EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Key initiatives of the European Medicines Regulatory Network to adopt AI in Health Care

CRT on artificial intelligence

Dr. Florian Lasch, European Medicines Agency

Disclaimer

The views expressed in this presentation are my personal views and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

AI in Healthcare | Regulatory Drivers

Regulatory submissions

Regulate applications of AI in medicines to help create value for public health

Process Analytics

Improve **efficiency** by automating and digitalizing processes

Healthcare Analytics

Structure information and increase insights into data to inform decision-making

Extracting public health benefits from AI in the medicine's lifecycle

Out now…

EUROPEAN MEDICINES AGENCY
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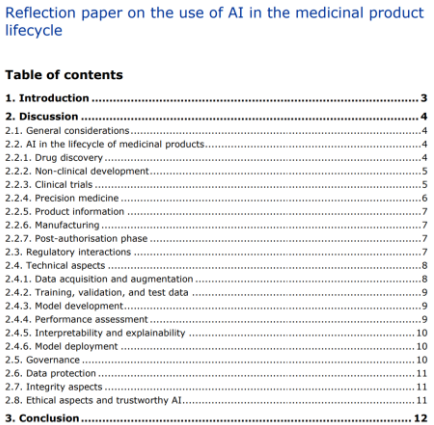
9 September 2024
EMA/CHMP/CVMP/83833/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

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

Guidance | AI Reflection Paper

General considerations & risk



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

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- AI and ML tools can effectively support the acquisition, transformation, analysis, and interpretation of data within the medicinal product lifecycle.
- A risk-based approach for development, deployment and monitoring of AI and ML tools allows developers to pro-actively define risks to be managed throughout the AI lifecycle.
- The degree of risk may depend on
  - the AI technology,
  - the context of use,
  - the degree of influence the AI technology exerts and
  - may vary throughout the lifecycle of the AI-system.
- MAA/MAHs planning to deploy AI/ML technology are expected to consider and systematically manage relevant risks from early development to decommissioning.

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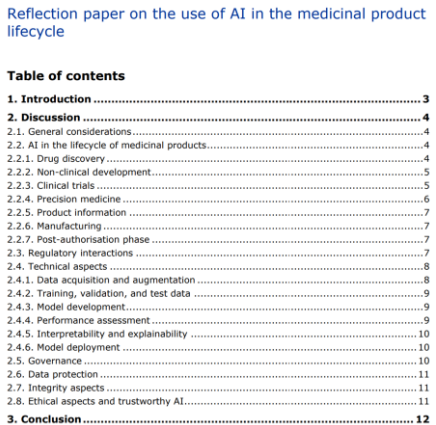
Benefit-risk



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- If an AI/ML system is used in the context of medicinal product development, evaluation or monitoring, and is expected to impact, even potentially, on the benefit-risk of a medicinal product, early regulatory interaction is advised
- E.g., qualification of innovative development methods for a specific intended use in the context of research and development in relation to pharmaceuticals, or scientific advice
- The level of scrutiny would depend on the level of risk and regulatory impact posed by the system

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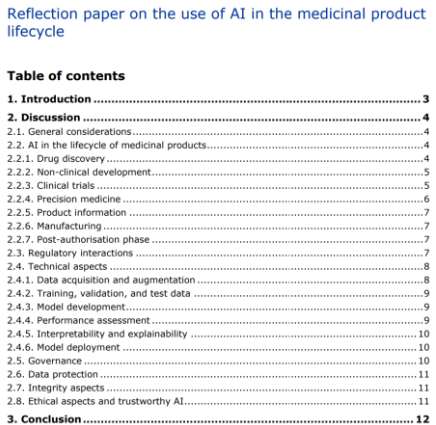
Key principles



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- Responsibility of the marketing authorisation applicant or MAH to ensure that all algorithms, models, datasets, and data processing pipelines used are fit for purpose and are in line with ethical, technical, scientific, and regulatory standards as described in GxP standards and current EMA scientific guidelines.
- For all requests for advice or opinions the applicant or MAH is expected to provide a scientific base along with sufficient technical details to allow comprehensive assessment of any AI/ML systems used in the medicinal product lifecycle, the integrity of data and generalizability of models to the target population and for a specific context of use.

Interaction channels with the EMA

- EMA Innovation Task Force meetings
- EMA Portfolio & Technology meetings
- Scientific Advice Working Party

The journey continues…

Guidance

Offer clear, balanced, guidance to developers, marketing authorisation holders, etc.

