

22 July 2024  
EMA/339502/2024  
European Medicines Agency

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

19 July 2024, 10.30am - 12.00pm (CET time)

Co-Chairs: Peter Arlett -EMA (apologies from 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 mHealth data to support EU regulatory decision making	Pyry Eskelinen (EMA) BDSG discussants: Sandra Bertulat, Ioana Agache, George Paliouras, Eleonora Agricola, Anne Cambon-Thompsen	For discussion	30'
3.	EU Network data strategy	Nick Halsey (EMA) / Georg Neuwirther (AGES) BDSG discussants: Sandra Bertulat, Anne Cambon-Thompsen	For discussion	20'
4.	Network data governance optimisation: mandate of the Network Data Steering Group	Francois Domergue (EMA)	For information	10'
5.	Registry workshop next steps (incl. data qualification)	Kelly Plueschke (EMA) BDSG support: Patricia McGettigan (PRAC)	For information	10'
6.	RWE learnings publication	Stefanie Prilla (MA)	For information	10'
7.	A.O.B. Data science curriculum	Stefania Simou (EMA)	For information	5'

Role	Name
Attendance	Peter Arlett (EMA), Aleksandra Dacic-Pilcevic (EMA), Flora Musuamba Tshinanu (SAWP), Eleonora Agricola (EU-IN), Florian Klinglmueller (AGES, AT), Kristin Karlsson (MWP), Aina Stasiuniene (EMA), Paul Lynn (EMA), Patrice Verpillat (EMA), Gabriel Westman (MPA, SE), Patricia McGettigan (PRAC), Francois Domergue (EMA), Régis Lassalle (Health Data Hub, FR), Carla Torre (CHMP), George Paliouras (Demokritos, GR), Ana López de la Rica Manjavacas (AEMPS, ES), Christina Kyriakopoulou (EC), Stefanie Prilla (EMA), Stefania Simou (EMA), Nick Halsey (EMA), Kelly Plueschke (EMA), Dmitry Etin (EMA), Georg Neuwirther (AGES, AT), Licinio Kustra Mano (EC), Katrien Oude Rengerink (CBG-MEB, NL), Hans Bigalke (EDQM), Pyy Eskelinen (EMA), Valerie Denux (ANSM, FR), Miguel Bley (ANSM, FR).
Apologies:	Anne Cambon-Thomsen (CNRS, FR), Antti Hyvärinen (FIMEA, FI), Niklas Hedberg (TLV, SE), Vincent Gazin (ANSM, FR), Joerg Zinserling (BfArM, DE), 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), Jeppe Larsen (DKMA), Britta Haenisch (BFARM, DE), Hugues Malonne (FAGG, BE), Emmanuel Bacry (Health Data Hub FR), Marjon Pasmooij (MEB, NL), David Asturiol (EC), Kaisa Immonen (EMA), 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 24<sup>th</sup> June 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website ([here](#)).

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

Pyy Eskelinen (EMA) presented the draft mHealth data report to support EU regulatory decision making, which focuses on the utility of such data, generated by or collected with mHealth devices. The group was introduced with the research questions used and the report drafting process, including the consultation with the panel of experts. Several use cases for regulatory decision-making, the methodological challenges and opportunities for mHealth data were presented to the group for discussion. The group welcomed the report and congratulated the team on the excellent work done. The BDSG discussed the report findings and its recommendations, with the following feedback collected for further reflection:

- Consider engaging with the NCA innovation offices, in addition to Innovation Task Force (ITF), to promote early interaction with regulators.
- Consider utility of such data for HTA bodies and support their evaluation process.
- The importance of interplay with medical devices should be further emphasized.
- A recommendation to create a common EU Patient data platform to collect patient (mHealth) data is very ambitious and can prove to be challenging due to data governance aspects.

- Consider mentioning in the report that development of statistical methods can minimise challenges identified with the mHealth data and increase their usability. This can be subject for further discussion and interaction with the Methodology working party.
- The data security and cyber security aspects were flagged as important.
- BDSG members to consider identifying key areas/recommendations for active BDSG engagement and inclusion in the new workplan, whilst other areas/recommendations would only be monitored.
- Consider mentioning the notion of 'composite endpoints' in the report, as clinical endpoints augmented/optimized by bringing together different dimensions and types of data.
- To consider organising a multi-stakeholder workshop in 2025.

**Action:** EMA to present the draft report on mHealth data to the Methodology Working Party in Autumn 2024.

**Action:** BDSG members to provide written comments on mHealth data report recommendations by the end of August 2024.

### **3. EU Network data strategy**

Nick Halsey (EMA) presented the draft EMRN Data Strategy, its vision, structure and principles. The document was prepared in collaboration between EMA and EU Network experts from BDSG and Network Data Board (NDB). The scope of this document was already endorsed by BDSG in March 2024. The drafting concluded in June 2024, with exception of the Ethical considerations chapter, which is currently under final review. The drafting group considered the Veterinary Big Data Strategy to ensure alignment.

Georg Neuwirther (AGES, NDB) then provided an overview of the data strategy objectives that will feed into the development of the work plan of the new Network Data Steering Group in 2025.

The draft will be released for public consultation in autumn 2024, aiming to have the document finalised at the end of 2024.

