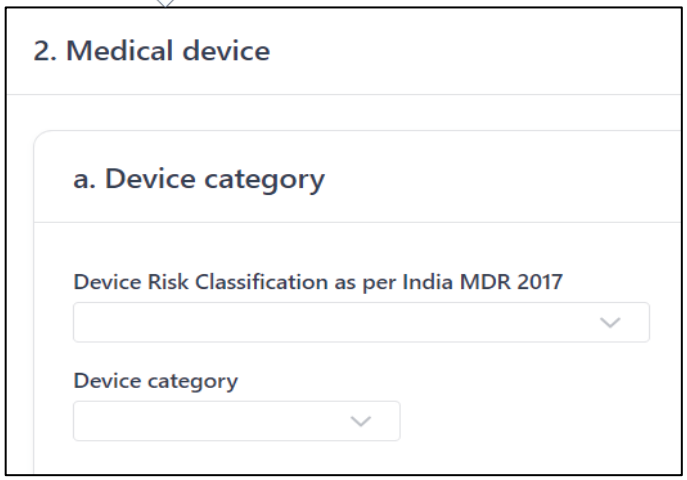


Click "Next" → for the Next Page

Reporting MDAE contd.

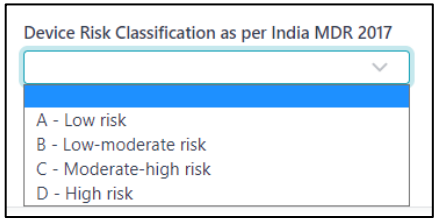
Medical Device Information

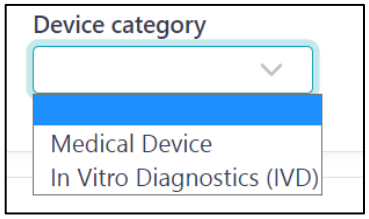
a. Device category



This Section of the form Covers the medical device details

- **Device Category**
- **Device Classification**

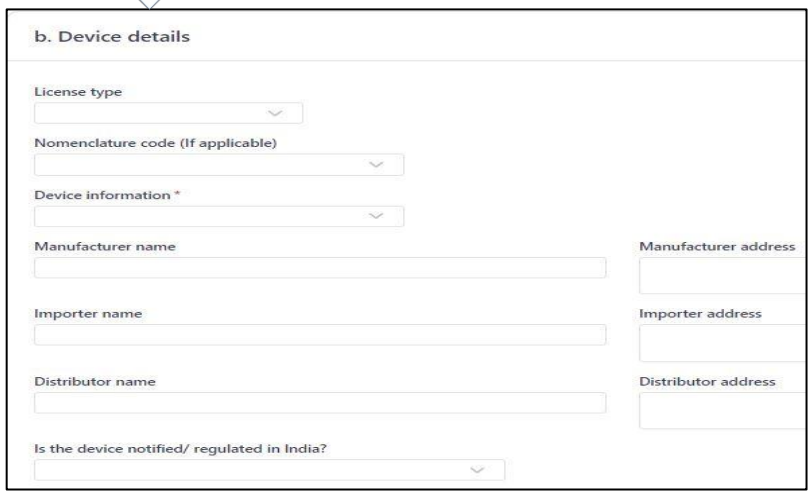




Reporting MDAE contd.

