BENCHMARK

Artificial Intelligence Regulatory Sandboxes

Instituto de Tecnologia & Sociedade do Rio

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Lessons Learned from the United Kingdom in Artificial Intelligence Regulatory Sandboxes

How to Structure an Artificial Intelligence Regulatory Sandbox?

A Benchmark for Innovation in Brazil

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Executive Summary

Innovation requires exploring unknown territory and taking risks that have not yet been mitigated. To address the uncertainty inherent in the innovation process, regulatory sandboxes have emerged as a mechanism that enables collaboration among cross-sectoral stakeholders, under the supervision of one or more regulatory authorities, to test new solutions in a controlled experimental environment aligned with the applicable regulatory framework.

The creation of an experimental environment by regulators can accelerate the development of innovative solutions while enhancing the technical capabilities and institutional knowledge of both regulators and innovators. This collaborative process enables the identification and implementation of necessary regulatory adjustments, grounded in evidence and validated practices.

Regulatory sandboxes have been in use since 2016 in sectors such as finance, healthcare, and data governance across more than 60 jurisdictions worldwide. However, their application to the development of emerging technologies such as Artificial Intelligence (AI) remains at an early stage, generating debate about how to apply this tool to promote innovation and security in a technological field characterized by rapid evolution and significant ethical challenges.

From this perspective, we examined the United Kingdom's experience with regulatory sandboxes. The country is a pioneer in applying this methodology, from its initial use in the financial sector to its AI policy, which incorporates regulatory flexibility as a tool to foster innovation.

This report presents a benchmark of the British experience, with the aim of identifying pathways for Brazilian stakeholders interested in exploring models that combine regulatory certainty and innovation, fostering the development of a robust, responsible, and socially beneficial national AI industry.

The following key assumptions and conclusions of

this report stand out:

- The United Kingdom's experience with regulatory sandboxes does not follow a single model. On the contrary, findings and interviews with regulators indicate that the country adopts different formats tailored to the specific needs of the stakeholders involved.
- Although there is no single definition, we identified that regulatory sandboxes share certain fundamental characteristics, namely: (i) temporality; (ii) limited scope; (iii) focus on innovation; (iv) regulatory oversight; and (v) collaboration.
- Regulatory sandboxes are not appropriate in all circumstances. Their adoption should be preceded by a clear identification of needs and expected outcomes. Furthermore, the conclusion of a sandbox due to the infeasibility of a solution does not constitute a failure; rather, it fulfills its primary objective: generating evidence to support regulatory decision-making.
- As Brazil prepares to establish its regulatory framework for AI, regulatory sandboxes represent a viable methodology for promoting innovation and strengthening small and medium--sized enterprises (SMEs) and startups, thereby increasing their competitiveness in the market.
- The British experience demonstrates that regulatory sandboxes mature over time through practical learning. To reduce the uncertainties associated with implementing this methodology, this benchmark is complemented by a practical guide that provides operational parameters such as evaluation criteria, resource allocation, and timelines.

By providing this material, we seek to contribute to the structuring and implementation of regulatory sandboxes in Brazil, promoting responsible innovation and a more dynamic and inclusive regulatory environment.

About this Report

Developed through collaboration between ITS Rio and the British Government, through the UK–Brazil Tech Hub and the Science and Innovation Network, and informed by discussions held at the roundtable event **"Varanda: Regulatory Sandboxes and AI – Innovation and Precaution,"**[1] this report draws on the United Kingdom's experience as a case study to inform the understanding and development of regulatory sandboxes. The report emphasizes the core principles of transparency and cross-sectoral collaboration, which are essential to ensuring that the outcomes of regulatory sandboxes are accessible, inclusive, and broadly beneficial to society.

It seeks to broaden the understanding of innovation by highlighting regulatory sandboxes as a strategic opportunity to advance digital transformation across multiple sectors, while underscoring the commitment to ensuring that AI is developed and deployed in an ethical, safe, and responsible manner, thereby promoting sustainable innovation. It also incorporates the consultations and perspectives of civil society organizations, academia, and Brazilian and British government stakeholders, providing a solid foundation for future cooperation initiatives.

Finally, we emphasize that this document is not intended as a "one-size-fits-all" solution. On the contrary, it recognizes the need to adapt the methodology to Brazil's cultural, economic, and regulatory specificities and seeks only to serve as a reference point for exploring paths that have not yet been pursued in Brazil, but are reflected in the country's broader trajectory toward consolidating its role as a global leader in the digital arena.

1 The event featured renowned experts from Brazil and the United Kingdom, including Deborah Morgan (Alan Turing Institute), Thiago Moraes (ANPD), Juliana Sakai (Transparência Brasil), and Silvana Bahia (Olabi), as well as representatives from regulatory authorities and civil society organizations. The full event is available at: https://www.youtube.com/live/29pVRXha8co?si=e-7CIEF4F4VrB9_Bk.

Introduction

Creating an ecosystem that fosters innovation, supported by the infrastructure and standards necessary to ensure its safe operation, is a complex and delicate task. On the one hand, the absence of regulation or inadequate regulation may leave society exposed to risks and uncertainties. On the other hand, excessive regulation can stifle innovation, preventing new ideas from developing and generating social and economic benefits. Striking a balance between these two approaches is one of the central challenges facing public policymakers.

In the case of Artificial Intelligence (AI), this tension is even more pronounced. The rapid pace of development and societal adoption of AI technologies places significant pressure on regulators, who must address the risks and potential harm associated with these innovations without hindering technological progress. Traditional regulatory approaches are often perceived as ill-suited to keep pace with the sector's dynamism and constant evolution. It is within this context that regulatory sandboxes have emerged – experimental environments in which regulators permit new technologies, products, services, or business models to be tested under flexible and temporary regulatory conditions. These sandboxes provide an intermediate solution, enabling innovation to proceed in a controlled setting while allowing space for adaptation and learning.

Examining the origins of regulatory sandboxes and their expansion across different sectors and technologies is essential to understanding which characteristics and underlying premises have evolved over time and which have become established in response to the needs of public and private stakeholders in the context of Artificial Intelligence.

The United Kingdom's Pro-Innovation Approach to Regulatory Sandboxes

The concept of the regulatory sandbox was formally introduced in the United Kingdom by the Financial Conduct Authority (FCA) in 2016, within the framework of Project Innovate. The regulatory sandbox emerged from the urgent need to address the rapid growth of fintech companies and the inability of traditional regulatory frameworks to keep pace with technological innovation, which risked hindering the development of innovative financial solutions. Prior to this initiative, the financial sector had faced challenges in aligning new ideas with existing rigid regulatory standards, resulting in inflated costs and extended time-to-market for innovative companies seeking to launch products.[2]

The turning point came when the FCA recognized that innovation required a more flexible regulatory environment and proposed the creation of a "safe space" for experimentation. The sandbox enabled companies to test new products, services, and business models under regulatory supervision, without immediately being subject to the full set of traditional regulatory requirements.

The first cohort of the sandbox opened for applications in 2016, and the response was immediate: 146 applications were received in the first year, with 50 companies admitted. The innovations tested ranged from blockchain technologies to personal financial management tools. Early findings indicated that the sandbox reduced the time and costs associated with bringing products to market, while also enabling both the FCA and partici-

2 Alliance for Innovative Regulation. The Financial Conduct Authority's Innovation Journey: Moving Forward in the Face of Uncertainty. Amy Friend, Senior Advisor to AIR. March 2021. Available at: https://regulationinnovation.org/wp-content/uploads/2021/03/The-FCAs-Innovation-Journey-Moving- Forward-n-the-Face-of-Uncertainty-AIR-Final-2.pdf.

pating companies to identify regulatory gaps and areas requiring policy adjustments. In addition, the sandbox introduced an additional layer of consumer protection, as testing took place in a controlled environment and under predefined conditions designed to mitigate risks.[3]

The initiative not only fostered innovation but also prompted a shift in mindset among incumbents, such as banks and large financial institutions, which began adopting similar models to compete with fintech companies. The success of the sandbox in the United Kingdom quickly spread, and more than 60 jurisdictions worldwide have adopted regulatory sandboxes as instruments to promote innovation.[4]

Thus, the United Kingdom continues to serve as a leader in this field, using lessons learned to shape new policies and expand international collaboration, as reflected in the creation of the Global Financial Innovation Network (GFIN), a global network that promotes cross-border testing and knowledge exchange among regulators by identifying shared challenges or policy issues faced by companies operating across different jurisdictions.[5]

Over time, the concept of regulatory sandboxes has expanded to additional sectors, including artificial intelligence, healthcare, fintech, and data governance, emerging as an alternative tool for addressing the uncertainties and risks associated with technological innovation.[6] These environments enable regulators and innovators to identify gaps and necessary adjustments while minimizing risks to consumers and to the regulatory system itself. Sandboxes strike a balance between the absence of regulation – accepting the risks of potential social and economic harm arising from technologies not subject to safety standards – and excessive regulation, which may inhibit the development and implementation of new technologies.[7]

3 Ibidem.

4 Eník, Ivo, and Schan Duff. How to Build a Regulatory Sandbox: A Practical Guide for Policy Makers. Washington, DC: CGAP, 2020. Available at: https://documents1.worldbank.org/curated/en/126281625136122935/.

