

# MG REGISTRY QUICK START GUIDE

**APRIL 2023** 

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# 1. About the MGBase Registry

The MGBase Registry is the first international, observational registry dedicated to ongoing longitudinal data collection for Myasthenia Gravis (MG), launched by the MSBase Foundation in December 2021. It provides a platform for international collaboration dedicated to sharing, tracking, and evaluating outcomes data in MG. Membership of the Registry is open to all practicing neurologists and their healthcare teams, worldwide. The MGBase Registry platform enables the collection of data for studies of MG regionally, nationally, or globally, with customizable sub-study functionality that filters data according to research themes. The Registry is owned and operated by the MSBase Foundation Ltd.

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



## 2. Joining the Registry

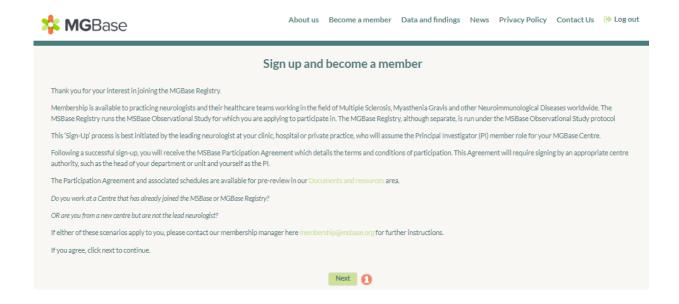
If your centre is not a member of the MGBase Registry, then you will need to apply for membership. <u>Membership benefits</u> are detailed on our website.

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

To apply, please visit the <u>Sign Up</u> link on our website. You will be required to fill some basic personal information and professional details to complete your membership application.



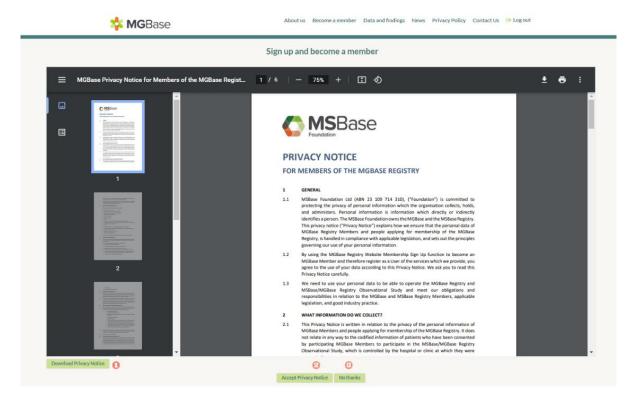
The landing page of the sign-up section contains basic information about the membership application process, governance documentation and contact information. Once you have familiarised yourself with this content, please select (1) Next to continue.



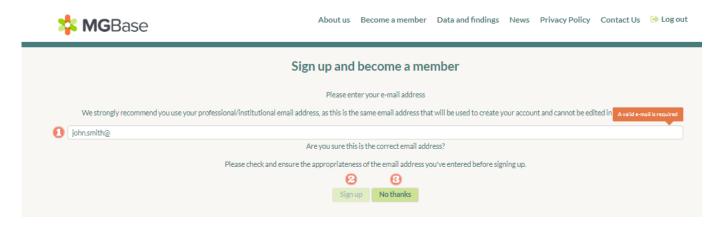
You will then be required to read and accept the MSBase Foundation Privacy Notice for Members of the MGBase Registry. The MGBase Registry provides the capability to (1) download, and (2) accept the Privacy Notice.

If you do not accept the Privacy Notice, please select option (3). This will automatically end the Sign-up process.





To complete the Sign-up process, you will need to (1) provide a valid email address. Once this is completed, you will have the option to finalise the process by selecting (2) Sign-up, or to cancel (3).



Once you have submitted the online registration form, the MSBase Foundation Membership & Administrative Officer will review your application and advise if your centre has been approved or if additional information is required. All Principal Investigators must read and sign the MSBase and MGBase 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 MGBase Registry.

In order to import data into the MGBase Registry, members must use the MSBase Foundation owned MSBase Dataentry Software (MDS).

