



Assessing the Return on Investment (ROI) of HEOR & RWE to the Biopharma Industry: Case Example of Economic Modeling in HTA Submissions

HTA53

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Background & Rationale

- Economic modeling has long been an essential component of Health Technology Assessment (HTA) agency submissions
- Model quality has been reported to vary widely across manufacturer submissions (Daly 2022; Osipenko 2024)
- This can impact the duration and outcome of HTA deliberations and, ultimately, marketplace success of the product
- The objective of this study was to understand the ROI to a biopharmaceutical company of investing additional resources to enhance model quality in HTA submissions

Methods

- Decision-analytic model designed to characterize risks, costs, potential agency recommendations, and commercial outcomes of the HTA submission process, highlighting the impact of investment in model quality enhancements (Figure 1)
- As the manufacturer decision on modeling approach is made before regulatory decision, initial branching of the decision tree is for whether or not product is approved
- Next chance node indicates whether approach to HTA appraisal results in a high- or low-quality model
- Terminal nodes are linked to net present value (NPV) calculations reflecting research & HTA submission costs and product revenue accrual over time, discounted back to the modeling investment decision
- Revenue accrued modeled over 15-year period:
 - Attaining peak by year 6 (Robey 2017)
 - Remaining at peak in years 7-12 (DiMasi 2016)
 - Rapidly declining following loss of exclusivity in final 3 years (IQVIA 2019)
- Model used to estimate expected NPV for each arm and ROI calculated as in DiMasi 2023:

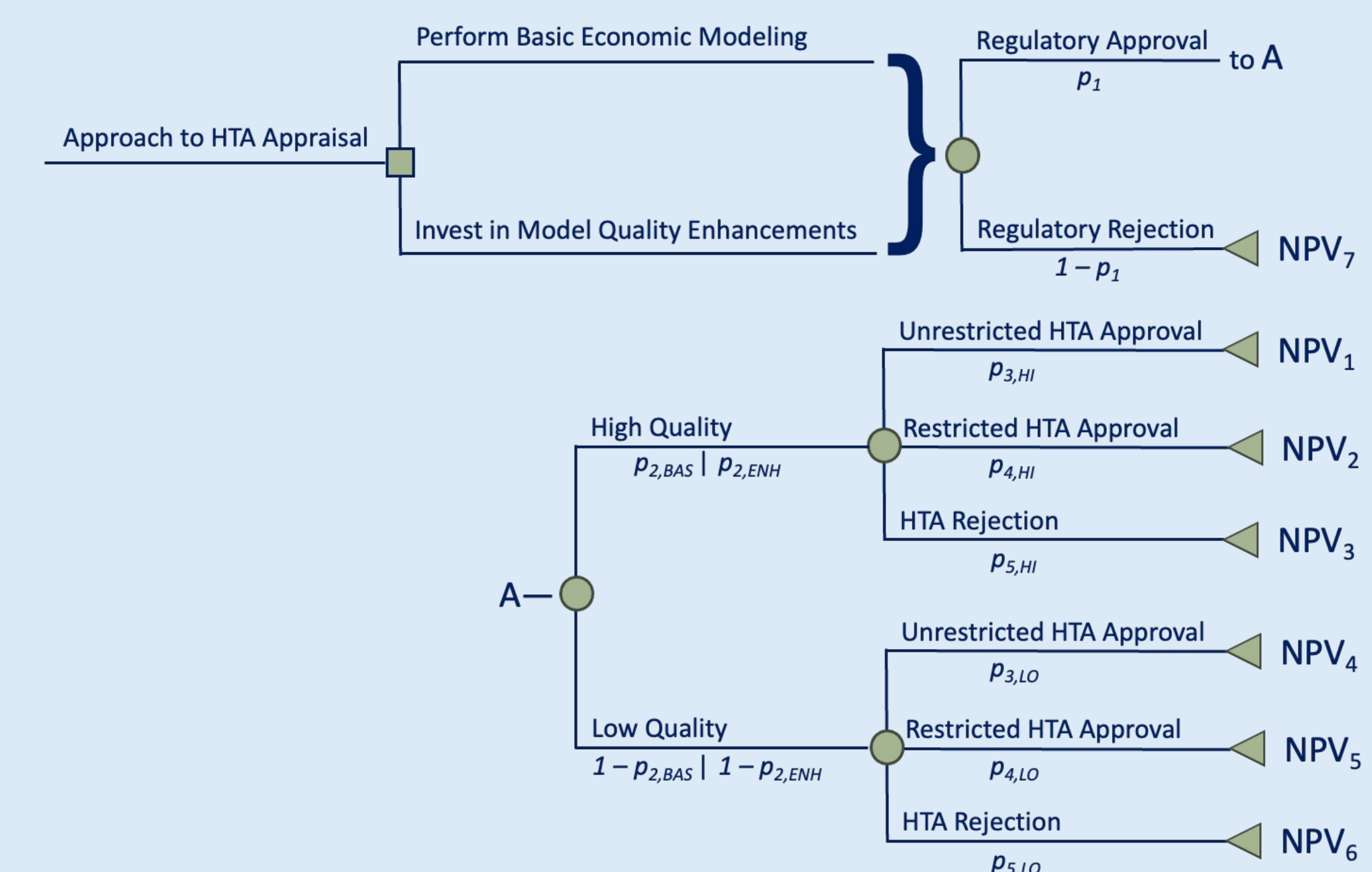
$$ROI = \frac{\Delta eNPV}{I} \cdot 100\%$$

