



PViMS

User Manual



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SIAPS 
Systems for Improved Access
to Pharmaceuticals and Services

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The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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ACRONYMS AND ABBREVIATIONS

AE	Adverse Event
DR-TB	Drug Resistant Tuberculosis
MedDRA	Medical Dictionary for Regulatory Activities
NTP	National Tuberculosis Program
PViMS	Pharmacovigilance Monitoring System
TB	Tuberculosis
WHO	World Health Organization

1 Introduction

The Challenge

Active surveillance for monitoring the safety and effectiveness of medical products is increasingly recognized as an approach that complements passive (or spontaneous) reporting, which is the most common method used by countries' pharmacovigilance systems. Active surveillance is particularly important to support the introduction of new medicines in low- and middle- income countries whose regulatory systems are developing and need support. In resource-limited settings, active surveillance can help determine the real-life frequency, risk factors, and impact of clinically significant adverse drug events on treatment outcomes in the population. However, many of these countries lack the resources and capacity to implement active surveillance activities. One major resource constraint is the lack of a data collection and analysis tool to support active safety surveillance.

The Solution

The Pharmacovigilance Monitoring System (PViMS) is a web-based application used by clinicians, regulatory bodies, and implementing partners to monitor the safety and effectiveness of medicines.

The application can improve overall clinical documentation. It is designed to ensure completion of required fields, including clinical stage, concomitant medications, test results, co-morbid conditions, and treatment regimen initiation date to improve clinical documentation at participating sites. It provides for the use of common terms, checklists, and adoption of standard terminologies. Users enter the common terms or choose from pre-coded causality assessment lists and scales such as the Medical Dictionary for Regulatory Activities (MedDRA), the National Cancer Institute Common Terminology Criteria for Adverse Events, WHO, and Naranjo; or users can develop a local dictionary using standard terms.

PViMS provides for detailed description of adverse event (AE) outcomes and for generating safety signals. Description of AEs, severity and seriousness, laboratory values, AE outcomes, and AE management can be used to generate signals of increased incidence to inform for action or further evaluation.

It is interoperable with third-party clinical systems and statistical tools. PViMS can import and export data from third-party electronic medical record or dispensing tools in XML, CSV, and Excel. Analyses can be cross-checked by analyzing data with previously validated statistical tools. Additionally, PViMS has the ability to export case safety data in E2B interface, and is health level-7 (HL7) compliant.



For information about the MedDRA dictionary contact your system administrator.

1.1 Using the Manual

This document discusses functional requirements for the electronic pharmacovigilance system (PViMS) framework.

1.2 Purpose of the Document

A user manual defines the software program's functionalities. The document aims to ensure that any reader or user gains complete system knowledge of the product. The document should also function as a reference guide and training manual for new system users.

This User Manual will outline the system functionality that is currently included in the PViMS application framework, and will be updated throughout the various incremental development iterations and any system upgrades.

1.3 Audience

The intended audiences for this document are identified as follows:

- All project stakeholders
- System super users
- General system users
- New system users

2 PViMS Structure

PViMS consists of five portals:

- Clinical
- Analytical
- Reporting
- Publishing
- Administration

The **Clinical** portal is the centralized hub for all patient and adverse drug event data collection, patient information and standardized patient care.

The **Analytical** portal is the centralized hub for causative drug assessment using traditional internationally recognized rating scales, standardized terminology and risk detection.

The **Reporting** portal allows the user to generate and print reports.

The **Publishing** portal is a centralized hub for report and document publication and presentation.

The **Administration** portal also allows the system administrator to manage the system to include, remove, and change users and manage the system structure. For information on the Administration portal, please see the *PViMS Administrator Manual*.

You use the icon bar to select the portal in which you want to work:



3 Using the System

PViMS is a web-based system, so you will need a web browser to run this application. Several Internet navigators (browsers) are available, and each one offers specific characteristics and resources. To have the system working properly, you must enable Java-script in your browser. If it's not enabled, please contact your system administrator.



PViMS has been tested using Google chrome and it is therefore recommended that Chrome be used as the preferred browser of choice when accessing PViMS.

3.1 Launching the Browser

To start the application, open your browser and enter the system URL. If you don't know the system URL, contact the NTP representatives for instructions.



Note 1. What is a URL?

URL is the abbreviation for *uniform resource locator*. It's a global address of documents and other resources on the World Wide Web. The URL of PViMS depends on where it was installed. SIAPS maintains a demonstration version of the system at the URL <http://dc-cpm-pvimsdemo.msh.org>

Check with your technical support for the right URL of the system in use.

3.2 Logging in to PViMS

When you enter the correct URL, the system shows you the login page. The login page is used to authenticate the user in the system.



Welcome to the SIAPS tool for strengthening pharmacovigilance services

<div style="border: 1px solid #ccc; padding: 10px; background-color: #f9f9f9;"><p style="text-align: center;">Spontaneous Reporting</p><p>Spontaneous reporting by medical personnel and general public</p><p>You will be taken to a separate section of the site where you will be able to create the spontaneous report.</p><div style="text-align: right; margin-top: 10px;"><input type="button" value="Create Report"/></div></div>	<div style="border: 1px solid #ccc; padding: 10px; background-color: #f9f9f9;"><p style="text-align: center;">Pharmacovigilance Monitoring System</p><p>Username <input type="text"/></p><p>Password <input type="password"/></p><p><input checked="" type="checkbox"/> Stay signed in</p><div style="text-align: right; margin-top: 10px;"><input type="button" value="Log in"/></div></div>
---	--

To access the system, you'll need a user login and password. If you don't have one, please contact your system administrator.

- Enter your assigned username and password.
- Check the stay signed in checkbox to automatically log you into PViMS on the next access of the PViMS online portal.
- Click the log in button.

3.3 End User License Agreement

The first time you log on, you will be asked to read the terms and conditions of the PViMS software license agreement. You will not be able to log into PViMS unless the EULA is accepted.

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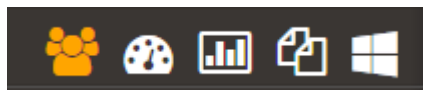
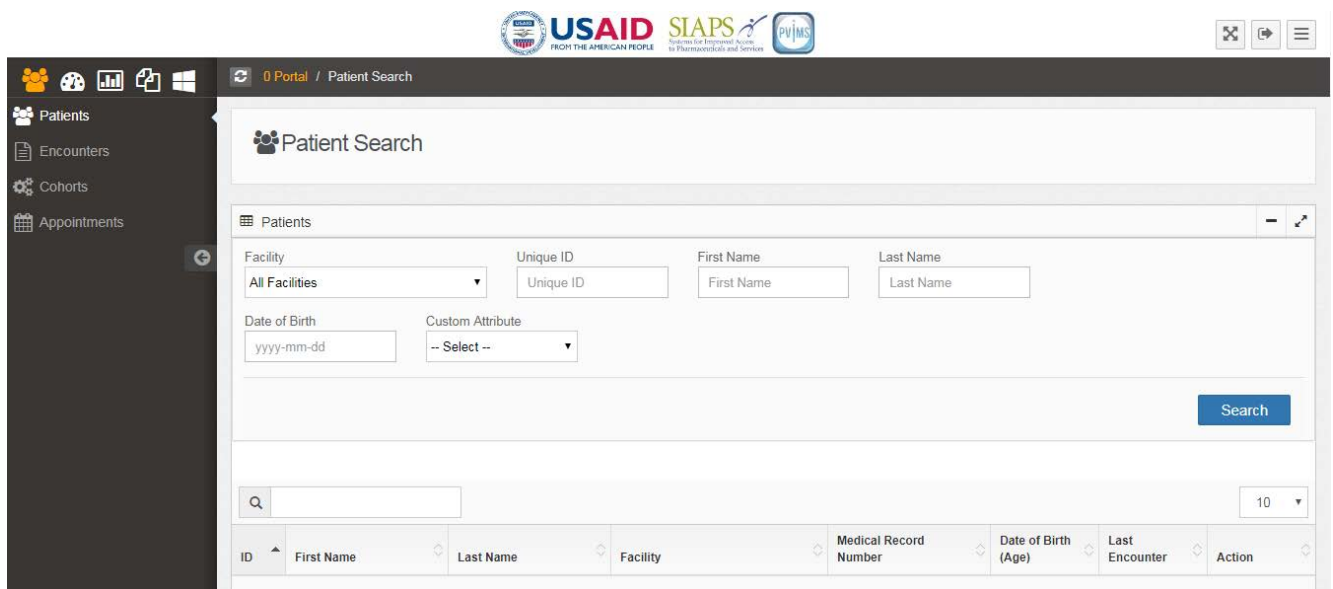
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- The licensing and use of the MedDRA (Medical Dictionary for Regulatory Activities) Dictionary does not fall within any licensing granted through the use of PViMS.
- In the Analytical portal, Exposed Cases ONLY include cases where the Adverse Drug Reaction falls within the start and end date of the medication.
9. **Indemnification.** You agree to indemnify, defend, and hold harmless Licensor and its affiliates, and their respective directors, officers, employees, agents, and assigns and licensors, as applicable, against any and all claims, damages, losses, and expenses (including reasonable attorneys' fees), as incurred, arising from or in connection with or otherwise with respect to any claim, demand, or legal action by a licensee, employee, consultant, independent contractor, or agent of Licensee, or by a third party, related directly or indirectly to the Licensee's use of the Product or the Source Code for any purpose ("Third-Party Claim"). Licensor may, at its option, conduct the defense in any such Third-Party Claim (subject to reimbursement by the Licensee of actual expenses incurred therewith), and Licensee agrees to cooperate fully with such defense.
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Do Not Accept Accept

Click the **Accept** button to confirm the acceptance of the EULA and continue to access the system, or click the **Do Not Accept** button to exit the system.

3.4 The Home Page

After you complete the login page, the system will direct you to the system’s **Home/Patient Search** page.



Use the portal icons listed above to navigate among the four different portals (**Clinical, Analytical, Reporting, Information, and Administration**).

4 Clinical Portal

At the **Home/Patient Search** page, you will be presented with the following options:

- Patients
- Encounters
- Cohorts
- Appointments

The clinical portal is the centralized hub for all patient and adverse drug event data collection, patient information and standardized patient care.

Note: the following roles have access to the clinical portal:

Administrator. The administrator has FULL permissions to the clinical portal.

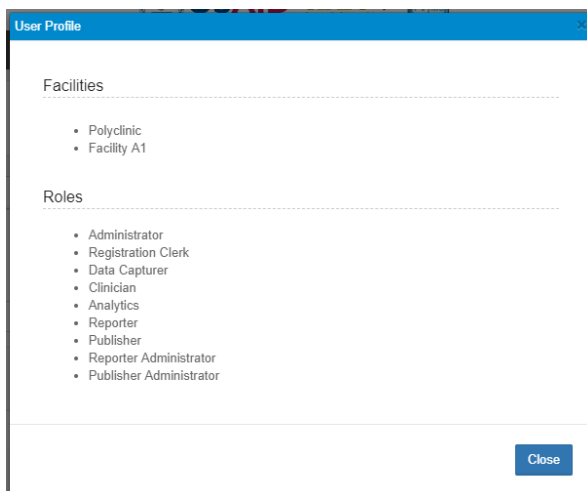
Registration Clerk. The registration clerk is able to add and amend a patient record and create appointments.

Data Capturer. A data capturer is able to add and amend a patient record and add and amend an encounter record.

Clinician. A clinician is able to add and amend a patient record and add and amend an encounter record.



Click on your user name in the application footer to view roles you currently have access to.

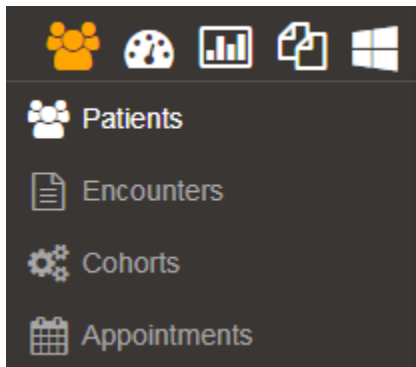


4.1 Patients

In the **Patients** function you can **Search** for patients, **Add** a new patient, and **Edit** patient information.

4.1.1 Search for Patients

The **Patient Search** function can be accessed through the **Patients** menu.



There are five ways to search for a patient. You can search by:

- Facility
- Patient Unique ID
- First Name and Last Name
- Date of Birth
- Custom Attribute

4.1.1.1 Search by Facility

- Click the **arrow** in the **Facility** field to select from the facility drop down list
- Select the facility you would like to search against specifically or select **All Facilities** if you would like to search against all facilities
- Click the **Search** button



You will only be able to search against facilities that you have been assigned access to. Please speak to your system administrator if you are unable to search against the necessary facility

The system will display a list of patients according to the filter selected, please note the Unique ID of the patient in column 1.

Patients

Facility: All Facilities | Unique ID: Unique ID | First Name: First Name | Last Name: Last Name

Date of Birth: yyyy-mm-dd | Custom Attribute: -- Select --

Add Patient Search

23 row(s) matching criteria found...

ID	First Name	Last Name	Facility	Medical Record Number	Date of Birth (Age)	Last Encounter	Action
262	Unique	PatientOne	Facility A1	83155297	2012-03-02 (5)	2018-07-09	View Patient
263	Unique	PatientFive	Facility A1	83155301	2014-03-01 (3)	2017-06-12	View Patient
264	Unique	PatientSix	Facility A1	83155302	1996-11-01 (21)	2017-01-25	View Patient
265	Unique	PatientSeven	Facility A1	83155303	2007-04-01 (11)	No Encounters	View Patient
266	Unique	PatientEight	Facility A1	83155304	1992-10-07 (25)	2017-06-20	View Patient
267	Unique	PatientNine	Facility A1	83155305	2014-03-01 (3)	No Encounters	View Patient
268	Unique	PatientTen	Facility A1	83155306	1998-01-21 (20)	No Encounters	View Patient
269	Unique	PatientEleven	Facility A1	83155307	2002-02-01 (16)	No Encounters	View Patient
270	Unique	PatientTwelve	Facility A1	8	1999-12-31 (18)	No Encounters	View Patient
271	Unique	PatientTwo	Facility A1	83155298	1943-01-01 (75)	No Encounters	View Patient

Showing 1 to 10 of 23 entries

Previous 1 2 3 Next

4.1.1.2 Search by Patient Unique ID



Each patient is allocated a unique system id when they are created in the system. It is possible to search for this patient using this id.

If you know the patient's unique ID, enter it in the **Unique ID** field and click **Search**.

Patient Search

Patients

Facility: All Facilities | Unique ID: 262 | First Name: First Name | Last Name: Last Name

Date of Birth: yyyy-mm-dd | Custom Attribute: --Select--

Add Patient Search

1 row(s) matching criteria found...

ID	First Name	Last Name	Facility	Medical Record Number	Date of Birth (Age)	Last Encounter	Action
262	Unique	PatientOne	Facility A1	83155297	2012-03-02 (3)	2018-07-09	View Patient

Showing 1 to 1 of 1 entries

4.1.1.3 Search by First Name or Last Name

You can also search by the patient's **First name** or **Last Name**. Enter the name(s) in one or both of these areas and click the **Search** button.



It is possible to do a partial search by entering the first letters of the **First** or **Last names**. The system will return all matching records if a partial search is executed.

Patient Search

Patients

Facility: All Facilities | Unique ID: Unique ID | First Name: Un | Last Name: PatientO

Date of Birth: yyyy-mm-dd | Custom Attribute: --Select--

Add Patient Search

1 row(s) matching criteria found...

ID	First Name	Last Name	Facility	Medical Record Number	Date of Birth (Age)	Last Encounter	Action
262	Unique	PatientOne	Facility A1	83155297	2012-03-02 (3)	2018-07-09	View Patient

Showing 1 to 1 of 1 entries

4.1.1.4 Search by Date of Birth

You can also search by the patient's **Date of Birth**. Select the date of birth and click the **Search** button.

Patient Search

Patients

Facility: All Facilities

Unique ID: Unique ID

First Name: Un

Last Name: Last Name

Date of Birth: 2012-03-02

Custom Attribute: -- Select --

1 row(s) matching criteria found...

Last Name	Facility	Medical Record Number	Date of Birth (Age)	Last Encounter	Action	
Unique	PatientOne	Facility A1	83155297	2012-03-02	2018-07-09	View Patient

Showing 1 to 1 of 1 entries

4.1.1.5 Search by Custom Attribute

The final search filter available is the ability to search by a **Custom Attribute**.



Custom attributes can be activated for filtering by the system administrator. Please consult your administrator if you would like to activate the ability to filter by a specific attribute.

- Select the custom attribute variable that you would like to search against (e.g., Medical Record Number)
- Enter the search value you would like to filter against and click the **Search** button.

Patient Search

Patients

Facility: All Facilities Unique ID: Unique ID First Name: Un Last Name: Last Name

Date of Birth: yyyy-mm-dd Custom Attribute: Medical Record Number Search Value: 83155297

Add Patient Search

1 row(s) matching criteria found...

ID	First Name	Last Name	Facility	Medical Record Number	Date of Birth (Age)	Last Encounter	Action
262	Unique	PatientOne	Facility A1	83155297	2012-03-02 (6)	2018-07-09	View Patient

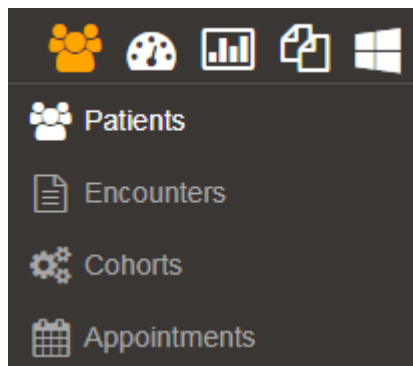
Showing 1 to 1 of 1 entries

Previous 1 Next

4.1.2 Return to the Patient Search Page

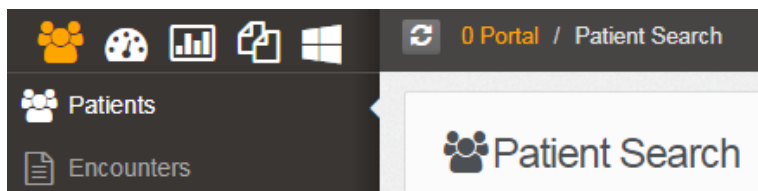
You can return to the **Patient Search** page from any place in the system by using either the **Menu Bar** or the **Title Bar**.

4.1.2.1 Menu Bar



The menu bar is located on the left-hand side of the page.

4.1.2.2 Title Bar



The **Title Bar** is located to the right of the Portal Icon.

4.1.3 View an Existing Patient

After selecting the appropriate search filter and you have clicked the **Search** button, the system will present all matches as displayed in a table.

Patient Search

Patients

Facility: All Facilities | Unique ID: Unique ID | First Name: First Name | Last Name: Last Name

Date of Birth: yyyy-mm-dd | Custom Attribute: - Select -

Add Patient Search

23 row(s) matching criteria found...

ID	First Name	Last Name	Facility	Medical Record Number	Date of Birth (Age)	Last Encounter	Action
262	Unique	PatientOne	Facility A1	83155297	2012-03-02 (1)	2018-07-09	View Patient
263	Unique	PatientFive	Facility A1	83155301	2014-03-01 (4)	2017-06-12	View Patient
264	Unique	PatientSix	Facility A1	83155302	1996-11-01 (21)	2017-01-25	View Patient
265	Unique	PatientSeven	Facility A1	83155303	2007-04-01 (11)	No Encounters	View Patient
266	Unique	PatientEight	Facility A1	83155304	1992-10-07 (25)	2017-06-20	View Patient
267	Unique	PatientNine	Facility A1	83155305	2014-03-01 (4)	No Encounters	View Patient
268	Unique	PatientTen	Facility A1	83155306	1998-01-21 (20)	No Encounters	View Patient
269	Unique	PatientEleven	Facility A1	83155307	2002-02-01 (16)	No Encounters	View Patient
270	Unique	PatientTwelve	Facility A1	8	1999-12-31 (18)	No Encounters	View Patient
271	Unique	PatientTwo	Facility A1	83155298	1943-01-01 (75)	No Encounters	View Patient

The columns in the table are described below:

ID	Unique identification number assigned by the system
First Name	Patient's first name as captured in the system
Last Name	Patient's last name as captured in the system
Facility	Facility associated with the patient
Medical Record Number	ID number associated with the patient
Date of Birth (Age)	Patients date of Birth and Age indicator <ul style="list-style-type: none"> • Ages in black ovals are adults • Ages in grey ovals are children
Last Encounter	Last encounter date, the date the patient last visited the facility
Action	Ability to view the patient's information



It is possible to filter the results of a table by entering your additional search criteria in the search text box at the top of the grid

23 row(s) matching criteria found...

ID	First Name	Last Name	Facility	Medical Record Number
262	Unique	PatientOne	Facility A1	83155297

- To view a patient entered in the system, locate the patient in the patient table.
- Click the **View Patient** button in the **Action** column.

Patient Search

Patients

Facility: All Facilities | Unique ID: Unique ID | First Name: First Name | Last Name: Last Name

Date of Birth: yyyy-mm-dd | Custom Attribute: -- Select --

Add Patient Search

23 row(s) matching criteria found...

ID	First Name	Last Name	Facility	Medical Record Number	Date of Birth (Age)	Last Encounter	Action
262	Unique	PatientOne	Facility A1	83155297	2012-03-02 (6)	2018-07-09	View Patient
263	Unique	PatientFive	Facility A1	83155301	2014-03-01 (4)	2017-06-12	View Patient
264	Unique	PatientSix	Facility A1	83155302	1996-11-01 (21)	2017-01-25	View Patient

- The system will then open the **Patient View** page and allow you to view the demographics for this patient.

Patient View has been segregated into the following core sections:

- Patient Information
- Additional Information
- Clinical Information
- Identifiers and Audit Information
- Condition Groups
- Analytical Reporting

4.1.3.1 Patient Information - Details

The **Details** tab is further divided into **Basic Information** and **Patient Demographic Information**.

Basic Information

* First Name: Unique
 * Last Name: PatientTwo
 Middle Name:
 * Date of Birth: 1943-01-01
 Age: 75
 Age Group: Elderly > 69 years
 * Facility: Facility A1
 Date Entered In System: 2017-01-20

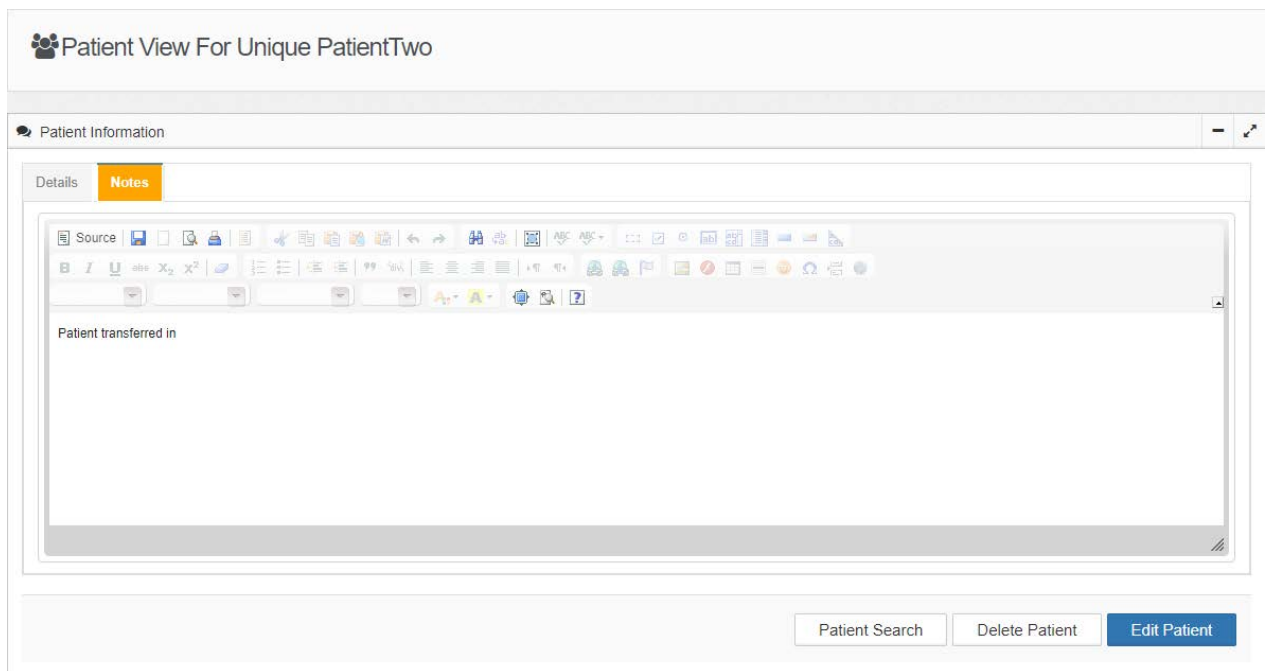
Patient Demographic Information

Medical Record Number	83155298	By Admin on 2017-01-20
Medical Record Number Type		
Patient Identity Number	497499416	By Admin on 2017-01-20
Identity Type	National identity	By Admin on 2017-01-20
Gender	Male	By Admin on 2017-01-20
Marital Status		
Employment Status		
Occupation		
Language		
Address		
Address Line 2		
City		
State		
Postal Code		
Patient Contact Number		
Country of Birth		

Patient demographic information will by enlarge remain rather static but should be verified and updated on a visit by visit basis to reflect up to date information. Various attributes defined as part of demographic information can be used as risk factors when identifying signals in the analytical portal and therefore remain critical through the clinical portal data collection process.

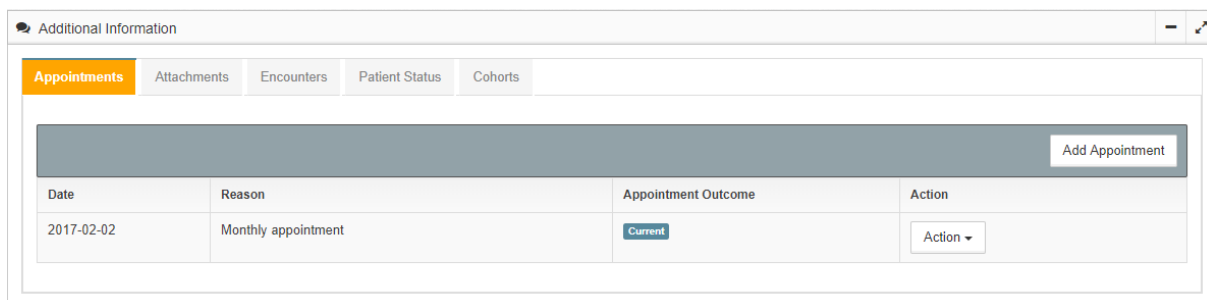
4.1.3.2 Patient Information - Notes

The **Notes** tab is where you can note generic information relating to the patient at the discretion of the clinician.



4.1.3.3 Additional information - Appointments

The **appointments** tab can be used to track upcoming appointments for the patient. This function can be leveraged to track additional clinical or demographic information if sufficient information was not collected in any of the patient’s previous encounters.



The columns in the appointments table are described below:

Date	Date of the appointment
Reason	Reason for the appointment
Appointment Outcome	Did the patient arrive for their appointment? Did the patient miss their appointment?
Action	Ability to edit the appointment information or to delete the appointment from the calendar



It is possible to sort the appointment table by any one of the columns noted above by clicking on the corresponding column name.

4.1.3.4 Additional Information - Attachments

The **attachments** tab can be used to store physical file attachments for the associated patient. The number of attachments and size of attachments are configurable parameters within PViMS and can be adjusted based on your site's requirements.



The following file types are supported within PViMS:

- MS Word 2003-2007 Document
- MS Excel 2003-2007 Document
- MS Word Document
- MS Excel Document
- Portable Document Format
- Image | JPEG
- Image | PNG
- Image | BMP
- XML Document

Additional Information
-
↗

Appointments
Attachments
Encounters
Patient Status
Cohorts

Select File...

Choose File
No file chosen

File Description

Description

Add Attachment
Download All

Type	Name	Description	Created By	Action
Image PNG	Patient_Xray.png	Patient XRAY	By Admin User on 2018-08-07 14:13	Action ▾

The columns in the attachments table are described below:

Type	Describes the file type (e.g., PDF, Word, Excel)
Name	Name of the file
Description	Description of the file entered
Created by	Name of the person who uploaded the file, and date of upload
Action	Ability to download or delete the file

4.1.3.5 Additional Information - Encounters

The **encounters** tab can be used to track all facility visits by the patient. Encounters effectively form part of the holistic longitudinal record for the patient and store contextual clinical data collected during that visit.

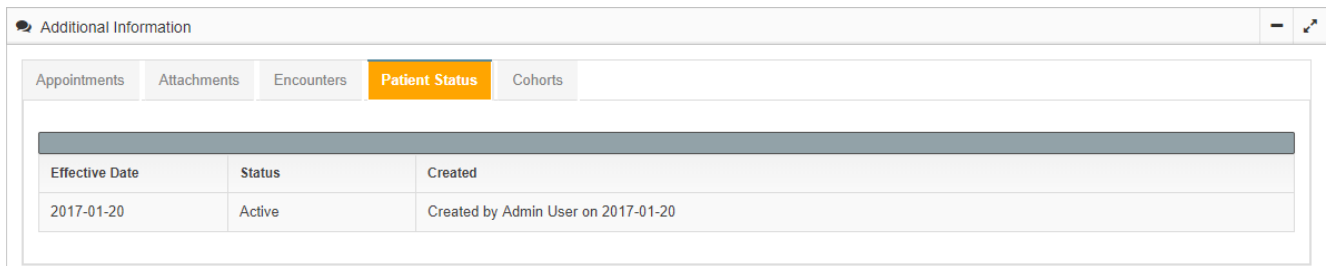
Date	Type	Action
2018-07-09	Unscheduled Visit	View Encounter
2017-11-09	Treatment Initiation Visit	View Encounter
2017-11-07	Pre-Treatment Visit	View Encounter
2017-08-01	Pre-Treatment Visit	View Encounter
2017-01-25	Pre-Treatment Visit	View Encounter
2017-01-24	Pre-Treatment Visit	View Encounter

The columns in the encounters table are described below:

Date	Date of the encounter
Type	Type of encounter when the encounter was created (e.g., Pre-treatment Visit, Treatment initiation Visit, Unscheduled Visit)
Encounter Status	Open or Closed, if Open changes can still be made to the information for the encounter.
Action	Ability to View or Delete and encounter

4.1.3.6 Additional Information - Patient Status

The **patient status** tab can be used to track if the patient is currently active or if the patient is now deceased. Status change is driven by an effective date for efficient accurate analysis.



The columns in the status table are described below:

Effective Date	Date the person was entered into the system
Status	To indicate if the patient is active or inactive
Created	Name of the person who effected the status change, and date of this status change

4.1.3.7 Additional Information - Cohorts

The **cohort** tab can be used to track what cohorts a patient has been enrolled in. Analysis can be subdivided by cohort to target signal detection effectively.

Cohort	Cohort Start	Enrolled Date	De-enrolled Date	Action
9MTR Study (OR9MT)	2016-05-01	Not Enrolled	Not De-enrolled	Enroll
BDQ Study (ORBDQ)	2016-06-01	2017-01-25	Not De-enrolled	Action ▾
9MTR Program Condition (PC9MT)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
18MTR Program Condition (PC18M)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
XDRTB Program Condition (PCXDR)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
Finn (F-16)	2015-01-01	Not Enrolled	Not De-enrolled	Enroll
Test (TestC)	2017-07-20	Not Enrolled	Not De-enrolled	Enroll

The columns in the **Cohorts** table are described below:

Cohort	Name of cohort
Cohort Start	Date the cohort started
Enrolled Date	Date the patient was enrolled in the cohort
De-enrolled Date	Date the patient was de-enrolled from the cohort
Action	Ability to enroll, de-enroll, or remove patient from a cohort

4.1.3.8 Clinical information – Patient Conditions

The **patient condition** tab can be used to track a history of concomitant conditions the patient has experienced. Being exposed to concomitant conditions as well as specific types of concomitant conditions can be used as risk factors to signal detection within the analytical portal.

Condition Name	Start Date	Outcome Date	Outcome	Actions
Rashes, eruptions and exanthems NEC	2017-08-10	2017-11-03		Action ▾
Tuberculosis	2017-09-05			Action ▾

The columns in the **Patient Conditions** table are described below:

Condition Name	Medical term for the patient’s diagnosis (or symptoms if diagnosis is not available)
Start Date	Date the condition started
Outcome Date	Date the condition ended
Outcome	Outcome of the Condition
Actions	Ability to Edit or Delete the condition

4.1.3.9 Clinical information – Adverse Events

The **adverse events** tab can be used to track a history of adverse events the patient has experienced. The registration of an adverse event as part of the patient’s longitudinal clinical record, results in the creation of a new adverse event report within the analytical portal for consumption by the designated Pharmacovigilance team. Progress against this registration can be tracked in the Analytical Reporting widget within the patient view.

Description	Onset Date	Reported Date	Resolution Date	Is Serious	Actions
Benign essential hypertension antepartum	2017-12-19				Action
Benign essential hypertension complicating pregnancy, childbirth, and the puerperium, unspecified as	2017-12-19				Action
Benign essential hypertension with delivery	2017-12-19				Action
Benign essential hypertension, postpartum	2017-12-19				Action
Bruising	2017-06-13	2017-06-13		Yes	Action
Dizziness	2016-08-03			No	Action
Dizziness exertional	2017-12-19				Action
Hypertension not adequately controlled	2017-12-19				Action
Hypertension portal	2017-12-19				Action
Hypertension worsened	2017-12-27				Action

Showing 1 to 10 of 14 entries

The columns in the **Adverse Events** table are described below:

Description	Description of the event from the MedDRA dictionary
Onset Date	Date the event started
Reported Date	Date the event was reported to the facility
Resolution Date	Date the event was resolved or stabilized
Actions	Ability to Edit or Delete the adverse event

4.1.3.10 Clinical information – Patient Medications

The **patient medications** tab can be used to track a history of medications the patient has been exposed to. A comprehensive medications history is critical to ensure accurate signal detection within the analytical portal.

Drug Name	Dose	Dose Unit	Dose Frequency	Start Date	End Date	Indication Type	Actions
abacavir + lamivudine				2018-02-07			Action
acetysalicylic acid				2017-04-01	2017-04-06	Pre-existing condition	Action
amitriptyline	10	mg	daily	2016-06-01	2016-06-30		Action
capreomycin	1000	mg	daily	2016-10-12			Action
ceftriaxone	1000	milligram	daily	2016-06-02	2016-10-19		Action
cyclizine	1000	milligram	daily	2016-06-19	2016-08-23		Action
doxycycline	1000	milligram	daily	2016-06-03			Action
ethionamide	1000	milligram	daily	2016-04-01	2016-07-03		Action
ibuprofen	1000	milligram	daily	2016-04-01			Action
kanamycin	1000	milligram	daily	2016-03-12	2016-03-18		Action

The columns in the **Patient Medication** table are described below:

Drug Name	Name of drug from the country drug dictionary
Dose	Number of units
Dose Unit	Unit of dose (e.g., mg, mEq, IU)
Dose Frequency	Number of times per day the dose is administered
Start Date	Date the patient started taking the medicine
End Date	Date the patient stopped taking the medicine
Indication Type	Purpose of medication (e.g., treat primary condition, treat pre-existing condition, or to treat and adverse event)
Actions	Ability to Edit or Delete the Patient Medication

4.1.3.11 Clinical information – Tests and Procedures

The **tests and procedures** tab can be used to track a history of tests and procedures the patient has been exposed to.

Test	Test Date	Test Result (Coded)	Test Result (Value)	Test Unit	Range Limits	Actions
AFB Smear Result	2017-07-12	Abnormal	SCANTY	mg/dL		Action ▾
CD4 Count	2017-01-24		555.00	cells/mm ³	Lower: 500 Upper: 1500	Action ▾
Glucose	2017-01-25		80.00	mg/dL		Action ▾
Haemoglobin	2018-07-09		10	mg/dL		Action ▾

Showing 1 to 4 of 4 entries

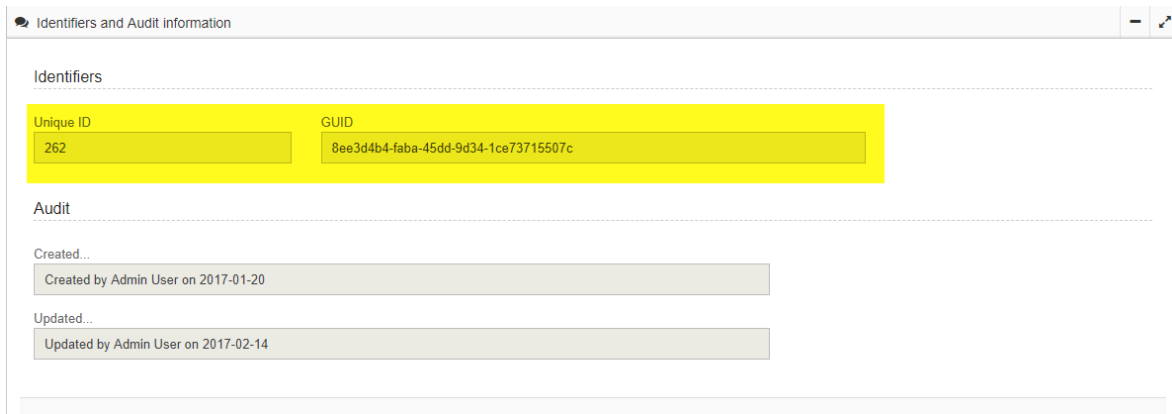
The columns in the **Tests and Procedures** table are described below:

Test	Name of lab test or clinical evaluation
Test Date	Date the test was conducted
Test Result (Coded)	Qualitative test result
Test Result (Value)	Quantitative test result - Number of units
Test Unit	Type of unit
Actions	Ability to Edit or Delete Tests and Procedures

4.1.3.12 Identifiers and Audit information - Identifiers

The **Identifiers** section displays the following unique identifiers stored per patient record:

- The patient’s Unique ID assigned by the system
- A Globally Unique Identifier (GUID) assigned by the system



4.1.3.13 Identifiers and Audit information – Audit Information

The **Audit** section keeps a user record of any patient information changes.

Created	Gives the User Name of the person who created the file and the Date it was created
Updated	Gives the User Name of the person who last updated the information and the Date of the update



4.1.4 Add a New Patient

Adding a new patient to the PViMS database requires the completion of a patient search. This is to mitigate the potential risk of registering a patient more than once. If you are not able to find the patient in the existing database, you can add a new patient by clicking on **Add Patient** button.

