

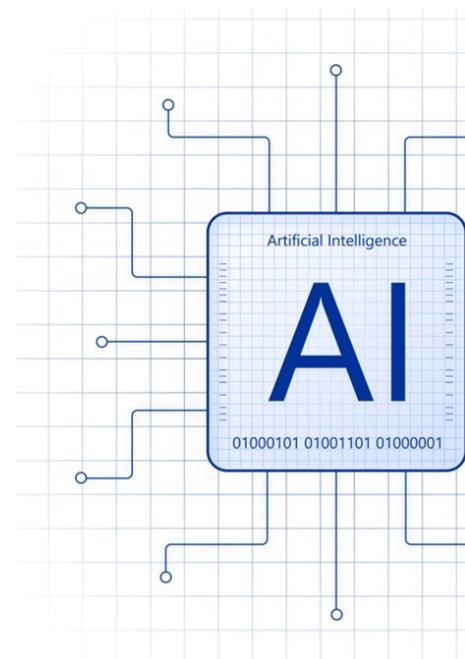


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Artificial Intelligence: Multi-annual AI workplan 2023-2028

Industry Standing Group (ISG) meeting, 28 June 2024

Presented by Peter Arlett – Head of Data Analytics and Methods Task Force (TDA)
Zaide Frias – Head of Digital Business Transformation Task Force (TDT)





Background

- Long history of work on AI in the EMRN
- In 2020 EMA establishes two taskforces:
 - Digital Business Transformation Taskforce
 - Data Analytics and Methods Taskforce
- AI public workshops in 2021 and 2023
- Adoption of AI multi-annual workplan by EMA Management Board in December 2023.





