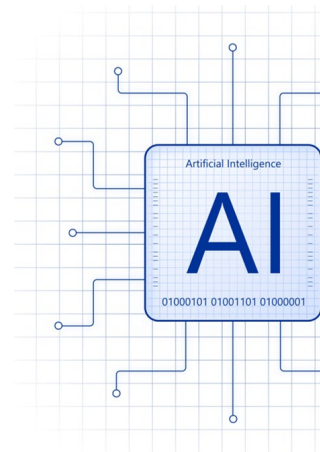


EU Big Data Stakeholder Forum 2023

04 December 2023

Session 4: Regulatory preparedness on Artificial Intelligence: AI workplan

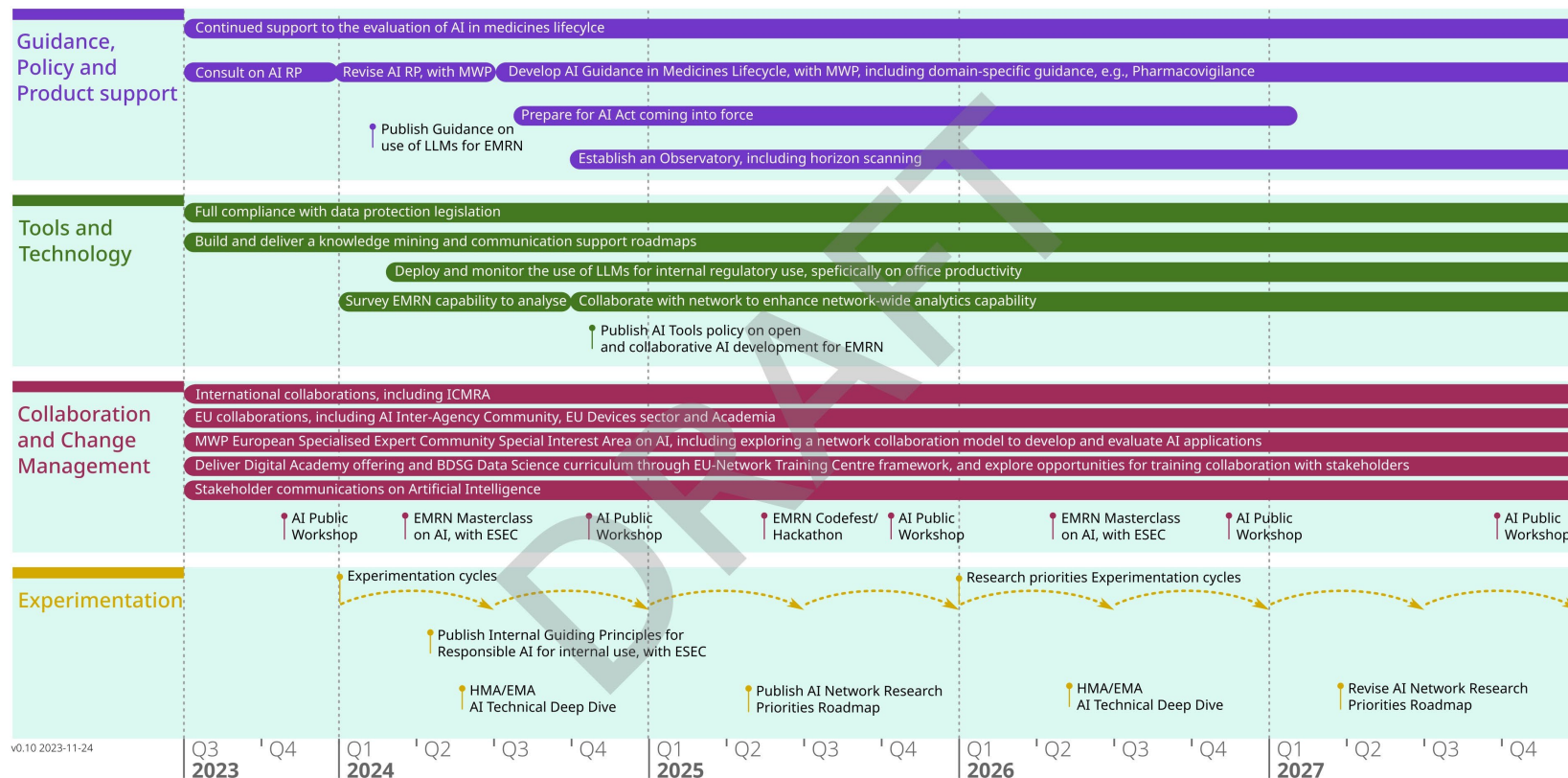
Presented by Gabriel Westman
MPA, BDSG member



