The big Multiple Sclerosis data network

## 2nd progress report - December 2020

# Big MS Data Network (BMSD)

Karolinska Institutet (KI) will perform the coordination of the Big MS Data Network and the tasks are described in the BMSD coordination synopsis. The Big MS Data Network has reached out to several pharmaceutical companies asking for financial support for the coordination efforts and has currently agreements for 1-5 years with Biogen, Merck, Novartis, Roche and Sanofi. Agreement with BMS (Celgene) is awaiting signatures.

This is the **2nd progress report**, issued December 2020 describing activities during 2020.

Naturally, many plans for 2020 were changed and priorities were re-considered as a result of the SARS-CoV2 pandemic. Not only were our everyday clinical and scientific work affected by the many adaptations in our MS centers, hospitals and universities, but meetings were cancelled and interactions turned digital. The collection of data in our registries also noted a decrease due to changes in out-patient care. Last but not least, our scientific efforts were to an important extent re-focused on the collection and analysis of Covid19 amongst MS patients. In spite of this challenge the BMSD network was able to maintain active collaboration and to propel our efforts further.

### Support for BMSD co-ordination

At the start of 2020, we had a signed agreement with one pharma company for support. During this year, we have come to agreements with four more pharma sponsors and a fifth expected to be signed within soon. Accordingly, we now have strong basis for our continued work.

### BigMS Data PASS Forum

Currently, BMSD registries take part in PASS projects run by Biogen, Merck and Roche. During the year discussions have been taken place regarding upcoming or planned PASS project sponsored by Sanofi and Novartis. Thus, interactions with pharma in the MS area are central to the activities of BMSD.

On February 14, BMSD held its annual **BigMS Data PASS Forum in Lyon**, gathering representatives of seven pharma with ongoing or planned BMSD-formatted Post Authorization Safety Studies, and agreed on common activities for the coming year. This will include a joint task force between BMSD and pharma to agree on a joint analysis plan with common definitions of drug exposures and adverse events with the ambition to form a standard for future PASS projects.

Discussions were held with pharma representatives on the interest for **joint analysis** of pooled patient level data and such an interest was clearly expressed. Although no PASS projects have so far included such analyses, KI is preparing a structure for secure data storage and management for this purpose. Likewise, the interest of pharma for pregnancy aspects of PASS was inquired with a positive response and BMSD registries are prepared to agree on such efforts when asked for.

## Seeking a qualification opinion by EMA

BMSD has the ambition to play a role in developing the standards of PASS' in the MS area and in order to be recognized by EMA would be important, both for BMSD as a network but also for the participating registries as such.

A briefing document dossier has been submitted on 2 October, 2020 to **EMA** for a qualification opinion on BMSD and PASS. As part of the pre-submission procedure in November there was a scientific advice meeting between KI and EMA who presented a list of comments which is now being addressed and included in the modified briefing document to be submitted by early January in order for the start of procedure by 11 January 2021. The briefing document will be shared with the BMSD sponsors. The contents of the briefing document cover a presentation of BMSD and the participating MS registries including number of MS patients and coverage, data collection, SAEs, quality control, analysis methods and PASS (ongoing, planned and BMSD coordinated).

## Data management

**Data management** development within BMSD is ongoing. The mapping of **MedDRA** codes (i.e. using the same codes) has been planned and will be done in the same way as what is currently up and running in MSBase. The **quality control** standards have been developed by Johannes Lorscheider as part of the checking and data merge codes of one of the demonstrator projects and can be applied for other BMSD collaborations. The **mapping of data** between the BMSD registries has also been done and this has been formalized as code by Johannes.

## MS-Covid19

As a consequence of the **SARS-CoV2 pandemic**, all BMSD registries have adapted their data collections to allow the gathering of information of MS patients with COVID-19. All registries have used their data for scientific analysis and reported results in different contexts. Based on this data, the Danish, Czech and Swedish registries and MSBase have contributed to the COVID-19 & MS global data-sharing initiative (GDSI). The French and Italian teams have been leaders in their national MS-Covid19 efforts. Altogether, the BMSD registries have been critical in capturing data allowing the identification of treatment related risks for severe Covid19 infection.

Finally, in order to put our data to the best use, we have agreed to enter a BMSD organized MS-COVID-19 project aimed at the analysis of risk factors associated with development and severity of COVID-19 in MS patients which will be led by the Italian team. This analysis will build on previously collected data on the MS-Covid19 patients including disability progression and treatment sequencing that other MS-COVID19 data sets lack. This effort has recently been initiated and the coordination of data is ongoing.

## Horizon2020 application: EuCoMS

BMSD decided in the spring of this year to embark on a joint project application and an application with the acronym EuCoMS (a **Eu**ropean study of **Co**-morbidities in **MS**) was submitted to the European Commission for **Horizon 2020** – Work Program 2018-2020 - Health, demographic change and wellbeing. The project was focused on MS and comorbidities and coordinated by the French OFSEP team under the leadership of Sandra Vukusic. Although the project received excellent scores and was rated as number eight out of 78 applications, there were only seven applications that received funding and the BMSD application has been put on a reserve list. This of course was very disappointing, but we remain at first position if extra financial means become available, which is often the case at the end of a program such as Horizon 2020. If no funding can be obtained from the European Commission other funding opportunities will be sought as we consider the proposal very strong with a potential of forming the scientific backbone of BMSD for several years.

## Communications

The **BMSD homepage** https://bigmsdata.org/ has been developed and is due to be launched before the end of the year. There will be separate login information to access protocols and reports to be shared with pharma. The sponsor page will be available once all companies have confirmed the display of their logos.

A **review paper** on the BigMS Data effort is in preparation will be submitted within the near future. M**anuscripts** have been submitted for the Biogen sponsored demonstrator projects and these have been or are soon to submitted for publication. BMSD participated in ACTRIMS-

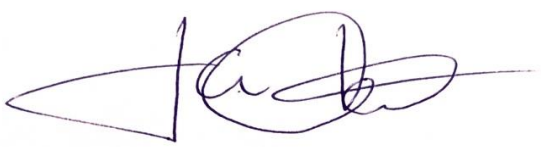
ECTRIMS 2020 as a non-profit organization.

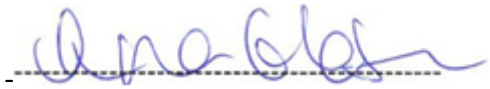
**Upcoming meetings**

The **BMSD PASS Forum 2021** is planned for **26 March 2021** (please save the date). The plan is for a virtual meeting. Further information will follow.

We conclude that 2020 has been an active period for the BigMS Data network and we expect that next year will be equally productive.

December 15, 2020





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