
# PViMS

# User Manual


USAID
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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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## Contents

## ACRONYMS AND ABBREVIATIONS

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

# 1 Introduction

**The Challenge**

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

**The Solution**

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

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

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

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


For information about the MedDRA dictionary contact your system administrator.

## 1.1 Using the Manual

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

## 1.2 Purpose of the Document

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

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

## 1.3 Audience

The intended audiences for this document are identified as follows:

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

# 2 PViMS Structure

PViMS consists of five portals:

- Clinical
- Analytical
- Reporting
- Publishing
- Administration

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

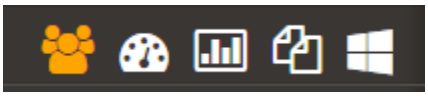
The **Analytical** portal is the centralized hub for causative drug assessment using traditional internationally recognized rating scales, standardized terminology and risk detection.

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

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

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

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



# 3 Using the System

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


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

## 3.1 Launching the Browser

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


**Note 1. What is a URL?**

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

## 3.2 **Logging in to PViMS**

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


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

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

## 3.3 End User License Agreement

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

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   The licensing and use of the MedDRA (Medical Dictionary for Regulatory Activities) Dictionary does not fall within any licensing granted through the use of PViMS.

   In the Analytical portal, Exposed Cases ONLY include cases where the Adverse Drug Reaction falls within the stard and end date of the medication.

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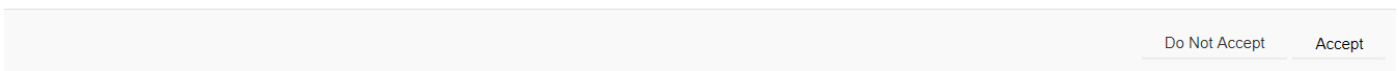
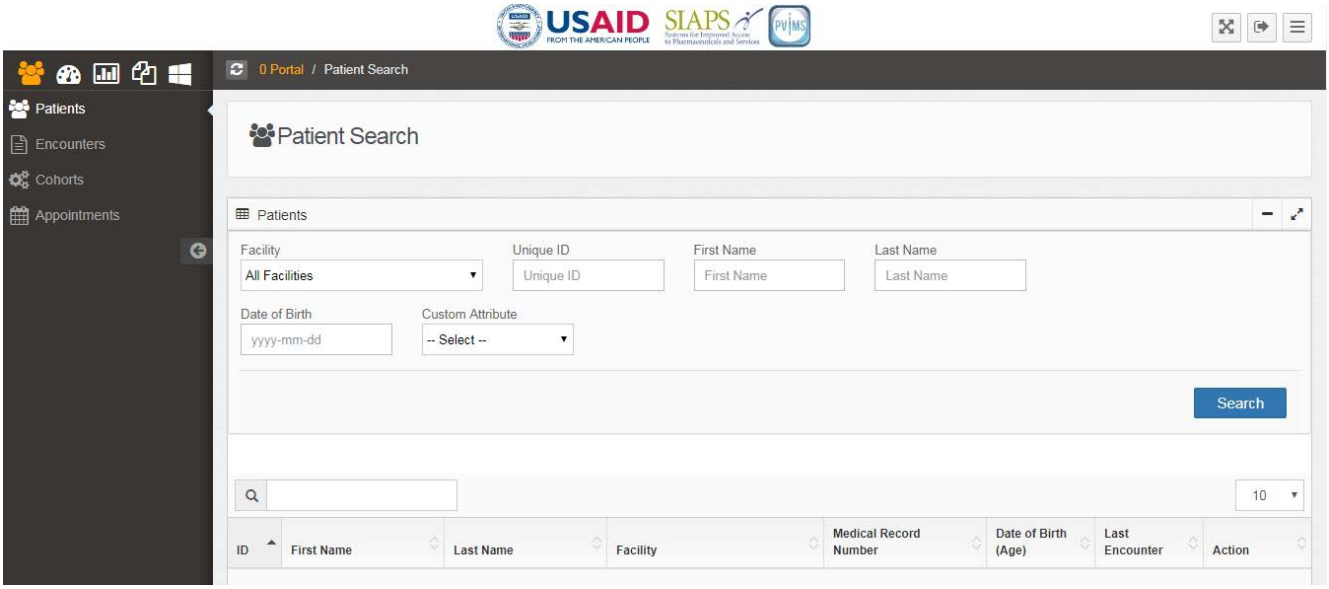


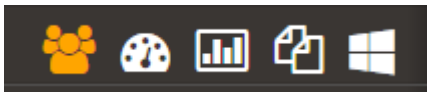

Click the **Accept** button to confirm the acceptance of the EULA and continue to access the system, or click the **Do Not Accept** button to exit the system.

## 3.4 The Home Page

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







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

# 4 Clinical Portal

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

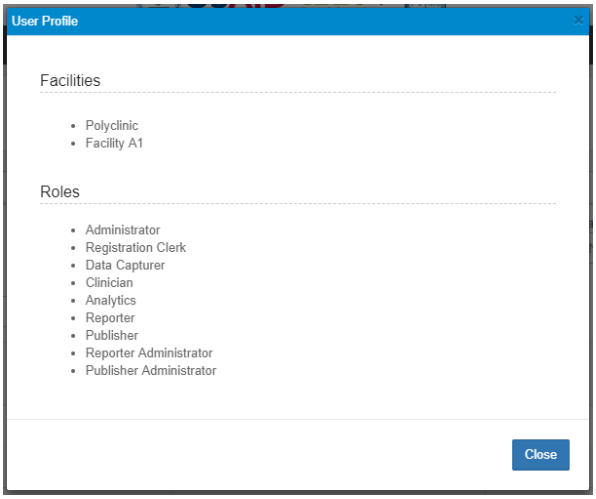
- Patients
- Encounters
- Cohorts
- Appointments

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

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

**Administrator.** The administrator has FULL permissions to the clinical portal.
**Registration Clerk.** The registration clerk is able to add and amend a patient record and create appointments.
**Data Capturer.** A data capturer is able to add and amend a patient record and add and amend an encounter record.
**Clinician.** A clinician is able to add and amend a patient record and add and amend an encounter record.


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

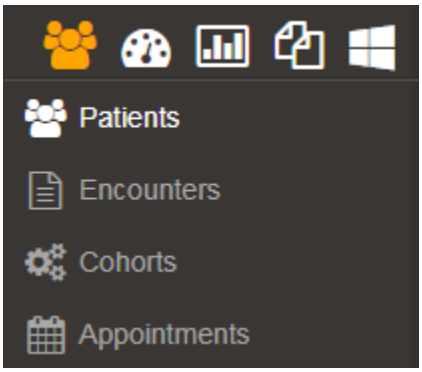


## 4.1 Patients

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

### 4.1.1 Search for Patients

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

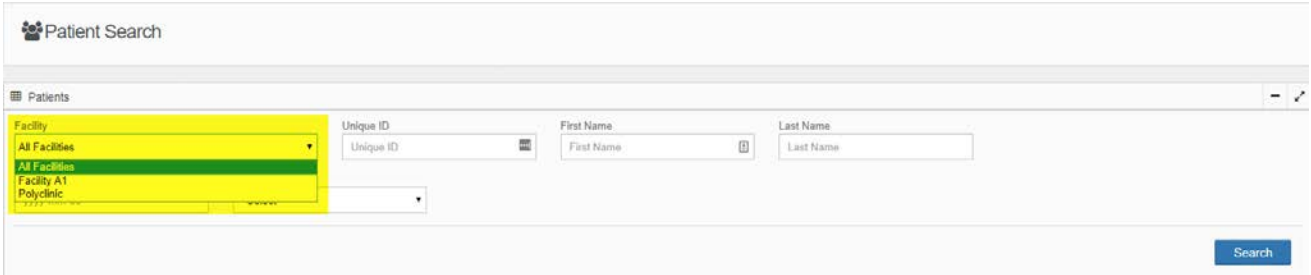



There are five ways to search for a patient. You can search by:

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

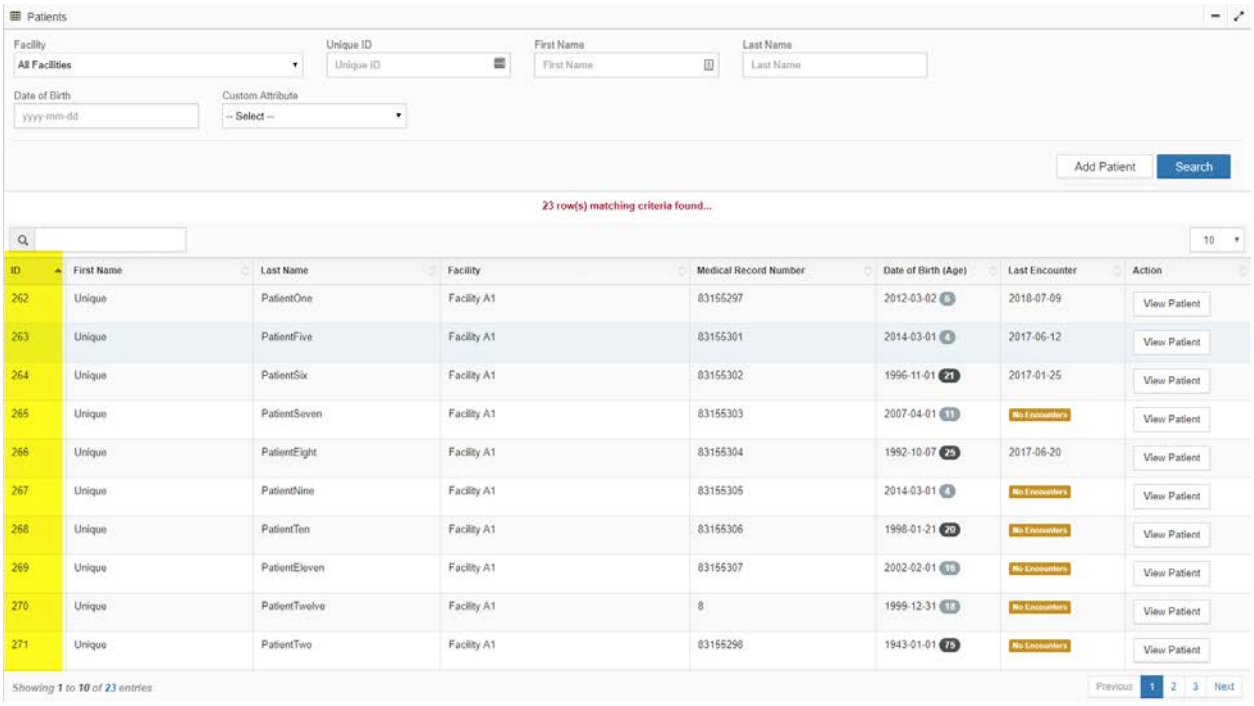
#### 4.1.1.1 Search by Facility

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




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

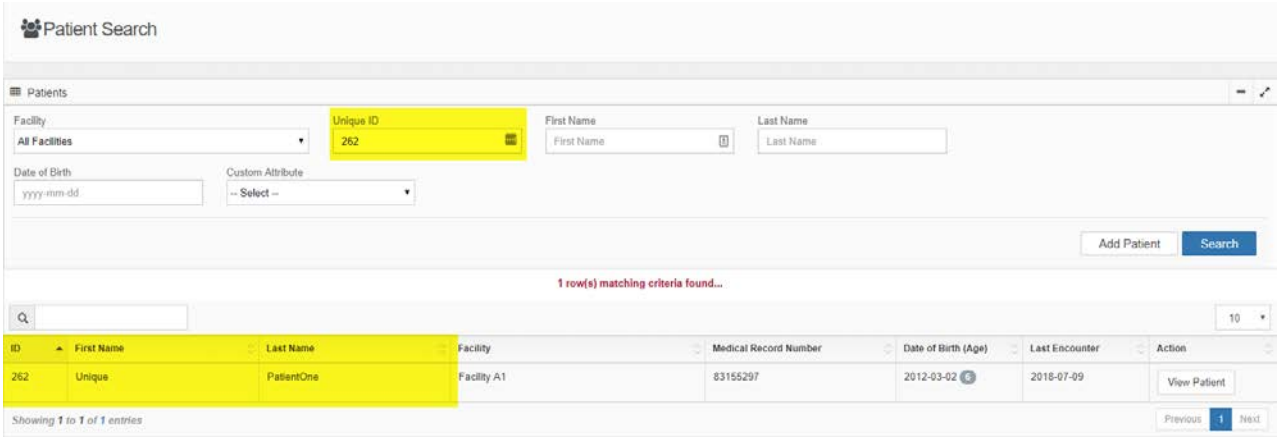
The system will display a list of patients according to the filter selected, please note the Unique ID of the patient in column 1.



#### 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.

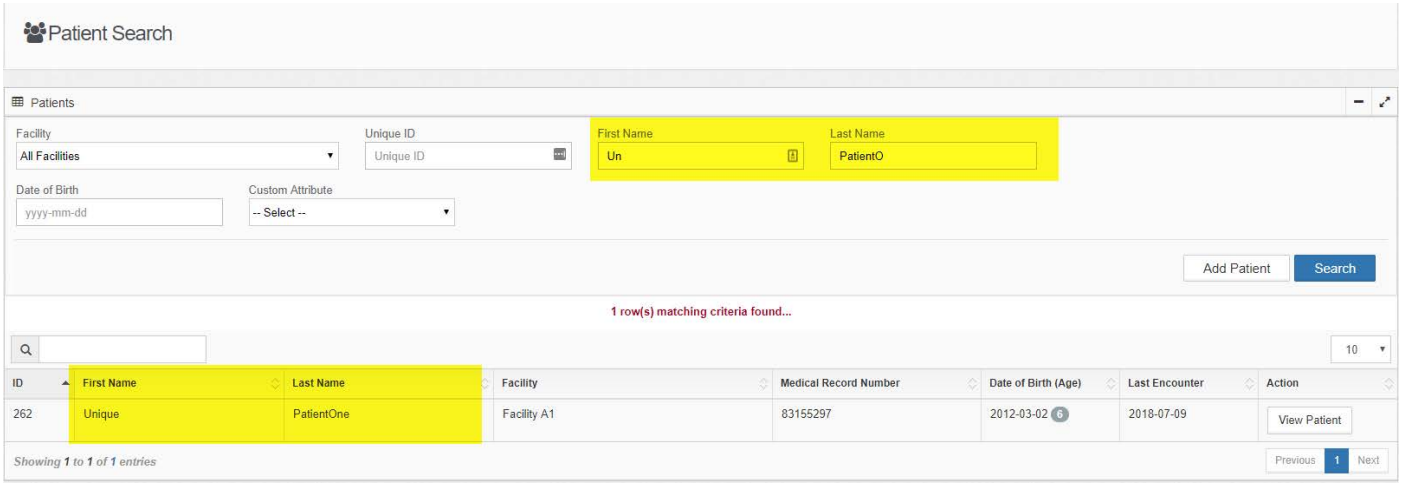
If you know the patient's unique ID, enter it in the **Unique ID** field and click **Search**.




#### 4.1.1.3 Search by First Name or Last Name

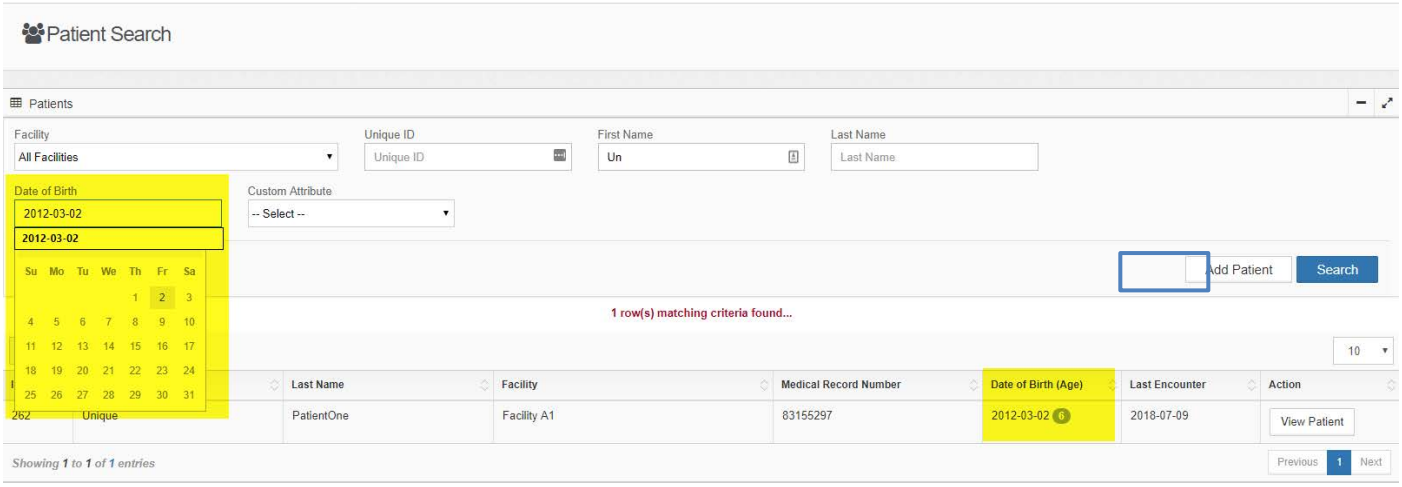
You can also search by the patient's **First name** or **Last Name**. Enter the name(s) in one or both of these areas and click the **Search** button.


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



#### 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.

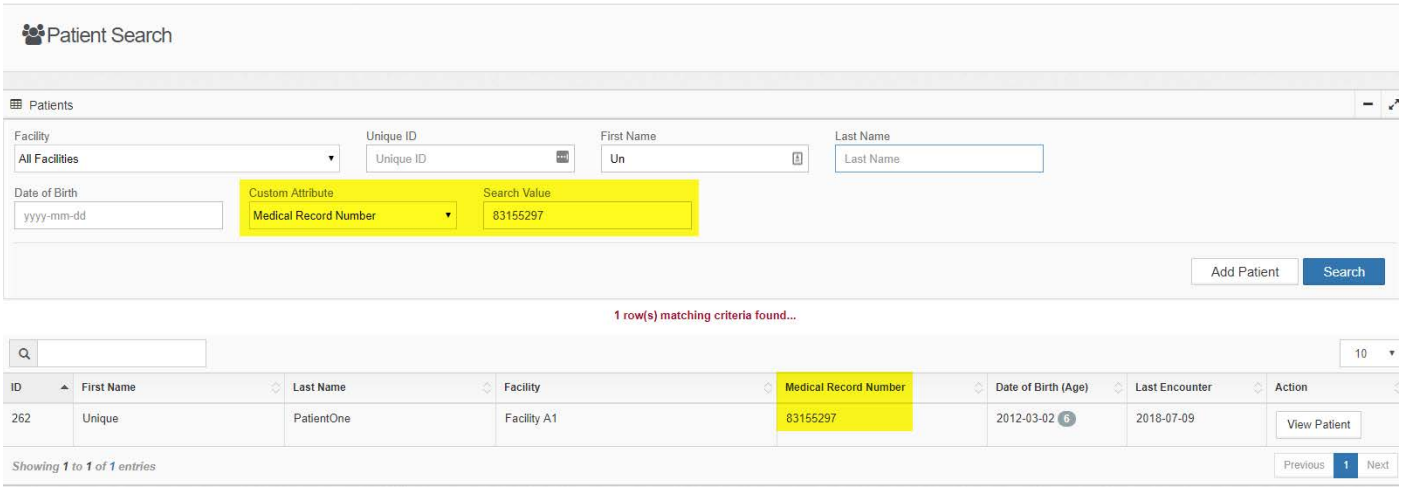



#### 4.1.1.5 Search by Custom Attribute

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.

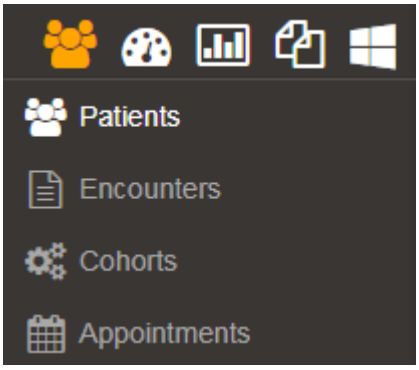
- Select the custom attribute variable that you would like to search against (e.g., Medical Record Number)
- Enter the search value you would like to filter against and click the **Search** button.




### 4.1.2 Return to the Patient Search Page

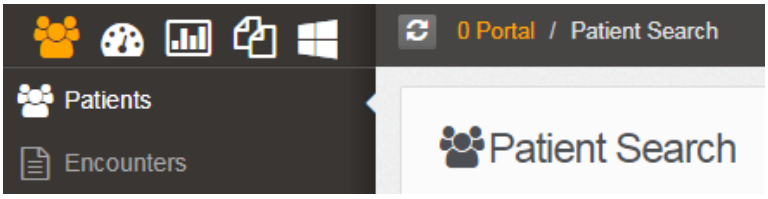
You can return to the **Patient Search** page from any place in the system by using either the **Menu Bar** or the **Title Bar**.

#### 4.1.2.1 Menu Bar




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

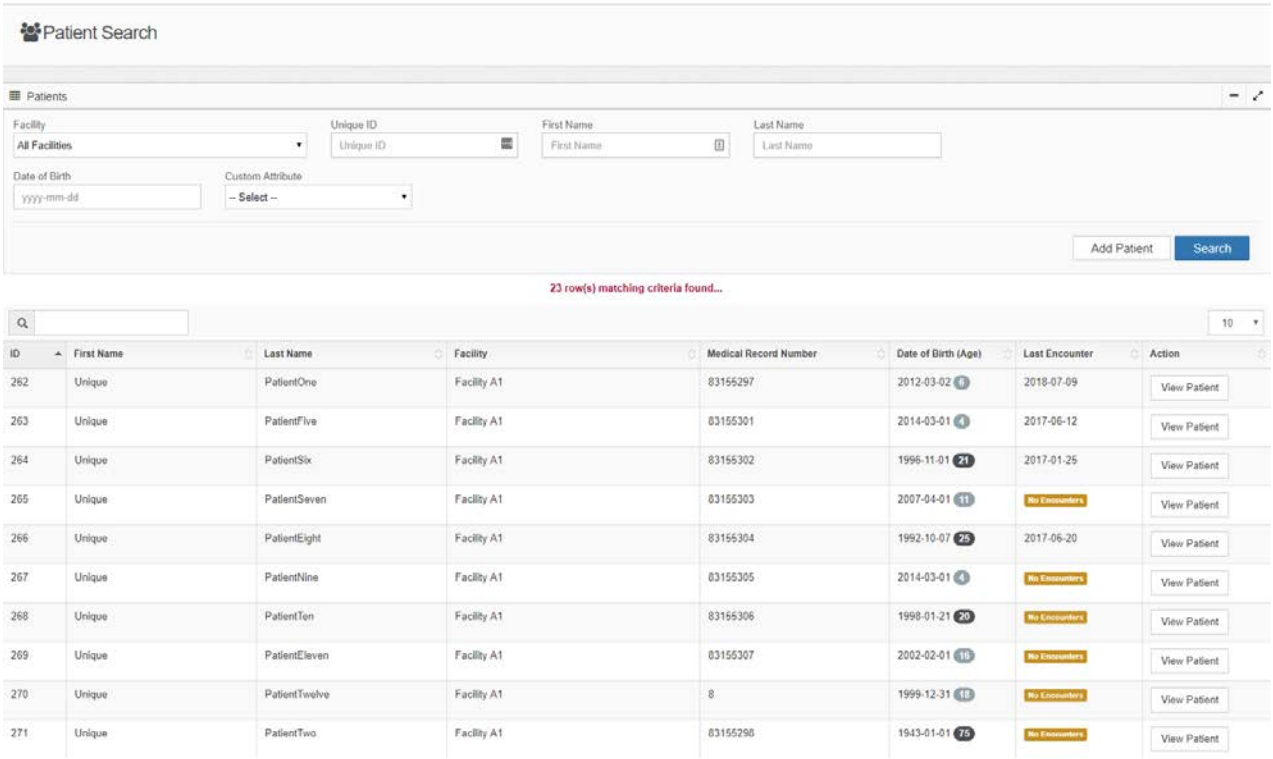
#### 4.1.2.2 Title Bar




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

### 4.1.3 **View an Existing Patient**

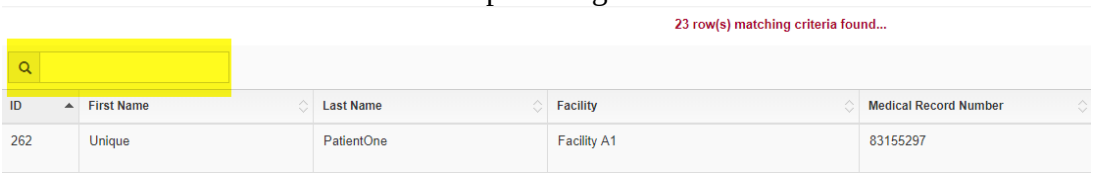
After selecting the appropriate search filter and you have clicked the **Search** button, the system will present all matches as displayed in a table.



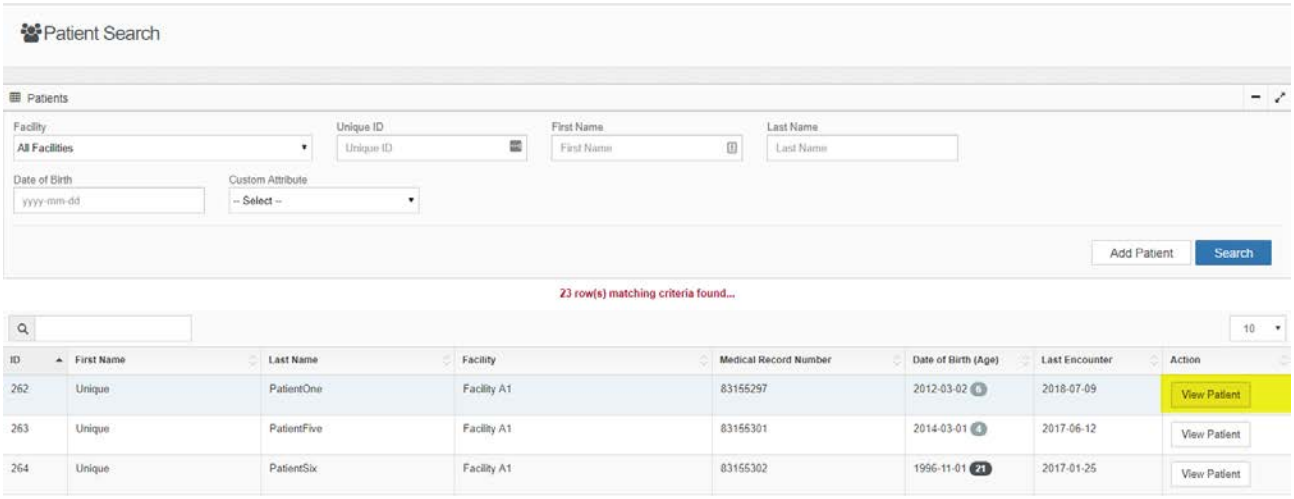
The columns in the table are described below:

| | |
|---|---|
| ID | Unique identification number assigned by the system |
| First Name | Patient's first name as captured in the system |
| Last Name | Patient's last name as captured in the system |
| Facility | Facility associated with the patient |
| Medical Record Number | ID number associated with the patient |
| Date of Birth (Age) | Patients date of Birth and Age indicator<br>• Ages in black ovals are adults<br>• Ages in grey ovals are children |
| Last Encounter | Last encounter date, the date the patient last visited the facility |
| Action | Ability to view the patient's information |


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




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



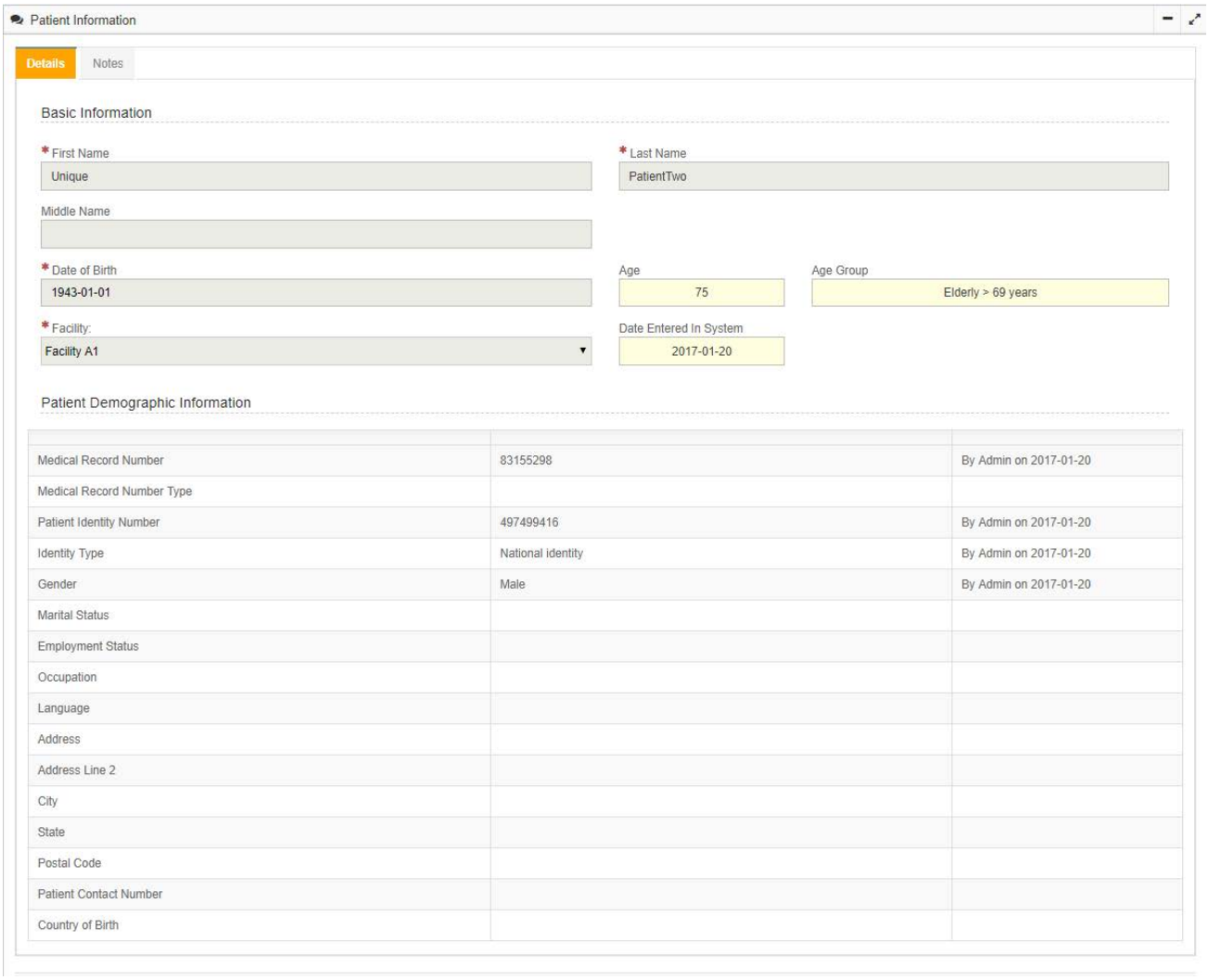

- The system will then open the **Patient View** page and allow you to view the demographics for this patient.

**Patient View** has been segregated into the following core sections:

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

#### 4.1.3.1 Patient Information - Details

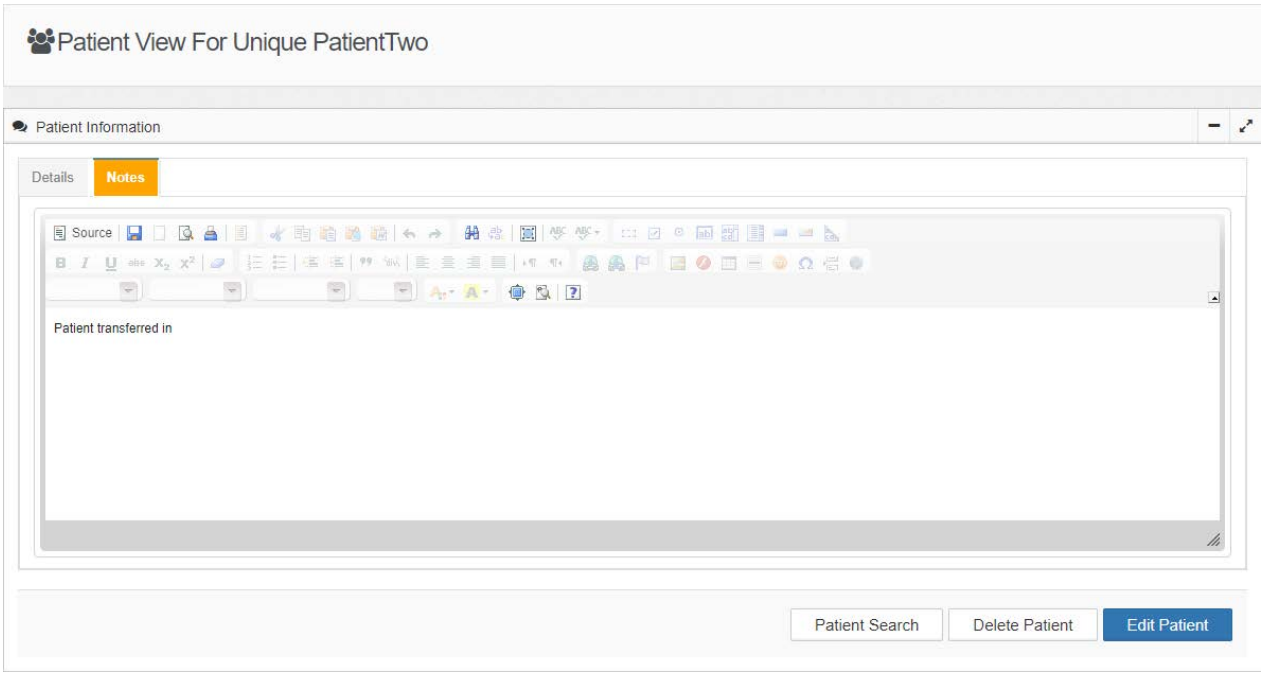
The **Details** tab is further divided into **Basic Information** and **Patient Demographic Information**.




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

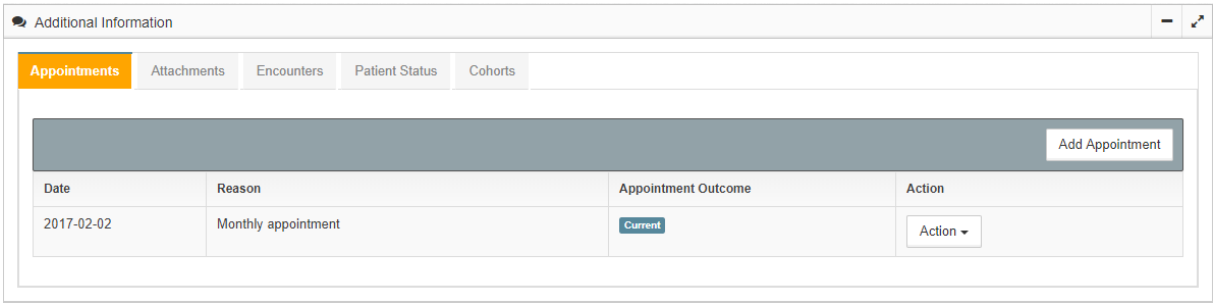
#### 4.1.3.2 Patient Information - Notes

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




#### 4.1.3.3 Additional information - Appointments

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



The columns in the appointments table are described below:

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

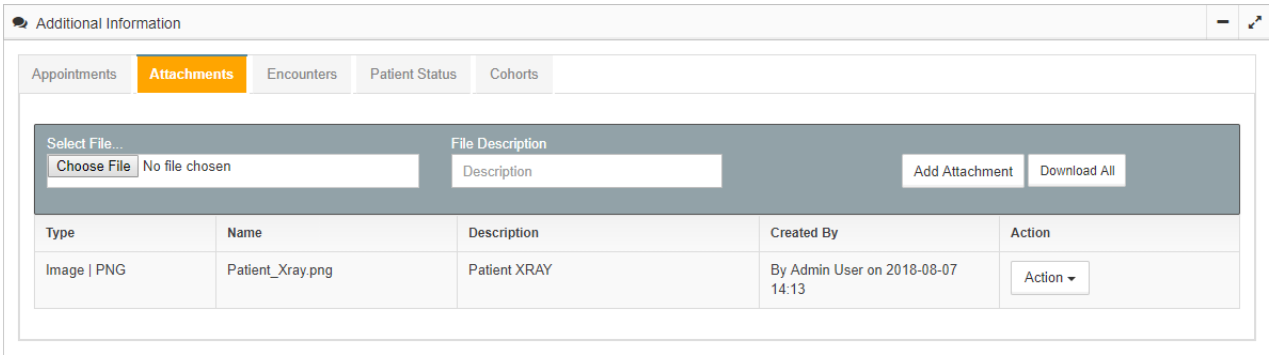

It is possible to sort the appointment table by any one of the columns noted above by clicking on the corresponding column name.

#### 4.1.3.4 Additional Information - Attachments

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


The following file types are supported within PViMS:

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

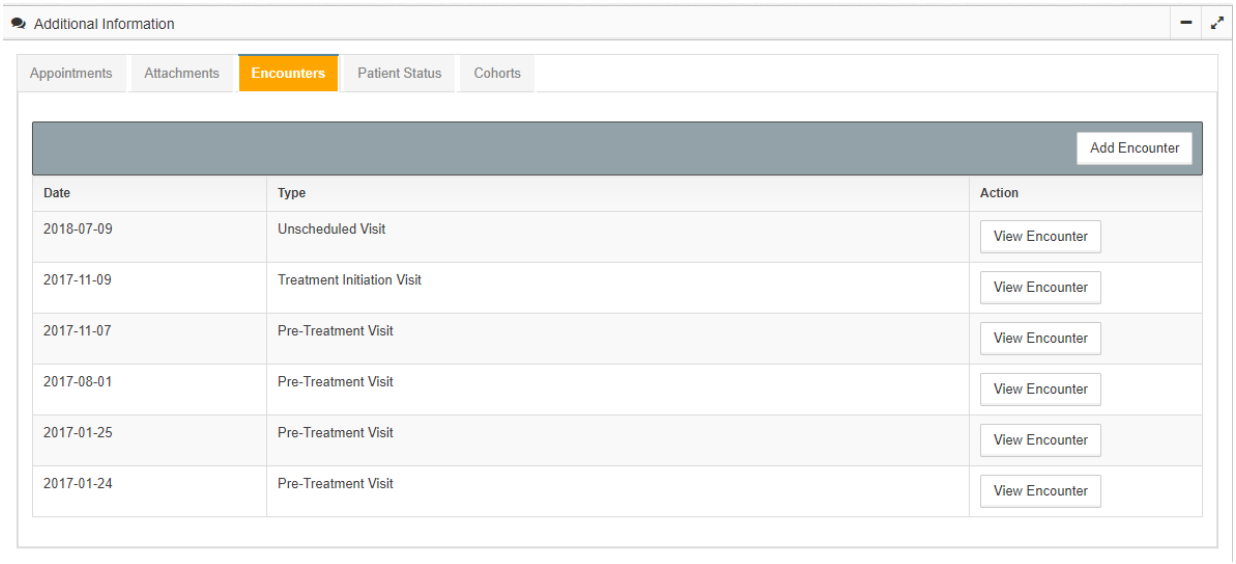



The columns in the attachments table are described below:

| | |
|---|---|
| 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.

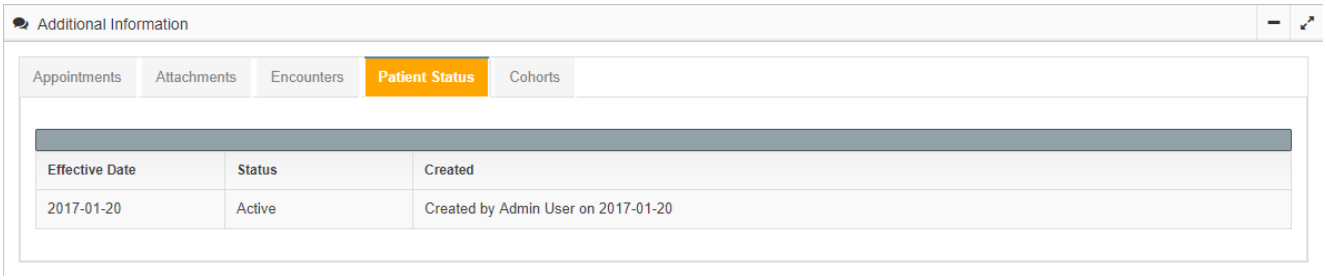



The columns in the encounters table are described below:

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

#### 4.1.3.6 Additional Information - Patient Status

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

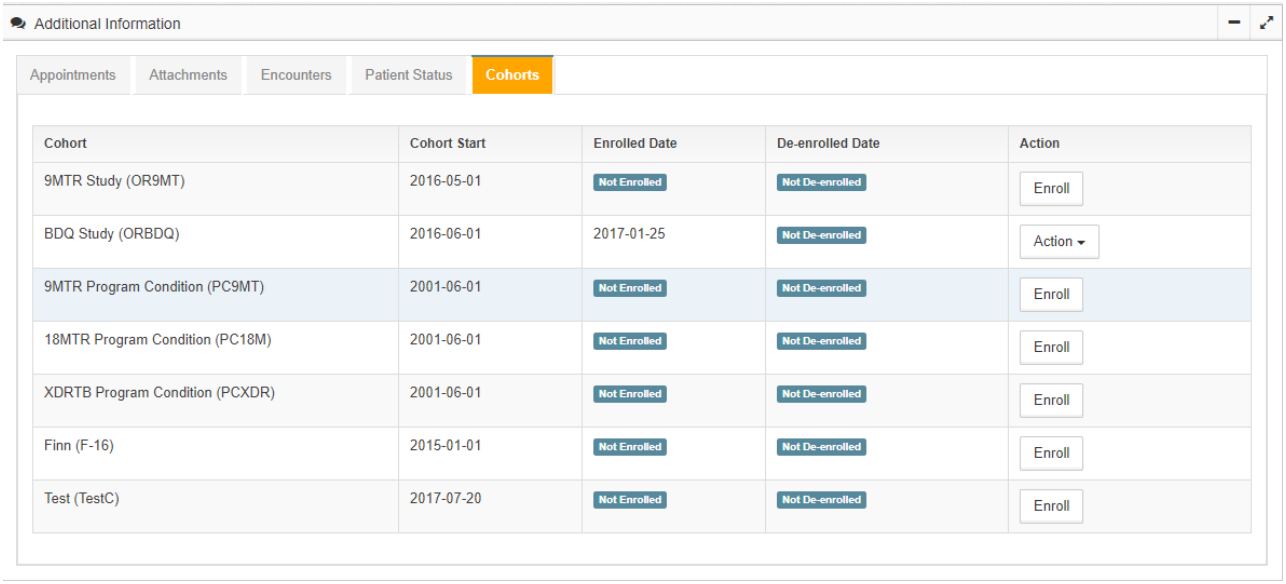



The columns in the status table are described below:

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

#### 4.1.3.7 Additional Information - Cohorts

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

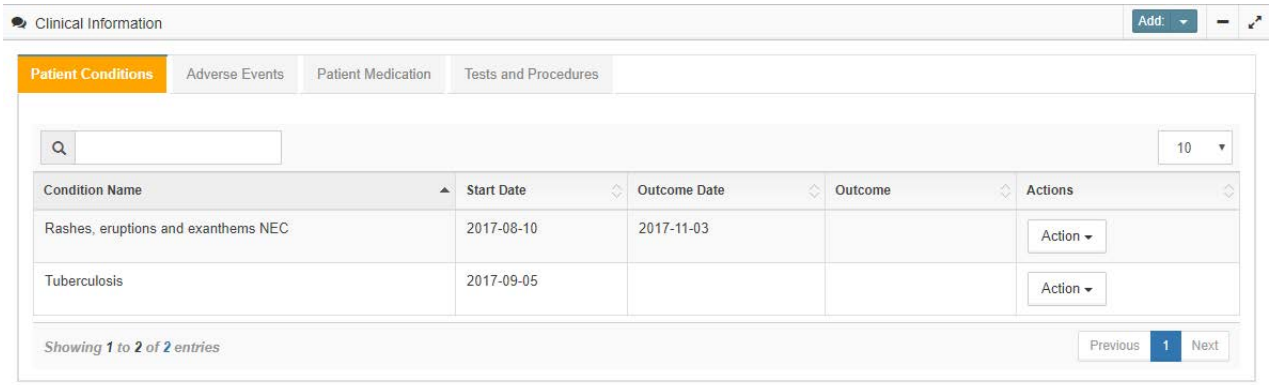



The columns in the **Cohorts** table are described below:

| | |
|---|---|
| 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.

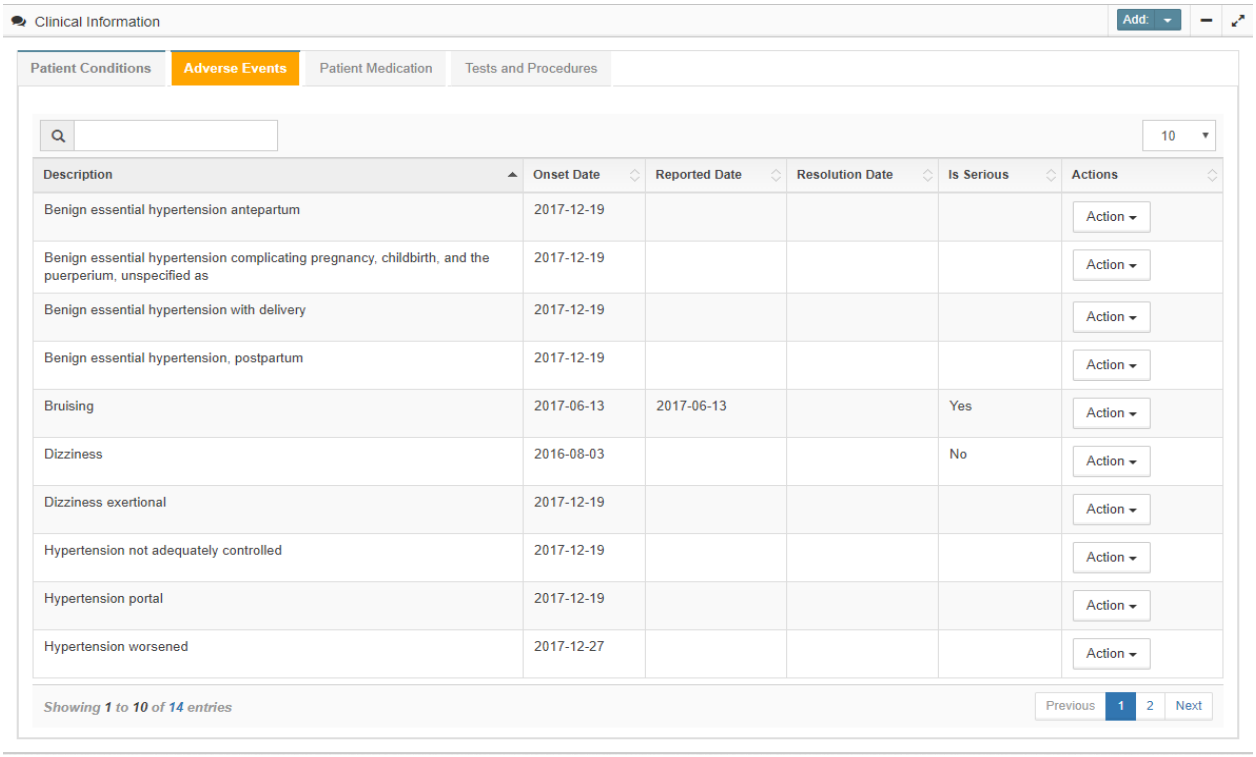



The columns in the **Patient Conditions** table are described below:

| | |
|---|---|
| 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.

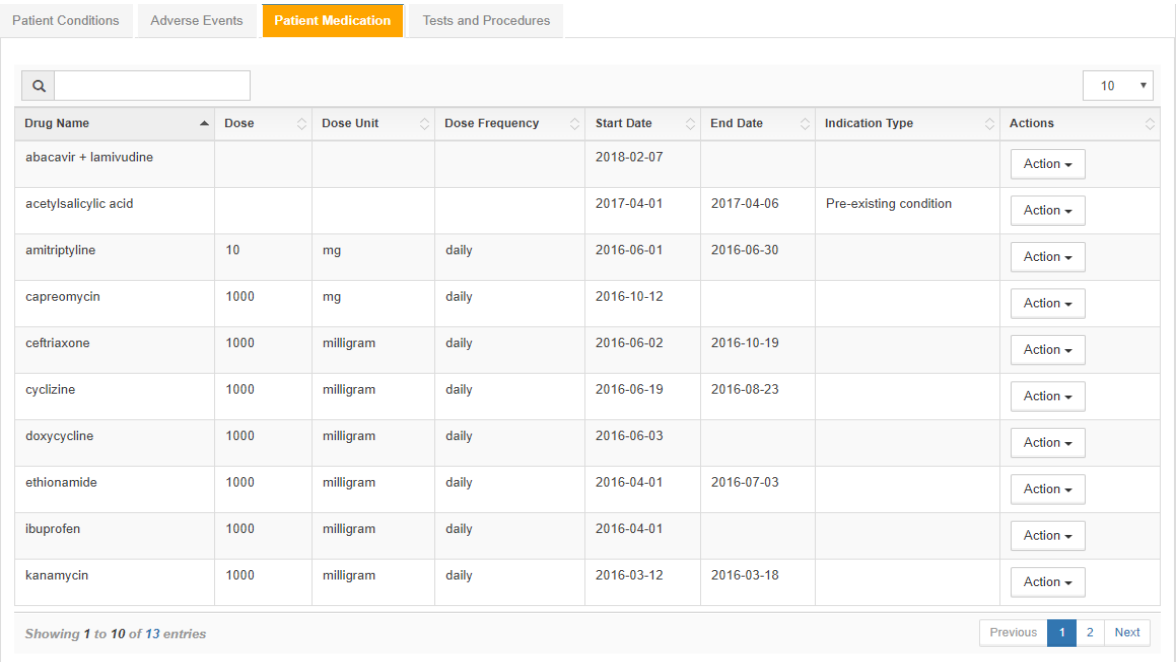



The columns in the **Adverse Events** table are described below:

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

### 4.1.3.10 **Clinical information – Patient Medications**

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

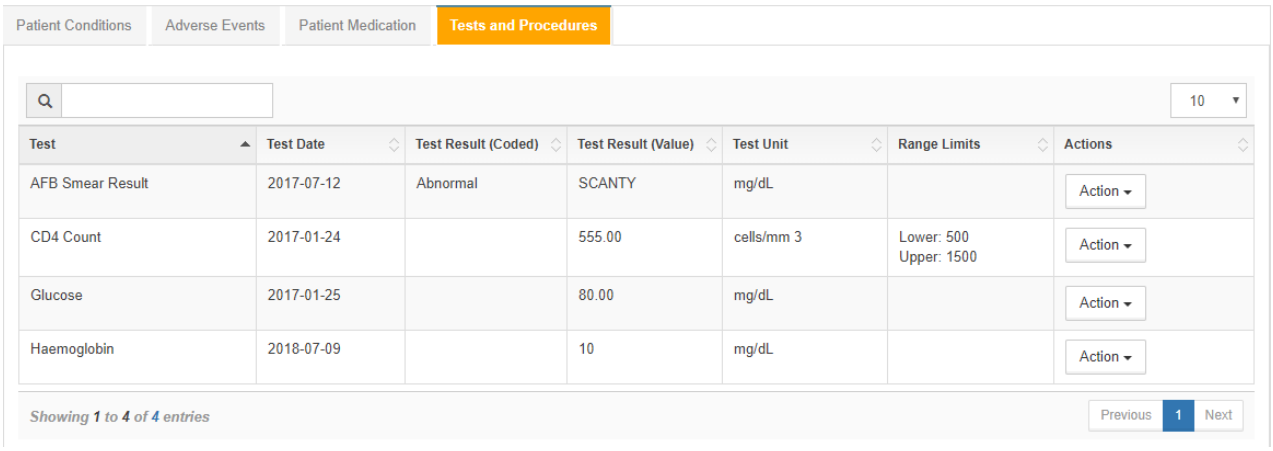



The columns in the **Patient Medication** table are described below:

| | |
|---|---|
| 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 tread and adverse event) |
| Actions | Ability to Edit or Delete the Patient Medication |

### 4.1.3.11 **Clinical information – Tests and Procedures**

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



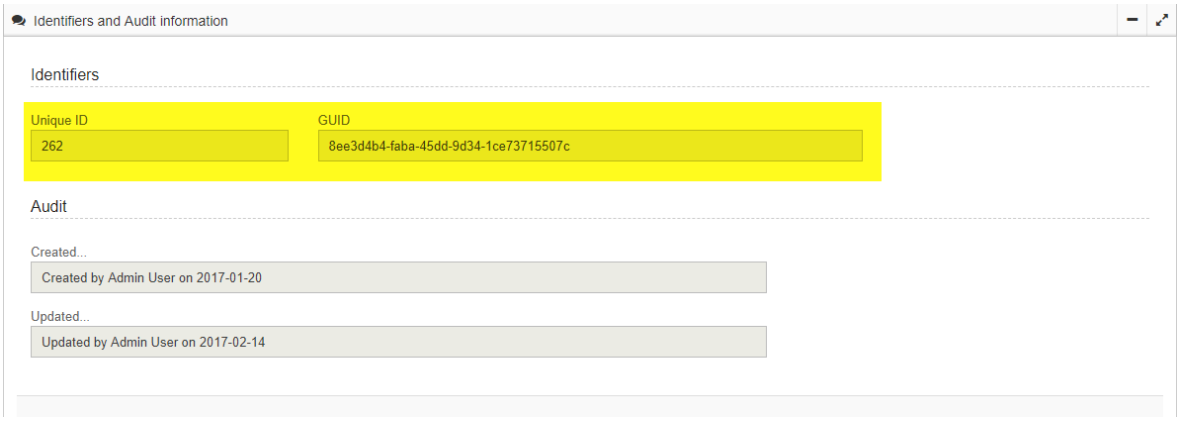

The columns in the **Tests and Procedures** table are described below:

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

#### 4.1.3.12 **Identifiers and Audit information - Identifiers**

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

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



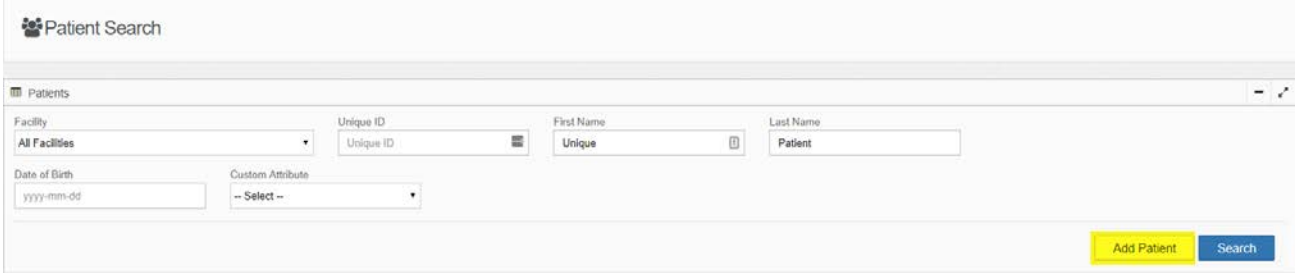

#### 4.1.3.13 **Identifiers and Audit information – Audit Information**

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

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

### 4.1.4 Add a New Patient

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

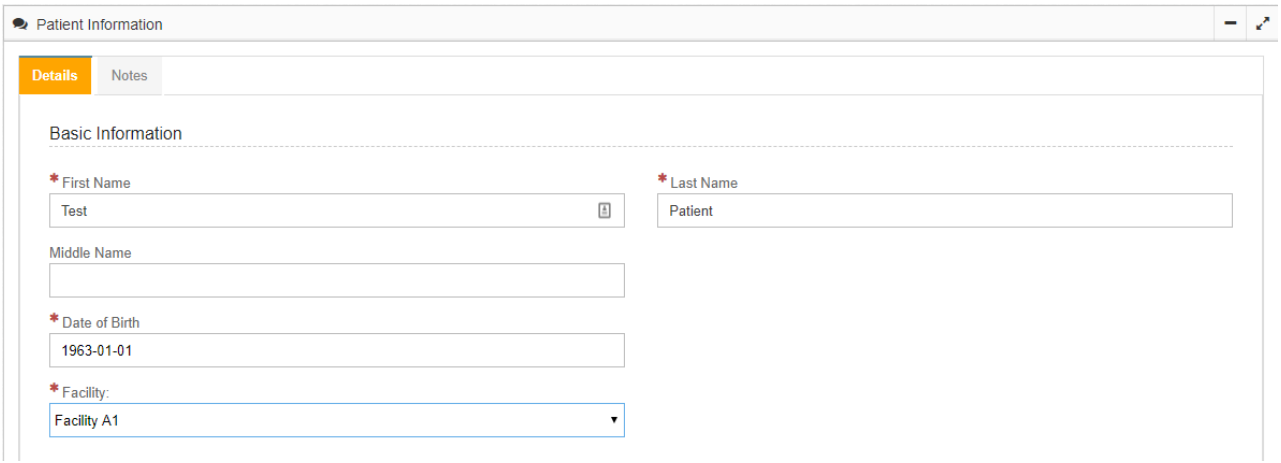



The system will open a new **Patient View** page with two sections **Patient Information** and **Additional Information** needing to be captured.

#### 4.1.4.1 Patient Information – Basic Information

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

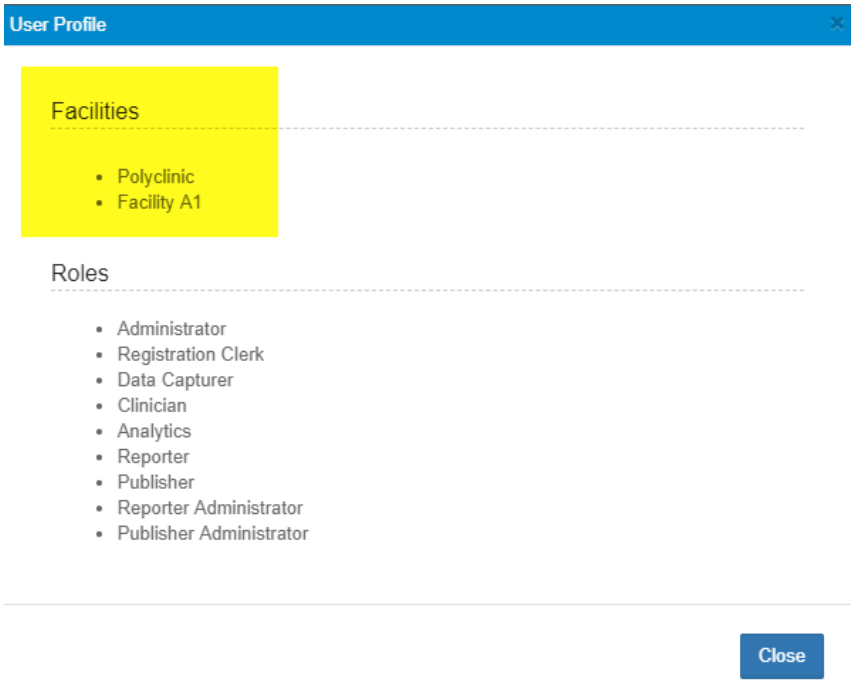
To enter patient information, **enter text** in the corresponding fields (e.g., **First Name**, **Last Name**). Or click the **arrow** in a selected field to display a list of values, and select one value from the list. Please ensure that all elements with a red asterisk (mandatory) are captured.




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

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

All fields marked with a red star (*) are compulsory fields that must be completed before proceeding.
Greyed out fields are automatically filled by the system and cannot be edited.
You will only be able to add patients to facilities you have been granted access to. To view which facilities, you have been granted access to, click on your user name in the footer of the page.



#### 4.1.4.2 Patient Information - Patient Demographics

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

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

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

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

Patient Demographic Information

| | | |
|---|---|---|
| Medical Record Number | HPRS//123/123434 * | |
| Medical Record Number Type | DR-TB | |
| Patient Identity Number | 4974994161 * | |
| Identity Type | National identity | |
| Gender | Male | |
| Marital Status | Single | |
| Employment Status | Unemployed | |
| Occupation | | |
| Language | English | |
| Address | | |
| Address Line 2 | | |
| City | | |
| State | | |
| Postal Code | | |
| Patient Contact Number | | |
| Country of Birth | Philippines | |

#### 4.1.4.3 Additional Information – Primary Condition Group

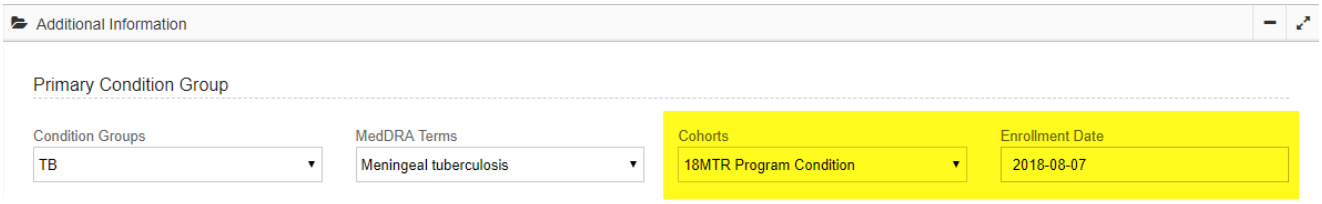
The **Primary Condition Group** section allows you to assign a patient to a patient condition based on their medical condition (e.g., TB, HIV, and Malaria). The patient must be assigned to a patient condition group for their data is to be included when using the **Analytical Portal**.

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

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


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.

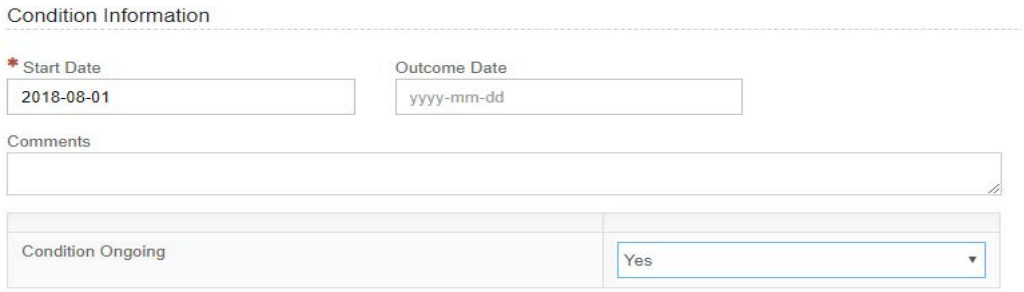

You will only be able to allocate patients to cohorts that are assigned to this specific condition group.



