EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

NDSG workplan 2025-2028

Data and AI in medicines regulation

Joint HMA/EMA Network Data Steering Group
VERSION 1.4 – July 2025

NDSG@ema.europa.eu

OUR VISION

Trusted medicines by unlocking the value of data

Contents

Introduction

The joint HMA/EMA Network Data Steering Group (NDSG) is the strategic advisory group established to maximise data interoperability and exchange, to improve access to data and evidence generation, and to leverage Artificial Intelligence (AI) for the benefit of public and animal health in the European Union (EU).

The NDSG vision is '*Trusted medicines by unlocking the value of data'*.

This document introduces the NDSG workplan, covering activities until 2028. The workplan was adopted by NDSG in March 2025 and will be updated annually, informed by feedback from stakeholders and EU network experts.

The NDSG workplan also contributes to the implementation of the EMAN strategy to 2028 to leverage data, digitalisation and AI (Theme 2).

Throughout the implementation of the workplan, the NDSG will ensure that data are managed and used within an ethical framework and in compliance with the EU data protection legislation and all other applicable EU legislative data requirements.

The scope of most activities under the workplan covers human and veterinary medicines. Specific veterinary aspects are also highlighted where relevant.

Workstreams

The NDSG workplan is organised in six workstreams:

Strategy and governance:

- Strategy
- Governance

Data analytics:

- Review of advanced or innovative methodologies and of new data types for evidence generation
- Real-world data, clinical study data, EudraVigilance data, non clinical data, genomic data

Artificial Intelligence :

- Guidance, policy and product support
- Tools and technologies
- Collaboration and change management
- Experimentation

Data interoperability:

- Data asset discovery, cataloguing and metadata management
- Data quality management
- Organisational and semantic interoperability

Stakeholder engagement and change management:

- Change management strategy
- Network skills and knowledge
- Stakeholder engagement and communication

Guidance and international initiatives :

- Guidance
- International initiatives

Workplan

Strategy and governance

Data analytics

Artificial intelligence

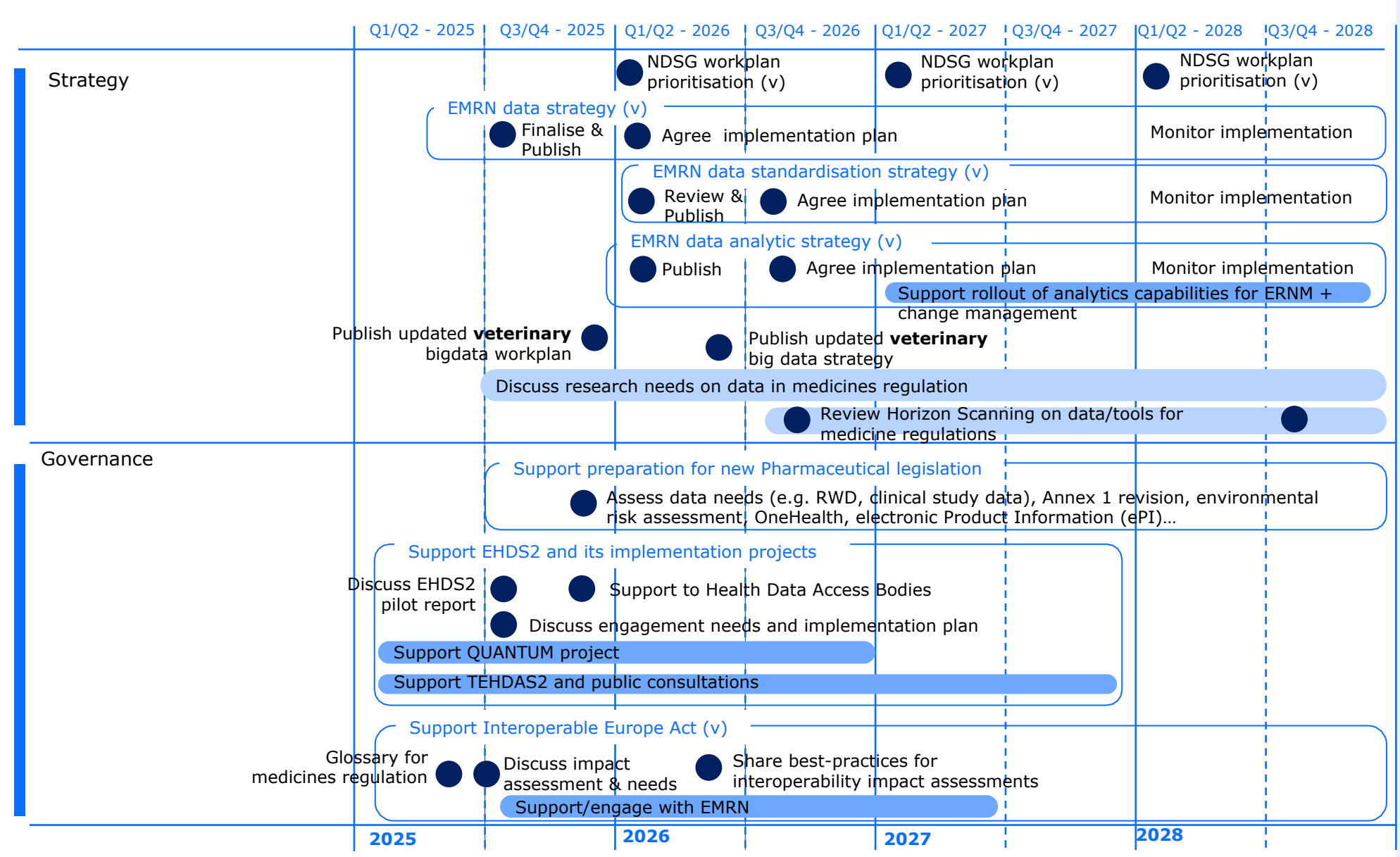
Data interoperability

Stakeholder engagement and change management

Guidance and international initiatives

WORKSTREAM OVERVIEW

Strategy and governance



Deliverable/activity Timeframe (v): Scope applicable to veterinary aspects

Strategy

A coordinated strategic approach to data management and utilisation across the network is essential.

