

21 April 2026  
EMA/88790/2026

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

15 April 2026, 09:30-11:30am, 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 on delivery of AI activities: Delivery of AI solutions for the EMRN: planning for an EMRN prompt community pilot	Joaquim Jornet Berenguer	For information	15'
3.	EMRN data standardization framework (v), Workflow and decision-making process	Nick Halsey  Discussants: Ana Lopez de la Rica	For discussion	25'
4.	Review of Biostatistics and Modelling & Simulation methods: consolidated considerations	Katrien Oude Rengerink, Flora Musuamba Tshinanu  Discussants: Florian Klinglmueller, Joerg Zinserling, Frank Petavy	For discussion	25'
5.	Analysis of clinical study data: progress update on pilot and on change management activities	Stefanie Prilla  Discussants: Katrien Oude Rengerink, Florian Klinglmueller, Kristin Karlsson, Flora Musuamba Tshinanu	For discussion	25'
6.	A.O.B.  <ul style="list-style-type: none"> <li>Call for volunteers for the review of innovative methodologies and data type</li> <li>Call for volunteers for AI &amp; Data forum programme committee</li> </ul>			

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Harald von Aschen (BfArM, DE), Claus Møldrup (DKMA, DK), Kristin Karlsson (MWP), Dag Jordbru (NOMA, NO), Anthony Oshea (EDQM), Aina Staisiuniene (EMA), Joerg Zinserling (BfArM, DE), Patricia McGettigan (PRAC), Gianmario Candore (EMA), Tomas Lundqvist (MPA, SE), Katrien Oude Rengerink (CBG-MEB, NL), Flora Musuamba Tshinanu (SAWP), Stefanie Prilla (EMA), Pelle Persson (MPA, SE), Jacobus van Wyk (EMA), Laure Baduel (CVMP), Paul Lynn (EMA), Rico Slingerland (CMDv), Ivelina Gushlekova (CTCG), Gabriel Westman (MPA, SE), Vaia Apostolidou (EC), Nick Halsey (EMA), Edurne Lazaro (AEMPS, ES), Frank Petavy (EMA), Joaquim Berenguer (EMA), Steven Le Meur (EMA), Hilmar Hamann (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Angelo Molinaro (AIFA, IT), Vincent Gazin (ANSM, FR), Konstantina Boumaki (EPF), Anastasia Pagida (EC), Florian Klinglmueller (AGES, AT), Jerome De Barros (EC), Eleonora Agricola (EU-IN), Paolo Alcini (EMA), Carla Torre (CHMP), Stefanie Prilla (EMA).
Apologies:	Anne-Marie van Nederkassel (EMA), Anabela Marcal (EMA), Francisco Penaranda (EMA), Momir Radulovic (Jazmp, SI), Georg Neuwirther (AGES, AT), Marta Slomka (Payers), Siobhán O’Sullivan (Ethics), Christina Kyriakopoulou (EC), Christopher Javris (EDQM), Sandra Bertulat (BVL, DE (vet)), Javier Martínez Arribas (Payers), Kaisa Immonen (EMA), Aimad Torqui (MEB, NL), Markus Kalliola (SITRA, FI), Niklas Hedberg (HTA), Pier Paolo Olimpieri (AIFA, IT), Kimmo Porkka (EHA), Patrice Verpillat (EMA), Pero Ivanko (CIPH, HR), Alessandro Blasimme (Ethics representative), Michael Vogl (EMA), Bruno Delafont (CHMP).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

## 1. Adoption of the draft agenda & minutes

A minor adjustment to the agenda was noted, with the planned discussion on AI guidance development postponed to a future NDSG meeting to allow further preparatory discussions. The draft agenda was adopted. The minutes of 9<sup>th</sup> March 2026 NDSG meeting were adopted as final.

## 2. Update on delivery of AI activities: Delivery of AI solutions for the EMRN: planning for an EMRN prompt community pilot

Joaquim Berenguer (EMA) provided an update on the delivery of two workplan items under the Tools and Innovation swimlane (Artificial Intelligence workstream), with a particular focus on planning a pilot for an EMRN prompt community. The planned pilot will be conducted initially at EMA (running in Q1 and Q2) and will focus on a single use case - quality assurance in assessment reports. The objective is to test the feasibility of a prompt community model, generate practical experience, and identify governance, technical and resourcing implications before considering any expansion to network level. The lessons learned from the EMA pilot will be presented to NDSG in Q3 2026, together with a proposal for possible next steps.

The NDSG group members raised questions about technical dependencies, system access for network assessors, and the financial implications of providing AI systems network-wide. The discussion clarified

that the pilot's outputs will be embedded in regulatory systems for network use, but careful evaluation and resource planning will be required. The group agreed that clearly defined success criteria and a structured evaluation approach are essential for the pilot. It was noted that statisticians should be involved in designing the pilot evaluation approach, and that input from assessors is required to validate the AI prompt-generated reports in the pilot.

The NDSG supported the phased approach for the prompt community establishment and agreed to proceed as planned, with an emphasis on providing a structured evaluation of the pilot and its success, and early involvement of assessors and methodologists.

**Action:** Joaquim Berenguer to develop a structured evaluation framework for the AI Prompt Community pilot, including clearly defined performance metrics and methodologies for assessing success. The framework will be presented to the NDSG as part of the EMA prompt community pilot results in Q3 2026 and as a pre-requisite to start the EMRN prompt community pilot.