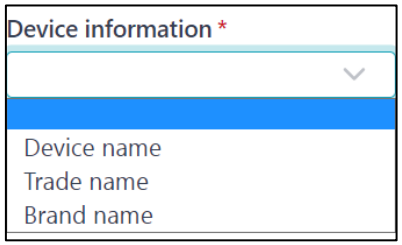
Medical Device Information

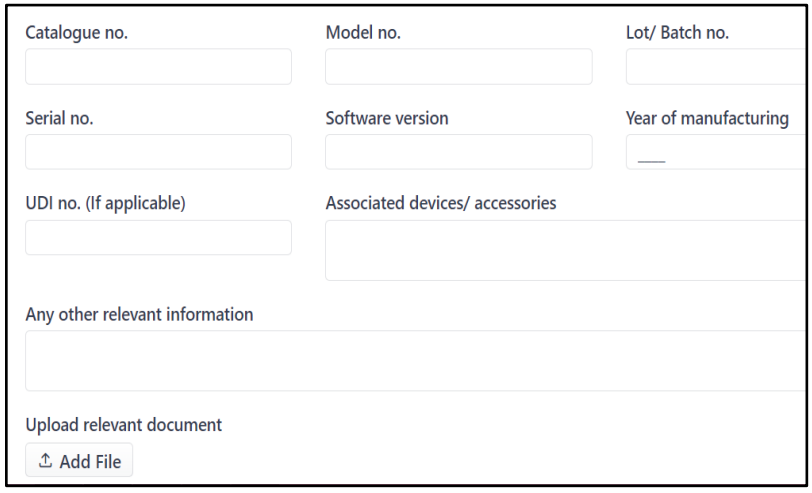
b. Device details



This Section of the form Covers the device information

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





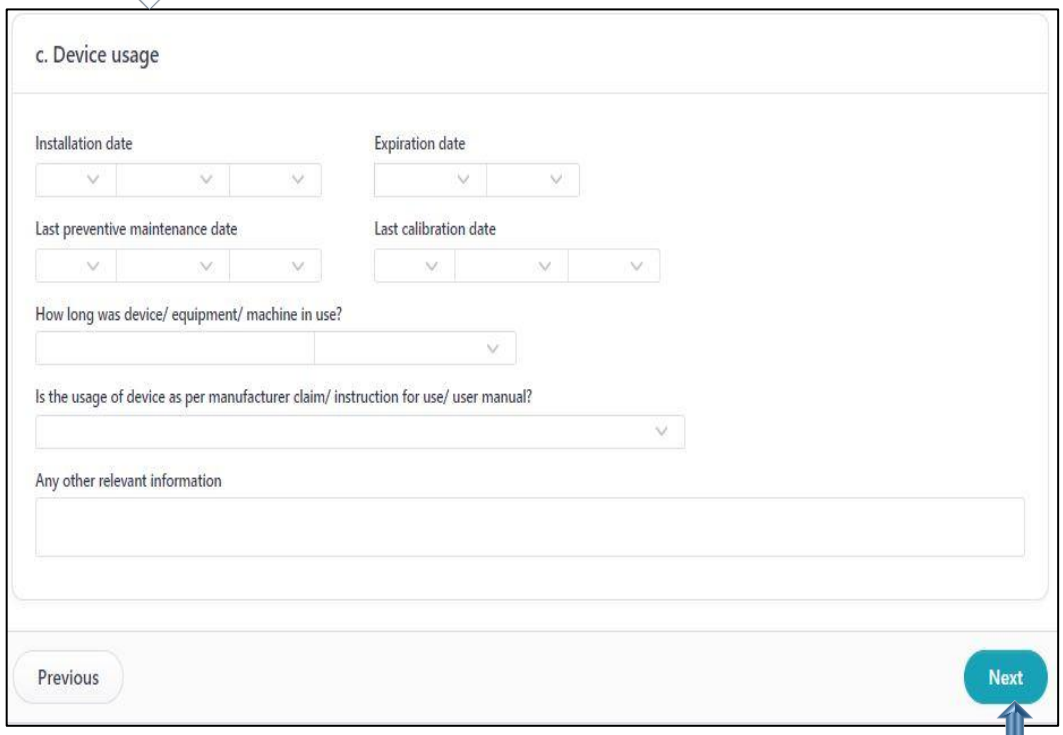
This Section of the form Covers the device information

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

Reporting MDAE contd.

