EMA
EUROPEAN MEDICINES AGENCY

Regulatory and policy approaches to AI

- in view of EMA's mandate and mission

Denise Umuhire (Senior Specialist, Data Analytics and Methods Taskforce)
Orsolya Eotvos (Legal Officer and Assistant DPO, Legal Department)

Presentation at AAE Webinar on AI Governance and Risk Management - perspectives from Insurance, Medicine and Space sectors

13 April 2026

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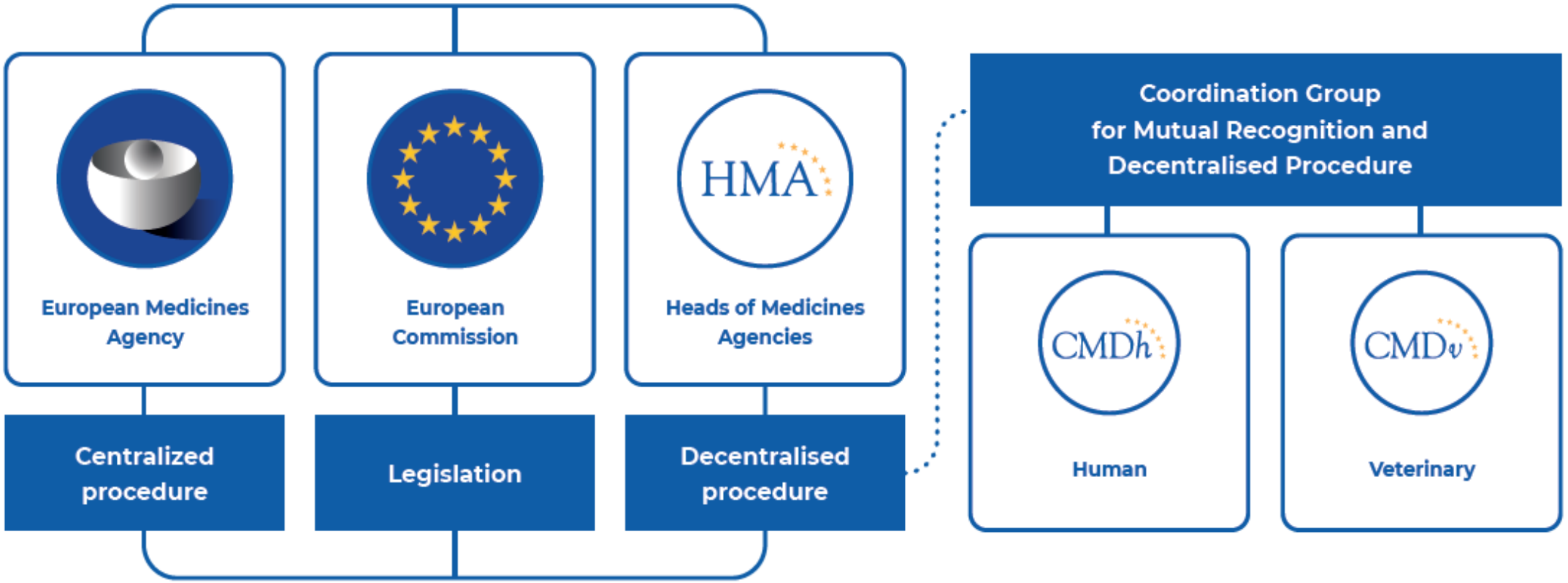
1.

EMA’s mission

Science, Medicines, Health.

To foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the EU.

