Proceedings of Business and Economic Studies, 2025, Volume 8, Issue 7
http://ojs.bbwpublisher.com/index.php/PBES
Online ISSN: 2209-265X
Print ISSN: 2209-2641

Analysis of Key Pathways for the Technological Innovation and Clinical Translation of Medical Devices

Bo Xu*

Chinese Medicine Education Association, Beijing 100071, China

**Author to whom correspondence should be addressed.*

Abstract: Medical devices, as the core support of the healthcare industry, are directly linked to the enhancement of healthcare service quality through their technological innovation and clinical translation efficiency. However, the field still faces a series of challenges throughout the entire value chain, including misalignment of demand, insufficient collaboration, and a lack of engineering capabilities, which hinder the clinical application of many innovative results. Based on the actual conditions of the industry, this paper provides a comprehensive analysis of key issues in various stages, such as source innovation, medical-engineering collaboration, pilot-scale translation, clinical trials, and policy support. Subsequently, targeted optimization strategies are proposed, offering references for advancing the translation of medical device innovations from the laboratory to clinical application, thus achieving a precise match between technological value and healthcare demand.

Keywords: Medical devices; Technological innovation; Clinical translation; Medical-engineering integration; Pilot-scale development

Online publication: December 9, 2025

1. Introduction

The healthcare model is undergoing a transformation toward precision and minimally invasive approaches, which places higher demands on the adaptability and technological innovation of medical devices in clinical settings. Currently, most technological research and development is concentrated on breakthroughs within the laboratory, yet it is often disconnected from actual clinical application scenarios. There is a lack of effective mechanisms for interdisciplinary collaboration, and there are significant gaps in the technical integration and resource consolidation during the translation phase. These existing challenges make it difficult for innovative outcomes to be rapidly implemented, preventing timely responses to the actual needs of healthcare services. This forms the core real-world context for the present study.

1. 1. Overview of technological innovation and clinical translation of medical devices

The technological innovation and clinical translation of medical devices represent a multidimensional system engineering process, involving technological concepts, research and development iterations, engineering adaptation, and ultimately clinical application. It spans key stages such as basic research, technological breakthroughs, product validation, and market access [1]. The central logic is to leverage technological advancements to address practical pain points in clinical diagnosis and treatment, achieving a precise match between technological feasibility and clinical practicality. From a practical perspective, the source of innovation may originate from the clinical experience of healthcare providers or from interdisciplinary technological integration, such as materials science or artificial intelligence. For instance, innovations in minimally invasive surgical devices arise from the clinical demand for minimizing trauma, while upgrades in *in vitro* diagnostic equipment rely on breakthroughs in biosensor technology [2]. During the translation process, the stages include laboratory prototype development, medical-engineering collaboration optimization, pilot-scale production validation, and clinical trial evaluation. Ultimately, after regulatory approval, these innovations can be industrialized and implemented, serving as a core support for enhancing healthcare service efficiency and expanding the boundaries of diagnosis and treatment.

2. Analysis of key issues in the technological innovation and clinical translation of medical devices

2.1. Misalignment between source innovation and real clinical needs

There is often a gap that is difficult to bridge between the refinement of technical parameters and the adaptation to clinical scenarios. The core of this misalignment lies in the disconnection between the source of innovation and clinical needs: on the research and development (R&D) side, there is a tendency to focus on breakthroughs in materials upgrading and algorithm optimization, becoming preoccupied with parameter competition and academic value. However, this often overlooks the practical constraints in clinical diagnosis and treatment [3].

In reality, true clinical demands are often hidden in the details of the treatment process, including the ease of operation, compatibility with existing equipment, as well as patient tolerance and the operational conditions of primary healthcare institutions. Most demand surveys only scratch the surface, failing to immerse R&D teams deeply in clinical settings. As a result, while innovative products may have technological advancements, they often struggle to integrate into actual clinical workflows due to issues such as not aligning with doctors' operational habits or being limited in their adaptation to clinical scenarios. This leads to a dual dilemma of wasted technological resources and unmet clinical needs.

