Multi-annual AI Workplan - Update

HMA/EMA Big Data Steering Group

PCWP/HCPWP meeting with all eligible organisations
20 November 2024

Luis Pinheiro
Data Analytics and Methods Taskforce

Artificial Intelligence (AI) Workplan

- Or use a search engine to search:
  - EMRN artificial intelligence workplan

Vision

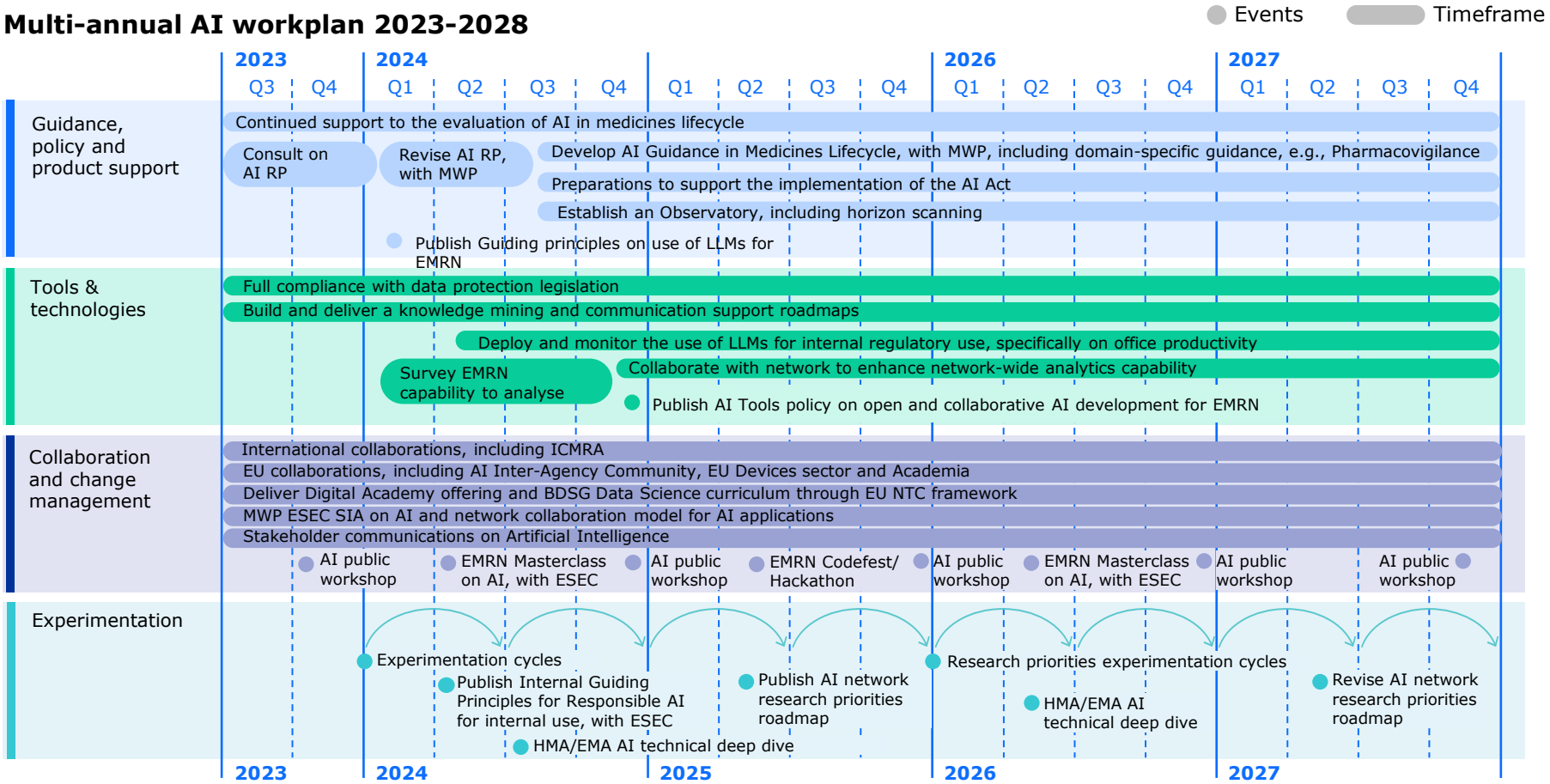
Enabling safe and responsible use of AI for the benefit of public and animal health

