EMA
EUROPEAN MEDICINES AGENCY

Artificial intelligence tools in pharmacovigilance

Reunião Anual do Colégio de Especialidade de Assuntos Regulamentares | Ordem dos Farmacêuticos, Lisboa

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[Some slides courtesy of Luís Pinheiro, Data Analytics and Methods Task Force, EMA]

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Contents

- Foundations for a responsible use of AI in PV
- Designing digital innovation in PV
- Lessons and outlook

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The case for AI in pharmacovigilance

High-volume workflows

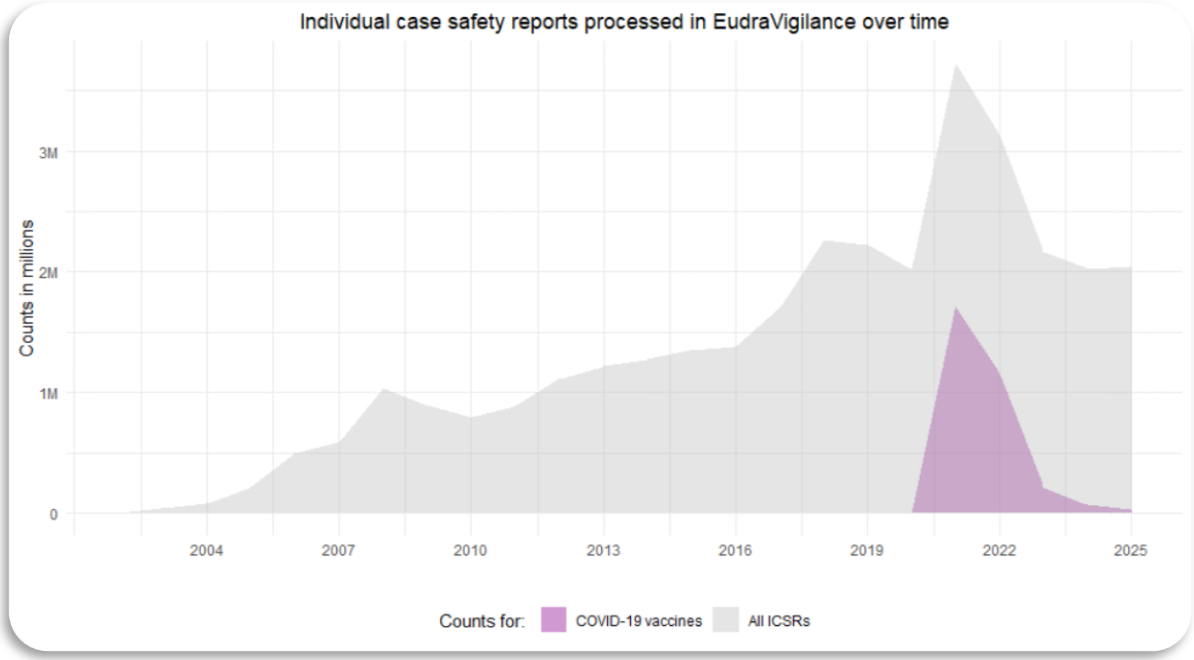
Mature processes

Untapped unstructured data

Diverse information sources

Risk-based error tolerance

Collaboration opportunities



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#1

Foundations for a responsible use of AI in PV

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EMA-FDA common principles

1. Human-centric by design
2. Risk-based approach
3. Adherence to standards
4. Clear context of use
5. Multidisciplinary expertise
6. Data governance & documentation
7. Model design & development practices
8. Risk-based performance assessment
9. Life cycle management
10. Clear, essential information

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EMA considerations

Reflection paper on the use of AI in the medicinal product lifecycle

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2.3.7. Post-authorisation phase

It is foreseen that AI/ML tools can effectively support post-authorisation activities, such as post-authorisation efficacy and safety studies (PAES and PASS) for human medicines and post-marketing surveillance studies for veterinary medicines, as well as pharmacovigilance activities including adverse event report management and signal detection, in line with current good pharmacovigilance practices requirements available for both human and veterinary medicines.

Applications within pharmacovigilance may allow a more flexible approach to AI/ML modelling and deployment, where incremental learning can continuously enhance models for classification and severity scoring of adverse event reports as well as signal detection. However, it remains the responsibility of the MAH to validate, monitor and document model performance and include AI/ML operations in the pharmacovigilance system, to mitigate risks related to all algorithms and models used.

