

Roles and Responsibilities of the MSBase/MGBase Principal Investigator

RESPONSIBILITIES

THE PRINCIPAL INVESTIGATOR SHALL:

1. Be a legally qualified and practicing neurologist treating patients with MS or other relevant NIDs (MG, NMO etc).
2. Inform an appropriate Centre Authority that they intend to collaborate in the MSBase/MGBase Registry Observational Study with the intent to share their Centre's pseudonymised data on certain and consented patients.
3. Provide the Participation Agreement, its schedules and appendices, to the Centre Authority and receive delegated authority to perform all Study Procedures. Delegated authority is demonstrated by the signature on this Participation Agreement.
4. Ensure, as a representative of the Centre, that the Centre is conducting the Study in accordance with this Agreement and all laws, rules and directives applicable in their jurisdiction and practice setting.
5. Ensure, as a representative of the Centre, that an applicable Institutional Review Board (IRB) or Ethics Committee (EC) approve the MSBase/MGBase Registry Observational Study, or deem the Study exempt from ethics approval (if applicable).
6. Ensure all patients who are participating in the Study are informed and give explicit consent by signing a Patient Information and Consent Form (PICF) in a language the patient understands.
7. Ensure that other Investigators at the Centre, who are participating in this Study, are aware of their applicable responsibilities listed in the Participation Agreement.
8. Share the participating Centre's pseudonymised data from their locally installed data-entry software to the MSBase/MGBase Registry at least biannually.
9. Adhere to all other relevant MSBase/MGBase protocols and procedures, such as the Data Use Agreement (applicable to Investigator-initiated analyses) and the Authorship Agreement (applicable to Investigators submitting manuscripts for publication or presentation)

ROLES

THE PRINCIPAL INVESTIGATOR SHALL HAVE THE AUTHORITY, FROM THE RESPECTIVE CENTRE, TO:

1. Manage their MSBase/MGBase Centre's membership profile and assign the appropriate level of permissions to other MSBase/MGBase Members of their Centre who are participating in the Study.
2. Create, lead and manage Investigator-initiated sub-studies.
3. Join Investigator-initiated sub-studies.
4. Submit data requests so that they can conduct scientific analyses using the Registry dataset.
5. Opt-out the use of their Centre data from Investigator-initiated analyses that are proposed from other Investigators.
6. Submit manuscripts that utilise the MSBase/MGBase dataset to peer-reviewed journals for publication (and uphold the Authorship Agreement as stated in the Responsibilities above).
7. Be offered co-authorship on eligible MSBase/MGBase publications and accept or reject the offer.
8. Request access to the MSBase Foundation Statistician services for research analyses.
9. Request to join various MSBase/MGBase committees and sub-committees if desired.