



Breakthrough Regulatory Innovation and Development through sandbox Environments

BRIDGE Perspective on Regulatory Sandboxes in the New Pharmaceutical Legislation

From legislative provisions to a practical sandbox implementation blueprint

EMA / EC Workshop | 21 September 2026





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.



Co-funded by
the European Union

Healthcare Innovation is a complex endeavour that cannot be tackled in isolation
Engagement across sectors and multi-disciplinary collaboration are essential

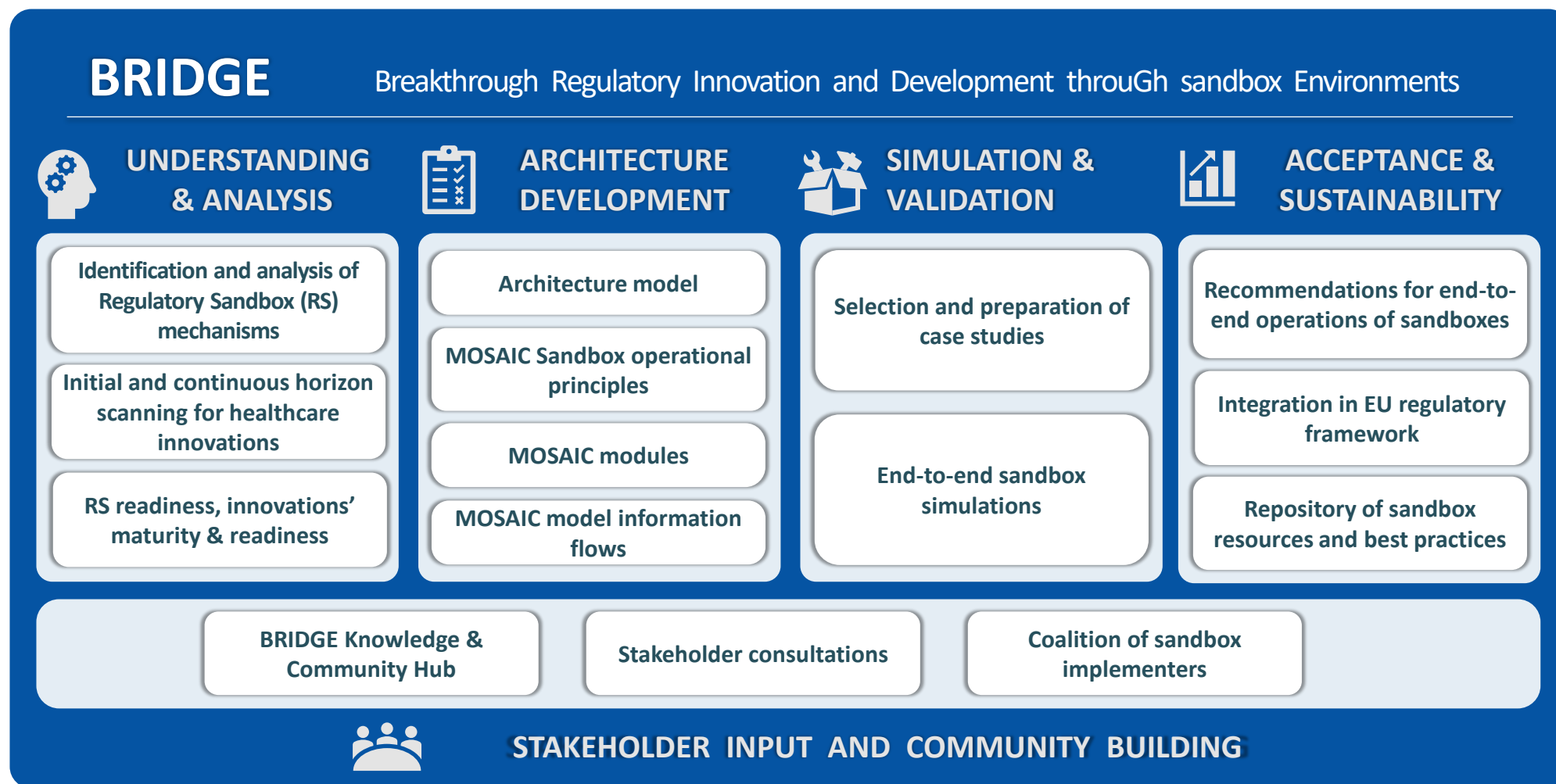


→ Building trust is essential to ensure the adoption of the resulting mechanisms and future outputs

