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Network Data Steering Group (NDSG): 2025 report

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Foreword by Karl Broich, President of BfArM and NDSG co-chair, and Peter Arlett, Head of Data Analytics and Methods Task Force at EMA and NDSG co-chair

As this report is published, January 2026 marks the first anniversary of the establishment of the Network Data Steering Group (NDGS) — a milestone that reflects not only a year of progress, but the acceleration of transformation across the European medicines regulatory network (EMRN) for a fast, efficient path from scientific innovation to safe and effective medicines for patients.

We are at a pivotal moment: shifting from an information-based medicines regulatory system to a truly data-driven regulation system.

This transition is reshaping how we generate insights, integrate evidence and take decisions. By drawing on data from clinical trials, real-world healthcare databases, patient experience data, quality and manufacturing, and non-clinical sources — and by embedding advanced analytics including AI — we are building a regulatory model fit for the future.

The NDSG builds on five years of momentum from the Big Data Steering Group, expanding the scope of work to include two essential enablers of a modern regulatory ecosystem: data governance and data interoperability. These pillars ensure that high-quality data can flow ethically, efficiently, and securely across systems, empowering better processes, trustworthy AI, and smarter regulation.

Peter Arlett, Head of Data Analytics and Methods Task Force at EMA, NDSG co-chair

Karl Broich, President of BfArM, NDSG co-chair

Solid foundations are already in place, and many initiatives are visibly delivering impact:

- DARWIN EU® reached its 3rd anniversary in 2025, with 100 studies initiated and a growing network of data partners.
- The pilot on analysing individual patient data from clinical trials has proven successful, supporting the upcoming implementation of the new pharmaceutical legislation.
- A set of ten guiding principles for the use of AI now supports EU regulators and strengthens international collaboration.
- 61 use cases for AI capabilities were collected and are shaping the development of the roadmap for Knowledge Mining and AI in medicines regulation.
- We are moving closer to a single submission and single source of product master data.

The work of the NDSG is directly helping EMRN to deliver and bring to life the European Medicines Agencies Network strategy to 2028, ensuring that we are not only responding to today's challenges, but preparing with confidence for the future.

The journey ahead is both ambitious and exciting. As we continue to learn, improve and collaborate with all our stakeholders and partners, we move closer to NDSG shared vision: Trusted medicines by unlocking the value of data.

1. Introduction

The joint HMA-EMA Network Data Steering Group (NDSG) vision is of 'Trusted medicines by unlocking the value of data'. Thanks to its diverse composition and expertise (from regulatory to ethics, innovation and stakeholder perspective), it aims to:

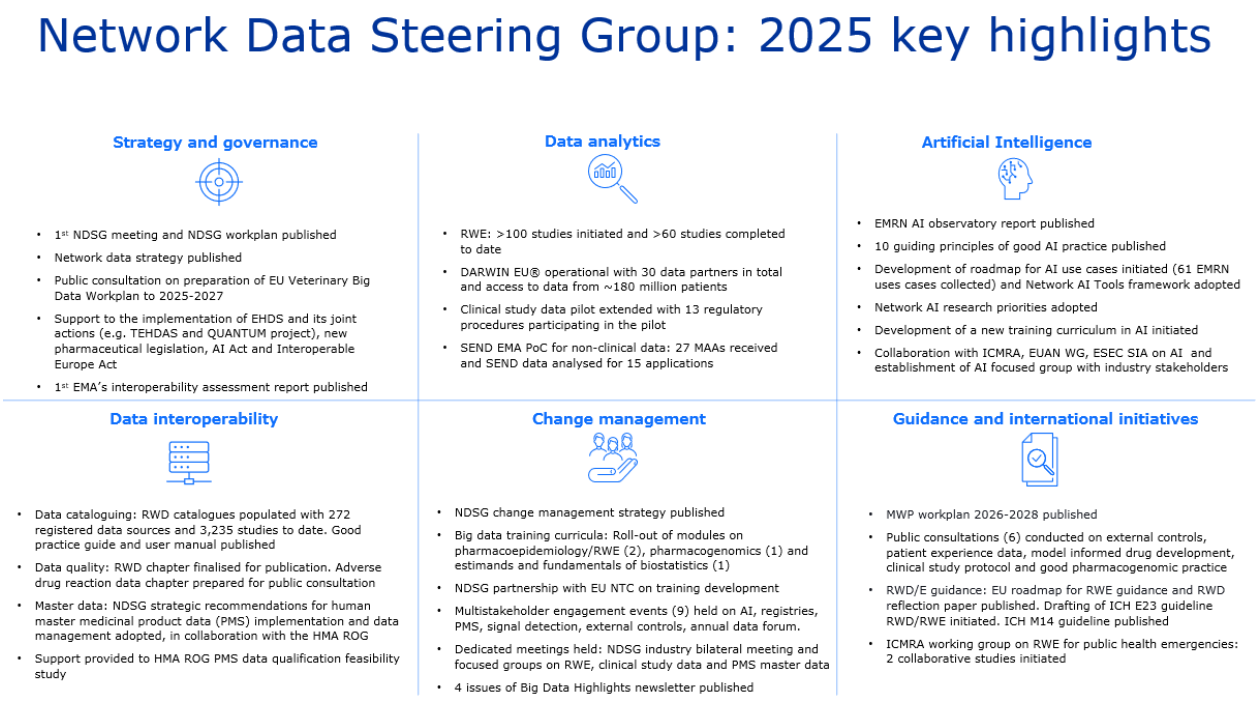
- maximise data use, exchange and interpretation;
- improve access to data and evidence generation;
- leverage use of artificial intelligence for better decision-making.

