



PViMS

User Manual



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SIAPS Systems for Improved Access
to Pharmaceuticals and Services

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About SIAPS

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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SIAPS Program. 2017. *PViMS User's Guide*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA.

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Contents

1	Introduction.....	8
1.1	Using the Manual	9
1.2	Purpose of the Document.....	9
1.3	Audience	9
2	PViMS Structure.....	10
3	Using the System	11
3.1	Launching the Browser	11
3.2	Logging in to PViMS.....	12
3.3	End User License Agreement	13
3.4	The Home Page.....	14
3.5	System Toolbar	15
3.5.1	Refresh meta data.....	15
3.5.2	Online and offline status	15
3.5.3	Change the display theme	15
3.5.4	Change the default language.....	16
3.5.5	About PViMS.....	17
3.5.6	Logging out of PViMS.....	18
4	Clinical Portal	19
4.1	Patients.....	20
4.1.1	Search for Patients	20
4.1.2	Return to the Patient Search Page	25
4.1.3	View an Existing Patient.....	26
4.1.4	Add a New Patient	39
4.1.5	Condition Groups.....	47
4.1.6	Analytical Reporting	47
4.1.7	Add or Edit Patient Information.....	49
4.1.8	Add or Edit Additional Information.....	51
4.2	Encounters.....	60
4.2.1	Search for an Encounter	60

4.2.2	View an Existing Encounter	66
4.2.3	Add or Edit Encounter Information	69
4.2.4	Add or Edit Clinical Information	75
4.3	Cohorts.....	95
4.3.1	View Cohorts	95
4.4	Feedback	98
4.4.1	View Feedback.....	98
4.4.2	View New Feedback	99
4.4.3	Search for Feedback for Report	101
4.5	Appointments	102
4.5.1	View Appointments	102
4.5.2	View Appointments for a specified day.....	104
4.5.3	View Patient Record	104
4.5.4	Mark Appointment as Did Not Arrive	105
4.6	Deleting Records.....	106
4.6.1	Patient View - Additional Information	106
4.6.2	Encounter View – Clinical Information.....	115
4.6.3	Delete an Entire Patient Record	121
5	Analytical Portal	123
5.1	Spontaneous Reporting	124
5.2	Active Reporting.....	125
5.3	Pharmacovigilance Activities	125
5.3.1	Terminology.....	126
5.3.2	Process Flow	126
5.3.3	Identifying New Reports.....	127
5.3.4	Search for a Report	128
5.4	Pharmacovigilance Activities - General	134
5.4.1	Viewing Activity History for Report	134
5.4.2	Viewing a Patient Record	136

5.4.3	Extracting a Patient Summary.....	137
5.4.4	Updating a Spontaneous Report.....	138
5.5	Pharmacovigilance Activities – Confirm Report Data.....	139
5.5.1	Deleting a Report	139
5.5.2	Confirming a Report	141
5.6	Pharmacovigilance Activities – Set MedDRA and Causality	143
5.6.1	Set MedDRA Terminology	143
5.6.2	Causality Assessment using the WHO Scale	150
5.6.3	Causality Assessment using the Naranjo Scale.....	155
5.6.4	Confirming Causality Set.....	160
5.7	Pharmacovigilance Activities – Extract E2B	162
5.7.1	Create E2B	162
5.7.2	Adding Information to and Updating an E2B File	164
5.7.3	Preparing a Report for E2B Submission	166
5.7.4	Viewing the E2B XML File.....	168
5.7.5	Viewing the Clinical Data Associated to the E2B XML File	170
5.7.6	Confirming a Report for E2B Submission	172
5.8	Analyser	174
6.8.1	Methodology	174
5.8.2	Generating Unadjusted Relative Risk Ratios	176
5.8.3	Generating Adjusted Relative Risk Ratios.....	183
5.8.4	Downloading a Dataset for Further Analysis.....	193
6	Reporting Portal	194
6.1	List of Standard System Reports.....	194
6.2	Report Customization	195
6.2.1	Types of Reports	195
6.2.2	Adding a New Report	195
6.2.3	Modifying and Deleting an Existing Report	203
7	Information Portal	204

7.1	Viewing the home page.....	204
7.2	Viewing the Reference page	206
7.3	Viewing the Frequently Asked Questions page	210
7.4	Modifying Content in the Information Portal	213
7.4.1	Adding a New Page.....	213
7.4.2	Adding a Widget to a Page	215
7.4.3	Adding or Changing a Widget's Content.....	218
7.4.4	Publishing a Widget	222
7.4.5	Deleting a Widget	225
7.4.6	Moving a Widget to a New Page	226
8	Spontaneous Reporting	228
8.1	Accessing Spontaneous Reporting.....	228
8.1.1	Add a New Report.....	229
9	Appendix A: Forms Reference Guide.....	239

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.

Tip!

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.

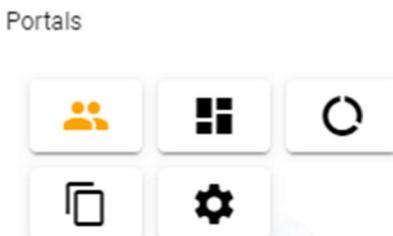
The **Analytical** portal is the centralized hub for causative drug assessment using traditional internationally recognized rating scales, standardized terminology and risk detection.

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.



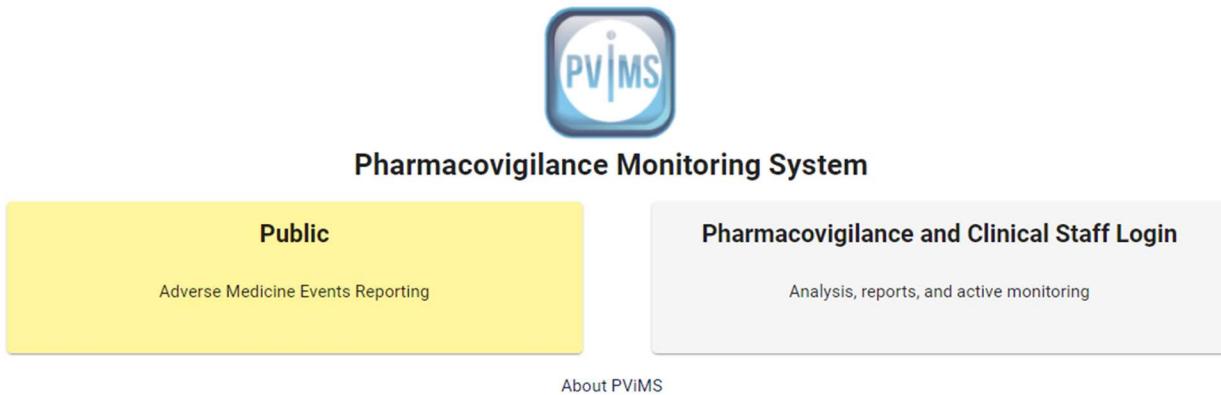
Note 1. What is a URL?

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.



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.
- 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.

Accept End User License Agreement

End User License Agreement for PViMS
PViMS® SOFTWARE LICENSE

READ THE TERMS AND CONDITIONS OF THIS PViMS® SOFTWARE LICENSE AGREEMENT ("EULA") CAREFULLY BEFORE DOWNLOADING, INSTALLING, OR USING THE PViMS® SOFTWARE PROGRAM, THE SOURCE CODE, TOOLS, AND RELATED DOCUMENTATION ("PRODUCT"). YOU MAY USE THE PRODUCT ONLY ON THE CONDITION THAT YOU ACCEPT ALL OF THE TERMS CONTAINED IN THIS EULA. IF YOU DO NOT AGREE TO THE TERMS AND CONDITIONS OF THIS EULA, DO NOT DOWNLOAD, INSTALL, OR USE THE PRODUCT. BY ACCESSING AND USING ANY PART OF THIS PRODUCT, YOU AGREE TO BE BOUND BY THE TERMS OF THIS EULA.

1. **General.** Except as provided in Section 3 below, the PViMS® Software Program is provided in object code format, for your internal uses only. Any reference to "You" or "Licensee" means any individual or entity accessing and using, in any manner, the Product.

2. **License.**

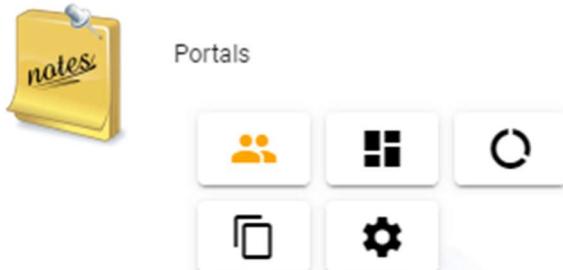
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- If You wish to use the Product for any purpose other than Permitted Purposes, You must purchase a standard commercial license from Licensor.
- You may make one copy of the Software Program for backup and archival purposes only. No other copies or copying of the Product or any part thereof is authorized. On any copy You make, You must duplicate on any back-up copy of the PViMS® Software Program all copyright, trademark, confidentiality, and patent notices found thereon.
- The U.S. Government and others acting on its behalf, has a paid-up nonexclusive irrevocable worldwide license to reproduce, prepare derivative works and display publicly by or on behalf of the Government.

Accept **Do not 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 return to the login page.

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 five different portals (**Clinical, Analytical, Reporting, Information, and Administration**).

3.5 System Toolbar

The system toolbar provides the user with the following abilities:

3.5.1 Refresh meta data



This icon allows the user to initiate a refresh of meta data. Please see the administrator manual for additional information.

3.5.2 Online and offline status



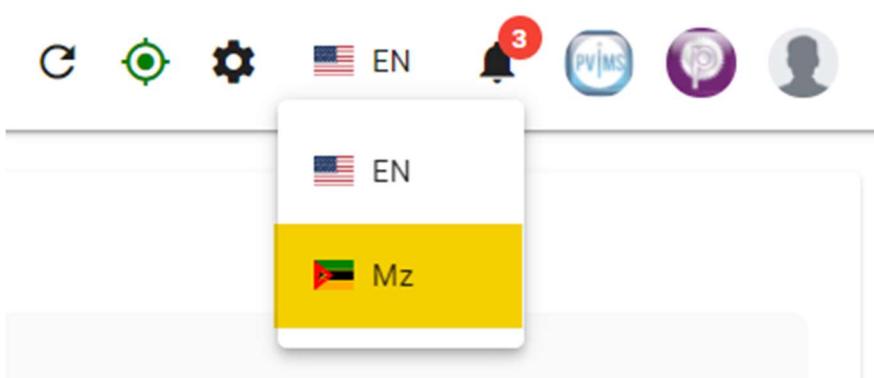
This icon allows the user to check the offline status of PViMS. If the icon is green, PViMS is connected to the internet and is operational. If the icon is red, PViMS is not connected to the internet and can only function in an offline status when capturing forms. Clicking on the icon refreshes this status.

3.5.3 Change the display theme



This icon allows the user to change the colour theme for the site. The user is able to set header, sidebar, material themes and footer colours,

3.5.4 Change the default language



To change the default language that all text is displayed in, click on the flag in the top toolbar of PViMS. Once the flag has been selected, all system text will be translated to the language specified.

3.5.5 About PViMS



By clicking on this icon, the user will be about to view additional PViMS information.

About PViMS

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

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PViMS Version: 2.0.0 **Last Updated:** 2020-06-24

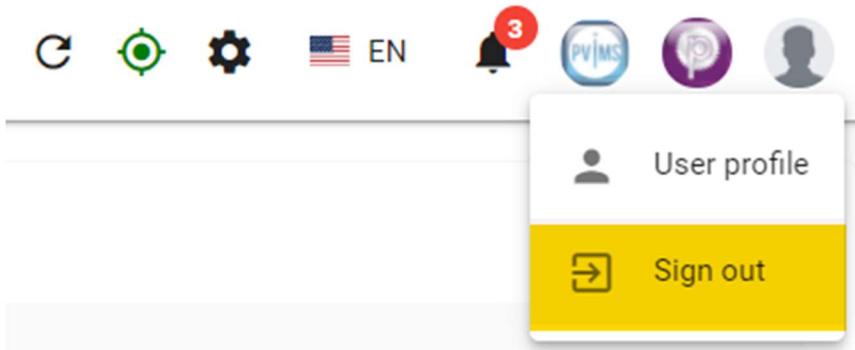
Manuals: <https://github.com/MSH/PViMS-2/tree/master/Manuals>

This application is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID) contract no. 7200AA18C00074 (MTaPS Program, 2018-2023) and cooperative agreement no. AID-OAA-A-11-00021 (SIAPS Program, 2011-2018). The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

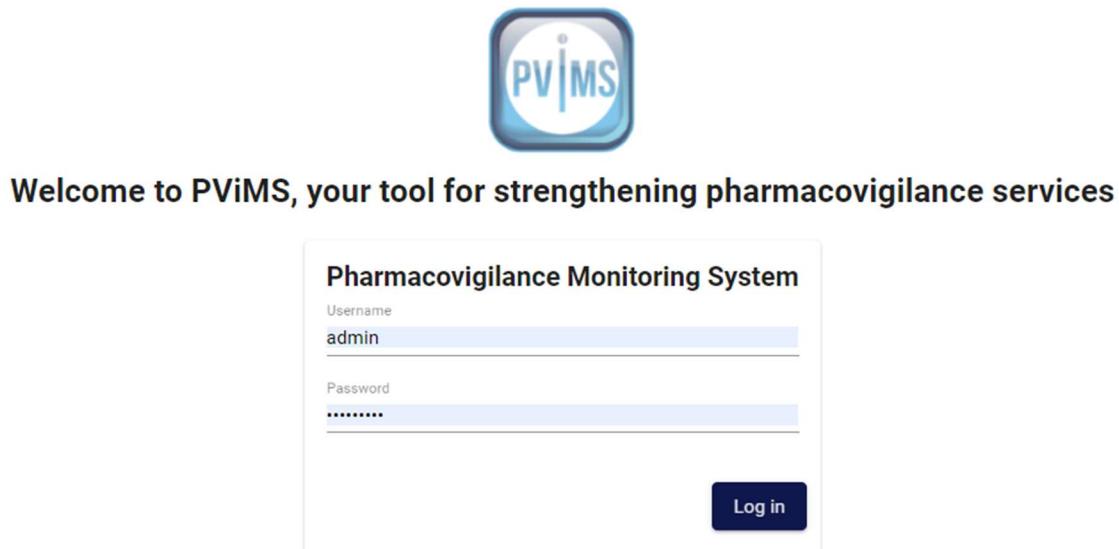


Close

3.5.6 Logging out of PViMS



To log out of PViMS, click on the **Sign Out** menu and the user will be redirected to the login screen.



4 Clinical Portal

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

- Patients
- Encounters
- Cohorts
- Feedback
- Appointments
- Forms
- Synchronise

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.

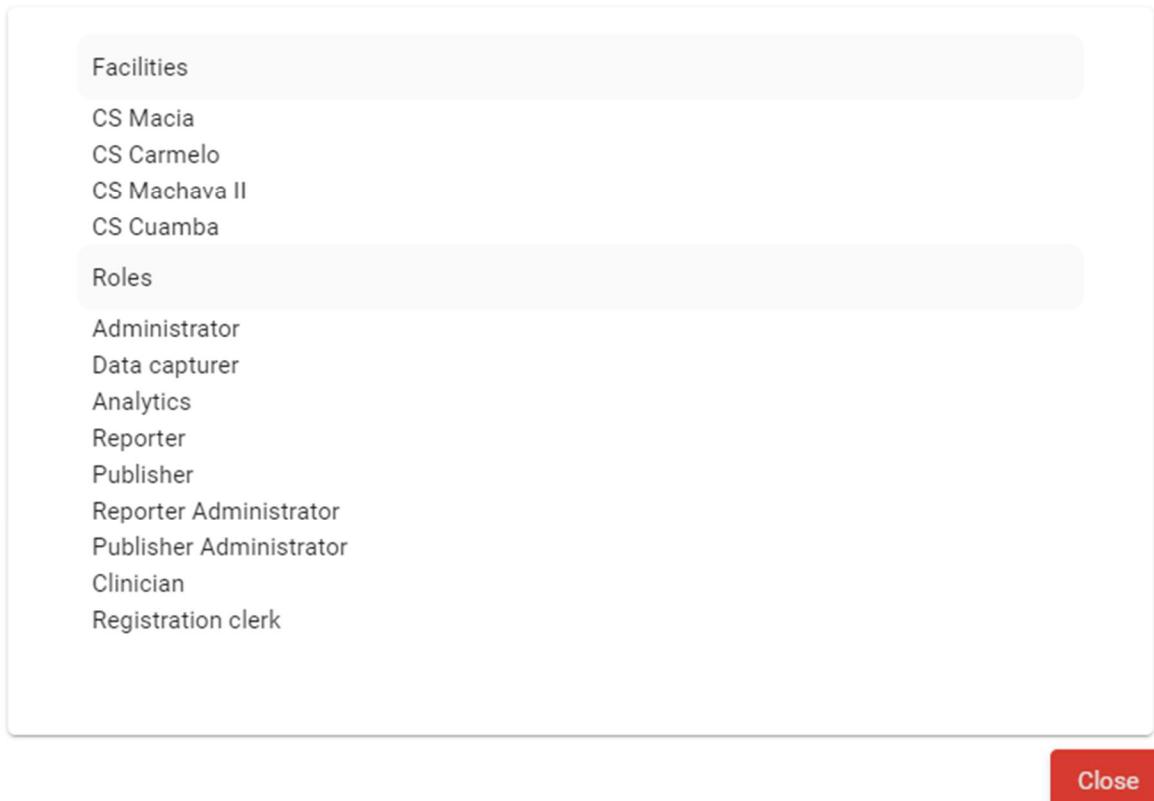
Data Capturer. A data capturer is able to add and amend a patient record and add and amend an encounter record.

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



Click on the user profile menu option which appears when clicking on the profile icon to view roles and facilities you currently have access to.

User profile

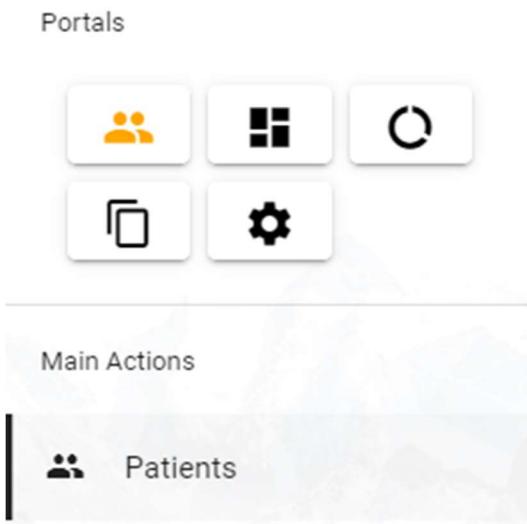


4.1 Patients

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

Patient Search

Facility	Unique ID	First name	Last name
All facilities		Maximum length 30	Maximum length 30
CS Carmelo			
CS Cuamba			
CS Machava II			
CS Macia			

Tip! 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.

Patient Search

The screenshot shows a search interface for patients. At the top, there are filters for Facility (All facilities), Unique ID, First name (Maximum length 30), Last name (Maximum length 30), Date of birth, and Custom attribute. A 'Search' button is located on the right. Below the filters is a table with columns: Id, First name, Last name, Facility name, Medical record number, Date of birth, Last encounter, and Actions. The table contains 9 rows of patient data, each with a unique ID (e.g., 262, 263, 264, 265, 266, 267, 268, 269, 270) and a corresponding row number (e.g., 8, 6, 23, 13, 27, 6, 22, 18, 20) in a yellow circle next to the date of birth.

Id	First name	Last name	Facility name	Medical record number	Date of birth	Last encounter	Actions
262	Unique	PatientOne	Facility A1	83155297	03/02/2012 8	01/15/2020	
263	Unique	PatientFive	Facility A1	83155301	03/01/2014 6	06/12/2017	
264	Unique	PatientSix	Facility A1	83155302	11/01/1996 23	11/26/2018	
265	Unique	PatientSeven	Facility A1	83155303	04/01/2007 13		
266	Unique	PatientEight	Facility A1	83155304	10/07/1992 27	06/20/2017	
267	Unique	PatientNine	Facility A1	83155305	03/01/2014 6		
268	Unique	PatientTen	Facility A1	83155306	01/21/1998 22		
269	Unique	PatientEleven	Facility A1	83155307	02/01/2002 18		
270	Unique	PatientTwelve	Facility A1	8	12/31/1999 20		

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

Facility All facilities	Unique ID 262	First name	Last name				
Date of birth	Custom attribute	Search					
Id	First name	Last name	Facility name	Medical record number	Date of birth	Last encounter	Actions
262	Unique	PatientOne	Facility A1	83155297	03/02/2012 8	01/15/2020	

Items per page: 10 | 1 - 1 of 1 | < >

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 any three letters of the **First or Last names**. The system will return all matching records if a partial search is executed.

Patient Search

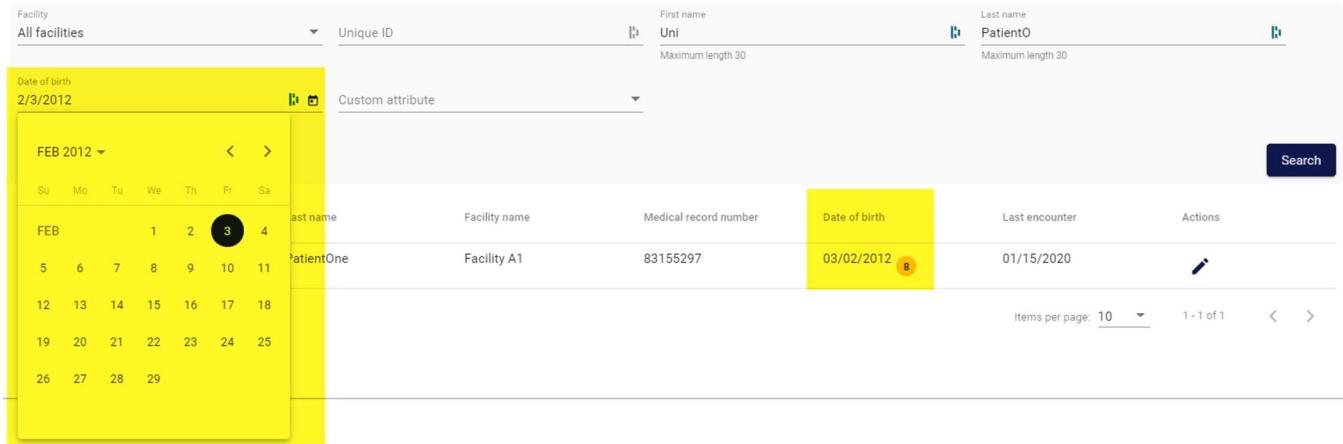
Facility All facilities	Unique ID	First name Uni	Last name PatientO				
Date of birth	Custom attribute	Search					
Id	First name	Last name	Facility name	Medical record number	Date of birth	Last encounter	Actions
262	Unique	PatientOne	Facility A1	83155297	03/02/2012 8	01/15/2020	

Items per page: 10 | 1 - 1 of 1 | < >

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



The screenshot shows the Patient Search interface. At the top, there are fields for Facility (All facilities), Unique ID, First name (Uni), and Last name (PatientO). Below these is a date picker for Date of birth, set to 2/3/2012. To the right of the date picker is a dropdown for Custom attribute, currently set to "Medical record number". A table below lists patients, with one row highlighted in yellow for PatientOne. The table columns are Id, First name, Last name, Facility name, Medical record number, Date of birth, Last encounter, and Actions. The Date of birth column for PatientOne shows 03/02/2012 with a red circle containing the number 8. The bottom right of the interface shows pagination controls: Items per page: 10, 1 - 1 of 1, and navigation arrows.

4.1.1.5 Search by Custom Attribute

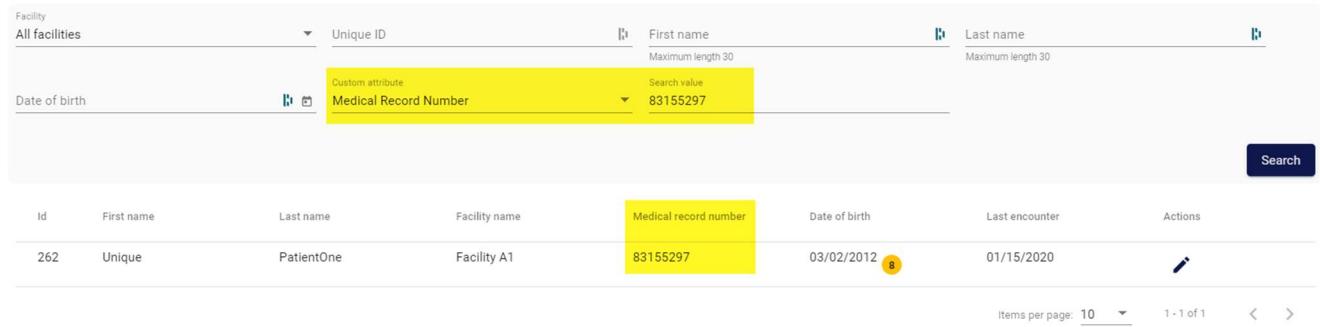
The final search filter available is the ability to search by a **Custom Attribute**.