#### 4.1.4.4 Additional Information – Condition Information

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

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




#### 4.1.4.5 Additional Information - Encounter information

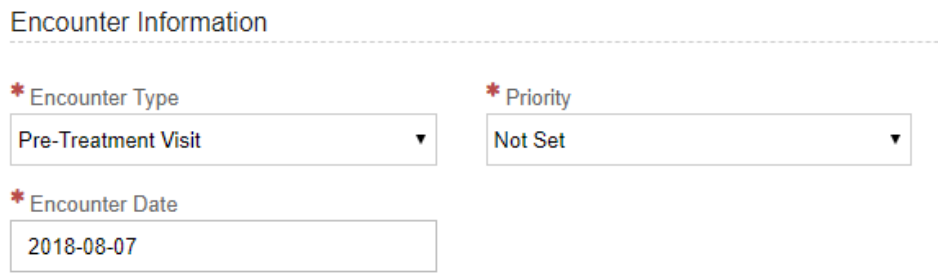

**PViMS Term - Encounter**

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

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

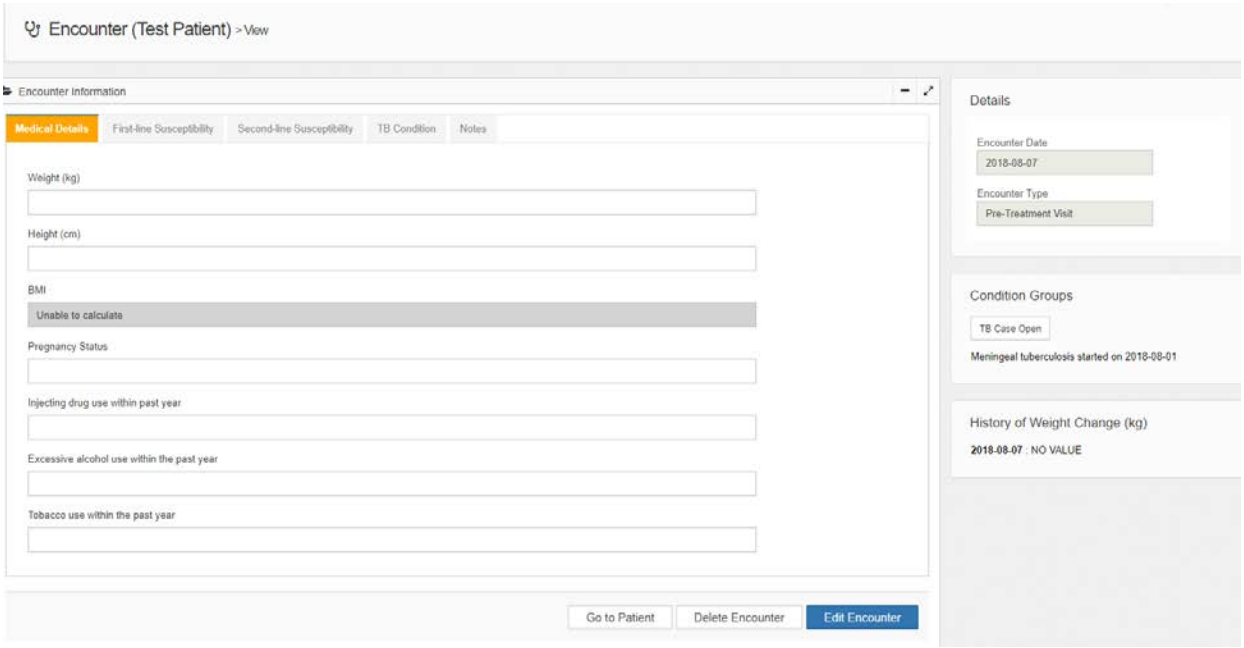
Set the priority for the encounter by clicking on the **arrow** in the **Priority** field. The system will display a **Priority** list. Select a **Priority** option from the list.

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



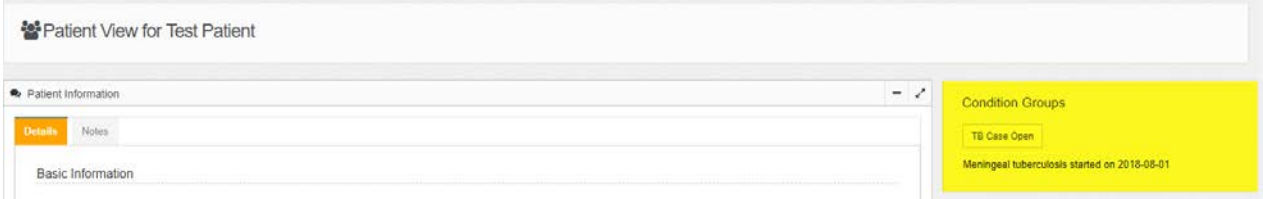

When all information for the page has been entered, click the **Save** button or click the **Cancel** button to cancel the action.

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



### 4.1.5 **Condition Groups**

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

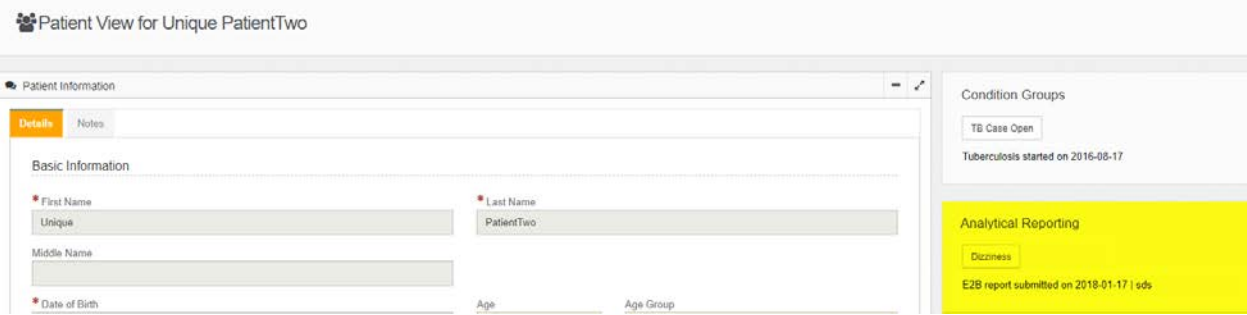




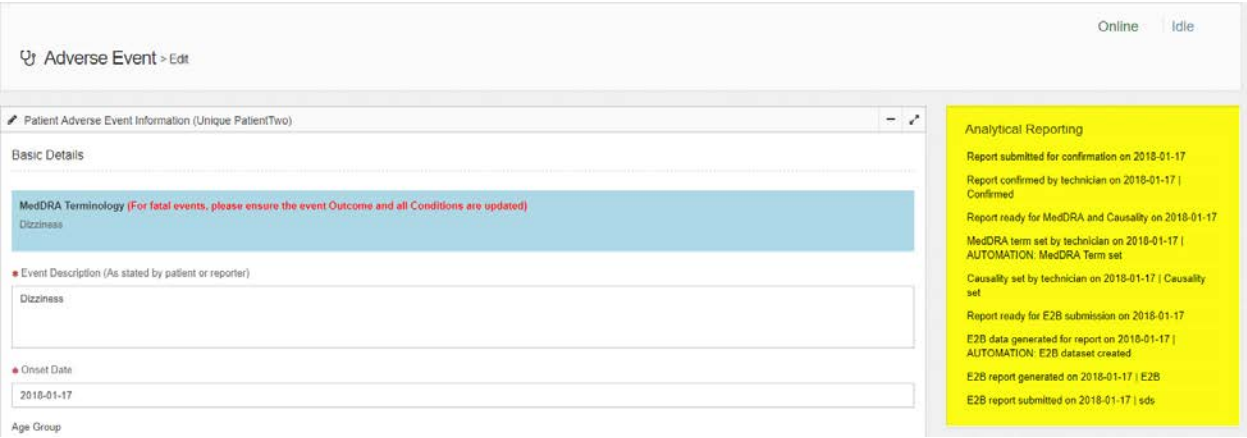
Only **Open** conditions will be displayed on the **Patient View** page.
A patient can be assigned to more than one condition group at the same time (e.g., the TB condition group and the HIV condition group).

### 4.1.6 **Analytical Reporting**

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



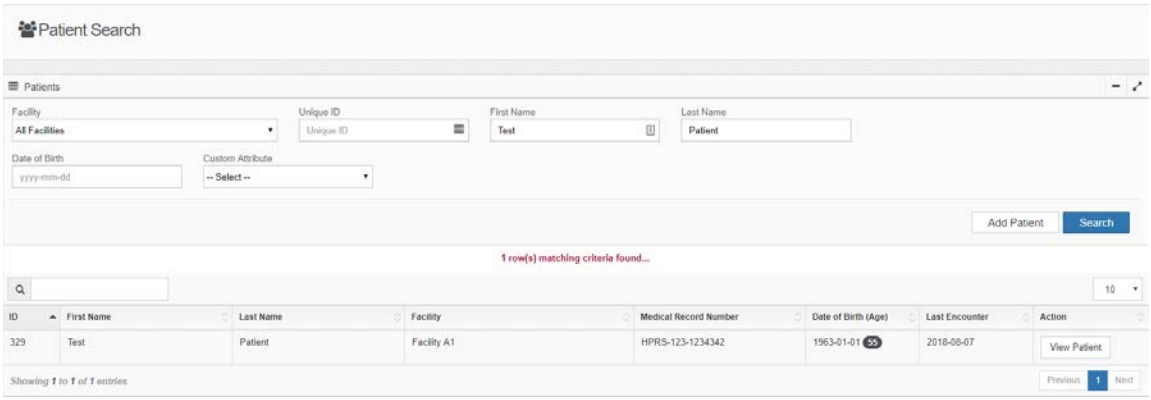

By clicking on the adverse event button, the system will navigate you to the adverse event page for this event where you will be able to view a comprehensive history of pharmacovigilance activities for this event.



### 4.1.7 Add or Edit Patient Information

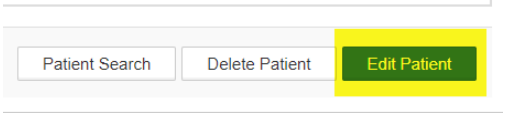
You can add or edit patient information at the **Patient View** page. But first, you need to locate the patient you would like to amend by searching for the patient using the Patient Search function. Click on the patient menu to access the **Patient Search** screen.

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




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

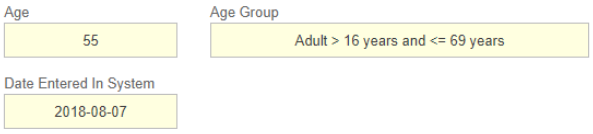
Click the **Edit** button and the system will display a **Patient View** page that can be edited.




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

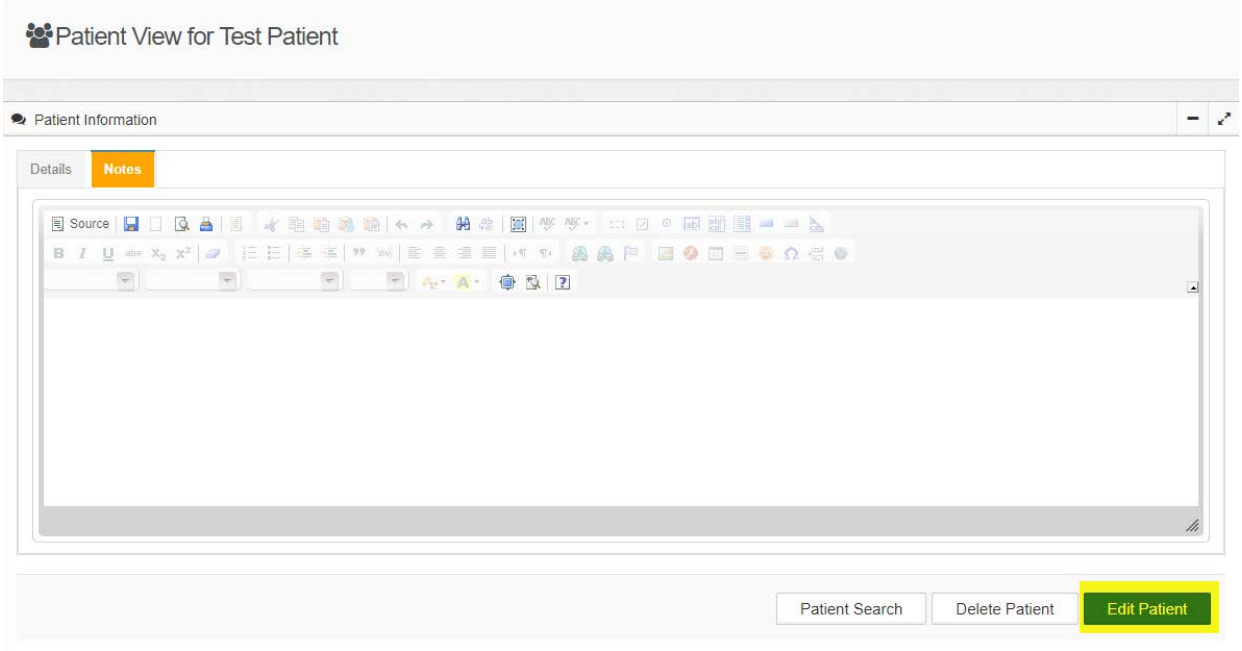
After clicking the **Save** button the system will update and display the **Patient View** page with the updated information and a **Patient Saved Successfully** confirmation message

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



#### 4.1.7.1 Additional Notes

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



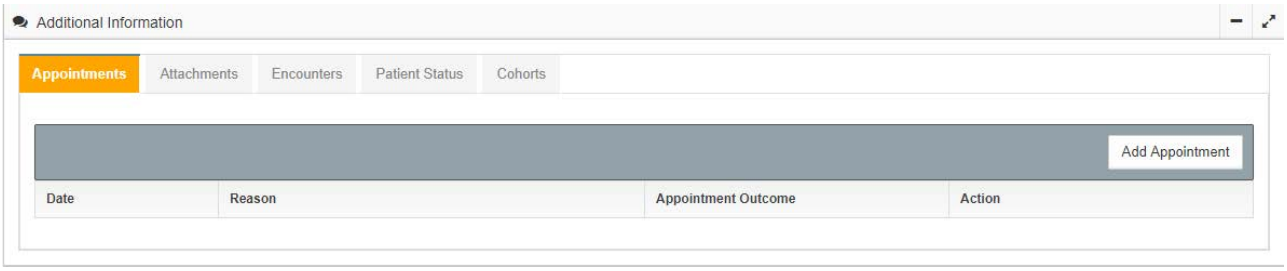

Click the **Edit** button and the system will allow you to edit the generic notes for the patient.

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

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

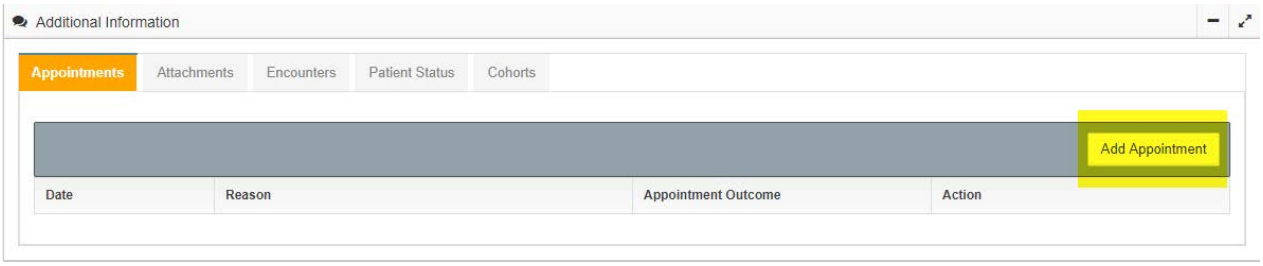
### 4.1.8 Add or Edit Additional Information

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

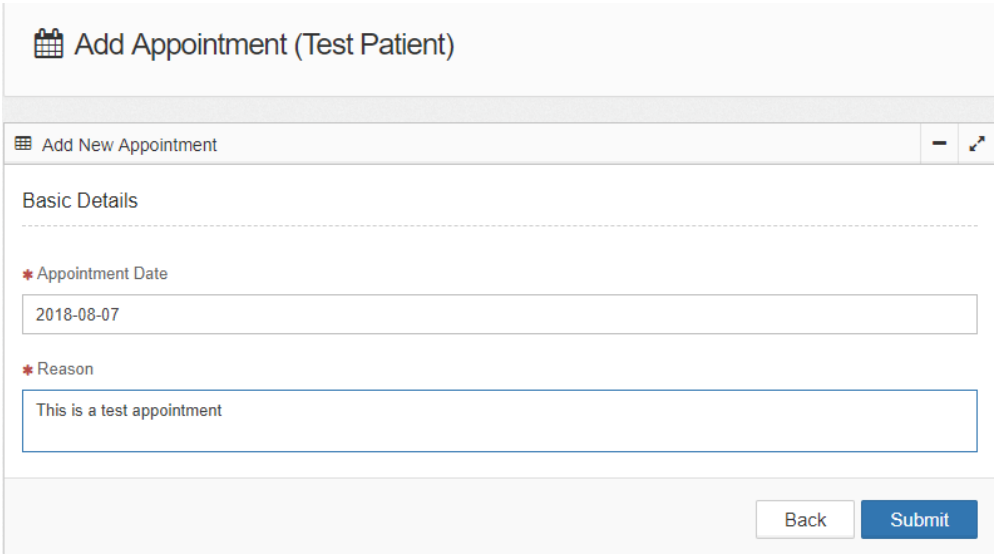



#### 4.1.8.1 Add Appointments

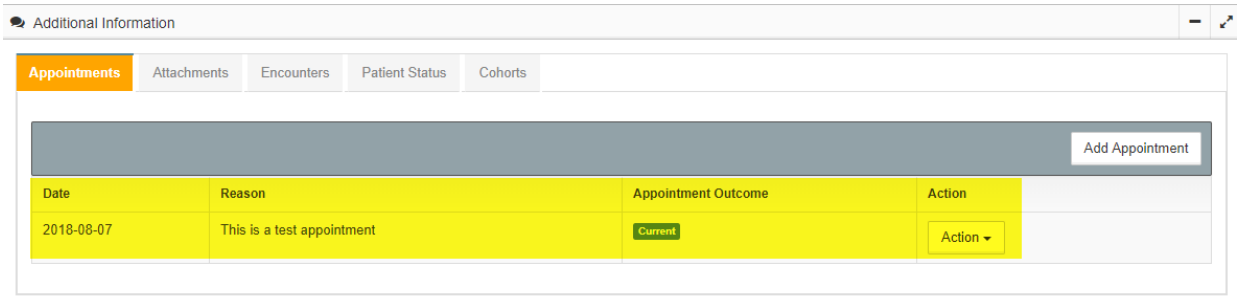
At the **Appointments** tab click the **Add Appointments** button, after which the system will open the **Add Appointment** page




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

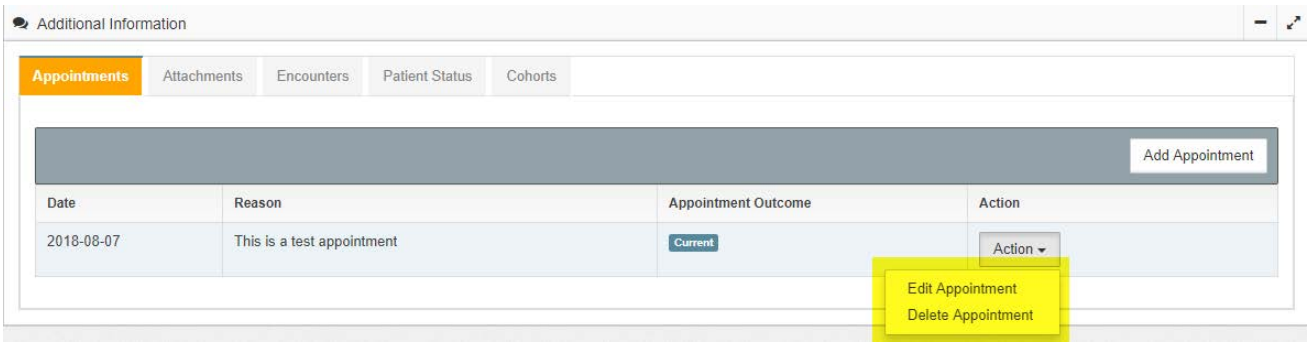



- After clicking on **Submit** the system will display the updated table under the **Appointments** tab.



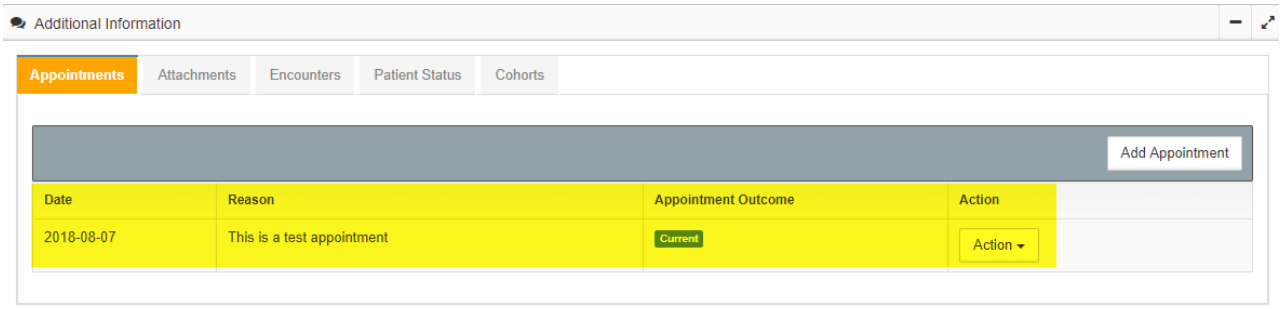

### 4.1.8.2 Edit an Appointment

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



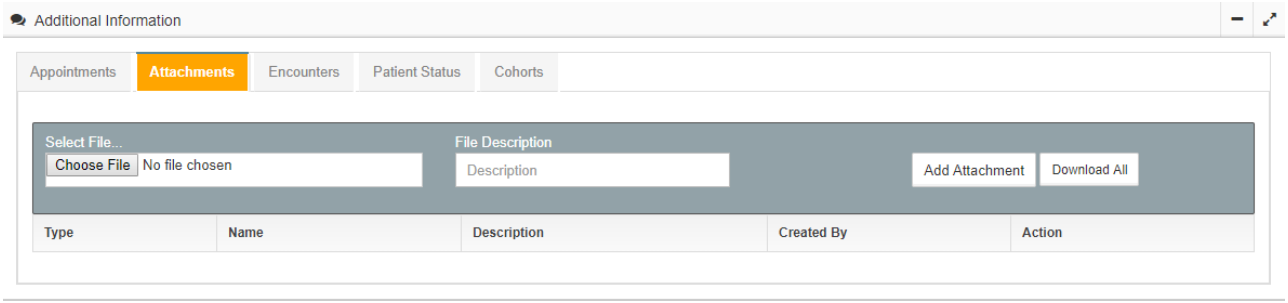
Make changes as needed then click the **Submit** button to complete the edit, or click the **Back** button to undo it and return to the previous page.

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



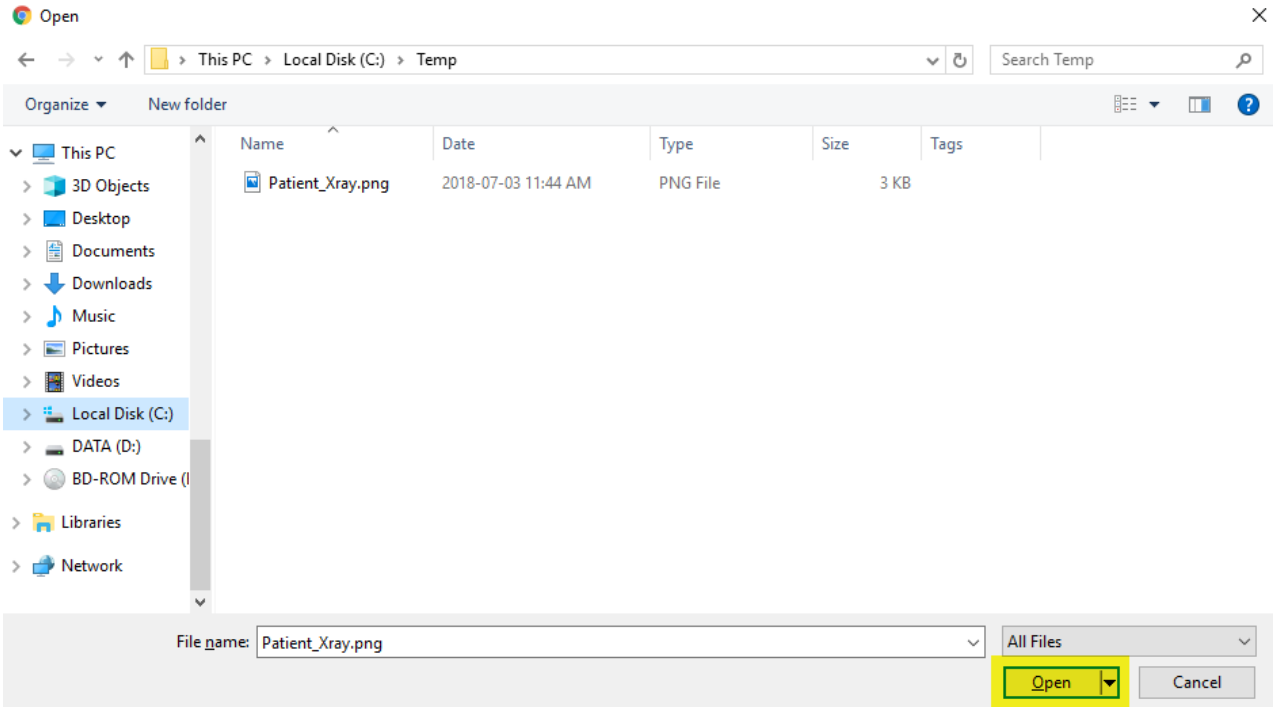
### 4.1.8.3 Add an Attachment

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



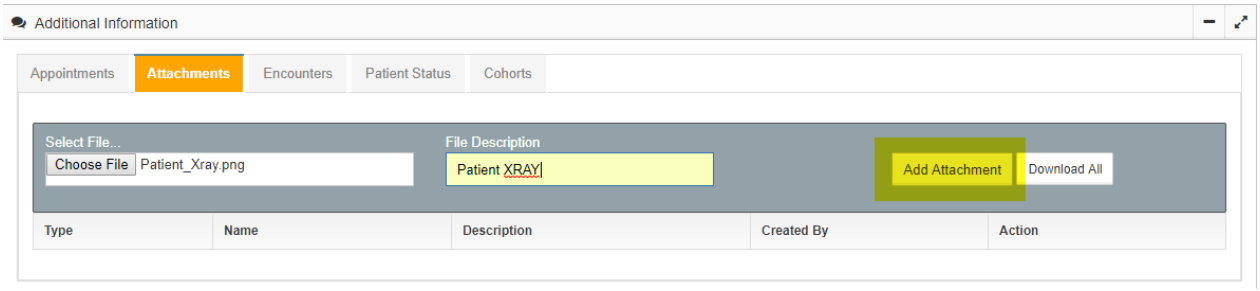

To add an attachment, click the **Choose File** button. The system will allow you then to search for the file to be attached.

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

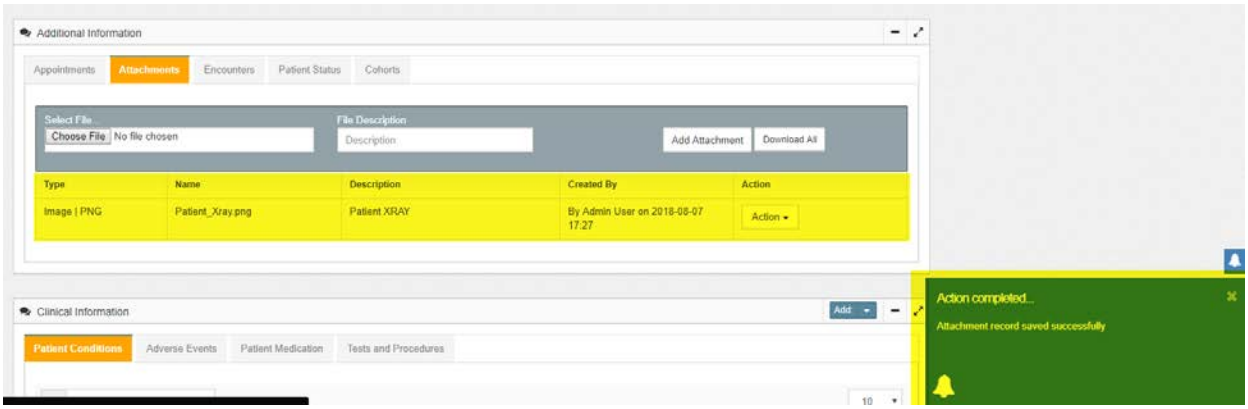



The system will return to the **Attachments Table** page and will reflect that the file that was selected. You can add a description in the **File Description** field.

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



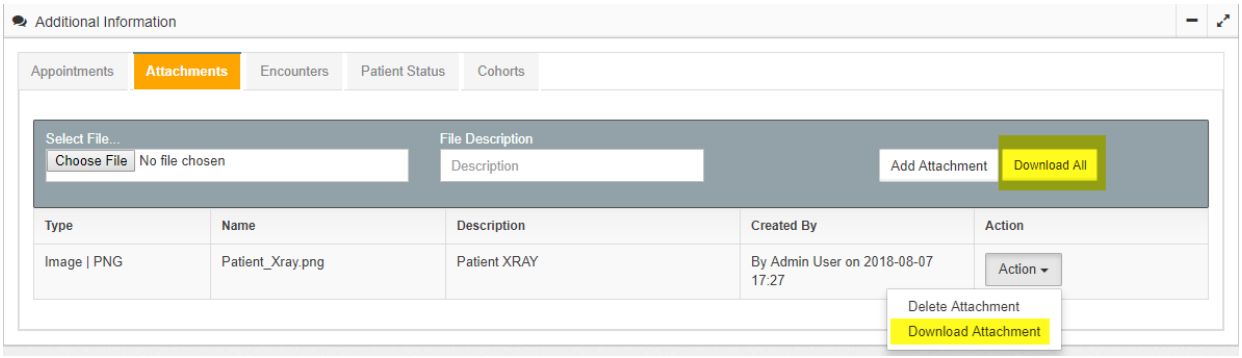

The system will show a confirmation message and an updated **Attachments Table** listing the newly added attachment.



#### 4.1.8.4 Download an Attachment

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

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




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

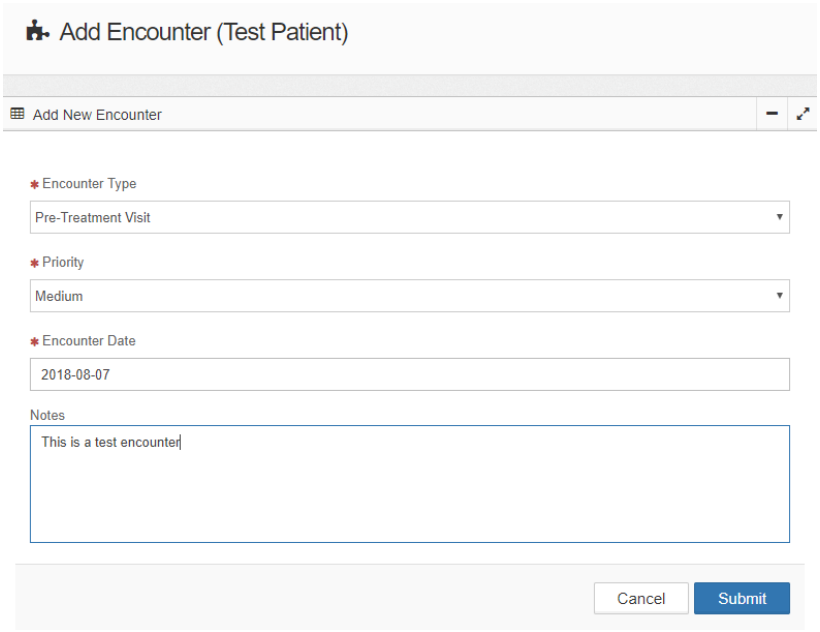
#### 4.1.8.5 Add an Encounter


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

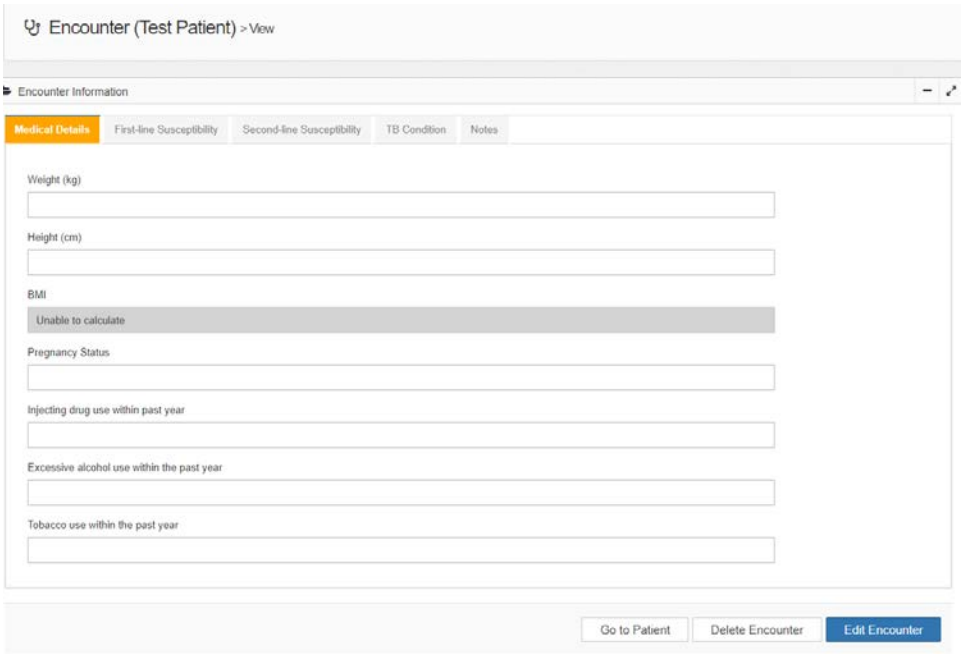
Select the **Encounters Tab** to view a list of encounters.


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


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



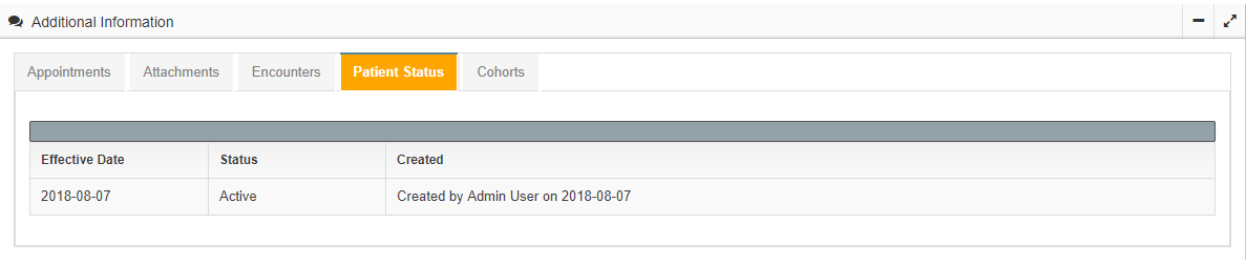

- Click the **Submit** button or click the **Cancel** button to undo the action and return to the previous page.
- After clicking the **Submit** button, the system will display **Encounters View** page where you can **Add** or **Edit** clinical information obtained during the encounter.



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

#### 4.1.8.6 Patient Status – Read Only

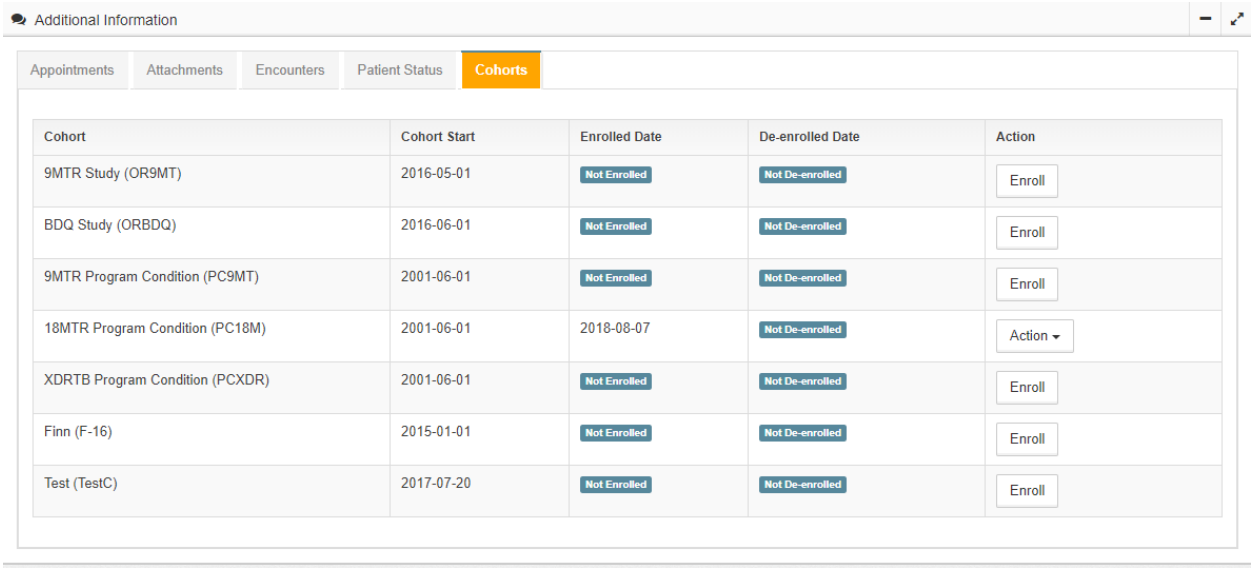
Select the **Patient Status Tab** to view a history of status changes.



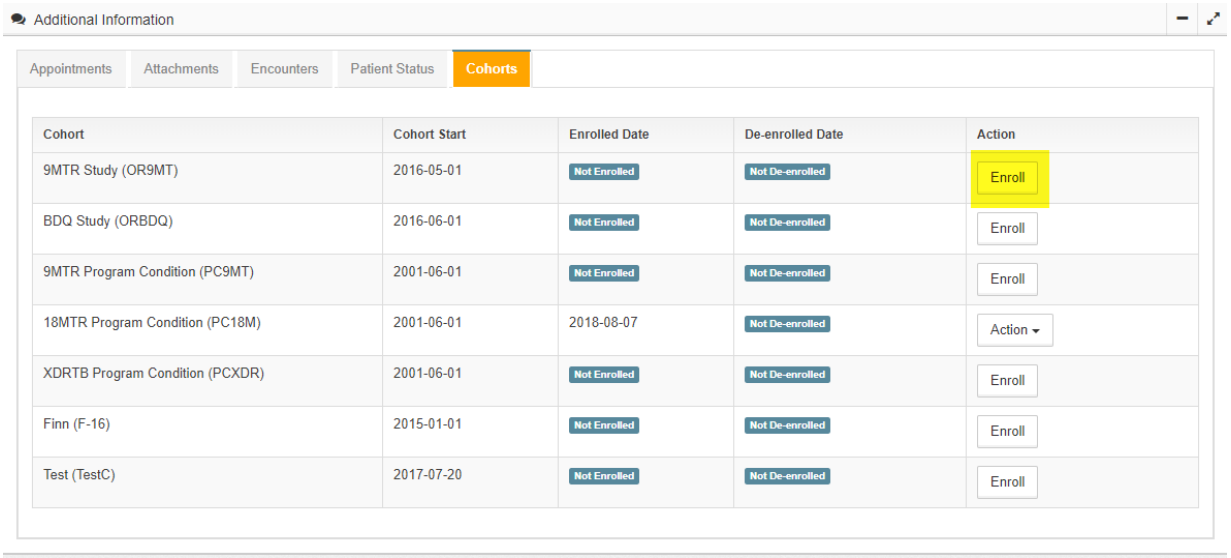

The information in the **Status Table** is view only, and cannot be updated from this page. A patient's status will change from **Active** to **Deceased** when the system is updated in the **Condition Group** section in the **Encounter View** (e.g., the patient completed treatment, died, or lost to follow-up).

### 4.1.8.7 Cohort Enrolment

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



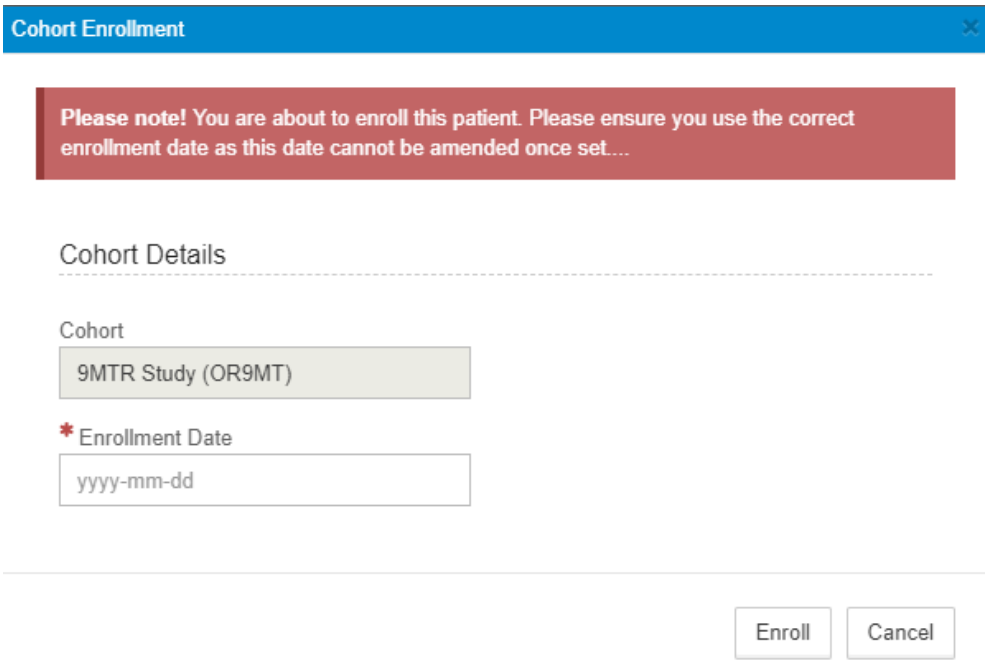

To enroll a patient in a cohort, first locate the **Cohort** in the table. Click the **Enroll** button in the action column for the cohort in which to enroll the patient.



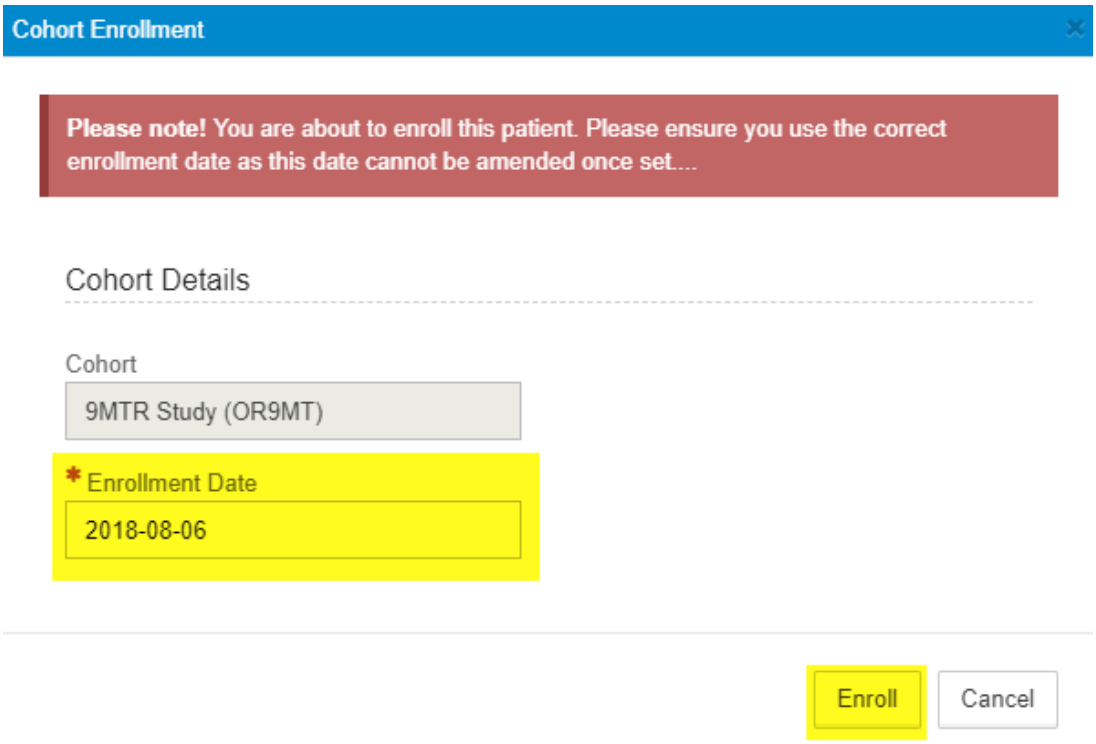


You may only enroll the patient into a cohort that is assigned to the same condition group the patient belongs to. So, for instance, an HIV patient may not be enrolled into a TB cohort.

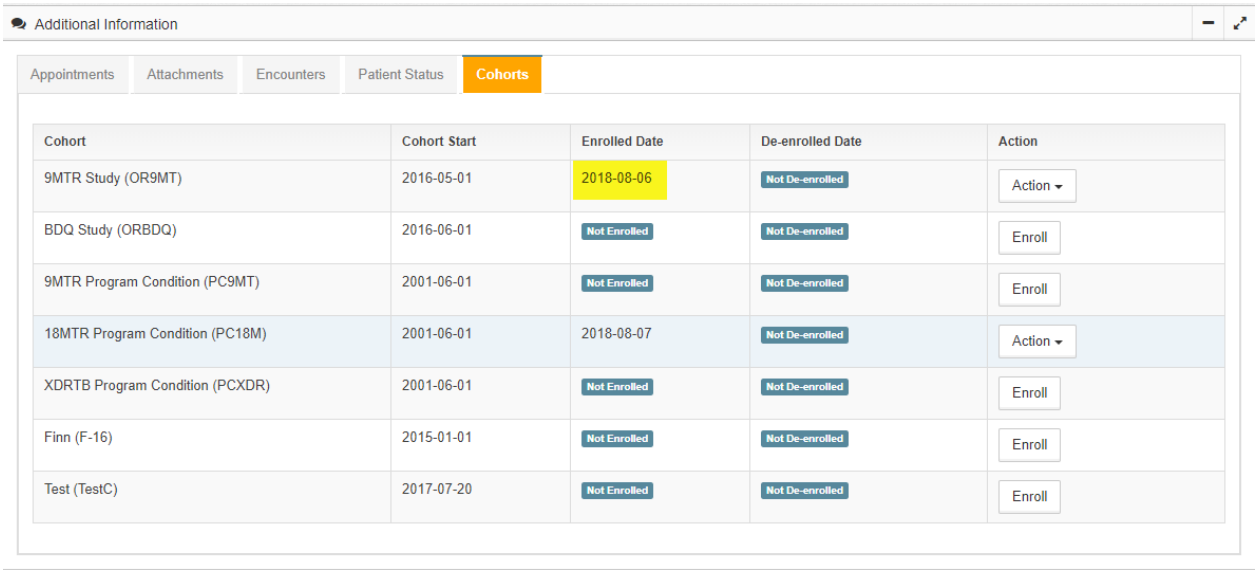
The system will display a **Cohort Enrollment** confirmation box (Figure 81).




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



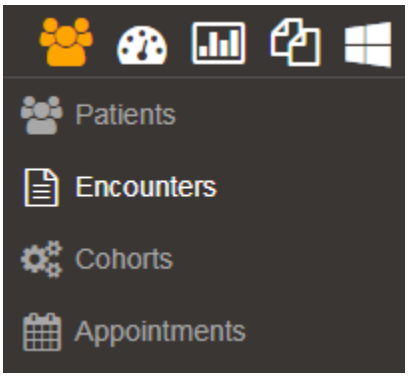

After clicking on the enroll button the system will display the updated information in the Cohort table.



## 4.2 Encounters

### 4.2.1 Search for an Encounter

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

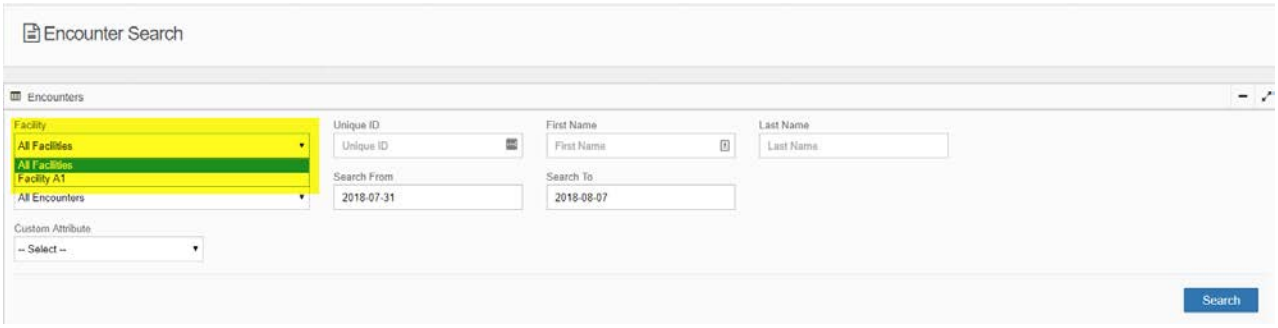



There are six ways to search for an encounter. You can search by:

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

#### 4.2.1.1 Search by Facility

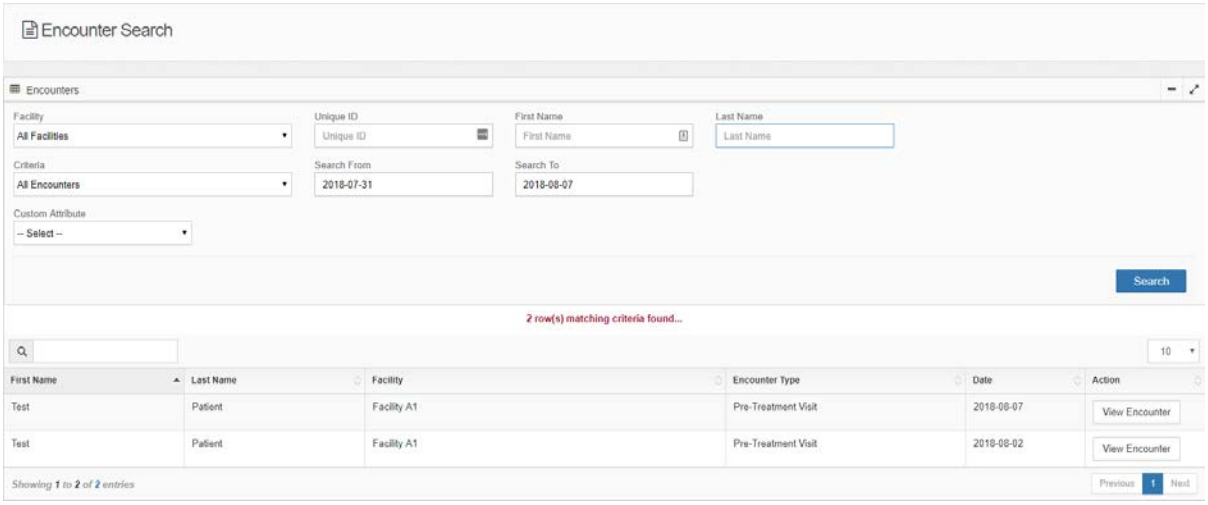
- Click the **arrow** in the **Facility** field to select from the facility drop down list.
- Select the facility you would like to search against specifically or select **All Facilities** if you would like to search against all facilities.
- Enter the **Search From** date and the **Search To** for the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





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

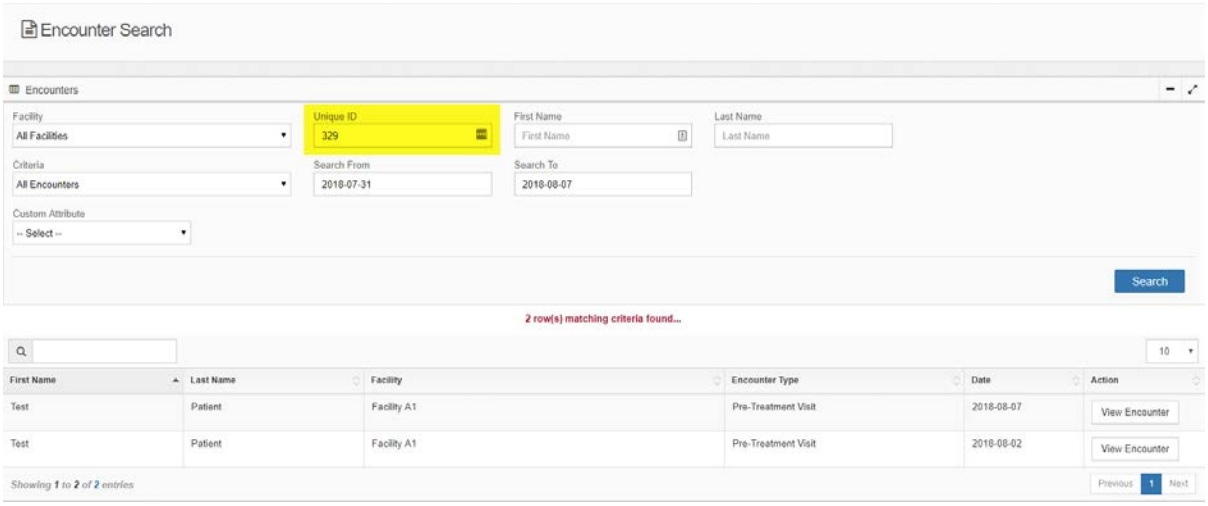
The system will display a list of encounters according to the filter selected.




### 4.2.1.2 Search by Patient Unique ID


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

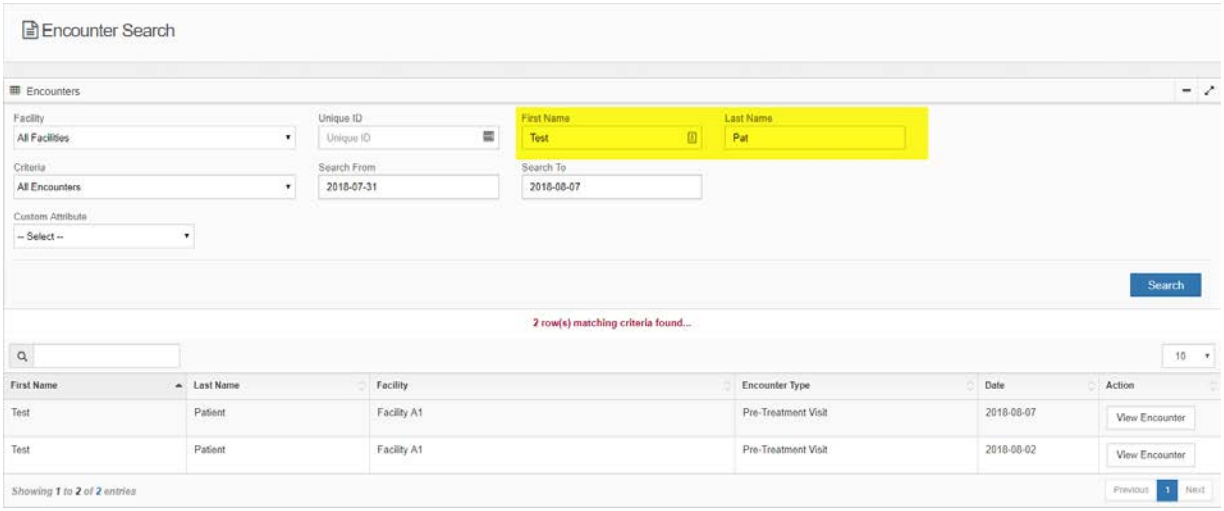
- If you know the patient's unique ID, enter it in the **Unique ID** field.
- Enter the **Search From** date and the **Search To** for the date range to search as it is compulsory to enter a date range.
- Click the **Search** button.



#### 4.2.1.3 Search by First Name or Last Name

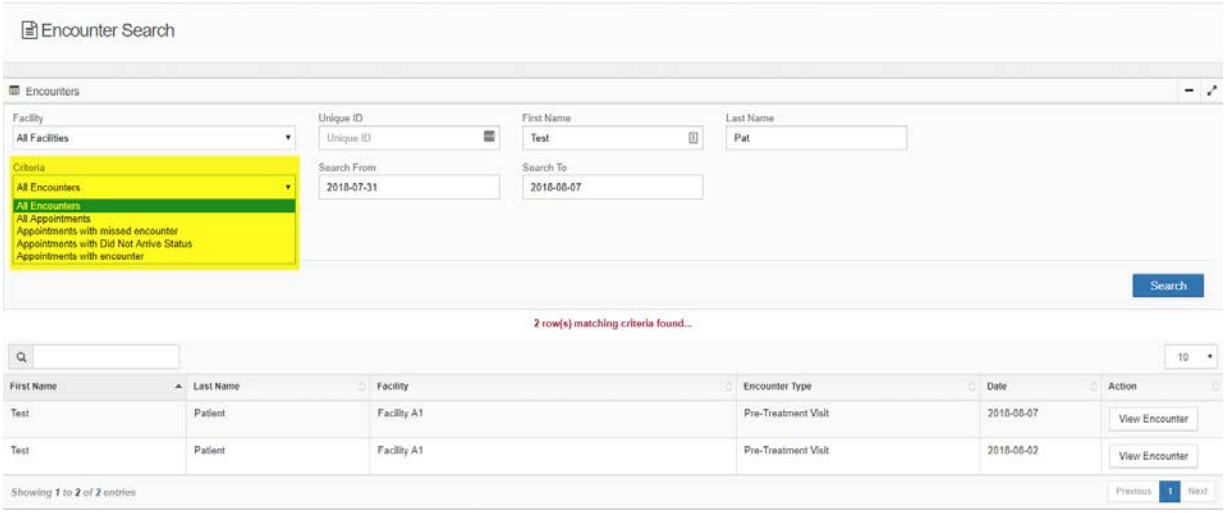
- You can also search by the patient's **First name** or **Last Name**. Enter the name(s) in one or both of these areas.
- Enter the **Search From** date and the **Search To** for the date range to search as it is compulsory to enter a date range.
- Click the **Search** button.


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



#### 4.2.1.4 Search by Criteria

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

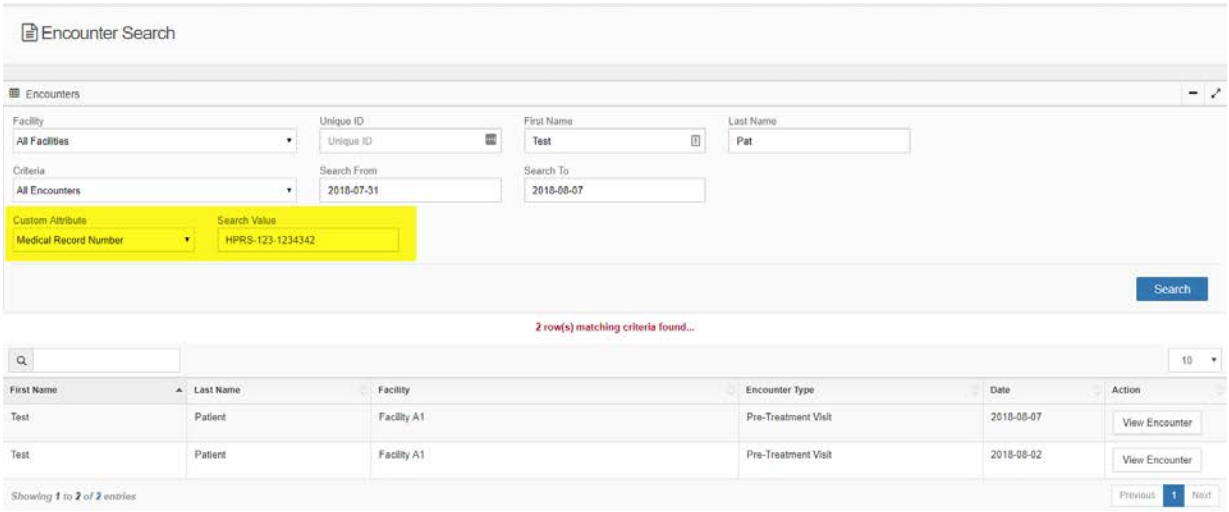


#### 4.1.4.3 Search by Custom Attribute

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

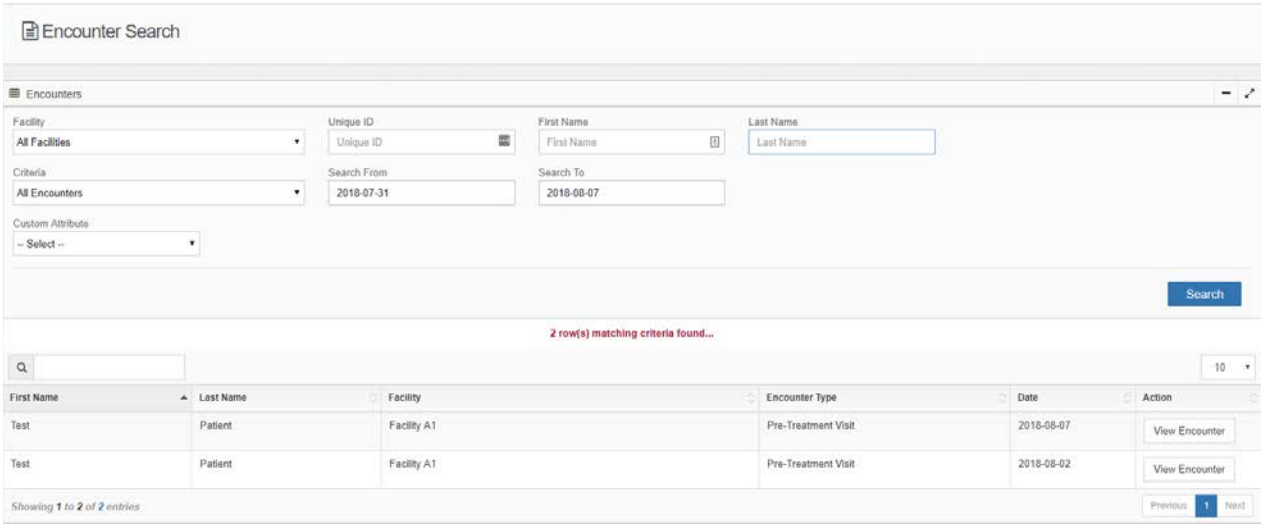

Custom attributes can be activated for filtering by the system administrator. Please consult your administrator if you would like to activate the ability to filter by a specific attribute.

