EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

NDSG workplan 2026-2028

Data and AI in medicines regulation

Joint HMA/EMA Network Data Steering Group
VERSION 2.0 – February 2026

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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'*.

The first NDSG workplan was adopted in March 2025. This current document constitutes the first annual revision. It introduces the NDSG workplan, covering activities until 2028. It was adopted by NDSG in February 2026 and will be updated annually, informed by feedback from stakeholders and EU network experts.

The NDSG workplan provides a major contribution to the implementation of the EMAN strategy to 2028 to leverage data, digitalisation and AI (Theme 2) and support its other themes.

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

Artificial Intelligence:

- Guidance, policy and product support
- Tools and Innovation
- Collaboration and change management

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

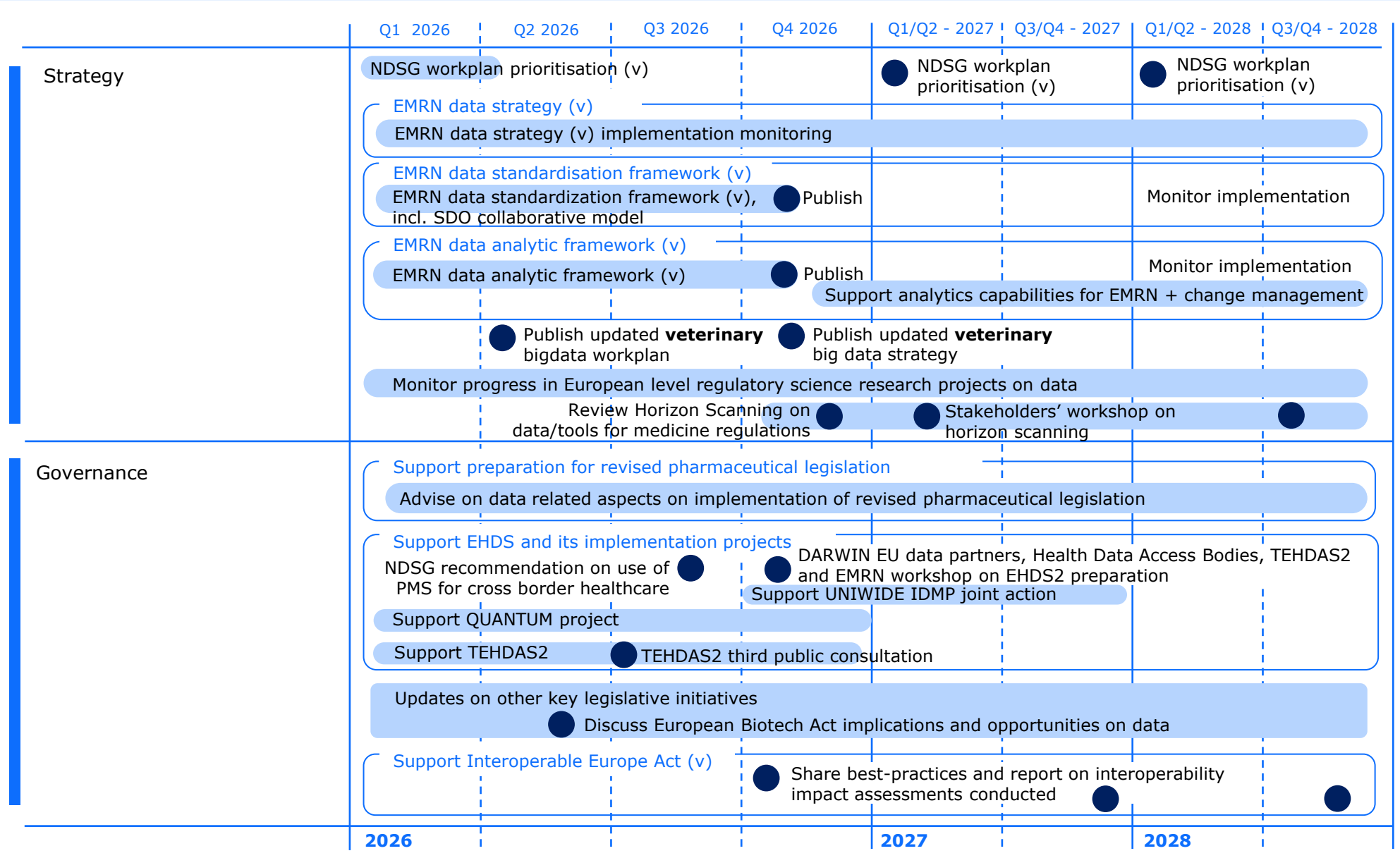
Data interoperability

Stakeholder engagement and change management

Guidance and international initiatives

WORKSTREAM OVERVIEW

Strategy and governance



Deliverable/activity Timeframe (v): Specific veterinary aspects are included

Strategy

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

- The EMRN data strategy and data standardisation framework will ensure the EMRN data assets meet high quality standards, are appropriately managed, standardised and easy to share.
- The EMRN data analytic framework 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 progress in European level regulatory science research projects on data. Insights and priorities for the future will be shaped together with stakeholders, whose feedback will be gathered during a dedicated workshop in 2027.

