Management Board
12 December 2024

ARTIFICIAL INTELLIGENCE AT EFSA

IMPLEMENTING SAFE AND ETHICAL SOLUTIONS TO SUPPORT RISK ASSESSMENT

Barbara Gallani

Head of Communication and Partnership Department

EUROPEAN FOOD SAFETY AUTHORITY

AI TODAY (AI INDEX 2024)

1. AI beats humans on some tasks, but

2. Industry continues to

3. Frontier models get way more

4. The United States leads China, the EU, and the U.K. as the leading source o top AI models.

In 2023, 61 notable AI mode originated from U.S.-based institutions, far outpacing th European Union's 21 and Ch

5. Robust and standardized evaluations for LLM

6. Generative AI investment skyrockets.

7. The data is in: AI makes workers more productive and leads to higher quality work.

In 2023, several studies assessed AI's impact on labor, suggesting that AI enables workers to complete tasks more quickly and to improve the quality of their output. These studies also demonstrated AI's potential to bridge the skill gap between low- and high-skilled workers. Still other studies caution that using AI without proper oversight can lead to diminished performance.

8. Scientific progress accelerates even further, thanks to AI.

In 2022, AI began to advance scientific discovery. 2023, however, saw the launch of even more significant science-related AI applications—from AlphaDev, which makes algorithmic sorting more efficient, to GNoME, which facilitates the process of materials discovery.

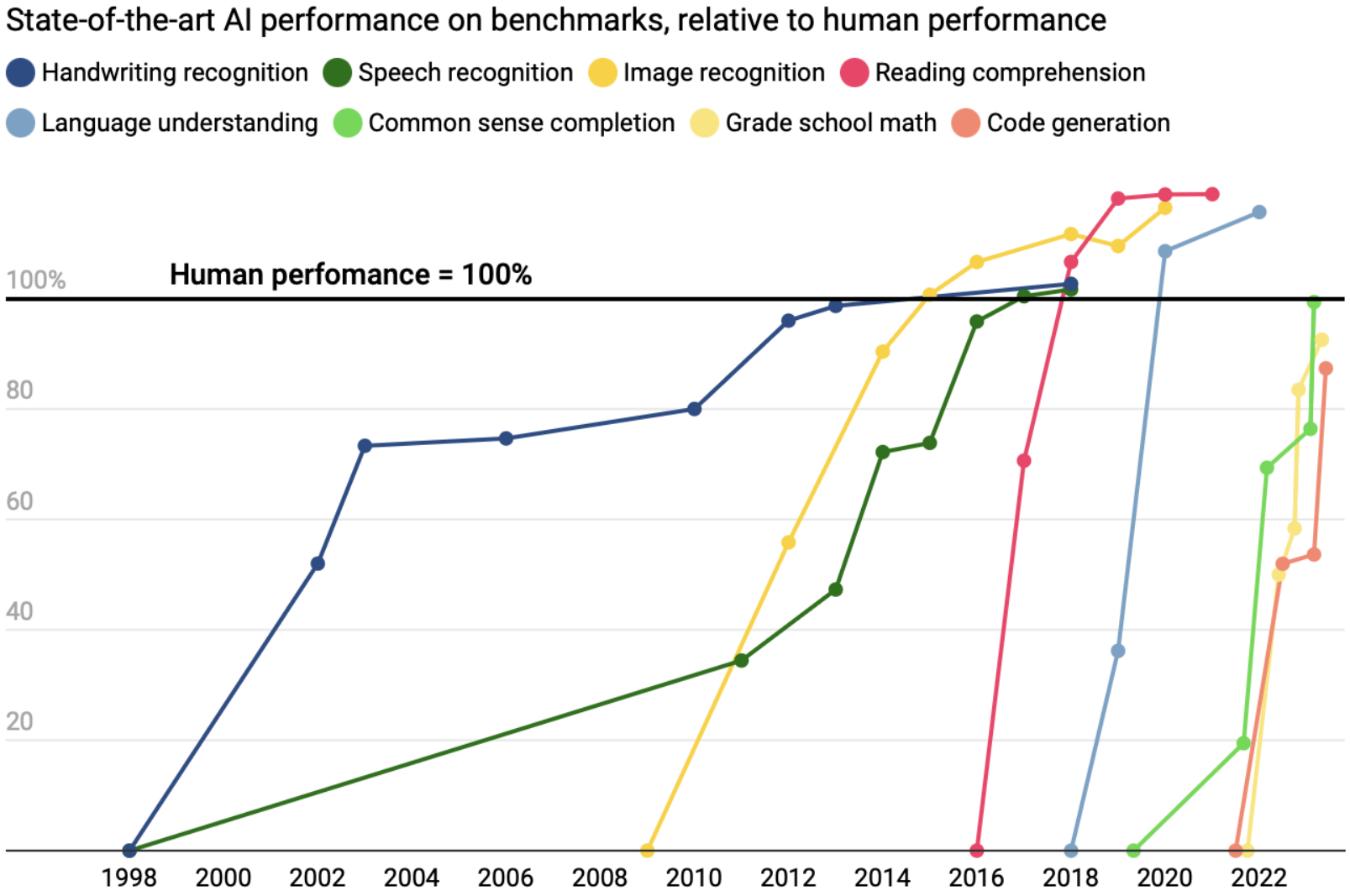
9. The number of AI regulations in the United States sharply increases.

The number of AI-related regulations in the U.S. has risen significantly in the past year and over the last five years. In 2023, there were 25 AI-related regulations, up from just one in 2016. Last year alone, the total number of AI-related regulations grew by 56.3%.

10. People across the globe are more cognizant of AI's potential impact—and more nervous.

A survey from Ipsos shows that, over the last year, the proportion of those who think AI will dramatically affect their lives in the next three to five years has increased from 60% to 66%. Moreover, 52% express nervousness toward AI products and services, marking a 13 percentage point rise from 2022. In America, Pew data suggests that 52% of Americans report feeling more concerned than excited about AI, rising from 38% in 2022.

AI HAS SURPASSED HUMANS AT A NUMBER OF TASKS AND THE RATE AT WHICH HUMANS ARE BEING SURPASSED AT NEW TASKS IS INCREASING (TIME)



