



Sandbox IA

EXIT REPORT

SPANISH ARTIFICIAL INTELLIGENCE
SANDBOX PILOT

EXECUTIVE SUMMARY



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Ministry for Digital Transformation and the Civil Service

EXECUTIVE SUMMARY

The entry into force of Regulation (EU) 2024/1689 marks a turning point in the development and governance of artificial intelligence in Europe.

For the first time, providers, deployers and public authorities have a common regulatory framework to ensure that AI systems are developed and used safely, transparently and with due regard for fundamental rights.

However, putting this new framework into practice poses significant technical, organisational and governance challenges that require specific expertise, methodologies and tools.

To anticipate these challenges, Spain launched Europe's first AI regulatory sandbox, a pioneering initiative designed to translate the requirements of the Regulation from the regulatory framework into the reality of organisations developing and deploying high-risk AI systems.

THE SANDBOX AT A GLANCE

What was it?

A controlled testing environment where real organisations addressed the challenges of adapting to a complex regulatory framework.

What was its purpose?

To reduce uncertainty for companies and generate practical knowledge for the wider AI ecosystem.

For over a year, eleven organisations from different strategic sectors took part in a controlled testing environment where they could assess their systems, apply the technical guidelines developed by the public administration, identify adaptation needs and generate practical evidence on the future application of the Regulation.

At the same time, the experience helped validate and improve these guidelines, generate useful knowledge for future supervisory authorities and develop a methodology that can be replicated in future regulatory sandboxes.

KEY OBJECTIVES OF THE PILOT

- **Validate** the technical guidelines through real-world use cases.
- **Identify** the main implementation challenges.
- **Improve** the available methodological tools.
- **Generate knowledge** for companies and public bodies conducting future sandboxes.

This report presents the main results of this collective experience. Beyond describing the activities carried out, it summarises the lessons learned, identifies the main challenges faced by participating organisations and provides the ecosystem with a set of conclusions that may inform future national and international initiatives.

The results show that the main challenge for organisations lies not only in understanding the obligations set out in the Regulation, but in effectively integrating them into their internal processes, governance structures and control mechanisms.

KEY LESSON

The greatest challenge was not understanding the Regulation, but translating its requirements into processes, documented evidence and governance mechanisms that could be applied systematically across organisations.

The experience also shows that **organisational maturity and system complexity have a greater impact on the adaptation process than the size of the organisation.**

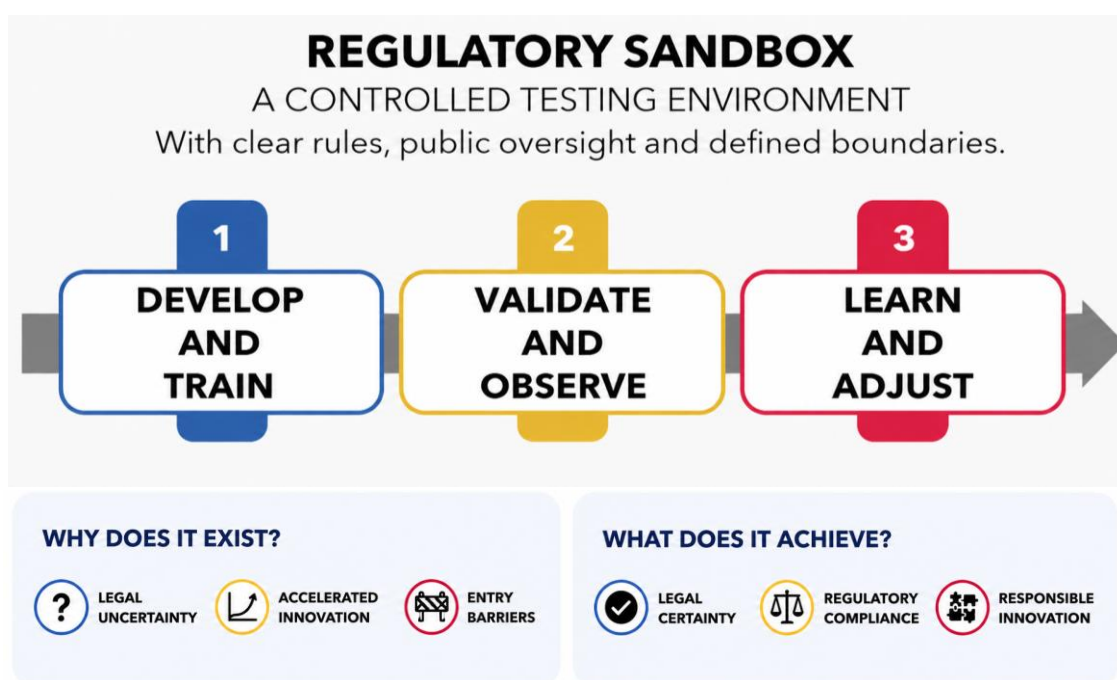
The pilot also highlighted the value of collaboration between public administrations, companies, independent experts and future supervisory authorities. This approach created a shared learning environment that helped improve both the technical guidelines and the supervisory mechanisms provided for in the Regulation.

