

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

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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.

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.

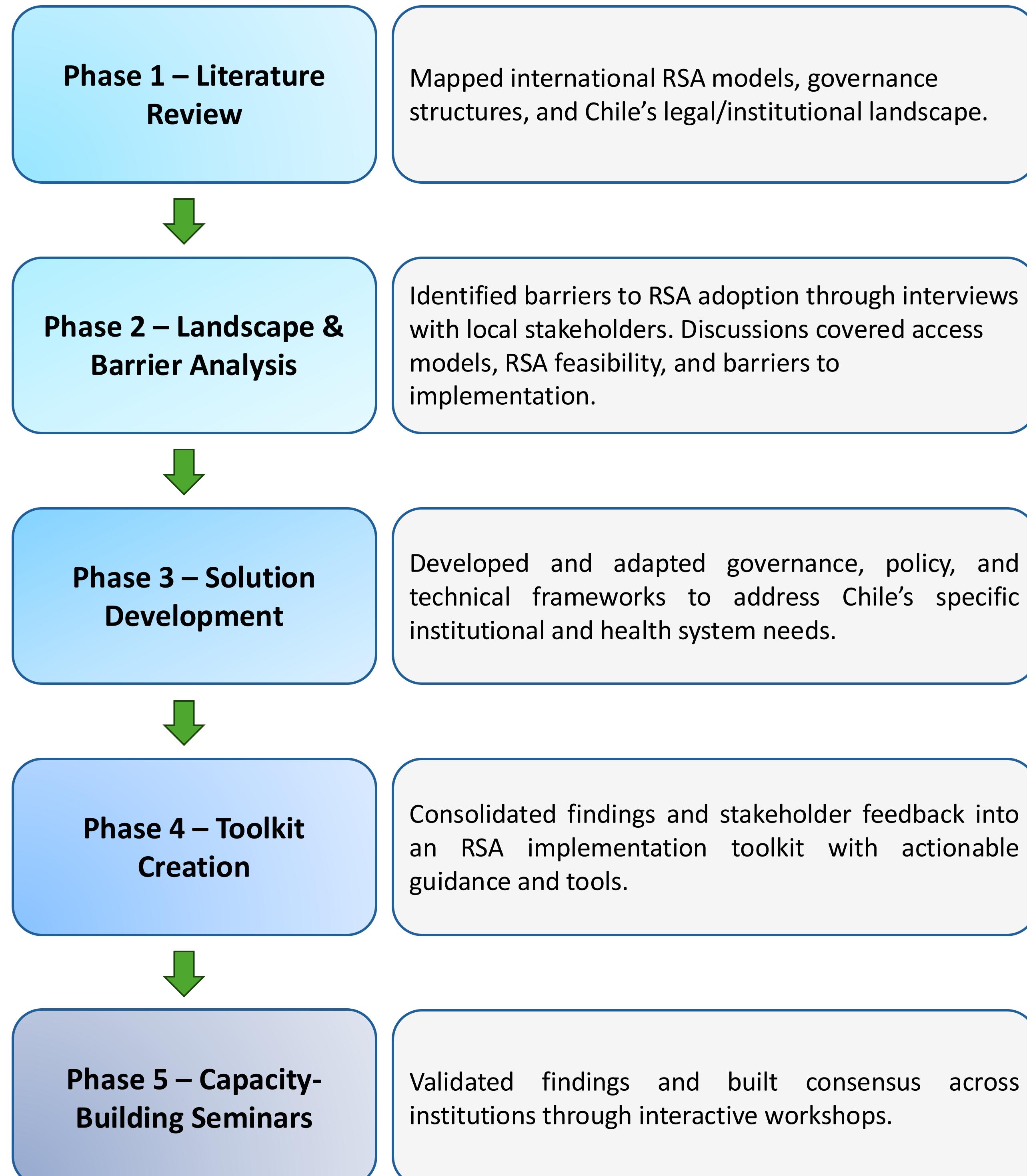
Transparency & Trust: Public procurement laws prevent confidential pricing; lack of protection for commercial information discourages manufacturer participation.

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.

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

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

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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