**UNISINOS UNIVERSITY**

**PRODUCTION AND SYSTEMS ENGINEERING GRADUATE PROGRAM**
**MASTER OF SCIENCE DEGREE**

**GIOVANA DALPIAZ**

# AN INTEGRATED MODEL INCORPORATING CRITICAL SUCCESS FACTORS AND RISK MANAGEMENT FOR THE DEVELOPMENT OF *IN VITRO* DIAGNOSTIC TECHNOLOGIES

**São Leopoldo**

**2025**

GIOVANA DALPIAZ

# AN INTEGRATED MODEL INCORPORATING CRITICAL SUCCESS FACTORS AND RISK MANAGEMENT FOR THE DEVELOPMENT OF *IN VITRO* DIAGNOSTIC TECHNOLOGIES

Dissertation presented to the UNISINOS University in partial fulfillment of the requirements for the Degree of Master of Science in Production and Systems Engineering.

Advisor: Prof. Dr. Débora Oliveira da Silva

Co-advisor: Dr. Mariana Rost Meireles

São Leopoldo

2025

D149i Dalpiaz, Giovana.
An integrated model incorporating critical success factors and risk management for the development of in vitro diagnostic technologies / Giovana Dalpiaz. – 2025.
219 f. : il. ; 30 cm.

Dissertação (mestrado) – Universidade do Vale do Rio dos Sinos, Programa de Pós-Graduação em Engenharia de Produção e Sistemas, 2025.
"Advisor: Prof. Dr. Débora Oliveira da Silva
Co-advisor: Dr. Mariana Rost Meireles".

1. Inovações em saúde. 2. Diagnóstico in vitro. 3. Gestão de riscos. 4. Desenvolvimento de novos produtos. I. Titulo.

CDU 658.5:004

Dados Internacionais de Catalogação na Publicação (CIP)
(Bibliotecária: Amanda Schuster Ditbenner – CRB 10/2517)

**ACKNOWLEDGEMENTS FOR THE SCHOLARSHIP SUPPORT**

This work was supported by the TECNOSINOS/SENAI scholarship, intended for studies focused on strategic themes such as Management, Science, Technology, Innovation and Entrepreneurship.

## ACKNOWLEDGEMENTS

I chose to write my acknowledgments in portuguese, as they are dedicated to people who have been deeply important in my academic journey and life:

A jornada entre o ensino básico e a pós-graduação não é simples, mas certamente teria sido muito mais difícil sem o apoio da minha família. Agradeço, com todo o meu coração, à minha mãe Cristiane, ao meu pai João e à minha irmã Manu, que sempre valorizaram a minha educação e compreenderam as muitas renúncias de tempo e momentos em nome dos estudos. A presença, o amor e o apoio de vocês tornaram essa caminhada possível e muito mais leve. Agradeço também à minha família, em especial aos avós, tios, tias e primas, pelo carinho e incentivo durante essa trajetória. Ser a primeira mestranda (futura mestre) da família é uma conquista que divido com todos vocês.

Ao meu parceiro de vida, meu namorado Lucas, meu imenso agradecimento. Você foi meu maior incentivador durante o mestrado, aquele que muitas vezes me deu o empurrão e a tranquilidade que eu precisava para seguir. Foram inúmeras noites estudando juntos, e tudo isso com a certeza de que também colheremos os frutos juntos. Obrigada por acreditar tanto em mim. Agradeço também à sua família, pelo acolhimento e pelo apoio durante essa caminhada.

À minha orientadora, a Professora Dra. Débora, agradeço por todo o incentivo desde os nossos primeiros contatos, por despertar meu interesse pelo universo da inovação e por me guiar na construção dessa dissertação que une dois mundos que me encantam: a saúde e a inovação. À minha coorientadora Dra Mariana, que foi muito mais do que isso — uma mentora, uma irmã — agradeço pela sabedoria, pela disponibilidade e pelo apoio em tantas fases deste processo (e da vida).

Aos professores do PPGEPS, meu muito obrigada. Como biomédica, entrei nesse Programa sem saber nada sobre Engenharia de Produção, e vocês me ensinaram como ver o mundo da engenharia pelo olhar de uma profissional da saúde. Espero ter conseguido transpor esses conhecimentos em meu trabalho. Além disso, agradeço a todos os professores que me acompanharam desde as séries iniciais, contribuindo para a minha formação profissional e pessoal.

Às colegas e amigas, meu agradecimento especial. Muriel, por todos os momentos compartilhados e pelo suporte constante do dia a dia. Lívia, minha dupla de mestrado, que tantas vezes foi meu braço esquerdo e direito. Ao grupo de pesquisa da Professora Débora, obrigada pela parceria e por fazerem parte dessa trajetória. Aos amigos que estiveram presentes, mesmo que apenas ouvindo meus desabafos, obrigada por fazerem parte desse ciclo

Agradeço também à empresa Biosens e aos meus colegas de trabalho. Como pesquisadora em parceria com a empresa, tive uma experiência que foi essencial para o meu crescimento profissional. Aprendi muito sobre dispositivos médicos e pude compreender, ainda mais, sua importância para a assistência em saúde.

Por fim, agradeço a Deus por me conceder coragem, sabedoria e ciência para concluir mais esta etapa. Este mestrado me desafiou, me tirou da zona de conforto e me fez crescer. **Termino com a certeza de que a educação e a ciência transformam, e que estudar é sempre o melhor caminho.**

## ABSTRACT

Health innovation is essential for improving the quality of life, enabling solutions that expand access to and efficiency of healthcare services. Medical devices, particularly *in vitro* diagnostic tests (IVDs), which are conducted on biological samples outside the human body, play a critical role in diagnosis and treatment management, facilitating decentralized care and bringing healthcare closer to patients. However, developing such technologies is complex, as it involves technical, regulatory, market, and managerial challenges. In this context, the New Product Development (NPD) process helps address these barriers by guiding the use of management practices and tools that support development. Among these, NPD models structure processes, assist decision-making, support risk monitoring, and facilitate cross-functional integration. Although numerous models exist in the literature, a gap was observed regarding models specifically focused on IVD development, which is relevant because more general models may limit applicability in this context. Therefore, this study aimed to propose a model incorporating critical success factors and risk management practices to support the development of new *in vitro* diagnostic technologies. To achieve this, the Design Science Research (DSR) method was adopted. The DSR method guides the construction of artifacts (the NPD model) capable of solving real-world problems, in this case, providing a structured representation of the NPD process. Initially, a Systematic Literature Review was conducted to map gaps and identify models applicable to medical device development. Based on these findings, the development stages, six critical areas, and a risk management approach were defined, which underpinned the first version of the model (v.1). Subsequently, interviews and questionnaires with seven professionals allowed the identification of challenges, critical factors, and stakeholders, leading to the first optimization (v.2) by integrating empirical data with literature findings. Evaluation with six specialists and a focus group led to a second optimization (v.3), incorporating practical context insights and confirming the model's potential for IVD applications. Finally, the last stage consolidated the lessons learned, resulting in the final version of the model (v.4), named IRIS (Integrated Risk and Innovation Strategic), accompanied by supporting materials to facilitate its application in real-world scenarios. This study presents an innovative proposal by developing an NPD model tailored to IVDs, even though it integrates existing elements. The tool, which has a national focus, contributes to expanding knowledge and consolidating good practices related to critical success factors and risk management. Among the limitations, the following stand out: the small number of respondents and the fact that the model may not yet address all IVD-specific requirements, necessitating continuous refinement. These limitations, however, open opportunities for future research, such as applying the model in real projects and enhancing it with new tools and metrics. In summary, the developed model not only expands academic knowledge but also serves as a practical resource to support the development of diagnostic technologies that positively impact health and quality of life.



Keywords: Health innovations; *In vitro* diagnostics; New Product Development; Risk management.

## RESUMO

A inovação em saúde é essencial para melhorar a qualidade de vida, permitindo soluções que ampliam o acesso e a eficiência dos serviços. Os dispositivos médicos, especialmente os testes de diagnóstico *in vitro* (IVDs), realizados em amostras biológicas fora do corpo humano, são fundamentais para o diagnóstico e o gerenciamento de tratamentos, favorecendo a descentralização e aproximando o cuidado de saúde do paciente. No entanto, desenvolver esse tipo de tecnologia é complexo, pois envolve desafios técnicos, regulatórios, de mercado e de gestão. Nesse sentido, o processo de Desenvolvimento de Novos Produtos (NPD) contribui para enfrentar tais barreiras, pois orienta o uso de práticas e ferramentas de gestão que apoiam o desenvolvimento. Entre elas, os modelos de NPD estruturam os processos, apoiam a tomada de decisão, o monitoramento de riscos e a integração de áreas. Embora existam muitos modelos na literatura, observou-se uma lacuna quanto a modelos focados no desenvolvimento de IVDs, o que é relevante, pois modelos mais gerais podem limitar a aplicabilidade nesse contexto. Assim, o objetivo deste estudo foi propor um modelo que incorpore fatores críticos de sucesso e práticas de gerenciamento de risco para dar suporte ao desenvolvimento de novos produtos em tecnologias de diagnóstico *in vitro*. Para tanto, adotou-se o método *Design Science Research*, cuja finalidade é orientar a construção de artefatos (o modelo de NPD), capazes de solucionar problemas reais, neste caso, oferecendo uma representação estruturada do processo de NPD. Inicialmente, foi realizada uma Revisão Sistemática da Literatura para mapear lacunas e identificar modelos aplicáveis ao desenvolvimento de dispositivos médicos. Com base nisso, definiu-se os estágios que ocorrem o desenvolvimento, seis áreas críticas e uma abordagem de gestão de riscos, que fundamentaram a primeira versão do modelo (v.1). Em seguida, entrevistas e questionários com sete profissionais permitiram identificar desafios, fatores críticos e *stakeholders*, levando à primeira otimização (v.2) ao integrar os dados empíricos com os achados da literatura. A avaliação com seis especialistas e um grupo focal promoveu a segunda otimização (v.3), incorporando observações do contexto prático e confirmando o potencial de uso do modelo para IVDs. Por fim, a última etapa envolveu a consolidação das lições aprendidas, resultando na versão final do modelo (v.4), denominado IRIS (*Integrated Risk and Innovation Strategic*), acompanhada de material de apoio para facilitar sua aplicação em cenários reais. Este estudo apresenta uma proposta inovadora ao desenvolver um modelo de NPD orientando aos IVDs, mesmo que integre elementos já existentes. A ferramenta, que possui um enfoque nacional, contribui para ampliar o conhecimento, consolidar boas práticas relacionadas a fatores críticos de sucesso e à gestão de riscos. Entre as limitações, destaca-se o número reduzido de entrevistados e o fato de que o modelo ainda pode não contemplar todas as especificidades de um IVD, sendo necessário seu constante aprimoramento. Essas limitações abrem oportunidades para pesquisas futuras, como aplicar o modelo em projetos reais, e aprimorá-lo com novas ferramentas e métricas. Em síntese, o modelo desenvolvido amplia o conhecimento acadêmico e se apresenta como um recurso prático para apoiar o desenvolvimento de tecnologias de diagnóstico que impactam positivamente a saúde e a qualidade de vida da população.



Palavras-chave: Inovações em saúde; Diagnóstico *in vitro*; Desenvolvimento de Novos Produtos; Gestão de riscos.

## LIST OF FIGURES

## LIST OF TABLES

## NOMENCLATURE

| | |
|---|---|
| ANVISA | Agência Nacional de Vigilância Sanitária |
| CEIS | Health Economic-Industrial Complex |
| CVI | Content Validity Index |
| DSR | Design Science Research |
| DTM | Document-Term Matrix |
| FDA | Food and Drug Administration |
| IAMDT | Technology Development Model Assessment Instrument |
| IVD | *In Vitro* Diagnostics |
| ICF | Informed Consent Form |
| IEC | International Electrotechnical Commission |
| ISO | International Organization for Standardization |
| IRL | Investment Readiness Level |
| LDA | Latent Dirichlet Allocation |
| LGT | Literature Grounded Theory |
| MVP | Minimum Viable Product |
| NPD | New product development |
| PNCTIS | National Policy on Science, Technology, and Innovation in Health |
| PNVS | National Health Surveillance Policy |
| POCT | Point of Care Testing |
| PRISMA | Preferred Reporting Items for Systematic reviews and Meta-Analyses |
| PMI | Project Management Institute |
| R&D | Research and Development |
| SUS | Unified Health System (Sistema Único de Saúde) |
| SMEs | Small and Medium-sized Enterprises |
| SDG | Sustainable Development Goals |
| SLR | Systematic Literature Review |
| TBFs | Technology-based firms |
| TRL | Technology Readiness Level |
| UMAP | Uniform Manifold Approximation and Projection |
| UN | United Nations |

## TABLE OF CONTENTS

# 1 INTRODUCTION

The development of new products in the healthcare sector plays a significant role in transforming healthcare and medical assistance by facilitating patient diagnosis and monitoring, while promoting improvements in quality of life and service delivery (Moorman *et al*., 2024; Flessa & Huebner, 2021). However, such progress relies on continuous innovation, as research and developing new technologies and procedures are essential to driving advancement in the sector (Zaman & Tanewski, 2024; Flessa & Huebner, 2021).

The advancements enabled by the continuous development of new products have benefited the population by improving disease treatment, monitoring, and prevention, particularly in previously more complex conditions to manage (Mahara *et al*., 2023). Moreover, health technologies contribute to more accurate decision-making and can be applied in preventive actions, reducing the operational costs of healthcare systems (De la Torre *et al*., 2025).

To this end, various technologies can be employed, particularly medical devices, which are instruments used to diagnose, prevent, or treat a clinical condition (Ferrusi *et al*., 2009). Among these, *in vitro* diagnostic (IVD) medical devices stand out due to their significant applicability in diagnosing and managing specific treatments, surveillance or therapies (Wang *et al*., 2023). According to the Food and Drug Administration (FDA), *an IVD* encompasses tests performed on biological samples, such as blood or tissue, collected from the human body to detect diseases or other health conditions (FDA, 2024).

The IVD market has experienced rapid growth, accounting for approximately 5% of the global healthcare economy (Byrne, 2020). This expansion is driven by the increasing demand for healthcare services and the need for faster and more accurate diagnostic methods (Wang *et al*., 2023). Technological advances have enabled the development of efficient and accessible devices, such as point-of-care testing (POCT) or rapid tests, which are characterized by their ease of use and high sensitivity and specificity in target detection (Wang *et al*., 2023). These devices have expanded access to diagnostics in hard-to-reach regions and low-complexity healthcare systems, helping to reduce costs and accelerate clinical decision-making, thereby positively impacting treatment effectiveness (Zhang *et al*., 2020). In Brazil's Unified Health System (Sistema Único de Saúde – SUS), for example, a list of

available tests allows for the early diagnosis of several clinical conditions, such as hepatitis, HIV, syphilis, among others (Brazil, 2022).

Moreover, the potential applicability of new medical devices becomes even more relevant in light of population ageing and the high prevalence of morbidities and chronic diseases (Guérineau, 2024; Ryan *et al*., 2018). The United Nations (UN) projects that by 2050, the global elderly population will more than double (UN, 2023). In this context, increased life expectancy leads to greater demand on healthcare systems, making the development of technologies that optimise and facilitate healthcare delivery essential (De la Torre *et al*., 2025; Abernethy *et al*., 2022).

Nevertheless, the process of developing, validating, manufacturing, and commercializing an IVD is particularly complex, as it involves not only critical stages common to various types of technological innovation, but also stringent regulatory requirements, robust clinical validation, and compliance with specific standards to ensure diagnostic safety and efficacy (Das & Dunbar, 2022). Furthermore, one of the main challenges identified in the healthcare sector is not a lack of innovation, but rather the difficulty in disseminating and translating these innovations into viable market products (Flessa & Huebner, 2021; Berwick, 2003).

Innovations in medical technologies are characterised by their complexity, high costs, and lengthy development cycles, which can range from 12 to 15 years (Dutta & Dhar, 2024). Among the main challenges are the initial phases of the process, particularly in product design, including the selection of the target to be identified and the definition of the biological reactions involved (Oliveira *et al*., 2024). These stages require thorough analysis and integration of knowledge from multiple disciplines, such as engineering and biology (David & Judd, 2020). An imprecise definition of parameters and specifications at this stage can lead to rework, schedule delays, and increased costs, compromising the product's commercial success (Fearis & Petrie, 2017).

These challenges become even more complex when dealing with projects within the healthcare sector, which is often associated with radical innovations involving a high degree of uncertainty and risk during development. In this context, understanding and structuring the new product development (NPD) process through systematic and integrated management, from conception to commercialisation, becomes essential to fostering product success (Flessa & Huebner, 2021).

The NPD consists of a structured sequence of stages, activities, and decisions aimed at bringing a new product or service to the market. This process integrates strategic analyses, risk assessment, and evaluation of operational feasibility, which are vital factors for a company's competitiveness (Kheir, Jacoby, & Verwulgen, 2022; Salgado *et al*., 2017). Various tools and models have been applied to support this process, often represented graphically to facilitate understanding and implementation. These tools contribute to knowledge dissemination, decision-making support, and efficient innovation management. Among the widely recognized models are the "development funnel" and the stage-gate approach, both highlighted as influential in innovation management (Wang & Chen, 2023; Salerno *et al*., 2015). Thus, adopting appropriate tools and decision-support models is essential for NPD success and is also influenced by organizational factors such as culture, commitment, and strategy (Medina, Kremer, & Wysk, 2013; Ernst, 2002).

In this regard, the models and tools guiding NPD have demonstrated positive effects on the development of medical devices, such as reducing time to market, optimizing resource allocation, and improving organizational portfolio planning (Tiedemann, Johansson, & Gosling, 2020). In the case of IVDs, their development often leads to radical innovations that potentially transform healthcare delivery. However, although traditional NPD models offer general benefits, they prove limited in addressing the particularities of this type of development, especially in projects characterized by a high degree of uncertainty. This underscores the need to adapt and evolve NPD practices to meet the specific demands of this sector better (Eng, 2004).

When properly adapted, NPD practices in the development of new medical products not only enhance the efficiency and effectiveness of the process but also contribute to the sustainability and growth of companies (Kheir *et al*., 2022). In addition, these practices allow for the identification of risks, uncertainties, and critical success factors, which correspond to specific areas of development. When effectively managed within their respective domains, these factors can promote successful competitive performance for the organization (Russell & Tippett, 2008; Rockart, 1979). In the context of medical devices, critical factors may include stakeholder communication, compliance with regulatory requirements, and technological complexity (Guérineau, 2024; Tsai, Wang, & Chen, 2023).

The development of health technologies drives medical innovation and aligns with the United Nations Sustainable Development Goals (SDGs), such as SDG 3 (Good Health and Well-being) and SDG 9 (Industry, Innovation, and Infrastructure) (UN, 2024). IVDs enable faster and more accurate diagnostics, aiding disease control and improving quality of life (SDG 3). At the same time, innovation in medical devices strengthens industry and expands access to diagnostic solutions (SDG 9) (Kruk *et al*., 2018). More structured and efficient development reduces costs, optimizes timelines, and broadens these technologies' social and economic impact (Sinha, 2024).

Based on the aspects mentioned, this study focuses on the analysis and optimization of processes for the development of new products aimed at *in vitro* diagnostic medical devices. The research seeks to contribute to the improvement of innovation processes, enhance the competitiveness of companies in the sector, and, above all, enable the development of technologies with the potential to improve the population’s quality of life. In the next section, the subject of the study and the research question are presented.

## 1.1 PURPOSE OF THE STUDY AND RESEARCH QUESTION

NPD in the medical device sector is driven by the need to enhance healthcare delivery and tailor technologies to clinical demands. However, this process faces several challenges, including limited funding, inadequate resource allocation, and a lack of market credibility, which hinder the implementation and diffusion of innovations (Babu, 2021).

Among the various types of medical devices, IVDs present specific characteristics, such as the need for rigorous analytical and clinical validation, strict regulatory oversight, and rapid technological advancement, making their development particularly challenging (Amaral *et al*., 2024; Chiku *et al*., 2024). These challenges go beyond those involved in creating a new diagnostic laboratory method, as developing an IVD requires transforming that method into a viable final product, regulated, safe, reproducible, and scalable (Wang *et al*., 2023). Furthermore, IVDs are inherently more complex due to their use in diagnosing and assessing clinical conditions, which critically influence medical decision-making. This feature implies a higher potential health risk in the event of failure, especially when compared to other

types of medical devices whose use is not directly associated with clinical decision-making (Tallarico *et al*., 2022; Tase *et al*., 2022)

Given these particularities, the obstacles are further intensified by the involvement of radical innovations, which demand robust management in the face of high uncertainties inherent to the development process and the complexities associated with creating new products and markets (Rakic, 2020; Flessa & Huebner, 2021). Effectively managing innovation becomes a critical factor in enabling technological advancements and ensuring that the solutions developed positively impact population quality of life (Chatterjee *et al*., 2023).

Identifying the critical success factors for NPD in IVDs is therefore essential to mitigate the adverse effects associated with these challenges (Medina, Kremer, & Wysk, 2013). NPD processes have consequently been studied and refined, particularly given that approximately 88% of organizations involved in medical technology development fail to achieve financial returns (Marešová *et al*., 2020). In this context, a strategic evaluation of these processes is crucial to ensure successful development that aligns with stakeholders' requirements (Flessa & Huebner, 2021; Marešová *et al*., 2020).

Although NPD models for medical devices are already described in the literature, there remains a lack of standardization specific to practices applied to IVDs. As a result, these practices tend to be generalist, overlooking the unique characteristics of this type of product, which require tailored approaches within models adapted to their specific *in vitro* diagnostic context (Marešová *et al*., 2020). Moreover, the models and methods used to identify and monitor critical success factors and development stages are limited. These approaches often rely on linear and subjective strategies, without adopting a holistic perspective that encompasses all phases of the development process and provides adequate support to the teams involved (Lister *et al*., 2017; Joly, 2017; Medina, Kremer, & Wysk, 2013).