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



#### 3. Password Management

#### 3.1 Password Reset

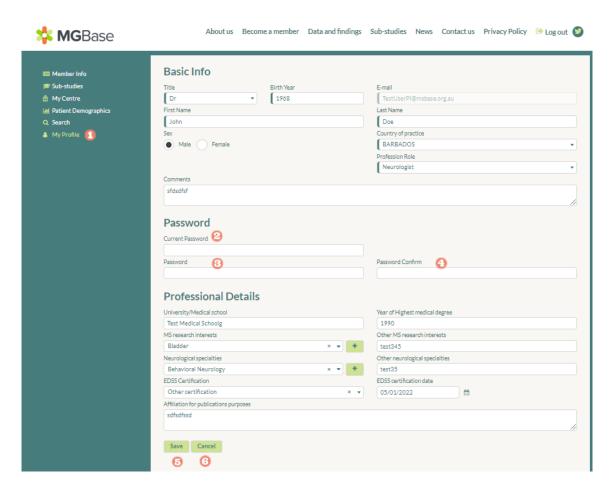
Have you forgotten your password and need to reset it? Simply navigate to the <u>Forgot Password link</u> at the Login screen. Once you have entered your email address then an email will be sent with a reset password link.

## 3.2 Password Change

The MGBase Registry provides users with the capability to change their password via (1) My Profile menu. To change your password, you will first need to enter your (2) current password, then you will need to enter and confirm your new password (3), (4) which must adhere to the following password requirements:

- A combination of at least one character from each of the following four listed character types:
- English uppercase letters (A-Z),
- English lowercase letters (a-z)
- Base 10 digits (0-9)
- Non-alphanumeric (such as `~!@ # \$ % ^ & \* () \_ + -= {} | \: "; ' <> ?, . / and space)

Once the password is updated, you can either (5) save or (6) cancel this change request.



If you experience any difficulty in resetting or changing your password, please contact us on <a href="mailto:info@msbase.org">info@msbase.org</a> for support.



## 4. Member roles and viewing your data

#### 4.1 Roles

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

**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 assist to upload patient data and enrol patients into sub-studies. As Investigators have the ability to contribute data, they can be listed as co-authors in MSBase Foundation publications if approved by the centre PI.

**Member:** This role is usually assigned to staff who provide administrative assistance within the centre. Member's do not hold the authority to upload patient data or enrol patients into sub-studies and therefore cannot be listed as a coauthors in publications.



## 5. Sub Studies

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".

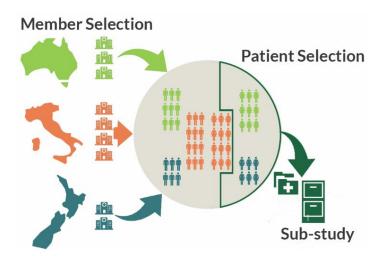


Figure 1: Visualisation of the selection process of All females from Australian and New Zealand centres. Note Italian females were not included as they did not meet the Member Selection criteria.

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. These studies require members Manual enrolment of patients to sub-studies. Reasons why Manual enrolment may be required 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.

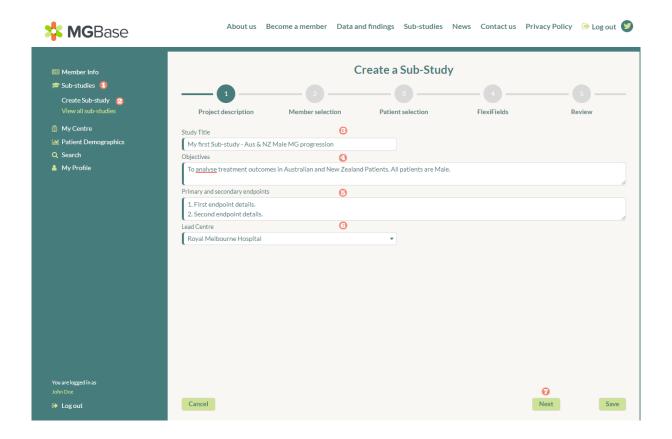
All sub-studies will be approved by the MSBase Foundation Operations team after submission. If you have any questions, please contact the team at <a href="mailto:info@msbase.org">info@msbase.org</a>.



