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Policy Brief

# How can AI regulatory sandboxes realise their potential under the AI Act?

Conditions for an effective regulatory instrument within a sovereign and adaptive AI ecosystem in Europe

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# Foreword

Europe has set itself ambitious goals: With the AI Continent Action Plan, the European Commission is pursuing the goal of becoming the world's leading continent for artificial intelligence (AI). This is more than just a technological agenda; it is a political promise. AI innovations require not only data centres and data spaces, but also courageous decisions, adaptive institutions, and suitable spaces for experimentation.

This is precisely where AI regulatory sandboxes, established under the AI Act, come into play; they enable new technologies to be tested and monitored under real-world conditions, responsibly and with an eye to their social impact. At a time when technological developments often outpace regulatory processes, AI regulatory sandboxes are an indispensable regulatory instrument for actively shaping the interaction between innovation, law, and the common good.

As the appliedAI Institute for Europe, we see ourselves as bridge-builders between the worlds of technology development, value-adding applications, political governance, and societal expectations. With this policy brief, we are contributing to the urgently needed objectification and technical and strategic sharpening of the debate on AI regulatory sandboxes. We highlight the conditions under which these regulatory instruments can realise their potential – as a lever for cooperative learning processes, as a building block of European innovation policy, and as a bridge between regulation and technological reality.

We would like to thank everyone who contributed to this publication, especially the experts who shared their experiences. And we invite decision-makers from politics, administration, business and civil society to view AI regulatory sandboxes not as a marginal technical tool, but as a contribution to European digital sovereignty.

I invite you to use this impulse as a starting point for new partnerships and the further development of your institution, as well as for a political culture that shapes uncertainty rather than managing it.

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# Summary

**The EU AI Act challenges European governments and institutions to balance the protection of fundamental rights with innovation, particularly when it comes to AI systems with high-risk potential.** AI regulatory sandboxes have a central role to play in this area of tension: they are key to creating the necessary strategic leeway to promote learning, cooperative, and evidence-based regulation and innovation, while clarifying uncertainties where existing law reaches its limits.

**AI regulatory sandboxes are not a new concept, but rather a proven instrument that must be further developed and strategically utilised in the context of AI regulation.** This will fill a key gap: the ability to not only regulate innovative AI systems, but also to shape them jointly in an experimental dialogue.

**However, the effectiveness of AI regulatory sandboxes depends crucially on their design.** In order to avoid being misunderstood as mere compliance boosters, they require conscious institutional design, clear objectives and authorities capable of taking action.

**We have identified seven conditions for effective AI regulatory sandboxes:**

1. **Enable cooperative learning:** In order to jointly develop standards and practical knowledge, regulators and innovators must systematically exchange experiences.
2. **Focus case selection on AI systems that are socially relevant and subject to regulatory uncertainty:** It is only when there is a high degree of innovation and uncertainty that real learning gains are generated.
3. **Purposefully manage regulatory flexibility:** This ranges from interpretative guidelines to the use of experimental clauses. There is a need for legally secure, graduated frameworks.
4. **Safeguard attractiveness for innovators:** Predictability, access to data and testing infrastructures, and incentives for participation are crucial, especially for SMEs and start-ups.
5. **Systematically document and provide feedback on learning outcomes:** Individual and publicly accessible exit reports, alongside a European information portal, will ensure that learning is shared collectively beyond individual cases.
6. **Ensure institutional coherence within the multi-level system:** This requires clear responsibilities, sector-specific batches, and functional separation between market supervision and innovation units.
7. **Ensure professional capability through interdisciplinary teams and resources:** An independent resource strategy is required, as well as the establishment of interdisciplinary teams. This must be done in close co-operation with external experts, whose involvement is necessary not only in terms of capacity, but also to ensure high acceptance among participating organisations.

**Time is short until August 2026 — the course must be set now.** With the AI Act, Europe is committing to a new understanding of regulation: adaptable, participatory, and evidence-based. AI regulatory sandboxes are both testing grounds and levers for innovative development in a dynamic technological field. In the following, we therefore set out key recommendations for European and national decision-makers:

**Recommendations on the Implementing Act, Article 58 AI Act.**

- The fundamental goal of AI regulatory sandboxes is to enable testing under real-world conditions. Theories and simulations often fail to provide sufficient insights to resolve uncertainties relevant to practical application. Therefore, it is crucial to design the framework so that testing under real-world conditions is possible, involving real-world data, real user groups, and the involvement of all relevant stakeholders. Without such experimentation under real-world conditions, there is a risk that the AI regulatory sandbox will be limited to legally less complex or purely formal questions and fail to realise its potential.
- To maximise the impact of regulatory learning, clear eligibility requirements for participation ('selection criteria') must be established to ensure that AI regulatory sandboxes generate significant insights. Priority should be given to innovative AI systems that are: highly novel; associated with significant legal uncertainty; and socially beneficial. This will ensure that AI regulatory sandboxes focus on transformative technologies, improving legal clarity, regulatory learning, and market access in the EU.
- The use of a standardised template provided by the EU should be mandatory for exit reports. In addition, consent to the publication of key findings should be a prerequisite for eligibility. This will create a consistent EU-wide reporting system which avoids fragmentation, systematically captures regulatory learning, and balances transparency with the protection of confidential information. It will also build a scalable knowledge base for the further development of the European AI governance framework.

**Recommendations for the EU Commission and EU Member States:**

- Existing national and European initiatives for digital innovation — such as “AI on Demand”, European Digital Innovation Hubs, AI Factories, and national competence centres — should establish interfaces for low-bureaucracy co-operation with AI regulatory sandboxes. It must be ensured that genuine synergies arise between these instruments and that parallel structures or isolation are avoided.
- To comprehensively enable experimentation under real-world conditions, existing experimental clauses in EU and national law — particularly in strategically relevant or highly regulated sectors — should be systematically identified, and existing regulatory gaps should be analysed. Building on this, targeted new experimental clauses should be created. This will establish a clear, legally secure framework that enables regulatory flexibility at the operational level and significantly strengthens the effectiveness of AI regulatory sandboxes.
- AI regulatory sandboxes should adopt a sector-specific batch approach oriented towards specific regulatory uncertainties in particular industries, especially those identified as highly relevant by start-ups and SMEs. These batches could be organised by sector, technology, or according to the key requirements of the AI Act (e.g., cybersecurity or human oversight). This will create targeted, practical tests; concentrated expertise; reduced administrative burden; and greater regulatory clarity — precisely where the market needs it most.
- AI regulatory sandboxes should be operated by an organisationally independent entity in order to avoid conflicts of interest with market supervision and to ensure an innovation-friendly, experimentation-oriented working approach. For a professionally sound operation, sector-specific expertise must be made available in an agile manner — through targeted training, interdisciplinary teams, inter-agency co-operation, and the involvement of external experts from academia, industry, and civil society (e.g., via “expert pools”).
- Depending on the batch, any potential conflicts arising from cross-sector regulations should be identified ex-ante, in advance of operating an AI regulatory sandbox, and mitigation strategies should be developed beforehand. These include: (i) the timely involvement of the relevant authorities in cases of regulatory overlap prior to commencement; and (ii) the establishment of co-ordinated procedures, such as joint regulatory reviews and binding communication protocols, to ensure coherent oversight, avoid friction losses, and enable the rapid acquisition of insights.



