iMed Web User Guide

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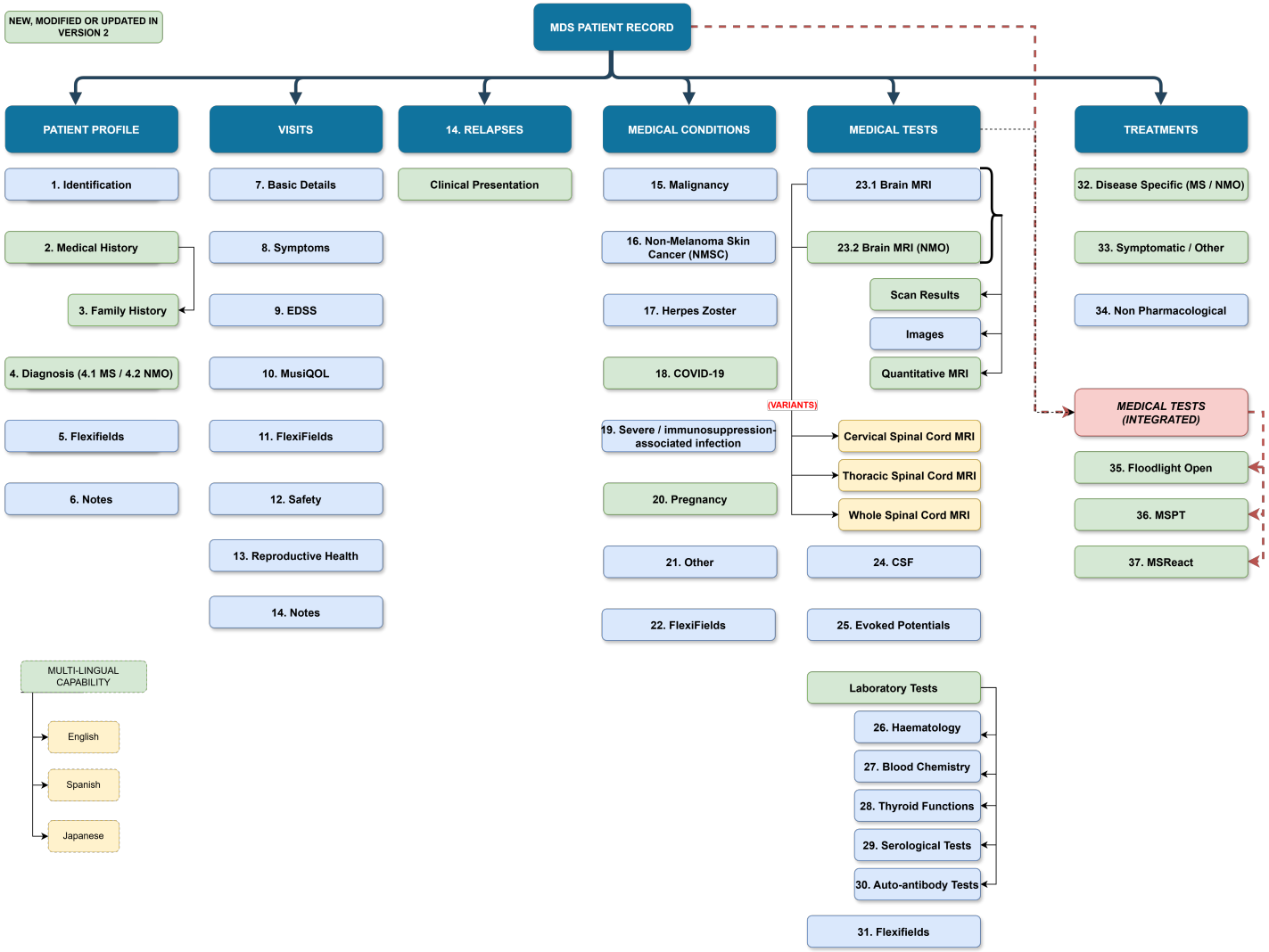
Contents

1. User guide overview & Content map

When working with iMed Web, it is important to familiarise yourself with the application's features and its relationship with the MSBase Registry.

This guide outlines the core capabilities of iMed Web and provides guidance on common user tasks, such as logging in and entering patient information, as well as more advanced functionality, including sub-study creation, search, and Flexifield administration.

Below is a content map that presents the iMed Web Patient Record in a hierarchical structure. It is organised into six major sections (modules), shown in dark blue, with each section further broken down into its associated data entry forms.



2. What is iMed Web

iMed Web is a web-based data collection tool designed to collect clinical data related to Multiple Sclerosis (MS). It is developed and maintained by the MSBase Foundation and is available exclusively to MSBase Members. iMed Web communicates with the MSBase Registry and uploads a defined subset of patient data for consenting patients.

The MSBase Registry is an ongoing, longitudinal, strictly observational database that commenced in 2004. It provides a platform for international collaboration focused on sharing, tracking and evaluating outcomes data in Multiple Sclerosis (MS) and other Neuro Immunological Diseases (NIDs). Membership of the Registry is open to all practicing neurologists and their healthcare teams worldwide.

The MSBase Registry platform supports data collection for MS and NID studies at regional, national and global levels, with configurable sub-study functionality that enables filtering according to specific research themes.

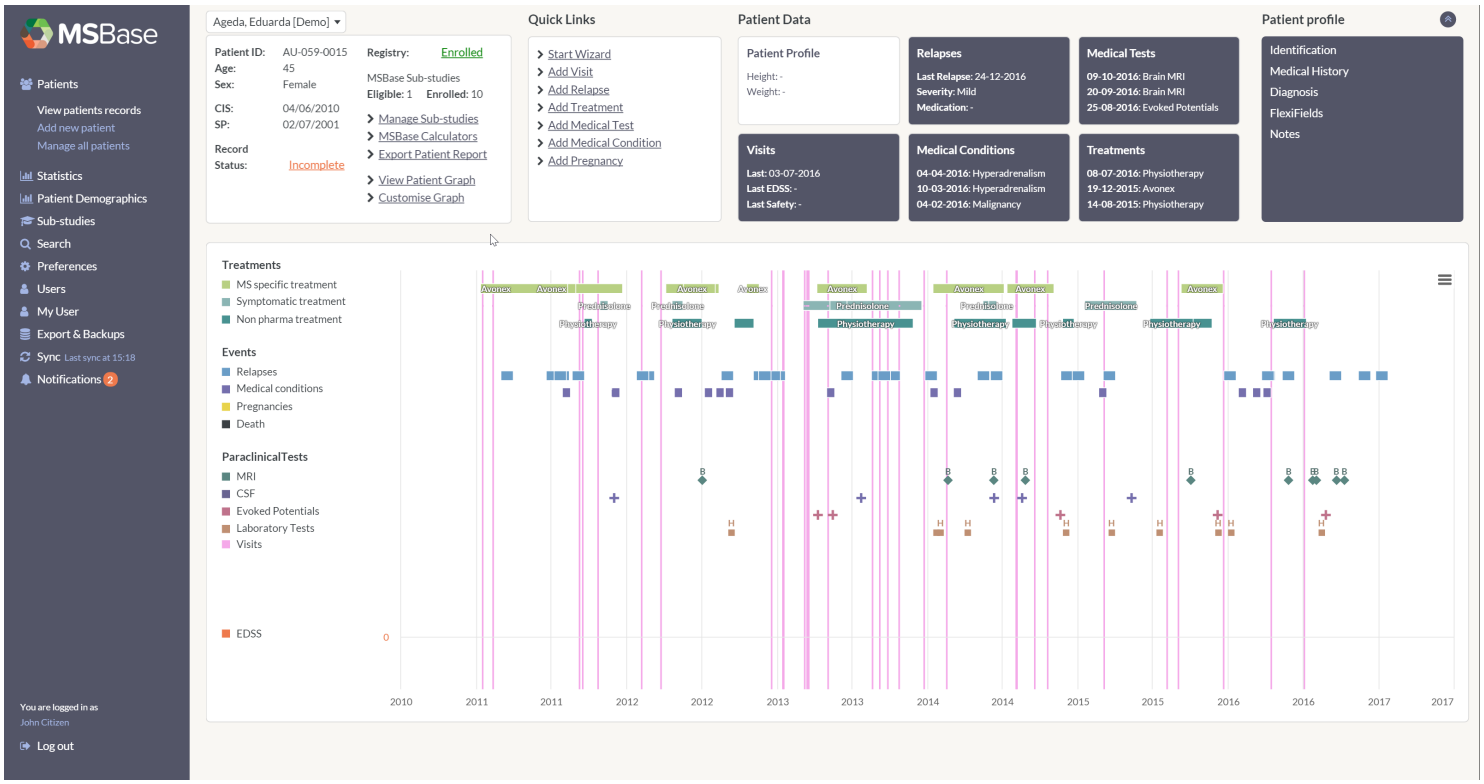


Figure 1 - iMed Web

3. Before you start

3.1. Are you an MSBase Registry member?

To use iMed Web you must be a member of the MSBase Registry.

You are considered a member if:

- You are a Principle Investigator (PI) who has been approved by the MSBase Operations team, or
- You have been invited by your centre's PI or Co-PI.

If you are not a member of the MSBase Registry, please stop here and sign up at: www.msbase.org

3.2. Have you forgotten your password?

If you were previously a member and can no longer log in, please reset your password at www.msbase.org/forgot-password .

Your username will be your institutional email address.

If your site is configured to use Microsoft Entra ID, select Log in with Entra on the login screen.

If you are unsure which login method applies to your site, or if you experience issues logging in please contact MSBase support via https://www.msbase.org/contact-us/.

4. iMed Web Overview

4.1. Log in

Launch iMed Web by navigating to your sites unique URL. If you are unsure contact your Principal Investigator.

You will be presented with the login screen. Enter your username (institutional email address) and password, then select Log In to proceed.

If your site is configured to use Microsoft Entra ID, select Log in with Entra ID and follow the on-screen prompts to authenticate.

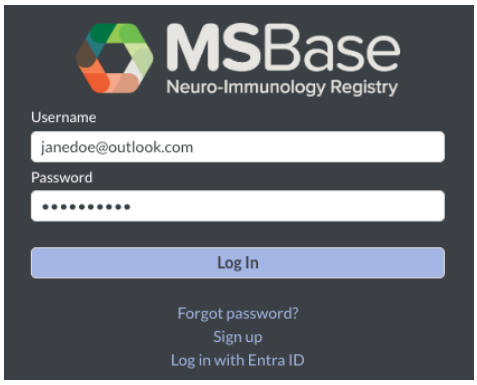


Figure 2 – iMed Web Login screen

4.2. Basic Navigation

Your iMed Web home screen will resemble the below image. The interface is divided into seven regions:

- **iMed Web Menu**: Navigate the main sections of iMed Web, such as Statistics, Patient Demographics, Sub-studies and Search, by selecting the relevant menu item.
- **Patient Selector**: Select, change, or search for a specific patient.
- **Patient Card**: View an overview of the selected patients and access patient-specific functions.
- **Quick Links**: Access commonly used actions from the Quick Links sections.
- **Category Selector**: Access data entry forms by selecting one of the six category buttons. The available options in the Context Menu update based on the selected category.
- **Context Menu**: Displays options related to the selected category. For example, selecting Patient Profile displays Identification and Medical History forms, while selecting Visits displays all visists recorded for the selected patient.
- **Patient Overview Graph**: Provides a graphical overview ot the patient's clinical history and recorded events.

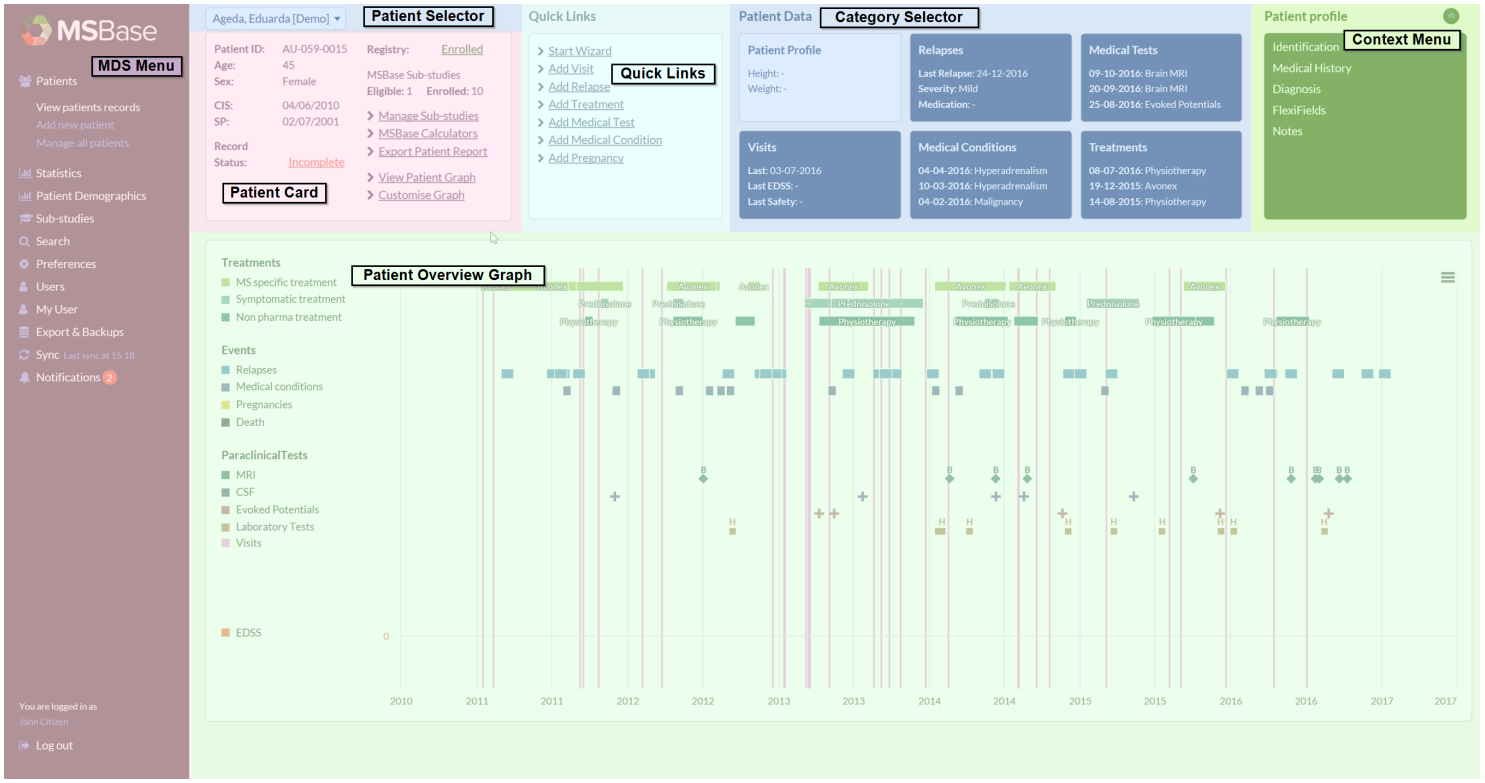


Figure 3 – iMed Web Layout

4.1. Patient Selector

To switch between patients, use the Patient Selector. Your centre may have hundreds or even thousands of patients, and locating a patient by scrolling alone may be time-consuming. To find a patient more quickly, select the Patient Selector and begin by typing the first few letters of the patients first or last name. This list will automatically narrow to a more manageable set of results.

If a patient is deleted from iMed Web, they will no longer appear in the Patient Selector.

If you have performed a search or applied a filter in the Statistics section, the Patient Selector will display only those patients that meet the active search or filter criteria.

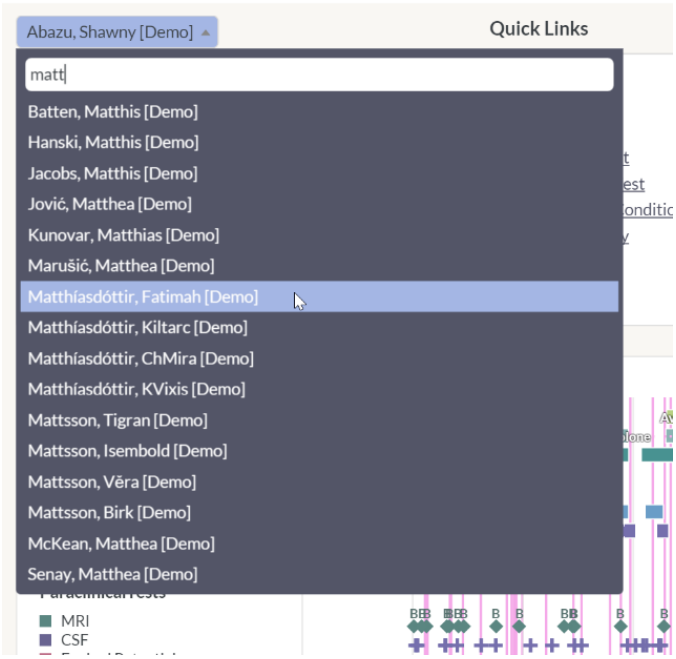


Figure 4 - Patient Selector and Search

Good to know!

The Patient Selector dropdown menu is limited to 1,000 patients to maintain optimal performance. If you have more than 1,000 patients, please use the filter function to locate specific patients, or alternatively, access the patient through the Manage All Patients section.

4.2. Recommended Minimum Data Set

The MSBase Registry recommends—but does not mandate—a minimum patient data set for submission. Supplying this helps improve the quality of registry information and research. Details of the minimum data set are outlined below.

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

Complete Records fields

	Field	Frequency	Definition
Patient Profile	Patient ID	Entry Visit	Patient globally unique ID (system creates)
	Sex	Entry Visit	M / F
	Birth date	Entry Visit	Month and year only
	Date of MS onset	Entry Visit	Date
Visits	Visit Date	Entry & Annual #	Date
	KFS – 8 items	Entry & Annual #	0 to 5 / 0 to 6 / 0 to 12
	EDSS*	Entry & Annual #	0 to 10
Paraclinical tests	Test date	Entry & Annual #	Date
	Test type	Entry & Annual #	MRI, CSF, EP, Biochemistry
Relapses	Relapse Date	Entry & Annual #	Date
	CNS region	Entry & Annual #	Pyramidal, Cerebellum, Brainstem, Sensory functions, Bowel bladder, Visual functions, Neuropsychological functions
	Corticosteroids	Entry & Annual #	Yes, No
Treatments	Treatment ID	Entry & Annual #	Treatment names
	Start date	Entry & Annual #	Date
	End date	Entry & Annual #	Date

Good to know!

A patient may be uploaded to the Registry even if the minimum dataset requirements are not fulfilled; however, the Patient Card will display a notification indicating that the patient record is *Incomplete*.

4.3. Mandatory Fields and Field Validation

S Some forms in iMed Web contain mandatory fields that must be completed before the form can be saved. Examples include a patient's First Name and Last Name, or the date of a visit. Mandatory fields are indicated by a blue highlight and will trigger an alert message if left blank when you attempt to save the form.

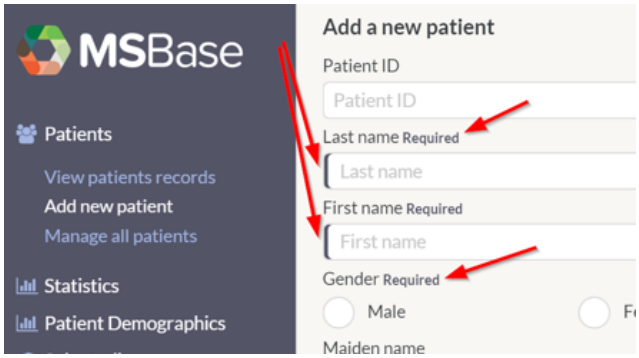


Figure 5 - Mandatory fields in iMed Web

In addition, iMed Web applies field validation rules and may prevent a form from being saved, or display a warning, if invalid data is entered. Common validation examples include:

- Field length: Certain fields restrict the number of characters that can be entered.
- Impossible dates: iMed Web iMed Web will not accept dates that are logically invalid, such as a medical event recorded after a patient's date of death.
- Number Parsing: Some numeric fields do not allow negative values or enforce limits on decimal places.

If any validation rule is breached, iMed Web will display an appropriate error message to guide the user.

Figure 6 - Field validation errors

5. Preferences

You can use the iMed Web Preferences section to configure your iMed Web installation for your Centre. This includes general settings—such as enforcing the use of MedDRA classification—as well as centre-specific configuration options, including the management of Care Professionals, the creation of MS-specific treatments, and the maintenance of reference data such as custom flexifields.

These preferences are described in detail in the sections below.

5.1. Centre Information

The centre information section allows you to update details about your Centre. This feature is available only when an active internet connection is present.

Good to know!

In this section, users can be required to use the Visit Assistant when creating a Visit. When enabled, the Safety and EDSS components are automatically presented, supporting completion of the MSBase Registry minimum data set.

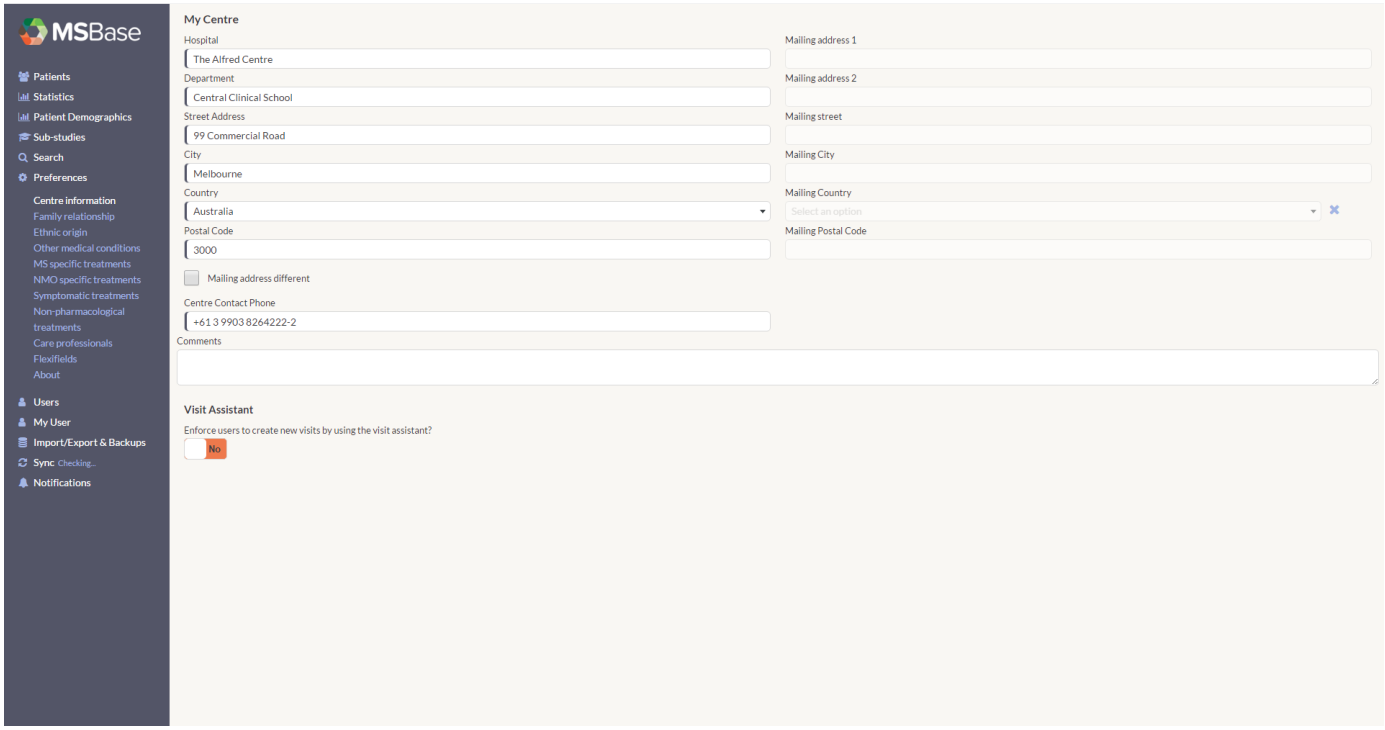


Figure 7 - Centre Information modification

5.2. Family Relationships

The list of family relationship types (for example, son, daughter, father, mother) between patients can be modified to allow familial events to be captured in greater detail. The default values, however, are sufficient for most use cases.

To add a new family relationship, select Add, enter the new relationship, and select the Save icon.

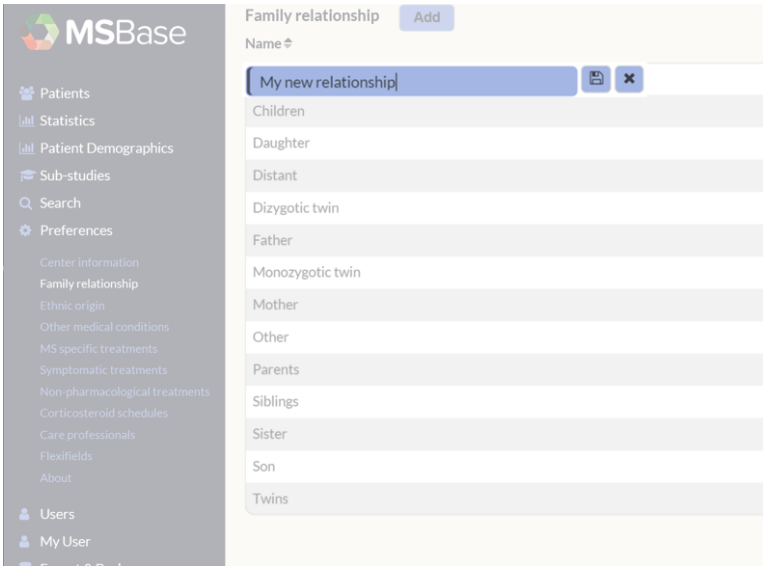


Figure 8 - Adding a new family relationship type

5.3. Ethnic Origin

Additional Ethnic Origin types can be added where the default values are not sufficient.

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

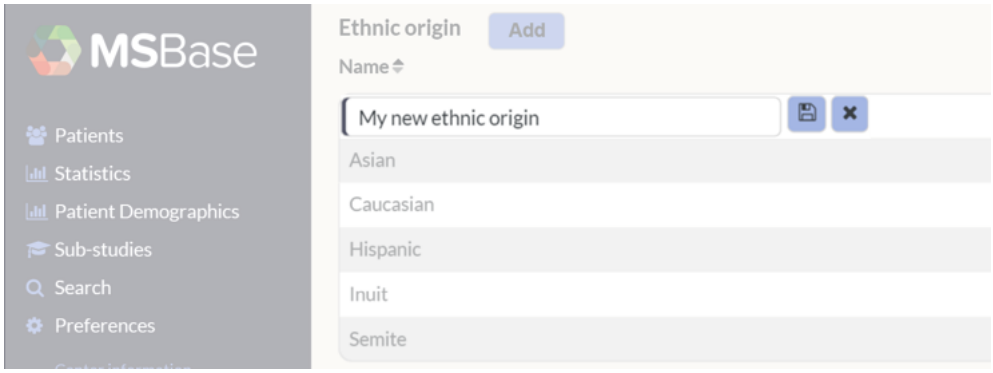


Figure 9 - Adding a new ethnic origin type

5.4. Other Medical Conditions

iMed Web uses two methods to identify adverse events and other medical conditions. The first, and preferred, method is the use of MedDRA. MedDRA is a hierarchical medical event classification schema that enables standardised data entry.