The screenshot shows the 'Patient Search' window. It has a title bar with a close button and a search icon. Below the title bar is a search form with the following fields:

- Facility: A dropdown menu with 'All Facilities' selected.
- Unique ID: A text input field with 'Unique ID' as a placeholder.
- First Name: A text input field with 'Unique' as a placeholder.
- Last Name: A text input field with 'Patient' as a placeholder.
- Date of Birth: A date picker field with 'yyyy-mm-dd' as a placeholder.
- Custom Attribute: A dropdown menu with '-- Select --' as a placeholder.

 At the bottom right of the form are two buttons: a yellow 'Add Patient' button and a blue 'Search' button.

The system will open a new **Patient View** page with two sections **Patient Information** and **Additional Information** needing to be captured.

4.1.4.1 Patient Information – Basic Information

The **Basic Information** section captures basic patient demographic information.

To enter patient information, **enter text** in the corresponding fields (e.g., **First Name**, **Last Name**). Or click the **arrow** in a selected field to display a list of values, and select one value from the list. Please ensure that all elements with a red asterisk (mandatory) are captured.

The screenshot shows the 'Patient Information' window with the 'Details' tab selected. The 'Basic Information' section contains the following fields:

- * First Name: A text input field with 'Test' as the value.
- * Last Name: A text input field with 'Patient' as the value.
- Middle Name: An empty text input field.
- * Date of Birth: A date picker field with '1963-01-01' as the value.
- * Facility: A dropdown menu with 'Facility A1' selected.

 There are also 'Notes' and 'Details' tabs at the top of the form area.

Fields in the **Basic Information** Section are described below:

First Name	Text field to enter the patient’s first name
Last Name	Text field to enter the patient’s last name
Middle Name	Text field to enter the patient’s first name
Facility	Dropdown list to select the patient’s facility
Age	Auto-calculated by the system
Age Group	Auto-calculated by the system
Date Entered in System	Auto-calculated by the system

All fields marked with a red star (*) are compulsory fields that must be completed before proceeding.

Greyed out fields are automatically filled by the system and cannot be edited.

You will only be able to add patients to facilities you have been granted access to. To view which facilities, you have been granted access to, click on your user name in the footer of the page.

✕
User Profile

Facilities

- Polyclinic
- Facility A1

Roles

- Administrator
- Registration Clerk
- Data Capturer
- Clinician
- Analytics
- Reporter
- Publisher
- Reporter Administrator
- Publisher Administrator

Close

4.1.4.2 Patient Information - Patient Demographics

The **Patient Demographic Information** section captures comprehensive patient demographic information.

To enter patient information, **enter text** in the corresponding fields (e.g., **Medical Record Number, Medical Record Number Type, etc.**). Or click the **arrow** in a selected field to display a list of values, and select one value from the list (e.g., **Gender**).

Fields in the **Patient Demographic Information** section are described below:

Medical Record Number	Text field to enter the patient's medical record number
Medical Record Number Type	Dropdown menu to select the medical record type
Patient Identity Number	Text field to enter the patient's identity number
Identity Type	Dropdown menu to select the identity type
Gender	Dropdown menu to select the patient's gender
Marital Status	Dropdown menu to select the patient's marital status
Employment Status	Dropdown menu to select the patient's employment status
Occupation	Text field to enter the patient's occupation
Language	Dropdown menu to select the patient's language
Address	Text field to enter the patient's address
Address Line 2	Text field to enter the patient's address
City	Text field to enter the patient's address
State	Text field to enter the patient's address
Postal Code	Text field to enter the patient's address
Patient Contact Number	Text field to enter the patient's contact number
Country of Birth	Dropdown menu to select the patient's country of birth

Patient Demographic Information

Medical Record Number	<input type="text" value="HPRS//123/123434"/> *	
Medical Record Number Type	<input type="text" value="DR-TB"/> ▼	
Patient Identity Number	<input type="text" value="4974994161"/> *	
Identity Type	<input type="text" value="National identity"/> ▼	
Gender	<input type="text" value="Male"/> ▼	
Marital Status	<input type="text" value="Single"/> ▼	
Employment Status	<input type="text" value="Unemployed"/> ▼	
Occupation	<input type="text"/>	
Language	<input type="text" value="English"/> ▼	
Address	<input type="text"/>	
Address Line 2	<input type="text"/>	
City	<input type="text"/>	
State	<input type="text"/>	
Postal Code	<input type="text"/>	
Patient Contact Number	<input type="text"/>	
Country of Birth	<input type="text" value="Philippines"/> ▼	

4.1.4.3 Additional Information – Primary Condition Group

The **Primary Condition Group** section allows you to assign a patient to a patient condition based on their medical condition (e.g., TB, HIV, and Malaria). The patient must be assigned to a patient condition group for their data is to be included when using the **Analytical Portal**.

To assign a **Primary Condition Group** click the arrow in the **Condition Groups** field. The system will display a list of conditions to choose from. Select the appropriate condition by clicking on the corresponding condition in the list.

The system will then prompt you to select the MedDRA term associated with the condition in the **MedDRA Terms** field.

Additional Information

Primary Condition Group

Condition Groups: TB

MedDRA Terms: Meningeal tuberculosis

Cohorts: [Empty]

Enrollment Date: yyyy-mm-dd

You also have the option to assign a patient to a cohort established by the public health program. To assign a patient to a cohort, click the **arrow** in the **Cohorts** field. The system will display a list of **Cohorts**. Click the cohort the patient should belong to in the list and enter the date the patient was enrolled in the cohort.



You will only be able to allocate patients to cohorts that are assigned to this specific condition group.

Additional Information

Primary Condition Group

Condition Groups: TB

MedDRA Terms: Meningeal tuberculosis

Cohorts: 18MTR Program Condition

Enrollment Date: 2018-08-07

4.1.4.4 Additional Information – Condition Information

Enter the **Start and Outcome dates** (only enter the outcome date if one is applicable) for the condition and any **Comments** regarding the condition if appropriate.

Click the **arrow** in the **Condition Ongoing** field and select **Yes** if the condition is ongoing, and **No** if the condition has an outcome date.

Condition Information

* Start Date Outcome Date

Comments

Condition Ongoing

4.1.4.5 Additional Information - Encounter information



PViMS Term - Encounter

A patient's longitudinal health record is composed of multiple **encounters**. An encounter is effectively a signal that a patient has been seen by a health care provider such as a clinician and clinical data has been collected in context with this encounter.

Click the arrow in the **Encounter Type** field. The system will display an **Encounter Type** list. Click the appropriate **Encounter Type** from the list.

Set the priority for the encounter by clicking on the **arrow** in the **Priority** field. The system will display a **Priority** list. Select a **Priority** option from the list.

Finally enter the encounter date in the **Encounter Date** field. The encounter date will be the date the patient was encountered at the facility.

Encounter Information

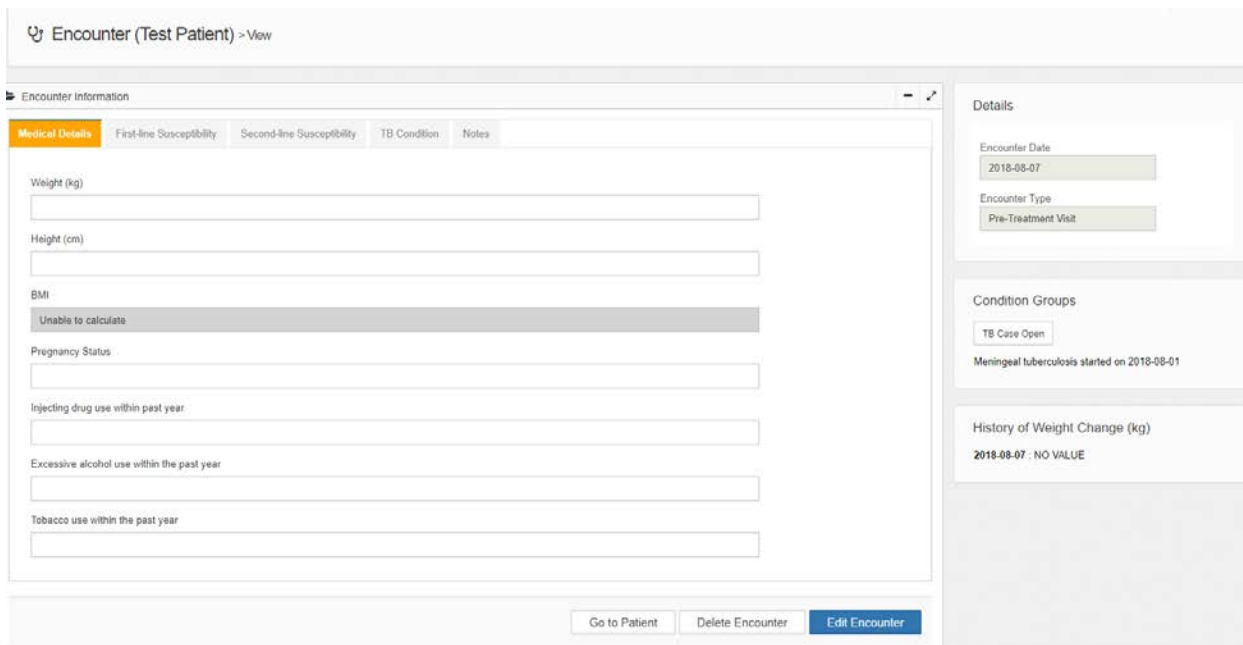
* Encounter Type
 Pre-Treatment Visit ▼

* Priority
 Not Set ▼

* Encounter Date
 2018-08-07

When all information for the page has been entered, click the **Save** button or click the **Cancel** button to cancel the action.

The system will then take you to the patient’s **Encounter View** page where you can **Add** or **Edit**, encounter information described in Section 4.2.



4.1.5 Condition Groups

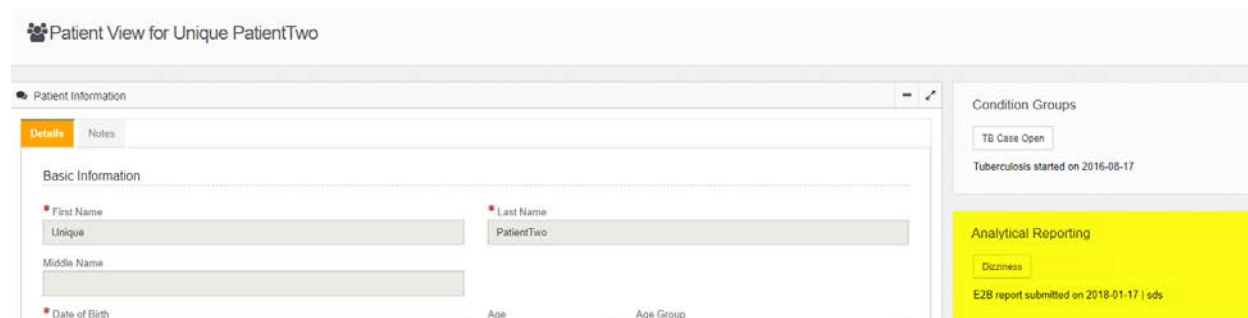
The **Condition Groups** widget which is accessible from within the patient view provides the name of the condition group the patient is assigned to, and the start of the condition. The condition group **Case Button** indicates whether the case is **Open** or **Closed**.



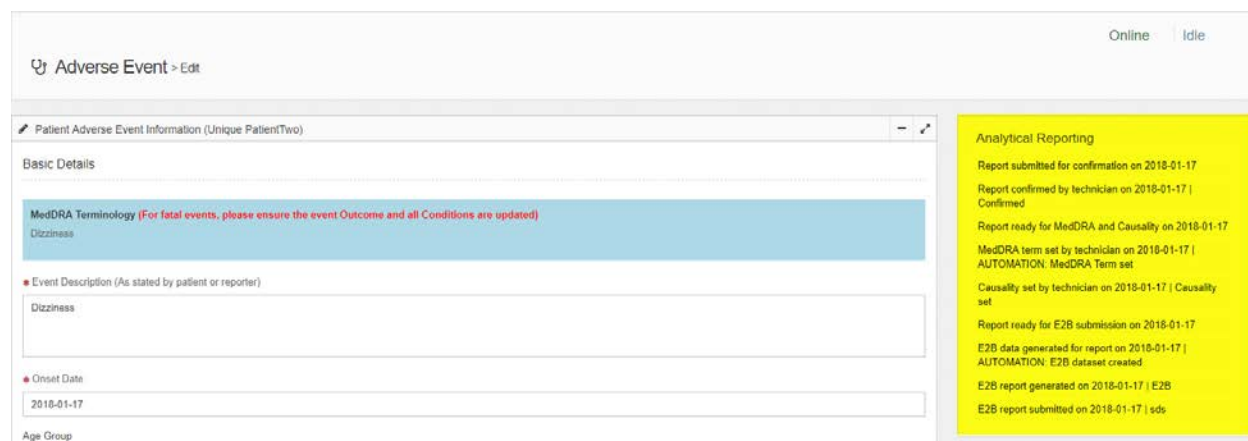
Only **Open** conditions will be displayed on the **Patient View** page. A patient can be assigned to more than one condition group at the same time (e.g., the TB condition group and the HIV condition group).

4.1.6 Analytical Reporting

The **Analytical Reporting** widget accessible from within the patient view provides the current status of any pharmacovigilance activities that have been conducted within the analytical portal against adverse events that have been registered against this patient.



By clicking on the adverse event button, the system will navigate you to the adverse event page for this event where you will be able to view a comprehensive history of pharmacovigilance activities for this event.



4.1.7 Add or Edit Patient Information

You can add or edit patient information at the **Patient View** page. But first, you need to locate the patient you would like to amend by searching for the patient using the Patient Search function. Click on the patient menu to access the **Patient Search** screen.

Enter the appropriate search criteria and click the search button. You will be presented with a list of patients that match the search criteria entered.

1 row(s) matching criteria found...

ID	First Name	Last Name	Facility	Medical Record Number	Date of Birth (Age)	Last Encounter	Action
329	Test	Patient	Facility A1	HPRS-123-123432	1963-01-01 (55)	2018-08-07	View Patient

Showing 1 to 1 of 1 entries

Click the **View Patient** button and the system will display the **Patient View** page for the selected patient.

Click the **Edit** button and the system will display a **Patient View** page that can be edited.

Make changes as appropriate then click the **Save** button to continue or click the **Cancel** button to undo the action and go back to the previous page.

After clicking the **Save** button the system will update and display the **Patient View** page with the updated information and a **Patient Saved Successfully** confirmation message

Note: The **Age**, **Age Group**, and **Date Entered in System** fields displayed with a yellow background are auto-filled by the system. They are read-only and cannot be edited by the user.

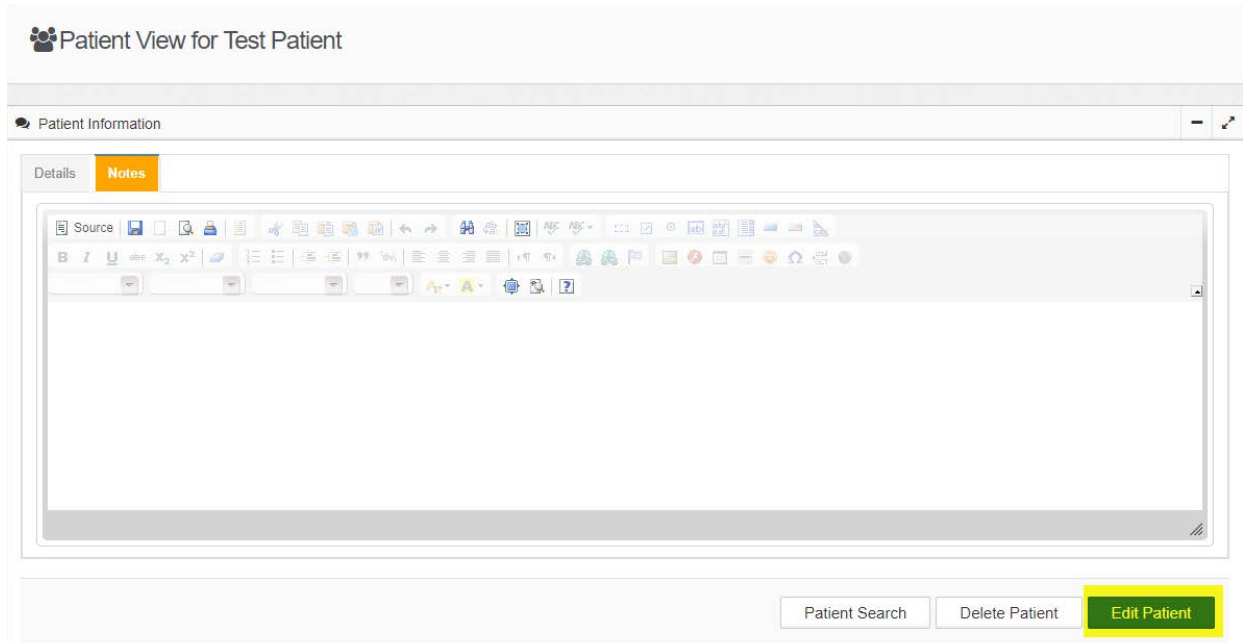
Age: 55

Age Group: Adult > 16 years and <= 69 years

Date Entered in System: 2018-08-07

4.1.7.1 Additional Notes

To make changes to the notes, click the **Notes** tab. The system will display the **Notes** section.



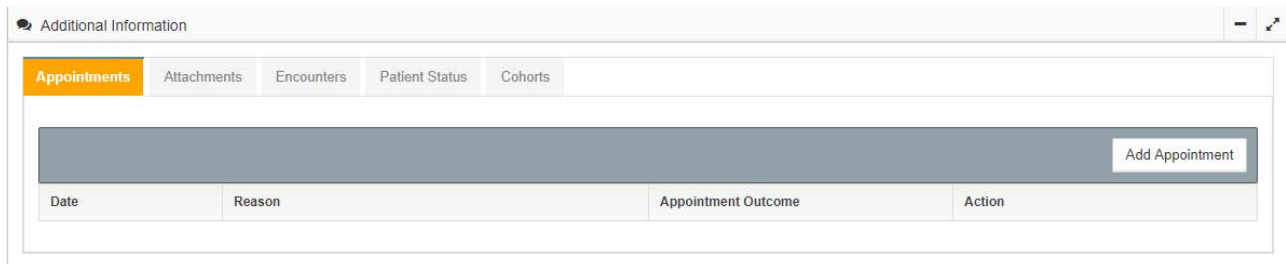
Click the **Edit** button and the system will allow you to edit the generic notes for the patient.

Once you have added or edited the notes section click the **Save** button to continue or click the **Cancel** button to undo the action and return to the patient view.

After clicking the **Save** button the system will display the **Patient View**.

4.1.8 Add or Edit Additional Information

On the **Patient View** page, you can **Add** or **Edit** information in the **Additional Information** section.



Additional Information

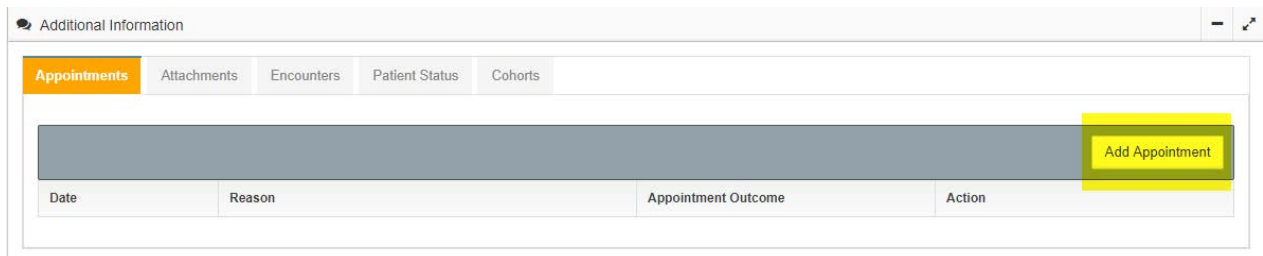
Appointments Attachments Encounters Patient Status Cohorts

Add Appointment

Date	Reason	Appointment Outcome	Action
------	--------	---------------------	--------

4.1.8.1 Add Appointments

At the **Appointments** tab click the **Add Appointments** button, after which the system will open the **Add Appointment** page




Additional Information


Appointments Attachments Encounters Patient Status Cohorts

Add Appointment

Date	Reason	Appointment Outcome	Action
------	--------	---------------------	--------

- Enter the **Appointment Date**
- Enter the **Reason** for the appointment
- Click the **Submit** button to create the appointment, or click the **Back** button to cancel the action and go back to the previous page.

 Add Appointment (Test Patient)

 Add New Appointment - ↗

Basic Details

* Appointment Date

2018-08-07

* Reason

This is a test appointment

Back Submit

- After clicking on **Submit** the system will display the updated table under the **Appointments** tab.

Additional Information - ↗

Appointments | Attachments | Encounters | Patient Status | Cohorts

Add Appointment			
Date	Reason	Appointment Outcome	Action
2018-08-07	This is a test appointment	Current	Action ▾

4.1.8.2 Edit an Appointment

To edit an existing appointment, locate the appointment in the table. Click the **Edit** button in the action column for the appointment date to be edited. The system will display the **Edit Appointment**.

Additional Information - ↗

Appointments | Attachments | Encounters | Patient Status | Cohorts

Add Appointment			
Date	Reason	Appointment Outcome	Action
2018-08-07	This is a test appointment	Current	Action ▾

Edit Appointment
 Delete Appointment

Make changes as needed then click the **Submit** button to complete the edit, or click the **Back** button to undo it and return to the previous page.

The system will display the updated **Appointment** Table.

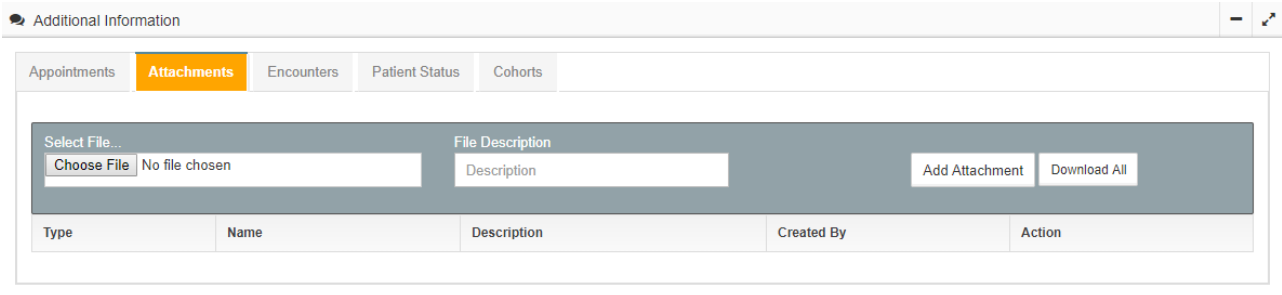
Additional Information - ↗

Appointments
Attachments
Encounters
Patient Status
Cohorts

				Add Appointment
Date	Reason	Appointment Outcome	Action	
2018-08-07	This is a test appointment	Current	Action ▼	

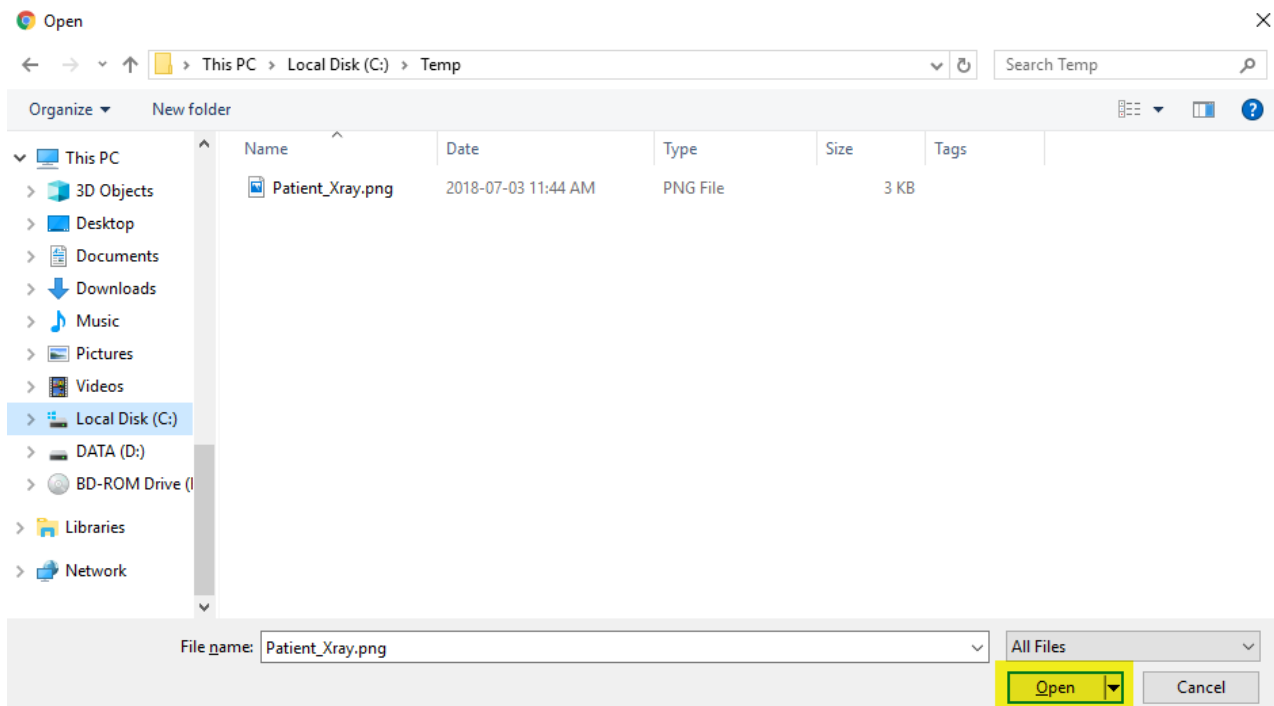
4.1.8.3 Add an Attachment

Select the **Attachments Tab** to view the list of attachments.



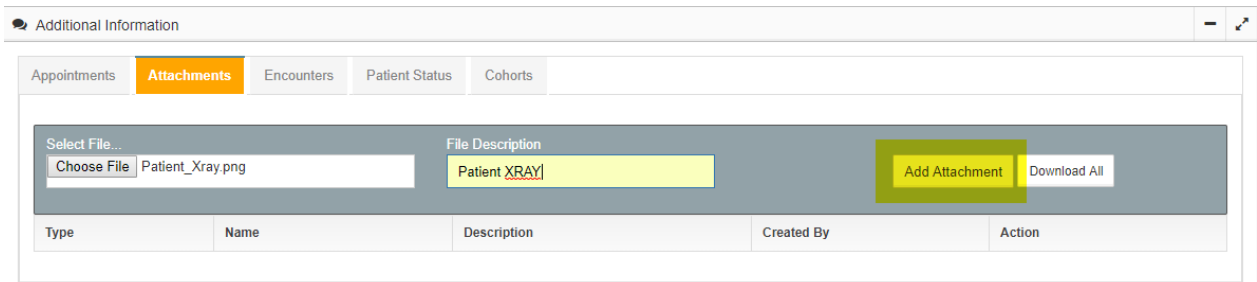
To add an attachment, click the **Choose File** button. The system will allow you then to search for the file to be attached.

Select the file to upload and click the **Open** button.

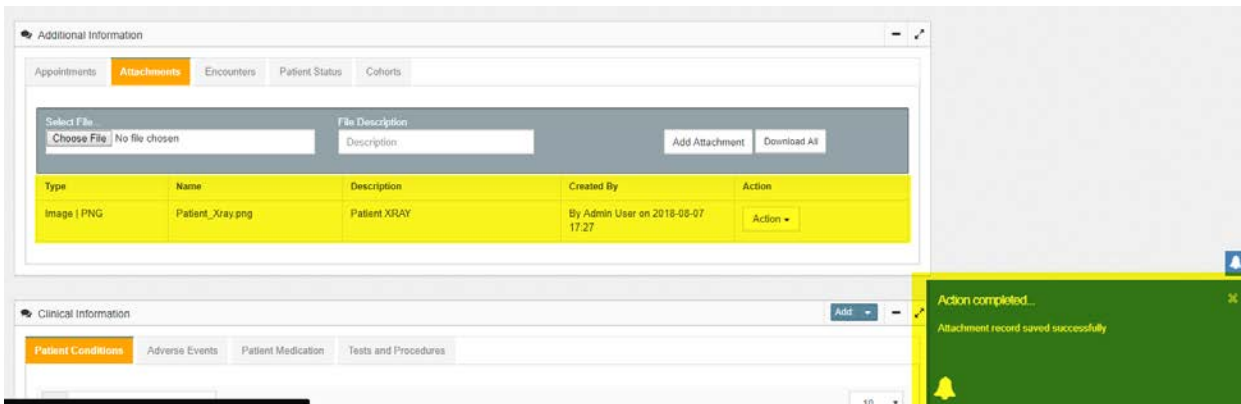


The system will return to the **Attachments Table** page and will reflect that the file that was selected. You can add a description in the **File Description** field.

Click the **Add Attachment** button to upload the attachment to PViMS.



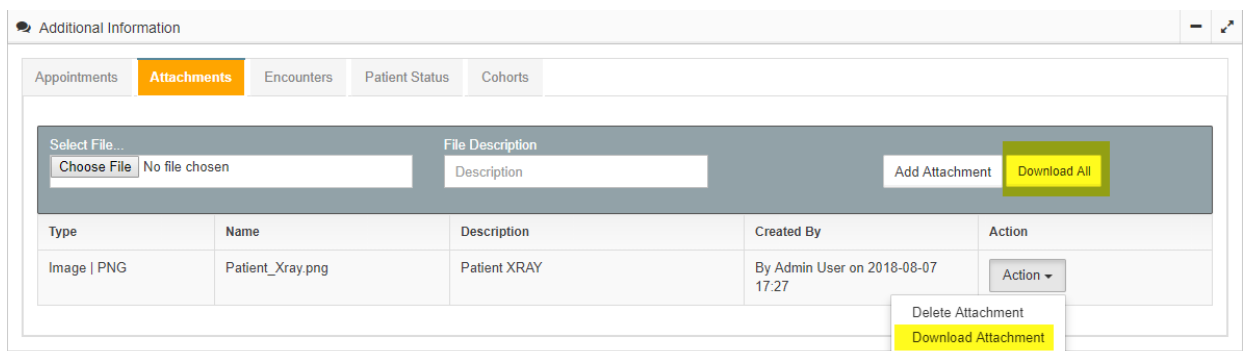
The system will show a confirmation message and an updated **Attachments Table** listing the newly added attachment.



4.1.8.4 Download an Attachment

There are two ways of downloading an attachment to your local computer for viewing. By clicking on the **Download All** button, all attachments associated with this patient will be compressed into a single zip file and downloaded to your local computer.

To download a single attachment, locate the attachment in the table, click the arrow in the action column next to the attachment to download and click the **Download Attachment** button displayed.



The screenshot shows the 'Additional Information' window with the 'Attachments' tab selected. At the top, there is a 'Select File...' section with a 'Choose File' button and a text field containing 'No file chosen'. To the right of this section are 'Add Attachment' and 'Download All' buttons. Below this is a table with the following data:

Type	Name	Description	Created By	Action
Image PNG	Patient_Xray.png	Patient XRAY	By Admin User on 2018-08-07 17:27	Action ▼

The 'Action' dropdown menu for the first row is open, showing two options: 'Delete Attachment' and 'Download Attachment'.

The system will show a message that the attachment has been **Downloaded Successfully**. The downloaded file will typically appear in your computer's **Downloads** or **My Documents** folder.

4.1.8.5 Add an Encounter



A patient may only have **one** encounter per day.

Select the **Encounters Tab** to view a list of encounters.

Additional Information		
Appointments	Attachments	Encounters
		Add Encounter
Date	Type	Action
2018-08-07	Pre-Treatment Visit	View Encounter

Click the **Add Encounter** button to add a new encounter for this patient after which the system will open the **Add Encounter** page.

Additional Information		
Appointments	Attachments	Encounters
		Add Encounter
Date	Type	Action
2018-08-07	Pre-Treatment Visit	View Encounter

- At the **Add Encounter** page click the arrow in the **Encounter Type** field. The system will display an **Encounter Type** list to select from. Select the **Encounter Type**.
- Click the arrow in the **Priority** field. The system will display a **Priority** list to select from. Select the **Priority**.
- Enter the **Encounter Date** as well as any free format **Notes** regarding the encounter as appropriate.

Add Encounter (Test Patient)

Add New Encounter

* Encounter Type
 Pre-Treatment Visit

* Priority
 Medium

* Encounter Date
 2018-08-07

Notes
 This is a test encounter

Cancel Submit

- Click the **Submit** button or click the **Cancel** button to undo the action and return to the previous page.
- After clicking the **Submit** button, the system will display **Encounters View** page where you can **Add** or **Edit** clinical information obtained during the encounter.

Encounter (Test Patient) -> View

Encounter Information

Medical Details | First-line Susceptibility | Second-line Susceptibility | TB Condition | Notes

Weight (kg)

Height (cm)

BMI
 Unable to calculate

Pregnancy Status

Injecting drug use within past year

Excessive alcohol use within the past year

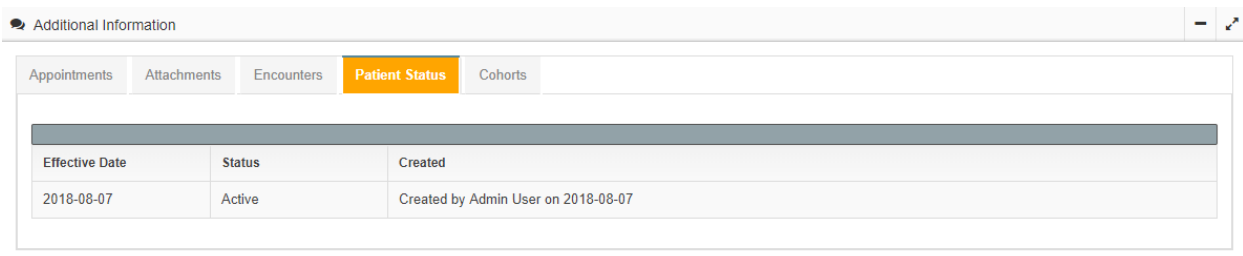
Tobacco use within the past year

Go to Patient Delete Encounter Edit Encounter

Refer to the Encounters Section for details on how to **Add** or **Edit** Encounter information. To return to the **Patient View** page click the **Go to Patient** button. The system will display the **Patient View**.

4.1.8.6 Patient Status – Read Only

Select the **Patient Status Tab** to view a history of status changes.



Effective Date	Status	Created
2018-08-07	Active	Created by Admin User on 2018-08-07

The information in the **Status Table** is view only, and cannot be updated from this page. A patient's status will change from **Active** to **Deceased** when the system is updated in the **Condition Group** section in the **Encounter View** (e.g., the patient completed treatment, died, or lost to follow-up).

4.1.8.7 Cohort Enrolment

Click the **Cohorts** tab to view a list of cohorts that the patient is or can be enrolled into.

Additional Information

Appointments Attachments Encounters Patient Status **Cohorts**

Cohort	Cohort Start	Enrolled Date	De-enrolled Date	Action
9MTR Study (OR9MT)	2016-05-01	Not Enrolled	Not De-enrolled	Enroll
BDQ Study (ORBDQ)	2016-06-01	Not Enrolled	Not De-enrolled	Enroll
9MTR Program Condition (PC9MT)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
18MTR Program Condition (PC18M)	2001-06-01	2018-08-07	Not De-enrolled	Action ▾
XDRTB Program Condition (PCXDR)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
Finn (F-16)	2015-01-01	Not Enrolled	Not De-enrolled	Enroll
Test (TestC)	2017-07-20	Not Enrolled	Not De-enrolled	Enroll

To enroll a patient in a cohort, first locate the **Cohort** in the table. Click the **Enroll** button in the action column for the cohort in which to enroll the patient.

Additional Information

Appointments Attachments Encounters Patient Status **Cohorts**

Cohort	Cohort Start	Enrolled Date	De-enrolled Date	Action
9MTR Study (OR9MT)	2016-05-01	Not Enrolled	Not De-enrolled	Enroll
BDQ Study (ORBDQ)	2016-06-01	Not Enrolled	Not De-enrolled	Enroll
9MTR Program Condition (PC9MT)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
18MTR Program Condition (PC18M)	2001-06-01	2018-08-07	Not De-enrolled	Action ▾
XDRTB Program Condition (PCXDR)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
Finn (F-16)	2015-01-01	Not Enrolled	Not De-enrolled	Enroll
Test (TestC)	2017-07-20	Not Enrolled	Not De-enrolled	Enroll



You may only enroll the patient into a cohort that is assigned to the same condition group the patient belongs to. So, for instance, an HIV patient may not be enrolled into a TB cohort.

The system will display a **Cohort Enrollment** confirmation box (Figure 81).

Cohort Enrollment

Please note! You are about to enroll this patient. Please ensure you use the correct enrollment date as this date cannot be amended once set...

Cohort Details

Cohort

9MTR Study (OR9MT)

* Enrollment Date

yyyy-mm-dd

Enroll Cancel

Enter the date the patient was enrolled in the cohort. Click the **Enroll** button to confirm or click the **Cancel** button to undo the action and return to the previous page.

Cohort Enrollment

Please note! You are about to enroll this patient. Please ensure you use the correct enrollment date as this date cannot be amended once set...

Cohort Details

Cohort

9MTR Study (OR9MT)

* Enrollment Date

2018-08-06

Enroll

Cancel

After clicking on the enroll button the system will display the updated information in the Cohort table.

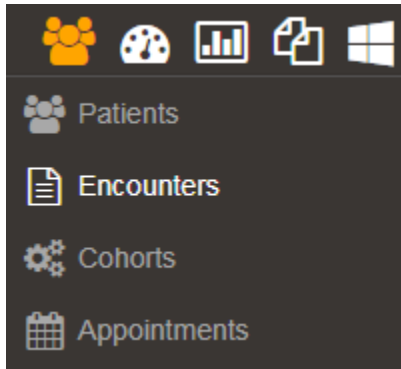
Additional Information

Appointments	Attachments	Encounters	Patient Status	Cohorts
Cohort	Cohort Start	Enrolled Date	De-enrolled Date	Action
9MTR Study (OR9MT)	2016-05-01	2018-08-06	Not De-enrolled	Action ▾
BDQ Study (ORBDQ)	2016-06-01	Not Enrolled	Not De-enrolled	Enroll
9MTR Program Condition (PC9MT)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
18MTR Program Condition (PC18M)	2001-06-01	2018-08-07	Not De-enrolled	Action ▾
XDRTB Program Condition (PCXDR)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
Finn (F-16)	2015-01-01	Not Enrolled	Not De-enrolled	Enroll
Test (TestC)	2017-07-20	Not Enrolled	Not De-enrolled	Enroll

4.2 Encounters

4.2.1 Search for an Encounter

The **Encounter Search** function can be accessed through the **Encounters** menu.

