knoell

worldwide registration

Introduction of AI at knoell – Insights, Successes, and Challenges

22-10-2025, ABIM, Dr. Milena Stephan

Who is knoell and where can AI support us?

Regulatory solutions for your key market

knoell worldwide registration

We assist you in obtaining and maintaining market access for your portfolio – globally.

ANIMAL HEALTH

BIOCIDES

CHEMICALS

CROP PROTECTION & BIOCONTROL

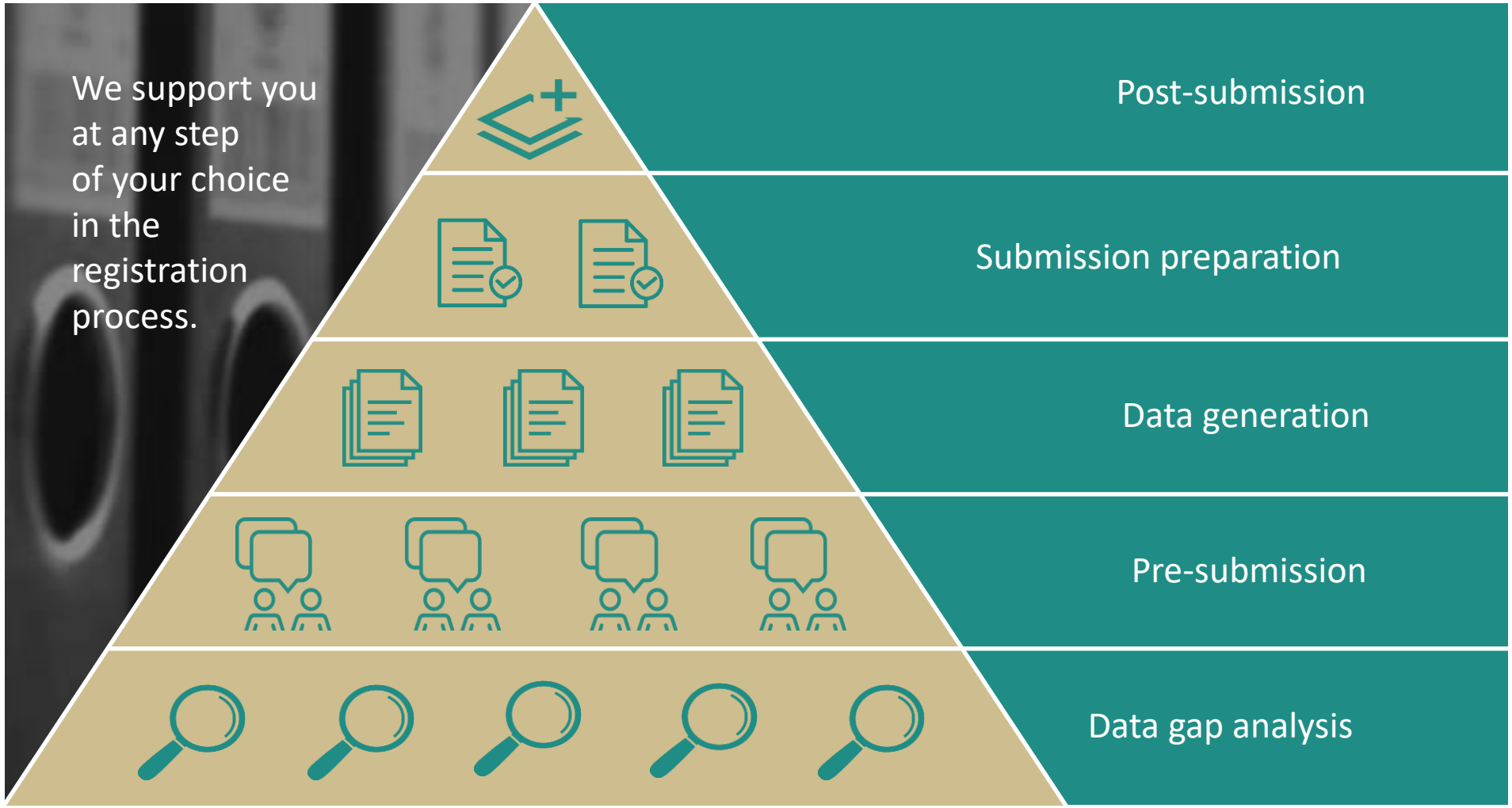
CROP NUTRITION

COSMETICS

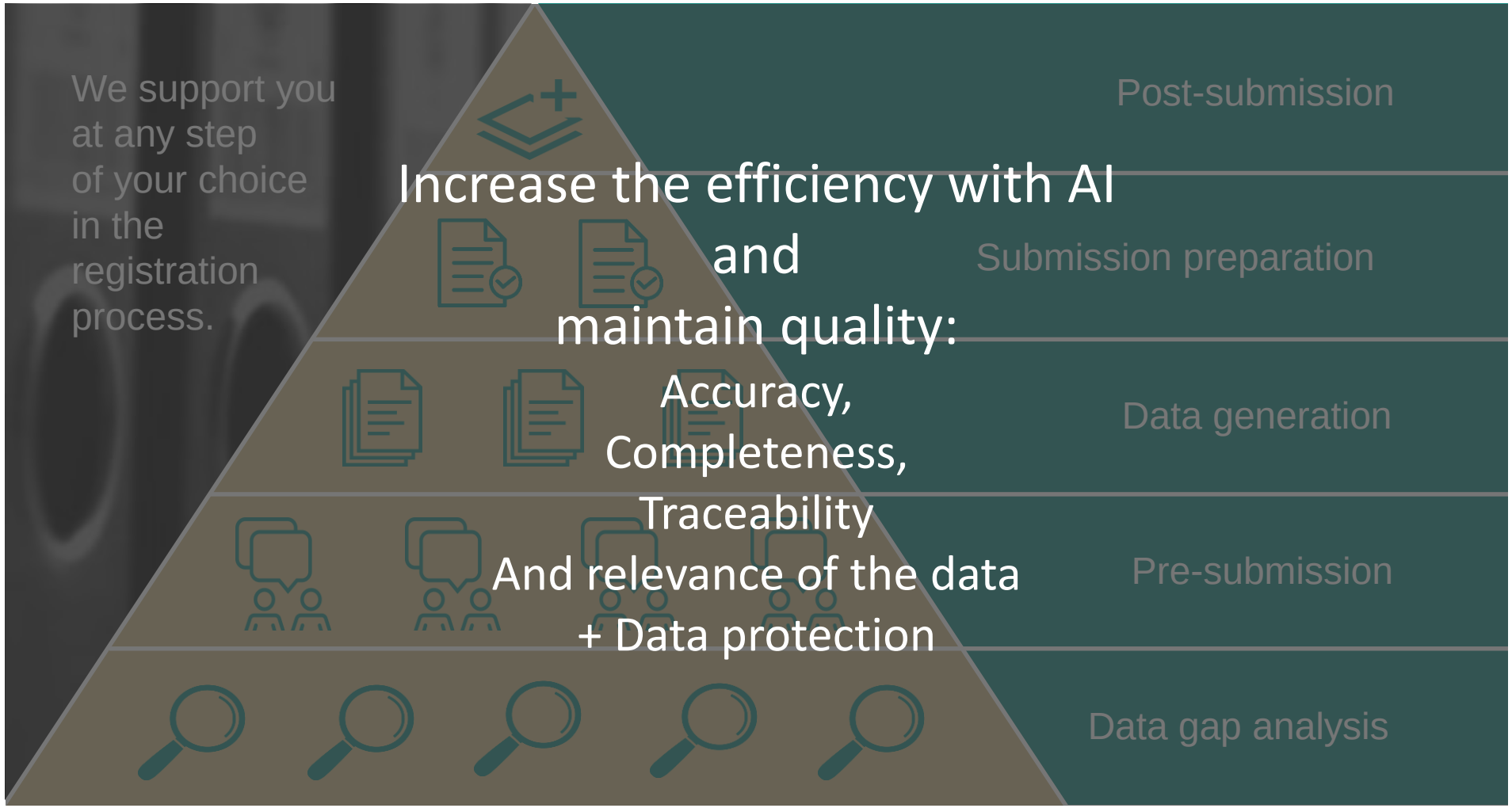
FOOD & FOOD CONTACT MATERIALS

MEDICAL DEVICES

Where AI can support us



Where AI can support us



Our guiding principles

knoell worldwide registration

Legal Requirements

- EU AI Act
- Other AI laws and frameworks
- Data protection laws
- Copyright

Client Requirements

- Client contracts
- NDAs

Standards/ Certifications