AI TODAY

IDEAS MADE TO MATTER | ARTIFICIAL INTELLIGENCE

How generative AI can boost highly skilled workers' productivity

by Meredith Somers | Oct 19, 2023

Study Finds Applying Generative AI Correctly Can Improve Productivity by 40%

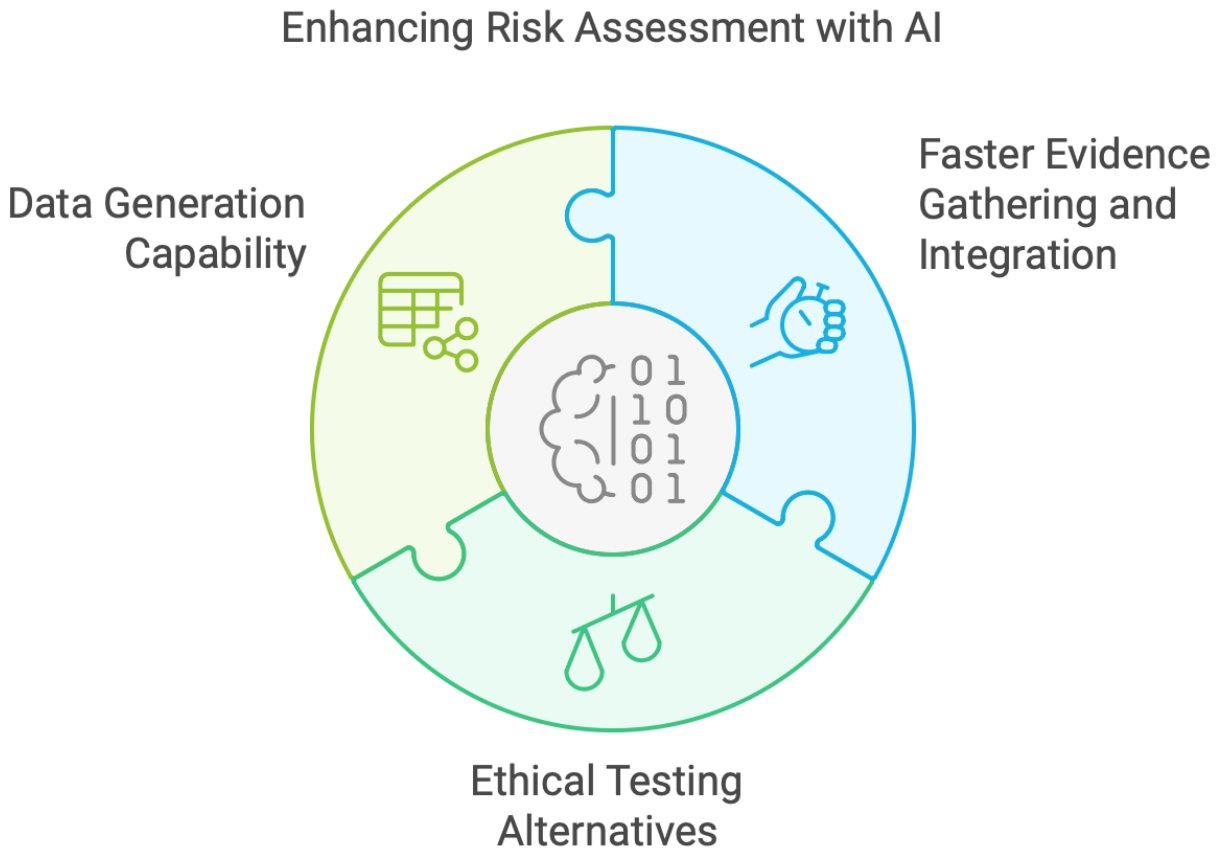
By: Sarah Roberts

by Maria Korolov
Contributing writer

3 areas where gen AI improves productivity — until its limits are exceeded

Feature
13 Mar 2024 • 11 mins

AI TODAY IN REGULATORY SCIENCE



Food for Thought ...

ToxAIcology – The Evolving Role of Artificial Intelligence in Advancing Toxicology and Modernizing Regulatory Science

Thomas Hartung[1,2]

[1]Center for Alternatives to Animal Testing (CAAT), Doerenkamp-Zbinden-Chair for Evidence-based Toxicology, Johns Hopkins University, Bloomberg School of Public Health, Baltimore, MD, USA; [2]CAAT Europe, University of Konstanz, Konstanz, Germany

Artificial intelligence (AI)–it's the end of the tox as we know it (and I feel fine)

Nicole Kleinstreuer [1], Thomas Hartung [2 3]