The NDSG was established in late 2024 and combines the former Big Data Steering Group (BDSG) and the Network Data Board (NDB) into one data governance group (see mandate of the group). NDSG also advises HMA and EMA Management Board on the implementation of the European medicines agencies network strategy to 2028, in particular for the strategic theme 2 on data, digitalisation and AI.

In 2025, significant progress continued to be seen in the transformation to a more data-driven regulation. This report provides a summary of the key activities and achievements of the NDSG in 2025.

2. 2025 highlights

Figure 1 below provides a summary of the key NDSG highlights presented in the context of the workstreams of the NDSG workplan.



3. Description of the 2025 highlights of the NDSG workplan

3.1. Strategy and governance

Strategy

The NDGS held its first face to face meeting in January 2025 and published its NDSG workplan for 2025-2028 in May 2025 to progress the activities launched under the former BDSG and NDB and to address new topics. It sets out how the European medicines regulatory network (EMRN) plans to leverage large volumes of regulatory and health data as well as new tools to support regulatory decision-making. In 2025 the NDSG met nine times virtually and twice in person. Minutes of the meetings are published here.

Informed by a public consultation in 2024, the European Medicines Agencies Network data strategy was published in October 2025 and marked an important milestone. It provides the vision, principles and objectives for implementing effective data management to transform the EMRN into a data-driven regulatory ecosystem that promotes innovation, efficiency, and better coordinated decision-making among national authorities and the EMA. Its key strategic objectives relate to data governance, data quality management, data interoperability, data cataloguing and metadata management, knowledge and change management, and analysis of data. It applies to the human and veterinary domains.

The next iteration of the EU Veterinary Big Data Workplan to 2025-2027 was developed in 2025 in partnership with the Veterinary Data Hub (a multi-disciplinary team of Network experts from Belgium, France, Germany, Portugal, Spain, and Sweden). A public consultation to collect stakeholders' feedback will be launched in early 2026.

Governance

Over the coming years, key European Union legislative initiatives will be implemented and will reinforce the framework for accessing and exchanging data, and for generating evidence to support regulatory decision making.

In 2025, NDSG continued to prepare for the future European Health Data Space (EHDS) and the new Pharmaceutical Legislation with regular updates and participation to various fora and workshops. NDSG also continued its collaboration with the second Joint Action Towards the European Health Data Space (TEHDAS2) and the QUANTUM project for HealthData@EU by providing input into public consultation on specific deliverables and participation in their advisory boards.

Finally, NDSG discussed the implementation of the Interoperable Europe Act and how the Network can benefit from its implementation to better align National Competent Authorities (NCA) systems and EMA systems and how it can facilitate data exchange across the Network. In 2025, EMA's first interoperability assessment report on EMA's European Shortages Monitoring Platform (ESMP) was published by EMA in compliance with the Interoperable Europe Act.

3.2. Data Analytics

Real World Data

DARWIN EU ® has continued to grow its real-world data (RWD) network through 2025. DARWIN EU is now instrumental in enabling the EU network to access valid and reliable evidence based on RWD to complement information from clinical trials and to support regulatory decision making.

In 2025, DARWIN EU has been fully operational. It supports the evaluation work of EMA's scientific committees, as well as the work of national competent authorities, the European Centre for Disease Prevention and Control, Health technology assessment bodies and payers.

During 2025, ten additional data partners have been selected for on-boarding into DARWIN EU, further expanding the network with additional countries and more specialized data types. In total, thirty data partners are now providing access to data from more than one hundred and eighty million patients from sixteen European countries. Assessment of additional sources to join the network is on-going to reach forty data partners in quarter one 2026. The list of newly onboarded data partners is published on the DARWIN EU website.

DARWIN EU data partners have access to RWD from a large variety of sources such as hospitals, primary care practices, health insurance databases, registries and biobanks. Study protocols and reports of all DARWIN EU studies are publicly available in the HMA-EMA Catalogue of RWD studies.

Between February 2024 and February 2025, 107 research topics have been addressed via one of the three pathways available at EMA to generate real world evidence (RWE), and 33 studies have been completed, included 25 studies via DARWIN EU. Since the launch of DARWIN EU in February 2022, more than 100 studies have been initiated and over 60 studies completed by end of 2025. This includes studies to inform vaccine safety and effectiveness, as well as studies to support and prepare for public health emergencies.

