TELLING THE WHOLE STORY: AN INTEGRATED APPROACH TO VALUE PROPOSITION CREATION

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Market shifts are underway, emphasizing the need for value propositions that are more seamless and integrated across functions. Adapting to these changes will be critical if manufacturers want to maximize pricing opportunities and avoid missing opportunities to generate data to demonstrate their product's value effectively with different audiences.

The most robust value propositions require expertise from strategy, clinical, value and evidence, as well as agency execution, but the siloed nature of many manufacturers can make this an operational challenge. By leveraging an integrated, cross-functional approach to value proposition development, manufacturers will gain the ability to define evidence gaps, opening up more opportunities to partner with potential payers in order to close those gaps.

This article will examine some of the market trends currently underway that are driving the need for a more integrated approach to value proposition development. We will also detail EVERSANA's approach to creating more value from the value story by eliminating siloes and redundancies and aligning the value story with the health economic strategy, which is ultimately reflected in payer marketing materials.

Market Evolutions

Multiple U.S. market evolutions are impacting the value and access of new medicines (see sidebar). With the continued increasing costs of healthcare, greater scrutiny is being put on value-based pricing in the U.S., and this focus is putting pressure on manufacturers to define and articulate the value of their medicines for payers, providers, and patients. Payers and organized providers need an early line of sight into new treatment options to manage their business and enhance access to the best medicines for their members. To support this need, there have been multiple emerging efforts ranging from policy to healthcare stakeholder approaches and frameworks.

Price Reform and Transparency

A priority for the U.S. federal government is reducing the cost of prescription drugs, and the current administration has put forth a number of proposals to achieve this.[1] First, the administration wants to allow Medicare to negotiate drug prices. Second, the administration would like to establish a cap on the amount that Medicare beneficiaries have to pay out of pocket for drugs each year.

The administration also plans to build on steps already taken, including an executive order designed to allow the federal government to work with local or regional healthcare authorities to import lower-cost prescription drugs from Canada and accelerate the development and uptake of generic and biosimilar drugs.

The Rise of Value Assessment Frameworks

Multiple stakeholders and advocacy groups are driving the coverage conversation to be more value-based. Notable organizations that have proposed or implemented value assessment frameworks include the Institute for Clinical and Economic Review (ICER), the American College of Cardiology, the American Heart Association, the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), Memorial Sloan Kettering Cancer Center (MSKCC), USC-Schaeffer Group, ISPOR, Innovation and Value Initiative, and the National Pharmaceutical Council.

Market Evolutions

End of savings from the patent cliff, a focus on personalized medicine and targeted treatments (often for rare diseases), the emergence of biosimilars, and increasing use of HTA frameworks to assess the cost effectiveness of products

Currently available value assessment frameworks vary widely in their focus and approach. ASCO, MSKCC, and NCCN focus on cancer drugs, whereas others such as ICER have a broader purview. ASCO and NCCN are geared toward physician-patient shared decision-making, whereas ICER focuses on payers and health plans. ICER incorporates conventional Cost Effectiveness Analysis that uses the outcomes metric of the QALY, whereas others do not.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has recently collaborated with leading experts and key stakeholders to inform guidelines to a "U.S. Value Assessment Framework" for payers to consider when assessing value, specifics about context and perspectives, incremental costs and benefits, and development of value thresholds. This initiative culminated with the creation of seven Special Task Force Reports, were published in a themed issue of *Value in Health* in February 2018.

Ultimately, regardless of the focus or approach, the result is a requirement to demonstrate that the pricing of the product is commensurate with the overall value to the healthcare system.

Continued Emphasis on Value Assessment Frameworks Expected in the Future

We expect payers to adopt these value frameworks in the future. Manufacturers will need to prepare evidence-backed messaging to resonate in this changing environment. A more structured approach with more standardized measures of value will be needed.

It will also be important to incorporate insights, demonstrated by real-world evidence and economics, into the patient journey and experience, the overall value strategy, in addition to identifying areas where value can be strengthened. Use of RWE is becoming more and more accepted to demonstrate value, and manufacturers should be leveraging randomized control trials and real-world evidence (RCT+RWE) in value strategies.

The Future of Value Proposition Strategy

The future of value proposition strategy requires alignment across the entire organization, with the ability to customize the value story for different audiences, whether it is an IDN, an MCO, a PBM, etc. A good value story also needs to be backed by scientific rigor; it should be researched and tested; and it should be co-created, getting payers' input on the story prior to finalization.

