# Designing and Governing Digital Health Regulatory Sandboxes

*A Conceptual Framework and Comparative Case studies*

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# What are Regulatory Sandboxes?

A regulatory sandbox **is a controlled**, live environment that **allows firms to test innovative products**, services, or business models with real customers for a limited time, while under the supervision of regulators

**Experiment**

Firms can test novel products in a safe, bounded environment

**Protect**

Consumers and public interests remain safeguarded throughout

**Inform**

Insights from the sandbox directly feed into possible regulatory reform

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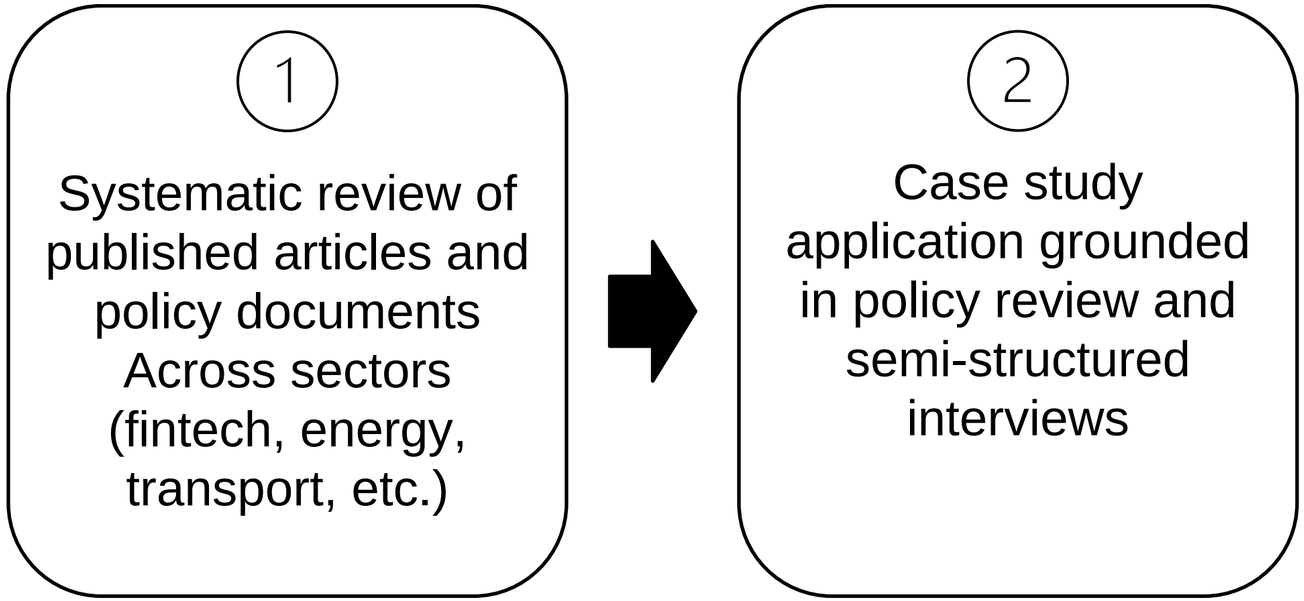
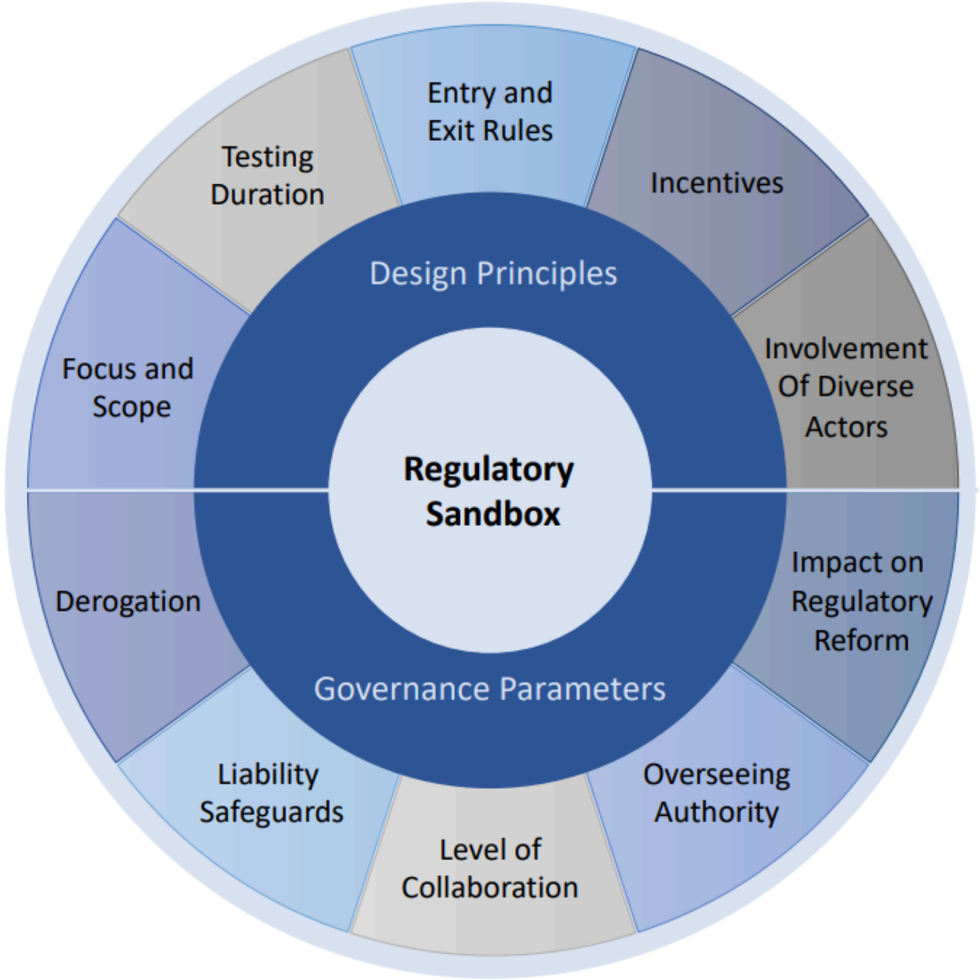
# Aim and study design