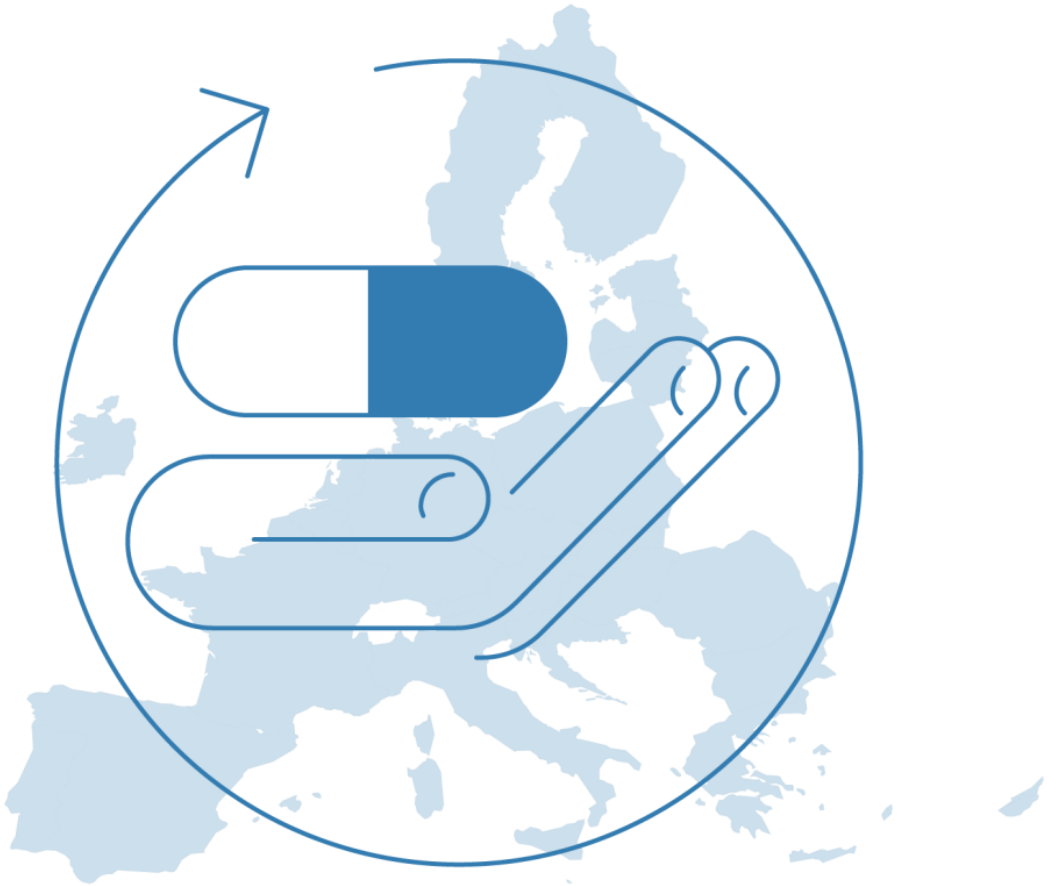
European regulatory network



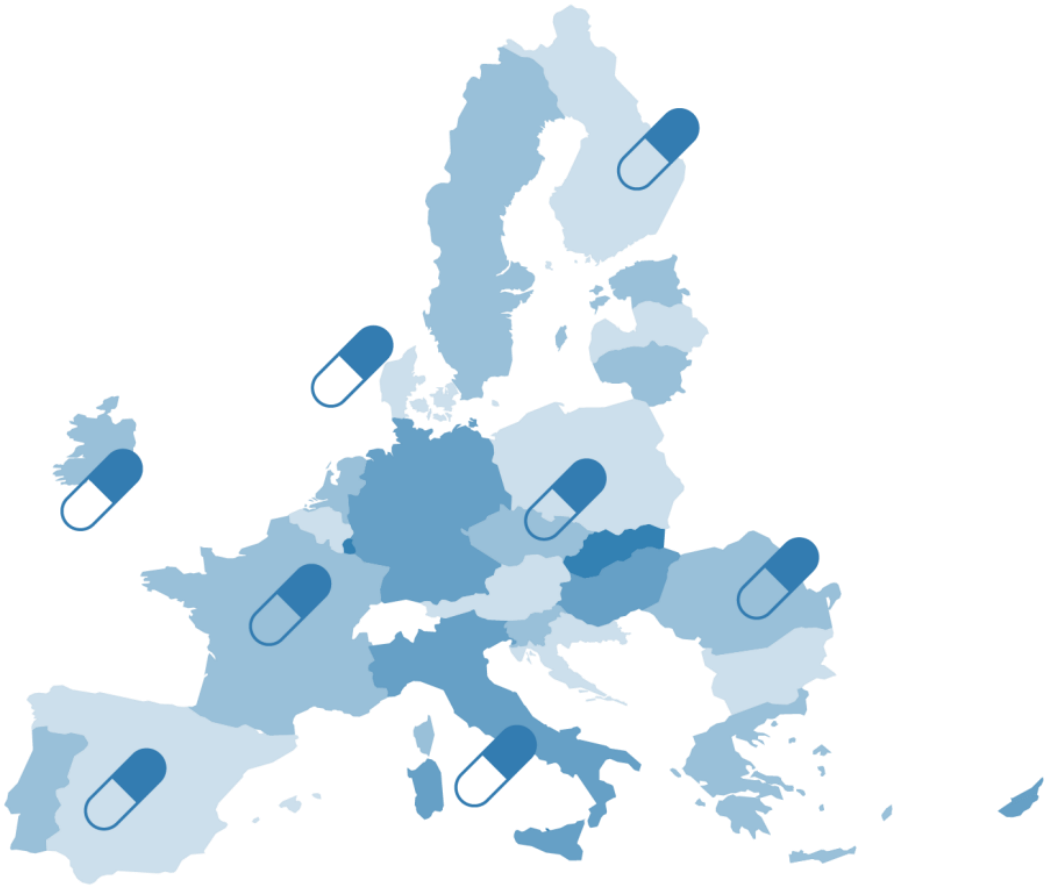
The cooperation between EMA, the National Competent Authorities in the Member States, and the European Commission is key

How are medicines approved?

Different authorisation routes: one set of common rules



Centralised procedure (via EMA)



National procedures (via Member States)

EU Approval Routes

National Procedure

Mutual Recognition procedure

Decentralised Procedure

Centralised Procedure (via EMA)

1 MA in a MS

No MA in <u>any</u> of MSs

Application to an individual NCA

Authorisation by several MSs, based on main assessment by Reference EU MS

***Mandatory scope -** Art. 3(1) Regulation (EC) No 726/2004*

Application to EMA, authorisation by European Commission, valid in all EU MSs

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SCIENCE MEDICINES HEALTH

EMA

How do we do it?

EMA

CHMP **CAT** **PRAC** **COMP** **PDCO** **HMPC**

~ 50+ EU National Competent Authorities

~ 4000 European experts

24 Official languages

1 Application ¦ 1 Assessment ¦ 27 Member States

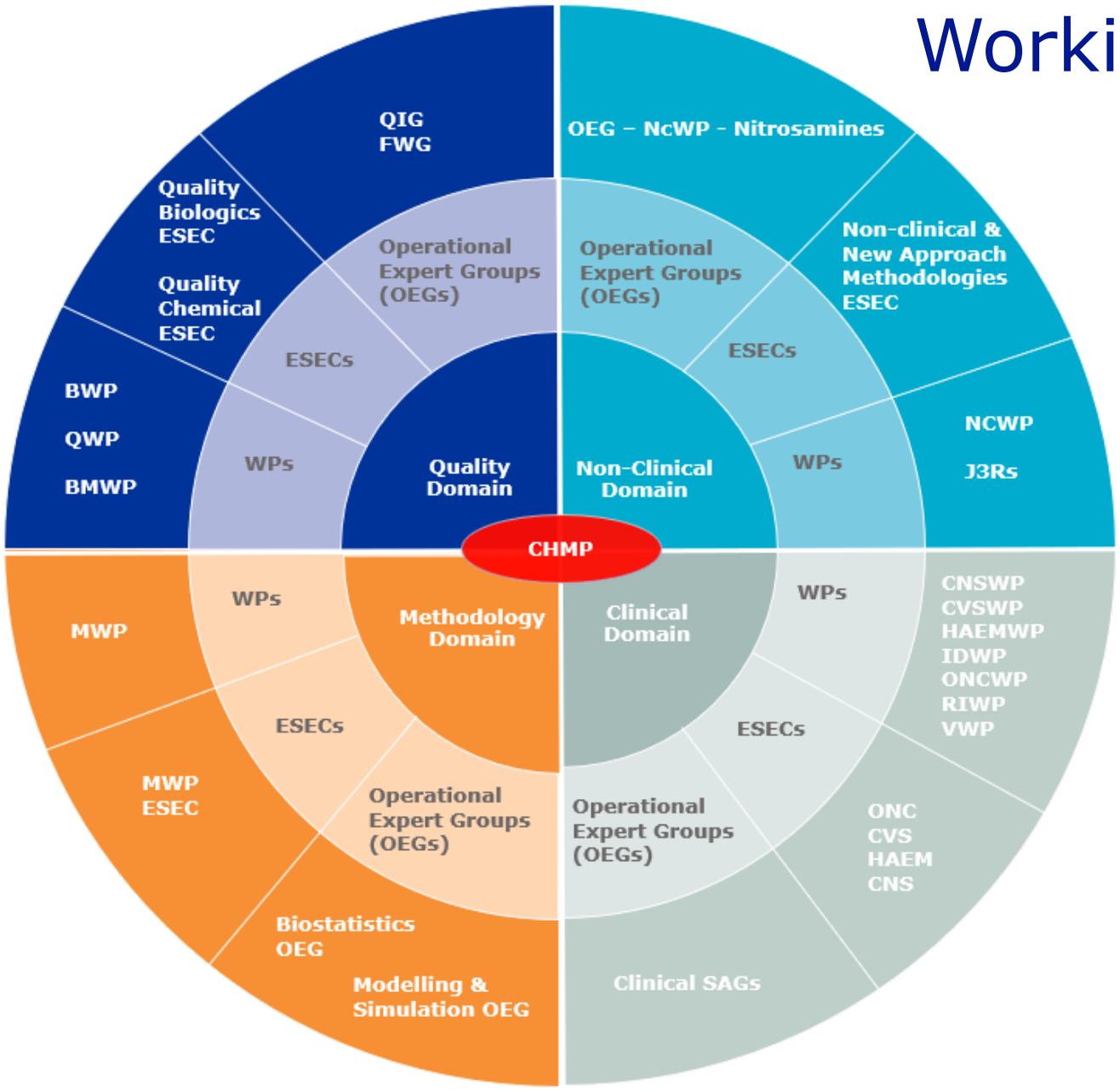
EU institutions

European Parliament

European Commission

- **CHMP** – Review of Q,S and E and of B/R for new human medicines
- **CAT** – Advanced therapies medicines
- **PRAC** – Risk management of medicines – risk management plan
- **COMP** – Orphan medicinal product designations
- **PDCO** – Paediatric investigation plans
- **HMPC** – EU monographs on well established & traditional herbal substances