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

Key dates:

Q1 2026	NDSG workplan prioritisation (v)
Q2 2026	Publish updated veterinary bigdata workplan
Q4 2026	Publish updated veterinary big data strategy
	Review Horizon Scanning on data/tools for medicine regulations
	Publish EMRN data standardization framework (v), incl. SDO collaborative model
	Publish EMRN data analytic framework (v)
2026-2028	Monitor progress in European level regulatory science research projects on data
2026-2028	EMRN data strategy (v) implementation monitoring
2027-2028	Support analytics capabilities for EMRN + change management
Q1 2027	Stakeholders' workshop on horizon scanning

Governance

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

To support stakeholders and the Network, the NDSG will contribute to the implementation of:

- The revised pharmaceutical legislation for Europe. NDSG may provide advice on RWD, clinical study data, Annex 1 revision, environmental risk assessment, OneHealth, ePI.
- 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 UNIWIDE IDMP joint action).
- The Interoperable Europe Act and the related European Interoperability Framework, specifically in the domain of semantic interoperability (for EMRN critical data assets) by sharing best-practices and report on interoperability impact assessments conducted.

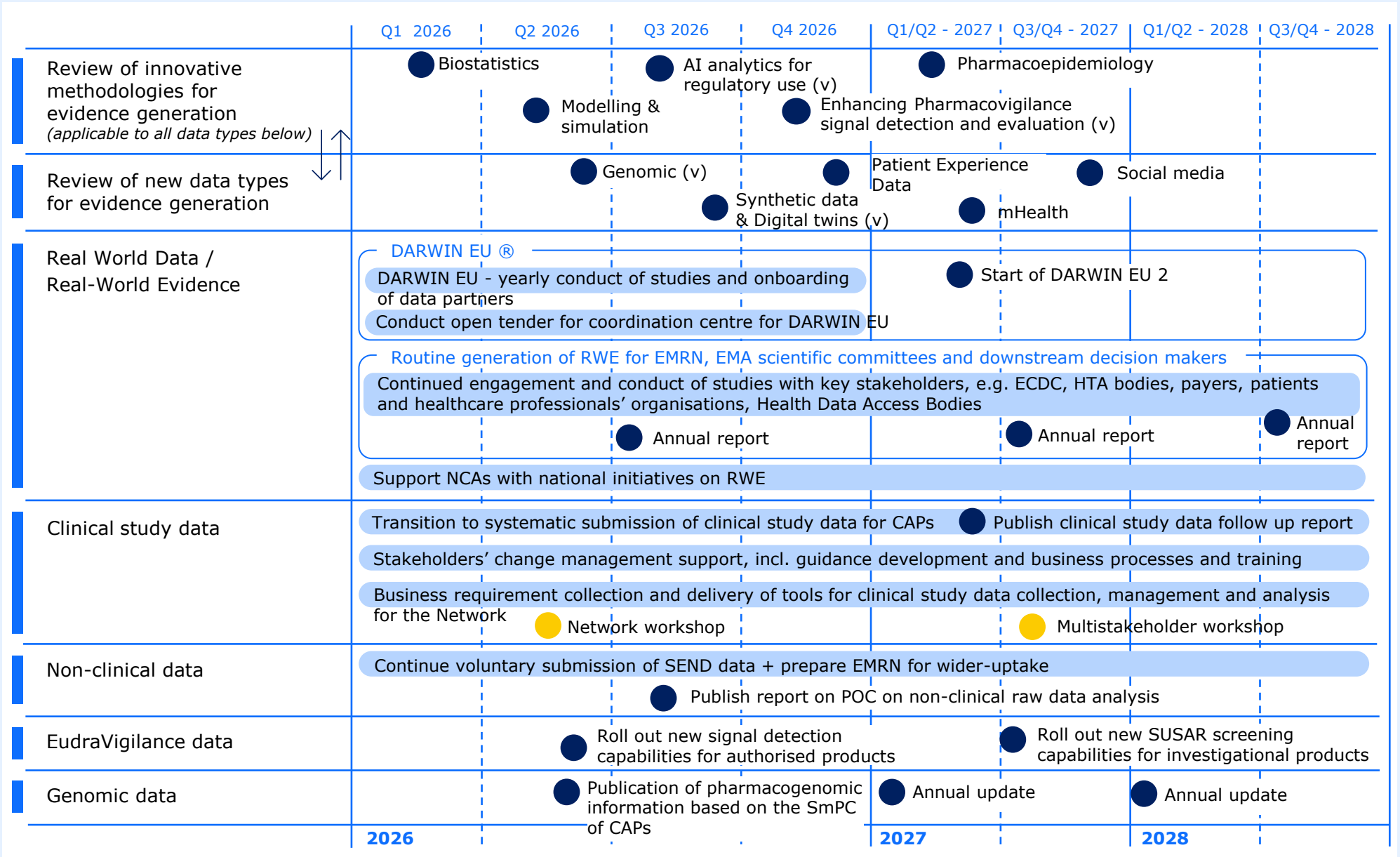
NDSG will continue to follow and discuss progress in other key legislative initiatives, notably the forthcoming European Biotech Act and its implications and opportunities on data. Additional area of focus may include the Medical Device regulation, the Data Union strategy and the EU digital omnibus, ensuring the Network remains aligned with the evolving EU policy landscape.

Key dates:

Q2 2026	Discuss European Biotech Act implications and opportunities on data
Q3 2026	NDSG recommendation on use of PMS for cross border healthcare
	TEHDAS2 third public consultation
Q4 2026	DARWIN EU data partners, Health Data Access Bodies, TEHDAS2 and EMRN workshop on EHDS2 preparation
Q4 2026-2027	Support UNIWIDE IDMP joint action
Q4 2026	Share best-practices and report on interoperability impact assessments conducted
2026	Support QUANTUM project
2026-2028	Advise on data related aspects on implementation of revised pharmaceutical legislation

WORKSTREAM OVERVIEW

Data analytics



Deliverable/activity Timeframe (v): Specific veterinary aspects are included Event

Review of innovative methodologies and data types for evidence generation

Data and methods are intricately linked, 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 innovative methodologies (including biostatistics, signal detection, modelling & simulation data, AI and pharmacoepidemiology) and data types that can complement established 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 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 its value will be established to support regulatory decision-making.