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

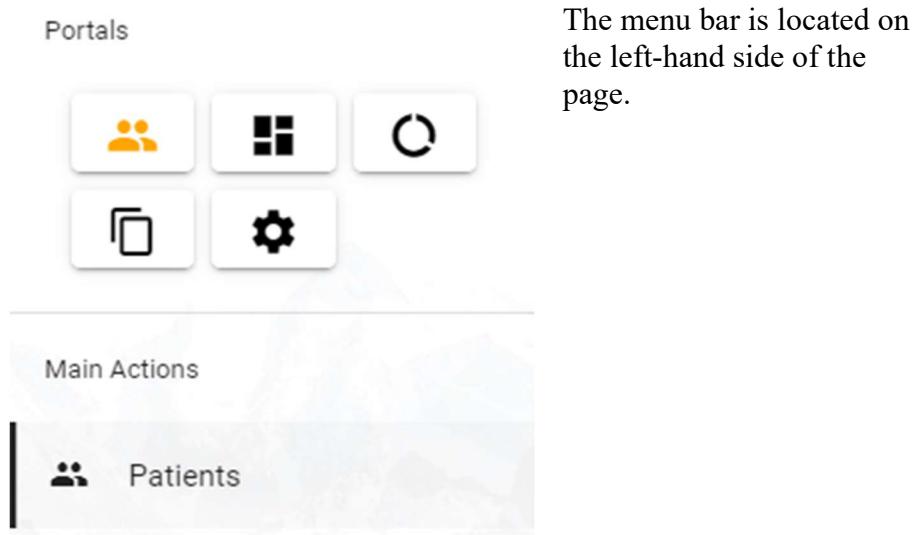


The screenshot shows the Patient Search interface. At the top, there are fields for Facility (All facilities), Unique ID, First name (Maximum length 30), and Last name (Maximum length 30). Below these is a dropdown for Custom attribute, set to "Medical Record Number". A search value "83155297" is entered in the search input field. The bottom part of the interface shows a table of patients, with one row highlighted in yellow for PatientOne. The table columns are Id, First name, Last name, Facility name, Medical record number, Date of birth, Last encounter, and Actions. The Medical record number column for PatientOne shows 83155297 with a red circle containing the number 8. The bottom right of the interface shows pagination controls: Items per page: 10, 1 - 1 of 1, and navigation arrows.

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 the **Menu Bar**.

4.1.2.1 Menu Bar



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

The screenshot shows a search interface with the following fields:

- Facility:** All facilities
- Unique ID:** (Input field)
- First name:** (Input field, maximum length 30)
- Last name:** (Input field, maximum length 30)
- Date of birth:** (Input field)
- Custom attribute:** (Input field)
- Search:** (Dark blue button)

The results table has the following columns:

ID	First name	Last name	Facility name	Medical record number	Date of birth	Last encounter	Actions
262	Unique	PatientOne	Facility A1	83155297	03/02/2012 8	01/15/2020	
263	Unique	PatientFive	Facility A1	83155301	03/01/2014 6	06/12/2017	
264	Unique	PatientSix	Facility A1	83155302	11/01/1996 23	11/26/2018	
265	Unique	PatientSeven	Facility A1	83155303	04/01/2007 13		
266	Unique	PatientEight	Facility A1	83155304	10/07/1992 27	06/20/2017	
267	Unique	PatientNine	Facility A1	83155305	03/01/2014 6		
268	Unique	PatientTen	Facility A1	83155306	01/21/1998 22		
269	Unique	PatientEleven	Facility A1	83155307	02/01/2002 18		
270	Unique	PatientTwelve	Facility A1	8	12/31/1999 20		
271	Unique	PatientTwo	Facility A1	831552981	01/01/1943 77		

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 name	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 •
Last Encounter	Last encounter date, the date the patient last visited the

	facility
Action	Ability to view the patient's information

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

Patient Search

The screenshot shows the Patient Search interface. At the top, there are search fields for Facility (set to All facilities), Unique ID, First name (Maximum length 30), Last name (Maximum length 30), Date of birth, and Custom attribute. Below the search bar is a table of patient records:

Id	First name	Last name	Facility name	Medical record number	Date of birth	Last encounter	Actions
262	Unique	PatientOne	Facility A1	83155297	03/02/2012 (8)	01/15/2020	
263	Unique	PatientFive	Facility A1	83155301	03/01/2014 (6)	06/12/2017	
264	Unique	PatientSix	Facility A1	83155302	11/01/1996 (23)	11/26/2018	

- 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
- Audit Information
- Condition Groups
- Analytical Reporting

The screenshot shows the Patient View page. On the left is a sidebar with the following sections: Patient Information, Additional Information, Clinical Information, Audit Information, Condition Groups, and Analytical Reporting. The Patient Information section is highlighted with a yellow background.

4.1.3.1 Patient Information – Basic and Detail Information

The **Patient Information** tab is divided into **Basic Information**, **Detail Information** and **Notes**.

Basic Information	Detail Information	Notes
First name Unique	Middle name	Last name PatientOne
Date of birth 02-03-2012	Age 8	Age group Child > 4 years and <= 11 years
Facility Facility A1 (FAC-01)	Date entered in system 2017-01-20 01:59:08 PM	

Update Patient

Patient demographic information will remain 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 detail 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.

Basic Information Detail Information Notes

B I U S " " , H1 H2 ≡ ≡ x₂ x² ≡ ≡ ↪ Normal ↪ Normal ↪ A A Sans Serif ↪ ≡ ↪

Patient transferred in

Update Patient

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.

Appointments	Attachments	Encounters	Patient Status	Cohorts	
					Add Appointment
Appointment date	Reason	Outcome	Actions		
02/05/2020	Monthly Appointment		 		

The columns in the appointments table are described below:

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

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

Appointments	Attachments	Encounters	Patient Status	Cohorts	
					Download All Add Attachment
Type	Name	Description	Created date	Actions	
Portable Document Format	Urgent Care.pdf		2017-02-09 09:09:27 PM		

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.

Appointments	Attachments	Encounters	Patient Status	Cohorts
Add Encounter				
Encounter date	Type			Actions
24/01/2017	Pre-Treatment Visit			
25/01/2017	Pre-Treatment Visit			
01/08/2017	Pre-Treatment Visit			
07/11/2017	Pre-Treatment Visit			
09/11/2017	Treatment Initiation Visit			
09/07/2018	Unscheduled Visit			
15/01/2020	Pre-Treatment Visit			

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)
Action	Ability to View an 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.

Appointments	Attachments	Encounters	Patient Status	Cohorts
Effective date	Status			Created date
20/01/2017	Active			2017-01-20 01:59:08 PM

The columns in the status table are described below:

Effective Date	The effective date of the status change
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.

Appointments		Attachments		Encounters		Patient Status	Cohorts
Cohort name		Start date	Enroled date	De-enroled date	Actions		
9MTR Study (OR9MT)		01/05/2016	04/03/2020	04/03/2020			
BDQ Study (ORBDQ)		01/06/2016	03/03/2020	04/03/2020			
9MTR Program Condition (PC9MT)		01/06/2001					
18MTR Program Condition (PC18M)		01/06/2001					
XDRTB Program Condition (PCXDR)		01/06/2001					
Finn (F-16)		01/01/2015					
Test (TestC)		20/07/2017					

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.

Conditions	Adverse Events	Medications	Tests and Procedures	
Add Condition				
Condition	Start date	Outcome date	Outcome	Actions
Acute HIV syndrome	19/06/2016	23/08/2016		 
Tuberculosis	05/09/2017			 
Rashes, eruptions and exanthems NEC	10/08/2017	03/11/2017		 

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.

Conditions	Adverse Events	Medications	Tests and Procedures		
Add Adverse Event					
Description	Onset date	Reported date	Resolution date	Is serious	Actions
Dizziness	03/08/2016			No	
Bruising	13/06/2017	13/06/2017		Yes	
Benign essential hypertension antepartum	19/12/2017				
Dizziness exertional	19/12/2017				
Benign essential hypertension	19/12/2017				
Accelerated hypertension	19/12/2017				
Benign essential hypertension complicating pregnancy, childbirth, and the puerperium, unspecified as	19/12/2017				
Benign essential hypertension with delivery	19/12/2017				

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
Is Serious	Is this a serious reaction?
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.

Conditions	Adverse Events	Medications	Tests and Procedures				
Add Medication							
Drug name	Dose	Dose unit	Frequency	Start date	End date	Indication	Actions
kanamycin	1000	milligram	daily	12/03/2016	18/03/2016		
kanamycin	1000	milligram	daily	08/10/2016	17/10/2016		
capreomycin	1000	mg	daily	12/10/2016			
ethionamide	1000	milligram	daily	01/04/2016	03/07/2016		
prothionamide	1000	milligram	daily	01/04/2016	25/08/2016		
ibuprofen	1000	milligram	daily	01/04/2016			
cyclizine	1000	milligram	daily	19/06/2016	23/08/2016		
ondansetron	1000	milligram	daily	19/06/2016	11/12/2016		

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 an 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.

Conditions	Adverse Events	Medications	Tests and Procedures	
Add Test and Procedure				
Test	Test date	Test result (coded)	Test result (value)	Test unit
CD4 Count	24/01/2017		555.00	cells/mm ³
Glucose	25/01/2017		80.00	mg/dL
AFB Smear Result	12/07/2017	Abnormal	SCANTY	mg/dL
Haemoglobin	09/07/2018		10	mg/dL

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

Audit Information

Unique ID
262

Guid
8ee3d4b4-faba-45dd-9d34-1ce73715507c

Created
2017-01-20 01:59:08 PM

Updated
2017-02-14 03:11:30 PM

4.1.3.13 Identifiers and Audit information – Audit Information

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

Audit Information

Unique ID
262

Guid
8ee3d4b4-faba-45dd-9d34-1ce73715507c

Created
2017-01-20 01:59:08 PM

Updated
2017-02-14 03:11:30 PM

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' interface. It includes fields for 'Facility' (set to 'All facilities'), 'Unique ID', 'First name' (with a note 'Maximum length 30'), 'Last name' (with a note 'Maximum length 30'), 'Date of birth', 'Custom attribute', and buttons for 'Add Patient' (highlighted with a yellow box) and 'Search'.

The system will open a new **Patient** pop up form with several sections needing to be captured.

4.1.4.1 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 an asterisk (mandatory) are captured.

Add Patient

The screenshot shows the 'Add Patient' pop-up form. It has tabs for 'Basic Information' (selected), 'Detail Information', 'Primary Condition Group', and 'Encounter Information'. Under 'Basic Information', there are fields for 'First name *' (maximum length 30), 'Last name *' (maximum length 30), 'Middle name' (maximum length 30), 'Date of birth *', 'Facility' (dropdown), and buttons for 'Save' and 'Cancel'.

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
Date of birth	Date field to select the patient's date of birth

All fields marked with an asterisk (*) are compulsory fields that must be completed before proceeding.

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 profile in the profile menu in the top right-hand corner of the page.

User profile

The screenshot shows a modal window titled "User profile". It has two main sections: "Facilities" and "Roles".

Facilities:

- Facilities
- Facility A1
- Polyclinic

Roles:

- Administrator
- Analytics
- Clinician
- Data capturer
- Publisher
- Publisher Administrator
- Registration clerk
- Reporter
- Reporter Administrator

Close

4.1.4.2 Detail Information

The **Detail 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**).

Add Patient

Basic Information	Detail Information	Primary Condition Group	Encounter Information
Medical Record Number *	Medical Record Number Type		
Maximum length 50			
Patient Identity Number *	Identity Type *		
Maximum length 11			
Gender *	Marital Status		
Employment Status	Occupation		
	Maximum length 50		
Save			Cancel

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

4.1.4.3 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** 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.

Add Patient

Basic Information	Detail Information	Primary Condition Group	Encounter Information
Condition *	Meddra term *		
TB	Meningeal tuberculosis		
Cohorts	Enroled date		
9MTR Study	5/4/2020		
Start date *	Outcome date		
5/4/2020			
Comments			
Maximum length 100			
<input type="button" value="Save"/>		<input type="button" value="Cancel"/>	

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.

Add Patient

Basic Information	Detail Information	Primary Condition Group	Encounter Information
Condition *		Meddra term *	
TB		Meningeal tuberculosis	
Cohorts		Enroled date	
9MTR Study		5/4/2020	
Start date *		Outcome date	
5/4/2020			
Comments			
Maximum length 100			

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.

Add Patient

Basic Information	Detail Information	Primary Condition Group	Encounter Information
Condition *	TB	Meddra term *	Meningeal tuberculosis
Cohorts	9MTR Study	Enroled date	5/4/2020
Start date *	5/4/2020	Outcome date	
Comments	Maximum length 100		

Save **Cancel**

4.1.4.4 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 registered at the facility.

Add Patient

Basic Information	Detail Information	Primary Condition Group	Encounter Information
Encounter type *	Treatment Initiation Visit	Priority *	Urgent
Encounter date *	5/1/2020	Save	Cancel

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 back to the to the **Patient View** page where you can **Add** or **Edit**, patient information described in Section 4.1.7.

4.1.5 Condition Groups

The **Condition Groups** tab 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 column indicates whether the case is **Open** or **Closed**.

Condition Groups		
Condition	Details	Actions
TB Case Open	Tuberculosis started on 2017-09-05	



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** tab which is 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.

Analytical Reporting		
Adverse event	Details	Actions
Vertigo (excl dizziness)	E2B data generated for report on 2018-11-26 AUTOMATION: E2B dataset created	
Hypertension	Report submitted for confirmation on 2020-06-04	

By clicking on the **View Adverse Event** icon, the system will display an adverse event pop up form for this event where you will be able to view a comprehensive history of pharmacovigilance activities and any terminology that has been set.

View Adverse Event

Analytical Reporting	Terminology	Basic Information	Detail Information
Status date	Status	Comments	
2018-07-09	Report submitted for confirmation		
2018-07-09	Report confirmed by technician	I am happy with the quality of report	
2018-07-09	Report ready for MedDRA and Causality		
2018-07-09	MedDRA term set by technician	AUTOMATION: MedDRA Term set	
2018-07-09	Causality set by technician	Causality has been set	
2018-07-09	Report ready for E2B submission		
2018-07-09	E2B data generated for report	AUTOMATION: E2B dataset created	
2018-07-09	E2B report generated	I am happy with the quality of report	
2018-07-09	E2B report submitted	Submitted on	

Close

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.

The screenshot shows the 'Patient Search' interface. At the top, there are search fields for Facility (All facilities), Unique ID, First name (Maximum length 30), Last name (Maximum length 30), Date of birth, and Custom attribute. Below the search bar are two buttons: 'Add Patient' (yellow) and 'Search' (dark blue). The results table has columns: Id, First name, Last name, Facility name, Medical record number, Date of birth, Last encounter, and Actions. One row is shown for a patient with Id 262, First name Unique, Last name PatientOne, Facility name Facility A1, Medical record number 83155297, Date of birth 03/02/2012 (with a yellow circle containing the number 8), Last encounter 01/15/2020, and Actions (a pencil icon). At the bottom, there are pagination controls for items per page (10), page 1 of 1, and navigation arrows.

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

To update patient information, click the **Update Patient** button and the system will pop up a patient edit form where you can edit basic and detailed information as well as patient notes.

The screenshot shows the 'Patient Edit' form. It has three tabs: Basic Information, Detail Information, and Notes. Under Basic Information, there are fields for First name (Unique), Middle name, and Last name (PatientOne). Under Detail Information, there are fields for Date of birth (02-03-2012), Age (8), and Age group (Child > 4 years and <= 11 years). Under Notes, there are fields for Facility (Facility A1 (FAC-01)) and Date entered in system (2017-01-20 01:59:08 PM). At the bottom right is a large yellow 'Update Patient' button.

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.

Update Patient

Basic Information	Detail Information	Notes
First name * Unique Maximum length 30	Last name * PatientOne Maximum length 30	
Middle name Maximum length 30	Date of birth * 3/2/2012	
Facility * Facility A1		

Save **Cancel**

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

4.1.8 Add or Edit Additional Information

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

Appointments	Attachments	Encounters	Patient Status	Cohorts
Add Appointment				
Appointment date	Reason	Outcome	Actions	
02/05/2020	Monthly Appointment			

4.1.8.1 Add Appointments

At the **Appointments** tab click the **Add Appointments** button, after which the system will open the **Add Appointment** pop up form.

Appointments	Attachments	Encounters	Patient Status	Cohorts
Add Appointment				
Appointment date	Reason	Outcome	Actions	
02/05/2020	Monthly Appointment			

- Enter the **Appointment Date**. The appointment date may only be in the future and within the next 2 years
- Enter the **Reason** for the appointment
- Click the **Save** button to create the appointment or click the **Cancel** button to cancel the action and go back to the previous page

Add Appointment

Appointment date *

5/24/2020



Reason *

This is a test appointment

Maximum length 250

Save

Cancel

- After clicking on **Save** the system will confirm the update has completed successfully and will display the updated table under the **Appointments** tab

Appointments	Attachments	Encounters	Patient Status	Cohorts	
					Add Appointment
Appointment date	Reason	Outcome			Actions
24/05/2020	This is a test appointment				

4.1.8.2 Edit an Appointment

To edit an existing appointment, locate the appointment in the table. Click the **Update Appointment** icon in the action column for the appointment to be edited after which the system will open the **Update Appointment** pop up form.

Appointments	Attachments	Encounters	Patient Status	Cohorts	
					Add Appointment
Appointment date	Reason	Outcome			Actions
24/05/2020	This is a test appointment				

Make changes as needed then click the **Save** button to complete the edit or click the **Cancel** button to undo your changes and return to the previous page.

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

4.1.8.3 Add an Attachment

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

Appointments	Attachments	Encounters	Patient Status	Cohorts
Type	Name	Description	Created	Actions

To add an attachment, click the **Add Attachment** button after which the system will open the **Add Appointment** pop up form. Click the **Choose File** button to search for the file to be attached.

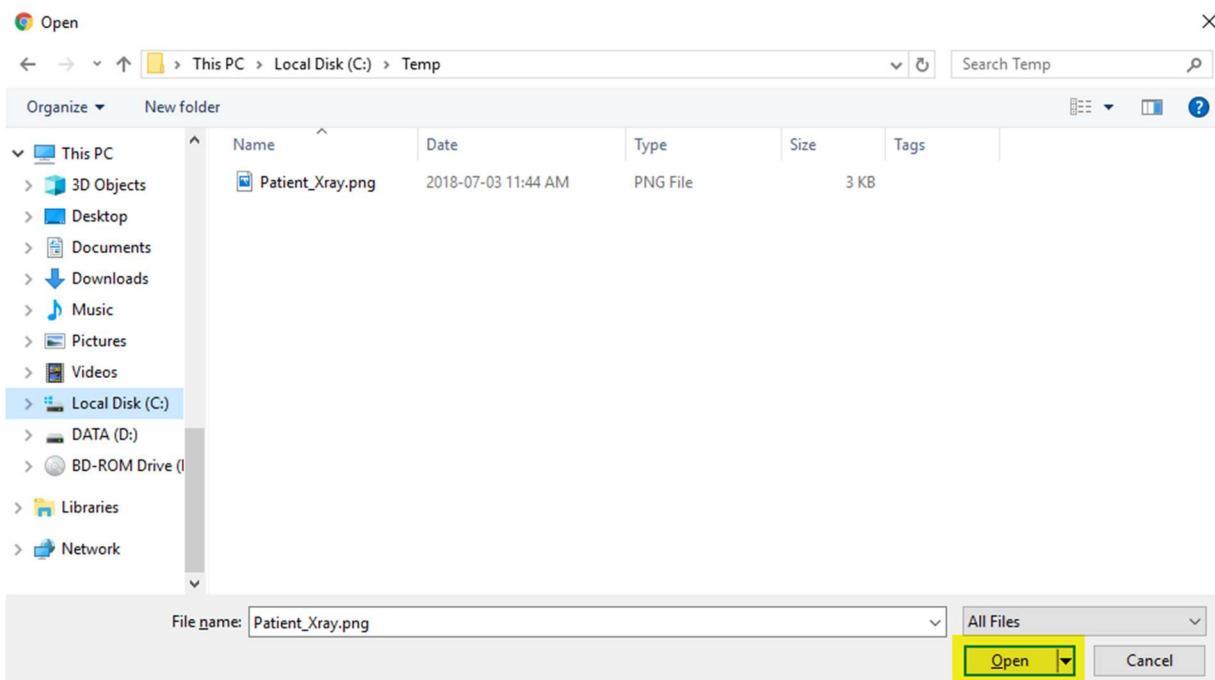
Add Attachment

No file chosen

Description

Maximum length 100

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



The system will return to the **Add Attachment** form and will reflect that the file that was selected. You can add a description in the **Description** field.

Click the **Save** button to complete the attachment upload or click the **Cancel** button to undo your changes and return to the previous page.

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

Attachments				
Type	Name	Description	Created	Actions
Portable Document Format	Urgent Care.pdf		2017-02-09 09:09:27 PM	
MS Word Document	DSD COVID19 HIGH LEVEL TECHNICAL.docx	assas	2020-05-27 02:41:18 PM	

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 and click the **Download Attachment** icon in the action column next to the attachment to download.

Appointments	Attachments	Encounters	Patient Status	Cohorts	
Type	Name	Description	Created	Actions	
Portable Document Format	Urgent Care.pdf		2017-02-09 09:09:27 PM	 	
MS Word Document	DSD COVID19 HIGH LEVEL TECHNICAL.docx	assas	2020-05-27 02:41:18 PM	 	

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

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

Appointments	Attachments	Encounters	Patient Status	Cohorts
Add Encounter				
Encounter date	Type			Actions
24/01/2017	Pre-Treatment Visit			
25/01/2017	Pre-Treatment Visit			
01/08/2017	Pre-Treatment Visit			
07/11/2017	Pre-Treatment Visit			
09/11/2017	Treatment Initiation Visit			

Click the **Add Encounter** button to add a new encounter for this patient.

Appointments	Attachments	Encounters	Patient Status	Cohorts
Add Encounter				
Encounter date	Type			Actions
24/01/2017	Pre-Treatment Visit			

After clicking the **Add Encounter** button, the system will open the **Add Encounter** pop up form.

- Select the date of encounter using the date pop up control.
- 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 any free format **Notes** regarding the encounter as appropriate.

Add Encounter

Encounter date *

5/30/2020

Encounter type *

Pre-Treatment Visit

Priority *

Medium

Notes

This is a test encounter

Maximum length 500

SaveCancel

- Click the **Save** button to save the new encounter or click the **Cancel** button to undo the action and return to the previous page.
- After clicking on **Save** the system will confirm the save has completed successfully and will display the updated table under the **Encounters** tab.

Appointments	Attachments	Encounters	Patient Status	Cohorts	
					<button>Add Encounter</button>
Encounter date	Type				Actions
24/01/2017	Pre-Treatment Visit				/
25/01/2017	Pre-Treatment Visit				/
01/08/2017	Pre-Treatment Visit				/

Refer to the Encounters Section for details on how to **Add** or **Edit** Encounter information.

4.1.8.6 Patient Status – Read Only

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

Appointments	Attachments	Encounters	Patient Status	Cohorts
Effective date	Status		Created	
20/01/2017	Active		2017-01-20 01:59:08 PM	

The information in the **Status table** is read 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.

Appointments	Attachments	Encounters	Patient Status	Cohorts	
Cohort name			Start date	Enroled date	De-enroled date
9MTR Study (OR9MT)			01/05/2016	04/03/2020	04/03/2020
BDQ Study (ORBDQ)			01/06/2016	03/03/2020	04/03/2020
9MTR Program Condition (PC9MT)			01/06/2001		
18MTR Program Condition (PC18M)			01/06/2001		
XDRTB Program Condition (PCXDR)			01/06/2001		
Finn (F-16)			01/01/2015		
Test (TestC)			20/07/2017		

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

Tip!

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** pop up form.

Enter the date the patient was enrolled in the cohort. Click the **Save** 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 enrol this patient. Please ensure you use the correct enrolment date as this date cannot be amended once set....

Cohort 9MTR Program Condition (PC9MT)	Condition start date 2017-09-05
Enroled date 5/27/2020	
Save	Cancel

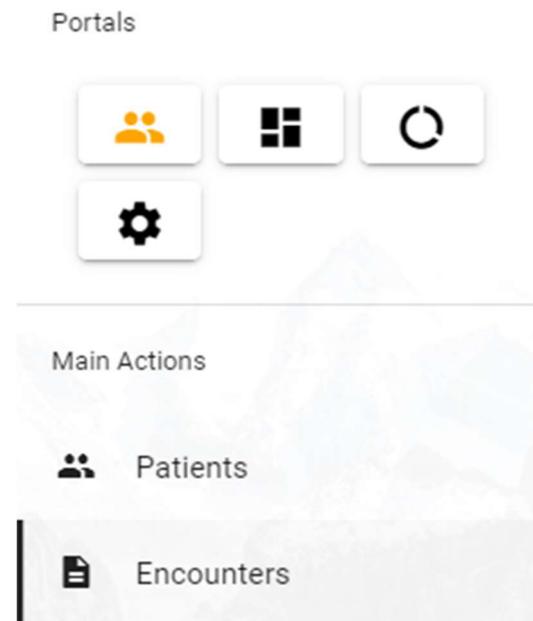
After clicking on the **Save** button the system will display the updated information in the Cohort table.

Appointments	Attachments	Encounters	Patient Status	Cohorts
Cohort name		Start date	Enroled date	De-enroled date
9MTR Study (OR9MT)		01/05/2016	04/03/2020	04/03/2020
BDQ Study (ORBDQ)		01/06/2016	03/03/2020	04/03/2020
9MTR Program Condition (PC9MT)		01/06/2001	27/05/2020	

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

All facilities	Unique ID	First name Maximum length 30	Last name Maximum length 30
Facility A1	Search from	Search to	Custom attribute
Polyclinic			

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 or appointments according to the filter selected.

