

BigMSData Network



The big Multiple Sclerosis data network

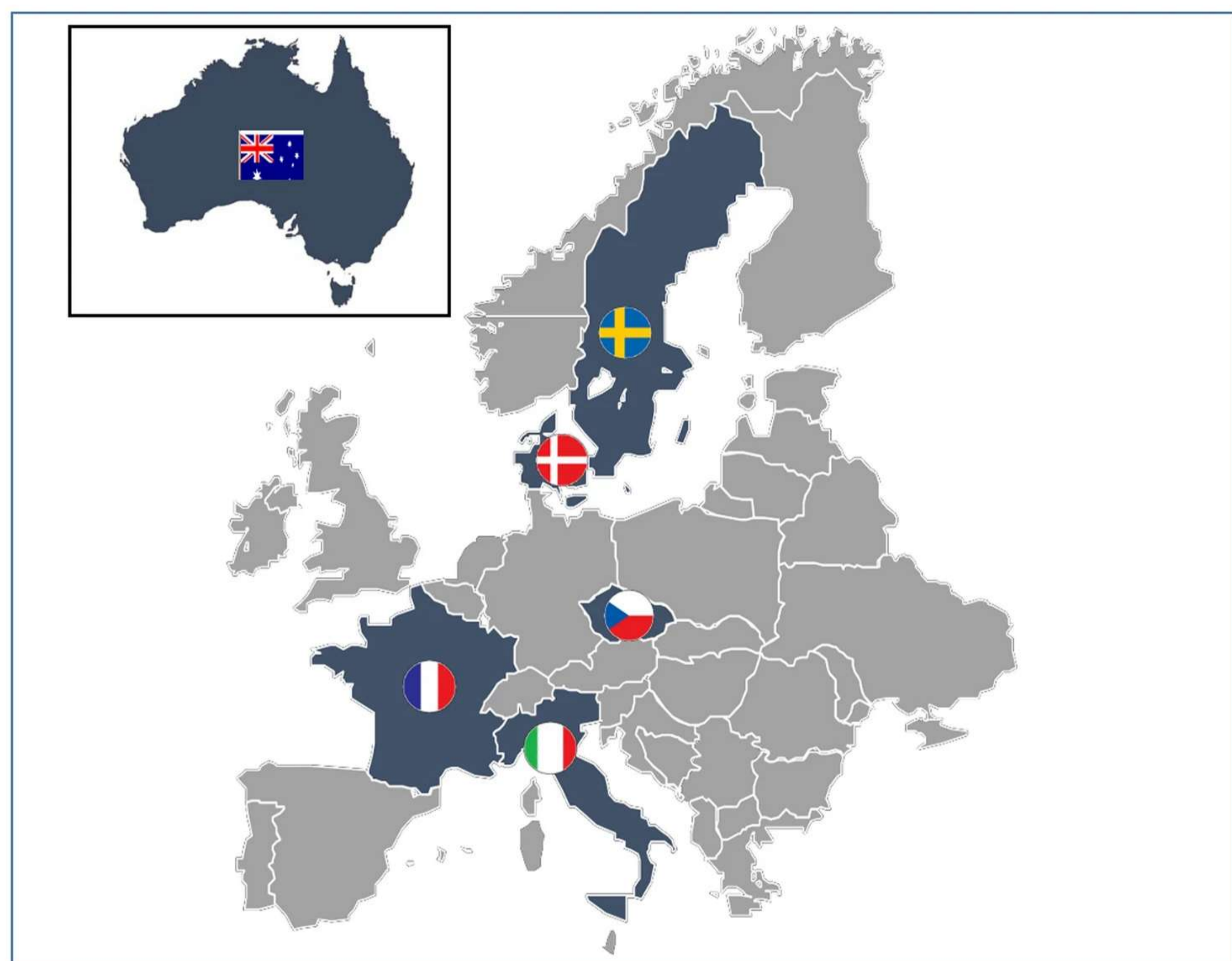
The home of MS Real World Evidence



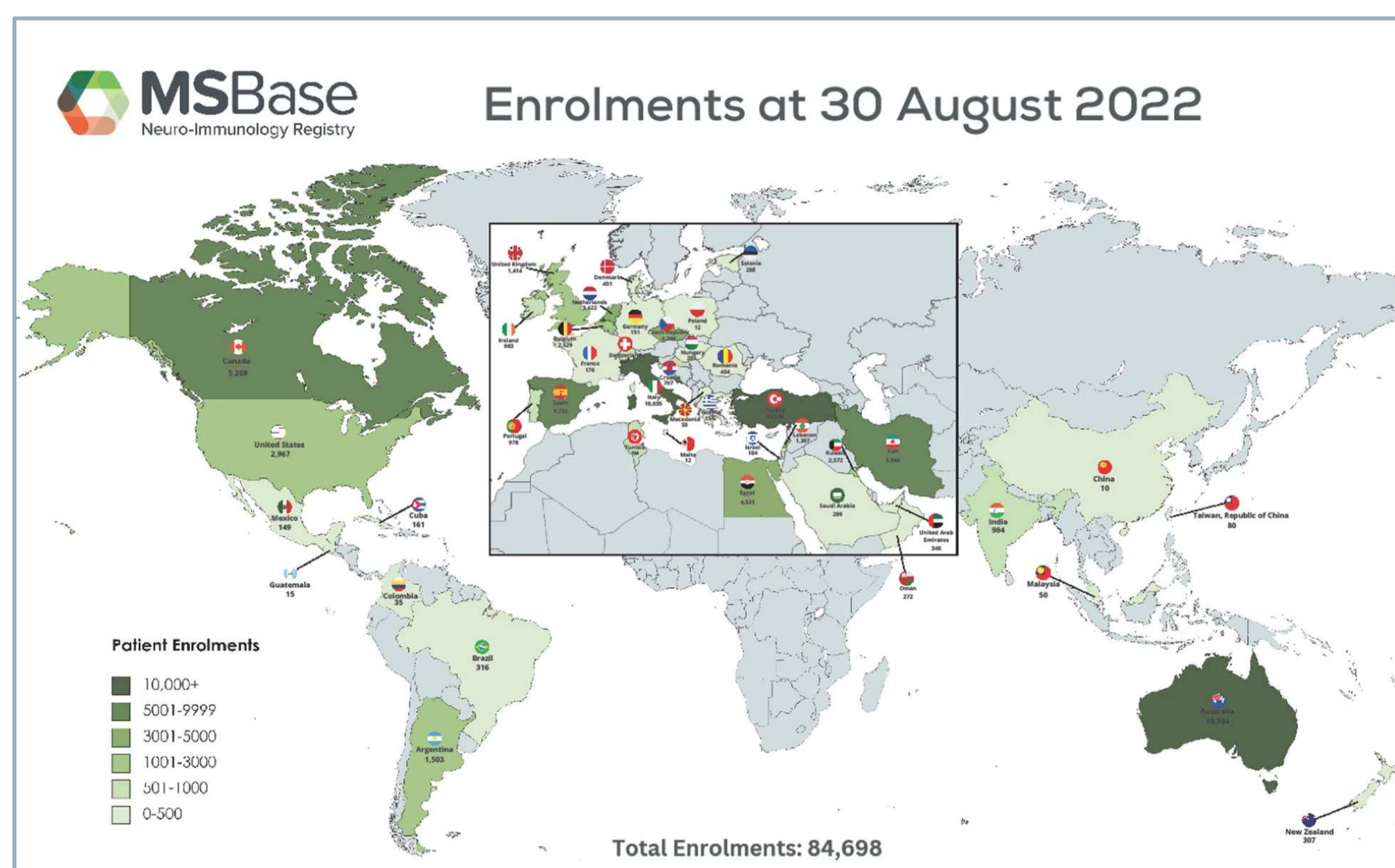
Background

Multiple sclerosis (MS) registries, both national and international, have a long history of gathering structured longitudinal clinical data. These registries have contributed significant information about MS, particularly regarding long-term outcomes in studies of the disease's natural course and the efficacy of interventions like disease-modifying therapies. In MS real-world evidence studies, statistical power is frequently challenging due to the complexity of clinical data, necessitating the use of very large, high-quality longitudinal data sets.

The Big Multiple Sclerosis Data (BMSD) network (<https://bigmsdata.org>) was initiated in 2014 and includes the national multiple sclerosis (MS) registries of the Czech Republic, Denmark, France, Italy, and Sweden as well as the international MSBase registry. The BMSD network is made up of well-developed registries, with reasonable coverage of local MS patients, providing a reliable framework for the network and containing data from a large number of people with MS. Each of these registries is well established as data sources for multiple scientific publications over the years. BMSD has addressed the ethical, legal, technical, and governance-related challenges for data sharing.



Map of MS registries. The national MS registries of Czech Republic, Denmark, France, Italy, Sweden and the international MSBase home in Australia.



Map of MSBase registries.

Data collection, management and analysis

The data collected by the respective registries and their governance frameworks are a result of many years of development and has evolved by consensus within each registry organization. Despite the independent nature of data collection, the similarities between data collected within the core dataset are striking. These similarities reflect a common aim to include variables that hold clinical significance. All BMSD registries are designed to collect SAEs, constituting the optimal basis for post-authorization safety studies (PASS). In its early phase, BMSD mapped the member registry datasets to a minimum data set and common data model (CDM) of variables, definitions and data structure.