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



### 4.2.2 View an Existing Encounter

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

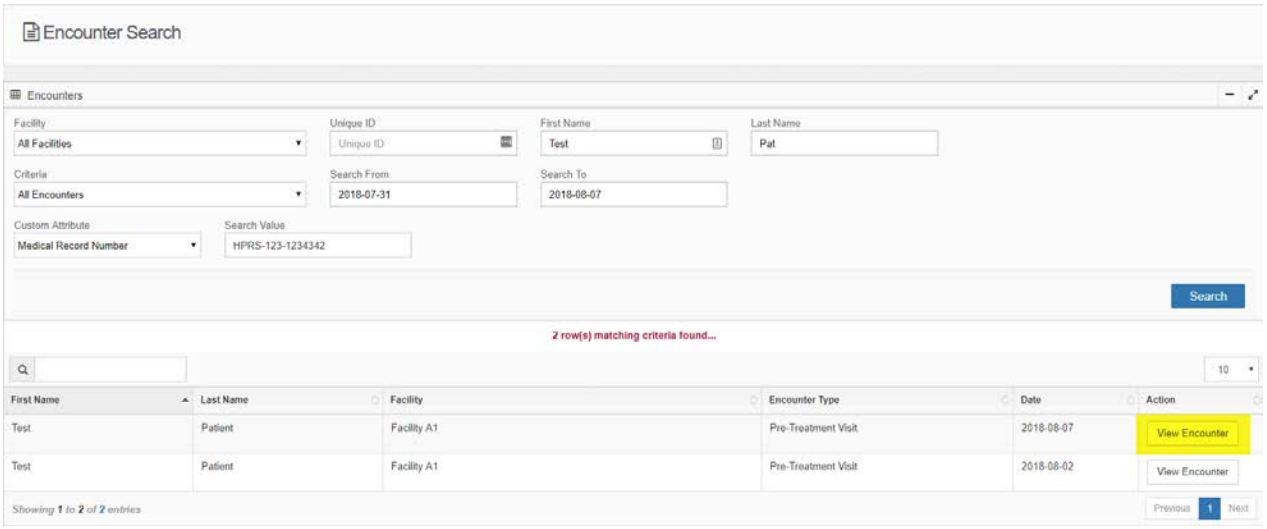



The columns in the encounter table are described below:

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


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


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

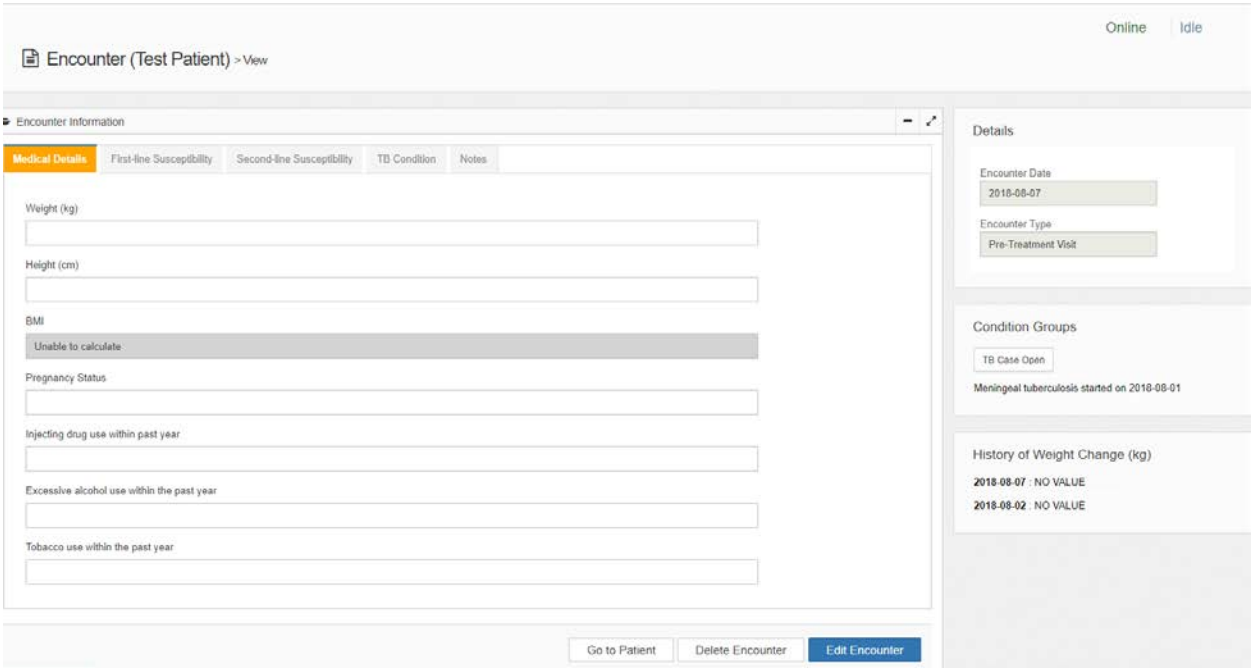



- The system will then open the **Encounter View.**

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

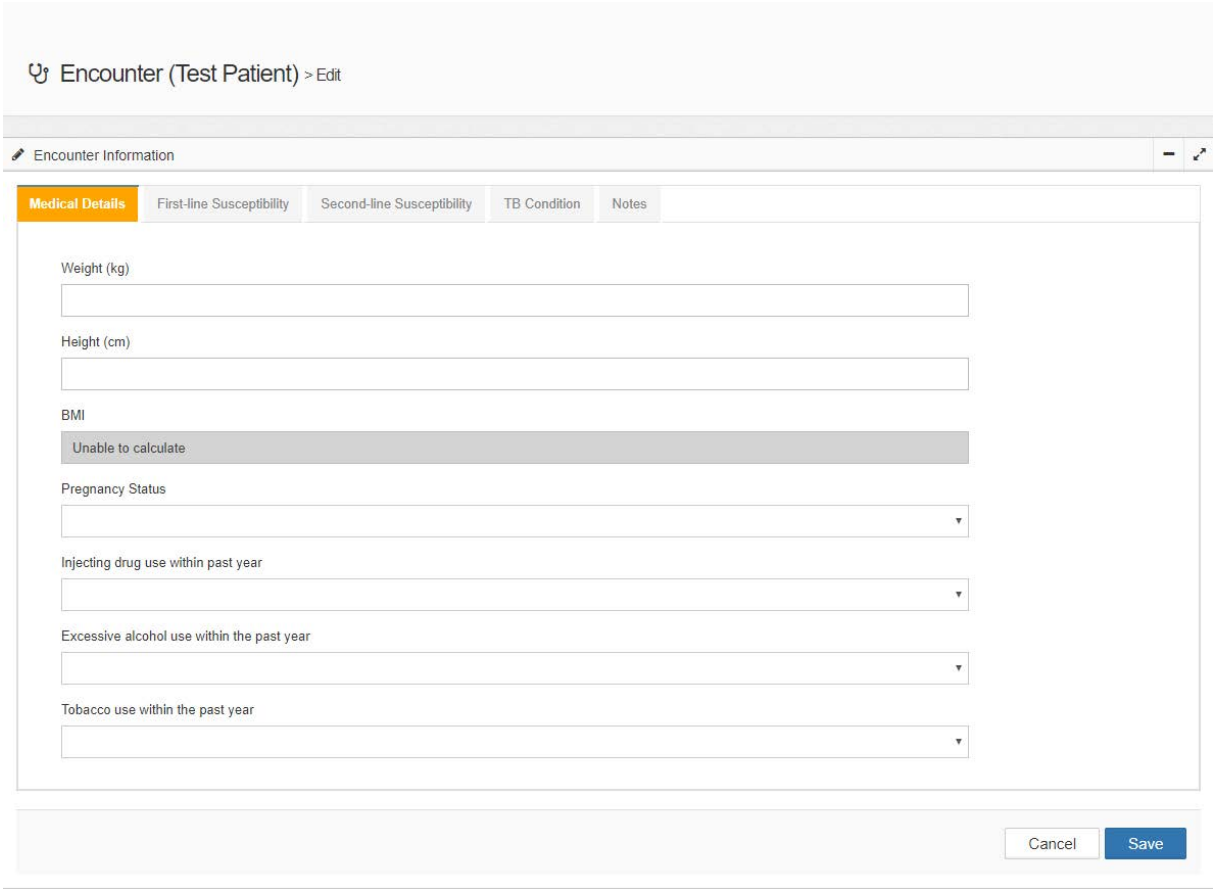
- Medical Details
- First-Line Susceptibility
- Second-Line Susceptibility
- TB Condition
- Notes


**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.


Online
Idle
Encounter (Test Patient) > View
Encounter Information
Medical Details
First-line Susceptibility
Second-line Susceptibility
TB Condition
Notes
Weight (kg)
Height (cm)
BMI
Unable to calculate
Pregnancy Status
Injecting drug use within past year
Excessive alcohol use within the past year
Tobacco use within the past year
Go to Patient
Delete Encounter
Edit Encounter
Details
Encounter Date
2018-08-07
Encounter Type
Pre-Treatment Visit
Condition Groups
TB Case Open
Meningeal tuberculosis started on 2018-08-01
History of Weight Change (kg)
2018-08-07 : NO VALUE
2018-08-02 : NO VALUE

### 4.2.3 **Add or Edit Encounter Information**

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



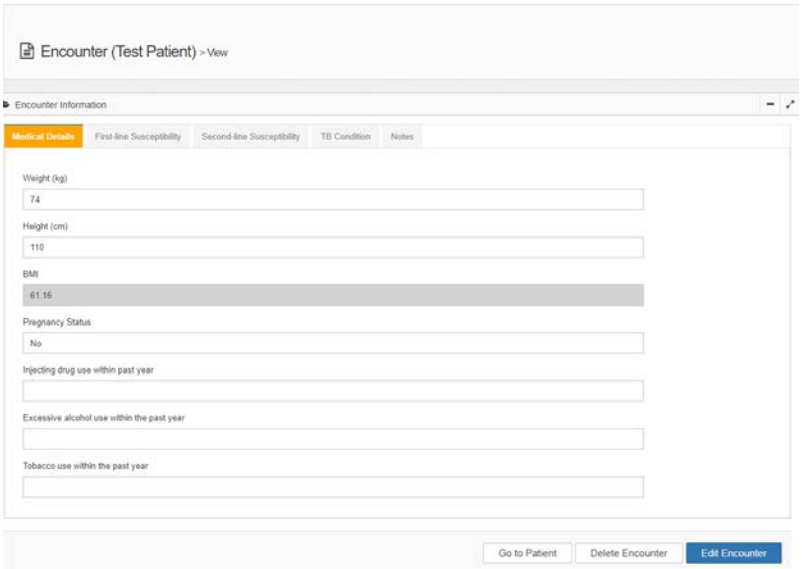
#### 4.2.3.1 **Medical Details**

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

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

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

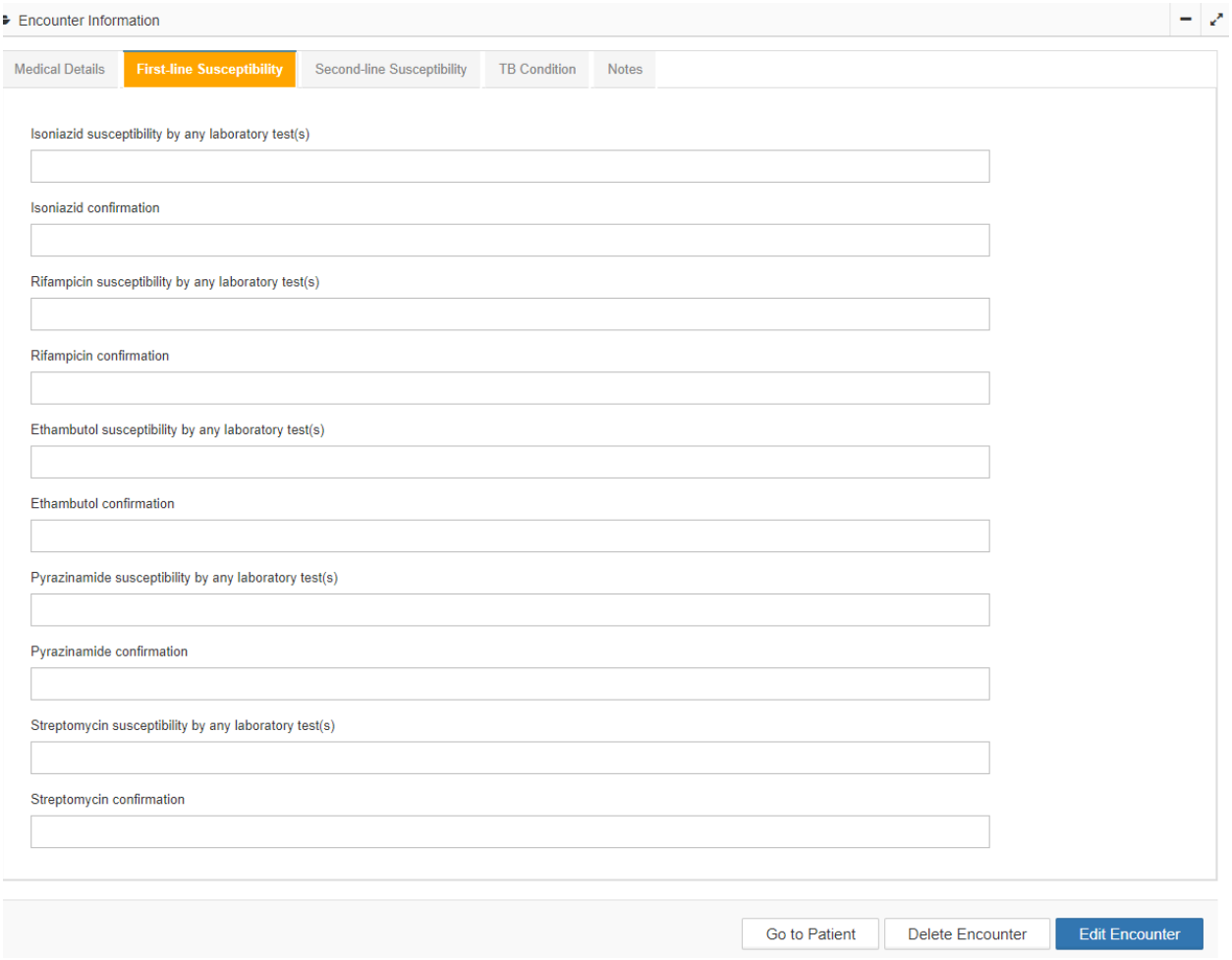
After clicking the **Save** button, the system will update the **Medical Details** page.



### 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 |

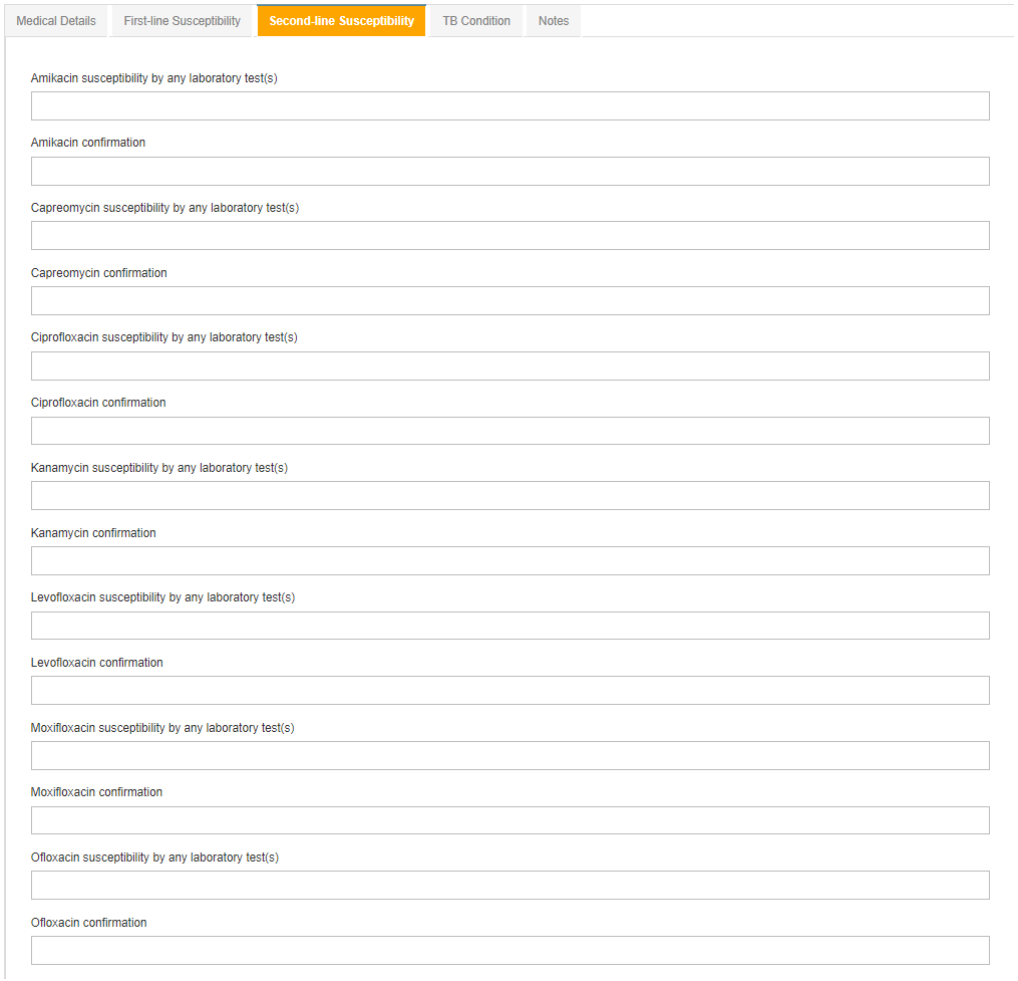
Add information or make changes to the fields on the page as appropriate. Click the **Save** button to continue or click the **Cancel** button to undo the action and return to the previous page.

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

#### 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 |

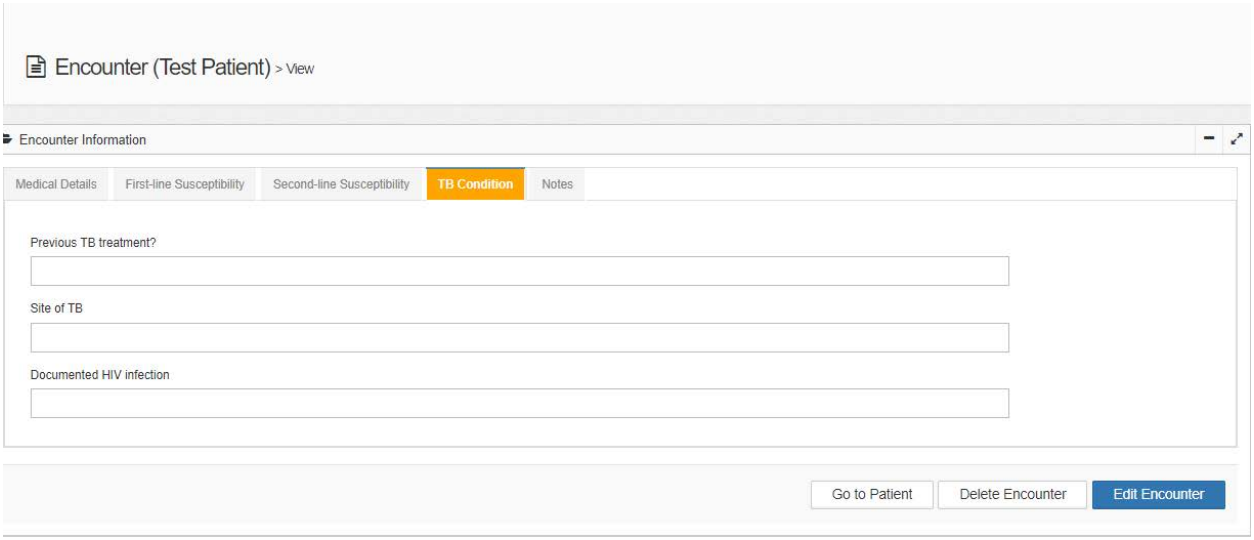
Add information or make changes to the fields on the page as appropriate. Click the **Save** button to continue or click the **Cancel** button to undo the action and return to the previous page.

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

#### 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:

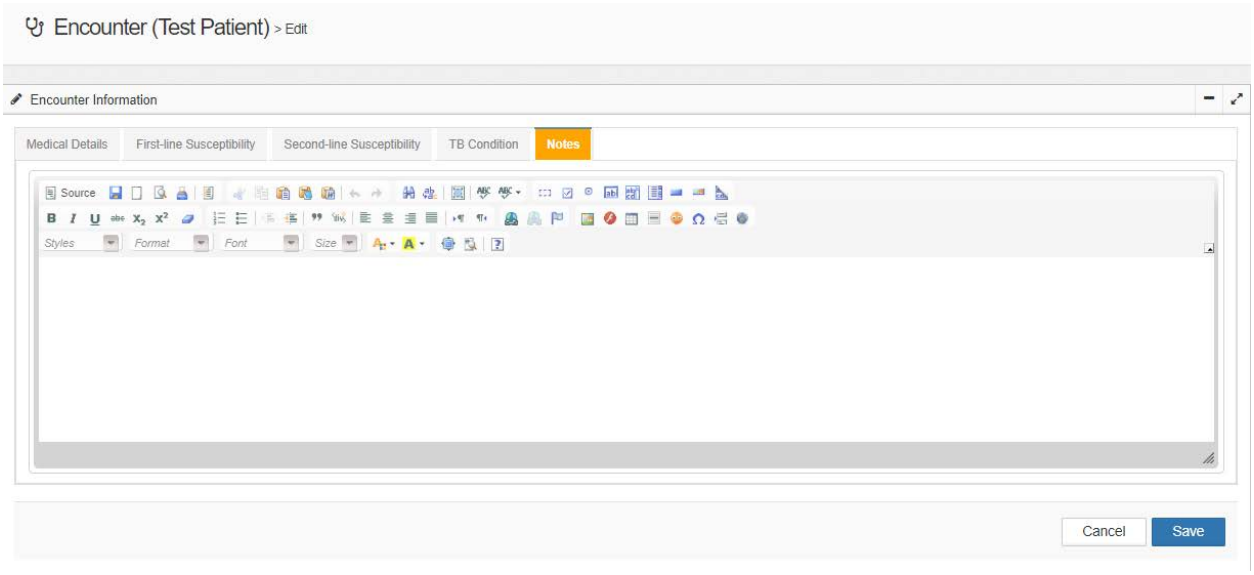
| | |
|---|---|
| Previous TB treatment? | Dropdown list of responses; No, Unknown, Yes |
| Site of TB | Dropdown list of anatomical sites |
| Documented HIV infection | Dropdown list of responses; No, Unknown, Yes |

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.

#### 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.



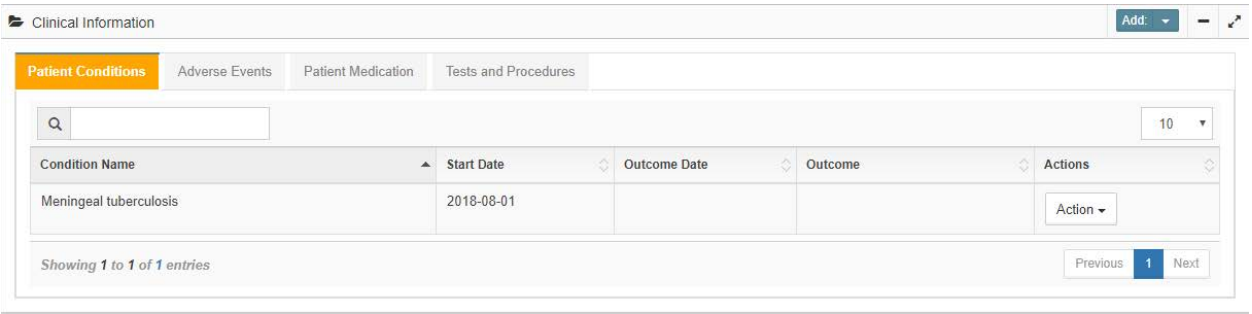

Add information or make changes to the notes as appropriate. Click the **Save** button to continue or click the **Cancel** button to undo the action and return to the previous page.

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

### 4.2.4 Add or Edit Clinical Information

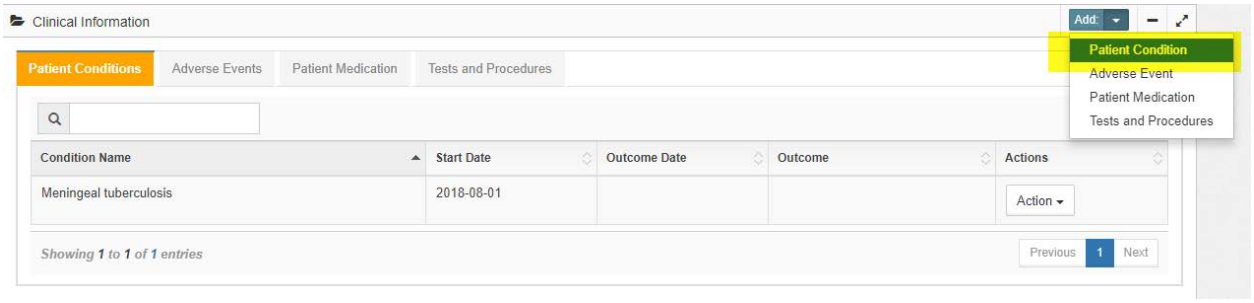
The Clinical Information section is divided into four tabs:

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



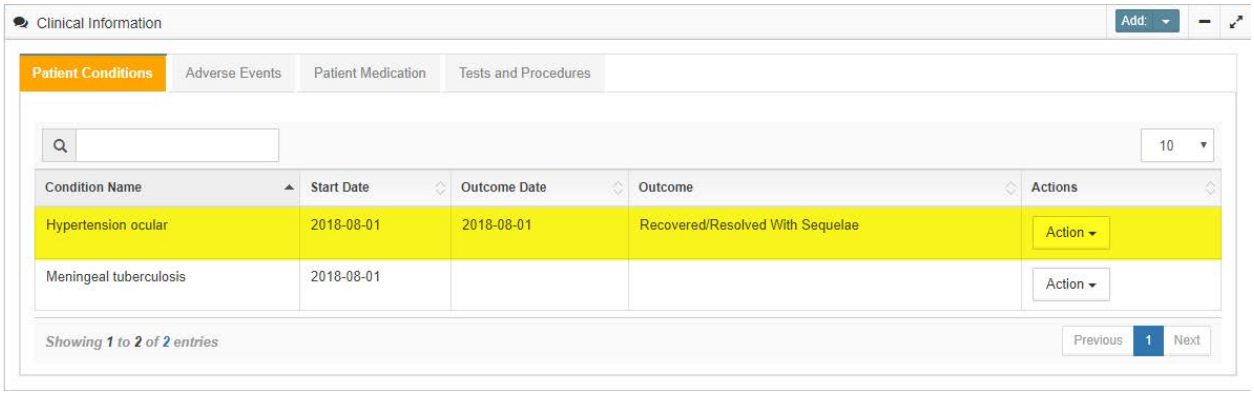

#### 4.2.4.1 Add Patient Condition

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




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


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



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

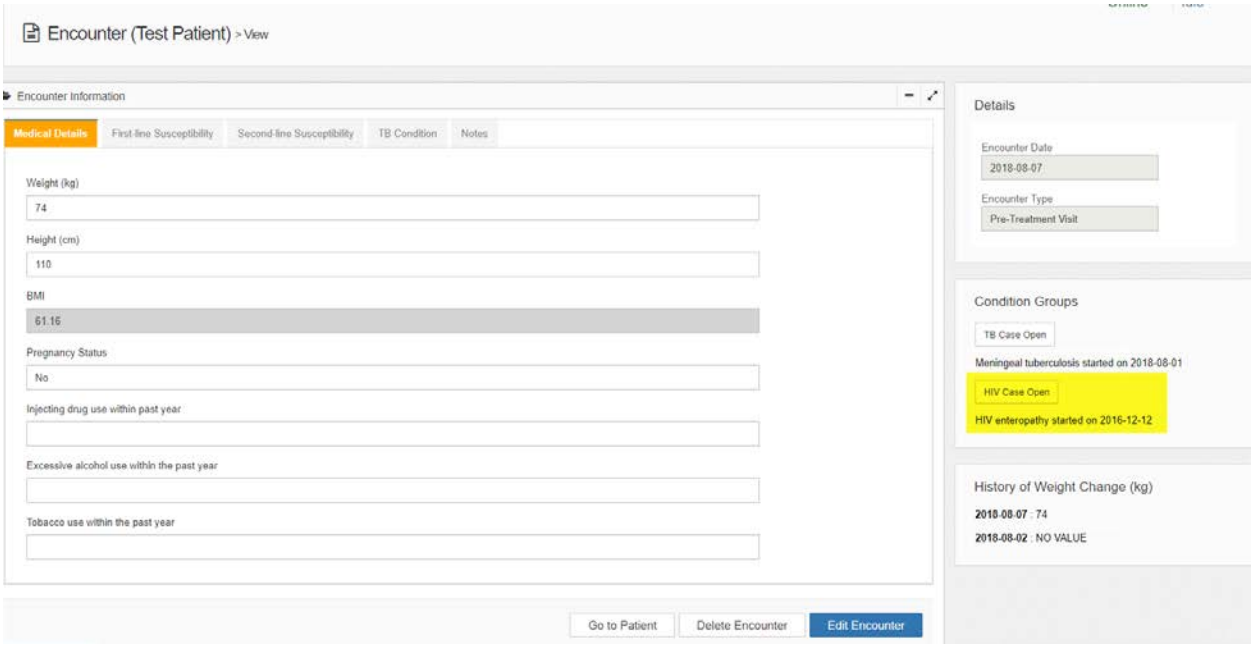
| | |
|---|---|
| Term Type | Dropdown list of MedDRA term hierarchy; Lowest level term, Preferred term, High level term, High level group term, or System organ class |
| Find By Term | Text field; Enter name of condition |
| Term Results | System generated list; Select appropriate term |
| Condition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

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

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

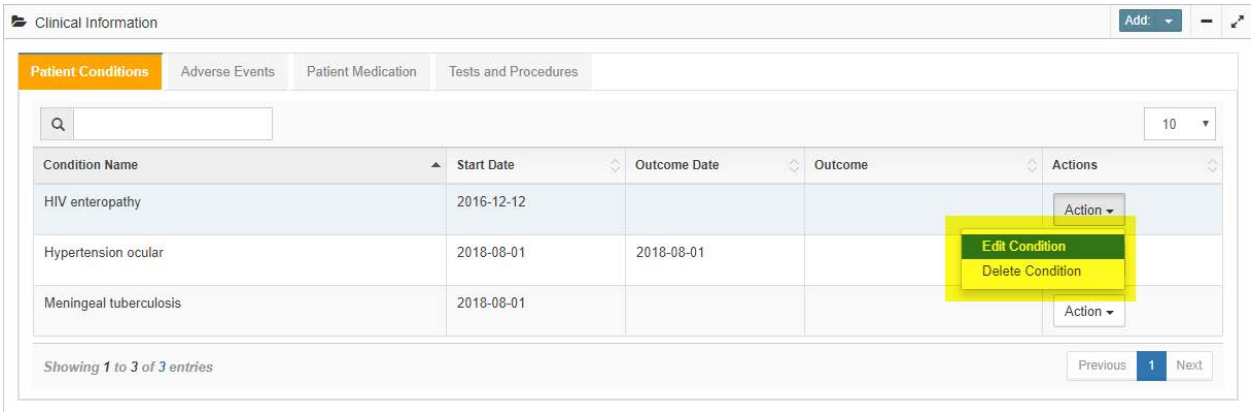
At the most specific level, called “Lowest Level Terms” (LLTs), there are more than 70,000 terms that parallel how information is communicated. These LLTs reflect how an observation might be reported in practice. This level directly supports assigning MedDRA terms within the PViMS database.

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



### 4.2.4.2 Edit a Patient Condition

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




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

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

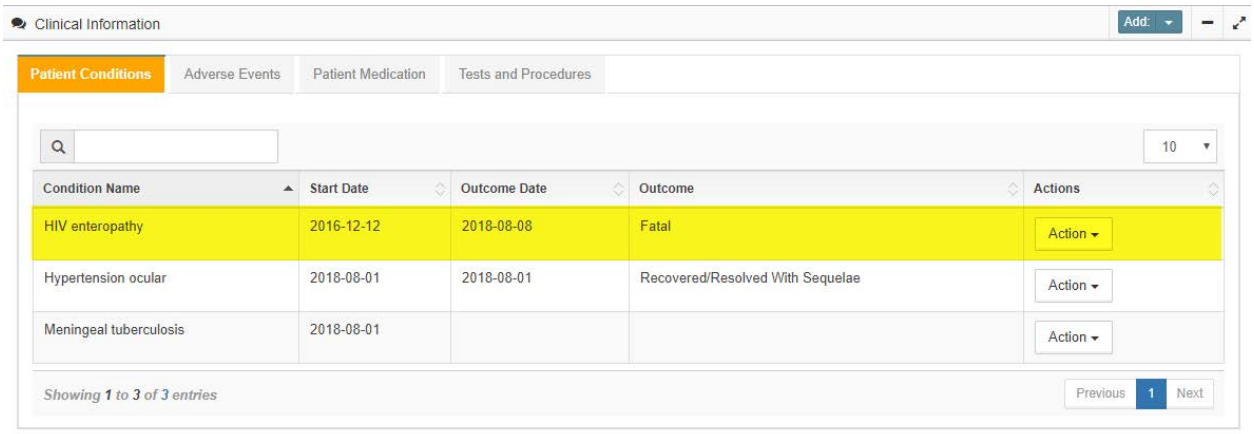
Click the **Submit** button or click the **Back** button to cancel the action and return to the previous page.

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

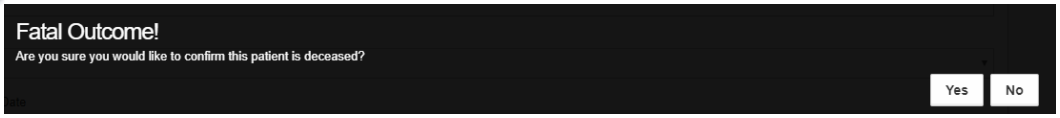

Click the **OK** button.

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

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

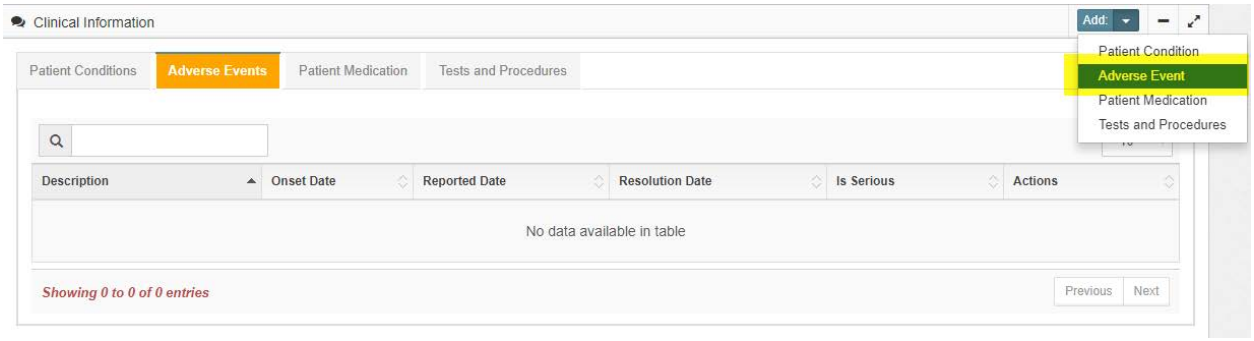



If the patient's outcome has been set to fatal, the system will request confirmation of this status change.

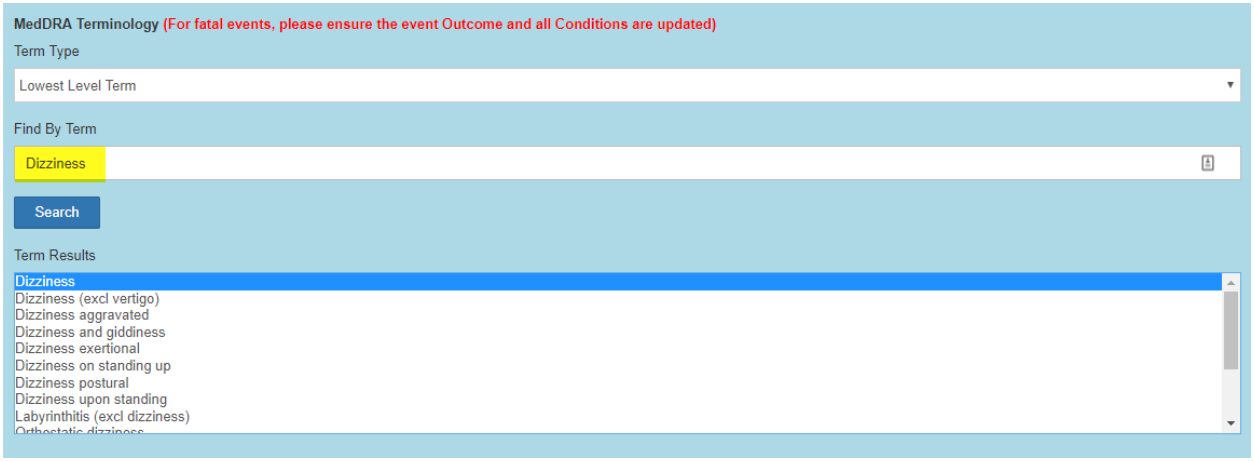


### 4.2.4.3 Add Adverse Event

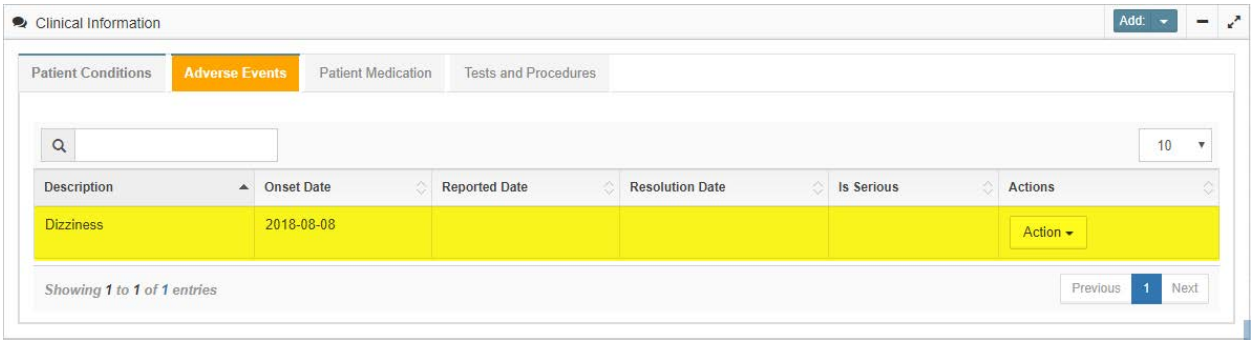
At the **Adverse Events** tab click the **Add Adverse Event** button, after which the system will open the **Add Adverse Event** page.




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




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



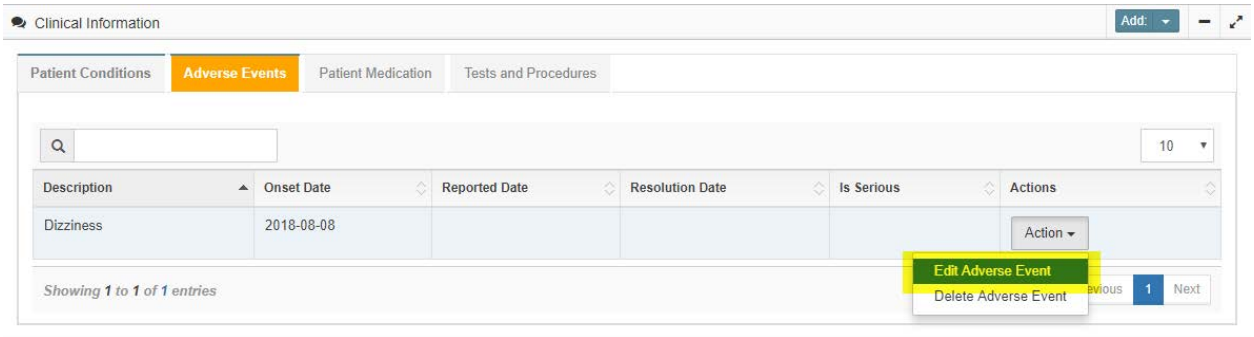

The fields on the **Add Adverse Event** page are described below:

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

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

#### 4.2.4.4 Edit an Adverse Event

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

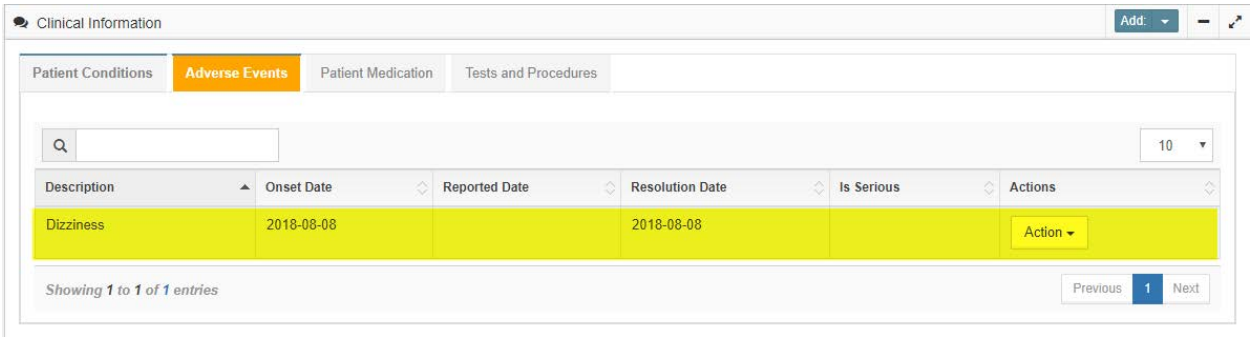



**NOTE:** The system will not allow you to change the Patient's Adverse Event **MedDRA Term**. To change the **MedDRA Term** you will need to delete the record and enter the Patient Adverse Event as a new entry.

Add information or make changes to the page as appropriate.

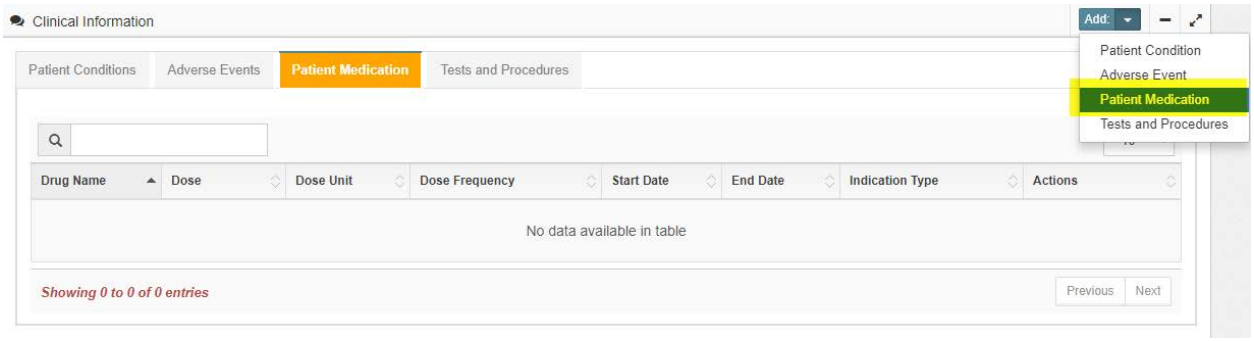
Click the **Submit** button or click the **Back** button to cancel the action and return to the previous page.

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

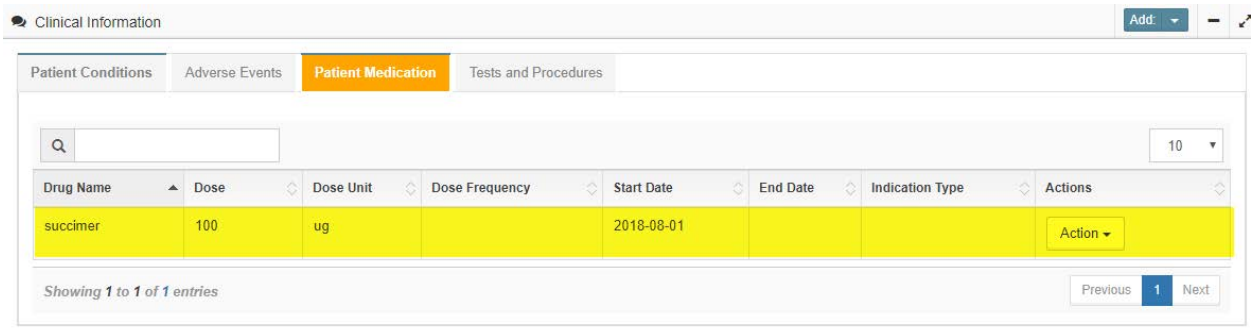


#### 4.2.4.5 Add a Patient Medication

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




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

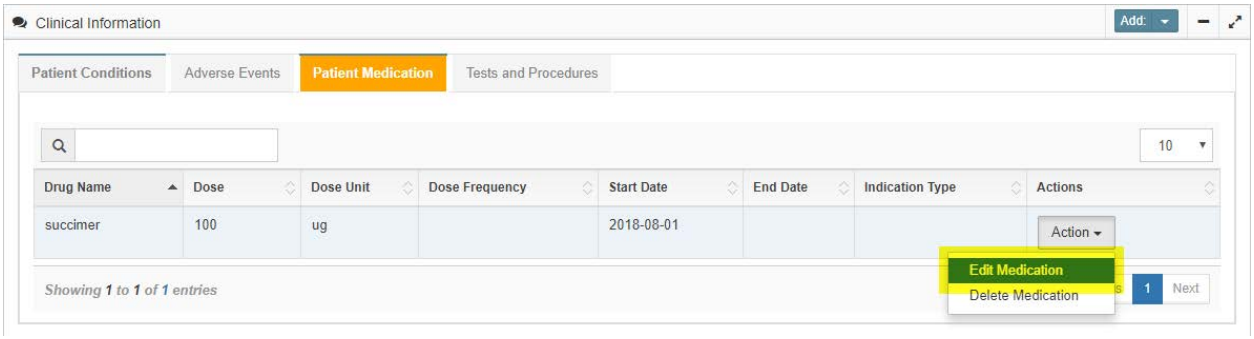



The fields on the **Add Patient Medication** page are described below:

| | |
| --- | --- |
| Medication | Dropdown list; Select medication from a list managed by the system administrator |
| Start Date | Text field; Enter date patient started taking the medication |
| End Date | Text field; Enter date patient stopped taking the medication |
| Dose | Text field; Enter the dose prescribed |
| Dose Unit | Dropdown list; Select the unit prescribed |
| Dose Frequency | Text field; Enter the dose frequency prescribed |
| Route | Dropdown list; Select the route of administration |
| Frequency in $_{days}$ 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

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

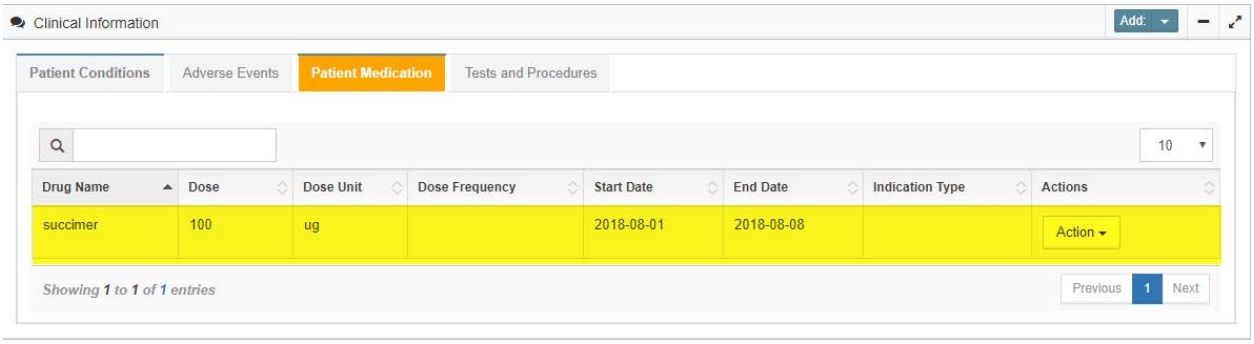



**NOTE:** The system will not allow you to change the **Medication** name. To change the **Medication,** you will need to delete the record and enter the **Medication** as a new entry.

Add information or make changes to the page as appropriate.

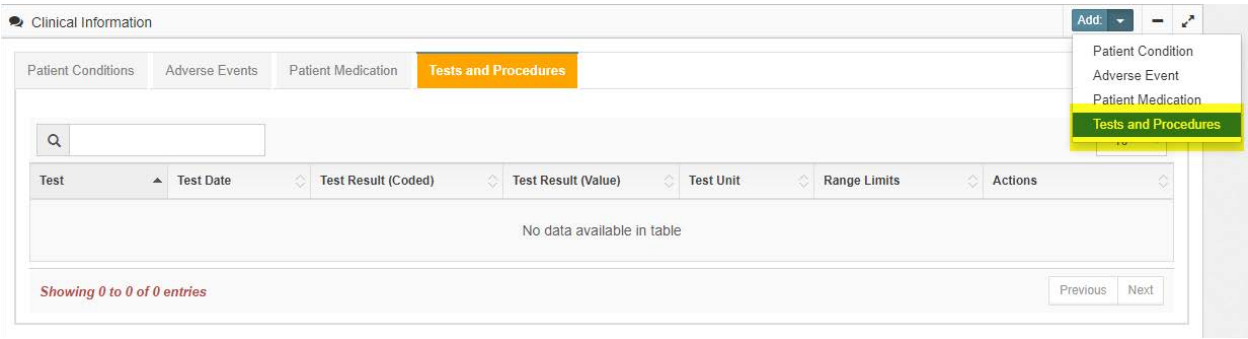
Click the **Submit** button or click the **Back** button to cancel the action and return to the previous page.

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

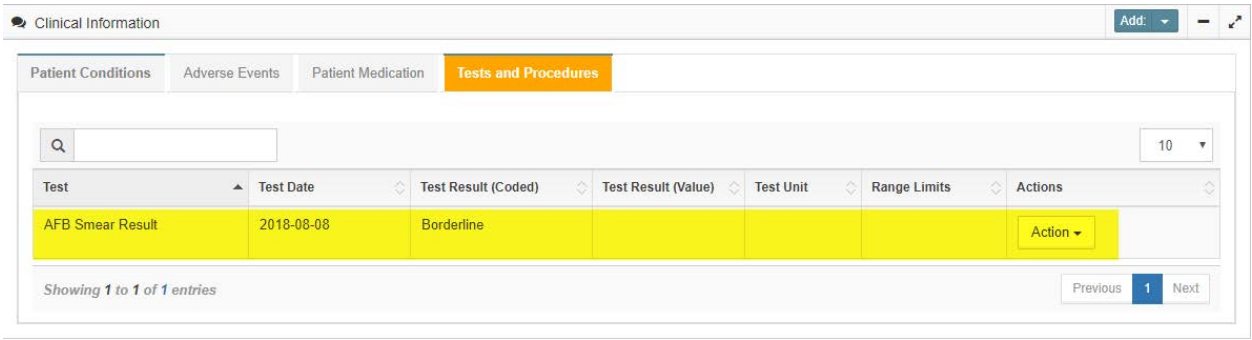


### 4.2.4.7 Add a Test or Procedure

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




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

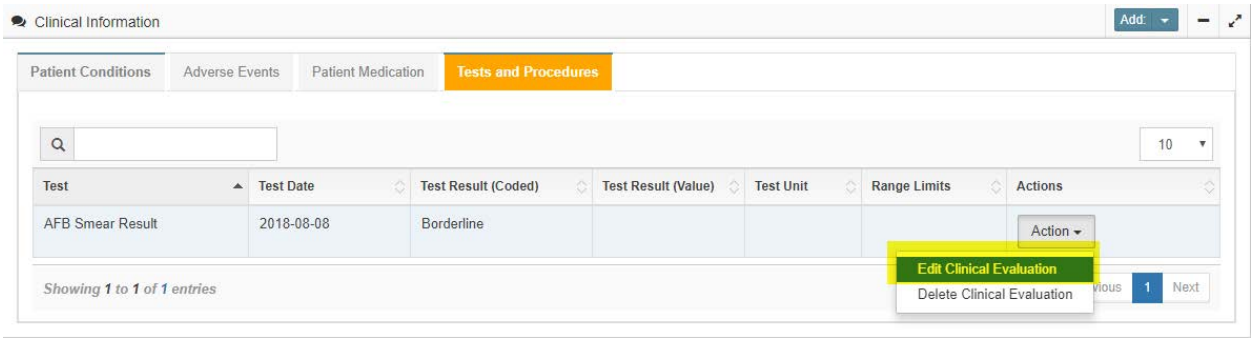



The fields on the **Tests and Procedures** page are described below:

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

### 4.2.4.8 Edit an Existing Test or Procedure

At the patient's **Encounter View** page, start on the **Tests and Procedures** tab, find the test to edit in the T**ests and Procedures Table** and click the **Edit** button. The system will display the patient's **Edit Test and Procedure** page.

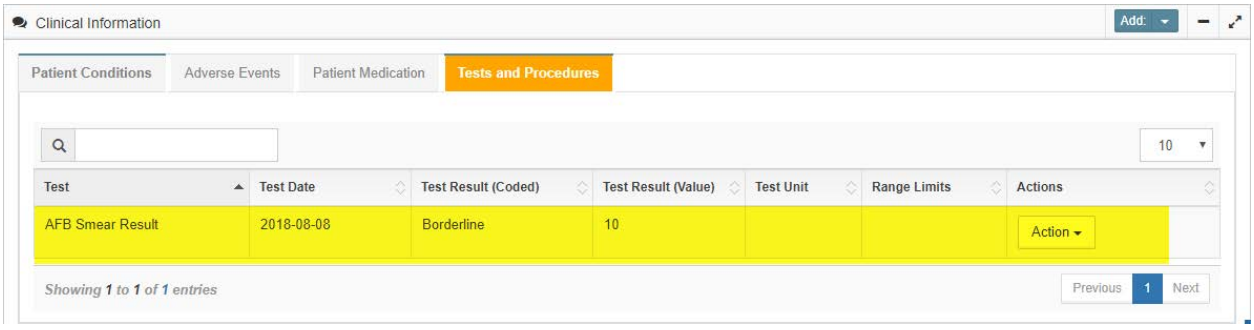



**NOTE:** The system will not allow you to change the **Test** or **Procedure** name. To change the **Test** or **Procedure** name you will need to delete the record and enter the **Test** or **Procedure** as a new entry.

Add information or make changes to the page as appropriate.

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

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

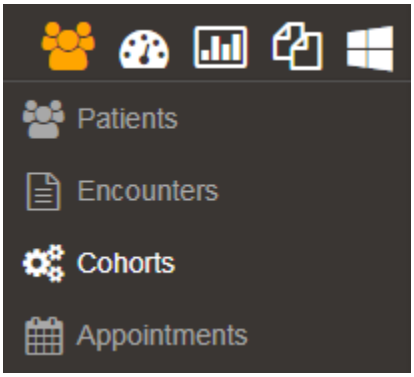


## 4.3 Cohorts

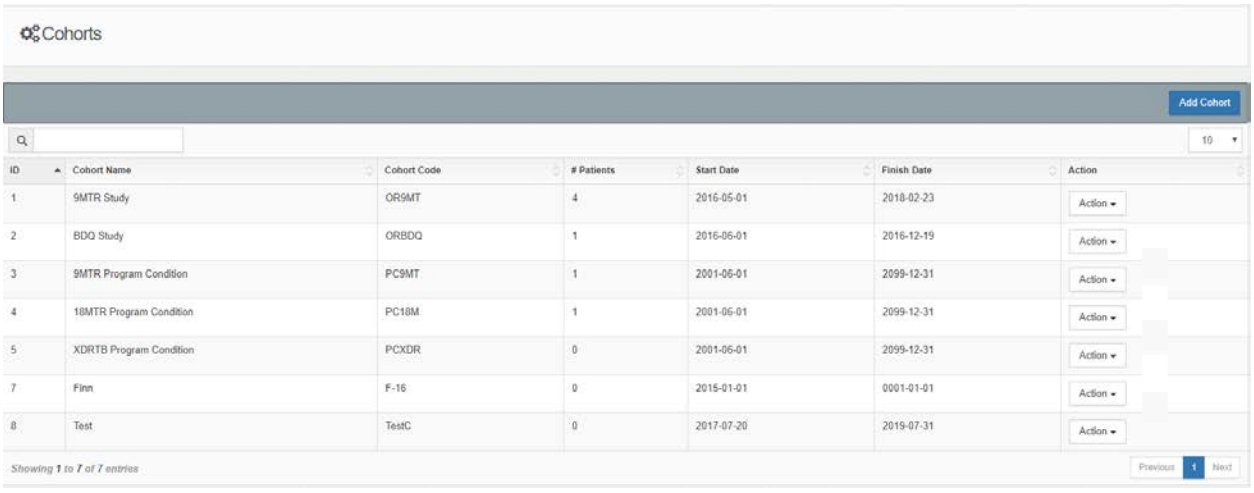
Cohorts can be used to track a sub-group of patients within a Condition Group. Cohorts in the system are determined by the Public Health Program or the System Administrator.

### 4.3.1 View Cohorts

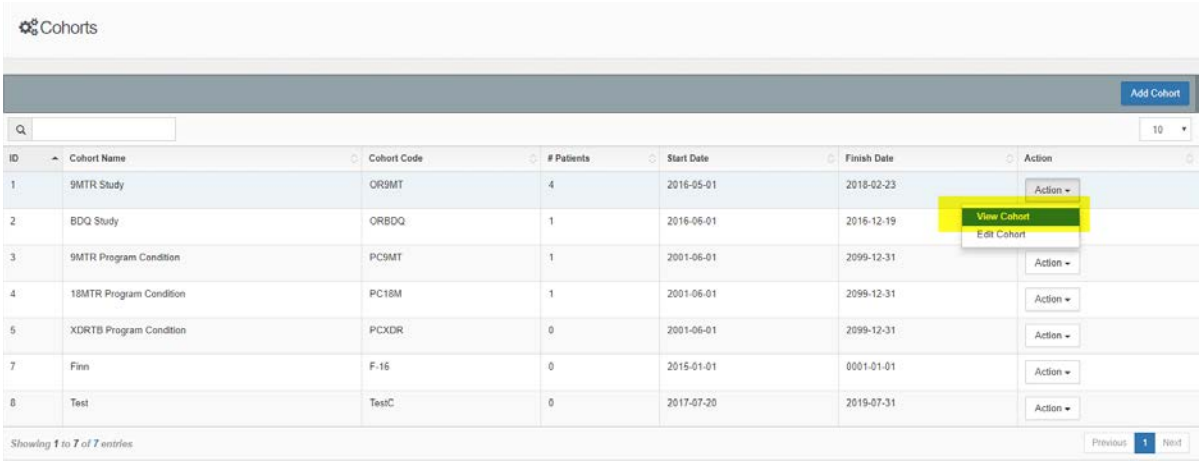
The **Cohort** function can be accessed through the **Cohorts** menu.



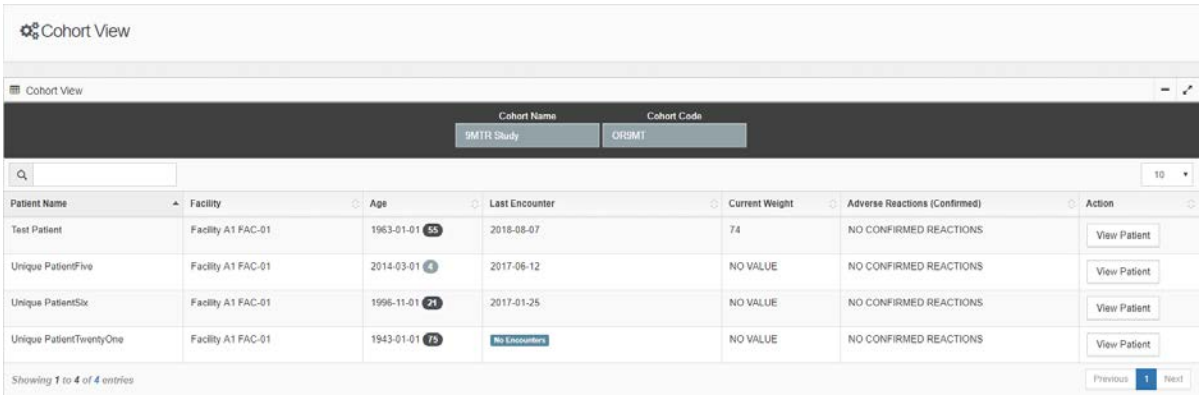

The system will display the **Cohorts View** page, which lists all currently registered cohorts in the system.



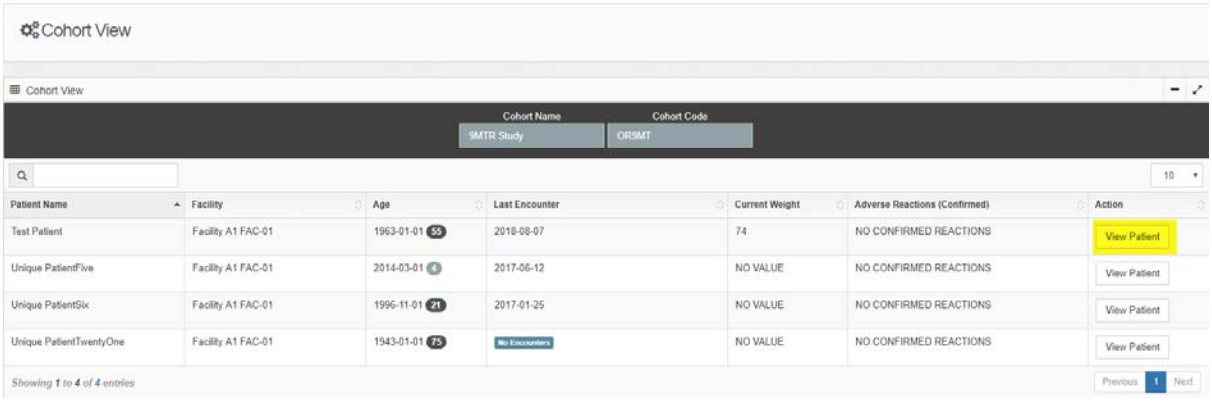
Find the **Cohort** you would like to view in the table. Click the **View Cohort** button in the Action Column for the cohort to view.




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




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



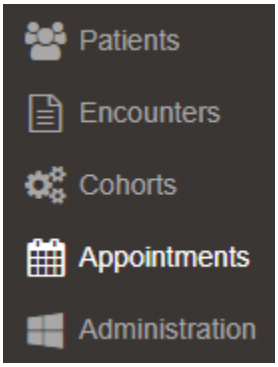

Click the **View Patient** button in the Action column for the patient to view. The system will display the **Patient View** page.

## 4.4 Appointments

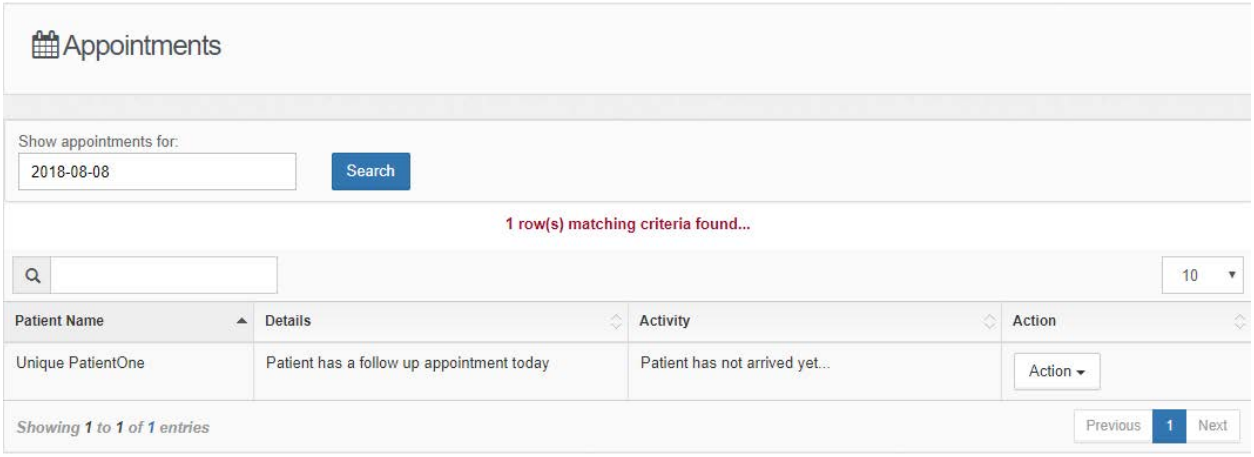
Appointments can be used to monitor an patient return date to the facility. This is particularly effective for patients in a cohort where ongoing monitoring for adverse events is expected.

