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Bridging Multiple Valleys of Death in Medical Device Innovation: A Matrix-Based Decision-Support Framework

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Abstract

Innovators of medical devices often face overlapping phases marked by insufficient funding, regulatory complexities, and underdeveloped infrastructures. These overlapping phases are commonly referred to as "Valleys of Death." To navigate these hurdles, this article presents a matrix-based decision-support tool, integrating known innovation bottlenecks, stakeholder roles, and infrastructure needs across the nine technology readiness levels. By mapping key undesired effects and their corresponding alleviations onto a structured matrix, innovators can identify strategic interventions well before severe project failures occur. Using the event history analysis method and South Africa's National Ventilator Project as a case study, the article demonstrates how this tool provides insight into potential resource misalignment, regulatory delays, and stakeholder disengagement. The framework's flexibility makes it a valuable guide for managing medical device projects across different healthcare settings.

Keywords

Valleys of death, technology readiness levels, undesired effects, alleviations, event history analysis, national ventilator project

1. Introduction

The invention and commercialization of medical devices has become increasingly critical to address global healthcare challenges, ranging from improving patient care standards to managing complex diseases and pandemics (Hoagland and Kipping, 2024). The medical devices industry operates at the intersection of multiple domains, including engineering, clinical practice, regulatory compliance, and market dynamics, making the pathway to commercialization inherently complex. As a result, promising technologies often fail to transition from conceptual research to scalable, market-ready

solutions. The valley of death (VoD) metaphor captures these critical junctures where technology projects can stall due to misalignment of resources, unclear regulatory procedures, or insufficient market traction (Markham et al., 2010; Pietzsch et al., 2009).

While prior research has explored funding gaps and regulatory challenges in product innovation, a gap remains in the existing literature on a unified, stage-specific, and integrative roadmap tailored to the unique constraints of medical devices (McClelland et al., 2023). Traditional innovation frameworks tend to address either broad financial hurdles or singular regulatory bottlenecks, all overlooking how these issues overlap and intensify in a highly regulated environment, such as those of medical devices (Lottes et al., 2022). Moreover, the majority of existing guides for developing medical technology do not systematically map each hurdle to corresponding remedial strategies across the entire product lifecycle (Pietzsch et al., 2009).

While substantial work has already been done on innovation systems, readiness levels, and functional frameworks (Freeman, 1987; Hekkert et al., 2007), a research gap remains for an actionable decision-support instrument derived from a consolidation of these three perspectives. More specifically, existing stage-gate or TRL frameworks outline development phases but rarely incorporate the complex interplay among stakeholders (regulators, manufacturers, end-users) (Turner et al., 2024). Furthermore, commonly cited VoD frameworks highlight financial shortages without adequately addressing multiple concurrent bottlenecks, such as infrastructure gaps or governance constraints, that can derail medical device projects (Bergsland et al., 2014; Carpenet et al., 2011). Finally, while conceptual studies diagnose system failures, practical, matrix-based tools designed to integrate solutions, such as, for example, strategic networking, alternative supply chains, into each phase of TRL progression are comparatively scarce (Yfanti and Sakkas, 2023).

1.1 Objectives

Against this backdrop, the main research question driving this study is: *How can medical device innovators systematically identify and address the overlapping Valleys of Death throughout the Technology Readiness Levels, thereby increasing the likelihood of successful commercialization?*
To address this question, we propose and validate a matrix-based decision-support framework that aligns known bottlenecks ("Undesired Effects") and solutions ("Desired Effects") with the critical TRL milestones. By doing so, we aim to provide a holistic tool that:

1. Anticipates resource shortages and regulatory delays before they reach crisis points,
2. Maps responsible stakeholders and institutions to each developmental phase, and
3. Guides innovators through step-by-step action plans rooted in proven best practices.

Following this introduction, we present a literature review that situates the matrix-based framework within established research on multiple VoD, TRL/IRL progression, and linking theory. We then detail our methodological approach - particularly the use of Event History Analysis - and demonstrate real-world applicability via a case study of South Africa's National Ventilator Project. The article concludes with insights on future refinements and broader implications for healthcare innovation policy.

2. Literature Review

2.1 Medical Device Innovation Landscape

The development of medical devices spans a complex ecosystem involving manufacturers, hospitals, clinicians, investors, and regulatory agencies (Hoagland and Kipping, 2024). Collaboration among these diverse entities is critical to ensure that the final product satisfies safety requirements, meets patient needs, and remains commercially viable. However, lack of end-user engagement, poor knowledge diffusion, and weak coordination often lead to delayed or failed market entry (Pietzsch et al., 2009; Bergsland et al., 2014).

Moreover, specific national contexts face infrastructural constraints such as unreliable electricity, weak distribution channels, or insufficient local manufacturing capacity, making the innovation journey highly susceptible to disruptions (Carpenet et al., 2011). In these environments, bridging the Valleys of Death demands far more than just financial resources - it requires robust institutional support, strategic partnerships, and clear regulatory pathways (Freeman, 1987).

2.2. Innovation Systems in Medical Device Development

At its core, an innovation system consists of interconnected actors, networks, institutions, and infrastructures that collectively support the development and commercialization of innovations (Hekkert et al., 2007). These systems

facilitate interactions between various actors, including research institutions, government regulators, private industry, and healthcare providers.