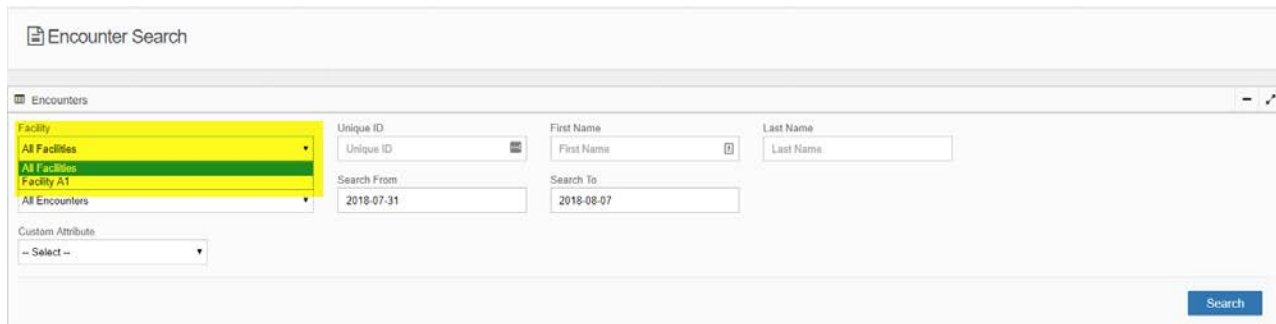


There are six ways to search for an encounter. You can search by:

- Facility
- Patient Unique ID
- First Name and Last Name
- Criteria
- Date Range
- Custom Attributes

4.2.1.1 Search by Facility

- Click the **arrow** in the **Facility** field to select from the facility drop down list.
- Select the facility you would like to search against specifically or select **All Facilities** if you would like to search against all facilities.
- Enter the **Search From** date and the **Search To** for the date range to search as it is compulsory to enter a date range.
- Click the **Search** button.



Encounter Search

Encounters

Facility

- All Facilities
- All Facilities
- Facility A1
- All Encounters

Unique ID: Unique ID

First Name: First Name

Last Name: Last Name

Search From: 2018-07-31

Search To: 2018-08-07

Custom Attribute: -- Select --

Search



You will only be able to search facilities that you have been assigned access to. Please speak to your system administrator if you are unable to search against the necessary facility.

The system will display a list of encounters according to the filter selected.

The screenshot shows the 'Encounter Search' interface. At the top, there are search filters: Facility (All Facilities), Unique ID (empty), First Name (empty), Last Name (empty), Criteria (All Encounters), Search From (2018-07-31), and Search To (2018-08-07). A 'Search' button is located at the bottom right of the filter section. Below the filters, a message states '2 row(s) matching criteria found...'. A table displays the results with columns for First Name, Last Name, Facility, Encounter Type, Date, and Action. Two rows are shown, both for 'Test' patients at 'Facility A1' with 'Pre-Treatment Visit' encounters on 2018-08-07 and 2018-08-02. A 'Showing 1 to 2 of 2 entries' message is at the bottom left, and navigation buttons (Previous, 1, Next) are at the bottom right.

4.2.1.2 Search by Patient Unique ID



Each patient is allocated a unique system ID when they are created in the system. It is possible to search for any encounters for this patient using this ID.

- If you know the patient’s unique ID, enter it in the **Unique ID** field.
- Enter the **Search From** date and the **Search To** for the date range to search as it is compulsory to enter a date range.
- Click the **Search** button.

This screenshot is identical to the one above, but the 'Unique ID' field is highlighted in yellow and contains the value '329'. The rest of the interface, including the search filters, results table, and navigation elements, remains the same.

4.2.1.3 Search by First Name or Last Name

- You can also search by the patient’s **First name** or **Last Name**. Enter the name(s) in one or both of these areas.
- Enter the **Search From** date and the **Search To** for the date range to search as it is compulsory to enter a date range.
- Click the **Search** button.



It is possible to do a partial search by entering the first letters of the **First** or **Last names**. The system will return all matching records if a partial search is executed.

Encounter Search

Encounters

Facility
All Facilities

Unique ID
Unique ID

First Name
Test

Last Name
Pat

Criteria
All Encounters

Search From
2018-07-31

Search To
2018-08-07

Custom Attribute
-- Select --

[Search](#)

2 row(s) matching criteria found...

First Name	Last Name	Facility	Encounter Type	Date	Action
Test	Patient	Facility A1	Pre-Treatment Visit	2018-08-07	View Encounter
Test	Patient	Facility A1	Pre-Treatment Visit	2018-08-02	View Encounter

Showing 1 to 2 of 2 entries

Previous [1](#) Next

4.2.1.4 Search by Criteria

- You can also search by additional **Encounter Criteria**. Click the arrow in the **Criteria** field. The system will display a list of criteria to choose from. Select the **Criteria** you would like to filter on.
- Enter the **Search From** date and the **Search To** for the date range to search as it is compulsory to enter a date range.
- Click the **Search** button.

Encounter Search

Encounters

Facility: All Facilities
 Unique ID: Unique ID
 First Name: Test
 Last Name: Pat
 Search From: 2018-07-31
 Search To: 2018-06-07

Criteria: All Encounters

All Encounters
 All Appointments
 Appointments with missed encounter
 Appointments with Did Not Arrive Status
 Appointments with encounter

Search

2 row(s) matching criteria found...

First Name	Last Name	Facility	Encounter Type	Date	Action
Test	Patient	Facility A1	Pre-Treatment Visit	2018-06-07	View Encounter
Test	Patient	Facility A1	Pre-Treatment Visit	2018-06-02	View Encounter

Showing 1 to 2 of 2 entries

Previous 1 Next

4.1.4.3 Search by Custom Attribute

The final search filter available is the ability to search by a **Custom Attribute**.



Custom attributes can be activated for filtering by the system administrator. Please consult your administrator if you would like to activate the ability to filter by a specific attribute.

- Select the custom attribute variable that you would like to search against (e.g., Medical Record Number).
- Enter the **Search From** date and the **Search To** for the date range to search as it is compulsory to enter a date range.
- Enter the search value you would like to filter against and click the **Search** button.

Encounter Search

Encounters

Facility: All Facilities | Unique ID: Unique ID | First Name: Test | Last Name: Pat

Criteria: All Encounters | Search From: 2018-07-31 | Search To: 2018-08-07

Custom Attribute: Medical Record Number | Search Value: HPRS-123-1234342

Search

2 row(s) matching criteria found...

First Name	Last Name	Facility	Encounter Type	Date	Action
Test	Patient	Facility A1	Pre-Treatment Visit	2018-08-07	View Encounter
Test	Patient	Facility A1	Pre-Treatment Visit	2018-08-02	View Encounter

Showing 1 to 2 of 2 entries

4.2.2 View an Existing Encounter

After selecting the appropriate search filter and clicking the **Search** button, the system will present all matches as displayed in a table.

The screenshot shows the 'Encounter Search' interface. It includes a search bar at the top, followed by a 'Search' button. Below the search bar, there are several filter fields: Facility (All Facilities), Unique ID (Unique ID), First Name (First Name), Last Name (Last Name), Criteria (All Encounters), Search From (2018-07-31), Search To (2018-08-07), and Custom Attribute (-- Select --). A message indicates '2 row(s) matching criteria found...'. Below this is a table with columns: First Name, Last Name, Facility, Encounter Type, Date, and Action. The table contains two rows of data, both for 'Test' patients at 'Facility A1' with 'Pre-Treatment Visit' encounters on 2018-08-07 and 2018-08-02. Each row has a 'View Encounter' button. At the bottom, it says 'Showing 1 to 2 of 2 entries' and has 'Previous' and 'Next' navigation buttons.

The columns in the encounter table are described below:

ID	Unique encounter ID number assigned by the system
First Name	Patient’s first name
Last Name	Patient’s last name
Facility	Facility where patient is registered
Encounter Type	Type of encounter (e.g., pre-treatment, treatment initiation, scheduled follow-up or unscheduled visits)
Date	Date the encounter occurred
Action	Ability to view the encounter



It is possible to filter the results of a table by entering your additional search criteria in the search text box at the top of the grid.

2 row(s) matching criteria found...

First Name	Last Name	Facility	Encounter Type	Date	Action
Test	Patient	Facility A1	Pre-Treatment Visit	2018-08-07	View Encounter
Test	Patient	Facility A1	Pre-Treatment Visit	2018-08-02	View Encounter

- To view an encounter entered in the system, locate the encounter in the encounter table.
- Click the **View Encounter** button in the **Action** column.

Encounter Search

Encounters

Facility: All Facilities | Unique ID: Unique ID | First Name: Test | Last Name: Pat

Criteria: All Encounters | Search From: 2018-07-31 | Search To: 2018-08-07

Custom Attribute: Medical Record Number | Search Value: HPRS-123-1234342

[Search](#)

2 row(s) matching criteria found...

First Name	Last Name	Facility	Encounter Type	Date	Action
Test	Patient	Facility A1	Pre-Treatment Visit	2018-08-07	View Encounter
Test	Patient	Facility A1	Pre-Treatment Visit	2018-08-02	View Encounter

Showing 1 to 2 of 2 entries

- The system will then open the **Encounter View**.

The **Encounter View** is sub-divided into the following sections:

- Medical Details
- First-Line Susceptibility
- Second-Line Susceptibility
- TB Condition
- Notes



Medical Details and **Notes** tabs will be displayed for each patient.

TB Condition, **First-Line Susceptibility**, and **Second-Line Susceptibility** tabs will only appear for patients in the **TB Condition Group** as they are specific to tuberculosis.

The system administrator is responsible for managing the **Condition Group** specific tabs.

Encounter (Test Patient) > View Online | Idle

Encounter Information

Medical Details | First-line Susceptibility | Second-line Susceptibility | TB Condition | Notes

Weight (kg)

Height (cm)

BMI
Unable to calculate

Pregnancy Status

Injecting drug use within past year

Excessive alcohol use within the past year

Tobacco use within the past year

Details

Encounter Date
2018-08-07

Encounter Type
Pre-Treatment Visit

Condition Groups

TB Case Open

Meningeal tuberculosis started on 2018-08-01

History of Weight Change (kg)

2018-08-07 : NO VALUE
2018-08-02 : NO VALUE

[Go to Patient](#) [Delete Encounter](#) [Edit Encounter](#)

4.2.3 Add or Edit Encounter Information

To edit **Encounter Information**, click the **Edit Encounter** button to change this view into edit mode.

🔗 Encounter (Test Patient) > Edit

✎ Encounter Information - ↗

Medical Details	First-line Susceptibility	Second-line Susceptibility	TB Condition	Notes
<p>Weight (kg) <input style="width: 100%;" type="text"/></p> <p>Height (cm) <input style="width: 100%;" type="text"/></p> <p>BMI <div style="background-color: #cccccc; padding: 2px;">Unable to calculate</div></p> <p>Pregnancy Status <input style="width: 100%;" type="text" value="▼"/></p> <p>Injecting drug use within past year <input style="width: 100%;" type="text" value="▼"/></p> <p>Excessive alcohol use within the past year <input style="width: 100%;" type="text" value="▼"/></p> <p>Tobacco use within the past year <input style="width: 100%;" type="text" value="▼"/></p>				

4.2.3.1 Medical Details

Fields on the **Medical Details** page are described below:

Weight	Numeric field to enter the patient’s weight in kilograms
Height	Numeric field to enter the patient’s height in centimeters
BMI	Auto-calculated by the system
Pregnancy Status	Dropdown list to indicate yes, no, uncertain or NA
Injecting Drug Use Within The Past Year	Dropdown list to indicate yes, no, or unknown
Excessive Alcohol Use Within The Past Year	Dropdown list to indicate yes, no, or unknown
Tobacco Use Within The Past Year	Dropdown list to indicate yes, no, or unknown

Add or **Edit** information on the page as appropriate. After all changes have been made, click the **Save** button to continue or click the **Cancel** button to undo the action and go back to the previous page.

After clicking the **Save** button, the system will update the **Medical Details** page.

The screenshot shows a web interface for a patient encounter. At the top, it says "Encounter (Test Patient) - View". Below this is a tabbed interface with "Medical Details" selected. The form contains the following fields:

- Weight (kg): 74
- Height (cm): 110
- BMI: 61.16
- Pregnancy Status: No
- Injecting drug use within past year: (empty dropdown)
- Excessive alcohol use within the past year: (empty dropdown)
- Tobacco use within the past year: (empty dropdown)

At the bottom of the form, there are three buttons: "Go to Patient", "Delete Encounter", and "Edit Encounter".

4.2.3.2 First-line Susceptibility

Select the **First-line Susceptibility** tab, after which the system will display clinical data related to determining susceptibility for first-line drugs.



TB Condition, First-Line Susceptibility, and Second-Line Susceptibility tabs will only appear for patients in the **TB Condition Group** as they are specific to tuberculosis.

Encounter Information

Medical Details **First-line Susceptibility** Second-line Susceptibility TB Condition Notes

Isoniazid susceptibility by any laboratory test(s)

Isoniazid confirmation

Rifampicin susceptibility by any laboratory test(s)

Rifampicin confirmation

Ethambutol susceptibility by any laboratory test(s)

Ethambutol confirmation

Pyrazinamide susceptibility by any laboratory test(s)

Pyrazinamide confirmation

Streptomycin susceptibility by any laboratory test(s)

Streptomycin confirmation

Go to Patient Delete Encounter Edit Encounter

Fields on the **First-line Susceptibility** page for each medicine are described below:

Medicine susceptibility by any laboratory test(s)	Dropdown list of test results; Indeterminate, Resistant, Susceptible, Unknown
Medicine confirmation	Dropdown list of diagnostic tools; LPA, Unknown, Xpert, DST

Add information or make changes to the fields on the page as appropriate. Click the **Save** button to continue or click the **Cancel** button to undo the action and return to the previous page.

After clicking the **Save** button the system will update the **First-line Susceptibility** page accordingly.

4.2.3.3 Second-line Susceptibility

Select the **Second-line Susceptibility** tab, after which the system will display clinical data related to determining susceptibility for second-line drugs.



TB Condition, First-Line Susceptibility, and Second-Line Susceptibility tabs will only appear for patients in the **TB Condition Group** as they are specific to tuberculosis.

Medical Details	First-line Susceptibility	Second-line Susceptibility	TB Condition	Notes
Amikacin susceptibility by any laboratory test(s)				
<input type="text"/>				
Amikacin confirmation				
<input type="text"/>				
Capreomycin susceptibility by any laboratory test(s)				
<input type="text"/>				
Capreomycin confirmation				
<input type="text"/>				
Ciprofloxacin susceptibility by any laboratory test(s)				
<input type="text"/>				
Ciprofloxacin confirmation				
<input type="text"/>				
Kanamycin susceptibility by any laboratory test(s)				
<input type="text"/>				
Kanamycin confirmation				
<input type="text"/>				
Levofloxacin susceptibility by any laboratory test(s)				
<input type="text"/>				
Levofloxacin confirmation				
<input type="text"/>				
Moxifloxacin susceptibility by any laboratory test(s)				
<input type="text"/>				
Moxifloxacin confirmation				
<input type="text"/>				
Ofloxacin susceptibility by any laboratory test(s)				
<input type="text"/>				
Ofloxacin confirmation				
<input type="text"/>				

Fields on the **Second-line Susceptibility** page for each medicine are described below:

Medicine susceptibility by any laboratory test(s)	Dropdown list of test results; Indeterminate, Resistant, Susceptible, Unknown
Medicine confirmation	Dropdown list of diagnostic tools; LPA, Unknown, Xpert, DST

Add information or make changes to the fields on the page as appropriate. Click the **Save** button to continue or click the **Cancel** button to undo the action and return to the previous page.

After clicking the **Save** button the system will update the **Second-line Susceptibility** page accordingly.

4.2.3.4 TB Condition

Select the **TB Condition** tab, after which the system will display clinical data related to TB.



TB Condition, **First-Line Susceptibility**, and **Second-Line Susceptibility** tabs will only appear for patients in the **TB Condition Group** as they are specific to tuberculosis.

Encounter (Test Patient) > View

Encounter Information

Medical Details | First-line Susceptibility | Second-line Susceptibility | **TB Condition** | Notes

Previous TB treatment?

Site of TB

Documented HIV infection

Go to Patient | Delete Encounter | Edit Encounter

Fields on the **TB Conditions** page are described below:

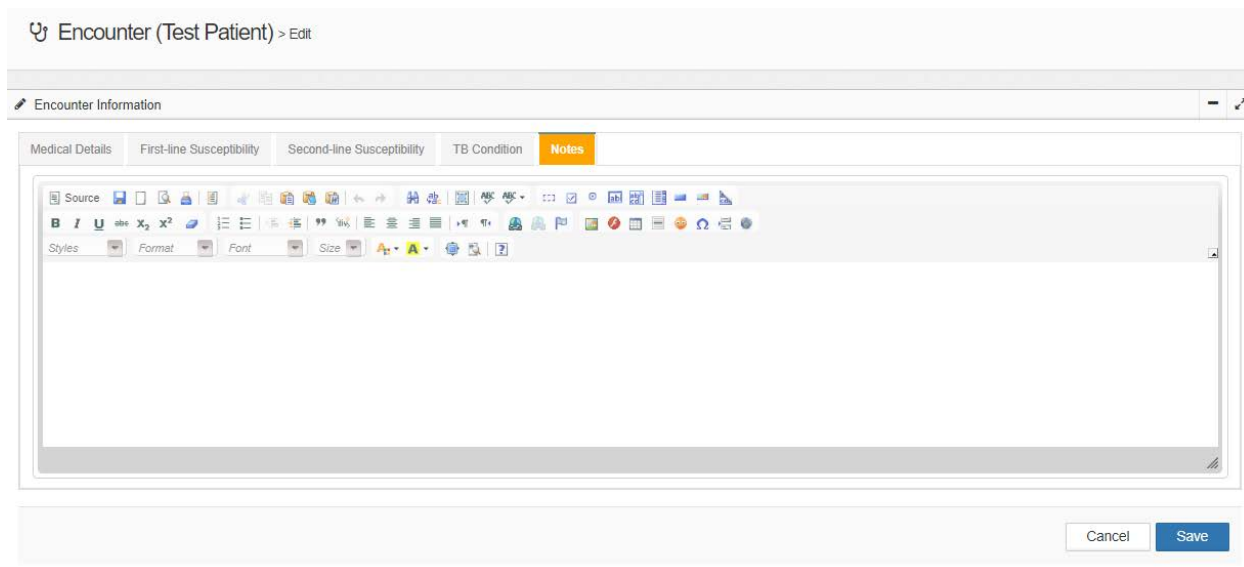
Previous TB treatment?	Dropdown list of responses; No, Unknown, Yes
Site of TB	Dropdown list of anatomical sites
Documented HIV infection	Dropdown list of responses; No, Unknown, Yes

Add information or make changes to the fields on the page as appropriate. Click the **Save** button to continue or click the **Cancel** button to undo the action and return to the previous page.

After clicking the **Save** button the system will update the **TB Conditions** page accordingly.

4.2.3.5 Notes

Select the **Notes** tab, after which the system will display the free format notes field for this patient's encounter.



Add information or make changes to the notes as appropriate. Click the **Save** button to continue or click the **Cancel** button to undo the action and return to the previous page.

After clicking the **Save** button the system will update the **Notes** page accordingly.

4.2.4 Add or Edit Clinical Information

The Clinical Information section is divided into four tabs:

- Patient Conditions
- Adverse Events
- Patient Medication
- Tests and Procedures

Clinical Information

10

Condition Name	Start Date	Outcome Date	Outcome	Actions
Meningeal tuberculosis	2018-08-01			Action

Showing 1 to 1 of 1 entries

Previous 1 Next

4.2.4.1 Add Patient Condition

At the **Patient Conditions** tab click the **Add Patient Condition** button, after which the system will open the **Add Patient Condition** page.

Clinical Information

Condition Name	Start Date	Outcome Date	Outcome	Actions
Meningeal tuberculosis	2018-08-01			Action

Showing 1 to 1 of 1 entries

Previous 1 Next

Add

- Patient Condition
- Adverse Event
- Patient Medication
- Tests and Procedures

Enter the condition name in the **Find By Term** field. Click the **Search** button and the system will then provide a list of **Term Results** from the MedDRA dictionary that match the term that you have searched on.

MedDRA Terminology

Term Type
 Lowest Level Term

Find By Term
 Hypertension

Search

Term Results

- Accelerated hypertension
- Associated with pulmonary arterial hypertension
- Benign essential hypertension
- Benign essential hypertension antepartum
- Benign essential hypertension comp preg, childbirth, and the puerperium, unspc as to eoc
- Benign essential hypertension complicating pregnancy, childbirth, and the puerperium
- Benign essential hypertension complicating pregnancy, childbirth, and the puerperium, unspecified as
- Benign essential hypertension with delivery
- Benign essential hypertension, postpartum
- Benign essential hypertension, with delivery, with mention of postpartum complication

- Select the corresponding term.
- Enter the **Condition Start Date** and complete the remaining fields as appropriate.
- Click the **Submit** button to create the condition, or click the **Back** button to cancel the action and go back to the previous page.
- After clicking on **Submit** the system will display the updated the table under the **Patient Conditions** tab.

Clinical Information Add: - ↗

Patient Conditions | Adverse Events | Patient Medication | Tests and Procedures

Q 10

Condition Name	Start Date	Outcome Date	Outcome	Actions
Hypertension ocular	2018-08-01	2018-08-01	Recovered/Resolved With Sequelae	Action
Meningeal tuberculosis	2018-08-01			Action

Showing 1 to 2 of 2 entries Previous 1 Next

The fields on the **Add Patient Condition** page are described below:

Term Type	Dropdown list of MedDRA term hierarchy; Lowest level term, Preferred term, High level term, High level group term, or System organ class
Find By Term	Text field; Enter name of condition
Term Results	System generated list; Select appropriate term
Condition Start Date	Text field; Enter date condition started
Condition Outcome	Dropdown list of Outcomes; Select either Fatal, Not Recovered/Not Resolved, Recovered/Resolved, Recovered/Recovered with Sequelae, Recovering/Resolving, or Unknown
Condition Outcome Date	Text field; Enter condition outcome date
Treatment Outcome	Dropdown list of Outcomes; Select either Cured, Died, Lost to Follow-up, Not evaluated, Treatment Completed, or Treatment Failed
Comments	Text field; Enter comments about the condition not captured on the page
Condition Ongoing	Dropdown list of options; Select either No, Unknown, or Yes



The **Term Type** field displays the level of MedDRA hierarchy terms (from very general to very specific) to display. The table below describes the five levels.

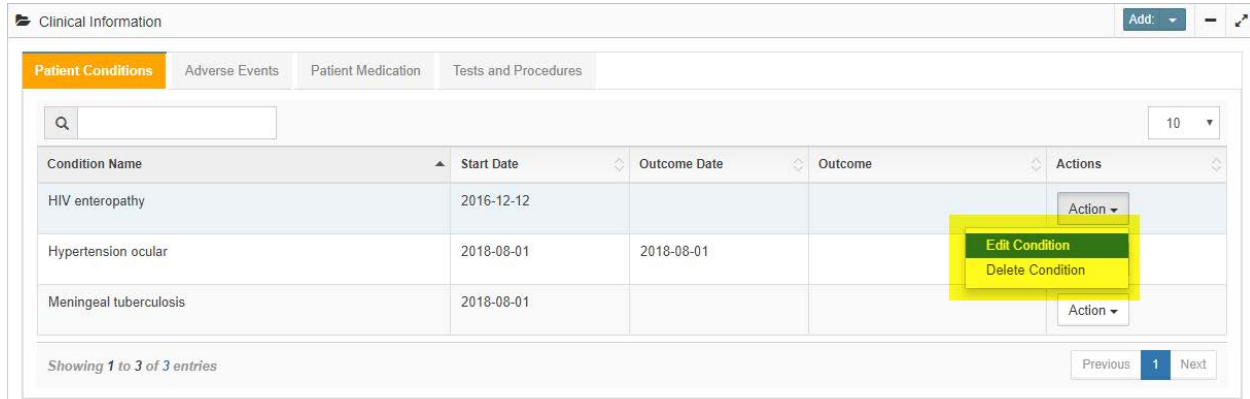
Level	Example
System Organ Class	Gastrointestinal Disorders
High Level Group Term	Gastrointestinal Signs and Symptoms
High Level Term	Nausea and Vomiting Symptoms
Preferred Term	Nausea
Lowest Level Term	Feeling Queasy

At the most specific level, called “Lowest Level Terms” (LLTs), there are more than 70,000 terms that parallel how information is communicated. These LLTs reflect how an observation might be reported in practice. This level directly supports assigning MedDRA terms within the PViMS database.

When the new condition is a **Condition Group Term**, a corresponding **Condition Group** button will appear in the encounter view.

4.2.4.2 Edit a Patient Condition

At the patient's **Encounter View** page, start on the **Patient Condition** tab, find the condition to edit in the **Patient Condition Table** and click the **Edit** button. The system will display the patient's **Edit Condition** page.



Condition Name	Start Date	Outcome Date	Outcome	Actions
HIV enteropathy	2016-12-12			Action ▾
Hypertension ocular	2018-08-01	2018-08-01		Edit Condition Delete Condition Action ▾
Meningeal tuberculosis	2018-08-01			Action ▾

Showing 1 to 3 of 3 entries

Previous 1 Next

Add information or make changes to the page **Condition Start Date**, **Condition Outcome**, **Treatment Outcome**, **Comments**, or **Condition Ongoing** fields as appropriate.

NOTE: The system will not allow you to change the Patient's Condition **MedDRA Term**. To change the **MedDRA Term** you will need to delete the record and enter the Patient Condition as a new entry.

Click the **Submit** button or click the **Back** button to cancel the action and return to the previous page.

After clicking the **Submit** button, the system will display a confirmation message.



Click the **OK** button.



The system will remind you to ensure the patient medication history is updated accordingly.

The system will take you to the **Encounter View Page** and will display the updated **Conditions Table**.

Clinical Information Add: ▾ - ↗

Patient Conditions | Adverse Events | Patient Medication | Tests and Procedures

Q 10 ▾

Condition Name ▲	Start Date ◇	Outcome Date ◇	Outcome ◇	Actions ◇
HIV enteropathy	2016-12-12	2018-08-08	Fatal	Action ▾
Hypertension ocular	2018-08-01	2018-08-01	Recovered/Resolved With Sequelae	Action ▾
Meningeal tuberculosis	2018-08-01			Action ▾

Showing 1 to 3 of 3 entries Previous 1 Next



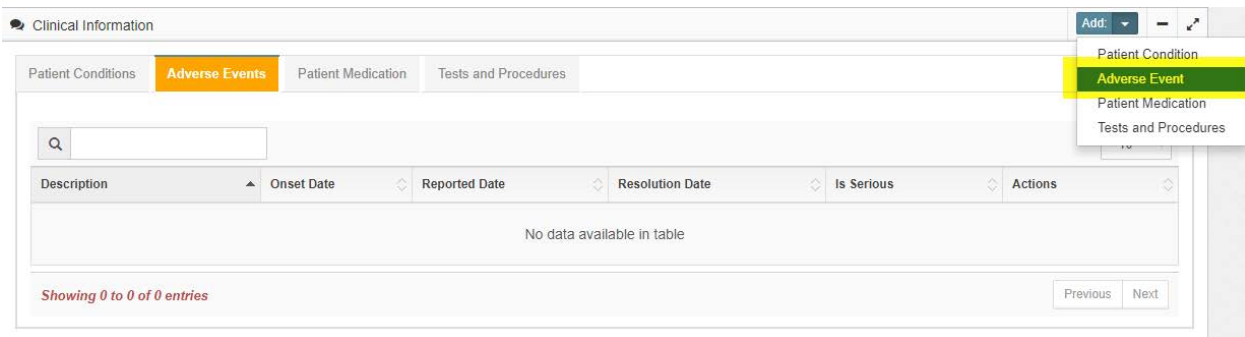
If the patient's outcome has been set to fatal, the system will request confirmation of this status change.

Fatal Outcome!

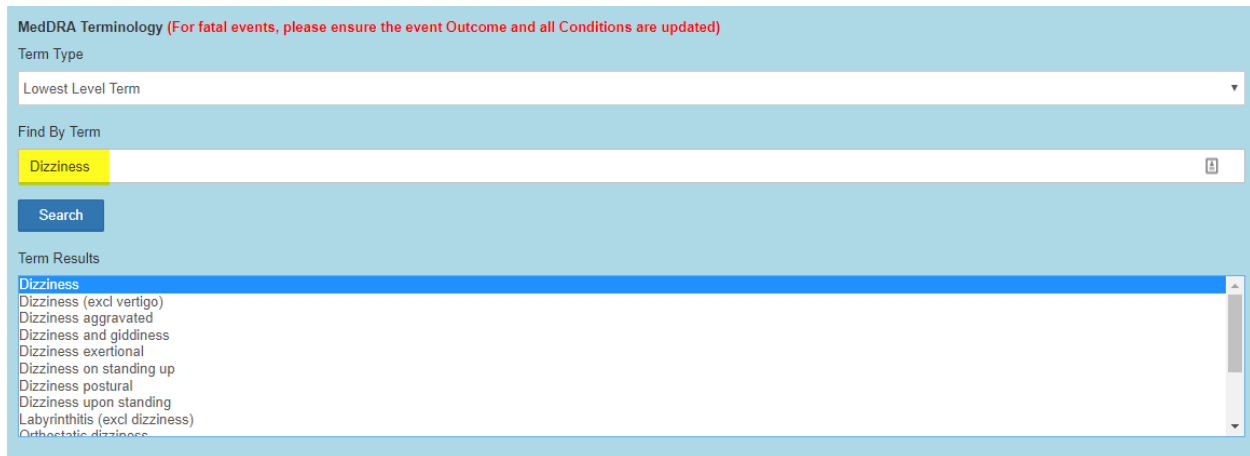
Are you sure you would like to confirm this patient is deceased?

4.2.4.3 Add Adverse Event

At the **Adverse Events** tab click the **Add Adverse Event** button, after which the system will open the **Add Adverse Event** page.



Enter the Adverse Event name in the **Find By Term** field. Click the **Search** button and the system will then provide a list of **Term Results** from the MedDRA dictionary that match the term that you have searched on.



- Select the term that best corresponds to the adverse event.
- Enter the **Event Description as stated by the patient or reporter.**
- Enter the Adverse Event **Onset Date.**
- Complete any other fields for which you have data.
- Click the **Submit** button to create the adverse event, or click the **Back** button to cancel the action and go back to the previous page.
- After clicking on **Submit** the system will display the updated table under the **Adverse Events** tab.

Clinical Information Add: ▾ - ↗

Patient Conditions
Adverse Events
Patient Medication
Tests and Procedures

10 ▾

Description	Onset Date	Reported Date	Resolution Date	Is Serious	Actions
Dizziness	2018-08-08				Action ▾

Showing 1 to 1 of 1 entries Previous 1 Next

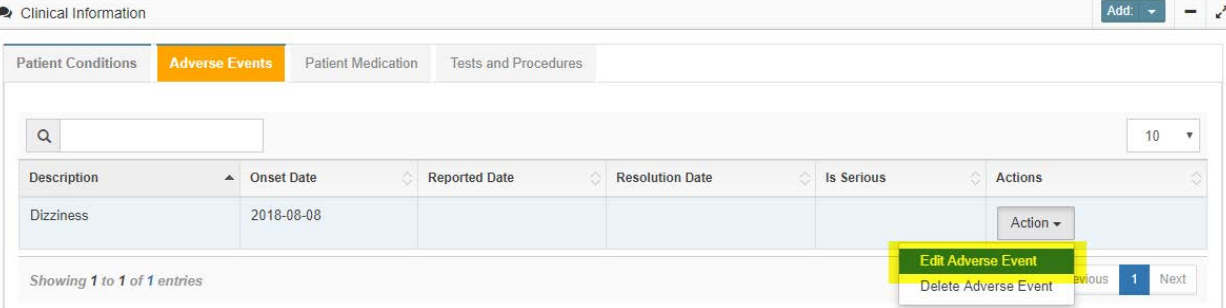
The fields on the **Add Adverse Event** page are described below:

Term Type	Dropdown list of MedDRA term hierarchy; Lowest level term, Preferred term, High level term, High level group term, or System organ class
Find By Term	Text field; Enter name of condition
Term Results	System generated list; Select appropriate term from the list
Event Description (As stated by patient or reporter)	Text field; enter event term as stated in the medical records
Onset Date	Text field; Enter date condition started
Resolution Date	Text field; Enter condition outcome date
Event Duration	Auto-calculated by the system
Intensity (Severity)	Dropdown list; Select from Mild, Moderate, or Severe
Treatment of Reaction	Dropdown list; Select from No Treatment, Non-Medical Treatment, Medical Treatment, Dialysis, Surgery, or Unknown
Was the AE attributed to one or more drugs?	Dropdown list; Select from Yes, No, or Unknown
Expected or Unexpected AE	Dropdown list; Select from Expected or Unexpected
Outcome	Dropdown list of Outcomes; Select either Fatal, Not Recovered/Not Resolved, Recovered/Resolved, Recovered/Recovered with Sequelae, Recovering/Resolving, or Unknown
Was the event reported to national PV?	Dropdown list; Select from Yes, No, or Unknown
Is the adverse event serious?	Dropdown list; Select from Yes, No, or Unknown
Seriousness	Dropdown list; Select from Congenital Anomaly or Birth Defect, Persistent or Significant Disability or Incapacity, Death, Initial or Prolonged Hospitalization, Life-threatening, or a Medically Important event
Admission Date	Text field; Enter date patient was admitted

(will only appear if Hospitalized)	
Discharge Date (will only appear if Hospitalized)	Text field; Enter date patient was discharged
Date of Death (will only appear if reason for Seriousness is Death)	Text field; Enter date patient died
Autopsy Done? (will only appear if reason for Seriousness is Death)	Dropdown list; Select from Yes or No
Severity Grade	Dropdown list; Select from Grade 1, Grade 2, Grade 3, Grade 4, or Grade 5
Severity Grading Scale	Dropdown list; Select the SAE Grading Reference (e.g., DAIDS, CTCAE)
Full Name of Reporter	Text field; Enter name of the person who reported the event
Date of Report	Text field; enter the date the event was first reported by the facility
Type of Reporter	Dropdown list; Select from Physician, Pharmacist, Other Health Professional, Lawyer, Consumer or Other Non-Health Professional
Reporter Contact Number	Text field; Enter a contact number for the reporter
FDA SAE Number (For use only by FDA officers)	Text field; Enter the SAE file number assigned by the FDA

4.2.4.4 Edit an Adverse Event

At the patient's **Encounter View** page, start on the **Adverse Event** tab, find the event to edit in the **Adverse Events Table** and click the **Edit** button. The system will display the patient's **Edit Adverse Event** page.



Clinical Information Add: ▾ - ↗

Patient Conditions **Adverse Events** Patient Medication Tests and Procedures

Q 10 ▾

Description	Onset Date	Reported Date	Resolution Date	Is Serious	Actions
Dizziness	2018-08-08				Action ▾

Showing 1 to 1 of 1 entries

Previous 1 Next

NOTE: The system will not allow you to change the Patient's Adverse Event **MedDRA Term**. To change the **MedDRA Term** you will need to delete the record and enter the Patient Adverse Event as a new entry.

Add information or make changes to the page as appropriate.

Click the **Submit** button or click the **Back** button to cancel the action and return to the previous page.

The system will take you to the **Encounter View Page** and will display the updated **Adverse Events Table**.



Clinical Information Add: ▾ - ↗

Patient Conditions **Adverse Events** Patient Medication Tests and Procedures

Q 10 ▾

Description	Onset Date	Reported Date	Resolution Date	Is Serious	Actions
Dizziness	2018-08-08		2018-08-08		Action ▾

Showing 1 to 1 of 1 entries

Previous 1 Next

4.2.4.5 Add a Patient Medication

At the **Patient Medications** tab click the **Add Patient Medication** button, after which the system will open the **Add Patient Medication** page.

- Select the medication.
- Enter the date the patient started taking the medicine.
- Complete any other fields for which you have data.
- Click the **Submit** button to create the medication, or click the **Back** button to cancel the action and go back to the previous page.
- After clicking on **Submit**, the system will display the updated table under the **Patient Medication** tab.

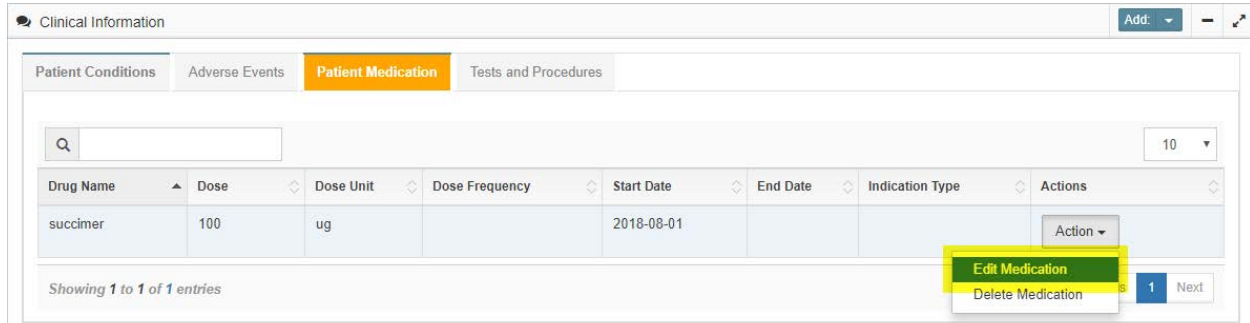
Drug Name	Dose	Dose Unit	Dose Frequency	Start Date	End Date	Indication Type	Actions
succimer	100	ug		2018-08-01			Action

The fields on the **Add Patient Medication** page are described below:

Medication	Dropdown list; Select medication from a list managed by the system administrator
Start Date	Text field; Enter date patient started taking the medication
End Date	Text field; Enter date patient stopped taking the medication
Dose	Text field; Enter the dose prescribed
Dose Unit	Dropdown list; Select the unit prescribed
Dose Frequency	Text field; Enter the dose frequency prescribed
Route	Dropdown list; Select the route of administration
Frequency in <small>days</small> per week	Dropdown list; Select number of days per week the medicine is administered
Still On Medication	Dropdown list; Select Yes or No
Indication	Text field; Enter the reason the medicine was prescribed
Type of Indication	Dropdown list; Select Primary, Pre-existing Condition, or Treat AE
Reason For Stopping	Dropdown list; Select from the list provided (e.g., Adverse Event, Cost, Course Completed)
Clinician action taken with regard to medicine if related to AE	Dropdown list; Select Dose Not Changed, Dose Reduced, Drug Interrupted, Drug Withdrawn, or Not Applicable
Batch Number	Text field; Enter the medicine Batch Number
Effect OF Dechallenge (D) & Rechallenge (R)	Dropdown list; Select from the list provided (e.g., Not Applicable, D – AE improved/resolved when medicine dose reduced/interrupted/withdrawn, R – AE Recurred on medicine re-admission/dose increase)

4.2.4.6 Edit an Existing Patient Medication

At the patient's **Encounter View** page, start on the **Patient Medication** tab, find the medication to edit in the **Patient Medications Table** and click the **Edit** button. The system will display the patient's **Edit Patient Medication** page.



