

Artificial Intelligence Act:

A Policy Prototyping Experiment

EU AI Regulatory Sandboxes



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About Open Loop

Open Loop is a global program that connects policymakers and technology companies to help develop effective and evidence-based policies around artificial intelligence (AI) and other emerging technologies.

The program, supported by Meta (previously Facebook), builds on the collaboration and contributions of a consortium composed of regulators, governments, tech businesses, academics, and civil society representatives. Through experimental governance methods, Open Loop members co-create policy prototypes and test new and different approaches to laws and regulations before they are enacted, improving the quality of rulemaking processes in the field of tech policy.

This report presents the findings and recommendations of the second part of Open Loop's policy prototyping program on the European Artificial Intelligence Act (AIA), which was rolled out in Europe from June 2022 to December 2022, in partnership with Estonia's Ministries of Economic Affairs and Communications and Justice as well as Malta's Digital Innovation Authority (MDIA).

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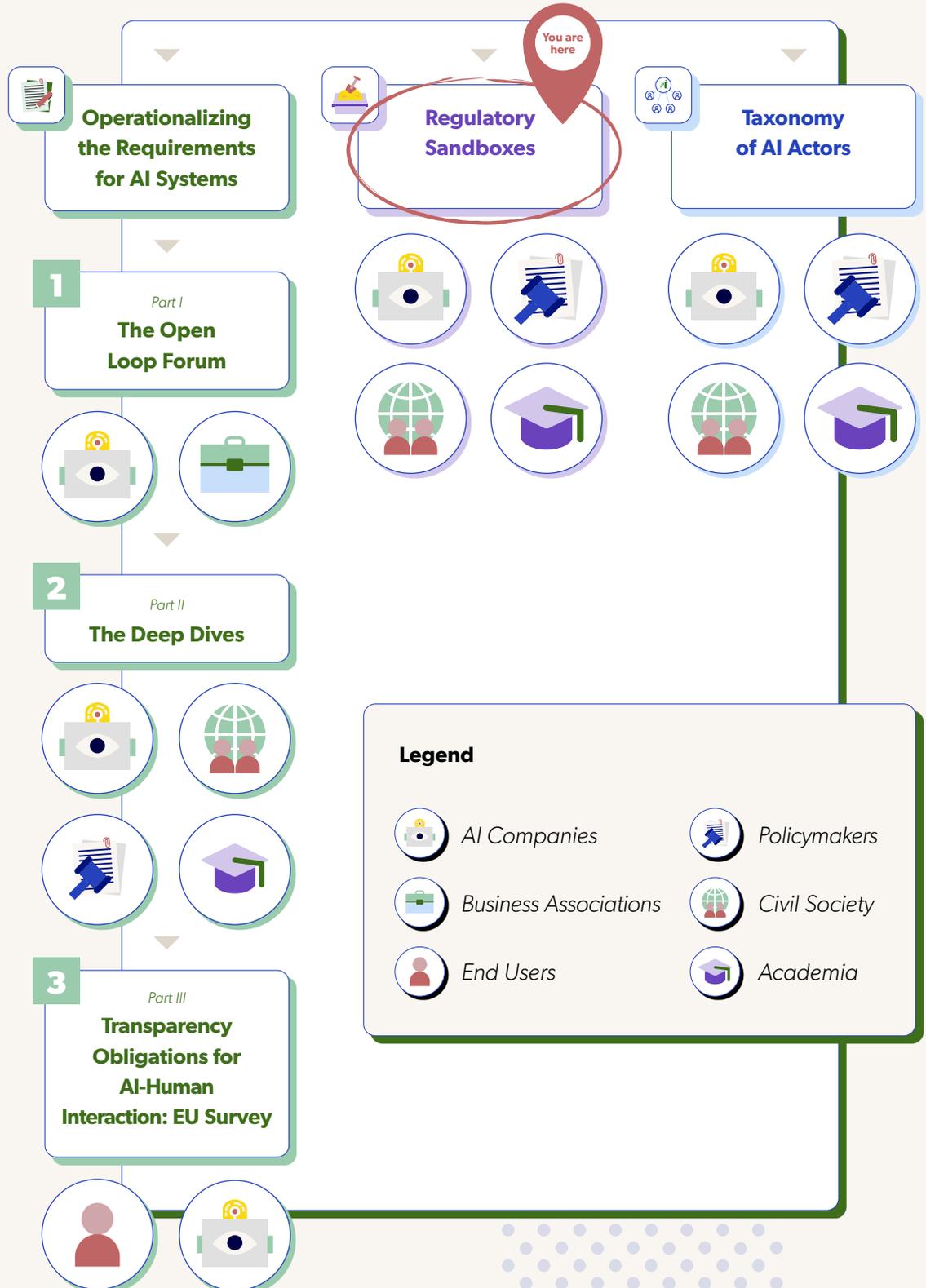


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Artificial Intelligence Act: A Policy Prototyping Experiment

Overview of the Open Loop Program on the AI Act and the stakeholders involved



Executive summary	10
1 Introduction	13
Reading guide	14
Methodology	14
2 Regulatory sandboxes and experimental governance	16
What is a regulatory sandboxes?	17
Alternatives to regulatory sandboxes	17
3 Objectives for the EU AI regulatory sandbox	20
Objectives in the EU AIA	21
Alternative and additional objectives	23
4 Conditions for a successful AI regulatory sandbox	24
Clear goals and focus	25
Generalizable results	25
Clear roles and responsibilities for participants	26
Objective selection criteria	26
Collaboration	26
Clear and limited timelines	26
Technical expertise	26
Regulatory leeway	26
Benefits for participants	27
Confidentiality & governance of sandbox assets	27
Transparency and openness	27
Cross-border eligibility	27
Clear exit criteria	28

5 Analysis of the EU AI regulatory sandbox 29

Outstanding issues regarding the EU AI regulatory sandbox30

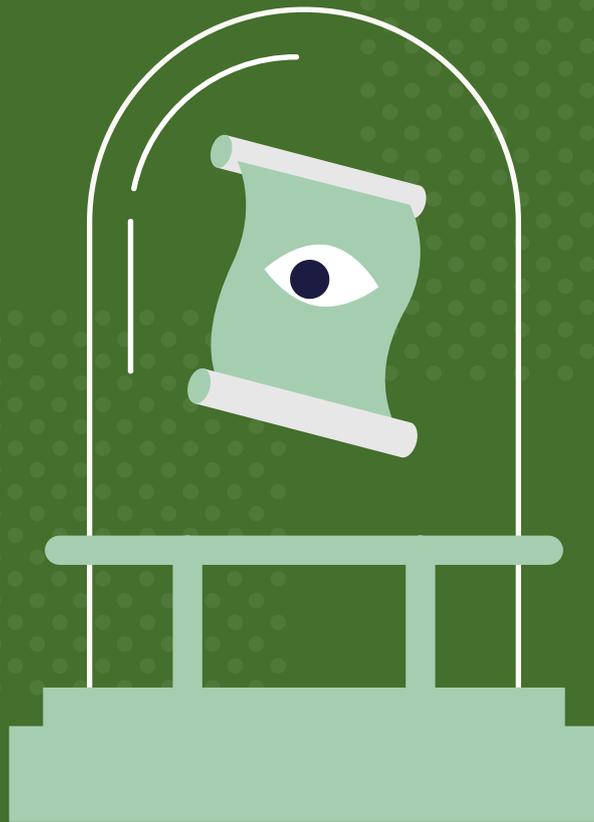
Analysis34

6 Summary and conclusions 36

Annex 1: Contents of sandbox documentation 40

Annex 2: Interviewees & List of participants in the Design Jam 42

Endnotes 44



Executive summary

Executive summary

This report, which is part of the Open Loop Program on the EU Artificial Intelligence Act (AIA), explores the AI regulatory sandbox provision described in article 53 of the AIA.¹ More specifically, we explored the goals of the AI regulatory sandbox and the conditions necessary to achieve them. In particular, we sought answers to the following research questions (RQs):

- 1 **RQ1: What are the objectives of the EU AI regulatory sandbox?**
- 2 **RQ2: What conditions are necessary to achieve the objectives of the EU AI regulatory sandbox?**
- 3 **RQ3: Does article 53 of the AIA enable the necessary conditions for a successful EU AI regulatory sandbox?**
- 4 **RQ4: Are there alternative governance mechanisms to achieve the objectives of the EU AI regulatory sandbox?**

To answer the RQs, we collected data from three different sources: desk research, interviews with experts, and a Sandbox Policy Design Jam. This mixed-method approach allowed us to triangulate the data and address the four RQs from various perspectives.

