



Assessing the Return on Investment (ROI) of HEOR & RWE to the Biopharma Industry: Case Example of Comparative Effectiveness Research

RWD102

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Background & Rationale

- Comparative effectiveness research (CER) often involves analyses of secondary real-world data (RWD) sources by HEOR teams
- Biopharmaceutical manufacturers typically perform CER with other commercialization activities to expand market access, secure reimbursement, and protect competitive positioning versus other products in class
- The objective of this study was to understand the ROI of CER in this context

Methods

- Decision-analytic model designed to characterize risks, costs, and potential revenue impact of CER (Figure 1)
- Terminal nodes are linked to net present value (NPV) calculation reflecting project costs and product revenue accrual over time, discounted to project decision
- Revenue accrual 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 in expected NPV (CER – No CER); and
 I is the undiscounted investment in the CER project

Scenario Analyses

- As CER could be performed for a variety of reasons, no one representative “base case” exists and model parameters would vary from one situation to the next
- We therefore used the model to conduct various “what-if” analyses of potential relevance to decision makers wanting to assess the ROI of a \$1M CER project
- Scenarios evaluated included projects intended to:
 - Support expansion of within-label prescribing
 - Support acceleration of within-label prescribing
 - Support both expansion & acceleration of within-label prescribing
- Parameter assumptions & rationales for each scenario are provided in the tables below:

Scenario 1: Expand Prescribing

Parameter	Value	Rationale
p_1	0.8	Study assumed to have 80% statistical power
p_2	0.75	Decision maker has strong expectations for a favorable result
p_3	0.0	No impact on pace of revenue accrual is anticipated with favorable result
p_4	1.0	Favorable result assumed to increase revenues 0-6%
p_5	0.0	No impact on pace of revenue accrual is anticipated with unfavorable result
p_6	1.0	Unfavorable result assumed to decrease revenues 0-6%

Scenario 2: Accelerate Prescribing

Parameter	Value	Rationale
p_1	0.8	Study assumed to have 80% statistical power
p_2	0.75	Decision maker has strong expectations for a favorable result
p_3	1.0	Favorable result assumed to accelerate revenue accrual 0-6 months
p_4	0.0	No revenue increase is anticipated with favorable result
p_5	1.0	Unfavorable result assumed to decelerate revenue accrual 0-6 months
p_6	0.0	No revenue decrease is anticipated with unfavorable result

