

# *From risk to reliability: RISE's risk assessment analysis of AI Systems and CitCom's proposed TEF Label*

25th November 2025



Time	Session	Presenter
11.30-11.35	Welcome and Introduction	<b>David Brunelleschi, Pablo Ivankovich</b> <i>Intellera Consulting</i>
11.35-11.50	Risk assessment analysis of AI systems	<b>Kateryna Mishchenko</b> <i>RISE (CitCom.ai)</i>
11.50-12.05	CitCom.ai label for building trust among partners and clients	<b>Alessio Buscemi</b> <i>Luxembourg Institute of Science and Technology (CitCom.ai)</i>
12.05-12.25	Q&A Session	Moderated by <b>Alberto Venditi</b> <i>Intellera Consulting</i>
12.25-12.30	Closing remarks & Next steps	<b>Pablo Ivankovich</b> <i>Intellera Consulting</i>



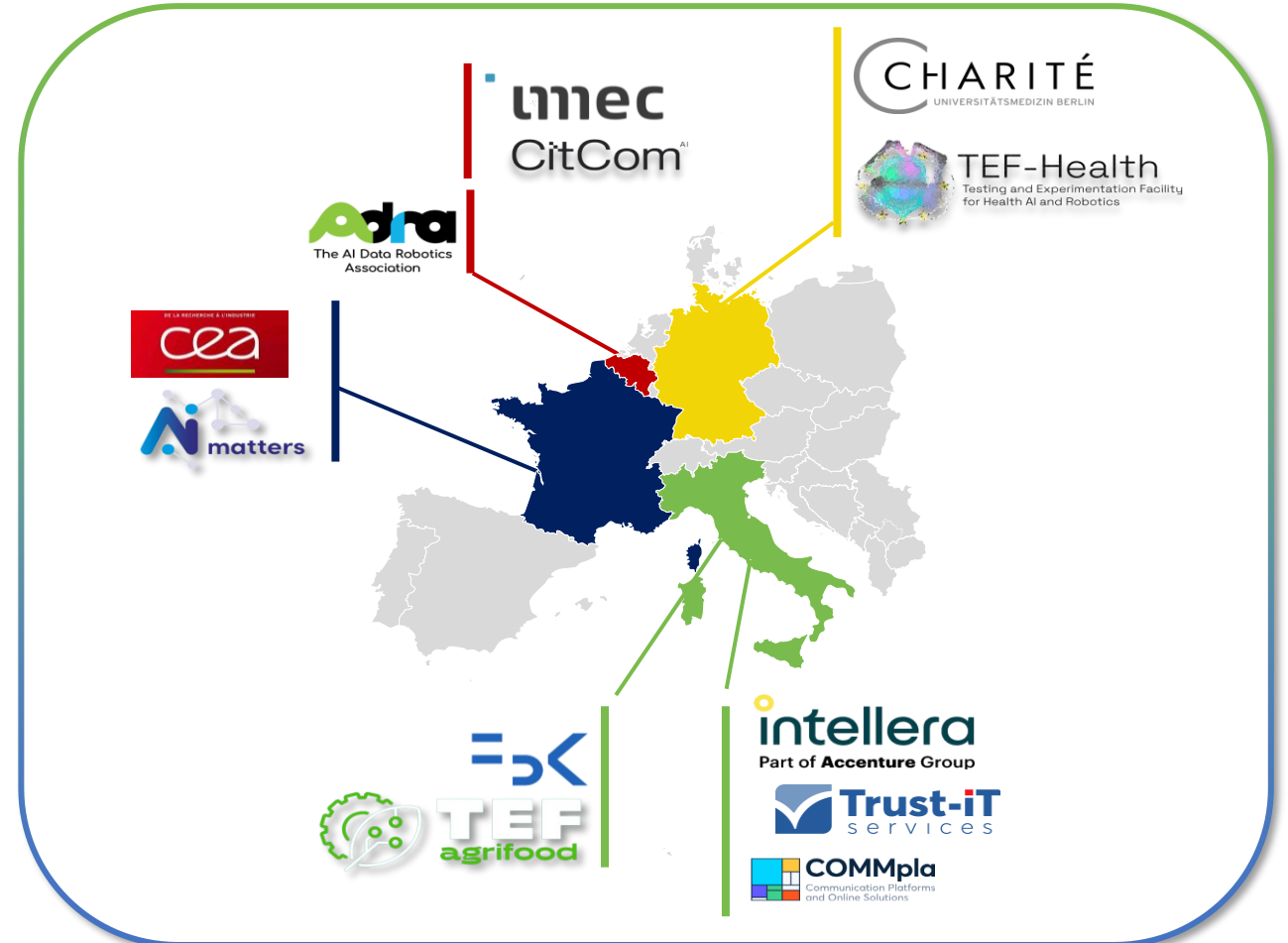
CoordinaTEF strengthens Europe's commitment to ethical AI and innovation by **uniting and coordinating AI sectorial TEFs**, amplifying their visibility, impact, and collective reach