2.2. Insufficient medical-engineering integration and interdisciplinary collaboration in the early stages of R&D

The disconnect between the clinical needs of medicine and the technical implementation logic of engineering is often due to a lack of deeply integrated collaborative mechanisms. In the early stages of R&D, disciplines such as medicine, engineering, and materials science are often working in isolation, with knowledge barriers between them leading to communication errors. The practical requirements of clinicians are difficult to translate accurately into technical parameters, and engineering teams frequently overlook the specific needs of clinical scenarios.

Due to the absence of fixed interdisciplinary joint R&D platforms and communication mechanisms, personnel from different fields find it difficult to advance the development process synchronously. This often leads to technical solutions that fail to meet clinical safety standards or product designs that do not consider the adaptability to treatment workflows. As a result, the R&D direction may diverge from actual needs, product iteration cycles become longer, and in some cases, the process may be forced to halt due to defects in collaboration during the mid-stage.

2.3. Weak engineering and industrialization foundations in the transition from concept validation to pilot-scale development

The technological feasibility demonstrated during the laboratory phase is often difficult to translate directly into stable performance during large-scale production. The core weakness of this phase lies in the lack of engineering conversion capabilities and the absence of industrialization infrastructure. Laboratory trials primarily focus on functional validation but often overlook key elements such as process standardization and the scaling-up of parameters on the production side. During the process scale-up, nonlinear scale effects often cause the failure of parameter transfer, and the shortage of suitable equipment and insufficient capacity for customized modifications exacerbate the disconnect between technologies. Additionally, pilot-scale platforms are often resource-poor, GMP production conditions are not well-established, and the supply chain and quality control systems are incomplete. These issues lead to batch-to-batch variability, high costs, and other problems, ultimately hindering the translation process, and in some cases, even causing it to stagnate [4].

2.4. Issues with clinical trial design quality and insufficient real-world evidence capabilities

The disconnect between the design logic of clinical trials and real-world clinical scenarios, coupled with an underdeveloped real-world evidence (RWE) system, constitutes a critical barrier in the translation process. On the design front, issues often arise, such as overly strict inclusion criteria and insufficient representation of target populations. Additionally, endpoints tend to focus more on surrogate markers rather than core clinical values, and the design of control groups and statistical methods lacks scientific rigor. As a result, the trial results are difficult to generalize to broader clinical settings. Regarding real-world evidence, data sources are fragmented and lack standardization, with quality issues such as missing data and inconsistent coding. Furthermore, the methodologies for bias control and causal inference are insufficiently supported. The lack of transparency in research and poor reproducibility further reduce the credibility of the evidence, making it difficult to gain regulatory approval or be effectively adopted in clinical decision-making, thus delaying the translation of innovative medical devices.

2.5. Insufficient support from financing mechanisms and payment policies for innovation translation

Innovative medical devices are characterized by long cycles and high risks in their translation process, which creates a significant gap between the existing financing and payment systems, forming core barriers in terms of funding and market access during the translation process. On the financing side, there are notable issues such as “early-stage shortfalls” and “mid-stage gaps.” During the early stages of R&D, due to the uncertainty of returns, it is difficult to attract angel investors and venture capital (VC) funding. In contrast, during the pilot-scale and clinical trial stages, the funding needs become more concentrated, but there is a lack of patient capital

and specialized funds to support these efforts, leading to a high risk of funding shortages.

In terms of payment policies, the medical insurance approval process is often lengthy, and the evaluation criteria tend to focus more on cost control rather than fully recognizing the technological value and clinical benefits of innovative products. The pricing mechanisms also lack flexibility. Payment methods based on project-based reimbursement are insufficient to incentivize hospitals to adopt innovative devices. Furthermore, high patient co-payment rates suppress market demand, which ultimately prevents innovative products, even if they are approved, from achieving widespread clinical use or large-scale industrial implementation.

3. Optimization of key pathways from technological innovation to clinical translation of medical devices

3.1. Construction of a source innovation path driven by real clinical needs

To transform implicit clinical demands into practical, actionable technical specifications, a comprehensive "demand discovery - translation implementation - iterative validation" pathway must be established. This pathway should break down information silos and ensure that the clinical side is deeply involved throughout the entire innovation process, rather than merely providing initial needs. A regular clinical needs survey mechanism can be set up, leveraging embedded R&D contacts in clinical departments, on-site observation of diagnostic processes, and patient feedback sessions to fully capture real pain points. The goal is to build a demand conversion model that decomposes qualitative demands into quantifiable technical parameters. For example, addressing the need for improved radiotherapy positioning accuracy for oncology patients in primary healthcare settings, a collaboration could be formed between a top-tier hospital's radiotherapy department and a biomedical engineering team from a university.

