

22 July 2025
EMA/198426/2025

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

27 June 2025, 13:30-15:30pm, Webex

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.	The draft EMRN Data Strategy	Georg Neuwirth, Nick Halsey	For adoption	20'
3.	ICH Structured Product Quality Submissions (SPQS)	Nick Halsey	For discussion	40'
4.	NDSG change management strategy	Aina Staisiuniene Discussant: Eleonora Agricola	For agreement	30'
5.	AI observatory report	Laurent Brassart	For discussion	20'
6.	A.O.B. Sixth EMA/HMA Big Data Stakeholder Forum: call for volunteers to join a programme committee	All		5'

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Harald von Aschen (BfArM, DE), Hilmar Hamann (EMA), Florian Klinglmueller (AGES, AT), Siobhán O'Sullivan (Ethics), Anne Cambon-Thomsen (CNRS, FR), Gabriel Westman (MPA, SE), Aina Staisiuniene (EMA), Francois Domergue (EMA), Vincent Gazin (ANSM, FR), Eleonora Agricola (EU-IN), Ana López de la Rica Manjavacas (AEMPS, ES), Joerg Zinserling (BfArM, DE), Aimad Torqui (MEB, NL), Angelo Molinaro (AIFA, IT), Vaia Apostolidou (EC), Carla Torre (CHMP), Laure Baduel (CVMP), Claus Møldrup (DKMA, DK), Jacobus van Wyk (EMA), Dmitry Etin (EMA), Edurne Lazaro (AEMPS, ES), Luis Pinheiro (EMA), Hans-Joachim Bigalke (EDQM), Katrien Oude Rengerink (CBG-MEB, NL), Pedro Pina Ferreira (EMA), Julien Delaye (Eurordis), Kristin Karlsson (MWP), Konstantina Boumaki (EPF), Paul Lynn (EMA), Marianne Lunzer (AGES, AT), Patricia McGettigan (PRAC),

	Pelle Persson (MPA, SE), Francisco Penaranda (EMA), Patrice Verpillat (EMA), Marianne van Heers (EMA), Vittoria Abgnale (EMA), Niklas Hedberg (HTA).
Apologies:	Flora Musuamba Tshinanu (SAWP), Georg Neuwirther (AGES, AT), Dag Jordbru (NOMA, NO), Jerome De Barros (EC), Kimmo Porkka (EHA), Rico Slingerland (CMDv), Beyhan Mustafov (EMA), Paolo Alcini (EMA), Kaisa Immonen (EMA), Christina Kyriakopoulou (EC), Pier Paolo Olimpieri (AIFA, IT), Sandra Bertulat (BVL, DE (vet)), Markus Kalliola (SITRA, FI), 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 draft minutes from the 28th May meeting were adopted as final. Three new NDSG members were welcomed into the group: Jerome de Barros, replacing David Asturiol from EC, Marta Slomka (Payers representative) and Javier Martinez Arribas (Payers representative - alternate).

2. The draft EMRN Data Strategy

Georg Neuwirther (AGES, AT) and Nick Halsey (EMA) presented the draft Network Data Strategy, highlighting the main changes implemented in the final draft document and proposed amendments. The Strategy is a key deliverable of the [NDSG workplan 2025-2028](#), which has been drafted with input from the experts from the Network (the former Big Data Steering Group, the Network data board and the Network data steering group) and stakeholders (via a public consultation in 2024).

The Strategy sets out a number of principles and strategic goals to ensure the EMRN data assets meet high quality standards, are appropriately managed, standardised, easy to share and to use for regulatory decision-making and the benefit of public health. The scope of the Strategy is focused on Network data assets that are shared between Medicines Agencies, such as regulatory submissions data, master data (e.g. substance, product, organisation and referential (SPOR)) and healthcare data (e.g. spontaneously reported adverse drug reactions; clinical trials data from CTIS).

The NDSG adopted the EMRN Data Strategy and noted that oversight of the Strategy implementation will be undertaken by NDSG, also acknowledging that most of the activities to implement the EMRN Strategy have already been included in the NDSG workplan.