5 Global Experiences from Regulatory Sandboxes. Financial Competitiveness & Innovation Global Practice – Fintech Note no. 8. World Bank Group. 2020. Available at: https://documents.worldbank.org/en/publication/documents-reports/documentdetail/912001605241080935/Global-Experiences-from- Regulatory-Sandboxes.

6 Eník, Ivo, and Schan Duff. How to Build a Regulatory Sandbox: A Practical Guide for Policy Makers. Washington, DC: CGAP, 2020. Available at: https://documents1.worldbank.org/curated/en/126281625136122935/.

7 Outside the box: National and International Sandbox Experiences. Datasphere Initiative, May 2025. Available at: https://www.thedatasphere.org/news/outside-the-box-national-and-international- sandbox-experiences/.

1.1 The Expansion of the Regulatory Sandbox Framework

The exponential growth in the adoption of regulatory sandboxes worldwide has allowed different initiatives to be tailored to specific circumstances and local contexts. In many instances, the concept has taken on varying forms, without a clear and consistent consensus regarding its definition.

In the Brazilian context, the Legal Framework for Startups (Complementary Law No. 182/2021) establishes a broader definition of the instrument,[8] emphasizing its role in promoting business development and proposing a model of sandboxes with special and temporary conditions applicable across multiple sectors. Bill No. 2,338/2023, which seeks to establish a regulatory framework for Artificial Intelligence, introduces provisions under which sandboxes may be used to foster innovation in the development of AI-related systems and public policies, adopting a more flexible regulatory sandbox model that may be implemented by public authorities.

Inductively, in both national and international contexts, certain common characteristics can be identified that lend coherence to the concept, namely:

Temporality
Projects are developed over a predefined period, during which results are evaluated and necessary adjustments are made, including determining whether the product, service, or business model may be deployed more broadly in the market. There is no fixed duration, given the use of sandboxes across different sectors; however, there is general agreement that a clear, predefined time limitation should be established and communicated to all relevant stakeholders, including participants and the market.
Limited Scope
The experimental and testing nature of regulatory sandboxes presupposes limitations on the scope of availability of the proposed initiative. This restriction may apply to the number or profile of participants involved (typically consumers), or to the geographic area in which the test is conducted (such as a city, neighborhood, or region, among others). The purpose is to contain systemic effects and to assess, within the boundaries of the experiment, the resulting impacts, as well as the necessary safeguards and mitigation measures.

8 Complementary Law No. 182/2021 Article 2. For the purposes of this Complementary Law, the following definitions apply: (...) II – experimental regulatory environment (regulatory sandbox): a set of simplified special conditions under which participating legal entities may receive temporary authorization from agencies or entities with sectoral regulatory authority to develop innovative business models and test experimental techniques and technologies, subject to compliance with criteria and limits previously established by the competent regulatory authority and through a simplified procedure.

Focus on Innovation
Given their experimental nature, priority is generally afforded to projects that offer innovative and potentially transformative solutions to existing market or societal challenges. Similarly, in light of the diversity of initiatives and sectors involved, there is no single definition of innovation; rather, it is understood as a practice aimed at generating positive transformation and change in the market and/or society.
Regulatory Oversight
The establishment of an experimental environment typically arises from a regulatory need, whether to explore potential changes to existing regulations (including the development of entirely new rules) or to clarify how a proposed initiative may interact with current regulatory frameworks. In this context, initiatives tend to be developed in close coordination with a regulatory authority, which closely monitors the development and implementation of new proposals, assessing, analyzing, and providing guidance throughout the process.
Collaboration
The rationale underlying regulatory sandboxes is that they depend on interaction among different stakeholders within the market and society. Accordingly, there is an incentive to foster collaborative relationships among innovators, regulators, and other relevant stakeholders, including society at large – whether through consumers, citizens, organized civil society, academia, or technical experts.[9]

The regulatory sandbox differs from other forms of experimental regulation focused on innovation – such as pilot tests, innovation hubs, and innovation guidance initiatives – primarily due to its structured design and the requirement of continuous interaction with regulatory authorities.[10]

Unlike initiatives such as "innovation labs" or "pilot tests," which may have a broader and less targeted scope, sandboxes provide a specific environment for testing discrete initiatives that are expected to culminate in an assessment of potential regulatory compliance or the need for regulatory adaptation. As a result, regulatory uncertainty is reduced and risk exposure for participants is limited. This approach not only accelerates the innovation process but also provides regulators with insights into how innovative technologies (and business models) operate and what risks they may present.

9 The list of characteristics was developed with reference to various documents and reports. The following report served as a primary source of inspiration: 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. Available at: https://goingdigital.oecd.org/data/notes/No2_ToolkitNote_Sandboxes.pdf.

10 Dirk A. Zetzsche et al., Regulating a Revolution: From Regulatory Sandboxes to Smart Regulation, 23 Fordham Journal of Corporate & Financial Law 31, 64 (2017). Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3018534.

INNOVATION HUBS

These structures are being established globally by regulatory authorities with the objective of supporting innovators – particularly startups and small and medium-sized enterprises (SMEs) – by providing technical and regulatory guidance and advisory services. Innovation hubs often serve as a point of contact for regulatory dialogue, facilitating navigation of the existing regulatory framework. An example is the Innovation Hub of the United Kingdom's Office of Gas and Electricity Markets (Ofgem). The hub operates as an umbrella for initiatives that include a £450 million fund (approximately R$3.3 billion) designed to drive the innovation required to transform gas and electricity networks toward a low-carbon future. It also provides support for innovators seeking rapid feedback on the regulatory implications of their proposals, assistance in navigating the sector, and access to the agency's regulatory sandbox initiatives.[11]

PILOT TESTS

Authorizations granted to companies and organizations to test products, services, or business models on a limited scale under controlled conditions. In this case, however, the focus is on assessing feasibility and potential impacts primarily from a technical perspective, rather than from a regulatory standpoint.[12]

GUIDANCE CENTERS

Public initiatives designed to provide guidance – typically through publications and official documents – on how existing innovations fit within current regulatory frameworks or how new innovations may be regulated. These initiatives assist entities seeking to innovate by clarifying regulatory requirements and supporting the development of products or services in alignment with the prevailing regulatory environment.

REGULATORY SANDBOXES

Unlike other mechanisms, the regulatory sandbox not only facilitates market entry within an environment characterized by greater regulatory flexibility but also enables the collection of real-world data to support evidence-based decision-making. This, in turn, assists regulators in adjusting existing regulations or developing new ones that promote innovation in a safe and context-sensitive manner. In addition, the sandbox provides a setting for mutual learning between regulators and innovators, reducing uncertainty and risk for all stakeholders, from the testing phase through broader market implementation. This results in a more comprehensive understanding of emerging technologies and their implications, supporting a proactive regulatory approach and the sustainable development of innovation.

11 The Office of Gas and Electricity Markets (Ofgem). Innovation Hub. Available at: https://www.ofgem. gov.uk/energy-policy-and--regulation/policy-and-regulatory--programmes/innovation-hub.

12 In some cases, these initiatives are referred to as operational sandboxes, given that their objectives are more focused on technological development than on regulatory adaptation. The terminology was used by ITS Rio in: ITS Rio, AI Development Model for the Brazilian Justice Ecosystem: The Experience of the Artificial Intelligence Operational Sandbox at the Rio de Janeiro Public Defender's Office (DPRJ), 2023. Available at: https://itsrio.org/pt/projetos/data-4-justice/. The term "operational sandbox" is also used in international contexts. See: Datasphere Initiative, Sandboxes for Data: Creating Spaces for Agile Solutions Across Borders, 2022. Available at: https://www. thedatasphere.org/datasphere-publish/sandboxes-for--data/.