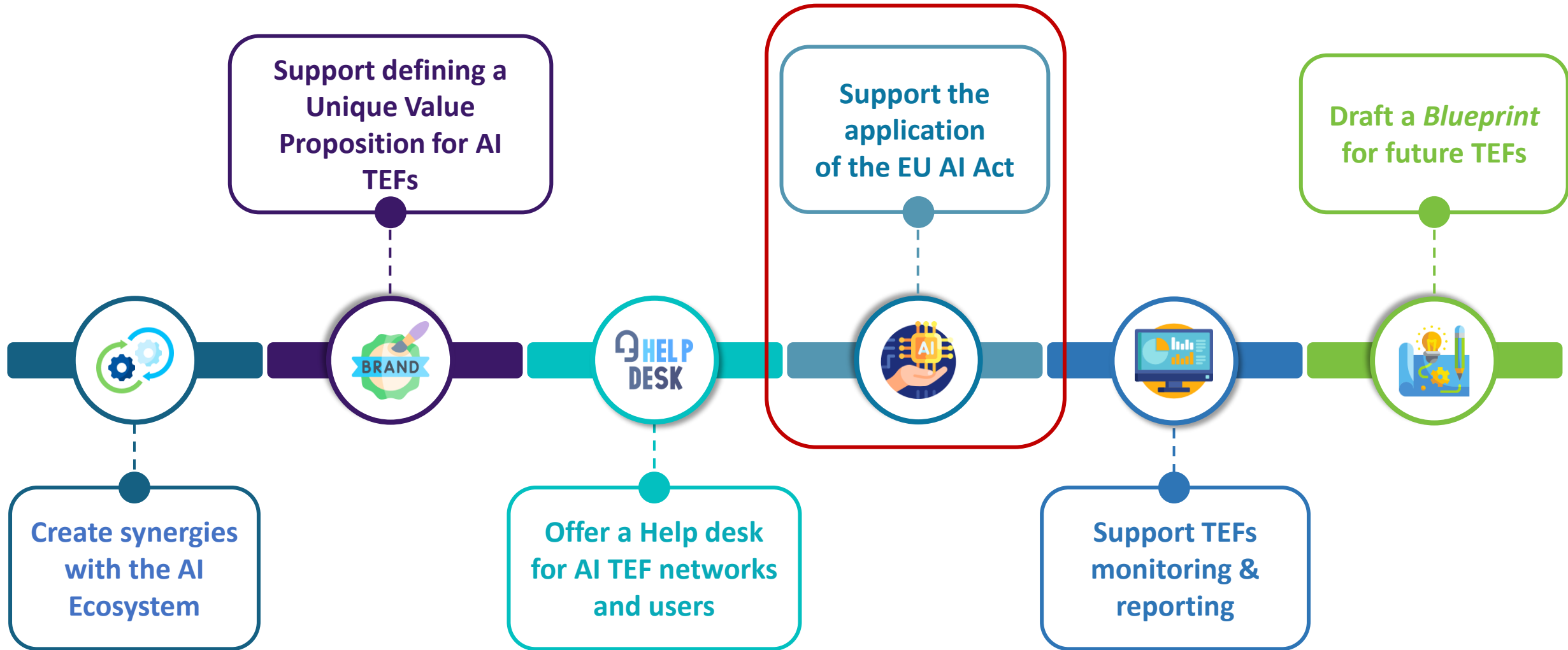
## Coordination and Support Action under the Digital Europe Programme



Consortium composed of AI sectorial TEFs coordinators and organisations providing specialised expertise to **foster synergies and drive joint efforts**



# CoordinaTEF key objectives





**COORDINATEF**  
Boosting European AI innovation, together.

# Risk assessment analysis of AI systems

*Kateryna Mishchenko*  
*RISE (CitCom.ai)*



Funded by  
the European Union



## EU Artificial Intelligence Act (Reg. 2024/1689)

Establishes harmonised rules on AI systems on a risk-based approach.

Title I. General Provisions (Art. 1–4): Defines scope, key terms, and promotes AI literacy.

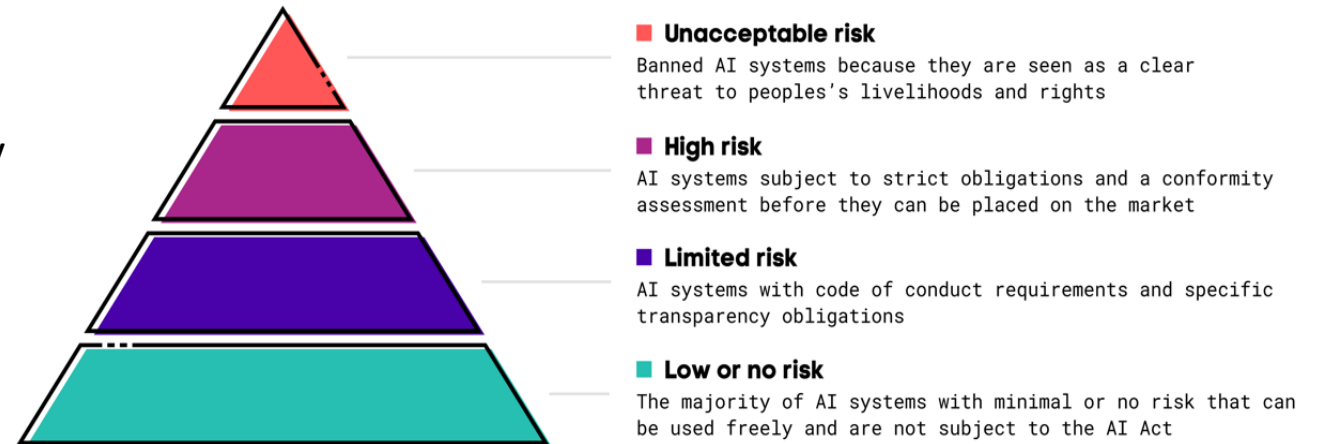
Title II. Prohibited Practices (Art. 5): Bans AI that exploits vulnerabilities, enables social scoring, or biometric ID in public.

Title III. High-Risk AI (Art. 6–43):

Requirements include:

- Risk management, data governance, documentation, transparency, human oversight, accuracy, cybersecurity,...
- Also covers provider obligations and conformity assessment.

Title IV. Transparency (Art. 50–52): AI must inform users when interacting with humans, using biometrics, or generating content.



## Purpose

Help organisations determine whether their AI systems may fall under the **High-Risk** category of the **EU AI Act** and support early preparation for compliance, <https://citcomtef.eu/services/ai-act-risk-level-evaluation>

## Scope

Applies to industrial automation, energy and utilities, critical infrastructure, mobility, agrifood, healthcare, and public-sector AI.  
Focus on classification triggers described in Articles 5 and 6, Annex I and Annex III.

## What does the service provide

- A structured methodology that translates AI Act requirements into a practical assessment, supported by relevant international and sectoral standards.
- Initial screening of model type, use case, deployment domain, risk indicators, testing approaches, and role-based obligations.
- Early insights into classification outcomes, compliance gaps, and readiness for conformity assessment.
- A foundation for informed decision-making and strategic planning for AI-based products and services.

