



EU Regulatory Sandboxes for AI (EUSAiR)

Roadmap

March 2025

EUSAiR in a Nutshell

The AI Act mandates that Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at the national level. AI regulatory sandboxes are controlled environments for innovation, facilitating the development, training, regulatory testing, and validation of innovative AI systems before they are placed on the market.

EUSAiR is a two-year project funded by the European Union’s Digital Europe program, working in cooperation with the AI office to support the implementation of AI regulatory sandboxes across the EU. This initiative aims to foster AI innovation and competitiveness, improve legal certainty for innovators, and facilitate regulatory compliance with the AI Act.

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Concept

“AI is a rapidly developing family of technologies that requires regulatory oversight and a safe and controlled space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that promotes innovation, is future-proof and resilient to disruption, Member States should ensure that their national competent authorities establish at least one AI regulatory sandbox at national level to facilitate the development and testing of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service. Member States could also fulfil this obligation through participating in already existing regulatory sandboxes or establishing jointly a sandbox with one or more Member States’ competent authorities, insofar as this participation provides equivalent level of national coverage for the participating Member States. AI regulatory sandboxes could be established in physical, digital or hybrid form and may accommodate physical as well as digital products. Establishing authorities should also ensure that the AI regulatory sandboxes have the adequate resources for their functioning, including financial and human resources.

[...]

The objectives of the AI regulatory sandboxes should be to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase with a view to ensuring compliance of the innovative AI systems with this Regulation and other relevant Union and national law. Moreover, the AI regulatory sandboxes should aim to enhance legal certainty for innovators and the competent authorities’ oversight and understanding of the opportunities, emerging risks and the impacts of AI use, to facilitate regulatory learning for authorities and undertakings, including with a view to future adaptations of the legal framework, to support cooperation and the sharing of best practices with the authorities involved in the AI regulatory sandbox, and to accelerate access to markets, including by removing barriers for SMEs, including start-ups.”

EUSAiR aims to support the **implementation of AI regulatory sandboxes across the EU as mandated by the AI Act**. The project focuses on providing **standardised frameworks, technical and legal capacities**, and fostering **cooperation among Member States**. It also aims to ensure broad access to sandboxes for AI innovators, particularly **SMEs and startups**, by reducing **compliance costs and market barriers**.

EUSAiR plans to coordinate the implementation of these sandboxes, offer **support to national authorities and innovators**, develop guidelines, analyse results for future regulations, engage stakeholders, and collaborate with existing AI initiatives.

By fostering **multi-disciplinary engagement** and emphasizing SME access, EUSAiR envisions a network of sandboxes involving various key players in the AI ecosystem. The project’s innovative approach incorporates **policy advocacy, independent analysis** of sandboxes, involvement of **European digital infrastructures** (such as those in AI Factories, EDIHs, and TEFs), **engagement with SMEs and innovation networks**, interdisciplinary research competencies, and **scalable training models**.

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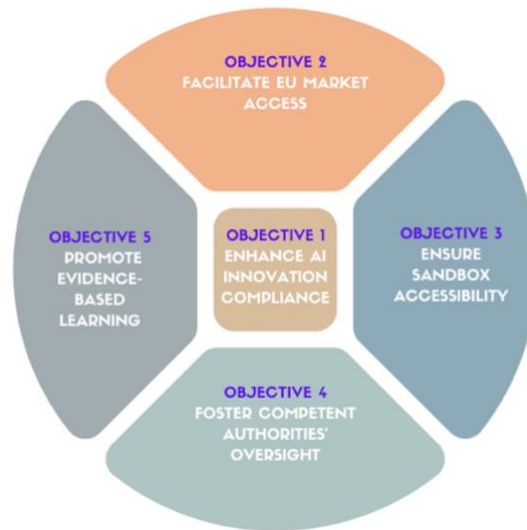


Additionally, EUSAiR aims to enhance **legal certainty**, support **regulatory compliance**, promote **accessibility** to AI markets, and facilitate **cross-border sandbox development** while nurturing evidence-based regulatory learning through pilot projects involving SMEs and AI providers. A backbone of the project is synergizing with other Digital Europe initiatives, regarding the value of conducting sandbox pilot tests within diverse, large-scale digital infrastructures.

