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INTRODUCTION

- In the competitive landscape of the pharmaceutical industry, the success of a new drug depends not only on its scientific and clinical attributes but also on its market acceptance and positioning¹
- Early value assessment (EVA) is a new evidence-based approach designed to improve the care of people through quicker access to promising health technologies that address national unmet need²
- It champions stronger partnership working between regulatory, healthcare and research organizations to benefit people and better support innovators while ensuring value for money for the stakeholders²
- Value may mean differently to different stakeholders, however, for a pharmaceutical company, capturing this multi-dimensional value across the key stakeholders early by identifying and de-risking the uncertainties is critical

OBJECTIVE

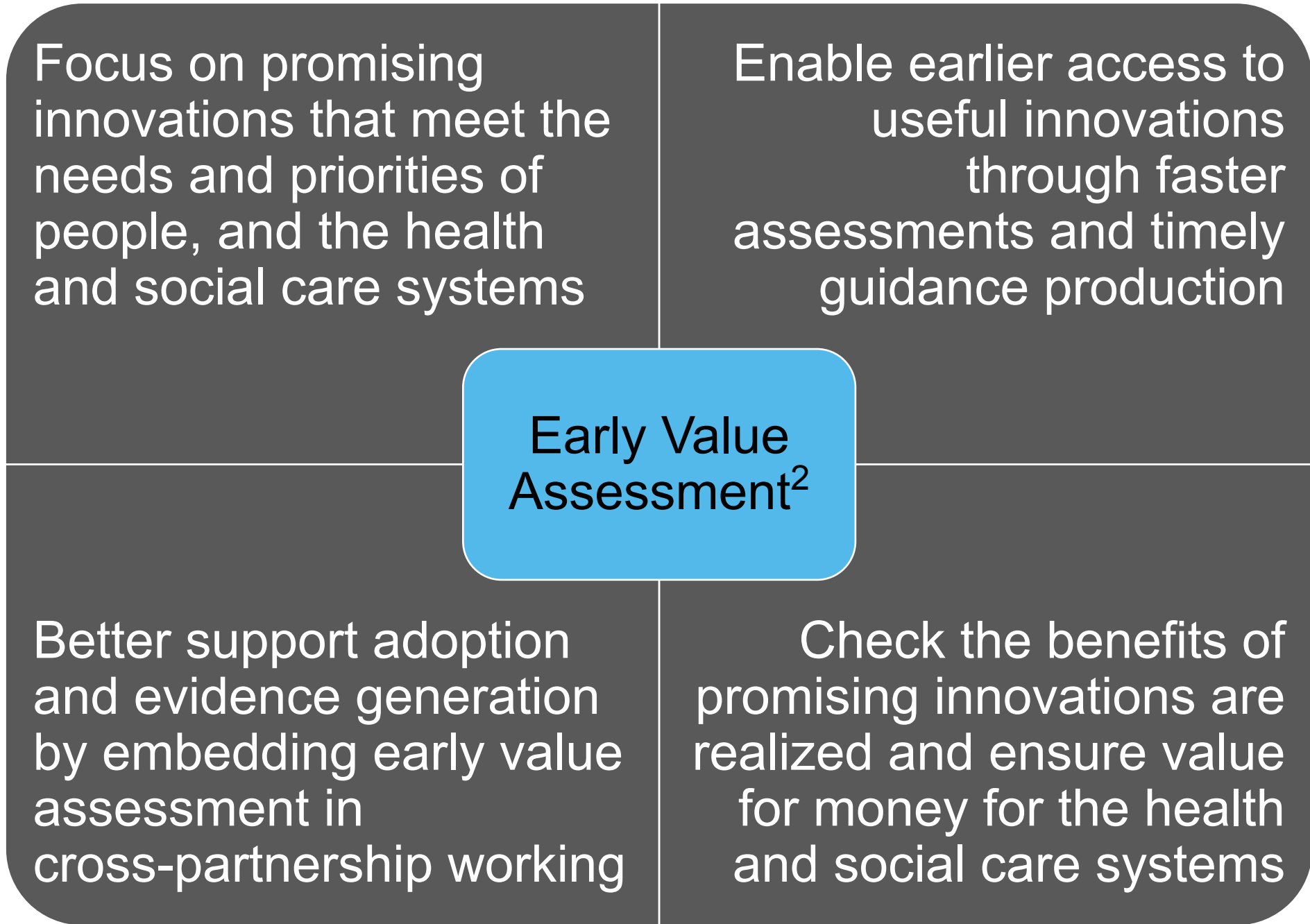
- The overall goal of this research was to understand the significance of strategic early valuation in facilitating a successful drug launch, as well as to identify the critical and influencing factors

METHOD

- Conducted a literature review of relevant academic literature, market access reports, HTA (Health Technology Assessment) documents, and recent publications in Health Economics and Outcomes Research (HEOR) to identify critical attributes for early assessment of pharmacologic therapies
- Systematically analyzed the HTA and Market Access reports to understand the impact of early value assessment on drug launch

