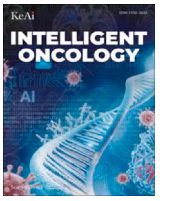
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Review

Regulatory sandbox expansion: Exploring the leap from fintech to medical artificial intelligence

Yingpeng Qiu[a,#], Han Yao[b,#], Ping Ren[a], Xueqing Tian[a], Mao You[a,*]

[a] China National Health Development Research Center, Beijing 100226, China
[b] School of Health Policy and Management, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing 100730, China

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ABSTRACT

This paper explores the expansion from fintech-based regulatory sandboxes to those that include medical artificial intelligence (AI) by examining their potential to foster innovation and accelerate market access while ensuring safety and compliance, especially considering how they provide a flexible framework for medical AI companies to develop and test new technologies. This work also highlights the key risks involved, including data privacy, ethical concerns, real-world validation, and regulatory consistency, and proposes strategies for mitigation. Using case studies from the United States, the United Kingdom, the European Union, Indonesia, Japan, and China, this paper illustrates how regulatory sandboxes can support AI-driven healthcare innovation. Overall, although regulatory sandboxes present several risks, they are valuable for advancing medical AI, granted that they balance innovation with robust oversight to ensure patient safety and long-term benefits.

1. Introduction

In the context of technological revolution and industrial transformation, medical artificial intelligence (AI), which is driven by computing power, algorithms, data, and knowledge, is changing the traditional medical ecosystem and posing challenges to the regulatory logic of the health system.[1] Under the traditional regulatory model, medical AI companies—in promoting product research and development, market access, clinical application, and pricing and payment—need to bear high upfront investment costs and highly uncertain market risks to obtain real-world data and respond to cross-verification from various regulatory parties. Many countries are adopting AI and incorporating AI technologies into their national strategies, but novel risk factors have also emerged. Therefore, regulatory reform is required to maintain a balance between innovation and risk.

A regulatory sandbox is a tool for developing 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 related to the impact of innovations, allowing beneficial innovations to reach the marketplace.[2,3] Since the Financial Conduct Authority (FCA) of the United Kingdom (UK) officially launched the regulatory sandbox mechanism in May 2016, many countries and regions have introduced it into their own financial technology development strategies, creating localized regulatory sandbox mechanisms suitable for their national conditions and stages of development.[4,5] These successful cases have greatly promoted the development and technological progress of the financial technology industry on an international scale.[6,7] Generally, a regulatory sandbox is designed to provide

* Corresponding author.
E-mail address: ym@nhei.cn (M. You).
# These authors contributed equally to this work.

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companies with a specific regulatory environment that allows them to develop and test AI applications before bringing them to market, thereby validating the impact of innovative technologies within the existing regulatory framework. Ultimately, the regulatory sandbox has a dual role: 1) it promotes business learning—that is, the development and testing of innovations in a real environment; and 2) it supports regulatory learning—that is, the formulation of experimental legal systems, guiding and supporting corporate innovation activities under the supervision of regulatory authorities. In practice, this approach aims to facilitate experimental innovation within a framework of risk control and supervision and to improve regulatory authorities' understanding of new technologies.

Notably, breakthroughs in generative AI have caused a major paradigm shift, and the rapid development of this technology has triggered a series of issues, such as algorithmic bias, privacy violations, and national security threats.[8] These challenges increasingly expose the lag and inadaptability of traditional regulatory concepts and models. Achieving a dynamic balance between AI innovation and regulation has thus become one of the core challenges in the construction of AI governance systems worldwide. Therefore, this study aims to comprehensively summarize the international practices of regulatory sandboxes, providing guidance for the development of regulatory sandboxes in the field of medical AI.