EVERSANA delivers a turnkey approach regardless of whether the manufacturer is a fully staffed commercial organization or emerging biopharmaceutical company. We bring all of the necessary functions—strategy, clinical, health economics and outcomes research (HEOR), as well as agency execution—and can work with companies in a tailored way while offering efficiencies as a result of all functions being part of one company. The strategy group identifies the potential of the product to meet the unmet need. The clinical team can create the defendable scientific story, weaving together literature and scientific product information. HEOR adds economic evidence, aligned with the product objectives, and the agency creates materials that resonate with stakeholders.

EVERSANA also often pressure-tests the value proposition with cross-functional teams on the client side, mirroring client functions and working closely with them while giving them space to focus on their overarching strategy. In addition, we can bring in data and analytics. With access to claims data, we can analyze historical data and further pressure-test hypotheses. The resulting evidence can be used to bolster future messages and fill evidence gaps.

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Anatomy of a "Value Proposition"

The ideal approach to creating and supporting a value strategy includes a phased approach that builds on prior work.

Phase 1

Phase 1 of the process involves the development of a Value & Evidence Platform. The Value & Evidence Platform serves as a repository of evidence, value messages, and sources of the data referenced. It also includes claims to be used in payer communication materials and a gap assessment and roadmap for future evidence generation to advance the value story.

- Supports the brand aspiration (Brand Today/Brand Tomorrow; internal ambition statement for the brand)
- Comprehensive, internal strategic document containing a list of the core unbranded and branded value message pillars, secondary supporting messages, and takeaways within each pillar
- All messages supported by existing evidence derived from clinical trial data, real-world evidence, and other published data
- All content appropriately referenced

Phase 2a

Phase 2 brings in the Global Value Dossier and the Payer Value Proposition (PVP) messages. The Global Value Dossier is the core reference document, capturing all clinical, safety, and economic evidence. Given that it is central to the payer communication strategy, it should be a strategic tool that weaves in the value story throughout. Regional Dossiers can be developed based on the Global Value Dossier and can be used to support payer/HTA review at launch.

- External, clinical document that contains the product's comprehensive summary of clinical efficacy, safety, and health economic data
- Format to follow a specified framework; may be global or follow regional specifications (e.g., AMCP dossier)

Phase 2b

The PVP provides a directed payer value story derived from data based on the Value & Evidence Platform. It is an internal-facing document that is more common for global or earlier-phase products, and it can be used pre-approval (PIE deck in the U.S.—see sidebar) and post-approval (PVP).

- Strategic resource that identifies the story flow and can be a foundation for payer messaging (may be an internal or external resource, based on client needs)
- Articulation of cogent value story that is tailored by customer archetype (e.g., plan type, stakeholder segment)
- Contains "elevator speech" summary
- Can be executed as a static PowerPoint or interactive digital initiative

Pre-approval Information Exchange (PIE)

Mechanisms are in place to engage payers before a product has been approved as payers are thinking about cost. While there has always been regulation and guidance on how manufacturers can engage with payers in an economic conversation before a product is approved, those guidelines were codified in the United States through the 21st Century Cures Act, which amended FDAMA 114 to expand the audience for communications and allow dissemination of underlying clinical information supporting economic comparisons.

Phase 3

Phase 3 brings in the Value Story Collateral Materials. These are developed after the Value Story has begun and can be developed in parallel with the PVP.

External, supplemental resources developed to highlight key elements of the value story and reinforce customer engagement

Tactical execution can include Value Briefs, Formulary Kit Product Monograph, Digital/ Omnichannel Assets, Congress Presentation (e.g., AMCP Science & Innovation Theater, Asembia)

