EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

AI in pharmacovigilance – EMA update

Industry Stakeholder Platform – Operation of EU Pharmacovigilance

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An agency of the European Union

Contents

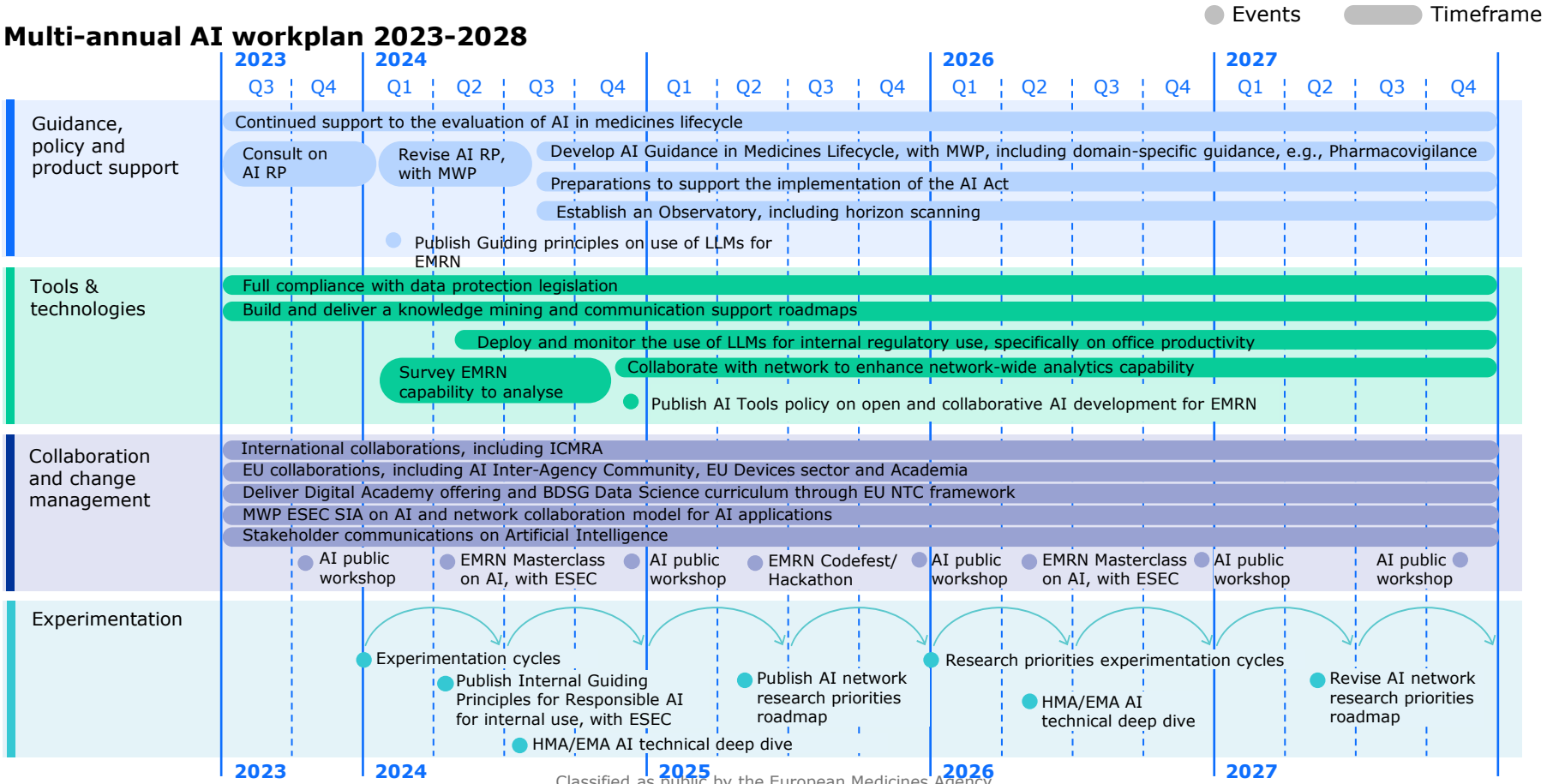
- Multi-annual AI workplan
- AI workshop
- Experimentation with health data
- Collaborations

Multi-annual AI workplan

Workplan pillars

Guidance, policy and product support	Continuous support to products as well as the development and evaluation of appropriate guidance for the use of AI in the lifecycle of a medicine. Preparations to support the implementation of the EU AI Act.
Tools & technologies	Identify and provide frameworks across the network to use AI tools to increase efficiency, enhance understanding and analysis of data and support decision-making. Full compliance with data protection legislation.
Collaboration and change management	Initiatives designed to continuously develop capacity and capability of the network, partners and stakeholders to keep ahead of the evolving field of AI.
Experimentation	Several actions are proposed to ensure a structured approach to experimentation across the network to accelerate learning and gain new insights.

