

PViMS Administrator Manual





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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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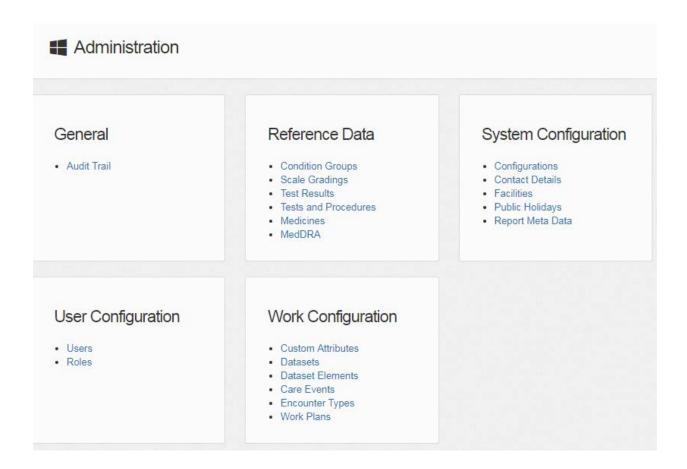
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The purpose of this manual is to explain the options in PViMS that the system administrator can define and control. These options give the administrator the ability to tailor PViMS to a site's needs, without requiring any programming skills. The options are found in the Administration portal of PViMS. Click the icon made up of four squares to open the Administration portal. This is only visible and available to users with Administration rights.



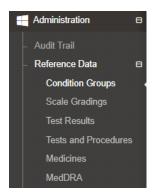


1 Reference Data

1.1 **Condition Groups**

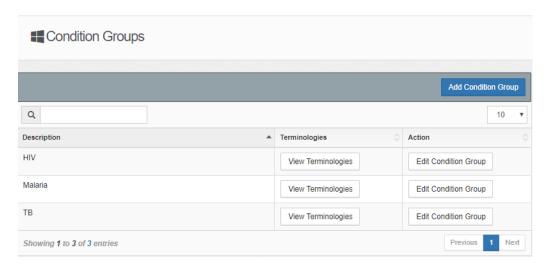
Condition groups facilitate collective analysis across similar adverse event groups.

The condition groups administration function can be accessed through the **Administration** → **Reference Data** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage Condition Groups reference page where the system will return a list of conditions that have been configured within the system.

The system will return the list and the total number of conditions that have been found and will provide the option of adding a new condition group.



Click the **View Terminologies Button** to view all MedDRA terms that have been associated with that condition.

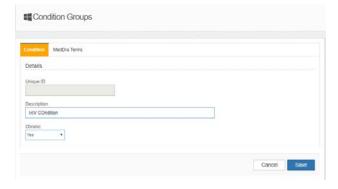
1.1.1 Adding a New Condition Group

To add a new condition group, click on the Add Condition Group Button.



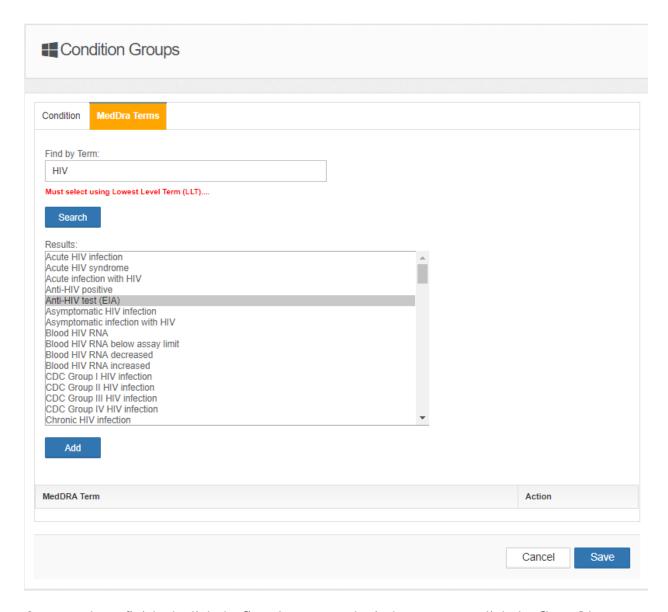
The system will navigate you to the admin page for adding a new condition group. Enter details of the condition group as per the description of each field below.

Description	The unique name of the condition group This field is mandatory
Chronic	Is this condition chronic



Once information has been entered, proceed to the MedDRA terms tab to select all MedDRA terms that have been associated to this condition group.

Enter the search term to locate the MedDRA term and click search. Once you have selected the corresponding LLT, click the **Add Button** to add the term to the condition group.



Once you have finished, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the condition list.

Please note: when analysing data, condition groups are used to aggregate analysis across disparate MedDRA terms using the condition group as the unifier. If an adverse event is not incorporated into analysis, this is likely due to the term not being associated to the condition group.

1.1.2 Editing an Existing Condition Group

To edit an existing condition group, click on the **Edit Condition Group Button** alongside the corresponding condition.

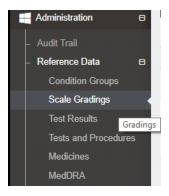


The system will navigate you to the admin page for editing a condition group. You are able to add new lab tests, medications and MedDRA terms associated to the condition group in this admin function as well as remove existing items.

1.2 Scale Gradings

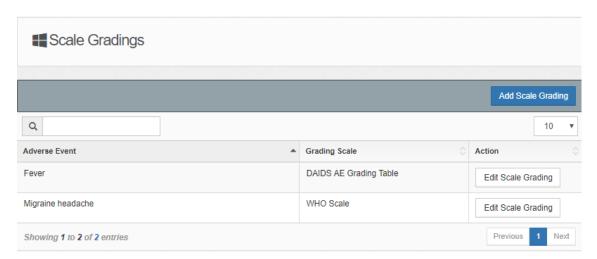
Scale gradings provide addition descriptions that assist in the grading of an adverse event based on the scale used.

The scale gradings administration function can be accessed through the **Administration** → **Reference Data** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage Scale Gradings reference page where the system will return a list of grades that have been configured within the system.

The system will return the list and the total number of grades that have been found and will provide the option of adding a new scale grading.



1.2.1 Adding a New Scale Grading

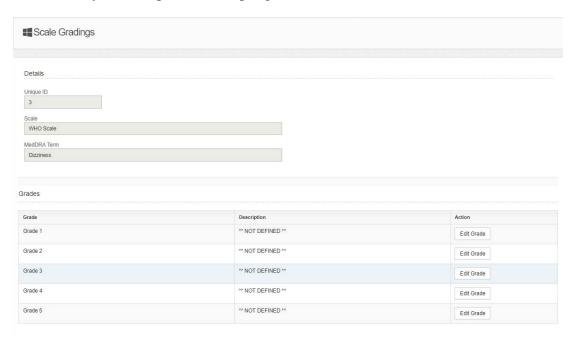
To add a new scale grading, click on the Add Scale Grading Button.



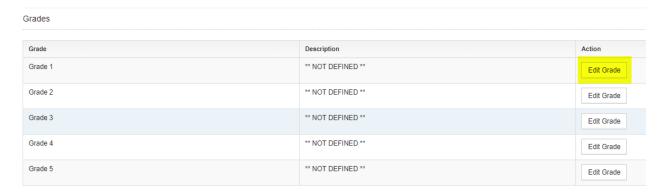
The system will navigate you to the admin page for adding a new scale grading.

Scale	The scale that the grade is being associated to This field is mandatory
MedDRA Event	The MedDRA event that the definition is for

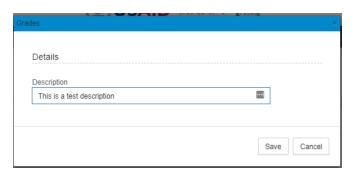
Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the test and procedure list. The system will automatically create a place holder per grade.



To edit the definition for the specific grade, click the **Edit Grade Button** for the corresponding grade.

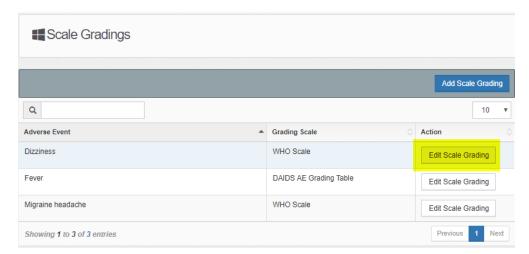


The system will pop up a grade definition modal form. Update details of the grade definition and click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the grade list.



1.2.2 Editing an Existing Scale Grading

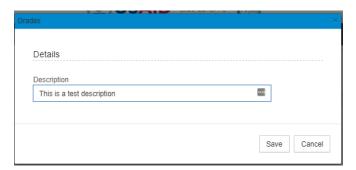
To edit an existing grade scaling, click on the **Edit Scale Grading Button** alongside the corresponding scale.



The system will navigate you to the admin page for editing a scale grading. To edit the definition for the specific grade, click the **Edit Grade Button** for the corresponding grade.

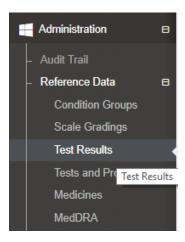


The system will pop up a grade definition modal form. Update details of the grade definition and click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the grade list.



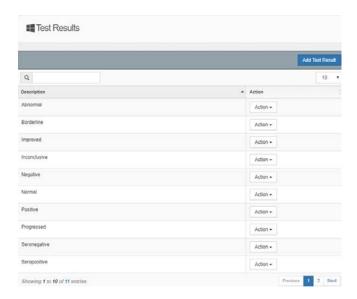
1.3 Test Results

The test results administration function can be accessed through the **Administration** → **Reference Data** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage Test Results reference page where the system will return a list of results that have been configured within the system.

The system will return the list and the total number of results that have been found and will provide the option of adding a new test result.



1.3.1 Adding a New Test Result

To add a new test result, click on the Add Test Result Button.



The system will pop up an add new test result modal form. Enter details of the test result as per the description of each field below.



Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the test and procedure list.



1.3.2 Editing an Existing Test Result

To edit an existing test result, click on the **Edit Test Result Button** alongside the corresponding test result.



The system will pop up a test result modal form. Update details of the test result and click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the test and procedure list.

1.3.3 Delete an Existing Test Result

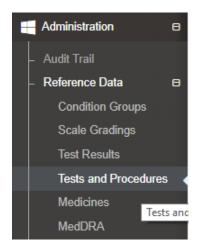
To delete an existing test result, click on the **Delete Test Result Button** alongside the corresponding test result.



The system will pop up a test result modal form. Confirm the details of the test result you would like to delete and click the **Delete** button to submit the request or click the **Cancel** button to cancel the action and return to the test and procedure list.

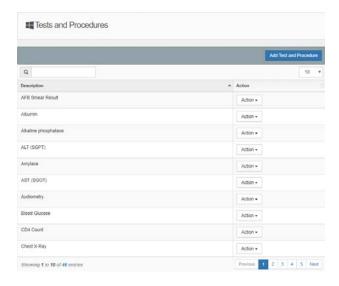
1.4 Tests and Procedures

The tests and procedures administration function can be accessed through the **Administration** → **Reference Data** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage Tests and Procedures reference page where the system will return a list of tests and procedures that have been configured within the system.

