The Hows and Whys of Estimating Return on Investment (ROI) of HEOR to the Biopharmaceutical Industry

Criteria for HEOR Project Selection

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How to go about it?

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- Not all HEOR projects are equally suited for ROI estimation
- .... attempting to measure everything threatens dilution of credibility
- Challenge is to turn criteria into something decision-oriented, concrete, and insightful
- Ultimately, we want to further understand and demonstrate that HEOR can make a difference, change a decision
  - From Valued Tactical ➡ **Valued Strategic** partner

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We propose three criteria to prioritize HEOR projects for ROI Estimation

Topicality

Is the project relevant now?

Quantifiability

Can its impact be measured credibly?

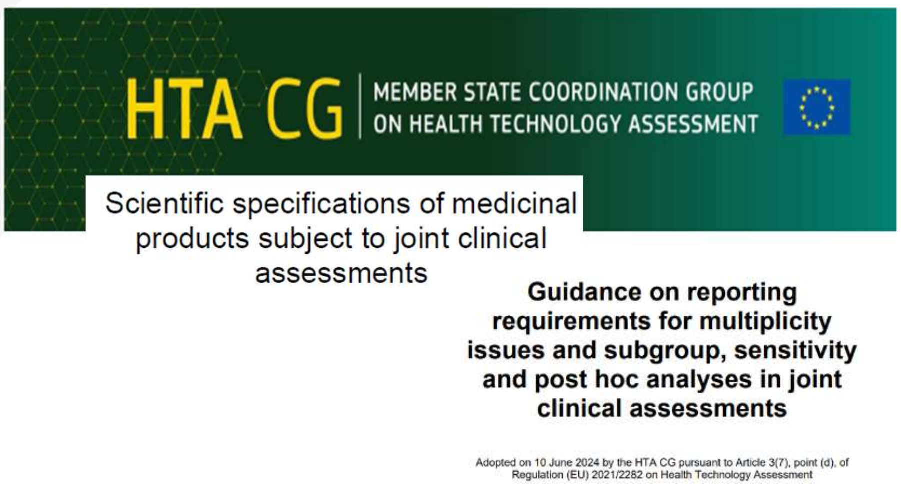
Applicability

Does it represent a meaningful share of HEOR investment?

Prioritization Criteria #1: Topicality

Is the work aligned with relevant and current developments?

- Projects that sit at intersection of active debate and/or current methodological innovation
  - Disruptive: Decision makers are seeking evidence
  - Methods are evolving or under scrutiny
  - HEOR has a visible seat at the table



Prioritization Criteria #1: Topicality

Is the work aligned with relevant and current developments?

Examples

- Early phase PICOS development
  - Endpoint strategy
  - Comparative efficacy & safety
- Economic modeling & global pricing interdependency (MFN)
- RWE: External control arms (ECA)/Trial emulation

Implementation

- Pre-emptively address JCA requirements
  - Trial input & Analysis Plans
  - Planning Indirect Treatment Comparisons (ITC)
- Seek global pricing alignment (MFN)
- Clinical trial design (RWD/synthetic control arms)

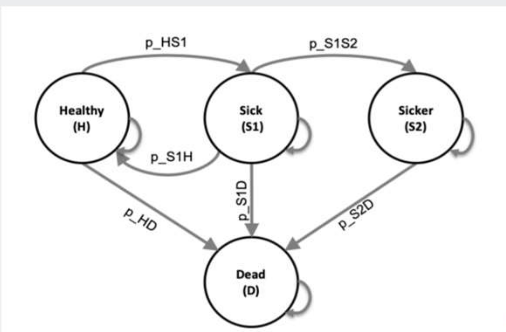
Why it matters to ROI

- High visibility & organization attention
  - Easier attribution of impact
- Outcomes likely influence high-stakes decisions
  - JCA drives EU/HTA comparative effectiveness metrics
  - MFN pricing spills over effects across markets, launch sequencing
  - ECAs reduce trial investment and increase speed to regulatory approval

Prioritization Criteria #2: Quantifiability

Can one credibly measure the impact in economic or decision terms?

- Projects where inputs, outcomes and downstream consequences can be linked in a transparent and defensible way
  - Without ROI it becomes speculative



Economic Models

Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints For Regulatory Decision-Making

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

DRAFT GUIDANCE

COA Dossiers

Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

COA=Clinical Outcomes Assessments

Prioritization Criteria #2: Quantifiability

Can one credibly measure the impact in economic or decision terms?

Examples

- Economic modeling supporting HTA evaluation and pricing negotiations
- Label enabling evidence on COAs/PRO validation to support promotional claims
- RWE / External Control Arms
  - Trial resources optimization
  - Accelerated drug uptake

Implementation

- Link to specific decisions (e.g., access, price, regulatory decision making)
- Translate investment into economic value narrative
- Clear counterfactual:

“What would happen without HEOR investment?”

