

# Revisiting Archetypes: New Archetypes for Strategic Global Value Evidence Planning

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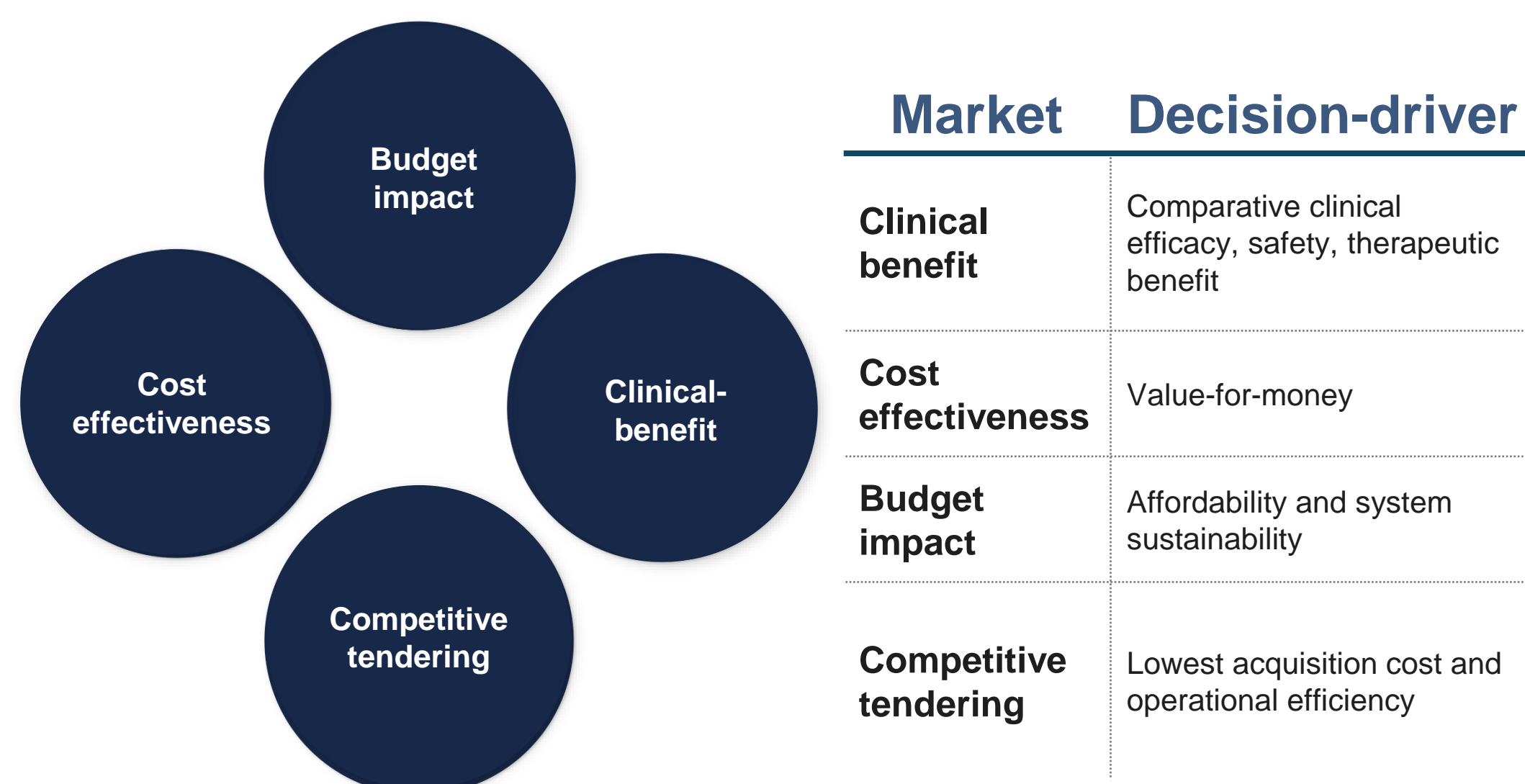
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## Background

- Global Health Economics and Outcomes Research (GHEOR) teams face challenges developing efficient evidence strategies due to heterogeneity in payer decision-making frameworks across markets.
- Traditional payer archetypes (Figure 1) describe overarching decision-making tendencies (eg, clinically driven, cost-effectiveness focused), but do not adequately characterize the full scope of evidence requirements across countries, particularly the evolving mix of clinical, economic, and real-world evidence needed at decision points.<sup>1</sup>
- Global teams may not be familiar with all markets, and so misalignment between global and local teams can lead to underestimating resource needs and missed opportunity in value demonstration.