Key dates:

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

Real World Data / Real-World Evidence

The Data Analysis and Real-World Interrogation Network (DARWIN EU®) is the EMRN's 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 EMRN.

Each year, additional data partners will be onboarded and increasing numbers of studies will be conducted.

National competent authorities' initiatives on real-world evidence (RWE) will be supported and cooperation with the European Centre for Disease Prevention and Control (ECDC), bodies responsible for Health Technology Assessments (HTA), payers, Health Data Access Bodies, as well as patients and healthcare professionals' organisations, will continue.

Following an open tender in 2026, DARWIN EU 2 will be launched in 2027, as an extension of DARWIN EU .

Key dates:

2026	DARWIN EU ® - yearly conduct of studies and onboarding of data partners
	Conduct open tender for coordination center for DARWIN EU
Q3 2026-2028	Annual report
2026-2028	Continued engagement and conduct of studies with key stakeholders, e.g. ECDC, HTA bodies, payers, patients and healthcare professionals' organisations, Health Data Access Bodies
	Support NCAs with national initiatives on RWE
Q2 2027	Start of DARWIN EU ® 2

Clinical study data

Analysis of patient level clinical study data will strengthen regulatory decision-making for faster and better authorisation of medicines.

In light of the finalisation of the revised pharmaceutical legislation for Europe, the CHMP clinical study data pilot will transition to systematic submission of clinical study data for CAPs.

The pilot results will advise EMRN on optimal way to rollout of clinical study data analysis and for managing changes (including business requirement and delivery of tools, 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:

2026-2028	Transition to systematic submission of clinical study data for CAPs
	Stakeholders' change management support, including guidance development and business processes and training
	Business requirement collection and delivery of tools for clinical study data collection, management and analysis for the Network
Q2 2026	Network workshop
Q2 2027	Publish clinical study data follow up report
Q3 2027	Multistakeholder workshop

Non-clinical data

After completion of the Proof of Concept (PoC) study to evaluate implementation of the Standard for Exchange of Nonclinical Data (SEND) in 2025, voluntary submission of SEND data by MAHs will continue and preparatory work for wider uptake with the Network and stakeholders will start.

The analysis of non-clinical data can improve the quality and efficiency of routine assessment but also of procedures where data is complex and requires visualization or independent analysis.

It can also be useful for procedures where rapid regulatory input is needed (e.g. rolling review, accelerated procedures, PRIME) and for regulatory science projects to facilitate harmonization, policy or guideline recommendations.

Key dates:

Q3 2026	Publish report on POC on non-clinical data analysis
2026-2028	Continue voluntary submission of SEND data + prepare EMRN for wider-uptake

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 for authorised products,
- new clinical trial Suspected Unexpected Serious Adverse Reports (SUSAR) screening capabilities for the EU network.

Key dates:

Q2 2026	Roll out new signal detection capabilities for authorised products
Q2 2027	Roll out new SUSAR screening capabilities for investigational products

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 2026, 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 experience will be shared with the EMRN.

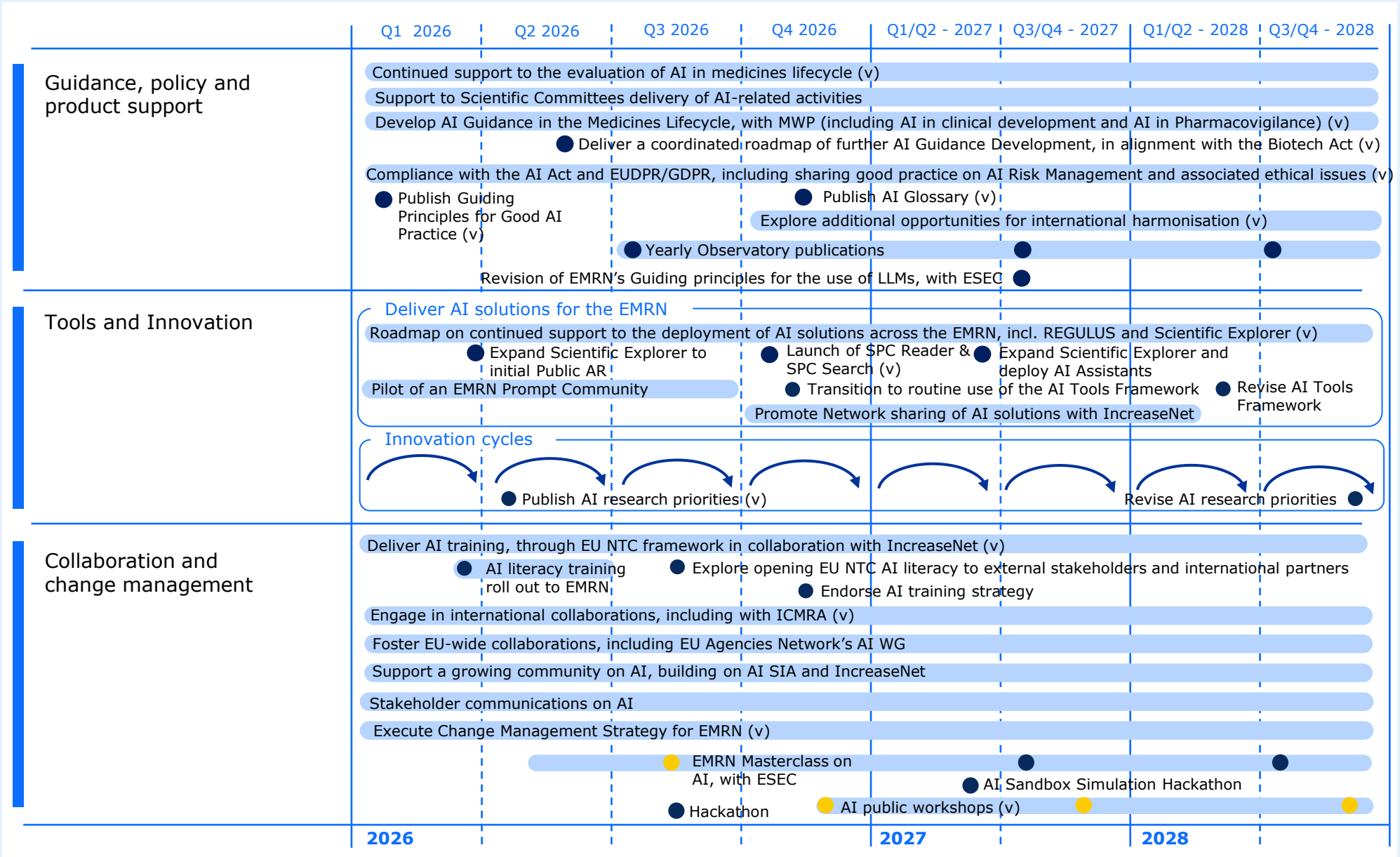
Additional activities on genomic data are also captured under the 'review of new data types for evidence generation' in this workstream and under the 'Guidance and international initiatives' workstream.