1.2 Benefits and Challenges of Regulatory Sandboxes

By providing a controlled environment for testing new ideas and technologies, regulatory sandboxes have the potential to clarify – and in some cases redefine – the boundaries between existing regulatory frameworks and emerging innovations. However, this methodology is not universally applicable as a tool for promoting innovation, and it is essential to carefully assess the specific needs of the regulatory authority and the intended outcomes.[13] Accordingly, the decision to adopt a regulatory sandbox should be grounded in a thorough analysis of sectoral demands and project objectives.

One of the primary advantages of regulatory sandboxes is that they enable innovation and experimentation within a controlled setting. This is particularly relevant in highly regulated sectors, such as finance, healthcare, and energy, where testing new technologies and business models may otherwise be unfeasible due to regulatory uncertainty or rules that are not aligned with the characteristics of a new proposal. The establishment of an experimental environment by one or more regulatory authorities can accelerate the development of novel solutions while simultaneously enhancing the knowledge base and institutional capacity of both regulators and innovators, who can jointly identify necessary regulatory adjustments.

This arrangement may create a mechanism for direct feedback and collaboration. Participants in a regulatory sandbox provide regulators with direct access to the outcomes of their tests, fostering open dialogue regarding innovation, implementation challenges, and regulatory compliance. This dynamic enables potential adjustments at various stages of the process and by all parties involved.

Initial testing within a sandbox reduces uncertainty and allows for a more proportionate allocation of responsibilities related to innovation by establishing a structured experimental environment. Sandboxes help mitigate the regulatory uncertainty that often discourages investment in new technologies or business models. The process of testing a solution or product in a sandbox may reveal regulatory gaps that can be addressed by the regulator and

13 How To Build a Regulatory Sandbox – A Practical Guide for Policy Makers. Ivo Jeník and Schan Duff. September 2020. Available at: https://documents.worldbank.org/curated/en/126281625136122935/pdf/How-to-Build-a-Regulatory-Sandbox-A-Practical-Guide-for-Policy--Makers.pdf.

identify the need for adjustments in the interpretation and application of existing rules, thereby making regulatory requirements clearer and more accessible to participants.

Alain Kapper, a member of the Digital Regulation Cooperation Forum, highlights both the benefits and risks associated with regulatory sandboxes:

> "[...] For new innovative companies to emerge, reach the market, and deploy products, they may seek to test whether their solutions comply with the various regulations in force in the United Kingdom. Clearly, [regulatory sandboxes] offer certain advantages. However, a key concern is ensuring that any data or datasets used in testing these models are compliant with data protection regulations."

It is also important to consider the advantages from the perspective of consumers and citizens. The limitations imposed on risks and potential harms – whether systemic or specific – can be assessed and measured. This contributes to consumer protection, as continuous monitoring within regulator-controlled environments supports precautionary measures, mitigation strategies, and oversight mechanisms designed to prevent unfair outcomes, harmful practices, or potentially unsafe products and services.

Nevertheless, several challenges must be acknowledged and have already been identified. Some of these issues will be examined in greater detail below in the context of sandboxes for emerging technologies, particularly Artificial Intelligence. At this stage, we highlight selected elements to provide an overview.

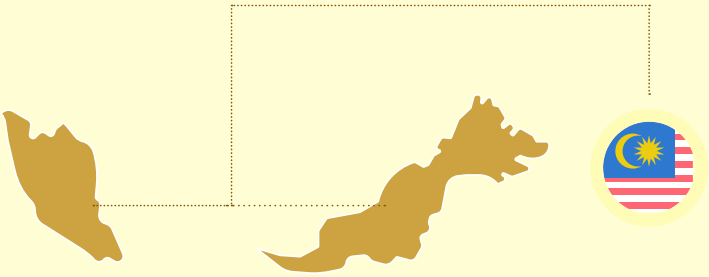
One of the key challenges associated with regulatory sandboxes is the potential exclusion of smaller participants, which may favor larger companies with greater resources to engage in such initiatives. This dynamic can concentrate benefits within a limited group, restricting the broader diffusion of knowledge and innovation throughout the ecosystem.

Small businesses and startups often encounter barriers to entry that limit their participation in innovation

processes. To mitigate this issue, transnational initiatives such as the Global Financial Innovation Network (GFIN) and the API Exchange (APIX) have been established to promote inclusion by facilitating the participation of a broader range of companies. APIX, for example, connects financial institutions and fintech companies within a collaborative cross-border sandbox environment, advancing digital transformation and financial inclusion in the Asia-Pacific region[14].

14 Early Lessons on Regulatory Innovations to Enable Inclusive FinTech: Innovation Offices, Regulatory Sandboxes, and Regtech February 22, 2019. United Nations Secretary-General's Special Advocte for Inclusive Finance for Development. Available at: https://www.unsgsa.org/publications/early-lessons- regulatory-innovations-enable-inclusive-fintech-innovation-offices-regulatory-sandboxes-and-regtech.

15 Ibidem.



MALAYSIA

In Malaysia, Bank Negara Malaysia's (BNM) experience in establishing its Regulatory Sandbox Framework in 2016 included a successful early case involving the participation of the UK-based international money transfer company WorldRemit. At the time, Malaysian regulations required customer identity verification to be conducted in person – posing a significant barrier to online account opening, particularly in rural areas. The sandbox implemented by BNM enabled WorldRemit to deploy its digital identity verification solution within a controlled environment under the bank's supervision. The trial was well received by customers, and the bank expressed confidence in the effectiveness of the remote solution in promoting financial inclusion. As a result, BNM amended its regulations to permit providers to verify customer identities through selfies and other remote authentication mechanisms, while maintaining its regulatory sandbox framework in continuous operation within the financial sector.[15]

Over time, as tested technologies become more widely adopted, the need for sandboxes may diminish, since regulatory knowledge expands and more comprehensive frameworks can be applied. Moreover, the experimental nature of sandboxes may expose consumers to unforeseen risks – particularly in the case of emerging technologies – which underscores the importance of carefully identifying objectives and designing regulatory sandboxes in a structured and comprehensive manner.[16]

Additionally, depending on their design, regulatory sandboxes may give rise to conflicts among regulatory authorities across different sectors. Sandboxes are often implemented by a single regulatory entity responsible for the initiative. However, new business models, products, or services may have cross-sectoral implications. For example, a sandbox promoted by a health authority to test new medical technologies may raise data protection concerns, thereby requiring coordination with the authority responsible for personal data protection.[17]

In the United Kingdom, a successful example of fostering innovation and interagency cooperation is the Digital Regulation Cooperation Forum (DRCF),[18] established to promote collaboration among regulators and facilitate coordinated approaches to digital and artificial intelligence issues. The DRCF serves as a platform for regulatory cooperation across sectors such as telecommunications (Office of Communications – Ofcom), finance (Financial Conduct Authority – FCA), and data protection (Information Commissioner's Office – ICO), enabling these authorities to share information and align their regulatory approaches. This cross-sectoral perspective minimizes duplication of regulatory efforts and helps ensure that innovative solutions remain consistent with existing regulatory standards.

In conclusion, regulatory sandboxes constitute an innovative public policy instrument that enables new solutions to be tested in a controlled environment. They offer significant advantages for innovators, regulators, and society at large; however, they must be carefully designed to prevent conflicts and to ensure that innovation develops in a safe and inclusive manner.

16 To learn about all the requirements and complete step-by--step instructions for each phase of implementing a regulatory sandbox, access the practical guide that serves as a complementary document to this study.

17 The British government has been considering four structural models for the relationship between regulatory bodies and the sectors involved. These models are explored in detail in Topic 1.0 of the practical guide that follows this report.

18 Information Commissioner's Office (ICO). Digital Regulation Cooperation Forum. Available at: https:// ico.org.uk/about-the-ico/what-we-do/digital-regulation-cooperation-forum/.

Regulatory Sandboxes for Emerging Technologies

In the United Kingdom, the financial sector's pioneering initiative in establishing regulatory sandboxes quickly expanded to other sectors. In this context, the following examples illustrate how different actors – engaged in initiatives led by various regulatory authorities – addressed challenges and leveraged opportunities to develop solutions based on emerging technologies within the controlled environment of a regulatory sandbox.

NHS Digital, the national information and technology partner for the UK health and care system, participated in the Information Commissioner's Office (ICO) regulatory sandbox project – the UK data protection authority – with the objective of developing the "Permission to Contact" (PtC) service to support COVID-19 vaccine research.[19] Launched in 2020, the initiative sought to create a centralized mechanism through which individuals could consent to being contacted by researchers conducting vaccine studies, thereby increasing public participation and accelerating research efforts.