A regulatory system harnessing the capabilities of AI for personal productivity, process automation, systems efficiency, increased insights into data and stronger decision-support mechanisms and extracting benefits for public and animal health.

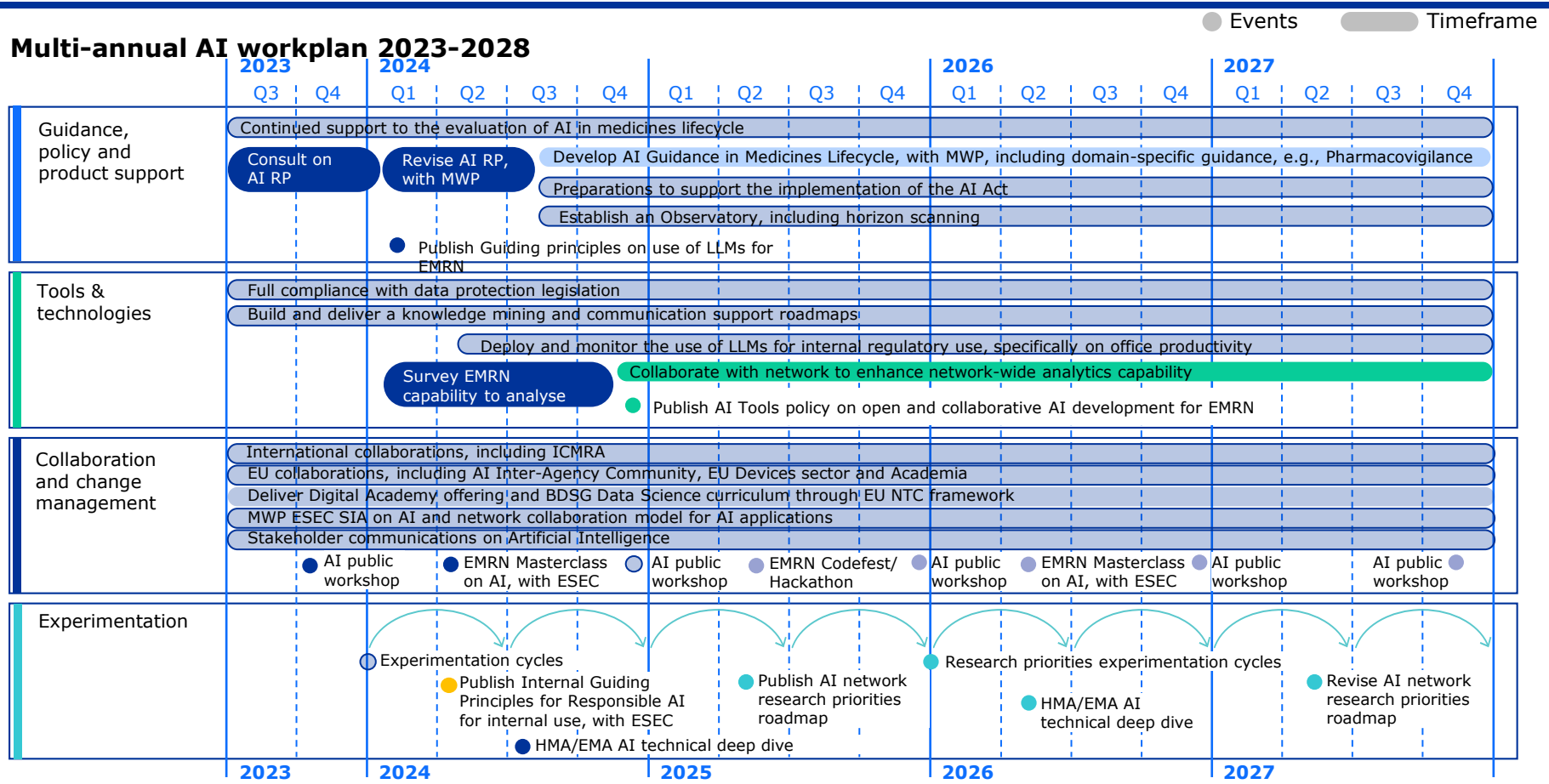
Workplan pillars

Guidance, policy and product support	Continuous support to products as well as the development and evaluation of appropriate guidance for the use of AI in the lifecycle of a medicine. Preparations to support the implementation of the EU AI Act.
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. Full compliance with data protection legislation.
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.
Experimentation	Several actions are proposed to ensure a structured approach to experimentation across the network to accelerate learning and gain new insights.

Multi-annual AI workplan 2023-2028



Multi-annual AI workplan 2023-2028



Completed

- Revise AI RP, with MWP
- Consult on AI RP
- Publish Guiding principles on use of LLMs for EMRN
- Survey EMRN capability to analyse
- AI public workshop
- EMRN Masterclass on AI, with ESEC
- HMA/EMA AI technical deep dive

Ongoing/on track

- Continued support to the evaluation of AI in medicines lifecycle
- Preparations to support the implementation of the AI Act
- Establish an Observatory
- Full compliance with data protection legislation
- Build and deliver a knowledge mining and communication support roadmaps
- Deploy and monitor the use of LLMs for internal regulatory use, specifically on office productivity
- International collaborations
- EU collaborations
- Deliver Digital Academy offering and BDSG Data Science curriculum
- MWP ESEC SIA on AI and network collab.
- Stakeholder communications on AI
- Experimentation cycles
