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SCIENCE MEDICINES HEALTH

Digital and AI Transformation in EU Regulatory space
Building the Future Today

INFARMED Annual Symposium, 20 November 2024, Lisbon

Presented by Zaide FRIAS
Head of Digital Business Transformation, EMA

An agency of the European Union

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The presenter does not have any conflict of interests.

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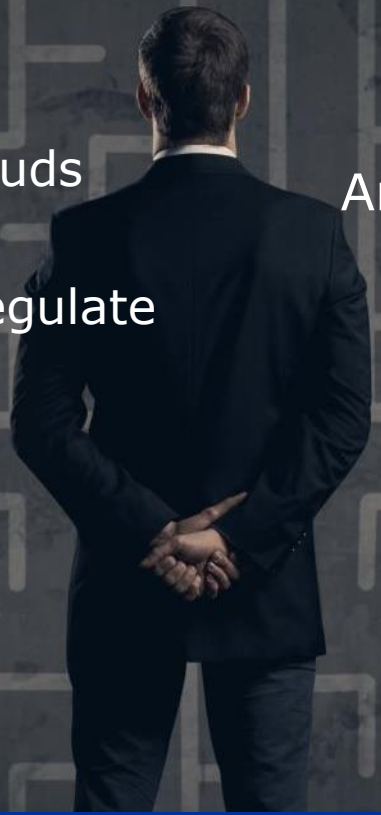
AI: The Catalyst for a New Regulatory Era:

From chatbots to health clouds

—

AI is revolutionizing how we regulate and innovate.



Are we prepared to lead this change?

EMANS Strategy to 2028

Joint EMA/HMA AI workplan 2028

New Pharma legislation

European Medicines Regulatory Network 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.

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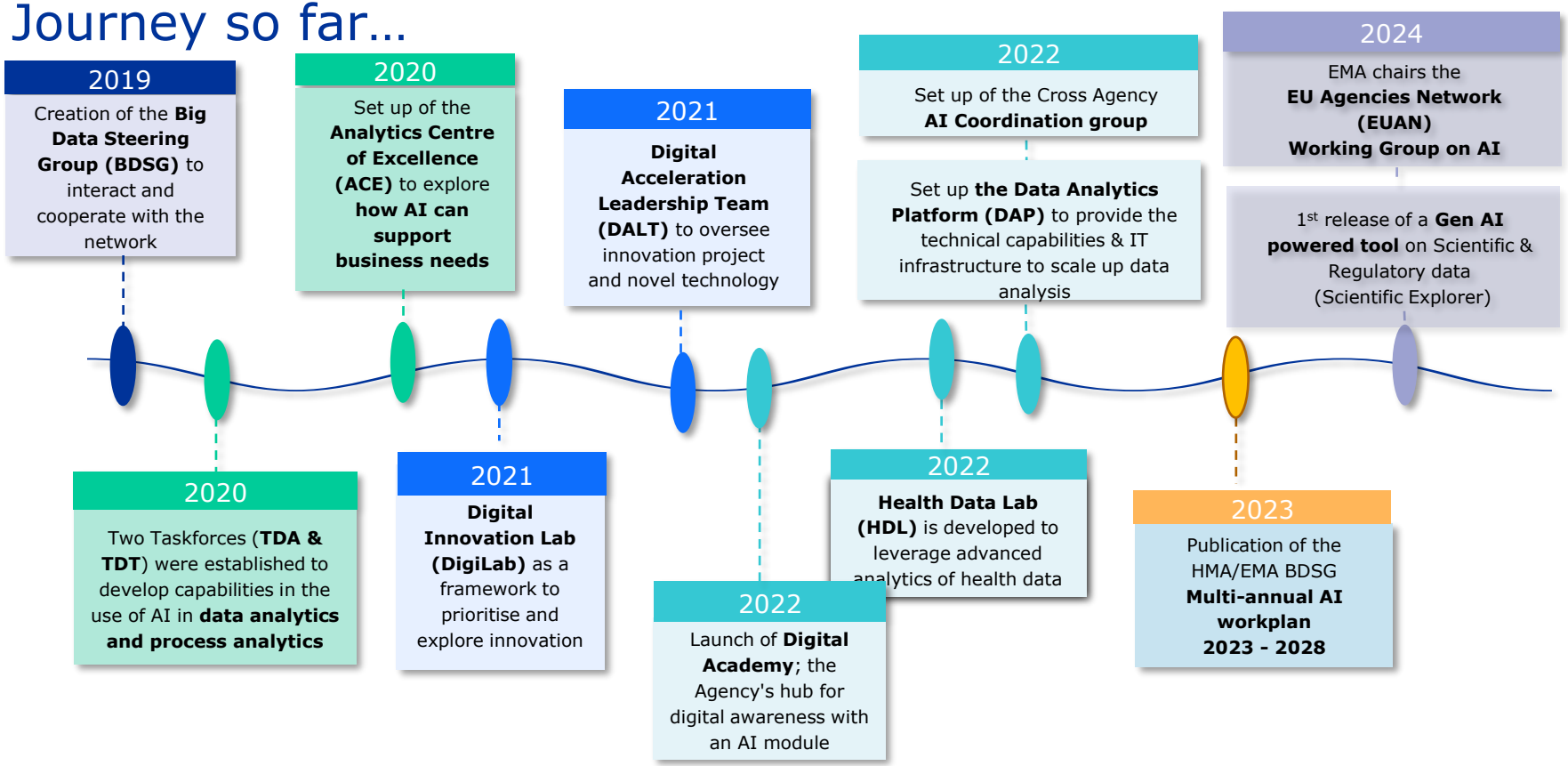
Journey so far…



