17 December 2025
EMA/323786/2025

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

8 December 2025, 13:00-18:00pm, MS Teams Meeting, Meeting room 0B

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.	Reflecting on experience from the 1st year of NDSG	Katrien Oude Rengerink/ Ana López de la Rica Manjavacas / Konstantina Boumaki	For discussion	20'
3.	EHDS implementation update	Jerome De Barros	For information	30'
4.	EMRN data analytic framework: 1st discussion	Jacobus van Wyk	For discussion	45'
5.	AI research priorities	Joerg Zinserling	For adoption	10'
6.	AI Tools framework to support sharing collaboration on AI tools in the EMRN	Georg Neuwirther and Vittoria Abagnale Discussants: Joerg Zinserling, Gabriel Westman, Pelle Persson, Luis Pinheiro	For adoption	30'
7.	Knowledge mining use cases and AI roadmap update – Moving from discussion to action	Joaquim Berenguer Jornet Discussants: Joerg Zinserling, Gabriel Westman, Georg Neuwirther	For discussion	30'
8.	DARWIN EU experience and learnings	Denise Umuhire Discussants: Claus Møldrup, Edurne Lazaro, Vincent Gazin, Carla Torre, Bruno Delafont,	For discussion	45'

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
		Patricia McGettigan, Dag Jordbru, Joerg Zinserling, Konstantina Boumaki		
9.	NDSG consultation on final RWD quality chapter	Ana Cochino	For information	10'
10.	ROG PMS data qualification feasibility study update	Georg Neuwirther Discussants: Pelle Persson, Harald von Aschen, Aimad Torqui	For information	15'
11.	PMS master data implementation: • Working arrangements / roles responsibilities • Data quality framework	Ana Cochino Discussants: Georg Neuwirther, Pelle Persson, Harald von Aschen, Aimad Torqui, Hilmar Hamann	For discussion	30'

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), Joerg Zinserling (BfArM, DE), Patricia McGettigan (PRAC), Michael Vogl (EMA), Anthony Oshea (EDQM), 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), Stefanie Prilla (EMA), Paolo Alcini (EMA), Angelo Molinaro (AIFA, IT), Vincent Gazin (ANSM, FR), Isabel Chicharo (EMA), Jerome De Barros (EC), Jacobus van Wyk (EMA), Pier Paolo Olimpieri (AIFA, IT), Roelof Otterspeer (EMA), Eleonora Agricola (EU-IN), Markus Kalliola (SITRA, FI), Georg Neuwirther (AGES, AT), Gabriel Westman (MPA, SE), Patrice Verpillat (EMA), Konstantina Boumaki (EPF), Pero Ivanko (CIPH, HR), Frank Petavy (EMA), Ana Cochino (EMA), Aimad Torqui (MEB, NL), Momir Radulovic (Jazmp, SI), Vaia Apostolidou (EC), Emer Cooke (EMA), Zaide Frias (EMA).
Apologies:	Marianne Lunzer (AGES, AT), Dmitry Etin (EMA), Carla Torre (CHMP), Christina Kyriakopoulou (EC), Alessandro Blasimme (Ethics representative), Siobhán O'Sullivan (Ethics), 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 Co-Chairs opened the meeting, welcomed in person and remote participants and adopted the draft agenda. The group members were invited to submit any final comments on the draft minutes from the 6th of November 2025 meeting by 19th December or else these will be considered as adopted.

2. **Reflecting on experience from the 1st year of NDSG**

The NDSG members were invited to provide reflections on experience from the 1st year of NDSG.

Katrien Oude Rengerink (CGB-MEB) highlighted the importance of connecting diverse topics and stakeholders while translating strategy into practical tools, and also emphasised that a good dialogue among stakeholders with complementary perspectives was key to develop a strategy that fits the Network and leads to a successful implementation. Additionally, reserving sufficient time for dialogue in meetings and starting from the purpose rather than the data when designing projects was recommended.

Ana López de la Rica Manjavacas (AEMPS) shared the CMDh perspective, noting how inspiring NDSG was for developing CMDh's IT & digitalisation plans, also noting that participation in the group increased CMDh's understanding of data analysis, AI legislation, and interoperability.

Konstantina Boumaki (EPF) shared her experience as a new member and stressed the importance of maintaining openness and collaboration as the group's work becomes more complex.

The Co-Chairs reflected that NDSG has moved from set up into delivery of key topics and that diverse perspectives are essential to solve complex and detailed actions of the workplan. Participants also noted differences in preparedness across the Member States on data use and asked NDSG to strengthen engagement with NCAs that have more limited experience, and to consider CMDh/CMDv linkages in 2026–2027 planning.