### **3. EMRN data standardization framework (v), Workflow and decision-making process**

Nick Halsey (EMA) presented the proposed EMRN data standardisation framework, which builds on principles agreed by the NDSG in October 2025. The framework aims to provide a clear and transparent governance structure for assessing, prioritising and coordinating data standardisation activities across the network, including engagement with standard development organisations (SDOs) such as ICH, ISO, HL7 and others.

The framework introduces a high-level process for handling both internal (Network) proposals and external proposals received from international partners or SDOs. It clarifies roles and responsibilities, proposes a structured approach to prioritisation, and seeks to improve coordination between standard development and IT implementation to shorten implementation timelines. The document includes templates for proposal submission and assessment. In addition, it proposes establishing an expert community for standards development, regular monitoring of relevant standards, and maintaining a catalogue of standards and contact points.

NDSG members welcomed the proposal and provided the following feedback:

- It is important to keep the process simple and avoid unnecessary administrative burden, given limited availability of expert resources across the network.
- It was noted to include additional information on adopting and implementing an existing standard. This will cover the option to run a pilot implementation before deciding on moving to full implementation.
- Consider launching a public consultation prior finalising the document within the Network.

Post meeting note: It was agreed to launch a public consultation over the summer to collect stakeholder input before finalising the document.

- There is a need to consider change management aspects, which are currently included as part of the Agile governance process for implementation phase.

As a next step, the framework document will be finalised for NDSG consultation, followed by a public consultation and finally adoption of the framework planned for Q4 2026-Q1 2027.

#### **4. Review of Biostatistics and Modelling & Simulation methods: consolidated considerations**

A consolidated overview of key considerations from previous discussions on biostatistics and modelling & simulation methods was presented by Katrien Oude Rengerink (MEB, NL) and Flora Musuamba Tshinanu (SAWP). The presentation summarised feedback from the previous NDSG meeting and follow-up expert discussions.

Bayesian methods and evidentiary standards were prioritised within the biostatistics methods area, while paediatric extrapolation was identified as a priority topic for modelling and simulation.

The consolidated 'main' considerations focused on the establishment of mentoring systems and the creation of topic-focused foresight groups (for Biostatistics), and enhanced multidisciplinary collaboration and strengthened training and knowledge-sharing activities (for M&S).

A multi-stakeholder workshop on pediatric extrapolation is proposed for 2027, with the objective of using this topic as a high-impact use case for the implementation of new ICH guidelines and for strengthening expertise and consistency across the Network.

Both domains highlighted the need for more specialised expertise, with suggestions to escalate resource requirements to senior Network management.

'Secondary' considerations also focused on training development, data/tools, guidance and regulatory science research. It is proposed to address them by leveraging planned EMRN activities and NDSG deliverables (e.g. establishment of the EMRN data analytic framework, inclusion of the development of targeted training for assessors and the integration of biostatistics and methodological topics into assessor events.)

The group welcomed the update and supported the proposed approach for both domains, which focused on practical and implementable solutions. Many synergies were identified between the two areas, and the key considerations were noted to be multidisciplinary rather than area-specific. As a next step, the key considerations will be validated with MWP and relevant SIAs of the MWP ESEC, and the table of key considerations (opportunities and challenges) will be maintained by the relevant SIAs of the MWP ESEC to inform the future workplan updates of the MWP and the NDSG.

**Action** (NDSG secretariat): It was agreed to consolidate the considerations on expertise and resource needs arising from the biostatistics and modelling & simulation domains, together with relevant considerations from the additional NDSG reviews planned for 2026, into a single report for submission to the HMA and the EMA Management Board in late 2026, co-sponsored by the MWP and the NDSG. This should be drafted in the context of the preparation of the implementation of the revised pharmaceutical strategy for Europe. The report should be submitted to HMA Management Group before being submitted to HMA and the EMA Management Board.

**Action** (NDSG secretariat): It was agreed to organise a multi-stakeholder workshop on pediatric extrapolation in 2027, in collaboration between NDSG and MWP. The NDSG secretariat to debrief with the NDSG/MWP co-chairs and relevant NDSG members to initiate the preparation of this workshop in 2026.

#### **5. Analysis of clinical study data: progress update on pilot and on change management activities**

Stefanie Prilla (EMA) presented an update on the ongoing clinical study data pilot, highlighting progress since the interim report and the preparatory work for the transition towards implementation under the

new pharmaceutical legislation (NPL). The NPL will introduce systematic requirements for the submission of clinical trial data in electronic format for most of the initial MAAs in the centralised procedures and will allow flexibility for regulators regarding the scope and purpose of data analysis.

The pilot has expanded, with additional procedures and increased participation from NCAs, and has demonstrated clear added value for regulatory assessments, including efficacy and safety evaluations, PK/PD modelling, and GCP oversight. The pilot will run until the end of 2026, after which it is expected to transition into NPL implementation. The planned activities for 2026 include a network-wide survey to collect NCAs' business requirements (to be launched in mid-April), tools and training needs, as well as a dedicated in-person workshop for the Network scheduled for 29 June 2026. The workshop will aim to share experiences, gather requirements, and inform planning for future guidance and IT development.

The NDSG welcomed the update and highlighted the need for a strategic discussion on resource allocation, prioritisation, and change management, which is expected to be addressed at the upcoming workshop.

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

The group was reminded of the ongoing calls for volunteers to review innovative methodologies and data types, and join the AI & Data Forum programme committee.

**Action:** NDSG secretariat to send email reminders to NDSG members requesting volunteers to review additional methodologies and data types, and to join the programme committee for the Q4 public workshop on AI and data.