2. Conceptualization of the regulatory sandbox

2.1. Conceptualization of regulatory sandbox in fintech

In the face of market changes driven by technological advancements, regulatory bodies need to place greater emphasis on enhancing the foresight and flexibility of digital governance. The application of regulatory sandboxes is critical for the in-depth popularization and healthy development of emerging technologies and their applications. Statistics indicate that 28% of global AI-related policies in 2023 were categorized as adaptive regulation.[9] This shows that flexible regulation has gradually evolved into a vital component of AI governance. The regulatory sandbox, a model that has gained traction across numerous countries and regions in the financial technology sector, is now increasingly being considered essential in the realm of AI regulation. Drawing an analogy to computer science, a sandbox is designed to offer a secure and expeditious testing ground for innovations within a confined domain. By conducting controlled experiments with stringent parameters and comprehensive oversight, the sandbox not only anticipates, identifies, and mitigates the potential risks and adverse effects of new developments but also expedites the market launch or reduces regulatory costs through a prompt and efficient review process.[10] This approach optimally positions enterprises to engage in innovation responsibly, ensuring that the market is well-informed and prepared for genuine advancements. In essence, the regulatory sandbox provides a fertile ground for companies to cultivate innovations that are not only safe and sustainable but also profoundly beneficial to society, offering effective incentives for progress that align with broader public interests.

In March 2015, the FCA pioneered the concept of the regulatory sandbox within the financial sector.[11] The FCA established a dedicated Innovation Hub to support the development of financial technology, offering startups appropriate preferences in taxation and investment, assisting innovative companies in engaging with regulatory authorities, providing limited authorization requirements, and creating an environment conducive to innovation in the financial technology industry. Subsequently, various countries and regions, such as Singapore,[12,13] Australia,[14] Hong Kong, China,[15,16] Japan,[17] and Thailand,[18] also actively promoted regulatory sandboxes in the field of financial technology; however, there are several differences regarding the regulatory bodies, applicant entities, testing requirements, and exit mechanisms[19] (Table 1). China's mainland began to apply the regulatory sandbox model in the financial sector at the end of 2019. Specifically, the People's Bank of China launched the first pilot programs for financial technology innovation supervision in Beijing, Shanghai, Chengdu, Guangzhou, Shenzhen, and Chongqing, selecting six innovative applications, including digital finance scenarios.[20,21]

2.2. Operational model of the regulatory sandbox

The regulatory sandbox implementation process primarily consists of three phases and their corresponding core mechanisms.[22]

2.2.1. Admission phase

During the admission phase, it is important to clearly define the overall design philosophy and set the criteria for entry into the regulatory sandbox. This involves specifying the types of businesses eligible to participate and the services or products that can be tested within the sandbox environment. Additionally, adequate technical and managerial support, such as computing and storage infrastructure, should be provided to facilitate technological research and testing.

2.2.2. Testing phase

In the testing phase, mechanisms for information disclosure and communication, exemptions, and mid-term modifications should be established following relevant guidelines. Disclosure should cover data monitoring, testing duration, test reports, and explanations for any special circumstances, including early exits. Exemptions should be granted based on the regulatory exemption requests submitted by participating companies, in line with specific authority guidelines and policy directions. This allows for flexibility while ensuring compliance with legal and regulatory frameworks. Mid-term modifications enable companies to propose extensions, additional test subjects, or adjustments to test projects based on actual conditions, subject to approval by the regulatory authority.

Table 1
Regulatory sandbox applications in different countries and regions.

Country and region	Launch time	Supervising body	Entities of application	Test item application requirements	Test cycle	Exit mechanism
UK	May 2016	Financial Conduct Authority	Financial institutions and fintech enterprises	Financial products and services are innovative but fall within the scope of the Financial Services and Markets Act	6 months	The test period is full
United States	September 2016	Federal Reserve Board, Department of the Treasury, and Securities and Exchange Commission	Fintech companies	Products use or combine new or emerging technologies, or use existing technologies in new ways to solve problems or provide convenient services or products	2 or 3 years	The test period is full
Australia	March 2016	Australian Securities and Investments Commission	Fintech companies and individuals	Financial services and credit activities; financial products and credit contract products	12 months	The test period expires or individuals can apply in advance
Singapore	June 2016	Monetary Authority of Singapore	Fintech companies	Suitable for technological innovation and new methods application in fintech	Depends on the specific situation	Individuals can apply for an extension
Hong Kong, China	September 2016	Hong Kong Monetary Authority (HKMA)	Banks	Banking-related services, including mobile payment services, blockchain, robotics, and biological authentication	Depends on the specific situation	The testing range is beyond the HKMA regulation