- The EMRN data strategy and data standardisation strategy will ensure the EMRN data assets meet high quality standards, are appropriately managed, standardised and easy to share.
- The EMRN data analytic strategy will guide the network investment in data and analytics to maximise the utility of EMRN data assets for the benefit of human and animal health.
- The EU veterinary big data strategy and the EU veterinary big data workplan will be reviewed to progress activities specific to the veterinary domain.

To keep abreast with advances in data and tools and make recommendations on future network engagement and priorities, the NDSG will horizon scan and monitor research and innovation projects.

Informed by stakeholders and network expert input, the NDSG will update and prioritise its workplan annually.

Key dates:

Q3 2025	Finalise EMRN data strategy and Publish (v)
Q3 2025	Publish updated veterinary big data workplan (v)
Q1 2026	Publish EMRN data analytic strategy (v)
Q1 2026	Review & Publish EMRN data standardisation strategy (v)
Q1 2026	Agree EMRN data standardisation implementation plan
Q2 2026	Publish updated veterinary big data strategy (v)
Q3 2026	Agree EMRN data analytic strategy implementation plan
Q3 2026	Agree EMRN data strategy implementation plan
Q3 2026	Review Horizon Scanning on data/tools for medicine regulation
2025-2028	Discuss research needs for data in medicines regulation
2027-2028	Support rollout of analytics capabilities for ERNM + change management

Governance

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

To ensure preparedness of stakeholders and the Network, the NDSG will support the implementation of:

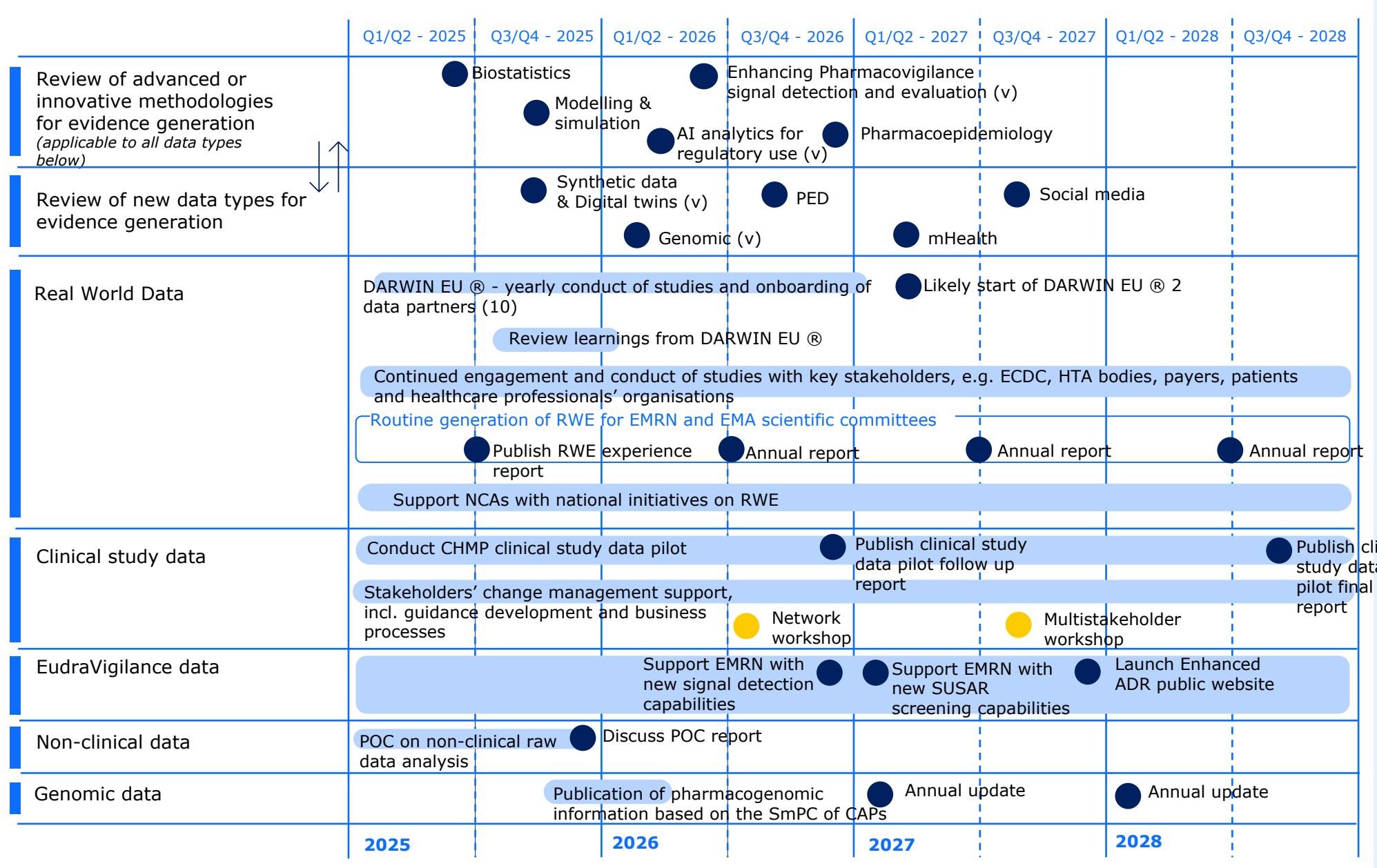
- The new pharmaceutical legislation for Europe.
- The European Health Data Space (EHDS), its joint action TEHDAS2 and the related implementation projects (e.g. HealthData@EU projects and the health data quality label QUANTUM project).
- The Interoperable Europe Act and the related European Interoperability Framework, specifically in the domain of semantic interoperability (for EMRN critical data assets).

Key dates:

Q2 2025	Interoperability glossary for medicines regulation
Q2 2025	Discuss impact assessment & needs for Interoperability (v)
Q3 2025	Discuss EHDS2 pilot report
	Support EHDS2: Discuss engagement needs and implementation plan
Q4 2025	Support EHDS2: support to Health Data Access Bodies
	Support preparation for new pharmaceutical legislation: discuss data needs (e.g. RWD, clinical study data), Annex 1 revision, environmental risk assessment, OneHealth, electronic Product Information (ePI).
Q1 2026	Develop best-practices for interoperability impact assessments
2025-2026	Support QUANTUM project
	Support TEHDAS2 and public consultations

WORKSTREAM OVERVIEW

Data analytics



Deliverable/activity Timeframe (v): Scope applicable to veterinary aspects

Review of advanced or innovative methodologies and data types for evidence generation

Data and methods are intricately linked and working together to generate evidence to support decision-making.

