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

11 February 2026, 10:00-12:00pm, 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	Francois Domergue, Luis Pinheiro Discussants: NDSG members	For discussion	60'
3.	ADR Data Quality chapter	Tom Paternoster-Howe Discussants: Edurne Lazaro, Patricia McGettigan	For discussion before public consultation	20'
4.	Report on POC on non-clinical raw data analysis	Francisca van Doesum-Wolters	For discussion	25'
5.	A.O.B.			

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)), Angelo Molinaro (AIFA, IT), Vincent Gazin (ANSM, FR), Jerome De Barros (EC), Jacobus van Wyk (EMA), Joerg Zinserling (BfArM, DE), Edurne Lazaro (AEMPS, ES), Francisca van Doesum-Wolters (EMA), Ivelina Gushlekova (CTCG), Momir Radulovic (Jazmp, SI), Javier Martínez Arribas (Payers), Georg Neuwirther (AGES, AT), Anastasia Pagida (EC), Katrien Oude Rengerink (CBG-MEB, NL), Pelle Persson (MPA, SE), Richeal Egan (EMA), Dag Jordbru (NOMA, NO), Tom Paternoster-Howe (EMA), Vaia Apostolidou (EC), Florian Klinglmueller (AGES, AT), Kaisa Immonen (EMA), Patricia McGettigan (PRAC), Francisco Penaranda (EMA), Aimad Torqui (MEB, NL), Anthony Oshea (EDQM), Michael Vogl (EMA), Eleonora Agricola (EU-IN), Anne-Marie van Nederkassel (EMA), Markus Kalliola (SITRA, FI), Claus Møldrup (DKMA, DK), Carla Torre (CHMP), Flora Musuamba Tshinanu (SAWP), Konstantina

	Boumaki (EPF), Kristin Karlsson (MWP), Hilmar Hamann (EMA), Niklas Hedberg (HTA), Pier Paolo Olimpieri (AIFA, IT), Stefanie Prilla (EMA), Paolo Alcini (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Christina Kyriakopoulou (EC), Eftychia-Eirini Psarelli (EMA)
Apologies:	Kimmo Porkka (EHA), Patrice Verpillat (EMA), Pero Ivanko (CIPH, HR), Alessandro Blasimme (Ethics representative), Bruno Delafont (CHMP), Laure Baduel (CVMP), Paul Lynn (EMA), Rico Slingerland (CMDv), Gabriel Westman (MPA, SE), Christopher Javris (EDQM), Siobhán O'Sullivan (Ethics), Marta Slomka (Payers), Anabela Marcal (EMA).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda was adopted. The minutes of 13th January 2026 NDSG meeting were adopted as final.

The group welcomed Anne-Marie van Nederkassel who joined the NDSG in February, as the EMA's digital business transformation representative to NDSG.

2. NDSG and AI workplan update: 2nd discussion

Francois Domergue (EMA) presented the latest updates to the Network Data Steering Group (NDSG) workplan 2026-2028 and summarised the process of collecting and integrating feedback received during the January meeting and follow up consultations.

Minor updates had been made to the workplan, and specific actions were taken to address other feedback not translating into the workplan deliverables, e.g. such as topics for workshops, discussion with IncreaseNET on AI use. The workplan was updated to include veterinary-specific deliverables and to discuss key EU legislative updates such as the Biotech Act. The group discussed the best approach to identify the veterinary topics in the workplan and agreed to further consult the veterinary representatives to NDSG.

Action: Francois Domergue to have an offline discussion with the NDSG colleagues representing veterinary domain to agree the approach to document in the workplan how to best indicate the veterinary applicability of key NDSG deliverables (e.g. item by item or via a general statement in the work plan).

Action: NDSG secretariat to share additional information to Anastasia Pagida, clarifying the analytical capabilities to be introduced in the UPD, including details on intended users and functionalities.

Luis Pinheiro (EMA) presented the changes introduced in the AI workstream. Discussion within the group focused on the addition of a coordinated roadmap for further development of AI guidance, the separation of the AI glossary from guiding principles, and the introduction of new deliverables such as the AI sandbox simulation hackathon and collaboration with IncreaseNet for training and solution sharing.

