

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

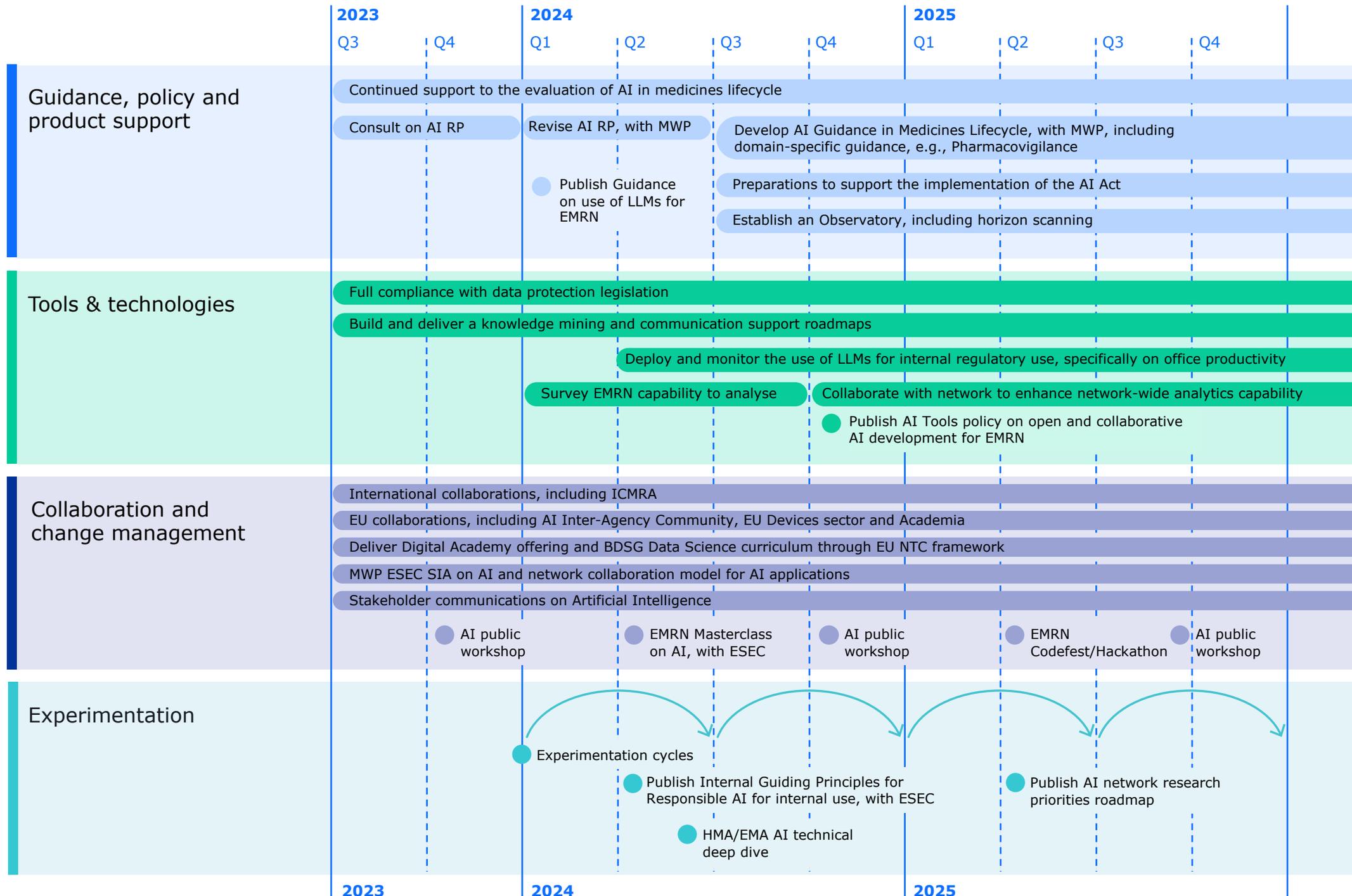
The HMA-EMA joint Big Data
Steering Group workplan on AI