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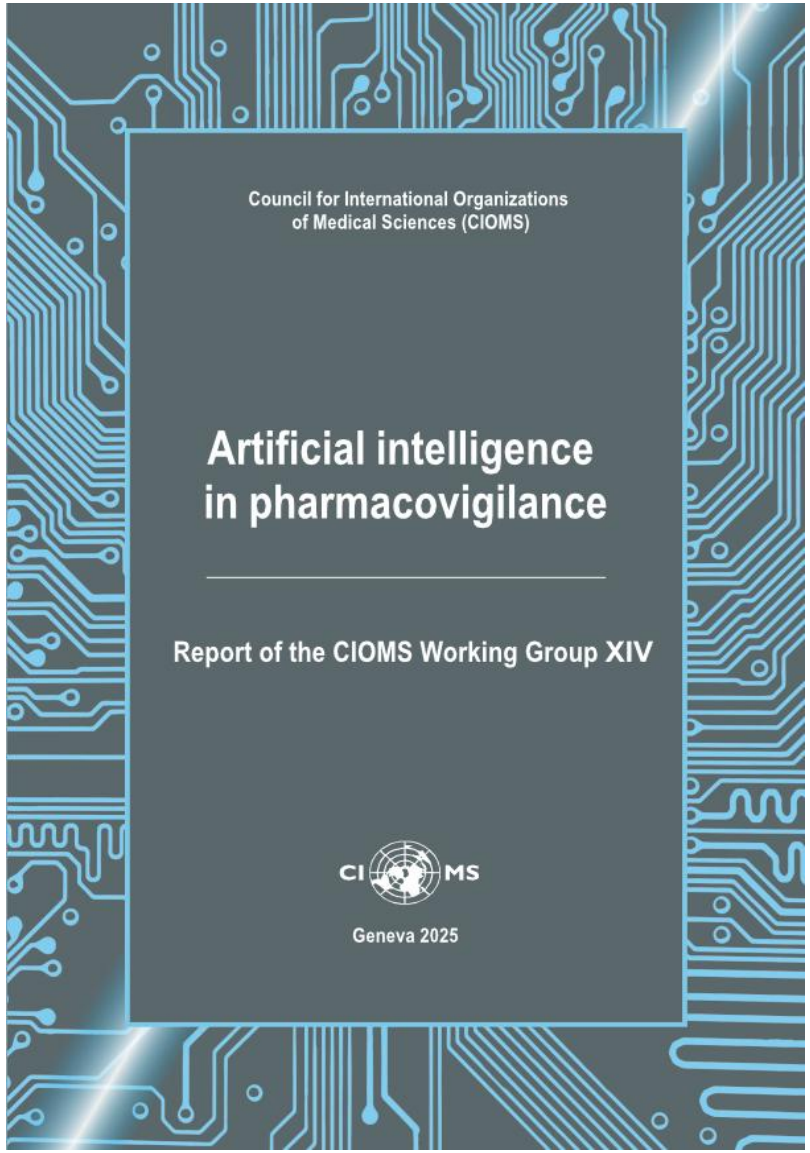
CIOMS consensus

- 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

Guiding principles

- Chapter 10 - Future considerations
- Appendices



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#2

Designing digital innovation in PV

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Simplified innovation framework at 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 --

