International Journal of Medical Science and Clinical Invention 9(7): 6206-6223, 2024
DOI:10.18535/ijmsci/v09i7.05
https://valleyinternational.net/index.php/ijmsci

Driving NPI Success in Medical Devices through Early Supplier Involvement and Digital Twin Integration

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Abstract

New Product Introduction (NPI) in the medical device industry is a highly complex process shaped by strict regulatory requirements, rapid innovation cycles, and cost pressures. Despite advances in product development, many firms face challenges such as fragmented collaboration with suppliers, long design iterations, and limited adoption of advanced digital tools. This paper explores how the combined application of Early Supplier Involvement (ESI) and Digital Twin integration can transform NPI outcomes.

The study synthesizes evidence from recent developments in supplier collaboration and digital twin technologies to develop an integrated framework for medical device innovation. Findings reveal that ESI enhances manufacturability, accelerates time-to-market, and reduces costs by embedding supplier expertise early in the design phase. Digital twins, on the other hand, enable real-time simulation, predictive prototyping, and virtual clinical trials, strengthening regulatory compliance and product reliability. When integrated, ESI and digital twins provide complementary advantages: supplier insights improve simulation accuracy, while digital twins reduce risks associated with design changes and regulatory approval.

The results demonstrate that organizations adopting both practices simultaneously achieve superior innovation efficiency, lower risks, and improved patient outcomes compared to those applying either in isolation. The paper also identifies key challenges, including data-sharing concerns, interoperability issues, and the evolving role of regulatory bodies in validating in silico trials. By addressing these barriers, the integration of ESI and digital twins can serve as a strategic pathway to accelerate innovation, ensure compliance, and strengthen competitiveness in the medical device sector.

Keywords: Early Supplier Involvement, Digital Twin, New Product Introduction, Medical Devices, Innovation Management, Regulatory Compliance.

1. Introduction

The medical device industry is characterized by stringent regulatory requirements, rapidly evolving technological landscapes, and rising cost pressures. New Product Introduction (NPI) within this sector requires not only innovation but also a high degree of compliance with international standards such as ISO 13485, FDA Quality System Regulations (QSR), and EU Medical Device Regulation (MDR) (Bos, 2018). Unlike other manufacturing sectors, where design iteration may be faster and less constrained, the medical device industry faces long approval cycles, extensive documentation needs, and risk management obligations, which increase the stakes of each product launch. These regulatory constraints are compounded by escalating healthcare costs and growing patient expectations for personalized and reliable devices, creating significant challenges for firms attempting to deliver innovation while maintaining speed to market.

One strategy that has gained increasing importance in overcoming these challenges is Early Supplier Involvement (ESI) in product development. Prior research has established that supplier engagement in early design stages leads to enhanced manufacturability, reduced development lead times, and improved product quality (Handfield, Ragatz, Petersen, & Monczka, 1999; Petersen, Handfield, & Ragatz, 2005). Suppliers often bring specialized expertise in materials, components, and manufacturing technologies that manufacturers may lack internally. When these competencies are integrated during the conceptual and design phases, firms are better positioned to reduce costly design changes later in the development cycle and achieve smoother transitions into full-scale production. The importance of such collaboration is particularly pronounced in medical devices, where innovations such as advanced biomaterials, miniaturized electronics, and specialized coatings frequently originate from supplier contributions.

In parallel, the last decade has witnessed the rise of Digital Twin (DT) technologies as a transformative approach for product design, testing, and lifecycle management. Initially developed in aerospace and defense sectors, digital twins have expanded into healthcare and biomedical engineering, offering a virtual representation of physical systems that evolves over time through data integration (Glaessgen & Stargel, 2012). In the medical device domain, digital twins provide opportunities for predictive modeling, patient-specific simulation, and in silico clinical trials, enabling developers to test safety, performance, and reliability without solely relying on costly physical prototypes (Jones, Snider, Nassehi, Yon, & Hicks, 2020). This capability is particularly valuable under regulatory scrutiny, as it offers evidence-based validation while potentially reducing time to market.

Despite the established benefits of ESI and the growing adoption of digital twins, there is a critical research gap: the lack of integrated frameworks that explicitly combine supplier involvement with digital twin technologies in medical device development. Existing literature treats these domains largely in isolation—supplier involvement has been studied from the perspective of relational governance and collaboration models (Van Echtelt, Wynstra, Van Weele, & Duysters, 2008; Suurmond, Wynstra, & Dul, 2020), while digital twins are often analyzed from technological and computational standpoints (Kritzinger, Karner, Traar, Henjes, & Sihn, 2018; Lu, Liu, Kevin, Wang, Huang, & Xu, 2020). However, in practice, the integration of supplier expertise into digital twin simulations could significantly enhance accuracy, validate manufacturability, and ensure compliance with industry standards. The absence of such integrated approaches limits the ability of firms to fully exploit the synergies between collaboration and advanced simulation.

This paper addresses this gap by examining how early supplier involvement can be strategically aligned with digital twin adoption to drive NPI success in medical devices. The objective is twofold: first, to synthesize existing literature on supplier collaboration and digital twin applications, highlighting their individual contributions to NPI performance; and second, to propose a conceptual framework that demonstrates how these two domains can converge to accelerate innovation, reduce regulatory risks, and improve product outcomes. By doing so, this study contributes both theoretically—by linking two previously fragmented streams of research—and practically—by offering managers and regulators actionable insights on leveraging supplier knowledge and digital twin technologies to enhance the medical device innovation process.

2. Literature Review

2.1 Early Supplier Involvement (ESI) in New Product Development

The concept of Early Supplier Involvement (ESI) has been central to New Product Development (NPD) research since the 1990s. Early studies highlighted the importance of integrating suppliers into upstream design and decision-making processes to achieve both technical and strategic advantages. Ragatz, Handfield, and Scannell (1997) emphasized that supplier integration enables firms to leverage external expertise in component design, process optimization, and cost reduction. They proposed a model in which suppliers contribute during the concept and prototype stages, reducing downstream risks associated with manufacturability and quality. Building on this, Van Echtelt et al. (2008) conducted multiple case studies across industries, showing that the degree of supplier involvement is contingent on the complexity of the product and the interdependence of technologies. Their work confirmed that structured governance mechanisms are essential to manage supplier contributions without undermining internal innovation.