A subset of this type of system is the technological innovation system (TIS). TISs focus specifically on developing emerging technologies within structured innovation environments (Bergek et al., 2008). The TIS framework identifies seven key functions contributing to technological advancement (Hekkert et al., 2007):

- **Entrepreneurial Activity**: Transforming research into commercial opportunities.
- **Knowledge Development**: Generating and refining scientific and technological knowledge.
- **Knowledge Diffusion**: Facilitating collaboration and information exchange.
- **Guidance of Search**: Directing resources toward promising innovations.
- **Market Formation**: Creating demand for new technologies.
- **Resource Mobilization**: Securing financial, human, and technical resources.
- **Creation of Legitimacy**: Overcoming institutional resistance and achieving regulatory approval

These functions operate within a dynamic ecosystem, where the alignment of stakeholders, such as regulatory bodies, manufacturers, end-users, technology partners, and sponsors, determines the success of an innovation (Freeman, 1987).

2.3 Multiple Valleys of Death (VoD)

One of the most critical challenges in medical device development is navigating the Valleys of Death (VoD), periods where promising innovations struggle to progress from research to commercialization due to funding, regulatory, and market adoption barriers (Turner et al., 2024). The concept of VoD initially emerged in high-tech industries and has since been widely applied to healthcare innovation (Gbadegeshin et al., 2022).

VoD occurs at multiple stages of development:

- Early-stage Valley of Death: The transition from research to prototype development is often constrained by high risk and uncertain funding (Ellwood et al., 2022).
- Technical and Regulatory Valley of Death: Innovations must meet stringent safety, efficacy, and compliance requirements, delaying market entry (Rodriguez-Manzano et al., 2024)
- Market Adoption Valley of Death: Even after regulatory approval, products may struggle with user acceptance, distribution logistics, and competitive pricing (Smit et al., 2024).

These challenges require targeted interventions, including strategic partnerships, government incentives, and industry-led support mechanisms (Yfanti and Sakkas, 2023). Furthermore, in addition to financial investment, research suggests that addressing VoD also requires improved governance structures, strategic decision-making, and regulatory facilitation (Pietzsch et al., 2009).

2.4 Technology Readiness Levels (TRLs) in Healthcare

Technology Readiness Levels (TRLs) originated from NASA to assess a technology's maturity, ranging from theoretical research (TRL 1) to validated, operational systems (TRL 9). Over time, both public and private sector organizations have adapted TRLs to manage innovation more effectively in domains like defense, aerospace, and energy (Lottes et al., 2022). Similarly, TRLs serve as critical markers of progress, ensuring that technical, regulatory, and clinical milestones align with the device's evolving maturity in healthcare and the medical device development field.

Unlike general engineering projects, medical device innovation also has to consider patient safety, clinical trial requirements, and rigorous regulatory oversight (Pietzsch et al., 2009). Thus, each TRL often includes parallel checkpoints for:

- Clinical Feasibility: Early prototypes (TRL 3–4) may require laboratory validation under simulated physiological conditions, ensuring baseline safety and efficacy.
- Regulatory Milestones: Mid-stage prototypes (TRL 5–6) must increasingly adhere to guidelines, such as the U.S. FDA's 510(k) or PMA requirements, or the EU's Medical Device Regulation (MDR) (Lottes et al., 2022).
- Health Economics and Market Access: By TRL 7–8, innovators must demonstrate not only technical feasibility but also cost-effectiveness, reimbursement potential, and readiness for scale-up (Turner, 2023).

Because healthcare settings vary widely, spanning high-resource urban hospitals to under-resourced rural clinics, development pathways may incorporate additional design constraints for durability, ease of use, and maintenance

availability (Smit et al., 2024).Consequently, medical device developers often use a modified TRL scale that merges engineering tasks (e.g., mechanical validation) with regulatory guidance and user-centric testing.

2.5 TRLs as a Strategic Communication Tool

A major benefit of TRLs is their function as a common vocabulary. Researchers, investors, and regulators can quickly gauge a project's developmental phase by referencing its TRL, streamlining funding decisions and regulatory interactions (Turner et al., 2024). For instance, a device entering TRL 5 generally signals that it has moved beyond basic lab testing, prompting more thorough regulatory scrutiny or pilot clinical trials. This clarity allows:

- Sponsors to assess funding thresholds,
- Regulators to anticipate upcoming documentation,
- Industry Partners to plan for manufacturing scale-up.

Nonetheless, critics caution that TRLs alone do not capture market factors like cost-effectiveness or reimbursement pathways (McClelland, 2023). They also may overlook local cultural contexts and institutional barriers in resource-limited settings (Carpenet et al., 2011). As such, TRLs are most effective when integrated within a broader framework that maps out bottlenecks, governance structures, and cross-sector partnerships at each stage, precisely the gap addressed by the matrix-based tool proposed in this article.

2.6 Event History Analysis (EHA) in Innovation Systems Research

Event History Analysis (EHA) offers a temporal and process-oriented lens for examining the evolution of innovation systems (Suurs and Hekkert, 2009). While conventional frameworks like TIS and value-chain analysis often provide static snapshots of key actors, institutions, and infrastructures, EHA complements these by capturing the chronological order and causality of events that shape the system's trajectory (Hekkert et al., 2007; McClelland, 2023).

EHA originated in organizational and social studies to document how particular events, such as policy changes, funding injections, or forming partnerships, systematically influence project outcomes (Van de Ven and Engleman, 2004). In an innovation context, EHA typically involves:

- Data Collection: Identifying and recording the timeline of relevant milestones (e.g., patent filings, clinical trial approvals, standard-setting initiatives).
- Database Construction: Organizing events chronologically, often in spreadsheets or specialized software, to facilitate pattern recognition.
- Function or Role Allocation: Mapping each event to specific innovation system functions (e.g., Resource Mobilization, Guidance of Search) or stakeholder roles (Suurs & Hekkert, 2009).
- Narrative Construction: Developing a coherent story that explains how sequential or overlapping events accumulate to accelerate (or hinder) technological progress.