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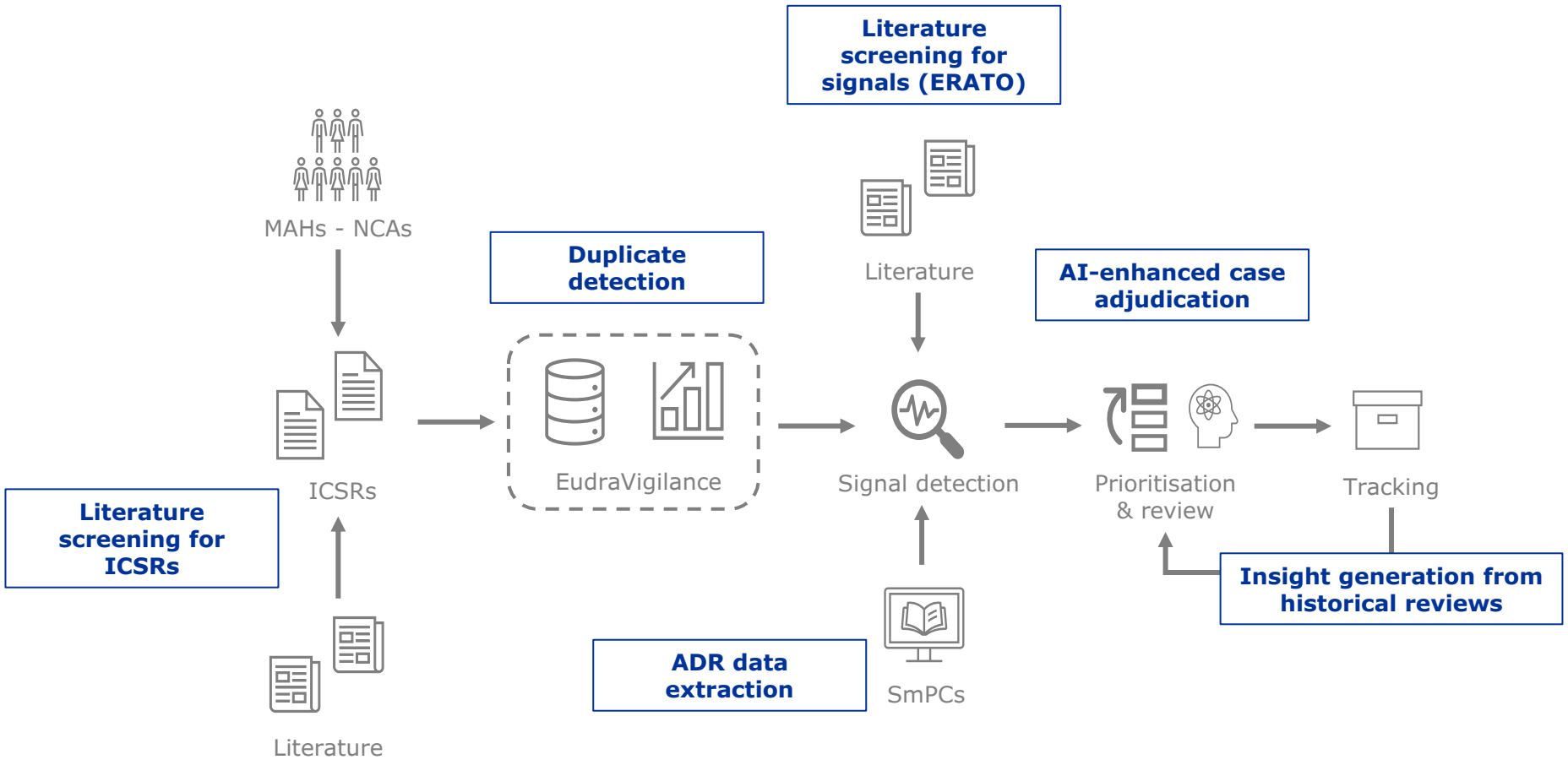
Health Data Lab initiatives along PV workflow



