REGISTRY QUICK START GUIDE

MAY 2022
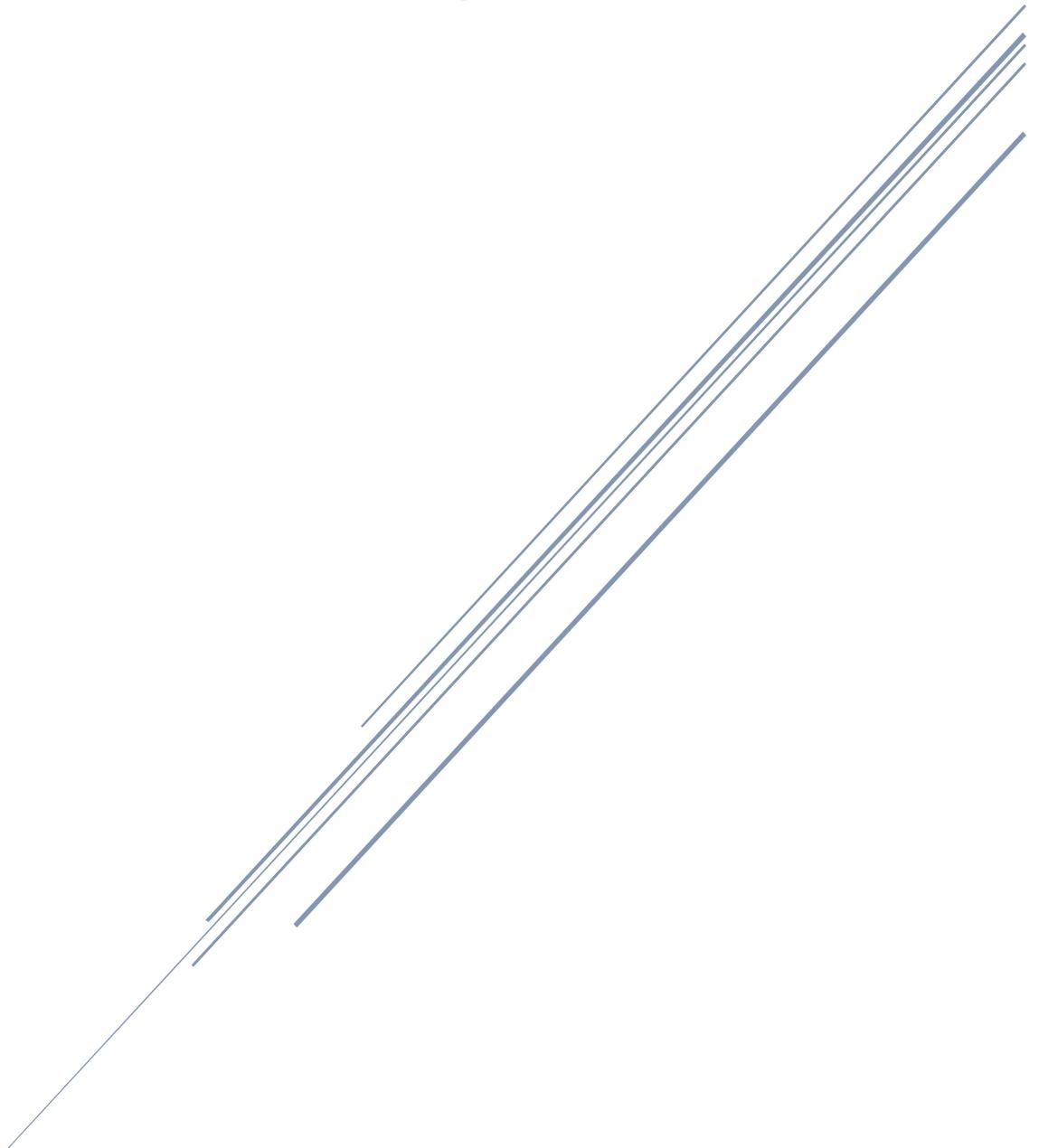
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1. About the MSBase Registry

The MSBase Registry is an ongoing, longitudinal, strictly observational database that commenced in 2004. It provides a platform for international collaboration dedicated to 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 enables the collection of data for studies of MS/NIDs regionally, nationally, or globally, with customizable sub-study functionality that filters data according to research themes.

The purpose of this guide is to provide a quick introduction to the website features.

2. Joining the Registry

If your centre is not a member the MSBase Registry, then you will need to apply for membership. Membership benefits are detailed on our website.

Centre membership must be initiated by the lead Neurologist in charge of the MS or other NID Unit at your hospital/clinic, who will assume the role of centre Principal Investigator. Other MS and NID staff can then become Investigators (I) or Members of the centre, under the PI's lead.