The lack of comprehensive management and research in this area contributes to the failure of *in vitro* product development projects. Key challenges include inadequate management of uncertainties and risks, difficulties navigating the regulatory process, limitations in adapting to human, technical, and organizational changes, misalignment with the market and with the expectations of customers and clinical practice, and communication failures among stakeholders. Therefore, developing multifaceted approaches to healthcare innovation is essential to mitigate

the high failure rates in NPD of medical devices, considering that fewer than 6% of these devices reach the market annually (Nirali P. Shah, 2024; Warty *et al*., 2021).

In this context, optimizing NPD processes becomes essential, as inefficiencies can lead to inadequate resource allocation, imprecise investments, or unnecessary costs, as well as the prioritization of variables that may cause delays in development timelines (Kim, Park, & Sawng, 2016). These factors prolong time-to-market, resulting in lost market opportunities and compromising the expected performance of the innovation and the company's competitiveness. Furthermore, they can negatively affect the company's position within the sector and limit opportunities for improving healthcare delivery to the population (Manetti, Lettieri, & Ni, 2023; Bergsland, Elle, & Fosse, 2014).

While some barriers, such as those related to regulatory stages, are inherently time-consuming aspects of the NPD process, others can be mitigated through strategies aimed at more efficient management of the development phases (Bergsland, Elle, & Fosse, 2014). Accordingly, this research sought to answer the question: *How can critical success factors and risk management practices be translated into a model for new product development in the IVD sector?*

## 1.2 OBJECTIVES

The objectives of this study are defined as a general objective and specific objectives, as described below.

### 1.2.1 General objective

The general objective of this study is to propose a model that incorporates critical success factors and risk management practices to support new product development in *in vitro* diagnostic technologies.

### 1.2.2 Specific objectives

To address the general objective of this study, the following specific objectives will be pursued:

a) To map practices reported in the literature applicable to new product development in the medical device sector.

b) To identify the main critical success factors for *in vitro* medical device development through a case study.

c) To evaluate an integrative model based on theoretical and empirical findings, considering its applicability to new product development in *in vitro* diagnostics.

As presented in Table 1, the specific objectives outlined in this research will be addressed across the different articles comprising this dissertation.

Table 1 – Relationship between the general and specific objectives of the dissertation

| General Objective | Specific Objectives | Article |
|---|---|---|
| To propose a model that incorporates critical success factors and risk management practices to support new product development in *in vitro* diagnostic technologies. | To map practices reported in the literature applicable to new product development in the medical device sector. | Article 1: Assessment of Practices for New Product Development in Medical Devices: A Systematic Literature Review |
| | To identify the main critical success factors for *in vitro* medical device development through a case study. | Article 2: Innovating *In Vitro* Diagnostics: Critical Success Factors and an Integrative Model for Medical Device Development |
| | To evaluate an integrative model based on theoretical and empirical findings, considering its applicability to new product development in *in vitro* diagnostics. | |

Source: elaborated by the author (2025).

## 1.3 JUSTIFICATION

Innovations in healthcare contribute to improvements in both the quality of services provided and patients' quality of life, particularly in the case of IVDs, which, as reported in the literature, inform approximately 66% of clinical decision-making (Rohr *et al*., 2016). Nevertheless, during the development process, many of these products may fail to succeed due to the challenges associated with overcoming barriers to innovation (Flessa & Huebner, 2021).

The development of faster and more accessible diagnostic solutions, from conception to market introduction, relies on structured stages of development, testing, and validation. The IVD industry is characterized by multifaceted challenges that contribute to the high failure rates observed in this sector (Nirali P. Shah, 2024; Marešová *et al*., 2020). The literature highlights the implementation of NPD as a strategic element for enabling effective innovation (Roberts; Palmer; Hughes, 2022). Recognizing the importance of adopting NPD practices throughout the development process aligns with industry data, which estimate that only 25% of venture capital–backed medical technology companies succeed in bringing their products to market (Goldenberg & Gravagna, 2017).

In this context, two aspects stand out as potentially beneficial to the development process: (i) the identification of critical success factors and (ii) the adoption of risk and uncertainty management practices. Critical success factors are measurable and identifiable elements that enable organizations to allocate efforts more efficiently and support strategic decision-making (Sony; Antony; Tortorella, 2023). The literature indicates that prioritizing these factors can contribute to resource optimization throughout the development cycle by highlighting elements that effectively add value to the product (Degerli; Ozkan Yildirim, 2022). Additionally, risk management has been widely recognized within the context of NPD for its ability to help organizations balance innovation with mitigating failures and financial losses through the systematic mapping of risks and uncertainties (Peljhan; Marc, 2023). This approach has been the subject of numerous studies applied to the healthcare sector (Kheir; Jacoby; Verwulgen, 2022; Singh; Selvam, 2020).

Although the benefits of NPD and the optimization of its processes are widely recognized in the literature, there is a noted shortage of studies specifically applied to the healthcare sector (Friebe *et al*., 2022). Moreover, many companies face challenges in implementing innovation management practices, exhibiting limitations in addressing risks and uncertainties, particularly those related to developing new technologies. These vulnerabilities impact organizations' portfolio management practices (Cooper, 2023). This gap is further supported by studies indicating that less than half of the "best companies" possess an adequate management system to monitor their innovation portfolio (Knudsen *et al*., 2023). Therefore, managers must adopt approaches and tools grounded in best practices to support decision-making and strengthen innovation management (Cooper, 2023).

In this regard, to analyze the existing literature on NPD in IVDs, searches were conducted in the Scopus database in May 2025. Table 2 presents the articles initially retrieved, highlighting a substantial body of scientific literature on medical devices and innovation, reflecting the growing interest in developing these technologies. However, more specific searches focused on NPD processes in medical devices revealed a considerably smaller number of publications. When narrowing the scope to *in vitro* diagnostics, there is a noticeable absence of studies on this topic, indicating gaps in the literature and opportunities for future research.

Table 2 - Search in Scopus databases

| Search terms | Search field | Result |
|---|---|---|
| “medical device” | Article title, Abstract and Keywords | 88512 |
| “innovation” AND “medical device” | Article title, Abstract and Keywords | 2975 |
| ("new product development" OR "NPD") AND "medical device" | Article title, Abstract and Keywords | 137 |
| ("new product development" OR "NPD") AND "*In Vitro* Diagnostics" | Article title, Abstract and Keywords | 2 |

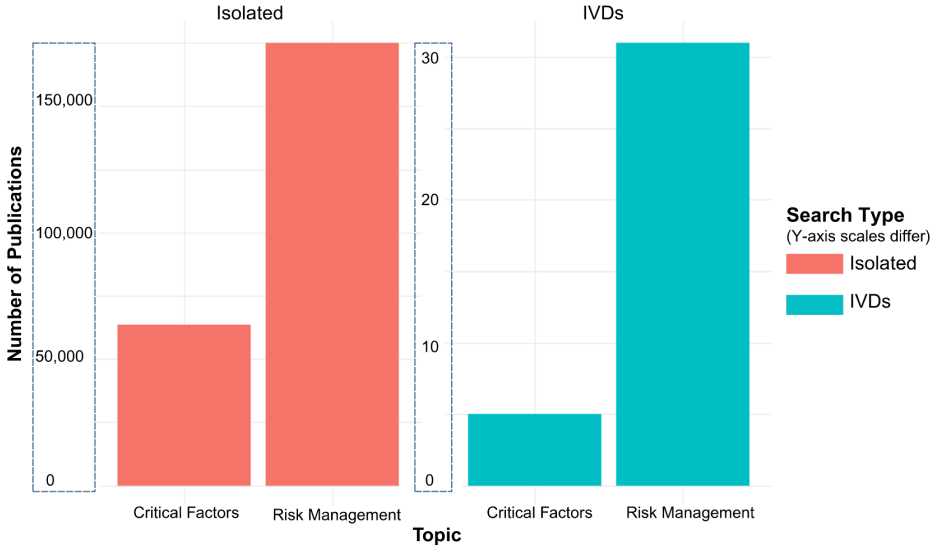
Source: Prepared by the author (2025).

The second phase of the research, also conducted using the Scopus database, aimed to map studies addressing critical success factors and risk management practices in NPD for *in vitro* technologies. Investigating these themes is essential to support more informed decision-making throughout the development process (Kim, 2022). As illustrated in Figure 1, the analysis revealed a limited number of publications specifically focused on these aspects, particularly in the context of *in vitro* technologies, underscoring the need for a deeper understanding of the impact of adopting such practices in the sector.

The literature review highlights a scarcity of studies specifically focused on IVD devices. While several publications address medical devices more broadly, few differentiate between types of products analyzed. This distinction, however, is crucial, as IVDs possess unique technical and regulatory characteristics that set them apart from other types of healthcare technologies. The absence of such delineation limits

the practical applicability of research findings and reinforces the need for more targeted investigations within this specific segment.

Figure 1 - Publication on critical success factors and risk management




Caption: Y-axes use different scales. “Isolated” searches yield thousands of publications, while “IVD” searches return only dozens.

Source: Prepared by the author (2025).

Moreover, it is important to highlight the limitations of traditional NPD models and tools when applied to the development of IVDs, due to the specific characteristics of this segment, which is highly technological and subject to numerous barriers throughout the process, particularly in the regulatory stages (Chakravarty, 2022). As a result, many healthcare projects require hybrid models or more flexible and less structured approaches that can foster enhanced communication, productivity, and a more agile response to market demands (Trott *et al.*, 2022).

This need to tailor NPD practices underscores the importance of further research on the topic and the development of resources to support organizations in identifying and adopting methods suited to their specific contexts. Such an approach facilitates the integration of critical success factors into NPD, aligned with strategies aimed at optimizing development processes.

The importance of NPD can be better understood by examining its application in case studies involving other medical devices. In one example, adopting an

adapted stage-gate approach for developing an imaging technology led to a more structured decision-making environment. It enhanced the team's ability to monitor project progress (Martin; Barnett, 2012). In the study by Kruachottikul *et al* (2024), more efficient management of regulatory processes was observed, along with greater stakeholder engagement and improved alignment with market demands, which increased the likelihood of successfully transitioning a project into a commercially viable clinical product (Kruachottikul *et al.*, 2024). These findings reinforce the relevance of structured NPD practices, as they strengthen project governance and increase innovation success rates.

Thus, the present project offers contributions across multiple domains. In the academic sphere, the research is grounded in studies focused on product development in the healthcare sector, enabling the identification of critical success factors for the NPD of IVDs and the design of a model that integrates all the mapped elements.

In the professional context, the project contributes by integrating diverse perspectives, combining expertise in the healthcare field with a systematic view of NPD. In the business domain, the project plays a strategic role by promoting the development of new products, optimizing processes, reducing costs and risks, enhancing competitiveness, and, most notably, supporting management decisions.

Moreover, the study is aligned with Brazilian public policies, such as the National Strategy for the Development of the Health Economic-Industrial Complex (CEIS) (Brazil, 2023), the National Policy on Science, Technology, and Innovation in Health (PNCTIS) (Brazil, 2009), and the National Health Surveillance Policy (PNVS) (Brazil, 2018), by contributing to the advancement of technical-scientific knowledge related to IVD medical devices. By addressing this topic, the study provides a more targeted and evidence-based approach to support informed decision-making and guidelines, aiming to strengthen the medical device industry and enhance the quality of technology development for diagnostics.

Based on the arguments presented, the discussions presented justify the development of this study:

a) The IVD industry presents unique technical and regulatory characteristics and specific challenges, making it essential to adopt a targeted approach that considers these particularities in product development;

b) The effective implementation of NPD can foster innovation in healthcare by reducing failures, optimizing processes, and strategically allocating resources, thereby increasing the likelihood of clinical and commercial success;
c) The scarcity of studies specifically applied to NPD in IVDs limits the practical applicability of scientific findings, highlighting the need for deeper knowledge to support more informed decision-making in the sector;
d) This study aligns with public policies on science, technology, and innovation in health, contributing to the development of resources that may support the strengthening of the national medical device industry;
e) Academically, the present study proposes a framework that integrates critical success factors and risk management practices in NPD for IVDs.

This research is particularly relevant as it proposes a model for developing IVD technologies, identifying critical success factors and managing risks and uncertainties. By focusing specifically on IVDs, the study addresses a gap in the literature, taking into account the technical and regulatory particularities of this sector. In doing so, it contributes to reducing failures, optimizing resources, and enhancing efficiency in the innovation process, thereby supporting more informed decision-making. Furthermore, it aligns with national public policy guidelines on science, technology, and health, reinforcing the strategic role of IVDs within the healthcare system.

## 1.4 DELIMITATIONS

This study is delimited to the development of a NPD model specifically designed for *in vitro* technologies, incorporating critical success factors and risk management practices. The main delimitations include the technological scope, as it focuses primarily on IVDs and does not encompass other types of medical devices or therapeutic areas. In the geographical and regulatory domains, the focus is on the Brazilian context, considering its specific regulatory (ANVISA), structural, and market characteristics. The results may inspire applications in other contexts but were not tested in other countries. Nevertheless, this is not considered a barrier to future practical application, since ANVISA is internationally recognized as a high-level

regulatory authority, and this orientation may also support the development of similar initiatives in other settings.

Regarding temporality and data, the study is based on information collected between October 2024 and July 2025, including a Systematic Literature Review (SLR) and multiple case studies involving six companies and seven participants. Accordingly, the research comprised the following stages: (i) an SLR conducted to identify NPD models and practices applied more broadly in the medical device industry, with this wider scope justified by the scarcity of studies specifically focused on IVDs; (ii) multiple case studies aimed at mapping critical factors in national companies with active R&D (Research and Development) teams operating in Brazil; and (iii) the development and evaluation of the integrative model named IRIS. The detailed analysis of specific phases, such as clinical testing or regulatory validation, was not an objective of this study, which instead focused on the macro-stages of the development process.

Regarding the limitations of generalization, although the model may provide insights applicable to other segments of medical devices, its implementation beyond the defined scope may require adaptations. Nevertheless, the results can generate valuable insights and recommendations for the medical device industry, thereby contributing to more effective innovation management practices in the healthcare sector.

## 1.5 WORK STRUCTURE

This research project is structured as follows: Chapter 1 presents the introduction, including the research topic, definition of the object and problem, general and specific objectives, justification, scope, and overall structure of the study.

Furthermore, Chapter 2 outlines the methodological procedures proposed for the study, detailing the methodological approach, research design, scientific method, and research and work methods. Subsequently, Chapter 3 presents the first article of this research. Its main objective was to identify and analyze product development process models applied in the diagnostic technology industry, based on existing literature. The results presented in this chapter address the first and second specific objectives proposed in this study.

Chapter 4 presents the second article of this dissertation, which proposes a validated NPD model tailored to IVDs. By providing a structured and applicable framework, this model has the potential to enhance NPD practices within the segment. Thus, this chapter contributes to a deeper understanding of the challenges and success factors specific to IVDs and addresses specific objectives “b” and “c” of the research.

To conclude the study, Chapter 5 presents the final considerations of the dissertation. This chapter highlights the main findings and lessons learned throughout the research, discusses the connections and complementarities between the two articles, and reflects on the limitations and challenges encountered during the study. Additionally, it outlines possible directions for future research and practical implications for the medical device industry.

# 2 METHODOLOGICAL PROCEDURES

This chapter will present the design, research and work methods adopted in the development of this study.

## 2.1 RESEARCH DESIGN AND RESEARCH METHOD

Research methods comprise a set of guidelines and procedures for collecting, analysing, and interpreting data, with the objective of generating scientific knowledge and addressing research questions (Barnes, 2001). In this context, research design represents a critical stage, guiding the methodological decisions shaping the procedures adopted throughout the study.

Research design is characterized by the planning of the study, with an emphasis on data collection and the variables involved (Gil, 2017). Although related to the research design, the research method defines the strategy for addressing the investigated problem (Dresch, Lacerda, & Antunes, 2015). To answer the research question, this study adopted the Design Science Research (DSR) method, as it aims to understand a problem and, based on this understanding, construct and evaluate artifacts that help bridge the gap between theory and practice (Dresch, Lacerda, & Antunes, 2015). In this regard, the present study employed the DSR method, as it sought to understand the challenges of the NPD process in *in vitro* medical devices and, based on this understanding, proposed a model applicable to the medical device industry.

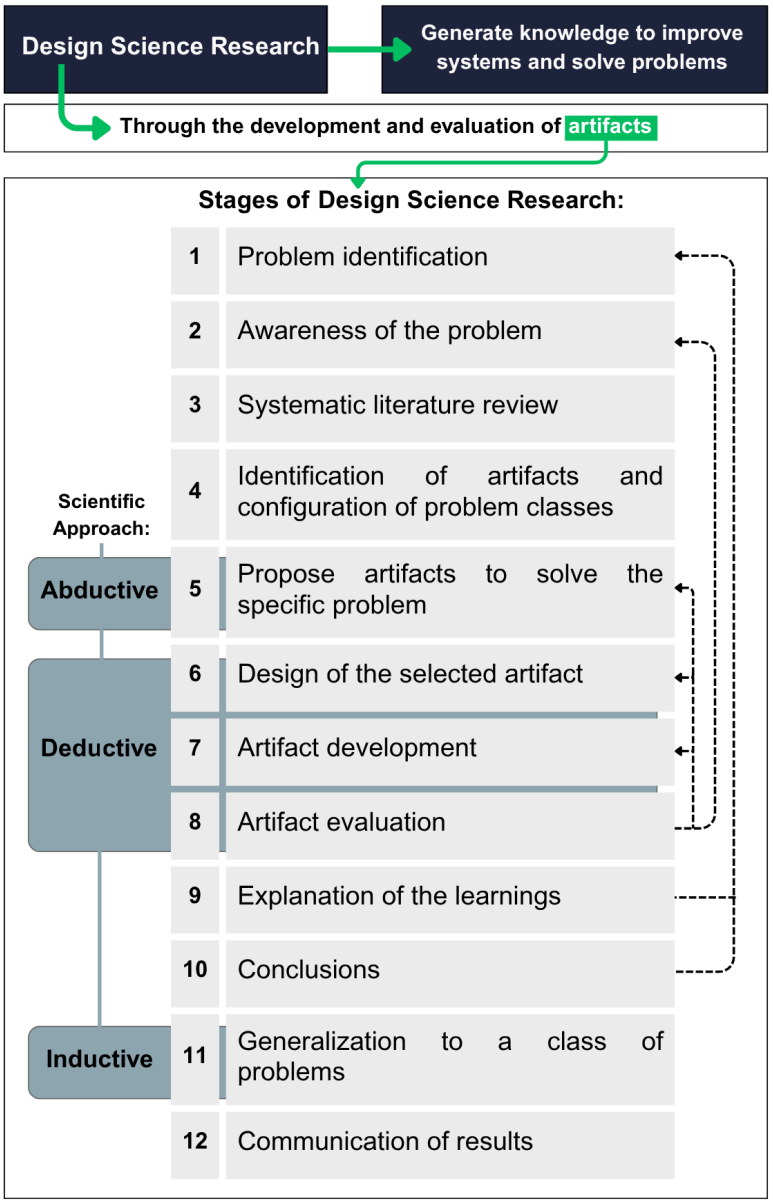
The DSR approach focuses on the development of practical knowledge to design actions or processes that enable the achievement of effective and useful outcomes in real-world contexts (Van Aken; Chandrasekaran; Halman, 2016). As its main contribution, DSR aims, through knowledge, to improve existing solutions and attain satisfactory resolutions to specific problems (Van Aken; Chandrasekaran; Halman, 2016; Dresch, Lacerda, & Antunes, 2015).

From this perspective, DSR strengthens the knowledge base by developing artifacts (Dresch, Lacerda, & Antunes, 2015), defined as designed and evaluated objects intended to solve specific problems (Goecks *et al*., 2021). In this study, a model was developed as an artifact, understood as a set of propositions that express relationships between constructs (March & Smith, 1995). Thus, the proposed model

provides systematic guidance for the NPD process applied to *in vitro* medical devices.

Based on these stages, a protocol for conducting DSR was developed (Appendix A), following the guidance of Dresch, Lacerda, and Antunes (2015), aiming to ensure research rigor. By developing the protocol, it is possible to detail the steps and insights and provide support for the artifact development. Furthermore, a graphical representation of the DSR conduct is presented in Figure 2 to facilitate understanding of this methodological process.

Figure 2 - Design Science Research steps




Source: adapted from Dresch, Lacerda and Antunes (2015).

The other classification criteria of the present study (Table 3) is characterized as applied research, focusing on the search for practical solutions to a real-world problem. In terms of the problem approach, a qualitative perspective is adopted, utilizing contextual data to understand a phenomenon rather than quantify it (Barratt, Choi, & Li, 2011). Furthermore, the study is classified as exploratory and explanatory, as it aims to deepen the understanding of the problem and identify the factors influencing the phenomenon under investigation (Gil, 2017). Finally, an inductive approach relies on observations to develop scientific knowledge (Saunders, 2012).

Table 3 - Criteria for research method

| **Criteria** | **Classification** |
|---|---|
| Nature of research | Applied |
| Problem approach | Qualitative |
| Objective | Exploratory and prescriptive |
| Scientific method | Inductive |
| Research method | Design Science Research |
| Data collection technique | Interview and direct observation in case study |

Source: Elaborated by the author based on Soares (2006).