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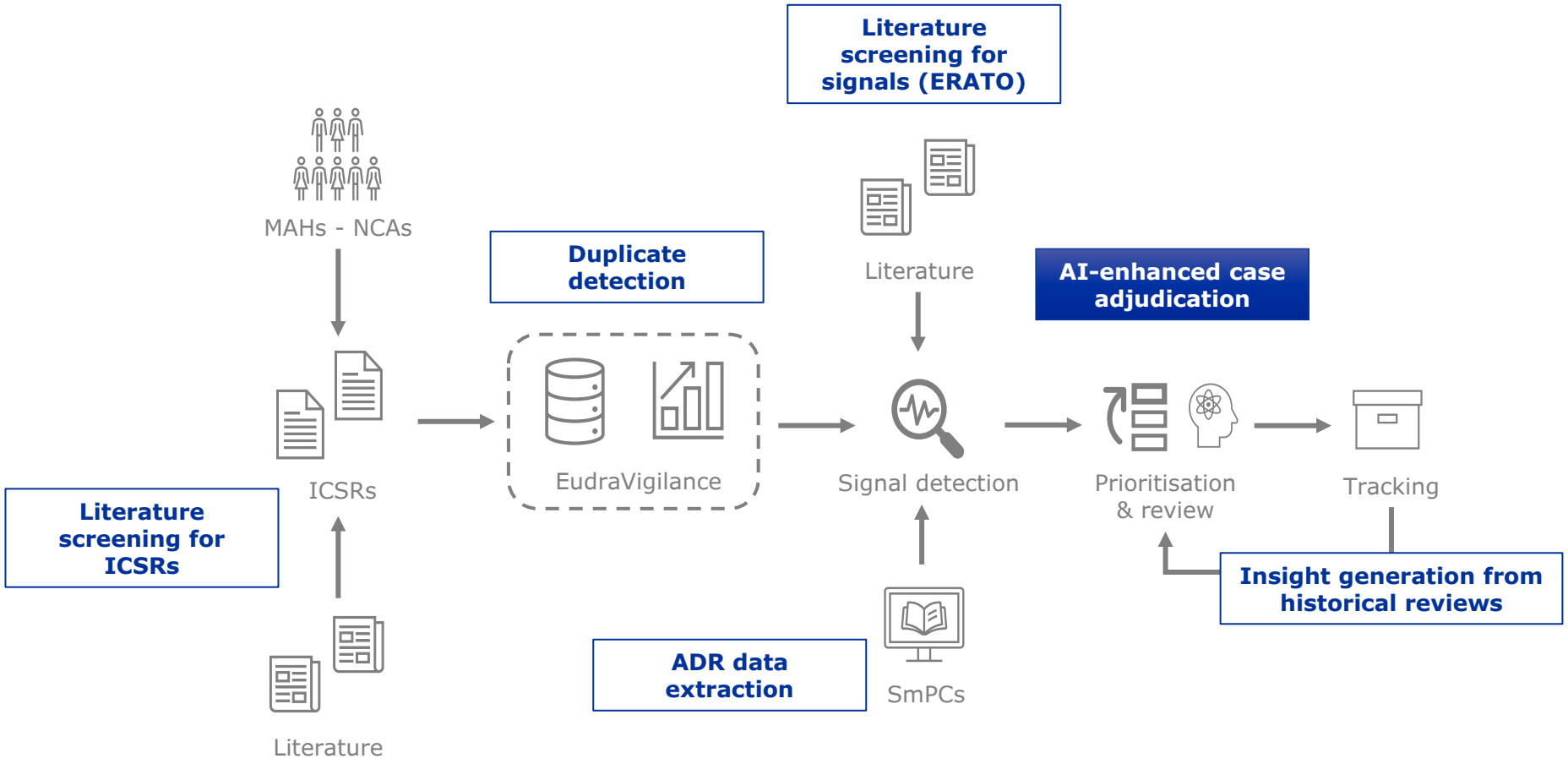
Example of AI-enhanced case adjudication