- ISO 27001 (certified since 2024)
- ISO 9001 (certified since 2025)
- Sustainability rating (EcoVadis)

Internal Standards

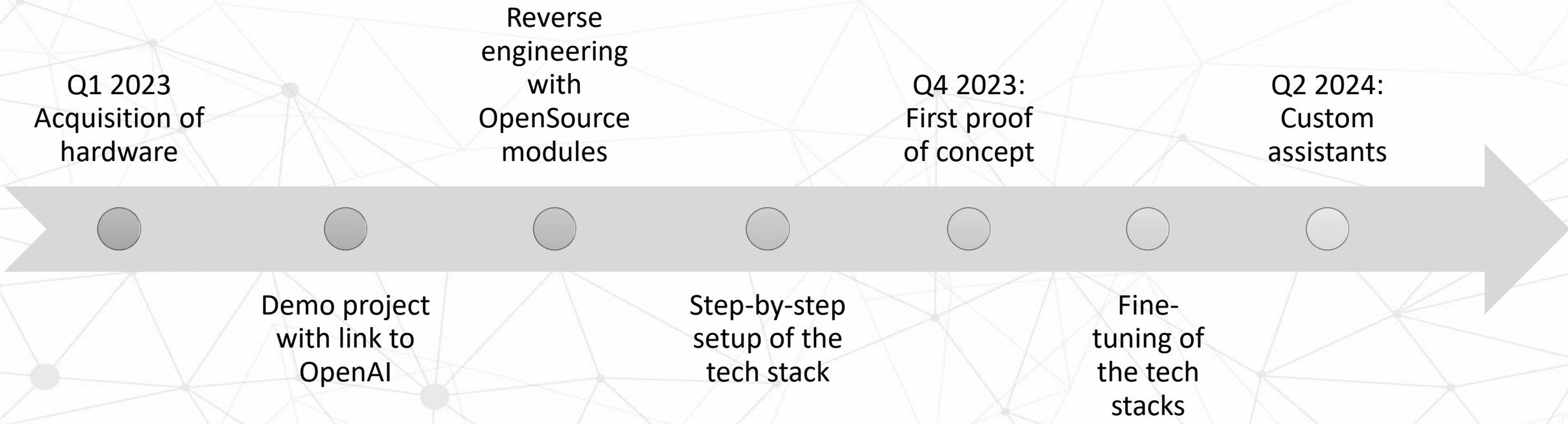
- Internal quality requirements

Development of a knoell AI solution – Why?

- Data protection and sovereignty
- Copyright
- Uniform quality
- Finetuning to our use case – Customized assistants
- Global political situation
  - Independence