The system will return the list and the total number of tests and procedures that have been found and will provide the option of adding a new test and procedure.



1.4.1 Adding a New Test and Procedure

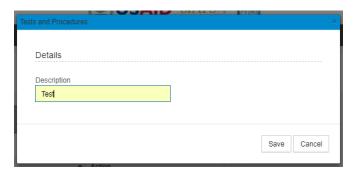
To add a new test and procedure, click on the Add Test and Procedure Button.



The system will pop up an add new test and procedure modal form. Enter details of the test and procedure as per the description of each field below.



Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the test and procedure list.



1.4.2 Editing an Existing Test and Procedure

To edit an existing test and procedure, click on the **Edit Test and Procedure Button** alongside the corresponding test and procedure.



The system will pop up a test and procedure modal form. Update details of the test and procedure and click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the test and procedure list.

1.4.3 **Delete an Existing Test and Procedure**

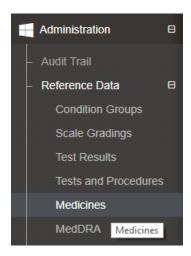
To delete an existing test and procedure, click on the **Delete Test and Procedure Button** alongside the corresponding test and procedure.



The system will pop up a test and procedure modal form. Confirm the details of the test and procedure you would like to delete and click the **Delete** button to submit the request or click the **Cancel** button to cancel the action and return to the test and procedure list.

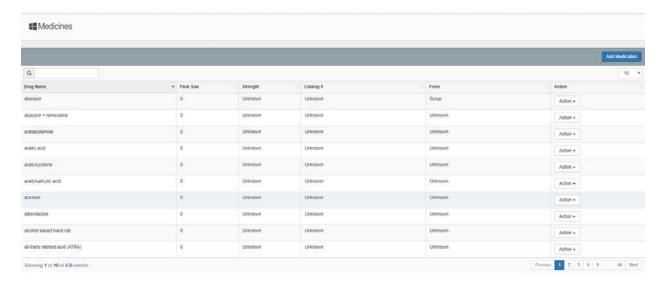
1.5 Medicines

The medicine administration function can be accessed through the **Administration** → **Reference Data** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage Medicines reference page where the system will return a list of medicines that have been configured within the system.

The system will return the list and the total number of medicines that have been found and will provide the option of adding a new medication.



1.5.1 Adding a New Medication

To add a new medication, click on the Add Medication Button.



The system will pop up an add new medication modal form. Enter details of the medication as per the description of each field below.

Drug Name	The trade name of the medication This field is mandatory
Pack Size	The pack size of the medication
Strength	The strength of the medication
Catalog	The unique catalog number of the medication
Form	The form of the medication

Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the medicine list.



1.5.2 Editing an Existing Medication

To edit an existing medication, click on the **Edit Medication Button** alongside the corresponding medication.



The system will pop up a medication modal form. Update details of the medication and click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the medicine list.

1.5.3 **Delete an Existing Medication**

To delete an existing medication, click on the **Delete Medication Button** alongside the corresponding medication.

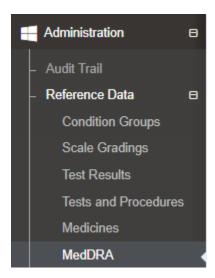


The system will pop up a medication modal form. Confirm the details of the medication you would like to delete and click the **Delete** button to submit the request or click the **Cancel** button to cancel the action and return to the medicine list.

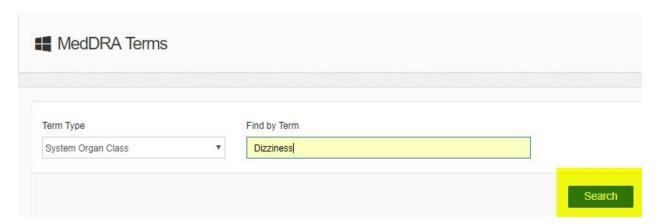
1.6 **MedDRA Terminology**

Search for existing MedDRA terms and import a new MedDRA dataset. MedDRA reference data is used when assigning a MedDRA term to a spontaneous report

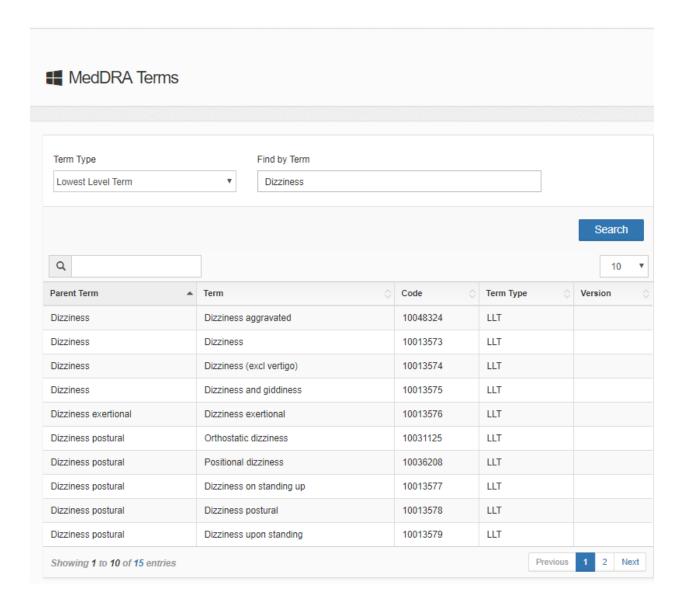
The MedDRA administration function can be accessed through the **Administration** → **Reference Data** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage MedDRA Terms reference page. To search for a MedDRA term, select the term type and enter a term to search for. Click the **Search** button to search for the corresponding term.



The system will return the list and the total number of terms that have been found.



Please note: it is not possible to add a new term, edit or delete an existing term. Modifications to each term can only be facilitated through the MedDRA import function.

1.6.1 Importing a New MedDRA dataset

To import a new MedDRA dataset, download the latest MedASCII files from http://www.meddra.org and compress these files into a ZIP file named medascii.zip. The zip file must be comprised of the following individual files: -

Soc.asc, hlgt.asc, hlt.asc, llt.asc, pt	Contains full set of reference data for each class
soc_hlgt.asc	Link HLGT terms to SOC parent class
hlgt_hlt.asc	Link HLT terms to HLGT parent class
hlt_pt.asc	Link PT terms to HLT parent class

Once you have created the medascii.zip file, upload this file by clicking on the **Choose File** button. Browse to the location of the medascii.zip file and click the **Open** button. Click the **Import** button to import the latest reference set.



Please note: this process may take some time to complete.

Once the process has completed, the latest version number will be displayed.



2 System Configuration

2.1 Configurations

System configurations are used to configure specific functions within the system.

The configuration administration function can be accessed through the **Administration** → **System Config** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage Configurations reference page where the system will return a list of configurations that are applicable within the system.

Once you have clicked on this menu, the system will navigate you to the Configuration List reference page where you will be presented with a list of system configurations.

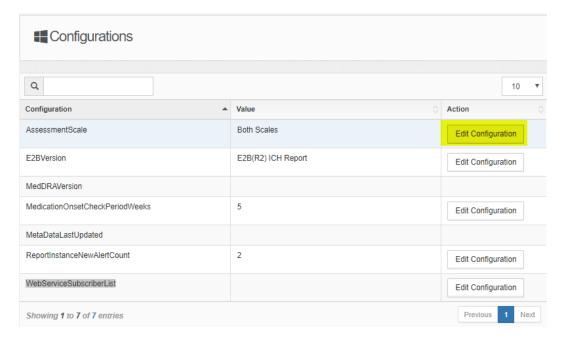
AssessmentScale	Assessment scale to be used
MedDRAVersion	The current version of MedDRA ** Read only **
MedicationOnsetCheckPeriod Weeks	Number of weeks before and after onset date that medications should be checked for causality
MetaDataLastUpdated	The last updated date for reporting meta data
ReportInstanceNewAlertCount	New report count triggered based on this parameter (number of days)
WebServiceSubscriberList	Unique identifier for third part systems submitting data to PViMS

Please note: it is not possible to add new configurations as these configurations are system

defined.

2.1.1 Update a System Configuration

To update a system configuration, locate the configuration you would like to update and click on the **Edit Configuration** button for the corresponding type.



Update the configuration value as necessary and click the **Save** button to save the configuration or the **Return to Config List** button to cancel the action and return to the previous page.

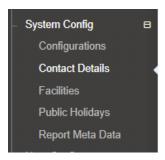
The following modifications can be made per config type:

AssessmentScale	Assessment scale to be used Both Scales Naranjo Scale WHO Scale
E2BVersion	The version of E2B to be used E2B(R2) ICH Report E2B(R3) ICH Report

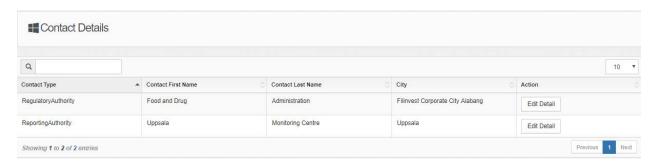
2.2 Contact Details

Contact details are used to configure address details for the regulatory authority and reporting authority. Both addresses are used when exporting an adverse event into E2B.

The contact details administration function can be accessed through the **Administration > System Config** menu and is accessible to administrators of the system.

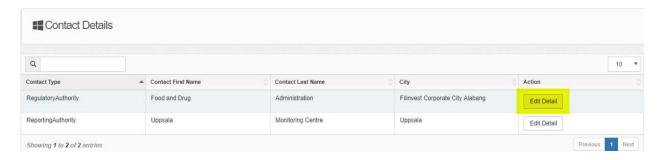


Once you have clicked on this menu, the system will navigate you to the Manage Contact Details reference page where the system will return the captured address for both the reporting and regulatory authority.

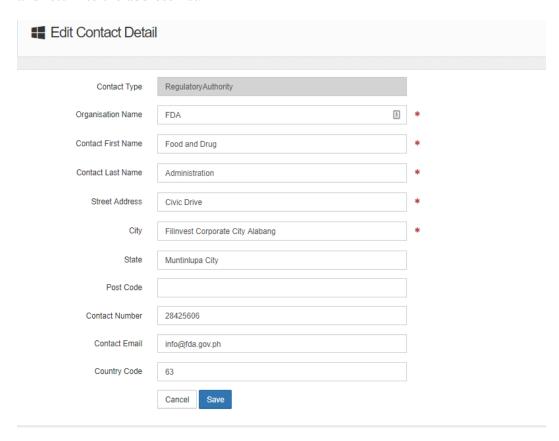


2.2.1 Updating a Contact Address

To edit an existing contact address, click on the **Edit Detail Button** alongside the corresponding address.

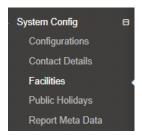


The system will navigate you to the admin page for the address. Update the address as necessary and click the **Save Button** to submit the request or click the **Cancel** button to cancel the action and return to the address list.



