

Trustworthy AI for Tomorrow's Medicines

PHUSE CSS 2025

Luis Correia Pinheiro

Data Analytics and Methods Taskforce



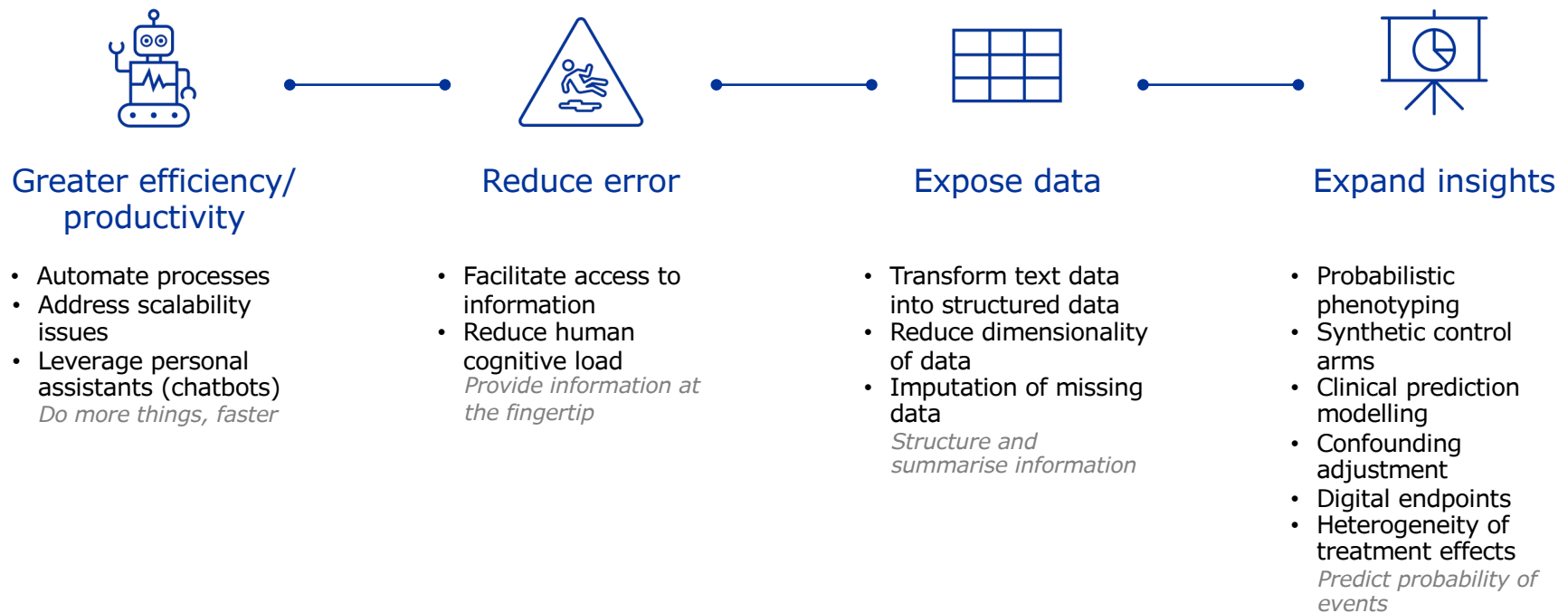
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The promise of AI



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Generative AI | Specific Generative AI use cases



Research and structuring of information

- Access and structure of available information (questions only, no data provided)



Data Summary and Extraction

- Summarize text data and extract information (e.g., Scientific Explorer) (data provided)



Data Analysis / Troubleshooting

- Interpret simple data sets and generate visuals (charts, presentations)



Coding

- Statistical programming (LLMs stand out because it is more structured than natural language)

The EMRN vision for AI is for a regulatory system leveraging AI to harness systems efficiency, increased insights into data and strengthened decision-making, for the benefit of public and animal health.

PERSPECTIVE

Artificial Intelligence in European Medicines Regulation: From Vision to Action. Harnessing the Capabilities of Artificial Intelligence for the Benefit of Public and Animal Health

Luis Correia Pinheiro^{1,*} , Peter Arlett¹ , Kit Roes² , Flora Musuamba Tshinanu³ , Gabriel Westman⁴ , Zaide Frias¹, Hilmar Hamann¹, Joaquim Berenguer Jornet¹, Iftekhar Khan⁵ , Jeppe Larsen⁶, Karl Broich⁷ and Emer Cooke¹

The European Medicines Regulatory Network (EMRN) has developed a multi-annual workplan to leverage artificial intelligence (AI)

lifecycle for the benefit of public and animal health.

