10 February 2025
EMA/46938/2025

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

28 January, 13:00pm – 18:00pm (CET time), 29 January, 08:30am – 13:00pm (CET time), Meeting room 0A, Webex

Co-Chairs: Karl Broich (HMA), Peter Arlett (EMA)

Item	Preliminary draft agenda	Presenters / Discussants	Action	Time
Day 1: 28 January 2025				
1.	Welcome and adoption of the draft agenda	Karl Broich/Peter Arlett	For adoption	15’
2.	Introductions of NDSG members	All		45’
3.	Setting the scene: • Background, modus operandi and key achievements • EMANS to 2028 • Legislative and regulatory update (EHDS and AI act) Group Q&A / discussion	 Peter Arlett Karl Broich David Asturiol All	For information	70’ 30’ 10’ 10’ 20’
4.	Delivering better public health through master product data • Introduction and role of NDSG • Benefits and uses cases of Master data • Current implementation status • Current implementation challenges • Roles and responsibilities and moving forward Front row comments	Isabel Chicharo / Ana Cochino Aimad Torqui / Pelle Persson / Hilmar Hamann	For discussion	90’ 30’ 30’

Item	Preliminary draft agenda	Presenters / Discussants	Action	Time
	Group discussion • Workplan proposed items • What are the priority use cases for the NDSG? • What are the views on the step-wise approach to achieving Target operating model? • Does NDSG agree we need detailed discussion on Data Quality and validation?	Peter Arlett (moderator) / All		30’
5.	Defining the NDSG vision on data for medicine regulation Break-out sessions • Group 1 • Group 2 • Group 3	Peter Arlett/Aina Staisiuniene Facilitators	For discussion Meeting room 0A Meeting room 0C Meeting room 0D	60’
6.	A.O.B.	All		5’

Item	Preliminary draft agenda	Presenters / Discussants	Action	Time
Day 2: 29 January 2025				
1.	Welcome (Day 2)	Karl Broich/ Peter Arlett		5’
2.	NDSG work planning: transversal areas • Structuring the work of the NDSG • Strategy and Governance • Stakeholder engagement	 Francois Domergue Francois Domergue Aina Staisiuniene	For discussion	50’
3.	NDSG work planning: specific areas • Introduction to break-out sessions Break-out sessions • Group 1: Data analytics • Group 2: Artificial Intelligence • Group 3: Interoperability	 Peter Arlett Facilitators	 For information Meeting room 0A Meeting room 0C Meeting room 0D	70’ 10’ 60’
4.	Feedback from break-out sessions • Data Analytics: group 1 report and discussion • Artificial intelligence: group 2 report and discussion • Interoperability: group 3 report and discussion	 Facilitator: Jacobus van Wyk Facilitator: Peter Arlett Facilitator: Hilmar Hamann	For discussion	105’
5.	Wrap up & close of the meeting	Karl Broich/Peter Arlett		15’

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), Joerg Zinserling (BfArM, DE), Eleonora Agricola (EU-IN), Markus Kalliola (SITRA, FI), David Asturiol (EC), Kristin Karlsson (MWP), Aina Staisiuniene (EMA), Paul Lynn (EMA), Claus Møldrup (DKMA, DK), Joaquim Berenguer Jornet (partial attendance, EMA), Nick Halsey (EMA), Luis Pinheiro (partial attendance, EMA), Gabriel Westman (partial attendance, MPA, SE), Christina Kyriakopoulou (EC), 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), Christopher Jarvis (partial attendance, EDQM), Laure Baduel (CVMP), Rico Slingerland (CMDv), Julien Delaye (Eurordis), Konstantina Boumaki (EPF), Kimmo Porkka (EHA), Jacobus van Wyk (EMA), Hilmar Hamann (EMA), Francisco Penaranda (partial attendance, EMA), Pedro Pina Ferreira (EMA), Aimad Torqui (MEB, NL).
Apologies:	Sandra Bertulat (BVL, DE (vet)), Patrice Verpillat (EMA), Carla Torre (CHMP), Harald von Aschen (BfArM, DE), Bruno Delafont (CHMP).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

Day 1 – 28 January 2025, 13:00pm – 18:00pm

1. Welcome and adoption of the draft agenda

The Co-chairs of Network Data Steering Group (NDSG) opened the meeting and welcomed participants representing National Competent Authorities (NCAs), European Commission (EC), EHDS community on secondary uses of health data, Health Data Access Bodies, EU Innovation Network (EU-IN), Network ICT Advisory Committee (NICTAC), European Directorate for the Quality of Medicines & HealthCare (EDQM), EU Patient and healthcare professional associations, ethic bodies, Regulatory Optimisation Group (ROG), European Medicines Agency and EMA committees' representatives.