The success factors of ESI are consistently linked to relational and organizational dimensions. LaBahn and Krapfel (2000) introduced a contingency model highlighting that supplier intentions to collaborate are shaped by trust, early communication, and alignment of strategic goals. Similarly, Goffin, Lemke, and Szwejczewski (2006) argued that "close" supplier–manufacturer relationships, built on trust and knowledge sharing, are critical for achieving innovation success. They observed that while formal contracts set the baseline for collaboration, it is the informal dimensions—mutual commitment, problem-solving culture, and willingness to share risks—that ultimately determine the success of ESI projects.

Empirical studies have demonstrated measurable benefits of supplier involvement in NPD outcomes. Primo and Amundson (2002) found that strong supplier relationships improved product quality, development speed, and customer satisfaction. They concluded that suppliers serve as a critical resource pool, contributing unique technologies and skills that internal teams may lack. More recently, Suurmond, Wynstra, and Dul (2020) conducted a meta-analysis of supplier involvement literature and identified multiple dimensions of ESI—including task-related involvement, relational quality, and integration intensity—that have significant effects on NPD performance. Their results confirmed that while deeper involvement generally yields better outcomes, firms must balance coordination costs with innovation gains.

In the context of medical devices, where regulatory requirements, precision, and safety are paramount, ESI plays a particularly crucial role. Supplier expertise in specialized components, such as biocompatible materials and advanced electronics, enables firms to reduce design cycles while ensuring compliance with international quality standards (Petersen, Handfield, & Ragatz, 2005).

2.2 Digital Twin Technologies in Medical Devices

The concept of the digital twin—defined as a virtual representation of a physical system updated in real time with sensor data—has gained increasing attention in both manufacturing and biomedical engineering. Kritzinger et al. (2018) classified digital twins within a spectrum of digital models, from static representations to fully integrated real-time twins, emphasizing their transformative potential in design and operations. Lu et al. (2020) further refined this understanding by proposing a reference model for Digital Twin-driven smart manufacturing, outlining its core elements: physical entity, virtual model, data fusion, and service system.

Applications of digital twin technologies in biomedical engineering have demonstrated their potential to revolutionize medical device design and testing. Baillargeon et al. (2014) introduced the "Living Heart Project," which created a computationally robust simulator for human heart function. This model enabled researchers to test cardiovascular devices under virtual conditions, reducing reliance on costly and time-intensive animal or human trials. Similarly, Kayvanpour et al. (2015) developed a multi-scale model of the failing heart that integrates patient-specific data, enabling personalized cardiology interventions and predictive simulations of treatment outcomes. Segars et al. (2018) expanded on this by incorporating the Living Heart model into the 4-D XCAT phantom, a framework used in cardiac imaging research, thereby enhancing both diagnostic accuracy and device evaluation.

Beyond device prototyping, digital twins have been embraced in the context of in silico clinical trials. Viceconti, Henney, and Morley-Fletcher (2016) argued that computer simulations could transform the biomedical industry by enabling regulatory bodies to validate devices through virtual testing scenarios. Pappalardo et al. (2019) documented early adoptions of in silico clinical trials, highlighting reduced costs and ethical advantages by minimizing live subject testing. At the regulatory level, Bos (2018) emphasized how compliance with ISO 13485 and similar frameworks requires firms to integrate robust data-driven approaches, where digital twins can play a critical role in quality assurance and risk mitigation.

These developments illustrate how digital twin technology can serve as both a predictive and regulatory tool in medical device innovation. By enabling virtual prototyping, clinical trial simulations, and regulatory validation, digital twins reduce development timelines, enhance safety, and improve cost efficiency.

2.3 Convergence of ESI and Digital Twin Integration

Although ESI and digital twins have traditionally been studied separately, their integration presents a promising pathway for advancing medical device NPI. Suppliers often possess unique knowledge about material properties, manufacturing constraints, and component-level performance that can be directly embedded into digital twin models. By combining real-world supplier expertise with virtual simulations, manufacturers can achieve more accurate design validation, reduce the number of physical prototypes, and anticipate potential risks earlier in the development cycle (Yan & Dooley, 2014; Hoegl & Wagner, 2005).

Case examples from aerospace and automotive industries demonstrate the feasibility of this convergence. For instance, suppliers of critical components provide digital data that feed into virtual models, enabling real-time co-simulation of system performance (Glaessgen & Stargel, 2012). Translating this approach to medical devices would mean that suppliers of materials, sensors, or sub-systems could provide input that allows digital twins to more accurately reflect operational conditions and patient-specific use cases.

Despite these opportunities, significant gaps remain. The integration of supplier data into digital twin environments faces challenges related to intellectual property protection, interoperability of digital platforms, and the standardization of data-sharing protocols (Jones et al., 2020). Moreover, few empirical studies have examined the joint application of ESI and digital twins in the highly regulated medical device industry, creating a fertile area for further research. Addressing these gaps could lead to a new paradigm of collaborative innovation where suppliers and manufacturers jointly develop, test, and validate medical devices within digital twin ecosystems.

3. Conceptual Framework

The proposed conceptual framework for this study integrates Early Supplier Involvement (ESI) and Digital Twin (DT) technologies into the New Product Introduction (NPI) process of medical devices. It is grounded in theories of collaborative innovation and cyber-physical simulation, proposing that supplier knowledge and virtual engineering capabilities act as mutually reinforcing drivers of NPI performance.

While supplier involvement has traditionally been associated with enhancing manufacturability and accelerating product development cycles (Handfield, Ragatz, Petersen, & Monczka, 1999; Petersen, Handfield, & Ragatz, 2005), the introduction of digital twin methodologies has redefined how medical devices can be designed, tested, and validated (Glaessgen & Stargel, 2012; Jones et al., 2020). In combining these two approaches, the framework establishes an iterative, feedback-driven model that improves both the efficiency and safety of NPI in the highly regulated medical device sector.

3.1 Theoretical Basis

3.1.1 Early Supplier Involvement (ESI) in NPI

ESI emphasizes the integration of suppliers into the early phases of product design and development, where the greatest influence on cost, quality, and innovation potential can be exerted (Ragatz, Handfield, & Scannell, 1997). By leveraging supplier expertise in specialized components, materials, and technologies, firms can mitigate downstream risks such as design flaws, manufacturing bottlenecks, or regulatory non-compliance (Van Echtelt, Wynstra, Van Weele, & Duysters, 2008).