The capacity for studies will continue to be further scaled up, in line with the need from the Network, to enhance data-driven decision making on medicines in the EU.

DARWIN EU continued to be supported by the multi-stakeholder DARWIN EU Advisory Board to provide strategic advice and recommendations on DARWIN EU, to ensure coordination and alignment with relevant European and EU Member State initiatives and policies, and to optimise communication on DARWIN EU with stakeholders. Agendas and minutes are published on the DARWIN EU ® webpage.

The third report on conducting studies with RWD was published in June 2025, based on experience gathered between February 2024 and February 2025. The report highlights the EMRN's continued efforts to better integrate RWE into regulatory decisions as well as learnings not only from studies conducted via DARWIN EU but also from other pathways used to generate RWE. During the reporting period:

- The proportion of feasible studies addressing initial requests increased from the previous reporting period (78% vs. 60%).
- Fifty-nine studies were either completed or ongoing, marking a 47.5% increase compared to the previous reporting year.
- DARWIN EU studies have now a median duration of four months from protocol approval to final study results, facilitating the use of the evidence generated in regulatory procedures.
- These studies support an extensive range of decision-makers, including EMA's scientific committees and working parties, national competent authorities, as well as the European Centre for Disease Prevention and Control (ECDC), Health Technology Assessment (HTA) bodies and the European Commission.

Clinical study data pilot

Launched in 2022, the clinical study data pilot (formerly known as raw data pilot) continued in 2025 to investigate the benefits of visualising and analysing clinical study data to support the scientific

assessment of medicinal products. In the pilot, clinical study data are submitted voluntarily by applicants or marketing authorisation holders as part of their regulatory applications.

Based on the initial insights from the pilot including early evidence of the potential for such data analysis to speed up the authorisation of new medicines (see pilot interim report), the pilot's duration was extended and pilot participation requests from pharmaceutical industry continue to be accepted. Guidance for industry was updated to reflect the new timelines and interim lesson learned. As of December 2025, thirteen regulatory procedures have been selected for the pilot.

The pilot continues to be supported by the Network Advisory Group on Raw Data, the Network Community on Raw Data and the Industry Group focusing on Clinical Study Data. Support to Marketing Authorisation Holders (MAH) has been important, and in 2025, EMA published an update to the Questions and Answers about the clinical study data proof-of-concept pilot for industry.

Non-Clinical raw data

The EMA Proof of Concept (PoC) study to evaluate implementation of the Standard for Exchange of Nonclinical Data (SEND) was launched in 2023. The PoC is looking at how SEND could improve the quality and efficiency of routine assessment but also of procedures where data is complex and requires visualization or independent analysis. The PoC is also looking at how it could be useful for procedures where rapid regulatory input is needed (e.g., rolling review, accelerated procedures, PRIME) and for regulatory science projects or read-across activities to facilitate harmonization, policy or guideline recommendations.

The first Marketing Authorisation Application with SEND data was received in September 2024. As of December 2025, SEND data for twenty-seven marketing authorisation application were received and for fifteen of them the SEND data have been analysed. Access to the SEND Explorer Warehouse environment was granted to sixty-nine reviewers from six EU countries.

Trainings for the Network assessors are regularly organized and a questions-and-answers document for applicants is available since June 2025 and includes information on the terms of participation and the technical details on how to submit SEND datasets.

The Proof-of-concept phase was completed at end of 2025 and results will be reported in 2026.

3.3. Artificial Intelligence

Guidance, policy and product support

In 2025 support continued to the development and evaluation of AI in the medicines' lifecycle through dedicated support to Portfolio and Technology Meetings (PTM), Innovation Task Force (ITF) meetings, Scientific Advice, Qualification procedures and EMA scientific committees.

The first annual report of the European medicines regulatory network's AI Observatory was published in July 2025 and included the results of horizon scanning (human and veterinary domains). This report compiles the Network's experience with AI during 2024 in enhancing productivity, automating tasks and supporting data-driven decisions across a medicine lifecycle, and captures and shares experiences and trends in AI to inform future work. In addition to the report, two other related documents have also been published: a compilation of examples of AI use in medicine regulation and a horizon scanning short report, helping to identify gaps, challenges and opportunities for integrating AI in medicine regulation.

In 2025, NDSG adopted a set of ten guiding principles to inform and enhance the use of AI for generating evidence across the medicinal product lifecycle for the human and veterinary domains.

These were drafted in close collaboration with the US Food and Drug Administration (FDA) to promote safe and responsible use of AI. These principles lay the foundation for those developing medicines, as well as for marketing authorisation applicants and holders. They will act as a compass for medicines regulators as they steer academics and companies. The principles will underpin future AI guidance and support enhanced international collaboration among regulators, organisations setting technical standards and other stakeholders.

