Research Article ISSN 2693-2504

Journal of Bioscience & Biomedical Engineering

A Value-First Commercialization Framework for Wound Care Technologies

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Submitted: 9 Nov 2026; **Accepted:** 21 Nov 2026; **Published:** 25 Nov 2026

Citation : Yung-Chie (2026). A Value-First Commercialization Framework for Wound Care Technologies. *J B & Bio Engine 6*(3): 1-9. DOI : https://doi.org/10.47485/2693-2504.1068

Abstract

Bringing innovative wound care technologies into clinical practice requires evidence of clinical performance, usability, and affordability in the intended market. This Perspective proposes a Value–Need–Affordability (VNA) framework for wound care technologies, with a focus on medical devices. The framework distinguishes unmet medical needs from the practical needs of patients and caregivers and uses these needs, measurable value, and affordability to guide product design. Early market research examines care pathways, treatment burden, reimbursement, procurement, pricing, and partner capabilities. These findings inform product specifications, evidence planning, and launch sequencing alongside regulatory assessment, manufacturing scale-up, and intellectual property planning. Digital tools, including artificial intelligence, may support wound measurement, remote follow-up, and the collection of outcomes in routine care. Their use depends on whether they address a defined need and can be validated for the intended setting. A hypothetical device illustrates how the framework could inform design and market access decisions before design specifications are finalized. The framework offers a set of propositions for future evaluation.

Keywords: Affordability, commercialization, digital health, market access, medical devices, patient needs, wound care

Introduction

Chronic wounds, including diabetic foot ulcers, venous leg ulcers, pressure injuries, and other difficult-to-heal lesions, are associated with prolonged inflammation, impaired tissue repair, infection risk, disability, and substantial healthcare utilization (Everett & Mathioudakis, 2018; Jalilian et al., 2020; Mavrogenis et al., 2018). Effective wound management frequently requires debridement, pressure offloading where appropriate, vascular assessment, infection control, glycemic management, and maintenance of a suitable local wound environment (Singh et al., 2005).

For biotechnology and medical device companies, the central commercialization challenge is often framed as a question of product differentiation: how unique is the technology, how novel is the mechanism, or how superior is the product profile? This article proposes a different starting point. In wound care, technological uniqueness has commercial value only when it resolves an important medical need, addresses practical patient and caregiver needs, creates measurable clinical or economic value, and remains affordable enough to be adopted. Therefore, innovation should be treated as an enabling tool rather than the primary commercial objective.

A conventional innovation-first process frequently begins with a technology or product concept and only later asks where it should be launched, how it will be reimbursed, what price the market can sustain, or whether patients can use and afford it. The proposed value-first process reverses this order. Medical need, patient need, value, and affordability are assessed before finalizing design specifications. Market research, launch sequencing, reimbursement, pricing, and partner strategy become upstream development inputs rather than downstream launch activities.

This Perspective presents a value-first commercialization framework for wound care medical devices. It proposes that product features and evidence plans should reflect unmet medical needs, patient and caregiver needs, measurable value, and affordability. The framework draws on the author's experience in healthcare commercialization, particularly in wound care, and is informed by published clinical, regulatory, and market access literature.

The Value–Need–Affordability (VNA) Framework

The Value–Need–Affordability (VNA) framework uses three dimensions to guide wound care commercialization. The need dimension distinguishes unmet clinical needs from the practical needs of patients and caregivers. Together with value and affordability, these two aspects of need yield four development questions.

The framework contains four linked questions. First, medical need: Which clinical problem remains insufficiently addressed by current wound care practice? Second, patient need: What barriers, burdens, preferences, adherence challenges, and daily-use requirements matter to patients and caregivers? Third, value: What measurable improvement would matter to clinicians, providers, payers, procurement bodies, and health

systems? Fourth, affordability: Can patients or health systems sustainably pay for the solution at the frequency and duration required in real-world wound care?

Only after these four questions are answered should the developer finalize the target product concept, evidence plan, price range, launch sequence, and partnership model. The framework therefore places market access inside the design process rather than at the end of it.

Conceptual Contribution of the VNA Framework

Unmet medical need, patient-centered design, value assessment, affordability, health technology assessment (HTA), and market access are established concepts in healthcare development. The contribution of the VNA framework lies in how it integrates and sequences these concepts. It uses the four development questions to guide product definition, evidence generation, pricing, launch sequencing, and partnership strategy.