The major effort is therefore to create a more complete CDM, a work which is now being finalized and which will be published in the coming year. The basis of the CDM is the BMSD data dictionary which contains close to a hundred items with agreed upon common definitions and descriptions. In addition, we have developed a BMSD CDM software which will translate a local database into the BMSD data format and generate a report on the success of the transformation of data and a second report on data quality. BMSD aspires to pioneer further development of federated approaches for joint analyses of data, including federated learning, to allow more complex analyses without merging data. Furthermore, another aim of BMSD is to actively promote the standardization of definitions and procedures in MS RWE research, including PASS studies.

Country	MS registry	Number of people with MS included	Estimated coverage of prevalent MS population
Czech Republic	ReMuS	21,500 (January 2024)	80%
Denmark	DMSR	33,142 (February 2024)	95%
France	OFSEP	81,325 (December 2023)	50%
Italy	RISM	87,045 (February 2024)	60%
Sweden	SMSreg	23,567 (February 2024)	85%
International	MSBase	97,263 (February 2024)	variable

Future perspectives

BMSD will soon renew an application to EMA for a qualification opinion regarding PASS. If approved, this would provide standardized expectations for MS registries when participating in regulator-demanded studies as well as guidelines for registries interested in joining the BMSD network. It is a clear ambition of BMSD to include more MS registries in the future. Having spent time and effort to define common scope and properties, harmonize variables and definitions in a common data model which also provides means of assessing data quality and density, BMSD will expect MS registries wanting to join BMSD to prove their fit-for-purpose at a similar level as the current six registries.