1 THE SANDBOX IN CONTEXT

Before the final adoption of the European Artificial Intelligence Regulation, Spain launched a controlled testing environment to anticipate how the new requirements could be applied in practice and identify potential challenges for organisations.

The pilot, structured through Royal Decree 817/2023, allowed organisations with real systems to work on future regulatory requirements using the technical guidelines developed by SEDIA as a reference framework.

Its objective was twofold: to help organisations understand and apply regulatory requirements in practice, while generating knowledge to improve the guidelines and prepare authorities and the ecosystem for the implementation of the Regulation.



This experience anticipated the regulatory sandbox model provided for in the European Artificial Intelligence Regulation.

AN EXPERIENCE WITH REAL- WORLD SYSTEMS

The pilot selected **12 high-risk AI systems**, 11 of which completed the process. They represented organisations of different sizes and from different sectors subject to regulatory requirements.

The diversity of participants made it possible to observe how the guidelines were applied across different technological and organisational contexts, and to assess which factors actually influence the effort required to move towards regulatory compliance.

12

selected systems

11

completed the pilot

5

areas of application



MEDICAL DEVICES



ACCESS TO BENEFITS AND SERVICES



**MACHINERY AND CRITICAL
INFRASTRUCTURE**



BIOMETRICS



EMPLOYMENT

HOW THE PILOT WAS CONDUCTED

The Sandbox was designed as a progressive learning and adaptation process in which participating organisations could assess their AI systems against regulatory requirements, identify gaps and implement specific measures to move towards compliance.

The process combined training, assessment, specialised support and practical implementation. This approach allowed the technical guidelines to be tested against real systems and provided practical insight into the difficulties encountered during implementation. At the same time, the pilot served a dual purpose: helping organisations prepare for the new regulatory framework while generating evidence to improve the tools and methodologies used.

A COLLABORATIVE MODEL

The pilot was based on a collaborative model bringing together public administration bodies, mentoring teams, independent experts and market surveillance authorities.

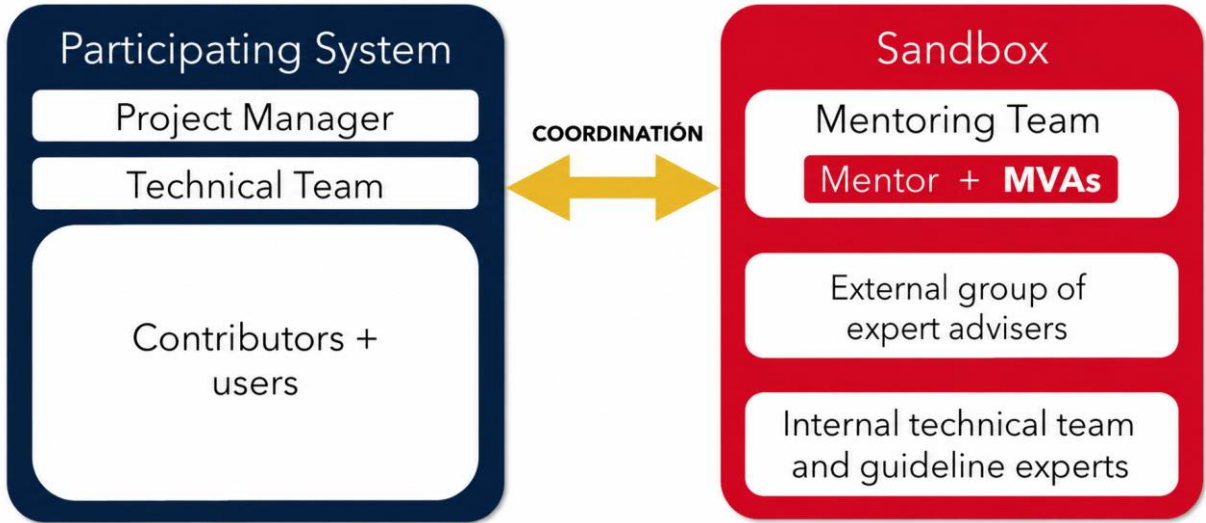
The SEDIA provided the strategic direction and overall coordination of the Sandbox, while participating organisations applied the guidelines to their systems, identified gaps and implemented the necessary adaptation measures.