In 2025, a group focused on AI with industry stakeholders (human and veterinary domains) was established to facilitate open dialogue with industry stakeholders on the development and use of AI in the medicines' lifecycle. The first meeting took place in November 2025. It aimed to:

- 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.

It complements other existing stakeholder engagement fora, including stakeholder engagement by the EMA Quality Innovation Group and by the EMA Methodology Working Party (e.g. 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.

Tools and technologies

In 2025, NDSG continued to be a place to discuss national AI initiatives in the medicines' lifecycle and for regulatory science. A series of workshop with national competent authorities (Human and veterinary domains) were organised to collect AI use cases and to discuss existing or potential solutions and concepts that could be used for the implementation of such cases.

Sixty-one uses cases were collected covering three main AI capabilities:

- drafting and summarization of information,
- validation and quality assurance,
- and knowledge mining and retrieving of information.

This work will inform the development of the roadmap for Knowledge Mining and AI use cases in 2026.

Finally, NDSG has also adopted a network AI Tools framework to support the sharing and development of AI tools across the Network (human and veterinary domain), to foster collaboration, integration and reusability of tools and models.

Collaboration and change management

Collaboration with stakeholders and partners continued in 2025 at international level and under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA).

At European Union level, EMA is chairing the EU Agencies Network Working Group (EUAN WG) on AI. The EUAN WG aims to support the EU agencies network on the implementation of AI fostering knowledge sharing and increasing the AI maturity level to provide guidance and common approaches. The group met in June 2025 at EMA premises, with the participation of thirty-three EU Agencies.

The European Specialised Expert Community (ESEC) of the EMA Methodology Working Party (MWP) is now fully established and met regularly in 2025 to provide a forum for collaboration and knowledge sharing across the Network.

In 2025, NDSG agreed to establish a new training curriculum in AI, under the framework of the EU Network Training Centre (EU-NTC) and the ownership of the Methodology Working Party (MWP). Members of the ESEC with specific expertise on AI and data science will contribute on behalf of the MWP together with the NDSG to the drafting of the training curriculum in AI. The AI training curriculum will be developed iteratively, reviewed and updated as needed in this rapidly changing field. It will also provide the overarching framework for the AI training developed for the EMRN, for example under initiatives such as the EU4Health Joint Action supporting the increased capacity and competence building of the EU medicines regulatory network (EU4Health Joint Action IncreaseNET). The AI general literacy training was rolled out across EMA in Q4 2025 and will be extended to the Network in 2026.

The HMA/EMA multi-stakeholder workshop on artificial intelligence (AI) was held in November 2025 to discuss with stakeholders the evolving regulatory environment and HMA/EMA activities on AI (see also section 3.5 of this document). Thousands of stakeholders participated online and in-person in the event to listen to keynotes on AI state-of-the-art and discuss the evolving regulatory environment, HMA/EMA activities on AI and AI use cases across the medicines' lifecycle. The outcome of the workshop will inform the revision of the NDSG workplan.

Experimentation

In 2025, the NDSG launched a survey to gather stakeholders' perspectives on the priority research areas related to the use of AI in medicine development and evaluation. Insights gathered informed the drafting of the Network AI research priorities that will guide future research efforts led by academia and research organisations at large. Results may also inform future MWP activities and workplan considerations for AI applications in the medicinal product lifecycle. The Network AI research priorities were adopted by NDSG in late 2025 and will be published in early 2026. They apply to human and veterinary domain.

3.4. Data Interoperability

Data asset discovery, cataloguing and metadata management

Data cataloguing and metadata management of EMRN critical data assets are essential to enable efficient discovery, access, and utilisation of data assets across the Network to support regulatory decision-making.

The HMA-EMA catalogues of real-world data sources and studies were launched in February 2024. The catalogues help medicines regulators, researchers and pharmaceutical companies to identify the most suitable data sources to address specific research questions and support the assessment of study protocols and results. They promote transparency, encourage the use of good practices, and build trust in research based on RWD. Aligning with 'FAIR' data principles for Findable, Accessible, Interoperable and Reusable data, they use an agreed set of metadata to describe and connect data sources to studies. This is based on the metadata list for real-world data sources and studies, for which an update was published in June 2025.

Users of the catalogues are supported by:

- Good practice guide for the use of the HMA-EMA Catalogues of real-world data sources and studies – which provides regulators, researchers and other stakeholders with recommendations

on how to use the catalogues effectively to identify and assess the suitability of data sources. An update was published in April 2025.

- User guide of the HMA-EMA Catalogues of real-world data sources and studies – provides descriptions of the data fields and definitions, as well as guidance on how to submit and maintain records in the catalogues. It was first published in June 2025.

In 2025, a new feature has been introduced in the HMA-EMA RWD Catalogue of data sources enabling users to compare key characteristics across data sources. With this functionality, it is possible to select up to three data sources for a head-to-head comparison. This enhancement supports users more effectively in understanding data sources and their strengths and limitations against other data sources, as well as in identifying a suitable data source for a specific research question.