Clinical Information

Patient Conditions Adverse Events **Patient Medication** Tests and Procedures

10

Drug Name	Dose	Dose Unit	Dose Frequency	Start Date	End Date	Indication Type	Actions
succimer	100	ug		2018-08-01			Action

Showing 1 to 1 of 1 entries

Edit Medication
Delete Medication

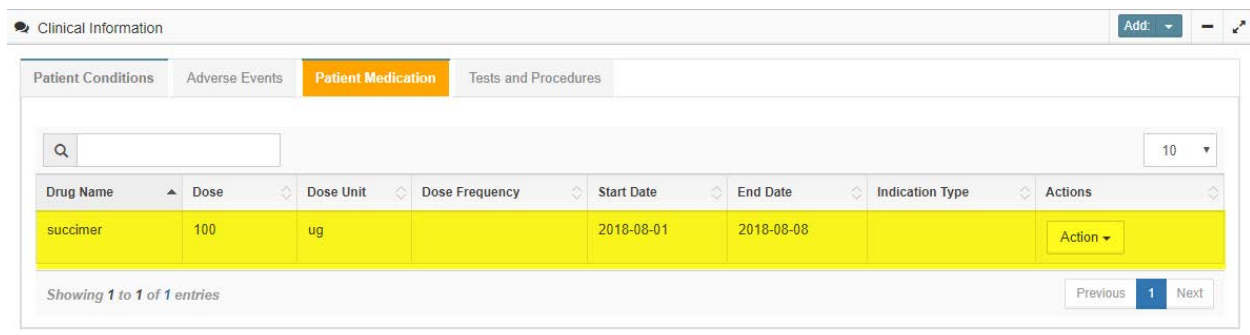
1 Next

NOTE: The system will not allow you to change the **Medication** name. To change the **Medication**, you will need to delete the record and enter the **Medication** as a new entry.

Add information or make changes to the page as appropriate.

Click the **Submit** button or click the **Back** button to cancel the action and return to the previous page.

The system will take you to the **Encounter View Page** and will display the updated **Patient Medication** Table.



Clinical Information

Patient Conditions Adverse Events **Patient Medication** Tests and Procedures

10

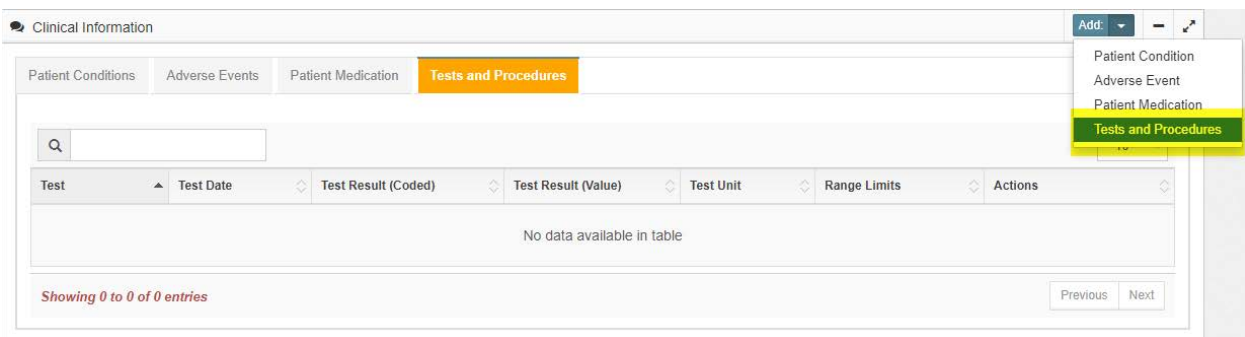
Drug Name	Dose	Dose Unit	Dose Frequency	Start Date	End Date	Indication Type	Actions
succimer	100	ug		2018-08-01	2018-08-08		Action

Showing 1 to 1 of 1 entries

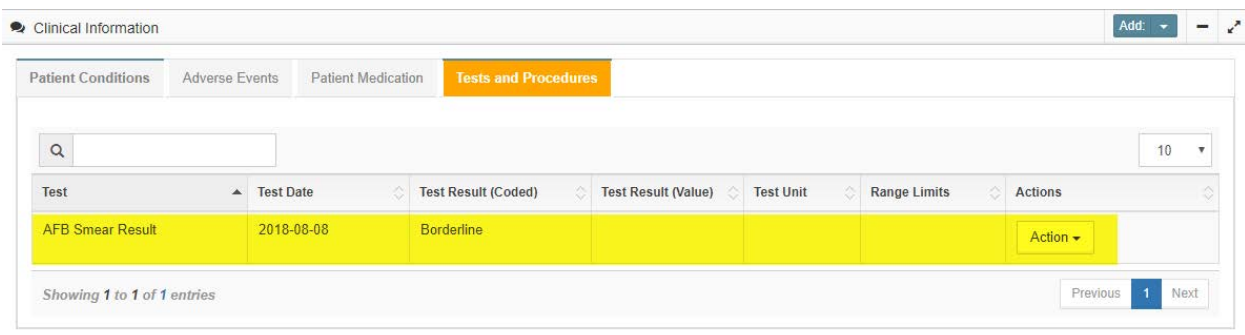
Previous 1 Next

4.2.4.7 Add a Test or Procedure

At the **Tests and Procedures** tab click the **Add Tests and Procedures** button, after which the system will open the **Add Tests and Procedures** page.



- Select the test or procedure.
- Enter the date the patient had the test completed.
- Complete any other fields for which you have data.
- Click the **Submit** button to create the test and procedure, or click the **Back** button to cancel the action and go back to the previous page.
- After clicking on **Submit** the system will display the updated the table under the **Tests and Procedures** tab.

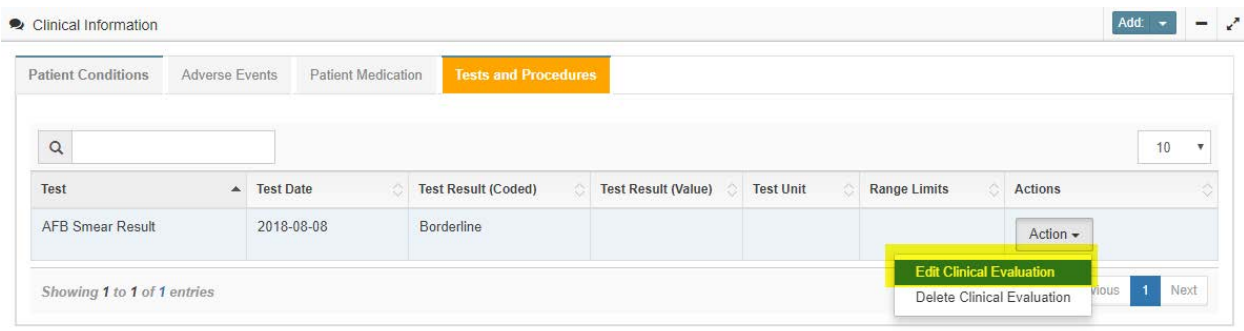


The fields on the **Tests and Procedures** page are described below:

Test	Dropdown list; Select name of the Test or Procedure (e.g., Blood Glucose, Chest X-ray)
Test Date	Text field (dates only); Enter date the Test or Procedure was performed
Test Result (coded)	Dropdown list; Select qualitative Test or Procedure result (e.g., Positive, Negative, Normal, Abnormal) if appropriate
Test Result (value)	Text field (numbers only); Enter the value for the test result
Reference Range – Lower Limit	Text field (numbers only); Enter the value for the lower limit of normal defined by the laboratory
Reference Range – Upper Limit	Text field (numbers only); Enter the value for the upper limit of normal defined by the laboratory
Test Unit	Dropdown list; select corresponding unit for the Test or Procedure Result (e.g., %, mg, millisecond)
Remarks	Text field; Enter additional information about the Test or Procedure if needed

4.2.4.8 Edit an Existing Test or Procedure

At the patient’s **Encounter View** page, start on the **Tests and Procedures** tab, find the test to edit in the **Tests and Procedures Table** and click the **Edit** button. The system will display the patient’s **Edit Test and Procedure** page.

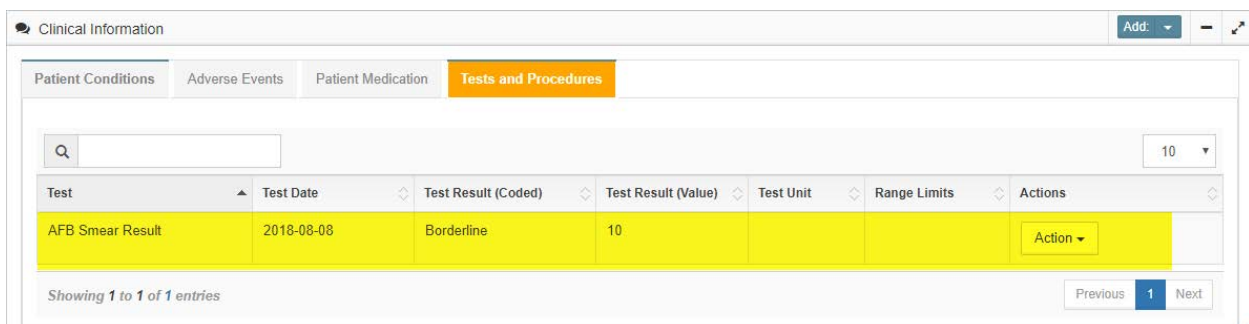


NOTE: The system will not allow you to change the **Test** or **Procedure** name. To change the **Test** or **Procedure** name you will need to delete the record and enter the **Test** or **Procedure** as a new entry.

Add information or make changes to the page as appropriate.

Click the **Submit** button or click the **Back** button to cancel the action and return to the previous page.

The system will take you to the **Encounter View Page** and will display the updated **Tests and Procedures Table**.

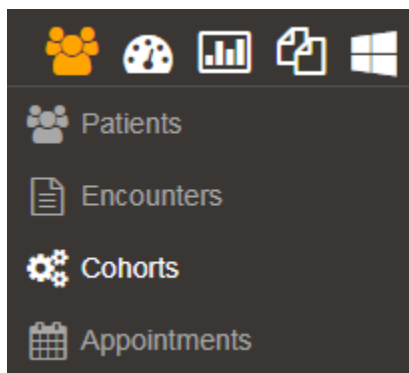


4.3 Cohorts

Cohorts can be used to track a sub-group of patients within a Condition Group. Cohorts in the system are determined by the Public Health Program or the System Administrator.

4.3.1 View Cohorts

The **Cohort** function can be accessed through the **Cohorts** menu.



The system will display the **Cohorts View** page, which lists all currently registered cohorts in the system.

⚙️ Cohorts

[Add Cohort](#)

Q 10 ▾

ID	Cohort Name	Cohort Code	# Patients	Start Date	Finish Date	Action
1	9MTR Study	OR9MT	4	2016-05-01	2018-02-23	Action ▾
2	BDQ Study	ORBDQ	1	2016-06-01	2016-12-19	Action ▾
3	9MTR Program Condition	PC9MT	1	2001-05-01	2099-12-31	Action ▾
4	18MTR Program Condition	PC18M	1	2001-05-01	2099-12-31	Action ▾
5	XDRTB Program Condition	PCXDR	0	2001-06-01	2099-12-31	Action ▾
7	Firm	F-16	0	2015-01-01	0001-01-01	Action ▾
8	Test	TestC	0	2017-07-20	2019-07-31	Action ▾

Showing 1 to 7 of 7 entries Previous 1 Next

Find the **Cohort** you would like to view in the table. Click the **View Cohort** button in the Action Column for the cohort to view.

ID	Cohort Name	Cohort Code	# Patients	Start Date	Finish Date	Action
1	9MTR Study	OR9MT	4	2016-05-01	2018-02-23	Action - View Cohort Edit Cohort
2	BDQ Study	ORBDQ	1	2016-06-01	2016-12-19	Action -
3	9MTR Program Condition	PC9MT	1	2001-06-01	2099-12-31	Action -
4	18MTR Program Condition	PC18M	1	2001-06-01	2099-12-31	Action -
5	XDRTB Program Condition	PCXDR	0	2001-06-01	2099-12-31	Action -
7	Finn	F-16	0	2015-01-01	0001-01-01	Action -
8	Test	TestC	0	2017-07-20	2019-07-31	Action -

Showing 1 to 7 of 7 entries

The system will display the **Cohort View** page with a table listing all of the patients enrolled in that cohort.

Patient Name	Facility	Age	Last Encounter	Current Weight	Adverse Reactions (Confirmed)	Action
Test Patient	Facility A1 FAC-01	1963-01-01 55	2018-08-07	74	NO CONFIRMED REACTIONS	View Patient
Unique PatientFive	Facility A1 FAC-01	2014-03-01 4	2017-06-12	NO VALUE	NO CONFIRMED REACTIONS	View Patient
Unique PatientSix	Facility A1 FAC-01	1996-11-01 21	2017-01-25	NO VALUE	NO CONFIRMED REACTIONS	View Patient
Unique PatientTwentyOne	Facility A1 FAC-01	1943-01-01 75	No Encounters	NO VALUE	NO CONFIRMED REACTIONS	View Patient

Showing 1 to 4 of 4 entries

From the **Cohort View** page, you are able to view a patient enrolled in the cohort. Find the patient to view in the table.

Cohort View

Cohort View

Cohort Name: 9MTR Study Cohort Code: ORSMT

Q

Patient Name	Facility	Age	Last Encounter	Current Weight	Adverse Reactions (Confirmed)	Action
Test Patient	Facility A1 FAC-01	1963-01-01 55	2018-08-07	74	NO CONFIRMED REACTIONS	View Patient
Unique PatientFive	Facility A1 FAC-01	2014-03-01 3	2017-06-12	NO VALUE	NO CONFIRMED REACTIONS	View Patient
Unique PatientSix	Facility A1 FAC-01	1996-11-01 21	2017-01-25	NO VALUE	NO CONFIRMED REACTIONS	View Patient
Unique PatientTwentyOne	Facility A1 FAC-01	1943-01-01 75	No Encounters	NO VALUE	NO CONFIRMED REACTIONS	View Patient

Showing 1 to 4 of 4 entries Previous **1** Next

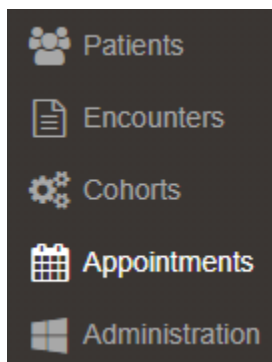
Click the **View Patient** button in the Action column for the patient to view. The system will display the **Patient View** page.

4.4 Appointments

Appointments can be used to monitor an patient return date to the facility. This is particularly effective for patients in a cohort where ongoing monitoring for adverse events is expected.

4.4.1 View Appointments

The **Appointments** function can be accessed through the **Appointments** menu.



The system will display the **Appointments** page, which lists all appointments registered within the system for a given date.

📅 Appointments

Show appointments for:

1 row(s) matching criteria found...

10 ▾

Patient Name	Details	Activity	Action
Unique PatientOne	Patient has a follow up appointment today	Patient has not arrived yet...	Action ▾

Showing 1 to 1 of 1 entries

The columns in the appointments table are described below:

Patient Name	Reflecting the patient's name and surname as captured in the system when the appointment was scheduled.
Details	Reason for the appointment
Activity	Has the patient arrived for their appointment? Has the patient missed their appointment?
Action	Ability to view patient Ability to open an encounter Ability to mark the appointment as Did Not Arrive

PViMS Term - Did Not Arrive

If an appointment is marked as **Did Not Arrive**, this means the patient has been confirmed as missing their appointment. This status serves to confirm this scenario in situations where encounters are retrospectively captured into the system in a delayed data capture mode.

4.4.2 View Appointments for a specified day

Enter the specified day in the **Show Appointments For** field and click the **Search** button. The system will display the **Appointments** page for the specified day.

The screenshot shows the 'Appointments' page. At the top, there is a search bar labeled 'Show appointments for:' with the date '2017-01-31' entered and a 'Search' button. Below the search bar, it indicates '1 row(s) matching criteria found...'. A table with columns 'Patient Name', 'Details', 'Activity', and 'Action' is displayed. The table contains one row with 'Unique PatientOne' as the patient name, 'test' as details, and 'Patient has not arrived yet...' as activity. The 'Action' column has a dropdown menu. At the bottom, it says 'Showing 1 to 1 of 1 entries' and has navigation buttons for 'Previous', '1', and 'Next'.

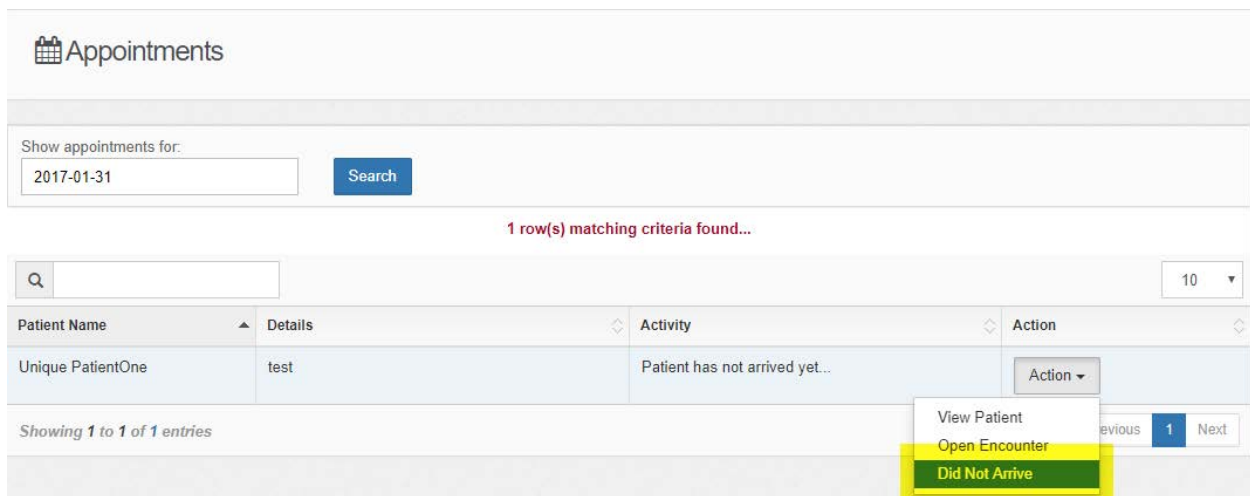
4.4.3 View Patient Record

Select the patient in the table whose record you wish to view and click the **View Patient** button. The system will display the **Patient View** page for the selected patient.

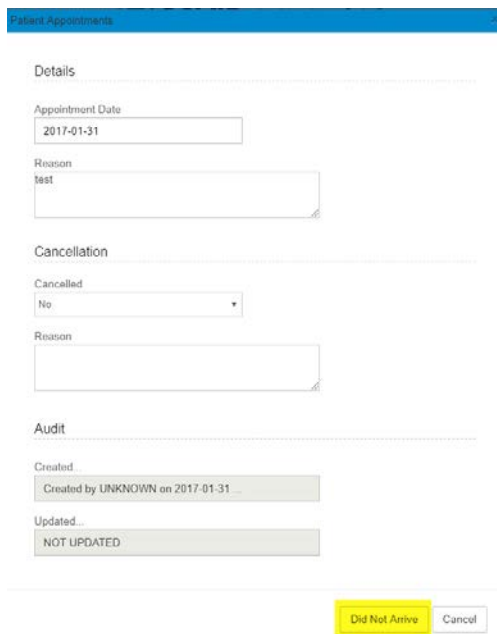
This screenshot is similar to the previous one, but with a dropdown menu open for the 'Action' column of the table. The menu options are 'View Patient', 'Open Encounter', and 'Did Not Arrive'. The 'View Patient' option is highlighted with a yellow box. The rest of the page, including the search bar and table structure, remains the same.

4.4.4 Mark Appointment as Did Not Arrive


Select the patient in the table whose record you wish to confirm as did not arrive and click the **Did Not Arrive** Button.



Click the **Did Not Arrive** button to confirm that the patient did not arrive for their visit.



The system will update the appointment with the update reflected in the appointments table.

 Appointments

Show appointments for:

1 row(s) matching criteria found...

Patient Name	Details	Activity	Action
Unique PatientOne	test	Appointment has been marked as Did Not Arrive	Action ▾

Showing 1 to 1 of 1 entries Previous **1** Next



You will not be able to mark an appointment as DNA until at least 3 days have passed from the original appointment date.

4.5 Deleting Records

User rights assignment policies determine which Users or User Profile groups are able to delete records from the system. Check with your administrator regarding user right assignments.



After deletion the record is placed in an archive, thus not permanently deleted from the system.

4.5.1 Patient View - Additional Information

4.5.1.1 Delete an Appointment

Within the **Patient View**, at the **Appointments** tab, find the appointment you would like to delete.

Additional Information

Appointments Attachments Encounters Patient Status Cohorts

Add Appointment

Date	Reason	Appointment Outcome	Action
2017-02-02	Monthly appointment	Current	Action ▾
2018-08-30	This is a test appointment for deletion	Current	Action ▾

Edit Appointment
Delete Appointment



You will only have the opportunity to delete appointments within the future. Existing appointments will need to be cancelled.

Click the **Delete Appointment** button after which the system will take you to a **Delete Appointment** screen.

Appointment > Delete

Delete Appointment (Unique PatientTwo)

Please note! You are about to delete this record. This action is not reversible....

Basic Details

Appointment Date
2018-08-30

* Reason

Back Delete

Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the appointment or click the **Back** button to undo the action.

After confirming the deletion, the system will update the **Appointment** table.

Additional Information

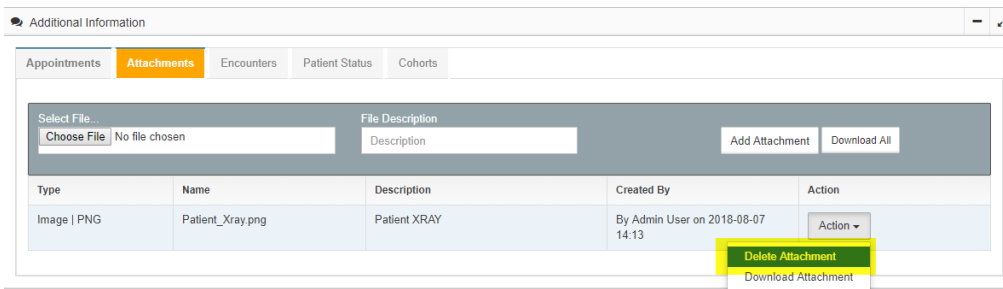
Appointments Attachments Encounters Patient Status Cohorts

Add Appointment

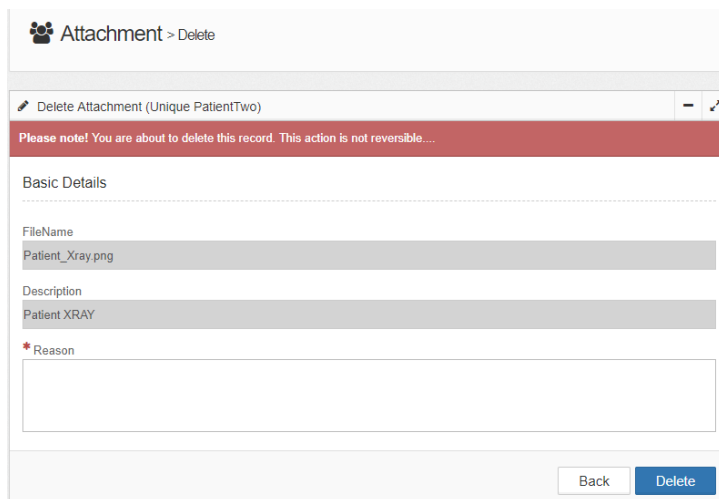
Date	Reason	Appointment Outcome	Action
2017-02-02	Monthly appointment	Current	Action ▾

4.5.1.2 Delete an attachment

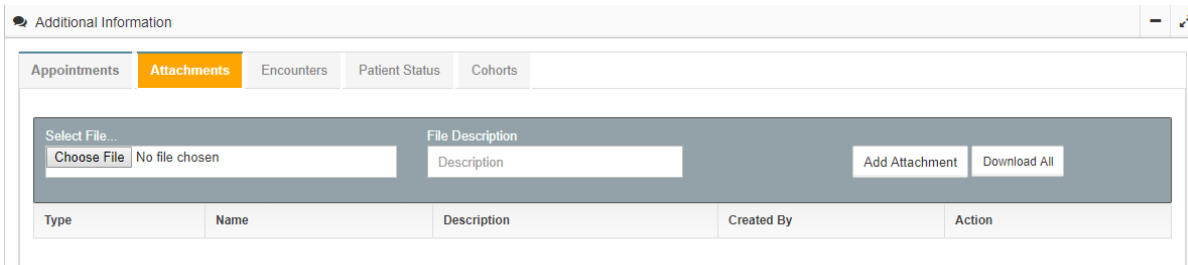
Within the **Patient View**, at the **Attachments** tab, once you have uploaded an attachment, the attachment can easily be removed again.



Click the **Delete Attachment** button after which the system will take you to a **Delete Attachment** screen.



Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the attachment or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Attachment** table.



4.5.1.3 Delete an Encounter

Within the **Patient View**, at the **Encounters** tab, locate the **Encounter** you would like to remove and click the **View Encounter** button.

Additional Information

Appointments Attachments **Encounters** Patient Status Cohorts

Add Encounter

Date	Type	Action
2018-08-07	Pre-Treatment Visit	View Encounter
2018-08-02	Pre-Treatment Visit	View Encounter

The system will navigate you to the **Encounter View**.

Encounter Information

Medical Details First-line Susceptibility Second-line Susceptibility TB Condition Notes

Weight (kg)

Height (cm)

BMI
 Unable to calculate

Pregnancy Status

Injecting drug use within past year

Excessive alcohol use within the past year

Tobacco use within the past year

Go to Patient **Delete Encounter** Edit Encounter

Click the **Delete Encounter** button after which the system will pop up a **Delete Encounter** box.

Encounter Deletion

Patient Full Name

Encounter Type

Encounter Date

* Reason

Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the attachment or click the **Cancel** button to undo the action. After confirming the deletion, the system will update the **Encounter** table.

Additional Information

Appointments Attachments **Encounters** Patient Status Cohorts

Add Encounter

Date	Type	Action
2018-08-07	Pre-Treatment Visit	View Encounter

4.5.1.4 De-enroll a Patient from a Cohort

Within the **Patient View**, at the **Cohorts** tab, find the **Cohort** you would like to de-enroll the patient from.

Cohort	Cohort Start	Enrolled Date	De-enrolled Date	Action
9MTR Study (OR9MT)	2016-05-01	2018-08-06	Not De-enrolled	Action ▾
BDO Study (ORBDQ)	2016-06-01	Not Enrolled	Not De-enrolled	De-enroll Delete
9MTR Program Condition (PC9MT)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
18MTR Program Condition (PC18M)	2001-06-01	2018-08-07	Not De-enrolled	Action ▾
XDRTB Program Condition (PCXDR)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
Finn (F-16)	2015-01-01	Not Enrolled	Not De-enrolled	Enroll
Test (TestC)	2017-07-20	Not Enrolled	Not De-enrolled	Enroll

Click the **De-enroll** button after which the system will display a **Cohort Enrollment** confirmation box.

Cohort De-enrollment

Please note! You are about to de-enroll this patient. Please ensure you use the correct de-enrollment date as this date cannot be amended once set...

Cohort Details

Cohort

Enrollment Date

*** De-enrollment Date**

Enter the de-enrollment date and click the **De-enroll** button. The system will display the updated **Cohorts Table**.

Additional Information - ↗

Appointments Attachments Encounters Patient Status **Cohorts**

Cohort	Cohort Start	Enrolled Date	De-enrolled Date	Action
9MTR Study (OR9MT)	2016-05-01	2018-08-06	2018-08-07	
BDQ Study (ORBDQ)	2016-06-01	Not Enrolled	Not De-enrolled	Enroll
9MTR Program Condition (PC9MT)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
18MTR Program Condition (PC18M)	2001-06-01	2018-08-07	Not De-enrolled	Action ▾
XDRTB Program Condition (PCXDR)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
Finn (F-16)	2015-01-01	Not Enrolled	Not De-enrolled	Enroll
Test (TestC)	2017-07-20	Not Enrolled	Not De-enrolled	Enroll

4.5.1.5 Deleting A Cohort Enrolment

Within the **Patient View**, at the **Cohorts** tab, find the **Cohort** you would like to de-enroll the patient from.

Cohort	Cohort Start	Enrolled Date	De-enrolled Date	Action
9MTR Study (OR9MT)	2016-05-01	2018-08-06	2018-08-07	
BDQ Study (ORBDQ)	2016-06-01	Not Enrolled	Not De-enrolled	Enroll
9MTR Program Condition (PC9MT)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
18MTR Program Condition (PC18M)	2001-06-01	2018-08-07	Not De-enrolled	Action ▾
XDRTB Program Condition (PCXDR)	2001-06-01	Not Enrolled	Not De-enrolled	De-enroll Delete
Finn (F-16)	2015-01-01	Not Enrolled	Not De-enrolled	Enroll
Test (TestC)	2017-07-20	Not Enrolled	Not De-enrolled	Enroll

Click the **Delete** button after which the system will display a **Cohort Enrollment Deletion** confirmation box.

Cohort Enrollment Deletion

Cohort Details

Cohort
18MTR Program Condition (PC18M)

* Reason
Enrolled into incorrect cohort

Enter the reason for deletion and click the **Delete** button. The system will display the updated **Cohorts Table**.

Additional Information

Appointments Attachments Encounters Patient Status **Cohorts**

Cohort	Cohort Start	Enrolled Date	De-enrolled Date	Action
9MTR Study (OR9MT)	2016-05-01	2018-08-06	2018-08-07	
BDQ Study (ORBDQ)	2016-06-01	Not Enrolled	Not De-enrolled	Enroll
9MTR Program Condition (PC9MT)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
18MTR Program Condition (PC18M)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
XDRTB Program Condition (PCXDR)	2001-06-01	Not Enrolled	Not De-enrolled	Enroll
Finn (F-16)	2015-01-01	Not Enrolled	Not De-enrolled	Enroll
Test (TestC)	2017-07-20	Not Enrolled	Not De-enrolled	Enroll

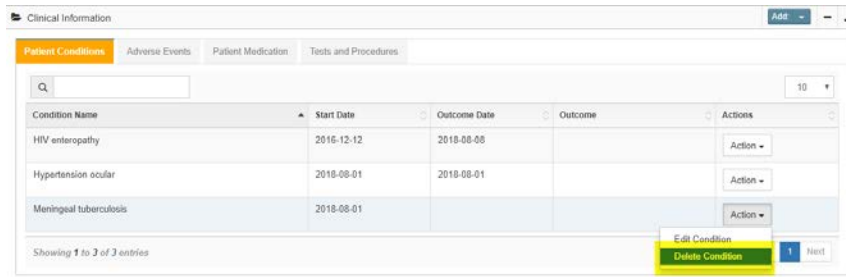


Deleting a cohort enrolment allows the patient to be re-enrolled into that cohort. De-enrollment means the patient cannot be re-enrolled into the same cohort again.

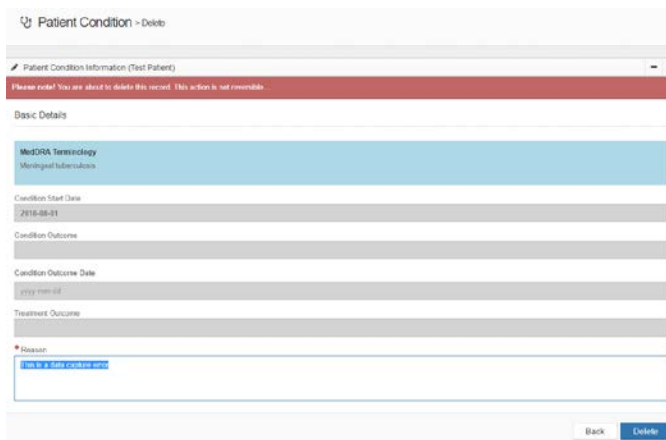
4.5.2 Encounter View – Clinical Information

4.5.2.1 Delete A Patient Condition

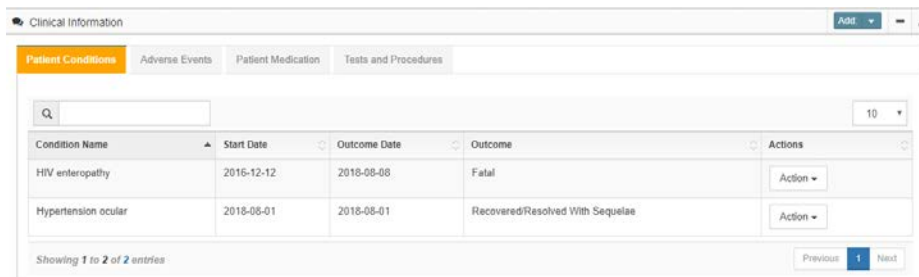
Within the **Encounter or Patient View**, at the **Patient Conditions** tab and locate the condition you would like to delete.



Click the **Delete Condition** button after which the system will take you to a **Delete Condition** screen.

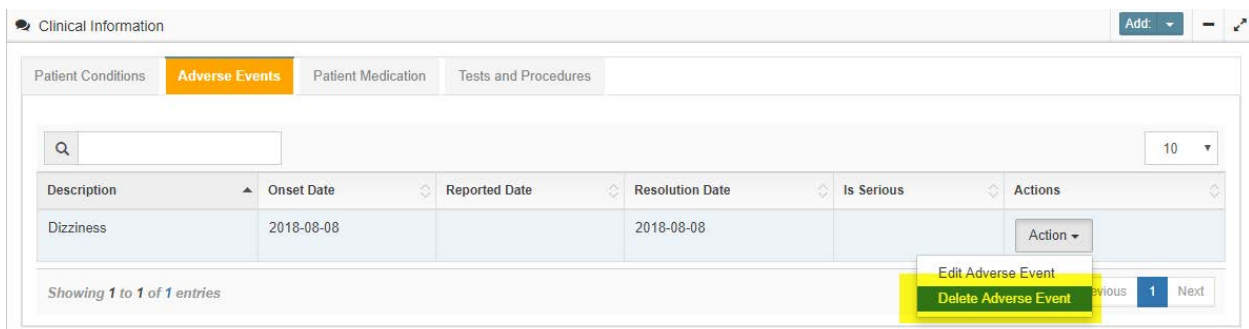


Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the condition or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Patient Condition** table.

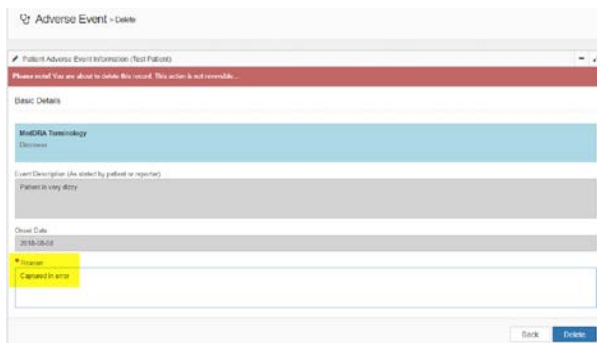


4.5.2.2 Delete An Adverse Event

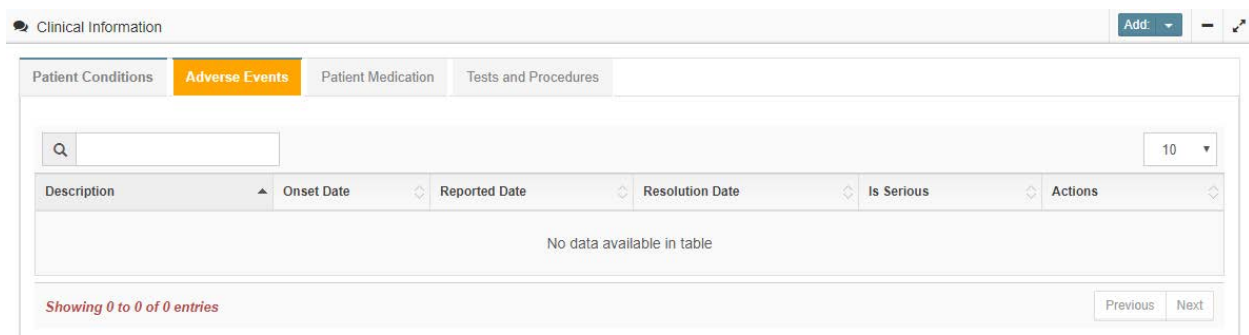
Within the **Encounter or Patient View**, at the **Adverse Events** tab and locate the event you would like to delete.



Click the **Delete Adverse Event** button after which the system will take you to a **Delete Adverse Event** screen.

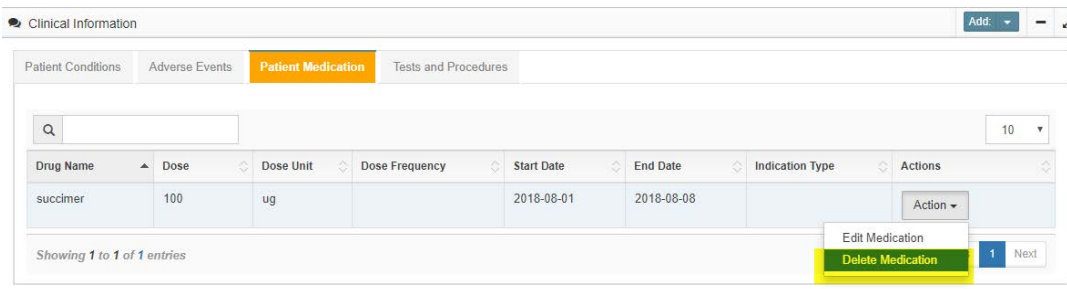


Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the adverse event or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Adverse Events** table.

