2 February 2024
EMA/51677/2024
European Medicines Agency

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

30 January 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 Welcome new BDSG members	All	For adoption	5'
2.	Demo series of AI tools: AI@MPA toolbox	Gabriel Westman (MPA)	For information	30'
3.	Multi-annual AI workplan – planning the work on AI	Gabriel Westman (MPA) / Luis Pinheiro (EMA)	For discussion	50'
4.	AOB	All	For information	5'

Role	Name
Attendance	Peter Arlett (EMA), Jeppe Larsen (DKMA), Aina Staisiuniene (EMA), Francois Domergue (EMA), George Paliouras (Demokritos, GR), Gabriel Westman (MPA, SE), Luis Pinheiro (EMA), Paolo Alcini (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Anne Cambon-Thomsen (CNRS, FR), Antti Hyvärinen (FIMEA, FI), Patricia McGettigan (PRAC), Patrice Verpillat (EMA), Vincent Gazin (ANSM, FR), Christina Kyriakopoulou (EC), Kaisa Immonen (EMA), Hugues Malonne (FAGG, BE), Flora Musuamba Tshinanu (SAWP), Marjon Pasmooij (MEB, NL), Ioana Agache (EAACI, RO), Steffen Hess (BFARM, DE), Sara Rafael Almeida (EC), Kristin Karlsson (MWP), Carla Torre (CHMP), Paul Lynn (EMA), Markus Kalliola (SITRA, FI), Florian Klinglmueller (AGES, AT), Joerg Zinserling (BfArM, DE), Pyry Eskelinen (EMA), Sandra Bertulat (BVL, DE (vet)), Jakub Hasiec (EMA), David Asturiol (EC), Fia Westerholm (EMA), Wahiba Oualikene-Gonin (ANSM, FR), Francesca Cerreta (EMA).
Apologies:	Eleonora Agricola (EU-IN), Ana Vidal (EMA), Jerome de Barros (EC, DG SANTE), Peter Bachmann (EU NDB), Frank Petavy (EMA), Juan Garcia (EMA),

	Licinio Kustra Mano (EC, DG SANTE), Gunilla Andrew-Nielsen (CTCG), Emmanuel Bacry (Health Data Hub FR), Ricardo Carapeto García (CVMP).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda and minutes from 5th December 2023 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website (here).

Peter Arlett (EMA) introduced and welcomed the new HMA BDSG co-chair Jeppe Larsen, who is a Head of the Medical Devices department at the Danish Medicines Agency. Jeppe was appointed by the HMA Management Group in January 2024 to replace Jesper Kjaer, who left the Danish Medicines Agency in December 2023.

The BDSG members also welcomed Anne Cambon-Thomsen (CNRS, FR), who is an Ethics representative to the Big Data Steering Group.

Action EMA: to organise a dedicated call between the BDSG co-chairs and Anne Cambon-Thomsen, to discuss how to enrich the BDSG work programme from the ethics perspective.

2. Demo series of AI tools: AI@MPA toolbox

Gabriel Westman (MPA) gave a brief introduction to the AI@MPA toolbox, a secure, GDPR-compliant cloud-based platform to access AI-powered regulatory support systems developed by MPA. Four tools were presented to BDSG members (three tools in production and one in deployment):

- PICROSS – natural language processing (NLP) to identify semantically similar sentences in the complete corpus of European medical product information documents.

- M-RECON – Semantic document-level matching to identify relevant guidelines and approved products of relevance for a specific procedure.

- PACKSIM – Computer vision for detecting drug package similarity.

- PhaVAI – NLP for predicting serious events from reported terms and free text to improve efficiency in pharmacovigilance by triaging incoming adverse event reports by seriousness.

The AI@MPA toolbox was deployed on 10 November 2023, with seven NCAs having access to this hub so far. An invitation to request access to the toolbox was issued to the other EU Agencies during the meeting and BDSG members' organisations willing to access the system should contact Gabriel Westman directly for further details.

The 'AI in pharmacovigilance (PhaVAI)' tool is not yet accessible outside the Swedish Medicines Agency. NCAs have already been invited to join (by expression of interest directly to Gabriel Westman) the training on the multi-lingual ADR triage model through federated machine learning at the MPA on-premise infrastructure. The group congratulated Gabriel Westman and MPA colleagues with the launch of the AI@MPA toolbox and noted that a survey on user experience and regulatory usefulness of the toolbox will be launched by MPA in the second half of 2024.

BDSG members noted the launch and roll out of several national initiatives on AI and the need to reflect this under experimentation topic of the AI workplan to 2028 to map the Network AI activities

and signpost to the different AI tools available for the EU Regulatory Network **(Action Luis Pinheiro (EMA)**.

3. Multi-annual AI workplan – planning the work on AI

The Multi-annual AI workplan to 2028, prepared under the joint HMA-EMA Big Data Steering Group, was adopted by EMA MB and HMA in December 2023. As the implementation and maintenance of this workplan will be overseen by BDSG, the detailed planning exercise is required to identify the key milestones and deliverables, define roles and responsibilities, and appoint the BDSG sponsors.

The group discussed the activities foreseen under the 'Guidance, policy and product support' and 'Tools and technologies' workstreams, with the discussions sponsored by Gabriel Westman and Luis Pinheiro.

The detailed summary of the meeting discussions for two workstreams is captured in the attached document.

AI workplan - swimlanes.docx

Action Luis Pinheiro (EMA) to rename the 'Guidance on use of LLM' in the AI workplan to 'Guidance on the use of Large Language Models / generative AI / 3rd party models for regulatory purposes'

Action BDSG: additional BDSG members who would like to sponsor the AI workplan activities should contact BDSG secretariat.

Action EMA: A call for volunteers to join the Programme committee to organise a webinar for NCAs on the use of Large Language Models / generative AI / 3rd party models for regulatory purposes to be issued to BDSG members.

Action EMA: A call for expression of interest for a new member in the AI Specialised Interest Area of the MWP ESEC to be sent to BDSG after the meeting.

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 Staisiuniene (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		
123	Jan-24	BDSG members who would like to sponsor the AI workplan activities should contact BDSG secretariat.	BDSG members	In progress