**AIM: Identify Key Design Principles of Regulatory Sandboxes and Compare these Design Principles across comparitative case studies**



27 articles and policy documents

Inductive coding

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# Case Studies

Singapore
## LEAP

*Licensing Experimentation & Adaptation Programme*

Period: 2018-2021
Focus: Telemedicine & mobile medicine
Scope: Narrow
Output: Informed Healthcare Services Acts 2023

United Kingdom
## CQC

*Care Quality Commission Sandbox*

Period: 2019-2020
Focus: Digital triage, AI diagnostics, digital personal assistants
Scope: Broad
Output: Inspection frameworks & soft regulatory guidance

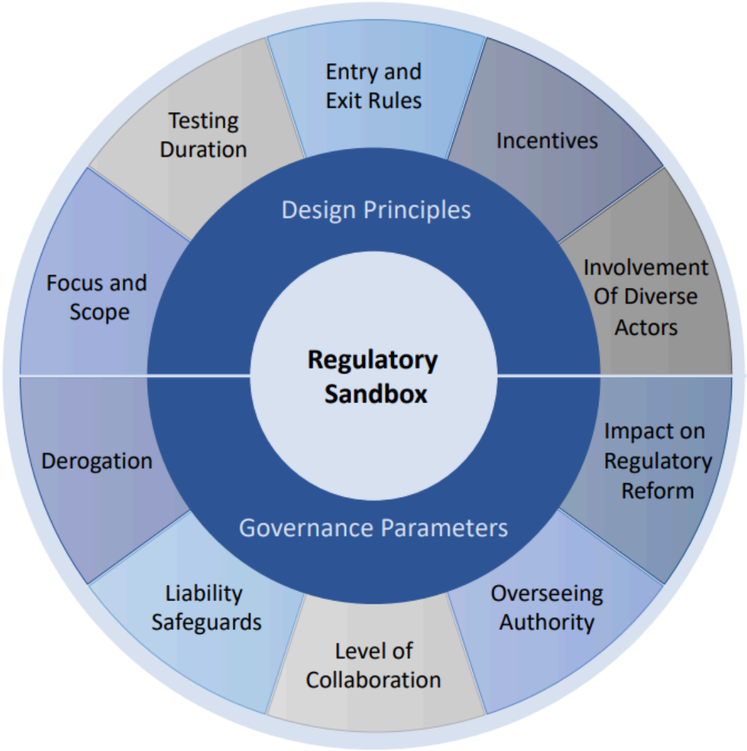
United Kingdom
## ICO

*Information Commissioner's Office Sandbox*

Period: 2018-ongoing
Focus: Personal data use across industries, including health
Scope: Broad (cross-sectoral)
Output: GDPR compliance guidance for firms

# Design Principles

- Scope & Focus — What the sandbox tests.
  - Narrow scope tends to produce more concrete regulation; broad scope yields more generic guidance.
- Testing Duration — The defined period for participation and evidence collection. Depends on technology complexity, regulatory maturity, and participant risk profiles. Build in contingency for delays.
- Entry & Exit Rules — Entry criteria cover novelty, risk management capability, and fit with the sandbox's focus. Exit rules specify conditions for removal — safety breaches, misconduct, or failure to meet objectives.
- Incentives — Rarely financial. Firms are drawn by regulatory clarity, direct access to regulators, the opportunity to shape future rules, and reputational legitimacy.
- Involvement of Diverse Actors — Clinical, technical, legal, policy, and consumer expertise should all be represented. Broader participation improves credibility, reduces regulatory capture, and strengthens design.