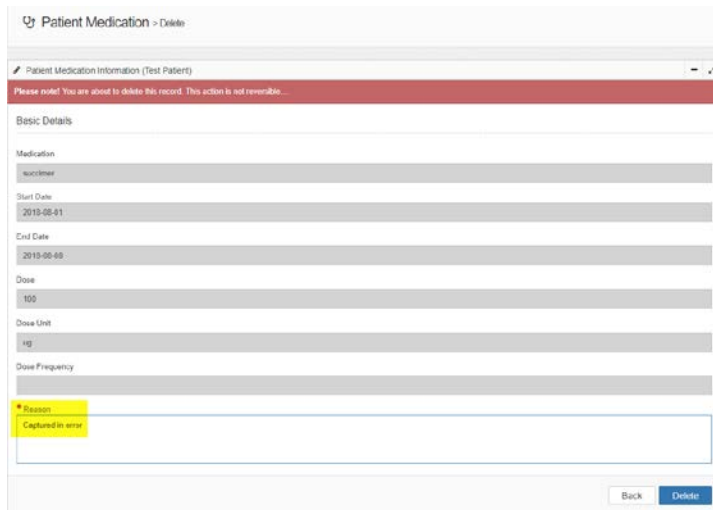


4.5.2.3 Delete A Patient Medication

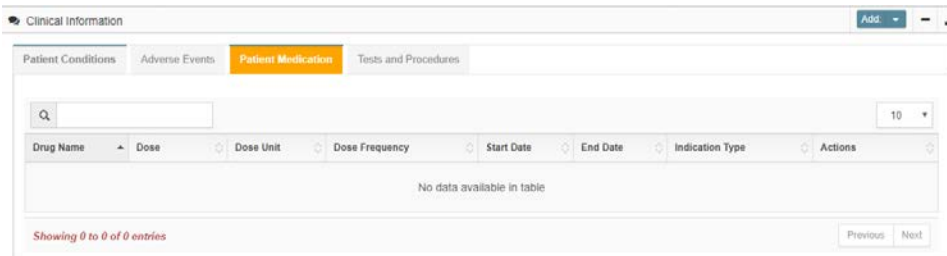
Within the **Encounter or Patient View**, at the **Patient Medications** tab and locate the medication you would like to delete.



Click the **Delete Medication** button after which the system will take you to a **Delete Patient Medication** screen.

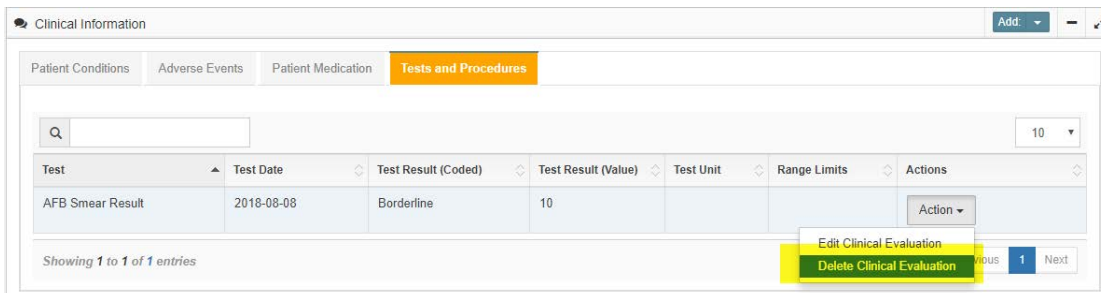


Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the medication or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Patient Medications** table.

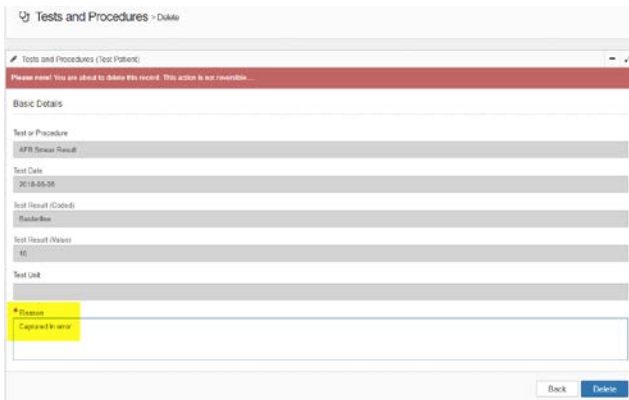


4.5.2.4 Delete A Test and Procedure

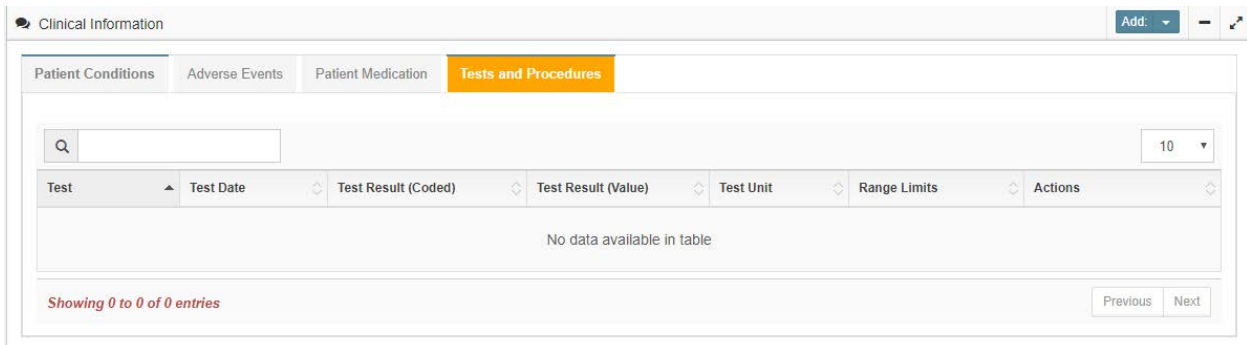
Within the **Encounter or Patient View**, at the **Tests and Procedures** tab and locate the test and procedure you would like to delete.



Click the **Delete Clinical Evaluation** button after which the system will take you to a **Delete Test and Procedure** screen.



Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the test and procedure or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Tests and Procedures** table.




4.5.3 Delete an Entire Patient Record


Within the **Patient View**, click the **Delete** button to delete an entire patient record.

Patient Demographic Information

Medical Record Number	HPRS-123-1234342	By Admin on 2018-08-07
Medical Record Number Type	DR-TB	By Admin on 2018-08-07
Patient Identity Number	49749941612	By Admin on 2018-08-07
Identity Type	National Identity	By Admin on 2018-08-07
Gender	Male	By Admin on 2018-08-07
Marital Status	Single	By Admin on 2018-08-07
Employment Status	Unemployed	By Admin on 2018-08-07
Occupation		
Language	English	By Admin on 2018-08-07
Address		
Address Line 2		
City		
State		
Postal Code		
Patient Contact Number		
Country of Birth	Philippines	By Admin on 2018-08-07

The system will take you to a **Delete Patient** screen.

 Delete Patient (Test Patient)

 Delete Patient - ↗

Please note! You are about to delete this record which has associated clinical data, appointments or encounters. This action is not reversible....

Patient Name

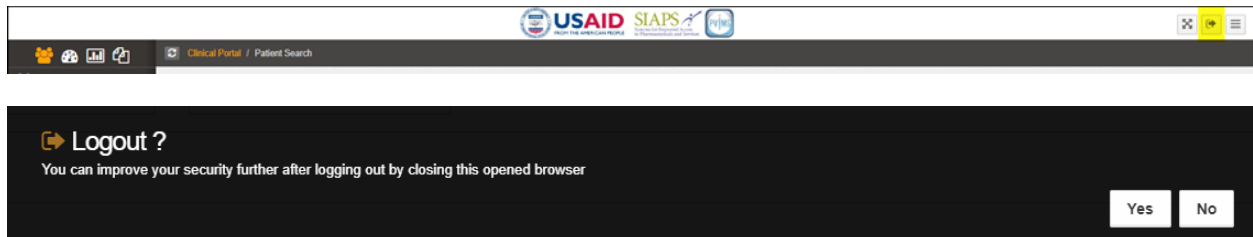
✦ Reason



Deleting a patient will archive all patient information and will remove the patient from any analysis they may have been part of previously.

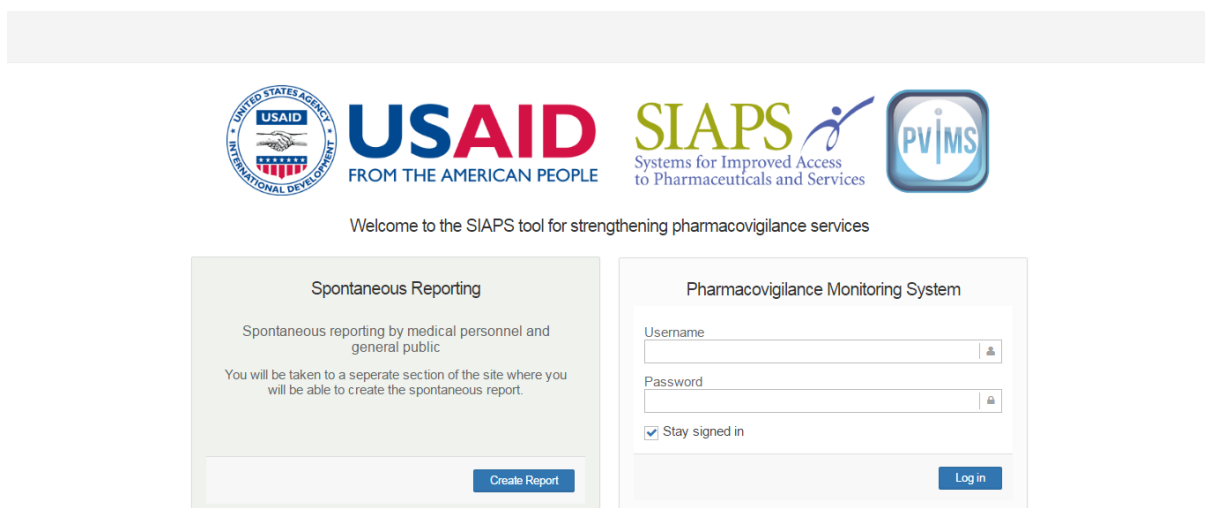
4.6 Log Out of the System

At the end of your work on PViMS, to log out of the session, click the logout icon.



Click the **Yes** button to logout, or click the **No** button to remain logged in.

After clicking on the **Yes** button, the system will display the Login page (Figure 189)



5 Analytical Portal

At the **Home Page** of the Analytical Portal, you will be presented with the following options:

- Spontaneous and Active Reports
- Spontaneous and Active Analyzer

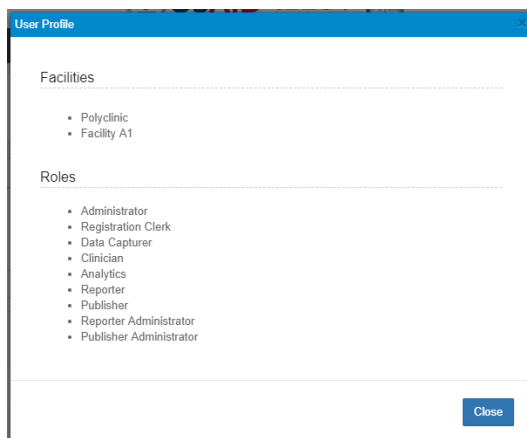
The analytical portal is the centralized hub for causative drug assessment using traditional recognized rating scales, standardized terminology, and risk detection with exposed versus non-exposed risk ratios.

Note: the following roles have access to the analytical portal:

- **Administrator.** The administrator has FULL permissions to the analytical portal.
- **Analyst.** An analytics user is able to assign terminology, set causality and run analysis on collected data.



Click on your user name in the application footer to view roles you currently have access to.



5.1 Spontaneous Reporting

Spontaneous reports are termed spontaneous as they take place during the clinician's normal diagnostic appraisal of a patient, when the clinician is drawing the conclusion that the drug may be implicated in the causality of the event.

Spontaneous reporting system relies on vigilant physicians, other healthcare professionals, and patients who not only generate a suspicion of an ADR, but also report it.

It is an important source of regulatory actions such as taking a drug off the market or a label change due to safety problems. Spontaneous reporting is the core data-generating system of international pharmacovigilance, relying on healthcare professionals (and, in some countries, consumers) to identify and report any adverse events to their national pharmacovigilance center.

Spontaneous reports are, by definition, submitted voluntarily.

PViMS facilitates a public facing interface that allows clinicians or the public itself to spontaneously report on adverse event related data. See chapter 8 for more information.

5.2 Active Reporting

Active surveillance for monitoring the safety and effectiveness of medical products is increasingly recognized as a complement to spontaneous reporting commonly used by pharmacovigilance systems. Integrated mechanisms and processes for monitoring the safety of medicines are essential to a well-functioning pharmaceutical sector. A positive benefit-to-risk balance should precede access to market; however, most regulatory decisions take place early in the product lifecycle and are based on limited data from clinical trials that may be of relatively short duration with limited numbers and types of subjects.

It is critical, therefore, that medicines continue to be monitored for safety and effectiveness once they enter the market under real-life conditions. For some medicines, issues will only emerge under real-world conditions as a result of prolonged use, use in specific subpopulations or in patients with multiple comorbidities, or use in combination with other medicines. In some cases, rare adverse effects only emerge after a product is used for many years, by large numbers of patients, or both.

Active surveillance is particularly important to support the introduction of new essential medicines in LMICs whose regulatory systems are being developed and are in need of support. In resource-limited settings, active surveillance can help determine the real-life frequency, risk factors, and impact of clinically significant adverse medicine events on treatment outcomes.

5.3 Pharmacovigilance Activities

This section describes the common processes adopted by the pharmacovigilance unit in responding to both spontaneous and active reports submitted through PViMS.

PLEASE NOTE: In relation to spontaneous reports, the patient identified in the report does **NOT** form part of the active reporting patient dataset. Therefore, spontaneous reports do not form part of any analysis conducted through the analyzer.

The following activities are facilitated in the Analytical portal:

- Verify quality of report data
- Set terminology for adverse drug reaction (MedDRA)
- Set causality per drug (Naranjo or WHO)
- Create and update E2B files (Export to XML)
- Generate a patient summary

5.3.1 Terminology

Causality Assessment Scale or Terms. The assessment scales or terms were developed to help standardize assessment of causality for all adverse drug reactions. The result is determined by an algorithm designed by Naranjo or WHO for determining the likelihood of whether an adverse drug event is actually due to the drug rather than the result of other factors. Probability is assigned via a score termed definite, probable, possible or doubtful (Naranjo) or certain, probable/likely, possible, unlikely, conditional, unassessable or unclassified (WHO). Values obtained from this algorithm are sometimes used in peer reviews to verify the validity of author's conclusions regarding adverse drug reactions.

MedDRA Terminology. MedDRA or Medical Dictionary for Regulatory Activities is a clinically validated international medical terminology dictionary by regulatory authorities in the pharmaceutical industry during the regulatory process, from pre-marketing to post-marketing activities, and for data entry, retrieval, evaluation, and presentation. In addition, it is the adverse event classification dictionary endorsed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

E2B. The international standard for transmitting medicine adverse event reports specified by the ICH.

5.3.2 Process Flow

<p>Activity: Start of Process Clinician adds a new adverse event to the patient record. Reporter adds a new spontaneous report. System generates a new report for the PV unit to action:</p> <ul style="list-style-type: none"> • Report has a unique identifier • Report has a default activity of Confirm Report Data • Report has a sub status of UNCONFIRMED 	<p>Confirm Report Data The purpose of this activity is to facilitate the checking, vetting, and updating of the clinical data collected for the adverse event logged. The PV unit will be unable to perform any causality or terminology configurations until the data is confirmed as accurate and comprehensive. The PV specialist has the following options:</p> <ul style="list-style-type: none"> • Delete Report • Confirm Report
<p>Activity: Confirm Report Data Step 1: PV specialist and clinician/reporter update clinical data until there is sufficient information to perform causality and terminology configurations. For active reporting the patient record is modified through the clinical portal. For spontaneous reporting the report is modified directly in the analytical portal. Step 2: Once data has been confirmed, the PV specialist will confirm the report is ready for assessment by selecting the Confirm report option. Step 3: The report is moved into a new activity: Set MedDRA and Causality.</p>	
<p>Activity: Set MedDRA and Causality Step 1: PV specialist sets the terminology for the adverse event. This will be the terminology used for analysis purposes. Step 2: PV specialist then sets the causality per medication that was in use at the onset date of the adverse event. <i>Please note: the specialist is unable to set causality until the MedDRA term has been selected.</i> Step 3: On completion, the PV specialist confirms causality has been set. Step 4: The report is moved into a new activity: Extract E2B.</p>	<p>Set MedDRA and Causality The purpose of this activity is to facilitate the setting of the MedDRA terminology for the event and to set causality per medication using either the Naranjo or WHO causality scales. The PV specialist has the following options:</p> <ul style="list-style-type: none"> • Set Terminology • WHO Causality • Naranjo Causality • Confirm Causality Set

Activity: Extract E2B

Step 1: PV technician creates an E2B XML file for submission.

Please note: a patient summary is stored at the time of generating the E2B XML to allow for data verification.

Step 2: PV technician then confirms that the E2B XML file has been submitted to WHO.

- A receipt code and time can be noted here

Please note: submission to WHO UMC is a manual process.

Extract E2B

The purpose of this activity is to facilitate sharing of E2B adverse drug reactions with the WHO Uppsala Monitoring Centre using the ICH ICSR E2B specification.

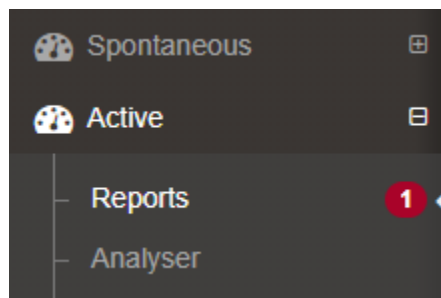
The PV specialist has the following options:

- Create E2B
- Confirm E2B submission

PROCESS COMPLETED

5.3.3 Identifying New Reports

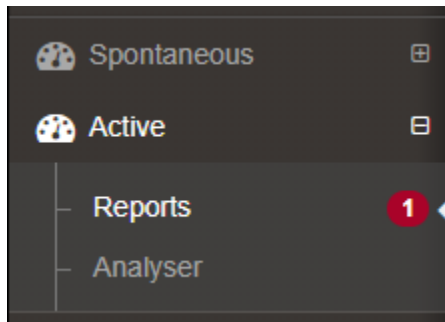
It is possible to identify new active or spontaneous reports using the main reporting menu for either of these report types. The number of new reports registered within a pre-defined period of time is displayed as an alert value next to the corresponding menu.



This alert will vary in count depending on the **ReportInstanceNewAlertCount** configuration. Please speak to your system administrator to confirm what this value is set to in days.

5.3.4 Search for a Report

In the **Reports** function for Spontaneous and Active Reporting, you can **Search** for new reports that have been created. The **Report Search** function can be accessed either through the Spontaneous or Active menu.



There are two ways to search for a report. You can search by:

- Criteria (All reports or reports by stage)
- Report date range

5.3.4.1 Search by Criteria

- Click the **arrow** in the **Report Criteria** field to select a criteria option
- Select the criteria that you would like to search against.



Confirm Report Data Stage: Search on all reports that are newly submitted and are not yet VERIFIED.

Set MedDRA and Causality: Search on all reports that have been VERIFIED and are in the process of being defined through terminology.

Extract E2B: Search on all reports that have all terminology defined and are ready to extract information for submission to the WHO Uppsala Monitoring Centre.

- Click the **Search** button.

Active Reports

Report Criteria: All Reports

Report Date From:

Report Date To:

1 row(s) matching criteria found...

The system will display a list of reports according to the filter selected, please note the Unique Identifier of the report in column 2.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-10 | Report Date To: 2018-08-09 | Search

3 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedORA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram			Dizziness	NOT SET	Confirm Report Data UNCONFIRMED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine; capreomycin, 1000 mg doxycycline, 1000 milligram ibuprofen, 1000 milligram tenofovir disoproxil fumarate, 1000 milligram	Certain		Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUBMITTED	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data UNCONFIRMED	Action

Showing 1 to 3 of 3 entries | Previous 1 Next

5.3.4.2 Search for all Reports within a Date Range

- Enter the **Report Date From** and **Report Date To** for the date range to search.
- Click the **Search** button.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-10 | Report Date To: 2018-08-09 | Search

3 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedORA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne				Dizziness			
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine;	Certain		Vertigo (excl dizziness)			

The system will display a list of reports according to the filter selected, please note the Unique Identifier of the report in column 2.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-10 | Report Date To: 2018-08-09 | Search

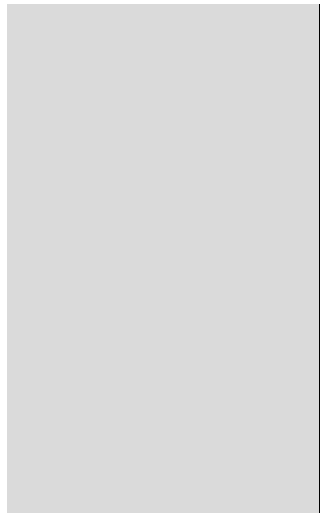
3 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin: 1000 milligram	Dizziness	NOT SET	Confirm Report Data UNCONFIRMED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine; capreomycin: 1000 mg doxycycline: 1000 milligram ibuprofen: 1000 milligram tenofovir disoproxil fumarate, 1000 milligram	Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUBMITTED	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer: 100 ug	Dizziness	NOT SET	Confirm Report Data UNCONFIRMED	Action

Showing 1 to 3 of 3 entries | Previous 1 Next

The columns in the report table are described below:

Created	The date the report was registered in the analytical portal
Identifier	Unique identifier for the report (system generated)
Patient	Patient name
Medication Summary	Overview of all medications associated with the patient at the time of the event, including the WHO or Naranjo causality assessment outcome once that has been set
Adverse Event	The adverse event experienced by the patient
MedDRA Terminology	The unique and internationally recognized MedDRA term defined for the event
Status	Current status of the report
Action	<p>Confirm Report Data Stage View Activity History Confirm or Delete Report View Patient (Active Only) View SAE Report or Patient Summary Update Report (Spontaneous Only)</p> <p>Set MedDRA and Causality Stage View Activity History Set Terminology (MedDRA), Naranjo or WHO Causality Term</p>



- Confirm Causality Set
- View Patient (Active Only)
- View SAE Report or Patient Summary
- Update Report (Spontaneous Only)

Extract E2B Stage

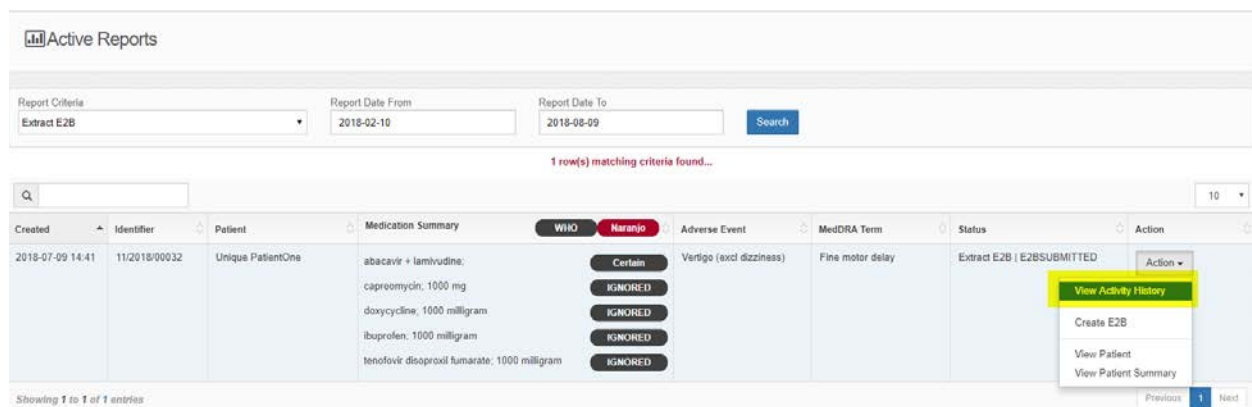
- View Activity History
- Create or Update an E2B file
- Prepare or Confirm E2B file for submission
- Download XML file
- View Patient (Active Only)
- View SAE Report or Patient Summary
- Update Report (Spontaneous Only)

5.4 Pharmacovigilance Activities - General

5.4.1 Viewing Activity History for Report

Irrespective of the stage the report is currently in, you will be able to view a comprehensive history for the report detailing all actions that have occurred, who effected the action, and any additional comments.

Once you have searched for a report, click on the **View Activity History** menu for the associated report you would like to view.



The system will navigate you to the **View Activity History** page.

 Activities

Activity	Execution Event	Executed By	Executed Date	Comments	Receipt Date	Receipt Code	Actions
Confirm Report Data	UNCONFIRMED	Admin User	2018-07-09 14:41				
Confirm Report Data	CONFIRMED	Admin User	2018-07-09 14:50	I am happy with the quality of report			
Set MedDRA and Causality	NOTSET	Admin User	2018-07-09 14:50				
Set MedDRA and Causality	MEDDRASET	Admin User	2018-07-09 14:52	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	Admin User	2018-07-09 14:55	Causality has been set			
Extract E2B	NOTGENERATED	Admin User	2018-07-09 14:55				
Extract E2B	E2BINITIATED	Admin User	2018-07-09 14:56	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	Admin User	2018-07-09 14:58	I am happy with the quality of report			Action ▼
Extract E2B	E2BSUBMITTED	Admin User	2018-07-09 15:02	Submitted on	2018-07-10	dfdsf	

The columns in the activity history table are described below:

Activity	The primary activity stage performed by the analyst
Execution Event	The primary activity performed by the analyst. Activities are dependent on the stage the report is in.
Executed By	Which user executed the activity
Execution Date	The date and time the user executed the activity
Comments	Any comments noted by the user at the point of completing the activity
Receipt Date	Particular to the E2B Extract Stage. Confirmation an E2B extract has been received by UMC and this is the associated receipt date
Receipt Code	Particular to the E2B Extract Stage. Confirmation an E2B extract has been received by UMC and this is the associated receipt code that may be supplied by UMC
Action	View Patient Summary View Patient Extract View E2B File

5.4.2 Viewing a Patient Record

The **View Patient** button allows the user to navigate to the Patient View for the patient so that the analyst may gather additional information to the adverse event.

Once you have searched for a report, click on the **View Patient** menu for the associated report you would like to view.

The screenshot shows the 'Active Reports' section of a software interface. At the top, there are search filters for 'Report Criteria' (set to 'All Reports'), 'Report Date From' (2018-07-10), and 'Report Date To' (2018-08-09), with a 'Search' button. Below the filters, a message indicates '1 row(s) matching criteria found...'. A table displays the search results with columns for 'Created', 'Identifier', 'Patient', 'Medication Summary', 'Adverse Event', 'MedDRA Term', 'Status', and 'Action'. The first row shows a report created on 2018-08-08 16:11 for 'Test Patient' with medication 'succimer, 100 ug' and adverse event 'Dizziness'. The status is 'UNCONFIRMED'. The 'Action' column has a dropdown menu open, with 'View Patient' highlighted in yellow. Other options in the menu include 'View Activity History', 'Confirm Report', 'Delete Report', and 'View Patient Summary'.

The system will navigate you to the **Patient View** page in the Clinical Portal.



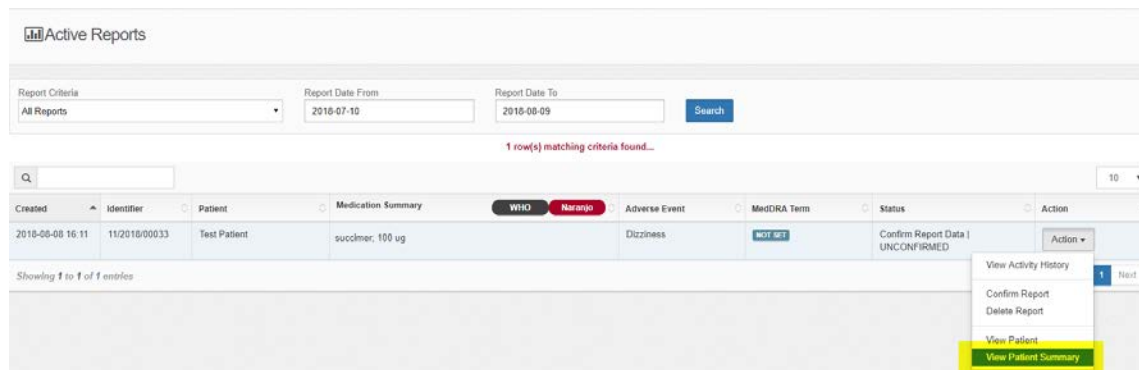
This menu item will only be made available under the following circumstances:

- Active reports only
- If the user has the Registration Clerk, Data Capture or Clinician role assigned to their user profile

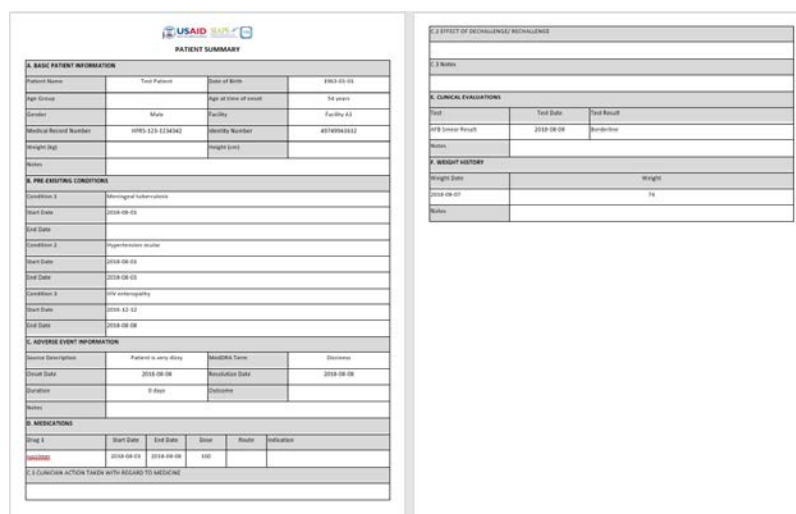
5.4.3 Extracting a Patient Summary

The **View Patient Summary** menu allows the user to generate an overall summary of the patient clinical record in MS Word format. This is the preferred method of granting access to the clinical record for the analyst.

Once you have searched for a report, click on the **View Patient Summary** menu for the associated report you would like to view.



The system generates an extract of the patient summary:



If the event is defined as serious, the system will include additional information that explains the seriousness of the report. The menu item for generating the extract will be changed to **View SAE Report**.

5.4.4 Updating a Spontaneous Report

The **Update Report** button allows the user to navigate to the spontaneous report for the patient and allow the analyst the ability to amend the report.

Once you have searched for a report, click on the **Update Report** menu for the associated report you would like to amend.

Spontaneous Reports

Report Criteria: All Reports | Report Date From: 2012-02-10 | Report Date To: 2018-08-09 | Search

2 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-01-28 12:13	12/2018/00029	SIK				Dizziness	NOT SET	Confirm Report Data UNCONFIRMED	Action
2018-02-01 20:52	12/2018/00030	7701215090				Dizziness	Dizziness	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 2 of 2 entries

- View Activity History
- Set Terminology
- WHO Causality
- Confirm Causality Set
- Update Report
- View SAE Report

The system will navigate you to the **Spontaneous View** page for the report.



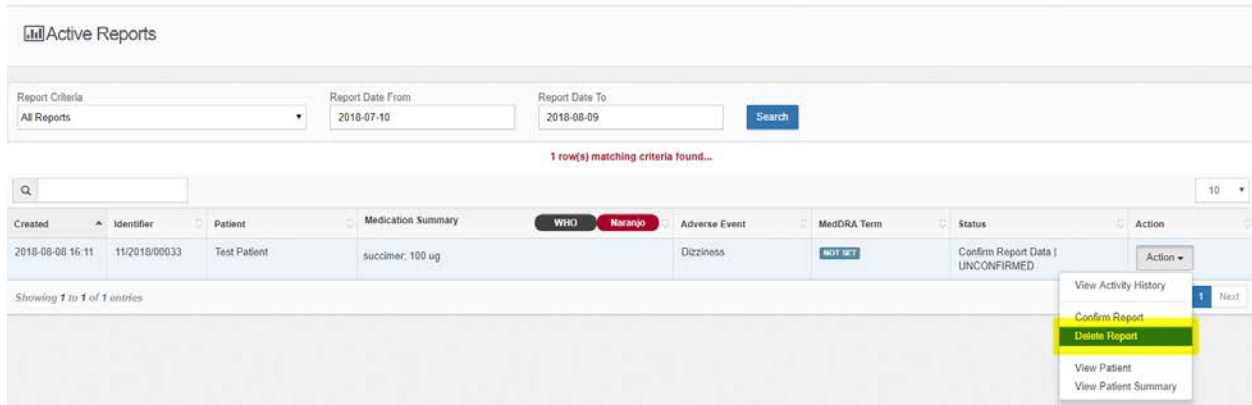
This menu item will only be available for spontaneous reports.

5.5 Pharmacovigilance Activities – Confirm Report Data

5.5.1 Deleting a Report

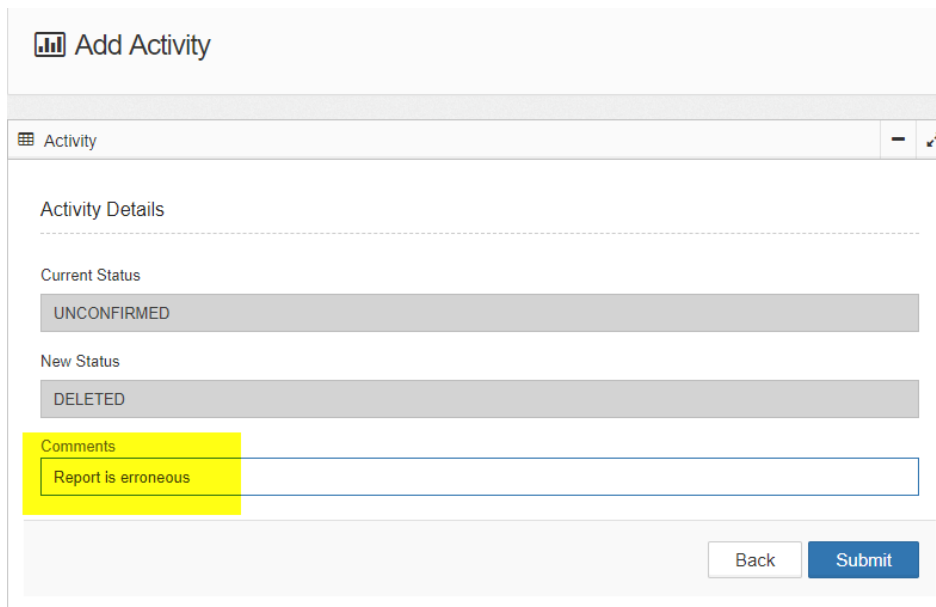
The **Confirm Report Data** stage enforces a process whereby the analyst ensures the necessary clinical data is of sufficient quality to allow terminology and causality to be completed. In the event a report is deemed to be insufficient, inaccurate, or erroneous, a report may be deleted, which will effectively remove it from analysis.

Once you have searched for a report, click on the **Delete Report** menu for the associated report you would like to delete.

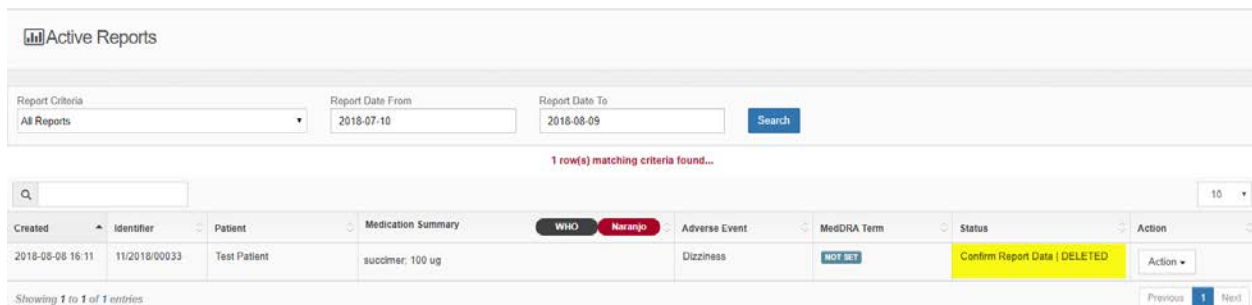


The system will navigate you to the **Add Activity** page.

Specify the reason for deleting the record and click **Submit** to confirm the deletion or **Back** to cancel the action and return to the previous page.



The system will update the status of the report accordingly.





Once a report is deleted, it is not possible to re-include the report for analysis. Please ensure you are correct in deleting the report before committing the action.

5.5.2 Confirming a Report

The **Confirm Report Data** stage enforces a process whereby the analyst ensures the necessary clinical data is of sufficient quality to allow terminology and causality to be completed. When a report is deemed to be sufficient and accurate, the report should be confirmed, which will effectively allow terminology definition to commence.


Once you have searched for a report, click on the **Confirm Report** menu for the associated report you would like to confirm.


The screenshot displays the 'Active Reports' section of the PViMS interface. It includes a search bar, filters for 'Report Criteria' (set to 'All Reports'), 'Report Date From' (2018-07-10), and 'Report Date To' (2018-08-09). A search button is present. Below the filters, it indicates '2 row(s) matching criteria found...'. A table lists two reports with columns for 'Created', 'Identifier', 'Patient', 'Medication Summary', 'WHO Naranjo', 'Adverse Event', 'MedDRA Term', 'Status', and 'Action'. The second report, 'Cluster headaches', has an 'Action' dropdown menu open, showing options: 'View Activity History', 'Confirm Report' (highlighted in yellow), 'Delete Report', 'View Patient', and 'View Patient Summary'. A 'Next' button is visible at the bottom right of the table.

Created	Identifier	Patient	Medication Summary	WHO Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug		Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour			Cluster headaches	NOT SET	Confirm Report Data UNCONFIRMED	Action

The system will navigate you to the **Add Activity** page.

Specify any additional comments for confirming the record and click **Submit** to confirm the deletion or **Back** to cancel the action and return to the previous page.

 Add Activity

 Activity - ↗

Activity Details

Current Status

UNCONFIRMED


New Status

CONFIRMED

Comments

I am happy with the quality of report

The system will update the status of the report accordingly.

 Active Reports

Report Criteria: All Reports | Report Date From: 2018-07-10 | Report Date To: 2018-08-09 |

2 row(s) matching criteria found...

