EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Summary report of the annual Network Data Steering Group meeting with industry stakeholders

3 July 2025 – co-chaired by Karl Broich (BfArM) and Peter Arlett (EMA), Webex

1. Welcome and opening remarks

The co-chairs of Network Data Steering Group (NDSG) opened the meeting and welcomed participants representing the NDSG and pharmaceutical industry associations of ACRO, AESGP, Association of Veterinary Consultants, EFPIA, EUCOPE and EuropaBio.

2. NDSG workplan and 2025 priorities

The participants were introduced to the mandate of the joint HMA/EMA Network Data Steering Group (NDSG), which was established to advise the EMA Management Board and Heads of Medicines Agencies (HMA) on prioritisation, planning and monitoring of actions relevant to the European Medicines Agencies Network Strategy (EMANS) to 2028, especially in the areas of leveraging data, digitalisation and AI. It is a strategic advisory group that oversees data strategy and governance in the EMRN. The NDSG began its work in January 2025 and adopted its workplan in March 2025. The workplan is structured in six workstreams and includes a detailed narrative for each workstream and its deliverables. The scope of most activities under the workplan covers human and veterinary medicines.

The NDSG members presented the NDSG workplan highlights for the six workstreams and priorities for 2025. The veterinary perspective and priorities were also outlined, highlighting that veterinary deliverables featured in the NDSG workplan are in alignment with the Veterinary Big Data Strategy for shared requirements thereby avoiding duplication of efforts. Any specific veterinary needs are covered in Veterinary Big Data Strategy and Veterinary Big data workplan.

Additional updates included the list of the key events scheduled for 2025 and 2026.

Industry feedback and priorities

The EFPIA representative presented the industry feedback on the NDSG workplan and sought clarifications in the areas of: Real-World data and change management; data quality management;

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guidance and international initiatives. The provided input captured the EFPIA perspective, which was shared with other industry stakeholders in advance of this meeting.

A discussion on the points raised took place and the following was noted:

- DARWIN EU® is the main pathway for EMA to deliver regulator-led RWD studies. The current DARWIN EU® contract runs until February 2027. A new procurement procedure for continuation of DARWIN EU® beyond February 2027 will likely be launched in Q1/Q2 2026. Ahead of this, industry learnings on the DARWIN EU® framework will be collected via representatives at the DARWIN EU® Advisory Board and via the industry focus group on RWE.

  Action: EMA to consider whether additional means to collect structured feedback from industry and other stakeholders on DARWIN EU® are required.

- The activities to support NCAs with national initiatives on RWE has already been initiated via MWP a specialised community on RWE, training activities etc. In addition, NCAs can now channel national questions to DARWIN EU®, to clarify situation in their home country but also in other countries. All national questions channelled through DARWIN EU® can be found in the HMA-EMA catalogues of real-world data sources and studies and will feature in the next yearly report on the experience gained with regulator-led studies.

- The RWE change management activities will focus on ensuring appropriate integration of RWE into the core regulatory business processes where this has not yet been fully realised.

- NDSG has not had any explicit discussion on the intersection between RWD and AI and it will be considered for future planning. However, the use of real-world data sets by industry to develop AI algorithms is provisioned in the EHDS regulation and will be an important area to follow in the future.

- Two collaborative studies on background incidence rates of vaccine adverse events of special interest and on utilisation of GLP-1 RA will be initiated under the ICMRA working group on RWE for Public Health Emergencies.

- The timelines for development of the concept paper on the use of pragmatic trials in regulatory decision making was discussed. Some inconsistencies on the development timelines for this guideline were noted between MWP workplan and the 'Journey towards a roadmap for regulatory guidance on real-world evidence' document. **Action**: MWP secretariat to align the timelines between the two documents at the next update.

- The detailed update on the development timelines for the AI guidelines will be provided to stakeholders at the next HMA/EMA multi stakeholder workshop on Artificial Intelligence on 20-21 November 2025.

- The group discussed the scope of two new documents that are being developed: the Q&A document on RWE and a concept paper on the use of the evidence assessment framework, also noting the development of two new ICH guidelines on Efficacy and Registries.

  Action: EMA to ensure that these documents complement each other and that planning documents are consistent.

- A request to communicate the guidance development timelines was reiterated by industry, noting the specific interest in use of data guidance from the over the counter sector.

  Action: EMA representative to provide a report on ongoing discussions at the industry group focused on RWE to NDSG.

3. NDSG and Industry engagement opportunities

A status update on discussions undertaken at the industry group focused on use of RWD and generation of RWE, which already met twice in 2025, was provided to the group. The meeting participants were reminded that an overall objective of this group is to share knowledge and experience with use of RWD and generation of RWE to advance integration of relevant and reliable RWE in regulatory decision making.

A draft mandate of the new group focused on AI with industry stakeholders, which is planned to be established in Q3 2025, was presented. This new group will be complementary to the already existing stakeholder engagement fora and will aim to facilitate open dialogue with industry stakeholders on the development and use of AI.

The group was also reminded about the ongoing interactions with industry in the dedicated forum which was established in 2022 to support the Raw Data pilot. The EMA-CHMP clinical study data pilot (previously called Raw Data pilot) has been extended until further notice and there is a need to further intensify interactions between EMA/EMRN and industry. It has been proposed to rename the group to 'Industry group focused on clinical study data', broaden the current membership to include technical profiles (to be launched in Autumn 2025) and further enhance expertise through a call for subject matter experts to support with IT development (to be launched in 2026 via Network Portfolio Board).

Lastly, NDSG colleagues presented the status update of the ongoing activities to develop a model for the working arrangements within the Network for product master data management, including roles and responsibilities, and highlighted the opportunities for industry to engage on this topic.

Industry feedback and priorities

The industry representative provided feedback on behalf of EUCOPE on strategic and topic specific engagements between EMA/EMRN and industry. Very positive feedback was noted for exchange at the industry group focused on use of RWD and generation of RWE and she congratulated EMA on facilitating the deep dive discussions on individual topics. Additional feedback on engagements at the other topic specific focus groups will be provided in writing by industry, if deemed necessary.

Industry would welcome an earlier identification of topics and earlier circulation of documents for future interactions, as coordination amongst industry associations is considered critical to have a well informed and structured dialogue, also securing availability of relevant expertise for the meetings.
Action: NDSG secretariat to ensure earlier planning of industry engagement opportunities (workshops, public consultations, availability of meeting documents).

4. Wrap up and conclusions

The NDSG co-chairs thanked the meeting attendees for their participation and contribution to this meeting.