

25 June 2024
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European Medicines Agency

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

24 June 2024, 13.00pm - 15.00pm (CET time)

Co-Chairs: Peter Arlett -EMA (with apologies from Jeppe Larsen - DKMA)

Item	Preliminary draft agenda	Presenters	Action	Time
1.	Adoption of the draft agenda & minutes	All	For adoption	10'
2.	The draft Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities	Luis Pinheiro (EMA)	For endorsement	20'
3.	Needs for MWP guidance	Kristin Karlson (MPA, SE)	For discussion	30'
4.	Network data governance review	Peter Arlett (EMA)	For information	20'
5.	The BDSG workplan review	Francois Domergue (EMA)	For discussion	30
6.	A.O.B. <ul style="list-style-type: none"> Publication of minor update of the current BDSG workplan 2023-2025 Publication of the change management activities delivery plan 	All	For information For information	10'

Role	Name
Attendance	Peter Arlett (EMA), Anne Cambon-Thomsen (CNRS, FR), Antti Hyvärinen (FIMEA, FI), Aleksandra Dacic-Pilcevic (EMA), Flora Musuamba Tshinanu (SAWP), Eleonora Agricola (EU-IN), Florian Klinglmueller (AGES, AT), Kristin Karlsson (MWP), Niklas Hedberg (TLV, SE), Aina Staisiuniene (EMA), Vincent

	Gazin (ANSM, FR), Joerg Zinserling (BfArM, DE), Paul Lynn (EMA), Patrice Verpillat (EMA), Gabriel Westman (MPA, SE), Sandra Bertulat (BVL, DE (vet), Patricia McGettigan (PRAC), Francois Domergue (EMA), Steffen Hess (BFARM, DE), Markus Kalliola (SITRA, FI), Luis Pinheiro (EMA), Régis Lassalle (Health Data Hub, FR).
Apologies:	Ioana Agache (EAACI, RO), Carla Torre (CHMP), 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), George Paliouras (Demokritos, GR), Marjon Pasmooij (MEB, NL), David Asturiol (EC), Ana López de la Rica Manjavacas (AEMPS, ES), Christina Kyriakopoulou (EC), Kaisa Immonen (EMA), Claus Møldrup (DKMA, DK).
Administrative support and minutes	Malgorzata Durka-Grabowska (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda and minutes from 27th May 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website ([here](#)).

2. The draft Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities

Luis Pinheiro (EMA) presented the group with the draft gguiding principles document on the use of large language models in regulatory science and for medicines regulatory activities. This was drafted with a group of experts and in consultation with the Network via the AI Masterclass organised earlier this year and the ESEC SIA AI.

This document is for Network users of Large Language Models and not aimed at developers. Each principle in the document is supported by a set of recommendations. Principles include the safe input of data, quality assurance to outputs, how to use LLMs effectively, who to consult on concerns and report issues and organisational principles for a safe and responsible use, maximising value for users and sharing experiences.

The group discussed the following:

- The wording of section 5.2 should be reviewed to be a bit more prescriptive. **Action:** Luis Pinheiro (EMA) to 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 document. Final version of the document to be shared as soon as possible, in parallel of formatting/medical writers review.
- Translation in national languages might benefit adoption of these guiding principles at national level. **Action:** Luis Pinheiro (EMA) to discuss with EMA communication team and raise this topic with HMA secretariat.
- Communication for the publication of the guiding principle should highlight application to each NCA and the importance of collaborating and sharing experience.

- The lesson learned from EMA ChatGPT pilot was considered in the drafting of the document.
Action: Luis Pinheiro (EMA) to share outcome of the EMA ChatGPT pilot with BDSG members (in writing or at an upcoming meeting).

BDSG members congratulated the expert drafting group for this achievement and endorsed conditionally the document at the meeting today, pending the review of section 5.2 wording and acknowledging that the document will undergo medical writers review and will be formatted in line with EMA publication guidelines.

3. Needs for MWP guidance

Kristin Karlsson (MWP) informed the group about the planned update of the MWP workplan, covering 2025 to 2027.

A new workplan structure will be used, providing more explicit focus on ongoing work started but not completed, work to be started in first year of workplan (e.g. 2025) and work to be started in subsequent years of workplan. It will also aim to highlight better the strategy of MWP as well as the resource needs over the course of the workplan, and the prioritisation. The main focus will remain on guidelines being developed as well as workshops planned and training and development.

