10 October 2024
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European Medicines Agency

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

4 October 2024, 13.00pm - 14.30pm (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.	EU Network data strategy	Nick Halsey (EMA)	For endorsement before public consultation	15’
3.	Ethics and data sharing in the context of Open Science policies	Anne Cambon-Thomsen (BDSG)	For discussion	30’
4.	Report on AI WP implementation progress	Luis Pinheiro (EMA) / Gabriel Westman, Flora Musuamba Tshinanu, Florian Klinglmueller (BDSG)	For discussion	15’
5.	Flash updates on information items • Publication of one-year review on RWE – key highlights and considerations for next year • Publication of interim report on clinical trials raw data pilot – next steps for the pilot extension • Overview of data training offering for the network and next steps	 Stefanie Prilla (EMA) Eftychia-Eirini Psarelli (EMA) Aina Staisiuniene (EMA)	For information	25’ 5’ 5’ 5’ 5’ 5’

Item	Preliminary draft agenda	Presenters	Action	Time
	• Feedback from Pharmacogenomics workshop • Network Data Steering Group: update and next steps	Cristina Urseiu (EMA) Francois Domergue (EMA)		
6.	A.O.B. • Draft agenda of upcoming annual big data forum • Draft agenda of upcoming AI workshop	All Circulated in mailing		5’

Role	Name
Attendance	Peter Arlett (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Anne Cambon-Thomsen (CNRS, FR), Antti Hyvärinen (FIMEA, FI), Carla Torre (CHMP), Jeppe Larsen (DKMA), Eleonora Agricola (EU-IN), Markus Kalliola (SITRA, FI), Luis Pinheiro (EMA), Régis Lassalle (Health Data Hub, FR), David Asturiol (EC), Katrien Oude Rengerink (CBG-MEB, NL), Florian Klinglmueller (AGES, AT), George Paliouras (Demokritos, GR), Nick Halsey (EMA), Joerg Zinserling (BfArM, DE), Flora Musuamba Tshinanu (SAWP), Kristin Karlsson (MWP), Patricia McGettigan (PRAC), Niklas Hedberg (TLV, SE), Aina Staisiuniene (EMA), Steffen Hess (BFARM, DE), Vincent Gazin (ANSM, FR), Francois Domergue (EMA), Frank Petavy (EMA), Eftychia-Eirini Psarelli (EMA), Cristina Urseiu (EMA), Julia Schmitz (EC).
Apologies:	Aleksandra Dacic-Pilcevic (EMA), Paul Lynn (EMA), Gabriel Westman (MPA, SE), Kaisa Immonen (EMA), Patrice Verpillat (EMA), Christina Kyriakopoulou (EC), Sandra Bertulat (BVL, DE (vet)), 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), 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 6th September 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website (here).

2. EU Network data strategy

Nick Halsey (EMA) gave a status update on the draft EMRN Data Strategy, which was prepared in collaboration between EMA and EU Network experts from BDSG and Network Data Boad (NDB). Following the BDSG and NDB consultation and implementation of the comments received, the draft has been finalised for public consultation.

The group endorsed the release of the document for public consultation and noted that it will be presented to NDB as a final step on 17 October 2024. The final EU Network data strategy is expected to be published in Q1 2025, following the endorsement by the new Network Data Steering Group.

Action: Florian Klinglmueller to submit any minor comments on the draft EMRN Data Strategy by cob 16 October 2024 to Nick Halsey.

Action: The drafting group to review and amend (where needed) the references to EHDS proposal throughout the document.

3. Ethics and data sharing in the context of Open Science policies

Anne Cambon-Thomsen (BDSG) presented to the group the general elements on ethics and its place at EU level. Ethics plays a crucial role in shaping the practices, institutions, cultures, and social impact of science. In EU, the European Group on ethics of science and new technologies (EGE) has been established to provide an independent advice to European Commission on all aspects of EU legislation and policies, where ethical, societal and fundamental rights issues intersect with the development of science and new technologies.