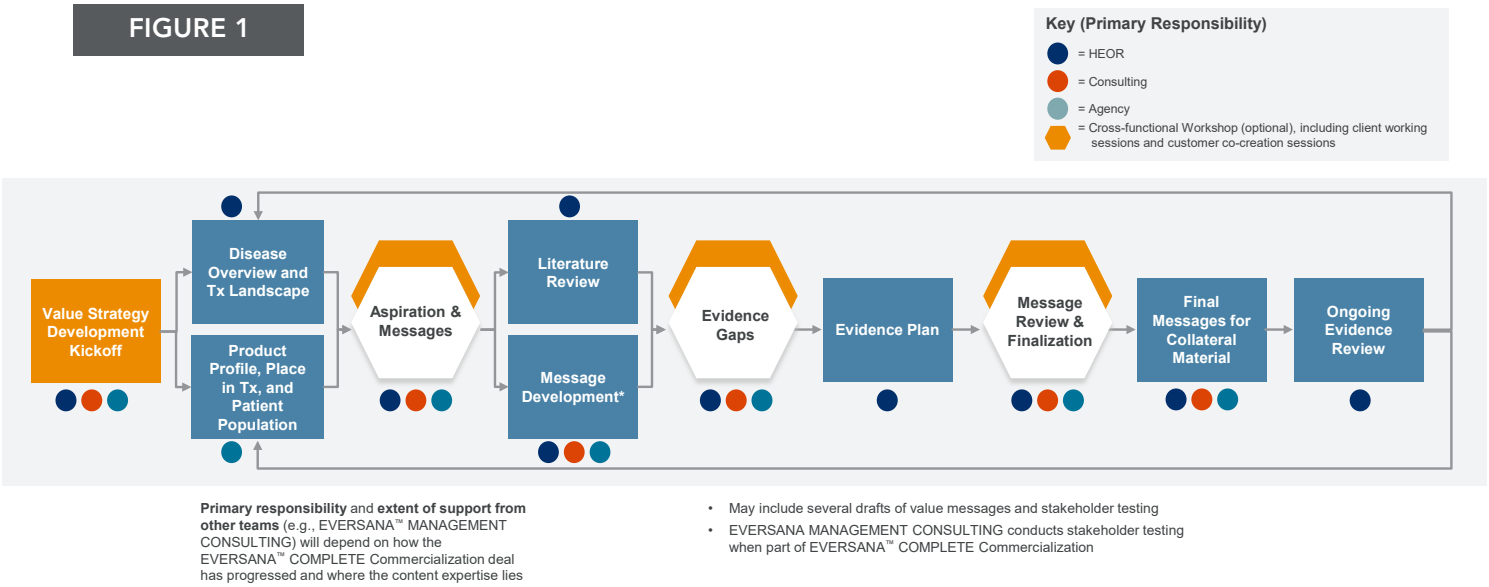
The Integrated Approach

In EVERSANA's COMPLETE Commercialization approach to value story development, experts from three functions—Management Consulting, HEOR, and Agency—are brought together to create a single, integrated team to guide development of the value story. Beyond these three core groups, we seamlessly tap into the deep expertise across EVERSANA to bring forward innovative value propositions and value strategy.

The cross-functional EVERSANA team members remain involved throughout development of all four components of the value story. The truly integrated team participates in frequent, regular internal team meetings to ensure alignment across work streams while best meeting client needs.

Phases 1 and 2 are the most collaborative—with significant involvement from Management Consulting, HEOR, and Agency —as the value platform and value proposition provide the foundation for other value materials.

