

25 September 2025
EMA/309999/2025

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

16 September 2025, 10:00-12:00pm, 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.	Review of Methodology Working Party workplan	Kristin Karlsson	For discussion	20'
3.	Network skills and knowledge: <ul style="list-style-type: none"> Network collaboration on training development in AI NDSG approach and next steps for training development 	Marianne Van Heers	For discussion	20'
4.	Update on ROG PMS data qualification feasibility study	Georg Neuwirth	For Information	20'
5.	eHealth Network Guideline on ePrescription and eDispensation of Authorised Medicinal Products: Stakeholder Consultation in the context of the EHDS implementation	Isabel Chicharo	For Information	20'
6.	Agree the approach for review of: <ul style="list-style-type: none"> advanced or innovative methodologies (Biostat and M&S) data (Synthetic data & digital twins) 	Frank Petavy Discussants: Flora Musuamba Tshinanu, Florian Klinglmueller, Kristin Karlsson, Joerg Zinserling	For discussion	20'
7.	A.O.B.	All	For information	5'

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Harald von Aschen (BfArM, DE), Aina Staisiuniene (EMA), Angelo Molinaro (AIFA, IT), Alessandro Blasimme (Ethics representative), Ana Cochino (EMA), Anabela Marcal (EMA), Pedro Pina Ferreira (EMA), Hilmar Hamann (EMA), Christina Kyriakopoulou (EC), Claus Møldrup (DKMA, DK), Dag Jordbru (NOMA, NO), Dmitry Etin (EMA), Eleonora Agricola (EU-IN), Edurne Lazaro (AEMPS, ES), Flora Musuamba Tshinanu (SAWP), Florian Klinglmueller (AGES, AT), Frank Petavy (EMA), Gabriel Westman (MPA, SE), Georg Neuwirther (AGES, AT), Hans-Joachim Bigalke (EDQM), Ina Rondak (EMA), Isabel Chicharo (EMA), Jacobus van Wyk (EMA), Joerg Zinserling (BfArM, DE), Julien Delaye (Eurordis), Katrien Oude Rengerink (CBG-MEB, NL), Kristin Karlsson (MWP), Laure Baduel (CVMP), Mart Slomka (Payers), Marianne Lunzer (AGES, AT), Marianne van Heers (EMA), Michael Vogl (EMA), Patricia McGettigan (PRAC), Paul Lynn (EMA), Siobhán O'Sullivan (Ethics), Vaia Apostolidou (EC), Rico Slingerland (CMDv), Stefania Simou (EMA), Markus Kalliola (SITRA, FI).
Apologies:	Patrice Verpillat (EMA), Francisco Penaranda (EMA), Vincent Gazin (ANSM, FR), Pero Ivanko (CIPH, HR), Jerome De Barros (EC), Ana López de la Rica Manjavacas (AEMPS, ES), Carla Torre (CHMP), Pelle Persson (MPA, SE), Niklas Hedberg (HTA), Aimad Torqui (MEB, NL), Konstantina Boumaki (EPF), Kimmo Porkka (EHA), Kaisa Immonen (EMA), Pier Paolo Olimpieri (AIFA, IT), Sandra Bertulat (BVL, DE (vet)), 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 17th July 2025 meeting were adopted as final.

2. Review of Methodology Working Party workplan

Kristin Karlsson (MWP) presented the Methodology Working Party workplan for 2026-2028, which is being revised on an annual basis. The group was reminded of the MWPs strategic goals and presented the updates on guidance, training and workshop activities for the upcoming years. The group was asked to provide feedback on key opportunities and priorities in regulatory decision-making, as well as any potential gaps.

The following feedback was collected:

- For further input, MWP may want to consider reviewing relevant ongoing European collaborative projects (Horizon Europe) and their outputs.
- Ensure continuous alignment between NDSG and MWP workplans and planned activities.
Action: NDSG secretariat to organise a dedicated (offline) discussion with NDSG co-chairs and MWP representatives to explore how MWP activities can be elevated to NDSG planning and leveraged to give visibility to a wider range of stakeholders.

- MWP to consider including additional activities for the Clinical Study pilot initiative in the MWP workplan.
- Consider developing a signpost document or a tool to easily retrieve regulatory guidelines.
Action: Noting that tools are available to experts within the regulatory Network, NDSG secretariat to reflect on how to support stakeholders in navigating the complexity of the guidelines landscape.
- Any additional comments/feedback on the MWP workplan 2026-2028 should be sent to NDSG secretariat.

Action: NDSG secretariat to re-circulate the call for additional registrations for the HMA/EMA Mechanistic Models Workshop, which is scheduled to take place on 8-9 October 2025.

3. Network skills and knowledge

Marianne van Heers (EMA) gave an overview of the current NDSG workplan activities planned for the network skills and knowledge streamline, and presented an outline of the existing training curricula, current offerings and plans for future. A proposal to collaborate on training development, with particular focus on AI, was presented to the group.

