

# MSBase Registry

AN INTERNATIONAL PLATFORM  
DEDICATED TO LINKING  
MULTIPLE SCLEROSIS RESEARCHERS

## OBSERVATIONAL PLAN

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**The MSBase registry is owned and operated by the MSBase Foundation Ltd, a not for profit company registered in Australia. Contact details:**

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The MSBase Foundation has delegated responsibility for the oversight of the MSBase Registry research activities to a Scientific Leadership Group (SLG). All members, including the chairperson of the SLG, are chosen among neurologists, scientists and nurses with senior experience in the field of multiple sclerosis.

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**List of Abbreviations**

CIS	Clinically Isolated Syndrome
CNS	Central Nervous System
CRO	Contract Research Organization
EDSS	Expanded Disability Status Scale
iMed	Electronic data capture instrument
IT	Information Technology
KFS	Kurtzke Functional Systems
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
PASAT	Paced Auditory Serial Addition Test
PI	Principal Investigator
I	Investigator
QOL	Quality-Of-Life
RRMS	Relapsing-Remitting Multiple Sclerosis
SLG	Scientific Leadership Group
SAE	Serious Adverse Event
T8m	8-meter (25 ft) Timed Walk
9HPT	Nine Hole Peg Test

## 1 Synopsis

The MSBase Registry is a longitudinal, strictly observational Multiple Sclerosis database open to all practicing Neurologists and their team, worldwide. In collaboration with participating Neurologists, the MSBase Registry has established a unique, web-based platform dedicated to sharing, tracking and evaluating outcomes data in Multiple Sclerosis (MS) and other Central Nervous System (CNS) demyelinating diseases. In particular, MSBase aims to advance multi-centre, multi-national epidemiological and outcomes research by providing a freely accessible resource to compile, combine, compare and analyse large datasets.

The Principal Neurologists at participating centres submit coded clinical information using any compatible data collection software. The most commonly used software is the freely available iMed software as it is easily linked to the MSBase web platform and it contains the MSBase minimum dataset. The data to be collected (see Appendix 2), comprises key parameters relating to demographic data, diagnosis, serial neurological examinations (Kurtzke Functional Systems Score and Expanded Disability Status Score, EDSS), relapse information, specific safety related data and treatment exposures. All aspects of patient management are entirely at the discretion of the managing neurologist and his or her patient.

Coded aggregate data generated from the MSBase Registry will be reported to participating Neurologists on a regular basis. Important findings will be shared with the general neurology community at scientific meetings and through journal publications.

The MSBase Scientific Leadership Group (SLG) acts as the Scientific Advisory Board to the MSBase Foundation Ltd. The SLG has been delegated the role of custodian of the composite data, while individual datasets at all times remain the property of the participating centre, under management of the Principal Investigator (PI). The MSBase SLG will ensure data integrity and monitor all MSBase activities including core study designs, promotion and implementation, and perform composite data analyses.

## 2 Rationale

Multiple Sclerosis is a chronic, inflammatory, demyelinating disease of the Central Nervous System (CNS) and is one of the most common causes of neurological disability in young adults. It is characterized by multi-focal recurrent attacks of neurological symptoms and signs with variable recovery. Eventually, the majority of patients develop a progressive clinical course [1-3]. The exact cause of multiple sclerosis is unknown, although an autoimmune process has been implicated. The clinical course of MS is highly variable, ranging from sub-clinical disease to rapidly progressive MS.

The major rationale for the MSBase project is the creation of a web-based platform to facilitate the conduct of large, multi-centre, multi-national clinical studies. The major challenges for investigator-initiated clinical research of this nature include the identification of collaborators, ongoing communication between study sites, data quality assurance, and all aspects of data management. The MSBase platform is dedicated to providing investigators with the best possible independent logistic solution to these challenges at no cost.