Throughout the process, organisations received support from mentoring teams and specialised expertise from the advisory group and market surveillance authorities.

This combination of capabilities allowed the process to be approached from different perspectives, creating a shared learning environment across organisations, public administration, expert knowledge and supervision.

**SEDIA · PARTICIPATING ORGANISATIONS ·
MENTORING TEAMS · ADVISORY GROUP · MARKET
SURVEILLANCE AUTHORITIES**

SANDBOX GOVERNANCE MODEL



Governance and collaboration model of Spain's first AI Sandbox pilot.

The governance model structured the relationships between participating organisations and the different support and supervisory teams, defining responsibilities, coordination channels and support mechanisms throughout the different stages of the pilot.

TECHNICAL GUIDELINES AS A WORKING TOOL

The technical guidelines were the Sandbox's main methodological tool. Developed by SEDIA, they provided a common framework for interpreting the regulatory requirements applicable to high-risk AI systems and translating them into processes and systems within participating organisations.

Using these guidelines, organisations could assess their starting point, identify potential compliance gaps and define the measures needed to move towards adaptation.

The guidelines covered the main requirements set out in the Regulation: risk management, data governance, technical documentation, records, transparency, human oversight, accuracy, robustness and cybersecurity, and post-market monitoring.



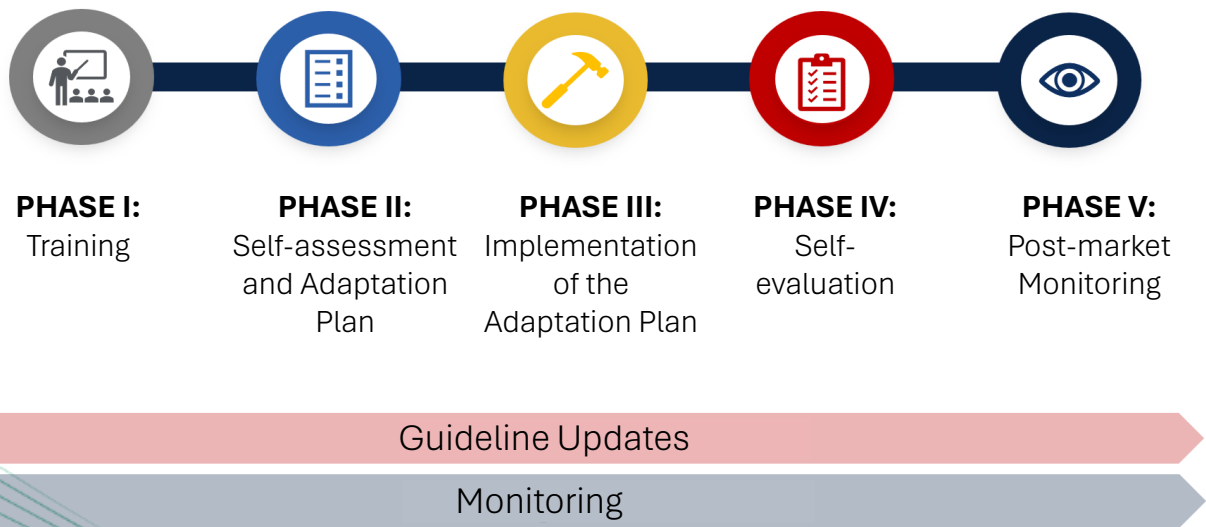
However, their role was not limited to providing guidance to participating entities. Applying the guidelines to real-world systems also made it possible to assess their practical usefulness and identify areas of difficulty and opportunities for improvement.