### 4.4.1 View Appointments

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




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



The columns in the appointments table are described below:

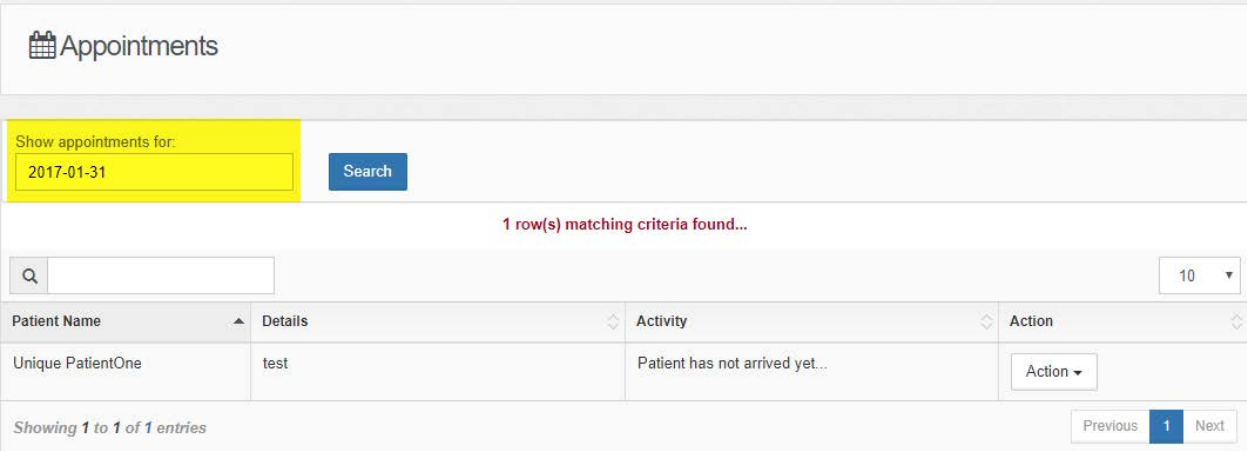
| | |
|---|---|
| Patient Name | Reflecting the patient's name and surname as captured in the system when the appointment was scheduled. |
| Details | Reason for the appointment |
| Activity | Has the patient arrived for their appointment?<br>Has the patient missed their appointment? |
| Action | Ability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

**PViMS Term - Did Not Arrive**

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

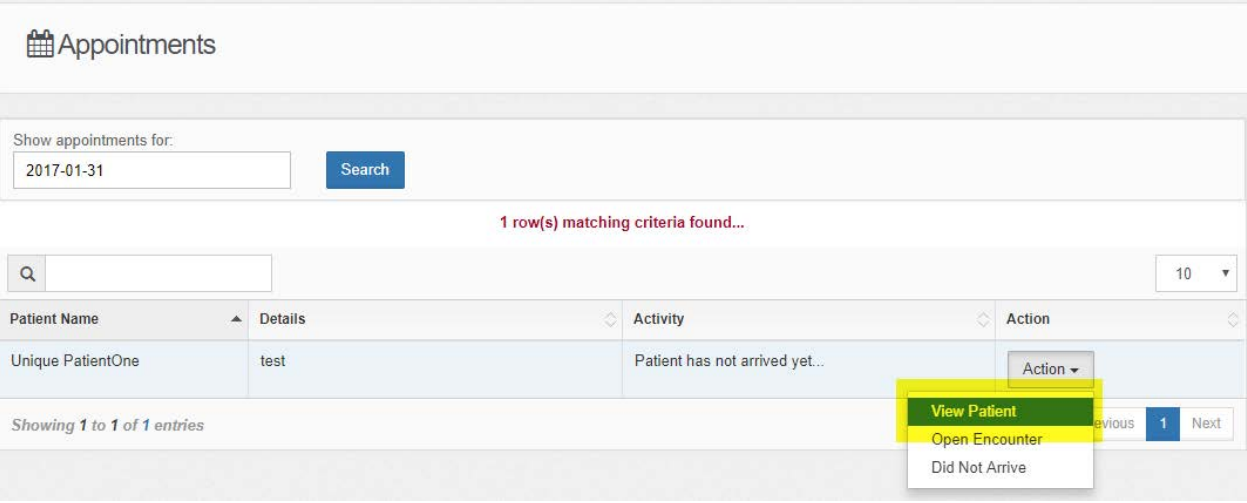
### 4.4.2 View Appointments for a specified day

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



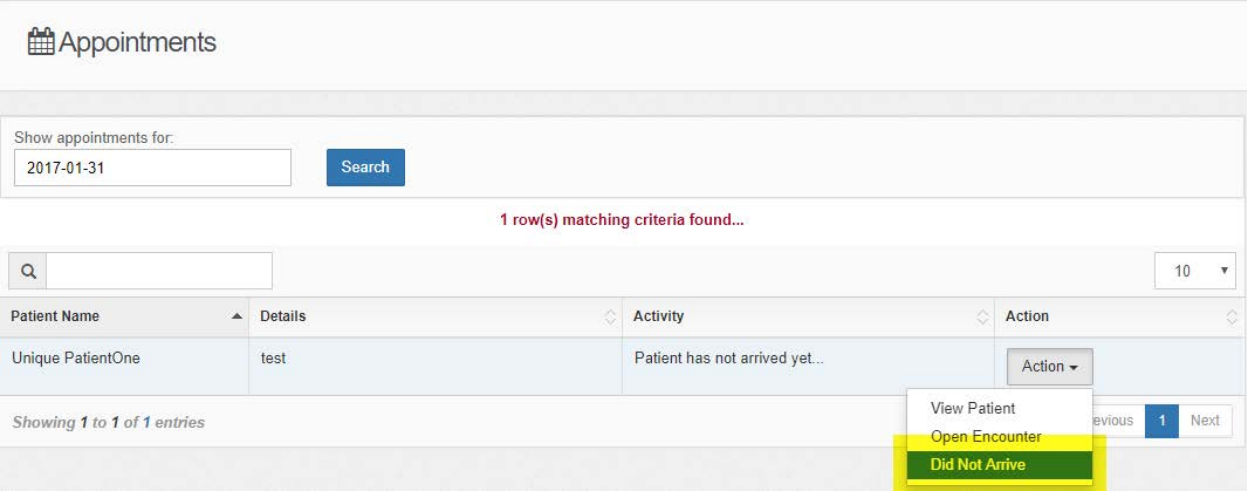

### 4.4.3 View Patient Record

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

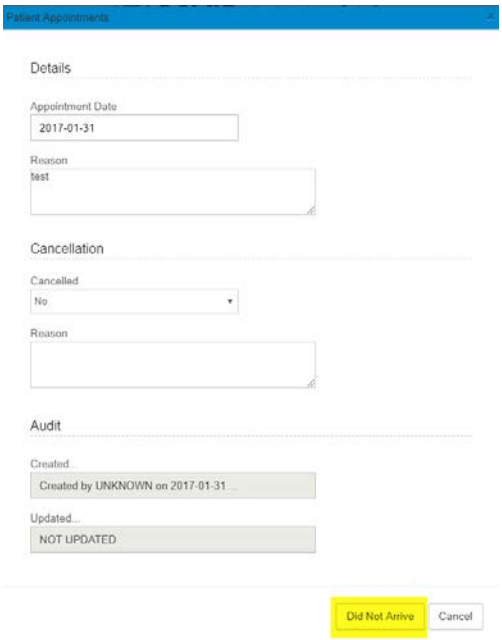


### 4.4.4 Mark Appointment as Did Not Arrive

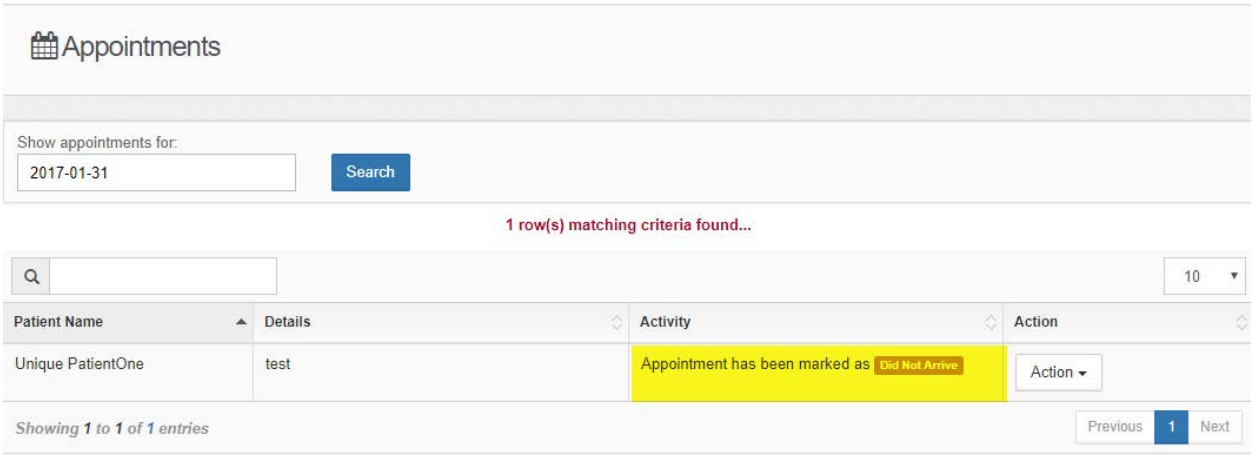
Select the patient in the table whose record you wish to confirm as did not arrive and click the **Did Not Arrive** Button.




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



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





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

## 4.5 Deleting Records

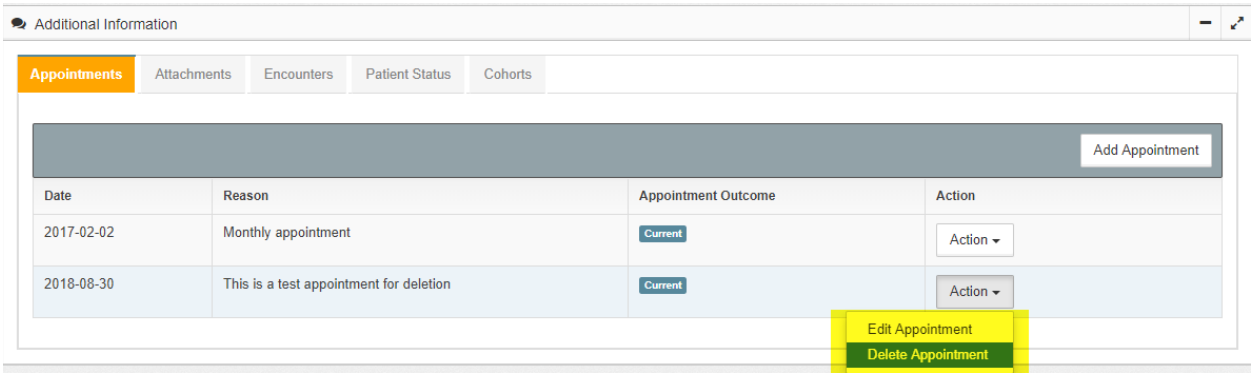
User rights assignment policies determine which Users or User Profile groups are able to delete records from the system. Check with your administrator regarding user right assignments.


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

### 4.5.1 Patient View - Additional Information

#### 4.5.1.1 Delete an Appointment

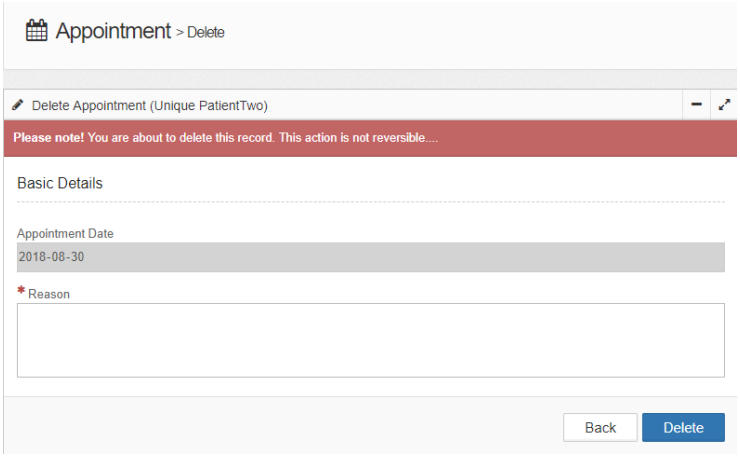
Within the **Patient View,** at the **Appointments** tab, find the appointment you would like to delete.





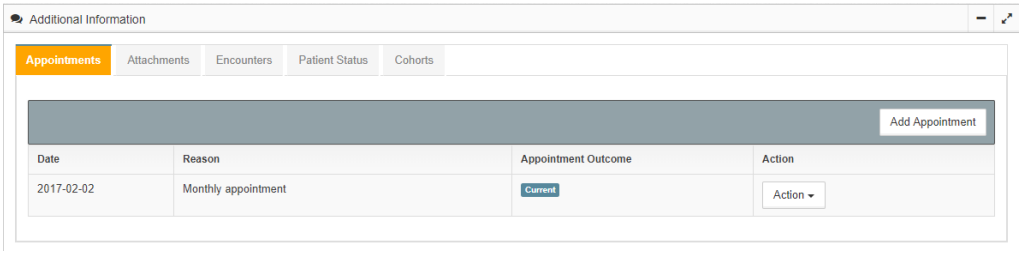
You will only have the opportunity to delete appointments within the future. Existing appointments will need to be cancelled.

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



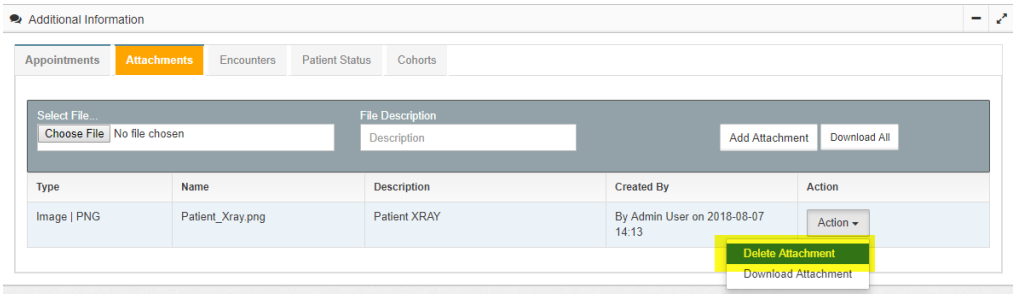

Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the appointment or click the **Back** button to undo the action.

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

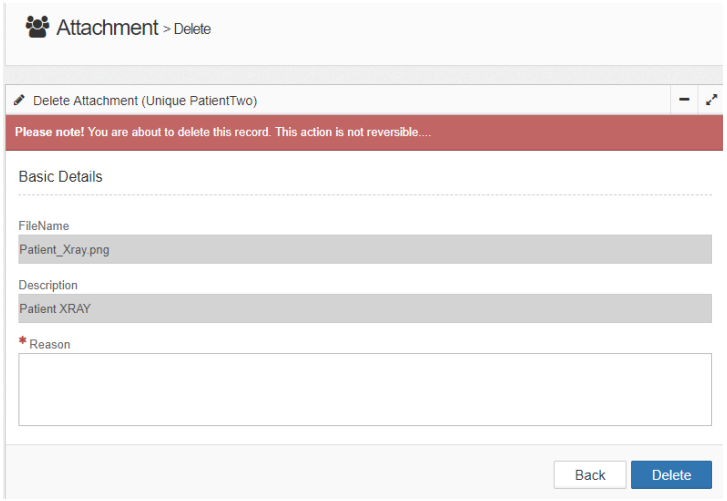


### 4.5.1.2 Delete an attachment

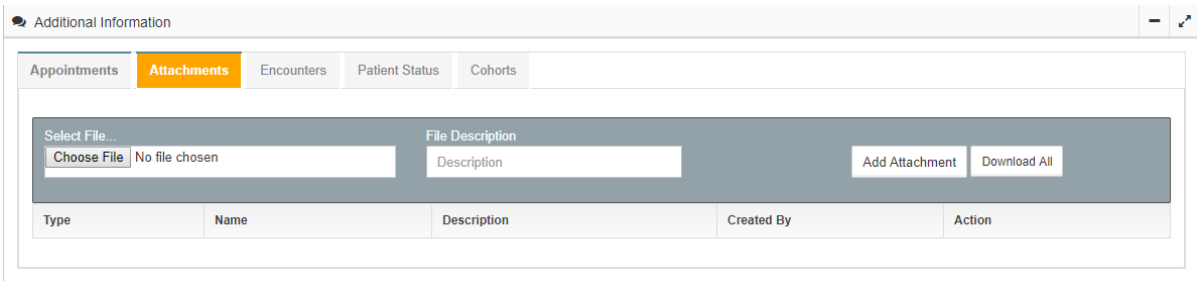
Within the **Patient View,** at the **Attachments** tab, once you have uploaded an attachment, the attachment can easily be removed again.




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

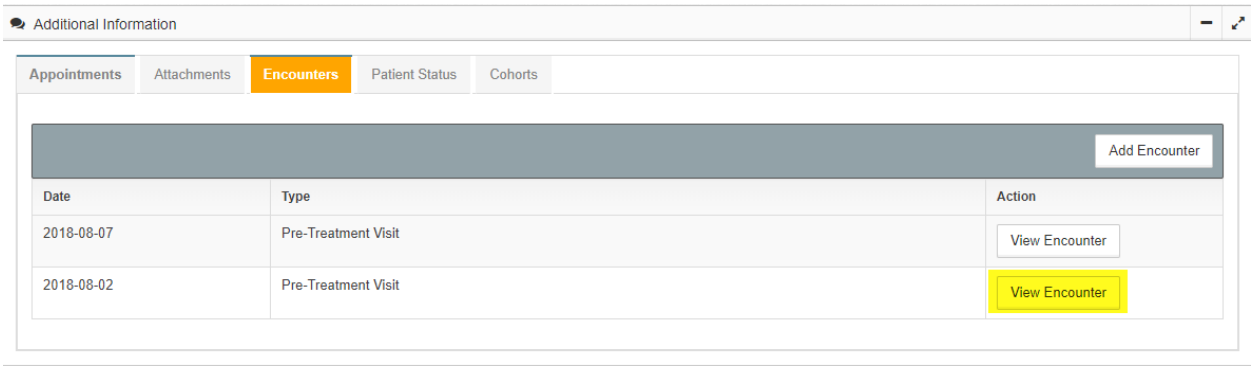



Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the attachment or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Attachment** table.

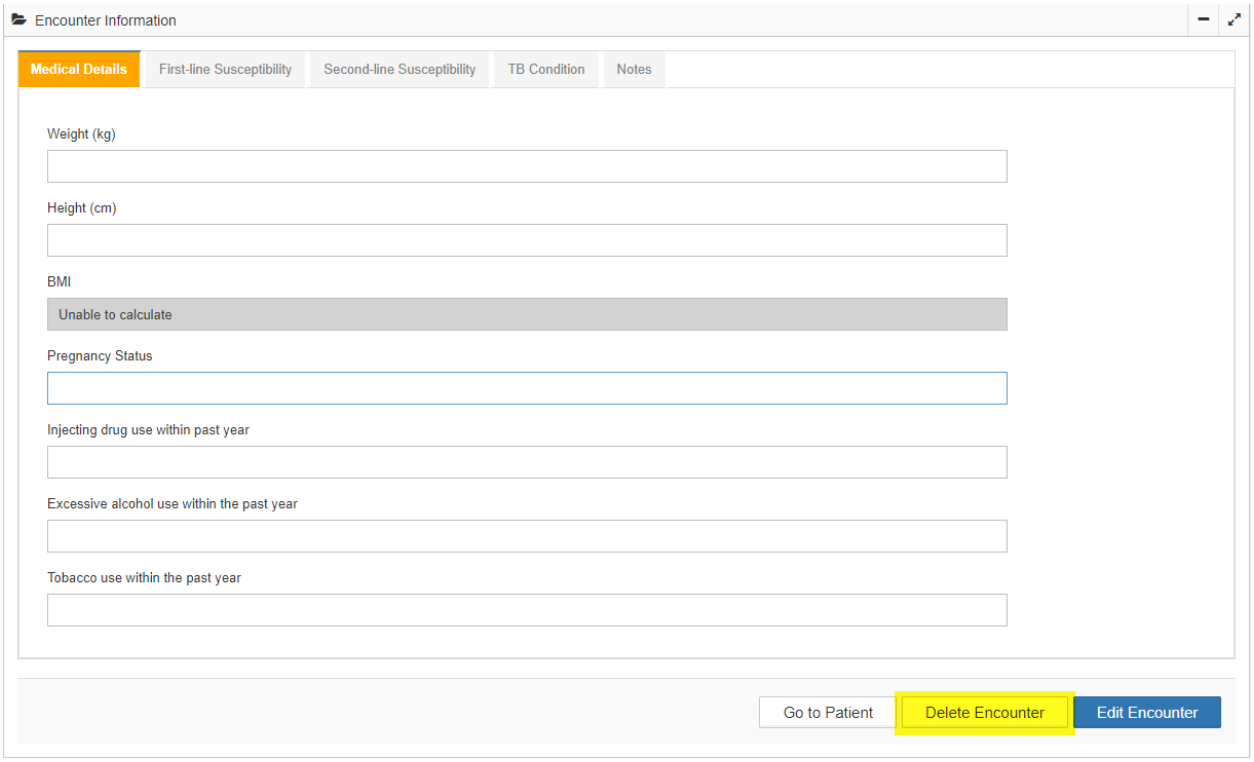


#### 4.5.1.3 Delete an Encounter

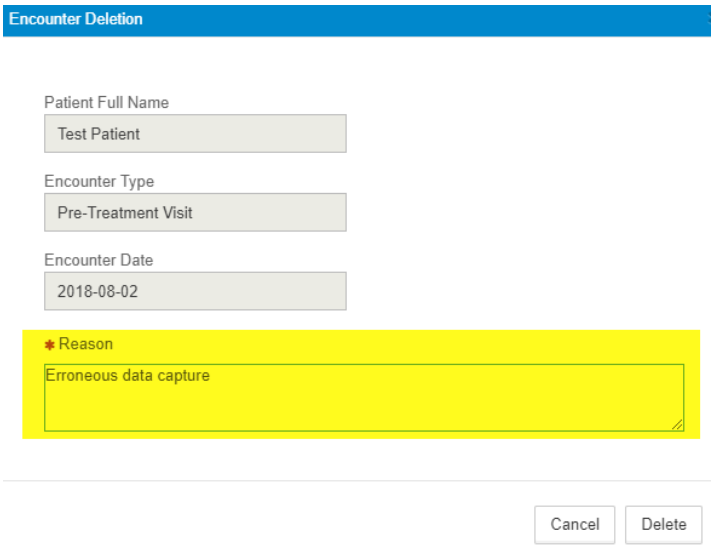
Within the **Patient View,** at the **Encounters** tab, locate the **Encounter** you would like to remove and click the **View Encounter** button.



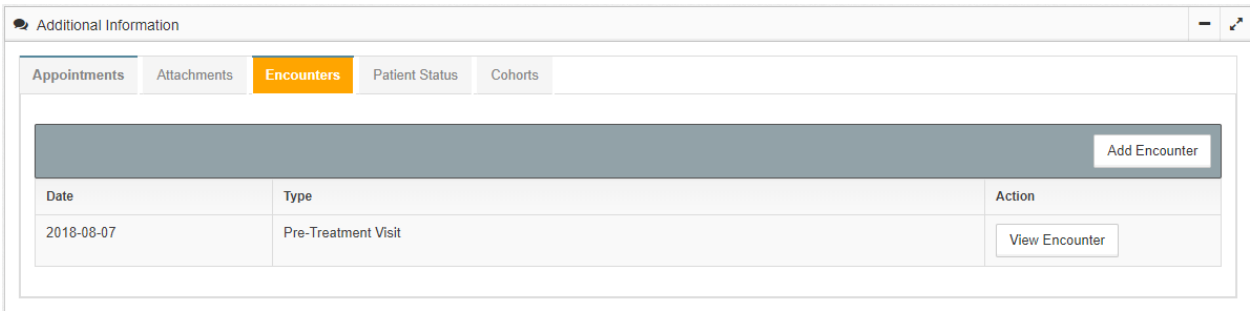

The system will navigate you to the **Encounter View.**




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

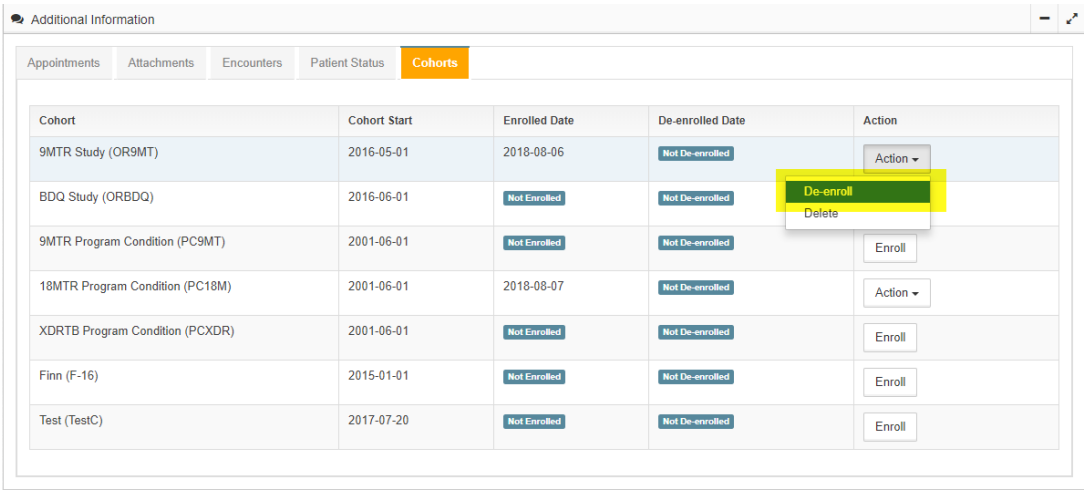



Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the attachment or click the **Cancel** button to undo the action. After confirming the deletion, the system will update the **Encounter** table.

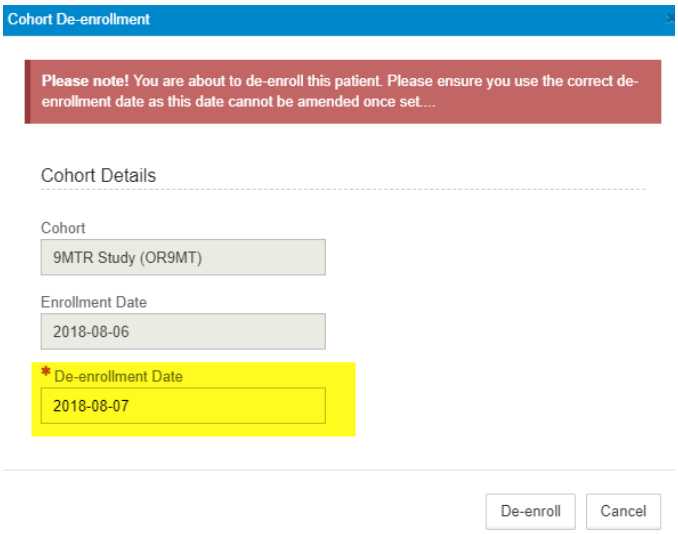


#### 4.5.1.4 De-enroll a Patient from a Cohort

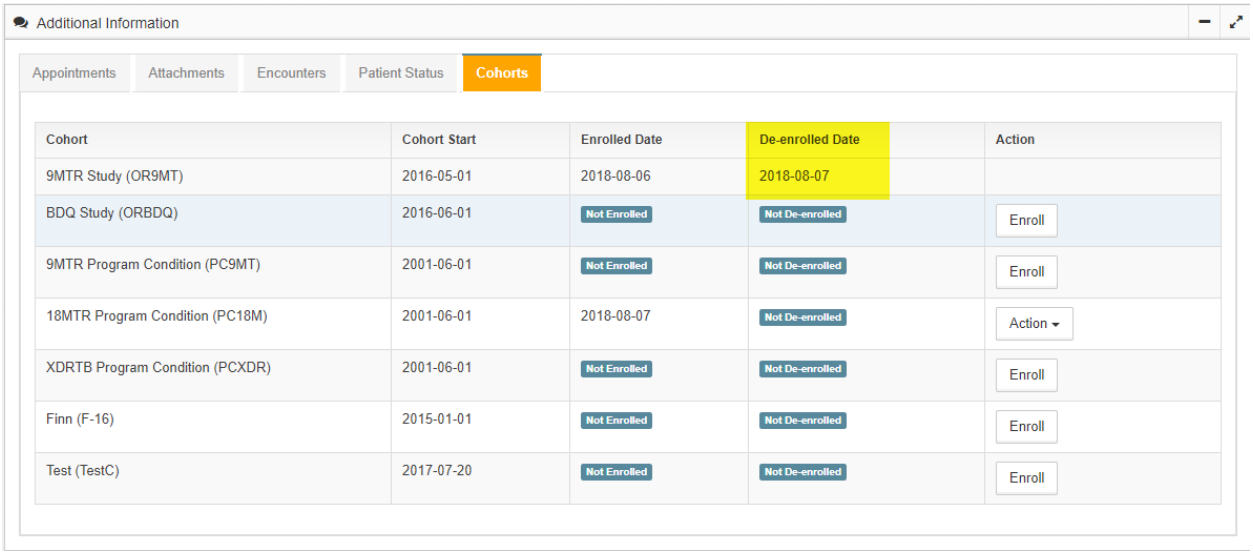
Within the **Patient View,** at the **Cohorts** tab, find the **Cohort** you would like to de-enroll the patient from.




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

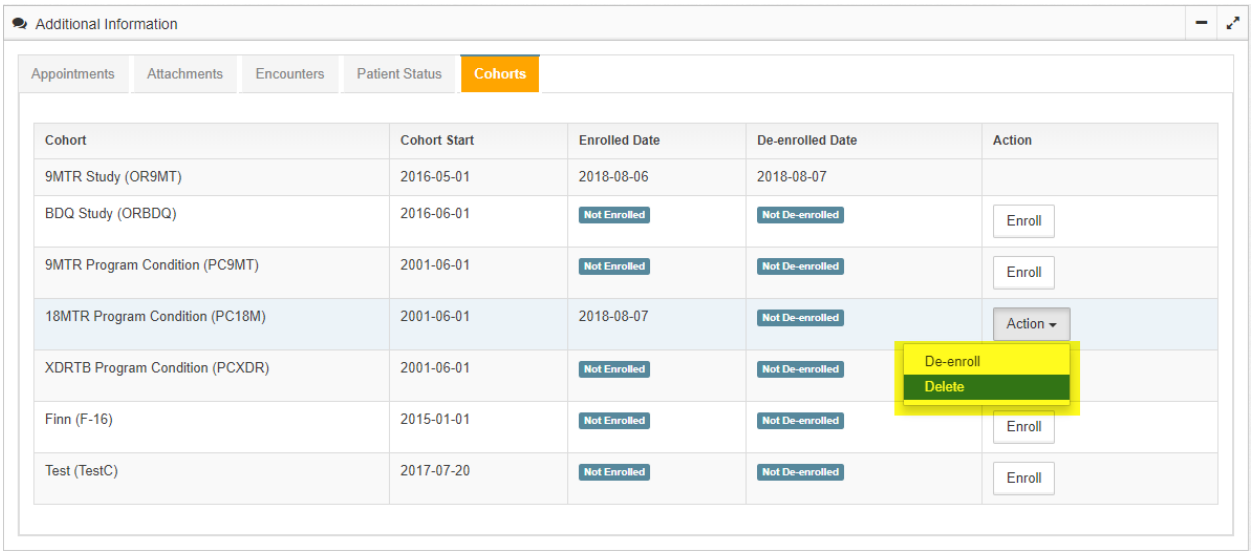



Enter the de-enrollment date and click the **De-enroll** button. The system will display the updated **Cohorts Table**.

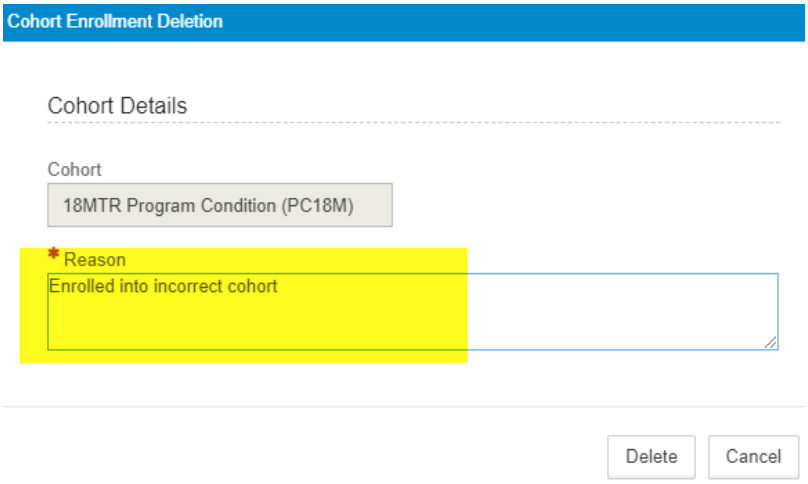

Additional Information
Appointments
Attachments
Encounters
Patient Status
Cohorts
Cohort
Cohort Start
Enrolled Date
De-enrolled Date
Action
9MTR Study (OR9MT)
2016-05-01
2018-08-06
2018-08-07
BDQ Study (ORBDQ)
2016-06-01
Not Enrolled
Not De-enrolled
Enroll
9MTR Program Condition (PC9MT)
2001-06-01
Not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

### 4.5.1.5 Deleting A Cohort Enrolment

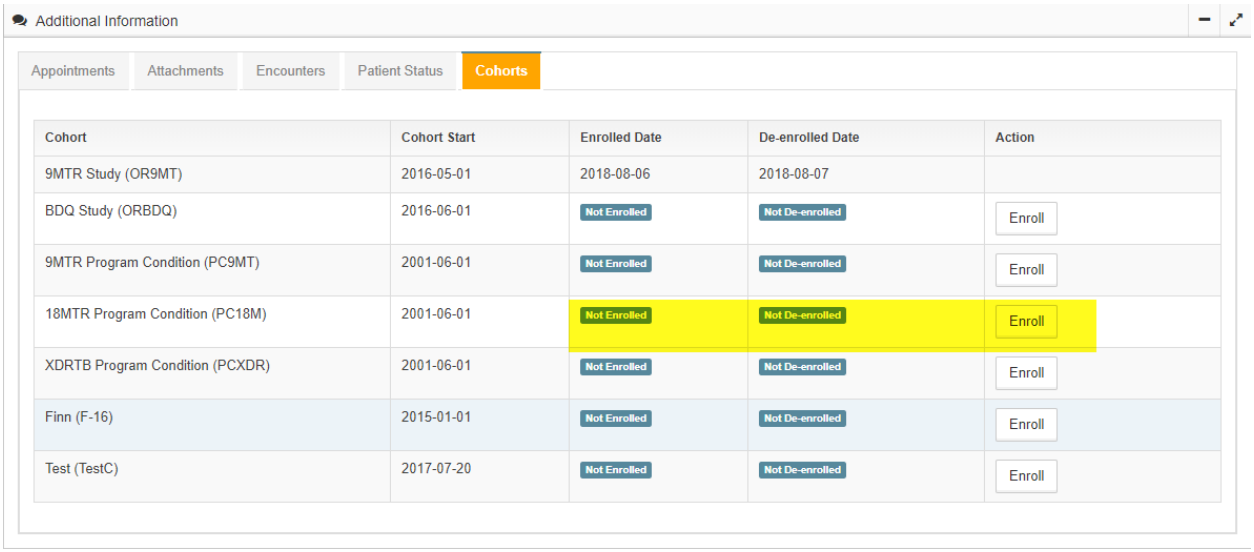
Within the **Patient View,** at the **Cohorts** tab, find the **Cohort** you would like to de-enroll the patient from.




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




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



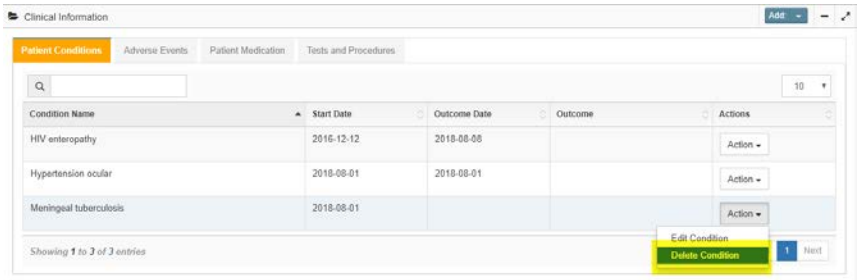


Deleting a cohort enrolment allows the patient to be re-enrolled into that cohort. De-enrollment means the patient cannot be re-enrolled into the same cohort again.

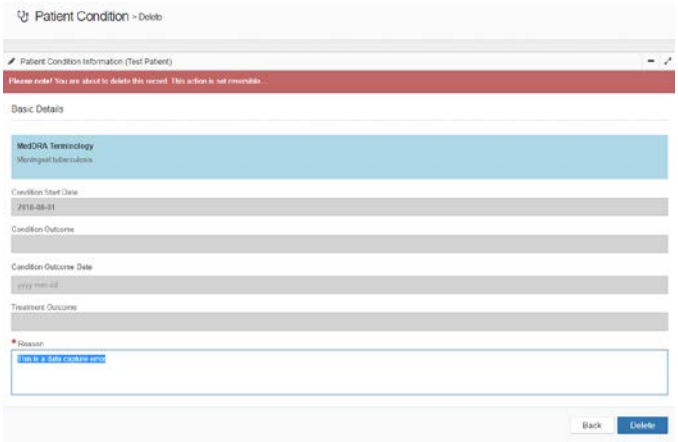
### 4.5.2 Encounter View – Clinical Information

#### 4.5.2.1 Delete A Patient Condition

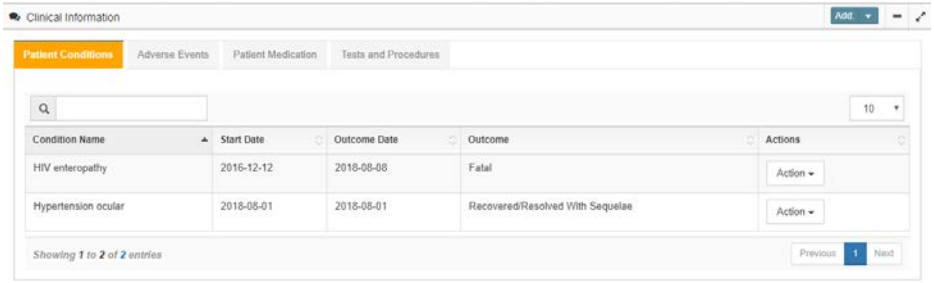
Within the **Encounter or Patient View,** at the **Patient Conditions** tab and locate the condition you would like to delete.




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

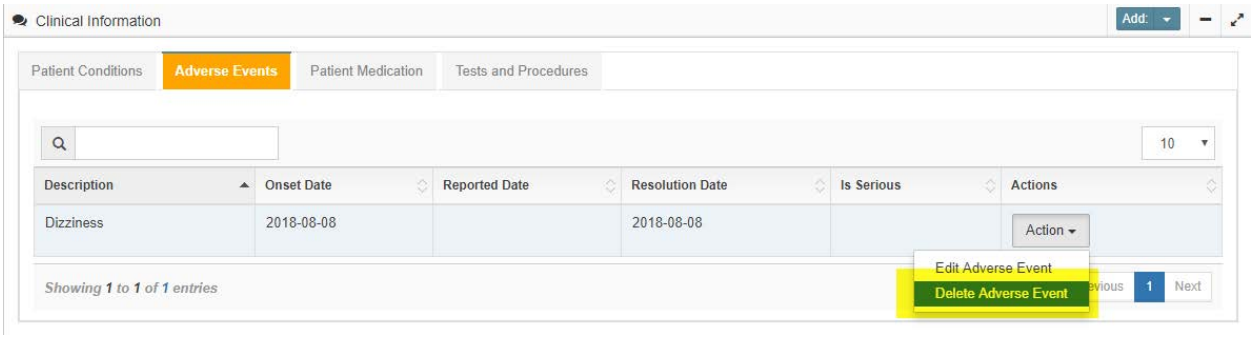



Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the condition or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Patient Condition** table.

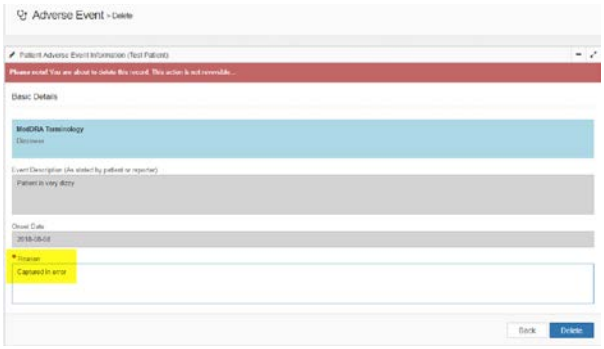


### 4.5.2.2 Delete An Adverse Event

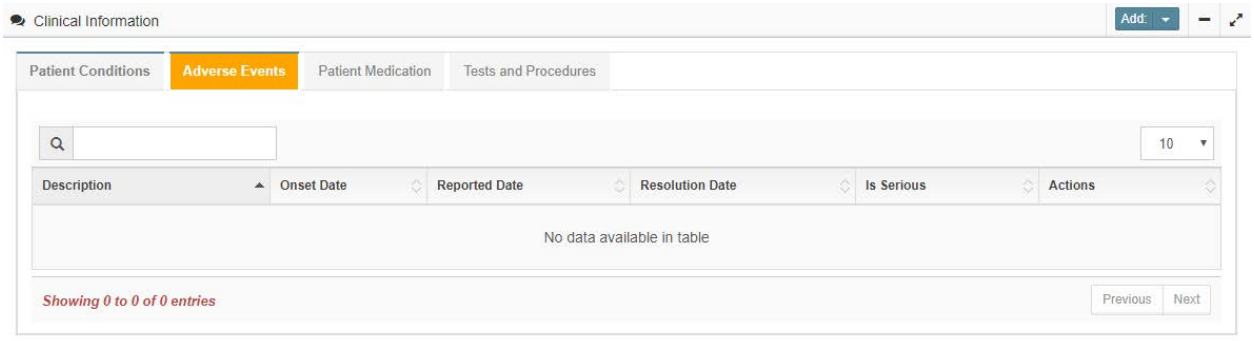
Within the **Encounter or Patient View,** at the **Adverse Events** tab and locate the event you would like to delete.




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

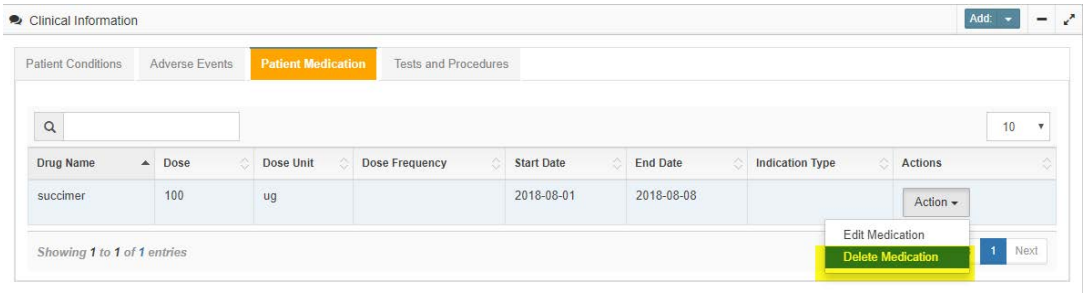



Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the adverse event or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Adverse Events** table.

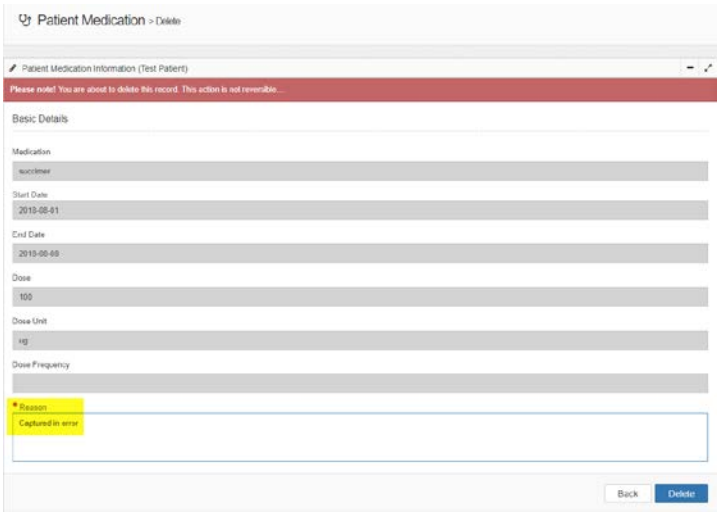


### 4.5.2.3 Delete A Patient Medication

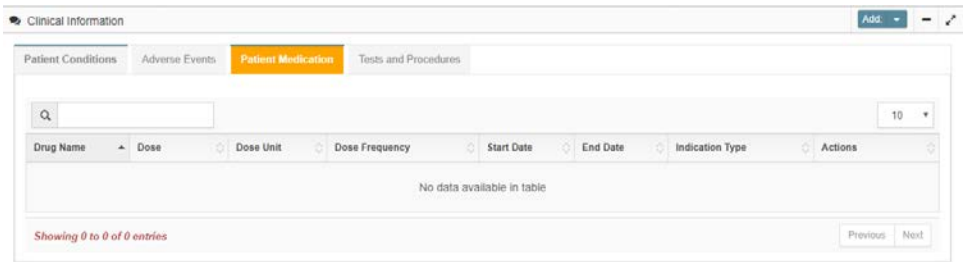
Within the **Encounter or Patient View,** at the **Patient Medications** tab and locate the medication you would like to delete.




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

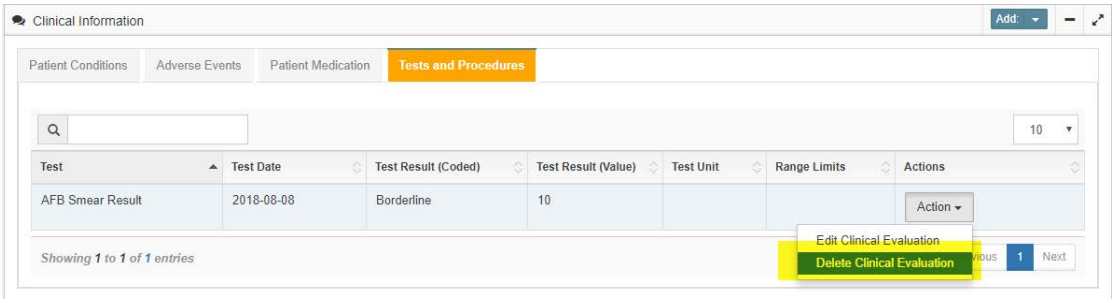



Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the medication or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Patient Medications** table.

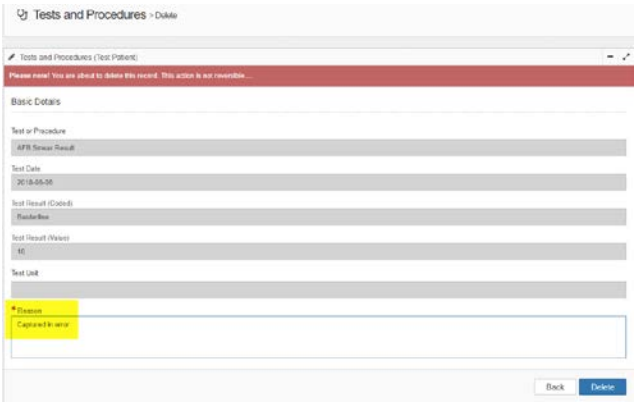


#### 4.5.2.4 Delete A Test and Procedure

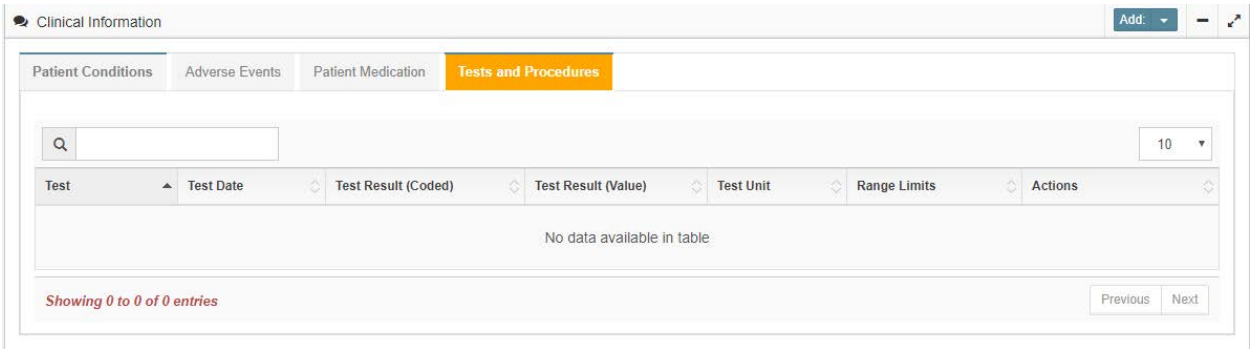
Within the **Encounter or Patient View,** at the **Tests and Procedures** tab and locate the test and procedure you would like to delete.




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

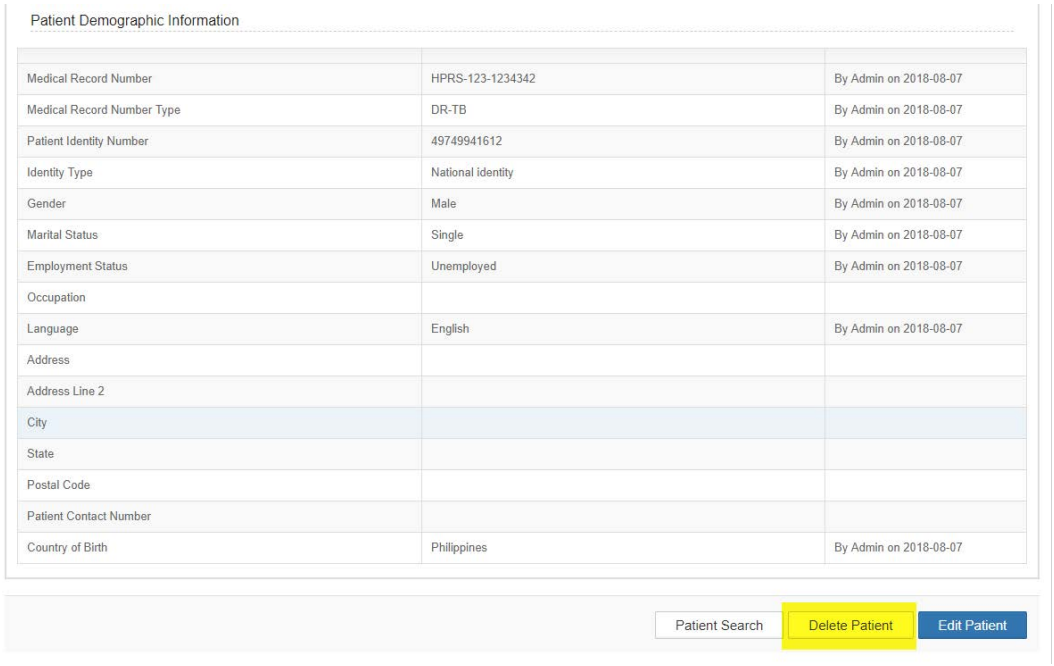



Enter a reason for the deletion (this is compulsory) and click on the **Delete** button to delete the test and procedure or click the **Back** button to undo the action. After confirming the deletion, the system will update the **Tests and Procedures** table.

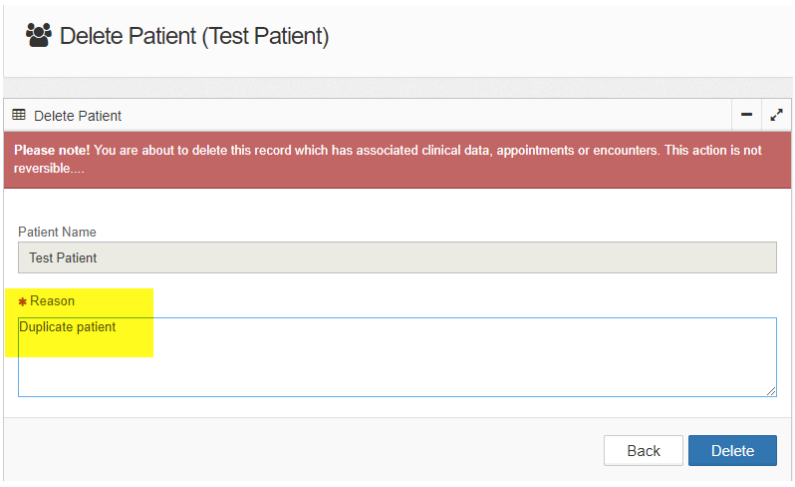


### 4.5.3 **Delete an Entire Patient Record**

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




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

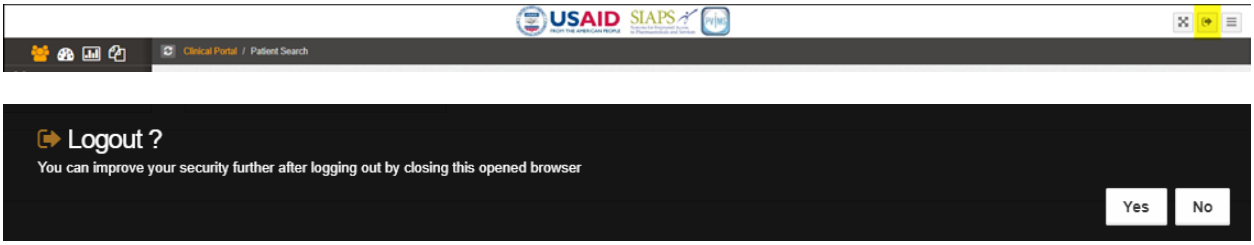




Deleting a patient will archive all patient information and will remove the patient from any analysis they may have been part of previously.

## 4.6 Log Out of the System

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




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

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

# 5 Analytical Portal

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

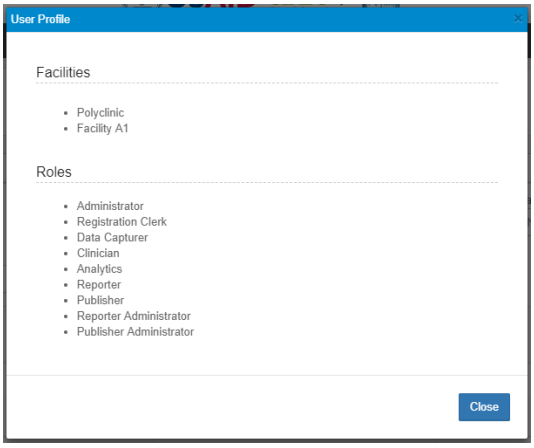
- Spontaneous and Active Reports
- Spontaneous and Active Analyzer

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

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

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


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



## 5.1 Spontaneous Reporting

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

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

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

Spontaneous reports are, by definition, submitted voluntarily.

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

## 5.2 Active Reporting

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

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

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

## 5.3 **Pharmacovigilance Activities**

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

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

The following activities are facilitated in the Analytical portal:

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

### 5.3.1 **Terminology**

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

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

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

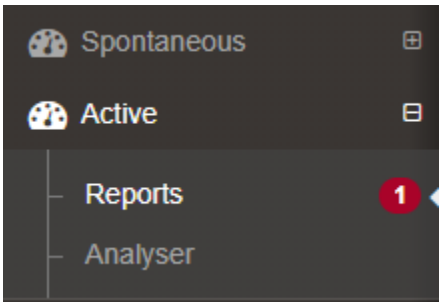
### 5.3.2 **Process Flow**

<table>
<tr><td>Activity: Start of Process<br>Clinician adds a new adverse event to the patient record.<br>Reporter adds a new spontaneous report.<br>System generates a new report for the PV unit to action:<ul><li>Report has a unique identifier</li><li>Report has a default activity of Confirm Report Data</li><li>Report has a sub status of UNCONFIRMED</li></ul></td><td>Confirm Report Data<br>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.<br>The PV specialist has the following options:<ul><li>Delete Report</li><li>Confirm Report</li></ul></td></tr>
<tr><td colspan="2">Activity: Confirm Report Data<br>Step 1: PV specialist and clinician/reporter update clinical data until there is sufficient information to perform causality and terminology configurations.<br>For active reporting the patient record is modified through the clinical portal.<br>For spontaneous reporting the report is modified directly in the analytical portal.<br>Step 2: Once data has been confirmed, the PV specialist will confirm the report is ready for assessment by selecting the Confirm report option.<br>Step 3: The report is moved into a new activity: Set MedDRA and Causality.</td></tr>
<tr><td>Activity: Set MedDRA and Causality<br>Step 1: PV specialist sets the terminology for the adverse event. This will be the terminology used for analysis purposes.<br>Step 2: PV specialist then sets the causality per medication that was in use at the onset date of the adverse event.<br>Please note: the specialist is unable to set causality until the MedDRA term has been selected.<br>Step 3: On completion, the PV specialist confirms causality has been set.<br>Step 4: The report is moved into a new activity: Extract E2B.</td><td>Set MedDRA and Causality<br>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.<br>The PV specialist has the following options:<ul><li>Set Terminology</li><li>WHO Causality</li><li>Naranjo Causality</li><li>Confirm Causality Set</li></ul></td></tr>
</table>

| | |
| --- | --- |
| **Activity: Extract E2B**<br>**Step 1:** PV technician creates an E2B XML file for submission.<br>*Please note: a patient summary is stored at the time of generating the E2B XML to allow for data verification.*<br>**Step 2:** PV technician then confirms that the E2B XML file has been submitted to WHO.<br>• A receipt code and time can be noted here<br>*Please note: submission to WHO UMC is a manual process.* | **Extract E2B**<br>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.<br>The PV specialist has the following options:<br>• Create E2B<br>• Confirm E2B submission |
| **PROCESS COMPLETED** | |

### 5.3.3 Identifying New Reports

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

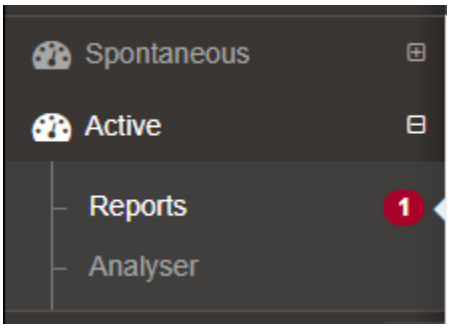




This alert will vary in count depending on the **ReportInstanceNewAlertCount** configuration. Please speak to your system administrator to confirm what this value is set to in days.

### 5.3.4 Search for a Report

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




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

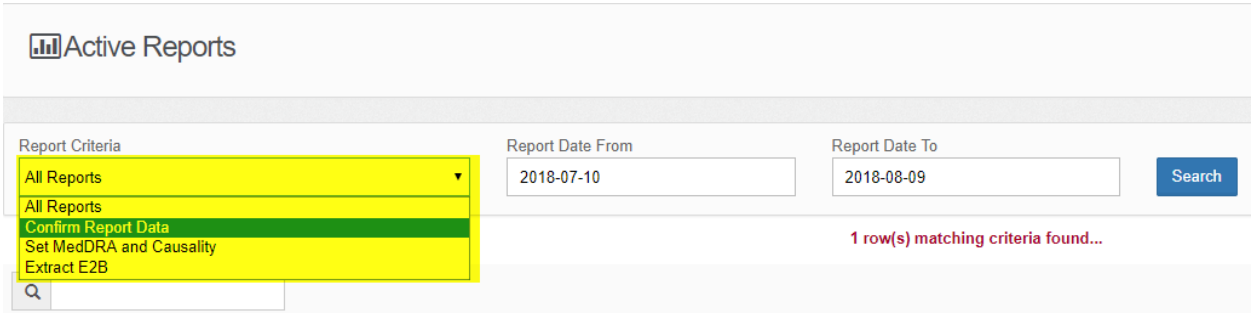
- Criteria (All reports or reports by stage)
- Report date range

#### 5.3.4.1 Search by Criteria

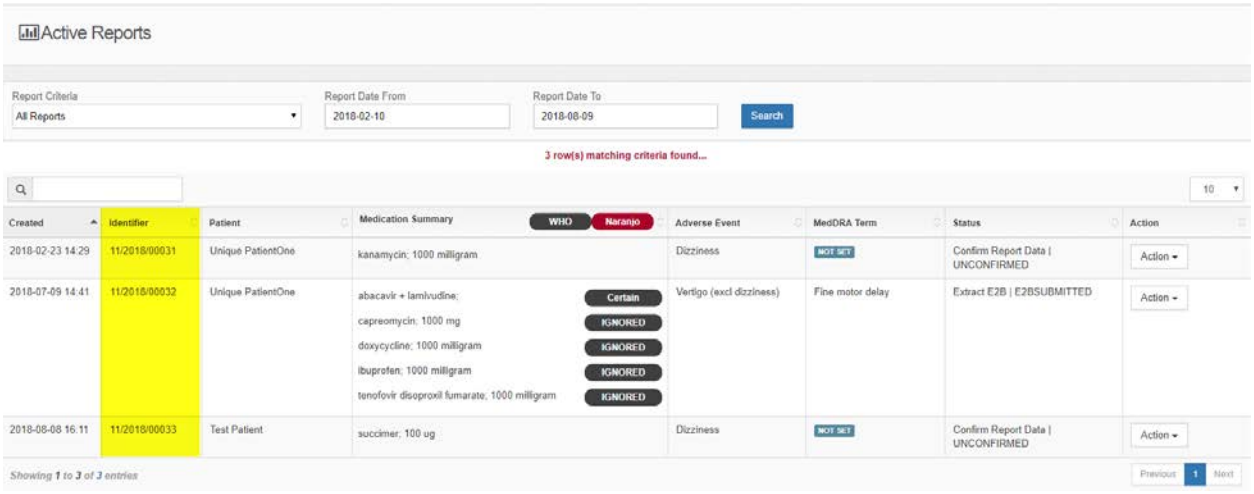
- Click the **arrow** in the **Report Criteria** field to select a criteria option
- Select the criteria that you would like to search against.


**Confirm Report Data Stage:** Search on all reports that are newly submitted and are not yet VERIFIED.
**Set MedDRA and Causality:** Search on all reports that have been VERIFIED and are in the process of being defined through terminology.
**Extract E2B:** Search on all reports that have all terminology defined and are ready to extract information for submission to the WHO Uppsala Monitoring Centre.

- Click the **Search** button.

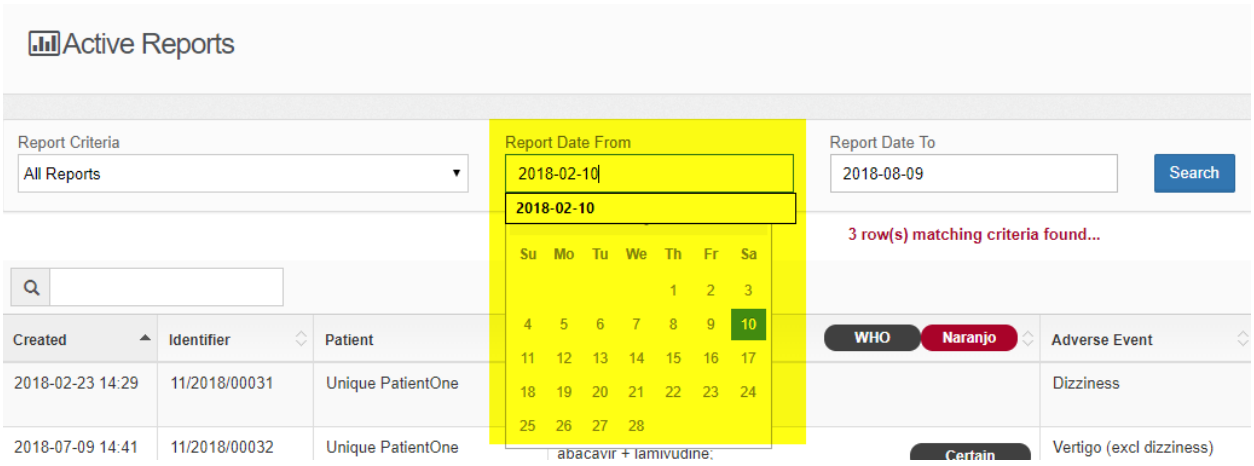



The system will display a list of reports according to the filter selected, please note the Unique Identifier of the report in column 2.