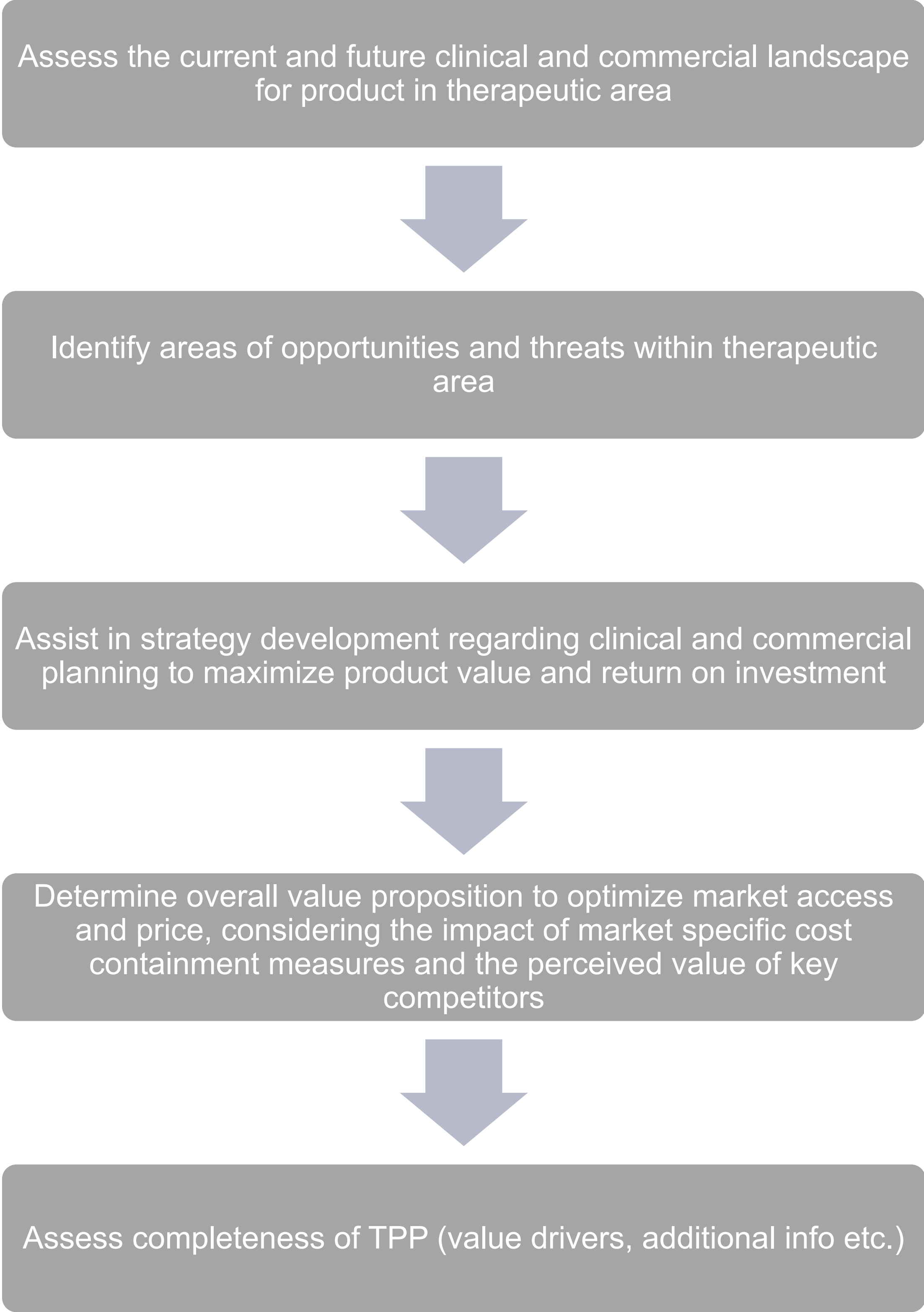
RESULTS

- EVA process and methods explores in detail the potential of technologies to address unmet need; assess existing evidence; and identify key gaps in evidence³
- This also produces greater opportunities for stakeholders and health system partners to understand and support further evidence generation for promising new technologies³
- The process involves a comprehensive evaluation of various factors such as epidemiology, disease burden, unmet needs, clinical efficacy, safety, competitive landscape, and the market dynamics⁴
- A value map based on critical data from the variables helps provide an understanding on where the drug asset falls from a clinical and economic value perspective⁴



Product-Specific Evidence Generation	Competitive Landscape	Market-Specific Health System Dynamics	Manufacturer's Negotiation Power and Portfolio Strength	Unmet Need and Patient Population
<ul style="list-style-type: none">• Drug name• Dosing• Target patient population• Safety and efficacy• Manufacturer information with portfolio strength	<ul style="list-style-type: none">• Existing products• Patient population• Comparative safety and efficacy• Cost-effectiveness	<ul style="list-style-type: none">• Current trends• Market share• Risk and barriers to market entry• Current and future competitive landscape	<ul style="list-style-type: none">• Drug pricing• Past/Future Drug Design• Reputation of company	<ul style="list-style-type: none">• Epidemiology• Economic and humanistic burden of illness• Limitations with existing treatments

Key Steps in Early Value Assessment⁴



CONCLUSIONS

- Given that drug launch decisions are often made years before commercialization, an accurate early value assessment can influence the development path, regulatory strategy, and market-entry approaches
- The EVA approach enables a rapid, early, evaluation of technologies clinical effectiveness and value for money
- Using a systematic early drug value assessment, key stakeholders and decision makers can pre-emptively identify opportunities to enhance a product's value proposition, thereby optimizing pricing and access

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