As the next step, the EMRN Data Strategy will be submitted for endorsement to the HMA at their next meeting in September and EMA Management Board in October. Following the endorsement by both bodies the Strategy will be published on the EMA and HMA websites. Additionally, NDSG supported several communication initiatives to promote the strategy's visibility, including webinars introducing the EMRN Data Strategy and its goals (targeting EMA, NCAs, ROG and Portfolio Board), as well as the collection of feedback on its implementation status.

The conduct of survey will be considered, to EMRN members to gain insights into how data governance is being performed at a local level and identify how NDSG can further support the EMRN, (**Action:** Nick Halsey).

3. ICH Structured Product Quality Submissions (SPQS)

Nick Halsey (EMA) presented the background terminology, flagged the revision of the ICH M4Q guideline, highlighted the IT systems and data assets that may be affected by the ICH SPQS (ICH M16) topic, and discussed the requirements for an EU expert that needs to be appointed to participate at the ICH SPQS Expert Working Group as well as a pathway to identify one.

ICH M16, also known as “Structured Product Quality Submissions” aims to harmonise international standards for structured data in the quality part of the CTD and will complement the on-going work on the revision of ICH M4Q (eCTD module 3, quality). As the next step for the ICH M4Q revision process, the EU delegation need to be formed to represent EC at the ICH meetings. It was noted that there is one nomination so far received for the EU expert (assessment expert from BfArM) and an additional EU expert (data and standards expert) to assist with conceptual data modelling and structuring information, and to develop the data exchange for SPQS, is needed. A call to the Network will be launched shortly, and the establishment of a group of experts to support the ICH participants will be either addressed at a later stage or included in the same call for expression of interest.

Action: EMA colleagues to launch a dedicated call to NDSG and HMA, to identify a technical expert to support the ICH SPQS. The call will clearly specify the requirements for this role.

Action: NDSG secretariat to plan a regular status update at NDSG on ICH M16 topic, as relevant.

4. NDSG change management strategy

Aina Staisiuniene (EMA) presented the high-level change management approach to support implementation of the NDSG workplan and sought to re-confirm the NDSG priority areas for change management. The change management strategy is built around 3 pillars: communication, engagement and knowledge & expertise building, with the main change management activities detailed in the delivery plan until the end of 2026.

The group endorsed the change management strategy approach and reiterated that artificial intelligence, real world evidence, product master data/services and clinical study data remain the NDSG priority areas, and these can be expanded going forward.

Action: NDSG secretariat will launch a dedicated written consultation with NDSG members on how to reach out and engage NCAs assessors.

5. AI observatory report

Laurent Brassart (EMA) presented the Artificial Intelligence (AI) observatory report for 2024, compiling information on use of AI in medicine lifecycle. The report was created as part of the HMA-EMA Big Data Steering Group 2023-2028 Multi-annual AI workplan deliverable, with the objective to capture and share experience and trends in AI to inform the EU Network for the implementation of its multi-annual AI workplan. The report includes two annexes: compilation of 2024 experience and review of AI/ML applications in medicines lifecycle. As the next step, the report will be published on the dedicated EMA and HMA websites and shared with the EMA Management Board and HMA.

The group welcomed the report and provided the following feedback for consideration for future reports:

- Share this experience more widely within the Network and broader range of stakeholders (e.g academia).

- Prior to publishing the 2024 report, a thorough check should be performed not to disclose any commercially confidential information.
- Review of literature could be supported through a network peer-review to improve comprehensiveness.
- Explore the inclusion of AI in clinical trial applications for future reports.
- Consider structuring the report according to different stages of the life cycle and use cases.
- Going forward, explore different means for advertising report (e.g. scientific publication etc).

6. A.O.B.

Karl Broich (BfArM, DE) informed the group that a dedicated call for volunteers to join the programme organising committee for the upcoming annual Big Data Forum will soon be issued to NDSG members.