

20 November 2025
EMA/323786/2025

Final Minutes – HMA-EMA joint Network Data Steering Group meeting

6 November 2025, 09:00-11:00am, MS Teams Meeting

Co-Chairs: Karl Broich (HMA), Peter Arlett (EMA)

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
1.	Adoption of the draft agenda & minutes	Karl Broich, Peter Arlett	For adoption	5'
2.	AI research priorities	Joerg Zinserling Discussants: Gabriel Westman, Konstantina Boumaki, Siobhán O'Sullivan, Luis Pinheiro	For discussion / adoption	30'
3.	Veterinary big data workplan consultation	Paul Lynn Discussants: Laure Baduel, Rico Slingerland	For discussion	30'
4.	Approach to the implementation of the Interoperable Europe Act (v)	Roelof Otterspeer Discussants: Hilmar Hamann, Georg Neuwirth, Pelle Persson	For information	30'
5.	A.O.B. EMA Data Board activities: 2025 highlights	All	For information	5'

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Harald von Aschen (BfArM, DE), Aina Staisiuniene (EMA), Luis Pinheiro (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Sandra Bertulat (BVL, DE (vet)), Amanda Langston (EMA), Hans-Joachim Bigalke (EDQM), Joerg Zinserling (BfArM, DE), Patricia McGettigan (PRAC), Michael Vogl (EMA), Anthony Oshea (EDQM), Marie Orre

	(EMA), Francisco Penaranda (EMA), Paul Lynn (EMA), Katrien Oude Rengerink (CBG-MEB, NL), Laure Baduel (CVMP), Edurne Lazaro (AEMPS, ES), Hilmar Hamann (EMA), Claus Møldrup (DKMA, DK), Niklas Hedberg (HTA), Pelle Persson (MPA, SE), Flora Musuamba Tshinanu (SAWP), Kimmo Porkka (EHA), Pedro Pina Ferreira (EMA), Dag Jordbru (NOMA, NO), Rico Slingerland (CMDv), Kristin Karlsson (MWP), Anabela Marcal (EMA), Stefanie Prilla (EMA), Paolo Alcini (EMA), Angelo Molinaro (AIFA, IT), Florian Klinglmueller (AGES, AT), Vincent Gazin (ANSM, FR), Isabel Chicharo (EMA), Jerome De Barros (EC), Jacobus van Wyk (EMA), Pier Paolo Olimpieri (AIFA, IT), Marta Slomka (Payers), Roelof Otterspeer (EMA), Eleonora Agricola (EU-IN), Christopher Jarvis (EDQM).
Apologies:	Markus Kalliola (SITRA, FI), Marianne Lunzer (AGES, AT), Georg Neuwirther (AGES, AT), Gabriel Westman (MPA, SE), Patrice Verpillat (EMA), Konstantina Boumaki (EPF), Dmitry Etin (EMA), Pero Ivanko (CIPH, HR), Frank Petavy (EMA), Carla Torre (CHMP), Christina Kyriakopoulou (EC), Alessandro Blasimme (Ethics representative), Ana Cochino (EMA), Siobhán O'Sullivan (Ethics), Vaia Apostolidou (EC), Aimad Torqui (MEB, NL), Kaisa Immonen (EMA), Bruno Delafont (CHMP).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda was adopted. The draft minutes from the 6th of October 2025 meeting were adopted as final.

The group welcomed Anthony O'Shea, as the new EDQM representative, who replaced Hans-Joachim Bigalke and noted that Christopher Jarvis will remain the EDQM alternate. The group thanked Hans-Joachim Bigalke for his contributions to the group's work.

2. AI research priorities

Joerg Zinserling (BfArM, DE) presented the preliminary results from the stakeholder survey on AI research priorities. The survey was distributed to a broad range of stakeholders aiming to gather different perspectives and received 273 responses across NCAs, industry, SMEs, patients, healthcare professionals, and academia.

