



# Global trends in managed entry agreements

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Associates

Different Approaches to Pricing and  
Reimbursement of Innovative  
Drug in Oncology

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# Structure of the presentation

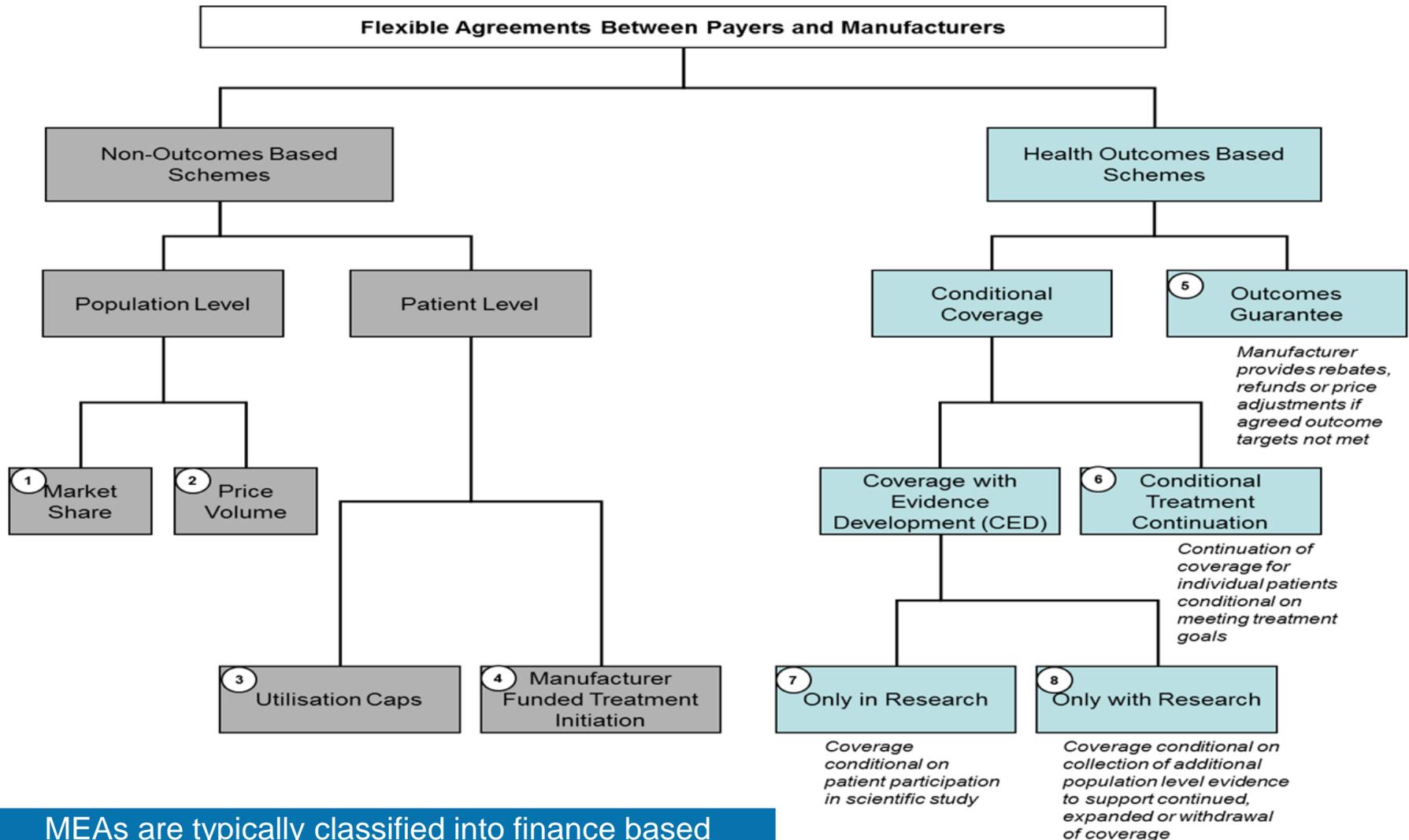
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- Introduction
- Global trends in the use of management entry agreements (MEAs)
- Lessons regarding the use of different forms of agreement and the role of outcomes based agreements
  - Using MEAs selectively
  - Issues associated with transparency
- The evolution of agreements and the role of data collection and registries
- The interaction between MEAs and financing mechanisms
- Conclusions

