

AI in pharmacovigilance – EMA update

Industry Stakeholder Platform
Operation of EU Pharmacovigilance
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AI workplan updates

NDSG workplan 2025-2028

Data and AI in medicines regulation

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 :

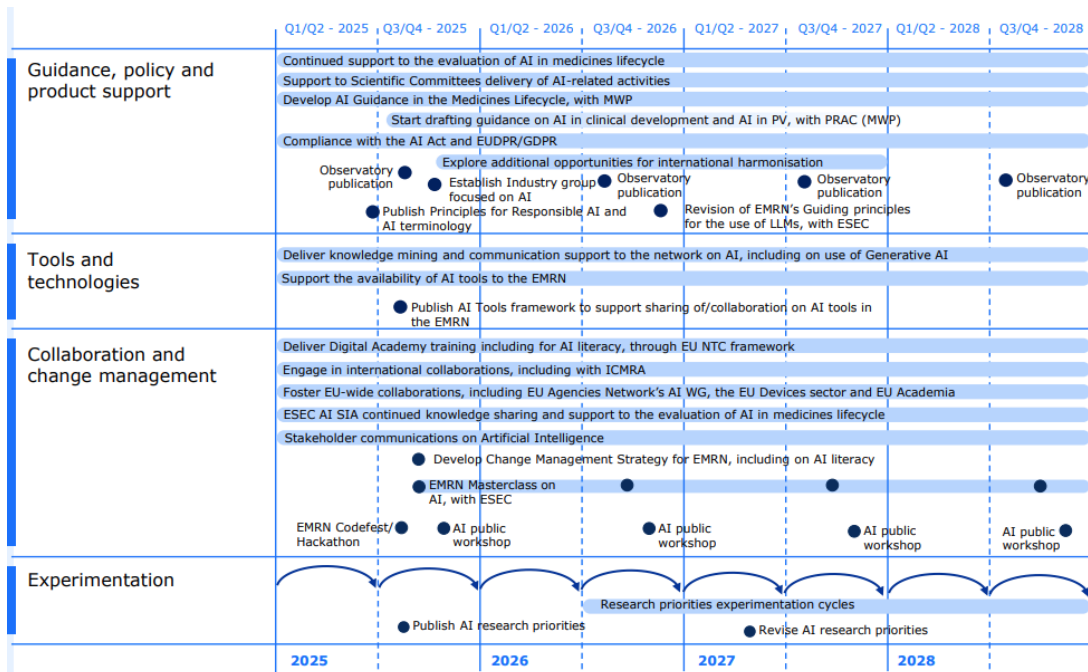
- Guidance
- International initiatives



Multiple workstreams
relevant to
pharmacovigilance
activities

NDSG workplan 2025-2028

AI workstream



- Guidance on AI in PV
- PRAC involvement
- AI principles & terminology
- International harmonisation
- Industry group
- Research priorities

Experimentation with health data

Innovation @EMA

Digital Innovation Lab (DigiLab)

Established 2021 to accelerate digital innovation and experimentation

Analytics Centre of Excellence

Explore analytics, AI, ML and robotics to
**build pragmatic solutions and experiment with
new technology**

-- Process analytics --

Health Data Lab (pilot)

Develop innovative analytics to **extract insights from
healthcare data**, to provide
answers/recommendations and maximise intelligence

