03 October 2024
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Joint HMA-EMA Network Data Steering Group

Mandate

Within the European Medicines Agencies Network (EMAN), the joint HMA-EMA Network Data Steering Group (NDSG) is a strategic advisory group established to maximise data interoperability, exchange and use across the EU network, the access to data and generation of evidence, and the beneficial utilisation of Artificial Intelligence (AI) for the benefit of public and animal health in the European Union (EU). It also ensures that the perspectives of patients, healthcare professionals, pet and livestock owners are considered.

The NDSG focuses on:

- **Regulatory data:** Data submitted to, created by or controlled within regulatory procedures throughout the lifecycle of human and veterinary medicinal products. This includes master data essential for the network's interoperable operations and product shortage and safety monitoring, regulatory submissions, and procedure data.
- **Data supporting evidence on medicines:** Data used to generate evidence on the use, safety, quality or efficacy/effectiveness of medicines. This includes clinical trial raw data, pooled clinical trials data, real world data such as electronic health records, registry data and claims data, datasets from spontaneously reported suspected adverse drug reaction, and genomics, proteomics and metabolomics datasets. This may also include non-clinical data, chemistry, manufacturing and controls (CMC) data, and supply data.

The NDSG supports the delivery of the EMAN strategy to 2028 (particularly theme 2: Leverage Data, Digitalisation and AI), optimising and unifying the data governance bodies of the network to continue the data driven transformation of the EMAN and to build on the achievements of the Big Data Steering Group (EMA/96120/2023) and the Network Data Board (EMA/MB/96104/2023).

The NDSG makes proposals and gives advice to HMA and EMA MB for the prioritisation, planning and monitoring of actions relevant to the EMAN strategy to 2028 (particularly its Theme 2: Leverage Data, Digitalisation and AI) and the EMA multi-annual workplan.

1. Role of the NDSG

The tasks of the NDSG include:

1. **Strategy:** Proposing and agreeing network strategies and related implementation plans, recommendations, positions and guidance for data, interoperability, and AI.
2. **Data Governance:** Without prejudice to the decision-making structure of the network portfolio governance, acting as the advisory expert reference point for data related matters escalated by EMA or National Competent Authorities (NCAs); Ensuring that proportionate network data governance is in place for managing EMAN data assets in compliance with data protection and data security and for generating value for the network.

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3. **Data Analysis:** Maximising evidence generation for decision-making by EMANs, its committees and stakeholders via access to data, analysis, guidance, and piloting of innovative design of clinical studies, as well as new analytical approaches.
4. **Interoperability:** Enabling effective management and use of high-quality data across the network; Enabling high levels of interoperability and exchange of data through the use of standards, terminologies and master data.
5. **Artificial Intelligence:** Overseeing the work to realise the EMAN vision to harness AI capabilities for personal productivity, process automation and systems efficiency, data insights and strengthened decision-support, while ensuring that uncertainty is adequately explored, and risks are mitigated.
6. **Legislation:** Contributing to implementation of relevant EU legislative initiatives (including the European Health Data Space, the Pharmaceutical Strategy for Europe, the AI Act and the Interoperable Europe Act).
7. **International alignment:** Fostering international collaboration, alignment and harmonization (e.g. on ICH, VICH, HL7, ISO, CDISC) on data interoperability, use of standards, data quality, analysis, methods and data use in medicines regulation.
8. **Capacity Building:** Supporting network capability and capacity building and engaging with EMAN's stakeholders. This will include development of training (e.g. data science, biostatistics, pharmacoepidemiology and real-world data), collaboration with EU projects (e.g. HealthData@EU projects) and organisation of multistakehodler events for knowledge sharing.
9. **Network IT Portfolio:** Collaborating and providing strategic advice (e.g. to Quarterly Portfolio Reviews and the Network Portfolio Advisory Group); Supporting relevant business cases (epics); Being informed about calls for experts requiring data expertise.
10. **Horizon Scanning:** Monitoring product marketing authorisation applications and regulatory business pipeline relevant to data and of advances in data science, technology, legislation and data regulation to identify opportunities and threats and make recommendations to HMA and EMA Management Board; Monitoring emerging standards, research, and innovation projects to make recommendations on network engagement and support resource allocation when needed (including liaising with standardization organizations and assessing external requests for participation).

2. Composition and appointments

Members of the NDSG represent Member States' NCAs, EMA, EC and selected stakeholders. They represent expertise in IT and data, including analysis, use and decision-making as well as data management, interoperability and standardization.

Competencies of NDSG members (mainly applying to regulatory members) should include:

- Methodological expertise including biostatistics, modelling and simulation, data science, artificial intelligence and machine learning, and specifically with a focus on applications in design and analysis of clinical studies, as well as business support.
- Data management, standardisation and interoperability with insight in data needs of the business and the technological constraints and opportunities of the existing IT infrastructure and applications.

