

10 June 2025  
EMA/198426/2025

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

28 May 2025, 09:00-11:00am, Webex

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	10'
Artificial Intelligence workstream				
2.	AI workstream: 2025 workplan overview	Luis Pinheiro	For information	5'
Guidance, Policy and product support swim lane				
3.	Industry group focused on AI: draft mandate	Luis Pinheiro <i>NDSG sponsors: Gabriel Westman, Joerg Zinserling</i>	For adoption	10'
4.	Principles for responsible AI and AI terminology: status update	Joerg Zinserling <i>NDSG sponsors: Gabriel Westman</i>	For information	15'
Collaboration and change management swim lane				
5.	Delivering AI literacy training: experience to date and training development plans	Harald von Aschen, Vincent Gazin, Edurne Lazaro, Marianne Van Heers <i>NDSG sponsors: Gabriel Westman, Joerg Zinserling, Eleonora Agricola, Julien Delaye</i>	For discussion	30'
Tools & technologies swim lane				

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
6.	Knowledge mining and use of generative AI: status update	Luis Pinheiro  <i>NDSG sponsors: Gabriel Westman</i>	For information	30'
7.	Network AI Tools framework: status update and next steps	Vittoria Abagnale  <i>NDSG sponsors: Gabriel Westman</i>	For discussion	15'
8.	A.O.B. <ul style="list-style-type: none"> <li>Need for a network for information security (NCAs and EMA)</li> <li>Reminder on Draft EMRN Data strategy - Review of goals against the NDSG workplan by 30 May 2025</li> </ul>	All  Karl Broich  Peter Arlett		5'

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Harald von Aschen (BfArM, DE), Hilmar Hamann (EMA), Florian Klinglmueller (AGES, AT), Siobhán O'Sullivan (Ethics), Anne Cambon-Thomsen (CNRS, FR), Gabriel Westman (MPA, SE), Aina Staisiuniene (EMA), Francois Domergue (EMA), Vincent Gazin (ANSM, FR), Eleonora Agricola (EU-IN), Ana López de la Rica Manjavacas (AEMPS, ES), Joerg Zinserling (BfArM, DE), Aimad Torqui (MEB, NL), Angelo Molinaro (AIFA, IT), Vaia Apostolidou (EC), Carla Torre (CHMP), Laure Baduel (CVMP), Claus Møldrup (DKMA, DK), Jacobus van Wyk (EMA), Dmitry Etin (EMA), Edurne Lazaro (AEMPS, ES), Luis Pinheiro (EMA), Hans-Joachim Bigalke (EDQM), Katrien Oude Rengerink (CBG-MEB, NL), Pedro Pina Ferreira (EMA), Julien Delaye (Eurordis), Kristin Karlsson (MWP), Konstantina Boumaki (EPF), Paul Lynn (EMA), Marianne Lunzer (AGES, AT), Patricia McGettigan (PRAC), Pelle Persson (MPA, SE), Francisco Penaranda (EMA), Patrice Verpillat (EMA), Marianne van Heers (EMA), Vittoria Abgnale (EMA), Niklas Hedberg (HTA).
Apologies:	Flora Musuamba Tshinanu (SAWP), Georg Neuwirther (AGES, AT), Dag Jordbru (NOMA, NO), Jerome De Barros (EC), Kaisa Immonen (EMA), Kimmo Porkka (EHA), Rico Slingerland (CMDv), Beyhan Mustafov (EMA), Paolo Alcini (EMA), Ana Cochino (EMA), Kaisa Immonen (EMA), Christina Kyriakopoulou (EC), Johanna Seppänen (THL, FI), Pier Paolo Olimpieri (AIFA, IT), Sandra Bertulat (BVL, DE (vet)), Markus Kalliola (SITRA, FI), Bruno Delafont (CHMP).

### 1. Adoption of the draft agenda & minutes

The draft agenda was adopted. The draft minutes from the 30<sup>th</sup> April meeting were adopted as final.

### 2. AI workstream: 2025 workplan overview

Luis Pinheiro (EMA) provided an overview of the Artificial Intelligence workstream activities to be undertaken in 2025, highlighting the fundamental activities that will facilitate the delivery of other items in the workplan.

### 3. Industry group focused on AI: draft mandate

The draft mandate for establishing an industry group focused on AI was presented to the NDSG for endorsement. Based on the same model as the existing groups focused on real-world evidence and clinical study data, the group's primary objective will be to facilitate open dialogue with industry stakeholders on the development and use of AI. No specific medicinal product related discussion will take place. The current draft outlines the scope, objectives and organisational aspects in further details. The NDSG reviewed the proposed mandate and agreed that further revision is required to address the following aspects:

- Clarify the scope of the group's mandate to ensure it is not interpreted as a discussion forum on medical devices.
- Clarify the scope of the group's mandate to ensure no overlap in scope with the existing stakeholder engagement groups, e.g. MWP annual interested parties' meeting, noting that this group is intended as a complementary forum rather than a replacement for existing ones.
- Specify the experts' nomination process for NDSG members and how experts from the network and wider community will be engaged to support the discussions at the AI-focused group.
- Reconsider the frequency of meetings.