Working parties, Advisory bodies



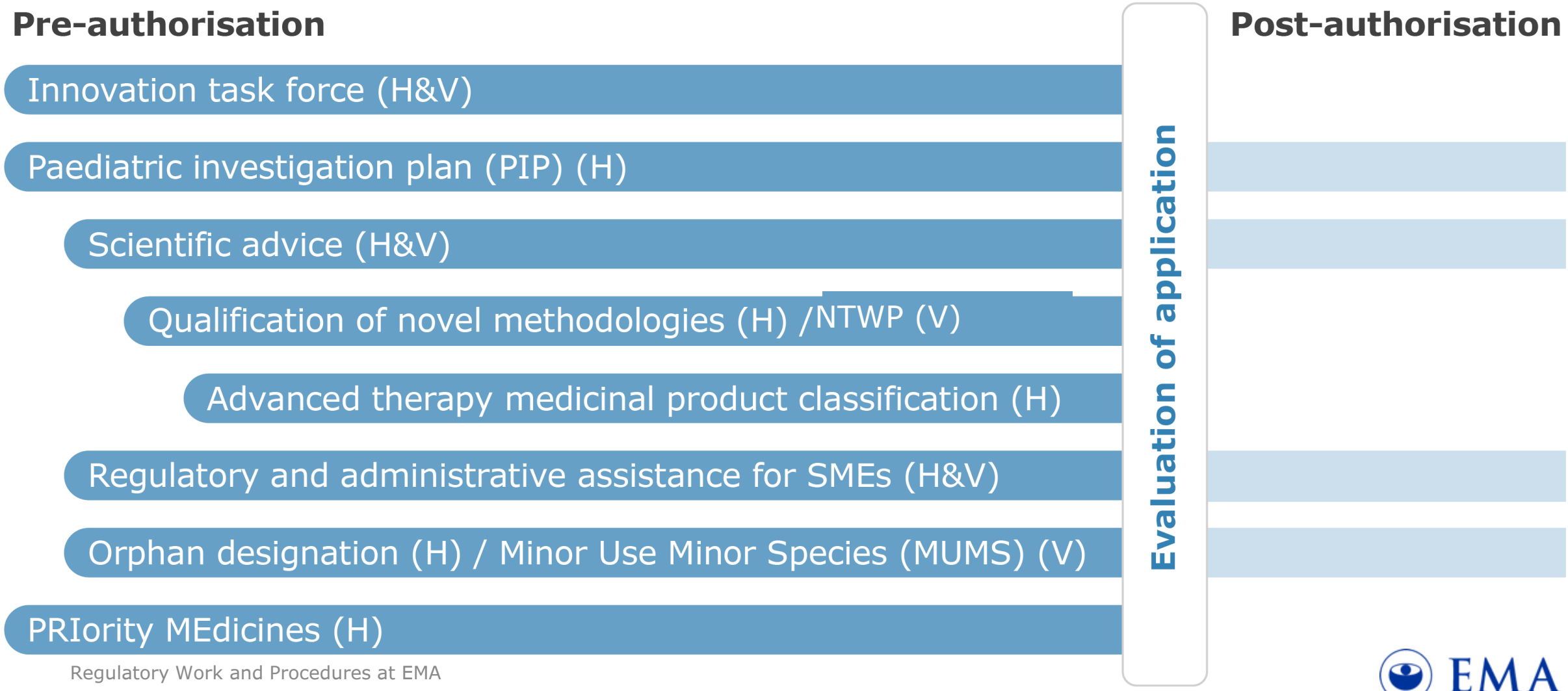
Working parties (WPs)

- Provide **advice on regulatory procedures**
- Support the drafting of **scientific guidelines**
- Reinforced advice provided to the Committees on **specific requests** across different scientific areas

Scientific Advisory Groups (SAGs) and Ad-Hoc Expert Groups (AHEGs)

- Therapeutic Areas covered by **SAGs**: **Vaccines, Oncology, Neurology, Cardiovascular, Infectious diseases, Immune and Inflammatory Diseases**; rest of areas are covered by AHEGs.
- Deliver **answers to specific questions** asked by the Committees; these bodies are not responsible for establishing or concluding on the B/R of a medicine.
- The members/participants are clinical experts and patient representatives
- Public call for interest to become a SAG member

Supporting research and innovation of medicines

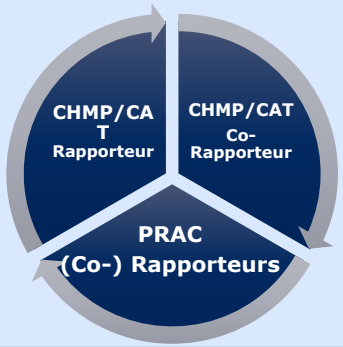


EMA support and product team

Network

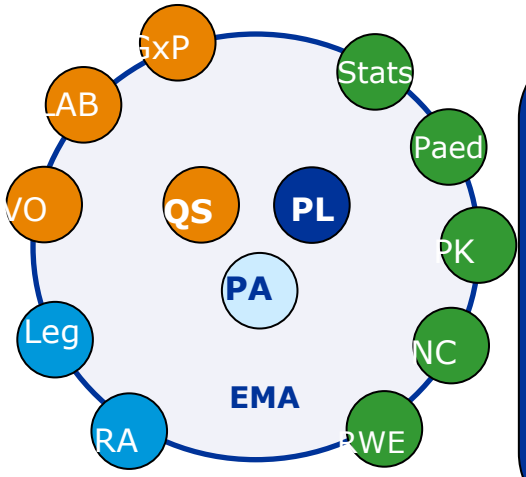
QWP

BWP



Rapporteur

- Lead the scientific assessment and evaluation
- Represent the CHMP, CAT and PRAC in liaison with applicant
- Presentation to committees



Product Lead

- Leads the product team output
- Provides input on procedural, regulatory & scientific matters to the Rapporteurs, Committee and applicant

Specialist Functions: Responsible for delivery of specific components of the opinions

Advisory Functions: Provide Legal/RA advice, support when needed

Consultation Functions: Consulted on specific technical aspects if required

*QWP – quality working party

*BWP – biological working party

*QS – quality specialist

*GMP – good manufacturing practices

*GCP – good clinical practices

*GLP – good laboratory practices

*RA- regulatory affairs
*PK – pharmacokinetics
*RWE – real world evidence

*LAB – labelling
*VO – validation officer
* leg – legals

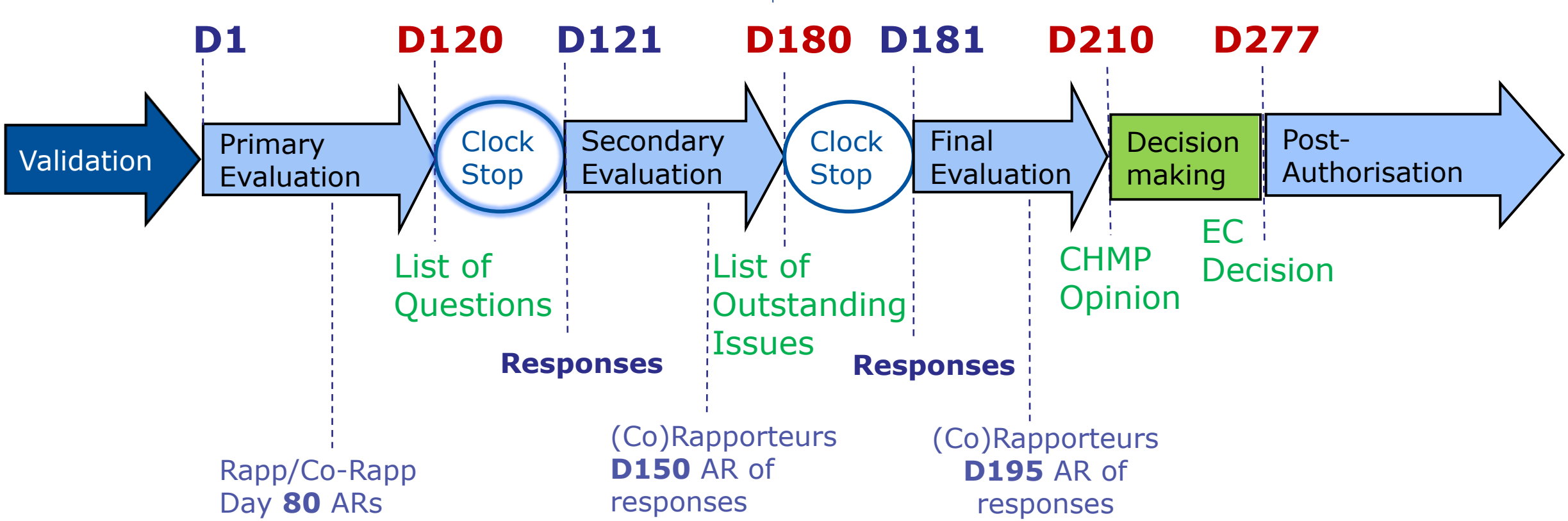
*NC – non-clinical

*Paed – paediatrics

*Stats - statistics

Overview of the assessment process for initial MAA

EMA – CHMP - CAT – PRAC



Potential additional steps:

- GMP, GLP, GCP Inspections
- Consultation of Scientific Advisory Group (SAG) or *ad hoc* expert group, other committees or WP
- Oral explanation

Final CHMP Opinion

CHMP opinion + Annex A (listing all authorised presentations)

Annex I: Summary of the Product characteristics (basis for healthcare professionals on how to use the medicine)

Annex II: information on manufacturers, legal status (on prescription or not, etc.)

Annex III: Labelling and Package Leaflet

Annex IV MA Specificities: similarity, derogation for orphans, eMA, cMA, additional data exclusivity*

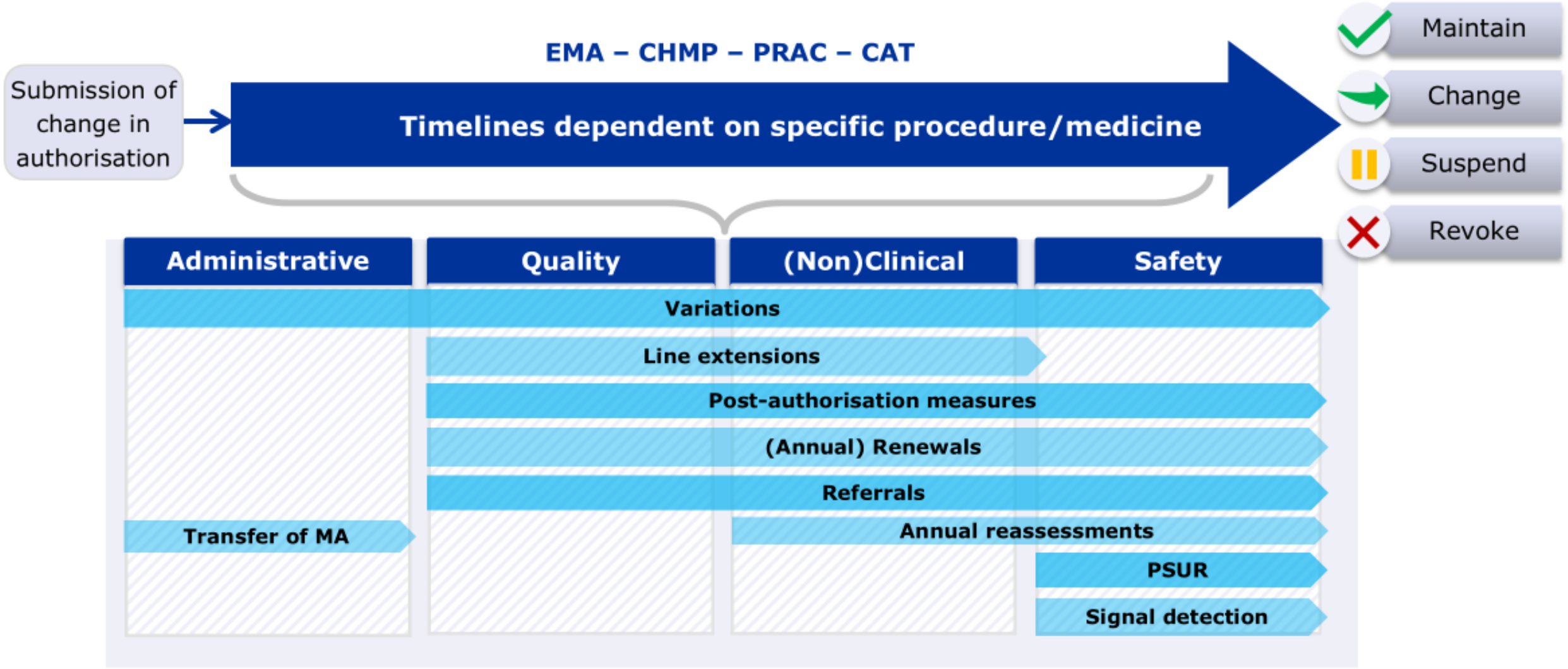
Annex 127a: Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states*

CHMP Assessment report (EN only)

Post-opinion phase

- **Linguistic review** (27 days) – translations in all EU official languages
- European Commission (EC) prepares **draft decision**
- **Standing Committee** on Medicinal Products for Human Use (representatives from Member States) gives Opinion on the draft decision
- EC **adopts the decision** on granting (or refusing) MA, which takes effect from the date of notification

Post-authorisation procedures



Transparency

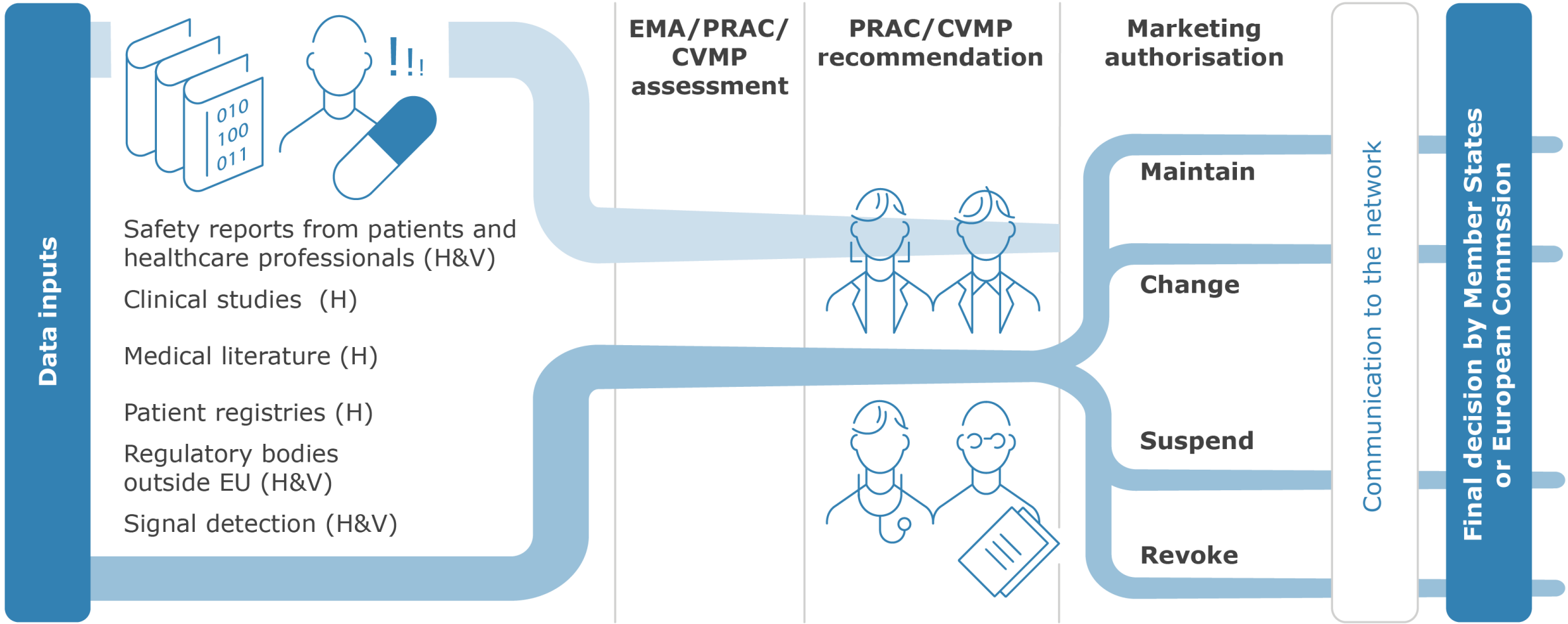
Upon adoption of an Opinion:

- Announcement in CHMP highlights + Publication of patient-friendly summary of the Opinion

Positive as well as negative Opinions

- Also publish information on applications **withdrawn** by the applicant
- EPAR is published once the Commission has issued the Decision granting (or not) the MA
- Information on new safety issues, MA suspensions or products withdrawn from the EU market

How do we monitor the safety of medicines already on the market?



