

14 May 2025
EMA/156282/2025

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

30 April 2025, 10:00-12:00pm, Webex

Co-Chairs: Karl Broich (HMA), Peter Arlett (EMA)

| Item | Preliminary draft agenda | Presenters / Discussants | Action | Time |
|------|--|--|------------------------|------|
| 1. | Adoption of the draft agenda & minutes | Karl Broich, Peter Arlett | For adoption | 10' |
| 2. | Product Master System: Strategic recommendations for PMS implementation and data management | Speaker: Isabel Chicharo Discussants: Aimad Torqui, Georg Neuwirther, Pelle Persson, Harald von Aschen, Hilmar Hamann | For adoption | 50' |
| 3. | The draft EMRN Data Strategy | Georg Neuwirther, Nick Halsey | For discussion | 45' |
| 4. | A.O.B. NDSG workplan HMA and EMA MB endorsement | All Francois Domergue | For discussion | 15' |

| Role | Name |
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| Attendance | Peter Arlett (EMA), Karl Broich (BfArM, DE), Angelo Molinaro (AIFA, IT), Ana López de la Rica Manjavacas (AEMPS, ES), Flora Musuamba Tshinanu (SAWP), Georg Neuwirther (AGES, AT), Harald von Aschen (BfArM, DE), Patricia McGettigan (PRAC), Pelle Persson (MPA, SE), Hilmar Hamann (EMA), Laure Baduel (CVMP), Isabel Chicharo (EMA), Claus Møldrup (DKMA, DK), Dag Jordbru (NOMA, NO), Dmitry Etin (EMA), Aina Staisiuniene (EMA), Francois Domergue (EMA), Vincent Gazin (ANSM, FR), Eleonora Agricola (EU-IN), Edurne Lazaro (AEMPS, ES), Nick Halsey (EMA), Hans-Joachim Bigalke (EDQM), Jeromme De Baros (EC), Kaisa Immonen (EMA), Joerg Zinserling |

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| | (BfArM, DE), Kimmo Porkka (EHA), Florian Klinglmueller (AGES, AT), Konstantina Boumaki (EPF), Kristin Karlsson (MWP), Niklas Hedberg (HTA), Francisco Penaranda (EMA), Pedro Pina Ferreira (EMA), Patrice Verpillat (EMA), Rico Slingerland (CMDv), Beyhan Mustafov (EMA). |
| Apologies: | Katrien Oude Rengerink (CBG-MEB, NL), Anne Cambon-Thomsen (CNRS, FR), Paul Lynn (EMA), Gabriel Westman (MPA, SE), Vaia Apostolidou (EC), Julien Delaye (Eurordis), Jacobus van Wyk (EMA), Marianne Lunzer (AGES, AT), Paolo Alcini (EMA), Ana Cochino (EMA), Kaisa Immonen (EMA), Christina Kyriakopoulou (EC), Carla Torre (CHMP), Aimad Torqui (MEB, NL), Johanna Seppänen (THL, FI), Pier Paolo Olimpieri (AIFA, IT), Sandra Bertulat (BVL, DE (vet)), Markus Kalliola (SITRA, FI), David Asturiol (EC), Bruno Delafont (CHMP), Siobhán O’Sullivan (Ethics) |
| Administrative support and minutes | Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA). |

1. Adoption of the draft agenda & minutes

The draft agenda was adopted. The draft minutes from the 31st March meeting were adopted as final.

Two new NDSG members were welcomed into the group: Niklas Hedberg (HTA representative) and Siobhán O’Sullivan (Ethics representative).

2. Product Master System: Strategic recommendations for PMS implementation and data management

Isabel Chicharo (EMA) presented the updated high-level guiding principles (NDSG recommendations) paper for human Product Master Data implementation and data management. The updated draft incorporated feedback received from NDSG members during a written consultation, which was launched to the group on 14 April 2025, and the key comments were discussed at the meeting.

