

Global Trends in Risk Sharing Agreements

ISPOR 7th Asia Pacific Conference, Singapore

Kevin Haninger, PhD
Deputy Vice President
PhRMA

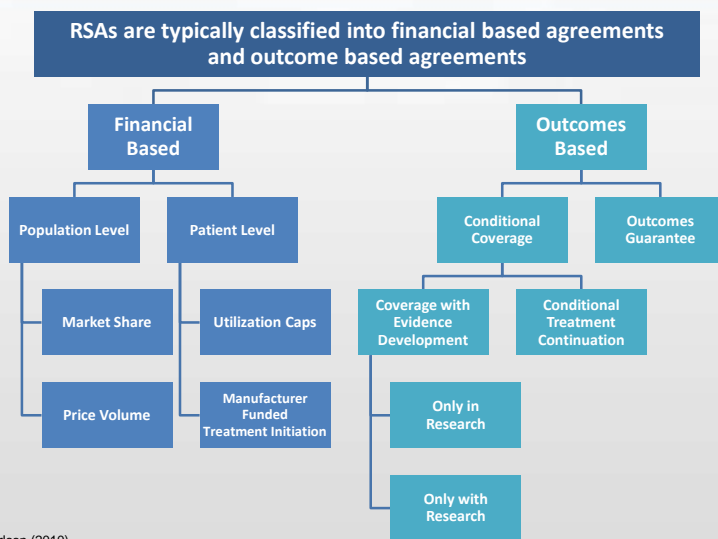
Overview

- Definition and Types of Risk Sharing Agreements (RSAs)
- Trends in Use of RSAs
- Why Do Countries Use Different Forms of RSAs?
- Value of RSAs when Appropriately Used

- What are Risk Sharing Agreements?

“...an arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize effective their use, or limit their budget impact.”

Types of RSAs



Source: Carlson (2010)

Trends in Use of RSAs

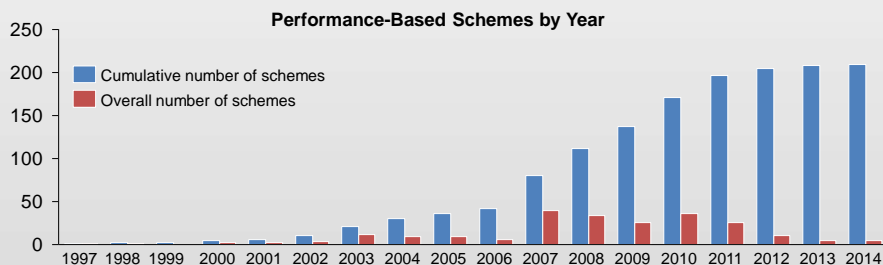


- RSAs are not new
 - Financial arrangements to manage budget uncertainty for the payer have existed for decades (PVAs, rebates based on sales)
 - Outcome guarantees have been used for some time
 - Many countries have already embedded RSAs in their P&R systems
- In recent years, we observe a number of trends:
 - The **number of countries** using RSAs has increased significantly
 - The **composition** of RSAs differ across countries and are generally tailored to the challenges of the local P&R system
- Different countries have used different types of RSAs to solve different types of problems
 - Majority of RSAs used for **budgetary reasons**

Use of RSAs is Increasing



- Cumulative rise of RSAs as countries focus intensely on managing budgets due to economic pressures and the increasing use of HTA
- New outcome based RSAs are decreasing, reflecting the high implementation costs and administrative burdens associated

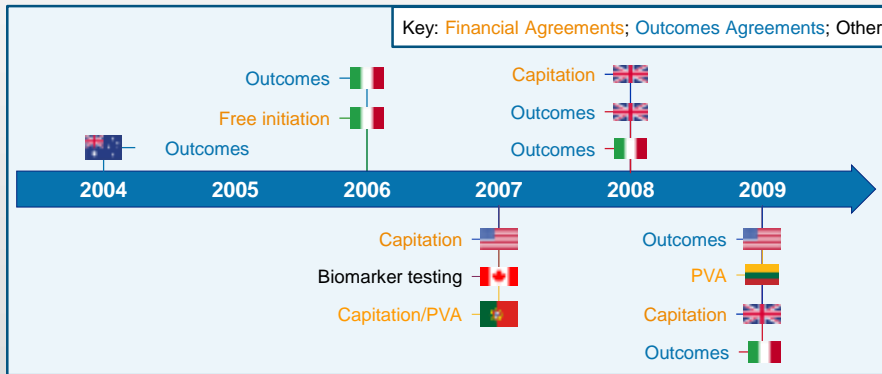


Source: Garrison (2014)

RSAs Traditionally Association with a Small Selection of Countries



- Both financial and outcomes based agreements have been present for some time, though these were initially limited to specific countries (or isolated cases in others)

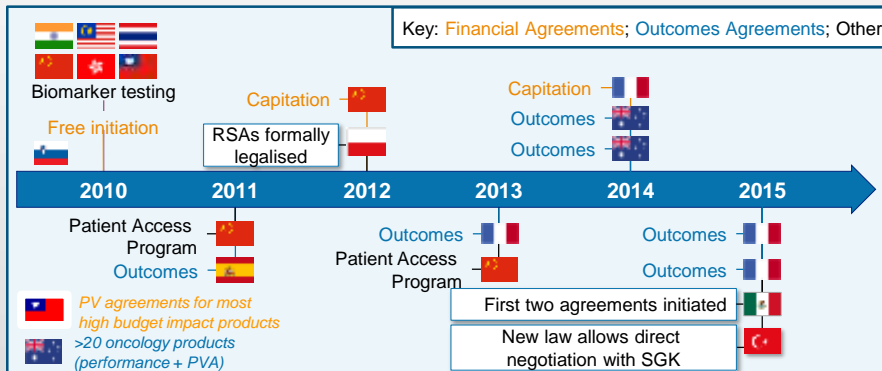


Source: CRA Analysis (2015)

