BMSD Network – TC meeting – EMA Qualification Opinion Application	
Date: 19 March 2026 8:00 – 9:00 CET	
Venue: Microsoft Teams meeting	
Attendees:	Mario Alberto Battaglia, Helmut Butzkueven, Romain Casey, Lars Forsberg, Anna Glaser, Jan Hillert, Lars Forsberg, Pietro Iaffaldano, Elena Flavia Mouresan, Luigi Pontieri, Marco Salivetto, Maria Trojano, Irena Vukusic

Meeting Agenda

1. **Definition of the Life Cycle Management framework to demonstrate sustained data quality to the EMA**

Main discussion points

Key Discussion Points:

Participants discussed the structure of the report required to demonstrate the ongoing maintenance of the EMA Qualification Opinion (QO) by the Network. The objective of the document is to propose to the EMA a general methodology for proving sustained data quality, with the understanding that this approach may be subject to future revisions. The report will be based on validation script results (referring to the "PASS population") adapted to the CDM, which will also allow for a longitudinal comparison of these indicators over time. It was noted that the EMA has not yet issued official guidelines regarding the formal structure of such a report.

Report Structure and Content:

- Table 1 will present key statistics per BMSD registry (to indicate overall registry activity).
- Table 2 will provide a description of the "PASS population" from each registry, with variables that are grouped according to the following data quality dimensions presented in the EMA Data Quality Framework (DQF): representativeness, completeness, consistency, and accuracy.
- A section will be dedicated to verify if substantial changes have occurred regarding the collection of adverse events and other key variables (comorbidities, other medications, laboratory data, pregnancy-related information) over the past year.
- The criteria for the inclusion of new registries will be described, including: adherence to the Common Data Model (CDM), evidence of consistent validation script results, and the reporting of adverse events in alignment with other BMSD registries.
- Description of the CDM update over the years.

Data Collection Process:

- Each registry will be responsible for filling out its own column/section in the tables.
- A common script, previously tested by some of the BMSD registries, will be used to generate the necessary statistics for tables 1 and 2.
- Registries will only need to run the script once a year.

Other items:

- The BMSD coordinating group (currently Italy) is proposed to manage the annual collection of information from all registries.
- Participants agreed to publish the report on the BMSD website and the EMA RWD Catalogue.

Next steps:

The Czech registry group will finalize Section 5 regarding CDM updates.
The draft will be circulated among all participants for final review.
The completed document will be submitted to the EMA at the beginning of next week.