14 January 2026
EMA/8958/2026

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

13 January 2026, 13:00-15:00pm, 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.	Update the NDSG and AI workplan: approach and 1st discussion	Francois Domergue /Luis Pinheiro /NDSG members	For discussion	60'
3.	Update on Joint action on ISO Identification of Medicinal Products (IDMP)	Pelle Persson, Georg Neuwirther	For discussion	20'
4.	Approach to catalogue Network data assets	Jos Olaerts	For discussion	20'
5.	ADR Data Quality chapter	Tom Paternoster-Howe Discussants: Edurne Lazaro, Patricia McGettigan	For discussion before public consultation	10'
6.	A.O.B. • 2025 NDSG annual report • HMA EMA Annual data forum report	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), Sandra Bertulat (BVL, DE (vet)), Joerg Zinserling (BfArM, DE), Laure Baduel (CVMP), Edurne Lazaro (AEMPS, ES), Hilmar Hamann (EMA), Francisco Penaranda (EMA), Paul Lynn (EMA), Katrien Oude Rengerink (CBG-MEB, NL), Pelle Persson (MPA, SE), Flora Musuamba Tshinanu (SAWP), Pedro Pina Ferreira (EMA), Dag Jordbru (NOMA, NO), Rico Slingerland (CMDv), Kristin Karlsson (MWP), Michael Vogl (EMA), Stefanie Prilla (EMA), Paolo Alcini (EMA), Angelo Molinaro (AIFA, IT), Vincent Gazin (ANSM, FR), Jerome De Barros (EC), Jacobus van Wyk (EMA), Pier Paolo Olimpieri (AIFA, IT), Eleonora Agricola (EU-IN), Markus Kalliola

	(SITRA, FI), Gabriel Westman (MPA, SE), Momir Radulovic (Jazmp, SI), Christopher Javris (EDQM), Siobhán O'Sullivan (Ethics), Tom Paternoster-Howe (EMA), Jos Olaerts (EMA), Vaia Apostolidou (EC), Marta Slomka (Payers), Anabela Marcal (EMA), Anastasia Pagida (EC), Yiannos Tolias (EC), Ana López de la Rica Manjavacas (AEMPS, ES), Gianmario Candore (EMA), Kaisa Immonen (EMA).
Apologies:	Patricia McGettigan (PRAC), Anthony Oshea (EDQM), Claus Møldrup (DKMA, DK), Niklas Hedberg (HTA), Kimmo Porkka (EHA), Georg Neuwirther (AGES, AT), Patrice Verpillat (EMA), Konstantina Boumaki (EPF), Pero Ivanko (CIPH, HR), Aimad Torqui (MEB, NL), Dmitry Etin (EMA), Carla Torre (CHMP), Christina Kyriakopoulou (EC), Alessandro Blasimme (Ethics representative), 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 members were invited to submit their final comments on the draft minutes of 8th December 2025 NDSG meeting by close of business 16th January 2026. In the absence of any substantial comments, the minutes will be considered as adopted and published thereafter.

The group welcomed:

- Ivelina Gushlekova from Bulgarian Drug Agency, as the new Clinical Trials Coordination Group (CTCG) representative, who replaced Marianne Lunzer.

- Momir Radulovic from Slovenian Medicines and Medical Devices Agency, who joined NDSG as observer to link to the IncreaseNET and EU-NTC activities.

The group thanked Pedro Pina Fereira for his contributions to the group's work. Pedro Pina Fereira, who represented the digital business transformation at EMA, will transition to a new role at EMA and his replacement will be confirmed in the coming weeks.

2. NDSG and AI workplan update: approach and 1st discussion

Peter Arlett (EMA) introduced the review of the NDSG and AI work plan, noting that this is the first discussion and that detailed comments would be collected for a final discussion and potential adoption in February 2026. Francois Domergue (EMA) then presented the high-level approach to updating the work plan, which involved integrating lessons from past achievements, stakeholder events, upcoming legislation (including the AI Act and Biotech Act), and aligning with the EU Network strategy to 2028.

Strategy and Governance Work Stream

Francois Domergue (EMA) presented the proposal for the three key priorities for 2026: embedding data management and governance into core activities, strengthening data standardisation and analytics, and supporting new legislation and the network strategy to 2028. The workplan updates include continued monitoring of the Network data strategy, drafting and publishing frameworks for data standardisation and analytics, and planning a stakeholder workshop on horizon scanning results in early 2027.

The work plan continues to support the implementation of new legislations, e.g. pharmaceutical legislation, expanding the focus to both primary and secondary use of data under EHDS, and considers the implications of the Biotech Act.

The group agreed with the proposed workstream updates. They also suggested that, for the NDSG activity on monitoring European regulatory-science data projects, the work should include relevant initiatives such as IHI projects, the IncreaseNet programme, and the European Regulatory Science Platform.

Data Analytics Work Stream

Francois Domergue (EMA) presented the proposed three priorities for 2026: reviewing data and methods, embedding data analysis into core Network activities, and enhancing stakeholder engagement, particularly with CMDh and CMDv. The plan updates include: quarterly reviews of different data and method approaches; transition from pilot to systematic submission of clinical study data in line with new pharmaceutical legislation; development of tools for clinical study data management and analysis; continuation of real-world data initiatives and publication of annual reports.