How can AI regulatory sandboxes realise their potential under the AI Act?

# Introduction

**The European Commission's Action Plan for the AI Continent sets out its ambition to make Europe the leading location for the development and application of trustworthy AI (EU Commission, 2025).** This leadership aspiration encompasses technological excellence, industrial scaling, regulatory capacity, democratic legitimacy, and institutional learning ability. Europe's digital sovereignty will be measured by whether it succeeds in enabling innovation not despite, but through values-based regulation.

**A key foundation for this is the AI Act, which reinforces this ambition and, for the first time, establishes a horizontal, cross-application regulatory framework for AI systems.** It replaces the supposed "either-or" between innovation and regulation with a structural compromise. One expression of this compromise is the regulatory instrument of regulatory sandboxes, which enable innovative AI systems to be tested under real-world conditions[1] and accompanied from a regulatory perspective. This facilitates co-operative learning and innovation through collaboration between authorities and innovators (Art. 57, Section 1 AI Act).

**Figure 1:** Timetable for implementing the requirements for AI regulatory sandboxes in accordance with the AI Act


Source: Own illustration in accordance with Art. 57 AI Act

1 Article 3, No. 55 of the AI Act states that testing can take place under real-world conditions. Alternatively, testing in a simulated environment or a purely theoretical examination of the AI system is also possible.





**According to the AI Act, Member States must ensure that at least one national AI regulatory sandbox is fully operational within 24 months of the law coming into effect.** This means that, by August 2026, national authorities must have established an operational AI regulatory sandbox (or be participating in another Member State's AI regulatory sandbox), with clear responsibilities, procedures, and resources.[2] In this short timeframe, it will be decided whether the regulatory tool of AI regulatory sandboxes will become an effective tool for steering innovation or become a misunderstood side instrument without impact.

**Yet, in political and regulatory discourse, the concept of AI regulatory sandboxes is often underestimated or misunderstood.** All too often, it is reduced to a mere preliminary compliance check or a funding mechanism for start-ups. This narrow view fails to recognise the strategic intentions of legislators and the potential for structural innovation inherent in enabling experimentation in controlled regulatory uncertainty. When properly understood, AI regulatory sandboxes are a vital tool for flexible, collaborative, evidence-based governance in the digital age.

**The aim of this policy brief is to unlock this potential — by precisely defining the conditions under which AI regulatory sandboxes can be effective.** Following the seven conditions, the policy brief sets out concrete recommendations for the implementation and further development of AI regulatory sandboxes — for example, with regard to the implementing act still to be adopted under Article 58 of the AI Act. It is thus addressed to political decision-makers at the European and national levels, to regulatory and supervisory authorities, to innovation actors in business and civil society, as well as to institutions that design and support regulatory experimentation spaces.

**The analysis is based on a multi-stage methodology that combines legal review, practical comparison, and expert interviews.** As well as a systematic analysis of the relevant provisions of the AI Act, existing and emerging (regulatory) sandbox models from Zurich, Norway, the Netherlands, the United Kingdom, Singapore, and Bulgaria were examined. Furthermore, background conversations with stakeholders were incorporated into the results of this policy brief. Insights from discussions within the international expert group on AI regulatory sandboxes, initiated by the appliedAI Institute, and from participation in the EUSAIR workshop in May 2025 also contributed to the analysis. Finally, the conceptual foundation was supported by a secondary analysis of relevant academic publications.

2 According to Article 57, Section 2 of the AI Act, additional AI regulatory sandboxes are also possible at regional or local level.

# The challenge: From the misconception of a supposed compliance booster to a strategic learning tool

**Regulatory sandboxes are often misunderstood in political discourse, resulting in their impact being underestimated.** All too often, they are viewed primarily as tools for accelerating compliance processes or as testing grounds for technology policy-driven projects. This perspective reduces AI regulatory sandboxes to an administrative relief function ahead of market supervision, treating them as an extension of supervisory authorities to prepare for regulatory approval. However, this interpretation falls short and overlooks their central potential: AI regulatory sandboxes are not technocratic service providers; rather, they are strategic spaces for experimenting with innovation-friendly, adaptable regulation, explicitly allowing trial and error and the use of regulatory flexibility.

**The AI Act explicitly positions AI regulatory sandboxes as a tool for co-operative learning between regulators and innovators.** Article 57, Section 9 of the AI Act makes it clear that the objective is not to conduct risk-based assessments of individual AI systems, but rather to promote institutionalised collaboration in order to further develop the legal framework by gaining new insights through practical application. The aim is to jointly explore unknown technical and normative territories where existing rules no longer apply, their application is unclear, or no best practices have been established. AI regulatory sandboxes are therefore not an ex-post control mechanism, but rather a space for anticipatory regulation in uncertain conditions.

**AI systems present a challenge to traditional regulatory practice by operating within complex, technological and dynamic environments.** They make regulatory learning a prerequisite for effective supervision. Many AI systems span multiple sectors, produce probabilistic outcomes, and impact fundamental rights, markets, and societal processes. For regulatory authorities, this means that their usual instruments — such as standard-setting, licensing, and control — cannot be applied straightforwardly. They face what is known as the 'pacing problem': the challenge of developing regulatory approaches that keep pace with rapid technological progress (Pacing Problem, 2011). For this reason, hands-on understanding is required to correctly judge new technologies, spot dangers, and successfully utilise protective measures. Regulatory sandboxes provide a space in which such knowledge can be systematically developed in collaboration with innovators.

**AI regulatory sandboxes can provide innovators with orientation during a phase of maximum uncertainty and high investment risks.** Many developers face the question of how their innovative AI systems will be classified from a regulatory perspective, and how they can be aligned with values-based requirements, especially in the transition between the development environment and market readiness. The AI regulatory sandbox creates an early warning structure by enabling experimentation and dialogue with the regulator. This allows for timely feedback, reduces misinvestments, and increases the regulatory quality of innovations. For start-ups and SMEs, this can therefore be a key factor in achieving success — not despite regulatory requirements, but because of them.

