

Agreement analysis of the **Italian Multiple Sclerosis and Related Disorders Register** for the evaluation of treatment safety in multiple sclerosis: study protocol



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INTRODUCTION

- ✓ **Multiple Sclerosis (MS)** is an autoimmune disease of the central nervous system. MS treatments, named “high-efficacy therapies” (HETs), proved to be highly effective but showed to cause potential (**serious**) **adverse events** - (S)AEs in the long-term period
- ✓ **Patient registries** can generate insights into the occurrence of long-term and rare AEs of MS therapies. In Italy, the **Italian Multiple Sclerosis and Related Disorders Register (RISM)** [1] serves as a valuable source of Real-World Data (RWD), having gathered clinical information on more than **96,000** people with MS (PwMS), with contributions from **161** actively participating MS centers

OBJECTIVE

To evaluate the **validity of safety data** recorded in RISM by analysing the **level of agreement** between the information gathered through **semi-structured interviews** with the same information extracted from RISM

OUTCOMES

- ✓ **Primary outcome:** SAEs of special interest (e.g. malignancies, late-onset and acute-onset opportunistic infections) and all other SAEs
- ✓ **Secondary outcome:** All the non-serious AEs

METHODS

EXTERNAL DATA SOURCE

Semi-structured interviews will be administered to PwMS by clinicians with experience in MS to collect data about the presence of predefined (S)AEs up to five years before the interview



Participating MS clinical centers

STUDY COHORT AND INCLUSION CRITERIA

Study cohort: random sample of PwMS under HETs from eight clinical centers

Inclusion criteria:

- MS diagnosis
- Age \geq 18 years
- HET for at least 1 year before the interview
- Enrolled in RISM
- At least 1 visit per year

STATISTICAL ANALYSIS

Calculations of prevalence, percentage agreement, and suitable agreement indices such as Cohen's Kappa, will be used to compare safety information derived from interviews against corresponding entries in the RISM database on an individual level

REFERENCES

- [1] Trojano M, et al. The Italian multiple sclerosis register. *Neurol Sci.* 2019 Jan;40(1):155-165. doi: 10.1007/s10072-018-3610-0

CONCLUSION AND FUTURE PERSPECTIVES

This study evaluates the **quality** and **completeness** of RISM safety data to determine the **reliability** of registry-based RWD for benefit-risk assessments of HETs in MS. In line with EMA recommendations, feasibility studies are needed to assess patient registries for accurate data collection of safety events

The study is promoted by the Italian Multiple Sclerosis Foundation – FISM ETS



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