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Objectives



EUSAiR objectives hinge on the establishment of AI regulatory sandboxes that adhere to guidelines across the entire EU. This project seeks to create a menu of robust frameworks that not only facilitate innovation but also ensure compliance with regulatory standards, thereby promoting a coherent approach to AI governance throughout the European Union.

Objective 1 - Enhance AI Innovation

Compliance: Foster AI innovation and competitiveness, support trustworthy AI, improve legal certainty for innovators and facilitate regulatory compliance with the AI Act and other relevant EU legislation supervised in the AI regulatory sandboxes.

Objective 2 - Facilitate EU Market

Access: Accelerate access to the EU market for innovative AI systems by providing a safe regulatory space for innovation and removing barriers in the sandboxes, with a particular focus on SMEs and startups.

Objective 3 - Ensure Sandbox

Accessibility: Promote wide accessibility of the AI regulatory sandboxes across the EU Member States, common approaches and coordination in their implementation, economies of scale, and scale up of AI innovation projects at EU level.

Objective 4 - Foster Competent

Authorities' Oversight: Foster competent authorities' oversight by providing guidance for sandbox operations, conducting training needs analysis, developing operational standards, and generating data on AI trends to inform policymakers on emerging risks and opportunities.

Objective 5 - Promote Evidence-Based

Learning: Contribute to evidence-based regulatory learning by analysing AI sandbox experiences, collecting best practices, and sharing lessons learned through structured dissemination on a co-creation platform for broad accessibility.

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Current Challenges

EUSAiR aims to assist National Competent Authorities and offer a menu of robust frameworks for AI regulatory sandboxes across EU Member States. Several significant and intertwined challenges exist that need to be addressed:

- 1. Models, AI Innovation Pipeline, and Ecosystem:** The operational structure of sandboxes varies markedly across different phases of AI technology development. For instance, early-stage sandboxes intended to provide regulatory guidance may employ an advisory model focusing on compliance fundamentals, assisting innovators in understanding the mandatory provisions of legislation like the AI Act. This model often includes workshops, guidance documents, and pre-application consultations, which are essential for fledgling entrepreneurs. Conversely, sandboxes catering to late-stage AI systems preparing for industrial scale-up might adopt a more intensive operational paradigm, emphasizing rigorous testing and real-world simulations under controlled regulatory conditions. This raises questions about the necessary frameworks and resources required to facilitate such diverse operational structures effectively. The AI innovation pipeline should also allow AI providers to revisit earlier development stages for updates or rechecks as needed. This approach underscores the necessity for harmonization between pre-market and post-market processes, particularly if the aim of a sandbox is to simulate aspects of the conformity assessment. This raises questions about the necessary frameworks and resources required to facilitate such diverse operational structures effectively. As a result, the EUSAiR project must identify clear methodologies to ensure synergistic and structured transitions between sandbox phases, preventing gaps in support and guidance throughout the AI innovation lifecycle. In order for these transitions to occur in a controlled manner and smoothly from the perspective of AI providers, it is important to view the sandbox as a process consisting of different stages, each with clear entry, transition, and exit points.
- 2. AI Compliance Tools:** The current landscape seems to reveal gaps in comprehensive AI compliance toolsets that can adequately support National Competent Authorities and AI providers operating within sandboxes. Existing tools often fall short of effectively covering the nuances of the AI Act, leading to potential compliance ambiguities and inconsistencies. For sandboxes thought to simulate future conformity assessment processes, it is crucial that these compliance tools collectively interpret all relevant AI Act provisions, enabling participants to navigate the legal landscape confidently. This includes clarifying conformity assessment requirements specific to high-risk AI systems and ensuring data governance and risk management processes meet regulatory standards (see Challenge 1 above).