- Publish Internal Guiding Principles for Responsible AI for internal use, with ESEC

In planning/not started

- Develop AI Guidance in Medicines Lifecycle, with MWP, including domain-specific guidance, e.g., Pharmacovigilance
- Collaborate with network to enhance network-wide analytics capability
- Publish AI Tools policy on open and collaborative AI development for EMRN
- AI public workshop(s)
- EMRN Codefest/ Hackathon
- EMRN Masterclass on AI, with ESEC
- Research priorities experimentation cycles
- Revise AI network research priorities roadmap
- HMA/EMA AI technical deep dive
- Publish AI network research priorities roadmap

Guidance, policy and product support | Tools & technologies | Collaboration and change management | Experimentation

Guidance | AI Reflection Paper

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

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 (*deadline for comments*)	31 December 2023
Final version agreed by MWP	6 September 2024
Final version adopted by CHMP	9 September 2024
Final version adopted by CVMP	11 September 2024

Table of contents

Guiding principles on the use of LLMs | EMRN-specific

HMA
Heads of Medicines Agencies

EMA
EUROPEAN MEDICINES AGENCY

29 August 2024

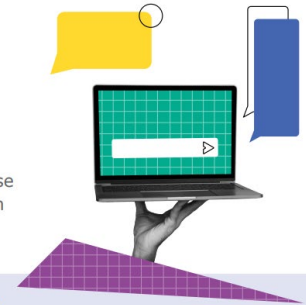
European Medicines Agency

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

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

AI Workplan

Taking stock

- Much has been done in 12 months, but AI is a fast evolving ethical, legal, technological, and regulatory topic
- The multi-annual AI workplan was created to be flexible and allow annual take stocks
- The AI Workshop was a key opportunity for stakeholders to offer their views on the future of this workplan:
  - New topics
  - Topics that have become redundant
  - Reprioritisations
- Following stakeholder comments, revision is ongoing