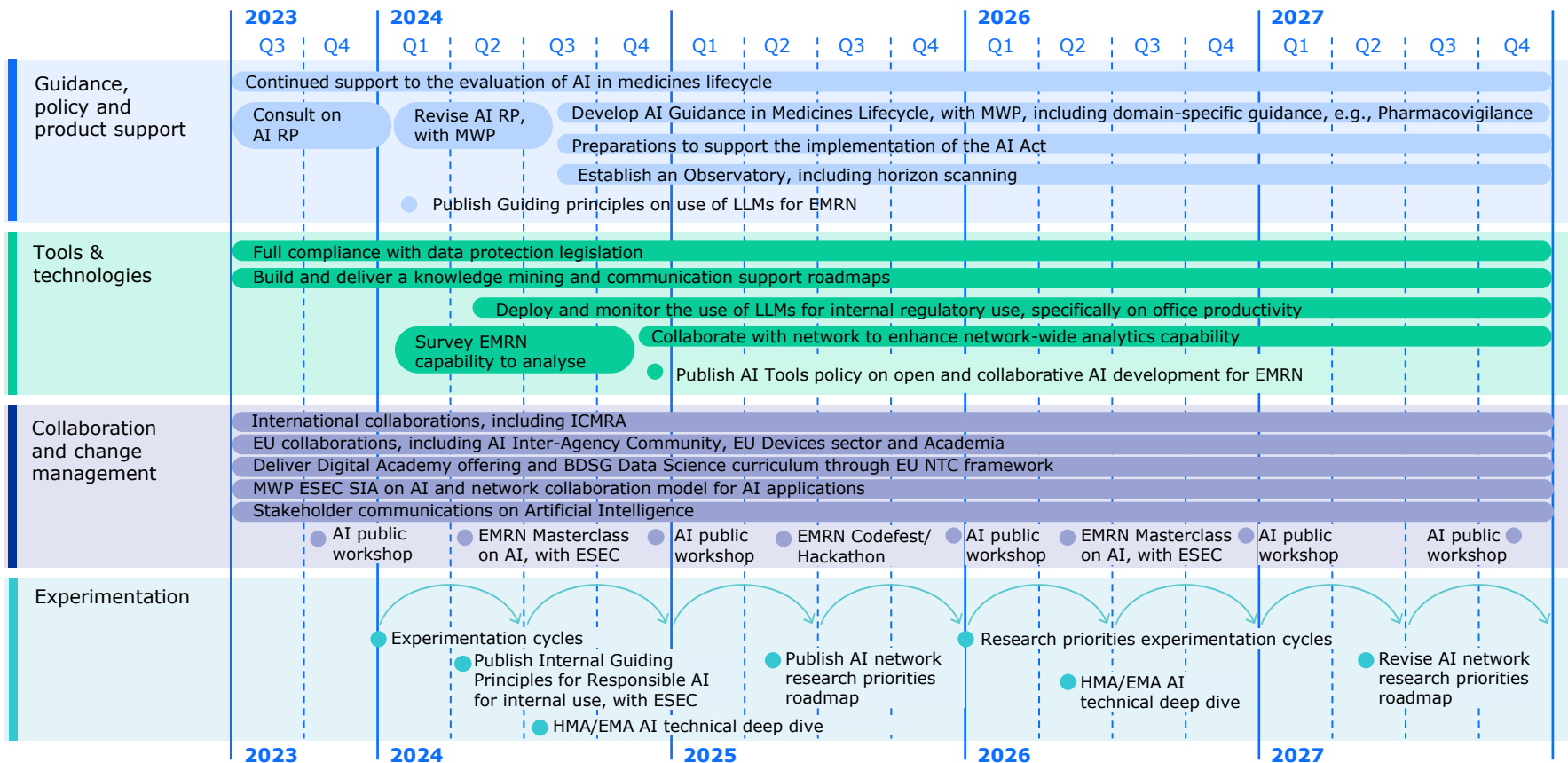
AI Workplan to 2028

- The AI Workplan to 2028 was developed in collaboration with the Network and stakeholders
- The drafting was informed by:
 - BDSG discussions in September/October 2023 where national and EMA initiatives were presented
 - Feedback from stakeholders at AI Workshop on 20/21 November 2023
- The AI workplan was endorsed by HMA and EMA MB in December 2023
- Given the rapid evolution in this field, the AI workplan implementation and maintenance will be overseen by the BDSG, with regular update to HMA and EMA MB



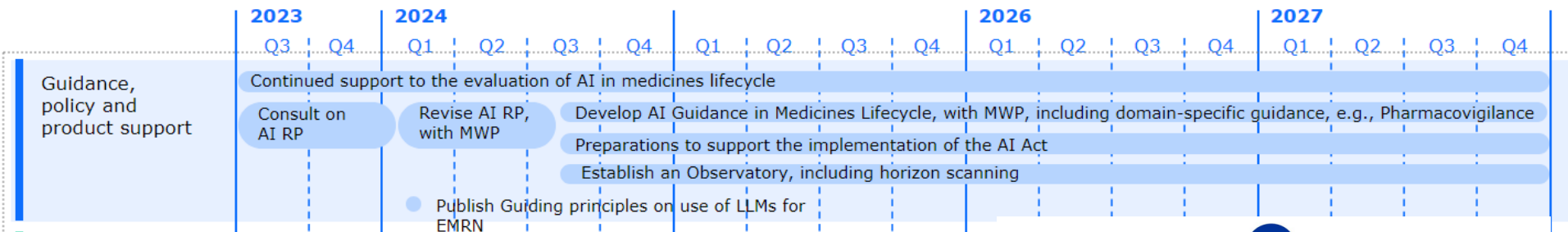
Multi-annual AI workplan 2023-2028

● Events Timeframe





Guidance, Policy and Product support

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- Key activities will include:
 - Publication of the AI Reflection Paper
 - ✓ ([public consultation](#) until 31 Dec. 2023)
 - Preparation for the AI Act
 - Phased implementation of an AI Observatory

13 July 2023
EMA/CHMP/CVMP/83833/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

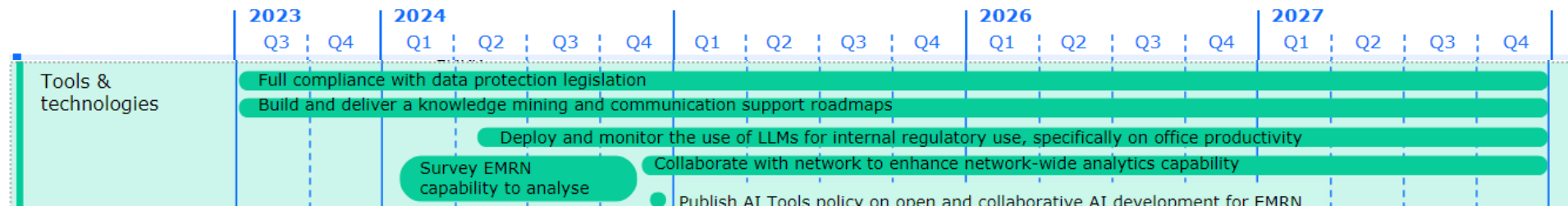
Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Draft