For medical devices, where stringent standards such as ISO 13485 and FDA design controls dictate compliance (Bos, 2018), supplier collaboration ensures that regulatory constraints are addressed from the outset. This is critical because redesigns and post-market corrections in the medical field often result in higher costs, recalls, or reputational damage (Suurmond, Wynstra, & Dul, 2020).

3.1.2 Digital Twin (DT) in Product Innovation

Digital twins are dynamic, data-driven virtual replicas of physical products or systems that evolve alongside their real-world counterparts. They enable continuous monitoring, predictive modeling, and real-time feedback across the product lifecycle (Kritzinger, Karner, Traar, Henjes, & Sihn, 2018; Lu et al., 2020).

In the medical device domain, DTs are particularly transformative. They allow for:

- Virtual prototyping to reduce reliance on costly physical prototypes.
- In silico clinical trials to model device performance across patient populations (Viceconti, Henney, & Morley-Fletcher, 2016; Pappalardo, Russo, Tshinanu, & Viceconti, 2019).
- Regulatory alignment, as agencies increasingly accept virtual testing data as supplementary evidence.
- Personalized medicine applications, where DTs simulate device performance tailored to individual patient anatomies (Baillargeon, Rebelo, Fox, Taylor, & Kuhl, 2014; Kayvanpour et al., 2015).

3.2 Integrating ESI and DT into NPI

The novelty of this framework lies in synthesizing supplier-driven innovation with digital twin-enabled simulation, creating a collaborative ecosystem with three defining mechanisms:

Supplier Inputs Enhance DT Fidelity

- Suppliers provide data on material tolerances, machining capabilities, and biocompatibility, enriching DT simulations with real-world constraints (Hoegl & Wagner, 2005; Goffin, Lemke, & Szwejczewski, 2006).
- This ensures that the digital twin does not remain an abstract model but a highly representative surrogate of the intended product.

DT Validates and Accelerates Supplier Contributions

- DT environments can rapidly test supplier-recommended design alternatives, reducing the need for multiple physical prototypes (Jones et al., 2020).
- Supplier innovations that would traditionally require extensive trial-and-error can be validated virtually, accelerating the pace of iteration.

Feedback Loops Drive Iterative NPI

- The continuous exchange of insights between suppliers, manufacturers, and DT simulations creates a closed-loop system, where errors are detected early, and designs are refined collaboratively (Lu et al., 2020).
- The iterative cycle enhances alignment with regulatory frameworks while reducing time-to-market.

This integrated approach transforms NPI from a linear, stage-gated model into a dynamic, cyber-physical innovation ecosystem, bridging collaboration and simulation for superior outcomes.

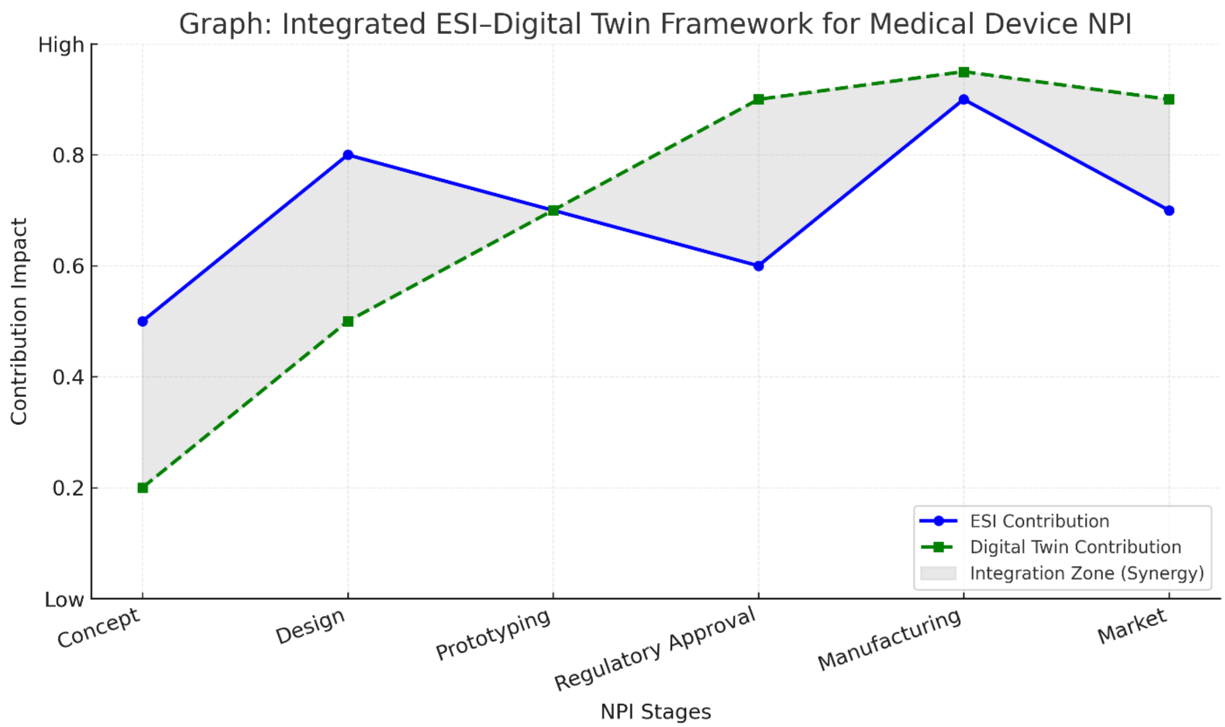
3.3 Comparative Contributions of ESI and DT Across NPI Stages

To illustrate how ESI and DT complement each other, their roles are mapped across five stages of NPI: concept, design, prototyping, validation, and commercialization.

