

04 September 2023
EMA/130876/2023
European Medicines Agency

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

29 September 2023, 12.30am - 14.00pm (CET time)

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

Item	Preliminary draft agenda	Presenters	BDSG sponsor discussants	Action	Time
1.	Adoption of the draft agenda & minutes	All		For adoption	5'
2.	The new BDSG composition and BDSG workplan	New BDSG members /Francois Domergue (EMA)	All	For information	30'
3.	Patient Experience Data reflection paper – drafting and next steps	Juan García Burgos (EMA) / Rosa Gonzalez-Quevedo (EMA)	George Palliouras (Patient representative to BDSG)	For discussion/ endorsement	25'
4.	Artificial Intelligence - Orientations and next steps	Gabriel Westman (MAP, SE) / Luis Pinheiro (EMA)		For discussion	25'
5.	AOB	All		For information	5'

Role	Name
Attendance	Ilaria Del Seppia (EMA), Jesper Kjaer (DKMA), Joerg Zinserling (BfArM, DE), Peter Arlett (EMA), Aina Stasiuniene (EMA), Francois Domergue (EMA), Fia Westerholm (EMA), Sandra Bertulat (BVL, DE (vet)), Eleonora Agricola (EU-IN), George Paliouras (Demokritos, GR), Christina Kyriakopoulou (EC), Gabriel Westman (MPA, SE), Jerome de Barros (EC, DG SANTE), Patrice Verpillat (EMA), Markus Kalliola (SITRA, FI), Luis Pinheiro (EMA), Peter Bachmann (EU NDB), Hugues Malonne (FAGG – AFMPS, ES), Antti Hyvärinen (FIMEA, FI), Kristin Karlsson (MWP), Vincent Gazin (ANSM, FR), Carla Torre (CHMP), Paul Lynn (EMA), Patricia McGettigan (PRAC), Juan Garcia (EMA), Fia Westerholm (EMA), Paolo Alcini (EMA), Aina Stasiuniene (EMA), Rosa Gonzalez-Quevedo (EMA), Kaisa Immonen (EMA), Florian Klinglmüller

	(AGES, AT), Ana López de la Rica Manjavacas (AEMPS, ES), Flora Musuamba Tshinanu (SAWP).
Apologies:	Steffen Hess (BFAMR, DE), Marjon Pasmooij (MEB, NL), Licinio Kustra Mano (EC, DG SANTE), Ricardo Carapeto García (CVMP), Sara Rafael Almeida (EC), 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 16th June BDSG meeting were adopted without change.

2. The new BDSG composition and BDSG workplan

The co-chairs welcomed the new and reappointed BDSG members and gave the floor to each member for a short introduction. The current group membership can be found in the slides attached. The group also noted that the updated [Big Data Workplan 2022-2025](#) was published in July and will guide the work of the Big Data Steering Group in the coming years.



Agenda item 2_
BDSG workplan and n

Action: EMA to ensure that the updated BDSG Workplan is also published on the [HMA website](#).

3. Patient Experience Data reflection paper – drafting and next steps

Juan Garcia (EMA) gave an update on the Patient Experience Data (PED) initiative and its relevance for the Big Data Steering Group work. The work progresses in line with the actions established following the 2022 multi stakeholders' workshop and with the key priorities identified, namely the development of the PED reflection paper and exploring how to improve the PED data transparency.

Rosa Gonzalez-Quevedo (EMA) then presented the main deliverables of the prioritised actions and focused on the areas of synergies and collaboration with BDSG. It was highlighted that the updated BDSG workplan already includes some of the PED actions, e.g. review on the utility of eHealth/social data, input into the reflection paper, engagement to populate HMA EMA data catalogues, dialogue with patients' organisations on training needs.

The group was also informed that the reflection paper (RP) is anticipated to be released for public consultation by the end of Q1 2024 and will aim set out the high-level principles on the EU approach to generate, collect and analyse PED in the EU. The first proposal for elements to be included in reflection paper was discussed with the BDSG members. The document will be drafted with experts from the Network which will decide on elements to be included in this RP. A call for BDSG volunteers to join the external drafting group (for PED RP) will be issued after the meeting to BDSG members. The volunteers will also be added to the PED expert community, a group that will provide expertise on subsequent deliverables on PED.

Action: EMA to send a call for volunteers to BDSG to join the PED expert community and the RP drafting group via a dedicated email.

George Paliouras (Demokritos, GR) welcomed the initiative and acknowledged the multiple challenges that need to be addressed and considered in the RP: systematic data collection, data quality aspects, diversity of data, selection of data sources etc.

The following additional comments were voiced by the group for consideration for the RP drafting:

- Potential data governance issues: conflicts of interest, transparency, data ownership, etc.
- Consider aspects of registration/cataloguing PED studies in the HMA EMA catalogues of data sources
- Guidance for assessors when to use PED in drug evaluation.
- The key deliverables of the future RP that will be relevant to BDSG should be reflected in the BDSG workplan.
- Launching a programme of proof-of-concept studies to establish PED value.

4. Artificial Intelligence - Orientations and next steps

Gabriel Westman (MPA, SE) gave a quick update on the status of the reflection paper (RP) on the use of AI in the medicinal product lifecycle, which was released for public consultation in July 2023. The [document](#) is open for comments until the end of this year.

Luis Pinheiro (EMA) informed the group on the key AI related activities undertaken at EMA, including the development of an AI roadmap to 2027, which is being developed in collaboration with the network. The detailed discussion/consultation with the BDSG members is scheduled at the October BDSG meeting. A request to provide an overview of the major ongoing AI activities in their respective organisations will be sent to BDSG members in early October.

Action: 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.

5. A.O.B

BDSG members to note the key upcoming events/meetings until the end of the year:

- 30th October - BDSG meeting
- 20th/21st November – [AI workshop – Smart regulation in a rapidly evolving world](#)
- 23rd November - [Third Veterinary Big Data Stakeholder Forum](#)
- 24th November - BDSG meeting
- 27th November - BDSG Industry meeting
- 4th December - HMA EMA Big data multi stakeholder forum
- 5th December - BDSG meeting (face to face)

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
91	Nov-22	Further presentations at the BDSG meeting on the other 4 projects of the HORIZON-HLTH-2022-TOOL-11-02 call will be organised by BDSG secretariat (Action EMA).	EMA	In progress – So far, Real4Reg, REDDIE, More Europa and ONCOVALUE projects have been presented. REALM project is being planned.

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 governance (e.g. centralized/decentralized) and interfaces (global)	EMA	In progress
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