Action: When initiating the work on the AI sandbox simulation hackathon, Luis Pinheiro to prepare a short concept note (purpose, scope, stakeholders, legal references) for discussion with NDSG, noting that that intent is exploratory and stakeholder engagement, and not a formal regulatory sandbox.

Action: NDSG secretariat to plan a dedicated information item on the ICH M16 guidance (structured quality/manufacturing data) at a future NDSG meeting, with presenter Georg Neuwirther and the BfArM M16 working group member.

The NDSG endorsed the workplan in principle, with agreement to incorporate editorial changes and clarify veterinary aspects. The final version will be circulated for written adoption, and the plan will be communicated to the HMA and EMA Management Board.

Action: NDSG secretariat to send out a clean version of the work plan for final review to NDSG, incorporating amendments and clarifications discussed.

3. ADR Data Quality chapter

Tom Paternoster-Howe (EMA) presented the Adverse Drug Reaction (ADR) Data Quality Framework chapter, seeking NDSG endorsement to release the document for public consultation.

The ADR chapter was developed, informed by a multi-stakeholder workshop, landscape analysis, and interviews with experts from regulatory, industry, academia, and veterinary sectors. The framework aligns with ICH E2D and includes input from various EMA working groups on targeted sections of the document.

The framework identifies challenges in ADR reporting, such as reliability, extensiveness, coherence, timeliness, and relevance, and provides seven groups of recommendations, including education, integration of clinical pharmacology, standard implementation, data validation, feedback mechanisms, data immutability, and duplicate detection.

Some concerns were raised about the clarity of veterinary inclusion in the framework, noting differences in terminology and legislative requirements. It was also suggested to include practical examples to aid implementers and making expectations clearer for clinical trials vs spontaneous settings.

Following the group discussions, it was agreed to proceed with the public consultation, allowing for further technical and operational feedback during the public consultation and noting that practical implementation details could be added as annexes in future iterations, as needed.

Action: Tom Paternoster-Howe to review and update ADR Data Quality Chapter document to ensure that veterinary requirements and terminology are appropriately reflected.

Post meeting note: A dedicated email was circulated to NDSG on 13 February 2026, informing the group that the draft DQF ADR reporting Chapter will undergo another round of expert review (including consultation with the Pharmacovigilance Business Team) before being released for public consultation. The revised version will be circulated to NDSG before the public consultation.

4. Report on POC on non-clinical raw data analysis

Francisca van Doesum (EMA) presented the results of the proof-of-concept study initiated in 2024 to evaluate if non-clinical information in SEND format will improve quality, consistency and efficiency of assessments.

During the pilot the SEND Explorer Warehouse environment was used and MAHs were encouraged to submit SEND data, resulting in 34 submissions, of which 29 were included in the study. This pilot included participation from assessors in the Netherlands, Germany, Sweden, Belgium, France, and Austria, with 69 assessors received training on the SEND software.

The pilot found that SEND data facilitated sharing and understanding of toxicology and toxicokinetic data, especially for applications with larger datasets. It also revealed the need for initial training and familiarisation, as well as the importance of expanding access to more NCAs.

Industry feedback was generally positive, though some companies opted out due to transparency concerns and the voluntary nature of the pilot. Future steps include continued voluntary submission, broader access for NCAs, and alignment with upcoming pharmaceutical legislation.

The group congratulated the team on the successful pilot and discussed the need to clarify SEND data handling under EMA transparency policies and to automate data management processes. Also, there was a discussion about methodological support, collaboration with the clinical raw data pilot, and the potential for open-source software solutions. Finally, it was suggested to review the approach in light of the soon to be published 'New Pharmaceutical legislation' which may include relevant provisions.

Action: Francisca van Doesum to present the results of the non-clinical raw data pilot to MWP and SAWP. Once the New Pharmaceutical Legislation is adopted and final, EMA to prepare an analysis and plan for next steps.

5. **A.O.B.**

The group was informed about the publication of the following documents on the dedicated EMA webpages.

- Network Data Steering Group Annual report 2025

- Report - HMA EMA Annual Data Stakeholder 2025