Over three months, they would observe and document errors and challenges in the positioning process. Then, a team of clinicians, engineers, and data experts could work together to break down the needs into specific metrics, such as "positioning error ≤ 0.5mm," "≤ 5 steps in the operational process," and "compatible with existing CT equipment in primary care settings." Every three weeks, a clinical trial review would take place to gather feedback from healthcare professionals to optimize the positioning algorithm and interface design. The final product would be a precision positioning device that requires no modification to existing equipment, perfectly fitting the needs of grassroots healthcare settings.

3.2. Strengthening early collaborative design and iterative pathways for medical-engineering integration

To fundamentally resolve the translation challenges caused by disciplinary barriers, it is essential to integrate clinical medical expertise with engineering innovation capabilities from the outset of the R&D process. The key to this pathway is to create a "collaborative and boundaryless, efficient iterative" working model that drives cross-disciplinary forces to coalesce into a powerful innovation synergy.

On one hand, a fixed medical-engineering joint R&D team should be formed, with clearly defined roles for clinical doctors, engineers, materials experts, and quality control specialists. A regular communication mechanism should be established, with weekly meetings to ensure the free exchange of information on R&D data and progress. Collaborative platforms, both physical and online, should be used to share developments in real-time, ensuring that clinical operational needs, technological boundaries, and safety/compliance requirements are constantly communicated.

On the other hand, a closed-loop process of "rapid prototyping - clinical testing - precise iteration" should be established. Technologies such as 3D printing and digital simulation can be employed to shorten prototype development cycles, enabling clinical staff to test product performance in simulated clinical scenarios. For instance, in the case of precision control needs for minimally invasive surgical instruments, clinicians would participate throughout the R&D process, providing timely feedback on issues such as grip feel, operational sensitivity, and compatibility with endoscopic devices. Meanwhile, engineers would adjust structural designs and transmission mechanisms, and materials experts would optimize the instrument's tip material based on surgical force requirements. Each prototype iteration would be completed within two weeks, and after multiple rounds of cross-disciplinary collaboration, the final instrument would meet the precise surgical operation needs while also adhering to clinical safety standards, significantly reducing the risks associated with later-stage adaptations.

3.3. Optimizing the engineering conversion path from concept validation to pilot-scale development

To achieve a smooth transition from laboratory prototypes to large-scale production, it is essential to establish an engineering conversion system that involves process standardization, platform specialization, and supply chain collaboration.

Process parameters should be standardized and scaling-up adaptation work must be promoted. Core parameters from the small-scale trial phase should be reviewed, and scaling models should be constructed using techniques such as digital simulation and orthogonal experimentation. This will help clarify material selection and establish quantifiable standards for the production process. For instance, in the case of *in vitro* diagnostic reagents, simulation technologies can be used to model the impact of different batch reaction conditions, determine the optimal process window, and convert manual laboratory procedures into automated production line parameters, thus avoiding performance fluctuations caused by scale effects.

Specialized pilot-scale platforms should be leveraged to overcome bottlenecks in the translation process. Collaboration with shared pilot-scale facilities can facilitate process validation and small-batch production using GMP-adapted production lines and precision testing equipment. For example, modular production units can quickly adapt to product assembly requirements, while multiple rounds of trial production help optimize production cycles and solve practical issues such as equipment compatibility and process integration.

A collaborative mechanism for the supply chain and quality control (QC) should be established. Early engagement with key component suppliers is essential to clarify quality standards and create a comprehensive QC system. For example, implementing standardized raw material inspection protocols and using IoT technologies to monitor production data in real-time can ensure the stability of product batches and provide a solid foundation for industrialization.

3.4. Enhancing clinical trial design and real-world evidence evaluation pathways

To ensure that clinical trial results align more closely with real-world clinical scenarios and to enhance the scientific rigor and credibility of RWE, an integrated evaluation pathway of "design optimization - data standardization - methodological support" must be established.