To apply, please visit the Sign Up link on our website.
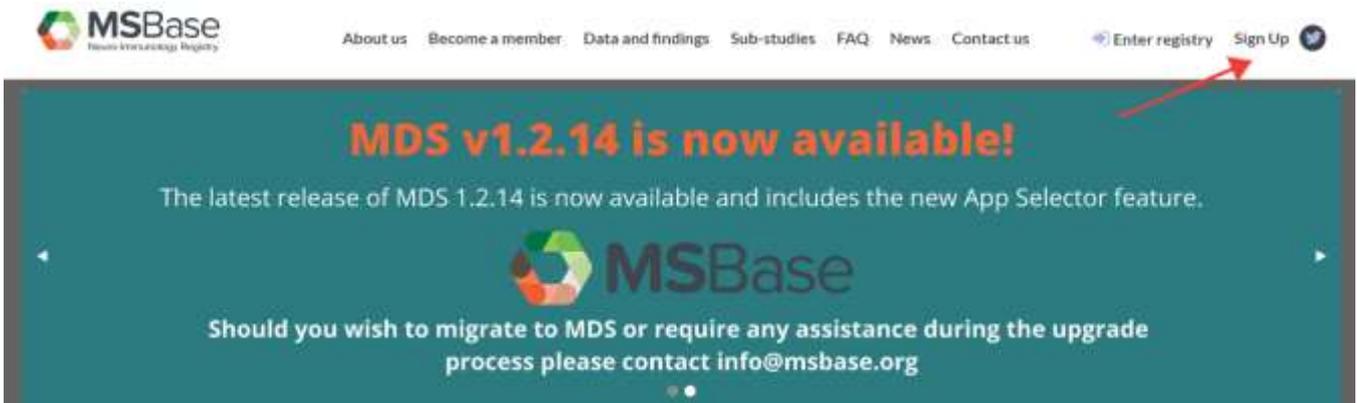
You will be required to fill some basic personal and professional details to complete your membership application. Once you have submitted the online registration form, the MSBase Membership Manager will review your application and will advise if your centre has been approved or if additional information is required. All Principal Investigators must read and sign the MSBase Registry Participation Agreement and associated schedules, prior to their centre being approved.

Once your application has been approved and you have agreed to the terms and conditions, your centre will be initialized and be ready for contributing data to the MSBase Registry.

There are two ways that data can be imported into the MSBase Registry. For users that already have iMed installed, you have the choice to contribute data using that platform. Alternatively, the MSBase Foundation has developed its own MSBase Data-entry Software (MDS), which is similar to iMed but contains additional and more advanced features and functionality. The MSBase IT team will be able to advise you on which platform is right for you.

Should you have any questions regarding the joining process or data entry software, please email us at info@msbase.org.

3. Existing Members

In June 2017, the MSBase Registry website was updated. MSBase members that were members prior to this date will need to use their email to login and reset their password. Password reset details are below.

4. Password Reset

Have you forgotten your password and need to reset it? Simply navigate to the [Forgot Password link](#) at the Login screen. Once you have entered your email address then an email will be sent with a reset password link.

Still having problems? Contact info@msbase.org for support.

5. Member roles and viewing your data

5.1 Roles

Once you have logged into the MSBase Registry, your ability to perform specific functions will depend on your Role. The roles are detailed below:

Principal Investigator (PI): This role is reserved for the lead Neurologist of the centre who can authorize the centre's participation to the Registry, including the transfer of pseudonymised patient data. The PI signs the MSBase Participation Agreement and is responsible for 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. *The Principal Investigator is also responsible for the data and data governances and will be the primary contact for the MSBase Operations team.*

Co-Principal Investigator (Co-PI): This role is similar to the PI role and would be applicable to a senior administrative member at the centre. Where your centre requires more than one administrator, assign those extra users as Co-Principal Investigators. A Co-PI can perform the same functions as a PI, with the exception of creating a new sub-study.

Investigator (I) and **Member:** The permissions for an Investigator and/or Member are more restricted than the earlier two categories. These users are unable to create or join sub-studies.

An Investigator is usually another medical or research staff who can upload patient data and enrol specific patients into sub-studies. As Investigators have the ability to contribute data, they are therefore able to be listed as co-authors in MSBase publications, if approved by their centre PI.

A Member role is usually assigned to medical or other administrators within your centre who provide administrative assistance. This role is more restricted than an Investigator as they do not hold the authority to upload patient data and enrol specific patients into sub-studies and therefore cannot be listed as a co-author in publications.

5.2 My Data

The My Data section contains all your patients. To view patients you have uploaded to the Registry, select Patient Records **(1)** and use the list to find your patient **(2)**. Once you have located your patient, you can use the category or section **(3)** and relevant screen **(4)** to navigate and view the submitted data.

5.3 Manual Import

This feature should only be used when your iMed is unable to synchronize directly with the Registry. This may be due to a firewall or security restriction in your centre. To use this feature locate the MSBaseExtract.xml.zip, typically located in *C:\iMed\MSBase_Dataset* folder using the Select File **(1)** button. Once the file is located, Start Upload **(2)**.

NB: Please note that any iMed centres participating in sub-studies, must use the direction integration (Send now functionality) that is available within iMed. Using the portal below to manually import patients, will send patient data to the MSBase Registry, but will not pull down the relevant sub-study information or data for participating iMed centres.
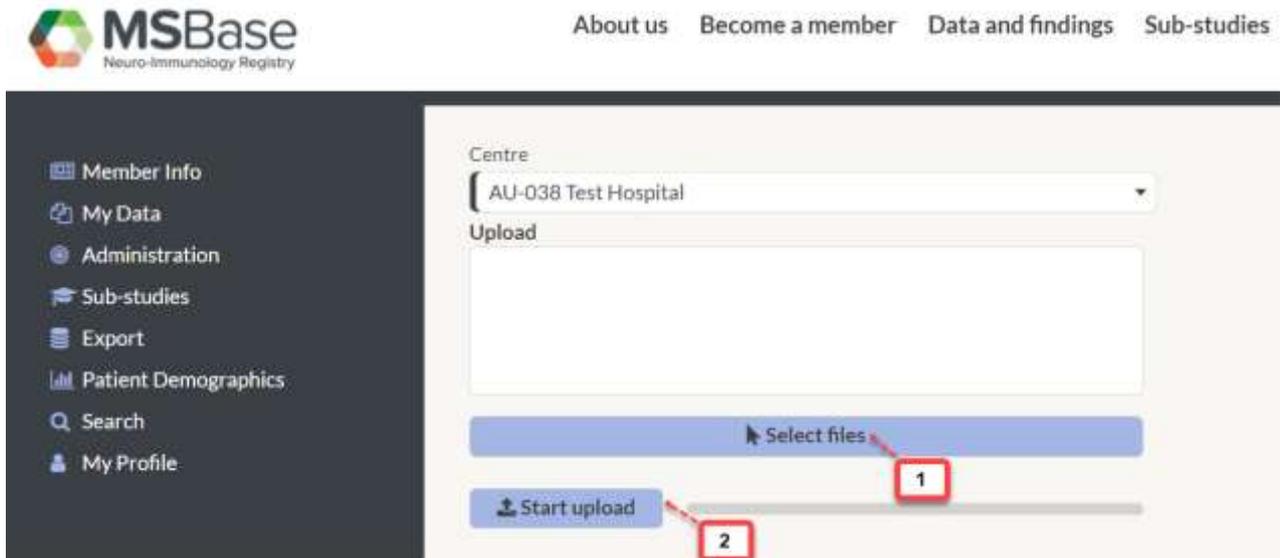
6. Sub Studies