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Multi-annual AI workplan

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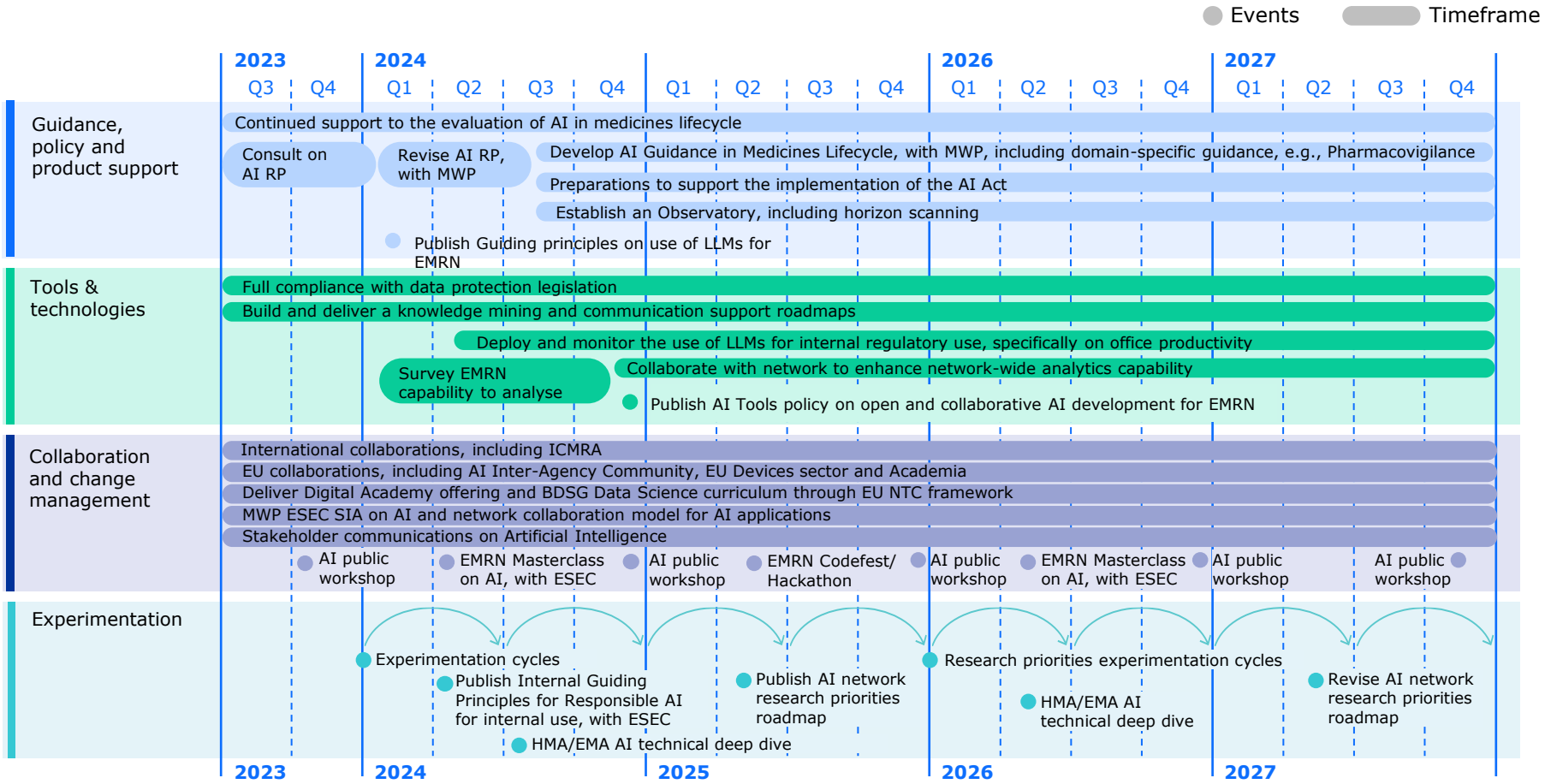