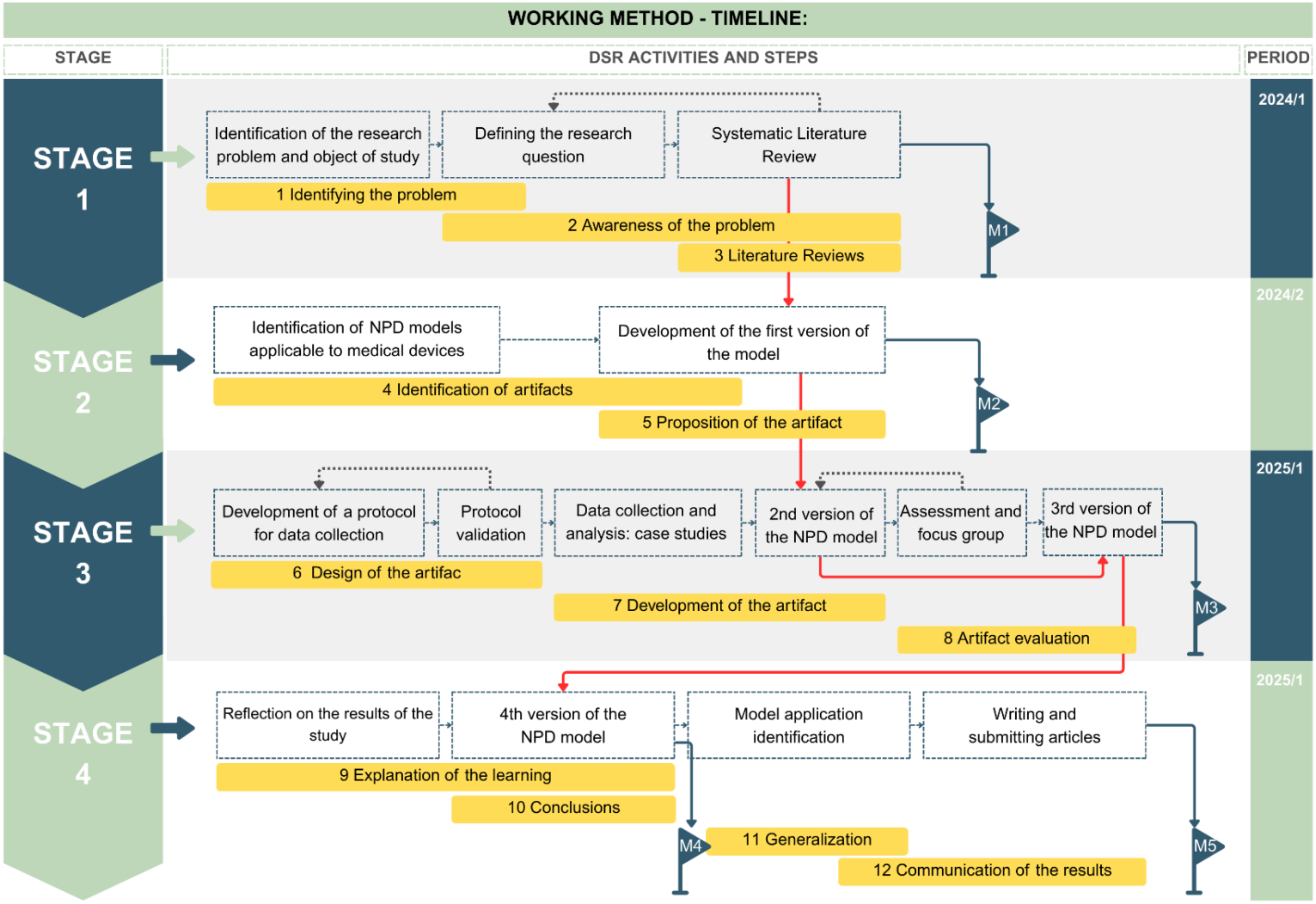
The working method used to conduct this research will be presented below.

## 2.2 WORK METHOD

To guide the execution of the study, a work method was developed and structured into four stages, divided according to the 12 steps of the DSR framework proposed by Dresch, Lacerda, and Antunes (2015), as shown in Figure 3. The figure presents the activities organized in chronological order. Each activity is associated with one or more DSR steps, which are highlighted in yellow at the bottom of the diagram. The dashed arrows indicate potential feedback loops between the execution of the steps, while the red arrows represent the relationships between the different versions of the developed NPD model. Additionally, the milestones marked with the letter “M” (M1 to M5) indicate the points at which significant deliverables of the study were produced. The analyses and deliverables corresponding to these

steps are described below to facilitate understanding. A more detailed explanation can be found in the methodological procedures sections of the articles that comprise this dissertation.

Figure 3 - Work method: timeline



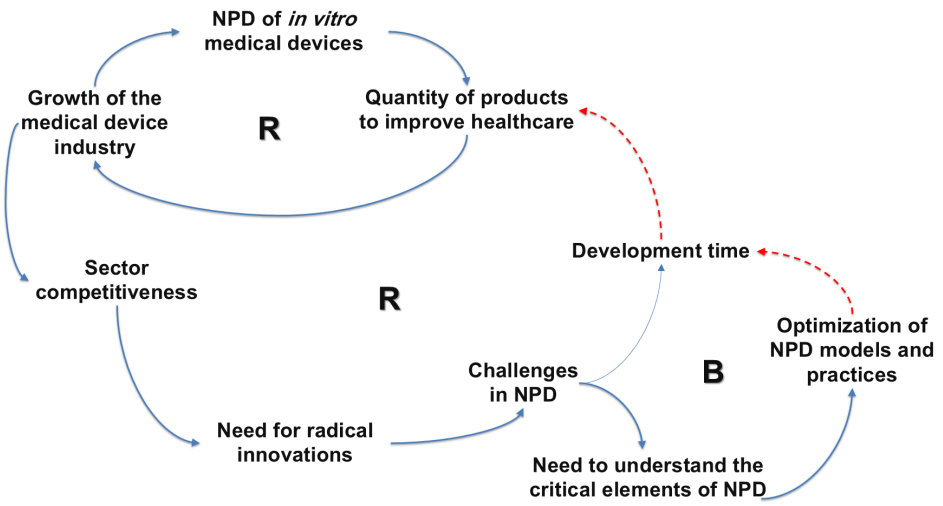

Source: elaborated by the author (2025).

### 2.2.1 Stage 1 and 2: Conceptual-theoretical structure of the artifact

The first stage of the research method involved defining the problem and the object of study, comprising the steps of (1) problem identification and (2) problem awareness. A representation was developed using a systemic structure to guide the formulation of the research question, aiming to identify factors and interrelationships that could contribute to simplifying the understanding of the issue (Senge, 2013).

The systemic structure presented in Figure 4 illustrates the core problem addressed in this study. The growth of the medical device industry has driven an increase in the NPD of *in vitro* technologies, leading to the introduction of more products aimed at improving healthcare delivery. However, this growth has also intensified industry competitiveness, increasing the demand for radical innovations. Consequently, the challenges associated with NPD have grown. As these challenges become more complex, product development timelines tend to lengthen, reducing the number of products reaching the market. On the other hand, the greater the challenges, the stronger the need to understand the critical elements of NPD and to optimize models and practices to shorten development time and ensure a greater number of products are delivered to the market. Based on this structure, the research problem, objectives, and justification for the present study were defined, as outlined in Chapter 1 of this dissertation (1st milestone of the dissertation).

Figure 4 - Systemic structure




Source: elaborated by the author (2025).

Subsequently, a literature mapping and research gaps were identified to structure the concepts underpinning the research (Cauchick, 2007). To this end, stage (3) SLR was conducted, which allows the results to be synthesized in a systematic, transparent and re-applicable manner (Littel, 2008). The SLR was delimited with a comprehensive focus on medical devices to obtain broader information on NPD practices in this sector, since a gap was observed in studies specifically focused on *in vitro* products.

A qualitative and configurative approach was adopted for conducting the SLR, aiming to generate or explore theories (Ermel *et al*., 2022, p. 115). The review was carried out using the Literature Grounded Theory (LGT) method proposed by Ermel *et al*. (2022). The process was structured through a research protocol (Appendix B), developed by LGT guidelines and validated by four experts. In this context, several support tools were employed, including the PICOC framework (Population, Intervention, Comparison, Outcome, Context) for formulating the review question and the software tools Rayyan (Yu, Liu, & Sharmin, 2022) and Atlas.ti (Scientific Software Development, Berlin) for *corpus* selection and analysis.

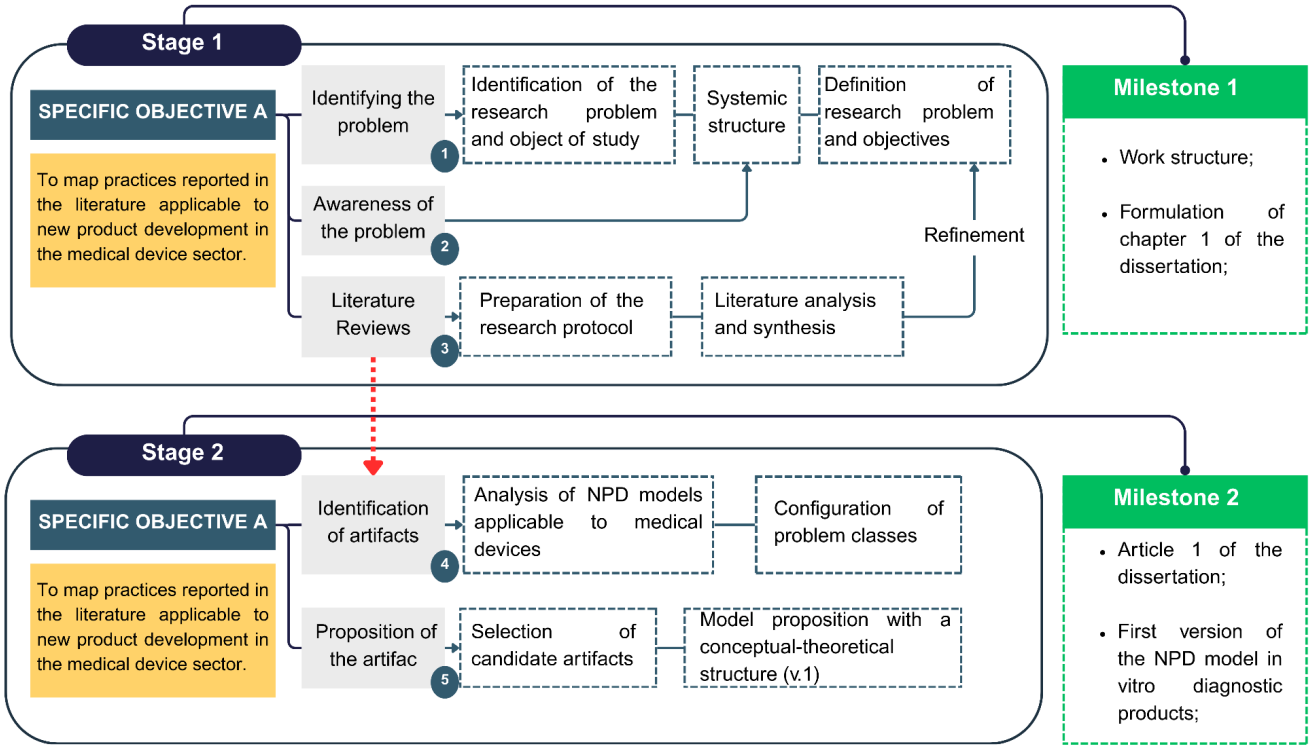
Subsequently, evidence analysis and synthesis were conducted to answer the following review question: *What are the main new product development models applied in the diagnostic medical device industry, and how do these models contribute to product success?* To address this question, 37 studies were included in the SLR, covering 2004 to 2024, following the inclusion and exclusion criteria (Appendix C). The complete list of studies included in the analysis *corpus* is presented in Appendix D. This stage contributed to refining the research problem and to the final formulation of the study objectives by providing a deeper understanding of the object of study.

Based on these findings, the second stage of the research method involved (4) the identification and (5) the proposition of artifacts. These activities were carried out using data from the analysis of NPD models applicable to medical devices, as identified in the SLR. Through the analysis of the selected studies, the problem class was identified as the limitations of existing NPD models when applied to IVDs products. As a result, a model (version 1) was proposed through a conceptual-theoretical framework grounded in the practices identified in the literature.

Accordingly, a construct was proposed, which was developed and evaluated in the subsequent stage. The results from stages 3, 4, and 5 are presented in Article 1

of this study, entitled "Assessment of Practices for New Product Development in Medical Devices: A Systematic Literature Review" (Section 3.1). It is worth noting that these results address specific objective “a” of the study (2nd milestone of the dissertation). For a clearer understanding of these stages, Figure 5 provides a detailed overview of the research method corresponding to stages 1 and 2.

Figure 5 - Work method: stage 1 and 2




Source: elaborated by the author (2025).

### 2.2.2 Stage 3 and 4 - Artifact development

The third stage of the research method involved the development of the artifact, comprising the activities of (6) design, (7) development, and (8) evaluation. During the design phase, the necessary procedures were defined for both the construction of the artifact and its subsequent evaluation. These procedures were then implemented in the following development and evaluation phases.

In the design phase, it was initially decided to collect data through multiple case studies in companies within the IVDs medical device sector. This decision

stemmed from the previous SLR stage, which was conducted with a broader scope due to the gap identified in the literature. Thus, during data collection with the companies, the aim was to gain a deeper understanding of aspects related to IVDs and the organizations in this segment, to incorporate empirical data into the artifact.

Following this decision, a protocol was developed for conducting the case study (Appendix E), which provides a structured guide for data collection and enhances the reliability of the research (Rowley, 2002; Stuart *et al*., 2002). Developing a case study protocol allows for establishing a methodological roadmap that outlines the research scope, supports data collection, and defines the analytical procedures (Burnard, 2024).

The protocol was presented to an expert (technical-scientific consultant for a medical device company), who recommended data collection until theoretical saturation was reached (Rahimi; Khatooni, 2024). Additionally, the expert emphasized that it would not be feasible to consider a large number of collaborators within the same company, since R&D teams in the healthcare sector are generally small, thereby limiting the possible sample size per organization.

Based on this, criteria for selecting the units of analysis were established, which are essential for obtaining data that address the research objectives through the delimitation of the sampling population (Yin, 2014; Eisenhardt, 1989). Considering that data collection was conducted through a multiple case study, the selection of different cases allows for comparisons between them (Burnard, 2024). Accordingly, guiding criteria were defined for the selection of the units of analysis, which are as follows:

a) Only Brazilian organizations and professionals will be included in the study, since the focus of the research is on the national market, which has regulatory, economic and structural particularities that differentiate it from more developed countries.

b) Organisations that have developed *in vitro* diagnostic products already registered with ANVISA or are currently in the clinical validation and market introduction phases will be considered.

c) Professionals with proven experience in the stages of market evaluation (Market Access or Commercialization of Health Technologies) or regulatory processes (in the context of ANVISA) related to IVD devices.

d) Training companies, software developers for medical technologies, and suppliers of inputs and products will not be included in the analysis.

e) The selection of interviewees will consider individuals with diverse educational backgrounds and genders, as indicated by Cauchick (2007).

It is important to emphasize that there is no predefined ideal number of cases in a research design. However, studies adopting this approach often utilize between four and ten cases, a range considered adequate for obtaining relevant details (Eisenhardt, 1989). Within this context, this research aimed to follow this parameter for case selection, including 6 companies with a total of 7 responses. It is worth noting that the identification and selection of participants were carried out based on nominations. Further details regarding this selection will be provided below.

Additionally, in the design phase, the approaches for data collection and analysis were defined, which are presented separately in the following sections to facilitate understanding.

- Data collection procedures

Based on the selection of the units of analysis, data collection methods were determined, considering multiple sources of evidence, including semi-structured interviews, a questionnaire and direct observation (Dresch; Lacerda; Antunes, 2015). The materials developed for data collection, presented in Appendix F, aimed to guide the identification of critical factors for success in medical device development.

Initially, an interview guide was developed containing topics related to the subject, based on the studies by Lobato *et al*. (2009) and O'Dwyer and Cormican (2017), which similarly sought to evaluate and optimize the NPD process for medical technologies. However, it was also decided to include a questionnaire in the data collection, using a Likert scale to enable complementary analyses. It should be noted that this questionnaire was adapted based on the study by Toledo *et al* (2008), which assessed respondents' perceptions of various factors influencing success in medical device development.

For conducting the interviews and administering the questionnaire, the developed structure was validated through a pilot test by a professional experienced in R&D of *in vitro* medical devices. The objective was to assess the procedures based on the established protocol, aiming at their improvement (Cauchick, 2017).

The interviews lasted on average 60 minutes, while the questionnaire required approximately 10 minutes to complete. The interviews were conducted remotely via the Teams platform, which allowed synchronous communication between participants, whereas the questionnaire was distributed in advance through an online electronic form. It is worth noting that these methods enable better recording of responses and the possibility of recording the interviews, which contributes to more accurate data analysis.

Additionally, before commencing data collection, it was necessary to obtain the participants' signed Informed Consent Form (ICF), available in Appendix G. The purpose of this form is to ensure ethical compliance with research principles involving human subjects (Souza *et al*., 2013). The ICF was provided to participants through the online electronic form alongside the data collection questionnaire.

The profile of the study participants can be found in Table 4, and the results obtained during the data collection phase are organized and detailed in Appendix H, providing a comprehensive overview of the evidence gathered for the analysis proposed in this study.

Table 4 - Interviewee profile of the study

| **Interviewee (INT)** | **Academic level and professional field** | **Company profile** | **Company identification** |
|---|---|---|---|
| INT1 | - Biomedical, MSc;<br>- Head of Research and Development; | Electrochemical point-of-care testing | Company A |
| INT2 | - Biologist, PhD;<br>- Production Manager in R&D; | Immunochromatographic test | Company B |
| INT3 | - Mechanical engineering, MSc;<br>- Co-Founder and CEO; | Immunochromatographic test | Company B |
| INT4 | - Doctor, MSc;<br>- Medical Director; | Point-of-care equipment and point-of-care testing: immunochromatographic, colorimetric, electrochemical, microscopy, molecular | Company C |
| INT5 | - Biomedical Engineering, MSc;<br>- Founder and CEO; | Point-of-care troponin measurement | Company D |

| | | | |
|---|---|---|---|
| INT6 | - Biomedical, MSc;<br>- Sales Executive | Sale of *in vitro* diagnostic solutions | Company E |
| INT7 | - Biologist, MSc;<br>- CEO | Electrochemical point-of-care testing | Company F |

Source: elaborated by the author (2025).

- Procedures for data analysis

Following data collection, the analysis of data obtained through interviews and questionnaires was conducted, beginning with the coding process, which served as the foundation for addressing this study's research question (Cauchick, 2007). This coding was guided by categories previously identified from the data analyzed in the SLR, as presented in Table 5. Subsequently, data triangulation was performed, enabling a more comprehensive and reflective analysis (Pope, 2000), supported by the software Atlas.ti (Scientific Software Development, Berlin). After data triangulation, statistical analyses were conducted using R Studio. These included distribution analyses of the scale applied during the interviews and content analysis to support the interpretation of the results.

Table 5 - Analysis categories for coding

| **Codification** | **Reference** |
|---|---|
| Product technology and features | Kirkire; Rane; Abhyankar, 2020; Guerineau, 2024; ; Medina; Kremer; Wysk, 2013; Kruachottikul *et al*., 2023; Browne; Sutton; Zhang, 2023. |
| Human resources | Alagumalai; Kadambi; Appaji, 2019. |
| Stakeholders | Medina; Kremer; Wysk, 2013; Kirkire; Rane; Abhyankar, 2020; Craig *et al*., 2015; Goldenberg; Gravagna, 2018; Busch *et al*., 2021 |
| Management | Russell; Tippett, 2008; Marešová *et al*., 2020b; Ttsai; Wang; Chen, 2023; O'Dwyer; Cormican, 2017; Lobato *et al*., 2019; Peter *et al*., 2020; Pietzsch *et al*., 2009; |
| Regulatory requirements | Brooks, 2017; Medina; Kremer; Wysk, 2013; Pietzsch *et al*., 2009; |
| Market | Brooks, 2017; Russell; Tippett, 2008; Barkaoui *et al*., 2023; Lobato *et al*., 2019; Shin *et al*., 2023; Ocampo; Kaminski, 2019. |

Source: elaborated by the author (2025).

After the data analysis and coding, the NPD model's first optimisation phase for *in vitro* diagnostic products (version 2) was carried out. This refinement involved a cross-analysis between the SLR findings and the results obtained from the case studies, aiming to identify points of convergence and divergence between theory and practice. Thus, the model became more aligned with the reality observed in companies within the sector.

- Procedures for artifact evaluation

In the evaluation stage, the second version of the model was presented to assess its performance and the potential benefits of its implementation within the system. To this end, an analytical evaluation was conducted, involving the analysis of the artifact's content and structure (Dresch, Lacerda, & Antunes, 2015).

To this end, the evaluation was conducted in two stages: (i) expert evaluation, and (ii) a focus group discussion. The expert evaluation involved six professionals: a specialist in R&D in the healthcare sector, a specialist in ANVISA regulation, three specialists in NPD models, and a specialist in DSR. The model was sent to the participants in advance for review, followed by individual online conversations to collect feedback, each lasting approximately one hour.

For each thematic domain, specific topics were developed tailored to the participants' expertise. Table 6 lists the consulted specialists and the theoretical references that guided the experts' assessment discussions. The main feedback is presented in Appendix I.

Table 6 - Experts consulted for evaluation

| Expert | Domain | Academic background | Contribution | References |
|---|---|---|---|---|
| Expert 1 | NPD Specialist | Bs in Social Communication, Ms and PhD in Business Administration | Vice-coordinator of both the Innovation Management Lab and Engineering Education Lab. She combines academic leadership with a solid background in innovation and project management | Florén *et al*., 2018; Cooper, 2015 |
| Expert 2 | | Bs in Mechanical Engineer, Ms | Experience in product development management, | |

| | | | | |
|---|---|---|---|---|
| | | and PhD in Production engineering | Industry 4.0, and engineering education strengthens the research's technological and methodological foundation | |
| Expert 3 | | Bs and Ms in Mechanical Engineer and PhD in Systematization of Production | Co-author of reference books widely used in academia and industry, including *Gestão de Desenvolvimento de Produtos* e *Gerenciamento de Processos de Negócio*. | |
| Expert 4 | R&D Specialist | BS in Microbiology, MS in Biological Sciences, PhD in Biochemistry, MBA in Business Administration | Former Innovation Consultant at Biominas Brazil and co-founder/executive of biotech and deeptech startups, offering strategic insight into NPD and technology transfer | Ocampo & Kaminski, 2019; Kruachottikul *et al*., 2023; Durfee; Iaizzo, 2019; Lobato *et al*., 2019; Busch *et al*., 2021; Pietzsch *et al*., 2009; Kheir; Jacoby; |
| Expert 5 | ANVISA Specialist | BS in Chemistry and MBA in quality, management and process engineering | Over 13 years of experience as an auditor and consultant for ANVISA, specializing in medical devices | Kheir; Jacoby; Verwulgen, 2022; Foo; Tan, 2017; Harkin; Sorensen; Thomas, 2024 |
| Expert 6 | DSR Specialist | BS in Production Engineering, MS in Production Engineering, and PhD in Production Engineering | One of the authors of the book "Design Science Research: a research method for advancing science and technology" | Dresch, Lacerda, & Antunes, 2015; Van Aken; Chandrasekaran; Halman, 2016 |

Source: elaborated by the author (2025).