To enable regulatory decision-making to benefit from evolving methods and clinical evidence generated from a spectrum of data types, the NDSG will review advanced or innovative methodologies (e.g. biostatistics, signal detection, modelling & simulation data, AI and Pharmacoepidemiology) and data types that can complement clinical data (e.g. genomic data, synthetic data, digital twins data, patient experience data (PED), mobile health data and social media data).

This will allow NDSG to discuss the current progress, opportunities, challenges and applications of such methods and data types for evidence generation for regulatory decision-making. Ultimately NDSG will be able to agree common network positions and actions that the group will take and/or sponsor to enable the use of such methods and data types. Over time, informed by NDSG strategic review, pilot studies will be conducted, and learnings will be shared with the EMRN.

Gradually the use of such evidence will be enabled, and their value will be established to support regulatory decision-making.

Key dates:

Q2 2025	Review of methodologies: Biostatistic
Q3 2025	Review of methodologies: Modelling & simulation
Q4 2025	Review of new data types: synthetic data & digital twins (v)
Q1 2026	Review of methodologies: AI analytics for regulatory use, e.g. novel clinical trial designs, AI-driven patient evaluation, clinical data analysis (v)
Q1 2026	Review of new data types: genomic data (v)
Q2 2026	Review of methodologies: enhancing Pharmacovigilance signal detection (v)
Q3 2026	Review of new data types: Patient Experience Data (PED)
Q4 2026	Review of methodologies: Pharmacoepidemiology
Q1 2027	Review of new data types: mobile Health (mHealth) data
Q3 2027	Review of new data types: social media data

Real World Data

The Data Analysis and Real-World Interrogation Network (DARWIN EU®) is the federated network to enable access and analysis of real-world data (RWD). It is now fully operational and routinely supports the evaluation work of EMA's scientific committees. Learnings and experiences are shared regularly with stakeholders and the Network.

Every year, onboarding of additional data partners and increasing numbers of studies will continue.

Studies will also be conducted to support national competent authorities' initiatives on real-world evidence (RWE) and to cooperate with the European Centre for Disease Prevention and Control (ECDC), bodies responsible for Health Technology Assessments (HTA), payers, as well as patients and healthcare professionals' organisations.

Learnings from the DARWIN EU will inform the possibility of a follow-on infrastructure 'DARWIN EU 2'.

Key dates:

2025–2026	DARWIN EU ® yearly conduct studies and onboarding of new data partners
Q3–Q4 2025	Review learnings from DARWIN EU ®
2025-2028	Continued engagement and conduct of studies with key stakeholders, e.g. ECDC, HTA bodies, payers, patients and healthcare professionals' organisations
	Routine generation of RWE for EMRN and EMA scientific committees + annual publication of RWE experience report
	Support NCAs with national initiatives on RWE
Q2 2027	Likely start of 'DARWIN EU ® 2'

Clinical study data

Evidence generated from clinical study data analysis will strengthen regulatory decision-making for faster and better authorisation of medicines.

Informed by decisions on the new pharmaceutical legislation, the CHMP clinical study data pilot will continue to clarify the benefits and practicalities to access individual patient data from clinical trials.

The pilot results will advise EMRN on options for the targeted rollout of clinical study data analysis and for managing changes (including business process, organisational aspects, guidance development and training for the different types of EMRN assessors).

Collaboration with key stakeholders will be essential, notably through the organisation of workshops and sharing of the pilot learnings and experience.

Key dates:

2025-2028	Conduct CHMP clinical study data pilot
2025-2028	Stakeholders' change management support, including guidance development and business processes
Q3 2026	Network workshop
Q4 2026	Publish clinical study data pilot follow up report
Q3 2027	Multistakeholder workshop
Q3 2028	Publish clinical study data pilot final report

EudraVigilance data

Improved (human) pharmacovigilance signal detection capabilities for EMRN assessors, marketing authorisation holders (MAHs) and the general public will be delivered.

These includes:

- new signal detection capabilities for the EU network,
- new clinical trial Suspected Unexpected Serious Adverse Reports (SUSAR) screening capabilities for the EU network and ethics bodies,
- an enhanced public website for the publication of suspected Adverse Drug Reaction reports (ADR).

Key dates:

Q4 2026	Support EMRN with new signal detection capabilities
Q1 2027	Support EMRN with new SUSAR screening capabilities
Q4 2027	Launch Enhanced ADR public website

Non-clinical data

In 2025, the Proof of Concept (PoC) study to evaluate implementation of the Standard for Exchange of Nonclinical Data (SEND) will continue, after the first marketing authorisation application with SEND data was received in September 2024.

The PoC aims to clarify the benefits and practicalities of 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.

Key dates:

2025	POC on non-clinical raw data analysis
Q4 2025	Discuss POC report

Genomic data

In 2024, the joint EC/HMA/EMA multi-stakeholder workshop on pharmacogenomics recommended to optimise the availability of pharmacogenomic information for approved medicines to better inform pharmacogenomic-guided treatments.

In 2025, pharmacogenomic information based on the Summary Product Characteristics (SmPC) of centrally authorised medicinal products (CAPs) will be published and updated annually for the Network and its stakeholders.

In the future, other steps will be taken to enable the use of genomic data for regulatory decision-making. Pilot studies might be conducted and learnings/experience will be shared with the EMRN.