Encounter Search

Facility	Unique ID	First name Maximum length 30	Last name Maximum length 30
All facilities	Search from	Search to	Custom attribute
Criteria			
All encounters			

Search

Id	First name	Last name	Facility name	Encounter type	Encounter date	Actions
115	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-01-24	
116	Unique	PatientFive	Facility A1	Pre-Treatment Visit	2017-01-25	
117	Unique	PatientSix	Facility A1	Pre-Treatment Visit	2017-01-25	
118	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-01-25	
144	Unique	PatientFive	Facility A1	Unscheduled Visit	2017-06-12	
145	Unique	PatientEight	Facility A1	Treatment Initiation Visit	2017-06-20	
178	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-08-01	
187	Unique	PatientThirteen	Facility A1	Pre-Treatment Visit	2017-07-03	
188	Unique	PatientThirteen	Facility A1	Pre-Treatment Visit	2017-07-04	

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 encounters using this ID.

- If you know the patient's unique ID, enter it in the **Unique ID** field.
- Click the **Search** button.

Encounter Search

The screenshot shows the 'Encounter Search' interface. At the top, there are dropdown menus for 'Facility' (set to 'All facilities') and 'Criteria' (set to 'All encounters'). A yellow highlighted input field contains the value '262' under the heading 'Unique ID'. To the right of this are fields for 'First name' (with placeholder 'Maximum length 30') and 'Last name' (with placeholder 'Maximum length 30'). Below these are date pickers for 'Search from' and 'Search to', and a dropdown for 'Custom attribute'. A large blue 'Search' button is located at the bottom right of the search bar. The main area displays a table of search results:

ID	First name	Last name	Facility name	Encounter type	Encounter date	Actions
115	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-01-24	
118	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-01-25	
178	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-08-01	
197	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-11-07	
198	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2017-11-09	
199	Unique	PatientOne	Facility A1	Unscheduled Visit	2018-07-09	
203	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-01-15	
204	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2020-05-03	
205	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-05-25	

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.
- 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

Facility All facilities	Unique ID	First name Unique Maximum length 30	Last name Pat Maximum length 30			
Criteria All encounters	Search from	Search to	Custom attribute			
Search						
Id	First name	Last name	Facility name	Encounter type	Encounter date	Actions
115	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-01-24	
116	Unique	PatientFive	Facility A1	Pre-Treatment Visit	2017-01-25	
117	Unique	PatientSix	Facility A1	Pre-Treatment Visit	2017-01-25	
118	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-01-25	
144	Unique	PatientFive	Facility A1	Unscheduled Visit	2017-06-12	
145	Unique	PatientEight	Facility A1	Treatment Initiation Visit	2017-06-20	
178	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-08-01	
187	Unique	PatientThirteen	Facility A1	Pre-Treatment Visit	2017-07-03	
188	Unique	PatientThirteen	Facility A1	Pre-Treatment Visit	2017-07-04	

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.
- Click the **Search** button.

Encounter Search

Last name	Facility name	Appointment date	Status	Actions
PatientOne	Facility A1	2020-05-25	Appointment met	
PatientOne	Facility A1	2020-05-25	Appointment met	
PatientOne	Facility A1	2020-06-16	Appointment	
PatientOne	Facility A1	2020-05-29	Appointment	

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 value you would like to filter against and click the **Search** button.

Encounter Search

Facility All facilities	Unique ID	First name Maximum length 30	Last name Maximum length 30	Criteria All encounters	Search from	Search to	Custom attribute Medical Record Number	Search value 83155297	Search																																																																						
<table border="1"><thead><tr><th>Id</th><th>First name</th><th>Last name</th><th>Facility name</th><th>Encounter type</th><th>Encounter date</th><th>Actions</th></tr></thead><tbody><tr><td>115</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Pre-Treatment Visit</td><td>2017-01-24</td><td></td></tr><tr><td>118</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Pre-Treatment Visit</td><td>2017-01-25</td><td></td></tr><tr><td>178</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Pre-Treatment Visit</td><td>2017-08-01</td><td></td></tr><tr><td>197</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Pre-Treatment Visit</td><td>2017-11-07</td><td></td></tr><tr><td>198</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Treatment Initiation Visit</td><td>2017-11-09</td><td></td></tr><tr><td>199</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Unscheduled Visit</td><td>2018-07-09</td><td></td></tr><tr><td>203</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Pre-Treatment Visit</td><td>2020-01-15</td><td></td></tr><tr><td>204</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Treatment Initiation Visit</td><td>2020-05-03</td><td></td></tr><tr><td>205</td><td>Unique</td><td>PatientOne</td><td>Facility A1</td><td>Pre-Treatment Visit</td><td>2020-05-25</td><td></td></tr></tbody></table>										Id	First name	Last name	Facility name	Encounter type	Encounter date	Actions	115	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-01-24		118	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-01-25		178	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-08-01		197	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2017-11-07		198	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2017-11-09		199	Unique	PatientOne	Facility A1	Unscheduled Visit	2018-07-09		203	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-01-15		204	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2020-05-03		205	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-05-25	
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204	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2020-05-03																																																																										
205	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-05-25																																																																										

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.

Encounter Search

Facility All facilities	Unique ID	First name Maximum length 30	Last name Maximum length 30			
Criteria All encounters	Search from 5/1/2020	Search to	Custom attribute Medical Record Number Search value 83155297			
Search						
Id	First name	Last name	Facility name	Encounter type	Encounter date	Actions
204	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2020-05-03	
205	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-05-25	
206	Unique	PatientOne	Facility A1	Scheduled Follow-Up Visit	2020-05-26	
207	Unique	PatientOne	Facility A1	Scheduled Follow-Up Visit	2020-05-03	
211	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2020-05-26	
212	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-05-12	

Items per page: 10 | 1 - 6 of 6 | < >

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 name	Facility where patient is registered
Encounter type	Type of encounter (e.g., pre-treatment, treatment initiation, scheduled follow-up or unscheduled visits)
Encounter date	Date the encounter occurred
Action	Ability to view the encounter

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

Encounter Search

Id	First name	Last name	Facility name	Encounter type	Encounter date	Actions
204	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2020-05-03	
205	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-05-25	
206	Unique	PatientOne	Facility A1	Scheduled Follow-Up Visit	2020-05-26	
207	Unique	PatientOne	Facility A1	Scheduled Follow-Up Visit	2020-05-03	
211	Unique	PatientOne	Facility A1	Treatment Initiation Visit	2020-05-26	
212	Unique	PatientOne	Facility A1	Pre-Treatment Visit	2020-05-12	

Items per page: 10 1 - 6 of 6 < >

- 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.

The screenshot shows the PViMS Encounter View for a patient named Unique PatientOne (Facility A1). The interface includes a left sidebar with links for Encounter Information, Clinical Information, Audit Information, Condition Groups, and History of Weight Change. The main area features a toolbar with various icons for text styling and data entry. Below the toolbar, a message states "This is a test encounter". At the bottom right are two buttons: "Delete Encounter" (red) and "Update Encounter" (blue).

4.2.3 Add or Edit Encounter Information

To edit **Encounter Information**, click the **Update Encounter** button after which the system will display an encounter pop up form.

Update Encounter

Medical Details	First-line Susceptibility	Second-line Susceptibility	TB Condition	Notes
B <i>I</i> <u>U</u> S “ ” „ „ H ₁ H ₂ ≡ ≡ x ₂ x ² ≡ ≡ † Normal ‡ Normal ‡ A 	Sans Serif ‡ ≡ I _x   			

This is a test encounter

Save

Cancel

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
Date of last menstrual period	Date field to enter the patient's LMP
Estimated gestation (weeks)	Numeric field to enter patient's gestational period in weeks
Breastfeeding mother	Dropdown list to indicate yes, no, NA or unknown
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.

Medical Details	First-line Susceptibility	Second-line Susceptibility	TB Condition	Notes
Weight (kg) 63.5 Valid between 1.1 and 159.9	BMI Unable to calculate	Height (cm) Valid between 1 and 250	Pregnancy Status Yes	
Date of last menstrual period		Estimated gestation (weeks) 11 Valid between 1 and 44		
Breastfeeding mother Unknown		Injecting drug use within past year No		
Excessive alcohol use within the past year No		Tobacco use within the past year No		

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.

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.

Medical Details	First-line Susceptibility	Second-line Susceptibility	TB Condition	Notes
Isoniazid susceptibility by any laboratory test(s)	Susceptible	Isoniazid confirmation Xpert		
Rifampicin susceptibility by any laboratory test(s)	Indeterminate	Rifampicin confirmation Unknown		
Ethambutol susceptibility by any laboratory test(s)	Indeterminate	Ethambutol confirmation Unknown		
Pyrazinamide susceptibility by any laboratory test(s)		Pyrazinamide confirmation		
Streptomycin susceptibility by any laboratory test(s)		Streptomycin confirmation		

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.

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.

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

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.

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.

Medical Details	First-line Susceptibility	Second-line Susceptibility	TB Condition	Notes
Previous TB treatment?			Site of TB	
No		PTB only		

Documented HIV infection	
No	

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

Conditions		Adverse Events		Medications		Add Condition
Condition		Start date	Outcome date	Outcome	Actions	
Acute HIV syndrome		19/06/2016	23/08/2016			
Tuberculosis		05/09/2017				
Rashes, eruptions and exanthems NEC		10/08/2017	03/11/2017			

4.2.4.1 Add Patient Condition

At the **Conditions** tab click the **Add Condition** button, after which the system will display an **Add Condition** pop up form.

Conditions	Adverse Events	Medications	Tests and Procedures	Add Condition
------------	----------------	-------------	----------------------	---------------

- Select the MedDra term for the condition by clicking on the plus icon.
- Select the term type for the term and enter the condition name in the **Find by term** field. Click the **Search** button (magnifying glass) and the system will then provide a list of results from the MedDRA dictionary that match the term that you have searched on.

Select Meddra Term

Term type *

Lowest Level Term

Find by term *

Hypertension



Description	Actions
Portopulmonary hypertension	>
Neurogenic hypertension	>
Intra-abdominal hypertension	>
Chronic thromboembolic pulmonary hypertension	>
Malignant essential hypertension	>

Items per page:

1 - 5 of 144



Cancel

- Click the right arrow for the corresponding term that you would like to select.
- Enter a free format description of the condition as defined by the reporter or patient.
- Enter the **Start Date** and complete the remaining fields as appropriate.
- Click the **Save** button to create the condition or click the **Cancel** button to cancel the action and go back to the previous page.

Add Condition

Please note! Ensure Start and Outcome dates are captured timely and accurately as they are critical to determine the patient's contribution to analysis within the analytical portal

Basic Information Detail Information

Condition description (As stated by patient or reporter) *

Hypertension

Maximum length 200

MedDra term *

Neurogenic hypertension



Start date *

5/6/2020



Outcome date



Outcome

Recovered/Resolved

Treatment outcome

Save

Cancel

- After clicking on **Save** the system will display the updated the table under the **Conditions** tab.

Conditions	Adverse Events	Medications	Tests and Procedures	Add Condition
Condition	Start date	Outcome date	Outcome	Actions
Acute HIV syndrome	19/06/2016	23/08/2016		
Tuberculosis	05/09/2017			
Rashes, eruptions and exanthems NEC	10/08/2017	03/11/2017		
Hypertension	06/05/2020		Recovered/Resolved	

The fields on the **Add Condition** form are described below:

Condition description	A free format description of the condition by the reporter or patient
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
Start date	Text field; Enter date condition started
Outcome	Dropdown list of Outcomes; Select either Fatal, Not Recovered/Not Resolved, Recovered/Resolved, Recovered/Recovered with Sequelae, Recovering/Resolving, or Unknown
Outcome Date	Date 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.

Condition Groups

Condition	Details	Actions
TB Case Open	Tuberculosis started on 2017-09-05	

4.2.4.2 Edit a Patient Condition

In either the patient or encounter view for the patient, navigate to the **Clinical Information** tab. Within the **Condition** tab, find the condition to edit in the table and click the **Edit Condition** icon after which the system will display the **Edit Condition** pop up form.

Conditions	Adverse Events	Medications	Tests and Procedures	
Add Condition				
Condition	Start date	Outcome date	Outcome	Actions
Acute HIV syndrome	19/06/2016	23/08/2016		
Tuberculosis	05/09/2017			
Rashes, eruptions and exanthems NEC	10/08/2017	03/11/2017		
Hypertension	06/05/2020		Recovered/Resolved	

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

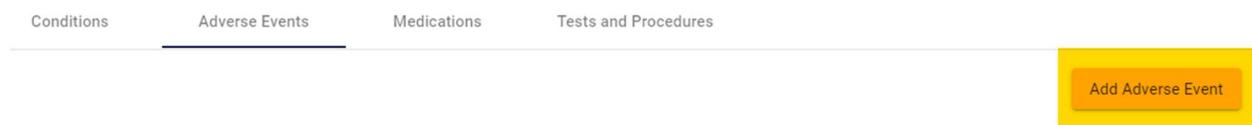
NOTE: The system will not allow you to change the Patient's Condition **MedDRA Term**. To change the **MedDRA Term** you will need to delete the record and enter the Patient Condition as a new entry.

Click the Save button or click the Cancel button to cancel the action and return to the previous page. If the patient's outcome is fatal, the patient's status will be updated to deceased.

Appointments	Attachments	Encounters	Patient Status	Cohorts
Effective date	Status		Created	
20/01/2017	Active		2017-01-20 01:59:08 PM	
03/06/2020	Died		2020-06-03 08:57:57 AM	

4.2.4.3 Add Adverse Event

At the **Adverse Events** tab click the **Add Adverse Event** button, after which the system will display an **Add Adverse Event** pop up form.



- Select the MedDra term for the adverse event by clicking on the plus icon.
- Select the term type for the term and enter the adverse event in the **Find by term** field. Click the **Search** button (magnifying glass) and the system will then provide a list of results from the MedDRA dictionary that match the term that you have searched on.

Select Meddra Term

Term type *

Lowest Level Term

Find by term *

Neurogenic hyper



Description	Actions
Neurogenic hypertension	>

Items per page: 5 1 - 1 of 1 < >

Cancel

- Click the right arrow for the corresponding term that you would like to select.
- Enter a free format description of the adverse event as defined by the reporter or patient.
- Enter the **Onset Date** and complete the remaining fields as appropriate.

- Click the **Save** button to create the adverse event or click the **Cancel** button to cancel the action and go back to the previous page.

Add Adverse Event

Basic Information
Detail Information

Event description (As stated by patient or reporter) *

Hypertension

Maximum length 250

MedDRA term (For fatal events, please ensure the event outcome and all conditions are updated) *

Neurogenic hypertension

Onset date *

Resolution date

+

Save
Cancel

- After clicking on **Save** the system will display the updated the table under the **Adverse Events** tab.

Conditions	Adverse Events	Medications	Tests and Procedures		
				Add Adverse Event	
Description	Onset date	Reported date	Resolution date	Is serious	Actions
Dizziness	03/08/2016			No	
Bruising	13/06/2017	13/06/2017		Yes	
Benign essential hypertension antepartum	19/12/2017				
Hypertension worsened	27/12/2017				
Vertigo (excl dizziness)	09/07/2018				
Hypertension	04/05/2020				

The fields on the **Add Adverse Event** form 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 adverse event
Term results	System generated list; Select appropriate term from list
Event description (As stated by patient or reporter)	Text field; enter event term as stated in the medical records
Onset date	Date field; Enter date condition started
Resolution date	Date field; Enter condition outcome date
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 (will only appear if Hospitalized)	Date field; Enter date patient was admitted
Discharge Date	Date field; Enter date patient was discharged

(will only appear if Hospitalized)	
Date of Death (will only appear if reason for Seriousness is Death)	Date 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	Date 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

In either the patient or encounter view for the patient, navigate to the **Clinical Information** tab. Within the **Adverse Event** tab, find the adverse event you would like to edit within the table and click the **Update Adverse Event** icon. The system will display the **Update Adverse Event** pop up form.

Conditions	Adverse Events	Medications	Tests and Procedures			Add Adverse Event
Description	Onset date	Reported date	Resolution date	Is serious	Actions	
Dizziness	03/08/2016			No	 	
Bruising	13/06/2017	13/06/2017		Yes	 	
Benign essential hypertension antepartum	19/12/2017				 	
Hypertension worsened	27/12/2017				 	
Vertigo (excl dizziness)	09/07/2018				 	
Hypertension	04/05/2020				 	

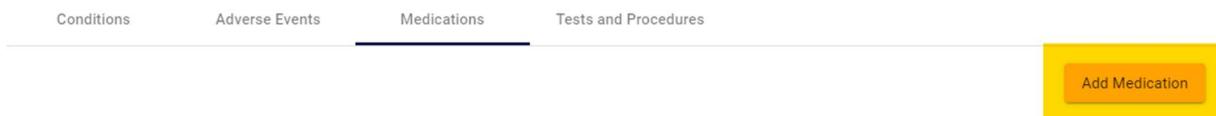
NOTE: The system will not allow you to change the Patient's Adverse Event **MedDRA Term**. To change the **MedDRA Term** you will need to delete the record and enter the Patient Adverse Event as a new entry.

Add information or make changes to the page as appropriate.

Click the Save button or click the Cancel button to cancel the action and return to the previous page

4.2.4.5 Add a Patient Medication

At the **Medications** tab click the **Add Medication** button, after which the system will display an **Add Medication** pop up form.



- Enter a free format description of the medication as defined by the reporter or patient.
- Select the medication by clicking on the plus icon.
- Select the option you would like to use for searching for the medication. You can either search by active ingredient or the product name
- Enter the active ingredient or product name in the **Find by term** field. Click the **Search** button (magnifying glass) and the system will then provide a list of results from the list of concepts that match the term that you have searched on.

Select Medication

Search option *

By product

Find by term *

Abacavir



Description	Actions
Abacavir, sulfato 300mg (Bottle) (ABAC TABLETS)	>
Abacavir 300mg (Bottle) (ABACAVIR)	>
Abacavir, Sulfato +Lamivudina 60mg + 30mg (Bottle) (ABACAVIR SULFATE/LAMIVUDINE60mg/30mg)	>
Abacavir, sulfato + Lamivudina 600mg + 300mg (Bottle) (ABACAVIR SULFATO ANDLAMIVUDINE)	>
Abacavir, sulfato 300mg (Bottle) (ABACAVIR SULFATO TABLETS)	>

Items per page: 5 1 - 5 of 10 < >

Cancel

- Click the right arrow for the corresponding medication that you would like to select.
- Enter the **Start Date** and complete the remaining fields as appropriate.
- Click the **Save** button to create the medication or click the **Cancel** button to cancel the action and go back to the previous page.

Add Medication

PLEASE NOTE: Ensure Medication Start and End Dates are captured timely and accurately as they are critical to determine the patient's contribution per medicine to analysis within the analytical portal

Basic Information

Detail Information

Medication description (As noted at source)*

Abacavir

Maximum length 200

Medication *

Abacavir 300mg (Bottle) (ABACAVIR)



Start date *

6/1/2020



End date



Dose

120

Dose unit

microgram

Save

Cancel

- After clicking on **Save** the system will display the updated the table under the **Medications** tab.

Conditions	Adverse Events	Medications	Tests and Procedures				
Add Medication							
Drug name	Dose	Dose unit	Frequency	Start date	End date	Indication	Actions
kanamycin	1000	milligram	daily	12/03/2016	18/03/2016		 
capreomycin	1000	mg	daily	12/10/2016			 
prothionamide	1000	milligram	daily	01/04/2016	25/08/2016		 
ondansetron	1000	milligram	daily	19/06/2016	11/12/2016		 
amitriptyline	10	mg	daily	01/06/2016	30/06/2016		 
ceftriaxone	1000	milligram	daily	02/06/2016	19/10/2016		 
doxycycline	1000	milligram	daily	03/06/2016			 
Abacavir	120	ug		01/06/2020			 

The fields on the **Add Medication** form are described below:

Medication description (As stated by patient or reporter)	Text field; enter medicine term as stated in the medical records
Find by term	Text field; Enter name of medication
Term results	System generated list; Select appropriate medication from list
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 days 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

In either the patient or encounter view for the patient, navigate to the **Clinical Information** tab. Within the **Medications** tab, find the medication you would like to edit within the table and click the **Update Medication** icon. The system will display the **Update Medication** pop up form.

Conditions	Adverse Events	Medications	Tests and Procedures				
Add Medication							
Drug name	Dose	Dose unit	Frequency	Start date	End date	Indication	Actions
kanamycin	1000	milligram	daily	12/03/2016	18/03/2016		 
capreomycin	1000	mg	daily	12/10/2016			 
prothionamide	1000	milligram	daily	01/04/2016	25/08/2016		 
ondansetron	1000	milligram	daily	19/06/2016	11/12/2016		 
amitriptyline	10	mg	daily	01/06/2016	30/06/2016		 
ceftriaxone	1000	milligram	daily	02/06/2016	19/10/2016		 
doxycycline	1000	milligram	daily	03/06/2016			 
Abacavir	120	ug		01/06/2020			 

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 Save button or click the Cancel button to cancel the action and return to the previous page.

4.2.4.7 Add a Test or Procedure

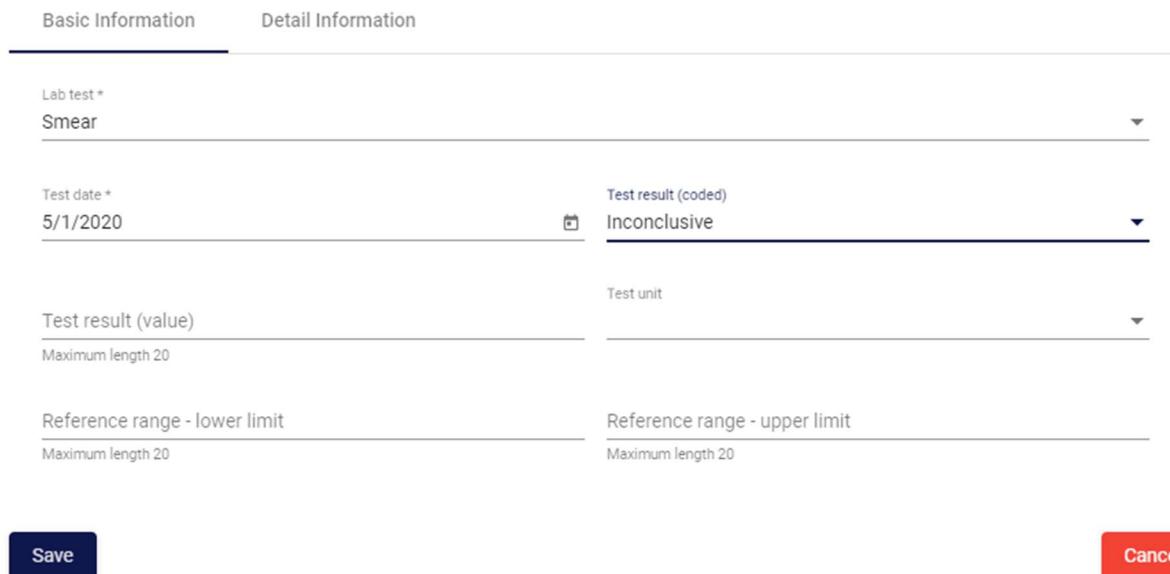
At the **Tests and Procedures** tab click the **Add Test and Procedure** button, after which the system will display an **Add Test and Procedure** pop up form.



The screenshot shows a navigation bar with four tabs: 'Conditions', 'Adverse Events', 'Medications', and 'Tests and Procedures'. The 'Tests and Procedures' tab is currently selected. Below the tabs is a yellow rectangular button labeled 'Add Test and Procedure' with a small icon of a test tube.

- 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 **Save** button to create the test or procedure or click the **Cancel** button to cancel the action and go back to the previous page.

Add Test and Procedure



The screenshot shows the 'Add Test and Procedure' form with the 'Basic Information' tab selected. It includes fields for 'Lab test *' (set to 'Smear'), 'Test date *' (set to '5/1/2020'), 'Test result (coded)' (set to 'Inconclusive'), 'Test result (value)' (with a note 'Maximum length 20'), 'Test unit' (with a note 'Maximum length 20'), 'Reference range - lower limit' (with a note 'Maximum length 20'), and 'Reference range - upper limit' (with a note 'Maximum length 20'). At the bottom are 'Save' and 'Cancel' buttons.

- After clicking on **Save** the system will display the updated the table under the **Tests and Procedures** tab.

Conditions	Adverse Events	Medications	Tests and Procedures		
Add Test and Procedure					
Test	Test date	Test result (coded)	Test result (value)	Test unit	Actions
CD4 Count	24/01/2017		555.00	cells/mm ³	
Glucose	25/01/2017		80.00	mg/dL	
AFB Smear Result	12/07/2017	Abnormal	SCANTY	mg/dL	
Haemoglobin	09/07/2018		10	mg/dL	
Smear	01/05/2020	Inconclusive			

The fields on the **Add Test and Procedure** form are described below:

Lab 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
Test Unit	Dropdown list; select corresponding unit for the Test or Procedure Result (e.g., %, mg, millisecond)
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
Comments	Text field; Enter additional information about the Test or Procedure if needed

4.2.4.8 Edit an Existing Test or Procedure

In either the patient or encounter view for the patient, navigate to the **Clinical Information** tab. Within the **Tests and Procedures** tab, find the test or procedure you would like to edit within the table and click the **Update Test and Procedure** icon. The system will display the **Update Test and Procedure** pop up form.

Conditions	Adverse Events	Medications	Tests and Procedures	Add Test and Procedure	
Test	Test date	Test result (coded)	Test result (value)	Test unit	Actions
CD4 Count	24/01/2017		555.00	cells/mm ³	
Glucose	25/01/2017		80.00	mg/dL	
AFB Smear Result	12/07/2017	Abnormal	SCANTY	mg/dL	
Haemoglobin	09/07/2018		10	mg/dL	
Smear	01/05/2020	Inconclusive			

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.