Development of knoell AI

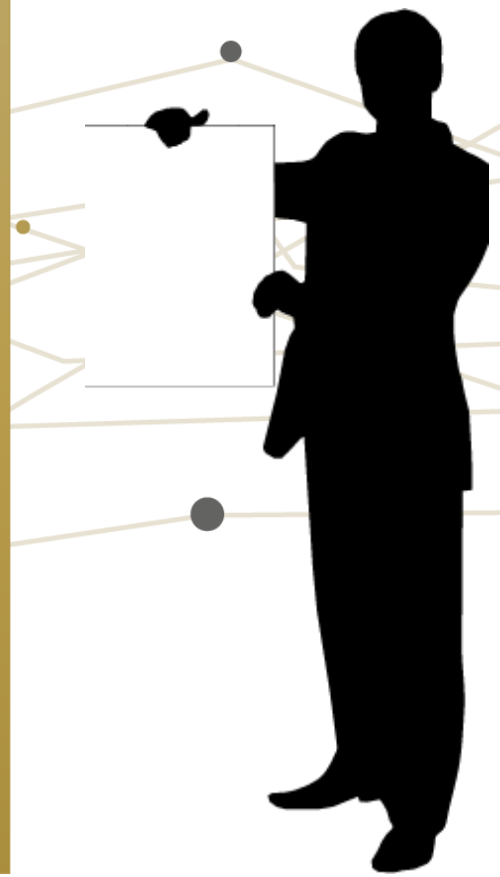
knoell AI – Development Process and Technology

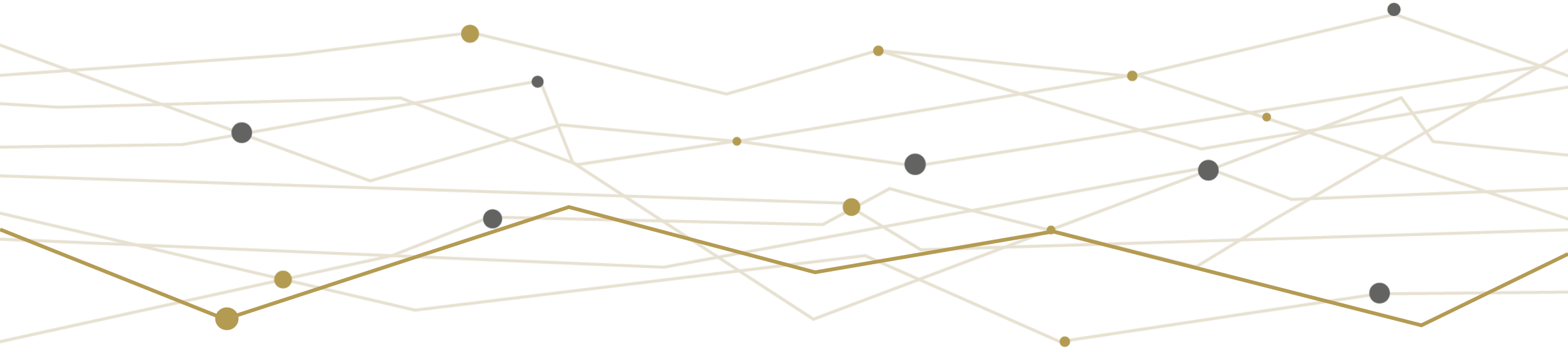


AI Policy

- Input of internal and confidential data such as:
  - Customer data
  - Personal data

  only into the knoell internal chatbot.
- Use of external AI tools such as Perplexity / ChatGPT only for publicly accessible information.
- Information from AI solutions must be verified by reliable sources.





knoell AI

Example: Customized Assistants

Cu

Wha

20 of

> Thinking done.