Q: 10 ▾

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succmer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action ▾
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	NOT SET	Set MedDRA and Causality NOTSET	Action ▾

Showing 1 to 2 of 2 entries Previous 1 Next



Confirming a report will move the report into the next stage: **Set MedDRA and Causality.**

5.6 Pharmacovigilance Activities – Set MedDRA and Causality

5.6.1 Set MedDRA Terminology

The **Set MedDRA and Causality** stage facilitates the process of confirming the final MedDRA term for the adverse event and allows assignment of causality per relevant medication using either the World Health Organization or the Naranjo Causality Scale.

Once you have searched for a report, click on the **Set Terminology** menu for the associated report you would like to set terminology for.

The screenshot shows the 'Active Reports' section of the system. It includes search filters for 'Report Criteria' (set to 'All Reports'), 'Report Date From' (2018-07-10), and 'Report Date To' (2018-08-09). A search button is present. Below the filters, a message states '2 row(s) matching criteria found...'. A table displays two reports. The second report, dated 2018-08-09 17:44, has an 'Action' dropdown menu open, with 'Set Terminology' highlighted. Other options in the menu include 'View Activity History', 'View Patient', and 'View Patient Summary'. The table columns include 'Created', 'Identifier', 'Patient', 'Medication Summary', 'WHO' (set to 'Naranjo'), 'Adverse Event', 'MedDRA Term' (both 'NOT SET'), 'Status', and 'Action'.

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succlmer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	NOT SET	Set MedDRA and Causality NOTSET	Action

The system will navigate you to the **MedDRA Terminology** page.

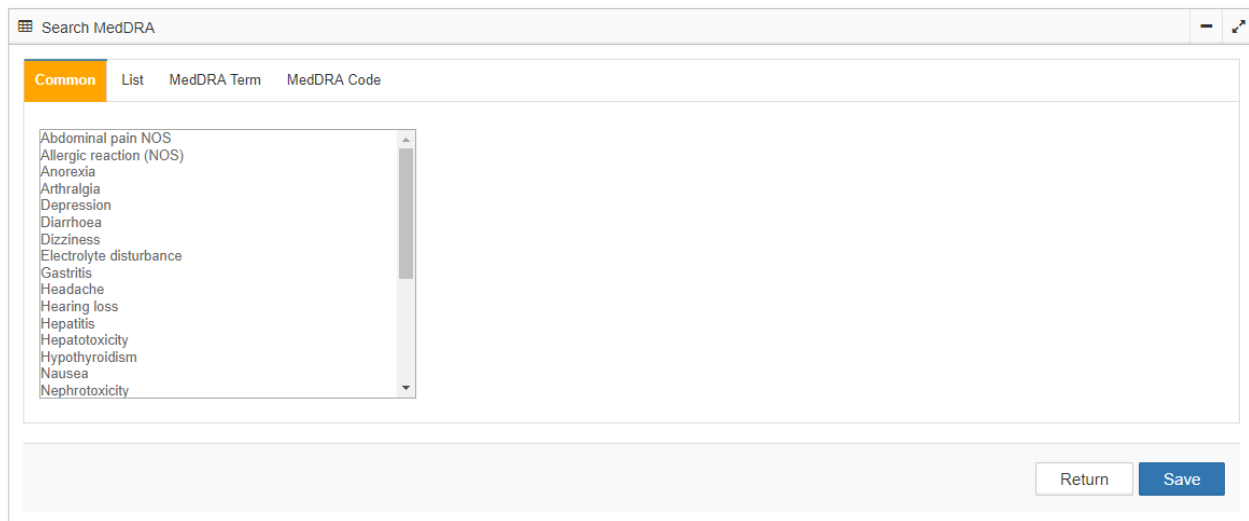
The **MedDRA Terminology** page displays the adverse event as reported by the clinician and/or reporter.

The screenshot shows the 'MedDRA Terminology' page. It features two input fields. The first field, labeled 'Facility Level Verbatim Description', contains the text 'Cluster headaches'. The second field, labeled 'Facility Level MedDRA Term', also contains the text 'Cluster headaches'.

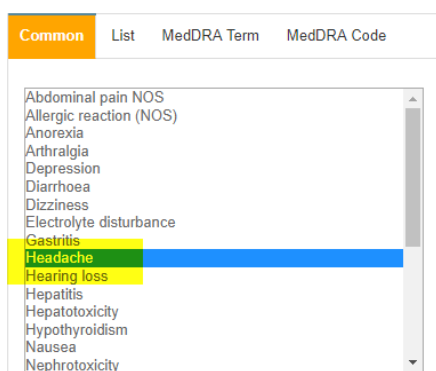
MedDRA terms can be searched in the following ways:

- Search by Common Term
- Search by List
- Search by MedDRA Term
- Search by MedDRA Code

5.6.1.1 Search for MedDRA Term by Common Term

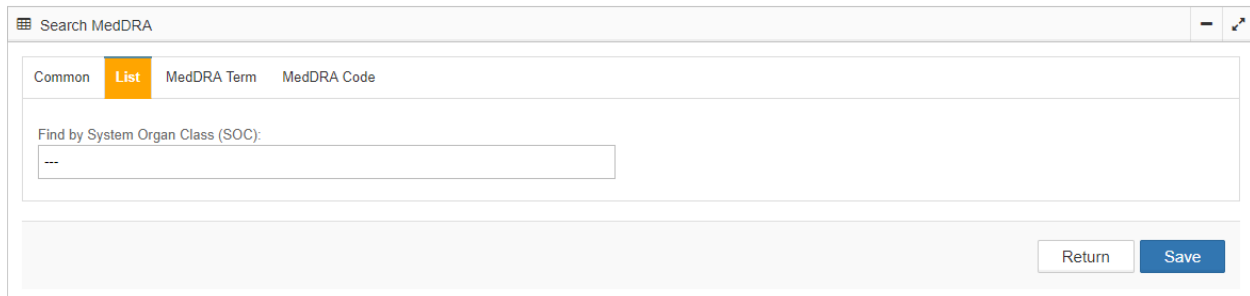


Common terms are listed terms for events that occur most frequently in your setting. Select the term in the list that that most accurately reflects the reported term.



Click the **Save** button to assign the term, or click the **Return** button to cancel the action and return to the previous page. The report will be updated with the new term accordingly.

5.6.1.2 Search for MedDRA Term by List



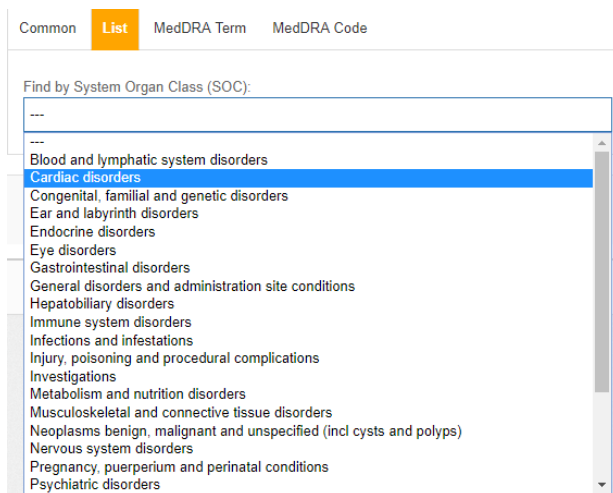
Search MedDRA

Common **List** MedDRA Term MedDRA Code

Find by System Organ Class (SOC):

Return Save

The list search function allows the user to navigate the MedDRA dictionary using the hierarchical structure of the dictionary. Select the System Organ Class field to select a SOC.



Common **List** MedDRA Term MedDRA Code

Find by System Organ Class (SOC):

- Blood and lymphatic system disorders
- Cardiac disorders**
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders

Continue selecting through the hierarchy (HLGT, HLT, PT) until you have selected the Low-Level Term that matches the adverse event.

Common	List	MedDRA Term	MedDRA Code
Find by System Organ Class (SOC):			
<input type="text" value="Hepatobiliary disorders"/>			
Find by High Level Group Term (HLGT):			
<input type="text" value="Bile duct disorders"/>			
Find by High Level Term (HLT):			
<input type="text" value="Obstructive bile duct disorders (excl neoplasms)"/>			
Find by Preferred Term (PT):			
<input type="text" value="Bile duct stenosis traumatic"/>			
Find by Lowest Level Term (LLT):			
<input type="text" value="Bile duct stenosis traumatic"/>			
<input type="text" value="Bile duct stricture traumatic"/>			

Click the **Save** button to assign the term, or click the **Return** button to cancel the action and return to the previous page. The report will be updated with the new term accordingly.

5.6.1.3 Search by MedDRA Term

Searching by a MedDRA term allows you the ability to filter through MedDRA using a partial or fully defined term.

In the **Term Type** field, select the level of specificity for the search (SOC, HLTG, HLT, PT, or LLT).

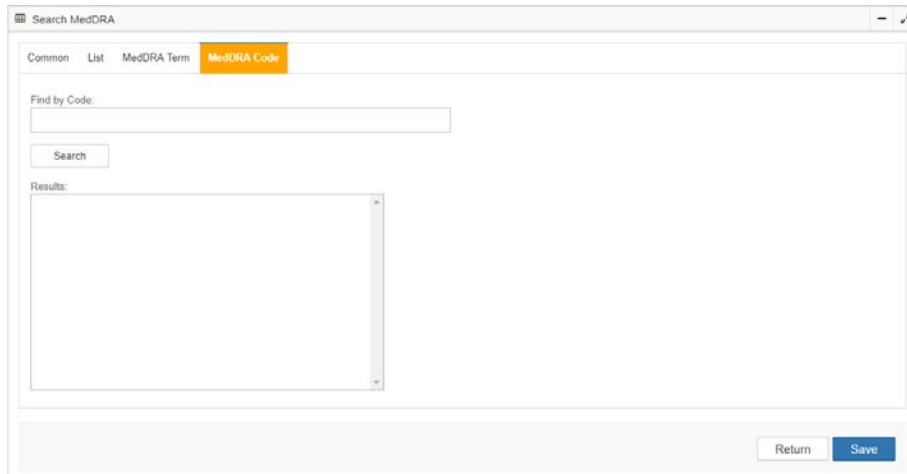
In the **Find by Term** field, enter the term you are searching for.



It is possible to complete a partial search by entering as few as 3 characters that form part of the overall term.

Click the **Save** button to assign the term, or click the **Return** button to cancel the action and return to the previous page. The report will be updated with the new term accordingly.

5.6.1.4 Search by MedDRA Code



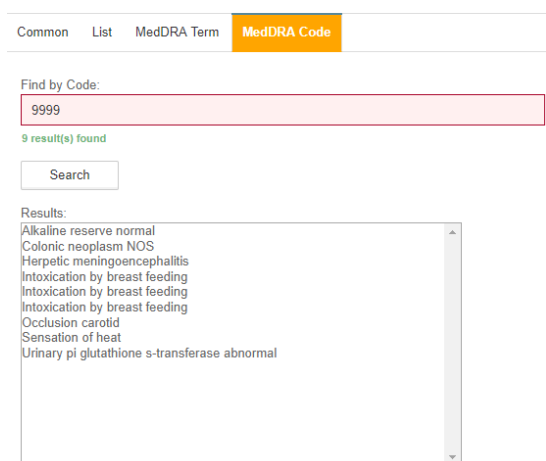
The screenshot shows a web application window titled "Search MedDRA". At the top, there are four tabs: "Common", "List", "MedDRA Term", and "MedDRA Code". The "MedDRA Code" tab is currently selected and highlighted in orange. Below the tabs, there is a "Find by Code:" label followed by a text input field. A "Search" button is positioned below the input field. Underneath, there is a "Results:" label followed by a scrollable list area. At the bottom right of the window, there are two buttons: "Return" and "Save".

Searching by a MedDRA code allows you the ability to filter through MedDRA using an associated code which can be fully defined or partial in nature.

In the **Find by Code** field, enter the code you are searching for.



It is possible to complete a partial search by entering as few as 4 numerical characters that form part of the overall code.



This screenshot shows the same "Search MedDRA" interface. The "MedDRA Code" tab is still selected. The "Find by Code:" input field now contains the text "9999". Below the input field, it says "9 result(s) found" in green. A "Search" button is visible. The "Results:" section is populated with a list of terms: "Alkaline reserve normal", "Colonic neoplasm NOS", "Herpetic meningoencephalitis", "Intoxication by breast feeding", "Intoxication by breast feeding", "Intoxication by breast feeding", "Occlusion carotid", "Sensation of heat", and "Urinary pi glutathione s-transferase abnormal".

Click the **Save** button to assign the term, or click the **Return** button to cancel the action and return to the previous page. The report will be updated with the new term accordingly.

5.6.2 Causality Assessment using the WHO Scale

The **Set MedDRA and Causality** stage facilitates the process of confirming the final MedDRA term for the adverse event and allows assignment of causality per relevant medication using either the World Health Organization or the Naranjo Causality Scale.

Once the MedDRA terminology for the event has been set, the report will be updated accordingly.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-07-10 | Report Date To: 2018-08-09 | Search

2 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 2 of 2 entries | Previous 1 Next

Setting the terminology will further allow the setting of causality per medication. Click on the **WHO Causality** menu option for the associated report you would like to set causality for.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-07-10 | Report Date To: 2018-08-09 | Search

2 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 2 of 2 entries | Previous 1 Next

- View Activity History
- Set Terminology
- WHO Causality**
- Naranjo Causality
- Confirm Causality Set
- View Patient
- View Patient Summary

The system will navigate you to the **WHO Causality Assessment** page.

The **WHO Causality Assessment** page displays the adverse event as reported by the clinician and/or reporter, the MedDRA Terminology set as well as the onset date of the event.

WHO Causality Assessment

Onset Date	2018-08-01
Facility Level MedDRA Term	Cluster headaches
Central Level MedDRA Term	Headache NOS

The **WHO Causality Assessment** page also displays the list of medications that the patient was exposed to at the onset of the adverse event.

The analyst can perform the following actions against each medication the patient was exposed to:

- Ignore the medication (the medication is definitely not responsible for the adverse event)
- Set causality for the medication

5.6.2.1 Ignoring the Medication

Medication	Start Date	End Date	Indication Type	Causality	Action
kanamycin; 1000 milligram	2016-03-12	2016-03-18		NOT SET	Action ▾

Set Causality
Ignore Medication

Ignoring the medication means that a causality assessment need not be set for that medication.

To ignore assigning a WHO causality assessment for this medication, click the **Ignore Medication** menu or click on the **Return** button to undo the action and return to the previous page. The system will assign **Ignored** as the causality term.

Medication	Start Date	End Date	Indication Type	Causality	Action
kanamycin; 1000 milligram	2016-03-12	2016-03-18		IGNORED	Action ▾

5.6.2.2 Set Causality

Medication	Start Date	End Date	Indication Type	Causality	Action
kanamycin; 1000 milligram	2016-03-12	2016-03-18		IGNORED	Action ▾

Set Causality
 Ignore Medication

By clicking the **Set Causality** link, the system will enable you to set causality for this medication.

Medication	Start Date	End Date	Indication Type	Causality
kanamycin; 1000 milligram	2016-03-12	2016-03-18		IGNORED

kanamycin; 1000 milligram

The system displays a series of questions for assigning the WHO causality term.

Click the appropriate response (Yes or No) for question 1 and continue to respond to the first five questions.

If responses to all five questions are **Yes**, the system will assign **Certain** as the causality term.

WHO Causality Tool		
Certain		
1.	Event or laboratory test abnormality, with plausible time relationship to drug intake	Yes ▾
2.	Cannot be explained by disease or other drugs	Yes ▾
3.	Response to withdrawal plausible (pharmacologically, pathologically)	Yes ▾
4.	Event definitive pharmacologically or phenomenologically	Yes ▾
5.	Rechallenge satisfactory, if necessary	Yes ▾
Causality		Certain

Click the **Save** button and the system will assign the term as **Certain** in the system, or click the **Cancel** button to undo the action.

Click the **Return** button at any time to undo the action and return to the previous page.

If any of the questions in the Certain category have a response of **No** the system will display questions for the Probable/Likely category.

WHO Causality Tool		
Certain		
1.	Event or laboratory test abnormality, with plausible time relationship to drug intake	Yes
2.	Cannot be explained by disease or other drugs	Yes
3.	Response to withdrawal plausible (pharmacologically, pathologically)	Yes
4.	Event definitive pharmacologically or phenomenologically	Yes
5.	Rechallenge satisfactory, if necessary	No
Probable/Likely		
6.	Event or laboratory test abnormality, with reasonable time relationship to drug intake	--SELECT--
7.	Unlikely to be attributed to disease or other drugs	--SELECT--
8.	Response to withdrawal clinically reasonable	--SELECT--
9.	Rechallenge not required	--SELECT--
Causality		

Continue this process until you have answered **Yes** to all questions in a specific category. This will result in the classification for that medication being set to that category.

In the event you reach the **Unassessable/Unclassified** category, if one of the two questions asked in that category is answered as **No**, the system will trigger an alert.

Assessment

The answer to questions 17 and 18 cannot be 'no'. Please review all of the questions to which you answered 'no' in the list above to determine which one of them should be 'yes'. Information on drug withdrawal may be lacking or unclear.

OK

Once the term has been assigned click the **Save** button to continue, or click the **Cancel** button to undo the action and return to the previous page. The system will update the causality assessment for that medication accordingly.

Medications					
Medication	Start Date	End Date	Indication Type	Causality	Action
kanamycin; 1000 milligram	2016-03-12	2016-03-18		Probable	Action

5.6.3 Causality Assessment using the Naranjo Scale

The **Set MedDRA and Causality** stage facilitates the process of confirming the final MedDRA term for the adverse event and allows assignment of causality per relevant medication using either the World Health Organization or the Naranjo Causality Scale.

Once the MedDRA terminology for the event has been set, the report will be updated accordingly.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-07-10 | Report Date To: 2018-08-09 | Search

2 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 2 of 2 entries

Setting the terminology will further allow the setting of causality per medication. Click on the **Naranjo Causality** menu for the associated report you would like to set causality for.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-10 | Report Date To: 2018-08-09 | Search

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram	Probable		Dizziness	Dizziness	Set MedDRA and Causality MEDDRASET	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine, capreomycin, 1000 mg doxycycline, 1000 milligram ibuprofen, 1000 milligram tenofovir disoproxil fumarate, 1000 milligram	Certain		Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUB	View Activity History Set Terminology WHO Causality Naranjo Causality Confirm Causality Set
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data	View Patient View Patient Summary
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries

The system will navigate you to the **Naranjo Causality Assessment** page.

The **Naranjo Causality Assessment** page displays the adverse event as reported by the clinician and/or reporter, the MedDRA Terminology set as well as the onset date of the event.

Naranjo Causality Assessment

Onset Date	2016-02-12
Facility Level MedDRA Term	Dizziness
Central Level MedDRA Term	Dizziness

The **Naranjo Causality Assessment** page also displays the list of medications that the patient was exposed to at the onset of the adverse event.

The analyst can perform the following actions against each medication the patient was exposed to:

- Ignore the medication (the medication is definitely not responsible for the adverse event)
- Set causality for the medication

5.6.3.1 Ignoring the Medication

Medication	Start Date	End Date	Indication Type	Causality	Action
kanamycin; 1000 milligram	2016-03-12	2016-03-18		NOT SET	Action ▾

Set Causality
Ignore Medication

Ignoring the medication means that a causality assessment need not be set for that medication.

To ignore assigning a Naranjo causality assessment for this medication, click the **Ignore Medication** menu or click on the **Return** button to undo the action and return to the previous page. The system will assign **Ignored** as the causality term.

Medication	Start Date	End Date	Indication Type	Causality	Action
kanamycin; 1000 milligram	2016-03-12	2016-03-18		IGNORED	Action ▾

5.6.3.2 Set Causality

Medication	Start Date	End Date	Indication Type	Causality	Action
kanamycin, 1000 milligram	2016-03-12	2016-03-18		IGNORED	Action ▾

Set Causality
Ignore Medication

By clicking the **Set Causality** link, the system will enable you to set causality for this medication.

Medication	Start Date	End Date	Indication Type	Causality
kanamycin, 1000 milligram	2016-03-12	2016-03-18		IGNORED

kanamycin, 1000 milligram

The system displays a series of questions for calculating the Naranjo causality score.

Click the appropriate response (Yes or No) for question 1 and continue to respond to all remaining questions. Once all responses have been selected, click the Calculate button.

Naranjo Causality Tool			
1.	Are there previous conclusive reports on this reaction?	Yes ▾	1
2.	Did the adverse event appear after the suspected drug was administered?	No ▾	-1
3.	Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	Yes ▾	1
4.	Did the adverse reaction reappear when the drug was readministered?	Yes ▾	2
5.	Are there alternative causes (other than the drug) that could on their own have caused the reaction?	No ▾	2
6.	Did the reaction reappear when a placebo was given?	Yes ▾	-1
7.	Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	Do not know ▾	0
8.	Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	Yes ▾	1
9.	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	Yes ▾	1
10.	Was the adverse event confirmed by any objective evidence?	Do not know ▾	0
<input type="button" value="Calculate"/>			Probable 6

Click the **Save** button and the system will assign the term as per the calculation in the system, or click the **Cancel** button to undo the action. Click the **Return** button at any time to undo the action and return to the previous page.

Medication	Start Date	End Date	Indication Type	Causality	Action
kanamycin, 1000 milligram	2016-03-12	2016-03-18		Probable	Action ▾

5.6.4 Confirming Causality Set

The **Set MedDRA and Causality** stage facilitates the process of confirming the final MedDRA term for the adverse event and allows assignment of causality per relevant medication using either the World Health Organization or the Naranjo Causality Scale.

Once causality for all medications has been set, the report will be updated accordingly.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-10 | Report Date To: 2018-08-09 | Search

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram	Probable	Probable	Dizziness	Dizziness	Set MedDRA and Causality MEDDRASET	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine, capreomycin, 1000 mg, doxycycline, 1000 milligram, ibuprofen, 1000 milligram, tenofovir disoproxil fumarate, 1000 milligram	Certain	IGNORED	Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUBMITTED	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries | Previous 1 Next

Click on the **Confirm Causality Set** menu for the associated report you would like to confirm causality set for.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-10 | Report Date To: 2018-08-09 | Search

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram	Probable	Probable	Dizziness	Dizziness	Set MedDRA and Causality MEDDRASET	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine, capreomycin, 1000 mg, doxycycline, 1000 milligram, ibuprofen, 1000 milligram, tenofovir disoproxil fumarate, 1000 milligram	Certain	IGNORED	Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUBMITTED	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries | Previous 1 Next

Context menu for the second row (2018-07-09 14:41):

- View Activity History
- Set Terminology
- WHO Causality
- Naranjo Causality
- Confirm Causality Set**
- View Patient
- View Patient Summary

The system will navigate you to the **Add Activity** page.

Specify any comment if necessary and click **Submit** to confirm the deletion or **Back** to cancel the action and return to the previous page.

Add Activity

Activity

Activity Details

Current Status
MEDDRASET

New Status
CAUSALITYSET

Comments

Back Submit

The system will update the status of the report accordingly.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-10 | Report Date To: 2018-08-09 | Search

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin: 1000 milligram	Probable	Probable	Dizziness	Dizziness	Extract E2B NOTGENERATED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine, capreomycin: 1000 mg, doxycycline: 1000 milligram, ibuprofen: 1000 milligram, tenofovir disoproxil fumarate, 1000 milligram	Certain		Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUBMITTED	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer: 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries | Previous 1 Next

5.7 Pharmacovigilance Activities – Extract E2B

5.7.1 Create E2B

BUZZWORDS

ICH E2B: An E2B dataset facilitates the Electronic Transmission of Individual Case Safety Reports (ICSRs) and can be used to submit such reports to WHO. The E2B dataset within

PViMS is implemented using the standard adopted by the ICH1 for electronic transmission of ICSRs according to the ICH E2B(R3) message standard.

The **Extract E2B** stage generates an E2B extract for submission to the World Health Organization Uppsala Monitoring Centre.



By clicking this menu item, the system generates an E2B dataset that is populated with clinical information from the source form. This E2B dataset can be amended by you to reflect additional clinical information pertinent to WHO.

Once you have searched for a report, click on the **Create E2B** menu for the associated report you would like to create E2B for.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-11 | Report Date To: 2018-08-10 | Search

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram	Probable	Probable	Dizziness	Dizziness	Extract E2B NOTGENERATED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine; capreomycin, 1000 mg doxycycline, 1000 milligram ibuprofen, 1000 milligram tenofovir disoproxil fumarate, 1000 milligram	Certain		Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUB	View Activity History Create E2B View Patient View Patient Summary
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries | Previous 1 Next

The system will navigate you to the **E2B ICH Report** page which contains the following 13 tabs:

- Message Header
- Safety Report
- Primary Source
- Sender
- Receiver
- Patient
- Medical History Episode
- Past Drug Therapy
- Patient Death

- Reaction
- Test
- Drug
- Summary

5.7.1.1 Message Header

The message header section provides administrative and identification information about the report itself.

All fields are all automatically populated by the system and cannot be edited by the user.

Message Header	Safety Report	Primary Source	Sender	Receiver	Patient	Medical History Episode	Past Drug Therapy	Patient Death	Reaction	Test	Drug
Summary											
Message Type											
ICHICSR											
Message Format Version											
2.1											
Message Format Release											
1.0											
Message Number											
00000770											
Message Sender Identifier											
FDA											
Message Receiver Identifier											
UMC											
Message Date Format											
204											
Message Date											
20180810120000											

5.7.1.2 Safety Report

The Safety Report section provides information about the case (other than patient or clinical information).

Message Header	Safety Report	Primary Source	Sender	Receiver	Patient	Medical History Episode	Past Drug Therapy	Patient Death	Reaction	Test	Drug
Summary											
Safety Report Version											
1											
Safety Report ID											
PH.FDA.000031											
Primary Source Country											
PH											
Occur Country											
PH											
Transmission Date Format											
102											
Transmission Date											
20180810											
Report Type											
2											

The fields in the Safety Report section are described below:

Safety Report Version	Not an E2B data element, used for technical transmission purposes
Safety Report ID	Sender's (Case) Safety Report Unique Identifier Text Field
Primary Source Country	Country from where the report was sent Text Field
Occur Country	For example, this should be the country where the reaction was detected while the patient was traveling, but the report was made by a health professional on the patient's return Text Field
Transmission Date Format	Date format CCYYMMDD (e.g., 20171020 for October 20 2017)
Transmission Date	Date E2B was sent

Report Type

- Spontaneous
- Report from study
- Other
- Not available to sender (unknown)

Serious

2=No

Seriousness Death

Seriousness Life Threatening

Seriousness Hospitalization

Seriousness Disabling

Seriousness Congenital Anomaly

Seriousness Other

Serious	Dropdown list Yes, No
Seriousness Death	Dropdown list Yes, No
Seriousness Life Threatening	Dropdown list Yes, No
Seriousness Hospitalization	Dropdown list Yes, No
Seriousness Disabling	Dropdown list Yes, No
Seriousness Congenital Anomaly	Dropdown list Yes, No

Seriousness Other

Dropdown list
Yes, No

Receive Date Format

102

Date report was first received

yyyy-mm-dd

Receipt Date Format

102

Date of most recent info

20180810

Additional Document

Document List

Fulfill Expedite Criteria

2=No

Duplicate

2

Case Nullification

Nullification Reason

Medically Confirm

Receive Date Format	Date format CCYYMMDD (e.g., 20171020 for October 20 2017)
Date report was first received	For senders dealing with initial information, this is always be the date the information was received from the primary source. When retransmitting information received from another regulatory agency or another company or any other secondary source, enter the date the re-transmitter first received the information. Date field
Receipt Date Format	Date format CCYYMMDD (e.g., 20171020 for October 20 2017)
Date of most recent info	Date of receipt of the most recent information for this report Date field
Additional Document	Dropdown list Yes, No
Document List	List of documents held by sender Text field
Fulfill Expedite Criteria	Does this case fulfill the local criteria for an expedited report? Dropdown list Yes, No
Duplicate	Other case identifiers in previous transmissions
Case Nullification	Cancel this report? Dropdown Yes
Nullification Reason	Reason(s) for cancelling the report Text field
Medically Confirm	Was the case medically confirmed, if not initially from health professional? Dropdown list Yes, No

5.7.1.3 Primary Source

The Primary Source section provides information about the first person who reported the event to authorities.

Message Header	Safety Report	Primary Source	Sender	Receiver	Patient	Medical History Episode	Past Drug Therapy	Patient Death	Reaction	Test	Drug
Summary											
Reporter Title											
<input type="text"/>											
Reporter Given Name											
<input type="text"/>											
Reporter Middle Name											
<input type="text"/>											
Reporter Family Name											
<input type="text"/>											
Reporter Organization											
<input type="text"/>											
Reporter Department											
<input type="text"/>											

The fields in the Primary Source section are described below:

Reporter Title	Text field
Reporter Given Name	Text field
Reporter Middle Name	Text field
Reporter Family Name	Text field
Reporter Organization	Text field
Reporter Department	Text field

Reporter Street

Reporter City

Reporter State

Reporter Postcode

Reporter Country

Qualification

Study Name

Sponsor Study Number

Observation Study Type

Reporter Street	Text field
Reporter City	Text field
Reporter State	Text field
Reporter Postcode	Text field
Reporter Country	Text field ISO3166 Country Code e.g., Philippines = PH
Qualification	Physician Pharmacist Other Health Professional Lawyer Consumer or other non-health professional

Study Name	Text field
Sponsor Study Number	Text field
Observation Study Type	Study type in which the reaction(s)/event(s) were observed Dropdown list Clinical trials Individual patient use Other studies

5.7.1.4 Sender

The Sender section provides information about the first person who reported the event to authorities.

[Message Header](#)
[Safety Report](#)
[Primary Source](#)
[Sender](#)
[Receiver](#)
[Patient](#)
[Medical History Episode](#)
[Past Drug Therapy](#)
[Patient Death](#)
[Reaction](#)
[Test](#)
[Drug](#)

Summary

Sender Type

Sender Organization

Sender Department

Sender Title

Sender Given Name

Sender Middle Name

Sender Family Name

The fields in the Sender section are described below:

Sender Type	Dropdown list Pharmaceutical Company Regulatory Authority Health professional Regional Pharmacovigilance Center WHO Collaborating Center for International Drug Monitoring Other
Sender Organization	Text field
Sender Department	Text field
Sender Title	Text field
Sender Given Name	Text field
Sender Middle Name	Text field
Sender Family Name	Text field

Sender Street Address

Sender City

Sender State

Sender Postcode

Sender Country

Sender Tel Number

Sender Tel Extension

Sender Tel Country Code

Sender Fax

Sender Fax Extension

Sender Fax Country Code

Sender Email Address

Sender Street Address	Text field
Sender City	Text field
Sender State	Text field
Sender Postcode	Text field
Sender Country	Text field

Sender Tel Number	Text field
Sender Tel Extension	Text field
Sender Fax	Text field
Sender Fax Extension	Text field
Sender Fax Country Code	ISO3166 Country Code Text e.g., Philippines = PH
Sender Email Address	Text field



Sender address details can be configured within the administration section of PViMS. Please consult your system administrator if any of these contact details need to change.

5.7.1.5 Receiver

The Receiver section provides information about the person or organization you are sending the report to.

Message Header Safety Report Primary Source Sender **Receiver** Patient Medical History Episode Past Drug Therapy Patient Death Reaction Test Drug

Summary

Receiver Type

Receiver Organization

Receiver Department

Receiver Title

Receiver Given Name

Receiver Middle Name

Receiver Family Name

The fields in the Receiver section are described below:

Receiver Type	Dropdown list (e.g., WHO; Regulatory Authority; Health Professional)
Receiver Organization	Text field
Receiver Department	Text field
Receiver Title	Text field
Receiver Given Name	Text field
Receiver Middle Name	Text field
Receiver Family Name	Text field

Receiver Street Address

Receiver City

Receiver State

Receiver Postcode

Receiver Country

Receiver Tel

Receiver Tel Extension

Receiver Tel Country Code

Receiver Fax

Receiver Fax Extension

Receiver Fax Country Code

Receiver Email Address

Receiver Street Address	Text field
Receiver City	Text field
Receiver State	Text field
Receiver Postcode	Text field
Receiver Country	Text field
Receiver Tel	Text field
Receiver Tel Extension	Text field

Receiver Tel Country Code	Text field
Receiver Fax	Text field
Receiver Fax Extension	Text field
Receiver Fax Country Code	Text field
Receiver Email Address	Text field



Sender address details can be configured within the administration section of PViMS. Please consult your system administrator if any of these contact details need to change.

5.7.1.6 Patient

The Patient section provides details about the person who experienced the event.

Message Header Safety Report Primary Source Sender Receiver **Patient** Medical History Episode Past Drug Therapy Patient Death Reaction Test Drug

Summary

Patient Initial

Patient GP Medical Record Number

Patient Specialist Record Number

Patient Hospital Record Number

Patient Investigation Number

Patient Birthdate Format

Patient Birthdate

Patient Onset Age

Patient Onset Age Unit

The fields in the Patient section are described below:

Patient Initial	Text field
Patient GP Medical Record Number	Text field
Patient Specialist Record Number	Text field
Patient Hospital Record Number	Text field
Patient Investigation Number	Text field
Patient Birthdate Format	Auto-filled by system
Patient Birthdate	Date field
Patient Onset Age	Text field
Patient Onset Age Unit	Dropdown list (e.g., Year, Month, Day, Week)

Gestation Period

Gestation Period Unit

Patient Age Group

Patient Weight

Patient Height

Patient Sex

Last Menstrual Date Format

Patient Last Menstrual Date

Patient Medical History Text

Results Tests Procedures

Gestation Period	Text field
Gestation Period Unit	Dropdown list (e.g., Month, Week, Day, Trimester)
Patient Age Group	Dropdown list (e.g., Infant, Child, Adolescent, Adult)
Patient Weight	Number field
Patient Height	Number field
Patient Sex	Dropdown list (e.g., Male, Female)
Last Menstrual Date Format	Auto-filled by system
Patient Last Menstrual Date	Date field
Patient Medical History Text	Text field
Results Tests Procedures	Text field

5.7.1.7 Medical History Episode

The Medical History Episode section describes any relevant medical history for the patient.



Multiple history episode records can be created per patient.

The fields in the Medical History Episode section are described below:

Patient Episode Name MedDRA Version	Auto-filled by the system
Patient Episode Name	Text field
Patient Medical Start Date Format	Auto-filled by the system
Patient Medical Start Date	Date field
Patient Medical Continue	Dropdown list (e.g., Yes, No, Unknown)
Patient Medical End Date Format	Auto-filled by the system
Patient Medical End Date	Date field
Patient Medical Comment	Text field

5.7.1.8 Past Drug Therapy

The Past Drug Therapy section describes any relevant medicines taken by the patient around the time of the event.



Multiple therapy records can be created per patient

The fields in the Past Drug Therapy section are described below:

Drug Name	Text field
Drug Start Date Format	Auto-filled by the system
Drug Start Date	Date field
Drug End Date Format	Auto-filled by the system
Drug End Date	Date field
Indication MedDRA Version	Auto-filled by the system
Indication	Text field

5.7.1.9 Patient Death

The Patient Death section provides information specific to a fatal event.

Message Header	Safety Report	Primary Source	Sender	Receiver	Patient	Medical History Episode	Past Drug Therapy	Patient Death	Reaction	Test	Drug	Summary
Patient Death Date Format												
102												
Patient Death Date												
yyyy mm-dd												
Patient Autopsy												
▼												
Patient Death Report MedDRA Version												
v20												
Patient Death Report												
Patient Determined Autopsy MedDRA Version												
v20												
Patient Determine Autopsy												

The fields in the Patient Death section are described below:

Patient Death date Format	Auto-filled by the system
Patient Death date	Date field
Patient Autopsy	Dropdown list to indicate if an autopsy was performed (e.g., Yes, No, Unknown)
Patient Death Report MedDRA Version	Auto-filled by the system
Patient Death Report	Text field to enter the cause of death according to the autopsy
Patient Determined Autopsy MedDRA Version	Auto-filled by the system
Patient Determine Autopsy	Text field to enter the cause of death according to the reporter

5.7.1.10 Reaction

The Reaction section provides information specific to the adverse event.

The fields in the Reaction section are described below:

Primary Source Reaction	Text field for term entered by the reporter
Reaction MedDRA Version LLT	Auto-filled by the system
Reaction MedDRA LLT	Text field to enter the MedDRA LLT
Reaction MedDRA Version PT	Auto-filled by the system
Reaction MedDRA PT	Text field to enter the MedDRA PT
Term Highlighted	Dropdown list to indicate if the reporter judged the event as serious (e.g., Yes, highlighted by the reporter as serious)
Reaction Start Date Format	Auto-filled by the system
Reaction Start Date	Date field

Reaction End Date Format	Auto-filled by the system
Reaction End Date	Date field
Reaction Duration	Number field
Reaction Duration Unit	Dropdown list to indicate the time unit of the duration (e.g., day, week, month)
Reaction First Time	Number field to indicate the time interval between beginning of suspect drug administration and start of reaction/event
Reaction First Time Unit	Dropdown list to indicate the time interval unit between suspect drug administration and start of reaction/event (e.g., second, minute, hour, day)
Reaction Last Time	Number field to indicate the time interval between last dose and start of reaction/event
Reaction Last Time Unit	Dropdown list to indicate the time interval unit between last dose and start of reaction/event (e.g., second, minute, hour, day)
Reaction Outcome	Dropdown list to indicate the outcome of reaction/event at the time of last observation (e.g., recovered/resolved, fatal, unknown)

5.7.1.11 Test

The Test section provides information about clinical tests and procedures that are relevant to the adverse reaction.

Test Date	Test Name	Test Result	Test Unit	Low Test Range	High Test Range	
20180709	Haemoglobin	10	mg/dL			Action ▾
20170712	AFB Smear Result	SCANTY	mg/dL			Action ▾
20170125	Glucose	80.00	mg/dL			Action ▾
20170124	CD4 Count	555.00	cells/mm ³	500	1500	Action ▾

[Add Test History Item](#)

The fields in the Test section are described below:

Test Date Format	Auto filled by the system
Test Date	Date field
Test Name	Text field
Test Result	Text field
Test Unit	Text field
Low Test Range	Text field
High Test Range	Text field
More Information	Dropdown list to indicate if more information is available (e.g., Yes, No)

5.7.1.12 Drug

The Drug section provides information about medicines taken around the time of the adverse event. Depending on your regulatory requirements, this is usually all medicines taken on the day the event started.

Note that some authorities have additional requirements, e.g., all medicines taken for up to two weeks before and including the day of the event.