During the past seven years, several clinical trials have shown efficacy of disease-modifying drug therapies in reducing the relapse rate in active RRMS [4-8]. It remains uncertain whether these therapies impact the development of progressive disability. One major interest of the MSBase Scientific Leadership Group is the creation of an international cohort study of early MS to collect up to date, prospective disease data, specifically attempting to discern the effect, if any, of currently available treatments upon long-term disease progression. In this context, prospective databasing in MS has some advantages over clinical trials in assessing efficacy of therapies, primarily because the focus is on long-term effectiveness in an entire population rather than short-term statistical significance in a highly selected population [9].

It is important that data collection is, wherever possible, embedded into the routine of a standard MS clinic, and, ideally, provide added value. With this purpose in mind, iMed [10], an electronic MS patient monitoring system, has been developed as a standardized data collection tool. It is characterized by relative ease of use and display features that can directly enhance the quality of patient management in the clinic. Other electronic documentation systems exist on the market, and can be used to send data to MSBase provided they are compatible with the technical requirements published by MSBase. Alternatively, neurologists can enter coded data online using the MSBase data entry web form.

### **3 Key Features and Scope of MSBase**

#### **3.1 MSBase: An observational registry**

MSBase is an ongoing, longitudinal, strictly observational registry that tracks outcomes of routine clinical practice for patients with MS. No experimental intervention is involved. Thus, a patient will receive clinical assessments, medications, and treatments as solely determined by the patient's physician. Release of data and publication related to the MSBase Registry, will be controlled by the Scientific Leadership Group (see section 11.3).

#### **3.2 Investigator support & sub-studies**

The MSBase Registry platform is also a logistic support tool for investigator-initiated studies (hereafter termed sub-studies). Sub-studies can be conducted freely through the MSBase website/server and it is the responsibility of each participating member of a sub-study to ensure that the research fulfils local regulatory and ethics requirements. Each participating member agrees to indemnify the MSBase Foundation Ltd against any loss, damage, claim or costs to the extent such losses, damages, claims or costs are caused by any omission or failure on the part of the member to meet local regulatory and ethics requirements. However the SLG retains the right to remove any sub-studies that are considered to be contrary to universally accepted ethical practice. Any MSBase registry PI may initiate a sub-study, and, as study leader, accept or reject applications from co-investigators (PIs) to join. The MSBase web platform will enroll patients according to the inclusion criteria specified by the Principal Investigators of a sub-study, and will provide accumulated data to the study leader in a format suitable for statistical analysis.

The MSBase website provides online facilities for communication, case discussion, clinic benchmarking, EDSS certification, private messages and the provision of other value-added content for MS physicians.

The MSBase Foundation Ltd is the sponsor of the MSBase Registry and its sub-studies. The MSBase Foundation may provide funding to participating research centres to help offset the cost of data collection.

## **4 Patient Eligibility**

Any patient diagnosed with MS, or CNS demyelinating diseases, including Clinically Isolated Syndrome (CIS); first demyelinating event (FDE) suggestive of MS; Neuromyelitis Optica Spectrum disorders (NMO); Radiologically Isolated Syndrome (RIS); or Acute Disseminated Encephalomyelitis (ADEM) should be encouraged to participate in this Registry. There are no exclusion criteria. In order to avoid selection bias each participating physician should aim to include all of his/her patients seen in their practice or clinic. At a minimum, all newly diagnosed patients should be included consecutively. All diagnostic and treatment related costs are the responsibility of the patient and his/her individual health insurance.

## **5 Regulatory and Data Protection Requirements**

Individual regulatory and data protection requirements have to be fulfilled according to all applicable regulations and laws in each participant country.

The MSBase Registry PI (or by delegation to centre co-investigators) will fully explain the MSBase Registry to all potential participants and give the opportunity for questions to be asked. All patients willing to participate in the MSBase registry will be required to sign a consent form authorizing release of their coded medical information to the central Registry. The signed consent form must be filed in the individual's hospital or clinic chart and a copy must be made available to the patient. An institutional review board or responsible ethics committee must approve the MSBase Registry project or declare it exempt from approval. If no responsible ethics committee, institutional review board or equivalent legal entity exists, the MSBase Registry PI must still obtain informed consent and the registry participant must still sign a standard consent form in a language fully understood by the participant. A sample consent form (in English) is provided on the MSBase website.