The framework treats the product profile as the outcome of an early assessment of needs, value, and affordability. The author proposes this sequence as a testable approach to wound care commercialization.

Materials and Methods

The author developed the VNA framework from experience in healthcare and biotechnology commercialization and examined it in light of five bodies of literature and guidance:

1. chronic wound healing research,
2. regulatory definitions and classification principles for medical devices,
3. device design, risk management, manufacturing, and usability,
4. patient preferences and health technology assessment, and
5. international market access and licensing.

The sources informed the framework and the development questions it addresses.

The framework evaluates wound care innovation across eight domains: unmet medical need; patient and caregiver need; value creation; affordability; device design and usability; evidence generation; market sequencing and access; and licensing/partner strategy. The analytical sequence is value-first rather than product-first. Product profile, claims, technical features, and innovation choices are treated as downstream outputs of this upstream analysis.

No new patient-level data were generated or reanalyzed. Numerical findings from previously published studies are cited solely as examples of how public evidence can inform development hypotheses, endpoint selection, risk assessment, and future study design. The manuscript does not claim equivalence between any published investigational product and an undisclosed new device.

Table 1: The proposed Value–Need–Affordability framework for wound care commercialization.

VNA element	Core question	Research required at design stage	How it changes development
Medical need	Which important clinical need remains unmet?	Disease burden; current treatment failure; unmet clinical need; care-pathway bottlenecks	Defines the priority indication and clinically meaningful outcome
Patient need	What matters to patients and caregivers in real-world use?	Patient interviews; preference research; adherence barriers; convenience; treatment burden	Changes usability, frequency, packaging, training, endpoints, and support model
Value	What measurable benefit matters to decision makers?	Clinical benefit; workflow impact; resource utilization; payer/provider value; comparator analysis	Defines evidence endpoints and economic value proposition
Affordability	Can patients and health systems afford continued use?	Reimbursement; out-of-pocket exposure; willingness to pay; procurement; cost-to-serve; channel margin	Shapes design-to-cost, price range, package configuration, launch sequence, and partner model

Commercialization Propositions

Commercial Proposition 1: Value Precedes Product Profile

The first proposition is that product profile should not be the starting point of commercialization. A product profile becomes meaningful only after the developer has identified the unresolved medical problem, the patient burden, the value required by decision makers, and the affordability threshold. A highly differentiated technology may still fail commercially when these conditions are not met, whereas a less technically novel solution may achieve stronger adoption if it resolves a high-priority need at an acceptable total cost.

Commercial Proposition 2: Patient Need Is a Design Variable

Materials from the U.S. Food and Drug Administration (FDA) on patient preference information recognize that patients and caregivers may value benefits, risks, and product attributes differently from clinicians or manufacturers, and that patient-preference information can inform medical device design and the selection of clinical study outcomes. In wound care, patient needs may include ease of application, pain, mobility, treatment frequency, dressing burden, caregiver dependence, visibility of healing progress, travel burden, and out-of-pocket cost. These variables should be investigated before finalizing design specifications rather than treated as post-launch feedback (FDA, 2026b).

Commercial Proposition 3: Affordability Is Part of Innovation

Affordability should be treated as a design constraint rather than a discounting exercise performed after launch. If the expected clinical and economic value cannot support the required price, the developer should reconsider product configuration, target segment, evidence burden, manufacturing model, packaging, service requirements, or launch geography before further investment. In this sense, affordability research is a feasibility test of the innovation itself.

How Published Evidence Can Inform Development

Wound repair is metabolically demanding and requires coordinated immune activity, cell migration, angiogenesis, extracellular-matrix formation, and re-epithelialization. Preclinical research has explored the role of cellular-energy availability in tissue regeneration. Experimental systems for delivering adenosine triphosphate (ATP) have accelerated wound repair in several animal models (Chiang et al., 2007; Howard et al., 2014; Mo et al., 2020; Sarojini et al., 2017; Wang et al., 2010).

Published studies have examined adenine salvage pathways and AMP-activated protein kinase (AMPK) signaling. Cheng et al. (2015) reported AMPK activation by adenine in endothelial cells. Young et al. (2021) described accelerated wound healing in a preclinical model of diabetes after modulation of an adenine salvage pathway. These studies inform hypotheses about cellular energy regulation in wound repair.

