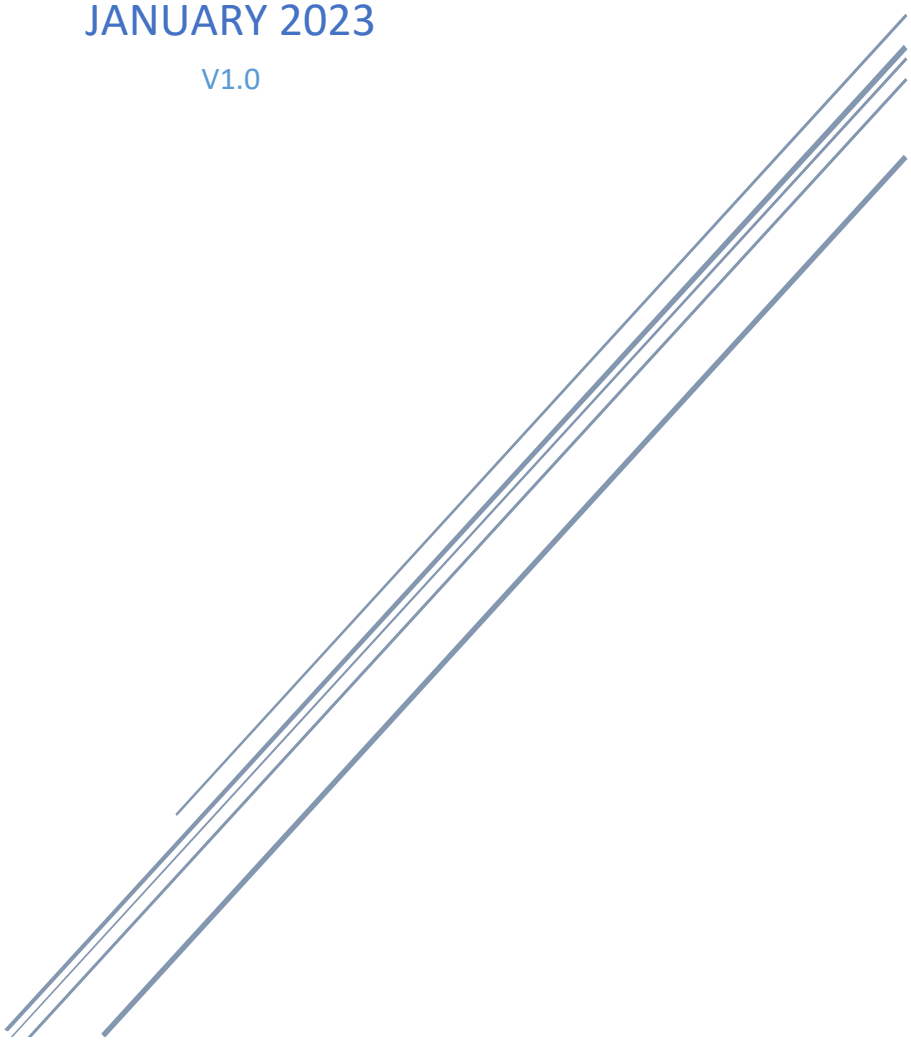
MGBase
Data-entry Software (MDS)

MDS - MG USER GUIDE

JANUARY 2023

V1.0



For the most recent version of this document, login to the MSBase Registry User Portal and download from the Members Section.

DISCLAIMER:

Note this document is subject to change at every major release of MDS.

Please note that any data used is completely synthetic and purely for demonstrative purposes.

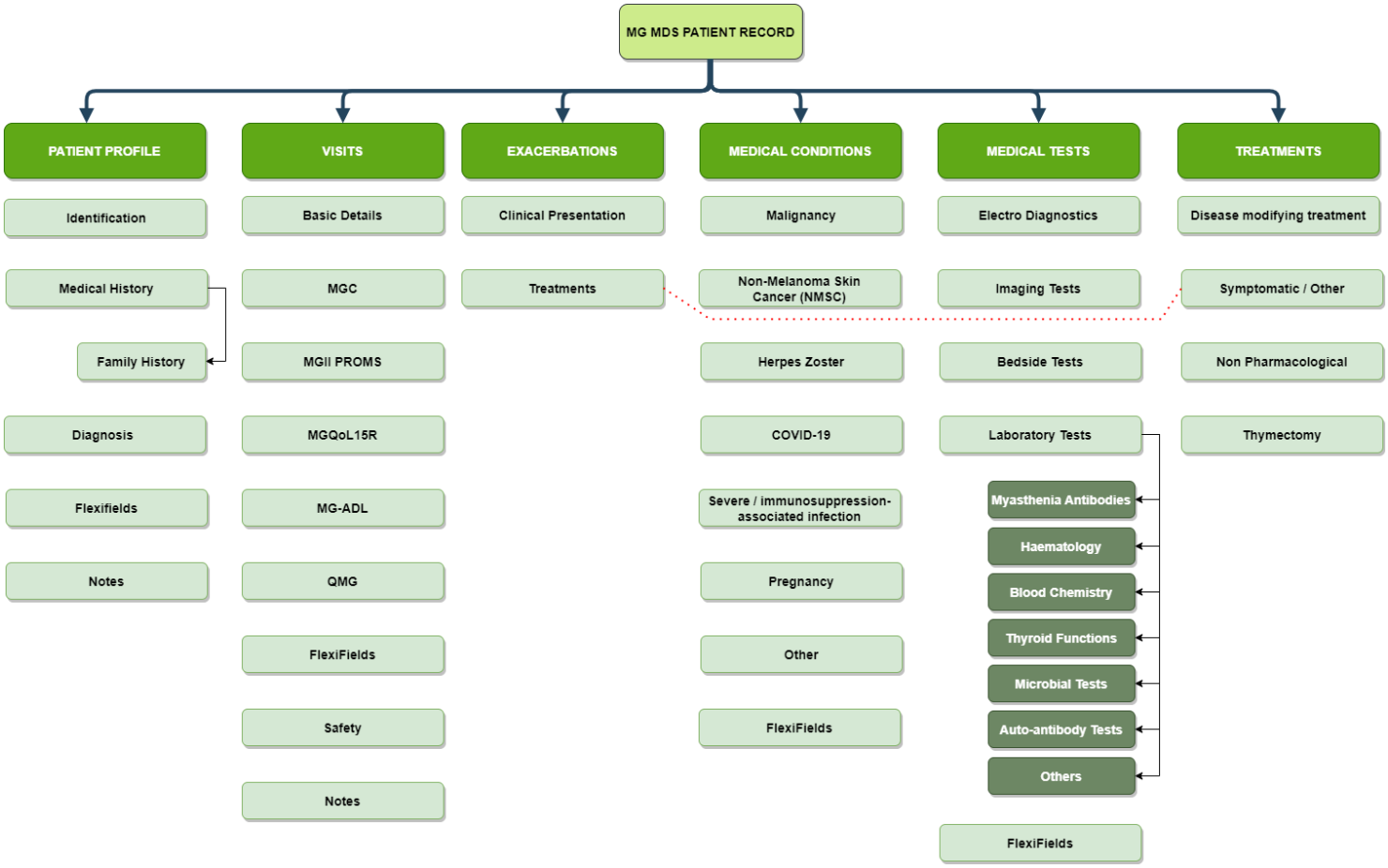
Contents

1. User guide overview & content map

When working with MDS, it is important to familiarise yourself with the software's features and relationship with the MGBase Registry.

This guide outlines the capabilities of MDS and provides guidance on simple user functions, such as logging in and entering patient information as well as more complicated functionality like creating sub-studies, search, and flexifield administration.

Below is a content map outlining all the data elements in a hierarchical list starting with the MDS Patient Record, broken into the 6 major sections or modules in dark blue, and for each section below that further broken down into it's associated forms.



2. What is MDS?

MDS is a desktop data collection tool built specifically for collecting data related to Multiple Sclerosis (MS) and other Neuro Immunological Diseases (NIDs) such as Myasthenia Gravis. This user guide is specific to MG users of the MDS Application.

The MDS application is developed and built by the MSBase Foundation and is only available for Members who have signed up to the “MGBase Registry” online. MDS communicates with the MGBase Registry and uploads a subset of patient data for consenting patients.

The MSBase Registry is an ongoing, longitudinal, strictly observational database that commenced in 2004. The MGBase Registry was built leveraging the same technology and went live in 2021.

MGBase will provide a platform for international collaboration dedicated to share, track and evaluate outcomes data in Myasthenia Gravis. Membership of the Registry is open to all practicing neurologists and their healthcare teams, worldwide.

The MGBase Registry platform enables the collection of data for studies of MG regionally, nationally or globally, with customizable sub-study functionality that filters data according to research themes.

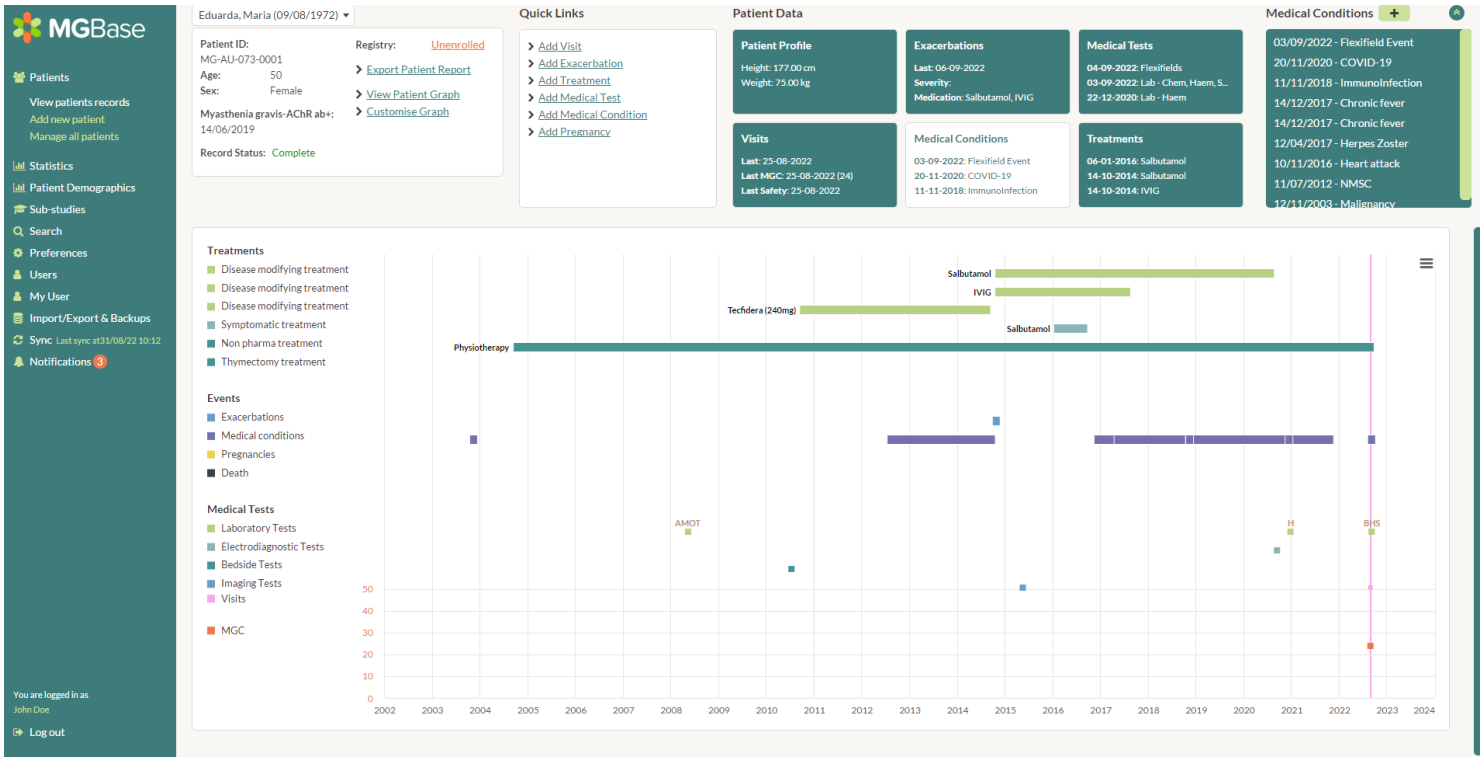


Figure 1 - The MDS application

3. Installation and System Requirements

The installation of MDS is covered in the MDS Installation Guide and will not be covered in this document.

MDS can be installed three different ways:

- **Stand-alone**: Single user (or multiple users, but all using the same PC / Laptop)
- **Peer-hosted**: usually around 2-4 users, a "master" PC is required, and other PC's require access to the database on the "master" PC
- **Managed server / network installation**: Can accommodate many users, the database is installed on a centralised SQL Server, multiple users can connect simultaneously via the network, with the app installed on each PC.

To run MDS your PC should meet the following minimum specifications:

CPU	Core i3 1.8GHz
RAM	4GB RAM
HDD	4GB Free Space
GPU	Intel HD 4000 (integrated graphics)
Operating System	Windows 10 (version 1903) or above – Minimum Requirement
	.NET Framework 4.8 – Minimum Requirement
Internet Connection	Online features including centre registration and patient synchronisation require a stable internet connection.
Administrator Privileges	Required to complete the installation of MDS.
Screen Resolution	The MDS software is best viewed with a minimum 1280 X 768 screen resolution.
MAC Compatibility	A MAC version of MDS is not available or technically supported. Apple users can use virtualisation software to complete a MAC installation. MSBase recommends the use of Parallels as the virtualisation software of choice https://www.parallels.com/

4. Before you start

4.1. Are you a MGBase Registry member?

To use MDS you must be a member of the MGBase Registry. This means that you are either a Principal Investigator (PI) and have already been approved by the MGBase Operations team, or you have been invited by your centre's PI/Co-PI. If you are not a member of the MGBase Registry, please stop now and sign-up at www.MGBase.org.

4.2. Have you forgotten your password?

If you used to be a member and can no longer log-in, then please attempt to reset your password at www.MGBase.org/forgot-password . Your log-in will be your email address.

5. MDS Overview

5.1. Log in

Launch MDS by double-clicking the desktop icon & you will be presented with the login screen. Enter your username (email) and password. Click Log In to proceed.

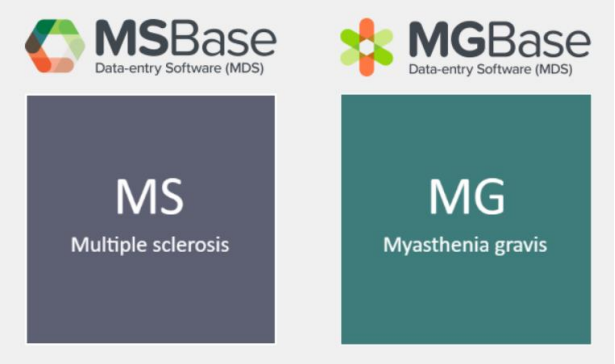


Figure 2 App Selector Screen

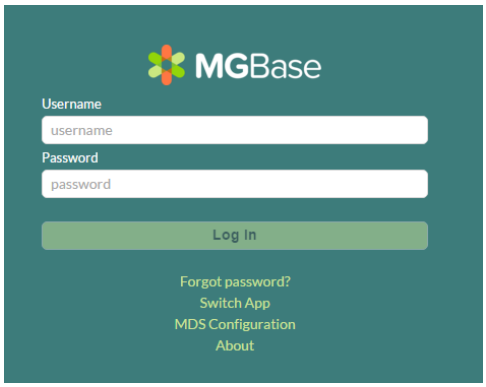


Figure 3 - MDS Login screen

5.2. Basic Navigation

Your MDS home screen will look like the below image. You will notice that the interface is divided into seven regions:

- **MDS Menu**: Navigate the main sections of MDS. See Statistics, Patient Demographics, Sub-studies, Search etc by selecting the corresponding menu item
- **Patient Selector**: Select, change or search for a specific patient
- **Patient Card**: See an overview of the patient and perform patient specific functions
- **Quick Links**: Perform common functions in the Quick Links sections
- **Category Selector**: The Category Selector can be used to access data entry forms. By selecting one of these six buttons, then the Context Menu will update with different options
- **Context Menu**: The Context Menu changes based on the Category Selector. For example, if the *Patient Profile* is selected, then the user will see Identification, Medical History etc (as per the image below). If the user selects Visit, then the user will be presented with all the Visits registered with that patient
- **Patient Overview Graph**: The patient overview graph gives a graphical overview of the patient

5.1. Patient Selector

To change between patients, you must use the Patient Selector. Your centre may have hundreds or even thousands of patients and locating that user by scrolling alone may be time consuming. To help you locate your patient faster simply click on the Patient Selector and type in the first few letters of the patients first or last name. This will refine your list of patients to a more manageable number.

If a patient is ever deleted from MDS then they will be removed from the Patient Selector menu.

If you have conducted a search, or you have applied a filter in the Statistics section, then the Patient Selector will only display the patients that meet the search/filter criteria.

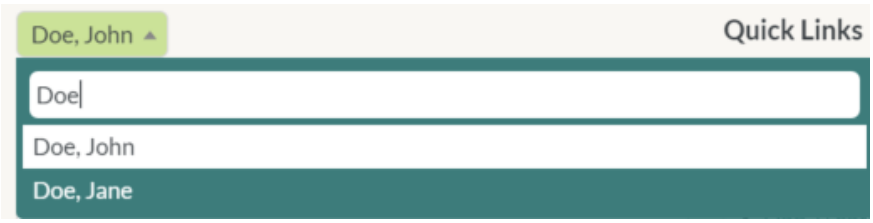


Figure 4 - Patient Selector and Search

Good to know!

The Patient Selector dropdown menu is limited to 1000 patients to ensure satisfactory performance. If you have more than 1000 patients you will need to use the filter to locate your patients, alternatively the patient can be located in the Manage all Patients section.

5.2. Online and offline functions

MDS should be operated in an internet connected environment. However, if the system does not have an internet connection, then MDS can still function, albeit in a limited capacity.

When MDS is unable to contact the MGBase Registry, the following features will no longer function:

- **Patient demographics**: The comparison of the centre's statistics with those on the MGBase Registry
- **Sub-studies**: MGBase Registry Sub-studies are a data sharing collaboration between centres, hence viewing and enrolling into Sub-Studies is an online function
- **My User**: Your profile is the information that you supplied to MGBase Registry at sign-up. Updating this information is an online feature only.

MDS will notify you if there is a problem accessing the internet with a red flashing alert.

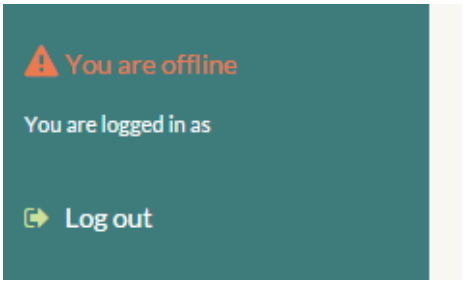


Figure 5 - Offline indicator

5.3. Recommended Minimum Data Set

The MGBase Registry has a non-mandatory recommended minimum data set for patients to be uploaded to the Registry. Meeting this criterion increases the quality of the data in the Registry and subsequently the research we can perform. The MGBase minimum data set is specified below:

Records are considered complete when the fields in **red text** in the table below have been filled.

Fields that are **not** in red text, are all fields that are *recommended* to complete annually, for the purposes of capturing quality data.

Section	Field	Frequency	Definition
Patient profile	Patient ID	Entry visit	Patient globally unique ID
	Last name	Entry visit	
	First name	Entry visit	
	Gender	Entry visit	M / F
	Birth date	Entry visit	Month and year only
MG Diagnosis	Disease category	Entry visit	Disease names
	Date of onset	Entry visit	Date
Visit	**MRS**	Annual #	Value
	MGC	Annual #	Total
	MGC		With scores
	MGFA		Value
	MGFA PIS		Value
	MG-ADL		Total
	MG-ADL		With scores
Paraclinical tests	Test date	If entered	Date
Exacerbation	Date of onset	If entered	Date
	Symptoms	If entered	Symptom names
	Treatment site	If entered	Value
Treatment	Treatment type	If entered	Treatment names
	Start date	If entered	Date
	End date	If entered	Date

Good to know!

A patient can still be uploaded to the Registry without meeting the minimum dataset, however a notification on the Patient Card will inform you that the patient is *Incomplete*

5.4. Mandatory Fields and Field Validation

Some forms in MDS have fields that are required to be populated, for example the First Name and Last Name of the patient, or the date of a visit. You must have a value for these fields to save the form. Mandatory fields are identified by a green shadow and will display an alert message if not populated when attempting to save.

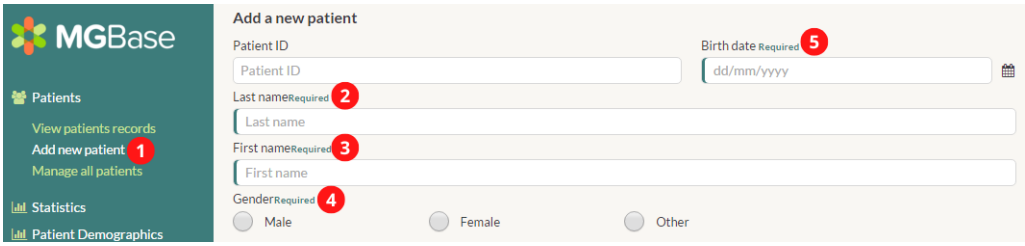


Figure 6 Mandatory Field Figures

MDS also enforces field validation, and in some instances may refuse to save the form or display a warning if the user attempts to create invalid data. The most common examples are below:

- Field length: Some fields limit the number of characters allowed to be entered.
- Impossible dates: MDS will not allow a user to enter what is considered an impossible date. For example, this might include a Medical Event created after the patient's death.
- Number Parsing: Some number fields will not allow negative numbers or may apply a limit on the number of decimal places.

MDS will display an error message should any of the above events occur.

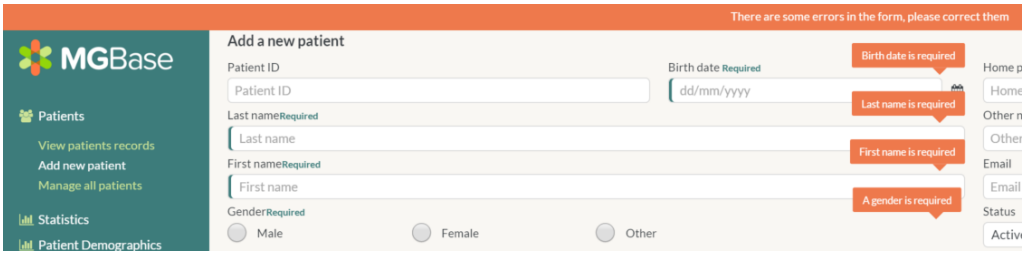


Figure 7 Field Validation Example

6. Preferences

You can use the MDS Preferences section to customise your MDS installation. This includes basic preferences, such as forcing a centre to use MedDRA classification, or modification of reference data such as custom flexifields. These preferences are explained below in further detail.

6.1. Centre Information

The centre information section enables you to change information about the centre. This feature is only available when an internet connection is available.

Good to know!

In this section you can force users in your centre to use the Visit Assistant as the mechanism to create a Visit. This will mean that Basic and MGC fields will be presented to the user, encouraging the MGBase Registry minimum data set to be complete

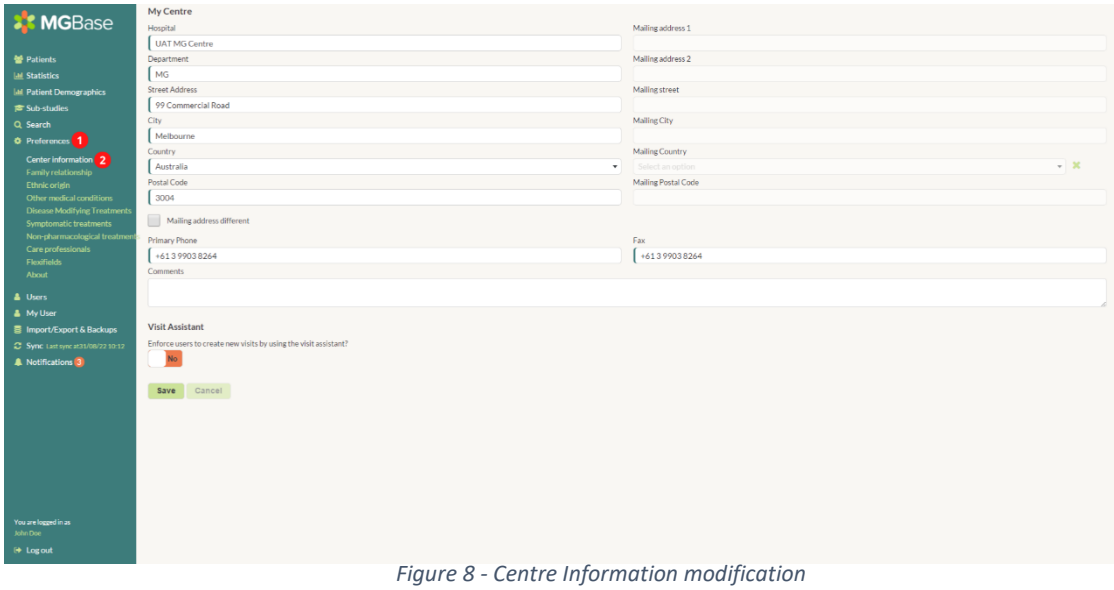


Figure 8 - Centre Information modification

6.2. Family Relationships

The list of family relationship types (for example *son, daughter, father, mother*) between patients can be modified should you want to capture familial events in greater detail. The default values however should be sufficient for most instances.

To add a new family relationship, click Add, enter the new relationship, and click the save icon.

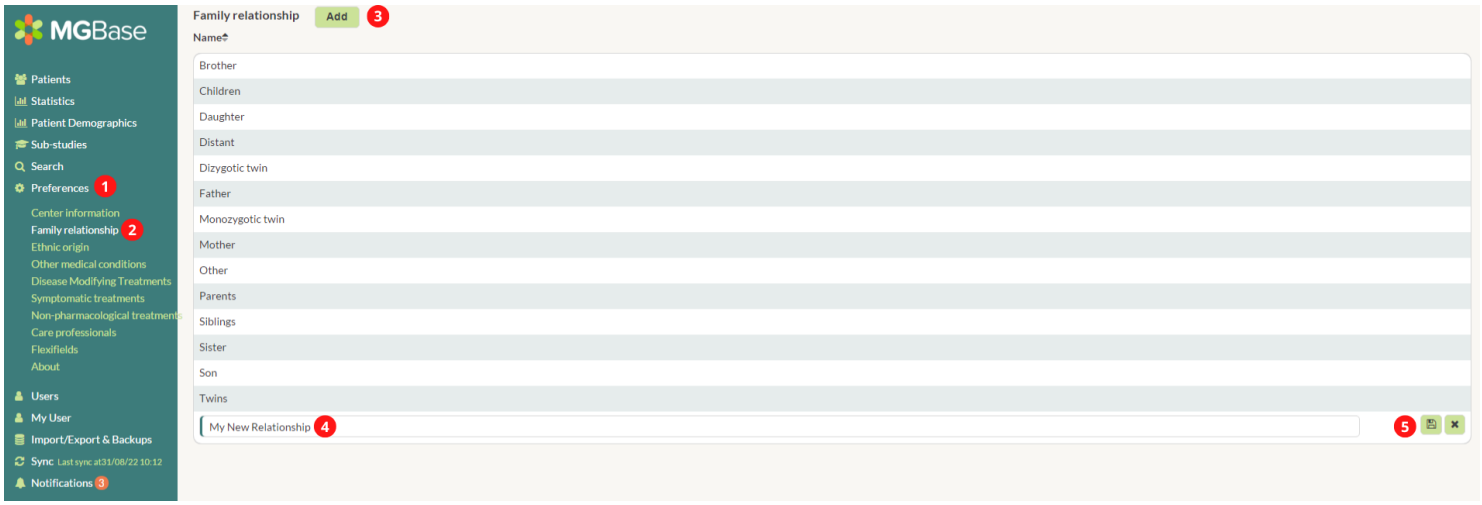


Figure 9 - Adding a new family relationship type

6.3. Ethnic Origin

You can add additional *Ethnic Origin* types where the defaults are not extensive enough.

To add an Ethnic Origin, select Add, enter your new value and then click the Save icon.

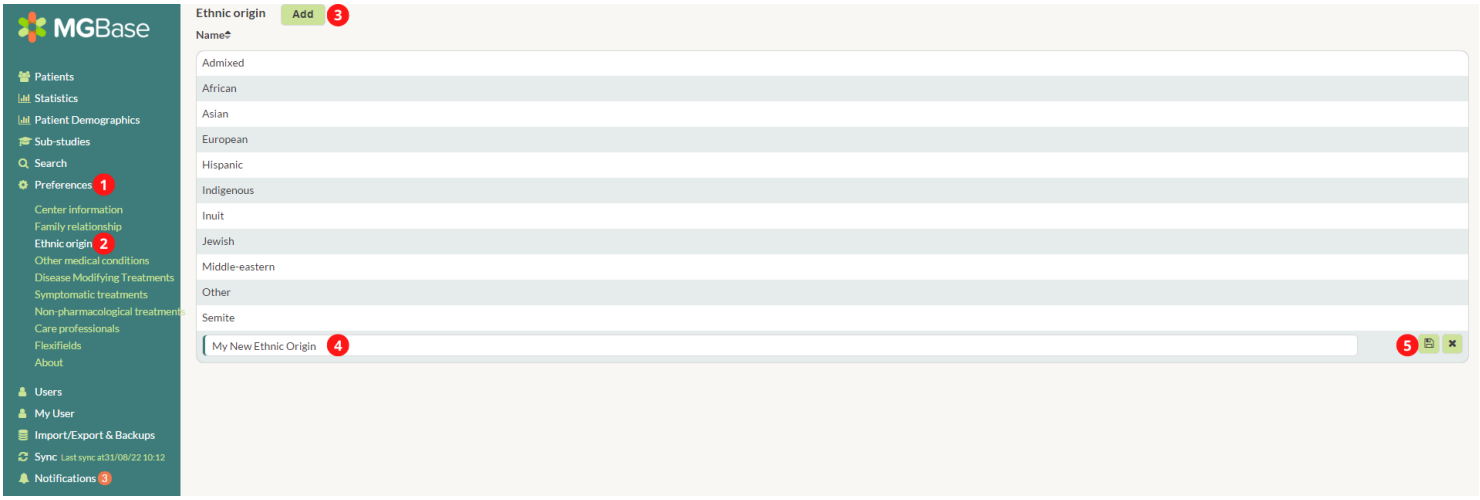


Figure 10 - Adding a new ethnic origin type

6.4. Other Medical Conditions

MDS uses two methods of identifying adverse events/other medical conditions. The first and preferred way is using MedDRA. MedDRA is hierarchical medical event classification schema that allows data entry to be standardised. The other option is list of Centre Medical Conditions that can be customised to each site.