Where, $\Delta eNPV$ is the difference between arms in expected NPV; and I is the undiscounted total investment in model quality enhancements

- Analyses performed for hypothetical development compound with \$250 million annual revenue potential in the countries represented by the HTA agencies

Model Structure

Figure 1. Decision-Analytic Model of Economic Modeling Investment



Parameter Estimates & Data Sources

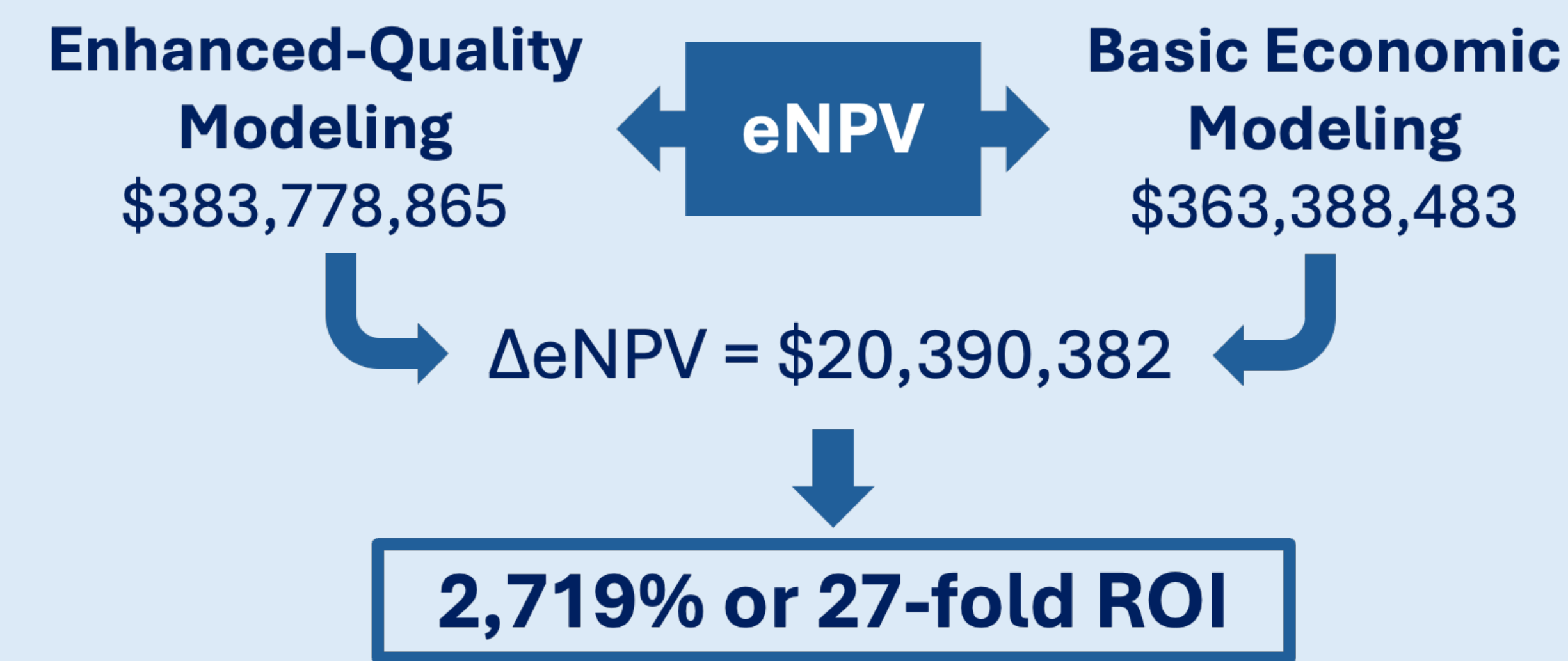
- All model parameters related to HTA deliberations and decisions were estimated based on analyses of initial submissions for single-technology appraisals to NICE (UK & Wales), CDA (Canada), and PBAC (Australia) for the period, 2020-2025 (HTA-Hive 2026)