Technical Equivalence Assessment for Microorganisms in the EU

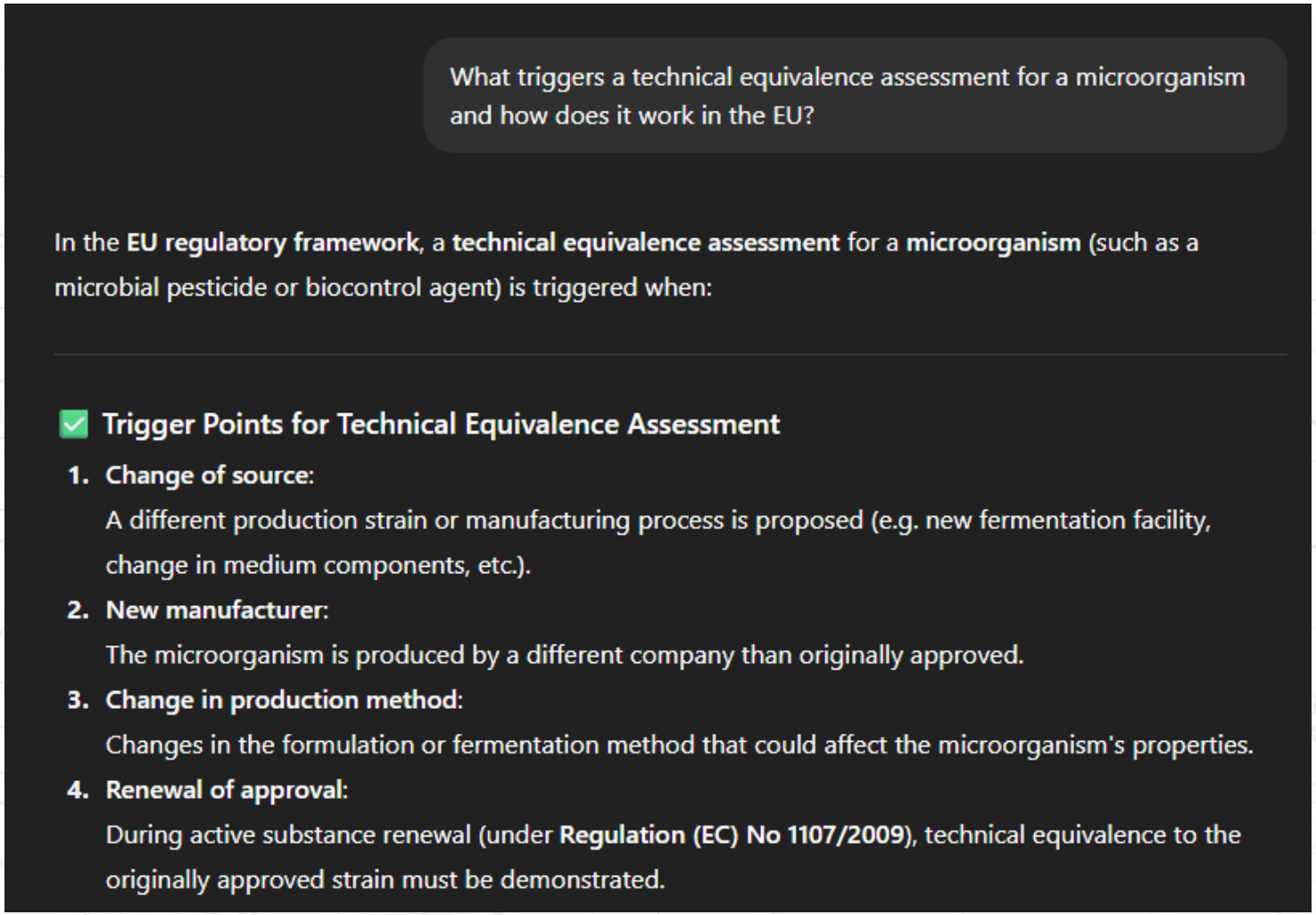
This structured summary outlines the triggers and processes for technical equivalence assessments of microorganisms under EU regulations, based on the provided documentation.

