



PVIMS USER MANUAL

Version # 1.3

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www.pv.dgda.gov.bd



USAID
FROM THE AMERICAN PEOPLE

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CHAPTER 01: INTRODUCTION

Background

Funded by the U.S. Agency for International Development (USAID), the Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, implemented by Management Sciences for Health with a consortium of partners, provides pharmaceutical system strengthening assistance for sustained of 6 improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage.

The goal of the global, five-year (2018–2023) program is to enable low- and middle-income countries to strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and medicine-related pharmaceutical services. To achieve this goal, the MTAPS program has the following objectives:

- Strengthening pharmaceutical sector governance
- Increase institutional and human resource capacity for pharmaceutical management and services, including regulation of medical products
- Improve availability and use of pharmaceutical information for decision making and advance global learning agenda
- Optimize pharmaceutical sector financing, including resource allocation and Use
- Enhance pharmaceutical services, including product availability and patient centered care to achieve desired health outcomes

The USAID Mission in Bangladesh has provided funding to the MTaPS to continue the work that begun under the predecessor program, Systems for Improved Access to Pharmaceuticals and Services (SIAPS) to strengthen the Ministry of Health and Family Welfare (MOHFW) and its key directorates, i.e., Directorate General of Health Services (DGHS), Directorate General of Family Planning (DGFP), and Directorate General of Drug Administration (DGDA). MTaPS has been supporting DGDA in the following regulatory functions: Registration and Marketing Authorization, Licensing Establishment, Regulatory Inspection, and Pharmacovigilance (PV).

User's of this document

- HealthCare facilities
- Public Health professionals
- Marketing Authorization Holder
- Consumers

About PViMS

PViMS, or the Pharmacovigilance Monitoring System, is a web-based application used to monitor the safety of medicines. The application was developed by the USAID-funded Systems for Improved Access to Pharmaceuticals and Services [SIAPS] program (2011-2018) and is implemented by the USAID-funded Medicines, Technologies, and Pharmaceutical Services [MTaPS] program (2018-2023), both led by Management Sciences for Health (MSH), a global health nonprofit. PViMS is maintained by MSH.

[JBRSOFT](#), a leading software development company in Bangladesh, has been working closely with the Directorate General of Drug Administration and the MSH MTAps team to customize the PViMS for the country context, build the Microservice for dashboard, case management and reporting, and provide technical support to users.

Quick access links

Areas of portal	Links
Data entry panel	http://pv.dgda.gov.bd/
User personal portal	https://pvimsdashboard.com/my/portal/login
User manual	https://pvimsdashboard.com/user/guideline
Video tutorials	https://pvimsdashboard.com/admin/video/tutorials
Admin panel	https://pvimsdashboard.com
Live support panel	https://pvimsdashboard.com/support

CHAPTER 02: YELLOW-CARD ACCESS

Visit the DGDA website (<http://dgda.gov.bd>) or PViMS website (<https://pv.dgda.gov.bd>) to submit new case information using the Yellow-card.

You can find ‘Adverse Drug Reaction Reporting’ menu under the Pharmacovigilance Menu. The routing paths are given below:

DGDA website (<http://dgda.gov.bd>) >> Pharmacovigilance >> Online Reporting System >> Adverse Drug Reaction Reporting.

The landing page for the PViMS can be accessed by clicking this link as follows:

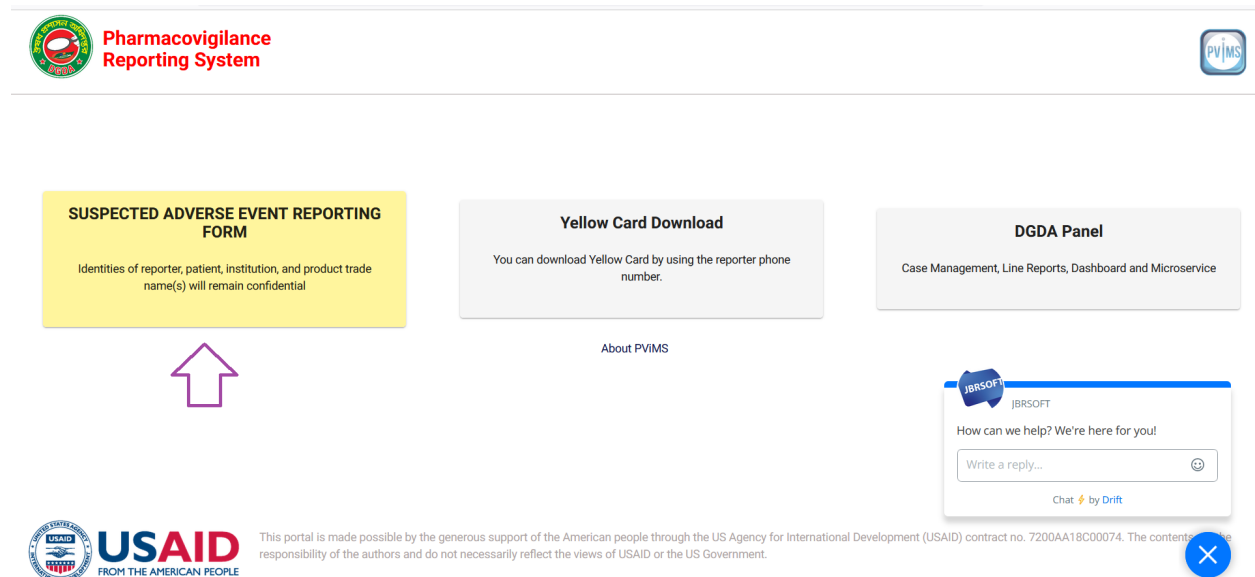


Figure 1: PViMS landing page

You must now click on the Yellow-card box to begin entering data.

CHAPTER 03: YELLOW CARD

The DGDA Yellow Card has been converted into an electronic format. It now consists of four main sections: patient information, suspected adverse event details, suspected drug/vaccine information, and reporter information.

The screenshot shows the 'Yellow Card' data entry form, which is organized into six numbered sections:

- General Instructions:** A dropdown menu containing instructions for completing the form, such as 'Detailed information about each field can be found in the instructions available in the DGDA website (www.dgda.gov.bd)' and 'Fill in as much information as possible. Do not leave anything blank. If unknown, write "unknown" or "N/A" if not applicable.'
- A. PATIENT INFORMATION:** Fields for Name/Initial, Contact Number, Patient Weight (KG), Age (Year, Month, Days), Gender, Pregnant Status, Division, District, Upazila, and Union. Includes a field for Post Office/Village/Road/House information.
- B. SUSPECTED ADVERSE EVENT INFORMATION:** Fields for Type of event, Description, Start/Stopped dates, Whether treated, Action taken after reaction, Event information, Did reaction reappear, Seriousness of the event, Outcomes attributed to the event, and Other relevant history.
- C. SUSPECTED DRUG/VACCINE INFORMATION:** Fields for Brand/Trade name, Generic Name with strength, Indication, Medication Start/End dates, Dosage Form, Frequency (Daily Dose), Batch/Lot number, Manufacturer, and Diluent information. Includes a section for concomitant medicine/vaccine information.
- D. REPORTER INFORMATION:** Fields for Source of reporting, Reporting Type, Initial Report ID, Reporter Name, Post Office/Village/Road/House information, Other information (Email Address, Mobile phone, Occupation), and Date of report submission (1/9/2024) and Organization.
- Submission:** 'Submit Report' and 'Cancel' buttons at the bottom.