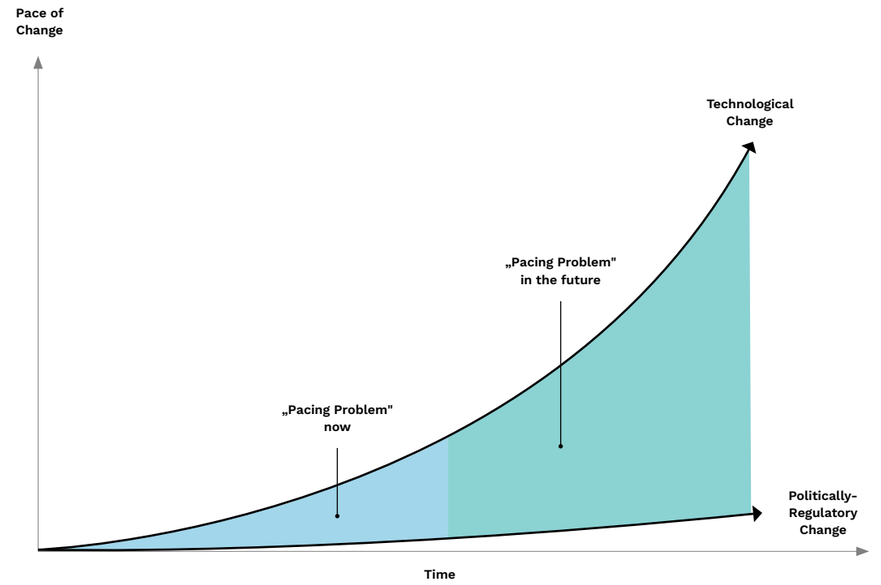
**When understood properly, AI regulatory sandboxes are a new governance tool.** They enable the relationship between regulation, innovation, and social responsibility to be recalibrated. The aim is not to relax rules, but rather to apply them in an informed, differentiated, and evidence-based way. In this way, the AI regulatory sandbox also becomes a place of institutional innovation, testing not only technologies, but also forms of supervision, co-ordination, and policy steering. Its value lies in its ability to connect technical realities with normative orientation.





**The vision is clear: AI regulatory sandboxes provide Europe with the strategic scope it needs to enable evidence-based regulation, while also fostering responsible innovation.** They exemplify a governance model that embraces uncertainty and addresses it productively. When implemented properly, they facilitate co-operative experimentation and dialogue, and encourage an innovative regulatory culture, thereby strengthening Europe's digital sovereignty.

**Figure 2:** The pacing problem in highly technological dynamic environments




Source: Own illustration; graphic based on POPVOX Foundation: https://www.popvox.org/blog/ai-tools-for-congress

# The conditions for effective AI regulatory sandboxes

**For AI regulatory sandboxes to reach their full potential, a purely legal-formal interpretation of the AI Act's requirements is insufficient.** Their effectiveness will be determined by their implementation in practical environments — in the procedures, priorities, and institutional routines with which they are operated. The key issue is whether it is possible to establish the regulatory sandbox as a strategic learning instrument while operationalising it in practice. Ultimately, this involves developing a new institutional capability for supervisory authorities: the ability to navigate uncertainty, regulate co-operatively, and foster the productive relationship between innovation and regulation.

**The following conditions outline the key prerequisites for AI regulatory sandboxes to fulfil their new steering role effectively.** These conditions are based on a systematic analysis of the European legal framework, current implementation debates, and international practical experience. Rather than being understood as a checklist, the seven conditions should be viewed as interconnected building blocks of an adaptable regulatory architecture. AI regulatory sandboxes can only become an effective tool of European AI policy if these conditions are addressed jointly and in a context-sensitive way.

1

## The overarching impact objective of AI regulatory sandboxes is to encourage co-operative learning between regulators and innovators.

**AI regulatory sandboxes are institutionalised spaces for learning and collaboration between innovators and regulators, with the aim of jointly testing the regulatory feasibility of new technologies.** The mandate for mutual learning, enshrined in Article 57, Section 9 of the AI Act, is the central impact objective of the AI regulatory sandbox. This clear focus distinguishes them fundamentally from other forms of experimentation, which primarily target technology or user research. The short- and medium-term learning objectives are:

- **For regulators:** AI regulatory sandboxes enable authorities, through co-operative experimentation and dialogue with innovators, to better understand how new technology should be classified from a regulatory perspective, and whether existing protective frameworks remain viable. In the short term, this creates a space for practical learning: regulatory authorities deepen their technical understanding, recognise the real-world impacts of innovative AI systems early on, and clarify grey areas — an important competence for effective and rapid market supervision in accordance with the AI Act.
- **For innovators:** At the same time, AI regulatory sandboxes allow innovators to better understand how their novel technologies would be assessed and regulated within the legal framework — before irreversible investments are made or AI systems fail in the market. In the early phase of the innovation process, between concept development and validation, testing in an AI regulatory sandbox provides guidance on how innovative AI systems must be designed from a regulatory standpoint to be deployable in critical sectors. While this feedback does not replace certification, it provides a solid basis for decision-making.

**The explicit objective of mutual learning distinguishes regulatory sandboxes from other types of experimental environment.** While test beds focus primarily on technical research and scaling up, and living labs explore the participatory or user-centred impacts of new technologies in a social context, regulatory sandboxes concentrate on the interaction between technological innovation and regulatory frameworks (European Commission, 2023). They focus on the early phase of the innovation process, with the strategic goal of proactively considering the effects on later market entry, as well as the societal consequences and risks, through experimentation under



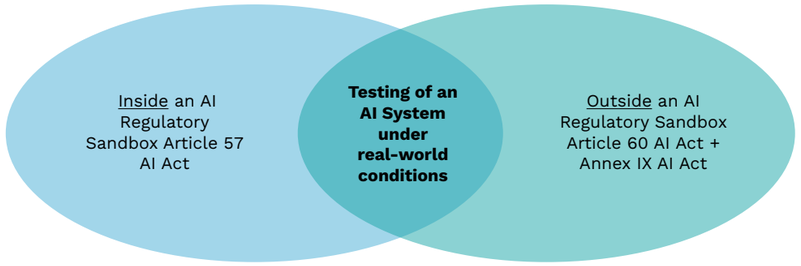


the most realistic conditions possible, supported by experimental clauses. The difference between a regulatory sandbox and other testing environments is particularly evident in terms of 'testing under real-world conditions': an AI regulatory sandbox, as defined in Article 57 of the AI Act, involves active supervision by the relevant authority and enables regulatory flexibility through experimental clauses. In contrast, tests under Article 60 of the AI Act are carried out without such legal exemptions and without direct regulatory supervision — the authority merely approves the project rather than participating actively.

**Figure 3:** AI Regulatory Sandbox: Testing under real-world conditions with regulatory flexibility

- Testing with regulatory flexibility (use of experimental clauses)
- Testing of the AI system is actively accompanied and supervised by a competent authority

- Testing without regulatory flexibility (no use of experimental clauses)
- The competent authority merely approves the testing of the AI system but does not actively participate in any testing




Source: Own illustration.

**In the long term, regulatory sandboxes contribute to the evidence-based development of regulatory frameworks, including secondary legislation, and promote adaptive regulation in the public interest.** Regulation is not a final endpoint but rather a temporary status shaped by experience, expectations, political compromises, power dynamics, economic conditions, societal developments, and technical understanding at the time of enactment. The objective is not to relax rules but rather to ensure their informed and risk-aware application to new situations. When these learning processes are institutionally anchored, systematically documented, and fed back into the system, a European innovation environment emerges that combines regulatory clarity with technological dynamism, serving both the public good and competitiveness (EU Council, 2020).