As of December 2025, the RWD Catalogues contain 272 registered data sources and 3,235 studies. These are geographically distributed across various regions of the world: Europe has the highest number of data source and study registrations, with Italy (75 data sources), Spain (74), the United Kingdom (71) and Germany (70) as the top countries for data sources. The United Kingdom (1,083 studies), Germany (977) and Spain (875) are the top three for study registrations. Outside of Europe, the most represented countries for data sources are the United States (20), Israel (16) and Turkey (16) and for studies - the United States (786), Canada (233) and Japan (148).

In 2025 stakeholder engagement continued to encourage population of the catalogues with additional RWD sources and non-interventional studies. All European data holders, marketing authorisation holders, networks, researchers, and institutions interested in having their data used for medicines regulation or are obligated by policy on non-interventional post-authorisation safety studies (PASS), are encouraged to register and keep information up to data in the catalogues.

In 2025, the HMA-EMA catalogues of real-world data sources has been prepared to include veterinary real-world data sources and will be rolled out to the public in 2026.

In 2026, a comprehensive approach to data cataloguing and metadata management for the Network critical data assets (human and veterinary domains) will be developed and a new Network data assets catalogue will be rolled out to the Network.

Data Quality Management

To inform the selection of data for evidence generation and increase interoperability, data quality of the data used by the Network should be understood, and efforts should be made to strengthen it.

In 2025, the RWD quality chapter of the EU Data Quality Framework for EU medicines regulation was updated to include the feedback from the public consultation in 2024. The final version was adopted by NDSG in 2026 and will be published in 2026 to offer insights on key considerations for RWD quality including practical recommendations that cover characterisation of the systems and processes that underpin data. It will also provide a set of metrics to assess data quality dimensions and a guideline on assessing data quality in relation to a research question.

A chapter on Adverse Drug Reaction (ADR) data quality has been prepared in 2025, and stakeholders' feedback will be collected via a public consultation in early 2026.

More work will continue in 2026 with the development of a specific quality chapters for medicinal product master data in the Product Management Service (PMS).

Organisational and Semantic interoperability

Master data is essential to strengthen interoperability of the Network data assets and systems.

One of the essential master datasets for the Network relates to medicinal product data. NDSG recognised the PMS system as a shared source of product master data for all EU medicinal products supporting EU-wide use cases.

In 2025, NDSG progressed the work on implementation within the Network and published strategic recommendations for human master data implementation and data management. These included input from the EMA-HMA Regulatory Optimisation Group (ROG) to support effective and efficient implementation and use. The NDSG recommended a stepwise delivery approach that will include a first transitional step enabling the submission of product master data in ISO IDMP/FHIR format under the Article 57 legal basis, with discontinuation of XEVMPD once consuming systems had been repointed to PMS

The goal is to achieve a shared centralised repository of human medicinal product information at EU level, supporting the product data lifecycle via a unified entry point for initial and subsequent product data submissions.

In 2025, the NDSG also supported the HMA ROG PMS data qualification feasibility study that is exploring the practicalities of the Network validation (alternatively referred to as qualification) of PMS data submitted by MAHs and managed in the PMS system.

Informed by this pilot, in 2026 the NDSG in collaboration with the ROG will publish a model for the working arrangements within the Network for product master data management, including roles and responsibilities.

3.5. Stakeholder engagement and change management

Change management strategy

Change management plays a critical role in fostering a data-driven culture across the Network. It helps to build trust among partners and stakeholders while preparing them to embrace the changes outlined in the NDSG workplan. In 2025, NDSG published an overview of its change management activities for 2025-2026, and engaged in change management discussions on the high-priority topics of real-world evidence, clinical study data analysis and artificial intelligence.

Network skills and knowledge

To support the development of an expert workforce in the Network able to advise on data and interpret evidence, training programs continue to be rolled out to the Network via the EU Network Training Centre (EU NTC) platform. The development of the big data training curricula was previously initiated under the joint HMA/EMA Big Data Steering Group (BDSG), in close collaboration with the MWP and scientific expertise from the relevant ESEC SIAs.

In 2025, two additional training modules have been rolled out in Pharmacoepidemiology and RWE (Modules on 'The journey from real-world data to real-world evidence' and 'Practicals'), which now complete the full programme of the Pharmacoepidemiology and RWE training curriculum.

A new curriculum on genomics, with a focus on pharmacogenomics, was also launched (first module on 'Introduction to Human Genetics').

Additional training modules are to be rolled out in 2026 in data science (e.g. data quality and omics data).

New trainings on Estimands and fundamentals of biostatistics have been released as part of the biostatistics and clinical trial methodology training curriculum. Further biostatistics training modules

are being developed in collaboration with the EU4Health Joint Action IncreaseNet (e.g. on adaptive trial designs) and as part of the development of reflection papers and guidelines.