The alternative option is a list of Centre Medical Conditions, which can be customised for each site.

This section allows the centre to enforce the use of MedDRA only, or alternatively to allow the use of both MedDRA and Centre Medical Conditions. Make the appropriate selection in the section below.

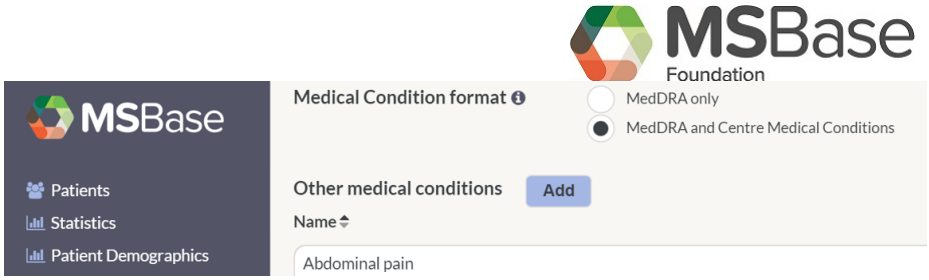


Figure 10 - MedDRA only can be enforced in iMed Web

Good to know!

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

If you are migrating data from an existing database, you may already have Centre Medical Conditions defined. If MedDRA only is selected, these Centre Medical Conditions will be retained. You can either leave these records unchanged or recode them into MedDRA format.

To add a Centre Medical Condition that users can select, select Add, enter the medical condition, and select the Save icon.

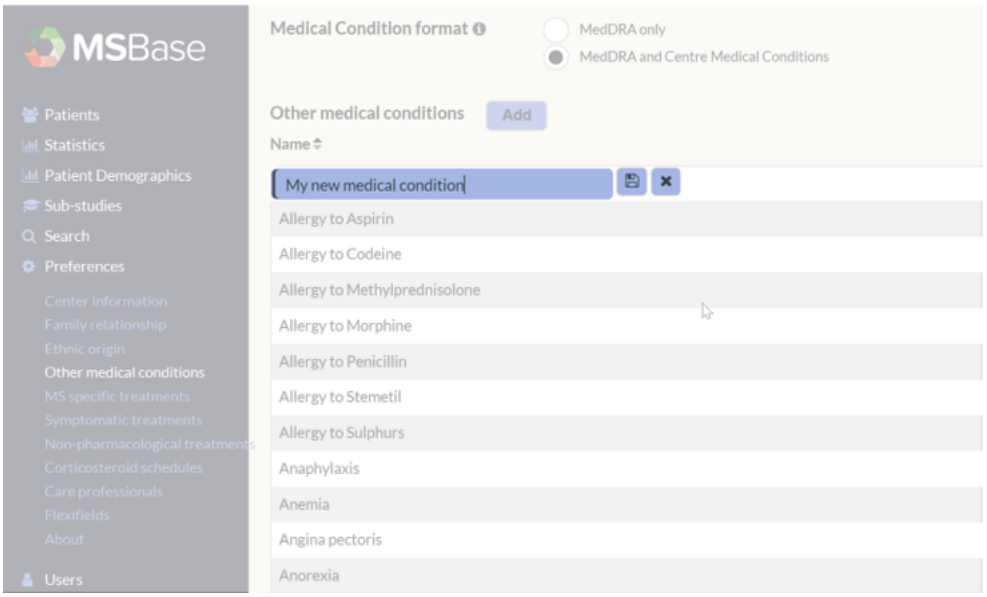


Figure 11 - Adding a centre medical condition

5.5. MS Specific Treatments

Treatments in iMed Web are handled differently depending on whether they are Disease-Modifying Therapy (DMT) / MS-specific treatments, NMO-specific treatments, Symptomatic treatments, or Non-pharmacological treatments.

iMed Web is installed with a set of default MS-specific treatments, for which the treatment names and dosages are standardised. For alternative dosage variations, or for treatments not included in the default list, additional treatments can be added.

Good to know!

When a treatment is assigned to a patient, the default values are applied by default; however, the dosage can be adjusted for the individual patient if required.

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

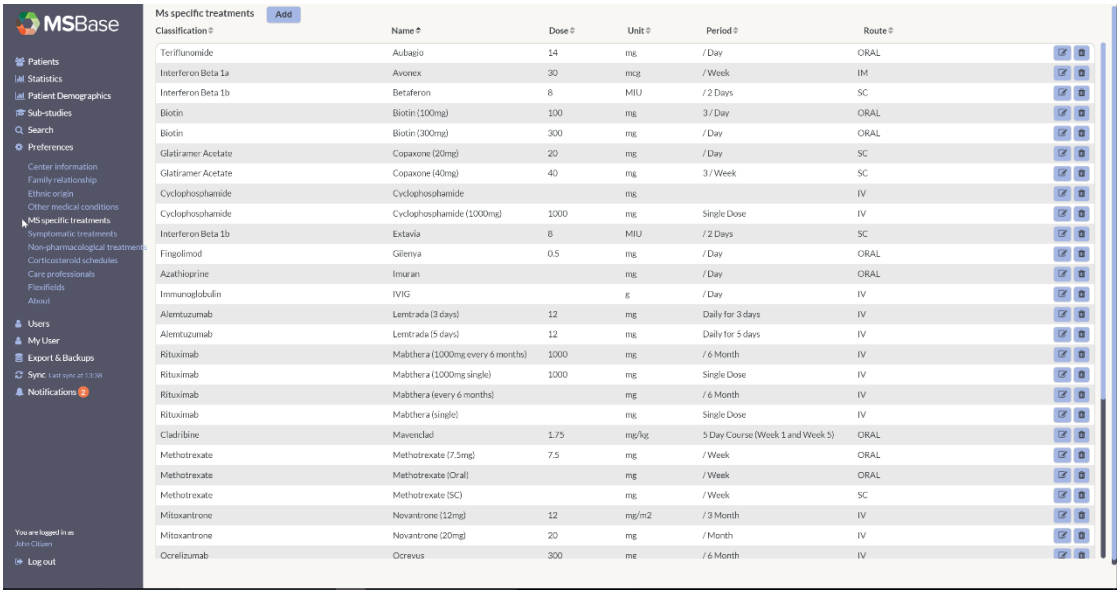


Figure 12 - MS Specific Treatments

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

Figure 13 - Entering MS Specific Treatment type

5.6. NMO Specific Treatments

iMed Web is also installed with a set of default NMO-specific treatments, where the treatment names and dosages are standardised. For alternative dosage variations, or for treatments not listed as defaults, additional treatments can be added.

Good to know!

When a treatment is assigned to a patient, the default values are applied by default; however, the dosage can be adjusted for the individual patient if required.

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

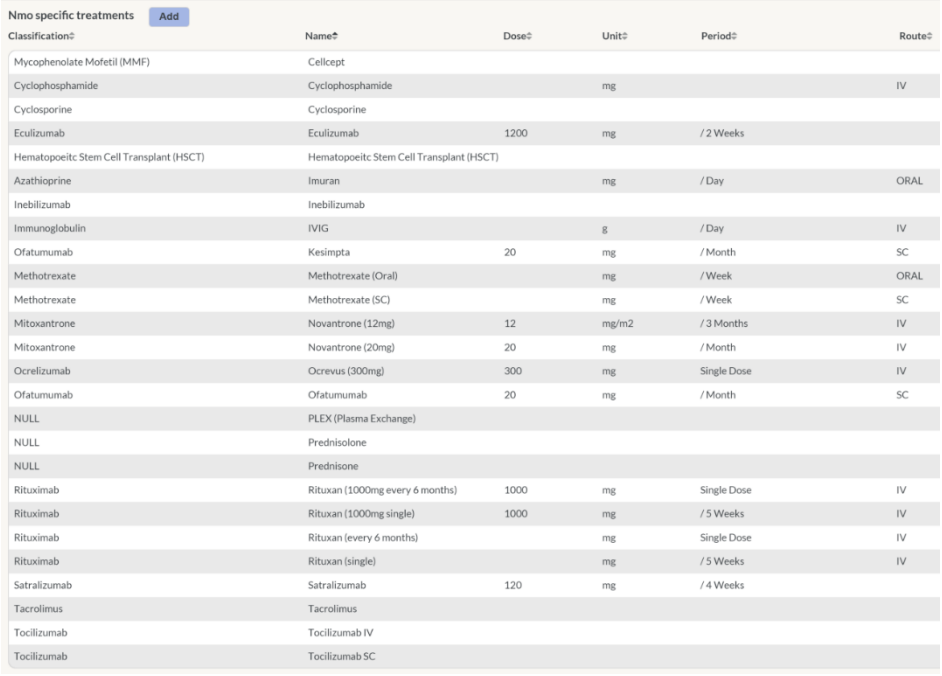


Figure 14 - NMO Specific Treatments

5.7. Symptomatic Treatments

A set of default Symptomatic treatments is provided with iMed Web. An example is shown below.

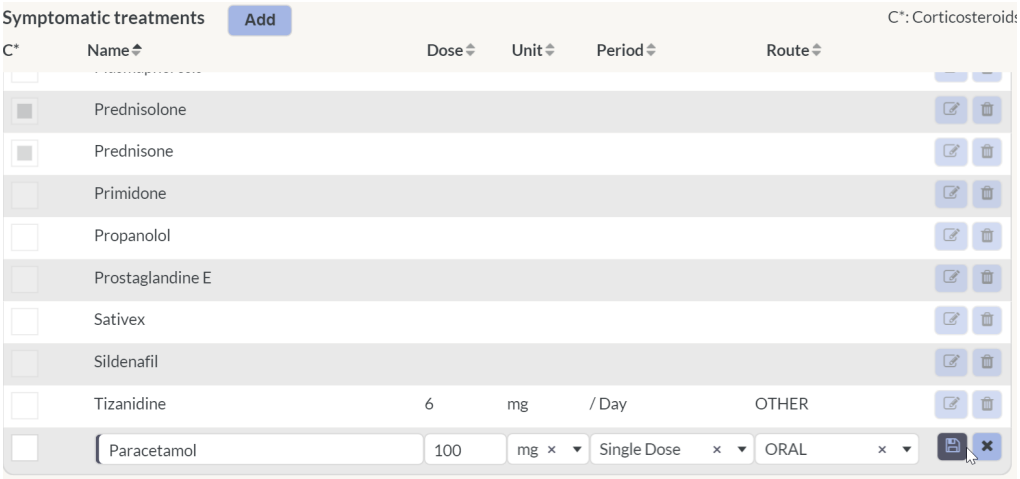
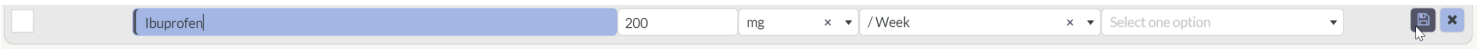


Figure 15 - Example of default treatment types

To add treatments beyond the default list, select **Add** enter the required details, and select the Save icon. Corticosteroids must be identified using the checkbox on the far left to allow assignment to the Corticosteroid field when creating a relapse.



5.8. Non-pharmacological treatments

In iMed Web, non-pharmacological treatments are classified differently from the MS-specific and Symptomatic treatments described above.

iMed Web is shipped with a set of default non-pharmacological treatments. As with other treatment types, additional treatments can be added and existing treatments modified as required.

To add a non-pharmacological treatment, select Add, enter the treatment type, and select the Save icon.`

5.9. Care Professionals

The Care Professionals section in iMed Web allows the centre to record and manage general practitioners (GPs) and other healthcare professionals who regularly refer patients to the centre.

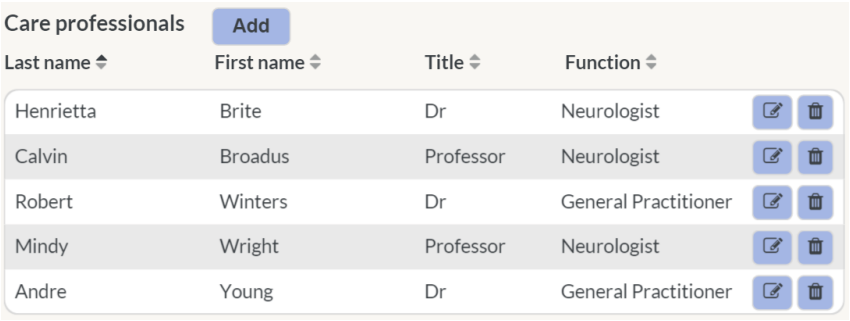


Figure 16 - Care professional list

Good to know!

The Care Professionals section is used to populate the patients "Referred By" field. This information is optional, is not part of the MSBase Minimum Dataset and is not uploaded to the Registry.

To add a Care Professional, select Add and enter the required details.

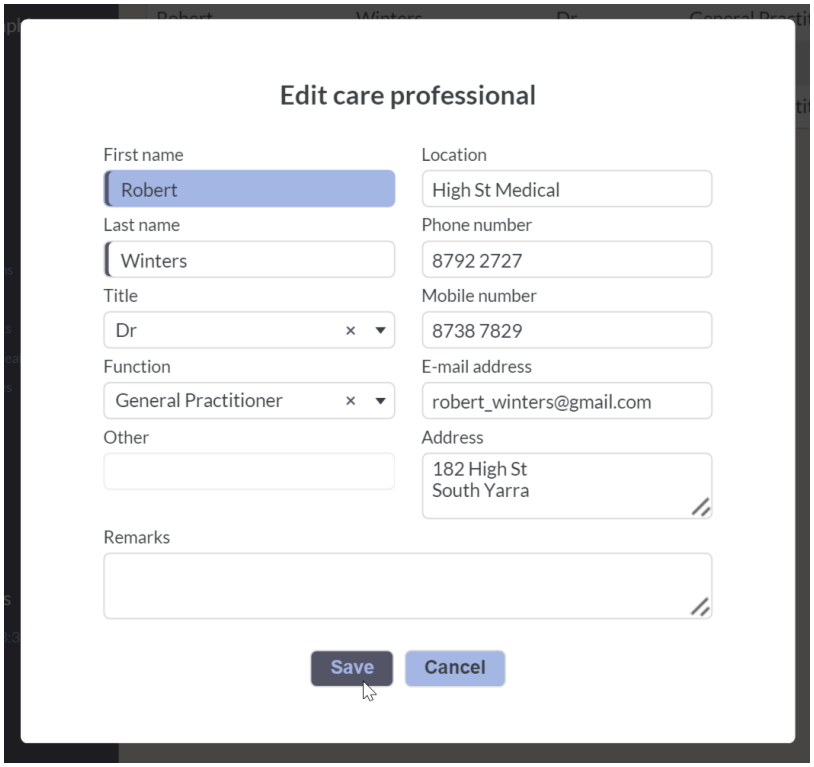


Figure 17 - Care professional data form

5.10. Flexifields

5.10.1. Overview

Flexifields are custom data fields that allow centres to capture information in addition to the standard fields provided by iMed Web. These may be used to record centre-specific data, such as supplement use or administrative information, for internal or research purposes.

Good to know!

Centre-specific Flexifields allow centres to capture additional patient information beyond the standard iMed Web fields. This information is not shared with the Registry and can be exported, searched, and graphed in the same way as other fields in iMed Web.

Further information about Flexifields and iMed Web:

- Flexifields can be entered as either one-off data fields (for example, Health Insurance Number) or as time-series values (for example, Vitamin D level).
- Centre-specific Flexifields are never shared with the Registry or any other centre. This information remains within your centre and may be used to capture personally identifiable or other confidential information.
- Multiple field types are available. For example, numeric fields can be used to capture dosages, text fields to record short comments, and dropdown lists to enforce consistent data entry.
- Flexifields belong to the centre and can be exported in either XLSX or CSV format.
- Numeric time-series Flexifields can be displayed on the Patient Overview Graph.
- Flexifields are searchable in the same way as other fields in iMed Web.

In the example below, a Flexifield form has been created in the Visit section. This allows data to be captured and recorded across multiple time points. Flexifields may be used to collect both clinical and administrative information.

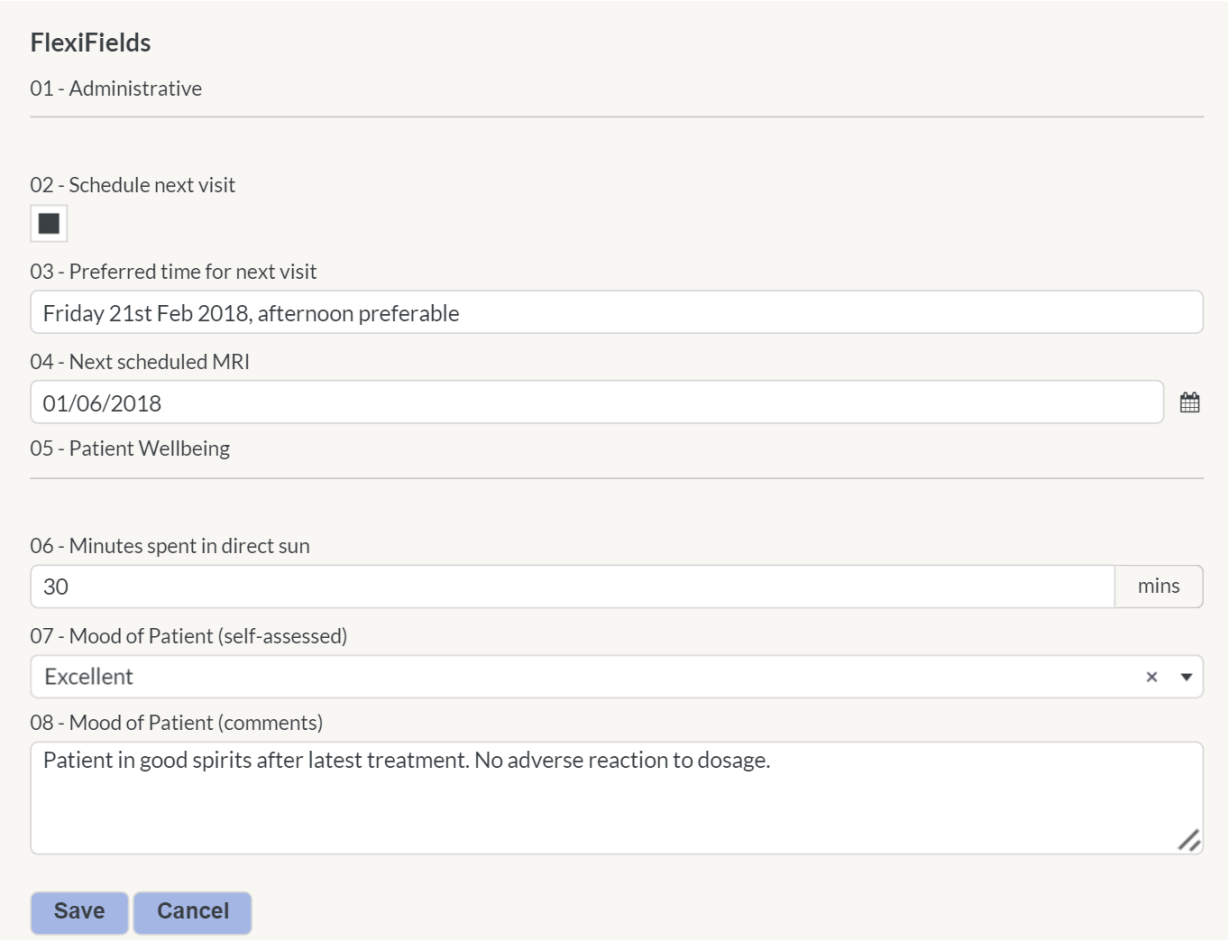


Figure 18 - Flexifield example

5.10.2. Data types

There are seven different field types available in iMed Web that can be used as Flexifields. Each field type is described below.

- **Checkbox**: Used to capture true or false values. Examples include Patient Consent or whether to book a follow-up appointment. Checkbox fields cannot be graphed but can be searched using “Yes” or “No”.
- **Date**: Used to capture a specific date. Dates must include a valid day, month, and year. Where only the month or year is known, either use an arbitrary day value or capture the information using a Text field. When searching date fields, the =, <, and > operators may be used.

- **Dropdown**: Used where standardised responses are required. For example, a field such as “Patient mood” may include options like “Excellent”, “Good”, “Mediocre”, “Bad”, or “Terrible”. Dropdown fields cannot be graphed but are searchable.
- **Header**: Used to organise Flexifields into logical sections within a form.
- **Numeric**: Used to capture numeric values of up to 20 digits. Numeric fields are searchable and can be graphed when used in Visits, Medical Events, or Paraclinical Tests.
- **Text**: Used to capture short alphanumeric values such as names, phone numbers, or insurance references. Text fields are searchable but not graphable.
- **TextArea**: Used to capture longer text entries, such as clinical or administrative notes. TextArea fields are searchable but not graphable.

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 Flexifields section, first determine which category it should belong to. There are four available options:

- **Patient Profile**: Flexifields in this section should be used only to capture once-off patient information and should not be used for time-series data. Examples include Patient Insurance Reference, consent to upload data for research, or hair colour.
- **Visits**: Flexifields in the Visits section are intended for time-series values that may change over time. Examples include centre-specific administrative fields, such as identifying when the next MRI is due.
- **Medical Tests**: This category can be used to create custom medical tests to capture time-series test outcomes. For example, a centre-specific disability scale being assessed over time.
- **Medical Events**: Medical Event Flexifields are used to capture custom, time-series medical events. Similar to Paraclinical Tests, this section can be used to create structured data collection forms for specific events. For example, a centre may collect additional pregnancy-related data beyond the standard Pregnancy form, which would be recorded in the Medical Events section.

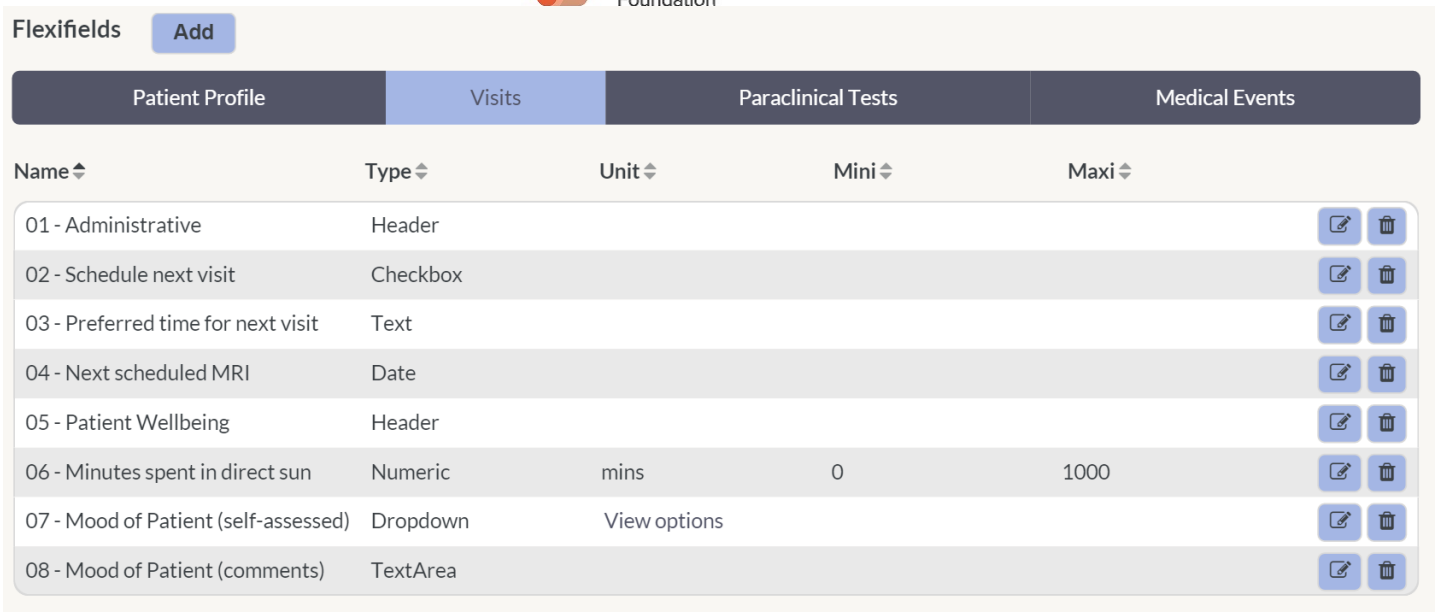


Figure 19 - Flexifield administration screen

After selecting the appropriate category, create the Flexifield by selecting Add and completing the remaining fields. Save the Flexifield, then save your changes.

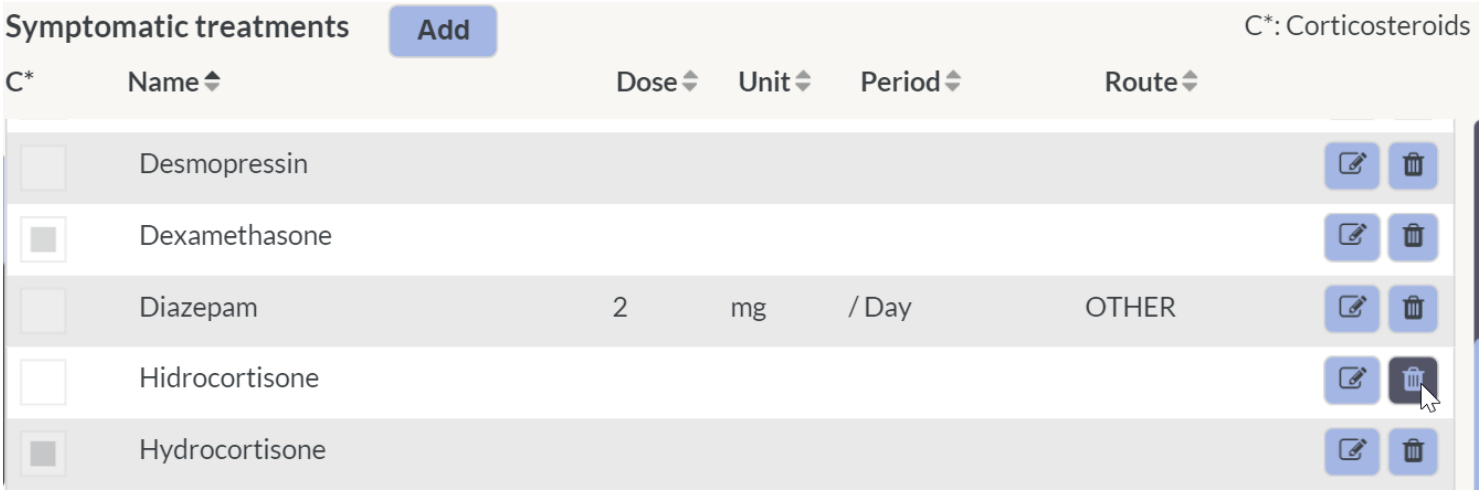
Good to know!