2

# Focus case selection strategically on innovative AI systems with high regulatory uncertainty.

**AI regulatory sandboxes have a significant impact on regulatory learning, particularly when addressing specific novel applications associated with high regulatory uncertainty.** It is crucial that only projects with concrete questions and clearly identified uncertainties are included. The aim is not to conduct a comprehensive assessment of an AI system in terms of 'overall compliance', but rather to facilitate targeted learning on specific, well-defined issues — precisely where regulatory clarification is needed to promote innovation. This requires the targeted selection of innovative, legally novel, and socially relevant AI systems that offer the greatest potential for learning for regulatory authorities and participating stakeholders alike.

**AI regulatory sandboxes are most valuable where a chain of uncertainties acts as a barrier to innovation.** The example of the start-up Avisé Labs[3] illustrates how practical, legal, and supervisory uncertainties can reinforce each other. Without access to real-world testing conditions and extensive clinical data, it is unclear how the AI system for providing early warnings in patient care functions in everyday practice. At the same time, unclear or conflicting regulatory requirements — for instance, those between medical device law and the EU AI Act — hinder the development of legally compliant solutions. Supervisors often lack the knowledge to assess novel, dynamic AI systems. There is a lack of established benchmarks, practical experience, and sometimes the technical understanding required to make decisions that balance innovation and safety. These uncertainties create complex, resource-intensive demands that can overwhelm start-ups and SMEs in particular, resulting in promising technologies failing to reach market maturity despite clear societal demand and benefits. An AI regulatory sandbox that targets precisely those areas where uncertainty inhibits innovation and enables experimentation in a protected environment can offer meaningful relief (World Bank, 2020).



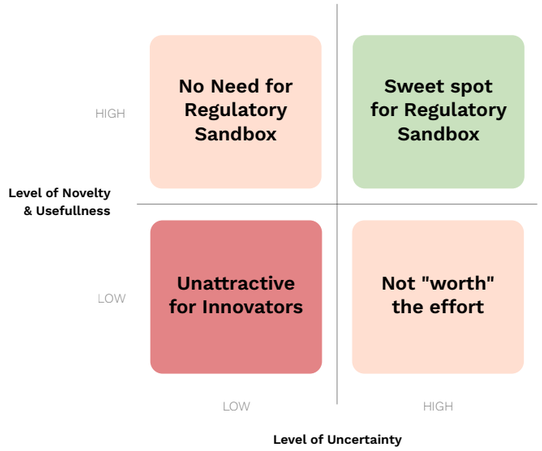


**The eligibility criteria for suitable innovative AI systems according to Article 57, Section 9 AI Act:** The limited resources of AI regulatory sandboxes must be used effectively. Clear eligibility criteria are therefore required.

| Criterion | Meaning |
|---|---|
| **Level of Novelty** | The more novel an AI system is, the greater its potential for regulatory learning, particularly if there are no comparable applications on the market and if new risks are involved. |
| **Level of Uncertainty** | The greater the practical, legal, and supervisory uncertainty, the more value a test provides — for example, when it is unclear which laws, standards, or requirements apply, or how to design the AI system in compliance with legal requirements. |
| **Level Usefulness** | Innovations create particular value when they address real needs and deliver measurable benefits — for example, in areas such as health, the environment, public administration, or education. The AI Act highlights this aspect as a key criterion (see Recital 142). |

**Innovation-intensive AI systems can only be prioritised by combining these eligibility criteria — focusing on those that address not just company-specific uncertainties, but also clarify legal or technical questions relevant to the wider market.** Such AI systems provide guidance to other market participants and supervisory authorities, and generate structural insights for the overall regulatory system.

**Figure 4:** Eligibility criteria for AI Regulatory Sandboxes: Matrix for prioritising innovative AI systems




Source: Own illustration.

3 These findings were discussed in depth in the context of a practical interview with the start-up Avisé Labs (see Appendix, Interview 1).

## 3 Carefully weigh, interpret, and institutionalise regulatory flexibility

**An effective AI regulatory sandbox requires that the competent authorities operating the testing have the ability to make differentiated decisions about the purpose, extent, and institutional anchoring of regulatory flexibility.** Without this deliberate steering, there is a risk that the instrument will be reduced to mere (theoretically) advisory services — or that regulatory standards may be unintentionally undermined. Regulatory flexibility is therefore not a by-product but a central steering element of learning-oriented regulation (OECD, 2023).

**The appropriateness of regulatory flexibility should be assessed based on multiple objectives:** it can lower specific market entry barriers for innovators through legal exemptions, provide regulatory authorities with practical insights into grey areas, and contribute to the achievement of political goals, such as those relating to health, safety, and environmental protection. A key prerequisite is that these objectives are explicitly stated and weighed transparently in the political process. This is the only way to ensure that regulatory flexibility serves the public interest rather than merely catering to individual case interests.

**The degree of regulatory flexibility is a controllable parameter with graduated levels of intensity, ranging from non-legally binding bespoke guidance and temporary non-enforcement letters to time-limited legal exemptions.** Depending on the risk profile, level of innovation, and societal relevance, careful decisions must be made about which form of regulatory flexibility is appropriate (BMWi, 2019). Too little flexibility hinders practical learning outcomes, while too much can undermine protective interests. The goal is to strike a balance between enabling innovation through testing under relaxed regulatory conditions and setting boundaries in line with responsible regulation. The forms of regulatory flexibility can be assigned to three key levers of impact, which may be combined on a case-by-case basis:

- **Bespoke Guidance:** A standard component of every AI regulatory sandbox — the starting point of every test is the clearly defined set of questions regarding the specific AI system, established at the outset. The insights gained through testing and dialogue result in non-binding, case-specific assessments by the competent authorities. These provide both innovators and supervisory authorities with orientation on how to ensure legal compliance in the design of the AI system and reduce legal uncertainty (see Article 57, Sections 6–7 of the AI Act). The level of detail in the authorities' guidance remains at the discretion of the competent authorities. Since there is currently no explicit legal provision on this, it is recommended that national sandbox laws establish a binding mandate for providing bespoke guidance within AI regulatory sandboxes.
- **No-Enforcement Letters:** At this level, the competent authority commits to refraining from imposing certain predefined sanctions (such as fines) during participation in the AI sandbox, provided that the defined conditions are met, even if not all legal requirements are fully satisfied (see Article 57, Section 12 of the AI Act). While this creates planning certainty for testing phases, it requires clear internal procedures and trust in the responsible behaviour of participants (UK Fintech, 2015).
- **Legal Exemptions:** The most intensive form of regulatory flexibility involves temporary exemptions from applicable legal obligations, for example through experimental clauses in sector-specific legislation (such as the GDPR exemption in Article 59 of the AI Act). This allows for testing under real-world conditions despite formal deviations from legal requirements — provided that appropriate legal foundations and safeguards are in place (e.g., supervision, risk mitigation, and evaluation).