Key dates:

Q2 2026	Publication of pharmacogenomic information based on the SmPC of CAPs
2027-2028	Annual update

WORKSTREAM OVERVIEW

Artificial Intelligence



Deliverable/activity Timeframe (v): Specific veterinary aspects are included Event

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 three critical dimensions to facilitate the development and use of safe and responsible AI across human and veterinary medicines, 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 to reflect technological, regulatory and scientific developments.

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

Guidance, policy and product support

Continued support will be provided for the development and evaluation of AI throughout the medicines lifecycle, including dedicated contributions to Portfolio and Technology Meetings (PTM), the Innovation Task Force (ITF), Scientific Advice, and Qualification procedures.

Support will also be given to EMA Scientific Committees in delivering their AI-related activities, including work on AI literacy, development of AI tools, and the preparation of guidance.

A coordinated roadmap for future AI-related guidance, aligned with the proposed Biotech Act, will be developed. This will ensure that all guidance activities proceed in a consistent and strategically aligned manner.

Compliance with the AI Act and the EU-DPR/GDPR will be ensured, and good practices on risk management will be shared across the Network.

Information on activities, trends, and emerging AI domains will be published annually under the Network AI Observatory.

Guiding principles on responsible AI and an accompanying terminology document -including mapping of glossaries - will be developed. This work may serve as a foundation for future international harmonisation efforts.

Key dates:

Q1 2026	Publish Guiding Principles for Good AI Practice (v)
Q2 2026	Deliver a coordinated roadmap of further AI Guidance Development, in alignment with the Biotech Act
Q4 2026	Publish AI Glossary (v)
	Yearly Observatory publications
Q4 2026 - 2028	Explore additional opportunities for international harmonisation (v)
2026-2028	Continued support to the evaluation of AI in medicines lifecycle (v)
	Support to Scientific Committees delivery of AI-related activities
	Develop AI Guidance in the Medicines Lifecycle, with MWP (including AI in clinical development and AI in Pharmacovigilance) (v)
	Compliance with the AI Act and EUDPR/GDPR, including sharing good practice on AI Risk Management associated ethical issues (v)
Q3 2027	Revision of EMRN's Guiding principles for the use of LLMs, with ESEC

Tools and Innovation

Core AI capabilities will continue to be strengthened, and new collaborative approaches will be piloted across the Network.

Several existing AI solutions will be further supported and expanded, including REGULUS and Scientific Explorer - Scientific Explorer will be extended to initial Public assessment reports - while new tools will be deployed, including SPC Reader and additional AI assistants.

To build Network-wide expertise in prompting and generative-AI practices, an EMRN Prompt Community will be piloted from Q1 to Q3 2026, supporting the effective delivery and use of AI assistants.

AI research priorities will be published in Q2 2026 and subsequently revised in 2028 to incorporate new developments and emerging needs.

The AI Tools Framework will be implemented in late 2026 to foster collaboration and sharing of AI tools across the European Medicines Regulatory Network.

In parallel, IncreaseNet's initiative to promote cross-network sharing of AI solutions will be supported and will inform the 2028 update of the AI Tools Framework, ensuring strong coordination and collaboration across European agencies.

Key dates:

Q1 2026	Expand Scientific Explorer to initial Public AR
Q2 2026	Publish AI research priorities (v)
Q4 2026	Launch of SPC Reader & SPC Search (v)
Q1 2026 - Q3 2026	Pilot of an EMRN Prompt Community
Q4 2026	Transition to routine use of the AI Tools Framework
Q4 2026 – 2027	Promote network sharing of AI solutions with IncreaseNet
2026-2028	Roadmap on continued support to the deployment of AI solutions across the EMRN, incl. REGULUS and Scientific Explorer (v)
Q2 2027	Expand Scientific Explorer and deploy AI Assistants
Q1 2028	Revise AI Tools Framework
Q4 2028	Revise AI research priorities

Collaboration and change management

AI literacy remains a critical priority (and a legal obligation under the AI Act). Therefore, the EU-Network Training Centre will roll out AI literacy initiatives across the European Medicines Regulatory Network while expanding and delivering training on AI. Opening the training to external stakeholders will be explored.