The bigger picture

Promoting good, evidence-based information for patients

Aligning with global regulators to address common challenges

Building trust in science and public health in the EU

2.

Regulatory and policy approaches to AI

Joint HMA-EMA Network Data Steering Group (NDSG) workplan 2026-2028

The NDSG workplan (current version published on **9 March 2026**) 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

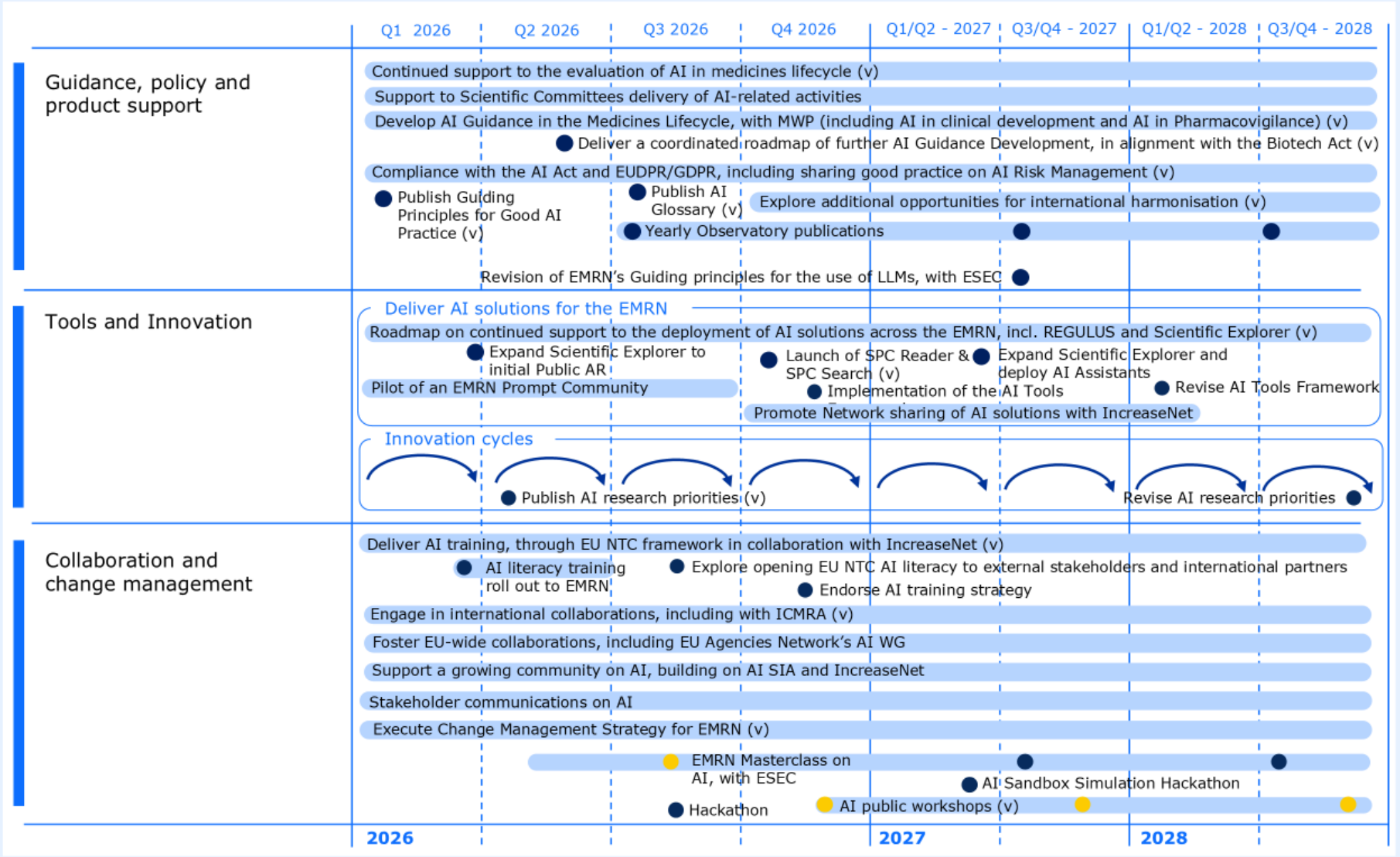
Guidance and international initiatives:

- Guidance
- International initiatives

Network Data Steering Group (NDSG) 2025 report published on 29 January 2026.