Throughout the process, the ICO provided guidance to ensure that the PtC service was developed in compliance with the UK Data Protection Act and the Children's Code, with particular attention to transparency, data minimization, and the protection of individuals' rights. NHS Digital worked closely with the ICO to prepare a Data Protection Impact Assessment (DPIA), identifying risks associated with data processing and implementing appropriate mitigation measures. Among the primary challenges identified was the risk of phishing attacks, for which the ICO issued detailed guidance on informing users about potential

19 UK Government. Regulatory Sandbox Final Report: NHS Digital A summary of NHS Digital's participation in the ICO's Regulatory Sandbox Beta. December 2020. Available at: https://ico.org.uk/media/for-organisations/documents/2618905/nhs-digital-regulatory--sandbox-final-report.pdf.

fraud, thereby enhancing security and user awareness.

Ultimately, participation in the sandbox enabled NHS Digital to develop the PtC service with greater legal certainty and operational confidence, ensuring that privacy considerations were appropriately addressed. The initiative demonstrated how collaboration between technological innovation and data protection authorities can produce successful outcomes, particularly in sensitive areas such as public health.

With respect to emerging technologies such as Artificial Intelligence (AI), there is a growing recognition of a phenomenon referred to in academic literature as the "pacing problem."[20] This concept describes the misalignment between the capacity for regulatory adaptation and the speed of technological development, which often advance at different rates. This temporal mismatch is frequently inherent to regulatory processes. Regulation typically represents the culmination of multiple experiments that eventually crystallize into standards and rules to be followed by market participants or the broader community.[21]

AI-related technologies can be examined through the lens of the "3Vs" framework – Velocity, Volume, and Variability – which seeks to explain technological acceleration and its societal implications.[22] Originally associated with the rapid expansion of the data ecosystem, the "3Vs" framework highlights the growing challenges of designing policy responses in an environment characterized by increasing quantities of data, higher processing speeds, and greater diversity of data types. These dynamics are even more pronounced in the context of emerging technologies, particularly AI systems. In a brief period, for example, developments in Generative Artificial Intelligence ("GenAI") have significantly influenced regulatory proposals such as the European Union's AI Act, which had been under discussion for several years.[23]

In response to these rapidly evolving technologies, policymakers have adopted a range of approaches to innovative – and often disruptive – developments.[24] Emerging technologies, especially digital technologies, challenge not only the boundaries of regulatory authorities' sector-specific mandates but also the broader

20 Thierer, A. D., R. Hagemann, and J. Skees. 2018. Soft Law for Hard Problems: The Governance of Emerging Technologies in an Uncertain Future. Colorado Technology Law Journal. 17(1): 37-130. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3118539. A perspective also adopted by the Inter-American Development Bank (IDB) in 2020. See: Inter-American Development Bank (IDB), Regulatory Sandboxes, and Innovation Testbeds: A look at international experience and lessons for Latin America and the Caribbean, 2020. Available at: https://publications.iadb.org/en/regulatory-sandboxes--and- innovation-testbeds-a-look-at--international-experience-in-latin-america-and-the-caribbean.

21 Cambridge University. European Journal of Risk Regulation (2022), 13, 270–294. A Sandbox Approach to Regulating High-Risk Artificial Intelligence Applications. Jon Truby; Rafael Dean Brown; Imad Antoine Ibrahim; and Oriol Caudevilla Parellada. Available at: https://doi.org/10.1017/err.2021.52.

22 Laney, Doug. 3D data management: Controlling data volume, velocity, and variety. In: Meta Group. 2001. Available at: http://blogs.gartner.com/doug-laney/files/2012/01/ad949-3D-Data-Management- Controlling-Data-VolumeVelocity-and--Variety.pdf.

23 This is intended solely to illustrate the impact that shifts in mainstream technology have had on the regulatory debate. Kohn, B.; and L. van Neerven. 2023. "Will Disagreement Over Foundation Models Put the EU AI Act at Risk?" Tech Policy Press, November 29, 2023. Available at: https://www.techpolicy.press/will- disagreement-over-foundation-models-put-the-eu-ai-act-at-risk/.

24 The term "disruptive" is frequently used to describe broad structural change within a market, sector, or field. The term appears in multiple policy documents addressing the need for new public policy instruments to regulate emerging technologies. See, for example: Inter-American Development Bank (IDB), Regulatory Sandboxes, and Innovation Testbeds: A look at international experience and lessons for Latin America and the Caribbean, 2020. Available at: https://publications.iadb.org/en/

regulatory architecture itself.

The speed and scale of technological change give rise to different regulatory responses. The Organisation for Economic Co-operation and Development (OECD), for example, has identified at least three categories of responses adopted by public policymakers:

→ Ban outright;

→ Wait and see; and

→ Implement innovative testing mechanisms ("test and learn")[25].

As for the third approach, it appears necessary to establish a sufficiently flexible regulatory environment capable of accommodating the responsible development of emerging technologies and the new business models they enable. This involves striking a balance between fostering innovation and applying appropriate safeguards.[26] In this context, regulatory sandboxes assume a vital role.

2.1 The United Kingdom's Experience with Artificial Intelligence Regulatory Sandboxes

Recognizing the need to adopt a regulatory model capable of advancing the country's innovation agenda, the United Kingdom commissioned a white paper[27] setting out the government's consolidated vision of Artificial Intelligence (AI) as a tool to promote social and economic development.

The document proposed public policy measures to harness the benefits of AI, which already contributes significantly to the British economy, job creation, and advancements in sectors such as healthcare and agriculture.[28] The British government acknowledges that as AI evolves rapidly, concerns arise regarding privacy, security, and fairness – particularly in decisions that directly affect individuals' lives, such as loan approvals and medical diagnoses.

The white paper establishes five core principles to guide the safe and innovative use of AI:

→ Safety, Security and Robustness;

→ Appropriate Transparency and Explainability;

→ Fairness;

→ Accountability and Governance; and

→ Contestability and Redress.

With respect to measures designed to foster innovation,

regulatory-sandboxes-and-innovation-testbeds-a-look-at-international-experience-in-latin-america--and-the-caribbean.

25 Zetzsche, D. A., R. P. Buckley, J. N. Barberis, and D. W. Arner. 2017. Regulating a Revolution: From Regulatory Sandboxes to Smart Regulation. Fordham Journal of Corporate and Financial Law, 23(1). Available at: https://ir.lawnet.fordham.edu/jcfl/vol23/iss1/2/.

26 OCDE, 2023. Available at: https://www.oecd-ilibrary.org/docserver/8f80a0e6-en.pdf?expires=1708348396&id=id&accname=guest&checksum=47E38D9242881298919C19DB8DC66FC9.

27 UK Government. UK unveils world leading approach to innovation in first artificial intelligence white paper to turbocharge growth. March 29, 2023. Available at: https://www.gov.uk/government/news/ uk-unveils-world-leading--approach-to-innovation-in-first--artificial-intelligence-white-paper--to- turbocharge-growth.

28 Ibidem.

the government adopted the regulatory sandbox methodology, allocating initial funding of €2 million (approximately R$15 million) to enable companies to test AI products in controlled environments prior to market deployment. This initiative is grounded in an experimental model based on cross-sectoral collaboration. Since then, the United Kingdom has advanced the implementation of AI regulatory sandboxes across multiple sectors. The following examples illustrate this approach:

Health

FlyingBinary, a deep-tech company, participated in the ICO's regulatory sandbox, gaining valuable insights into the applicable regulatory framework and enabling it to innovate within the boundaries of data protection law.[29] FlyingBinary's objective was to develop the "lookafterme" application – an AI-based solution designed to support mental health patients, including children – by preventing exposure to harmful online content that could exacerbate conditions such as eating disorders.

FlyingBinary entered the regulatory sandbox in November 2020 to ensure compliance with the Data Protection Act and the Children's Code, particularly in relation to data minimization, lawful basis for processing, and age-appropriate design. The project was conducted collaboratively, with the company receiving guidance from the ICO on implementing the principle of "privacy by design." This principle requires that data protection safeguards be integrated from the initial design phase and throughout the entire life cycle of projects, systems, products, or processes involving personal data.[30]

Accordingly, the focus was placed on establishing appropriate technical and organizational measures, including Data Protection Impact Assessments (DPIAs) and accountability mechanisms. FlyingBinary and the ICO worked jointly on critical issues such as user authentication, minimization of personal data, and the protection of children's rights. A significant outcome of this process was the development of a customized DPIA addressing the risks associated with processing children's data

29 UK Government. Regulatory Sandbox Final Report: FlyingBinary A summary of FlyingBinary's participation in the ICO's Regulatory Sandbox. August 2022. Available at: https://ico.org.uk/media/ about-the-ico/documents/4021302/flyingbinary-exit-report-202208.pdf.