Flexifields are sorted alphanumerically by field name by default. To enforce a specific order, prefix field names with a number, as shown in the example above.

5.11. Deleting Reference Data

There may be situations where reference data needs to be deleted. This may occur when a field value is no longer required or when multiple values need to be consolidated into a single, standardised value. iMed Web does not allow reference data to be orphaned; therefore, when deleting reference data that is already associated with patient records, you will be required to map the deleted value to an existing value.

For example, you may identify two spelling variations of the same treatment, such as Hydrocortisone and Hidrocortisone (with Hidrocortisone being incorrect).



There are two possible scenarios when deleting reference data. If the treatment has never been used in iMed Web, it can be deleted directly. If the treatment has been used, the value must be replaced and then deleted.

Good to know!

What happens if a patient has already been treated with “Hidrocortisone”?

If this treatment were deleted, the patient record would retain the dosing schedule, duration, and notes, but the treatment name would be removed. To prevent this, the Replace and Delete option must be used.

When selected, iMed Web prompts you to choose an existing treatment to replace the deleted value. In this example, all records referencing Hidrocortisone are replaced with Hydrocortisone, after which the incorrect reference is deleted.

This behaviour applies not only to MS/NMO-specific treatments, but also to Symptomatic Treatments, Family Relationships, Ethnic Origin, and Non-pharmacological treatments.

6. MedDRA

6.1. What is MedDRA?

MedDRA is the preferred method for capturing medical conditions in iMed Web. It is an internationally recognised and clinically validated medical terminology dictionary used across the medical and pharmaceutical industries. MedDRA is available in multiple languages, including English, Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese, Spanish, and Japanese, and is widely used worldwide for pre-marketing and post-marketing safety activities.

6.2 Structure of MedDRA

MedDRA is structured as a hierarchical tree, organised by System Organ Class (SOC) and further divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT), and finally Lowest Level Terms (LLT). When assigning a medical condition to a patient, selection is made at the LLT level, and only LLT values are available for entry.

In the example below, a patient is classified as having Sleep Apnoea. When searched, the relevant LLT is returned and can be selected. Each LLT belongs to a corresponding PT, and LLTs can be considered synonymous terms for that PT. In this case, any of the available LLT terms would be correctly classified under the PT Sleep Apnoea Syndrome.

MedDRA PT terms may belong to more than one hierarchy, a characteristic known as multiaxiality. As shown in the example below, Sleep Apnoea may be classified not only as a respiratory disorder, but also as a psychiatric or nervous system disorder. As a result, when searching in iMed Web, a PT may be returned for multiple SOC-based searches.

For reporting and display purposes, iMed Web uses MedDRA's primary hierarchy, in which only a single SOC is applied. The primary hierarchy is defined by MedDRA, ensures consistency, and prevents "double counting" of medical conditions. In the diagram below, the primary hierarchy for Sleep Apnoea is shown in red.

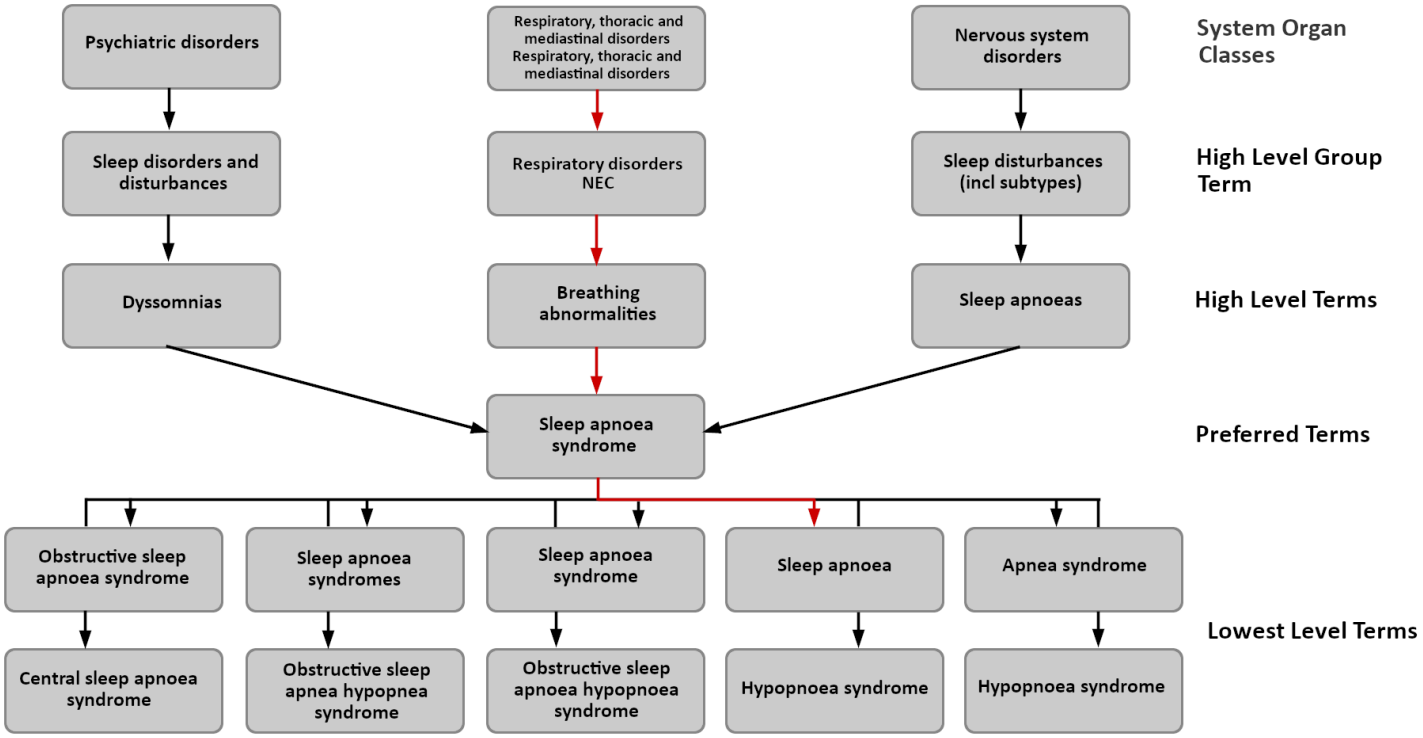


Figure 20 - MedDRA hierarchy for Sleep Apnoea

6.1.1. Browsing MedDRA

MedDRA definitions can be applied to a patient either by browsing and selecting a Lowest Level Term (LLT) or by searching directly for an LLT. To browse, expand the hierarchy by selecting the SOC, HLGT, HLT, and PT levels. Once the appropriate LLT is located, select and save the entry.

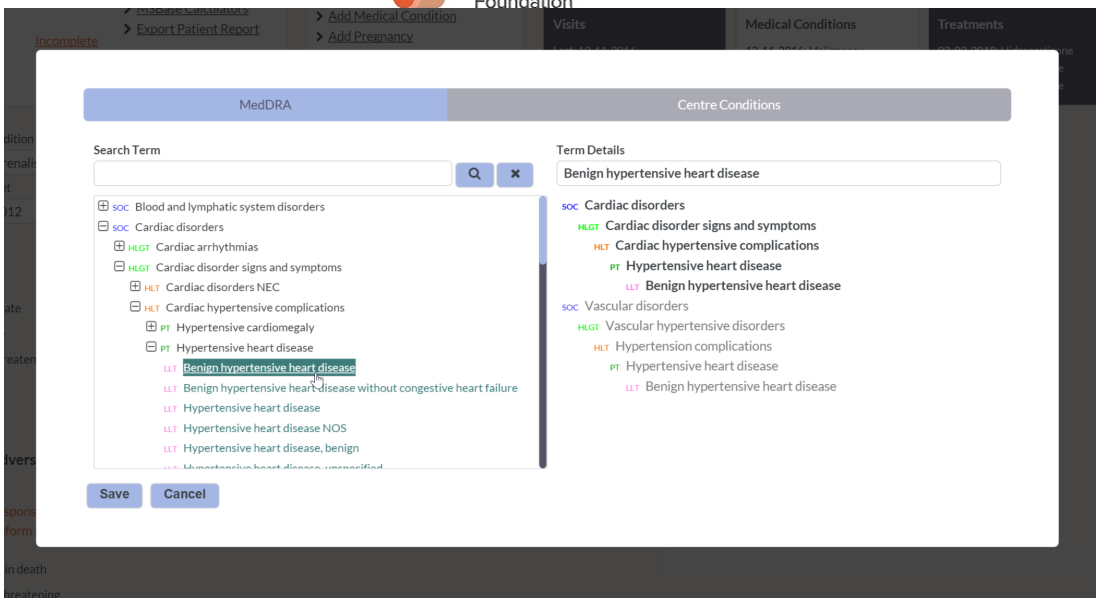


Figure 21 - Browsing with MedDRA

6.1.2. Searching

Searching MedDRA is a more efficient method for locating a Lowest Level Term (LLT) when the condition is known. Enter a search phrase and select the Search icon. iMed Web will return the closest matching LLT and rank results by relevance. Select the appropriate LLT and save to assign it to the patient.

If no LLT is returned, check the spelling of the search term or try a less specific search. Alternatively, refer to the section above and browse the MedDRA hierarchy to locate the required LLT.

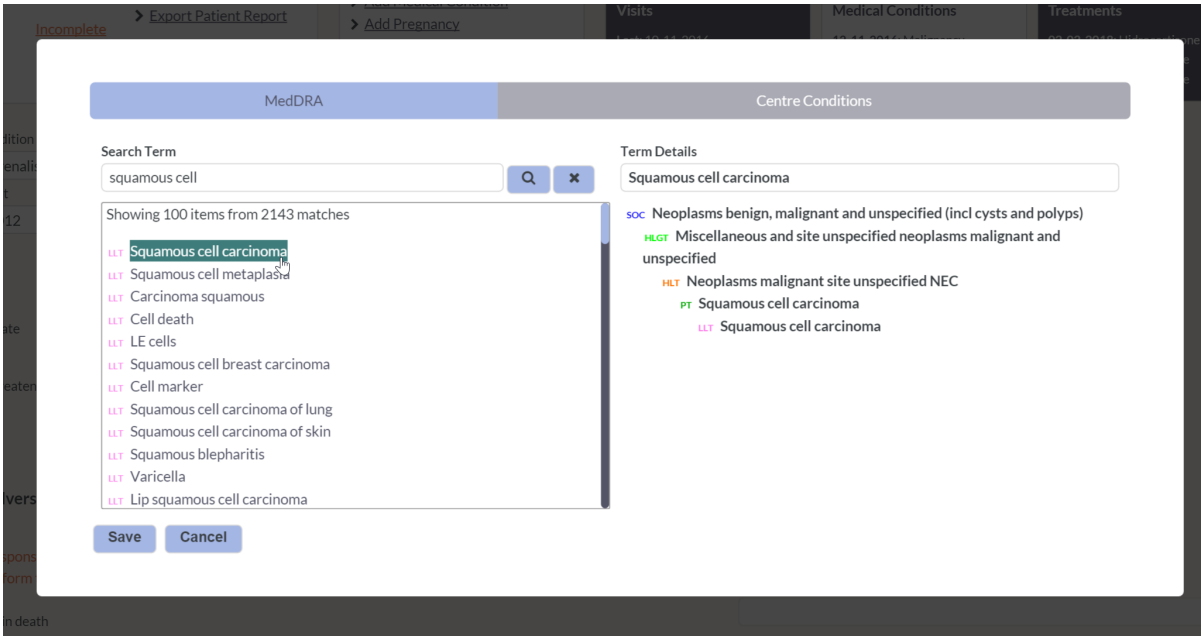


Figure 22 -Searching for a LLT

7. Patients

7.1. Adding a new patient

To add a patient in iMed Web, expand the Patients option in the iMed Web menu and select Add new patient. Ensure all mandatory fields are completed before selecting Create Patient. Once the patient has been created, Visits, Treatments, Medical Events, and other records can be added as required.

Good to know!

After the patient is created, they are not yet enrolled in the MSBase Registry. The patient can be enrolled either via the Manage All Patients section or by selecting the Registry [Unenrolled] button in the Patient Card, which will then update to [Enrolled].

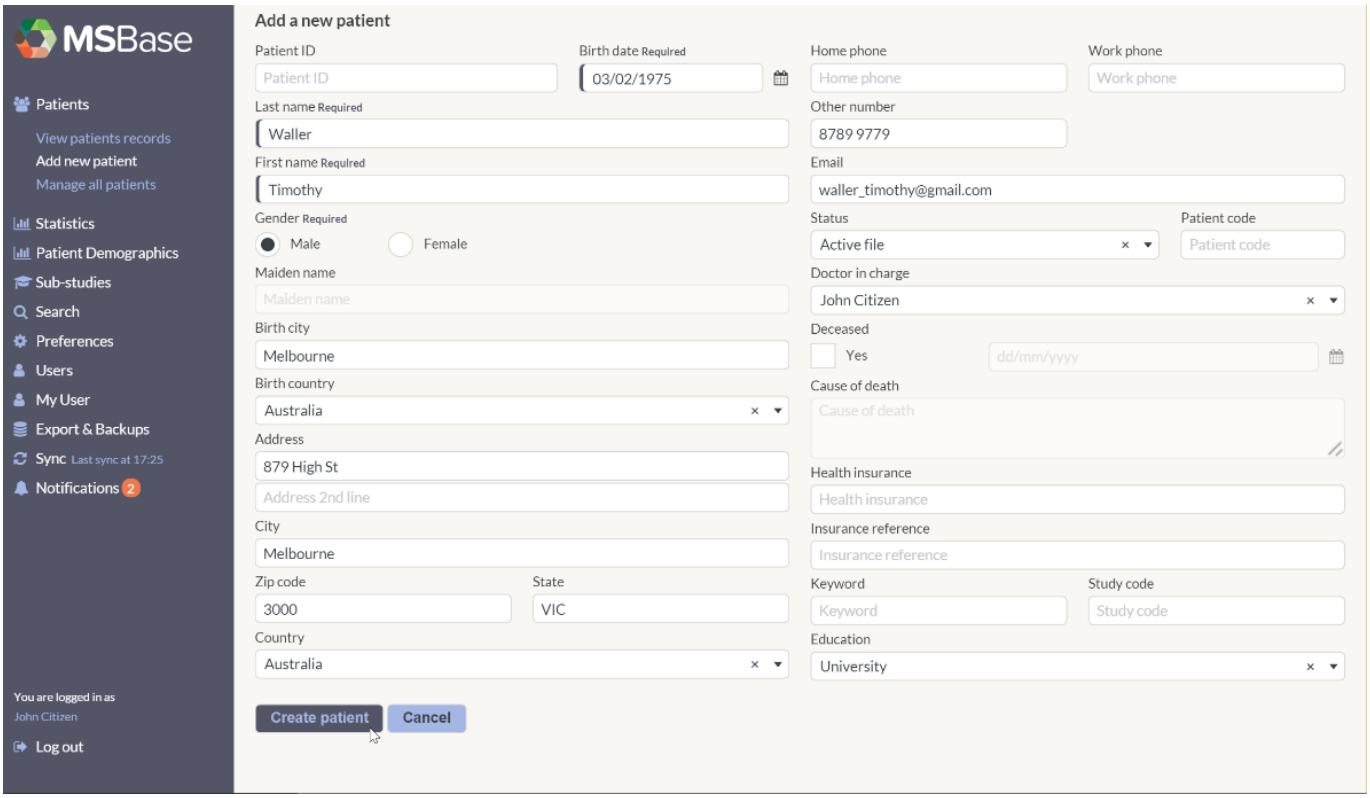


Figure 23 - Adding a patient

7.2. Manage all patients

The Manage All Patients screen provides a high-level view of patients and supports bulk actions. For example, this screen can be used to enrol multiple patients into the Registry. Additional functions available in this screen include:

- Check Completeness: Identifies patients with incomplete records. Select Fix to view incomplete elements. If no Fix option is displayed, the patient record is complete.
- Enrol/Unenrol: Enables identification of patients who are not yet enrolled in the Registry and supports enrolment actions, which are otherwise typically performed on an individual basis.
- Delete/Restore: Allows patients to be removed from iMed Web, for example where a record is a duplicate or the patient no longer attends the clinic. iMed Web performs a soft delete only, meaning the patient record can be restored if required. Deleted patients do not appear in the Patient Selector.

Navigation within the Manage All Patients screen is limited to sorting by column values. For more detailed analysis, patient data should be exported to Excel or CSV format.

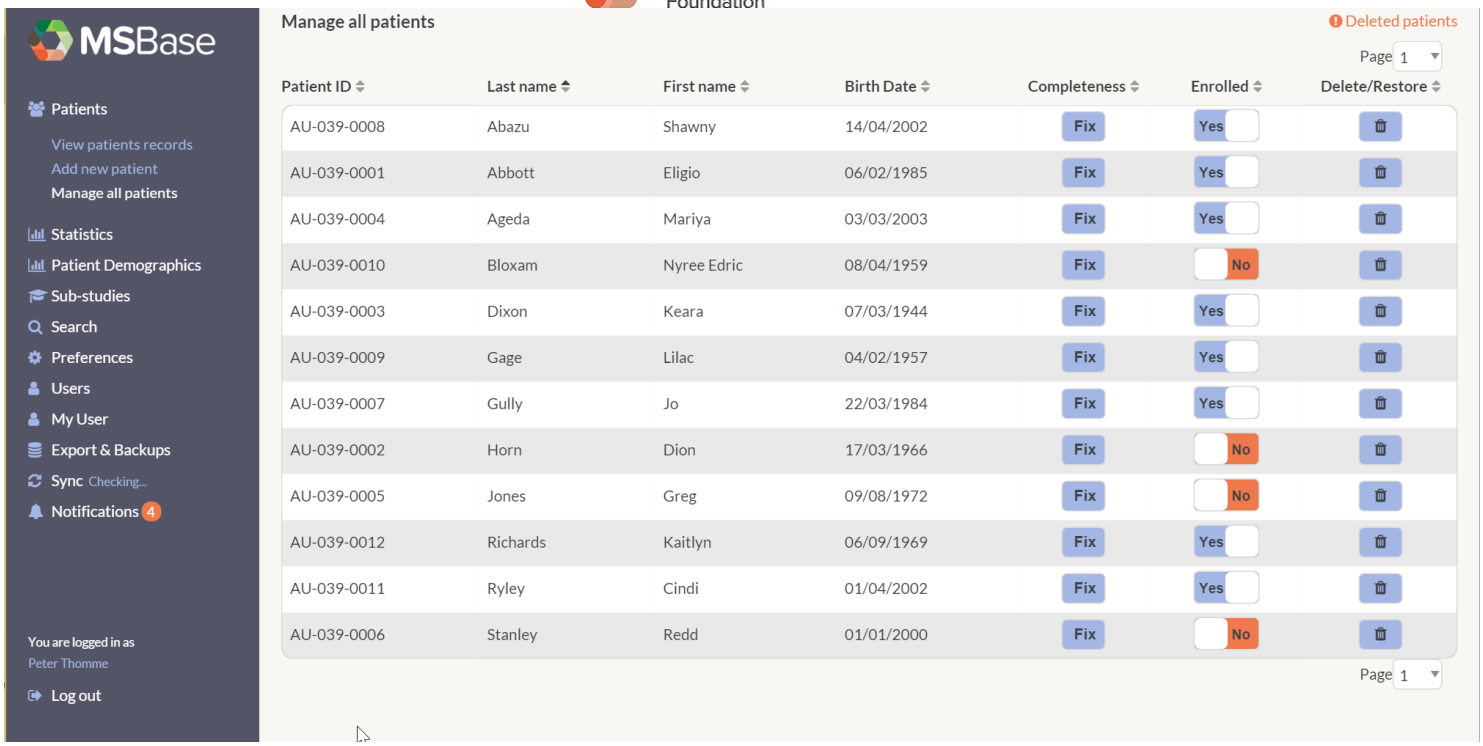


Figure 24 - Manage all patients screen

7.3. Deleting a patient

When a patient is deleted, they are not permanently removed from the system. Instead, the record is soft-deleted. This means the patient is excluded from synchronisation events, no longer appears in search results, and is removed from the Patient Selector list.

Soft-deleted patients are identified in the Patient Management screen by an orange exclamation mark ( ). The record can be restored at any time by selecting the restore button ( ).

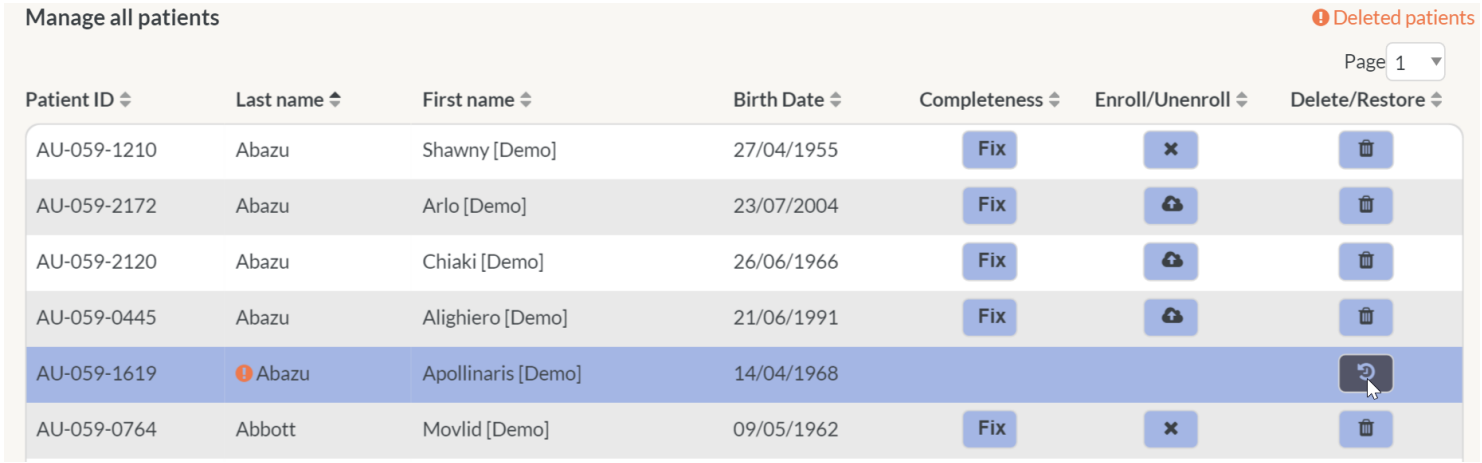


Figure 25 - Restoring a deleted patient

7.4. Patient Card (Record)

When a patient is selected in iMed Web, the Patient Card (Record) displays a summary of the patient and provides access to a limited set of actions. The following functions are available:

- **Check patient completeness:** Review whether the patient's record is complete and meets the MSBase recommended completeness criteria.

- **Check Registry enrolment:** View the patient's Registry enrolment status and enrol the patient if they are not already enrolled.
- **Manage sub-studies:** View the sub-studies the patient is enrolled in and enrol the patient into additional sub-studies that require manual enrolment.
- **MSBase calculators:** Access patient-specific calculators and prediction models (coming soon).
- Export patient report: Export the patient report in PDF or RTF format for printing or filing.
- **View patient graph:** Open the Patient Overview Graph.
- **Customise graph:** Customise the Patient Overview Graph display.

Figure 26 - Patient Card functions in iMed Web

7.5. Patient Quick Links

The Patient Quick Links section provides quick access to commonly used actions, such as launching the Wizard and adding Visits, Relapses, Treatments, and Medical Tests and Conditions.

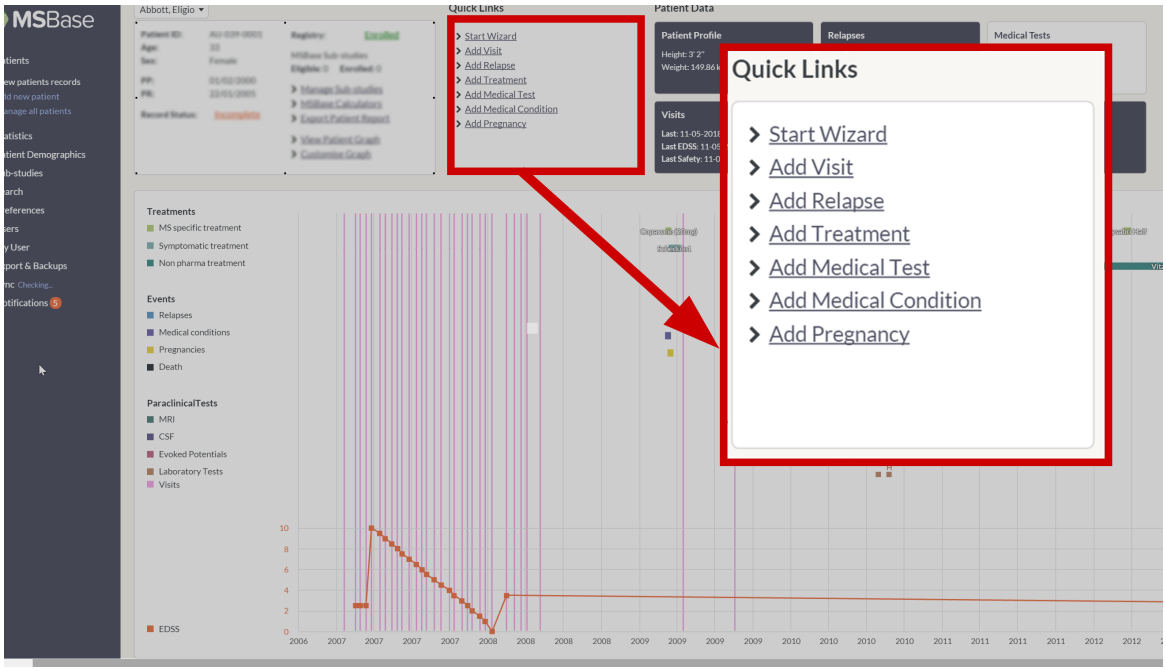


Figure 27 – iMed Web Quick Links

7.6. Patient Report

The Patient Report provides a high-level summary of the patient and may be used where a local policy requires patient data to be uploaded to an electronic medical record (EMR). The report can be exported in either Rich Text Format (RTF) or PDF.

To export a patient report, ensure the required patient is selected. Select Export Patient Report. In the export window, either enter a file path or select the Path icon to browse to a location using Windows Explorer. Choose the export format (PDF or RTF) and select Run. iMed Web will notify you when the export is complete and the file is ready to view.