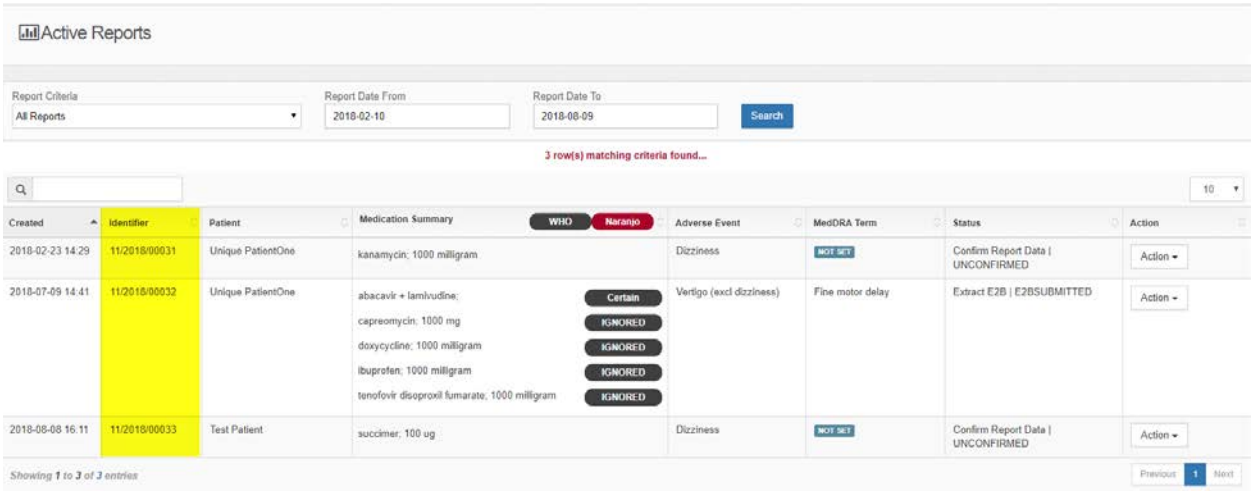



### 5.3.4.2 Search for all Reports within a Date Range

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




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




The columns in the report table are described below:

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

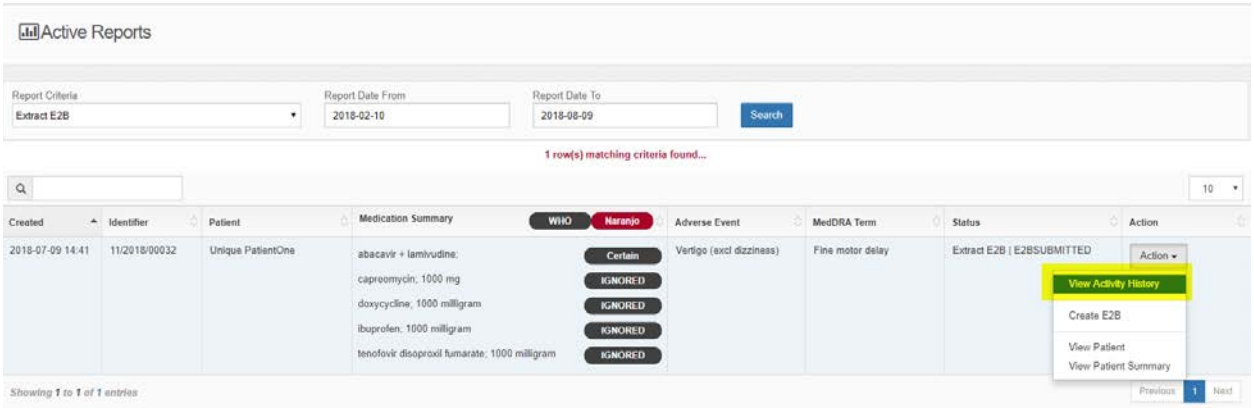
| | |
|---|---|
| | Confirm Causality Set<br>View Patient (Active Only)<br>View SAE Report or Patient Summary<br>Update Report (Spontaneous Only)<br><br>**Extract E2B Stage**<br>View Activity History<br>Create or Update an E2B file<br>Prepare or Confirm E2B file for submission<br>Download XML file<br>View Patient (Active Only)<br>View SAE Report or Patient Summary<br>Update Report (Spontaneous Only) |

## 5.4 Pharmacovigilance Activities - General

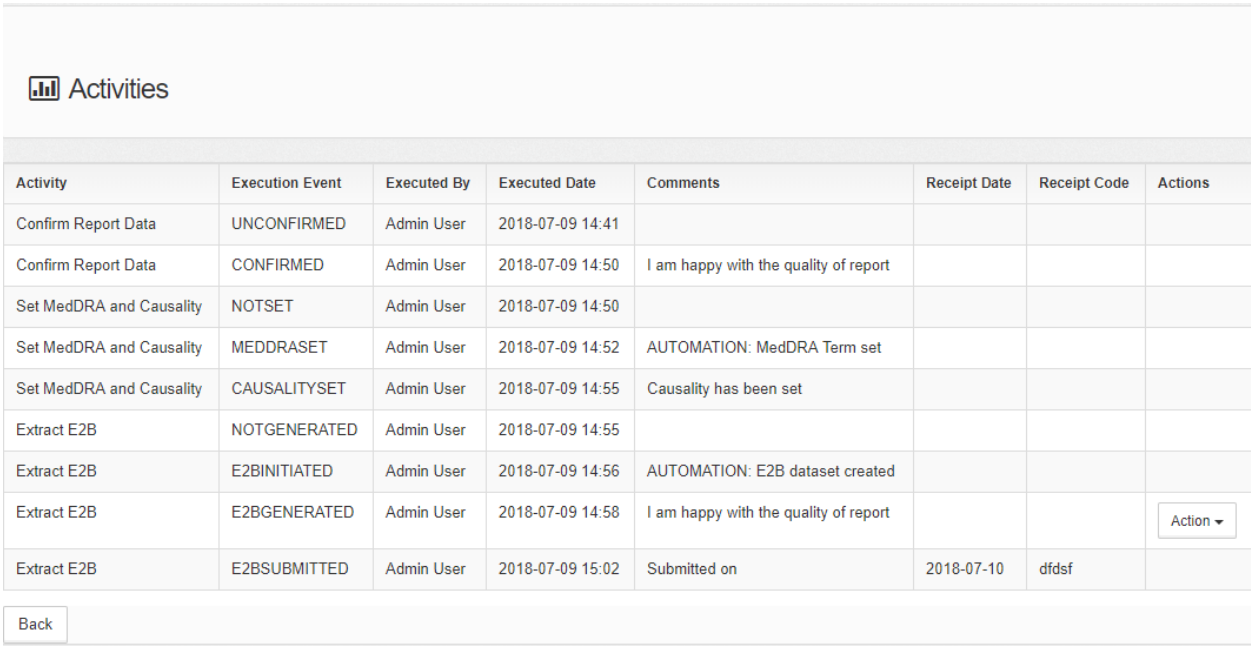
### 5.4.1 Viewing Activity History for Report

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

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




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



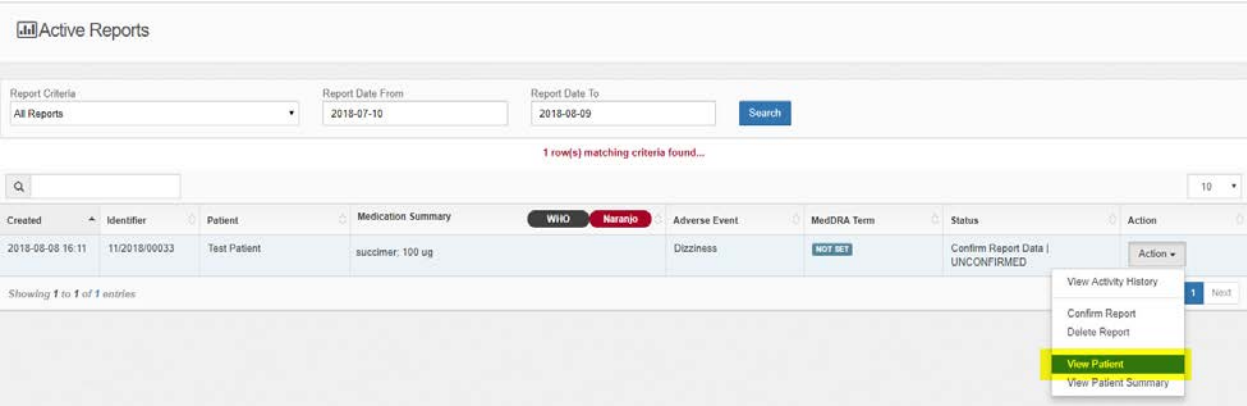

The columns in the activity history table are described below:

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

### 5.4.2 Viewing a Patient Record

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

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




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

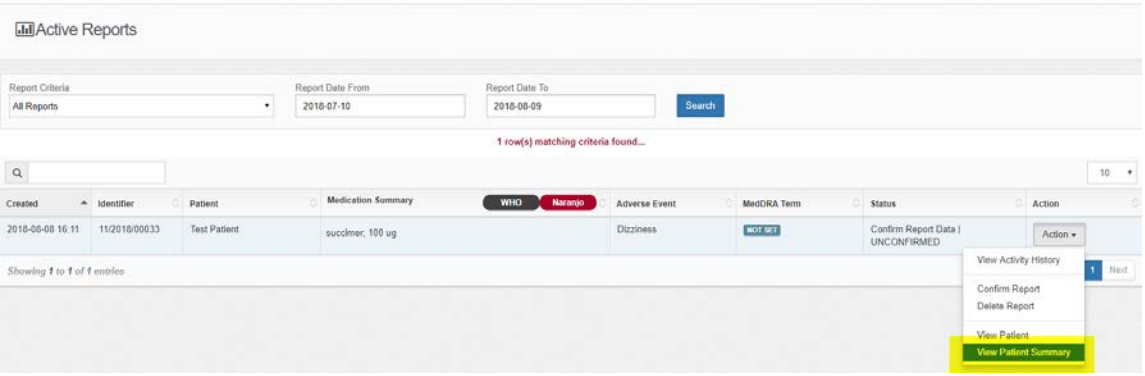

This menu item will only be made available under the following circumstances:

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

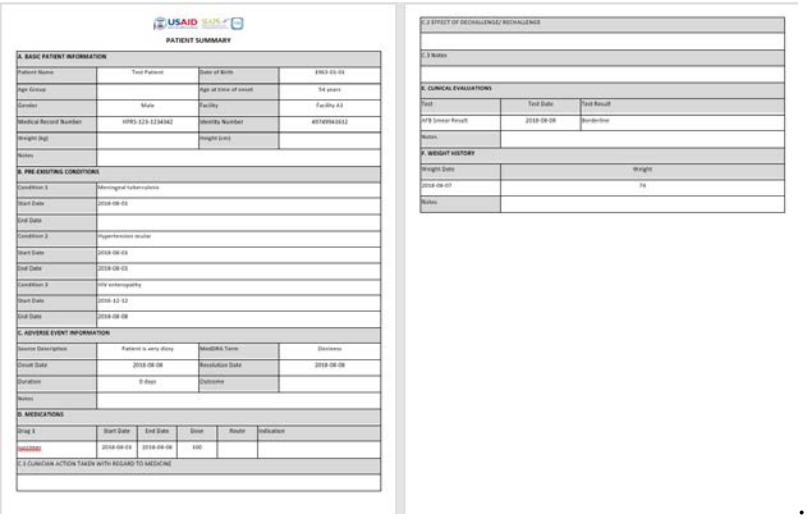
### 5.4.3 Extracting a Patient Summary

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

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




The system generates an extract of the patient summary:



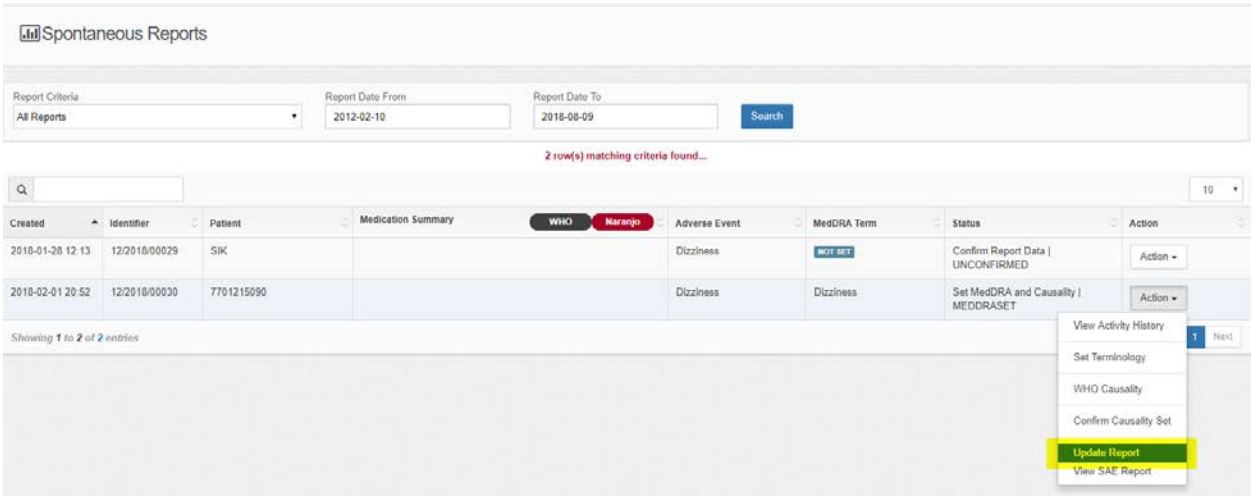


If the event is defined as serious, the system will include additional information that explains the seriousness of the report. The menu item for generating the extract will be changed to **View SAE Report.**

### 5.4.4 Updating a Spontaneous Report

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

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




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

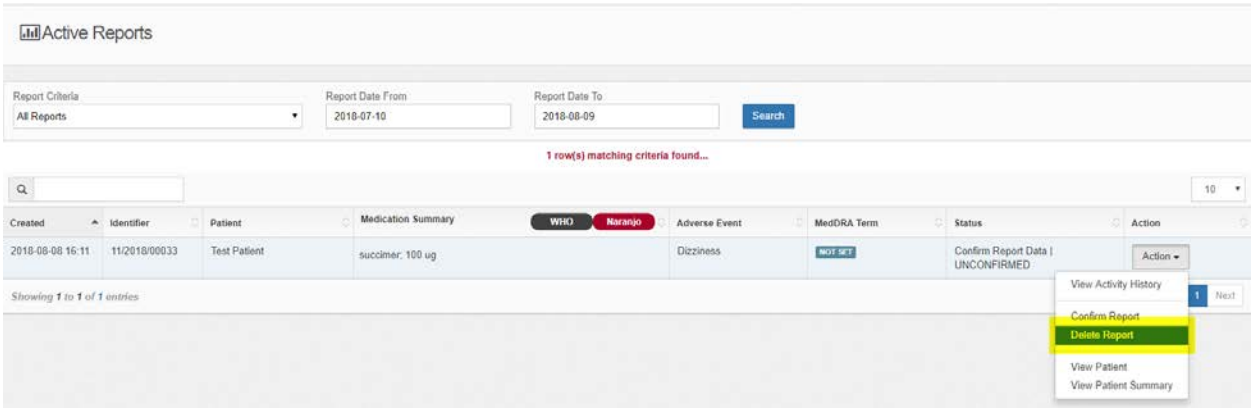

This menu item will only be available for spontaneous reports.

## 5.5 Pharmacovigilance Activities – Confirm Report Data

### 5.5.1 Deleting a Report

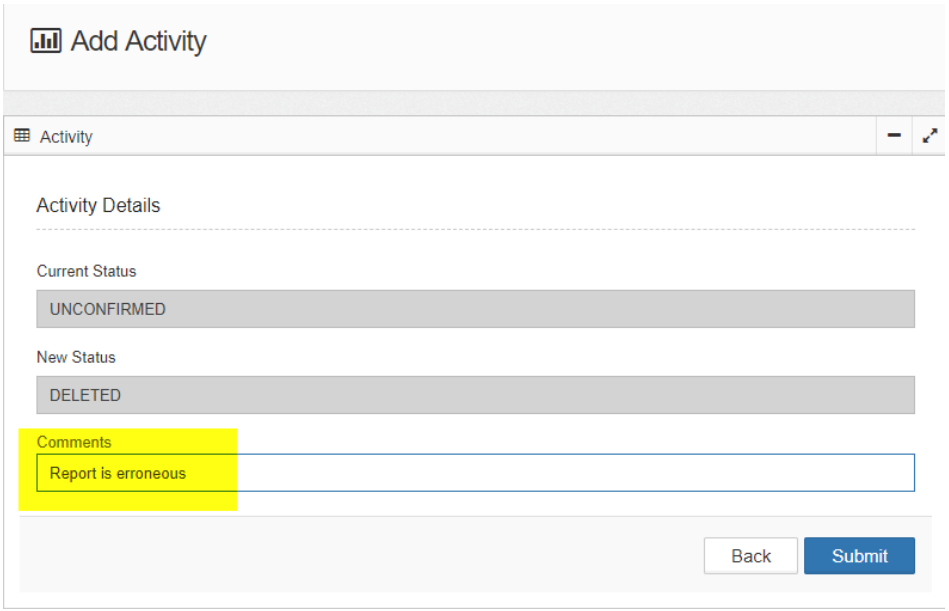
The **Confirm Report Data** stage enforces a process whereby the analyst ensures the necessary clinical data is of sufficient quality to allow terminology and causality to be completed. In the event a report is deemed to be insufficient, inaccurate, or erroneous, a report may be deleted, which will effectively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

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

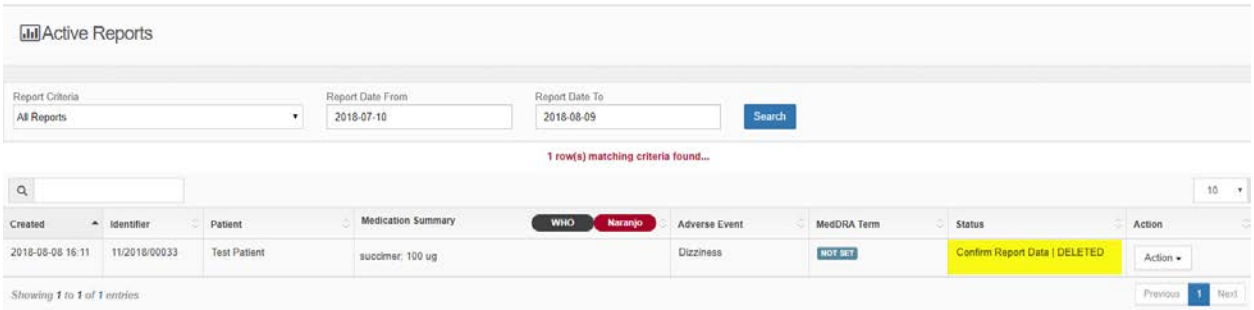



The system will navigate you to the **Add Activity** page.

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




The system will update the status of the report accordingly.

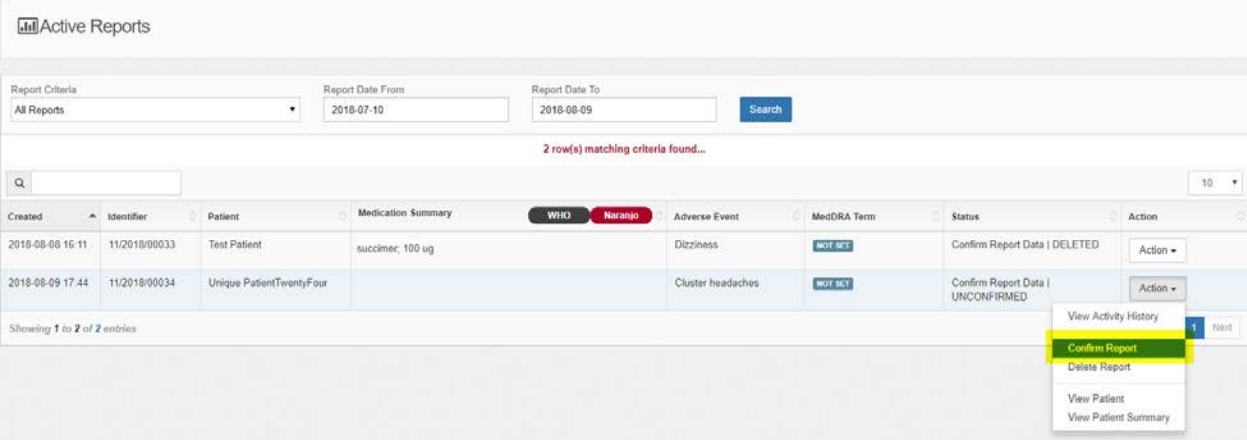



Once a report is deleted, it is not possible to re-include the report for analysis. Please ensure you are correct in deleting the report before committing the action.

### 5.5.2 **Confirming a Report**

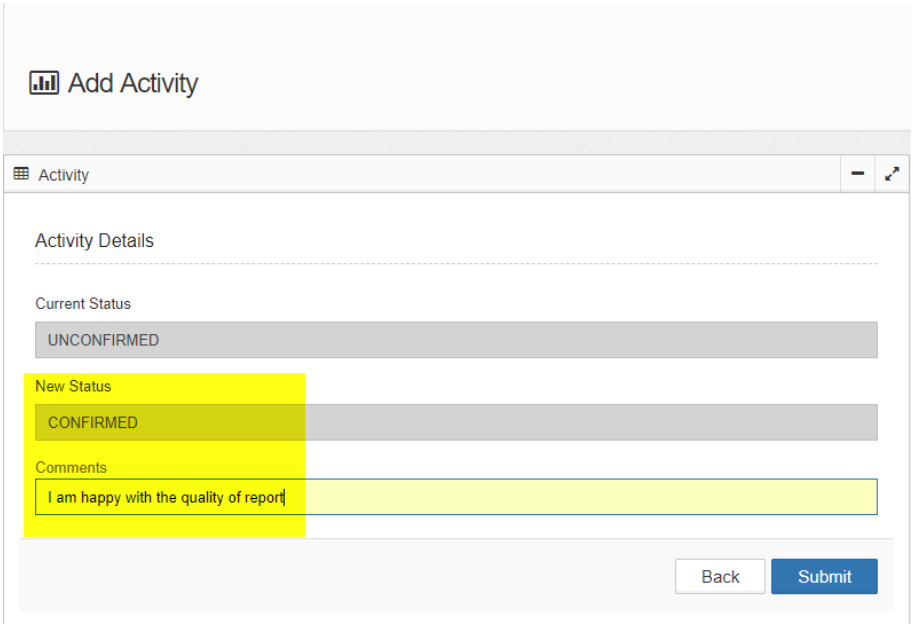
The **Confirm Report Data** stage enforces a process whereby the analyst ensures the necessary clinical data is of sufficient quality to allow terminology and causality to be completed. When a report is deemed to be sufficient and accurate, the report should be confirmed, which will effectively allow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

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

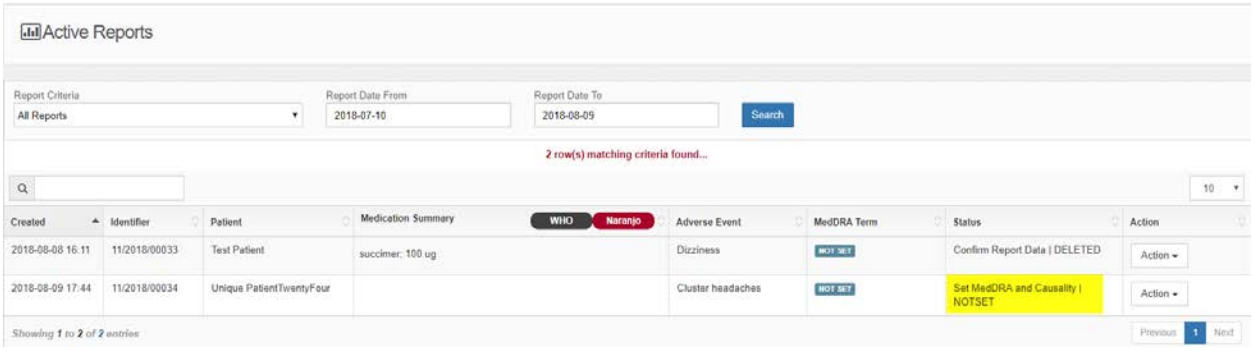



The system will navigate you to the **Add Activity** page.

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




The system will update the status of the report accordingly.





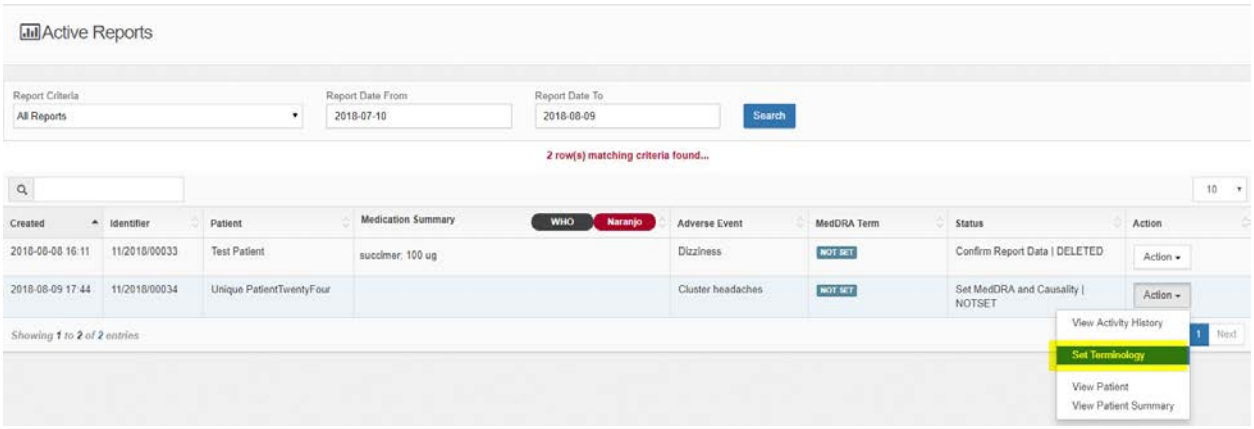
Confirming a report will move the report into the next stage: **Set MedDRA and Causality.**

## 5.6 Pharmacovigilance Activities – Set MedDRA and Causality

### 5.6.1 Set MedDRA Terminology

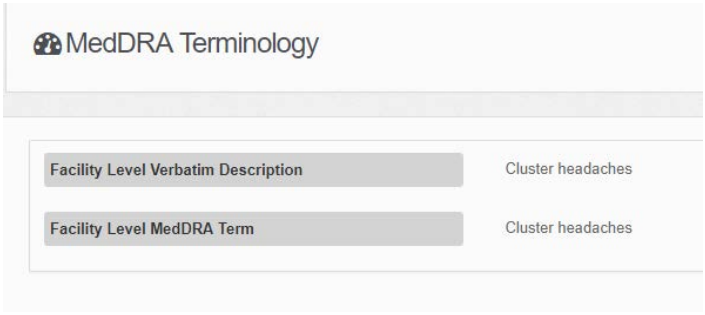
The **Set MedDRA and Causality** stage facilitates the process of confirming the final MedDRA term for the adverse event and allows assignment of causality per relevant medication using either the World Health Organization or the Naranjo Causality Scale.

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




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

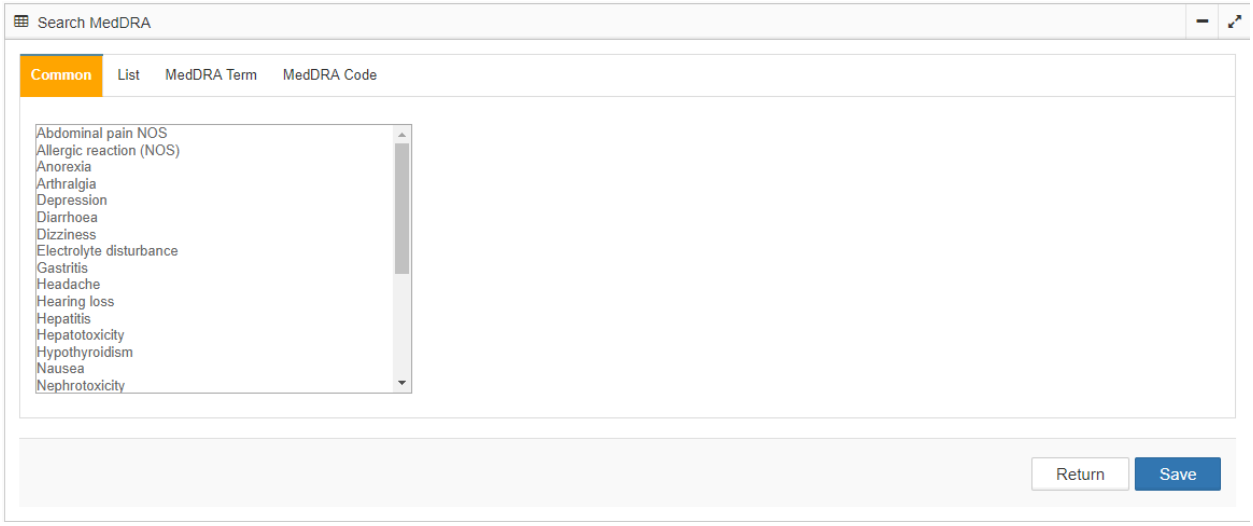
The **MedDRA Terminology** page displays the adverse event as reported by the clinician and/or reporter.



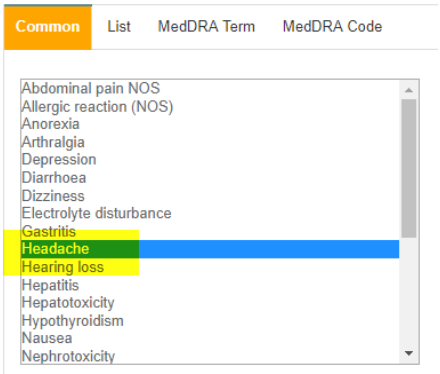
MedDRA terms can be searched in the following ways:

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

#### 5.6.1.1 Search for MedDRA Term by Common Term

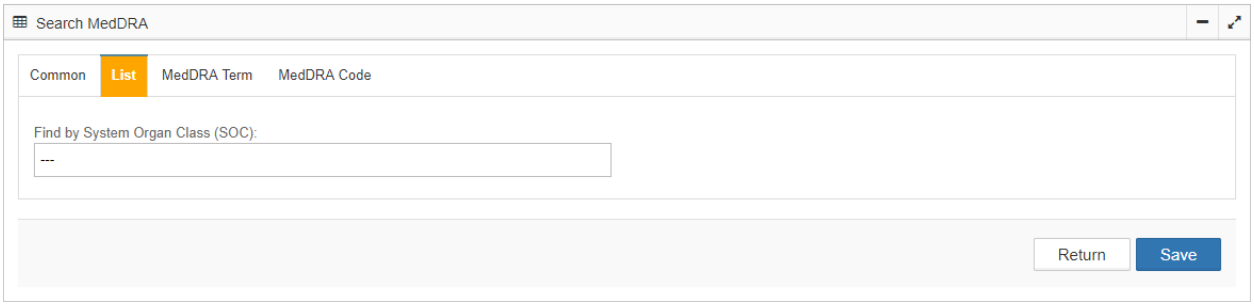



Common terms are listed terms for events that occur most frequently in your setting. Select the term in the list that that most accurately reflects the reported term.

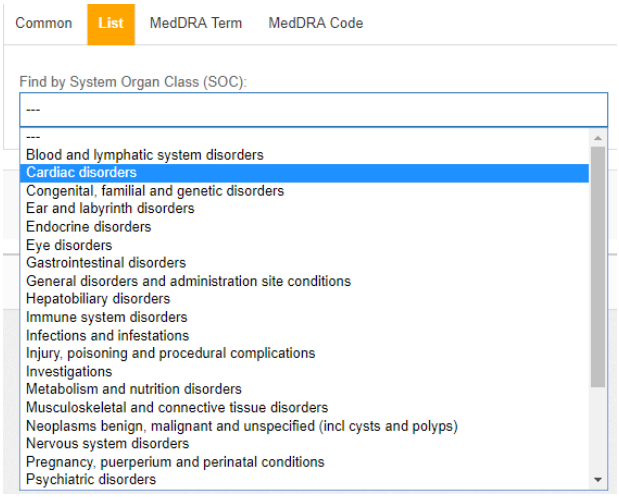



Click the **Save** button to assign the term, or click the **Return** button to cancel the action and return to the previous page. The report will be updated with the new term accordingly.

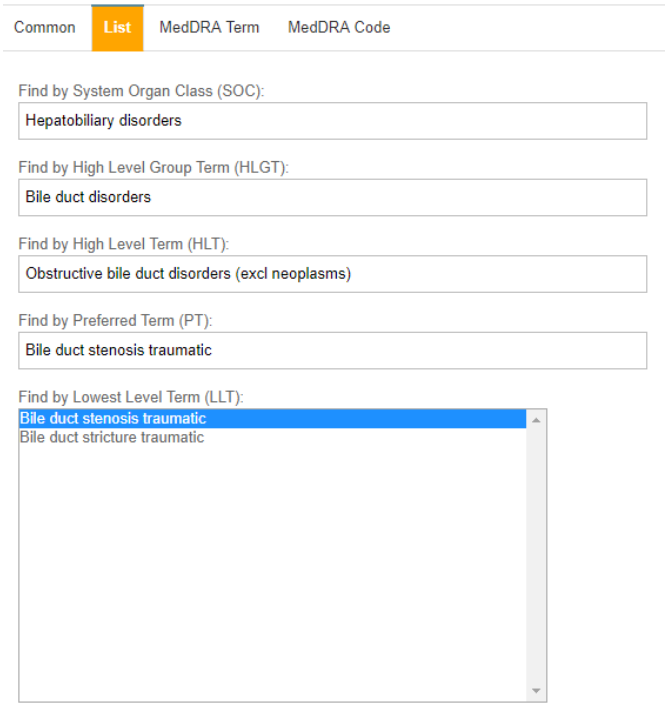
### 5.6.1.2 Search for MedDRA Term by List




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.

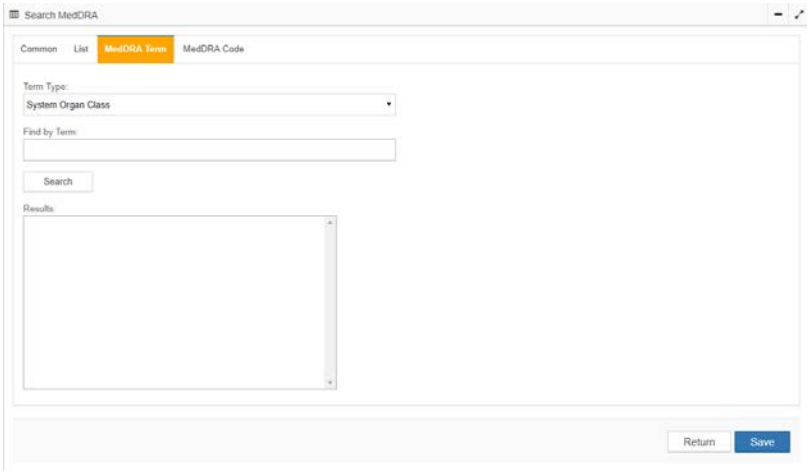



Continue selecting through the hierarchy (HLGT, HLT, PT) until you have selected the Low-Level Term that matches the adverse event.




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

### 5.6.1.3 Search by MedDRA Term

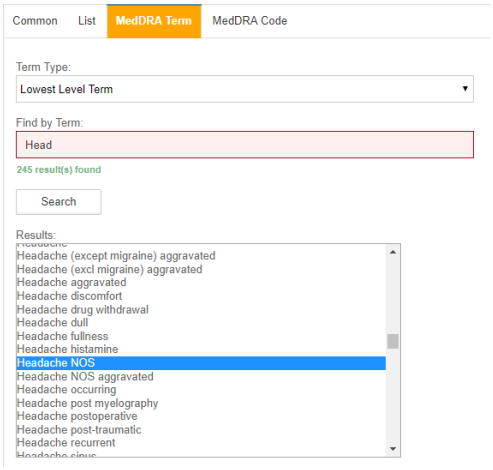



Searching by a MedDRA term allows you the ability to filter through MedDRA using a partial or fully defined term.

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

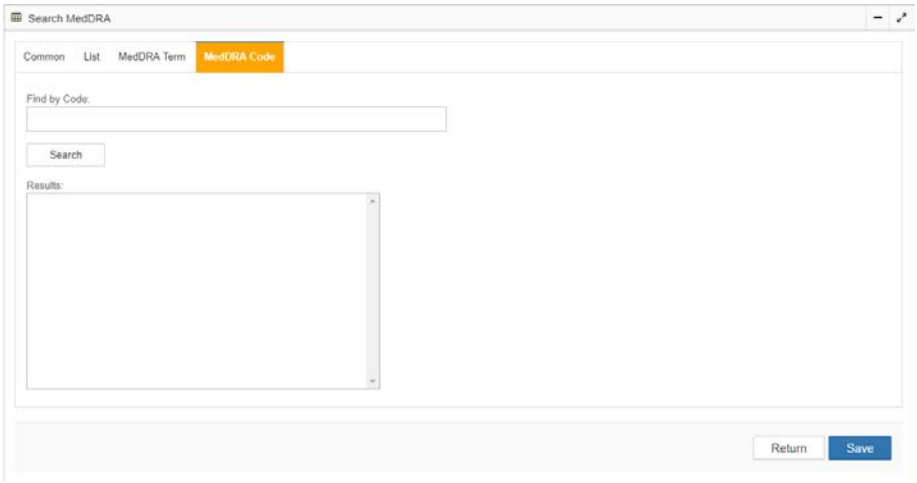
In the **Find by Term** field, enter the term you are searching for.


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




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

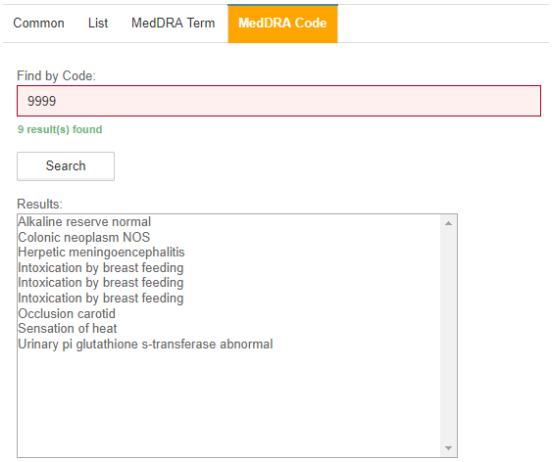
### 5.6.1.4 Search by MedDRA Code




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.

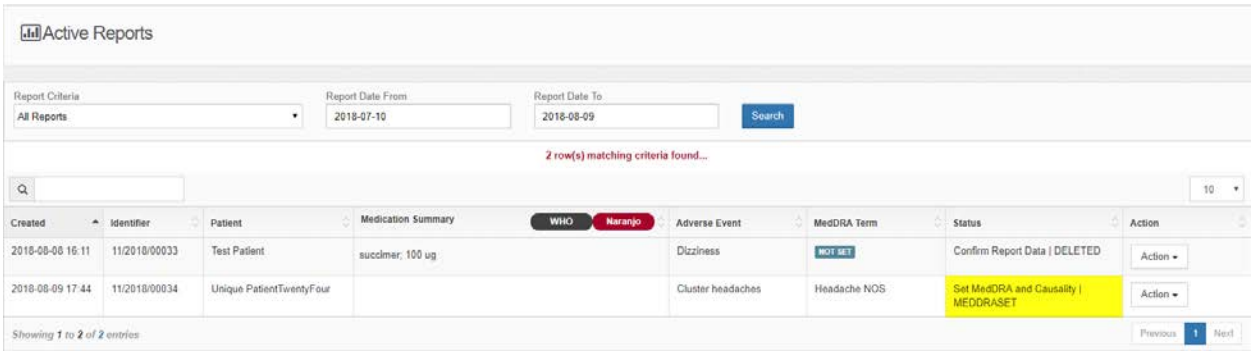



Click the **Save** button to assign the term, or click the **Return** button to cancel the action and return to the previous page. The report will be updated with the new term accordingly.

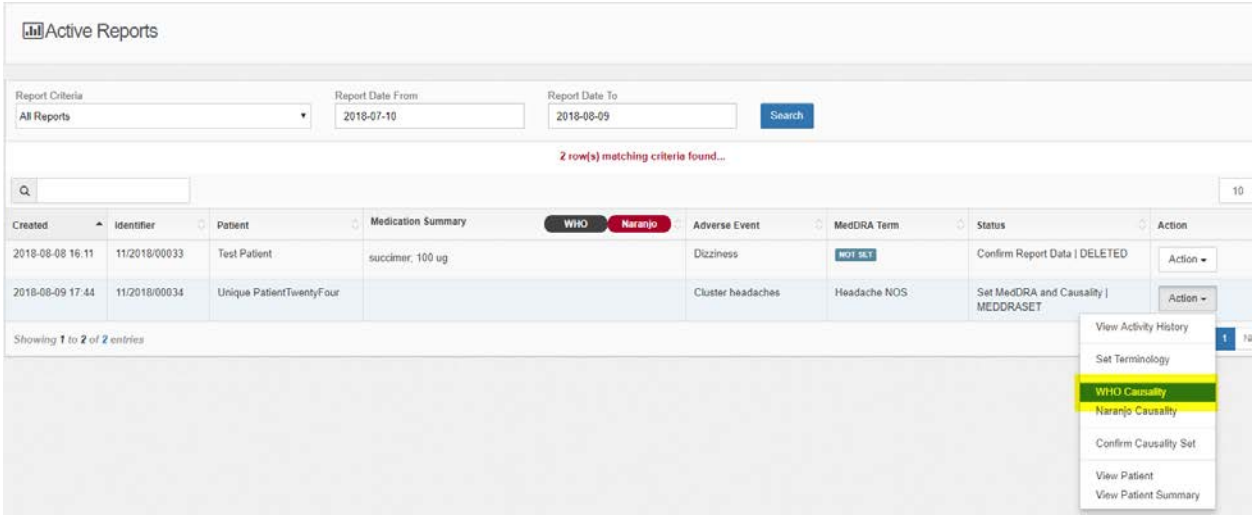
### 5.6.2 Causality Assessment using the WHO Scale

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

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

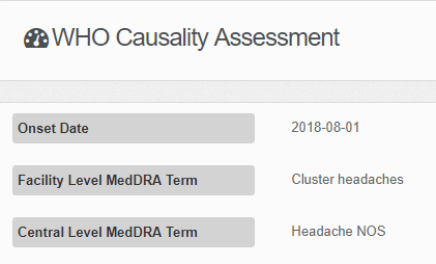



Setting the terminology will further allow the setting of causality per medication. Click on the **WHO Causality** menu option for the associated report you would like to set causality for.




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

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

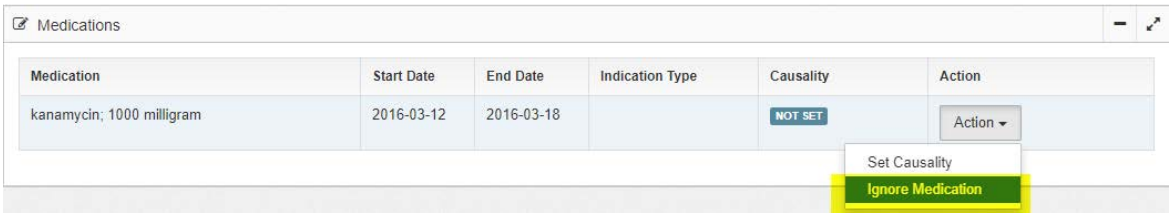



The **WHO Causality Assessment** page also displays the list of medications that the patient was exposed to at the onset of the adverse event.

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

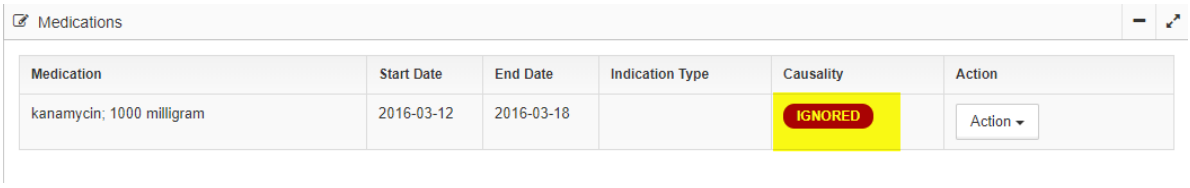
- Ignore the medication (the medication is definitely not responsible for the adverse event)
- Set causality for the medication

#### 5.6.2.1 Ignoring the Medication

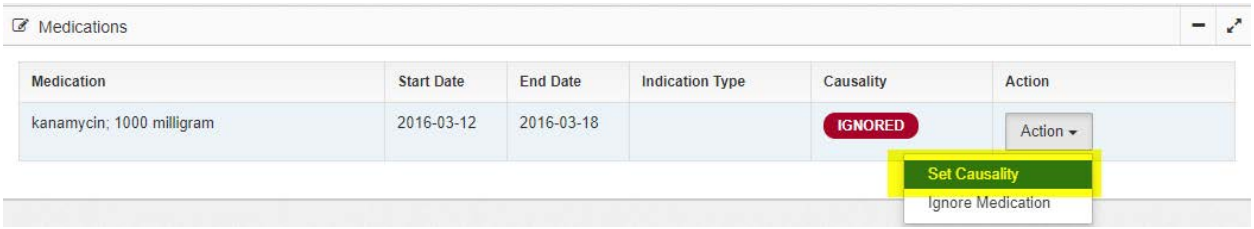



Ignoring the medication means that a causality assessment need not be set for that medication.

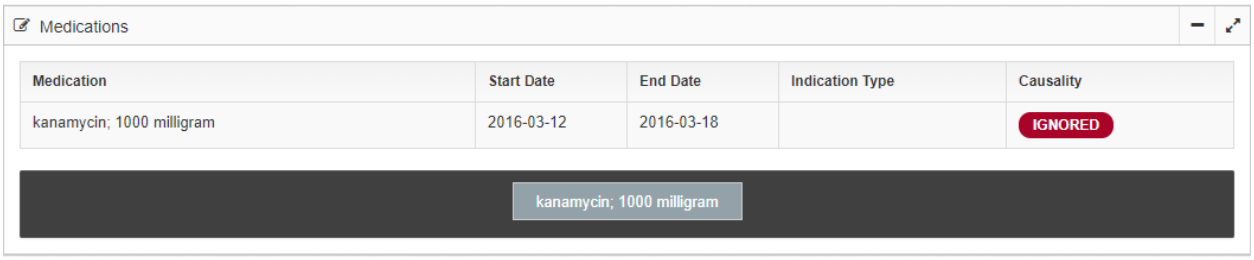
To ignore assigning a WHO causality assessment for this medication, click the **Ignore Medication** menu or click on the **Return** button to undo the action and return to the previous page. The system will assign **Ignored** as the causality term.



### 5.6.2.2 Set Causality



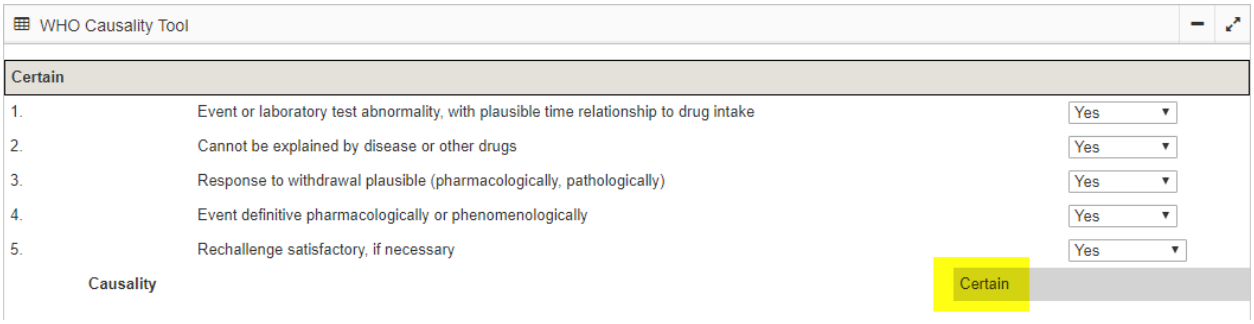

By clicking the **Set Causality** link, the system will enable you to set causality for this medication.




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.

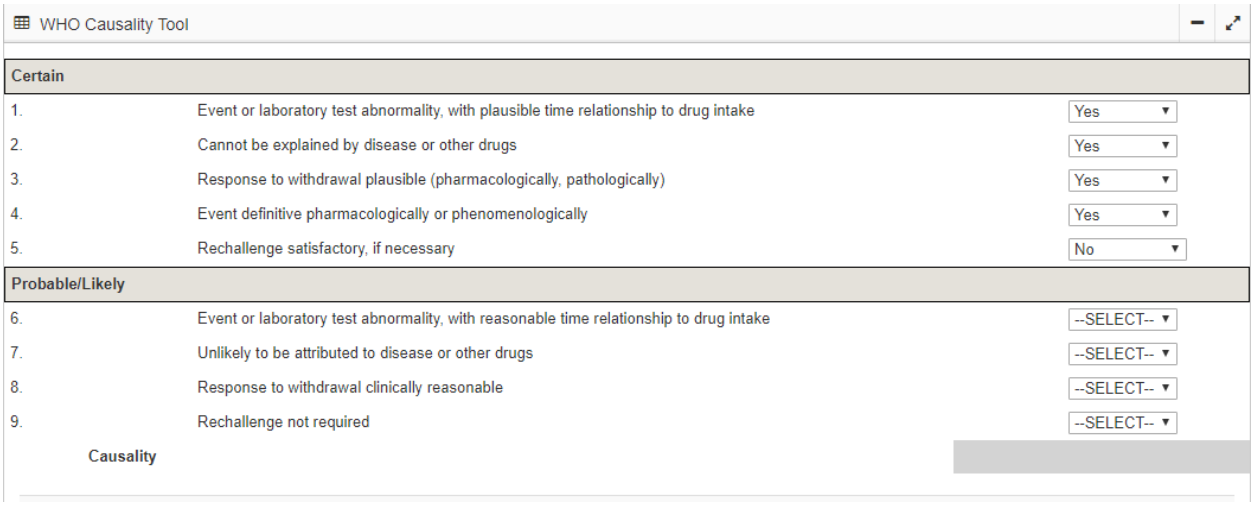
If responses to all five questions are **Yes,** the system will assign **Certain** as the causality term.




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

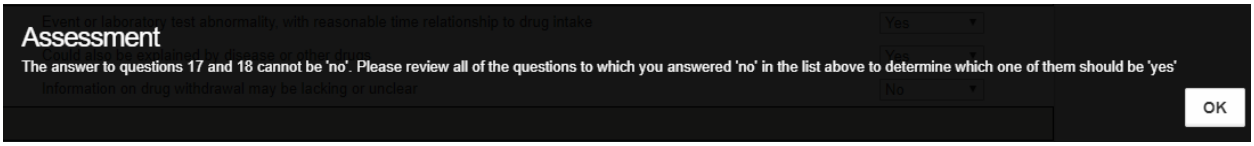
Click the **Return** button at any time to undo the action and return to the previous page.

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

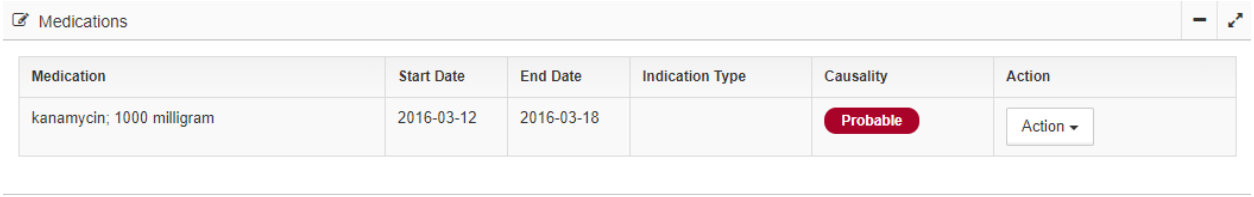



Continue this process until you have answered **Yes** to all questions in a specific category. This will result in the classification for that medication being set to that category.

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.



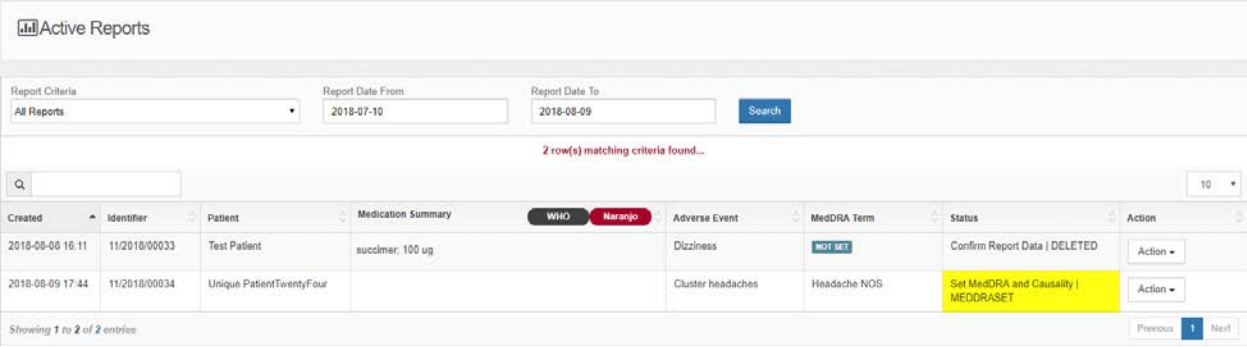

Once the term has been assigned click the **Save** button to continue, or click the **Cancel** button to undo the action and return to the previous page. The system will update the causality assessment for that medication accordingly.



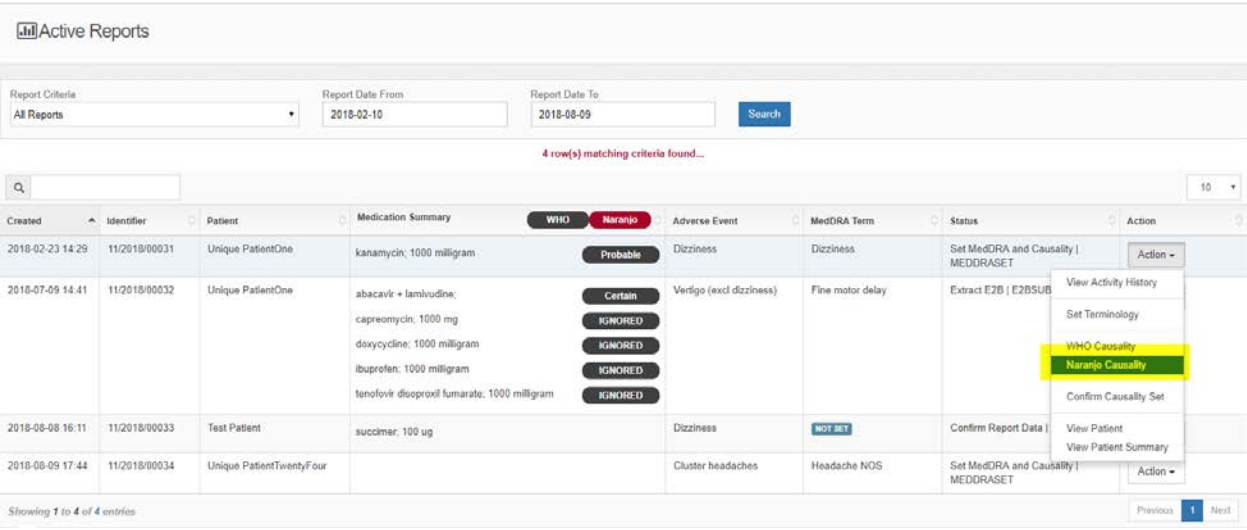
### 5.6.3 Causality Assessment using the Naranjo Scale

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.

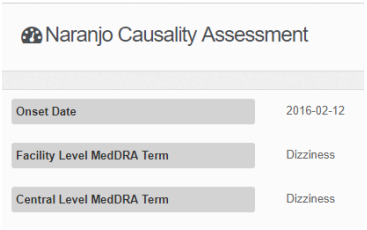



Setting the terminology will further allow the setting of causality per medication. Click on the **Naranjo Causality** menu for the associated report you would like to set causality for.




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

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

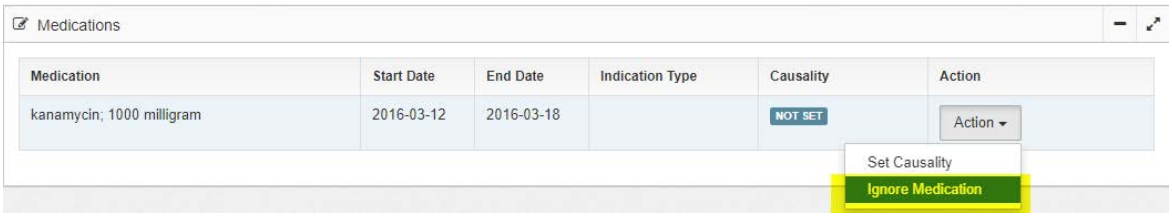



The **Naranjo Causality Assessment** page also displays the list of medications that the patient was exposed to at the onset of the adverse event.

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

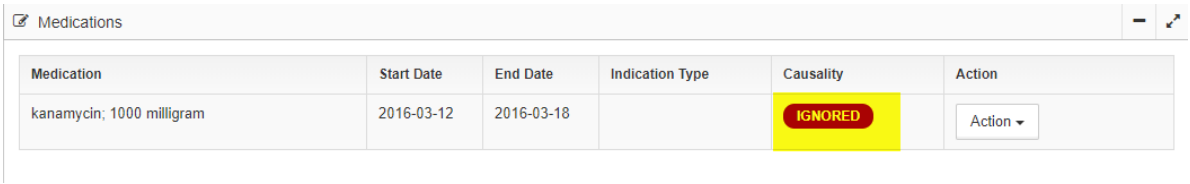
- Ignore the medication (the medication is definitely not responsible for the adverse event)
- Set causality for the medication

#### 5.6.3.1 Ignoring the Medication

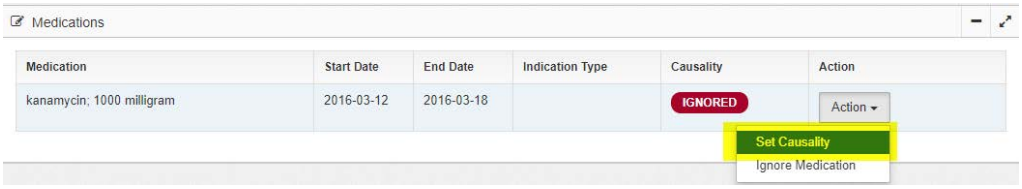



Ignoring the medication means that a causality assessment need not be set for that medication.

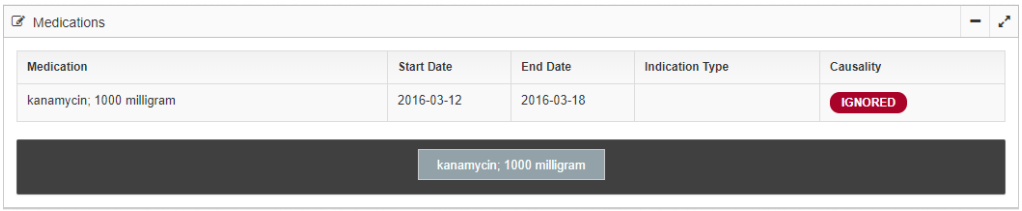
To ignore assigning a Naranjo causality assessment for this medication, click the **Ignore Medication** menu or click on the **Return** button to undo the action and return to the previous page. The system will assign **Ignored** as the causality term.



### 5.6.3.2 **Set Causality**

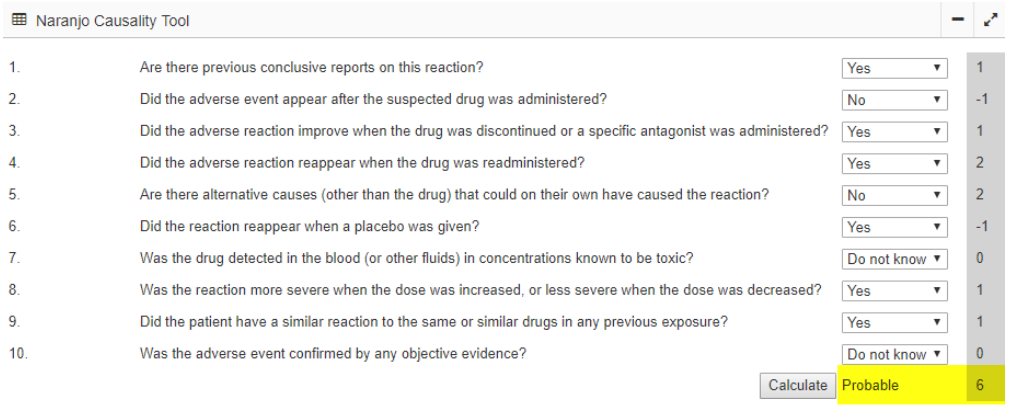



By clicking the **Set Causality** link, the system will enable you to set causality for this medication.

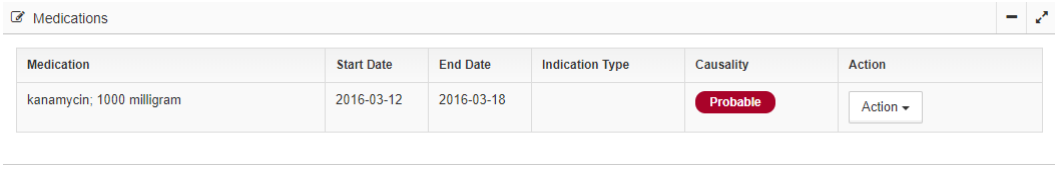



The system displays a series of questions for calculating the Naranjo causality score.

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



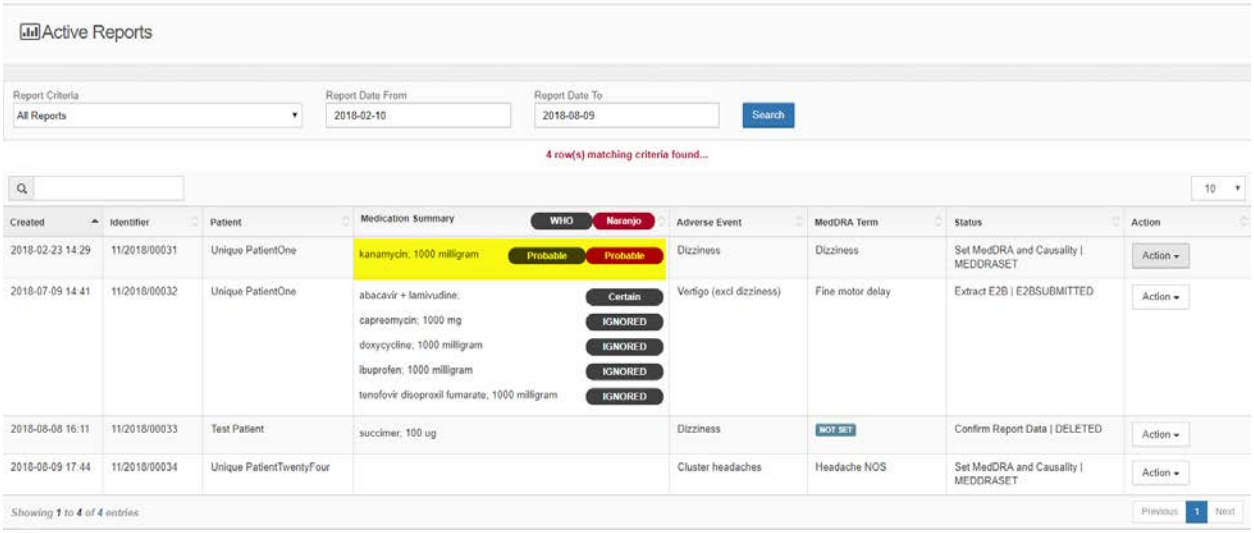

Click the **Save** button and the system will assign the term as per the calculation in the system, or click the **Cancel** button to undo the action. Click the **Return** button at any time to undo the action and return to the previous page.



