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BACKGROUND

Traditional healthcare investment due diligence centers on clinical data and regulatory pathways, yet returns increasingly depend on market access, pricing sustainability, and payer acceptance. Three converging policy shifts now reshape the risk landscape: the **US Inflation Reduction Act (IRA)**, with the first ten Maximum Fair Prices in effect since January 2026 (38 to 79% discounts versus list prices) and small-molecule negotiation eligibility 4 years earlier than biologics, compressing the NPV window for chemical drugs [1]; **Most-Favored-Nation (MFN) pricing models** proposed by CMS for Medicare Part B (GLOBE) and Part D (GUARD), with public comment closed February 2026 [2]; and the **EU Joint Clinical Assessment (JCA)**, in force since 12 January 2025 for oncology and Advanced Therapy Medicinal Products, mandating comparison against the best available comparator with consolidated PICO-based assessment, mandatory for orphan medicines from 2028 and all centrally authorised products from 2030 [3].

OBJECTIVES

To propose a conceptual framework repositioning Health Economics and Outcomes Research (HEOR) from a **perceived cost center into a risk mitigation instrument for healthcare investors**, where modest economic-evidence investment protects substantially larger clinical development capital exposed to market access, pricing, and policy risk.

METHODS

A conceptual framework was developed integrating **three analytical dimensions**:

(1) **Investment magnitude differential** between HEOR programs and clinical development.

(2) **Market share compression** from inadequate value positioning, anchored in published HTA evidence: Vreman et al. reported that 87% of Conditional Marketing Authorisation drugs did not receive an unrestricted positive HTA recommendation [4]; ABPI 2025 reported UK uptake at 52 to 62% of comparator-country averages [5].

(3) **Policy exposure** to IRA, MFN models, and EU JCA.

Each dimension was mapped to development stages from preclinical through Launch / M&A to specify a calibrated HEOR deliverable. The framework is methodologically agnostic and accommodates Markov modeling, microsimulation, partitioned survival, network meta-analysis, budget impact, and GCEA / SROI approaches. Quantitative ranges presented are illustrative, based on industry benchmarks.

ANCHORED EVIDENCE: MARKET ACCESS RISK INDICATORS

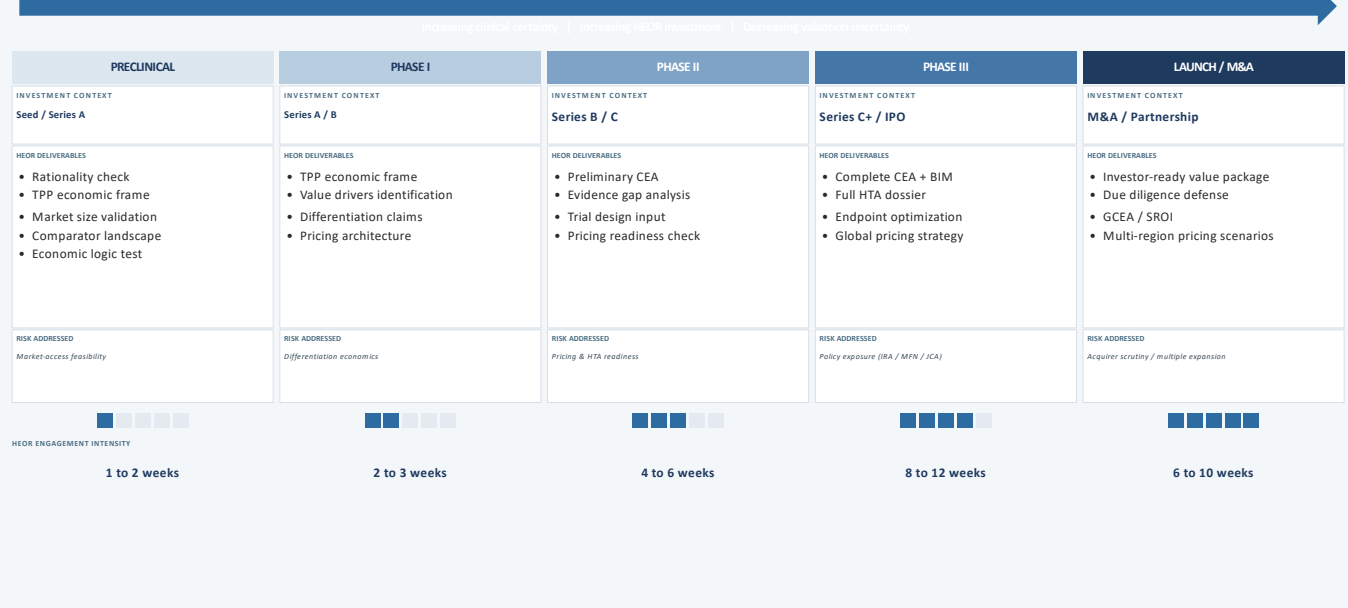
87%	of Conditional Marketing Authorisation drugs did not receive an unrestricted positive HTA recommendation [4].
33%	of orphan medicines were rejected outright by the Scottish Medicines Consortium [7].
52% / 62%	UK uptake of innovative medicines in year 1 / year 5 versus comparator-country averages; only 37% of new medicines fully available [5].
1st → 9th	England's ranking for new-medicine availability among European countries has slipped under a decade [8].
38 to 79%	range of IRA Maximum Fair Price discounts off list price for the first ten drugs effective January 2026 [1].