Medical Device Information

c. Device usage



This Section of the form Covers the device information

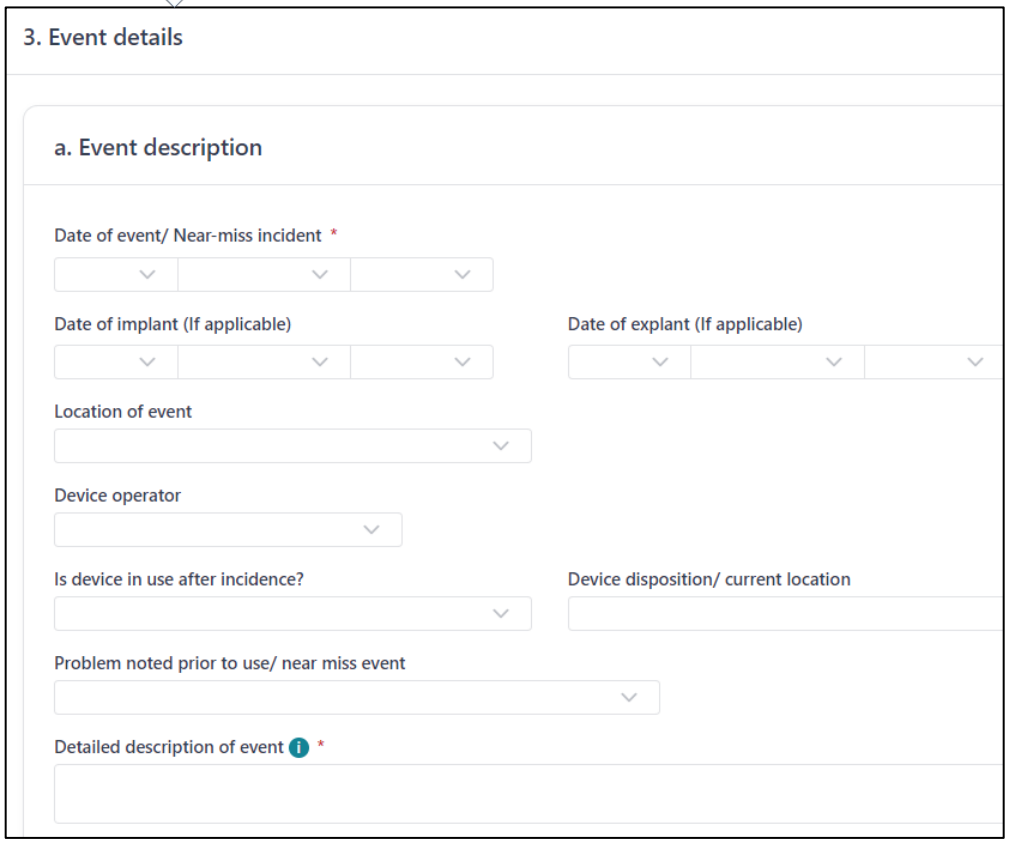
- **Installation Date**
- **Expiration Date**
- **Last Preventive Maintenance Date**
- **Last Calibration Date**

Click "Next" → for the Next Page

Reporting MDAE contd.

Event Information

a. Event description



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

This Section of the form covers event outcome

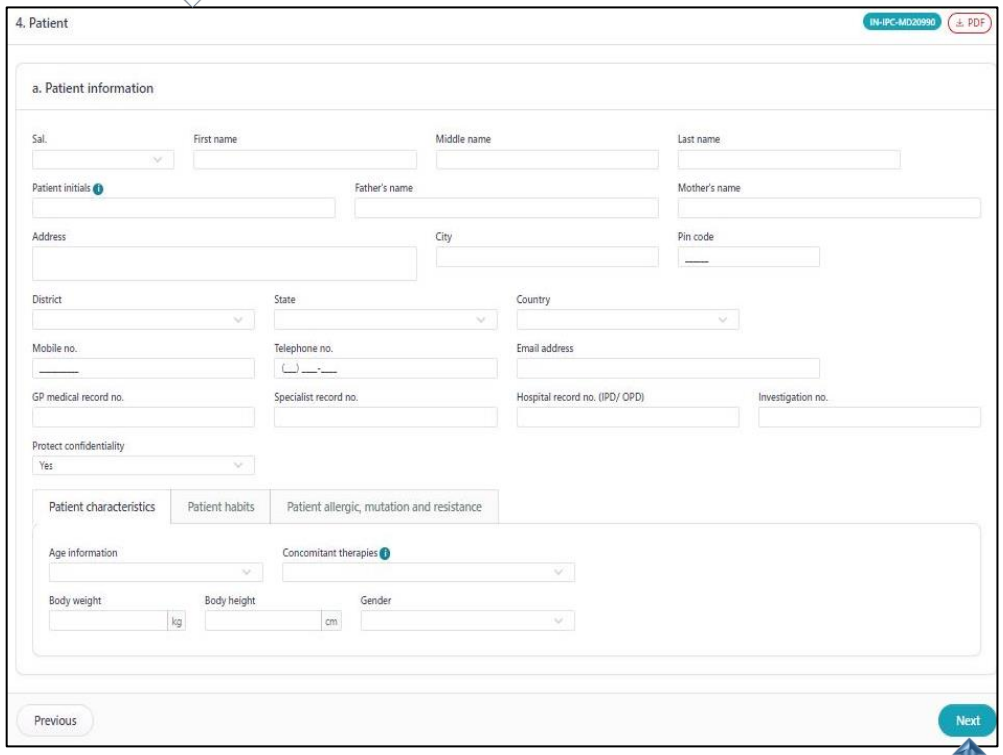
- **Patient outcome**
- **Any other relevant information**