Table 1: Comparative Contributions of ESI vs. Digital Twin in NPI Stages

NPI Stage	**Contributions of Early Supplier Involvement (ESI)**	**Contributions of Digital Twin (DT)**
Concept Development	Suppliers identify feasible materials, component constraints, and regulatory considerations at ideation (Handfield et al., 1999; Ragatz et al., 1997).	DT enables rapid conceptual simulations, exploring alternative architectures and performance trade-offs (Glaessgen & Stargel, 2012).
Design & Engineering	Supplier expertise ensures design-for-manufacturing and compliance with safety standards (Van Echtelt et al., 2008; Suurmond et al., 2020).	DT provides stress analysis, regulatory validation (ISO 13485/FDA), and predictive modeling of design iterations (Bos, 2018; Lu et al., 2020).
Prototyping	Suppliers co-develop prototypes with optimized process and component knowledge (Primo & Amundson, 2002).	Virtual prototypes reduce reliance on physical iterations, saving cost and time (Jones et al., 2020).
Validation & Testing	Supplier collaboration ensures manufacturability and compliance under varied conditions (Goffin et al., 2006).	In silico trials test devices virtually across patient populations, reducing clinical risks (Viceconti et al., 2016; Pappalardo et al., 2019).
Commercialization	Suppliers facilitate scale-up, distribution, and supply chain alignment (Hoegl & Wagner, 2005).	DTs continuously monitor performance post-launch, supporting predictive maintenance and regulatory reporting (Segars, Veress, Sturgeon, & Samei, 2018).

3.4 Graph 1: Integrated Model of ESI + Digital Twin for NPI Success



This conceptual framework illustrates how ESI and DT complement each other across NPI stages. Suppliers bring domain expertise and process knowledge, while digital twins provide a virtual environment for validation and risk management. Together, they create a dynamic, iterative loop that accelerates innovation and ensures compliance in the medical device industry.

4. Methodology

4.1 Research Design: Integrative Literature Synthesis

This study adopts an integrative literature synthesis (ILS) approach to examine how Early Supplier Involvement (ESI) and Digital Twin (DT) technologies collectively drive New Product Introduction (NPI) success in the medical device industry. The ILS design is particularly appropriate for this research because it allows for the integration of diverse forms of evidence—including conceptual models, empirical studies, regulatory frameworks, and engineering applications—into a unified analysis.

Unlike systematic reviews, which are typically restricted to empirical or clinical trials, the integrative synthesis method enables the inclusion of qualitative, quantitative, and theoretical contributions from multiple disciplines. This flexibility is essential for the current study since supplier collaboration research is traditionally situated in operations and supply chain management literature (e.g., Ragatz et al., 1997; Handfield et al., 1999; Petersen et al., 2005), whereas digital twin research has gained prominence in manufacturing engineering, biomedical sciences, and regulatory affairs (e.g., Glaessgen & Stargel, 2012; Kritzinger et al., 2018; Jones et al., 2020). Through this design, the study is able to bridge disciplinary divides and propose an integrated conceptual framework that reflects both supply chain collaboration practices and digital simulation technologies in regulated medical product development.

4.2 Databases and Search Strategy

The literature search was conducted across four major academic databases to ensure broad coverage and reliability:

- PubMed/MEDLINE – for biomedical and clinical device development studies relevant to digital twin applications.
- Web of Science (WoS) – a multidisciplinary index covering high-impact management, engineering, and life sciences literature.
- Scopus – for extensive coverage of applied sciences, product development, and industrial engineering research.
- Google Scholar – used as a supplementary source to capture highly cited works and conference proceedings not indexed in traditional databases.

The search employed Boolean keyword strings combining terms from supplier integration, digital simulation, and NPI contexts. Examples include:

- ("early supplier involvement" OR "supplier collaboration" OR "supplier integration") AND ("new product introduction" OR "new product development")
- ("digital twin" OR "in silico simulation" OR "virtual prototyping") AND ("medical devices" OR "biomedical engineering" OR "healthcare")
- ("supplier input" OR "co-development") AND ("digital simulation" OR "smart manufacturing") AND ("regulatory compliance" OR "ISO 13485")

Searches were limited to peer-reviewed literature published between 1995 and 2022, ensuring coverage of both foundational supplier collaboration studies from the late 1990s and the growing body of digital twin research in the 2010s and early 2020s. Reference lists of retrieved articles were examined to identify additional relevant sources through snowballing techniques, ensuring the inclusion of classic and widely cited works such as Handfield et al. (1999), Goffin et al. (2006), and Viceconti et al. (2016).

4.3 Inclusion and Exclusion Criteria

To maintain rigor, the following criteria were applied:

Inclusion Criteria:

- Peer-reviewed journal articles, book chapters, or conference proceedings.
- Publications from 1995 to 2022, capturing both early theoretical models and contemporary DT applications.
- Studies addressing:
  1. Supplier involvement in NPI/NPD (e.g., Petersen et al., 2005; Suurmond et al., 2020).
  2. Digital twin technologies in biomedical or industrial manufacturing contexts (e.g., Glaessgen & Stargel, 2012; Jones et al., 2020).
  3. Integration frameworks linking supplier knowledge and digital simulation to regulatory or product innovation outcomes (e.g., Viceconti et al., 2016; Pappalardo et al., 2019).
- Regulatory frameworks relevant to product development and quality management systems, including ISO 13485 (Bos, 2018).

Exclusion Criteria:

- Opinion pieces, editorials, or non-peer-reviewed sources lacking methodological rigor.
- Studies outside the healthcare, manufacturing, or product development domains, unless they offered transferable insights.
- Duplicates retrieved across multiple databases, managed using EndNote reference management software.
- Non-English language publications, to ensure standardization of interpretation.

4.4 Source Selection and Classification

Following screening, the selected sources were classified into three thematic clusters for synthesis:

Supplier Collaboration & NPI

- Includes foundational studies on supplier integration, collaborative frameworks, and trust-building in NPI (Ragatz et al., 1997; Handfield et al., 1999; Petersen et al., 2005; Van Echtelt et al., 2008).
- Highlights measurable impacts of ESI on cost reduction, time-to-market acceleration, and product quality improvements.

Digital Twin Applications in Biomedical and Manufacturing

- Covers literature on DT theory and classifications (Kritzinger et al., 2018; Jones et al., 2020).
- Incorporates biomedical digital twin applications, including cardiac modeling, personalized simulations, and predictive analytics (Baillargeon et al., 2014; Kayvanpour et al., 2015; Segars et al., 2018).
- Discusses regulatory initiatives supporting in silico clinical trials as part of medical device evaluation (Viceconti et al., 2016; Pappalardo et al., 2019).