The Network will continue to collaborate closely with international and European partners, including the International Coalition of Medicines Regulatory Authorities (ICMRA), EU Agencies through the EU Agencies Network AI working group, and other relevant stakeholders.

The AI Special Interest Area will collaborate with the IncreaseNet to support a growing community of practice on AI, extending knowledge sharing to a broader range of staff.

The Network-wide change management strategy will continue to be implemented to ensure support for AI organisational transformation.

Topic-specific public workshops, masterclasses and hackathons will further strengthen upskilling efforts and enhance engagement with stakeholders and the wider data science community. Stakeholder feedback will guide the selection of topics to ensure relevance and impact.

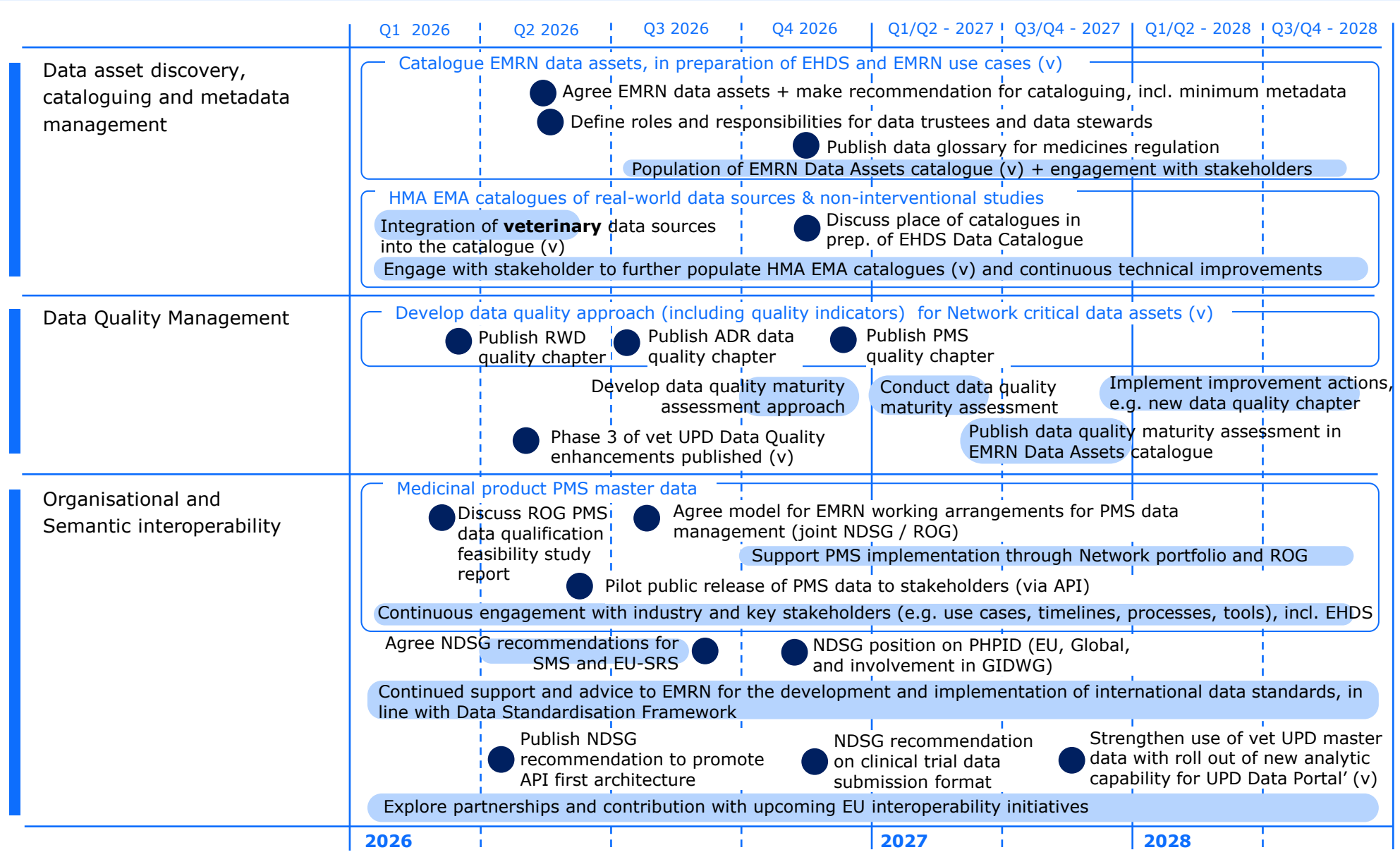
In Q2 2027, a regulatory sandbox simulation hackathon will be conducted to explore challenges and regulatory considerations in hypothetical AI use-case scenarios.

Key dates:

Q1 2026	AI literacy training roll out to EMRN
Q3 2026	EMRN Masterclass on AI, with ESEC
	Explore opening EU NTC AI literacy to external stakeholders and international partners
	Hackathon
Q4 2026	Endorse AI training strategy
	AI public workshops (v)
2026 - 2028	Deliver AI training, through EU NTC framework in collaboration with IncreaseNet (v)
	Engage in international collaborations, including with ICMRA (v)
	Foster EU-wide collaborations, including EU Agencies Network's AI WG
	Support a growing community on AI, building on AI SIA and IncreaseNet
	Stakeholder communications on AI
	Execute Change Management Strategy for EMRN (v)
Q2 2027	AI Sandbox Simulation Hackathon

WORKSTREAM OVERVIEW

Data interoperability



Deliverable/activity Timeframe (v): Specific veterinary aspects are included

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 be supported by the definition of clear roles and responsibilities for data trustees and data stewards, as well as a data glossary for medicines regulation. This will also consider the preparation of the European Health Data Space (EHDS).