30 ITS Rio, Como tratar dados pessoais sensíveis? Cinco recomendações que você precisa saber. Available at: https://itsrio.org/pt/artigos/5-recomendacoes-para-tratar-dados-sensiveis-que-voce-precisa-saber/.

and joint controllership arrangements with healthcare providers, ensuring that data processing was limited to specific purposes and conducted in compliance with data protection legislation.

The ICO sandbox also supported FlyingBinary in refining its data-sharing approach, particularly in balancing patient confidentiality with the need to share data for healthcare delivery and research purposes. Ultimately, FlyingBinary's participation in the sandbox strengthened its compliance capabilities and reinforced the regulatory foundations of its AI-based product.

Nuclear Sector

The Office for Nuclear Regulation's (ONR) experiment with an AI regulatory sandbox sought to explore the application of this emerging technology within the nuclear sector – a highly regulated environment with significant implications for safety, security, and environmental compliance. This initiative was pioneering, representing the first regulatory sandbox applied to nuclear regulation globally and providing a structured environment in which regulators and industry stakeholders could assess how AI technologies might be effectively regulated.

The primary objective of this sandbox was to test the implementation of AI in two principal areas: (1) structural integrity, where AI could be used to monitor and predict maintenance needs for critical components in nuclear power plants; and (2) application within a robotic glovebox used for handling radioactive materials. The ONR also aimed to develop a regulatory approach capable of ensuring the safe and efficient adoption of AI in the nuclear industry without compromising stringent safety standards.

The sandbox was organized in stages, including rapid workshops ("sprints") and in-depth sessions ("deep dives"). During these meetings, regulators and industry experts worked collaboratively to identify and address key challenges associated with AI adoption, such as building confidence in AI system performance, ensuring data integrity, and assessing potential risks, including system failures and unintended consequences.

The project demonstrated that implementing AI in the

nuclear sector requires a phased approach, whereby systems are introduced gradually to build confidence and mitigate risks. The sandbox also underscored the importance of understanding the complexity of human–AI interaction, suggesting that AI should initially be deployed as a decision-support tool, with critical decisions remaining subject to human oversight.

Ultimately, the ONR's experience with the regulatory sandbox was regarded as successful and generated a series of recommendations, including the need to develop specialized AI expertise among regulators and operators, as well as the importance of adopting a flexible, principles-based regulatory approach capable of addressing diverse AI applications. The project also contributed to the development of an international regulatory sandbox concept, with the ONR collaborating with other regulatory authorities – such as the U.S. Nuclear Regulatory Commission (NRC) and the Canadian Nuclear Safety Commission (CNSC) – to draft a set of principles for AI regulation within the nuclear sector.

These experiences contributed to a broader understanding that emerging technologies such as AI require robust data and empirical evidence to support the development of regulatory frameworks that are coherent and resilient in the face of market volatility and technological change.

These experiences have demonstrated that:

1	Participation in the sandbox enabled FlyingBinary's proposed solution to be developed in compliance with data protection and child protection legislation, through practical and tailored guidance provided by the regulatory authority.
2	The incorporation of privacy by design principles and the development of a customized Data Protection Impact Assessment (DPIA) were essential to identifying and mitigating risks associated with the processing of sensitive data, particularly children's data.
3	Collaboration with the regulator and healthcare providers helped balance confidentiality and data--sharing requirements, strengthening the legal and ethical safeguards underpinning the final product.

4	The ONR sandbox highlighted the need to develop specialized AI capabilities among regulators and operators to ensure decisions are grounded in reliable data.
5	A flexible, principles-based regulatory framework is essential to address the diversity of AI applications.
6	International collaboration strengthened the development of shared guidelines for AI regulation in the nuclear sector.

2.2 Sandboxes for Evidence-Based Regulation

The absence of sufficient data often leads regulators either to prohibit certain technologies as a precautionary measure or to adopt a laissez-faire approach, allowing market forces to self-regulate. While both approaches may be appropriate in specific contexts, they generally lack a more granular assessment of the actual impacts of these technologies.[31]

Regulatory risks affect all stakeholders in the case of emerging technologies with significant transformative potential. In the absence of experimental spaces such as those provided by regulatory sandboxes, the burden of developing and introducing an emerging technology within a context of regulatory gaps or overlapping mandates frequently falls on first movers in the market. This dynamic can ultimately discourage innovation.[32]

As noted by the OECD, regulatory sandboxes provide an opportunity for regulators and innovators to collaborate in testing new products and services within a controlled environment. These environments foster mutual learning, enabling technologies to be assessed based on empirical data and allowing regulatory frameworks to be adjusted as necessary to address the specific demands and challenges posed by innovation.

In this manner, sandboxes promote regulatory compliance while simultaneously encouraging innovation. They support the development of solutions grounded in concrete evidence rather than abstract assumptions, helping to mitigate risks without undermining the transformative potential of new technologies.

31 OECD. Regulatory Sandboxes in Artificial Intelligence. July 2023. Available at: https://www.oecd-ilibrary.org/science-and-technology/regulatory-sandboxes-in-artificial-intelligence_8f80a0e6-en.

32 Pelkmans, Jacques and Renda, Andrea. Does EU Regulation Hinder or Stimulate Innovation? (November 19, 2014). CEPS Special Report No. 96, Available at SSRN: https://ssrn.com/abstract=2528409.

The advantages in this context are manifold:

Regulator
For regulators, sandboxes not only enable a better understanding of new technologies and business models but also allow them to assess in practice the implications of their own regulatory frameworks – including how those frameworks may promote innovation while protecting consumers, citizens, and markets. They also enhance regulatory responsiveness by reducing the time between the market entry of a new product or service and the availability of precautionary and supervisory tools.
Innovators
For innovators, sandboxes primarily reduce legal uncertainty and strengthen their capacity to comply with existing or adapted regulatory requirements established by the relevant authority or authorities. At a later stage, sandboxes also help accelerate time to market. Additionally, they encourage investment and support the potential development of new technologies and business models, which may attract greater investor interest due to increased clarity regarding existing regulatory opportunities and constraints.
Consumers and Society
For consumers and society, regulatory sandboxes may reduce risks (and potential harms) associated with the implementation of new technologies and business models. Ongoing monitoring by regulatory authorities enables more timely intervention in response to potential impacts. Likewise, the fact that these initiatives operate as limited experiments restricts broader effects, particularly systemic ones.

In conclusion, regulatory sandboxes offer an effective mechanism for balancing innovation and consumer protection. They enable the development of regulatory measures based on evidence generated within a controlled experimental setting that approximates real-world conditions. However, different regulatory approaches may be adopted to govern the conduct of participating actors during the testing phase, each tailored to distinct objectives and regulatory contexts.

Regulatory Action: Interpretation or Suspension of Regulation?

Since their introduction by the United Kingdom's financial regulator, regulatory sandboxes have enabled the temporary suspension or relaxation of certain rules – often referred to as a "regulatory holiday"– to facilitate experimentation and the development of new products, services, or business models. Approaches adopted within regulatory sandboxes vary according to regulatory objectives and the level of risk involved. Broadly speaking, these approaches can be categorized into three types:

(i) those that do not provide for the suspension of rules or address issues of civil liability;

(ii) those that allow for the suspension of specific rules, particularly those related to enforcement proceedings; and

(iii) those that, in addition to suspending certain rules, also limit civil liability, while maintaining liability in cases of intent or negligence.

FlyingBinary's participation in the UK ICO regulatory sandbox illustrates how regulatory flexibility mechanisms can support innovation in technologies designed to protect personal data, particularly in cases involving children's data. During the development of the "lookafterme" application, the ICO adopted a flexible interpretation of certain stringent regulatory requirements, including the data minimization principle and the lawful basis for processing children's data. This approach enabled FlyingBinary to explore innovative methods for complying with these requirements, refining its data collection practices to balance application functionality with the protection of children's sensitive information.

In addition, certain obligations under the Data Protection Act relating to authentication and access control requirements for children's data were applied with flexibility, which was essential for the company to conduct testing within a controlled environment. This approach allowed FlyingBinary to experiment with authentication and access control mechanisms without being immediately constrained by regulatory requirements that could have impeded technological development.

This collaboration demonstrated that compliance with data protection law need not constitute a barrier to innovation; rather, it can function as a mechanism for promoting the responsible development of new technologies. The flexibility afforded by the sandbox thus created a controlled space for regulatory risk, enabling authorities to better understand the practical implications of legal requirements within the innovation process.

Even within a regulatory sandbox – where testing conditions are structured and limited – regulatory and legal risks remain relevant.