Number of Countries Using RSAs Has Increased



- Increase of countries both within and outside of Europe opening to RSAs in both isolated events (e.g. Mexico), and through changes in legislation (e.g. Poland, Turkey)



Source: CRA Analysis (2015)

Problems and Solutions



Problem	RSA Solution
Budget Uncertainty: Management of budget impact	Financial Based Agreements: <ul style="list-style-type: none"> Price volume agreements Budget caps Dosage caps Discounts Price-match with comparator Free initiation
Value Uncertainty: Management of value for money (utilization to optimize performance)	Outcomes Based Agreements: <ul style="list-style-type: none"> Performance linked agreements Conditional reimbursement for limited time with parallel collection of additional evidence on drug effectiveness Reimbursement decisions updated following assessment of new evidence
Clinical Uncertainty: Management of uncertain clinical effectiveness	

Different RSAs Can Be Used to Solve Separate Issues



- Financial and outcome based contracts can address value and clinical uncertainty, whereas financial agreements can address budget uncertainty

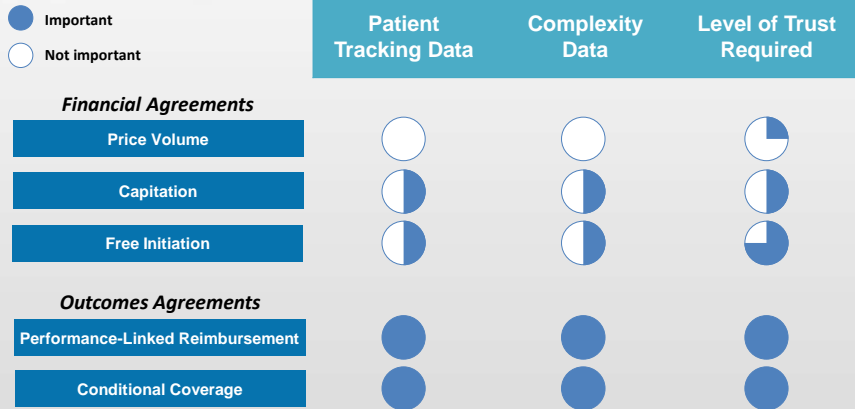
	Budget Certainty	Value Certainty	Clinical Certainty
Financial Agreements			
Price Volume	●	◐	◑
Capitation	●	◐	◑
Free Initiation	●	◐	◑
Outcomes Agreements			
Performance-Linked Reimbursement	◑	●	●
Conditional Coverage	◑	●	●

Source: CRA Analysis (2015)

Different RSAs Have Different Infrastructure Requirements



- Some RSAs require a significantly more sophisticated set-up in order to be effectively implemented and managed



Source: CRA Analysis (2015)

RSAs Are Not a Panacea



	Advantages	Disadvantages
Patients	<ul style="list-style-type: none"> Greater access to promising treatments which promotes choice in treatment or provides treatment where there is none Further innovation promoted Potential for future influential involvement in design Possible greater influence as reimbursement no longer binary 	<ul style="list-style-type: none"> Barriers to and administrative burden associated with participation Possible withdrawal at the end Data protection issues More robust research not done Limited engagement opportunities
Payers and Providers	<ul style="list-style-type: none"> Encourages products to show value before providing resources Avoid dilemma: pay for risky & expensive drug vs deny patients Build evidence base Limit total budget impact More cost effectiveness: VBP 	<ul style="list-style-type: none"> Costs & bureaucracy associated with negotiation, design and implementation Uncertain accuracy of reporting system for health outcomes based MEAs Difficult to withdraw technologies if ultimately fail May have limited ability to assess and implement evidence Uncertainty in expenditure if MEA based on health outcomes
Manufacturers	<ul style="list-style-type: none"> Access for new therapies Best product performance through targeted use Discounting without list price / international referencing Better public image 	<ul style="list-style-type: none"> Costs & bureaucracy associated with implementation Lost price / volumes if targets are not reached and revenues lower than non-MEA approval Challenge to business model if use increases

Conclusions



- RSAs serve a number of different purposes

Reduce Delay in Access

Improve Diffusion

Offer Discounts

Change Incentives

Provide Financial Insurance

Guarantee of Performance

- Each of these has value in a negotiation between a buyer and a seller under the “right” conditions
- However, universal application, especially of performance based schemes would bring significant costs in terms of:
 - Impact on market access from negotiation time
 - Cost of monitoring and compliance
 - Impact from contagion
- RSAs should reflect the challenges facing a particular country and particular medicines and be used with considerable care

Conclusions



There is considerable international experience regarding the use of RSAs to draw upon

- RSAs are not mandatory in any market. Use of RSAs should be selective and based on negotiation between the manufacturer and the payers.
- Simple agreements are generally preferred
 - Interest from payers tends to focus on financial agreements with mixed interest in outcomes-based deals
 - Outcomes-based agreements are more difficult to execute but can add value
- RSAs can improve access but when RSAs are used as a cost containment process on top of other cost containment processes, they can increase delays with little benefit
- It is important to use RSAs that address the challenges in the market but an appropriate process is also required
 - Predictability, defined timelines and confidentiality are key components
- Countries should assess the impact of RSAs periodically to ensure that they are working as intended (i.e. overcoming the key challenges faced)