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

Key dates:

Q1–Q2 2026	Integration of veterinary data sources into the catalogue (v)
Q2 2026	Agree EMRN data assets + make recommendation for cataloguing, incl. minimum metadata
	Define roles and responsibilities for data trustees and data stewards
Q3 2026-2028	Population of EMRN Data Assets catalogue (v) + engagement with stakeholders
Q4 2026	Publish data glossary for medicines regulation
	Discuss place of catalogues in prep. of EHDS Data Catalogue
2026-2028	Engage with stakeholder to further populate HMA EMA catalogues (v) and continuous technical improvements

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 developed, informed by and aligned with the relevant EU data quality initiatives, notably the data quality framework for EU medicines regulation and the veterinary Union Product Database (UPD) data quality framework.

Specific quality chapters will be published for selected data domains, starting with Real-world data (RWD), Adverse Drug Reaction (ADR) and Product Master System (PMS) data. Additional enhancements to the veterinary UPD data quality framework will be published.

Data quality maturity assessments will be performed and published via the EMRN data asset catalogue to ensure the data quality of the Network's critical data assets is well understood.

Key dates:

Q1 2026	Publish RWD quality chapter
Q2 2026	Phase 3 of vet UPD Data Quality enhancements published (v)
Q3 2026	Publish ADR data quality chapter
Q4 2026	Publish PMS quality chapter
	Develop data quality maturity assessment approach
Q1-Q2 2027	Conduct data quality maturity assessment
Q3-Q4 2027	Publish data quality maturity assessment in EMRN Data Assets catalogue
2028	Implement improvement actions, e.g. new data quality chapter

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 datasets relates to 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.

Additional PMS master data will be made available to stakeholders via the launch of a public API. More generally, the NDSG will promote API first architecture for the development of the Network tools.

Key dates:

Q1 2026	Discuss ROG PMS data qualification feasibility study report
Q2 2026	Pilot public release of PMS data (via API) to stakeholders
	Publish NDSG recommendation to promote API first architecture
Q3 2026	Agree model for EMRN working arrangements for PMS data management (joint NDSG / ROG)
	Agree NDSG recommendations for SMS and EU-SRS
Q4 2026-2028	Support PMS implementation through Network portfolio and ROG
Q4 2026	NDSG position on PHPID (EU, Global, and involvement in GIDWG)
	NDSG recommendation on clinical trial data submission format
2026-2028	Continuous engagement with industry and key stakeholders (e.g. use cases, timelines, processes, tools), incl. EHDS

Organisational and Semantic interoperability

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

NDSG will provide continuous support and advice to the EMRN for the development and implementation of international data standards (e.g. HL7, ISO, ICH…) for the ERMN, in line with Data Standardisation Framework.

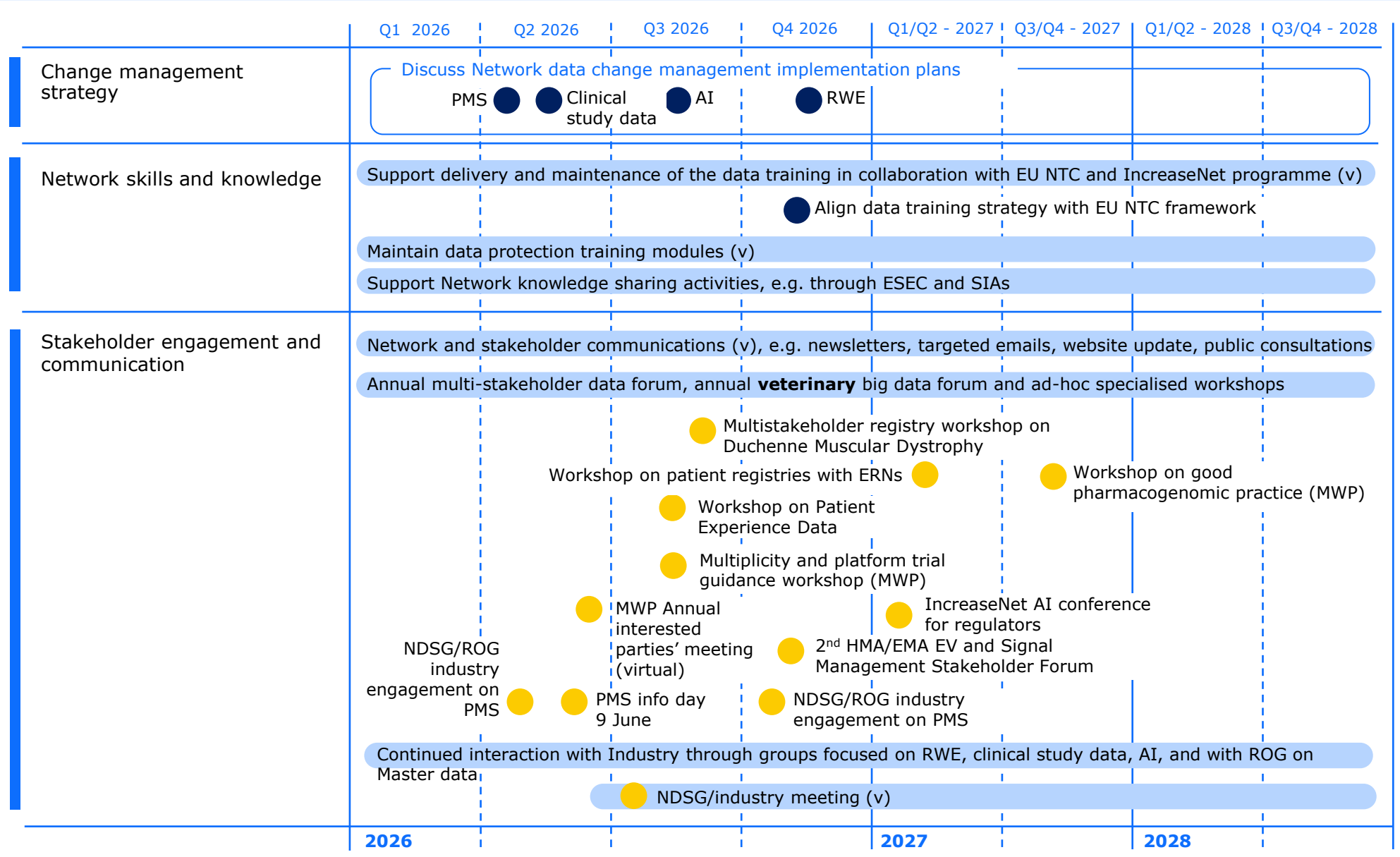
Partnerships and contributions with broader EU funded initiatives on interoperability will also be explored.