The knowledge generated during the pilot was subsequently incorporated into the revision of the guidelines, turning the experience of participating entities into a transferable outcome for the ecosystem as a whole.

The guidelines worked in both directions: they supported participating entities in adapting to the requirements while, at the same time, being enriched by the experience gained through their practical application.

A STRUCTURED FIVE-PHASE PROCESS

The pilot was carried out through five successive phases, from initial training to post-commercialisation monitoring. Throughout the process, the guidelines were applied consistently across participating entities and updated based on the experience gained.



4 PILOT RESULTS

WHAT HAPPENED DURING THE SANDBOX?

MOST of the planned measures were implemented and documented

87.8 %

QUALITY

83.9 %

CYBERSECURITY

82 %

DATA

The pilot made it possible to move from assessment to implementation and to identify, in real-world systems, where the main challenges and adaptation needs arose.

AN ADAPTATION SHAPED BY CONTEXT

The analysis of the Sandbox results shows how organisations with different characteristics, capabilities and systems approached the practical application of the technical guidelines and the measures set out in their adaptation plans.

The diversity of participating systems made it possible to analyse the results using two main variables: **the size of the organisations and their sector of activity**. This comparison revealed differences in perceived difficulty, adaptation needs and the effort required throughout the process.

The results show that **organisation size alone does not explain the differences observed in the adaptation process**.

The application of technical requirements was more strongly influenced by the sector of each system, while the effort required to move towards compliance was related to factors such as system complexity and organisational maturity.

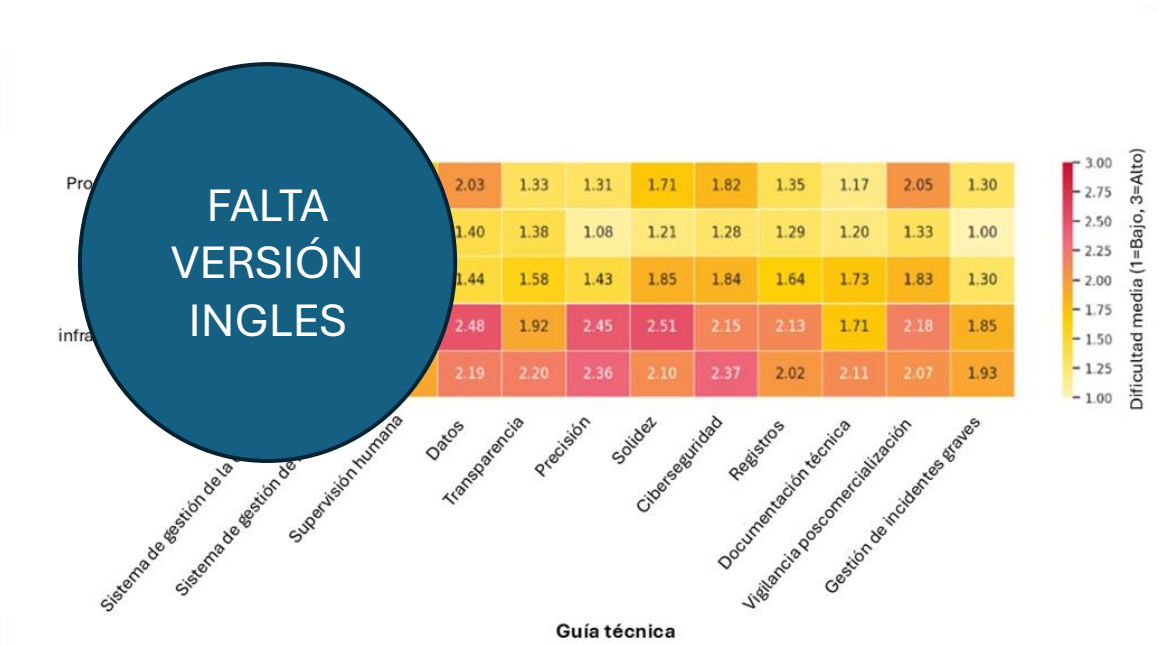
Adaptation effort does not depend solely on organisation size: sector, system complexity and organisational maturity emerged as particularly relevant factors.

