

# Informing the Sustainable Development of Novel Therapies using Value-based Real Options Analysis

EE553



Regulatory Science Lab

Hope, accelerated

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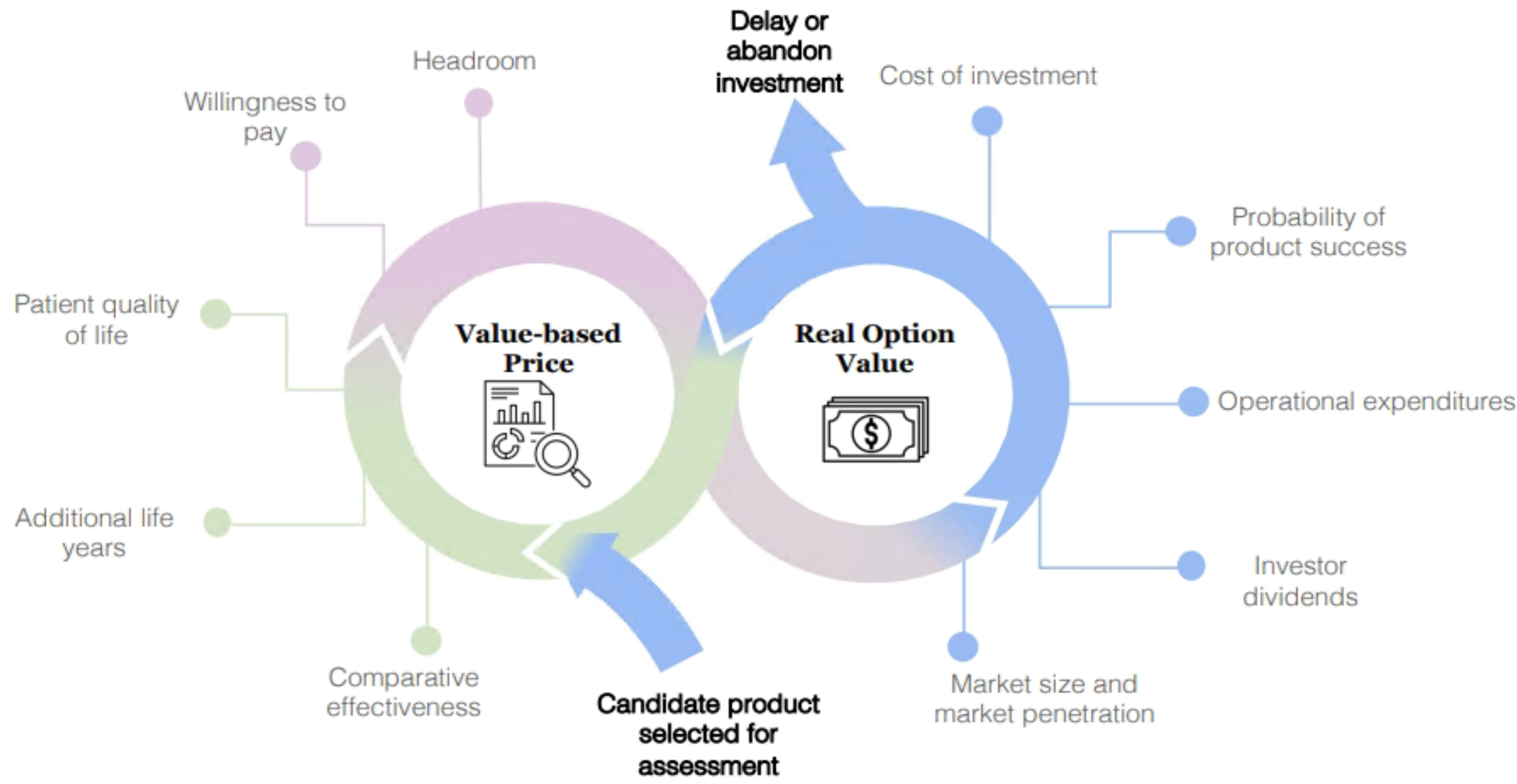
## Background

The translational pathway for novel health products is time consuming.

Developers must embed patient and health system value considerations into R&D decision-making for commercial viability and market success.

We present a novel method integrating patient and payor value into return on investment (ROI) calculations: value-based real options analysis (VB-ROA).

