

# Building Risk-Sharing Agreements in Chile: Feasibility and Policy Options

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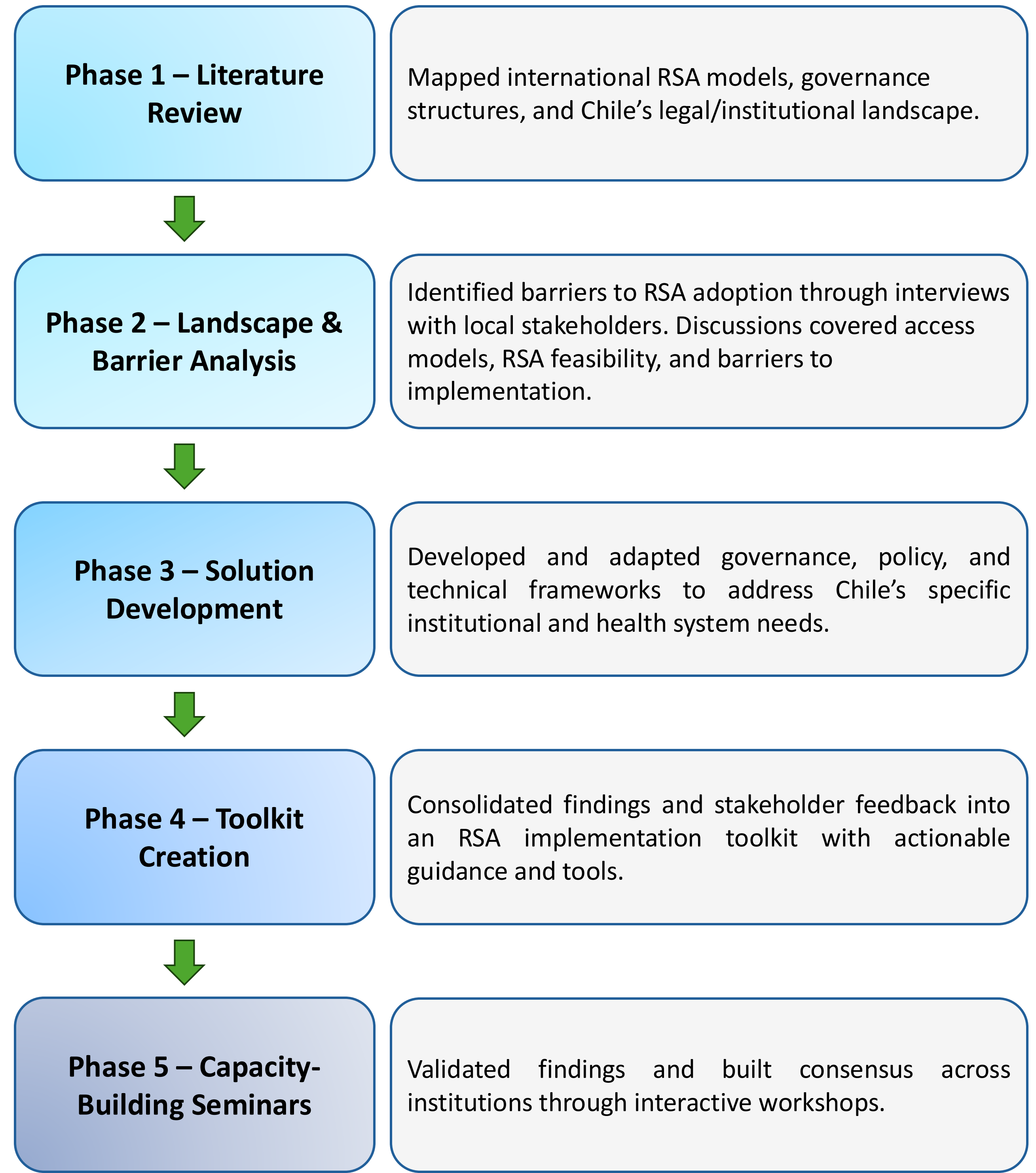
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## BACKGROUND