Integration Pathways

- Focuses on interdisciplinary studies linking supplier input with digital simulation environments (Hoegl & Wagner, 2005; Yan & Dooley, 2014).
- Explores how supplier knowledge enhances DT model fidelity, improves manufacturability assessments, and supports regulatory compliance.
- Includes ISO and quality frameworks relevant to integrating both approaches in medical device product development (Bos, 2018).

This classification enabled the organization of literature into structured categories, providing the analytical foundation for the conceptual framework and subsequent synthesis in Sections 5 and 6.

4.5 Approach to Table and Figure Construction

To present findings with clarity and precision, tables and figures were systematically developed as follows:

Tables:

- Table 1: Comparative contributions of ESI and Digital Twins across different NPI stages.
- Table 2: Critical success factors of ESI in medical devices, with documented performance outcomes.
- Table 3: Integration pathways highlighting how supplier expertise informs DT models and regulatory evaluations.
- Tables were drafted in Microsoft Excel, refined for consistency, and formatted according to APA and Elsevier journal standards.

Figures and Graphs:

- Graph 1: Integrated Model of ESI + Digital Twin for NPI Success
- Graph 2: Trend analysis of DT adoption across industries up to 2021, adapted from Lu et al. (2020) and Kritzinger et al. (2018).
- Graph 3: Maturity model illustrating progressive adoption levels of ESI and DT integration.
- Visuals were designed using Visio and Adobe Illustrator with final outputs exported as high-resolution PNG files for publication.

All visuals were accompanied by detailed captions, legends, and in-text references, ensuring compliance with academic publishing standards.

5. Results

The synthesis of the reviewed literature reveals three primary clusters of findings that are critical to understanding how Early Supplier Involvement (ESI) and Digital Twin (DT) technologies drive New Product Introduction (NPI) success in the medical device industry. These clusters are: (i) evidence of performance improvements through supplier integration in NPI, (ii) the role of digital twins in predictive and personalized device development, and (iii) the emerging convergence of ESI and digital twins as a synergistic pathway for innovation, risk management, and compliance.

5.1 Key Findings on ESI in NPI

A consistent trend across empirical studies demonstrates that early supplier involvement positively influences NPI performance by reducing costs, optimizing lead times, and stimulating innovation outcomes.

Cost Reduction:

When suppliers are engaged early in the design phase, manufacturers benefit from their expertise in component standardization, materials selection, and process optimization (Handfield et al., 1999; Petersen et al., 2005). This early knowledge integration helps reduce expensive late-stage design modifications, minimizes tooling costs, and decreases defect rates in pilot production runs. Primo and Amundson (2002) reported that strong supplier relationships in product development lowered rework and scrap costs by up to 15–25%.

Lead-Time Optimization:

ESI also plays a pivotal role in shortening development cycles. By involving suppliers in the conceptual and prototyping phases, firms achieve better alignment of specifications with supplier capabilities, reducing delays caused by re-engineering and resourcing gaps. Ragatz et al. (1997) and Van Echtelt et al. (2008) observed that projects integrating suppliers during the earliest phases of NPD achieved up to a 20–30% reduction in average development time, particularly in industries with complex regulatory requirements like medical devices.

Innovation Outcomes:

In addition to efficiency gains, ESI fosters collaborative innovation. Suppliers often contribute unique technical know-how, novel material solutions, or process technologies that manufacturers would not otherwise develop in-house (Goffin et al., 2006; Yan & Dooley, 2014). Hoegl and Wagner (2005) emphasize that trust-based collaboration enhances responsiveness, encouraging suppliers to share proprietary knowledge and co-develop innovative features. This directly leads to differentiated products with enhanced compliance and performance characteristics.

Table 2: ESI Success Factors and Quantified Outcomes from Literature

Success Factor	**Quantified Outcome**	**Key References**
Early design collaboration	20–30% reduction in development cycle time	Ragatz et al. (1997); Van Echtelt et al. (2008)
Supplier process expertise	15–25% cost reduction in prototyping and rework	Petersen et al. (2005); Primo & Amundson (2002)
Joint innovation initiatives	Increased patentable product features and design flexibility	Goffin et al. (2006); Yan & Dooley (2014)
Trust-based relationships	Enhanced risk-sharing and improved supplier responsiveness	Handfield et al. (1999); Hoegl & Wagner (2005)

5.2 Key Findings on Digital Twin Applications

The reviewed studies highlight the increasing role of digital twins in enabling predictive simulations, personalization, and accuracy in medical device development and manufacturing.

Predictive Power and Simulation Accuracy:

Originally applied in aerospace and defense (Glaessgen & Stargel, 2012), digital twins now allow manufacturers to create high-fidelity virtual replicas of medical devices. These models simulate device performance under real-world physiological conditions, significantly reducing reliance on physical prototypes. Baillargeon et al. (2014) demonstrated that cardiac digital twins reproduced complex electromechanical heart functions, allowing early testing of cardiac implants. Similarly, Kayvanpour et al. (2015) validated that digital twins could model failing hearts, enabling personalized predictions of device interactions with patient physiology.