The current eLearning offering is complemented by the following trainings (also available on the EU NTC platform):

- Real-World Academy (RWA): a series of webinars to share and build knowledge on RWE generation and its use and facilitate the interpretation and use of study results for regulatory decisions. In 2025, the following topics were addressed: "Non-interventional and external control arm studies", "Appraising protocols and reports with confidence- pitfalls in pregnancy studies", "Target trial emulation framework" and "Feasibility assessment". The recordings of the previous webinars are available here: EU Network Training Centre (NCAs).
- EU NTC Digital Academy (training on AI and data analytics): an EMA initiative designed to support digital skill-building and awareness across the EMRN. It offers a collection of interactive e-learning modules, available through the EU NTC platform and focused on key digital transformation topics, including on AI and data analytics (see also section 3.3 on Artificial Intelligence).

In 2025, the NDSG partnered with the EU NTC to align more closely its approach to training development with the EU NTC methodology and framework. This will form the basis for training prioritisation, and enhanced design, development and delivery of learning from 2026.

Stakeholder engagement and communication

Collaborations with external stakeholders and partners continued in 2025 and several multistakehodler events were organised.

- The Product Management Service (PMS) information day was held in May 2025 to enable stakeholders to engage directly with senior leaders and opinion setters on the future of PMS and its role in the Network strategy and share knowledge and alignment towards a successful EU implementation of PMS.
- The HMA/EMA workshop on the use of Bayesian statistics in clinical development was held in June 2025 as part of the published Methodology Working Party 2025-2027 workplan and the Accelerating Clinical Trials in the EU (ACT EU) multi-annual workplan 2025-2026. It aimed to discuss the potential benefits and challenges when using Bayesian statistics in clinical development in informed future guidance development.
- The HMA/EMA workshop on reporting and qualification of mechanistic models for regulatory assessment was held in October 2025 to discuss the experience with the current regulatory landscape around the application and assessment of mechanistic models to support drug development and identify opportunities for future regulatory qualification of mechanistic models.
- The first HMA/EMA multi-stakeholder forum on EudraVigilance and signal detection was held in November 2025 to inform and foster collaboration with stakeholders on ongoing and forthcoming developments in international guidance, adverse drug reaction case processing, signal management and data analysis in EudraVigilance.
- The HMA/EMA workshop on the use of external controls for evidence generation in regulatory decision-making was held in November 2025 as part of the published Methodology Working Party 2025-2027 workplan and the Accelerating Clinical Trials in the EU (ACT EU) multi-annual workplan 2025-2026. To inform the drafting of a reflection paper on the use of external controls for evidence generation in regulatory decision-making - Scientific guideline, the MWP

engaged with external stakeholders to explore the opportunities and the potential use of external controls in the regulatory setting and to discuss related methodological challenges to draw causal conclusions.

- The fifth Veterinary Big Data Stakeholder Forum was held in November 2025 as part of the implementation of the EU veterinary big data strategy and focused on real-world applications of big data and artificial intelligence (AI) in the veterinary medicinal regulatory domain.
- The HMA/EMA multi-stakeholder workshop on artificial intelligence (AI) was held in November 2025 to update stakeholders on the evolving regulatory environment and HMA/EMA activities on AI.
- The HMA/EMA annual data forum was held in December 2025 to discuss progress on evidence generation, interoperability, use and exchange of medicines data across the EU network, and inform the future work planning of the group.
- The HMA/EMA workshop on Patient Registries for Alzheimer's disease was held in December 2025 to agree on recommendations for optimising stakeholders' collaboration to facilitate the long-term follow-up of patients using registries, and enable the generation of meaningful evidence on the safety and effectiveness of medicines using patient registries.

The Methodology Working Party's Interested Parties meeting took place on 26 September 2025, giving Industry stakeholders the opportunity to raise and share reflections on MWP's 2026 priorities. Comments and suggestions were accounted for in the finalisation of MWP's workplan 2026-2028 which will be integrated with the NDSG workplan 2026-2028.

A dedicated NDSG industry stakeholder meeting was organised in July 2025 in the context of EMA's continuous endeavours to foster regular interactions with industry stakeholders on data topics. Agenda and minutes are published on EMA website. A specific Industry focus group on Artificial Intelligence was established November in 2025 to facilitate open dialogue with industry stakeholders on the development and use of AI in the medicines' lifecycle. Interaction with Industry continued in 2025 through groups focused on RWE, clinical study data and with the ROG on PMS Master data.

The EMA Big data newsletter was published four times in 2025, to update stakeholders on the on progress on the delivery of the NDSG workplan.

3.6. Guidance and international initiatives

Guidance

The Methodology Working Party (MWP) was established in 2022 and is responsible for the drafting of methodology guidance and to support their implementation. Its Consolidated 3-year rolling work plan for the Methodology Working Party 2025-2027 has been published in February 2025. It is supported by the methodology ESEC that has been established with two hundred and nine experts from more than twenty-one European countries including EMA. The ESEC strengthens the MWP, bringing together a broad range of expertise.