**Action:** BDSG members to submit any final comments on the draft EMRN Data Strategy by cob on 16 August 2024.

### **4. Network data governance optimisation: mandate of the Network Data Steering Group**

Francois Domergue (EMA) presented an update on the draft Network Data Steering Group (NDSG) mandate, following a written consultation with the BDSG and NDB in July 2024. The feedback received and how this has been addressed in the mandate document was discussed. The key feedback received revolved around the size of the group and the nominations process. The group agreed with the proposed updates to the mandate document but raised the following additional comments:

- To consider including representatives from CMDh and CMDv as part of the Member states representatives.
- To consider specifying which Veterinary Association will appoint a representative.
- To consider adding expertise from statistical modelling and simulation area.

- NDSG should discuss priorities of all activities that falls under its scope and include only the priority areas in the new workplan.

As next step, the draft will be submitted for endorsement at the next HMA and EMA Management Board in Autumn, with a call for membership launched thereafter. It is expected for the new group to have its kick off meeting either in December 2024 or January 2025.

**Action:** BDSG secretariat to circulate the final draft mandate to BDSG for information, once available.

## 5. Registry workshop next steps (incl. data qualification)

Kelly Plueschke (EMA) provided short feedback from the Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Multistakeholder workshop on Patient Registries, which took place on 12 & 13 February 2024. The meeting led to clear recommendations on measures to optimise the qualification of patient registries, which will be taken forward by the Core Group for future proofing the Qualification of Novel Methodology (QoNM) procedure, as well as on ways to promote higher quality and discoverability of registry data. The final workshop report is available in the dedicated [event's page](#).

**Action:** EMA to consider preparing an infographic for academia linking relevant guidance on registries (key points to consider).

## 6. RWE learnings publication

Stefanie Prilla (EMA) gave a short introduction to the second report on the experience gained with regulator-led studies to support regulatory decision. This is a continuation of the previous report and covers period from 8 Feb 2023 – 7 Feb 2024 (12 months). The document lists all studies conducted during the reporting period, including studies conducted in relation to the Pharmacovigilance impact strategy or to inform vaccine safety & effectiveness and public health emergencies. The report features the outcome of survey on the use of RWD by NCAs and gives a status update on implementation of recommendations (based on first review).

The final report will be published on the EMA Big Data webpage by the end of July 2024.

**Action:** A more detailed presentation on the learnings from the 2nd report to be presented at a future BDSG meeting (Action: EMA).

## 7. A.O.B.

- Data Science Curriculum

The first five modules of the Data Science Curriculum have now been finalised and will be published in Autumn this year. The development of two additional modules on data processing and data visualisation & dashboarding will be starting soon. A call for volunteers to review a table of content, to ensure it addresses the current needs of the Network, will be launched to BDSG members. The work is foreseen to be finalised by mid-September and the estimated time effort should not exceed one working day. The group also noted that going forward only the development of the regulatory focus training materials should be considered by the Network.

**Action:** EMA to launch a call for BDSG volunteers to review a table of content for two additional Data science curriculum modules.

**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
66	Feb-22	The results of the RSRN relevant to BDSG should be discussed with BDSG members when available.	EMA	In progress
67	Feb-22	Input from the BDSG to inform the new RSRN lists should be added in the new BDSG workplan.	EMA	Planned for Q3/Q4
89	Oct-22	BDSG members noted the need to further explore how ideas from the BDSG on the use of big data to support the EU regulatory network can be fed back to IHI or DG RTD D2 calls in the future.	EMA	In progress
98	Mar-23	EMA in collaboration with the More EUROPA project to identify possible work items for BDSG workplan.	EMA	In progress
109	Oct-23	The BDSG secretariat to consider organising a follow up session on ongoing AI activities in the EU Network in 6-month time.	EMA	In progress
128	Feb-24	Jakub Hasiiec (EMA) to clarify internally the delivery timelines for the offerings by Digital Academy and feedback to BDSG.	Jakub Hasiiec (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
135	Apr-24	The drafting team to consider validating the reflection paper with the relevant national guidance (on use of RWD in non-interventional studies to generate RWE) during the public consultation period.	Juan Jose Abellan (EMA)	In progress
137	Jun-24	Liaise with Joerg Zinserling (BfArM, DE) and the document drafting group to review and agree revised wording of the recommendations in section 5 of the draft guiding principles document on LLM use. Final version of the document to be shared as soon as possible, in parallel of formatting/medical writers review.	Luis Pinheiro (EMA)	In progress
138	Jun-24	To discuss with EMA communication team possibility to translate the of the draft guiding principles document on LLM use and raise this topic with HMA secretariat	Luis Pinheiro (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
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
142	Jul-24	EMA to present the draft report on mHealth data to the Methodology Working Party in Autumn 2024.	EMA	In progress

143	Jul-24	BDSG members to provide written comments on mHealth data report recommendations by the end of August 2024.	BDSG members	In progress
144	Jul-24	BDSG group to submit any final comments on the draft EMRN Data Strategy by cob on 16 August 2024.	BDSG members	In progress
145	Jul-24	BDSG secretariat to circulate the final draft mandate to BDSG for information, once available.	BDSG secretariat	In progress
146	Jul-24	The more detailed presentation on the learnings from the 2nd report to be presented at a future BDSG meeting.	BDSG secretariat	In progress
147	Jul-24	EMA to consider preparing an infographic for academia linking relevant guidance on registries.	EMA	In progress