Published mechanistic and clinical evidence can reduce scientific uncertainty and inform future study design, but it cannot establish equivalence or substitute for validation of a new finished device. This distinction is particularly important in wound care, where formulation, delivery, intended use, standard of care, and patient heterogeneity may materially affect outcomes.

Lessons from Published Clinical Wound-Healing Evidence

A multicenter, randomized, double-blind phase II trial reported by Yang et al. (2022) evaluated ENERGI-F703, an adenine-containing topical gel, in diabetic foot and leg ulcers. The study is useful here as a published example of clinical translation from a bioenergetic wound-healing hypothesis to human investigation. It is not presented as evidence for any unpublished product.

In the intention-to-treat population, complete ulcer closure at the end of treatment occurred in 36.7% of patients in the ENERGI-F703 group and 26.2% in the vehicle group. The 95% confidence interval for the between-group difference included zero. Exploratory subgroup analyses suggested larger differences in selected groups. The investigators noted limitations related to wound classification, pressure offloading, and heterogeneity of the study population (Yang et al., 2022).

These findings illustrate several transferable development lessons. First, wound heterogeneity can dilute treatment effects. Second, classification systems and wound location can affect interpretation. Third, standard-of-care procedures, especially offloading and infection control, should be specified prospectively. Finally, a clinically plausible signal does not eliminate the need for a product-specific evidence program.

Table 2: Clinical development considerations informed by published wound healing studies.

Clinical issue	Published lesson	Implication for future device development
Wound heterogeneity	Response can vary by ulcer grade, size, site, and underlying disease	Define a clinically coherent target population and prespecified strata
Outcome measurement	Complete closure is clinically meaningful but slow and sensitive to follow-up design	Combine closure with validated dimensional and time-to-event measures where appropriate
Standard of care	Off-loading, infection control, debridement, and vascular management affect outcomes	Standardize background care to reduce confounding
Safety interpretation	High-risk wound populations often have substantial comorbidity	Distinguish device-related events from disease-related morbidity
External evidence	Published studies can reduce uncertainty	Do not substitute public evidence for finished-device validation

Medical-Device Regulatory Strategy

Regulatory classification should be assessed early because it determines the applicable evidence pathway. In the United States, a product must meet two conditions related to its mechanism to qualify as a device. Chemical action in or on the human or animal body cannot be how the product achieves its primary intended purposes, and achieving those purposes cannot depend on the product being metabolized (FDA, n.d.-a; FDA, 2017). In the European Union, a device must achieve its principal intended action by means other than pharmacological, immunological, or metabolic means. Such means may assist its function (European Parliament & Council of the European Union, 2017).

Early publications can focus on general development principles while regulatory classification and intellectual property review are underway. The development team should align proposed product claims with design inputs, risk management, biological safety, usability, and the evidence plan.

Regulatory timelines depend on classification, novelty, risk class, clinical evidence requirements, quality system readiness, and the applicable regulatory pathway.

Design Control, Manufacturing, and Intellectual Property

Commercial acceleration begins with design discipline. Critical performance attributes should be defined before pivotal validation. For a wound-contact device, these may include physical stability, material compatibility, microbial quality, packaging integrity, usability, and reproducibility of application. The specific values and proprietary engineering solutions, however, should remain confidential until adequately protected. Human-factors and usability engineering should be incorporated early to reduce use-related risks and improve safe, effective use in intended environments (FDA, 2026a).

Manufacturing scale-up can introduce changes in mixing, filling, rheology, container performance, and material interactions. Technology transfer should therefore include validated specifications, supplier controls, change management, stability programs, and traceable manufacturing records.

Intellectual-property strategy should be integrated with technical development. Potentially novel composition, device architecture, use claims, manufacturing know-how, digital integration, and combinations of these elements should be evaluated before broad disclosure. From a commercialization perspective, strong protection and freedom to operate can increase partnering value while allowing the scientific publication to focus on generalizable development principles.

Digital Tools and Artificial Intelligence in Wound Care

Digital wound assessment is becoming increasingly relevant to clinical practice. Published reviews describe the use of image analysis and machine learning for wound recognition, segmentation, tissue classification, dimensional measurement, healing-trajectory assessment, and remote follow-up (Rippon et al., 2024; Reifs Jiménez et al., 2025). Three-dimensional imaging may add depth and volume information to conventional photography, although stronger standardization and prospective validation are still needed (Mehl et al., 2025; Zhao et al., 2024).

