EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Delivering on stakeholders' requirements for AI

PCWP/HCPWP and all eligible organisations meeting

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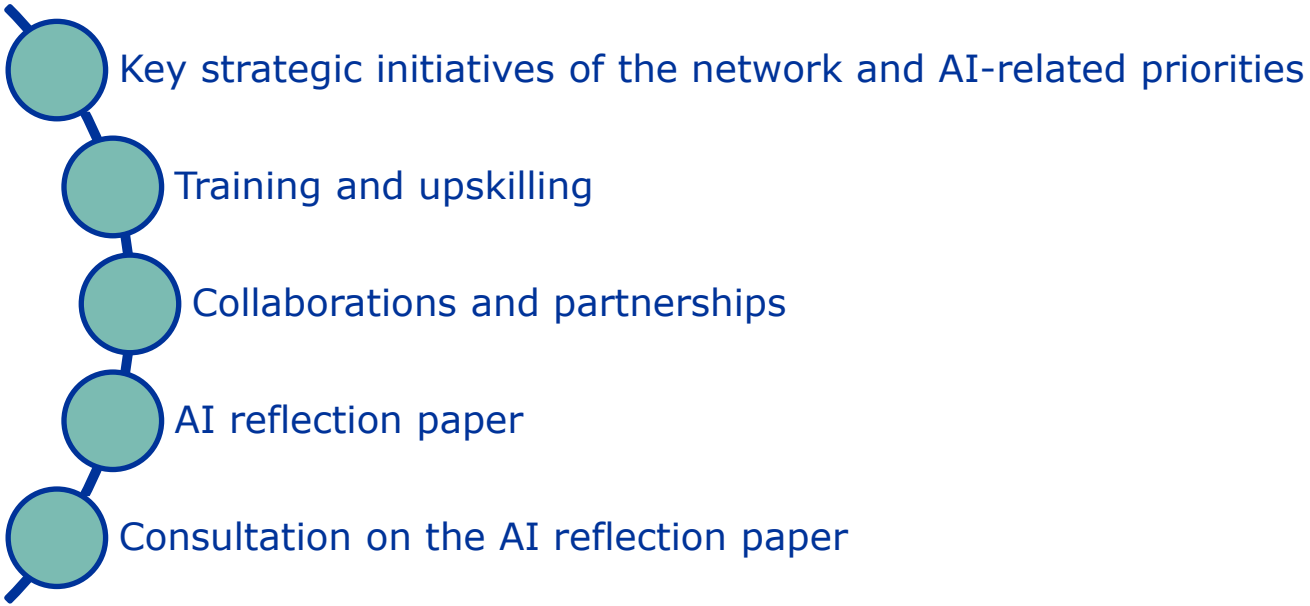
With thanks to Gabriel Westman, MPA, Head of AI

An agency of the European Union

Content



Key strategic initiatives | AI priorities and stakeholder's views

Key strategic initiatives

- HMA/EMA Big Data Taskforce
- Regulatory Science Strategy to 2025
- European Medicines Agencies Network Strategy to 2025

AI related recommendations

- Topics
- Learning & skills gap
- Methods & guidelines
- Governance
- Initiatives
- Partnerships & collaborations
- Promote experimentation

AI Workshop 2021

(collect stakeholder views)

- Stakeholders
- MedTech, HCP, Patients, Consumers, Inspectors, Pharma, General Industry, Research, Academia, Innovation Network

13 Presentations
27 Speakers
Max Attendance 525

Stakeholder priorities and actions

- Priorities
  - Develop guidelines and framework to assess AI
  - Build multi-stakeholder and international partnerships/collabs
  - Upskill EMRN
- *Mapped to actions*
  - BDSG, EMA workplan, AI Coordination/ Technical group

HMA – Heads of Medicines Agencies
ERMN – European Medicines Regulatory Network
BDSG – Big Data Steering Group

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Training and upskilling | Essential for Digital and AI transformation

On-demand training (via EU-NTC)

Digital Academy – AI Module
(introductory, jargon-busting course)

BDSG Data Science Curriculum
(includes advanced training on AI topics)

Communities of Practice

AI Technical Group (previous code club)
(EMA group of AI interested people & coders)

European Specialised Expert Community
(Special interest area on AI)

Collaborations and partnerships | Alignment and learning

- Big Data Steering Group
- ESEC AI
- FDA
- ICMRA
- Swissmedic
- CIOMS
- WHO
- …

AI Reflection paper | Objectives and approach

- Provides considerations on the **use of artificial intelligence (AI) and machine learning (ML) in the lifecycle of medicinal products [human & veterinary]**
  - Describes the current experience in context of the European Medicines Regulatory Network
  - Acknowledges fast evolution of scientific knowledge on AI/ML
  - Should be read in coherence with both legal requirements and overarching EU principles on AI, data protection, and medicines regulation
  - *This reflection paper is not to be considered a regulatory guidance document.*
- Lead responsibility: CHMP Methodology Working Party (MWP)

  Coordinating author: Gabriel Westman, MWP (MPA, SE); contributions by MWP, experts, and EMA
- Link to page & AI RP: Reflection paper on the use of artificial intelligence in the lifecycle of medicines | European Medicines Agency (europa.eu)

AI RP | Overview

AI RP | Introduction

- Data are generated and used increasingly across sectors, including those related to the lifecycle of medicines. AI is a key part of digital transformation that enables increased use of data for analysis and decision-making.
- AI often displaces some human activity potentially introducing risks that need to be managed
- Given the rapid development in this field, the aim of this draft reflection paper is to reflect on the scientific principles that are relevant for regulatory evaluation
- It is crucial to identify aspects of AI/ML that would fall within the remit of EMA or the National Competent Authorities of the Member States as the level of scrutiny into data during assessment will depend on this remit
- Important differences exist between the human and veterinary domain including legal bases, regulatory requirements and guidance, ethical issues, risks of bias and other sources of discrimination – further reflections necessary.

AI RP | General considerations & risk

- AI and ML tools can, if used correctly, 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.

AI RP | Benefit-risk

- 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

AI RP | Key principles

- 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.

AI RP | Public consultation

Written comments

Through EU survey tool

When? - End of consultation **31 December 2023**

How? - All written comments should be provided through dedicated digital EU survey tool

HMA/EMA AI workshop

20-21 November 2023 (broadcasted)

Workshop objectives:

- Engage stakeholders on AI technology, policy developments and potential use in medicines regulation
- Inform on the HMA/EMA activities to deliver the stakeholder's priorities on AI
- Discuss with stakeholders and experts on the draft AI RP