

## BMSD Network – TC 7 meeting

**Date:** 25 November 2025 8:00 – 9:00 CET

**Venue:** Microsoft Teams meeting

<b>Attendees:</b>	Mario Alberto Battaglia, Helmut Butzkueven, Massimiliano Copetti, Jenni Lilian Dalsgaard, Jiří Drahota, Katharina Fink, Anna Glaser, Orla Gray, Tommaso Guerra, Jan Hillert, Pietro Iaffaldano, Hanna Poulina Joensen, Pernilla Klyve, Giuseppe Lucisano, Elena Flavia Mouresan, Marco Salivetto, Karel Škubal, Tim Spelman, Maria Trojano, Irena Vukusic, Sandra Vukusic, Anneke Van der Walt
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### Meeting Agenda

1. Update on funding
2. BMSD Annual Report (Dic 2025) and deliverables for pharma companies supporting the network
3. 2026 BMSD Annual Meeting
4. Research project proposals: update
5. BMSD Registration on the EMA RWD Catalogue
6. Update on the inclusion of German and Finnish registries
7. BMSD Statistical Meeting Position paper

### Main discussion points

#### 1. Update on funding

Maria reported that there have been no further updates to the BMSD budget since the version presented in Matera.

#### 2. BMSD Annual Report (Dec 2025) and deliverables for pharma companies supporting the network

Other than the 2<sup>nd</sup> BMSD 2025 Annual Report (Dec 2025), pharma companies supporting the network requested specific deliverables to be shared with them. Accordingly, the upcoming Annual Report should include information on expected outcomes related to data quality, the BMSD PASS protocol, code harmonization, CDM implementation, and the results of the feasibility study. These outputs should be provided not only to Merck, but to all pharma partners supporting the network. Jan noted that these expectations may be interpreted very strictly, making it challenging to fully meet them. Mario underlined the need to find a balance between industry requests and the level of support they provide. Helmut suggested using the outputs from ongoing PASS projects as a form of “data quality report.” Jiri added that we can include the results of the CDM transformation already published (see the CDM poster presented at ECTRIMS), along with the validation log. In the future, a dedicated BMSD data quality report could be developed and updated regularly.

*Actions:*

- *The Italian group will coordinate the work to prepare the Dec 2025 Annual Report and the deliverables to be shared to pharma.*

#### 3. 2026 BMSD Annual Meeting

The 2026 in-person meeting will be held in Genoa. Participants discussed the possible timing of the meeting; the most suitable dates currently appear to be either September (17–19 or 24–26) or later in November/December. Proposals will be shared to find the best option.

#### **4. Research project proposals: update**

Current project proposals were discussed. OFSEP will share its project on sex-related therapeutic gap in MS and has just proposed a new project that aims to study postpartum relapses in women exposed to cladribine as the last DMT before pregnancy. Pietro updated that for the Italian project the legal framework on the use of data to generate synthetic information needs to be clarified before proceeding. Maria shared her thoughts about the need to clarify the possibility of data sharing from all the registries. Helmut said that currently MS Base cannot send data within the BMSD but they are preparing a data sharing framework that will be sent to all members for their evaluation.

#### **5. BMSD Registration on the EMA RWD Catalogue**

Marco shared the information requested to register the BMSD network on the EMA catalogue. Profiles that are registered as “Institutions” on the platform can be linked to the BMSD page.

*Actions:*

- *The Italian group will register the BMSD network on the EMA Catalogue.*

#### **6. Update on the inclusion of German and Finnish registries**

Pietro shared the completed checklist from the Finnish registry, which will be circulated to all members. He noted that clarification with the Finnish group is still required regarding data-sharing procedures for international projects.

The German registry is currently finalizing its checklist and has recently requested additional clarifications. Once their completed document is received, a confirmation of their inclusion can be sent.

#### **7. BMSD Statistical Meeting Position Paper**

Pietro reminded co-authors to send the draft of each paragraph to complete the manuscript.

#### **8. Project proposal from Juvisé**

Maria presented a project proposal from Juvisé entitled “Real-world outcomes of Ponesimod in the BigMS registry: impact on relapses and PIRA”. Juvisé is willing to fund the network and asked the number of treated patients with ponesimod from each registry. Sandra clarified that Juvisé needs to contact OFSEP to access French data. Maria concluded that the information on patient numbers will be shared to Juvisé, while the study protocol could be discussed during the next TC meeting.