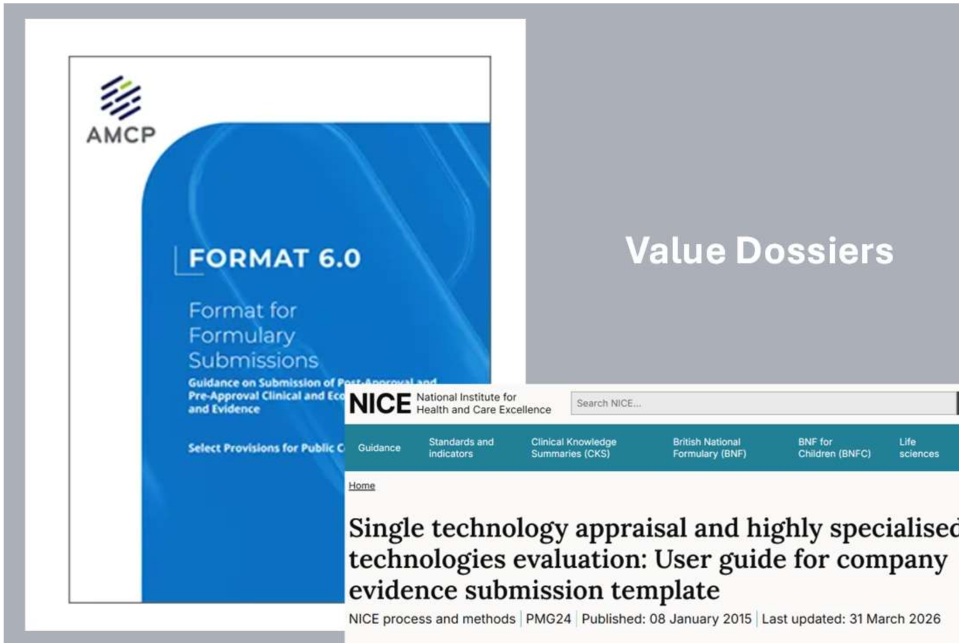
Why it matters to ROI

- Enables credible value demonstration
- Resources are limited
- Reproducible, scalable
- Reduces skepticism from leadership

Prioritization Criterion #3: Applicability
Does project represent where we actually spend time and money?

- Ensure that ROI analyses focus on HEOR activities that are material to the organization
  - Increases relevance to leadership
  - Scalability across programs, indications, geographies

Comparative Effectiveness Research



Value Dossiers

Prioritization Criteria #3: Applicability
Does project represent where we actually spend time and money?

Examples

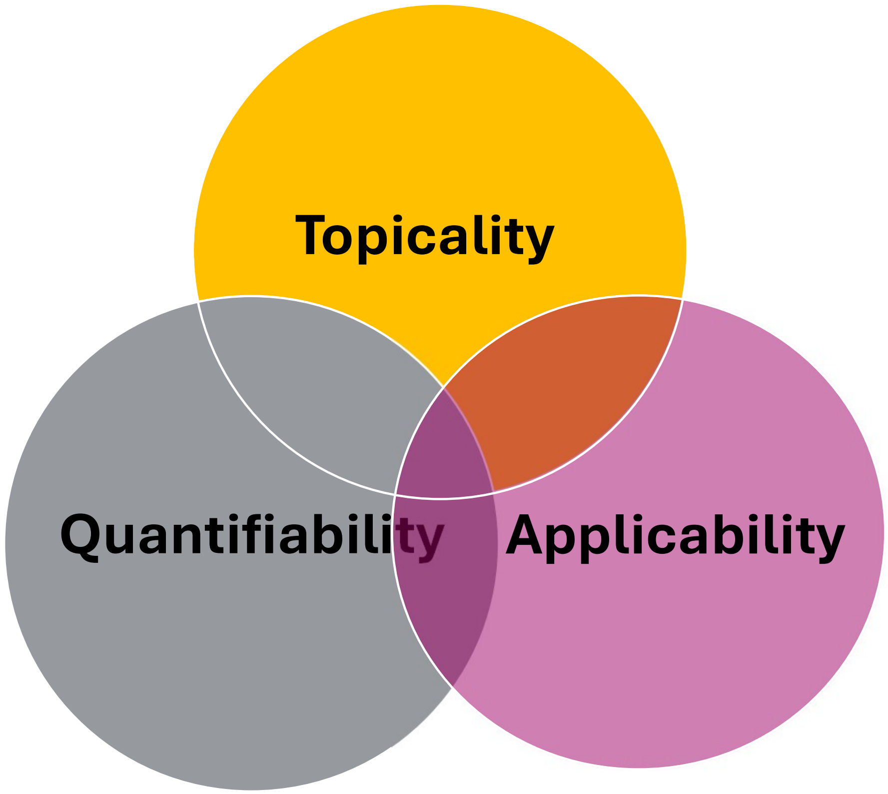
- Observational/pragmatic comparative studies and indirect treatment comparisons (ITC)
- Value dossiers (AMCP, global, country-specific HTA submissions)
- Global cost-effectiveness and budgetary impact models

