



Breakthrough Regulatory Innovation and Development throuGh sandbox Environments

Manifesto for Effective Regulatory Sandboxes Enabling an Adaptive Regulatory Ecosystem in European Health Innovation

Why we need change

Healthcare innovation in Europe is advancing faster than regulatory frameworks designed to regulate them. To ensure that innovation remains safe, effective and aligned with societal values, Europe needs mechanisms that bridge emerging regulatory gaps **without overburdening the innovators and the regulators** while **complementing** the established regulatory system.

Embracing Regulatory Sandboxes in Health

We believe regulatory sandboxes will play a central role as they can provide **temporary, structured and transparent environments** where regulators, innovators, evaluators, clinicians and patients can work together to explore how emerging innovation that the current regulatory system does not fully accommodate should be assessed, validated and governed. Regulatory sandboxes will strengthen and complement the regulatory toolbox at disposal of EU authorities in supporting and informing their respective role in assessing healthcare innovation sector and defining corresponding regulatory and legislative frameworks.

Regulatory sandboxes should offer early clarity and collaboration, by enabling agile, anticipatory responses to innovation where current regulatory frameworks cannot adequately accommodate. They should **accelerate development timelines and learning cycles**, advancing regulatory science, **enable responsible testing of emerging** services, methodologies, technologies, products, and approaches. They should also **encourage high-quality, trustworthy innovation** that can reach patients and health systems timely and safely.

This manifesto sets out shared principles for a reliable, collaborative and adaptive European regulatory ecosystem that supports innovation via design, development and implementation of regulatory sandboxes in practice.

Our Goals

BRIDGE enhances **EU preparedness** to establish effective regulatory sandboxes by developing practical recommendations on their design, eligibility criteria, setup, operation, evaluation of outcomes, and translation into regulatory practice.

These recommendations will ensure that sandboxes will serve as reliable problem-focused instruments to navigate regulatory uncertainties and bridge the gap for emerging health innovations where existing frameworks are insufficient. This action will support the development of an attractive and adaptive health-innovation ecosystem in Europe, grounded in transparency, fairness, accountability and strong ethical foundations.



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Our Commitment

- **Multi-Stakeholder Perspective & Engagement:** As a public-private partnership, the BRIDGE community brings a multi-stakeholder perspective on approaching its mission with representation of regulators, innovators, evaluators, health technology assessors, payers together with legal and methodological experts, in a purpose-driven and proportionate manner, enabling shared understanding, exploration and development of recommendations. We also utilise a participatory approach, and ensure diverse perspectives are sought from those stakeholders, including citizens, clinicians, patients and healthcare providers, informing the project's output.
- **Ethical Oversight and Fairness:** The project embeds "ethics by design" into innovation and regulatory processes and ensures the framework is aligned with public needs
- **Data & IP:** Adherence to EU data regulations and privacy standards; use of open standards for interoperability; clear IP and confidentiality terms; sharing non-sensitive methods and benchmarks.
- **Governance:** Transparent roles and decision-making, safeguards against conflicts of interest.