Figure 1. Traditional Payer Archetypes



## Methods

To inform a more holistic evidence strategy, the authors aimed to classify value evidence needs by HTA bodies and key payer decision-makers into more actionable archetypes that enable GHEOR teams to allocate resources and communicate value effectively across diverse markets.

A multi-phase methodology was employed to account for heterogeneity in healthcare decision-making practices across markets:

- Market Selection:** Thirteen representative markets were selected based on geographic diversity and variation in healthcare decision-making structures.
- Policy Review:** A comprehensive review of local HTA and payer policy guidance documents was conducted to identify the value assessment methods and evidence elements considered in each market (Table 1).

Table 1. Describing Value Methods and Elements

Value method	Definition	List
	Tools or analytic approaches used to describe, quantify or demonstrate value of a medicine	Budget impact model (BIM) & Cost calculators; Clinical outcomes assessments (COAs) & Patient-reported outcomes (PROs); Clinical trial data; Cost-effectiveness analysis (CEA) / Cost-utilization analysis (CUA); Indirect treatment comparisons (ITC) / Network meta-analyses (NMAs); Mandated long-term data collection; Outcomes-based agreement (OBA) experience; Patient experience data (PED); Real-world evidence (disease) (RWE); Real-world evidence (treatment) (RWE); Systematic review
	Individual dimensions or aspects that contribute to the overall value of a medicine	Adherence/Persistence; Burden of illness (epidemiological focus); Burden of illness (patient focus); Caregiver / Family Spillovers; Direct costs; Environmental Impact; Equity; Implementation costs; Innovation; Patient Preferences / Satisfaction; Productivity/Absenteeism; QALY (Quality-Adjusted Life Year); QoL (Quality of Life); Resistance (Virology/infectious disease perspective); Subpopulations

## Methods (continued)

- Rating Evidence Importance:** Each value method and element was rated for its importance to decision-making (Table 2)—first based on formal policy documentation and then refined through consultation with AESARA market experts. To mitigate subjectivity, internal expert assessments were only applied where policy guidance was unclear or silent, and structured criteria were used to support consistent evaluation across markets. Final importance rankings were validated in consultation with Gilead local country experts.
- Grouping by Evidence Needs:** Minimum value evidence needs for each market were identified and similarities across countries were evaluated to define value evidence archetypes.
- Archotyping Additional Markets:** To test the useability of the framework, the authors mapped additional markets to the value evidence archetypes, in collaboration with Gilead local experts.

Table 2. Describing Value Methods and Elements

	Definition
<b>Decision-driver</b>	<ul style="list-style-type: none"> <li>Required per HTA or payer policy</li> <li>Recognized by experts as an important factor in decision-making</li> </ul>
<b>Supportive</b>	<ul style="list-style-type: none"> <li>Any methods or value elements that can be included based on the guidance document</li> <li>These may be submitted as supplemental evidence but may not be decision-drivers/ may impact HTA decision-making in specific cases</li> </ul>
<b>Future</b>	<ul style="list-style-type: none"> <li>Not a current decision-driver or supportive factor, however the market may be exploring consideration in the future</li> </ul>
<b>Not valued</b>	<ul style="list-style-type: none"> <li>Either not accepted, or may be submitted but has not impacted HTA decision-making</li> <li>May include methods that are 'accepted' but have a very high bar for acceptance (e.g., ITCs / NMAs in Germany)</li> </ul>

## Results

- The analysis identified four value evidence archetypes with some overlap (Figure 2):
- Most markets now require diverse evidence types including cost effectiveness analyses in addition to clinical effectiveness.
- Some countries rely exclusively on the CEA/CUA with clear established thresholds, others leverage it as an entry requirement to negotiations preferring to rely on other direct cost-evaluations (eg, Budget Impact Analysis).