By focusing on when events occur, who initiates them, and how they influence subsequent actions, EHA uncovers feedback loops, bottlenecks, and triggers that might be overlooked in more static analytical methods (McClelland, 2023). Within Technological Innovation Systems (TIS), the functions framework (F1–F7) provides a conceptual map of what needs to happen, such as knowledge diffusion or entrepreneurial experimentation, to sustain innovation (Hekkert et al., 2007). However, TIS does not inherently detail when or in what sequence these functions unfold (Suurs & Hekkert, 2009). EHA bridges this gap by:

- Temporal Mapping: Placing TIS functions on a timeline, revealing cumulative causation and interdependencies. For instance, early entrepreneurial experiments (F1) might be heavily dependent on resource mobilization (F6), which in turn may require market formation (F5).
- Contextualizing Actors and Institutions: EHA pinpoints critical moments where regulatory bodies (institutions) either facilitate or delay the system's growth, or where new market entrants (actors) disrupt existing networks (McClelland, 2023).
- Identifying Feedback Loops: Overlaps or recurrences in function performance (e.g., repeated attempts at knowledge diffusion (F2)) can be traced back to key triggers like policy shifts or investor interest.

This synthesis of EHA and TIS clarifies how an innovation system evolves dynamically, capturing the formative events that promote or impede technology uptake (Suurs and Hekkert, 2009; Van de Ven and Engleman, 2004).

2.7 Linking Theory and Matrix-Based Tools

According to Phaal et al. (2006), matrix-based decision-support tools provide a structured and systematic approach to aligning technological, regulatory, and market activities in innovation processes. These tools use a grid format where columns represent core components (in the case of TISs, it would be stakeholders, infrastructures, and policies), and rows correspond to TRL stages, enabling innovators to map development phases to relevant actors, resources, and constraints (Turner et al., 2024).

By clarifying roles and responsibilities, matrix tools reduce fragmentation in multi-actor innovation ecosystems, minimizing duplication, streamlining regulatory compliance, and improving stakeholder coordination (Freeman, 1987; Pietzsch et al., 2009). Furthermore, their visual structure allows innovators to compare strategic trade-offs, facilitating scenario planning and risk mitigation throughout the commercialization process (Phaal et al., 2006).

Linking theory enhances this approach by integrating technological, business, and regulatory elements, ensuring that the matrix serves as a descriptive tool and an actionable framework. (Turner et al., 2024). This enables targeted interventions at each bottleneck, helping innovators navigate the complexities of medical device development. Moreover, the flexibility of matrix-based tools allows for the adaptation to different regulatory environments, while their human-centric design fosters collaboration among engineers, clinicians, and business leaders.

Turner et al. (2024) further demonstrated how these tools bridge the gap between clinical and technical development, as they align investment strategies, regulatory approvals, and product life cycles to support commercialization. Thus, by integrating structured decision-making with scenario-based planning, matrix tools provide a comprehensive roadmap that ensures that medical innovations meet both scientific rigor and market needs while anticipating regulatory and market fluctuations (Phaal et al., 2006).

3. Combination of TISs, TRL and Matrix-Based Tools

The development of the decision-support tool follows a structured approach that integrates three established theoretical models to address the key challenges medical device innovators face. The framework is designed to provide actionable guidance at different stages of the innovation process, ensuring that innovators can effectively navigate the VoD (Gbadegeshin et al., 2022) and progress from concept invention to commercialization. To achieve this, the framework incorporates TRLs, the TIS framework, and linking theory, ensuring that every stage of the innovation process is supported with relevant insights and interventions.

The first step in developing the framework is to identify the core bottlenecks that frequently obstruct medical device innovation. A detailed literature review and analysis of real-world case studies revealed several recurring obstacles, including regulatory delays, funding shortages, infrastructure limitations, and market adoption challenges (Turner et al., 2024). These barriers, referred to in the framework as Undesired Effects (UEs), highlight the critical pain points that innovators encounter as they attempt to bring medical devices to market. Simultaneously, the study identified solutions, referred to as Alleviations (A) that have been successfully employed to mitigate these bottlenecks. Strategies such as alternative funding mechanisms, strengthened stakeholder collaboration, digital transformation, and streamlined regulatory pathways were identified as important components of a structured support system. This foundation ensures that the framework does not merely document challenges but actively proposes targeted interventions.

To systematically structure these elements, the TIS framework was used as the foundation of the framework (Hekkert et al., 2007), which provides a comprehensive model for understanding the actors, infrastructures, and institutions that drive innovation. By categorizing stakeholders into six key groups, including regulatory bodies, manufacturers, end-users, educational institutions, technology partners, and sponsors, the framework ensures that innovators can easily identify the relevant *innovation actors* at each stage of development (Arnouts et al., 2022). In parallel, it accounts for the necessary *infrastructure* required to support medical device innovation, including prototyping and testing facilities, clinical trial sites, manufacturing plants, and digital infrastructure. Finally, i*nstitutional* elements, such as regulatory compliance bodies, certification agencies, funding institutions, and public-private partnerships (PPPs), are also incorporated to ensure a holistic view of the innovation system (Östlund et al., 2023).