We concluded that the EU AI Regulatory Sandbox must contribute to the following goals:

- **foster innovation by ensuring compliance through controlled experimentation;**
- **create legal certainty;**
- **enhance the competent authorities' oversight and understanding; and**
- **accelerate market access.**

To achieve these goals, several conditions need to be in place. In our research, we identified the following conditions for a successful regulatory sandbox:

- **Clear goals and focus**
- **Regulatory leeway**
- **Generalizable results**
- **Benefits for participants**
- **Clear roles and responsibilities for participants**
- **Confidentiality & governance of sandbox assets**
- **Objective selection criteria**

- **Transparency and openness**
- **Collaboration**
- **Cross-border eligibility**
- **Clear and limited timelines**
- **Clear exit criteria**
- **Technical expertise**

We conclude that, by itself, article 53 of the AIA does not enable the necessary conditions for successful regulatory sandboxes. Article 53 of the AIA formulates the general goals for the sandbox but is not explicit on how these goals should be accomplished. In particular, it does not specify relevant conditions for a successful regulatory sandboxes. Although this sounds worrying, it is not necessarily problematic, as the actual conditions can be created through the implementing act(s) described in article 53(6) of the AIA. Furthermore, the changes proposed by the European Parliament and the Council of the European Union cover many of the necessary conditions for successful AI regulatory sandboxes discussed in this report.

A particular challenge for AI regulatory sandboxes is to make them sufficiently attractive for AI providers. Given that an AI regulatory sandbox does not provide any benefits in terms of regulatory leeway, other incentives are needed for participants to join. These can be offered in the form of direct interaction with the regulator, access to knowledge and other resources, a collaborative learning environment, etc. At the same time, member states should avoid creating conditions that are too favorable for participants in the sandbox, as this may lead to a distortion of the level playing field for the development of AI in Europe.

Regarding these conditions through implementing acts and rules for the governance of individual sandboxes, ensuring a harmonized approach is advised. That is, the conditions for AI regulatory sandboxes and the rules for governance should be more or less the same to avoid “sandbox shopping” and to promote a level playing field for participation in sandboxes.

Finally, although an AI regulatory sandbox may contribute to the goals set out by the EU legislator, it is not a “silver bullet.” Member states should therefore also explore additional and alternative experimental governance means to achieve the goals mentioned in the AIA, such as guidance, innovation hubs, testbeds, and experimental legislation.



Introduction

With the EU AI Act (AIA), the European Commission has introduced the concept of an **AI regulatory sandbox**. The main goal of the AI regulatory sandbox is to support innovation and promote the use of AI.² More specifically, the AI regulatory sandbox supports the goal of creating a legal framework that is innovation-friendly, future-proof, and resilient to disruption.³ As part of the Open Loop Program on the AIA, we explored the AI regulatory sandbox provision described in article 53 of the AIA. The Program has three pillars: 1) operationalizing the requirements for AI systems, 2) regulatory sandboxes, and 3) the taxonomy of AI actors. In the first pillar, the requirements for developing, building, and maintaining AI systems were explored. In the third pillar, the taxonomy of actors provided by the AIA (e.g., provider, user) was assessed. In this report, we describe the results of our research on AI regulatory sandboxes (pillar 2).⁴ More specifically, we explore the goals of the AI regulatory sandbox and the conditions necessary to achieve them.

In our research, we sought answers to the following research questions (RQs):

- 1 **RQ1: What are the objectives of the EU AI regulatory sandbox?**
- 2 **RQ2: What conditions are necessary to achieve the objectives of the EU AI regulatory sandbox?**
- 3 **RQ3: Does article 53 of the AIA enable the necessary conditions for a successful EU AI regulatory sandbox?**
- 4 **RQ4: Are there alternative governance mechanisms to achieve the objectives of the EU AI regulatory sandbox?**

Reading guide

The report is structured as follows. In Chapter 2, we describe the concept of regulatory sandboxes and their place in the landscape of experimental governance and regulation.

In Chapter 3, we explore the goals of an AI regulatory sandbox. We look at both the goals set by the EU in the AIA and the goals we found in the literature, interviews, and the Sandbox Policy design Jam we organized as part of this program.

In Chapter 4, we discuss the conditions that must exist to achieve the goals of the AI regulatory sandbox identified in Chapter 3.

Taking into account the insights from chapters 3 and 4, and to address research questions 3 and 4, we discuss the outstanding issues with the AI regulatory sandbox in Chapter 5.

Based on the findings in this report, we list the relevant requirements and conditions that can be captured in sandbox documentation (e.g., general communications, sandbox regulations or charters, and terms & conditions) in Annex 1.

Methodology

To answer the research questions, we collected data from three different sources: desk research, semistructured interviews with experts, and a Sandbox Policy Design Jam. For desk research, we used academic literature from publicly available sources as well as relevant documents from the legislative process of the AIA. Interviews with experts in the field guided our research and allowed us to select key aspects to assess during the Policy Design Jam, which is described in depth in the box below. A list of the interviewees and the participants of the Policy Design Jam is available in annex 2 of this report.

This mixed-method approach allowed us to triangulate the data and address the research questions from various perspectives.

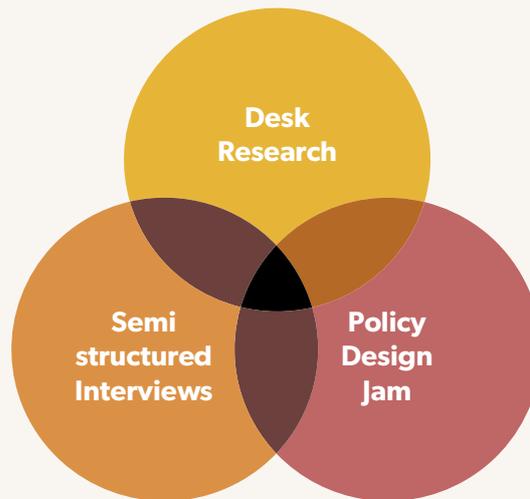


Figure 2. Mixed-methods methodology

Box 1

What is a Sandbox Policy Design Jam?

To receive feedback on the goals and necessary conditions for a regulatory sandbox, we organized an online Policy Design Jam with sandbox experts, policymakers, and AI providers. A design jam is a collaborative brainstorming exercise whereby participants collectively generate ideas and solutions for design challenges. With the Sandbox Policy Design Jam, the objective was not so much to design a product or service but rather to design a policy. The design challenge for the Sandbox Policy Design Jam was how to create a successful regulatory sandbox by identifying conditions for success.

In the Sandbox Policy Design Jam, we first brainstormed and discussed the goals of an AI regulatory sandbox. Next, we brainstormed and discussed the relevant conditions for a successful sandbox. The results were captured in a tool for online brainstorming (Mural).



Figure 3. Pictures from the Sandbox Policy Design Jam

2



Regulatory sandboxes and experimental governance



What is a regulatory sandboxes?

According to the Organisation for Economic Co-operation and Development (OECD), a regulatory sandbox refers to a limited form of regulatory waiver or flexibility for firms, enabling them to test new business models with reduced regulatory requirements.⁵

Regulatory sandboxes provide a scheme to enable firms to test, pursuant to a specific testing plan agreed upon and monitored by a dedicated function of the competent authority, innovative products, services, or business models. Sandboxes may also imply the use of legally provided discretion by the relevant supervisor, but they do not entail the disapplication of regulatory requirements.⁶

Sandboxes are generally applied in scenarios where there is existing legislation that forms a barrier to entry for new participants or hampers innovation. More specifically, regulatory sandboxes are found in the financial world, where there are generally very specific market entry requirements that are based on existing business models. As fintech companies do not fit this traditional regulatory mold, they have difficulties entering the market.

We may discern between two main types of regulatory sandboxes:⁷

Product testing sandboxes:

The objective of a product testing sandbox is to allow a product to see the light of day with a lower initial regulatory burden. The primary output of a product testing sandbox is the launch of a service into the marketplace under either an existing or a modified license.⁸

Policy testing sandboxes:

Within a policy testing sandbox, a specific regulatory hypothesis is tested (i.e., whether a specific rule or regulation should change in light of a specific test result) rather than the commercial viability of the underlying technology. The sandbox becomes the final step in a regulatory continuum, which begins with informal guidance on regulatory uncertainties and ends with a test to determine whether the business model requires the modification of an existing rule or regulation. The primary output of a policy testing sandbox is then the revision, cancellation, or endorsement of a legacy rule or policy.⁹

The main function of a regulatory sandbox is thus to gather evidence about how a new product, technology, or business model (innovation) works and the outcomes it produces. Evidence gathering can help assuage (or confirm) regulatory concerns about the impact of innovations, thus allowing beneficial innovations to reach the marketplace.¹⁰

Alternatives to regulatory sandboxes

Whereas a regulatory sandbox may be an effective way to achieve policy goals (e.g., stimulate innovation and provide guidance to market participants), it may also have drawbacks. For instance, it is time and resource-intensive for regulators and may upset the level playing field between those who have access to the sandbox and those who do not. Therefore, policymakers should consider alternatives to regulatory sandboxes, as some of the goals of regulatory sandboxes may also be achieved through other mechanisms. Below,

we describe some mechanisms that could be used instead of or in addition to regulatory sandboxes. In chapter 5, we will revisit these alternatives when we discuss the necessity of sandboxes.