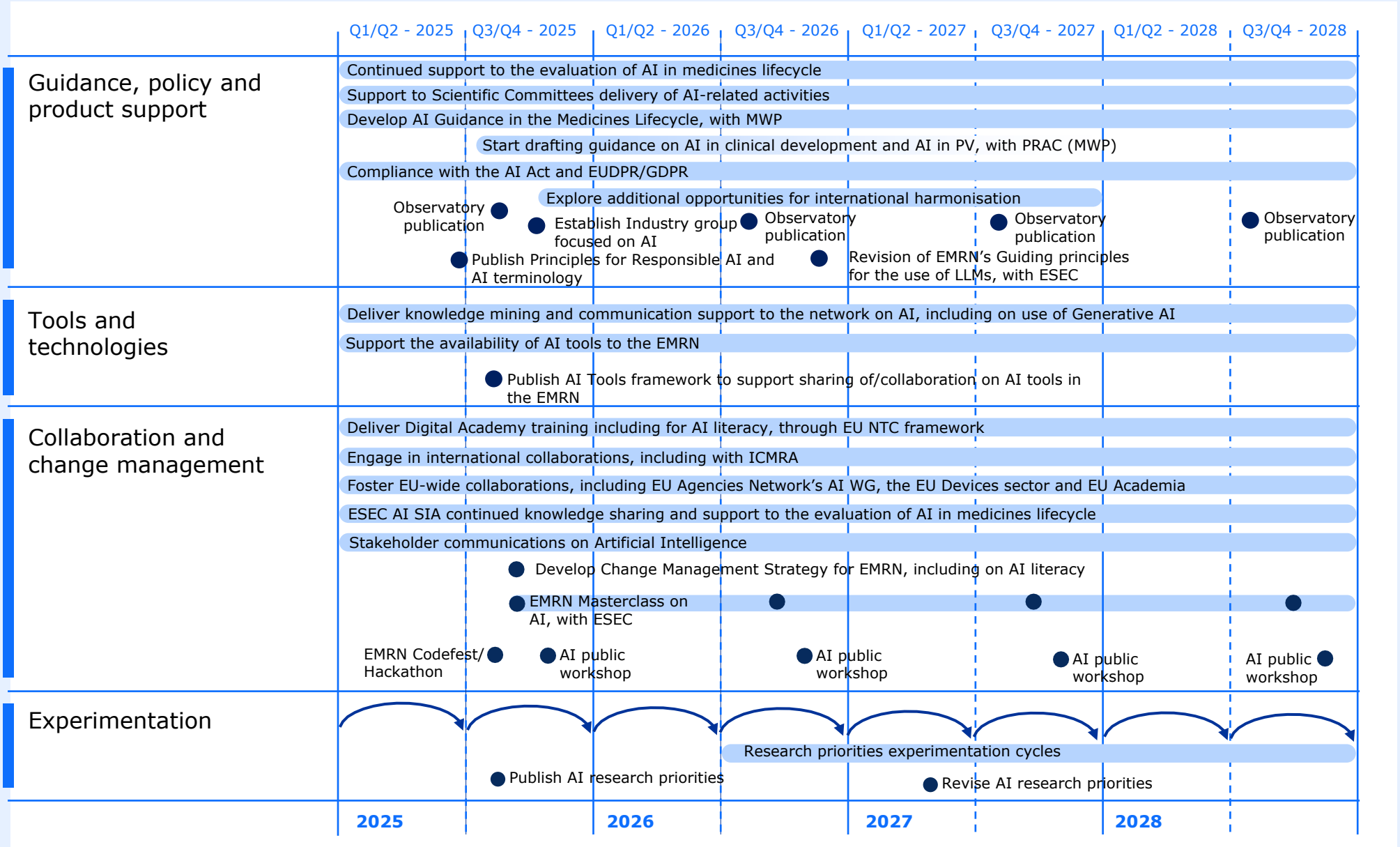
Additional activities on genomic data are also captured under the 'review of new data types for evidence generation' in this workstream and under the 'Guidance and international initiatives' workstream.

Key dates:

Q4 2025 – Q1 2026	Publication of pharmacogenomic information based on the SmPC of CAPs, followed by yearly updates

WORKSTREAM OVERVIEW

Artificial Intelligence



Deliverable/activity Timeframe

WORKSTREAM OVERVIEW

Artificial Intelligence

Artificial Intelligence (AI) systems are becoming a central tool supporting intellectual work and powering automation across many walks of life.

The European medicines regulatory network's (EMRN) vision for AI is for a regulatory system leveraging AI to harness systems efficiency, increased insights into data and strengthened decision-making, for the benefit of public and animal health.

The increasingly sophisticated nature and the pace of change of AI bring opportunities but also challenges. The application of AI requires a collaborative, coordinated strategy to maximise the benefits from AI while ensuring that uncertainty is adequately explored, and risks are mitigated.

This plan focuses on four critical dimensions to facilitate the development and use of safe and responsible AI, by including an ethical dimension across all deliverables, and by focusing on enabling the development of beneficial AI that delivers for public and animal health.

AI is fast evolving: this plan will therefore be regularly updated.

Throughout the execution of the workplan, stakeholders will be consulted, engaged and informed.

Guidance, policy and product support

Continued support to the development and evaluation of AI in the medicines' lifecycle will be provided, including dedicated support to Portfolio and technology meetings (PTM), Innovation task force (ITF), Scientific Advice and Qualification procedures.

As EMA's scientific committees include AI activities in their specific workplans, support to the delivery of these activities will be provided, such as on literacy, tools development and supporting guidance development.

Compliance with AI Act and EUDPR/GDPR will be ensured.

Information on activities, trends and emerging AI domains will be published on a yearly basis under the umbrella of a Network AI observatory.

Guiding principles on responsible AI and a terminology document, including comparison of international glossaries will be conducted. This could serve as a foundation for potential future international harmonisation.

Key dates:

Q2 2025	Publish responsible principles on AI and AI terminology
Q3 2025	Establish an Industry group focused on AI
Q4 2025	Explore the development of an ICH guideline with international partners
2025- 2028	Annual publication of the AI observatory report

Tools & technologies

Knowledge mining and communication support to the network on AI, including on use of Generative AI, will be delivered.

Support will be given to the EMRN for the availability of AI tools.

To foster collaboration, integration and reusability of tools and models, a Network AI Tools framework to support the sharing of AI tools and a Network collaboration on AI tool development, will be created.

Key dates:

Q2 2025	Publish AI Tools framework to support sharing of/collaboration on AI tools in the EMRN

Collaboration and change management

AI literacy is critical, and the EU-Network Training Centre will provide the framework to expand and deliver Digital Academy training on AI and Data Analytics.