- Risk-Sharing Agreements (RSAs) are used globally to improve access to high-cost innovative therapies while maintaining financial sustainability. By linking payment to real-world outcomes, they help manage both clinical uncertainty and budgetary risk.
- In Chile, RSAs, were formally recognized under Exempt Resolution N° 410/2025, which establishes four implementation pillars: regulatory, institutional, procedural, and technical. However, Chile remains in an early stage, with few precedents, unclear legal mandates, and fragmented governance.
- To date, only two isolated cases have been documented:
  - ✓ Trastuzumab, a volume-based discount arrangement.
  - ✓ Zolgensma, a performance-based instalment contract tied to patient survival.
- This study explores the main barriers and enablers for RSA implementation within Chile’s legislative and HTA context and identifies practical steps to move the process forward.

## METHODOLOGY

The study used a five-step mixed-methods approach that combined literature review, stakeholder input, and practical tool design to support RSA implementation.




- Ethical Approval**
- Approved by **LSE Research Ethics Committee (Ref. 493367)**
  - All participants gave informed consent; data anonymized and securely stored


## RESULTS

### Barriers to RSA Implementation


Analysis of literature and stakeholder interviews revealed five main categories of barriers:




**Legal & Structural:** Absence of a standardized legal framework; unclear institutional authority; procurement laws requiring fixed prices and annual budgets hinder multi-year or conditional contracts.




**Institutional & Bureaucratic:** Staff turnover, fragmented responsibilities, and slow multi-layered decision-making delay negotiations and weaken continuity.



**Transparency & Trust:** Public procurement laws prevent confidential pricing; lack of protection for commercial information discourages manufacturer participation.



**Data & Evidence Gaps:** No centralized patient registries, and weak capacity to track long-term outcomes limit feasibility of outcome-based RSAs.



**Financial & Budgetary Constraints:** Annual budgeting prevents multi-year commitments; no standardized approach to guide agreements.

### Strategic Pillars for RSA Governance and Implementation

The analysis identified four key domains essential for the successful implementation of RSAs in Chile, each with targeted priorities and expected system-wide impacts.

Domain	Key Priorities	Expected Impact
Governance & Policy	<ul style="list-style-type: none"><li>• Define national RSA strategy and scope</li><li>• Establish National Commission + Technical Secretariat</li><li>• Ensure continuous policy review</li></ul>	<ul style="list-style-type: none"><li>✓ Clear leadership and long-term coordination</li></ul>
Legal & Procedural Framework	<ul style="list-style-type: none"><li>• Strengthen legal basis and enforcement tools</li><li>• Develop standardized templates and KPIs</li><li>• Manage transparency and confidentiality</li></ul>	<ul style="list-style-type: none"><li>✓ Legally sound, transparent, and replicable RSAs</li></ul>
Technical Capacity & Data Systems	<ul style="list-style-type: none"><li>• Build institutional expertise in HTA, law, economics</li><li>• Create centralized monitoring platform</li><li>• Pilot MCDA tools for prioritization</li></ul>	<ul style="list-style-type: none"><li>✓ Strengthened analytical and operational capacity</li></ul>
Implementation & Learning	<ul style="list-style-type: none"><li>• Conduct early manufacturer dialogue</li><li>• Launch pilot RSAs (financial → outcome-based)</li><li>• Integrate real-world data and continuous evaluation</li></ul>	<ul style="list-style-type: none"><li>✓ Practical experience and data-driven scale-up</li></ul>

## CONCLUSIONS

- RSAs offer a viable pathway to improve access to high-cost medicines in Chile while maintaining fiscal responsibility.
- Successful implementation requires legal clarity, coordinated governance, data infrastructure, and technical capacity across institutions.
- A phased approach, starting with pilot agreements, can generate local evidence, build trust, and support the transition toward outcome-based reimbursement models.

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