

26 March 2024  
EMA/51677/2024  
European Medicines Agency

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

22 March 2024, 10.30am - 12.00pm (CET time)

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

Item	Preliminary draft agenda	Presenters	Action	Time
1.	Adoption of the draft agenda & minutes Welcome to the new members	All	For adoption	15'
2.	Finalisation of AI workplan implementation and update	Luis Pinheiro (EMA)	For information	25'
3.	RWE support to the EU Network	Stefanie Prilla (EMA)/ Olaf Klungel (ESEC RWD SIA co-lead)	For discussion	20'
4.	Drafting of the EMRN data strategy: scope, vision, principles and next steps	Nick Halsey (EMA) / Peter Bachmann (BfArM)/ Gabriel Westman (MPA)/ Marjon Pasmooij (MEB)/ Sandra Bertulat (BVL)	For discussion	25'
5.	AOB	All	For information	5'

Role	Name
Attendance	Peter Arlett (EMA), Jeppe Larsen (DKMA), Niklas Hedberg (TLV, SE), Aina Stasiuniene (EMA), George Paliouras (Demokritos, GR), Gabriel Westman (MPA, SE), Paolo Alcini (EMA), Anne Cambon-Thomsen (CNRS, FR), Antti Hyvärinen (FIMEA, FI), Vincent Gazin (ANSM, FR), Florian Klinglmueller (AGES, AT), Joerg Zinserling (BfArM, DE), Ioana Agache (EAACI, RO), Sandra Bertulat (BVL, DE (vet)), Flora Musuamba Tshinanu (SAWP), Marjon Pasmooij (MEB, NL), Kaisa Immonen (EMA), Peter Bachmann (EU NDB), Francois Domergue (EMA), Patrice Verpillat (EMA), Carla Torre (CHMP), Fia Westerholm (EMA), Emmanuel Bacry (Health Data Hub FR), Eleonora Agricola (EU-IN), Paul Lynn (EMA), Luis Pinheiro (EMA), Steffen Hess (BFARM, DE), Patricia McGettigan (PRAC), Olaf Klungel (UU, NL), Nick Halsey

	(EMA), Aleksandra Dacic-Pilcevic (EMA), Dmitry Etin (EMA), Malgorzata Durka-Grabowska (EMA).
Apologies:	Ana López de la Rica Manjavacas (AEMPS, ES), Christina Kyriakopoulou (EC), Hugues Malonne (FAGG, BE), Kristin Karlsson (MWP), Markus Kalliola (SITRA, FI), Pyry Eskelinen (EMA), Jakub Hasiec (EMA), David Asturiol (EC), Francesca Cerreta (EMA), Frank Petavy (EMA), Ricardo Carapeto García (CVMP), Juan Garcia (EMA), Licinio Kustra Mano (EC, DG SANTE), Gunilla Andrew-Nielsen (CTCG), Ana Vidal (EMA).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

## 1. Adoption of the draft agenda & minutes

The draft agenda and minutes from 26<sup>th</sup> February 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website ([here](#)).

Peter Arlett (EMA) welcomed two new BDSG members: Aleksandra Dacic-Pilcevic as the new EMA IT representative and Julia Schmitz from the European Commission who replaced Sara Rafael Almeida.

The group bid farewell to Peter Bachmann (BfArM, Network data board representative to BDSG) and thanked him for his contributions to the work of the BDSG since its establishment.

## 2. Finalisation of AI workplan implementation and update

Luis Pinheiro (EMA) presented an overview of the BDSG sponsors for the Multi-annual AI workplan activities, who were identified during the January and February BDSG meetings. A reminder was issued to the group that members willing to sponsor the AI workplan activities should contact the BDSG secretariat, particularly noting the areas/activities where sponsors have not yet been identified or sponsorship is scarce.

The group was then provided a quick update on the Multi-annual AI workplan (noting that some initial terminology has been updated) and the status update of the ongoing activities in the workplan, also listing the activities that are still to be initiated.

A proposal for the oversight of the Multi-annual AI workplan 2023-2028 implementation was presented, which includes: a monthly meeting by a swim lane; a bi-weekly monitoring meeting for the whole workplan (EMA project coordination); a quarterly reporting to BDSG and MB, with the standing report to MWP and ESEC; escalation of issues and risks to be channelled through BDSG.

The group noted the need to oversee the implementation and monitoring of the AI workplan in a pragmatic and agile way, and optimise the involvement of the Network colleagues as much as possible, considering national workplan.

**Action:** Peter Arlett (EMA) to be added as a BDSG sponsor for the Data Protection and International activities in the AI WP.

**Action:** Francois Domergue (EMA) to review the draft survey on the Network capability to analyse data, simplify the level of details in the current proposed draft and organise the survey to be sent out.

**Action:** Peter Bachmann (BfArM) to peer review the revised draft survey prior it is distributed to the Network for completion.

**Action:** Luis Pinheiro (EMA) to update a proposal for the oversight of the AI workplan implementation by adding HMA to the quarterly reporting cycle.

### **3. RWE support to the EU Network**

The [2023-2025](#) BDSG workplan foresees that by 2025 the use of real-world evidence (RWE) is enabled and the value of RWE is well established within the EU Network. To achieve this vision, several change management activities, complementary to the RWD/E pilots have been launched: the RWE news flash, the publication of the RWD summary guide and the launch of the Real-World Academy. Stefanie Prilla (EMA) provided a status update on implementation of these activities and what is planned for later in 2024.