The key findings and interpretation of results are summarised below:

- Seven domains were assessed, with accuracy and reliability of AI tools emerging as the top priority, followed by data governance, confidentiality and consent, and ethics, fairness and bias prevention. Other domains included research integrity/intellectual property, regulation and oversight, resources for AI use, and impact on jobs and skills.
- All domains were rated important; none were deprioritised.
- Sub-questions highlighted needs for mechanisms to prevent misuse, ensure transparency, and strengthen reproducibility.
- Stakeholders emphasised bias detection, consent models for secondary data use, and gaps in regulatory guidance.

As the next step, the drafting group will finalise the research priority list, liaise with EMA regulatory science research colleagues and present results at the November AI workshop. The survey results will be published, following the NDSG endorsement.

The group discussed and shared the following feedback:

- Low academic engagement was noted; strategies to improve outreach should be explored.
- Stratified analysis by AI expertise is underway and shows broadly consistent priorities.
- Members suggested correlating overlapping AI domains and identifying training needs based on expertise gaps.
- Veterinary NCAs requested analysis of their responses separately.

Action: Drafting group to finalise the detailed analysis of the results:

- analyse the survey responses from the National Competent Authorities (NCAs), including veterinary NCAs, to identify differences in knowledge level and engagement with AI technologies.
- conduct a stratified analysis of the AI research survey results by respondent experience level.
- identify new strategies to increase academic stakeholder engagement in future surveys.

3. Veterinary big data workplan consultation

Paul Lynn (EMA) provided an update on the veterinary big data work plan, highlighted achievements under the 2022–2025 veterinary big data workplan (97% delivery rate). The highlights included:

- Enhancements to the data quality framework (109 weekly checks, migration to FHIR, AI-enabled SmPC validation).
- Analysis of barriers to AI adoption in veterinary NCAs.
- Data landscape mapping to populate EMA's real world data catalogue (~400 sources targeted).
- Process automation pilots showing significant efficiency gains.
- Continued focus on governance, literacy, and stakeholder engagement, including the annual Veterinary Big Data Forum (10 November) and potential hackathon.

It was noted that the plan closely aligns with the NDSG objectives while addressing the veterinary-specific needs. It complements the NDSG workplan 2025-2028, that include activities common to human and veterinary domains. The next iteration of the work plan will involve stakeholder consultation in 2026, identification of new and enhanced work items, with a focus on sequencing and timing of activities to maximise value and avoid overloading resources.

The group welcomed the alignment with human-domain activities and suggested adding use cases for inspections and real-world data.

Action: Paul Lynn to consider adding AI use in veterinary inspections as a topic in the next iteration of the veterinary big data work plan.

4. Approach to the implementation of the Interoperable Europe Act (v)

Roelof Otterspeer (EMA) presented an overview of the Interoperable Europe Act, its obligations for EMA and Member States, and implementation of interoperability assessments. It was explained that the Act

requires EU institutions and Member States to conduct and publish interoperability assessments for cross-border digital public services. EMA has already published its [first assessment](#) (European Shortages Monitoring Platform) and plans to expand to other services.

The group then discussed the role of NDSG and practical implications for data exchange and standardisation. The importance of semantic and organisational interoperability was highlighted, suggesting that NDSG should focus on data standards, alignment of processes, and providing strategic guidance, particularly in the area of medicinal product master data. It was also clarified that while the Act's obligations primarily apply to EU-level bodies, its principles are relevant for national competent authorities and external organisations, with the potential for voluntary adoption and alignment to facilitate data exchange and interoperability.

Action: NDSG secretariat to raise the relevance of the Interoperable Europe Act to the group drafting on the establishment of the data standards framework in 2026.

5. A.O.B.

Francois Domergue (EMA) provided an update on the establishment of a new AI training curriculum in partnership with the EU Network Training Centre. As part of a written consultation, NDSG members were reminded to provide feedback on the AI training curriculum establishment proposal to be submitted to HMA for endorsement at their November 2025 meeting.

The group also noted that the report on the EMA Data Board Activities: 2025 highlights was shared with NDSG for information.