

## BMSD Network – TC 2 meeting

**Date:** 05 March 2025 8:00 – 9:00 CET

**Venue:** Microsoft Teams meeting

**Attendees:** Mario Alberto Battaglia, Helmut Butzkueven, Jiří Drahota, Jenni Lilian Dalsgaard, Frederik Elberling, Gregor Fistravec, Lars Forsberg, Anna Glaser, Tommaso Guerra, Jan Hillert, Dana Horáková, Pietro Iaffaldano, Pernilla Klyve, Giuseppe Lucisano, Melinda Magyari, Elena Flavia Mouresan, Luigi Pontieri, Marco Salivetto, Maria Trojano, Sandra Vukusic

### Meeting Agenda

1. **Update CC:**
  - a) Next BMSD F2F 2025 meeting + statistical meeting in Italy
  - b) Update on BMSD funding
  - c) New contact email: bigmsdata@fismets.it
  - d) Update on the BMSD website
2. **Update EMA qualification opinion:**
  - a) CDM
  - b) Feasibility study
  - c) Request tool/ Data quality
3. **EMA documents on RWE in registries**
4. **Research project proposal:**
  - a) Feedback on the project application submitted by the Danish team (Melinda)
  - b) Legal requirements, limitations and possibilities for sharing data at the patient level within the network for academic projects
5. **Topics for next Statistical meeting**
6. **ECTRIMS 2025: booth reservation**
7. **Other**

### Main discussion points

- **Update CC:**
  - a) Next BMSD F2F 2025 meeting + statistical meeting in Italy (September 17-20)

The location of the next annual meeting will be Matera.

An online form will be shared among the registry groups. Each participant will need to fill in the form with the requested information, then the dedicated staff of the Italian MS Foundation will be responsible for organizing the travels and the accommodation.

- b) Update on BMSD funding

The funding from Merck was recently finalized. Maria added that she and Mario will meet the representative from Juvisé Pharma to discuss about possible funding. The funding from Roche is pending, and it was discussed which contact person to consider to ask for economic support.

Neuraxpharm should be considered as well; it was decided that both Melinda and Mario could contact pharma representatives to ask about their availability.

- c) New contact email: bigmsdata@fismets.it
- d) Update on the BMSD website

A new email address will be dedicated to the BMSD initiative.

The BMSD website was recently updated with new contents. As for the governance section, it was proposed to add the list of members who are part of the Steering and DM Committees. The slides with all the names will be shared and if all agree this information will be added on the website.

*Actions: Online form to be shared for event registration*

*Slide with list of members of the Committees will be shared for revision*

## 2. Update EMA qualification opinion:

### a) CDM

Jiri shared possible scientific journals where the manuscript on the CDM will be sent. Then Jiri described the content of the manuscript. It was discussed how to show that CDM delivers reliable results, one option is to replicate previously published data from national registries in the CDM format. Luigi shared some critical issues on that point and suggested that a validation with external data sources would be ideal. Jiri agreed on that, adding that the comparison with previous published data would be an additional part of the paper and does not have to be conducted with all registries. He also asks the registry groups to send the co-authorships for the publication.

As for the work on the CDM conducted by the German and Finnish registries, Jiri and Gregor shared that they did not receive updates from them. Maria added that it would be ideal to know the results of the CDM before the annual meeting where the two registries will be invited.

### b) Feasibility study

Elena provided an update on the EMA QO feasibility study. The analysis is being performed again on the data from the Manuscript study, and the Czech registry is evaluating the possibility of a linkage between registry data and the national healthcare database. In addition to contributing to the EMA application, the results could be part of a future publication.

### c) EMA qualification

As for the EMA qualification, Jan updated the group saying that once the feasibility study is complete, we could be ready for the submission. Before that, it was agreed to share the draft of the application with all the BMSD members for revision. It was also agreed that supporting pharma will not receive the draft but they will be informed about the submission.

*Actions: list of co-authors to be sent for the CDM manuscript*

*EMA application to be shared once finished to BMSD members for their feedback*

## 3. EMA documents on RWE in registries

Jan described the comments he sent to EMA on behalf of the network as regards the DQF document for RWD, which was open to the public for consultation and feedback. Participants shared their worries about the high standards and document requirements that would complicate future research with RWD. The scope and use of secondary data should be clarified in the document, with an evidence-based approach. The advantages of registries should be emphasized and the level of complexity of the DQF document is not needed for the research questions that registry-based studies can answer. There is also the risk that industries will take this document as a reference standard when they ask registries to conduct research studies.

## 4. Research project proposal:

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

### c) Legal requirements, limitations and possibilities for sharing data at the patient level within the network for academic projects

Maria said that the Italian Scientific Committee approved the Danish project, and clarified that the extracted data can be analysed only by statisticians within the BMSD network. The OFSEP Scientific Committee asked for further details on the project before approving it. Sandra added that a general process for data sharing within the network should first be assessed by registry leaders before involving legal persons. The Swedish group would also participate with their data in the Danish project.

## 5. Topics for next statistical meeting

Pietro shared the two main topics that have been scheduled for the next statistical meeting and asked for suggestions.

Sandra presented a French research project about the creation of an individualized predictive tool with OFSEP data, and that the person dedicated to this project could be invited to describe the project to the BMSD network. It was agreed that this person could contact Maria and Pietro.

*Actions: BMSD members can send other proposals for the statistical meeting.*

#### 6. **ECTRIMS 2025: booth reservation**

Marco advised that it is already possible to book a space at the NPO village for the next ECTRIMS Congress.