Key dates:

2026-2028	Explore partnerships and contribution with upcoming EU interoperability initiatives
	Continued support and advice to EMRN for the development and implementation of international data standards, in line with Data Standardisation Framework
Q4 2027	Strengthen use of vet UPD master data with roll out of new analytic capability for UPD Data Portal' (v)

WORKSTREAM OVERVIEW

Stakeholder engagement and change management



Deliverable/activity Timeframe (v): Specific veterinary aspects are included 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 oversee the implementation of the Network change management plans (on data) to ensure effective communication, engagement and knowledge-building for high-priority topics, such as real-world evidence, artificial intelligence, clinical study data analysis and Product Master System (PMS) data.

Key dates:

Q2 2026	Discuss Network data change management implementation plan on PMS
	Discuss Network data change management implementation plan on Clinical study data
Q3 2026	Discuss Network data change management implementation plan on AI
Q4 2026	Discuss Network data change management implementation plan on RWE

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 rolled out to the Network and relevant stakeholders when appropriate via the EU Network Training Centre (EU NTC) and in collaboration with the IncreaseNet programme.

Training programs cover at least biostatistics, pharmacoepidemiology/real world evidence, data science, pharmacogenomic, AI and data protection.

Skills will be further enhanced on the basis of a review of the training strategy, in line with the EU NTC framework.

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:

Q4 2026	Align data training strategy with EU NTC framework
2026-2028	Support delivery and maintenance of the data training in collaboration with EU NTC and IncreaseNet programme (v)
	Maintain data protection training modules (v)
	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, registries, Patient Experience Data, signal detection and PMS…) and workshops supported by the EMA Methodology Working Party (MWP) held throughout the period of this workplan.

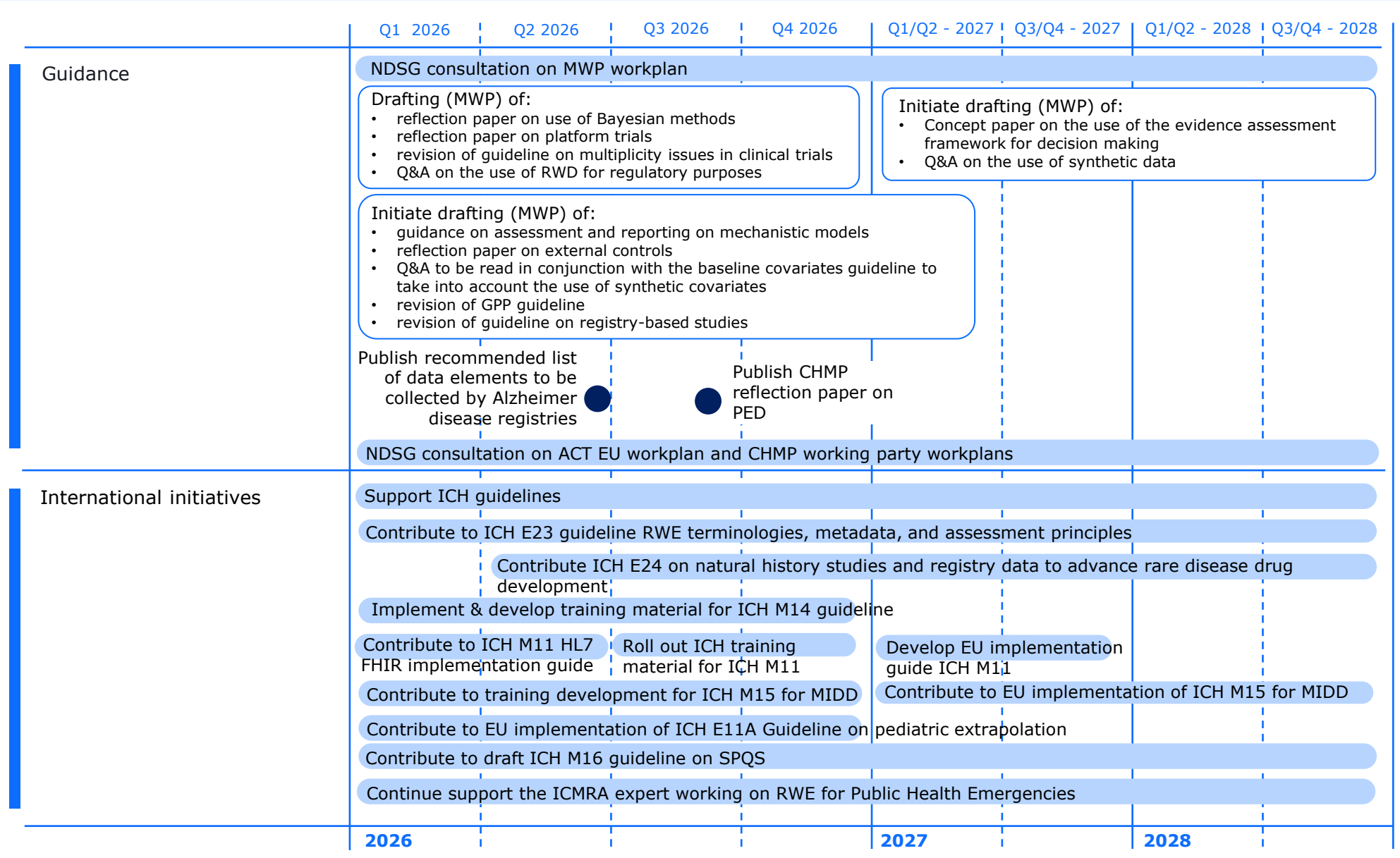
Interaction with industry will be organised through groups focused on RWE, clinical study data, and AI, and, in collaboration with the Regulatory Optimisation Group (ROG) on master data.