 This portal is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200A18C00074. The contents are the responsibility of the authors and do not necessarily reflect the views of USAID or the US Government.

Figure 2: Yellow card single page data entry form

3.1 USER INSTRUCTIONS

You can find the user instructions in this section. It will also help you to explore all user's guidelines.

3.2 SELECT ADVERSE REPORT

Please click on the mandatory field named "Select Adverse Report for**" option. Select from the option as

- Drug or
- Vaccine



Figure 3: Selection of adverse event report

3.3 PATIENT INFORMATION (SECTION A)

You need to fill-out the following information:

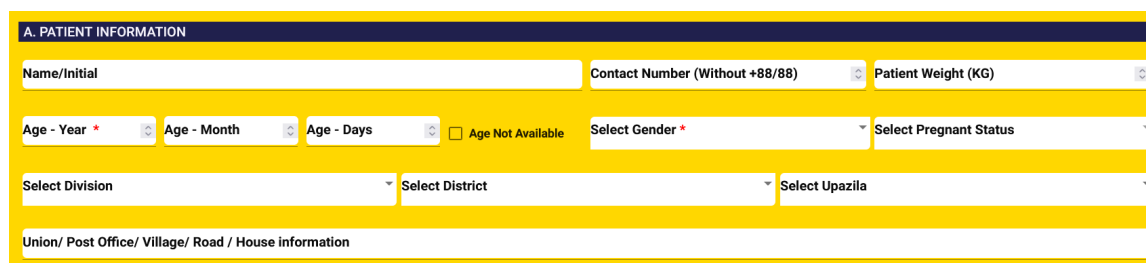


Figure 4: Yellow card patient information

- **Name/Initial:** Enter the patient's full name. It is not mandatory.
- **Contact Number:** Enter the phone number. It is not mandatory.
- **Age*:** Enter patient age as Year, Month and Day.
- **Weight:** Enter weight in KG. It is not mandatory.
- **Gender*:** Select gender. If you select gender as Female then another dropdown will appear with status. Please select pregnancy status.
- **Division:** Select division.
- **District:** List of districts will appear under this dropdown and select district.
- **Upazila:** List of Upazila/Thana will appear under this dropdown and Select Upazila/Thana.
- **Street address:** Enter Union/Post Office/Village/ Road/ House information.

Notes: * refers to mandatory fields

3.4 SUSPECTED ADVERSE EVENT INFORMATION (SECTION B)

B. SUSPECTED ADVERSE EVENT INFORMATION

Type of event *
Others

If others, Please Specify *

Describe event including relevant tests and laboratory results *

Event Start date * N/A

Event Stopped date * N/A

Was the adverse event treated?
Yes

If Yes, Please Specify *

Action taken after reaction
Dose reduced

Did reaction subside after stopping / reducing the dose of the suspected product?
No

Event information
Others

If others, Please Specify *

Did reaction appear after reintroducing the suspected product?
No

Seriousness of the adverse event
Serious

If serious, please select *

Outcomes attributed to the adverse event *
Fatal/ Death

If fatal, please select date of death *

Other relevant history: (pre-existing medical history)
Others (Please specify)

If others, Please Specify *

Figure 5: Yellow card suspected adverse event information

- **Type of events***: Select type of events (Multiple selection is allowed)
 - Adverse drug reaction
 - Adverse event following immunization
 - Medication error
 - Vaccination error
 - Product quality problem
 - Others
- **If other, please specify***: If you select Others, a new mandatory text field named “If other, please specify” will be visible.
- **Describe event including relevant tests and laboratory results***: You can provide the relevant information here.
- **Event start date***: Select event start date
- **Event stop date***: Select event stop date
- **Was the adverse event treated?** Select Yes/No/Not available
- **If yes, please specify***: If you select Yes, please enter the details.
- **Action taken after reaction**: Please select one action from the dropdown list.
 - Dosed stopped
 - Dose reduced
 - No action taken
 - Not available
- **Did reaction subside after stopping / reducing the dose of the suspected product?** Select Yes/No/Not applicable/Unknown
- **Event Information**:
 - Fever
 - Muscle pain
 - Headache

- Nausea
- Vomiting
- Coughing
- Breathing difficulty
- Back pain
- Joint pain
- Abscess
- Insomnia
- High BP
- Low BP
- Increased heart rate
- Heart failure
- Myocardial Infarction
- Anaphylaxis
- Unconscious
- Others
- **If Others, please specify*:** If you select Others, a new mandatory text field named “If other, please specify” will be visible.
- **Did reaction appear after reintroducing the suspected product?** Select Yes/No/Not applicable
- **Seriousness:** Select Seriousness of the adverse event.
- **If serious, please specify*:** Multiple selection.
 - Not Serious
 - Hospitalization or prolongation of hospitalization
 - Disability or permanent damage
 - Congenital anomaly / birth defect
 - Life threatening
 - Death
 - Other Medically important
- **Outcomes attributed to the adverse event*:** Select outcome.
- **If fatal, please select date of death*:** If you select Fatal/Death, a new mandatory text field named “If fatal, please select date of death” will be visible.
- **Other relevant history: (pre-existing medical history):** Please select from multiple selection.
 - Hypersensitivity
 - Allergies
 - Hypertension
 - Liver or kidney problems
 - Smoking
 - Alcohol
 - Diabetes
 - Others (Please specify):
- **If Others, please specify*:** If you select Others, a new mandatory text field named “If other, please specify” will be visible.