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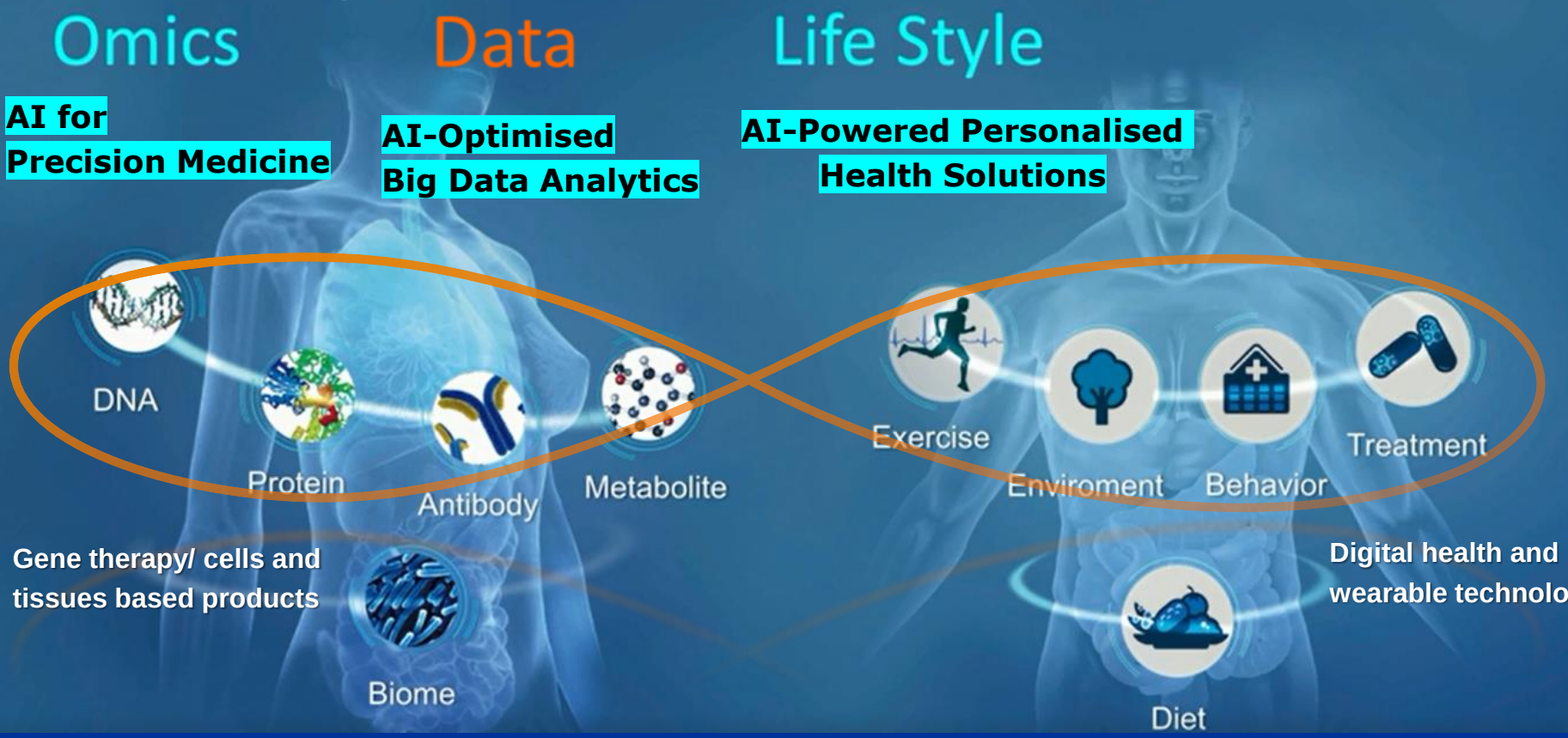
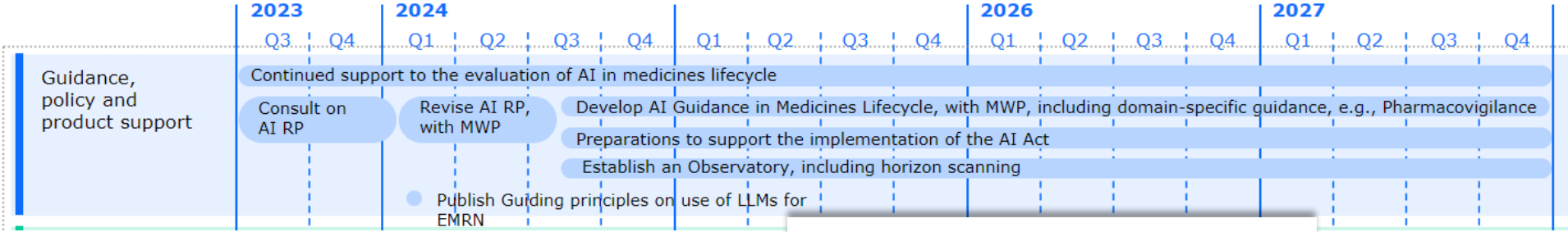
