

15 December 2023  
EMA/130876/2023  
European Medicines Agency

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

30 October 2023, 10.00am - 12.00pm (CET time)

Co-Chairs: Jesper Kjær (DKMA), Peter Arlett (EMA)

Item	Preliminary draft agenda	Presenters	Action	Time
1.	Adoption of the draft agenda & minutes	All	For adoption	5'
2.	Multi-year AI workplan	Luis Pinheiro (EMA)	For discussion	30'
3.	Ongoing AI activities in the EU Network <ul style="list-style-type: none"> <li>Learnings from the Network: fire session (5' each)               <ul style="list-style-type: none"> <li>MEB, NL - Stefan Verweij, Marjon Pasmooij</li> <li>DKMA, DK – Jesper Kjaer</li> <li>PEI, DE - Liam Childs, Renate König</li> <li>FIMEA, FI - Elina Asikanius, Antti Hyvärinen</li> <li>MPA, SE – Gabriel Westman</li> <li>AEMPS, ES – Ana López de la Rica</li> <li>EMA - Jakub Hasiec</li> <li>Patient perspective – George Palliouras</li> <li>FAGG – AFMPS, BE - Flora Musuamba Tshinanu</li> <li>DKMA, DK – Jesper Kjaer</li> </ul> </li> </ul>	Speakers	For information/discussion	80'
4.	AOB <ul style="list-style-type: none"> <li><a href="#">Joint HMA/ EMA AI workshop – Smart regulation in a rapidly evolving world</a> – 20-21 November 2023</li> <li>Biannual Big Data Steering Group and industry stakeholders meeting (27/11/2023)</li> <li><a href="#">HMA/EMA Big Data Stakeholder Forum 2023</a> – 4 December 2023</li> </ul>	All	For information	5'

Role	Name
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Attendance	Jesper Kjaer (DKMA), Joerg Zinserling (BfArM, DE), Peter Arlett (EMA), 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), Antti Hyvärinen (FIMEA, FI), Eleonora Agricola (EU-IN), Florian Klinglmueller (AGES, AT), Juan Garcia (EMA), Hugues Malonne (FAGG – AFMPS, ES), Patricia McGettigan (PRAC), Ricardo Carapeto García (CVMP), Sara Rafael Almeida (EC), Steffen Hess (BFARM, DE), Patrice Verpillat (EMA), Vincent Gazin (ANSM, FR), Christina Kyriakopoulou (EC), Kaisa Immonen (EMA), Pyry Eskelinen (EMA), Jakub Hasiec (EMA), Liam Childs (PEI, DE), Renate Koenig (PEI, DE), Britta Haenisch (BFARM, DE), Elina Asikanius (FIMEA, FI), Julie Durand (EMA), Ana Vidal (EMA).
Apologies:	Sandra Bertulat (BVL, DE (vet)), Jerome de Barros (EC, DG SANTE), Markus Kalliola (SITRA, FI), Peter Bachmann (EU NDB), Kristin Karlsson (MWP), Carla Torre (CHMP), Paul Lynn (EMA), Fia Westerholm (EMA), Flora Musuamba Tshinanu (SAWP), Marjon Pasmooij (MEB, NL), Licinio Kustra Mano (EC, DG SANTE), Joaquim Berenguer (EMA), Gunilla Andrew-Nielsen (CTCG), Ioana Agache (EAACI, RO), Emmanuel Bacry (Health Data Hub FR).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA)

## 1. Adoption of the draft agenda & minutes

The draft agenda and minutes from 29<sup>th</sup> September BDSG meeting were adopted without change. The minutes of the 29<sup>th</sup> September are now [published](#) on EMA website.

## 2. Multi-year AI workplan

Luis Pinheiro (EMA) presented the Big Data Steering Group (BDSG) multi-year Artificial Intelligence (AI) workplan to 2028. The AI workplan was developed to manage the increasing complexity in the area of AI and the need to collaborate and coordinate activities across the EU network to maximise the value extracted from AI. The drafting of the document will be further informed by the consultation of a wide range of stakeholders at the joint HMA/EMA AI workshop, scheduled to take place on 20-21 November 2023. Feedback received during the workshop will be implemented and the final draft version will be shared with BDSG. It was noted that the final workplan will not only include a plan on a page but also a vision statement and a narrative text accompanying the identified activities in the plan. The multi-year AI workplan will be submitted for endorsement at the HMA meeting on 1 December 2023 and for adoption at the EMA Management Board meeting on 14 December 2023.

At this BDSG meeting, the group was consulted on a draft plan on a page, where activities are clustered in four swim lanes: Guidance, Policy and Product support; Tools and Technology; Training and Collaboration; Experimentation.