## Service foundations

### Two-Path High-Risk Assessment Logic

#### Article 6 (High-Risk AI Systems)

##### Path A – Product-Based (Art. 6(1)(a)(b))

*“AI systems that are safety components of products, or which are themselves products, covered by the Union harmonization legislation listed in Annex I, and that are subject to a third-party conformity assessment under that legislation.”*

##### Path B – Use-Based (Art. 6(2))

*“AI systems that are intended to be used in any of the areas listed in Annex III.”*

### Standards & Reference Frameworks

**Interim:** ISO/IEC 23894, ISO/IEC 42001, ISO 12100,

**AI Act:** prEN 18286 (emerging harmonized standard)

**Complementary:** NIST AI RMF, JRC AI Watch

## Process Flow



### Tools and Inputs:

- ❖ Assessment Questionnaire (system purpose, context of use, technical design, deployment patterns, and potential regulatory triggers)
- ❖ Screening Matrix (Article 5) (prohibited use)
- ❖ Legal Mapping Template (Article 6) (high-risk identification)
- ❖ Compliance Gap Table (missing elements as RM, fundamental rights assessment, oversight mechanisms, etc)
- ❖ Actor-Role Identification Template (Provider, Deployer, Importer, or Distributor, etc)

### Deliverables:

- ❖ Preliminary Risk Classification Report summarising outcomes, rationale, regulatory references, and contextual considerations.
- ❖ Validated Questionnaire and Evidence Record including clarifications and assumptions.
- ❖ Compliance Gap Table highlighting missing or partial measures required under the EU AI Act.
- ❖ Optional Testing and Compliance Roadmap presenting further recommendations.



## Visual Quality Inspection (Manufacturing)

Deep-learning defect detection (approve/reject).

Deployment via PLCs, robotic integration, semi-automated or automated modes.

Results:

**Path A may apply if the AI acts as a safety function under Machinery Regulation (EU) 2023/1230.**

**Path B applies only in specific critical-infrastructure contexts.**

**For now: Minimal-Risk (Article 52 transparency obligations)**

<https://citcomtef.eu/news/gimic-first-to-undergo-rises-new-ai-risk-assessment-service>

## District-Heating Forecasting (Energy Infrastructure)

Forecasts heat demand, indoor temperature, and distribution delays.

Integrated with SCADA and PLCs (operator-in-the-loop).

Results:

**Path B applies: Confirmed High-Risk under Annex III.2 (critical infrastructure).**

**Path A may apply if future versions execute autonomous control functions.**

### Gimic first to undergo RISE's new AI risk assessment service



Fri, 24. Oct. 2025

By Marie Elmquist

The company Gimic develops AI-based systems for automated quality control in the manufacturing industry and is the first to undergo RISE's new Risk Assessment Analysis Service for evaluating systems in relation to the EU AI Act. The service has been developed within the framework of CITComAI TEF.

"We received a clear report showing where we stand today and what steps we need to take going forward," says Anders Cederlund, Project Manager at Gimic.

#### Supporting decision-making and strategic planning

The goal of the service is to support decision-making and strategic planning for AI-based products and services, focusing on analysis and compliance with the AI Act and other AI-related regulations.

#### AI as the final puzzle piece

Gimic develops AI-based systems for automated quality control in industrial production. Instead of an operator manually inspecting, for example, a gear to identify defects, cameras and AI models are used.

"We see our technology as the final puzzle piece in fully automated factories. Today, almost the entire production flow is automated, but the final inspection is often still manual. With our solution, the process can become fully automated."

# Risk assessment analysis framework: Challenges and Lessons Learned

1

## Limited Information Visibility and Documentation

Providers often hesitate to share technical or deployment details, even under NDA.

Deployment information is frequently incomplete or undocumented, making classifications conditional and dependent on actual use cases.

2

## Uncertainty in Applying Article 6 (Path A / Path B)

Determining whether AI is a **safety component** under the Machinery Regulation (Path A) or falls within **critical-infrastructure domains** under Annex III (Path B) remains difficult.

Ambiguous Annex III wording complicates borderline cases, especially for industrial control systems.

3

## Strong Dependence on Deployment Context

Classification outcomes rely more on **where and how** the AI system is used than on its core function.

Technical integration into robotics or control systems can elevate risk under **Article 6(2)**.

4

## Lack of Harmonised Standards and Compliance Pathways

Harmonised AI Act standards are not yet available and providers struggle to demonstrate compliance (e.g., robustness, accuracy, cybersecurity).

Interim reliance on **ISO 23894**, **ISO 42001**, **IEC 62443** offers procedural support, and the forthcoming **prEN 18286** will be central for conformity.

5

## Questionnaire and Methodology Practicalities

Designing universally applicable questions is challenging; many items cannot be answered with simple yes/no choices.

The structured, stepwise process (screening → classification → obligations mapping) improves traceability but requires time and customer engagement.

6

## Customer Awareness, Expectations, and Sensitivity

Many organisations remain unaware of the AI Act and underestimate their likelihood of falling into the High-Risk category.

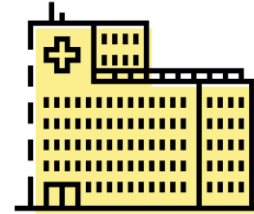
Customers expect not only classification results but also practical guidance on compliance.

Risk classification reports can be sensitive, especially in critical sectors, requiring attention to confidentiality and contractual arrangements.

- ❖ CitCom TEF continues to develop the Risk Classification Analysis Service, extending it into new application sectors.
- ❖ The service will be adapted to upcoming harmonised standards, new secondary legislation, and related EU directives.
- ❖ Expansion to other TEFs (Health, AgriFood) is planned, requiring additional work on identifying and integrating sector-specific standards.
- ❖ The full report on Risk Classification has been prepared at CitCom.
- ❖ A scientific article on the challenges of risk classification for industrial and ICS-related AI systems is under development.

Please, reach out to us for any further details concerning the service!

## ❖ TEFs at RISE



Health



AgriFood



Smart and sustainable  
cities and societies

CitCom<sup>AI</sup>



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Boosting European AI innovation, together.

