

## Global Trends in Risk Sharing Agreements

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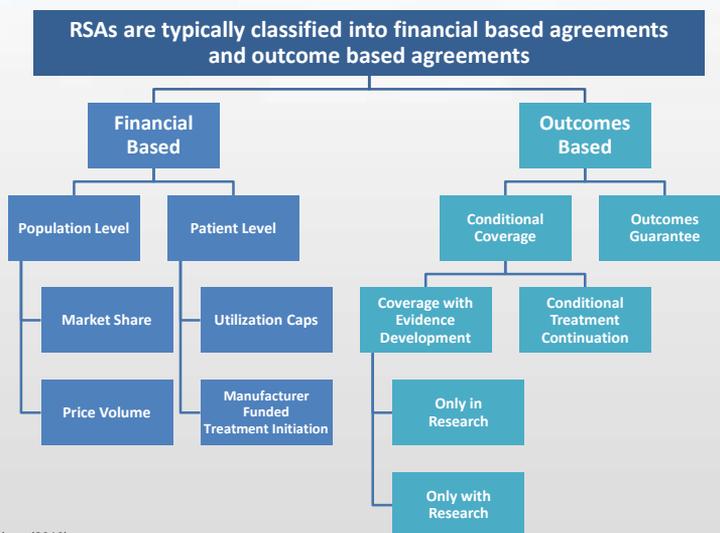
### Overview

- 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

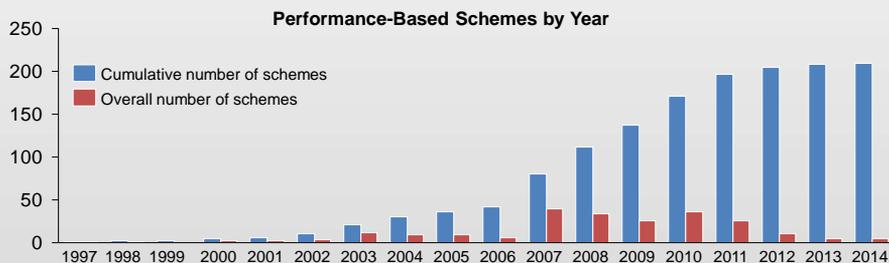


- RSAs are not new
  - Financial arrangements to manage budget uncertainty for the payer have existed for decades (PVAs, rebates based on sales)
  - Outcome guarantees have been used for some time
  - Many countries have already embedded RSAs in their P&R systems
- In recent years, we observe a number 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)



# Problems and Solutions



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

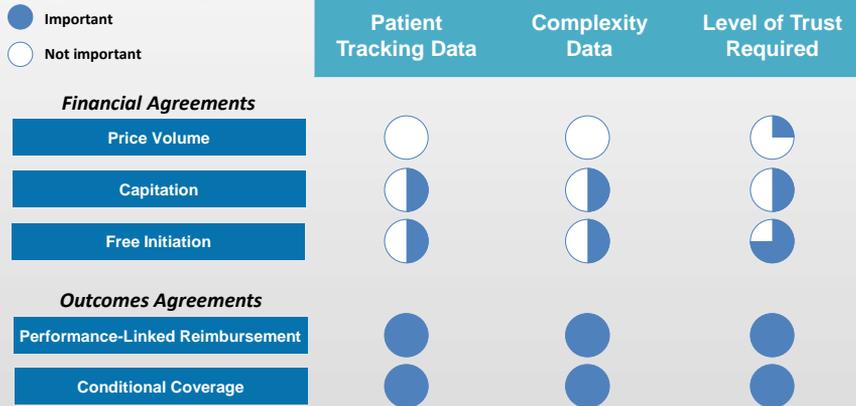
	Budget Certainty	Value Certainty	Clinical Certainty
<b>Financial Agreements</b>			
Price Volume	●	◐	◑
Capitation	●	◐	◑
Free Initiation	●	◐	◑
<b>Outcomes Agreements</b>			
Performance-Linked Reimbursement	◑	●	●
Conditional Coverage	◑	●	●

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

## 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)