Figure 1. VB-ROA framework



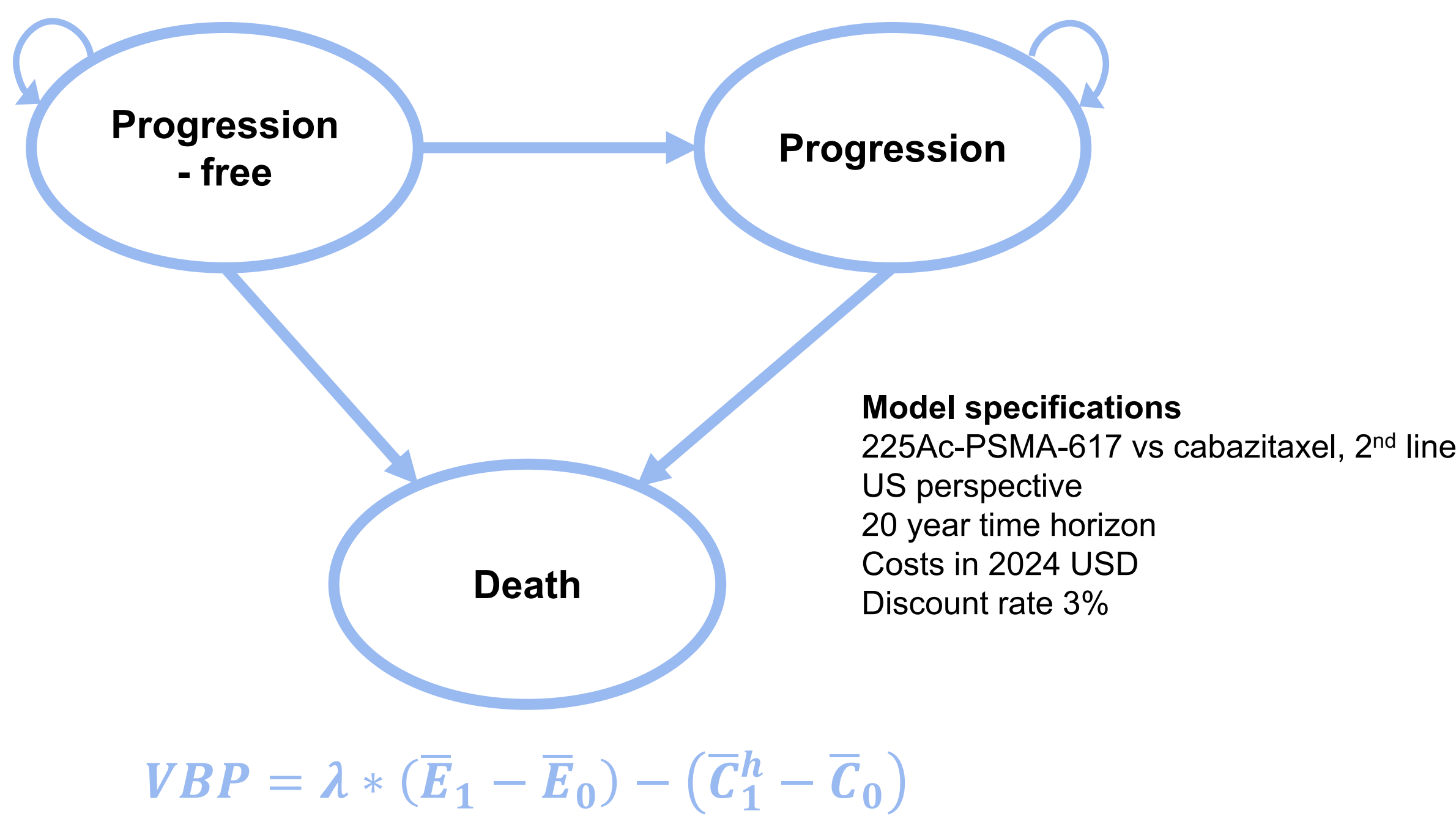
## Methods

We applied VB-ROA to an Actinium-225 radiopharmaceutical (225Ac-PSMA-617) for metastatic castration-resistant prostate cancer.

We determined a value-based price (2024 USD) for 225Ac-PSMA-617 through headroom analysis.