Multi-annual AI workplan 2023-2028



Completed

- Revise AI RP, with MWP
- Consult on AI RP
- Publish Guiding principles on use of LLMs for EMRN
- Survey EMRN capability to analyse
- AI public workshop
- EMRN Masterclass on AI, with ESEC
- HMA/EMA AI technical deep dive

Ongoing/on track

- Continued support to the evaluation of AI in medicines lifecycle
- Preparations to support the implementation of the AI Act
- Establish an Observatory
- Full compliance with data protection legislation
- Build and deliver a knowledge mining and communication support roadmaps
- Deploy and monitor the use of LLMs for internal regulatory use, specifically on office productivity
- International collaborations
- EU collaborations
- Deliver Digital Academy offering and BDSG Data Science curriculum
- MWP ESEC SIA on AI and network collab.
- Stakeholder communications on AI
- Experimentation cycles
- Publish Internal Guiding Principles for Responsible AI for internal use, with ESEC

In planning/not started

- Develop AI Guidance in Medicines Lifecycle, with MWP, including domain-specific guidance, e.g., Pharmacovigilance
- Collaborate with network to enhance network-wide analytics capability
- Publish AI Tools policy on open and collaborative AI development for EMRN
- AI public workshop(s)
- EMRN Codefest/ Hackathon
- EMRN Masterclass on AI, with ESEC
- Research priorities experimentation cycles
- Revise AI network research priorities roadmap
- HMA/EMA AI technical deep dive
- Publish AI network research priorities roadmap

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

Experimentation with health data at EMA

AI at EMA | Set up

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 --

Pharmacovigilance | Methods innovation approach – a timeline

- Establishment of Pharmacovigilance Risk Assessment Committee
  - As PRAC was established in 2012, two groups under its remit were also developed:
    - SMART Processes: explore and discuss process improvements in signal detection and management
    - SMART Methods: explore and collaborate on methods innovation in pharmacovigilance (Experts from European National Competent Authorities + Experts from UMC)
- Establishment of Digital Transformation and Data and Methods taskforces
  - From 2020, new innovation framework established to support innovation across the agency (not just PhV) and benefit from digitalisation and machine learning under a DigiLab
  - An Analytics Centre of Excellence was established to support process efficiency, digitalisation and personal productivity
  - Health Data Lab pilot established in 2023 to explore opportunities for methods development with healthcare data

Pharmacovigilance | What innovation will it benefit from?

- Signal detection is essentially knowledge discovery using "Big data":
  - Data quality: cleaning (e.g. deduplication), completeness (e.g. filtering cases)
  - **Data analytics: advanced algorithms**
  - **Knowledge mining: combining sources of data, linking information (e.g. terminology mapping)**
  - Information management: case review management

- Likely new methodologies will:
  - Extend from rule-based algorithms (ROR, PRR) to data-driven (AI/ML) algorithms
  - Harvest the power of Large Language Models to improve insights and streamline information

AI in Pharmacovigilance | A fertile ground

Procedures are elaborate, mature, and high-sensitivity: good fit for automation and allow for some error tolerance

Multiple information flows are required including scientific literature, regulatory documentation

ICSRs carry a wealth of unstructured information

Many organisations have overlapping responsibilities, we can learn together

At times faced with high velocity data, can benefit from methods that help scale processes

Error tolerance affects trade-off between explainability and performance on a risk-based approach

AI in pharmacovigilance | Opportunities in signal detection

ICSR data

Deduplication
Structuring text data

Summary report

AI-enhanced SDRs

Potential signals

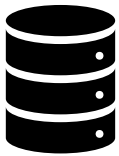
AI-enhanced prioritisation

Case line listing

AI-enhanced signal review
Automated adjudication of cases (filtering)

Tracking

AI-enhanced prioritisation



DRUG X	ADR A	10	Σ	Σ
DRUG X	ADR B	12	Σ	Σ
DRUG Y	ADR A	4	Σ	Σ
DRUG Y	ADR F	34	Σ	Σ
DRUG Z	ADR B	12	Σ	Σ
DRUG Z	ADR K	4	Σ	Σ
…	…	8	Σ	Σ

DRUG Y	ADR A	check
DRUG Z	ADR K	check

#1	NL	Drugs	Reactions
#2	FR	Drugs	Reactions
#3	PT	Drugs	Reactions
#4	SK	Drugs	Reactions