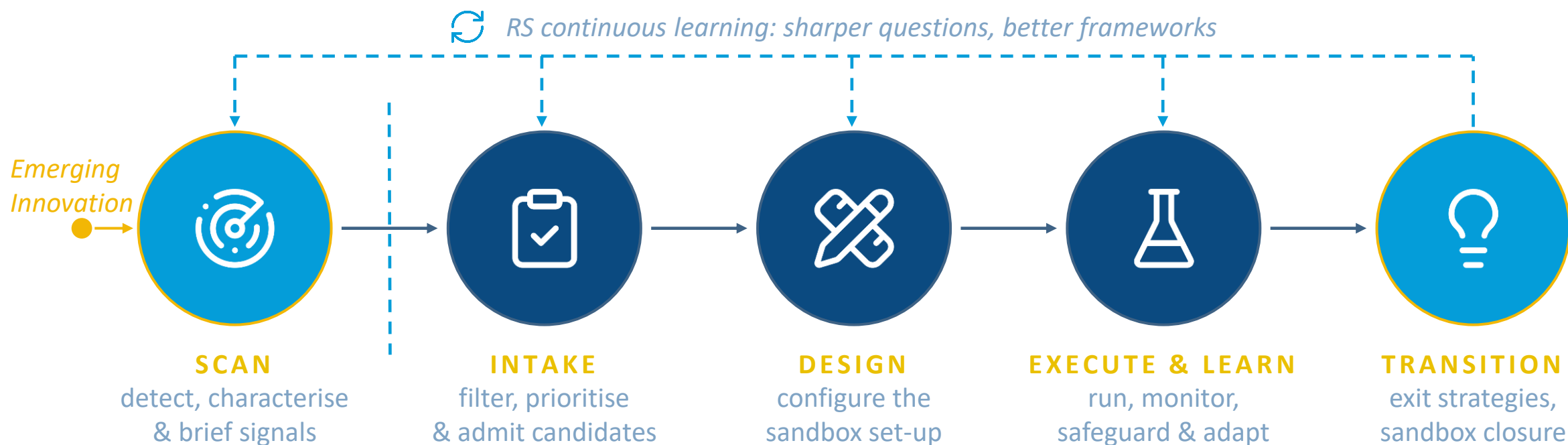
Duration: November 2025 – October 2028 (36 months)

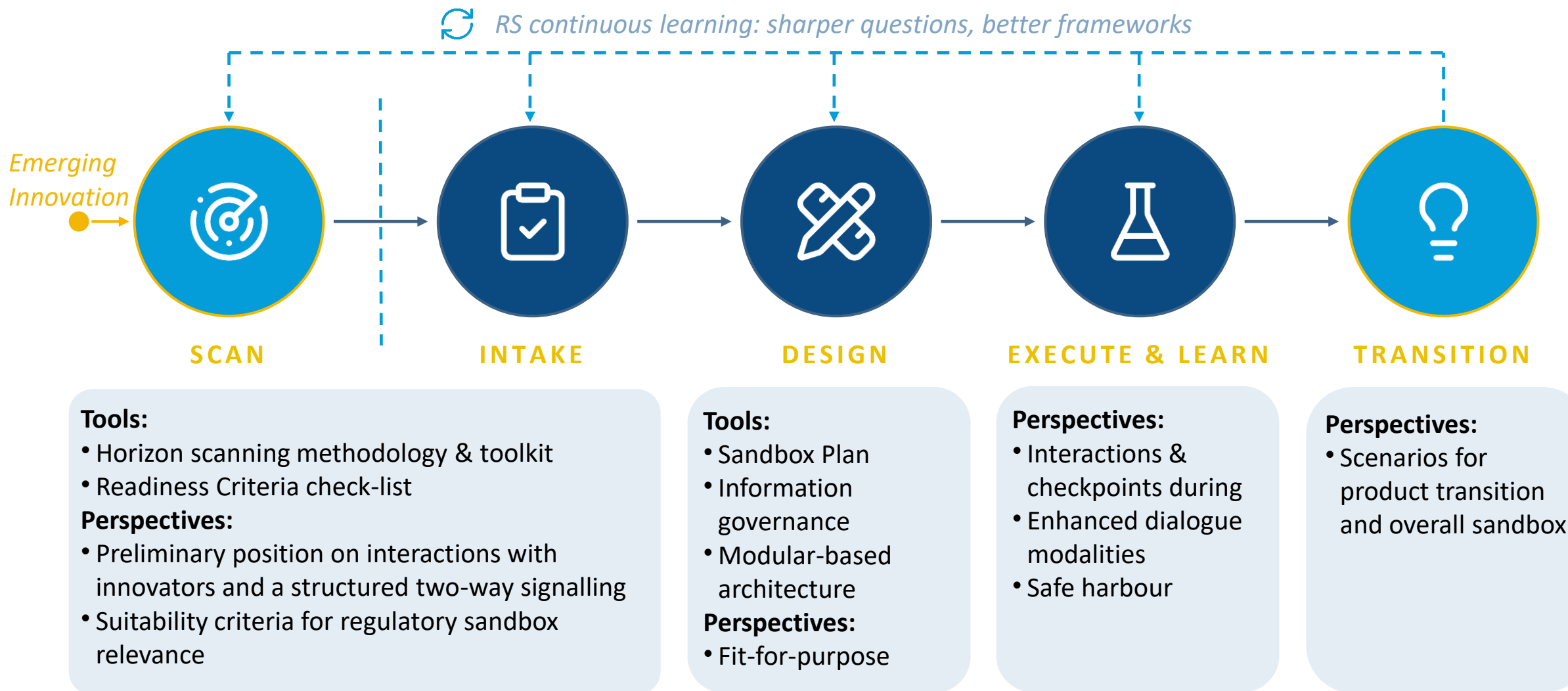
Scientific coordinator: VITO (Belgium); Industry coordinators: MSD and ROCHE

