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

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Disclosures

I am employed by Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA and may own stock and/or options in Merck & Co., Inc., Rahway, NJ, USA

Should industry consider ROI when planning HEOR work?

Cons

- Non-promotional investment
- Relatively small investments
- Data needs and complexity / uncertainty
- Necessity for access
- RWE costs is already factored into program ROI
- Risk concentrating resources in few programs and countries

Pros

- Routinely assessed for clinical programs
- More research ideas than resources
- Systematic and fair process
- Optimize research investment portfolio
- Allocates resources to maximize benefit
- Strengthen value recognition for HEOR organization

Should industry consider ROI when planning HEOR work?

Yes

…but, consider:

- General principles and high-level estimation
- Necessary versus strategic investments
- Multi-purpose and interconnected research
- Diminishing returns and diversification

Consideration 1: Finite Inputs and High Level Estimation

Project Type	Probabilities	Payoffs
• External Control Arm	• Trial success • Regulatory approval • Favorable access / reimbursement	• Earlier time to access
• Economic Modeling Quality	• Regulatory approval *(invariant to modeling)* • HTA success	• Earlier time to access • Acceptance of value-based price
• Comparative effectiveness research	• Study success • Expanded access	• Increase uptake • Reduce erosion

Assessment at a high level: be mindful of the probabilities and the payoffs

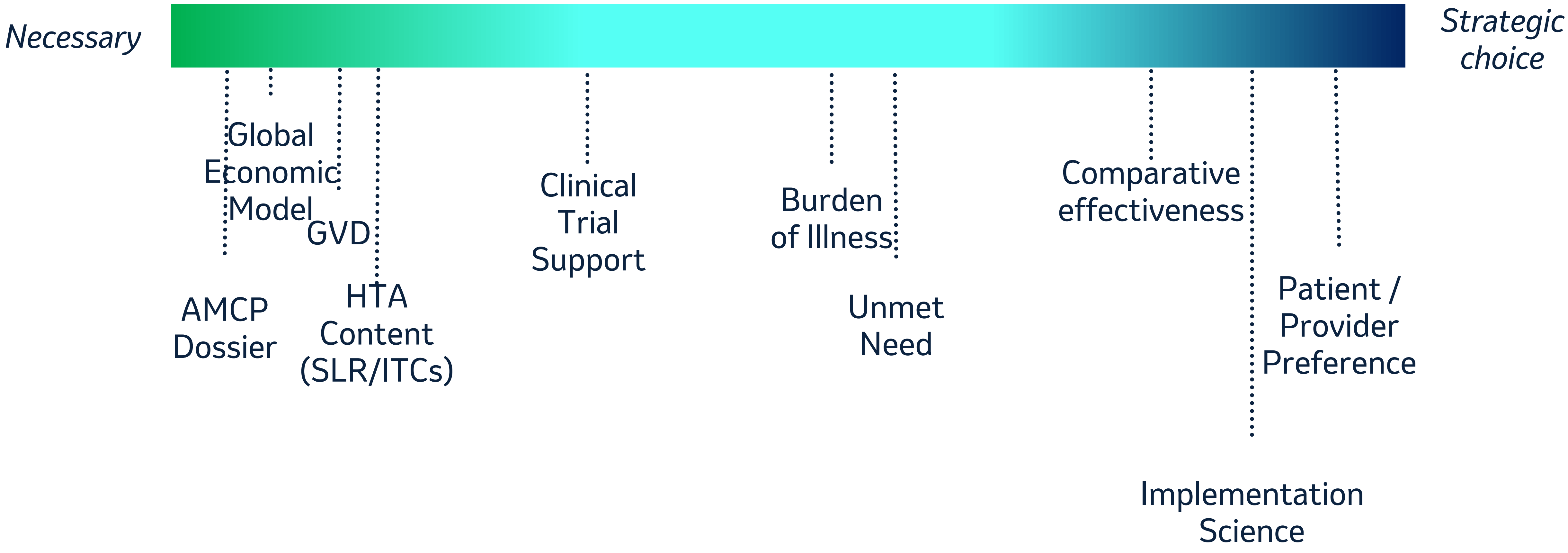
Q's for probabilities

- Who is this information for?
- What decision is informed by the information?
- How important is this data for the decision?
- How will they receive the information?
- How certain are we of the approach?

