BMSD Network – TC 5 meeting	
Date: 11 September 8:00 – 9:00 CET	
Venue: Microsoft Teams meeting	
Attendees:	Pietro Iaffaldano, Maria Trojano, Mario Alberto Battaglia, Dana Horáková, Melinda Magyari, Jan Hillert, Anneke Van Der Walt, 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 the home page, design, and maintenance of the website
    b) Update on BMSD funding
    c) Update on ECTRIMS booth (poster, USB stick) - Organization of attendance at the ECTRIMS BMSD booth
    d) Update on Registries Meeting at ECTRIMS (Logistic; Attendees)
2. Efforts needed for the Qualification opinion EMA re-application
3. Update Feasibility study
   Update CDM (and ECTRIMS booth presentation)
4. New collaborative project proposals:
    - Gender Diversity and MS
    - De-escalation therapy
    - Paediatric MS
    - Use of Synthetic data to facilitate data sharing and Big data analysis

Main discussion points

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

- The domain of the BMSD website was transferred from the Swedish to the Italian team. Updates on the website will be scheduled after the ECTRIMS Congress.

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

- Mario pointed out that as BMSD we need to send a document describing the milestones and deliverables of the network for the next 3 years when we ask for their support.
- Maria added that funding was confirmed from BMS, Novartis, Sandoz, maybe Merck and Alexion. It is planned to meet Alexion representatives at the ECTRIMS Congress.
- Jan added that Sanofi is willing to support the network for the EMA Qualification process.

1. Update from the BMSD coordinating center:
c) Update on ECTRIMS booth (poster, USB stick) - Organization of attendance at the ECTRIMS BMSD booth

- Pietro gave an update on the stand material (posters and USB sticks) that will be presented at the ECTRIMS Congress and on the organization of the stand.
- Jiří proposed to organize a meeting at their booth to present the Czech registry and leave some time for discussion. He asked for support to promote the initiative and received positive feedback.

1. Update from the BMSD coordinating center:
d) Update on Registries Meeting at ECTRIMS (Logistic; Attendees)

- The organization of the meeting with the German and Finnish registries was discussed.

Actions: the agenda will be finalised before the meeting.

2. Efforts needed for the Qualification opinion EMA re-application

- The Swedish group is working on the main application for the QO, which will be submitted by the end of the year. Biogen asked for some results before the end of the month. Anna added that it would be good to share part of the application with the pharma companies to get their feedback. Jan gave details on the documentation that needs to be completed, such as a checklist specific to registries and the PASS protocol. Important steps are to adapt all the registries to the CDM and decide what indicators will be applied to evaluate data quality within the BMSD network. There is also the need to define a population of patients with high-quality data ("PASS-population") within each registry on which to apply the CDM.

3. Update Feasibility study

- Elena presented the steps of the feasibility studies. Elena asked the remaining registries to provide a description of how AEs are collected. Step 3 (comparison of incidence rates between MS registries and national patient registries) was done in Sweden and Denmark, while step 4 (comparison of incidence rates between all the registries) is still ongoing. Sanofi approval is needed to use the data from their ECCS feasibility, thus it would be possible to compare data from the Czech Republic, Sweden and Denmark. The comparison of the feasibility study will regard only groups of DMTs, not individual drugs, and the same method will be used with the Manuscript data. The Czech group is evaluating the possibility to link data between the ReMuS and the Czech administrative database.
  The results from the study will be included in the EMA application and could potentially be published.

Actions: the remaining registries will send their description of how safety events are collected to Elena.

Update CDM (and ECTRIMS booth presentation)

- Jiří gave an update on the project status of the CDM. The harmonisation was conducted in the Swedish, Czech registries and MS Base, while the activity is ongoing for the Italian and French registries. The results from all the registries are the last missing part before publishing the CDM work.

- Jan pointed out that it is necessary to include the completed CDM work in the EMA application to increase the chances of a positive response. It is important to run the CDM on the "PASS-population" to provide reliable results.

Actions: the remaining registries will complete the data harmonisation to provide results for the EMA application and CDM publication.

4. New collaborative projects proposals:

- **Gender Diversity and MS**
- **De-escalation therapy**
- **Paediatric MS**
- **Use of Synthetic data to facilitate data sharing and Big data analysis**

- A format to send the project proposals will be shared with who is interested. The project proposals were described and it was pointed out the importance of promoting new projects within the network. Sandra suggested to organize specific meetings to discuss the protocol of the research proposals.