

BMSD Network – TC 4 meeting

Date: 14 April 2026 8:00 – 9:00 CET

Venue: Microsoft Teams meeting

Attendees:	Mario Alberto Battaglia, Helmut Butzkueven, Massimiliano Copetti, Jiří Drahota, Katharina Fink, Lars Forsberg, Anna Glaser, Orla Gray, Tommaso Guerra, Jan Hillert, Pietro Iaffaldano, Pernilla Klyve, Giuseppe Lucisano, Melinda Magyari, Elena Flavia Mouresan, Luigi Pontieri, Marco Salivetto, Alexander Stahmann, Maria Trojano, Irena Vukusic, Sandra Vukusic, Clemens Warnke
-------------------	---

Meeting Agenda

1. Update on funding
2. EMA QO Application Update
3. Collaborative projects
4. Data-sharing among registries
5. ACTRIMS/ECTRIMS: shared booth
6. BMSD Annual Meeting in Genoa: update

Main discussion points

1. Update on funding

Maria confirmed the supports received from Sandoz (for 2026-2027) and Merck (for 2025-2026). Contract with Juvisé is currently being finalized.

2. EMA QO Application Update

Anna provided an update on the EMA QO. The life cycle management plan was submitted in March. A draft of the qualification opinion for review is expected in June 2026. Following this, there will be a public consultation period before the final decision.

3. Collaborative projects

The following updates were shared for each project:

a) De-escalation Project (Danish Group):

Various registries (French, Italian, Swedish, Czech, German) are in different stages of legal and administrative approval. The Italian and French registries completed the internal approval process. The Swedish registry is currently resolving legal department queries. The Czech group is finalizing the data processing agreement. The German registry needs to sign a data transfer agreement with the Danish registry.

b) Gender Inertia Project (French Group):

Each registry received the SAP and the R script to run the analysis independently. The Danish and German registries are already working on the project. The Czech group and MS Base are willing to join the project after receiving the internal approval to analyse data. The Italian registry will discuss the project in the upcoming scientific committee meeting in late April.

- c) Prevalence and predictors of postpartum disease activity in women with RRMS after preconception Cladribine treatment

Despite low patient numbers in individual registries, the members agreed on the necessity of pooling data to achieve a meaningful sample size. Denmark, Sweden, Germany, the Czech Republic, and Italy confirmed their intent to participate.

- d) MS TEAM Project (Czech Group)

Each registry received the application proposal. The project will be discussed in each registry scientific committee.

- e) Project on ponesimod from Juvisé

The scientific committee of the Italian registry has approved the project. Other registries are willing to participate but clarified that they first need to be contacted by Juvisé to join the project; they have not yet received proposals from them.

4. Data sharing among registries

Participants discussed the need to find a simplified legal framework to allow each registry to share data among network members. The process needs to be clarified, considering that national applications of GDPR vary. Participants agreed to dedicate a specific session of the upcoming Genoa Annual Meeting to these legal issues and, prior to that, to organise an online meeting with legal experts and representatives from each registry.

Actions: Each registry is asked to share the contact of a legal expert that could be invited to help define common procedures for data sharing within the Network.

5. ACTRIMS/ECTRIMS: shared booth

Participants discussed what to present at the next ACTRIMS/ECTRIMS Congress in Toronto. The 2025 posters regarding the network presentation will be updated, and a new one on the EMA QO Application could be presented if the network receives a final answer from EMA in the coming weeks. Another poster will be prepared on the BMSD criteria for including new registries. As in previous years, USB drives will be shared; each drive will include an updated registry presentation.

6. BMSD Annual Meeting in Genoa: update

The list of participants was shared among registry members. The meeting programme will be discussed soon and will include a dedicated session with legal experts and representatives from each registry to discuss data-sharing possibilities.