## Managed Entry Agreements (MEAs) have different definition(s)

- A widely accepted definition for MEAs used by the Health Technology Assessment International :
  - *“A Managed Entry Agreement is 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”*

# Managed Entry Agreement terminology



MEAs are typically classified into finance based agreement and outcome based agreements

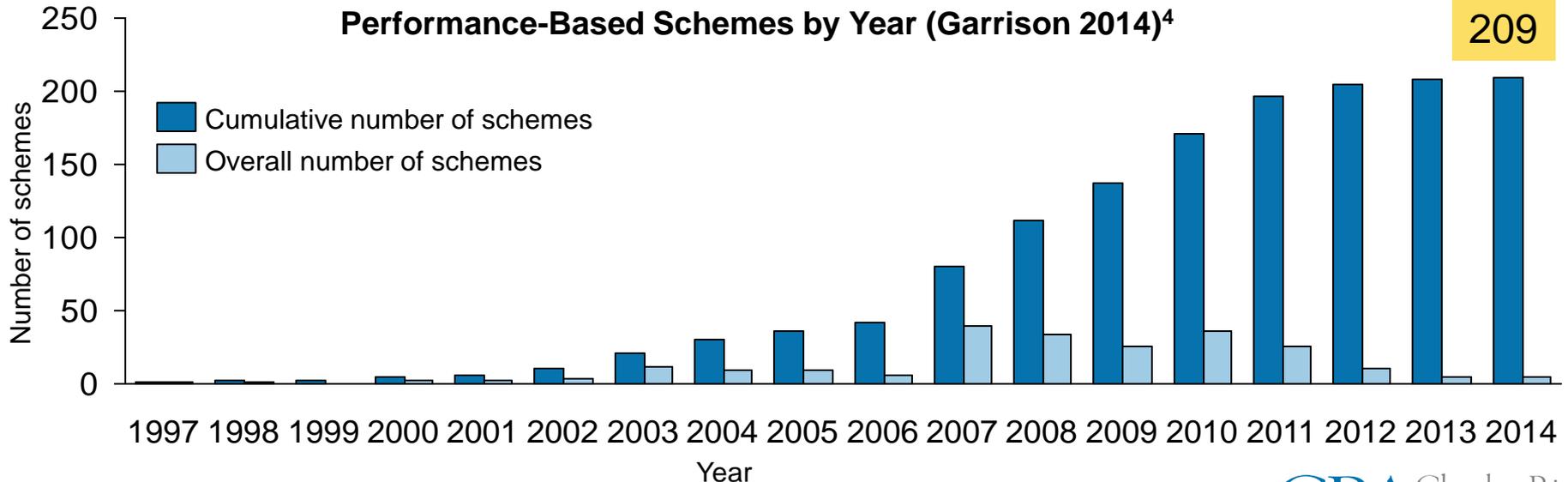
# Trends in the use of MEAs

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

# The use of MEAs is on a dramatic rise

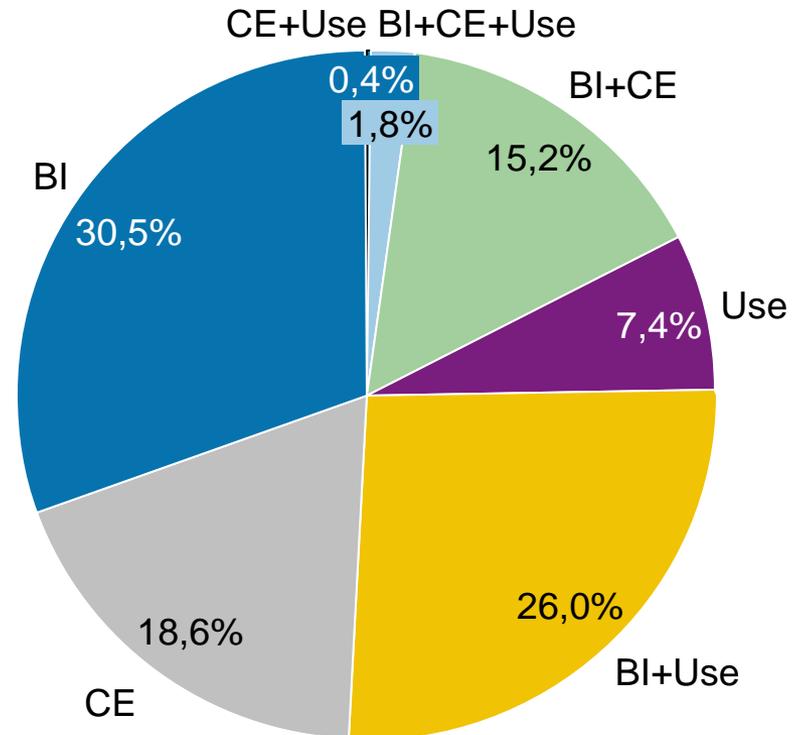
- The cumulative number of performance-based reimbursement schemes has grown substantially since 1997. This is associated to countries focusing intensely on managing budgets due to economic pressures and the increasing use of HTA<sup>1</sup>
- However, the number of new MEAs are decreasing, reflecting the high implementation costs and administrative burdens associated with MEAs<sup>2</sup>
- In general, market share covered by MEAs was small (less than 5%), although two countries reported shares >20%<sup>3</sup>