# CitCom.ai label

*Alessio Buscemi*

*Luxembourg Institute of Science and Technology (CitCom.ai)*



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- The municipal administration of Luxembourg City was experimenting with a third-party provider a citizen-facing chatbot to operate as the first line of interaction between residents and municipal services.
- Before releasing the chatbot, the administration requested LIST to perform an assessment of social biases, focusing on whether the system treats different groups equitably and avoid harmful stereotypes
- a
- The goal was to verify that the chatbot behaves consistently across equivalent prompts, does not make group dependent assumptions, and provides accurate, neutral, and actionable guidance to all citizens.
- Therefore, using our AI Sandbox, we conducted an extensive bias assessment of the chatbot using use case relevant challenges co-designed with the City administration
- We initially identified a few issues, which were solved with the addition of safety guardrails

- 1. How can the City ensure that the positive results of this one-off bias assessment can be reproduced consistently in future updates or in other municipal chatbots?**
- 2. How can third-party providers and municipalities demonstrate to citizens that such bias testing meets a recognised, minimum standard rather than relying on an ad-hoc evaluation?**
- 3. How can policymakers and administrators communicate transparently that the chatbot has passed a trustworthy and independently verifiable assessment, beyond simply stating that “the issues were fixed”?**



AI labels are a way solve the communication gap between technical and non-technical stakeholders [1]:

## Make AI understandable

Translate complex technical details into clear, visual summaries for non-experts.

## Bridge communication gaps

Help technical and non-technical stakeholders make shared, informed decisions.

## Increase transparency and trust

Show key performance, data, and robustness indicators clearly.

## Promote responsible use

Highlight ethical and sustainability aspects like fairness and energy efficiency.

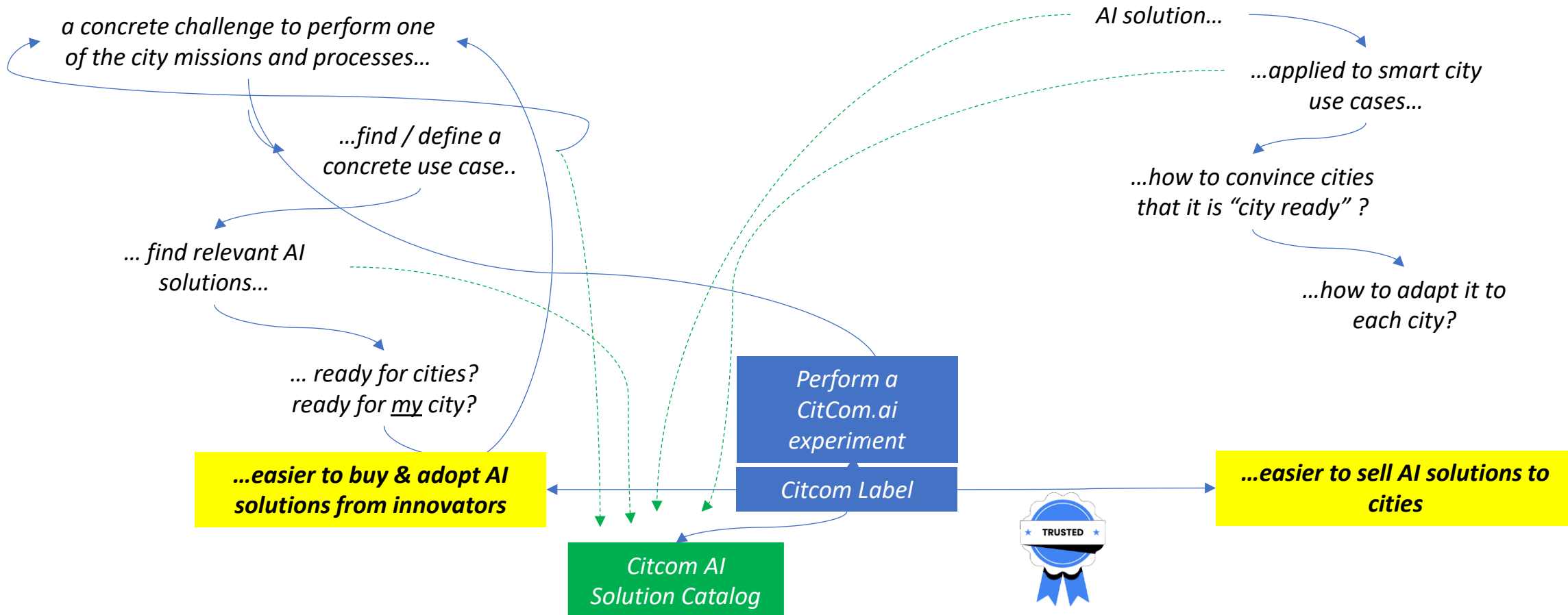
## Support better governance

Offer insights that complement detailed AI documentation.

# CitCom.ai: where cities and AI innovators find each other ..... and create mutual trust

## City Journey

## AI Innovator Journey





- We have identified key deliverables to guide the next phase of development:

- **Launch of the AI Assessment catalogue**
- **Formalisation of Guidelines and Evaluation Reports**
- **Creation of the Citcom Label**
- **Pilot Implementation**

- A fundamental step before the actual creation of the catalogue, is the identification of categorisation guidelines for testing solutions, in a way that allows easy matching with the use cases requiring the assessment
- This are the criteria we identified:

## Current assessment capabilities across Citcom

Solution name	Provider	Licensing Type	Project Phase/ TRL	Domain of Application	Ethical Dimensions	Security & Securitization of Data	Assessment Type	Example of use case	Resources
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## Citcom experiments requiring AI Assessment

