Network Data Steering Group (NDSG)

Group focused on AI with industry stakeholders

Mandate

1. Background

The rapid advancements in artificial intelligence (AI) require medicines regulators to develop smart and flexible approaches to regulation. To effectively navigate this evolving landscape, the European Medicines Regulatory Network (EMRN) should have greater insights into industry plans for AI-enabled products and solutions.

Furthermore, the ecosystem of laws and guidance surrounding AI is increasingly sophisticated, encompassing the AI Act, AI reflection paper, Good Manufacturing Practice's (GMP) annex 22, future clinical development and pharmacovigilance guidance, Medical Device Regulation, and interactions with other relevant laws and guidance, such as on data protection. Effective development and implementation will benefit from greater exchange of information with key stakeholders, especially the pharmaceutical and medical device industries.

Finally, there are significant opportunities for global convergence, and these can benefit from closer interaction with EU stakeholders.

Considering the abovementioned, the Network Data Steering Group (NDSG) has defined in the revised NDSG workplan on data and AI to 2028 the establishment of a group focused on AI with industry stakeholders.

This group complements other existing stakeholder engagement fora, including stakeholder engagement by the Quality Innovation Group and by the Methodology Working Party (i.e. MWP annual interested parties' meeting), providing a more AI-specific, and more frequent forum for engagement with industry on AI in the context of the implementation of the AI activities of the NDSG workplan.

This document provides the mandate of the group.

2. Aim

The primary aim of the group is to facilitate open dialogue with industry stakeholders on the development and use of AI in the medicines' lifecycle.

The specific objectives are:

- Understand use cases and discuss the development, validation, and deployment of AI solutions
- Provide a forum for industry stakeholders to share feedback

- Clarify regulatory expectations and the evolving regulatory landscape
- Explore opportunities for safe and responsible innovation with AI

3. Organisational aspects

3.1. Membership and attendance

The group will consist of two representatives from each human and veterinary pharmaceutical trade association and medical device trade associations, as well as members of the EMRN, comprising.

- Human and veterinary pharmaceutical trade associations (~10)
- Medical device trade associations (~2)
- European Medicines Regulatory Network, including National Competent Authorities (NCA) and European Medicines Agency (EMA)
- Ad-hoc attendance by subject matter experts for specific topics is envisaged.

No formal discussion of product-specific issues and assessments will take place in this group.

3.1.1. Network nomination process

Network experts are either standing members or attend ad-hoc.

Standing Network experts will be selected by the co-chairs of the NDSG Group Focused on AI with industry stakeholders following the launch of an expression of interest to NDSG and European Specialised Expert Community (ESEC) Special Interest Area (SIA) on AI and Data Science's network membership.

Ad-hoc attendance is based on subject matter expertise and may be in the form of an invitation from the co-chairs of the NDSG Group Focused on AI with industry stakeholders or via consultation of the NDSG and ESEC SIA AI.

3.2. Meetings

The focus group will convene up to four times a year, with the frequency of meetings reviewed annually.

Meetings will normally last 90 minutes. Group members will be consulted on future agenda topics.

Meetings will be co-chaired by representatives from EMA and HMA.

Adopted by NDSG in August 2025.