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3. **Support for Participation and Incentives:** One of the central challenges involves encouraging AI providers, particularly SMEs and startups, to engage meaningfully in regulatory sandboxes. These entities must view participation as valuable despite the lack of mandatory obligations to do so. Active participation can yield insights regarding the regulatory landscape, potentially influencing the creation of guidelines and frameworks. Thus, it becomes imperative to articulate and communicate a clear value proposition tailored to these participants. Key incentives may include simplified compliance processes, enhanced access to investments and financial resources, collaboration with regulatory bodies, visibility in the market, and the potential for sandboxes to shorten the time to the market. Additionally, SMEs and startups must benefit from networking opportunities that result from sandbox participation, as these can bolster their prospects for investment and market traction.
4. **Synergies with Initiatives (such as EDIHs, TEFs, AI Factories):** Exploiting synergies with existing initiatives such as EDIHs, TEFs, and AI Factories may be essential for the effective establishment and execution of AI regulatory sandboxes. These initiatives can provide resources, technical support, competencies, and infrastructure for sandbox projects, thereby alleviating some operational constraints possibly faced by NCAs and participants. Furthermore, they can facilitate the involvement of private actors—such as industry associations, developer communities, and NGOs—which can help create a truly effective community of AI providers and deployers. Coordinating across diverse initiatives and operational goals presents a challenge. Collaborative efforts may benefit from transparent communication protocols, shared objectives, and aligned governance structures that ensure seamless integration. For maximum effectiveness, the EUSAiR project supports channels for information sharing and collaborative efforts among these entities, creating a cohesive ecosystem that supports innovation while navigating the regulatory landscape.
5. **Specific Regulatory Issues:** The establishment of specific regulatory frameworks for the design and operation of sandboxes poses inherent challenges. The governance structure must clearly delineate roles, responsibilities, and accountability among multiple stakeholders, including NCAs and AI providers. Issues may arise if regulatory guidelines are not uniformly interpreted, leading to potential compliance issues. Additionally, the mechanisms for evaluating and selecting participants need to be smooth, clearly defined and consistently applied to ensure fairness and transparency. Standards must be established to ensure that all stakeholders understand eligibility requirements and the criteria for participation to prevent confusion and exclusion. Automation at some level could be advisable (see Challenge 2 above).

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- 6. Resources, Sustainability, Supervision Capability, and Administrative Burdens:** Ensuring resource sustainability for the operation of regulatory sandboxes is another challenge. As demand for participation grows, NCAs may experience difficulties managing the increased workload within existing supervisory capabilities. This could lead to administrative burdens that compromise the integrity of the sandbox oversight. To address these issues, ideas for scalable resource allocation plans must be devised, allowing NCAs to draw upon shared resources, including technical expertise and financial support from broader EU initiatives. Furthermore, training for regulatory staff will be crucial to equip them with the skills needed for effective supervision and support, particularly given the rapid pace of AI developments (see Challenge 7 below).
- 7. Training:** The effective functioning of AI regulatory sandboxes relies on proper training for all stakeholders involved, such as through microcredentials, especially the personnel within regulatory bodies. Training programs must cover a range of competencies, from understanding the technical complexities of AI systems to grasping the legal implications of the AI Act and other regulatory requirements. Tailored educational initiatives can help supervisory staff become proficient in ethical assessments, compliance evaluations, and risk management specific to AI technologies. For AI providers, particularly SMEs and startups, workshops and seminars can provide essential insights into the regulatory landscape, enabling them to understand how to leverage the sandbox for their benefit. Collaborative training efforts that include industry experts, legal professionals, and technologists will foster a comprehensive learning environment that equips participants with the knowledge needed to navigate the complexities of AI regulation effectively.
- 8. Co-creation:** Co-creation is crucial for aligning the interests of diverse stakeholders involved in the development and implementation of AI regulatory sandboxes. This strategic approach facilitates a collaborative environment where AI providers, regulators, and other interested parties can contribute their perspectives and insights, leading to the development of guidelines and tools that are attuned to real-world needs and challenges. Establishing structured engagement channels, such as advisory panels or workshops, can help bridge these gaps and encourage open dialogue. Regular feedback mechanisms, such as surveys or focus groups, can also enable continuous input from participants regarding their experiences and the effectiveness of the regulatory frameworks in place. By creating a context of collaboration, the EUSAiR project can enhance stakeholder buy-in and foster a more effective regulatory environment for AI innovation.