A key element of the framework is its alignment with the TRL model (Turner, 2023), which allows innovators to track their progress through nine stages of technology development. By linking specific bottlenecks and alleviations to each TRL stage, the framework provides a stage-specific roadmap that highlights potential risks in addition to offering

solutions tailored to the current maturity level of the innovation and readiness. In the early stages (TRL 1-3), where basic research and concept validation takes place, the primary challenges include a lack of funding and regulatory uncertainty. Here, the framework helps innovators identify potential funding sources and regulatory preparation strategies. As development progresses into the prototype and early testing phases (TRL 4-6), issues such as high costs, infrastructure limitations, and compliance hurdles become more prominent. The framework provides guidance on optimizing testing facilities, leveraging cost-mitigation strategies, and engaging with regulatory bodies early. In the final TRL 7-9 stages, where testing, approval, and commercialization occur, the emphasis shifts towards regulatory approvals, market adoption, and scaling production. The framework helps innovators prepare for regulatory submissions, develop market entry strategies, and align manufacturing capabilities with anticipated demand.

To ensure that the framework enables structured decision-making, the linking theory (Phaal et al., 2006) was applied to connect various components of the innovation system. This approach allows innovators to see how different stakeholders, infrastructures, and institutions interact across the TRL stages, ensuring that important gaps are proactively addressed. Furthermore, by integrating these elements into a matrix-based decision-support tool (Turner, 2024), the framework visually organizes key information, helping innovators anticipate challenges and implement alleviation strategies in real-time. This structured methodology enables a dynamic and adaptable support system that can be tailored to different types of medical devices and varying regulatory environments.

The final decision-support tool is structured as a comprehensive visual framework that maps the TRL stages against the seven TIS functions (Hekkert et al., 2007). It incorporates a detailed mapping of bottlenecks and their corresponding alleviations, ensuring that innovators have a clear, step-by-step guide to overcoming these barriers. Additionally, it provides insights into the relevant stakeholders, infrastructures, and institutions needed at each stage, making it a holistic and practical tool for navigating the complexities of medical device innovation.

By integrating insights from the three frameworks, namely TRLs, TIS, and Linking Theory, this proposed framework ensures that medical device innovators receive the necessary support to successfully transition through the various stages of technology development and commercialization. It serves as both a diagnostic tool to identify barriers and a strategic guide to overcoming them, making it a valuable asset in ensuring smoother, faster, and more efficient medical device innovation (Figure 1).

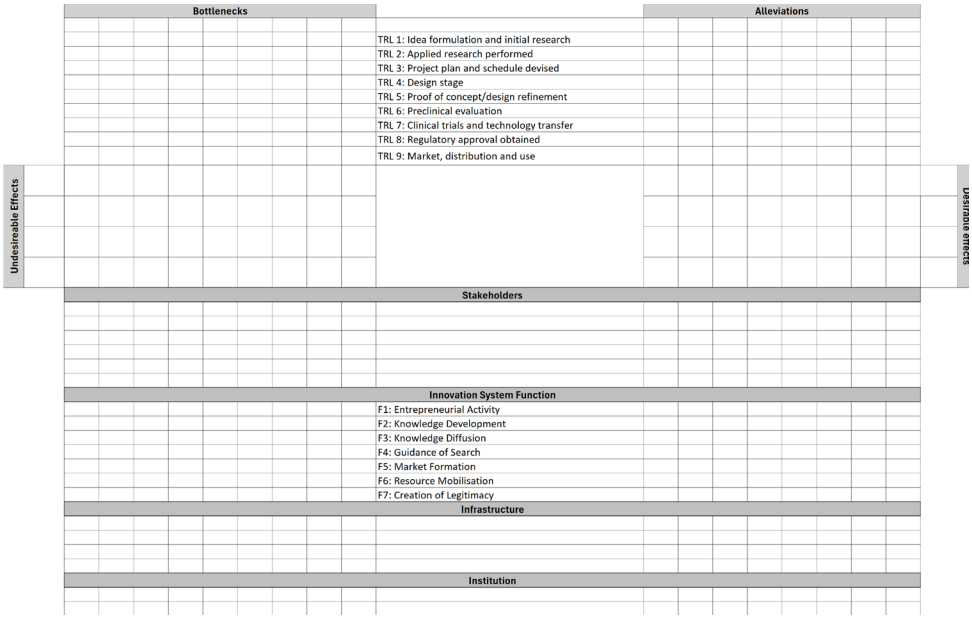

Figure 1. Support Tool Framework

4. Methodology

To evaluate the practical utility of the decision-support tool, it was applied to a real-world case study, namely the National Ventilator Project (NVP). This project provided a relevant example of medical device innovation involving

multiple stakeholders, regulatory processes, and rapid technological development. The tool was implemented using EHA to systematically trace the evolution of the project, identifying key decision points, stakeholder interactions, and barriers encountered at various stages (Van de Ven and Engleman, 2004).

4.1 Data Collection

A comprehensive data collection process was undertaken to reconstruct the events that shaped the NVP. Beyond secondary sources, primary data was gathered through interviews with key stakeholders involved in the project. These stakeholders included government officials, engineers, clinicians, project coordinators, and supply chain experts, each offering unique perspectives on the challenges faced and the strategies employed.

4.2 Database Construction

After data collection, the data was systematically organized into a chronological event database to provide a structured representation of the project's development. Every identified event was logged in sequence, ensuring that each action was positioned within the appropriate innovation phase. An important feature of the database was its integration of the Technology Readiness Levels (TRLs). Events that shared similar characteristics were grouped under thematic categories which facilitated the identification of patterns and common bottlenecks.