#### 6.1 Creating a sub-study

As a PI, to create a sub-study, select Sub-studies (1), then Create Sub-Study (2), and fill the required details (3)(4),(5) and (6). These details will be used by other members to decide whether they wish to contribute data to your research, therefore it is important to be descriptive. Your sub-study details will also be visible on the MGBase website, so please take this into consideration should your research topic contain any confidential or sensitive content. Finally, please ensure that the title and description is in English.

Once you have finished entering details about your sub-study, click Next (7).

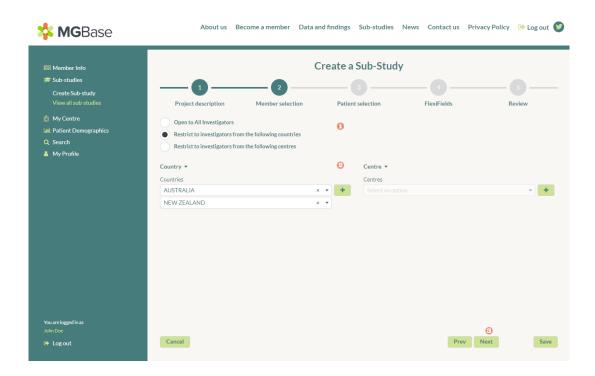




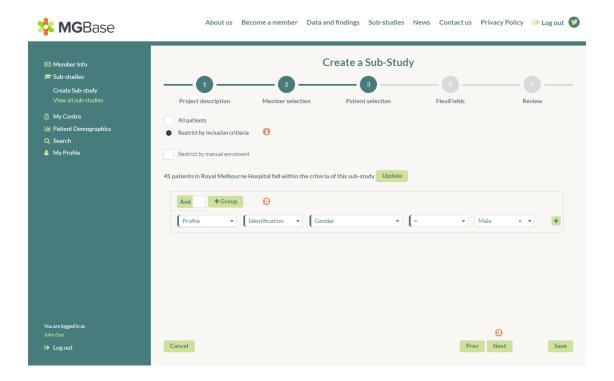
When selecting Members, there are three options.

- 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 Foundation Operations team at <a href="mailto:info@msbase.org">info@msbase.org</a>. 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

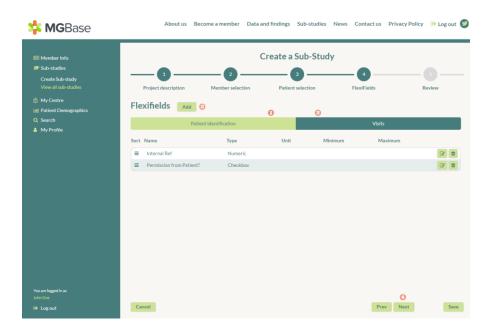
Do you have specific data you require about each patient for your research? For each sub-study it is possible to capture custom data fields – these are referred to as "Flexifields". Data types include:

- 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

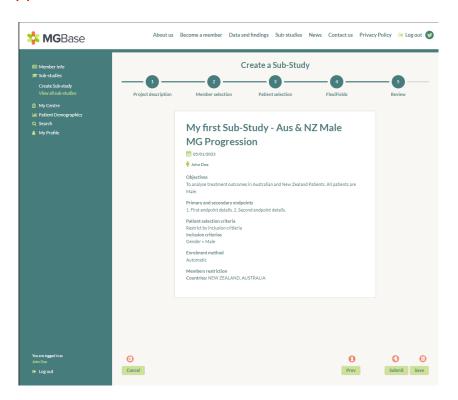


Data can be captured at the Patient Identification level (1) and at a Visit (2) level. Patient Identification should be used for data that will be captured only once and won't change over time (for example patient permission acknowledgement, eye-colour or phone-number). Visit data is captured at each 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)