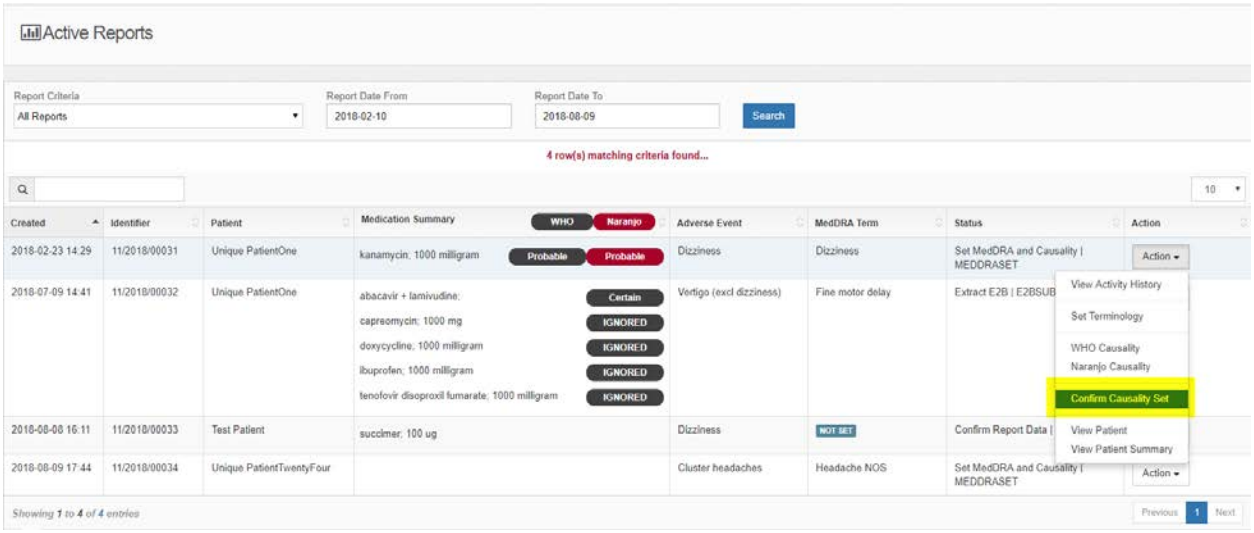
### 5.6.4 **Confirming Causality Set**

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.



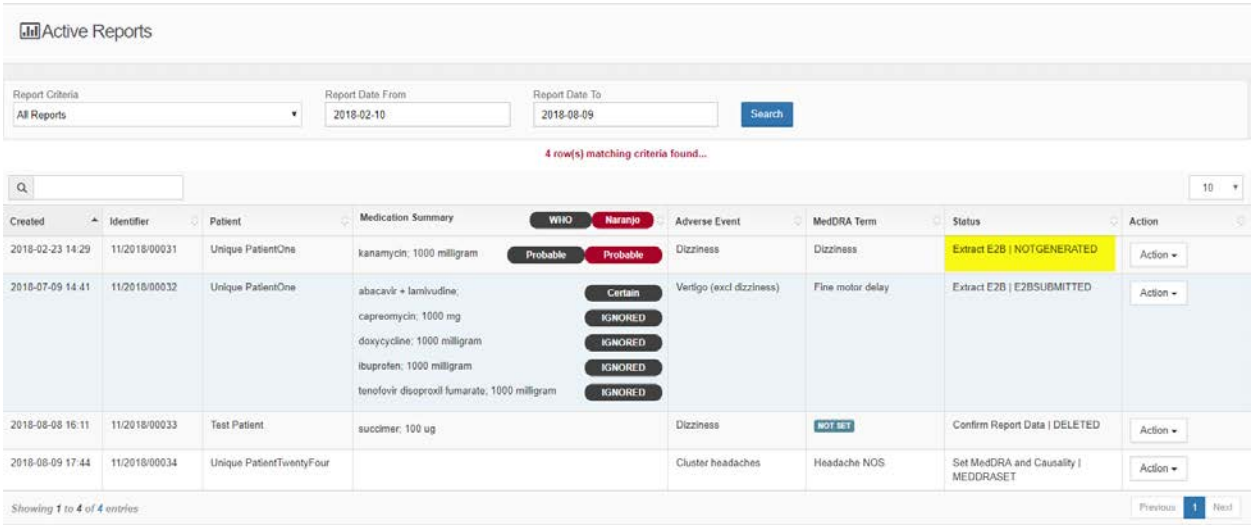

Click on the **Confirm Causality Set** menu for the associated report you would like to confirm causality set for.




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

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


The system will update the status of the report accordingly.




## 5.7 **Pharmacovigilance Activities – Extract E2B**

### 5.7.1 **Create E2B**

**BUZZWORDS**

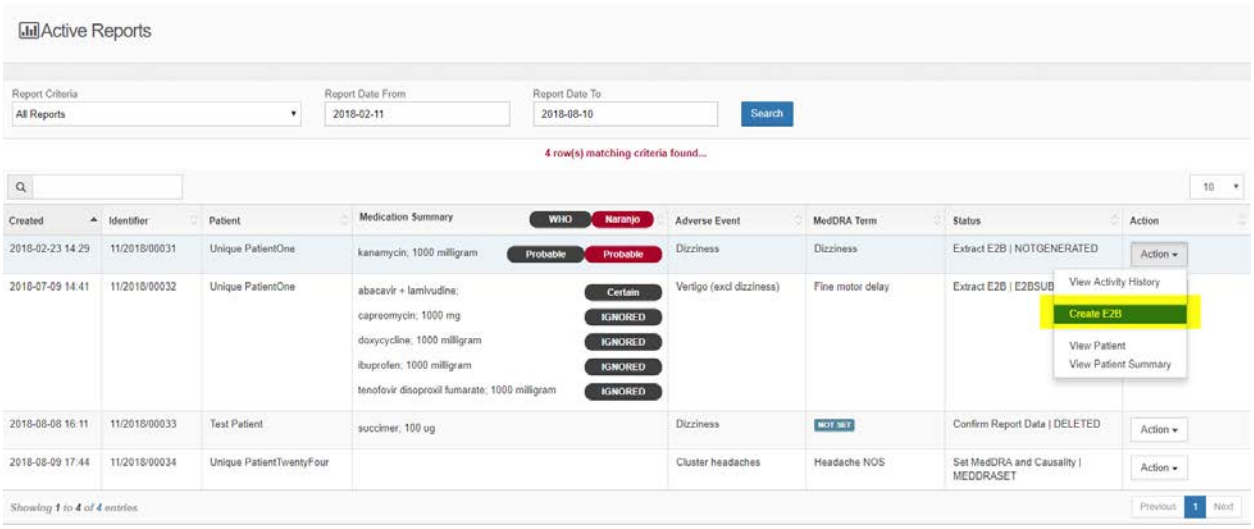
**ICH E2B:** An E2B dataset facilitates the Electronic Transmission of Individual Case Safety Reports (ICSRs) and can be used to submit such reports to WHO. The E2B dataset within

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

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


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

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




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

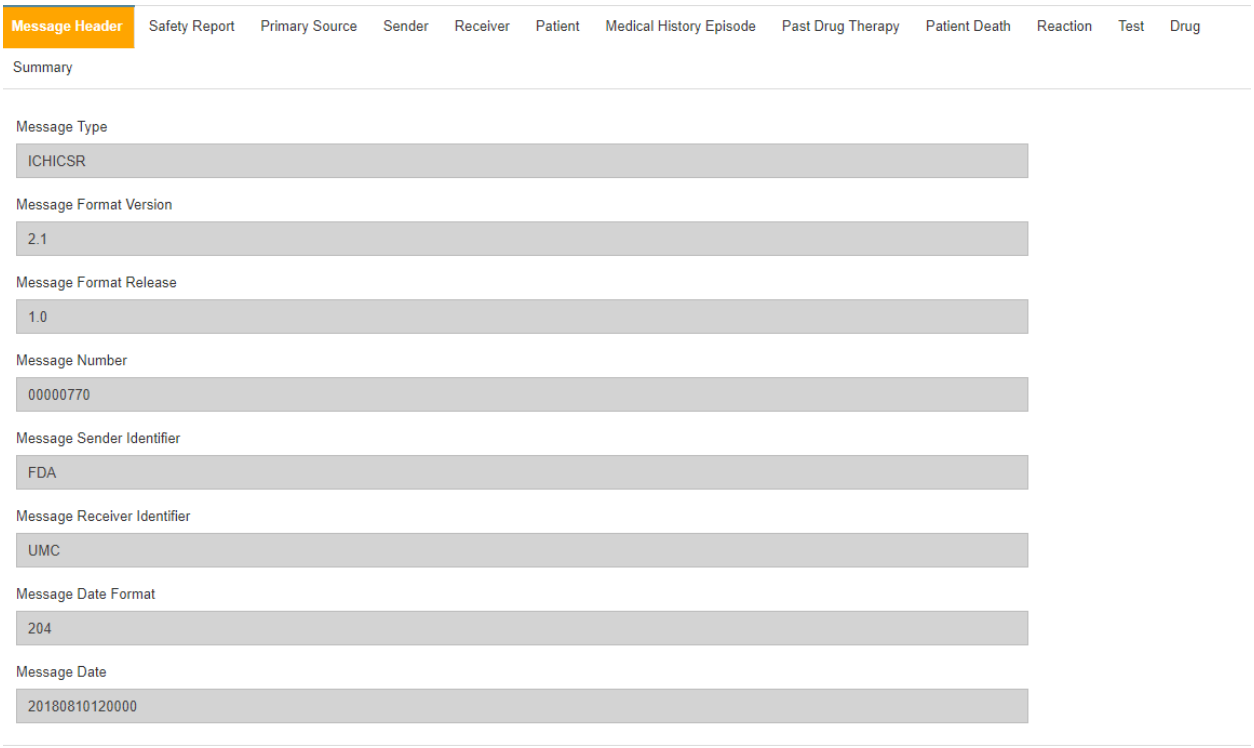
- Message Header
- Safety Report
- Primary Source
- Sender
- Receiver
- Patient
- Medical History Episode
- Past Drug Therapy
- Patient Death

- Reaction
- Test
- Drug
- Summary

#### 5.7.1.1 **Message Header**

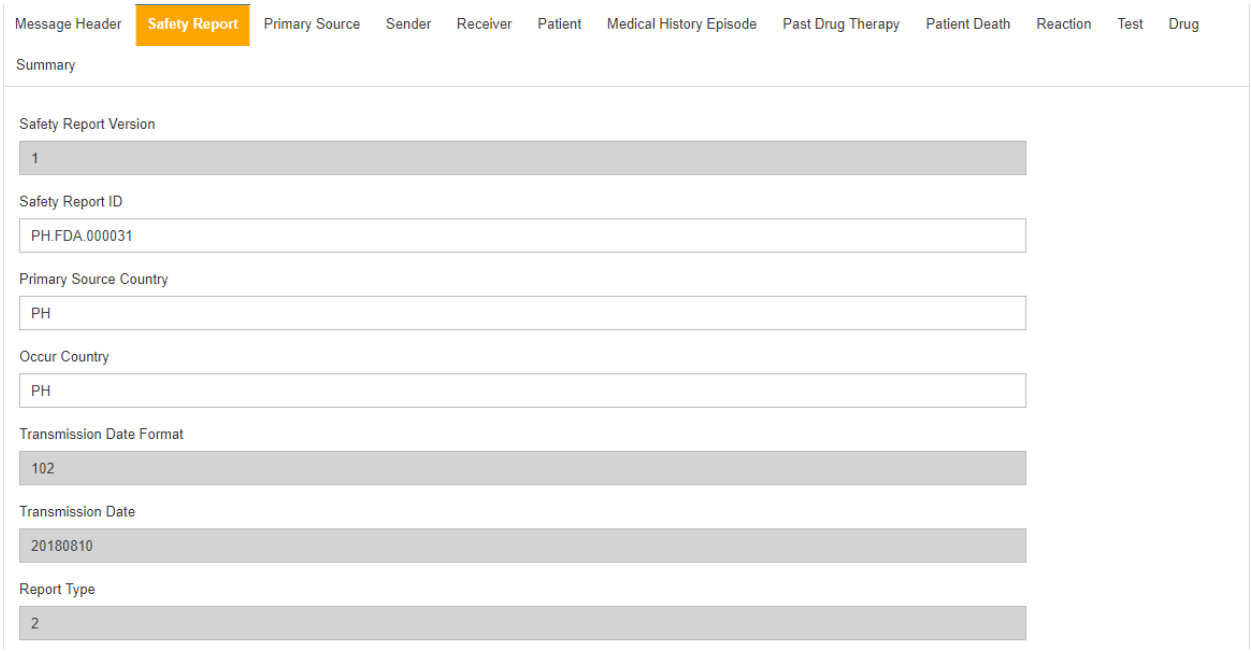
The message header section provides administrative and identification information about the report itself.

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



### 5.7.1.2 **Safety Report**

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



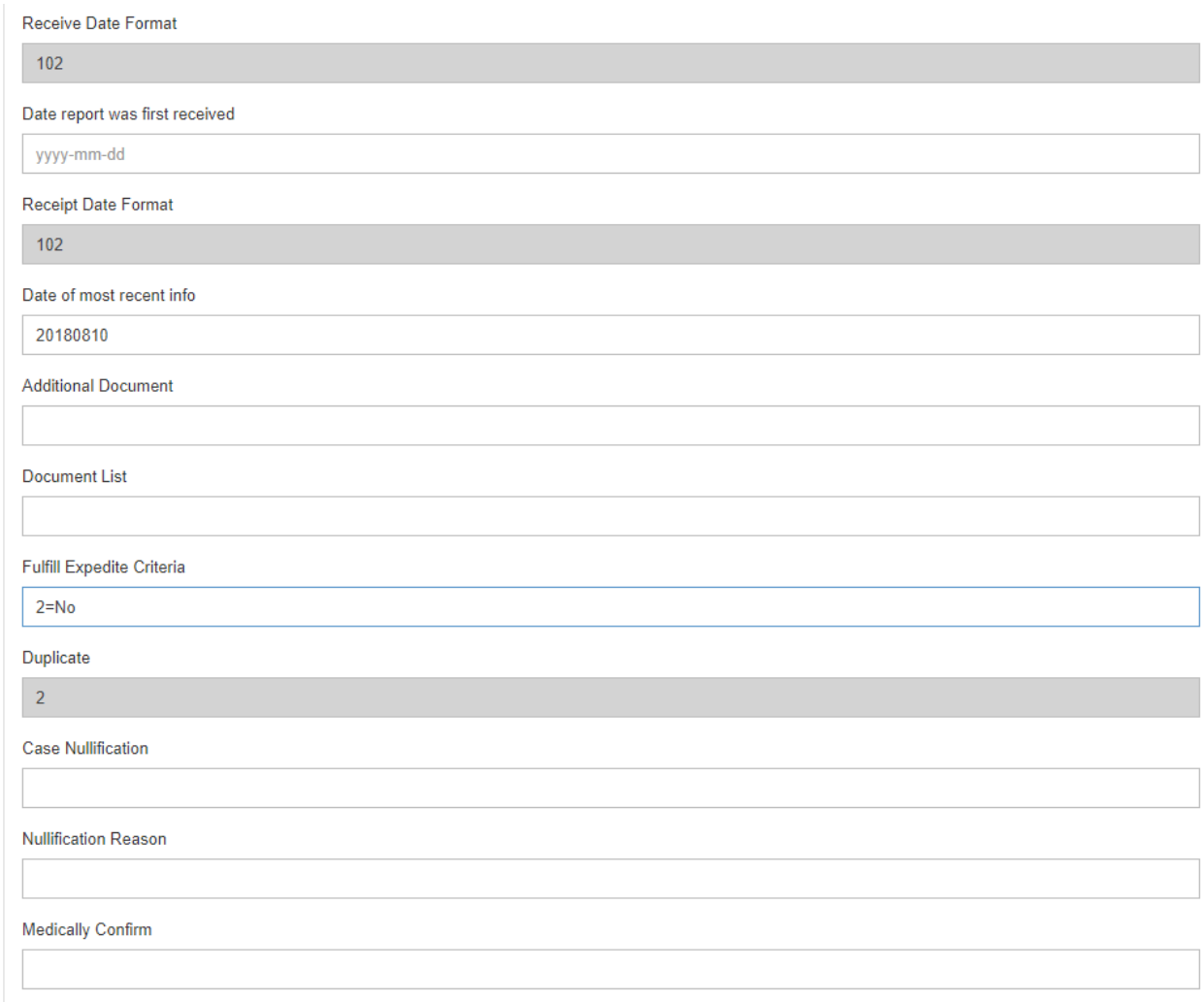

The fields in the Safety Report section are described below:

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

| | |
| --- | --- |
| Report Type | Spontaneous<br>Report from study<br>Other<br>Not available to sender (unknown) |


| | |
| --- | --- |
| Serious | Dropdown list<br>Yes, No |
| Seriousness Death | Dropdown list<br>Yes, No |
| Seriousness Life Threatening | Dropdown list<br>Yes, No |
| Seriousness Hospitalization | Dropdown list<br>Yes, No |
| Seriousness Disabling | Dropdown list<br>Yes, No |
| Seriousness Congenital Anomaly | Dropdown list<br>Yes, No |

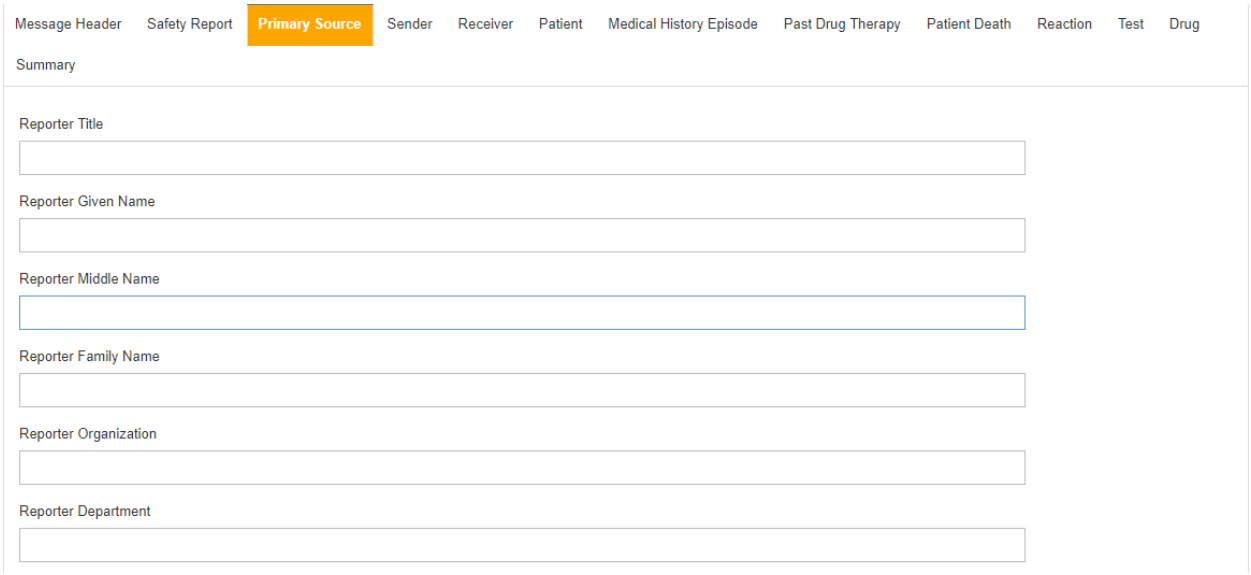
| | |
|---|---|
| Seriousness Other | Dropdown list<br>Yes, No |



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

### 5.7.1.3 **Primary Source**

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




The fields in the Primary Source section are described below:

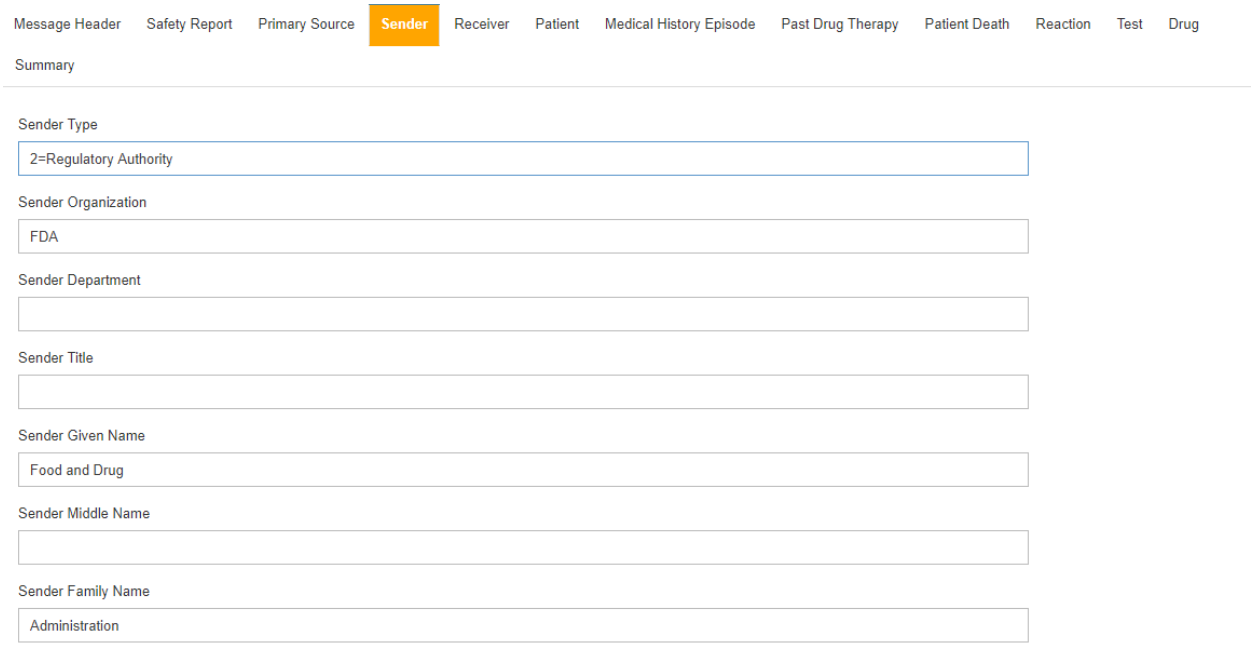
| | |
|---|---|
| Reporter Title | Text field |
| Reporter Given Name | Text field |
| Reporter Middle Name | Text field |
| Reporter Family Name | Text field |
| Reporter Organization | Text field |
| Reporter Department | Text field |


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

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

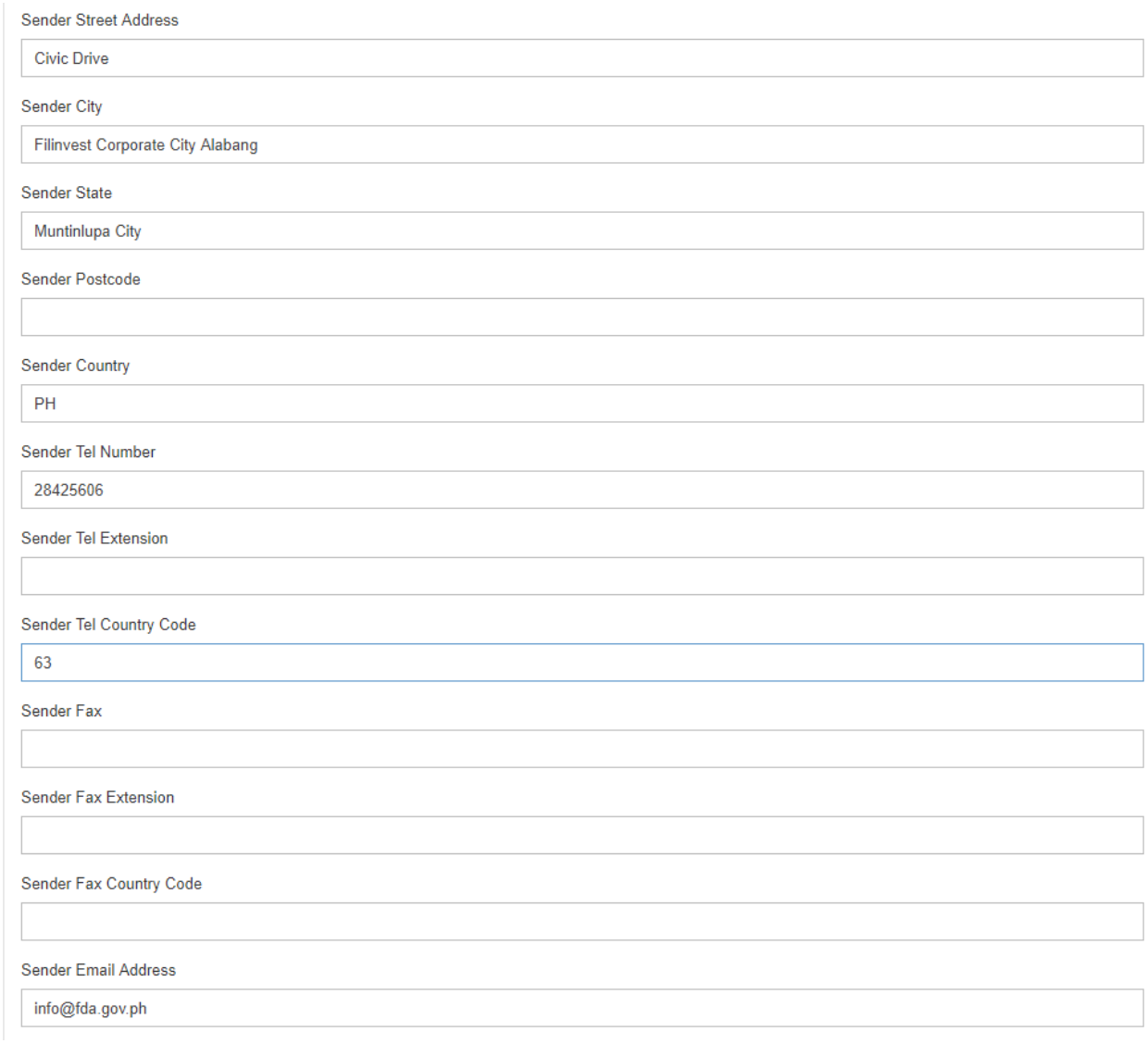
#### 5.7.1.4 **Sender**

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



The fields in the Sender section are described below:

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



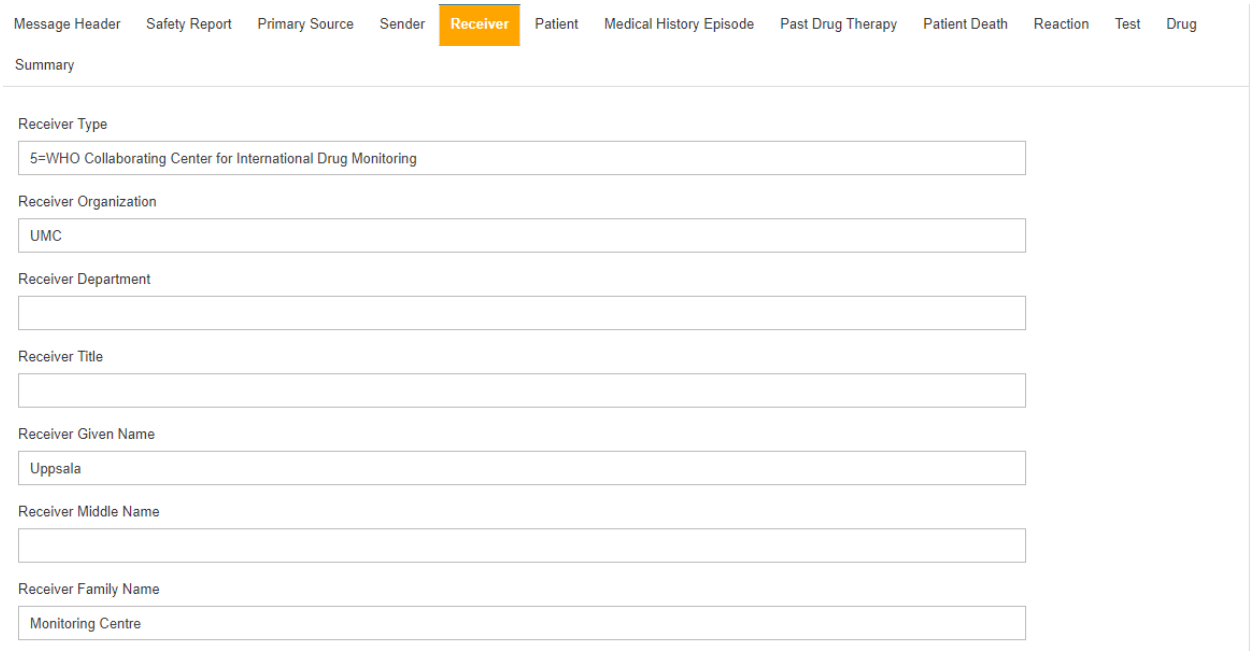

| | |
|---|---|
| Sender Street Address | Text field |
| Sender City | Text field |
| Sender State | Text field |
| Sender Postcode | Text field |
| Sender Country | Text field |

| | |
|---|---|
| Sender Tel Number | Text field |
| Sender Tel Extension | Text field |
| Sender Fax | Text field |
| Sender Fax Extension | Text field |
| Sender Fax Country Code | ISO3166 Country Code<br>Text<br>e.g., Philippines = PH |
| Sender Email Address | Text field |


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

### 5.7.1.5 **Receiver**

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




The fields in the Receiver section are described below:

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

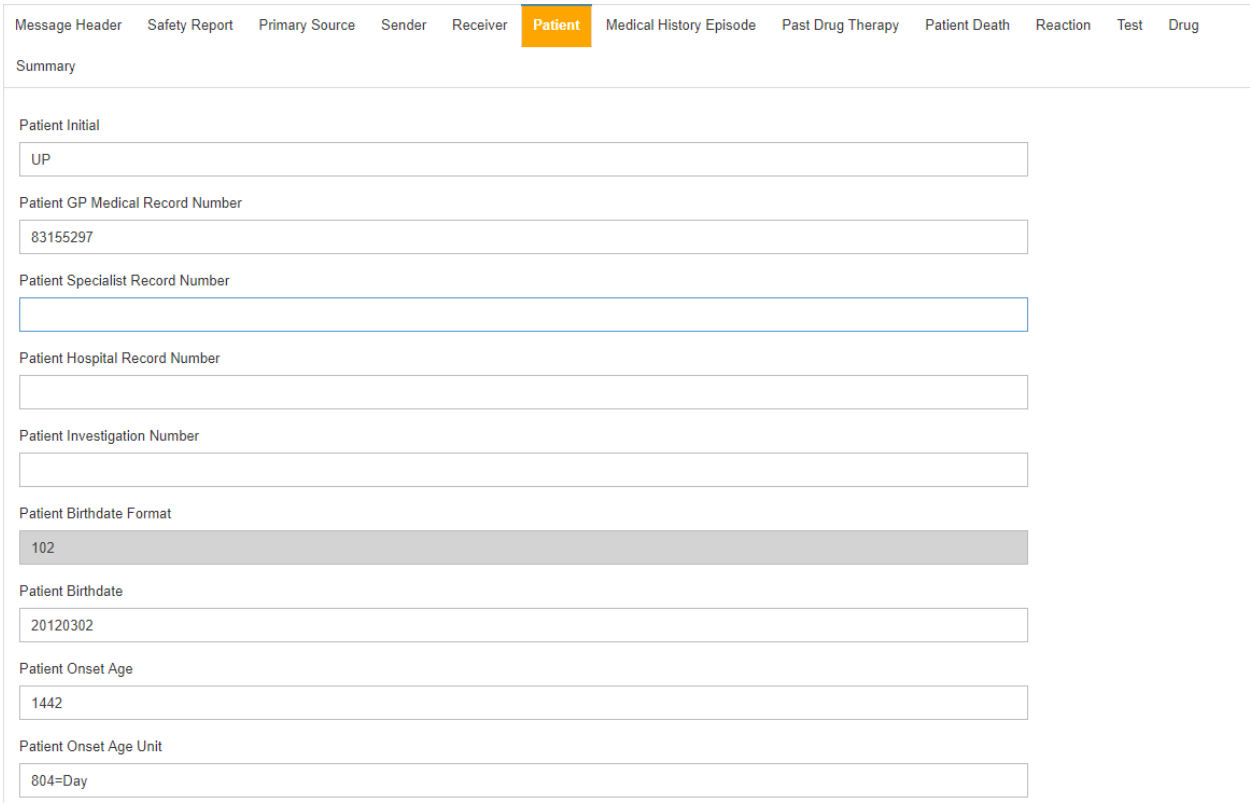

| | |
|---|---|
| Receiver Street Address | Text field |
| Receiver City | Text field |
| Receiver State | Text field |
| Receiver Postcode | Text field |
| Receiver Country | Text field |
| Receiver Tel | Text field |
| Receiver Tel Extension | Text field |

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


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

#### 5.7.1.6 **Patient**

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



The fields in the Patient section are described below:

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

Gestation Period

Gestation Period Unit

Patient Age Group

Patient Weight

Patient Height

Patient Sex

1=Male

Last Menstrual Date Format

102

Patient Last Menstrual Date

yyyy-mm-dd

Patient Medical History Text

Results Tests Procedures

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

### 5.7.1.7 **Medical History Episode**

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



Multiple history episode records can be created per patient.

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

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

### 5.7.1.8 **Past Drug Therapy**

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



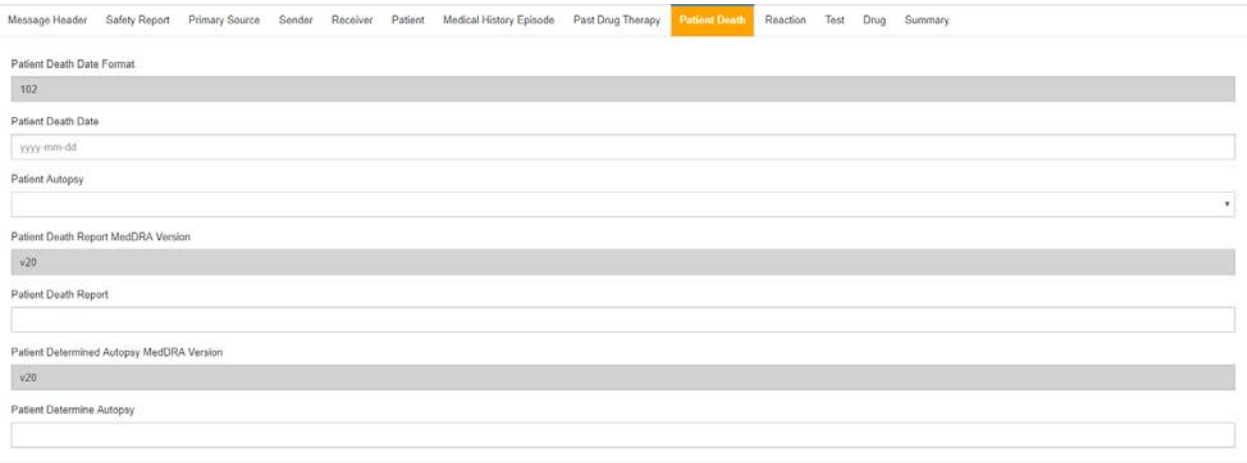
Multiple therapy records can be created per patient

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

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

### 5.7.1.9 **Patient Death**

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

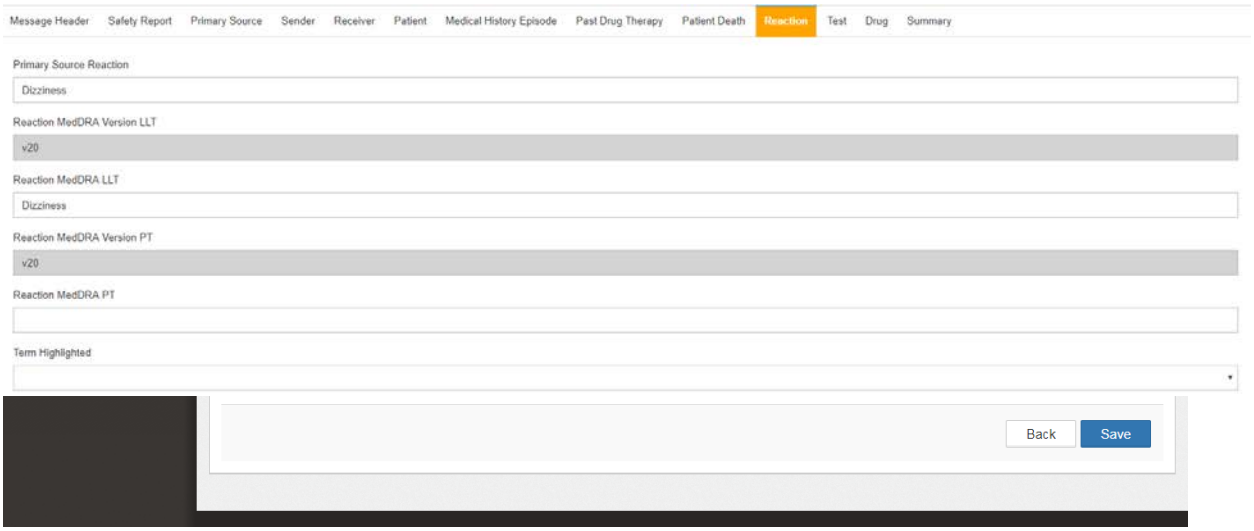



The fields in the Patient Death section are described below:

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

### 5.7.1.10 **Reaction**

The Reaction section provides information specific to the adverse event.



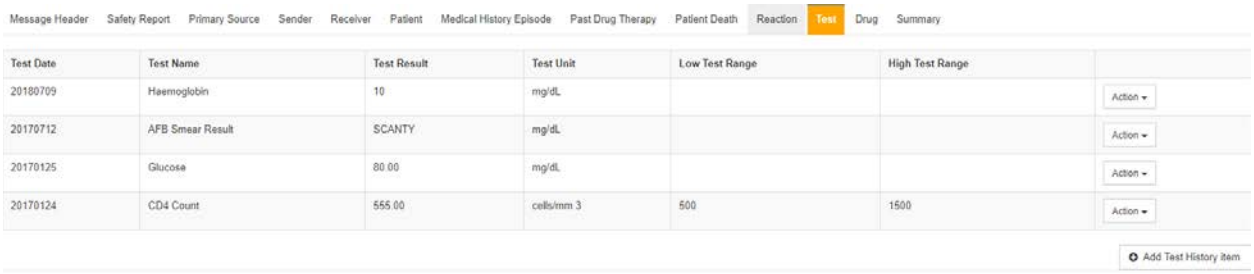

The fields in the Reaction section are described below:

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

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

### 5.7.1.11 **Test**

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




The fields in the Test section are described below:

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

### 5.7.1.12 **Drug**

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

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


The fields in the Drug section are described below:

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

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

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

#### 5.7.1.13 **Summary**

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

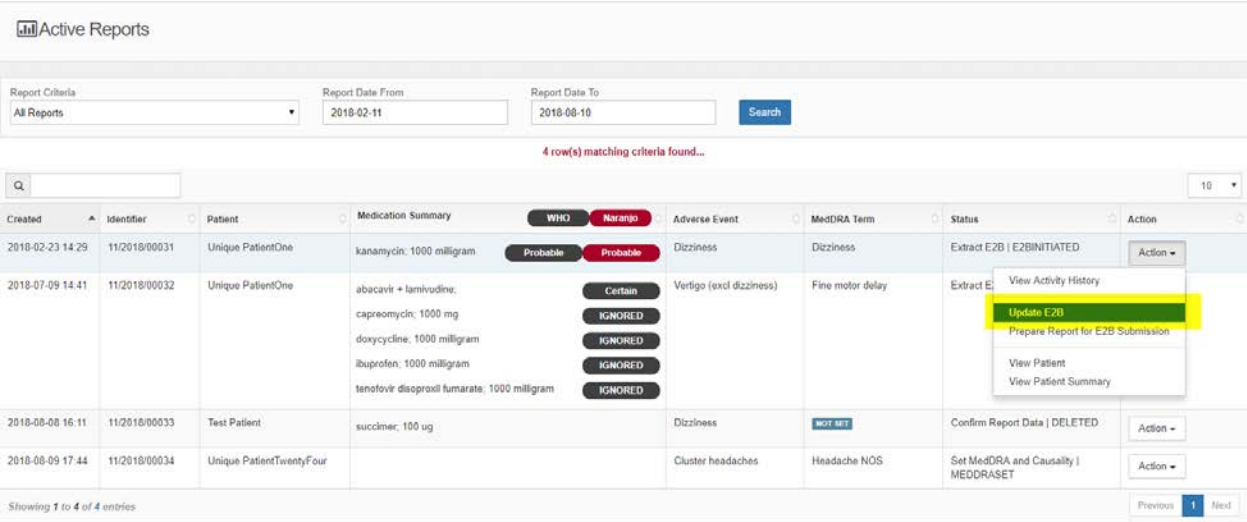

The fields in the Summary section are described below:

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

### 5.7.2 Adding Information to and Updating an E2B File

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

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



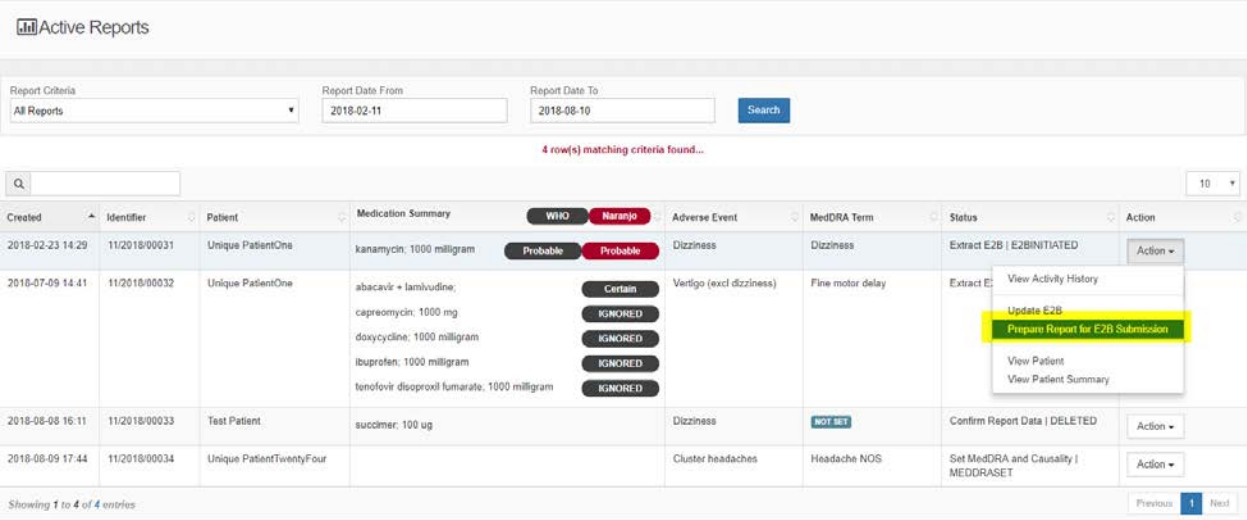

The system will navigate you to the **E2B ICH Report** page for the file.

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

### 5.7.3 **Preparing a Report for E2B Submission**

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

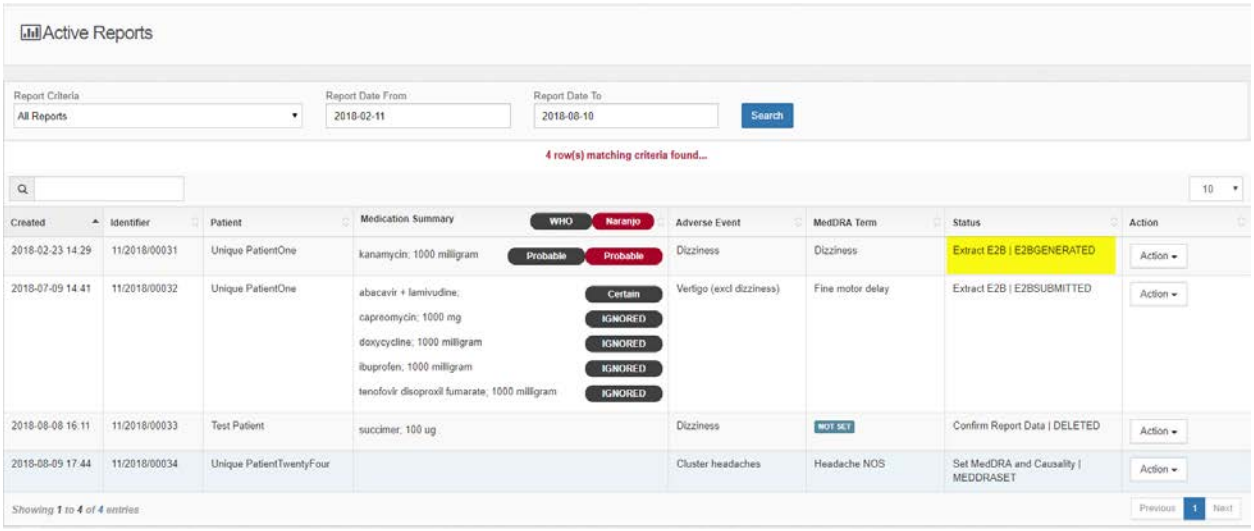
Once you have created an E2B file and searched for the report, click on the **Prepare Report for E2B Submission** menu for the associated report you would like to prepare.




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

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

The system will update the status of the report accordingly.

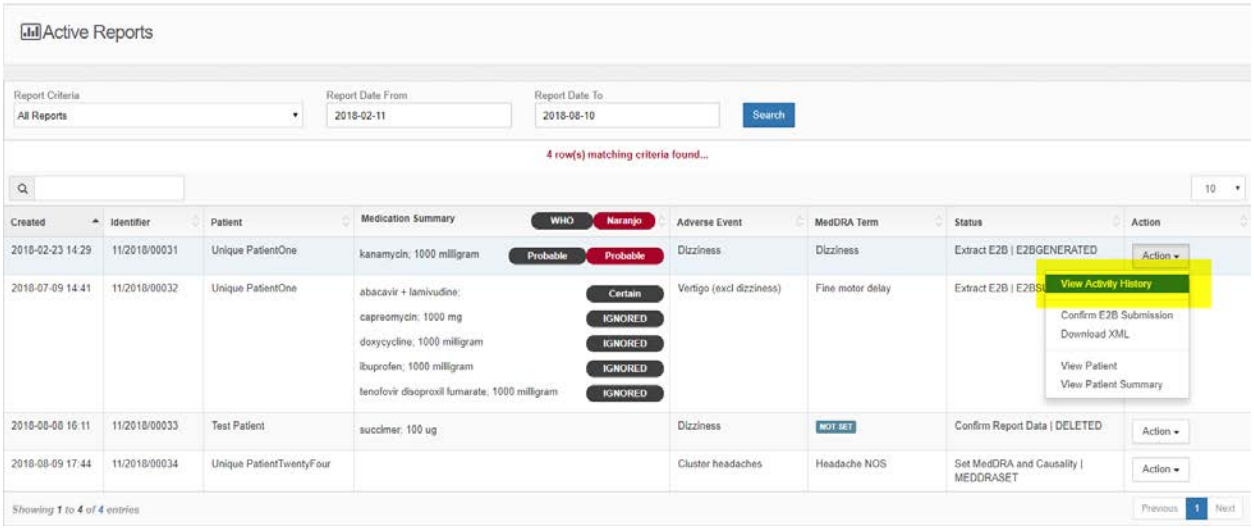




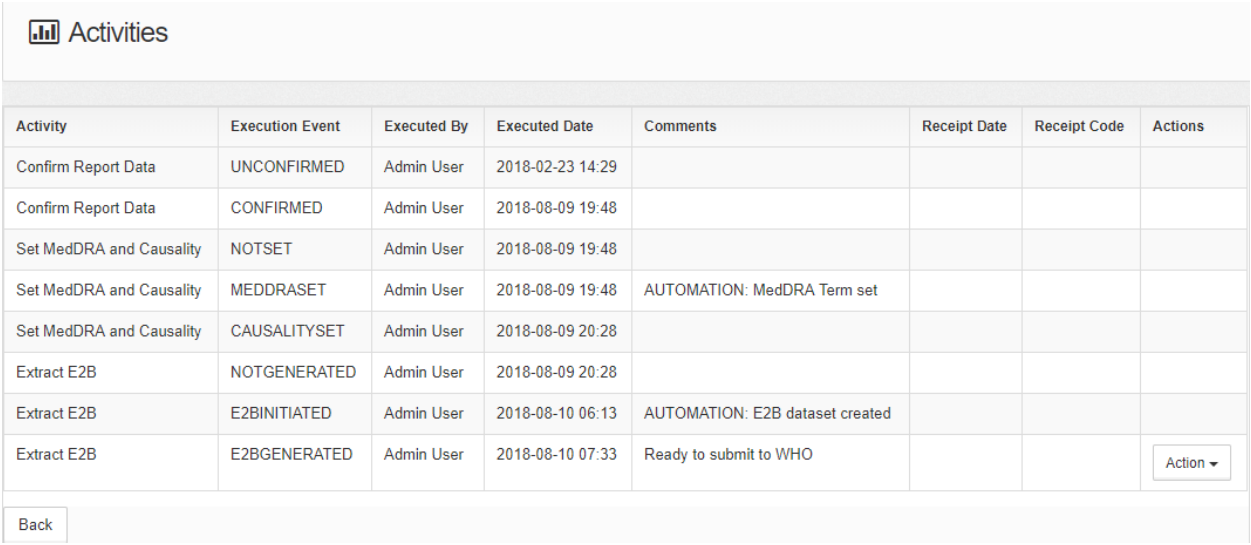
It is during this stage that PViMS prepares the XML file for submission. It also prepares an associated patient summary and patient extract that correspond to the clinical data at the point of generating the submission.

### 5.7.4 **Viewing the E2B XML File**

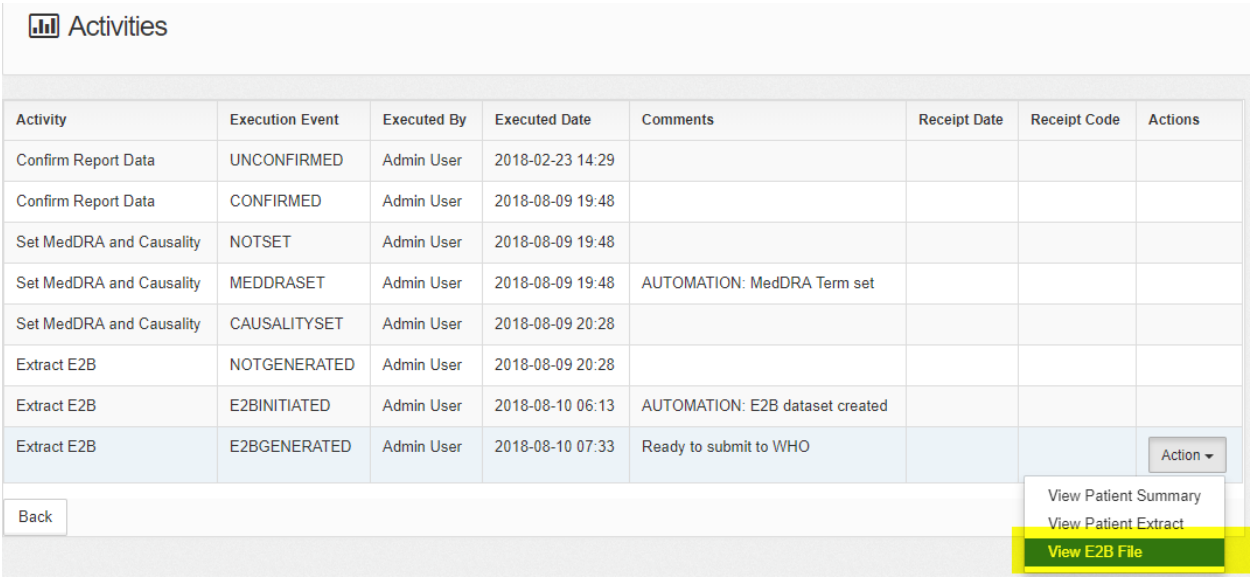
Once you have prepared the E2B file for submission and searched for the report, click on the **View Activity History** menu for the associated report you would like to view the XML file for.



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.




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



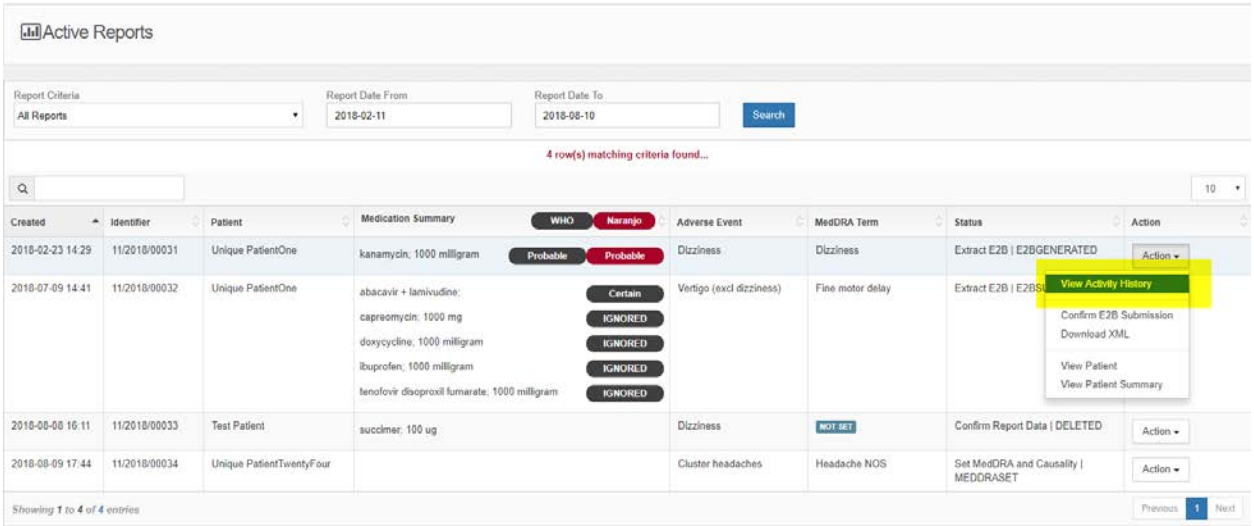

The system will automatically generate the XML file for the E2B submission to WHO. Save the file on your local computer for referral when sending to WHO.