Within the VNA framework, digital technology should be adopted only when it addresses a defined need. Examples include reducing measurement variability, making wound progress easier for patients and clinicians to understand, supporting remote follow-up, improving adherence, reducing unnecessary visits, or creating structured longitudinal evidence. The relevant question is therefore not whether AI makes a product more innovative, but whether the digital function creates measurable clinical, patient, workflow, or economic value.

Digital tools may also contribute to market access by improving real-world outcome collection and postmarket evidence. Predictive or diagnostic functions, however, require appropriate validation, representative datasets, data governance, cybersecurity, human oversight, and regulatory assessment. Digital capability should therefore remain a supporting component of a wound care value proposition rather than the central basis of commercialization.

Global Commercialization and Market Access

Regulatory authorization in an initial market may support licensing discussions by demonstrating readiness for that jurisdiction. Launch sequencing should be evaluated before regulatory submission. Relevant criteria include whether clinical evidence can support later submissions, whether patients can obtain the product, and whether local partners can support registration, reimbursement, distribution, clinical education, and engagement with healthcare institutions.

A general commercialization framework can organize markets into three archetypes: reference markets, where regulatory and clinical credibility can create external validation; strategic growth markets, where local scale justifies dedicated licensing or access planning; and partner-led regional markets, where local registration, reimbursement, distribution, and affordability considerations favor collaboration. Market research should begin during early development and continue through design verification, evidence generation, and launch preparation.

Market access should also reflect local affordability and payment architecture. Aggregate GDP alone is insufficient; pricing and access decisions should consider GDP per capita or household income, healthcare expenditure, reimbursement coverage, out-of-pocket burden, public versus private procurement, comparator pricing, treatment duration, and patient ability to pay. Health technology assessment adds further dimensions by evaluating comparative clinical benefit, cost implications, organizational impact, and broader social considerations. Accordingly, a device may meet regulatory requirements yet face barriers to adoption if its evidence does not address payer or procurement needs.

An affordability-sensitive licensing framework can permit different price ranges, packaging approaches, evidence plans, and channel strategies across regions while preserving a common clinical and quality platform. Pricing should be developed as a corridor rather than a single global number: the upper boundary is constrained by demonstrated clinical and economic value and relevant comparators, while the lower boundary is constrained by cost-to-serve, channel economics, partner margins, and sustainable supply. The final local price should then be tested against reimbursement, procurement thresholds, and patient affordability.

Table 3: Commercialization roadmap for an innovative wound care device.

Stage	Primary question	Core activity	Protected information	Academic output
Need and value discovery	Which clinical and patient needs should the device address, and what benefits should it deliver?	Unmet-need analysis, patient burden; care pathway; stakeholder value mapping; affordability threshold	Confidential product concept and proprietary implementation details	Value-based design brief and go/no-go criteria
Design and verification	Can the device perform reproducibly?	Bench testing, biological safety, usability, stability, risk controls	Engineering specifications and manufacturing know-how	Design-control framework
Product-specific evidence	What evidence supports the final claims?	Clinical/performance validation appropriate to classification	Unpublished protocol details and competitive strategy	Evidence-generation principles
Reference-market readiness	Is the dossier transferable and partner-ready?	Quality system, regulatory package, clinical evidence, health-economic rationale	Confidential regulator feedback and filing tactics	General regulatory-commercial integration
Licensing and regionalization	Which partnership model fits the market?	Partner diligence, registration, reimbursement, distribution, pricing	Named partners, deal terms, launch sequence	Licensing and affordability framework
Post-market learning	How will adoption and outcomes be monitored?	Real-world evidence, complaints, training, adherence support	Proprietary analytics and algorithms	Post-market evidence principles

Using Market Access Research to Inform Product Design

Market access should be treated as a design input because medical need, patient need, value, and affordability can all change what should be built. Market research at the concept stage should determine whether the intended technology solves a sufficiently important problem, whether patients can realistically use it, whether the resulting outcomes matter to decision makers, and whether the required price can be sustained. Only after these questions are answered should the target product concept be finalized.

A practical VNA process begins with four workstreams running in parallel: clinical unmet-need analysis, patient-need research, value mapping, and affordability analysis. The outputs then feed into launch sequence, evidence planning, target price, reimbursement strategy, partner requirements, and product design. This reverses the common sequence in which a technology is developed first and market access is addressed later.