Innovation offices/hubs

One of the goals of a regulatory sandbox is to provide guidance to participants. Innovation offices provide similar functionality. The goal of an innovation office (also called innovation hub) is to enhance an organization's understanding of the regulatory and supervisory expectations regarding innovative business models, products, and services. This is done by providing firms with a contact point for asking questions of, and initiating dialogue with, competent authorities regarding the application of regulatory and supervisory requirements to innovative business models.¹¹ Innovation offices/hubs commonly provide organizations with non-binding guidance on the conformity of their proposed business models with regulatory requirements.¹² An example of an innovation hub is that of the two Dutch financial regulators, Autoriteit Financiële Markten (AFM) and De Nederlandsche Bank (DNB): InnovationHub.¹³

Innovation testbeds

Innovation testbeds are programs that provide access to physical or virtual environments in which companies or public sector stakeholders can test, develop, and introduce new products, services, processes, organizational solutions, and business models.¹⁴ Testbeds can be not only highly controlled (virtual) environments but also real world environments.

An example of a testbed is the cross-border testbed for autonomous vehicles operated by France, Germany, and Luxembourg.¹⁵ Although testbeds and sandboxes take a similar approach, a testbed is generally not directly aimed at facilitating market entry but rather at stimulating the development and application of new products and services.

Guidelines

Guidelines can provide explanations of legal provisions and guidance on how to comply with these provisions. Guidelines may be issued by the legislator or provided by the regulator. Examples of these would be the European Data Protection Board (EDPB) Guidelines that interpret certain provisions of the EU General Data Protection Regulation (GDPR).

Horizon scanning

Horizon scanning is a foresight method used for discovering early signs of potential change. It is a systematic process that enables the legislator to spot trends and identify key action points to proactively shape desirable futures.¹⁶ Through horizon scanning, a legislator may identify aspects that require regulatory intervention. The United Kingdom's government, for instance, has a dedicated Horizon Scanning Programme Team.¹⁷ Although it is more of a theoretical exercise than a practical exercise like a regulatory sandbox, horizon scanning may also yield valuable insights into the future requirements for law and policy.

Experimental legislation

Experimental legislation can be described as follows:

“New temporary regulations with a circumscribed scope that, derogating existing law or exempting a number of existing legal requirements, are designed to try out novel legal approaches or to regulate new products or services so as to gather more information about them.”¹⁸

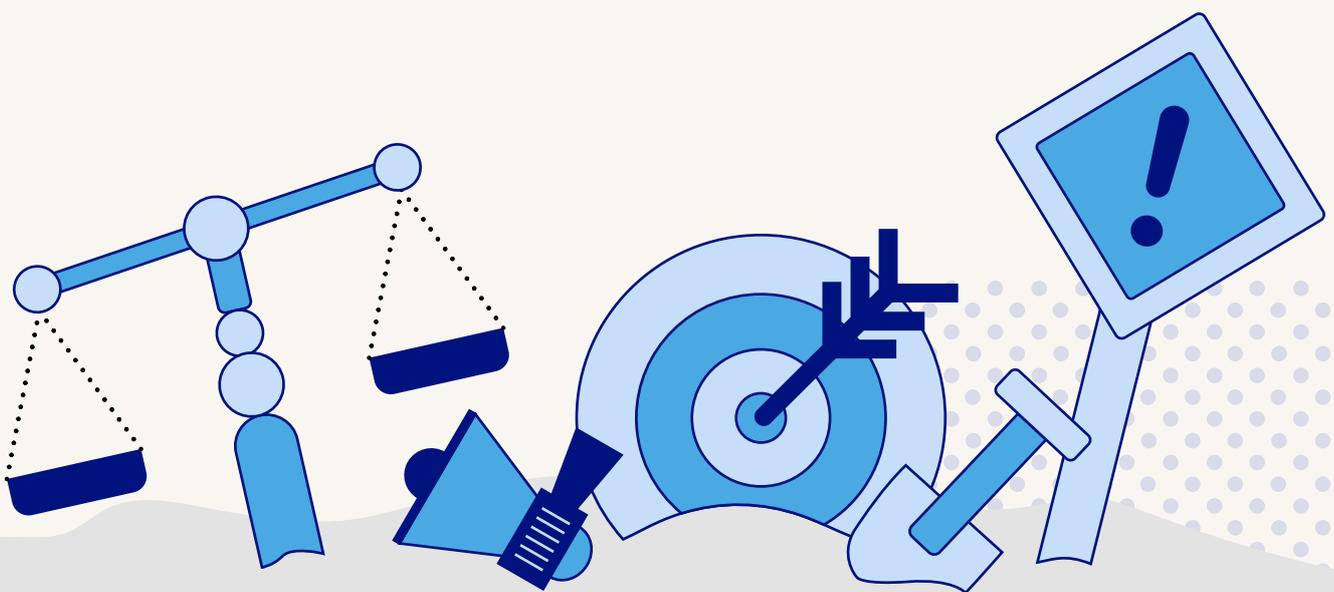
Experimental legislation is subjected to a periodic or final evaluation, after which the legislator should decide on whether the experiment should be extended to a larger part of the



population, generalized and converted in a permanent legislative act, or terminated.¹⁹ An example of experimental legislation in practice is EU Regulation 2020/1043 on COVID-19. The COVID-19 Regulation was aimed at speeding up the development of genetically modified organism (GMO) based COVID-19 treatments or vaccines by temporarily suspending requirements that otherwise would have made for time-consuming and burdensome authorization processes.²⁰

Changes to legislation

When issues with existing legislation are clear (inadequate protection of human rights, barriers to innovation, etc.), the most obvious choice is to change the legislation. For instance, when existing licensing requirements are too strict or are not fit for newcomers in the market, the legislator could decide to change these requirements or create a permanent exemption for newcomers.





Objectives for the EU AI regulatory sandbox

Objectives in the EU AIA

The AIA encourages member states to set up AI regulatory sandboxes. Article 53(1) of the AIA reads:

“AI regulatory sandboxes established by one or more Member States competent authorities or the European Data Protection Supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.”

Based on the text of the draft AIA and the explanatory memorandum, we see that the AI regulatory sandbox sets out to achieve different objectives. Recital 71 of the AIA states:

“Artificial intelligence is a rapidly developing family of technologies that requires novel forms of regulatory oversight and a safe space for experimentation, while ensuring responsible innovation and integration of appropriate safeguards and risk mitigation measures. To ensure a legal framework that is innovation-friendly, future-proof and resilient to disruption, national competent authorities from one or more Member States should be encouraged to establish artificial intelligence regulatory sandboxes 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.”

Recital 72 of the AIA builds on this and states:

“The objectives of the 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 Member States legislation; to enhance legal certainty for innovators and the competent authorities’ oversight and understanding of the opportunities, emerging risks and the impacts of AI use, and to accelerate access to markets, including by removing barriers for small and medium enterprises (SMEs) and start-ups (...).”

We may deduce from this text that there are four separate but interrelated goals:

Foster innovation by ensuring compliance through controlled experimentation

The first objective of the AI regulatory sandbox according to recital 72 is to foster AI innovation by establishing a controlled experimentation and testing environment in the development and pre-marketing phase. The aim of this experimentation and testing environment is to ensure compliance.²¹ The sandbox should support small and medium enterprises (SMEs) in complying with the AIA and help reduce their costs.²² Finally, the sandbox might facilitate the development of trustworthy AI. Within the sandbox, tools and processes may be developed (e.g., AI explainability methods and methods for documenting the AI development process) that will contribute to the overall goal of creating trustworthy AI.

Create legal certainty

The second objective of the AI regulatory sandbox is to enhance legal certainty for innovators. Within the sandbox, innovators may, for instance, consult with the regulator and thus get a more concrete idea on what compliance would entail in their particular use case.

Enhance the competent authorities' oversight and understanding

The third objective is to enhance the competent authorities' oversight and understanding of the opportunities, emerging risks, and impacts of AI use. By observing and monitoring the developments in the sandbox, competent authorities get a "hands on" understanding of the emerging risks and impacts of AI use. In the interviews, regulators underlined the importance of sandboxes in helping identify new market trends. Furthermore, the interviews and Sandbox Policy Design Jam revealed a "scanning factor"—that is, the importance of reducing the risk of harmful AI systems entering the market. By gaining a better understanding of

the impacts of AI through the sandbox, the regulator can gain a clearer picture of potential risks and act accordingly. The goal of "Council of the European Union (Council)"²⁵ mentioned by the Council solidifies this approach as a specific goal of the regulatory sandbox.