The group reviewed the planned activities and noted the following for EMA to consider:

- Renaming the 'Develop AI Guidance in Medicines Lifecycle, with MWP' activity, to include committees (e.g. CMHP and PRAC), as the owners of such guidance.

- List/promote 'Continued support to the evaluation of AI in medicines lifecycle' as the top activity for the Guidance, Policy and Product support swim lane (**Action:** EMA to update).
- Include additional AI guidance which is being developed as part of the Methodology Working Party (MWP) workplan.
- 'Survey the network on capability to analyse data' topic should have a timeline which precedes the 'Collaborate to enhance network-wide analytics capability' activity.
- The narrative text for the 'Implement and monitor the use of LLMs for internal regulatory use' activity should clearly indicate the array of use cases.
- The introductory text for the overall multi-year AI workplan, should acknowledge/state that the AI field is a rapidly changing area and the plan includes only high-level activities.
- Adding an additional task/bar 'Overarching observatory monitoring' (**Action:** EMA to update).
- The EU network strategy and EU network data strategy should be explicitly linked to this workplan (**Action:** EMA to consider).

**Action:** BDSG members to submit any final comment on the draft plan on a page to the BDSG secretariat by cob 3 November 2023.

### 3. Ongoing AI activities in the EU Network

The group was presented with the ongoing AI activities in the EU Network via a quick-fire session. The session questions were captured and addressed in the meeting chat and colleagues were encouraged to follow up directly with the speakers in case of any additional questions on the presented content.

The co-chairs welcomed the updates and noted a lot of synergies and similar use cases identified across the Network. The group supported the idea to establish the AI inventory for the Network and document use cases and possible solutions. The group also endorsed the idea on establishing a common virtual platform for AI experimentation, however a careful consideration should be given to the GDPR compliance for such platform. Peter Arlett (EMA) reminded the group that a thorough impact assessment was completed a year ago on data protection for Darwin EU, which could inform GDPR compliance discussion for a possible AI experimentation platform in the future. In addition, an advanced assessment of data protection has been conducted by Microsoft Azure for the Agency.

**Action:** Peter Arlett to share lessons learnt from the data protection assessment (from Microsoft Azure) with BDSG and consider organising a dedicated webinar.

**Action:** EMA to consider the presented content during the review of the Multi-year AI workplan.

**Action:** the BDSG secretariat to consider organising a follow up session on ongoing AI activities in the EU Network in 6-month time.

The final slides are attached below for the ease of reference.



Agenda item 3 - AI activities in the EU N

### 4. A.O.B

BDSG members to note the key upcoming events/meetings:

- 20<sup>th</sup>/21<sup>st</sup> November – [AI workshop – Smart regulation in a rapidly evolving world](#)

- 27<sup>th</sup> November - BDSG Industry meeting
- 4<sup>th</sup> December - HMA EMA Big data multi stakeholder forum

**Possible topics for future meetings:**

- DG research RWE HORIZON-HLTH-2022 call – projects presentation
- EHDS Legal proposal and overview of the EC initiatives complementary to the BDSG work and DARWIN EU
- BDSG work: alignment of activities with CT and Medical devices group
- Structuring of Clinical Study Protocols and Reports

**List of events**

For information on related past meetings and workshops, see [Big data | European Medicines Agency \(europa.eu\)](https://bigdata.europa.eu)

**Open actions list:**

ID	Created on:	Description	Assigned to:	Status
39	May-21	EMA to organize a dedicated discussion on EU NTC at a future BDSG meeting.	EMA	In progress
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
43	Jun-21	EMA to consider inviting the relevant EC colleagues to give an update on the Medical Devices group activities.	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
50	Oct-21	EMA to consult BDSG on the governance and life cycle management (maintenance) of the list of metadata at a future meeting	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
93	Nov-22	A more detailed discussion to be organised to discuss the interface between MWP and BDSG workplan.	EMA	In progress
95	Jan-23	EMA to consider creating a table to include the different dimensions of the EMRB governance discussed at the meeting, i.e. type of data, role of EU network in the governance (e.g. data holder, data user, data judge/adviser), organisation of	EMA	In progress

		governance (e.g. centralized/decentralized) and interfaces (global)		
97	Jan-23	EMA to investigate how to share the Data Protection in medicines and public health training modules with patients.	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	
105	Sep-23	EMA to ensure that the updated BDSG Workplan is also published on the HMA website.	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 data protection assessment (from Microsoft Azure) with BDSG and consider organising a dedicated webinar.	EMA	In progress
108	Oct-23	EMA to consider the presented content during the review of the Multi-year AI workplan.	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