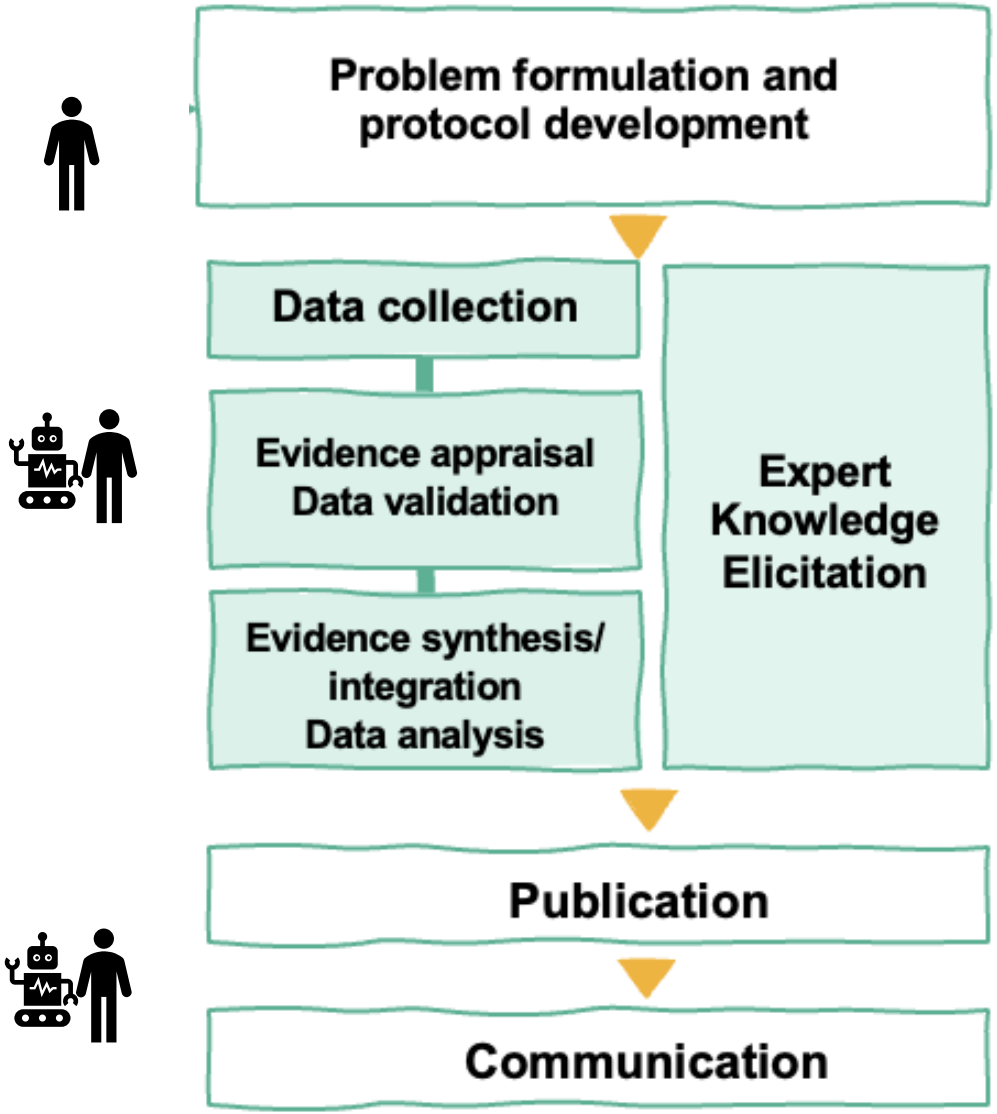
Affiliations + expand

PMID: 38244040 PMCID: PMC10861653 DOI: 10.1007/s00204-023-03666-2

Artificial intelligence as the new frontier in chemical risk assessment

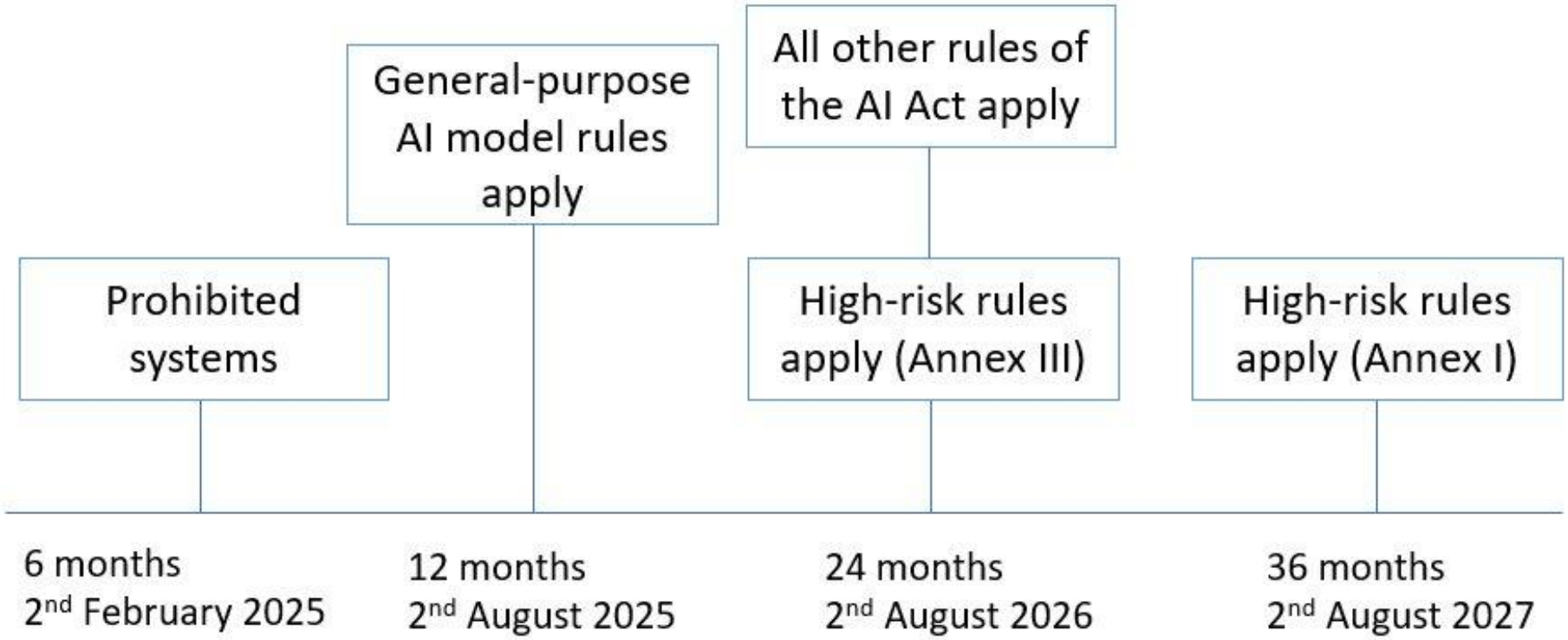
Thomas Hartung[1,2*]