Message Header Safety Report Primary Source Sender Receiver Patient Medical History Episode Past Drug Therapy Patient Death Reaction Test **Drug** Summary

Drug Characterization	Medicinal Product	Drug Dosage Text	Drug Dosage Form	Drug Start Date	Drug End Date	
1= Suspect	kanamycin	1000	Unknown	20160312	20160318	Action ▾

[Add Medicinal Products item](#)

The fields in the Drug section are described below:

Drug Characterization	Dropdown list to indicate if the medicine's relationship to the medicine (e.g., suspect, concomitant, interacting)
Medicinal Product	Text field to enter the name of the medicine
Obtain Drug Country	Text field to enter the Identification of the country where the drug was obtained
Batch Number	Text field to enter the medicine's batch number
Authorization Number	Text field to enter the medicine's authorization or application number
Authorization Country	Text field to enter the two letter country code ISO3166 Country Code e.g., Philippines = PH
Authorization Holder	Text field to enter the name of the authorization holder or applicant
Structured Dosage	Number field to enter the number of doses
Structured Dosage Unit	Dropdown list to enter the dose unit (e.g., mg, mL, Meq, Mmol)
Number Separate Dosages	Number field to indicate the number of separate dosages

Number Units In Interval	Number field to indicate the number of units in the interval
Interval Definition	Dropdown list to define the interval (e.g., day, week, month)
Cumulative Dose to First Number	Number field to indicate the cumulative dose to first reaction
Cumulative Dose to First Unit	Dropdown list to indicate the cumulative dose to first reaction unit (e.g.,
Drug Dosage Text	Number field to indicate the medicine dose
Drug Dosage Form	Text field to indicate the physical form of the medicine
Drug Administration Route	Dropdown list to indicate the route of administration (e.g., oral, i.m., topical)
Drug Paradministration	Dropdown list to indicate parent route of administration (in case of a parent child/fetus report) (e.g., oral, i.m., topical)
Reaction Gestation Period	Parent route of administration (in case of a parent child/fetus report)
Reaction Gestation Period Unit	Number field to indicate gestation period at time of exposure
Drug Indication MedDRA Version	Dropdown list to indicate gestation period at time of exposure (e.g., week, month, trimester)
Drug Indication	Text field to indicate why the medicine was administered
Drug Start Date Format	Auto-filled by the system
Drug Start Date	Date field
Drug Start Period	Number field to indicate the time interval between beginning of drug administration and start of reaction or event

Drug Start Period Unit	Dropdown list to indicate the unit of time for the interval between beginning of drug administration and start of reaction or event (e.g., day, week, month)
Drug Last Period	Number field to indicate the time interval between last dose of drug and start of reaction or event
Drug Last Period Unit	Dropdown list to indicate the unit for the time interval between last dose of drug and start of reaction or event (e.g., day, week, month)
Drug End Date Format	Auto-filled by the system
Drug End Date	Date field
Drug Treatment Duration	Number field
Drug Treatment Duration Unit	Dropdown list to indicate the unit for the duration unit (e.g., day, week, month)
Drug Action	Dropdown list to indicate what action was taken with respect to the medicine (e.g., drug withdrawn, dose reduced, dose increased, dose not changed, unknown, or not applicable)
Recurrence Administration	Dropdown list to indicate if reaction recurred on re-administration (e.g., Yes, no, unknown)
Source of Assessment	Text field to indicate the source of causality assessment (e.g., WHO or Naranjo)
Assessment Result	Text field to enter the causality assessment term (e.g., certain, possible, unrelated)
Additional Information	Text field to enter any additional information about the medicine.

5.7.1.13 Summary

The Summary section provides the ability to add a narrative about the adverse event.

The screenshot shows a navigation menu at the top with the following items: Message Header, Safety Report, Primary Source, Sender, Receiver, Patient, Medical History Episode, Past Drug Therapy, Patient Death, Reaction, Test, Drug, and Summary (highlighted in orange). Below the menu are several text input fields: Narrative Include Clinical, Reporter Comment, Sender Diagnosis MedDRA Version (with a grey bar below it), Sender Diagnosis, and Sender Comment.

The fields in the Summary section are described below:

Narrative Include Clinical	Text field to enter any additional information about the event
Reporter Comment	Text field to enter comments from the reporter
Sender Diagnosis MedDRA Version	Auto-filled by the system
Sender Diagnosis	Text field to enter the diagnosis according to the sender
Sender Comment	Text field to enter comments from the sender

5.7.2 Adding Information to and Updating an E2B File

Once an E2B file is created, the **Update E2B** menu allows the user to add information to or updating existing information populated in an E2B file.

Once you have searched for a report, click on the **Update E2B** menu for the associated file you would like to amend.

The screenshot shows the 'Active Reports' section of the PViMS system. At the top, there are search filters for 'Report Criteria' (set to 'All Reports'), 'Report Date From' (2018-02-11), and 'Report Date To' (2018-08-10), with a 'Search' button. Below the filters, it indicates '4 row(s) matching criteria found...'. A table lists four reports. The second report, dated 2018-07-09 14:41, is selected. Its 'Action' menu is open, showing options: 'View Activity History', 'Update E2B' (highlighted in yellow), 'Prepare Report for E2B Submission', 'View Patient', and 'View Patient Summary'. The table columns include 'Created', 'Identifier', 'Patient', 'Medication Summary', 'WHO', 'Naranjo', 'Adverse Event', 'MedDRA Term', 'Status', and 'Action'.

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin: 1000 milligram	Probable	Probable	Dizziness	Dizziness	Extract E2B E2BINITIATED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine, capreomycin: 1000 mg, doxycycline: 1000 milligram, ibuprofen: 1000 milligram, tenofovir disoproxil fumarate: 1000 milligram	Certain		Vertigo (excl dizziness)	Fine motor delay	Extract E	View Activity History, Update E2B, Prepare Report for E2B Submission, View Patient, View Patient Summary
2018-08-08 16:11	11/2018/00033	Test Patient	succimer: 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

The system will navigate you to the **E2B ICH Report** page for the file.

Once you completed making amendments, click on the **Save** button to save the changes or the **Back** button to cancel the action and return to the previous page.

5.7.3 Preparing a Report for E2B Submission

The **Extract E2B** stage facilitates the process of generating an E2B extract for submission to the World Health Organization Uppsala Monitoring Centre.

Once you have created an E2B file and searched for the report, click on the **Prepare Report for E2B Submission** menu for the associated report you would like to prepare.

The screenshot shows the 'Active Reports' interface. At the top, there are search filters for 'Report Criteria' (set to 'All Reports'), 'Report Date From' (2018-02-11), and 'Report Date To' (2018-08-10). Below the filters, a message indicates '4 row(s) matching criteria found...'. A table lists four reports with columns for 'Created', 'Identifier', 'Patient', 'Medication Summary', 'Adverse Event', 'MedDRA Term', 'Status', and 'Action'. The second report is selected, and a dropdown menu is open over its 'Action' column, with 'Prepare Report for E2B Submission' highlighted in yellow. Other options in the menu include 'View Activity History', 'Update E2B', 'View Patient', and 'View Patient Summary'.

The system will navigate you to the **Add Activity** page.

Specify any additional comments for preparing the record and click **Submit** to confirm the deletion or **Back** to cancel the action and return to the previous page.

The screenshot shows the 'Add Activity' page. It features a 'Current Status' section with 'E2BINITIATED' selected. Below it, a 'New Status' section has 'E2BGENERATED' highlighted in yellow. A 'Comments' section contains a text input field with the text 'Ready to submit to WHO' also highlighted in yellow. At the bottom right, there are 'Back' and 'Submit' buttons.

The system will update the status of the report accordingly.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-11 | Report Date To: 2018-08-10 | Search

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram	Probable	Probable	Dizziness	Dizziness	Extract E2B E2BGENERATED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine, capreomycin, 1000 mg, doxycycline, 1000 milligram, ibuprofen, 1000 milligram, tenofovir disoproxil fumarate, 1000 milligram	Certain	IGNORED	Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUBMITTED	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries



It is during this stage that PViMS prepares the XML file for submission. It also prepares an associated patient summary and patient extract that correspond to the clinical data at the point of generating the submission.

5.7.4 Viewing the E2B XML File

Once you have prepared the E2B file for submission and searched for the report, click on the **View Activity History** menu for the associated report you would like to view the XML file for.

Active Reports


Report Criteria: All Reports | Report Date From: 2018-02-11 | Report Date To: 2018-08-10 | Search

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram	Probable	Probable	Dizziness	Dizziness	Extract E2B E2BGENERATED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine, capreomycin, 1000 mg, doxycycline, 1000 milligram, ibuprofen, 1000 milligram, tenofovir disoproxil fumarate, 1000 milligram	Certain	IGNORED	Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUBMITTED	View Activity History Confirm E2B Submission Download XML View Patient View Patient Summary
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries


The system will navigate you to the **Activities** page where you will be able to view a comprehensive history of activities by the analyst against this adverse event.

 Activities

Activity	Execution Event	Executed By	Executed Date	Comments	Receipt Date	Receipt Code	Actions
Confirm Report Data	UNCONFIRMED	Admin User	2018-02-23 14:29				
Confirm Report Data	CONFIRMED	Admin User	2018-08-09 19:48				
Set MedDRA and Causality	NOTSET	Admin User	2018-08-09 19:48				
Set MedDRA and Causality	MEDDRASET	Admin User	2018-08-09 19:48	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	Admin User	2018-08-09 20:28				
Extract E2B	NOTGENERATED	Admin User	2018-08-09 20:28				
Extract E2B	E2BINITIATED	Admin User	2018-08-10 06:13	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	Admin User	2018-08-10 07:33	Ready to submit to WHO			Action ▾

Back

Locate the **E2BGENERATED** execution event for the report, click the action menu, and select the **View E2B file** menu.

 Activities

Activity	Execution Event	Executed By	Executed Date	Comments	Receipt Date	Receipt Code	Actions
Confirm Report Data	UNCONFIRMED	Admin User	2018-02-23 14:29				
Confirm Report Data	CONFIRMED	Admin User	2018-08-09 19:48				
Set MedDRA and Causality	NOTSET	Admin User	2018-08-09 19:48				
Set MedDRA and Causality	MEDDRASET	Admin User	2018-08-09 19:48	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	Admin User	2018-08-09 20:28				
Extract E2B	NOTGENERATED	Admin User	2018-08-09 20:28				
Extract E2B	E2BINITIATED	Admin User	2018-08-10 06:13	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	Admin User	2018-08-10 07:33	Ready to submit to WHO			Action ▾

Back

- View Patient Summary
- View Patient Extract
- View E2B File

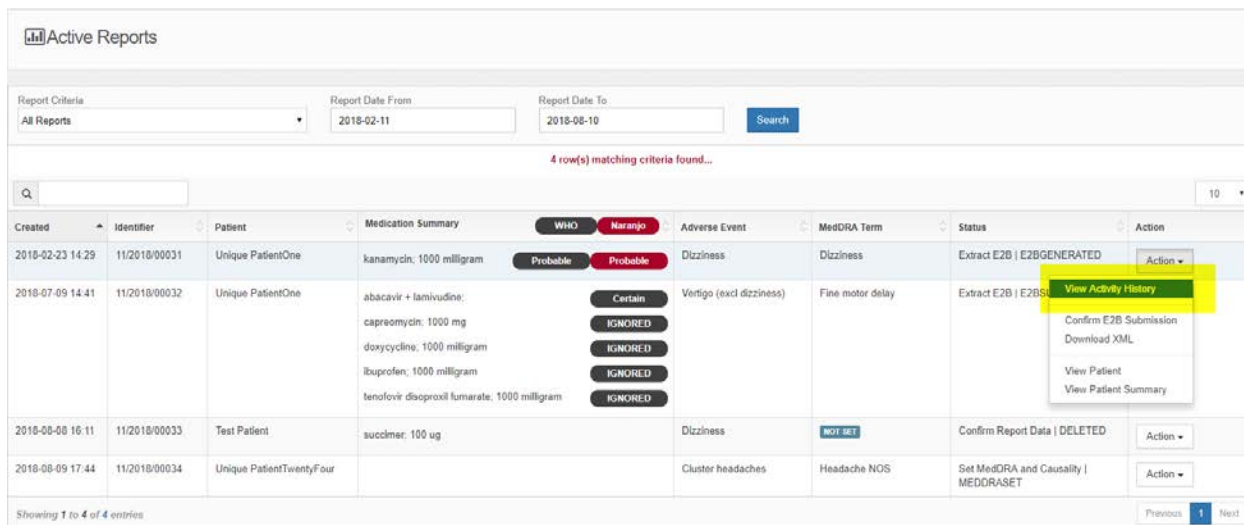
The system will automatically generate the XML file for the E2B submission to WHO. Save the file on your local computer for referral when sending to WHO.

The extract below is the XML generated for the Message Header section of the XML file.


```
<?xml version="1.0" encoding="utf-16"?>
<ichicsr lang="en">
  <ichicsrmessageheader>
    <messagetype>ICHICSR</messagetype>
    <messageformatversion>2.1</messageformatversion>
    <messageformatrelease>1.0</messageformatrelease>
    <messagenumb>00000770</messagenumb>
    <messagesenderidentifier>FDA</messagesenderidentifier>
    <messagereceiveridentifier>UMC</messagereceiveridentifier>
    <messagedateformat>204</messagedateformat>
    <messagedate>20180810120000</messagedate>
  </ichicsrmessageheader>
```

5.7.5 Viewing the Clinical Data Associated to the E2B XML File

Once you have prepared the E2B file for submission and searched for the report, click on the **View Activity History** menu for the associated report you would like to view the XML file for.




The system will navigate you to the **Activities** page where you will be able to view a comprehensive history of activities by the analyst against this adverse event.

 Activities

Activity	Execution Event	Executed By	Executed Date	Comments	Receipt Date	Receipt Code	Actions
Confirm Report Data	UNCONFIRMED	Admin User	2018-02-23 14:29				
Confirm Report Data	CONFIRMED	Admin User	2018-08-09 19:48				
Set MedDRA and Causality	NOTSET	Admin User	2018-08-09 19:48				
Set MedDRA and Causality	MEDDRASET	Admin User	2018-08-09 19:48	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	Admin User	2018-08-09 20:28				
Extract E2B	NOTGENERATED	Admin User	2018-08-09 20:28				
Extract E2B	E2BINITIATED	Admin User	2018-08-10 06:13	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	Admin User	2018-08-10 07:33	Ready to submit to WHO			Action ▾

Back

Locate the **E2BGENERATED** execution event for the report, click the action menu, and select the **View Patient Summary** or **View Patient Extract** menu.

 Activities

Activity	Execution Event	Executed By	Executed Date	Comments	Receipt Date	Receipt Code	Actions
Confirm Report Data	UNCONFIRMED	Admin User	2018-02-23 14:29				
Confirm Report Data	CONFIRMED	Admin User	2018-08-09 19:48				
Set MedDRA and Causality	NOTSET	Admin User	2018-08-09 19:48				
Set MedDRA and Causality	MEDDRASET	Admin User	2018-08-09 19:48	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	Admin User	2018-08-09 20:28				
Extract E2B	NOTGENERATED	Admin User	2018-08-09 20:28				
Extract E2B	E2BINITIATED	Admin User	2018-08-10 06:13	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	Admin User	2018-08-10 07:33	Ready to submit to WHO			Action ▾

Back

- View Patient Summary
- View Patient Extract
- View E2B File

If you select the **View Patient Summary** menu, the system will generate a MS Word extract of the associated clinical data. See [Extracting a Patient Summary](#).

If you select the **View Patient Extract** menu, the system will generate an MS Excel extract of the associated clinical data.

A	B	C	D	E	F	G	H	I	J	
Assdt/Jsar	Patient	SourceTerminologyMedOr	PatientClinicalEventGuid	SourceDescription	OnsetDate	ResolutionDate	Archived	ArchivedDate	ArchivedReason	AgeGroup
2	Bee3d4b4-faba-4566-9d34-1ce73715507c	Dizziness	f54d1d55-1c6f-4643-962a-3639aed12b86	Dizziness	2016-08-03		False			Child > 4 year
3	Bee3d4b4-faba-4566-9d34-1ce73715507c	Brusings	2a5a828a-3c6b-4399-8537-f7512631d5ef	Brusings easily	2017-06-13		False			Child > 4 year
4	Bee3d4b4-faba-4566-9d34-1ce73715507c	Benign essential hypertension antepartum	f93c35c0-9992-4584-8549-40294929ea39	Dizziness	2017-12-19		False			Child > 4 year
5	Bee3d4b4-faba-4566-9d34-1ce73715507c	Dizziness essential	efc486ca-3231-4c29-80e1-aac01186a0	Dizziness	2017-12-19		False			Child > 4 year
6	Bee3d4b4-faba-4566-9d34-1ce73715507c	Benign essential hypertension complicating pregnancy, childbirth, and the puerperium, unspecified as	d9bd3926-bd07-465a-8c5c-f31881f43d46	hy	2017-12-19		False			Child > 4 year
7	Bee3d4b4-faba-4566-9d34-1ce73715507c	Benign essential hypertension with delivery	f5a33a28-a050-4854-997b-1c25cd49d4f1	h	2017-12-19		False			Child > 4 year
8	Bee3d4b4-faba-4566-9d34-1ce73715507c	Benign essential hypertension, postpartum	ata9d1a6-812-4c50-8d25-158000c0fa06	sd	2017-12-19		False			Child > 4 year
9	Bee3d4b4-faba-4566-9d34-1ce73715507c	Other benign secondary hypertension	b7560972-e0c7-45e6-82a4-3e28b4fb686a	Hypertension999	2017-12-19		False			Child > 4 year
10	Bee3d4b4-faba-4566-9d34-1ce73715507c	Hypertension not adequately controlled	dc0d2f1f-3093-48ba-b0ea-32a62b703506	dhfsd	2017-12-19		False			Child > 4 year
11	Bee3d4b4-faba-4566-9d34-1ce73715507c	White coat hypertension	c6564645-2061-4219-b967-9a74ebc94d29	Hypertension	2017-12-20		False			Child > 4 year
12	Bee3d4b4-faba-4566-9d34-1ce73715507c	Unspecified non-vascular hypertension	d8a6c02-b0d7-4089-8189-9d016c3e1128	sd	2017-12-04		False			Child > 4 year
13	Bee3d4b4-faba-4566-9d34-1ce73715507c	Hypertension portal	4590a652-89c5-44a4-b784-b6a4733a8bd	d	2017-12-19		False			Child > 4 year
14	Bee3d4b4-faba-4566-9d34-1ce73715507c	Hypertension worsened	e4467ee6-28a5-406a-aeaf-c9e6275ce0b	sdsd	2017-12-27		False			Child > 4 year
15	Bee3d4b4-faba-4566-9d34-1ce73715507c	Vertigo (excl dizziness)	b8068d2-0b64-4052-8abe-775ba97c7169	Patient is very dizzy	2018-07-09		False			Child > 4 year



In both the Patient Extract and Summary above, these files are stored along with the XML file as a reference to the clinical data associated with the XML file at the point the XML file was generated.

5.7.6 Confirming a Report for E2B Submission

Once you have prepared the E2B file for submission and searched for the report, click on the **Confirm E2B Submission** menu for the associated report you would like to submit.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-11 | Report Date To: 2018-08-10 | [Search](#)

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram	Probable Probable	Dizziness	Extract E2B E2BGENERATED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abecavir + lamivudine, capreomycin, 1000 mg, doxycycline, 1000 milligram, ibuprofen, 1000 milligram, tenofovir disoproxil fumarate, 1000 milligram	Certain IGNORED IGNORED IGNORED	Vertigo (excl dizziness)	Extract E2B E2BSI	View Activity History Confirm E2B Submission Download XML View Patient View Patient Summary
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug		Dizziness	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour			Cluster headaches	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries | Previous 1 Next

The system will navigate you to the **Add Activity** page.

Specify any additional comments for confirming the submission and click **Submit** to confirm the deletion or **Back** to cancel the action and return to the previous page.

Add Activity

Activity

Activity Details

Current Status
E2BGENERATED

New Status
E2BSUBMITTED

Comments
Report is ready for submission

Receipt Date
2018-08-09

Receipt Code
DCF-02012

Back Submit



The receipt date and code can be used to note correspondence with WHO on the receipt of the E2B XML submission file.

The system will update the status of the report accordingly.

Active Reports

Report Criteria: All Reports | Report Date From: 2018-02-11 | Report Date To: 2018-08-10 | Search

4 row(s) matching criteria found...

Created	Identifier	Patient	Medication Summary	WHO	Naranjo	Adverse Event	MedDRA Term	Status	Action
2018-02-23 14:29	11/2018/00031	Unique PatientOne	kanamycin, 1000 milligram	Probable	Probable	Dizziness	Dizziness	Extract E2B E2BSUBMITTED	Action
2018-07-09 14:41	11/2018/00032	Unique PatientOne	abacavir + lamivudine, capreomycin, 1000 mg doxycycline, 1000 milligram ibuprofen, 1000 milligram tenofovir disoproxil fumarate, 1000 milligram	Certain		Vertigo (excl dizziness)	Fine motor delay	Extract E2B E2BSUBMITTED	Action
2018-08-08 16:11	11/2018/00033	Test Patient	succimer, 100 ug			Dizziness	NOT SET	Confirm Report Data DELETED	Action
2018-08-09 17:44	11/2018/00034	Unique PatientTwentyFour				Cluster headaches	Headache NOS	Set MedDRA and Causality MEDDRASET	Action

Showing 1 to 4 of 4 entries | Previous 1 Next

5.8 Analyser

This section is used to generate the relative risk for a specified adverse drug reaction based on an exposed and non-exposed population set over a defined period of time.

The analyser user can access the following functionality within the analytical portal:

- Define population set (cohort or condition group)
- Define reporting period
- Specify additional risk factors
- View risk ratios per exposed drug
- Download dataset for further analysis

5.8.1 Methodology

The following formulas, calculations and definitions are used in the calculation of the relative risk for a specific medication and adverse reaction.

5.8.1.1 Incidence Rate

The incidence rate is the number of new cases per population in a given time period

$$IR = (ADR / Population) * 1000$$

Where

IR = Incidence Rate

ADR = Number of adverse drug reactions *

Population = Total patient years in reporting period **

Note

* Where causality is set to possible, probably/likely or Certain for WHO assessments and where causality is set to possible, probable or definite for Naranjo assessments

** Population is represented in patient years. For example, if the reporting period is 30 days, and 10 patients were on treatment for all 30 days, the total patient years is $300 / 365.25$ which is 0.82.

Example

Cases = 11

Non-Cases = 170

Population = 181 (11 + 170)

Incidence Rate = $11/181 * 1000 = 60.77$

5.8.1.2 Relative Risk

Relative risk is defined as the incidence in the exposed over incidence in the non-exposed.

$$RR = IR1 / IR2$$

Where

RR = Relative Risk

IR1 = Incidence Rate for exposed population. The exposed population is defined as the patient population that have been exposed to a medication in the reporting period.

IR2 = Incidence Rate for non-exposed population. The exposed population is defined as the patient population that have NOT been exposed to a medication in the reporting period.

Example

Incidence Rate Exposed = 60.77

Incidence Rate Non-Exposed = 45.12

RR = **1.35**

5.8.1.3 Confidence Interval

A confidence interval is a range of values so defined that there is a specified probability that the value of a parameter lies within it. Most commonly, the 95% confidence interval is used.

$$CI = \log(RR) \pm SE \times z_{\alpha}$$

Where

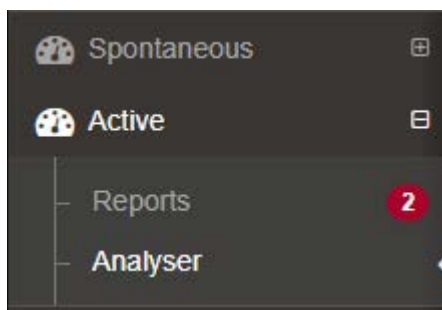
z_{α} is the standard score for the chosen level of significance and SE the standard error.

5.8.2 Generating Unadjusted Relative Risk Ratios

To implement the methodology for generating an **Unadjusted Relative Risk Ratio**, the following parameters will need to be specified:

- The population target (condition group or Cohort)
- The date range for the analysis

The **Analysers** function can be accessed through the main menu.



5.8.2.1 Specifying the Population Group

 A screenshot of the 'Analysis Criteria for Active Reporting' dialog box. The title bar shows a speech bubble icon, the text 'Analysis Criteria for Active Reporting', and window control icons. The dialog has three tabs: 'Patient Population' (selected and highlighted in orange), 'Date Range', and 'Risk Factors'. Below the tabs is a dark grey instruction bar: 'To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.' Underneath, there are two dropdown menus. The first is labeled 'Primary Condition Group Risk Factor' and is currently empty. Below it is the text '-- OR --'. The second dropdown menu is labeled 'Cohort' and is also currently empty.

By selecting a **Condition Group** or **Cohort**, you are effectively able to target a specific set of patients for analysis.

To specify a **Condition Group**, click the Primary Condition Group Risk Factor field and select the primary condition you would like to run analysis against. If this option is selected, all patients that belong to the corresponding Condition Group will be included in the analysis.

Analysis Criteria for Active Reporting

Patient Population | Date Range | Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Primary Condition Group Risk Factor

- TB
- Malaria
- HIV

Analyse

To specify a **Cohort**, click the Cohort field and select the primary cohort you would like to run analysis against. If this option is selected, all patients that belong to the corresponding Cohort will be included in the analysis.

Analysis Criteria for Active Reporting

Patient Population | Date Range | Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Primary Condition Group Risk Factor

-- OR --

Cohort

- 18MTR Program Condition
- 9MTR Program Condition
- 9MTR Study
- BDQ Study
- Finn
- Test
- XDRTB Program Condition

Analyse

5.8.2.2 Specifying the Date Range for the Analysis

Analysis Criteria for Active Reporting

Patient Population **Date Range** Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Search From: 2012-02-03 Search To: 2018-08-10

Analyse

By selecting a **Date Range**, the system will determine which patients should be included into the analysis from the Patient Population specified in the previous step. Patients that have been actively exposed to medication within that range will be included.

5.8.2.3 Running the Analysis

Once the **Patient Population** and **Date Range** parameters have been selected, click on the **Analyse** button to execute the analysis.

Analysis Criteria for Active Reporting

Patient Population **Date Range** Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Search From: 2012-02-03 Search To: 2018-08-10

Analyse

The system will conduct an initial analysis that will identify what Adverse Drug Reactions have been identified over the reporting period and will return how many types of Drug Reactions there were.

Analysis Criteria for Active Reporting
- ↗

Patient Population

Date Range

Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Primary Condition Group Risk Factor

-- OR --

Cohort

Results

2 row(s) matching criteria found...

Select the **Adverse Drug Reaction** that you would like to detect signals for.

Results

2 row(s) matching criteria found...

- Please select a reaction --
- Dizziness
- Fine motor delav

You are able to now view a 2 by 2 table illustrating relative risk and 95% Confidence Interval for the selected reaction.

- Incidence Rate for exposed group
- Incidence Rate for non-exposed group
- Relative Risk for the associated medication
- 95% Confidence Interval for the associated medication

Results

Drug	Exposed				Non-Exposed				Unadj. RR	Adj. RR	CI 95%
	Cases	Non-Cases	Population	IR	Cases	Non-Cases	Population	IR			
abacavir + lamivudine	0	1	4.02	0.00	77	98	585.54	440.00	0.00	** N/A **	0.00 - 0.00
capreomycin	0	50	60.11	0.00	77	49	529.45	611.11	0.00	** N/A **	0.00 - 0.00
cycloserine	0	49	57.02	0.00	77	50	532.54	606.30	0.00	** N/A **	0.00 - 0.00
ethambutol	7	43	60.09	140.00	70	49	529.48	588.24	0.24	** N/A **	0.12 - 0.48
ethionamide	27	25	60.02	519.23	50	47	529.54	515.46	1.01	** N/A **	0.73 - 1.39
kanamycin	0	49	57.00	0.00	77	50	532.56	606.30	0.00	** N/A **	0.00 - 0.00
levofloxacin	1	48	57.02	20.41	76	50	532.54	603.17	0.03	** N/A **	0.00 - 0.24
moxifloxacin	7	43	60.09	140.00	70	49	529.48	588.24	0.24	** N/A **	0.12 - 0.48
p-aminosalicylic acid	7	43	60.09	140.00	70	49	529.48	588.24	0.24	** N/A **	0.12 - 0.48
prothionamide	7	40	57.09	148.94	70	52	532.47	573.77	0.26	** N/A **	0.13 - 0.52
pyrazinamide	21	28	57.02	428.57	56	50	532.54	528.30	0.81	** N/A **	0.56 - 1.17

5.8.2.4 Viewing the Contributing Patient List

Once analysis has been executed, it is possible to view the list of patients that have contributed to the analysis population set through the Patient List which appears at the end of the analysis screen.

Patient List

Showing 1 to 10 of 855 entries

Patient Name	Drug	Contribution				Risk Factor			
		Start Date	Finish Date	Days	Reaction	Factor	Criteria	Criteria Met	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Adolescent (11 to 16 years)	No	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Adult <= (16 to 69 years)	Yes	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Child (4 to 11 years)	No	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Elderly > (over 69 years)	No	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Infant (1 month to 4 years)	No	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Neonate (0 to 1 month)	No	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Secondary Condition	Has HIV	No	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Secondary Condition	Has Malaria	No	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Secondary Condition	Has TB	Yes	
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Gender	Is Male	Yes	

The columns in the patient list table are described below:

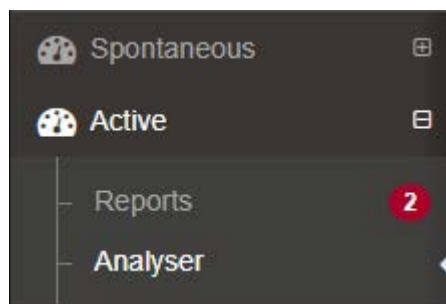
Patient Name	The name of the patient contributing to the patient population
Drug	The drug the patient was exposed to during the period of analysis
Start Date	The date the patient started the medication
Finish Date	The date the patient finished the medication
Days	The number of days the patient contributed to the patient population
Reaction	Did the patient suffer a reaction during the period of analysis
Risk Factor	Which risk factor does the patient match

5.8.3 Generating Adjusted Relative Risk Ratios

To implement the methodology for generating an **Adjusted Relative Risk Ratio**, the following parameters will need to be specified:

- The population target (condition group or Cohort)
- The date range for the analysis
- The risk factors to be applied

The **Analysers** function can be accessed through the main menu.



5.8.3.1 Specifying the Population Group

Analysis Criteria for Active Reporting

Patient Population Date Range Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Primary Condition Group Risk Factor

-- OR --

Cohort

By selecting a **Condition Group** or **Cohort**, you are able to target a specific set of patients for analysis.

To specify a **Condition Group**, click the Primary Condition Group Risk Factor field and select the primary condition you would like to run analysis against. If this option is selected, all patients that belong to the corresponding Condition Group will be included in the analysis.

Analysis Criteria for Active Reporting

Patient Population Date Range Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Primary Condition Group Risk Factor

- TB
- Malaria
- HIV

Analyse

To specify a **Cohort**, click the Cohort field and select the primary cohort you would like to run analysis against. If this option is selected, all patients that belong to the corresponding Cohort will be included in the analysis.

Analysis Criteria for Active Reporting

Patient Population Date Range Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Primary Condition Group Risk Factor

-- OR --

Cohort

- 18MTR Program Condition
- 9MTR Program Condition
- 9MTR Study
- BDQ Study
- Finn
- Test
- XDRTB Program Condition

Analyse

5.8.3.2 Specifying the Date Range for the Analysis

Analysis Criteria for Active Reporting

Patient Population Date Range Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Search From Search To

2012-02-03 2018-08-10

Analyse

By selecting a **Date Range**, the system will determine which patients should be included into the analysis from the Patient Population specified in the previous step. Patients that have been actively exposed to medication within that range will be included.

5.8.3.3 Specifying Risk Factors for the Analysis

Patient Population Date Range **Risk Factors**

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Risk Factor	Option	
-- Please select a factor --	-- Please select an option --	Add Factor

Factor	Condition	Remove

Analyse

To specify a **Risk Factor**, click the Risk Factor field and select the risk factor you would like to include into the analysis. Once you have selected the risk factor, select the appropriate option associated to that risk factor and click the **Add Factor** button to add the risk factor to the selected list.

Patient Population Date Range **Risk Factors**

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Risk Factor	Option	
Age Group	Adolescent (11 to 16 years)	Add Factor

Factor	Condition	Remove

Analyse

You are able to add as many risk factors as you would like to include into the analysis by following the process above.

Patient Population Date Range **Risk Factors**

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Risk Factor: Gender Option: Is Male Add Factor

Factor	Condition	Remove
Age Group	Adolescent (11 to 16 years)	Remove
Gender	Is Male	Remove

Analyse

By including **Risk Factors** into the analysis, the system will determine which patients match the criteria stipulated by the set of risk factors and the corresponding **Relative Risk Ratio** will be adjusted based on the new population set.

5.8.3.4 Running the Analysis

Once the **Patient Population, Date Range, and Risk Factor** parameters have been selected, click on the **Analyse** button to execute the analysis.

Analysis Criteria for Active Reporting

Patient Population **Date Range** Risk Factors

To determine the correct population for the analysis, select either a cohort OR primary condition group risk factor.

Search From: 2012-02-03 Search To: 2018-08-10

Analyse

The system will conduct an initial analysis that will identify what Adverse Drug Reactions have been identified over the reporting period and will return how many types of Drug Reactions there were.

Select the **Adverse Drug Reaction** that you would like to detect signals for.

Results

You are able to now view a 2 by 2 table illustrating relative risk and 95% Confidence Interval for the selected reaction.

- Incidence Rate for exposed group
- Incidence Rate for non-exposed group
- Relative Risk for the associated medication
- 95% Confidence Interval for the associated medication

Results

Drug	Exposed				Non-Exposed				Unadj. RR	Adj. RR	CI 95%
	Cases	Non-Cases	Population	IR	Cases	Non-Cases	Population	IR			
abacavir + lamivudine	0	1	4.02	0.00	77	98	585.54	440.00	0.00		0.00 - 0.00
capreomycin	0	50	60.11	0.00	77	49	529.45	611.11	0.00		0.00 - 0.00
cycloserine	0	49	57.02	0.00	77	50	532.54	606.30	0.00		0.00 - 0.00
ethambutol	7	43	60.09	140.00	70	49	529.48	588.24	0.24		0.12 - 0.48
ethionamide	27	25	60.02	519.23	50	47	529.54	515.46	1.01	3.18	0.73 - 1.39
kanamycin	0	49	57.00	0.00	77	50	532.56	606.30	0.00		0.00 - 0.00
levofloxacin	1	48	57.02	20.41	76	50	532.54	603.17	0.03	3.18	0.00 - 0.24
moxifloxacin	7	43	60.09	140.00	70	49	529.48	588.24	0.24	3.18	0.12 - 0.48
p-aminosalicylic acid	7	43	60.09	140.00	70	49	529.48	588.24	0.24	3.18	0.12 - 0.48
prothionamide	7	40	57.09	148.94	70	52	532.47	573.77	0.26	3.18	0.13 - 0.52
pyrazinamide	21	28	57.02	428.57	56	50	532.54	528.30	0.81	3.18	0.56 - 1.17

5.8.3.5 Viewing the Contributing Patient List

Once analysis has been executed, it is possible to view the list of patients that have contributed to the analysis population set through the Patient List which appears at the end of the analysis screen.

Patient List

Patient Name	Drug	Contribution			Risk Factor			
		Start Date	Finish Date	Days	Reaction	Factor	Criteria	Criteria Met
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Adolescent (11 to 16 years)	No
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Adult <= (16 to 69 years)	Yes
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Child (4 to 11 years)	No
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Elderly > (over 69 years)	No
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Infant (1 month to 4 years)	No
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Age Group	Neonate (0 to 1 month)	No
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Secondary Condition	Has HIV	No
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Secondary Condition	Has Malaria	No
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Secondary Condition	Has TB	Yes
Unique PatientEight	dasabuvir	2016-06-03	2016-08-14	72	No	Gender	Is Male	Yes

Showing 1 to 10 of 855 entries

The columns in the patient list table are described below:

Patient Name	The name of the patient contributing to the patient population
Drug	The drug the patient was exposed to during the period of analysis
Start Date	The date the patient started the medication

Finish Date	The date the patient finished the medication
Days	The number of days the patient contributed to the patient population
Reaction	Did the patient suffer a reaction during the period of analysis
Risk Factor	Which risk factor does the patient match

5.8.4 Downloading a Dataset for Further Analysis

Click the **Download Data** button to able to download a comprehensive dataset of patient clinical data in XLSX format for importation into a third party statistical tool.

Legend

Exposed	Number of patients in the target population treated or having been treated with the medicine of interest during the reporting period	Unexposed	Number of patients in the target population who have not been treated with the medicine of interest during the reporting period
Cases	Number of patients in the target population who did experience the adverse event of interest during the reporting period	Non-Cases	Number of patients in the target population who did not experience the adverse event of interest during the reporting period
Population	Calculated in patient years over analysis period	IR	Incidence Rate per Thousand Person-Years: $((\text{Number of ADRs}) / (\text{Cohort Population} * \text{Study Duration in Years})) * 1000$
Unadj. RR	Unadjusted Relative Risk - Incidence in exposed/incidence in non-exposed with no risk factor adjustment	Adj. RR	Relative Risk- Incidence in exposed/incidence in non-exposed with risk factor adjustment

PLEASE NOTE: Exposed Cases ONLY include cases where the Adverse Drug Reaction falls within the start and end date of the medication.

For third party statistical analysis, to download all patient related data click the button below.

[Download Dataset](#)



If you are unable to locate this function, please liaise with your system administrator as the ability to download a dataset for external consumption will need to be assigned to your user profile.

6 Reporting Portal

The reports portal is the centralized hub for system reporting.

Note: the following roles have access to the report's portal:

- **All users.** All users have view access to pages defined within the portal.
- **Administrator.** The administrator has FULL permissions to the information portal.
- **Reporter Administrator.** The reports administrator has the ability to add and customize reports.

6.1 List of Standard System Reports

The reports portal includes several reports as part of the base configuration of the system. These reports are listed below:

Patients on Treatment	Aggregated number of patients per facility that have a serious event, non-serious event, and the percentage that have events
Adverse Events	Number of patients with an adverse event by age group, facility and drug
Adverse Events Quarterly	Number of patients with an adverse event by MedDRA system organ class per quarter and grade
Adverse Events Annual	Number of patients with an adverse event by MedDRA system organ class per year and grade
Causality	List adverse events where causality has been set and not set
Patients by Drug	Number of patients on a specific medication
Outstanding Visits	Patients who did not attend an appointment

6.2 Report Customization

The Reports Portal gives PViMS report publishers the ability to add new and modify existing reports within this portal. This provides PViMS analysts with an integrated platform to customize what reports are available to end users.