Q's for payoffs

- What is the total size of the opportunity?
- What is current / future market share (or patient share)?
- How much could this change with new information?
- When will we complete the study?
- What is remaining life of the product?
- What is future competitive landscape?

Consideration 2: Necessary versus strategic investments



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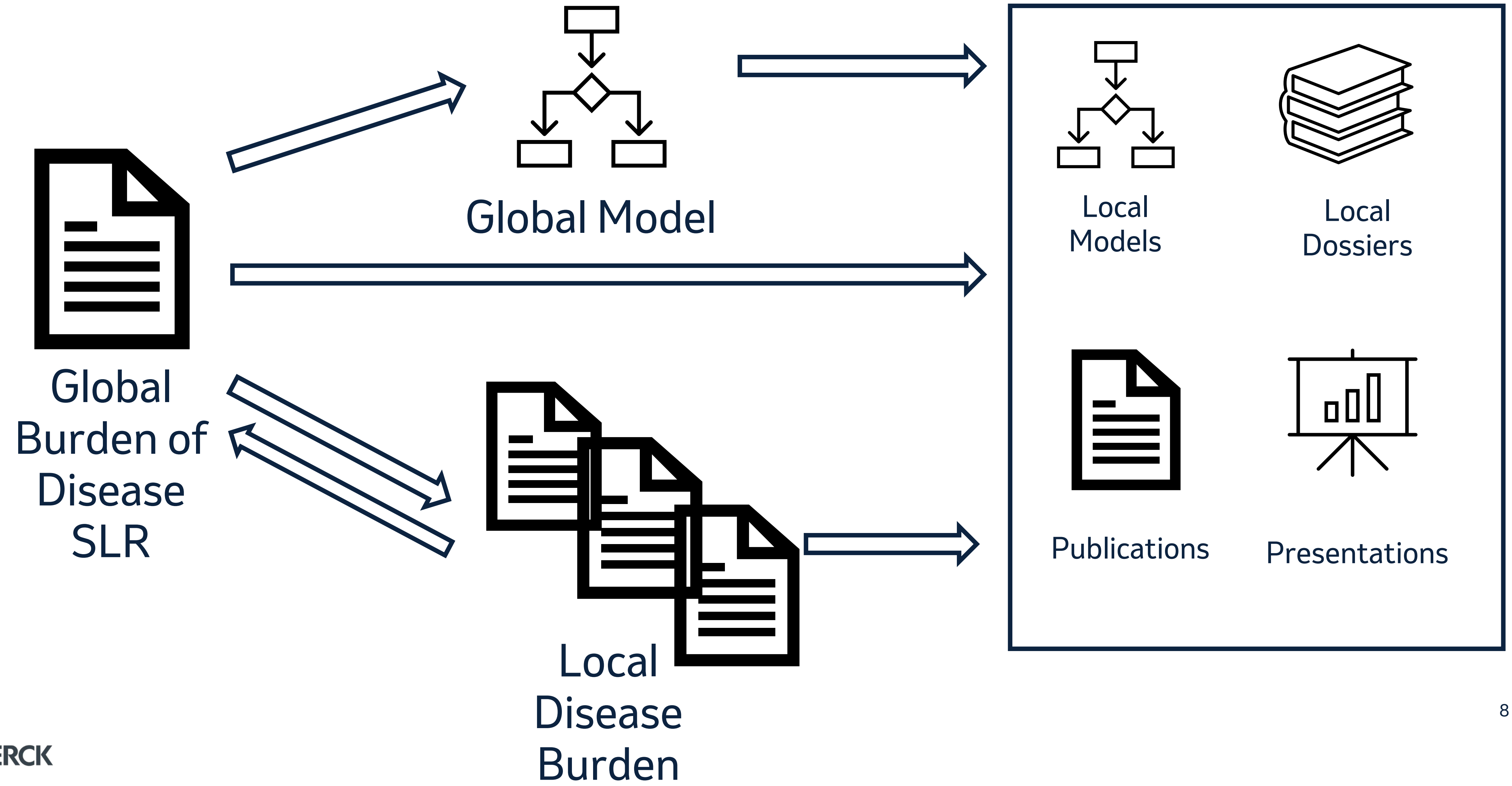
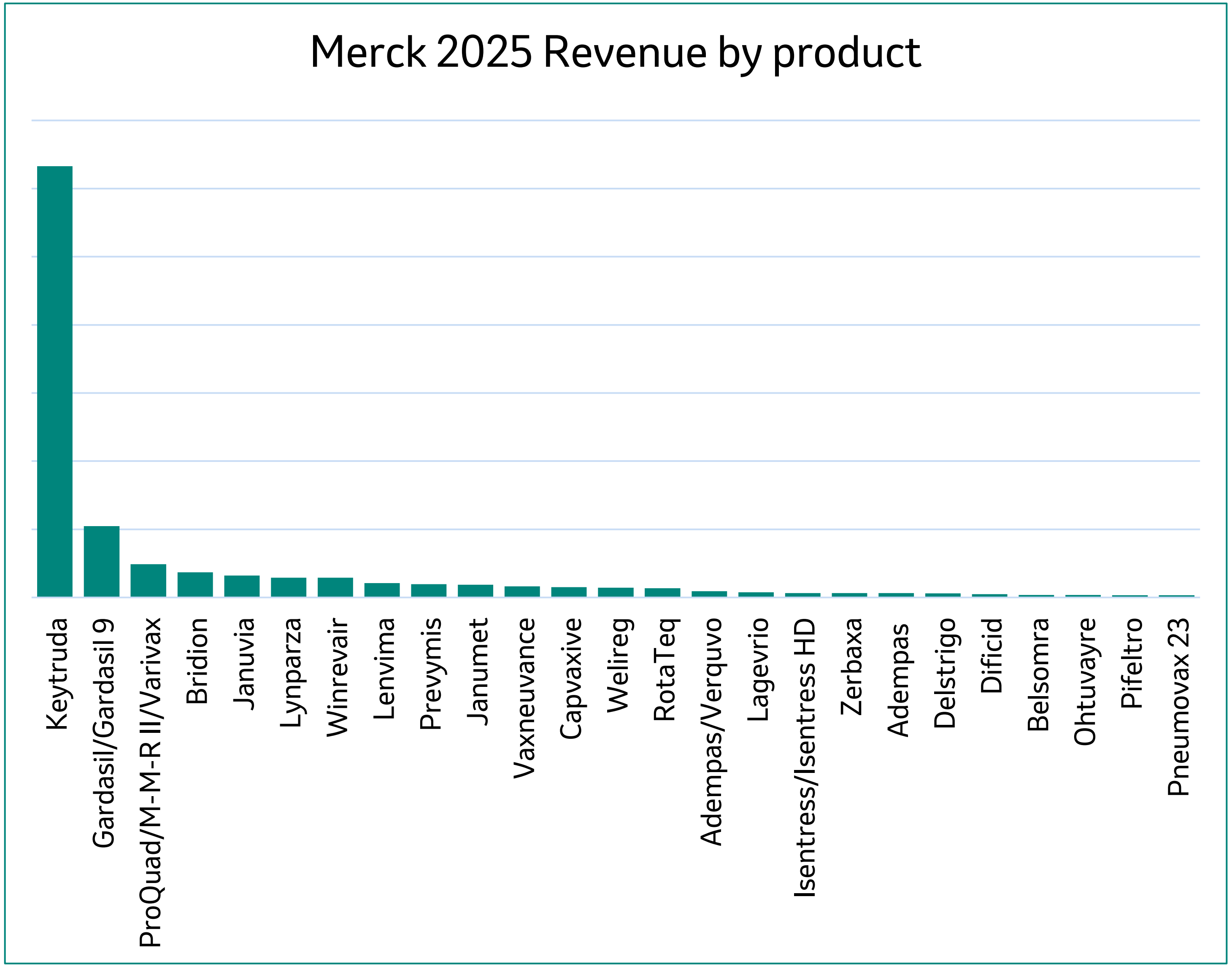
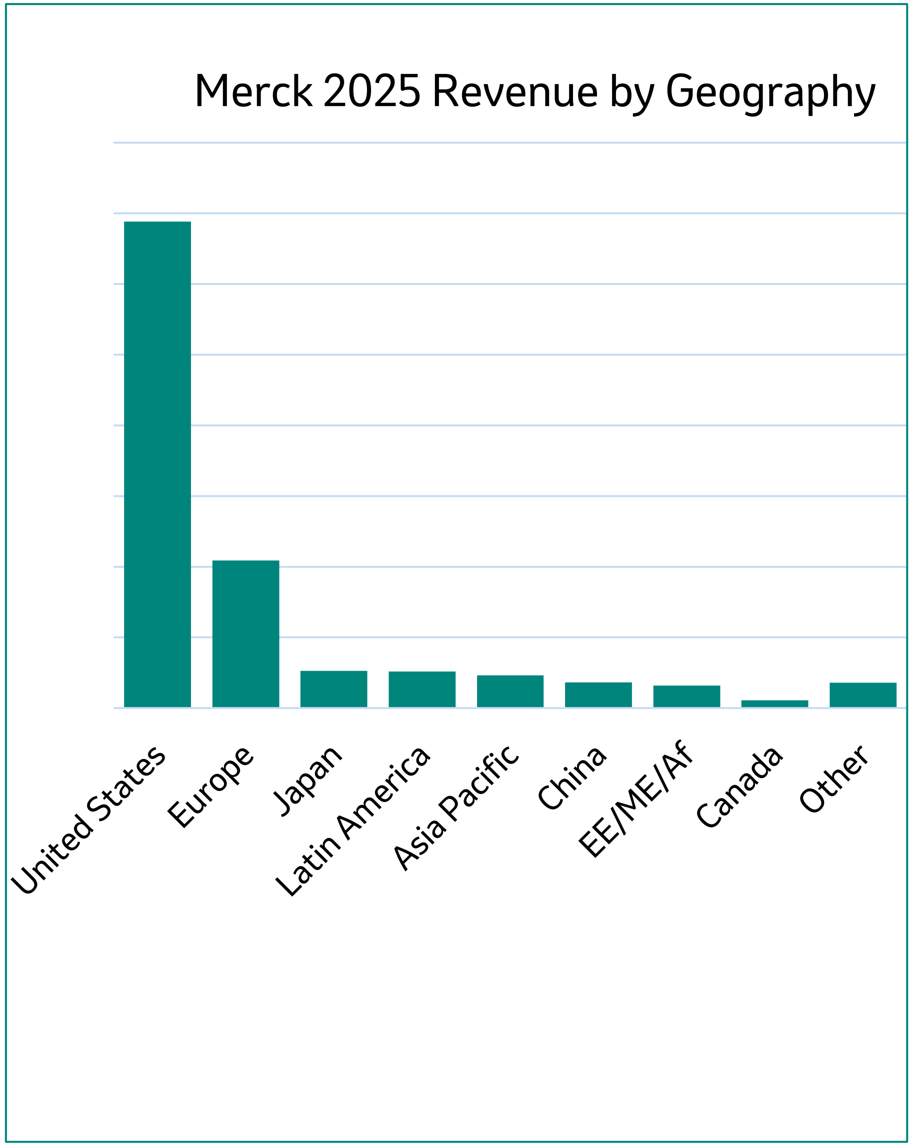
Consideration 3: Multipurpose and interconnected research



Consideration 4: Diminishing returns and diversification





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Additional Considerations for ROI of HEOR work

- $250k is 0.025% of $1.0 B: a small change in uptake can generate positive return
- Cost of investment often a minor factor when payoff is large
- ROI is several fold higher early in the life of a product
- Communication of information is important to fully realize ROI
- Equity considerations may be important, particularly in low / middle income countries or diseases of public health interest

How a team may consider ROI across a proposed research portfolio

- For small investments, consider interrogating the probabilities and payoffs
- Differentiate between necessary work (post-approval reimbursement) and strategic investments
- Consider the product size and lifecycle when allocating research budget, as well as diminishing returns and diversification
- Consider direct ROI assessment when investment level is high
- *Speak the language and communicate value!*

Thank you

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