2.2.3. Exit phase

The exit phase includes two scenarios: “Exit within the rules,” where companies successfully complete their predefined objectives and exit the sandbox as planned, and “Exit outside the rules,” where companies terminate testing early because of unforeseen circumstances, such as risk hazards or violations of exemption rules.

3. A regulatory sandbox model suitable for public health

The concept of regulatory sandboxes is still emerging in the public health sector but has primarily been applied in high-income countries to support the rapid adoption of novel technologies, particularly in digital health. This regulatory framework is designed to encourage innovation, safeguard consumer rights, and provide real-time risk assessment and oversight to regulators.[23] The key objective is to balance technological advancement with public safety, ensuring that regulatory processes remain adaptive in the face of emerging challenges.

3.1. Access: facilitating market entry for medical technologies

Regulatory sandboxes in public health are increasingly demonstrating their distinct value. A notable example is the U.S. Food and Drug Administration’s Emergency Use Authorization process, which enabled the expedited approval of critical medical products and devices during the COVID-19 pandemic. This rapid-response mechanism was crucial in facilitating the timely introduction of essential technologies while maintaining rigorous safety and efficacy standards.[24] The Emergency Use Authorization mechanism highlights the potential of regulatory sandboxes to accelerate market entry for medical technologies, particularly during health crises.

3.2. Diagnosis and innovation: real-world testing and validation of technology

In the UK, the National Health Service (NHS)’s Testbed program serves as a prime example of how regulatory sandboxes can promote the adoption of innovative health technologies. By testing new technologies and services in real-world healthcare environments, this program has enabled the integration of novel diagnostic tools and treatment methods into clinical practice, ensuring that they meet the practical needs of both patients and healthcare professionals.[25] This case underscores the role of regulatory sandboxes in validating new technologies in real-world settings, fostering their smooth transition into the healthcare system.

3.3. Surveillance and intervention: enhancing disease monitoring and treatment efficacy

In Indonesia, regulatory sandboxes have been leveraged to introduce cutting-edge digital health solutions aimed at improving disease surveillance and treatment. One such initiative, the electronic malaria (e-Malaria) program, utilizes digital platforms to enhance the accuracy and timeliness of malaria monitoring. The program’s ability to integrate real-time data collection with health intervention strategies exemplifies how regulatory sandboxes can contribute to more effective and responsive public health management, especially in the context of infectious disease control.[26]

3.4. Data security and transparency: blockchain applications in clinical trials

Japan’s use of blockchain technology in breast cancer clinical trials illustrates the potential of regulatory sandboxes to enhance data security and transparency in medical research. By applying the blockchain for data validation and verification, this initiative has not only improved the reliability of clinical trial data but also fostered greater trust among patients and stakeholders. Furthermore, it has empowered regulators with more robust data support, ensuring the integrity of clinical research processes.[27] This case highlights how regulatory sandboxes can play a critical role in ensuring transparency and trust in health-related innovations.

3.5. Innovation and regulation: addressing challenges in biomedical product development

The European Union (EU) has proposed the use of regulatory sandboxes to address the regulatory challenges associated with biomedical product innovation. These frameworks are intended to facilitate the development and timely delivery of innovative medical products while maintaining rigorous safety and efficacy standards. By providing a controlled environment for testing new biomedical products, regulatory sandboxes help harmonize the pace of innovation with regulatory oversight, ensuring that patients can access groundbreaking treatments without compromising public health standards.[28]

In summary, these cases demonstrate that regulatory sandboxes not only accelerate the innovation and market entry of medical technologies but also enhance the overall effectiveness of healthcare systems. These frameworks safeguard public health and safety, particularly during times of health crises. By offering a flexible and adaptive regulatory tool, regulatory sandboxes facilitate rapid responses to medical challenges and support the ongoing evolution of healthcare. As the global healthcare landscape continues to encounter new complexities, regulatory sandboxes will remain an essential mechanism for advancing medical innovation and improving patient care.