The draft agenda for Day 1 was adopted.

2. Introductions of NDSG members

The group members introduced themselves, shared their background, expertise and expected contributions to the NDSG.

3. Setting the scene

Peter Arlett (EMA) introduced the NDSG mandate and presented key achievements from the Big Data Steering Group, the multi-annual Artificial Intelligence (AI) workplan to 2028, and feedback from the Network Data Board work planning discussions at their face-to-face meeting in October 2024. As part

of the setting the scene session, an update on the draft European Medicines Agencies Network Strategy 2028 (EMANS 2028) was provided by Karl Broich (BfArM, DE), highlighting the role of NDSG to deliver EMANS to 2028.

A legislative and regulatory update, focusing on EHDS and AI Act implementation timelines, was presented by David Asturiol (EC), which was complemented by an oral update from Vaia Apostolidou (EC) on the New Pharmaceutical Legislation (NPL).

Action: NDSG secretariat to schedule a more detailed discussion on the NPL and its impact on data-driven medicine regulation at a future NDSG meeting in 2025.

The following suggestions on the NDSG work planning were captured during the questions and answers session from the group members:

- To further promote the NDSG work and its deliverables, raise awareness and engagement within the Network through change management activities;
- Tools delivered should serve final users (including assessors) and address their needs;
- Understand and map the ongoing activities on data at the Network level and engage with relevant stakeholders, including industry;
- There are major opportunities to leverage clinical trial data for policy making and product development support;
- Enhance network collaboration across methodology domains.

4. Delivering better public health through master product data

Isabel Chicharo (EMA) presented background information on the master product data and focused on the product management services (PMS). It was noted that PMS currently supports the authorised products for human use with a vision to cover the whole product lifecycle in the future. An update on the current use cases, benefits for stakeholders, implementation status and current product data flow was provided to the group.

Ana Cochino (EMA) presented a proposal for a transitional step towards a future target operating model for product data and discussed challenges and opportunities to be leveraged. To strengthen PMS as central product data repository it will be important that XEVMPD for product data submissions is replaced by PMS, thus enabling the electronic application forms (eAF) integration with PMS (to deliver integration with regulatory submission). However, this will require that systems and processes that currently consume XEVMPD data will need to be aligned to the PMS data structure.

The NDSG continued the topic discussions with the specific feedback provided by the ROG, NICTAC and EMA representatives.

Aimad Torqui (MEB, NL) provided the regulatory optimization group (ROG) perspective, and noted that PMS was identified as a priority topic for ROG last year. Consequently, a PMS operational subgroup was established, to oversee PMS implementation, raise awareness within the Network and validate proposed approaches for implementation. The next PMS operational subgroup meeting will take place on 12 February and will be looking into the data validation/qualification processes. Aimad emphasised the opportunity for NDSG to work collaboratively with ROG to deliver the vision of PMS as the source of product master data for all products authorised in the EU as well as for products in development.

Action: an update from the PMS operational subgroup meeting of 12 February 2025 to be given at the next NDSG meeting.

Pelle Person (MPA, SE) acknowledged that PMS/SPOR implementation is central to enhance interoperability within the network. It is a high interest area for NCAs, however the maturity of implementation of ISO IDMP standards and more generally of product master data is diverse across the Network due to differences in capacity, funding and priorities between NCAs. Working together would be a success factor going forward, potentially through joint projects to address some restrictions at NCAs level, e.g. UNICOM2 project.

Hilmar Hamann (EMA) discussed the important strategic leadership role of NDSG for the PMS implementation and encouraged this group to bring different perspectives together, ensure timely dialogue with relevant stakeholders, to work together in defining the roles and responsibilities, and provide recommendations and advice on PMS delivery and maintenance to EMA Management Board and HMA as per its mandate.

The NDSG was then invited to have a group discussion on the proposed workplan items. Overall, NDSG supported that PMS as the source of product master data for all products authorised in the EU as well as for products in development was a priority for the NDSG workplan. There was support for the transitional step enabling a single submission of product master data under the Article 57 legal basis, with discontinuation of XEVMPD once consuming systems had been repointed to PMS. The need for an approach to data validation (alternatively referred to as qualification) was highlighted including that one size will not fit all in terms of NCA involvement. The following additional comments were collected:

- There is a need to identify priority use cases for stakeholders;
- Ensure that data held and shared by regulators to other stakeholders are of high quality;
- Ensure that the use of PMS data is provided for in the EHDS guidelines due in 2027 to support cross border health care;
- Consider the lessons learned from the UPD (Vet product database) implementation;
- There is a need to facilitate the identification of financial/resource needs (roadmap) for PMS implementation;
- Ensure data consistency between the national data sets and a central (European) data set;
- Alignment is crucial between data, technology and process elements for PMS system;
- Change management is key to successful delivery.

