

21 July 2026  
EMA/168658/2026

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

17 July 2026, 13:00-15:00pm, MS Teams Meeting

Chair: 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.   | NDSG consultation on EMRN data standardization framework (v), incl. SDO collaborative model | Ana López de la Rica, Nick Halsey | For endorsement for public consultation | 25'  |
| 3.   | NDSG 1 <sup>st</sup> orientation on Data analytics Framework                                | Jacobus van Wyk                   | For discussion                          | 25'  |
| 4.   | NDSG 1 <sup>st</sup> orientation on EMRN data asset catalogues                              | Jos Olaerts                       | For discussion                          | 25'  |
| 5.   | Progress update on AI and Data training strategy in line with the EU NTC framework          | Marianne Van Heers                | For discussion                          | 25'  |
| 6.   | A.O.B.<br>ADR data quality framework: status and information about Network consultation     | Tom Paternoster-Howe              | For information                         | 5'   |

| Role       | Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Attendance | Peter Arlett (EMA), Georg Neuwirther (AGES, AT), Gabriel Westman (MPA, SE), Karl Broich (BfArM, DE), Florian Klinglmueller (AGES, AT), Katrien Oude Rengerink (CBG-MEB, NL), Joerg Zinserling (BfArM, DE), Harald von Aschen (BfArM, DE), Flora Musuamba Tshinanu (SAWP), Pelle Persson (MPA, SE), Marta Slomka (Payers), Aimad Torqui (MEB, NL), Rico Slingerland (CMDv), Sandra Bertulat (BVL, DE (vet)), Paul Lynn (EMA), Patricia McGettigan (PRAC), Konstantina Boumaki (EPF), Nick Halsey (EMA), Tom Paternoster (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Kristin Karlsson (MWP), Laure Baduel (CVMP), Eleonora Agricola (EU-IN), Jacobus van Wyk (EMA), Christopher Javris (EDQM), Javier Martínez Arribas (Payers), Jos Olaerts (EMA), Angelo Molinaro (AIFA, IT), Stefanie Prilla (EMA), Gianmario Candore (EMA), Pier Paolo Olimpieri (AIFA, IT), Marianne Van Heers (EMA), Patrice Verpillat (EMA). |

|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Apologies:                         | Anastasia Pagida (EC), Anthony Oshea (EDQM), Claus Møldrup (DKMA, DK), Aina Staisiuniene (EMA), Vaia Apostolidou (EC), Pero Ivanko (CIPH, HR), Paolo Alcini (EMA), Michael Vogl (EMA), Niklas Hedberg (HTA), Edurne Lazaro (AEMPS, ES), Christina Kyriakopoulou (EC), Anne-Marie van Niderkassel (EMA), Ivelina Gushlekova (CTCG), Hilmar Hamann (EMA), Frank Petavy (EMA), Francisco Penaranda (EMA), Siobhán O’Sullivan (Ethics), Vincent Gazin (ANSM, FR), Kaisa Immonen (EMA), Dag Jordbru (NOMA, NO), Carla Torre (CHMP), Markus Kalliola (SITRA, FI), Momir Radulovic (Jazmp, SI), Kimmo Porkka (EHA), Alessandro Blasimme (Ethics representative). |
| Administrative support and minutes | Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

## 1. Adoption of the draft agenda & minutes

The co-chairs welcomed members to the meeting and noted the NDSG membership changes, including the replacement of Jerome De Barros by Iordana Eleftheriadou at the European Commission and the resignation of Bruno Delafont as alternate CHMP representative.

The draft agenda was adopted. The draft minutes from the June NDSG meeting were adopted as final.

## 2. NDSG consultation on EMRN data standardization framework (v), incl. SDO collaborative model

Ana López de la Rica (AEMPS, ES) presented the draft EMRN Data Standardisation Framework, which was developed to provide a structured and transparent approach to data standardisation across the network. The framework aims to strengthen interoperability, improve governance, clarify responsibilities, and establish closer alignment between standards development and implementation planning.

During the discussion, the following comments were noted:

- It was agreed that, following the public consultation, the drafting group will consider introducing a feedback and monitoring mechanism to evaluate the effectiveness of the framework and capture lessons learned from its implementation (**Action EMA**). Members also noted that the proposed framework approach is now being tested in practice through the ongoing ICH M16 implementation.
- The framework should also specify that existing EU artefacts will be used to support the implementation of upcoming standards.
- The draft framework will be updated to explicitly clarify its applicability to both human and veterinary medicines.
- It was clarified that consultation on a specific standard with relevant working parties and other subject matter experts will be conducted on an ad hoc basis, depending on the standard and its stage of development. A small group of subject matter experts will determine which stakeholders to consult and at what stage of the process.

Members welcomed the proposal and considered it a mature document suitable for public consultation. It was agreed that the drafting group will update the draft data standardisation framework document to reflect the meeting comments and send it out for final feedback, allowing 48 hours for any last

comments before launching public consultation. **Action EMA:** Nick Halsey to coordinate the updates and consultation process.