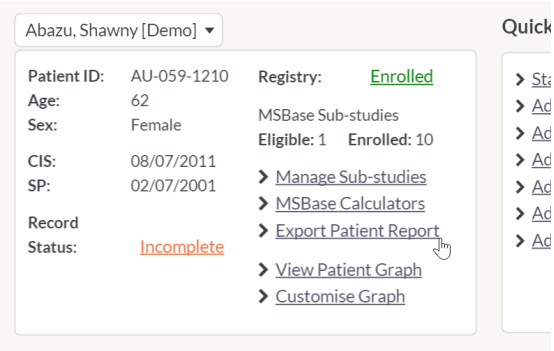


Figure 28 - Export a patient report

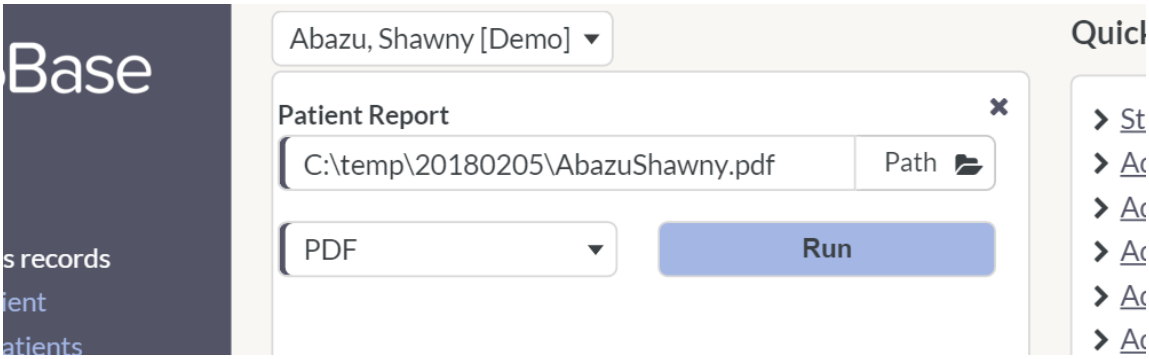


Figure 29 - Saving a patient report

7.7. Enrolling into Registry

When a patient is first created in iMed Web, they are not yet enrolled in the Registry. The Patient Card displays Unenrolled in orange text to indicate this status. Selecting this text prompts the user to confirm their decision to enrol the patient.

Unenrolling a patient is performed in the same manner.

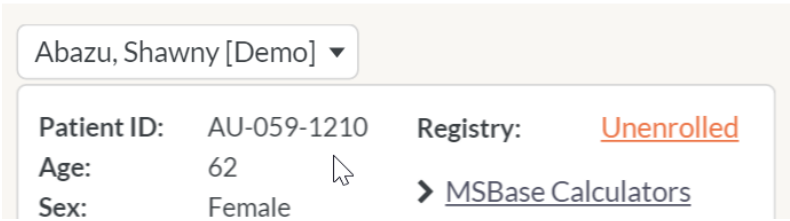


Figure 30 - Enroll a patient into the Registry

Once a patient is enrolled, iMed Web displays **Enrolled** in bold green text, and MSBase sub-studies become available for enrolment.

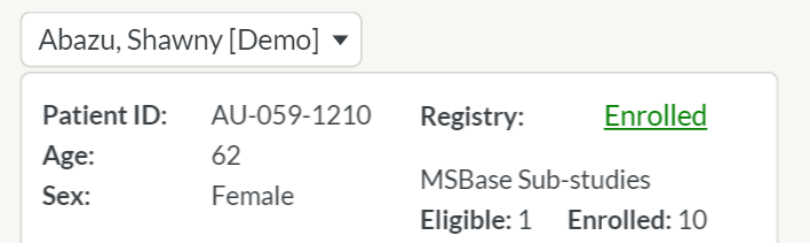


Figure 31 - An enrolled patient

7.8. Enrolling into Sub-study

Sub-studies enable collaboration and data sharing between centres. If your centre has already joined a sub-study, additional action may still be required to contribute data where the study requires Manual Enrolment.

For most sub-studies, patient enrolment is Automatic, meaning that if a patient meets the selection criteria, their data will automatically contribute to the study. Manual enrolment is used where selection criteria are subjective or difficult to capture, or where additional ethics approval or permissions are required. In a manual sub-study, patients must be enrolled individually by the user.

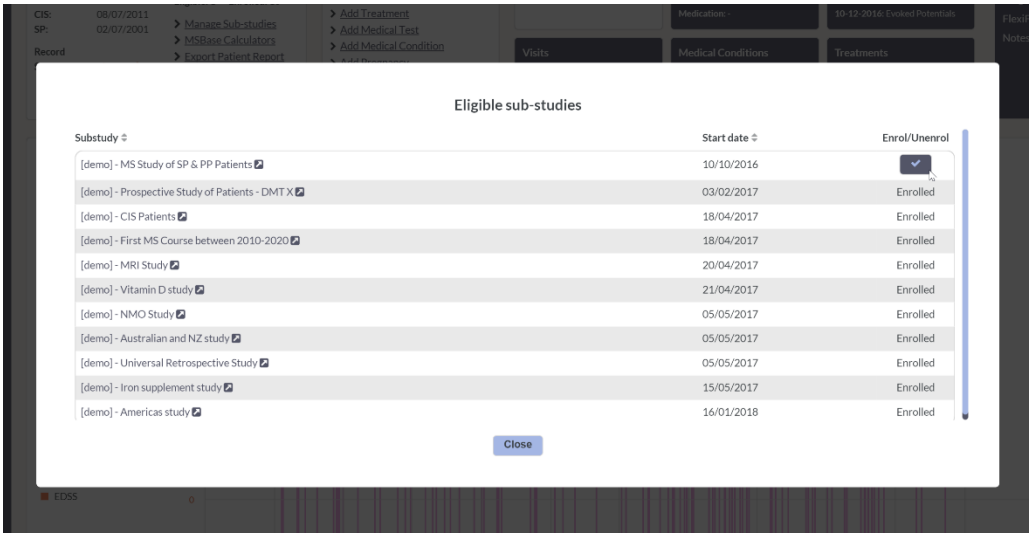


Figure 32 - Manage Sub-studies screen

Selecting Manage sub-studies displays a list of sub-studies that the patient is either enrolled in or eligible for. For studies with automatic enrolment, eligible patients are enrolled automatically. Where a sub-study requires manual enrolment, the user must select Yes in the Enrolled column.

Once a patient is enrolled, and after synchronisation with the Registry has occurred, any additional sub-study flexifields (if applicable) will become visible to the user.

7.9. Patient Completeness

Patient completeness builds on the MSBase Minimum Dataset and is intended to ensure that patient records are sufficiently complete to support robust and reliable statistical analysis. The following components of the patient record should be considered when assessing patient completeness.

Figure 33 - An incomplete patient

Visit

- At least 1 visit within the previous 12 months
- At least 1 EDSS Selected Score within the previous 12 months
- At least 1 complete EDSS (all functional systems scores supplied) within the previous 12 months

Brain MRI

- At least 1 Brain MRI recorded

Relapse

- All relapses must have a recorded CNS value (Pyramidal, Cerebellum, Brainstem, Sensory, Bowel Bladder, Visual functions, Neuropsychological, Other)
- Where a relapse treatment is either Hospital or Ambulatory then a related Corticosteroid value Yes/No must be captured
- Where a relapse has been treated with a corticosteroid, then that treatment must be captured

**Note – The NMO Minimum Dataset is broadly similar to the MSBase Minimum Dataset; however, it includes several additional and differing fields that must be completed. Details are provided in the separate NMO Minimum Dataset document.*

The Patient Completeness report is displayed as shown in the image below and indicates whether any elements of the patient record are incomplete.

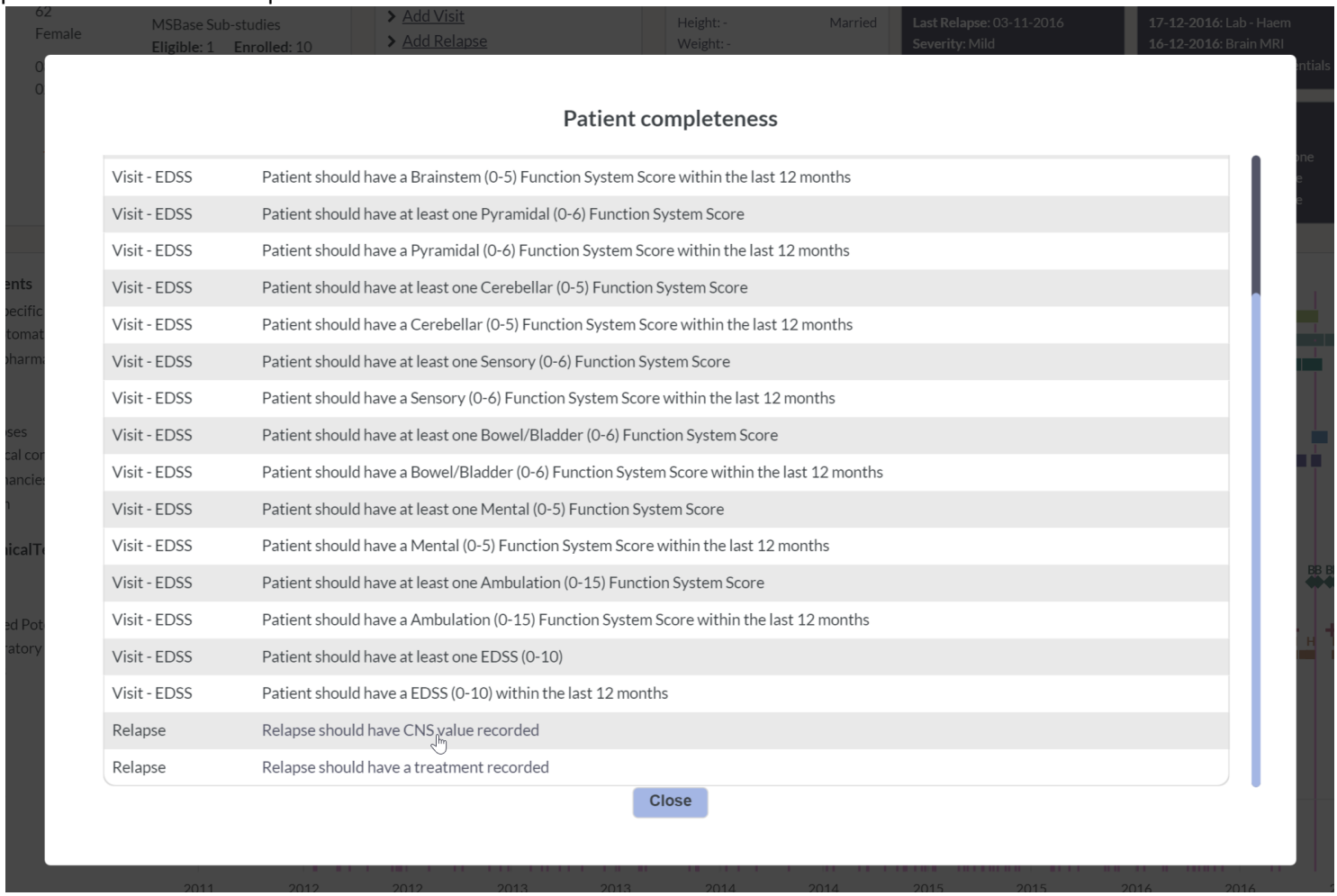


Figure 34 - Patient completeness report

8. MS Course

The MS Course is calculated in iMed Web based on information entered in the Patient Profile – Diagnosis screen, together with the date of the first relapse, which is used to determine Relapse Remitting or Progressive Relapsing disease courses. Further details on MS Course classification are outlined below.

8.1.1. CIS stream

CIS – **Clinically Isolated Syndrome:** A patient is classified as CIS when an Onset Date has been recorded and no relapse has occurred after this date.

RR – Relapse Remitting: A patient is classified as RR from the date a Confirmed Diagnosis Date is recorded. Alternatively, the occurrence of any relapse after the Date of Onset will also result in the patient being classified as RR from the date of that relapse.

SP – Secondary Progressive: A patient may be classified as SP when the date of the Secondary Progression Phase occurs after the RR date, which is defined by either the Confirmed Diagnosis Date or the date of the first relapse. A Confirmed MS Diagnosis Date is required in iMed Web for SP to be assigned.

iMed Web calculates the MS Course and will display the values in the below manner:

Not enough data to calculate disease course	Not enough information entered, or a date is invalid, for example a relapse date before the date of onset.
MS Course: CIS — Start Date: 06/03/2002	This patient is currently assigned as CIS.
MS Course: CIS — Start Date: 31/03/2002; RR — 09/07/2003	This patient was CIS between 31-03-2002 to 08-07-2003. From 09-07-2003 onward the patient is RR.
MS Course: CIS — Start Date: 19/03/2001; SP — 31/03/2008	Prior 31-03-2008 this patient was CIS, after that period the patient is SP.
MS Course: CIS — Start Date: 31/03/2002; RR — 09/07/2003; SP — 27/08/2006	This patient's MS profile has undergone three phases, CIS, RR and from 27-08-2006 onwards the patient is classified as SP.

8.1.1. PP stream

PP – Primary Progressive: A patient is classified as PP when a Date of Onset is recorded and the Progression from Onset checkbox is selected.

PR – Progressive Relapsing: A patient is classified as PR when they meet the criteria for PP and subsequently experience a relapse after the Date of Onset.

Not enough data to calculate disease course	Not enough information entered, or a date is invalid, for example a relapse date before the date of onset.
MS Course: PP — Start Date: 07/03/2001	Primary progressive is determined by the user having "Progression from Onset" checked and the date taken from the Onset date.
MS Course: PP — Start Date: 06/03/2001; PR — 19/03/2002	Progressive Relapsing is determined by a "Progression from Onset" checked any the date of the first relapse after the onset date is determined as the Progressive Relapsing date.

9. Patient Overview Graph (POG)

9.1. Overview

The Patient Overview Graph (POG) provides a visual representation of a patient's medical history. By default, the following elements are displayed:

- Visits are displayed as vertical red 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.
- Relapses are displayed as a block of time where a Relapse duration is supplied, or as a square icon where no relapse length is given. Where a relapse has been treated with a corticosteroid then that relapse is represented with an Asterix above it *.
- 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.
- MRI are displayed as a diamond icon on the date the MRI was performed. Above each MRI there is a letter identifying the different type of MRI: Brain (B), Spinal Cord (S), Thoracic Cord (T) and Cervical Cord (C).
- Cerebral Spinal Fluid (CSF) tests are displayed as the blue cross (+) icon
- Evoked Potentials are displayed as a blue cross (+) icon
- Laboratory tests are displayed as a square icon. In iMed Web, there are five categories of laboratory tests: Haematology (H), Blood Chemistry (B), Thyroid Functions (T), Serological Tests (J) and Auto-antibody (A) Tests. iMed Web will recognise which categories of tests have been completed in each of the Laboratory Tests and display that information to the user. For example, if only the Red Cell Count was populated (Haematology), then the icon would be displayed as H. If the Pregnancy-test (beta-HCG) value was populated, then the icon would indicate a Serological Test (S). It is possible to have up to 5 different letters display on the indicator. A laboratory test that has values in all forms would have all 5 characters displayed (ABHJT).

In the bottom section of the POG there is a section where any time-series numeric value can be displayed. By default, iMed Web will show the EDSS score of the patient. This section will explain how to customise this graph should you need to.

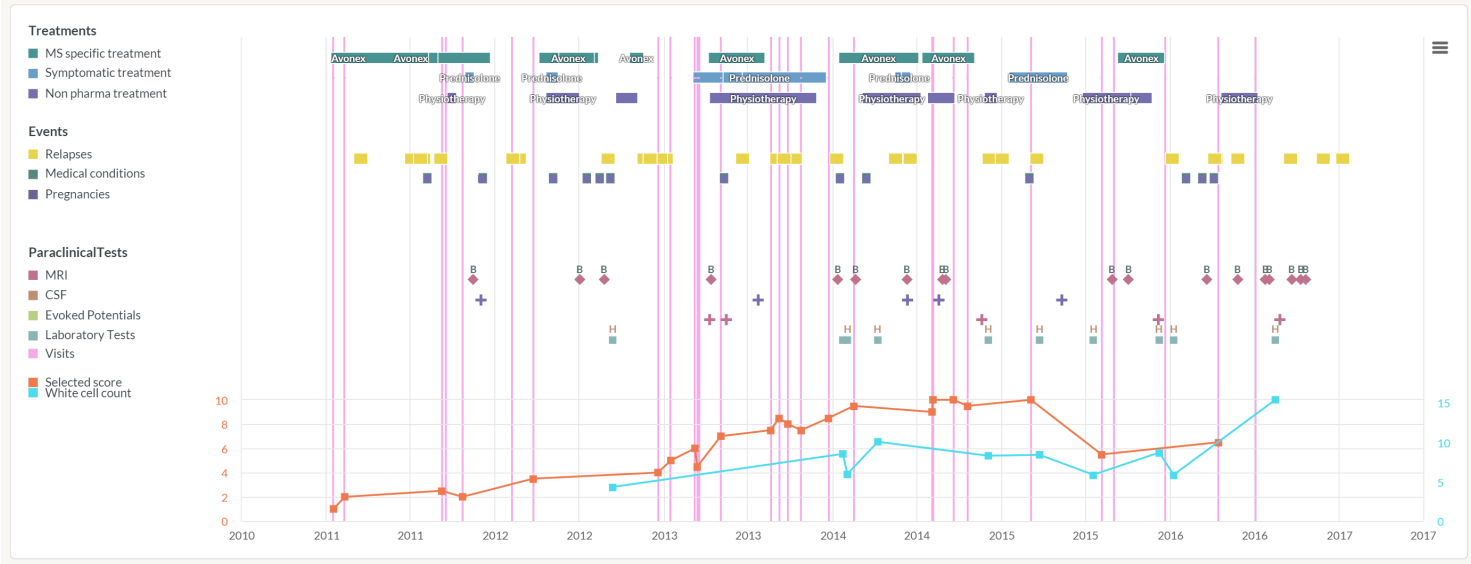
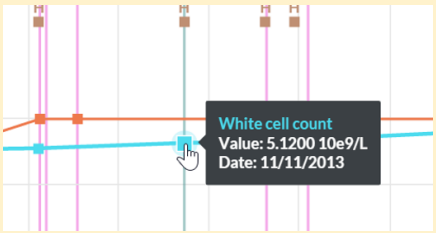


Figure 35 - The patient overview graph

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 toggle on/off the corresponding indicators.



9.2. 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.

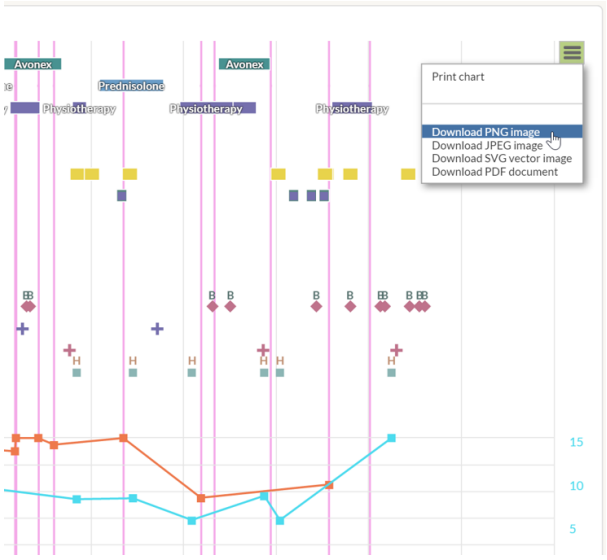


Figure 36 - Printing and exporting the graph

9.3. Graph field customisation

You can display any numeric time-series value in the lower panel of the POG. To do this, select *Customise Graph* from the *Patient Card*. This opens the POG customisation window.

By default, *EDSS – Selected Score* is plotted on the left Y-axis, and the right Y-axis is blank. You can assign a numeric time-series value to either axis from the following areas: Visits, CSF, Evoked Potentials, Lab Tests, MRI, Medical Events – Flexifield, Paraclinical Tests – Flexifield, Pregnancy, Quantitative MRI, and Relapse. For example, you could plot *MRI T1 lesion count* alongside *EDSS* to explore whether changes in lesion count coincide with changes in EDSS. When viewing the graph, hover over any marker to display the recorded value and unit (where applicable).

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.

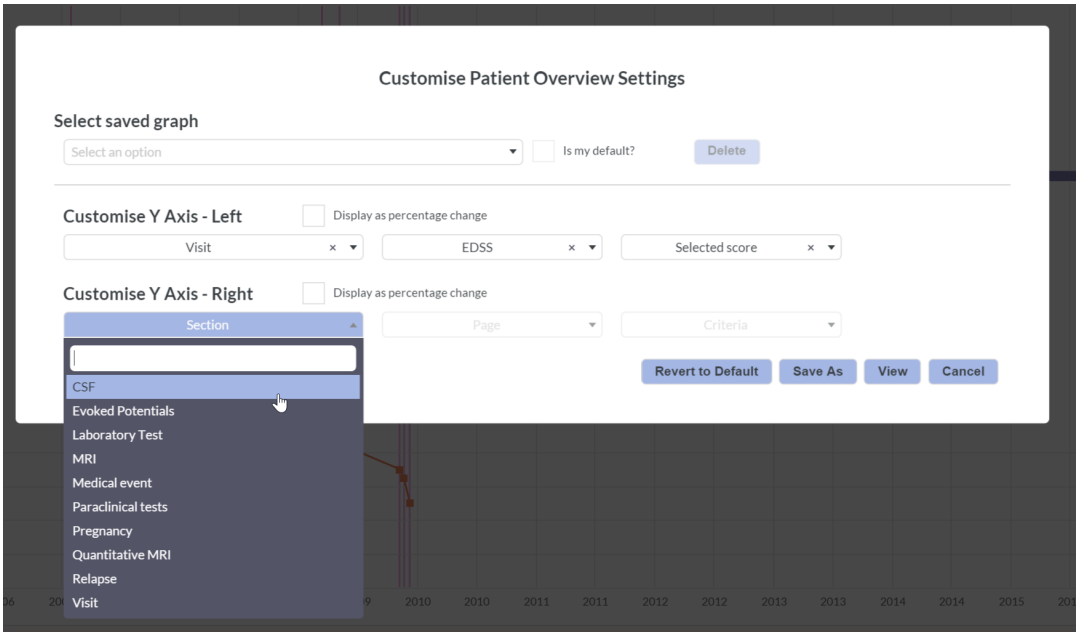


Figure 37 - Customise Graph Options

9.4. Percentage Change

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

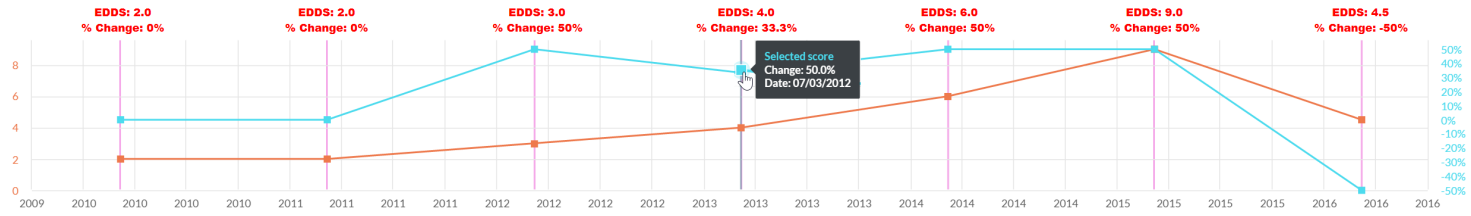


Figure 38 - EDSS vs EDSS % Change

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.

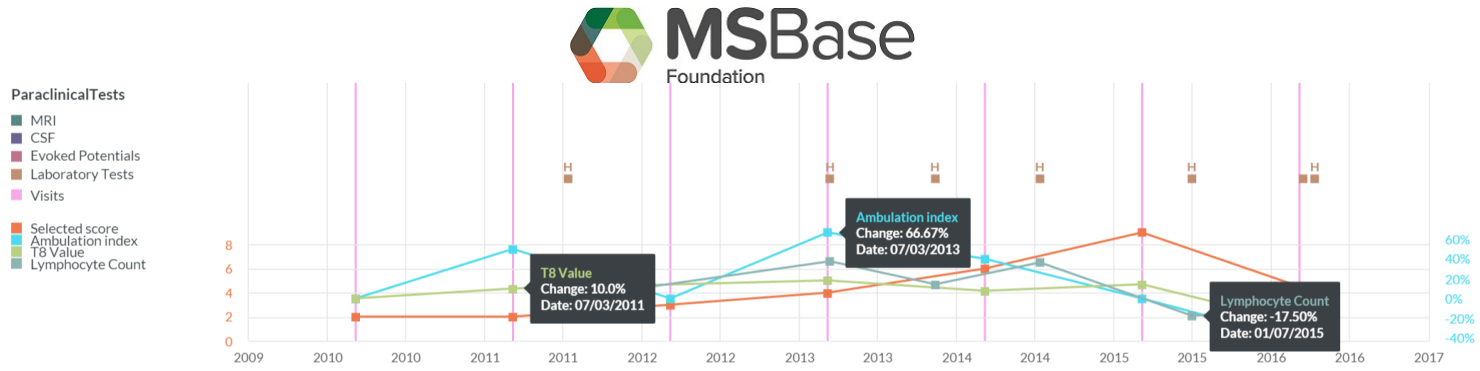


Figure 39 - Custom graph of Time to Walk 8 seconds, Ambulation Index and Lymphocyte Count

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.