**In order for these forms of regulatory flexibility to be legally legitimate and effective in the long term, they must be anchored in clear institutional procedures and normative foundations.** This applies to both organisational responsibility — for example, through specifically mandated authority units or co-ordination bodies — and legal safeguards through appropriate regulations. Robust experimental clauses in sector-specific law are particularly essential for no-enforcement letters and legal exemptions; these must be identified and implemented in light of the rapid development of AI technologies. Experimental clauses already exist, albeit sparsely, in some legislation (they have existed in Germany since the 1950s — BMWK, 2025), with more recent examples found in areas such as transport, finance, and administrative law. Against the backdrop of rapid digital transformation in





society, there is an increasing need to develop new, comprehensive regulatory experimentation frameworks (Initiative für einen handlungsfähigen Staat, 2025; EU Council, 2020). The design of experimental clauses can only succeed through close co-operation between supervisory authorities, sectoral ministries, and legislators. Such institutional anchoring ensures that exemptions are applied transparently and comprehensibly, in alignment with the public interest, while also preventing informal flexibility practices from becoming detached and undermining legal coherence.

## 4 Ensure attractiveness for innovators through incentives and certainty in planning.

**Regulatory sandboxes can only be effective if they are designed to be accessible, predictable, and substantially rewarding for innovators — particularly for start-ups and SMEs.** Participation in an AI regulatory sandbox involves considerable effort for innovators: extensive application procedures, co-ordination on the sandbox testing plan, disclosure of confidential information (such as trade secrets or intellectual property), allocation of personnel resources, and the risk of the testing process being discontinued at any time all represent structural barriers. These hurdles can be particularly discouraging for smaller actors — without targeted incentives, the AI sandbox risks missing precisely those target groups and areas of innovation that, according to Recital 139 of the AI Act, it is primarily intended to support.

**In order to encourage the participation of the relevant innovators of AI systems, a combination of material, procedural, and strategic incentives is required.** Innovators must clearly understand the specific benefits that participation will bring to their development process, such as the certainty they will gain when navigating regulatory requirements, and when actionable insights will be available. The aim is to provide structured support for high-quality, well-regulated innovation, not merely to reduce burdens.

**Key levers for increasing attractiveness include, among others:**

- Planning certainty is achieved through early clarity on the possible forms of regulatory flexibility within the AI regulatory sandbox, for example, in the form of graduated regulatory flexibility.
- Procedural clarity and acceleration, for example, through standardised evaluation procedures, fixed response times, and transparent selection criteria that align with the dynamics of real-world innovation processes.
- Access to resources, such as high-quality data, testing infrastructures, and computing power, including integration with Testing and Experimentation Facilities (TEFs), AI factories, and data spaces.
- Follow-up support and assistance with conformity assessment procedures after successful participation, for example, through preferential access to funding programmes and public procurement opportunities.
- As set out in Article 57, Section 7 AI Act, maintaining a written record of activities within the AI regulatory sandbox enables subsequent conformity assessment procedures to be expedited by submitting these documents.

**Such a supportive environment not only helps to increase the participation of innovators but also enhances the quality of the innovative AI systems involved.** The diversity of applications tested, the practical applicability of regulatory requirements, and the overall legitimacy of the AI regulatory sandbox depend crucially on whether structured access is ensured for a broad range of innovation actors — extending beyond traditional large enterprises.

4 A critical aspect of the final sentence of Article 57, Section 8 AI Act is that these exit reports are only published to the wider AI ecosystem with the express consent of both parties — the participating innovator and the competent authority.

5

## Systematically harnessing learning insights through standardised documentation and feedback.

**The societal and regulatory added value of AI regulatory sandboxes does not arise solely from solutions to individual cases, but from the systematic processing and scaling up of insights and learnings gained.** The aim is not merely to provide legal certainty for a specific application but also to encourage collective learning that contributes to developing, clarifying, and harmonising the regulatory framework — following the principle: "Help many by helping one" (Datatilsynet, 2024).

**This requires standardised, transparent, and traceable documentation of individual AI regulatory sandbox cases.** In particular, publicly accessible exit reports — final reports structured for each test case — should be mandatory.[4] These exit reports enable insights, such as interpretations of vague legal terms, practical hurdles, or risk effects, to be shared with other innovators, supervisory authorities, and legislators. To ensure that sensitive information remains protected, a standardised reporting template with modular disclosure (e.g., public versus confidential sections) is required.

**To ensure that insights gained from AI regulatory sandboxes inform legal development, there must be institutionalised feedback processes between sandbox operators and legislative or supervisory bodies.** As provided for in Article 57, Section 16 AI Act, national authorities should report annually and present recommendations for further developing the legal framework. These reports must be structured, tailored to their target audiences, and embedded within formal reporting processes for national and European decision-makers. The goal of evidence-based regulation will only be fulfilled when these learning outcomes are incorporated into impact assessments, delegated acts, guidelines, or legislative adjustments.

**To prevent regulatory learning from being restricted by national borders or institutional silos, a co-ordinated European infrastructure is required to disseminate consolidated insights.** Results from one Member State must be usable by others. The Single Information Portal set out in the AI Act (Article 57, Section 17) should be developed into a functional knowledge platform with clear requirements for content to be discoverable, comparable, and machine-readable. Only through such a European dissemination system can a cross-border learning space emerge that improves regulatory quality, avoids unnecessary duplication of work, and enhances the legal framework with practical knowledge.

6

## Ensure institutional coherence in the multi-level system through co-ordinated management and clear responsibilities.

**Regulatory sandboxes require a robust governance structure to ensure the coherent co-ordination of cross-sectoral and inter-institutional regulatory processes.** Since AI systems, in addition to the AI Act, frequently touch upon several (vertical) sector-specific legal areas simultaneously (Hacker, 2024) — such as data protection, medical device law, or labour law — there is a risk, without co-ordinated management, of institutional fragmentation leading to delays, jurisdictional conflicts, or even the premature termination of sandbox cases. Experience shows that fragmented responsibilities can only be overcome through clearly structured, institutionally anchored procedures.[5]

4 A critical aspect of the final sentence of Article 57, Section 8 AI Act is that these exit reports are only published to the wider AI ecosystem with the express consent of both parties — the participating innovator and the competent authority.
5 These findings were discussed in depth in the context of a practical interview with the start-up Katulo (see Appendix, Interview 1).