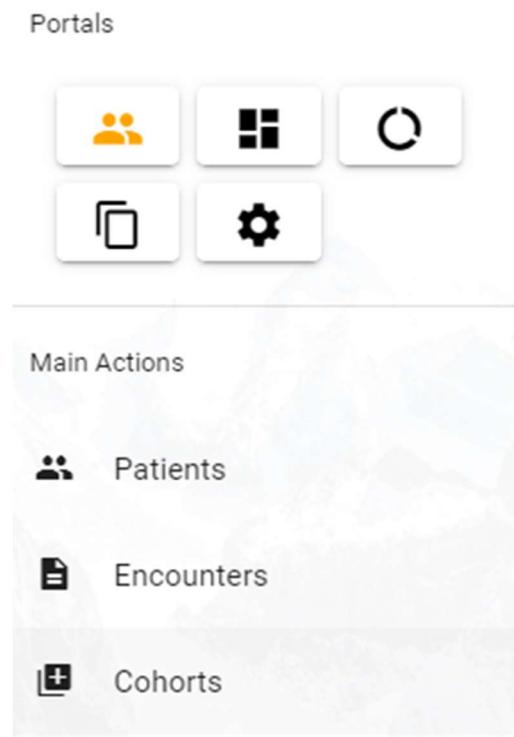
Click the Save button or click the Cancel button to cancel the action and return to the previous page.

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** page, which lists all currently registered cohorts in the system.

Cohorts

[Add Cohort](#)

ID	Cohort name	Code	Primary condition	Patient count	Start date	End date	Actions
1	9MTR Study	OR9MT	TB	1	2016-05-01	2018-02-23	
2	BDQ Study	ORBDQ	TB	1	2016-06-01	2016-12-19	
3	9MTR Program Condition	PC9MT	TB	1	2001-06-01	2099-12-31	
4	18MTR Program Condition	PC18M	TB	0	2001-06-01	2099-12-31	
5	XDRTB Program Condition	PCXDR	TB	0	2001-06-01	2099-12-31	
8	Test	TestC	TB	0	2017-07-20	2019-07-31	
9	Test cohort	TST01	Malaria	0	2020-06-01	2020-06-23	

Items per page: 10 ▼ 1 - 7 of 7 < >

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

Cohorts

[Add Cohort](#)

ID	Cohort name	Code	Primary condition	Patient count	Start date	End date	Actions
1	9MTR Study	OR9MT	TB	1	2016-05-01	2018-02-23	

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



Cohort View

Cohort Details				Event Summary		
Cohort name 9MTR Study	Code OR9MT	Primary condition TB	Patient count 1	Non serious events 6	Serious events 1	
Patient name	Facility	Date of birth	Last encounter	Weight (kg)	Non serious events	Serious events
Unique PatientOne	Facility A1	2012-03-02	2020-05-26	6	1	
				Actions		

Items per page: 10 ▼ 1 - 1 of 1 < >

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

The screenshot shows the 'Cohort View' page. At the top left is a back arrow icon. Below it is a table with two sections: 'Cohort Details' and 'Event Summary'. The 'Cohort Details' section contains four rows: 'Cohort name' (9MTR Study), 'Code' (OR9MT), 'Primary condition' (TB), and 'Patient count' (1). The 'Event Summary' section contains three rows: 'Non serious events' (6), 'Serious events' (1), and a row with a yellow circle containing the number '8'. Below these sections is a table with columns: Patient name, Facility, Date of birth, Last encounter, Weight (kg), Non serious events, Serious events, and Actions. A single row is shown: Unique PatientOne, Facility A1, 2012-03-02, 2020-05-26, 6, 1, and an 'Actions' column with a yellow eye icon. At the bottom right are pagination controls: 'Items per page: 10', '1 - 1 of 1', and navigation arrows.

Cohort Details		Event Summary		
Cohort name	9MTR Study	Code	OR9MT	Primary condition
Patient count	1	Non serious events	6	Serious events
				1

Patient name	Facility	Date of birth	Last encounter	Weight (kg)	Non serious events	Serious events	Actions
Unique PatientOne	Facility A1	2012-03-02	2020-05-26	6	1		

Items per page: 10 1 - 1 of 1

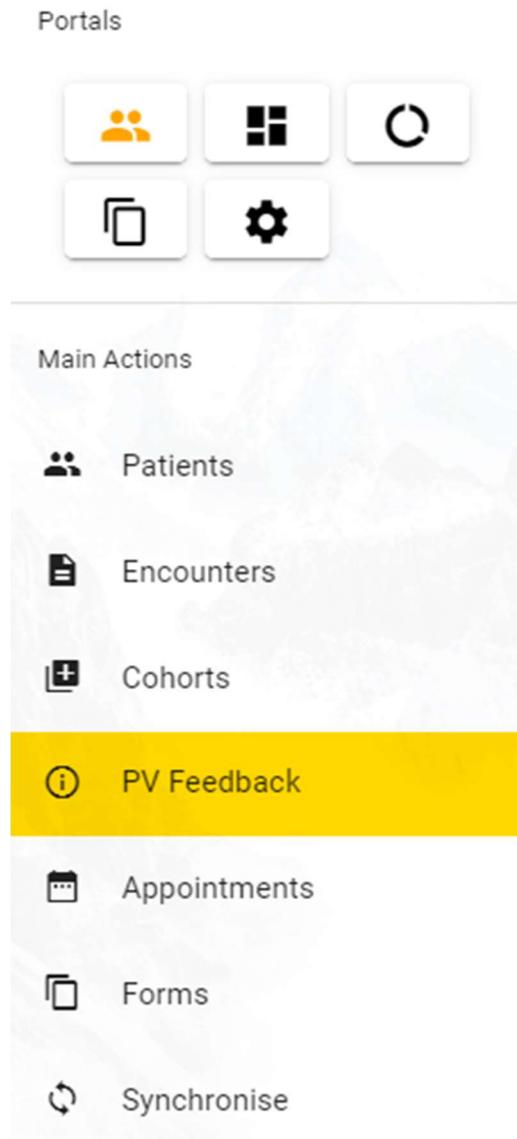
Click the **View Patient** button in the Action column for the patient to view. The system will display the **Patient View** page.

4.4 Feedback

Feedback can be used to track all analysis concluded by the Pharmacovigilance technician for all adverse events logged within the clinical portal. Feedback is generated by the system as causality and terminology has been set by the technician.

4.4.1 View Feedback

The **Feedback** function can be accessed through the **PV Feedback** menu.

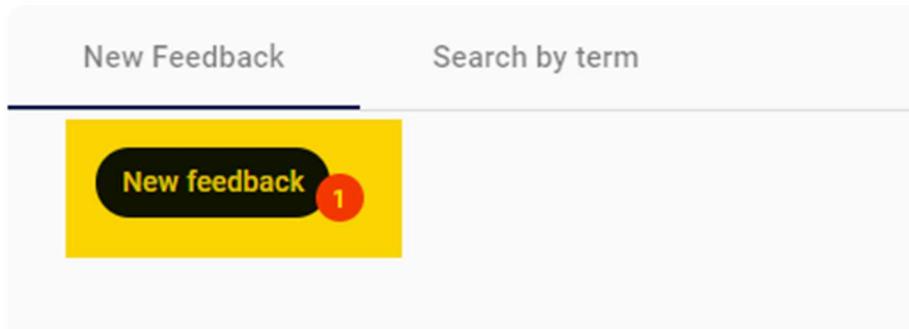


The system will display the **feedback** page, which provides the user with the ability to view feedback via a new and search by term tab.

4.4.2 View New Feedback

The **New feedback** tab represents all new feedback that has been generated by the technician within a recent time period. This period is administrable by your system administrator within the administrator portal. The number in the red circle represents the number of new reports that have recent feedback.

PV Feedback



To view feedback for a report, click on the visibility icon for the report you would like to view feedback for.

A screenshot of the 'PV Feedback' interface showing a single report in a table. The columns are: Created, Identifier, Patient, Adverse event, MedDra term, and Actions. The data for the report is: Created - 2020-07-13 05:00:24 PM, Identifier - 11/2020/00086, Patient - Unique PatientEleven, Adverse event - Accelerated hypertension, MedDra term - Accelerated hypertension, and Actions - a yellow square with a magnifying glass icon. At the bottom, there are pagination controls: 'Items per page: 10', '1 - 1 of 1', and navigation arrows.

The system will navigate the user to a **View Adverse Event** pop up form where the user will be able to view the following feedback:

- **Terminology and Causality.** Ability to view MedDRA term and causality per medication as set by the technician

Terminology and Causality	PV Analytical History	Basic Information	Detail Information
MedDra term set to : Accelerated hypertension			
Identifier abacavir 100mg/ml (Solution);	Naranjo WHO	Certain	

- **PV Analytical History.** Ability to view a full history of all activity by the technician

View Adverse Event

Terminology and Causality	PV Analytical History	Basic Information	Detail Information
Date	Activity	Event	Comments
2020-07-28 07:15:45 AM	Extract E2B	E2B report submitted	UniqueAgain
2020-07-13 05:01:12 PM	Extract E2B	E2B report generated	
2020-07-13 05:01:08 PM	Extract E2B	E2B data generated for report	AUTOMATION: E2B dataset created
2020-07-13 05:01:03 PM	Extract E2B	Report ready for E2B submission	
2020-07-13 05:01:03 PM	Set MedDRA and Causality	Causality set by technician	
2020-07-13 05:00:45 PM	Set MedDRA and Causality	MedDRA term set by technician	AUTOMATION: MedDRA Term set
2020-07-13 05:00:33 PM	Set MedDRA and Causality	Report ready for MedDRA and Causality	
2020-07-13 05:00:33 PM	Confirm Report Data	Report confirmed by technician	
2020-07-13 05:00:24 PM	Confirm Report Data	Report submitted for confirmation	

Close

- **Basic and Detailed Information.** Adverse event information captured in the clinical portal

View Adverse Event

The screenshot shows a user interface for viewing an adverse event. At the top, there are four tabs: 'Terminology and Causality', 'PV Analytical History', 'Basic Information' (which is underlined, indicating it is the active tab), and 'Detail Information'. Below the tabs, there are three main sections: 1) 'Event description (As stated by patient or reporter)' containing the text 'Hypertension'; 2) 'MedDRA term (For fatal events, please ensure the event outcome and all conditions are updated)' containing the text 'Accelerated hypertension'; and 3) two boxes for dates: 'Onset date' (2020-07-01) and 'Resolution date'.

4.4.3 Search for Feedback for Report

The **Search by term** tab allows the user to search for feedback for a report using the following criteria:

- Patient name
- MedDRA term as set by the clinician and technician
- Report identifier
- Medications

The search function uses a partial term to search all reports on the terms noted above. For instance, searching for the term Accelerated returns all reports that have that partial term in the MedDRA term for the report.

The screenshot shows a search results page for PV Feedback. At the top, there are two tabs: 'New Feedback' and 'Search by term' (which is underlined). Below the tabs is a search input field with placeholder text: 'Please enter a term below to search by patient name, MedDra term as set by the clinician, the MedDra term as set by the PV specialist, the report identifier or medications used in the analysis...'. The search term 'Accelerated' is entered into this field. A yellow box highlights the search term. Below the search bar is a table with columns: 'Created', 'Identifier', 'Patient', 'Adverse event', 'MedDra term', and 'Actions'. Two rows of data are shown: 1) Created: 2020-07-13 05:00:24 PM, Identifier: 11/2020/00086, Patient: Unique PatientEleven, Adverse event: Accelerated hypertension, MedDra term: Accelerated hypertension, Actions: edit icon. 2) Created: 2020-05-21 12:00:00 AM, Identifier: 11/2017/00026, Patient: Unique PatientTen, Adverse event: Accelerated hypertension, MedDra term: Nephrotoxicity, Actions: edit icon.

Created	Identifier	Patient	Adverse event	MedDra term	Actions
2020-07-13 05:00:24 PM	11/2020/00086	Unique PatientEleven	Accelerated hypertension	Accelerated hypertension	
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	Accelerated hypertension	Nephrotoxicity	

4.5 Appointments

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

4.5.1 View Appointments

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

Portals



Main Actions

- Patients
- Encounters
- Cohorts
- PV Feedback
- Appointments

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

Appointments

Search from *	Search to *			Search
1/1/2020	12/31/2020			
Patient name	Details	Appointment date	Activity	Actions
Unique PatientOne	This is a test appointment	2020-08-01	Appointment	🕒

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
Appointment date	The date of the appointment
Activity	Has the patient arrived for their appointment? Has the patient missed their appointment?
Action	Ability to view patient Ability to view 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.

4.5.2 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.

Appointments

Search from *	Search to *	
8/1/2020	8/2/2020	
Patient name	Details	Appointment date
Unique PatientOne	This is a test appointment	2020-08-01

4.5.3 View Patient Record

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

Activity	Actions
Appointment	

4.5.4 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** icon.

Appointments

Search from * 1/1/2020 Search to * 12/31/2020

Patient name	Details	Appointment date	Activity	Actions
Unique PatientOne	This is a test appointment	2020-08-01	Appointment	
Unique PatientOne	This is a test appointment another	2020-06-16	MISSED	

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

Did not arrive

Please note! You are about to mark this appointment as DNA. This change cannot be reversed....

Appointment date
06/16/2020

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

Appointments

Search from * 1/1/2020 Search to * 12/31/2020

Patient name	Details	Appointment date	Activity	Actions
Unique PatientOne	This is a test appointment	2020-08-01	Appointment	
Unique PatientOne	This is a test appointment another	2020-06-16	Did Not Arrive	



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

4.6 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.

4.6.1 Patient View - Additional Information

4.6.1.1 Delete an Appointment

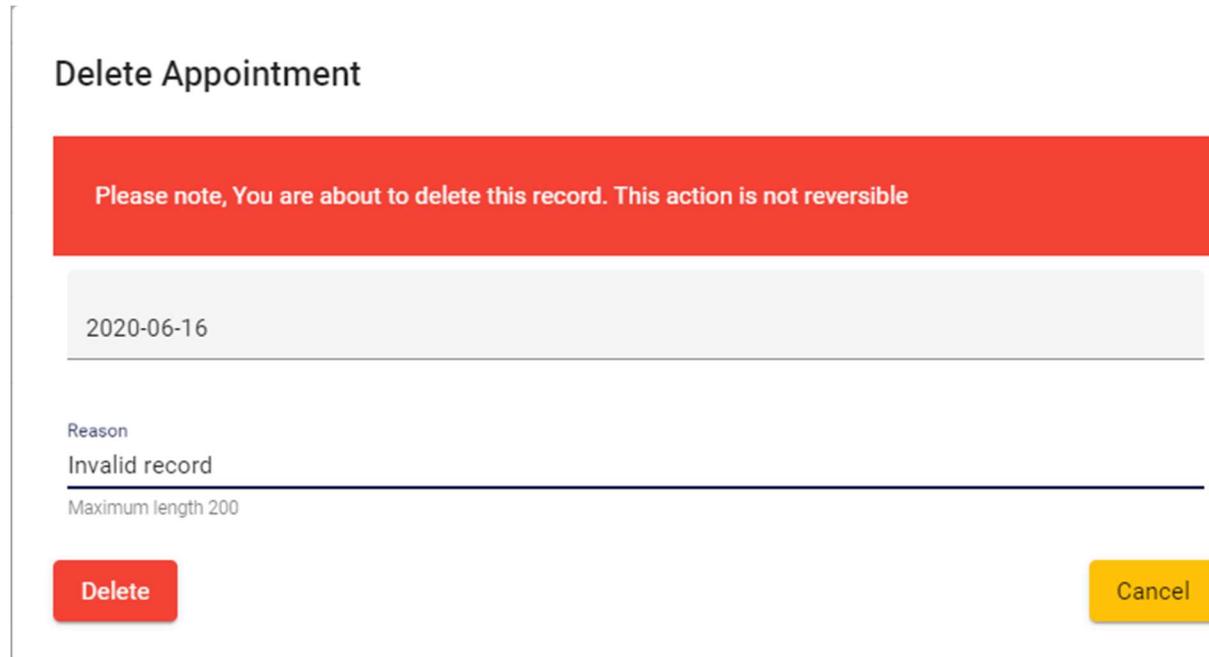
Within the **Patient View**, at the **Appointments** tab, find the appointment you would like to delete.

Appointments	Attachments	Encounters	Patient Status	Cohorts	
					Add Appointment
Appointment date	Reason	Outcome		Actions	
01/08/2020	This is a test appointment				
16/06/2020	This is a test appointment another		Did not arrive		



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

Click the **Delete Appointment** icon after which the system will take you to a **Delete Appointment** pop up form.



The image shows a 'Delete Appointment' dialog box. At the top, it says 'Delete Appointment'. Below that is a red bar with the text 'Please note, You are about to delete this record. This action is not reversible'. The main area contains the date '2020-06-16'. Under 'Reason', there is a text input field with 'Invalid record' typed into it, followed by the note 'Maximum length 200'. At the bottom are two buttons: a red 'Delete' button on the left and a yellow 'Cancel' button on the right.

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

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

Appointments	Attachments	Encounters	Patient Status	Cohorts	Add Appointment
Appointment date	Reason	Outcome	Actions		
01/08/2020	This is a test appointment		 		

4.6.1.2 Delete an attachment

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

Appointments	Attachments	Encounters	Patient Status	Cohorts	
Type	Name	Description	Created	Actions	
Image PNG	MSH_4c.png	MSH Logo	2020-05-27 04:45:04 PM	 	

Click the **Delete Attachment** icon after which the system will take you to a **Delete Attachment** pop up form.

Delete Attachment

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

MSH_4c.png

Reason

Invalid record

Maximum length 200

Delete

Cancel

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 **Attachment** table.

Appointments	Attachments	Encounters	Patient Status	Cohorts
Type	Name	Description	Created	Actions

4.6.1.3 Delete an Encounter

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

Appointments	Attachments	Encounters	Patient Status	Cohorts
Add Encounter				
Encounter date	Type			Actions
24/01/2017	Pre-Treatment Visit			/
25/01/2017	Pre-Treatment Visit			/
01/08/2017	Pre-Treatment Visit			/
07/11/2017	Pre-Treatment Visit			/
09/11/2017	Treatment Initiation Visit			/
09/07/2018	Unscheduled Visit			/
15/01/2020	Pre-Treatment Visit			/

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

Medical Details	First-line Susceptibility	Second-line Susceptibility	TB Condition	Notes
Weight (kg) 34.5			Height (cm) 110	
BMI 28.51			Pregnancy Status Uncertain	
Date of last menstrual period 2017-02-28T22:00:00.000Z			Estimated gestation (weeks) 12	
Breastfeeding mother Yes			Injecting drug use within past year Yes	
Excessive alcohol use within the past year No			Tobacco use within the past year Yes	
<div style="text-align: right;">Delete Encounter Update Encounter</div>				

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

Delete Encounter

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

Encounter date 2017-11-07
Encounter type Pre-Treatment Visit
Reason Invalid record
Maximum length 200
<div style="text-align: left;">Delete Cancel</div>

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

4.6.1.4 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.

Appointments	Attachments	Encounters	Patient Status	Cohorts		
Cohort name			Start date	Enroled date	De-enroled date	Actions
9MTR Study (OR9MT)			01/05/2016	04/03/2020	04/03/2020	
BDQ Study (ORBDQ)			01/06/2016	03/03/2020	04/03/2020	
9MTR Program Condition (PC9MT)			01/06/2001	27/05/2020		
18MTR Program Condition (PC18M)			01/06/2001	01/05/2020		
XDRTB Program Condition (PCXDR)			01/06/2001			
Test (TestC)			20/07/2017			
Test cohort (TST01)			01/06/2020			

Click the **De-enroll** icon after which the system will display a **Cohort De-enrollment** confirmation pop up form.

Cohort De-enrolment

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

Cohort
9MTR Program Condition (PC9MT)

Enrolment Date
2020-05-27

De-enrolment Date
6/1/2020 

Save

Cancel

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

Appointments	Attachments	Encounters	Patient Status	Cohorts	
			Start date	Enroled date	De-enroled date Actions
9MTR Study (OR9MT)			01/05/2016	04/03/2020	04/03/2020
BDQ Study (ORBDQ)			01/06/2016	03/03/2020	04/03/2020
9MTR Program Condition (PC9MT)			01/06/2001	27/05/2020	01/06/2020
18MTR Program Condition (PC18M)			01/06/2001	01/05/2020	 
XDRTB Program Condition (PCXDR)			01/06/2001		
Test (TestC)			20/07/2017		
Test cohort (TST01)			01/06/2020		

4.6.1.5 Deleting A Cohort Enrolment

Within the **Patient View**, at the **Cohorts** tab, find the **Cohort** you would like to delete the enrolment for .

Appointments	Attachments	Encounters	Patient Status	Cohorts		
Cohort name			Start date	Enroled date	De-enroled date	Actions
9MTR Study (OR9MT)			01/05/2016	04/03/2020	04/03/2020	
BDQ Study (ORBDQ)			01/06/2016	03/03/2020	04/03/2020	
9MTR Program Condition (PC9MT)			01/06/2001	27/05/2020	01/06/2020	
18MTR Program Condition (PC18M)			01/06/2001	01/05/2020		
XDRTB Program Condition (PCXDR)			01/06/2001			
Test (TestC)			20/07/2017			
Test cohort (TST01)			01/06/2020			

Click the **Delete** icon after which the system will display a **Cohort Enrollment Deletion** confirmation pop up form.

Delete Enrolment

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

18MTR Program Condition

Reason

Enrolled into incorrect cohort

Maximum length 200

Delete

Cancel

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

Appointments		Attachments		Encounters		Patient Status	Cohorts	
Cohort name				Start date	Enroled date	De-enroled date	Actions	
9MTR Study (OR9MT)			01/05/2016	04/03/2020	04/03/2020			
BDQ Study (ORBDQ)			01/06/2016	03/03/2020	04/03/2020			
9MTR Program Condition (PC9MT)			01/06/2001	27/05/2020	01/06/2020			
18MTR Program Condition (PC18M)			01/06/2001					
XDRTB Program Condition (PCXDR)			01/06/2001					
Test (TestC)			20/07/2017					
Test cohort (TST01)			01/06/2020					



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.

4.6.2 Encounter View – Clinical Information

4.6.2.1 Delete A Patient Condition

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

Conditions	Adverse Events	Medications	Tests and Procedures	Add Condition
Condition	Start date	Outcome date	Outcome	Actions
Tuberculosis	05/09/2017			 
Rashes, eruptions and exanthems NEC	10/08/2017	03/11/2017		 
Patient fell	02/06/2020			 

Click the **Delete Condition** icon after which the system will take you to a **Delete Condition** pop up form.

Delete Patient Condition

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

Patient fell

Reason

Invalid record

Maximum length 200

Delete

Cancel

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

Conditions	Adverse Events	Medications	Tests and Procedures	
Add Condition				
Condition	Start date	Outcome date	Outcome	Actions
Tuberculosis	05/09/2017			
Rashes, eruptions and exanthems NEC	10/08/2017	03/11/2017		

4.6.2.2 Delete an Adverse Event

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

Conditions	Adverse Events	Medications	Tests and Procedures	
Add Adverse Event				
Description	Onset date	Reported date	Resolution date	Is serious
Dizziness	03/08/2016			No
Bruising	13/06/2017	13/06/2017		Yes
Benign essential hypertension antepartum	19/12/2017			
Hypertension worsened	27/12/2017			
Vertigo (excl dizziness)	09/07/2018			
Hypertension	04/05/2020	02/06/2020		
Patient feel	07/04/2020			

Click the **Delete Adverse Event** icon after which the system will take you to a **Delete Adverse Event** pop up form.

Delete Patient Clinical Event

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

Patient feel

Reason

Invalid record

Maximum length 200

Delete

Cancel

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

Conditions	Adverse Events	Medications	Tests and Procedures		
Add Adverse Event					
Description	Onset date	Reported date	Resolution date	Is serious	Actions
Dizziness	03/08/2016			No	 
Bruising	13/06/2017	13/06/2017		Yes	 
Benign essential hypertension antepartum	19/12/2017				 
Hypertension worsened	27/12/2017				 
Vertigo (excl dizziness)	09/07/2018				 
Hypertension	04/05/2020	02/06/2020			 

4.6.2.3 Delete A Patient Medication

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

Conditions	Adverse Events	Medications	Tests and Procedures				
Add Medication							
Drug name	Dose	Dose unit	Frequency	Start date	End date	Indication	Actions
kanamycin	1000	milligram	daily	12/03/2016	18/03/2016		 
capreomycin	1000	mg	daily	12/10/2016			 
prothionamide	1000	milligram	daily	01/04/2016	25/08/2016		 
ondansetron	1000	milligram	daily	19/06/2016	11/12/2016		 
amitriptyline	10	mg	daily	01/06/2016	30/06/2016		 
ceftriaxone	1000	milligram	daily	02/06/2016	19/10/2016		 
doxycycline	1000	milligram	daily	03/06/2016			 
Abacavir	120	ug		01/06/2020			 

Click the **Delete Medication** icon after which the system will take you to a **Delete Patient Medication** pop up form.