1. Triggers for Technical Equivalence Assessment

A technical equivalence assessment is required when changes to the production of a microorganism-based plant protection product (PPP) occur. These changes may affect the properties of the microorganism, necessitating regulatory evaluation. Key triggers include:

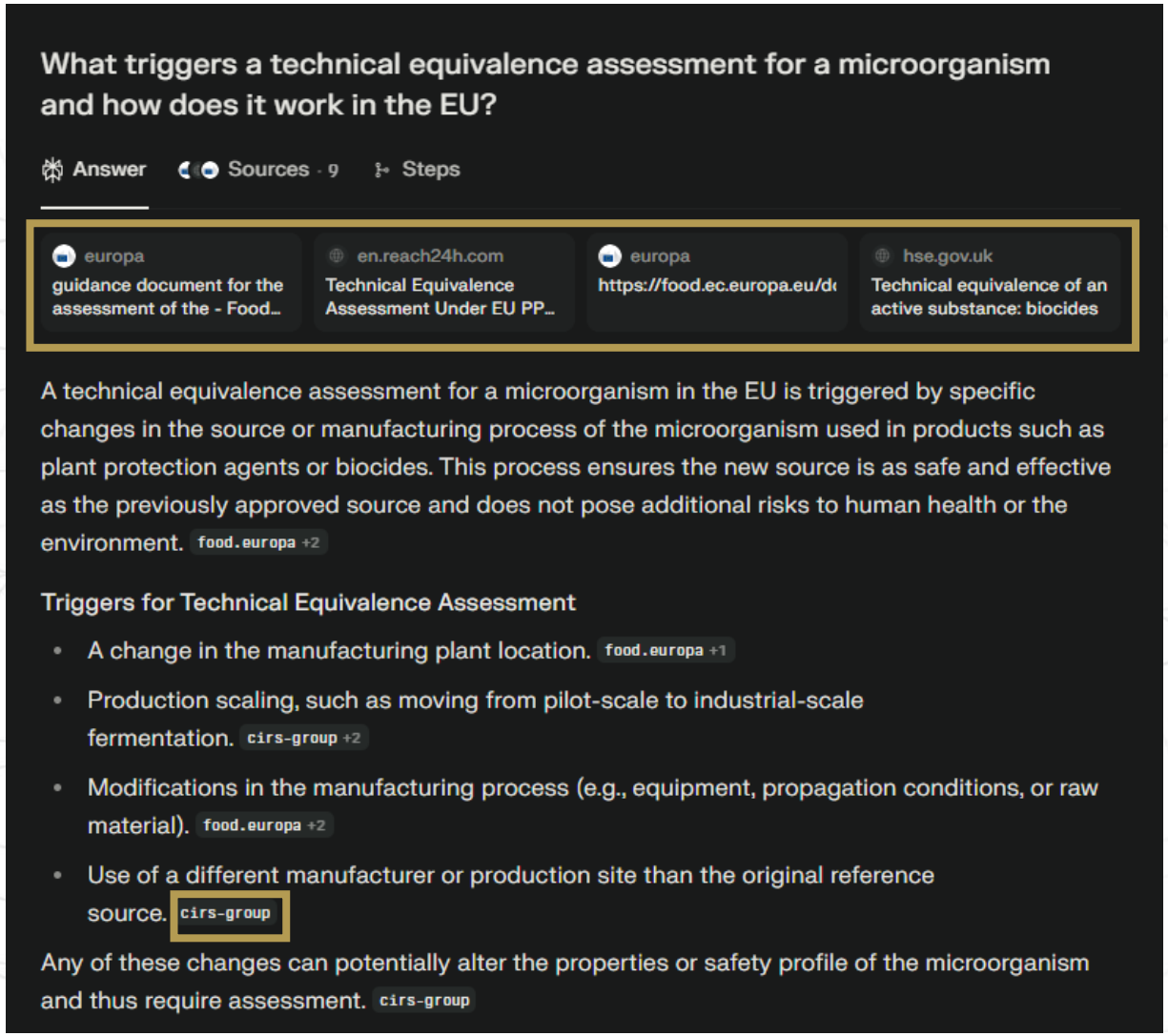
- **Change in Manufacturing Location:**
  - Relocating production to a new facility (e.g., moving from a pilot plant to an industrial-scale site).
  - Example: *SANCO/12823/2012 –rev. 4* (Documentation, p. 2–3).
- **Scale-Up of Production:**
  - Increasing the size of fermentation vessels (e.g., from lab-scale to commercial-scale production).
  - Example: *ENV/JM/MONO(2014)2* (Documentation, p. 21, 61).
- **Modification of Manufacturing Process:**
  - Altering production methods, equipment, or propagation conditions (e.g., temperature, media composition).
  - Example: *Commission Regulation (EU) No 546/2011* (Documentation, p. 28).