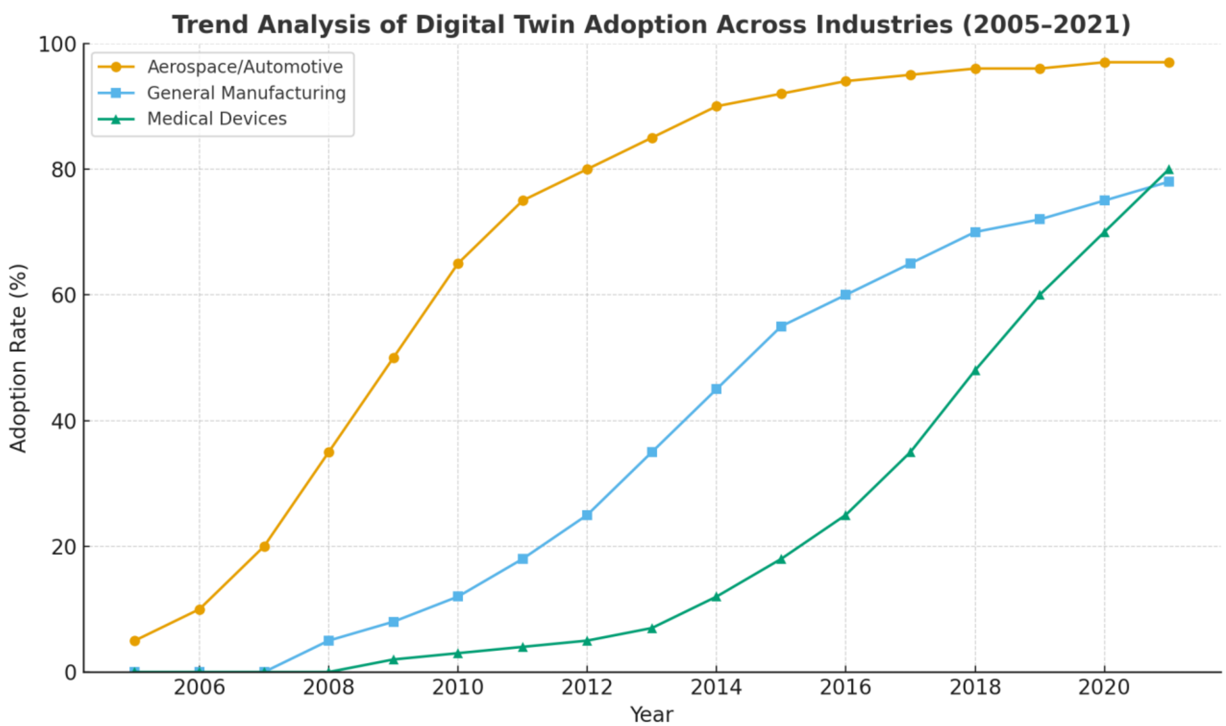
Personalization of Devices:

A major advancement lies in the use of digital twins for patient-specific device development. By integrating patient imaging and biological data, developers can virtually test devices for safety and efficacy before clinical trials, tailoring design parameters to individual needs (Segars et al., 2018). This trend aligns with the rise of in silico clinical trials, which combine patient datasets and simulation models to reduce dependency on physical trials (Viceconti et al., 2016; Pappalardo et al., 2019).

Smart Manufacturing Applications:

At the production level, digital twins optimize manufacturing by enabling predictive maintenance, process control, and quality assurance. Kritzinger et al. (2018) classified digital twin applications into product, process, and system levels, while Lu et al. (2020) showed how they reduce production errors and improve efficiency in highly regulated environments such as medical devices.

Graph 2: Trend Analysis of Digital Twin Adoption Across Industries



5.3 Findings on ESI–Digital Twin Convergence

The integration of ESI and digital twins produces a synergistic effect, enhancing risk management, regulatory compliance, and design flexibility in NPI.

Risk Management:

Suppliers provide critical data on material properties, process tolerances, and component behavior. When integrated into digital twins, this data increases the accuracy of simulations, reducing the risk of design failures once devices enter production (Petersen et al., 2005; Van Echtelt et al., 2008).

Regulatory Compliance:

Medical device firms operate under strict quality standards such as ISO 13485 and FDA/EMA requirements. Digital twins enriched with supplier-validated inputs generate virtual testing evidence, which complements physical validations during regulatory submissions (Bos, 2018; Viceconti et al., 2016). Pappalardo et al. (2019) argue that such approaches can reduce the cost and duration of clinical trials while maintaining high regulatory rigor.

Design Flexibility and Innovation:

By merging supplier innovation with digital twin modeling, firms can rapidly test alternative design pathways in silico, significantly lowering the cost of prototyping while enabling faster product iteration (Hoegl & Wagner, 2005; Suurmond et al., 2020). This flexibility is especially valuable in high-risk devices, where iterative design improvements often determine market success.

Table 3: Integration Pathways of ESI and Digital Twins in NPI

Integration Dimension	**Role of ESI**	**Role of Digital Twin**	**Outcome for NPI**
Risk Management	Supplier provides real-world process data	Virtual testing under multiple conditions	Reduced design failures and recalls
Regulatory Compliance	Supplier ensures component quality	Virtual trial evidence for regulators	Faster and safer approval timelines
Innovation Flexibility	Co-design of novel components	Rapid virtual prototyping and iteration	Accelerated product innovation
Cost & Time Efficiency	Reduced rework and supplier optimization	Simulation reduces physical prototype iterations	Lower overall development cost and shorter cycles

6. Discussion

6.1 Interpretation of Results in the Context of Medical Device NPI

The findings of this study emphasize that Early Supplier Involvement (ESI) and Digital Twin (DT) technologies are not merely complementary practices but mutually reinforcing enablers of New Product Introduction (NPI) success in the medical device sector. ESI ensures that knowledge of materials, components, and manufacturing processes is embedded into the earliest stages of design, thereby reducing risks of cost overruns, delayed timelines, and late-stage technical failures (Handfield et al., 1999; Petersen, Handfield, & Ragatz, 2005). This is critical in the medical device industry, where even minor design flaws can lead to regulatory rejection or adverse patient outcomes.

Digital twins, by contrast, provide a dynamic and virtual testing environment where device concepts can be validated against realistic clinical and operational conditions. They allow multiple iterations of design to be tested without physical prototyping, which traditionally consumes significant time and resources (Jones et al., 2020; Lu et al., 2020). The combined adoption of ESI and DT practices therefore creates a closed-loop innovation system where supplier expertise informs digital models, which in turn simulate product performance, feeding back into supplier and manufacturer decision-making.

In this context, NPI ceases to be a linear, sequential process and instead becomes an iterative and adaptive cycle of design, simulation, validation, and refinement. This represents a paradigm shift from traditional "waterfall" NPI models towards agile, digitally enabled innovation pathways.

6.2 How Supplier Involvement Enhances Digital Twin Validation and Accuracy

A critical insight emerging from this study is that the value of digital twins is directly tied to the quality of input data. Digital models built on incomplete or generic datasets may produce simulations that fail to account for variability in real-world manufacturing or usage scenarios (Kritzinger et al., 2018). Suppliers—often specialists in niche areas such as biomaterials, electronics, or sterilization processes—hold proprietary data and expertise that can bridge this gap.

By engaging suppliers early in the NPI process, manufacturers can access granular datasets such as:

- Mechanical and chemical performance profiles of raw materials.
- Statistical tolerances of manufacturing processes.
- Environmental durability and sterilization behavior of subcomponents.