This design-stage logic is consistent with the European Union health technology assessment framework, in which Joint Scientific Consultations allow health technology developers, including medical device developers, to obtain advice during planning of clinical studies and investigations on evidence needs for subsequent joint clinical assessment (European Commission, n.d.).

Launch sequencing should also follow value logic rather than market size alone. The first market should be the one that creates the strongest combination of unmet need, patient access, evidence leverage, reimbursement feasibility, price sustainability, and downstream licensing value. A smaller market may rationally precede a larger one if it creates stronger reference evidence or a more credible value benchmark.

Pricing strategy should begin during design because affordability can invalidate a technically attractive concept. Early price research should test the willingness and ability of payers, providers, patients, and distribution channels to support the expected total cost of treatment. If the target price is not sustainable, this is not merely a commercial problem; it is evidence that the product concept, cost base, service model, or target segment may need redesign. This approach is consistent with HTA principles that consider clinical, economic, ethical, and social value and the implications of adoption and reimbursement (World Health Organization, 2025).

Table 4: Value-first commercialization workflow: from medical need to launch.

Development stage	Market-access question	Research activity	Design/evidence consequence	Decision output
Need / value discovery	What problem is worth solving, for whom, and at what affordability threshold?	Epidemiology; care pathway; unmet need; patient burden; buyer/payer mapping; comparator scan	Initial value requirements, user, setting, and affordability target	Go/no-go on value proposition
Feasibility / design	Can the proposed product achieve and sustain market access?	Early price research; affordability; channel economics; partner interviews	Claims, configuration, pack size, service model, cost target	Design-to-value requirements
Evidence planning	What additional evidence is needed to support market access?	Payer/HTA evidence gap analysis; endpoint and comparator research	Clinical endpoints, follow-up, resource-use and patient-reported outcomes	Integrated evidence plan for regulatory and market access requirements
Market sequencing	Which market should launch first and why?	Regulatory feasibility; evidence transferability; access complexity; competition; partner capability	Dossier architecture and localization plan	Reference / strategic / partner-led sequence
Pre-launch	Can the market adopt at the intended price?	Pricing corridor; reimbursement pathway; procurement; Consultation with clinical experts and distribution partners	Final value proposition, contracting and education plan	Launch readiness and price range
Post-launch	Is value demonstrated in routine use?	Real-world evidence, adherence, utilization, budget impact, complaints	Label expansion, training, access refinement	Lifecycle evidence and geographic expansion

Applying the VNA Framework to a Hypothetical Device

Consider a hypothetical chronic-wound device whose developers initially believe that technical novelty will be the main basis of differentiation. Before finalizing design specifications, they apply the VNA framework. Medical-need research shows that clinicians are less concerned with novelty itself than with delayed healing, repeated dressing changes, infection-related visits, and workload. Patient research shows that frequent clinic attendance, painful dressing changes, caregiver dependence, and cumulative out-of-pocket expense are major burdens.

Value mapping then shows that different decision makers define success differently: clinicians prioritize reliable healing and usability; providers value reduced visits and staff time; payers value lower total episode cost; patients value convenience, pain reduction, independence, and affordability. These findings change the development plan. The company adds resource-use and treatment-burden outcomes to the evidence strategy instead of relying only on a wound-closure endpoint.

Affordability analysis shows that the original device configuration would require a price sustainable in a high-income reference market but unrealistic in settings with higher out-of-pocket payment. Rather than simply discounting after launch, the company redesigns packaging, service requirements, and channel economics. It also considers a digital option: AI-assisted wound measurement and remote follow-up are added only if they can reduce unnecessary visits, improve adherence, or generate evidence that offsets their implementation cost. The first launch market is selected on evidence leverage, patient access, reimbursement feasibility, and future licensing value rather than epidemiological size alone.

The hypothetical example illustrates how identifying unmet needs, defining measurable value, and testing affordability could inform product design, evidence generation, and launch sequencing.

Table 5: Illustrative market-prioritization matrix for the hypothetical wound care device.

Market archetype	Regulatory leverage	Evidence transferability	Access/affordability	Partner need	Illustrative role in sequence
Reference market A	High	High	Moderate complexity	Moderate	Early credibility / value benchmark
Reference market B	High	High	HTA and country-level access variation	Moderate	Evidence validation / regional leverage
Strategic growth market	Moderate	Partial; localization often needed	Price and local access highly relevant	High	Dedicated licensing after core evidence matures
Partner-led regional markets	Variable	Variable	High affordability sensitivity	Very high	Staged expansion with local partners

Table 6: Potential digital and AI applications within a value-first wound care strategy.