This underscores two critical dimensions:

(1) Regulatory liability, including administrative enforcement proceedings in cases of non-compliance with applicable standards;

(2) Civil liability for damages arising from the initiatives under testing.

In the case of the ICO sandbox, these responsibilities – particularly those related to defining the roles of data controller and data processor – were addressed from the outset. Even where temporary flexibility was granted in relation to certain regulatory obligations, the allocation of responsibilities was clearly established at an early stage, ensuring that testing was conducted in compliance with applicable legal requirements.

The regulatory sandbox implemented by the Office for Nuclear Regulation (ONR) in the United Kingdom provides an example of a flexible yet controlled regulatory approach. Its primary objective was to test the application of Artificial Intelligence in the nuclear sector – an environment in which safety is paramount. In the ONR case, the regulatory strategy emphasized normative interpretation rather than the outright suspension of rules. Instead of

relaxing or removing regulatory requirements, the ONR worked collaboratively with stakeholders to interpret and apply existing standards within the context of AI deployment. This approach enabled the testing of new technologies without compromising the stringent safety standards governing the nuclear sector.

The ICO sandbox exemplifies a model in which certain requirements may be applied with flexibility to enable experimentation, while maintaining liability for violations of fundamental rights, such as data protection. By contrast, the ONR sandbox adopted an approach more closely aligned with regulatory interpretation rather than suspension: existing rules were not waived but rather interpreted in a manner that enabled AI testing within the nuclear sector. In this case, strict nuclear safety standards remained fully in force but were operationalized in a way that accommodated technological innovation without compromising safety, thereby striking a balance between regulatory oversight and the promotion of innovation.

3.1 Waiving the Application of Laws or Regulations

Another crucial element in the debate on regulatory flexibility concerns the limits of what may be waived within the regulatory framework. In regulatory practice, it is generally accepted that specific rules issued by a regulatory authority may be relaxed or temporarily suspended, particularly where such rules fall within that authority's regulatory competence. However, the issue becomes more complex when experimentation or adjustment involves obligations established by statute.

Emerging technologies, such as Artificial Intelligence, have cross-sectoral impacts and may produce significant structural transformations. In certain circumstances, it may be appropriate to conduct experimentation within predefined parameters with the objective of informing future regulatory approaches. Nevertheless, it is essential to clearly delineate the scope of any exemptions before, during, and after the testing phase. Failure to do so may generate regulatory uncertainty and create risks of abuse of discretion, including distortions of competition.

Within the context of the European Union's AI Act, for example, Recital 140[33] establishes a specific legal

33 European Union. EUR-Lex - Access to European Union law. Regulamento da Inteligência Artificial. Available at: https://eur-lex.europa.eu/legal-content/PT/TXT/?uri=CELEX:32024R1689

basis allowing providers and prospective providers of AI systems operating within regulatory sandboxes to use personal data originally collected for other purposes, provided that such use is directed toward the development of specific AI systems serving the public interest and is subject to strictly defined conditions. Although this provision introduces a degree of flexibility in relation to certain obligations under the General Data Protection Regulation (GDPR), all other data subject rights and controller obligations remain fully applicable. This includes, for example, the right to data protection and the obligation to ensure data security.

The text further clarifies that the AI Act cannot serve as a legal basis for automated decision-making as regulated under the GDPR. In addition, providers must implement appropriate safeguards, cooperate with competent authorities, and act promptly and in good faith to mitigate any significant risks identified with respect to safety, health, or fundamental rights during development and testing conducted within a regulatory sandbox.

In Brazil, the Legal Framework for Startups (Complementary Law No. 182/2021) established an important foundation for fostering innovation by authorizing regulatory agencies and entities to suspend the application of rules within their respective jurisdictions in the context of regulatory sandbox programs. This approach creates meaningful opportunities for startups and small and medium-sized enterprises (SMEs), enabling them to test innovative solutions in a controlled environment with technical and regulatory support.

Furthermore, Bill No. 2,338/2023, which proposes a regulatory framework for Artificial Intelligence in Brazil, reinforces this approach by stipulating that regulatory sandboxes must uphold fundamental rights and consumer protection standards, thereby ensuring a safe and flexible environment for innovation. Although the bill does not permit the limitation of participants' civil liability, it provides a structured space in which startups and SMEs may test new technologies with greater legal certainty and institutional support.

3.2 Participation of Small and Medium-Sized Enterprises (SMEs), Startups, and Other Entities

A vital issue in the context of regulatory sandboxes concerns the scope of participation and whether entities beyond those formally categorized as startups may benefit from these experimental environments. It is essential to recognize that innovation may originate from a wide range of actors. The core purpose of regulatory sandboxes is precisely to create spaces for regulatory experimentation in which different organizations – whether emerging companies, established corporations, or even public agencies – can test innovative solutions. This inclusive approach helps prevent undue restrictions on competition and broadens the overall impact of such initiatives.

The reference to regulatory sandboxes in the Legal Framework for Startups may, at first glance, suggest that these environments are limited to startups. However, the definition provided by Complementary Law No. 182/2021 indicates otherwise, describing regulatory sandboxes as:

> "A set of simplified special conditions under which participating legal entities may receive temporary authorization from agencies or entities with sectoral regulatory authority to develop innovative business models and test experimental techniques and technologies, subject to compliance with criteria and limits previously established by the regulatory agency or entity and through a simplified procedure".

The objective, therefore, is to foster innovation regardless of its source, allowing the participation of any legal entity, including established companies. The inclusion of regulatory sandboxes in this legislation is intended primarily to stimulate innovation rather than to restrict participation to a specific category of companies.

In the Brazilian context, Bill No. 2,338/2023 does not explicitly define the nature of eligible sandbox participants or clearly specify which actors may take part. Nonetheless, it would be beneficial for the legislative text to clarify the possibility of including entities of varying sizes

and sectors, as well as public agencies and other institutions. Such clarification would ensure that all actors interested in testing innovative solutions may access the benefits of regulatory sandboxes.

In the United Kingdom, for example, the regulatory sandboxes administered by the Information Commissioner's Office (ICO) explicitly state that the program is available to organizations of all sizes that meet the relevant eligibility criteria and thematic priorities. By employing the broader term "organizations of all sizes," the ICO signals that participation is not restricted by legal form or corporate classification, but rather by compliance with established requirements.

It is important to acknowledge that entities of varied sizes may benefit from regulatory sandboxes. However, not all organizations possess the technical capacity or financial resources required to navigate the procedural and compliance demands involved. Regulatory sandboxes may entail substantial costs, including the allocation of qualified personnel and the assumption of risks associated with testing.

This challenge is particularly acute in models that do not provide regulatory exemptions or limitations of liability for potential damages. Accordingly, it is essential to create mechanisms that facilitate and incentivize the participation of small and medium-sized enterprises (SMEs) and startups, ensuring equitable access to and contribution within regulatory testing environments.

Law No. 11,196/2005, commonly known as the "Lei do Bem" ("Good Law"), provides a notable example of how public incentives can stimulate innovation. This legislation grants tax incentives to companies investing in research and development, including deductions from Corporate Income Tax and the Social Contribution on Net Income (CSLL). This type of policy instrument may serve as a model for strengthening regulatory sandboxes in Brazil, particularly in the field of Artificial Intelligence.

Just as the "Lei do Bem" promotes technological innovation through financial incentives, regulatory sandboxes may be structured to incorporate financial and technical support for participating startups and SMEs. Such support could include grants for project development, specialized technical assistance, and tax

incentives during the sandbox testing period. These measures would help participating entities overcome initial barriers while promoting the practical implementation of new technologies within a controlled environment and in compliance with existing legislation.

The incentive framework established by the "Lei do Bem" demonstrates that well-designed public policies can reduce both risks and costs for innovative enterprises. Incorporating similar mechanisms into regulatory sandbox programs could transform them into effective instruments for driving innovation in Brazil, encouraging companies to explore new technological frontiers while maintaining regulatory certainty and compliance.

3.3 Cross-sectoral Participation

Regulatory sandboxes focused on Artificial Intelligence may serve a wide range of purposes, all aimed at fostering innovation in a responsible manner and in alignment with ethical and regulatory values. Among their primary objectives are promoting knowledge exchange among diverse stakeholders, generating data and evidence to assess the responsible performance of products, services, and business models, and supporting the development of new regulations or the interpretation of existing regulatory frameworks.

These experimental environments also enable the testing of new technologies across different contexts, the identification of gaps within the regulatory framework, and the promotion of interoperability among systems, thereby strengthening the innovation ecosystem in a sustainable and inclusive manner.