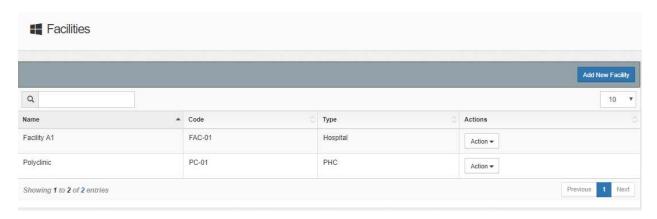
2.3 Facilities

The facilities administration function can be accessed through the **Administration** \rightarrow **System Config** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage Facilities reference page where the system will return a list of facilities that have been configured within the system.

The system will return the list and the total number of facilities that have been found and will provide the option of adding a new facility.



2.3.1 Adding a New Facility

To add a new facility, click on the Add New Facility Button.



The system will navigate you to a new facility form. Enter details of the facility as per the description of each field below.

Facility Name	The unique name of the facility This field is mandatory
Facility Code	A unique code for the facility This field is mandatory
Facility Type	The type of facility Unknown, Hospital, Community Health Centre, Primary Health Centre
Region	The region the facility belongs to (OrgUnit table must be manually populated with geographical location of facility)
Telephone Number	The contact number of the facility (used in E2B extract)
Mobile Number	The mobile number of the facility (used in E2B extract)
Fax Number	The fax number of the facility (used in E2B extract)

Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the facility list.



2.3.2 Editing an Existing Facility

To edit an existing facility, click on the **Edit Facility Button** alongside the corresponding facility.

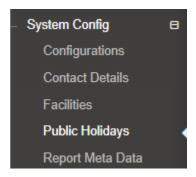


The system will navigate you to a facility administration form. Update details of the facility and click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the facility list.

2.4 **Public Holidays**

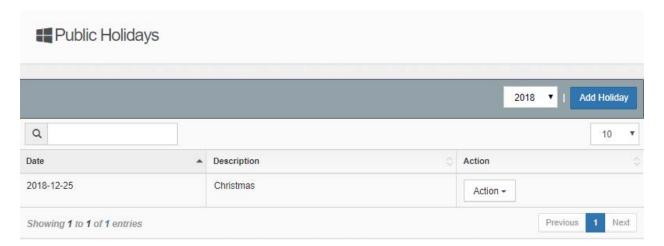
Public holidays are used for patient appointments, acting as a warning that there is a public holiday in the event this date is selected for the appointment.

The public holidays administration function can be accessed through the **Administration** → **System Config** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Manage Public Holidays reference page where the system will return a list of holidays that have been configured within the system.

The system will return the list and the total number of holidays that have been found and will provide the option of adding a new public holiday.



2.4.1 Adding a New Public Holiday

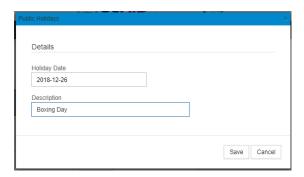
To add a new holiday, click on the Add Holiday Button.



The system will pop up an add new holiday modal form. Enter details of the holiday as per the description of each field below.

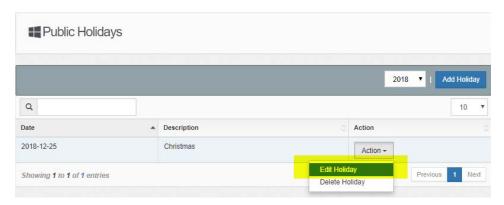
Holiday Date	The date of the holiday This field is mandatory
Description	Holiday details

Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the holiday list.



2.4.2 Editing an Existing Holiday

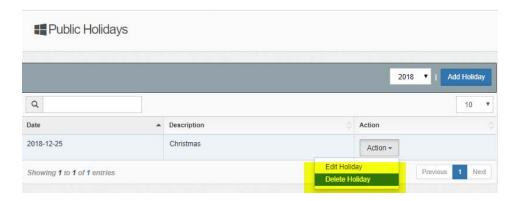
To edit an existing holiday, click on the Edit Holiday Button alongside the corresponding date.



The system will pop up a holiday modal form. Update details of the holiday and click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the holiday list.

2.4.3 **Delete an Existing Holiday**

To delete an existing holiday, click on the **Delete Holiday Button** alongside the corresponding date.



The system will pop up a holiday modal form. Confirm the details of the holiday you would like to delete and click the **Delete** button to submit the request or click the **Cancel** button to cancel the action and return to the holiday list.

2.5 Report Meta Data

Report Meta Data are the system meta attributes which allow custom reporting to take place.

The report meta data administration function can be accessed through the **Administration** → **System Config** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Report Meta Data reference page where the system will return a meta data summary and list of meta attributes that are applicable within the system.

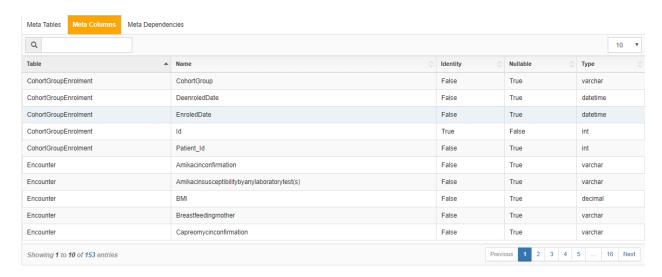
2.5.1 Meta Tables

Contains a list of queryable entities as defined within PViMS.



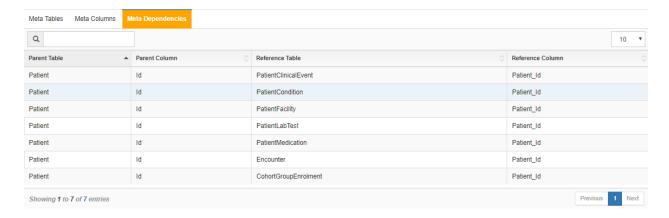
2.5.2 Meta Columns

Contains a list of queryable columns per entities as defined within PViMS.



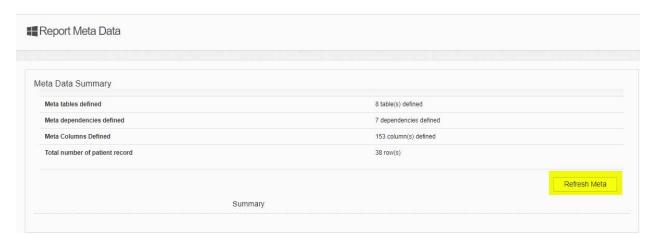
2.5.3 Meta Dependencies

Contains a list of dependencies that effectively join meta tables to each other.



2.5.4 Refresh Meta Data

To refresh meta data, click on the Refresh Meta Button.



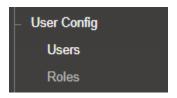
The system will refresh all meta tables, columns and dependencies and will refresh all data within the meta repository for up to date reporting.

Please note: new data elements will not be available for reporting unless meta data is refreshed

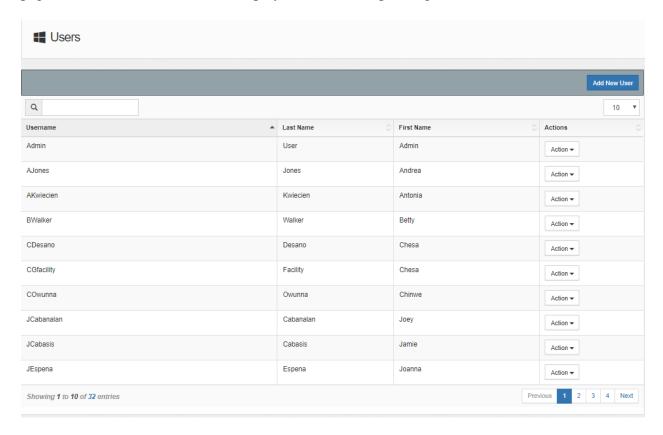
3 User Configuration

3.1 Users

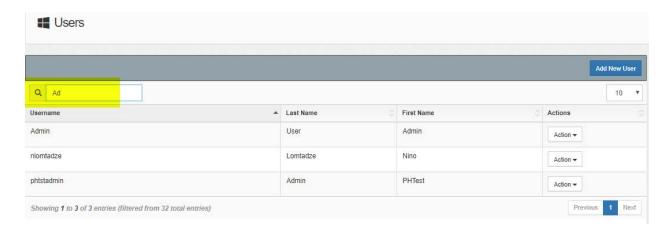
The user administration function can be accessed through the Administration \rightarrow User Config menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the User List reference page where a list of users will be displayed in the corresponding user list table.

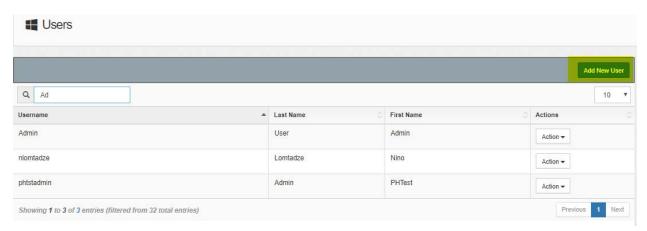


You are able to filter the user list table by entering a search term in the place provided.



3.1.1 Adding a New User

To add a new user, once you have opened the User List, click on the Add New User button.

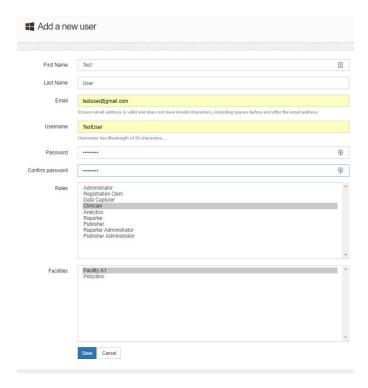


The system will navigate you to a new user page. Enter details of the user as per the description of each field below.

First Name	The first name of the user This field is mandatory
Last Name	The last name of the user This field is mandatory
Email	The email address of the user This field is mandatory
Username	The user name that the user will enter to gain access to the

	site This field is mandatory
Password and Confirm Password	The password that the user will enter to gain access to the site This field is mandatory
Roles	The list of roles that have been allocated to the user This field is mandatory
Facilities	The list of facilities that have been allocated to the user This field is mandatory

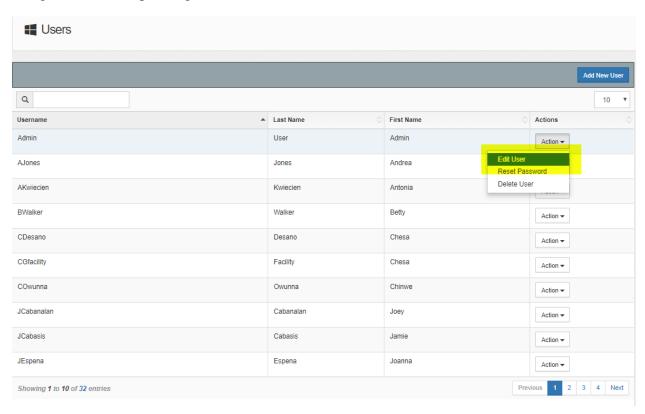
Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the user list.



The user will be added to the system.

3.1.2 Editing an Existing User

To edit an existing user, once you have opened the User List, click on the **Edit User** button alongside the corresponding user.

