Multi-annual AI workplan
2023-2028

HMA-EMA Big Data Steering Group
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Introduction

Artificial Intelligence (AI) systems are gradually becoming a dominant tool supporting intellectual work and powering automation across all walks of life.

The European medicines regulatory network’s (EMRN) vision on AI is for a regulatory system harnessing the capabilities of AI for personal productivity, process automation and systems efficiency, increased insights into data and strengthened decision-support for the benefit of public and animal health.

The increasingly sophisticated nature and the pace of change of AI bring opportunities but also challenges. The application of AI requires a collaborative, coordinated strategy to maximise the benefits from AI while ensuring that uncertainty is adequately explored, and risks are mitigated.

This first version of the BDSG multi-annual AI workplan focuses on four critical dimensions to facilitate the development and use of responsible and beneficial AI.

AI technology is fast evolving, as are the ethical and policy aspects related to it. As these evolve this plan will be regularly updated under the oversight of the HMA-EMA Big Data Steering Group.

Throughout the execution of the workplan, stakeholders will be consulted, engaged and informed.
Workplan
The HMA-EMA joint Big Data Steering Group workplan on AI
Multi-annual AI workplan 2023-2028

### Guidance, policy and product support

- **2023 Q3**: Continued support to the evaluation of AI in medicines lifecycle
- **2023 Q4**: Consult on AI RP
- **2024 Q1**: Revise AI RP, with MWP
- **2024 Q2**: Publish Guidance on use of LLMs for EMRN
- **2024 Q3**: Develop AI Guidance in Medicines Lifecycle, with MWP, including domain-specific guidance, e.g., Pharmacovigilance
- **2024 Q4**: Preparations to support the implementation of the AI Act
- **2025 Q1**: Establish an Observatory, including horizon scanning
- **2025 Q2**: Full compliance with data protection legislation
- **2025 Q3**: Build and deliver a knowledge mining and communication support roadmaps
- **2025 Q4**: Deploy and monitor the use of LLMs for internal regulatory use, specifically on office productivity
- **2025 Q3**: Publish Guidance on use of LLMs for EMRN
- **2025 Q4**: Collaborate with network to enhance network-wide analytics capability

### Tools & technologies

- **2023 Q3**: Full compliance with data protection legislation
- **2023 Q4**: Build and deliver a knowledge mining and communication support roadmaps
- **2024 Q1**: Deploy and monitor the use of LLMs for internal regulatory use, specifically on office productivity
- **2024 Q2**: Survey EMRN capability to analyse
- **2024 Q3**: Collaborate with network to enhance network-wide analytics capability
- **2024 Q4**: Publish AI Tools policy on open and collaborative AI development for EMRN
- **2025 Q1**: International collaborations, including ICMRA
- **2025 Q2**: EU collaborations, including AI Inter-Agency Community, EU Devices sector and Academia
- **2025 Q3**: Deliver Digital Academy offering and BDSG Data Science curriculum through EU NTC framework
- **2025 Q4**: MWP ESEC SIA on AI and network collaboration model for AI applications

### Collaboration and change management

- **2023 Q3**: International collaborations, including ICMRA
- **2023 Q4**: EU collaborations, including AI Inter-Agency Community, EU Devices sector and Academia
- **2024 Q1**: Deliver Digital Academy offering and BDSG Data Science curriculum through EU NTC framework
- **2024 Q2**: MWP ESEC SIA on AI and network collaboration model for AI applications
- **2024 Q3**: Stakeholder communications on Artificial Intelligence
- **2024 Q4**: AI public workshop
- **2025 Q1**: EMRN Masterclass on AI, with ESEC
- **2025 Q2**: AI public workshop
- **2025 Q3**: EMRN Codefest/Hackathon
- **2025 Q4**: AI public workshop

### Experimentation

- **2023**: Experimentation cycles
- **2024**: Publish Internal Guiding Principles for Responsible AI for internal use, with ESEC
- **2025**: HMA/EMA AI technical deep dive
- **2025**: Publish AI network research priorities roadmap

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**Guidance, policy and product support**
- Continued support to the evaluation of AI in medicines lifecycle
- Develop AI Guidance in Medicines Lifecycle, with MWP, including domain-specific guidance, e.g., Pharmacovigilance
- Preparations to support the implementation of the AI Act
- Establish an Observatory, including horizon scanning