EFSA'S EVIDENCE BASED CORE PROCESS – TRANSPARENCY REGULATION AND EU AI ACT COMPLIANT

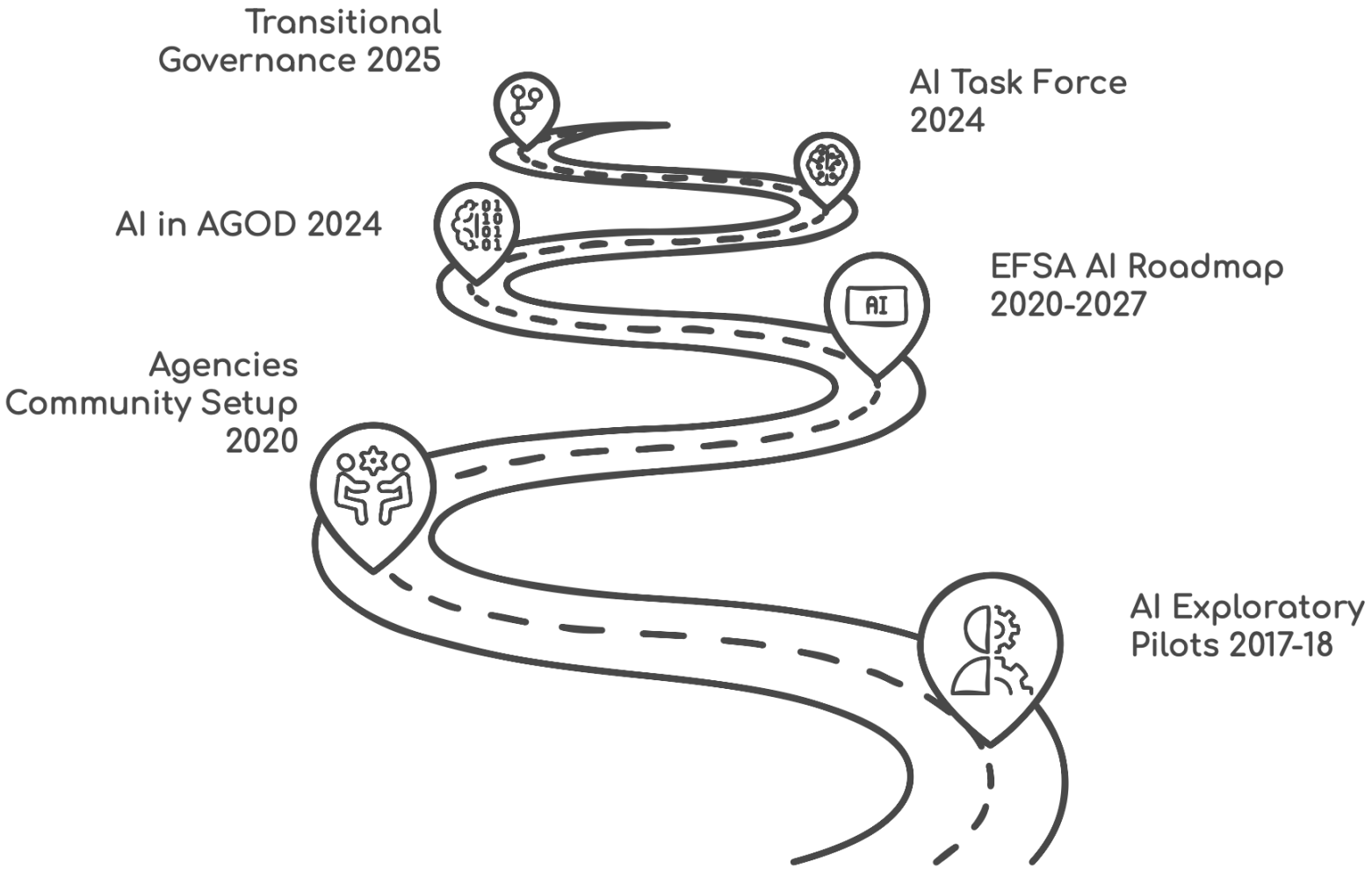


AI ACT

AI Act entry into force timeline

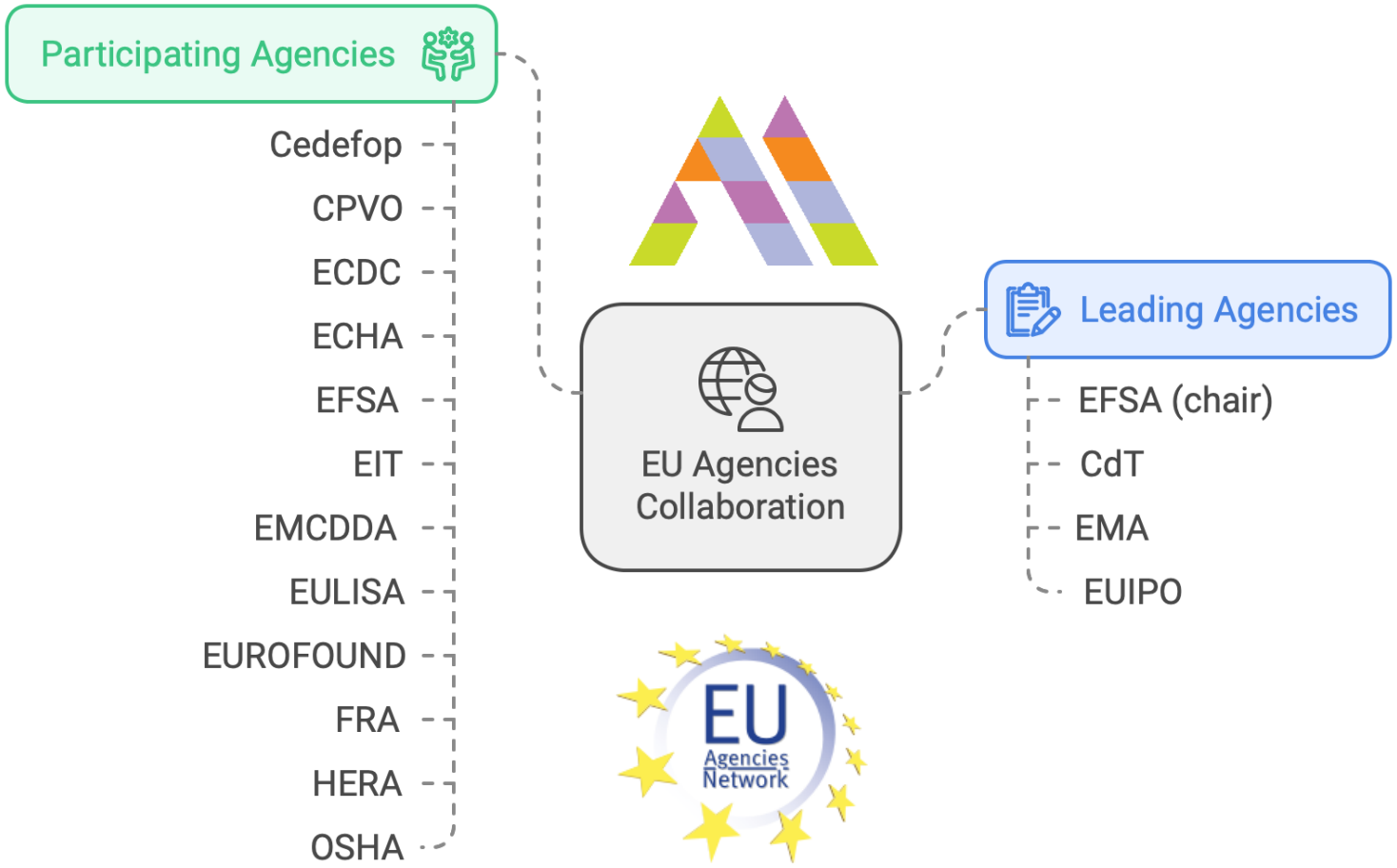


AI TIMELINE


Transitional
Governance 2025
AI Task Force
2024
AI in AGOD 2024
EFSA AI Roadmap
2020-2027
AI
Agencies
Community Setup
2020
AI Exploratory
Pilots 2017-18

AGENCIES COMMUNITY 2020

"We strive for the use of trustworthy and human-centric Artificial Intelligence for increased collaboration amongst EU Agencies…"



THE EFSA ROADMAP 2020

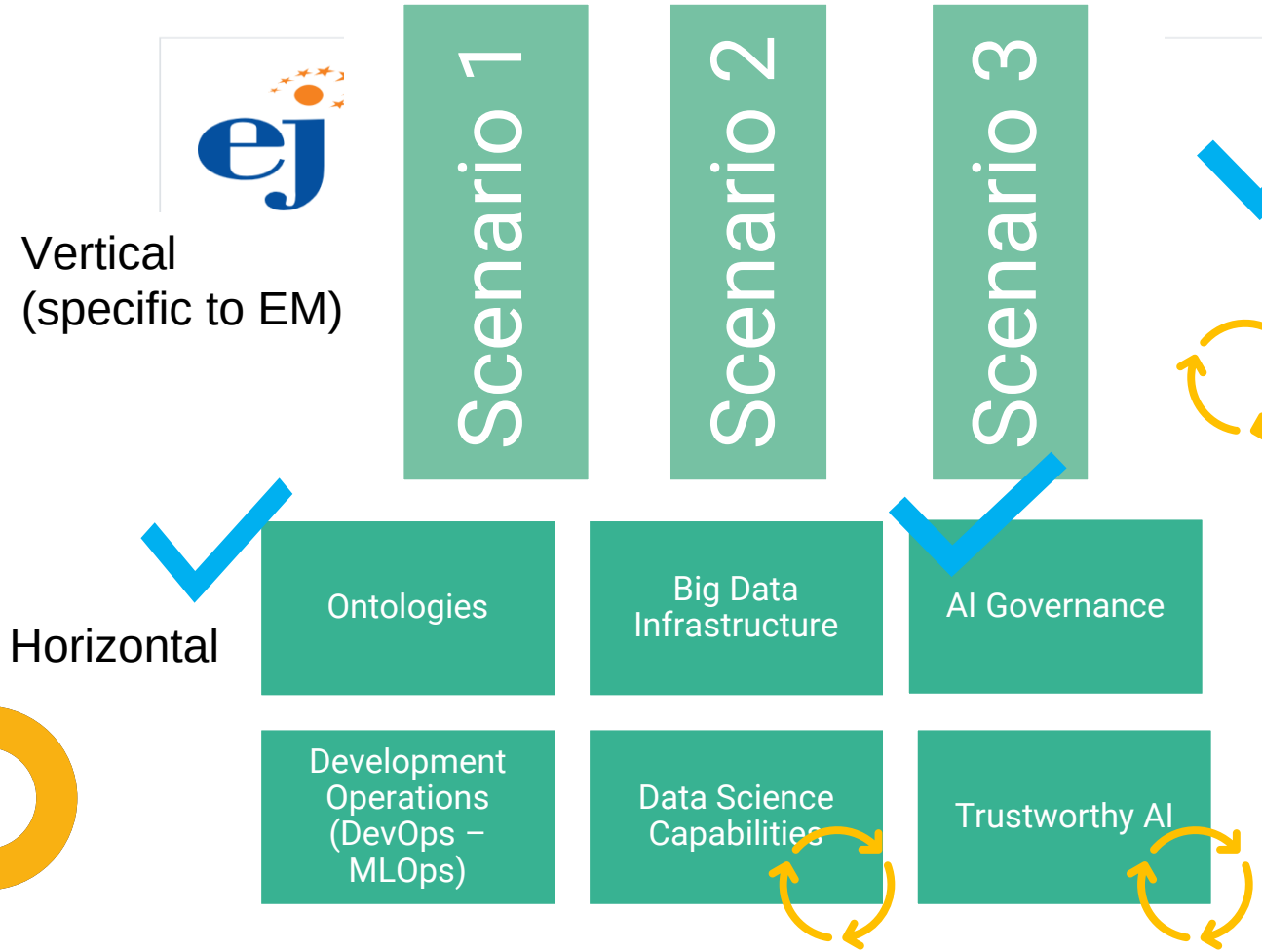
Artificial intelligence for evidence management in risk assessment