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

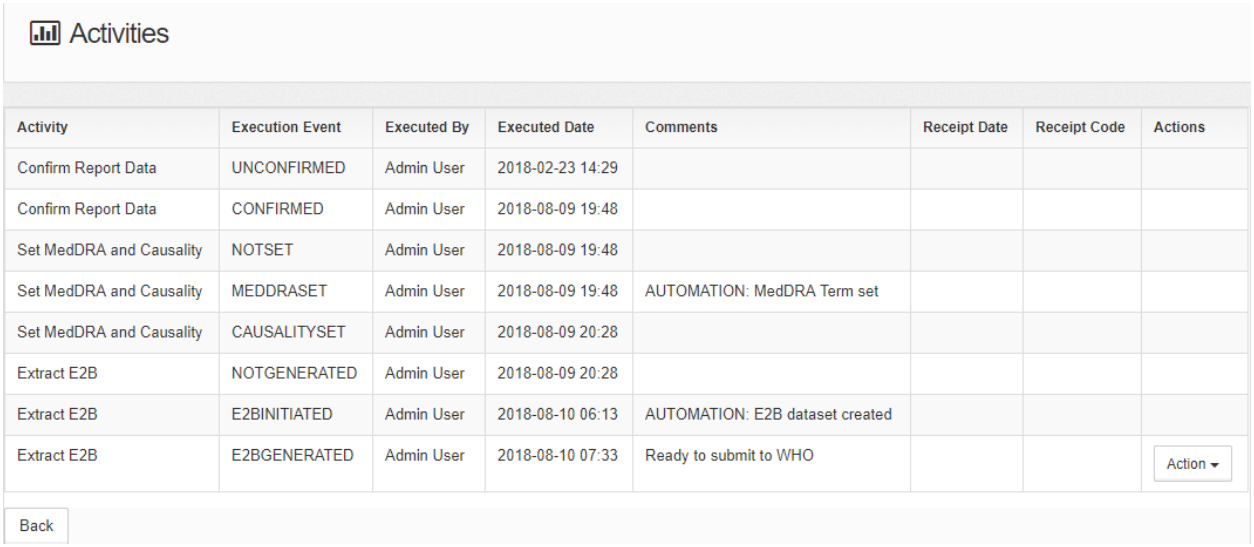
```
<?xml version="1.0" encoding="utf-16"?>
<ichicsr lang="en">
  <ichicsrmessageheader>
    <messagetype>ICHICSR</messagetype>
    <messageformatversion>2.1</messageformatversion>
    <messageformatrelease>1.0</messageformatrelease>
    <messagenumb>00000770</messagenumb>
    <messagesenderidentifier>FDA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

### 5.7.5 Viewing the Clinical Data Associated to the E2B XML File

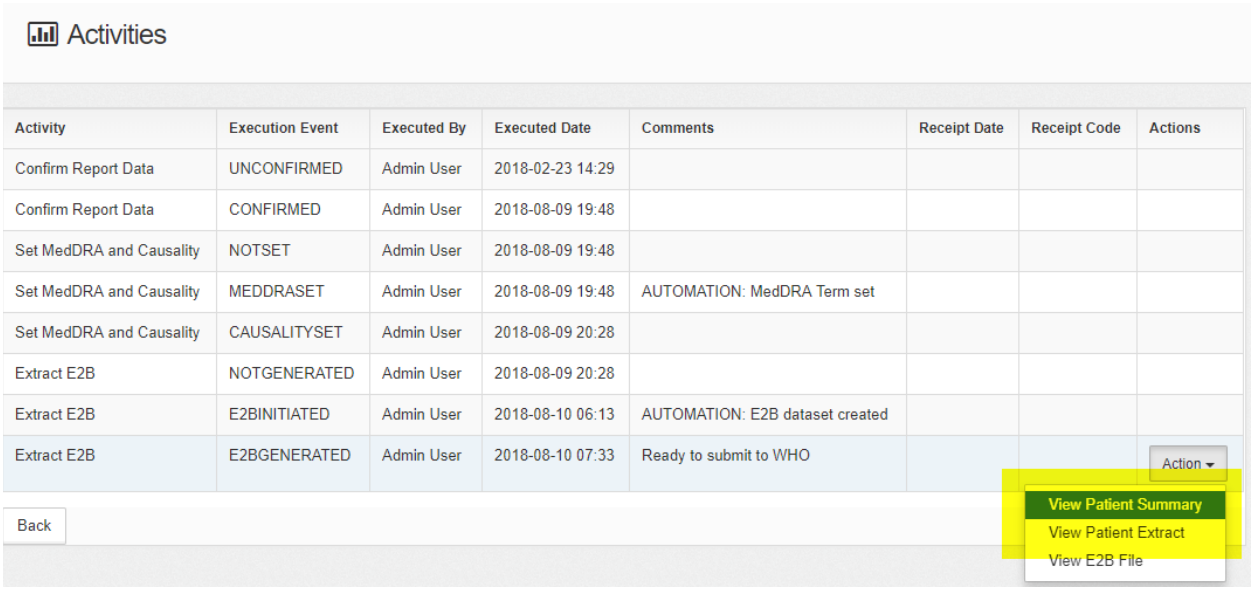
Once you have prepared the E2B file for submission and searched for the report, click on the **View Activity History** menu for the associated report you would like to view the XML file for.




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

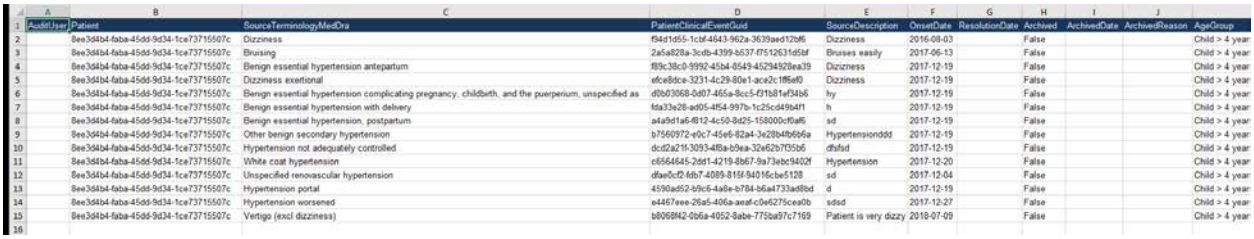



Locate the **E2BGENERATED** execution event for the report, click the action menu, and select the **View Patient Summary or View Patient Extract** menu.




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

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

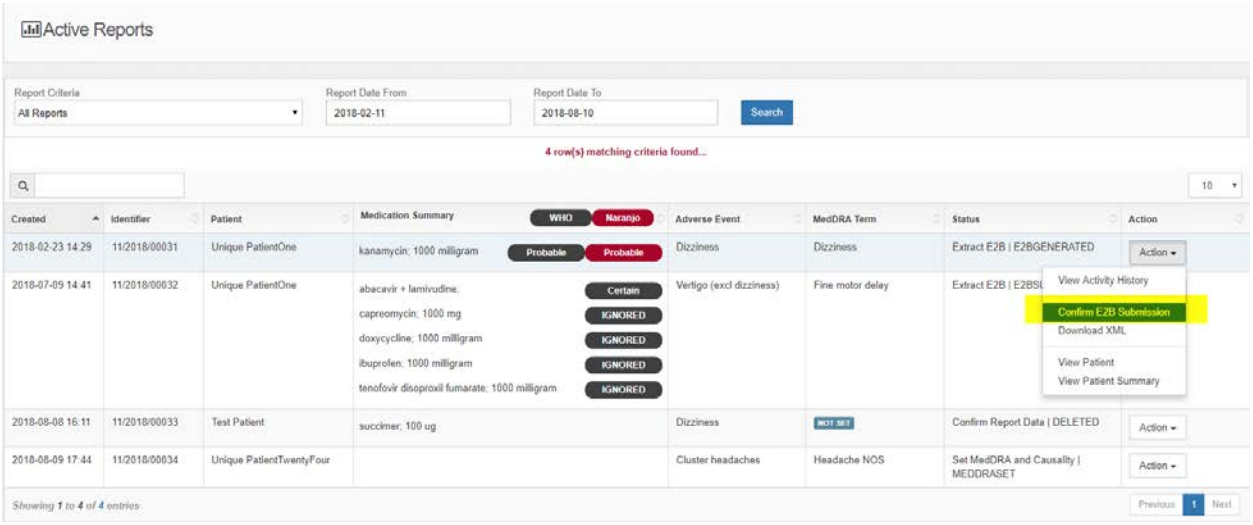


| AuditUser | Patient | SourceTerminologyMedDra | PatientClinicalEventGuid | SourceDescription | OnsetDate | ResolutionDate | Archived | ArchivedDate | ArchivedReason | AgeGroup |
|---|---|---|---|---|---|---|---|---|---|---|
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Dizziness | f94d1d55-1cbf-4643-962a-3639aed12bf6 | Dizziness | 2016-08-03 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Bruising | 2a5a828a-3cdb-4399-b537-f7512631d5bf | Bruises easily | 2017-06-13 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Benign essential hypertension antepartum | f89c38c0-9992-45b4-8549-45294928ea39 | Dizizness | 2017-12-19 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Dizziness exertional | efce8dce-3231-4c29-80e1-ace2c1ff6ef0 | Dizziness | 2017-12-19 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Benign essential hypertension complicating pregnancy, childbirth, and the puerperium, unspecified as | d0b03068-0d07-465a-8cc5-f31b81ef34b6 | hy | 2017-12-19 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Benign essential hypertension with delivery | fda33e28-ad05-4f54-997b-1c25cd49b4f1 | h | 2017-12-19 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Benign essential hypertension, postpartum | a4a9d1a6-6f12-4c50-8d25-158000cf0af6 | sd | 2017-12-19 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Other benign secondary hypertension | b7560972-e0c7-45e6-82a4-3e28b4fb6b6a | Hypertensionddd | 2017-12-19 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Hypertension not adequately controlled | dcd2a21f-3093-4f8a-b9ea-32e62b7f35b6 | dfsfsd | 2017-12-19 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | White coat hypertension | c6564645-2dd1-4219-8b67-9a73ebc9402f | Hypertension | 2017-12-20 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Unspecified renovascular hypertension | dfae0cf2-fdb7-4089-815f-94016cbe5128 | sd | 2017-12-04 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Hypertension portal | 4590ad52-b9c6-4a8e-b784-b6a4733ad8bd | d | 2017-12-19 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Hypertension worsened | e4467eee-26a5-406a-aeaf-c0e6275cea0b | sdsd | 2017-12-27 | | False | | | Child > 4 year |
| | 8ee3d4b4-faba-45dd-9d34-1ce73715507c | Vertigo (excl dizziness) | b8068f42-0b6a-4052-8abe-775ba97c7169 | Patient is very dizzy | 2018-07-09 | | False | | | Child > 4 year |


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

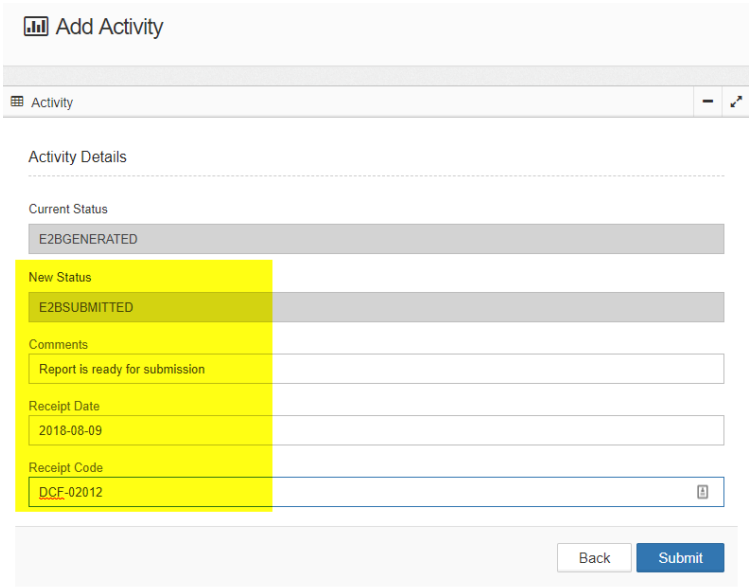
### 5.7.6 **Confirming a Report for E2B Submission**

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




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

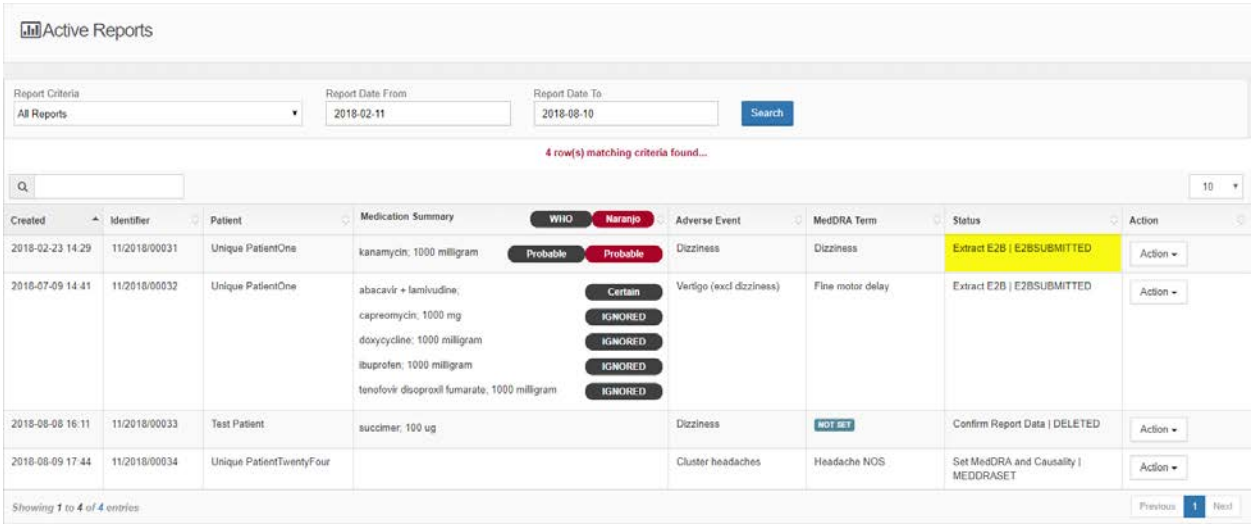
Specify any additional comments for confirming the submission and click **Submit** to confirm the deletion or **Back** to cancel the action and return to the previous page.





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.



## 5.8 Analyser

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

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

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

### 5.8.1 Methodology

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

#### 5.8.1.1 Incidence Rate

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

IR = (ADR / Population) * 1000

**Where**
IR = Incidence Rate
ADR = Number of adverse drug reactions *
Population = Total patient years in reporting period **

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

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

**Example**
Cases = 11
Non-Cases = 170
Population = 181 (11 + 170)
Incidence Rate = 11/181 * 1000 = **60.77**

#### 5.8.1.2 **Relative Risk**

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

RR= IR1 / IR2

**Where**
RR = Relative Risk
IR1 = Incidence Rate for exposed population. The exposed population is defined as the patient population that have been exposed to a medication in the reporting period.
IR2 = Incidence Rate for non-exposed population. The exposed population is defined as the patient population that have NOT been exposed to a medication in the reporting period.

**Example**
Incidence Rate Exposed = 60.77
Incidence Rate Non-Exposed = 45.12
RR = **1.35**

#### 5.8.1.3 **Confidence Interval**

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

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

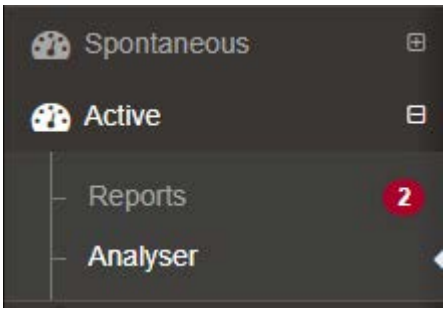
**Where**
$z_\alpha$ is the standard score for the chosen level of significance and SE the standard error.

### 5.8.2 Generating Unadjusted Relative Risk Ratios

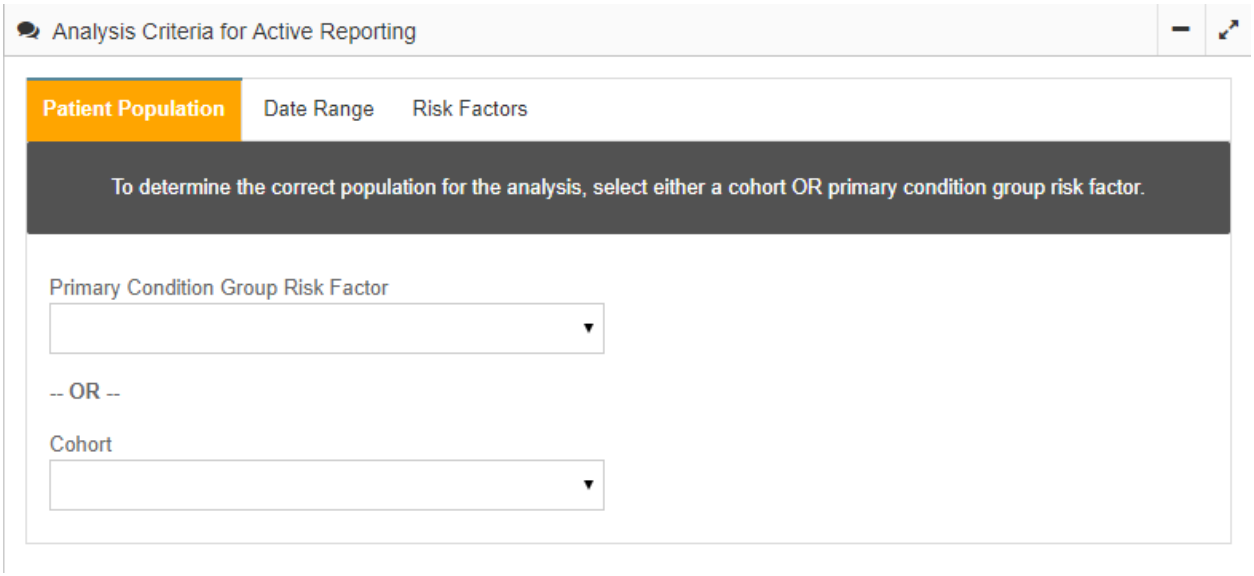
To implement the methodology for generating an **Unadjusted Relative Risk Ratio,** the following parameters will need to be specified:

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

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

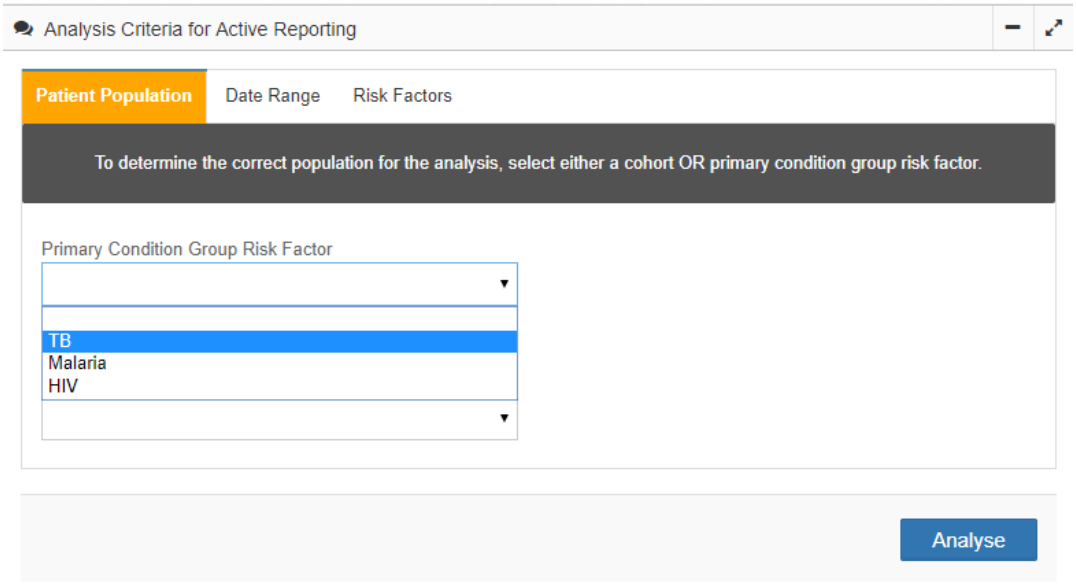



#### 5.8.2.1 Specifying the Population Group

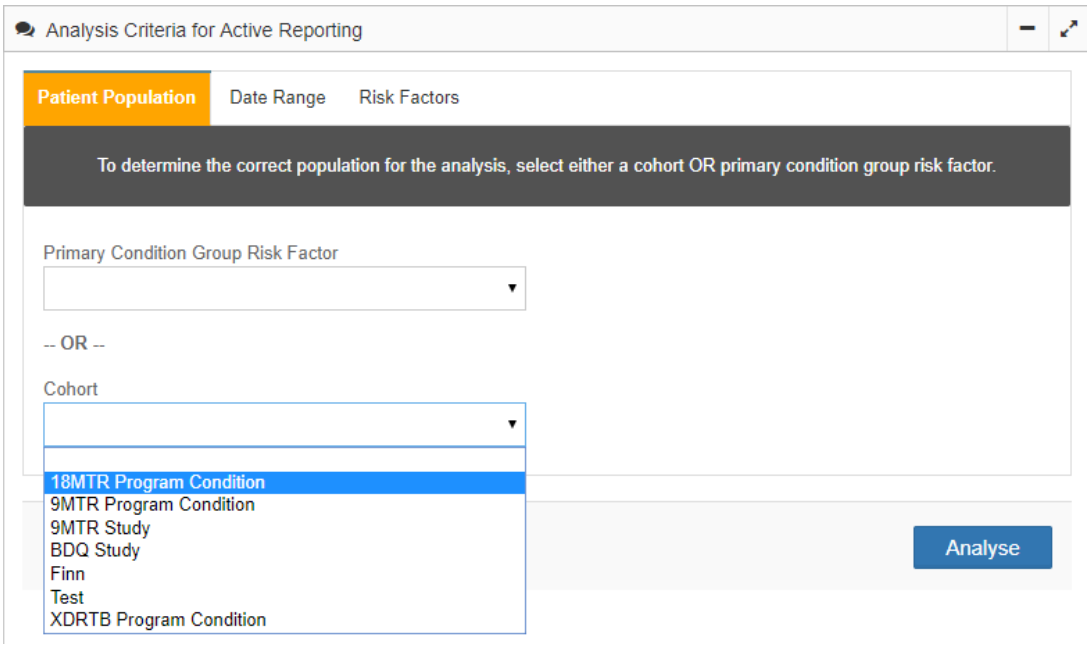



By selecting a **Condition Group** or **Cohort**, you are effectively able to target a specific set of patients for analysis.

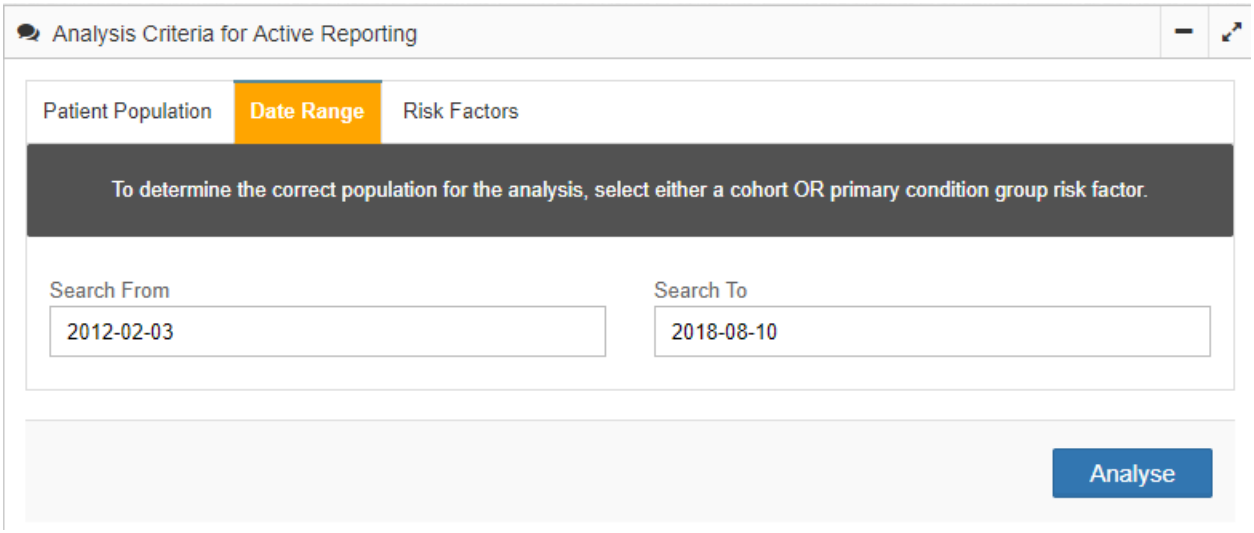
To specify a **Condition Group,** click the Primary Condition Group Risk Factor field and select the primary condition you would like to run analysis against. If this option is selected, all patients that belong to the corresponding Condition Group will be included in the analysis.




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.



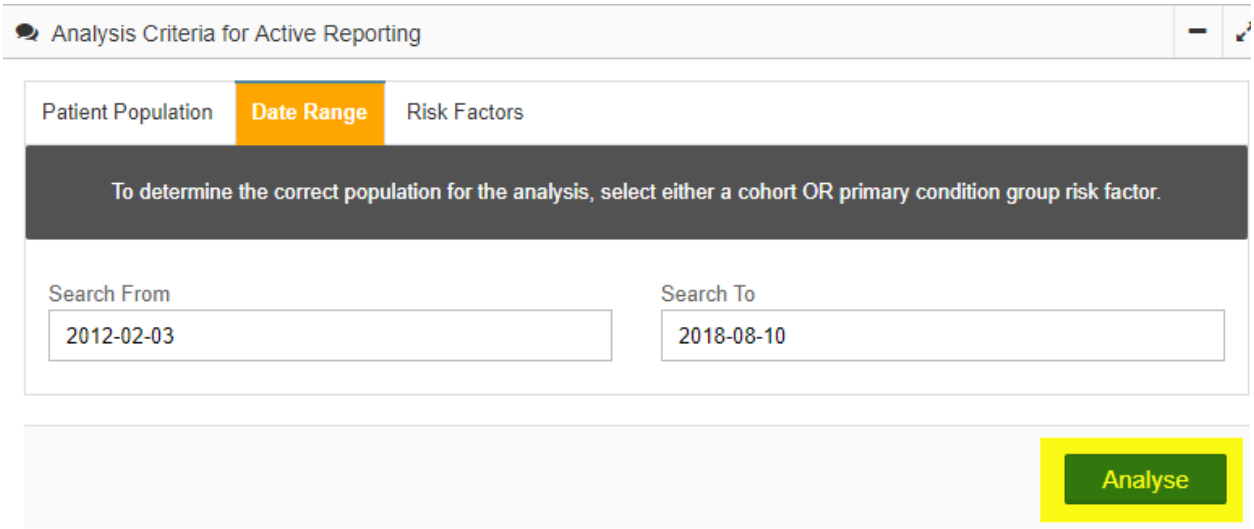
### 5.8.2.2 Specifying the Date Range for the Analysis



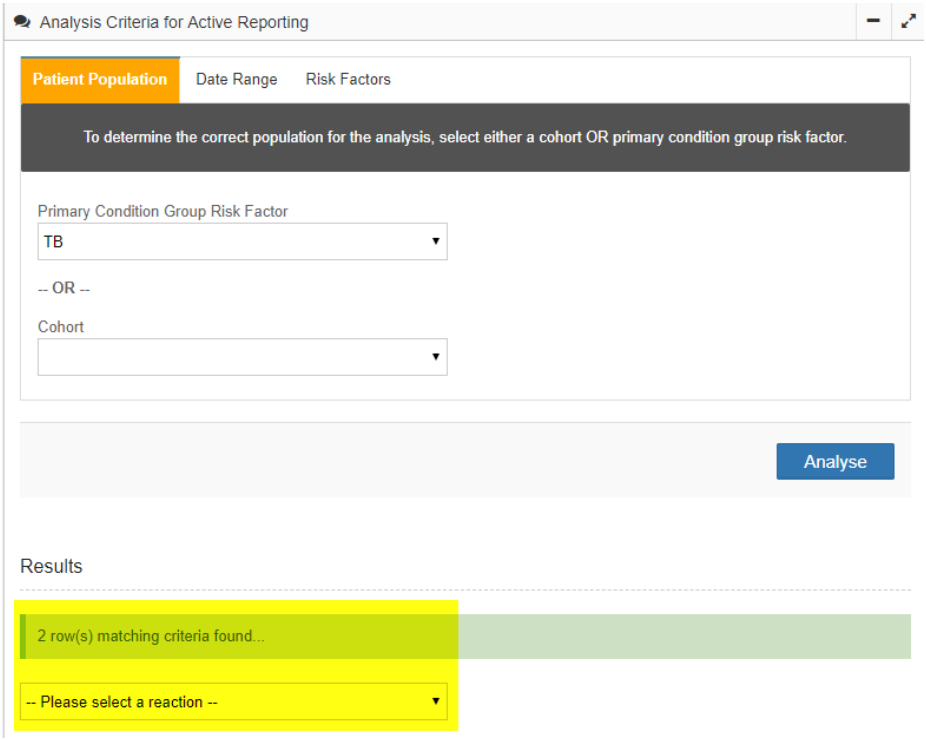

By selecting a **Date Range**, the system will determine which patients should be included into the analysis from the Patient Population specified in the previous step. Patients that have been actively exposed to medication within that range will be included.

### 5.8.2.3 Running the Analysis

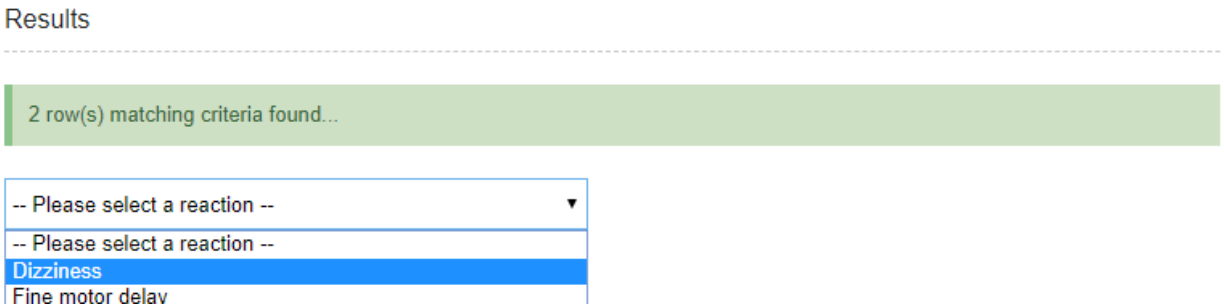
Once the **Patient Population** and **Date Range** parameters have been selected, click on the **Analyse** button to execute the analysis.



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

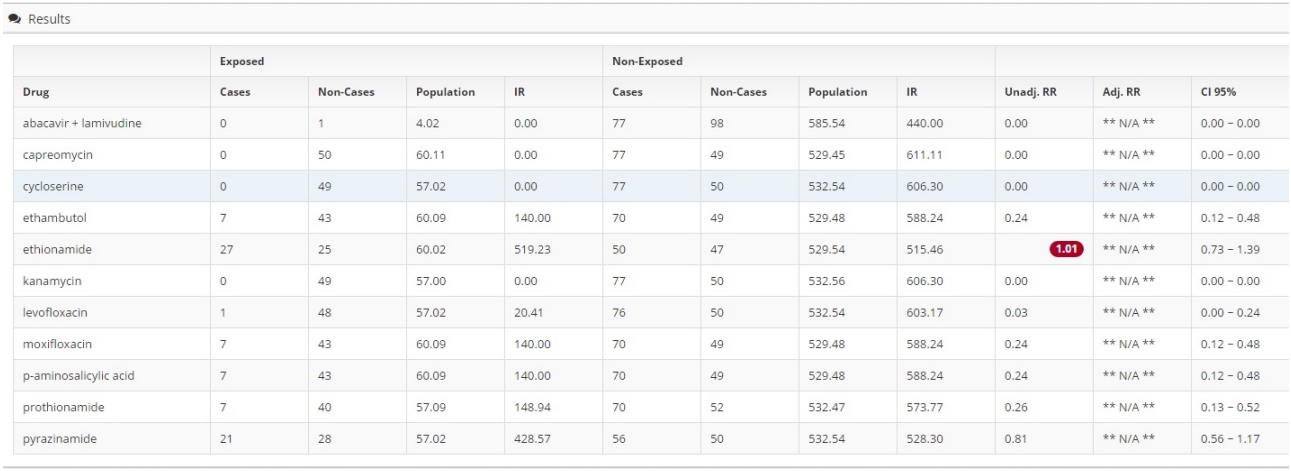



Select the **Adverse Drug Reaction** that you would like to detect signals for.



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

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

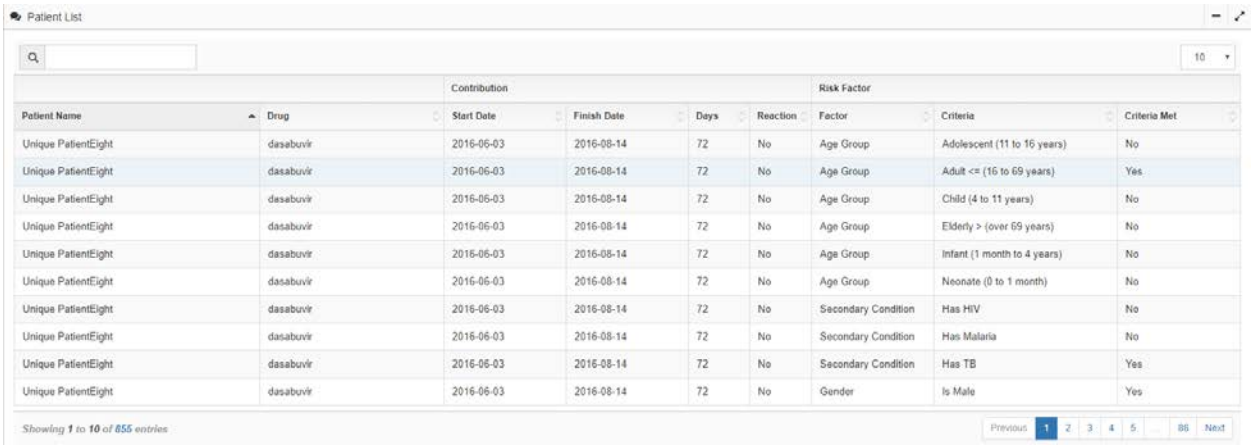


Results

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

### 5.8.2.4 **Viewing the Contributing Patient List**

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



Patient List

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

Showing 1 to 10 of 855 entries

Previous 1 2 3 4 5 ... 86 Next

The columns in the patient list table are described below:

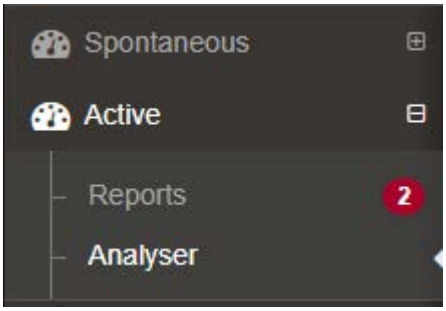
| | |
|---|---|
| Patient Name | The name of the patient contributing to the patient population |
| Drug | The drug the patient was exposed to during the period of analysis |
| Start Date | The date the patient started the medication |
| Finish Date | The date the patient finished the medication |
|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

### 5.8.3 **Generating Adjusted Relative Risk Ratios**

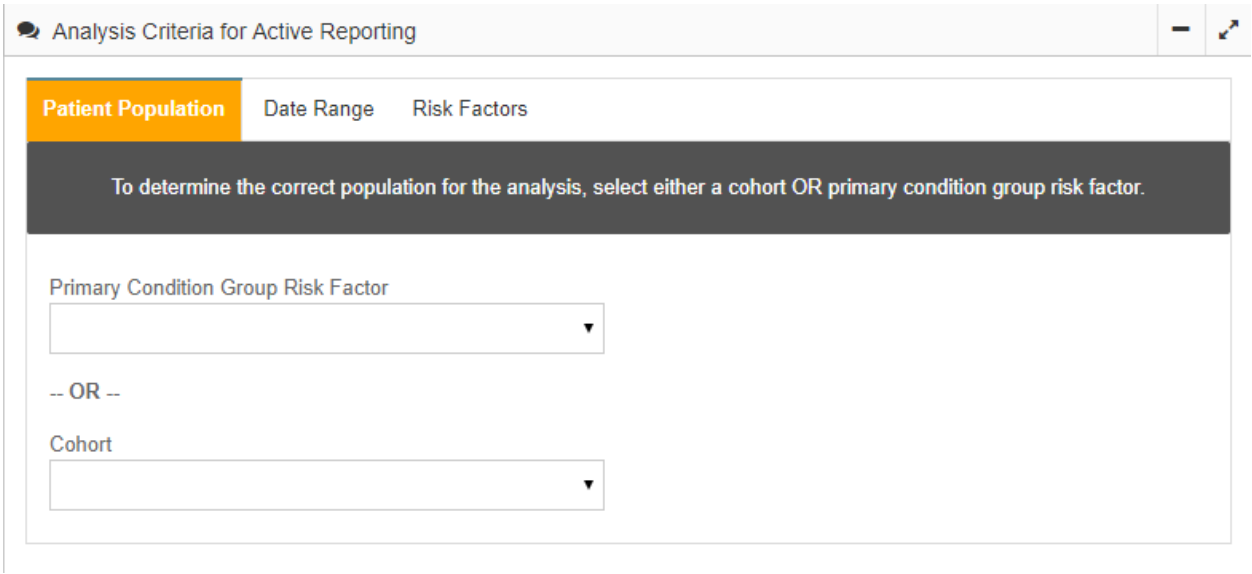
To implement the methodology for generating an **Adjusted Relative Risk Ratio,** the following parameters will need to be specified:

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

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

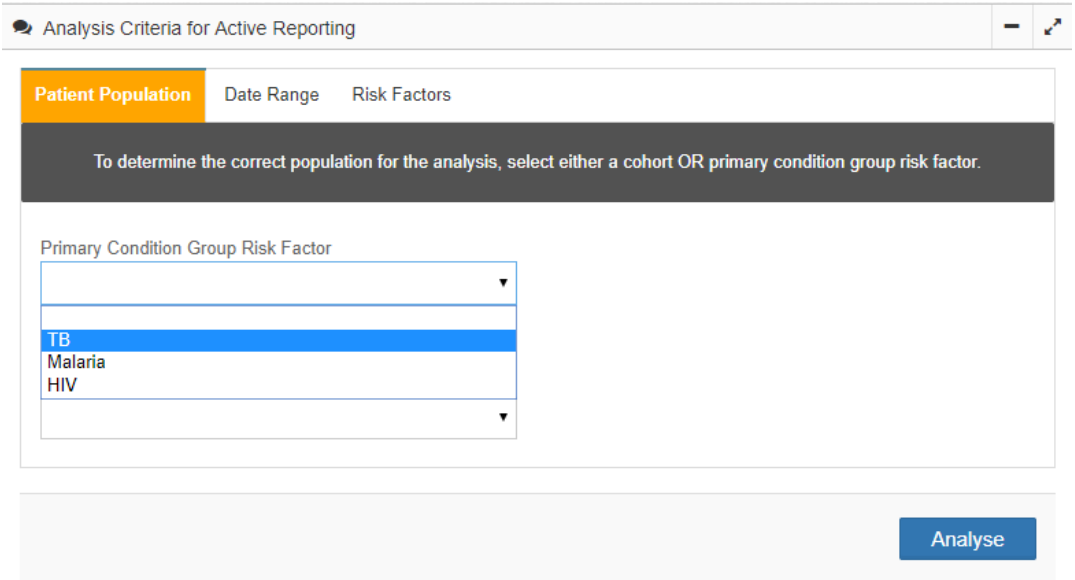


#### 5.8.3.1 Specifying the Population Group

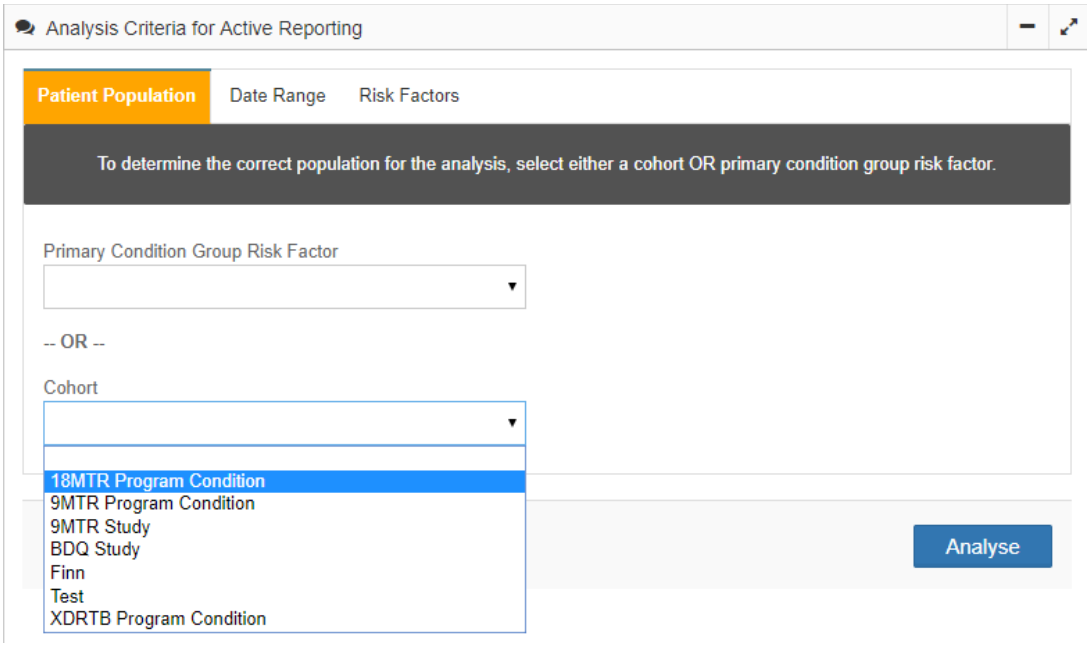



By selecting a **Condition Group** or **Cohort**, you are able to target a specific set of patients for analysis.

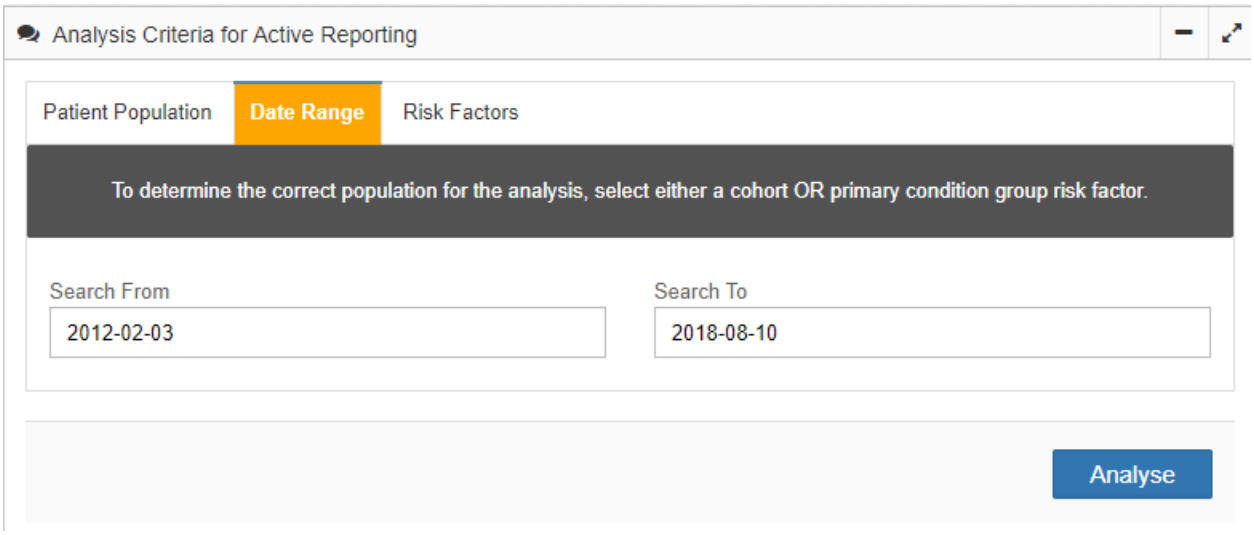
To specify a **Condition Group,** click the Primary Condition Group Risk Factor field and select the primary condition you would like to run analysis against. If this option is selected, all patients that belong to the corresponding Condition Group will be included in the analysis.



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.

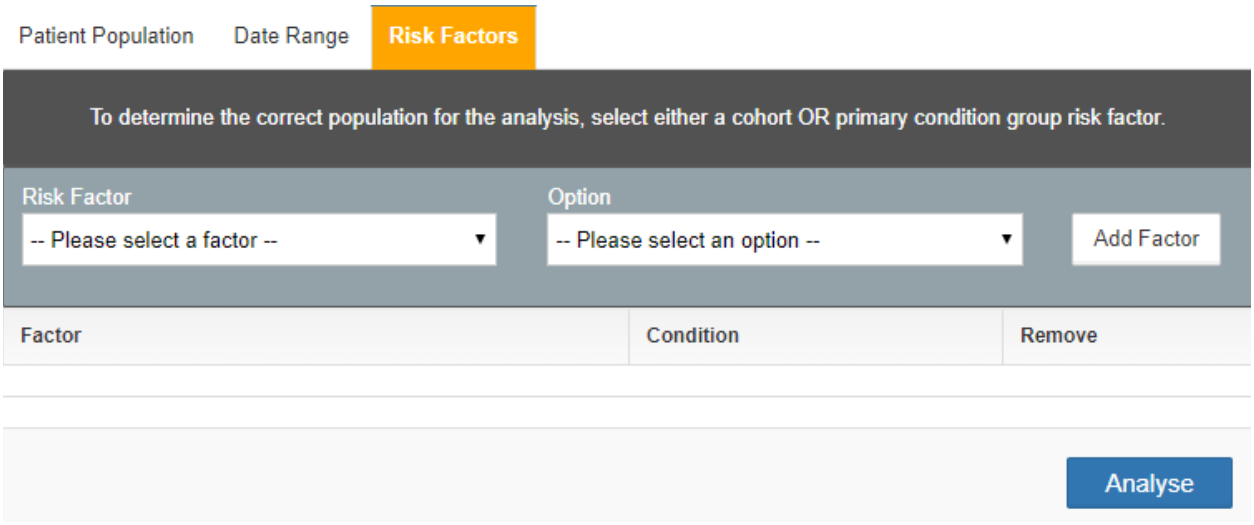



### 5.8.3.2 Specifying the Date Range for the Analysis

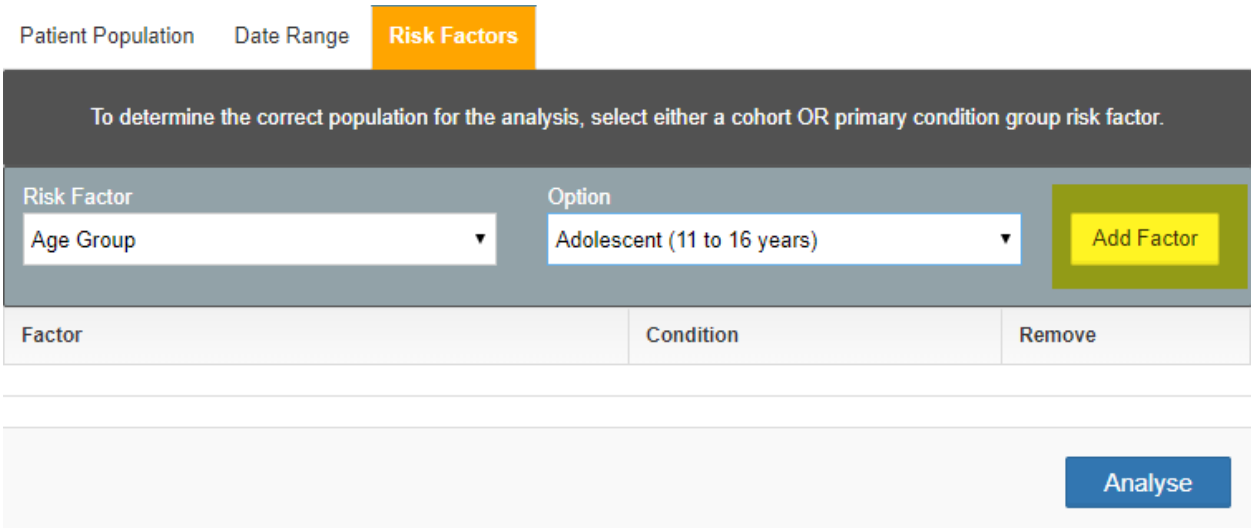



By selecting a **Date Range**, the system will determine which patients should be included into the analysis from the Patient Population specified in the previous step. Patients that have been actively exposed to medication within that range will be included.

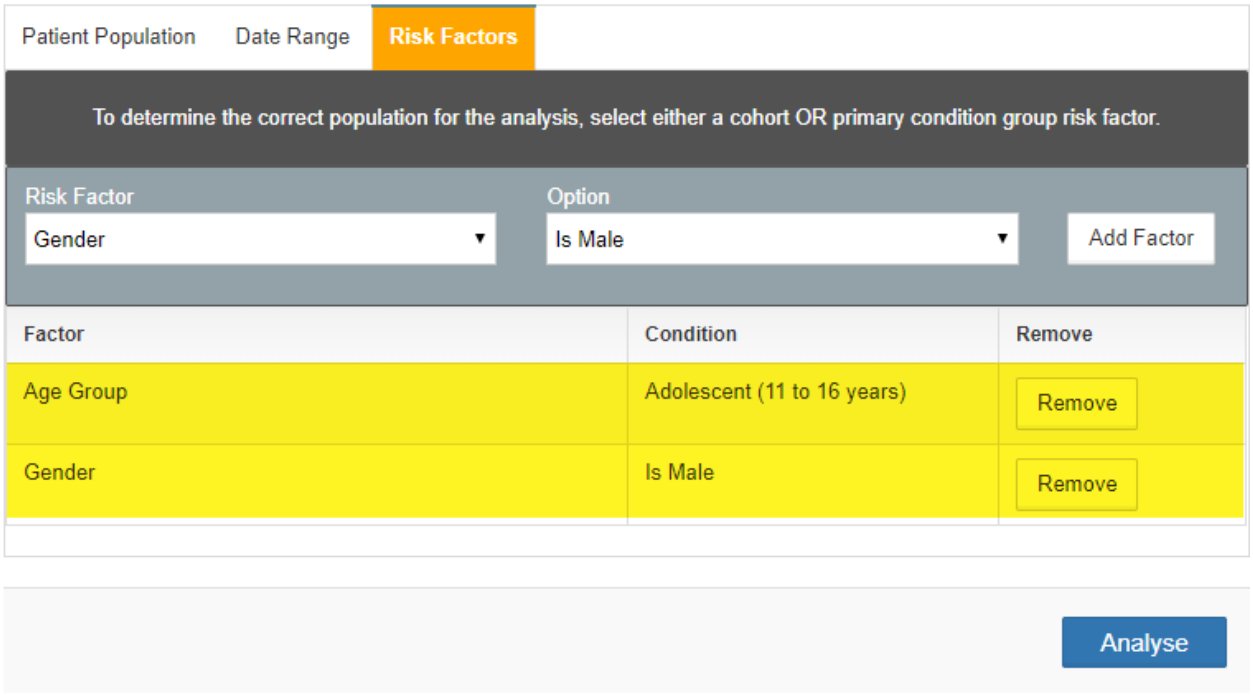
### 5.8.3.3 Specifying Risk Factors for the Analysis




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



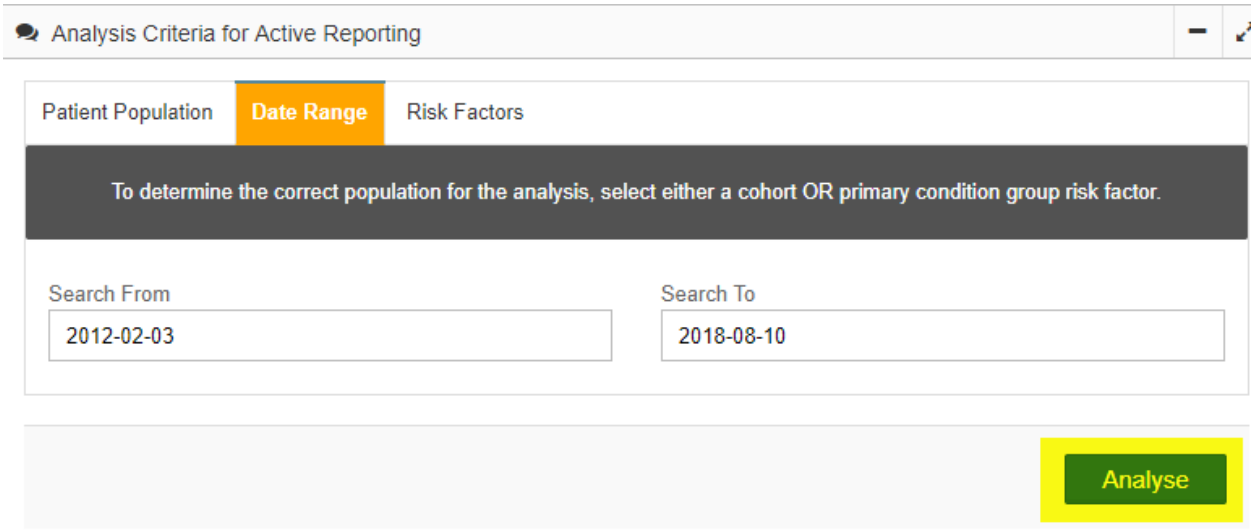

You are able to add as many risk factors as you would like to include into the analysis by following the process above.



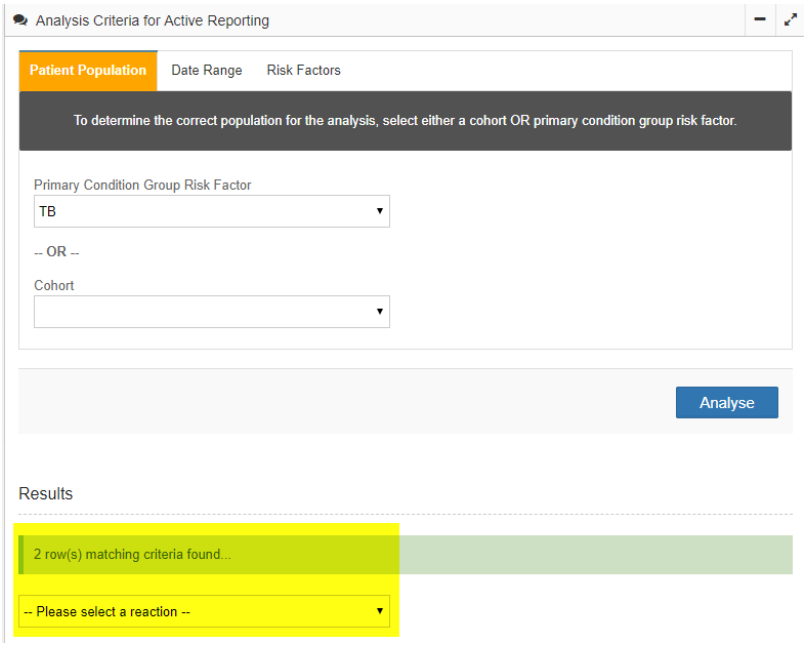

By including **Risk Factors** into the analysis, the system will determine which patients match the criteria stipulated by the set of risk factors and the corresponding **Relative Risk Ratio** will be adjusted based on the new population set.

#### 5.8.3.4 Running the Analysis

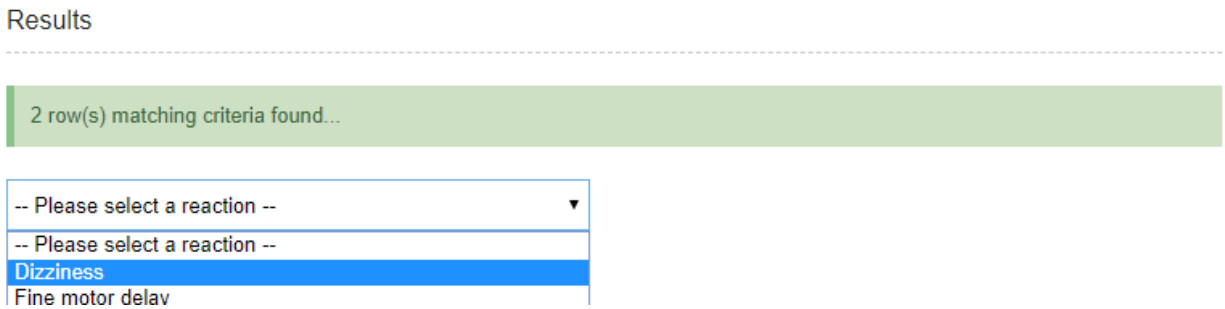
Once the **Patient Population, Date Range, and Risk Factor** parameters have been selected, click on the **Analyse** button to execute the analysis.



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




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




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

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

Results

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

### 5.8.3.5 **Viewing the Contributing Patient List**

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

Patient List

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

Showing 1 to 10 of 855 entries

Previous 1 2 3 4 5 86 Next

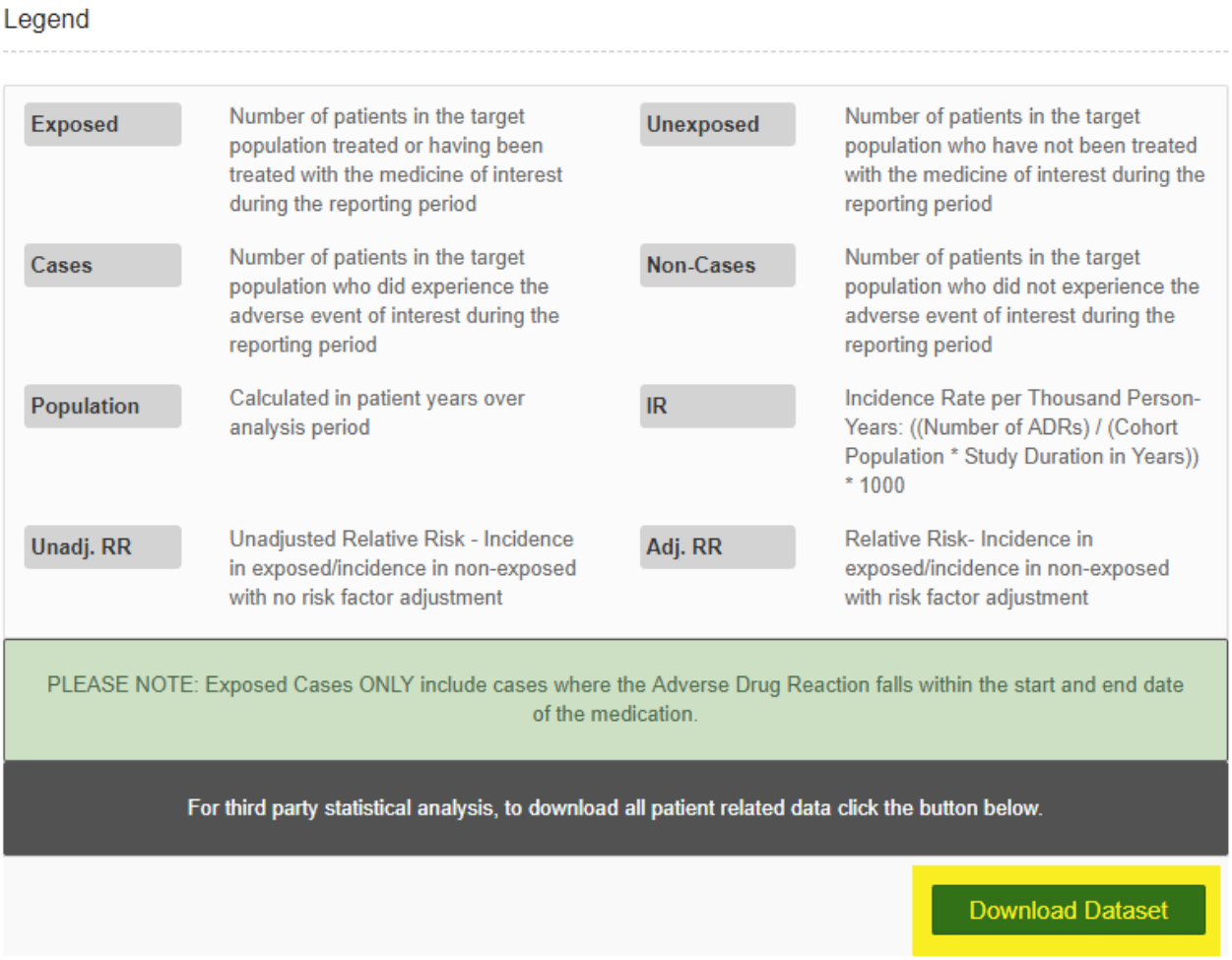
The columns in the patient list table are described below:

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

| | |
| --- | --- |
| Finish Date | The date the patient finished the medication |
| Days | The number of days the patient contributed to the patient population |
| Reaction | Did the patient suffer a reaction during the period of analysis |
| Risk Factor | Which risk factor does the patient match |

### 5.8.4 **Downloading a Dataset for Further Analysis**

Click the **Download Data** button to able to download a comprehensive dataset of patient clinical data in XLSX format for importation into a third party statistical tool.




If you are unable to locate this function, please liaise with your system administrator as the ability to download a dataset for external consumption will need to be assigned to your user profile.

# 6 Reporting Portal

The reports portal is the centralized hub for system reporting.

**Note**: the following roles have access to the report's portal:

- **All users.** All users have view access to pages defined within the portal.
- **Administrator.** The administrator has FULL permissions to the information portal.
- **Reporter Administrator.** The reports administrator has the ability to add and customize reports.

## 6.1 List of Standard System Reports

The reports portal includes several reports as part of the base configuration of the system. These reports are listed below:

| | |
|---|---|
| Patients on Treatment | Aggregated number of patients per facility that have a serious event, non-serious event, and the percentage that have events |
| Adverse Events | Number of patients with an adverse event by age group, facility and drug |
| Adverse Events Quarterly | Number of patients with an adverse event by MedDRA system organ class per quarter and grade |
| Adverse Events Annual | Number of patients with an adverse event by MedDRA system organ class per year and grade |
| Causality | List adverse events where causality has been set and not set |
| Patients by Drug | Number of patients on a specific medication |
| Outstanding Visits | Patients who did not attend an appointment |

## 6.2 Report Customization

The Reports Portal gives PViMS report publishers the ability to add new and modify existing reports within this portal. This provides PViMS analysts with an integrated platform to customize what reports are available to end users.

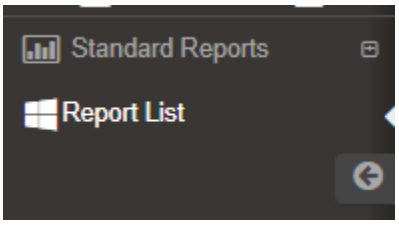
### 6.2.1 Types of Reports

When adding a new report, you first need to specify the type of report to be incorporated. There are currently two report types that can be customized within PViMS: A summary report that provides aggregated reporting based on the stratification criteria specified, and a list report that allows for a line by line rendering of the report in a non-aggregated manner.

### 6.2.2 Adding a New Report

In order to add a new report to the Reports Portal, you need to have the **Reporter Administrator** role assigned to your user profile.

To add a new report, click on the **Report List** menu.



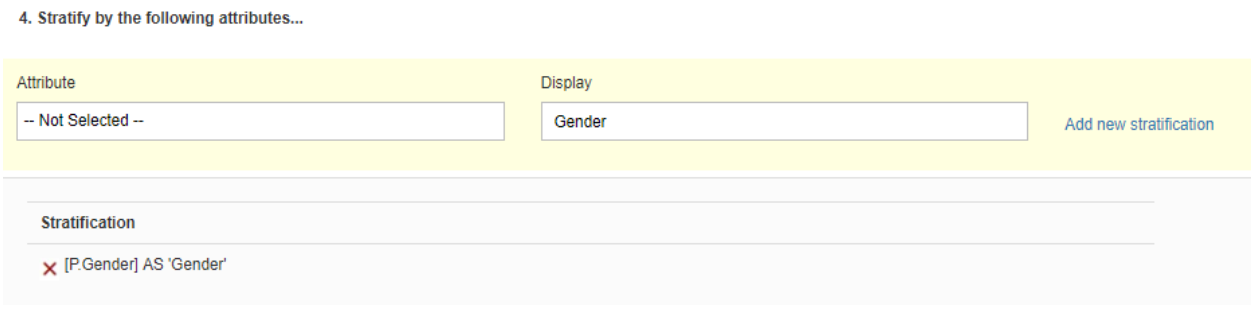

Then click on the **Add Report** button so you can define the core characteristics of the report.

The following information must be entered when publishing a new report:

| | |
|---|---|
| Report Name | The unique name for the report |
| Definition | Provide additional information that describes the report |
| Report Type | Is this a summary or a list report? |
| Core Entity | The primary entity that should be reported on:<br>• Patient, report on patient specific criteria<br>• PatientClinicalEvent, report on adverse event information<br>• PatientCondition, report on concomitant conditions<br>• PatientFacility, report on facility and patient<br>• PatientLabTest, report on lab test information<br>• PatientMedication, report on medication history<br>• Encounter, report on clinical data collected per encounter<br>• CohortGroupEnrolment, report of cohort enrolment data |

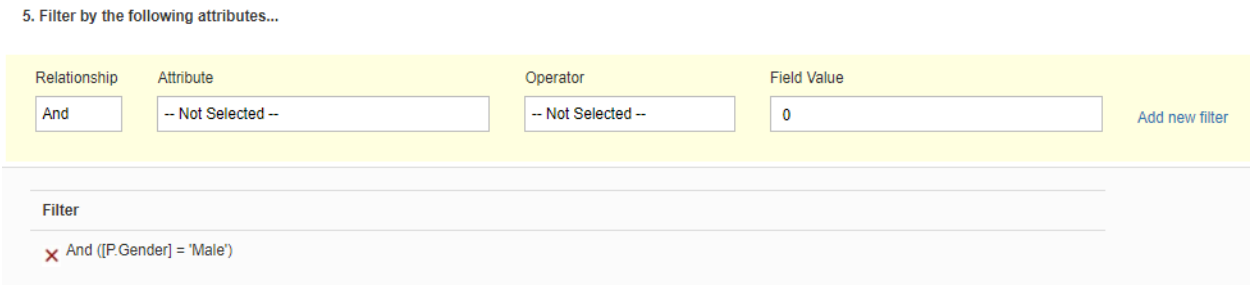
#### 6.2.2.1 **Summary Report**

Once the base report is configured, stratification-related information may now be specified. All attributes specified as part of the stratification list will be aggregated based on these attributes. To add a new stratification item, select the attribute from the list, specify the name of column in the display field and click the **Add new stratification** link. The attribute will be added to the stratification list.



Once the stratification list is specified, filter-related information may now be specified. All attributes specified as part of the filter list will be used to filter the result set by the end user. To add a new filter item, add the filter item as per the field description below and click the **Add new filter** link:

| | |
|---|---|
| Relationship | Specify **AND** if this filter criteria must be true in conjunction with other attributes<br>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:<br>• Dates and numerics allow the following operators: Equals, Not Equals, Greater Than, Less Than, GreaterEqual Than, LessEqual Than, Between<br>• Text fields allow the following operators: Equals, Not Equals<br>• DropDown Lists allow the following operators: Equals, Not Equals, In |
| Field Value | • The value that should be compared to |

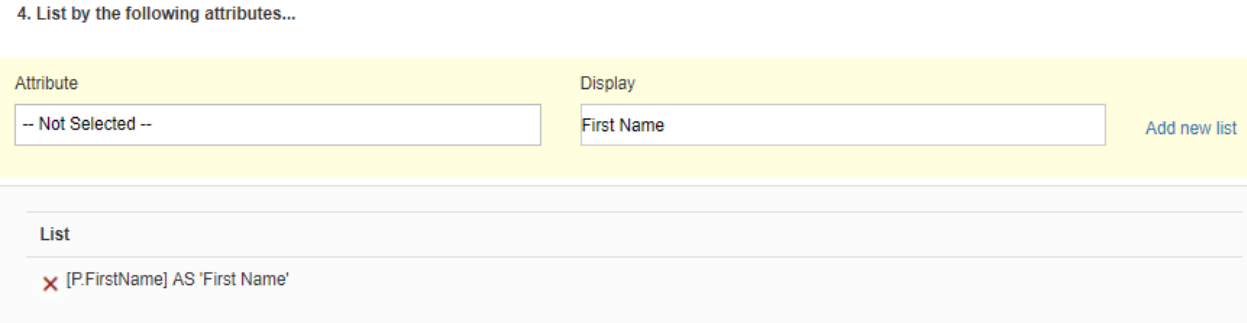



Enter the relevant information as defined above for the report. You can preview the results by clicking **View Results**. If you are satisfied with the results, click the **Publish** button to save your new report. If you don't want to save it, use the browser's back button to navigate away from the screen.

The system will navigate you to the new report once it has been published and the new report will appear in the custom report portal menu.

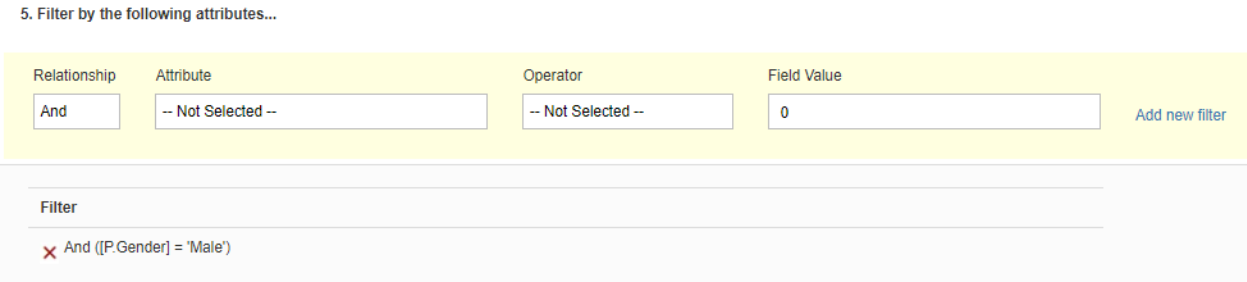
#### 6.2.2.2 List Report

Once the base report is configured, list-related information may now be specified. All attributes specified as part of the list will be included as separate columns in the report. To add a new list item, select the attribute from the list, specify the name of column in the display field, and click the **Add new list** link. The attribute will be added to the list.




Once the list is specified, filter-related information may now be specified. All attributes specified as part of the filter list will be used to filter the result set by the end user. To add a new filter item, add the filter item as per the field description below and click the **Add new filter** link:

| | |
|---|---|
| Relationship | Specify **AND** if this filter criteria must be true in conjunction with other attributes<br>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<br>• Dates and numerics allow the following operators, Equals, Not Equals, Greater Than, Less Than, GreaterEqual Than, LessEqual Than, Between<br>• Text fields allow the following operators, Equals, Not Equals<br>• DropDown Lists allow the following operators, Equals, Not Equals, In |
| Field Value | • The value that should be compared to |




Enter the relevant information as defined above for the report. You can preview the results by clicking **View Results**. If you are satisfied with the results, click the **Publish** button to save your new report. If you don't want to save it, use the browser's back button to navigate away from the screen.

The system will navigate you to the new report once it has been published and the new report will appear in the custom report portal menu.

### 6.2.3 Modifying and Deleting an Existing Report

Browse to the report using the custom report menu in the Reports Portal. To modify or delete a report, you need to have the **Reporter Administrator** role assigned to your user profile.

To modify a report, click on the **Customise Report** button. To delete a report, click on the **Delete Report** button.

# 7 Information Portal

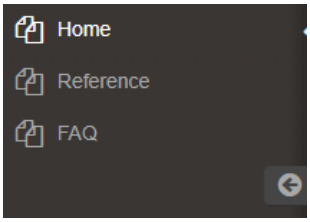
The information portal is the centralized hub for publication and presentation. PVIMS information publishers have the ability to share trends, analysis, graphs, and important information about pharmacovigilance activities.

**Note**: the following roles have access to the information portal:

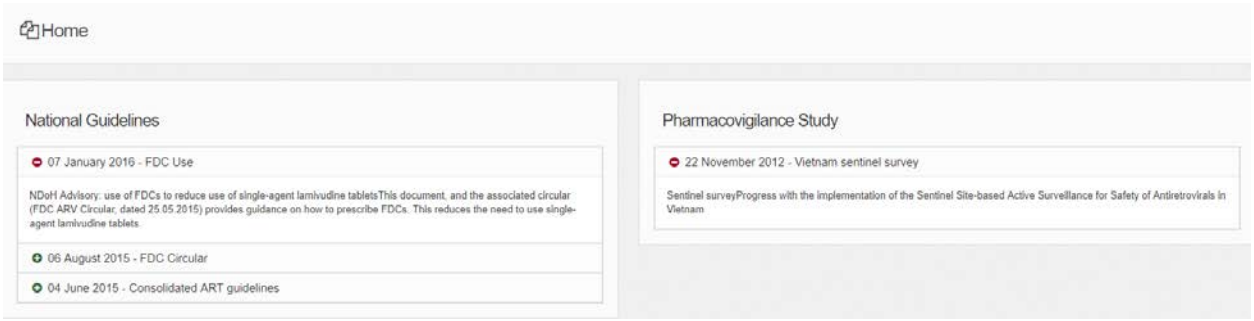
- **All users.** All users have view access to pages defined within the portal.
- **Administrator.** The administrator has FULL permissions to the information portal.
- **Publisher.** The publisher has the ability to add new pages and update content of existing pages

## 7.1 Viewing the home page

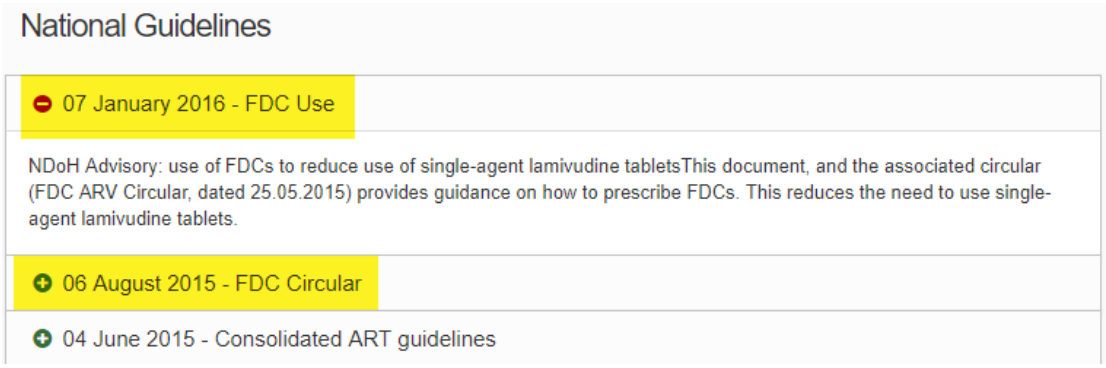
The Information Portal **Home Page** can be used to show information about upcoming pharmacovigilance activities as well as outcomes from existing and previous activities and reports. To access the **Home Page,** click on the **Home** menu in the Information Portal.




The system will navigate you to the **Home Page** where you are able to view, e.g., national guidelines or other information you post that would be relevant to most PViMS users.

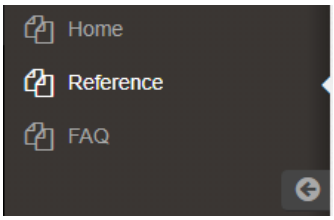



To view information for an existing date, click on the green plus icon to expand that guideline or the red minus sign to compress that guideline.