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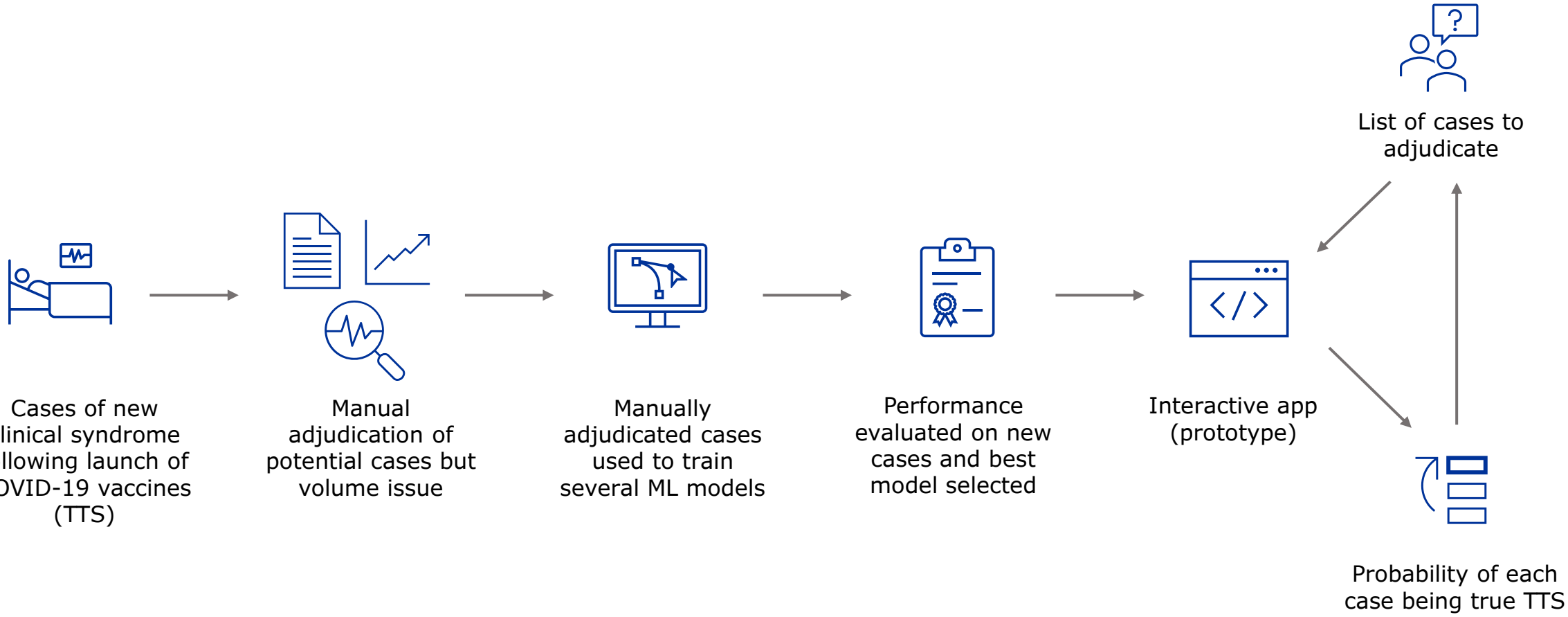
ML-assisted adjudication of thrombosis with thrombocytopenia syndrome (TTS)



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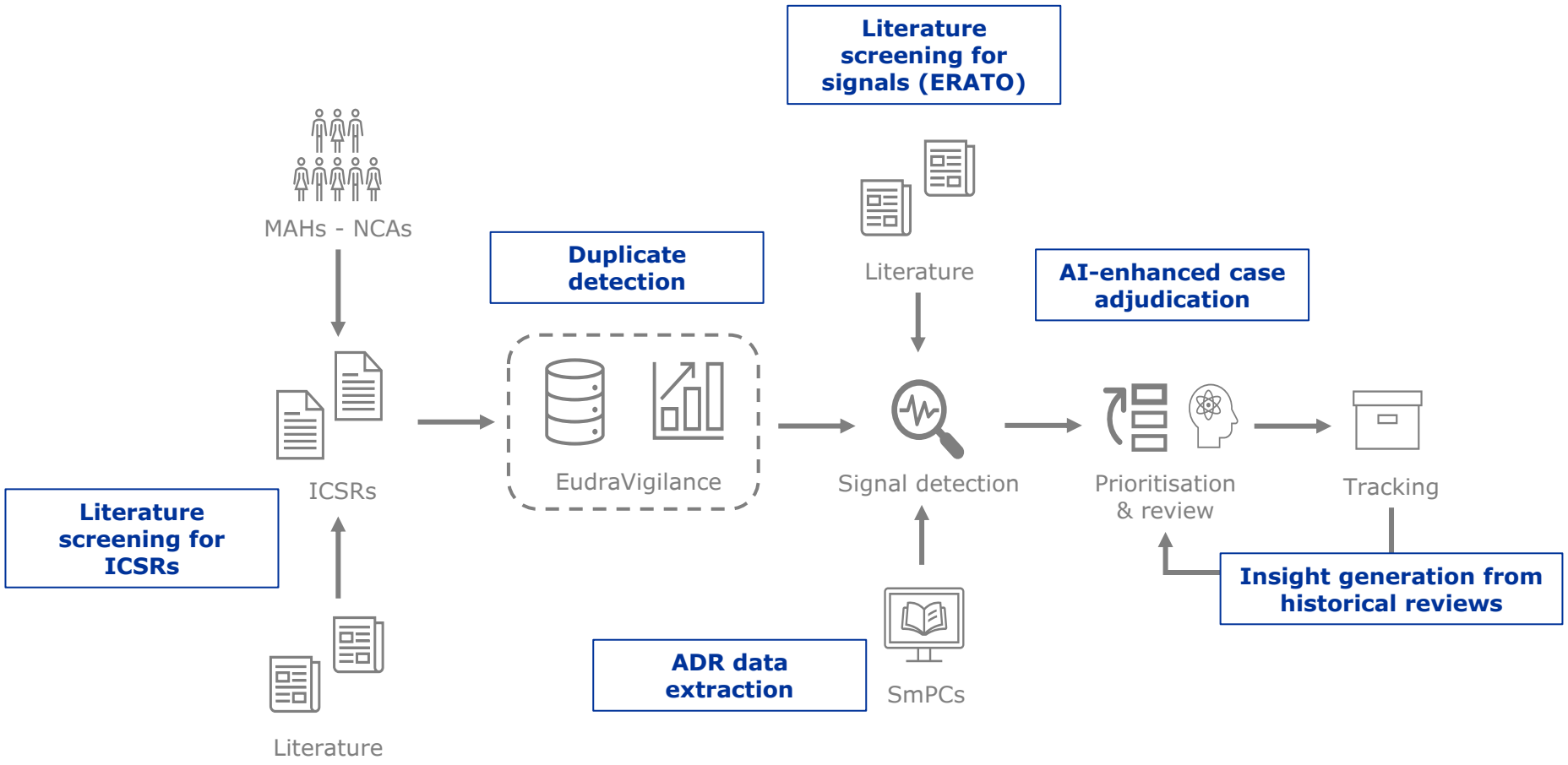
Health Data Lab initiatives along PV workflow