Delete Patient Medication

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

Abacavir

Reason

Invalid record

Maximum length 200

Delete

Cancel

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

Conditions	Adverse Events	Medications	Tests and Procedures				
				<button>Add Medication</button>			
Drug name	Dose	Dose unit	Frequency	Start date	End date	Indication	Actions
kanamycin	1000	milligram	daily	12/03/2016	18/03/2016		
capreomycin	1000	mg	daily	12/10/2016			
prothionamide	1000	milligram	daily	01/04/2016	25/08/2016		
ondansetron	1000	milligram	daily	19/06/2016	11/12/2016		
amitriptyline	10	mg	daily	01/06/2016	30/06/2016		
ceftriaxone	1000	milligram	daily	02/06/2016	19/10/2016		
doxycycline	1000	milligram	daily	03/06/2016			

4.6.2.4 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.

Conditions	Adverse Events	Medications	Tests and Procedures	Add Test and Procedure	
Test	Test date	Test result (coded)	Test result (value)	Test unit	Actions
CD4 Count	24/01/2017		555.00	cells/mm ³	
Glucose	25/01/2017		80.00	mg/dL	
AFB Smear Result	12/07/2017	Abnormal	SCANTY	mg/dL	
Haemoglobin	09/07/2018		10	mg/dL	
Smear	01/05/2020	Inconclusive			

Click the **Delete Test and Procedure** icon after which the system will take you to a **Delete Test and Procedure** pop up form.

Delete Patient Lab Test

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

Smear

Reason

Invalid record

Maximum length 200

Delete

Cancel

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

Conditions	Adverse Events	Medications	Tests and Procedures	
Add Test and Procedure				
Test	Test date	Test result (coded)	Test result (value)	Test unit
CD4 Count	24/01/2017		555.00	cells/mm ³
Glucose	25/01/2017		80.00	mg/dL
AFB Smear Result	12/07/2017	Abnormal	SCANTY	mg/dL
Haemoglobin	09/07/2018		10	mg/dL

4.6.3 Delete an Entire Patient Record

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

Patient View For | Unique PatientTwo (831552981)

Patient Information	Basic Information	Detail Information	Notes
Additional Information	First name Unique	Middle name	Last name PatientTwo
Clinical Information	Date of birth 1943-01-01	Age 77	Age group Elderly > 69 years
Audit Information	Facility Facility A1	Date entered in system 2017-01-20 01:59:17 PM	
Condition Groups			
Analytical Reporting			
	Delete Patient		Update Patient

The system will take you to a **Delete Patient** pop up form.

Delete Patient

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

Unique PatientTwo (831552981)

Reason

Invalid record

Maximum length 200

Delete

Cancel

Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the patient or click the **Cancel** button to undo the action. After confirming the deletion, the return you to the patient search form.



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

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.

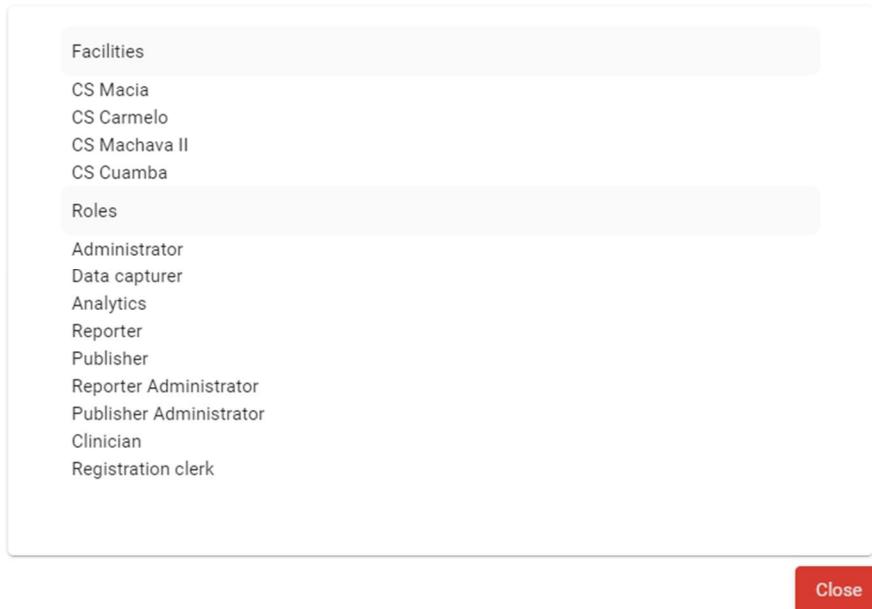
Note: the following roles have access to the analytical portal:

- **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 the user profile menu option which appears when clicking on the profile icon to view roles and facilities you currently have access to.

User profile



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

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: <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	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: <ul style="list-style-type: none">• Delete Report• Confirm Report
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>Activity: Set MedDRA and Causality</p> <p>Step 1: PV specialist sets the terminology for the adverse event. This will be the terminology used for analysis purposes.</p> <p>Step 2: PV specialist then sets the causality per medication that was in use at the onset date of the adverse event.</p> <p><i>Please note: the specialist is unable to set causality until the MedDRA term has been selected.</i></p> <p>Step 3: On completion, the PV specialist confirms causality has been set.</p> <p>Step 4: The report is moved into a new activity: Extract E2B.</p>	<p>Set MedDRA and Causality</p> <p>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.</p> <p>The PV specialist has the following options:</p> <ul style="list-style-type: none"> • Set Terminology • WHO Causality • Naranjo Causality • Confirm Causality Set
<p>Activity: Extract E2B</p> <p>Step 1: PV technician creates an E2B XML file for submission.</p> <p><i>Please note: a patient summary is stored at the time of generating the E2B XML to allow for data verification.</i></p> <p>Step 2: PV technician then confirms that the E2B XML file has been submitted to WHO.</p> <ul style="list-style-type: none"> • A receipt code and time can be noted here <p><i>Please note: submission to WHO UMC is a manual process.</i></p>	<p>Extract E2B</p> <p>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.</p> <p>The PV specialist has the following options:</p> <ul style="list-style-type: none"> • Create E2B • Confirm E2B submission
<p>PROCESS COMPLETED</p>	

5.3.3 Identifying New Reports

It is possible to identify new active or spontaneous reports using the notification panel in the main system header. A number next to the notification icon indicates you either have a new adverse event report requiring analysis or new terminology has been defined for an existing report.



The number of new reports registered within a pre-defined period of time is displayed as a value in the notification list of menu items.

Notifications

X



New ACTIVE reports with causality and terminology

2020-06-25 04:41:35 PM



New ACTIVE reports for analysis (14)

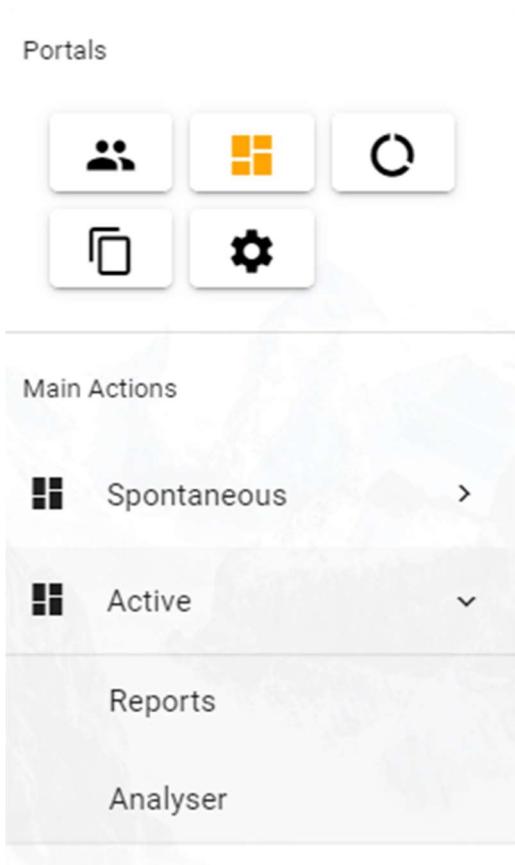
2020-06-25 04:41:35 PM



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 **Reports** function can be accessed either through the Spontaneous or Active menu.



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

- Activity (what stage of analysis the report is currently in)
- Report date range
- By a search term

5.3.4.1 Search by Active Work

Searching by activity allows you to search for all incomplete reports by the current stage a report may be in or by listing all new reports that have been identified as per the **ReportInstanceNewAlertCount** configuration.

- Select the **New Reports** button to view a list of new reports within the system

Active Reports

Active Work Search by date Search by term

Please select an activity below...

New reports 14 **Confirm Report Data** 5 **Set MedDRA and Causality** 3 **Extract E2B** 9



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.

Active Reports

Active Work Search by date Search by term

Please select an activity below...

New reports 14 **Confirm Report Data** 5 **Set MedDRA and Causality** 3 **Extract E2B** 9

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

Active Work Search by date Search by term

Please select an activity below...

New reports 14 Confirm Report Data 5 Set MedDRA and Causality 3 Extract E2B 9

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension		Set MedDRA and Causality NOTSET	⋮

Items per page: 10 1 - 3 of 3 < >

5.3.4.2 Search for all Reports within a Date Range

Search by date range searches for all complete and incomplete reports within a given date range.

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

Active Reports

Active Work Search by date Search by term

Please select a date range to list all reports within that range, irrespective of status...

Search from * 3/26/2020 Search to * 6/26/2020

JUN 2020 ▾ < >

Created	Identifier	Patient	Adverse event	MedDra term	Status	Actions

Items per page: 10 0 of 0 < >

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

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-14 07:23:45 PM	11/2020/00055	Unique PatientNine		Acute duodenal ulcer		Confirm Report Data UNCONFIRMED	⋮
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BINITIATED	⋮
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Extract E2B E2BINITIATED	⋮
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set MedDRA and Causality MEDDRASSET	⋮

5.3.4.3 Search Reports by Term

The **Search by term** tab allows the user to search for all reports using the following criteria:

- Patient name
- MedDRA term as set by the clinician and technician
- Report identifier
- Medications

The search function uses a partial term to search all reports on the terms noted above. For instance, searching for the term Accelerated returns all reports that have that partial term in the MedDRA term for the report.

Active Reports

Active Work Search by date Search by term

Please enter a term below to search by patient name, MedDra term as set by the clinician, the MedDra term as set by the PV specialist, the report identifier or medications used in the analysis...

Term: Accelerated

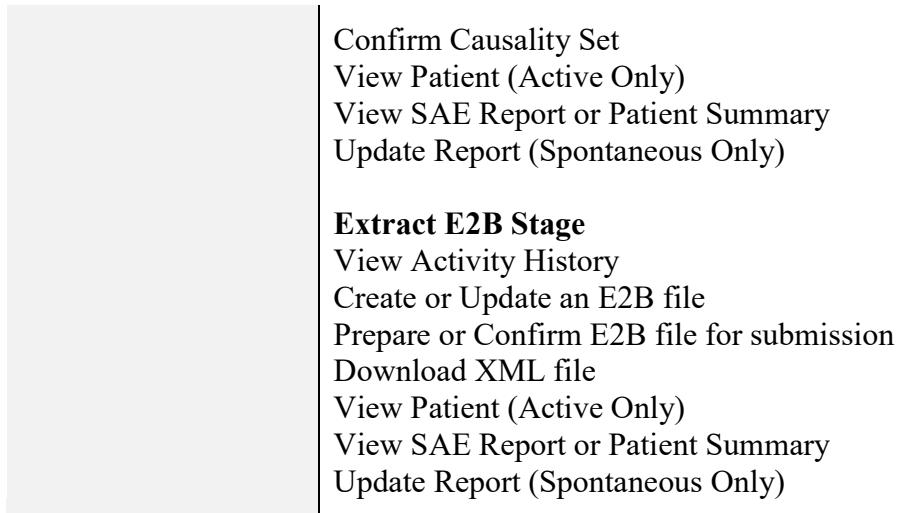
Search

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-07-13 05:00:24 PM	11/2020/00086	Unique PatientEleven	View	Accelerated hypertension	Accelerated hypertension	Extract E2B E2BSUBMITTED	⋮
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension	Benign essential hypertension	Set MedDRA and Causality MEDDRASSET	⋮
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	View	Accelerated hypertension	Nephrotoxicity	Extract E2B E2BGENERATED	⋮

Items per page: 10 1 - 3 of 3 < >

The columns in the report table are described below:

Created	The date and time 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
Actions	<p>Confirm Report Data Stage</p> <p>View Activity History</p> <p>Confirm or Delete Report</p> <p>View Patient (Active Only)</p> <p>View SAE Report or Patient Summary</p> <p>Update Report (Spontaneous Only)</p> <p>Set MedDRA and Causality Stage</p> <p>View Activity History</p> <p>Set Terminology (MedDRA), Naranjo or WHO Causality Term</p>



5.4 Pharmacovigilance Activities - General

5.4.1 Viewing Activity History for Report

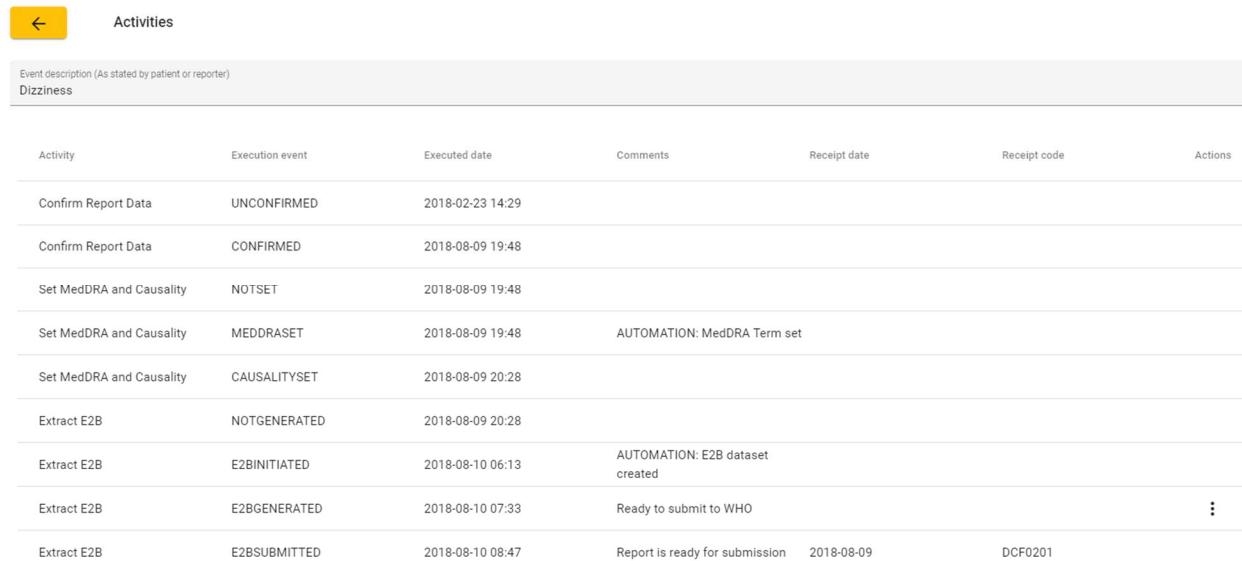
Irrespective of the stage the report is currently in, you will be able to view a comprehensive history for the report detailing all actions that have occurred, who effected the action, and any additional comments.

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

The screenshot shows a table of 'Active Reports' with columns: Created, Identifier, Patient, Medications, Adverse event, MedDra term, Status, and Actions. There are four rows of data. A context menu is open over the third row, with the 'View activity history' option highlighted in yellow. The menu also includes options: Confirm report, Delete report, View patient, and Download summary.

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-14 07:23:45 PM	11/2020/00055	Unique PatientNine		Acute duodenal ulcer		Confirm Report Data UNCONFIRMED	⋮
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Confirm Report Data UNCONFIRMED	⋮
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne	View	Neurogenic hypertension		Confirm Report Data UNCONFIRMED	⋮
2020-06-04 09:59:30 AM	11/2020/00042	Unique PatientOne		Neurogenic hypertension		Confirm Report Data UNCONFIRMED	⋮

The system will navigate you to the **View activity history** page.



The screenshot shows a table titled "Activities" with the following columns: Activity, Execution event, Executed date, Comments, Receipt date, Receipt code, and Actions. The table lists several activities performed on different dates, including "Confirm Report Data" and "Set MedDRA and Causality". The "Comments" column contains notes like "AUTOMATION: MedDRA Term set" and "Ready to submit to WHO". The "Actions" column includes a dropdown menu icon for the last row.

Activity	Execution event	Executed date	Comments	Receipt date	Receipt code	Actions
Confirm Report Data	UNCONFIRMED	2018-02-23 14:29				
Confirm Report Data	CONFIRMED	2018-08-09 19:48				
Set MedDRA and Causality	NOTSET	2018-08-09 19:48				
Set MedDRA and Causality	MEDDRASET	2018-08-09 19:48	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	2018-08-09 20:28				
Extract E2B	NOTGENERATED	2018-08-09 20:28				
Extract E2B	E2BINITIATED	2018-08-10 06:13	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	2018-08-10 07:33	Ready to submit to WHO			:
Extract E2B	E2BSUBMITTED	2018-08-10 08:47	Report is ready for submission	2018-08-09	DCF0201	

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.
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	Download summary Download extract Download E2B file

5.4.2 Viewing a Patient Record

The **View patient** menu 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.

Active Reports

Active Work Search by date Search by term

Please select an activity below...

New reports 13 Confirm Report Data 4 Set MedDRA and Causality 3 Extract E2B 9

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BINITIATED	View activity history
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertens		Update E2B
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	View	Accelerated hypertension	Nephrotoxicity		Prepare report for E2B submiss...
2020-05-21 12:00:00 AM	11/2018/00027	Unique PatientTwo	View	Dizziness	Abdominal pain NOS		View patient
2018-08-09 05:44:15 PM	11/2018/00034	Unique PatientTwentyFour		Cluster headaches	Headache NOS		Download summary
2018-02-23 02:29:47 PM	11/2018/00031	Unique PatientOne	View	Dizziness	Dizziness		
2017-12-30 07:37:52 AM	11/2017/00025	Unique PatientEleven		Benign essential hypertension comp preg, childbirth, and the puerperium, unspec as to eoc	Allergic reaction (NOS)	Extract E2B E2BINITIATED	View activity history

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 **Download 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 **Download Summary** menu for the associated report you would like to view.

Active Reports

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality I MEDDRASSET	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set M MEDD	⌚ View activity history ➡ Set terminology ✓ Confirm causality set 👤 View patient
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension		Set M NOTS	

Please select an activity below...

New reports 13 Confirm Report Data 4 Set MedDRA and Causality 3 Extract E2B 9

Items per page: >

Download summary

The system generates an extract of the patient summary:

A. BASIC PATIENT INFORMATION

Patient Name	Test Patient	Date of Birth	1963-01-01
Age Group		Age at time of consult	54 years
Gender	Male	Facility	Facility A1
Medical Record Number	HFRS-123-1234567	Identity Number	40749941512
Weight (kg)		Height (cm)	
Notes:			

B. PRE-EXISTING CONDITIONS

Condition 1	Meningeal tuberculosis
Start Date	2018-08-01
End Date	
Condition 2	Hypertension ocular
Start Date	2018-08-01
End Date	2018-08-01
Condition 3	UVF enteropathy
Start Date	2018-01-12
End Date	2018-08-08

C. ADVERSE EVENT INFORMATION

Severe Description	Patient is very dizzy	MedDRA Term	Dizziness
Onset Date	2018-08-08	Resolution Date	2018-08-08
Duration	0 days	Outcome	
Notes:			

D. MEDICATIONS

Drug 1	Start Date	End Date	Dose	Route	Indication
Medicine A	2018-08-01	2018-08-08	100		

E. CLINICIAN ACTION TAKEN WITH REGARD TO MEDICINE



If the event is defined as serious, the system will include additional information that explains the seriousness of the report. The heading of the extract will be changed to **Serious Adverse Event**.

5.4.4 Updating a Spontaneous Report

The **Update report** menu 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

Active Work Search by date Search by term

Please select an activity below...

Confirm Report Data ④ Set MedDRA and Causality ① Extract E2B ②

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-01-15 11:44:30 AM	12/2020/00039	SIK		SDD		Confirm Report Data UNCONFIRMED	⋮
2018-09-26 08:34:22 AM	12/2018/00036	TST011	<button>View</button>	Dizziness		Confirm Report Data UNCONFIRMED	View activity history
2018-08-14 08:32:54 AM	12/2018/00035	SIK	<button>View</button>	Dizziness		Confirm Report Data UNCONFIRMED	Confirm report
2018-01-28 12:13:56 PM	12/2018/00029	SIK		Dizziness		Confirm Report Data UNCONFIRMED	Delete report
							Update report

Items per page: 10 >

Download summary

The system will navigate you to the **Spontaneous View** pop up form 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 screenshot shows the 'Active Reports' section of the PViMS interface. At the top, there are tabs for 'Active Work', 'Search by date', and 'Search by term'. Below this, a message says 'Please select an activity below...'. There are four buttons: 'New reports' (13), 'Confirm Report Data' (4), 'Set MedDRA and Causality' (3), and 'Extract E2B' (9). The main table lists reports with columns for Created, Identifier, Patient, Medications, Adverse event, MedDra term, Status, and Actions. One row for 'Unique PatientTwo' is selected. A context menu is open over this row, listing: 'View activity history', 'Confirm report' (with a checkmark), 'Delete report' (highlighted in yellow), 'View patient', and 'Download summary'. The 'Status' column for this row shows 'Confirm Report Data | UNCONFIRMED'.

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-14 07:23:45 PM	11/2020/00055	Unique PatientNine		Acute duodenal ulcer		Confirm Report Data UNCONFIRMED	⋮
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extr	View activity history
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Extr	Confirm report
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MEI	Delete report
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforationMEI	Set MEI	View patient
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension		Set MEI	Download summary
						NOTSET	⋮

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

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

Delete Report

Please note, You are about to change the status of this activity. This action is not reversible

Current status
UNCONFIRMED

New status
DELETED

Comments

Report is erroneous|

Maximum length 100

Save

Cancel

The system will update the status of the report accordingly.

Active Reports

Active Work

Search by date

Search by term

Please select an activity below...

New reports 13

Confirm Report Data 3

Set MedDRA and Causality 3

Extract E2B 9

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-14 07:23:45 PM	11/2020/00055	Unique PatientNine		Acute duodenal ulcer		Confirm Report Data DELETED	:
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BINITIATED	:
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Extract E2B E2BINITIATED	:



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 shows the 'Active Reports' section of the PViMS interface. At the top, there are search filters: 'Active Work', 'Search by date', and 'Search by term'. Below these, a message says 'Please select an activity below...'. There are four buttons: 'New reports' (13), 'Confirm Report Data' (3, highlighted in blue), 'Set MedDRA and Causality' (3), and 'Extract E2B' (9). The main table lists three reports. The first report is for 'Unique PatientOne' on 2020-06-05 at 11:55:16 AM, with 'Dizziness exertional' as the adverse event and 'MedDra term' as 'UNCONFIRMED'. The second report is for 'Unique PatientOne' on 2020-06-04 at 10:45:39 AM, with 'Neurogenic hypertension' as the adverse event and 'Status' as 'UNCONFIRMED'. The third report is for 'Unique PatientOne' on 2020-06-04 at 09:59:30 AM, also with 'Neurogenic hypertension' and 'Status' as 'UNCONFIRMED'. A context menu is open over the second report, listing actions: 'Confirm Report Data | UNCONFIRMED', 'View activity history', 'Confirm report' (highlighted in yellow), 'Delete report', 'View patient', and 'Download summary'.

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Confirm Report Data UNCONFIRMED	⋮
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne	View	Neurogenic hypertension		Confirm Report Data UNCONFIRMED	⋮
2020-06-04 09:59:30 AM	11/2020/00042	Unique PatientOne		Neurogenic hypertension		Confirm Report Data UNCONFIRMED	⋮

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

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

Confirm Report

Please note! You are about to change the status of this activity. This action is not reversible

Current status
UNCONFIRMED

New status
CONFIRMED

Comments
Happy with the quality of the report

Maximum length 100

Save

Cancel

The system will update the status of the report accordingly.

Active Reports

Active Work

Search by date

Search by term

Please select an activity below...

New reports 13

Confirm Report Data 2

Set MedDRA and Causality 4

Extract E2B 9

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality MEDDRASET	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set MedDRA and Causality MEDDRASET	⋮
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension		Set MedDRA and Causality NOTSET	⋮
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Set MedDRA and Causality NOTSET	⋮



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.

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality MEDDRASET	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set MedDRA and Causality MEDDRASET	⋮
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension		Set MedDRA and Causality NOTSET	⋮
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Set Me NOTSET	<ul style="list-style-type: none">⌚ View activity history▶ Set terminology (highlighted)👤 View patient☁ Download summary

The system will pop up a **MedDRA Terminology** form.

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

Set Terminology

Event description (As stated by patient or reporter)
Accelerated hypertension

MedDRA terms can be searched in the following ways:

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

5.6.1.1 Search by MedDRA Term

Set Terminology

Event description (As stated by patient or reporter)
Accelerated hypertension

Select an option below, enter a term and then click on the magnifying class to search for a MedDRA term

Search option*
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.

Set Terminology

Event description (As stated by patient or reporter)
Accelerated hypertension

Select an option below, enter a term and then click on the magnifying class to search for a MedDRA term

Search option *

MedDRA term

Term type

Lowest Level Term

Find by term

headache

Maximum length 100



Description

Actions

Band-like headache



Cervicogenic headache



Chronic headaches



Cluster headache



Cluster headaches



Items per page: 5 1 - 5 of 60



Cancel

Click the **Select** icon next to the term you would like to assign or click the **Cancel** 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 by MedDRA Code

Set Terminology

Event description (As stated by patient or reporter)
Accelerated hypertension

Select an option below, enter a code and then click on the magnifying class to search for a MedDRA term

Search option
MedDRA code

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.