Click "Next" → for the Next Page

Reporting MDAE contd.

Patient Details

a. Patient information



This section of the form covers Patient details

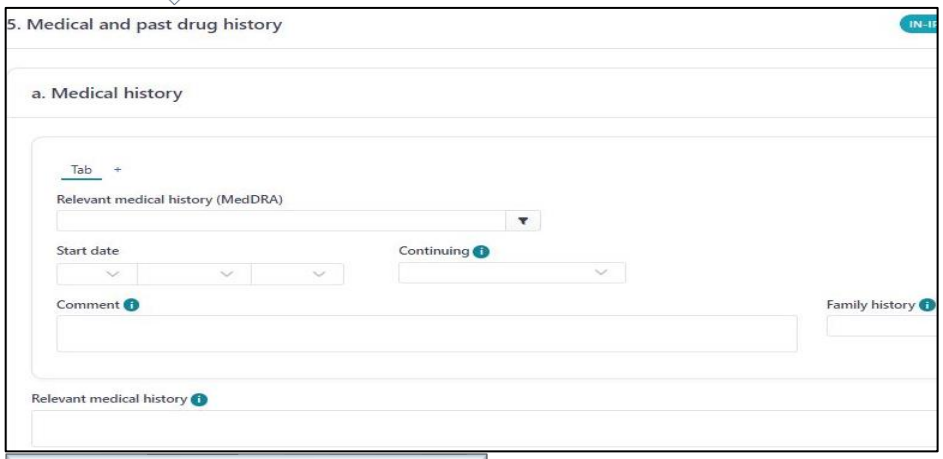
- **Patient Name**
- **Patient Address**
- **Mobile no. of the patient**

Click "Next" → for the Next Page

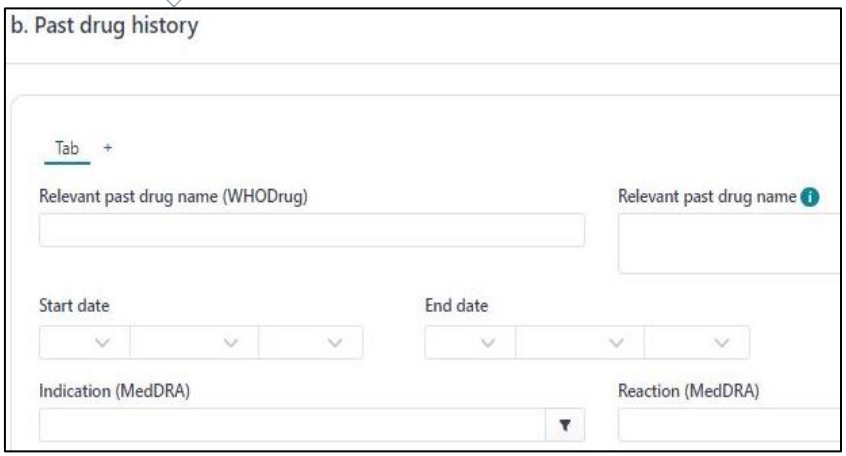
Reporting MDAE contd.