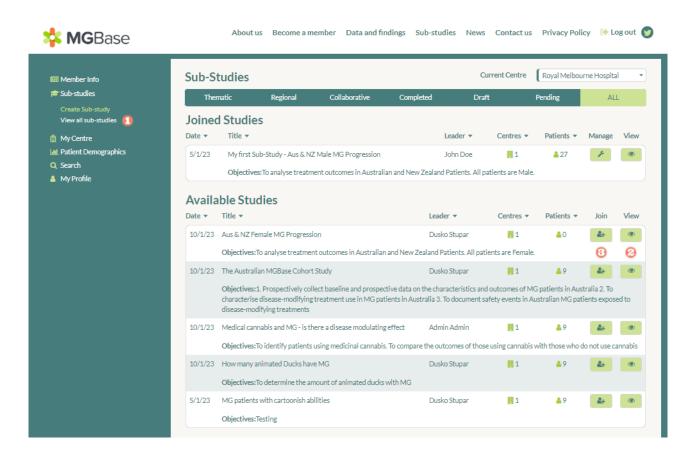




Congratulations! Your sub-study is now awaiting approval from the MSBase Foundation Operations team. You can enquire about progress at any time by contacting the team on <a href="mailto:info@msbase.org">info@msbase.org</a>. You will be notified by email if your sub-study is successful. All eligible members will also be sent an email advising them that a new sub-study has been created.

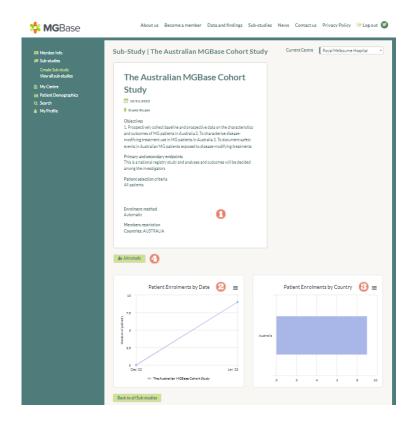
## 6.3 Viewing and joining sub-studies

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 substudy 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, select Sub-Studies (1), then (2) View all sub-studies and find the sub-study relevant to you. Once you have located the required sub-study, select Manage (3).

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.

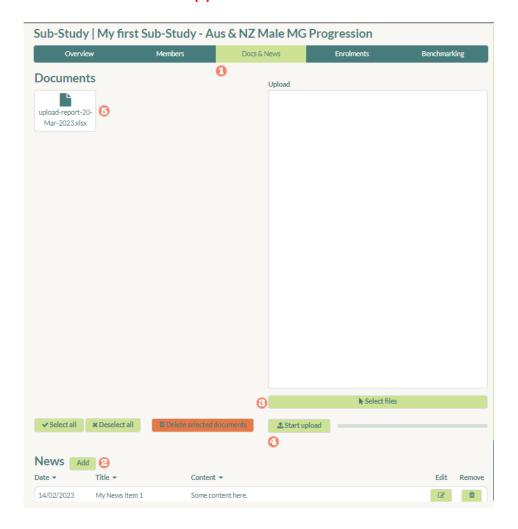






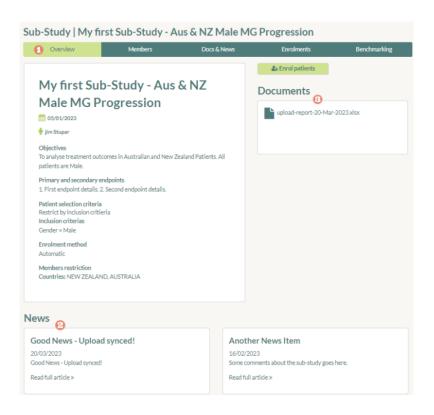


As the leader of a sub-study, you can communicate with your members by posting Docs & News (1) to keep members up to date. Selecting Add (2) will open a text editor, allowing you to add sub-study news. You can also upload documents relevant to the sub-study. Select Files (3) that you want to upload and select (4) Start Upload. Once uploaded, the content with be visible in the Documents section (5).



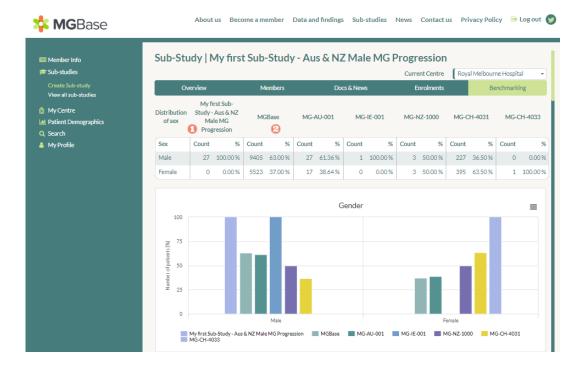


All members of the sub-study will have access to the Overview (1) section, where they will have the capability to review News (2) and Documents (3) that have been added. Members will also receive an email notification of the News item and Document addition.