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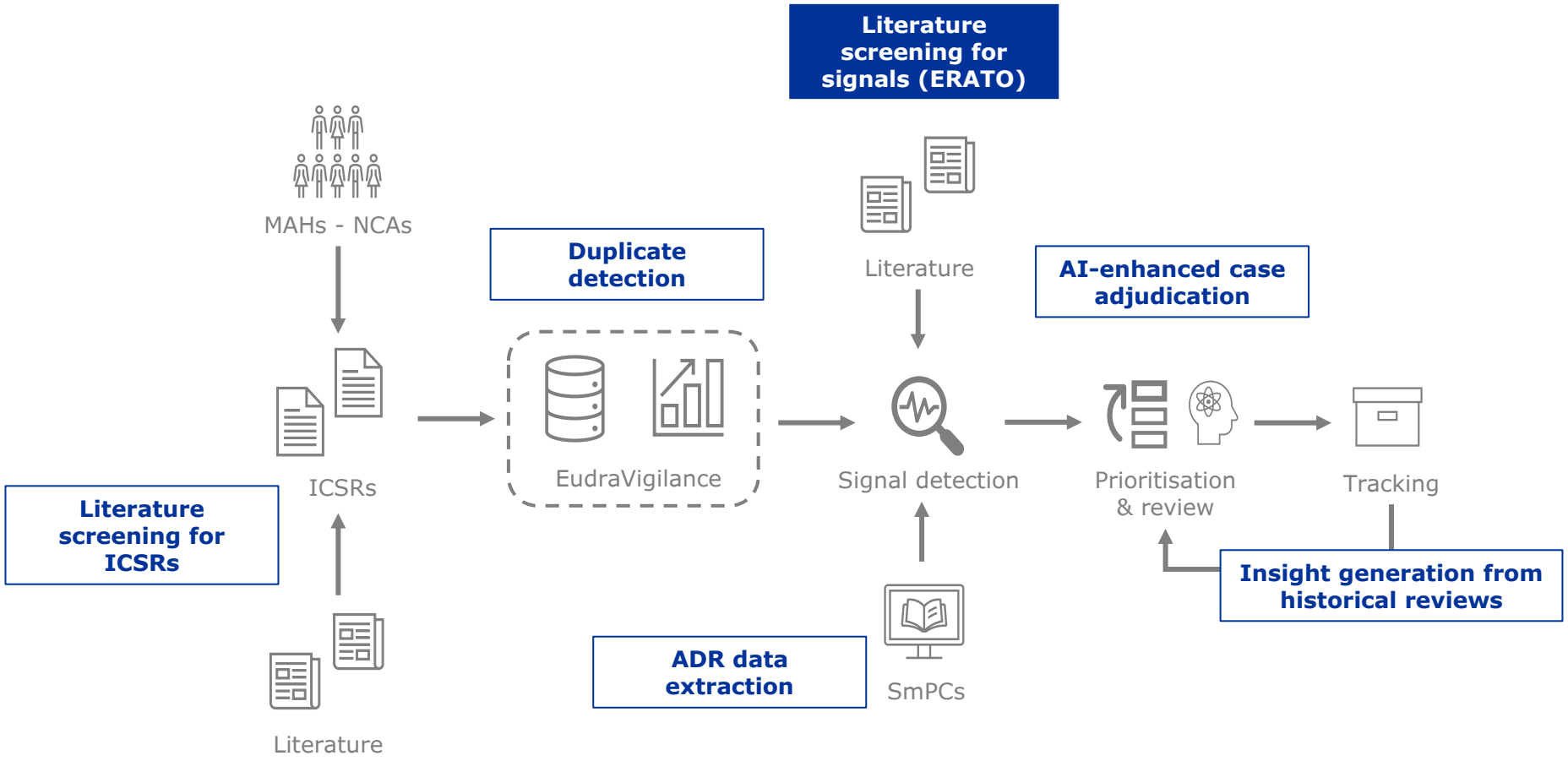
Spotlight on ERATO



