

#### Update on AI in pharmacovigilance at EMA

Industry Stakeholder Platform – Operation of EU Pharmacovigilance

22 November 2023

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### Artificial Intelligence at EMA | Drivers



#### External collaboration

Be an effective collaborator, including on legislation and guidance development



### AI at EMA | Operational aspects

**AI Coordination Group:** promote oversight and a harmonised approach with EMA initiatives as well as legislative and international initiatives in the field of AI

AI Technical Group: community of practice that supports AI Coordination Group

Close interaction and cooperation are ensured with the **Big Data Steering Group** and the Agency's committees and WPs, in particular the Methodology Working Party (**MWP**).

Two **task forces** established to **develop capabilities** in the use of AI in data analytics and process analytics and to **strengthen collaboration** across the Agency.

**DigiLab:** provides a prioritisation and experimentation framework, supporting the following:

- Analytics Centre of Excellence (ACE): explore how AI can support business needs and deliver solutions
- Health Data Lab: leverage novel digital technologies using healthcare data (e.g. pharmacovigilance)



### **Reflection paper**

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Draft agreed by Committee for Medicinal Products for Human Use (CHMP) Methodology Working Party	July 2023
Draft adopted by CVMP for release for consultation	13 July 2023
Draft adopted by CHMP for release for consultation	10 July 2023
Start of public consultation	19 July 2023
End of consultation (deadline for comments)	31 December 2023

#### Public workshop 20-21 Nov 2023 "Smart regulation in a rapidly evolving world"

- ✓ engage stakeholders
- ✓ inform on HMA/EMA activities
- $\checkmark$  discuss the draft AI reflection paper

Overall vision: allow companies to extract potential **benefits from the use of AI** for public health while ensuring that **risks are managed** and mitigated.

"It is foreseen that AI/ML tools can effectively **support** [...] **pharmacovigilance activities** including adverse event report management and signal detection, in line with current **good pharmacovigilance practices** requirements."

"Applications within pharmacovigilance may allow a **more flexible approach** to AI/ML modelling, where incremental learning can continuously enhance models for classification and severity scoring of adverse event reports as well as signal detection."

"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."



#### Pharmacovigilance: a good fit for AI

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 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

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### AI in pharmacovigilance | Opportunities in signal detection





### AI in PV | EMA experiments

- Extraction of ADRs from SmPCs
- Probabilistic phenotyping: identify patients likely to have a certain genotype by modelling ADR manifestation (*example: 5-FU toxicity*)
- Literature screening: identify articles containing ADRs, prioritise articles most likely to trigger signals
- Automated case adjudication: improve scalability of processes by identifying most supportive cases *(example: thrombosis with thrombocytopenia syndrome)*
- Prioritisation of potential signals based on historical data
- Screening of PSURs for signal discussions
- Prediction model for drug abuse

ARTICLE

An Application of Machine Learning in Pharmacovigilance: Estimating Likely Patient Genotype From Phenotypical Manifestations of Fluoropyrimidine Toxicity

Luis Correia Pinheiro<sup>1,\*</sup>, Julie Durand<sup>1</sup> and Jean-Michel Dogné<sup>2,3</sup>

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## AI in PV | New collaborations

#### **CIOMS Working Group XIV on AI in Pharmacovigilance**

- Formed in 2022, drafting group of senior experts in PhV and/or AI from regulators, industry, research organisations, academia, WHO
- Objective of future report: provide framework for critical appraisal, implementation, maintenance of AI solutions for pharmacovigilance

#### **FDA/EMA cluster on AI in Pharmacovigilance**

• Objectives:

- Exchange and explore alignment on policies, guidance and regulation
- Foster leadership and collaboration on international regulatory initiatives
- Share experience and lessons learnt on use cases
- Discuss research needs
- 2-monthly TCs, kick-off in Oct. 2023



### Final thoughts





# Thank you for your attention

#### Further information

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