How BRIDGE structures and develops its work



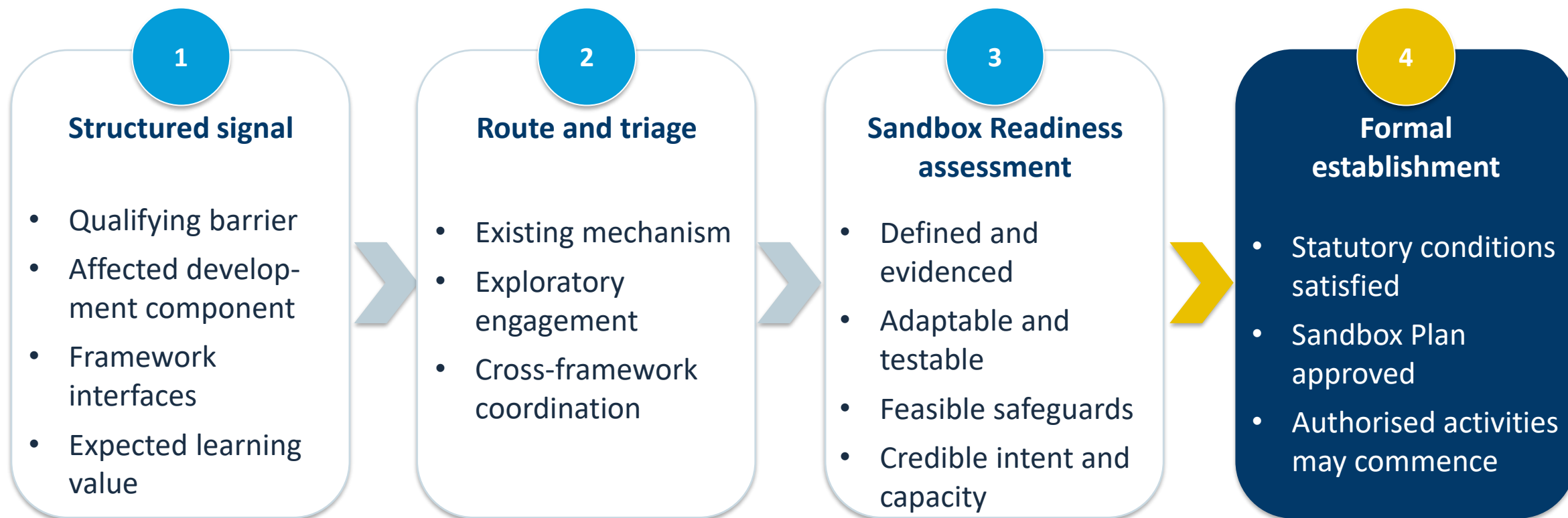
What implementation tools BRIDGE is developing





End-to-end detailed guidelines on operations | European Repository of Sandbox Best Practices | Training

Practical output 1: What could support regulatory sandbox establishment?



From Application to Execution: The Three Core Documents Structuring a Regulatory Sandbox

- 1 Baseline evidence package** Barrier, affected component, evidence, proposed experimentation, safeguards, intent and capacity.
- 2 Authority-approved Sandbox Plan** Authorised scope, duration, regulatory objective, permitted activities or adaptations, assurance benchmark, responsibilities, safeguards, information use, change control and transition.
- 3 Activities and Evidence Plan** Studies, protocols, evidence activities, responsibilities, timelines, checkpoints, decision points and outputs.



Information model

- Participant-confidential.
- Cohort-restricted methodological.
- Aggregated regulatory learning.
- Public non-confidential outputs.

What it preserves

- Applicable law and authority powers.
- Quality, safety and reporting obligations.
- Independent later assessment.
- Data-protection and competition safeguards.