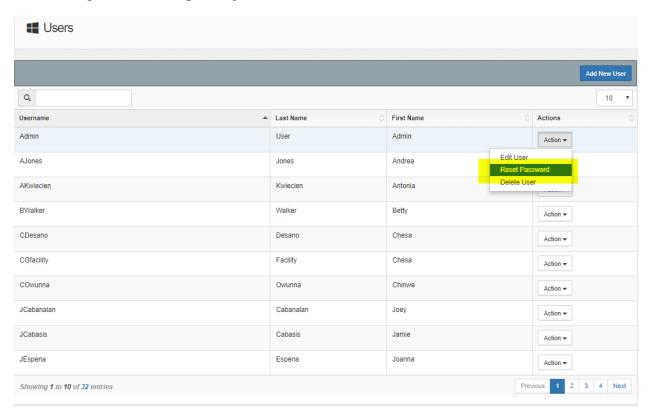


The system will navigate you to the user profile. Update details of the user and click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the user list.

Please note: it is not possible to reset a password through this function. You will be able to change the user name, email address, user name and associated facilities and roles. You are also able to confirm if the user is still active and if the user has the ability to download data through the analysis portal.

3.1.3 **Resetting a Password**

To reset a user's password, once you have opened the User List, click on the **Reset Password** button alongside the corresponding user.



The system will navigate you to the user profile where you will be able to reset the password of the user. Enter the new password as well as the password confirmation and click the **Save** button to save the new password or click the **Cancel** button to cancel this action and return the user to the user list.

Please note: passwords must adhere to the following conventions:

Minimum length of 6 characters

Passwords must have at least one non-letter or digit character

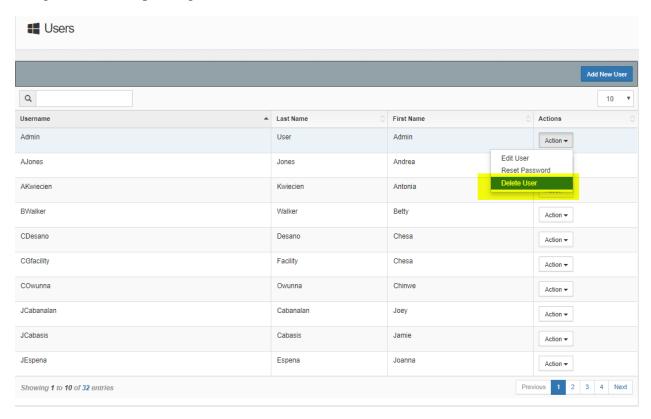
Passwords must have at least one digit ('0'-'9')

Passwords must have at least one uppercase ('A'-'Z')

The user profile will be updated in the system.

3.1.4 **Deleting an Existing User**

To delete an existing user, once you have opened the User List, click on the **Delete User** button alongside the corresponding user.



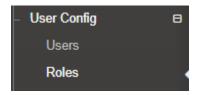
The system will navigate you to a delete user page. Click the **Delete** button to submit the request or click the **Cancel** button to cancel the action and return to the user list.

Please note: this action is not reversible. Please mark the user as inactive for users who no longer require access.

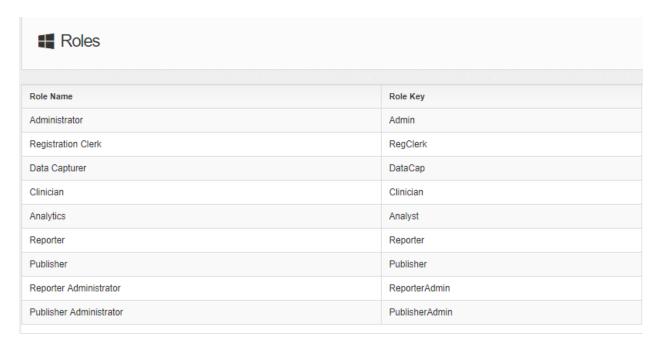
The user profile will be removed from the system.

3.2 Roles

The roles administration function can be accessed through the Administration \rightarrow User Config menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Role List reference page where a list of roles will be displayed in the corresponding role list table.



Please note: roles are pre-defined and not configurable within the system.

Role	Administrator
Description	The administrator of the system is able to configure PViMS according to the requirements of the facility and Pharmacovigilance Unit
Functions	 Manage custom attributes Manage facilities Manage public holidays Manage users Manage care events Manage encounter types Manage work plans Manage datasets Manage cohort groups
Role	Registration Clerk
Description	A registration clerk has the ability to manage the general patient flow of a facility through the registration of new patients and the check-in of existing patients. The registration clerk will only have access to patient demographic data and not to clinical data specifically.
Functions and allocated permissions	 View appointments for date using calendar Mark appointment as DNA (Did Not Arrive) (DNAAPPOINTMENT) Add appointment (ADDAPPOINTMENT) Edit appointment (EDITAPPOINTMENT) Delete appointment (DELETEAPPOINTMENT) Search for patient (VIEWPATIENT) Add patient (ADDPATIENT) Edit patient (EDITPATIENT) Delete patient (DELETEPATIENT) Check patient into facility (ADDENCOUNTER) Discharge patient (DISCHARGEENCOUNTER) Delete encounter (DELETEENCOUNTER) Add attachment (ADDATTACHMENT) Delete attachment (DELETEATTACHMENT) Download attachment (DOWNLOADATTACHMENT)

Role	Data Capturer
Description	A data capturer has the ability to retrospectively capture clinical data for a patient in the event the existing clinical record was not updated at source.
Functions	 Search for appointment (VIEWAPPOINTMENT) Search for patient (VIEWPATIENT) Edit patient (EDITPATIENT) Check patient into facility (ADDENCOUNTER) Discharge patient (DISCHARGEENCOUNTER) Search for encounter (VIEWENCOUNTER) Load clinical data (EDITENCOUNTER)
Role	Clinician
Description	A clinician is a facility resource (Doctor or Nurse) that has the ability to view a longitudinal clinical history for the patient and update this history on an encounter by encounter basis.
Functions	 Search for appointment (VIEWAPPOINTMENT) Add appointment (ADDAPPOINTMENT) Edit appointment (EDITAPPOINTMENT) Delete appointment (DELETEAPPOINTMENT) Search for patient (VIEWPATIENT) Add patient (ADDPATIENT) Edit patient (EDITPATIENT) Discharge patient (DISCHARGEENCOUNTER) Add attachment (ADDATTACHMENT) Delete attachment (DELETEATTACHMENT) Download attachment (DOWNLOADATTACHMENT) Search for encounter (VIEWENCOUNTER) Load clinical data (EDITENCOUNTER) Assign patient to cohort group (ASSIGNCOHORT) Remove patient from cohort group (REMOVECOHORT) De-enroll patient from cohort group (REMOVECOHORT)

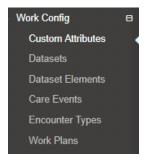
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Role	Analyst
Description	An analyst has the ability to set causality through a ratings scale, set MedDRA terminology, administer risk factor templates for signal detection and review the outputs of any signals detected.
Functions	 Set adverse event causality – WHO rating scale (SETCAUSALITY) Set adverse event causality – Naranjo rating scale (SETCAUSALITY) Set MedDRA terminology (SETMEDDRA) Configure task (SETTASK) View task results (VIEWTASKHISTORY)

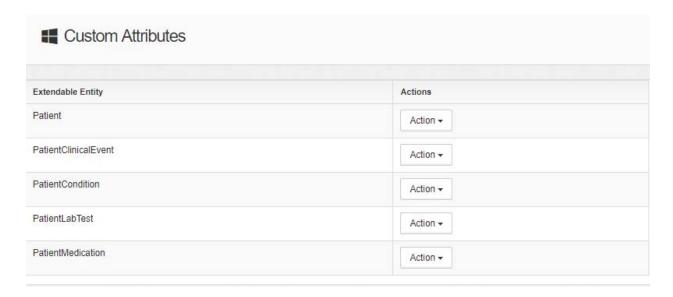
4 Work Configuration

4.1 **Custom Attributes**

The custom attributes administration function can be accessed through the **Administration** → **Work Config** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Custom Attribute List reference page where you will be presented with a list of system entities which are configured for customisation.



4.1.1 What is a Custom Attribute

Customisable entities allows further extension of the dynamic entity framework within PViMS. All clinical elements are fundamentally rendered at run time in context of the associated dataset relationship to a system work plan.

However, there are 5 primary entities that are pre-defined within PViMS and these primary entities can be extended through the concept of customisable attributes. These primary entities can be defined as follows: -

- Patient core patient
- PatientClinicalEvent core adverse event history
- PatientMedication core medication history
- PatientCondition core condition history
- PatientLabTest core labs history

Each entity contains a set of first class properties (available in all PViMS instances) as well as a set of customisable properties (can be modified per PViMS instance).

4.1.2 Customisation Attributes

Core entities can be extended through the definition of attributes that are effectively appended to the entity itself. The following attribute types can be created: -

- Numeric attribute
- String attribute
- Selection attribute
- DateTime attribute

4.1.3 **Core Entities**

Entity	Patient
Description	Contains patient demographics. Unique patient record.
First Class Properties (immutable attributes)	 Date of birth First name Middle name Last name Notes Globally unique identifier
Second Class Properties (Customised attributes)	String Attributes Patient File Number Patient Identity Number Occupation Address Address Address Line 2 City State Postal Code Patient Contact Number Selection Attributes Identity Type Gender Marital Status Employment Status Language
Entity	PatientClinicalEvent
Description	Contains a history of patient adverse events.
First Class Properties (immutable attributes)	 Onset date Resolution date Verbatim description of event Clinician MedDRA term for event PV Specialist MedDRA term for event Globally unique identifier

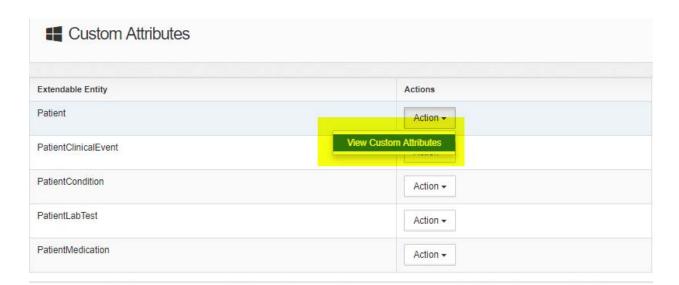
Second Class Properties (Customised attributes)	Selection Attributes Outcome Intensity (Severity) Grading Scale Grading Is the adverse event serious? Seriousness Was the AE attributed to one or more drugs? Was the event reported to national PV? Condition Ongoing Route Days/week Still On Medication
Entity	PatientCondition
Description	Contains a history of patient conditions
First Class Properties (immutable attributes)	 Start date End date Treatment start date MedDRA term for condition Comments Globally unique identifier
Second Class Properties (Customised attributes)	Selection Attributes • Condition Ongoing
Entity	PatientLabTest
Description	Contains a history of patient lab tests
First Class Properties (immutable attributes)	 Test date Test result Lab test Test unit Lab value Globally unique identifier
Second Class	None defined

Properties (Customised attributes)	
Entity	PatientMedication
Description	Contains a history of patient medications
First Class Properties (immutable attributes)	 Start date End date Dose Dose frequency Dose unit Medication Globally unique identifier
Second Class Properties (Customised attributes)	String Attributes Indication Selection Attributes Route Days/week Still On Medication Type of Indication Indication Judgement Reason for Stopping Clinician action taken with regard to medicine suspected of causing AE Rechallenge

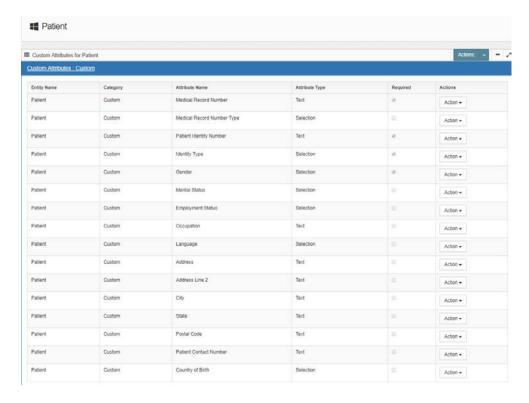
4.1.4 Managing an Entities Custom Attributes

To manage the list of attributes associated to an entity, click the **View Custom Attributes Button** for the corresponding entity.