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ERATO | Expected benefits

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

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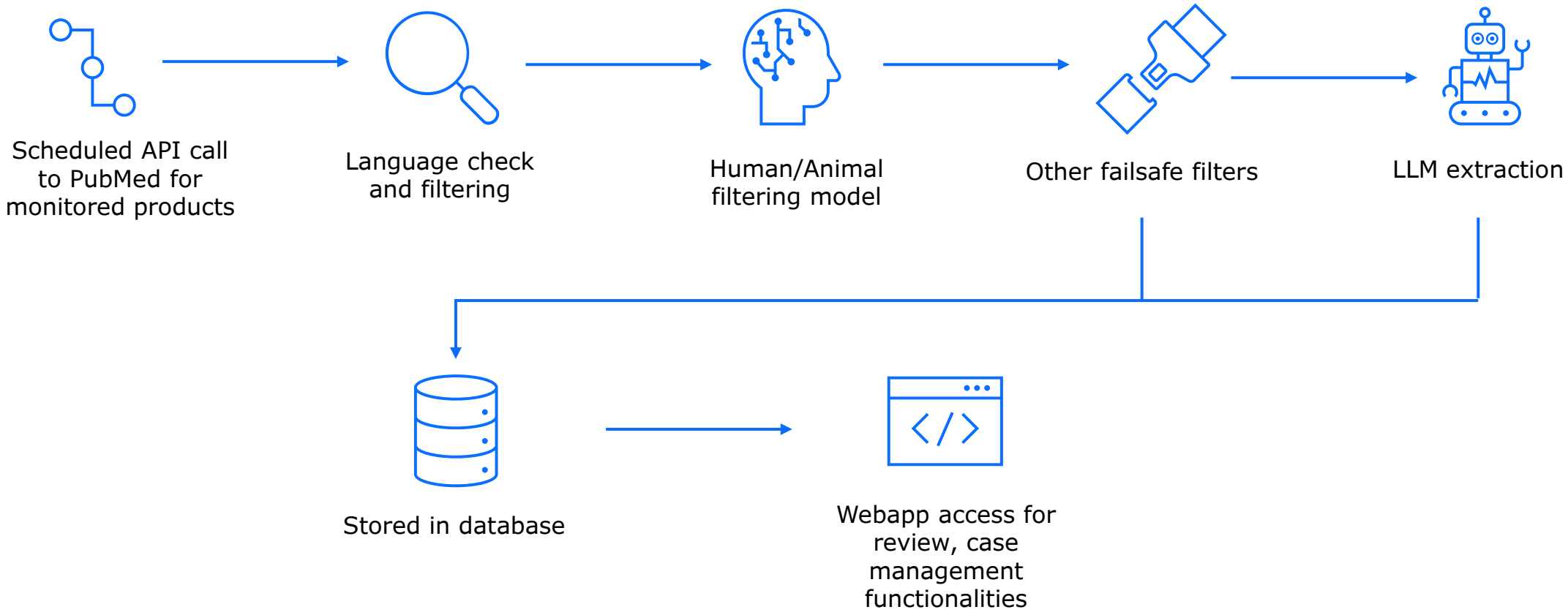
ERATO | Design