- **Vision:** by 2027 EFSA to achieve
  - i) an increase in the accessibility and the breadth of the body of evidence,
  - ii) enhancing the trustworthiness in the risk assessment process, and
  - iii) apply human centric artificial intelligence in close co-existence with the human expertise
- **Roadmap for action**: Oct 2021
- **Implementation**: Dec 2021 onwards

THE EFSA ROADMAP 2020-2027

Roadmap for actions on artificial intelligence for evidence management in risk assessment

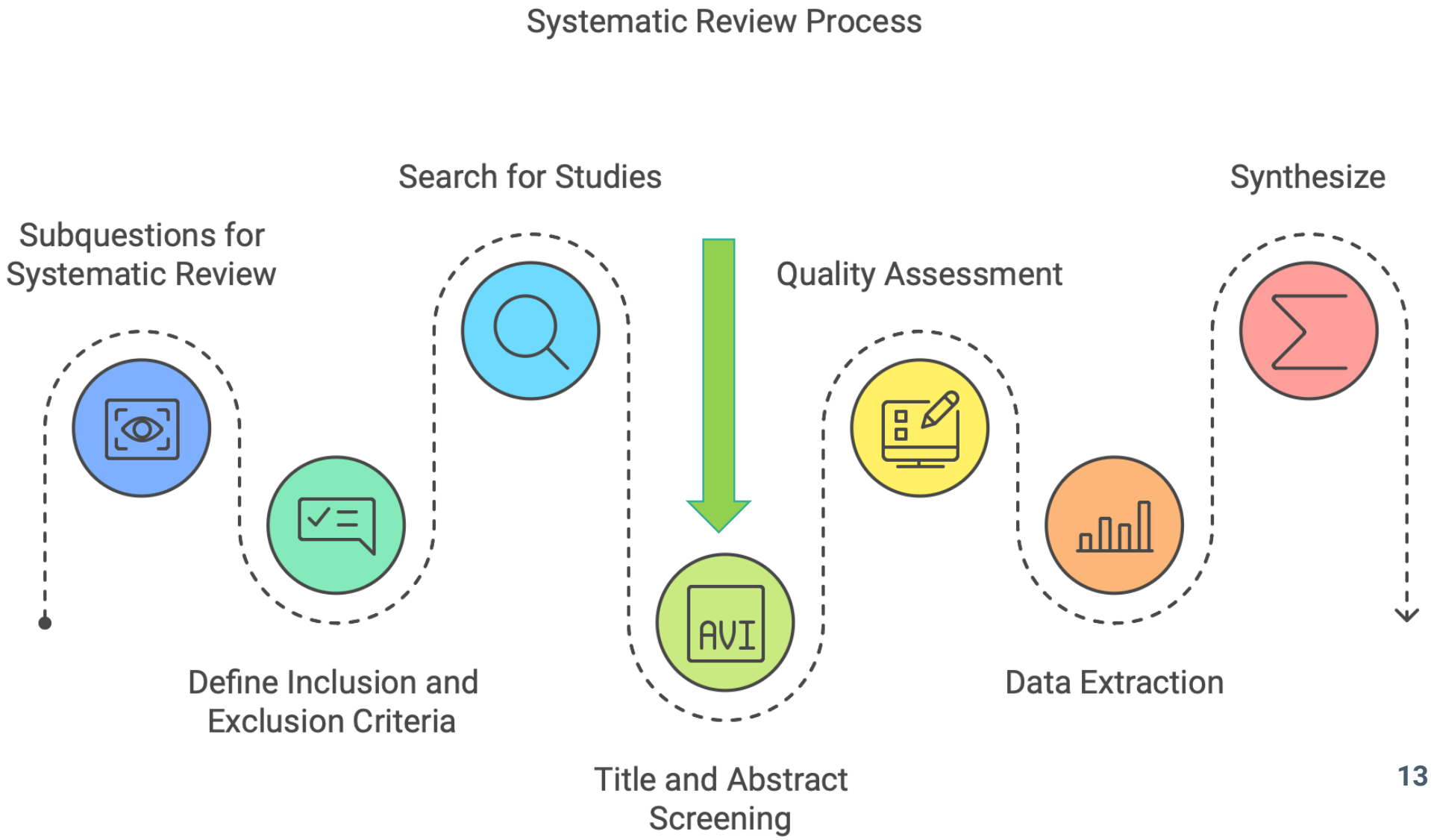
Published: 16 Maggio 2022 **Approved:** 1 Aprile 2022