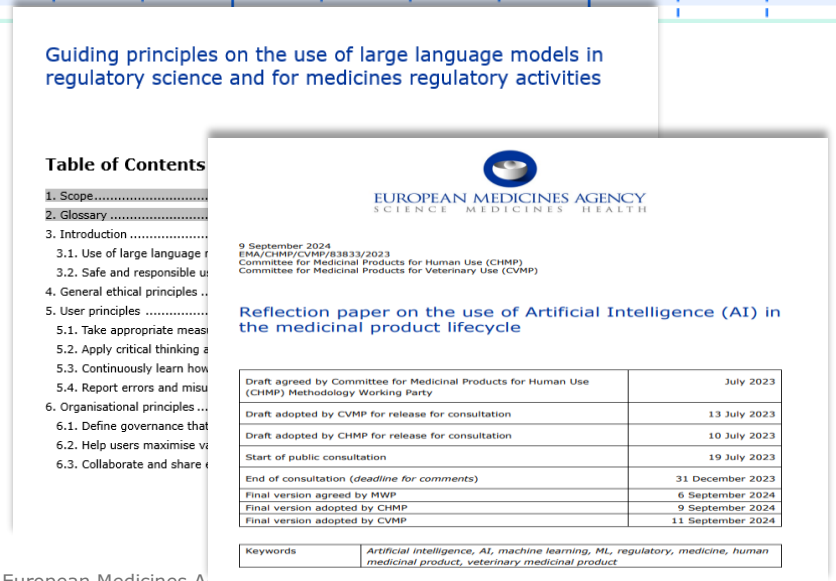
Transforming Science, Data, and Patient-Centric Care