WHERE WERE THE MAIN CHALLENGES IDENTIFIED?

During the self-assessment phase, participating organisations assessed their position against the measures set out in the technical guidelines and identified the areas requiring the greatest adaptation effort.

The results show that **perceived difficulty was not uniform across requirements or participating sectors**. The specific characteristics of each field of activity, existing regulatory frameworks and the nature of the systems influenced how easily organisations were able to address the proposed measures.

This diversity highlights that applying a common regulatory framework does not necessarily require the same level of effort from every organisation. **The starting point and specific context play an important role in the capacity to adapt.**

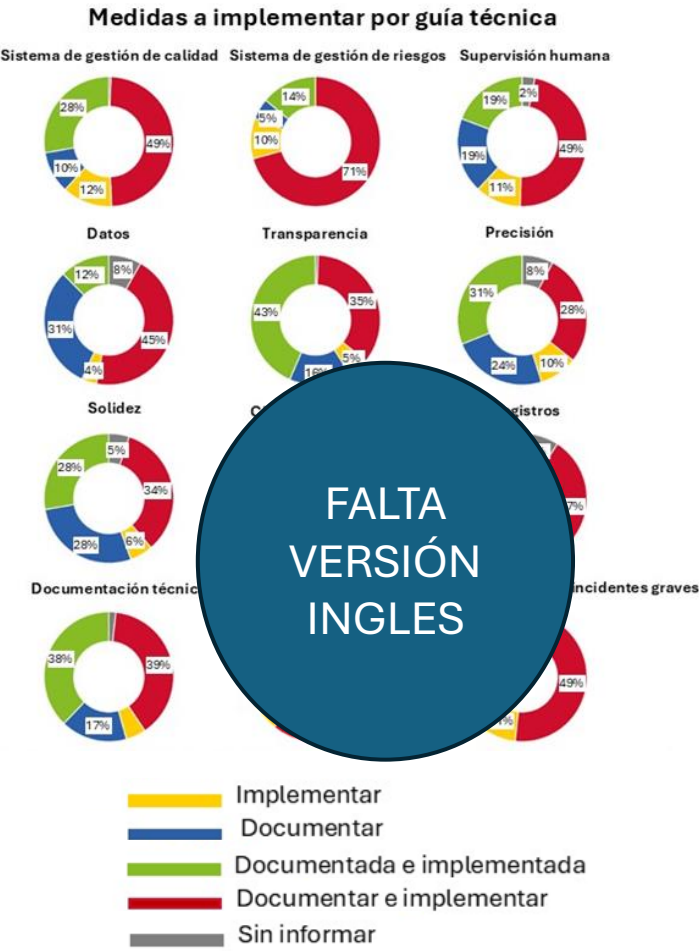


Average perceived difficulty by sector and technical guideline

FROM ASSESSMENT TO ADAPTATION

The self-assessment made it possible to translate the initial assessment into specific adaptation plans for each system. Based on the gaps identified, participating organisations defined the measures to be addressed, setting priorities, resources and timelines for implementation.

The number and nature of these measures varied across systems and requirements, reflecting different starting points and levels of maturity. The aggregated analysis helps identify the areas where the greatest adaptation needs were concentrated and provides an initial indication of where organisations may need to focus their efforts when addressing the requirements applicable to high-risk AI systems.