### 3. NDSG 1<sup>st</sup> orientation on Data analytics Framework

Jacobus van Wyk (EMA) presented the key elements to be included in the draft of the Data Analytics Framework and outlined its vision, objectives, guiding principles, and process. The framework's vision is to unlock the value of data for stakeholders, with short-term objectives including enabling modern analytics, self-service dashboards and ethical governance, and long-term goals of increasing analytics maturity, interoperability and continuous improvement across the network.

The framework is based on principles of structured, repeatable analytics identification, mapping requirements against use cases, driving network-wide maturity and iterative improvement. It includes process steps covering analytical need identification, capability mapping, gap assessment, solution options, monitoring and continuous improvement.

The group welcomed the initial proposal for the Data Analytics Framework and during the discussions highlighted several areas for further development:

- A more explicit reference to the data protection considerations should be added.
- Questions were also raised regarding the scope of the framework, and the need to clarify the use cases (distinction between business and regulatory analytics), as well as the relationship with existing initiatives.
- The need to avoid duplication and ensure alignment with other framework documents was flagged as important. The group supported the development of a visual overview illustrating how the various workstreams and deliverables interconnect. **Action:** NDSG secretariat.
- The group discussed the potential need for some form of catalogue of analytics capabilities and existing solutions to support knowledge sharing and reuse across the network. While specific metrics for monitoring the framework have not yet been developed, the drafting group confirmed that these will be addressed during the next phase of work.

The NDSG group supported the proposed vision, objectives and principles and agreed for the drafting group to continue development of the framework for future discussion. **Action EMA** to coordinate the updates and finalisation of the drafting of the data analytic framework.

### 4. NDSG 1<sup>st</sup> orientation on EMRN data asset catalogues

Jos Olaerts (EMA) presented the initial draft of the EMRN Data Asset Catalogue, developed to support the Network Data Strategy objective to establish a comprehensive inventory of network data assets. The proposed catalogue aims to provide visibility of available Network data assets, support analytics and regulatory activities and facilitate future data governance activities across the network. The presentation outlined the proposed definition of a network data asset, inclusion and exclusion criteria, governance roles, metadata elements and the process for maintaining and expanding the catalogue.

Several suggestions were proposed during the discussions:

- To add a reference to the pharmacovigilance and inspection-related data assets within the inclusion criteria.

- To clarify the relationship with existing real-world data catalogues and exclusion criteria to avoid confusion for users.
- To ensure that the document clearly specifies the access considerations applicable to network data assets.
- To consider where the topic of data products is best situated; within the data analytics framework or already as part of this catalogue?
- Consider adding data provenance or origin information as a metadata element to help users assess fitness for analytics purposes.
- It was agreed to follow a phased approach, starting with a practical first version focused on identifying and cataloguing network data assets and ownership information.

The group endorsed the proposed approach and agreed to conduct additional review of the draft EMRN Data Asset Catalogues by 14 August 2026. Following incorporation of feedback, a revised version will be presented to NDSG later in the year for adoption.

**Action:** The NDSG Secretariat to launch a dedicated consultation with the NDSG on the draft EMRN Data Asset Catalogues and the review of network-level data assets, with comments requested by close of business on 14 August 2026.

**Action EMA:** Jos Olaerts to organise one further drafting group meeting in September to finalise the second version of the catalogue.

**Action EMA:** Jos Olaerts to consult colleagues at the European Commission dealing with the European Health Data Space (EHDS) to ensure alignment and awareness where necessary.

**Action:** The NDSG Secretariat to circulate a save-the-date announcement to NDSG members for the EHDS workshop planned for January 2027.

## **5. Progress update on AI and Data training strategy in line with the EU NTC framework**

Marianne Van Heers (EMA) presented an update on the AI and Data training strategy and its alignment with the EU Network Training Centre (UNTC) framework. The presentation outlined the development of the EUNTC learning maps, presented the mapping of historical 'big data' curricula, summarised the key outcomes of the mapping exercise and described the planned next steps. In addition, the group noted the feedback received from Momir Radulovic, which highlighted capability mapping as an important bridge between network needs, IncreaseNET deliverables, and future training investments.

The discussion highlighted both the value and complexity of developing common capability frameworks across the network.

The NDSG members also stressed the importance of ensuring that training remains closely linked to practical regulatory needs and that opportunities to leverage existing external expertise and training resources are fully explored. Some clarifications were requested regarding the governance arrangements, ownership of learning maps and referencing to the Methodology Working Party. It was noted that further work and alignment is needed in all areas pointed out by the group, and that the document will be made available for comments at the end of summer.

## **6. A.O.B.**

### **ADR data quality framework: status and information about Network consultation**

Tom Paternoster-Howe (EMA) provided a brief update on the Adverse Drug Reaction Data Quality Framework (DQF). Following substantial revision in response to previous feedback, the document has undergone extensive consultation with relevant expert groups and is now subject to a second round of network consultation. The NDSG members were invited to provide comments by 14 August 2026, with the intention of presenting a final version to NDSG in September for approval and subsequent public consultation.

**Action:** NDSG secretariat to circulate the updated version of Adverse Drug Reaction DQF to NDSG for comments by 14 August 2026.