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ERATO | Realised benefits

All manuscripts

148,534

Proposed safety concerns

31,210

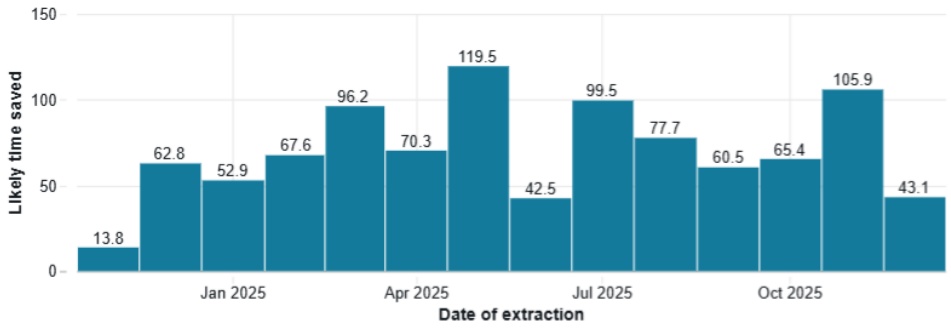
Total time likely saved

In hours (distinct manuscripts)

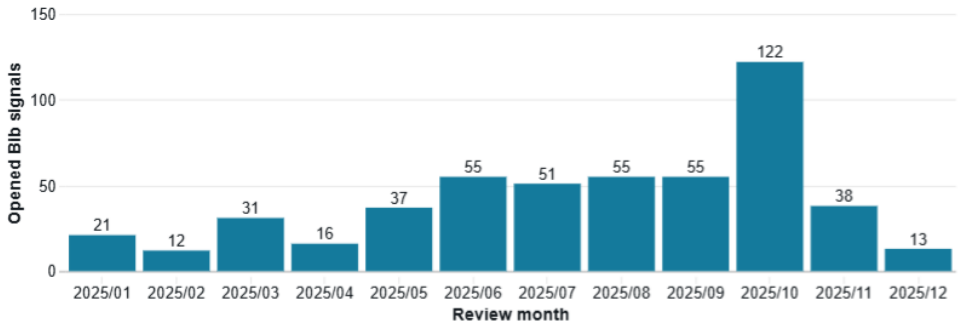
977.7

Time saved details

Tiime potentially spent per month



Reviews highlighted by month



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#3

Lessons and outlook

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Early lessons and general remarks

Piloted tools suggest gains in efficiency and capacity

Multidisciplinary expertise and co-creation

Robust and agile innovation and governance frameworks

AI meant to support, not replace PV expertise

No AI model is perfect (risk-based approach and human oversight)

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HORIZON-JU-IHI-2025-11-two-stage
AI-Powered Signal Detection in Pharmacovigilance

- **EU public-private partnership**
- Industry, regulators, academics, international organisations
- Proposal evaluation in final stages
- 5-year duration (2027-2031)

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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*Along with the **enormous potential** for AI in PV, there are many **challenges** which warrant future consideration, particularly around oversight of autonomous AI systems, and how AI may impact data privacy and ethical frameworks.*

*It is critical that the guiding principles outlined in this report remain as core considerations, but with the understanding that they will need to evolve and adapt […] to **ensure AI use in PV remains unbiased, transparent, and secure** to prevent misuse or accidental harm.*

*The appropriate **human oversight**, including **regulatory and ethical safeguards**, will be as crucial as the technological advancements being applied.*

Artificial intelligence in pharmacovigilance, Report of the CIOMS WG XIV

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Obrigada pela vossa atenção

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Abbreviations

- ADR: adverse drug reaction
- AI: artificial intelligence
- API: application programming interface
- CIOMS: Council for International Organizations of Medical Sciences
- EMA: European Medicines Agency
- ERATO: Enhanced Review of Abstracts with Transformer mOdels
- FDA: US Food and Drug Administration
- FTE: full-time equivalent
- ICSR: Individual Case Safety Report
- IHI: Innovative Health Initiative
- JU: joint undertaking
- LLM: large language model
- MAH: marketing authorisation holder
- ML: machine learning
- NCA: national competent authority
- PV: pharmacovigilance
- SmPC: summary of product characteristics
- TTS: thrombosis with thrombocytopenia syndrome
- WG: working group

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