EMRN VISION FOR AI IN EUROPEAN MEDICINES REGULATION

There are three areas of focus for the EMRN's AI transformation: the ability to regulate products that include AI in their lifecycle as required, the ability to leverage AI for process improvement and analytics, and the ability to leverage AI for advanced healthcare data analytics. These focus areas underpin the EMRN's vision for AI: "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."³

FROM VISION TO ACTION—A MULTI-ANNUAL WORKPLAN ON AI

In November 2023, the EMRN held a public workshop⁴ to hear the views of

European Medicines Regulatory Network AI Drivers



Regulate AI in the medicine
lifecycle



Process analytics



Healthcare analytics

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Network Data Steering Group – unlocking value of data

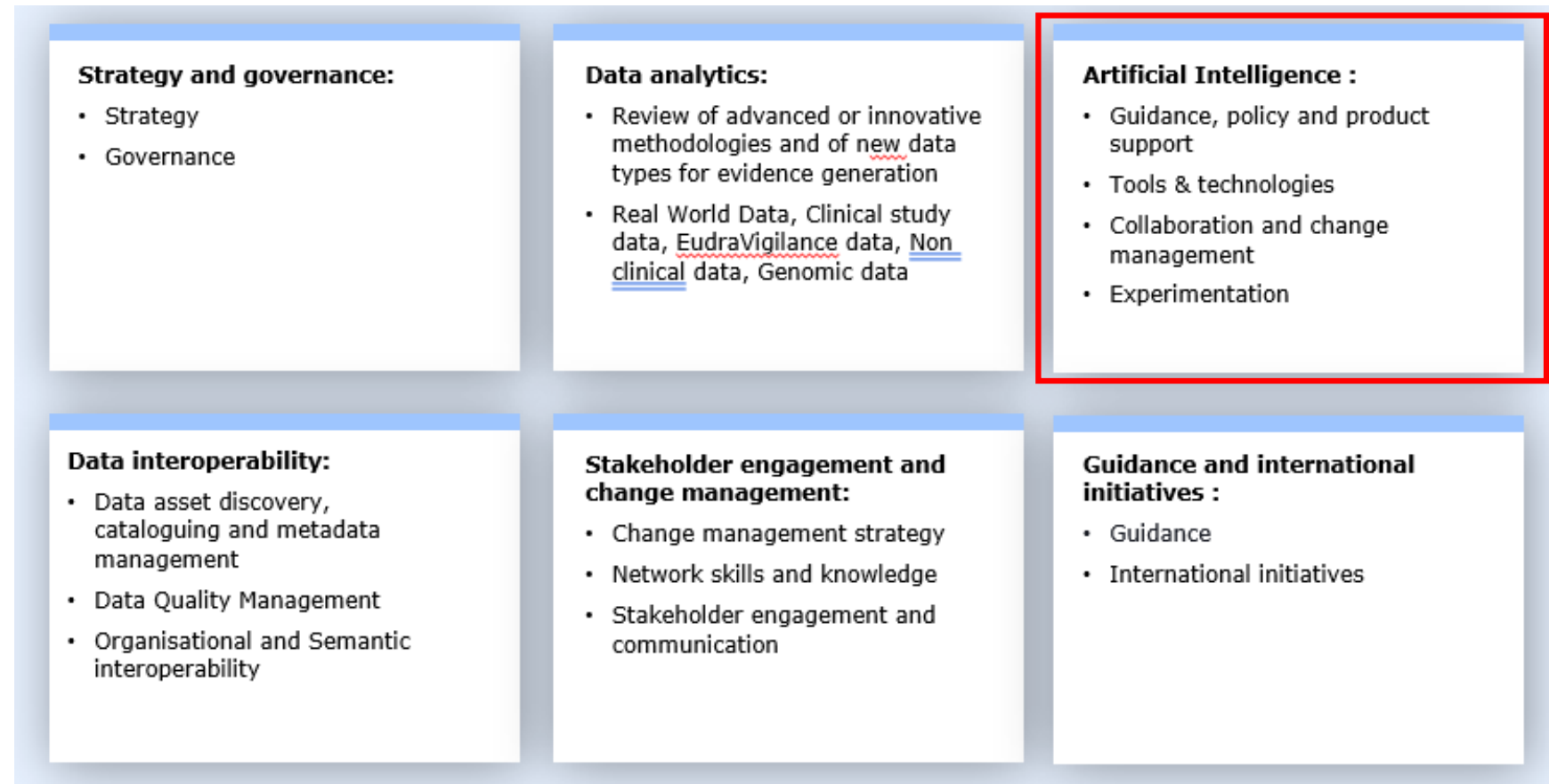
Key priorities 2025

Strategy and governance	 Support to New Pharma Legislation, EHDS2 and AI Act	 EMRN data strategy, incl. data standardisation strategy, data quality and cataloguing	 EMRN data analytics strategy, incl. strengthening network capabilities
	 Continue ongoing initiatives of DARWIN EU® and clinical study raw data	 Medicines master data implementation - EHDS1 as priority use case	 Artificial intelligence
	 Communication	 Training and guidance	 Stakeholder engagement