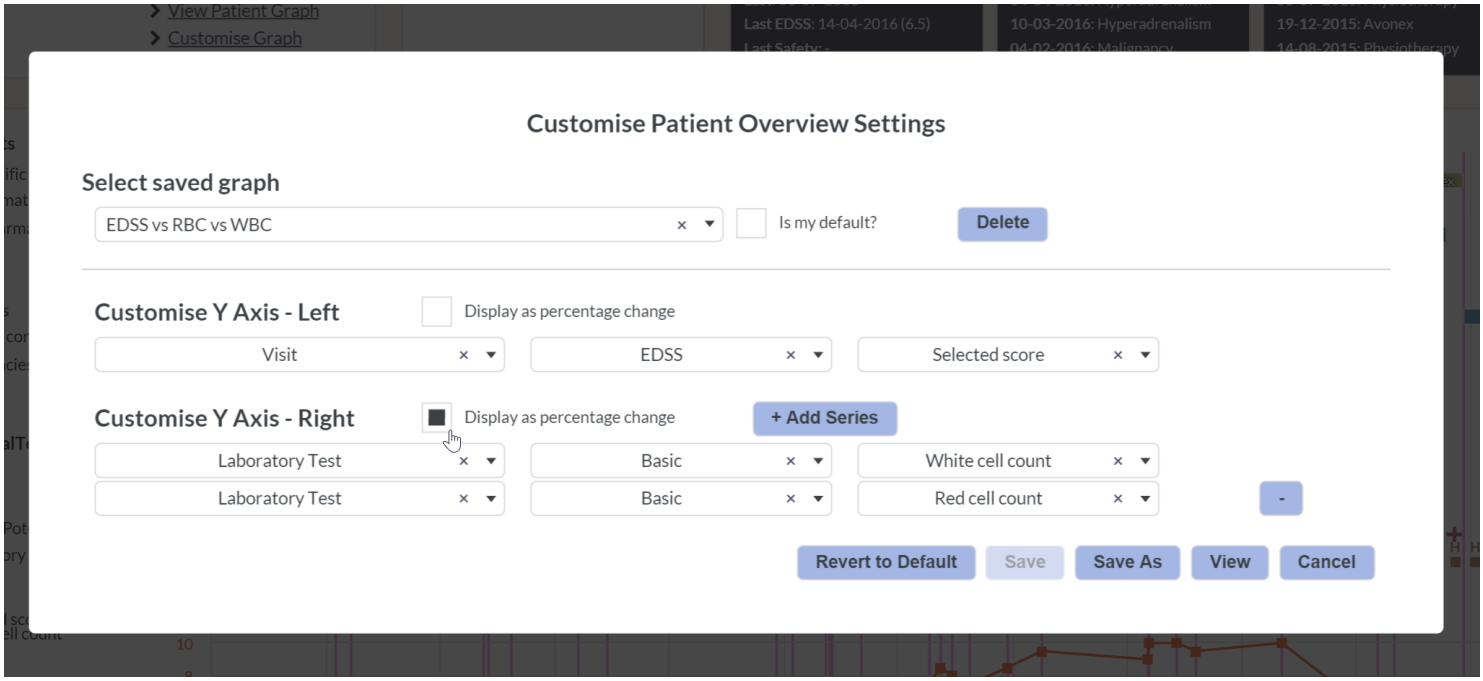


Figure 40 - Adding percentage change fields

9.5. 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 iMed Web.

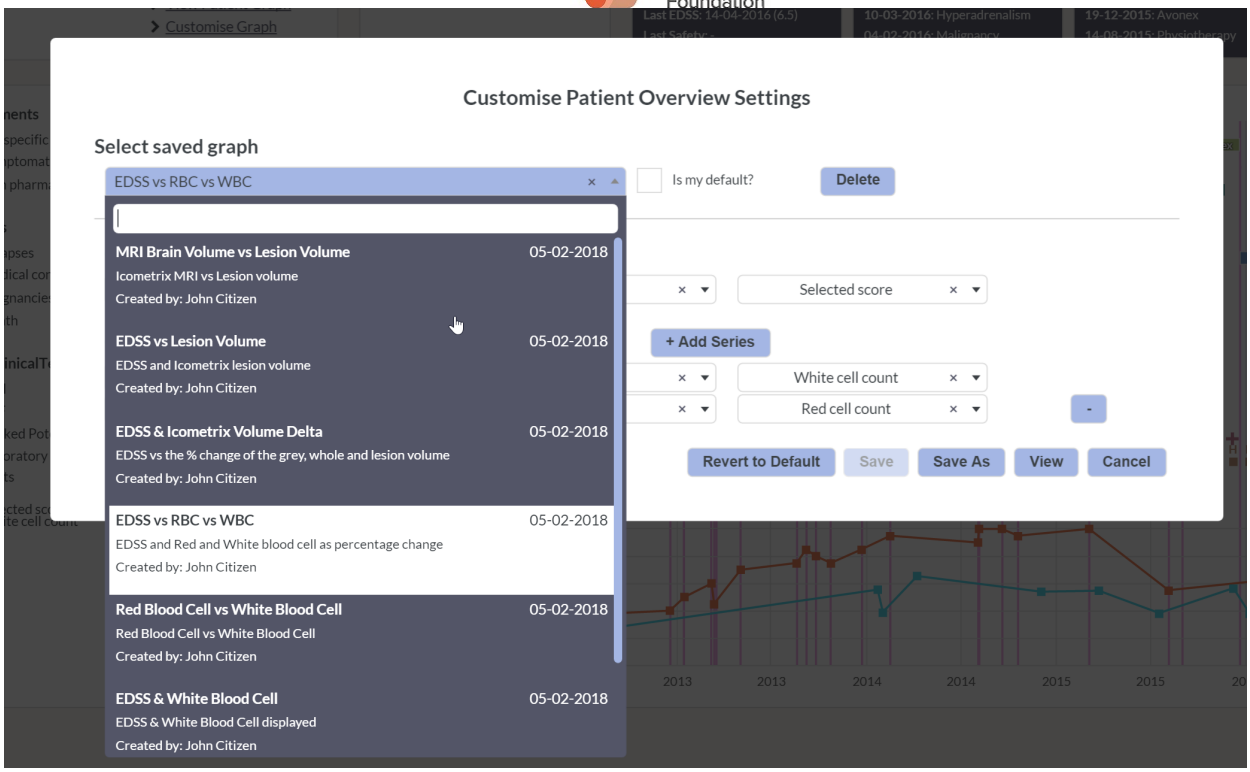


Figure 41 - Selecting a saved graph

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.

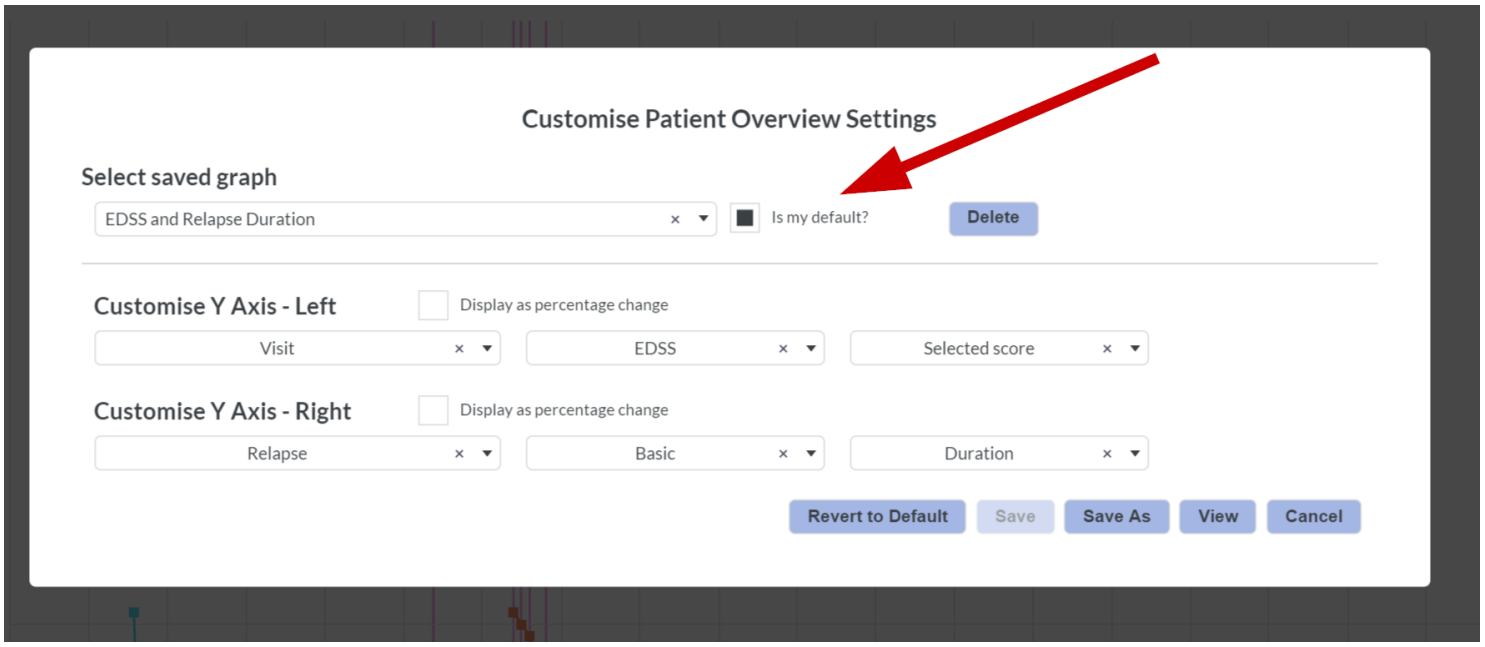


Figure 42 - Setting a default POG

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.

10. User Forms

10.1. Overview

iMed Web enables the capture of patient demographic information (Patient Profile), as well as Treatment, Relapse, Visit, Medical Test, and Medical Condition data. The following sections provide further detail on each form. Additional information on individual data fields and validation rules is available in the iMed Web MS Data Dictionary, which can be accessed from the Members Document section when logged into the Registry [MSBase | Member documentation]

MSBase recognises that many medical professionals have limited time for detailed data entry. For this reason, iMed Web has been designed with the minimum number of mandatory fields required to support high-quality data collection. Refer to the sections below for details on mandatory fields. Where insufficient information is entered, iMed Web will notify the user that the form cannot be saved.

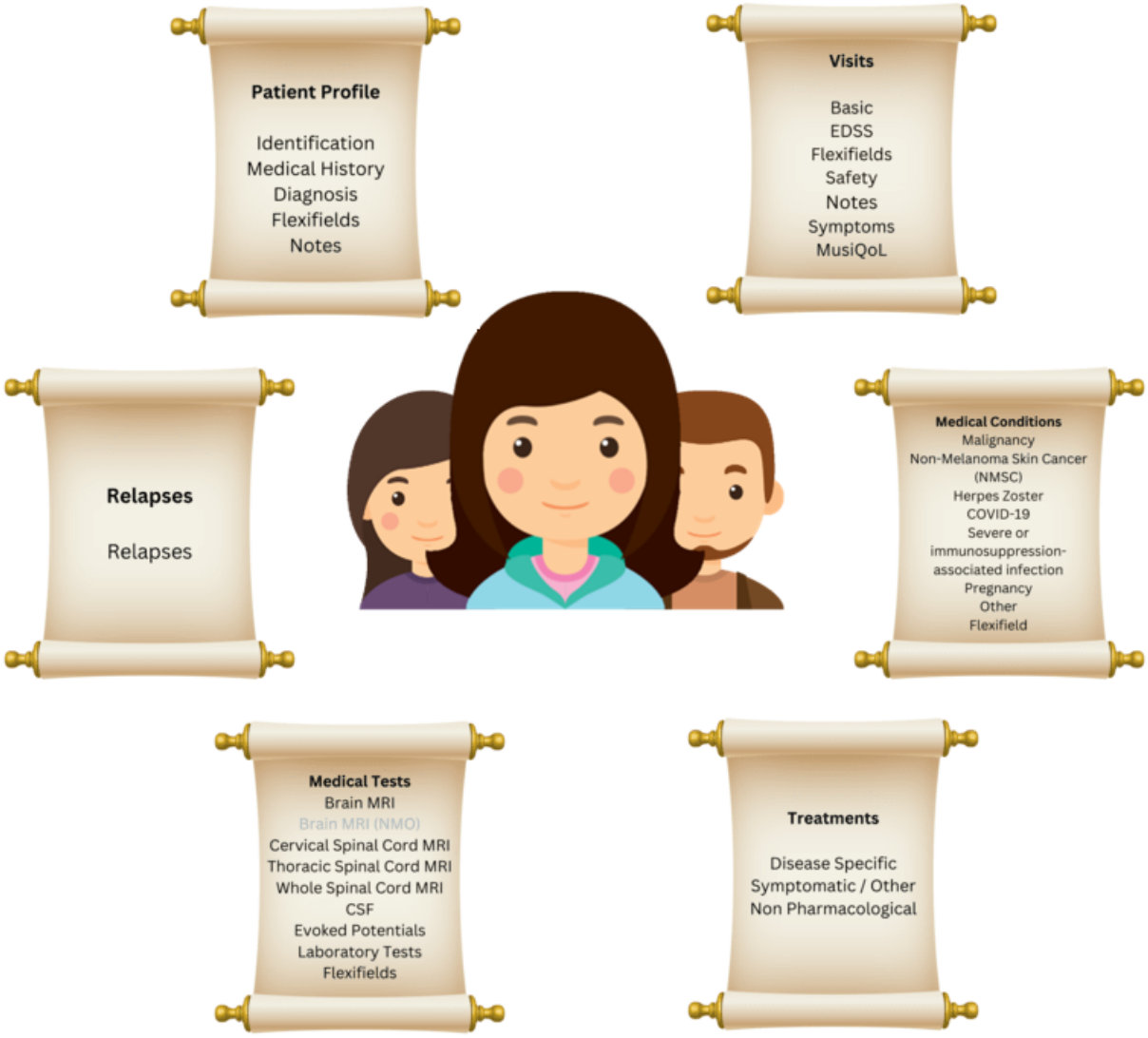


Figure 43 - Forms used by iMed Web to capture patient information

10.1.1.Patient Profile

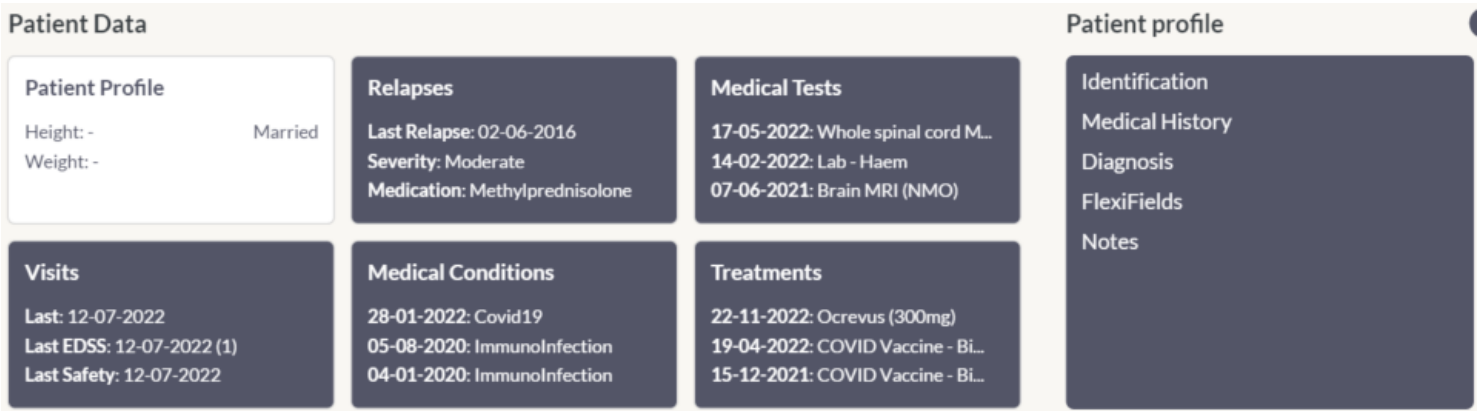


Figure 44 - Patient Profile Section

The Patient Profile section captures basic information about the patient. Unlike the other forms in iMed Web, 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. Users can also select between MS and NMO now under "Select Disease". Changing the disease will switch the Diagnosis screen and Brain MRI form to be specific to the selected disease. This is reversible, and all previously captured data is retained. NMO also displays additional first symptoms not available for an MS patient. It's possible to view NMOSD Criteria for either NMOSD "Definite" or NMOSD "Probable" diagnosis.
- **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 here.
- **Notes** section allows the user to capture notes about the patient.

10.1.2.Relapse

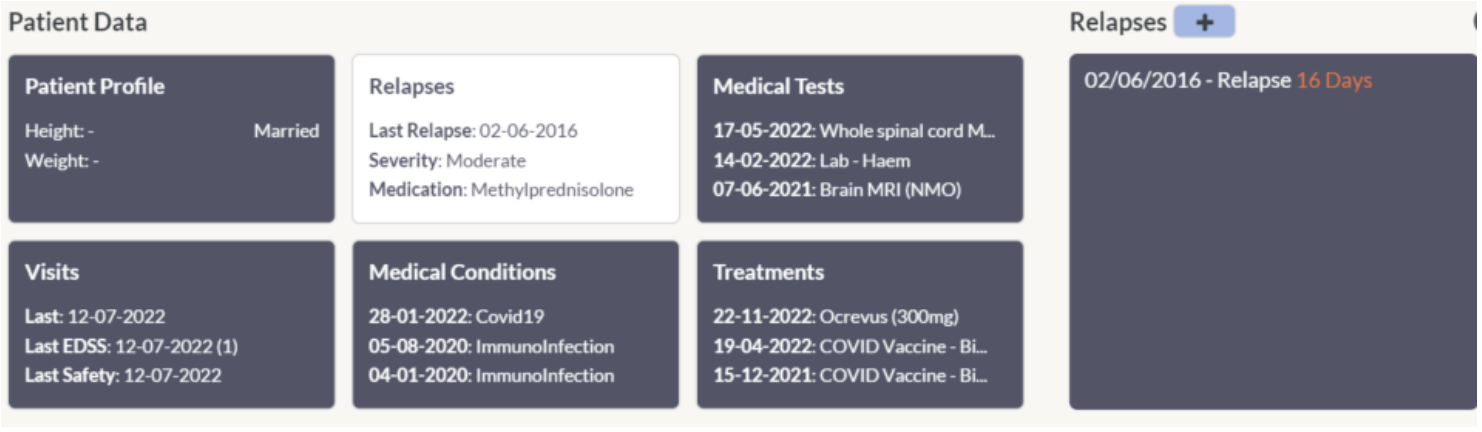


Figure 45 – Relapses Section

Relapse captures information about the patient's relapses in a time-series format. One patient can have multiple Relapse events captured. Note that for NMO patients, there is an additional section with a multi-selection list under "Clinical presentation"

10.1.3.Medical Tests

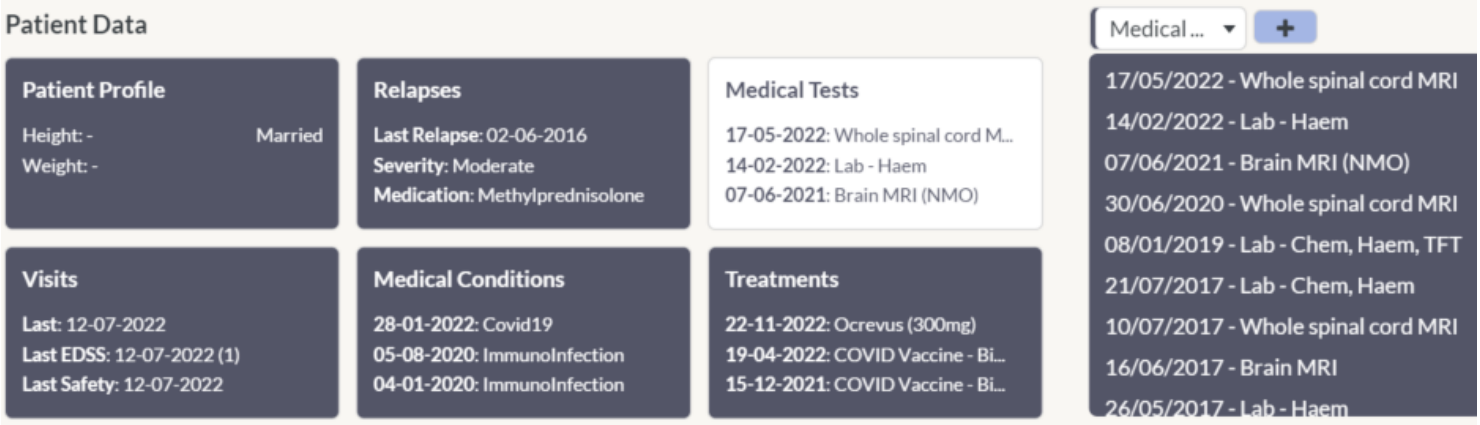


Figure 46 - Medical Tests Records Section

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 iMed Web:

- The **MRI** form captures information about the patients MRI and will also allow you to save images (in JPG, PNG and GIF format) and make notes about the patient's MRI. Whole spinal cord, Cervical and Thoracic all share the same form, while Brain MRI has a more detailed form. iMed Web does not support the storage of DICOM images.
    - Additionally, some centres may have additional capability to view *integrated data* of **Quantitative MRI** for relevant MRI scans, from either **Icometrix** or in the future **MSBIR**. If an MSBIR QMRI record exists for a patient, a clinician will in the future be able to click a link to "View Report" which will open the associated scan and report in a browser window.
- With the addition of NMOSD, the **Brain MRI (NMO)** form has been added. There are a number of additional data elements and fields specific to NMO that can be captured here.
- **CSF** captures information about cerebrospinal fluid tests performed on the patient.
- **Evoked Potentials** captures the results from an EP test.
- **Laboratory Tests** captures information about **Haematology**, **Blood Chemistry**, **Thyroid Functions**, **Serological Tests** and **Auto-antibody tests**. 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.
- Some centres may have additional capability to view *integrated data* from Medical tests such as **Floodlight Open**, or **Improve MS** (MSPT, MSReactor), if the Centre is a participant with such enrolled patients.

10.1.4.Visits

Figure 47 - Visits Section

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 **EDSS** tab is the calculator used to assist you to decide on a patients EDSS score. Note that the calculated score on this visit will automatically be displayed at the bottom of the calculator in the "EDSS Score" field. *The value in this field will automatically be set in the "Basic" tab under "Impairment" – EDSS field.*
- 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 safety study (PASS). This page is also known as the "30-second safetly module" and also allows users to add relevant Diseases and Medical conditions using the MedDRA selector.
- The **Notes** tab allows you to capture notes about the patient.
- **Symptoms** allows you to capture symptoms that the patient may be experiencing. *This is currently a legacy inclusion and MSBase recommends the use of MedDRA instead.*
- **MusiQOL** tab is a questionnaire with a calculator that can help assist in the determination of the patients MS Quality of Life (MusiQOL) value.

10.1.5.Medical Conditions

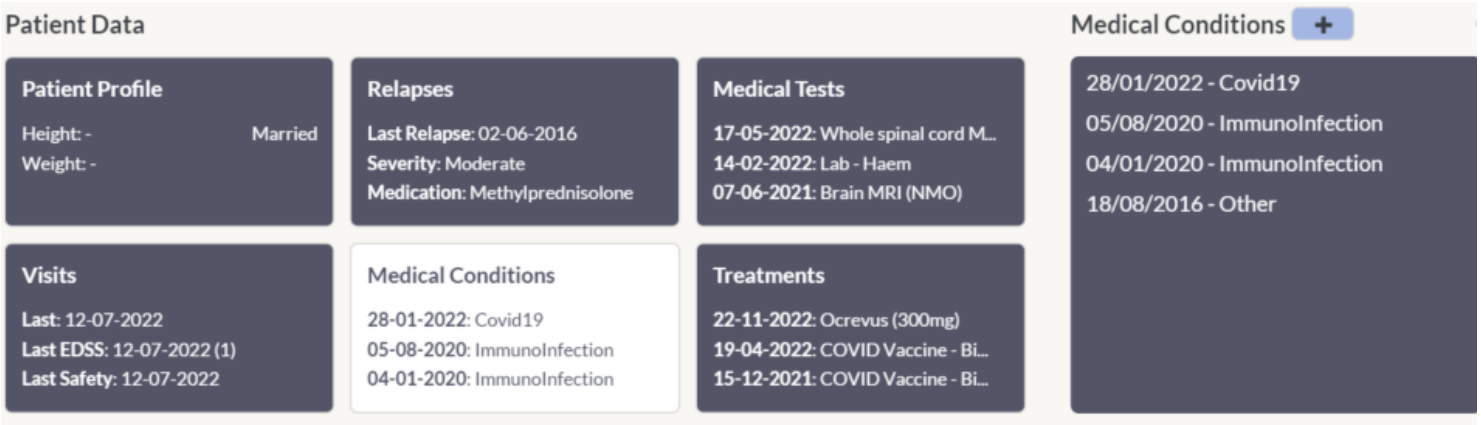


Figure 48 - Medical Conditions Section

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, MedDRA classification should be used.
- **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.

  The Pregnancy module in iMed Web allows recording of occurrences and detailed information related to pregnancy for all female patients. The Pregnancy page is only visible for patients recorded as female and supports standardized capture of maternal, pregnancy, and infant outcomes. Pregnancy data entered via this module may also contribute to the MGBase Long-Term Observational Pregnancy and Infant Outcomes and Safety Study, where applicable.

  The module enables collection of a structured set of pregnancy-related data, including maternal details, pregnancy characteristics, and outcome information. Data fields that may be collected include Last Menstrual Period (LMP), Estimated Delivery Date (EDD), Assisted Reproductive Technology (ART) method, maternal ethnicity, substance use during pregnancy, and maternal congenital abnormalities. Pregnancy outcome data include pregnancy end date, gestational age (system-calculated), infant weight (grams or pounds), infant sex, breastfeeding status, obstetric and maternal complications, delivery method, and pregnancy outcome. Where present, congenital abnormalities can be selected and recorded under a dedicated "Congenital Abnormality" field using EUROCAT classification.

  The Infant Outcomes module captures longitudinal health information for each infant following a recorded pregnancy outcome, becoming available once the pregnancy outcome is saved and consent for infant data collection is recorded. It includes the infant's date of birth (auto-filled from the pregnancy outcome), survival status, weight at the current visit (with the option to add multiple weights from routine health checks), hospitalisation status, and the presence of any diagnosed diseases. Specific conditions—such as neurological disease, immune system deficiency, and other diseases—are recorded using MedDRA lowest level terms. Data

should be updated at every relevant maternal visit, and in cases of multiple gestational births (e.g. twins), separate infant outcome records are completed for each infant.