This section allows you to enforce the centre to use just MedDRA, or alternatively you can use MedDRA or the Centre Medical Conditions. Make the appropriate selection in the section below.

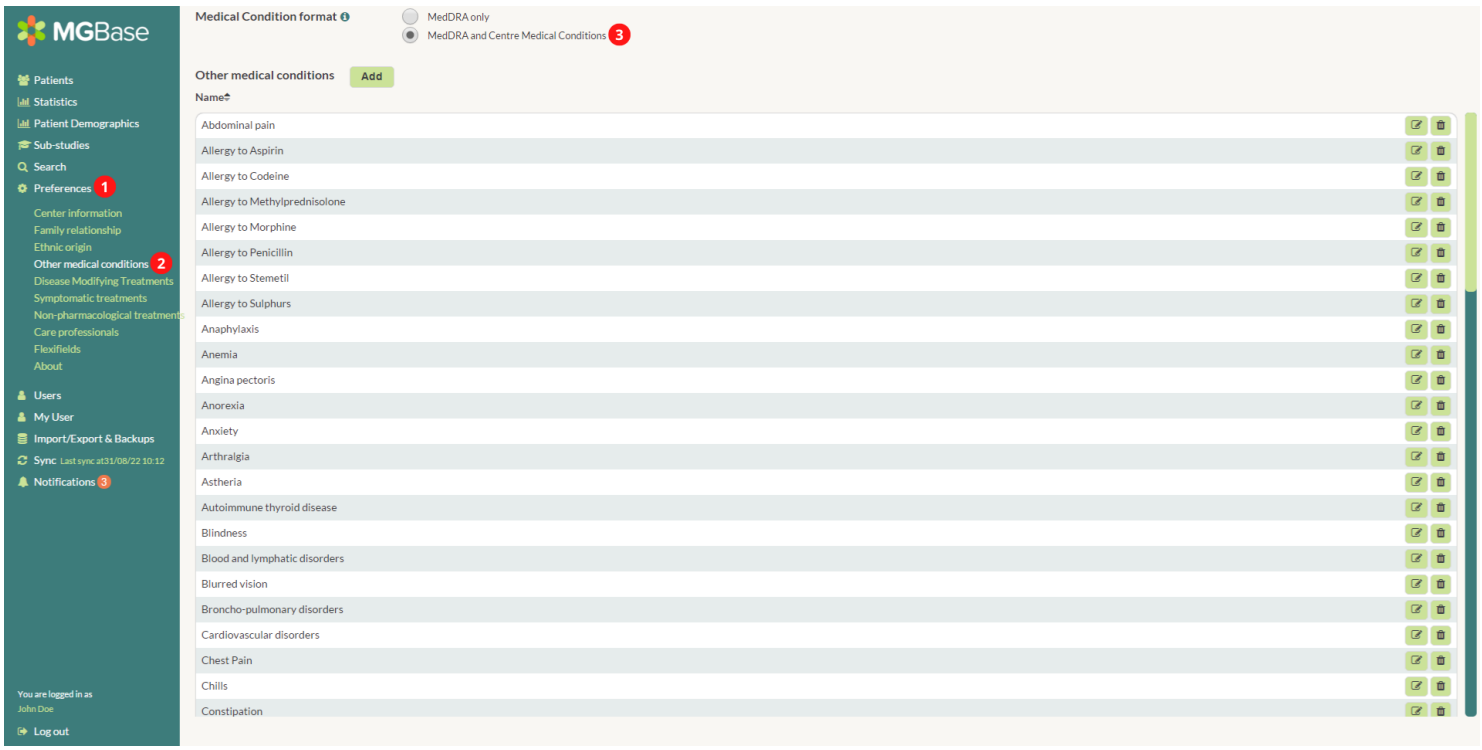


Figure 11 - MedDRA only can be enforced in MDS

Good to know!

We recommend *MedDRA only* to ensure medical condition coding is standardised. For more information, refer to the MedDRA section within this document.

If you are migrating your data from an existing database, then you may have existing Centre Medical Conditions. If you select MedDRA only, then these Centre Medical Conditions will be kept. You can either leave these records as they are or recode them into MedDRA format.

To add a Centre Medical Condition a user can select, simply select “Add”, enter the medical condition, and click the Save icon

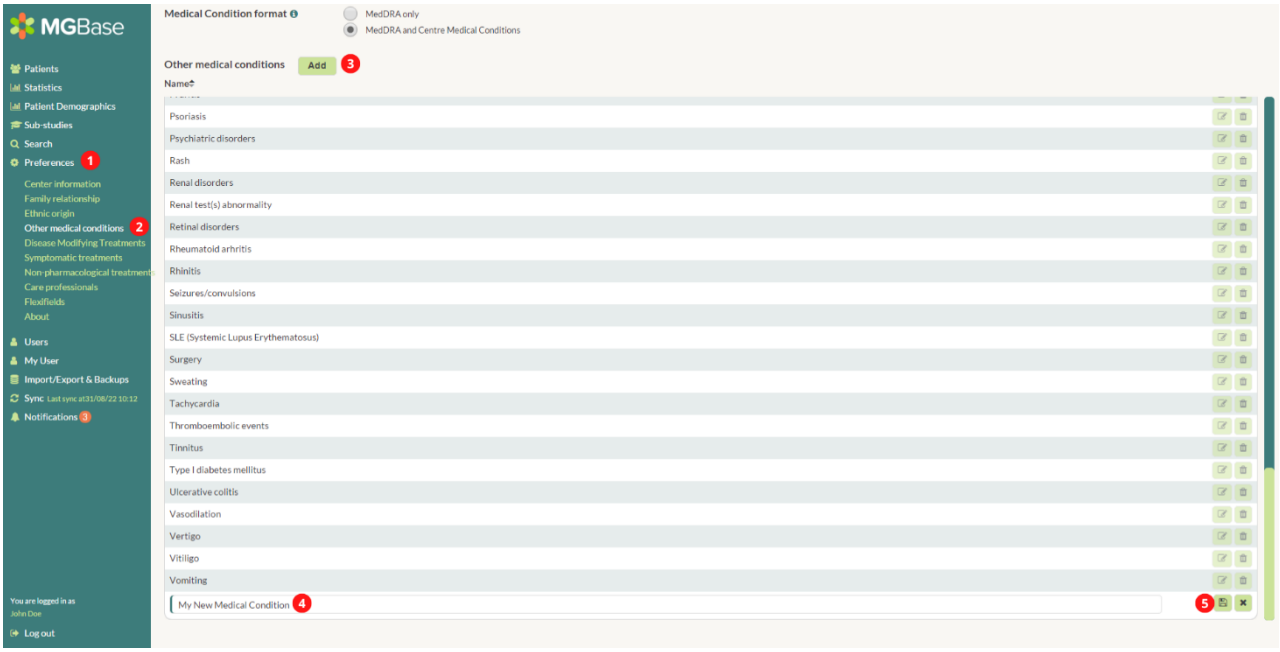


Figure 12 Adding Centre Medical Conditions

6.5. MG Specific Treatments

Treatments are handled differently in MDS depending on whether they are a DMT/MG Specific treatment, a Symptomatic treatment, or a non-Pharmacological treatment.

MDS is installed with a set of default MG Specific treatments, where the name and dosage of these values are standardised. For alternative dosage variations, or for drugs not listed as a default treatment, the user is able to add a treatment.

Good to know!

When assigning a treatment to a patient, the default values will be selected and assigned to the patient. However, the user can still change the dosage for that individual treatment.

The default treatments and dosages are captured in the adjacent image.

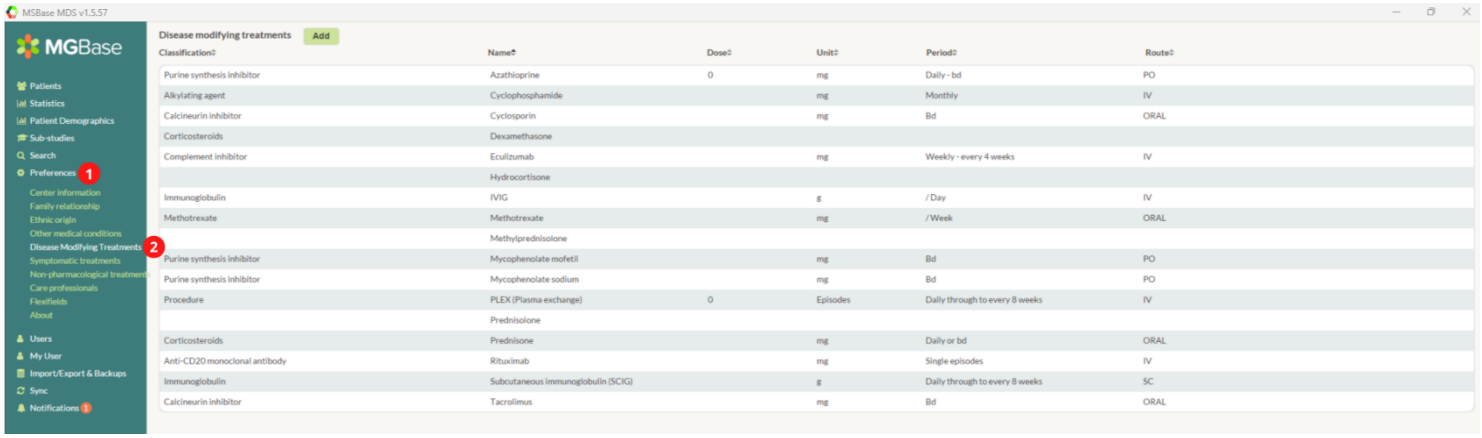


Figure 13 - MG Specific Treatments

To add a treatment click Add, then enter the generic name, the common name, dosage details and click Save.

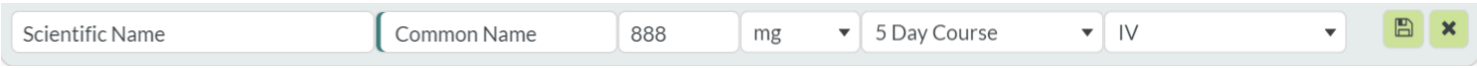


Figure 14 - Entering MG Specific Treatment type

6.6. Symptomatic Treatments

A set of default Symptomatic treatments are provided with MDS. An example of these are captured below.

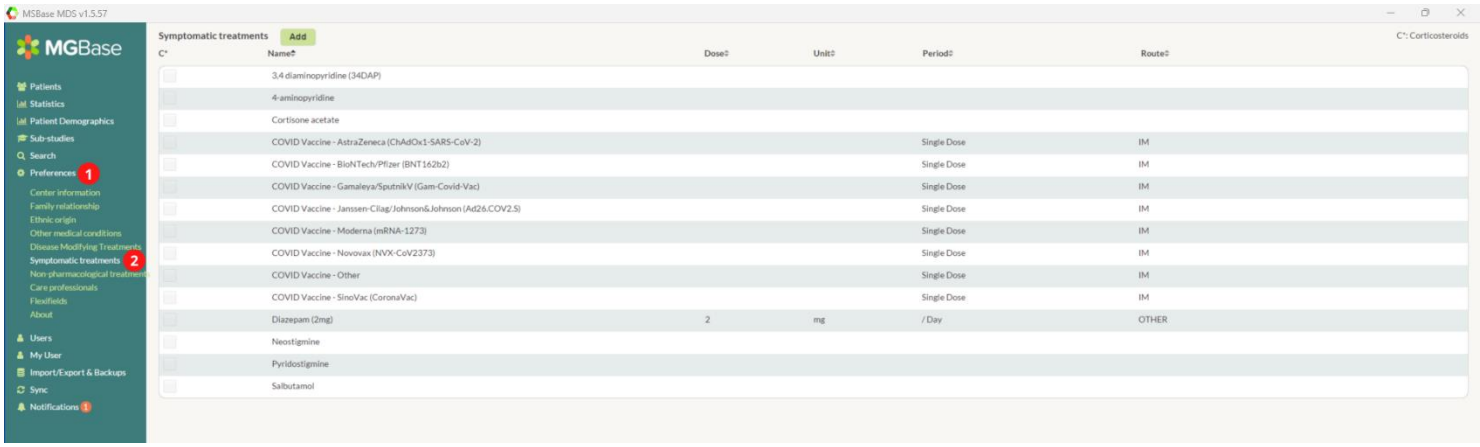


Figure 15 - Example of default treatment types

Should you need to add additional treatments to the default, simply click the **Add** button, enter the details, and then click save. MDS requires corticosteroids to be identified using the checkbox on the far left. This allows the treatment to be assigned to the Corticosteroid field when creating a relapse.

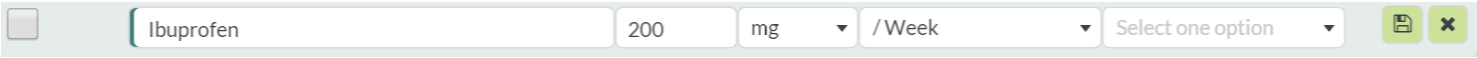


Figure 16 Adding a Treatment

6.7. Non-pharmacological treatments

In MDS non-pharmacological treatments are classified differently to the Disease Modifying Treatments and Symptomatic treatments above.

MDS is shipped with the below default non-pharmacological treatments. Like the above treatments, there is also the ability to add and modify the pharmacological treatments.

To add a non-pharmacological treatment, select Add then enter and save the treatment type.

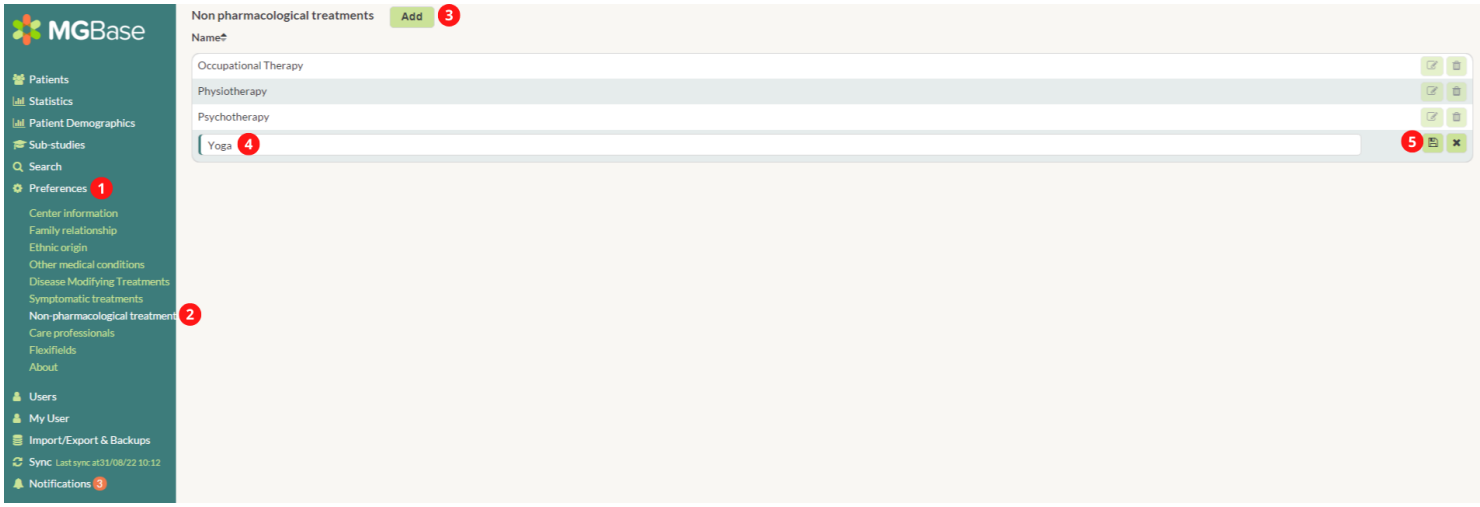


Figure 17 Adding Non-Pharmacological Treatments

6.8. Care Professionals

The Care Professionals section in MDS enables the centre to identify GP's and other practitioners that constantly refer patients to the centre.

Good to know!

The Care Professionals section is used in the patients "Referred By" field. This functionality is not required by MGBase Minimum Dataset or uploaded to the Registry, and is at the discretion of the user to enter.

To add a Care Professional, click the Add button and then fill in the details for the Care Professional.

Figure 19 - Care professional list

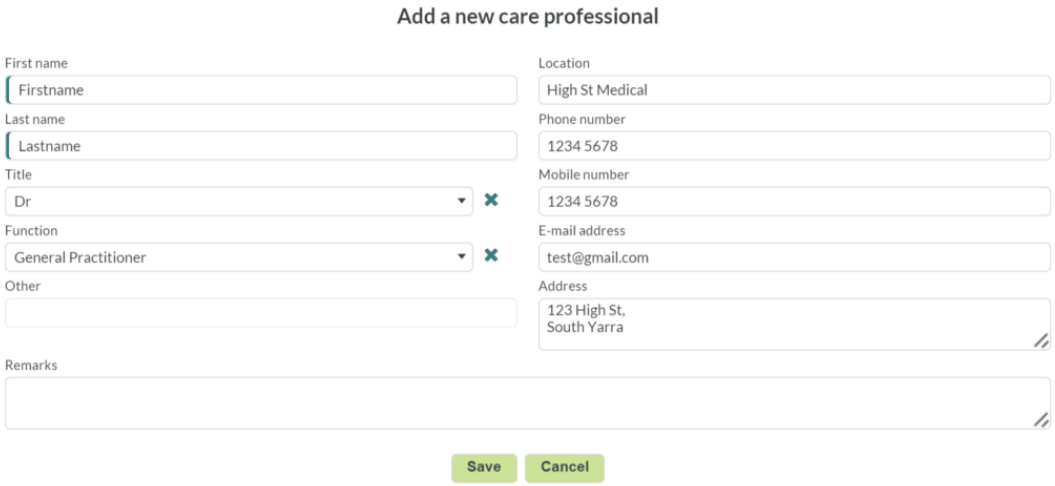


Figure 20 - Care professional data form

6.9. Flexifields

6.9.1. Overview

Flexifields are data fields in addition to the standard fields that MDS captures as a default. For example, your centre may want to capture supplement use, or administrative fields that are unique to your centre for internal or research purposes.

Good to know!

Centre-specific Flexifields are a great way to capture unique fields about your centre's patients. They are not shared with the Registry and can still be exported, searched on and graphed like any other field in MDS.

Further information about flexifields and MDS:

- Flexifields can be entered as a one-off data field (for example Health Insurance Number) or can be entered as a time series value (for example Vitamin D level).
- **Centre-specific Flexifields** are never shared with the Registry or any other centre. They will never leave your centre, so they may be used to capture personally identifiable information, or other confidential information.
- There are different types of fields. For example, numeric fields can be used to capture dosages, text fields can be used to capture brief comment, or drop-down boxes may be used to enforce consistent data entry.
- Flexifields belong to you. We therefore allow flexifields to be exported to either XLSX or CSV.
- Numeric time-series flexifields can be displayed on the Patient Overview Graph.
- Flexifields can be searched just like any other field in MDS.

In the below example we have created a flexifield form in the Visit section. This means that the below data could be captured and recorded over many different time points. Note that the flexifields capture clinical information as well as administrative information.

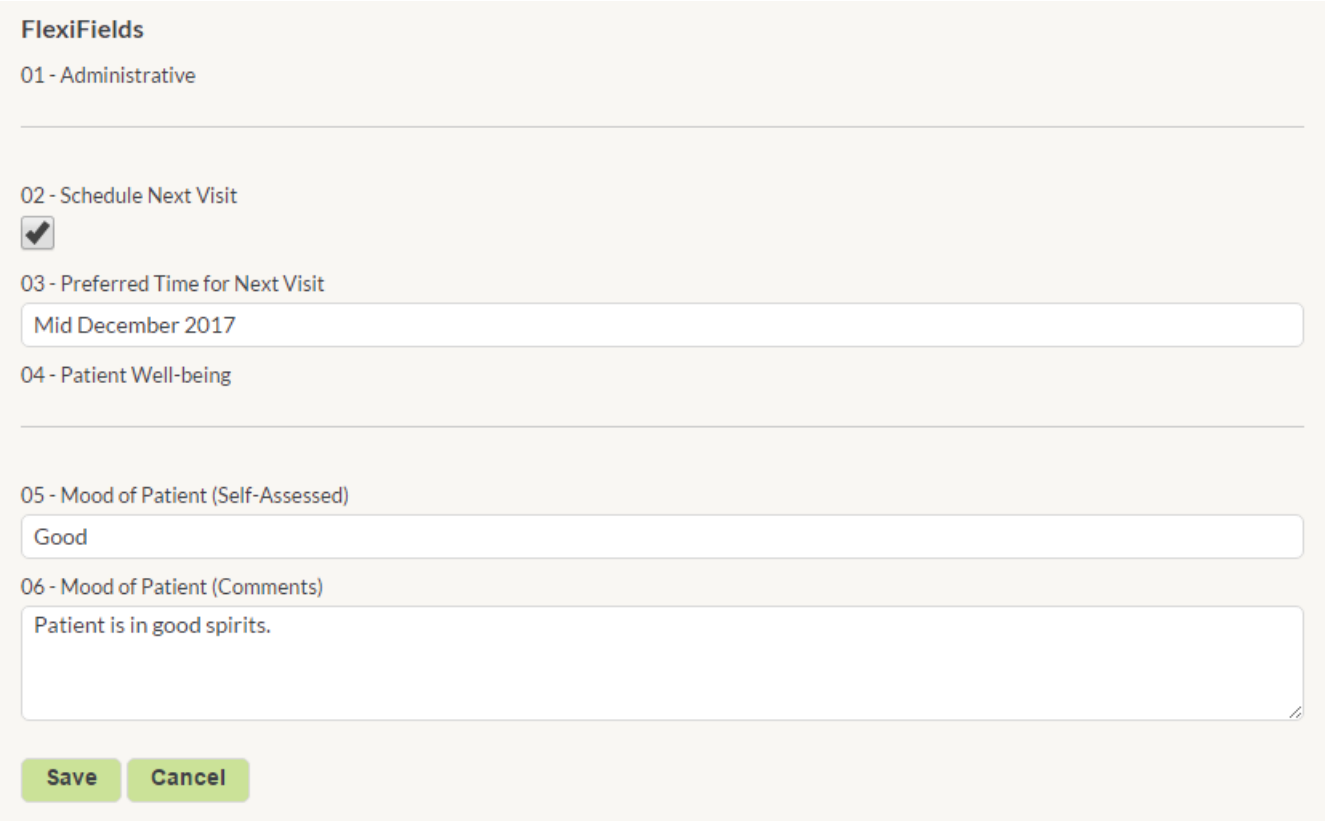


Figure 21 - Flexifield example

6.9.2. Data types

There are seven different types of fields in MGBase that you can use as flexifields. These are further explained below.

- **Checkbox**: A checkbox can be used to identify True or False values. For example, Patient Consent, whether to book another appointment etc. A checkbox cannot be graphed, but it can be searched as “Yes” or “No”.
- **Date**: A date field is used to capture a specific date. The date must be valid and contain a day, month and year. Where dates are abstracted to month or year only, then either use an arbitrary day value, or use the Text field instead. When searching the date fields then the = < > operators may be used.
- **Dropdown**: Where the centre wishes to promote standardised answers, the dropdown option may be used. For example, a field may be “Mood of patient”, with the dropdown options including “Excellent”, “Good”, “Mediocre”, “Bad”, “Terrible”. This field cannot be graphed but can be searched.
- **Header**: The header field allows you to organise your fields into different sections.
- **Numeric**: The numeric field allows numbers up to 20 digits to be captured. This field is searchable and graphable if used in Visits, Medical Events or Paraclinical Tests.
- **Text**: The text field should be used to capture short, simpler alphanumeric values. For example, it might be used to store a name, a phone number or an insurance reference. The field can be searched, but not graphed.
- **TextArea**: A TextArea field is like a text field, but instead should be used for longer text. For example, capturing notes about a patient. The field can be searched, but not graphed.

Field Type	Unit	Max Length/Format
Checkbox	No	N/A
Date	No	DD/MM/YYYY
Dropdown	No	N/A
Header	No	N/A
Numeric	Yes	N/A
Text	No	100 Characters
TextArea	No	100 Characters

When adding a field to the flexifield section, first decide what category it should fall into. There are four options available:

- Patient Profile: Flexifields in this section should only be used to capture once off data about the patient. This section should not be used for time-series values. Examples of use include: Patient Insurance Reference, Consent to Upload to use data for research, Hair colour etc.
- Visits: Flexifields in the visits section can be used for time-series values. These are values that can change overtime. For example, this might be some type of centre administration field identifying when the next MRI should be.
- Medical Tests: Medical tests can be created to capture time-series test outcomes. For example, this may be a custom disability scale being assessed for efficacy.
- Medical Events: Medical event flexifields are used to capture time-series custom medical events. Like Paraclinical Tests, this section can be used to create a custom data collection form for medical events. For example, the centre you are working in may be collecting data on pregnancies in addition to the fields being collected in the current Pregnancy form. This collection would be performed in the Medical Events section.

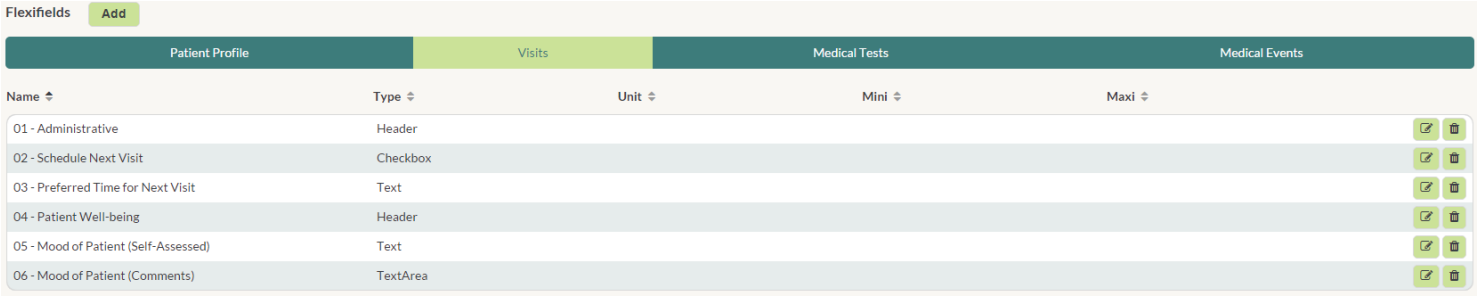


Figure 22 - Flexifield administration screen

Once you have decided where the fields you wish to collect should go then create the flexifield by clicking the Add button and populating the remainder of the fields. Once the flexifield is saved, save your changes.

Good to know!

Flexifields will sort alphanumeric by fieldname as a default. To force an order, prefix them with a number like the above example.

6.10. Deleting Reference Data

There may be instances where you wish to delete reference data. This might be a field value that is no-longer used, or it might be multiple fields that you wish to consolidate into a single field. MDS will not allow values to be orphaned, so when deleting reference data that already has patients associated with it, MDS will require you to assign the deleted value to an existing value.

For example, in the below we would like to delete the treatment Hydrocortisone.

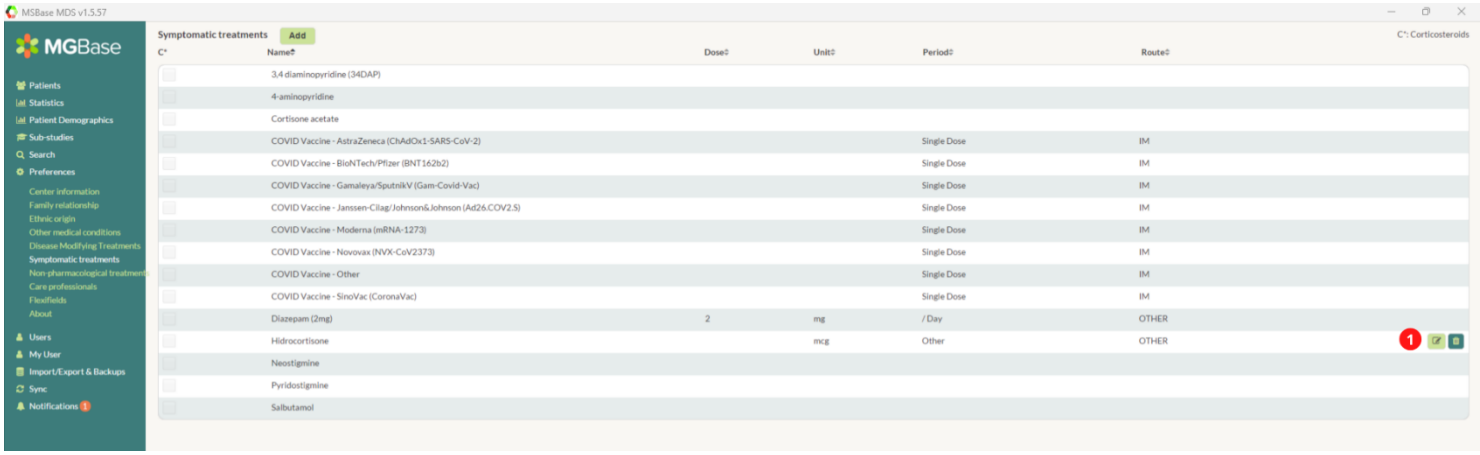


Figure 23 Deleting Reference Data

There are two scenarios that can occur when deleting data, either the treatment has never been used in MDS and you can simply delete, or the treatment has been used and you need to delete and replace.

Good to know!

What happens if we have already treated a patient with “Hidrocortisone”? If you were to delete that treatment, then we would have an empty treatment name associated with the patient, but still have a dosing schedule, duration, and notes. In this instance you need to Replace and Delete. MDS will prompt you with which treatment you wish to replace the deleted treatment with. In this example, we replace all records referring to Hidrocortisone with Hydrocortisone and then delete the Hidrocortisone reference.

This happens to not just Disease Modifying Treatments, but also Symptomatic Treatments, Family Relationships, Ethnic Origin and non-Pharmacological treatments.

