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Shaping the future of regulatory data in the AI era – An EMA perspective

CDISC China Interchange 2026
August 14, 2026

Presented by Eftychia Eirini Psarelli

Data Analytics and Methods Task force, European Medicines Agency

Disclaimer

The presenter does not have any conflict of interests.

Meet the speaker

Eftychia Eirini Psarelli

Title: Scientific specialist, Clinical Study Data Lead

Clinical Trials Transformation, Data Analytics and Methods Task Force

Organisation: European Medicines Agency

Eftychia is a scientific specialist at EMA in the Clinical Trials Transformation Workstream of the Data Analytics and Methods Task Force, where she has been managing EMA's Clinical Study Data initiative, focusing on utilising individual patient-level clinical study data to generate evidence for better and more efficient regulatory decision making.
Prior to joining the EMA in July 2020, she spent 8 years as a Senior Statistician at the Liverpool Clinical Trials Centre within the University of Liverpool, UK, where she has gained strong analytical skills in the area of statistical programming and data curation.

Eftychia fosters EMA activities where data standards can have an added value, particularly for clinical trial data. She is also an observer in Europe's CDISC Coordinating Committee (E3C).

Technology delivers benefits

AI in Healthcare | regulatory drivers

Regulatory submissions

Regulate applications of AI in medicines development

Process Analytics

Improve **efficiency** by automating and digitalising processes

Healthcare Analytics

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

AI in clinical trials | regulatory experience

HMA
Heads of Medicines Agencies

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12 May 2026
EMA/67888/2026
European Medicines Agency

2025 AI Observatory report

Innovation Task Force

Portfolio & Technology meeting

Scientific Advice & qualification opinion

Mark
Auth
Appl

AI in clinical trials | regulatory experience

Common themes:

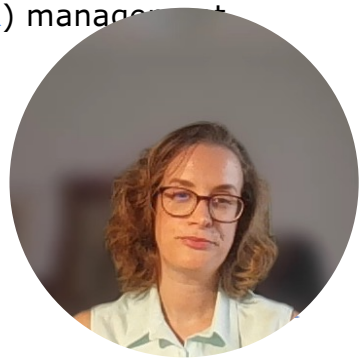
Across all medicines lifecycle stages
- Generative AI is used or explored to assist draft regulatory submissions and technical documentation or generate answers to queries

Pre-clinical development
- Drug discovery and evidence generation

Clinical development and Clinical Trials
- Clinical outcome prediction
- Clinical trial and patient selection
- Medical imaging
- Digital endpoints
- PROs
- Safety biomarker identification
- In silico trial

Product manufacturing
- Predictive Stability Modelling and shelf-life testing
- Pharmaceutical process models, including digital twins
- Good Manufacturing Practice (GMP)

Post-marketing authorisation
- Generation of RWE
- Individual Case Safety Report (ICSR) manage



AI in clinical trials | regulatory position

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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