The group was then introduced to data sharing and the importance of ethics in open science policies and the need for ethics by design in research. Open science is guided by principles and there are measures in place to ensure research integrity, including visibility of data, open publications, education, community action, and online tools for discussion and verification of papers.

Ethics play an important role in the delivery of the activities of the BDSG and should always be considered to be included by design.

4. Report on AI WP implementation progress

Luis Pinheiro (EMA) presented the progress report on the AI Multi-annual workplan to 2028 implementation, noting that one action was delayed and two activities not yet started, with the remaining twenty-two deliverables on target or completed.

The group welcomed the report and congratulated the team on excellent achievements during the first ten months of the workplan implementation. The group was reminded that the workplan is a live document and will be further updated/reviewed following the public AI workshop on 5 November 2024 and establishment of the new workplan for the Network Data Steering Group in Q1 2025.

5. Flash updates on information items

- Publication of one-year review on RWE – key highlights and considerations for next year

Stefanie Prilla (EMA) presented the key highlights from the 2nd report on conducting studies with real-world data. The report focuses on the European Medicines Regulatory Network's continued efforts to better integrate real-world evidence (RWE) into regulatory decisions on medicine development,

authorisation and monitoring. It builds on the previous report and provides a progress update on new studies, expanded data partners, lessons learned, and further recommendations and actions.

- Publication of interim report on clinical trials raw data pilot – next steps for the pilot extension

Eftychia-Eirini Psarelli (EMA) provided an update on the Clinical Trials raw data pilot, publication of interim pilot report in October and next steps for the pilot extension. The group was reminded of the pilot's phases and key timelines, noting a proposal to have a pilot extension for another two years, building on the previous experience/ learnings so far, validating a future target operating model, focusing on capacity and capability requirements across the network and technical requirements. The extension of the pilot will allow to work on intensifying the exploration of systematic use of raw data in support of regulatory assessment and decision-making, exploring IT solutions and intensifying the change management activities. The need to further clarify on resourcing of additional activities (e.g. support of technical receipt of data, data sharing, software for data analysis, training aspects) was raised as an important topic to be addressed soon. In addition, the group was reminded of the ongoing pilot (run by EMA independently of the clinical trials raw data pilot) to look at the analysis of non-clinical raw data and included in the BDSG workplan.

Action: EMA to provide an update at a subsequent BDSG meeting on the non-clinical raw data analysis pilot (quality data, manufacturing data etc).

- Overview of data training offering for the network and next steps

This was not presented during the meeting.

Action: EMA to send a dedicated email to BDSG with the key highlights regarding the progress of big data training efforts for the European Medicines Regulatory Network.

- Feedback from Pharmacogenomics workshop

This was not presented during the meeting.

Action: EMA to send a dedicated email to BDSG with the key highlights from the EC, HMA & EMA multi-stakeholder workshop on Pharmacogenomics, which took place on 24 September 2024.

- Network Data Steering Group: update and next steps

Francois Domergue (EMA) informed the group that the creation of the NDSG and its mandate was endorsed at the 117th HMA meeting on 12 September 2024 and by EMA Management Board at its 125th meeting on 3 October 2024. The nominations of NCA members will be run by HMA Management Group and the call will be issued in the coming weeks. The aim is to have the composition complete by the end of November and for the first meeting to take place in January 2025.

6. 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	Closed – to be addressed in 2025 as part of the Network data analytics strategy
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 November 24
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
141	Jun-24	BDSG secretariat to circulate short summary to the group of the 'Open science strategy for Europe'.	BDSG secretariat	Closed - part of October BDSG meeting
147	Jul-24	EMA to consider preparing an infographic for academia linking relevant guidance on registries.	EMA	In progress
150	Oct-24	The drafting group to amend the references to EHDS Regulation throughout the document (i.e. refer to the already adopted EHDS Regulation rather than EHDS initiative or proposal).	EMA	In progress
151	Oct-24	EMA to provide an update at a subsequent BDSG meeting on the non-clinical raw data pilot (quality data, manufacturing data etc).	EMA	In progress