Guidance, Policy and Product support



- Key activities include:
  - Publication of the AI Reflection Paper (Final)
  - Preparation for the AI Act
  - Phased implementation of an AI Observatory



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

Table of Contents

1. Scope
2. Glossary
3. Introduction
4. General ethical principles
5. User principles
6. Organisational principles

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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

Keywords	*Artificial intelligence, AI, machine learning, ML, regulatory, medicine, human medicinal product, veterinary medicinal product*

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Support of AI-driven innovation

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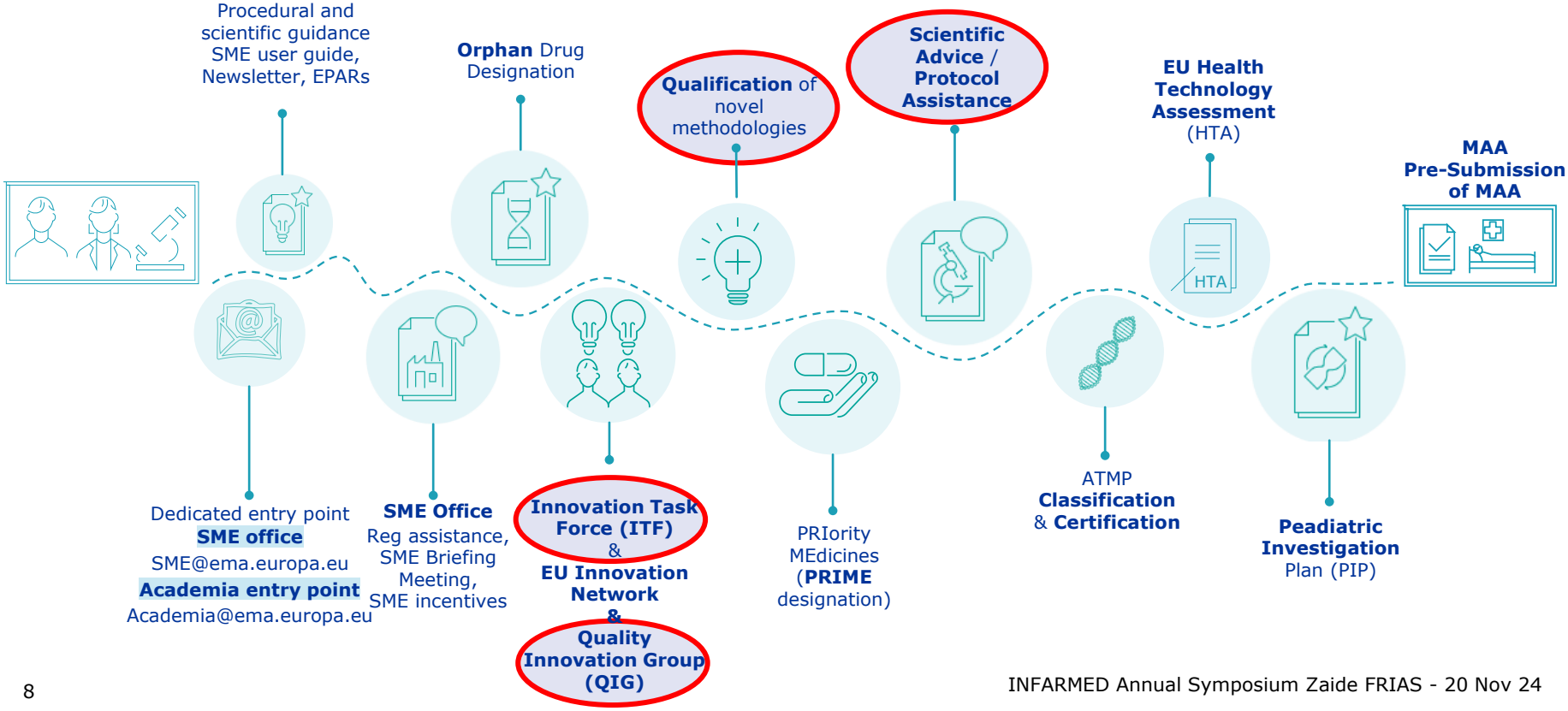
Opportunities for interaction with EMA/EU Network



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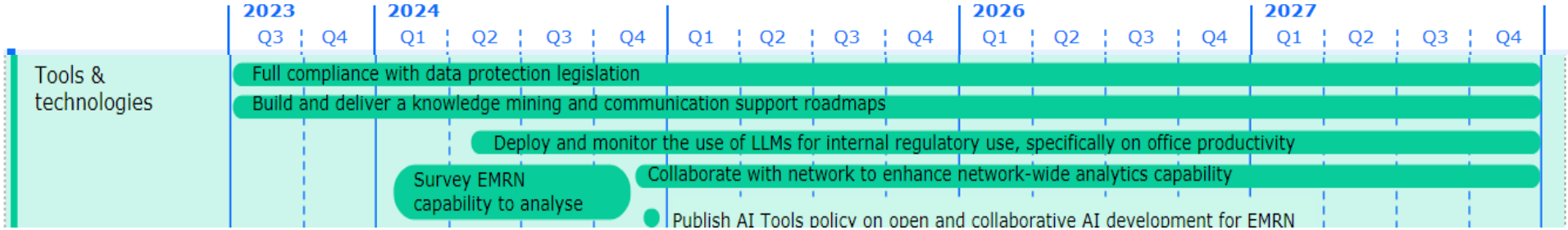
Unlocking the Power of Knowledge Mining and Analytics

