4 April 2025
EMA/122343/2025

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

31 March 2025, 15:00-17:00pm, 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 data: • Feedback from the ROG PMS implementation operational group meeting • Learnings from the Veterinary Union Product Database (UPD) implementation • IDMP - Community of Expertise • NDSG workplan and next steps, including stakeholder engagement plans for 2025 Group discussion	 Georg Neuwirther Rico Slingerland, Paul Lynn Pelle Persson, Georg Neuwirther Francois Domergue, Ana Cochino All	For discussion	75’ 10’ 10’ 10’ 10’ 35’
3.	HMA/EMA Network Data Steering Group workplan 2025 to 2028 • Updates to NDSG workplan • Call for NDSG sponsors	Francois Domergue	For adoption	30’
4.	A.O.B.	All		5’

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Florian Klinglmueller (AGES, AT), Katrien Oude Rengerink (CBG-MEB, NL), Ana López de la Rica Manjavacas (AEMPS, ES), Vincent Gazin (ANSM, FR), Francois Domergue (EMA), Anne

	Cambon-Thomsen (CNRS, FR), Harald von Aschen (BfArM, DE), Eleonora Agricola (EU-IN), Kristin Karlsson (MWP), Aina Staisiuniene (EMA), Paul Lynn (EMA), Luis Pinheiro (EMA), Gabriel Westman (MPA, SE), Georg Neuwirther (AGES, AT), Edurne Lazaro (AEMPS, ES), Dag Jordbru (NOMA, NO), Angelo Molinaro (AIFA, IT), Vaia Apostolidou (EC), Pelle Persson (MPA, SE), Hans-Joachim Bigalke (EDQM), Flora Musuamba Tshinanu (SAWP), Laure Baduel (CVMP), Rico Slingerland (CMDv), Julien Delaye (Eurordis), Jacobus van Wyk (EMA), Francisco Penaranda (EMA), Pedro Pina Ferreira (EMA), Marianne Lunzer (AGES, AT), Paolo Alcini (EMA), Ana Cochino (EMA), Dmitry Etin (EMA), Kaisa Immonen (EMA), Patrice Verpillat (EMA), Konstantina Boumaki (EPF), Hilmar Hamann (EMA), Christina Kyriakopoulou (EC), Claus Bo Jorgenssen (DKMA).
Apologies:	Carla Torre (CHMP), Aimad Torqui (MEB, NL), Kimmo Porkka (EHA), Johanna Seppänen (THL, FI), Pier Paolo Olimpieri (AIFA, IT), Claus Møldrup (DKMA, DK), Joerg Zinserling (BfArM, DE), Patricia McGettigan (PRAC), Sandra Bertulat (BVL, DE (vet)), Markus Kalliola (SITRA, FI), David Asturiol (EC), Christopher Jarvis (partial attendance, EDQM), 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 4th March meeting were adopted as final.

2. Product master data

- Feedback from the ROG PMS implementation operational group meeting

Georg Neuwirther (AGES, AT) provided a short update on the Regulatory Optimisation Group (ROG) PMS implementation operational group activities, undertaken during the 1st quarter of 2025. The NDSG was reminded of the ROG PMS subgroup mandate, which aims to propose how to reach a desirable quality of PMS data (notably for legacy data) for identified use cases and to strengthen the trust of these data to enable their use for regulatory activities at national and EU levels.

To achieve the above, PMS data qualification is being considered by ROG PMS subgroup with involvement of NCAs regarding the data for nationally authorised products and that will follow a stepwise approach for implementation. As a next step a feasibility study (pilot) is being planned to assess the qualification process for product master data and to identify relevant data elements, NCA participants and EMA contact points.

The group welcomed the update and noted the alignment with the NDSG views, discussed at the previous NDSG meetings, to progress harmonisation of PMS implementation and use.

The group raised additional points for consideration by the ROG PMS subgroup:

- The models for NCA involvement in data quality / qualification will need to embrace the diversity of capacity between MSs.

- Establish a prioritised list of key use cases and prioritise data elements needed to support these use cases (e.g. core data elements required to support the use case for cross-border prescription, etc).
- Use of Clinical Trials Information System (CTIS) should be added as an addition PMS use case.
- The PMS Data Quality chapter, proposed in the NDSG workplan in Q3-Q4 2025, will also support discussion on PMS data quality.