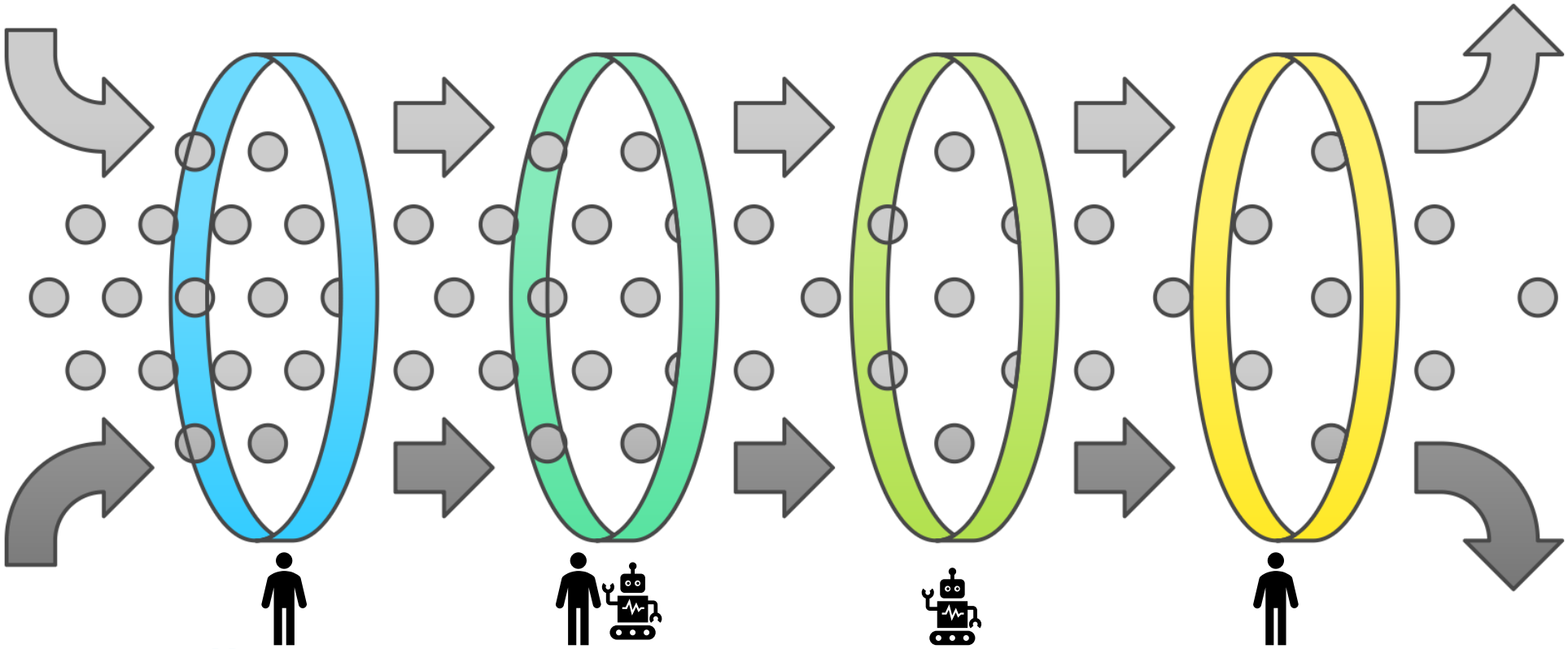
Use cases	Scenarios
Data Collection Terminology Assessment SLR Keywords Identification SLR Relevant Abstract Screening SLR Literature De-duplication Text Summarization SLR Literature Findings Clustering	1: buy
Quality Improvement of the Scientific Output	2: buy and adjust
Expert pool Identification Expert Selection Comparable Appraisals Detection	3: build by grant or procurement

THE ROADMAP IN PRACTICE

ABSTRACT SCREENING



AI SUPPORTED ABSTRACT SCREENING



Human Screening

Inclusion and exclusion criteria.

AI Learning

AI learns and reorders results.

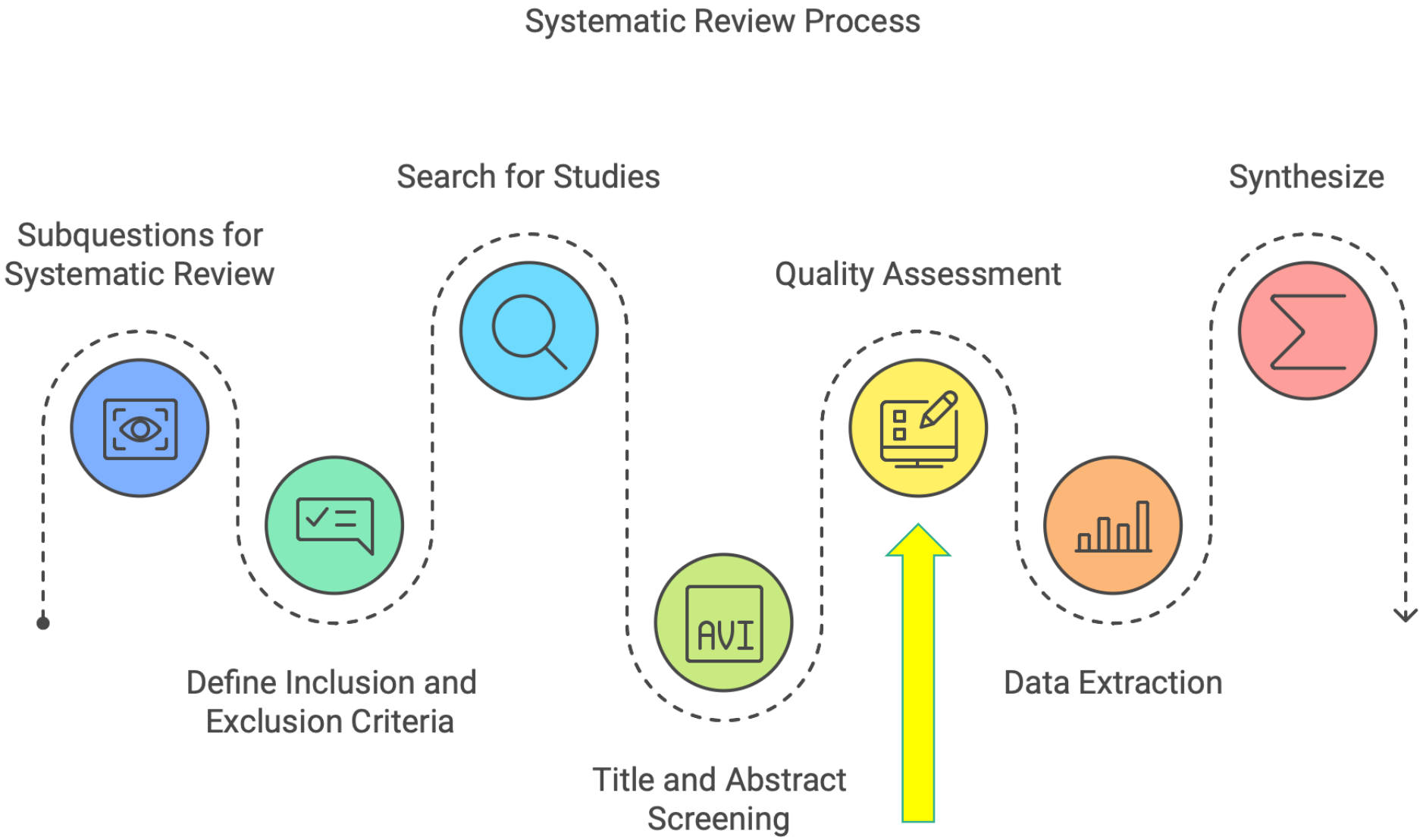
AI Screening

AI screens remaining results.

Human Review

Check final list

CRITICAL APPRAISAL



HIGHLIGHTED PDF

Long-Term Toxicity and Carcinogenicity Study of Cyclamate in Nonhuman Primates

Highlighting colors legend

Main Question Code	Main Question Text
Q1	Was administered dose or exposure level adequately randomized?
Q2	Was allocation to study groups adequately concealed?
Q5	Were experimental conditions identical across study groups?
Q6	Were the research personnel and human subjects blinded to the study grou
Q7	Were outcome data complete without attrition or exclusion from analysis?
Q8	Can we be confident in the exposure characterization?
Q9	Can we be confident in the outcome assessment?
Q10	Were all measured outcomes reported?
Q11a	Were statistical methods appropriate?

the intestinal flora (Renwick, 1986). The ADI for cyclamate established by the JECFA (1982) and the SCF (1985) is based on the NOAEL for testicular atrophy produced by cyclohexylamine in rats with the application of a 100-fold safety factor and assuming 18% metabolism per day (see Renwick, 1986).