Medical and Past drug history

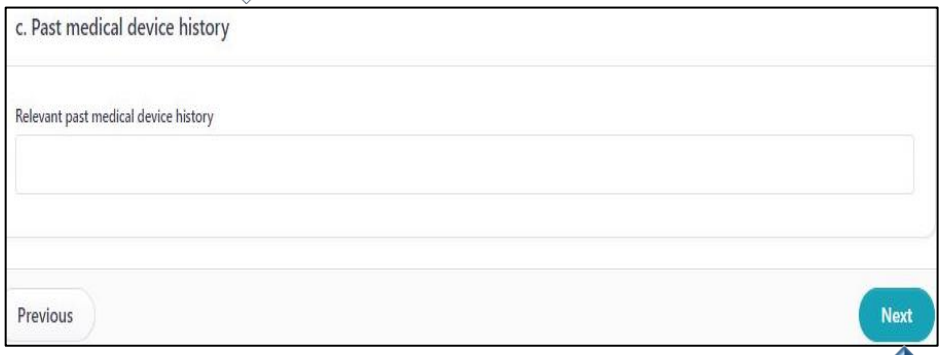
a. Medical history



b. Past drug history



c. Past medical device history



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

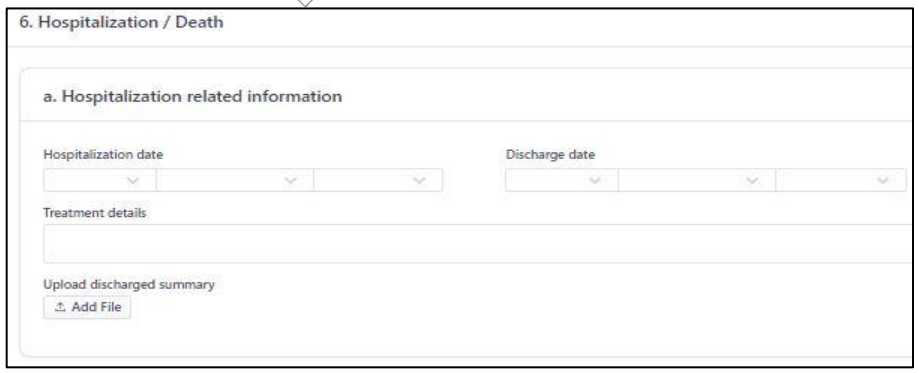
- **Medical history of patient**
- **Past drug history of patient**
- **Past medical device history of patient**

Click "Next" → for the Next Page

Reporting MDAE contd.