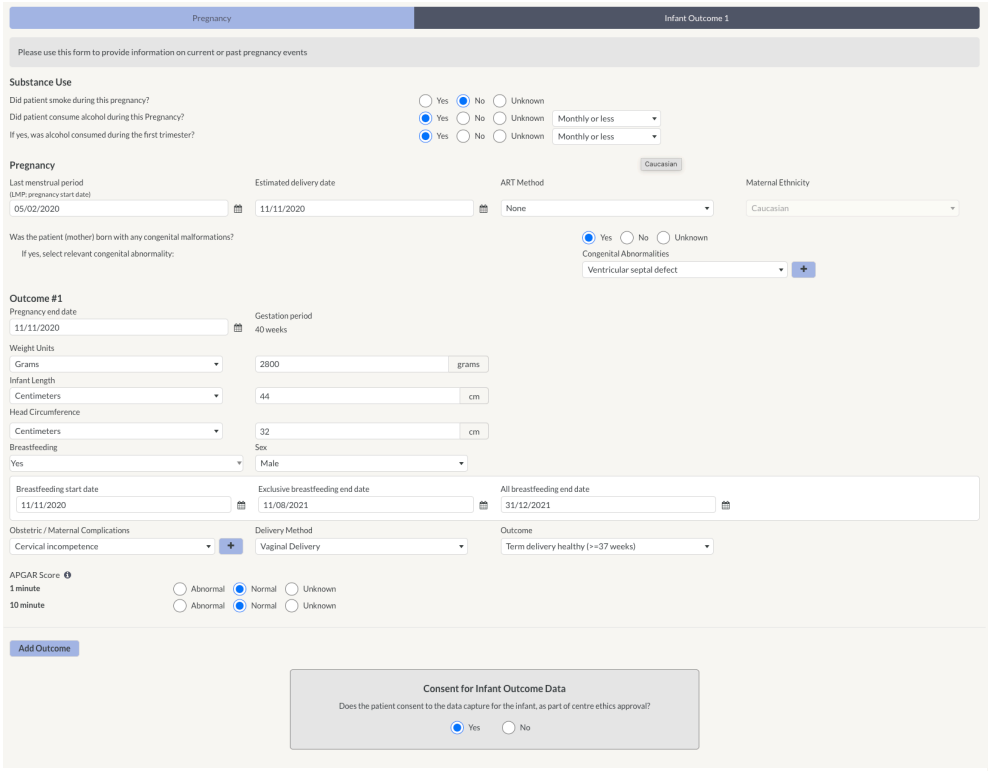


Figure 49 Pregnancy Module

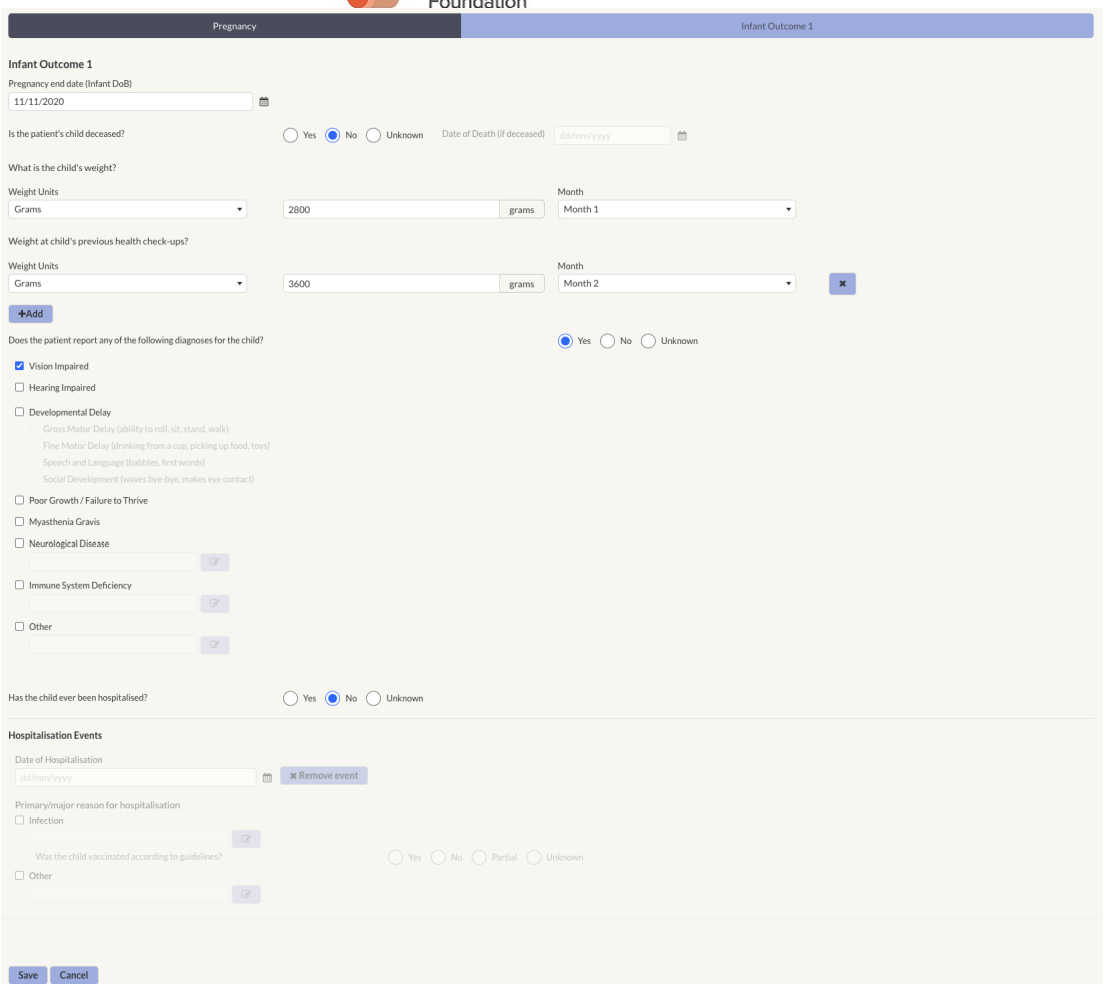


Figure 50 Infant Outcomes Module

- **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.

10.1.6. Treatments

Figure 51 - Treatments Section

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:

- **Disease Specific Treatment** captures information about the patients ongoing and complete MS / NMO 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, occupational therapy, physiotherapy or speech therapy.

11. Statistics

11.1. Overview

iMed Web provides an overview of patient statistics for your centre. The graphs display information about all patients in iMed Web, 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 iMed Web provides the following graphs/distributions:

- Duration of MS – The total number of years that the patient has had MS, as defined by the Onset Date.
- Disease Course – The distribution of the relevant disease course values for all patients in your centre.
- EDSS at last visit -The distribution of the EDSS value at last visit for all patients in your centre.
- Relapse rate per year – In the last 12/24 months, the distribution of the total relapse count for each patient in your centre. You can toggle between 12/24 months to see the different distributions.
- Age at onset – The distribution of Age at MS Onset for all the patients in your centre.
- Age – The Age distribution of all your patients in your centre.
- Ongoing Disease Specific Treatment – The distribution of all ongoing treatments within your centre.
- Gender – The sex distribution of all patients within your centre.

Figure 52 - The statistics section

11.1. Displaying statistics for a subset of patients

By default, iMed Web 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.

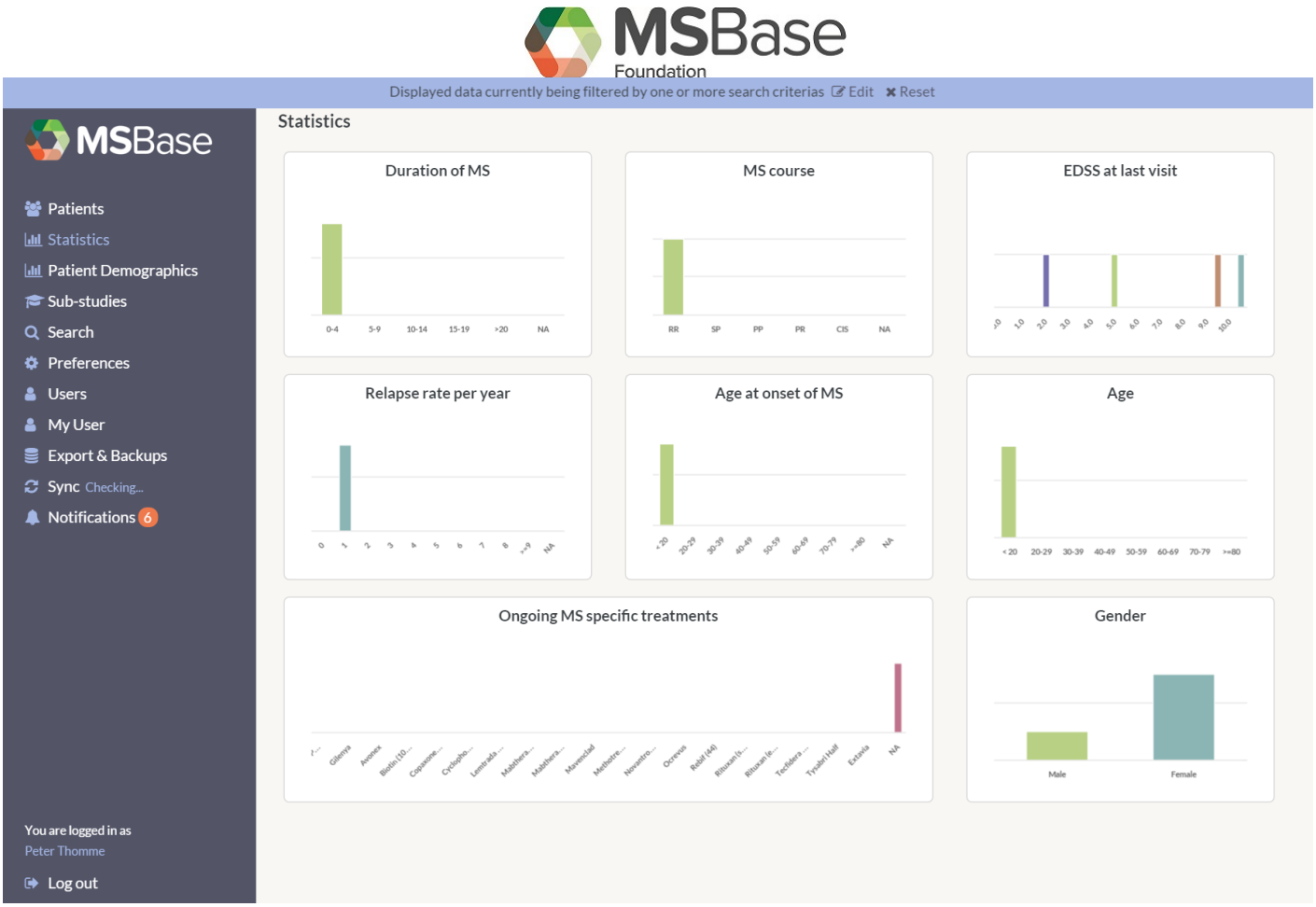


Figure 51 - Filtered statistics for patients younger than 20 years of age

11.2. Cumulative Filtering

iMed Web 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. For example, in the below example, the user has clicked on the Age = 30-39 & Duration of MS = 5-9 & MS Course = RR. This will result in all other graphs being updated to reflect the new patient sub-set.

Furthermore, if you were to navigate back to the Patients section, then the patients would be filtered to only display those that meet the criteria.

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

12. Sub-studies

12.1. 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.

12.2. 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".*

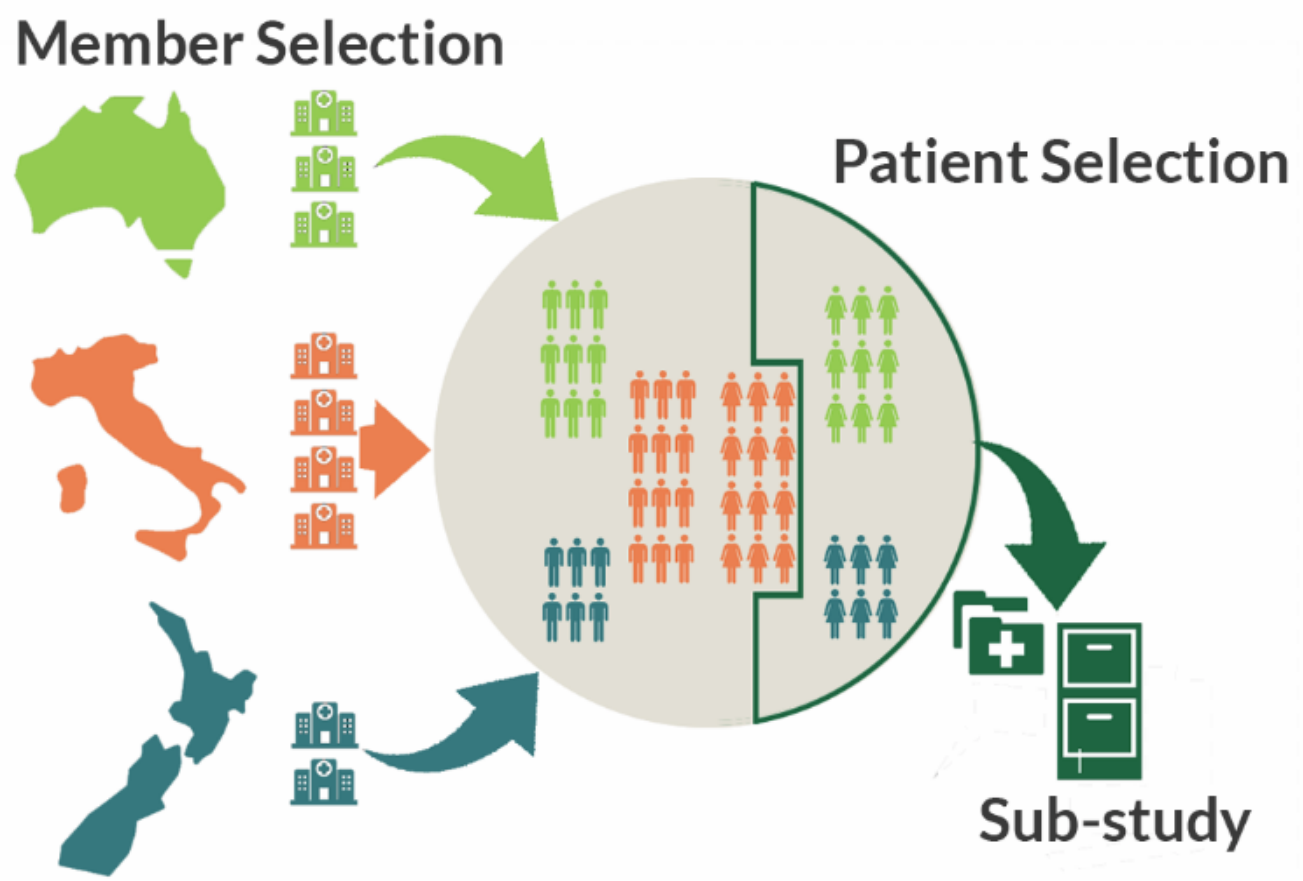


Figure 52: Visualisation of the selection process of All females from Australian and New Zealand centres. Note Italian females were not included as they did not meet the Member Selection criteria.

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 only 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 iMed Web or the Registry.

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

12.3. Viewing sub-studies

You can View sub-studies when logged into iMed Web, 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.

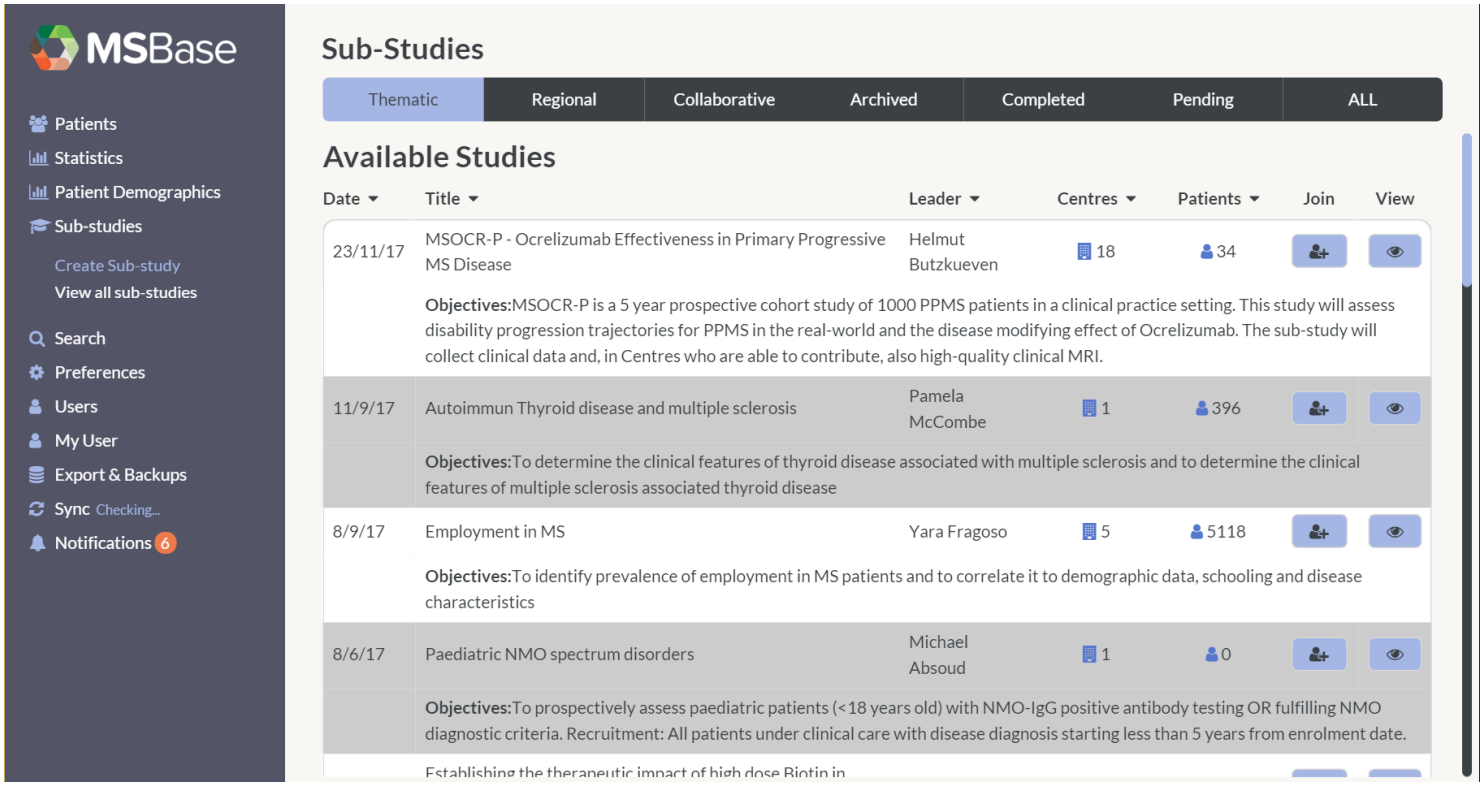


Figure 53 - Viewing sub-studies in iMed Web

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.

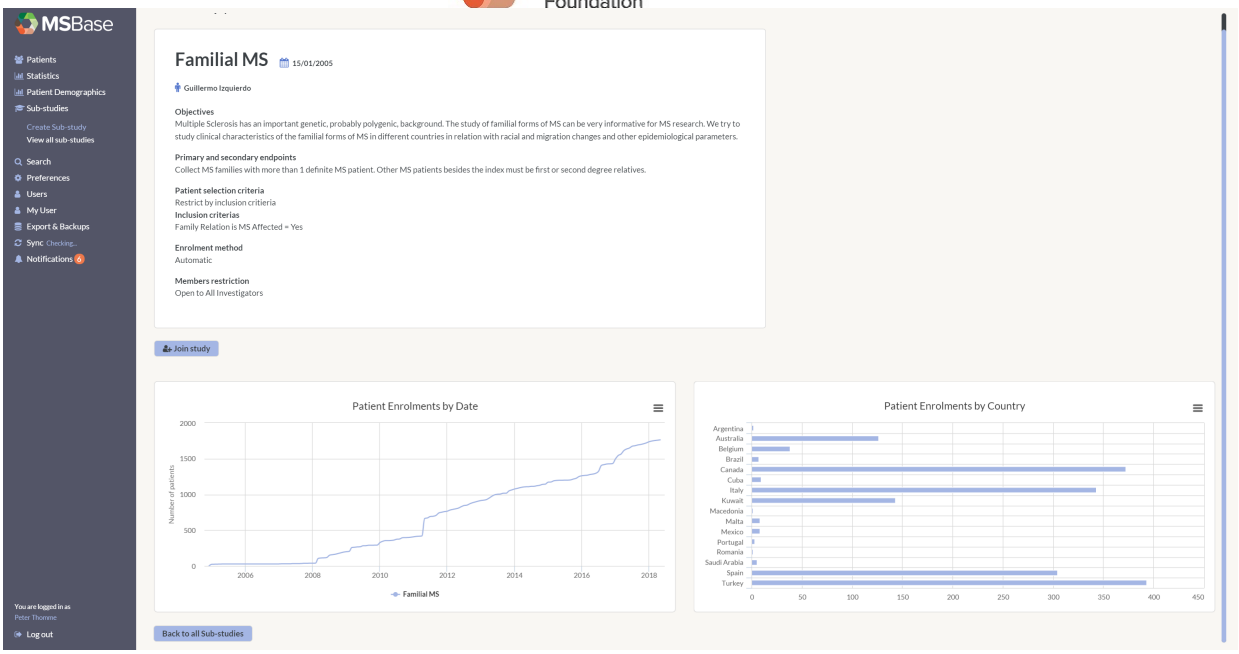


Figure 54 - Information about the Familial MS sub-study

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 MSBase member requests to join.

12.4. 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.

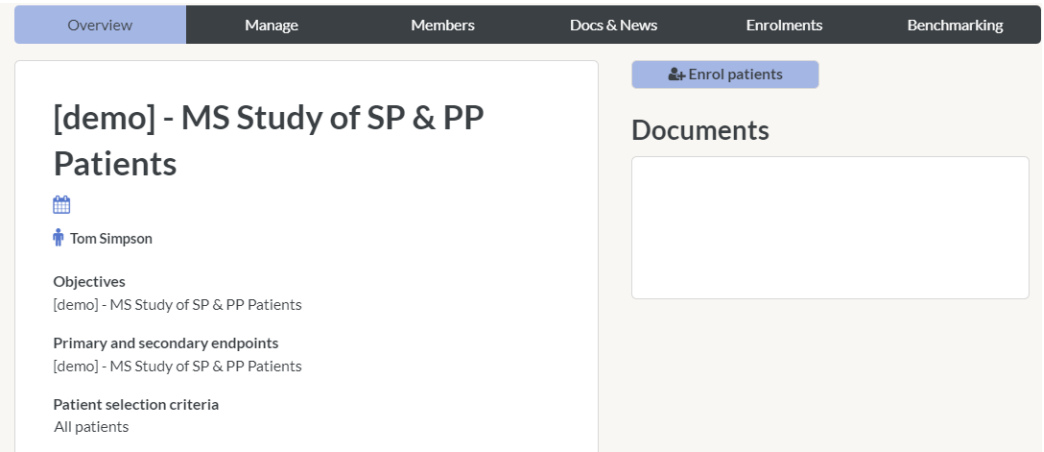


Figure 55 - Enrol a patient via the sub-study

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.

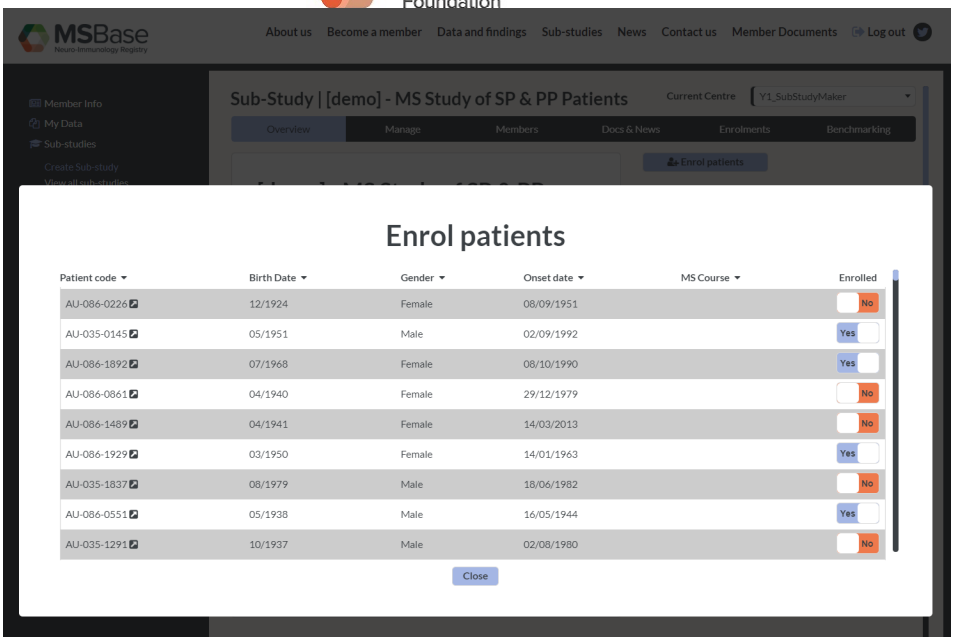


Figure 56 - Enrol a patient manually

An alternative way to enrol patients is in the Patient View, refer to earlier section7.8 *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.

12.5. 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 57 - 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.

12.1. 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.

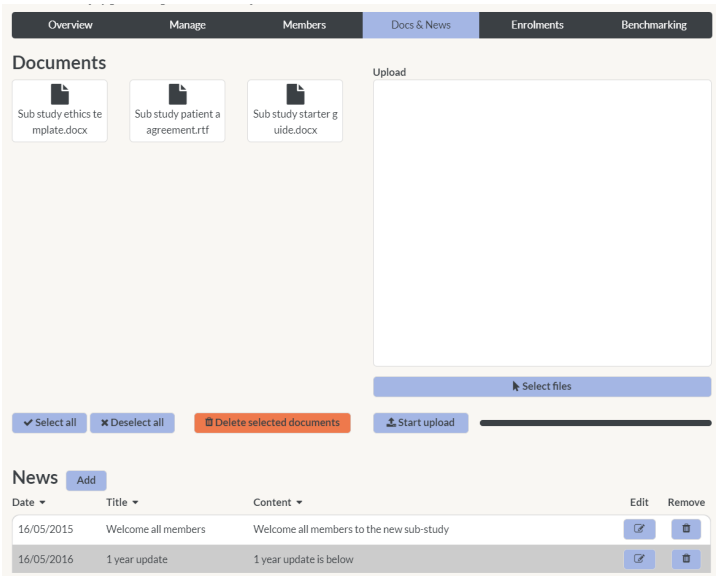


Figure 58 - Adding documents and news items

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.

12.2. 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.

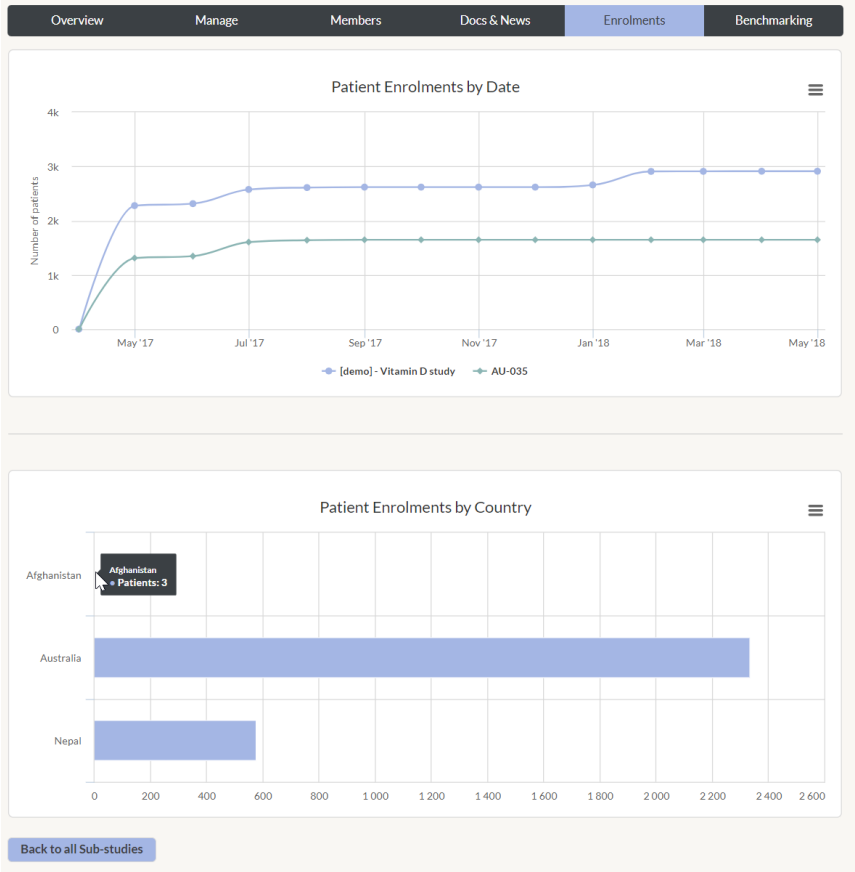


Figure 59 - Patient Enrolment

12.3. 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.