What it enables

- Prospectively agreed experimentation.
- Defined information uses and access.
- Non-prejudgment of compliant but unsuccessful results.
- Enhanced dialogue, clear escalation and closure.



SCAN



INTAKE



DESIGN



EXECUTE & LEARN



TRANSITION

Execute

- Enhanced dialogue and continuous coordination
- Evidence checkpoints
- Decision and escalation records
- Proportionate supervision and reassessment

Transition

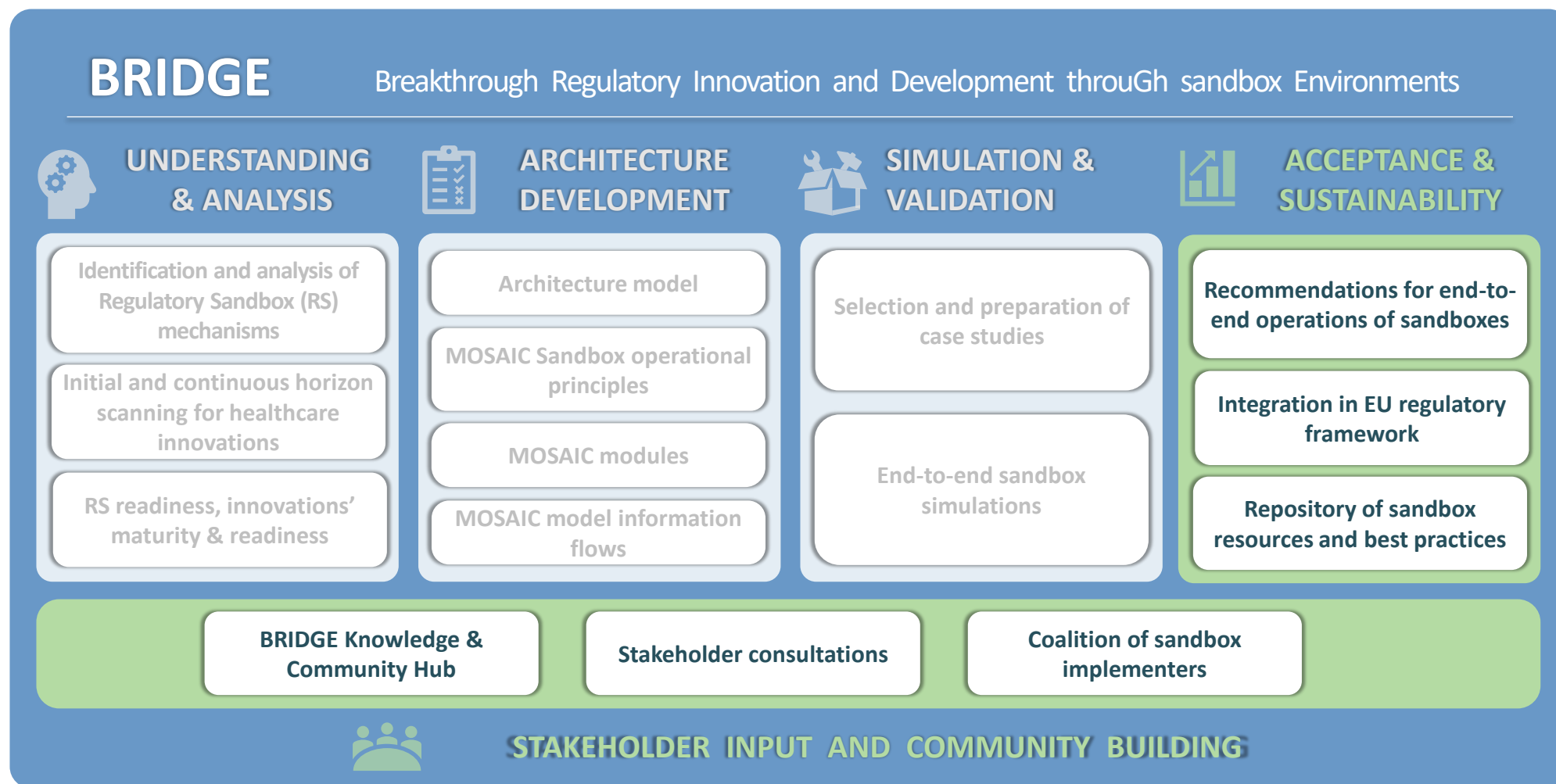
- Product affected-component progression
- Overall sandbox continuation or closure

Learning

- Evidence and assurance conclusions
- Residual uncertainty or regulatory divergence
- Evidence reuse
- Aggregated system learning



How BRIDGE integrates and challenges its outputs



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bridge-ihl.eu



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Thank you for your attention!

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