-- Healthcare data analytics --

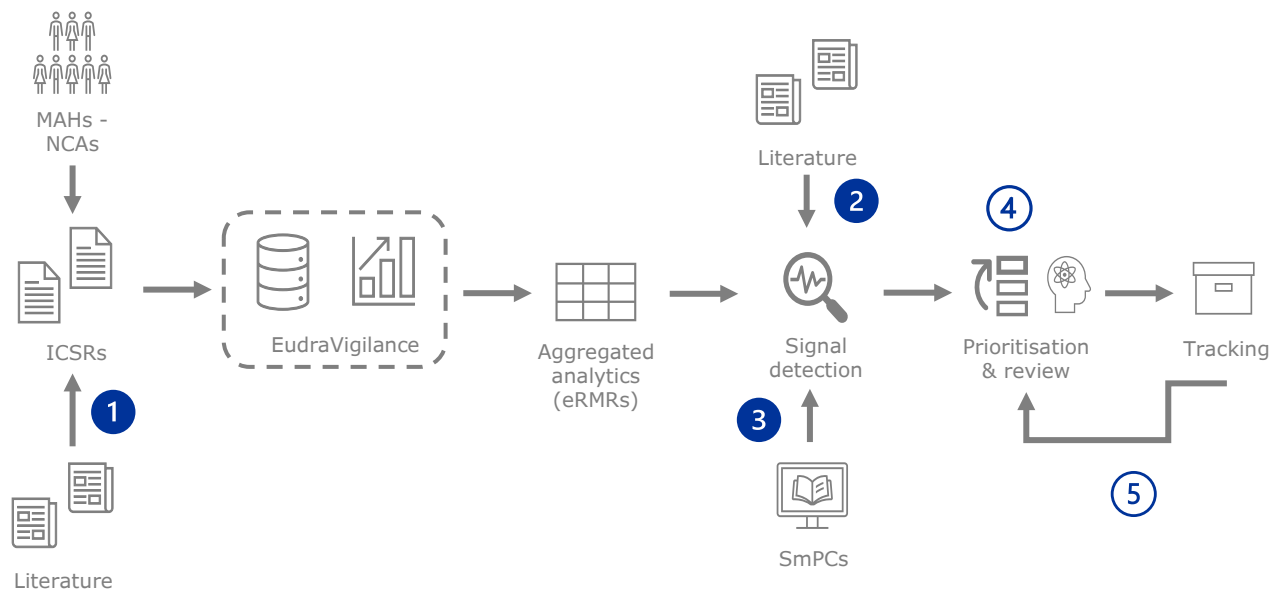
Infrastructure

Information Processing and Analytics

Improve the organisation's performance through streamlining information processing across the regulatory lifecycle.

-- Data analytics tools and platforms --

Use of AI in EMA signal detection workflow



Projects

1. Literature screening for ICSRs (OWLS)
2. Literature screening for signals (ERATO)
3. ADR data extraction (EurEKA)
4. AI-enhanced case adjudication (AERGIA)
5. Insight generation from historical reviews (MNEMOSiNE)