Tools and Technology



- Key activities include:
  - Roll-out of ‘knowledge mining tools’ for the EU 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

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AI Experimentation at EMA

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Scientific Explorer

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Interrogate Scientific Advice documents with AI Augmented Retrieval

Tool for Regulatory Knowledge Mining

- Facilitate **easy** and **precise searching** across various types of data, including IRIS data and content from regulatory documents.
- Initially working with scientific advice letters and associated data
- Uses **AI** as aid to **enhance searches**

Built for the EMR Network

- EMA scientific officers
- National Competent Authority assessors

Brings Efficiency & Accuracy in Data Access

Supports EMA and NCAs staff:

- In quickly and easily finding and summarizing relevant regulatory precedents
- In becoming more efficient and better informed for relevant regulatory procedures

Currently Being Developed

- 1st version available in March 2024

Speech to text & Speech to Speech

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Convert speech from any EU language to any other EU language

What it does

Speech to text:

- Transcribes speech from videos and live meetings into text (EU languages)
- Generates meeting notes and summarizes content of audio files
- Highlights the most important sentences and key points.

Speech to Speech:

- Performs real-time translation of speech from any EU language to any other EU language.

Why this tool matters

- EMA wants to **reach as many EU citizens as possible** by delivering more content in the languages of the EU citizens. We want to provide **automatic and real time translations** for Press briefings, Workshops, and Public meetings *etc.*
- EMA wants to make it possible for **patients** to speak their own language in panel discussions or oral hearings.
- EMA will become much more efficient in producing summaries of meetings.

Technology and data

- This tool uses Microsoft Azure automated transcription and translation technologies which have been augmented with a dictionary of EMA terminology and acronyms using a Custom Speech model.
- These tools are currently being piloted.

ASK Documents

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Find information about medicines in and across Product Information using a chat

What it does

- You ask a question in the chat on a centrally authorised medicine (CAP)
- It retrieves information in and across the Product Informations (PI) of the medicines it has access to
- It answers your question and shows in which PI it has found the answer
- You can ask follow-up questions if you wish a more specific answer

Why this tool matters

- We want to make it **as easy as possible** to **find information** in and across the **Product Information of medicines**.
- We want to make information about medicines **more accessible**.
- We expect **medical doctors** and **patients** but also **assessors** and other stakeholders will benefit from this tool.

Technology and data

- This tool uses the Large Language Models (LLM) from Microsoft (OpenAI and ChatGPT) and is in experimentation phase.
- Currently the tool has access to the Product Information of fifty medicinal products.

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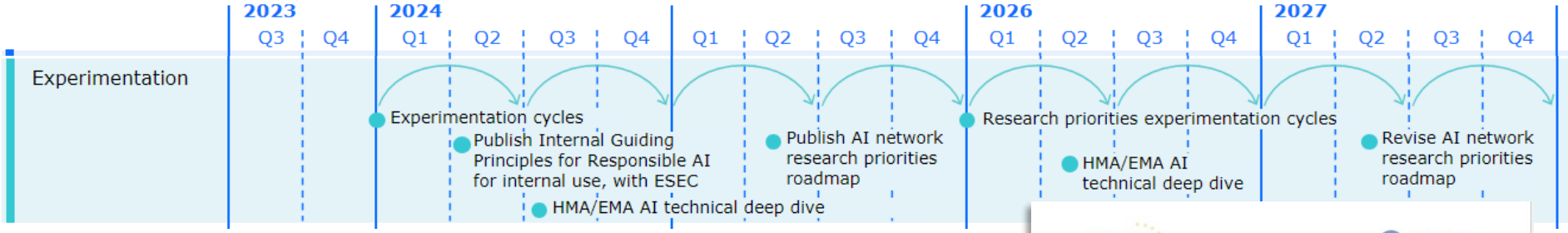
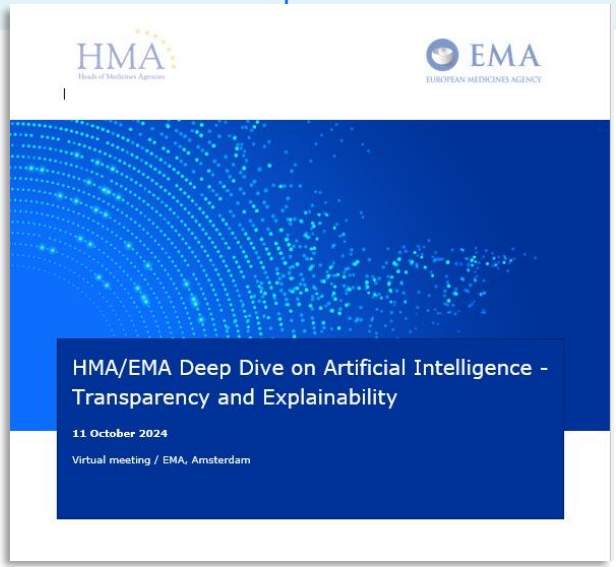
Experimentation



