

1st progress report - June 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 effort and has currently agreements for 1-5 years with Biogen, Merck, Novartis, Roche and Sanofi. Negotiations with Celgene are ongoing.

This is the 1st progress report, issued June 2020 describing activities during 2020.

On February 13, BMSD held its annual face-to-face meeting in Lyon hosted by the OFSEP team. An important outcome of this meeting was the decision to embark on a joint project application and on June 4 we submitted an application to the European Commission for Horizon 2020 – Work Program 2018-2020 - Health, demographic change and wellbeing. The project is focused on MS and comorbidities and is coordinated by the French OFSEP team under the leadership of Sandra Vukusic. If supported, this will be a scientific back-bone of BMSD during the coming years in parallel to the PASS efforts.

In the Lyon meeting, BMSD agreed to strive for the formation of a legal entity for BigMS Data and KI are seeking legal advice on how to proceed.

On February 14, BMSD held its annual BigMSData 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, but the KI is preparing a structure for secure data storage and management of 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.

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. Based on these data, members of the BMSD group are, together with other MS registries, actively

involved in the COVID-19 & MS global data-sharing initiative (GDSI). There will also be a specific BMSD effort 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 and French teams.

The BMSD co-ordination tasks include the preparation and submission of an EMA qualification application focused on PASS within the Big MS Data Group and the included MS registries. This procedure has been initiated with contacts with EMA and submissions of fee waiver and letter of intent. There is now an assigned contact person at EMA, Thorsten Vetter, with whom we have had initial discussions. The timeframe has been adjusted and the expected submission of the briefing documents is September 2020. The preparation of this document is ongoing and a draft version has been sent to EMA for their input which was recently received. The draft document aims to provide information for EMA to express a qualification opinion and includes a presentation of the individual MS registries and BMSD as well as describing similarities and differences between the registries. The contents of the briefing document cover: MS registry presentation including number of MS patients and coverage; Data collection; SAEs; Quality control; Analysis methods; PASS (ongoing, planned and BMSD coordinated).

BMSD homepage and database infrastructure are currently being developed at KI. A review paper on the BigMS Data effort will be authored during the summer and will be submitted in the autumn. A manuscript for the first Demonstrator Project, sponsored by Biogen, has been submitted and a manuscript on the second Demonstrator project is ready to be submitted in a week's time. Analyses for the third Demonstrator project are ongoing.

BMSD was planning to present the network as well as ongoing efforts at ACTRIMS-ECTRIMS 2020. We are currently anticipating a way to present BMSD in a virtual setting.

We conclude that the first six months of 2020 has been a very active period for the BigMSData and we predict that the rest of the year will see several important steps forward for our network.

June 26, 2020

A handwritten signature in dark ink, appearing to read 'Jan Hillert', with a stylized, cursive flourish at the end.

Jan Hillert (Professor)
Karolinska Institutet Coordination Centre BMSD