The new workplan will also contain more interdisciplinary work, work relevant to BDSG and the addition of diagnostics to the MWP portfolio (including radiopharmaceuticals). The proposed topics and the MWP preferred prioritisation were then presented to the group.

An early draft version of the MWP workplan will be shared with BDSG and feedback should be sent to MWP@ema.europa.eu. Following a public consultation, BDSG will be consulted for final comments later in the year (October foreseen) and final adoption is planned for December 2024.

The group identified the need to organize a strategic discussion on the place of synthetic data and digital twins in the methodology framework (**Action** Kristin Karlsson/EMA).

4. Network data governance review

Peter Arlett (EMA) informed the group about the need to continue to optimise data governance of the Network and the proposal to combine the BDSG with the Network Data Board (NDB) into a unified network data governance group. This is motivated by the current review of the EMAN Strategy to 2028 (Theme 2: Leverage data, digitalization and AI), the current drafting of EMRN Data Strategy, the planned update of the BDSG workplan to 2028 and the need to create a public workplan for the Network Data Board.

This 'evolved' strategic and advisory group, which is proposed to be called the Network Data Steering Group, will be established to maximise data interoperability, exchange and use across the EU network, the access to data and generation of evidence, and the beneficial utilisation of AI. It will focus on regulatory data as well as data supporting evidence on medicines. Chairmanship will continue to be shared between EMA and HMA with members representing NCAs, EMA, EC as well as key stakeholders. Its work will continue to be guided by a structured workplan.

The mandate for the Joint HMA/EMA Network Data Steering Group is planned to be adopted by HMA and EMA MB at their next meeting (September and October 2024 respectively).

The BDSG members raise important points to consider for the new group: continue to discuss methodological guidance for the network, include HTA representative, manage carefully meeting

discussions and agendas, establish a balanced workplan considering all areas of the mandate and the needs of NCAs size and capabilities, and to integrate better veterinary and human domains activities.

5. The BDSG workplan review

Considering the original BDSG mandate, vision and achievements, the draft strategic objectives of the EMANS to 2028 and the high-level environmental analysis influencing the Network from 2025 to 2028, the group discussed what are the strategic opportunities, gaps, recommendations and additional network environmental drivers to consider for the BDSG future work.

The following feedback was collected from BDSG members:

- Continuity with the existing BDSG and AI workplan is needed.
- Training should remain an important work item of the workplan. Action EMA to provide status update at an upcoming BDSG meeting.
- Synergies on training related activities exist with the other initiatives including the ongoing Joint Action [IncreaseNET](#). A survey on training needs which also includes Big Data Analysis and AI is ongoing and currently being led by FIMEA. AIFA is leading a task focused on deliver training courses on selected innovative topics by academia to regulators.
- Modelling and Simulation (M&S) activities should be considered as well as needs 'for special populations'. M&S can also help in the context of RWE, AI, Pharmacogenomics, drug and device bridging.
- There is a need to engage with the medical device domain/digital therapeutic/custom-made device (CMD), either via joint meeting, ad-hoc expertise or membership.
- There is a need to support pilot/experimentation on digital twins/synthetic data.
- The group should always consider the principles of the '[Open science strategy for Europe](#)' to guide its work. **Action** BDSG secretariat to circulate short summary to the group.
- Discussion on key important aspects of the revised pharmaceutical strategy for Europe will need to be include in the workplan, e.g. on environmental risk assessment, RWE, CT raw data, regulatory sandbox.
- The group should consider how to further embed learnings and work at national level and follow up on Cluster of Excellence paper discussion.
- The work on the veterinary domain and humain should be further integrated and coordinated.
- Further work on patient experience data needs to be planned.
- There is a need to continue to consider HTA needs and increase discussion on advice/planning of data capture, also relevant to HTA assessment activities.

6. A.O.B.

The group was informed about the publication of a minor update of the [current BDSG workplan 2023-2025](#) and of the [change management activities delivery plan](#).

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 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
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.	Luis Pinheiro (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
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 Network AI activities and signpost to the different AI tools available for the EU Regulatory Network.	Luis Pinheiro (EMA)	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 (EMA)	In progress
136	May-24	BDSG members to provide any additional comments on the interim pilot report to the following functional email address rawdatapilot@ema.europa.eu .	BDSG members	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	Luis Pinheiro (EMA)	In progress

		principles document on LLM use and raise this topic with HMA secretariat		
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	
141	Jun-24	BDSG secretariat to circulate short summary to the group of the ' Open science strategy for Europe '.	BDSG secretariat	In progress