The Network will continue to contribute to work with partners on AI internationally, including with the International Coalition of Medicines Regulatory Authorities (ICMRA) and at a European Union (EU) level, including with other EU Agencies as part of an EU Agencies Network AI working group as well as with the devices sector and academia.

The AI Special Interest Area of the European Specialised Expert Community (ESEC) of the EMA Methodology Working Party (MWP), will continue to provide a forum for collaboration and knowledge sharing, as well as reinforcing its support to the evaluation of AI in the medicines lifecycle.

A change management strategy for the whole network will be developed, with a particular focus on ensuring continued support to AI literacy.

Topic specific public workshops, masterclasses and hackathons will help upskill staff and connect to the wider stakeholder and data science community, informed by the views of the stakeholders on the selection of topics.

Key dates:

Q3 2025	Develop Change Management Strategy for the EMRN
2025-2028	Annual AI Masterclass for the EMRN
2025-2028	Annual AI Workshop

Experimentation

Experimentation is fundamental to expedite learning and reduce uncertainty about a technology or system.

Experimentation cycles of up to six months will be conducted throughout the coming years.

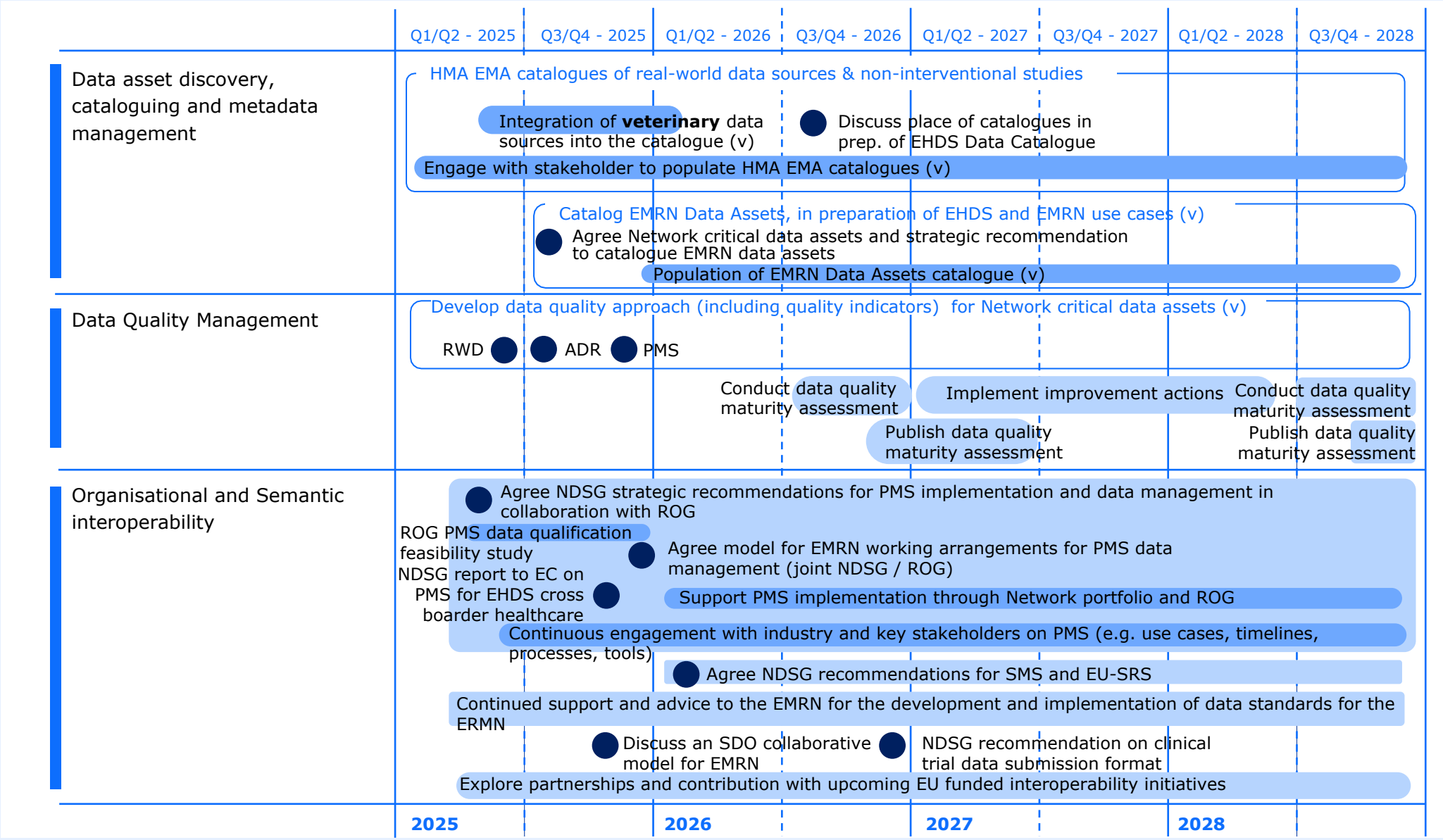
Network research priorities will be defined, and experimentation cycles will align with those priorities.

Key dates:

Q3 2025	Publish AI research priorities
Q3 2026	Research priorities experimentation cycles
Q2 2027	Revise AI research priorities

WORKSTREAM OVERVIEW

Data interoperability



Deliverable/activity Timeframe (v): Scope applicable to veterinary aspects

Data asset discovery, cataloguing and metadata management

Complementary to increasing data quality, 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.

A comprehensive approach to data cataloguing and metadata management for the Network critical data assets will be developed and rolled-out. This will consider the preparation of the European Health Data Space (EHDS).

After the launch of the EMA-HMA catalogues of data sources and non-interventional studies, integration with the veterinary domain and with the EHDS data catalogue will be explored. Engagement with stakeholder will also continue to help populate the catalogues.

Key dates:

Q2 2025-Q1 2026	Integration with veterinary domain of HMA EMA catalogues of data sources & non-interventional studies (v)
Q3 2025	Agree Network critical data assets and strategic recommendation to catalogue EMRN data assets
Q2 2026	Discuss place of the HMA EMA catalogues of data sources & non-interventional studies in preparation of the EHDS Data Catalogue and EMRN use cases
2025-2028	Engage with stakeholder to populate HMA EMA catalogues of data sources & non-interventional studies (v)
2026-2028	Population of EMRN Data Assets catalogue (v)

Data Quality Management

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

A data quality approach will be agreed, informed by the publication of the data quality framework for EU medicines regulation and aligned with relevant EU data quality initiatives, including the Union Product Database (UPD) data quality framework. Specific quality chapters will be published for new data domains, starting with Real-world data (RWD), Adverse Drug Reaction (ADR) and Product Master System (PMS) data.