4. Medical AI regulatory sandbox construction

Along with the increasing adoption of regulatory sandboxes in healthcare systems around the world, the integration of AI technologies into medical devices and services is gaining momentum. As AI applications become more prevalent in medical settings, regulatory bodies must develop frameworks that ensure their safety and efficacy. This section explores the evolving landscape of regulatory sandboxes designed specifically for AI in healthcare, with a focus on recent developments in the EU and the UK.

4.1. The EU's AI regulatory sandbox initiative

The EU has been a pioneer in developing regulatory frameworks for AI applications across multiple sectors. Since 2016, the EU has been actively working on legislation to address the challenges posed by AI technologies. In June 2023, after three rounds of revisions and negotiations, the EU adopted the Artificial Intelligence Act, which includes the establishment of AI regulatory sandboxes. These sandboxes provide a controlled environment for testing and validating innovative AI systems before they are deployed on the market. The primary objective of such regulatory frameworks is to give innovators the flexibility to test and develop their technologies while ensuring that consumer rights and safety are adequately protected.

The proposed AI regulatory sandbox concept involves granting public authorities the ability to oversee the development of AI systems in a structured and safe manner. This model allows for targeted testing in a controlled environment under the supervision of a regulatory authority. Such initiatives aim to foster innovation in the AI sector without compromising consumer protection or public trust in emerging technologies.[29]

4.2. The UK's AI medical device sandbox: a collaborative approach

The UK has strongly encouraged the use of regulatory sandboxes for AI in healthcare. The country's approach emphasizes collaboration between governmental bodies, regulatory agencies, and industry stakeholders to streamline the introduction of AI medical devices (AIaMDs) into healthcare systems. A key example is the AI Airlock, launched by the Medicines and Healthcare Products Regulatory Agency in partnership with the NHS and UK Association for Medical Device Approved Bodies in October 2023. This sandbox seeks to address challenges in AIaMD regulation, including issues related to data quality, unclear product review standards, and the lack of real-world testing environments.

The AI Airlock sandbox is designed to facilitate a more tailored and controlled environment for assessing AIaMD performance.[30] Initially, 4–6 products within the same category are selected for testing, with regulatory settings adjusted based on the unique characteristics of each device. By creating a regulated yet flexible environment for testing, manufacturers, healthcare institutions, and regulators can collaboratively evaluate product performance and safety. Furthermore, the sandbox includes mechanisms for continuous monitoring, risk management, and timely adjustments to maintain safety standards while promoting innovation.[31]

4.3. AI in healthcare service delivery: step-by-step implementation

The UK has also adopted a sandbox approach similar to that of medical devices to foster the integration of AI into healthcare service delivery. In February 2019, a multi-agency collaboration led by the Care Quality Commission and the Medicines and Healthcare Products Regulatory Agency launched a regulatory sandbox for AI-driven healthcare services. This initiative focused on pilot programs that assessed the safety and effectiveness of digital triage tools, AI-assisted diagnostics, and virtual healthcare services such as home virtual wards.

One marked outcome of this regulatory approach was the approval of the UK's first AI-powered virtual physiotherapy clinic for musculoskeletal diseases in June 2024. The platform allows patients to independently use the app or be referred by a general practitioner. Digital physiotherapists conduct video consultations, create personalized exercise and pain management plans, and monitor patients' progress. The AI system's ability to adjust treatment plans in real time offers substantial benefits in terms of accessibility, cost-effectiveness, and patient engagement.

