EMA
EUROPEAN MEDICINES AGENCY

AI in pharmacovigilance – EMA update

Industry Stakeholder Platform
Operation of EU Pharmacovigilance
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Pharmacovigilance a good fit for AI (?)

01 OPPORTUNITIES FOR AI IN PhV

WHERE AI MIGHT HELP ACROSS THE WORKFLOW

Data processing
Case intake; duplicate detection; literature screening for ICSRs

Summary statistics
Generating and summarising case-series overviews

Signal detection
Literature screening for signals; case adjudication, ADR data from SmPCs

Prioritisation
Supporting case review; insights from past assessments

Reporting
Drafting assessment reports and periodic summaries

WHY IT MAY FIT

Volume and repetition
Large, growing case volumes; many similar tasks

Standardisation
Defined workflows, MedDRA and E2B(R3)

Rich in text
Narratives and literature suit NLP and LLMs

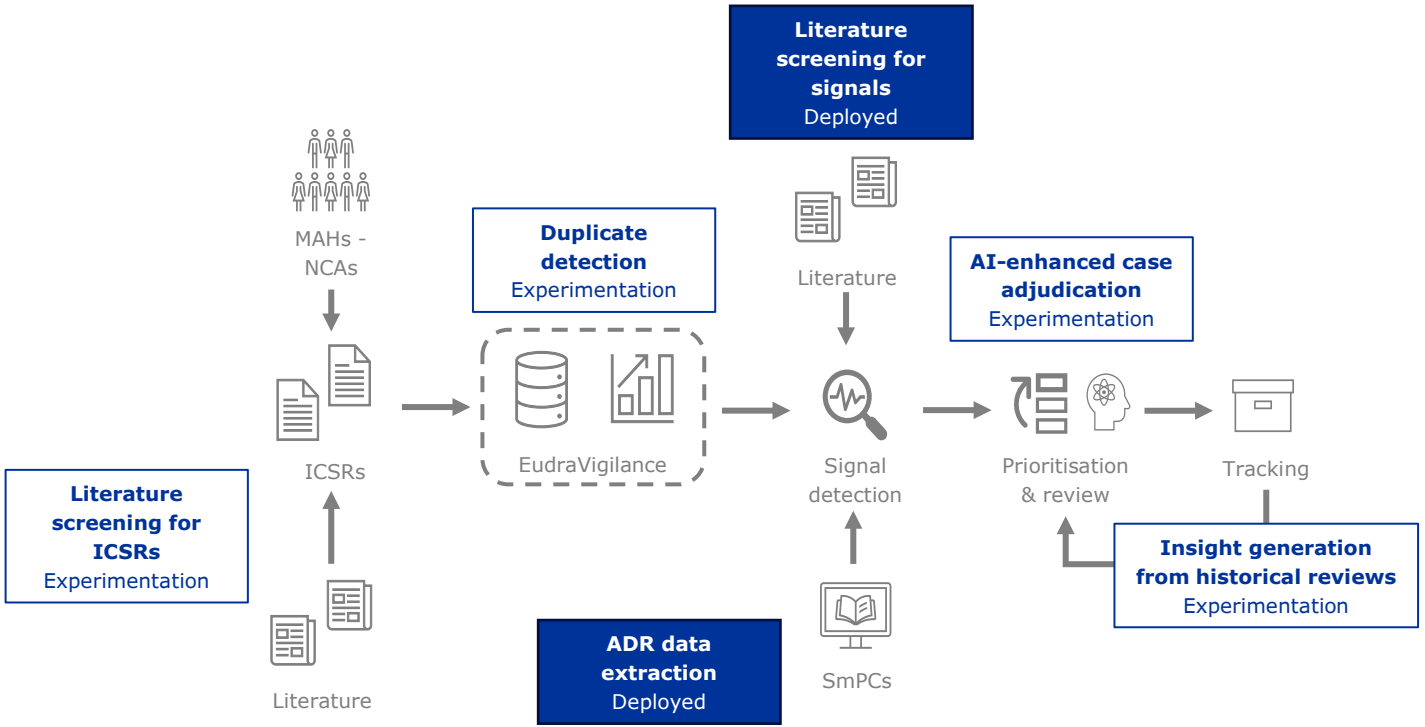
Risk-based workflows
Human review and QC can absorb some error