The paper includes the current status, opportunity for change, guiding principles for product master data implementation and data management, approach for delivery and benefits delivered by the proposal. The strategic goal of this paper is to achieve a shared centralised repository of human medicinal product information at EU level, supporting the product data lifecycle via a unified entry point and format for initial and subsequent product data submissions.

Notably, the key recommendations in the paper include:

- The NDSG recommendation for a step-wise delivery approach that will include a first transitional step enabling the submission of product master data in ISO IDMP/FHIR format under the Article 57 legal basis, with discontinuation of XEVMPD once consuming systems have been repointed to PMS. Ultimately, integration with the regulatory processes is the goal, with structured medicinal product data submitted throughout the regulatory lifecycle. In addition, national systems would be connected incrementally, depending on individual member states needs and priorities.
- The HMA/EMA ROG recommendation for data quality to be ensured following an agreed validation / qualification process and the NDSG recommendation for various models of NCA involvement to be considered to address the diverse demands, capabilities and capacities of the NCAs. The EMA/HMA

ROG feasibility study will inform on the data quality models for the NCAs and any involvement of MAHs and Sponsors.

Subject to implementation of some editorial changes agreed at the meeting, the NDSG recommendations paper entitled 'Medicinal Product master data for better regulation and better health' was adopted by the group. As the next step, a written consultation for endorsement will be launched to HMA and EMA Management Board.

Action: NDSG secretariat to circulate the adopted version to the group in the post meeting mailing.

3. The draft EMRN Data Strategy

Georg Neuwirther (AGES, AT) and Nick Halsey (EMA) gave a status update of the European Medicines Regulatory Network (EMRN) Data Strategy development, presented feedback received from the public consultation and introduced the strategic goals and actions/deliverables included in the draft paper.

The drafting of the document has been initiated under the former HMA EMA Big Data Steering Group and Network Data Board, and a 2-month public consultation was conducted in late 2024. The draft strategy was updated to incorporate received comments (19 responses/94 comments were received), to align with the NDSG vision and scope, and to follow the European medicines agencies network strategy 2028 structure.

This document will be a key vehicle to deliver the actions from the [EMANS to 2028](#), Theme 2 Leverage data, digitalization and AI. The key strategic goals of the document include:

- Data governance
- Data quality Management
- Interoperability
- Data cataloguing and metadata management
- Knowledge and change management
- Value of data through analysis and use of tools.

The group noted that several important items to implement the EMRN data strategy have already been included in the [NDSG workplan](#) and further review of implementation actions and alignment with the workplan will be scheduled at a future NDSG meeting, once this document has been finalised and adopted.

As the next step, a written consultation of the draft-final EMRN Data Strategy will be launched to NDSG. To support the group's review, a summary of the key goals and actions should be provided, including a mapping of the implementation items already incorporated in the NDSG workplan and the proposed key actors for implementation (**Action:** Nick Halsey).

Once adopted by the group (at a future NDSG meeting), the document will be submitted for endorsement to HMA and EMA Management Board.

4. A.O.B.

Francois Domergue (EMA) informed the group that the NDSG workplan was endorsed by EMA Management Board in April, following a written consultation. A parallel written consultation (for endorsement) was also conducted with HMA, from which one set of comments on the NDSG workplan (AI workstream) was received from the Belgian Agency. Most of these comments had already been

addressed and incorporated in the workplan, with some additional editorial clarifications added. The group agreed with the proposed resolution of the comments and requested Flora Musuamba Tshinanu to coordinate with the relevant Belgian colleagues to provide a response outlining the comments resolution.

Peter Arlett (EMA) informed the group that a call for volunteers will be launched to NDSG members, to participate in the review of two training modules that will be developed as part of the Data Science curriculum: Data Quality and Omics Data (**Action:** NDSG secretariat). The input from the group is particularly important to ensure that curriculum is regulatory focussed and is addressing the training needs of the network.