Accelerate market access

The fourth objective of the AI regulatory sandbox is to accelerate access to markets by removing barriers, particularly for SMEs and startups. Based on the text of the AIA, it is not entirely clear which barriers the legislator means.²³ In financial regulatory sandboxes, for instance, there is generally a (temporary) lifting of licensing requirements, allowing innovative companies to enter the market. Within the AI regulatory sandbox, however, all the rules still apply; therefore, in this sense, (legal) barriers are not removed. We hypothesize that the legislator therefore does not refer to legal barriers here but rather to practical barriers such as a lack of technical and legal knowledge on how to comply with the AIA. The European Parliament has proposed an amendment to include these goals in the actual text of the Regulation.²⁴ Furthermore, the Council has stated more clearly defined goals in its general approach. The following are goals formulated by the Council:

- a** foster innovation and competitiveness and facilitate the development of an AI ecosystem;
- b** facilitate and accelerate access to the Union market for AI systems, particularly when provided by SMEs, including startups;
- c** improve legal certainty and contribute to the sharing of best practices through cooperation with the authorities involved in the AI regulatory sandbox with a view to ensuring future compliance with this Regulation and, where appropriate, with other Union and member states legislation; and
- d** contribute to evidence-based regulatory learning.²⁶

Alternative and additional objectives

Based on our literature review, interviews with sandbox experts, and the Sandbox Policy Design Jam, we identified the following additional goals that may be of relevance for an AI regulatory sandbox:

Create a learning environment for the development of trustworthy AI

An AI regulatory sandbox could be a place for the safe exchange of ideas between industry and the regulator of best practices on compliance with the AIA. By enabling direct and open dialogue with enforcement authorities, a learning environment may be created. Furthermore, ideas and best practices may be shared between the sandbox participants, creating a collaborative environment for the development of trustworthy AI. The Council's goal of "contributing to the sharing of best practices" is aimed at creating such a learning environment, although it seems to be mainly focused on the interaction between the participants and the regulator and not so much on interactions between participants.

Provide input for AI governance and future regulatory initiatives

An AI regulatory sandbox can generate important knowledge that can provide input for other governance and regulation initiatives. First, the sandbox can provide input for the development of AI standards. The European Parliament proposed an amendment that specifically adds this point as a goal for the AI regulatory sandbox.²⁷ The Council has also stated this as an explicit goal by adding "evidence-based regulatory learning."²⁸

Next, the sandbox may help identify regulatory gaps and thus provide information for future regulatory initiatives. This may also apply to the AIA itself. In other words, the lessons learned from the AI regulatory sandbox could be used to revise and update the AIA. The European Parliament has proposed an amendment specifying this goal of the AI regulatory sandbox.²⁹

Furthermore, the sandbox may be helpful in determining the effectiveness and feasibility of AI requirements, including the use of associated tools and templates (e.g., technical documentation and impact assessments). By "piloting" these tools and templates in the sandbox, we may learn valuable lessons about their practical applications.

Foster economic development

Finally, the existence of an AI regulatory sandbox might improve the business climate in a particular region or country. Getting access to knowledge and expertise and ultimately shortening the time to market of their product or service is valuable for startups. As such, it might be attractive for startups to incorporate or do business in a region or country where they know there is a sandbox that can provide these benefits.



Conditions for a successful AI regulatory sandbox

Based on the goals set out by the EU and taking into account the additional goals we have identified, we can explore the conditions that are relevant for a successful AI regulatory sandbox.

These conditions were derived from the literature, the legislative process on the AIA, interviews with sandbox experts, and the Sandbox Policy Design Jam. Note that these conditions may not be all met within a single sandbox and may even be at odds with one another (e.g., confidentiality and transparency). It is up to the legislator and regulator to determine which conditions are most relevant and how they should be balanced.

The European Parliament has proposed an amendment to the AI Act requiring that, no later than 12 months following the entry into force of the AIA, procedures, processes, and bureaucratic requirements for application, selection, participation, and exiting the sandbox should be defined in implementing acts.³⁰

Clear goals and focus

Before starting a sandbox initiative, the goals of the sandbox should be clearly defined, and the operation of the sandbox must be aligned with these goals. Furthermore, creating a clear focus for the sandbox exercise is relevant.

Most of the sandbox initiatives currently in operation are focused on the financial sector. These sandboxes tend to focus on the operation of innovative companies in the financial space (financial technology, or fintech) and deal with specific licensing requirements. This narrow focus makes it easier to set clear goals for the sandbox and rules for participation in and governance of the sandbox.

The range of potential applications of AI across various sectors is vast, making it crucial to establish clear goals and focus for an AI regulatory sandbox. Without such clarity, there may be insufficient incentives for participants to join, or the sandbox may provide inadequate legal certainty. While a "general" AI sandbox may prove beneficial, a narrower focus could facilitate the selection of participants, enable the establishment of learning goals, and allow for the formulation of exit criteria.

Generalizable results

Interviewees mentioned that it is important that the results from the sandbox can be generalized. In other words, sandbox findings should not be too case- or participant-specific because this would limit the utility of the sandbox for society and may favor participants over non-participants. The sandbox should not "pick winners" and should provide (indirect) benefits to those outside of the sandbox. In other words, the sandbox should benefit not only the participants within the sandbox but also society at large. Findings that are useful for other AI companies and society at large could, for instance, be published in a sandbox exit report.³¹ The Council specifically mentions the importance of publishing the results of the AI regulatory sandbox:

"The national competent authority shall also provide an exit report detailing the activities carried out in the sandbox and the related results and learning outcomes."³²

“National competent authorities shall make publicly available annual reports on the implementation of the AI regulatory sandboxes, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legislation supervised within the sandbox.”³³

Clear roles and responsibilities for participants

To ensure the smooth operation of the sandbox, the roles and responsibilities of all participants must be clear. When it is clear how participants should conduct themselves and what responses they may expect from the regulator, mutual trust will grow. Ideally, clear metrics are also provided, for instance, on how compliance with a particular requirement from the AIA should be measured.

Objective selection criteria

To ensure fair and equal treatment of potential participants and to set clear expectations for them, objective selection criteria should be formulated. Clear and objective selection criteria will also help to avoid the arbitrary selection of participants and maintain a level playing field for AI providers.

Collaboration

AI providers that participated in our Sandbox Policy Design Jam underlined the importance of collaboration in the sandbox—not just between AI providers and the regulator administering the sandbox but also between participants. Part of the attractiveness of a regulatory sandbox for AI providers is the ability to learn from each other and share experiences.

Clear and limited timelines

Time in the sandbox should be limited. The goal of every sandbox should be that participants who successfully exit the sandbox can enter the market. An amendment proposed by the European Parliament also emphasizes the importance of time limitations in the sandbox and sets these at a maximum of 2 years.³⁴ In its general approach, the Council mentions the importance of clear timelines but leaves the decision on the time spent in the sandbox to the regulator operating the sandbox.³⁵

Technical expertise

In the Sandbox Policy Design Jam, the importance of technical expertise (especially at the side of the regulator) was mentioned. The regulator should be able to effectively surveil the sandbox as well as provide adequate guidance to participants. For these tasks, sufficient technical expertise is necessary.

Regulatory leeway

In order to promote innovation and accommodate new ideas, it is important for the regulatory sandbox to offer flexibility in terms of regulation, "regulatory leeway". This can be achieved by providing temporary exemptions or allowing experimentation clauses.³⁶ This approach enables testing of new technologies and business models without the fear of punishment or enforcement during the testing phase.³⁷ This approach can help companies overcome regulatory barriers and create new opportunities for growth and development.

Benefits for participants

Participation in the AI regulatory sandbox should provide clear benefits for AI providers.

The AI regulatory sandbox takes a somewhat different approach from other sandboxes, such as those in finance. In the financial world, it is oftentimes illegal to offer certain financial products or services without the prerequisite financial license, which is impossible to obtain for fintech companies that do not fit the existing regulatory mold. In these cases, the regulator may provide a stay from enforcement, thus allowing these companies to test their products in the regulatory sandbox under the supervision and guidance of the regulator. For the AI regulatory sandbox, this is not the case: all the rules of the AIA still apply to the participants, and there is no stay from enforcement. There is thus no difference between complying with the requirements of the AIA and participating in a sandbox. The latter becomes a compliance exercise and not an experimental exercise to support innovation through market entry and improve compliance procedures. Furthermore, successful participation in a sandbox is not a prerequisite for market entry.

As such, AI providers may avoid the sandbox if there are no clear benefits over normal market entry and if (administrative) burdens are prohibitively high compared with normal market entry. By providing clear benefits for participation (e.g., access to regulator guidance, experimentation facilities, stay from enforcement, easier access to data, and certification), the AI regulatory sandbox may become more attractive for participants.