3.5 SUSPECTED DRUG/VACCINE INFORMATION (SECTION C)

C. SUSPECTED DRUG/VACCINE INFORMATION

Brand/Trade name Generic Name with strength * Indication

Medication Start Date/Vaccination Date * N/A End Date/Vaccination Time * N/A Dosage Form Frequency (Daily Dose)

Batch/Lot number Manufacturer Diluent Information for vaccine

CONCOMITANT MEDICINE/VACCINE INFORMATION MEDICINE/VACCINE Not Available

Brand/ Trade Name * Generic Name * Dosage Form * Indication * Strength & Frequency * Add

Figure 6: Yellow card suspected drug/vaccine information

- **Brand/Trade name:** Enter the Brand/Trade name. Example: Napa
- **Generic name with strength*:** Enter the Generic name with strength. Example: Paracetamol 500 mg
- **Indication:** Enter the Indication. Example: Fever, Mild to moderate pain
- **Medication Start Date / Vaccination Date*:** Select the date from the calendar
- **Medication End Date/ Vaccination Time*:** Select the date from the calendar
- **Dosage Form:** Enter the Dosage Form. Example: Child: 2-4 months 60 mg as a single dose. May give a 2nd dose after 4-6 hours if needed. Max: 4 doses daily
- **Frequency (Daily Dose):** Enter the Daily Dose. Example: TDS, 1+0+1 etc
- **Batch/ Lot number:** Enter the batch or lot number
- **Manufacturer:** Enter the Manufacturer information
- **Diluent Information for vaccine:** Enter the Diluent Information for vaccine

3.6 CONCOMITANT MEDICINE/VACCINE INFORMATION

CONCOMITANT MEDICINE/VACCINE INFORMATION MEDICINE/VACCINE Not Available

Brand/ Trade Name * Generic Name * Dosage Form * Indication * Strength & Frequency * Add

Figure 7: Yellow card concomitant medicine/vaccine information

- **Brand/Trade Name*:** Enter the Brand/Trade name.
- **Generic Name*:** Enter the Generic Name.
- **Indication*:** Enter the Indication.
- **Dosage Form*:** Enter the Dosage Form.
- **Strength & Frequency*:** Enter the Strength & Frequency.

3.7 REPORTER INFORMATION (SECTION D)

Figure 8: Yellow card reporter information

- **Source of reporting***: Select the reporting source
- **Reporting type***: Enter the reporting type.
- **Initial report ID**: Enter previously submitted case ID.
- **Reporter Name***: Enter the reporter name.
- **Reporter address***: Enter the reporter address.
- **Reporter Email**: Enter the reporter email address.
- **Reporter Phone***: Enter the reporter's phone number.
- **Reporter Occupation***: Enter the reporter occupation.
- **Report submission date***: Select the submission date.
- **Organization/ Company***: Enter the facility/ company or organization information. It will populate following the source of reporting.
- **If other***: If you don't find your organization, you can select the "Other" option and specify your organization/ company name.

3.8 REPORT SUBMISSION

Figure 9: Yellow card report submission

Finally, click on the Submit Report button and submit it. An alert will appear before Submit.

Alert text: *The information provided here are true to the best of my knowledge.*

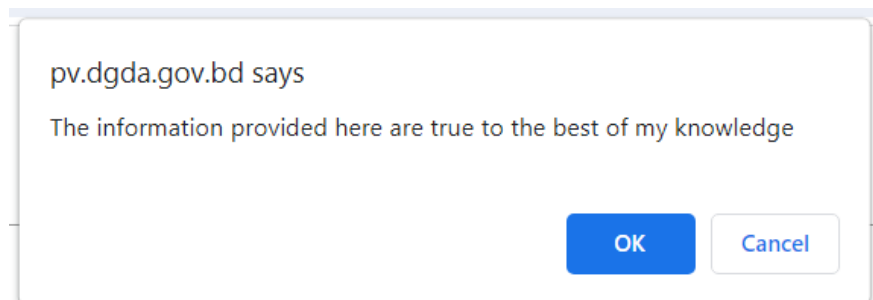


Figure 10: Yellow card pre-alert

Once it is successfully submitted the following unique registration number will be generated:

3.9 YELLOW-CARD GENERATE AND DOWNLOAD PROCESS

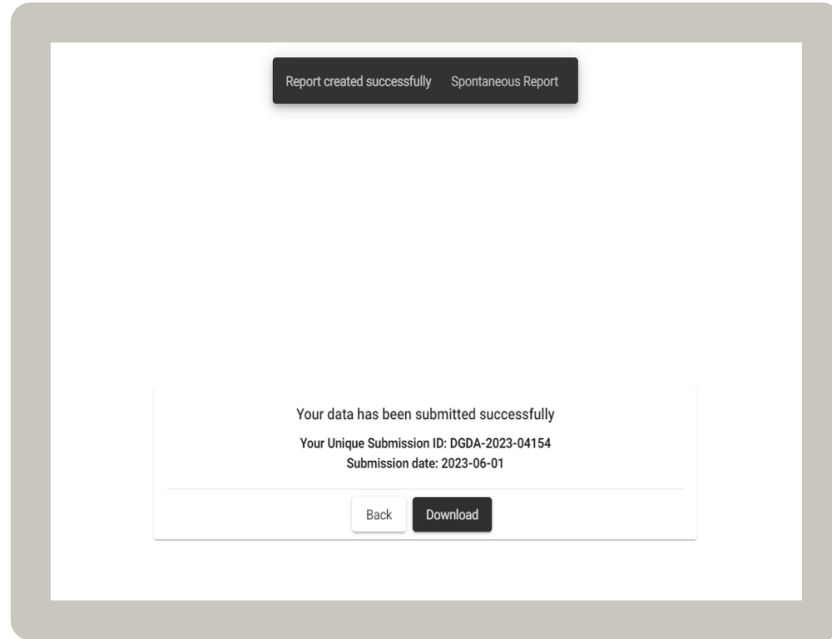


Figure 11: Yellow card case submission confirmation

Once it is successfully submitted the yellow card from the front end then it is stored in PViMS back end. You can easily generate and download the yellow card from the Spontaneous report any time.

CHAPTER-04: YELLOW CARD ACCESS AND DOWNLOAD

4.1 Current case status observations

Any user's or marketing authorization holders can see the current status of their submitted case. It is accessible from the following panel: <https://pvimsdashboard.com/report/status>.

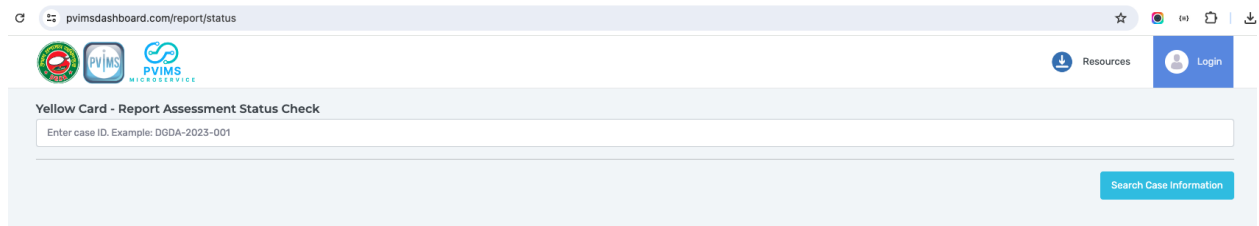


Figure 12: Case status checking panel

It requires Case-ID which was generated during a case submission. Once you enter a case information, you can see the following result.

