EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thoughts on how to adopt AI in Health Care

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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

Adopting AI in Health Care

EUROPEAN MEDICINES AGENCY
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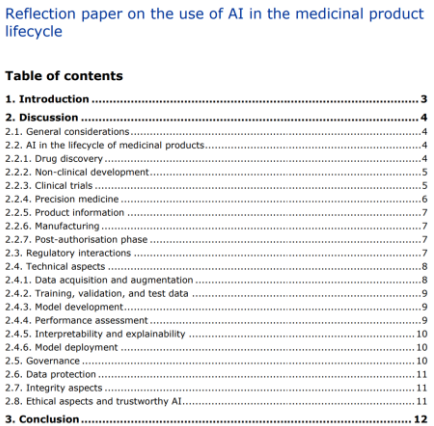
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

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.

Adopting AI in Health Care

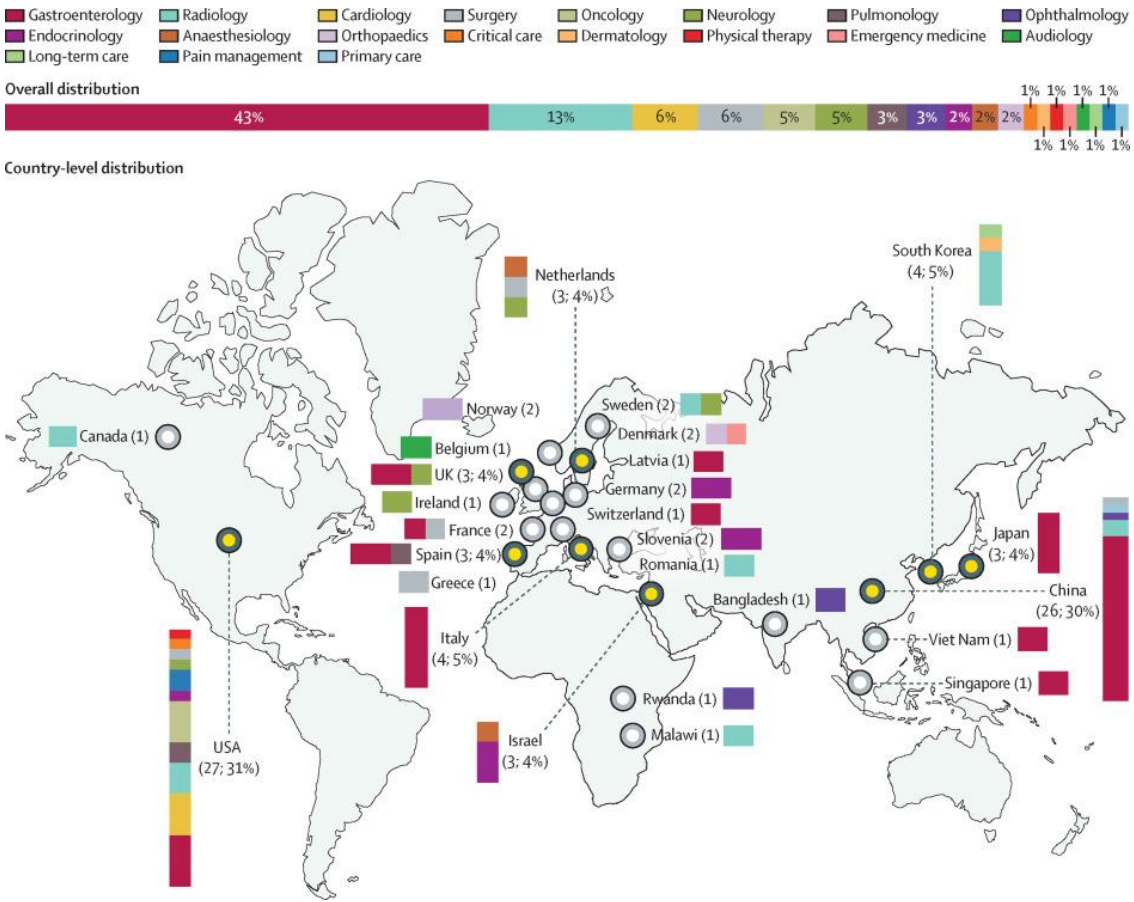
Translating the requirements from the AI reflection paper

- Data availability
  - Sharing and collaboration
  - Representativeness

- Risk setting
  - Low vs. high risk
  - low vs. high reward
  - Gaining experience & trust

Translating the requirements from the AI reflection paper

- Evidence generation
  - RCTs for AI applied in clinical trials
  - Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review – ScienceDirect
  - 86 trials identified between Jan 1, 2018, and Nov 14, 2023.
  - 37 (43%) were related to gastroenterology, 11 (13%) to radiology, five (6%) to surgery, and five (6%) to cardiology.
  - 54% of primary endpoints relating to diagnostic yield or performance, other primary endpoints were grouped according to care management (21%), patient behaviour and symptoms (17%), and clinical decision making (8%)



Adopting AI in Health Care

Han et al. RCTs evaluating AI in clinical practice

RCTs for AI in cardiology

Objectives

- trial fibrillation management
- Stroke medication management
- Statin management
- Low ejection fraction screening
- Cardiac function assessment

Endpoint

- New anticoagulant prescriptions
- Mean cumulative medication adherence
- Proportion of days covered
- New diagnoses
- Rate of substantial change in assessment relative to cardiologist

Discussion points

Key recommendations:

- Real-world evaluation of the developed tools is critical
- Future AI trials should prioritise patient-relevant outcomes to fully understand AI's true effects and limitations in health care

Any questions?

Further information

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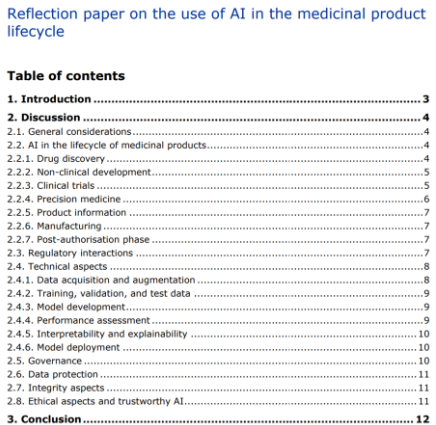
Benefit-risk



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

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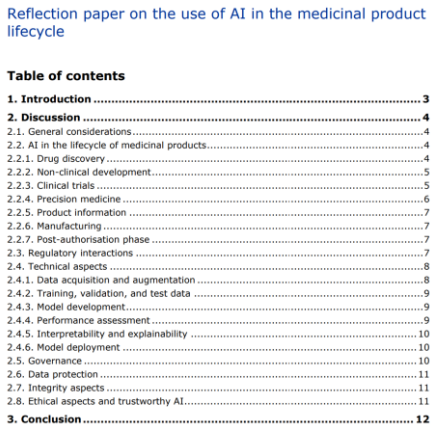
- If an AI/ML system is used in the context of medicinal product development, evaluation or monitoring, and is expected to impact, even potentially, on the benefit-risk of a medicinal product, early regulatory interaction is advised
- E.g., qualification of innovative development methods for a specific 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

Guidance | AI Reflection Paper

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.

Multi-annual AI workplan 2023-2028