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



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AI Experimentation at EU Network (presented to BDSG)

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DAC DATA ANALYTICS CENTRE | LÆGEMIDDELSTYRELSEN DANISH MEDICINES AGENCY

PHAIR: PHarmacovigilance by AI Real-time

Jesper Kjaer

Inhouse LLM at DKMA

As a tool to drive GDPR compliant digital transformation

agencia española de medicamentos y productos sanitarios

XLMeQA + NLP Platform + MedDRA Terms

Ongoing AI projects at AEMPS

Ana López de la Rica, AEMPS

fimea

Regulatory memory machine

Customized LLM applications to search from regulatory documents

Antti Hyvärinen, Elina Asikanius

LÄKEMEDELSVERKET SWEDISH MEDICAL PRODUCTS AGENCY

AI@MPA

Putting regulatory AI in production for EU network use

Gabriel Westman
Head of Artificial Intelligence, Swedish Medical Products Agency

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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

M-RECON	PICROSS	PACKSIM	PhaVAI triage
Medicines regulatory context engine	Product information cross search	Mock-up similarity search	API for triage of ADR reports

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

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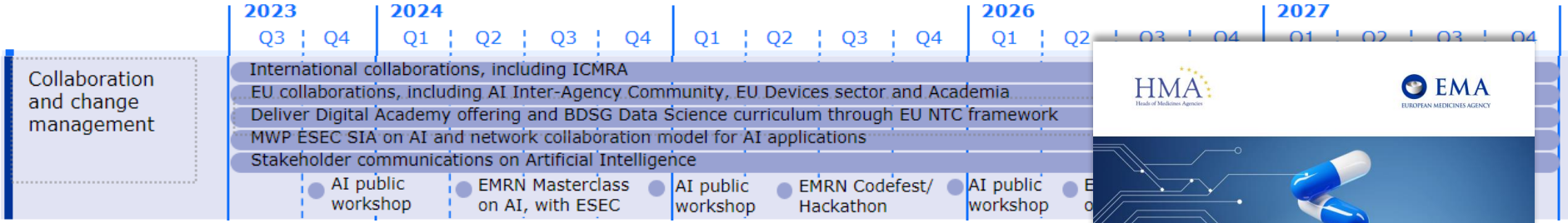
AI literacy is the cornerstone of progress

EU Network Training Center

BDSG Data Science Curriculum
Digital academy
AI Masterclass

Building Digital Foundations for an AI-Driven World

Collaboration and change management



- Key activities include:
  - Publication of Digital Academy modules
  - Phased roll-out of BDSG Data Science curriculum through EU NTC
  - EU Agencies Community on AI (EUAN) chaired by EMA
  - International collaboration
  - AI public workshops

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EU NTC training catalogue

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Digital, AI and Big Data training offers

EU Network Training Centre Newsletter

EMA EUROPEAN MEDICINES AGENCY

Training by the Network for the Network

BIG DATA, AI

First modules of the Data Science curriculum now available

The Data Science curriculum is a series of trainings on data science that have been specifically designed for the European Medicines Regulatory Network (EMRN) to enhance knowledge and develop skills in this field.

more

Data science curriculum

Follow us

Accessing EU NTC training

BIG DATA

DARWIN EU Autumn School: Population-level disease epidemiology and patient-level characterisation

This is the second webinar in a series to increase the understanding of different types of analyses conducted through the DARWIN EU® Network.

