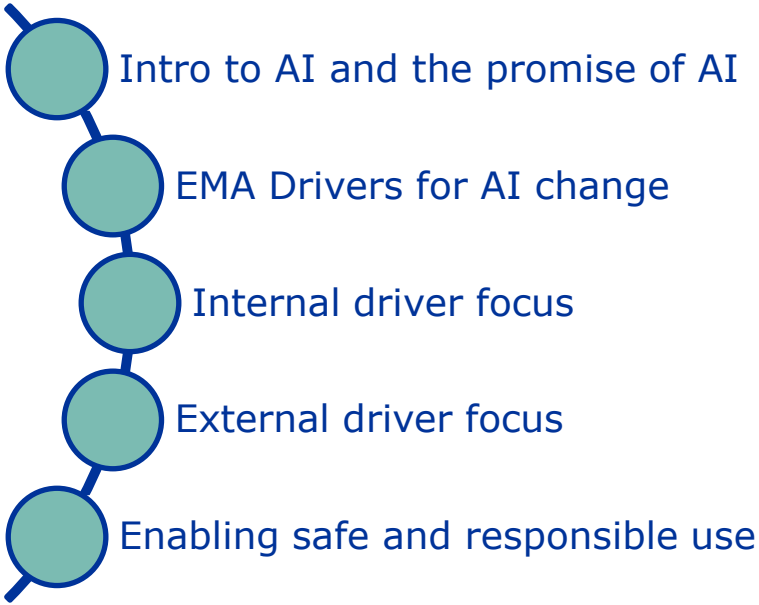
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Extracting value from Artificial Intelligence in Medicines Regulation

Regulatory Science Network Netherlands – June 2024

Luis Pinheiro, EMA, Data Analytics and Methods Taskforce

Content



Intro to AI & the promise of AI

Brief introduction to AI

AI is a catch-all term for a collection of novel digital technologies and methods

Allow machines to extract rules from data *(i.e., learn)*

Predict, classify or cluster similar patterns using those rules or execute autonomous actions

AI is data-driven

1. **Needs data** (data protection /security)
2. **Typically* needs *supervision*** (establish ground truth)
3. **Predicts/ classifies the past** (performance drops)
4. **Bias in data become rules** (ethical issues)
5. **Needs Human intelligence** (design issues)

Artificial intelligence | Types of AI

Analytic AI (Aim: group similar things or be accurate)		**Generative AI** (Aim: mimic)
Analyse, recognise patterns, predict, probabilistic classification, etc.	Capabilities	Generate content, structure text, support cognitive work. *Derives from Analytic AI.*
Automation, analysis, routine decision making, domain-specific interaction	General use	Support cognitive work, content generation, querying and structuring data
Usually structured data	Input	Usually unstructured data

The Promise of AI | AI promise across the medicine lifecycle

Greater efficiency /productivity

- Automate processes
- Address scalability issues
- Leverage personal assistants (chatbots)

Do more things, faster

Reduce error

- Facilitate access to information
- Reduce human cognitive load

Provide information at the fingertip

Expose data

- Transform text data into structured data
- Reduce dimensionality of data
- Imputation of missing data

Structure and summarise information

Expand insights

- Probabilistic phenotyping
- Synthetic control arms
- Clinical prediction modelling
- Confounding adjustment
- Digital endpoints
- Heterogeneity of treatment effects