2018



The system will navigate you to the view custom attributes page which renders a list of attributes that have been configured for the selected entity.



4.1.5 Adding a New Attribute

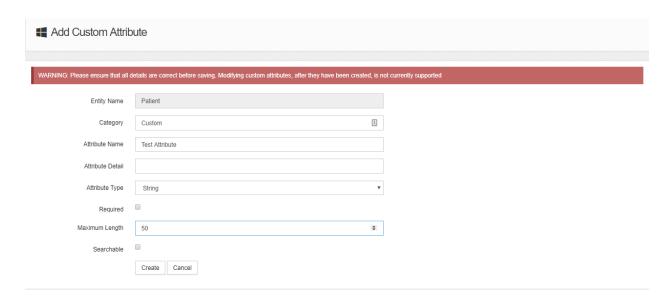
To add a new attribute to an entity, click on the Configure New Custom Attribute Button.



The system will navigate you to the custom attribute profile where you will be able to specify the details of the new attribute based on the details listed below.

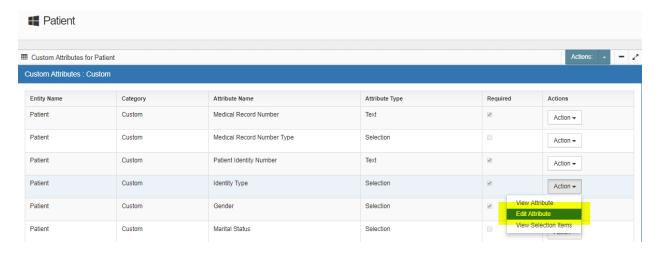
Entity Name	The name of the entity that the attribute is being added to This field is read only
Category	A free format category that the attribute belongs to This field is mandatory
Attribute Name	The unique name of the attribute This field is mandatory
Attribute Detail	Additional help for the attribute
Attribute Type	The type of attribute being added This field is mandatory
Required	Is the attribute mandatory
Minimum/Maximum value	Numerics only. Range of values to be allowed
Maximum Length	String only. The maximum length of the string
Allow Future/Past Dates Only	DateTime only. Date relationship to current date
Searchable	Should this attribute be searchable (patient and encounter search)

Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the entity.



4.1.6 Editing an Attribute

To modify an attribute's set of characteristics, once you have opened the Attribute List, click on the **Edit Attribute** button alongside the corresponding attribute.

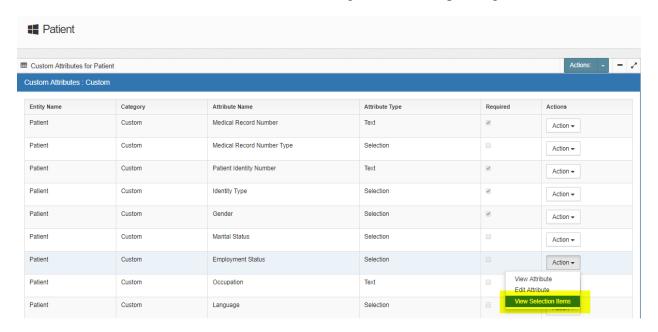


The system will navigate you to the attribute profile where you will be able to modify the attribute accordingly.

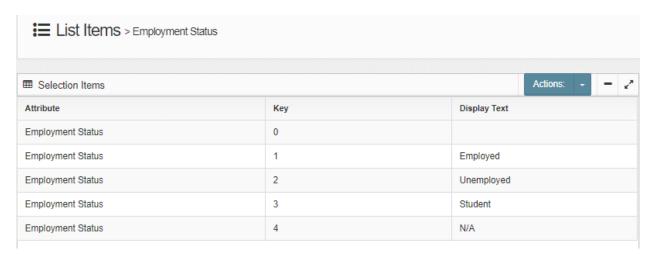
Please note: it is not possible to modify the attribute name, type and entity as these characteristics are locked once added.

4.1.7 Modify Selection Values

To modify a selection attributes set of dropdown values, once you have opened the Attribute List, click on the **View Selection Items** button alongside the corresponding attribute.

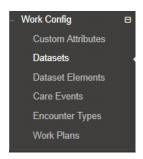


The system will navigate you to the attribute profile where you will be able to modify the attribute's list of selection values accordingly.



4.2 Datasets

The dataset administration function can be accessed through the **Administration** → **Work Config** menu and is accessible to administrators of the system.

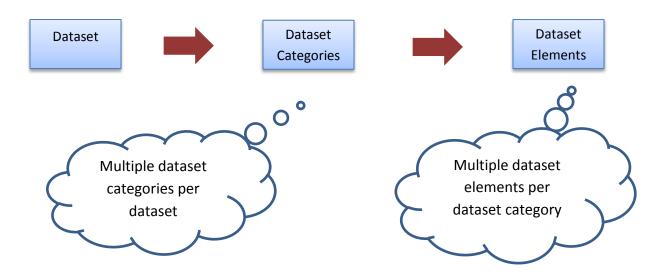


Once you have clicked on this menu, the system will navigate you to the Dataset List reference page, where you will be presented with a list of system datasets.



4.2.1 What is a Dataset

A dataset is effectively a collection of related dataset elements which are grouped within context of one or more dataset categories. An example of a dataset is a TB Chronic Condition Dataset where all clinical elements are related to the treatment of TB on an encounter by encounter basis.



4.2.2 Adding a New Dataset

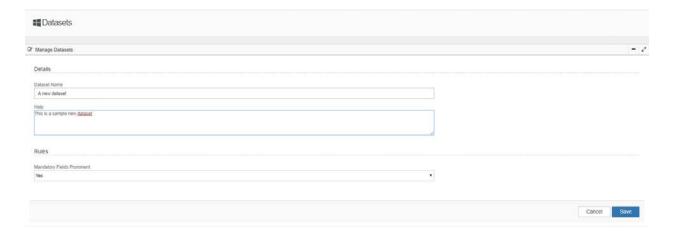
To add a new dataset, click on the Add Dataset Button.



The system will navigate you to the admin page for adding a new dataset. Enter details of the dataset as per the description of each field below.

Dataset Name	The unique name of the dataset This field is mandatory
Help	Additional help information for the dataset
Mandatory Fields Prominent	Used primarily for spontaneous reporting. Group all mandatory fields up front in a separate dataset category

Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the dataset list.



4.2.3 Editing a Dataset

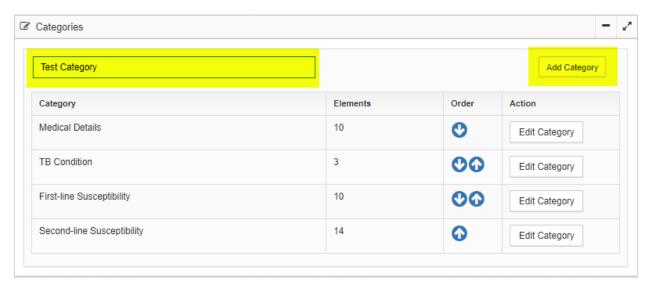
To modify dataset categories and elements within the framework of a dataset, once you have opened the Dataset List, click on the **Edit Dataset** button alongside the corresponding dataset.



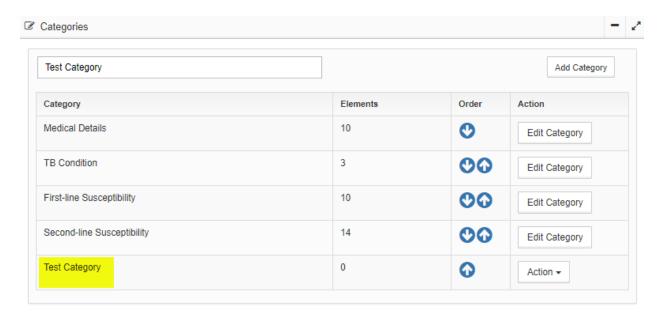
The system will navigate you to the dataset profile where you will be able to modify the dataset accordingly.

4.2.3.1 Add a New Category

To add a new category to the dataset, enter the category name in the category name field and click the **Add Category** button to add this category to the dataset.



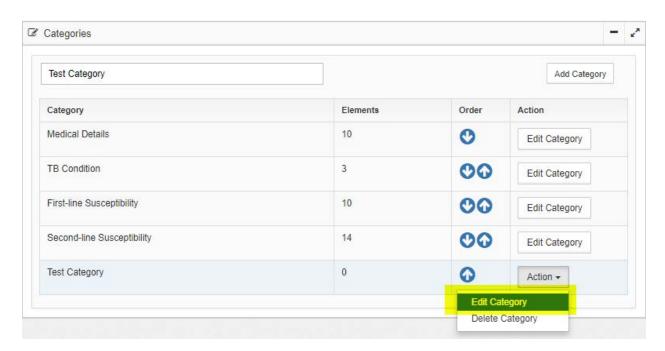
Once you have added the new category, the newly added category will appear in the category list.



Please note: once a category is added to the dataset, elements that have not been allocated as yet may be allocated to that category

4.2.3.2 Configuring a Category

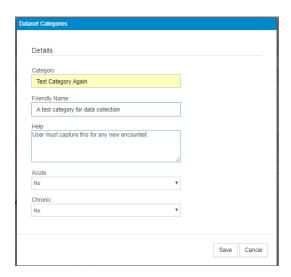
To configure a category, locate the category in the category list and click the **Edit Category** button to modify this category.



Once you have clicked the button, the system will pop up a category modal form for configuring the category. Enter details of the category as per the description of each field below.