WORKSTREAM OVERVIEW

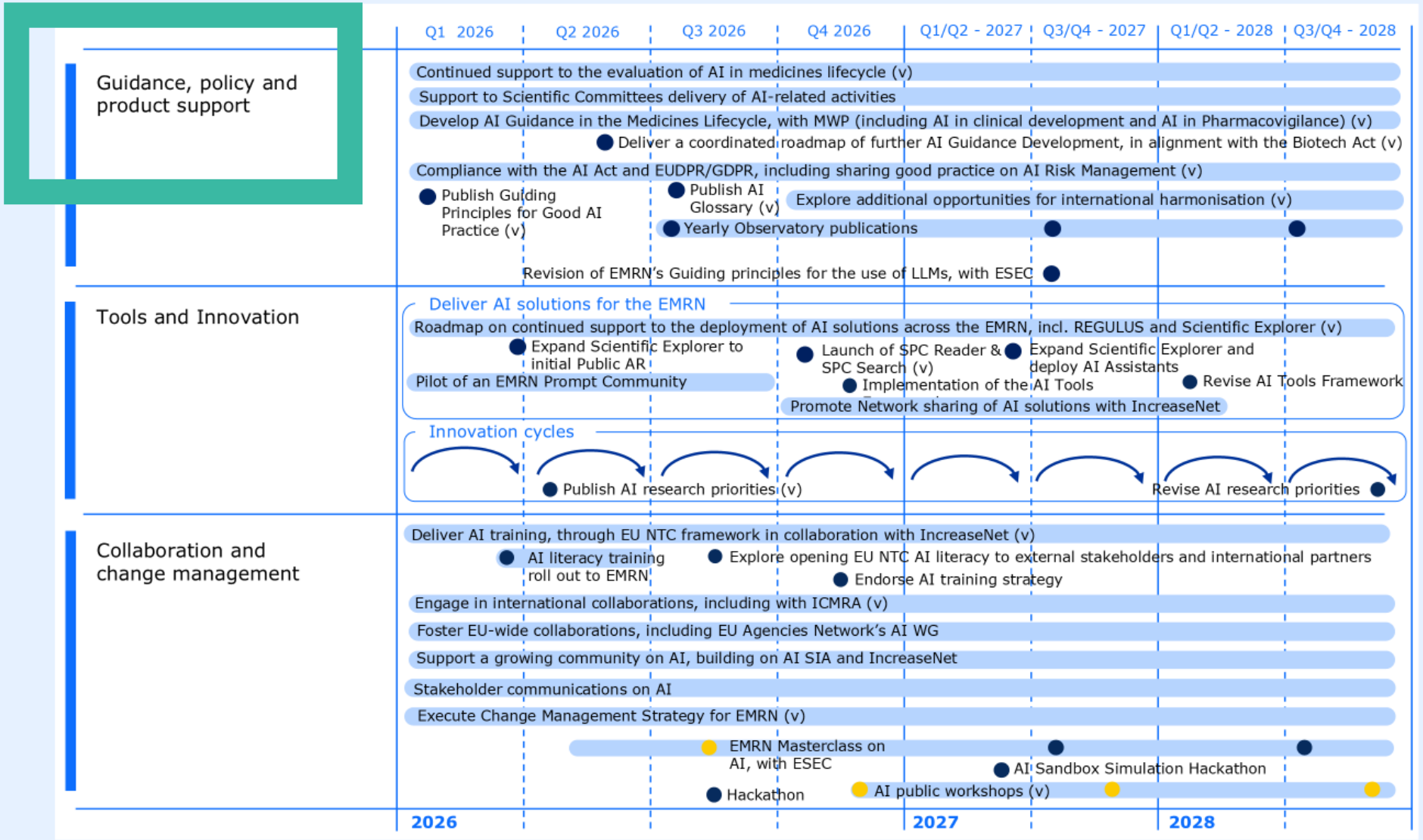
Artificial Intelligence



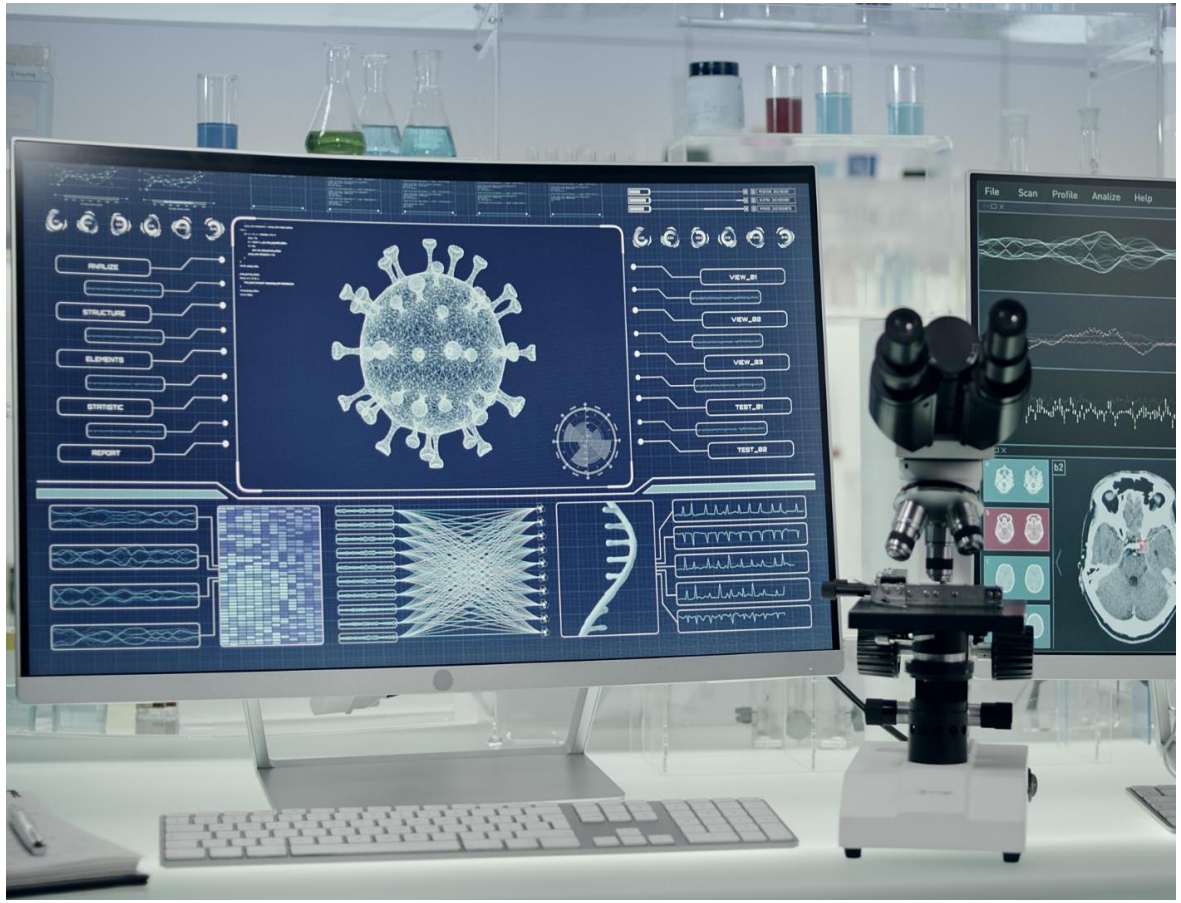
Deliverable/activity Timeframe (v): Specific veterinary aspects are included Event

WORKSTREAM OVERVIEW

Artificial Intelligence



EMA Reflection paper on AI in Medicine



Most comprehensive EMA guide

The reflection paper explains current regulatory views on using AI to improve the development, regulation, and use of human and veterinary medicines.

Accountability

Outlines key responsibilities of MAH/sponsor to comply with scientific, technical, ethical and legal standards.

Enhanced technical requirements

E.g. expected quality controls in place to ensure the veracity, reliability, and fairness of AI-generated documentation.

HMA/EMA Guiding principles on the use of LLM in regulatory science and medicines regulatory activities

Guiding principles written for regulatory staff

Clear expectations for the responsible use of large language models in regulatory science.

Standard of care for all stakeholders

Sponsors, applicants, and MAHs are expected to ensure equivalent care in using LLMs.

Safe and responsible use via practical implementation

- Principles from user and organisational perspective with practical recommendations in support of implementation.
- Ensure LLMs are used in a safe, responsible and transparent manner, in line with general ethical considerations.

Key regulatory references to AI in the pharmaceutical sector

AI in Manufacturing - GMP Guidelines, Annex 22: Artificial Intelligence

Once finalised, expected to become the first formal GMP standard for AI deployment in pharmaceutical manufacturing.

AI in Pharmacovigilance - CIOMS Working Group XIV report

The final report published in December 2025 addresses a set of common principles (such as human oversight, robustness, fairness, transparency and risk-based approach) applied to the cross-disciplinary field at the intersection of PV.

AI in medicinal product development

Expected EMA update: Qualification of novel methodologies (QoNM) and Q&A on digital technology-based methodologies in support of product approval

AI and medical devices - Interplay between the MDR & IVDR and the Artificial Intelligence Act (AIA)

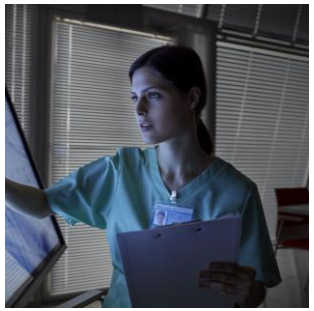
EMA Activities in Support of Innovation

AI in Medicines Lifecycle

Support to the development and evaluation of AI in the medicines' lifecycle through dedicated advice mechanisms.

Portfolio and Technology Meetings (PTM)

Capture innovative and disruptive technologies.
Anticipate the scientific and regulatory expertise needed to assess future applications.