## **6 Registry Procedures**

### **6.1 Scope**

Start date: September 2003

Intervals of observation: minimum annual

### **6.2 Data collection instrument**

Participating centres will submit information using iMed (or other MSBase compatible software), as a standardized electronic data collection instrument. The iMed software can import data from most other databases, via a process of field to field mapping. Completion and uploading of the minimum dataset (see Appendix 1) is recommended for complete patient inclusion in the MSBase Registry. It is the PI's responsibility to create the link between the data collection instrument and the MSBase registry, and to manage regular uploads to the MSBase registry.

Alternatively data can be entered online into the MSBase data entry form.

### 6.3 Patient confidentiality

Patient name, address, phone number or day of birth will not be transmitted in order to preserve confidentiality. Patients are identified by an assigned “globally unique identification number” (GUID) incorporating encoded site and physician number. Data is encrypted before transmission and uploaded via a secure connection to the MSBase Registry website ([www.msbase.org](http://www.msbase.org)) complying with local and international law.

Association of patient identifying information and their GUID is only possible within the participating physicians’ data collection program. The Extract file generated by iMed does not contain any identifying information specified above, which is therefore never uploaded to MSBase.

### 6.4 Entry visit

The following data will be collected at the entry visit:

- Patient demographic data
  - Gender
  - Month and year of birth
- Medical History
  - Date of onset of disease
  - Date of diagnosis
  - Diagnosis (subtype of MS, or CIS)
  - Key diagnostic tests (MRI, Visual Evoked Response, Lumbar puncture results)
  - Disease course
  - Neurological status (Kurtzke functional systems scores/EDSS)
  - Prior and current immunomodulatory therapy, including duration

### 6.5 Follow-up visits

Physicians determine the actual frequency of necessary assessments according to a patient’s individualized need for medical care and routine follow-up, as well as to published or local guidelines as appropriate.

For the purpose of reporting data to the MSBase Registry, reports should be submitted at least annually. Therefore, it is recommended that patient visits occur at least every twelve months (range 9-15 months). Annual evaluations of neurological status (KFS/EDSS), relapses, new paraclinical tests, changes of disease modifying treatments, and disease course should be performed and entered into the relevant data collection fields.

Ideally, relapses requiring admission or methylprednisolone treatment should be entered into the database with appropriate documentation of neurological and new diagnostic test findings in real-time, to avoid issues relating to inaccurate recall.

## 6.6 Withdrawal

If, at any point, the patient chooses to withdraw his/her participation in the program, the patient record can be excluded from future uploads within the data collection program. Previously uploaded data in relation to the patient will remain in the database, unless a specific request for removal is received by the MSBase registry and approved by the Chair of the SLG.

In the case of the PI withdrawing participation in the MSBase Registry, they must notify the MSBase Foundation within one month of their withdrawal and nominate a replacement PI for approval by the MSBase Foundation. Where a replacement PI cannot be nominated, or where an existing PI does not respond to communications from the MSBase Foundation it is assumed that the previously uploaded data can be used for all analyses performed by the MSBase Foundation.

## 7 Evaluation of Results

This is an open-ended Registry, and sample size is not based on statistical considerations.

Statistical analyses will be performed on clinical parameters such as relapse and disability outcomes, included in the minimum dataset. Analyses may also be performed on other parameters included in the uploaded datasets.

## 8 Adverse Events

### 8.1 Report responsibility

It is the sole responsibility of the participating PI to notify his/her local Authorities and/or the manufacturer of a therapeutic agent regarding the occurrence of serious adverse events (SAE), according to applicable regulations in their jurisdiction of practice. The MSBase Foundation will not have access to individual reports of serious adverse events uploaded to the central database at [www.msbase.org](http://www.msbase.org) or to any patient identifying information and therefore neither the sponsor nor the Scientific Leadership Group can in any way be responsible for reporting an adverse event to the manufacturer or responsible local Authorities.