4.3 Allocation of Functions

The next step involved assigning functions from the Technological Innovation System (TIS) framework (Hekkert et al., 2007) to the recorded events. Each event was carefully analyzed to determine its role in the development of the innovation system and was then mapped to the actors responsible for the events execution. This allowed for a deeper understanding of how different players contributed to the progression of the project (McClelland, 2023).

By adopting this structured allocation of events and functions, the framework helped construct a cohesive narrative of how interactions between stakeholders influenced the project's outcomes (Suurs & Hekkert, 2009). It also made it possible to track cumulative causation, highlighting how earlier actions and decisions shaped subsequent developments (Östlund et al., 2023). This step ensured that the analysis was descriptive and provided insights into the flow of resources, decision-making, and interdependencies within the system (Bast et al., 2021).

4.4 Data Summary & Analysis

The final stage involved synthesizing the collected data into a meaningful narrative. Each event was deconstructed to understand its significance within the broader innovation system, identifying the factors contributing to success or presenting barriers to progress (Arnouts et al., 2022). By examining the event sequences and each stakeholder interaction, patterns emerged that provide valuable lessons for future medical device projects.

The narrative analysis focused on identifying key enablers of success, such as effective collaboration, adaptive regulatory strategies, and well-coordinated funding mechanisms. Simultaneously, the framework helped pinpoint recurring challenges that included delays in regulatory approvals, supply chain disruptions, and gaps in stakeholder communication (Schnelle, 2024). The structured approach followed allowed for a comparative analysis of similar projects, reinforcing the tool's applicability beyond this case study (Turner, 2024). From this analysis, evidence-based recommendations were formulated, aimed at helping future projects anticipate potential pitfalls and implement proactive solutions.

5. Results and Discussion

5.1 The Matrix in Action: National Ventilator Project

The National Ventilator Project (NVP) was initiated in 2020 as a response to the COVID-19 pandemic. It aimed to address the urgent shortage of ventilators in South Africa. The initiative was coordinated through the Department of Trade, Industry, and Competition (DTIC) in collaboration with the South African Health Products Regulatory Authority (SAHPRA) and leading universities. The project focussed on rapid design, prototyping, regulatory approval, and mass production, complying with international medical device standards. Despite facing challenges like supply chain disruptions, regulatory hurdles, and funding constraints, the NVP successfully developed and delivered thousands of ventilators to the public healthcare system.

The project stands as a key example of collaborative innovation and South African manufacturing capability, demonstrating how coordinated efforts between government, academia, and industry can accelerate medical device development during public health crises.

The decision-support tool was populated using a structured process that integrated event tracking, stakeholder categorization, and intervention mapping. The TRLs framework (Turner et al., 2024) and the TIS framework (Hekkert et al., 2007) provided the analytical foundation for organizing data and identifying systemic interactions.

To create a comprehensive understanding of the project, the detailed event database (Table 2) and summary table(Table 1) are essential components of the analysis. Together, they offer a holistic view of the stakeholders, functions, infrastructures, institutions, and associated challenges and solutions that shaped the outcome of the South African National Ventilator Project (NVP). The summary table complements the in-depth event breakdown by distilling the core elements into a more digestible format, allowing for high-level insights to be drawn about the overall dynamics of the project.

The **stakeholder group (S1-S6)** outlines the key innovation actors involved, categorizing them based on their primary function within the NVP. For each stakeholder group, the number of associated bottlenecks and alleviations is recorded. This quantitative approach reveals which stakeholders were most frequently involved in bottlenecks and what actions were taken to mitigate these challenges. For example, S1 (Regulatory Bodies) encountered three significant bottlenecks,