7. MedDRA

7.1. What is MedDRA?

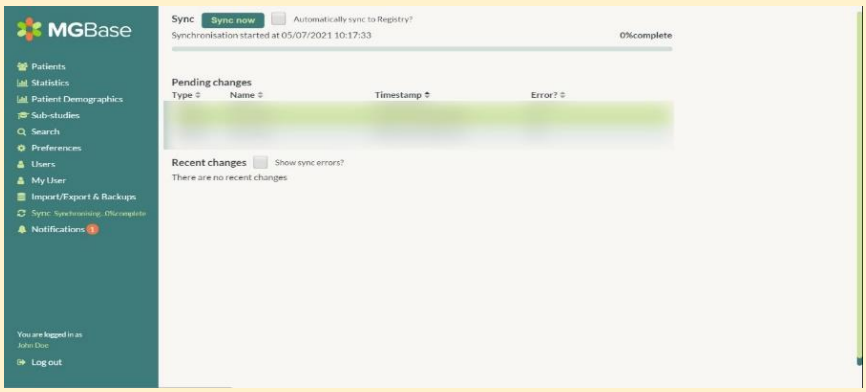
MedDRA is the preferred method to capture medical conditions throughout MDS. MedDRA is an internationally recognised and clinically validated medical terminology dictionary used by the medical and pharmaceuticals industries. MedDRA is available in multiple languages (English, Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese, Spanish and Japanese) and is widely used throughout the world in pre-marketing and post-marketing activities and safety.

7.2. Installing MedDRA

If you have just installed MDS you may have noticed that no MedDRA definitions are immediately available. Due to licensing limitations, MedDRA does not come packaged with MDS, instead you must synchronise with the Registry at least once to install the download files. Once this is complete, MedDRA definitions will be available.

Good to know!

To download MedDRA, simply click Synchronise Now in your Sync tab. If your centre is having problems downloading, wait for a few minutes and try again, otherwise contact info@msbase.org Also note that typically the PI of the Centre needs to do this at the first login, as a PI should have the relevant permissions required.



7.1. Structure of MedDRA

MedDRA is structured in a hierarchical tree, organized by System Organ Class (SOC) and then further divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT) and then finally Lowest Level Terms (LLT). When you are assigning a medical condition to a patient, the LLT level is used and only the LLT values will be available to select.

In the below example we wish to classify a patient as suffering with *Sleep Apnoea*. When searched the LLT is returned and we can select it. Every LLT belongs to a PT and often the LLT can be thought of a medical thesaurus for the PT. In this instance, we could select any of the 10 LLT terms and all would be correctly classified as *Sleep Apnoea Syndrome.*

MedDRA PT terms may belong to more than one hierarchy, this characteristic (called *Multiaxiality*) can be seen in the below, where Sleep Apnoea is not just a Respiratory disorder, but can also be considered a Psychiatric and a Nervous system disorder. This means that when searching in MDS, a PT may respond to many different types of SOC search values. MDS uses MedDRA's *primary* hierarchy for reporting and display where only a single SOC can be used. A *primary* hierarchy is MedDRA defined, is consistent and will ensure that "double counting" of the medical condition does not occur. In the diagram below, the primary hierarchy for Sleep Apnoea is displayed in red.

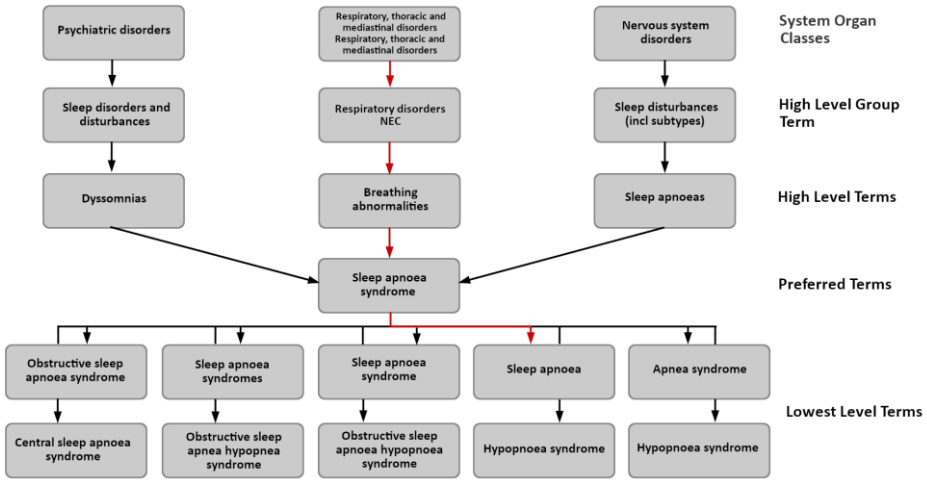


Figure 24 - MedDRA hierarchy for Sleep Apnoea

7.1.1. Browsing MedDRA

MedDRA definitions can be applied to a patient either by browsing and selecting a LLT, or alternatively you can search for a LLT. To browse for a LLT, click on the SOC, HLGT, HLT and PT to expand the tree. Once the LLT has been located, select and save the result.

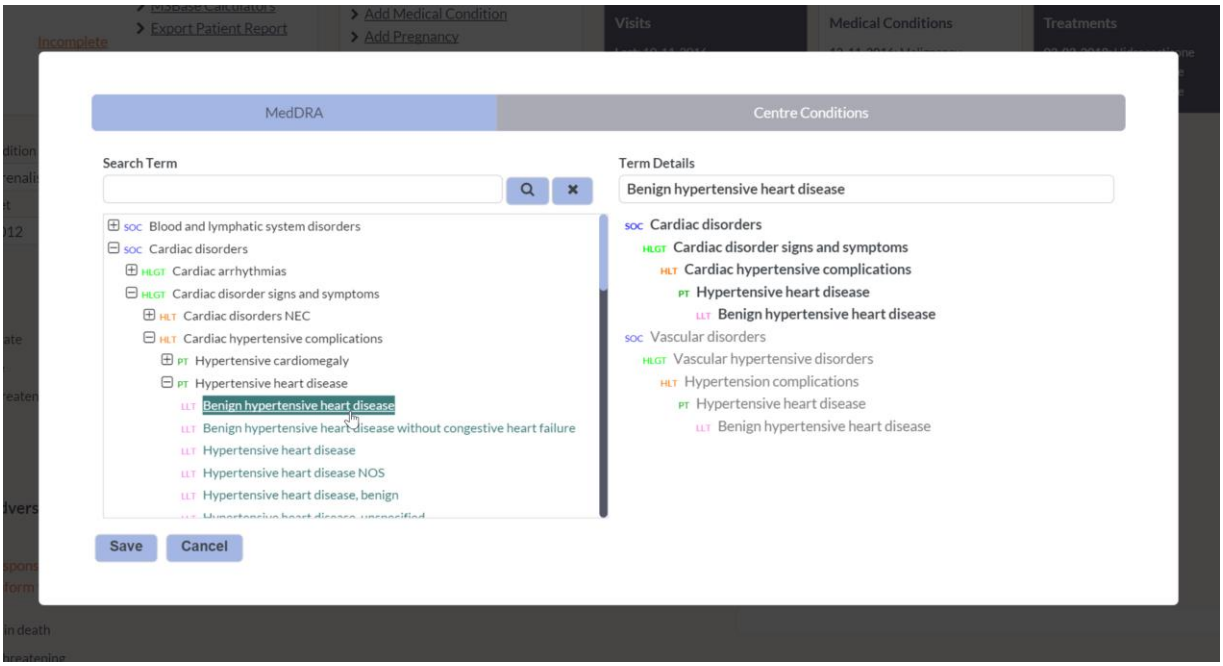


Figure 25 - Browsing with MedDRA

7.1.2. Searching

Searching MedDRA is a more efficient method to locate a LLT when the condition is known. Search a LLT by entering a search phrase and selecting the Search icon. MDS will locate the LLT which is the closest match to the search input and will order by relevancy. Select the desired LLT and save to assign to the patient.

No LLT being returned by your search? Check the spelling of your input string and/or try a less specific search. Alternatively refer to the above section and browse for the LLT.

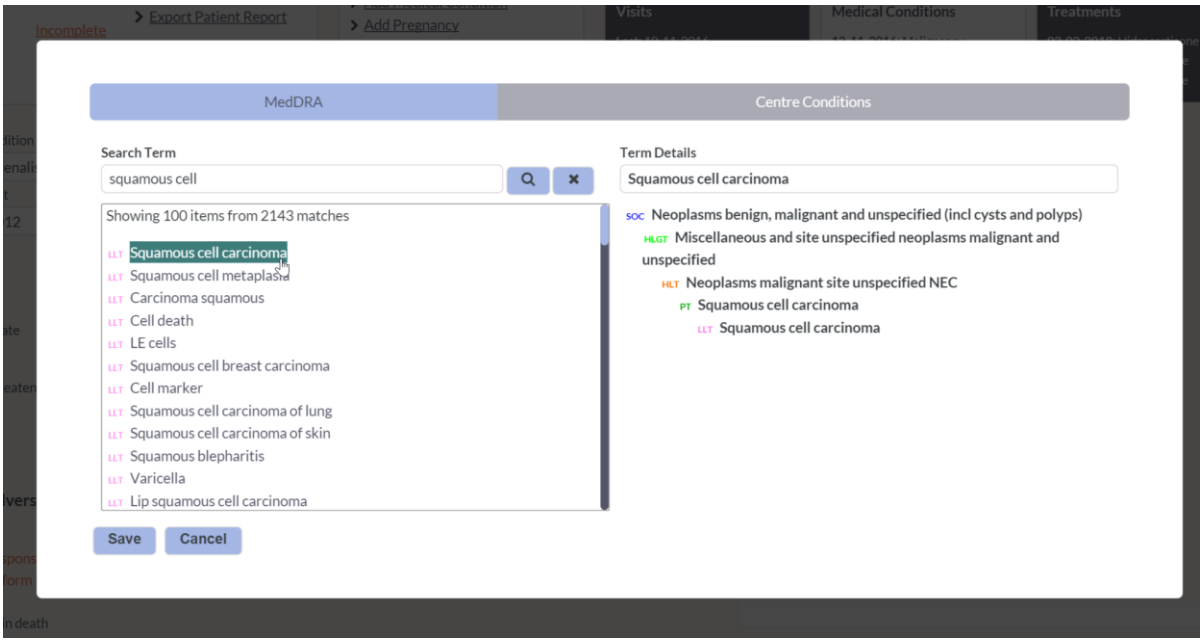


Figure 26 -Searching for an LLT

8. Patients

8.1. Adding a new patient

To add a patient in MDS, expand the Patients link in the MDS Menu and then select *Add new patient.* Ensure that the mandatory fields are complete prior to the clicking Create Patient. Once the patient is created, then Visits, Treatments, Medical Events etc can be added to the patient.

Good to know!

After the patient is created, he/she is still not enrolled into the MGBase Registry. Either enrol the patient in the Manage All Patients section or by selecting the Registry [Unenrolled] button in the Patient Card, which will then change to [Enrolled].

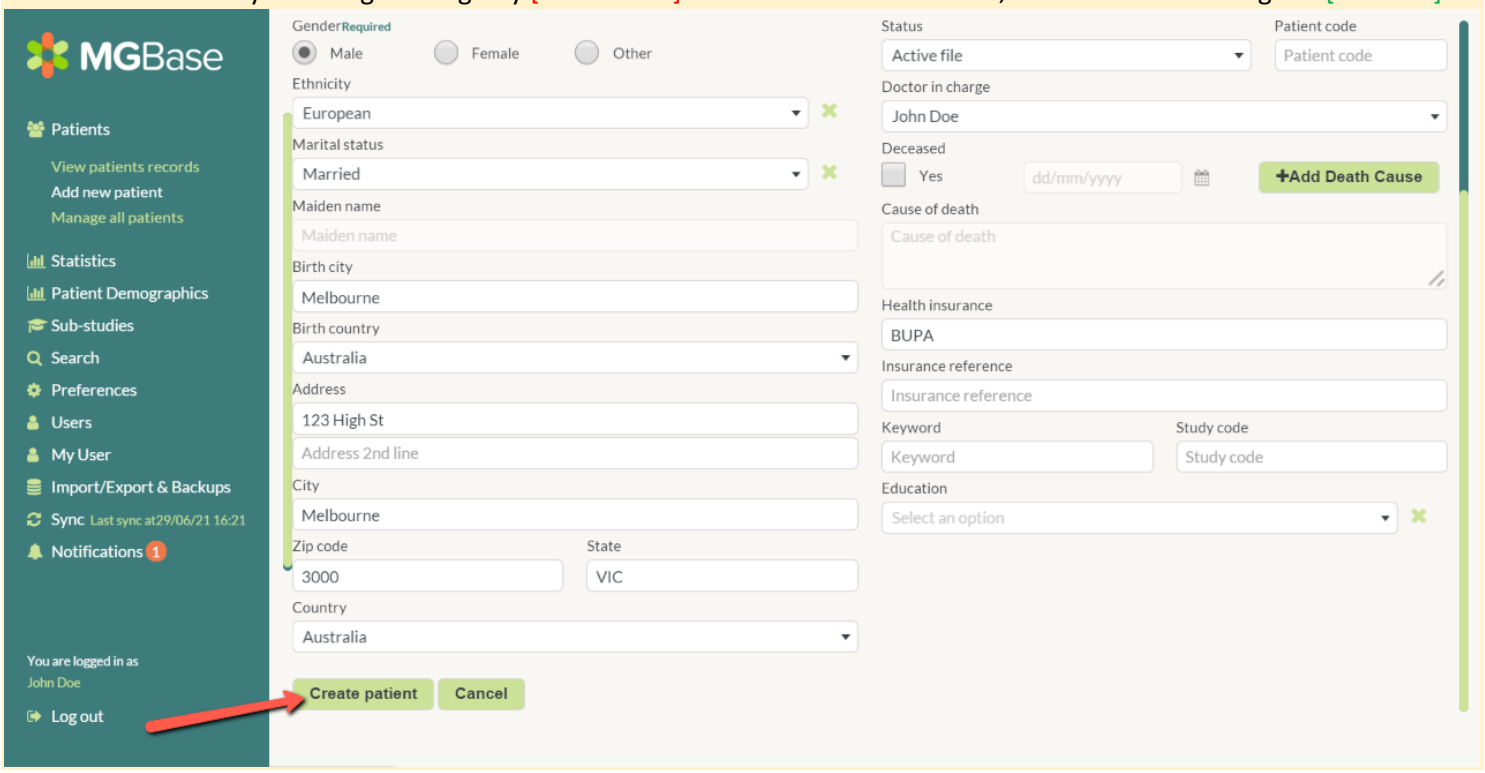


Figure 27 - Adding a patient

8.2. Manage all patients

The Manage all patients screen allows you to see your patients at a high level and perform bulk functions. For example, in this screen you can enrol multiple patients into the Registry. The other functions available in this screen include:

- **Check Completeness**: If patient completeness requires further attention, then click the Fix button and the incomplete aspects of the patient will be shown. If no Fix text is shown, then the patient is complete.
- **Enrol/Unenroll**: Patient enrolment is usually performed on an individual basis. This view will allow you to locate patients that are, for example, not yet enrolled in the Registry, and enrol them.
- **Delete/Restore**: Should the user want to delete a Patient from MDS, for example the patient is a duplicate record or no longer attends the clinic, then patient can be deleted. MDS performs a *soft-delete* only on data in MDS. This means that the patient can be restored should you need to. Deleted patients do not appear in the Patient selector list.

Navigation in the Manage all patients screen is limited to the ability to sort the table by the column values. Should more detailed analysis be required then the data should be exported to Excel/CSV first.

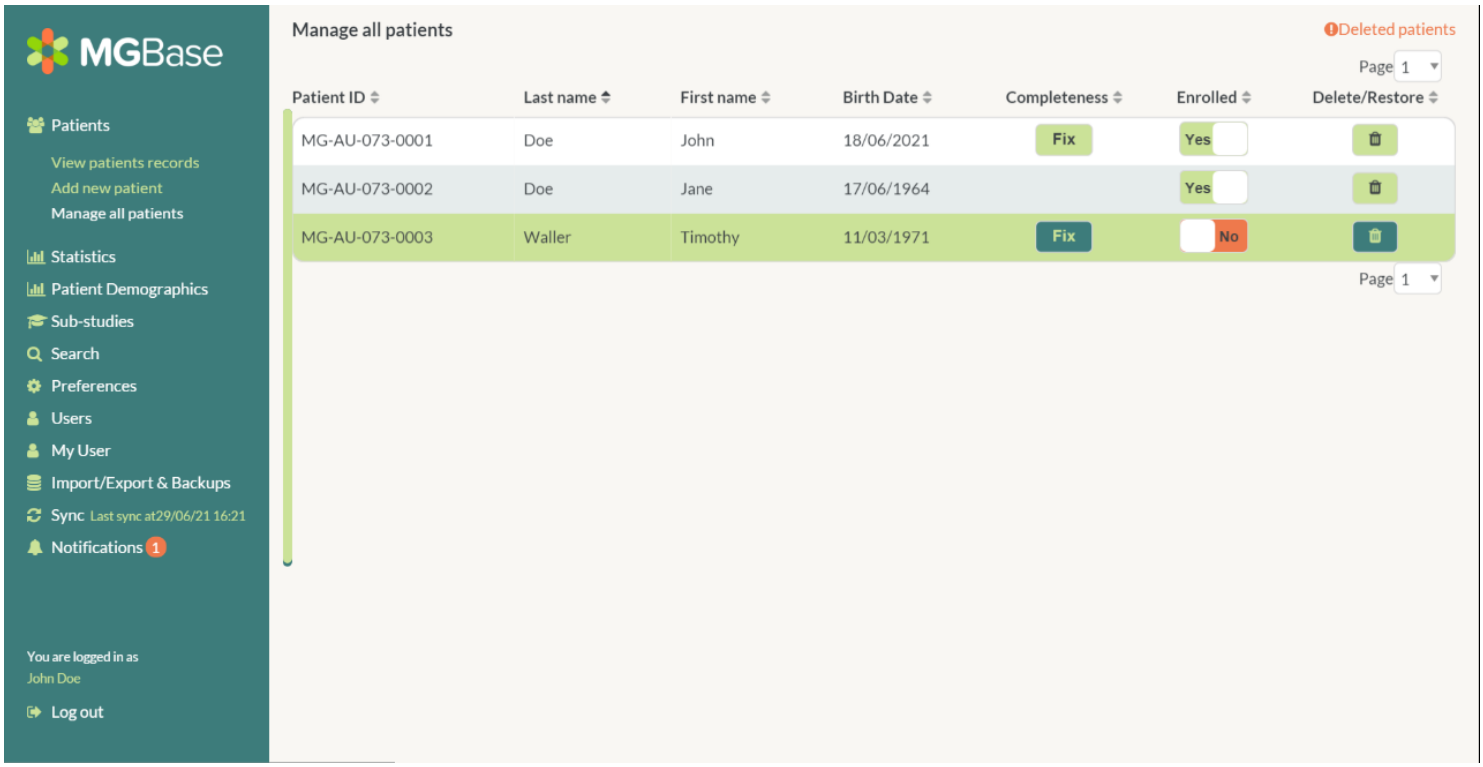


Figure 28 - Manage all patients screen

8.3. Deleting a patient

When you delete a patient that patient is not completely removed from the system, instead they are soft-deleted. This will remove the patient from any synchronisation events, will remove the patient from searches and the practitioner will not see the patient in the selector list.

A deleted patient is indicated in the Patient Management screen by an orange exclamation mark ( ). They can be restored by clicking the restore button ( ).

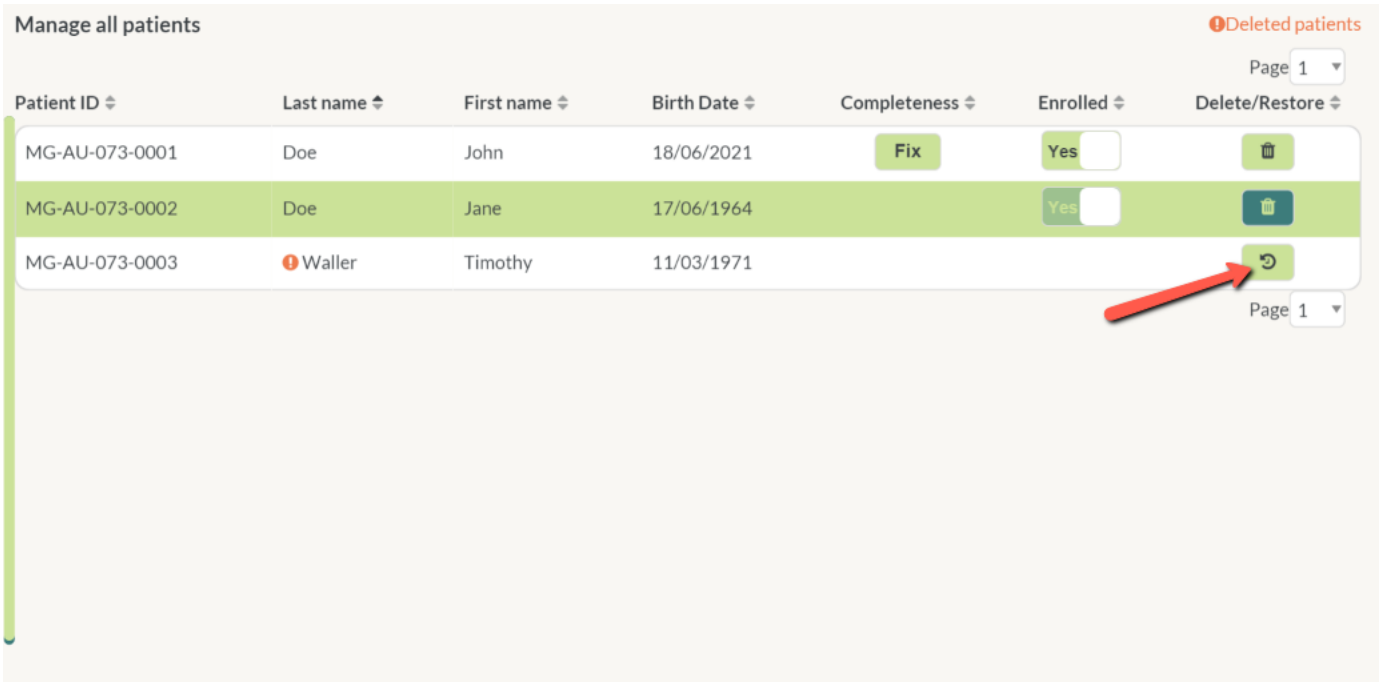


Figure 29 - Restoring a deleted patient

8.4. Patient Card (Record)

When a patient is selected in MDS, then the Patient Card will display a summary of the patient and allow the user to perform some limited features. Specifically, the following functions can be performed:

- **Check patient completeness**: Check whether the patient's record is complete and meets the MGBase recommended completeness
- **Check Registry Enrolment**: See whether the patient is enrolled in the Registry, and if not, enrol them.
- **Manage Sub-studies**: See which sub-studies the patient is enrolled in. Enrol the patient into further studies that require manual enrolment.
- **Export Patient Report**: Export the patient report to PDF or RTF for printing or filing.
- **View Patient Graph**: Navigate to the Patient Overview Graph.
- **Customise Graph**: Customise the Patient Overview Graph.

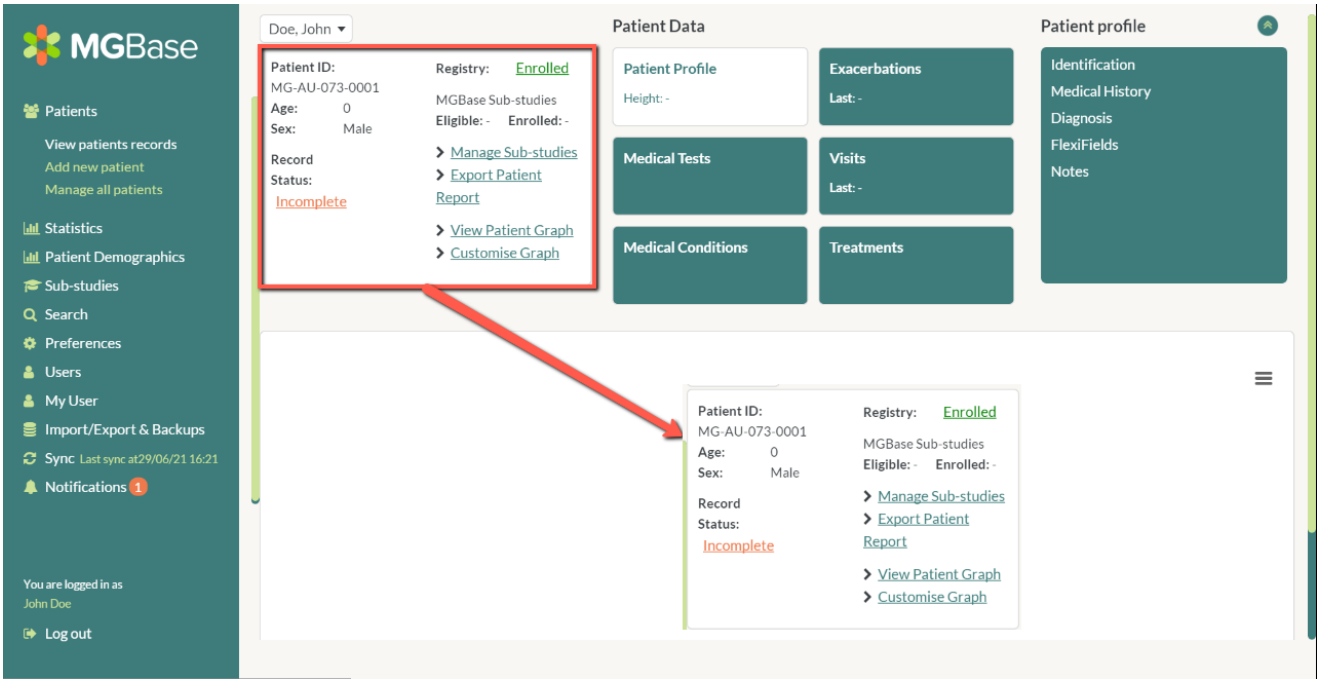


Figure 30 - Patient Card functions in MDS

8.5. Patient Quick Links

The Patient Quick Links presents you with a list of commonly accessed features, for example starting the Wizard, adding Visits, Exacerbations, Treatments and Medical Tests and Conditions.

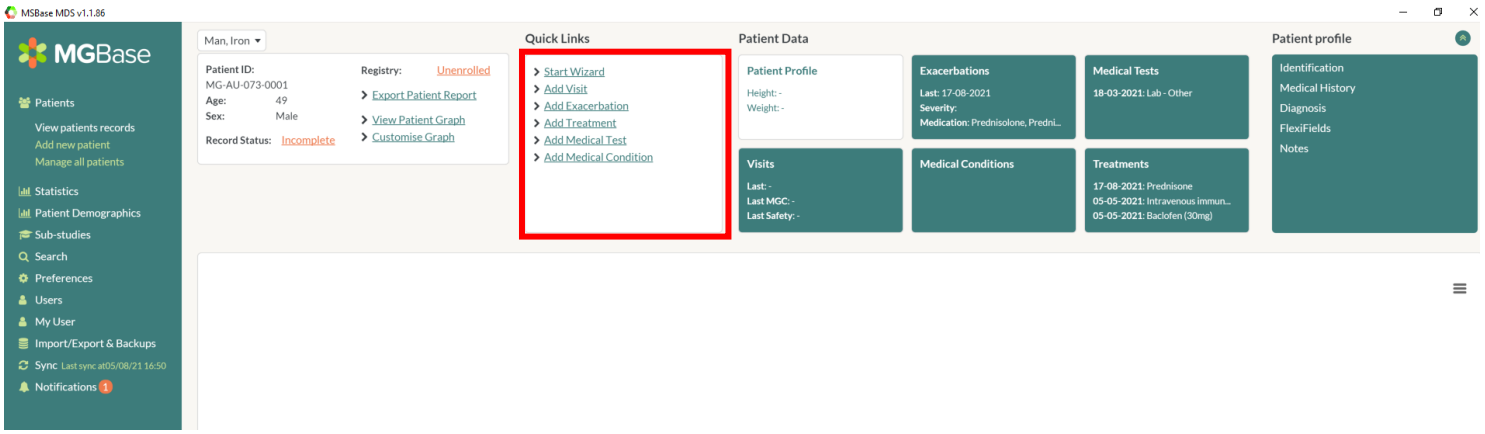


Figure 31 - MDS Quick Links

8.6. Patient Report

The patient report provides a high-level summary of the patient and can be useful where a local policy is in place to upload the data to an EMR. The Patient Report can be exported in either Rich Text Format (RTF), or as a PDF.

To export a patient report, ensure the patient you wish to export is selected. In this instance we are exporting John Doe. Select the *Export Patient report* link. In the resulting window, either enter a path to save the file, or click the Path icon to use Window Explorer to locate a directory. Select the export format, PDF or RTF, and select Run. MDS will notify you when complete and the file is ready to view.

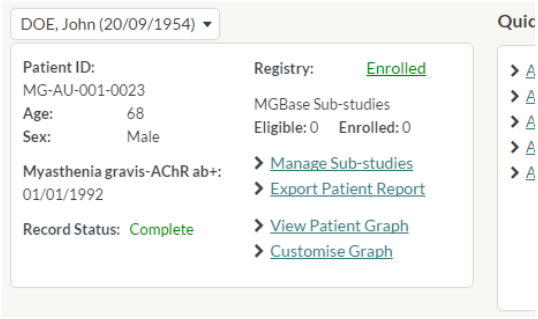


Figure 32 - Export a patient report

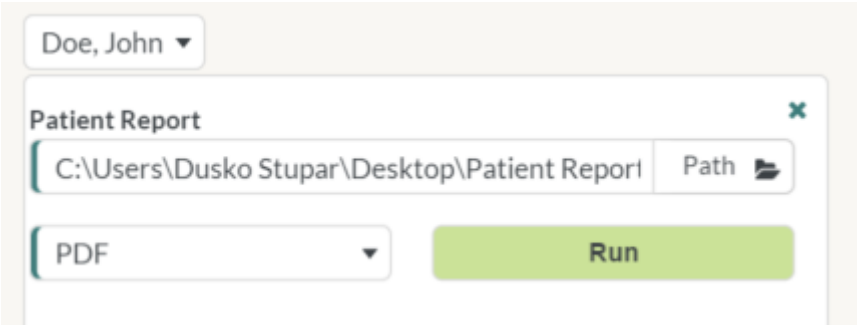


Figure 33 - Saving a patient report

8.7. Enrolling into Registry

When a patient is first created in MDS, that patient is not yet enrolled into the Registry. Orange text is shown in the Patient Card notifying you that the patient is **Unenrolled**. When clicked, this text will prompt the user to confirm their decision to enrol the patient.