## 6.5 Sub-studies - Benchmarking

The MGBase Registry allows members of a sub-study to benchmark their centre data against the overall data in the sub-study cohort as well as the entire MGBase Registry. In the below example we can see that the sub-study has (1) 27 males (100%), while the MGBase Registry consists of (2) 9,405 males (63%).

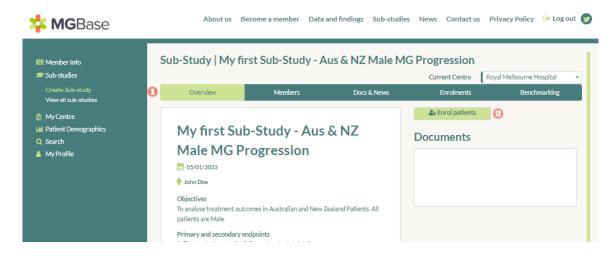




#### 6.6 Sub-studies - Manual Enrolment

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.

# **Enrol patients**

Patient code ▼	Birth Date ▼	Gender ▼	Onset date ▼	MS Course ▼	Enrolled
MG-AU-073-0002	06/1964	Female	17/06/2015		Yes
MG-AU-001-0025	03/1977	Female	25/06/2021		No
MG-AU-001-0023	09/1954	Female	01/01/1992		Yes

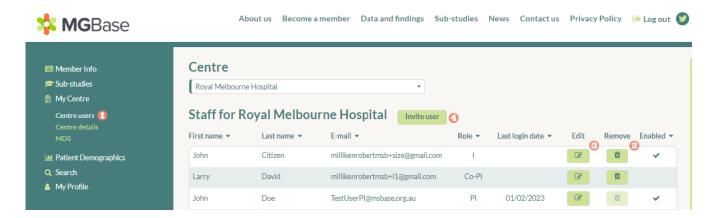




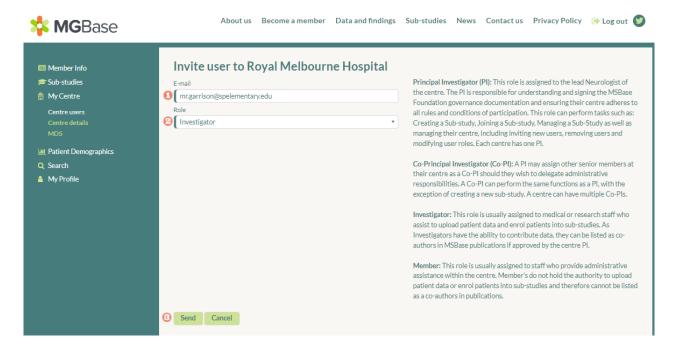
## 7. My Centre

#### 7.1 Centre users

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



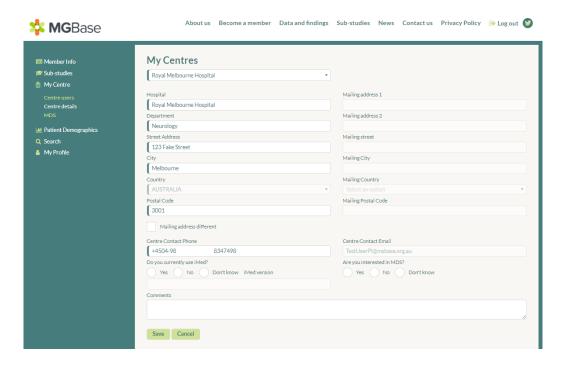
When inviting a new user to your centre, you will need to supply an email address (1) and the role (2). The Permissions role is for centres that are using MDS (the MSBase Data-entry System). If you are currently using iMed, or if you are in doubt, leave as Admin and the MSBase Foundation Operations team can further advise or can edit this role later as required. When complete, click Send (3). 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 can modify their profile by selecting My Profile (1). Mandatory fields are required and denoted by the blue cell padding on the left. Once fields have been completed select 'Save' (2).