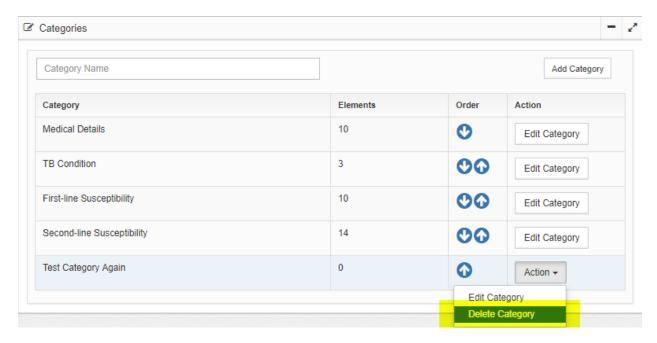
Category	The unique name of the category This field is mandatory
Friendly Name	A friendly name for the category. This is displayed to the user when adding or updating the dataset
Help	Additional help information for the category. This is also displayed to the user.
Acute	Should this category be displayed to acute patients
Chronic	Should this category be displayed to chronic patients? If yes, then a list of chronic conditions may be selected.

Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the dataset.



4.2.3.3 Removing a Category from a Dataset

To remove a category from the dataset, locate the category in the category list and click the **Delete Category** button to remove this category.

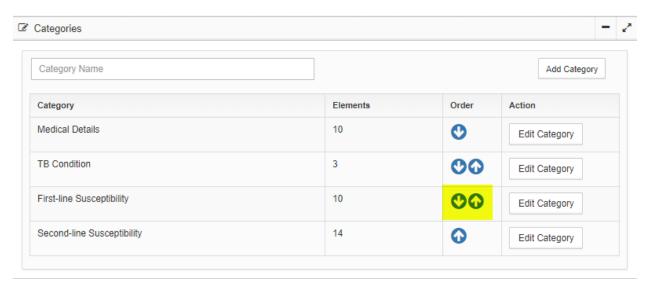


Click the **Delete** button to delete the category or the **Cancel** button to return to the dataset.

Please note: you may only delete a category if no element is currently allocated to that category

4.2.3.4 Reordering a Category within a Dataset

To reorder a category within the dataset, locate the category in the category list and either click the **up or down arrow** accordingly.

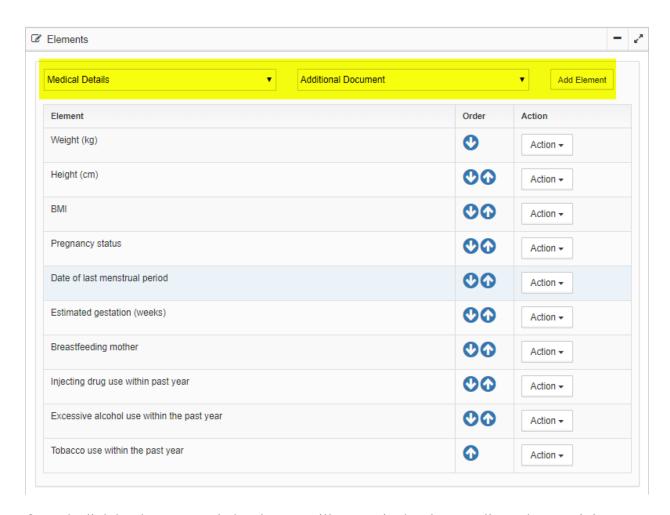


Please note: categories will be displayed for data collection in the order specified above.

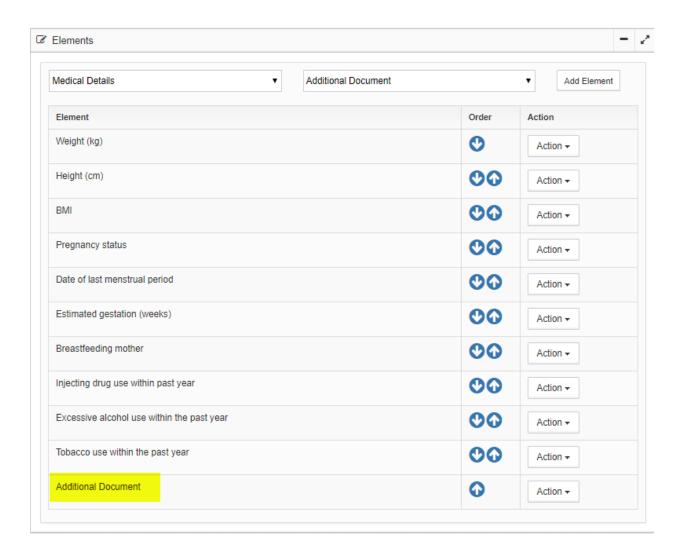
4.2.3.5 Link an Element to a Category

Linking an element to a category results in that element appearing in that category when adding or modifying the dataset.

To link an element to a category, first select the appropriate category and then select the element for linkage and then click the **Add Element** button to link the selected element to the selected dataset.



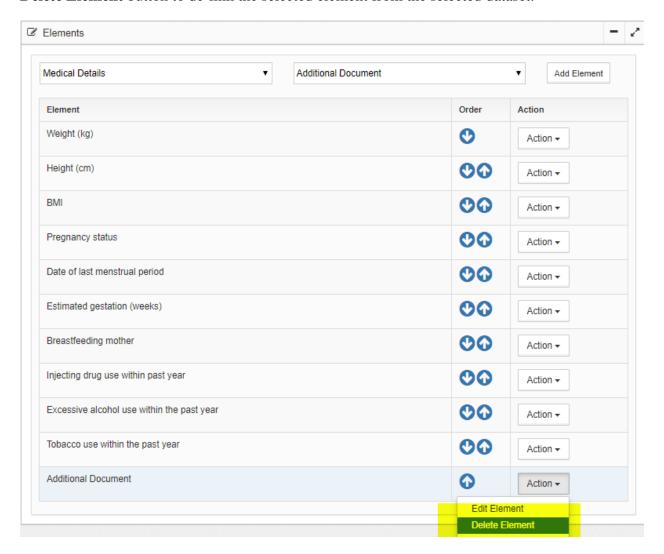
Once the link has been created, the element will appear in the elements list and means it is now available for data collection.



4.2.3.6 **De-Link an Element from a Category**

De-Linking an element from a category results in that element disappearing from that category when adding or modifying a dataset

To de-link an element from a category, locate the element in the elements list and click the **Delete Element** button to de-link the selected element from the selected dataset.



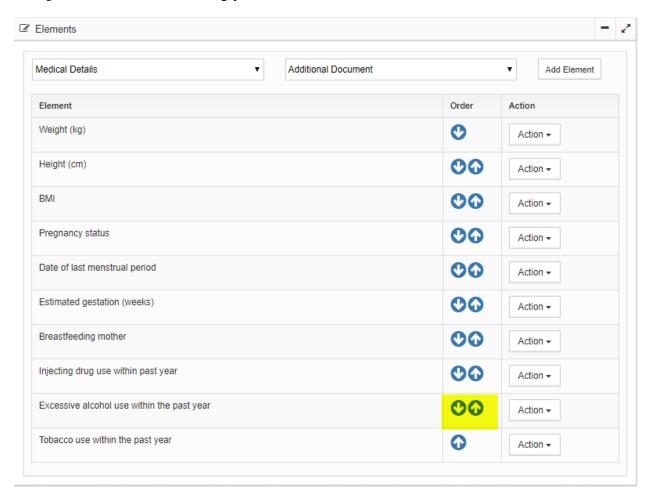
Click the **Delete** button to delink the element from the category or the **Cancel** button to return to the dataset.

Please note: deleting the element from the category does not remove the element from the database. Instead the element is just delinked from the category and becomes available for

allocation to a new category. Unlinked elements are not available for data collection.

4.2.3.7 Reordering an Element within a Category

To reorder an element within the category, locate the element in the element list and either click the **up or down arrow** accordingly.



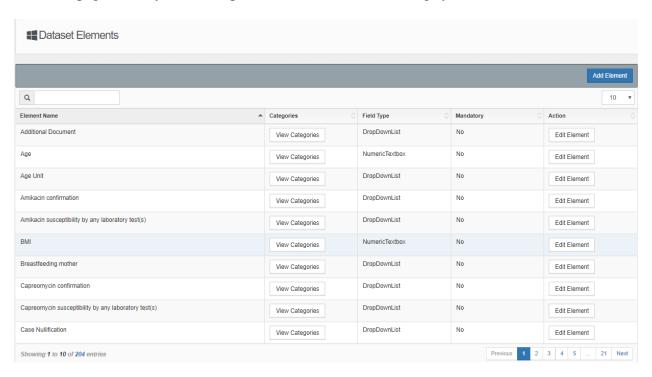
Please note: elements will be displayed per category for data collection in the order specified above.

4.3 **Dataset Elements**

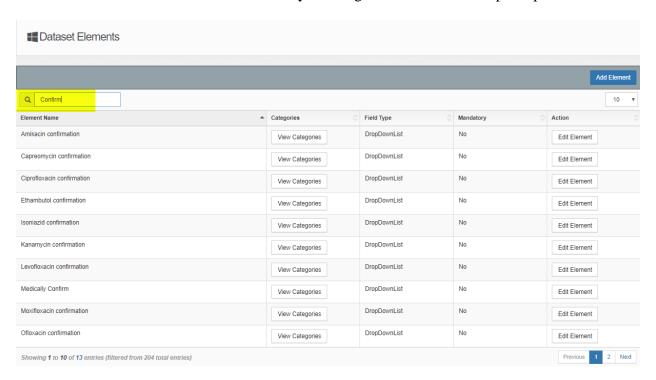
The dataset element administration function can be accessed through the **Administration > Work Config** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Dataset Element List reference page where you will be presented with a list of existing system dataset elements.



You are able to filter the element list table by entering a search term in the place provided.

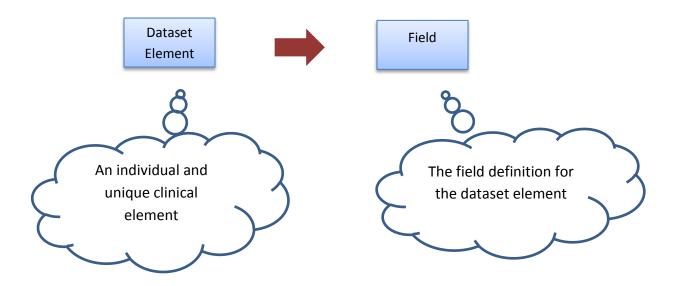


4.3.1 What is a Dataset Element?

A dataset element effectively represents an individual and unique clinical element. A dataset element further defines the type of data to be stored for that specific clinical element and inherently defines the data integrity rules that govern the content of that dataset element.

An example of a dataset element is the Weight (kg) field which is a numeric field that contains the weight of the patient in kg.