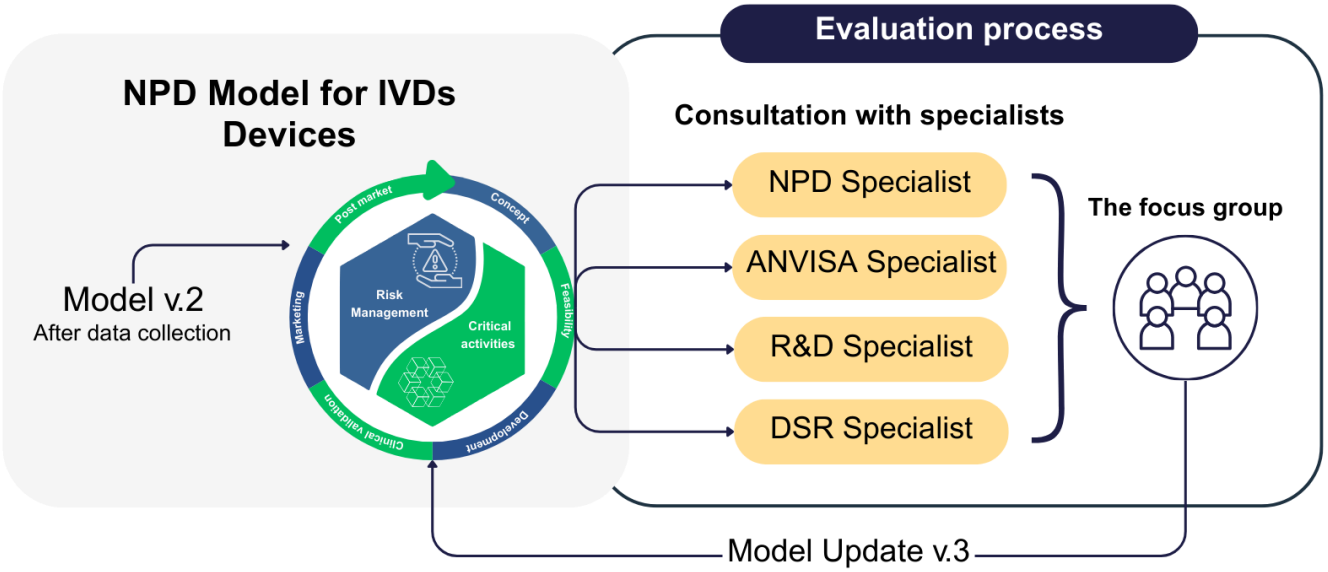
The focus group evaluation, defined as a technique involving collective discussion on a specific topic guided by a trained moderator (Sim; Waterfield, 2019), aimed to deepen the qualitative analysis of the proposed model. In this context, the model was presented to a group of professionals (n=12) working in R&D within the IVD sector to gather perceptions of its applicability, clarity, and practical relevance in real-world product development. Additionally, the evaluation sought to identify potential gaps, opportunities for improvement, and necessary adjustments before the finalization of the model version (O.Nyumba *et al*., 2018).

The focus group was conducted in an in-person meeting, lasting approximately one hour. The discussion content was based on the study by Salbego *et al*. (2023), which developed the Technological Development Model Assessment Instrument (IAMDT). An adapted version of this instrument was used to analyze the developed model, as detailed in Appendix I. The primary data collection methods included audio recording, real-time note-taking, and direct observations during the session (Stewart; Shamdasani, 1990). After the focus group session, the Content Validity Index (CVI) was calculated in RStudio to quantitatively assess the relevance of the developed model.

In parallel with the artifact evaluation process, version 2 of the developed model was also sent to Robert Cooper, the creator of the Stage-Gate model, due to his relevance in the field and the widespread adoption of his method, which guided part of the development. The feedback received is presented in Appendix J, given its importance for validating the proposed model

Thus, based on the evaluation process (Figure 6) and the data obtained, it was possible to carry out the second optimization of the model (version 3). This phase was crucial, as it incorporated observations from the real-world application context and identified the model's potential use within the IVD industry (3rd milestone of the dissertation).

Figure 6 - Evaluation process




Source: elaborated by the author (2025).

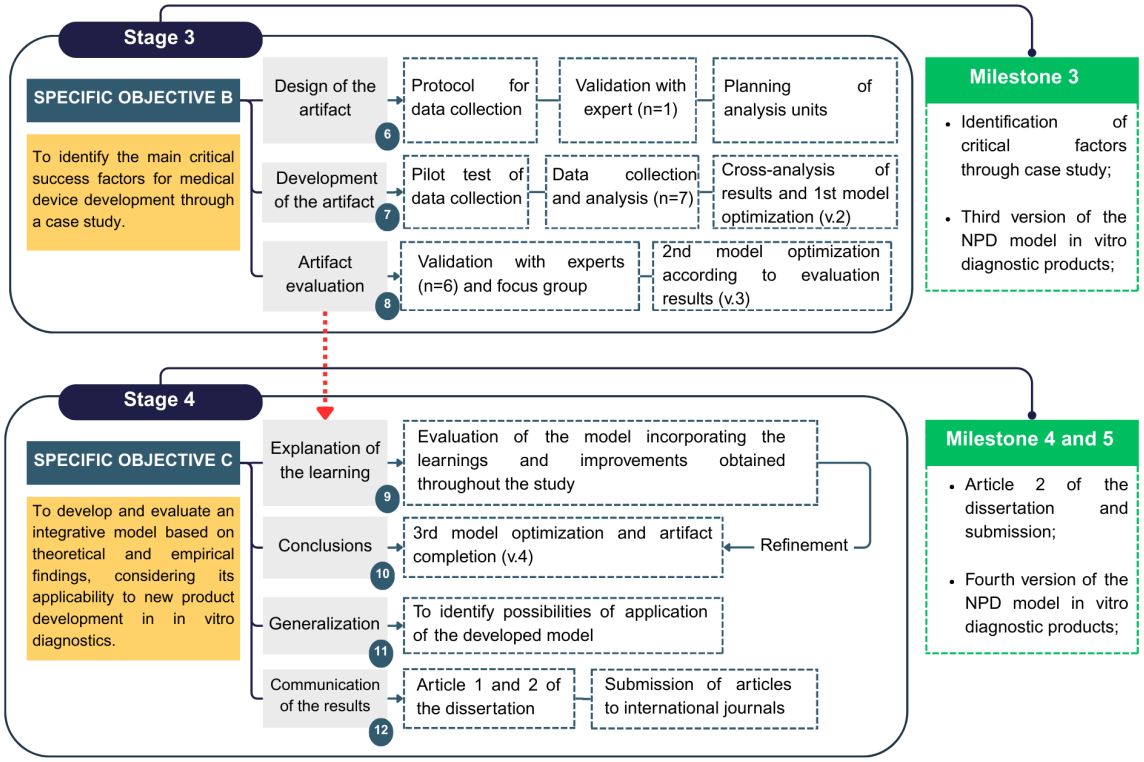
- Artifact completion

Based on these results, the fourth and final stage of the DSR process was initiated. In this stage, (9) explanations of the learned during the model's construction and evaluation were identified, and theoretical and practical insights gained throughout development were addressed in the (10) conclusion of the artifact. These steps resulted in the third and final optimization of the model (version 4 and 4th milestone of the dissertation). This fourth version did not involve adjustments to the structuring of the artifact itself but rather the development of a supporting material aimed at facilitating its future practical application, considering that the purpose of an artifact is to solve real-world problems. The version history and explanation of modifications can be viewed in Appendix K.

After the model was finalized, the step of (11) generalization was carried out to a class of problems, defined based on the contexts in which the artifact can be applied, such as: (i) development of new products in technology-based healthcare companies; (ii) structuring NPD in medical device companies; (iii) application of the model in NPD focused on *in vitro* diagnostic products; (iv) use of the model for educational purposes, aiming to train professionals and students in innovation management; (v) promotion of best practices in NPD and innovation management in technological environments.

The final stage of the work method was the (12) communication of the results, including the first article of the dissertation, and the second article, entitled "Innovating *In Vitro* Diagnostics: Critical Success Factors and an Integrative Model for Medical Device Development" (Section 4.1), which addresses the specific objectives "b" and "c" of the study (5th milestone of the dissertation). To facilitate understanding of these stages, Figure 7 presents a detailed overview of the work method, focusing on stages 3 and 4.

Figure 7 - Work method: stage 3 and 4




Source: elaborated by the author (2025).

Thus, the following sections will present the articles developed based on these methodological procedures, which guided all stages of the research and allowed the studies to be conducted systematically and in line with the proposed objectives.

# 3 ARTICLE 1 - SYSTEMATIC LITERATURE REVIEW

The first article, entitled "*Assessment of Practices for New Product Development in Medical Devices: A Systematic Literature Review*," addresses the first specific objective of this dissertation. To achieve this, a broadened SLR was conducted, aiming to understand the NPD process and identify the main models applied within the medical device industry. Given the scarcity of literature specifically focused on IVD devices, a broader approach was adopted to provide a solid theoretical foundation for subsequent scope delimitation.

Based on the literature analysis, it was possible to: (i) to map the main stages related to the development process; (ii) to identify the critical success factors for NPD; (iii) to propose a method for managing risks and uncertainties; and (iv) develop a framework containing key elements and actions required in an NPD model for medical devices.

This article's main contribution was proposing a framework that brings together best practices indicated in the literature for NPD of medical devices. This analysis served as the conceptual basis for developing the artifact, an NPD model, presented in the second article of this dissertation. The manuscript was submitted and approved for the ANPEPRO 2025 award and was submitted to the journal Technology Analysis & Strategic Management, as presented in Appendix L. The full version of the article can be found in the following section.

## 3.1 ARTICLE 1: FULL VERSION

### ASSESSMENT OF PRACTICES FOR NEW PRODUCT DEVELOPMENT IN MEDICAL DEVICES: A SYSTEMATIC LITERATURE REVIEW

**Abstract:** The New Product Development (NPD) is a structured approach that involves different stages, from the idea's conception to the launch in the market, focusing on meeting consumer needs and market demands. In health technologies, NPD is fundamental for developing medical devices for diagnosing, preventing, monitoring, or treating health conditions. This application is often guided by development models that seek to ensure quality and regulatory compliance. However, implementing these models is challenged by the complexity of the medical device sector, which requires adaptation to emerging technologies and effective integration between the parties involved, in addition to the need to incorporate the various variables of the innovation process. In this sense, the study aimed to identify

and analyze the leading product development process models applied in the diagnostic technologies industry. For this, a Systematic Literature Review was conducted in the Scopus, Science Direct, and PubMed databases, and 37 studies were selected according to established inclusion criteria. Based on the analysis of the evidence, six predominant stages in the development process were identified, and the critical factors of the NPD for medical devices were subsequently evaluated, technology, stakeholders, human resources, management, regulation, and market. In addition, a risk management approach was developed to identify and address potential uncertainties throughout the development process. Additionally, the study identified essential elements that should be incorporated into NPD models to improve their applicability and performance in the context of medical devices. The findings suggest that NPD models enhance the development of health technologies by providing structure, reducing risks, and aligning expectations. This study contributes by mapping key stages and aspects of NPD, especially amid limited resources, to systematically guide or assess innovation management.

**Key-words:** New Product Development; Innovation; Medical Devices; Risk Management; Critical Factors.

### 3.1.1 Introduction

Medical technologies play a fundamental role in public health and healthcare by facilitating medical care and, consequently, enhancing patients' quality of life (Kirkire, Rane, & Abhyankar, 2020; Gagliardi *et al*., 2018). In this context, medical devices are particularly noteworthy, as they are designed to monitor, diagnose, and treat a wide range of clinical conditions (Ocampo & Kaminski, 2019). Examples include point-of-care testing (POCT) and *in vitro* diagnostic tests, which enable the analysis of biological samples without the need for robust laboratory infrastructure (Wilson *et al*., 2018; Mugambi *et al*., 2018; Schroeder *et al*., 2016).

The global medical technology market, valued at approximately USD 414 billion in 2020, underscores its significance (Shin *et al*., 2023). However, despite this growth, many companies in the sector face a high risk of market exit due to lengthy development cycles and substantial associated costs. For instance, developing a medium-risk medical device requires investments ranging from USD 1 to 4 million (Graziadio *et al*., 2020). This scenario makes the healthcare sector particularly challenging compared to others (Lobato *et al*., 2019), as the development of medical products involves considerable uncertainty and high levels of risk (Marešová *et al*., 2020; Lee, Park, & Lee, 2019; Lee *et al*., 2018), with development timelines

influenced by both technical and organizational complexity (Guérineau, 2024; Zhang & Thomson, 2016).

While these challenges are well documented, there is a lack of systematic research that consolidates how organizations effectively manage such complexity, particularly in the context of diagnostic medical devices (Dutta & Dhar, 2024). Most studies focus on technological or clinical outcomes, leaving management and development processes underexplored (Mayrink *et al.*, 2025; Marešová *et al*., 2020).

Thus, to overcome these challenges in medical device development, five key factors are essential: process, organization, strategy, commitment, and an innovation-oriented culture (Javanmardi *et al*., 2024; O'Dwyer & Cormican, 2017). In this context, innovation management practices enable effective product development by identifying failures, managing timelines, and monitoring project performance (Zhang & Thomson, 2016; Hokkanen & Leppänen, 2015). Moreover, the success of innovations is directly linked to the ability to manage technological advancements, risks, and uncertainties while simultaneously striving for stability, efficiency, and profitability (Wang & Chen, 2023).

Innovation processes can be represented by models that establish structured approaches to innovation management. These models are particularly employed in the context of new product development (NPD), encompassing a variety of activities, stages, and decision points throughout the development of a new product or service (Salgado *et al*., 2017). The representation of these models enhances clarity and understanding among team members and stakeholders, supporting internal communication and facilitating the dissemination of the process (Fearis & Petrie, 2017).

Thus, several influential models in innovation management are widely recognized, such as the "development funnel" and the stage-gate approach (Salerno *et al*., 2015). However, these and other traditional models are primarily designed for large corporations and tend to be unsuitable for radical innovation projects, such as those in health technologies, which involve greater complexity and risk during development (Pich, Loch, & De Meyer, 2002). Furthermore, there is a notable gap in resources dedicated to guiding NPD in the healthcare sector, leaving the industry lacking managerial support during critical stages of development (O'Dwyer & Cormican, 2017; Da Silva, 2011).

Given this scenario, it becomes essential to identify or develop management models, tools, and techniques capable of supporting decision-making in innovation processes within the healthcare sector (Dutta & Dhar, 2024). However, there is still a lack of comprehensive understanding of which models and practices have been proposed or adapted for this context, especially for diagnostic technologies.

Therefore, this study aimed to map practices reported in the literature applicable to new product development in the medical device sector, identifying trends, gaps, and opportunities to enhance innovation management in this field. The findings are expected to guide both academic research and managerial practice, providing a clearer basis for decision-making and improving NPD in medical devices.

To this end, this article is organized into five sections in addition to the introduction. Chapter 3.1.2 presents the theoretical framework, outlining the key concepts related to the research topic. Chapter 3.1.3 describes the methodological procedures. The results and discussion are presented in Chapter 3.1.4 and Chapter 3.1.5 respectively, followed by the final considerations in Chapter 3.1.6.

## 3.1.2 Theoretical Framework

The theoretical framework was structured into two sections. The first section introduced the key concepts related to medical devices, and the second focused on aspects of new product development.

### 3.1.2.1 Medical Device

Medical devices are instruments, devices, tools, or implants used to diagnose, prevent, treat, or monitor clinical conditions (Browne, Sutton, & Zhang, 2023). This definition is supported by the Food and Drug Administration (FDA), one of the main regulatory health agencies in the United States (Singer, Hack, & Hanley, 2022; Franz *et al*., 2019; Korley *et al*., 2016).

The use of medical devices has the potential to transform healthcare by improving the quality and efficiency of equipment (Barkaoui *et al*., 2023). Innovations in medical technologies offer enhanced solutions for diagnosis, treatment, and patient monitoring, while also promoting greater personalization and accessibility of care.

Such approaches have gained increasing relevance in the current context marked by population ageing and the high prevalence of morbidities and chronic diseases (Guérineau, 2024; Ryan *et al*., 2018).

This scenario is further reinforced by the significant growth in the medical device industry, which accounts for approximately 5% of the global healthcare economy (Byrne, 2020). Moreover, in 2020, the market for these medical technologies reached USD 414 billion, highlighting its current significance and expansion potential (Shin *et al*., 2023). Despite its importance, medical device development involves complex design, planning, and regulation processes, which directly impact product success (Ocampo & Kaminski, 2019).

The growth of the medical device market, driven both by demand and innovation potential, heavily depends on stringent regulations that ensure the safety and efficacy of these products (Ocampo & Kaminski, 2019). Before new technologies can be implemented, they must be evaluated and approved by regulatory agencies due to their critical nature in development (Khan *et al*., 2024; Baylor, 2014).

Furthermore, the regulatory process requires the classification of devices according to their risk level to the patient; the higher the risk associated with the technology, the more stringent the regulatory controls. The FDA classifies devices into three classes: Class I (low risk and lower complexity), Class II (moderate risk and complexity), and Class III (high risk and complexity). At the Brazilian National Health Surveillance Agency (ANVISA), the classification follows a similar pattern but includes a Class IV for the highest-risk devices (Brazil, 2020; Brazil, 2015). To better illustrate, Table 1 presents this categorization based on diagnostic devices.

Table 1 - Classification of medical devices according to ANVISA

| **Category** | **Definition** | **Example** |
|---|---|---|
| Class I | Low risk to the individual and low risk to public health, subject to registration | Diagnostic reagents, calibration products, cleaning agents, genetic extraction kits, and sample collection materials |
| Class II | Medium risk to the individual and/or low risk to public health, subject to registration | Devices for human diagnosis and instrument control (calibrators, standards) |
| Class III | High risk to the individual and/or | Tests for blood typing, |

| | | |
|---|---|---|
| | medium risk to public health, subject to registration | infections, prenatal screening, genetics, pharmaceuticals, self-tests, and point-of-care diagnostics. |
| Class IV | High risk to the individual and high risk to public health, subject to registration | Detection and monitoring of transmissible agents in transfusions and transplants |

Source: Prepared by the authors. Adapted from Brazil (2015 and 2020).

Based on this categorization, medical devices that significantly impact healthcare, such as mechanical ventilators, pacemakers, catheters, and self-testing kits for diabetics (Byrne, 2020), can be identified. These products range from simple solutions to complex technologies, making the innovation process challenging and specific to each type of device (Barkaoui *et al*., 2023; Piuzzi *et al*., 2019).

The development of medical devices must be aligned with both technical feasibility and market demands, avoiding redundant solutions or those disconnected from clinical practice (Durfee & Iaizzo, 2019). This aspect is particularly relevant for medical diagnostic technologies requiring high precision and efficiency. Diagnostic products, such as those used for *in vitro* analysis of biological samples, serve the purpose of providing critical information for the diagnosis, monitoring, or screening of clinical conditions (Brazil, 2020).

Diagnosis is fundamental to healthcare but relies on various supplies and devices. Despite advancements, the rapid development and validation of products in emergency situations, such as the COVID-19 pandemic, still face challenges due to a lack of clear guidelines for effective NPD, making it difficult to enter the market and the crisis response (Firdausi, 2020; Vargas *et al*., 2017). Therefore, identifying best development practices can strengthen the resilience of healthcare systems in the face of future challenges (Oyewole *et al*., 2021).

Innovations in medical devices unlock new capabilities for healthcare; however, they are associated with high development costs and both technological and organizational complexities (Menshenin, Pinquié, & Chevrier, 2023; Mishra & Behdinan, 2023). Furthermore, these complexities are compounded by legal, regulatory, normative, commercial, and clinical challenges inherent to the medical technology sector (Guérineau, 2024). Therefore, identifying these obstacles before

development is essential to mitigate them and increase the likelihood of project success (Falahat, Chong, & Liew, 2024).

#### 3.1.2.2 New Product Development

The NPD process is an innovation management practice covering activities from the initial idea to the product's market launch (O'Dwyer & Cormican, 2017). These activities involve strategic decisions, operational feasibility, and meeting customer needs to ensure alignment between the final product and market requirements (Salgado *et al*., 2017; Figueiredo & Loiola, 2012).

Characterized by a nonlinear and interactive nature, the NPD process depends on critical thinking to support decision-making throughout its stages (Kruachottikul *et al*., 2023). Its definition and practical implementation play a crucial role in determining the success of product development initiatives (Busch *et al*., 2021).

In innovation management, there are proposed models to guide NPD, which adopt a flow with different stages of idea generation, screening, development, and market launch (Salerno *et al*., 2015). Among the most widespread models are: (i) Cooper's stage-gate approach (1993, 1994, 2008), based on predefined decision points called "gates" that direct project progression; and (ii) the development funnel model by Wheelwright and Clark, characterized by a broad input of ideas with progressive selection of the most promising projects, following a funnel logic (Wheelwright & Clark, 2011).