The document should be updated in line with the NDSG members comments. Depending on the number of changes to the initial version of the document, it should be circulated to the group for adoption via written procedure or included on the agenda for endorsement at the next NDSG meeting (**Action:** NDSG secretariat).

**Action:** Luis Pinheiro (EMA) to seek EMA advice to determine whether the participation of NCA assessors in the Industry group focused on AI discussions could be considered a conflict of interest with their assessment work at the national level. The response is to be circulated to the group for information.

### 4. Principles for responsible AI and AI terminology: status update

Joerg Zinserling (BfArM, DE) presented a status update on the co-development of a set of guiding principles on AI with US Food and Drug Administration (FDA). This work also includes mapping and aligning the terminology used by both agencies, with the aim to reach consensus on terms, where

possible. To support this work, a Temporary Drafting Group (tDG) has been established to work with U.S. FDA on AI principles and terminology.

The principles for good machine learning for medical devices (FDA/HC/MHRA) was used as a basis for the AI guiding principles development. The tDG has reviewed the initial FDA proposal and developed a draft EU version with 11 principles proposed. Further alignment with FDA on the EMRN proposal is ongoing.

A preliminary draft of terms to be included in the AI terminology paper has already been prepared and further work is required to progress this activity.

The group discussed the next steps for developing the two deliverables. It was noted that the more mature draft of the AI guiding principles will be consulted with the Network, which will be facilitated through the Methodology Working Party and should also include NDSG consultation.

**Action:** Joerg Zinserling (BfArM, DE) to facilitate the integration of the European Commission's High-Level Expert Group's Ethics Guidelines for Trustworthy AI and the OECD AI Principles into the draft documents.

**Action:** Luis Pinheiro to facilitate a dedicated consultation with the NDSG ethics representatives to discuss the inclusion of ethical considerations in the AI principles and terminology documents.

## **5. Delivering AI literacy training: experience to date and training development plans**

Harald von Aschen (BfArM, DE), Vincent Gazin (ANSM, FR) and Edurne Lazaro (AEMPS, ES) presented the approach to deliver the AI literacy training at their national competent authorities to enhance staff understanding of AI and its implications. Presenters also shared the experience gained to date and future training development plans.

Marianne van Heers (EMA) presented the EMA training development plans for the AI literacy in 2025, focusing on delivering fundamental/basic AI training courses for all staff. The basic AI literacy training is split into six pillars, where short micromodules (under 5 minutes) will be developed for each pillar. These training modules will be made available to the network through the EU Network Training Centre (NTC). A proposal was made to simplify the access requirements to the training modules via the EU NTC platform. It was also noted that the MPA's generative AI system REGULUS will be made accessible shortly to the network via AI@MPA toolbox.

The group noted the need for network collaboration on training development in AI. **Action:** NDSG secretariat to organise a follow up discussion.

*Post meeting note: A proposal to coordinate and codevelop the AI literacy training across the network will be drafted by EMA and further discussed with NDSG. This action has not been specifically discussed at the meeting and was added as a post meeting note, with an agreement by the NDSG co-chairs.*

## **6. Knowledge mining and use of generative AI: status update**

Luis Pinheiro (EMA) presented a status update on the development of the knowledge mining roadmap and AI use cases for the Network and discussed proposal to organise a dedicated Network workshop on Use Cases in June 2025 to further progress on this activity and prioritise the use cases. The group was reminded that a survey for AI use cases from the Network concluded with a total of 26 replies: 27 AI Solutions and 42 AI use cases collected. The following comments/suggestions were noted during the meeting:

- To consider in the prioritisation of use cases their feasibility based on availability of technology and data, maturity of tools and use (i.e. local vs central).
- To consider postponing the workshop to July, ensuring that the right stakeholders are involved (e.g. Pharmacovigilance assessors, Clinical assessors). Invitation should also be sent to NDSG and AI SIA members.
- Action: EMA to publish or make the survey results on AI use cases available to the Network/NDSG.

## **7. Network AI Tools framework: status update and next steps**

Vittoria Abagnale (EMA) presented the implementation approach for the AI tools framework, the purpose of the framework and scope, the high-level outline and associated timelines. As next step, a call for volunteers to develop the framework will be launched to the Network in June (via NDSG, NICTAC).

The NDSG noted the update and recommended to consider capturing the information not only on the tools but also information on data it processes. Additionally, it was proposed that the potential transferability of tools across the Network and sharing access to tools across the network are considered as an option in the framework. These topics should be discussed further during the development of the Network's framework in collaboration with the Network volunteers.

**Action:** NDSG secretariat to circulate a dedicated message to the NDSG to launch a call for volunteers to support the development of the AI tools framework.

## **8. A.O.B.**

Karl Broich (BfArM, DE) informed the group that a Network's community of practice on information and cybersecurity will be established in 2025 and this will be facilitated via IT Directors group and NICTAC.

Additionally, NDSG was reminded to provide comments on the draft EMRN Data strategy by 30 May 2025.