Comparison ChatGPT



- Same prompt
- No sources named
- Less detailed answer (None expert audience)

Comparison Perplexity



- Same prompt
- Sources named but these include online articles (Opinion not law)
- Less detailed answer (None expert audience)

Roll-out knoell AI -
Insights, successes and challenges

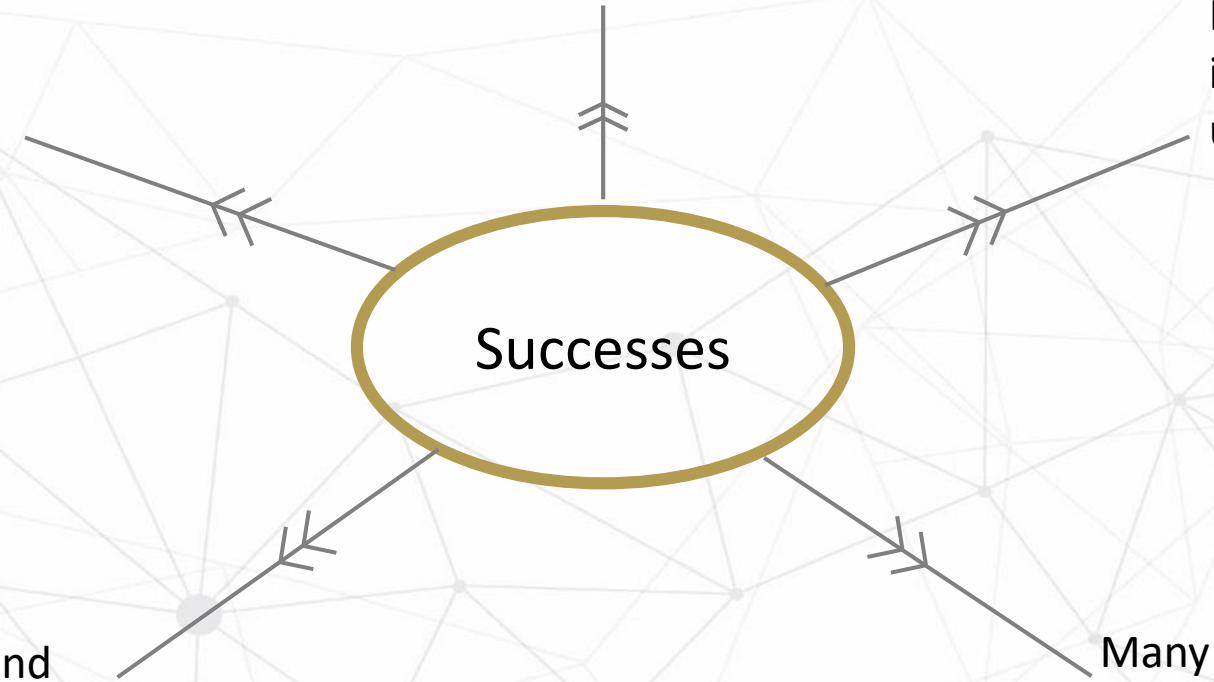
AI Competence

Result from a knoell internal survey at the beginning of roll-out:
AI competence is inhomogeneous