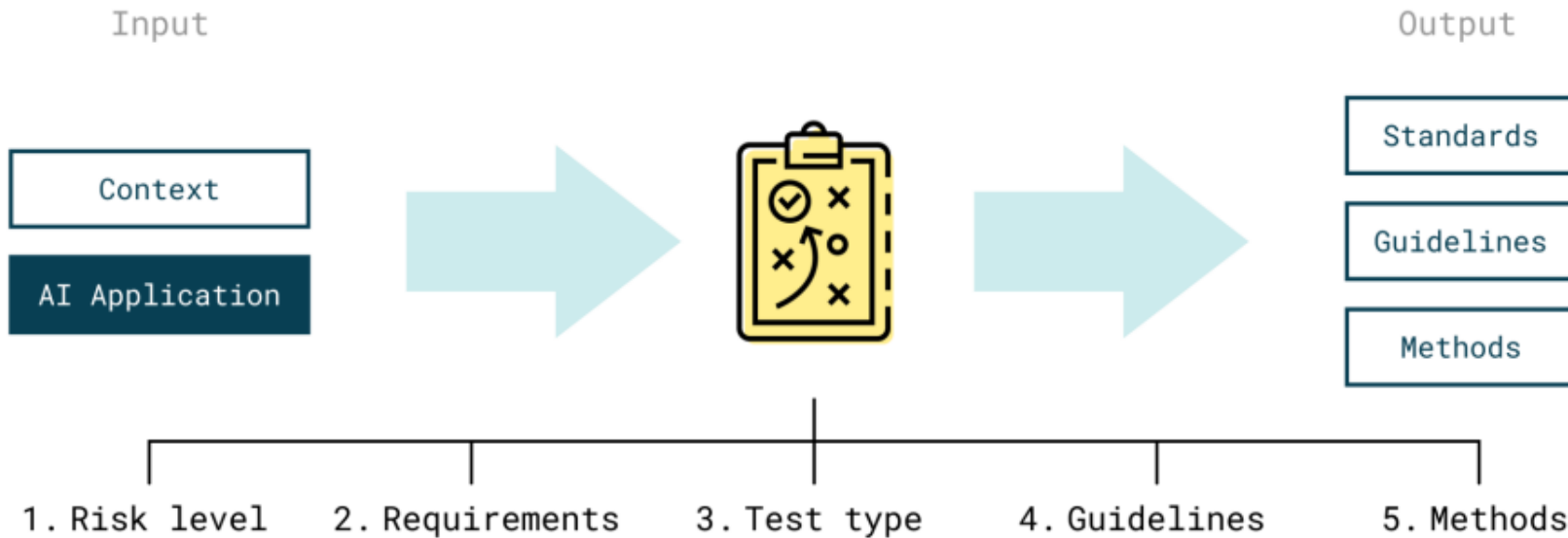
Experiment	City	Description	AI Innovator	Project Phase/ TRL	Assessment requirements	AI Risk Category	Ethical Dimensions	Security & Securitization of Data	Assessment Type	Resources
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- The next step is to create the actual catalogue collecting all assessment solutions operated by Citcom partners

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- LIST and RISE started the mapping from legal requirements to methods, based on RISE's methodology\*



- In our soon-to-be-released paper, we work on identifying:








Requirements

Sources

Assessment Dimensions

\*Mowla, N. et al., (2024). *From AI Act to structured testing of AI systems*. RISE Research Institutes of Sweden.

- We identified 11 categories of requirements that capture the key dimensions of AI trustworthiness & compliance
- The starting point was the 7 principles of Trustworthy AI defined by the European Commission's HLEG:

 <b>Human agency and oversight</b>	 <b>Robustness and safety</b>	
 <b>Privacy and data governance</b>	 <b>Transparency</b>	 <b>Accountability</b>
 <b>Fairness, diversity &amp; non-discrimination</b>	 <b>Societal and environmental well-being</b>	

- To complement these ethical foundations with more operational and procedural dimensions, we added 4 additional categories corresponding to key obligations introduced by the AI Act:

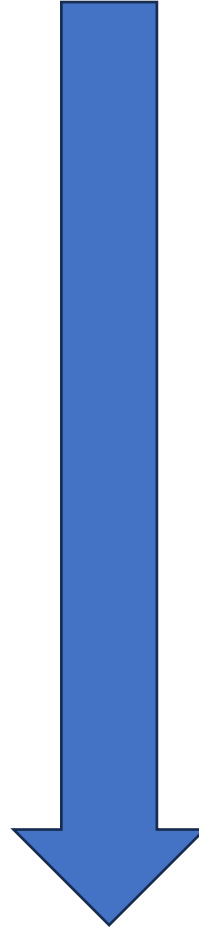
 <b>Quality management</b>	 <b>Risk Management</b>
 <b>Technical Documentation</b>	 <b>Record-keeping</b>

# Sources for controls and testing methods

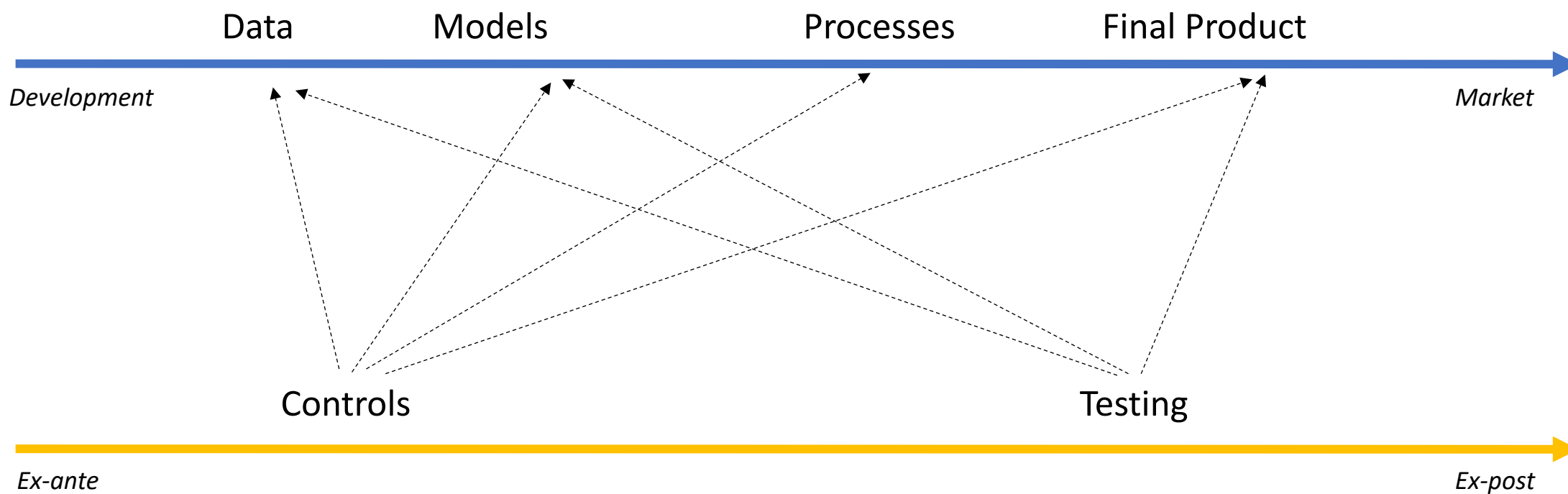
Binding or quasi binding  
regulatory sources  
(AI Act, GDPR etc.)