Some of the activities of the NDSG workplan refers to MWP activities and follow its workplan for the development of guidance (e.g. reflection paper, concept paper and Q&A) across data and methods.

A roadmap to produce guidance for the EU network on RWE to support regulatory decision-making was developed in 2025. It includes a review of existing RWE guidance that regulators have issued and proposes topics for further guidance development.

To ensure high quality decision making in this rapidly developing environment, the reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes was finalized and published in June 2025. It is aimed at all stakeholders involved in the planning, conduct and analysis of this type of non-interventional studies, including marketing authorisation holders and applicants.

In 2025, a public consultation was launched on the draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making. This concept paper outlines the scope and content of the future reflection paper to be developed to describe the main challenges with external controls and further discuss the circumstances and methodological constraints under which the use of external controls could be considered appropriate for generating pivotal or supportive evidence, either for efficacy, safety or other relevant regulatory decision-making objectives.

In 2025, EMA launched a public consultation on the Patient experience data (PED) reflection paper. This paper outlines key principles on collecting, analysing and integrating PED across the medicine lifecycle, and encourages stakeholders and developers to engage at an early stage with regulators to discuss inclusion of patient experience data (PED) in medicine development programmes and marketing authorisation applications (MAAs).

In December 2025, the CHMP endorsed the draft Concept paper on the guideline revision on good pharmacogenomic practice, under the umbrella of the MWP, for public consultation. Since its initial publication in 2018, this guideline has been instrumental in shaping best practices in pharmacogenomics, ensuring consistency, and providing a clear framework for regulators and stakeholders. As anticipated, the field of genomics has continued to evolve, driven by scientific progress and technological innovation, leading to emerging regulatory considerations. The concept paper details proposed amendments in pharmacogenomic methodology, interpretation of genomic results and recommendations and guidance on pharmacogenomic study design.

International initiatives

To foster international collaboration, alignment on data use in medicines regulation and increase interoperability, NDSG continue its engagement with stakeholders to listen to their needs and support implementation of international consensus guidelines and standards.

Progress in convergence with international partners on RWD/RWE continued in 2025.

Following the 2024 strategic approach for ICH to further enable the integration of RWE into regulatory submissions and decision-making, a concept paper proposing the development of a new ICH guideline on RWD/RWE terminologies, metadata, and assessment principles with a focus on effectiveness (aka ICH E23) was adopted by ICH management committee in November 2025. It aims to promote a common understanding of the types and scope of RWD/RWE; guide the discoverability, identification, and description of RWD; and inform the assessment of RWD/RWE for regulatory purposes. The expert working group started the drafting of the technical document in Q4 2025.

Following public consultation in 2024, the final version of the ICH M14 Guideline on general principles on planning, designing, analysing, and reporting of non-interventional studies that utilise Real-World Data for safety assessment of medicines was published in September 2025, marking the first harmonised guidance for non-interventional studies aiming to generate RWE for safety assessment. The guideline includes recommendations on study development and implementation, documentation, and regulatory interactions specific to non-interventional safety studies, although key principles can also apply to other types of studies such as drug utilisation and effectiveness studies.

Under the umbrella of ICMRA, a new working group on RWE for Public Health Emergencies (PHEs), co-chaired by EMA and Health Canada, continued activities from the former COVID-19 RWE and Observational Studies Working Group, and aim to be a global forum for regulators to enhance the efficiency of responses to PHEs by conducting collaborative studies based on RWD. The group has developed general operational principles and templates for collaboration, as well as a list of potential topics of interest to test the system. The first two collaborative studies (one on the use of Glucagon-Like Peptide-1 receptor agonists (GLP1 RA), and one on background incidence rates of adverse events of special interest to support early stages of vaccine safety signal evaluation) have started in 2025 and findings and lessons learnt are expected to be published in 2026.

The digital transformation of clinical trial information is currently being strengthened with initiatives such as the digital protocol (ICH M11) or the Patient Level Data Project. A second public consultation on the ICH M11 guideline, clinical study protocol template and technical specifications was conducted in 2025 following an update to the clinical study protocol template based on the stakeholder public feedback from the 2022 consultation and additional input from the EWG's ongoing work. The final guideline document will be published in early 2026.

Finally, in 2025, the public consultation on the draft ICH M15 guideline on general principles for model-informed drug development was conducted. It aims to define a harmonized framework for evaluating model-informed drug development (MIDD) evidence and to provide recommendations for related planning and regulatory interactions, implementation, reporting, and submission.