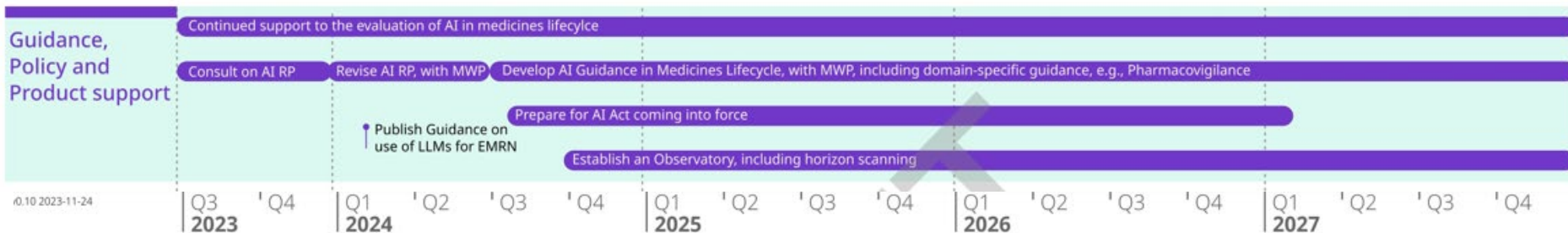
AI Workplan to 2028

- The AI Workplan to 2028 has been developed in collaboration with the network and stakeholders.
- The drafting has been informed by BDSG discussions and feedback from stakeholders at AI Workshop on 20/21 November 2023.
- The AI workplan will be published in 2024,

AI Workplan to 2028



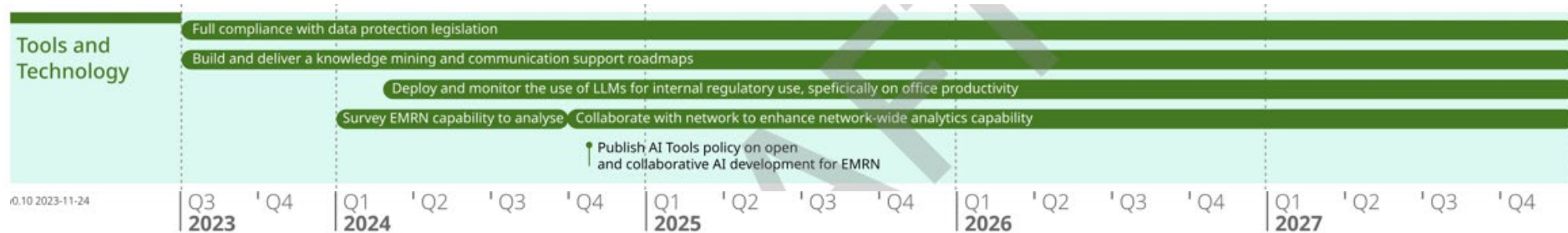
Guidance, Policy and Product support



- 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

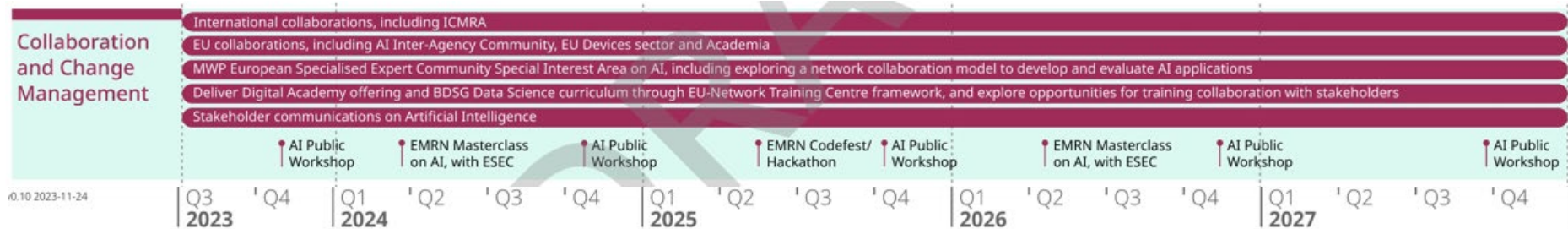
Draft agreed by Committee for Medicinal Products for Human Use (CHMP) Methodology Working Party	July 2023
Draft adopted by CVMP for release for consultation	13 July 2023
Draft adopted by CHMP for release for consultation	10 July 2023
Start of public consultation	19 July 2023
End of consultation (deadline for comments)	31 December 2023