Unenrolling a patient is performed in the same manner.

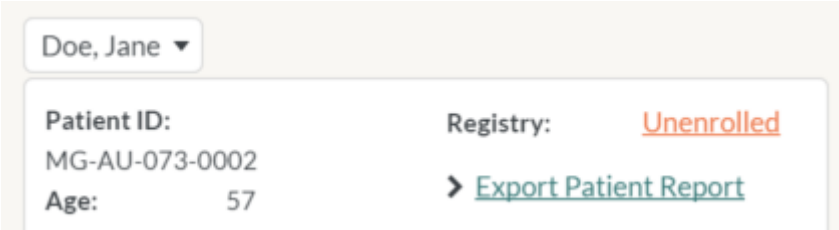


Figure 34 - Enroll a patient into the Registry

When the patient is enrolled then MDS will notify you with the bold green text **Enrolled** and MGBase sub-studies will become available.

Figure 35 - An enrolled patient

8.8. Enrolling into Sub-study

Sub-studies allow for collaboration and data sharing between centres. Assuming your centre has already joined a sub-study, some further action still may be required to contribute your data if the study requires Manual Enrolment. For most sub-studies, patient enrolment is Automatic, meaning that if the patient meets the selection criteria, then the patient will automatically have his/her data contribute to the study. Manual enrolment however is where the selection criteria is more subjective/difficult to capture, or special ethics/permissions must be sought. In a Manual sub-study, the user must manually enrol the patient into the sub-study.

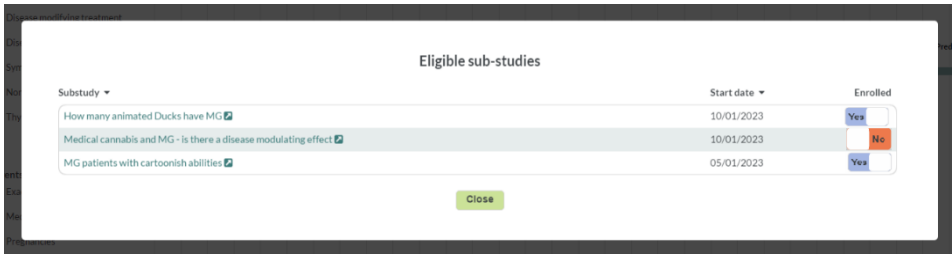


Figure 36 - Manage Sub-studies screen

When the user selects *Manage sub-studies* then the user is presented with a list of sub-studies that the patient is either enrolled in or eligible for. As clarified above, the patient may be enrolled into a sub-study if the enrolment method is automatic. Where the sub-study is Manual, then the user must select "Yes" in the enrolled column.

Once the patient is enrolled, and after synchronisation with the Registry has taken place, then any additional sub-study flexifields (if any) will be visible to the user.

8.9. Patient Completeness

The patient completeness is an extension of the MGBase Minimum dataset. It is designed to ensure the completeness of the data is thorough enough to make sound statistical inferences. The below components (highlighted in red) of the patient should be considered for patient completeness:

Figure 37 - An incomplete patient

Section	Field	Frequency	Definition
Patient profile	Patient ID	Entry visit	Patient globally unique ID
	Last name	Entry visit	
	First name	Entry visit	
	Gender	Entry visit	M / F
	Birth date	Entry visit	Month and year only
MG Diagnosis	Disease category	Entry visit	Disease names
	Date of onset	Entry visit	Date
Visit	**MRS**	Annual #	Value
	MGC	Annual #	Total

The Patient Completeness report will look like the below image and will inform you if there are incomplete elements.

Figure 38 - Patient completeness report

9. MGFA classification at confirmed diagnosis

9.1. CSR

No symptoms, no signs (except eye closure), no MG treatment 1 year

9.2. PR

No symptoms, no signs (except eye closure), no symptomatic MG therapy

9.3. MM

No symptoms nor limitations, minor weakness found on exam

9.4. MM-0

No symptoms, exam=MM, no MG treatment 1 year

9.5. MM-1

No symptoms, exam=MM, some immunosuppression, no symptomatic therapy >1 year

9.6. MM-2

No symptoms, exam=MM, only MG treatment <120mg pyridostigmine/day

9.7. MM-3

No symptoms, exam=MM, symptomatic and immunosuppression therapies in past year

9.8. I

Ocular

9.9. IIa

Mild generalised, predominantly limb/axial muscles

9.10. IIb

Mild generalised, predominantly oropharyngeal/respiratory muscles

9.11. IIIa

Moderate generalised, predominantly limb/axial muscles

9.12. IIIb

Moderate generalised, predominantly oropharyngeal/respiratory muscles

9.13. IVa

Severe generalised, predominantly limb/axial muscles

9.14. IVb

Severe generalised, predominantly oropharyngeal/respiratory muscles

9.15. V

Intubation

10. Patient Overview Graph (POG)

10.1. Overview

The Patient Overview Graph (POG) gives a visual representation of the patient's medical history. By default:

- Visits are displayed as vertical lines
- Treatments are displayed as blocks of time. Where a treatment is ongoing, the treatment will have an arrow-head up to the current date. MS-Specific, Symptomatic and Non-Pharmacological values are all displayed.
- Exacerbations are displayed as a block of time where an Exacerbation duration is supplied, or as a square icon where no exacerbation length is given.
- All medical conditions (Malignancy, NMSC, Herpes Zoster, Infection (severe), Other Adverse and flexifields) are displayed as a block of time, spanning from the begin date to the outcome date (where outcome might be remission or death).
- Pregnancy is displayed as a block of time, with the duration of the pregnancy defined by the beginning of the pregnancy and ending with either the birth or termination/miscarriage date.
- Electrodiagnostic Tests are displayed as a small teal square ( )
- Imaging tests are displayed as a small blue square ( )
- <insert Bedtime tests example>
- Laboratory tests are displayed as a square icon. In MDS, there are five categories of laboratory tests: Myasthenia antibodies, Haematology (H), Blood Chemistry (B), Thyroid Functions (T), Microbial Tests and Auto-antibody (A) Tests. MDS will recognise which categories of tests have been completed in each of the Laboratory Tests and display that information to the user.

In the bottom section of the POG there is a section where any time-series numeric value can be displayed. For MG the MGC Score will be displayed and is auto scaled to a value between 0-50 on the graph.

This section below will explain how to customise this graph should you need to.

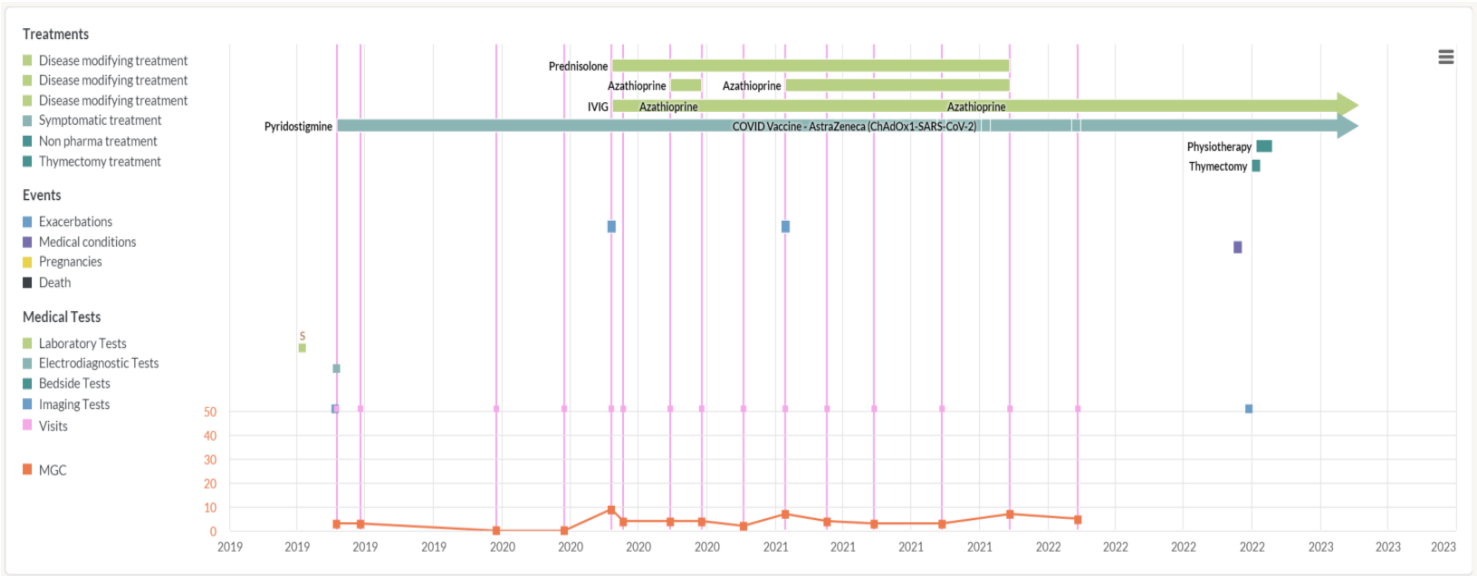


Figure 39 - The patient overview graph

Good to know!

The POG is interactive and will respond to user actions. When hovering over any of these elements, the graph will give a small description of the element and the date. Visits, Events and Paraclinical tests will take the user to the data entry form when selected. To focus on a specific time range, click on the graph and zoom (click and drag) into the desired region.

If you are finding the POG a little cluttered, by clicking on the elements in the left-margin/key, the user can turn on/off the corresponding indicators.

10.2. Export and Print

The POG can be exported to a variety of image formats (PNG, JPG, SVG and PDF), or printed. The POG will print in its current state. This means the graph will print the current zoomed range, any indicators that have been turned on/off and the time series shown at the bottom of the graph.

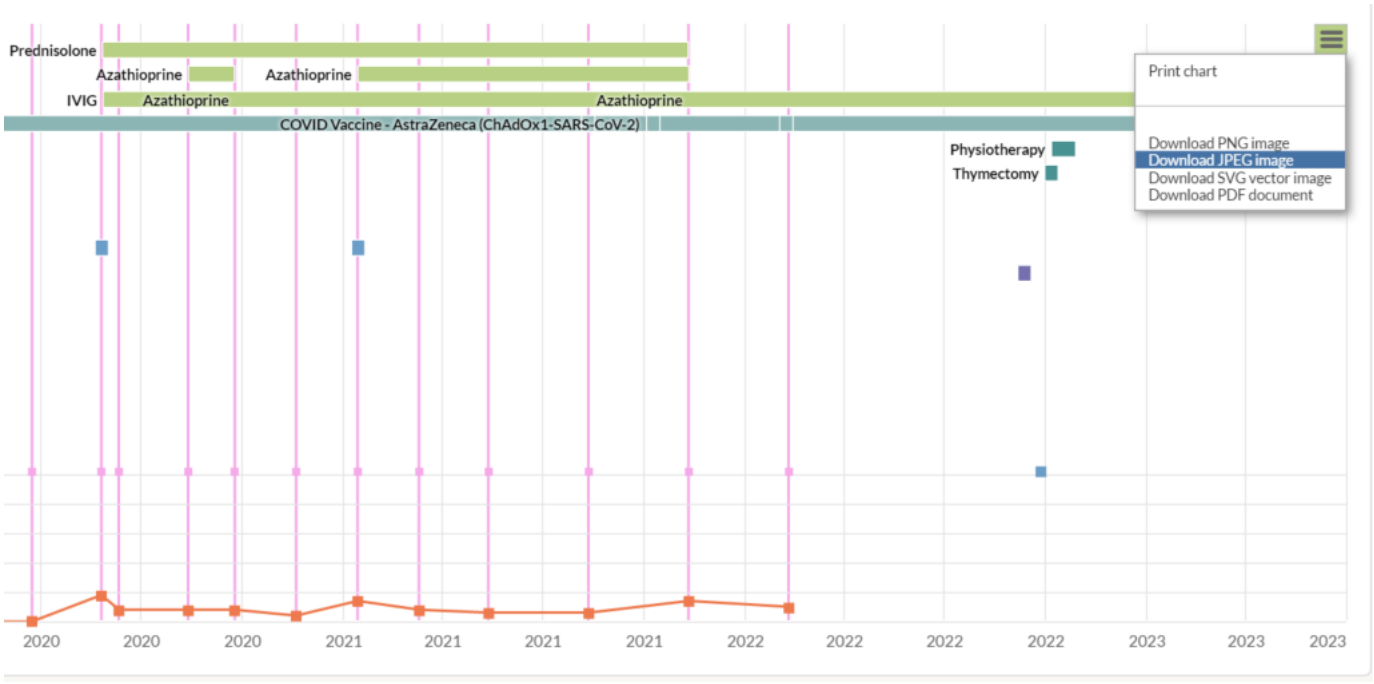


Figure 40 - Printing and exporting the graph

10.3. Graph field customisation

Any time-series numeric value can be displayed on the bottom of the POG. Do this by selecting *Customise Graph* in the *Patient Card* selector. This will open the POG customisation window.

In this window, by default, you should notice that the MGC – Selected Score will be plotted on the Y Axis Left and the series is not populated for Y Axis Right. You can select a numeric time-series value (from Exacerbation, Laboratory Test, Pregnancy, Treatment and Visit) for either Y Left/Right axis.

Good to know!

Since the new corticosteroid / variable dosing schedule functionality has been added, the POG can be customised to show a variable dosing schedule in graph format, for a particular treatment type. Do this by customising the “Y Axis – Right” section, select “Treatment” from the dropdown, then select “Dose Schedule” from the next drop-down, and select the relevant corticosteroid or IVIG / PLEX treatment. This can then be “Viewed” by clicking the “View” button and saved if required.

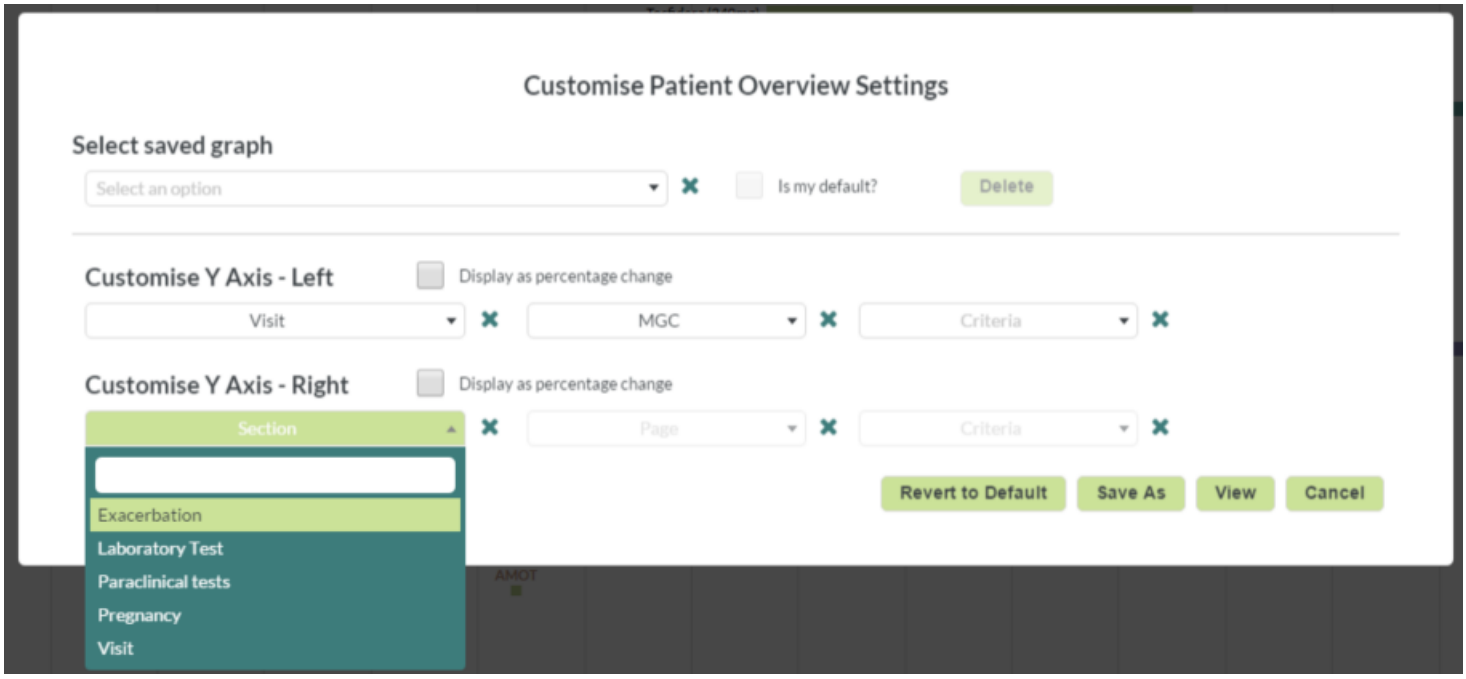


Figure 41 - Customise Graph Options

10.4. Percentage Change

MDS can display the percentage change of a time-series values rather than the absolute values. For example, below we show the MGC value versus the MGC % change, where the percentage change of MGC (Δe) for any given point in time n is $\Delta e_n = \frac{e_n - e_{n-1}}{e_{n-1}}$.

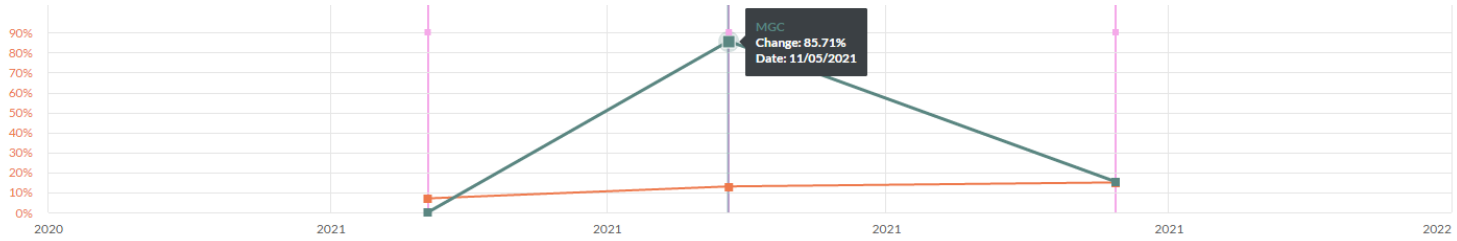


Figure 42 - MGC vs MGC % Change

The other advantage that percentage change gives you is the ability to display multiple values on the same index, despite being measured in ranges of differing magnitudes (for example display values in range 0.001 to 0.005 alongside values in the range 0.1 to 0.5) or different units (for example display seconds, ambulation index and lymphocyte values measured in 10^9/L). We demonstrate this in the below example where we display the *Time to walk 8m* in seconds*, Ambulation Index* and *Lymphocyte* count on a single axis.

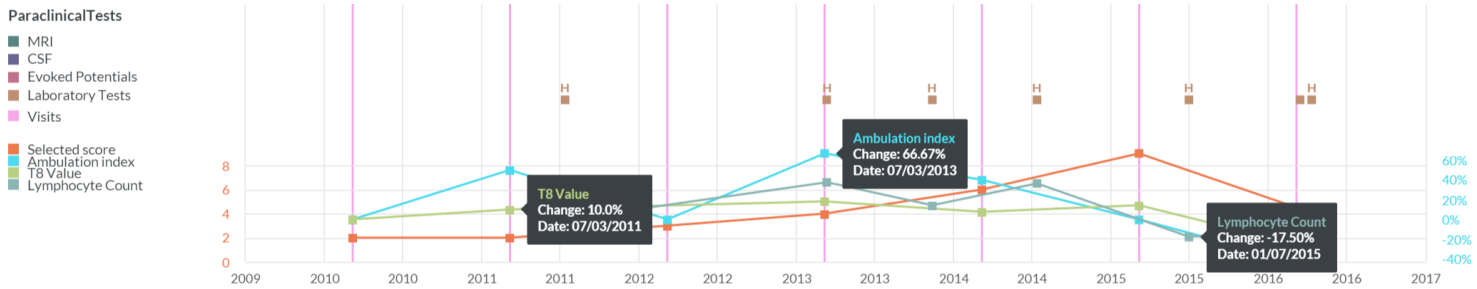


Figure 43 - Custom graph of Time to Walk 8 seconds, Ambulation Index and Lymphocyte Count

You can display percentage change by checking the “Display as percentage change” option. This will enable all values on that axis to be displayed as a percentage change. By selecting the Add Series option, additional time series can be displayed. Up to ten may be displayed on each axis.

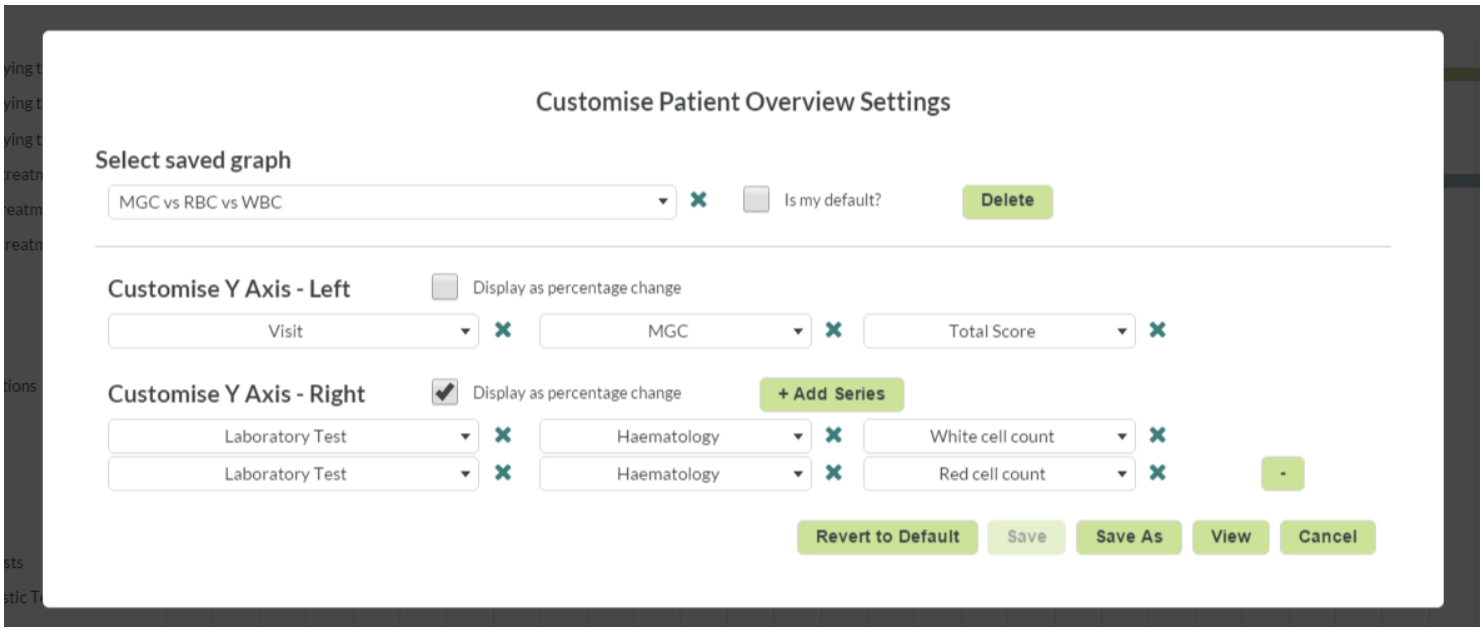


Figure 44 - Adding percentage change fields

10.5. Saving and sharing graphs

Graphs can be shared with other users in your centre. By selecting “Save As” and entering a title and description other users in your centre will be able to see and implement your graphs.

Saved graphs are available for all users and can be viewed and selected by using the dropdown list. There are no private graphs in MDS.

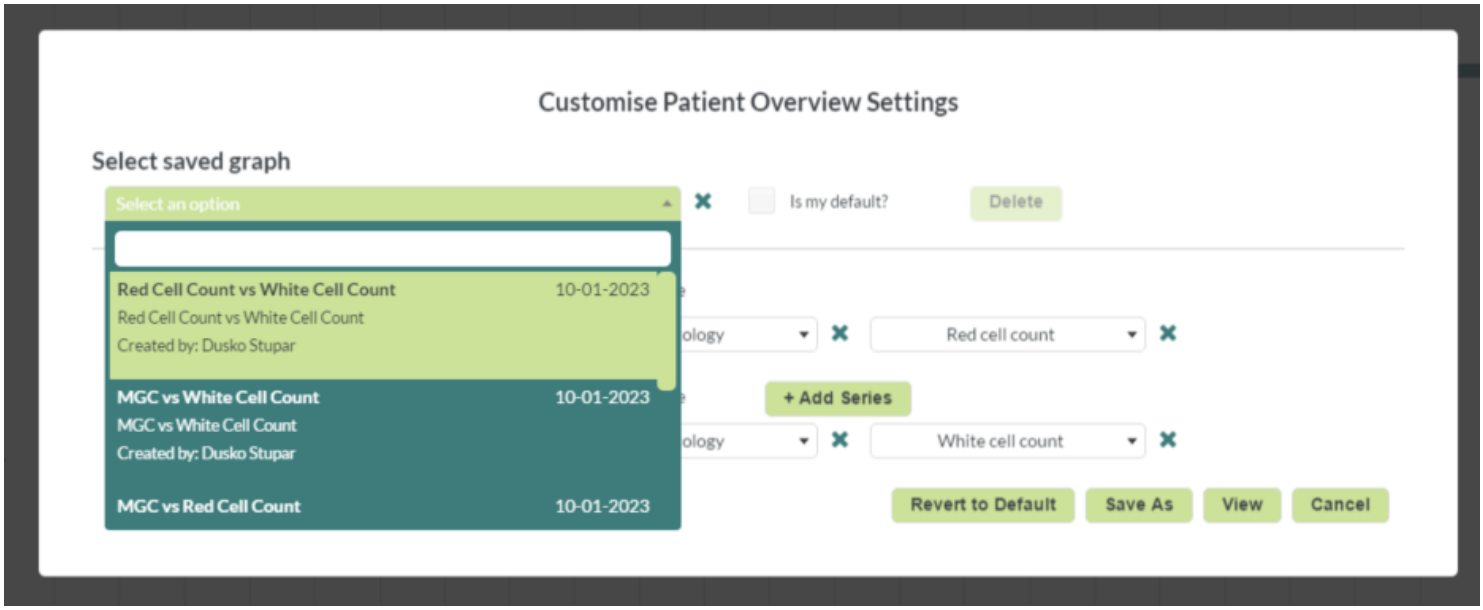


Figure 45 - Selecting a saved graph

Any user in your centre can set a default graph that will display when they login. Set the default by selecting a graph from the dropdown list, select the *Is my default* checkbox. Now, anytime the user logs in, the initial graph displayed will be selected graph.

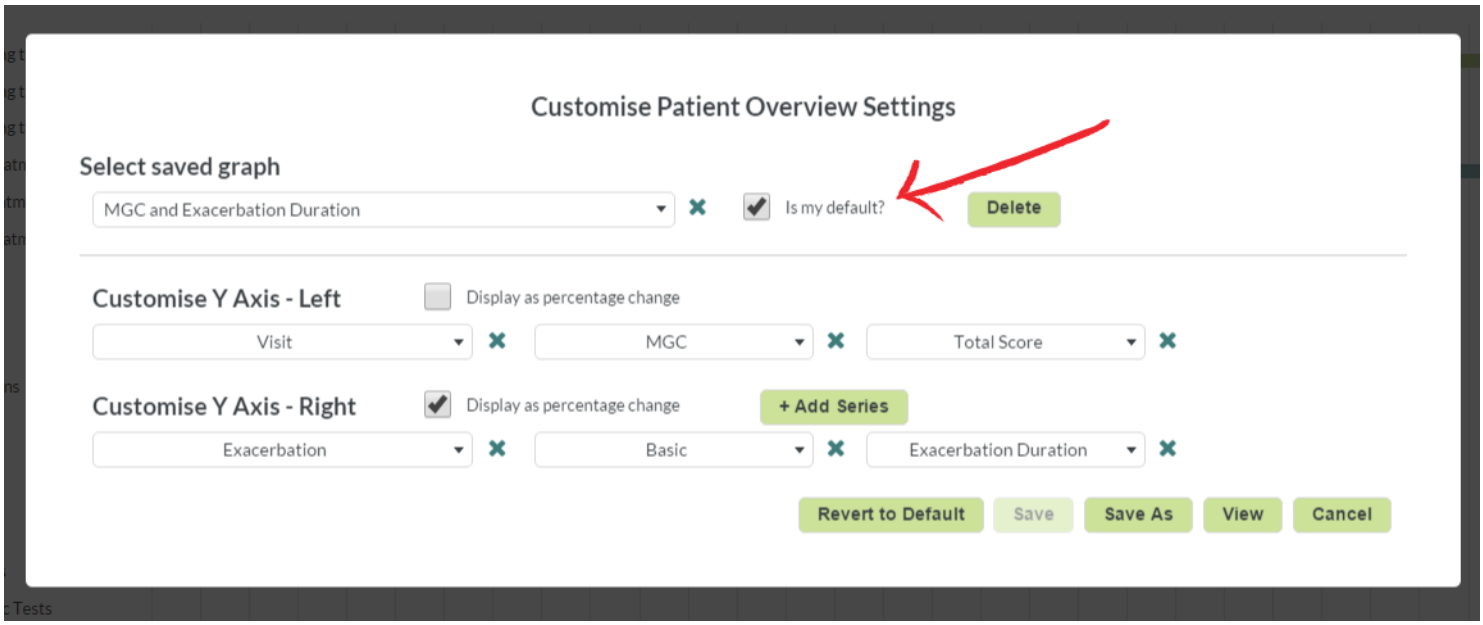


Figure 46 - Setting a default POG

If there are too many graphs in the dropdown menu then you can delete them by using the Delete option. Should a saved graph need to be updated, the graph can be selected, modified and then saved.

11. User Forms

11.1. Overview

MDS allows you to capture demographic (Patient Profile), Treatment, Relapse, Visit, Medical Test and Medical condition information about the patient.

MDS understands that many medical professionals do not have time for detailed data entry. That is why, when creating MDS, the MGBase foundation has intentionally kept mandatory fields to the absolute minimum. Refer to the documentation below for which fields are mandatory. Alternatively, MDS will inform you when the form does not have enough information to save.

