

BMSD Network – TC 4 meeting

Date: 10 June 2025 8:00 – 9:00 CET

Venue: Microsoft Teams meeting

Attendees:	Mario Alberto Battaglia, Bo Bekkouche, Massimiliano Copetti, Jenni Lilian Dalsgaard, Jiří Drahota, Frederik Elberling, Katharina Fink, Gregor Fistravec, Lars Forsberg, Anna Glaser, Tommaso Guerra, Jan Hillert, Pietro Iaffaldano, Hanna Paulina Joensen, Giuseppe Lucisano, Amin Nouhi, Luigi Pontieri, Marco Salivetto, Tim Spelman, Maria Trojano, Anneke Van Der Walt
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Meeting Agenda

1. Update CC:

- Next BMSD F2F 2025 meeting
- Update on BMSD funding
- Update on BMSD Progress Reports (December 2024)
- Update on BMSD members (Steering and DM Committees)
- Statistical Meeting Agenda

2. Final documents for EMA qualification opinion:

- CDM, Feasibility study, Core safety protocol, REQuEST Tool

3. Research project proposal:

- Feedback on the project application submitted by the Danish team (Melinda)
- Other projects

4. Planning for TC5 – July 2025: agenda

- F2F meeting in Matera: finalisation of the agendas for BMSD meeting + Statistical Workshop in Matera
- ECTRIMS 2025: BMSD booth

5. Other

Main discussion points

1. Update CC:

- Next BMSD F2F 2025 meeting

Maria provided an update about the registered participants. Pharma representatives have been invited to join the event in person or from remote. Remote access will be possible for those who cannot attend in person. The agenda of the BMSD Annual Meeting will be shared soon.

Actions:

- BMSD Annual Meeting agenda to be shared*
- for those who have booked the flights independently, please share your travel details (contact: bigmsdata@fismets.it) for the organization of the event logistics*
- Marco will send the invitation to the people who will attend the meeting remotely.*

- Update on BMSD funding

Maria informed the network that Sanofi is still interested in conducting a PASS on tolebrutinib with the BMSD network. She clarified they are planning a “classical” PASS, however they did not provide further information on liver enzyme data collection.

Sandra added that she was also contacted from Juvisé about a real-world study on ponesimod. She emphasized the importance of reminding pharma partners that BMSD coordinates activities, but individual registries must still be contacted directly for the conduction of these studies. Maria confirmed that Juvisé will support the network in 2025.

c) Update on the BMSD Progress Report (December 2024)

The latest BMSD progress report (December 2024) has been shared within the network. The draft report for June 2025, containing the latest updates on ongoing activities, will also be circulated for review.

d) Update on BMSD members (Steering and DM Committees)

The lists of the Steering and DM Committee members have been recently updated. The new list will be posted on the dedicated page of the BMSD website

Actions:

- *New list of the Steering and DM Committees to be added to the BMSD website*

e) Statistics Meeting agenda

Pietro presented the agenda for the statistics meeting, describing the main topics and presentations. Sandra asked to invite a French researcher, who would participate remotely. It was announced that each registry is free to invite people to participate remotely.

2. Final documents for EMA qualification opinion:

b) CDM, Feasibility study, Core safety protocol, REQuEST Tool

The Swedish group circulated the EMA QO documents to the other members for review. Anna said that it is planned to submit in July and asked which documents should be shared with pharma, in particular the more sensitive ones (i.e. the REQuEST Tool). A reflection on which documents should be disclosed and constantly updated to pharma is needed. Jan added that EMA is discussing a procedure for maintaining a qualification opinion, which does not exist yet. EMA published the Data Quality Framework for RWE studies, which is not official yet and much depends on how EMA will apply the standards proposed.

It was agreed to present all the EMA QO package during the meeting in Matera

Actions:

- *All members to review the EMA QO documents and provide their feedback within the next two weeks.*

3. Research project proposal:

a) Feedback on the project application submitted by the Danish team (Melinda)

Participating registries provided updates on the approval status of the Danish research project. Luigi updated that the scope of the original research proposal has changed.

b) Other projects

Sandra proposed to replicate in the network a French study where the difference between DMT exposure in men and women was analysed. Results showed that women are less likely to receive DMTs and tend to start treatment later, especially with HETs. She would send a proposal that will be discussed in Matera.

Pietro added that a project on AI and use of synthetic data to replicate RWD will be presented. The objective is to evaluate if it is possible to use synthetic data rather than real data to answer relevant research questions and overcome issues related to privacy and data sharing. Results of the comparison between the use of synthetic data and real data will be presented in Matera

As regards the CDM project, Jiri updated the network that the Finnish registry made relevant progresses. They managed to get a funding to conduct the project but they did not provide a timeline about the CDM implementation. As for the German registry, they are still working on it but they did not give us further news. Maria added that both the German and Finnish registries will be present in Matera and it would be valuable to have CDM results from both of them, in order to evaluate their inclusion into the BMSD network.

Lars informed the network that work is ongoing to run federated logistic regression among registries for the first time. Results could be discussed and presented in Matera.

4. Planning for TC5 – July 2025: agenda

- c) F2F meeting in Matera: finalisation of the agendas for BMSD meeting + Statistical Workshop in Matera
- d) ECTRIMS 2025: BMSD booth

It was agreed to schedule an additional TC meeting in July to finalize the agendas for both Matera meetings, and the materials to be presented at the BMSD booth during ECTRIMS. The proposal is to include updated versions of some 2024 posters and a new one illustrating the work done in preparation for the EMA QO application.

USB sticks will also be prepared, containing updated information of each registry presentation and a list of research publications from each registry over the past five years.

Actions:

- *Marco will share an Excel file where each registry can enter PubMed references for publications based on registry data from January 2020 to the present*
- *All registries have to prepare an updated presentation of their data, which will be included on the USB sticks.*
- *Marco will circulate a doodle to plan the TC meeting in July. Post-meeting note: the next TC is scheduled for 2 July, from 08:00 to 09:00 CET.*