This report presents results of a toxicity and carcinogenicity study of cyclamate in nonhuman primates that involved treatment for a period of up to 24 years, i.e., from 1970 to 1994.

MATERIALS AND METHODS

Animals and dosing. Of the 21 monkeys used in this study, there were nine (seven males, two females) cynomolgus (*Macaca fascicularis*), nine (four males, five female) rhesus (*Macaca mulatta*), and three (two males, one female) African green (*Cercopithecus aethiops*) monkeys. These three species had been used in earlier chemical carcinogenesis studies in this monkey colony and had exhibited comparable sensitivity to different test compounds with respect to tumor incidence, latent period, and tumor type (Thorgeirsson *et al.*, 1994). They were born and raised in a closed colony. Infants were hand-reared and began receiving cyclamate (a gift from Abbott Laboratories, Chicago, IL) in the Similac formula within the first few days of birth. At 6 months of age, the monkeys were placed in individual, wall-mounted, stainless steel cages equipped with an automatic watering device. The daily diet consisted of *ad libitum* Purina High Protein Monkey Chow #5045, a vitamin sandwich, and half an apple. The sodium cyclamate (dissolved in warm water at 200 mg/ml) was incorporated into the vitamin mixture, which consisted of the following ingredients: powdered milk (5 pounds); Parvo (folic acid supplement, 4 oz., 20% with starch, Roche Agricultural Products); Cecon (vitamin C supplement, 300 ml, Abbott Laboratories, Chicago, IL); molasses (2 l); and water (500 ml). The appropriate amounts of the vitamin mixture containing sodium cyclamate (0.5 ml/animal for the 100 mg/kg group and 2.5 ml/animal for the 500 mg/kg group) were placed onto sandwiches. The monkeys (four cynomolgus, four rhesus, two African green) in the 100 mg/kg group received one sandwich daily 5 days per week. The monkeys (five cynomolgus, five rhesus, one African green) in the 500 mg/kg group received two sandwiches daily for 5 days per week. When the study was initiated in 1970, the rationale for selecting these doses was to provide an adequate safety margin in relation to human exposure. The 100 mg/kg and 500 mg/kg dose levels are about 9 and 45 times higher than the current upper limit of the ADI of 11 mg/kg/day established by the JECFA and SCF. A group of 16 control animals (eight cynomolgus, [five males and three females] and eight rhesus monkeys [six males and two females]) received the vitamin sandwiches without sodium cyclamate. The monkeys were evaluated daily and weighed once a week. Physical examination was carried out by a veterinarian every 6 months when blood was drawn for

poor replicate values (>5% difference) were subject to further analyses to confirm the results. Triplicate standard curves of 3–5 different concentrations of cyclohexylamine spiked into the biologic matrix from control animals were analyzed with the samples; these were linear over the ranges studied (0–2 μg/ml for plasma; 0–10 μg/ml for urine; 0–10 μg/ml homogenate for testes) and showed intra-assay variability of 7% or less at each concentration. The sample data represent the means of 2–4 replicate values mostly within ±5%.

The urine samples showed a very wide range of concentrations of cyclohexylamine, so that they had to be diluted to different extents—up to 1 in 100. In each case, 0.5 ml of the final dilution was used for analysis. The testicular samples were homogenized in 0.1 M phosphate buffer, and aliquots were extracted and analyzed. Samples from control monkeys showed a small interfering peak on HPLC that corresponded to low concentrations of cyclohexylamine (see Results).

RESULTS

This study included 21 cyclamate monkeys and 16 age-matched controls (see Tables 1–3). The monkeys were dosed from a few days after birth until the time of death. In 1994 when a decision was made to terminate the study, 7 cyclamate-treated monkeys had died and 14 were still alive. A cyclamate-treated monkey (789J; 500 mg/kg dose) died accidentally at 2 years of age and did not show any specific abnormalities when necropsied. A second monkey (790J; 500 mg/kg dose) died at 7 years of age and showed renal tubular degeneration. No other problems were documented until 1985, when two monkeys (769J; 100 mg/kg, and 800J; 500 mg/kg) died during a varicella outbreak. The same year, one monkey died as a result of chronic myocarditis (782J; 500 mg/kg) and two females were euthanized due to severe symptoms from extensive pelvic endometriosis (773J; 100 mg/kg, and 795J; 500 mg/kg). When the cyclamate study was terminated in 1994, the remaining eight monkeys in the 100 mg/kg group and six in the 500 mg/kg group, as well as the controls, were euthanized and necropsied. At that time, kyphosis was observed in three of the cyclamate monkeys. No other external abnormalities or health problems were noted. Results of blood samples collected from these animals did not reveal any abnormalities in blood cell counts, liver function tests, electrolytes, or BUN (results not shown).

MULTILINGUALISM

WHY THIS PROJECT?

Responding to:

- 2020 European Ombudsman recommendations
- Advances in nerual machine translation
- Transaprency Regulation – clear & accessible comms

MULTILINGUALISM

Human translation for website “skeleton” - top menu, footer, labels, about section, glossary, selected content

Machine translation used for dynamic, non-sensitive content

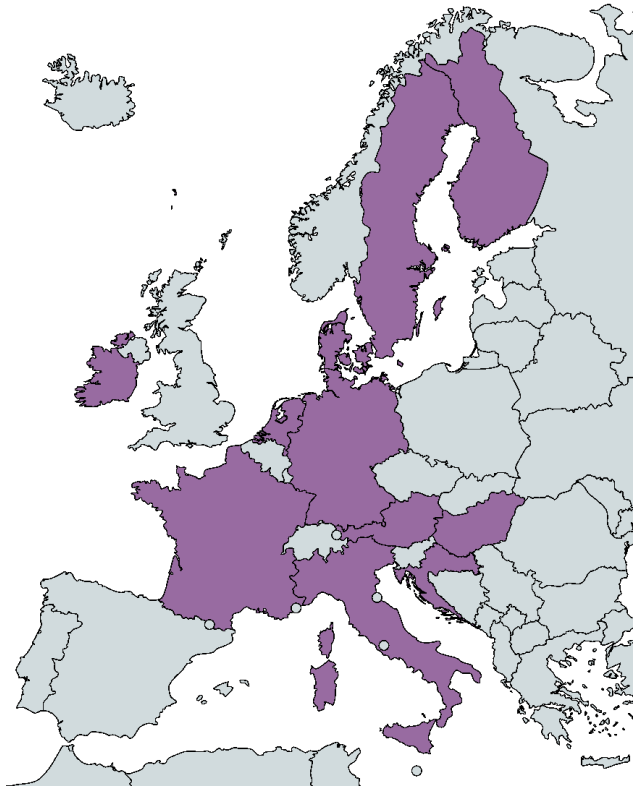
Covers **24 official languages** and more

Used by EU and national administrations

Traffic spike for all the new enabled languages

Increased visibility of the EFSA website on the main search engines

ADVISORY FORUM (AF) - ADVISORY GROUP ON DATA (AGOD) AND AI



MSs participating in AGoD in 2024
new MSs welcome!