The following feedback was captured during the group's discussions:

- There was a strong support for collaboration at the Network level to develop training, particularly in the area of AI methodologies and tools, to increase the Network's capabilities.
- The group agreed to align NDSG approach on training delivery with the EU Network Training Centre (NTC) methodology and framework. NDSG will continue to advise on training priorities and ensure the content is fit for regulatory purposes.
- Alignment with the already ongoing activities at EU (e.g. IncreaseNET programme) and national level is important, to leverage the existing trainings and avoid duplication of effort.
- The procurement of training content should be carefully considered, as there will be numerous AI training providers and a careful selection will be needed, so the training is valuable and addresses the Network's needs.
- NDSG agreed to establish an AI training curriculum in collaboration with the EU NTC and assigned MWP (with scientific expertise from the ESEC SIA on AI & data science) as an owner. Adequate support for the development and delivery of this activity, both in terms of resources and de-prioritisation of other activities, will be important.
- NDSG agreed to reassign ownership of the current training curriculum for Data Science from NDSG to MWP (with scientific expertise from the ESEC SIA on AI & data science).
- NDSG confirmed that MWP will own the current training curricula on RWE, Pharmacogenomics and Biostatistics.
- Prioritisation of delivery training modules for the Network will be needed. For AI, general AI literacy training has been flagged as top priority.
- Additionally, monitoring (post-training) on adherence to established policies and best practices will be important for AI use.

NDSG also endorsed the proposal to draft a short paper on Network collaboration on training development, with particular focus on AI, and submit this proposal to HMA at its November meeting. NDSG supported the development of the AI training curriculum, under the EU NTC leadership, and agreed to review the existing training curricula framework by the beginning of 2026.

4. Update on ROG PMS data qualification feasibility study

Georg Neuwirth (AGES, AT) informed NDSG about the activities undertaken by the ROG PMS subgroup to achieve the goal of PMS as a “Shared Repository of Trusted Medicinal Product Data”, with qualified and consistent data in PMS and national databases.

NDSG noted that a data qualification feasibility study will be launched shortly with the national competent authorities, with the aim to identify key challenges including an estimate of the required EMRN and industry effort to qualify and subsequently update PMS data, and to propose actionable recommendations towards EU-wide implementation.

The scope, timeframe and data elements included in the study were presented to the group. Following the study conduct, a report will be drafted, and results will be presented to NDSG and HMA in Q1 2026.

5. eHealth Network Guideline on ePrescription and eDispensation of Authorised Medicinal Products: Stakeholder Consultation in the context of the EHDS implementation

Isabel Chicharo (EMA) presented the background information on the European Health Data Space (EHDS) and the timelines for its implementation. The first implementing acts will be released in 2027, and preparatory works are underway.

Recently, the European Commission released artefacts for consultation on eHealth Network Guideline on ePrescription and eDispensation of authorised medicinal products, with a deadline for feedback to be provided by 15th September 2025. The EMA team, reviewed the documents and prepared technical comments, focusing on strategic alignment with existing guidelines and standards. An overview of proposed EMA comments was presented to the group, noting a strong recommendation to use PMS as a reference code system for medicinal products was proposed.

A clarification on the current proposal for the reference code system for medicinal products was sought. It was noted that the current draft Commission guideline does not provide detailed information and refers to a possibility of coexistence of several reference sources. A more detailed discussion may be required at a later stage on this and on implementation aspects.

Action: Vaia Apostolidou (EC) to share the presented slides with the relevant colleagues within EC.

6. Agree the approach for NDSG review of advanced or innovative methodologies and data

Frank Petavy (EMA) presented a proposal for agreement by the NDSG on an approach for review of advanced or innovative methodologies and data types for evidence generation. It is foreseen that one NDSG member will lead each review with support by relevant experts from EMA and the Network (e.g. relevant SIA (e.g. Biostatistics, M&S...), Working Party (MWP), NDSG members representing EMA scientific committees). The review should focus on different dimensions: resources, data, methods,

tools, use cases, training/knowledge sharing, research, guidance and international collaboration. Following the review, a presentation to NDSG will be prepared to discuss and identify recommendations and actions to address key challenges/gaps/opportunities for such methods/use of data types. These can later be considered for inclusion in the relevant workplans (e.g. NDSG, MWP).

The group agreed with the proposed approach and noted the following:

- Consider how the identified deliverables for future workplans can be aligned between NDSG and MWP workplans, due to different update timelines.
- A review should also include clear definitions and scope.
- A more detailed discussion on how to address data and methods (that are separated) may be needed and organised in the future.

Action: A dedicated call for volunteers to lead the first specific reviews will be launched after the September NDSG meeting (NDSG secretariat).

7. A.O.B.