4.4. Global adoption of AI health sandboxes

Other countries and regions are also embracing regulatory sandboxes to assess the safety and efficacy of AI-driven health technologies. The US, Canada, Japan, and Indonesia have initiated similar sandbox environments to promote regulatory innovation and assess digital health interventions, particularly AI applications. For example, Japan has focused on leveraging AI in clinical trials, and Indonesia has implemented AI-driven solutions for disease surveillance and treatment, such as its e-Malaria program.

In China, Beijing has made strides in establishing regulatory sandbox frameworks for key sectors, including healthcare, with specific plans proposed in 2023. However, the development of AI-focused health sandboxes is still in its early stages. As these systems continue to evolve, China is expected to build on global best practices, drawing inspiration from the EU and the UK to create tailored regulatory environments for AI in healthcare.

The construction of these regulatory sandboxes represents a vital step toward a more sustainable and prosperous future, where emerging technologies are introduced in a manner that balances innovation with safety and efficacy. As demonstrated by the experiences of the EU, UK, and other regions, these frameworks enable regulators to support the safe and controlled deployment of AI technologies, promoting both technological advancement and consumer protection. Moving forward, these sandboxes will play a

crucial role in shaping the future of AI in healthcare, providing a flexible and adaptive environment for both regulators and innovators.

5. Risks of regulatory sandboxes in medical AI applications

While regulatory sandboxes offer significant potential for advancing medical AI technologies, their application is not without inherent risks. These risks must be carefully considered and managed to ensure that the benefits of innovation do not outweigh the safety, privacy, and ethical concerns that come with the deployment of AI in healthcare.

5.1. Data privacy and security concerns

One of the primary concerns associated with regulatory sandboxes in the healthcare sector is the protection of patient data. Medical AI systems often require access to sensitive health data, including personal health records and genetic information. In a sandbox environment, where experimentation and testing are encouraged, the risk of data breaches or misuse is heightened.[32] Although regulatory frameworks typically include provisions for data protection, the dynamic and experimental nature of sandboxes can lead to lapses in compliance or unanticipated vulnerabilities.[33] To mitigate these risks, regulatory bodies must enforce stringent data security measures and ensure that all participating entities comply with robust data protection laws, such as the General Data Protection Regulation in the EU.[34] Regular audits and monitoring should be implemented to detect potential breaches early and confirm that patient consent and data anonymization procedures are strictly followed.

5.2. Ethical issues in AI decision-making

Another considerable risk is the potential for biases or unethical decision-making in AI models. Medical AI systems, if not carefully designed and tested, can perpetuate biases in diagnoses, treatment recommendations, or patient care.[35] For instance, AI systems trained on biased datasets may lead to suboptimal outcomes for underrepresented populations, exacerbating existing healthcare disparities.[36] In a sandbox setting, where real-world data and clinical environments are often utilized, the risk of these biases being perpetuated or exacerbated increases. To address these issues, regulators must ensure that AI systems undergo rigorous ethical assessments during their sandbox testing phases. This includes scrutinizing the datasets that are used for training AI models, ensuring diversity in the data, and incorporating mechanisms for identifying and mitigating bias.[37] Additionally, continuous monitoring of AI decision-making processes and the implementation of transparent reporting mechanisms can help identify ethical concerns early in the testing phase.[38]

5.3. Lack of real-world validation

Although regulatory sandboxes aim to replicate real-world conditions, they may still fall short of fully simulating the complexities of everyday healthcare settings. Medical AI systems tested within a controlled sandbox environment may perform well under specific conditions, but their effectiveness in diverse, high-pressure clinical situations remains uncertain.[39] This gap between controlled testing and real-world application poses a significant risk because AI systems may behave unpredictably when exposed to unforeseen challenges or edge cases.[40,41] To mitigate this risk, sandbox testing must be designed to incorporate as many real-world variables as possible. Collaboration with healthcare providers and clinicians can help create more realistic testing scenarios. Furthermore, a gradual transition from sandbox environments to broader clinical implementation, accompanied by phased, controlled rollouts, can help identify potential issues before full-scale deployment.