Cross-sectoral participation is a defining feature of regulatory sandboxes and is fundamental to the success of these experimental environments. Sandbox processes are not limited to interactions between the regulator and the entity conducting the tests. On the contrary, they are designed to involve a broad range of actors from the innovation ecosystem, including technical experts, academia, civil society, and affected communities. This cross-sectoral openness ensures a more inclusive and collaborative approach, enriching the development and evaluation of Artificial Intelligence technologies through diverse pers-

pectives and promoting more robust outcomes aligned with the interests of society at large. Five categories of participants may be identified:

INNOVATORS
Other members of the innovation ecosystem, including competitors, may be invited to participate in order to provide input and engage in discussions on implementation strategies, risk prevention, and mitigation, among other issues. While participation is not necessarily open to all actors, it should, to the greatest extent possible, allow contributions from a broad range of stakeholders. The circulation of information and data is essential, subject to appropriate safeguards concerning personal data and commercially sensitive information.

OTHER PUBLIC ADMINISTRATION BODIES
Given the expertise and regulatory competences of other public authorities, it may be appropriate to extend participation to additional regulators. This enables the anticipation of potential conflicts of competence and regulatory overlaps[34].

TECHNICAL EXPERTS
To ensure a rigorous assessment of both the proposals under review and the data generated during testing, the involvement of technical personnel is essential. Knowledge relating to emerging technologies such as Artificial Intelligence may be widely distributed across different sectors of society. An environment conducive to technical exchange can significantly enhance the evolution and refinement of such initiatives. In cases involving SMEs and startups, access to specialized technical expertise may be particularly valuable.

ACADEMIA
Academic institutions play a crucial role in providing critical analytical capacity during the experimentation phase and in evaluating the data and evidence collected. Academia contributes to the responsible development of solutions and supports the adaptation of public policies and regulatory frameworks based on empirical findings.

CIVIL SOCIETY
Civil society generally represents users and broader societal interests, ensuring that ethical considerations and fundamental rights remain central to the experimentation process.

In addition, consumers and directly affected groups may be invited to participate. Broader public consultation may also be conducted, and society at large may be granted access to data generated through regulatory sandbox experiments[35].

In the United Kingdom, cross-sectoral participation has been a key factor in the success of several regulatory sandbox initiatives, including those focused on Artificial Intelligence. One example is the regulatory sandbox conducted by the Office for Nuclear Regulation (ONR), which

34 This point is further elaborated below under the heading of institutional cooperation.

35 The considerations presented here represent a systematization of various national and international practices and recommendations. The structure adopted, however, follows the proposal developed by the Inter-American Development Bank (IDB). See: Inter--American Development Bank (IDB), Regulatory Sandboxes, and Innovation Testbeds: A look at international experience and lessons for Latin America and the Caribbean, 2020. Available at: https://publications.iadb.org/en/regulatory-sandboxes--and-innovation-testbeds-a-look--at-international-experience-in-latin-america-and-the-caribbean.

brought together experts in regulatory policy, human factors, data science, and AI, as well as experienced facilitators who contributed diverse perspectives and constructive feedback.

This collaborative setting created a safe environment in which participants could express their views openly and explore issues and solutions related to the application of AI in an inclusive manner. The regulatory sandbox enabled in-depth discussions on specific practical uses of AI within the nuclear sector, allowing participants to identify best practices and test regulatory models and governance arrangements. The deep-dive sessions facilitated detailed technical analysis, broadened understanding of AI applications in the sector, and strengthened the competencies of those involved.

One of the main conclusions of the sandbox was that the regulatory framework governing the nuclear sector must be sufficiently flexible to accommodate the specific characteristics of different AI applications. The experience suggested that a principles-based regulatory approach offers advantages over a prescriptive framework based on rigid rules.

In the Brazilian context, multistakeholder and cross-sectoral governance has emerged as a central element in the development of AI technologies, reflecting a commitment to inclusion and transparency. Bill No. 2,338/2023 reinforces this perspective by establishing, in Article 69, item I, that government actions in the field of Artificial Intelligence must follow guidelines ensuring transparent and cross-sectoral governance. At the same time, the National Data Protection Authority (ANPD), in its studies, has emphasized the importance of incorporating a cross-sectoral perspective in the design and implementation of regulatory sandboxes focused on AI.[36] These initiatives demonstrate that Brazilian authorities recognize the importance of broad and integrated collaboration processes, which are essential for creating experimental environments capable of promoting responsible innovation.

3.4 Transparency, Ethics, and Documentation

A regulatory sandbox should go beyond addressing

36 Autoridade Nacional De Proteção De Dados (ANPD); Banco De Desenvolvimento Da América Latina E Caribe (CAF). Consulta à Sociedade: Sandbox Regulatório de Inteligência Artificial e Proteção de Dados no Brasil. Brasília, DF: ANPD; CAF, 2023. Available at: https://www.gov.br/anpd/pt-br/documentos-e-publicacoes/anpd-sandbox-regulatorio-consulta-bilingue.pdf.

specific issues related to new AI-based business models, products, or services. Its primary objective should be to generate robust data and evidence capable of informing the future development of markets, innovation ecosystems, and the regulatory adjustments required to keep pace with technological transformation.

Experimentation within these environments should establish a benchmark for future initiatives, encouraging the replication of best practices and the incorporation of lessons learned. To that end, thorough documentation, transparency, and broad dissemination of results are essential to ensure that the benefits of regulatory sandboxes extend not only to direct participants but also to society and other relevant stakeholders.

Social participation plays a crucial role in disseminating both the initiatives undertaken and their outcomes. In addition, systematic data collection and structured reporting are fundamental to scaling these experiences and maximizing their impact. Clear methodologies and well-defined guidelines governing the data and evidence life cycle are indispensable in the design, structuring, and implementation of regulatory sandboxes.[37]

This approach underscores the importance of embedding ethical considerations throughout all stages of product development and implementation, ensuring that the resulting innovations are not only responsible but also socially beneficial and safe. Regulatory sandboxes play a strategic role in addressing structural challenges, whether social or market-related. In the Brazilian context, these environments may be designed to incorporate inclusion criteria that consider underrepresented groups – such as stakeholders from the North and Northeast regions – thereby promoting greater diversity and equity in technological development.

Regulatory sandboxes implemented in the United Kingdom have largely set an example in fostering inclusive and cross-sectoral regulatory experimentation. The Information Commissioner's Office (ICO), for instance, has published several exit reports from participants in its regulatory sandboxes,[38] including those relating to NHS Digital and the FlyingBinary project. These reports provide transparency regarding how such initiatives have

37 Regarding the stages of designing, structuring, and implementing a regulatory sandbox, we examine each in greater detail in the practical guide that complements this report.

38 All final reports and participant evaluations are available on the ICO website at: https://ico.org.uk/.

contributed to shaping data protection policy and the implementation of AI solutions in the UK.

The reports are drafted in clear and objective language and follow a structured format that sets out: the specific objectives of the project; a description of the product under review; key considerations concerning the allocation of roles and associated responsibilities; the legal bases identified; the data protection requirements that were maintained or flexibly applied within the scope of the project; and final assessments evaluating the project's outcomes, including successes and limitations. These reports are essential in extending the impact of regulatory sandboxes beyond direct participants, enabling other actors within the sector, academia, and civil society to benefit from the insights generated.

This commitment to transparency and continuous documentation is directly aligned with the objectives set out in the UK Government's white paper on Artificial Intelligence governance. The document clearly articulates a vision in which evidence generated through regulatory sandboxes informs the development of future regulatory frameworks and guidance. Sharing such data is therefore critical to ensure that regulatory processes are grounded in empirical evidence rather than speculation or purely theoretical assumptions.

At the European level, the EU AI Act establishes obligations concerning reporting and the specification of measurement and calculation methodologies, with a view to ensuring comparable and verifiable documentation. Such documentation is expected to include assessments of project outcomes, best practices, lessons learned, and recommendations for future initiatives.[39] In Brazil, Bill No. 2,338/2023 assigns transparency as a guiding principle of AI governance for public authorities (Article 68, item I). Similarly, the National Data Protection Authority (ANPD) has emphasized, in its discussions, the importance of transparency within regulatory experimentation processes, recognizing that the broader dissemination of results enables society at large to benefit from the lessons generated through innovation.

39 European Union. AI Act. Article 53(5). Available at: https://eur-lex.europa.eu/legal-content/PT/TXT/HTML/?uri=OJ:L_202401689.