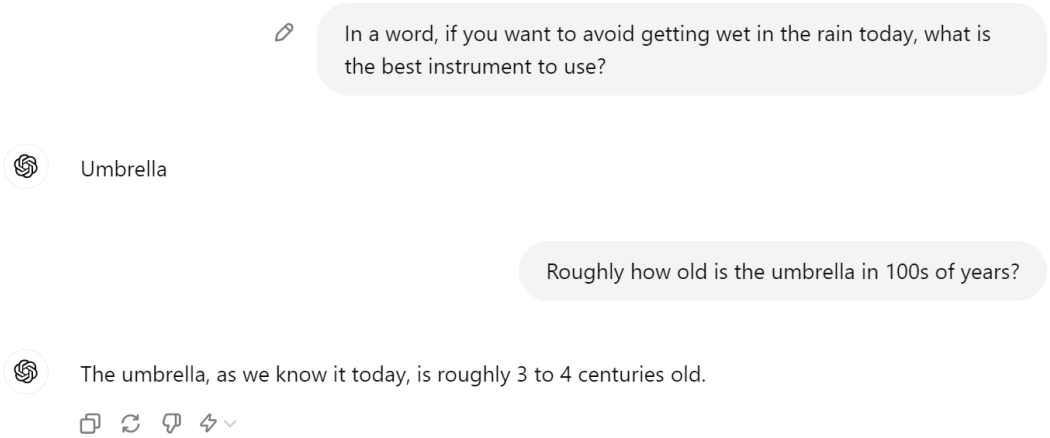
Predict probability of events

Safe and responsible use | AI can be wrong

describe the broken twig syndrome

The "broken twig syndrome" is a metaphor often used in psychology and counseling to describe a phenomenon where individuals become overly focused on small problems or setbacks, to the point where they exaggerate their significance and let them overshadow everything else. Just like how a twig breaking in a forest might capture someone's attention disproportionately, this syndrome suggests that people can become fixated on minor issues, ignoring the bigger picture and positive aspects of their lives. It's often associated with pessimism, anxiety, and a tendency to catastrophize. Therapeutic interventions for this syndrome typically involve helping individuals gain perspective, develop resilience, and cultivate a more balanced outlook.

Safe and responsible use | AI not always needed



Drivers for change

AI in Healthcare | Regulatory Drivers

Regulatory submissions

Process Analytics

Healthcare Analytics

AI in Healthcare | Regulatory Drivers

Regulatory submissions

Regulate applications of AI in medicines to help create value for public health

Process Analytics

Healthcare Analytics

AI in Healthcare | Regulatory Drivers

Regulatory submissions

Process Analytics

Improve **efficiency** by automating and digitalizing processes

Healthcare Analytics

AI in Healthcare | Regulatory Drivers

Regulatory submissions

Process Analytics

Healthcare Analytics

Structure information and increase insights into data to inform decision-making

Internal Drivers

Process analytics and healthcare data analytics

AI at EMA | Set up

Digital Innovation Lab (DigiLab)

Established 2021 to accelerate digital innovation and experimentation

Analytics Centre of Excellence

Explore analytics, AI, ML and robotics to **build pragmatic solutions and experiment with new technology**

-- Process analytics --

Health Data Lab (pilot)

Develop innovative analytics to **extract insights from healthcare data**, to provide answers/recommendations and maximise intelligence

-- Healthcare data analytics --

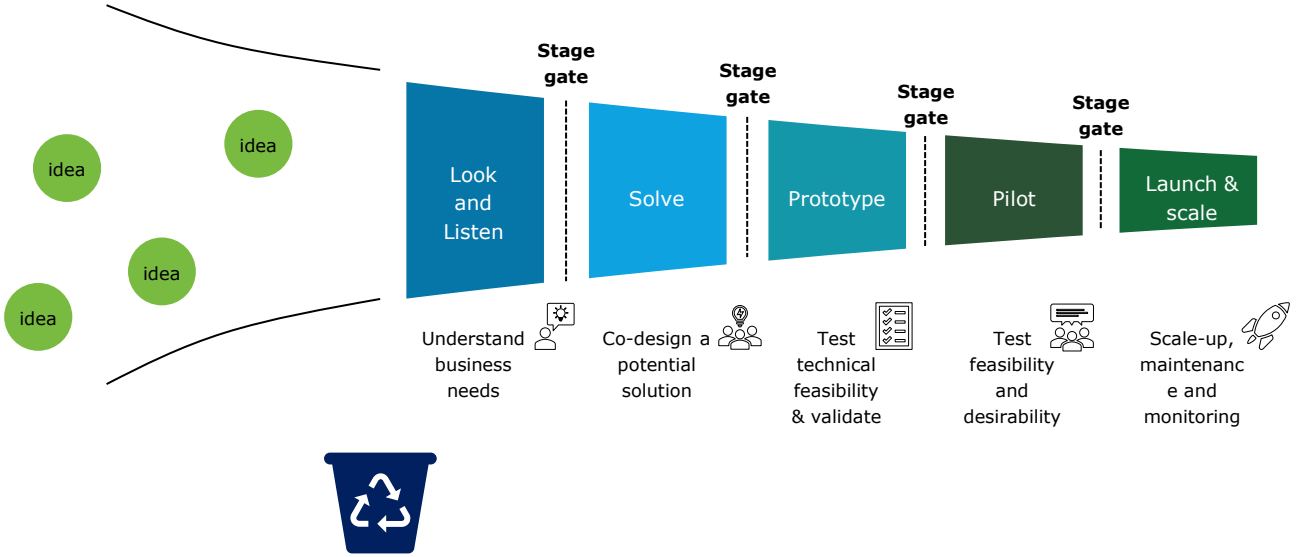
Infrastructure

Information Processing and Analytics

Improve the organisation's performance through streamlining information processing across the regulatory lifecycle.

