

## Thoughts on how to adopt AI in Health Care



#### 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



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.

## 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 <u>gastroenterology</u>, 11 (13%) to <u>radiology</u>, five (6%) to <u>surgery</u>, and five (6%) to <u>cardiology</u>.
  - 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%)



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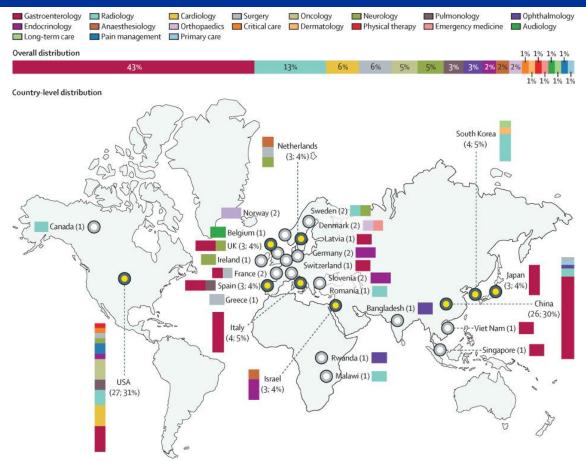


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Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review

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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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## Guidance | AI Reflection Paper

#### 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

### 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.