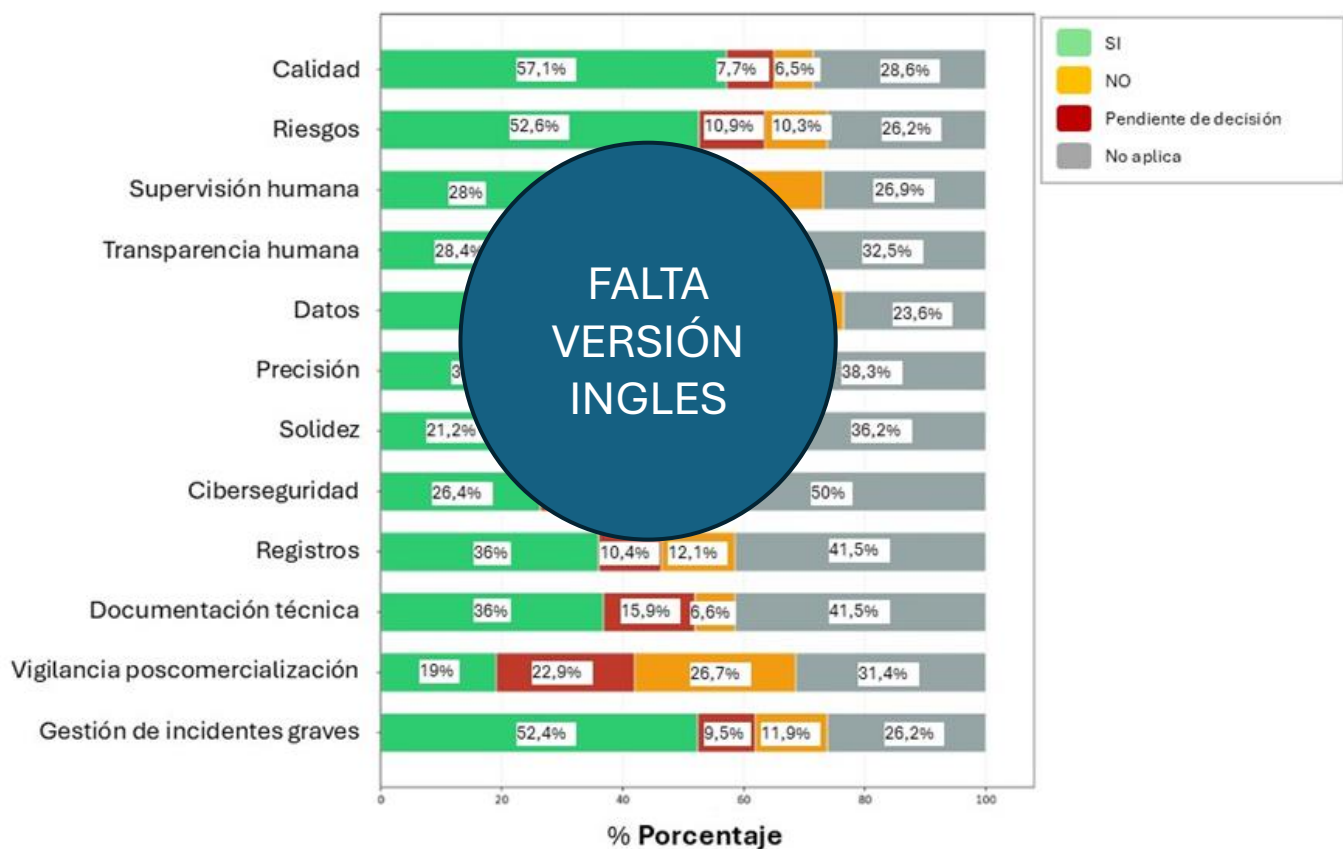
The self-assessment made it possible to translate regulatory requirements into specific adaptation roadmaps for each system.

SIGNIFICANT PROGRESS IN IMPLEMENTATION

Following the definition of the adaptation plans, participating organisations moved forward with implementing the identified measures and generating the processes, documentation and evidence required to demonstrate their implementation.

The results show **significant progress in the implementation of the adaptation plans**. Most organisations were able to implement and document a substantial proportion of the planned measures, although differences remained depending on the nature of the systems, the sectoral context and the organisational capabilities available.

The experience also showed that regulatory adaptation involves more than introducing technical changes to systems. A significant part of the work required developing formal processes, generating documentation, assigning responsibilities and incorporating governance mechanisms within organisations.



Estado de las medidas a abordar por requisito.

ADAPTATION EFFORT

One of the objectives of the analysis was to estimate the effort required to put the adaptation measures into practice.