**Tools & technologies**
- 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
- Collaborate with network to enhance network-wide analytics capability

**Collaboration and change management**
- International collaborations, including ICMRA
- EU collaborations, including AI Inter-Agency Community, EU Devices sector and Academia
- Deliver Digital Academy offering and BDSG Data Science curriculum through EU NTC framework
- MWP ESEC SIA on AI and network collaboration model for AI applications
- Stakeholder communications on Artificial Intelligence

**Experimentation**
- Research priorities experimentation cycles
- HMA/EMA AI technical deep dive
- Revise AI network research priorities roadmap

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Topic description
Guidance, policy and product support

Continued support to the development and evaluation of AI in the medicines’ lifecycle will be provided.

With the public consultation of the AI reflection paper (RP), the process of exploring the development of guidance has initiated, including considering whether multiple guidelines might be appropriate, including, e.g., on AI in pharmacovigilance. This process will continue to be led by the CHMP’s Methodology Working Party (MWP).

Large Language Models will become easily accessible and thus guidance for the European Medicines Regulatory Network (Network) on the use of large language models will be developed.

From mid-2024 work will be initiated in preparation of the AI Act coming into force.

The use of AI will require constant monitoring, both of the impact of AI as well as of the emergence of novel systems and approaches, thus an observatory will be created.

**Key dates:**

- **Dec 2023** – end of the AI RP public consultation
- **Q3 2024** – preparation for the AI Act
- **Q4 2024** – phased implementation of an AI Observatory
Tools & technologies

Full compliance with data protection legislation will be ensured.

Leveraging advances in natural language processing and generative AI, knowledge mining and communication support roadmaps will be developed and implemented.

Large Language Models, particularly chatbots, are likely to become a dominant tool in intellectual work as personal assistants. Their implementation will be phased and monitored to ensure the benefits of their implementation are maximised, especially for office productivity.

The Network will be surveyed on its capability to analyse data including the use of AI. This survey will inform collaborative efforts to enhance the analytics capability of the Network.

To foster collaboration, integration and reusability of tools and models, a Network Tools policy for open and collaborative AI development will be published.

Key dates:

- **Q1 2024** – initial knowledge mining tools to be rolled out for the Network
- **Q2 2024** – phased roll-out and monitoring of LLMs and related chatbots as personal assistants
- **Q3 2024** – completed survey of the network on capability to analyse data
- **Q4 2024** – publication of the AI tools policy for the EMRN
Collaboration and change management

The fast-paced progression of AI will require continuous collaboration and training.

The Network will continue to contribute to work with partners on AI internationally, including with the International Coalition of Medicines Regulatory Authorities (ICMRA) and at a European Union (EU) level, including with other EU Agencies, part of an AI Virtual Community as well as with the Devices sector and Academia.

The European Specialised Expert Community (ESEC) of the EMA Methodology Working Party (MWP), will establish a Special Interest Area (SIA) on AI, providing a Network community of practice as a forum for collaboration and knowledge sharing.

The EU-Network Training Centre will provide a framework and platform to expand Digital Academy offering on AI and Data Analytics as well as support the development and delivery of BDSG Data Science Curriculum. We will explore opportunities for collaboration on training with stakeholders.

Key dates:
- **Q1 2024** – publication of additional Digital Academy module and learning collection on AI and Data Analytics
- **Q1 2024** – phased roll-out of BDSG Data Science curriculum
- **Q3 2024-2027** – annual public workshops
A working model to allow collaborative development and evaluation of AI applications will be defined.

Topic specific public workshops, masterclasses and codefest/hackathons will help upskill staff and connect to the wider Stakeholder and Data Science community. We will seek the views of the stakeholders on the selection of topics.
Experimentation is fundamental to expedite learning and reduce uncertainty about a technology or system.

Experimentation cycles of up to six months will be conducted throughout the next few years.

Internal guiding principles for responsible AI for internal use will be defined, supported by the European Specialised Expert Community (ESEC).

Once the principles and a framework of experimentation are consolidated, a roadmap of network research priorities will be defined, and experimentation cycles will align with those priorities.

Technical deep dives, looking in detail at specific tools and techniques (e.g., digital twins), will help guide the experimentation.

Key dates:

- **Q1 2024** – first workplan experimentation cycle
- **Q2 2024/2026** – technical deep dives
- **Q2 2025** – publication of Network AI research priorities
- **Q2 2027** – revision of the research priorities