4. Web references

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European Medicines Agencies Network Strategy to 2028	https://www.ema.europa.eu/en/documents/other/seizing-opportunities-changing-medicines-landscape-european-medicines-agencies-network-strategy-2028-final_en.pdf
NDSG Workplan 2025–2028	https://www.ema.europa.eu/en/documents/other/network-data-steering-group-workplan-2025-2028_en.pdf
NDSG meetings & minutes page	https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other-sources/network-data-steering-group-ndsg
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TEHDAS2 (Joint Action toward EHDS)	https://tehdas.eu/
QUANTUM project for HealthData@EU	https://quantumproject.eu/

Name	Hyperlink
Interoperable Europe Act	https://interoperable-europe.ec.europa.eu/interoperable-europe/interoperable-europe-act
EMA Interoperability Assessment	https://www.ema.europa.eu/en/about-us/interoperability-assessment-ema
DARWIN EU® homepage	https://www.darwin-eu.org/
ECDC	https://www.ecdc.europa.eu/en
HTA bodies (EMA page)	https://www.ema.europa.eu/en/partners-networks/health-technology-assessment-bodies
DARWIN EU list of data partners	https://darwin-eu.org/index.php/data/data-network
Catalogue of DARWIN EU studies (HMA–EMA RWD Studies Catalogue)	https://catalogues.ema.europa.eu/search?f%5B0%5D=content_type%3Adarwin_study&search_api_fulltext=DARWIN
HMA–EMA RWD Catalogues	https://catalogues.ema.europa.eu/
Third report on conducting studies with RWD (Feb 2024–Feb 2025)	https://www.ema.europa.eu/en/documents/report/real-world-evidence-framework-support-eu-regulatory-decision-making-3rd-report-experience-gained-regulator-led-studies-february-2024-february-2025_en.pdf
DARWIN EU Advisory Board page	https://www.ema.europa.eu/en/about-us/how-we-work/big-data/real-world-evidence/data-analysis-real-world-interrogation-network-darwin-eu
DARWIN EU ® webpage (agendas & minutes)	https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu
Clinical study data pilot – interim report	https://www.ema.europa.eu/en/documents/report/proof-concept-pilot-using-data-clinical-studies-medicines-evaluation-interim-report_en.pdf
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SEND Proof-of-Concept page	https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/marketing-authorisation-guidance-documents/standard-exchange-non-clinical-data-send-proof-concept-study
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AI Observatory – compilation of 2024 examples	https://www.ema.europa.eu/en/documents/report/2024-ai-observatory-report-compilation-2024-experience_en.pdf
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HMA/EMA multi-stakeholder workshop on AI (Nov 2025)	https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-artificial-intelligence-ai
HMA–EMA Catalogues (RWD sources & studies)	https://catalogues.ema.europa.eu/
Metadata list for RWD sources & studies	https://www.ema.europa.eu/en/documents/other/list-metadata-real-world-data-catalogues_en.pdf
Good practice guide for use of the HMA–EMA RWD Catalogues	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guide-use-hma-ema-catalogues-real-world-data-sources-studies_en.pdf
User guide for HMA–EMA RWD Catalogues	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/user-guide-hma-ema-catalogues-real-world-data-sources-studies_en.pdf
EU Data Quality Framework (main doc)	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation_en.pdf
Draft RWD quality chapter (public consultation)	https://www.ema.europa.eu/en/documents/other/draft-data-quality-framework-eu-medicines-regulation-application-real-world-data_en.pdf
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EU Network Training Centre (RWA recordings – NCAs)	https://europeanm.plateau.com/learning/user/deeplink_redirect.jsp?linkId=CURRICULA&qualID=RWA&rootQualID=&nativelogin=y
PMS Information Day	https://www.ema.europa.eu/en/events/product-management-service-pms-information-day-2025
Workshop on Bayesian statistics in clinical development	https://www.ema.europa.eu/en/events/workshop-use-bayesian-statistics-clinical-development

Name	Hyperlink
Workshop on Mechanistic models – reporting & qualification	https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-reporting-qualification-mechanistic-models-regulatory-assessment
Workshop on EudraVigilance & signal detection (first multi-stakeholder forum)	https://www.ema.europa.eu/en/events/first-ema-hma-multi-stakeholder-forum-eudravigilance-signal-detection
Workshop on External controls for evidence generation	https://www.ema.europa.eu/en/events/workshop-use-external-controls-evidence-generation-regulatory-decision-making
HMA/EMA annual data forum (Dec 2025)	https://www.ema.europa.eu/en/events/ema-hma-annual-data-forum
Workshop on Patient registries for Alzheimer's disease	https://www.ema.europa.eu/en/events/joint-heads-medicines-agencies-hma-european-medicines-agency-ema-multistakeholder-workshop-patient-registries-alzheimers-disease
EMA Big Data page (newsletters & stakeholder items)	https://www.ema.europa.eu/en/about-us/how-we-work/big-data
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Methodology Working Party (MWP) homepage	https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/methodology-working-party
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Concept paper: Revision of good pharmacogenomic practice guideline	https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-guideline-revision-good-pharmacogenomic-practice_en.pdf