- Familiarity with data protection, data security, EU data legislation and policies, procedures, standards, guidelines, and practices.

The NDSG is composed of:

- Member State's NCA representatives (up to 11) following a call for interest through the HMA. Ideally, one to three representatives should come from a joint veterinary agency.
- A representative each from the CHMP, CVMP, PRAC, SAWP, MWP, CMDh and CMDv (7).
- A representative of Network ICT Advisory Committee (NICTAC) (1).
- A representative of CTCG / ACT EU (1).
- A representative of the EU Innovation Network (1).
- Representatives of the European Commission (3).
- A representative of the European Directorate for the Quality of Medicines & HealthCare (EDQM) (1).
- A representative of the EHDS community on secondary uses of health data (1) and a representative of the Health Data Access Bodies (1).
- Representatives of EU Patient associations (1), of EU healthcare professional associations (1) and of Veterinarian association (1).
- Representative of ethic bodies or networks (1).
- A representative of HTA bodies (1) and Payers (1).
- Representatives from EMA (5).

Observers can be invited to the meeting on ad-hoc basis. The group could also form ad-hoc topic groups within its membership on specific topics.

3. Appointment, terms and renewal

NCA NDSG members: The NCA representatives are nominated by HMA based on a call coordinated by HMA Management Group. Representatives should represent human and veterinary domains, ensure balance between agencies of different size and have a broad geographical spread. When nominating the NCA representatives, the competences that the nominee brings to the group should be described. If more than eleven persons are nominated, the co-chairs should select the nominees in a way that ensures the best combination of competences. Should an NCA representative be replaced during the course of the mandate, the new NCA representative will be selected from the pool of representative's candidates that expressed interest for the initial constitution of the group. In the absence of suitable candidate, a new call for nomination coordinated by HMA Management Group will be organised.

European Commission: Commission representation will be coordinated by DG SANTE and DG RTD and may include other DGs depending on the agenda topics being discussed. Commission representation will focus on ensuring coordination and alignment with Commission goals.

EHDS community on secondary uses of health data and Health Data Access Bodies: Nomination is coordinated by the Commission services. Participation should facilitate coordination with activities related to EHDS and its implementation, as well as facilitating communication with Health Data Access Bodies once established.

EU Patient associations, EU healthcare professional associations and Veterinarian associations: Nomination of representatives will be through the EMA Patients and Consumers Working Party and Healthcare Professionals Working Party and the Veterinarian association. Ideally the representative of healthcare professionals should be able to represent the views for human and veterinary medicines.

HTA bodies and Payers: Nomination is coordinated by the Commission services.

Co-Chairs: Co-chairs are nominated for NDSG for the duration of the mandate, representing EMA and HMA, respectively. The HMA co-chair is nominated based on a call coordinated by HMA Management Group. EMA co-chair is nominated by EMA Executive Director.

Terms and renewal: This mandate will be reviewed before the end of 2028, in line with the EMANS to 2028. The appointment of the NDSG and its members will be for the duration of this mandate.

4. Performance and reporting

Every year, the NDSG agrees a multi-annual workplan, structured with topics, in line with the priorities of the network and endorsed by HMA and EMA Management Board.

The NDSG makes public an annual report.

The NDSG reports at least bi-annually to both HMA and EMA Management Board.

5. Meetings

NDSG normally meets on a monthly basis. Most meetings are held virtually.

6. Interactions

NDSG is responsible for the interaction with:

- Experts: subject matter experts can be invited on ad-hoc basis to NDSG meetings on specific topics.
- The key data user groups or similar groups, when relevant.
- Other stakeholders such as industry/SME, international regulators/partners, academia, standardisation organisations, data holders and data access bodies, may be engaged when required.
- Meetings are organised to exchange on topical issues with the wider group of stakeholders. At least one multi-stakeholder meeting is organised annually.
- Meetings may be organised to exchange on specific needs and issues with industry association representatives.
- The NDSG is supported by the EMA Data Board.
- The EMA scientific committees and their respective working parties, e.g. Methodology working party, that are responsible for authorisation and supervision of medicinal products in the EU and for regulatory guidance.
- The NDSG interact with the HMA Regulatory Optimisation Group (ROG).

7. Secretariat

The secretariat is provided by EMA. This includes meeting organisation, agendas, minutes, monitoring of actions, progress and outcomes, and communication with the various NDSG stakeholders.

Agenda are built in line with the published workplan, agreed with the co-chairs and structured to ensure meaningful discussion and efficient decision-making.

Agendas and minutes of the NDSG meeting will be published on EMA website.

Endorsed by HMA at the 117th HMA (virtual) meeting on 12th September 2024.

Endorsed by EMA Management Board at the 125th Management Board (virtual) meeting on 3rd October 2024.