Status

- Launched (user testing)
- Ongoing / upcoming

ERATO | *Enhanced Review of Abstracts with Transformer mOdelS*

Use case

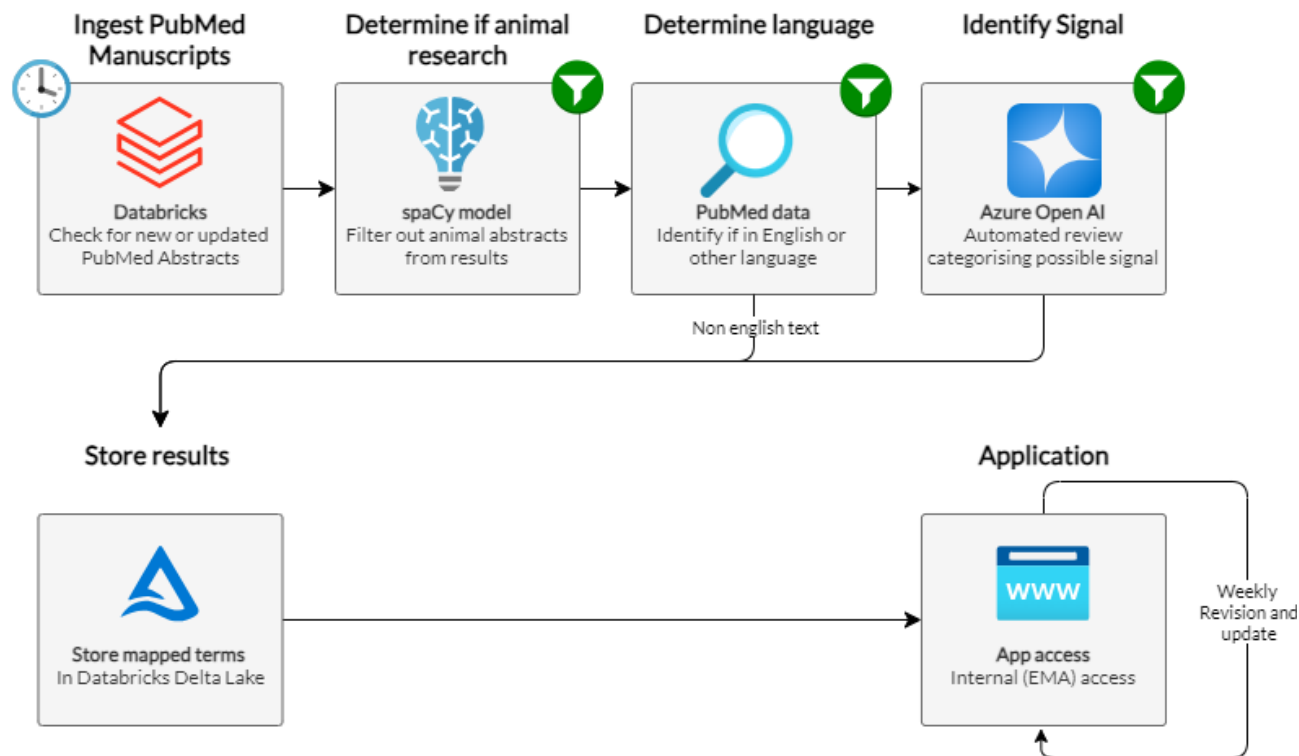
ERATO is intended to facilitate the screening of scientific abstracts for signal detection purposes and to establish a more robust tracking system for that review.

Expected benefits

Reduce FTE time to review literature abstracts and improve the efficiency of the review of scientific abstracts

Reduce time to signal detection, by providing a tracking system

ERATO | the *approach...*



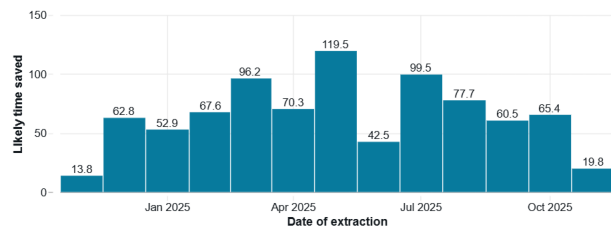
ERATO | *value (preliminary considerations)*

ERATO: Enhanced Review of Abstracts with Transformer mOdelS - value monitoring

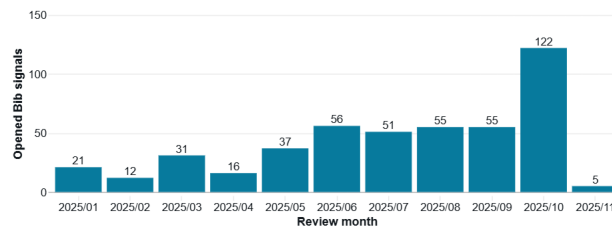
All manuscripts	Proposed safety concerns	Total time likely saved In hours (distinct manuscripts)
129,766	27,955	848.43

Time saved details

Time potentially spent per month



Reviews highlighted by month



FTE time:

ERATO potentially saved
>800h PhV review time in
2025

(based on the assumption of 30 sec
to 60 sec review time)

Time to detection:

Tracking system is
provided, assessment on
impact to be done

Collaborations

Signal Management Review Technical (SMART) Working Group

- Collaboration between Member States and EMA with the objective to strengthen and simplify the signal management process in the EU.
 - SMART Processes: signal management tools and processes
 - SMART Methods: methodological guidance and signal detection methods
- Expert input to PRAC
- SMART Methods – future priorities
 - Responsible use of AI in PV
 - Integration of RWE
 - Better collaboration, training and communication



