

10 September 2024  
EMA/423417/2024  
European Medicines Agency

## Final Minutes – HMA-EMA joint Big Data Steering Group teleconference

6 September 2024, 11.00am - 12.30pm (CET time)

Co-Chairs: Peter Arlett (EMA) & Jeppe Larsen (DKMA)

Item	Preliminary draft agenda	Presenters	Action	Time
1.	Adoption of the draft agenda & minutes	All	For adoption	5'
2.	Draft report on social media data to support EU regulatory decision making	Pyry Eskelinen BDSG discussants: Sandra Bertulat, Ioana Agache, George Paliouras, Eleonora Agricola, Anne Cambon-Thomsen	For discussion	30'
3.	EMRN computing capability survey results	Francois Domergue (EMA) BDSG discussants: Jeppe Larsen (DKMA), Garbiel Westman (MPA)	For discussion	30'
4.	Overview of data training offering for the network and next steps	Aina Staisiuniene (EMA)	For information	30'
5.	A.O.B.			

Role	Name
Attendance	Peter Arlett (EMA), Aleksandra Dacic-Pilcevic (EMA), Flora Musuamba Tshinanu (SAWP), Florian Klinglmueller (AGES, AT), Kristin Karlsson (MWP), Aina Staisiuniene (EMA), Paul Lynn (EMA), Gabriel Westman (MPA, SE), Patricia McGettigan (PRAC), Francois Domergue (EMA), Régis Lassalle (Health Data Hub, FR), Katrien Oude Rengerink (CBG-MEB, NL), Pyry

	Eskelinen, Anne Cambon-Thomsen (CNRS, FR), Antti Hyvärinen (FIMEA, FI), Vincent Gazin (ANSM, FR), Joerg Zinserling (BfArM, DE), Jeppe Larsen (DKMA), George Paliouras (Demokritos, GR), Denise Umuhire (EMA), Jerome De Baros (EC), Kaisa Immonen (EMA).
Apologies:	Eleonora Agricola (EU-IN), Patrice Verpillat (EMA), Carla Torre (CHMP), Ana López de la Rica Manjavacas (AEMPS, ES), Christina Kyriakopoulou (EC), Niklas Hedberg (TLV, SE), Sandra Bertulat (BVL, DE (vet)), Steffen Hess (BFARM, DE), Markus Kalliola (SITRA, FI), Ioana Agache (EAACI, RO), Ricardo Carapeto García (CVMP), Juan Garcia (EMA), Gunilla Andrew-Nielsen (CTCG), Hugues Malonne (FAGG, BE), Emmanuel Bacry (Health Data Hub FR), David Asturiol (EC), Claus Møldrup (DKMA, DK).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

## 1. Adoption of the draft agenda & minutes

The draft agenda and minutes from 19<sup>th</sup> July 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website ([here](#)).

## 2. Draft report on social media data to support EU regulatory decision making

Pyry Eskelinen presented the draft report on Social Media Data exploring the potential utility of such data to support regulatory decision making. The report reviewed scientific literature through the Embase database. Findings were used to identify potential regulatory use-cases for social media data, as well as relevant challenges and opportunities related to their use. In addition, draft recommendations were proposed to the group for consideration and discussion.

The group welcomed the report and discussed the following:

- The report should be considered as an expert report (state of play report) and a careful consideration should also be given to how this report will be perceived publicly, i.e. that the report is a literature review and does not necessarily reflect the views of the BDSG.
- While not one of the proposed recommendation in the report, the group exchanged views on the value to use social media to communicate directly with patients and a possible role to combat misinformation.
- A dedicated discussion on the report findings with patients' representatives, e.g. PCWP should be considered in the future.
- All social media data should not be regarded in the same way as there are different categories of social media data (from commercial and quality perspectives) and hence different principles will apply to select a social media platform from which such data could potentially be used for evidence generation.
- In our current society, a vast amount of data is being shared/generated via social media A BDSG position should be established on the potential use of such data, considering their challenges, e.g. on data quality, ethical considerations, differences of social media platforms, compliance with data protection requirements etc.

Overall, the group noted the potential utility of certain social media data but also of significant hurdles and challenges to use such data.

The BDSG agreed to have a follow up discussion on the potential regulatory use cases and next steps at a next future meeting, pending further detailed comments on the report following the written consultation with BDSG.

BDSG did not support the use of the word 'recommendations', it is proposed to use instead 'points for consideration'.

**Action:** EMA to update the draft report to reposition the current recommendations as 'points for consideration'.

**Action:** BDSG members to provide written comments on the draft social media report by the end of September 2024.

**Action:** BDSG secretariat to schedule a follow up discussion and present the revised draft report.

### **3. EMRN computing capability survey results**

Francois Domergue (EMA) presented the survey results, which was conducted in Spring 2024 to assess the existing demands and computing capabilities of the European Medicines Regulatory Network (EMRN) to analyse data. The questionnaire consisted of 14 questions and was circulated to all National Competent Authorities (NCAs) via IT Directors group and Heads of Medicines Agencies. It focused on human and veterinary data used for regulatory decision making and on the current technical computing capacities. The gathered information will complement future discussions on building a suitable and sustainable strategy of computing capacity within the EMRN.

The group welcomed the survey report and acknowledged that the survey responses showed an appetite within the EMRN for fostering data access and sharing between national agencies and developing analytics capabilities at EU level. The group also commented that BDSG might consider more work on analytics of quality and manufacturing and non clinical data in the future.

The feedback from this survey will be useful to inform the development of the new Network Data Steering Group workplan in 2025. Some of the recommendations/proposals, complementary to the Raw Data pilot report recommendations, will also be considered for the potential drafting of an EMRN data analytics strategy in 2025.

### **4. Overview of data training offering for the network and next steps**

Not discussed. The topic was postponed to the next BDSG meeting on 4 October 2024.

### **5. A.O.B.**

**Open actions list:**

<b>ID</b>	<b>Created on:</b>	<b>Description</b>	<b>Assigned to:</b>	<b>Status</b>
42	Jun-21	EMA to prepare a discussion on how to align the BDSG work with clinical trials activities, for a future BDSG meeting.	EMA	In planning
67	Feb-22	Input from the BDSG to inform the new RSRN lists should be added in the new BDSG workplan.	EMA	Public consultation planned for October to December 2024
98	Mar-23	EMA in collaboration with the More EUROPA project to identify possible work items for BDSG workplan.	EMA	In progress
133	Mar-24	Stefanie Prilla (EMA) to consider how best to incorporate patients input in the early stages of the RWE studies planning (e.g. design, approach, strategy).	Stefanie Prilla (EMA)	In progress
139	Jun-24	To share outcome of the EMA ChatGPT pilot with BDSG members (in writing or at an upcoming meeting).	Luis Pinheiro (EMA)	In progress
140	Jun-24	Need to organize a strategic discussion on the place of synthetic data and digital twins in the methodology framework	Kristin Karlsson/EMA	In progress – possibly in November BDSG meeting
141	Jun-24	BDSG secretariat to circulate short summary to the group of the <a href="#">‘Open science strategy for Europe’</a> .	BDSG secretariat	In progress - part of October BDSG meeting
147	Jul-24	EMA to consider preparing an infographic for academia linking relevant guidance on registries.	EMA	In progress
148	Sep-24	BDSG members to provide written comments on the draft social media report by the end of September 2024.	BDSG members	In progress
149	Sep-24	BDSG secretariat to schedule a follow up discussion and present the revised draft report on social media data.	EMA	In progress