Table 1. Database Summary

Stakeholder Group (S1-S6)	**Bottlenecks**	**Alleviations**
S1 (Regulatory Bodies)	B1 (Inadequate research), B3 (Excessively complicated processes), B8 (Poor governance)	A6 (Governance), A7 (Holistic idea generation), A8 (Strategic decision-making)
S2 (Manufacturers)	B2 (Lack of funding), B4 (Unforeseen resource disruption), B5 (Inadequate infrastructure), B9 (Lack of strategic decision-making/planning)	A1 (Funding), A2 (Alternative supply chains), A4 (Industry 4.0 and digitalisation)
S3 (End-user)	B6 (Poor networking), B7 (Lack of human resources)	A3 (Support), AS (Strategic networking)
S4 (Educational Institutes)	B1 (Inadequate research), B3 (Excessively complicated processes)	A4 (Industry 4.0 and digitalisation), A7 (Holistic idea generation), A6 (Governance)
S5 (Technology Partners)	B4 (Unforeseen resource disruption), B5 (Inadequate infrastructure), B6 (Poor networking)	A2 (Alternative supply chains), A5 (Strategic networking)
S6 (Sponsor)	B2 (Lack of funding), B6 (Poor networking), B8 (Poor governance)	A1 (Funding), A5 (Strategic networking), A6 (Governance)
TIS Function	**Bottlenecks**	**Alleviations**
F1 (Entrepreneurial Activity)	B5 (Inadequate infrastructure)	A3 (Support), A5 (Strategic networking)
F2 (Knowledge Development)	B1 (Inadequate research), B3 (Excessively complicated processes), B5 (Inadequate infrastructure)	A4 (Industry 4.0 and digitalisation), A7 (Holistic idea generation)
F3 (Knowledge Diffusion)	B6 (Poor networking)	A6 (Governance), A5 (Strategic networking)
F4 (Guidance of Search)	B1 (Inadequate research), B9 (Lack of strategic decision-making/planning)	A8 (Strategic decision-making), A7 (Holistic idea generation)
F5 (Market Formation)	B4 (Unforeseen resource disruption), B5 (Inadequate infrastructure), B6 (Poor networking)	A1 (Funding), A2 (Alternative supply chains, A5 (Strategic networking)
F6 (Resource Mobilisation)	B2 (Lack of funding), B4 (Unforeseen resource disruption)	A1 (Funding), A2 (Alternative supply chains
F7 (Creation of Legitimacy)	B6 (Poor networking), B8 (Poor governance), B9 (Lack of strategic decision-making/planning)	A5 (Strategic networking), A6 (Governance), A8 (Strategic decision-making)
TRL Level	**Bottlenecks**	**Alleviations**
TRL 3-4	B1, B9	A1, A7
TRL 4-5	B2, B9	A8
TRL4-5	B2 - B3, B6	A1, A5 - A3, A6
TRL 5-6	B1, B5 - B3, B9	A1, A4 - A3, A6
TRL 6-7	B7, B5 - B8, B9 - B3, B8 - B7, B5	A1, A4 - A6, A8 - A3, A6 -A1, A3
TRL 7-8	B4, B6 - B5, B7	A2, A4 - A3, A4
TRL8	B4, B5	A2, A4
TRL 8-9	B6, B8	A5, A6
TRL9	B6	A5
Infrastructures	**Bottlenecks**	**Alleviations**
IF1 (Manufacturing Facilities)	B2 (Lack of funding), B4 (Unforeseen resource disruption)	A1 (Funding), A2 (Alternative supply chains)
IF2 (Testing Labs)	B3 (Excessively complicated processes), B5 (Inadequate infrastructure)	A3 (Support), A4 (Industry 4.0 and digitalisation)
IF3 (Distribution and Storage)	B5 (Inadequate infrastructure), B6 (Poor networking), B8 (Poor governance)	A2 (Alternative supply chains), A5 (Strategic networking), A6 (Governance)
IF4 (Prototyping Facilities)	B1 (Inadequate research)	A7 (Holistic idea generation)
Institutions	**Bottlenecks**	**Alleviations**
In (Regulatory Bodies)	B3 (Excessively complicated processes), B6 (Poor networking), B8 (Poor governance)	A6 (Governance), A5 (Strategic networking), A8 (Strategic decision-making)
In2 (Research Institutes)	B1 (Inadequate research), B3 (Excessively complicated processes)	A4 (Industry 4.0 and digitalization) A7 (Holistic idea generation)
In3 (Funding Bodies)	B2 (Lack of funding), B9 (Lack of strategic decision-making/planning)	A1 (Funding), A8 (Strategic decision-making)
In4 (NGOs & Advocacy Groups)	B6 (Poor networking)	A5 (Strategic networking)

which included inadequate research (B1) and overly complex processes (B3), but addressed these through governance (A7) and strategic decision-making (A8). Similarly, S2 (Manufacturers) faced challenges related to funding and infrastructure (B2&5) but leveraged alternative supply chains and digitalization (A2&4) to mitigate these obstacles. The summary table shows how each stakeholder group navigated its respective issues, demonstrating the importance of collaboration and strategic intervention across different phases of the project.

The **TIS Functions** section offers a detailed look into how well the overall innovation framework supported or inhibited progress in the NVP. For example, Entrepreneurial Activity encountered bottlenecks related to inadequate infrastructure and human resources (B5), but these were offset by strategic networking and stakeholder support (A3&5). Other functions, such Knowledge Development and Resource Mobilization encountered issues related to research and funding, highlighting the systemic challenges that the project needed to overcome. However, the alleviations recorded, such as the use of Industry 4.0 technologies and holistic idea generation (A4&7), illustrate that the project was able to navigate these obstacles effectively. This analysis demonstrates the importance of a robust innovation system in enabling complex projects like the NVP.

The **TRL level** section categorizes events according to the Technology Readiness Level at the time of occurrence, ranging from TRL 3-4 (early-stage research and development) to TRL 9 (fully operational systems). Each TRL level is associated with specific bottlenecks and alleviations, giving a clear picture of how the project evolved through different stages of technological maturity. For example, early-stage events at TRL 3-4 were characterized by challenges related to inadequate research and strategic planning, while later-stage events at TRL 8-9 dealt with distribution issues and governance. The summary allows for a more systematic understanding of how the complexity of challenges shifted as the technology matured and moved closer to market readiness.

The **infrastructures (IF1-IF4)** summary highlights the critical physical and technological resources required at various project stages. These infrastructures, such as prototyping facilities, testing labs, and distribution networks, were essential to overcoming bottlenecks like inadequate infrastructure and resource shortages. Alleviations, such as digitalization and alternative supply chains, were crucial for ensuring that the necessary resources were available to keep the project on track. By cataloging these infrastructure-related challenges and solutions, the summary reveals the importance of physical and logistical support in facilitating complex innovation projects.

The **institutions (In1-In4)** section sheds light on the institutional support mechanisms that were critical to the NVP's progress. Institutions such as regulatory bodies, research institutions, and funding organizations played pivotal roles in shaping the project's trajectory. For example, regulatory bottlenecks related to overly complicated approval processes were alleviated through governance improvements and strategic decision-making. By aligning institutional actions with project needs, these entities were able to mitigate many of the challenges that arose during the NVP. The summary underscores the importance of institutional support in ensuring that regulatory, financial, and logistical challenges can be navigated effectively.