# Most MEAs are aimed at managing budget impact

- MEAs are attractive to countries (or regions) generally due to their link to uncertainty
- Managing budget Impact (BI) is the main reason for using MEAs in Europe
- Though not as widely used as BI, Cost-effectiveness (CE) and managing use (Use) are also key reason for MEAs

**Objectives Member States are trying to achieve through MEAs**



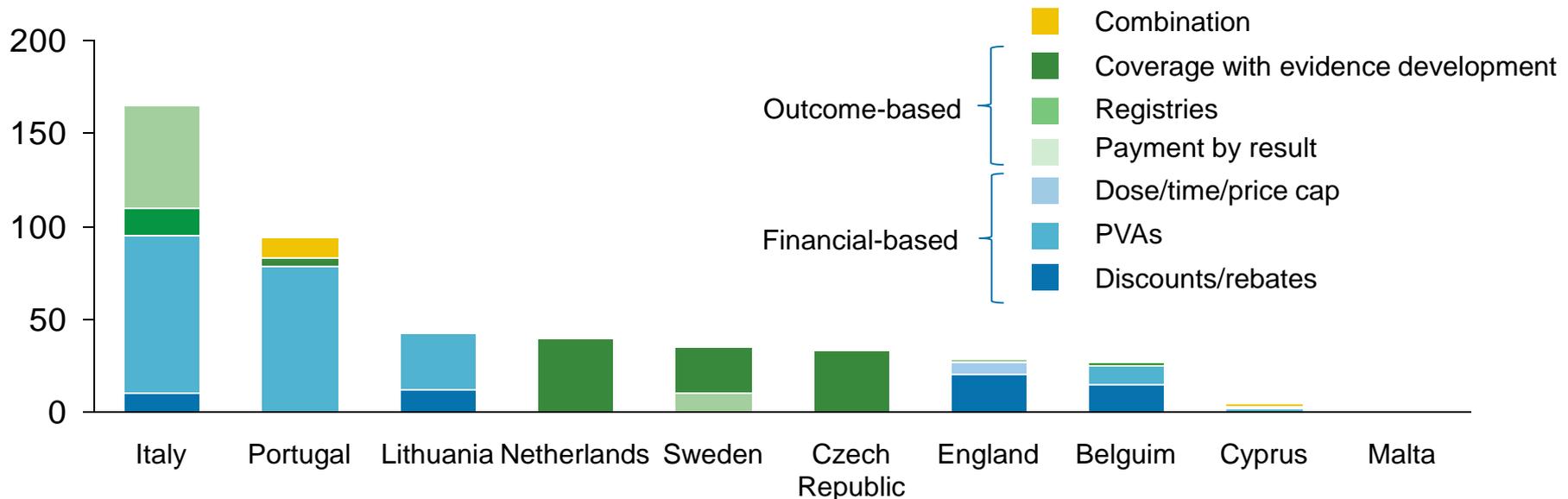
Source: EMINET 2013;

Note: BI: Limit budget impact, CE: Address uncertainties regarding the cost-effectiveness, Use: Monitor use in clinical practice, Access+CE: Improve patient access and cost-effectiveness

## The composition of MEAs differ across countries

- Significant differences between countries make like for like comparisons challenging
- The majority of agreements tend to be finance based rather than performance-based. In Europe, price-volume agreements (40%) and coverage with evidence development (30%) are most used

**Number and type of MEAs in Europe by country (EMINET, 2013)<sup>1</sup>**



Source: EMINet April 2013

Notes: Number of MEAs identified through systematic literature review conducted in 2011 and country survey conducted in 2011-2012; This has since evolved with more combinations MEAs