International standards or  
authoritative guidance  
(ISO, GPAI Code of Practice,  
ISACA etc.)

Recognised and highly cited  
scientific work



## AI Traceability



## Type of assessment

- We have identified key deliverables to guide the next phase of development:
  - **Launch of the AI Assessment catalogue**
  - **Formalisation of Guidelines and Evaluation Reports**
  - **Creation of the Citcom Label**
  - **Pilot Implementation**

- **Value proposition:** Independent third-party assessment of AI trustworthiness, with **non-binding compliance recommendations** to guide cities and procurement officers.
- **Badging system:** Result-specific badges awarded to innovators, with granularity based on market needs.
- **Credibility & thresholds:** Consistent credibility across badges ensured by harmonised guidelines and case-by-case expert evaluation.
- **Badge infrastructure:** Timestamped, tamper-proof badges linked to the Citcom Hub for verification, transparency, and metadata access.
- **Reporting & visibility:** Harmonised evaluation reports with **legal disclaimers**; public list of participating AI innovators hosted on the Citcom Hub.

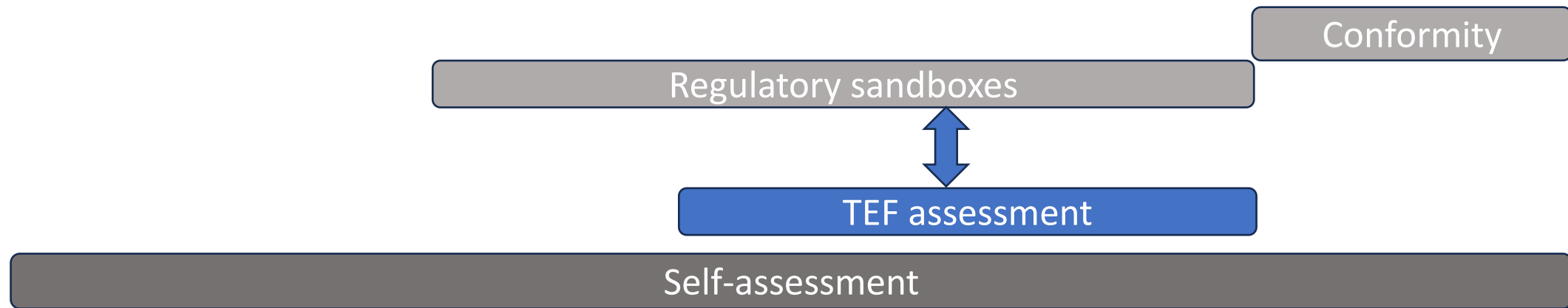


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Start Dev

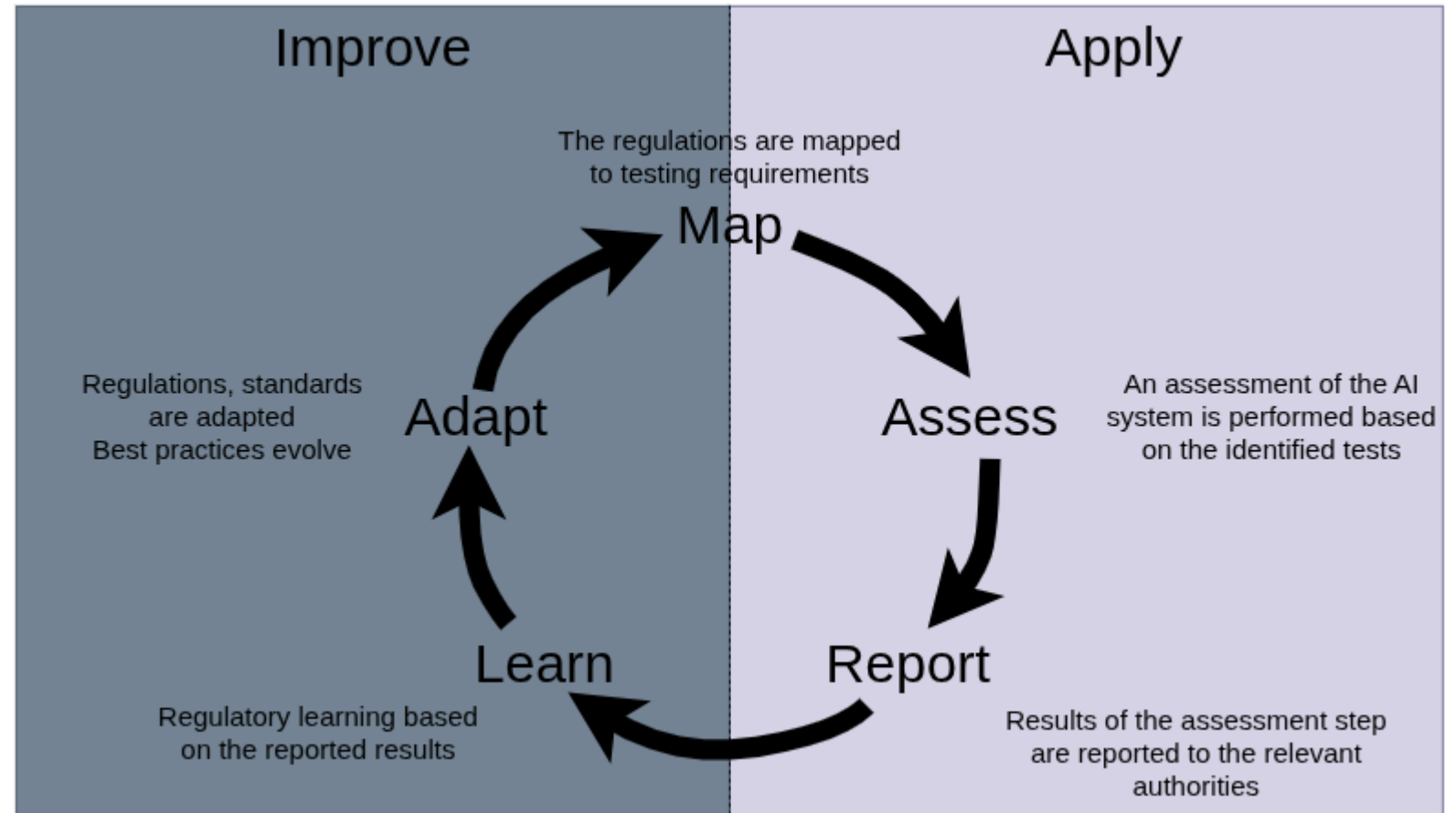
Product Maturity

Prod



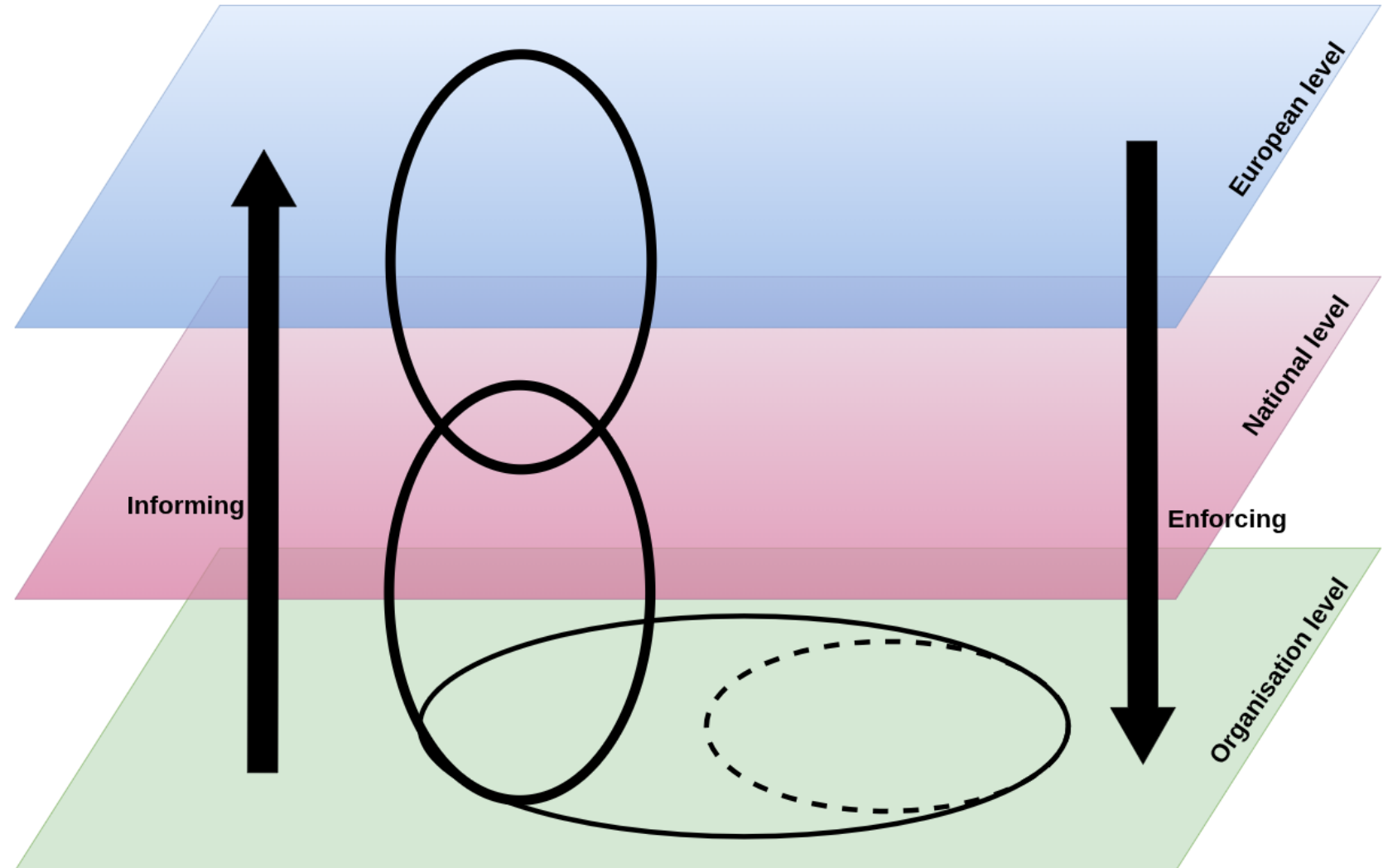
- We believe that TEF assessment could be also valuable with respect to AI Regulatory Sandboxes (AIRSes)
- The AI Act (Art. 58(2)(i)) explicitly mandates that AIRSes should *"facilitate the development of tools and infrastructure for testing, benchmarking, assessing and explaining dimensions of AI systems [..]"*
- Testing tools, thresholds, and result interpretations must be adapted to the specific sector and use case
- TEFs could serve as preferred partners for Competent Authorities seeking external technical expertise to carry out assessments in Regulatory Sandboxes within their respective domains

- Drawing from discussions and personal experience with regulators and legal experts, fostering effective communication between technical and legal professionals remains a major challenge.
- This dialogue is essential for practitioners to correctly interpret legal requirements and to foster regulatory learning, a key principle introduced by the AI Act.
- For this reason, within the Luxembourg AI Factory, we developed **MARLA**, a high-level framework designed to identify and structure the various stages of this cycle.



**MARLA** can be implemented on three complementary levels:

- **Organisational level:** to support internal learning and continuous improvement within companies or institutions.
- **National level:** to enable regulatory learning and structured dialogue with competent authorities.
- **European level:** to promote alignment, knowledge exchange, and coherence across Member States.