AGoD ToRs identify 9 strategic objectives, some of them are directly linked with AI initiatives

Governance Body	Think Thank	Program Steering Committee
Consulting Body	Knowledge Hub	Strategic Input
Thematic Subgroups	Commission Connection	Group Visibility

Legend
Regular activities
AI-linked activities

AGoD work is advanced by 4 subgroups. The Innovation subgroup spearheads AI activities

Data Governance

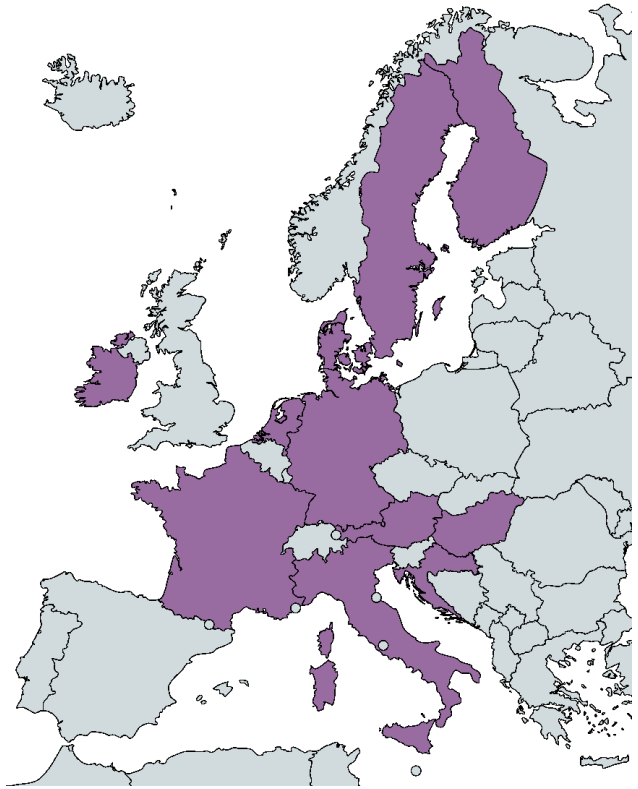
SG 1: Data Management
- Data Quality
- Data Modelling and Terminologies

SG 2: Tools & Eco-systems
- Digital Platforms and eco-systems
- Developing and sharing tools

SG 3: People & Capacity
- Data Literacy and Capacity preparedness

SG 4: Innovation
- Innovative data analytics
- New data streams
- AI
  - White paper on AI
  - Support a lighthouse project

ADVISORY FORUM (AF) - ADVISORY GROUP ON DATA (AGOD) AND AI



AGoD Member States Represented

- Hungary (Chair)
- Austria
- Croatia
- Denmark
- Finland
- France
- Germany
- Italy
- Ireland
- Netherlands
- Sweden

Governance Body	Think Thank	Program Steering Committee
Consulting Body	Knowledge Hub	Strategic Input
Thematic Subgroups	Commission Connection	Group Visibility

ADVISORY FORUM (AF) - ADVISORY GROUP ON DATA (AGOD) AND AI

Data Governance

- Governance bodies and roles
- Collaborative decision-making mechanisms

Data Management

- Data Quality
- Data Modelling and Terminologies
- Data Analysis and visualization

Tools & Eco-systems

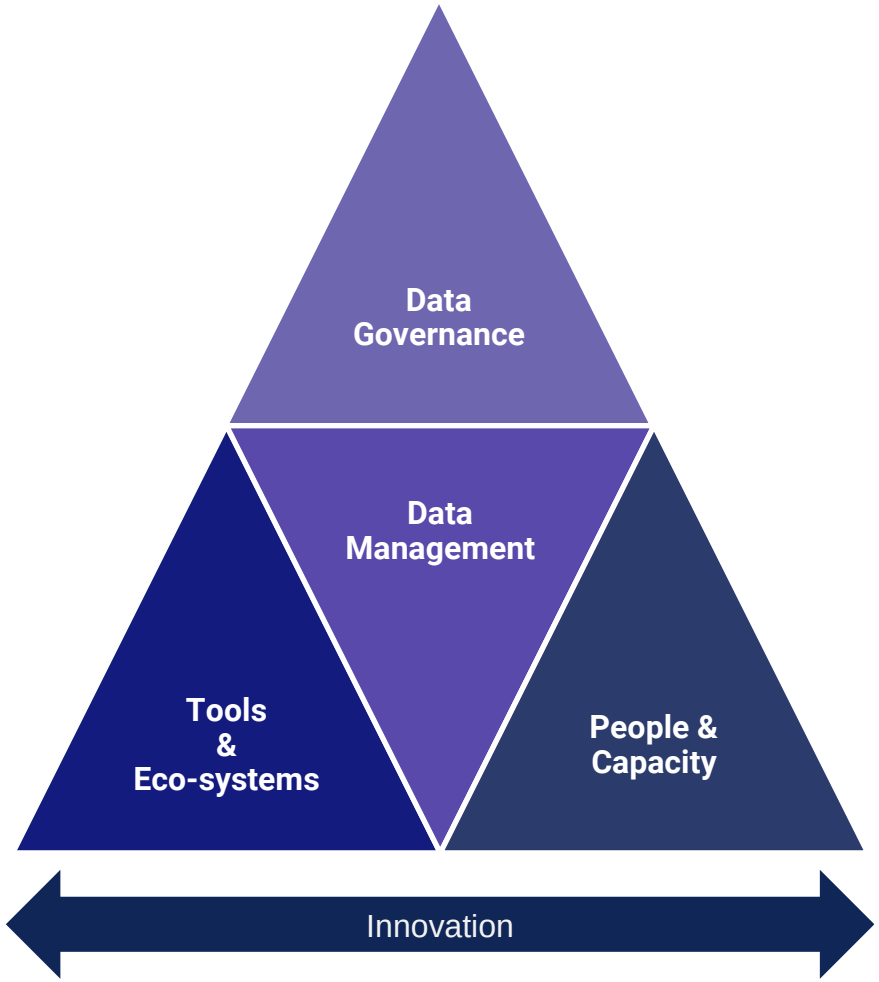
- Digital Platforms and eco-systems
- Developing and sharing tools

People & Capacity

- Data Literacy
- Data Capacity preparedness

Innovation

- Innovative data analytics
- New data streams
- AI



AI TASK FORCE: CHANGING THE WAY WE WORK

Learning and Development

Providing AI learning packages and training sessions to upskill staff.

Agile Methodologies

Adopting agile practices to improve flexibility and responsiveness in work processes.

Competency Enhancement

Implementing strategies to buy, build, or borrow skills and competencies.

AI Integration

Incorporating AI tools like GPT and MS Copilot to enhance daily operations.

Operational Transformation

Transforming operations through new governance and collaborative approaches.