

12 December 2024
EMA/475371/2024
European Medicines Agency

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

11 December 2024, 09.00-11.00am (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.	BDSG annual report and handover to the NDSG	Francois Domergue (EMA)	For information	10'
3.	Quick fire session: EU Network ongoing AI solutions and use cases <ul style="list-style-type: none"> • DKMA • FIMEA • AEMPS • CBG-MEB • PEI • BfArM • Scientific explorer • CoPilot • PONSA 	Claus Møldrup Antti Hyvärinen Ana López de la Rica Stefan Verweij, Bastian Hornung Liam Childs Steffen Heß Jane Moseley Lorenzo Bini Natalia Garcia, Jakub Hasiec	For information	70'
4.	Development of the network's knowledge mining roadmap	Joaquim Berenguer Jornet (EMA)	For discussion	15'
5.	AI workplan update and proposal for changes: report from the AI workshop on 5th November	Luis Pinheiro (EMA)	For information	15'
6.	A.O.B. For information: Good Practice Guide (GPG) for the use of the HMA-EMA Catalogues of real-world data	All		5'

Role	Name
Attendance	Peter Arlett (EMA), Antti Hyvärinen (FIMEA, FI), Paolo Alcini (EMA), Florian Klinglmueller (AGES, AT), Jeppe Larsen (DKMA), Katrien Oude Rengerink (CBG-MEB, NL), Patricia McGettigan (PRAC), Flora Musuamba Tshinanu (SAWP), Ana López de la Rica Manjavacas (AEMPS, ES), Sandra Bertulat (BVL, DE (vet)), Patrice Verpillat (EMA), Vincent Gazin (ANSM, FR), Francois Domergue (EMA), Anne Cambon-Thomsen (CNRS, FR), Régis Lassalle (Health Data Hub, FR), Joerg Zinserling (BfArM, DE), Eleonora Agricola (EU-IN), Markus Kalliola (SITRA, FI), David Asturiol (EC), Kristin Karlsson (MWP), Niklas Hedberg (TLV, SE), Aina Stasiuniene (EMA), Steffen Hess (BFARM, DE), Julia Schmitz (EC), Paul Lynn (EMA), Claus Møldrup (DKMA, DK), Régis Lassalle (Health Data Hub FR), Joaquim Berenguer Jornet (EMA), Lorenzo Bini (EMA), Bastian Hornung (MEB, NL), Liam Childs (PEI, DE), Laurent Brassart (EMA), Jane Moseley (EMA), Steven Le Meur (EMA), Nick Halsey (EMA), Luis Pinheiro (EMA), Tom Paternoster (EMA), Sonja Simpraga (EMA), Renate Koenig (PEI, DE), Natalia Garcia (EMA), Jakub Hasiec (EMA), Randi Tandle (NOMA, NO), Julia Schmitz (EC).
Apologies:	Carla Torre (CHMP), Aleksandra Dacic-Pilcevic (EMA), Kaisa Immonen (EMA), Fia Westerholm (EMA), George Paliouras (Demokritos, GR), Frank Petavy (EMA), Gabriel Westman (MPA, SE), Christina Kyriakopoulou (EC), Ioana Agache (EAACI, RO), Juan Garcia (EMA), Gunilla Andrew-Nielsen (CTCG), Hugues Malonne (FAGG, BE), 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 15th November 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website ([here](#)).

2. BDSG annual report and handover to the NDSG

Francois Domergue (EMA) presented the draft BDSG annual report, which summarises the key activities and accomplishments of the steering group for 2024.

Action: BDSG members are invited to submit comments on the draft 2024 BDSG annual report by cob 13 December 2024.

Action: Francois Domergue (EMA) to include the delivery of the ICH M15 guideline released for public consultation (under the auspices of MWP workplan) to the BDSG annual report.

Post meeting note: The 2024 BDSG annual report was published on the dedicated EMA [webpage](#) on 16 December 2024.

An overview of the key BDSG activities and achievements undertaken during the five-year period were also presented to the group. This was the last BDSG meeting in this composition and a huge gratitude was expressed to the steering group members for their valuable contributions to the delivery of the

BDSG mandate and its workplan. The work to progress the Big Data recommendations will continue through the Network Data Steering Group, which will start its work in January 2025.

Some clarifications were sought on plans to align the HMA/EMA real-world data sources and studies catalogues. The group noted that EMA is engaging with TEHDAS 2 and EC to ensure increased collaboration and alignment on data catalogues/data sources.

The group welcomed the update and acknowledged the major delivery during 5-years of BDSG and excellent engagement and collaboration from EU network and stakeholders.

3. Quick fire session: EU Network ongoing AI solutions and use cases

Six representatives from the national competent authorities presented their ongoing or planned AI solutions, with additional three use cases presented by the EMA colleagues. These use cases will inform the update and delivery of the [multi-annual AI workplan 2023-2028](#), inform the work of the Network and provide a collaborative framework across the network to develop and utilise AI tools to enhance medicines evaluation processes.

4. Development of the network's knowledge mining roadmap

Joaquim Berenguer Jornet (EMA) presented an update on the development of a knowledge mining roadmap and AI use cases for the Network. The steering group was informed about the current status, work objectives and indicative timelines, with the aim to finalise the roadmap by the end of March 2025.

As an immediate next step, a call to the Network will be launched (in December 2024) through HMA to identify potential use cases for AI that could make the daily work of the EU medicines regulatory network easier and more efficient. The outcome of this exercise will result in a mapping of the network's existing AI solutions and a prioritised list of AI use cases for which collaborative solutions will be needed.

The steering group welcomed the initiative for use cases collection and mapping of ongoing AI activities across the network. Some concerns were raised regarding the prioritisation of work, technical constraints, implementation of AI strategic vision and governance around the decision-making process.

As this piece of work is being overseen by the Network Data Steering Group, input received via survey will first be assessed by the AI Specialised interest area (SIA) leadership team, prior to wider consultation with the whole AI SIA group, where additional experts can be consulted and engaged as necessary, especially with respect to technical discussions.

Action: EMA to circulate the survey for the mapping of existing AI work and identification of potential use cases to the relevant EU Network groups, e.g. HMA, BDSG, IT fora, SIA etc.

5. AI workplan update and proposal for changes: report from the AI workshop on 5th November

Luis Pinheiro (EMA) presented a quick overview from the HMA/EMA AI Workshop 2024, focusing on outcomes of the research priorities and AI workplan sessions, including the next steps for each presented area.

The workshop report will be published on the dedicated event's [webpage](#).

6. A.O.B.

Open actions list:

ID	Created on:	Description	Assigned to:	Status
98	Mar-23	EMA in collaboration with the More EUROPA project to identify possible work items for BDSG workplan.	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
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
147	Jul-24	EMA to consider preparing an infographic for academia linking relevant guidance on registries.	EMA	In progress
151	Oct-24	EMA to provide an update at a subsequent BDSG meeting on the non-clinical raw data pilot (quality data, manufacturing data etc).	EMA	In progress