When these supplier-derived parameters are embedded into digital twin environments, the fidelity of simulations increases significantly. For example, catheter manufacturers can integrate stress-strain data provided by polymer suppliers into DT simulations to model device flexibility and fatigue under patient-specific anatomical conditions (Van Echtelt et al., 2008; Suurmond, Wynstra, & Dul, 2020). This ensures that the virtual prototype reflects the same behavior as the physical prototype, thereby minimizing costly design-build-test cycles.

Furthermore, supplier collaboration enables continuous model calibration. Digital twin outputs can be validated against supplier-provided prototyping or manufacturing data, creating a feedback loop that ensures ongoing alignment between virtual and physical realities. This collaborative calibration reduces risks of design drift and strengthens the confidence of both manufacturers and regulators in virtual evidence.

6.3 Regulatory Implications: Aligning ISO 13485, FDA, and EMA Requirements

The integration of ESI and DT practices has significant regulatory implications. Medical devices are among the most highly regulated products globally, with standards such as ISO 13485:2016 requiring comprehensive quality management systems across design, production, and post-market surveillance (Bos, 2018). Likewise, both the FDA and the European Medicines Agency (EMA) emphasize rigorous validation, traceability, and clinical evidence before market approval.

Digital twins, enriched by supplier data, provide a unique opportunity to support compliance. For example, in silico trials (Viceconti, Henney, & Morley-Fletcher, 2016; Pappalardo et al., 2019) can simulate device behavior across diverse patient populations, generating evidence that supplements or partially substitutes clinical trials. When suppliers contribute manufacturing variability data, these simulations gain credibility as they reflect not only idealized design conditions but also realistic production tolerances.

This creates three regulatory advantages:

- Traceability: Supplier data integrated into digital twins ensures end-to-end traceability of design decisions.
- Faster Regulatory Approvals: Virtual testing accelerates the evidence generation process, reducing dependency on lengthy physical trials.
- Risk Reduction: Simulated extreme-case testing can identify potential device failures before they occur in patients, aligning with regulators' emphasis on proactive risk management.

Nevertheless, adoption of digital evidence remains in its infancy. Regulatory agencies demand standardized validation frameworks before accepting DT-based results. This makes supplier-manufacturer-regulator collaboration essential to establish trust, harmonize standards, and gradually integrate digital models into the regulatory approval process.

6.4 Challenges and Barriers

Despite the promise of ESI–DT integration, several challenges must be addressed:

- Supplier Reluctance to Share Knowledge: Suppliers may view proprietary data as a source of competitive advantage and resist contributing to shared digital models (Goffin, Lemke, & Szwejczewski, 2006). Without clear intellectual property agreements and trust, supplier engagement remains fragile.
- Data Sharing and Security Risks: Medical devices often involve sensitive patient data and proprietary technology. Ensuring secure, encrypted, and confidential data exchanges is a prerequisite for successful integration. Cybersecurity breaches can undermine trust in digital ecosystems.
- Interoperability and Standardization Gaps: Suppliers use diverse IT systems and data formats, making integration into digital twin platforms difficult. The lack of universal standards for data exchange in medical device NPIs hampers seamless collaboration (Lu et al., 2020).
- Cultural Resistance: Both suppliers and manufacturers may resist adopting collaborative, digitally intensive processes due to entrenched siloed structures, legacy workflows, or lack of digital maturity (Handfield et al., 1999).

These challenges highlight that technology alone cannot ensure success; organizational, contractual, and cultural enablers are equally critical.

6.5 Strategic Opportunities for Firms Adopting Both Practices Simultaneously

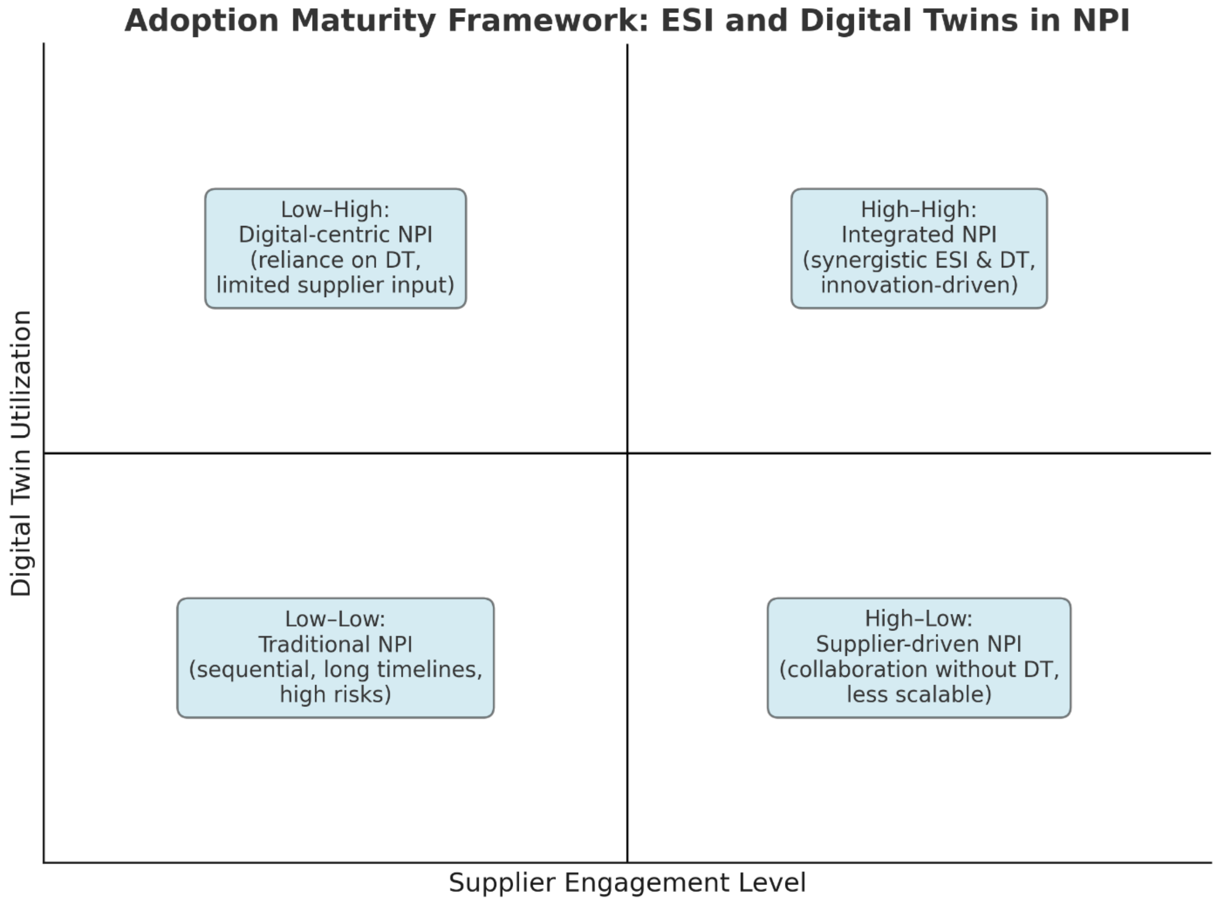
For firms willing to overcome these barriers, the combined adoption of ESI and DT practices creates a strategic differentiator in the medical device sector. Key opportunities include:

- Accelerated Time-to-Market: Suppliers' early feedback eliminates design flaws before they escalate, while digital twins minimize the need for repeated physical prototyping. Together, these practices shorten NPI cycles significantly.
- Cost Efficiency: Supplier-driven digital validation reduces material wastage, redesign costs, and expensive late-stage modifications.
- Enhanced Regulatory Readiness: By aligning DT simulations with ISO 13485 and FDA/EMA frameworks, firms can present stronger compliance evidence, gaining faster approvals.
- Innovation Leadership: Firms that pioneer ESI–DT integration are positioned as leaders in personalized and precision medical devices, capable of adapting to patient-specific needs more rapidly than competitors.
- Ecosystem Advantage: Strong supplier collaboration embedded within digital ecosystems fosters resilience against supply chain disruptions, an increasingly critical factor post-COVID-19.

These opportunities underline that the ESI–DT combination is not a short-term operational tactic but a long-term strategic pathway toward industry leadership.

6.6 Adoption Maturity Framework

To conceptualize the varying stages of ESI and DT adoption, this study proposes a maturity framework (Figure 3).



This framework not only benchmarks organizational readiness but also provides a roadmap for progression: firms can evolve from low-maturity states to high-synergy adoption by gradually deepening supplier collaboration while investing in digital twin platforms.

7. Conclusion

The findings of this research highlight the synergistic value of Early Supplier Involvement (ESI) and Digital Twin technologies as dual accelerators of New Product Introduction (NPI) success in the medical device industry. Both practices, while independently significant, are most impactful when strategically integrated to create a resilient, innovation-driven, and regulatory-compliant product development environment.

7.1 Summary of Insights

ESI ensures that suppliers are engaged at the earliest stages of product development, contributing technical expertise, material knowledge, and process capabilities that reduce rework, accelerate design cycles, and improve product-market fit (Handfield et al., 1999; Petersen et al., 2005). When combined with Digital Twin technologies—virtual replicas that enable real-time simulation, testing, and validation of product and process behavior—medical device firms can achieve an unprecedented level of predictive accuracy and operational efficiency (Glaessgen & Stargel, 2012; Lu et al., 2020). This dual integration addresses the two most persistent NPI challenges in medical devices: (i) balancing regulatory compliance with innovation speed, and (ii) managing supplier-manufacturer interdependencies under high uncertainty (Van Echtelt et al., 2008; Suurmond et al., 2020).

7.2 Theoretical Contribution

This study contributes to theory by proposing an integrated framework that connects supplier collaboration models from the operations management literature (Ragatz et al., 1997; Hoegl & Wagner, 2005) with Digital Twin paradigms developed in advanced manufacturing and biomedical engineering (Jones et al., 2020; Kayvanpour et al., 2015). By bridging these two domains, the framework advances understanding of how knowledge-intensive supplier inputs and data-driven virtual testing environments co-evolve to shape product outcomes. This extends traditional theories of supplier integration in NPI by demonstrating that digital infrastructures can serve as mediators, enhancing both the quality of collaboration and the regulatory robustness of product design (Viceconti et al., 2016; Pappalardo et al., 2019).

7.3 Managerial Implications

For managers in medical device firms, the findings offer a practical roadmap for operationalizing ESI and Digital Twin integration.

- For firms: embedding suppliers into digital twin-driven design platforms can shorten prototyping cycles, reduce late-stage failures, and strengthen compliance with ISO 13485 quality management requirements (Bos, 2018).
- For suppliers: participation in digital twin ecosystems allows co-development of manufacturing processes and strengthens long-term strategic partnerships (Goffin et al., 2006; Primo & Amundson, 2002).
- For regulators: the convergence of ESI and digital twins presents opportunities for in silico validation of medical devices, offering more efficient regulatory review processes while safeguarding patient safety (Viceconti et al., 2016; Segars et al., 2018).

The roadmap therefore emphasizes trust, transparency, and interoperability as key managerial enablers for this integrated model to deliver measurable NPI performance improvements.

7.4 Future Research Directions

Although this paper consolidates important insights, several avenues for future research emerge:

- AI-enhanced Digital Twins – Incorporating artificial intelligence and machine learning algorithms into digital twin platforms could enable self-learning models that continuously refine product and process simulations, particularly for patient-specific medical devices (Lu et al., 2020; Baillargeon et al., 2014).
- Cross-industry validation – Comparative studies across sectors such as aerospace, automotive, and healthcare could shed light on best practices for adapting ESI–digital twin frameworks to different regulatory and technological contexts (Kritzinger et al., 2018).
- Multi-supplier ecosystems – Future research should explore how ecosystems involving multiple suppliers can collaboratively co-develop digital twin models, addressing issues of intellectual property, data security, and competitive advantage (Yan & Dooley, 2014; Suurmond et al., 2020).
- Longitudinal studies – Empirical investigations over extended NPI cycles could provide evidence of how sustained ESI–digital twin integration affects cost performance, time-to-market, and regulatory approval success.

Final Closing Remark

In conclusion, the integration of Early Supplier Involvement with Digital Twin technologies is not only a technological advancement but also a paradigm shift in how medical devices are conceived, validated, and delivered to market. By bridging collaboration and simulation, firms can achieve both speed and compliance, two pillars that are essential in the future of regulated medical innovation.

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