Scenario 3: Expand & Accelerate Prescribing

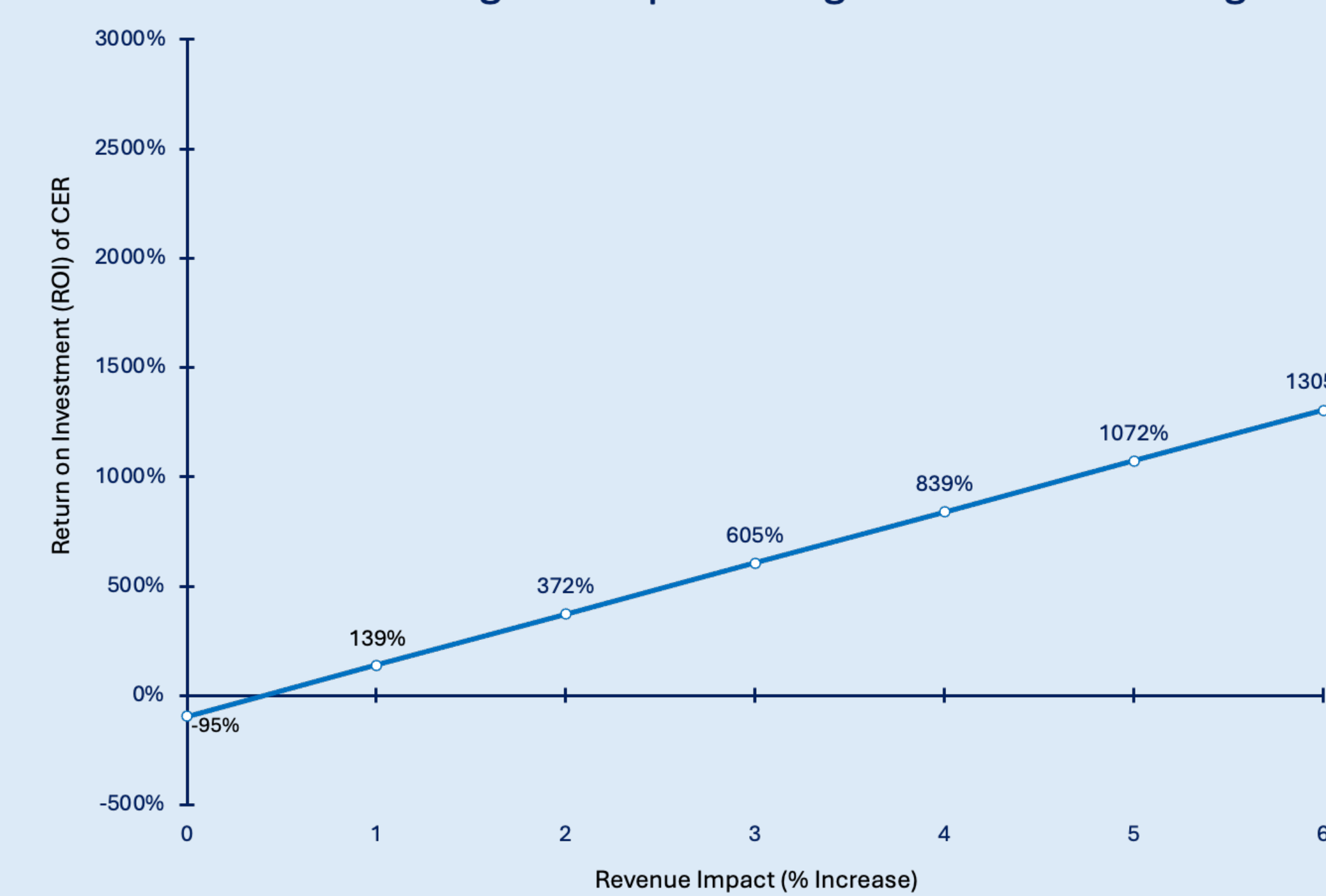
Parameter	Value	Rationale
p_1	0.8	Study assumed to have 80% statistical power
p_2	0.75	Decision maker has strong expectations for a favorable result
p_3	1.0	Favorable result assumed to accelerate revenue accrual 0-6 months
p_4	1.0	Favorable result assumed to increase revenues 0-6%
p_5	1.0	Unfavorable result assumed to decelerate revenue accrual 0-6 months
p_6	1.0	Unfavorable result assumed to decrease revenues 0-6%

- Analyses performed for hypothetical product launched 24 months prior with \$100M / yr revenue potential
- Varying magnitudes of impact were assessed related to increase/decrease (0-6%) and acceleration/deceleration (0-6 months) of revenue stream
- For symmetry, we assumed identical magnitudes of positive and negative revenue impacts associated with favorable and unfavorable study results
- We assumed that CER results would not be available until 36 months post-launch and therefore any impacts on revenues would begin in month 37