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The NDSG workplan is organised in six workstreams



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Key pillars



Guidance, policy and product support

Continuous support to products. Development of appropriate guidance for the use of AI in the lifecycle of a medicine. Implementation of the EU AI Act.



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.



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.



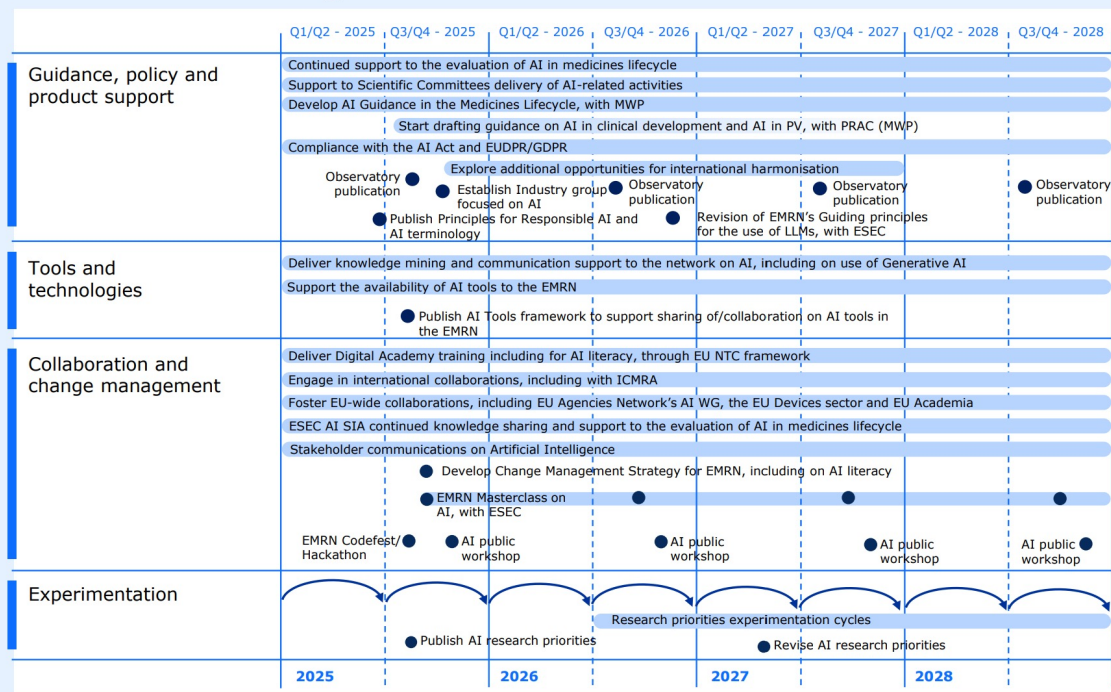
Experimentation

Ensure a structured approach to experimentation across the network to accelerate learning and gain new insights.

AI Workstream

WORKSTREAM OVERVIEW

Artificial Intelligence



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Initiated in 2023 under Big Data Steering Group

Revised in 2025 under Network Data Steering Group



Key initiatives

AI Reflection Paper



1 13 July 2023
2 EMA/CHMP/CVMP/83833/2023
3 Committee for Medicinal Products for Human Use (CHMP)
4 Committee for Medicinal Products for Veterinary Use (CVMP)

5 Reflection paper on the use of Artificial Intelligence (AI) in
6 the medicinal product lifecycle
7 Draft

Trustworth

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 (<i>deadline for comments</i>)	31 December 2023

8 Comments should be provided using this EUSurvey [form](#). For any technical issues, please contact the [EUSurvey Support](#).