Decision Tree Probabilities			
Parameter	Description	Estimate	Source(s)
p_1	Probability of regulatory approval given clinical trial success	.875	Leviton 2018
$p_{2,BAS}$	Probability that basic economic model will be of high quality	.500	Assumption
$p_{2,ENH}$	Probability that enhanced economic model will be of high quality	.660	Assumption
$p_{3,HI}$	Probability of unrestricted HTA recommendation, given high-quality economic modeling	.288	HTA-Hive 2026 Note: Model quality assessed based on numbers of uncertainties tallied in HTA reports (high quality, < 9; low quality, ≥ 9)
$p_{3,LO}$	Probability of unrestricted HTA recommendation, given low-quality economic modeling	.165	
$p_{4,HI}$	Probability of restricted HTA recommendation, given high-quality economic modeling	.535	
$p_{4,LO}$	Probability of restricted HTA recommendation, given low-quality economic modeling	.483	
$p_{5,HI}$	Probability of HTA rejection, given high-quality economic modeling	.177	
$p_{5,LO}$	Probability of HTA rejection, given low-quality economic modeling	.352	

Time Parameters			
Parameter	Description	Estimate	Source(s)
T_{BAS}	Duration of basic economic modeling project (months)	12	ROI of HEOR Working Group
T_{ENH}	Duration of enhanced-quality modeling project (months)	12	ROI of HEOR Working Group
T_{REG}	Duration of regulatory review (months)	12	DiMasi 2016; Levitan 2018
$T_{HTA-BAS}$	Duration of HTA review, basic economic modeling (months)	13	HTA-Hive 2026
$T_{HTA-ENH}$	Duration of HTA review, enhanced-quality modeling (months)	9	HTA-Hive 2026