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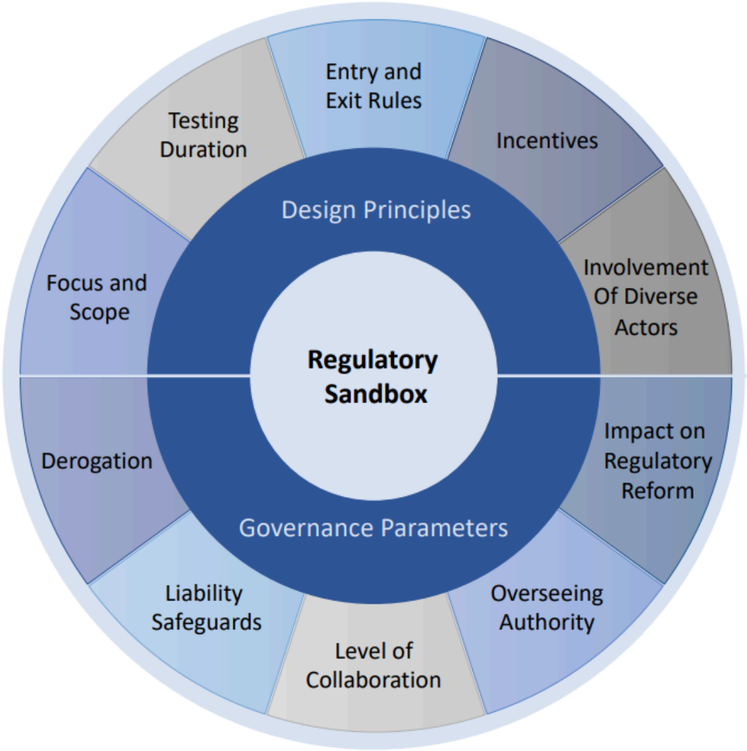
# Governance Parameters

- Derogation — The degree of regulatory flexibility granted.
- Collaboration — The depth of regulator–firm engagement, from genuine co-production to arms-length consultancy. Strong collaboration enables mutual learning but requires safeguards against regulatory capture.
- Liability — How responsibility for harm is allocated. Firms complying with sandbox protocols are typically protected; those in breach bear full liability. Consumer protections must be agreed upon up front.
- Overseeing Authority — A supervisory body separate from the day-to-day regulatory team, operating on four principles: transparency, legal certainty, public accountability, and equality.
- Regulatory Impact — The degree to which sandbox insights feed into legislative change. Can range from direct hard law reform (LEAP → HCSA) to soft guidance (CQC) to firm-specific advice (ICO).

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| Dimension | LEAP (SG) | CQC (UK) | ICO (UK) |
|---|---|---|---|
| **Scope** | Narrow (2 services) | Broad (digital health) | Broadest (cross-sector) |
| **Duration** | 3 years, 2 phases | 12–14 weeks / round | Ongoing (roll-on/off) |
| **Entry** | By invitation (MOH) | Approached by CQC | Open application |
| **Derogation** | None | None | None |
| **Collaboration** | High (MOH–provider) | High (co-production) | Consultancy model |
| **Reg. Impact** | High — shaped HCSA | Medium — soft guidance | Low — firm-specific |

# Key Takeaways

- **No single right model.** All three sandboxes achieved their goals despite very different designs. Sandbox architecture should be driven by objectives, not convention.
- **Scope is a strategic choice.** Narrow scope yields deeper, more binding regulation. Broad scope produces wider but softer guidance. Design it deliberately.
- **Healthcare is uniquely strict.** No sandbox offered regulatory leeway. Full compliance was maintained throughout. Patient safety is non-negotiable, even in experimental settings.
- **Co-creation works.** Direct, structured engagement between regulators and firms builds trust, improves regulation, and reduces arbitrage. Bottom-up beats top-down**.**
- **Capacity is the bottleneck.** Sustainable sandboxing requires political will, analytical expertise, and operational infrastructure. This is especially pressing in LMICs and for cross-border sandboxes**.**