Data quality maturity assessments will be performed and published to ensure the data quality of the network's critical data assets is well understood.

Key dates:

2025-2028	Develop data quality approach (including indicators) for Network critical data assets (v)
Q2 2025	Develop data quality approach for Network critical data assets – RWD
Q3 2025	Develop data quality approach for Network critical data assets – ADR
Q4 2025	Develop data quality approach for Network critical data assets – PMS
Q3-Q4 2026	Conduct data quality maturity assessment
Q4 2026-Q2 2027	Publish data quality maturity assessment
2027-Q2 2028	Implement improvement actions
Q3-Q4 2028	Conduct data quality maturity assessment
Q4 2028-Q2 2029	Publish data quality maturity assessment

Organisational and Semantic interoperability

Master data is essential to strengthen interoperability of the Network data assets and systems. By enabling the linkage of multiple data sources, it increases efficiency, reduces duplication and benefits evidence generation.

One of the essential master data relates to medicinal product data. NDSG recognised the PMS system as common source of product master data for all EU medicinal products supporting EU-wide use cases. NDSG will therefore work to progress and harmonise its implementation within the Network.

The HMA Regulatory Optimisation Group (ROG) PMS data qualification feasibility study will explore 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, the NDSG and the ROG will jointly agree a model for the working arrangements within the Network for product master data management, including roles and responsibilities.

The upcoming implementation of the EHDS1, notably in cross-boarder healthcare is an opportunity to strengthen the use of EMRN master data, e.g. PMS data.

NDSG will also discuss recommendations for substance master data in the SMS and EU-SRS systems.

Key dates:

Q2 2025	Agree NDSG strategic recommendations for PMS implementation and data management in collaboration with ROG
Q2 2025	NDSG report to EC on for product master data for EHDS, including cross boarder healthcare
Q2 2025–Q4 2025	ROG PMS data qualification feasibility study
Q3 2025	Continuous engagement with industry and key stakeholders (e.g. use cases, timelines, processes, tools)
Q4 2025	Agree model for EMRN working arrangements for PMS data management (joint NDSG ROG)
Q4 2025	Discuss an SDO collaborative model for EMRN
Q1 2026	Agree NDSG recommendations for SMS and EU-SRS
Q4 2026	NDSG recommendation on clinical trial data submission format

Organisational and Semantic interoperability

NDSG will provide continuous support and advice to the EMRN for the development and implementation of data standards for the ERMN.

The NDSG will discuss a collaborative model with Standards Development Organisations (SDO) for the Network, in line with the EMRN data standardisation strategy, to ensure EMRN expertise and requirements are represented across the spectrum of data standards (e.g. HL7, ISO, ICH…).

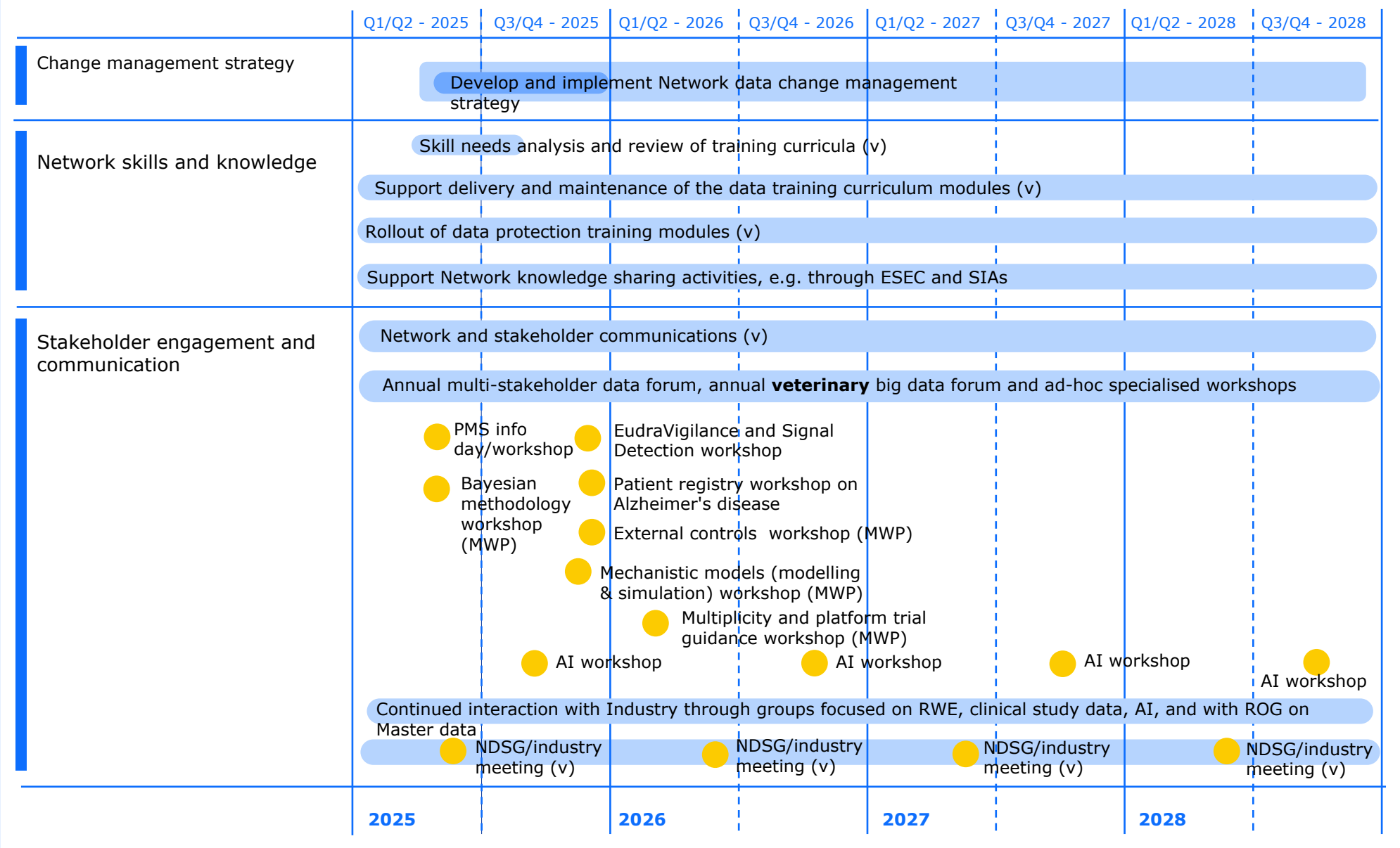
Partnerships and contributions with broader EU funded initiatives on interoperability will also be explored, such as the proposed UNICOM2 Joint Action project.