Interinstitutional Cooperation and Innovation

Innovations involving emerging technologies such as Artificial Intelligence are rarely confined to a single sector. Even when tools or applications are designed for use within a specific domain, their development and deployment often require consideration of regulatory frameworks from other sectors, as well as implementation strategies compatible with different markets. This is the case, for example, with AI tools developed for the healthcare sector, which may rely on personal data – including sensitive data – throughout their development and operational phases, as illustrated by the FlyingBinary case within the UK ICO's regulatory sandbox.

In this context, it may be beneficial for both healthcare authorities and data protection authorities to provide input. Moreover, a new business model for the provision of products or services may alter the way consumers engage with purchasing and access mechanisms, thereby making the involvement of consumer protection authorities equally relevant.

In scenarios characterized by sectoral transformation and market disruption, regulatory sandboxes can particularly benefit from collaborative approaches. Even where a specific authority is responsible for overseeing a broad category of technologies such as AI, the inherently cross-sectoral nature of these technologies makes openness to cooperation advantageous. Such cooperation can reduce the risk of regulatory fragmentation and leverage the expertise and institutional capacity of sector-specific regulators.

Mechanisms and institutional arrangements that facilitate interinstitutional cooperation can significantly enhance sandbox processes and support the implemen-

tation of innovations that are robust across multiple regulatory dimensions. An initiative exemplifying this model of partnership and cooperation between public authorities is the experience of the Financial Conduct Authority (FCA) in the United Kingdom. In 2021, the permanent "Digital Sandbox" program[40] was established in partnership with the City of London Corporation – the municipal governing body of the City of London responsible for maintaining standards in local public services. The program provides datasets in compliance with the Data Protection Act within a secure testing environment, alongside expert guidance from industry specialists and access to the fintech community to support experimentation and the scaling of proof-of-concept solutions.

Regarding cross-sectoral cooperation, the United Kingdom offers two emblematic examples: The participation of the civil society non-profit organization Global Cyber Alliance (GCA)[41] and the involvement of the Ministry of Housing, Communities and Local Government (MHCLG)[42] in the regulatory sandbox of the Information Commissioner's Office (ICO).

In the case of MHCLG, a government department, the initiative undertaken with the ICO aimed to improve the quality of private rental housing in Blackpool by integrating data from multiple sources, including Blackpool Council and the Department for Work and Pensions (DWP). Participation in the regulatory sandbox entailed cooperation among different public institutions and the processing of sensitive data to produce an updated dataset, thereby enabling a cross-sectoral strategy to strengthen regulatory enforcement and protect tenants' rights. This example demonstrates how the sandbox facilitated coordination among public authorities and supported the development of more effective housing policies, while ensuring compliance with data protection legislation.

By contrast, the GCA project within the regulatory sandbox sought to integrate data from ICO investigations into malicious domains into the Domain Trust cybersecurity platform. Although the project encountered challenges related to compliance with data protection legislation, it provided a unique opportunity to examine how international organizations, regulatory authorities, and cyber-

40 Financial Conduct Authority. Digital Sandbox. April, 2020. Available at: https://www.fca.org.uk/firms/ innovation/digital-sandbox.

41 Information Commissioner's Office (ICO). Regulatory Sandbox Final Report: Global Cyber Alliance – A summary of the Global Cyber Alliance's participation in the ICO's Regulatory Sandbox. Date: March 2022. Available at: https://ico.org.uk/media/for-organisations/documents/4019931/gca-sandbox-exit-202203.pdf?_gl=1*1gx27ml*_gcl_au*NTE5MTE2NjEzLjE3MjkwMzc4MzA.

42 Information Commissioner's Office (ICO). Regulatory Sandbox Final Report: The Ministry of Housing, Communities and Local Government (MHCLG) – A summary of MHCLG's participation in the ICO's Regulatory Sandbox Beta. Date: March 2021. Available at: https://ico.org.uk/media/for-organisations/documents/2619467/mhclg_final-report.pdf.

security stakeholders can collaborate to enhance Internet security. The GCA relied on guidance from the ICO to assess data protection risks, highlighting the importance of cross-sectoral cooperation – ranging from regulators to international organizations – in the development of innovative and secure technological solutions.

Both examples illustrate the value of regulatory sandboxes as platforms for experimentation and interinstitutional cooperation, providing a secure environment in which multiple sectors can collaborate to develop innovative solutions in compliance with applicable legal frameworks.

The approach adopted by the European Union clearly underscores the need for coordination at multiple governance levels, encompassing cooperation among national regulatory authorities as well as between national and EU-level bodies. Although this requirement reflects the institutional architecture of the European Union itself, the emphasis on cooperation among national authorities reveals a broader concern with preventing regulatory overlaps and conflicts that could undermine the effectiveness of regulatory sandboxes.

Regarding regulatory sandboxes more broadly, Brazil already has experience in fostering cooperation among regulatory authorities. Early sandbox initiatives involved coordinated efforts between the Central Bank and the Securities and Exchange Commission in structuring their respective program concurrently. Similarly, within the regulatory framework of the National Land Transport Agency (ANTT), there is a permissive approach to establishing cooperation mechanisms with other national institutions, including as a means of promoting regulatory harmonization. In the context of AI regulatory sandboxes, the National Data Protection Authority (ANPD) has expressed openness to cooperative approaches, including at the international level.

As Alain Kapper, a member of the Digital Regulation Cooperation Forum (DRCF), observed when discussing the importance of inter-agency collaboration:

“I believe I read a report indicating that [ANPD] was planning to work collaboratively with other government agencies in the near future, and I would strongly encourage that. In a country as vast as Brazil, ensuring regulatory consistency across independent regimes is a significant challenge. When one regulator adopts a position, it may directly affect entities under its jurisdiction, but it may also have indirect implications for the work of other regulators. For this reason, fostering dialogue and building trust among different regulatory authorities is essential.”

ALAIN KAPPER

Conclusion

Innovation is not a straightforward undertaking. For public authorities, the process can be bureaucratic, costly, and often provides no assurance that outcomes will fully meet the demands placed upon them. For innovators, it entails significant financial and reputational risks. For consumers, it may create vulnerabilities, exposing them to products that not only complicate everyday life but, in extreme cases, may compromise their safety. These uncertainties frequently discourage stakeholders and create substantial barriers to innovation.

The purpose of this report is to present Brazilian public managers with an example from another jurisdiction that, although it does not claim to have all the answers, has consistently invested in the development of collaborative solutions that have produced meaningful results. In the United Kingdom, regulatory sandboxes represent an innovative model of engagement between regulators and innovators, in which regulatory compliance ceases to function as an obstacle to innovation and instead becomes an opportunity to develop more effective, inclusive, and secure products and solutions.

The British experience demonstrates that interinstitutional cooperation, procedural transparency, and the systematic dissemination of results are central elements in the success of regulatory sandboxes. In the context of Artificial Intelligence – one of the most disruptive emerging technologies of our time – it is essential to adopt innovation models that not only maximize its transformative potential but also address the associated ethical concerns in a practical and continuous manner. Integrating such considerations from the initial conception through to the final implementation of projects is fundamental to ensuring that AI development is responsible and capable of generating tangible and inclusive societal benefits.

From this study, it is possible to conclude that:

1	AThe UK experience demonstrates that there is no single model for regulatory sandboxes; rather, they are tailored to the specific needs of the actors involved. This underscores the importance of regulatory flexibility to accommodate different sectors and contexts.
2	Despite structural variations, regulatory sandboxes share essential characteristics, including (i) temporality; (ii) limited scope; (iii) focus on innovation; (iv) regulatory oversight; and (v) collaboration. These features are critical to establishing a controlled and productive environment for innovation.
3	Regulatory sandboxes are not universally applicable to all situations; their effectiveness depends on clearly identifying the underlying needs and the expected outcomes. Moreover, the inability of a solution tested within a sandbox to prove viable should not be regarded as failure, but rather as a valuable learning outcome that generates data to support informed regulatory decision-making.
4	As Brazil advances toward the possible establishment of a regulatory framework for Artificial Intelligence, regulatory sandboxes emerge as a viable strategy to stimulate innovation and strengthen SMEs and startups, thereby enhancing competitiveness in the global market.

Finally, having examined the conceptual and theoretical foundations of regulatory sandboxes and the British experience, we invite public managers and other actors within the innovation ecosystem to explore the practical guide, How to Structure an Artificial Intelligence Regulatory Sandbox? – A Practical Guide for Brazil in Light of the British Experience. This material complements the present benchmark by providing practical guidance on the planning, design, and implementation phases of regulatory sandboxes, including estimates of the resources and timelines required for effective execution.

Through this series of studies, we hope to contribute to the development of regulatory experimentation environments in Brazil, fostering a dynamic and responsible innovation ecosystem capable of responding to the technological demands of both the present and the future.

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