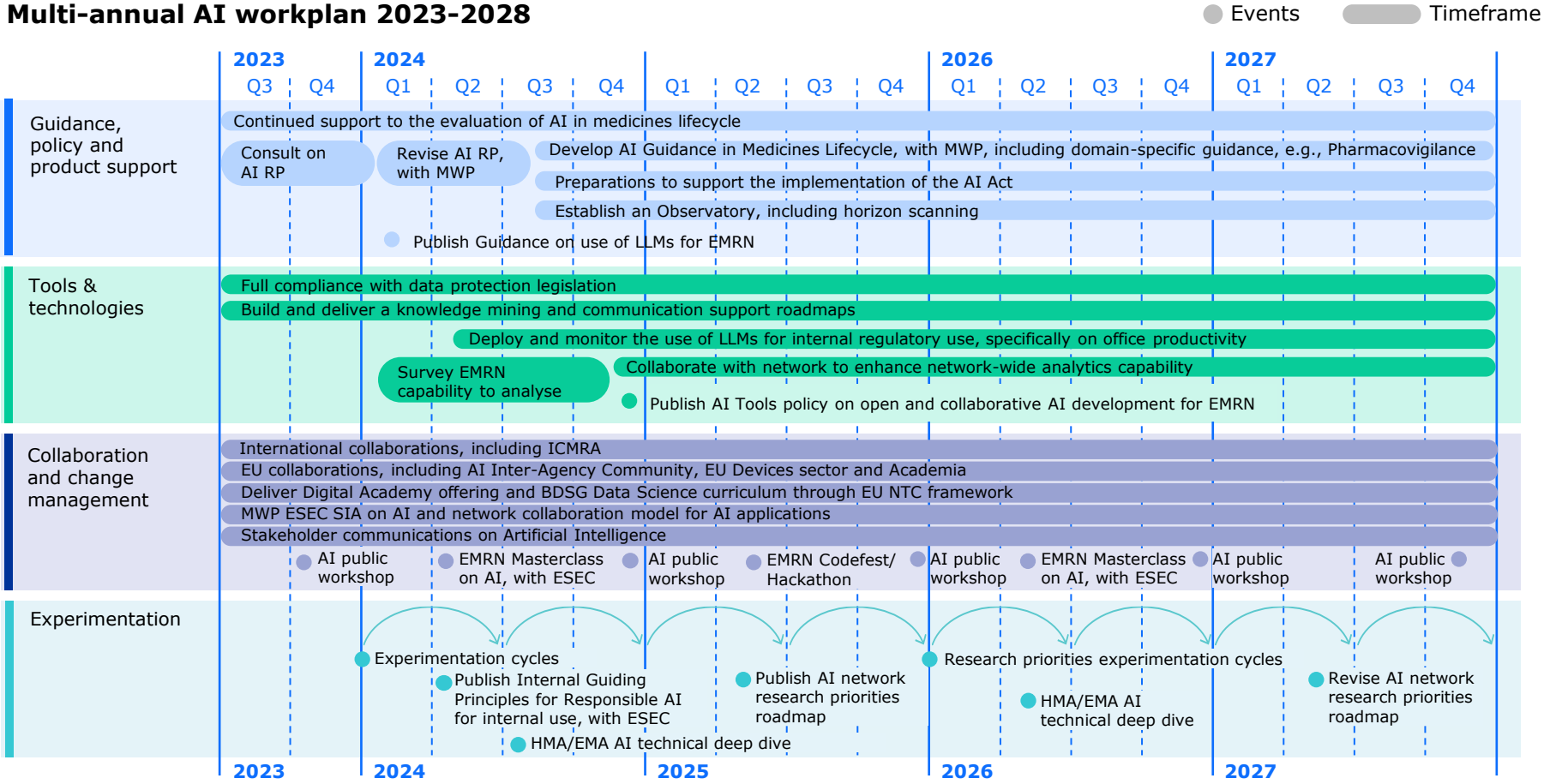
Upskilling

Provide training across the network to foster competent and responsible use/regulation of AI

Collaborations

Leverage collaborations to improve knowledge, reduce uncertainty and facilitate alignment

Multi-annual AI workplan 2023-2028



Any questions?

Further information

Florian.lasch@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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