Set Terminology

Event description (As stated by patient or reporter)
Accelerated hypertension

Select an option below, enter a code and then click on the magnifying class to search for a MedDRA term

Search option *

MedDRA code

Find by code

9999

Maximum length 10



Description	Actions
Alkaline reserve normal	>
Colonic neoplasm NOS	>
Herpetic meningoencephalitis	>
Intoxication by breast feeding	>
Intoxication by breast feeding	>

Items per page: 5 1 - 5 of 9



Cancel

Click the **Select** icon next to the term you would like to assign or click the **Cancel** 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 for MedDRA Term by List

Set Terminology

Event description (As stated by patient or reporter)
Accelerated hypertension

Select an option below, then use the filters to set your class and then click on the magnifying class to search for the MedDRA term

Search option *
MedDRA list

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.

Set Terminology

Event description (As stated by patient or reporter)
Accelerated hypertension

Select an option below, then use the filters to set your class and then click on the magnifying class to search for the MedDRA term

Search option *
MedDRA list

Find the System Organ Class (SOC)

Blood and lymphatic system disorders	Actions
Cardiac disorders	>
Congenital, familial and genetic disorders	>
Ear and labyrinth disorders	>
Endocrine disorders	>

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

Set Terminology

Event description (As stated by patient or reporter)
Accelerated hypertension

Select an option below, then use the filters to set your class and then click on the magnifying glass to search for the MedDRA term

Search option *

MedDRA list

Find by System Organ Class (SOC)

Hepatobiliary disorders

Find by High Level Group Term (HLGT)

Bile duct disorders

Find by High Level Term (HLT)

Bile duct infections and inflammations

Find by Preferred Term (PT)

Cholangitis acute

Description

Actions

Cholangitis acute



Cholangitis acute NOS



Items per page: 5 1 - 2 of 2



Cancel

Click the **Select** icon next to the term you would like to assign or click the **Cancel** 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.

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension	Benign essential hypertension	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Set MedDRA and Causality NOTSET	⋮

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

Active Work Search by date Search by term

Please select an activity below...

New reports 13 Confirm Report Data 1 Set MedDRA and Causality 3 Extract E2B 5

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedD MEDDRA
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	WHO causality
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension	Benign essential hypertension	Naranjo causality
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		✓ Confirm causality set
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne	View	Neurogenic hypertension	Neurogenic hypertension	Set MedD NOTSET

Items per page: 10 1 - 5 of 5

The system will open up the **WHO Causality Assessment** pop up form.

The **WHO Causality Assessment** form displays the adverse event as reported by the clinician and/or reporter and the MedDRA Terminology that has been set for the event.

WHO Causality

Additional Information Legend Medications

Event description (As stated by patient or reporter)
Neurogenic hypertension

Terminology set by specialist
Neurogenic hypertension

The **WHO Causality Assessment** form 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

WHO Causality

Additional Information	Legend	Medications		
Medication	Start date	End date	Causality	Actions
Abacavir 300mg (Bottle) (ABACAVIR); 120 ug			Unlikely	> 

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** icon. The system will assign **Ignored** as the causality term.

WHO Causality

Additional Information	Legend	Medications		
Medication	Start date	End date	Causality	Actions
Abacavir 300mg (Bottle) (ABACAVIR); 120 ug			IGNORED	> 

5.6.2.2 Set Causality

WHO Causality

Additional Information	Legend	Medications		
Medication	Start date	End date	Causality	Actions
Abacavir 300mg (Bottle) (ABACAVIR); 120 ug			IGNORED	> 

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

WHO Causality

[Additional Information](#)[Legend](#)[Medications](#)[WHO Scale](#)

Setting causality for : Abacavir 300mg (Bottle) (ABACAVIR); 120 ug

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

[Additional Information](#)[Legend](#)[Medications](#)[WHO Scale](#)

Setting causality for : Abacavir 300mg (Bottle) (ABACAVIR); 120 ug

Certain



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 ▾

Click the **Set causality icon** next to the causality assessment and the system will assign the term as **Certain** in the system.

Click the **Close** button at any time to undo the action and return to the list reports.

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[Additional Information](#)[Legend](#)[Medications](#)[WHO Scale](#)**Setting causality for : Abacavir 300mg (Bottle) (ABACAVIR); 120 ug****← Probable/Likely**

6. Event or laboratory test abnormality, with plausible time relationship to drug intake

7. Unlikely to be attributed to disease or other drugs

8. Response to withdrawal clinically reasonable

9. Rechallenge not required

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.

WHO Causality[Additional Information](#)[Legend](#)[Medications](#)[WHO Scale](#)**Setting causality for : Abacavir 300mg (Bottle) (ABACAVIR); 120 ug****← Unassessable/Unclassified**

17. Report suggesting an adverse reaction cannot be judged because information is insufficient or contradictory

No

18. Data cannot be supplemented or verified

No

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'

Once the term has been assigned click the **Close** button to continue.

WHO Causality

Additional Information	Legend	Medications		
Medication	Start date	End date	Causality	Actions
Abacavir 300mg (Bottle) (ABACAVIR); 120 ug			Unassessable	>

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

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality MEDDRASET	
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set MedDRA and Causality MEDDRASET	
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension	Benign essential hypertension	Set MedDRA and Causality MEDDRASET	
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Set MedDRA and Causality NOTSET	

Items per page: 10 1 - 4 of 4

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.

The screenshot shows the PViMS 'Active Reports' page. At the top, there are tabs for 'Active Work', 'Search by date', and 'Search by term'. Below these are buttons for 'New reports' (13), 'Confirm Report Data' (1), 'Set MedDRA and Causality' (5), and 'Extract E2B' (9). A message 'Please select an activity below...' is displayed. The main area lists six adverse events with columns for 'Created', 'Identifier', 'Patient', 'Medications', 'Adverse event', 'MedDra term', and 'Status'. The 'Status' column for the first event shows 'Set Me MEDD'. To the right of the table, a context menu is open, listing options: 'View activity history', 'Set terminology', 'WHO causality', 'Naranjo causality' (which is highlighted with a yellow background), 'Confirm causality set', 'View patient', and 'Download summary'. The 'Naranjo causality' option has a checkmark next to it.

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set Me MEDD
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set Me MEDD
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension	Benign essential hypertension	Set Me MEDD
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Set Me NOTSt
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne	View	Neurogenic hypertension	Neurogenic hypertension	Set Me MEDDRASET

The system will open up the **Naranjo Causality Assessment** pop up form.

The **Naranjo Causality Assessment** form displays the adverse event as reported by the clinician and/or reporter and the MedDRA Terminology set.

Naranjo Causality

The screenshot shows the 'Naranjo Causality' assessment form. At the top, there are three tabs: 'Additional Information' (which is selected and highlighted in blue), 'Legend', and 'Medications'. Below the tabs, under 'Additional Information', there is a section for 'Event description (As stated by patient or reporter)' containing the text 'Neurogenic hypertension'. Further down, under 'Terminology set by specialist', there is also the text 'Neurogenic hypertension'.

The **Naranjo Causality Assessment** form 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

Naranjo Causality

Additional Information	Legend	Medications		
Medication	Start date	End date	Causality	Actions
Abacavir 300mg (Bottle) (ABACAVIR); 120 ug	2020-06-01		Possible	> 

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** icon. The system will assign **Ignored** as the causality term.

Naranjo Causality

Additional Information	Legend	Medications		
Medication	Start date	End date	Causality	Actions
Abacavir 300mg (Bottle) (ABACAVIR); 120 ug	2020-06-01		IGNORED	> 

5.6.3.2 Set Causality

Naranjo Causality

Additional Information	Legend	Medications			
Medication		Start date	End date	Causality	Actions
Abacavir 300mg (Bottle) (ABACAVIR); 120 ug		2020-06-01		IGNORED	 

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

Naranjo Causality

Additional Information	Legend	Medications	Naranjo Scale
Setting causality for : Abacavir 300mg (Bottle) (ABACAVIR); 120 ug			

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, the system will automatically calculate the causality assessment.

Naranjo Causality

Additional Information	Legend	Medications	Naranjo Scale
Setting causality for : Abacavir 300mg (Bottle) (ABACAVIR); 120 ug			Probable ➤
1. Are there previous conclusive reports on this reaction?	Yes	2. Did the adverse event appear after the suspected drug was administered?	Yes
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	Yes	4. Did the adverse reaction reappear when the drug was readministered?	No
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	Do not know	6. Did the reaction reappear when a placebo was given?	Yes
7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	No	8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	No
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	No	10. Was the adverse event confirmed by any objective evidence?	Yes

Click the **Set causality icon** next to the causality assessment and the system will assign the term as per the calculation in the system.

Click the **Close** button at any time to undo the action and return to the list reports.

Naranjo Causality

Additional Information	Legend			
Medication	Start date	End date	Causality	Actions
Abacavir 300mg (Bottle) (ABACAVIR); 120 ug	2020-06-01		Probable ➤ ✖	

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.

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension	Benign essential hypertension	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Set MedDRA and Causality NOTSET	⋮
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne			Neurogenic hypertension	Set MedDRA and Causality MEDDRASSET	⋮

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

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-10 05:59:53 PM	11/2020/00045	Unique PatientSix		Accelerated hypertension	Benign essential hypertension	Set MedDRA and Causality MEDDRASSET	⋮
2020-06-05 11:55:16 AM	11/2020/00044	Unique PatientOne		Dizziness exertional		Set MedDRA and Causality NOTSET	⋮
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne			Neurogenic hypertension	Set MedDRA and Causality MEDDRASSET	⋮

The system will navigate you to the **Confirm Causality Set** form.

Specify any comment if necessary and click **Save** to confirm the setting of the causality or **Cancel** to cancel the action and return to the previous page.

Confirm Causality Set

Please note! You are about to change the status of this activity. This action is not reversible

Current status
MEDDRASET

New status
CAUSALITYSET

Comments

Maximum length 100

Save

Cancel

The system will update the status of the report accordingly. Please note the report will now be located in the Extract E2B tab.

Active Reports

Active Work

Search by date

Search by term

Please select an activity below...

New reports 13

Confirm Report Data 1

Set MedDRA and Causality 4

Extract E2B 10

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BINITIATED	⋮
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Extract E2B E2BINITIATED	⋮
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne	View	Neurogenic hypertension	Neurogenic hypertension	Extract E2B NOTGENERATED	⋮

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 ICSR 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. This menu item is only available for forms that are in the Extract E2B | NOTGENERATED stage.

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

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BINITIATED	⋮
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Extract E2B E2BINITIATED	⋮
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne	View	Neurogenic hypertension	Neurogenic hypertension	Extract E2B NOTGENERATED	⋮
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	View	Accelerated hypertension	Nephrotoxicity	Extract E2B	⋮
2020-05-21 12:00:00 AM	11/2018/00027	Unique PatientTwo	View	Dizziness	Abdominal pain NOS	Extract E2B	⋮
2018-08-09 05:44:15 PM	11/2018/00034	Unique PatientTwentyFour		Cluster headaches	Headache NOS	Extract E2B	⋮
2018-02-23 02:29:47 PM	11/2018/00031	Unique PatientOne	View	Dizziness	Dizziness	Extract E2B	⋮
2017-12-30 07:37:52 AM	11/2017/00025	Unique PatientEleven		Benign essential hypertension comp preg, childbirth, and the puerperium, Allergic reaction (NOS) unspec as to eoc		Extract E2B E2BINITIATED	⋮

Please select an activity below...

[New reports](#) (13) [Confirm Report Data](#) (1) [Set MedDRA and Causality](#) (4) [Extract E2B](#) (10)

[View activity history](#) [Create E2B](#) [View patient](#) [Download summary](#)

Once the system has created the E2B dataset, the status of the report will be updated to E2BINITIATED to indicate the dataset has been created.

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BINITIATED	⋮
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Extract E2B E2BINITIATED	⋮
2020-06-04 10:45:39 AM	11/2020/00043	Unique PatientOne	View	Neurogenic hypertension	Neurogenic hypertension	Extract E2B E2BINITIATED	⋮

The E2B dataset is constructed with the following sections (these sections are based on R2 of the E2B ICH definition):

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

ICH E2B: Please see the electronic Transmission of Individual Case Safety Reports Message Specification for detail specifications on the above categories. This specification can be found on https://admin.ich.org/sites/default/files/inline-files/ICH_ICSR_Specification_V2-3.pdf

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.

Active Reports

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BINITIATED	⋮
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	View activity history	
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Update E2B	
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Prepare report for E2B submiss...	
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	View	Accelerated hypertension	Nephrotoxicity	View patient	
2020-05-21 12:00:00 AM	11/2018/00027	Unique PatientTwo	View	Dizziness	Abdominal pain NOS	Download summary	

The system will pop up a **E2B ICH Report** form for the file.

Update E2B

Message Header	Safety Report	Primary Source	Sender	Receiver
Message Type ICHICSR		Message Format Version 2.1		
Message Format Release 1.0		Message Number 00000837		
Message Sender Identifier FDA		Message Receiver Identifier UMC		
Message Date Format 204		Message Date 20190201120000		

Save **Cancel**

Once you completed making amendments, click on the **Save** button to save the changes or the **Cancel** 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.

Active Reports

The screenshot shows the 'Active Reports' section of the PViMS interface. At the top, there are three search/filter options: 'Active Work' (selected), 'Search by date', and 'Search by term'. Below these is a message: 'Please select an activity below...'. A horizontal row of buttons includes 'New reports' (2), 'Confirm Report Data' (2), 'Set MedDRA and Causality' (2), and 'Extract E2B' (10). The main area displays a table of patient records:

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BINITIATED	⋮
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension		View activity history
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency		Update E2B
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation		Prepare report for E2B submiss...
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	View	Accelerated hypertension	Nephrotoxicity		View patient
2020-05-21 12:00:00 AM	11/2018/00027	Unique PatientTwo	View	Dizziness	Abdominal pain NOS		Download summary

A context menu is open over the fourth row (PatientFive). The menu items are: 'View activity history', 'Update E2B', 'Prepare report for E2B submiss...', 'View patient', and 'Download summary'. The 'Prepare report for E2B submiss...' option is highlighted with a yellow background.

The system will navigate you to the **Prepare report for E2B submission** pop up form.

Specify any additional comments for preparing the record and click **Save** to confirm the preparation or **Cancel** to cancel the action and return to the previous page.

Prepare report for E2B submission

Please note! You are about to change the status of this activity. This action is not reversible

Current status E2BINITIATED	New status E2BGENERATED
--------------------------------	----------------------------

Comments
Maximum length 100

Save **Cancel**

The system will update the status of the report accordingly.

Active Reports							
Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BGENERATED	:
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Extract E2B E2BINITIATED	:



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

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BGENERATED	⋮
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Ex	View activity history
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Ex	Confirm E2B submission
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Ex	Download XML
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	View	Accelerated hypertension	Nephrotoxicity	Ex	View patient
2020-05-21 12:00:00 AM	11/2018/00027	Unique PatientTwo	View	Dizziness	Abdominal pain NOS	Ex	Download summary
2018-08-09 05:44:15 PM	11/2018/00034	Unique PatientTwentyFour		Cluster headaches	Headache NOS	Extract E2B NOTGENERATED	⋮

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.

Activity	Execution event	Executed date	Comments	Receipt date	Receipt code	Actions
Confirm Report Data	UNCONFIRMED	2020-06-12 11:08				⋮
Confirm Report Data	CONFIRMED	2020-06-12 11:40				⋮
Set MedDRA and Causality	NOTSET	2020-06-12 11:40				⋮
Set MedDRA and Causality	MEDDRASET	2020-06-12 11:47	AUTOMATION: MedDRA Term set			⋮
Set MedDRA and Causality	CAUSALITYSET	2020-06-12 12:12				⋮
Extract E2B	NOTGENERATED	2020-06-12 12:12				⋮
Extract E2B	E2BINITIATED	2020-06-12 12:13	AUTOMATION: E2B dataset created			⋮
Extract E2B	E2BGENERATED	2020-09-08 11:21				⋮

Locate the **E2BGENERATED** execution event for the report, click the menu for that event, and select the **Download E2B File** menu.

Activity	Execution event	Executed date	Comments	Receipt date	Receipt code	Actions
Confirm Report Data	UNCONFIRMED	2020-06-12 11:08				
Confirm Report Data	CONFIRMED	2020-06-12 11:40				
Set MedDRA and Causality	NOTSET	2020-06-12 11:40				
Set MedDRA and Causality	MEDDRASET	2020-06-12 11:47	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	2020-06-12 12:12				
Extract E2B	NOTGENERATED	2020-06-12 12:12				
Extract E2B	E2BINITIATED	2020-06-12 12:13	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	2020-09-08 11:21				

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.

Active Reports

Active Work													
		Search by date		Search by term									
Please select an activity below...													
New reports 2 Confirm Report Data 2 Set MedDRA and Causality 2 Extract E2B 10													
Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions						
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BGENERATED	View activity history						
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Ex	View activity history						
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Ex	View activity history						
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Ex	View activity history						
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	View	Accelerated hypertension	Nephrotoxicity	Ex	View activity history						
2020-05-21 12:00:00 AM	11/2018/00027	Unique PatientTwo	View	Dizziness	Abdominal pain NOS	Ex	View activity history						
2018-08-09 05:44:15 PM	11/2018/00034	Unique PatientTwentyFour		Cluster headaches	Headache NOS	Extract E2B NOTGENERATED	View activity history						

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						
Event description (As stated by patient or reporter) Acute duodenal ulcer with haemorrhage						
Activity	Execution event	Executed date	Comments	Receipt date	Receipt code	Actions
Confirm Report Data	UNCONFIRMED	2020-06-12 11:08				
Confirm Report Data	CONFIRMED	2020-06-12 11:40				
Set MedDRA and Causality	NOTSET	2020-06-12 11:40				
Set MedDRA and Causality	MEDDRASET	2020-06-12 11:47	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	2020-06-12 12:12				
Extract E2B	NOTGENERATED	2020-06-12 12:12				
Extract E2B	E2BINITIATED	2020-06-12 12:13	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	2020-09-08 11:21				

Locate the **E2BGENERATED** execution event for the report, click the action menu, and select the **Download summary** or **Download extract** menu.

Activity	Execution event	Executed date	Comments	Receipt date	Receipt code	Actions
Confirm Report Data	UNCONFIRMED	2020-06-12 11:08				
Confirm Report Data	CONFIRMED	2020-06-12 11:40				
Set MedDRA and Causality	NOTSET	2020-06-12 11:40				
Set MedDRA and Causality	MEDDRASSET	2020-06-12 11:47	AUTOMATION: MedDRA Term set			
Set MedDRA and Causality	CAUSALITYSET	2020-06-12 12:12				
Extract E2B	NOTGENERATED	2020-06-12 12:12				
Extract E2B	E2BINITIATED	2020-06-12 12:13	AUTOMATION: E2B dataset created			
Extract E2B	E2BGENERATED	2020-09-08 11:21				

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

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

AuditUser	Patient	SourceTerminologyMedDra	C	PatientClinicalEventGuid	SourceDescription	OnsetDate	ResolutionDate	Archived	ArchivedDate	ArchivedReason	AgeGroup
1	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Dizziness		f94d1d55-1cb4-4f43-962a-3639aaed12b6f	Dizziness	2016-09-03		False		Child > 4 year	
2	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Bruising		2a5a628a-3ccb-4399-6537-07512631d65f	Bruises easily	2017-06-13		False		Child > 4 year	
3	8ee3d4b4-faba-45dd-9d34-1ce73715507c			f89c38c0-9992-45b4-8549-45294928ea39	Dizziness	2017-12-19		False		Child > 4 year	
4	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Benign essential hypertension antepartum		e1fc8dc4-3231-4c29-80e1-ac82cf1ffef0	Dizziness	2017-12-19		False		Child > 4 year	
5	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Dizziness exertional		d0bb3068-0007-465a-8cc5-f31b81fe34b6	hy	2017-12-19		False		Child > 4 year	
6	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Benign essential hypertension complicating pregnancy, childbirth, and the puerperium, unspecified as		fda33e20-ad05-4f54-997b-1c25cd9bf4f	h	2017-12-19		False		Child > 4 year	
7	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Benign essential hypertension with delivery		aaf951a6-8f12-4c5b-8025-158000cf0a6	sd	2017-12-19		False		Child > 4 year	
8	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Benign essential hypertension, postpartum		b7500972-e0c7-456-82a-3e28bf6b6a	Hypertensiondd	2017-12-19		False		Child > 4 year	
9	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Other benign secondary hypertension		dc2d21130934-4fb-e9ea-32eb2b7035b6	dfsf	2017-12-19		False		Child > 4 year	
10	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Hypertension not adequately controlled		c6564645-2dd1-4219-867-9a73ebc9402f	Hypertension	2017-12-20		False		Child > 4 year	
11	8ee3d4b4-faba-45dd-9d34-1ce73715507c	White coat hypertension		dfae0c72-fdb7-4099-8159-94016cbe5128	sd	2017-12-04		False		Child > 4 year	
12	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Unspecified renovascular hypertension		4590ad52-b9e5-4a8e-b784-b6a4733ad8bd	d	2017-12-19		False		Child > 4 year	
13	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Hypertension portal		e4467ee-26a5-405a-aaf0-c0e6275ceab0	sdsd	2017-12-27		False		Child > 4 year	
14	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Hypertension worsened		b806842-056a-4052-8abe-775ba97c7169	Patent is very dizzy	2018-07-09		False		Child > 4 year	
15	8ee3d4b4-faba-45dd-9d34-1ce73715507c	Vertigo (excl dizziness)									



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

Active Work Search by date Search by term

Please select an activity below...

New reports (2) Confirm Report Data (2) Set MedDRA and Causality (2) Extract E2B (10)

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BGENERATED	View activity history
2020-06-12 10:31:08 AM	11/2020/00048	Unique PatientTwo		Benign essential hypertension	Benign essential hypertension	Extract E2B	Confirm E2B submission
2020-06-10 06:47:56 PM	11/2020/00047	Unique PatientNine		Dizziness aggravated	Anaemia folate deficiency	Extract E2B	Download XML
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B	View patient
2020-05-21 12:00:00 AM	11/2017/00026	Unique PatientTen	View	Accelerated hypertension	Nephrotoxicity	Extract E2B	Download summary
2020-05-21 12:00:00 AM	11/2018/00027	Unique PatientTwo	View	Dizziness	Abdominal pain NOS	Extract E2B	
2018-08-09 05:44:15 PM	11/2018/00034	Unique PatientTwentyFour		Cluster headaches	Headache NOS	Extract E2B NOTGENERATED	

The system will navigate you to the **Confirm E2B Submission** pop up form.

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

Confirm E2B submission

Please note! You are about to change the status of this activity. This action is not reversible

Current status
E2BGENERATED

New status
E2BSUBMITTED

Comments
Report is ready for submission

Maximum length 100

Receipt date
5/13/2020 

Receipt code
DCF-06212

Maximum length 20

 Save Cancel

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. Please note that the report is removed from the Extract E2B tab as work for this report is now classified as finished. Use the **Search by date** or **Search by term** tabs to locate this report again.

Active Reports

The screenshot shows the 'Active Reports' section of the PViMS User Manual. At the top, there are three tabs: 'Active Work' (disabled), 'Search by date', and 'Search by term'. Below the tabs is a search input field with placeholder text: 'Please enter a term below to search by patient name, MedDra term as set by the clinician, the MedDra term as set by the PV specialist, the report identifier or medications used in the analysis...'. The search input field contains the term 'duo'. To the right of the input field is a 'Search' button. Below the search bar is a table with the following columns: Created, Identifier, Patient, Medications, Adverse event, MedDra term, Status, and Actions. There are three rows of data:

Created	Identifier	Patient	Medications	Adverse event	MedDra term	Status	Actions
2020-06-14 07:23:45 PM	11/2020/00055	Unique PatientNine		Acute duodenal ulcer		Confirm Report Data DELETED	⋮
2020-06-12 11:08:46 AM	11/2020/00054	Unique PatientTwo	View	Acute duodenal ulcer with haemorrhage	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B E2BSUBMITTED	⋮
2020-06-10 06:46:04 PM	11/2020/00046	Unique PatientFive		Dizziness aggravated	Acute duodenal ulcer with haemorrhage and perforation	Extract E2B NOTGENERATED	⋮

At the bottom right of the table area, there are buttons for 'Items per page: 10' (with a dropdown arrow), '1 - 3 of 3', and navigation arrows.

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

6.8.1 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

$$\text{IR} = (\text{ADR} / \text{Population}) * 1000$$

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.

$$\text{RR} = \text{IR}_1 / \text{IR}_2$$

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

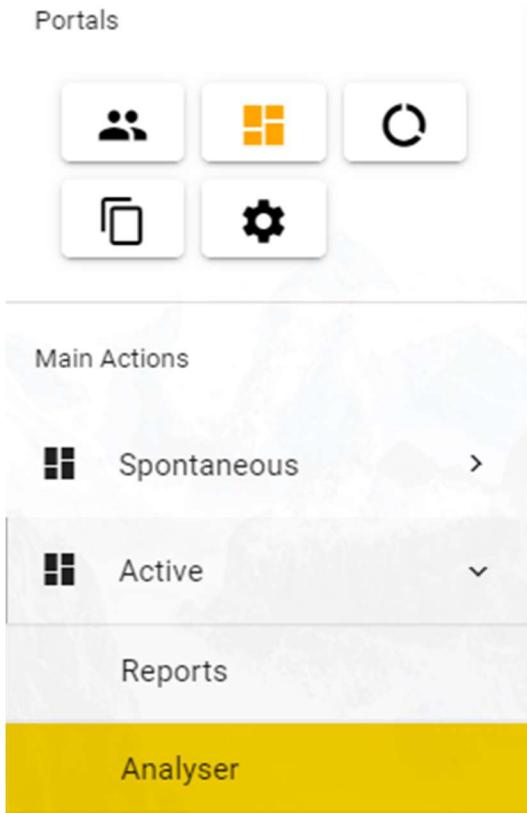
z_α is the standard score for the chosen level of significance and SE the standard error.