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.

How does a sub-study work?

Consider the following scenario: 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*".
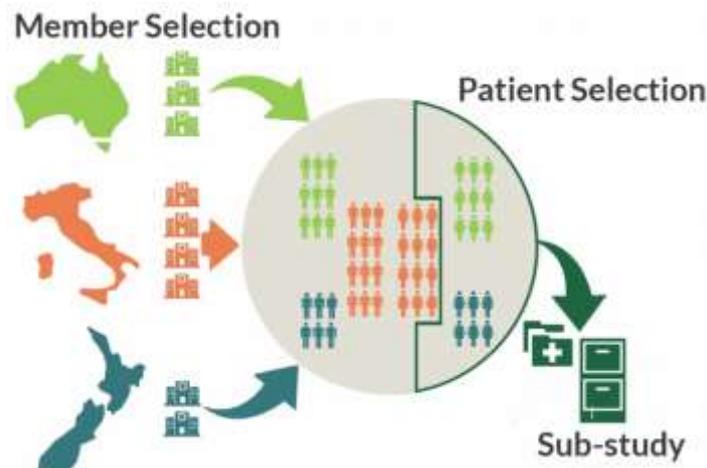

Figure 1: Visualisation of the selection process of All females from Australian and New Zealand centres. Note Italian females were not included as they did not meet the Member Selection criteria.

Once the sub-study is active, as soon as a member joins your sub-study, then the data of all "eligible" patients meeting the selection criteria will be available to download. This is called *Automatic enrolment* and is the default. 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 value judgement from the member
- Sub-study that requires special ethics or patient approval

Sub-studies can be created by the centre PI only. The below provides details on how to create a sub-study, manage that sub-study and view and join sub-studies.

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

6.1 Creating a sub-study

As a PI, to create a sub-study, select Create Sub-study **(1)** and fill in the required details **(2)**, **(3)** and **(4).** 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 **(5).**

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 centre's: This option will restrict member selection to centre

In our example we are restricting members by country **(1)**, and only allowing Australia and New Zealand members to join **(2)**. Once we have selected our members, click Next **(3)**
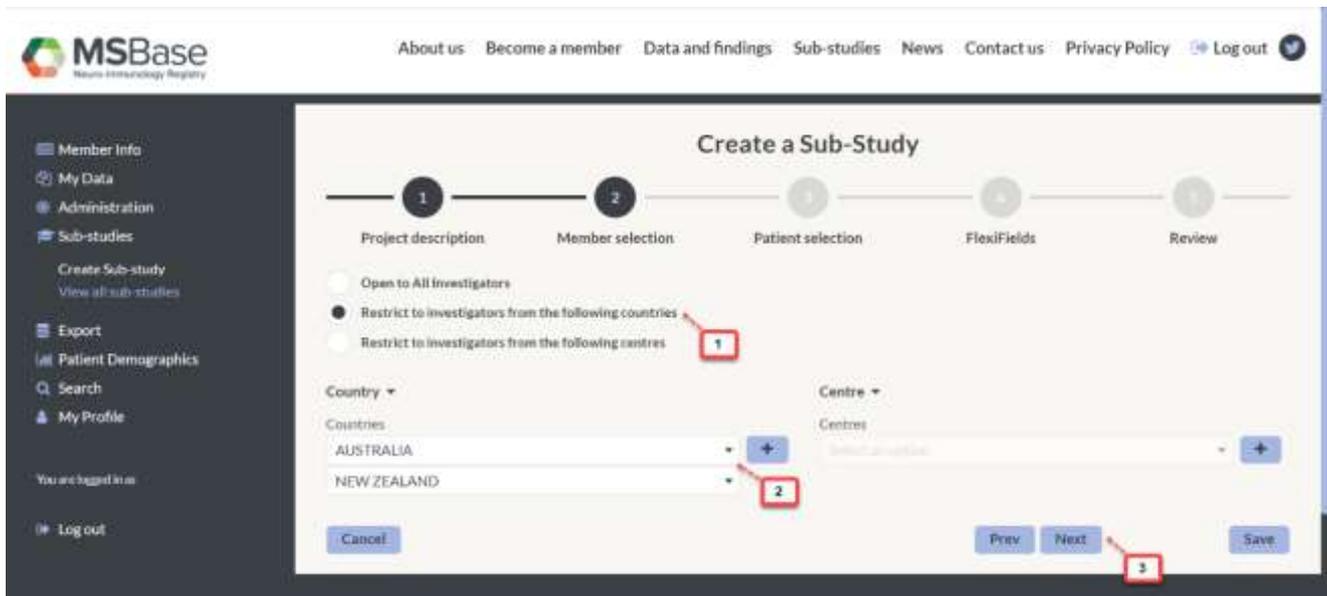
After selecting our members, we must then restrict the patient selection. Patients can be restricted in 3 ways:

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

In this example we have made the selection to restrict the patient inclusion by search criteria **(1).** We then enter the desired search criteria **(2)** and click Next **(3)**.