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 (<i>deadline for comments</i>)	31 December 2023



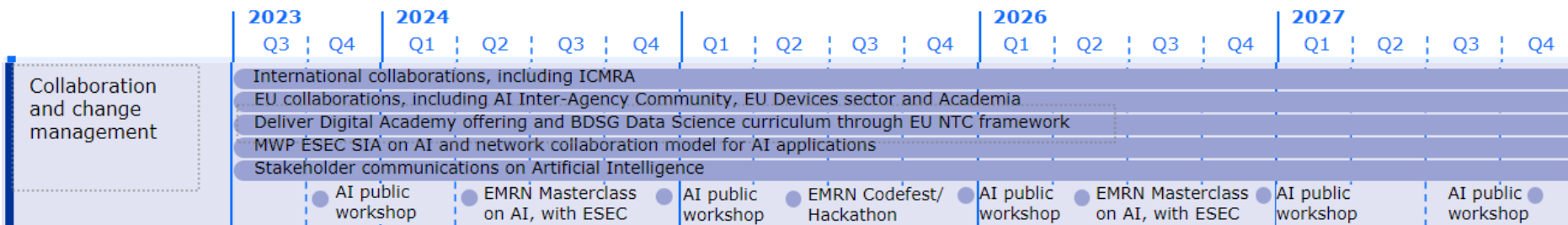
Tools and Technology



- Key activities will include:
 - Roll-out of knowledge mining tools for the Network
 - Phased roll-out and monitoring of LLMs and related chatbots as personal assistants
 - Survey of the network on capability to analyse data
 - Publication of the AI tools policy for the EMRN



Collaboration and change management



- Key activities include:
 - Publication of Digital Academy modules including AI and Digital Literacy
 - Phased roll-out of BDSG Data Science curriculum through EU NTC
 - EU Agencies Community on AI, chaired by EMA
 - International collaboration
 - Annual public workshops

Available modules



Upcoming modules





Digital Academy module and learning collection on AI

Artificial Intelligence - Digital Academy collection (12) Views: 62

In this collection you can find further learning opportunities on the topic of Artificial Intelligence, curated by Digital Academy topic leads Joaquim Berenguer and Luis Pinheiro.

★★★★★

Search within collection

Artificial Intelligence - Digital Academy intro module
Online Course
In this Digital Academy module we introduce you to Artificial Intelligence.
We invite you to learn more about:

What AI is and some important AI-related terms, such as machine learning and natural language pr...more

Digital Academy Lunchtime talk on AI (October 2023)
Online Course
This is a recording of the inaugural Digital Academy Lunchtime Talk on AI where we warmly welcomed EMA and network colleagues to join

Welcome & learning journey
LESSON 1 OF 16

Welcome to this Digital Academy module on Artificial Intelligence (AI). Let's explore the possibilities that AI unlocks for the future.

Let's begin with a video by our topic leads [Joaquim Berenguer](#) and [Luis Pinheiro](#), who will introduce this module on AI and guide you in your next steps.

By completing this module, you will learn:

- What AI entails and some important AI-related terms, such as machine learning and natural language processing.

AI Intro module

5/6 Automated document processing
LESSON 12 OF 16

EMA integrates AI technology to analyse types of documents received, assess their content, and notify specific assessors of document submissions.

In this section we invite you to explore three more examples of AI applications in projects supported by the Analytics Centre of Excellence (ACE) team at EMA.