SMART Methods

- 28 NCA members
- 12 EMA members
- 4 WHO-UMC members
- 2 academic centres
- 1 Independent Expert

Knowledge mining initiative & AI use cases

Steps towards a roadmap

1

Initial phase

EMA started an **internal call** of AI use cases for the Network

2

Cluster

Use cases has been clustered in different **categories**

3

Technology

EMA is focusing on **identifying solutions and technology** to deliver the use cases

4

Network

Call of **solutions and use cases in the Network** to enrich the list of use cases

5

Assessment

Overall assessment of the use cases collected, existing solutions and technology

6

Roadmap

Mapping of the network's existing AI solutions and a **prioritised list of AI use cases** for which collaborative solutions will be needed

Knowledge mining initiative & AI use cases

Clusters

Ask sources of information

(documents, websites, databases, etc.)

Extract and identify data and information from documents and databases

Check, review standards, validate documents content (quality, regulatory and technical elements)

Triage queries, public consultations, automatic replies and lines to take

Summarisation of documents, creation of content and translations

Cases studies: RWE, case duplication detection, signal detection, ADRs, Clinical Trials...

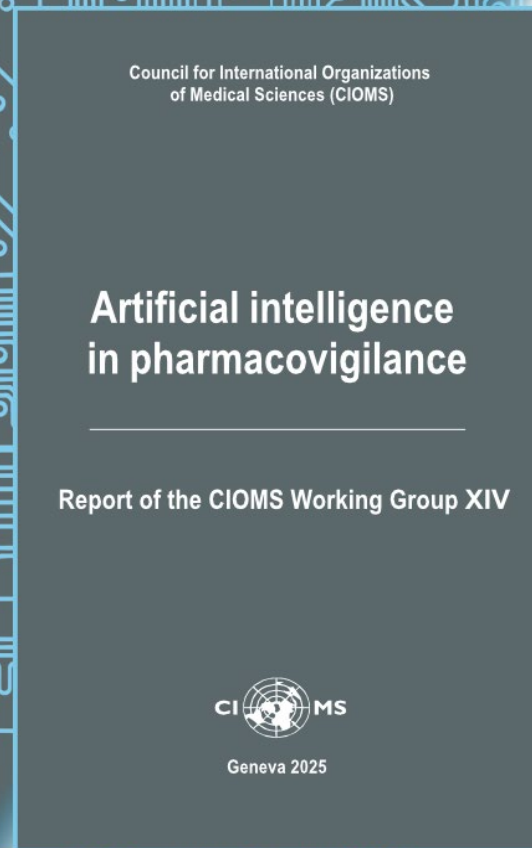
More than +150 use cases have been collected internal at EMA and from the Network
The called of use cases from the Network confirmed the alignment on the needs and requirements against the internal call of use cases at EMA

These clusters has been created based on business requirements, complexity and technology requirements needed to solve them.

CIOMS (coming soon)

- Executive summary
- Chapter 1 - Introduction
- Chapter 2 - Landscape analysis
- Chapter 3 - Risk-based approach
- Chapter 4 - Human oversight
- Chapter 5 - Validity & Robustness
- Chapter 6 - Transparency
- Chapter 7 - Data privacy
- Chapter 8 - Fairness & Equity
- Chapter 9 - Governance & Accountability
- Chapter 10 - Future considerations
- Appendices

Guiding principles





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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HMA/EMA Multi-stakeholder workshop on Artificial Intelligence (AI)

20 and 21 November 2025

Hybrid meeting / EMA, Amsterdam

The HMA/EMA's vision for Artificial Intelligence (AI) is for a regulatory system harnessing the capabilities of AI for personal productivity, process automation and systems efficiency, increased insights into data and strengthened decision-support for the benefit of public and animal health.

The HMA/EMA 2025 multi-stakeholder workshop on Artificial Intelligence follows on from previous AI workshops and is the first multi-stakeholder AI workshop under the new HMA/EMA NDSG multi-annual Data and AI Workplan.