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.
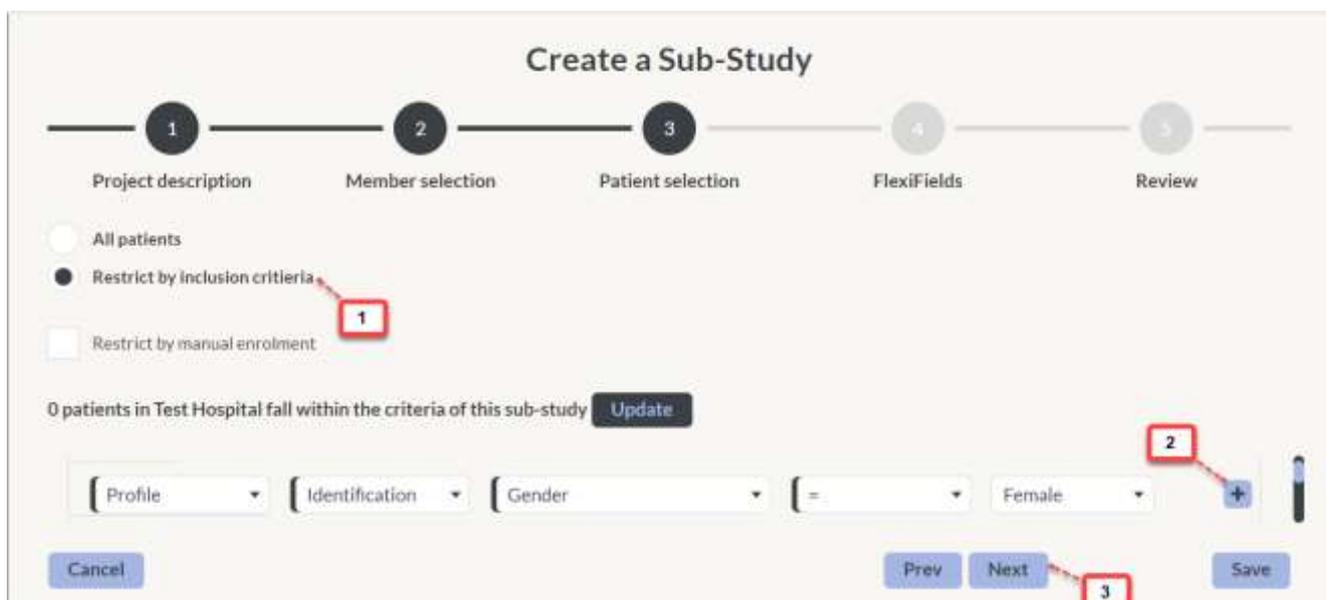
6.2 Custom Data Capture

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 – these are referred to as "Flexifields". Data types include:

- Text: Alphanumeric text restricted to 200 characters
- Numeric: Number only text 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: From complex data entry forms use the section break to sort the fields into logical sections

Data can be captured at the Patient Identification level **(1)** and at a Visit **(2)** 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 and click Add **(3)**. When finished, click Next **(4)**.

For our example, we are capturing Internal Ref (Numeric) and Permission from Patient (Checkbox).

Prior to submitting your sub-study, review the details and make any required changes by going to the 'Previous' pages **(1)**. You can 'Save' **(2)** to keep the sub-study as a draft for review later or 'Cancel' **(3)** at any point. When ready to submit your study, click Submit **(4)**

Congratulations! 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.

6.3 Viewing and joining sub-studies

All members can View **(1)** sub-studies when logged into the Registry, however only a PI or Co-PI will be able to join sub-studies. 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 **(2)** or you can join the sub-study by selecting Join **(3)**.
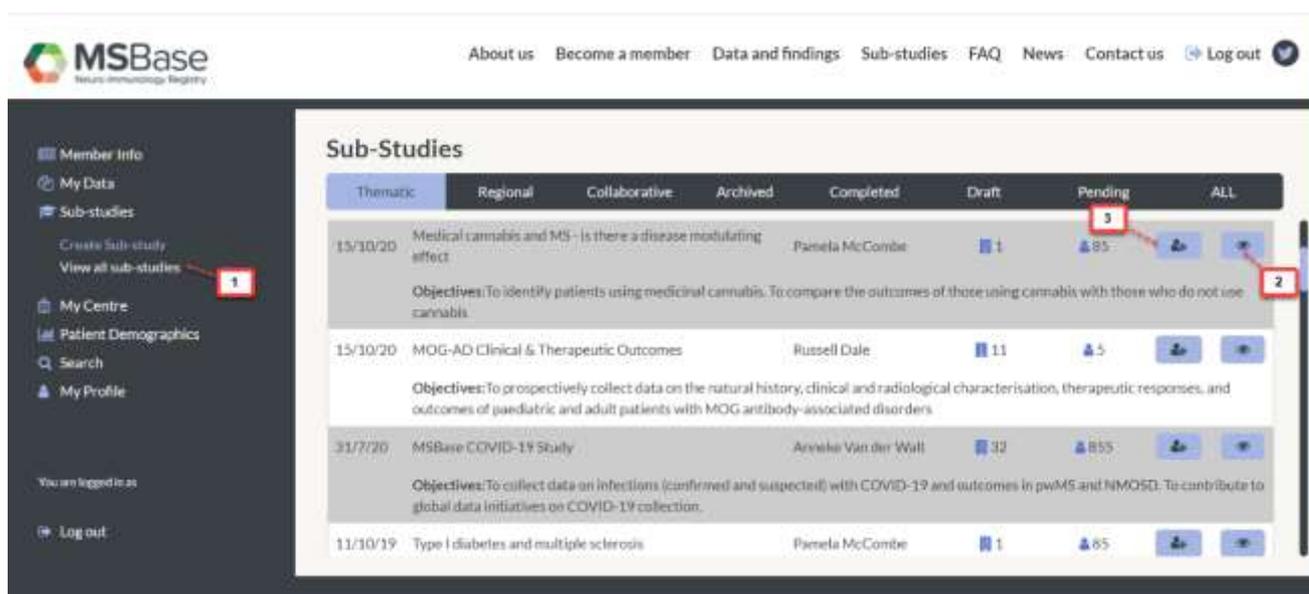
All users will be able to see basic information about the sub-study prior to joining. This information includes sub-study descriptions and endpoint **(1)**, Enrolment History **(2)** and Enrolment Country distributions **(3)**. You can also join the sub-study from this section **(4)**.