-- Data analytics tools and platforms --

DigiLab | Digital innovation framework



AI experimentation | Examples

Literature screening

Use of LLMs to identify abstracts with information on the occurrence of adverse reactions

Extraction of ADRs from SmPCs

(semi) Automated extraction of ADRs from product information

Automated adjudication of ADRs

Automated adjudication of ADRs

Improve signal detection with previous reviews

Using signal reviews to improve signal detection

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External Drivers

Regulate AI

Guidance | AI Reflection Paper

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1 13 July 2023
2 EMA/CHMP/CVMP/83833/2023
3 Committee for Medicinal Products for Human Use (CHMP)
4 Committee for Medicinal Products for Veterinary Use (CVMP)

5 Reflection paper on the use of Artificial Intelligence (AI) in
6 the medicinal product lifecycle
7 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 (*deadline for comments*)	31 December 2023

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Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

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

Reflection paper on the use of AI in the medicinal product lifecycle

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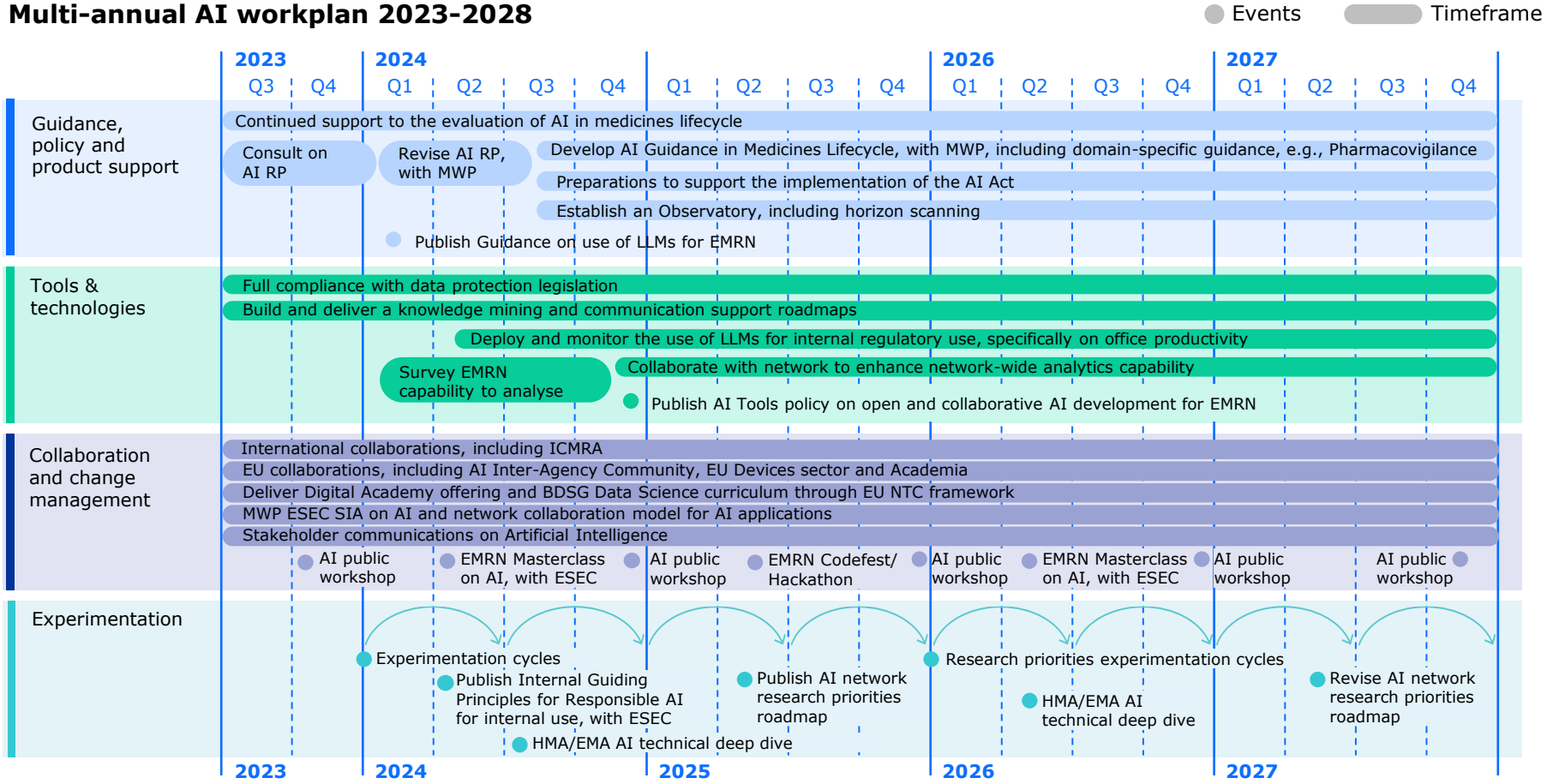
Bringing it all together

Enabling responsible and safe use of AI for the benefit of public and animal health

Multi-annual AI workplan 2023-2028



Any questions?

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