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:

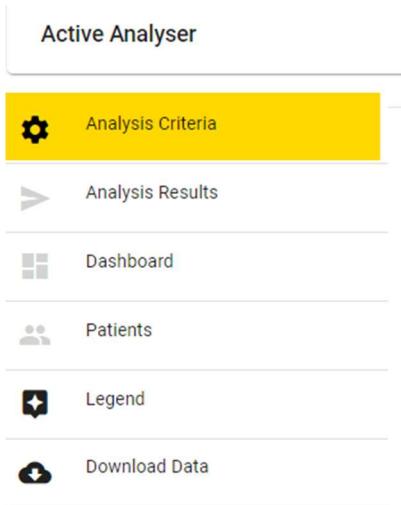
- The population target (condition group or Cohort)
- The date range for the analysis

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



5.8.2.1 Specifying the Population Group

Ensure the **Analysis Criteria** tab is selected to allow the selection of the patient population.



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

Primary condition group risk factor -- OR Cohort

Analyse

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.

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

TB
HIV
Malaria

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.

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

9MTR Study
BDQ Study
9MTR Program Condition
18MTR Program Condition
XDRTB Program Condition

Analyse

5.8.2.2 Specifying the Date Range for the Analysis

Patient Population Date Range Risk Factors

Search from * 9/8/2019

Search to * 9/8/2020

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.

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

Analyse

The system will conduct an initial analysis that will identify what Adverse Drug Reactions have been identified over the reporting period. All results are included in the **Analysis Results** tab. Please note that only adverse drug reactions where a MedDRA term has been selected by the PV technician will be selected.

Select an adverse drug reaction below to view signals for that reaction
PLEASE NOTE: Exposed Cases ONLY include cases where the Adverse Drug Reaction falls within the start and end date of the medication

Abdominal pain NOS Accelerated hypertension Fine motor delay Reset criteria

Exposed incidence rate Non exposed incidence rate Relative risk

Medication Cases Non cases Population Incidence rate

Select the **Adverse Drug Reaction** that you would like to detect signals for by clicking on the tab for that reaction. The selected tab will turn a dark blue to signify that it has been selected.

Select an adverse drug reaction below to view signals for that reaction
PLEASE NOTE: Exposed Cases ONLY include cases where the Adverse Drug Reaction falls within the start and end date of the medication

Abdominal pain NOS Accelerated hypertension Fine motor delay Reset criteria

Exposed incidence rate Non exposed incidence rate Relative risk

Please note that selecting the Adverse Drug Reaction will enable the Dashboard and Patients tab.

Active Analyser

 Analysis Criteria

 Analysis Results

 Dashboard

 Patients

 Legend

 Download Data

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

Exposed incidence rate		Non exposed incidence rate	Relative risk	
Medication	Cases	Non cases	Population	Incidence rate
abacavir 100mg/ml	0	1	0.21	0.00
cefixime 200mg	0	4	-3.04	0.00
diazepam 5mg/ml	0	4	-3.04	0.00
enalapril 20mg	0	1	-3.07	0.00
ibuprofen 200mg	0	3	-4.04	0.00

- Incidence Rate for non-exposed group

Exposed incidence rate		Non exposed incidence rate	Relative risk	
Medication	Cases	Non cases	Population	Incidence rate
abacavir 100mg/ml	0	8	-13.19	0.00
cefixime 200mg	0	5	-9.94	0.00
diazepam 5mg/ml	0	5	-9.94	0.00
enalapril 20mg	0	8	-9.91	0.00
ibuprofen 200mg	0	6	-8.94	0.00

- Relative Risk for the associated medication
- 95% Confidence Interval for the associated medication

Exposed incidence rate	Non exposed incidence rate	Relative risk	
Medication	Unadjusted relative risk	Adjusted relative risk	Confidence interval 95%
abacavir 100mg/ml	0.00	0.00	0.00 ~ 0.00
cefixime 200mg	0.00	0.00	0.00 ~ 0.00
diazepam 5mg/ml	0.00	0.00	0.00 ~ 0.00
enalapril 20mg	0.00	0.00	0.00 ~ 0.00
ibuprofen 200mg	0.00	0.00	0.00 ~ 0.00

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 **Patients** tab.

Patient name	Medication	Days contributed	Reaction	Risk factor	Criteria	Criteria met
Unique PatientEight	enalapril 20mg	-1120	No			
Unique PatientEighteen	cefixime 200mg	-921	No			
Unique PatientEighteen	ibuprofen 200mg	-921	No			
Unique PatientEleven	abacavir 100mg/ml	76	No			
Unique PatientNineteen	diazepam 5mg/ml	-921	No			
Unique PatientOne	cefixime 200mg	366	No			
Unique PatientOne	diazepam 5mg/ml	366	No			
Unique PatientSeventeen	diazepam 5mg/ml	-921	No			
Unique PatientThree	cefixime 200mg	366	No			
Unique PatientThree	ibuprofen 200mg	366	No			

The columns in the patient list table are described below:

Patient name	The name of the patient contributing to the patient population
Medication	The drug the patient was exposed to during the period of analysis
Days contributed	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

5.8.2.5 Resetting Criteria

If at any point you would like to alter the patient population or date range, click the **Reset criteria** tab alongside the list of Adverse Drug Reactions to reset analysis. Selecting this tab will remove existing analysis and reopen the Analysis Criteria tab for modification.

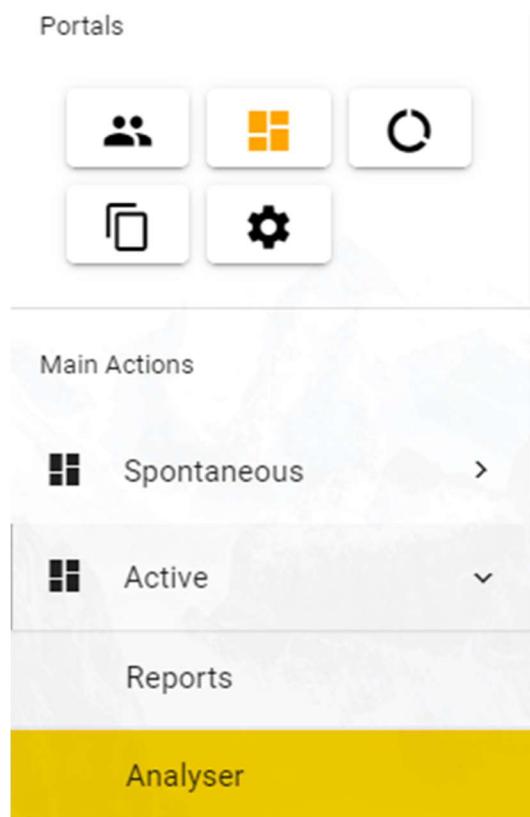


5.8.3 Generating Adjusted Relative Risk Ratios

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

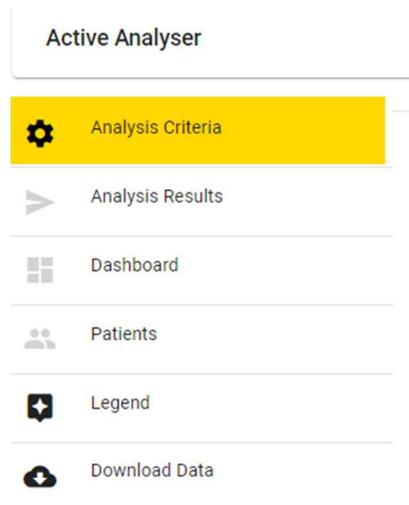
- The population target (condition group or Cohort)
- The date range for the analysis
- The risk factors to be applied

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



5.8.3.1 Specifying the Population Group

Ensure the **Analysis Criteria** tab is selected to allow the selection of the patient population.



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

Primary condition group risk factor -- OR Cohort

Analyse

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.

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

TB
HIV
Malaria

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.

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

9MTR Study
BDQ Study
9MTR Program Condition
18MTR Program Condition
XDRTB Program Condition

Analyse

5.8.3.2 Specifying the Date Range for the Analysis

Patient Population Date Range Risk Factors

Search from * 9/8/2019

Search to * 9/8/2020

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

Risk factor

Factor	Option	Actions
Gender	Is Male	

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** icon to add the risk factor to the selected list.

Patient Population Date Range Risk Factors

Risk factor

Factor	Option	Actions
Gender	Is Male	

Analyse

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

Patient Population Date Range Risk Factors

Risk factor
Age Group

Option
Adolescent (11 to 16 years)

+ (yellow button)

Factor	Option	Actions
Gender	Is Male	trash icon
Age Group	Adolescent (11 to 16 years)	trash icon

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.

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

-- OR --

Cohort

Analyse

The system will conduct an initial analysis that will identify what Adverse Drug Reactions have been identified over the reporting period. All results are included in the **Analysis Results** tab. Please note that only adverse drug reactions where a MedDRA term has been selected by the PV technician will be selected.

Select an adverse drug reaction below to view signals for that reaction
PLEASE NOTE: Exposed Cases ONLY include cases where the Adverse Drug Reaction falls within the start and end date of the medication

Abdominal pain NOS Accelerated hypertension Fine motor delay Reset criteria

Exposed incidence rate Non exposed incidence rate Relative risk

Medication Cases Non cases Population Incidence rate

Select the **Adverse Drug Reaction** that you would like to detect signals for by clicking on the tab for that reaction. The selected tab will turn a dark blue to signify that it has been selected.

Select an adverse drug reaction below to view signals for that reaction
PLEASE NOTE: Exposed Cases ONLY include cases where the Adverse Drug Reaction falls within the start and end date of the medication

Abdominal pain NOS Accelerated hypertension Fine motor delay Reset criteria

Exposed incidence rate Non exposed incidence rate Relative risk

Please note that selecting the Adverse Drug Reaction will enable the Dashboard and Patients tab.

Active Analyser



Analysis Criteria



Analysis Results



Dashboard



Patients



Legend



Download Data

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

Exposed incidence rate	Non exposed incidence rate	Relative risk		
Medication	Cases	Non cases	Population	Incidence rate
abacavir 100mg/ml	0	1	0.21	0.00
aciclovir 200mg	0	2	0.32	0.00
aciclovir 400mg	0	7	1.62	0.00
cefixime 200mg	0	4	7.14	0.00
ceftriaxone 10gm/vial	0	5	1.12	0.00
diazepam 5mg/ml	1	3	8.56	250.00
enalapril 20mg	0	2	0.32	0.00
ibuprofen 200mg	0	3	5.75	0.00
metformin 500mg/5ml	0	4	1.82	0.00
metronidazole 1%	0	3	1.21	0.00
paracetamol 500mg	0	5	0.26	0.00
prednisone 1mg	0	3	0.38	0.00

- Incidence Rate for non-exposed group

Abdominal pain NOS Accelerated hypertension Fine motor delay Reset criteria

Exposed incidence rate	Non exposed incidence rate	Relative risk		
Medication	Cases	Non cases	Population	Incidence rate
abacavir 100mg/ml	1	21	33.42	45.45
aciclovir 200mg	1	20	33.30	47.62
aciclovir 400mg	0	16	32.01	0.00
cefixime 200mg	1	18	26.49	52.63
ceftriaxone 10gm/vial	0	18	32.51	0.00
diazepam 5mg/ml	0	19	25.07	0.00
enalapril 20mg	1	20	33.30	47.62
ibuprofen 200mg	1	19	27.88	50.00
metformin 500mg/5ml	1	18	31.80	52.63
metronidazole 1%	1	19	32.42	50.00
paracetamol 500mg	1	17	33.37	55.56
prednisone 1mg	1	19	33.25	50.00

- Relative Risk for the associated medication
- 95% Confidence Interval for the associated medication

Exposed incidence rate	Non exposed incidence rate	Relative risk	
Medication	Unadjusted relative risk	Adjusted relative risk	Confidence interval 95%
abacavir 100mg/ml	0.00	0.00	0.00 ~ 0.00
aciclovir 200mg	0.00	0.00	0.00 ~ 0.00
aciclovir 400mg	0.00	0.00	0.00 ~ 0.00
cefixime 200mg	0.00	0.00	0.00 ~ 0.00
ceftriaxone 10gm/vial	0.00	0.00	0.00 ~ 0.00
diazepam 5mg/ml	0.00	0.00	0.00 ~ 0.00
enalapril 20mg	0.00	0.00	0.00 ~ 0.00
ibuprofen 200mg	0.00	0.00	0.00 ~ 0.00
metformin 500mg/5ml	0.00	0.00	0.00 ~ 0.00
metronidazole 1%	0.00	0.00	0.00 ~ 0.00
paracetamol 500mg	0.00	0.00	0.00 ~ 0.00
prednisone 1mg	0.00	0.00	0.00 ~ 0.00

5.8.4 Downloading a Dataset for Further Analysis

Select the **Download Data** tab and then click the **Download Dataset** button to able to download a comprehensive dataset of patient clinical data in XLSX format for importation into a third-party statistical tool.

The screenshot shows the 'Active Analyser' interface. On the left, there is a sidebar with the following items:

- Analysis Criteria
- Analysis Results
- Dashboard
- Patients
- Legend
- Download Data (highlighted with a yellow background)

The main area is titled 'Active Analyser' and contains the following text: 'For third party statistical analysis, to download patient related data, select a cohort and click on the action below.' Below this is a dropdown menu labeled 'Cohort' with the option 'All cohorts' selected. At the bottom right is a yellow button labeled '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
Quarterly Adverse Events	Number of patients with an adverse event by MedDRA system organ class per quarter and grade
Annual Adverse Events	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.

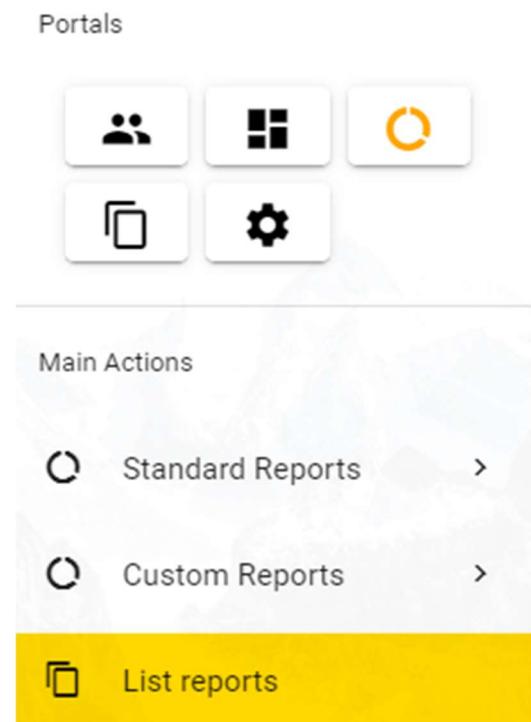
6.2.1 Types of Reports

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 **List Reports** menu.



Then click on the **Add Report** button so you can define the characteristics of the new report.



Reports				
Report name	Unique identifier	System	Report status	Actions
Adverse Events	28bf27d9-653d-4ae3-9376-1aa47d0bece6	Yes	Published	
Annual Adverse Events	74a659cd-0c78-40f3-8b11-9ee28d61bd69	Yes	Published	

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 status	Is the report to be published or unpublished. Published reports appear in the custom reports list in the reporting portal
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, first select the attributes menu option for the report you would like to customize.

Reports

[Add Report](#)

Report name	Unique identifier	System	Report status	Actions
Adverse Events	28bf27d9-653d-4ae3-9376-1aa47d0bece6	Yes	Published	
Annual Adverse Events	74a659cd-0c78-40f3-8b11-9ee28d61bd69	Yes	Published	
Causality	e20162d7-63b8-4476-8952-999f5329c550	Yes	Published	
Outstanding Visits	1b2521e3-b830-4c61-9d83-ab5aa2aa67bc	Yes	Published	
Patients by Drug	1626657b-e7d9-4eed-8455-aa4da40e0eb6	Yes	Published	
Patients on Treatment	2b8638ff-ece6-4325-a146-ec1bb7dc2f1f	Yes	Published	
Quarterly Adverse Events	461646eb-9291-4027-adac-9f18c1ead0b5	Yes	Published	
Test report	2ec3e491-8872-456d-b4a4-d968abba3a12	No	Published	

Select the attribute from the list, specify the name of column in the display field, the type of aggregation and click the **add** icon. The attribute will be added to the stratification list.

Set Attributes

Report name
Test report

Attributes represent columns within the customised report. Please select your attributes below

Attribute name *	Display name	Aggregate
IdentityType	Identity	COUNT
	Maximum length 50	

Attribute name	Aggregate	Display name	Actions
Address	GROUP	Address	
IdentityType	COUNT	Identity	

Save **Cancel**

Please note that at least one attribute must be specified as a group field and at least one attribute must be specified as an aggregate. A group field is the field that will be used for stratification. Once all attributes have been added, click the **Save** button to add each attribute to the report or the **Cancel** button to cancel this action and return to the previous page.

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, first select the filters menu option for the report you would like to customize.

Reports				
				Add Report
Report name	Unique identifier	System	Report status	Actions
Adverse Events	28bf27d9-653d-4ae3-9376-1aa47d0bece6	Yes	Published	
Annual Adverse Events	74a659cd-0c78-40f3-8b11-9ee28d61bd69	Yes	Published	
Causality	e20162d7-63b8-4476-8952-999f5329c550	Yes	Published	
Outstanding Visits	1b2521e3-b830-4c61-9d83-ab5aa2aa67bc	Yes	Published	
Patients by Drug	1626657b-e7d9-4eed-8455-aa4da40e0eb6	Yes	Published	
Patients on Treatment	2b8638ff-ece6-4325-a146-ec1bb7dc2f1f	Yes	Published	
Quarterly Adverse Events	461646eb-9291-4027-adac-9f18c1ead0b5	Yes	Published	
Test report	2ec3e491-8872-456d-b4a4-d968abba3a12	No	Published	   

Add the filter item as per the field description below and click the **add** icon:

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

Set Filters

Report name
Test report

Filters represent columns that can narrow the scope of the results in the customised report. Please select your filters below

Relation * ▼ Attribute name * ▼ Operator * ▼

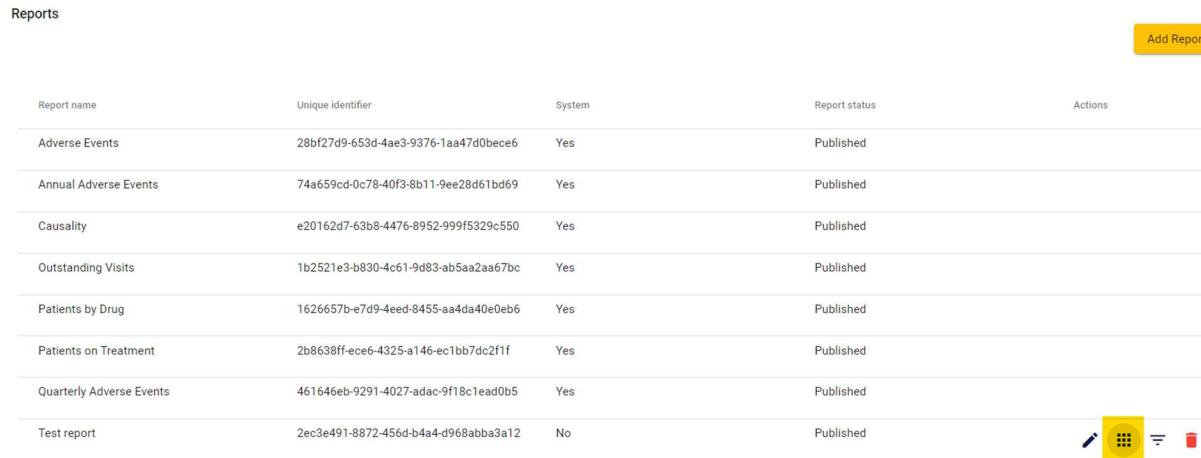
Relation	Attribute name	Operator	Actions
AND	Address	=	

Save Cancel

Once you are satisfied with the report configuration, change the status of the report to published. The new report will appear in the custom report menu once it is published. Please note, you may need to log out and log back in to view the new report..

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, first select the attributes menu option for the report you would like to customize.



The screenshot shows a table of reports with columns: Report name, Unique identifier, System, Report status, and Actions. The actions column includes icons for edit, delete, and refresh. The reports listed are:

Report name	Unique identifier	System	Report status	Actions
Adverse Events	28bf27d9-653d-4ae3-9376-1aa47d0bece6	Yes	Published	
Annual Adverse Events	74a659cd-0c78-40f3-8b11-9ee28d61bd69	Yes	Published	
Causality	e20162d7-63b8-4476-8952-999f5329c550	Yes	Published	
Outstanding Visits	1b2521e3-b830-4c61-9d83-ab5aa2aa67bc	Yes	Published	
Patients by Drug	1626657b-e7d9-4eed-8455-aa4da40e0eb6	Yes	Published	
Patients on Treatment	2b8638ff-ece6-4325-a146-ec1bb7dc2f1f	Yes	Published	
Quarterly Adverse Events	461646eb-9291-4027-adac-9f18c1ead0b5	Yes	Published	
Test report	2ec3e491-8872-456d-b4a4-d968abba3a12	No	Published	

Then select the attribute from the list, specify the name of column in the display field, and click the **add** icon. The attribute will be added to the list.

Set Attributes

Report name
Test Medication

Attributes represent columns within the customised report. Please select your attributes below

Attribute name *

Maximum length 50



Attribute name	Aggregate	Display name	Actions
Dose		Dose	

Save

Cancel

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, first select the filters menu option for the report you would like to customize.

Reports

[Add Report](#)

Report name	Unique identifier	System	Report status	Actions
Adverse Events	28bf27d9-653d-4ae3-9376-1aa47d0bece6	Yes	Published	
Annual Adverse Events	74a659cd-0c78-40f3-8b11-9ee28d61bd69	Yes	Published	
Causality	e20162d7-63b8-4476-8952-999f5329c550	Yes	Published	
Outstanding Visits	1b2521e3-b830-4c61-9d83-ab5aa2aa67bc	Yes	Published	
Patients by Drug	1626657b-e7d9-4eed-8455-aa4da40e0eb6	Yes	Published	
Patients on Treatment	2b8638ff-ece6-4325-a146-ec1bb7dc2f1f	Yes	Published	
Quarterly Adverse Events	461646eb-9291-4027-adac-9f18c1ead0b5	Yes	Published	
Test report	2ec3e491-8872-456d-b4a4-d968abba3a12	No	Published	   

Add the filter item as per the field description below and click the **add** icon:

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	<p>The operator that will be applied to the filter:</p> <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

Set Filters

Report name
Test report

Filters represent columns that can narrow the scope of the results in the customised report. Please select your filters below

Relation * ▼ Attribute name * ▼ Operator * ▼



Relation	Attribute name	Operator	Actions
AND	Address	=	

Save

Cancel

Once you are satisfied with the report configuration, change the status of the report to published. The new report will appear in the custom report menu once it is published. Please note, you may need to log out and log back in to view the new report.

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 **Update report**, **Set attributes** or **Set filters** icons. To delete a report, click on the **Delete report** icon.

Reports				
Report name	Unique identifier	System	Report status	Actions
Adverse Events	28bf27d9-653d-4ae3-9376-1aa47d0bece6	Yes	Published	
Annual Adverse Events	74a659cd-0c78-40f3-8b11-9ee28d61bd69	Yes	Published	
Causality	e20162d7-63b8-4476-8952-999f5329c550	Yes	Published	
Outstanding Visits	1b2521e3-b830-4c61-9d83-ab5aa2aa67bc	Yes	Published	
Patients by Drug	1626657b-e7d9-4eed-8455-aa4da40e0eb6	Yes	Published	
Patients on Treatment	2b8638ff-ece6-4325-a146-ec1bb7dc2f1f	Yes	Published	
Quarterly Adverse Events	461646eb-9291-4027-adac-9f18c1ead0b5	Yes	Published	
Test report	2ec3e491-8872-456d-b4a4-d968abba3a12	No	Published	

7 Information Portal

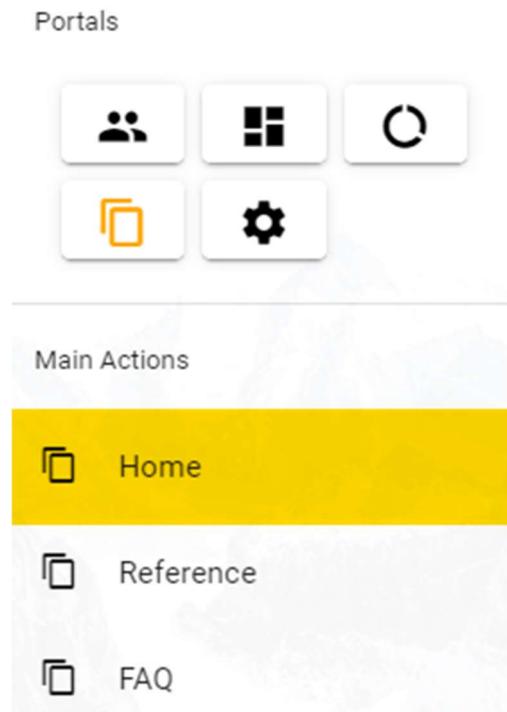
The information portal is the centralized hub for publication and presentation. PVIMS information publishers have the ability to share trends, analysis, graphs, and important information about pharmacovigilance activities.