5. Defining the NDSG vision on data for medicine regulation

The group was invited to discuss the NDSG's vision for data in medicines regulation in breakout sessions. The meeting participants were divided into three working groups, where each group had to create a vision statement for NDSG. The outcomes of the groups' discussions were presented to the main meeting plenary for voting via slido. The draft vision statement 'trusted medicines for everyone by unlocking the value of data' received the most support. The draft NDSG vision will be road-tested with communication experts and then further discussed with the potential for endorsement at a future NDSG meeting.

6. A.O.B.

Day 2 - 29 January, 08:30am – 13:00pm (CET time)

1. Adoption of the draft agenda for Day 2

The draft agenda for Day 2 was adopted.

2. NDSG work planning: transversal areas

Francois Domergue (EMA) presented an overarching approach for developing the NDSG workplan and its high-level structure. It was proposed to split the workplan into 5 workstreams: two transversal areas on "Strategy & Governance", and on "Stakeholders' engagement & Network capability/capacity"; and three specific areas on data analytics, artificial intelligence, interoperability. The draft workplan for discussion had been pre-populated with the suggestions for deliverables for consideration by the group. The proposals were based on the existing workplans (e.g. BDSG workplan to 2025, multiannual AI workplan to 2028, NDB face to face workplan discussions), workshop reports (e.g. RWE, registries, genomic) and strategy documents (draft EMANS to 2028, draft EMRN data strategy etc).

An overview of the "Strategy and Governance" workstream area was presented, including aims, proposed suggestions for the draft workplan, timelines and highlights. The key considerations, clarifications and suggestions noted during the discussions were:

- NDSG members should facilitate coordination and sharing of information within their respective/represented groups for the key deliverables (e.g. guidelines development, training activities). This is complementary to the communication and engagement activities (e.g. public consultation, workshop) organised by the NDSG secretariat and relevant operational teams;
- An alignment/information flow on the NPL implementation will be ensured by the EC representatives. **Action:** NDSG secretariat to plan dedicated NDSG discussions on the key topics in preparation for the new Pharma legislation (e.g. the replacement of the current Annex 1 of Direction 2001/83, and the report from clinical study data pilot);
- The group welcomed a proposal to include specific deliverables to support international activities in the NDSG workplan. In this context, NDSG role should be to facilitate stakeholder engagement and listen to their needs on guidance/standards implementation and to support implementation of international consensus guidelines;
- Mapping of resource and budget requirements for major workplan deliverables should be considered.

Aina Staisiuniene (EMA) introduced the "Stakeholders' engagement and network capability/capacity" workstream, provided a brief overview on the key stakeholder groups, engagement goals and main communication channels including existing engagement touchpoints with industry stakeholders. The group was invited to have a discussion on the NDSG engagement with industry stakeholders going forward. The group comments were captured below:

- ROG has regular bilateral meetings established with industry and continuation should be ensured going forward;
- Consider utilising the existing groups for engagement with industry, rather than creating new focus groups;
- An interaction with industry via public events could be considered, noting that some restrictions are in force to EMA experts (representing an official function/entity) attending public events organised by industry. **Action**: NDSG secretariat to circulate existing policies and

guidance documents re publications and external events to the NDSG members for information. *Post meeting note:* the guidance document is linked below Policy/0029 - Representing the Agency at external events;

- In future, NDSG should consider revising its stakeholders as new priorities emerge (e.g. registries);
- The key stakeholder events/workshops from the relevant Network fora should be included in the NDSG workplan (e.g. relevant MWP workshops);
- Change management and stakeholder engagement should be central to the thinking of all NDSG work streams. The areas of AI, real world evidence, clinical study data and master data should be prioritised in 2025.

Following the discussion, NDSG agreed to continue engaging with industry stakeholders via the channels already established under the former Big Data Steering Group:

- Bi-annual meeting;
- Annual multi-stakeholder data forum; and
- Focus/advisory groups established on real-world evidence and clinical study data.

In addition, NDSG will collaborate with the Regulatory Optimisation Group to establish a specific interaction with industry stakeholders on master data topics.