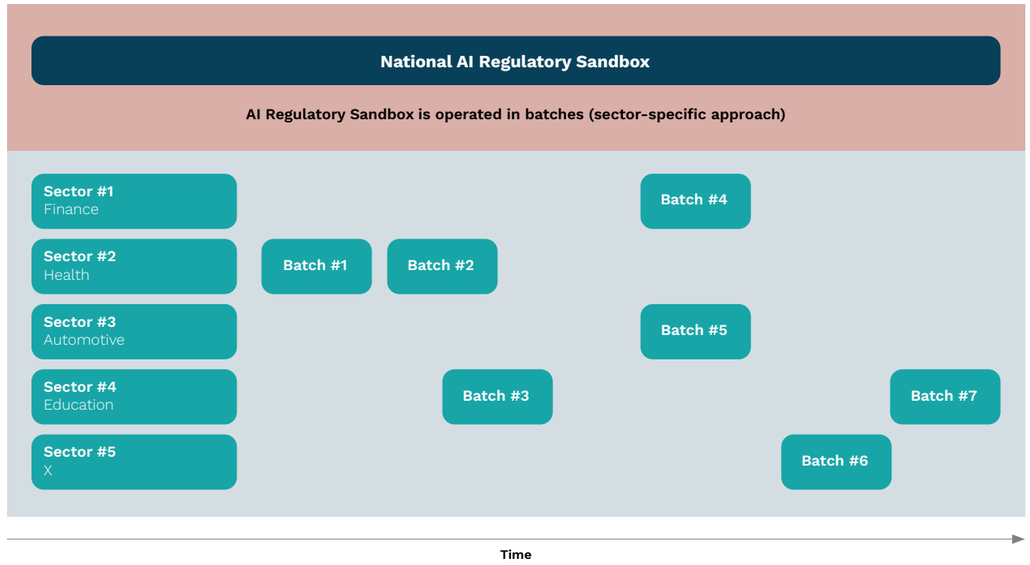




**Early and definitive co-ordination with sectoral authorities is essential. AI regulatory sandboxes require clear governance structures and co-ordinated engagement with these overlapping authorities.** Appointing a 'lead regulator' can help to streamline decision-making processes, manage cross-sectoral co-ordination, prevent conflicts with specialised authorities at an early stage, and proactively identify regulatory flexibilities, for example through experimental clauses. It is essential that decisions are made swiftly and have a binding effect.

**Clustering projects into batches based on themes or sectors increases both the technical efficiency and contextual relevance of sandbox activities.** Use cases can be organised according to sensitive application areas (e.g., healthcare, public administration, and emotion recognition) or horizontal regulatory issues (e.g., cybersecurity and transparency). This targeted sectoral focus enables AI regulatory sandboxes to flexibly align with current market needs and address areas where regulatory uncertainty is particularly evident among stakeholders (UK AI Airlock, 2025). This approach facilitates resource planning, as both internal and external expertise can be allocated to individual batches in a focused, sector-specific manner. Specialist staff do not need to engage with different sectors simultaneously, which increases efficiency. Additionally, co-ordination efforts, particularly with other responsible authorities, are reduced, and batch scheduling provides greater planning certainty. Peer learning among project participants is strengthened, and the comparability of insights gained for regulatory practice is improved.

**Figure 5:** Structured AI regulatory sandbox operation through sectoral batches.




Source: Own illustration.

**Additionally, an internal functional separation is required between market surveillance and innovation support within operating competent authorities to prevent conflicts of interest.** Traditional market oversight adheres to the precautionary principle and operates in a risk-averse manner — an approach that is incompatible with the open, experimental nature of an AI regulatory sandbox. Therefore, operational responsibility should lie with specialised, interdisciplinary innovation units that work closely with market surveillance but retain their own decision-making powers. This is the only way to create a safe space for regulatory learning without undermining the rule of law.

7

# Ensure professional competence through interdisciplinary teams and targeted resource structuring.

**AI regulatory sandboxes place high demands on the responsible competent authorities, both in terms of organisation and, above all, professional expertise and structural capability.** Therefore, a key requirement is the establishment of robust, interdisciplinary teams that can manage regulatory learning processes, understand technological developments, and assess societal impacts. Operating an AI regulatory sandbox cannot be treated as an additional duty — it requires a dedicated resource strategy. Crucially, capacity-building should not take place solely within the authorities, but in collaboration with external experts and specialised institutions — also because building up internal personnel alone is unlikely to be realistic given capacity and time constraints.

**The teams involved require expertise in four key areas:** firstly, technological understanding, including sector-specific functionalities (e.g., in healthcare, energy, or public administration); secondly, regulatory competence, covering both AI-specific legislation and cross-sectoral norms (e.g., data protection and product safety); thirdly, ethical and normative reflection skills, particularly with regard to human-centred design and the impact on fundamental rights; and fourthly, societal understanding, in order to take into account the socio-technical context, affected stakeholders, and public interest considerations.

**These competencies must not only be permanently embedded within institutions but also actively applied and, where necessary, supplemented in the context of specific sandbox cases.** These competencies must be permanently embedded within institutions and actively applied, supplemented where necessary, in the context of specific sandbox cases. Depending on the subject of innovation, risk profile or application context, additional specialist perspectives may be required. An effective learning-oriented regulatory sandbox structure incorporates external expertise, remains adaptable and anticipates case-specific competency needs.

**At the same time, acceptance by the participating organisations and experts is a fundamental prerequisite for the success of such teams.** Interdisciplinary collaboration can only succeed if the experts involved have recognised professional competence and are willing to co-operate institutionally and communicatively. In this context, acceptance is not generated solely through hierarchy or formal responsibility but through collaboration based on trust, equal footing, shared problem-solving approaches, and transparent procedures.

**Against this backdrop, it is hardly realistic to expect competent authorities to develop all the necessary expertise, either in terms of the breadth required or in view of time and financial constraints.** Instead, hybrid forms of co-operation involving external specialist institutions, civil society actors, research consortia, or specialised advisory units are needed. These should be engaged in a targeted manner. To ensure this is effective, dedicated interface roles must be created, and long-term partnerships must be embedded structurally.

**The seven conditions demonstrate that the effectiveness of AI regulatory sandboxes requires more than merely meeting the legal requirements of the AI Act or addressing technical implementation.** A strategic regulatory culture is needed that enables innovation by fostering the institutional intelligence of supervisory authorities and processes, strengthening co-operation between innovators and regulators, and focusing on evidence-based learning — not through deregulation, but through responsible, adaptive governance. AI regulatory sandboxes are therefore not an exception to the regulatory process but rather a response to the new norm of uncertainty, cross-sectoral complexity, and the requirement for learning-oriented governance in the context of rapidly evolving technological developments. Taking these conditions into account when designing AI regulatory sandboxes can transform them into strategic instruments of European technology regulation, supporting not just individual innovations but also forming the cornerstone of adaptive governance in times of disruptive change.

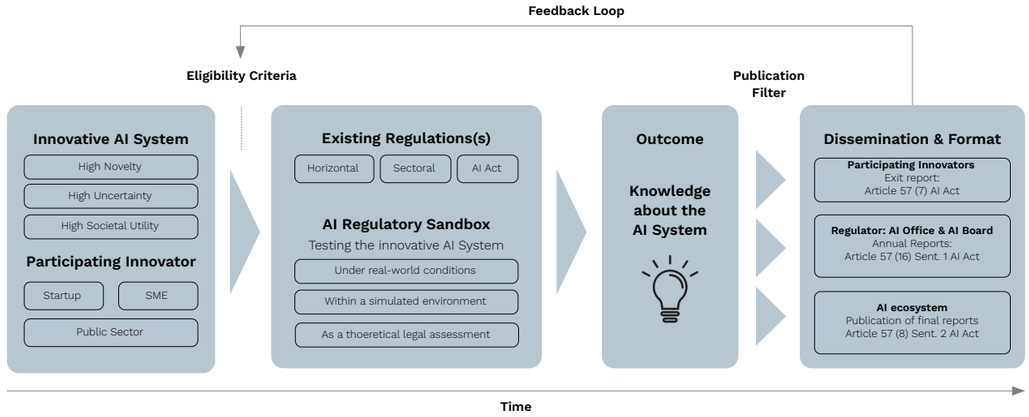




# Conclusion: AI regulatory sandboxes as the basis for a European regulatory culture

**AI regulatory sandboxes are not an ancillary instrument of the AI Act; rather, they are a pivotal means of adapting and regulating dynamic AI systems in Europe.** If Europe is to fulfil its ambition of regulating and shaping trustworthy AI, it must commit to consistently implementing institutional formats that address uncertainty through productive dialogue. AI regulatory sandboxes are a key testing ground for this, exemplifying a regulatory culture built on co-operation, evidence, and regulatory flexibility, rather than administrative rigidity or technological naivety.

