Decisions and Action Points from
Big MS Data Meetings February 21-22, 2019 in Stockholm

BMSD Participants: Maria Trojano, Pietro Iaffaldano, Dana Horakova, Charlotte Sartori, Helmut Butzkueven, Sandra Vukusic, Melina Magyari, Leszek Stawiarz, Anna Glaser, Jan Hillert

On Feb 22, meetings with Rob Hyde, Biogen and then with reps of Biogen, Roche, Novartis, Sanofi-Genzyme, Merck, Celgene and Medday. Xavier Kurz, EMA, participated via Skype

Decision 1:

BMSD will participate at ECTRIMS2019 with a poster and an exhibition booth together with each of the participating registries.

AP1. Jan to contact Ines Brunkow regarding a place in the exhibition

AP2. Jan and Anna to co-ordinate an abstract for ECTRIMS2019, with latest submission date April 24.

Decision 2:

BMSD will seek out possibilities to publish the BMSD PASS Core protocol in "Clinical Trials".

AP1. Jan will ask support for this from participating pharma

AP2. The PASS Core protocol will need to be updated. Anna and Jan to look into this but it is likely to include:

- Definitions of exposure to DMTs need to be aligned between PASS
- Definitions of SAEs
- A scientific scope that goes beyond the separate PASS, for EMA's questions (likely to come) and for our own interest
- Definitions of variables
- Modifications to preserve anonymity

Decision 3:

BMSD will seek certification (qualification opinion) from EMA as a network with the presumption that participating registries will thereby earn the same certification

AP1. Jan and Anna will contact EMA (Jane Moseley) to initiate the process, which most likely will not be May but after summer.

AP2. Jan and Anna will seek more information regarding the possibility/usefulness to seek certification also in the HTA context

Decision 4.

BMSD will perform patient level data analysis (where legally possible) for each of the drugs assessed by BMSD PASS projects

AP1. The core protocol will be developed and more detailed regarding the patient level data analysis

Decision 5.
BMSD will map legal constraints, by GDPR and national legislation, for sharing patient level data, by sending a questionnaire to the four national registries (MSBase excluded)

AP1. Jan and Anna to set up and send out a questionnaire, including:

- how can we report together?
- how can we report as individual registries?
- can we live up to EMAs requests for PASS?
- Conditions for scientific projects?

AP2. Each national registry to seek legal advice to respond correctly to the questionnaire

Decision 6.
BMSD will attempt true anonymization by reducing granularity when needed (i.e. detailed info such as birth date). Some variables will be retained at the national level but not in the merge.

AP1. Each national registry will identify constraints warranting such reduction of data

Decision 7.
BMSD Co-ordination tasks will include (but will also contain other tasks):

- Point of contact for BMSD
- Tracking progress of registries
- Certification process ("qualification opinion")
- Quality control of registries, benchmarking
- Co-ordination of patient level data merge and analysis
- Deal with questions from stakeholders such as EMA, pharma, EMSP etc
- Positioning of BMSD externally including home page, position papers, other publications

AP1. Jan and Anna to set up a complete list of responsibilities of the co-ordinating center.

Decision 8.

BMSD will seek financial support for co-ordination from each of the involved pharma, with a 3-5 year duration.

A budget for the co-ordination of BMSD PASS should cover costs such as

- Co-ordination tasks according to EMA document pages 25 and 29
- EMA Certification application ("qualification opinion")
- Co-ordination of data management, patient level data merge
- Meetings, travels to Brussels, etc
- Training sessions
- Data quality assessment-related management, including annual benchmarking

AP1. Jan and Anna will write a proposal including a project plan for the co-ordination tasks of BMSD to form a basis for requests for financial support to Karolinska from participating pharma for the BMSD co-ordination tasks. This request should be signed by all registry leaders.

AP2. A provisional budget of €200,000/year was discussed - Jan and Anna to look more closely into the budgetary conditions and modify if needed.

Decision 9.
BMSD should strive to offer solutions to research requests from pharma to avoid CROs role as intermediaries.

AP1. Jan will propose a BMSD solution to Novartis for the Research Center Network on SPMS.

Decision 10.
BMSD has the ambition to support the development of improved statistical methods in MS RWE research. This can be done by (co-)arranging workshops and publishing position papers of "preferred methods".

AP1.? Jan will contact Rob Hyde to discuss Biogen's support for organizing such a workshop.