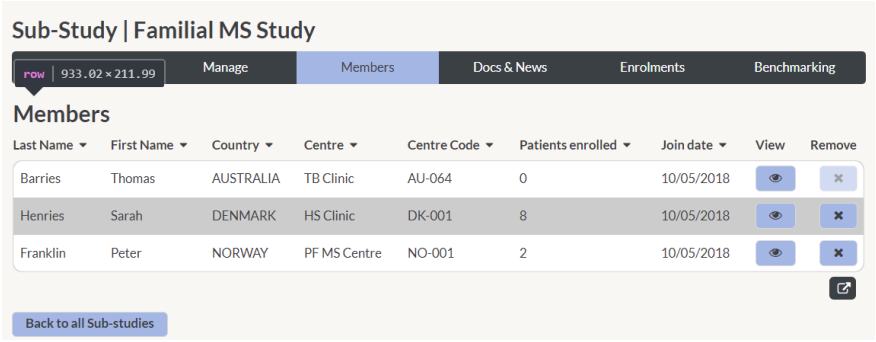


Figure 60 - Sub-study members section

12.4. Benchmarking

The MSBase 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 MSBase Registry. In the below example we can see that the sub-study has 5 females

(100%), while the MSBase Registry consists of 36,376 (70.46%) females and the sub-study members centre (AU-033) has just 1 (16.67%) female.

Distribution of sex	My first sub-study - Aus & NZ female MS Progression		MSBase		AU-033	
Sex	Count	%	Count	%	Count	%
Male	0	0.00%	15251	29.54 %	5	83.33 %
Female	5	100.00%	36376	70.46 %	1	16.67 %

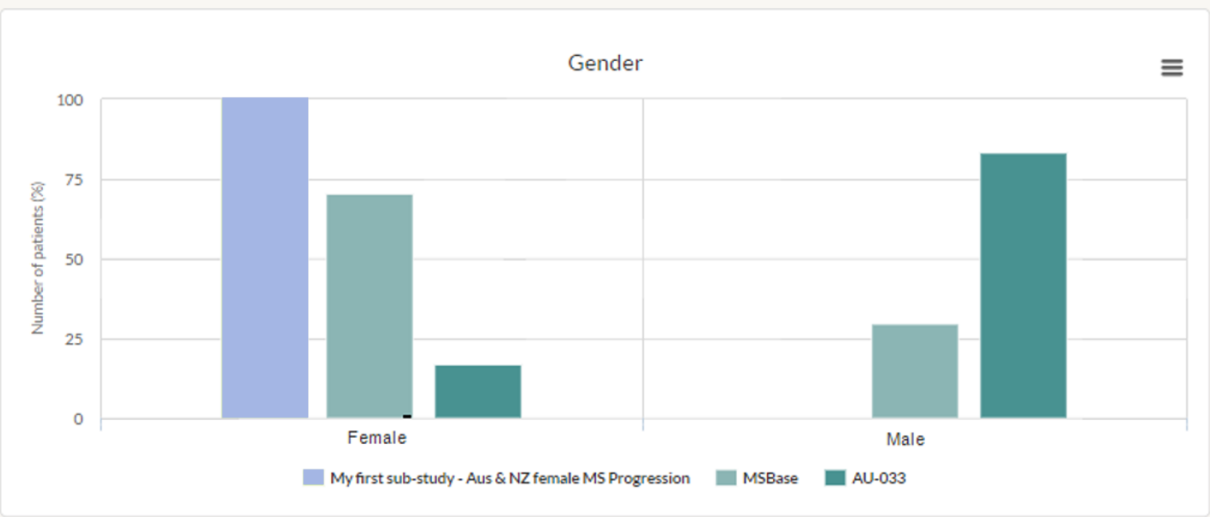


Figure 61 - Sub-study benchmarking

12.5. Creating sub-studies

12.5.1. 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 MSBase 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.

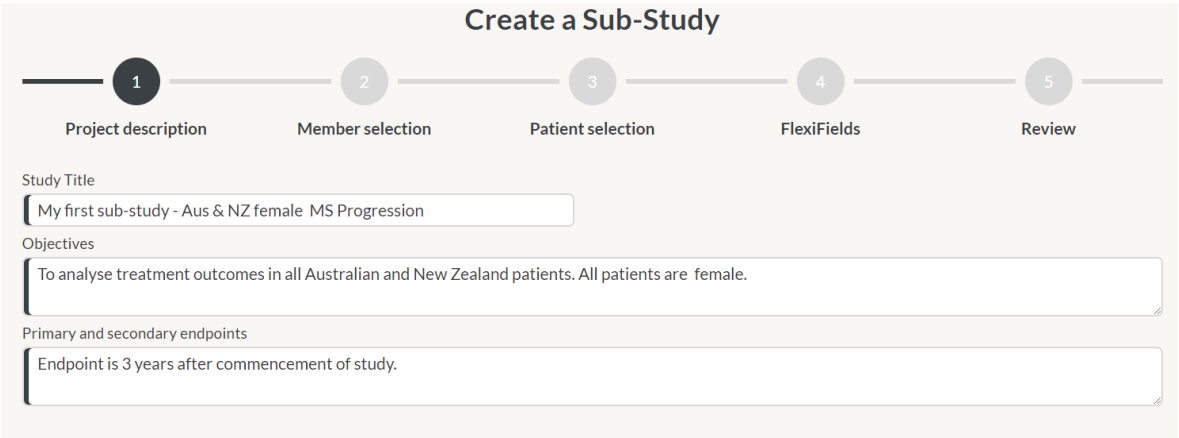


Figure 62 - Create sub-study - Step 1 - Project Description

12.5.2. 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.**

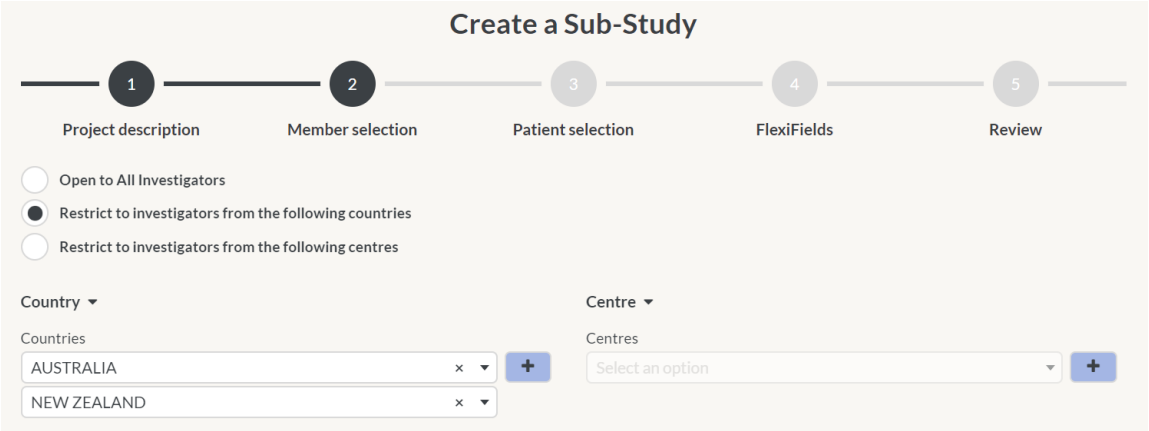


Figure 63 - Create sub-study - Step 2 - Centre Restrictions

12.5.3. 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.

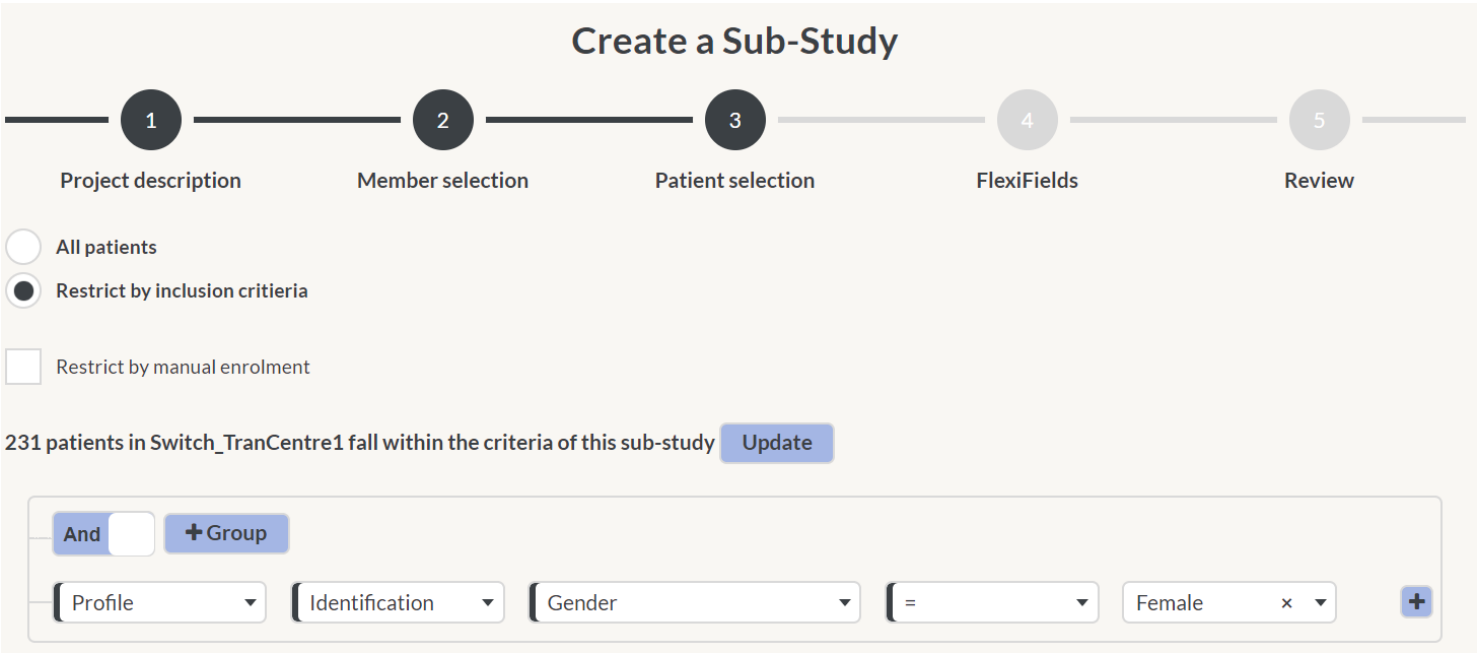


Figure 64 - Create sub-study - Step 3 - Patient Selection

Good to know!

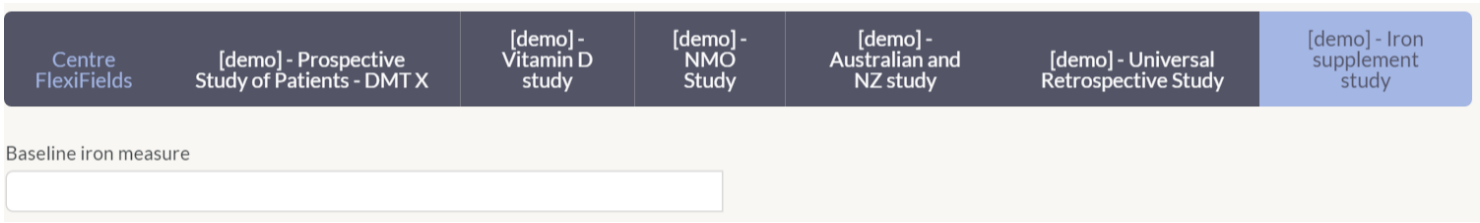
The Patient Selection screen will display how many patients in your centre meet the search criteria. In the above example 231 patients meet the search criteria (i.e., are female). If you have 0 patients meeting your search criteria, it may be an indicator that your search has an error or is overly specific.

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 MSBase Operations team at info@msbase.org . Additionally, for more complex searches, it may be preferable to be more inclusive and remove additional patients during data cleaning.

12.5.4. 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 iMed Web 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. In the below example we are viewing the sub-study Flexifield for the sub-study “Iron supplement study”.



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 Internal Ref (Numeric) and Permission from Patient (Checkbox).

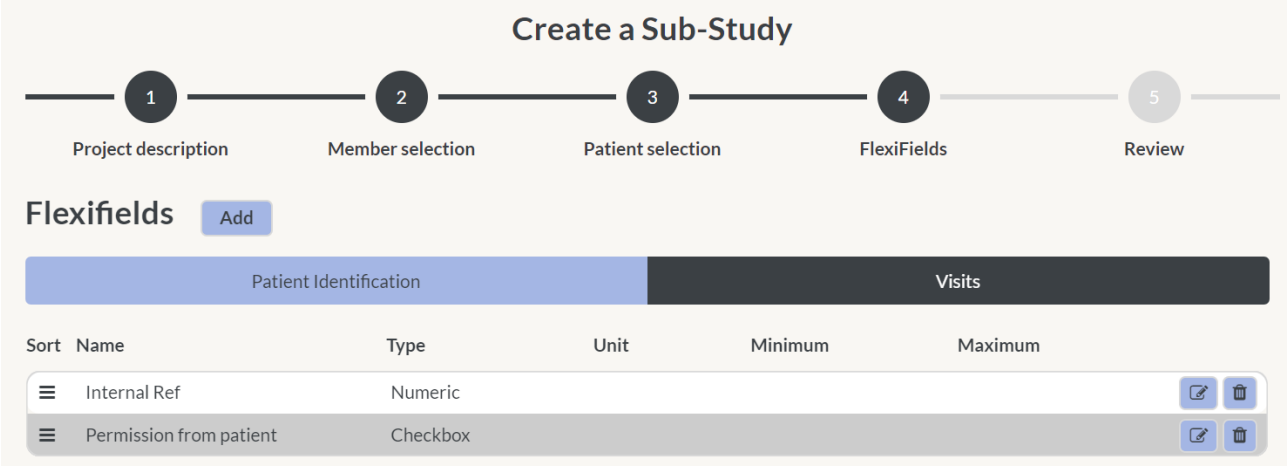


Figure 65 - Create sub-study - Step 4 - Flexifields

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.

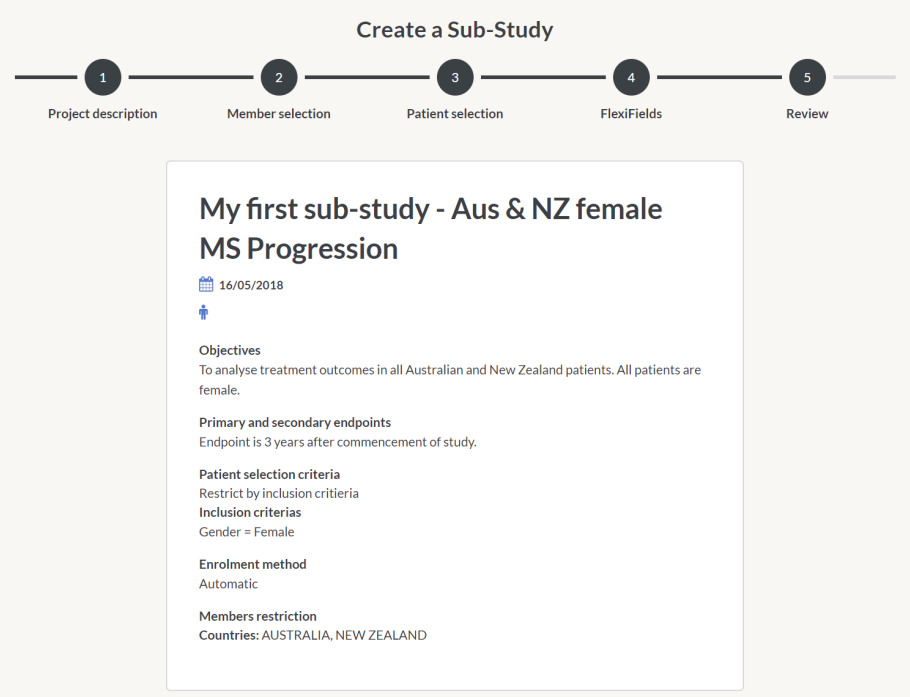


Figure 66 - Create sub-study - Step 5 - Review and Submit

Your sub-study is now awaiting approval from the MSBase 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.

13. Search

13.1. Introduction to search

iMed Web contains a powerful search interface which allows you to perform multiple nested searches. Nearly all fields are searchable within iMed Web. 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 a relapse after 2015
- Has a Visit after 2015
- Has MedDRA SOC value that is equal to *Respiratory* OR *Neoplasm* OR *Immune System*
- Has an MRI with a CNS equal to *Brain* or *Whole Spinal Cord*

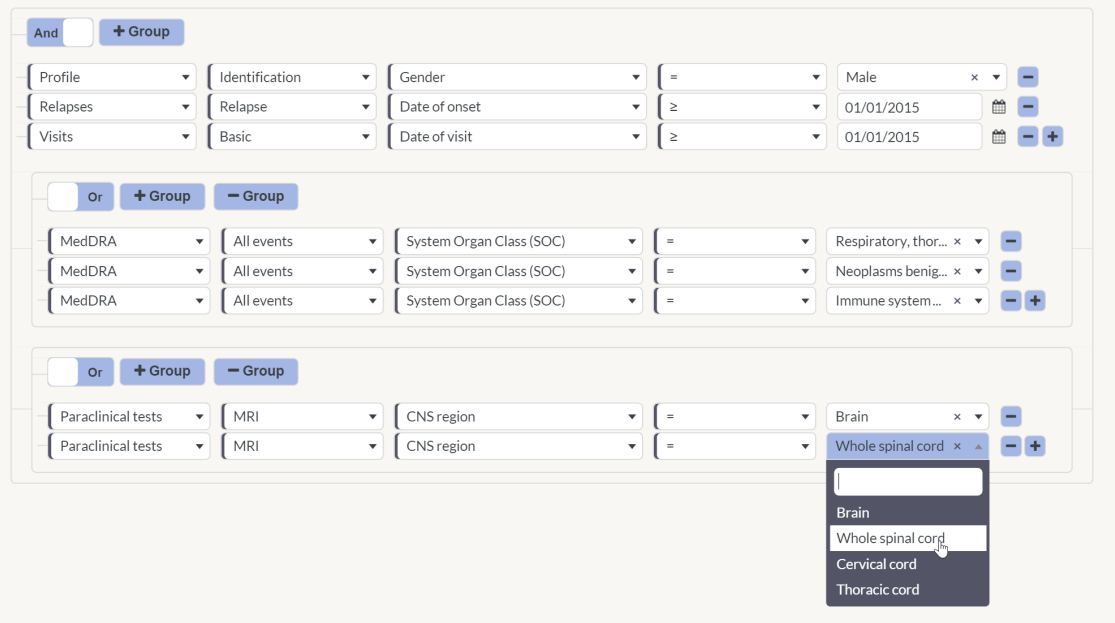


Figure 67 - A complex search in iMed Web

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 iMed Web 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 iMed Web and apply searches in Excel, SPSS or another statistical tool. When performing searches, apply search criteria iteratively to ensure the results appear correct.

13.2. New Search

13.2.1. 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.

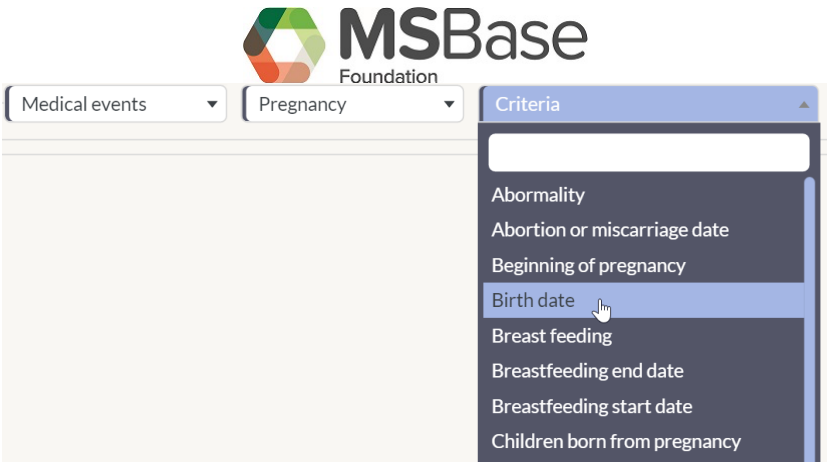


Figure 68 - Search field selection

13.2.2. 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

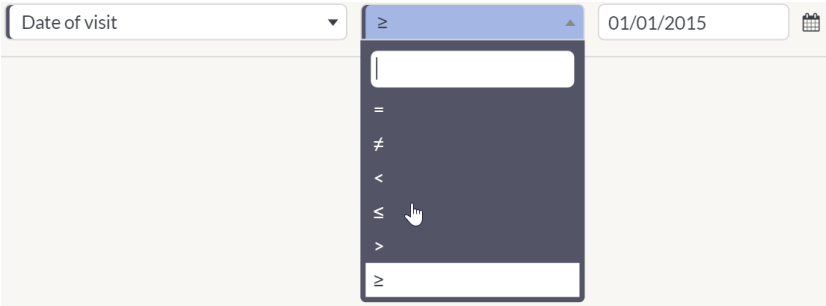


Figure 69 - Operators in iMed Web

13.2.3. 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.

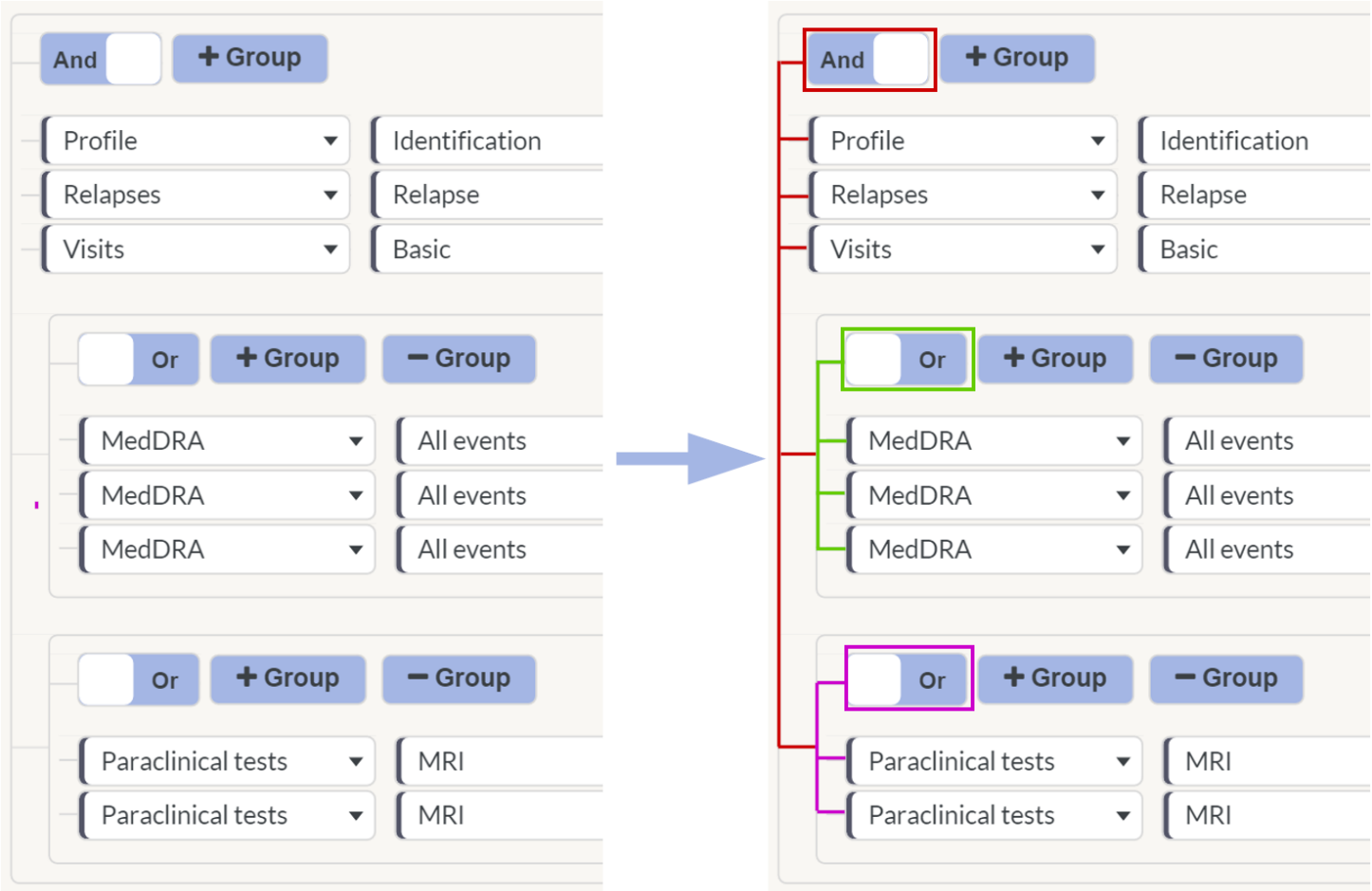


Figure 70 - And/Or operators and groups

13.3. 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.