**Figure 6:** AI regulatory sandboxes as a learning environment: eligibility, testing environments and dissemination of outcomes




Source: Own illustration.

**The seven conditions outlined in this policy brief make it clear that the effectiveness of AI regulatory sandboxes depends on political will, institutional clarity, and strategic implementation capacity.** Only if AI regulatory sandboxes enable co-operative learning, provide legally secure regulatory flexibility, are institutionally embedded, attractive to innovators, and aligned with the broader legal system can they realise their full potential — serving as a bridge between innovation and regulation, as a catalyst for new experiential knowledge, and as a building block for a future-oriented European technology policy.

**For policymakers, authorities, and implementation partners, this translates into a clear mandate:** AI regulatory sandboxes must be designed from the outset as strategic instruments — with clear objectives, sufficient resources, interdisciplinary teams, and a learning-oriented mindset. Only then can they help lay the regulatory foundations for Europe in the AI era: responsible, competitive, and forward-looking. And this is exactly what Europe needs right now.

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# Appendix

## Interview 1: The chain of uncertainty in a MedTech AI Startup

**Marius Khan**

**Avisé Labs AI System: What is the intended purpose of the AI System?**
Background: The AI System aims to mitigate the risk of premature transfers of patients from intensive care units (ICUs) to regular wards, which could happen due to a shortage of beds and resource limitations. This early transfer frequently leads to complications, such as sepsis (blood poisoning), which is the leading cause of prolonged hospital stay or even death. The absence of continuous monitoring in regular wards increases the risk of undetected health deterioration. The AI System addresses this by providing advanced continuous health monitoring tailored for regular wards.

Implementation: Using the combined data from in-ear sensor and smartwatch, the AI System collects real-time vital parameters, providing continuous data after the patients transition to regular wards. A web-based dashboard provides medical staff a clear, intuitive interface for real-time monitoring and alerts. Using neural networks for time series analysis, the AI System detects early signs of health decline that might be missed in regular ward conditions. Analysing the cardiovascular system, it assesses the patient's overall health status and predicts critical situations, delivering forecasts directly to the medical staff through the dashboard.

**Practical Uncertainty: In what ways does the lack of real-world testing opportunities hinder your startup's ability to develop and deploy your AI System?**
Mandatory ex-ante regulatory approvals make entering the hospital market a complex and lengthy process, restricting the critical practical experience needed to understand how the application will perform in real-world conditions. While Avisé Labs has a development environment, it lacks access to large-scale, real-world data critical for refining and validating the AI System. Simulations, though helpful, fail to capture the complexity of real-world conditions. Traditional trial methods, while an option, often incur significant cost, time-consuming and bureaucratic processes for startups. Additionally, securing trial access and a medical partner without an established proof of concept poses a significant challenge. Overcoming these barriers is essential to transition from cautious simulated pilots to bold, real-world implementations - This is where we as the developer begin to gain a deeper understanding of how the system works and interacts in a real-world context, necessary to ensure system effectiveness and safety.

**Legal Uncertainty: Are compliance challenges with existing laws in highly regulated environments a significant obstacle for introducing your innovative technology?**
Compliance is a major hurdle due to the novelty of the AI System and limited practical experience in real-world interactions. There are two main challenges: Firstly, identifying which specific legal requirements apply, and secondly, ensuring that these requirements are met in a legally sound manner. The recently introduced AI Act, particularly Articles 9-15, adds complexity and uncertainty alongside the stringent documentation standards set out in frameworks such as IEC 62304 of the EU Medical Device Directive. Aligning these sector frameworks with the AI Act requirements is particularly difficult without real-world data and established best practices, which are unavailable for such novel AI Systems. Demonstrating the evidence of safe and effective system behaviour is further complicated by the lack of practical use cases and challenges like device misuse (e.g. removed wristbands) or technical failures.

The dynamic nature of AI, which evolves and learns over time, introduces additional risks, such as the system developing inaccurate patterns or recommendations. “What happens if the system learns the wrong content?” needs to be addressed, to prevent potentially harmful outcomes. These risks often become evident only after the algorithm is deployed in real-world scenarios, where its performance can be monitored against a diverse set of cases. Continuous validation, real-world testing, and robust feedback loops are therefore essential to identify and mitigate these risks before they result in significant harm. This dynamic nature complicates compliance efforts and requires a continued focus on robust and transparent processes to meet regulatory standards.

**Supervisory Uncertainty: What is your stake about competent authorities balancing the need for innovation with the compliance expectations of a cautious regulatory environment?**
Competent authorities themselves often lack a deep understanding of the technology and functioning of such AI Systems. It is understandable that, given the novelty and practical uncertainty of such complex AI systems, they do not simply allow a trial-and-error approach. But simply saying "no" does not encourage innovation and is not sensible. Other jurisdictions are much more nimble in this regard, such as the UK, which has introduced frameworks to facilitate testing and experimentation, such as the AI Airlock.

**Given this chain of uncertainty: How can AI Regulatory Sandboxes help innovators like Avisé Labs navigate regulatory complexities? Which specific features would most effectively reduce uncertainty?**
The regulator-monitored safe space provided by an AI Regulatory Sandbox is attractive for innovators like Avisé Labs as it allows testing such novel AI Systems in real-world conditions through trial and error. This testing environment enables us as innovators to assess the quality of our AI system, generate robust evidence, identify outliers over time, and provide valuable insights for iterative improvements. Feedback from regulators will help us align with compliance requirements, jointly identify where our AI system needs to generate more of the evidence that is required for compliance, and resolve those regulatory challenges together. This approach also ensures patient safety while enabling earlier access to cutting-edge innovations that enhance care. Since traditional software development requires significant post-development revisions, iterative refinement is even more crucial for complex AI systems.