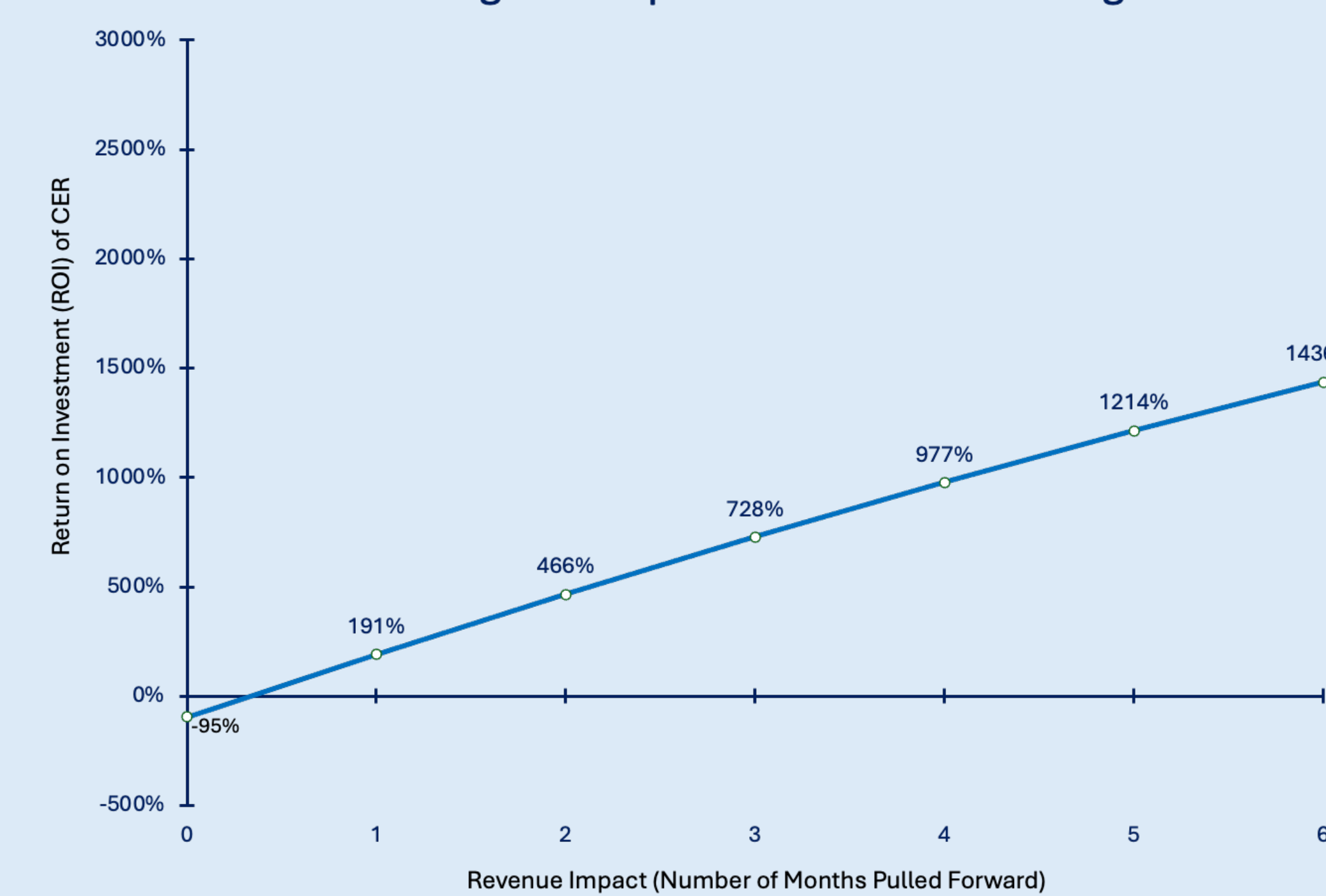
Results

- ROI is increasingly positive across the three scenarios (ie, $ROI_1 < ROI_2 < ROI_3$) and range of revenue impacts:

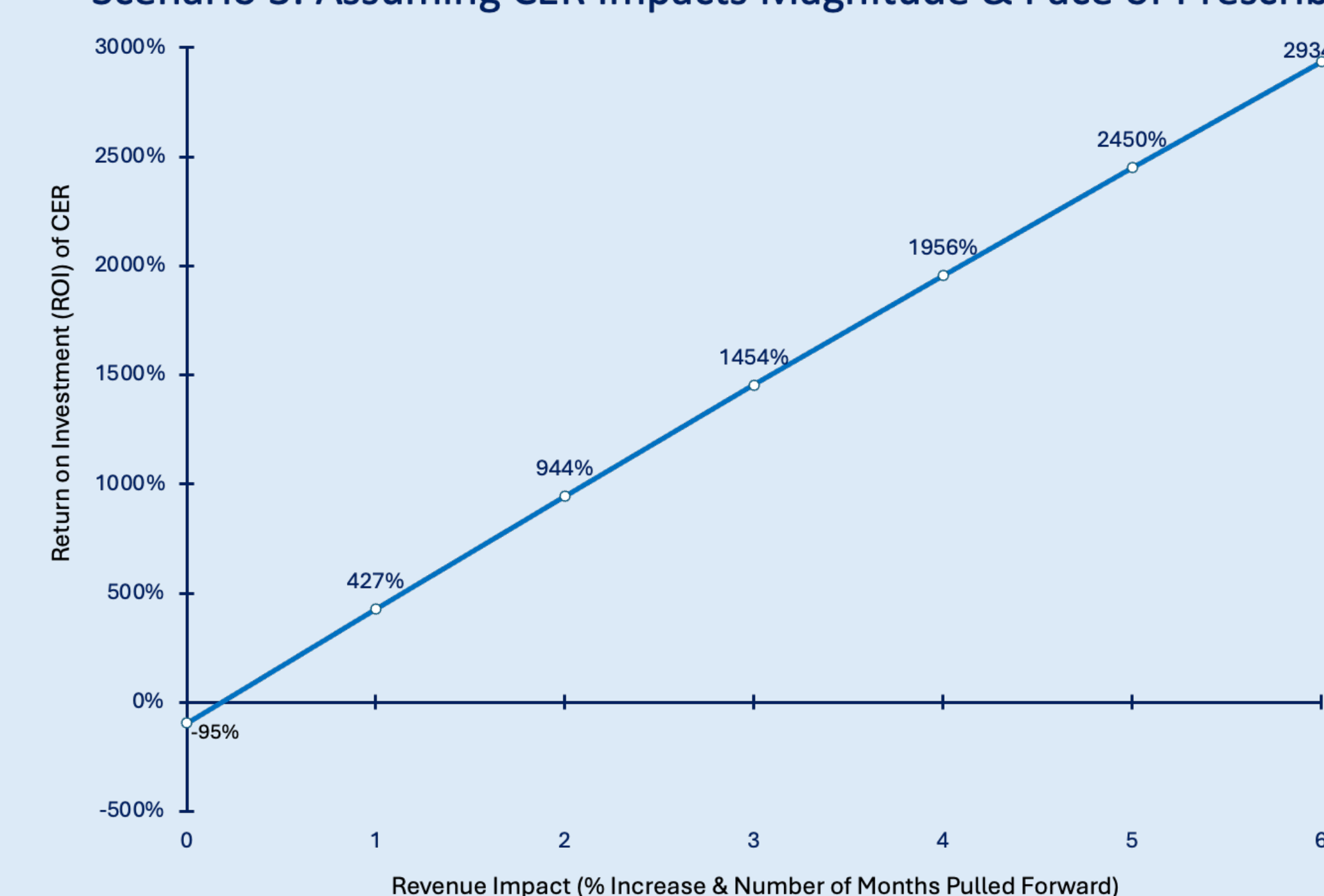
Scenario 1: Assuming CER Impacts Magnitude of Prescribing



Scenario 2: Assuming CER Impacts Pace of Prescribing



Scenario 3: Assuming CER Impacts Magnitude & Pace of Prescribing



Discussion

- Disentangling the influence that a CER project had on product uptake is a challenge amidst the wide array of commercialization activities that biopharma companies employ
- Even in project planning, predicting the unique impact of a CER project on future within-label drug prescribing is a speculative undertaking
- ROI framework has utility in this context as a planning tool that allows deliberate consideration of risks, costs, and potential impacts of CER in user-defined “what-if” scenarios of interest
- Our illustrative scenarios considered potential impacts on within-label prescribing and showed that even small impacts attributable to CER would yield a positive ROI:
 - A 1% increase or 1-month acceleration in prescribing each have a positive ROI as individual effects
 - Both of these effects combined yield a 4-fold ROI
- Of note, these ROI estimates would scale higher (lower) for products with higher (lower) peak revenue potential

Conclusions

- As part of a well-articulated commercialization strategy, CER utilizing secondary RWD can yield a positive ROI to a biopharmaceutical company by increasing and/or accelerating within-label product prescribing
- When input data are lacking, ROI framework can yield useful insights in “what-if” analyses of alternative scenarios in project planning

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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
- Funding:
 - The ROI of HEOR Working Group, with its respective affiliations, jointly funded this research



Figure 1. Decision-Analytic Model of CER Investment

