10 October 2025
EMA/323786/2025

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

6 October 2025, 15:00-17:00pm, 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.	Guiding Principles of Good AI Practice in Drug Development • Update on AI terminology and glossary	Joerg Zinserling Discussant: Luis Pinheiro	For adoption	30’
3.	EMRN data standardisation framework - Approach, vision, objectives	Nick Halsey Discussants: Aimad Torqui, Georg Neuwirther, Pelle Persson, Hilmar Hamann, Harald Von Aschen	For discussion	30’
4.	Proposed HMA/EMA approach to support the use of Patient Registries for regulatory purposes	Kelly Plueschke Discussants: Carla Torre, Patricia McGettigan, Edurne Lazarro	For discussion	30’
5.	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), Pau Garcia i Morales (EMA), Patricia McGettigan (PRAC), Francisco Penaranda (EMA), Paul Lynn (EMA), Michael Vogl (EMA), Markus Kalliola (SITRA, FI), Marianne Lunzer (AGES, AT), Georg Neuwirther (AGES, AT), Dag Jordbru (NOMA, NO), Edurne Lazaro (AEMPS, ES), Claus Møldrup (DKMA, DK), Hans-Joachim Bigalke

	(EDQM), Jacobus van Wyk (EMA), Joerg Zinserling (BfArM, DE), Nick Halsey (EMA), Katrien Oude Rengerink (CBG-MEB, NL), Luis Pinheiro (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Pelle Persson (MPA, SE), Niklas Hedberg (HTA), Julien Delaye (Eurordis), Kimmo Porkka (EHA), Laure Baduel (CVMP), Stefanie Prilla (EMA), Kelly Plueschke (EMA), Gabriel Westman (MPA, SE), Patrice Verpillat (EMA), Florian Klinglmueller (AGES, AT), Anabela Marcal (EMA), Jerome De Barros (EC), Konstantina Boumaki (EPF), Dmitry Etin (EMA), Pero Ivanko (CIPH, HR), Marta Slomka (Payers), Hilmar Hamann (EMA), Frank Petavy (EMA), Pedro Pina Ferreira (EMA), Rico Slingerland (CMDv), Carla Torre (CHMP), Eleonora Agricola (EU-IN), Christina Kyriakopoulou (EC).
Apologies:	Alessandro Blasimme (Ethics representative), Ana Cochino (EMA), Flora Musuamba Tshinanu (SAWP), Isabel Chicharo (EMA), Kristin Karlsson (MWP), Siobhán O'Sullivan (Ethics), Vaia Apostolidou (EC), Vincent Gazin (ANSM, FR), Aimad Torqui (MEB, NL), 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 16th September 2025 meeting were adopted as final.

2. Guiding Principles of Good AI Practice in Drug Development

Joerg Zinserling (BfArM, DE) presented the final draft Guiding Principles of Good AI Practice in Drug Development to the group for endorsement. This set of guiding principles was co-developed with US Food and Drug Administration (FDA) to inform the use of AI for generating evidence across the medicinal product lifecycle. A temporary Drafting Group (tDG) has been established to work with FDA, with the EU side (facilitated through MWP) leading the drafting group and engaging in regular exchanges with the FDA to refine the content and wording. The collaboration with FDA also includes mapping and aligning the terminology used by both agencies, with the aim to reach consensus on terms, where possible.

The final draft guiding principles were widely consulted within the Network and input sought from various committees, working parties, the European Commission, and inspectors. The feedback was generally supportive with minor edits proposed. These principles were endorsed by CHMP on 6 October 2025 and if supported by NDSG, will be published during the week of 13th October 2025 and presented at the face-to-face ICMRA summit on 22nd October 2025.

The NDSG congratulated the temporary drafting group with this major achievement and endorsed the guiding principles, noting that these will be used as a scientific reference and that additional targeted guidance will be developed in the future.

3. EMRN data standardisation framework

Nick Halsey (EMA) provided an overview of the current data standardisation strategy, learnings and potential improvements for the new strategy and approach. The need for a more practical, framework-based approach was identified to improve coordination and implementation of the data standardisation strategy.

Background information on the standard organisations relevant for the EMRN and an overview of their processes (timeframe, resource needs, etc) were provided to the group to understand where NDSG processes could be aligned for data standardisation.

Nick Halsey then presented a proposal of a new data standardisation framework and action plan, which focuses on prioritising and reviewing the network involvement in various standardisation activities, coordinating the network input, and monitoring progress. The proposal includes a flowchart (a decision tree) for NDSG approval (prioritisation) of a new standard development or a revision of the already existing one. The data standardisation framework and action plan should also include specific considerations such as processes affected, relevant stakeholder consultation, IT system requirements, need for an EU implementation guide, regulatory process change, change management etc. The roles and responsibilities for the proposed approach was presented, with an example of an action plan to track milestones and resource allocation.

The group discussed the proposal and emphasised the importance of network alignment going forward, challenges for implementation and priority that dictionaries of substances and organisations are in place.

NDSG endorsed the proposal to draft a new data standardisation framework and action plan, and agreed to focus on processes, prioritisation, and resourcing.

Action: NDSG secretariat to launch a call for volunteers to NDSG members to support the drafting of the data standardisation framework and action plan, with the work starting in November 2025.

4. Proposed HMA/EMA approach to support the use of Patient Registries for regulatory purposes

Kelly Plueschke (EMA) presented the current HMA/EMA approach to support the use of patient registries for regulatory purposes and outlined the three-pillar strategy: providing guidance and training (including guidelines, templates, and training modules), engaging stakeholders through workshops and trilogues (regulators/registry holders/industry), and supporting evidence generation via advice, studies, and direct engagement with registry holders.

NDSG discussed on improving alignment, communication, and scaling up of registry engagement activities, noting the following feedback:

- Update the relevant EMA webpage to provide clarity on existing guidance for stakeholders, to increase visibility on support activities and to scale up engagement;
- Consider creating training videos for stakeholders on registry data and develop a dedicated training on the use of data for regulatory network. It is important to consider clinical trial experts, NCAs and HTA input when developing training materials;
- Consider developing practical guidance /points for consideration (for data to meet regulatory requirements) for registry holders, and proactively engaging with registries in anticipation of future regulatory needs (through NCAs);
- Explore the impact of the qualification procedure by looking at how and to which extent registered registries are used for regulatory purposes c;
- Consider establishing a Patient registries community (across the Network) with interested experts from NCAs.

5. A.O.B.

NDSG was informed about the upcoming meetings, noting that the December meeting will take place at EMA (hybrid) on 8 December 2025 and will be followed by the Annual Data Forum event on 9 December 2025. A reminder was issued to the group to express interest to participate in the review of biostatistics modelling, simulation, digital twins, and synthetic data.