Overview of Performance-based managed entry agreements (MEA) for novel innovative medicines in OECD countries. [1]

Key Observations

1. **MEAs are used to manage uncertainty**
    - New medicines often face uncertainties in real-world effectiveness, safety, or long-term outcomes. MEAs serve as tools to bridge the gap between clinical trial evidence and real-world performance.
    - They help payers limit financial risk while fostering earlier access to innovations.
2. **Varied implementation across countries**
    - Some countries adopt many performance-based MEAs; others lean more on simple financial agreements or discounts.
    - Institutional capacity, data infrastructure, and regulatory context are major enablers or barriers.
3. **Design challenges & trade-offs**
    - Complex outcome-based contracts require robust data collection (registries, monitoring systems) and pose high administrative costs.
    - Negotiating metrics, thresholds, duration, and risk sharing is difficult, especially balancing incentives between manufacturers and payers.
    - Transparency is limited: many contracts are confidential, making it hard to evaluate overall performance across countries.
4. **Potential improvements & recommendations**
    - Encourage more **standardization** and **transparency** (e.g. standard outcome definitions).
    - Strengthen **data infrastructure**, including registries and capacity for real-world evidence generation.
    - Adopt **hybrid models**: combining financial and performance elements, or adjusting over time as evidence accumulates.
    - Tailor MEA structure to **contextual constraints**: administrative capacity, regulatory environment, and health system priorities.
5. **Limitations & research gaps**

[1] The summary is derived from a number of documents including OECD Health Working Paper No. 115 (2020) , Greco et al Clinical Therapeutics, 47 (2025) e16-e26.

- Few publicly available evaluations exist about whether MEAs actually reduce costs or improve outcomes.
- Lack of cross-country comparisons due to confidentiality of contracts. ONE
- More work is needed on governance, incentives, renegotiation processes, and stakeholder alignment.

Types of Managed Entry Agreements (MEA)

Below is a conceptual taxonomy of MEA types (with reference to the literature). The diagram at top (from e.g. ResearchGate) illustrates a common breakdown of financial vs performance-based MEAs.

Broad Classification

1. **Financial-based MEAs**
    - Focus primarily on controlling the payer's financial exposure, rather than linking reimbursement to clinical outcomes.
    - Mechanisms include discounts, rebates, price/volume agreements, budget caps, utilization caps.
    - Can be structured at **population level** (across all patients) or **patient (individual) level**.
2. **Performance-based MEAs**
    - Reimbursement or payment depends on achieving predefined performance or outcome targets.
    - Examples: "pay-for-performance," "coverage with evidence development," outcome guarantees, etc.
    - May include conditional coverage (initial access contingent on further data) or performance-linked continuation.
3. **Mixed / Hybrid MEAs**
    - Some agreements combine financial and outcome-based elements.
    - For instance, guaranteed minimum reimbursement plus bonus payments if outcomes exceed thresholds.

Detailed Mechanisms & Examples

Below is a stylized breakdown (based on the taxonomy) — these categories may overlap in practice:

Level / Focus	Financial MEAs	Performance/Outcome-Based MEAs	Hybrid / Mixed
Population-level	• Discount / percentage payback (manufacturer returns some revenue) • Price-volume agreements (rebates when volume exceeds threshold) • Budget caps (overall spending limited)	• "Outcome guarantee" across the population • Shared savings if performance exceeds expectations	E.g. a population-based rebate combined with outcome bonus payments
Patient (individual) level	• Utilization caps (e.g. limit on number of treatments per patient) • Free / discounted doses for a subset of patients	• **Conditional treatment continuation**: reimburse only if patient meets clinical milestones • **Coverage with evidence development (CED)**: allow access if patient enters registry / observational study • **Outcome-based payment**: payment tied to individual patient outcomes	E.g. provide a discount or rebate but also require demonstration of a response for full reimbursement

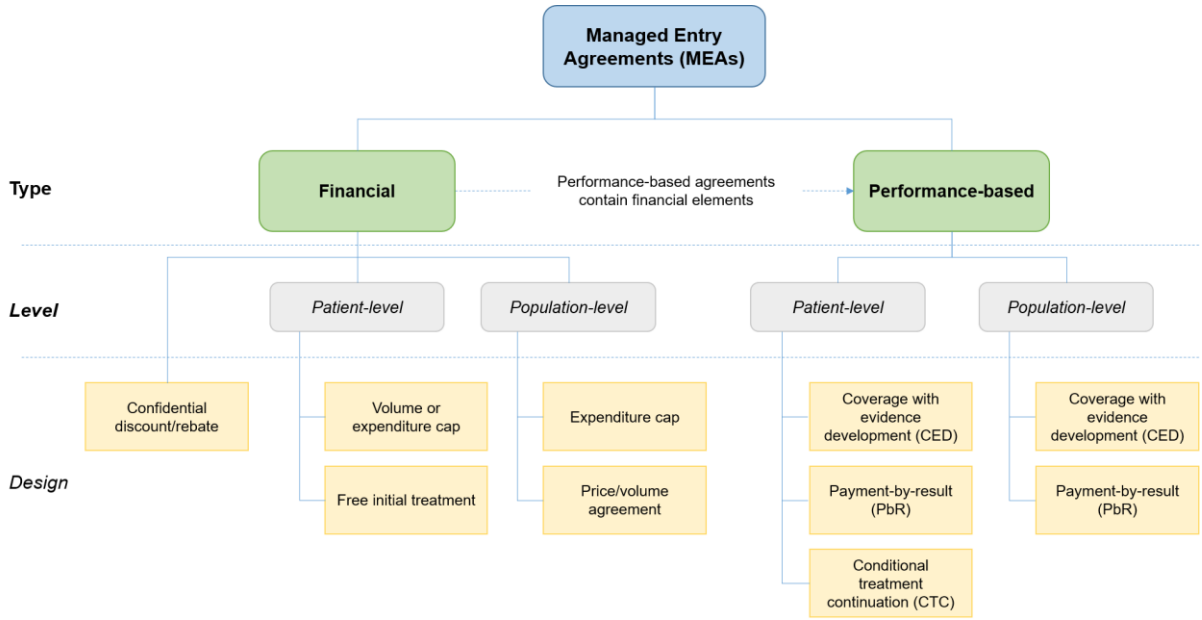
There are a number of illustrative mechanisms of how MEA work in practice, both financial based and outcome based. These are provided below:

Illustrative Mechanisms

- **Discount / rebate**: Manufacturer gives back part of the revenue if sales exceed a certain volume or if outcomes fall short.
- **Price-volume agreement**: The price per unit may decrease as volume increases.
- **Budget cap / expenditure cap**: Total spending is capped; beyond that, manufacturer may absorb costs or rebate.
- **Utilization / dose cap**: Limit number of doses reimbursed per patient.

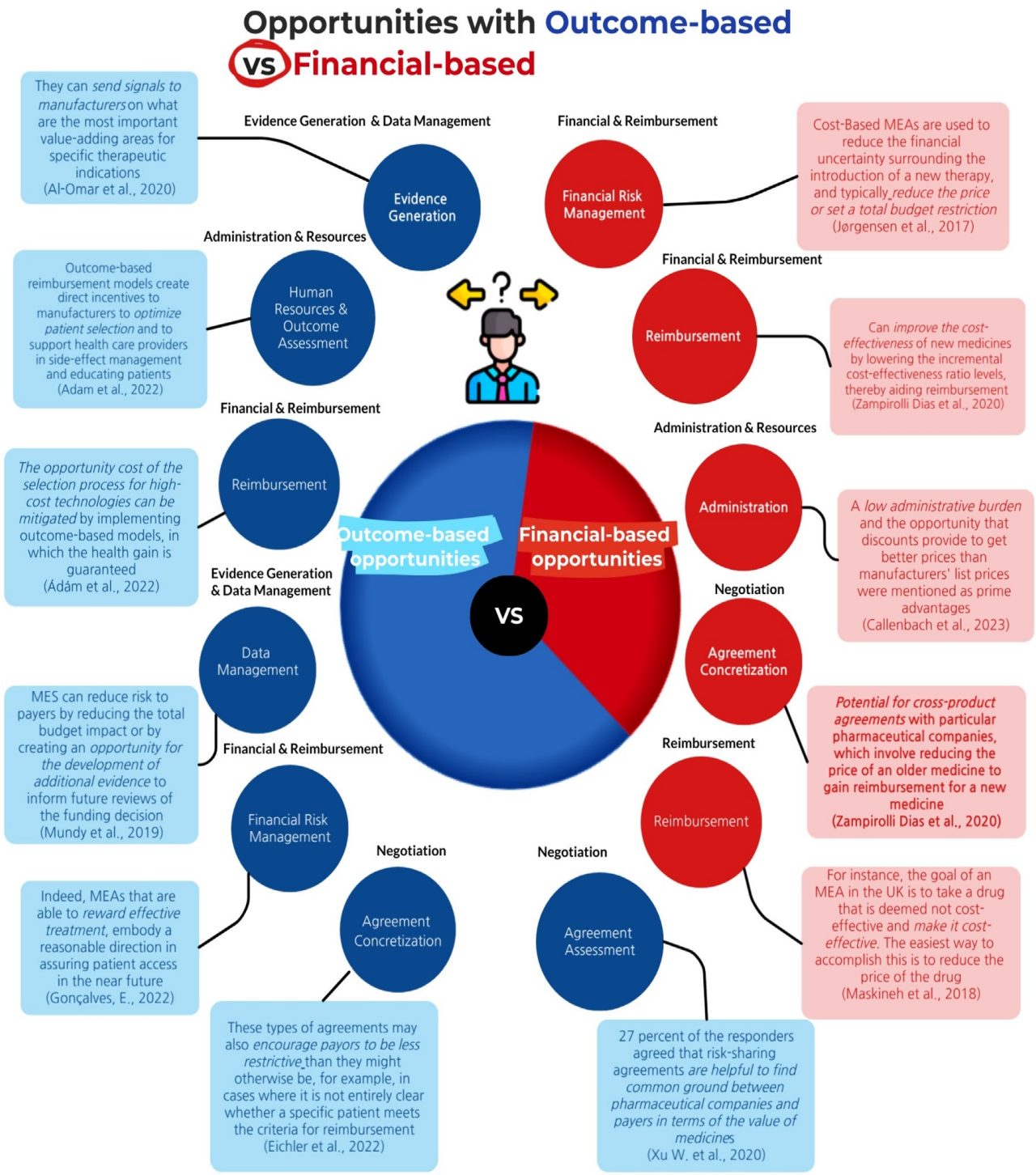
- **Conditional continuation**: Patient receives treatment initially; continued reimbursement is contingent on meeting clinical benchmarks.
- **Coverage with evidence development (CED)**: Access is allowed under the condition that data are collected (registry, observational study) to reduce uncertainty.
- **Outcome guarantee / pay-for-outcome/ payment by result**: If a predefined outcome is not met, manufacturer provides refunds, rebates, or reduces price.

(Note: the specific taxonomy and labels vary across literature; the version in the diagram below is one commonly used model.)



Illustrative Mechanisms

See comparative analysis of Opportunities relating to both Outcome-based and finance-based MEA on follow page 5.



Source: Greco et al Clinical Therapeutics, 47 (2025) e16-e26.