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FDA

Guiding principles of good AI practice in drug development

January 2026

AI in Healthcare | Regulatory Drivers

Regulatory submissions

Regulate applications of AI in medicines development

Process Analytics

Improve **efficiency** by automating and digitalizing processes

Healthcare Analytics

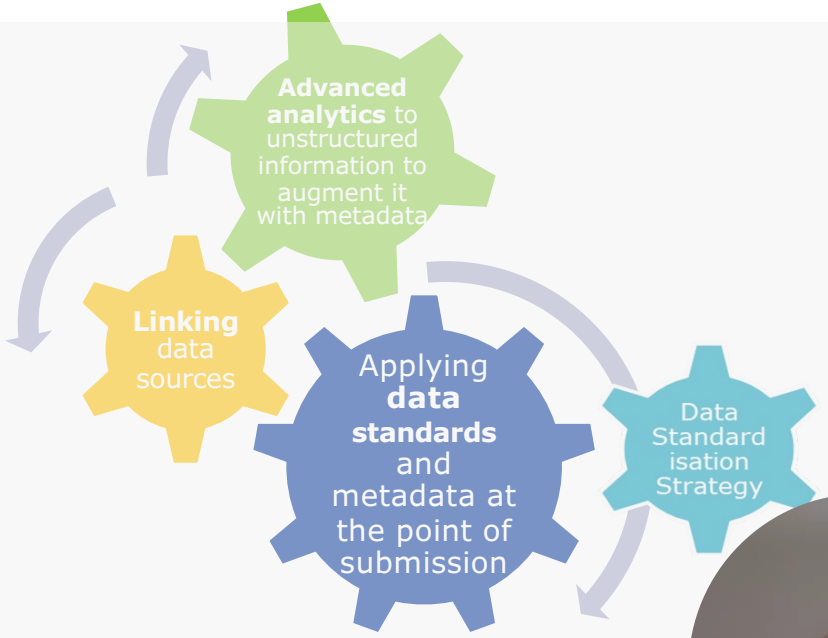
Structure information and increase insights into data to inform decision-making

Where we came from

- An ambitious vision in 2021
  - But struggling with the insufficient power of available natural language processing tools

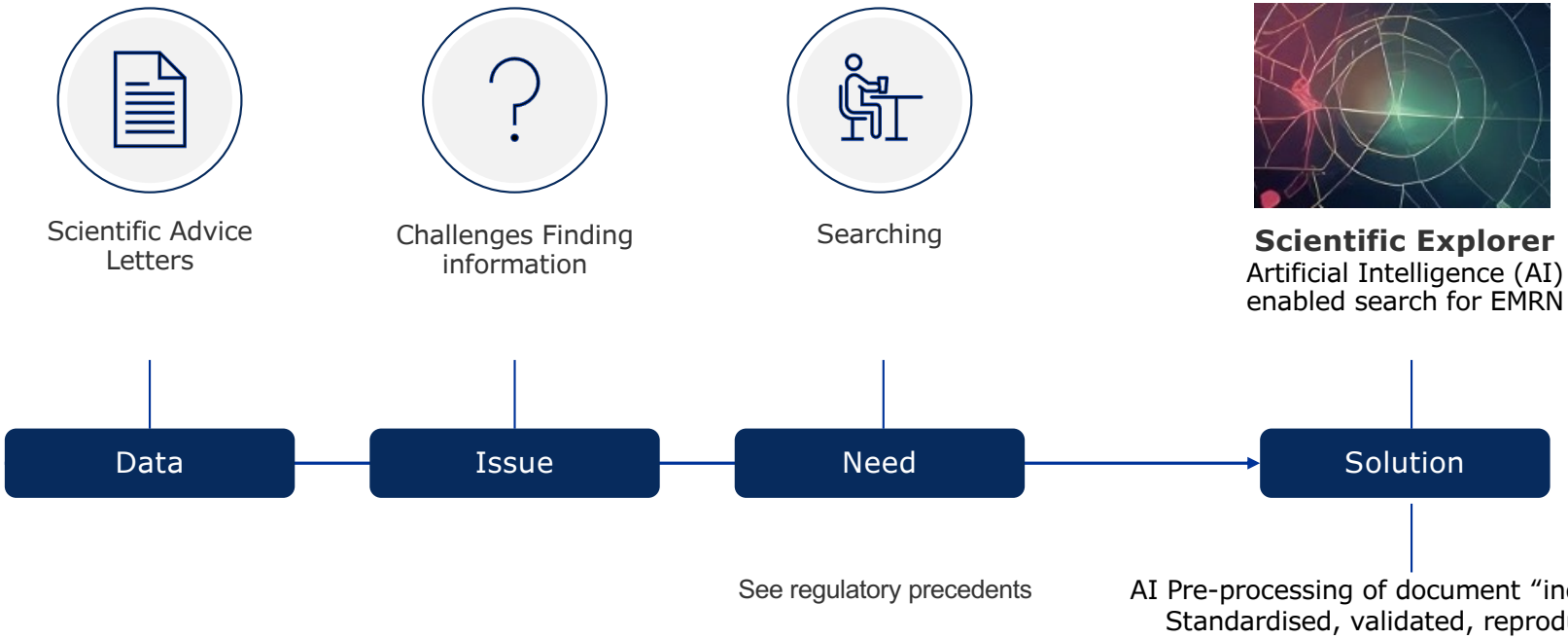
2021 project vision

The purpose of the project is to deliver effective generation of evidence in support of benefit/risk decision making from **data-driven interrogation of scientific information** within Lifecycle Regulatory Submissions.