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9. **Integration with the Broader Regulatory Framework:** The successful implementation of AI regulatory sandboxes must consider the broader regulatory landscape, including existing regulations related to data protection, intellectual property, and consumer safety. The challenge lies in ensuring that sandbox operations do not conflict with these existing frameworks, creating a coherent regulatory environment. Innovation often outpaces regulatory development, leading to potential legal ambiguities or loopholes in existing laws. To mitigate this risk, collaboration among regulatory bodies is essential, allowing for synchronized efforts in aligning sandbox regulations with overarching legal frameworks. Establishing clear lines of communication between various jurisdictions involved in AI regulation will promote coherent policy-making processes, reducing the likelihood of regulatory gaps. From the perspective of AI providers, it would be extremely beneficial for them to gain visibility into the entire regulatory landscape via the AI regulatory sandbox.
10. **Scalability and Adaptability of the Regulatory Framework:** As AI technologies continue to evolve, regulatory sandboxes must remain flexible and adaptable to accommodate emerging trends, use cases, and technological advancements. The risk of creating static frameworks that quickly become outdated is a significant concern in this fast-paced environment.

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Targeted Stakeholders



National Competent Authorities

Enhanced Operational Frameworks: Cooperation for a harmonized and effective framework for evaluating AI technologies, increasing oversight capabilities.

Collaborative Learning: Providing opportunities to share insights and improve regulatory practices.



AI Providers (especially Start-ups and SMEs)

Regulatory Compliance Support: Guidance on complying with the AI Act, which enhances legal certainty and reduces compliance costs.

Access to Sandbox Testing: Opportunity to test AI systems in a controlled environment and to accelerate innovation and market entry.



AI Factories, EDIHs, TEFs, Existing Sandboxes

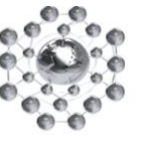
Knowledge Exchange: Share best practices and experiences and scaling-up them at the European level.

Fostering innovation: enhancing across different sectors the overall effectiveness of regulatory frameworks.



Authorities Supervising Human Rights

Incorporation of Ethical Standards: Ensure that human rights considerations are integrated into the implementation of regulatory framework, safeguarding public interests.



National and European Standard Organisations

Development of Standards: Participation and synergies in establishing uniform standards for AI governance, enhancing interoperability and compliance across Member States.



Notified Bodies

Clarified Compliance Processes: Gain access to predefined operational standards and benchmarks that streamline their assessment processes.



Civil Society Organisations

Input to Policy: Guarantee that societal concerns are represented in AI regulations, promoting transparency and accountability.

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Expected Results

Consistent and Tested Framework

A standardized set of guidelines, tools, and benchmarks across the EU to facilitate the establishment of AI regulatory sandboxes. This will enhance legal certainty and streamline regulatory compliance, reducing both the time and cost required for compliance through proven real-world testing.

Accelerated Market Access for Innovators

An environment that enables quicker entry to the EU market for a large number of AI innovators, with at least half being SMEs and startups. By refining sandbox processes and removing entry barriers, this approach will allow AI providers to expedite application approval, improve sandbox completion rates, and decrease time to market following sandbox testing.

Coordinated EU-Wide Implementation

Harmonious deployment of AI regulatory sandboxes across all 27 Member States, improving accessibility and efficiency for innovators. This includes developing standardized frameworks, promoting cross-border cooperation through a co-creation platform, and facilitating scale-up of AI projects.