The European Parliament has recognized the importance of the benefits for participation in the AI regulatory sandbox and has proposed an amendment mandating that participants in the sandbox are granted access to pre-deployment services, such as preliminary registration of an AI system, insurance, compliance, and research and development (R&D) support services; to all the other relevant elements of the Union's AI ecosystem and other digital single market

initiatives such as testing and experimentation facilities, digital hubs, centers of excellence, and EU benchmarking capabilities; and to other value-adding services such as standardization and certification, community social platform and contact databases, tenders and grant-making portal, and lists of potential investors.³⁸

Confidentiality & governance of sandbox assets

Participants in our design jam mentioned the importance of confidentiality and proper governance of sandbox assets. Protection and confidentiality of data and intellectual property are important for companies who want to retain their competitive advantage. Furthermore, given the fact that participants in the regulatory sandbox are not exempt from the requirements of the GDPR, proper handling of personal data is considered crucial. Confidentiality, in particular, needs to be balanced with other conditions for success, such as collaboration and transparency.

Transparency and openness

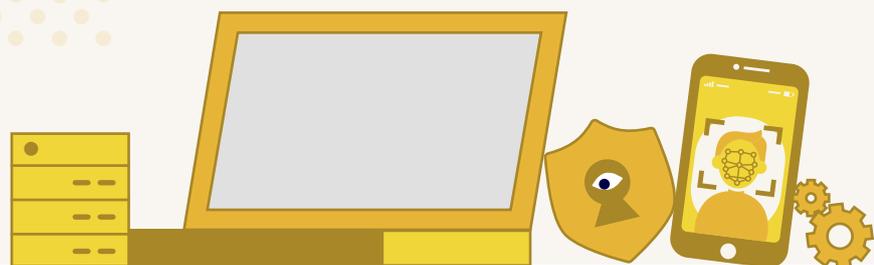
Transparency and openness are relevant for both participants in the sandbox and society at large. Transparency and openness in the sandbox will increase trust and (legal) certainty in the sandbox and will benefit those outside of the sandbox, as they may learn from experiences in the sandbox.

Cross-border eligibility

To ensure the harmonized application of the AIA and create a level playing field within the EU, there should be cross-border eligibility for participation in sandboxes.³⁹ Without cross-border eligibility, there is a risk of less exchange of AI knowledge, and the free flow of goods and services may be impaired. When it comes to cross-border eligibility, the risk of "sandbox shopping" does need to be considered.

Clear exit criteria

To create (legal) certainty for participants and to ensure that participants do not indefinitely remain in the sandbox, clear exit criteria must be formulated. What in any case seems to be an important exit criterion is that participants can meet the criteria for conformity assessment upon exiting the sandbox. If not, then the system will not be allowed on the EU market. Given the current framing of the AIA Regulatory sandbox section, in which regulators cannot give a waiver for meeting AIA requirements, this seems to be a minimum requirement for a “successful” exit that leads to direct market entry.⁴⁰





Analysis of the EU AI regulatory sandbox

Based on the goals described in chapter 3 and the conditions in chapter 4, we will discuss some potential outstanding questions and issues pertaining to regulatory sandboxes in this chapter: the necessity, focus, and attractiveness of sandboxes and the question of data protection. This will help us answer research questions 3 and 4.

- **RQ3: Does article 53 of the AIA enable the necessary conditions for a successful EU AI regulatory sandbox?**
- **RQ4: Are there alternative governance mechanisms to achieve the objectives of the EU AI regulatory sandbox?**

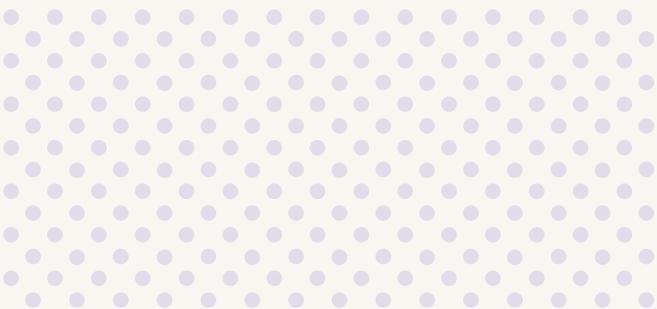
Outstanding issues regarding the EU AI regulatory sandbox

Necessity

In chapter 2, we discussed the alternative mechanisms for dealing with innovation and regulation. Although a regulatory sandbox for AI may be a good mechanism to achieve the goals described in chapter 3 of this report, there are alternatives that may yield similar, if not better, results. The regulatory sandbox is but one tool amongst many in the arsenal of legislators.

When it comes to supporting and fostering innovation, we need to take into account all the possible options. Regulatory sandboxes might not be the “silver bullet” that accomplishes all the goals that have been set out by the legislator.

Jenik and Duff have created a flowchart for policymakers that helps determine whether a sandbox is the proper tool to stimulate innovation or whether a different mechanism or tool is more appropriate.⁴¹



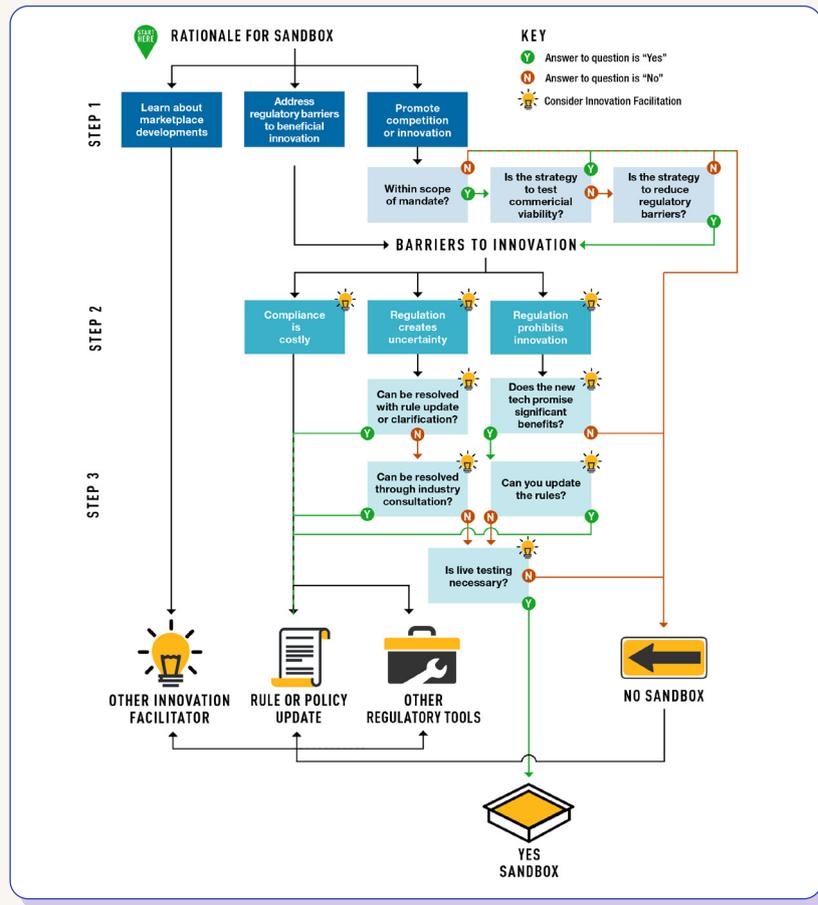


Figure 4. Is a regulatory sandbox the optimal policy intervention? ⁴¹

What we can learn from this chart is that a sandbox is best suited if certain requirements are met:

- 1 the new tech promises significant benefits;
- 2 the issue cannot be resolved through a rules update or clarification;
- 3 the issue cannot be resolved through industry consultation; and
- 4 live testing is necessary.

