BMSD Network – TC 1 meeting	
Date: 28 January 2025 8:00 – 9:00 CET	
Venue: Microsoft Teams meeting	
Attendees:	Mario Alberto Battaglia, Helmut Butzkueven, Massimiliano Copetti, Jiří Drahota and members of the ReMuS group, Jenni Lilian Dalsgaard, Frederik Elberling, Lars Forsberg, Anna Glaser, Tommaso Guerra, Orla Grey, Jan Hillert, Pietro Iaffaldano, Pernilla Klyve, Giuseppe Lucisano, Melinda Magyari, Elena Flavia Mouresan, Amin Nouhi, Luigi Pontieri, Marco Salivetto, Tim Spelman, Maria Trojano, Anneke Van Der Walt, Sandra Vukusic, Irena Vukusic

Meeting Agenda

1. **Update CC:**
   a) Next BMSD F2F 2025 meeting + statistical meeting in Italy (June 18-21; May 19-22; September 17-20)
   b) Update on New registries
   c) Update on BMSD funding
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. **Other**

Main discussion points

- **Update CC:**
  a) Next BMSD F2F 2025 meeting + statistical meeting in Italy (June 18-21; May 19-22; September 17-20)

Participants agreed to schedule the 2025 in-presence meeting from 17 to 20 September. Anneke's request to anticipate the statistical meeting and move the BMSD meeting and BMSD PASS Forum afterward will be considered when defining the meeting's schedule. The German and Finnish registries will be invited at the meeting, and remote participation will be arranged for those who need it.

- **Update CC:**
  b) Update on new registries
- **Update EMA qualification opinion**: CDM

Jiri provided an update on the current status of the BMSD CDM. Most of the registries have completed the transformation, while the Italian group is expected to complete this step in the next few days. As for the Finnish and German registries, a kick-off meeting was held in November, and both registries have been working on the CDM. The Finnish group has to solve problems regarding data access at the regional level before implementing the CDM. Jiri asked all data managers from each registry to share their results in order to finalize the BMSD CDM paper on the CDM. He will propose some dates to the registry data managers to organize a meeting within the next two weeks to discuss the CDM results.

- **Update CC:**
  c) Update on BMSD funding

- Sandra gave an update on the Sanofi study, which is not a proper PASS but rather an assessment of whether the safety test on liver enzymes has been conducted and if neurologists are aware of the Tolebrutinib risk minimization plan. They are not planning a PASS, as the EMA has not required them to conduct one. To investigate this aspect further, Jan suggested to contact members of the More-Europa project, and Maria that Sanofi could be contacted at national level and then a common document could be sent to the EMA.
- Anna added that she and Elena had a discussion with a person in Roche, and suggested to reach out this person to evaluate the possibility of funding from the pharma. Anna will let us know the contact person

2. **Update EMA qualification opinion:**
    b) Feasibility study

Elena provided an update on the current status of each step of the EMA QO feasibility study. She shared the results of the comparison between Czech Republic, Denmark and Sweden based on the Sanofi ECCS data. Results were discussed, the differences between the Danish and the Swedish data, and suggestions on how to review and interpret the results were shared. Maria added that a dedicated meeting could be organised to discuss the outcomes of the feasibility study.

3. **EMA documents on RWE in registries**

Participants shared their thoughts on the recent EMA document on RWE in patient registries, which is open for consultation until the end of January. There is the concern that it will be complex for registries to comply with all the requirements outlined in the document. Jan will prepare a comment on this issue and circulate it within the network in the coming days.

Actions: Jan will draft a comment on the document and share it with the network.
Post meeting note: Jan shared a link for a survey on the draft of EMA's guidelines on Data Quality framework for RWE. He suggested to complete the form, jointly or separately, to state a common point of view.

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

It was discussed whether registries can share data at the patient level. In the coming days, the Scientific Committees of both the French and Italian registries will review the project submitted by the Danish team. From the French and the Italian registries, it was anticipated that sharing patient-level data for international academic projects will not present significant issues. In Sweden, the ethical approval is needed, while in the Czech Republic, informed consent allows for the sharing of patient level data. Jiri added that this process should be conducted within the BMSD network under an agreed legal framework. For MS Base, centers belong to different countries, each with distinct legal requirements. A framework that defines the roles of data processors and sub-processors could potentially address legal issues related to data international sharing. This aspect should be investigated by legal experts in each registry.

5. **Topics for next statistical meeting**

Maria asked all members to send her proposals for topics of interest to be discussed at the next statistics meeting.

6. **Position paper**

Maria said she has received all parts of the position paper (with the exception of Charles Malpas') and is putting them together. She hopes to send the draft to everyone as soon as possible for review and completion.