Based on these models, other approaches to NPD have emerged (Bagno, Salerno, & da Silva, 2017), such as the open innovation model (Docherty, 2006), the pentathlon model (Goffin & Mitchell, 2010), the innovation value chain (Hansen & Birkinshaw, 2007), the unified development model (Rozenfeld, 2006), and the DNA model (O'Connor, 2008). Although they present different typologies, all aim to structure stages that enable the market introduction of new products and the success of NPD (Proença *et al*., 2015, p. 75).

The NPD models offer benefits such as reduced time to market, better resource allocation, and improved portfolio management (Tiedemann, Johansson, & Gosling, 2020). However, no ideal model or approach has been identified, as traditional models are generally more suitable for large companies with

well-established R&D (research and development) departments (Salerno *et al*., 2015). This challenge is even greater in projects characterized by high degrees of uncertainty and complexity, such as radical innovations, which require new NPD practices and specific management tools (Salerno *et al*., 2015; Pich, Loch, & De Meyer, 2002).

This need is particularly critical in healthcare projects, which require substantial investment, extensive technical and scientific knowledge, and face inherent uncertainties and risks (Fox, 2017; Eldar, 2002). For example, the lifecycle of biotechnological products lasts from 10 to 12 years and demands investments exceeding 650 million dollars (Uctu & Eksteen, 2022; Prasad & Mailankody, 2017; Paul *et al*., 2010). Given this scenario, efficient NPD, combined with risk management and effective communication among stakeholders, is essential to ensure that project objectives are achieved within established deadlines (Santos *et al*., 2020).

### 3.1.3 Methodological Procedures

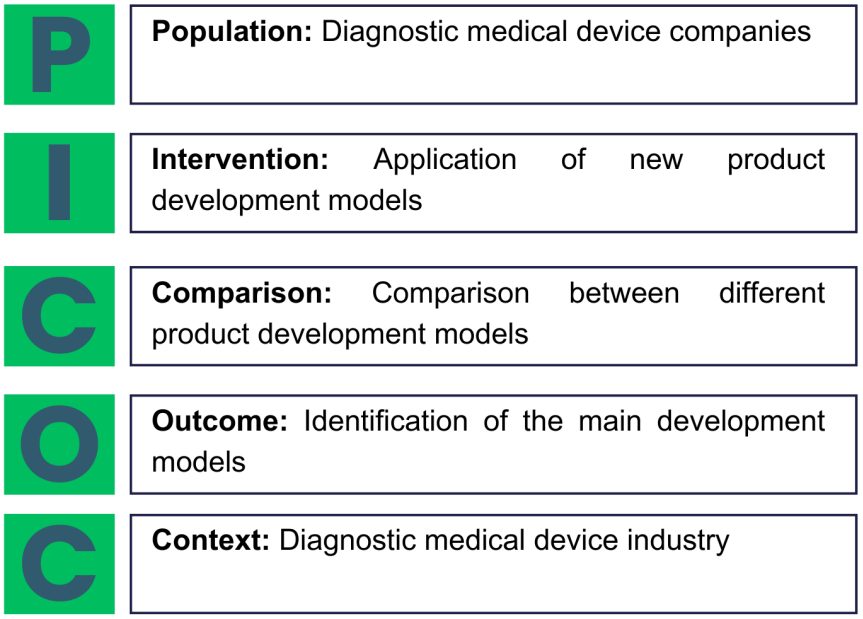
This article conducted a Systematic Literature Review (SLR) based on the Literature Grounded Theory (LGT) (Glaser; Strauss, 2017; Bryant; Charmaz, 2007) method with the objective of identifying and analyzing the main product development process models applied in the diagnostic technologies industry. The organizational structure of the research was adapted from the method proposed by Ermel *et al*. (2022), as illustrated in Figure 1.

Figure 1 - LGT organizational structure


Source: adapted from Ermel *et al*. (2022).

The initial stage focused on defining the research question, which was based on the PICOC acronym tool (Population, Intervention, Comparison, Outcome, Context), as described by Ermel *et al*. (2022). The formulated question was: *What are the main new product development models applied in the medical devices industry for diagnostics, and how do these models contribute to product success?* (Figure 2). Accordingly, the scope and type of review were defined as configurative, narrow, and in-depth, aiming at organizing and synthesizing knowledge from various studies on the topic of interest (Ermel *et al*., 2022, p. 162).

Figure 2 – Research question: PICOC acronym




Source: Prepared by the authors (2025).

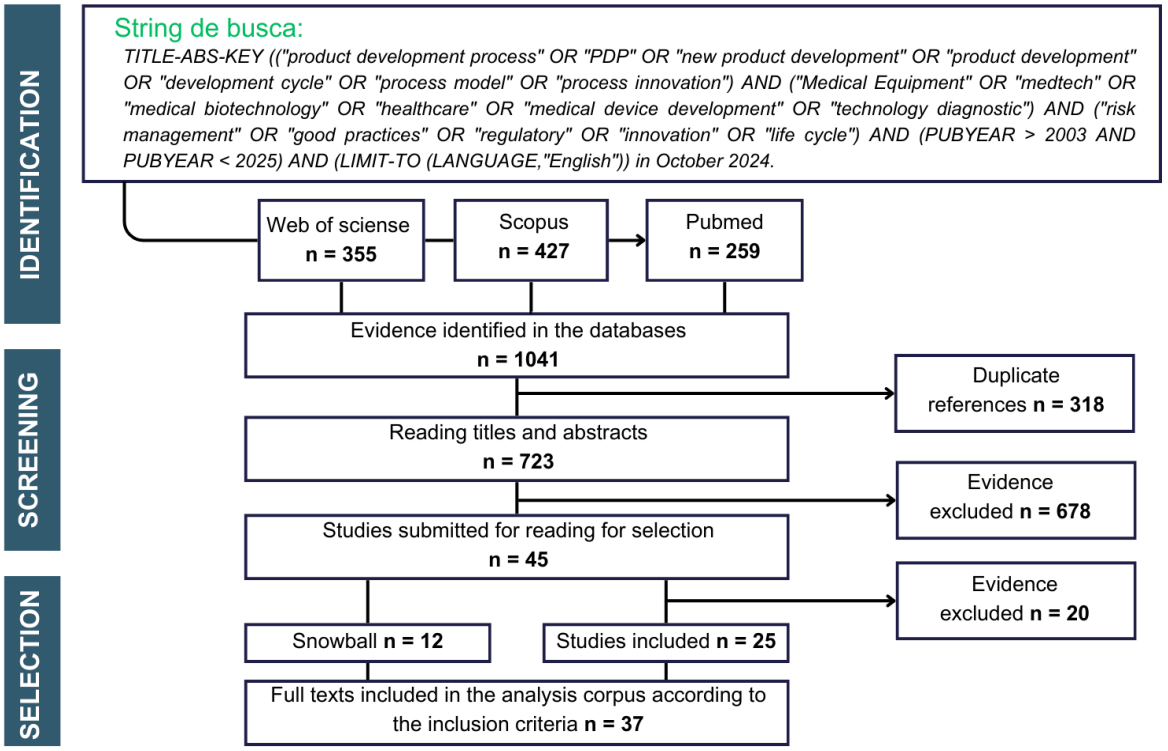
To guide the evidence search strategy, a research protocol was developed (Appendix B), which was reviewed by experts. Based on this protocol, studies were selected through the following search string: *TITLE-ABS-KEY (("product development process" OR "PDP" OR "new product development" OR "product development" OR "development cycle" OR "process model" OR "process innovation") AND ("Medical Equipment" OR "medtech" OR "medical biotechnology" OR "healthcare" OR "medical device development" OR "technology diagnostic") AND ("risk management" OR "good practices" OR "regulatory" OR "innovation" OR "life cycle") AND (PUBYEAR > 2003 AND PUBYEAR < 2025) AND (LIMIT-TO (LANGUAGE,"English"))*, in the databases Scopus, Web of Science, ScienceDirect, and PubMed, in October 2024.

Subsequently, the snowballing technique was applied based on the selected evidence to identify additional literature (Wohlin, 2014). This was conducted through both reference analysis (backward snowballing) and citation tracking (forward snowballing). Through this process, 1,341 articles were identified, of which 37 were selected according to the eligibility criteria presented in Appendix C.

The refinement of these articles was conducted using the Rayyan software (Yu, Liu, & Sharmin, 2022), which aims to classify and select studies. The filtering

process is represented by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart, illustrated in Figure 3, which graphically depicts the stages of the SLR as described by Moher *et al*. (2009).

Figure 3 – PRISMA Flowchart of the Systematic Literature Review



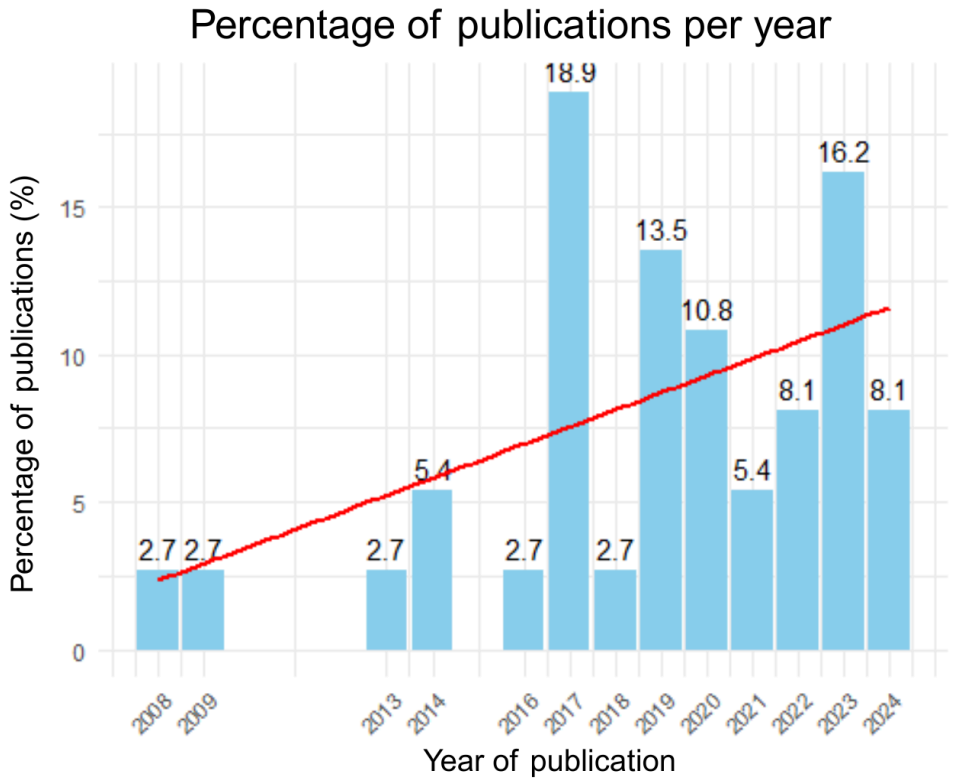

Source: Adapted from Moher *et al*. (2009) and Ermel *et al*. (2022).

Within this context, a data survey was conducted with the purpose of extracting knowledge on the proposed topic. For this, the software Atlas.ti 23 (Scientific Software Development, Berlin) was used for data organization and analysis (Souza Neto *et al*., 2019). This analysis included a review of the transcripts for coding the following aspects: evaluation of the SLR *corpus*, identification of development stages, critical development factors, risk management, and identified models.

### 3.1.4 Results

To achieve the objective of this SLR, the 37 selected studies that constitute the review *corpus* were analyzed. Additionally, a percentage distribution of publications by year was conducted (Figure 4), highlighting an increase in the number of studies over the years, particularly since 2017, which accounts for 18.9% of the publications. This underscores the effort to understand the factors driving innovation in medical devices and their relevance in development (Saidi; Douglas, 2022). This scenario reflects the growing academic interest in evaluating the development of technological innovations in the healthcare sector. However, this increase may also result in divergent factors in NPD management, complicating the consolidation of clear and applicable practices tailored to the specific context of medical device development.

Figure 4 – SLR *corpus* assessment




Source: Prepared by the authors (2025).

To deepen the analysis, the SLR was organized into subchapters addressing the main themes identified in the selected studies. These themes were defined based on an inductive thematic evaluation of the *corpus*. Subsequently, each theme is discussed separately to present the analysis of the reviewed literature.

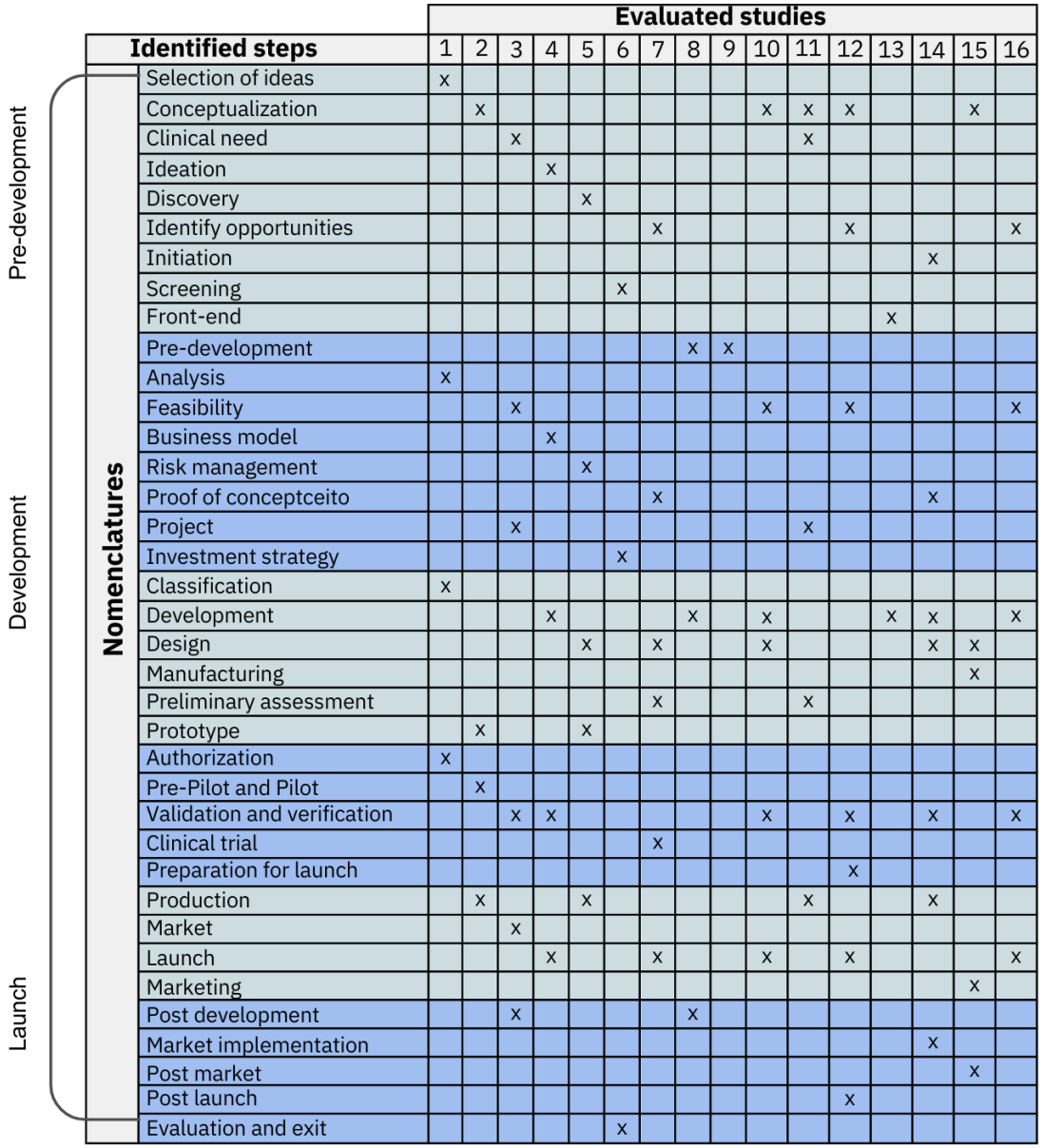
#### 3.1.4.1 Steps of medical device development

The medical device industry is characterized by short product life cycles, requiring continuous and iterative development (Marešová *et al*., 2020; Shin *et al*., 2023). This process involves successive prototyping, testing, improvements, and validations until the product is finalized (Alagumalai, Kadambi, and Appaji, 2019).

The product life cycle is structured into three main steps, as described by Cooper (1994), who defined them as the front end of innovation, the development pipeline, and the product maturity curve (Russell & Tippett, 2008; Cooper, 1994). However, when analyzing evidence regarding medical device development, an absence of a standardized division of steps was observed, resulting in inconsistencies in the terminology, sequencing, and definitions associated with each phase.

In this context, Figure 5 presents a matrix that synthesizes the steps identified in the NPD process. Although the SLR included 37 studies, only 16 described the development steps and were therefore considered in this specific analysis. The stages were organized chronologically, from the beginning to the end of the development process. Each row corresponds to one step or terminology, while the columns represent the evaluated studies. This matrix highlights the terminological variations found in the literature, emphasizing both the most prevalent and the more specific steps within the medical device development cycle.

Figure 5 – Medical device development steps identified across the literature



| | | Evaluated studies | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Identified steps | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| Pre-development | Selection of ideas | x | | | | | | | | | | | | | | | |
| | Conceptualization | | x | | | | | | | | x | x | x | | | x | |
| | Clinical need | | | x | | | | | | | | x | | | | | |
| | Ideation | | | | x | | | | | | | | | | | | |
| | Discovery | | | | | x | | | | | | | | | | | |
| | Identify opportunities | | | | | | | x | | | | | x | | | | x |
| | Initiation | | | | | | | | | | | | | | x | | |
| | Screening | | | | | | x | | | | | | | | | | |
| | Front-end | | | | | | | | | | | | | x | | | |
| Development | Pre-development | | | | | | | | x | x | | | | | | | |
| | Analysis | x | | | | | | | | | | | | | | | |
| | Feasibility | | | x | | | | | | | x | | x | | | | x |
| | Business model | | | | x | | | | | | | | | | | | |
| | Risk management | | | | | x | | | | | | | | | | | |
| | Proof of conceptceito | | | | | | | x | | | | | | | x | | |
| | Project | | | x | | | | | | | | x | | | | | |
| | Investment strategy | | | | | | x | | | | | | | | | | |
| | Classification | x | | | | | | | | | | | | | | | |
| | Development | | | | x | | | | x | | x | | | x | x | | x |
| | Design | | | | | x | | x | | | x | | | | x | x | |
| | Manufacturing | | | | | | | | | | | | | | | x | |
| | Preliminary assessment | | | | | | | x | | | | x | | | | | |
| | Prototype | | x | | | x | | | | | | | | | | | |
| | Authorization | x | | | | | | | | | | | | | | | |
| | Pre-Pilot and Pilot | | x | | | | | | | | | | | | | | |
| | Validation and verification | | | x | x | | | | | | x | | x | | x | | x |
| | Clinical trial | | | | | | | x | | | | | | | | | |
| | Preparation for launch | | | | | | | | | | | | x | | | | |
| Launch | Production | | x | | | x | | | | | | x | | | x | | |
| | Market | | | x | | | | | | | | | | | | | |
| | Launch | | | | x | | | x | | | x | | x | | | | x |
| | Marketing | | | | | | | | | | | | | | | x | |
| | Post development | | | x | | | | | x | | | | | | | | |
| | Market implementation | | | | | | | | | | | | | | x | | |
| | Post market | | | | | | | | | | | | | | | x | |
| | Post launch | | | | | | | | | | | | x | | | | |
| | Evaluation and exit | | | | | | x | | | | | | | | | | |

Nomenclatures

Caption: this figure summarizes the Medical Device Development steps identified across 16 studies that present NPD stages. Each number corresponds to a specific study as follows: (1) Russell; Tippett, 2008; (2) Pietzsch *et al*., 2009; (3) Ocampo; Kaminski, 2019; (4) Kruachottikul *et al*., 2023; (5) Songkajorn; Thawesaengskulthai, 2014; (6) Soenksen; Yazdi, 2017; (7) Durfee; Iaizzo, 2019; (8) Medina; Kremer; Wysk, 2013; (9) Fearis; Petrie, 2017; (10) Mugambi *et al*., 2018; (11) Shin *et al*., 2023; (12) Marešová *et al*., 2020b; (13) Barkaoui *et al*., 2023; (14) Maresova *et al*., 2020; (15) O'Dwyer; Cormican, 2017; (16) Lobato *et al*., 2019

Source: Prepared by the authors (2025).

The various studies analyzed adopt diverse terminologies to describe the process steps. It is important to emphasize that these terminological differences do

not merely represent synonyms, but rather reflect the multiplicity of activities carried out at each step. This diversity underscores the need for better alignment among stages to enhance process efficiency. In this context, Table 2 presents a compilation of the steps identified in the literature, along with a detailed description of each one. This serves as an analytical categorization of the development phases and includes a proposed nomenclature for each step.