Olaf Klungel (ESEC RWD SIA co-lead) gave a brief introduction on the mandate and the work undertaken to date by the ESEC RWD SIA (European specialised expert community real-world data specialised interest area).

The group welcomed the update and discussed how best to incorporate the patients' input into RWE work and the areas of their involvement. Patients are already involved in some activities, e.g. in the Real-World Academy first session, and will be involved in specific topic with the ESEC RWD SIA (format of involvement will be specific to the needs). The future work on Patient Experience Data (and its reflection paper currently being drafted) will also accelerate involvement of patients.

**Action:** 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).

**Action:** Stefanie Prilla (EMA) to follow-up in writing with BDSG members to seek their views on how to best collect feedback on national (NCA) activities on RWE to include this information in the annual report on RWE experience in 2024.

### **4. Drafting of the EMRN data strategy: scope, vision, principles and next step**

Nick Halsey (EMA) presented the outcome of the scoping discussions of the EMRN data strategy and the focus areas identified. The Data Strategy scope was defined by the drafting group from the EU Network Data Board and BDSG volunteers. A call for additional volunteers to draft (3-month drafting phase) the EMRN data strategy was issued. The aim is to finalise the document by the end of 2024. Due to time constraints the specific questions were not addressed during the meeting and will be discussed and considered within the drafting group.

**Action:** The BDSG secretariat to send a dedicated email to BDSG to seek additional volunteers to participate in drafting of the EMRN data strategy.

**Action:** Nick Halsey (EMA) to include a specific section in the data strategy document on Ethical considerations/ principles and consult Anne Cambon-Thomsen.

**Action:** Nick Halsey (EMA) to include Paul Lynn and Sandra Bertulat as Vet experts for the drafting of the Data Strategy document.

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

### Open actions list:

ID	Created on:	Description	Assigned to:	Status
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 progress
46	Jul-21	EMA to plan for the October meeting, with more MS examples presented, further discussion on how CoE will interact and work with the EMA Working Parties, within the European Regulatory Network governance, EC and TEHDAS.	EMA	In progress
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	In progress
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
100	May-23	Further discussion should be held to explore how the experience on RWE generated via national data sources could be integrated in the future to provide a comprehensive EU network perspective.	EMA	In progress
104	Jun-23	EMA to liaise with ESEC specialist interest area on AI to organise to survey to establish an inventory of AI related projects in the Network. This survey should also involve the NCAs of the CoE.	EMA	In progress
106	Sep-23	EMA to consider presenting a demo on the ChatGPT pilot and lessons learned on its use to understand technology and limitations for different use cases.	EMA	In progress
107	Oct-23	Peter Arlett to share lessons learnt from the risk assessment (from Microsoft Azure) with BDSG and consider organising a dedicated webinar.	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
117	Dec-23	EMA to send a dedicated email to BDSG members with the updated key messages defining the meaning of the data-driven medicines regulation transformation for further reflection and comments. Discussion on the big data stakeholders and communication and engagement approach will take place at a future meeting.	Aina Stasiuniene (EMA)	In progress
118	Dec-23	BDSG members willing to get engaged in the definition and execution of the Change Management deliverable of the BDSG workplan are welcome to contact the BDSG secretariat.	BDSG members	In progress
122	Jan-24	EMA to reflect the launch and roll out of several national initiatives on AI under the experimentation topic of the AI workplan to 2028 to map the	Luis Pinheiro (EMA)	In progress

		Network AI activities and signpost to the different AI tools available for the EU Regulatory Network.		
124	Feb-24	Action EMA to provide feedback from the joint FDA/ Korean Ministry of Food and Drug Safety (MFDS) workshop on the use of AI in medical product development at a future BDSG meeting.	Luis Pinheiro (EMA)	In progress
125	Feb-24	EMA to launch a call for additional BDSG sponsors of the AI workplan activities via a written procedure.	EMA	In progress
127	Feb-24	Flora Musuamba Tshinanu (SAWP) to consider whether a collaboration between ERAMET project and the ECHO community could be beneficial.	Flora Musuamba Tshinanu (SAWP)	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
129	Mar-24	Francois Domergue (EMA) to review the draft survey on the Network capability to analyse data, simplify the level of details in the current proposed draft and organise the survey to be sent out.	Francois Domergue (EMA)	In progress
130	Mar-24	Peter Bachmann (BfArM) to peer review the revised draft survey prior it is distributed to the Network for completion.	Peter Bachmann (BfArM)	In progress
131	Mar-24	Nick Halsey (EMA) to include a specific section in the data strategy document on Ethical considerations/ principles and consult Anne Cambon-Thomsen.	Nick Halsey (EMA)	In progress
132	Mar-24	Nick Halsey (EMA) to include Paul Lynn and Sandra Bertulat as Vet experts for the drafting of the Data Strategy document.	Nick Halsey (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
134	Mar-24	Stefanie Prilla (EMA) to follow-up in writing with BDSG members to seek their views on how to best collect feedback on national (NCA) activities on RWE to include this information in the annual report on RWE experience in 2024.	Stefanie Prilla (EMA)	In progress