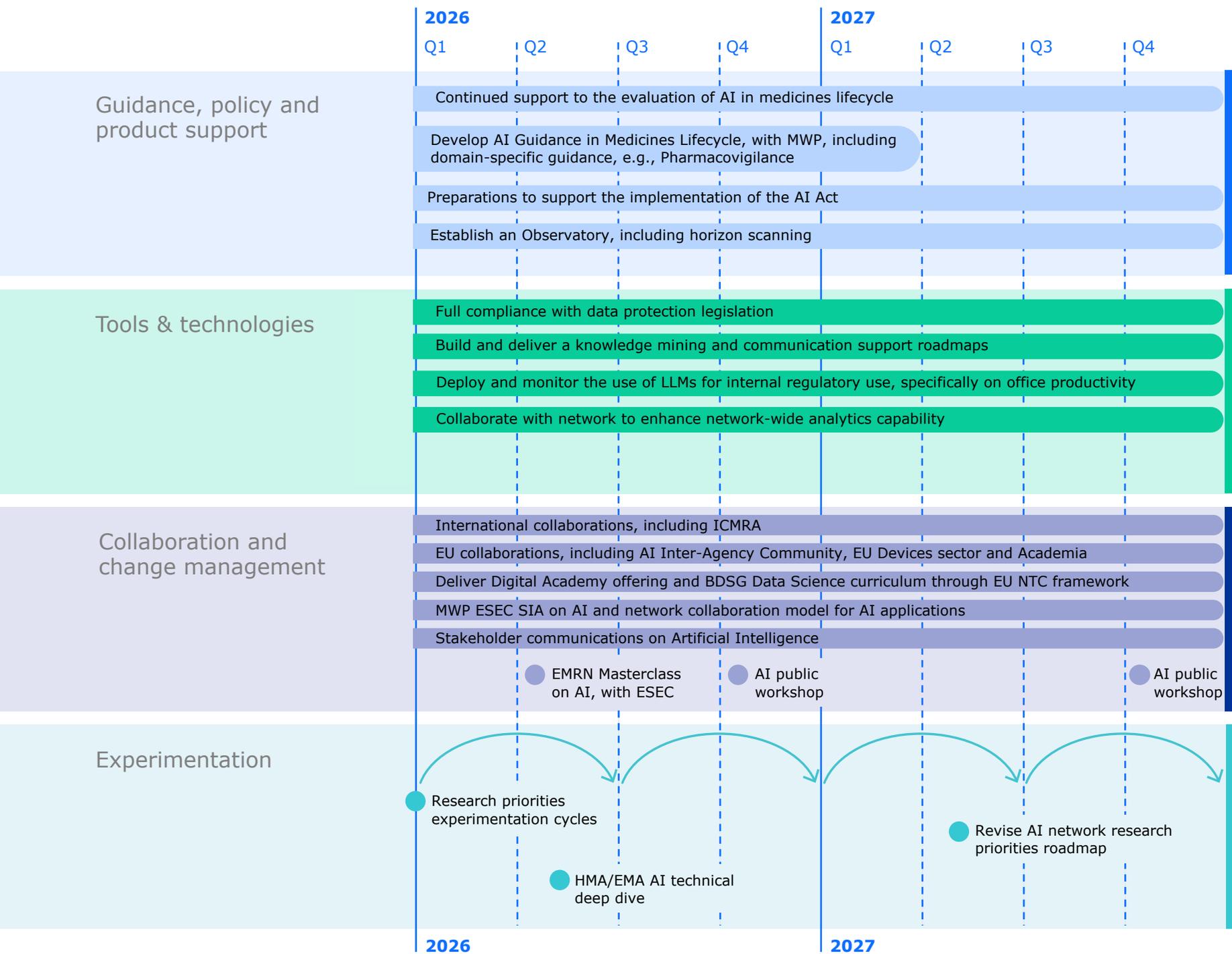


Multi-annual AI workplan 2023-2028

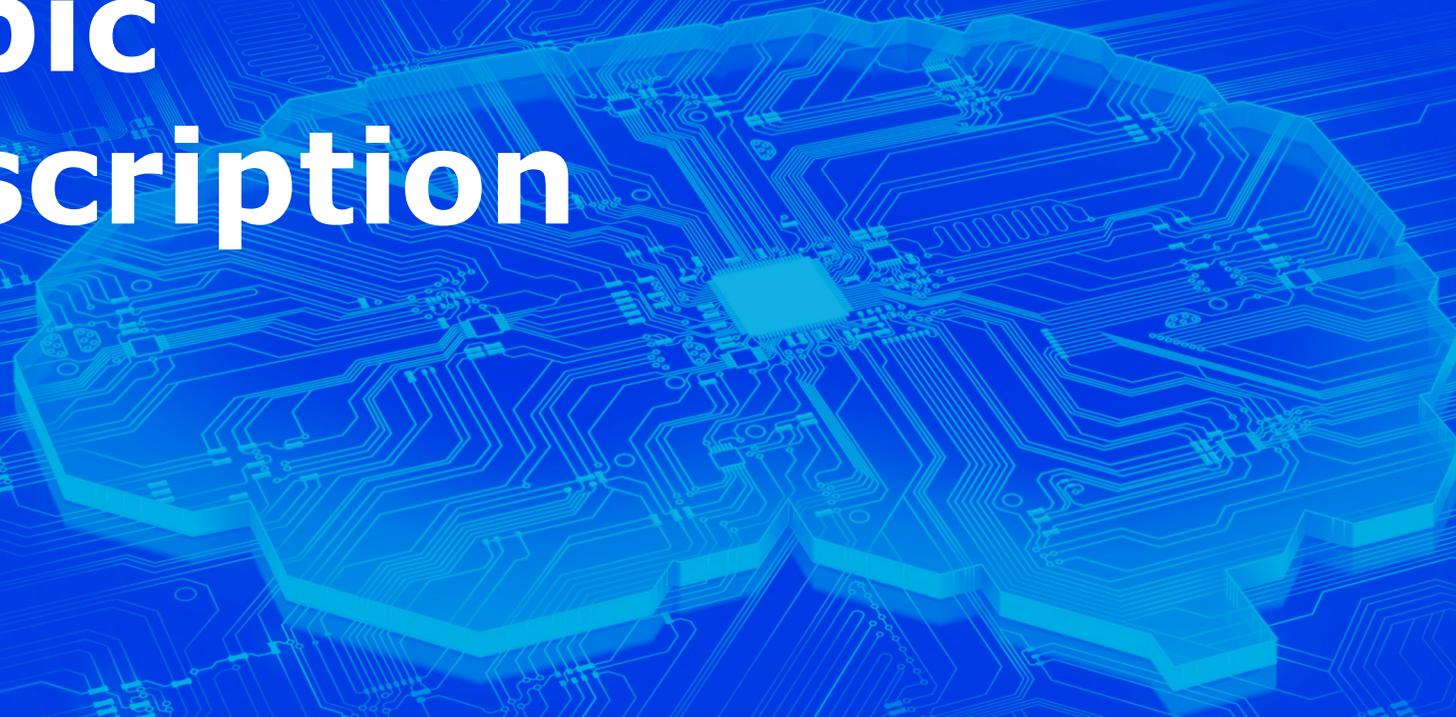
● Events

▬ Timeframe





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** – initial knowledge mining tools to be rolled out for the Network
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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