- GPT4's release in March 2023 turned things around !

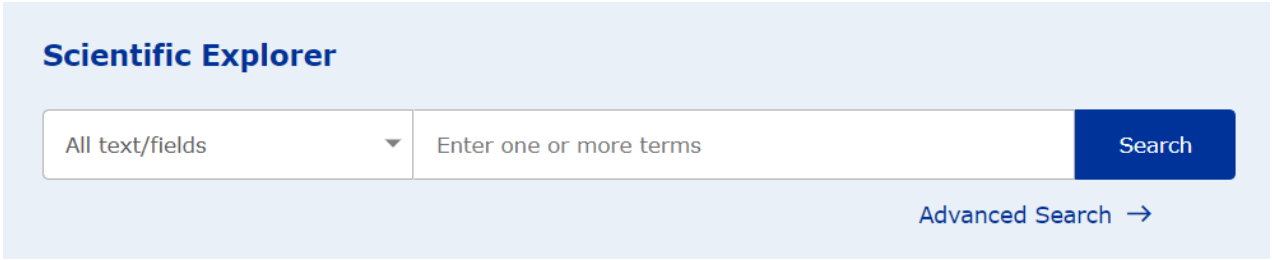
Scientific advice letters - recap
Problem and solution

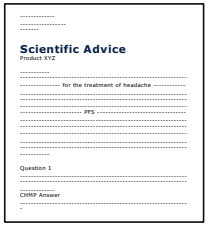


Supporting efficiency, consistency, quality; for EMA and for Netw

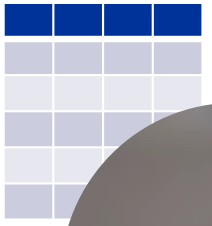
Scientific Explorer Enables

Fast, easy, precise **searching** and **interacting** with regulatory precedents, to support efficiency, quality, consistency of assessment