Hospitalization/ Death Information

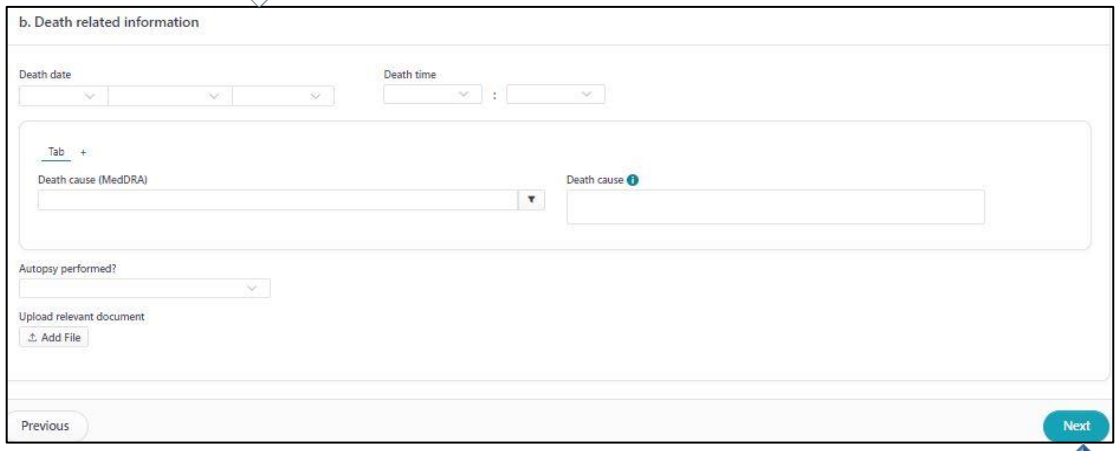
a. Hospitalization related information



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

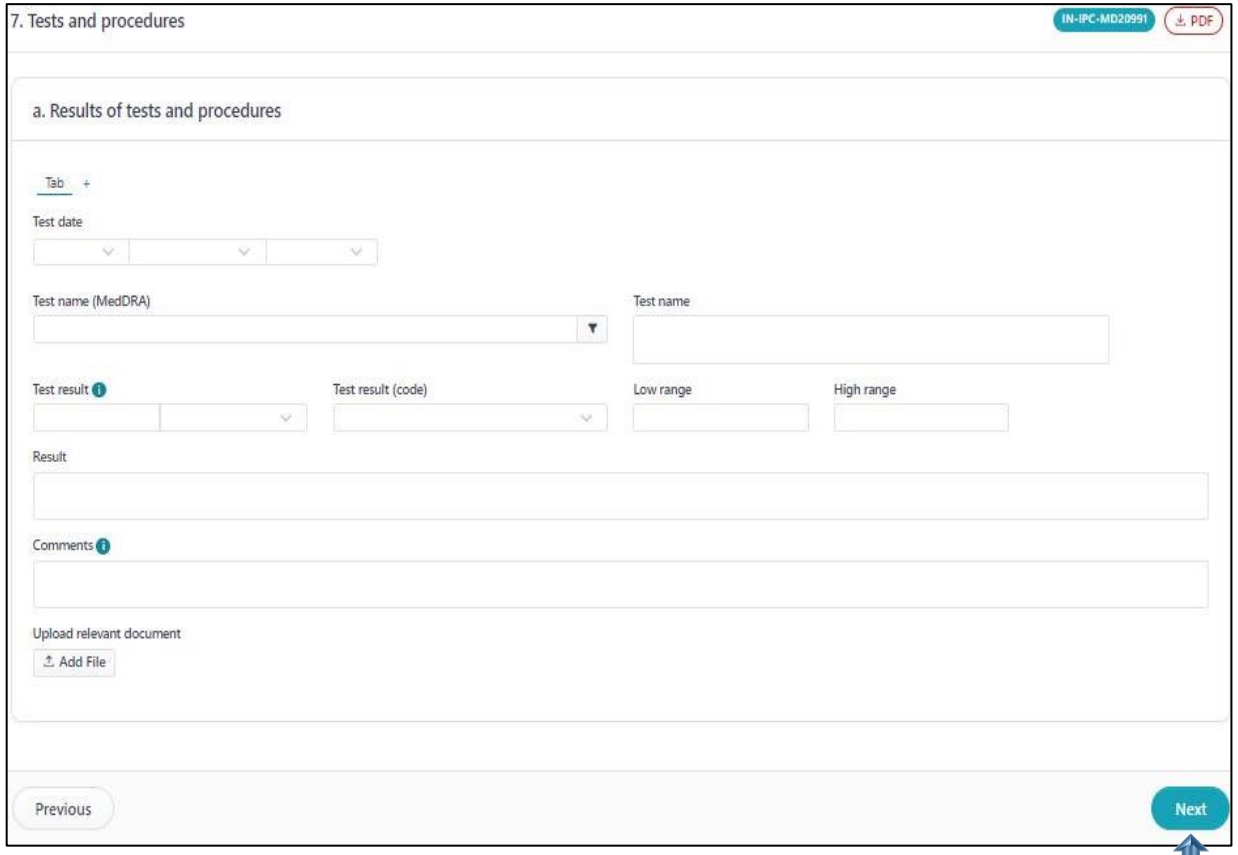


Click "Next" for the Next Page

Reporting MDAE contd.