When we apply this flowchart to the different goals defined by the AIA for AI regulatory sandboxes, we obtain the following results:

Policy goal	Innovation mechanism	Explanation
<p>1. Foster innovation by ensuring compliance through controlled experimentation</p>	<p>Regulatory sandbox, testbeds, experimentation clauses</p>	<p>A regulatory sandbox allows for controlled experimentation. A testbed can also achieve this goal, but it is earlier in the technology development cycle. Finally, experimentation clauses in the law can create (more) room for controlled experimentation. These clauses would then apply to all AI providers and not just to those who participate in the sandbox, creating a more level playing field and (potentially) placing fewer burdens on the regulator.</p>
<p>2. Create legal certainty for innovators</p>	<p>Guidelines, rules update</p>	<p>Both the legislator and the regulator can improve legal certainty through the development of clear guidelines. Another option is to simply change the rule, adapting it to the new reality.</p>
<p>3. Enhance the competent authorities' oversight and understanding</p>	<p>Horizon scanning, testbeds, innovation hubs</p>	<p>Although a sandbox may help regulators to understand the opportunities, risks, and impacts of AI, there are other ways to learn about the technology, such as horizon scanning. Furthermore, regulators may learn about market trends by becoming a stakeholder in a testbed or acting as an innovation hub. In acting as an innovation hub, for instance, regulators will need to build capabilities to understand the technology. They will also receive questions from the market, which will further broaden their understanding of AI, its application, and market trends.</p>
<p>4. Accelerate market access</p>	<p>Innovation hubs, guidelines, testbeds</p>	<p>The issue SMEs and start-ups generally face is uncertainty about how to interpret and implement rules. They can be more easily supported by clear guidance in the form of guidelines and support from innovation hubs, thus allowing them to benefit from the regulator's take on some of these issues. Unlike sandboxes, innovation hubs have little to no barriers to entry, ensuring that advice is more readily available for AI providers and that scale can be more easily achieved.</p>

Table 1. Results of applying the flowchart to the goals defined by the AIA for AI regulatory sandboxes

Based on this assessment, we can establish that an AI regulatory sandbox is of particular use when there is need for a controlled experimentation and testing environment to ensure compliance. The other goals (e.g., creating legal certainty and enhancing the understanding of the legislator) can oftentimes be more easily achieved using other mechanisms that require fewer resources and/or have fewer barriers to entry. Many of these mechanisms could also be more efficient and effective than an AI regulatory sandbox. Of course, it is possible to achieve several of the aforementioned goals at once within the sandbox. When contemplating building AI regulatory sandboxes, it is advised that member states set forth clear goals for the sandbox and design the sandbox with these goals in mind while considering alternative mechanisms to achieve these goals.

Focus

As described in the previous chapter, clear goals and focus are conditions that contribute to an effective sandbox. Given that AI has such a broad range of applications, to which different laws and regulations may apply, focusing on an AI regulatory sandbox might be problematic. When the focus is (too) broad, ensuring sufficient technical and subject matter expertise might be difficult. Cooperation between regulators is likely necessary to ensure that sufficient resources, technical expertise, and subject matter expertise are available for the sandbox.

Attractiveness

A particular question with the AI regulatory sandbox approach is how attractive it will be for participants.

Regulatory sandboxes, particularly in the finance sector, are of significant interest to participants, as they provide a temporary respite from licensing requirements. The AI regulatory sandbox presents an opportunity for companies to enter the market without encountering

any (or at least significant) legal barriers. However, from the perspective of market entry, AI providers may not have a compelling incentive to participate in the sandbox. Moreover, participation in the sandbox does not grant participants any exemption from the requirements of the AIA, either temporarily during the sandbox phase or permanently after leaving it. Consequently, from this perspective, AI providers appear to have little motivation to participate, especially considering that participation may lead to additional administrative burdens and expose them to rigorous regulatory scrutiny during the design phase.⁴² Finally, there seems to be no clear difference between AI providers exiting the sandbox and those who have not participated—for instance, there is no certification or formal approval for participants.

What could be a clear benefit is the access to personal data, as described in article 54 of the AIA. However, this comes with its own set of issues as we will describe in the following section. If the above points cannot be addressed, other ways of making the sandbox more attractive are available, such as guidance from the regulator, access to funding, and investor networks. Although these incentives may improve the appeal of the sandbox, they also raise the question of whether the sandbox is used for experimentation, as mainly a networking platform, or to get some form of preferential treatment vis-à-vis competitors outside of the sandbox.

Data protection

Article 54 of the AIA allows the processing of personal data lawfully collected for other purposes for the purposes of developing and testing certain innovative AI systems in the sandbox under particular conditions. This provision is problematic, as it interferes with a fundamental principle of data protection: purpose limitation.⁴³ Indeed, the EDPB and the European Data Protection Supervisor (EDPS) have already stated in a joint opinion that any processing of personal data within the sandbox must be compliant with the GDPR.⁴⁴

However, even if the exemption to the purpose limitation principle in the sandbox would remain in the final version of the AIA, the added value of this exemption may be limited. First, personal data may only be used for the purpose of complying with one or more of the requirements referred to in Title III, Chapter 2, where those requirements cannot be effectively fulfilled by processing anonymized, synthetic, or other non-personal data. In other words, the use of personal data is aimed at enabling compliance with the AIA and not so much at opening new uses of personal data using AI. Furthermore, the wordings of article 54 of the AIA and recital 72 seem to suggest that personal data may only be processed within the regulatory sandbox. This will significantly

reduce the usefulness of this article. For instance, if data are needed within the sandbox to comply with Chapter 2, it is highly likely that they are also needed outside of the sandbox. When the AI provider can no longer rely on the exemption because they have exited, they will need to find a legal basis for processing the data that were used in the sandbox, which might not always be possible. For instance, when the data were originally collected for a different purpose and the compatibility test of article 6(4) of the GDPR fails, the AI provider cannot argue that they may use the data on the basis of article 6(4) of the GDPR. This means that they must collect the data anew based on a legal basis in the GDPR (e.g., consent or legitimate interest).

Analysis

Considering the outstanding questions and issues discussed above, we can answer research questions 3 and 4.

- **RQ3: Does article 53 of the AIA enable the necessary conditions for a successful EU AI regulatory sandbox?**

Article 53 of the AIA outlines the general goals for the regulatory sandbox, but does not provide explicit details on how these goals should be achieved. **In fact, article 53 does not enable the necessary conditions for successful regulatory sandboxes.** Nonetheless, it is important to note that the implementing act(s) described in article 53(6) of the AIA can create the required conditions. Additionally, the proposed changes by the European Parliament and the Council of the European Union address many of the necessary conditions for successful AI regulatory sandboxes, as discussed in this report.

When it comes to creating favorable conditions for successful AI regulatory sandboxes, the conditions mentioned in chapter 3 could be considered. Further, when drafting the implementing acts, the issues described in chapter 4 should be considered. In particular, the attractiveness of the sandbox and the issues of data use and data protection are relevant to address.

The issue of attractiveness ties in with our fourth research question:

- **RQ4: Are there alternative governance mechanisms to achieve the objectives of the EU AI regulatory sandbox?**

The answer to this question is yes: the goals set forth in the AIA for the regulatory sandbox can, for the most part, also be achieved through other mechanisms, such as guidance. Depending on the circumstances, these mechanisms may be more accessible, effective, and efficient than regulatory sandboxes. When creating AI regulatory sandboxes, it is relevant to determine which of the goals can be achieved by the sandbox and which may be achieved through other mechanisms. In any case, it seems worthwhile to combine multiple goals in the sandbox.

The biggest challenge for the AI regulatory sandbox could be that of making it sufficiently attractive. As we have discussed, the AI regulatory sandbox does not create a space with less stringent application of rules or with temporary exemption from rules. It seems that the idea of the legislator is to create a space where AI providers and regulators may learn more about the application of the AIA through controlled experimentation. Although this might be worthwhile, it will strongly depend on the conditions within the sandbox and the benefits that participants experience by participating in the sandbox. If these benefits (direct interaction with the regulator, access to knowledge and other resources, a collaborative learning environment, etc.) are not sufficiently clear, AI providers may not participate. At the same time, it is not recommendable to create too favorable conditions for participants in the sandbox, as this may lead to a distortion of the level playing field for the development of AI.

6



Summary and conclusions

In this Open Loop program, we explored the AI regulatory sandbox provision in the AIA. We concluded on the basis of the AIA that the regulatory sandbox must contribute to the following goals:

- foster innovation by ensuring compliance through controlled experimentation;
- create legal certainty;
- enhance the competent authorities’ oversight and understanding; and
- accelerate market access.

Apart from these goals, the regulatory sandbox could contribute to achieving the following goals:

- create a learning environment for the development of trustworthy AI;
- provide input for AI governance and future regulatory initiatives; and
- foster economic development.

