BMSD Network – TC 6 meeting	
Date: 10 October 8:00 – 9:00 CET	
Venue: Microsoft Teams meeting	
Attendees:	Pietro Iaffaldano, Maria Trojano, Mario Alberto Battaglia, Dana Horáková, Melinda Magyari, Jan Hillert, Sandra Vukusic, Irena Vukusic, Tim Spelman, Elena Flavia Mouresan, Jiří Drahota, Pernilla Klyve, Anna Glaser, Lars Forsberg, Luigi Pontieri, Orla Grey, Hanna Poulina Joensen

Meeting Agenda

1. Update from the BMSD coordinating center:
    a) Update on BMSD funding
    b) Update on the home page, design, and maintenance of the website
2. Update on Registries Meeting held at the last ECTRIMS congress:
    - Preparation of the TC with the new registries
3. Update Feasibility study
4. Update CDM
5. Efforts needed for the Qualification opinion EMA re-application
    - To do list
6. Update More Europa Project

Main discussion points

1. **Update from the BMSD coordinating center:**
    a) Update on BMSD funding

- BMSD has secured funding for 2025 from Sandoz, Alexion, BMS, Novartis, Merck and most likely from Sanofi.

- A potential new PASS study from Sanofi on the drug Tolebrutinib is discussed. The main objective is to assess the effectiveness of risk minimization measures for regulatory requirements, and this involves the monitoring of liver enzymes. Registries have different ways to retrieve this information (data linkage vs additional workload for data collection), which is required for the Sanofi PASS study. It was agreed to communicate to Sanofi that registries are able to collect the requested data but in different ways and this implies time and cost for the activity. All this needs to be evaluated before submitting the study to EMA.

Actions: to communicate to Sanofi the interest of the BMSD network to participate in the PASS study but taking into account the technical differences among the registries. Further details can be discussed in a meeting with Sanofi.

1. **Update from the BMSD coordinating center:**
    b) Update on the home page, design, and maintenance of the website

- It was agreed to upload on the BMSD websites the slides shared during the ECTRIMS Congress in Copenhagen**.**

Actions: Registry slides will be uploaded on the BMSD website.

2. **Update on Registries Meeting held at the last ECTRIMS congress:**
    - **Preparation of the TC with the new registries**

- It is planned to have a TC with the German and Finnish registries once the most suitable date is chosen. The main point to be discussed will be the CDM.

Actions: The date of the TC will be defined on the basis of the result of the doodle survey.

3. **Update on Feasibility Study**

- Elena provided an update on the activities conducted so far from each registry. Some activities are ongoing and it is planned to finish everything before the end of 2024.

Actions: The activities for the Feasibility Study will be completed from the remaining registries by the end of 2024.

4. **Update CDM**

- Jiří presented the project status on the common data model within the BMSD network. It would be better to finish the work by the end of October to include the results from all the registries in the final draft paper that is planned to be submitted in November. Otherwise, the paper will be split into two parts.

Actions: The data harmonization to the CDM will be completed from the remaining registries by the end of October.

5. **Efforts needed for the Qualification opinion EMA re-application**

- Anna gave an update on the ongoing activities for the QO. The feasibility study and the CDM are the main efforts requested from all the registries. The Swedish group is working on the current application, that are the preparation of all the documentation and the finalization of the amendments, and plans to conclude the activity by the end of the year.
- Jan asked all the registries to run a script to identify the population eligible for PASS studies from each registry since it would be valuable to present quality measures to EMA. Lars added that it would be easy to run the script once the data were transformed to the common data format. Anna reminded the two main points from EMA in the previous application: reliable collection of adverse events and evaluation of data quality in the BMSD network.
- As for the update of the PASS protocol, Jan said that OXON updated the protocol format to be more similar to the format requested from EMA. Details on the CDM and data quality measures can be included. It is agreed to share the protocol among the registries and to complete it by the end of October/first days of November.

Actions: The new version of the protocol draft will be shared among the registries. The finalized PASS protocol will be sent by the end of October/first days of November.

6. **Update More Europa Project**

- Anna provided an update on the More Europa project on the comparison between rituximab and DMF that involves the Swedish, Czech, Danish and Italian registries. The project is in the second year of activity and will use a Federated Learning approach. Jan presented the project during a meeting at the EU committee and it received good feedback. Lars added that the Federated Learning method that was developed for the project only requires running an R script and it will allow to analyse data without pooling them. Jiří added that the connection of the outputs through Federated learning was already tested and it worked.

7. **Form for submission of research proposals**

- The form for the submission of research proposals was submitted to Melinda and Anneke. Melinda added that she will send the form and she agreed to have a meeting on their project once they are ready, maybe next month.