Action: NDSG to explore ways to strengthen engagement with NCAs, especially those that have limited experience in using data.

3. **EHDS implementation update**

Jerome De Barros (DG SANTE, EC) provided an update on the European Health Data Space (EHDS) and discussed the current status, timelines, support projects, and challenges related to the implementation of EHDS, including regulatory deadlines, Member States' readiness, and the need for continuous communication and collaboration.

Participants raised comments about varying levels of preparedness among Member States, the need for incentives for data holders, and the importance of balancing data access fees to avoid excluding academia from accessing and using the data that will be made available thanks to the EHDS implementation.

The group discussed the relationship between EHDS and ongoing projects such as DARWIN EU ®, the need to test data extraction processes, and the importance of aligning with other European health data initiatives. It was proposed to increase the visibility of the EHDS work items for the upcoming NDSG workplan update and consider organising events for Member State information sharing, ensuring that the Network remains informed and engaged as implementation progresses.

Action: EC colleagues to include primary use (e.g., XDHR) in the next EHDS update to NDSG.

Action: NDSG to elevate EHDS across the 2026–2027 workplan and consider organising information sharing events for NCAs on EHDS implementation.

4. EMRN data analytic framework: 1st discussion

Jacobus van Wyk (EMA) presented proposed an approach for drafting the new Network Data Analytics Framework. The purpose of the framework is to unlock the value in the Network's data assets as defined in the Network data strategy by supporting evidence generation for decision-making and facilitate the move from strategy to implementation. The framework will cover use case definition, technology and infrastructure, data management, analytics, people and processes, security, and monitoring. The drafting will start in 2026, with the adoption planned for Q2-Q3 2026.

The group discussed the need to incorporate existing frameworks on data standardisation and quality, ensure interoperability, address hardware and software requirements, and provide training and change management to support adoption among assessors and other users. The discussion highlighted the evolving roles of assessors in analysing real-world data, the importance of clear ownership and responsibilities, and the need for collaboration across regulatory, epidemiological, and data science domains.

The NDSG endorsed the approach for drafting and emphasised the need for clear scoping and iterative development of this framework.

Action: NDSG secretariat to send a dedicated email to the group requesting volunteers to participate in the drafting group for the Data Analytics Framework.

5. AI research priorities

Joerg Zinserling (BfArM) presented the final top ten AI research priorities, derived from the multi-stakeholder survey. The group was reminded of the survey design, which covered seven domains and collected 273 responses from a broad range of stakeholders. The team used a weighted ranking approach to identify the top ten research priorities, focusing on accuracy, reliability, data governance, ethics, and other key themes.

The group discussed the challenge of combining multiple questions in single points and agreed to maintain the current structure for clarity and consistency. Additionally, it was agreed to remove a reference to "transparent reasoning" in the context of explainability and to include a narrative/context to accompany the publication. The intended recipients are researchers and funders, with the aim of influencing future research.

The NDSG endorsed the list and agreed to publish the research priorities on the website (Artificial intelligence) and consider a peer-reviewed journal publication to reach a wider academic audience.

Action: The AI research priorities drafting team (via EMA) to share the AI research priorities communication plan with the group in early 2026 for information.

6. AI Tools framework to support sharing collaboration on AI tools in the EMRN

Georg Neuwirther (AGES) and Vittoria Abagnale (EMA) introduced the AI tools framework which aims to establish an AI tools catalogue and process for sharing, maintaining, and communicating information about AI tools across the network. The framework was developed in collaboration with NCAs and will be accessible to the Network via a Sharepoint site. The SharePoint site includes the AI

tools catalogue, a user guide, the AI tools framework and a form for submitting tool information. The framework and catalogue will be piloted in 2026, with iterative review and potential expansion based on feedback.

The communication plan was prepared, which includes emails to key stakeholders, news items, newsletters, presentations at relevant meetings, and walk-in clinics to support adoption and address questions.

The NDSG endorsed the framework, the pilot and the communications plan, and recommended organising a webinar in addition to the two walk-in clinics.

Action: The AI tools framework drafting team (via EMA) to review regularly the information in the AI tools catalogue to ensure relevance.

7. Knowledge mining use cases and AI roadmap update – Moving from discussion to action

Joaquim Berenguer Jornet (EMA) described the process of collecting and clustering over 100 AI use cases from network participants, assessing their business impact and technical feasibility, and identifying top priorities. Workshops and surveys were used to gather further input and prioritise needs. The three main capability/ needs were identified: knowledge retrieval/mining, drafting & summarisation, and validation & quality assurance.

The proposed delivery was presented to NDSG members for a 1st discussion and to collect orientations from the group.