Dataset element framework:



4.3.2 **Dataset Element Types**

An element field type effectively governs the type of data that a dynamic dataset element may implement. The following element types are catered for:

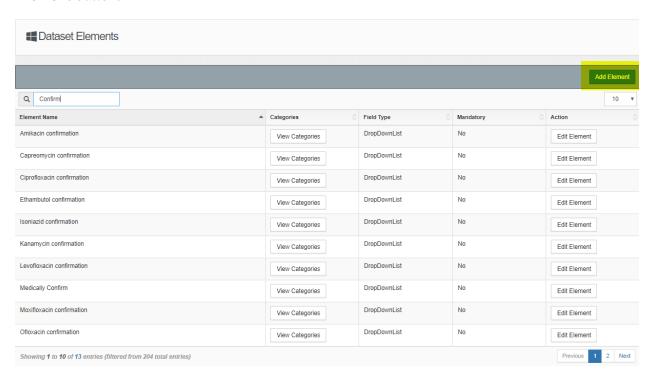
- Listbox
- DropDownList
- AlphaNumericTextbox
- NumericTextbox
- YesNo
- Date
- Table

Field Type	Listbox
Description	A list box allows the selection of one or more values from a dropdown list
Attributes	Specify list of available options
Field Type	DropDownList

Description	A dropdown list allows the selection of one value from a dropdown list	
Attributes	Specify list of available options	
Field Type	AlphaNumericTextBox	
Description	An alpha numeric text box allows the capturing of free format alphanumeric data	
Attributes	Maximum length of string	
Field Type	NumericTextBox	
Description	A numeric text box allows the capturing of integer or decimal based data	
Attributes	 Number of decimals Minimum range Maximum range 	
Field Type	YesNo	
Description	A yes/no field effectively allows the user to select a Boolean value of true or false.	
Attributes	Include drop down list values for Yes and No	
Field Type	Date	
Description	A date field effectively allows the capturing of a date value. Dates are stored in yyyy-mm-dd format.	
Attributes	N/A	
Field Type	Table	
Description	A table field effectively allows the construction of a sub table within the context of the primary element. A table allows the user to capture multiple rows for the specific primary element, with each row consisting of several sub data elements.	
Attributes	N/A	
	1	

4.3.3 Adding a New Dataset Element

To add a new element, once you have opened the Dataset Element List, click on the **Add Element** button.



The system will navigate you to a new element page. Enter details of the element as per the description of each field below.

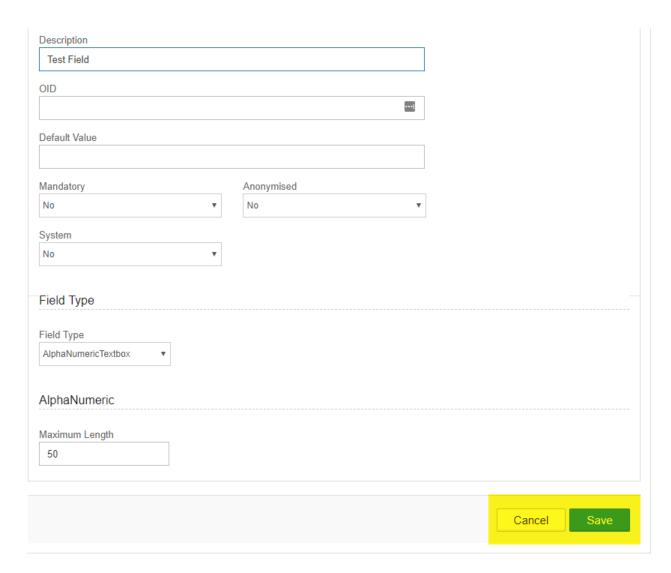
Element Name	The unique name of the element This field is mandatory
OID	The object identifier of the element. Used for extraction to E2B
Default Value	The default value of the element when extracting to E2B
Mandatory	Is this element mandatory when capturing a new spontaneous report
Anonymised	Is this element anonymized when extracting to a report
System	Is this a system defined data element

Rule - Element Can Only Link To Single Dataset	Can this element be linked to multiple datasets
Field Type	The type of element to be created Listbox DropDownList AlphaNumericTextbox NumericTextbox YesNo Date Table System DropDownList.Medicine This field is mandatory

The following information needs to be captured per field type.

AlphaNumericTextbox	Maximum length of the field
NumericTextbox	Number of decimals Minimum and maximum range

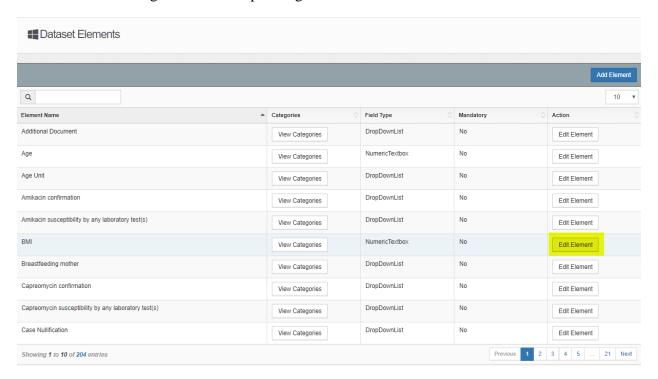
Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the element list.



Once the element has been saved, you will be navigated to the newly created element.

4.3.4 Editing a Dataset Element

To edit an existing element, once you have opened the Dataset Element List, click on the **Edit Element** button alongside the corresponding element.

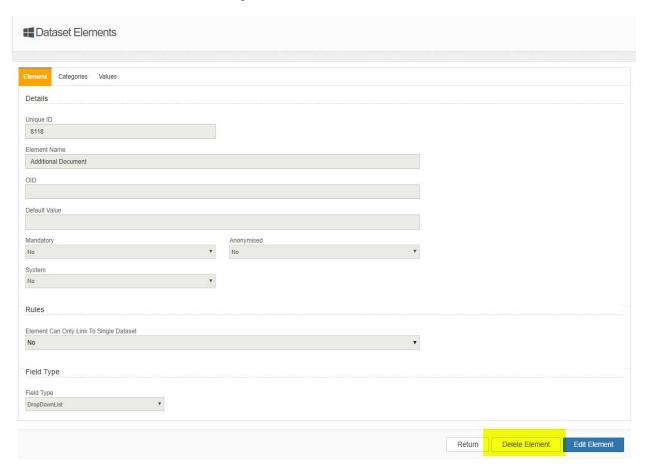


The system will navigate you to the dataset element page where you are able to modify details of the element or view how the element has been used within the system.

Please note: it is not possible to change the type of field once an element has been created. This is to maintain data integrity. If the field type has to change, it is recommended that the current element be marked as inactive and a new element be created.

4.3.5 **Deleting an Existing Element**

To delete an existing element, once you have opened the Dataset Element List, click on the **Delete Element** button when editing an element.

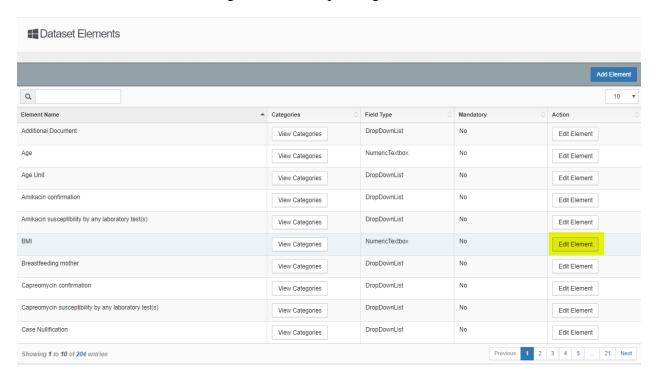


The system will navigate you to a delete element page. Click the **Delete** button to submit the request or click the **Cancel** button to cancel the action and return to the element list.

4.3.6 View Distinct Dataset Element Values

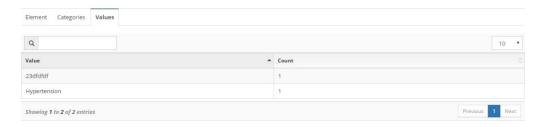
Please note: this function allows the administrator to view distinct values that have been collected against this dataset element.

To view a distinct set of element values, once you have opened the Dataset Element List, click on the **Edit Element** button alongside the corresponding element.



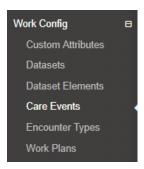
The system will navigate you to the dataset element page where you are able to modify details of the element or view how the element has been used within the system.

Select the Values tab and You will now be presented with a list of distinct values.

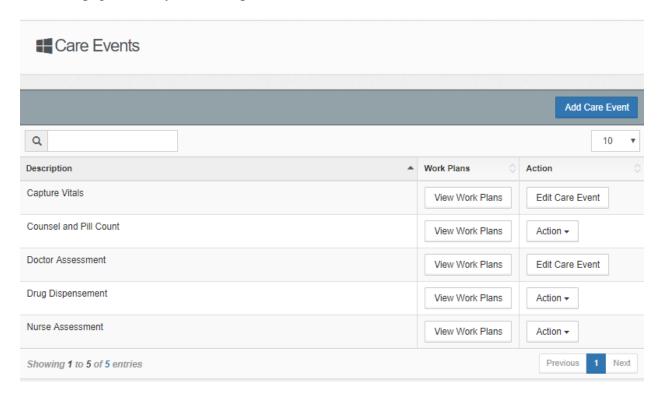


4.4 Care Events

The care event administration function can be accessed through the **Administration** → **Work Config** menu and is accessible to administrators of the system.



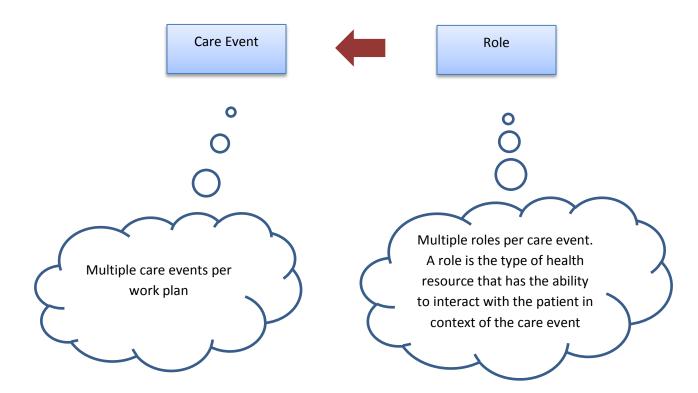
Once you have clicked on this menu, the system will navigate you to the Care Event List reference page where you will be presented with a list of care events.



4.4.1 What is a Care Event?

A care event is essentially the framework for interaction between a health resource and the patient themselves. Clinical data collected for the patient by the health resource is stored in context of an encounter using the framework of the care event.

An example of a care event is a Doctor Assessment. A doctor assessment can be defined as the interaction between the doctor and the patient who has presented him/herself at a facility as they are presently sick. Clinical data collected due to the assessment itself will be stored as part of the patient clinical record as part of their longitudinal history.

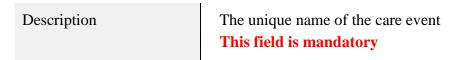


Adding a New Care Event

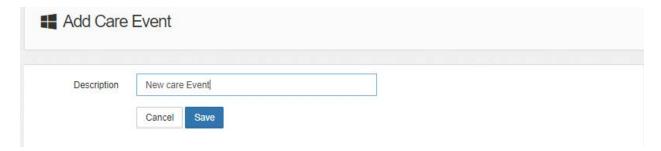
To add a new care event, click on the **Add Care Event Button.**



The system will navigate you to the admin page for adding a new care event. Enter details of the care event as per the description of each field below.