Tools and Technology



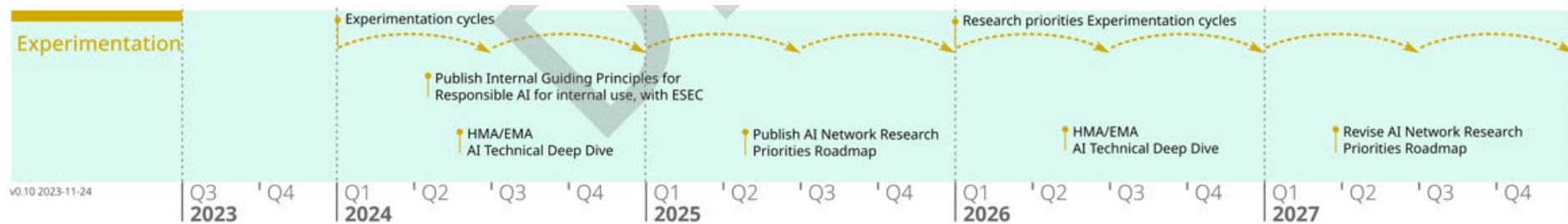
- Key activities will include:
 - Roll-out of knowledge mining tools for the Network
 - Phased roll-out and monitoring of LLMs and related chatbots as personal assistants
 - Survey of the network on capability to analyse data
 - Publication of the AI tools policy for the EMRN

Collaboration and change management



- Key activities will include:
 - Publication of additional Digital Academy content on AI and Data Analytics
 - Phased roll-out of BDSG Data Science curriculum
 - Annual public workshops

Experimentation



- Key activities will include:
 - First workplan experimentation cycle
 - Technical deep dives
 - Publication of network AI research roadmap and priorities
- See next slides on example of AI experimentation and use at NCAs and EMA

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



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



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



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



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

Launch of AI module in the Digital Academy

More information



[Big Data](#)

[Clinical Trials and ACT EU](#)



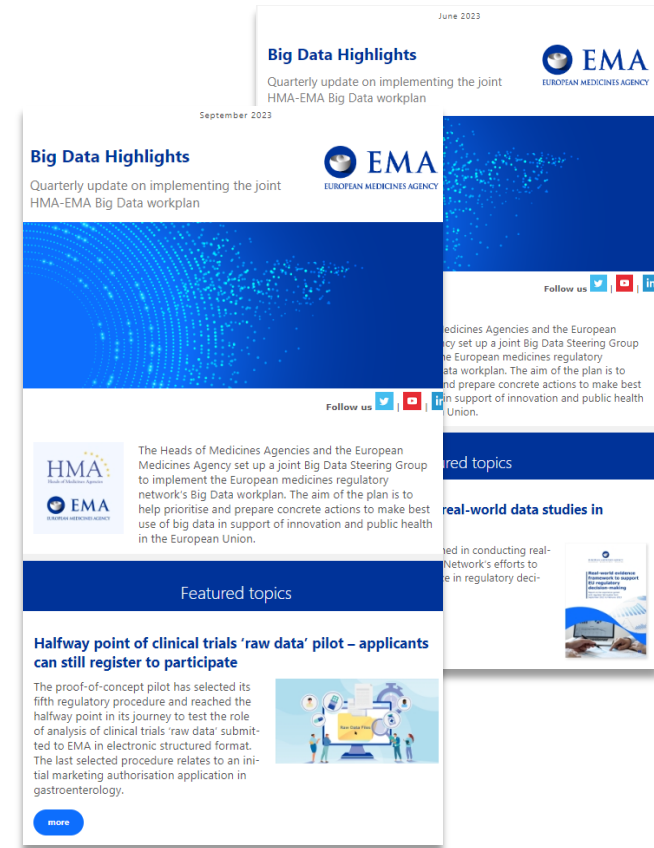
[Big Data Highlights](#)

(Subscribe at: bigdata@ema.europa.eu)

[Clinical Trials Highlights](#)



[EMA events](#)



Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is
an agency of the European Union