AI application	Potential medical/patient need	Potential commercial value	Key evidence requirement
Automated wound segmentation and measurement	Reduce manual variability and documentation burden	More reproducible outcomes; lower workflow burden	External validation across wound types, devices, skin tones, and care settings
3D depth/volume assessment	Improve assessment of irregular or deep wounds	Richer monitoring and clinical-study data	Validated acquisition protocol and repeatability
Healing-trajectory prediction	Identify wounds not progressing as expected	Earlier intervention; risk stratification; potential resource savings	Prospective validation, calibration, and clinically meaningful thresholds
Remote monitoring / telemedicine	Reduce travel and visit burden; support adherence	Expanded reach; continuity of care; potentially fewer unnecessary visits	Usability, privacy, workflow integration, and outcome evidence
AI-supported real-world evidence	Quantify longitudinal outcomes and utilization	Supports payer, HTA, licensing, and postmarket discussions	Data quality, governance, representativeness, interoperability

Discussion

The VNA framework uses unmet clinical needs, patient and caregiver needs, measurable value, and affordability to guide product definition. These inputs can also inform evidence planning, pricing, launch sequencing, and selection of commercial partners.

Published mechanistic, preclinical, and clinical studies can inform endpoint selection, risk assessment, and study design. Evidence on a different product can guide these decisions, while claims for the finished device require evidence appropriate to its intended use.

The timing of intellectual property review can influence which development details are appropriate to disclose. Publications can describe the framework, evidence requirements, and development decisions while protecting confidential technical and commercial information.

Regulatory authorization is one step toward adoption. Clinical workflow, procurement requirements, reimbursement, and patient affordability also influence uptake. Assessing these conditions early can inform device design and distribution plans. This approach is consistent with the FDA's Total Product Life Cycle perspective (FDA, n.d.-b).

Digital functions can be evaluated separately from the core device during early development. Their inclusion depends on technical feasibility, clinical utility, intellectual property considerations, and applicable regulatory requirements.

Market research can guide development decisions. Clinical and patient research can inform the target population and use requirements. Stakeholder research can identify outcomes relevant to clinicians, providers, payers, and patients. Affordability research can inform the target cost, pricing, and launch sequence.

AI functions should be evaluated against the needs they are intended to address, such as reducing measurement variability, supporting adherence, or improving workflow. Evaluation should consider performance in the intended setting and the cost of implementation.

Limitations

This article is a Perspective rather than a report of a new clinical study. The VNA framework is based on industry observation and synthesis of published evidence and has not yet been prospectively validated. Its propositions should therefore be tested in future product-development programs, comparative case studies, or empirical research.

The ENERGI-F703 trial is used only as a public example of clinical translation in wound healing. Its findings cannot be extrapolated to an undisclosed new device. The study's heterogeneous wound population and methodological limitations further support cautious interpretation (Yang et al., 2022).

Regulatory classifications and timelines vary by jurisdiction and depend on the final intended purpose, claims, risk class, and principal mode of action. Likewise, affordability cannot be inferred from GDP alone. Country-specific regulatory and market-access assessment remains necessary.

Finally, intellectual property, regulatory, reimbursement, and pricing conditions vary across jurisdictions. The framework is intended as a strategic development model and should be adapted to the legal, regulatory, clinical, and economic requirements of each market.

Conclusion

The VNA framework proposes four questions to address before finalizing the product profile. Which clinical need remains unmet? What do patients and caregivers need in routine use? What outcomes would demonstrate value to patients, clinicians, and economic decision makers? Can patients and health systems afford the technology at the expected frequency and duration of use? The answers can inform product specifications, evidence requirements, pricing, reimbursement planning, and launch sequencing. Future studies could examine how applying the framework affects development decisions, adoption, and affordability across markets.

Acknowledgments

The author acknowledges the researchers and organizations whose published work informed this Perspective.

Funding

This work received no external funding.

Conflict of Interest

The author declares no conflicts of interest.

Ethics Statement

Not applicable. This article is a perspective and does not report new research involving human participants.

Data Availability

No new datasets were generated.

Author Contribution and Editorial Assistance

The article concept, VNA framework, structure, industry observations, interpretation, and conclusions were developed by the author. AI tools were used only for language editing, formatting, and reference organization. The author reviewed and approved the final manuscript and is responsible for its content.

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