

BMSD Network – TC 6 meeting

Date: 07 July 2026 8:00 – 9:00 CET

Venue: Microsoft Teams meeting

Attendees:	Mario Alberto Battaglia, Helmut Butzkueven, Jiří Drahota, David Ellenberger, Katharina Fink, Lars Forsberg, Anna Glaser, Orla Gray, Tommaso Guerra, Kerstin Hellwig, Jan Hillert, Dana Horáková, Pietro Iaffaldano, Pernilla Klyve, Giuseppe Lucisano, Melinda Magyari, Marco Salivetto, Alexander Stahmann, Maria Trojano, Clemens Warnke
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Meeting Agenda

1. Collaborative projects and CDM
2. Update on EMA QO Application
3. Data-sharing among registries: legal framework
4. Update on new registries
5. Progress Report BMSD June 2026
6. ACTRIMS/ECTRIMS: update on shared materials
7. BMSD Annual Meeting in Genoa: participants and draft programme
8. Update on position paper (BMSD Statistical Workshop 2025 in Matera)

Main discussion points

1. Collaborative Projects and CDM

The following updates were shared for each project:

a) De-escalation Project (Danish Group):

Anna confirmed that the Swedish registry has completed the approval process and has started working on the project. Jiří reported that the Czech registry has received internal scientific approval. Alexander reported that the German registry has already started the analytical work and has shared preliminary data with the coordinating team.

b) Gender Inertia Project (French Group):

Jiří confirmed that the Czech registry has completed the internal approval process and is only awaiting the formal signed request before providing data.

Anna Glaser reported that the Swedish registry is currently processing the data and that the project is progressing.

Helmut Butzkueven stated that MSBase is expected to participate, most likely through a meta-analysis approach, and will confirm the approval status.

c) Prevalence and Predictors of Postpartum Disease Activity in Women with RRMS after Preconception Cladribine Treatment (French Group)

Maria informed the group that the Italian Scientific Committee approved participation despite the limited number of eligible patients.

Melinda confirmed that the Danish registry approved the project and will contribute through analyses based on linked data.

Anna reported that the Swedish registry is unlikely to participate because of the small number of eligible patients but will verify this.

d) MS TEAM Project (Czech Group)

Maria confirmed that the Italian Scientific Committee approved the project, and that details will be sent to the Czech group.

Jiří presented an update on the CDM manuscript. The manuscript is nearly complete, but additional validation analyses will be included to demonstrate that transforming registry data into the CDM reproduces previously published results while improving efficiency and harmonisation. This activity is part of the MS Team Project. The French registry provided comments and revisions on the MS Team project to the Czech team.

The Danish and Swedish registries confirmed their willingness to participate and to initiate their local approval procedures.

MSBase added that at the moment they could participate but they can only perform meta-analysis. The German Registry approved the project.

e) Project on Ponesimod from Juvisé

The project is ongoing within the Italian and German registries, while other registries have not been contacted.

2. Update on EMA Qo Application

Anna reported that the EMA Committee is expected to discuss the draft Qualification Opinion during the week beginning 20 July. If adopted, the draft document will be circulated for review during the following week, allowing five working days for comments before entering a six-week public consultation period. If the timeline is maintained, the final outcome may be available before the Annual Meeting.

3. Data-sharing among registries: legal framework

Mario explained that discussions are ongoing with Italian legal experts specialising in European data-sharing legislation. Once available, an online meeting will be scheduled with the legal representatives before the Annual Meeting (probably the first week of September). During the Annual Meeting, the possibility of a common data-sharing agreement will be explored.

4. Update on new registries

Jiří reported that implementation of the CDM within the Finnish registry is progressing, although no additional updates are currently available.

Maria informed the group that representatives of the Latin American MS/NMOSD/MOGAD registry expressed interest in joining the BMSD Network. Documentation describing the registry, its governance, patient population and minimum dataset has been requested. Once received, the documentation will be circulated to all members for evaluation before any decision is taken.

Jan emphasised the importance of carefully assessing candidate registries, highlighting that data quality should remain a key selection criterion.

5. Progress Report BMSD June 2026

Marco shared that the draft of the Progress Report will be circulated to all registries for comments before being finalised and shared with the supporting pharma companies.

6. ACTRIMS/ECTRIMS: update on shared materials

Marco reminded participants that four posters are being prepared for the BMSD booth and requested updated information from each registry. A template with the information requested and submission deadlines will be circulated by email. The group also discussed promoting all abstracts from each registry that have been accepted for oral or poster presentation at ACTRIMS/ECTRIMS.

All registries will be asked to:

- provide the information requested on the template by 31 August;
- submit registry presentations for USB drives by 15 September. Feel free to use your preferred style and format. Please remember to include the BMSD logo on the title slide of your presentation.
- notify the Italian team of accepted ACTRIMS/ECTRIMS oral and poster presentations.

7. BMSD Annual Meeting in Genoa: participants and draft programme

Marco presented the preliminary list of participants and reminded attendees to provide travel information to facilitate transfer arrangements.

Proposal of topics to be discussed were also shared:

- EMA Qualification Opinion (QO)
- Updates on BMSD Common Data Model (CDM)
- Collaborative Research Projects → (update on each research project - preliminary results – publications - new proposals)
- Procedures for Data Sharing Among Registries
- NMOSD/MOGAD Data Sharing or Comparison Between Registries
- PROMS Data Collection: Update on PROMS Survey
- ACTRIMS/ECTRIMS 2026 BMSD Booth Presentation

During the discussion, Jan, Melinda and Alexander proposed dedicating a specific session to the implementation of the European Health Data Space (EHDS), discussing its expected impact on registry governance, data sharing, sustainability and future funding. The group agreed that data sharing possibilities and EHDS-related developments represent a key topic that should receive dedicated attention during the Annual Meeting in Genoa.

8. Update on position paper (BMSD Statistical Workshop 2025 in Matera)

Pietro reminded that a shared Google Drive folder has been created with useful material for drafting the position paper. An introduction to the work will be circulated to facilitate contributions from all authors.

Regarding the feasibility study manuscript, Anna informed the group that a draft manuscript is already available and should be shared with the consortium shortly.