Figure 2. Value Evidence Archetypes Mapped

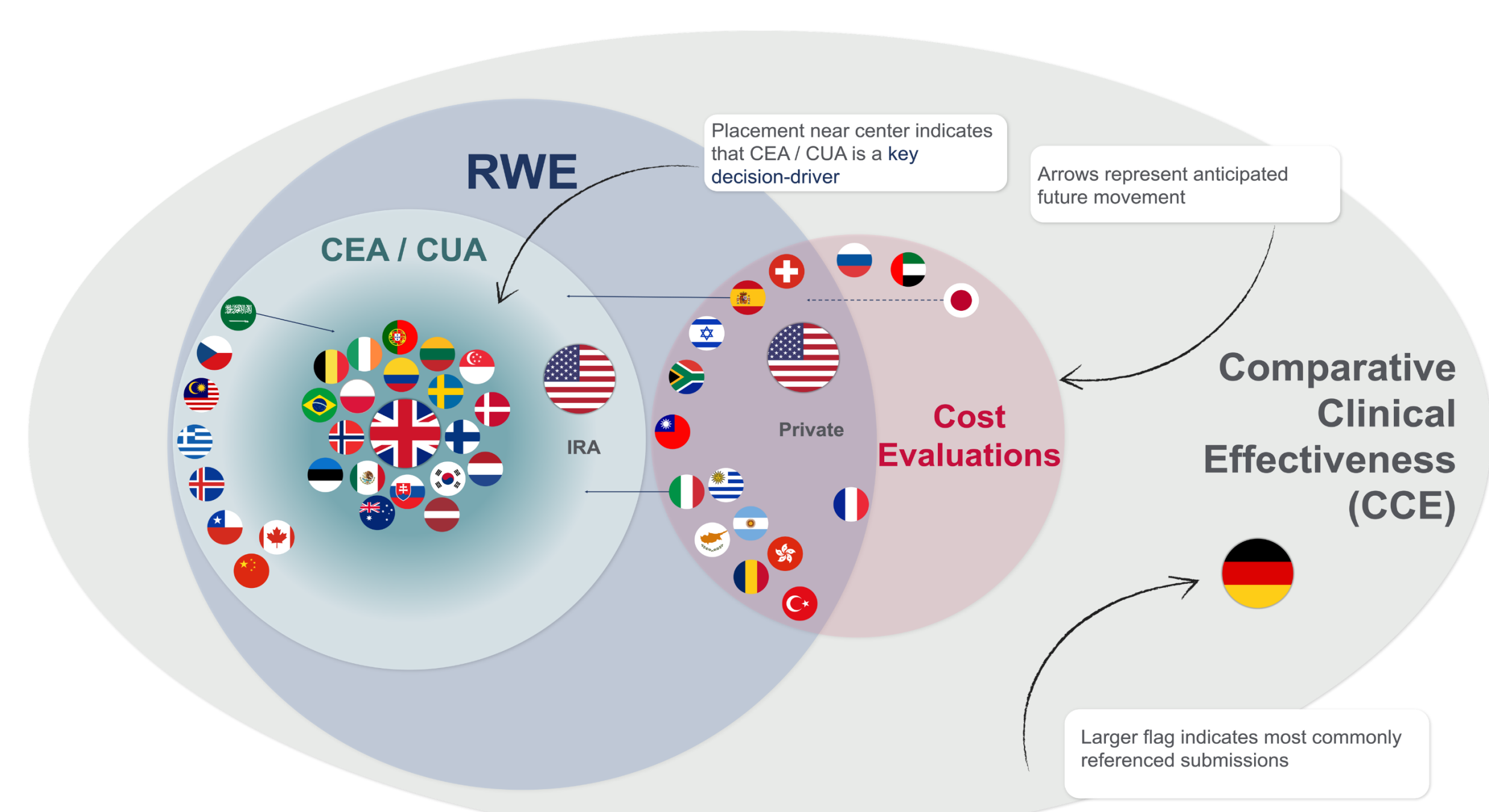


Table 3. Value Evidence Archetypes Defined by Minimum Value Evidence Needs

Value evidence archetype	Minimum value evidence package
<b>Comparative Clinical Effectiveness (CCE)</b>	<ul style="list-style-type: none"> <li>Comparative clinical trial data</li> </ul>
<b>CCE + Cost Evaluations + Real-world evidence (RWE)</b>	<ul style="list-style-type: none"> <li>Comparative clinical trial data</li> <li>Budget impact model, cost calculator, or other cost-based evaluations</li> <li>Real-world evidence to describe unmet need and/or clinical benefit; local data required</li> </ul>
<b>CCE + Cost effectiveness/utility analyses (CEA / CUA) + RWE</b>	<ul style="list-style-type: none"> <li>Comparative clinical trial data</li> <li>Cost-effectiveness / cost-utility analysis</li> <li>Real-world evidence to describe unmet need and/or clinical benefit; local data required</li> </ul>
<b>CCE + Cost Evaluations</b>	<ul style="list-style-type: none"> <li>Comparative clinical trial data</li> <li>Budget impact model, cost calculator, or other cost-based evaluations</li> </ul>

## Lessons Learned

### Continuous evolution in the use of HTA processes

- The overlaps observed for the archetypes reflect the difficulty healthcare decision-makers have in prioritizing high-priced medicines with limited budgets.
  - HTA bodies and payer decision-makers are broadening their value definitions and are looking for diverse evidence to make better access decisions
  - Market placement on the archetypes map (Figure 2) will drift over time as decision-makers continue to evolve their decision-making inputs and processes
- Value evidence archetypes do not align directly with traditional payer archetypes
  - Traditional payer archetypes focus on final pricing decisions, while evidence archetypes address pre- and post-approval evidence needs, enabling better effort and impact estimation for teams that generate value evidence
- RWE's role is expanding, underpinning both cost and clinical evaluations.

### CEA/CUA is becoming a standard evaluation tool

- Once an England/NICE-only tool, more countries are starting to require CEA/ CUA due to the difficulty of prioritizing new medical technologies given limited budgets