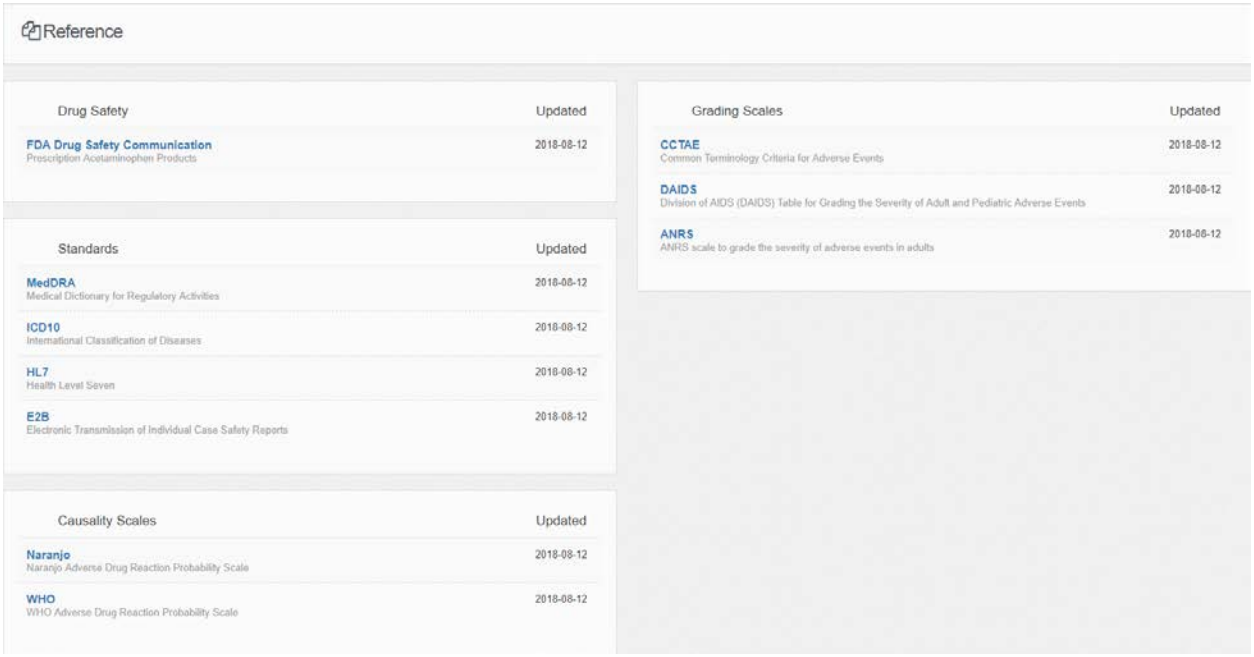



## 7.2 Viewing the Reference page

The Information Portal **Reference Page** contains a set of reference data particular to the implementation of PViMS for Pharmacovigilance activities. To access the **Reference Page,** click on the **Reference** menu in the Information Portal.



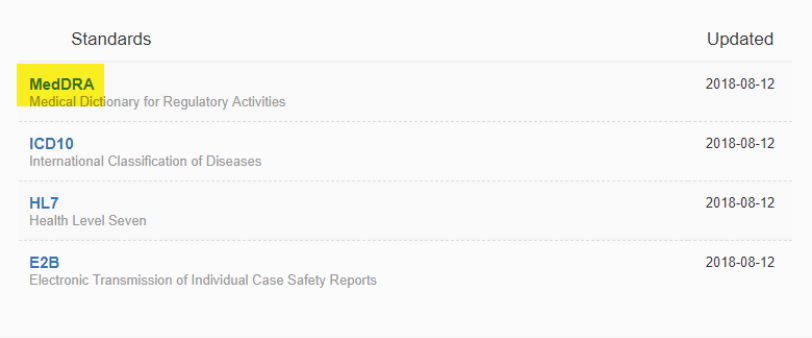

The system will navigate you to the **Reference Page** where you are able to view this reference information.




The following reference data is available for viewing: -

| | |
|---|---|
| MedDRA | Medical Dictionary for Regulatory Activities |
| ICD10 | International Classification of Diseases |
| HL7 | Health-Level 7 |
| E2B | Electronic Transmission of Individual Case Safety Reports |
| Naranjo | Naranjo Adverse Drug Reaction Probability Scale |
| WHO | WHO Adverse Drug Reaction Probability Scale |
| CCTAE | Common Terminology Criteria for Adverse Events |
| DAIDS | Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events |
| ANRS | ANRS scale to grade the severity of adverse events in adults |

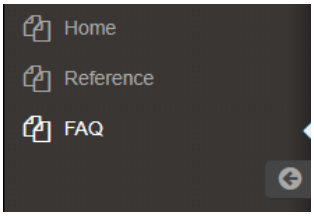
To view information about the reference, click on the blue header for that specific reference.



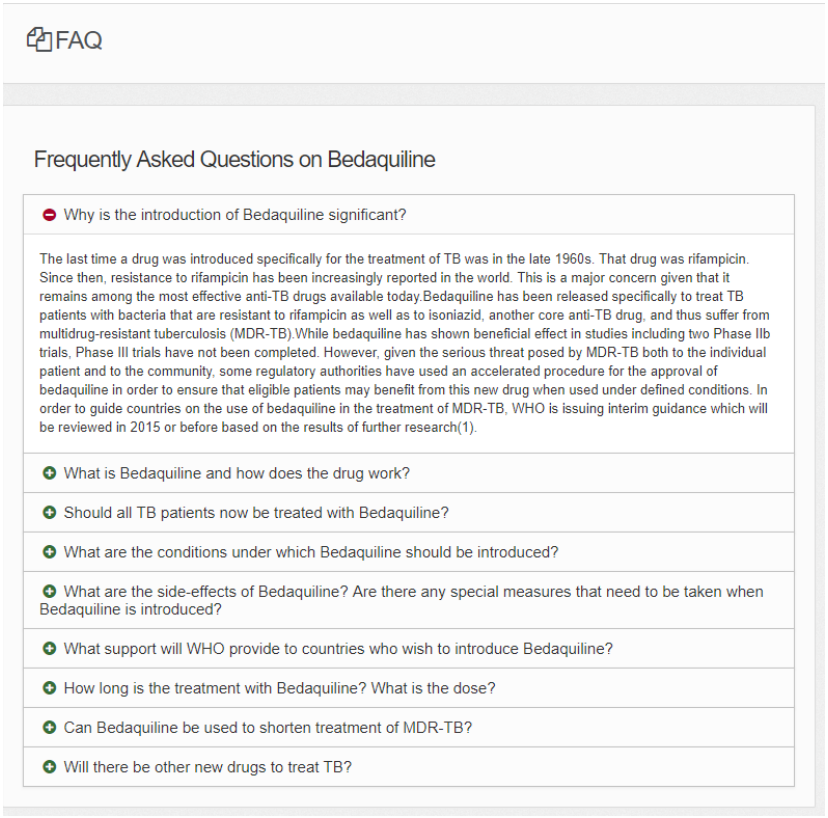

The system will navigate you to a reference page which contains additional information to that reference item.

## 7.3 Viewing the Frequently Asked Questions page

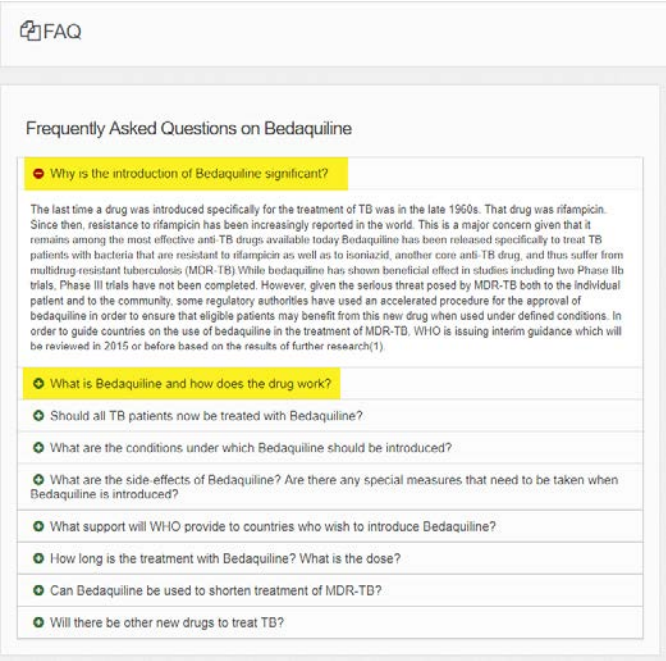
The Information Portal **FAQ Page** contains a list of frequently asked questions particular to the implementation of PViMS for Pharmacovigilance activities in relation to the use of Bedaquiline. To access the **FAQ Page,** click on the **FAQ** menu in the Information Portal.




The system will navigate you to the **FAQ Page** where you are able to view these questions.



To view the answer for a specific question, click on the green plus icon to expand that question or the red minus sign to compress that question.




## 7.4 Modifying Content in the Information Portal

The information Portal is based on a content management platform whereby PViMS publishers have the ability to add new and modify existing content within this portal in a collaborative manner. This provides PViMS analysts with an integrated platform to share details of their ongoing analysis to the health community at large.

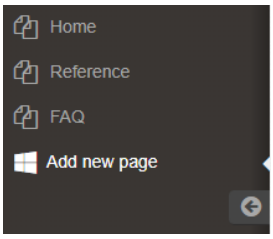
### 7.4.1 Adding a New Page

**BUZZWORDS**

**Page:** Consists of 1 to 6 widgets, with each widget containing content that is rendered as part of the overall page. Each page is accessible either from the main information portal menu or from within an existing widget.

When adding a new page, you are creating a platform to add content that is specific to the overall theme of that page. To add a new page to the Information Portal, you need to have the **Publisher** role assigned to your user profile.

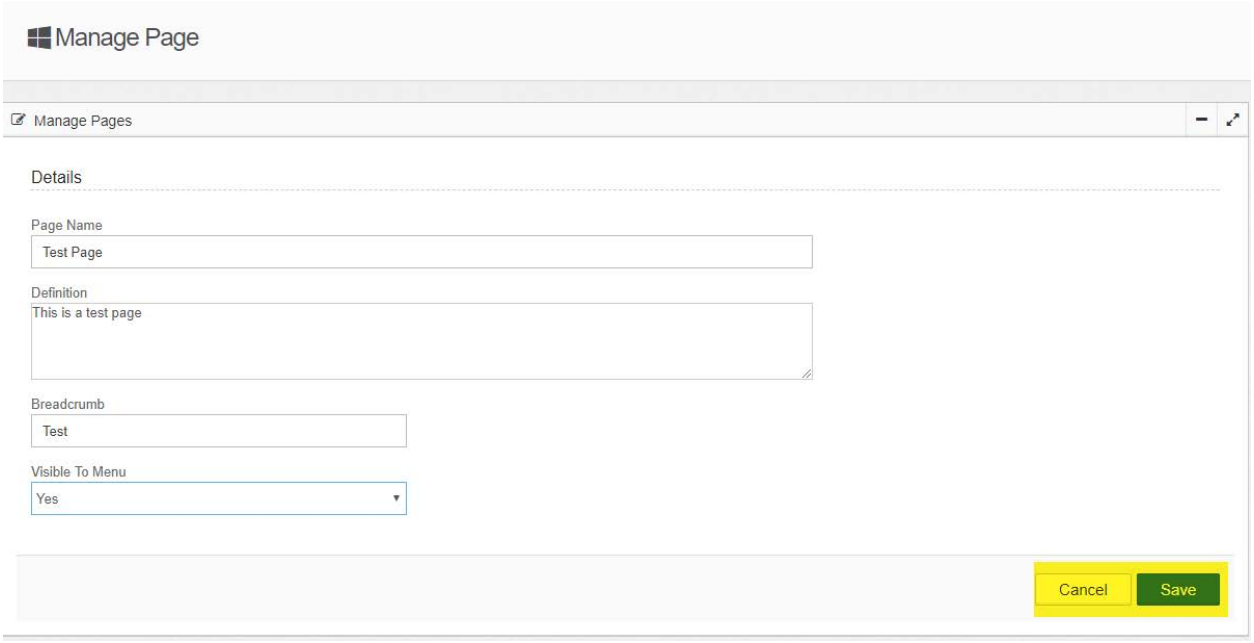
To add a new page, click on the **Add new page** menu.




The following information must be entered when saving a new page:

| | |
|---|---|
| Page Name | The unique name of the page. This is also the name of page header when viewing the page. |
| Definition | Provide additional information that describes the page |
| Breadcrumb | The name of the menu option that you can access to view the page |
| Visible to Menu | Should this page appear on the main list of menu items in the Information Portal? |

Enter the relevant information for the page and either click the **Save** button to save your new page or the **Cancel** button to cancel your action and return to the **Home** page of the portal.




The system will navigate you to the new blank page once it has been saved and the new page will appear in the main Information Portal menu if the visible to menu field is set to yes.


See the next section for information about how to add a widget to add content to this page.

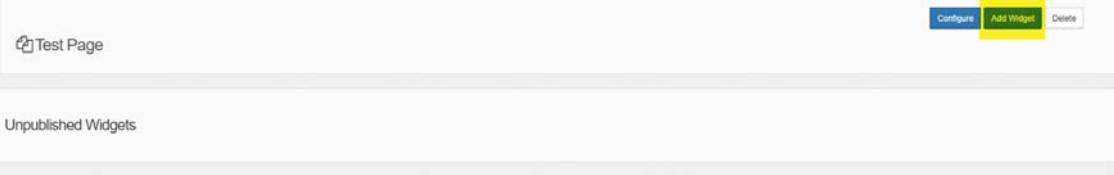
### 7.4.2 **Adding a Widget to a Page**

**BUZZWORDS**

**Widget:** A widget is an individual panel within a page that provides a container for rendering dynamic content defined by the PViMS publisher. A page within the Information Portal can store up to 6 widgets per page.

When adding a new widget, you are adding a container for new content that is specific to the overall theme of that page. To add a new widget to a page, you need to have the **Publisher** role assigned to your user profile.

To add a new widget, navigate to the page that you would like to add the widget to and click on the **Add Widget** button that appears in the page header.



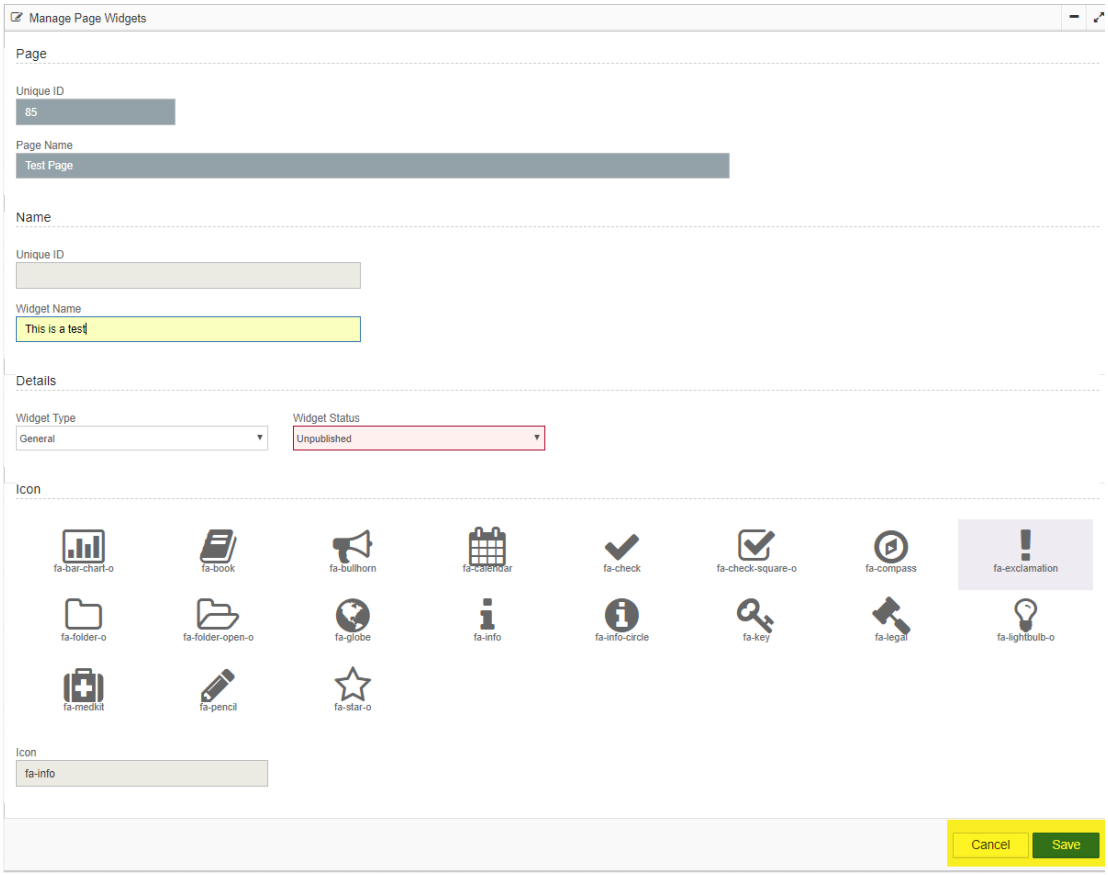

The system will navigate you to an **Add New Widget** page. The following information is displayed on this screen:

| | |
|---|---|
| Unique ID | The unique id of the page that the widget is been added to |
| Page Name | The name of the page that the widget is been added to |

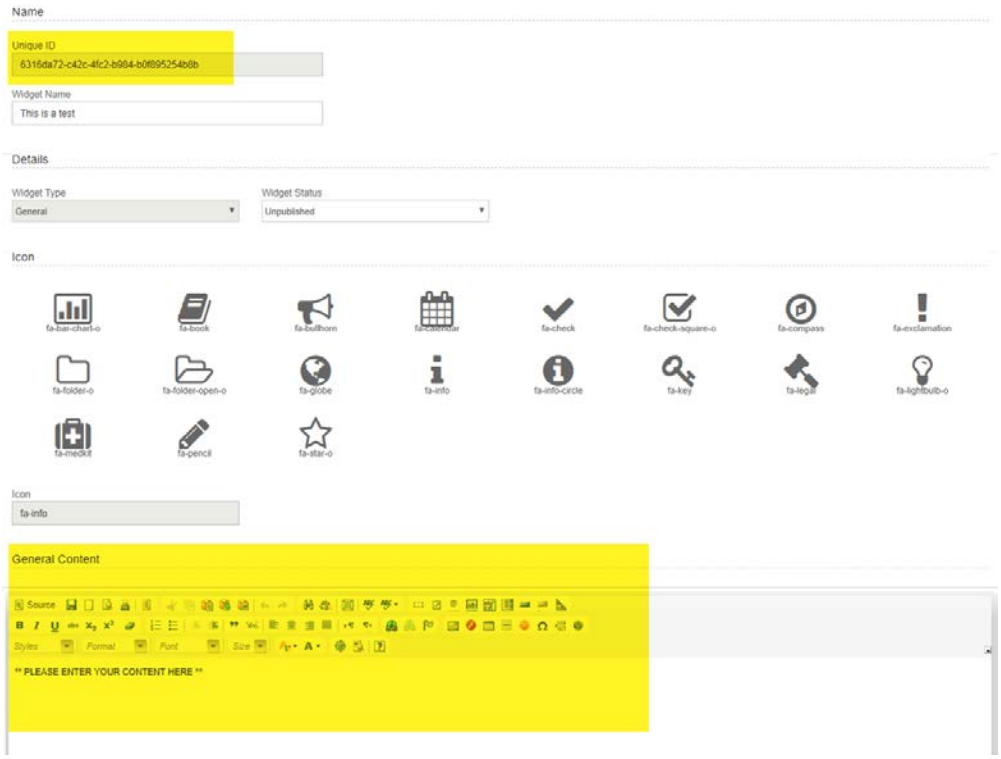

The following information must be entered when adding a new widget:

| | |
|---|---|
| Widget Name | The unique name for the widget. This name will be displayed as the title for the content. |
| Widget Type | The type of widget to be added (General, ItemList, Wiki) |
| Widget Status | The status of the widget (Published, Unpublished)<br>**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.

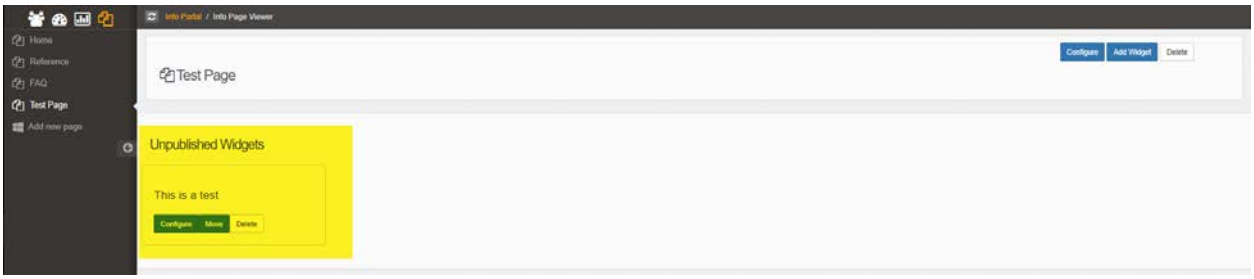


The system will add the new widget to the page and will now allow the user the ability to add content to the widget. Please note that a unique ID has now been allocated to the widget.




Please see the section on adding content to a widget for further information on modifying content for the new widget.

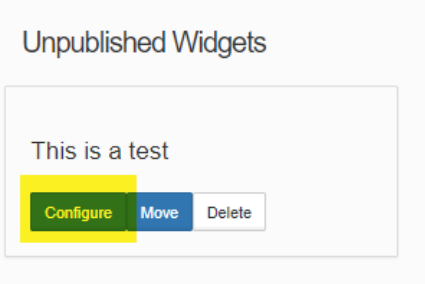
**Please note:** the new widget is allocated to the page as an unpublished widget. This widget therefore cannot be viewed by users who do not have the **Published** role assigned to their user profile.



### 7.4.3 Adding or Changing a Widget's Content

To add content to a new widget or edit content within an existing widget, you need to have the **Publisher** role assigned to your user profile.

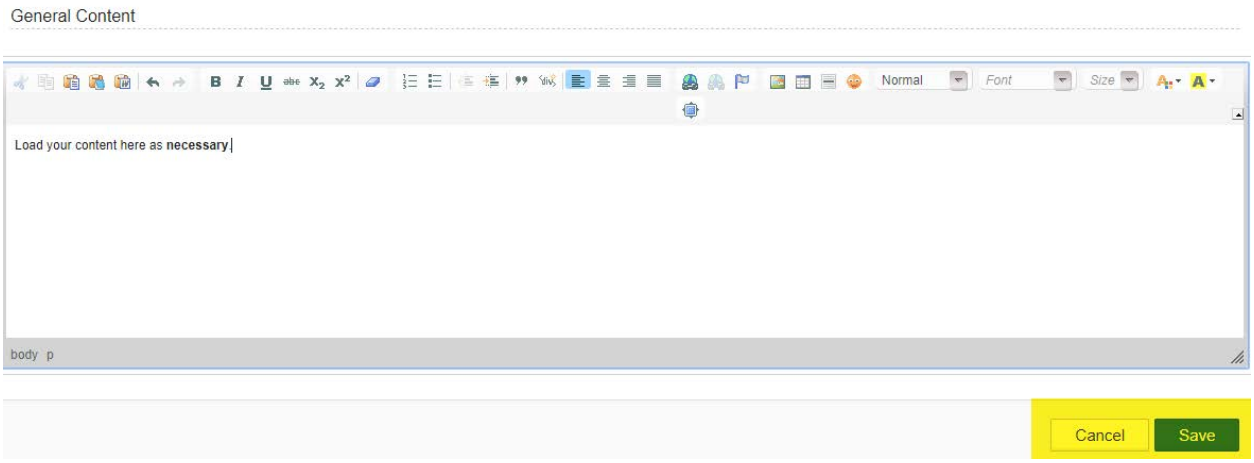
To add or edit content within a widget, navigate to the page that you would like to modify the content, locate the widget you would like to modify and click the **Configure** button for this widget.




The system will navigate you to the **Edit Widget** page where you will have the ability to edit your content.

#### 7.4.3.1 General Widget Content

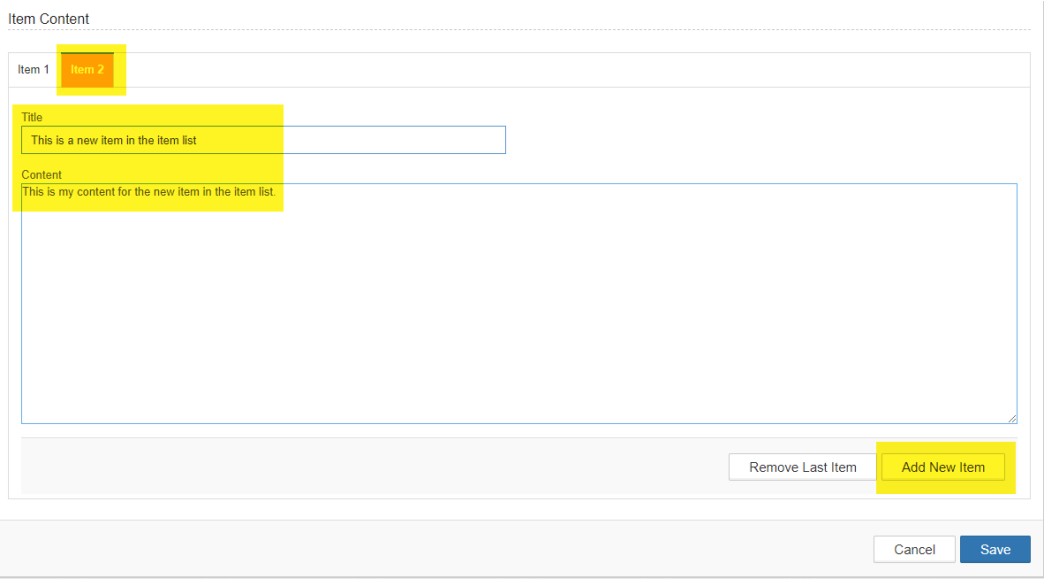
To change content for the general widget, locate the editor field in the General Content section for the widget and edit your content as necessary. Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.




#### 7.4.3.2 ItemList Widget Content

To change content for the ItemList widget, locate the Item Content section for the widget.

To add a new item to the item list, click the **Add New Item** button. Once you have clicked this button, you will see that a new item has been added to the tabbed panel at the top of this section. Enter the title for the new item as well as the content associated to this item.




Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.

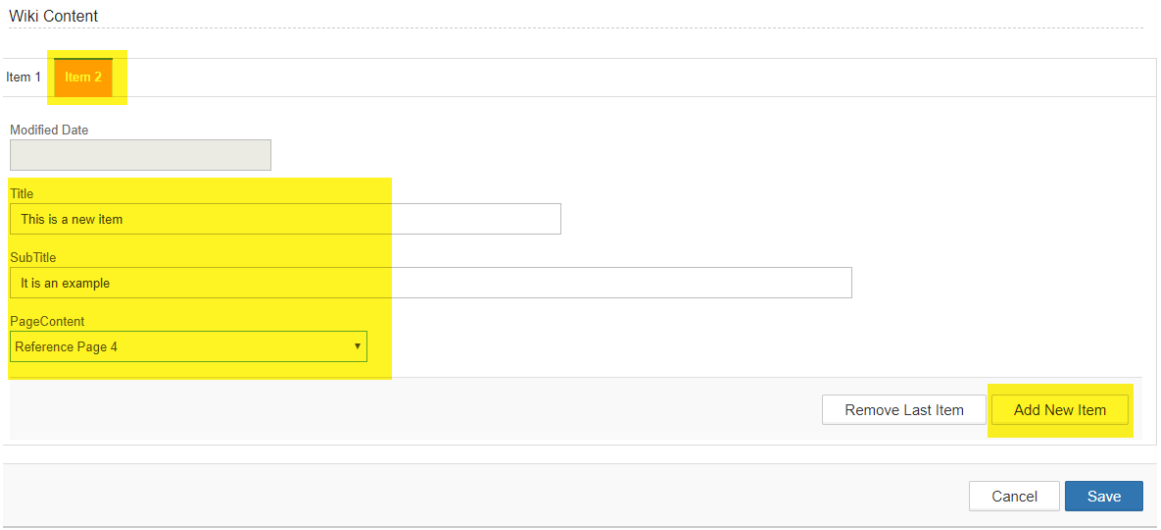
To remove an item from the list, click the **Remove Last Item** button. Once you have clicked this button, you will be able to note that the last item has been removed from the tabbed panel at the top of this section. Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.


It is only possible to remove the last item in the list. Please edit content from existing items if an item in the middle of the list is no longer valid.

### 7.4.3.3 Wiki Widget Content

To change content for the Wiki widget, locate the Wiki Content section for the widget.

To add a new item to the item list, click the **Add New Item** button. Once you have clicked this button, you will be able to note that a new item has been added to the tabbed panel at the top of this section. Enter the title for the new item as well as the sub-title and the page that the Wiki item should be routed to when clicked.




Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.

To remove an item from the list, click the **Remove Last Item** button. Once you have clicked this button, you will be able to note that the last item has been removed from the tabbed panel at the top of this section. Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.


It is only possible to remove the last item in the list. Please edit content from existing items if an item in the middle of the list is no longer valid.

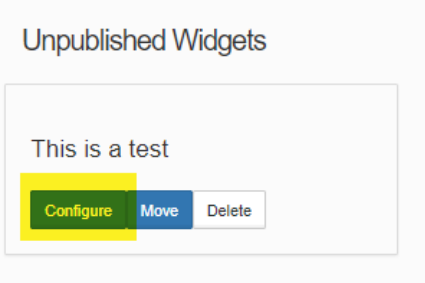
### 7.4.4 **Publishing a Widget**

**BUZZWORDS**

**Publish:** Widgets in an unpublished status are not viewable by standard users of the Information Portal (those who do not have the Publisher role assigned to their user profile). Conversely, widgets in a published status are viewable by all users.

Widgets are only to be published once the publisher is happy with the content submitted.

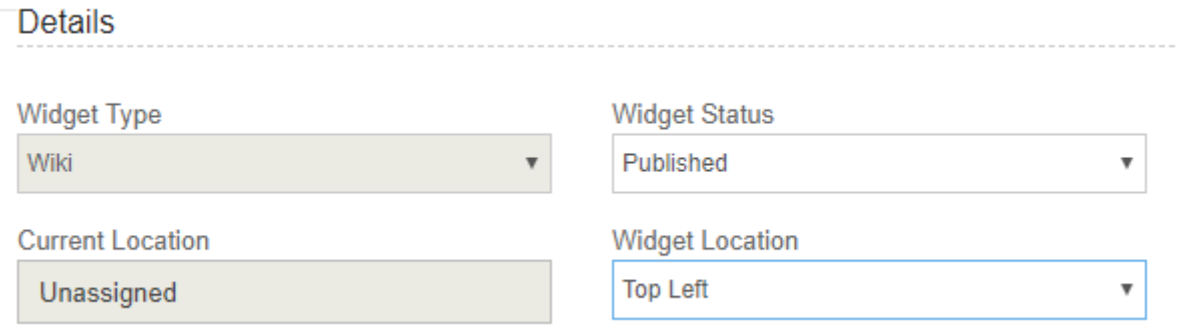
To publish a widget, navigate to the page that you would like to modify, locate the widget you would like to publish and click the **Configure** button for this widget.



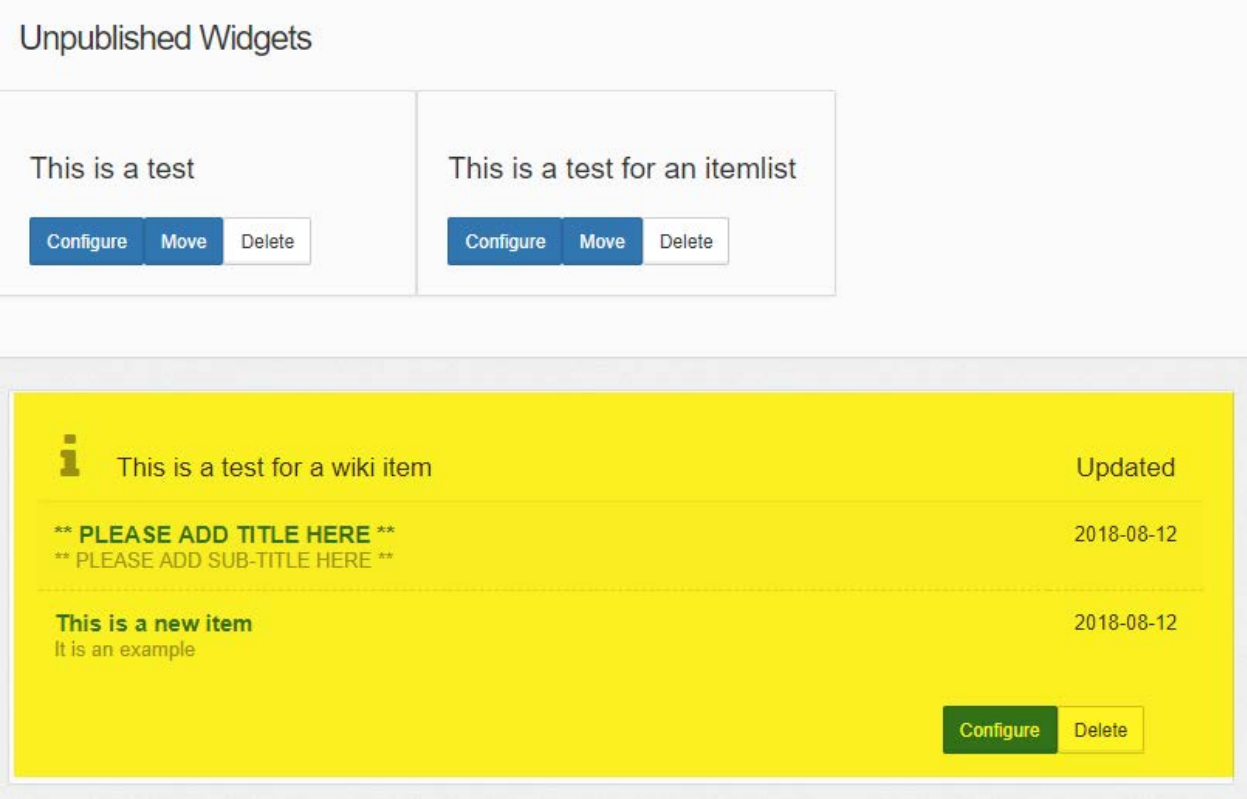

The system will navigate you to the **Edit Widget** page where you will have the ability to publish the widget.

Change the status of the widget to **Published** and confirm the location of the widget. Click the **Save** button to save your changes or the **Cancel** button to cancel this action and return to the page view.


The location determines where on the page the widget will appear. Only one widget can occur in each of the 6 allocated spaces on a page.



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.

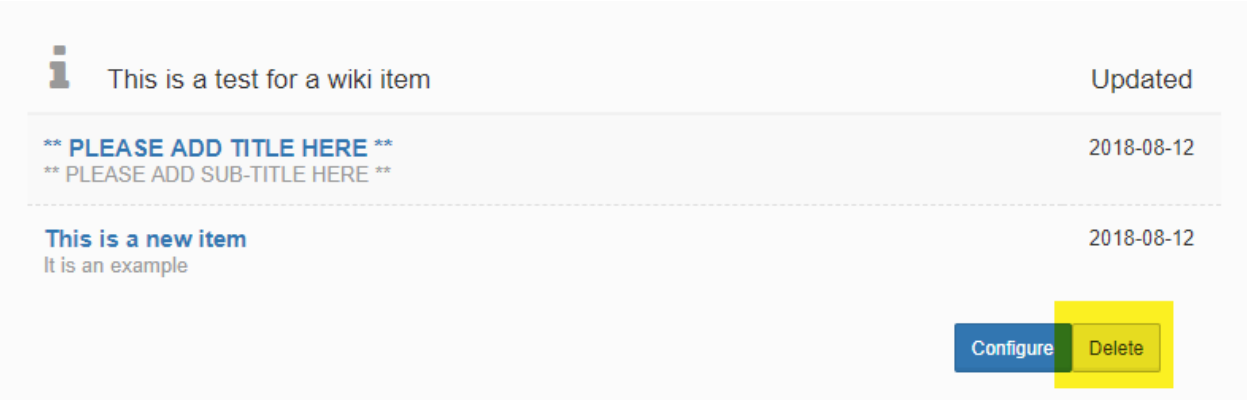




Saving a widget as unpublished will remove the widget from the page and move it to the Unpublished Widgets section. Widgets in this section are **not** viewable by standard users of the Information Portal.

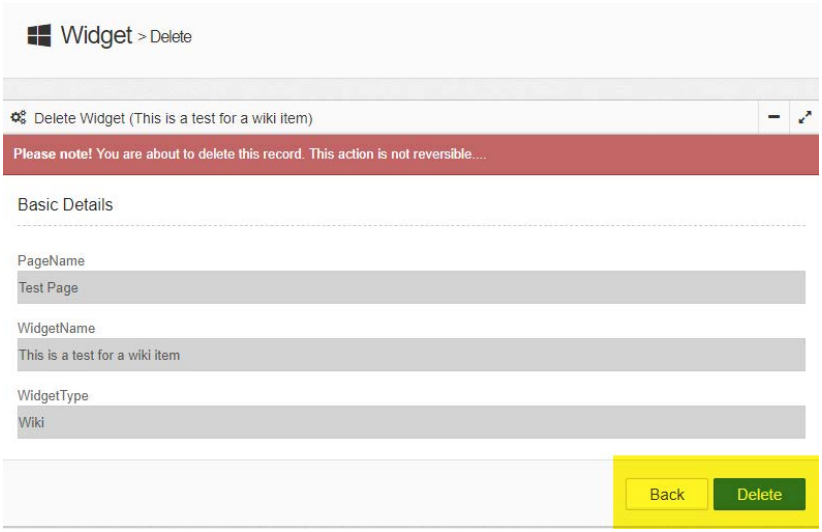
### 7.4.5 **Deleting a Widget**

To delete a widget, navigate to the page that you would like to modify, locate the widget you would like to delete and click the **Delete** button for this widget.




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

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



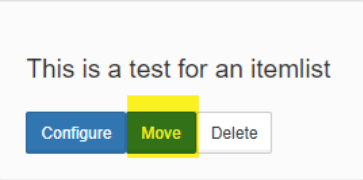


The widget and all related content will be deleted when clicking the **Delete** button.

### 7.4.6 **Moving a Widget to a New Page**

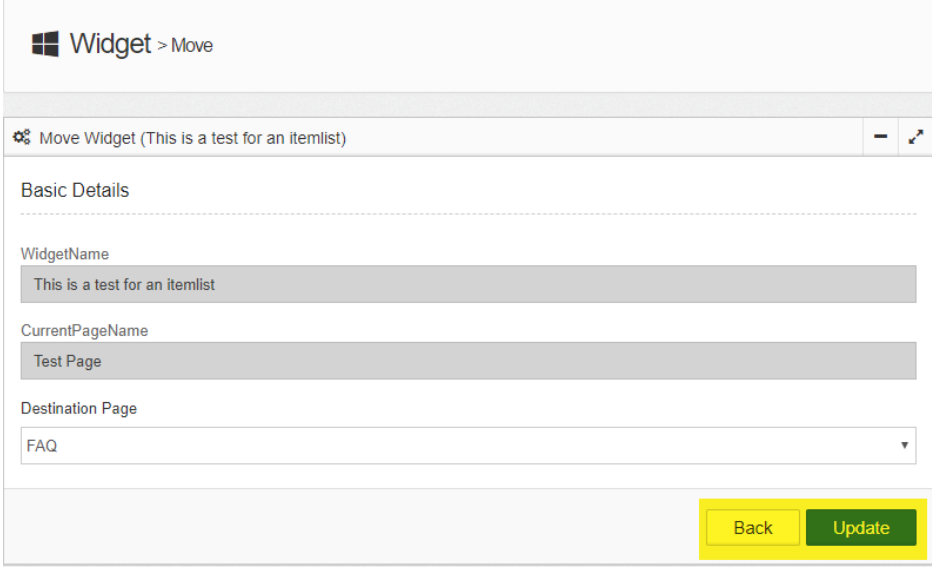
To move a widget, navigate to the page that you would like to modify, locate the widget you would like to move and click the **Move** button for this widget.


You are only able to move a widget if it is currently in an **Unpublished** status on the page it resides on.




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

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





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 **Create Report button**. The system will navigate you to a page where you can enter the spontaneous report.

### 8.1.1 Add a New Report

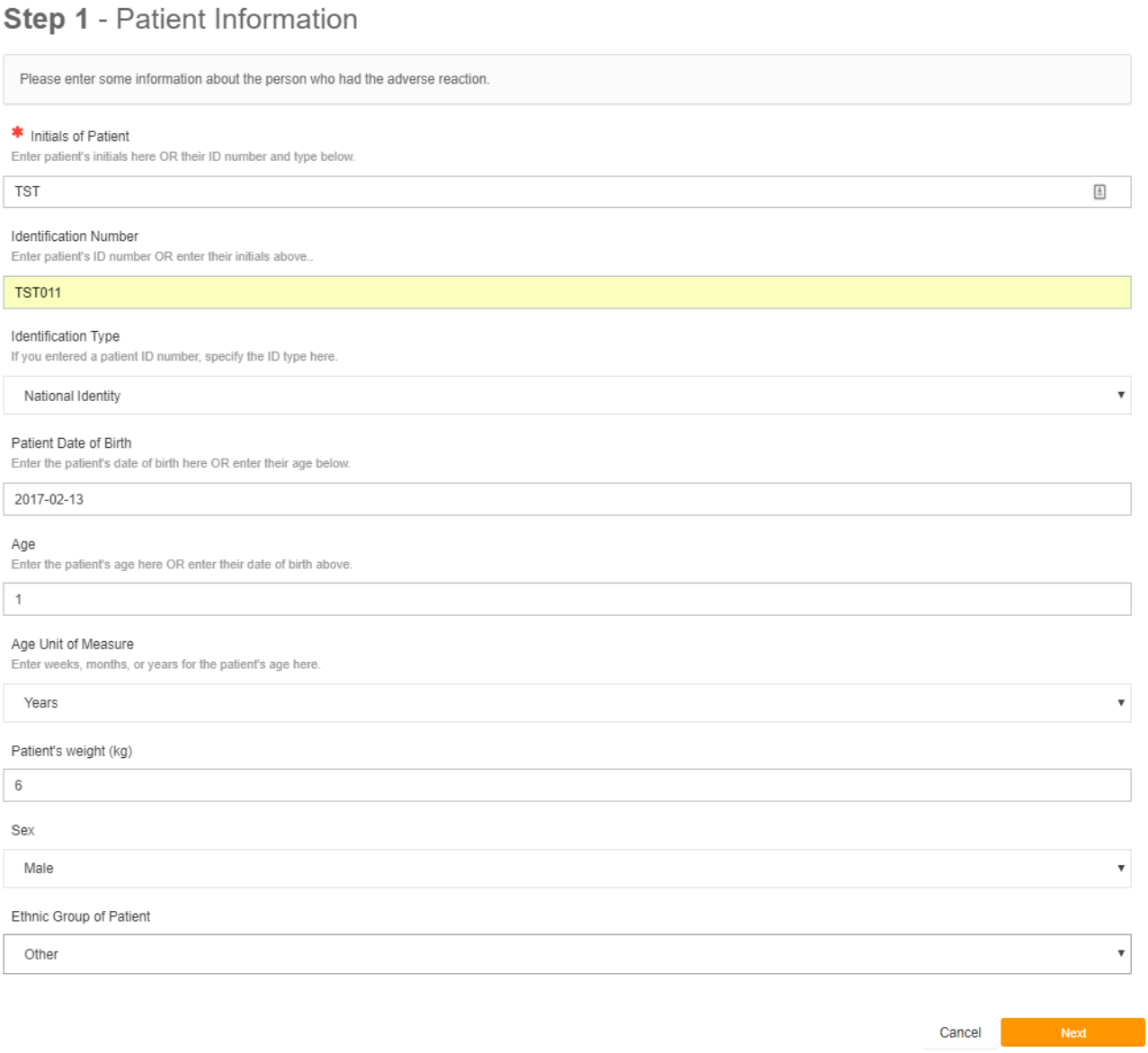
Spontaneous reports are composed of the following sections:

| | |
|---|---|
| Patient Information | Information related to the patient who suffered the adverse event |
| Product Information | Information related to the medication that potentially caused the adverse event |
| Test Result | Any test results that are relevant to the adverse event |
| Reaction and Treatment | Details of the adverse event |
| Reporter Information | Details of the person who has logged the adverse event |

#### 8.1.1.1 Patient Information

The **Patient Information** section captures basic patient demographic information about the person who suffered the adverse event.

To enter patient information, **enter text** in the corresponding fields (e.g., **Initials of Patient**). Or click the **arrow** in a selected field to display a list of values, and select one value from the list. All elements with a red asterisk are mandatory.


Step 1 - Patient Information
Please enter some information about the person who had the adverse reaction.
* Initials of Patient
Enter patient's initials here OR their ID number and type below.
TST
Identification Number
Enter patient's ID number OR enter their initials above..
TST011
Identification Type
If you entered a patient ID number, specify the ID type here.
National Identity
Patient Date of Birth
Enter the patient's date of birth here OR enter their age below.
2017-02-13
Age
Enter the patient's age here OR enter their date of birth above.
1
Age Unit of Measure
Enter weeks, months, or years for the patient's age here.
Years
Patient's weight (kg)
6
Sex
Male
Ethnic Group of Patient
Other
Cancel
Next

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

| | |
|---|---|
| Initials of Patient | Identification of the patient is facilitated through the capturing of their initials in a text field |
| Identification Number | Identification of the patient is facilitated through the capturing of their ID Number in a text field |
| Identification Type | Dropdown list to select the patient's type of identity number specified |
| Patient Date of Birth | Either specify the patient's date of birth |
| Age | Or specify the patient's age |
| Age Unit of Measure | If age is specified, specify the unit type for the age (e.g. days, months etc.) |
| Patient Weight (kg) | The weight of the page at the time of the adverse event, in kilograms |
| Sex | Dropdown list to specify the gender of the patient |
| Ethnic Group of Patient | Dropdown list to specify the ethnic group of the patient |

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

### 8.1.1.2 Product Information

The **Product Information** section captures a list of medications that the patient was taking at the time of the adverse event.

To enter medication information, click the **Add Product Information item** button. Once a product has been added, you are able to remove or edit the medication using the appropriate button next to the medication.


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

| | |
|---|---|
| Product | The name of the medication that the patient was taking (generic or brand name) |
| Drug Strength | Free format description of the drug strength, **e.g. 250** |
| Drug Strength Unit | Dropdown list specifying the unit of the drug strength, e.g., mg |
| Product Suspected | Is this product suspected of causing the adverse event |
| Dose Number | Drug dosage |
| Dose Unit | Dropdown list specifying the unit of the drug dosage |
| Route of Administration | Dropdown list specifying how the drug has been administered |
| Start and End Date | When did the patient start the drug and if they have completed taking the drug, when was the last date of administration |
| Treatment Duration | How long has the patient been on the drug |

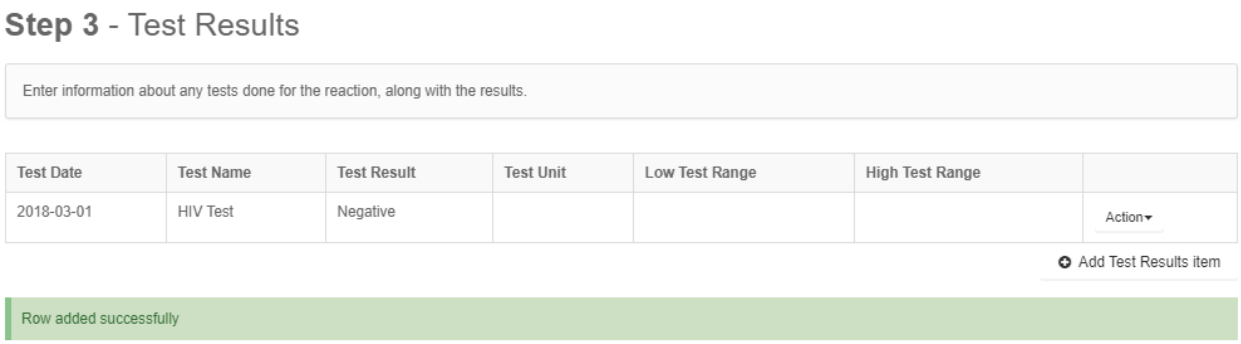
| | |
|---|---|
| Treatment Duration Unit | Dropdown list specifying the unit for the duration |
| Indication | Indication for why the patient is taking this drug |
| Frequency | How frequently is the patient taking the drug |
| Batch Number | The batch number the drug forms part of |
| Action Taken | What action was taken when the adverse event occurred |
| Product Challenge | Was a challenge performed on the product when suspected of the adverse event |
| Product Rechallenge | Was a rechallenge performed |

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

#### 8.1.1.3 Test Results

The **Test Results** section captures a list of test results that are applicable to the adverse event.

To enter test results, click the **Add Test Results item** button. Once a test has been added, you are able to remove the result or edit the test using the appropriate button.




Fields in the **Test Results** Section are described below:

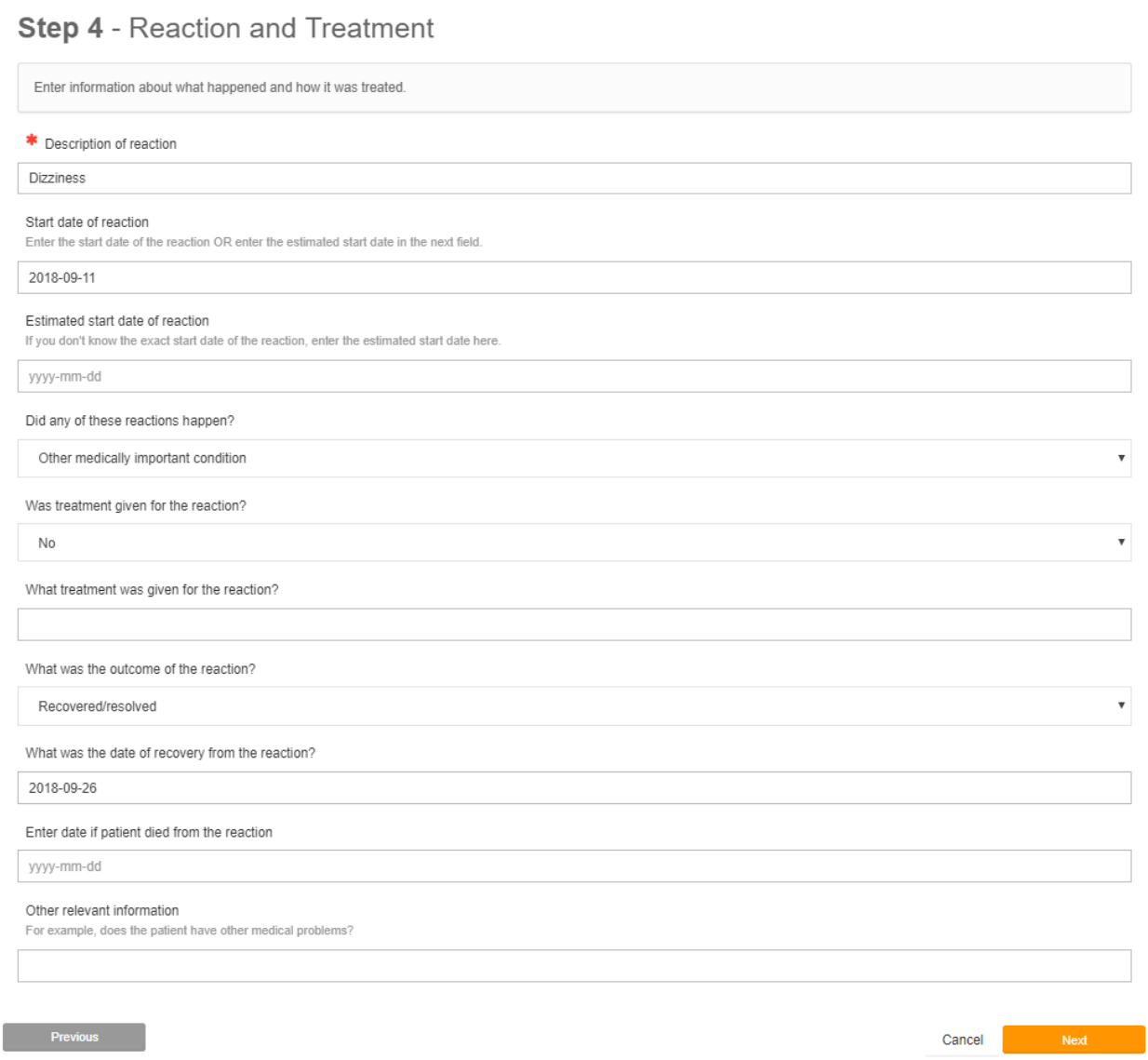
| | |
|---|---|
| Test Date | The date the test was conducted |
| Test Name | The name of the test conducted |
| Test Result | The result of the test conducted |
| Test Unit | Any unit associated to the test result |
| Low- and High-Test Range | Test result range that is considered normal |
| More Information | More information associated to the test result? |

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

#### 8.1.1.4 Reaction and Treatment

The **Reaction and Treatment** section captures details of the adverse event.

To enter reaction and treatment information, **enter text** in the corresponding fields (e.g., **Description of Reaction**). Or click the **arrow** in a selected field (e.g.) to display a list of values, and select one value from the list. All elements with a red asterisk are mandatory.


Step 4 - Reaction and Treatment
Enter information about what happened and how it was treated.
* Description of reaction
Dizziness
Start date of reaction
Enter the start date of the reaction OR enter the estimated start date in the next field.
2018-09-11
Estimated start date of reaction
If you don't know the exact start date of the reaction, enter the estimated start date here.
yyyy-mm-dd
Did any of these reactions happen?
Other medically important condition
Was treatment given for the reaction?
No
What treatment was given for the reaction?
What was the outcome of the reaction?
Recovered/resolved
What was the date of recovery from the reaction?
2018-09-26
Enter date if patient died from the reaction
yyyy-mm-dd
Other relevant information
For example, does the patient have other medical problems?
Previous
Cancel
Next

Fields in the **Reaction and Treatment** Section are described below:

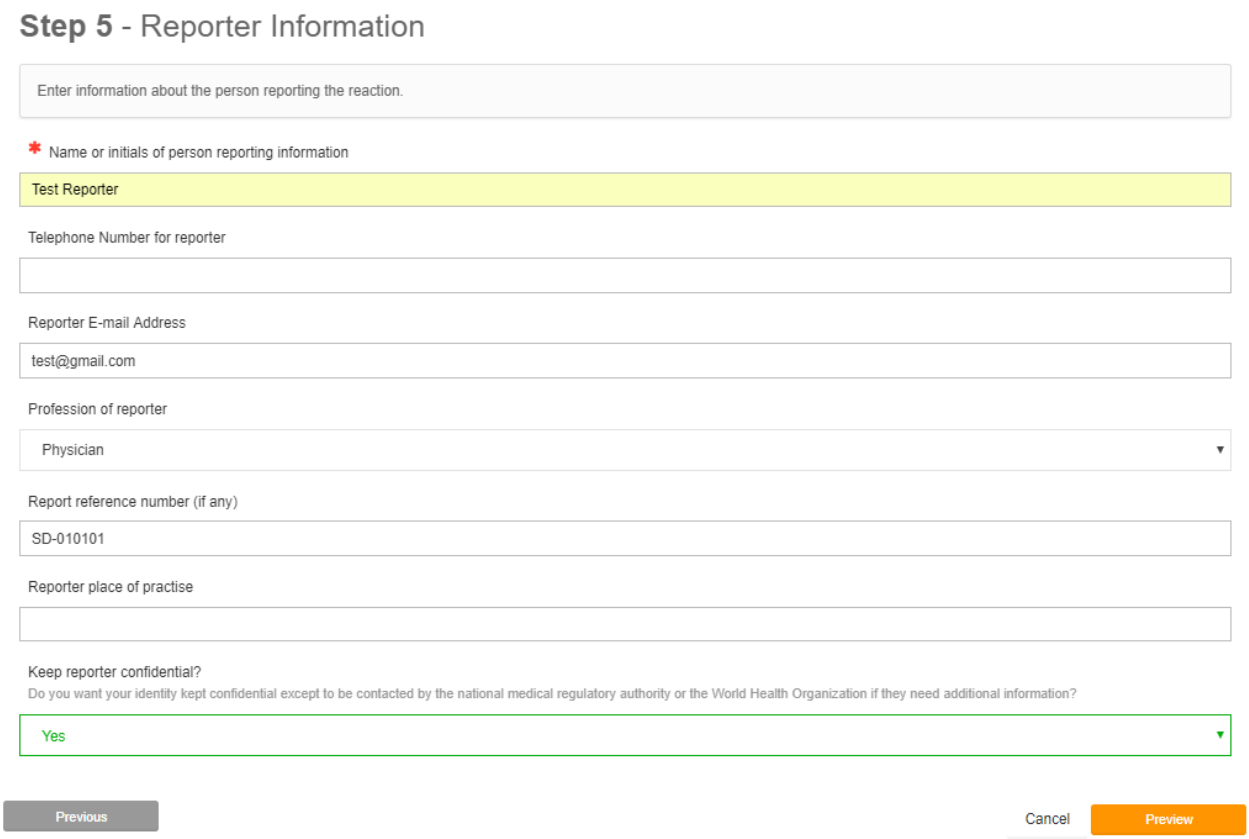
| | |
|---|---|
| Description of Reaction | A description of the adverse event |
| Start Date of Reaction | The date the reaction first appeared in the patient |
| Estimated Start Date of Reaction | Only specify this date if the exact start date is not known |
| Reactions | Did the patient experience a reaction |
| Treatment for Reaction | Was a treatment given for the reaction itself |
| What Treatment Given for Reaction | If a treatment was given for the reaction, what treatment was it |
| Reaction Outcome | What was the outcome of the reaction |
| Recovery Date | If the patient has recovered, what is the date of the recovery |
| Deceased Date | If the patient has died from the adverse event, what was the date of death |
| Other Relevant Info | Is there other information relevant to the adverse event |

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

### 8.1.1.5 Reporter Information

The **Reporter Information** section captures details of the person who has reported the event.

To enter reporter information, **enter text** in the corresponding fields (e.g. **Name or Initials of person reporting the event**). Or click the **arrow** in a selected field (e.g.) to display a list of values, and select one value from the list. All elements with a red asterisk are mandatory.



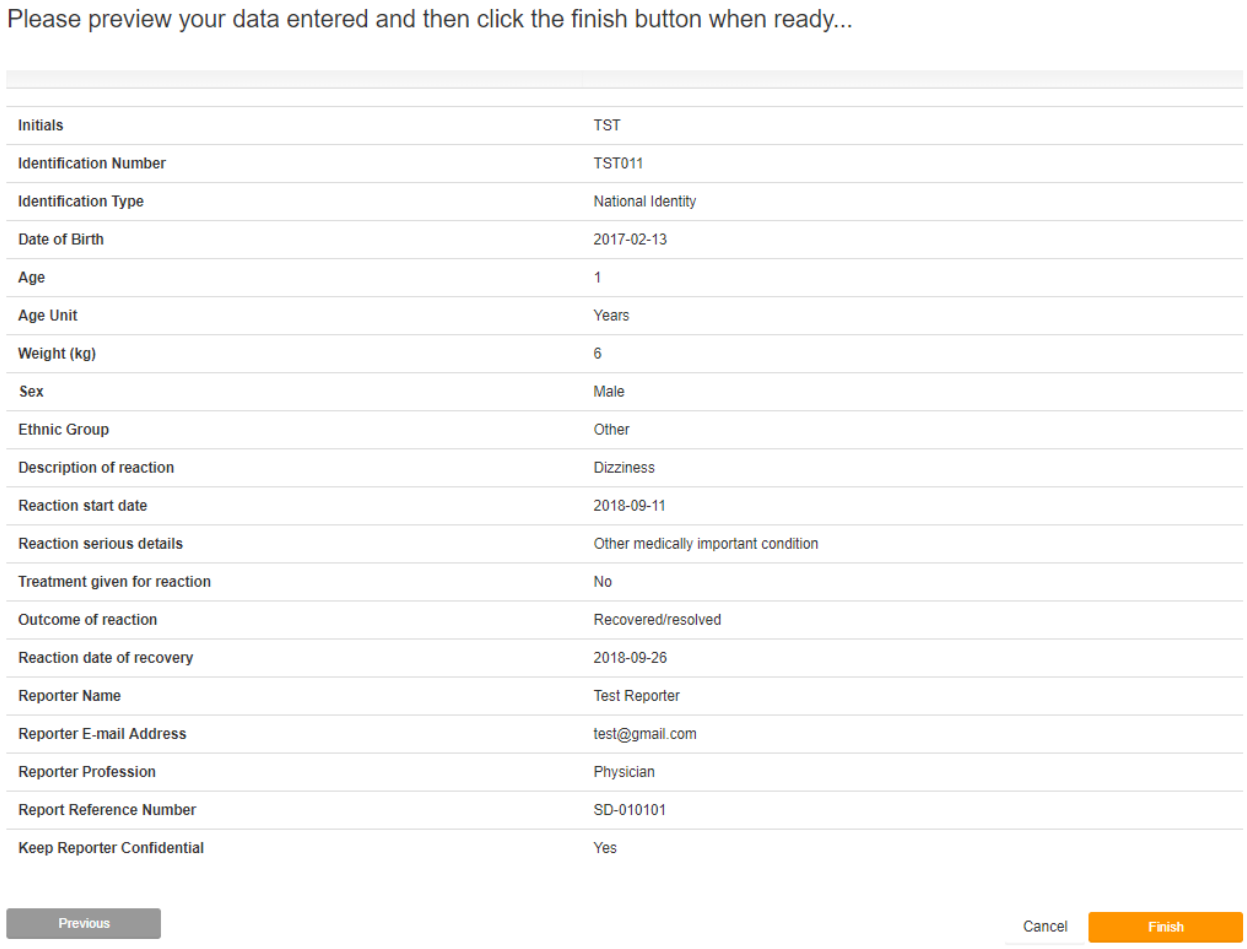
Fields in the **Reporter Information** Section are described below:

| | |
|---|---|
| Name or Initials | The name or initials of the person reporting the event |
| Telephone Number | Contact number of the person reporting the event |
| Email Address | Email address of the person reporting the event |
| Profession | The profession of the person who has reported the event |
| Reference Number | Reference number for the event that has been reported |
| Place of Practice | At which facility does the reporter work |
| Confidentiality | Should the report remain confidential |

Click the **Next button** to navigate to the next screen or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

### 8.1.2 **Preview Report**

Once you have completed all sections of the spontaneous report, click on the preview button to view a summary of the report.




Click the **Finish button** to submit the report or the **Cancel button** to cancel the registration of the spontaneous report and return to the login screen.

### 8.1.3 Confirmation

Once you have clicked the finish button, the report will be saved to the database and you will receive confirmation of this.