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.

6.4 Managing your sub-study

A PI or Co-PI can manage a sub-study. To do this, find your sub-study and click Manage **(1).** The Manage dashboard allows you to re-invite **(2)** members (an automatic email will be sent to all eligible centres) and download all the data of the participating patients **(3)**. New centres that wish to join your sub-study will need to be Accepted or Declined **(4)** before their data becomes accessible.

When a new centre is accepted, the patients will be automatically enrolled into your study (except where manual enrolment is set – see Section 6.6.). 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.

As the leader of a sub-study, you can communicate with you members by posting Docs & News **(1)** to keep members up to date. Selecting Add **(2)** 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 **(3)** that you want to upload and select Start Upload.


News **(1)** and Documents **(2)** will appear to members of the sub-study. Members will also receive an email notification of the News item and Document addition.
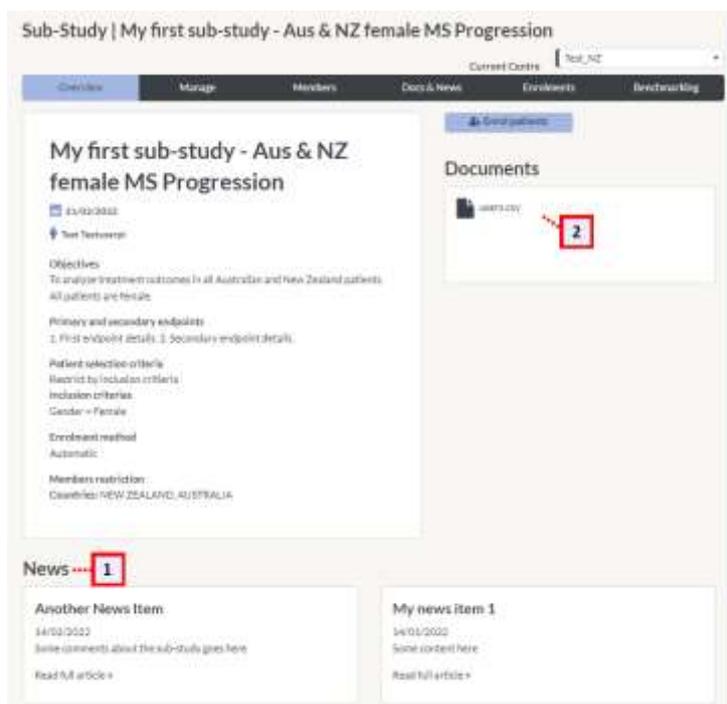
6.5 Sub-studies – Benchmarking