3. NDSG work planning: specific areas

The group was invited to discuss the work planning for the specific areas on data analytics, artificial Intelligence, interoperability in breakout sessions. The meeting participants were divided into three working groups, where each group collected initial feedback on proposed deliverables and identified any gaps for the draft NDSG workplan. The outcomes of the groups' discussions were presented to the main meeting plenary.

4. Feedback from break-out sessions

Group 1 report and plenary discussions

Feedback from the group 1 discussions on Data Analytics was presented. The following were of note:

- Support for the key activities outlined in the proposed workplan for the Data Analytics workstream was expressed. It was proposed to move the EMRN data analytics strategy under the Strategy and Governance workstream (transversal area) to ensure alignment between all work streams;
- The structure and visual representation of the workplan could be enhanced for better clarity;
- Further discussion on the scope for clinical study data is needed (e.g. there are different types of clinical data that can be submitted to regulators and assessors may require different support);
- Connect NDSG deliverables and relevant EMA working parties'/committees' deliverables when applicable;
- Indicate important decision points for the key activities (e.g. in the context of the clinical study data pilot), monitor risks, dependencies and avoid duplication of initiatives;

- Gap analysis should be embedded in the workplan plan delivery and seen as a routine/core activity of the NDSG;
- The duality of data analytics in delivering support (efficiency) to assessors and enhancing analysis of evidence was acknowledged (process vs. content). The EMRN data analytic strategy will be a key vehicle to prioritise and balance the different needs of the Network and activities of the NDSG;
- Consider including additional DARWIN EU work deliverables;
- Scoping discussions to be grouped together (e.g. Modelling and Simulation, Patient Experience Data (PED), genomics etc). Other suggestions for discussions included: a pilot project on social media monitoring for ADRs using AI; a pilot project on PED; engaging on mHealth data with Scientific Advice Working Party (SAWP); medical device stakeholders; Horizon Europe projects; activities from the Qualification of Novel Methodology (QoNM) action plan; Pharmacovigilance signal detection and methods.

Group 2 report and plenary discussions

Feedback from the group 2 discussions on Artificial intelligence was presented. The following suggestions were noted:

- Support for the key activities outlined in the proposed workplan for the Artificial Intelligence workstream was expressed;
- Consider including deliverables from the related work plans, such as the methodology working party, AI work plan;
- Explore deliverable to strengthen support to the SAWP qualification procedure;
- Consider how to share AI Act implementation information across the Network;
- Re-scope the proposal on guiding principles on algorithmic bias for the EMRN: make it more general and broader;
- Current technical terminology might need to be revised;
- Consider being more neutral in highlighting the specific stakeholders' collaborations;
- Explore a possibility to create a more technical group to engage on more technical discussions (outside AI Specialised Interest Area (SIA));
- Consider hierarchy of deliverables;
- Include a scope of deliverables in the experimentation swimlane; highlighting activities aimed for the Network vs stakeholders' deliverables.

Identified gaps:

- Ethical / data protection / data security considerations to be transversal to other deliverables;
- Consider explicit deliverables on open source/open science;
- Create an overarching network change management plan;
- Consider accountability and link to AI Act;
- Consider supporting the establishment of AI industry contact points;

- The group commented on the need to discuss having test environments for AI use cases in the network.

General NDSG feedback:

- There is a need to further strengthen expertise and skills within the European regulatory network to support industry in regard to artificial intelligence;
- Strengthen collaboration with academia to strengthen expertise in AI at the Network level.

Group 3 report and plenary discussions

Feedback from the group 3 discussions on Interoperability was presented. The following were of note:

- Support for the key activities outlined in the proposed workplan for the Interoperability workstream was expressed;
- The European interoperability framework is the foundation for the Interoperable Europe Act, which breaks down different layers of interoperability. When discussing interoperability topics, there is a need to specify which layers of interoperability are being addressed;
- Communication and alignment with other workstreams will be important (e.g. EHDS implementation);
- There is a need to engage the Network in preparations for implementation of the Interoperable Europe Act;
- PMS delivery timelines need to be aligned with the EHDS implementation timelines (please refer to the agenda item 4 on Day 1 for additional information);
- Workstream deliverables should be prioritised and clustered if possible;
- Identification of strategic risks could help to plan deliverables.

5. Wrap up & close of the meeting

The NDSG co-chairs thanked the meeting attendees for their participation and contribution to this meeting. The next NDSG meeting is scheduled to take place on 4 March 2025 via Webex.