

## BMSD Network – TC 5 meeting

**Date:** 02 July 2025 8:00 – 9:00 CET

**Venue:** Microsoft Teams meeting

<b>Attendees:</b>	Mario Alberto Battaglia, Massimiliano Copetti, Jenni Lilian Dalsgaard, Jiří Drahota, Katharina Fink, Gregor Fistravec, Lars Forsberg, Anna Glaser, Orla Gray, Jan Hillert, Dana Horáková, Pietro Iaffaldano, Hanna Paulina Joensen, Pernilla Klyve, Melinda Magyari, Mie Reith Mahler, Luigi Pontieri, Marco Salivetto, Karel Škubal, Tim Spelman, Maria Trojano, Irena Vukusic
-------------------	---

### Meeting Agenda

- 1. Update CC: BMSD Annual Meeting and Statistical Workshop in Matera**
  - a) BMSD Annual Meeting agenda: presentation of draft document and discussion
  - b) BMSD Statistical Workshop Agenda: presentation of the final document and discussion
- 2. ECTRIMS 2025: Material to be prepared for the BMSD Booth**
  - a) Update of each Registry (pptx presentation) + list of most recent publications from each Register
- 3. Research project proposals:**
  - a) Synthetic data
  - b) Proposal of observational study on ponesimod
- 4. Request from EMA: HMA-EMA Catalogues of Real-World Data Sources and Studies – Call for Data Source Registration**

### Main discussion points

- 1. Update CC: BMSD Annual Meeting and Statistical Workshop in Matera**
  - a) BMSD Annual Meeting agenda: presentation of draft document and discussion
  - b) BMSD Statistical Workshop Agenda: presentation of the final document and discussion

The draft agenda for the BMSD Annual Meeting was shared to facilitate discussion of the proposed topics across the network.

The morning of Day 1 will be dedicated to the presentation of the EMA QO documents, which the Swedish group plans to submit by the end of July. Participants agreed to discuss these documents, also considering the possibility of developing publications based on them.

In the afternoon, representatives from the German and Finnish registries will be invited to present the results of their Common Data Model (CDM) analysis. Jiri proposed contacting Pietro to set up scripts for the quality indicators that would be used to evaluate the inclusion of the two registries.

A dedicated session will focus on NMO/MOGAD, where registries could share available statistics and the types of data collected so far. Jan suggested allowing more time for this discussion point. It is important to demonstrate to pharma companies that we have sufficient data to support studies on these diseases.

Another topic will address PROs and PREMs data collection within registries. It was proposed to invite Paola Zaratin from the Italian MS Foundation to contribute to this discussion.

Research project proposals will be discussed in the afternoon as well. Dana will send a proposal for a study aimed at describing the quality of care and treatment approaches for MS patients across countries within the BMSD network.

On day 2, the program will be similar to the program of the morning session of day 1. The EMA QO documents will be presented to representatives from the pharma companies, who will then have the opportunity to comment and provide updates on ongoing and potential PASS projects.

Following this, the German and Finnish registries will introduce themselves and present their work, demonstrating their progress toward joining the network.

In the final part of the meeting, pharma representatives will be invited to share research proposals for potential collaboration with the network.

Maria informed the group that Juvisé had expressed interest in assessing the feasibility of an observational study on ponesimod to be conducted within the network.

*(Post-meeting note: Participants provided the number of patients treated with ponesimod in each registry)*

**Actions:**

- *Please inform us about which Registry is willing to present NMO/MOGAD data in Matera. We will update the agenda accordingly*
- *Those who will present a research proposal during the BMSD Annual Meeting, please share the correct title with us so we can add it to the agenda*

## **2. ECTRIMS 2025: Material to be prepared for the BMSD Booth**

- a) Update of each Registry (pptx presentation) + list of most recent publications from each Register

Marco presented the materials which will be prepared for the BMSD booth at ECTRIMS. The posters from last year will be updated, and a new one describing the activities carried out for the EMA QO application will be presented. Bracelet-shaped USB sticks will be prepared, containing updated information of each registry presentation and a list of research publications from each registry over the past five years.

**Actions:**

- *We kindly ask to provide the Registry pptx presentation + list of publications by Friday 22 August at the latest.*

## **3. Research project proposals:**

- a) Synthetic data

Pietro described a European project (*TRUST Project Goal*) focused on the generation of synthetic data from RWD sources. By the mid of September, registries who are interested to participate will need to sign a letter of intent. Jan pointed out that the proposal should be evaluated carefully before sharing data. Pietro is available to share more information on this project and he will arrange a call with the other data managers to further discuss the proposal.

## **4. Request from EMA: HMA-EMA Catalogues of Real-World Data Sources and Studies – Call for Data Source Registration**

All members were informed that EMA has proposed registering the BMSD initiative in the HMA-EMA Catalogues of Real-World Data Sources and Studies. Maria noted that pharma companies had requested each registry to join the platform. It was discussed that, ideally, both the individual registries and the BMSD network as a whole should register, although the procedure for doing so remains unclear.