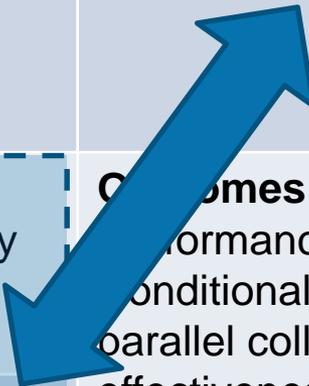
# The relationship between underlying cause and type of MEA

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Issue <sup>1</sup>	MEA solution
<b>Budget Uncertainty:</b> Management of budget impact	<b>Financial agreements:</b> PVAs, budget caps, dose caps, discounts, and price-match with comparator, free initiation
<b>Value Uncertainty:</b> Management of value for money (utilisation to optimize performance)	<b>Outcomes agreements:</b> Performance linked agreements, Conditional reimbursement for limited time with parallel collection of additional evidence on drug effectiveness, Reimbursement decisions updated post assessment of new evidence
<b>Clinical Uncertainty:</b> Management of uncertain or unacceptable clinical and or cost-effectiveness	

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# The process for agreeing MEAs varies significantly across countries

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- Although in principle MEAs offer a win-win solution to payers, patients and innovators, the way that they are implemented is as crucial as matching the MEA to the problem to be addressed



- Immediately launch and free pricing is possible in the UK, however, reimbursement depends critically on HTA appraisal by NICE (requiring MEA)
- In the most recent PPRS agreement, PAS are “explicitly intended to be the exception rather than the norm”



- Prices generally negotiated with AIFA based on relative value assessment, but it is common for MEAs to be used for some product categories
- There is no specific law that regulates the process of decision making on MEAs but monitoring registries established for diabetes, oncology, orphan drugs, psoriasis medicines, CV, RA



- 2012 reimbursement law makes provisions for MEAs (payment by results, discounts, price volume agreements, payback agreements and others).
- Since then, a number of financial and outcomes based scheme have been introduced (though predominantly financial).

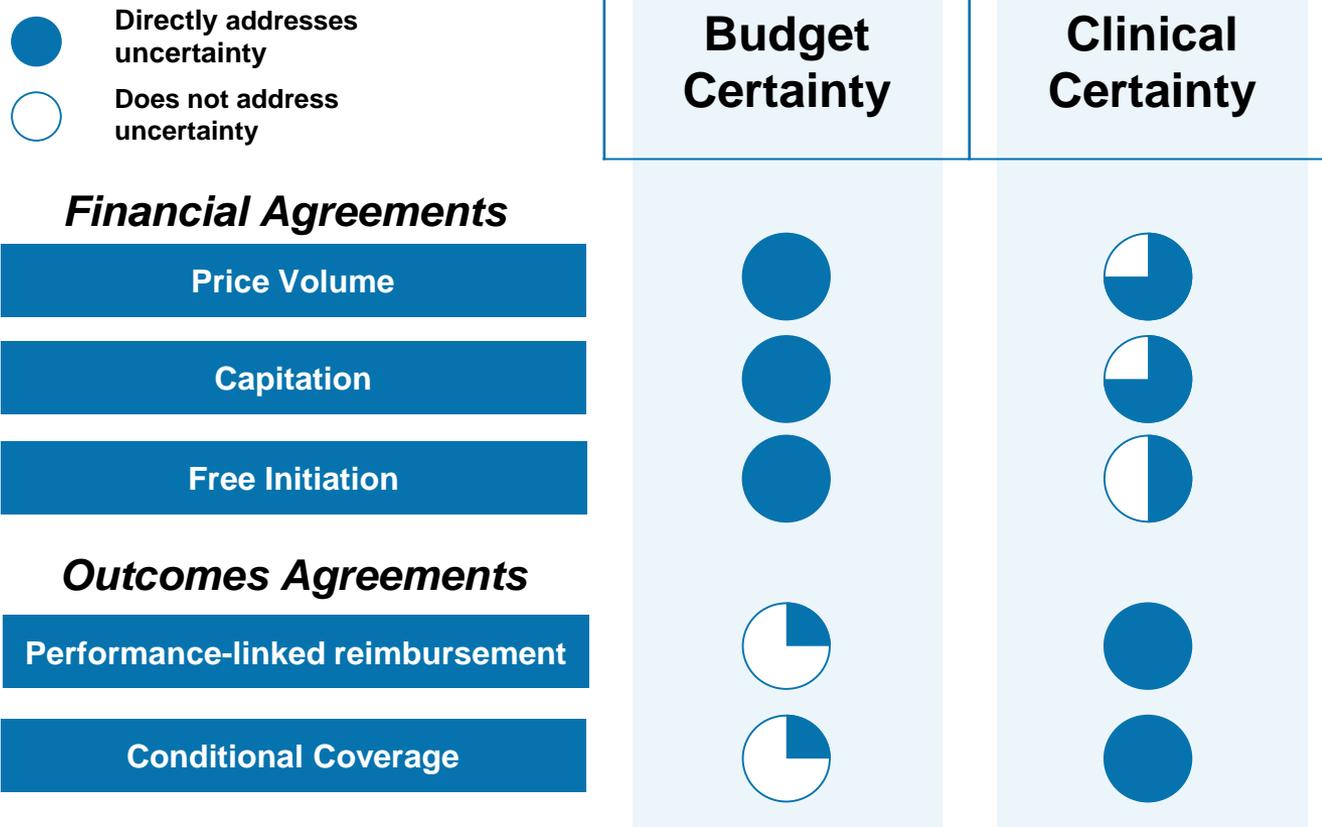
## Confidentiality is a common element across three markets