Enhanced National Authority Capabilities

Detailed operational guidelines and develop a Train-for-Trainers Kit along with a micro-credential model to boost national authorities' capacity for oversight and understanding of AI risks. This will enhance market knowledge and generate actionable insights for policymaking through pilot projects.

Comprehensive Co-creation Repository

A repository on a co-creation platform to collect, analyse, and disseminate at documented best practices and lessons learned from sandbox operations. This will provide structured access to knowledge and insights, aiding in continuous improvement and regulatory learning.

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Methodology

EUSAiR focuses on creating AI regulatory sandboxes compliant with the AI Act through comprehensive guidelines, frameworks, processes, and tools. EUSAiR's methodological principles are:

- **Support and Coordination:** we provide regulatory and operational solutions on infrastructure settlement, services, training, and facilitate EU-level coordination to aid competent authorities in sandbox establishment and management.
- **Practical Testing:** we include AI providers in pilot tests to ensure regulatory compliance and enhance learning, with experiences analysed for recommendations and policy insights.
- **Collaboration with Authorities:** we target national authorities responsible for national sandboxes, encouraging dialogue and co-creation with constant involvement of AI providers, especially SMEs.
- **Consultation with Key Initiatives:** we engage with AI factories, EDIHs, TEFs, and other relevant EU initiatives to enhance project outcomes.
- **Policy Advocacy and Co-Creation:** we partner with public policy networks for analysis and regulatory insights tailored to national contexts.
- **Independent Analysis:** we conduct thorough assessment and consultation of existing sandboxes.
- **European Digital Infrastructures:** we utilize large-scale digital infrastructures for diverse sandbox pilots, fostering comparative analysis.
- **Involvement of SMEs and Innovation Networks:** we engage digital SMEs and innovation ecosystems for model co-design and evaluation.
- **Interdisciplinary Research:** we combine governance, legal, ethical, business, and technological competencies.
- **Scalable Training Models:** we promote train-for-trainers models standardized via micro-credentials.