WHAT STILL NEEDS CARE

- Human oversight and accountability
- Validation against curated case sets
- Missed cases matter: watch false negatives
- Transparency for audit and inspection
- Protection of patient data in narratives

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AI-enabled initiatives along EMA's PV workflow



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Focus on pilot deployments: EurEKA & ERATO

EurEKA

Pilot deployment

EU SmPC Entity Extraction and Knowledge Acquisition

Extracts adverse reaction data from SmPCs and makes it searchable

PILOT TIMELINE

Pilot deployment in 2025

METHOD

Regex on a pre-trained ML model, LLM-enabled

BENEFITS

Faster checks of whether a reaction is already labelled; structured ADR data comparable across products

SELECTED METRICS

~155,000 ADRs mapped for ~1,500 products

ERATO

Pilot deployment

Enhanced Review of Abstracts with Transformer Models

Screens scientific literature for emerging safety signals

PILOT TIMELINE

Pilot deployment in 2025

METHOD

Generative AI (LLM)

BENEFITS

Less manual literature screening; earlier pick-up of emerging safety signals

SELECTED METRICS

~70% reduction in literature abstracts to review

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A framework to share tools across the network

Purpose and aim

Foster collaboration, integration and reusability of AI tools across the Network

Provide guidance and good practices for collecting and updating AI tool information

Provide transparent and trustworthy information to support the adoption and reuse of AI tools across the network.

Output

An AI tools catalogue that stores the information the framework requires about sharable AI tools

Audience

Network members that have developed AI tools that can be, or have been, shared with peers

Network users that are developing AI tools and want to offer them to peers outside their organisation

Goal: facilitate the effective sharing of AI tools across the Network, e.g. AI@MPA toolkit

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AI-Powered Signal Detection in PhV

05 HORIZON-JU-IHI-2025-11-two-stage



- **EU public-private partnership**
- Industry, regulators, academics, international organisations
- EMA has joined consortium
- Project start Jan 2027 (5 years)

Expected deliverables

1. Signal detection models
2. Data sources
3. Risk prediction models
4. Recommendations for implementation
5. Recommendations for human oversight
6. Templates and tools
7. Training plans and education materials

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Roadmap to a coherent portfolio of guidance

06 PATH TO GUIDANCE

Sept 2024

EMA Reflection Paper on AI in the medicinal product lifecycle

Q1 2026

Joint EMA–FDA Guiding Principles for Good AI Practice

Q2–Q4 2026

Coordinated guidance roadmap; Guidance Coordination Group Established

H1 2027

Shared EMA-FDA AI terminology

2027 onwards

Targeted guidance across the medicines lifecycle

WHERE GUIDANCE IS LIKELY TO LAND · EU BIOTECH ACT PROPOSAL

AI guidance foreseen for:

- Pre-clinical research
- Clinical development and trials
- Manufacturing
- Post-authorisation monitoring
- Authorisation procedures for medicinal products

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Questions & answers on AI in PV

Clear mandate

- NDSG AI workplan
- PRAC and MWP workplans
- Proposed EU Biotech Act
- Human and veterinary
- Industry and regulators

Scope shaped by stakeholders

- Survey to industry, assessors & inspectors
- 176 respondents
- Topics of interest include human oversight, documentation, risk-based approach, inspections…

SCOPING	DRAFTING	NETWORK CONSULTATION	PUBLIC CONSULTATION
Q3 2026	Q4 2026	Q1 2027	Q2 2027






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What AI-enabled PhV might look like in 2035

EVIDENCE BASE

Better clinical evidence from multi-modal data

PhV databases, RWD, pharmacogenomic data, EHDS, CTIs etc.

PRACTICE

AI-augmented Pharmacovigilance

AI leveraged to increase insights and improve scalability of PhV processes.

OUTCOME

Increasingly personalised evidence

Enabled by more and better data and digital technologies.

UNDERPINNED BY Good AI Practice & Guidance · Growing regulatory understanding · Meaningful human oversight · Transparency · Lifecycle governance

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Thank you

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