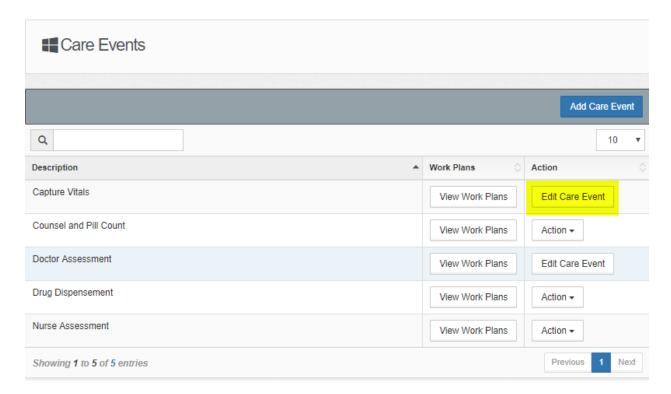


Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the care event list.



4.4.2 Editing a Care Event

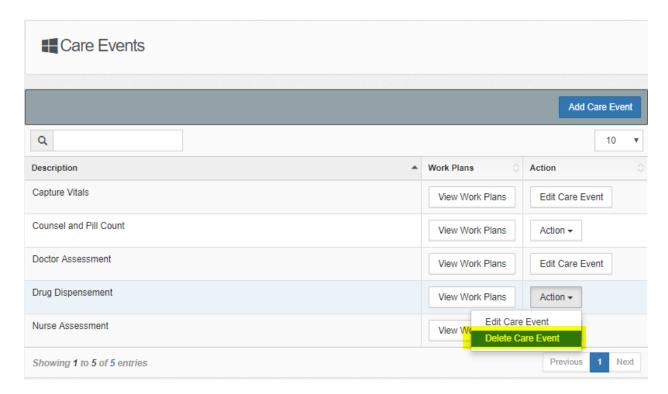
To modify a care event name, once you have opened the Care Event List, click on the **Edit Care Event** button alongside the corresponding care event.



The system will navigate you to the care event profile where you will be able to modify the care event name accordingly.

4.4.3 **Deleting a Care Event**

To delete a care event, once you have opened the Care Event List, click on the **Delete Care Event** button alongside the corresponding care event.

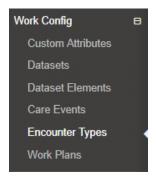


The system will delete the care event and refresh the care event list accordingly.

Please note: you will not be able to delete care events that have been allocated to a work plan.

4.5 **Encounter Types**

The encounter type administration function can be accessed through the **Administration > Work Config** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Encounter Type List reference page, where you will be presented with a list of encounter types.



4.5.1 Adding a New Encounter Type

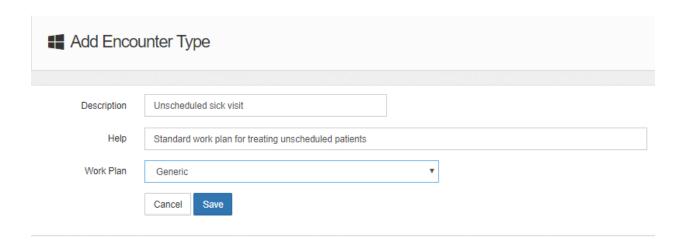
To add a new encounter type, click on the Add Encounter Type Button.



The system will navigate you to the admin page for adding a new encounter type. Enter details of the encounter type as per the description of each field below.

Description	The unique name of the encounter type This field is mandatory
Help	Additional help describing the encounter type
Work Plan	The work plan that has been associated to handle the encounter type

Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the encounter type list.



4.5.2 Editing an Encounter Type

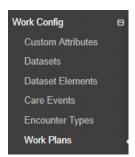
To modify an encounter type, once you have opened the Encounter Type List, click on the **Edit Encounter Type** button alongside the corresponding encounter type.



The system will navigate you to the encounter type profile where you will be able to modify the encounter type accordingly.

4.6 Work Plans

The work plan administration function can be accessed through the **Administration** → **Work Config** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Work Plan List reference page, where you will be presented with a list of work plans.



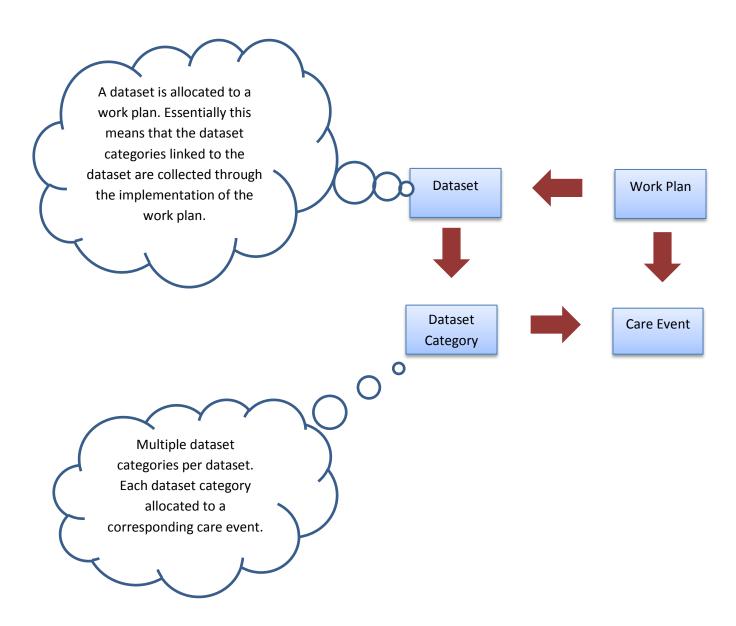
4.6.1 What is a Work Plan?

A work plan is essentially the framework for treating a patient in context of any interaction between health resources and the patient themselves. A work plan can be aligned with national guidelines and enforce the collection of critical elements and functions in relation to the work plan itself.

An example of a work plan is a Standard Plan for Chronic Assessment. This work plan may be comprised of several care events: -

- Triage (nurse collects vitals such as weight, blood pressure, respiratory rate, etc.)
- Doctor Assessment (doctor assesses patient as per WHO guidelines)

• Clinical Evaluations (recording evaluation results)



4.6.2 Adding a New Work Plan

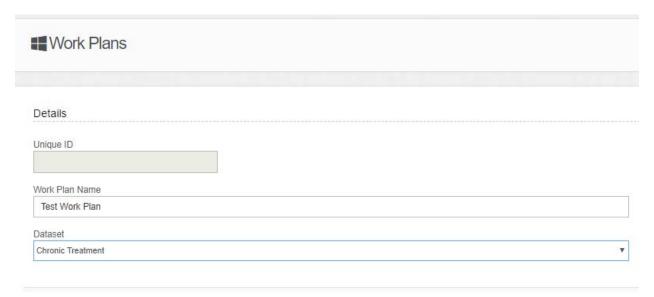
To add a new work plan, click on the Add Work Plan Button.



The system will navigate you to the admin page for adding a new work plan. Enter details of the work plan as per the description of each field below.

Work Plan Name	The unique name of the work plan This field is mandatory
Dataset	The dataset that should be used to render this dataset

Once information has been entered, click the **Save** button to submit the request or click the **Cancel** button to cancel the action and return to the work plan list.



4.6.3 Editing a Work Plan

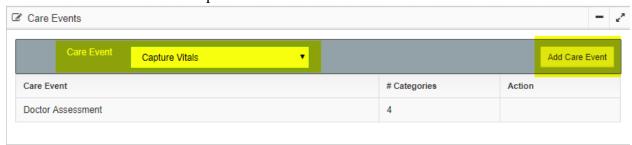
To modify care events and their associated dataset categories elements within the framework of a work plan, once you have opened the Work Plan List, click on the **Edit Work Plan** button alongside the corresponding dataset.



The system will navigate you to the work plan profile where you will be able to modify the work plan accordingly.

4.6.3.1 Linking a Care Event to a Work Plan

To link a care event to a work plan, select the care event and click the **Add Care Event** button to add this care event to the work plan.



Once you have added the new care event, the newly added event will appear in the care event list.



Please note: once an event is added to the work plan, categories that have not been allocated as yet may be allocated to that event.

4.6.3.2 Removing a Care Event from a Work Plan

To remove a care event from the work plan, locate the care event in the event list and click the **Delete Care Event** button to remove this event.



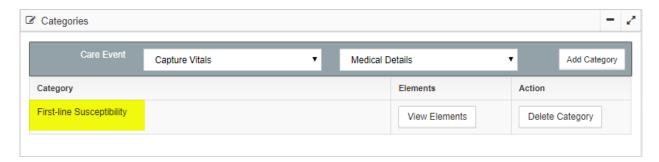
Please note: you may only delete a category if no category is currently allocated to that care event.

4.6.3.3 Linking a Dataset Category to a Care Event

To link a dataset category to a care event, select the dataset category and care event and click the **Add Category** button to add this category to this care event.



Once you have added the new category, the newly added category will appear in the category list.



4.6.3.4 Removing a Dataset Category from a Care Event

To remove a dataset category from a care event, locate the dataset category in the category list and click the **Delete Category** button to remove this category.



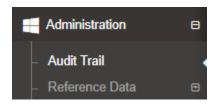
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5 General

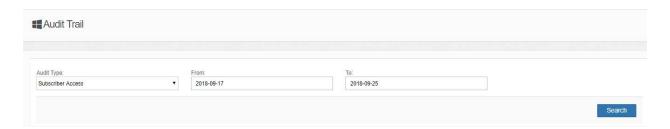
5.1 Audit Trail

View a comprehensive list of actions executed within the system over a selected period of time.

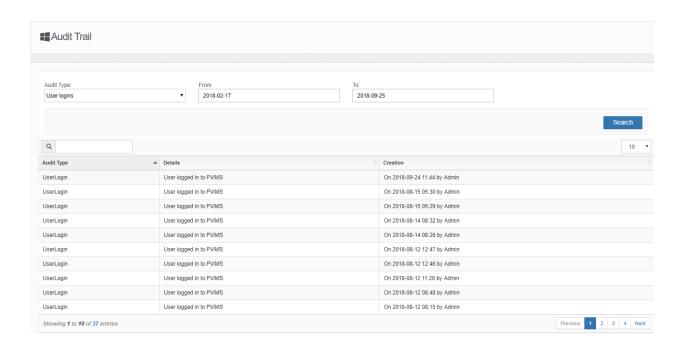
The audit trail administration function can be accessed through the **Administration** \rightarrow **Audit Trail** menu and is accessible to administrators of the system.



Once you have clicked on this menu, the system will navigate you to the Audit Trail reference page. Enter the type of audit log and date range to query and click the Search button to view a list of audit transactions over this period of time.



The system will return the transaction list and the total number of transactions that have been found and will provide the option of adding a new medication.



The following audit types can be filtered:

SubscriberAccess	All third-party requests for access
SubscriberPost	All third-party submissions into PViMS
MedDRAImport	Valid and invalid import of the MedDRA dataset
UserLogin	New login to the PViMS system