

26 April 2024
EMA/51677/2024
European Medicines Agency

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

22 April 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	All	For adoption	5'
2.	Planning of the annual BDSG workplan review	Peter Arlett (EMA)	For information	10'
3.	How to best capture national (NCA) activities with RWD/E for the drafting of the 2nd report on experience with regulatory-led RWD studies	Stefanie Prilla (EMA)	For discussion	20'
4.	Progress on RWE reflection paper	Olaf Klungel (UU, NL)	For discussion	30'
5.	Upcoming on LLM webinar and the guiding principles draft structure	Luis Pinheiro (EMA)	For information	20'
6.	A.O.B.			

Role	Name
Attendance	Peter Arlett (EMA), Jeppe Larsen (DKMA), Niklas Hedberg (TLV, SE), Aina Staisiuniene (EMA), George Paliouras (Demokritos, GR), Antti Hyvärinen (FIMEA, FI), Vincent Gazin (ANSM, FR), Florian Klinglmueller (AGES, AT), Joerg Zinserling (BfArM, DE), Christina Kyriakopoulou (EC), Paul Lynn (EMA), Luis Pinheiro (EMA), Steffen Hess (BFARM, DE), Aleksandra Dacic-Pilcevic (EMA), Marjon Pasmooij (MEB, NL), Kaisa Immonen (EMA), Anne Cambon-Thomsen (CNRS, FR), Sandra Bertulat (BVL, DE (vet)), Flora Musuamba Tshinanu (SAWP), Eleonora Agricola (EU-IN), Olaf Klungel (UU, NL), Kristin Karlsson (MWP), Ana López de la Rica Manjavacas (AEMPS, ES), Pyry Eskelinen (EMA), David Asturiol (EC), Patrice Verpillat (EMA), Fia Westerholm (EMA), Paolo Alcini (EMA), Frank Petavy (EMA), Aude Marville (Health Data Hub FR), Stefanie Prilla (EMA), Juan Jose Abellan Andres (EMA).
Apologies:	Gabriel Westman (MPA, SE), Ioana Agache (EAACI, RO), Francois Domergue (EMA), Carla Torre (CHMP), Emmanuel Bacry (Health Data Hub FR), Patricia

	McGettigan (PRAC), Hugues Malonne (FAGG, BE), Markus Kalliola (SITRA, FI), Francesca Cerreta (EMA), Ricardo Carapeto García (CVMP), Juan Garcia (EMA), 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 22nd March 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website ([here](#)).

2. Planning of the annual BDSG workplan review

Peter Arlett (EMA) informed the group about the upcoming BDSG workplan review. It is foreseen that the new iteration will be aligned with the Multi-annual AI workplan 2023-2028 and the ongoing revision of the EU Network Strategy to 2028. The revised BDSG workplan will incorporate any new activities or deliverables on topics that BDSG has an oversight of and will feature updates of the existing activities. A dedicated strategic discussion will be organised at a future BDSG meeting, to brainstorm and identify gaps or new areas where BDSG should consider actions for its workplan (longer term perspective).

In addition, the group noted the ongoing discussions at a senior EU leadership level regarding a wider data governance review (including BDSG and the Network Data Board), which could influence the planning and revision of the BDSG workplan (possibility of a combined workplan with the Network Data Board).

3. How to best capture national (NCA) activities with RWD/E for the drafting of the 2nd report on experience with regulatory-led RWD studies

Stefanie Prilla (EMA) reminded the group of the steps undertaken to capture the national (NCA) study-related activities with RWD/E. She raised a follow up discussion with BDSG (due to limited feedback received so far) on how best to collect information from NCAs for the 2nd report on experience with regulatory-led RWD studies and feature some of that information in the upcoming RWE News Flash.

BDSG agreed that collation of a comprehensive catalogue of all NCA studies will not be feasible. Instead, it was agreed to pursue a higher-level summary (qualitative) information on national study activities. To obtain relevant information it was suggested reaching out to colleagues outside the RWE ESEC Special Interest Area (e.g. HMA) and collect feedback via a short survey.

Noting that the, Swedish Medicines Agency (MPA) was the only NCA so far to have provided a detailed reply to the survey, the BDSG supported contacting MPA for an interview to feature relevant national activities in the next RWE News Flash. Other Member States could feature in future news flashes over time.

Action: Stefanie Prilla (EMA) to consider engaging the BDSG members in helping to draft a questionnaire for collection of information on national study activities and conduct direct interviews with the National Competent Authorities.

4. Progress on RWE reflection paper

Olaf Klungel (UU, NL) presented a status update of the draft Reflection Paper on Use of real-world data in non-interventional studies to generate real-world evidence. The reflection paper discusses methodological aspects of Non-interventional studies (NIS) to be addressed by relevant stakeholders involved in planning, conduct and analysis of NIS using RWD to generate RWE for regulatory purposes. The current draft document will be released for public consultation at the beginning of May, following the CHMP adoption in April 2024.

Olaf Klungel (UU, NL) briefly introduced the process for the development of this paper and presented an overview of each section (i.e. Scope, Legal and regulatory requirements, Study design, Governance and Transparency, Data quality, Statistical analyses).

Some clarifications were sought by the BDSG members regarding the paper scope, inclusion of ethical considerations for the data source and data quality aspects, also whether the draft guidance is aligned with the relevant existing EU national guidance.

The group welcomed the update and congratulated the drafting team on the major milestone achieved. It was also noted that the reflection paper will be introduced and presented at the joint HMA-EMA Big Data Steering Group workshop on RWE methods on 14 June 2024.

Action: The drafting team (coordinated by Juan Jose Abellan Andres (EMA)) 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.

Action: Patrice Verpillat (EMA) to send out the invitation to register for the RWE methods public workshop to BDSG.

5. Upcoming on LLM webinar and the guiding principles draft structure

Luis Pinheiro (EMA) gave a short introduction to the AI Masterclass webinar on the use of Large Language Models which is scheduled to take place on 26 April 2024. The webinar is part of the HMA-EMA Big Data Steering Group (BDSG) Multi-annual AI workplan 2023-2028 deliverable and is aimed at the EU Regulatory network colleagues only. The webinar is structured in three sessions and will offer an opportunity to discuss and further refine the draft Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities. The final draft of the guiding principles will be distributed to BDSG for consultation and a subsequent endorsement, with the publication expected in June 2024.

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	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
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 Hasiec (EMA) to clarify internally the delivery timelines for the offerings by Digital Academy and feedback to BDSG.	Jakub Hasiec (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	In progress