Tests and Procedures

a. Results of tests and procedures



This section of the form covers test and procedures related information

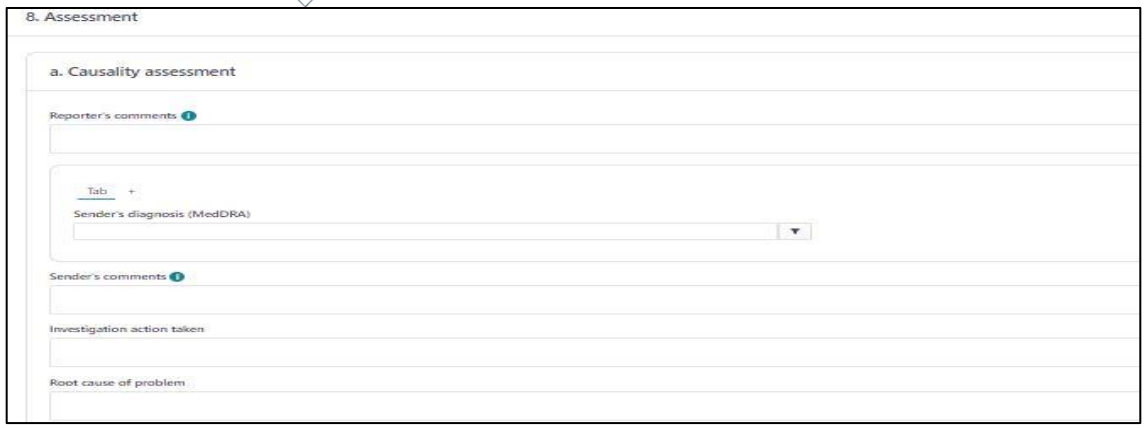
- **Test date**
- **Test name**
- **Test result**

Click "Next" → for the Next Page

Reporting MDAE contd.

Assessment

a. Causality assessment



b. Investigation & action taken

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

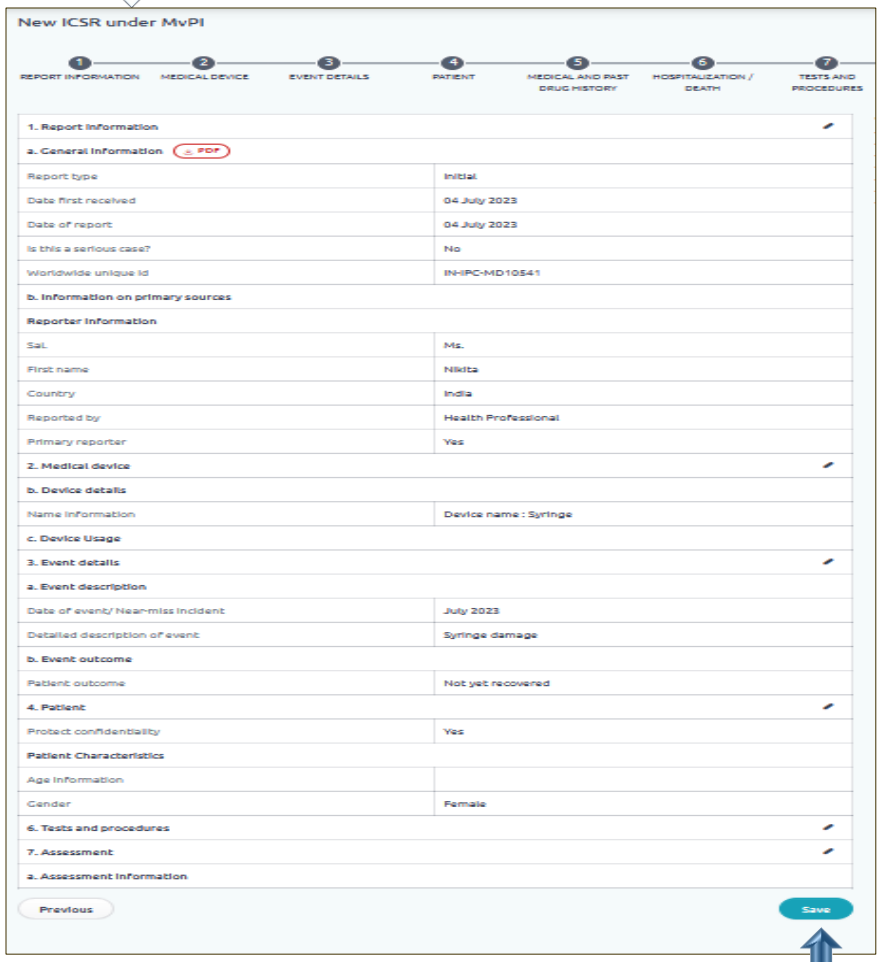
- **Causality assessment**
- **Manufacturer/ Authorized representative investigation & action taken**

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