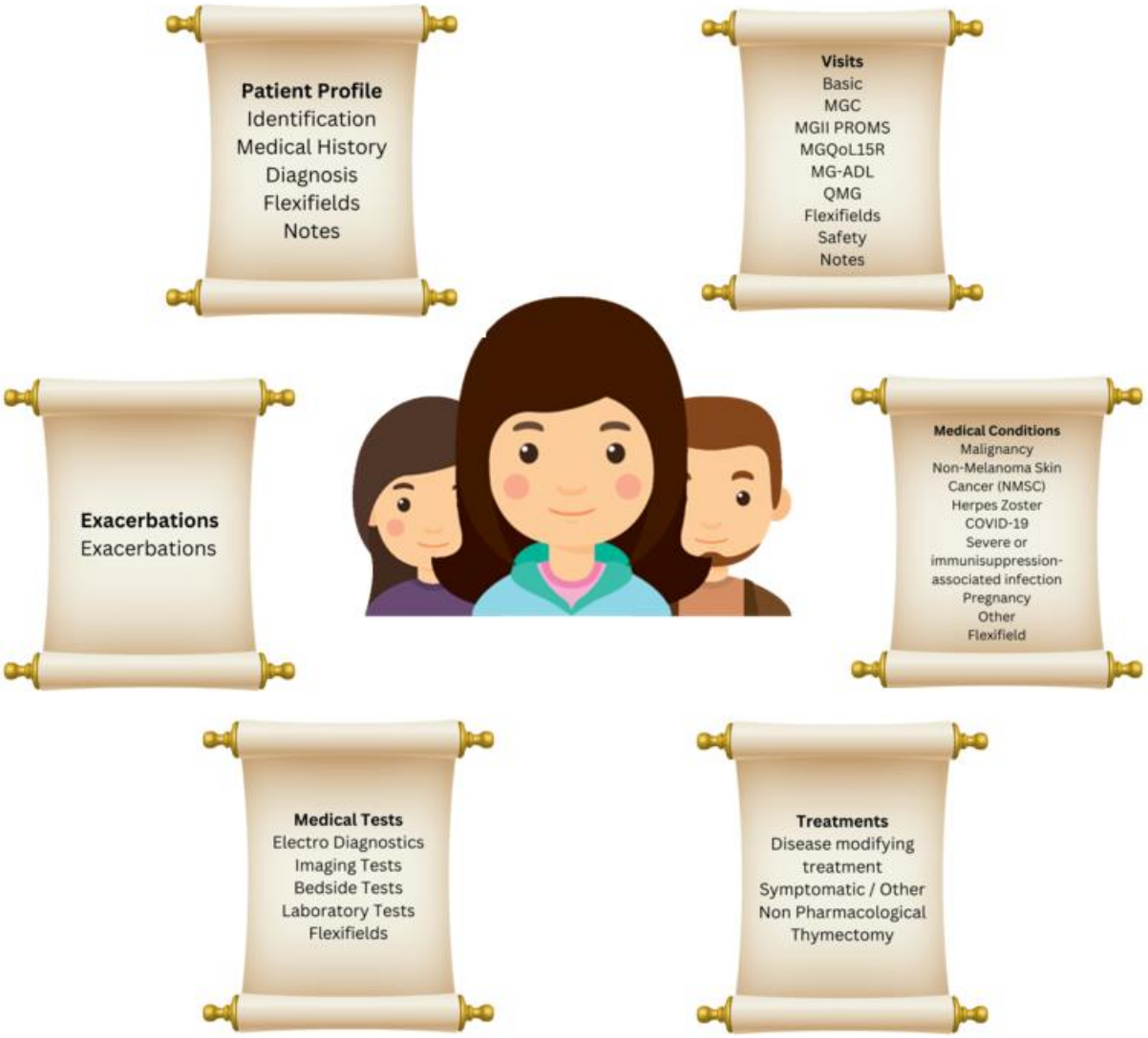


Figure 5 - Forms used by MDS to capture patient information

11.1. Patient Profile

The Patient Profile section captures basic information about the patient. Unlike the other forms in MDS, the Patient Profile forms are not time-series, meaning that a patient will only have one of the below forms. This section includes:

- The **Identification** form captures basic demographic details, for example the Age and Sex and demographic details of the patient.
- **Medical History** captures information about the patient's medical history and family medical history.
- **Diagnosis** captures MS specific diagnosis information about the patient and is the key component in determining the MS Course of the patient.
- **Flexifields** capture the additional centre specific fields if added by the centre. If the patient is enrolled in a sub-study that collects data, then the Sub-study flexifields will also be displayed.
- **Notes** section allows the user to capture notes about the patient.

11.1.1.Exacerbations

Exacerbations captures information about the patient's exacerbations in a time-series format. One patient can have multiple exacerbation events captured.

11.1.2. Treatments

The Treatments section captures basic information about the treatments assigned to the patient as time-series data. A patient with MS may have many different treatments over time. There are three types of treatment forms:

- **MG Specific Treatment** captures information about the patients ongoing and complete MG Specific treatments/DMT's (Disease Modifying Treatments). Some treatments may have an ongoing schedule, for example 30mg once per week or a **single dose** injection once every 6 months. For ongoing treatments, then the treatment should have a start and end date that spans the duration of the treatment. For a treatment that is a single dose, then the start and end date should be the same.
- **Symptomatic Treatment** captures information about ongoing and complete symptomatic treatments. An example may include Prednisone given to a patient to treat a relapse.
- **Non-Pharmacological** captures information about non-pharmacological treatments assigned to the patient. These may include, for example, physiotherapy or speech therapy.
- **Thymectomy** captures information about a thymectomy procedure including the types of procedure, data around preoperative treatment, hospital length of stay, postoperative complications and also comprises a section on pathology and thymus size**.**

11.1.3.Visits

The Visit section captures information about the patient when they visit the clinic. A patient may have many visits and each visit is separated into the below tabs:

- The **Basic** tab captures the commonly entered information about the patient during a visit. For example, the reason for their visit, height/weight and the results of clinical tests (8m-walk test, 9-hole-peg-test, blood-pressure, pulse).
- The MGC tab is the calculator used to select relevant values used to help determine the MGC score total.
- **The MGII PROMS tab contains 4 main sections with questions relevant to the MGII Patient Reported Outcomes Measures**
- **The MGQoL15R tab contains a calculator with 15 questions specific to this specific MG Quality of Life questionnaire. The total is calculated based on selections.**
- **The MG-ADL tab contains questions relevant to MG Activities of Daily Living with relevant scores and an auto-calculated score total.**
- **The QMG tab contains the Quantitative Myasthenia Gravis questionnaire with 13 questions and a total score auto-calculated depending on selections.**
- The **Flexifields** tab is where either centre specific flexifields, or sub-study specific flexifields, are captured.
- **Safety** allows you to capture information relating to post-authorisation safetystudy (PASS).
- The **Notes** tab allows you to capture notes about the patient.

11.1.4.Medical Tests

The Medical tests section captures information about medical tests performed on the patient. There are 5 different medical test forms that can be used in MDS:

Electro Diagnostics captures information about test results for SFEMG (single-fibre electromyography), Repetitive stimulation and NCS (Nerve conduction study)

Imaging Tests capture information primarily around imaging and type of Chest imaging modality (CXR, CT, MRI) and Chest finding (outcome)

Bedside Tests capture information around Edrophonium and Ice Test results

- **Laboratory Tests** captures information about Myasthenia Antibodies, Haematology, Blood Chemistry, Thyroid Tests, SMicrobial Tests, Auto-antibody tests and Others. Each tab contains a set of lab results, and each result can have a value, unit and comments. Where the values are out of range, or otherwise not normal, the *Normal?* column may be filled out and additional comments captured explaining the reason for abnormality, or other notes that the practitioner may want to enter.

- Custom **Flexifield** medical tests may also be captured. For example, your centre may have its own type of standardised testing that should be captured for each patient. These tests can be configured in the Preferences section and then added each time the patient performs a test.

11.1.5.Medical Conditions

Medical Conditions capture a wide range of ailments a patient might be experiencing.

- **Malignancy** allows you to record occurrences and details of malignancy. The MedDRA classification should be used to identify the type of malignancy and supplementary information provided in the fields (for example Stage and Treatment modality). If the malignancy is related to the death of the patient, then the malignancy should be recorded as an *Immediate/Underlying* cause of death.
- **Non-Melanoma Skin Cancer (NMSC)** allows you to record occurrences and details of NMSC. If the NMSC is related to the death of the patient, then the NMSC should be recorded as an *Immediate/Underlying* cause of death. MedDRA classification should be used to identify the type of NMSC.
- **Herpes Zoster** allows you to record occurrences and details of Herpes Zoster.
- **COVID-19** allows you to capture data related to a patient contracting the SARS-CoV-2 Virus. Fields include a MedDRA classification which defaults to COVID-19, a Date of onset, Diagnosis confirmed (note, if "Yes" choices present a list to select from including "PCR", "Serology / Rapid Antigen Test", "Typical Chest Imaging Finding". The following sections are also covered: Symptoms, Other Medical Conditions, Lab Tests, Severity Indicator, Hospital Related Incidents and Outcome.
- **Immuno-suppression or infection** allows you to capture medical conditions that are related to suppression of the immune system or other infection. You should use MedDRA to classify the condition and populate additional fields where required. If the infection is related to the death of the patient, then the infection should be recorded as an *Immediate/Underlying* cause of death.
- **Pregnancy** form allows you to record occurrences and details of pregnancy. The pregnancy page is only visible if patient is female and captures information about births and terminations/miscarriages.
- **Other Events** captures medical events that are not classified as Melanoma, Immuno-suppression related, NMSC or Herpes Zoster. A medical condition may be selected from the reference data, but MedDRA is the preferred classification format. If the condition is related to the death of the patient, then the condition should be recorded as an *Immediate/Underlying* cause of death. **If the condition is a result, or related to, a drug that the patient is taking, then link the drug with the medical event using the dropdown list (which will display all drugs that the patient has taken *prior* to the occurrence of the condition).**
- **Flexifield** captures custom medical events or paraclinical tests. For example, if your centre was investigating Migraines, then a form capturing each Migraine (with Migraine specific fields) should be captured for each Migraine event (this form might include Duration [number field], Time of headache [dropdown box including morning, afternoon, evening], See Aura? [checkbox] and Further Comments [free text area]). Furthermore, if your centre then wanted to extend the migraine research with a cognitive test (for example), then this custom test should be created as a Paraclinical test instance.

12. Statistics

12.1. Overview

MDS provides an overview of patient statistics for your centre. The graphs display information about all patients in MDS, not just those that are enrolled in the Registry. To see an overview of patients enrolled in just the Registry, refer to the Patient Demographics section. The statistics section can also be used to filter your patients to a sub-set instead of using the search function.

Currently MDS provides the following graphs/distributions:

- Duration of MG.
- MGC at last visit: The Myasthenia Gravis Composite Score at last visit.
- Exacerbations in the last 12 months.
- Age at onset of MG.
- Age at diagnosis of MG: The age at which your Myasthenia Gravis was diagnosed.
- Age: The length of time a person has lived.
- Gender.

Figure 47 - The statistics section

12.1. Displaying statistics for a subset of patients

By default, MDS will display the statistics for all patients in your centre, but statistics may be applied to a subset of patients by using the Search functionality. When you search for patients, the results will be filtered to meet the search criteria. If you then view the Statistics section, then only the statistics for the patients that meet your search criteria will be displayed. In the below example we have searched for all patients below 20 years of Age and are displaying the statistics for those patients only.

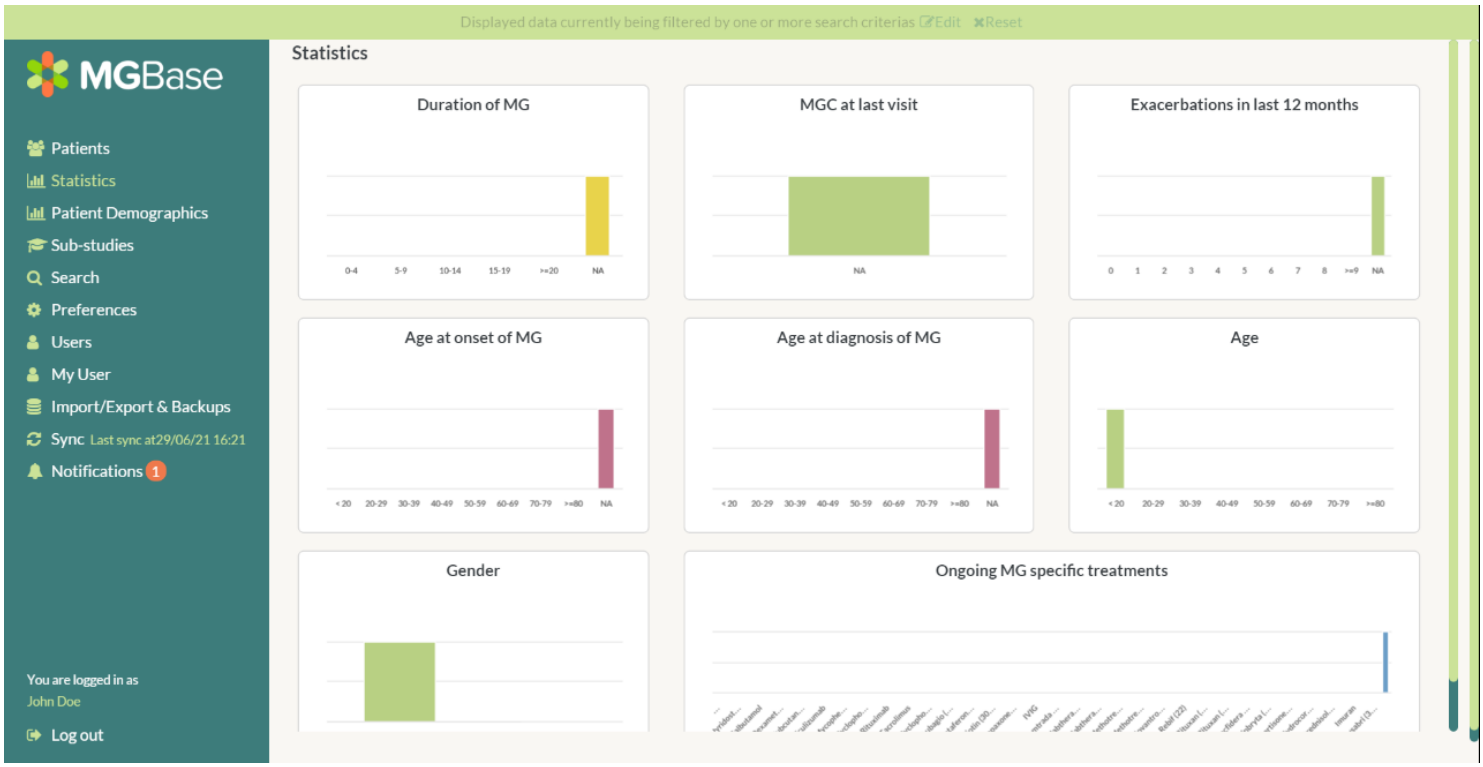
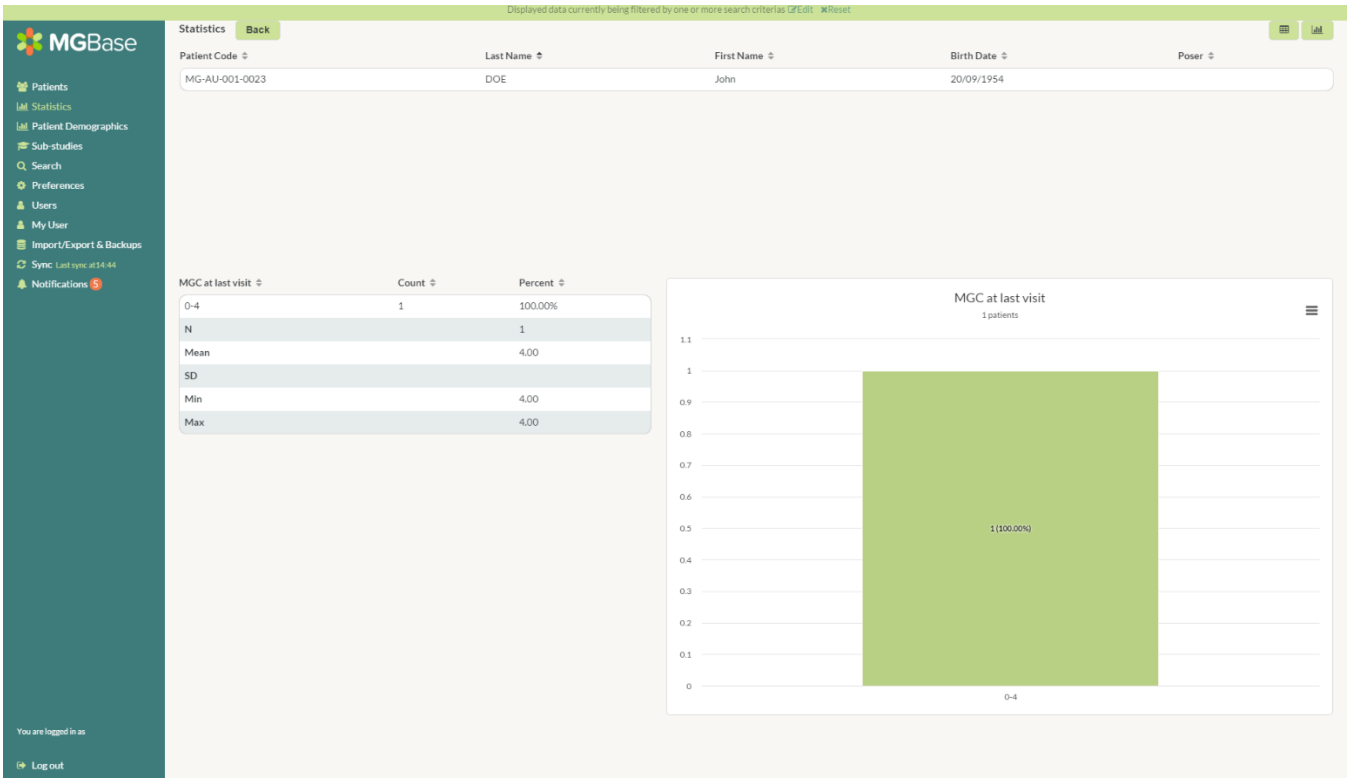


Figure 48 - Filtered statistics for patients younger than 20 years of age

12.2. Cumulative Filtering

MDS allows you to use the Statistics section as a visual search/filter function. By clicking into each distribution and selecting the desired bar, the results will filter. The below example visually represents all the males who have had a Total MGC at last visit of less than 5.



The filters can be removed by selecting “Reset Filter”.

13. Sub-studies

13.1. Overview

What is a sub-study? A sub-study is a mechanism that allows centres to share data for research purposes. Creating a sub-study is a way that you can request data from other centres, while joining an existing sub-study will allow you to contribute your centre's data for research.

13.2. How does a sub-study work?

For example, consider you want to analyse the data for "*All females from Australia and New Zealand*". Once you have entered the basic details about the sub-study, you then need to identify the Member Selection, Patient Selection and Flexifields. The Member Selection would be *countries that are equal to Australia or New Zealand* and the Patient Selection would be restricted to "*Gender = Female".*

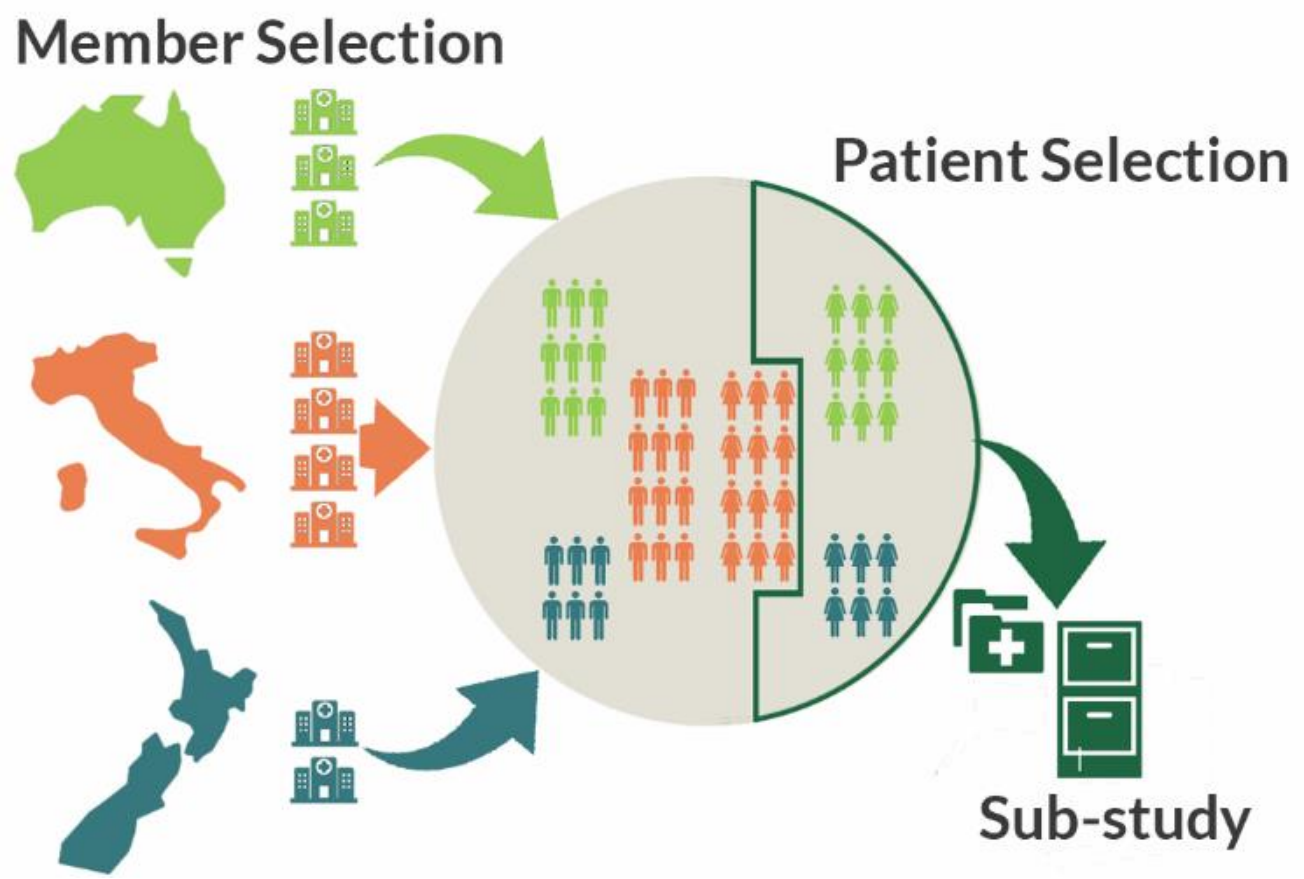


Figure 49: Visualisation of the selection process of All females from Australian and New Zealand centres. Note Italian females were not included as they did not meet the Member Selection criteria.

Once the sub-study is active, and as soon as a member joins your sub-study, then the data of all the patients meeting the selection criteria will be available to download for the creator of the sub-study only. This is called *Automatic enrolment* and is the default for most sub-studies. Some sub-studies may require *Manual enrolment*. These studies require members to manually enrol patients to the sub-study. Reasons for this method might include:

- Selection criteria that is complex or may require a medical/other judgement from the centre
- Sub-study that requires special ethics or patient approval

Sub-studies can be created if you have PI privileges. This section provides details on how to create a sub-study, manage that sub-study and view and join sub-studies. Studies can be created either in MDS or the Registry.

All sub-studies will require to be approved by the MGBase Operations team after submission. If you have any questions, please contact the team at info@msbase.org.

13.3. Viewing sub-studies

You can View sub-studies when logged into MDS, however only a PI will be able to join the centre to the study. Sub-studies that your centre is eligible to join will be presented first in the *Available Studies* section, while sub-studies that are not available for your centre (due to centre or country restrictions), are in the *Other Studies* section. You can view the details of the sub-study by selecting View or you can join the sub-study by selecting Join.

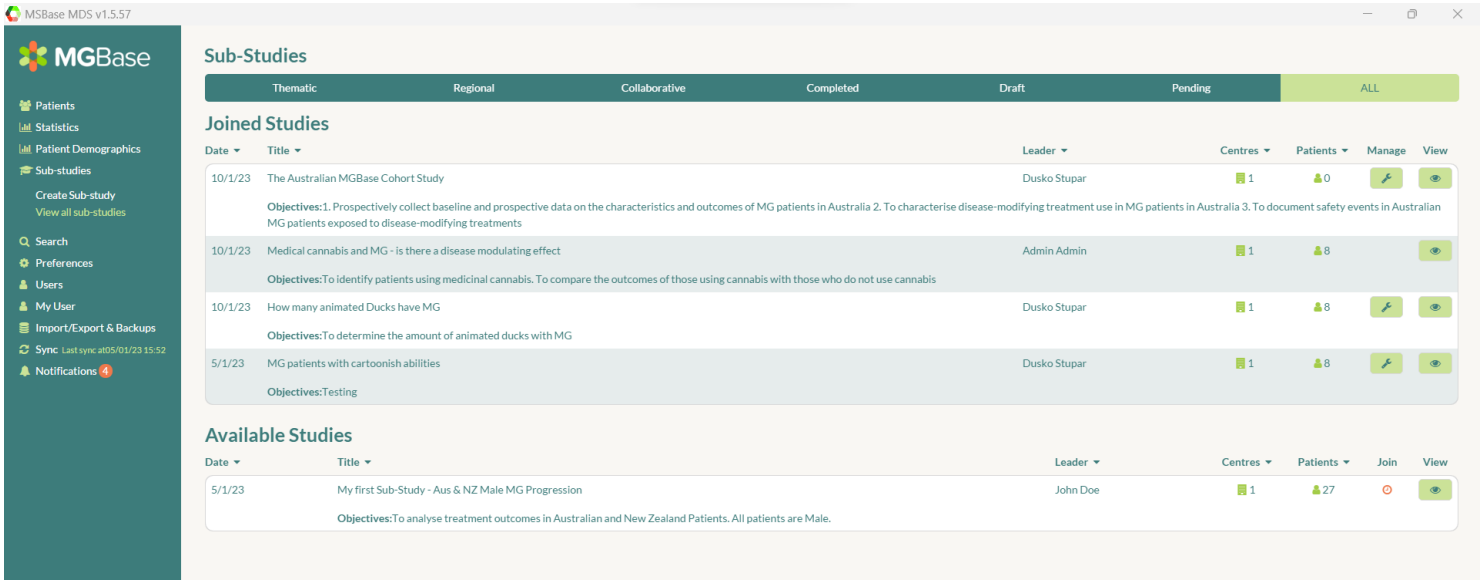


Figure 50 - Viewing sub-studies in MDS

All users will be able to see basic information about the sub-study when viewing the individual sub-study. This information includes sub-study descriptions and endpoint, Enrolment History and Enrolment Country distributions. You can also join the sub-study from this section by clicking Join Study.

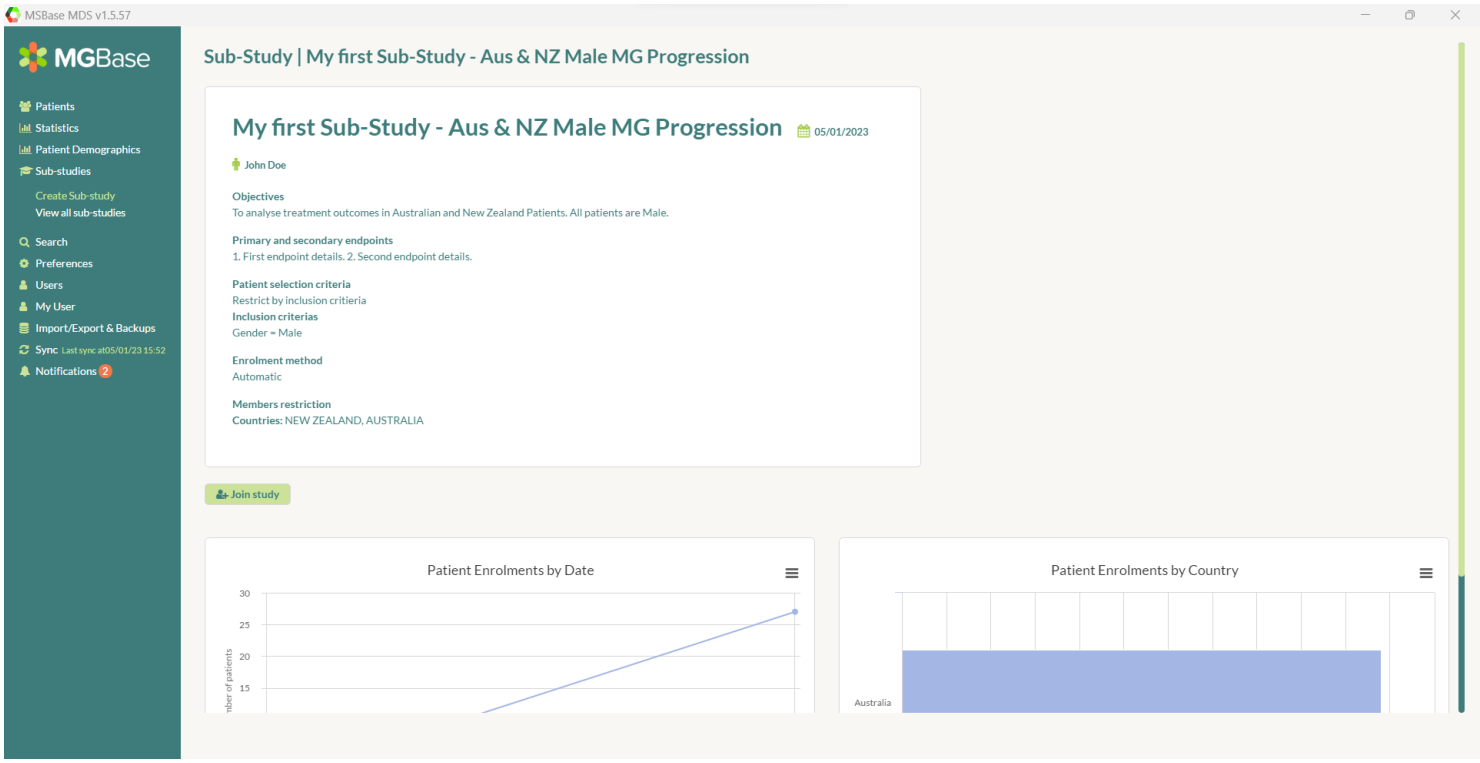


Figure 51 - Information about the Aus & NZ Male MG Progression sub-study

After joining a sub-study, the owner of the sub-study must accept your join request. Once the request has been approved then you will also be able to view other member information, news and documents and patient demographic data.