In Table 1 and Table 2, the bottlenecks represent key obstacles that hindered progress at various stages of the project, while the alleviations show how these challenges were addressed. By mapping each bottleneck to its corresponding alleviation, the summary table provides a quick reference for understanding which interventions were most effective in resolving specific challenges. For example, issues related to inadequate infrastructure were often mitigated through strategic networking, while governance challenges were addressed through improved decision-making processes.

In summary, the event database and the accompanying summary table together provide a complete understanding of the NVP in South Africa. The event database offers a detailed, step-by-step account of the project's progression, focusing on individual actions and stakeholder involvement, while the summary table provides a broader, more condensed view of the fundamental dynamics at play. By combining these two elements, we gain a comprehensive understanding of how the South African NVP navigated the many challenges it faced, from early-stage research to the final distribution of ventilators and how stakeholders, infrastructures, and institutions played crucial roles in overcoming bottlenecks through effective alleviations. This dual-layered approach ensures that both detailed analysis and high-level insights are available, making it easier to extract valuable lessons for future innovation projects.

5.2 Application of the Decision-Support Tool to the National Ventilator Project (NVP)

Each key phase in the NVP was aligned with TRL stages, ensuring that all phases of innovation were systematically assessed:

Table 2. TRL-based event categorization

TRL Stage	Key Milestones in NVP	Primary Bottlenecks Identified	Alleviations Applied
TRL 1-3	Concept development, initial feasibility studies	Limited funding for R&D, unclear regulatory landscape	Government grants, expert consultation with regulatory bodies
TRL 4-6	Prototype design, technical validation	Supply chain disruptions, clinical testing constraints	Strategic partnerships, local manufacturing incentives
TRL 7-9	Full-scale production, deployment, regulatory approval	Bureaucratic delays, market adoption resistance	Fast-tracked approval processes, targeted industry engagement

By categorizing these milestones, the decision-support tool provided a structured means of assessing where innovation challenges emerged and how targeted alleviations influenced the project's progression.

5.3 Populating Decision-Support Matrices

Two core matrices were populated with data from the NVP to capture stakeholder roles, resource flows, and intervention effectiveness. These matrices were built based on structured data collection, interviews, and secondary sources (Freeman, 1987; Pietzsch et al., 2009). The stakeholder engagement matrix categorizes stakeholders into Receivers (R), Givers (G), and Performers (P), mapping their contributions to different innovation stages. By structuring the matrix this way, the decision-support tool provided clear role delineations to help innovators anticipate when and how different actors engage in the development process (Table 3).

Table 3. Stakeholder engagement matrix

Stakeholder Group	TRL 1-3	TRL 4-6	TRL 7-9
Government Agencies	G (Funding)	P (Regulatory Support)	P (Policy Implementation)
Medical Engineers	P (Concept Development)	P (Prototype Design)	P (Final Product Testing)
Regulatory Bodies	R (Guidance)	G (Compliance Feedback)	P (Approval Process)
Manufacturers	-	R (Technical Input)	P (Production)
Healthcare Providers	-	R (Clinical Trials)	P (Deployment)

The bottleneck-intervention matrix was populated by identifying where key constraints emerged and which interventions were applied successfully. These matrices ensured that the decision-support tool was not just a descriptive model but an actionable framework for identifying and addressing systemic bottlenecks (Table 4).

Table 4. Bottleneck-intervention matrix

Bottleneck	TRL 1-3	TRL 4-6	TRL 7-9
Funding Constraints	Government R&D grants	Private sector investments	Public-private partnerships
Supply Chain Issues	Initial feasibility studies	Sourcing local components	Scaling up production
Regulatory Delays	Early engagement with regulators	Provisional testing approvals	Fast-tracked licensing
Market Adoption Resistance	Industry awareness campaigns	Clinician training programs	Deployment subsidies

5.4 Insights from Tool Application

The application of the decision-support tool to the South African NVP yielded several key insights. First, the tool's structured stakeholder matrix (Table 3) made it evident that the success of the NVP hinged on coordinating government agencies, regulatory bodies, and engineers early on. Furthermore, the Givers, Receivers and performers mapping across the TRL stages enabled the project team to see where each group's involvement was most critical and ensure timely engagement. Next, categorizing challenges and solutions by TRL level (Table 2 and Table 4) enabled the identification of typical VoD points, especially around TRL 4–6, the prototype design and technical validation levels and TRL 7–9,

the final approvals and market deployment levels. The TIS-based analysis (Table 1) repeatedly noted regulatory complexities (B3) and governance gaps (B8) as major barriers. By linking these bottlenecks directly to potential alleviations, the project now knows to address bureaucratic delays and overly complex approval processes more efficiently. The framework also identified poor networking (B6) across multiple stakeholder groups, indicating that siloed efforts were initially limiting knowledge sharing and resource coordination. The framework thus highlights that by prioritizing strategic networking (A5), for example, the NVP could improve information flow, validation and reduce time-to-market. Thus, by integrating these findings, the decision-support tool demonstrated its ability to streamline complex innovation processes and enhance decision-making in future medical device projects.

6. Conclusion

This study validated the decision-support tool's effectiveness in structuring innovation pathways, diagnosing bottlenecks, and optimizing interventions by applying it to the South African National Ventilator Project. The TRL-based categorization, stakeholder role mapping, and decision matrices provided a comprehensive and actionable roadmap for medical device development. The findings emphasized the importance of early engagement, adaptive regulatory frameworks, and structured decision-making in accelerating healthcare technology innovation.

Future applications of this tool could further refine its utility by integrating predictive analytics or expanding its applicability across different healthcare sectors. The insights drawn from this case study offer a practical reference for policymakers, industry stakeholders, and innovators seeking to enhance efficiency in medical device development.