The group agreed with the proposed workstream updates and requested a dedicated future NDSG discussion on the practical implementation of clinical study data submission, including technical considerations, training needs, and how such data will be integrated in assessment processes. (**Action**: NDSG secretariat).

AI Work Stream

Luis Pinheiro (EMA) presented the proposed three priorities for the workstream in 2026: developing AI guidance, progressing AI innovation priorities, and expanding AI literacy across the network. The proposed changes include merging the "tools and technologies" and "experimentation" swim lanes for better integration of complimentary activities, thereby reducing redundancy and duplication. The proposal also strengthened the support for the deployment of AI solutions, including REGULUS and Scientific Explorer, as well as continuing to develop and deliver further solutions, such as the extension of Scientific Explorer. Furthermore, the proposal included literacy and change management activities, in particular, exploring opening the EU Network Training Centre (EUNTC) to relevant external stakeholders.

The group agreed with the proposed workstream updates. The following feedback was collected for consideration for additional work stream plan updates:

- Strategic alignment with initiatives stemming from the Biotech Act involving AI and data is required, including strengthened coordination of the of AI guidance development mandated by the Act, by developing a Network roadmap for its monitoring and delivery.

- Alignment with the IncreaseNet activities is required to avoid duplication in the areas of training. **Action**: NDSG secretariat to organise a dedicated offline discussion with Flora Musuamba Tshinanu and Momir Radulovic to better integrate the IncreaseNet activities in the NDSG workplan.

- Consider including an activity in the workplan related to AI sandboxes, which could be delivered as a simulation-type hackathon.

- NDSG members to provide additional suggestions on engagement with academia in the area of AI (**Action**: NDSG members).

- NDSG members are invited to address the questions included in the summary of changes and points for discussion, namely, whether a specific deliverable on AI bias/ethics should be considered, how to ensure continued visibility of the AI deliverables and landscape, whether a new community in addition to the AI SIA, for the national agencies, is required.

Data Interoperability and Governance work stream

Francois Domergue (EMA) presented the key three priorities for 2026 and highlighted the updates to the interoperability work stream, which focuses on increasing the discoverability and quality of network data assets through cataloguing and maturity assessments. The key updates include defining roles and responsibilities for data stewards and developing a data glossary as part of the EMRN data assets cataloguing, adjusting timelines for the delivery of data quality chapters, and adjusting timelines for the harmonisation of implementation of medicinal product PMS master data.

The group agreed with the proposed workstream updates.

Stakeholder engagement and change management work stream

Francois Domergue (EMA) presented the three priorities for 2026 and walked through the key updates, including the quarterly change-management check-ins on priority topics, roll out the AI literacy curriculum and planned stakeholder events.

Guidance and international initiatives work stream

The updates to the workstream activities will be aligned with the MWP leadership team in the coming days and consequent changes will be incorporated in the updated workplan to be presented at the next meeting.

Finally, the group acknowledged the resource constraints across the Network and EMA and agreed to review must-have and nice-to-have deliverables when revising the workplan in February.

Action: NDSG members to provide written comments on the draft workplan over the next two weeks.

Action: NDSG secretariat to have a dedicated call with MWP leadership to ensure alignment between the NDSG and MWP workplans.

Action: NDSG secretariat to conduct bilateral discussions with the relevant NDSG members to ensure perspectives from ethics, veterinary medicines, and patient/academia representatives are fully integrated in the updated workplan. A near-final discussion is planned for the 11 February 2026 meeting.

3. **Update on Joint action on ISO Identification of Medicinal Products (IDMP)**

Pelle Persson (MPA, SE) provided an overview of the upcoming joint action named "UNIWIDE," aimed at continuing and expanding IDMP implementation across Europe. The project involves 42 participants, including 29 national competent authorities, and focuses on national IDMP implementations, AI use case exploration, knowledge sharing, and sustainability. The project is in the grant agreement drafting phase, aiming to start by the end of the year. The project updates to the group will be facilitated by Pelle Persson and Georg Neuwirther.

4. Approach to catalogue Network data assets

Jos Olaerts (EMA) introduced the initiative to develop a Network Data Assets Catalogue (NDAC), which aims to create a centralised, transparent, and standardised reference for data assets used across the European regulatory network. The catalogue would include metadata such as ownership, standards used, and data quality maturity indicators, and align with the European Health Data Space implementation. A staged approach to develop NDAC was proposed, starting with definition of scope, criteria and initial metadata model. A call for volunteers to join the drafting group will be launched after the meeting.

Action: NDSG secretariat to launch a dedicated call for volunteers via email.

5. ADR Data Quality chapter

The topic was deferred to the February NDSG meeting.

6. A.O.B.

The group was reminded to submit any final comments on the NDSG 2025 Annual Report by 16 January 2026. Additionally, colleagues who would like to participate in the drafting of the Data Analytics Framework should send their expressions of interest by close of business on Friday, 16 January 2026.