Implementation

- Scalable
- Relevant across assets, indications and geographies
- Represent core HEOR competencies, not one-offs

Why it matters to ROI

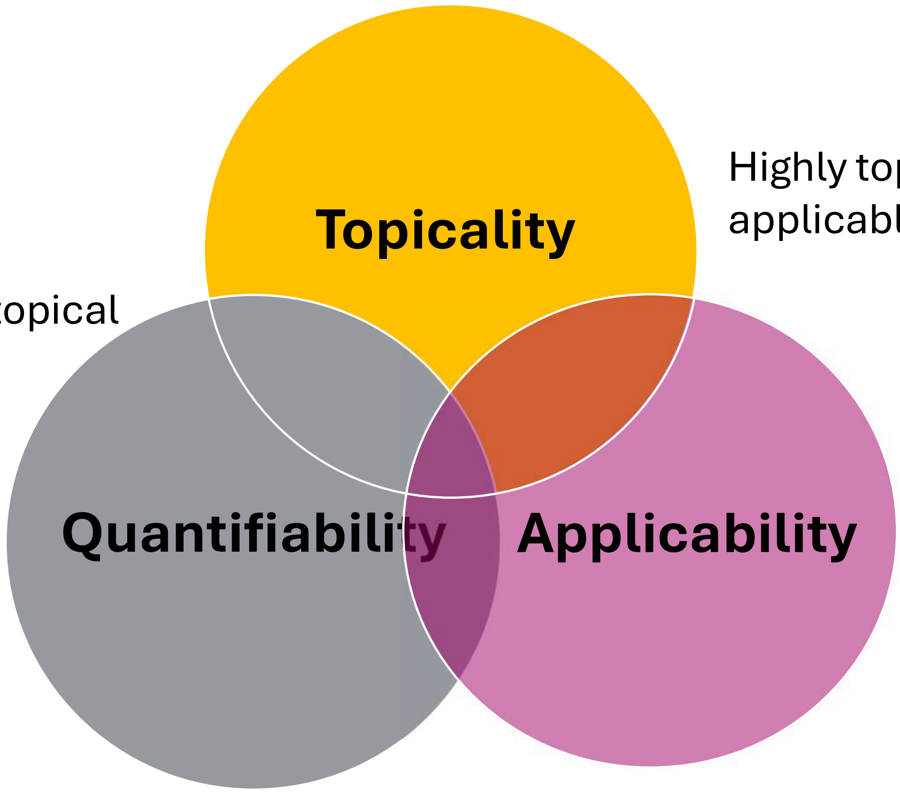
- Ensures generalizability across portfolio
- Meaningful share of HEOR budgets and FTE effort



Optimal ROI HEOR project candidates sit at the intersection of relevance, measurability and scale

But there are trade-offs

Highly quantifiable ≠ always topical



Highly topical ≠ always widely applicable

Highly applicable ≠ always easily quantifiable

Goal is Balance - not Maximixing a Single Dimension

Considerations

- **Time horizon matters,** may undervalue long-term investments
  - Short-term: launch acceleration, pricing outcomes seem quite tangible
  - Long-term investments behave more like building value infrastructure (e.g., registries, CE)
- **Attribution Complexity**
  - HEOR work is embedded within multiple functions (cross-functional)
  - ROI estimation should be viewed as contribution-based, not purely causal
- **Equity and Ethical Importance / External impact**
  - Not all investments have to maximize financial return
  - ROI should not replace broader notions of value
- **Additional criteria remain open for discussion and refinement**

CE=comparative effectiveness

In Closing

- **Selective ROI estimation strengthens the case for HEOR by focusing on:**
  - What **matters now**, can be **measured**, and represents **meaningful organizational investment**
- **Embedding ROI into company decision-making:**
  - Can be integrated into **portfolio prioritization and planning workstreams**
  - Provides a structured way to **inform investment trade-offs across assets**
- **Strategic impact:**
  - Elevates HEOR as an **enterprise-level function strengthening role in decision-making**

Ultimately, ROI is not just about measurement but positioning and reinforcing HEOR as a strategic driver of value across the organization

Thank You!