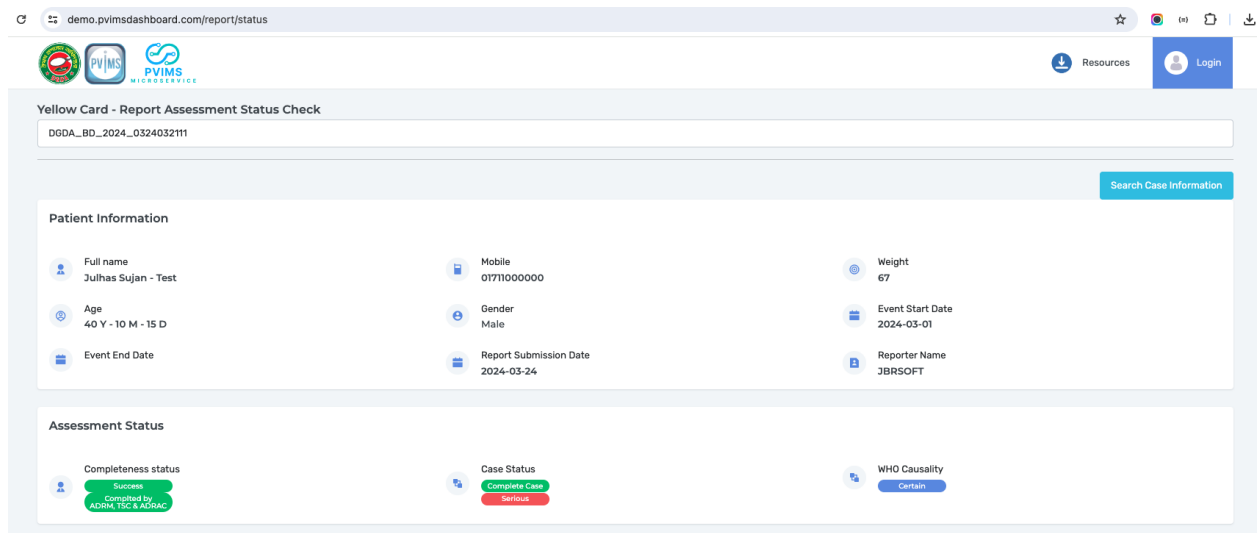


Figure 13: Case information (Test case)

4.2 Yellow Card Access and Download by Reporters (User's portal)

On the Microservice, a user's portal has been developed. Any of the data entry people can login into the portal and access their previously entered all reports. Link: <https://pvimsdashboard.com/my/portal/login>.

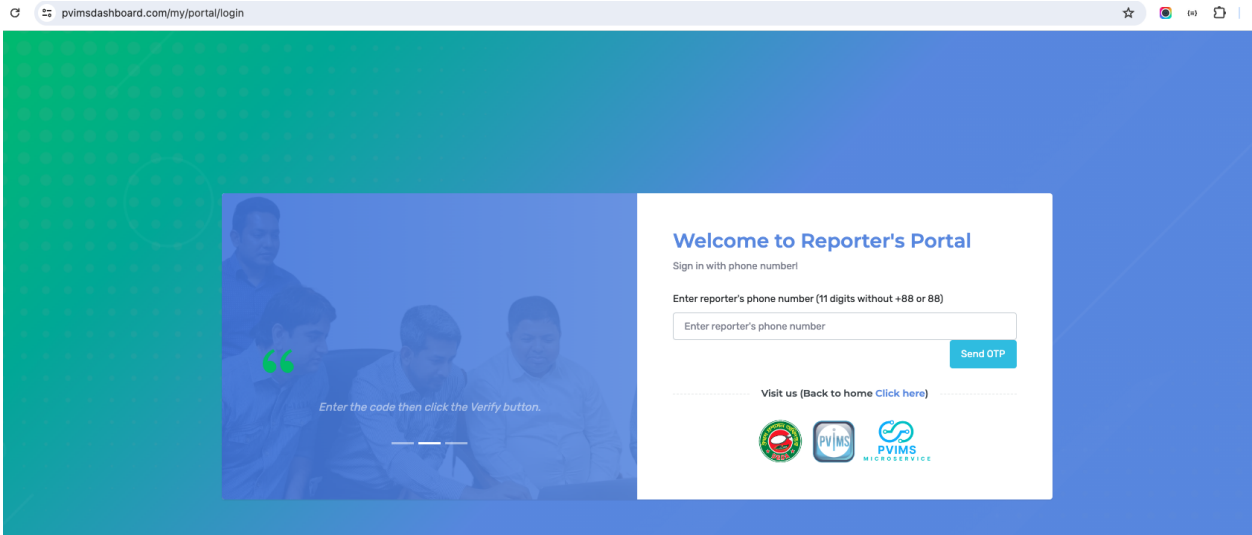


Figure 14: Reporter's panel

Step-1: Reporter's required to enter their phone number for its verification purposes. This panel will send an OTP (6 digits One Time Password) to their phone number.

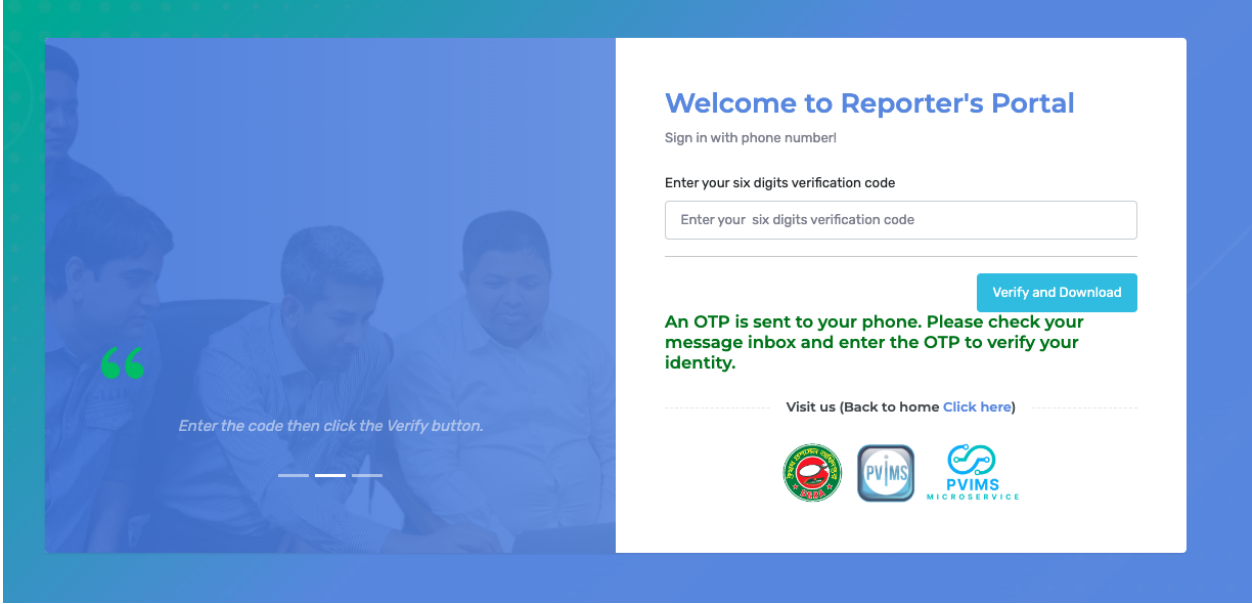


Figure 15: OTP verification

Once you enter wrong OTP, it will show the following message:

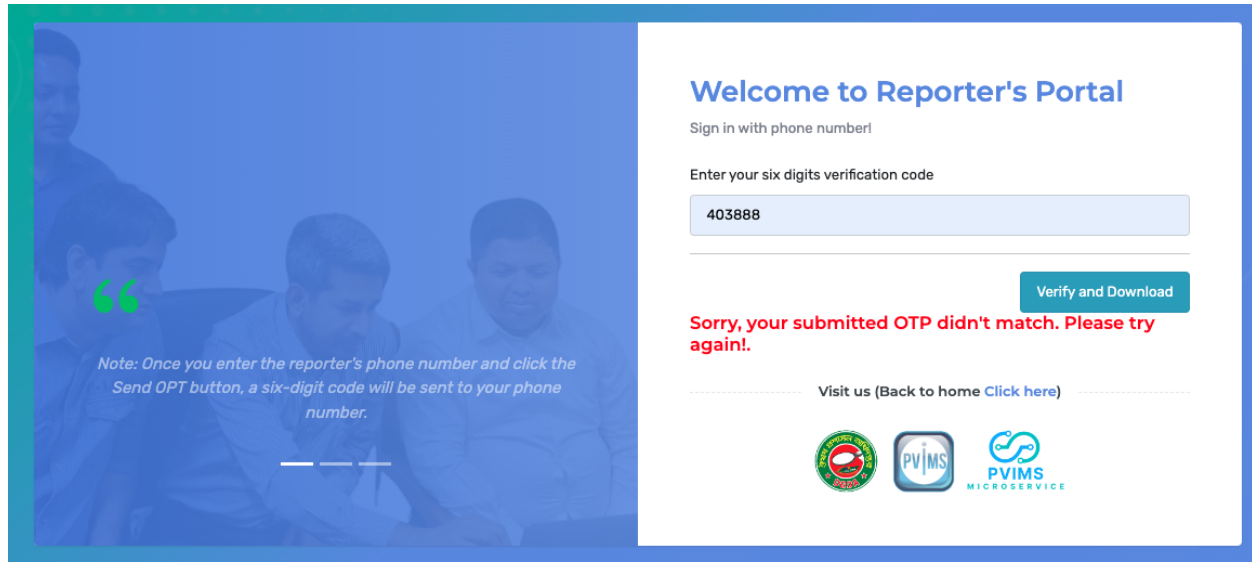


Figure 16: Wrong OTP

When you enter wright OTP, you can see the following options from your portal:

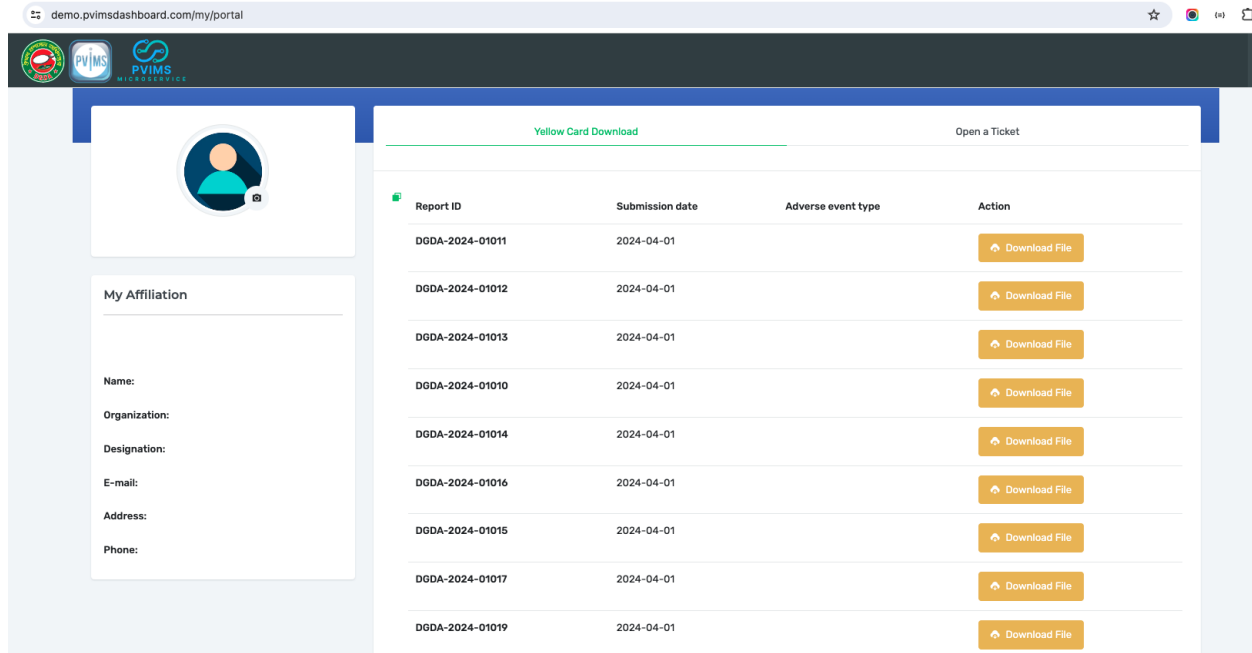


Figure 17: Reporter portal (Test data)

4.3 Support ticket

User can also open support ticket to get assistance from the DGDA and the technical team from the same panel:

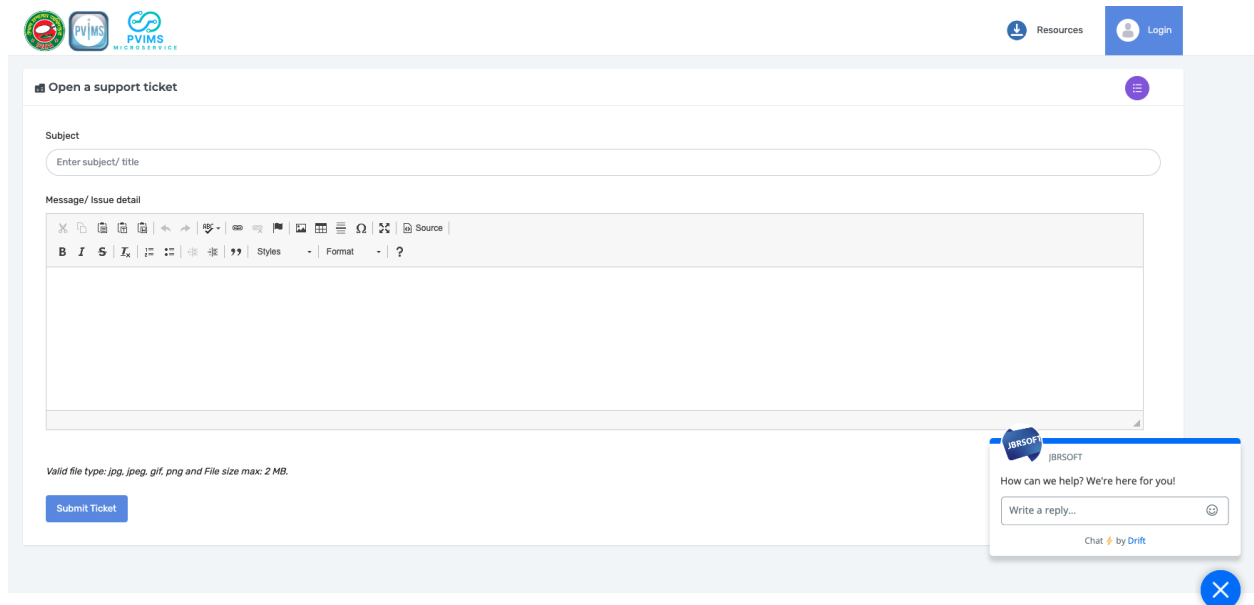


Figure 18: Create a new ticket

List of tickets:

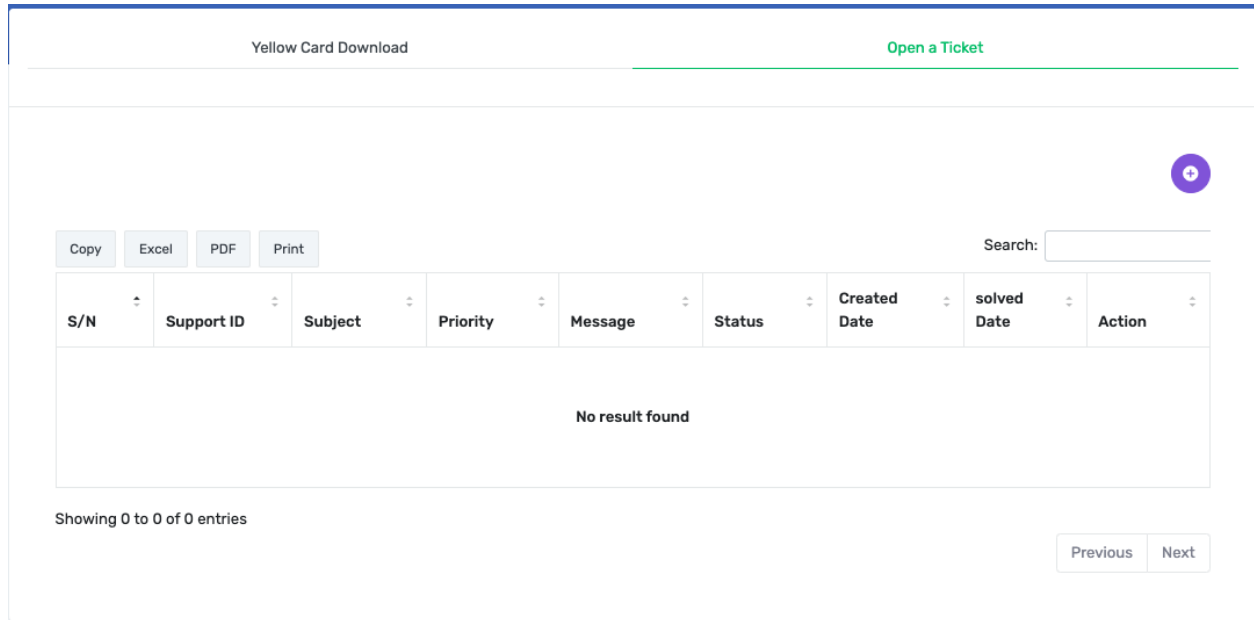


Figure 19: Support ticket panel

CHAPTER 09: GUIDELINE

You can browse the guideline by clicking on “Data Entry Guideline” from the “Guideline” menu. “Guideline” menus have two sub-menus. One is “Data Entry Guideline” and another is “Admin Video Tutorials”.

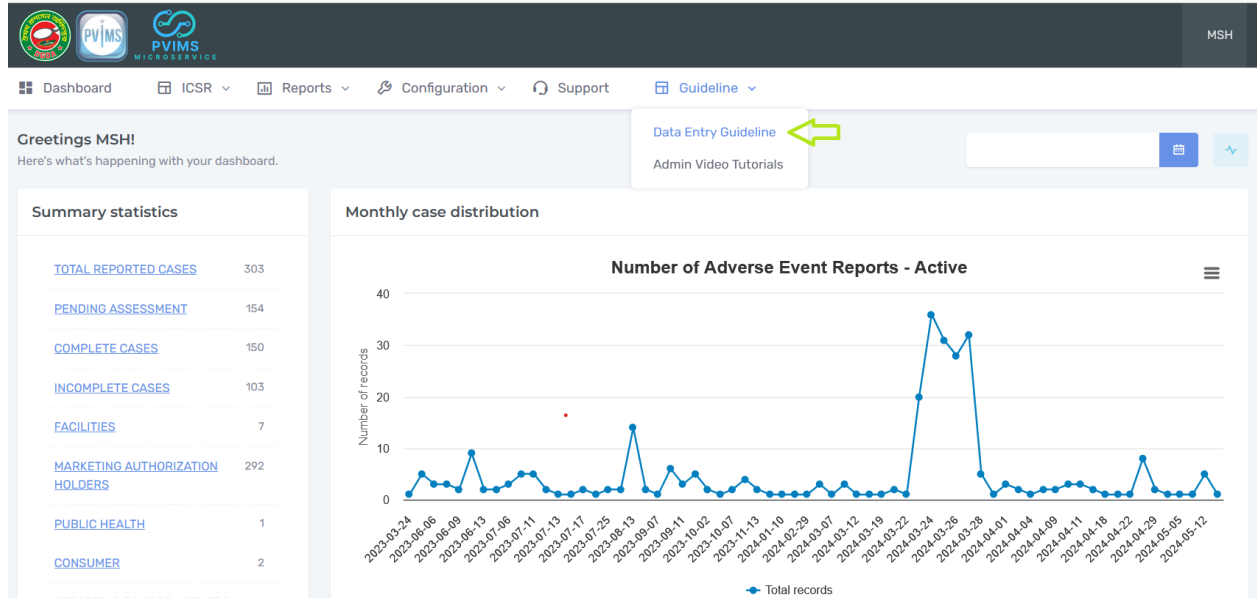


Figure 96: User guideline access

After clicking on “Data Entry Guideline”: You can browse Background, Yellow Card - Data Entry Video Tutorial and Step by step guideline. By default, it is opened in expand mode on “Data Entry Video Tutorial” collapse.