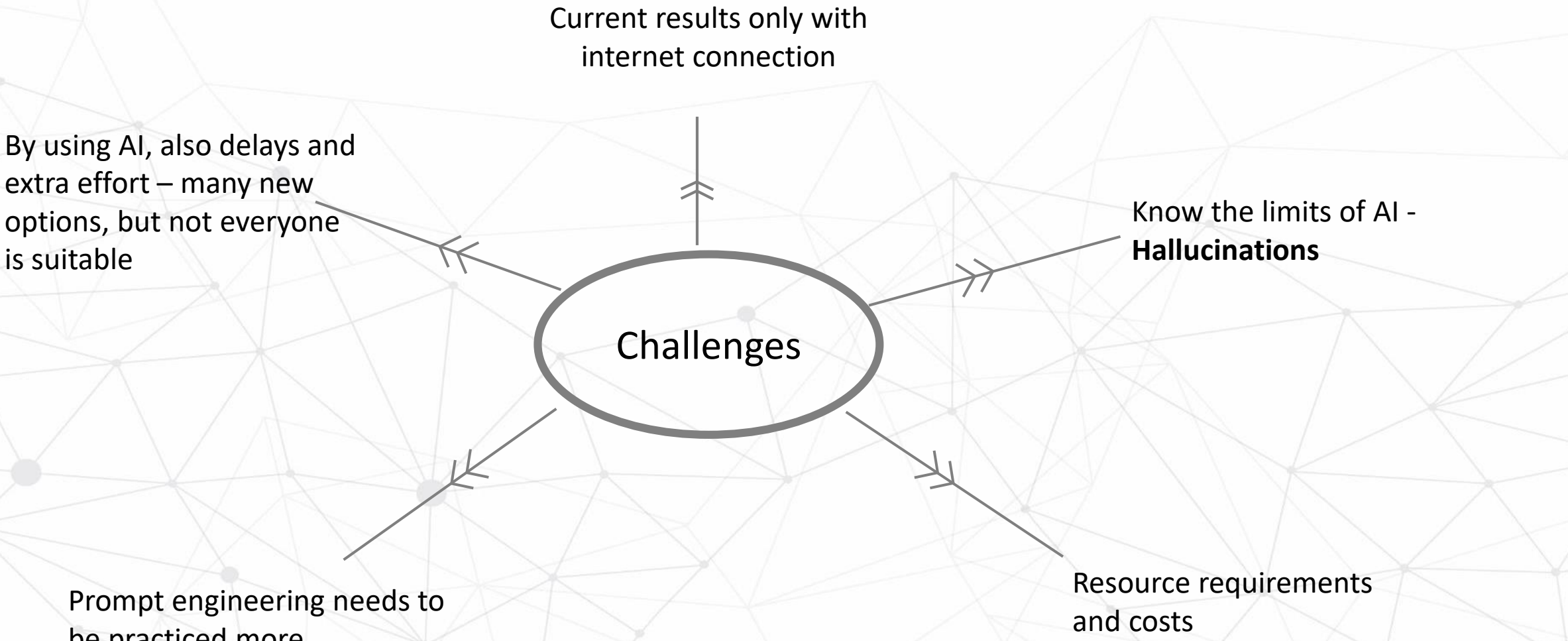
Measures:

- AI Tool Manuals
- AI Training Courses for different levels of expertise
- Application Workshops for Specialist Departments

Successes



Challenges



Conclusion

- Leveraging AI can help streamline operations and improve communication.
- Establishing specialized workflows is crucial for several key reasons:
  - Quality Assurance
  - Optimizing resource efficiency across humans and AI
- Human-Centric Roles: By automating routine tasks, workflows free up human resources to focus on higher-level analysis, strategic thinking, and quality control
  - Comprehensive training in AI fundamentals and prompt engineering is essential to empower employees to effectively collaborate with AI systems
- Provider Independence: Utilizing custom developed and on-premise tools minimizes dependency on a single AI provider and supports long-term sustainability.

→ Human interaction is necessary to ensure the correctness, completeness, and traceability of results.

→ The AI landscape is evolving rapidly, but it is essential to carefully evaluate both the costs and the benefits.

knoell Germany GmbH

Dr. Milena Stephan
Group leader
Global Regulatory Affairs – Biocontrol

E-mail: mstephan@knoell.com

www.knoell.com