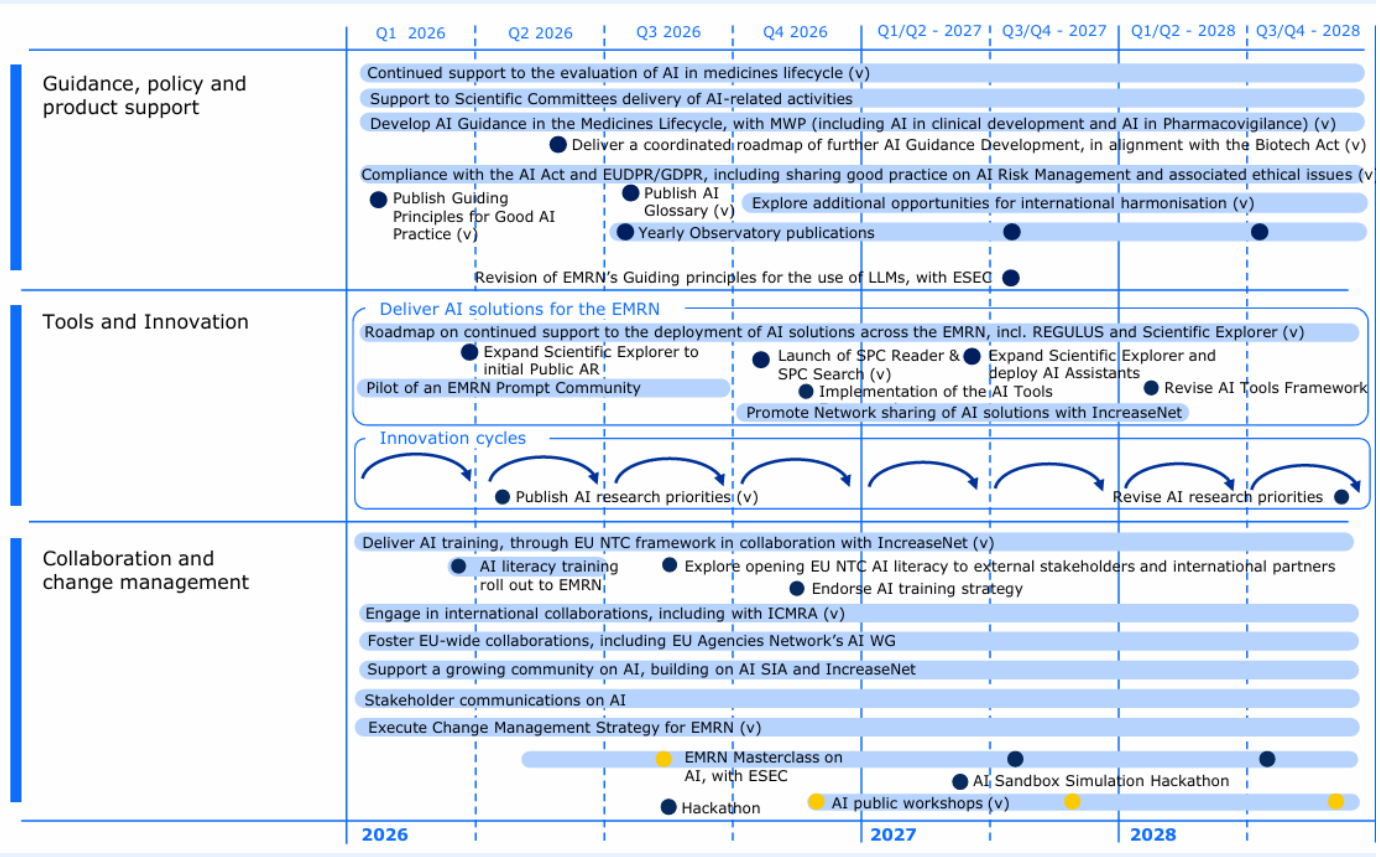


Across unstructured and **structured data**
(and we need to talk about standardised data…)



The first release focuses on **Scientific Advice** procedures on medicinal products for hu

AI in clinical trials | AI workplan to 2028



NDSG workplan 2026-2028

Data and AI in medicines regulation

AI in clinical trials | planned regulatory activities

EMA HMA

NDSG workplan 2026-2028

Data and AI in medicines regulation

- Glossary of AI terminology
- Workshop 'AI use in clinical trials'
- Guideline on AI in clinical development
- Annex to GCP Inspectors Working Group Guideline on computerised systems and electronic data in clinical trials

‘Trusted medicines by unlocking the value of data’

HMA-EMA Network data steering group’s vision

HMA-EMA Network Data Steering Group

NDSG workplan 2026-2028

Data and AI in medicines regulation

Workstreams

The NDSG workplan is organised in six workstreams:

Strategy and governance:

- Strategy
- Governance

Data analytics:

- Review of advanced or innovative methodologies and of new data types for evidence generation
- Real-world data, clinical study data, EudraVigilance data, non clinical data, genomic data

Artificial Intelligence :

- Guidance, policy and product support
- Tools and technologies
- Collaboration and change management
- Experimentation

Data interoperability:

- Data asset discovery, cataloguing and metadata management
- Data quality management
- Organisational and semantic interoperability

Stakeholder engagement and change management:

- Change management strategy
- Network skills and knowledge
- Stakeholder engagement and communication

Guidance and international initiatives :

- Guidance
- International initiatives

Additional initiatives & relevant regulation

- Development of a data standardisation framework
  - To facilitate **adoption and implementation of data standards** in the EU
- Definition of technical requirements for submission of **clinical study data**
  - To clarify **acceptable CDISC data standards, data formats** and any other data and IT-related requirements
- Ongoing **non-clinical (SEND) data** pilot
- Implementation of ICH M11 in clinical trial protocols
  - Following completion of ICH M11 (Step 5), to draft a **technical implementation guide** for the **submission of clinical trial protocols**