Table 2 – Analytical categorization of development step identified in the literature for medical device development

| Proposed Steps | Terminologies Identified in the Literature | Definitions | References |
|---|---|---|---|
| Step 1: Concept | Idea Selection<br>Conceptualization<br>Clinical Need<br>Ideation<br>Discovery<br>Identify Opportunities<br>Initiation<br>Screening<br>Front-End | Phase of research and strategy to understand the key elements of the market, users, technologies, and final product needs | 1, 2, 3, 4, 5, 7, 10, 11, 12, 13, 14, 15 e 16 |
| Step 2: Project Feasibility | Pre-development<br>Analysis<br>Feasibility<br>Preliminary assessment<br>Business model<br>Risk management<br>Concept testing<br>Investment strategy | Demonstrate the technical and financial feasibility of the product through a preliminary assessment and a business model . | 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 e 14 |
| Step 3: Technological Development | Classification<br>Development<br>Project execution<br>Design<br>Manufacturing<br>Prototype | Develop a functional MVP and refine the business model to reduce business risk | 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15 e 16 |
| Step 4: Validation | Authorization<br>Pre-Pilot and Pilot<br>Validation<br>Preparation for Launch<br>Verification<br>Clinical Trial | Obtain a commercial version of the MVP. Conduct validation and verification testing of the product's characteristics. Additionally, regulatory planning is required. | 1, 2 , 3, 4, 7, 10, 12, 14 e 16 |
| Step 5: Marketing | Production<br>Market<br>Planning | Product introduction to the market, accompanied by a | 2, 3, 4, 5, 7, 10, 11, 12, 14, 15 e 16 |

| | | | |
|---|---|---|---|
| | Launch<br>Sales | commercial plan for financial strategies. | |
| Step 6: Post market evaluation | Post-development<br>Market implementation<br>Post-market<br>Post-launch<br>Evaluation and exit | Analyze post-launch feedback and use the data to gain deeper insights into the target market. | 3, 4, 8, 12, 14 e 15 |

Caption: References - (1) Russell; Tippett, 2008; (2) Pietzsch *et al*., 2009; (3) Ocampo; Kaminski, 2019; (4) Kruachottikul *et al*., 2023; (5) Songkajorn; Thawesaengskulthai, 2014; (6) Soenksen; Yazdi, 2017; (7) Durfee; Iaizzo, 2019; (8) Medina; Kremer; Wysk, 2013; (9) Fearis; Petrie, 2017; (10) Mugambi *et al*., 2018; (11) Shin *et al*., 2023; (12) Marešová *et al*., 2020b; (13) Barkaoui *et al*., 2023; (14) Maresova *et al*., 2020; (15) O'Dwyer; Cormican, 2017; (16) Lobato *et al*., 2019.

Source: Prepared by the authors (2025).

As presented in Table 2, different terminologies were observed for the steps of NPD in medical devices. Generally, five to six main steps were identified, beginning with ideation and opportunity identification (Kruachottikul *et al*., 2023; Durfee & Iaizzo, 2019). Subsequently, an evaluation of technical and financial feasibility is conducted, alongside analyses of risks associated with the development process (Lobato *et al*., 2019; Durfee & Iaizzo, 2019; Fearis & Petrie, 2017).

In the next step, a minimum viable product (MVP) is developed, which undergoes validation and technological evaluation according to predefined requirements (Kruachottikul *et al*., 2023; Lobato *et al*., 2019; Mugambi *et al*., 2018). Subsequently, regulatory compliance must be ensured, and the product must be prepared for market introduction, including the definition of manufacturing steps (Kruachottikul *et al*., 2023). Finally, the product is launched into the market, accompanied by the execution of strategic commercialization plans and continuous evaluation of post-launch feedback (Kruachottikul *et al*., 2023; Ocampo & Kaminski, 2019; Medina *et al*., 2013).

This scenario, composed of multiple stages, highlights the complexity of medical device development, especially given that many activities occur concurrently (Marešová *et al*., 2020). In this context, the lack of efficient process organization and innovation management practices can increase the probability of errors, compromising both product quality and development timelines (Vargas *et al*., 2017).

The proposed analysis, based on the analytical categorization of the steps, provides a systematic overview of the different phases identified in the literature, based on the evaluation of 16 studies evaluated in the SLR. This analysis linked the

activities of each phase, followed by a categorization performed by the authors into six distinct steps, aiming for standardization. The proposed structure follows a chronological logic of the development process, from idea conception to market introduction and post-market activities.

Aligned with this standardization, several studies highlight the need to develop frameworks and tools to support decision-making during the development stages of medical devices, considering the scarcity of specific guiding materials for organizations (O'Dwyer; Cormican, 2017). To complement these frameworks, it is essential to identify critical success factors and best practices, since NPD in the medical device field is characterized by dynamic requirements, making the application of standardized approaches unfeasible (Khan *et al*., 2024; Barkaoui *et al*., 2023).

#### 3.1.4.2 Critical factors in the development of medical devices

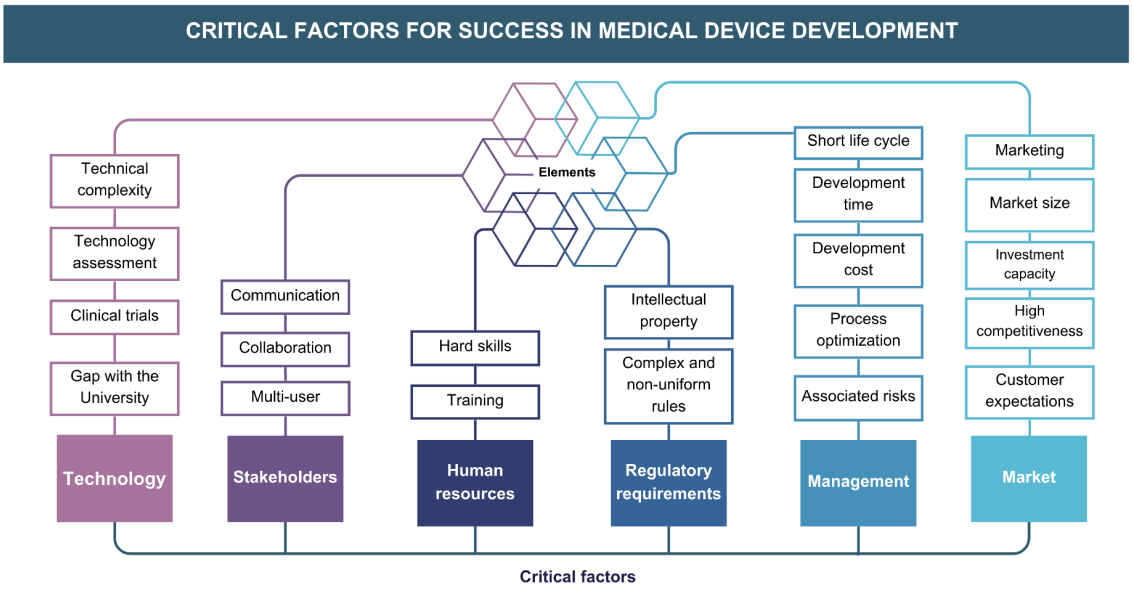
In the analyzed literature sought to identify the main critical success factors in the development of medical devices. These factors can be understood as the essential areas or conditions that must perform well to ensure the success and competitiveness of an organization (Rockart, 1979). Evaluating these factors makes it possible to determine priority areas for performance improvement and, at the same time, to identify critical aspects whose deficiencies may lead to failure in NPD, areas that are also fundamental to effective risk management (Durfee & Iaizzo, 2019; Russell & Tippett, 2008).

For this purpose, based on the evaluation of the studies, the critical factors were classified into six categories: (i) technology; (ii) human resources; (iii) stakeholders; (iv) management; (v) regulatory requirements; and (vi) market. Thus, the structure presented in Figure 6 was developed based on areas highlighted in the literature as determinants for success in medical device development, which are essential to ensure an efficient process (Tsai; Wang; Chen, 2023; Ocampo; Kaminski, 2019). In this context, the challenges of each category will be presented, emphasizing their influence on development.

Technological challenges related to the development of medical devices are extensive, ranging from the inherent technical complexity of projects (Guérineau, 2024; Shah; Arora, 2024) to difficulties in the health technology assessment process

(Brooks, 2017; Browne; Sutton; Zhang, 2023) and the conduction of clinical trials (Kirkire; Rane; Abhyankar, 2020). Furthermore, technology transfer between academia and industry represents a bottleneck in the innovation process, hindering the success of development (Kruachottikul *et al*., 2023).

Figure 6 – Critical elements for success in medical device development




Caption: The categories and their respective references are: **Technology:** Kirkire; Rane; Abhyankar, 2020; Guerineau, 2024; ; Medina; Kremer; Wysk, 2013; Kruachottikul *et al*., 2023; Browne; Sutton; Zhang, 2023; **Human resources:** Alagumalai; Kadambi; Appaji, 2019; **Stakeholders:** Medina; Kremer; Wysk, 2013; Kirkire; Rane; Abhyankar, 2020; Craig *et al*., 2015; Goldenberg; Gravagna, 2018; Busch *et al*., 2021; **Management:** Russell; Tippett, 2008; Marešová *et al*., 2020b; Ttsai; Wang; Chen, 2023; O'Dwyer; Cormican, 2017; Lobato *et al*., 2019; Peter *et al*., 2020; Pietzsch *et al*., 2009; **Regulatory requirements:** Brooks, 2017; Medina; Kremer; Wysk, 2013; Pietzsch *et al*., 2009; **Market:** Brooks, 2017; Russell; Tippett, 2008; Barkaoui *et al*., 2023; Lobato *et al*., 2019; Shin *et al*., 2023; Ocampo; Kaminski, 2019.

Source: Prepared by the authors (2025).

The critical elements related to human resources and stakeholders, which are closely interconnected, include the need for specialized professionals, as the development of medical devices requires a multidisciplinary approach based on knowledge from various sectors (Peter *et al*., 2020; Goldenberg; Gravagna, 2017). However, the medical technology industry faces a shortage of skilled professionals to drive the development of these products, which demands investment in training, making sector advancement costly and time-consuming (Alagumalai; Kadambi; Appaji, 2019).

On the other hand, communication and collaboration among stakeholders present challenges arising from factors such as unclear project objectives and the absence of a well-established innovation culture, which restrict effective development (Kirkire; Rane; Abhyankar, 2020). This scenario is particularly complex given the multi-user nature of medical device NPD, involving patients, healthcare professionals, and other stakeholders (Ocampo; Kaminski, 2019). To mitigate these challenges, it is essential to adopt strategies that foster team integration and promote a collaborative, flexible, and multidisciplinary approach (Busch *et al*., 2021).

In management, the challenges include the characteristics of the product, which, due to its short life cycle, requires constant improvements and accelerated innovation with continuous investments in R&D (Shin *et al*., 2023; Yeom *et al*., 2021). However, the development time for medical devices ranges from 1 to 5 years, and can reach 10 to 15 years depending on the technological complexity of the product (Guérineau, 2024; Pietzsch *et al*., 2009). Associated with this, development costs are higher than in other industries, mainly due to technological, regulatory, and clinical testing requirements (Guérineau, 2024; Russell; Tippett, 2008).

Furthermore, innovation management in the medical product industry frequently fails in the evaluation of technologies, which can generate risks associated with human, environmental, and organizational factors (Tsai; Wang; Chen, 2023). For this reason, it is necessary to optimize development processes, from planning through testing, validation, and market launch (Peter *et al*., 2020). To achieve this, maintaining updated documentation throughout the NPD process is essential, although this practice remains a gap in many organizations (Lobato *et al*., 2019). Proper record-keeping is crucial for development success, facilitating the identification of failure causes and applying tools and models that support the process (Salgado *et al*., 2017).

Another critical factor is regulatory requirements, as the NPD of medical products faces limitations related to patents and high regulatory barriers (Guérineau, 2024; Brooks, 2017). These restrictions affect various stages, such as development, manufacturing, marketing, and continuous improvement, and are constantly evolving (Ocampo; Kaminski, 2019; Medina; Kremer; Wysk, 2013). However, companies face difficulties in understanding the regulatory process, and there is a gap in guidance on how to manage these obligations throughout the NPD of medical devices (Shah; Arora, 2024; O'Dwyer; Cormican, 2017).

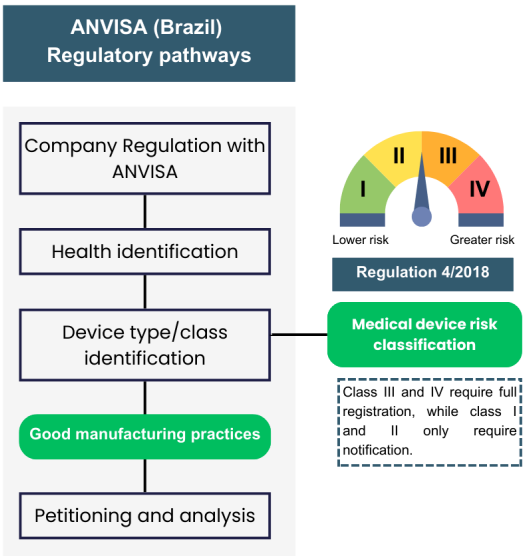
Thus, it is essential for companies to learn to manage their regulatory demands in parallel with the innovation process (O'Dwyer; Cormican, 2017). The literature confirms this challenge, which indicates that 90% of small companies fail to meet the regulatory requirements for their first product (Lobato *et al*., 2019). It is worth noting that these regulations are stringent due to the potential of medical devices to affect human life (Shin *et al*., 2023). Although the standards describe the requirements, they may not be clear to all users (Foo; Tan, 2017).

Thus, Figure 7 presents a compilation of indications regarding the regulatory process identified in the literature (Kheir; Jacoby; Verwulgen, 2022; Foo; Tan, 2017; Baylor, 2014), with global applicability, but illustrated from the context of the Brazilian medical device industry to exemplify its implementation. The figure shows two aspects related to the regulation of medical devices: (i) some international standards are listed that establish guidelines for different aspects of safety, performance, and quality of medical devices, from ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission); (ii) and a general guideline for the regulatory process according to ANVISA, also emphasizing the importance of the classification stage of devices according to their biological risk (ANVISA, 2021).

Figure 7 – Regulatory processes and standards identified in the literature

**International regulatory standards**

| STANDARD | DESCRIPTION |
|---|---|
| ISO 31000 | Identification and treatment of potential risks in various organizations. |
| ISO 10993 | Biological evaluation of medical devices |
| ISO 14971 | Risk management for medical devices |
| ISO 13485 | Quality management system requirements |
| ISO 14971 | Risk management application |
| IEC 60601 | Requirements for medical device safety and performance |
| IEC 62366 | Design and usability evaluation |




Source: Adapted from Brazil (2021), Kheir, Jacoby and Verwulgen (2022) and Foo and Tan (2017).

In this context, regulation is considered one of the primary barriers to the commercialization of medical devices (Barkaoui *et al*., 2023), representing the final category among the critical success factors: market challenges. Among these, the market size and high sector competitiveness stand out (Brooks, 2017; Russell & Tippett, 2008), which helps explain why approximately 88% of medical technology developers fail to generate financial returns for their investors (Marešová *et al*., 2020). Notably, the medical device market in developing countries is dominated by a small number of large companies, while the presence of small and medium-sized enterprises (SMEs) is significant, thereby limiting R&D investments for most firms (Khan *et al*., 2024; Shin *et al*., 2023).

Finally, a fundamental aspect of medical device development lies in meeting customer expectations and fulfilling the product's intended purpose (Lobato *et al*., 2019; Medina, Kremer, & Wysk, 2013). This underscores the importance of identifying critical success factors in development to enhance product quality and market success (Salgado *et al*., 2017).

Given the above, the identification and categorization of critical elements proposed in this study seek to support successful development by enabling a structured assessment of each group's specific challenges and risks throughout the development process. Furthermore, it is suggested that incorporating these aspects into guiding models for NPD may be essential for achieving an integrated and effective approach.

#### 3.1.4.3 Risk management

Identifying critical elements in the development of medical devices is directly linked to managing uncertainties and risks, aiming to reduce the probability of failures during the NPD process (Lobato *et al*., 2019; Pietzsch *et al*., 2009). Effective risk management contributes to a more accurate development process, favoring cost reductions and time required for product launch. Therefore, it is essential that risk identification practices be implemented from the outset of the project, as adjustments made in the early stages of product development tend to be more cost-effective than modifications carried out in later phases of the process (Lobato *et al*., 2019; Kheir, Jacoby, & Verwulgen, 2022).

At the beginning of the development process, uncertainty management should be the primary focus, as many variables and information remain incomplete or unavailable. As the project progresses and more data is gathered, uncertainty begins to be translated into more concrete risks. This process enables the identification of risks at both micro and macro levels, making it essential from the outset to distinguish those that have the potential to impact the entire development (Galli, 2017).

Risk management is essential in project development, particularly with the recognition that risks are inevitable. Its impact is also documented in the literature, such as in studies identifying a positive correlation between risk management practices and project performance, highlighting the benefits of its application (Kheir, Jacoby, & Verwulgen, 2022; Carvalho & Rabechini Junior, 2015). Thus, within the context of medical technology development, the risk management process can be structured into four main stages: risk analysis, risk assessment, control, and monitoring during production and post-production, in accordance with ISO 31000 and ISO 14971 standards. Overall, risk management focuses on the product, the process, and usability, aligning with the guidelines of certification (Kheir, Jacoby, & Verwulgen, 2022).

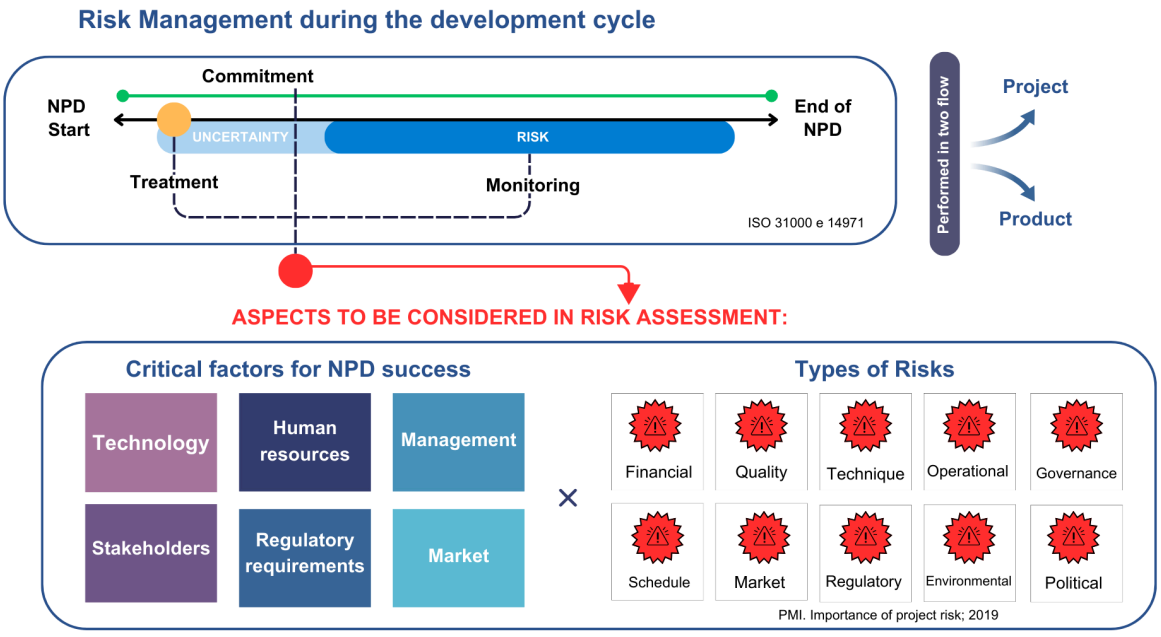
Furthermore, an NPD project may be associated with different types of risks. For instance, the study by Ahmed *et al*. highlighted that a project can face eight types of risks, including production planning risks such as resource shortages, and task dependencies such as shipment delays caused by third parties (Kheir, Jacoby, & Verwulgen, 2022). To facilitate the identification of these risks, the literature suggests evaluating them through two distinct streams: the project flow and the product flow, enabling more efficient mapping throughout the development lifecycle (Fontaine, 2016). Following risk identification, ISO standards 31000 and 14971 recommend implementing continuous monitoring processes and promoting stakeholder engagement to mitigate the risks involved in development (Kheir, Jacoby, & Verwulgen, 2022).

However, risk identification during development is a challenging task that requires analysis of critical areas within the NPD process needing attention in risk management, with the aim of mitigating threats and increasing the probability of product success (Kheir, Jacoby, & Verwulgen, 2022). To support this approach, the 10 types of risks recommended by the Project Management Institute (PMI) can be

employed, which helps broaden risk coverage and build a more comprehensive risk profile. These risks include financial, quality, technique, operational, governance, schedule, market, regulatory, environmental and political risks (Hopkinson, 2006; Ferreira de Araújo Lima; Marcelino-Sadaba; Verbano, 2021).

Based on the study by Kheir, Jacoby, and Verwulgen (2022), included in the RSL *corpus*, which proposed a risk monitoring matrix as the basis for a macro-level risk management framework (Figure 8). This framework emphasizes the stages of treatment, monitoring, and stakeholder engagement throughout the development cycle, considering the two primary flows: project and product. The figure emphasizes the initial stage as the period of greatest uncertainty, underscoring the importance of managing uncertainties at this phase. For risk identification, it is suggested to cross-reference the critical factors identified as essential in the present study with the 10 types of risks defined by the PMI, aiming to broaden risk coverage.

Figure 8 – Risk management framework throughout the medical device development lifecycle




Caption: In the Figure, the orange ball, the blue line and the green line represent treatment, monitoring and commitment during risk management, respectively.

Source: Prepared based on Kheir; Jacoby; Verwulgen (2022).

The application of this scheme has the potential to facilitate risk identification, considering that, in practice, these risks are often determined based on the judgments of stakeholders involved in the process (Kheir; Jacoby; Verwulgen, 2022). Thus, by systematizing the points that need to be evaluated, this process can reduce failures in risk identification and additionally minimize human bias, thereby helping to prevent errors in risk mapping.

However, for risks to be managed effectively, it is essential that the identification process be integrated into decision-making to ensure that actions align with the company's organizational strategy (Mobey; Parker, 2002). Furthermore, the developed systematization could be complemented by a checklist encompassing each risk, facilitating assessment and decision-making in specific contexts. Nonetheless, based on the reviewed literature, it was not possible to incorporate this approach into the systematization, representing a gap identified in the analyzed studies.

The proposed systematization contributes to a more comprehensive approach to identifying potential risks during the NPD of medical devices, as it aims to account for those that may not have been previously recognized. This, in turn, increases the chances of success and promotes the development of safer medical devices (Kheir, Jacoby, & Verwulgen, 2022).

#### 3.1.4.4 Identification of NPD models for diagnostic technologies

All the aspects previously discussed converge toward NPD models, whose primary goal is to guide product development based on information that supports decision-making (Lobato *et al*., 2019). These models aim to foster an organization capable of complying with established regulations and standards while maintaining flexibility and the ability to adapt to changes in the external environment (Guérineau, 2024). To achieve these objectives, such models should be simple, serving as an abstraction of the process, to identify risks, ensure product quality, user safety, and the sustainability of the organizational strategy (Lobato *et al*., 2019).