FIGURE 1

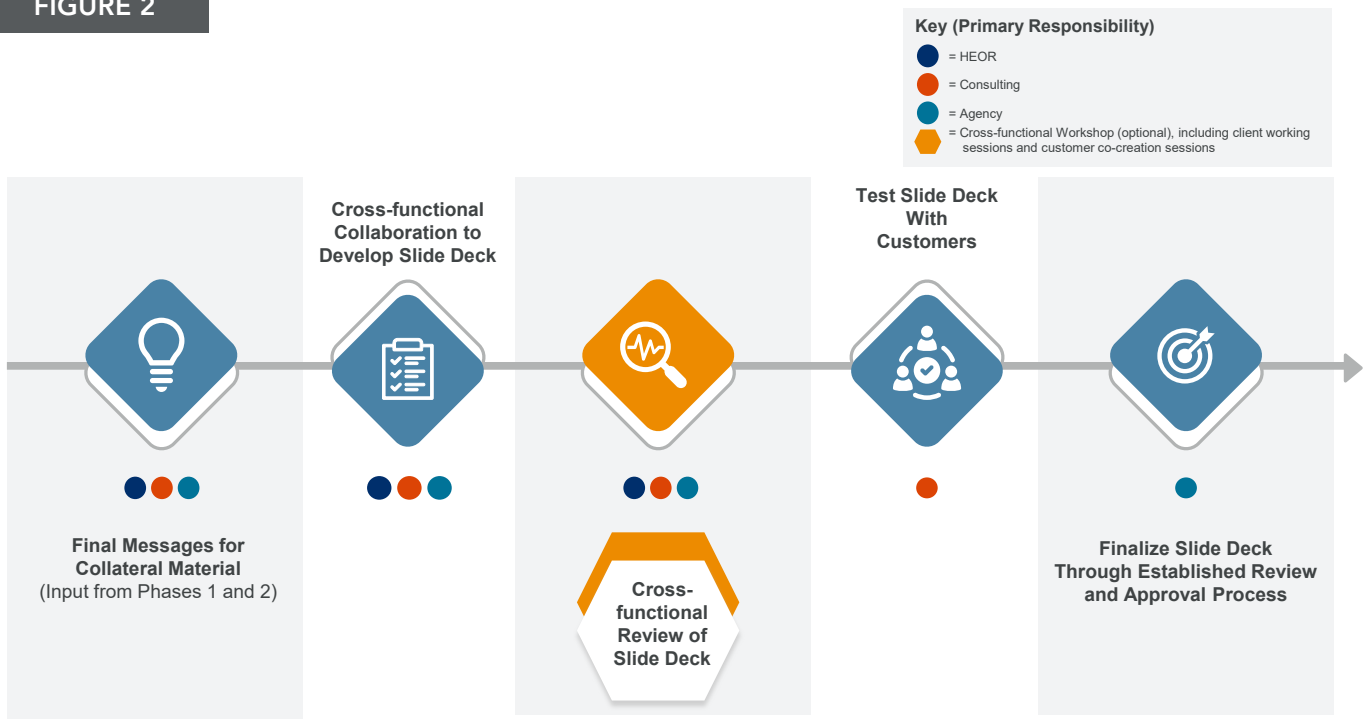


Primary responsibility and **extent of support from other teams** (e.g., EVERSANA™ MANAGEMENT CONSULTING) will depend on how the EVERSANA™ COMPLETE Commercialization deal has progressed and where the content expertise lies

- May include several drafts of value messages and stakeholder testing
- EVERSANA MANAGEMENT CONSULTING conducts stakeholder testing when part of EVERSANA™ COMPLETE Commercialization

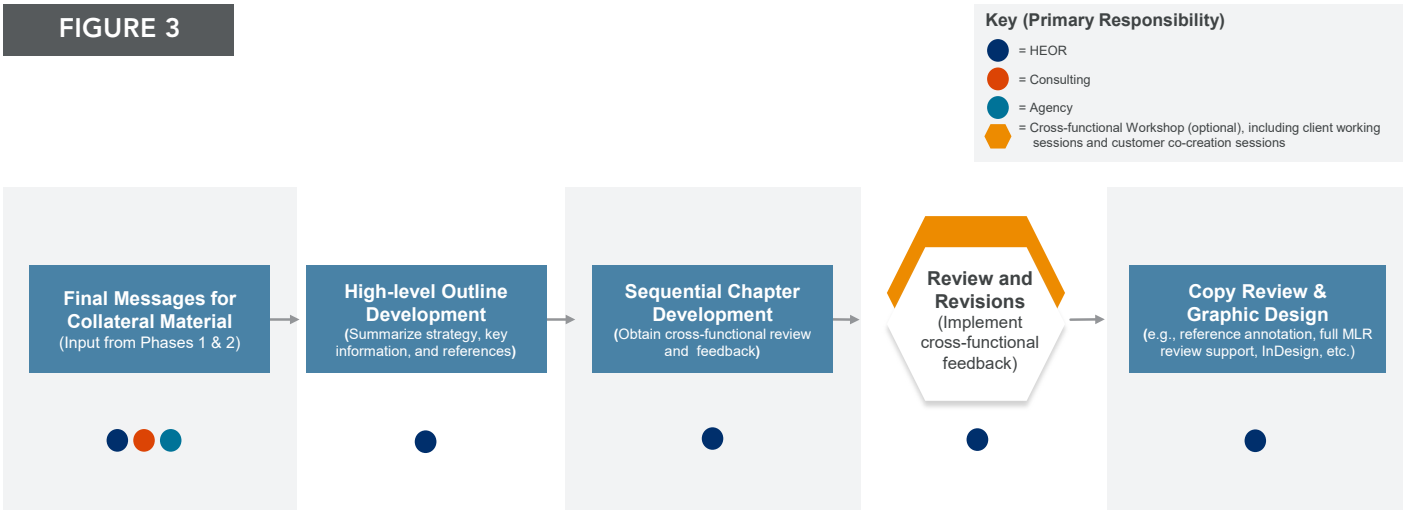
As the process shifts more fully to Phase 2, the Agency takes the lead for Value Story Core Materials Development, with the Consulting team responsible for stakeholder testing and all three business units aligning on output.