REFERENCES

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- [6] Ramagopalan SV, et al. J Comp Eff Res. 2023;14(5).
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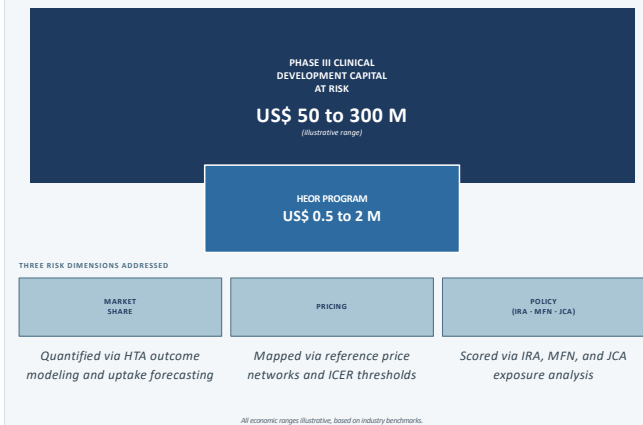
RESULTS: STAGE-GATED HEOR DE-RISKING FRAMEWORK

HEOR engagement intensity calibrated to development stage and decision stakes. Modest, staged economic-evidence investment protects substantially larger clinical development capital.



ASYMMETRIC CAPITAL-AT-RISK

HEOR programs represent an order of magnitude less investment than Phase III trials, creating asymmetric protection against market access failure.



DISCLOSURES

S. Roze: HOMAX Advisory (employee), P. Morgon: MORGON Advisors (employee). No additional financial disclosures.
AI-assisted content disclosure
AI-assisted technology was used to assist with abstract drafting and editing. In compliance with the ISPOR AI Policy.

KEY INSIGHTS & CONCLUSIONS

- Asymmetric return profile.** Modest economic-evidence spend protects substantially larger clinical capital exposed to market access failure.
- Stage-calibrated engagement.** Deliverables sized to decision context, scaling from rapid rationality checks to investor-ready value packages.
- Three convergent policy exposures.** IRA, MFN, and EU JCA reshape valuation variance not captured by traditional financial models.

TAKE-HOME MESSAGE

Reframed for investment decision-making rather than regulatory submission, HEOR functions as a risk mitigation instrument with asymmetric return characteristics.

Empirical validation of the paradigm, including portfolio-level retrospective analysis of HEOR engagement intensity versus market access outcomes, is the natural next step.

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