After closing collapse:

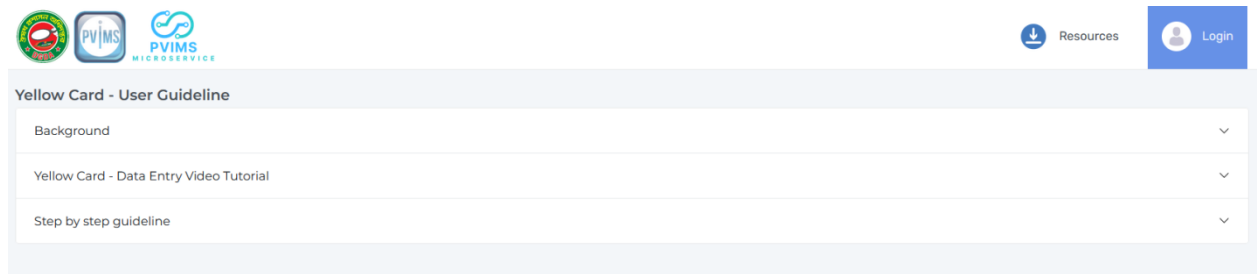
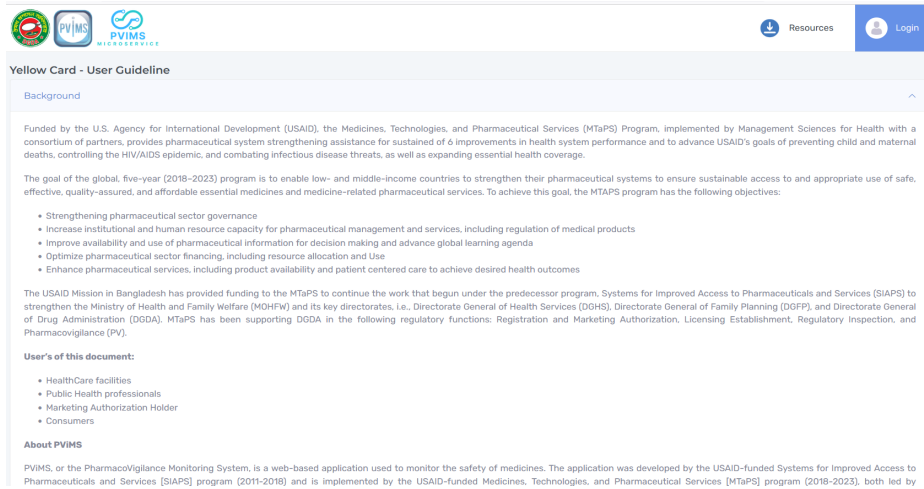


Figure 97: User guideline

Background:



The screenshot shows the 'Yellow Card - User Guideline' page for PVIMS. The page is titled 'Background' and contains the following text:

Funded by the U.S. Agency for International Development (USAID), the Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, implemented by Management Sciences for Health with a consortium of partners, provides pharmaceutical system strengthening assistance for sustained of 6 improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats, as well as expanding essential health coverage.

The goal of the global, five-year (2018-2023) program is to enable low- and middle-income countries to strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and medicine-related pharmaceutical services. To achieve this goal, the MTAAPS program has the following objectives:

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- Improve availability and use of pharmaceutical information for decision making and advance global learning agenda
- Optimize pharmaceutical sector financing, including resource allocation and Use
- Enhance pharmaceutical services, including product availability and patient centered care to achieve desired health outcomes

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User's of this document:

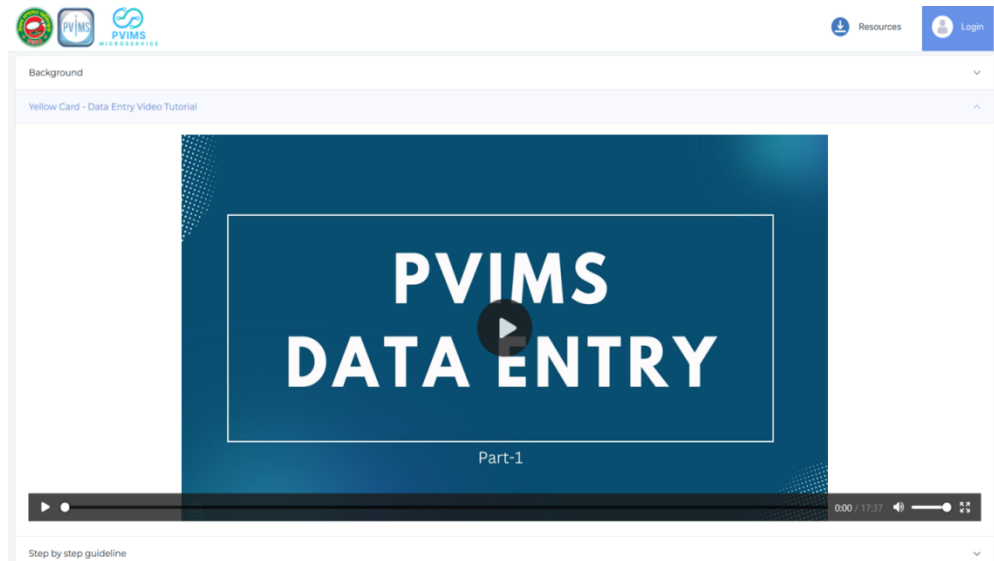
- HealthCare facilities
- Public Health professionals
- Marketing Authorization Holder
- Consumers

About PVIMS

PVIMS, or the Pharmacovigilance Monitoring System, is a web-based application used to monitor the safety of medicines. The application was developed by the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program (2011-2018) and is implemented by the USAID-funded Medicines, Technologies, and Pharmaceutical Services (MTaPS) program (2018-2023), both led by

Figure 98: User guideline - background

9.1 Video guidelines for data entry users



The screenshot shows a video player interface for a 'Data Entry Video Tutorial'. The video frame displays the text 'PVIMS DATA ENTRY' in large white letters on a dark blue background, with a play button icon in the center. Below the main text, it says 'Part-1'. The video player includes a progress bar at the bottom showing '0:00 / 17:37' and standard playback controls. The page title is 'Yellow Card - Data Entry Video Tutorial'.