9 Keywords Artificial intelligence, AI, machine learning, ML, regulatory, medicine, human medicinal product, veterinary medicinal product

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

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Key initiatives

Guiding principles on the use of LLMs



29 August 2024

European Medicines Agency

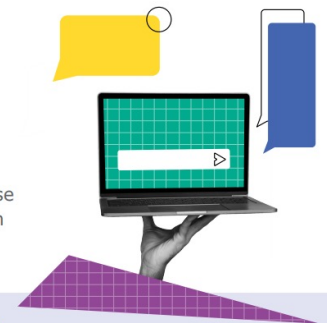
Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities
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Factsheet

4 principles for safe and responsible use of LLMs

Large language models (LLMs) are a category of generative artificial intelligence trained on large amounts of text. You can use LLMs to draft emails, create, proofread and rephrase text, search and summarise information, for learning, coding and more.



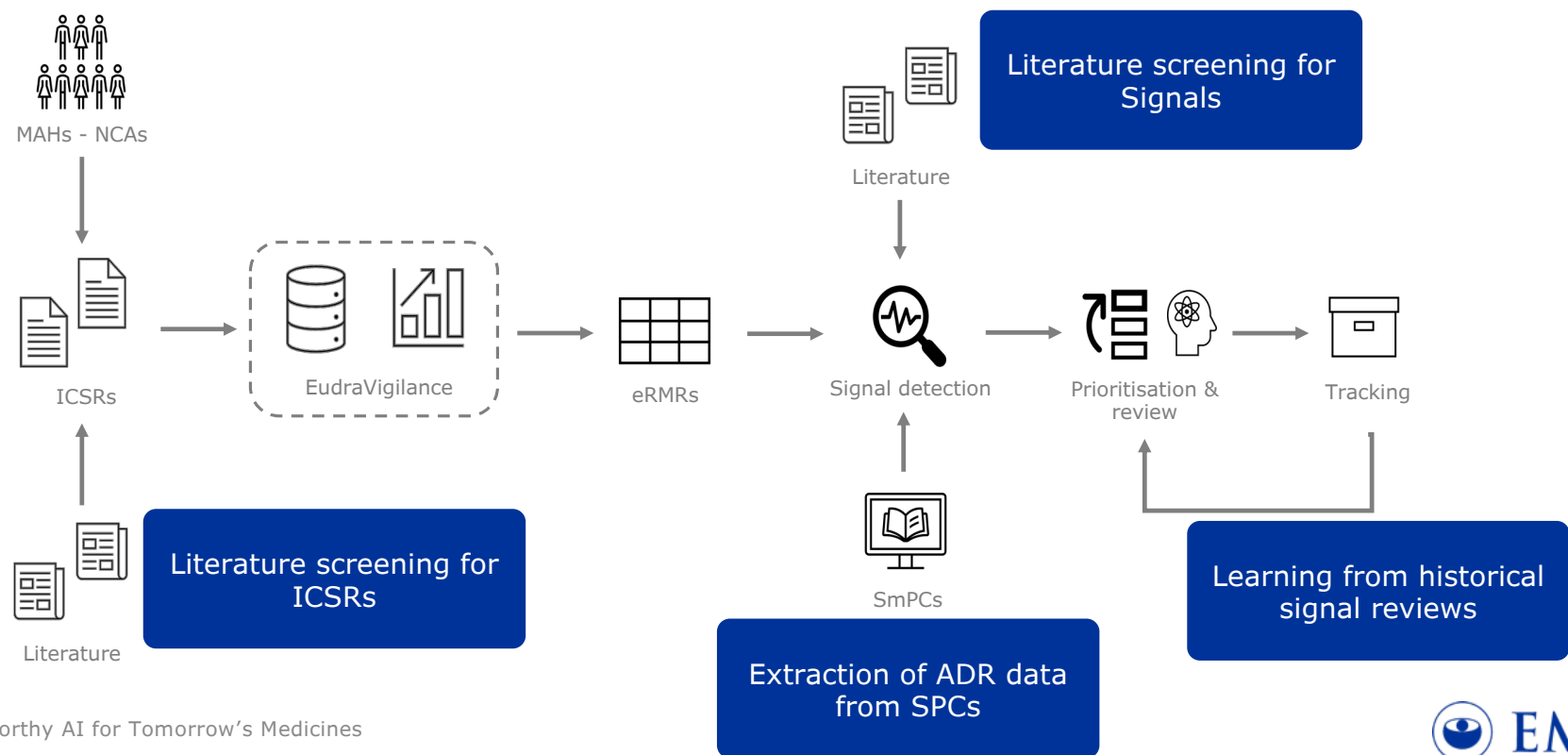
Recommendations for medicines regulatory staff



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Key initiatives

Health Data Lab experimentation



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NDSG Vision

Trusted medicines
by unlocking the
value of data



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

luis.pinheiro@ema.europa.eu

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