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 information such as national guidelines or other information you post that would be relevant to most PViMS users.

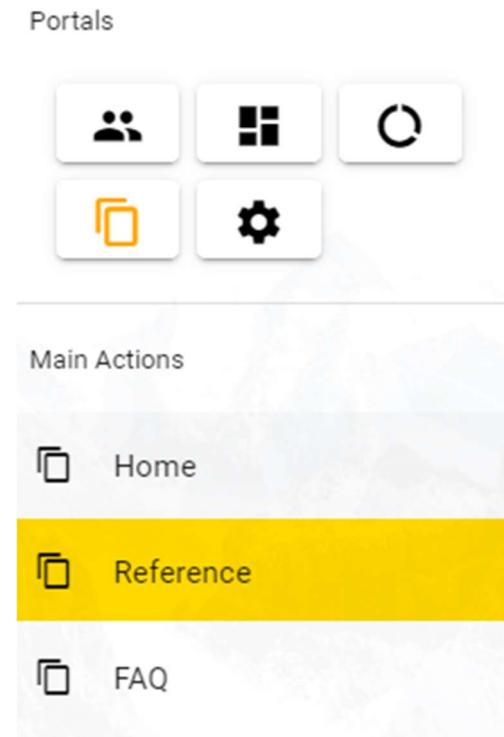
This screenshot shows the PViMS Home Page. It features two main sections: 'National Guidelines' and 'Pharmacovigilance Study'. The 'National Guidelines' section contains three items: '07 January 2016 - FDC Use', '06 August 2015 - FDC Circular', and '04 June 2015 - Consolidated ART guidelines'. The 'Pharmacovigilance Study' section contains one item: '22 November 2012 - Vietnam sentinel survey'.

To view information for an existing date, click anywhere on the row expand or compress that guideline as required.

This screenshot shows the PViMS Home Page with the 'National Guidelines' section expanded for the entry '07 January 2016 - FDC Use'. The expanded content describes an NDoH Advisory about the use of FDCs to reduce the use of single-agent lamivudine tablets. It states that this document and its associated circular (FDC ARV Circular, dated 25.05.2015) provide guidance on how to prescribe FDCs, which reduces the need to use single-agent lamivudine tablets. Below this expanded entry, the other two entries ('06 August 2015 - FDC Circular' and '04 June 2015 - Consolidated ART guidelines') are shown in collapsed form.

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 information.

Reference

Drug Safety		Grading Scales	
FDA Drug Safety Communication Prescription Acetaminophen Products	2020-09-08	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	2020-09-08 2020-09-08 2020-09-08 2020-09-08
Standards			
MedDRA Medical Dictionary for Regulatory Activities ICD10 International Classification of Diseases HL7 Health Level Seven E2B Electronic Transmission of Individual Case Safety Reports	2020-08-11 2020-08-11 2020-08-11 2020-08-11 2020-08-11 2020-08-11		
Causality Scales			
Naranjo Naranjo Adverse Drug Reaction Probability Scale WHO WHO Adverse Drug Reaction Probability Scale	2020-09-08 2020-09-08		

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 header for that specific reference.



Standards

MedDRA

Medical Dictionary for Regulatory Activities

2020-08-11

ICD10

International Classification of Diseases

2020-08-11

HL7

Health Level Seven

2020-08-11

E2B

Electronic Transmission of Individual Case Safety Reports

2020-08-11

The system will navigate you to a reference pop up which contains additional information to that reference item.

Reference Page 2

 PViMS Standards Used

Medical Dictionary For Regulatory Activities ^

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...

International Classification of Diseases ▼

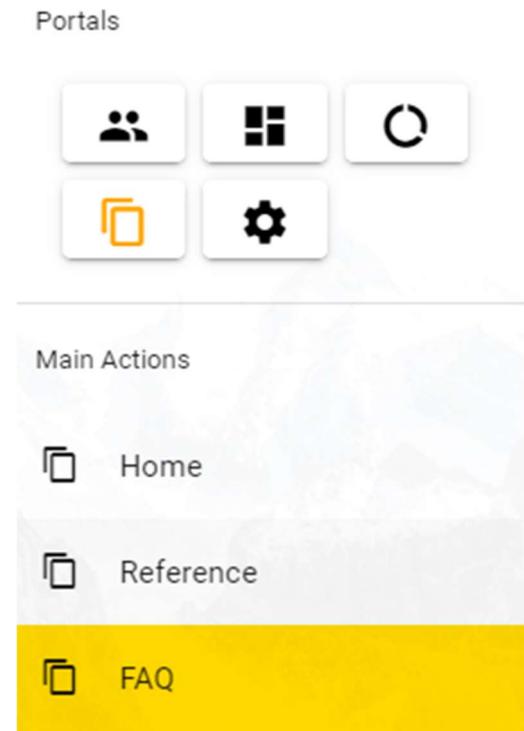
Health Level Seven ▼

Electronic Transmission of Individual Case Safety Reports ▼

 Close

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.



Frequently Asked Questions on Bedaquiline

Why is the introduction of Bedaquiline significant?



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?



Will there be other new drugs to treat TB?



To view the answer for a specific question, click anywhere on the row to expand or compress the answer for that question.

FAQ



Frequently Asked Questions on Bedaquiline

Why is the introduction of Bedaquiline significant?

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).

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?

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.

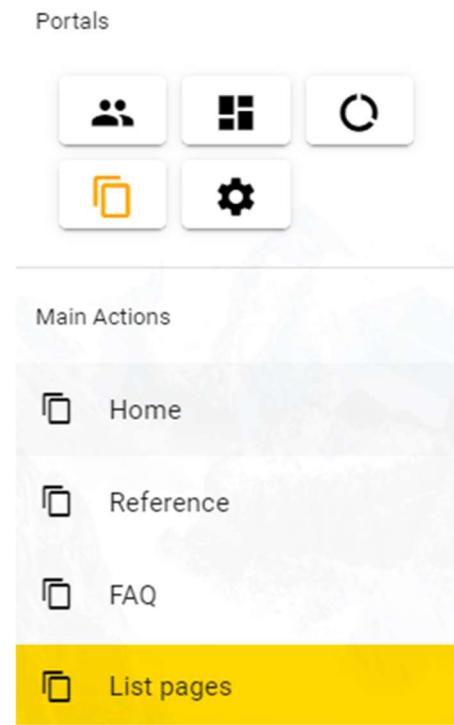
7.4.1 Adding a New Page

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 Administrator** role assigned to your user profile.

To add a new page, click on the **List Pages** menu.



Then click on the Add Page button to configure the core characteristics of the new page.

Pages				
page-name	Unique Identifier	System	Visible to menu	Actions
Home	a63e9f29-a22f-43df-87a0-d0c8dec50548	Yes	Yes	
Reference Page 1	cde6d1b5-6a09-47b2-a304-abbcc2c94dac	Yes	No	
Reference Page 2	8d62faa0-6fc0-4f1f-8714-924afdc5b03d	Yes	No	
Reference Page 3	14589ffb-506a-4299-9e1a-fef1c8bae881	Yes	No	
Reference Page 4	1e7fb80d-2ce2-4481-a9ba-d0538d425a5d	Yes	No	
Reference	89cadd84-eb24-4c70-b769-9183a5a7405a	Yes	Yes	
FAQ	942f501a-1f47-49a3-9f60-6814ea46c482	Yes	Yes	

Items per page: **10** ▾ 1 - 7 of 7 < >

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 previous page of the portal.

Add Page

Page name *

Test Page

Maximum length 50

Definition

This is a test page

Maximum length 250

Breadcrumb

Test

Maximum length 250

Visible to menu *

Yes

Save

Cancel

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 content to a page using widgets.

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 Administrator** role assigned to your user profile.

To add a new widget, navigate to the page that you would like to add the widget to by selecting the visibility icon for the appropriate report in the list reports menu.

Pages

[Add Page](#)

page-name	Unique identifier	System	Visible to menu	Actions
Home	a63e9f29-a22f-43df-87a0-d0c8dec50548	Yes	Yes	
Reference Page 1	cde6d1b5-6a09-47b2-a304-abbcc2c94dac	Yes	No	
Reference Page 2	8d62faa0-6fc4-4f1f-8714-924afdc5b03d	Yes	No	
Reference Page 3	14589ffb-506a-4299-9e1a-fef1c88ae881	Yes	No	
Reference Page 4	1e7fb80d-2ce2-4481-a9ba-d0538d425a5d	Yes	No	
Reference	89cadd84-eb24-4c70-b769-9183a5a7405a	Yes	Yes	
FAQ	942f501a-1f47-49a3-9f60-6814ea46c482	Yes	Yes	
Test Page	da9700df-6bae-41c2-b871-390f5efc8f09	No	Yes	

Items per page: 10

[View Page](#)

< >

Once the system has navigated you to the newly created page, click on the **Add Widget** icon that appears in the page header.



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, SubItems)
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.

Add Widget

Details

Widget name *

Test Widget

Maximum length 50

Widget type *

General

Icon *



Save

Cancel

The system will add the new widget to the page in the unpublished widgets section 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.

Test Page

Unpublished Widgets

Test Widget

⚙️ ➔ 🗑️

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 Administrator** 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 Administrator** 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 **Update widget** icon for this widget.



The system will navigate you to the **Edit Widget** pop up form 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.

Update Widget

Details
Content

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📅

** PLEASE ENTER YOUR CONTENT HERE **

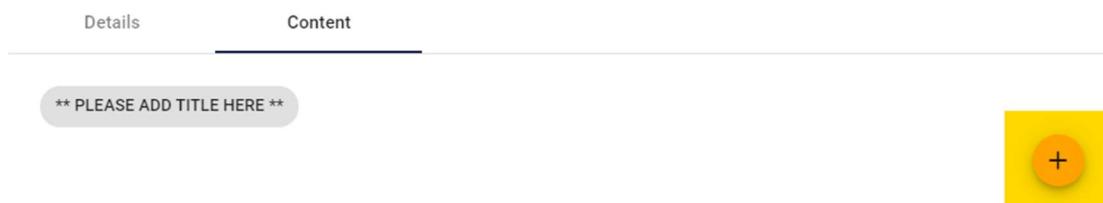
Save

Cancel

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** icon.

Update Widget



Select the tab you would like to edit content for and then enter the title for the new item as well as the content associated to this item.

A screenshot of the 'Content' tab interface. At the top, there are 'Details' and 'Content' tabs. The 'Content' tab is selected. Below the tabs, there is a placeholder message: '** PLEASE ADD TITLE HERE **'. Underneath this, there is a text input field with the placeholder 'Maximum length 100'. Below the input field is a toolbar with various text formatting icons: bold (B), italic (I), underline (U), strikethrough (S), quote (‘’), superscript (x²), subscript (x₂), etc. There are also alignment options (Normal, Center, Justify) and a font dropdown set to 'Sans Serif'. At the bottom of the content area, there is another placeholder message: '** PLEASE ADD CONTENT HERE **'. At the very bottom right, there are two buttons: a yellow 'Save' button with a blue outline and a red 'Delete' button with a white outline.

Click the **Save** icon to save the new content or the **Delete** icon to delete the tabbed item.

Once you are finished, click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.

7.4.3.3 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** icon.

Update Widget

Details Content

** PLEASE ADD TITLE HERE **



Select the tab you would like to edit content for and then 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.

Update Widget

Details Content

** PLEASE ADD TITLE HERE **



Title *
** PLEASE ADD TITLE HERE **
Maximum length 100

Subtitle
** PLEASE ADD SUB-TITLE HERE **
Maximum length 100

Content page *
Test Page



Click the **Save** icon to save the new content or the **Delete** icon to delete the tabbed item.

Once you are finished, click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.

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 Administrator role assigned to their user profile). Conversely, widgets in a published status are viewable by all users who have access to this portal.

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 **Update widget** icon for this widget.

Test Page

Unpublished Widgets

Test Widget



Test ItemList Widget



Test SubItem Widget



The system will navigate you to the **Update Widget** pop up form where you will have the ability to configure 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.

Tip!

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.

Update Widget

Details Content

Identifier d9b6e21e-68de-4443-a6cc-f719b2dad5f2	
Widget type General	Current location Unassigned
Widget name * Test Widget	
Maximum length 50	
Widget status Published	
Widget location must be assigned for published widget	
Widget location Top left	
Icon * 	

Save **Cancel**

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.

Test Page

Unpublished Widgets

Test ItemList Widget



Test SubItem Widget



Test Widget

** PLEASE ENTER YOUR CONTENT HERE **



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** icon for this widget.

The screenshot shows a "Test Page" header. Below it, a section titled "Unpublished Widgets" contains two items: "Test ItemList Widget" and "Test SubItem Widget". Each item has a blue gear icon, a blue arrow pointing right, and a yellow trash can icon.

The system will navigate you to a **Delete Widget** pop up form where you will have the ability to delete the widget.

Click the **Delete** button to confirm the deletion or the **Cancel** button to cancel this action and return to the page view.

Delete Widget

The screenshot shows a red warning bar with the text "Please note, You are about to delete this record. This action is not reversible". Below it, a white area displays the "Test ItemList Widget" name. At the bottom are two buttons: a red "Delete" button on the left and a yellow "Cancel" button on the right.



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** icon 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 screenshot shows a "Test Page" interface. At the top, it says "Test Page". Below that, under "Unpublished Widgets", there are two items: "Test ItemList Widget" and "Test SubItem Widget". Each item has three icons: a gear, a right-pointing arrow, and a trash bin. At the bottom, there is a "Move Widget" button.

The system will navigate you to a **Move Widget** pop up form where you will have the ability to select the destination page for the widget.

Select the destination page and click the **Save** button to confirm the move or the **Cancel** button to cancel this action and return to the page view.

Move Widget

Widget name

Test ItemList Widget

Destination page *

Reference

Save

Cancel



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.



To register a spontaneous report, click on the **Public** 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.

1 Patient Information 2 Product Information 3 Test Results 4 Reaction and Treatment 5 Reporter Information

Please enter some information about the person who had the adverse reaction.

Initials of patient *

Enter patients initials here OR their ID number and type below

Identification number

Enter patients ID number OR enter their initials above

Identification type

If you entered a patient ID number, specify the ID type here

Patient date of birth

Enter the patients date of birth here OR enter their age below.

Age

Enter the patients age here OR enter their date of birth above.

Age unit of measure

Enter weeks, months, or years for the patients age here.

Patients weight (kg)

Sex

Ethnic group of patient

Additional document

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.

Please enter information about the product you suspect caused the reaction and about other products taken.

Product name	Suspected	Start date	Actions

Cancel Previous Next

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**. Once a test has been added, you are able to remove the result or edit the test using the appropriate button.

The screenshot shows a user interface for entering test results. At the top, there is a horizontal navigation bar with five items: 1 Patient Information, 2 Product Information, 3 Test Results (which is highlighted with a blue circle), 4 Reaction and Treatment, and 5 Reporter Information. Below this is a yellow input field containing the placeholder text: "Enter information about any tests done for the reaction, along with the results." To the right of this field is a yellow circular button with a plus sign (+). Below the input field is a table with four columns: Lab Test, Test date, Test result, and Actions. In the Actions column, there are "Cancel" and "Next" buttons. The "Cancel" button is red, and the "Next" button is white with a grey border.

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.

1 Patient Information 2 Product Information 3 Test Results 4 Reaction and Treatment 5 Reporter Information

Enter information about what happened and how it was treated.

Description of reaction *

Start date of reaction

Enter the start date of the reaction OR enter the estimated start date in the next field.

Estimated start date of reaction

If you dont know the exact start date of the reaction, enter the estimated start date here.
Did any of these reactions happen?

Was treatment given for the reaction?

What treatment was given for the reaction?

What was the outcome of the reaction?

What was the date of recovery from the reaction?

Enter date if patient died from the reaction

Other relevant information
For example, does the patient have other medical problems?

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.

1 Patient Information 2 Product Information 3 Test Results 4 Reaction and Treatment 5 Reporter Information

Enter information about the person reporting the reaction.

Name or initials of person reporting information *

Telephone number for reporter

Reporter E-mail Address

Profession

Report reference number (if any)

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?

Cancel Previous Save Report

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.

Click the **Save Report** button to submit the report or the **Cancel** button to cancel the registration of the spontaneous report and return to the login screen. Please note that the **Save** button will only be activated once all mandatory fields and field validations are completed successfully.

9 Appendix A: Forms Reference Guide

Step 1: Navigate to the Forms menu in the clinical portal

Once you have logged into PViMS, ensure you have the **clinical** portal icon selected. You will then be presented with a list of menu options in the left-hand pane of the system. Look for the **Forms** menu and select this menu by pressing on it.

Portals



Main Actions

- Forms
- Synchronise



What is the clinical portal?

The clinical portal is the area of the PViMS application that focuses on the collection of longitudinal clinical data for the patient.



Step 2: Select the type of form you would like to capture

Once you have pressed on the **Forms** menu, you will be presented with a page that allows you to capture a new form and view all existing forms that have been captured. Press on the **Add Form A** button of the form to capture a new Form A.

Forms List

Add Form A

Add Form B

Add Form C



What is a button?

A button is a clickable or touchable object on a web page that allows the user to initiate a new or complete an existing action within the system.

Add Form A

Step 3: Complete the patient information section

Once you have pressed on the **Add Form** button, you will be presented with the capture screen for a new form. In all existing forms, section 1 contains patient demographic information used to identify the patient the form belongs to.

1. Press on the treatment site field to activate a drop-down list containing a list of all treatment sites you have been assigned to. Select the appropriate treatment site.
2. Press on the first name field to activate a free format text box that allows you to capture a patient's first name.
3. Press on the date of birth field to activate a date field where you can enter the patient's date of birth.
4. Proceed to capture all mandatory fields.

1 Patient Information

Treatment site *

First name *

NID *

Date of birth

Gender

Pregnant

Provide gestational age (weeks)
Valid between 4 and 44



What is a drop-down list?

Sometimes referred to as a pull-down menu, drop-down list, or drop-down box, a drop-down menu is a list of items that appear when pressing on a button or text selection.

Facility A1

Facility A2

Facility B3

Facility D1

Polyclinic

What is a free format field?

A free format field allows you to capture details relating to the field using any text and numeric characters. A free format field may allow text and numeric data or may be limited to numeric data only for fields such as weight. When applicable the system will also notify you of any numeric ranges applicable to the numeric field.

How do date fields work?

When pressing on the little calendar on the right of the field, you will be presented with a date control which allows you to navigate to the date you would like to select. Use the left and right arrows to change the year. Once you have selected the year, you will then be prompted to select the month followed by the day.

Date of Birth

2016 – 2039 ▲

< >

2016	2017	2018	2019
2020	2021	2022	2023
2024	2025	2026	2027
2028	2029	2030	2031
2032	2033	2034	2035
2036	2037	2038	2039

What is a mandatory field?

Mandatory fields are fields with an * at the end of the field name and mean that that field is required and must be captured before you are able to continue. If you do not capture this field, you will be presented with an error.

First name *

This is a required field

Step 4: Navigate to the next section of the form

Once you have completed the first section of the form and all mandatory fields are captured, you are able to navigate to the next section or save the form and exit.

Next

 Save and exit



What does it mean to save and exit the form?

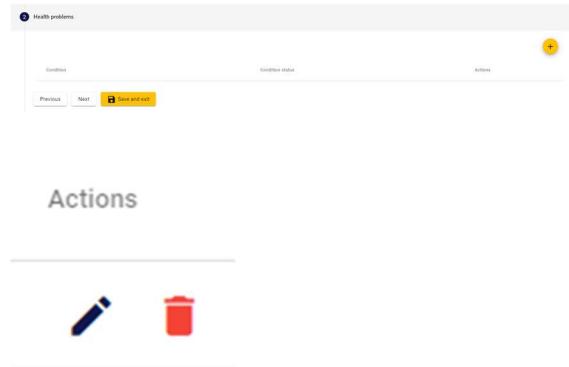
When saving and exiting, the form will be captured and stored on your device including any data that has been captured up to this point. You are then able to edit this form and continue where you left off at a later point in time.

Please note, if you save and exit, you will not be presented with a unique form identifier.

Step 5: Updating a section with a table

Once you have navigated to section 2 of the form, you will be presented with a table where you can add one or many conditions to the patient.

1. Add a new row to the conditions table by clicking on the plus button and then capturing all fields on the modal form presented.
2. Once you have added a new row, note that this row appears within the conditions table.
3. Edit the newly added row by clicking on the pencil button that appears next to the



row you would like to update. Update data in this row and click save.

4. Once you have updated the row, note that the table now contains updated information from the newly updated row.
5. To delete a row from the table, press on the red bin icon.



What is a table and how does it work?

A table is like an MS Excel spreadsheet where it is made up of multiple rows and columns. It is used to represent a one to many relationship between the patient and the area that the table is representing. In this situation each row in the condition table represents a separate condition that the patient has.

What is the plus button and how does it work?

You can add a new row to the conditions table at any point by pressing on the plus button at the top right-hand side of the table. When pressing on this button you will be presented with a modal form that allows you to capture the various details of the new condition.



What is a modal form and how does it work?

A modal form is a pop-up form that appears on top of the previous form you were busy on. Once you are finished completing the pop-up form or if you cancel out the pop-up form you will be returned to the exact position you were in previously.

A screenshot of a modal dialog box titled "Add Condition". The form contains fields for "Condition *", which is marked as a required field, and "Condition status *". There are "Next" and "Save" buttons on the left, and a "Cancel" button on the right.

Step 6: Marking a form as complete

Once you have completed updating all sections of the form, you are able to mark the form as completed. Press on the mark form as completed button that appears in the last section of the form to mark the form as completed. Once you have pressed on this button, you will be presented with a new modal form that specified what the unique identifier for the form is.



What does it mean for the form to be completed?

A form may not be synchronized to the server if you have not marked the form as complete. The action of marking a form as complete signifies to PViMS that you are happy with the status of the form and it is ready to be uploaded.

Form Completed

The following identifier has been created for your form. Please note this number on the form

Identifier
A-0908-144926

Close

What is the unique identifier used for?

On completion of the form, you will be presented with a unique identifier that can be written onto the paper-based form. This provides a measure of quality control to ensure the correct paper-based form is allocated to the electronic record.

Step 7: Searching for an existing form

To search for a form that has been captured, you may use the form list filter criteria to search for the form.

1. Specify if you would like to search for synchronized or completed forms
2. Specify the patients name, record or identity number in search field. You are able to specify partial search criteria where you only enter a few letters of the search term you are searching for.
3. Click search to search for existing forms

Forms List

Add Form A Add Form B Add Form C

Synchronised Forms Completed Forms Search

Created	Type	Identifier	Patient Identifier	Patient	Completed Status	Synchronisation Status	Actions
2020-07-15	FormA	A-0715-074918	33434344343	Shaun Krog	Complete	Not Synced	

Step 8: Taking a photo and attaching it to the form

Once you have searched for a form and the form is listed in the forms table, you will be presented with a camera icon that allows you take a photo for the form you have pressed on the icon for.

1. Once you have pressed on the camera icon, a modal form will appear.
2. Save the photo once you have placed the paper-based form in view of the camera.
3. Note that the camera icon has now been replaced with a picture icon, which allows you to view the newly taken picture.



What is the camera icon and how does it work?

Once you press on the camera icon, a modal form will pop up and present you with a visual stream from your device's camera. Click save to save the photo as an attachment to the form.



Search

Synchronisation Status	Actions
Not Synced	

What is the picture icon and how does it work?

Once you have taken a picture, you will be presented with a picture icon which when pressed will pop up and present you with a picture of the form you had taken a photo of. It is possible to delete the picture in this modal form which will allow you take the photo again.

Step 9: Checking if PViMS is offline

Forms capture can take place on your device irrespective of the online status of PViMS. However, it is not possible to synchronise unless PViMS is marked as online. To determine the current status of PViMS, note the colour of the connectivity icon located in the primary toolbar of PViMS.



- A green icon indicates PViMS is online
- A red icon indicates PViMS is offline

Please note, it is not possible to synchronise your form if PViMS is offline.

Step 10: Synchronising the newly added form to the server

Once you have taken the photo, you are now able to synchronise the form to the server. To synchronise a form, look for the **Synchronise** menu and select this menu by pressing on it. Once you have pressed on the **Synchronise** menu, you will be presented with a page that allows you to synchronise completed forms with photos attached.

Please note, it is not possible to synchronise a form until the photo has been taken and attached to the form. This is to ensure any data quality issues can be verified using the source form.

Sincronizar

A screenshot of the synchronization interface. At the top, there is a header with the word "Sincronizar". Below this is a toolbar with a checkbox labeled "All" and a yellow cloud icon. The main area is a grid of form entries. Each entry has three columns: "Identificadores", "Código do Paciente MAS", and "Estado". The first row shows a checkbox next to "All", a yellow cloud icon, and the identifier "A-0526-134613". The second row shows a checkbox next to "A-0001".

Identificadores	Código do Paciente MAS	Estado
<input type="checkbox"/> All		A-0526-134613
<input type="checkbox"/>	A-0001	

1. Either select the all forms option by pressing on the checkbox next to the word all or by pressing the checkbox next to the form in the forms grid. **Please note, the system will only synchronise forms you have selected.**
2. Click on the synchronise button to synchronise the form.
3. Note any issues highlighted by the server and update the form as necessary or note that

the form has been synchronized successfully.



What is the synchronise button and how does it work?

Once you press on the synchronise icon, the system will automatically prepare the form and upload it to the server. The server will then attempt to process the form and add it as a clinical record to the PViMS database.