ASSISTED VALIDATION SYSTEM	PERSONAL DATA RECOGNITION	DOCUMENT COMPARISON
Assisted Validation System for Vets is a tool that leverages AI to validate variations faster and more easily. The system automates many aspects of the applications sent to EMA by using a mix of AI technologies to: - flag documents that are missing from the application; - detect anomalies and differences between information submitted by applicants and data stored in EMA databases; and - identify changes made by applicants in their submissions across all EU languages. The benefit of this tool is automating the registration and the validation of Type IA, IB and		

AI learning collection

Upcoming:

- ✓ Continuously expanding learning resources on AI
- ✓ Q3 2024 – Digital Academy module on Data Literacy

EU Agencies (EUAN) AI Virtual Community

Chaired by EMA



Our Objectives

- ✓ Foster knowledge, learning and best practices **sharing between Community members** to increase the overall AI maturity level of EU Agencies and Members States
- ✓ **Leverage the EU Agencies network** to increase synergies and reuse between Community members
- ✓ Develop and share common initiatives, experiences and projects through **concrete AI use cases** that can be beneficial to the stakeholders

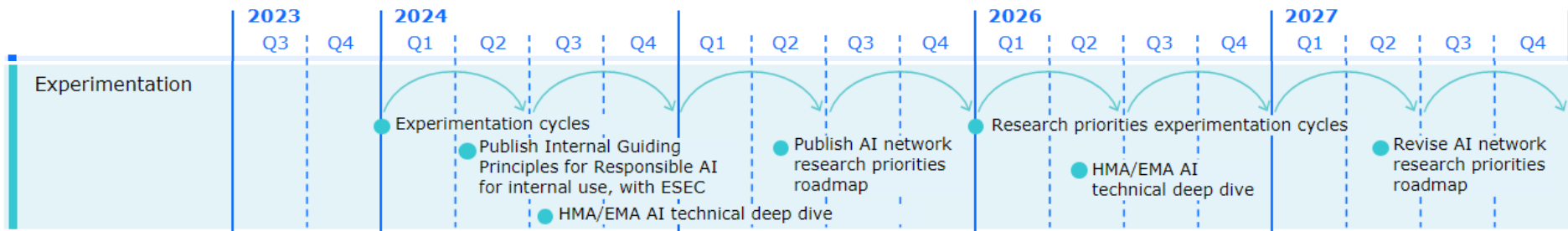
What are the benefits?

- ✓ Access to the **enriched EU AI knowledge network**, now linked with the EUAN as a Working Group on AI, offering collaboration opportunities with other EU Agencies and bodies
- ✓ Participate in **relevant virtual EUAN AI events** and **collaborative working sessions**
- ✓ Connect **with prominent AI stakeholders** in the EU
- ✓ Explore **AI use cases** with EU Agencies
- ✓ Receive the **latest AI news** and updates through EUAN channels



Non-exhaustive list

Experimentation



- Key activities will include:
 - First workplan experimentation cycle
 - Technical deep dives
 - Publication of network AI research roadmap and priorities



Examples of activities of AI experimentation and use at NCAs and EMA discussed at BDSG



PHAIR: PHarmacovigilance by AI Real-time

Jesper Kjaer

Inhouse LLM at DKMA

As a tool to drive GDPR compliant digital transformation

Paul-Ehrlich-Institut



BMG-KIMERBA - intelligent in-house automation of regulatory workflows

BMG-BLOODVIR - knowledge accumulation for AI assessment

BMG-RENUBIA - assessment and validation of AI-based tools in medicinal products



Regulatory memory machine

Customized LLM applications to search from regulatory documents

Antti Hyvärinen, Elina Asikanius



XLMeQA + NLP Platform + MedDRA Terms

Ongoing AI projects at AEMPS

Ana López de la Rica, AEMPS



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ChatGPT@EMA pilot

A pilot to explore ChatGPT use at EMA

Jakub Hasiec, Data Scientist - Analytics Centre of Excellence, TDT, EMA

TTS automated case adjudication

Can we use ML to streamline the review of ICSRs?

Luis Pinheiro, EMA and Julie Durand, EMA



AI@MPA

Putting regulatory AI in production for EU network use

Gabriel Westman
Head of Artificial Intelligence, Swedish Medical Products Agency

M-RECON

Medicines regulatory context engine

PICROSS

Product information cross search

PACKSIM

Mock-up similarity search

PhaVAI triage

API for triage of ADR reports



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