Clinical trial designs should be optimized by expanding participant inclusion criteria to enhance representativeness, and focusing endpoint measures on core clinical benefits. For example, in the case of

neurointerventional devices, patients of different ages and with various comorbidities should be included. The primary endpoints should focus on post-operative neurological recovery rates and complication rates, reducing reliance on surrogate markers.

Real-world data management should be standardized by establishing unified data collection standards and coding systems, integrating various data sources such as electronic medical records (EMR) and insurance claims data. For example, standardized templates can be used to extract key clinical and follow-up data, while blockchain technology can ensure data traceability, thus avoiding issues such as missing data or inconsistent coding.

Finally, methodological support should be strengthened by incorporating causal inference and bias control techniques. For instance, propensity score matching can be used to balance confounding factors between groups, and AI algorithms can handle missing data, improving the credibility of the evidence. This approach will provide reliable support for regulatory approvals and clinical decision-making, accelerating the translation process.

3.5. Pathway for achieving the value of synergy between investment and financing policies and payment policies

There is a lack of coordination between investment, financing, and payment policies, which hinders the successful realization of the value of innovative medical devices. Therefore, it is necessary to establish a dynamic, full-cycle investment and financing support system that is adaptable to evolving payment policies. The allocation of funds should be optimized based on the characteristics of each stage of the commercialization process. In the early stage, government-led funds should be utilized to stimulate private capital; in the mid-stage, the role of industrial funds and guarantee mechanisms should be strengthened; and in the later stage, the exit channels in the capital markets should be broadened. A pricing system based on clinical value should be established, and a streamlined process for medical insurance access should be introduced. Additionally, reforms in payment methods should be leveraged to align product benefits with market returns, fostering synergy between policies and capital.

For example, for a novel minimally invasive surgical device, local governments could use specialized medical technology transformation funds to support early-stage research and development. Universities' technology transfer centers could provide intellectual property services, and enterprises could be assisted in connecting with industrial funds to meet the needs of pilot testing and clinical trials. After the product receives approval, it could be included in a fast-track review process for innovative medical devices, and real-world evidence could be used for medical insurance negotiations. A pay-for-performance model could be implemented, incorporating clinical benefits such as reduced surgical trauma and shorter recovery times into the payment assessment criteria. Tax incentives could encourage continuous participation from investment institutions, ensuring a positive cycle of secured R&D funding and the realization of market value.

4. Conclusion

The technological innovation and clinical translation of medical devices are a complex, multi-disciplinary system engineering process. To achieve efficient implementation, it is essential to address critical issues throughout the entire value chain, such as demand misalignment, insufficient coordination, and weak

engineering capacity. The optimization pathways proposed in this paper, such as clinical demand-driven innovation, deep integration of medicine and engineering, seamless translation into engineering applications, upgrading of evaluation systems, and synergy between investment, financing, and payment policies, form a comprehensive solution that spans the entire innovation cycle. The key to these pathways lies in the creation of an integrated mechanism linking "technology-clinical-industry-policy" to ensure precise coordination across all stages. Only by continually strengthening multi-stakeholder collaboration and improving the support system can we expedite the clinical application of innovative outcomes, enhance the quality of medical services, and provide solid support for the high-quality development of the health industry.

Disclosure statement

The author declares no conflict of interest.

References

[1] Liang H, 2025, Research on Intelligent Supervision of Medical Devices from the Perspective of Technological Integration and Regulatory Innovation. Mold Manufacturing, 25(11): 249–251.

[2] Fan K, Cao Y, Feng B, 2025, Discussion on the Application and Innovation of Mechanical Engineering Technology in Medical Device Design. China Equipment Engineering, 2025(20): 50–52.

[3] Li X, Zhou L, Zhang F, et al., 2024, Analysis and Research on Innovative Technologies in the Medical Device Industry from the Perspective of Big Data. China Market Regulation Research, 2024(5): 48–51.

[4] Li J, Huang Y, Huang S, et al., 2020, Analysis and Thoughts on the Construction of High-end Medical Device Technology Standard Innovation Base. China Standardization, 2020(S1): 111–114.