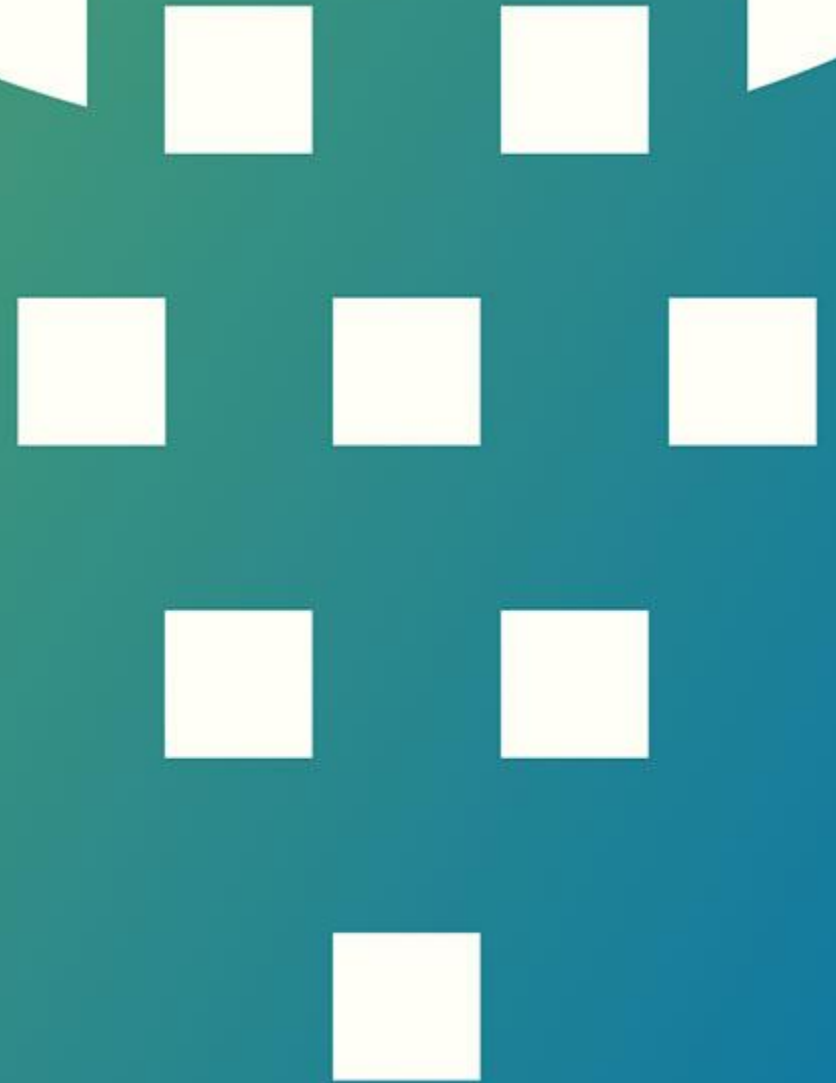


- The Citcom label is conceived as an independent third-party evaluation of AI trustworthiness, offering non-binding compliance recommendations to guide cities and procurement officers in their decision-making.
- It can serve as a blueprint for other TEFs
- The assessments conducted within the TEFs can serve as a benchmark in the European AI landscape for the sectors they cover.
- To ensure coherence and complementarity across domains, other TEFs are encouraged to contribute to the refinement of the assessment guidelines.
- Where sector-specific regulations apply, their additional requirements can be mapped and integrated into the proposed methodology.

# Q&A Session



# Closing remarks & Next Steps





1

Set up of a **working group** on **AI Regulatory Sandboxes** to establish connections among AIRS & TEFs

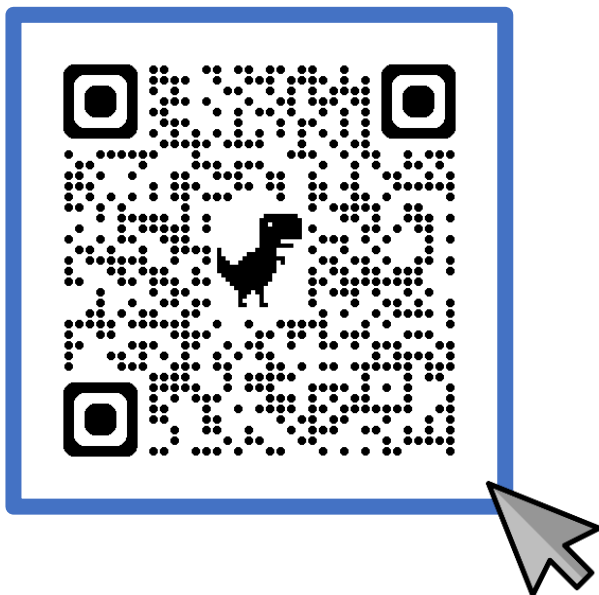
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Collection of **further TEF Consortia members compliance practices** thanks to the Workshop.

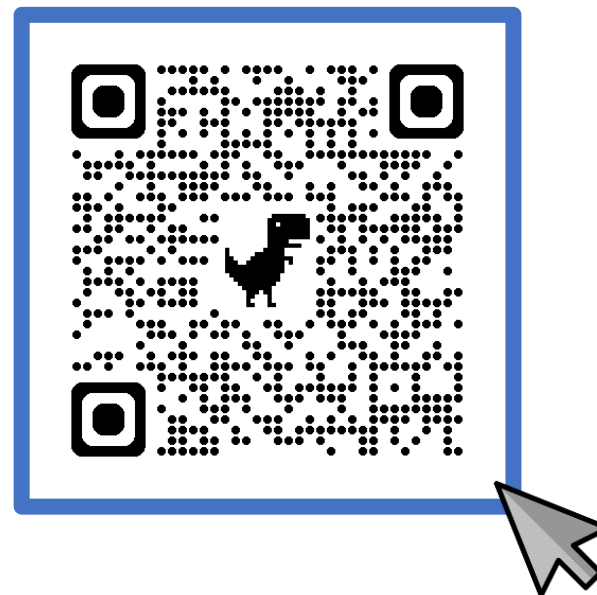
Engage with us and share your practices!

3

Development of a **common compliance framework** for TEFs in order to ensure **compliance** with the AI Act



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Thank you!