- Learnings from the Veterinary Union Product Database (UPD) implementation

Paul Lynn (EMA) and Rico Slingerland (MEB, NL) presented the key learnings from the Veterinary Union Product Database (UPD) implementation and UPD data quality considerations. The group welcomed the update noting that a key success of UPD implementation was a clear communication and continuous improvement following a minimum viable product approach.

- IDMP - Community of Expertise

Pelle Persson (MPA, SE) presented the background information on the IDMP implementation journey and the key activities that were initiated through the UNICOM I project. It was highlighted that IDMP implementation status still greatly varies across different NCAs and to further support IDMP implementation at national level, HMA has agreed to establish an IDMP Community of Expertise (CoE). A call for nominations to join the IDMP Community of Expertise has been launched to national competent authorities, as well as to EMA.

Georg Neuwirther (AGES, AT) presented the key objectives of the IDMP CoE, noting that it will build on the UNICOM I project work. In collaboration between national and EMA experts, it aims to continue knowledge sharing, support further IDMP implementation across Europe, building infrastructure and discuss data harmonisation. A proposal for a NDSG - IDMP CoE liaison was presented.

- PMS: NDSG workplan and next steps, including stakeholder engagement plans for 2025

Francois Domergue (EMA) presented the proposed PMS deliverables to be included in the NDSG workplan 2025 to 2028, highlighting the joint efforts and alignment between NDSG and ROG PMS subgroup to progress PMS implementation. Ana Cochino (EMA) then summarised immediate next steps for PMS, together with the upcoming plans for Industry and Network engagement in 2025.

Additional clarifications were noted during the group discussions:

- The draft strategic recommendations for PMS implementation and data management will be presented for NDSG adoption in April. These will be drafted in collaboration with the ROG PMS subgroup. Having a common EU Network position on the high-level principles for PMS implementation, will enable discussions with other key stakeholders, notably industry. Further details on level of engagement/involvement and impact to stakeholders will need to be clarified, prior a wider consultation with stakeholders.
- The joint (ROG/NDSG) agreement on model for network working arrangements for PMS data management and the ROG data qualification pilot will aim to clarify roles and responsibilities for data quality checking and data qualification, and to discuss resource implications for the network. A high-level agreement is expected to be endorsed by NDSG/ROG in late 2025.

- The group agreed with the proposed workplan. The key PMS deliverables and indicated timelines may evolve overtime and will be updated as the work progresses.

3. Update to the NDSG workplan

Francois Domergue (EMA) presented the updates introduced to the draft NDSG workplan, building on the discussions at the NDSG meeting on 4 March 2025, including amendments to the key NDSG priorities for 2025. The detailed overview of each workstream area was presented, noting that specific veterinary aspects were highlighted in the work programme where relevant. The following changes to be considered for the final draft work programme:

- Include an additional 'Pharmacoepidemiology' milestone for Q3/Q4 2026 under methodology sub-swimlane in the Data analytics workstream.
- Provide further clarification of the 'Review' term in the narrative section for evidence generation sub-swimlane.
- Provide explanation on synthetic data and digital twins in the narrative section, specifying that such data are to be considered complementary to clinical data.
- The mandate document for the establishment of the industry group focussed on artificial intelligence should further clarify the targeted industry audience (pharma vs biotech vs technology).
- Include an additional 'Clinical Study data' milestone for 2026 under organisational and semantic interoperability swimlane in the Data interoperability workstream, to capture the need for NDSG recommendation on clinical trial data submission format.

The joint HMA/EMA Network Data Steering Group workplan 2025 to 2028 was adopted by the group. An HMA and EMA Management Board endorsement (through a 2-week written consultation procedure) of the NDSG workplan 2025 to 2028 will be launched in April. Following the anticipated endorsement by both boards, the Network Data Steering Group workplan 2025 to 2028 will be published on the dedicated EMA and HMA websites. The NDSG workplan will be updated on an annual basis.

A call for NDSG sponsors for the workplan activities/swim lanes will be launched via a written procedure after the meeting (**Action**: NDSG secretariat).

4. A.O.B.