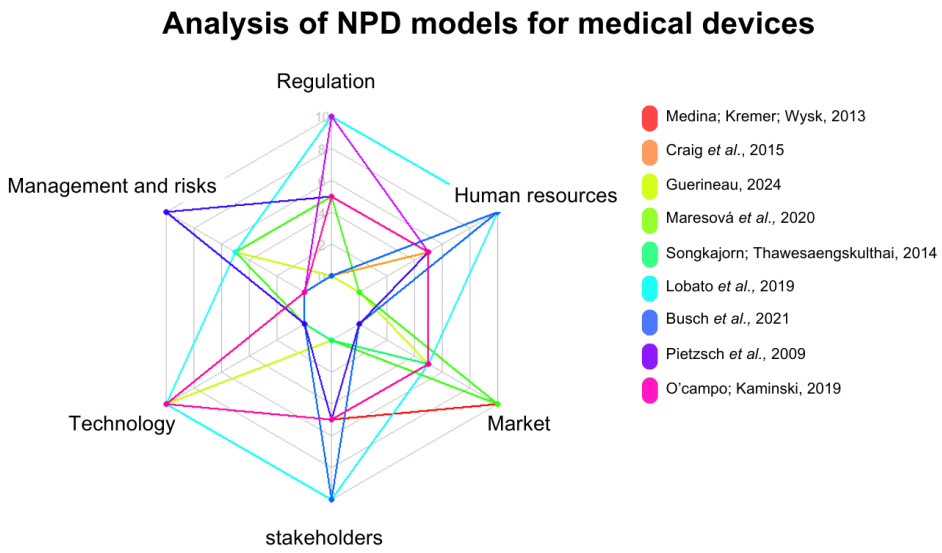
Moreover, NPD models can serve as a foundation for training in best practices, particularly in medical devices. These models also support identifying more efficient strategies by enabling the analysis of different scenarios involved in the development process (Kalinowska-Beszczyńska & Prędkiewicz, 2024). However,

companies have faced challenges in implementing such models, especially concerning project management and ensuring compliance throughout the development lifecycle (Guérineau, 2024; Medina, Kremer & Wysk, 2013).

The literature describes several approaches for structuring NPD; however, most focus on similar aspects, such as idea screening and project selection (Russell & Tippett, 2008). For example, although the Stage-Gate model is widely used in the healthcare sector, it provides limited guidance on executing critical activities throughout the development process. In addition, there is a clear lack of specific tools for evaluating investments in the health sciences or for supporting the early stages of development in this context (Soenksen & Yazdi, 2017; Girling *et al*., 2010).

In this context, an analysis was conducted using a radar chart to assess whether the models reviewed incorporate, within their scope, the critical factors identified in this study. As shown in Figure 9, each axis of the chart represents one of these factors: regulation, management, human resources, market, stakeholders, and technology. The assessment was based on a scale defined by the authors, where zero indicates the absence of the element in the model, five denotes its presence, and ten represents the ideal incorporation of the element in the model.

Figure 9 – Analysis of the presence of critical elements in NPD models for medical devices

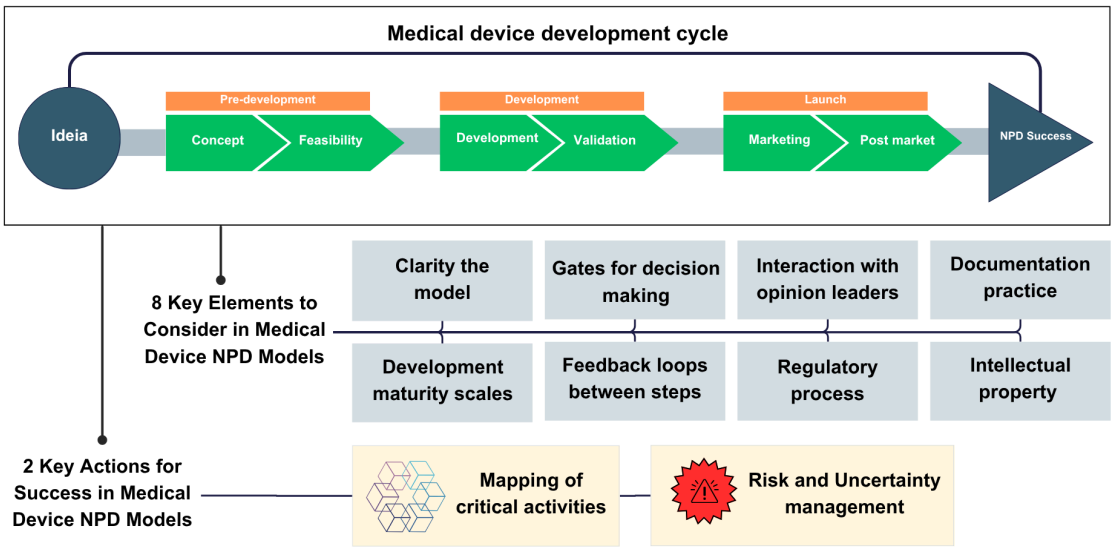



Source: Developed by the authors (2025).

Based on the results obtained from the radar chart analysis, it is evident that not all key areas of NPD are adequately represented in the models reviewed. These findings highlight the need for a more systematic and comprehensive approach to the NPD process. Consequently, a framework was developed encompassing the key elements of medical device NPD, based on the models identified and analyzed in the SLR, allowing for an assessment and identification of gaps in the literature.

The framework's structure, as illustrated in Figure 10, synthesizes key information extracted from the literature, highlighting the essential elements that favor decision-making and more efficient development (Kruachottikul *et al.*, 2023). It is important to note that not all of these characteristics considered fundamental were present in the models analyzed. One example is the study by Ocampo and Kaminski (2019), in which the lack of a defined structure compromises understanding of the development process.

Figure 10 – Key elements and action for structuring NPD models in medical devices



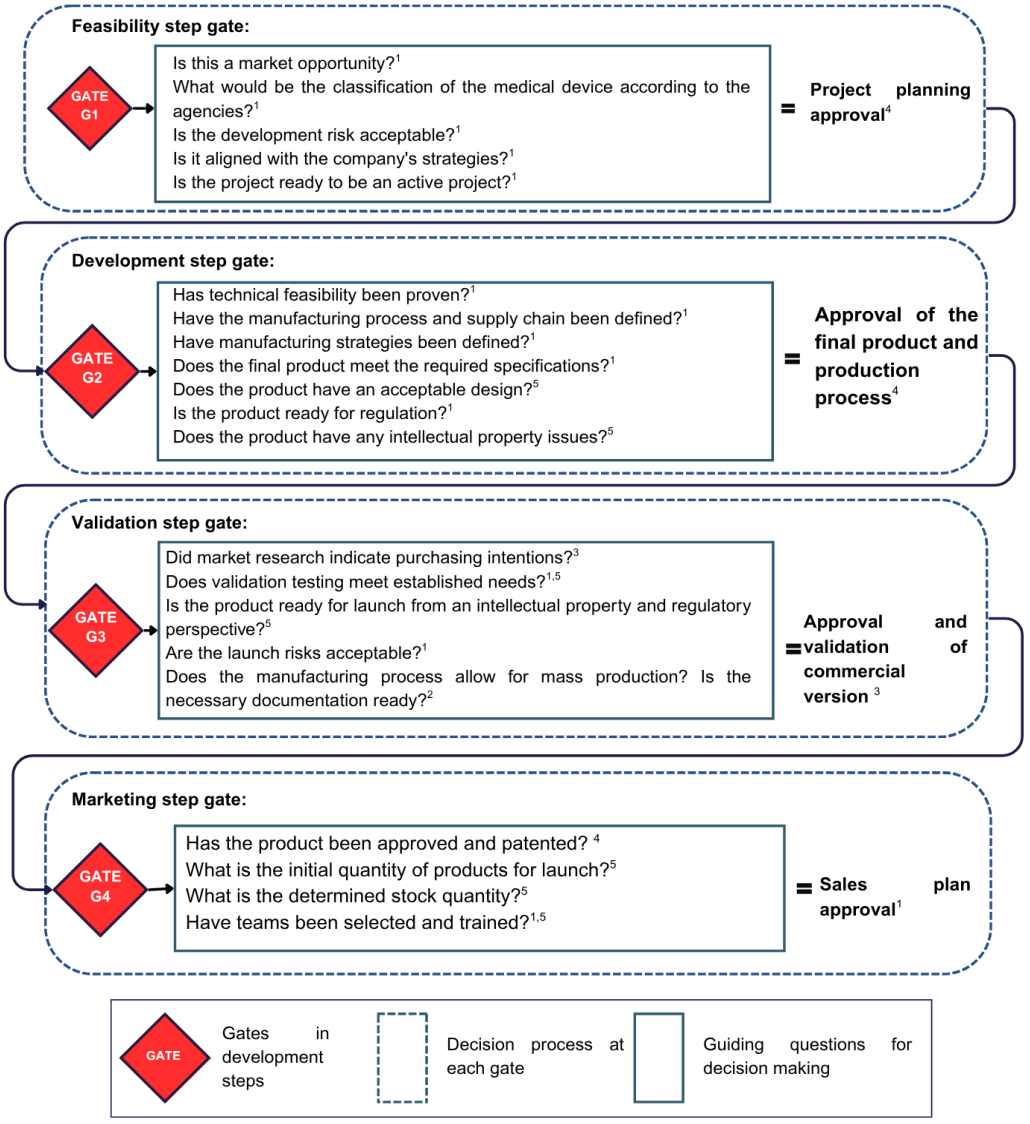

Caption: the upper part of the figure represents the development cycle, while the lower part presents the key elements that can be incorporated into an NPD model and the critical actions that support the process's success.

Source: Developed by the authors (2025).

The framework is based on elements that should be present throughout the development cycle, which is considered according to the six main stages defined in

this study: concept, feasibility, development, validation, commercialization, and post-market. In addition, three fundamental practices are highlighted to support decision-making. One of the practices involves the establishment of gates for progression between stages, enabling strategic evaluation of project actions (Ocampo & Kaminski, 2019; Lobato *et al*., 2019). To facilitate this, a supporting tool was developed (Figure 11), containing guiding questions and gates to be achieved in each phase.

Figure 11 - Guiding questions and gates for the steps of development




Caption: Numerical references cited in the figure: (1) Lobato *et al*., 2019; (2) Maresová *et al*., 2020a; (3) Kruachottikul *et al*., 2023; (4) Medina; Kremer; Wysk, 2013; (5) Pietzsch *et al*., 2009.

Source: Prepared based on Kheir; Jacoby; Verwulgen (2022).

Furthermore, one of the primary functions of the models is to guide the mapping of activities throughout the NPD process (Busch *et al*., 2021). This mapping can be conducted in various ways, as demonstrated in the studies by Lobato *et al*. (2019) and Pietzsch *et al*. (2009), who organized requirements through functional groups or categories. This practice is essential for strategy definition, team formation, adoption of best practices, regulatory compliance, and greeting of specific product requirements (Ocampo & Kaminski, 2019). To ensure this approach, the framework suggests mapping critical activities that make up the essential factors of development (predefined in this study) throughout the development cycle, allowing for the expansion of the scope of crucial actions during NPD. To support this process, a list of key activities identified in the literature was compiled and organized according to the development stages, as presented in Tables 3, 4, and 5.

Table 3 - Critical steps and activities in the pre-development stage

| | | Critical Activities Mapped | | References |
|---|---|---|---|---|
| | | **Activity** | **Critical factor** | |
| **Pre-development** | **Concept** | Product scope definition | Technology and market | Kruachottikul *et al*., 2023; Medina; Kremer; Wysk, 2013 |
| | | Market assessment and market-fit | Market and management | Lobato *et al*., 2019; Medina; Kremer; Wysk, 2013 |
| | | Application of economic methods for project evaluation such as cost-effectiveness assessment | Market | Maresová *et al*., 2020a |
| | **Viability** | Development approach planning | Management | Lobato *et al*., 2019; Medina; Kremer; Wysk, 2013 |
| | | Feasibility analysis | Technology, market and Human resources | Kruachottikul *et al*., 2023; Medina; Kremer; Wysk, 2013 |
| | | Risk assessment: financial, technological and regulatory | Market, technology and management | Lobato *et al*., 2019; Songkajorn, Thawesaengskulthai, 2014 |
| | | Financial, regulatory, team and product plan | Market, management, regulatory, technology, human resources | Lobato *et al*., 2019; Kruachottikul *et al*., 2023; Pietzsch *et al*., 2009 |
| | | Technology classification by security level | Technology | Songkajorn, Thawesaengskulthai, 2014 |
| | | Initial Intellectual Property Analysis | Management and Technology | Lobato *et al*., 2019; Kruachottikul *et al*., 2023; Pietzsch *et al*., 2009 |
| | | Project validation with experts | Management and Technology | Kruachottikul *et al*., 2023 |
| | | Purchase Intention Assessment | Management, Market and Stakeholders | Kruachottikul *et al*., 2023 |
| | | Financial plans: search for funding and investors | Management and human resources | Kruachottikul *et al*., 2023 |
| | | Determination of the specialized execution team | Human resources | Songkajorn, Thawesaengskulthai, 2014 |
| | | Prototype Validation - MVP and proof of concept | Technology | Lobato *et al*., 2019; Kruachottikul *et al*., 2023; Medina; Kremer; Wysk, 2013; Songkajorn, Thawesaengskulthai, 2014; Pietzsch *et al*., 2009 |

Source: Developed by the authors (2025).

Table 4 - Critical steps and activities in the development stage

| | | Critical Activities Mapped | | References |
|---|---|---|---|---|
| | | Activity | Critical factor | |
| Development | Technological development | Market validation according to product specifications | Market | Medina; Kremer; Wysk, 2013 |
| | | Determination of systematic recording practice | Management and human resources | Lobato et al., 2019; Songkajorn, Thawesaengskulthai, 2014 |
| | | Scenario analysis with the team | Management and stakeholders | Songkajorn, Thawesaengskulthai, 2014 |
| | | Supplier determination | Stakeholders | Medina; Kremer; Wysk, 2013 |
| | | Determine production capacity and manufacturing plan | Management and human resources and stakeholders | Lobato et al., 2019 |
| | | Intellectual Property Management: Patent Writing and Review | Management and technology | Lobato *et al* ., 2019; Kruachottikul *et al* ., 2023; Medina; Kremer; Wysk, 2013; |
| | | Stability and optimization testing | Technology | Medina; Kremer; Wysk, 2013 |
| | | Prototyping evaluation | Technology | Medina; Kremer; Wysk, 2013 |
| | | Validation and regulation plan - preparation of the initial regulatory technical dossier | Management, technology and regulation | Lobato *et al* ., 2019 |
| | | Continuous updating of the risk and uncertainty matrix | Management, technology and regulation | Kremer; Wysk, 2013; |
| | | Quality management: verification of product attributes | Technology | Lobato *et al* ., 2019; Pietzsch *et al* ., 2009 |
| | | Determination of product design | Technology | Pietzsch *et al* ., 2009 |
| | Validation | Pilot batch production and accuracy testing | Technology | Pietzsch *et al* ., 2009; Songkajorn, Thawesaengskulthai, 2014 |
| | | Carrying out clinical validation; | Technology | Lobato *et al* ., 2019; Medina; Kremer; Wysk, 2013; Songkajorn, Thawesaengskulthai, 2014 |
| | | Regulatory submission and approval; | Regulation | Busch et al., 2021; Pietzsch *et al* ., 2009 |
| | | Large-scale production process; | Technology and management | Lobato *et al* ., 2019; Medina; Kremer; Wysk, 2013 |
| | | Preparation of final manufacturing and quality documentation | Technology and management | Pietzsch *et al* ., 2009; Songkajorn, Thawesaengskulthai, 2014 |
| | | Assessment of health technology studies: market research on willingness to adopt and purchasing intentions | Technology and stakeholders | Maresová *et al* ., 2020 |

Source: Developed by the authors (2025).

Table 5 - Critical steps and activities in the launch stage

| | | Critical Activities Mapped | | References |
|---|---|---|---|---|
| | | Activity | Critical factor | |
| Launch | Marketing | Launch Planning and Marketing Plan | Management and stakeholders | Songkajorn, Thawesaengskulthai, 2014; Medina; Kremer; Wysk, 2013 |
| | | Training of production, sales and technical support staff | Management and human resources | Medina; Kremer; Wysk, 2013 |
| | | Release according to product and user requirements | Technology and stakeholders | Songkajorn, Thawesaengskulthai, 2014 |
| | Post market | After-sales monitoring | Management and stakeholders | Lobato *et al*., 2019; Medina; Kremer; Wysk, 2013 |
| | | Regulatory post-market surveillance | Regulation | Busch *et al*., 2021; 6- Pietzsch *et al*., 2009 |
| | | Audits for continuous improvement | Management | Lobato *et al*., 2019; Medina; Kremer; Wysk, 2013 |
| | | Critical evaluation of NPD success | Management | Songkajorn, Thawesaengskulthai, 2014 |
| | | Risk assessment and data collection for traceability | Management | Lobato *et al*., 2019; Guerineau, 2024 |

Source: Developed by the authors (2025).

Another essential practice involves continuous interaction with experts from various fields, ensuring greater accuracy of information related to the product and its clinical application (Busch *et al*., 2021; Vaquero Martín, Reinhardt, & Gurtner, 2016). Additionally, continuous project documentation is crucial to maintain traceability of data and decisions throughout the development process (Marešová *et al*., 2020; Ocampo & Kaminski, 2019; Lobato *et al*., 2019).

The models can also incorporate certain less prevalent features identified in the reviewed studies that may benefit the development process. Among these, the integration of monitoring scales, such as Technology Readiness Level (TRL) and Investment Readiness Level (IRL), stands out. These scales are used to assess, respectively, the technological maturity of the project and its investment viability (Kruachottikul *et al*., 2023). The application of these scales provides valuable insights to stakeholders and managers regarding project progress, thereby supporting strategic decision-making (Salvador-Carulla *et al*., 2024; GAO, 2020).

Additionally, some studies, such as those by Kruachottikul *et al*. (2023) and Busch *et al*. (2021), present interconnected stages that allow for interactions between phases with varying levels of technological maturity. Based on this approach, models can incorporate feedback loops, conceptualized as a bidirectional communication

process that reflects these interactions throughout development, thereby reinforcing the adaptability and flexibility of the NPD process.

Moreover, some studies incorporate activities related to regulatory processes and intellectual property within their models, as observed in the works of Guérineau (2024), Kruachottikul *et al*. (2023), and Medina, Kremer, and Wysk (2013). Notably, the study by Lobato *et al*. (2019) highlights the inclusion of applicable ISO standards and ANVISA regulations along the development process. These elements represent potential enhancements to be considered in NPD models to increase accuracy and effectiveness in addressing complex stages such as regulatory compliance and intellectual property management.

Finally, the analysis revealed the need to incorporate risk and uncertainty management into NPD models, recognizing that the specificities of the medical field influence nearly all stages of the development process. The pre-development phase focuses on identifying uncertainties, which gradually evolve into risks as the project progresses. These risks can be mapped by comparing the ten types of risks defined by the PMI with the critical factors previously discussed. Therefore, continuous risk monitoring across all development stages is essential, following industry best practices outlined in ISO 31000 and ISO 14971, to mitigate potential failures during the development process (Ocampo & Kaminski, 2019).

Considering the tools and models available to guide NPD, the proposed framework incorporates various elements that can be applied in developing medical device products. To optimize new models tailored to the healthcare sector, hybridization, the combination of two or more approaches to enhance the development process's performance, is recommended. This integration enables organizations to adapt methodologies to their specific contexts, promoting greater efficiency and alignment with operational and strategic needs (Guérineau, 2024; Arandia, Garate & Mabe, 2023).

### 3.1.5 Discussion

The analysis of the SLR highlighted that NPD in the medical device sector is a multifaceted process, shaped by regulatory, technological, and market-related factors (Nirali P. Shah, 2024; Warty *et al*., 2021). The approach adopted in this study, which involved categorizing the stages of the NPD process, identifying critical factors, and

addressing risk and uncertainty management, enabled a systematic understanding of the development process. This perspective revealed that decisions made at one step of NPD are interconnected with subsequent phases, underscoring the interdependence among the various stages of development.

The literature indicates that the stages and steps of NPD do not occur in isolation and may be influenced by critical factors that compromise the performance of the process (Medina, Kremer, & Wysk, 2013; Salgado *et al*., 2017). Elements such as stakeholder engagement, regulatory awareness from the early steps, and technical-scientific expertise can directly impact key phases, including the definition of product requirements and technical verification (Tsai, Wang, & Chen, 2023; Barkaoui *et al*., 2023). An illustrative example is the lack of clarity and delimitation of clinical validation during development, which can result in rework in subsequent stages, such as clinical trials and regulatory submission.

Moreover, risk and uncertainty management emerges as a transversal element within the NPD process, playing an integrated role in strategic and operational decision-making throughout development (Kheir, Jacoby, & Verwulgen, 2022). Risk mitigation practices are also closely linked to critical factors, as unidentified factors can evolve into project risks. This interrelationship among development steps, critical factors, and risk management reinforces the need to approach NPD as a system (Falahat, Chong, & Liew, 2024), to promote greater alignment between product performance and innovation (Knudsen *et al*., 2023).

Based on this understanding, a framework was developed that contains the key elements that should be present in NPD models to guide the development of medical devices, enabling the creation of systemic structures aligned with the healthcare sector. However, during the analysis, a gap in the literature was identified: most studies address the NPD for medical devices in a broad and generic manner, without specifying the type of product under development. This generalization may compromise the practical applicability of the proposed models, since different medical devices are subject to distinct technical and regulatory requirements (Falahat, Chong & Liew, 2024; Fink & Akra, 2023).

This finding highlights the need for more specific studies that consider the particularities of each category of medical devices to ensure greater accuracy in developing NPD models. Thus, the developed framework represents a conceptual

basis that can be adapted for the development of new NPD models in the healthcare sector.