### 8.2 Definitions

An SAE is defined as any untoward medical occurrence that at any dose:

- results in death;
- is life-threatening (i.e. the patient was at risk of death at the time of the event);
- requires inpatient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; and/ or
- is another medically important condition (i.e. one which may not be immediately life-threatening or result in death or hospitalization, but is clearly of major clinical significance. It may jeopardize the patient, or may require intervention to prevent one of the other serious outcomes. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm;

blood dyscrasias or convulsions that do not result in inpatient hospitalizations; or development of drug dependency or drug abuse.)

## 9 Monitoring

Since this is a non-interventional study (as explained in section 3 above), there will be no regular monitoring and no source data verification, unless a clinical audit is requested by the SLG (see section 11.3). However, the physician agrees to cooperate fully with all reasonable requests for information or training related to this Registry from the SLG. Written or telephone requests for information, training or meetings shall be answered in a timely manner. The SLG has the right to request an independent, clinical audit to verify patient files or source documents.

## 10 Data and Study Documents

The participating PI will send an electronic copy of the data using iMed or other MSBase compatible software, to a central database (the MSBase Registry) via a secured website ([www.msbase.org](http://www.msbase.org)) and will be responsible for ensuring that all Registry-related documents and data are complete, true and accurate. As stated in section 6.2, it is the PI's responsibility to create the link between the data collection instrument and the MSBase registry, and to manage regular uploads to the MSBase registry, however the upload function can be delegated to any Investigator member of their team.

Alternatively data can be entered online into the MSBase data entry form.

## 11 Administrative Organization

### 11.1 Physician responsibilities

Participating physicians are linked to the centre where they treat patients. One physician at each centre takes the role of Principal Investigator (PI) and agrees to personally conduct/supervise this Registry in accordance with this Observational Plan and any applicable policies of his/her affiliated institutions. If the PI represents a private or public institution, they must have the authority to authorise participation in MSBase for the relevant patients in their institution. Each PI should be prepared to include all of his/her patients and those of co-investigators at the centre. Furthermore, the PI is expected to fully comply with all regulatory responsibilities, in particular the reporting of serious adverse events (see section 8, if applicable in their jurisdiction) and all applicable data protection requirements. For the purpose of quality assurance, physicians entering data into the MSBase Registry should be accredited to perform EDSS examinations via an online test, made available to all MSBase Registry members and associated physicians in each centre. The PI will be requested to confirm the above requirements by returning a signed copy of this document.

PIs are able to invite neurologist colleagues, nurses, fellows and administration assistants at their centre to join as investigator members according to their roles (neurologists, other physicians, nurses, research scientists, administration staff).

## **11.2 MSBase Foundation responsibilities**

The independent MSBase Foundation Ltd, incorporated in Australia, is the sponsor and owner of the database. This entity is responsible for the set-up and the coordination of the MSBase Registry. The sponsor has a list of participating physicians. The MSBase Foundation's intention is to support this international MS registry over the long-term. However in the unforeseeable event that they must divest themselves of it due to a lack of ongoing funding, the database will be handed to the SLG for them to continue, or discontinue, the activities and identify another sponsor.

## **11.3 Scientific Leadership Group**

The MSBase Foundation has appointed a Scientific Leadership Group (SLG) to act as custodian of all uploaded data. The SLG will closely monitor all MSBase Registry activities and supervise the general conduct of the Registry. Members of the SLG will meet at minimum once per year, but may form sub-committees to oversee specific projects (e.g. publications, protocols). It is the duty of the SLG to take all reasonable steps to ensure credibility and integrity of the database, control publication of composite data and maintain confidentiality. The SLG therefore has the right to request an independent, random clinical audit to verify patient files or source documents.

### **11.3.1 Sub-studies and the SLG**

The SLG will not interfere in the creation or conduct of sub-studies involving mutually consenting PI's, with the exception of serious legal or ethical concerns.

The lead investigator of a sub-study may ask the MSBase SLG for information on potential collaborators. The MSBase Registry will search its entire database for datasets containing suitable patients, and, based on this information, will provide the requesting sub-study lead investigator with the specified email address/contact details of potential collaborators so that the lead investigator can approach them to join his study.