- There is variation in the degree to which CEA/ CUA influences actual decision-making with some markets relying exclusively on the CEA/ CUA with clear established thresholds, others leverage it as an entry requirement to the negotiations, preferring to rely on other direct cost-evaluations (eg, BIMs) to inform decision-making

### Empowering HEOR teams

- This archotyping will empower GHEOR teams to appropriately prioritize the evidence needs of the markets and to better communicate impact based on external healthcare decision-making needs

## Conclusions

- Traditional payer market archetypes are not fit-for-purpose in evidence generation planning for GHEOR teams
- Four evidence archetypes were identified, reflecting how markets prioritize different types of data (eg, clinical, cost-effectiveness, and real-world) in demonstrating value
- Cost-effectiveness and utility analyses (CEA/CUA) are increasingly required across markets
- Market variation exists as some countries utilize strict cost evaluation and budget thresholds while others use cost information as part of their value assessment
- The newly identified value evidence archetypes offer clearer guidance for evidence planning across multiple markets

## Plain Language Summary

- Markets ask for different types of data when deciding on if they will pay for new medicines
- Some want to see how well the medicine works in studies. Others care about how much it costs or how it helps people in real life.
- This makes it hard for global teams to know what information to prepare
- We looked at individual market requirements and grouped them into four types based on types of evidence that are needed
- Most countries now want more than clinical trial data, they also want expected costs and real-world information on the medicine's impact
- Cost-effectiveness studies are becoming a common requirement
- Grouping countries into the four types of markets will help GHEOR plan better and share the right information with the right countries

### References

1. Campbell J, Roibu C, Ivanova H, Macaulay R. PHP60 – PAYER ARCHETYPING – EXPANDING HORIZONS. Value in Health. 2018;21:S160.

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**Disclosures:** YA and DG are employees of Gilead Sciences, Inc., and may own stock in Gilead Sciences, Inc. **Correspondence:** Yumi Asukai, Yumi.Asukai@gilead.com