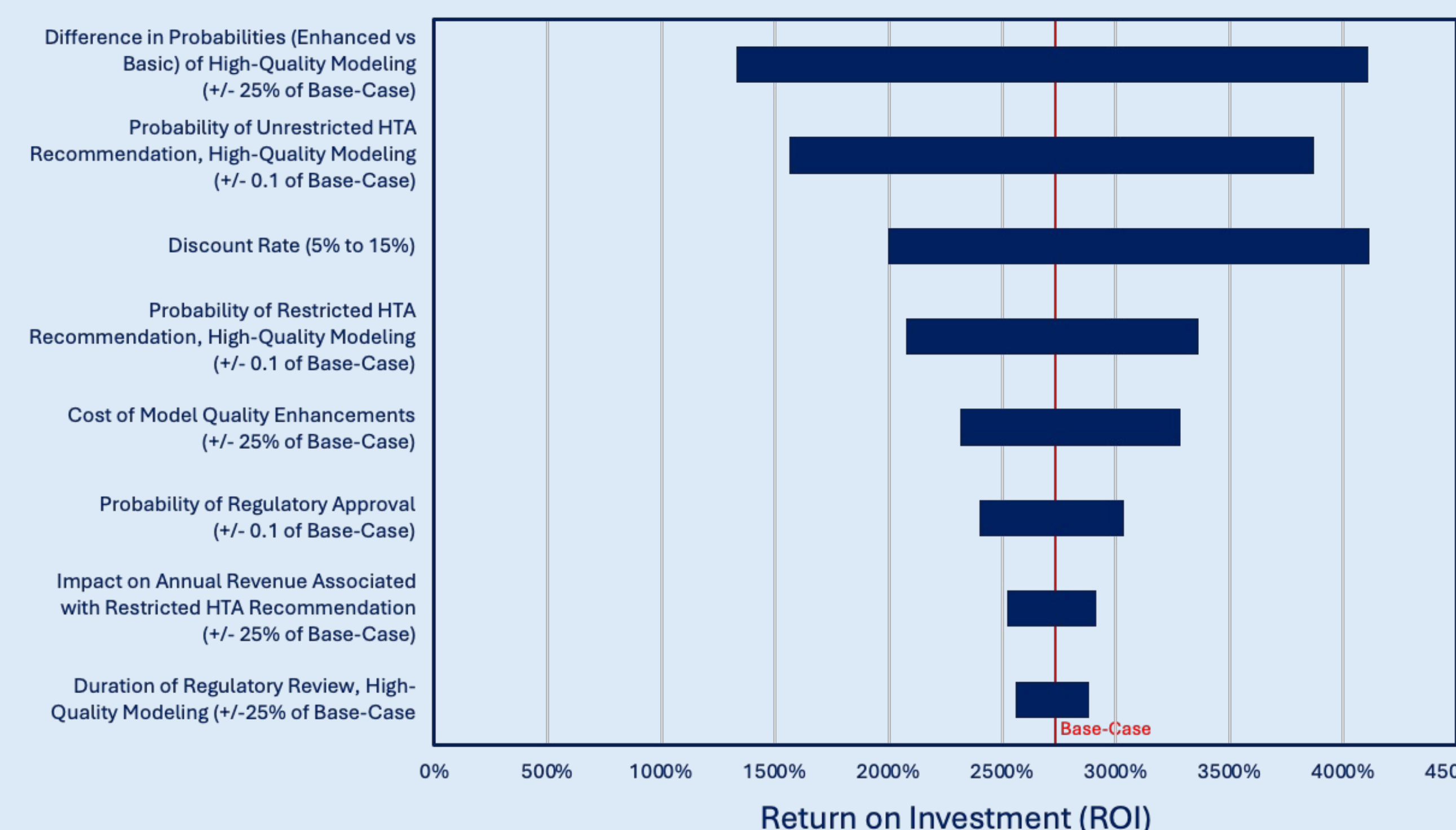
Cost & Revenue Parameters			
Parameter	Description	Estimate	Source(s)
C_{REG}	Cost of regulatory submissions (millions)	\$20.0	Leviton 2018
C_{HTA}	Cost of HTA submissions (millions)	\$1.0	Calculated as 5 HTAs @ \$200,000 each
C_{BAS}	Cost of basic economic modeling project	\$250,000	ROI of HEOR Working Group
C_{ENH}	Cost of model quality enhancements (ie, over & above base cost)	\$500,000	ROI of HEOR Working Group
R_{RES}	Impact on annual product revenue associated with restricted HTA decision	-61%	HTA-Hive 2026
R_{REJ}	Impact on annual product revenue associated with HTA rejection	-95%	Assumption
r	Discount rate (cost of capital)	10.5%	DiMasi 2016

Results



- In base-case analyses, investment in model quality enhancements yields a 27-fold ROI on the \$750,000 overall modeling cost
- One-way sensitivity analyses (Figure 2) show:
 - Widest variation in results associated with the model quality advantage that investing additional resources might yield
 - Comparably wide variations in results associated with the probability of unrestricted HTA recommendation for high-quality modeling and the discount rate
 - Relatively smaller variations in results associated with the duration of regulatory review for high-quality modeling, impact on annual revenue due to restricted HTA recommendation, and cost of model quality enhancements

Figure 2. Tornado Diagram Depicting One-Way Sensitivity Analyses



- ROI remains strong even if peak annual revenue potential is adjusted downward:



Discussion

- Published analyses highlighting differences in model quality in HTA submissions have been confirmed by analyses performed for this study (HTA-Hive 2026)
- Our study illustrates the consequences of including low-quality models in HTA submissions and assesses the ROI of investing greater upfront resources to increase the likelihood of high model quality
- In our base-case analysis, we assume that such quality enhancements would involve tripling the budget for the economic model; even so, the ROI for this strategy is substantial and robust to variation in key parameters
- While the idea may resonate that investing additional resources will improve the likelihood of producing a high-quality model, a limitation of our analysis is that this relationship has not been demonstrated empirically
- However, our analyses indicate that even a 1% increase in the likelihood of producing a high-quality model would have a positive ROI

Conclusion

- Biopharmaceutical company investments to enhance the quality of economic modeling in HTA submissions can yield a strong ROI, as mediated by streamlined HTA deliberations and higher likelihood of receiving more favorable HTA recommendations

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Author Disclosures & Poster Download

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- Conflict of interest:
 - The authors (collectively, "the ROI of HEOR Working Group") may hold equity in their employing companies
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