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Country	Transparency of MEA process
UK	<ul style="list-style-type: none"><li>• A summary of each scheme is published by NICE<ul style="list-style-type: none"><li>• Financially based schemes are usually confidential</li><li>• Outcomes based schemes can be more transparent</li></ul></li></ul>
Italy	<ul style="list-style-type: none"><li>• The official decision concerning the type of MEA is made publicly available by AIFA</li><li>• Some but not all details of MEAs can be found in published literature</li></ul>
Poland	<ul style="list-style-type: none"><li>• The very existence of a risk sharing scheme is considered a “trade secret”</li><li>• All aspects of the MEA are confidential</li></ul>

# Different MEAs can be used to solve separate issues

- In reality, both financial and outcome based contracts can address value and clinical uncertainty:



# Different MEAS have different infrastructure requirements

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

- Important
- Not important

	Patient tracking data	Complexity of data	Level trust required
<b>Financial Agreements</b>			
Price Volume	○	○	◐
Capitation	◐	◐	◐
Free Initiation	◐	◐	◑
<b>Outcomes Agreements</b>			
Performance-linked reimbursement	●	●	●
Conditional Coverage	●	●	●

# The relationship between MEAs and funding

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- Over the last few years, many countries have developed ring-fenced funds for innovative medicines.
- There vary in terms of focus
  - Innovative medicines
  - Orphan medicines
  - Therapy areas specific funds: Oncology, HCV medicines
- Increasingly eligibility for funding depends on HTA appraisal and MEA

## New feature of Cancer Drug Fund

All cancer drugs/indications appraised by NICE

Early funding option available, through new interim funding arrangements and clear entry and exit points for drugs in the CDF

Managed Access Agreements between NHS England and pharmaceutical companies, setting out the terms of a drug's entry into the CDF and the means by which data will be collected to resolve any uncertainty relating to a drug's clinical and cost-effectiveness over a 2 year period

Fund pays for medicines where evidence is not robust enough to allow a final decision to be made, the drug could be recommended for the CDF

# MEAs are not a panacea: there can be advantages and disadvantages depending on where and how they are used

	Advantages	Disadvantages
Patients	<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>
Payers / Providers	<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>
Manufacturers	<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 #1

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- MEAs serve a number of different purposes

Reduces delay in access

Improve diffusion

Offering discounts

Change incentives

Providing financial insurance

Guarantee of performance

- Each of these has value in a negotiation between a buyer and a seller under the 'right' conditions
  - Doesn't directly affect negotiating power between industry and payers
- 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
- MEAs should reflect the challenges facing a particular country and particular medicines and be used with considerable care

## Conclusions #2

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- There is considerable international experience regarding the use of MEAs to draw upon
  - MEAs are not mandatory in any market. The use of MEAs 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 in some cases
  - MEAs can, if used appropriately, improve access but when MEAs are used as a cost containment process on top of other cost containment processes, then it can increase delays with little benefit
  - It is important to use MEAs that address the challenges in the market but an appropriate process is also required
    - Predictability, defined timelines and confidentiality are key components in developing a successful MEA regime
  - Countries should assess the impact of MEAs periodically to ensure that they are working as intended (i.e. overcoming the key challenges faced)