Regarding knowledge mining, it was proposed to continue expanding Scientific Explorer beyond scientific advice to additional sources (e.g., public assessment reports, committee minutes) and start delivering different AI Agents integrated to different sources of information, such as committee minutes and different scientific areas' documents, e.g. orphans, paediatrics, etc. As the next step, it was proposed to expand on Network prioritised sources and establish a pipeline for implementation based on the information gathered via a survey to NCAs.

To enable other use cases and to better use the different AI solutions, prompts will be needed, and the development of a prompt library was proposed. This will be a collection of validated, reusable prompts for AI solutions, which will aim to harmonise and standardise AI usage across the network. The proposal included the establishment of a Network prompt library/community, that will first be piloted to harmonise instructions for narrow tasks. The results of this pilot will be shared with the Network. The goal is to embed validated prompts into the regulatory systems/tools.

Concerns were raised about the risks of prompt injection, variability in AI outputs, and the need for robust validation frameworks. Participants discussed integrating AI solutions with existing network systems, expanding the scope of knowledge mining to include working party documents, and ensuring that the approach remains agile and responsive to network needs.

The group supported the proposed approach for continuation of Scientific Explorer expansion, with the first AI Agents already under development for knowledge mining use cases, and agreed that a stepwise, use case-by-use case approach should be adopted to assess the value of prompt libraries before committing significant resources. There is a need for a clear governance and checkpoints to ensure reliability and manage risks. This will complement the Network AI tools and the AI Tools framework.

Action: EMA to launch the pilot on AI prompt libraries, including the design a validation framework and governance model (metrics, KPIs, repeatability checks) for prompt-based tasks.

Action: EMA to conduct a survey to prioritise knowledge sources for Scientific Explorer/agents; results to inform an EPIC under the Network Portfolio governance.

8. DARWIN EU experience and learnings

Denise Umuhire (EMA) provided an update on DARWIN EU, covering its impact on regulatory decision-making, network expansion, data quality improvements, and plans for DARWIN EU 2.0, with feedback from multiple national agencies and partners. DARWIN EU is now the primary pathway for EMA for generating real-world evidence (RWE). Over 50 studies have been completed (and almost 50 more ongoing), with an average execution time of under four months. The DARWIN EU network has grown to over 30 data partners across 16 countries, representing more than 180 million patients. In addition, preliminary considerations on the scope of DARWIN EU 2.0 framework were provided to the group, these include expanding beyond the OMOP common data model, strengthening links with EHDS, preparing for potential AI use cases, and continuing to engage a broad range of stakeholders.

The group welcomed the update and the success of DARWIN EU and supported moving forward with DARWIN EU 2.0. The group discussed the need to increase data granularity of data sources, more outreach to health data access bodies and the importance of integrating DARWIN EU with EHDS, the delivery of more complex studies, and ensuring broader awareness and use of DARWIN EU outputs.

9. Data Quality and Interoperability

Ana Cochino (EMA) reminded the group of the ongoing written consultation to endorse the final draft of the Real-World Data Quality Framework chapter, which has undergone a public consultation. The consultation feedback included proposals to improve clarity and usability of the document without changes to the core chapter principles. The framework is intended as a non-binding reference to support consistent assessment and improvement of data quality across the network. The document will be published in early 2026, following the endorsement by NDSG (via written procedure).

Action: NDSG members to submit any major comments or blocking concerns by 12th December or else it will be considered as adopted by NDSG.

Post meeting note: No comments were received from NDSG in December. The Real-World Data Quality Framework chapter is now considered as adopted.

10. ROG PMS data qualification feasibility study update

Georg Neuwirther (AGES) provided an update on the ongoing PMS data qualification feasibility study, involving 20 NCAs. The summary report will be provided to the Heads of Medicines Agencies in Q1 2026.

11. Product Master Data – Feasibility and Working Arrangements

Ana Cochino (EMA) presented the initial overview of ideas for the EMRN working arrangements document for PMS data management over the next 2–3 years. The draft model aims at defining roles and responsibilities for managing investigational and authorised product master data, with a focus on pragmatic, high-level guidance rather than detailed operational plans. The key principles include

simplifying submission flows, enabling optional NCA participation in data qualification, and enhancing EMA-led validation.

The group discussed the proposal and provided the following feedback:

- Alignment with CMDh will be important and consider options for NCA participation in data qualification, mandatory vs optional;

- Start early in defining business processes;

- Strategic discussion at HMA is needed on investment needs;

- Clarify and prioritise use cases (also at a national level);

- Align with the new pharmaceutical legislation, define governance, and prioritise interoperability for EHDS readiness.

12. A.O.B.

The Co-Chairs thanked NDSG members for their contributions and closed the meeting.