All collaboration in sub-studies is voluntary and at its core is a mutual agreement between the lead investigator and all other investigators of any sub-study.

The SLG will review sub-studies as they are created to actively facilitate collaboration between MSBase centres. For example, if a centre has contributed a sizable dataset that would be valuable for inclusion into another sub-study, the SLG will try to foster collaboration between the existing sub-study participants and the new centre.

### **11.3.2 Analysis of composite data in MSBase**

At times the MSBase registry SLG may perform global analyses on the entire dataset. The global analyses work on an 'opt out' system whereby a two stage process of permission will be sought from centre PIs. Analyses occur for research publication and for contract reports requested by Pharmaceutical companies. Analyses for contract reports are conducted by the MSBase Foundation team and only the reports are released to the company, with a copy to the PIs.

Consent for use of centre data is requested from the PI for the particular global analysis proposed. If consent is not given the centre's dataset will be removed by the technical team. If the neurologist does not request removal of their data (i.e. he/she provides or implies consent by a non -response), the data will be included in the analysis.

In the case of Contract Reports, a copy of the report will be distributed to all consenting PIs who

consented to include their data. In the case of analyses for research publication, a draft manuscript will be forwarded to the PI for comment and contribution prior to including co-authorship. If the PI does not wish to co-author the paper after the analyses have been performed they will be acknowledged as contributing their data to the analysis.

#### **11.4 Publication and acknowledgement**

All publications using the MSBase Registry service must acknowledge its use. A copy of any publication using the MSBase platform should be submitted to the MSBase Foundation administration office.

#### **11.5 Authorship**

The SLG shall ensure compliance with all regulations governing identification of the authors of scientific articles.

A submitted manuscript is the intellectual property of its authors. It is the responsibility of every person listed as the author to have contributed in a meaningful and identifiable way to the design, performance, analysis, and reporting of the work.

#### **11.6 MSBase SLG membership**

Members of the International Scientific Leadership Group are listed below:

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### **13 Agreement Signature**

I have read the foregoing Observational Plan and agree to participate according to the Observational Plan as Principal Investigator at my centre, named below, in the MSBase Registry approved by the Scientific Leadership Group and in accordance with ethical practices considered appropriate for human research. I also agree to notify MSBase within one month of my ceasing to act as a Principal Investigator at my centre.

**Signature of Participating Physician:**

**Participating Physician Name (printed):**

**Name of Centre and Date:**

Fax to: MSBase Foundation, Australia Fax: +61 3 9342 8070  
Or scan and email to: [info@msbase.org](mailto:info@msbase.org)

## Appendix 1

### Essential fields for minimum dataset

It is expected that Investigators will capture these events in iMED in real-time and perform as a minimum an annual upload to MSBase.

Section	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 and Annual	Date
	KFS – 8 items	Entry and Annual	0 to 5 / 0 to 6 / 0 to 12
	EDSS*	Entry and Annual	0 to 10
Paraclinical tests	Test date	Entry and Annual	Date
	Test type	Entry and Annual	MRI, CSF, EP, Biochemistry
Relapses	Relapse Date	Entry and Annual	Date
	CNS region	Entry and Annual	Pyramidal, Cerebellum, Brainstem, Sensory functions, Bowel bladder, Visual functions, Neuropsychological functions
	Corticosteroids	Entry and Annual	Yes, No
Treatments	Treatment ID	Entry and Annual	Treatment names
	Start date	Entry and Annual	Date
	End date	Entry and Annual	Date

\*If all 8 KFS items have a response the iMed system calculates an EDSS score, however the clinician must review the calculated score and enter a score in the EDSS field for this item to be complete.

### Desirable fields for minimum dataset

At the time of relapse it is recommended to capture the visit, paraclinical, relapse and treatment data.

### Associated documents available through the MSBase website

- Regulations of the Scientific Leadership Group of MSBase
- Regulations of the MSBase Foundation.