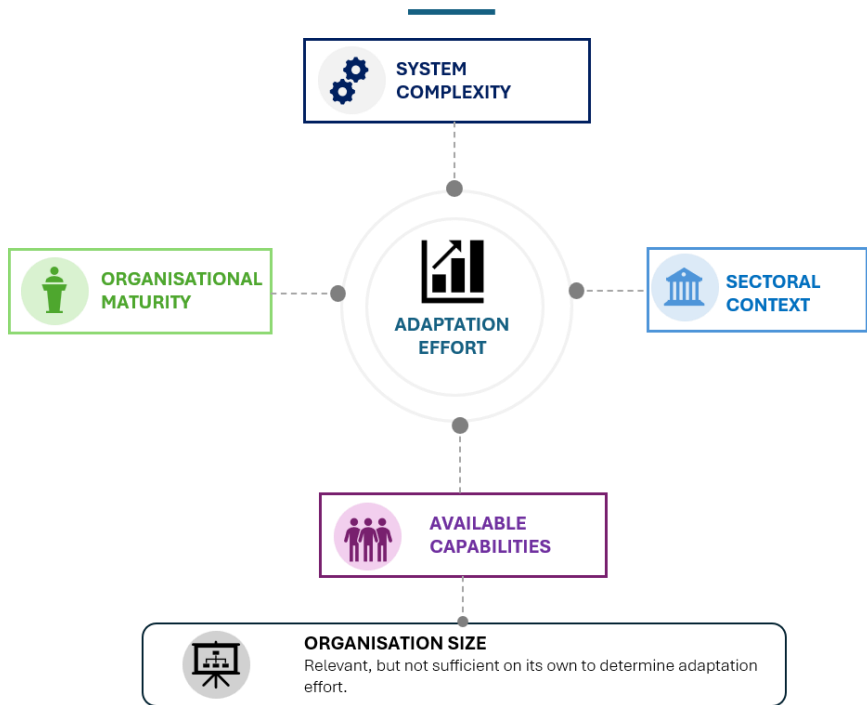
This effort cannot be understood solely in terms of time: it also depends on **system complexity, available capabilities and the level of maturity of existing processes within each organisation.**

The results show that **greater organisational size does not necessarily make the adaptation process easier.**

Organisations with larger structures may have more specialised resources, but they also manage systems, processes and organisational structures of greater complexity.

Overall, the experience indicates that **the complexity of the AI system and organisational maturity are relevant factors in understanding the effort required**, beyond an assessment based solely on organisation size.

WHAT SHAPES ADAPTATION EFFORT?



POST-MARKET MONITORING: FROM DESIGN TO INTEGRATION

The post-market monitoring phase examined how monitoring mechanisms could be integrated once systems were operating in a real-world environment.

The experience showed that one of the main challenges lies not only in designing these mechanisms, but in **integrating them effectively into organisations' processes and structures**. This means defining responsibilities, establishing monitoring procedures and ensuring that the information collected can be used to identify incidents, changes or new risks during system operation.

The lessons learned also reinforce the idea that regulatory compliance should be understood as **an ongoing process, rather than one that ends with the system's initial adaptation**.

Adaptation does not end with deployment: monitoring must become part of the system's day-to-day operation.

5 CONCLUSIONS

The first AI Sandbox pilot made it possible to apply the requirements of the European regulatory framework to real systems, identify their practical implications and generate useful knowledge for organisations and public administrations.

FROM REGULATION TO PRACTICE

Adaptation requires more than technical adjustments: it involves reviewing processes, generating evidence, defining responsibilities and incorporating control and monitoring mechanisms.

GUIDELINES: SUPPORT AND LEARNING

The guidelines helped steer the adaptation process and identify gaps. Applying them to real-world cases also helped identify difficulties and improve their interpretation.

ADAPTATION ACCORDING TO THE STARTING POINT

Adaptation effort varies according to each organisation's starting point. **System complexity, sector and organisational maturity** influence the path taken and the adaptation needs of each organisation.

TRANSFERABLE KNOWLEDGE

The challenges, good practices and needs identified provide useful knowledge for other organisations, future sandboxes and the application of the European AI Regulation.

The Sandbox's main legacy is not only anticipating the application of the Regulation, but generating practical knowledge on its real-world implementation.