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.

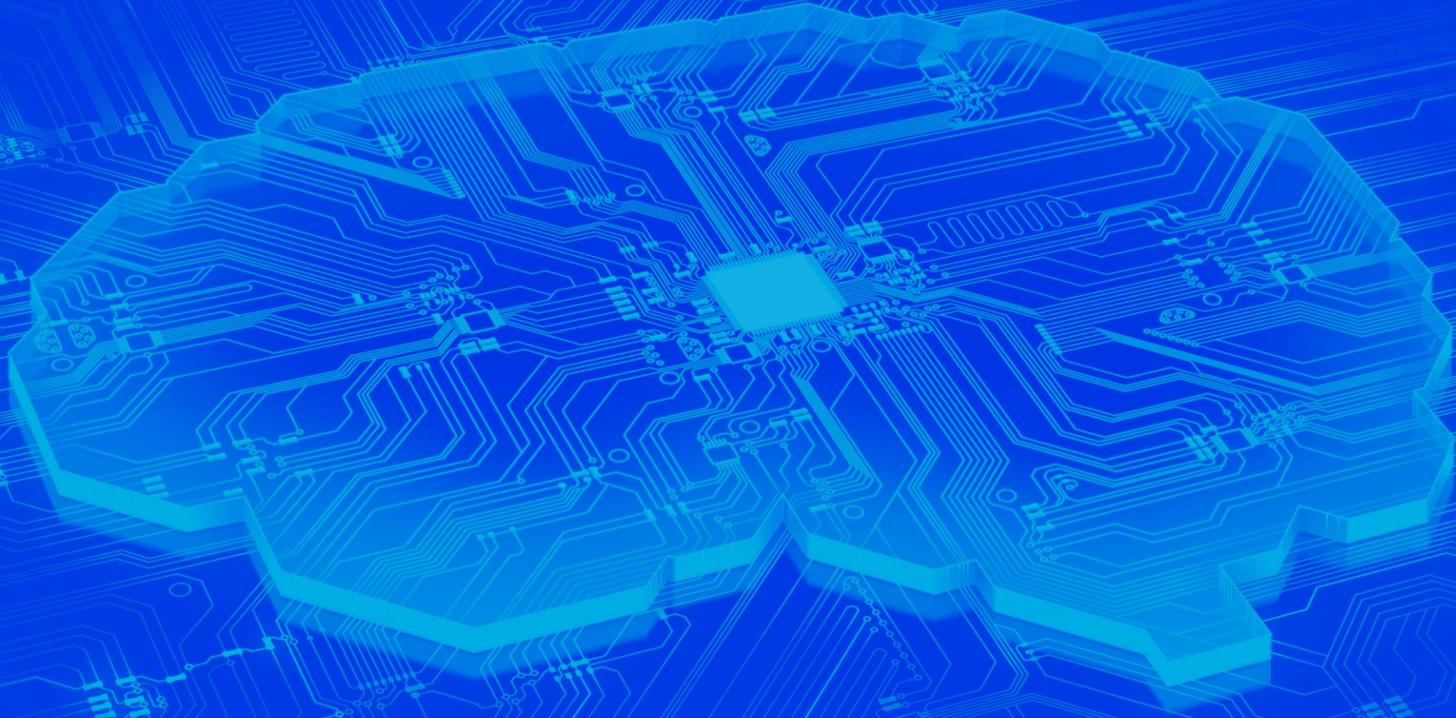
Internal guiding principles for responsible AI for internal use will be defined, supported by the European Specialised Expert Community (ESEC).

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



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