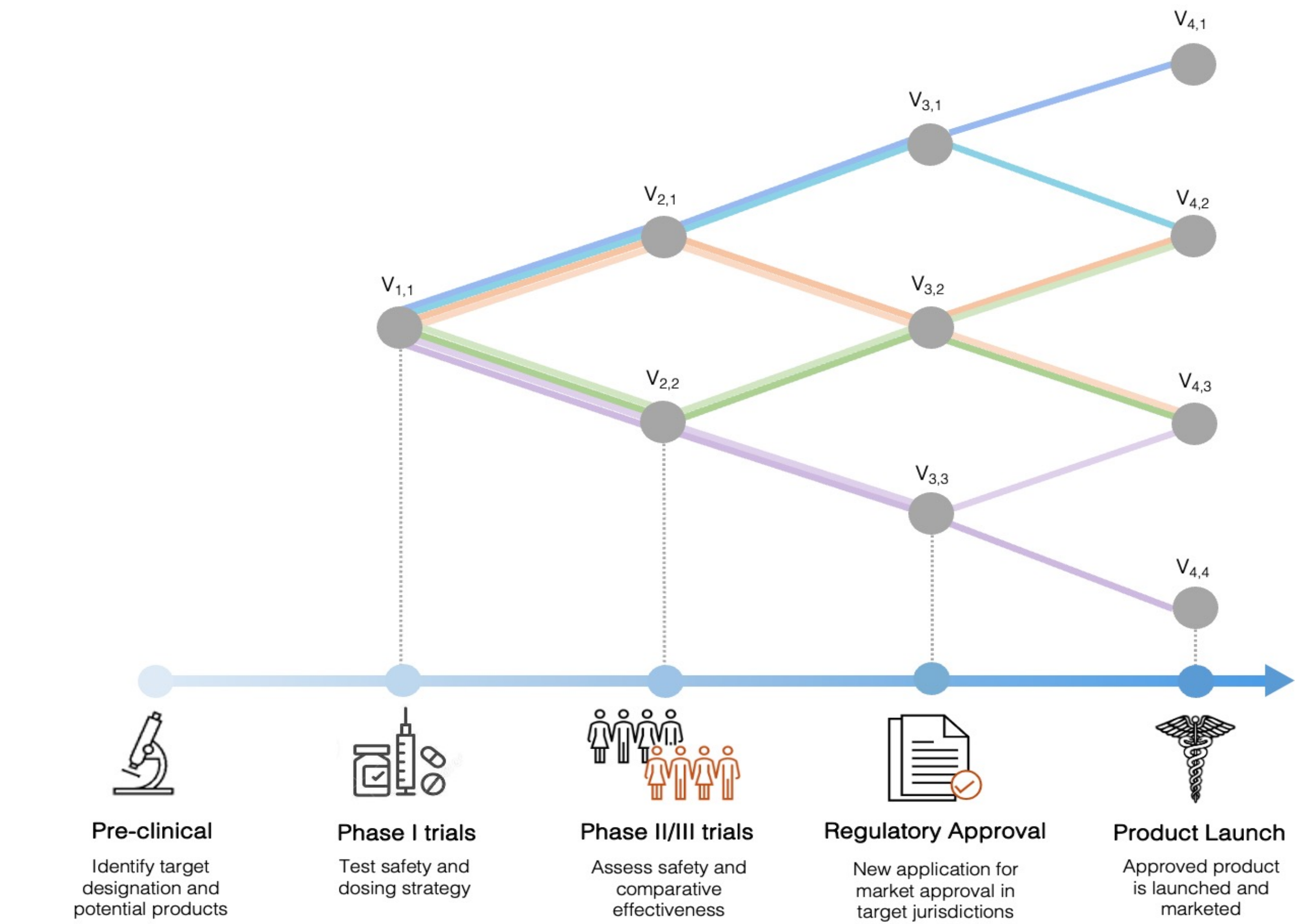
We estimated the real option value of investing in R&D using a binomial lattice model. Revenue projections, accounting for market potential and uncertainties, were based on the value-based price.