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 156 females (100%), while the MSBase Registry consists of 7994 (43.13%) females.
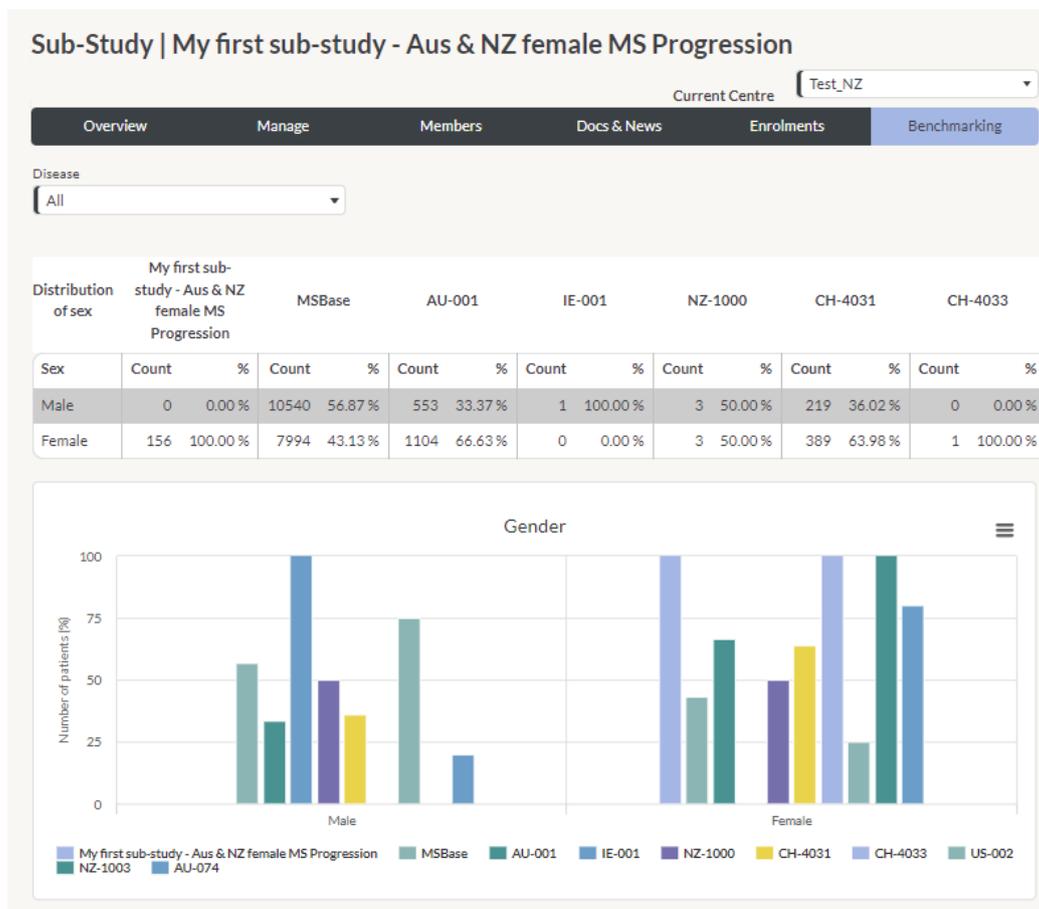

6.6 Sub-studies – Manual Enrolment

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. Go to the sub-study and on the Overview tab **(1)** select Enrol Patients **(2)**.

A new window will open to allow you to enrol patients by selecting the Yes/No toggle under Enrolled **(1)**. When finished enrolling patients, select Close **(2)**. 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.
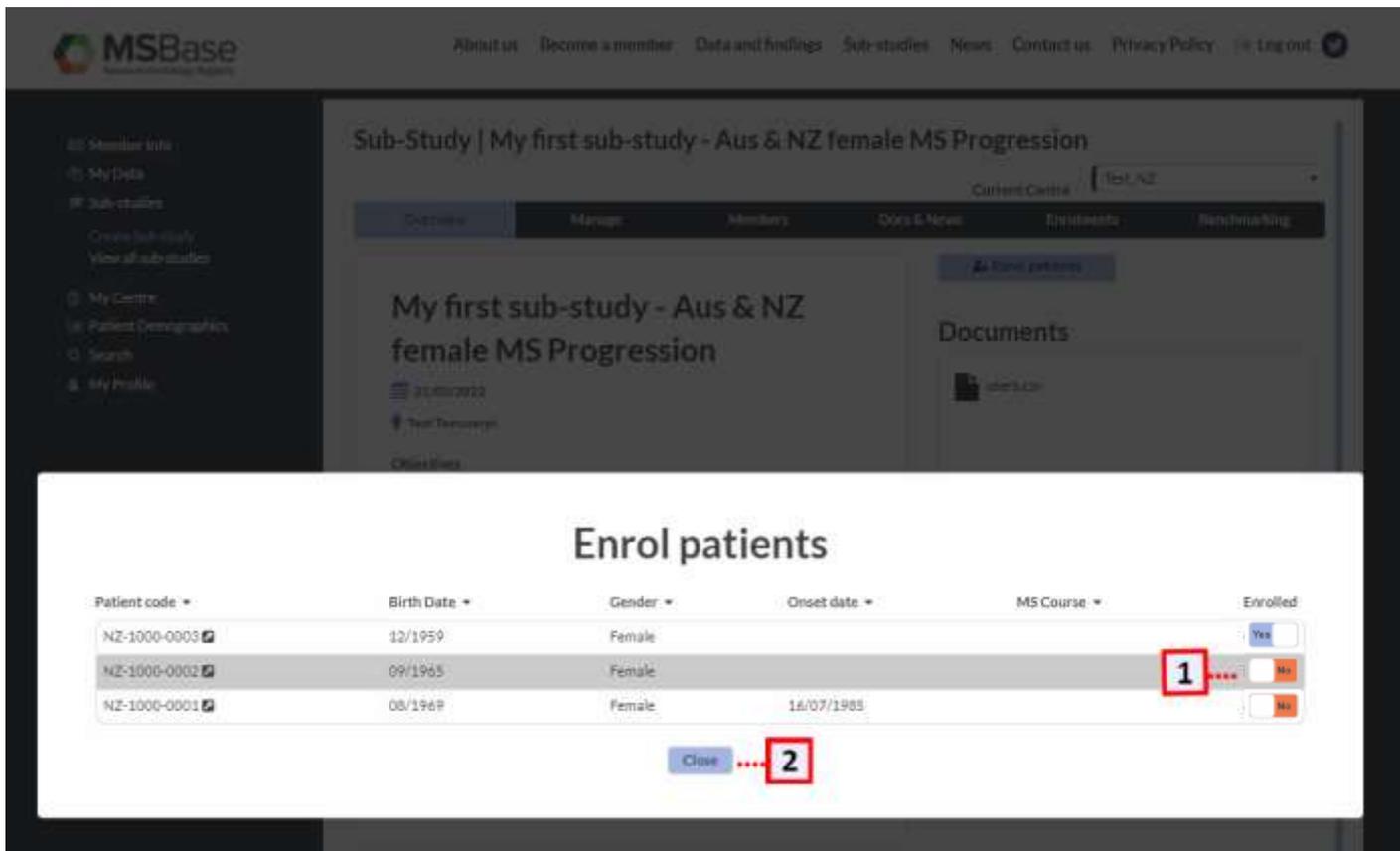
An alternative way to enrol patients is in the Patient View **(1)**. Navigate to the desired patient **(2)** and select the Sub-study option from the Patient Summary view **(3)**.
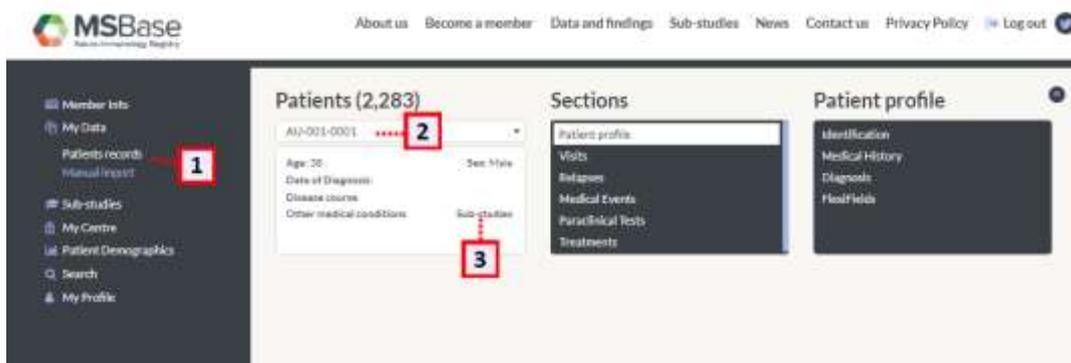
The Patient Summary view identifies the count of sub-studies that the patient belongs to or is eligible to join. This view also enables you to manually enrol the patient to one or more sub-studies. By selecting Manage enrolments **(1)** the user is presented with a list of all eligible and enrolled studies.
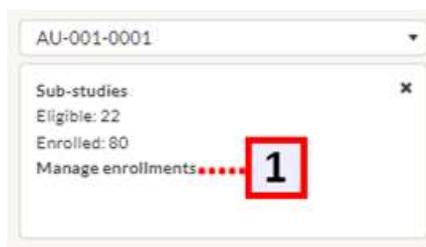
A window will display the sub-studies that the patient is eligible for, or enrolled in **(1)**. Where the patient is automatically enrolled, the 'Yes' button will be displayed **(2)** and there will be no option to unenroll the patient . To manually enrol a patient in any other eligible studies, select the 'No' to 'Yes' toggle **(3)** and Close **(4)** the window.