Innovation Task Force (ITF) and Scientific Advice

ITF briefing meetings for early dialogue on innovative medicines and assistance development programmes.

Scientific advice on the most appropriate ways to generate robust evidence on benefits and risks of medicines.

Compliance with the AI Act and EUDPR/GDPR

EDPS as Market Surveillance Authority and Notified Body

Under the AI Act the European Data Protection Supervisor acts as competent authority for the supervision of EU institutions and bodies (EUIs), including EMA.

AI Act Correspondents Network

EDPS proposed AI correspondents network to facilitate AI governance in EU public administrations, information exchange with the EC AI Office and collaboration between EUIs.

Third Meeting of the Network on 10 February 2026

EC update on AI Act's implementation, guidance progress, discussion on Digital Omnibus and impact on the AI Act's timeline and supervision.

EMA/FDA AI Guiding Principles

Foundation

These principles are intended to lay the foundation for developing good practice that addresses the unique nature of AI technologies.

Initial collaborative work to inform broader engagement

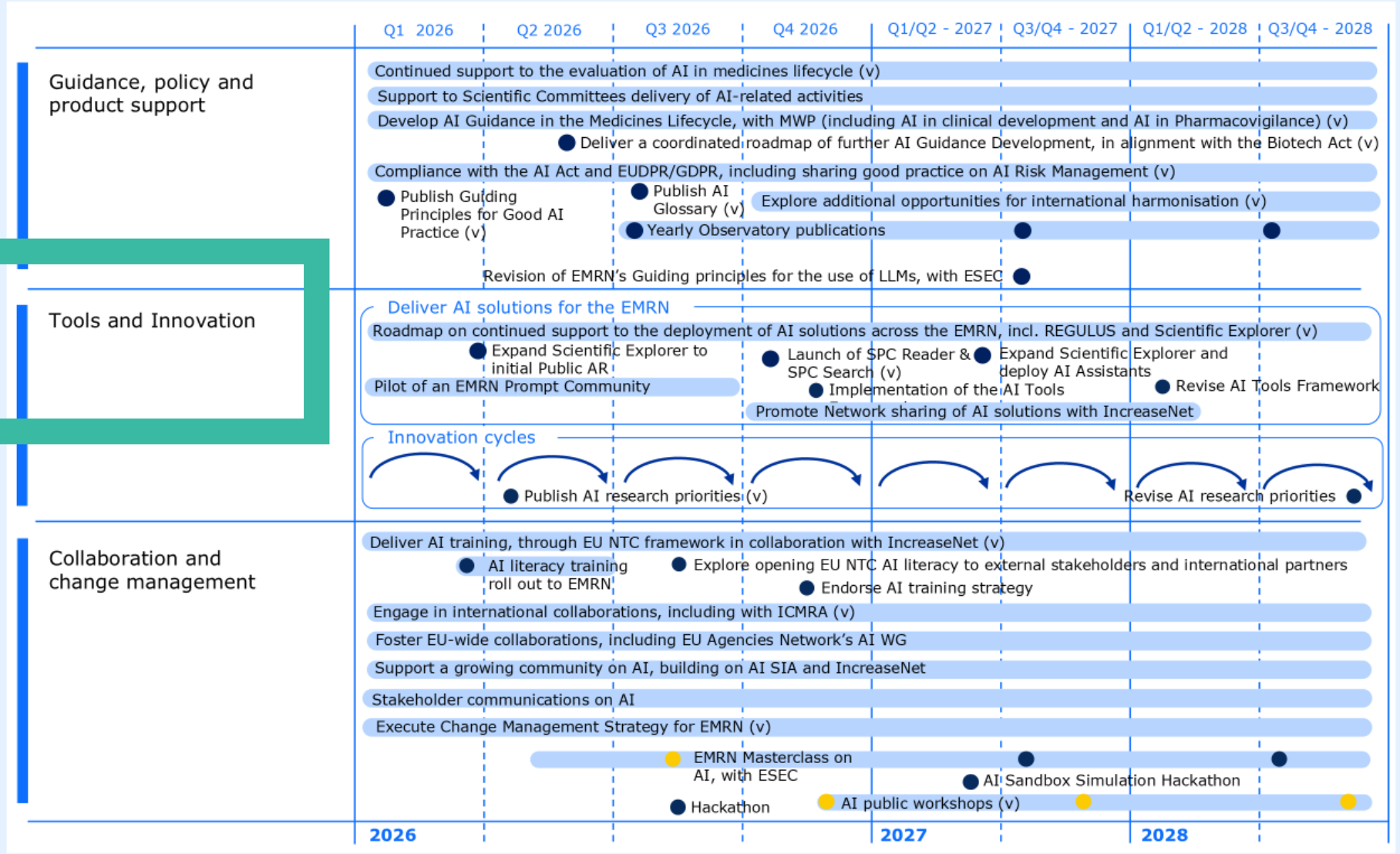
Identify areas where international regulators, international standards organisations, and other collaborative bodies could work to advance good practice.

Evolving standards

As the use of AI in drug development evolves, so too must good practice and consensus standards.

WORKSTREAM OVERVIEW

Artificial Intelligence



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

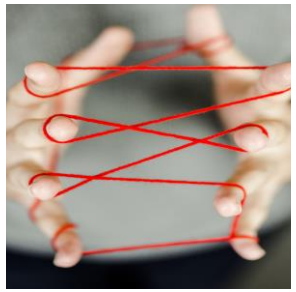
EMRN AI Tools Framework

European Medicines Regulatory Network (EMRN) collaboration

Support the sharing and development of AI tools across the Network.

Concerning both human and veterinary domain.

Foster collaboration, integration and reusability of tools and models.



NDSG endorsement in December 2025 and pilot launch in 2026

Planned multi-channel communication campaign, as a first step of an iterative approach for optimising sharing of AI tools within the Network over time.

Framework and catalogue

The adopted framework document establishes rules and responsibilities regarding the initiative and a template for building up the tools catalogue with relevant information to be provided (such as user guide).