Figure 2A. VB-ROA Model 1 - Markov model



VB-ROA incorporates downstream reimbursement into early decision-making to optimize R&D and accelerate value-based patient access

Figure 2B. VB-ROA Model 2 – Binomial lattice model

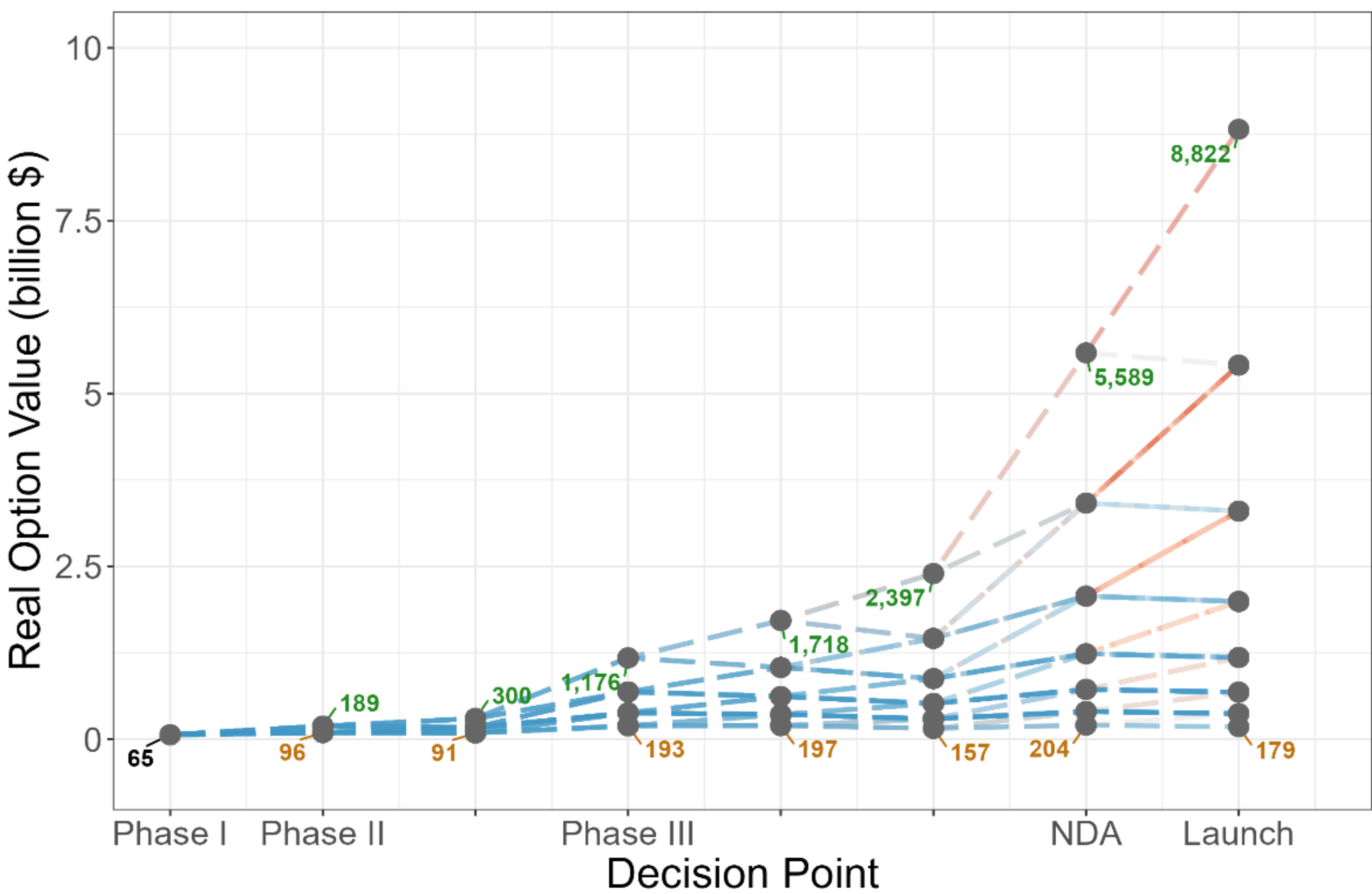


## Results

Headroom analysis estimated a mean value-based price of \$146,990 (95% CI: \$77,442, \$217,545) at a willingness-to-pay of \$100,000/QALY.

The estimated real option value was \$65 million at time of phase I trial, and \$179 million to \$8.8 billion at product launch, supporting R&D investment.

Figure 3. VB-ROA real option values for 225Ac-PSMA-617.



## Conclusion

VB-ROA integrates headroom analysis with ROA to estimate ROI for candidate health products.

Integrating developer and health system perspectives through VB-ROA can inform sustainable therapy development that enhances patient care.