This should provide sufficient context of the enrolment procedure. In both the sub-study specific view and the patient specific view, eligible patients/studies are listed with their current enrolment status displayed. Where 'Yes' indicates the patient has already been enrolled into the sub-study and 'No' is shown for those eligible but not enrolled yet.

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

7. My Centre

7.1 Centre users

The PI and Co-PI are able to manage their centre Users **(1)**. This includes removing **(2)** users, editing **(3)** the details of users and inviting new users **(4).**
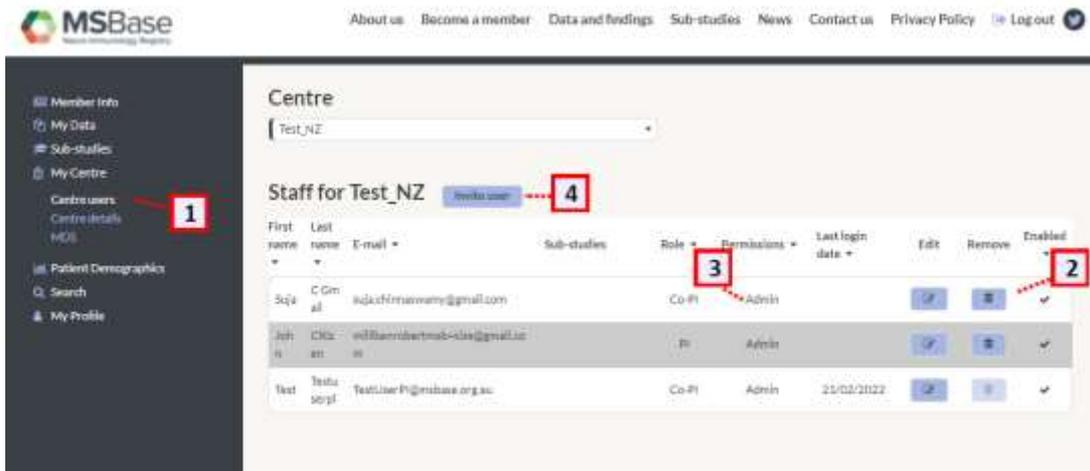