Key dates:

2026 - 2028	Network & stakeholder communications (v), e.g. newsletters, targeted emails, website update, public consultations
	Annual multi-stakeholder data forum, annual veterinary big data forum and ad-hoc specialised workshops
	Continued interaction with Industry through groups focused on RWE, clinical study data, AI, and with ROG on Master data
Q2 2026	NDSG/ROG industry engagement on PMS
	PMS info day 9 June
	MWP Annual interested parties' meeting (virtual)
Q3 2026	Multistakeholder registry workshop on Duchenne Muscular Dystrophy
	Workshop on Patient Experience Data
	Multiplicity and platform trial guidance workshop (MWP)
	NDSG/industry meeting (v)
Q4 2026	2nd HMA/EMA EV & Signal Management Stakeholder Forum
	NDSG/ROG industry engagement on PMS
Q1 2027	IncreaseNet AI conference for regulators
	Workshop on patient registries with ERNs
Q3 2027	Workshop on good pharmacogenomic practice (MWP)

WORKSTREAM OVERVIEW

Guidance and international initiatives



Deliverable/activity Timeframe (v): Specific veterinary aspects are included

Guidance

Expert guidance 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 CHMP working parties workplan.

Key dates:

2026-2028	NDSG consultation on MWP workplan NDSG consultation on ACT EU workplan and CHMP working party workplans
2026	Drafting (MWP) of: • reflection paper on use of Bayesian methods • reflection paper on platform trials • revision of guideline on multiplicity issues in clinical trials • Q&A on the use of RWD for regulatory purposes Initiate drafting (MWP) of: • guidance on assessment and reporting on mechanistic models • reflection paper on external controls • Q&A to be read in conjunction with the baseline covariates guideline to take into account the use of synthetic covariates • revision of GPP guideline • revision of guideline on registry-based studies
Q2 2026	Publish recommended list of data elements to be collected by Alzheimer disease registries
Q3 2026	Publish CHMP reflection paper on PED
2027	Initiate drafting (MWP) of: • Concept paper on the use of the evidence assessment framework for decision making • Q&A on the use of synthetic data

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 continue and progress will be made on implementation at EU level when relevant, e.g. in the area of RWD, clinical trial study protocol, Structured Product Quality Submissions, model-informed drug development and pediatric extrapolation. 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 its working group on RWE for Public Health Emergencies.

Key dates:

2026-2028	Support ICH guidelines
	Contribute to ICH E23 guideline RWE terminologies, metadata, and assessment principles
2026	Implement & develop training material for ICH M14 guideline
Q1-Q2 2026	Contribute to ICH M11 HL7 FHIR implementation guide
Q2-Q4 2026	Roll out ICH training material for ICH M11
Q2 2026-2028	Contribute ICH E24 on natural history studies and registry data to advance rare disease drug development
2026	Contribute to training development for ICH M15 for MIDD
	Contribute to EU implementation of ICH E11A Guideline on pediatric extrapolation
2026-2028	Contribute to draft ICH M16 guideline on SPQS
	Continue support the ICMRA expert-working group on RWE for Public Health Emergencies
2027	Develop EU implementation guide ICH M11
2027-2028	Contribute to EU implementation of ICH M15 for MIDD

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Visit Data in regulation: Big data and other sources

Acronyms

ACT EU	Accelerating Clinical Trials in the EU
ADR	Adverse Drug Reaction reports
AI	Artificial Intelligence
API	Application Programming Interface
AR	Assessment Report
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
ERN	European Reference Network
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
GIDWG	Global IDMP working group
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

Acronyms

MIDD	Model-Informed Drug Development
mHealth	Mobile Health
MWP	Methodology Working Party
NDSG	Network Data Steering Group
PED	Patient Experience Data
PHPID	Pharmaceutical Product Identification
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
SPQS	Structured Product Quality Submissions
TEHDAS	Towards the European Health Data Space
UNIWIDE	UNIWIDE IDMP Joint Action: UNIque Widespread IDentification for medicines in Europe