Key dates:

2025-2028	Continued support and advice to the EMRN for the development and implementation of data standards for the ERMN
2025-2028	Explore partnerships and contribution with upcoming EU funded interoperability initiatives
2026-2028	Support PMS implementation through Network portfolio and ROG

WORKSTREAM OVERVIEW

Stakeholder engagement and change management



Deliverable/activity Timeframe (v): Scope applicable to veterinary aspects Event

Change management strategy

Change management is essential to support a data-driven culture across the Network, to build trust amongst stakeholders and partners and prepare them to adopt the changes delivered under the NDSG workplan.

All stakeholders and partners should be equipped with the necessary knowledge and skills and consulted on changes when needed. Learnings and experiences should be shared, business processes optimised and tailored training programs on tools and skills rolled out. Additionally, good practices and guidance, including on methods, should be made available.

NDSG will develop a change management strategy to ensure effective communication, engagement and knowledge-building. Subsequently, NDSG will provide input on change management for high-priority topics, such as real-world evidence, artificial intelligence, clinical study data analysis and Product Master System (PMS) data.

Key dates:

Q2-Q4 2025	Develop and implement change management strategy
2025-2028	Change management approaches for real-world evidence, artificial intelligence, clinical study data analysis and Product Master System (PMS) data

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 will be rollout to the Network and relevant stakeholders when appropriate via the EU Network Training Centre (EU NTC).

Complementing the training already available on biostatistics, pharmacoepidemiology/real world evidence and data science, additional modules are already in preparation, notably on pharmacoepidemiology/real world evidence, pharmacogenomic data and data quality.

Skills will be further enhanced on the basis of a review of training delivery, as well as identification of further needs.

The Methodology European Specialised Expert Community (ESEC) and its Specialised Interest Areas (SIAs) will continue to serve as the forum for knowledge transfer for European experts on scientific and methodological topics.

Key dates:

Q2-Q3 2025	Skill need analysis and review of training curricula
2025-2028	Support delivery and maintenance of the data training curriculum modules
2025-2028	Rollout of data protection training modules
2025-2028	Support network knowledge sharing activities, e.g. through ESEC and SIAs

Stakeholder engagement and communication

Listening to stakeholders, increased transparency and excellent communication are critical to build trust in what is delivered and maximize the Network transformation to data-driven regulation.

A multi-stakeholder forum on data will be organised annually and will be complemented by specialised workshops (e.g. AI, RWE and PMS) and workshops supported by the EMA Methodology Working Party (MWP) held throughout the period of this workplan.

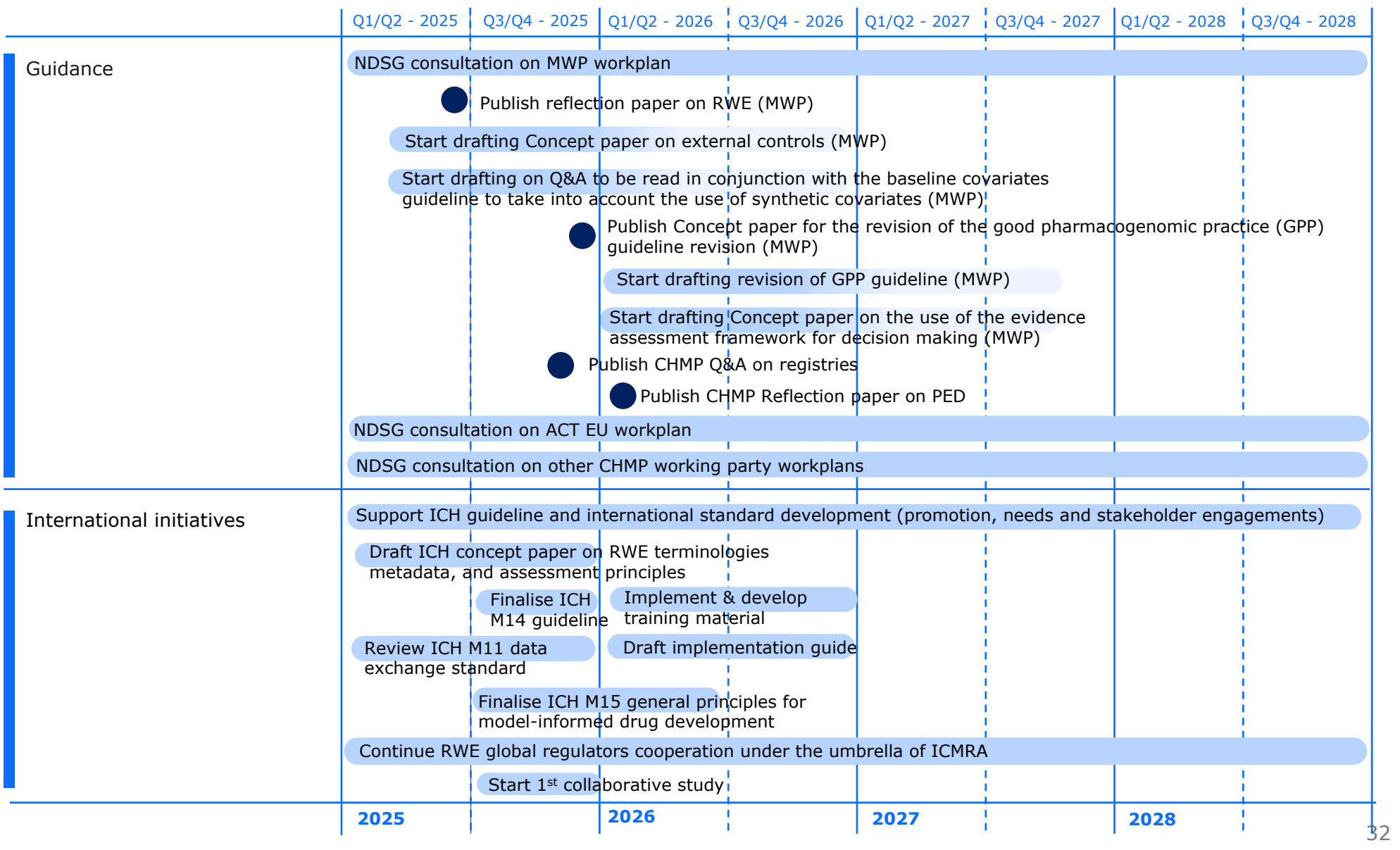
Interaction with industry will be organised through bilateral meetings, groups focused on RWE, clinical study data, and AI, and, in collaboration with the Regulatory Optimisation Group (ROG) on master data.