- **DARWIN EU®** - RWE use throughout medicinal product lifecycle
  - **Use of Common Data Model** (OMOP)
  - 40 data partners in 2026, access to data from over 250 million patients and approx. 110 studies delivered through DARWIN EU®
- **European Health Data Space (EHDS)**
  - Landmark EU regulation in force since 26 March 2025
  - Common legal, technical and governance framework for health data across all EU Member States
  - Primary and secondary use of data
  - Metadata standards, data catalog interoperability rules in support analytics under a trusted goverr

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Thank you

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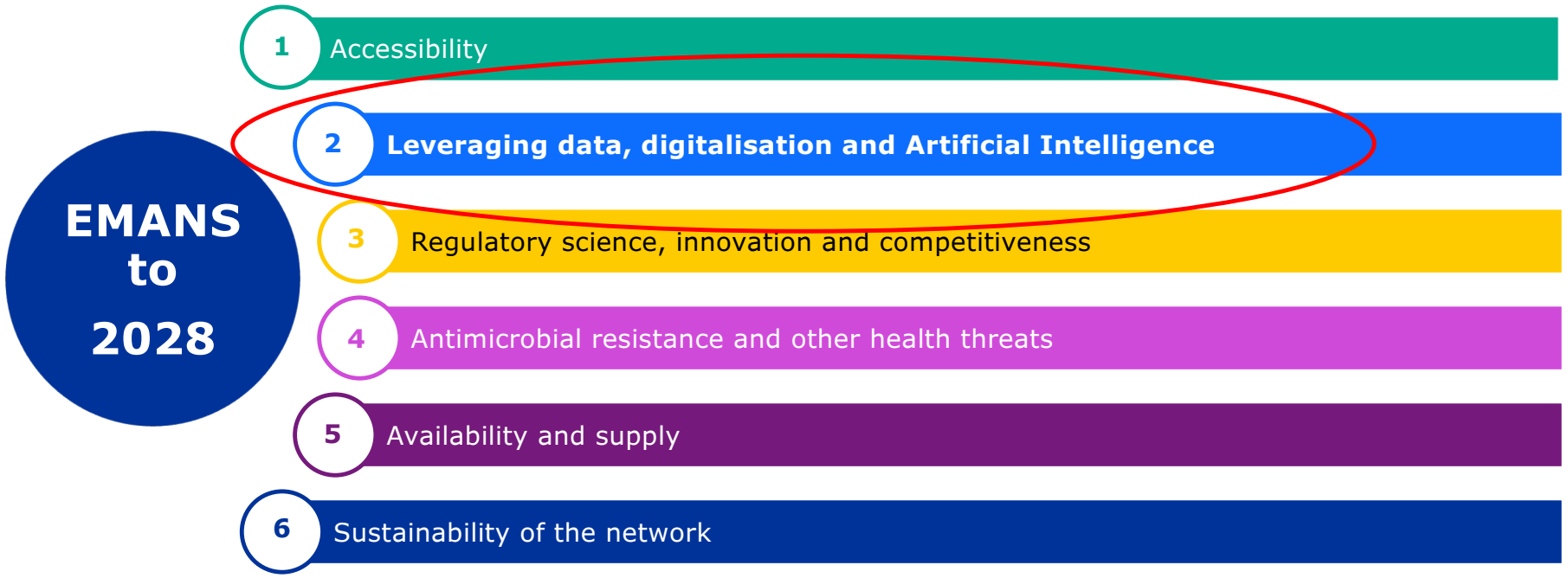
Follow us

Appendix

European medicines agencies network strategy (EMANS) to 2028: strategic focus areas



Useful links

- The European medicines agencies network strategy 2028
- NDSG workplan 2025-2028
- Artificial intelligence | European Medicines Agency (EMA)