If you are the manager of a sub-study, then you will receive an email notification when another MGBase member requests to join.

13.4. Joining sub-studies, Enrolment and Manual enrolment

Some sub-studies are specified as Manual Enrolment and operate on an opt-in basis. This is different to the automatic enrolment as it requires the member to manually select the patients they want to enrol. This may be useful if the patient inclusion criteria are subjective or complex.

If you have joined a sub-study that has manual enrolment, there are two ways you can add patients. One way to add them is at the sub-study level. To do this, go to the sub-study and on the Overview tab select Enrol Patients.

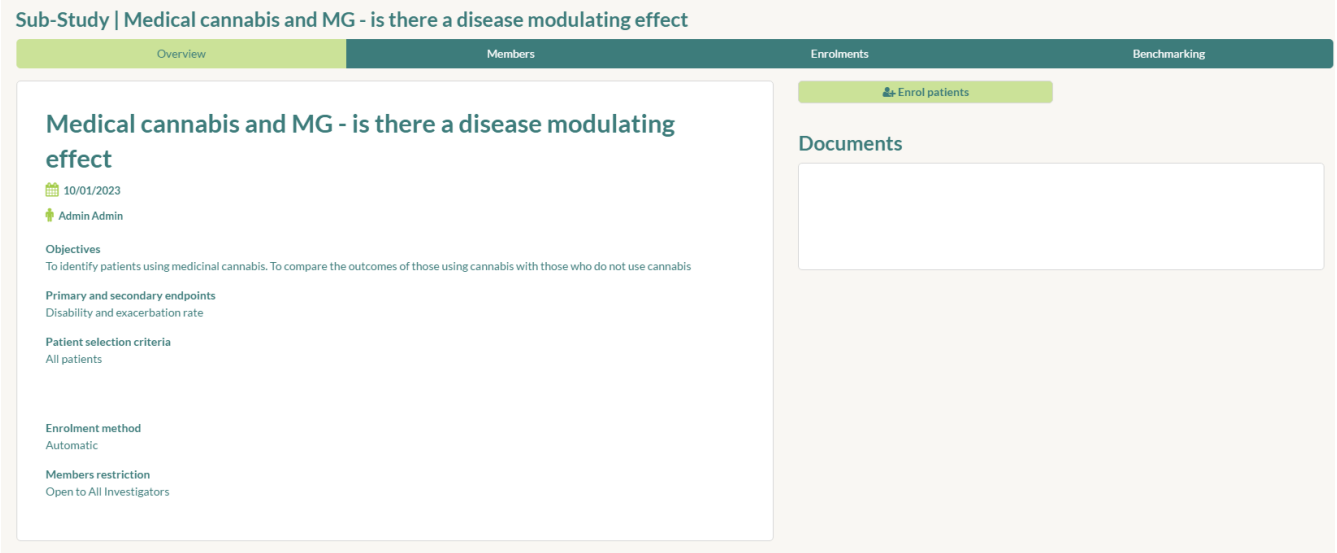


Figure 52 - Enrol a patient via the sub-study

A new window will allow you to add patients by selecting the Enrol and Unenroll button. In some cases, your patient will not be able to be enrolled to a manual sub-study. This is due to the patient criteria restricting access. For example, we can restrict a sub-study to females only and still require manual enrolment.

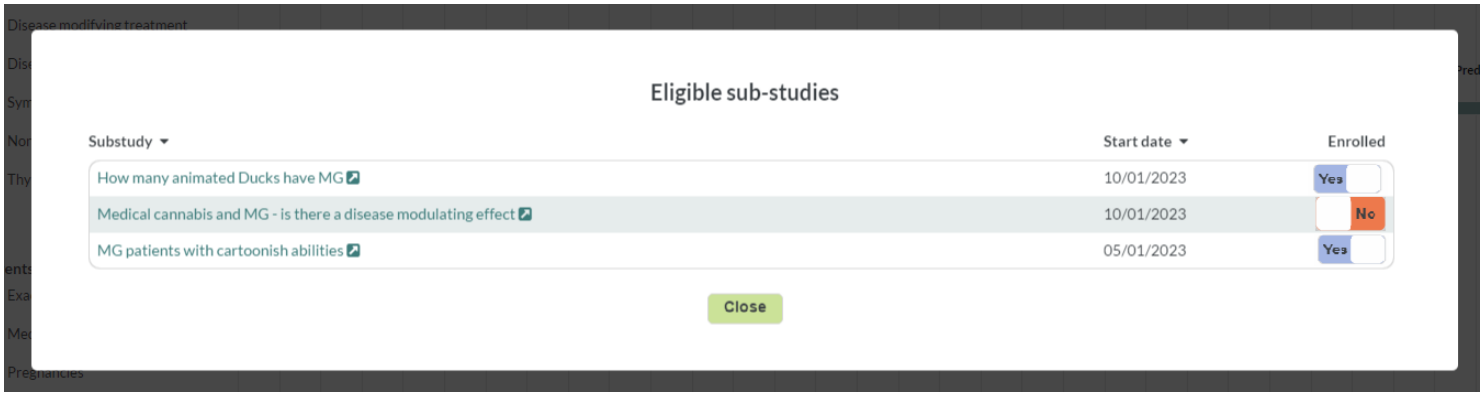


Figure 53 - Enrol a patient manually

An alternative way to enrol patients is in the Patient View, refer to earlier section8.8 *Enrolling into a Sub-study* for how to complete this.

Good to know!

In what circumstances should I use either view? The sub-study specific view detailed in this section should be used when you first join a sub-study and want to enrol multiple patients in bulk to the single sub-study. The patient specific view explained in earlier sections should be used when a patient is new to the Registry and you want to enrol him/her to one or more sub-studies.

13.5. Managing sub-studies

To manage your sub-study, find your sub-study and click Manage. The Manage dashboard allows you to re-invite members (an automatic email will be sent to all eligible centres) and download all the data of the participating patients. New centres that wish to join your sub-study will need to be Accepted or Declined before their data becomes accessible.

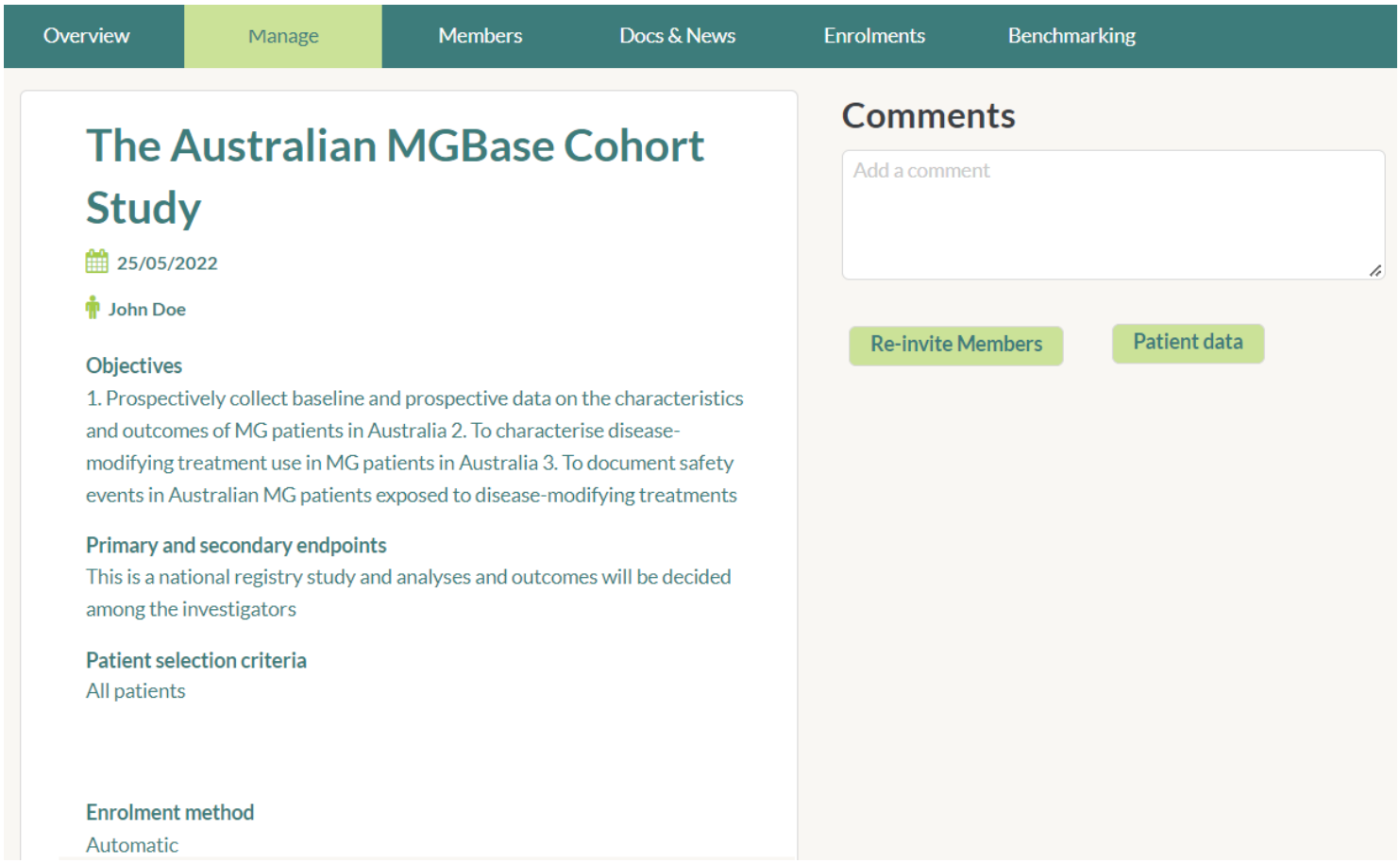


Figure 54 - Managing a sub-study

When a new centre is accepted, the patients will be automatically enrolled into your study (except where manual enrolment is set). As new patients from participating centres become eligible for your study, they will be automatically added to your sub-study. Once a patient is added to your study then they cannot be removed. For example, if your selection criterion is: "*Has an **ongoing** treatment of Drug X*" and a patient stops treatment, then that patient will stay in your sub-study.

13.1. Sub-study news and documents

As the leader of a sub-study, you can communicate with your members by posting Docs & News to keep members up to date. Selecting Add will open a text editor, allowing you to add sub-study news. You are also able to upload documents relevant to the sub-study. Select Files that you want to upload and select Start Upload.

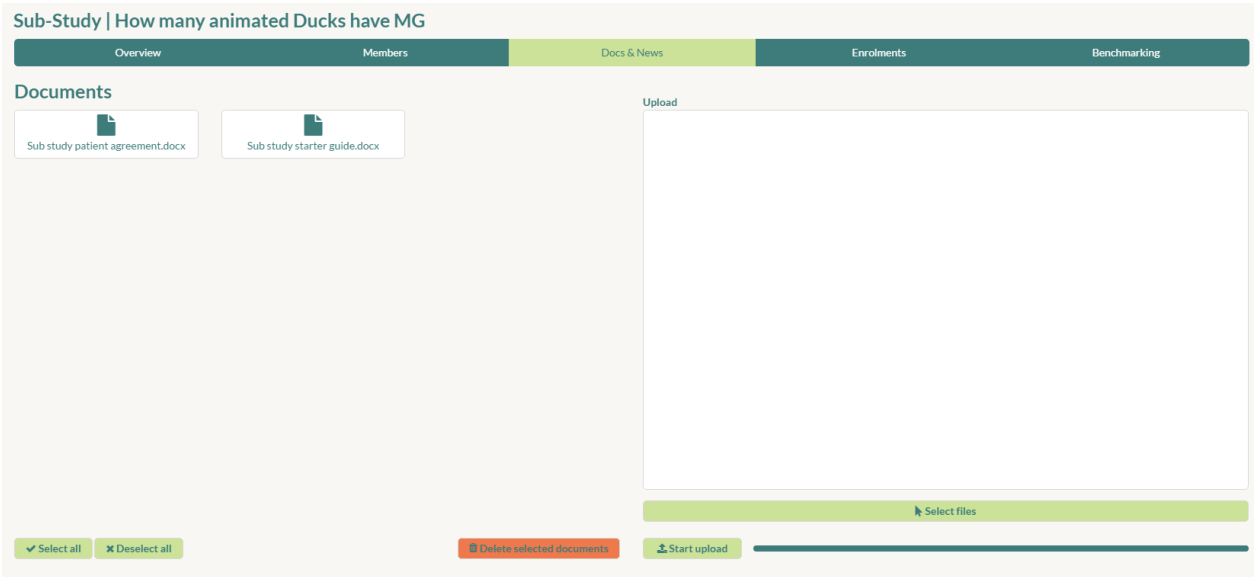


Figure 55 - Adding documents and news items

News and Documents will appear to all members of the sub-study. Members will also receive an email notification of the News item and Document addition.

13.2. Patient Enrolment graphs

Patient enrolment for the sub-study displays the enrolments by date and enrolments by country. By hovering over the markers in either graph, the tooltip will display exact numbers and date.

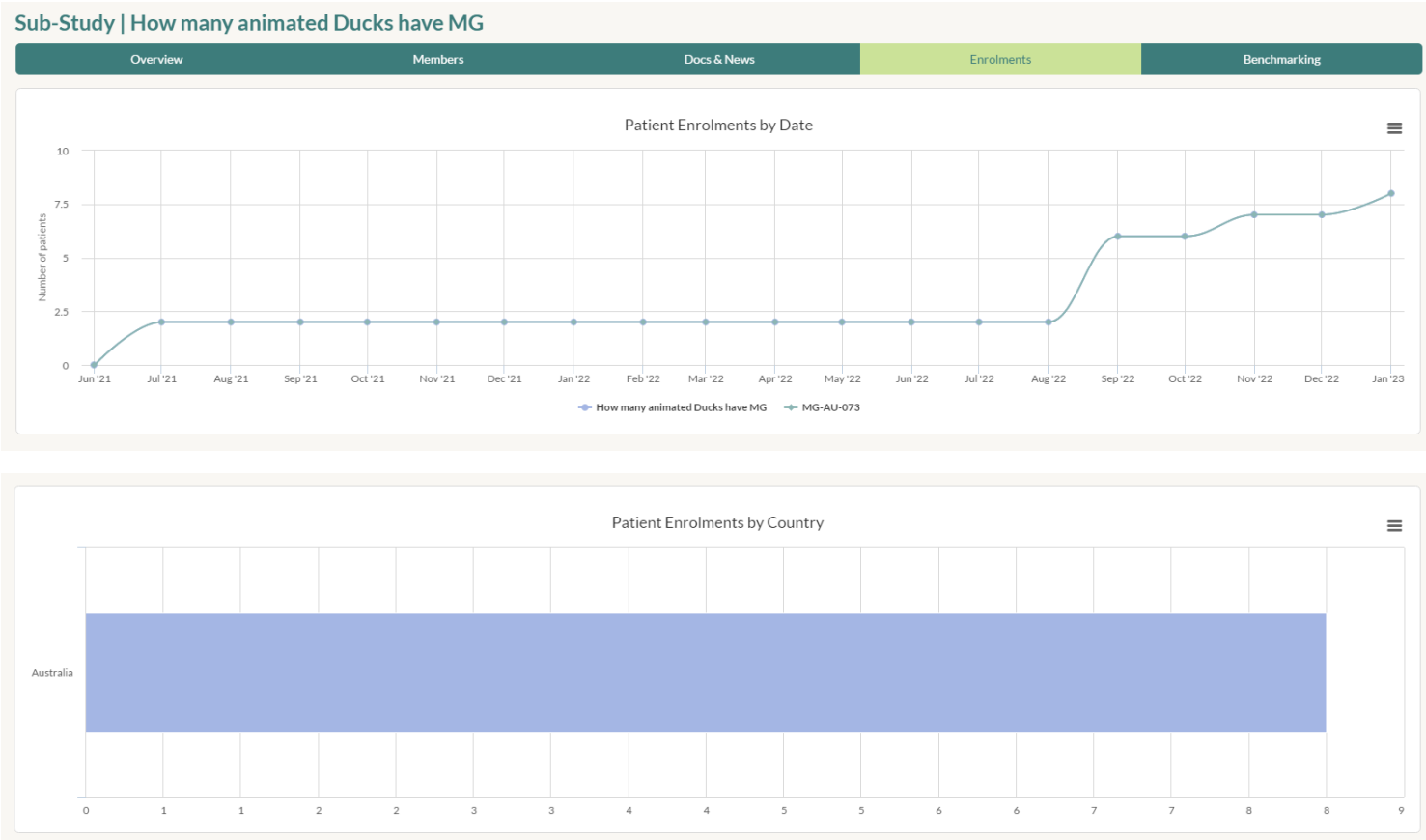


Figure 56 - Patient Enrolment

13.3. Displaying Members of a sub-study

Members of a sub-study can see other members, their contact details and their email address. To view the profile of a sub-study member, select the View option.

Figure 57 - Sub-study members section

13.4. Benchmarking

The MGBase Registry allows members of a sub-study to benchmark their centre data against the overall data in the sub-study cohort as well as the entire MGBase Registry. In the below example we can see that the sub-study has 5 females (100%), while the MGBase Registry consists of 36,376 (70.46%) females and the sub-study members centre (AU-033) has just 1 (16.67%) female.

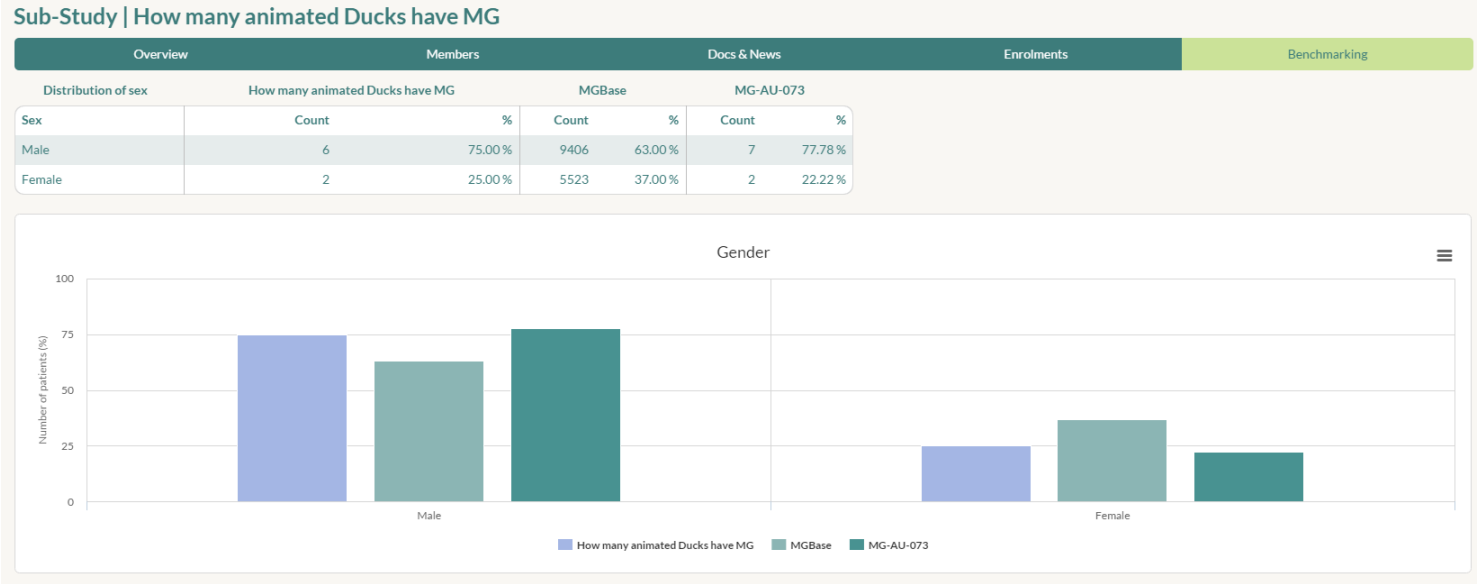


Figure 58 - Sub-study benchmarking

13.5. Creating sub-studies

13.5.1. Project Description

A sub-study can be created by a PI To create a sub-study, select Create Sub-study and fill in the required details. These details will be used by other members to decide whether they wish to contribute data to your research, therefore it is important to be descriptive. Your sub-study details will also be visible on the MGBase website, so please take this into consideration should your research topic contain any confidential or sensitive content. Finally, please ensure that the title and description is in English. Once you have finished entering details about your sub-study, click Next.

Figure 59 - Create sub-study - Step 1 - Project Description

13.5.2. Member Selection

When selecting Members, there are three options.

- Open to all Investigators: This option will allow any member from any country or centre to join
- Restrict to Investigators from the following countries: This option will restrict member selection to country
- Restrict to Investigators from the following centres: This option will restrict member selection to individual centres

In our example we are restricting members by country by only allowing Australia and New Zealand members to join. Once we have selected our members, click Next. **Your centre must be in the country that you are restricting by or must be one of the centres if restricting by centre.**

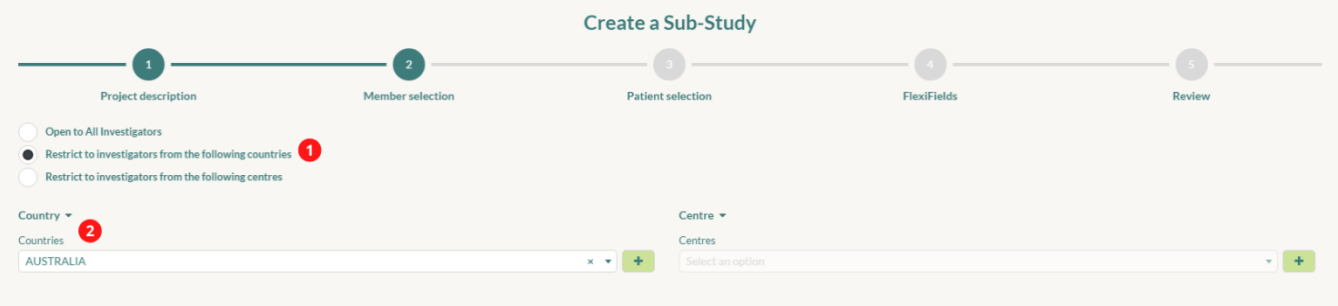


Figure 60 - Create sub-study - Step 2 - Centre Restrictions

13.5.3. Patient Selection

After selecting our members, we must then restrict the patient selection. Patients can be restricted in 3 ways:

- **All patients**: "All patients" removes all restrictions.
- **Restrict by inclusion criteria**: All patients that meet a specific search criterion
- **Restrict by manual enrolment**: Used in combination with the above, if this option is checked, then the member must manually enrol each patient individually.

In the below example we have made the decision to restrict the patient inclusion by search criteria. We then enter the desired search criteria and click Next.

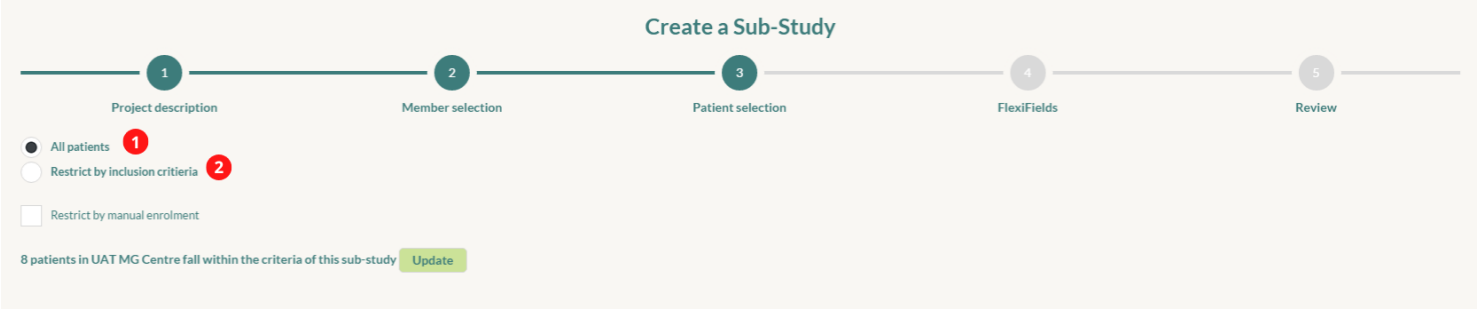


Figure 61 - Create sub-study - Step 3 - Patient Selection

Good to know!

The Patient Selection screen will display how many patients in your centre meet the search criteria. In the above example 231 patients meet the search criteria (i.e. are female). If you have 0 patients meeting your search criteria, it may be an indicator that your search has an error or is overly specific.

If you are unsure about which fields you need, or have complex search criteria, simply continue with the sub-study creation process and when finished send an email to the MGBase Operations team at info@MGBase.org . Additionally, for more complex searches, it may be preferable to be more inclusive and remove additional patients during data cleaning.

13.5.4. Flexifields

Do you have specific data you require about each patient for your research? For each sub-study it is possible to capture custom data fields. Patients that join that sub-study will have those fields sent to their MDS application for additional data entry.

If the patient is enrolled in a sub-study that has its own sub-study flexifields, then they will be displayed with different tabs.

There are 7 different types of fields that can be captured for a sub-study. Data types include:

- Text: Alphanumeric text restricted to 200 characters
- Numeric: Number only with a maximum of 3 decimal places
- Date: Date field for past and future dates
- Text-Area: Alphanumeric text for comments and longer text
- Dropdown: Allow the user to select 1 value from a list of many values
- Checkbox: For True (checked) and False (unchecked) values

- Section Break: For complex data entry forms use the section break to sort the fields into logical sections

Data can be captured at the Patient Identification level and at a Visit level. Patient Identification should be used for data that will be captured only once and won't change over time (for example patient permission acknowledgement, eye-colour or phone-number). Visit data is captured at each visit and utilises time-series/longitudinal fields (for example height, weight or current mood). Simply select the section you wish to add a field to, then click Add. When finished, click Next.

For our example, we are capturing Pulmonary Function – Total Lung Capacity (Numeric) and Pulmonary Function – Vital Capacity (Numeric)

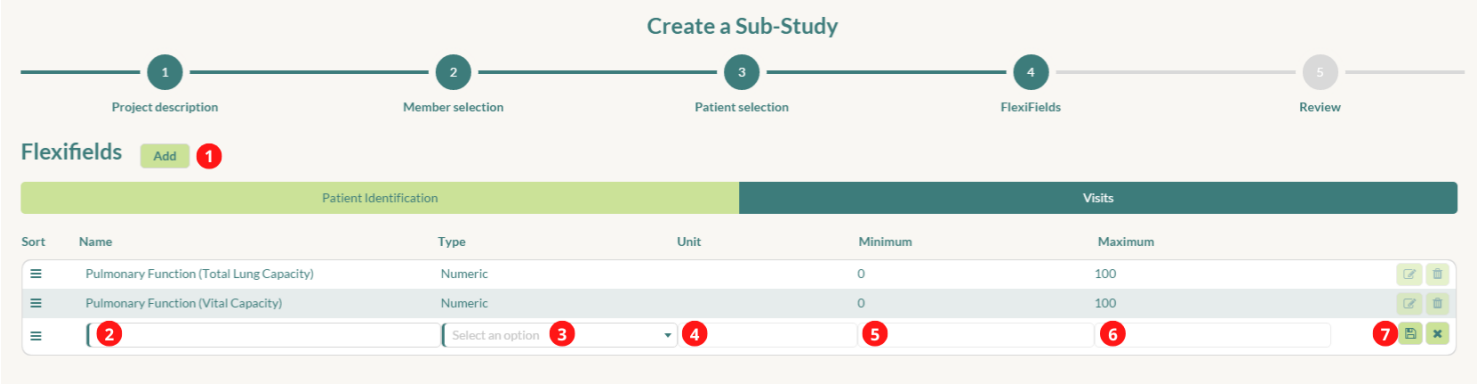


Figure 62 - Create sub-study - Step 4 - Flexifields

Prior to submitting your sub-study, review the details and change as required. When ready to submit your study for approval, click Save. You can Cancel the sub-study at any point.

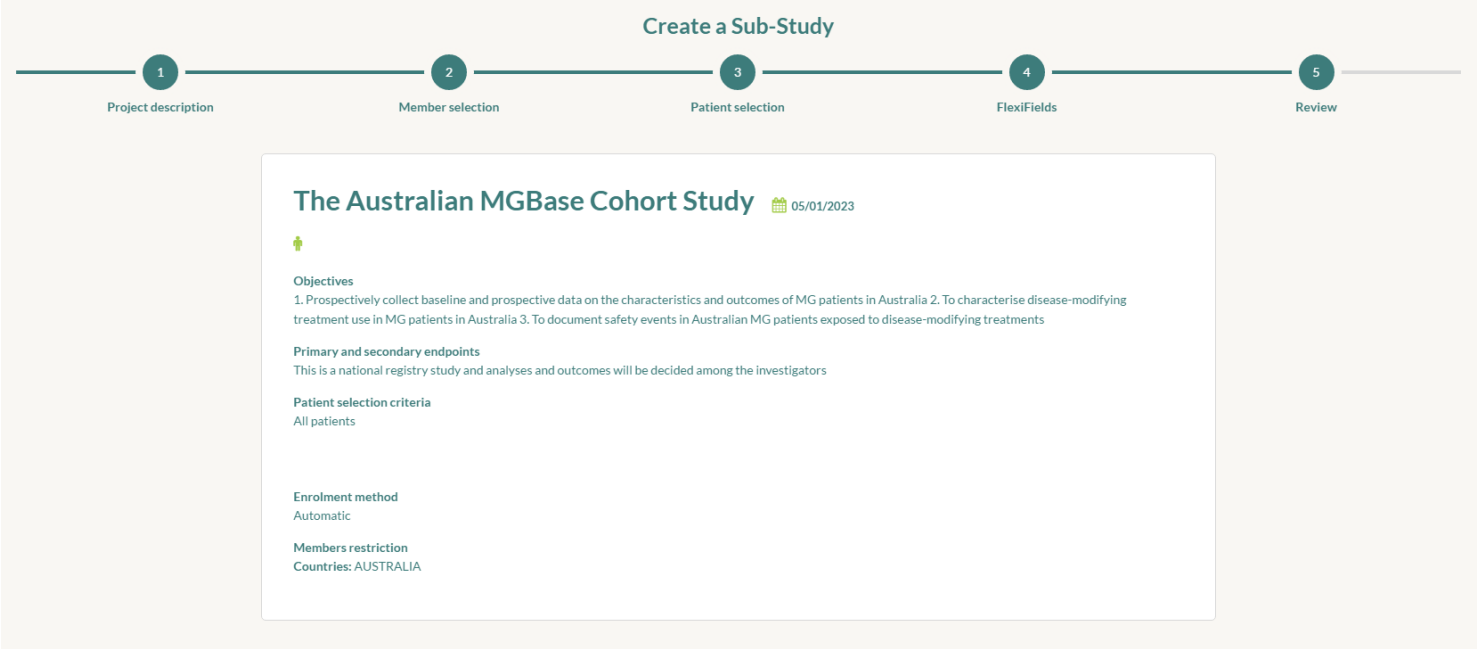


Figure 63 - Create sub-study - Step 5 - Review and Submit

Your sub-study is now awaiting approval from the MGBase Operations team. You can enquire about progress at any time with the Operation Team at info@msbase.org . You will be notified by email if your sub-study is successful. All eligible members will also be sent an email advising them that a new sub-study has been created.