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Appendix

Table 5. Detailed event database

nt no.	Event Description	TRL Level	IS Function	S1	S2	S3	S4	S5	S6	IF1	IF2	IF3	IF4	In1	In2	In3	In4	Alleviations	Bottlenecks
1	SARAO defined ventilator constraints and initiated call for proposals	TRL 3-4	F4 (Guidance of Search)	-	-	-	-	-	-	-	-	-	IF4	-	SARAO (In2)	-	-	A1, A8	B1, B9
2	Candidate X's proposal rejected due to profit-manufacturing conflicts	TRL 4-5	F4 (Guidance of Search)	-	Gablar Medical Group (R)	-	-	-	-	IF1	-	-	-	-	Gablar Medical (In2)	-	-	A1, A5, A8	B2, B9
3	SARAO narrowed proposals, coordinated design, prototyping, production	TRL 4-5	F6 (Resource Mobilisation)	-	-	-	-	CSIR (P)	Solidarity Fund (G)	IF1	IF2	-	IF4	-	SARAO (In2)	Solidarity Fund (In3)	-	A1, A5	B2
4	SARAO assisted SAHPRA in creating a framework for vetting ventilators	TRL 4-5	F3 (Knowledge Diffusion)	SAHPRA (R)	-	-	-	SARAO (P)	-	-	-	-	-	SAHPRA (In1)	SARAO (In2)	-	-	A6, A8	B3, B6
5	CSIR ventilator design selected as winning proposal	TRL 5-6	F2 (Knowledge Development)	SAHPRA (R)	CSIR (P)	-	UCT (P)	-	Solidarity Fund (G)	IF1	IF2	-	-	SAHPRA (In1)	CSIR, UCT (In2)	Solidarity Fund (In3)	-	A1, A7, A3	B1, B5
6	UCT developed ventilator verification protocol approved by SAHPRA	TRL 5-6	F2 (Knowledge Development)	SAHPRA (R)	-	-	UCT (P)	-	-	IF2	-	-	-	SAHPRA (In1)	UCT (In2)	-	-	A6, A8	B3, B9
7	WC Dept. of Health criticized ventilator design for usability issues	TRL 6-7	F1 (Entrepreneurial Activity)	-	-	Hospitals (R)	-	-	-	-	IF2	IF3	-	NDH (In1)	WC DoH (In2)	-	-	A1, A7	B7, B5
8	Conflict between SARAO and NDH over oxygen consumption and space	TRL 6-7	F7 (Creation of Legitimacy)	NDH (R)	Akacia Medical (P)	Public Hospitals (R)	-	-	Solidarity Fund (G)	IF1	IF2	IF3	-	NDH (In1)	SARAO (In2)	Solidarity Fund (In3)	-	A2, A6, A8	B8, B9
9	Lawyer X identified regulatory roadblocks with SAHPRA and NDH	TRL 6-7	F7 (Creation of Legitimacy)	SAHPRA (R), NDH (R)	-	-	-	Gift of the Givers (G)	-	-	-	-	-	SAHPRA (In1)	NDH (In1)	-	Gift of the Givers (In4)	A6, A8	B3, B8
10	Usability testing and SAHPRA approval required despite challenges	TRL 6-7	F1 (Entrepreneurial Activity)	SAHPRA (R)	-	Clinicians (R)	UCT (P)	-	-	-	IF2	-	-	SAHPRA (In1)	UCT (In2)	-	-	A3, A7, A8	B7, B5
11	CSIR faced challenges in managing local manufacturing partnerships	TRL 7-8	F6 (Resource Mobilisation)	-	South African Manufacturers (P), China (R)	-	-	Akacia Medical (P)	Solidarity Fund (G)	IF1	-	-	-	NDH (In1)	Akacia Medical (In2)	Solidarity Fund (In3)	-	A2, A4, A6	B4, B6
12	CSIR training videos created for ventilator use due to COVID	TRL 7-8	F3 (Knowledge Diffusion)	-	-	Clinicians (R)	UCT (P)	CSIR (P)	-	-	-	-	-	SAHPRA (In1)	CSIR (In2)	-	-	A3, A4	B5, B7
13	Akacia shifted from manual to injection mold production	TRL 8	F5 (Market Formation)	-	Akacia Medical (P)	-	-	Akacia Medical (P)	Solidarity Fund (G)	IF1	-	-	-	NDH (In1)	Akacia Medical (In2)	Solidarity Fund (In3)	-	A4, A2	B4, B5
14	SARAO and NDH failed to establish a partnership for distribution	TRL 8-9	F7 (Creation of Legitimacy)	NDH (R)	Akacia Medical (P)	Hospitals (R)	-	Gift of the Givers (G)	-	IF3	-	-	-	NDH (In1)	Akacia Medical (In2)	Gift of the Givers (In4)		A5, A6, A8	B6, B8
15	Akacia bypassed SARAO's distribution process with Gift of the Givers	TRL 9	F5 (Market Formation)	NDH (R)	Akacia Medical (P)	Hospitals (R)	-	Gift of the Givers (G)	-	IF3	-	-	-	NDH (In1)	Akacia Medical (In2)	Gift of the Givers (In4)		A5, A2	B6
16	Distribution issues persisted due to lack of DoH involvement	TRL 9	F7 (Creation of Legitimacy)	NDH (R)	Akacia Medical (P)	Hospitals (R)	-	-	-	IF3	-	-	-	NDH (In1)	Akacia Medical (In2)	-		A5, A6, A8	B6, B8