When inviting a new user to your centre, you will need to supply an email address **(1)** and the role **(2).** The Permissions role is for centres that are using MDS (the MSBase Data-entry System). If you are currently using iMed, or if you are in doubt, leave as Admin and the MSBase Operations team can further advise or can edit this role later as required. When complete, click Send **(4).**
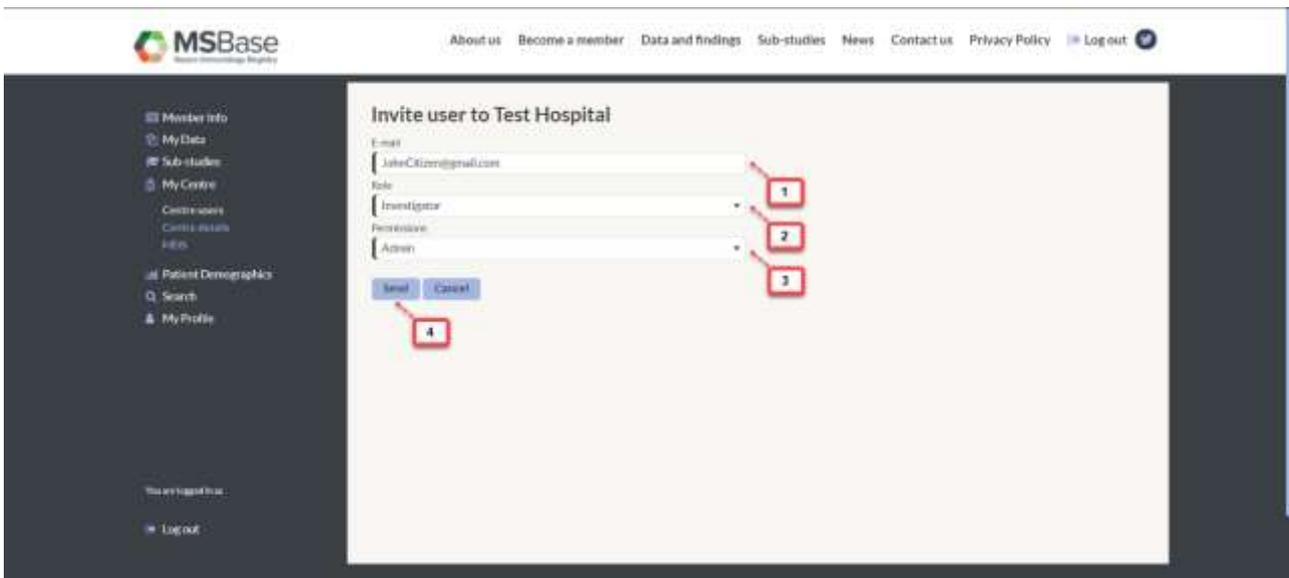
The invited user will receive an email invitation. Once they have completed the sign-up process, they will be active users of your centre.

7.2 Centre Details

A PI or Co-PI can change the contact details of the centre at any time by selecting centre details and updating the form.
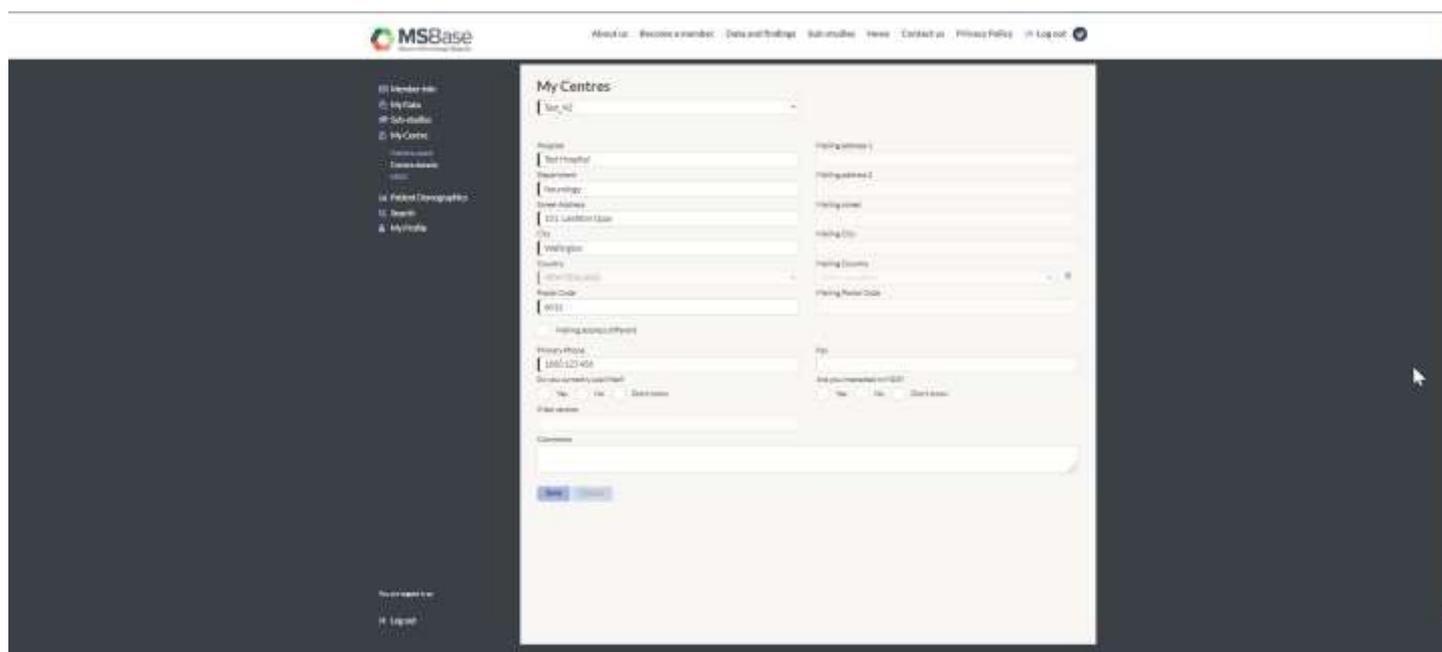
8. My Profile

All users are able to modify their profile by selecting My Profile **(1)**. For new users (or users just migrated), we encourage you to visit My Profile and update you details. Mandatory field are required and denoted by the blue cell padding on the left. Once fields have been completed select 'Save' **(2)**.