Key dates:

2025-2028	Network and stakeholder communications
2025-2028	Annual multi-stakeholder data forum, annual veterinary big data forum, and bi-annual specialised workshops
Q2 2025	PMS info day/workshop
Q3 2025	Bayesian methodology workshop of the MWP
Q4 2025	Patient registry workshop on Alzheimer's disease
Q4 2025	External controls workshop of the MWP
Q4 2025	Modelling & Simulation QSP / PBBK workshop of the MWP
Q4 2025	EudraVigilance and Signal Detection workshop
Q4 2025	AI workshop
Q1 2026	Multiplicity and platform trial guidance workshop of the MWP
2025-2028	Continued interaction with Industry through groups focused on RWE, clinical study data, AI and, with ROG on Master data
2025-2028	NDSG/industry meeting

WORKSTREAM OVERVIEW

Guidance and international initiatives



Guidance

Expert advice is needed to deliver robust assessment and decision-making by EMA regulatory committees and to guide stakeholders and partners.

The CHMP Methodology Working Party (MWP) is responsible for the drafting of methodology guidance and to support their implementation. Activities referred in the NDSG workplan follow the workplan of the CHMP MWP for the development of guidance (e.g. reflection paper, concept paper and Q&A) across data and methods.

To ensure integration with the totality of clinical evidence generation for decision-making, NDSG will also provide its expert input on the ACT EU workplan and other CHMP working parties workplan.

Key dates:

2025-2028	NDSG consultation on MWP workplan
Q2 2025	Publish reflection paper on RWE (MWP)
2025-2026	Start drafting concept paper on external controls (MWP)
	Start drafting on Q&A to be read in conjunction with the baseline covariates guideline to take into account the use of synthetic covariate (MWP)
	Start drafting concept paper on the use of the evidence assessment framework for decision making (MWP)
Q4 2025	Publish CHMP Q&A on registries
	Publish concept paper for revision of the good pharmacogenomic practice (GPP) guideline revision (MWP)
2026	Start drafting revision of GPP guideline (MWP)
Q1 2026	Publish CHMP reflection paper on Patient Experience Data (PED)
2025-2028	NDSG consultation on ACT EU workplan
2025-2028	NDSG consultation on other CHMP working parties workplan

International initiatives

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

The Network collaboration at ICH will intensify, e.g. in the area of RWD, data exchange and model-informed drug development. Further guidelines will be developed and new ICH topics will be considered. Activities referred to in the NDSG workplan follow the workplan of the CHMP MWP for the contribution to the development and implementation of methodological ICH guidelines.

International collaboration on RWE will continue throughout the workplan under the umbrella of ICMRA and the new working group on RWE for Public Health Emergencies, notably with the initiation of the first collaborative study on RWE.

Key dates:

2025-2028	Support ICH guideline and international standard development (promotion, needs and stakeholder engagements)
2025	Draft ICH concept paper on RWE terminologies metadata, and assessment principles
Q3-Q4 2025	Finalise ICH M14 guideline
2026	Implement & develop training material for ICH M14 guideline
2025	Review ICH M11 data exchange standard
2026	Draft implementation guide for ICH M11
Q3 2025-Q3 2026	Finalise ICH M15 general principles for model-informed drug development
2025-2028	Continue RWE global regulators cooperation under the umbrella of ICMRA
Q3-Q4 2025	Start 1st collaborative study

European Medicines Agency

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Visit Data in regulation: Big data and other sources

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Acronyms

ACT EU	Accelerating Clinical Trials in the EU
ADR	Adverse Drug Reaction reports
AI	Artificial Intelligence
CAP	Centrally Authorised medicinal Products
CHMP	Committee for Medicinal Products for Human Use
DARWIN	Data Analysis and Real-World Interrogation Network
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EHDS	European Health Data Space
EMA	European Medicines Agency
EMAN	European Medicines Agencies Network
EMRN	European Medicines Regulatory Network
ePI	Electronic Product Information
ESEC	European Specialised Expert Community
EU	European Union
EUDPR	European Union Data Protection Regulation
EU NTC	EU Network Training Centre
EU-SRS	European substance reference system
GDPR	General Data Protection Regulation
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessments
ICH	International Council for Harmonisation
ICMRA	International Coalition of Medicines Regulatory Authorities
ITF	Innovation task force
LLM	Large Language Model
MAH	Marketing Authorisation Holders
mHealth	Mobile Health
MWP	Methodology Working Party
NDSG	Network Data Steering Group
PED	Patient Experience Data

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Acronyms

PMS	Product Management Service
POC	Proof of Concept
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	PRIority MEdicines
PTM	Portfolio and technology meetings
ROG	Regulatory Optimisation Group
RWD	Real World Data
RWE	Real World Evidence
SDO	Standards Development Organisations
SEND	Standard for Exchange of Nonclinical Data
SIA	Special Interest Area
SmPC	Summary Product Characteristics
SMS	Substance Management Service
SUSAR	Suspected Unexpected Serious Adverse Reports
TEHDAS	Towards the European Health Data Space