14. Search

14.1. Introduction to search

MDS contains a powerful search interface which allows you to perform multiple nested searches. Nearly all fields are searchable within MDS. Spend some time familiarising yourself with this feature to ensure your searches are correctly formed.

In the below example, we are looking for all patients that meet **all the below** criteria

- All males
- Has an exacerbation after 2015
- Has a Visit after 2015
- Has MedDRA SOC value that is equal to *Respiratory* OR *Neoplasm* OR *Immune System*
- Has an Electro Diagnostic with a SFEMG equal to *Normal* or *Equivocal*

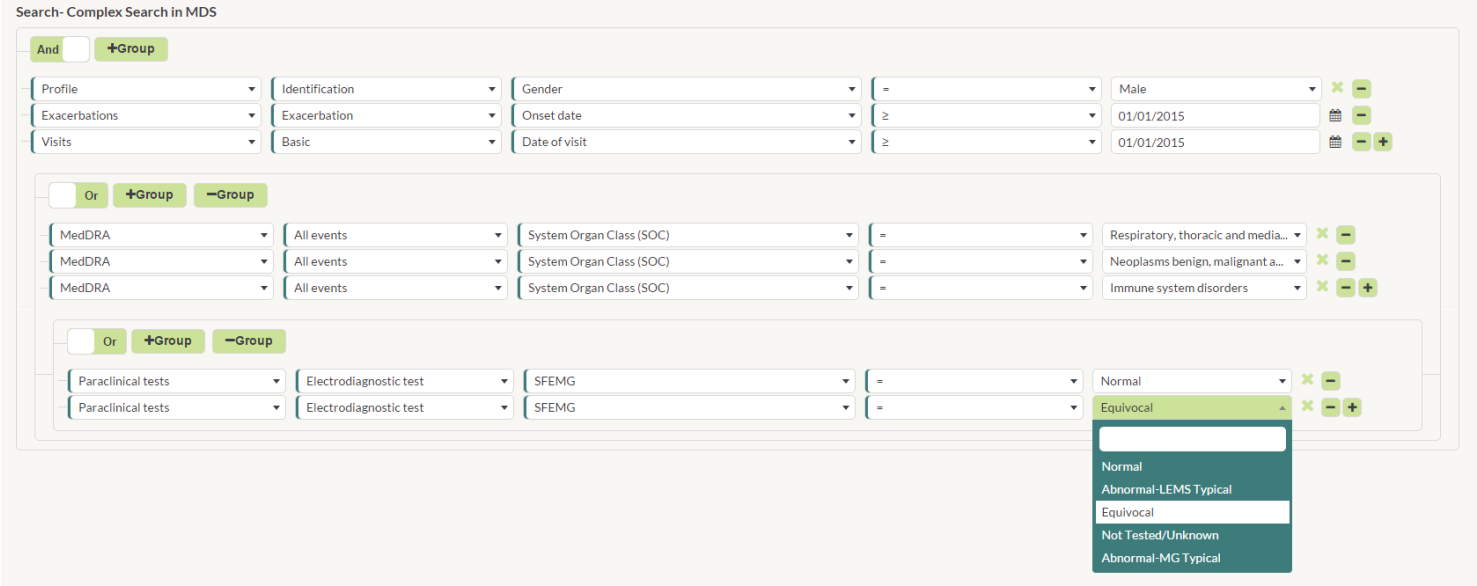


Figure 64 - A complex search in MDS

Note in the example that a new group is being used with an **Or** operator for both the MedDRA and MRI component of our search. This is because a patient should meet at least one of the criteria, but the patient does not need to meet *all* criteria.

A little confused? Read on below for further instructions.

Good to know!

The MDS search functionality is powerful but is not able to meet all the complex requirements for searches. You may be required to extract the data from MDS and apply searches in Excel, SPSS or another statistical tool. When performing searches, apply search criteria iteratively to ensure the results appear correct.

14.2. New Search

14.2.1. Field Selection

To find the field you wish to search, in the first drop-down list select the section the field appears in, then select the form in the second drop-down and finally the field name in third drop-down. You can also enter the name of the field and filter to locate the field faster.

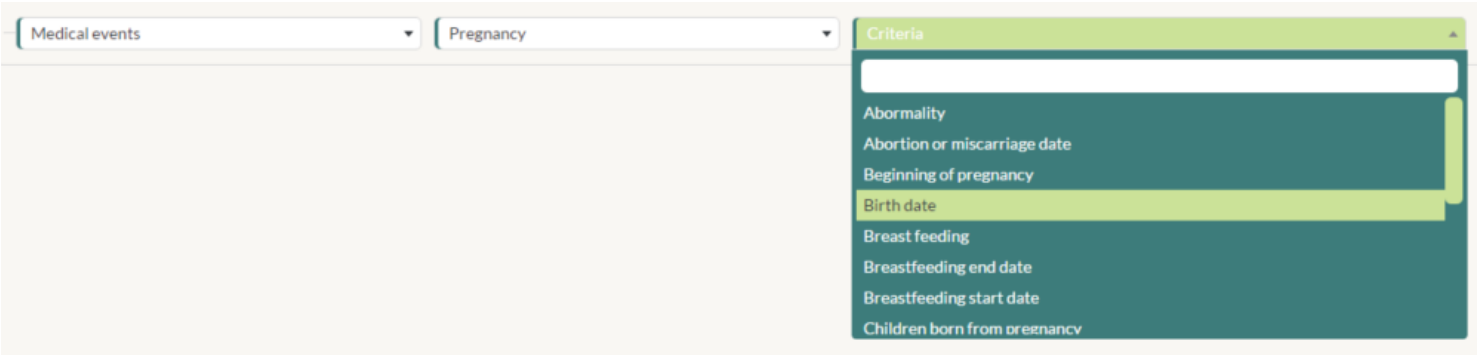


Figure 65 - Search field selection

14.2.2. Operators

The Operators allow you to give more precision to your search and are context dependent. For example, for number and date fields, we can apply an equal to, less than, greater than and not equal operators. Those operators are not applicable for a text field, so for text fields only Starts With and Contains is available. A complete list of operators is below.

- Number and Date Fields
  - = Equal to
  - ≠ Not equal to
  - < Less than
  - > Greater than
  - ≤ Less than or equal to
  - ≥ Greater than or equal to
- Drop Down lists, Options and Checkbox
  - = Equal to
  - ≠ Not equal to
- Text & Text Area
  - Starts With
  - Contains

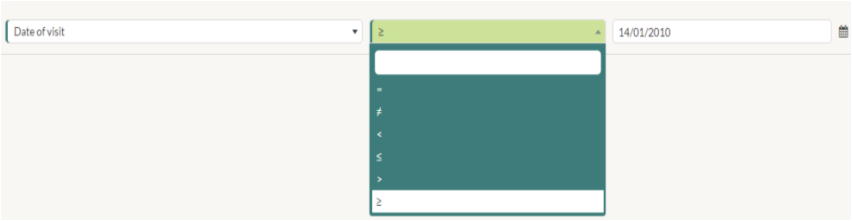


Figure 66 - Operators in MDS

14.2.3. Search - And/Or and Grouping

The And/Or operators join multiple criteria that are connected. This is more easily represented visually. In the below image we see that the *MedDRA Group (Green)* are joined by OR, meaning that for the group to be responsive, one or more of the three MedDRA criteria need to be met. Similar to *MRI Tests Groups (Purple)*, patients that meet one or more of the MRI requirements will be included. The *Parent Group (Red)* however is an AND operator, which means that for a patient to be returned in the search, all the 5 criteria must be met (Identification, Relapse, Basic, MedDRA Group, MRI Group) for a patient to be responsive to the search.

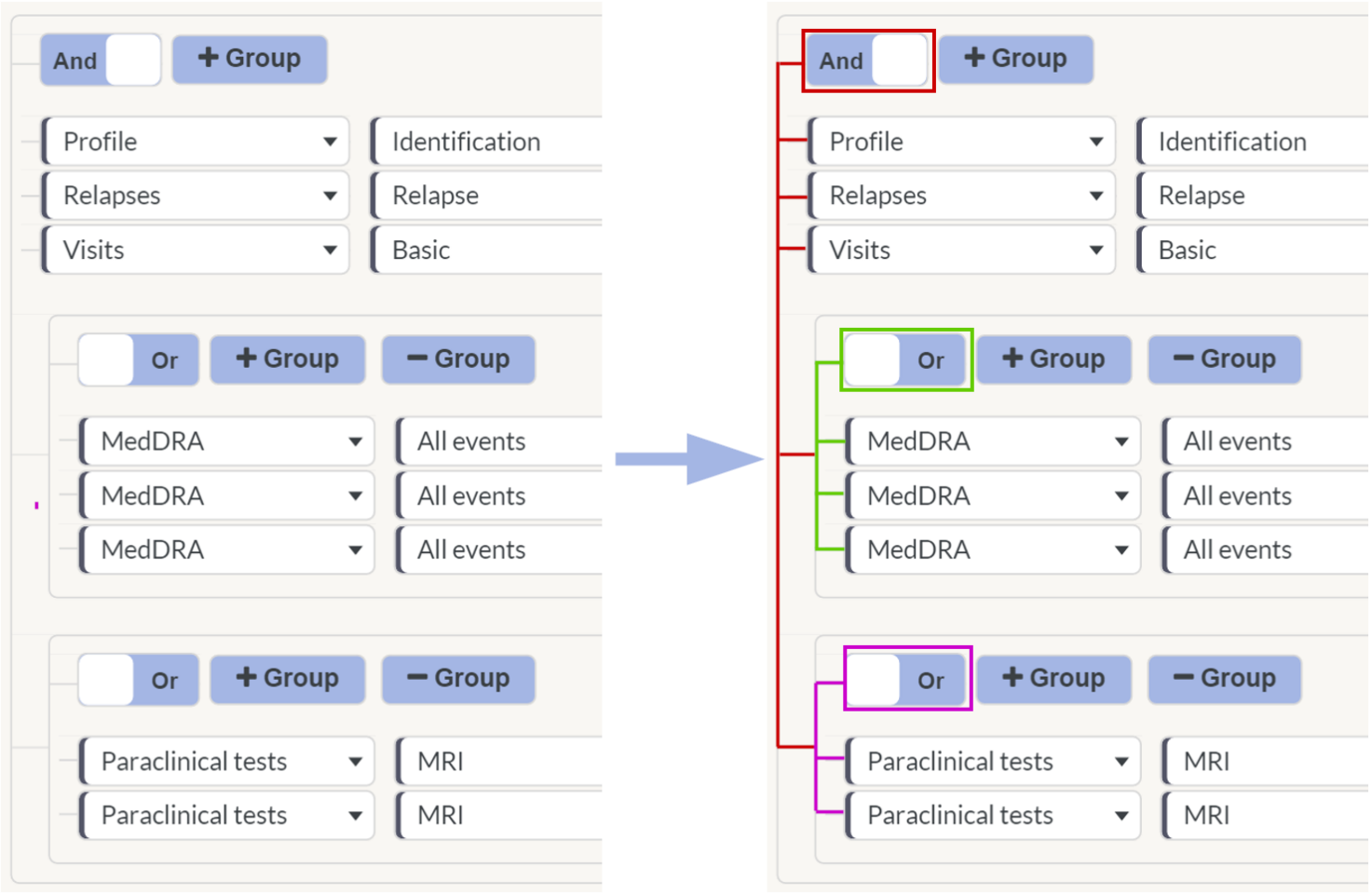


Figure 67 - And/Or operators and groups

14.3. Saved Search

Searches may be saved after they have been created. Simply select Save when constructing your search and enter a name for the search. Saved Searches are available for all other users in the centre to view and use. A saved search may also be edited as required.

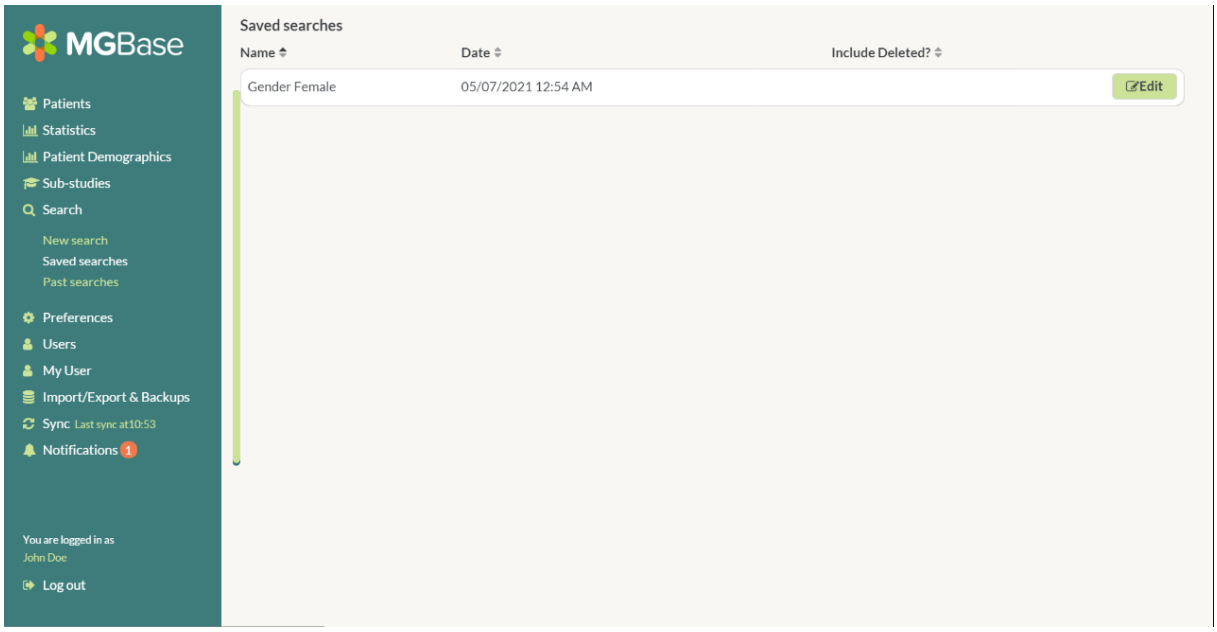
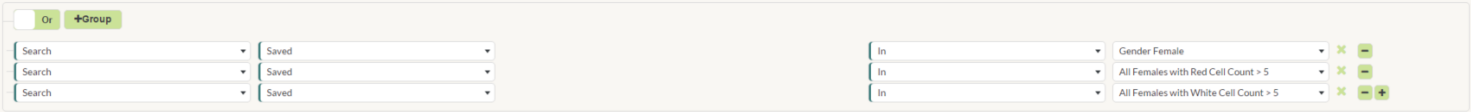


Figure 68 - MDS Saved Search

Good to know!

Saved Searches, and Past Search History below, can be used as a search parameter. This makes finding the union or intersection of two or more search results/history easy. Below we look for all Females or all Females with a Red Cell Count > 5 or all Females with a White Cell Count >5 by searching a set of saved searches.



14.4. Past Search History

Past Search History allows you to view and reapply previous searches performed in MDS. By clicking on the search, the results of the search are recalled and displayed.

Good to know!

What is the difference between the Search History (Past Searches) and Saved Searches? A Saved Search is **dynamic**, and the patients that are responsive to your search will change as your data changes, while the Search History is **static**, and will recall the original results.

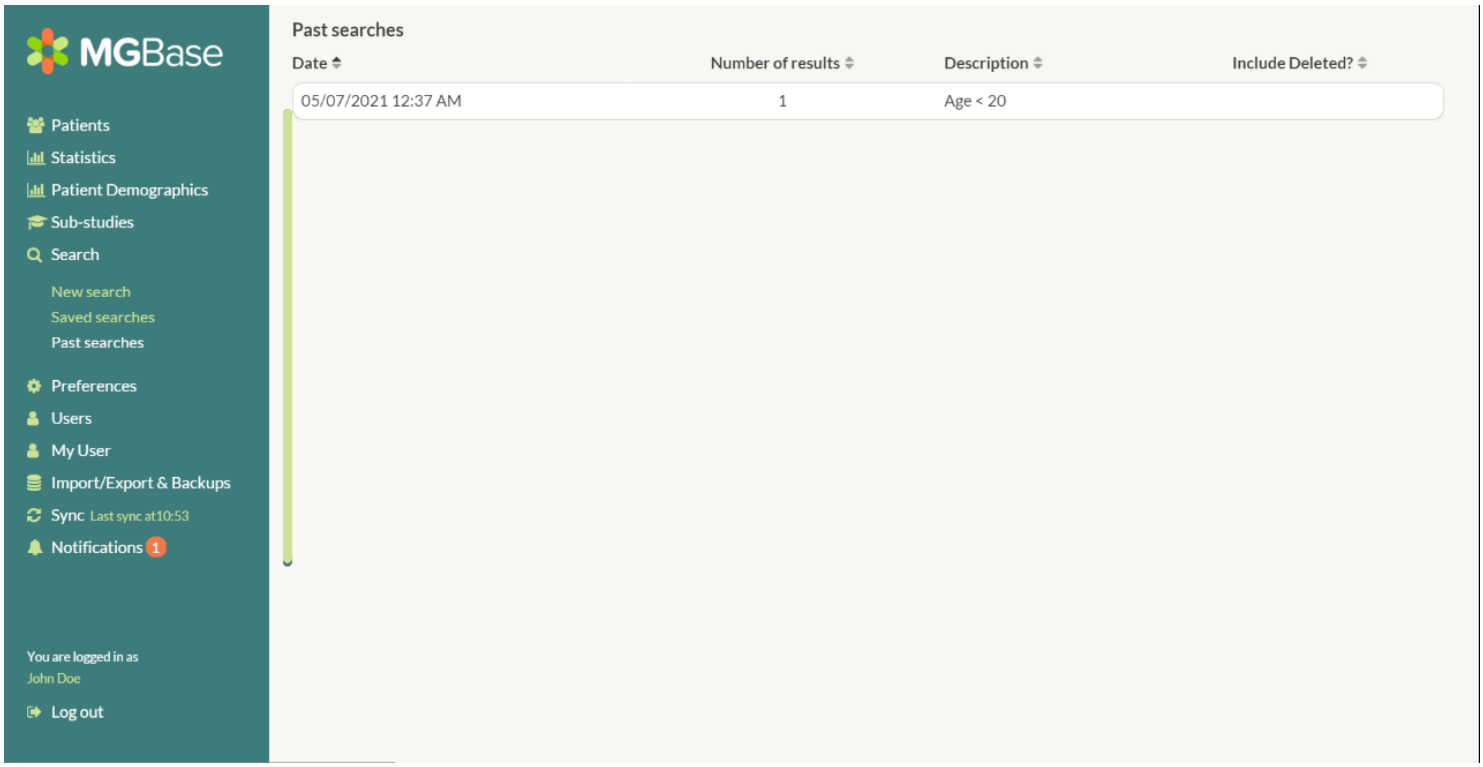


Figure 69 - Search History in MDS

14.1. Searching MedDRA

MedDRA can be searched in the same way as other fields. Refer to the earlier sections on the structure of MedDRA and multiaxiality to ensure that the searches are structured correctly. In the below example, *Small Cell Lung Cancer* will have multiple SOC, HLGT, HLT values.

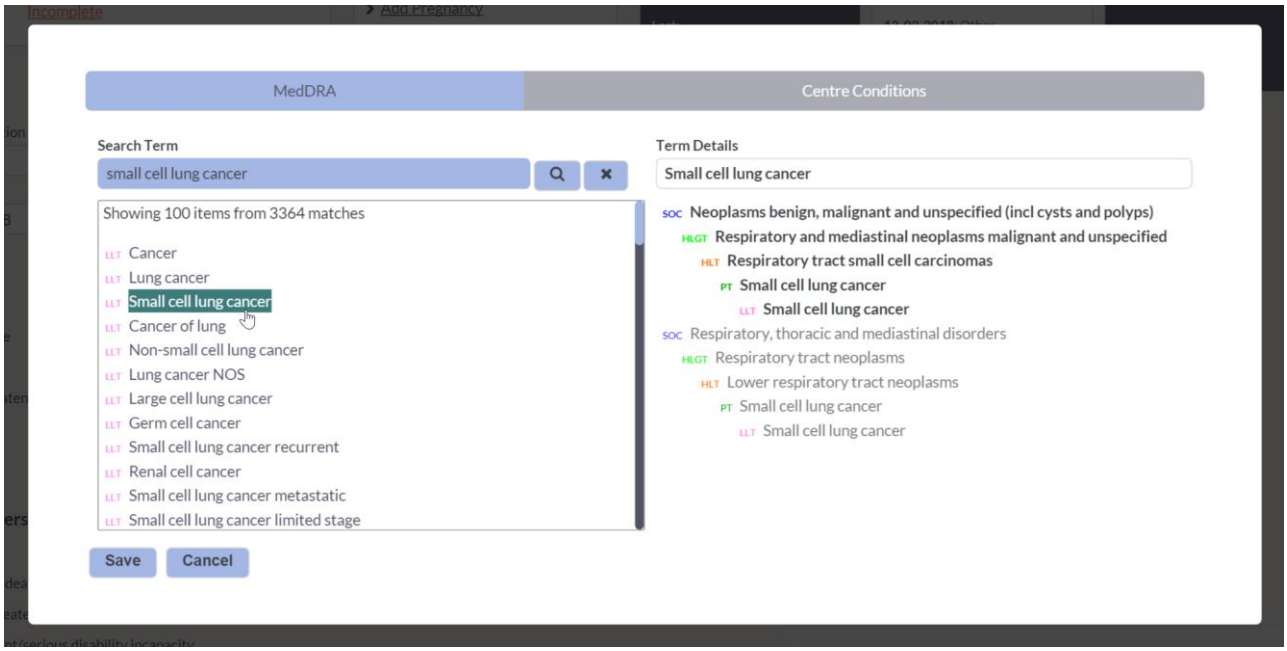
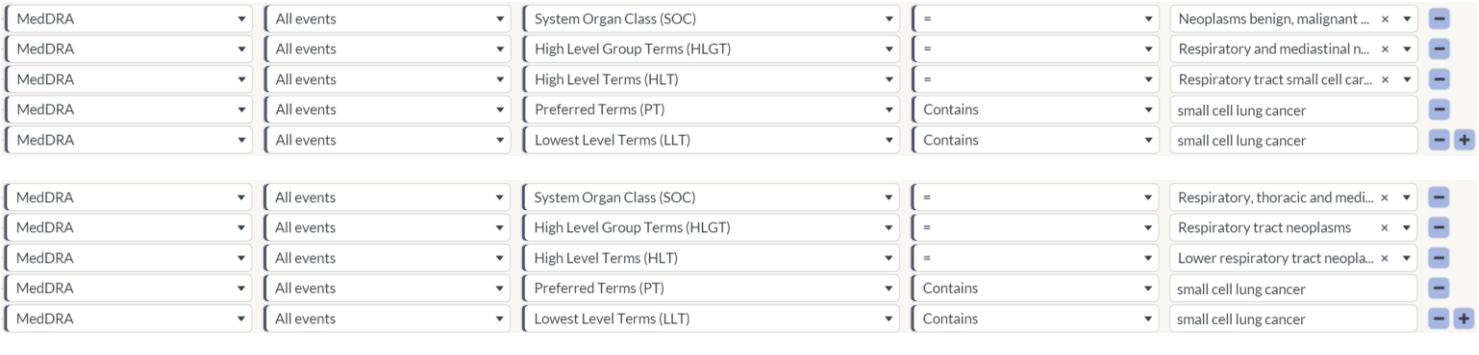


Figure 70 - MedDRA Small Cell Lung Cancer

Hence the any one of the below 10 searches would return a patient with *Small Cell Lung Cancer.*



15. User Options

15.1. Overview

This section explains how MDS handles the roles in the Registry and MDS. All users of MDS must be a member of the MGBase Registry.

15.2. User Permissions

15.2.1. Roles

There are 4 roles that a user can be assigned in MDS.

- **Principal Investigator (PI):** This role is assigned to the lead Neurologist of the centre. The PI is responsible for understanding and signing the MSBase Foundation governance documentation and ensuring their centre adheres to all rules and conditions of participation. This role can perform tasks such as: Creating a Sub-study, joining a Sub-study, managing a Sub-Study as well as managing their centre, including inviting new users, removing users and modifying user roles. Each centre has one PI.
- **Co-Principal Investigator (Co-PI):** A PI may assign other senior members at their centre as a Co-PI should they wish to delegate administrative responsibilities. A Co-PI can perform the same functions as a PI, with the exception of creating a new sub-study. A centre can have multiple Co-PIs.
- **Investigator:** This role is usually assigned to medical or research staff who create and modify patient data in MDS and enrol patients into sub-studies. As Investigators have the ability to contribute data, they can be listed as co-authors in MSBase publications if approved by the centre PI.
- **Member:** This role is usually assigned to staff who provide administrative assistance within the centre. Members do not hold the authority to upload patient data or enrol patients into sub-studies and therefore cannot be listed as a co-author in publications.

15.3. Viewing users

The list of users that can access MDS can be found in the Users section of MDS.

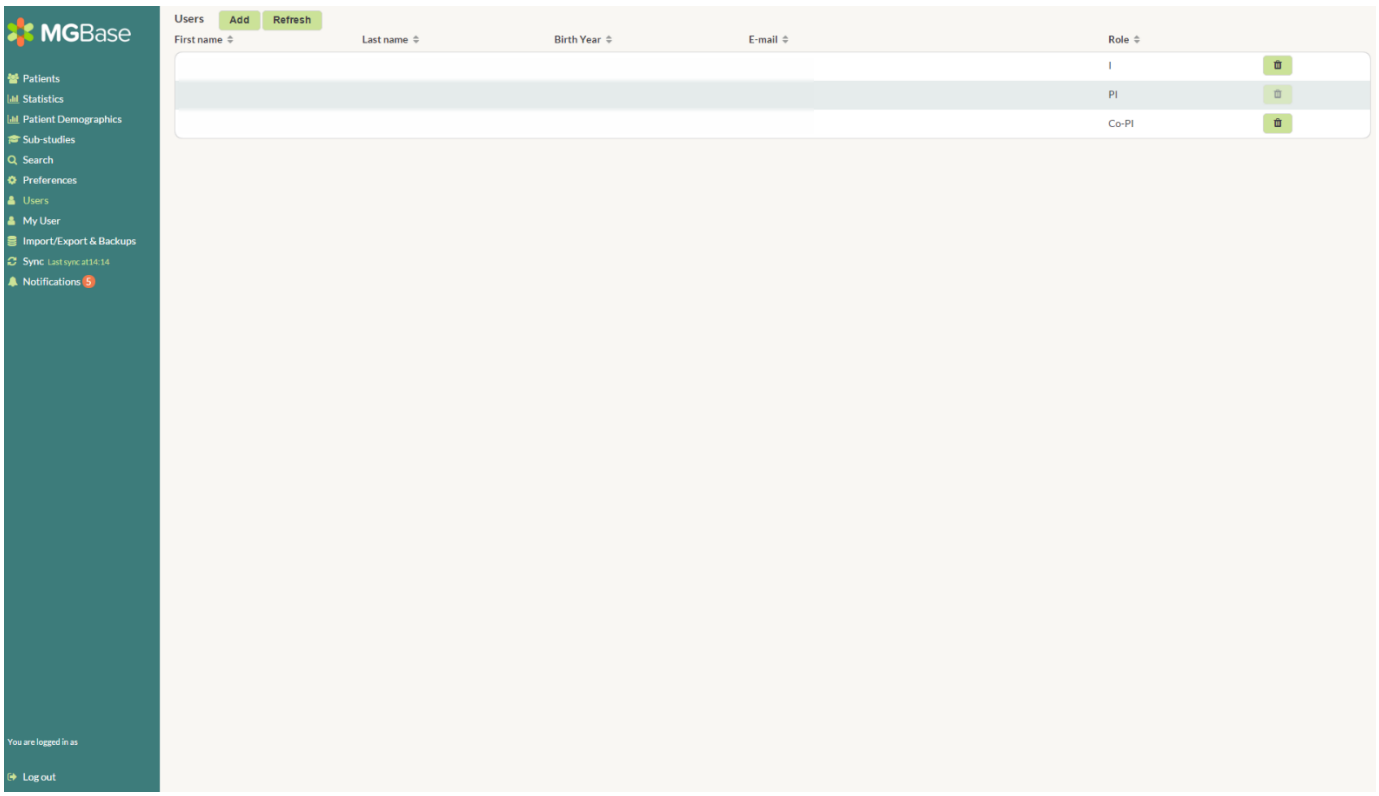


Figure 71 - Users List

15.4. Adding users

A user can be added by a PI or a Co-PI by selecting the Add option in the User section. Enter the new users email address, role and permissions and then Add User.

