| BMSD Network – TC 8 meeting | |
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| **Date:** 10 December 8:00 – 9:00 CET | |
| **Venue:** Microsoft Teams meeting | |
| **Attendees:** | Pietro Iaffaldano, Maria Trojano, Mario Alberto Battaglia, Jan Hillert, Sandra Vukusic, Irena Vukusic, Elena Flavia Mouresan, Tim Spelman, Jiří Drahota, Pernilla Klyve, Anna Glaser, Lars Forsberg, Jenni Lilian Dalsgaard, Luigi Pontieri, Orla Grey, Hanna Poulina Joensen, Mie Reith Mahler, Anneke Van Der Walt, Helmut Butzkueven, Massimiliano Copetti, Giuseppe Lucisano, Tommaso Guerra, Frederik Elberling. |

**Meeting Agenda**

1. **Update CC:**
   a) Update on BMSD funding
   b) Guidelines for research project presentation to BMSD (proposal)
   c) BMSD F2F 2025 meeting + statistical meeting in Italy
   d) Update on New registries
2. **Update EMA qualification opinion:**
   a) CDM
   b) Feasibility study
   c) Request tool
   d) Updated version of the PASS Core protocol
3. **Research project proposal:**
   De-escalation of High-Efficacy Disease-Modifying Therapy Compared to Continuation or Discontinuation in Patients Older than 50 Years with Non-Active Multiple Sclerosis
4. **Chairmanship change**
5. **Other**

## Main discussion points

**1. Update CC:**

a) Update on BMSD funding

- BMSD has finalized the funding with Alexion and Sandoz. The funding from Roche is pending conditional upon the completion of the EMA QO.
- Maria added that the 2025 funding from Sanofi is related to participation on the PASS study on the drug Tolebrutinib. Sandra suggested that Sanofi should first discuss with the BMSD network about the study before finalizing the protocol and submit it to EMA. One possibility could be to split the study into a global PASS and a specific study, which would include the collection of weekly liver enzyme levels for three months. Sandra will have a meeting with Sanofi global and she will share the thoughts and considerations of the network.

1. **Update CC:**

b) Guidelines for research project presentation to BMSD (proposal)

- Maria shared a proposal for an internal process to approve research projects within the BMSD network. Helmut proposed creating a governance system that allows the transfer of individual data among registries. This process could be described through an overarching agreement on data management and processing, otherwise each study would require a specific data transfer agreement. It was discussed in the group which type of agreement would be feasible, and all agreed to find a doable and easy way to transfer data within the network. However, it's important that each registry evaluates whether and which type of data can be shared at the patient level, considering national legal regulations. Jan and Sandra proposed that each registry could gather information on the constraints related to data transfer as well as potential solutions to ensure compliance with local legal requirements.

*Actions: each registry will assess the legal requirements, limitations, and possibilities for sharing patient-level data within the network.*

1. **Update CC:**
    c) BMSD F2F 2025 meeting + statistical meeting in Italy

- Maria shared three dates to organize the next BMSD F2F and statistical meetings in Italy. Possible locations would be Bari or Genoa.

*Actions: A doodle poll will be shared to find the best dates to plan the meetings.*

1. **Update CC:**
    *d)* Update on new registries

- Jiri provided an update on the current work of the German and Finnish registries. Both are implementing the CDM and they will soon be able to provide the results of data harmonization, however it is not known whether they can share the results or if internal approval is required. The results of this analysis would be used to evaluate data quality of the German and Finnish registries before inviting them to join the network. It was agreed to formalize a procedure requiring applicant registries seeking to join the BMSD network to meet a series of criteria. It's important to share a clear process so that new registries, like the German and Finnish, are well informed. Jan proposed inviting them to the next in-person meeting in 2025.

2. **Update EMA qualification opinion:**
    a) CDM

- Jiri anticipated that the manuscript on the CDM is closed to being finished. Regarding the CDM, it is important to finalize a script that can be applied to all the registries. Jiri proposed to include in the manuscript the number of individuals in the "PASS population" that can be analysed, and a practical application about the potential use of the CDM.

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

- Elena reported that the final part of the feasibility study (the comparison of MS registry incidence rates) is ongoing. Some information from individual registries are missing but will be completed soon. Elena shared a table comparing malignancy incidence rates across the registries, based on results from the Manuscript study. Before the completion of the study, additional information will be required from each registry to better characterize the study cohorts and assess potential differences between them.
- Jan said that the feasibility study and the manuscript on the CDM should be finalized by the end of January, after which the EMA QO application can be submitted.

3. **Research project proposal:** De-escalation of High-Efficacy Disease-Modifying Therapy Compared to Continuation or Discontinuation in Patients Older than 50 Years with Non-Active Multiple Sclerosis

- It was agreed that the project will be evaluated by the end of January.

4. **Chairmanship change**

- The Swedish team has handed over coordination of the network to the Italian group. Maria thanked Jan, Anna and all the staff at the Karolinska Institut for their excellent work over the last few years in setting up and developing the BMSD network.
- Jan shared a table showing the number of current patients from each registry and the number of MS patients on active treatment relevant to PASS studies.