5.4. Regulatory oversight and market distortions

A key risk in the use of regulatory sandboxes is the potential for inconsistent oversight and regulatory fragmentation. Different jurisdictions may have varying requirements for sandbox operations, leading to discrepancies in how medical AI is tested and approved across regions.[42,43] This lack of standardization may result in fragmented AI deployment, with some markets offering more lenient regulations, potentially jeopardizing patient safety.[44] Furthermore, there is the concern that prolonged sandbox testing may delay market entry for new medical AI technologies, hindering the overall adoption of beneficial innovations. Conversely, if sandboxes are not adequately regulated, technologies that have not been sufficiently tested may be prematurely pushed into broader markets, potentially compromising patient safety. To mitigate these risks, international cooperation and the development of global standards for regulatory sandboxes in medical AI are essential. This would ensure consistency in the testing, approval, and deployment processes. National regulatory bodies should work together to create frameworks that align sandbox regulations across borders and promote safe and equitable access to medical innovations.

5.5. Dependency on continuous innovation

Regulatory sandboxes encourage continuous innovation, but this can lead to the problem of constant experimentation without adequate long-term validation. AI technologies, especially those deployed in healthcare, require thorough, longitudinal testing to understand their long-term impacts on patient outcomes, treatment efficacy, and system-wide healthcare dynamics.[45] Without

adequate post-sandbox monitoring, there is a risk that innovations may be deployed before they are sufficiently validated for widespread use.[46] A robust post-sandbox surveillance mechanism is essential to ensure that AI systems continue to perform as expected once they enter the healthcare market. Ongoing monitoring and evaluation should be embedded in the regulatory process, with clear mechanisms for revising or retracting approvals if AI systems demonstrate unforeseen risks after deployment.

6. Conclusions: balancing innovation with caution

At its core, the regulatory sandbox offers an innovative pathway that circumvents the conventional approval processes of regulatory authorities, providing a controlled environment where new products and services can be tested and thereby allowing for a more agile and adaptive approach to innovation within the market. However, it is necessary to acknowledge that regulatory sandboxes are inherently risky and experimental, as they are designed to foster innovation while managing the associated uncertainties. As such, they are likely to be most effective in markets where there is inherent demand and where the benefits of innovation can be clearly articulated and measured.

Moreover, it is essential to recognize that the regulatory sandbox is not a one-size-fits-all solution. The adage “death cannot be undone” underscores the irreversible nature of certain consequences, which is equally applicable to the potential negative impacts of regulatory sandboxes in the public health sector. The scale effects of any adverse outcomes must be closely monitored, considering that the success or failure of a regulatory sandbox cannot be uniformly judged across different social environments or political contexts. Each implementation must be carefully tailored to the specific needs and risks of the sector and the region.

Despite these potential risks, the beneficial impacts of the regulatory sandbox have been demonstrated, highlighting the need for regulatory designs that are not only protective but also proactive in nurturing innovation. Sandboxes should be a feature of modern regulatory design, providing a platform for responsible experimentation that balances the drive for innovation with the need for consumer protection and market stability.

In conclusion, although regulatory sandboxes present certain risks and are not universally applicable, they are effective for fostering innovation in a controlled and responsible manner. As we look to the future, the continued evolution and refinement of regulatory sandboxes will be crucial in ensuring that they effectively serve their purpose without compromising public safety and well-being. Through this balanced approach, we can harness the power of innovation for the betterment of society as a whole.

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CRediT authorship contribution statement

Yingpeng Qiu: Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. **Han Yao**: Writing – original draft, Methodology, Formal analysis, Conceptualization. **Ping Ren**: Resources, Formal analysis, Conceptualization. **Xueqing Tian**: Resources, Formal analysis, Conceptualization. **Mao You**: Validation, Supervision, Funding acquisition, Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Consent for publication

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