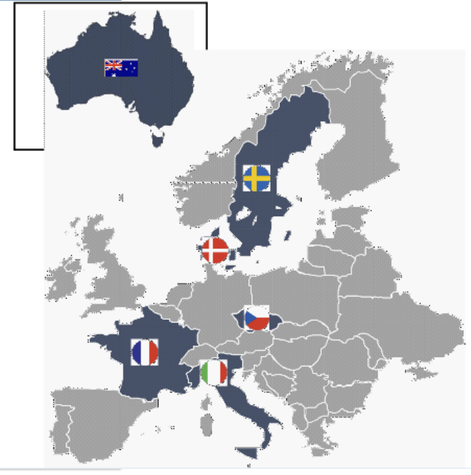
# From MS registries to regulatory evidence

**The 10-year journey to an EMA Qualification Opinion for the Big Multiple Sclerosis Data (BMSD) network**

***Real-world data. Real impact. For people with MS.***



BIG MS

**2016** — EMA Patient Registries Workshop

**2017** — EMA MS Registry Workshop

**2021/22** — Qualification Advice & Letter of Support

**2024** — HMA/EMA Registry Workshop

**2025** — Formal QO application

**July 2026** — Positive CHMP draft QO

**Oct 2026** — FINAL EMA QO PENDING

## Why qualification?

The European Medicines Agency (EMA) has long advocated the use of patient registry data for regulatory decisions. But only a few registries have been approved. Since 2019, BigMS has worked towards this goal in order to:

- ✓ Use MS registries for regulatory safety studies after authorization (PASS).
- ✓ Generate high-quality real-world evidence across countries.
- ✓ Increase sample size, diversity and generalizability.

## BigMS: Six independent MS registries

Svenska neuroregister · ReMuS® Registr pacientů s roztroušenou sklerózou · MSBase Neuro-Immunology Registry · RISM Registro Italiano Sclerosi Multipla e Patologie Correlate · OFSEP Observatoire Français de la Sclérose en Plaques

**Data quality standards**
Minimum requirements + key safety variables

↓

**Big MS Common Data Model (CDM)**
For data quality assessment and harmonized and federated data analysis

↓

**Study-specific feasibility**
Mandatory assessment for each PASS

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**Regulatory evidence**
PASS to inform regulatory decision-making

## What did it take?

The application consisted of a wide body of information on structures, processes and results to ensure data quality:

**Briefing Book**
Network + rationale

**Core Safety Protocol**
PASS framework developed in collaboration with pharma

**Common Data Model**
Harmonised analyses

**REQueST Tool**
Data + variables defined

**Feasibility Study**
All BigMS registries report sufficient SAE rates

**Life Cycle Management**
Continued quality assessment

## What does "qualified" mean?

✓ **YES — defined Context of Use**
EMA has assessed BMSD as suitable for a defined regulatory use.

✗ **NO — not automatically every study**
Fitness must still be demonstrated for the individual PASS.

● **THE BRIDGE — feasibility**
Mandatory study-specific feasibility assessment.

## Any day now: EMA QUALIFICATION OPINION ADOPTED

**BMSD and the six individual registries have received a positive opinion to be qualified within the agreed Context of Use. Final adoption decision expected later in autumn 2026**

**A milestone for multinational registry-based regulatory RWE!**

## Key conclusion

**the pending EMA qualification will confirm BMSD as a data source for post-authorisation safety studies (PASS) of MS disease-modifying therapies intended to inform regulatory decision-making.**

*To the best of our knowledge, BMSD is the first network of independent patient registries to receive an EMA Positive Qualification Opinion recommendation.*

Not a new registry —
a new way of making established registries work together.

MSToronto2026
10th Joint ACTRIMS-ECTRIMS Meeting
OCTOBER 21-23, 2026 | TORONTO, CANADA

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