# Interview 2: Why sector expertise is crucial for an effective AI Regulatory Sandbox

**Anne Mareike Schlinkert**

KATULU

**(1) Intended Purpose of the Katulu AI System:** Can you briefly describe the intended purpose of your AI System?
**Anne Mareike Schlinkert:** Our AI system enhances grid management by enabling predictive maintenance and improving the accuracy of energy consumption and production forecasts. It is designed for grid operators and large industrial consumers to optimize energy production, distribution, and consumption efficiency. Our decentralized AI infrastructure leverages data at its source to ensure compliance and privacy. Algorithms run where the data is generated or consumed, and only the algorithm updates - not the raw data - are shared with us. This approach allows us to learn just enough to provide accurate smart grid load forecasting without moving sensitive data. It bridges a crucial dilemma: only collaboration on real data can improve the system, yet this data is highly sensitive and must be protected from cyber threats. That’s why our solution is designed to keep sensitive data secure in line with the strictest privacy standards. Not even we can see the raw data. This is an essential feature in today’s interconnected energy landscape.

**(2) High-Risk Classification and Practical Sector Challenges:**
**Anne Mareike Schlinkert:** The intended purpose of your AI Systems falls under high-risk as per Annex III, No. 2 of the AI Act, given its operation within critical infrastructure. Compliance with the technical requirements outlined in Articles 9–15 of the AI Act is mandatory. Where do you see the practical challenges in achieving this compliance?

(Potential Input): A major challenge lies in reconciling the AI Act's requirements with sector-specific regulations, such as the Cyber Resilience Act, the Energy Industry Act, and GDPR. A key concern is an isolated perspective and conflicting regulatory obligations between those legislations, leading to regulatory uncertainty. For example, how does the Cyber Resilience Act align with Article 15 of the AI Act on cybersecurity? The complexity increases further when leveraging technologies like federated learning. Without clear guidelines addressing the alignment between these regulations, organizations risk compliance bottlenecks because of conflicting requirements that hinder innovation. At the same time, we urgently need to innovate in the area of critical infrastructure, balancing energy availability and cost.

**(3) AI Regulatory Sandbox:** Given the challenges you have outlined, participating in an AI Regulatory Sandbox could potentially help address these issues. What do you expect if you would participate in such a testing environment?
**Anne Mareike Schlinkert:** We expect the AI Regulatory Sandbox to be operated with extensive technical and legal expertise addressing our participating AI System. A deep understanding of both AI systems and the sector-specific context is crucial - without it, key challenges cannot be effectively addressed. An isolated focus on the AI Act alone is insufficient; regulators overseeing different sectors or industries like cybersecurity, energy operators, and data protection must actively cooperate and contribute their perspective to create a coherent regulatory framework.

One critical question is how consensus is reached: Which regulatory body has the final say as the “Lead Regulator” in cases of conflicting requirements? Additionally, input from non-governmental experts, including industry organizations, should be incorporated to ensure practical, real-world applicability. Such interdisciplinary collaboration is key to resolving regulatory conflicts and enabling a compliant AI System deployment in critical infrastructure. An AI Regulatory Sandbox with that sector peculiarities in mind, would provide much-needed clarity and guidance for organizations navigating these complex requirements.

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**Lajla Fetic is Head of AI Public Interest & Policy at the appliedAI Institute for Europe and a distinguished expert in public interest technology, AI governance, and digital policy.** She advises political decision-makers at the European, national, and local levels, as well as stakeholders from business and civil society, on the design of artificial intelligence in the public interest. As an expert, she has supported, among others, the European Parliament and the German Bundestag in the development and implementation of the European AI Act.

Most recently, she published the widely discussed study AI Regulation Made in Germany?, which identifies key areas of action for the national implementation of the AI Act and formulates concrete recommendations for trustworthy AI in Germany. Fetic serves on several advisory boards, including the KI-Cockpit project funded by the German Ministry of Labour and Social Affairs. Previously, she led projects on the development of public interest technology at the Bertelsmann Foundation, was instrumental in developing an AI ethics label, and chaired the Socio-Technical Systems working group in the German government's AI standardisation roadmap.

As a public speaker, she regularly addresses the societal impact of AI — including in her TEDx talk on AI's influence on democracy. For her contributions, she was recognised as one of the 100 Brilliant Women in AI Ethics. She holds a Master of Public Policy from the Hertie School in Berlin.

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**Demian Niemeyer is a fully qualified lawyer and works as an AI Regulatory Expert at the appliedAI Institute.** He studied law in Frankfurt am Main, specialising in "International Relations & the EU," and completed his Master of Laws (LL.M.) in Law in a Digital Economy in Lisbon in 2022.

With a passion for innovative technologies, his work focuses on the grey areas where AI innovators in highly regulated sectors — such as drones, healthcare, and robotics — can find space for experimentation and risk-taking despite strict regulations. He is always open to discussions on how to strike a balance between AI regulation and allowing room for creativity and innovation.

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**Till Klein is Head of AI Regulation at the appliedAI Institute for Europe and serves as an expert with OECD. AI and the Global Partnership on AI.** He works at the intersection of regulation and practice and has shaped the discourse on the AI Act from practical perspectives from its early drafts by engaging with policy makers on the European, national, and regional level. His focus lies on enabling start-ups, SMEs, and the public sector to achieve compliance with the AI Act as quickly and efficiently as possible.

Till brings several years of industry experience in regulatory affairs within high-tech sectors, particularly in medical technology and drones, but also as auditor for quality management systems. He holds a degree in industrial engineering and earned his PhD in economic geography, focusing on the evolution of innovation networks.





# About the appliedai Institute of Europe

The appliedAI Institute for Europe aims to strengthen the European AI ecosystem by engaging in research, developing knowledge around AI, providing trusted AI tools, and creating educational as well as interactive formats centred on high-quality AI content.

As a non-profit subsidiary of the appliedAI Initiative, the Institute was founded in Munich in 2022. The appliedAI Initiative itself is a joint venture of UnternehmerTUM and IPAI. The Institute is managed by Dr Andreas Liebl and Dr Frauke Goll.

The appliedAI Institute for Europe focuses on the people of Europe. It pursues the vision of shaping a common AI community and providing high-quality content in the age of AI for society as a whole. By promoting trustworthy AI, the Institute accelerates the application of this technology and strengthens trust in AI solutions.

With a focus on research, knowledge development, and the provision of trusted AI tools, the appliedAI Institute for Europe provides a valuable resource for companies, organisations, and individuals looking to expand their knowledge and skills in AI. Through educational and interactive formats, the Institute enables an intensive exchange of expertise and fosters collaboration between stakeholders from different fields.

The appliedAI Institute for Europe invites companies, organisations, start-ups, and AI enthusiasts to benefit from the Institute's diverse offerings and resources. The appliedAI Institute for Europe is supported by the IPAI Foundation gGmbH.

# Imprint

**Publication Date**
July 2025

**Publisher and Contact**
appliedAI Institute for Europe gGmbH
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The appliedAI Institute for Europe gGmbH is supported by the IPAI Foundation gGmbH and is a subsidiary of appliedAI Initiative GmbH.

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**Suggested Citation**
Fetic, L., Niemeyer, D., Klein, T. (2025). How can AI regulatory sandboxes realise their potential under the AI Act? Conditions for an effective regulatory instrument within a sovereign and adaptive AI ecosystem in Europe. appliedAI Institute for Europe. Munich.

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