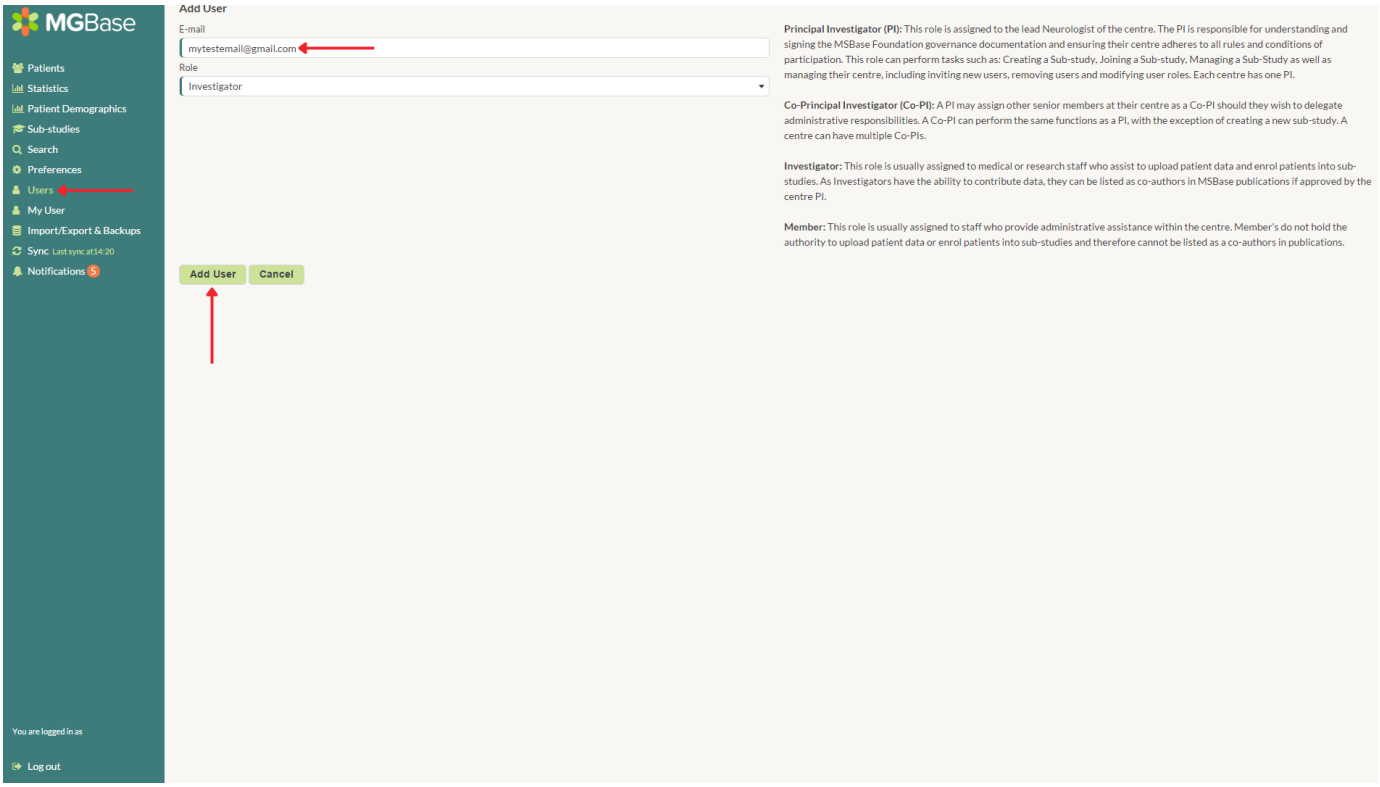


Figure 72 - Adding a user

The new user will now receive an email with a unique sign-up link. After they complete the new user form at the supplied link they will be able to log into the MDS using their email and entered password.

If the user has not yet signed up, then they will appear in your Users table as a user without any information. If they have lost the sign-up link email, then you are able to re-invite them with a new email.

If the member is already a member of MGBase, then they will be automatically added and will not need to complete a new user form.

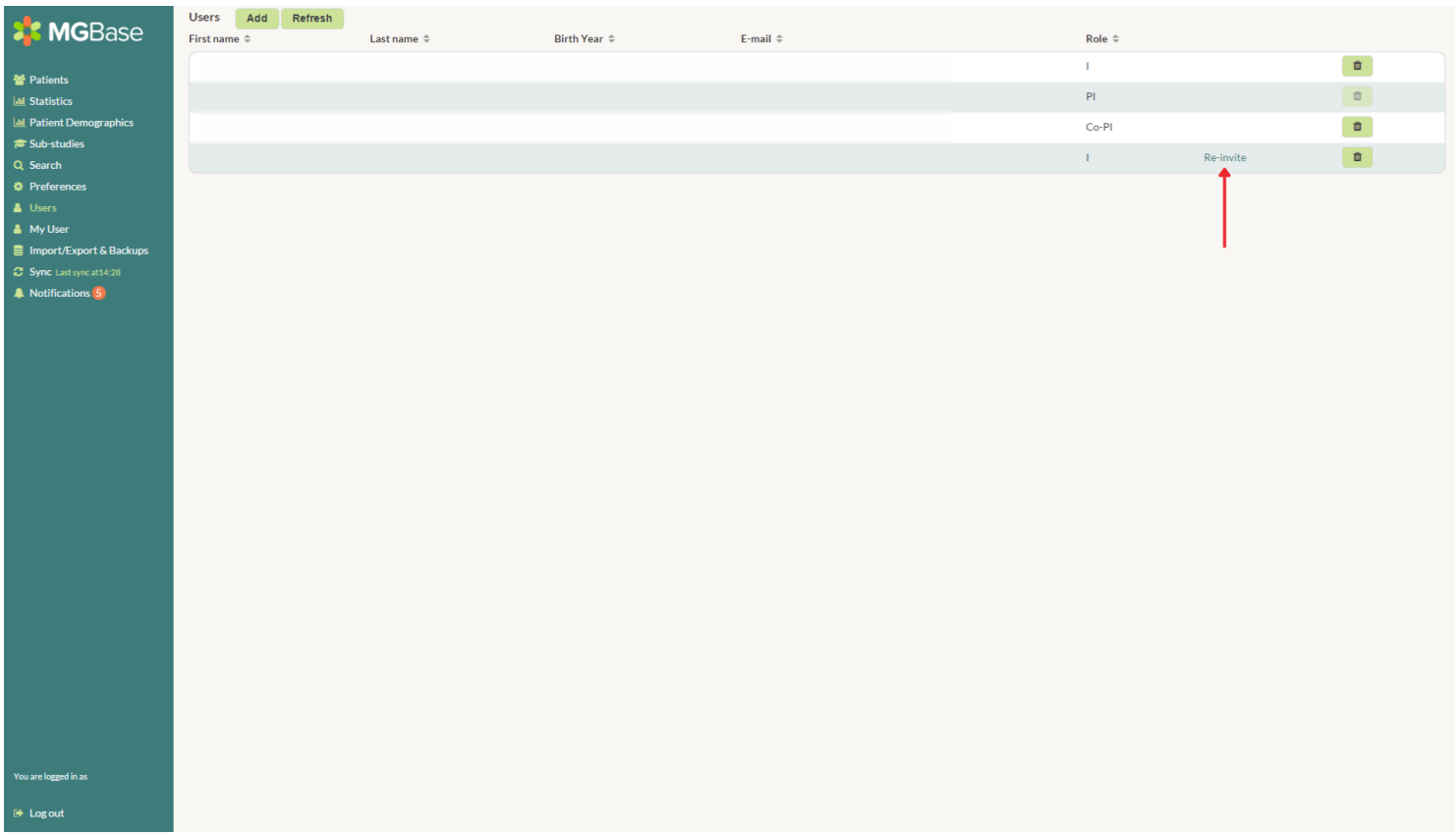


Figure 73 - New user and re-invite mechanism

15.5. Removing users

A user may no longer need access to your site and must be removed. To remove a user, simply click the trashcan icon and confirm the removal.

This method can also be used to change the role of the user. For example, an Investigator may become a Co-PI. By removing the user and re-adding as a Co-PI, this functionality can be achieved. The user will still be able to use the original login/password combination.

If the user is a member of multiple sites, then deleting will only remove the user from your centre. The user's access at other centres will not be affected.

16. My User Profile

16.1. Overview

Your patient profile is accessible in both MDS and the Registry. You can update your details by selecting the My User section and updating as required. Once updates have been completed, then click save.

It is important to realise that your MDS profile and your Registry profile is the same thing. That is, if you update your password in MDS, the password for the Registry will also be updated.

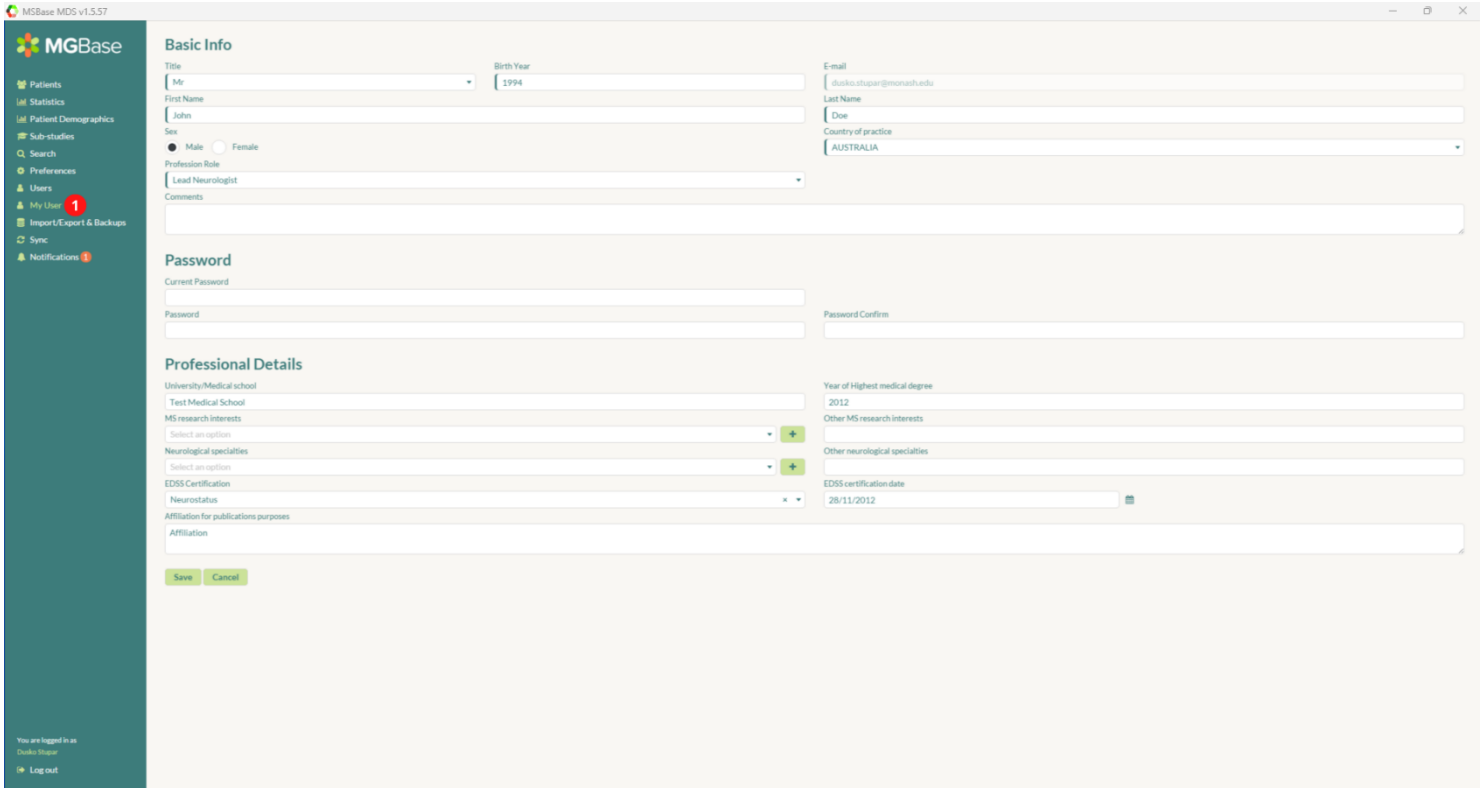


Figure 74 - My User profile

17. Exports and Backups

17.1. Backup overview

MDS recommends speaking to your IT Support/Service Provider on the best method of back-up. In many instances, a managed SQL server will have a back-up schedule and more robust disaster recovery protocols.

If your centre does not have a backup procedure, MDS can automatically schedule a backup. Select a back-up location and time for the backup to occur and click apply.

Important – Please note the below when using this feature

- **MDS needs to be running to perform a backup**
- **The backup location should be a network location, a USB stick or a safe location in the cloud. Backing up MDS to your hard-drive will not be satisfactory if your device fails or is stolen**
- **All backups are encrypted. Store your Restore Password somewhere safe. Without that password you will not be able to access your backup.**

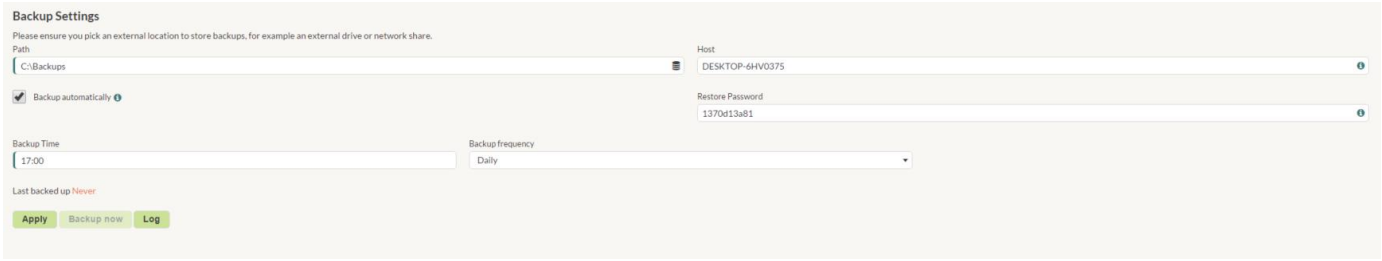


Figure 75 - Backup options in MDS

17.2. Export overview

Patient data may be exported to CSV or XLSX (Excel) format. MDS will export your patients that are currently displayed. By default, this will be all patients. You can export a subset of your patient by first applying a filter/search and then exporting the results.

Alternatively, you can export an individual patient.

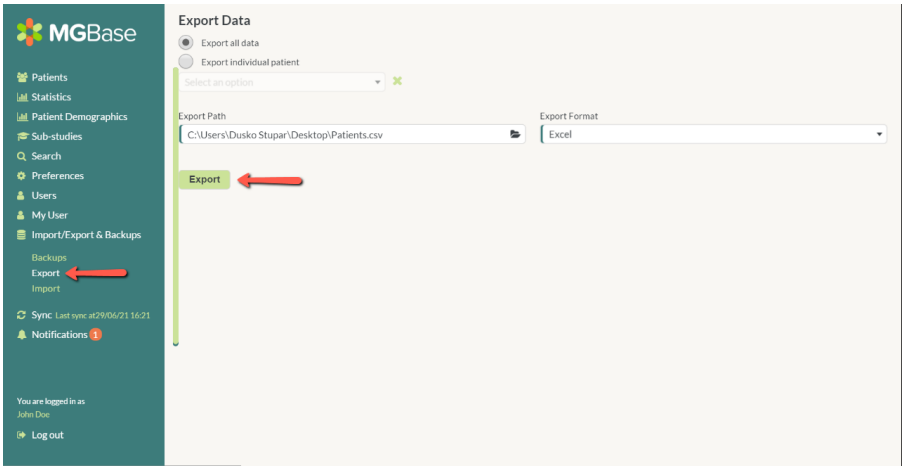


Figure 76 - MDS Export a patient

18. Synchronisation

18.1. Synchronisation overview

MDS synchronises any changes of Registry enrolled patient with the MGBase Registry. By default, automatic synchronisation is turned off. MGBase recommends enabling automatic synchronisation (by selecting the checkbox on the sync page). Automatic synchronisation will occur whenever a patient is saved and only the data for that enrolled patient will be sent. If automatic synchronisation is turned off, then you must manually sync the patients by selecting Sync Now.

All synchronisation events will occur in the background and will not affect normal MDS usability.

Good to know!

To get the most out of MDS and to ensure your patients are up to date, make sure Automatic Synchronisation is enabled for your centre by checking the option in the Sync section.

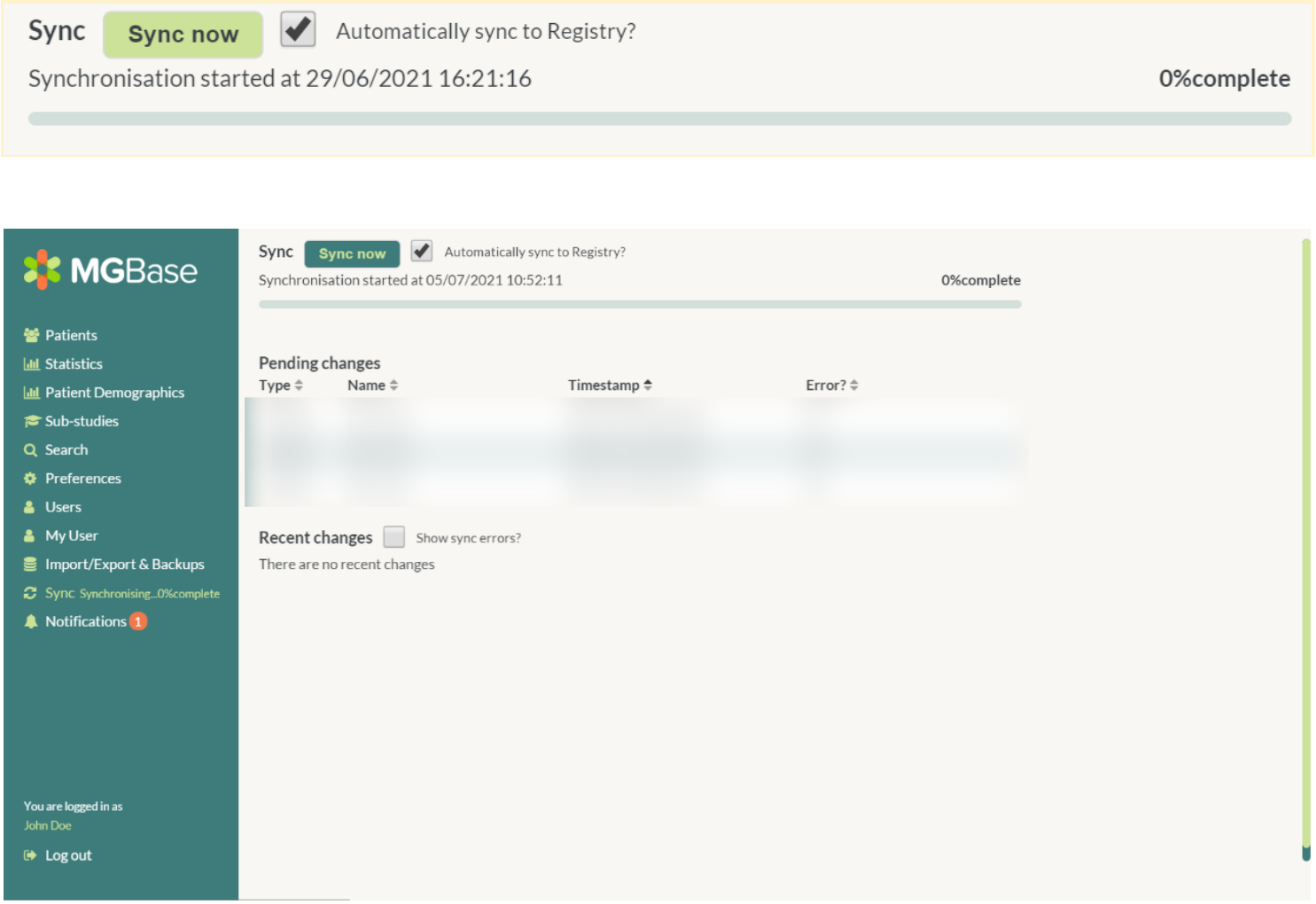


Figure 77 - MDS Synchronisation

19. Notifications

19.1. Notification types

Notifications are sent to MDS from the Registry to inform you of new sub-studies, any outstanding sub-study requirements, back-up notifications and any other miscellaneous issues. New notifications will be indicated by an orange notification symbol. To dismiss notifications (and remove the orange icon), simply click on the notification.

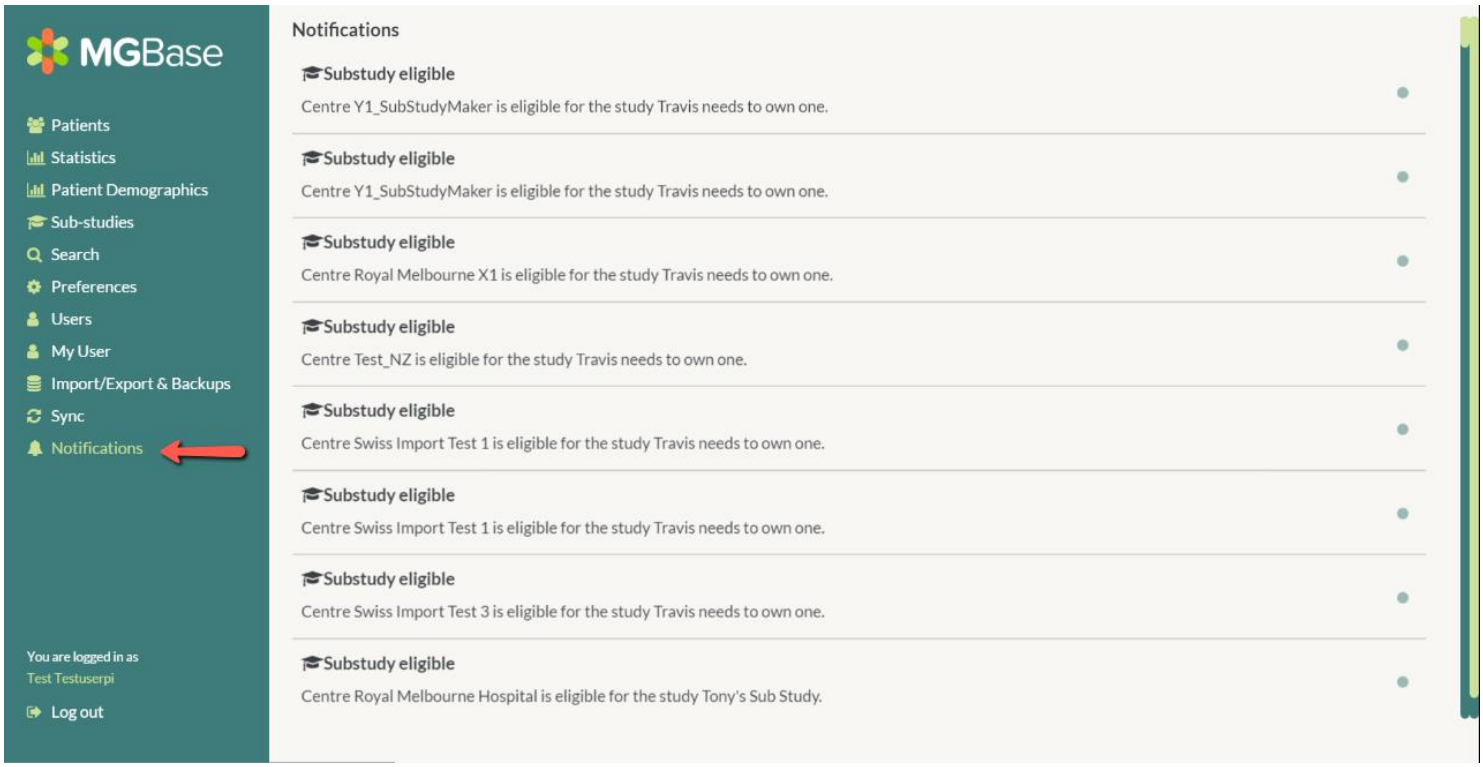


Figure 78 - Notifications in MDS

20. Configuration

20.1. Database settings

Refer to the MDS installation guide for further information on the Database settings, or contact info@MGBase.org

Figure 79 Database Settings

20.2. Proxy Settings

If your centre accesses the internet through a proxy server, enter these details here.

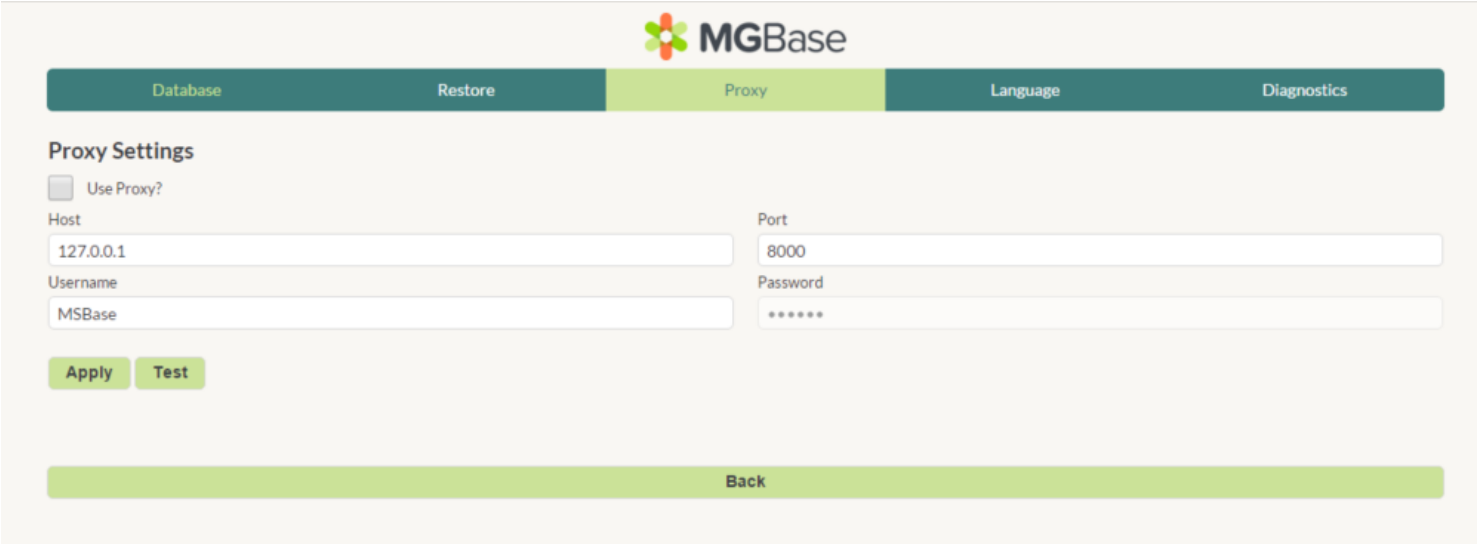


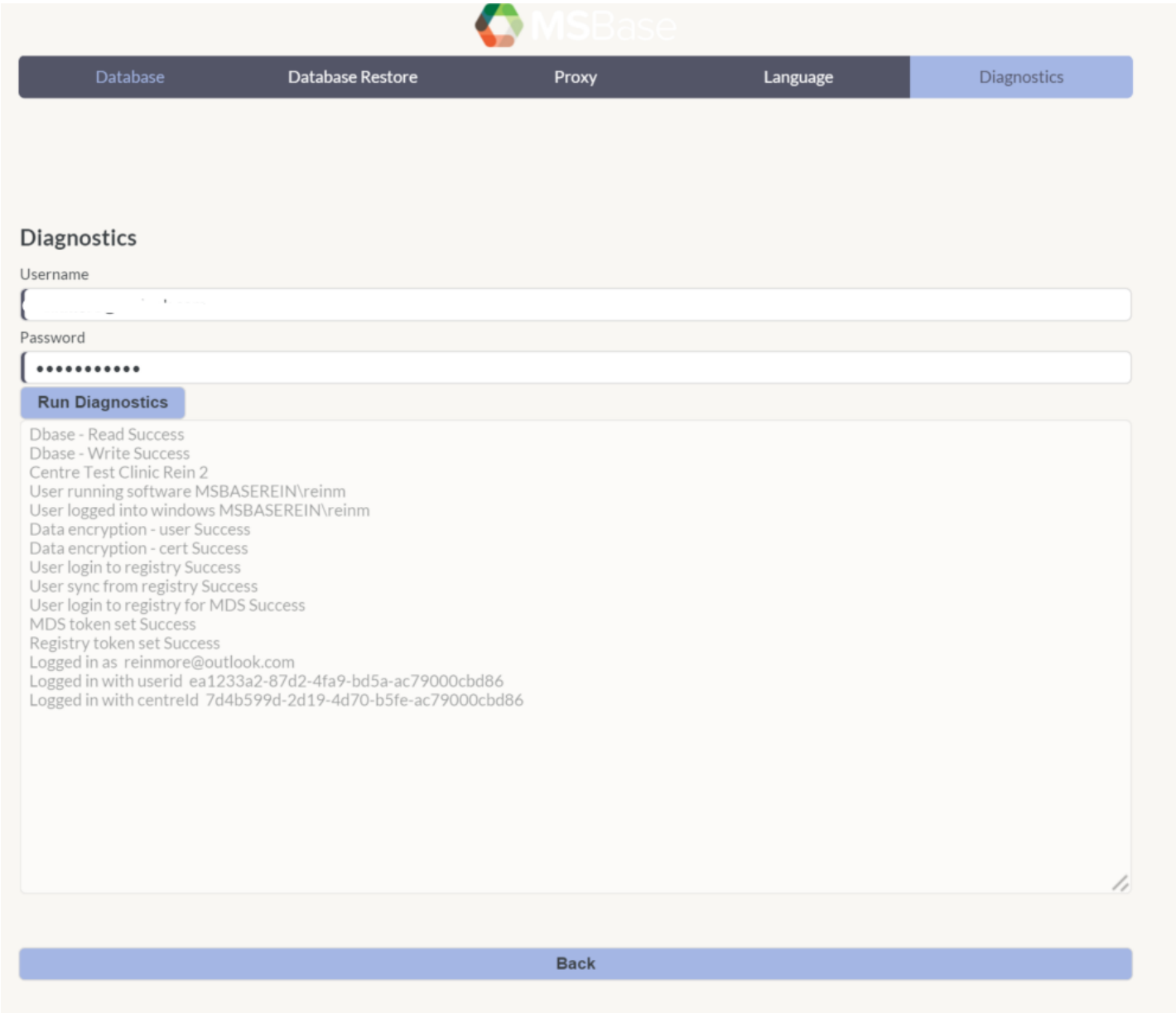
Figure 80 Proxy Settings

20.3. Language Settings

MDS currently has 3 languages available, with English being the primary and up-to-date language. The other 2 options are Spanish and Japanese, although currently there may be new modules in MDS where these languages haven't been incorporated yet.

20.4. Diagnostics panel

Should there be problems with MDS, the Diagnostics panel may be used to help determine any common problems, enter your relevant MSBase username and password and click “Run Diagnostics” then contact your Centre IT or info@msbase.org for further assistance.



END OF USER GUIDE