DARWIN EU

date 04/11/2024 - 05/11/2024

DIGITAL, DATA, DATA PROTECTION

Digital Academy intro modules and collections on Data Literacy and Data Protection

Increase your data literacy and data protection skills with the new Digital Academy interactive e-learning modules and accompanying learning resource collections

more

BIG DATA, RWD, RWE

How to ensure data quality in the generation of real-world evidence (RWE)

The course has been developed by the EMA Data Analytics and Methods Task Force, Real-World Evidence Workstream in liaison with Healthcare Data colleagues at EMA.

REAL-WORLD EVIDENCE, METHODOLOGY

Joint HMA/EMA Big Data Steering Group Workshop on RWE methods: Harnessing Real-World Data for Regulatory Use

The training consists of a recording of a one-day hybrid Big Data Steering Group (BDSG) workshop held on 14 June 2024. The programme was developed by the EMA Data Analytics and Methods Task Force, Real-World Evidence Workstream.

more

date 03/0

ARTIFICIAL INTELLIGENCE, PHARMACOVIGILANCE

Challenges and future role of artificial intelligenc chine learning in pharmacovigilance

This is a recording of a webinar held on 26 July 2024 on the challenges and future role of artificial intelligence and machine learning in pharmacovigilance. The webinar was delivered by Dr Dirk Mentzer, Head of Safety of Biomedicines and Diagnostics Division, Paul Ehrlich Institut.

more

DIGITAL

Digital Academy intro module and collection on Design Thinking

In this new Digital Academy 30-minute interactive e-learning module and accompanying learning resources collection, you will learn about Design Thinking.

more

BIG DATA, RWD, RWE

RWD in support of regulatory work in paediatrics – example of the RWD extrapolation framework with a pilot study in dermatomyositis and polymyositis - Real World Academy session 4

This 4th session of the Real World Academy focuses on the use of RWD to inform and support regulatory work in paediatrics.

date 04/10/2024

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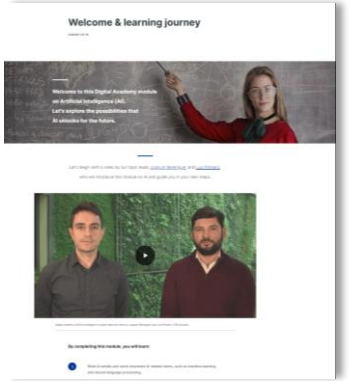
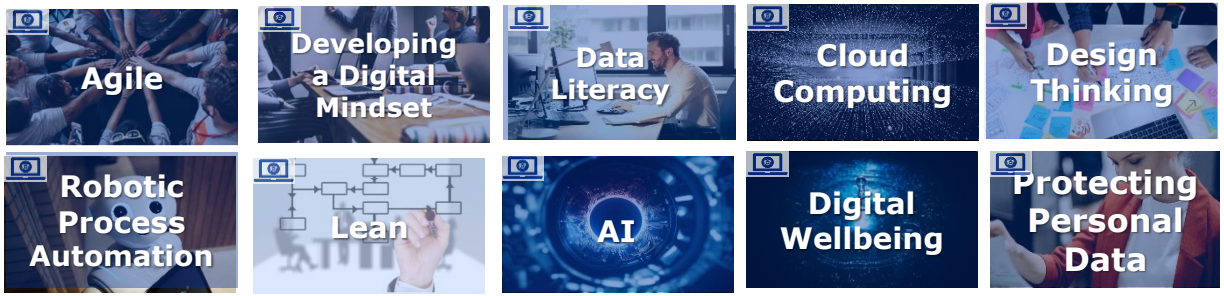
Our training catalogue: expanding our scope to digital

The Digital Academy: creating digital awareness and a starting point to develop digital skills

- Short, interactive micro-learning modules
- Focus on examples and illustrations
- Access to resources for continued learning
- Developed in-house in collaboration with EMA and network colleagues



Some of our Digital Academy modules



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Need to widen the collaboration horizon to harness the power of AI

With:

- **EU Regulatory authorities/Agencies**
- **Academics**
- **Patient advocacy and Healthcare professionals**
- **International collaboration**
- **Industry**
- **Technology disruptors**

Thank you for your attention!!!

Zaide FRIAS
Head of Digital Business Transformation
Task Force