FIGURE 2



The HEOR team then develops the Global Value Dossier with some input from Consulting and Agency, with all team members aware and aligned with the output.

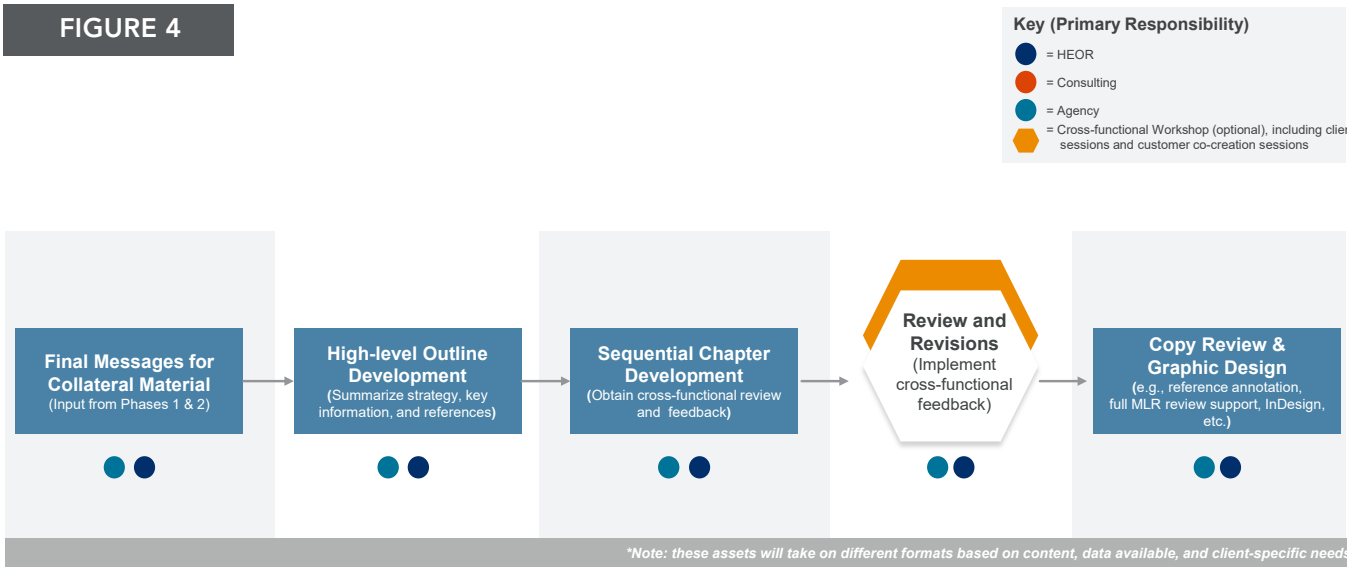
FIGURE 3



Then, in Phase 3, both Agency and HEOR develop value collateral materials. Ownership will be based on client needs and objectives of the materials. Materials can include:

- Formulary Kit/Product Monograph
- Value Brief
- AMCP Science & Innovation Theater Sessions
- Budget Impact Model/Cost-effectiveness Model
- Evidence Compendium
- Omnichannel Assets (to take on different formats based on content, data available, and client-specific needs)

FIGURE 4



Conclusion

A more efficient, impactful value proposition is critical because the market is evolving, with the rise of high-cost products for rare and ultra-rare diseases. Meanwhile, our stakeholders are also evolving, with increasing use of HTA frameworks to assess the cost effectiveness of products. And our time continues to be precious, which makes an integrated approach an ideal solution. Because we are integrated, our partners can have confidence that their value proposition is integrated, differentiated, and impactful.

The EVERSANA COMPLETE Commercialization approach delivers high-intensity launch support, with Management Consulting, HEOR, and Agency working cross-functionally with all EVERSANA teams to incorporate the value story consistently throughout the launch effort. The integrated approach leverages scientific rigor to meet any type of company's needs, with a team composed of all required skill sets (across teams), ensuring consistency of the value story across deliverables. It offers time and cost efficiencies and the ability to tap into central services for such activities as literature searches, market research, and creative/digital services. Finally, it offers a completely seamless one-stop shop for the manufacturer and full consistency of messages across deliverables.

References

[1]FACT SHEET: Executive Order on Promoting Competition in the American Economy, available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/. Accessed September 15, 2021