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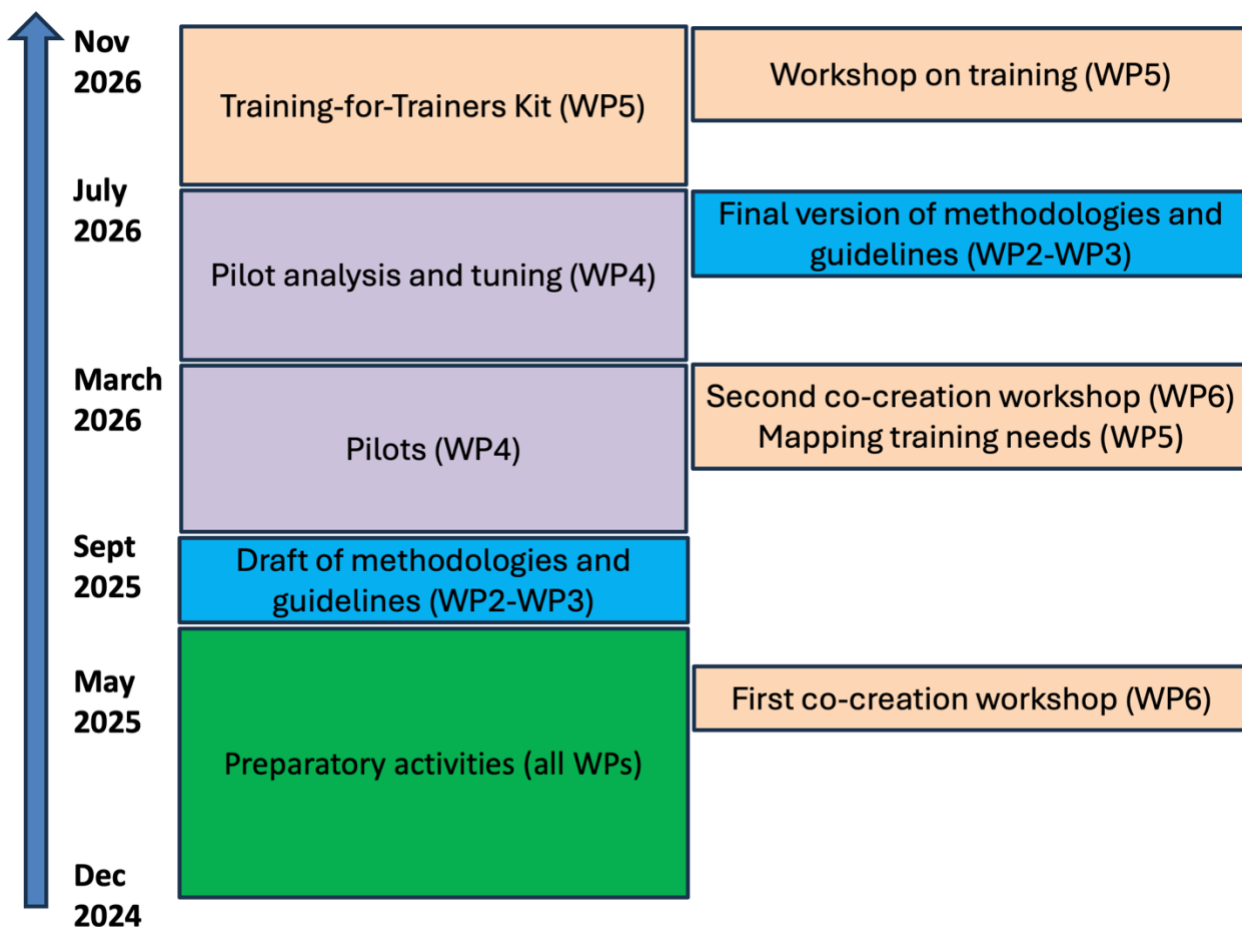


WP1	WP2	WP3
<p>Coordination and Project Management</p>	<p>Union Sandbox Framework, Advisory and Regulatory Learning</p> <p>This work package develops common regulatory guidelines, frameworks, processes, and tools for AI regulatory sandboxes. We establish a Union Sandbox Framework that responds to the regulatory requirements of AI Act in terms of 1) governance, (2) legal and ethical rules as well as regulatory standards, (3) eligibility and exit criteria for AI providers, (4) technological design and tools.</p>	<p>Operational Sandbox Scheme</p> <p>WP3 iteratively interplays with WP2, and focuses on designing all operational models, business and monitoring models, workflows and compliance processes for the Union AI Sandbox Framework. By designing operational models that align with regulatory frameworks and implementing necessary technological requirements, this WP enables seamless operation and compliance within the sandboxes.</p>
WP4	WP5	WP6
<p>Sandbox Pilots, Tuning and Scaling-up</p> <p>This work package involves conducting pilot projects to test the effectiveness of the Union Sandbox Framework and the Operational Sandbox Scheme in scenarios involving AI providers and cross-border cooperation. This will be achieved by evaluating outcomes, revising practices, and engaging with a wide array of key stakeholders, including innovation hubs and research centers.</p>	<p>Training</p> <p>Training national competent authorities' staff and other stakeholders equips them with the knowledge and skills necessary to operate within the AI Act and sandboxes effectively. By identifying training needs, designing tailored programs, and certifying trainers to disseminate essential knowledge, this work package ensures that regulatory authorities and other stakeholders are well-prepared to navigate the complexities of AI regulations.</p>	<p>Communication, Dissemination, Exploitation, and Co-creation Platform</p> <p>This WP coordinates communication, dissemination, and exploitation activities and focuses on establishing a Co-creation Platform to facilitate stakeholder mapping, consultation and engagement as well as effective communication, dissemination of knowledge, and collaboration among all project stakeholders. We will organise co-creation and training workshops.</p>

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Timeline



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