#1	DE	Drugs	Reactions
#2	SP	Drugs	Reactions
#3	PT	Drugs	Reactions

DRUG	ADR	Review	NO
DRUG	ADR	Review	NO
DRUG	ADR	Review	NO
DRUG	ADR	Review	NO
DRUG	ADR	Review	YES
DRUG	ADR	Review	NO
DRUG	ADR	Review	NO
…	…	…	YES

AI in Pharmacovigilance | Current areas of research/experiments

Signal detection

- Scientific literature
  - Handle ICSRs from the literature to avoid duplicates (quality)
  - Semi-automated literature screening (efficiency and capacity)
  - Extract and explore product information listed adverse reactions (efficiency and capacity)
- ICSRs
  - Automated adjudication of case reports

Signal management

- Prioritisation of signals to review based on cumulative information on signals (>25k signal reviews on EMA's signal tracking DB)

While being careful to observe data protection requirements, copyright and other legal obligations

Collaborations

CIOMS Working Group XIV

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Objectives

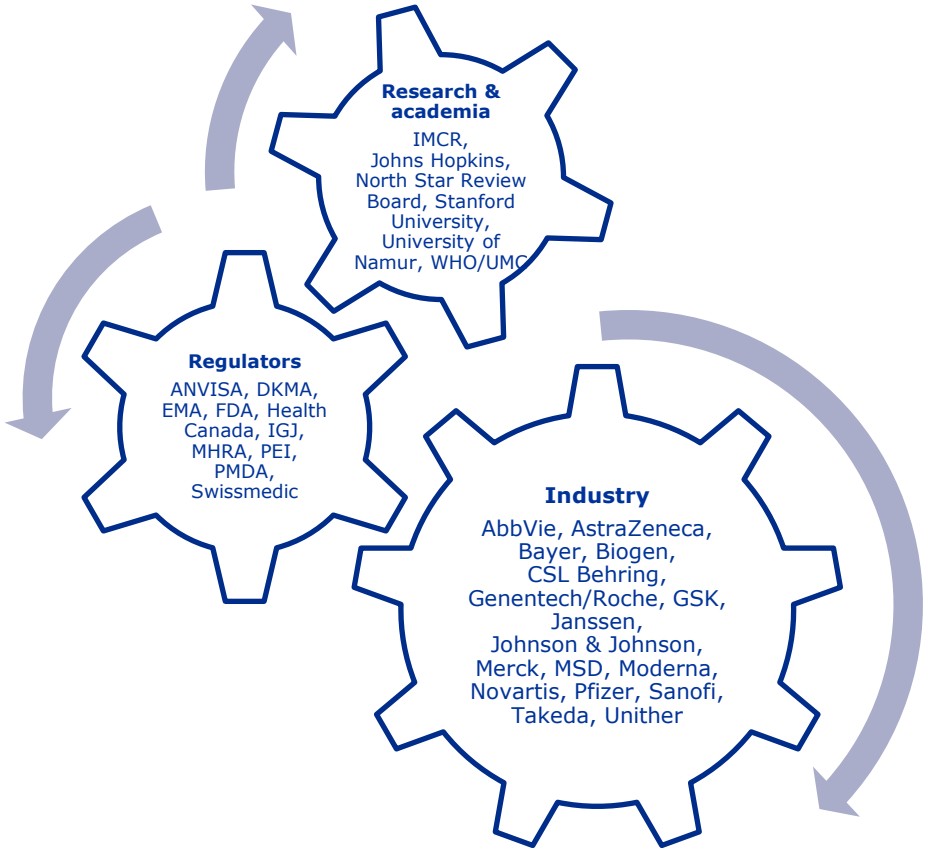
Establish and promote principles and guidance for the use of AI or intelligence augmentation in the field of PV building on and complementing broader initiatives underway

Guiding principles

Governance & Accountability | Risk Based Approach | Human Oversight | Validity & Robustness | Transparency | Explainability | Accountability | Data Privacy | Fairness & Equity

Status

- Advanced/restructured draft completed (Sept 2024)
- Further maturing by early 2025
- Public consultation Q1-Q2 (6 weeks)
- Final report 2025 TBC



FDA/EMA cluster on AI in PV

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Objectives

- **Exchange** information and views on policies, guidance and regulations relevant to the use and regulation of AI in PV
- Explore **alignment** between each agency's vision and approach on the use and regulation of AI in PV
- Foster leadership and **collaboration** on international regulatory initiatives
- **Share experience** and lessons learnt on the application of AI to PV use cases
- Discuss **research** needs pertinent to AI in PV

Participants

- **EMA/CDER/CBER staff** members with experience in AI and/or PV
- Observers from **PMDA** and **Health Canada**
- Within scope of confidentiality arrangements

Thank you for your attention

Further information

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