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

4 March 2025, 13:30-15:30pm, 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.	NDSG vision on data for medicines regulation	Aina Staisiuniene	For adoption	10'
3.	Update to the NDSG workplan: • High level priorities for 2025 • Strategy and Governance • Data Analytics • Artificial intelligence • Interoperability • Stakeholder engagement and change management • Connecting MWP and NDSG workplans NDSG group discussion	Francois Domergue, Luis Pinheiro, Kristin Karlsson NDSG members discussion	For discussion	50'
4.	Product master data: • Feedback from the ROG PMS implementation operational group meeting • Interplay with the NDSG workplan	Aimad Torqui, Georg Neuwirther Peter Arlett	For discussion	25'
5.	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), Patricia McGettigan (PRAC), Flora Musuamba Tshinanu (SAWP), 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), Joerg Zinserling (BfArM, DE), Eleonora Agricola (EU-IN), Kristin Karlsson (MWP), Aina Staisiuniene (EMA), Paul Lynn (EMA), Claus Møldrup (DKMA, DK), Luis Pinheiro (EMA), Gabriel Westman (MPA, SE), Georg Neuwirther (AGES, AT), Edurne Lazaro (AEMPS, ES), Dag Jordbru (NOMA, NO), Pier Paolo Olimpieri (AIFA, IT), Angelo Molinaro (AIFA, IT), Vaia Apostolidou (EC), Johanna Seppänen (THL, FI), Pelle Persson (MPA, SE), Hans-Joachim Bigalke (EDQM), Laure Baduel (CVMP), Rico Slingerland (CMDv), Julien Delaye (Eurordis), Kimmo Porkka (EHA), Jacobus van Wyk (EMA), Francisco Penaranda (EMA), Pedro Pina Ferreira (EMA), Aimad Torqui (MEB, NL), Carla Torre (CHMP), Marianne Lunzer (AGES, AT), Paolo Alcini (EMA), Isabel Chicharo (EMA), Ana Cochino (EMA), Jerome De Barros (EC), Dmitry Etin (EMA), Aleksandra Dacic-Pilcevic (EMA), Kaisa Immonen (EMA), Lilia Luchianov (EC).
Apologies:	Sandra Bertulat (BVL, DE (vet)), Patrice Verpillat (EMA), Markus Kalliola (SITRA, FI), David Asturiol (EC), Christina Kyriakopoulou (EC), Christopher Jarvis (partial attendance, EDQM), Konstantina Boumaki (EPF), Hilmar Hamann (EMA), 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 January kick off meeting will be circulated for adoption via written procedure.

2. NDSG vision on data for medicines regulation

Aina Staisiuniene (EMA) presented the final version of NDSG vision statement, which was slightly amended for better readability and clarity. The NDSG vision 'Trusted medicines by unlocking the value of data' was adopted by the group. This vision statement will be included in various communication materials and presentations.

3. Update to the NDSG workplan

Francois Domergue (EMA), Luis Pinheiro (EMA) and Kristin Karlsson (MWP co-chair) presented the updates introduced to the draft NDSG workplan, building on the discussions at the NDSG kick-off meeting in January. The key (high-level) priorities identified for 2025 were also highlighted. The detailed overview of each workstream area was presented and the following amendments/changes were proposed for further consideration:

- Strengthening Network capabilities (empowerment) in the context of the EMRN Data Analytics strategy delivery and implementation was recognised as a priority (slide 3). Additionally, change management was highlighted as an important focus area. It was agreed to explicitly mention training and guidance, as well as stakeholder engagement and communication as key components (slide 3).

- Support to the implementation of the new Pharma legislation, EHDS and AI act was recognised as a key priority for 2025 and years to come.

- The NDSG workplan needs to include more explicit veterinary data domain activities.

- Consider incorporating additional deliverables to support implementation of electronic product information (ePI) provision, in anticipation of the new pharma legislation.

- Horizon scanning within the 'Strategy and Governance workstream' should focus on data and tools, while the Skills needs analysis will be addressed under the 'Stakeholder engagement and change management workstream', building on existing initiatives (e.g. IncreaseNet program).

- The final version of the workplan should include a detailed narrative for each workstream and its deliverables. Ethics should be integrated throughout the workplan and its deliverables. Operating within an ethical framework should be clearly captured in the introductory section of the workplan narrative. **Action**: NDSG secretariat to circulate the final draft work plan with narratives well in advance before the next meeting on 31st March 2025.

- Discussions on digital twins and synthetic data should be merged and brought forward in the timeline.

- The structure of the 'Analytics and capabilities' swim lane in the 'Data Analytic' workstream should be refined to reflect that its scope will cover discussions related to different types of data as well as analytical methods.

- A scoping session on Biostatistics methods should be included in the workplan for Q2 2025, as part of the 'Analytics and capabilities' swim lane.

- **Action**: NDSG secretariat to provide more information to the NDSG members representing the veterinary domain on the clinical study data pilot to scope applicability to the veterinary data domain.

- The wording of deliverables that are also included in other workplans, such as MWP workplan, should be consistent. These deliverables should be clearly identified in the NDSG workplan. Additionally, the narrative should highlight that cross-linked activities are not duplicative but rather aligned efforts.

- The benefits of having a protected 'test' environment for the development of AI tools to support the EU Network was discussed and acknowledged by the co-chairs noting that specific information technology delivery is under the authority of the Network Portfolio governance. In the context of the NDSG, data aspects will be further discussed as part of the AI tools framework deliverable.

- The deliverables related to industry interaction in the NDSG workplan should be reworded to specify that engagement with industry will be through groups focused on RWE, Clinical study data and AI.

- The 'Interoperability' workstream should be revised by adding more deliverables focused on implementation, as well as adding a future discussion on substance master data.

- The group noted that activities in the 'change management and stakeholder engagement' workstream will need to include all stakeholders, together with Patients' and Health Care Professionals', for training and capacity building.

- The 'draft ICH concept paper for structured product quality submissions' should be removed from the NDSG workplan as the agreement at ICH is not yet reached nor public.

- Close collaboration between Methodology Working Party and NDSG will be essential to ensure alignment and delivery of cross-linked activities between the two groups.

4. Product master data

The topic was postponed to the next meeting. The slides will be circulated to the group for information and further discussion at the next meeting (**Action**: NDSG secretariat).

5. A.O.B.