Figure 99: User guideline – data entry

9.2 Step by step guidelines

1. USER INSTRUCTIONS: You can find the user instructions in this section.

2. PATIENT INFORMATION You need to fill-out the following information:

A. PATIENT INFORMATION

Name/Initial Contact Number Patient Weight (KG)

Age - Year * Age - Month Age - Days Age Not Available Select Gender * Select Pregnant Status

Select Division Select District Select Upazila Select Union

Post Office/ Village/ Road / House information

- Patient name: Enter patient fullname. It is not mandatory.
- Contact number: Enter phone number. It is not mandatory.
- Age*: Enter patient age as Year, Month and Day.
- Weight*: Enter weight in KG. It is mandatory.
- Gender*: Select gender. If you select gender as Female then another dropdown will appear with status. Please select pregnancy status.
- Division: Select division.
- District: List of districts will be appeared under this dropdown and select district.
- Thana: List of thana will be appeared under this dropdown and Select Thana.
- Street address: Enter house/ road/ village/ post office.

Notes: * refers to mandatory fields

3. SUSPECTED ADVERSE EVENT INFORMATION

Figure 100: User step-by-step guideline

9.3 Admin Video Tutorials

You can browse the Video guideline by clicking on “Admin Video Tutorials” from the “Guideline” menu. You can watch various videos by clicking on specific categories.

MSH

Dashboard ICSR Reports Configuration Support **Guideline**

ADMIN GUIDELINES

Data Entry Guideline
Admin Video Tutorials

Video Tutorials > Admin Guidelines

All Login & Profile ADRM TSC ADRAC Line Report VigiFlow Yellow Card: Data Entry

কিভাবে PVIMS এ লগইন করবেন?

ADRM এর কেস ম্যানেজমেন্ট প্রক্রিয়া

by JBRSoft Uploaded: 28-03-2024 by JBRSoft Uploaded: 28-03-2024

Figure 101: Video tutorials

Video Play and Close: Please click on Video to watch it and click on “X” sign when you want to close it.



Figure 102: Playing a video

CHAPTER 10: LOGOUT PROCESS

To log out of PViMS, click on the “Logout” menu and the user will be redirected to the public page (<https://pvimsdashboard.com/public>).

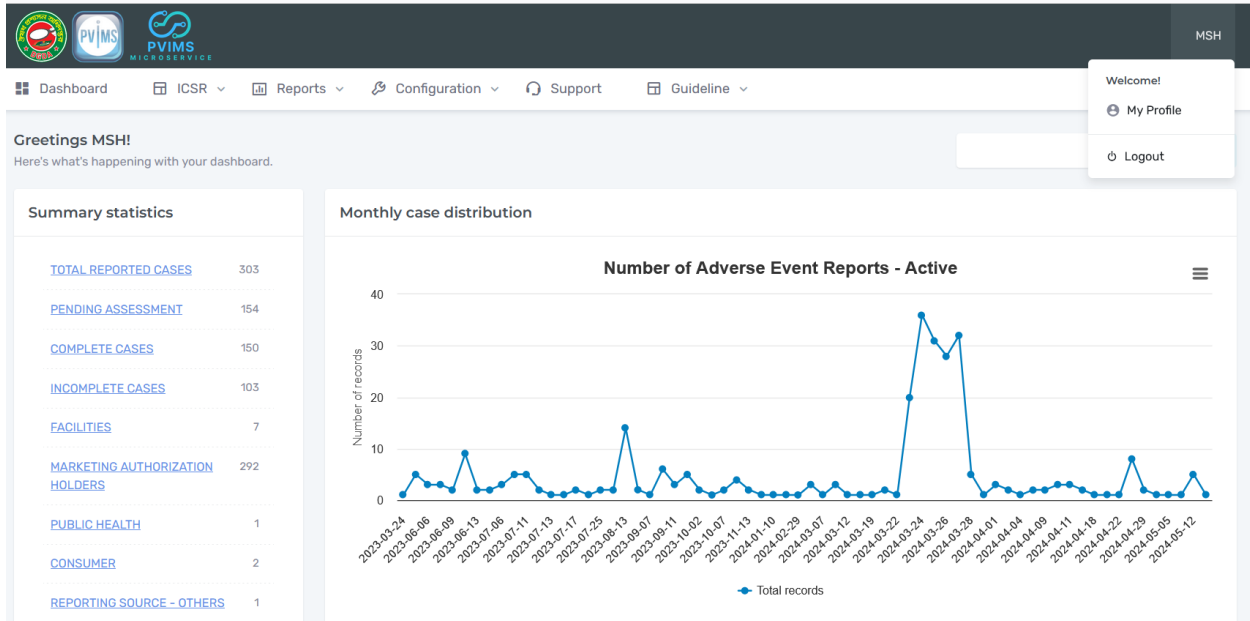


Figure 103: Logout link

After logout it is redirected to the given page.

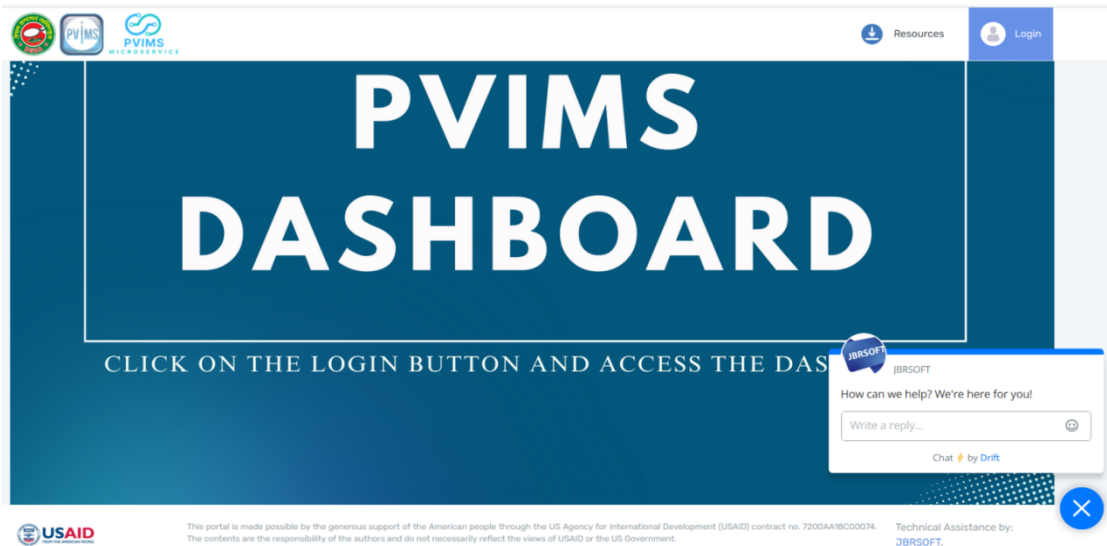


Figure 104: Open Dashboard

Developer’s Company Contact Information: JBRSOFT, Email: management@jbrsoft.com.

THE END