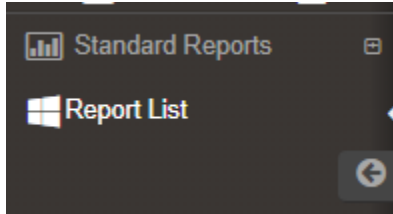
6.2.1 Types of Reports

When adding a new report, you first need to specify the type of report to be incorporated. There are currently two report types that can be customized within PViMS: A summary report that provides aggregated reporting based on the stratification criteria specified, and a list report that allows for a line by line rendering of the report in a non-aggregated manner.

6.2.2 Adding a New Report

In order to add a new report to the Reports Portal, you need to have the **Reporter Administrator** role assigned to your user profile.

To add a new report, click on the **Report List** menu.



Then click on the **Add Report** button so you can define the core characteristics of the report.



The following information must be entered when publishing a new report:

Report Name	The unique name for the report
Definition	Provide additional information that describes the report
Report Type	Is this a summary or a list report?
Core Entity	<p>The primary entity that should be reported on:</p> <ul style="list-style-type: none"> • Patient, report on patient specific criteria • PatientClinicalEvent, report on adverse event information • PatientCondition, report on concomitant conditions • PatientFacility, report on facility and patient • PatientLabTest, report on lab test information • PatientMedication, report on medication history • Encounter, report on clinical data collected per encounter • CohortGroupEnrolment, report of cohort enrolment data

6.2.2.1 Summary Report

Once the base report is configured, stratification-related information may now be specified. All attributes specified as part of the stratification list will be aggregated based on these attributes. To add a new stratification item, select the attribute from the list, specify the name of column in the display field and click the **Add new stratification** link. The attribute will be added to the stratification list.

4. Stratify by the following attributes...

Attribute	Display	
-- Not Selected --	Gender	Add new stratification
<hr/>		
Stratification		
✘ [P.Gender] AS 'Gender'		

Once the stratification list is specified, filter-related information may now be specified. All attributes specified as part of the filter list will be used to filter the result set by the end user. To add a new filter item, add the filter item as per the field description below and click the **Add new filter** link:

Relationship	Specify AND if this filter criteria must be true in conjunction with other attributes Specify OR if this filter criteria or other criteria must be true
Attribute	The attribute that is being filtered on
Operator	The operator that will be applied to the filter: <ul style="list-style-type: none"> Dates and numerics allow the following operators: Equals, Not Equals, Greater Than, Less Than, GreaterEqual Than, LessEqual Than, Between Text fields allow the following operators: Equals, Not Equals DropDown Lists allow the following operators: Equals, Not Equals, In
Field Value	<ul style="list-style-type: none"> The value that should be compared to

5. Filter by the following attributes...

Relationship	Attribute	Operator	Field Value	
And	-- Not Selected --	-- Not Selected --	0	Add new filter

Filter

✘ And ([P.Gender] = 'Male')

Enter the relevant information as defined above for the report. You can preview the results by clicking **View Results**. If you are satisfied with the results, click the **Publish** button to save your new report. If you don't want to save it, use the browser's back button to navigate away from the screen.

The system will navigate you to the new report once it has been published and the new report will appear in the custom report portal menu.

6.2.2.2 List Report

Once the base report is configured, list-related information may now be specified. All attributes specified as part of the list will be included as separate columns in the report. To add a new list item, select the attribute from the list, specify the name of column in the display field, and click the **Add new list** link. The attribute will be added to the list.

4. List by the following attributes...

Attribute	Display	
-- Not Selected --	First Name	Add new list

List

✘ [P.FirstName] AS 'First Name'

Once the list is specified, filter-related information may now be specified. All attributes specified as part of the filter list will be used to filter the result set by the end user. To add a new filter item, add the filter item as per the field description below and click the **Add new filter** link:

Relationship	Specify AND if this filter criteria must be true in conjunction with other attributes Specify OR if this filter criteria or other criteria must be true
Attribute	The attribute that is being filtered on
Operator	The operator that will be applied to the filter <ul style="list-style-type: none"> • Dates and numerics allow the following operators, Equals, Not Equals, Greater Than, Less Than, GreaterEqual Than, LessEqual Than, Between • Text fields allow the following operators, Equals, Not Equals • DropDown Lists allow the following operators, Equals, Not Equals, In
Field Value	<ul style="list-style-type: none"> • The value that should be compared to

5. Filter by the following attributes...

Relationship	Attribute	Operator	Field Value	
And	-- Not Selected --	-- Not Selected --	0	Add new filter

Filter

✕ And ([P.Gender] = 'Male')

Enter the relevant information as defined above for the report. You can preview the results by clicking **View Results**. If you are satisfied with the results, click the **Publish** button to save your new report. If you don't want to save it, use the browser's back button to navigate away from the screen.

The system will navigate you to the new report once it has been published and the new report will appear in the custom report portal menu.

6.2.3 Modifying and Deleting an Existing Report

Browse to the report using the custom report menu in the Reports Portal. To modify or delete a report, you need to have the **Reporter Administrator** role assigned to your user profile.

To modify a report, click on the **Customise Report** button. To delete a report, click on the **Delete Report** button.

7 Information Portal

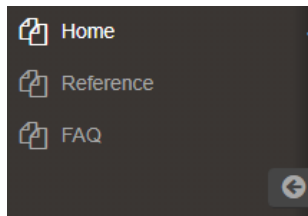
The information portal is the centralized hub for publication and presentation. PVIMS information publishers have the ability to share trends, analysis, graphs, and important information about pharmacovigilance activities.

Note: the following roles have access to the information portal:

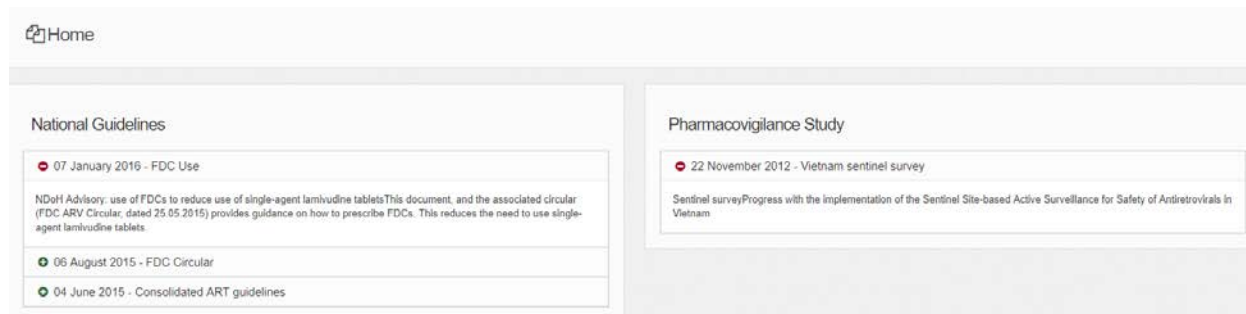
- **All users.** All users have view access to pages defined within the portal.
- **Administrator.** The administrator has FULL permissions to the information portal.
- **Publisher.** The publisher has the ability to add new pages and update content of existing pages

7.1 Viewing the home page

The Information Portal **Home Page** can be used to show information about upcoming pharmacovigilance activities as well as outcomes from existing and previous activities and reports. To access the **Home Page**, click on the **Home** menu in the Information Portal.



The system will navigate you to the **Home Page** where you are able to view, e.g., national guidelines or other information you post that would be relevant to most PVIMS users.



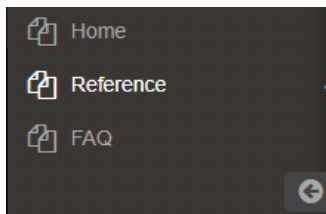
To view information for an existing date, click on the green plus icon to expand that guideline or the red minus sign to compress that guideline.

National Guidelines

➖ 07 January 2016 - FDC Use
NDoH Advisory: use of FDCs to reduce use of single-agent lamivudine tablets This document, and the associated circular (FDC ARV Circular, dated 25.05.2015) provides guidance on how to prescribe FDCs. This reduces the need to use single-agent lamivudine tablets.
➕ 06 August 2015 - FDC Circular
➕ 04 June 2015 - Consolidated ART guidelines

7.2 Viewing the Reference page

The Information Portal **Reference Page** contains a set of reference data particular to the implementation of PViMS for Pharmacovigilance activities. To access the **Reference Page**, click on the **Reference** menu in the Information Portal.



The system will navigate you to the **Reference Page** where you are able to view this reference information.

Reference

<p>Drug Safety Updated</p> <p>FDA Drug Safety Communication Prescription Acetaminophen Products 2018-08-12</p>	<p>Grading Scales Updated</p> <p>CCTAE Common Terminology Criteria for Adverse Events 2018-08-12</p> <p>DAIDS Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events 2018-08-12</p> <p>ANRS ANRS scale to grade the severity of adverse events in adults 2018-08-12</p>
<p>Standards Updated</p> <p>MedDRA Medical Dictionary for Regulatory Activities 2018-08-12</p> <p>ICD10 International Classification of Diseases 2018-08-12</p> <p>HL7 Health Level Seven 2018-08-12</p> <p>E2B Electronic Transmission of Individual Case Safety Reports 2018-08-12</p>	
<p>Causality Scales Updated</p> <p>Naranjo Naranjo Adverse Drug Reaction Probability Scale 2018-08-12</p> <p>WHO WHO Adverse Drug Reaction Probability Scale 2018-08-12</p>	

The following reference data is available for viewing: -

MedDRA	Medical Dictionary for Regulatory Activities
ICD10	International Classification of Diseases
HL7	Health-Level 7
E2B	Electronic Transmission of Individual Case Safety Reports
Naranjo	Naranjo Adverse Drug Reaction Probability Scale
WHO	WHO Adverse Drug Reaction Probability Scale
CCTAE	Common Terminology Criteria for Adverse Events
DAIDS	Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events
ANRS	ANRS scale to grade the severity of adverse events in adults

To view information about the reference, click on the blue header for that specific reference.

Standards	Updated
MedDRA Medical Dictionary for Regulatory Activities	2018-08-12
ICD10 International Classification of Diseases	2018-08-12
HL7 Health Level Seven	2018-08-12
E2B Electronic Transmission of Individual Case Safety Reports	2018-08-12

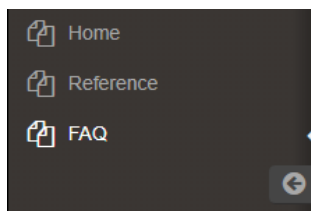
The system will navigate you to a reference page which contains additional information to that reference item.

PViMS Standards Used

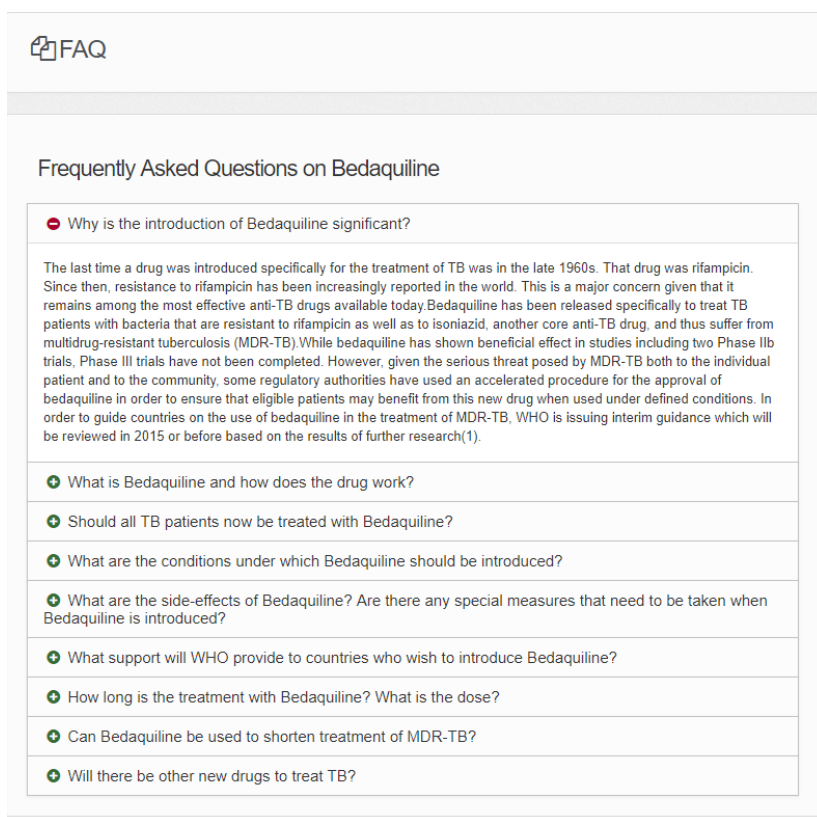
<p> Medical Dictionary For Regulatory Activities</p> <p>In the late 1990s, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) developed MedDRA, a rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans. ICH's powerful tool, MedDRA is available to all for use in the registration, documentation and safety monitoring of medical products both before and after a product has been authorised for sale. Products covered by the scope of MedDRA include pharmaceuticals, biologics, vaccines and drug-device combination products. Today, its growing use worldwide by regulatory authorities, pharmaceutical companies, clinical research organisations and health care professionals allows better global protection of patient health. Go to the MedDRA website...</p>
<p> International Classification of Diseases</p>
<p> Health Level Seven</p>
<p> Electronic Transmission of Individual Case Safety Reports</p>

7.3 Viewing the Frequently Asked Questions page

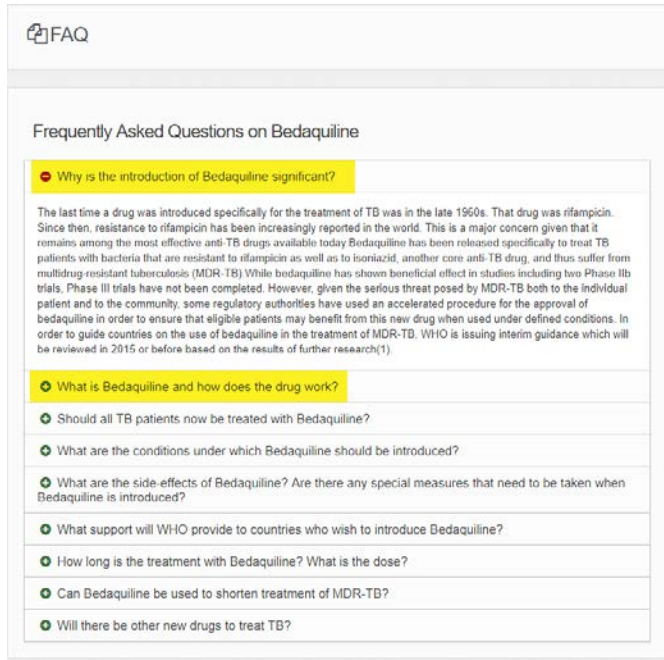
The Information Portal **FAQ Page** contains a list of frequently asked questions particular to the implementation of PViMS for Pharmacovigilance activities in relation to the use of Bedaquiline. To access the **FAQ Page**, click on the **FAQ** menu in the Information Portal.



The system will navigate you to the **FAQ Page** where you are able to view these questions.

A screenshot of a web page titled 'FAQ'. The page has a header with a 'FAQ' icon and title. Below the header, the main content is titled 'Frequently Asked Questions on Bedaquiline'. The first question is expanded, showing a red minus sign icon and the text: 'Why is the introduction of Bedaquiline significant?'. The answer text reads: 'The last time a drug was introduced specifically for the treatment of TB was in the late 1960s. That drug was rifampicin. Since then, resistance to rifampicin has been increasingly reported in the world. This is a major concern given that it remains among the most effective anti-TB drugs available today. Bedaquiline has been released specifically to treat TB patients with bacteria that are resistant to rifampicin as well as to isoniazid, another core anti-TB drug, and thus suffer from multidrug-resistant tuberculosis (MDR-TB). While bedaquiline has shown beneficial effect in studies including two Phase IIb trials, Phase III trials have not been completed. However, given the serious threat posed by MDR-TB both to the individual patient and to the community, some regulatory authorities have used an accelerated procedure for the approval of bedaquiline in order to ensure that eligible patients may benefit from this new drug when used under defined conditions. In order to guide countries on the use of bedaquiline in the treatment of MDR-TB, WHO is issuing interim guidance which will be reviewed in 2015 or before based on the results of further research(1)'. Below this are several other questions with green plus icons, which are collapsed: 'What is Bedaquiline and how does the drug work?', 'Should all TB patients now be treated with Bedaquiline?', 'What are the conditions under which Bedaquiline should be introduced?', 'What are the side-effects of Bedaquiline? Are there any special measures that need to be taken when Bedaquiline is introduced?', 'What support will WHO provide to countries who wish to introduce Bedaquiline?', 'How long is the treatment with Bedaquiline? What is the dose?', 'Can Bedaquiline be used to shorten treatment of MDR-TB?', and 'Will there be other new drugs to treat TB?'.

To view the answer for a specific question, click on the green plus icon to expand that question or the red minus sign to compress that question.



7.4 Modifying Content in the Information Portal

The information Portal is based on a content management platform whereby PViMS publishers have the ability to add new and modify existing content within this portal in a collaborative manner. This provides PViMS analysts with an integrated platform to share details of their ongoing analysis to the health community at large.

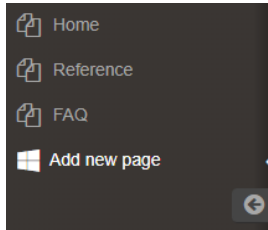
7.4.1 Adding a New Page

BUZZWORDS

Page: Consists of 1 to 6 widgets, with each widget containing content that is rendered as part of the overall page. Each page is accessible either from the main information portal menu or from within an existing widget.

When adding a new page, you are creating a platform to add content that is specific to the overall theme of that page. To add a new page to the Information Portal, you need to have the **Publisher** role assigned to your user profile.

To add a new page, click on the **Add new page** menu.



The following information must be entered when saving a new page:

Page Name	The unique name of the page. This is also the name of page header when viewing the page.
Definition	Provide additional information that describes the page
Breadcrumb	The name of the menu option that you can access to view the page
Visible to Menu	Should this page appear on the main list of menu items in the Information Portal?

Enter the relevant information for the page and either click the **Save** button to save your new page or the **Cancel** button to cancel your action and return to the **Home** page of the portal.

Manage Page

Manage Pages

Details

Page Name
Test Page

Definition
This is a test page

Breadcrumb
Test

Visible To Menu
Yes

Cancel Save

The system will navigate you to the new blank page once it has been saved and the new page will appear in the main Information Portal menu if the visible to menu field is set to yes.



See the next section for information about how to add a widget to add content to this page.

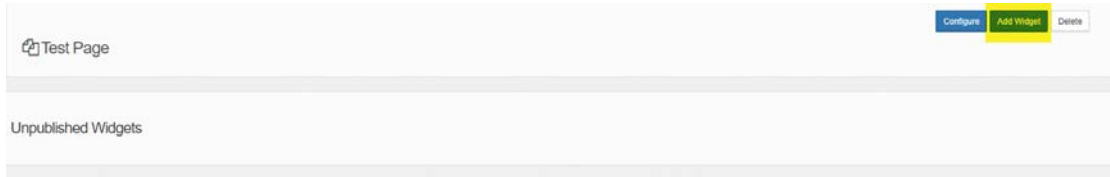
7.4.2 Adding a Widget to a Page

BUZZWORDS

Widget: A widget is an individual panel within a page that provides a container for rendering dynamic content defined by the PViMS publisher. A page within the Information Portal can store up to 6 widgets per page.

When adding a new widget, you are adding a container for new content that is specific to the overall theme of that page. To add a new widget to a page, you need to have the **Publisher** role assigned to your user profile.

To add a new widget, navigate to the page that you would like to add the widget to and click on the **Add Widget** button that appears in the page header.



The system will navigate you to an **Add New Widget** page. The following information is displayed on this screen:

Unique ID	The unique id of the page that the widget is been added to
Page Name	The name of the page that the widget is been added to



The following information must be entered when adding a new widget:

Widget Name	The unique name for the widget. This name will be displayed as the title for the content.
Widget Type	The type of widget to be added (General, ItemList, Wiki)
Widget Status	The status of the widget (Published, Unpublished) Please note: new widgets have to be added in an unpublished status
Icon	The icon that should accompany the title of the widget

Enter the relevant information for the widget and either click the **Save** button to add your new widget or the **Cancel** button to cancel your action and return to the page.

Manage Page Widgets

Page

Unique ID
85

Page Name
Test Page

Name

Unique ID

Widget Name
This is a test

Details

Widget Type
General

Widget Status
Unpublished

Icon

Icon
fa-info

Cancel Save

The system will add the new widget to the page and will now allow the user the ability to add content to the widget. Please note that a unique ID has now been allocated to the widget.

Name

Unique ID
6316da72-c42c-4fc2-b984-b0f895254bb6

Widget Name
This is a test

Details

Widget Type: General | Widget Status: Unpublished

Icon

Icon
fa-info

General Content

Source | Styles | Format | Font | Size | Sp | A | [Rich Text Editor]

** PLEASE ENTER YOUR CONTENT HERE **

Please see the section on adding content to a widget for further information on modifying content for the new widget.

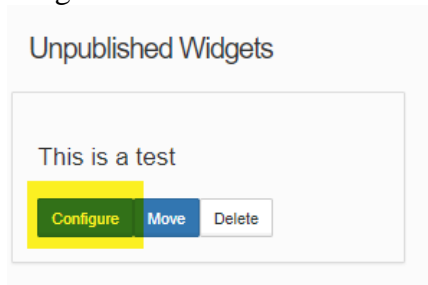
Please note: the new widget is allocated to the page as an unpublished widget. This widget therefore cannot be viewed by users who do not have the **Published** role assigned to their user profile.



7.4.3 Adding or Changing a Widget's Content

To add content to a new widget or edit content within an existing widget, you need to have the **Publisher** role assigned to your user profile.

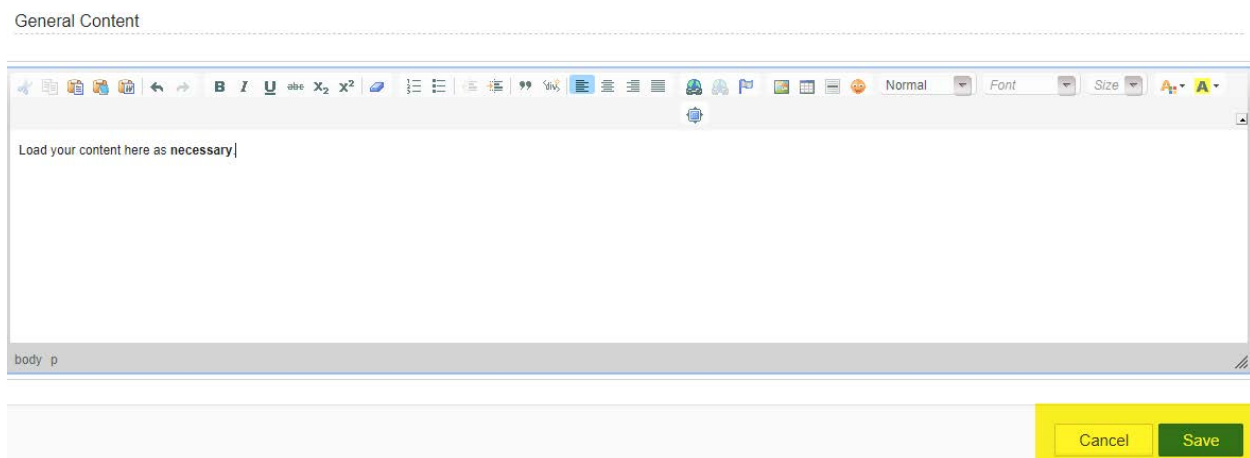
To add or edit content within a widget, navigate to the page that you would like to modify the content, locate the widget you would like to modify and click the **Configure** button for this widget.



The system will navigate you to the **Edit Widget** page where you will have the ability to edit your content.

7.4.3.1 General Widget Content

To change content for the general widget, locate the editor field in the General Content section for the widget and edit your content as necessary. Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.



7.4.3.2 ItemList Widget Content

To change content for the ItemList widget, locate the Item Content section for the widget.

To add a new item to the item list, click the **Add New Item** button. Once you have clicked this button, you will see that a new item has been added to the tabbed panel at the top of this section. Enter the title for the new item as well as the content associated to this item.

The screenshot shows a web interface titled "Item Content". At the top, there is a tabbed panel with two tabs: "Item 1" and "Item 2". The "Item 2" tab is active and highlighted in yellow. Below the tabs, there are two input fields. The first is labeled "Title" and contains the text "This is a new item in the item list". The second is labeled "Content" and contains the text "This is my content for the new item in the item list". At the bottom of the form, there are four buttons: "Remove Last Item" (grey), "Add New Item" (yellow), "Cancel" (grey), and "Save" (blue).

Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.

To remove an item from the list, click the **Remove Last Item** button. Once you have clicked this button, you will be able to note that the last item has been removed from the tabbed panel at the top of this section. Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.



It is only possible to remove the last item in the list. Please edit content from existing items if an item in the middle of the list is no longer valid.

7.4.3.3 Wiki Widget Content

To change content for the Wiki widget, locate the Wiki Content section for the widget.

To add a new item to the item list, click the **Add New Item** button. Once you have clicked this button, you will be able to note that a new item has been added to the tabbed panel at the top of this section. Enter the title for the new item as well as the sub-title and the page that the Wiki item should be routed to when clicked.

Wiki Content

Item 1 **Item 2**

Modified Date

Title

This is a new item

SubTitle

It is an example

PageContent

Reference Page 4

Remove Last Item **Add New Item**

Cancel **Save**

Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.

To remove an item from the list, click the **Remove Last Item** button. Once you have clicked this button, you will be able to note that the last item has been removed from the tabbed panel at the top of this section. Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.



It is only possible to remove the last item in the list. Please edit content from existing items if an item in the middle of the list is no longer valid.

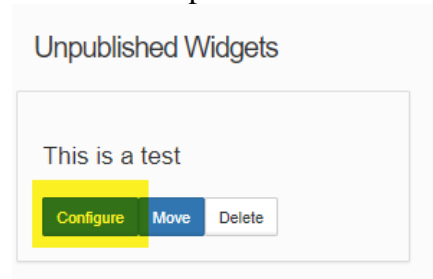
7.4.4 Publishing a Widget

BUZZWORDS

Publish: Widgets in an unpublished status are not viewable by standard users of the Information Portal (those who do not have the Publisher role assigned to their user profile). Conversely, widgets in a published status are viewable by all users.

Widgets are only to be published once the publisher is happy with the content submitted.

To publish a widget, navigate to the page that you would like to modify, locate the widget you would like to publish and click the **Configure** button for this widget.



The system will navigate you to the **Edit Widget** page where you will have the ability to publish the widget.

Change the status of the widget to **Published** and confirm the location of the widget. Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.



The location determines where on the page the widget will appear. Only one widget can occur in each of the 6 allocated spaces on a page.

Details

Widget Type

Widget Status

Current Location

Widget Location

The system will navigate you to the page that you have published the widget on. Please note that the widgets will be removed from the Unpublished Widgets section and the widget will now be viewable on the page itself.

Unpublished Widgets

<p>This is a test</p> <p>Configure Move Delete</p>	<p>This is a test for an itemlist</p> <p>Configure Move Delete</p>
--	--


 This is a test for a wiki item	Updated
<p>** PLEASE ADD TITLE HERE **</p> <p>** PLEASE ADD SUB-TITLE HERE **</p>	2018-08-12
<p>This is a new item</p> <p>It is an example</p>	2018-08-12
Configure Delete	



Saving a widget as unpublished will remove the widget from the page and move it to the Unpublished Widgets section. Widgets in this section are **not** viewable by standard users of the Information Portal.

7.4.5 Deleting a Widget

To delete a widget, navigate to the page that you would like to modify, locate the widget you would like to delete and click the **Delete** button for this widget.

 This is a test for a wiki item	Updated
** PLEASE ADD TITLE HERE ** ** PLEASE ADD SUB-TITLE HERE **	2018-08-12
This is a new item It is an example	2018-08-12

Configure Delete

The system will navigate you to a **Delete Widget** page where you will have the ability to delete the widget.

Click the **Delete** button to confirm the deletion or the **Back** button to cancel this action and return to the page view.

Widget > Delete

Delete Widget (This is a test for a wiki item)

Please note! You are about to delete this record. This action is not reversible....

Basic Details

PageName
Test Page

WidgetName
This is a test for a wiki item

WidgetType
Wiki

Back Delete



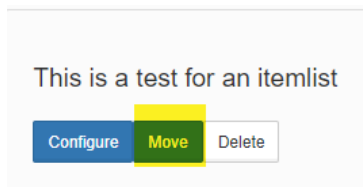
The widget and all related content will be deleted when clicking the **Delete** button.

7.4.6 Moving a Widget to a New Page

To move a widget, navigate to the page that you would like to modify, locate the widget you would like to move and click the **Move** button for this widget.



You are only able to move a widget if it is currently in an **Unpublished** status on the page it resides on.



The system will navigate you to a **Move Widget** page where you will have the ability to select the destination page for the widget.

Select the destination page and click the **Update** button to confirm the move or the **Back** button to cancel this action and return to the page view.

Widget > Move

Move Widget (This is a test for an itemlist)

Basic Details

WidgetName
This is a test for an itemlist

CurrentPageName
Test Page

Destination Page
FAQ

Back Update



The widget and all related content will be moved to the new page and will exist in an **Unpublished** status on the new page.

8 Spontaneous Reporting

PViMS provides the mechanism to register spontaneous reports by the public. While these reports form part of the overall PViMS adverse event repository where Pharmacovigilance activities can be performed against the report, they do not form part of the analysis.

Note: spontaneous reporting is available to the public and no login to PViMS is required.

8.1 Accessing Spontaneous Reporting

When you enter the correct URL to access PViMS, the system navigates you the login page. This page contains the primary link to register a spontaneous report.



USAID
FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access
to Pharmaceuticals and Services



Welcome to the SIAPS tool for strengthening pharmacovigilance services

Spontaneous Reporting

Spontaneous reporting by medical personnel and general public

You will be taken to a separate section of the site where you will be able to create the spontaneous report.

[Create Report](#)

Pharmacovigilance Monitoring System

Username

Password

Stay signed in

[Log in](#)

To register a spontaneous report, click on the **Create Report button**. The system will navigate you to a page where you can enter the spontaneous report.

8.1.1 Add a New Report

Spontaneous reports are composed of the following sections:

Patient Information	Information related to the patient who suffered the adverse event
Product Information	Information related to the medication that potentially caused the adverse event
Test Result	Any test results that are relevant to the adverse event
Reaction and Treatment	Details of the adverse event
Reporter Information	Details of the person who has logged the adverse event

8.1.1.1 Patient Information

The **Patient Information** section captures basic patient demographic information about the person who suffered the adverse event.

To enter patient information, **enter text** in the corresponding fields (e.g., **Initials of Patient**). Or click the **arrow** in a selected field to display a list of values, and select one value from the list. All elements with a red asterisk are mandatory.

Step 1 - Patient Information

Please enter some information about the person who had the adverse reaction.

*** Initials of Patient**

Enter patient's initials here OR their ID number and type below.

TST 🗨

Identification Number

Enter patient's ID number OR enter their initials above..

TST011

Identification Type

If you entered a patient ID number, specify the ID type here.

National Identity ▼

Patient Date of Birth

Enter the patient's date of birth here OR enter their age below.

2017-02-13

Age

Enter the patient's age here OR enter their date of birth above.

1

Age Unit of Measure

Enter weeks, months, or years for the patient's age here.

Years ▼

Patient's weight (kg)

6

Sex

Male ▼

Ethnic Group of Patient

Other ▼

Cancel

Next

Fields in the **Patient Information** section are described below:

Initials of Patient	Identification of the patient is facilitated through the capturing of their initials in a text field
Identification Number	Identification of the patient is facilitated through the capturing of their ID Number in a text field
Identification Type	Dropdown list to select the patient's type of identity number specified
Patient Date of Birth	Either specify the patient's date of birth
Age	Or specify the patient's age
Age Unit of Measure	If age is specified, specify the unit type for the age (e.g. days, months etc.)
Patient Weight (kg)	The weight of the page at the time of the adverse event, in kilograms
Sex	Dropdown list to specify the gender of the patient
Ethnic Group of Patient	Dropdown list to specify the ethnic group of the patient

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

8.1.1.2 Product Information

The **Product Information** section captures a list of medications that the patient was taking at the time of the adverse event.

To enter medication information, click the **Add Product Information item** button. Once a product has been added, you are able to remove or edit the medication using the appropriate button next to the medication.

Step 2 - Product Information

Please enter information about the product you suspect caused the reaction and about other products taken.

Product	Drug strength	Product Suspected	Drug strength unit	Dose Number	Dose Unit	
Penicilin	250	Yes	milligrams (mg)			Action▼

[Add Product Information item](#)

Row added successfully

Fields in the **Product Information** Section are described below:

Product	The name of the medication that the patient was taking (generic or brand name)
Drug Strength	Free format description of the drug strength, e.g. 250
Drug Strength Unit	Dropdown list specifying the unit of the drug strength, e.g., mg
Product Suspected	Is this product suspected of causing the adverse event
Dose Number	Drug dosage
Dose Unit	Dropdown list specifying the unit of the drug dosage
Route of Administration	Dropdown list specifying how the drug has been administered
Start and End Date	When did the patient start the drug and if they have completed taking the drug, when was the last date of administration
Treatment Duration	How long has the patient been on the drug

Treatment Duration Unit	Dropdown list specifying the unit for the duration
Indication	Indication for why the patient is taking this drug
Frequency	How frequently is the patient taking the drug
Batch Number	The batch number the drug forms part of
Action Taken	What action was taken when the adverse event occurred
Product Challenge	Was a challenge performed on the product when suspected of the adverse event
Product Rechallenge	Was a rechallenge performed

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

8.1.1.3 Test Results


The **Test Results** section captures a list of test results that are applicable to the adverse event.

To enter test results, click the **Add Test Results item** button. Once a test has been added, you are able to remove the result or edit the test using the appropriate button.

Step 3 - Test Results

Enter information about any tests done for the reaction, along with the results.

Test Date	Test Name	Test Result	Test Unit	Low Test Range	High Test Range	
2018-03-01	HIV Test	Negative				Action▼



Row added successfully

Fields in the **Test Results** Section are described below:

Test Date	The date the test was conducted
Test Name	The name of the test conducted
Test Result	The result of the test conducted
Test Unit	Any unit associated to the test result
Low- and High-Test Range	Test result range that is considered normal
More Information	More information associated to the test result?

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

8.1.1.4 Reaction and Treatment

The **Reaction and Treatment** section captures details of the adverse event.

To enter reaction and treatment information, **enter text** in the corresponding fields (e.g., **Description of Reaction**). Or click the **arrow** in a selected field (e.g.) to display a list of values, and select one value from the list. All elements with a red asterisk are mandatory.

Step 4 - Reaction and Treatment

Enter information about what happened and how it was treated.

***** Description of reaction

Dizziness

Start date of reaction

Enter the start date of the reaction OR enter the estimated start date in the next field.

2018-09-11

Estimated start date of reaction

If you don't know the exact start date of the reaction, enter the estimated start date here.

yyyy-mm-dd

Did any of these reactions happen?

Other medically important condition

Was treatment given for the reaction?

No

What treatment was given for the reaction?

What was the outcome of the reaction?

Recovered/resolved

What was the date of recovery from the reaction?

2018-09-26

Enter date if patient died from the reaction

yyyy-mm-dd

Other relevant information

For example, does the patient have other medical problems?

Previous

Cancel

Next

Fields in the **Reaction and Treatment** Section are described below:

Description of Reaction	A description of the adverse event
Start Date of Reaction	The date the reaction first appeared in the patient
Estimated Start Date of Reaction	Only specify this date if the exact start date is not known
Reactions	Did the patient experience a reaction
Treatment for Reaction	Was a treatment given for the reaction itself
What Treatment Given for Reaction	If a treatment was given for the reaction, what treatment was it
Reaction Outcome	What was the outcome of the reaction
Recovery Date	If the patient has recovered, what is the date of the recovery
Deceased Date	If the patient has died from the adverse event, what was the date of death
Other Relevant Info	Is there other information relevant to the adverse event

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

8.1.1.5 Reporter Information

The **Reporter Information** section captures details of the person who has reported the event.

To enter reporter information, **enter text** in the corresponding fields (e.g. **Name or Initials of person reporting the event**). Or click the **arrow** in a selected field (e.g.) to display a list of values, and select one value from the list. All elements with a red asterisk are mandatory.

Step 5 - Reporter Information

Enter information about the person reporting the reaction.

* Name or initials of person reporting information

Test Reporter

Telephone Number for reporter

Reporter E-mail Address

test@gmail.com

Profession of reporter

Physician

Report reference number (if any)

SD-010101

Reporter place of practise

Keep reporter confidential?

Do you want your identity kept confidential except to be contacted by the national medical regulatory authority or the World Health Organization if they need additional information?

Yes

Previous Cancel Preview

Fields in the **Reporter Information** Section are described below:

Name or Initials	The name or initials of the person reporting the event
Telephone Number	Contact number of the person reporting the event
Email Address	Email address of the person reporting the event
Profession	The profession of the person who has reported the event
Reference Number	Reference number for the event that has been reported
Place of Practice	At which facility does the reporter work
Confidentiality	Should the report remain confidential

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

8.1.2 Preview Report

Once you have completed all sections of the spontaneous report, click on the preview button to view a summary of the report.

Please preview your data entered and then click the finish button when ready...

Initials	TST
Identification Number	TST011
Identification Type	National Identity
Date of Birth	2017-02-13
Age	1
Age Unit	Years
Weight (kg)	6
Sex	Male
Ethnic Group	Other
Description of reaction	Dizziness
Reaction start date	2018-09-11
Reaction serious details	Other medically important condition
Treatment given for reaction	No
Outcome of reaction	Recovered/resolved
Reaction date of recovery	2018-09-26
Reporter Name	Test Reporter
Reporter E-mail Address	test@gmail.com
Reporter Profession	Physician
Report Reference Number	SD-010101
Keep Reporter Confidential	Yes

[Previous](#) [Cancel](#) [Finish](#)

Click the **Finish button** to submit the report or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

8.1.3 Confirmation

Once you have clicked the finish button, the report will be saved to the database and you will receive confirmation of this.

SPONTANEOUS REPORT ADDED SUCCESSFULLY

Your spontaneous report has been added successfully. If you have any queries, please contact us on

[Return to Home Page](#)