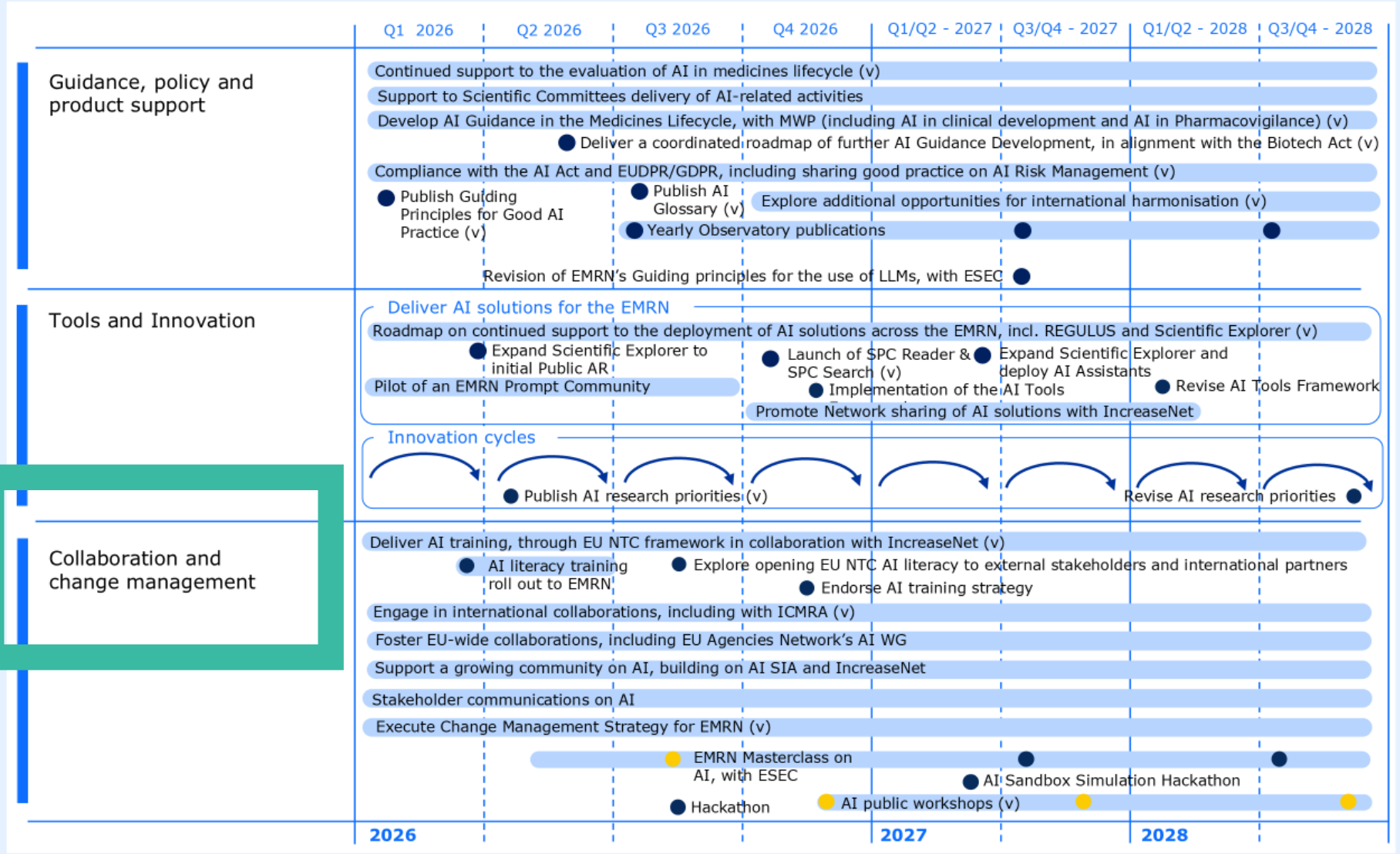
This initiative complements the NDSG work to collect **AI use cases from national competent authorities** and discuss existing/potential solutions.

Main capabilities covered:

- Drafting and summarization
- Validation and quality assurance
- Knowledge mining

WORKSTREAM OVERVIEW

Artificial Intelligence



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HMA/EMA multi-stakeholder workshop on AI

Workshop held in November 2026

Report, recording and agenda published on the Agency's website.

Keynotes on AI state-of-the-art

Discussion on regulator and industry use cases, updates and perspectives, opportunities for international convergence.

Dialogue with stakeholders and experts

Opportunities for enabling responsible innovation with AI.

HMA/EMA activities on AI and the execution of the Data and AI Workplan.

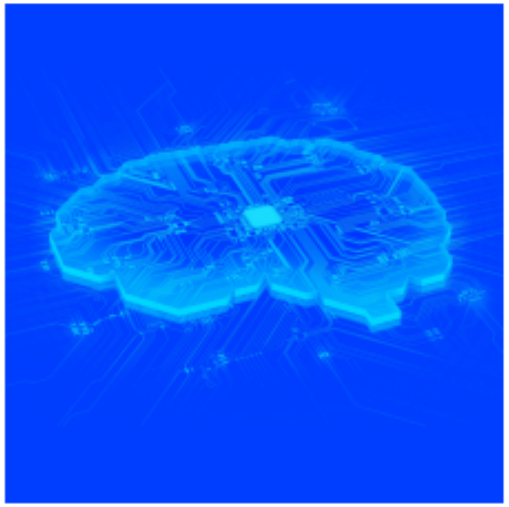
AI literacy training

DIGITAL ACADEMY

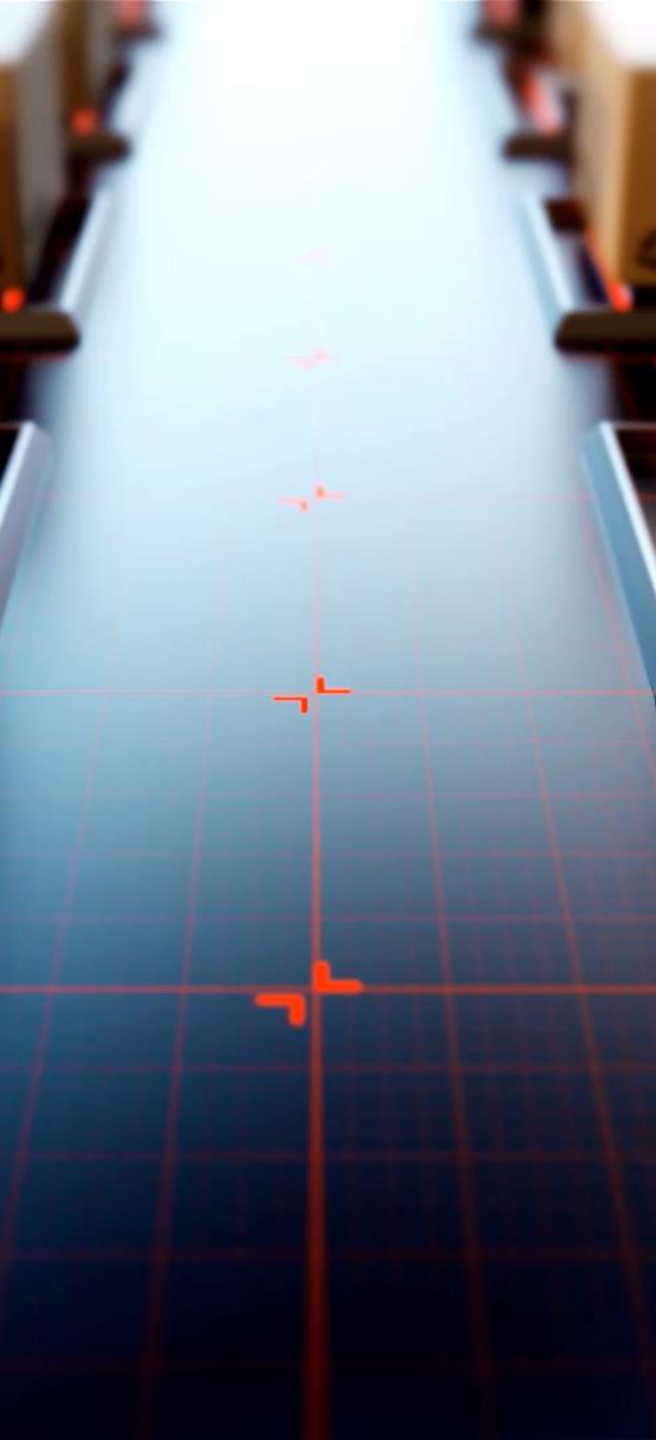
AI literacy programme for EU Medicines Regulatory Network

Don't know how to use AI safely at work? Think AI is only good for generating trendy images? In this bite-sized training, you'll get the essential knowledge you need to start using AI confidently and responsibly in a regulatory environment. Learn the basics, understand the risks, and build the skills to work with AI tools safely and effectively.

more



NDSG is also planning to explore opening the EU NTC AI literacy training to external stakeholders and international partners.



Key take away messages

EMA, EC and NCAs coordinate within the framework of the EU Medicines Regulatory Network (EMRN), in particular, the Network Data Steering Group to **optimise the use of data and AI**.

EMRN aims to enable regulatory systems in the EU to use the **capabilities** of AI while managing its **risks**.

The focus is on capabilities offering **personal productivity**, **process automation**, better **insights into data** and **decision-making support** for the benefit of public and animal health.

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