To achieve these goals, several conditions need to be met. In our research, we identified the following conditions for a successful regulatory sandbox (see Figure 5 below):

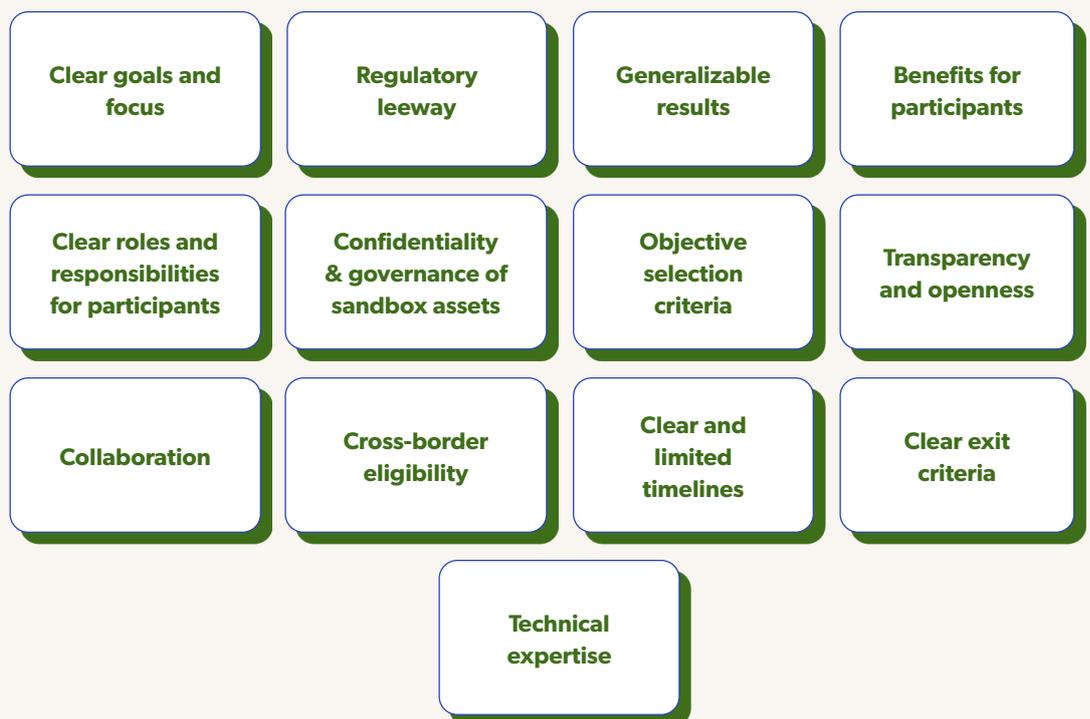


Figure 5. List of conditions for a successful regulatory sandbox

A particular challenge in this context is to make the AI regulatory sandbox sufficiently attractive for AI providers. Given that the sandbox does not provide any benefits in terms of regulatory leeway, other incentives are required for participants to join. These can be in the form of direct interaction with the regulator, access to knowledge and other resources, a collaborative learning environment, etc. At the same time, member states should avoid creating conditions that are too favorable for participants in the sandbox, as this may lead to a distortion of the level playing field for the development of AI in Europe.

When it comes to enabling these conditions through implementing acts and rules for the governance of individual sandboxes, ensuring a harmonized approach is advisable. That is, the conditions for sandboxes and the rules for governance should be the same to avoid “sandbox shopping” and to promote a level playing field for participation in sandboxes.

Finally, although an AI regulatory sandbox may contribute to achieving the goals set out by the EU legislator, it is not a “silver bullet.” Member states should therefore also explore additional and alternative means to achieve the goals mentioned in the AIA, such as guidance, innovation hubs, test-beds, and experimental legislation.



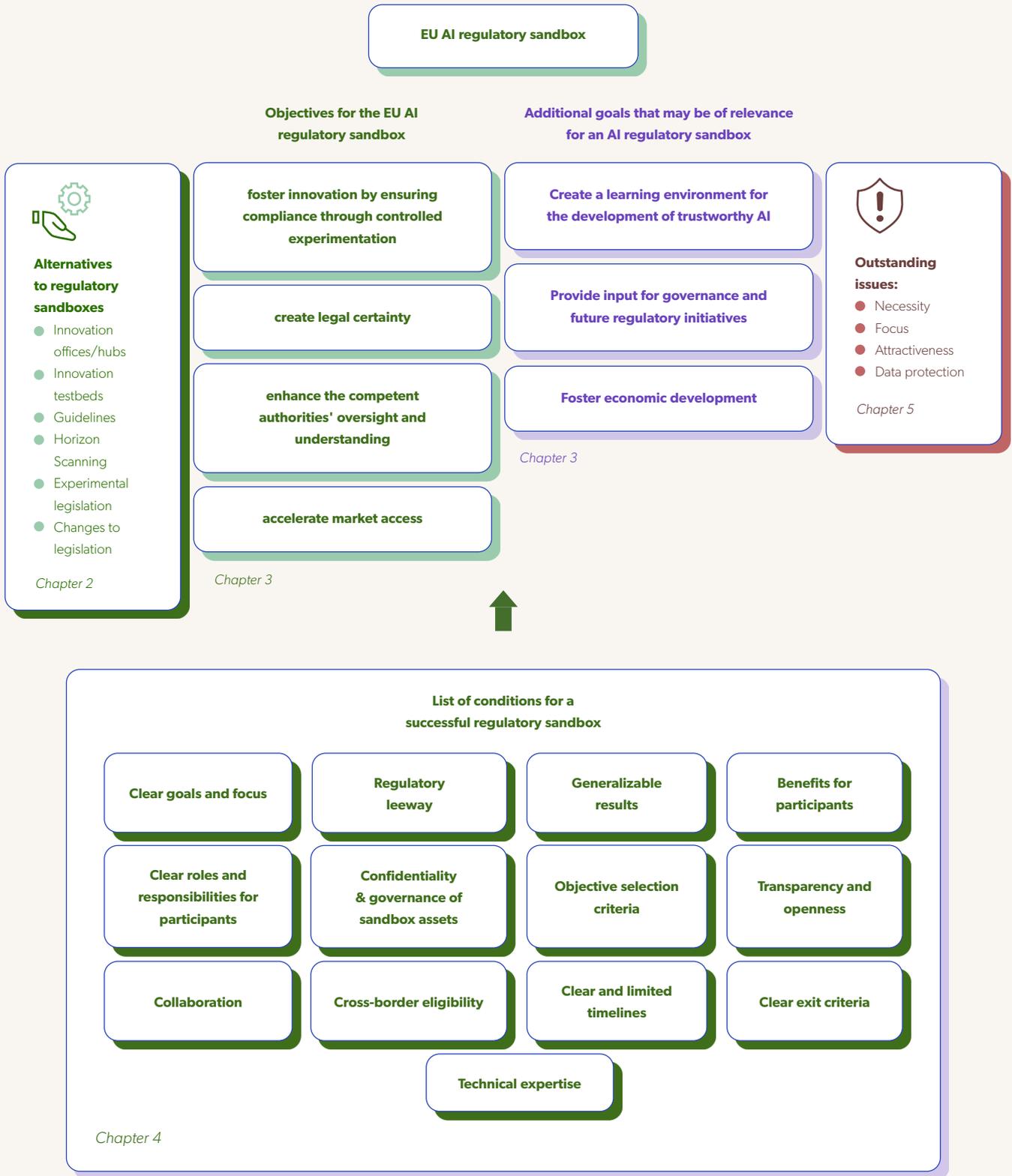
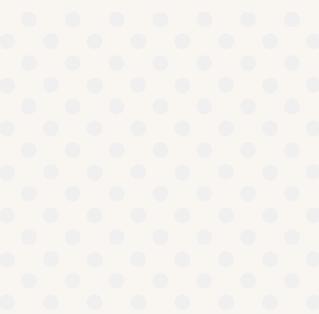


Figure 6. Overview of the elements discussed in this report on EU AI regulatory sandboxes



**Annex 1:
Contents of sandbox
documentation**



Based on the conditions identified in chapter 3, we can list the elements that must in any case be covered when operating a regulatory sandbox. These elements can be captured in sandbox documentation (e.g., general communications, sandbox regulations or charters, and terms & conditions).

- **Roles and definitions**

The roles of sandbox actors (participants, regulators, others) and provisions should be clear.

- **Entry criteria**

Clear criteria for entry must be formulated, with specific focus on SMEs and start-ups that have preferential access to the sandbox.

- **Testing plan**

Participants should deliver a testing plan. A testing plan includes timelines, relevant milestones, and the expected test results that demonstrate the functionality of a stated product or service.⁴⁵ The requirements for a testing plan should be clearly stated in the sandbox documentation.

- **Time restrictions**

Clear temporal restrictions should be placed on participation in the sandbox. Time limits for participation should be clearly communicated in the sandbox documentation.

- **Exit requirements**

Clear exit criteria should be formulated, with specific focus on meeting the requirements for conformity testing, as any high-risk AI system will need to meet these requirements upon exiting the sandbox and entering the market.

- **Data protection**

Rules on information security and data protection must be in place. Apart from clear rules for sandbox participants to comply with, for example, the GDPR, there should be proper notification of data subjects and avenues for them to exercise their data protection rights.

- **Comfort from enforcement**

To feel secure in the sandbox, participants should have clarity about a stay from enforcement (if any). Although the AIA does not allow for a (temporary) stay of enforcement, clarity about how and when regulators will enforce the AIA requirements is important.

- **Supervision**

The role and remit of the regulatory authority (or authorities) administering the sandbox must be made explicit. This relates to the point above on comfort from enforcement.