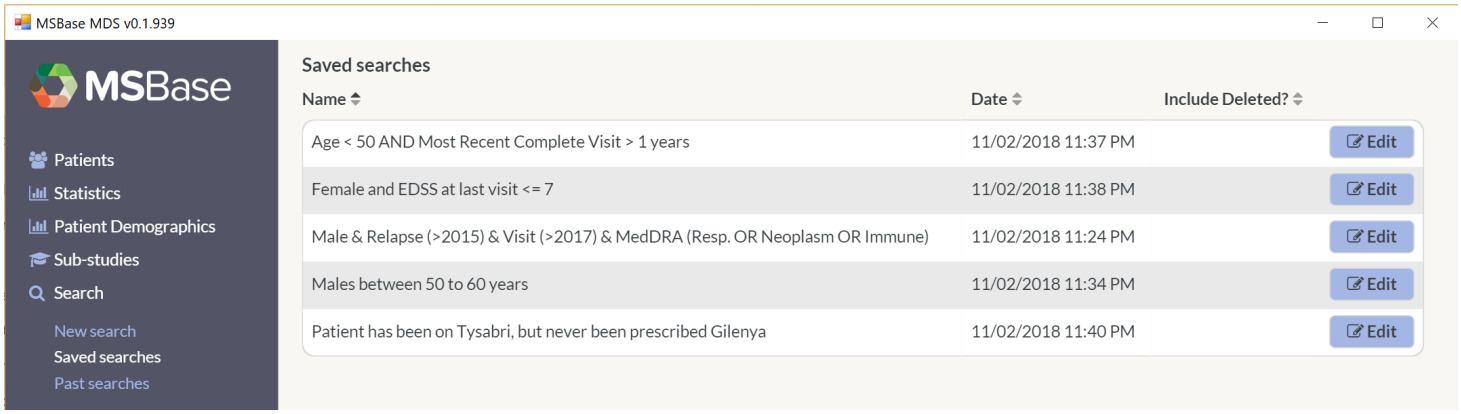
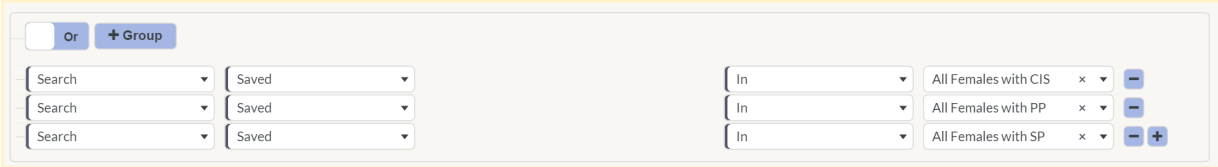


Figure 71 – iMed Web Saved Search

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 with CIS or PP or SP by searching a

set of saved searches.



13.4. Past Search History

Past Search History allows you to view and reapply previous searches performed in iMed Web. 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 (Past Searches) is **static** and will recall the original results.

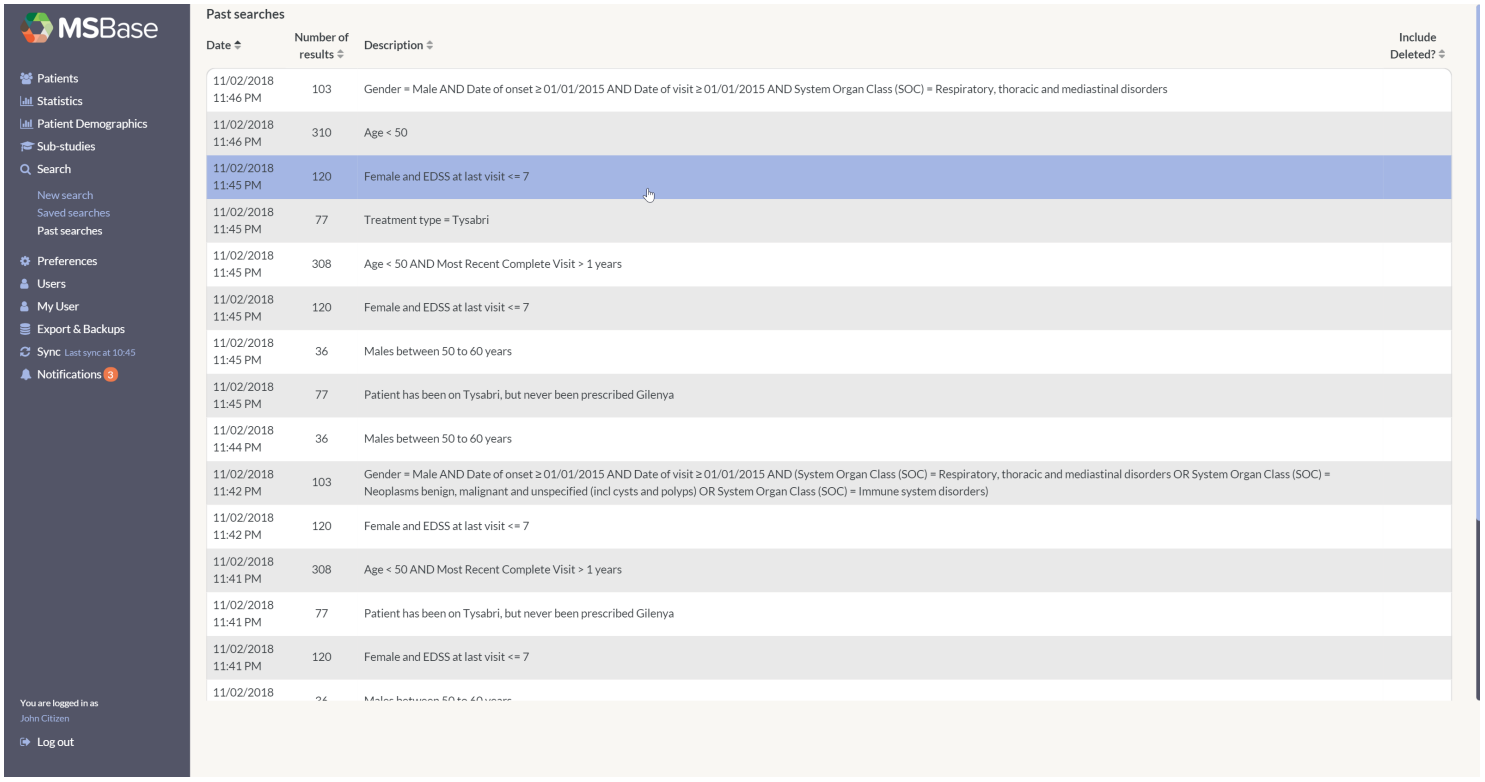


Figure 72 - Search History in iMed Web

13.1. 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.

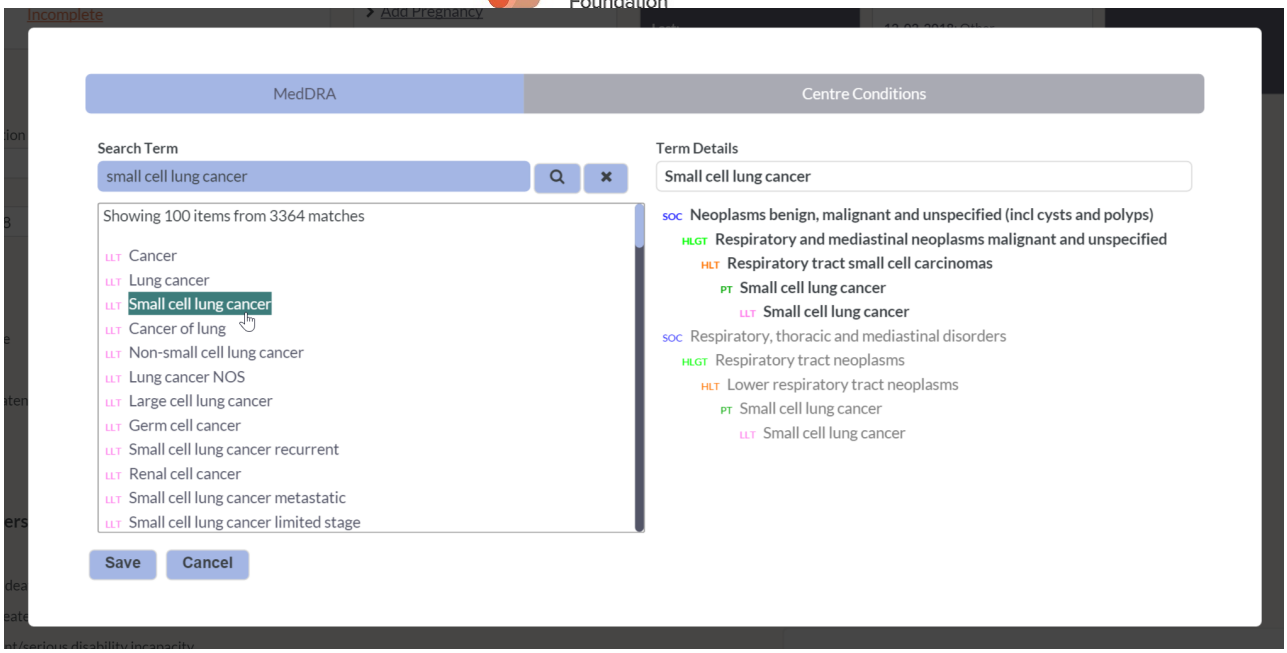


Figure 73 - MedDRA Small Cell Lung Cancer

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

MedDRA	All events	System Organ Class (SOC)	=	Neoplasms benign, malignant ...
MedDRA	All events	High Level Group Terms (HLGT)	=	Respiratory and mediastinal n...
MedDRA	All events	High Level Terms (HLT)	=	Respiratory tract small cell car...
MedDRA	All events	Preferred Terms (PT)	Contains	small cell lung cancer
MedDRA	All events	Lowest Level Terms (LLT)	Contains	small cell lung cancer

MedDRA	All events	System Organ Class (SOC)	=	Respiratory, thoracic and medi...
MedDRA	All events	High Level Group Terms (HLGT)	=	Respiratory tract neoplasms
MedDRA	All events	High Level Terms (HLT)	=	Lower respiratory tract neopla...
MedDRA	All events	Preferred Terms (PT)	Contains	small cell lung cancer
MedDRA	All events	Lowest Level Terms (LLT)	Contains	small cell lung cancer

14. User Options

14.1. Overview

This section explains how iMed Web handles the roles in the Registry and iMed Web. All users of iMed Web must be a member of the MSBase Registry.

14.2. User Permissions

14.2.1. Roles

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

- **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 iMed Web 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 have permissions to create or modify patient data or enrol patients into sub-studies and therefore cannot be listed as a co-authors in publications.

14.3. Viewing users

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

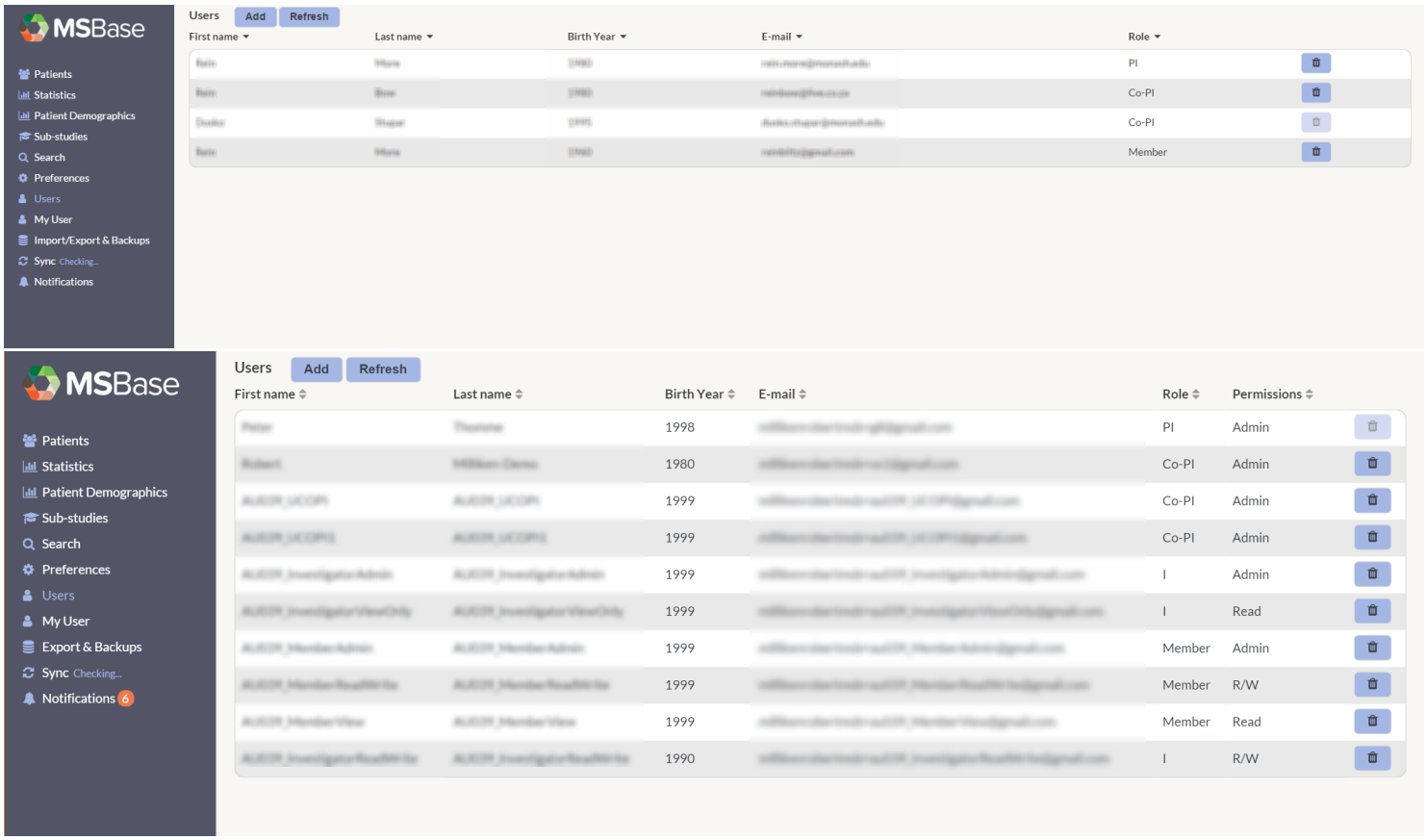


Figure 74 - Users List

14.4. 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.

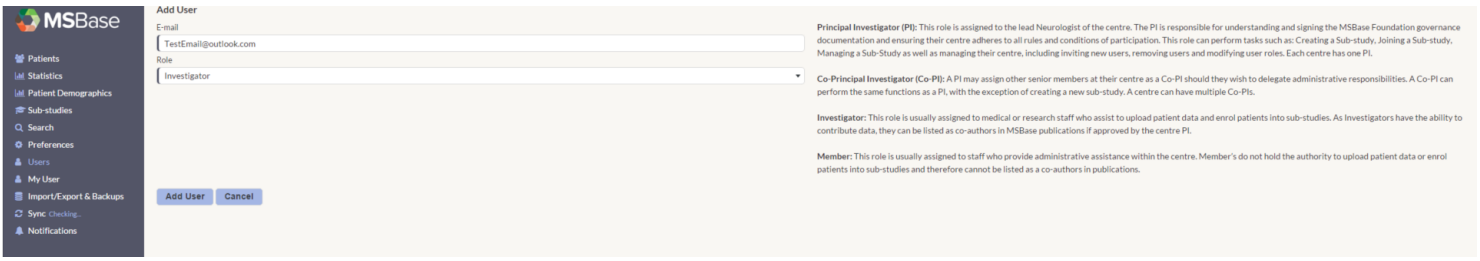


Figure 75 - Adding a user

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 iMed Web 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 MSBase, then they will be automatically added and will not need to complete a new user form.

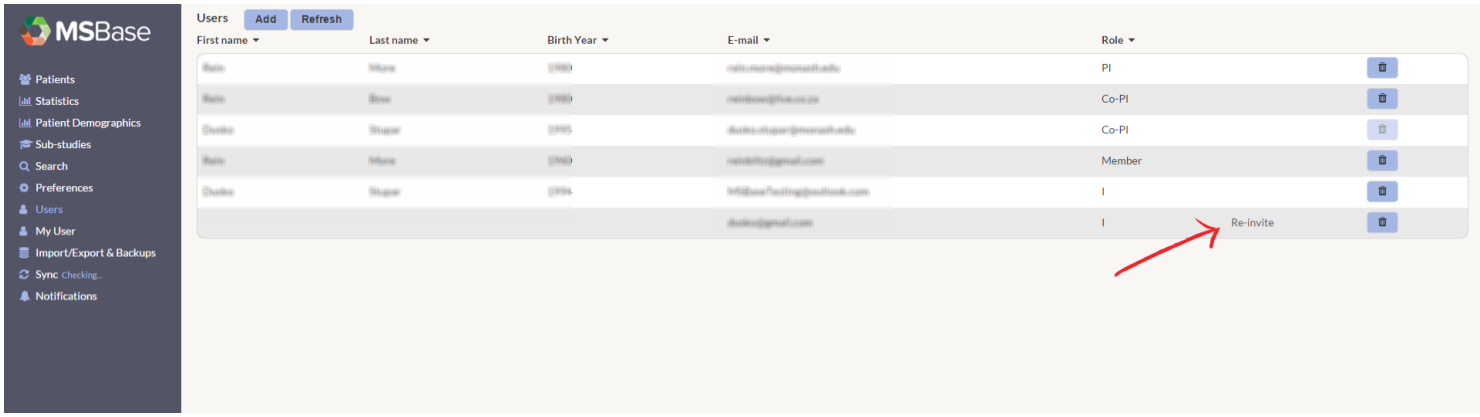


Figure 76 - New user and re-invite mechanism

14.5. 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. Note – Only a PI & Co-PI have the ability to remove users.

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.

15. My User Profile

15.1. Overview

Your patient profile is accessible in both iMed Web 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 iMed Web profile and your Registry profile is the same thing. That is, if you update your password in iMed Web, the password for the Registry will also be updated.

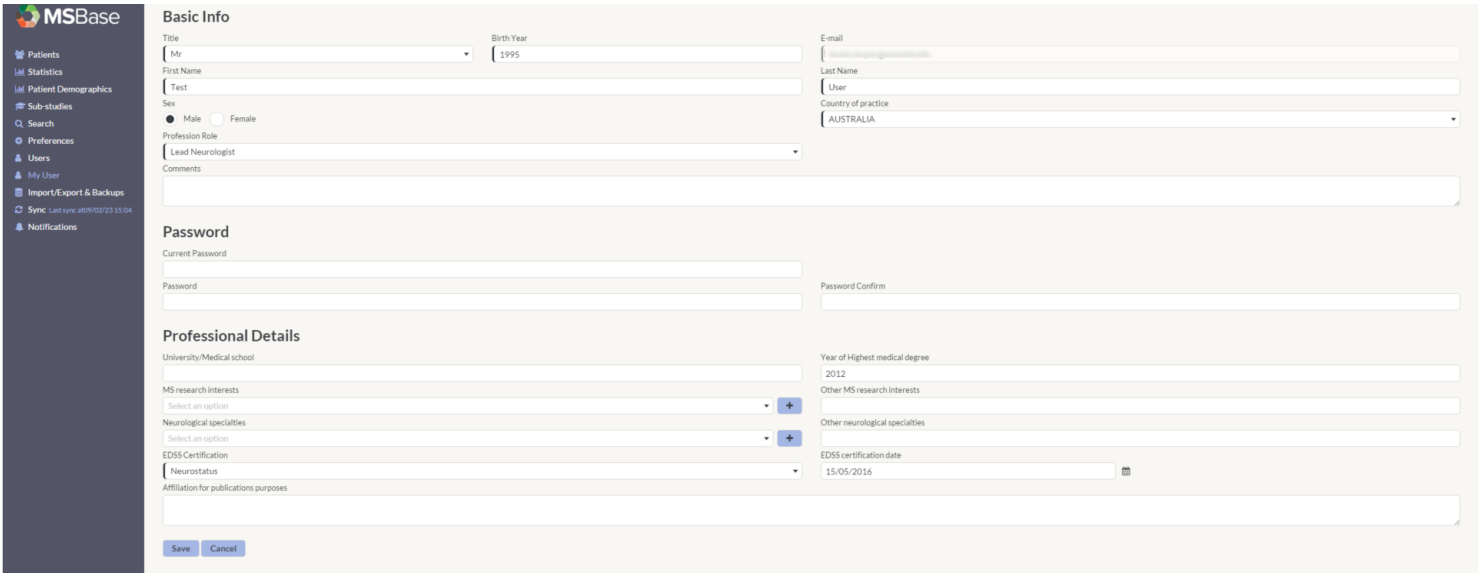


Figure 77 - My User profile

16. Import / Exports

16.1 Export overview

Patient data may be exported to CSV or XLSX (Excel) format. iMed Web 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.

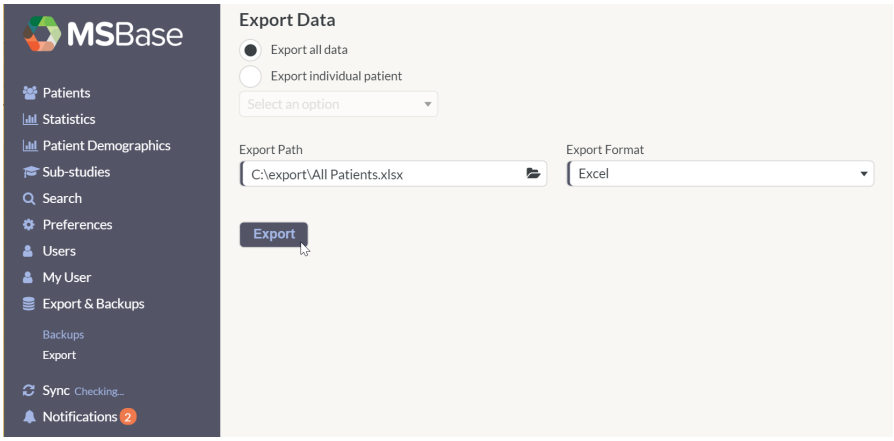


Figure 78 – iMed Web Export a patient

17. Synchronisation

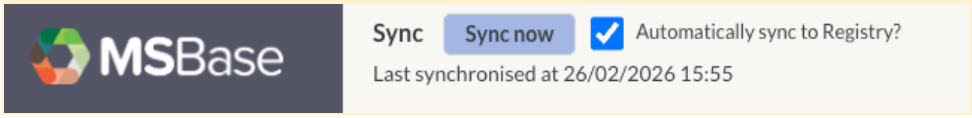
17.1. Synchronisation overview

iMed Web synchronises any changes of Registry enrolled patient(s) with the MSBase Registry. By default, automatic synchronisation is turned off. MSBase 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 iMed Web usability.

Good to know!

To get the most out of iMed Web 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.



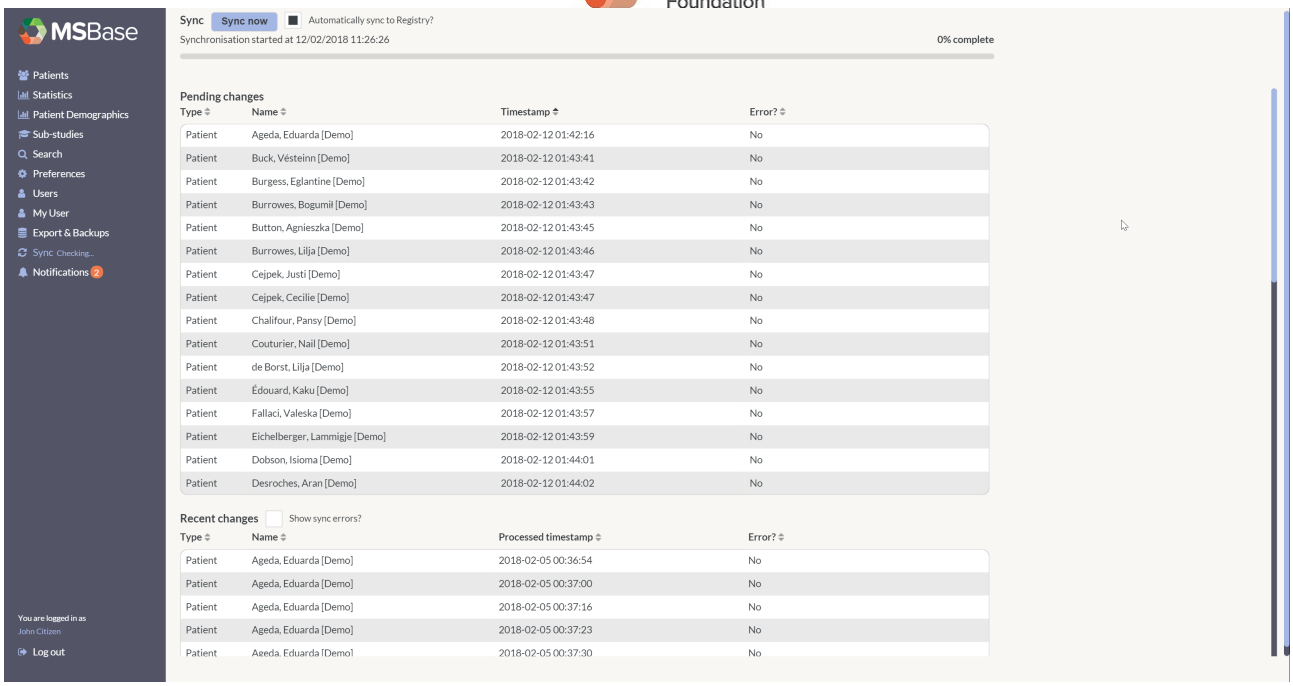


Figure 79 – iMed Web Synchronisation

18. Notifications

18.1. Notification types

Notifications are sent to iMed Web 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.

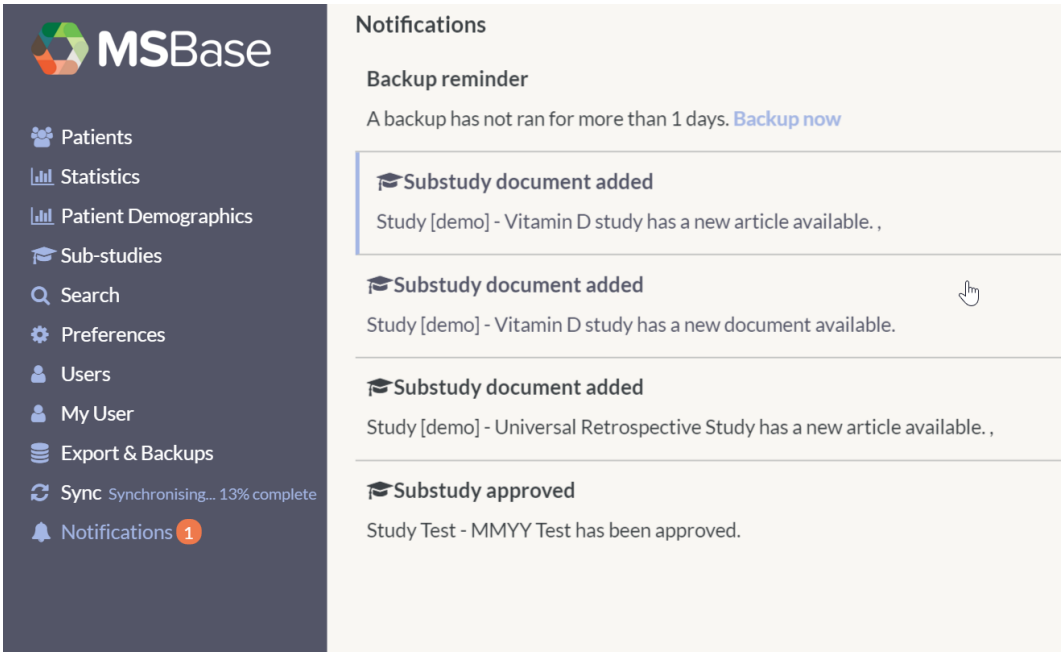


Figure 80 - Notifications in iMed Web

END OF USER GUIDE