- **Transparency & feedback**

A balance must be struck between protecting the intellectual property / trade secrets of the sandbox participants and ensuring transparency of the sandbox process (including using best practices / lessons learned). Rules on providing feedback and using lessons learned from participation in the sandbox must be made explicit. This will help create trust in the sandbox for participants and delineate what is considered confidential and/or proprietary information and what is information that can be used in public interest.

- **Liability**

When damage results from AI applications in the sandbox, there should be clear avenues for recourse for the victims.



**Annex 2:
Interviewees & List of
participants in the
Design Jam**

Interviewees

- **Andrea Renda**
Sr. Research Fellow, Head of Global Governance, Regulation, Innovation, and the Digital Economy at CEPS; Member of the International Advisory Board at the European Parliament's STOA; Professor at the European University Institute
- **Kari Laumann**
Head of Section for Research, Analysis and Policy/Project Manager of Regulatory Sandbox at Datatilsynet
- **Milly Doolan**
Managing Director at EuroNavigator
- **Stephen Almond**
Director of Technology and Innovation at ICO
- **Yordanka Ivanova**
Legal and Policy Officer for DG for Communications Networks, Content, and Technology at the European Commission
- **Paul Worthington**
Public Policy Manager, Europe, Meta Fin-Tech, Meta; Former Team Leader, Policy & Engagement, Innovate with FCA

List of participants in the Design Jam

- **Nele Nisu**
Estonian Ministry of Economic Affairs and Communications
- **Gordon Pace**
The Malta Digital Innovation Authority
- **Kenneth Brincat**
The Malta Digital Innovation Authority
- **Ian Gauci**
The Malta Digital Innovation Authority
- **Carolina Rossini**
Datasphere
- **Raphael Von Thiessen**
Canton of Zurich
- **Evi Fuelle**
Credo AI
- **Susannah Shattuck**
Credo AI
- **Sébastien Bratières**
Translated
- **Lucia Russo**
OECD
- **Katlin Goodrich**
EVO
- **Toni Lorente**
The Future Society



Endnotes

- 1 Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, RE, COM/2021/206 final.
- 2 Ibid, p. 8.
- 3 Ibid, p. 15.
- 4 For more information, visit: <https://openloop.org>
- 5 Attrey, A., M. Lesher and C. Lomax (2020), "The role of sandboxes in promoting flexibility and innovation in the digital age", Going Digital Toolkit Note, No. 2, https://goingdigital.oecd.org/data/notes/No2_ToolkitNote_Sandboxes.pdf
- 6 ESMA. (2019). FinTech: Regulatory sandboxes and innovation hubs (JC 2018 74). Paris: European Securities and Markets Authority.
- 7 UNSGSA. (2019). Early lessons on regulatory innovations to enable inclusive fintech: Innovation offices, regulatory sandboxes, and regtech, p. 27. For a more detailed description of sandboxes, see: The Datasphere Initiative. (2022). Sandboxes for data: Creating spaces for agile solutions across borders. Retrieved from <https://www.thedatasphere.org/wp-content/uploads/2022/05/Sandboxes-for-data-2022-Datasphere-Initiative.pdf>
- 8 Financial Conduct Authority. (2017). Regulatory sandboxes lessons learned report. London: Financial Conduct Authority.
- 9 UNSGSA. (2019). Early lessons on regulatory innovations to enable inclusive fintech: Innovation offices, regulatory sandboxes, and regtech, p. 27. New York: United Nations Secretary-General's Special Advocate for Inclusive Finance for Development.
- 10 Jenik, I., & Duff, S. (2020). How to build a regulatory sandbox: A practical guide for policy makers. Washington, DC: World Bank Group.
- 11 Supra note 8.
- 12 Ibid.
- 13 DNB. Innovation hub and regulatory sandbox. De Nederlandsche Bank. Retrieved from <https://www.dnb.nl/en/sector-information/supervision-stages/prior-to-supervision/innovationhub-and-regulatory-sandbox/>
- 14 Rosemberg, C., Viqueira, J., Espinosa, J. A., Navarro, S., & Araya, G. (2020). Regulatory sandboxes and innovation testbeds: A look at international experience and lessons for Latin America and the Caribbean (Final Report). Washington, DC: Inter-American Development Bank.
- 15 Nesta. Creating an appropriate regulatory environment. Retrieved from <https://www.nesta.org.uk/feature/why-use-real-world-testbed/creating-appropriate-regulatory-environment/>
- 16 Futures Platform. How to horizon scanning: Guideline. Retrieved from <https://www.futuresplatform.com/blog/how-to-horizon-scanning-guideline>
- 17 Horizon Scanning Programme Team. GOV.UK. Retrieved from <https://www.gov.uk/government/groups/horizon-scanning-programme-team>
- 18 Ranchordás, S. (2014). Constitutional sunsets and experimental legislation. Cheltenham, UK: Edward Elgar.
- 19 Ibid.

- 20 Ranchordás, S., & van Klink, B. (2022). Law and method, July 2022 (Editorial). *Law and Method*, 6(1), 1-3.
- 21 *Supra* note 1, p. 34 (recital 72).
- 22 *Ibid.*
- 23 *Ibid.*
- 24 Amendment 2303; Voss, A., Clune, D., & Maydell, E., Proposal for a regulation, Article 53—paragraph 1 c (new).
- 25 Evidence-based regulatory learning.
- 26 *Supra* note 25.
- 27 *Supra* note 24.
- 28 *Supra* note 25.
- 29 Tudorache, D., Chastel, O., Gheorghe, V., Ștefănuță, N., Strugariu, R., Pișlaru, D., Nicholsonová, L.D., Joveva, I., Azmani, M., Løkkegaard, M., & Mitu a, A., Proposal for a regulation, Article 53—paragraph 5 a (new).
- 30 Amendment 2334; Tudorache, D., Chastel, O., Gheorghe, V., Ștefănuță, N., Strugariu, R., Pișlaru, D., Nicholsonová, L.D., Joveva, I., Azmani, M., Hahn, S., Løkkegaard, M., & Mitu a, A., Proposal for a regulation, Article 53—paragraph 6.
- 31 See, for instance: <https://ico.org.uk/for-organisations/regulatory-sandbox/previous-participants/>
- 32 Council of the European Union, Interinstitutional File: 2021/0106(COD), 14954/22, Brussels, 25 November, 2022 (OR. en) (General Approach), article 53(4)a.
- 33 *Ibid.*, article 53(5).
- 34 Amendment 2312; Voss, A., Clune, D., & Maydell, E., Proposal for a regulation, Article 53—paragraph 2 a (new).
- 35 Council of the European Union, Interinstitutional File: 2021/0106(COD), 14954/22, Brussels, 25 November, 2022 (OR. en) (General Approach), article 53(5).
- 36 German Federal Ministry for Economic Affairs and Energy. (2019). Making space for innovation: The handbook for regulatory sandboxes (p. 7). Retrieved from https://www.bmwk.de/Redaktion/EN/Publikationen/Digitale-Welt/handbook-regulatory-sandboxes.pdf%3F__blob%3DpublicationFile%26v%3D2
- 37 *Ibid.*
- 38 Amendment 2338; Konečná, K., Arza, P.B., Ernst, C., & Kountoura, E., Proposal for a regulation, Article 53—paragraph 6 a (new).
- 39 The Datasphere Initiative. (2022). Sandboxes for data: Creating spaces for agile solutions across borders. Retrieved from <https://www.thedatasphere.org/wp-content/uploads/2022/05/Sandboxes-for-data-2022-Datasphere-Initiative.pdf>
- 40 Alternatively, an exit can also lead to the conclusion that the AI system is not yet ready for placement on the EU market. In this case, the AI provider may be provided with relevant “to dos” for guiding them toward a successful market entry.

- 41 Jenik, I., & Duff, S. (2020). How to build a regulatory sandbox: A practical guide for policy makers. Washington, DC: World Bank Group.
- 42 Data Innovation. (2022, October 13). EU's AI Regulatory Sandboxes Need Fixing. Retrieved from <https://datainnovation.org/2022/10/eus-ai-regulatory-sandboxes-need-fixing/>
- 43 See Article 5 General Data Protection Regulation.
- 44 European Data Protection Board & European Data Protection Supervisor. (2021, June 18). Joint Opinion 3/2021 on the EU Commission's Proposal for a Regulation on a European approach for Artificial Intelligence (AI) (2021/0106(COD)). Retrieved from https://edps.europa.eu/system/files/2021-06/2021-06-18-edpb-edps_joint_opinion_ai_regulation_en.pdf
- 45 Isle of Man Financial Services Authority. (n.d.). The Sandbox Approach. Retrieved April 17, 2023, from <https://www.iomfsa.im/innovation/the-sandbox-approach/>