### 3.1.6 Conclusions

The NPD of medical devices aims to achieve successful development by meeting product specifications, market trends, and customer and user satisfaction levels (Russell & Tippett, 2008). To reach this goal, a structured process aligned with stakeholder interests is necessary (Goldenberg & Gravagna, 2017). Although applying best practices in NPD does not guarantee product success, it can significantly increase the likelihood of achieving it (Ocampo & Kaminski, 2019; Durfee & Iaizzo, 2019).

This study contributes by identifying evidence that underpins the key stages and aspects to be evaluated during NPD, especially in resource-constrained contexts, providing systematic guidance for innovation management. This is particularly relevant in the highly competitive and fragmented healthcare sector (Kirkire, Rane, & Abhyankar, 2020). By enhancing the development of health technologies, the study supports the creation of more effective and accessible solutions, improving quality of life and healthcare delivery. The analytical categorization of NPD stages, identification of critical success factors, and risk mapping further provide tools for evidence-based decision-making and help evaluate often overlooked factors, thereby increasing the likelihood of success.

The developed framework allows for identifying key aspects that should be considered during the development of diagnostic medical devices. Its design is based on best practices extracted from the existing literature and is not limited to any specific type of diagnostic product. Consequently, one limitation of the study lies in the scope of the SLR, which encompassed a broad range of studies addressing different types of diagnostic medical devices and development contexts. Although this diversity allowed for a comprehensive overview of best practices, it also introduced heterogeneity in terms of technological complexity, regulatory requirements, and stages of development considered. Furthermore, the results are based exclusively on theoretical data, without empirical validation in real scenarios, which restricts the ability to assess the practical applicability and effectiveness of the identified factors.

Future research should focus on applying and testing the proposed framework in well-defined contexts, such as specific diagnostic technologies, product categories, or organizational environments. This would enable the evaluation of its practical applicability and the identification of potential adjustments needed to reflect real-world conditions more accurately. Additionally, expanding the literature review to include recent studies and diverse market perspectives could further strengthen the model's theoretical foundation. By combining theoretical refinement with empirical validation, future studies can enhance the framework's robustness, ensuring its greater relevance for both academia and the medical device industry.

# 4 ARTICLE 2 - INTEGRATIVE MODEL FOR NPD IN DIAGNOSTICS *IN VITRO*

The second article, entitled "*Innovating in vitro diagnostics: critical success factors and an integrative model for medical device development*", addresses the final version of the NPD model applicable to the context of IVDs. It encompasses the development of the artifact proposed in the study and complies with the dissertation's second and third specific objectives. The article was constructed based on the evaluation conducted in the SLR, which supported the initial version of the model. Subsequently, the model was refined through data collection and evaluation stages and its final version proposed.

The main contributions of this study include the identification of critical success factors and the definition of key challenges, based on empirical evidence collected through case studies in the medical device sector. From this information, it was possible to understand the real needs that an NPD model can address and align them with the theoretical data mapped in the first article of the dissertation. This manuscript will be subsequently submitted to the Journal of Product Innovation Management (JPIM). The full version of the article can be found in the following section.

## 4.1 ARTICLE 2: FULL VERSION

### INNOVATING *IN VITRO* DIAGNOSTICS: CRITICAL SUCCESS FACTORS AND AN INTEGRATIVE MODEL FOR MEDICAL DEVICE DEVELOPMENT

**Abstract:** Health innovation is crucial in advancing clinical diagnosis and healthcare delivery by introducing new technologies that improve organizational performance and patient outcomes. Among these innovations, *in vitro* diagnostic devices (IVDs) stand out for their capacity to decentralize and expedite disease detection, significantly contributing to early interventions and health system sustainability. However, the development of IVDs faces multifaceted challenges, including regulatory complexities, technological uncertainties, and alignment with market demands, which are compounded by these technologies' radical and disruptive nature. To address these challenges, New Product Development (NPD) offers a structured and systematic framework supporting the development process by aligning resources and timelines while ensuring regulatory compliance. NPD facilitates risk mitigation, enhances process efficiency, and fosters stakeholder coordination through the use of graphical models that clearly represent development stages and guide decision-making. Thus, the present study aims to identify the main critical success factors in the development of medical devices and apply them in the

structuring and evaluation of an integrative NPD model, specifically in the development of IVD, based on the Design Science Research (DSR) methodology. The model was developed through three phases: problem identification, solution design based on interviews with seven professionals in the Brazilian IVD sector, and artifact evaluation involving expert feedback and a focus group using a validated assessment instrument. The results revealed the identification of key challenges and the mapping of critical success factors in IVD development. Furthermore, it was possible to understand the key stakeholders involved in this sector's innovation process. Based on these elements, an NPD model was developed that encompasses risk management, critical factors, and integrating clinical, regulatory, and market strategies. This model was developed and evaluated using a hybrid approach, integrating empirical aspects and different methodologies, aligning them with concepts and practices found in the literature. This model provides a practical and sector-specific tool to support the efficient and sustainable development of *in vitro* diagnostic products, ultimately contributing to advancing healthcare technologies.

**Key-words:** *In vitro* diagnostic devices; New Product Development; Health innovation; Risk management; Design Science Research.

### 4.1.1 Introduction

Health innovation involves the adoption of new services or products that enable effective patient management and clinical diagnosis, while also enhancing organizational performance and allowing healthcare professionals to work more efficiently (Kruachottikul *et al*., 2024; Thakur, Hsu, & Fontenot, 2012). In this context, a solution is considered innovative when it is successfully introduced to the market (Feldman, 1994), representing an opportunity to improve service quality and patients' quality of life (Flessa & Huebner, 2021).

The advancement of the medical field is directly associated with the development of new technologies, such as pharmaceuticals, advanced therapies, and medical devices, which have contributed to the increase in life expectancy over the past century (Flessa & Huebner, 2021). In this context, technological innovations in health continue to evolve constantly, with medical devices standing out, defined as instruments, tools, or implants used to diagnose, prevent, treat, or monitor clinical conditions (Browne, Sutton, & Zhang, 2023).

With the capacity of medical devices to decentralize diagnosis, it becomes essential to promote the development of new technologies that enhance this capability, such as *in vitro* diagnostic devices (IVDs), considering that approximately 32% of diagnoses can be confirmed through these tests (Rohr *et al*., 2016; Wilke,

Schenker, & Hoffmann, 2002). Thus, the relevance of these devices lies not only in clinical support but also in their role as a fundamental tool for early interventions, as earlier diagnosis is directly associated with better prognoses and reduced costs in health systems (Rohr *et al*., 2016).

The IVDs are defined by the FDA (Food and Drug Administration) as tests performed on biological samples, such as blood or tissue, collected from the human body to detect diseases or other conditions (FDA, 2024). Among the most well-known examples of IVDs are point-of-care tests (POCTs), such as glucose tests, pregnancy tests, and more recently, COVID-19 detection tests (Li, 2019; Harpaldas *et al*., 2021). These devices enable rapid diagnoses by decentralizing the diagnostic process, allowing tests to be conducted near the patient without needing laboratory infrastructure (Nichols, 2020), and play a crucial role in disease surveillance and prevention (Amaral *et al*., 2024).

However, the development process of a new IVD is complex and multifaceted, particularly due to challenges such as regulatory barriers, technological uncertainties, misalignment between product and market, resource constraints, and inadequate risk management (Nirali P. Shah, 2024). Furthermore, the development of IVDs is often associated with radical innovations, as it involves technologies with the potential to transform healthcare and, consequently, reshape the market (Thijssen *et al*., 2023; Miller *et al*., 2005). This radical nature adds even more complexity to the process, due to the high level of uncertainty, instability, and unpredictability it entails (Bagno, Salerno, & da Silva, 2017). As a result, these factors directly impact the ability of organizations to develop and introduce innovations into the market in an efficient and sustainable manner (Hoveling *et al*., 2024).

In this context, technology-based firms (TBFs) play a central role, as they aim to develop disruptive solutions through scientific and technological knowledge (Tumelero *et al*., 2018). When focused on healthcare, particularly IVDs, their innovation process becomes even more complex due to sector-specific demands and the need for specialized expertise (Eldar, 2002; Fox, 2017). These firms also face declining productivity and difficulties in selecting projects that ensure competitiveness (Amir-Aslani & Negassi, 2006). Therefore, understanding their environment and challenges is crucial to designing strategies that foster innovative solutions (Dutta & Dhar, 2024; Garrido-Moreno, Martín-Rojas, & García-Morales, 2024).

The successful development of innovative medical technologies requires not only research and development but also structured product innovation management (Kruachottikul *et al*., 2024). In this context, New Product Development (NPD) practices provide a systematic framework that organizes the stages from idea conception to market introduction, ensuring alignment of deadlines, resources, product quality, and regulatory compliance (Flessa & Huebner, 2021; O'Dwyer & Cormican, 2017; Nirali P. Shah, 2024). Among the most consolidated NPD models are Cooper's stage-gate and Wheelwright and Clark's development funnel, which use graphical representations to facilitate understanding and dissemination while guiding innovation management and supporting more efficient development (Salerno *et al*., 2015).

Despite the relevance of NPD practices for developing IVDs, traditional models present limitations due to their lack of flexibility in addressing the specific challenges of the healthcare sector (Kruachottikul *et al*., 2024; Panda & Dash, 2014). Many of these models do not fully integrate the clinical, regulatory, and market strategies required to ensure the commercial viability of medical technologies (Namati, 2019; Panescu, 2009). Moreover, although the demand for innovation in healthcare continues to grow, there remains a scarcity of theoretical research that systematically addresses innovation and product development processes in this sector, limiting the consolidation of practices adapted to its particularities (Flessa & Huebner, 2021; Feldman, 1994).

Therefore, creating specific resources, such as NPD models adapted to the healthcare sector, is necessary, especially for developing IVDs (Friebe *et al*., 2022). This enables the construction of more comprehensive and effective resources that better guide development and increase the chances of success (Martins, Silva, & Magano, 2022). Thus, this study aimed to identify the main critical success factors in medical device development and apply them in structuring and evaluating an integrative NPD model, specifically in IVD development.

To this end, the article is structured into seven sections, in addition to the introduction. Chapter 4.1.2 addresses the main theoretical concepts related to the research topic. Next, Chapter 4.1.3 describes the methodological procedures adopted. The results, discussion, and implications are presented in Chapters 4.1.4, 4.1.5, and 4.1.6, respectively. Finally, Chapter 4.1.7 outlines the study's limitations and possibilities for future research.

### 4.1.2 Theoretical Framework

The theoretical framework was structured into three sections. The first section presents the role and challenges of technology-based health firms, focusing on IVD devices. The second addresses the foundations of new product development. The third explores ways to optimize NPD models.

#### 4.1.2.1 Challenges for *in vitro* diagnostic technologies in Brazil

IVDs have been established as strategic tools within the healthcare system. They enable tests to be conducted close to the patient without the need for laboratory infrastructure. By decentralizing diagnosis, these devices benefit regions with limited access to specialized services (CBDL, 2022).

These products represent an advancement for public health, particularly due to their ability to reduce turnaround time (the total time between test request and result delivery), accelerate clinical decisions, and enable more effective interventions (CBDL, 2022; Chaisirin *et al*., 2020). Additionally, POCTs bring laboratory testing closer to the patient and create an opportunity for more preventive and personalized care models, as they can guide up to 66% of clinical decisions (Rohr *et al*., 2016).

Despite these advantages, Brazil still faces challenges in boosting the domestic production of these technologies. One indicator of this limitation is the per capita consumption of *in vitro* diagnostic products, which is approximately US$9.60 per inhabitant per year, significantly lower than in countries such as the United Kingdom, where this figure reaches US$14.70. This gap highlights the need to strengthen the health innovation ecosystem for *in vitro* products (CBDL, 2022).

To achieve this, it is essential to understand the barriers that affect the research, development, and innovation (R&D) process of these products. Among the external factors, the regulatory process stands out, while essential to ensure population safety, it should not become an obstacle to innovation. Other challenges include dependence on imported inputs and instability in the supply chain, which undermines the autonomy of technological development (Mallet & Salerno, 2025; Gadelha, 2020). Regarding internal aspects, the challenges are related to the high technological complexity of the products, the shortage of qualified human resources, and limited financial investment (Dutta & Dhar, 2024; Babu, 2021).

A significant portion of innovations in this field is driven by TBFs, which play a central role in developing disruptive solutions. However, these companies, especially in the healthcare sector, often face limitations such as dependence on foreign technologies and difficulties in accessing strategic resources, which compromise their autonomy in the innovation process and reduce their market competitiveness (Mallet & Salerno, 2025). As a result, many promising ideas fail to become new products due to their inability to overcome these barriers (Flessa & Huebner, 2021).

In this context, expanding domestic production of these devices requires integrated actions to foster innovation, strengthen connections with universities, and enhance coordination among healthcare system actors to mitigate development challenges (CBDL, 2022). In addition, it is necessary to integrate knowledge and innovation management practices throughout the entire development cycle (Flessa & Huebner, 2021). Applying systematic methodologies can increase the chances of success by promoting the development and availability of more viable and valuable products for healthcare delivery (Kruachottikul *et al*., 2024).

#### 4.1.2.2 New Product Development (NPD): concepts

NPD is a structured process encompassing the initial stages of conception through to the product's launch on the market. This process aims to achieve three main objectives: (i) development speed, (ii) cost reduction, and (iii) final product quality (Knudsen *et al*., 2023). To meet these goals, NPD involves strategically managing outcomes and decision-making based on defined stages (Robson *et al*., 2023; Bianchi, Marzi, & Guerini, 2020; Kagan, Leider, & Lovejoy, 2018).

In general, NPD aims to meet market demands with innovative solutions that generate value for both the organization and the consumer, thereby strengthening competitive advantage (Falahat, Chong, & Liew, 2024). To support this process, graphical models are frequently used to represent the development stages and guide decision-making, as previously discussed (Salerno *et al*., 2015). However, despite being widely adopted and having their benefits reported in the literature (Cooper, Edgett, & Kleinschmidt, 2002; Cooper, 2015, 2008), many of these models present limitations, especially when faced with the challenges of radical innovations. This is because they were initially designed for incremental innovations in large companies, focusing on predictable and structured processes (Bers *et al*., 2014).

In this context, there is a need for NPD models that incorporate greater adaptability and multidimensional approaches to address the complexity of radical innovations. In the specific case of the medical device sector for IVDs, this adaptation is even more necessary, given the particularities and demands of the field (Kruachottikul *et al*., 2024; Panda & Dash, 2014). Moreover, traditional models often overlook stakeholder integration, which undermines identifying requirements and needs that could ensure greater product differentiation and market acceptance (Trott *et al*., 2022; Marešová *et al*., 2020).

Another relevant point is that, despite the extensive literature on NPD, few studies address knowledge management throughout the stages of the process. Integrating diverse knowledge is essential to generate products with high innovation and competitive advantage (Robson *et al*., 2023; Cooper & Sommer, 2016). Companies that develop successful products tend to use NPD processes that create and integrate knowledge about customers, competitors, and market dynamics (Van Oorschot, Eling, & Langerak, 2018; Rubera, Chandrasekaran, & Ordanini, 2016; Sullivan & Marvel, 2011).

However, even with the use of best practices, many companies still face difficulties in effectively aligning strategies, project portfolios, and process models. This lack of integration can undermine innovation performance and the successful market introduction of new products (Knudsen *et al*., 2023). In light of this, there is a clear need for further studies to guide the implementation of innovation management tailored to the healthcare sector, considering all dimensions involved in developing new diagnostic tools (Flessa & Huebner, 2021).

In this challenging context, where multiple variables impact the development of health innovations, there is a need for approaches that address the challenges posed by environments characterized by volatility, uncertainty, complexity, and ambiguity, the so-called VUCA context (Trott *et al*., 2022; USAHEC, 2019). Given this scenario, optimizing NPD models tailored to the *in vitro* products context is essential to enable innovative technologies and increase their likelihood of market success.

#### 4.1.2.3 Optimization of NPD models: risk management and critical factors

A literature review focused on this context was conducted to deepen the understanding of NPD models applicable to the development of medical IVD devices.

Appendix M presents a compilation of nine identified models, providing information on their objectives, the stages covered in the NPD process, and the inclusion of four important elements: regulation, risk management, market, and stakeholders. It is observed that the models vary in terms of purpose, scope of application, and the level of integration of these elements, allowing for a comparative analysis of their approaches and potential for optimization in the context of health innovation.

The analysis of NPD models revealed diverse approaches to the development of IVDs. Some models prioritize the incorporation of agile methodologies, as observed in Guérineau (2024), while others emphasize economic evaluation (Marešová *et al*., 2020) or adaptation to the particularities of small and medium-sized enterprises (Ocampo & Kaminski, 2019). Models such as those by Lobato *et al*. (2019) and Pietzsch *et al*. (2009) propose more comprehensive frameworks, covering stages from conception to post-launch. Although most models address the essential phases of NPD, few systematically integrate the analyzed elements (regulation, risk, market, and stakeholders). Notably, there is limited incorporation of stakeholders such as healthcare professionals, patients, and regulatory agencies. This gap represents a significant weakness, as engagement with these stakeholders is essential to ensure product effectiveness, acceptance, and differentiation in the healthcare market (Petkovic *et al*., 2023).

Given the need to optimize and adapt traditional NPD models to the demands of the healthcare sector, the hybridization approach emerges as a promising alternative. This approach involves combining different methodologies, such as integrating the Stage-Gate model with agile practices, aiming to make the development process more flexible, responsive, and aligned with the specificities of each project (Trott *et al*., 2022). By adopting hybrid models, it is acknowledged that there is no single path to innovation: companies must seek configurations that fit their organizational, technological, and market realities, thereby increasing their chances of success in launching new products (Trott *et al*., 2022; Salerno *et al*., 2015).

Based on the above and given the inherent complexity of developing and launching IVDs, this study focuses on developing an NPD model that integrates two fundamental pillars: risk management and identifying critical success factors. This focus recognizes that *in vitro* product development involves a high level of uncertainty, especially due to being a highly regulated and dynamic sector (Rodriguez-Manzano *et al*., 2024). It is estimated, for example, that approximately

75% of medical device startups in the United States fail, often due to failures in the early stages of development (Nirali P. Shah, 2024; Mark, 2022).

In this context, risk management is an essential tool for coordinating and controlling the innovation process, as it identifies, analyzes, and mitigates threats throughout the product's entire lifecycle (Peljhan & Marc, 2023). To ensure effective risk management, it is crucial to align it with the identification of critical factors that directly influence project performance. Recognizing these factors provides a foundation for risk assessment, guides strategic decision-making, and aligns development with organizational capabilities and market demands (Arena & Arnaboldi, 2014).

Critical success factors are specific areas that, when effectively managed, directly enhance the competitiveness and performance of innovation projects (Russell & Tippett, 2008; Rockart, 1979). One of the main challenges in developing radical innovations is identifying these factors, particularly in contexts characterized by technical uncertainties, resource constraints, and regulatory requirements (Niroumand *et al*., 2021; Pisoni, Michelini, & Martignoni, 2018). Based on a systematic review (first article – section 3.1), this study identified six critical factors considered essential for developing IVDs: human resources, stakeholders, management, technology, regulation, and market. Table 1 summarizes these elements, highlighting their key aspects and relevance within the context of NPD for medical devices.

Table 1 - Definition of the groups of critical factors evaluated in the study

| **Critical factor** | **Justification** | **References** |
|---|---|---|
| Technology | Technical and scientific foundation refers to the essential knowledge and capabilities for medical device development, including technical complexity, technology assessment, clinical trials, and collaboration between academia and industry. | Kirkire; Rane; Abhyankar, 2020; Guerineau, 2024; ; Medina; Kremer; Wysk, 2013; Kruachottikul *et al*., 2023; |
| Human Resources | This refers to the technical capabilities needed for R&D teams to operate effectively in innovative environments, where skilled and well-prepared teams are essential to managing uncertainties and the specific demands of the medical device sector. | Alagumalai; Kadambi; Appaji, 2019 |
| Stakeholders | Stakeholder engagement refers to interaction, communication, and collaboration with all parties | Medina; Kremer; Wysk, 2013; Kirkire; Rane; |

| | | |
|---|---|---|
| | involved in product development (healthcare professionals, users, government, and investors). | Abhyankar, 2020; Busch *et al*., 2021; |
| Management | Refers to the planning, execution, and control of development projects. It encompasses time, cost, short product life cycles, process optimization, and risk management to ensure strategic focus, efficient resource use, and a greater likelihood of success. | Russell; Tippett, 2008; Marešová *et al*., 2020b; Tsai; Wang; Chen, 2023; O'Dwyer; Cormican, 2017; Lobato *et al*., 2019; |
| Market | Refers to the external conditions affecting product success, including market size, customer expectations, investment capacity, and competitiveness. These conditions guide product positioning and alignment with real sector demands. | Russell; Tippett, 2008; Barkaoui *et al*., 2023; Lobato *et al*., 2019; Shin *et al*., 2023; Ocampo; Kaminski, 2019 |
| Regulation | Encompasses the legal and regulatory requirements for the approval, safety, and commercialization of medical devices, essential for ensuring compliance and minimizing the risk of rejection. | Brooks, 2017; Medina; Kremer; Wysk, 2013; Pietzsch *et al*., 2009; |

Source: Prepared by the author (2025).

Evaluating the six critical factors defined in this study is fundamental to ensuring a strategic and integrated approach to developing IVDs. Each of these elements represents an essential area of the innovation process: human resources relate to technical capacity and project execution in uncertain environments (Falahat, Chong, & Liew, 2024; MacCormack & Verganti, 2003); stakeholders influence product acceptance, validation, and adaptation (Niroumand *et al*., 2021); management guides decisions and resource allocation aimed at competitiveness (Nirali P. Shah, 2024; Niroumand *et al*., 2021); technology involved in the product acts as an innovation catalyst and is the main development element (Falahat, Chong, & Liew, 2024); regulation imposes critical criteria for viability and safety (Chettri & Ravi, 2024); and the market defines alignment with real demands and opportunities (Nirali P. Shah, 2024).

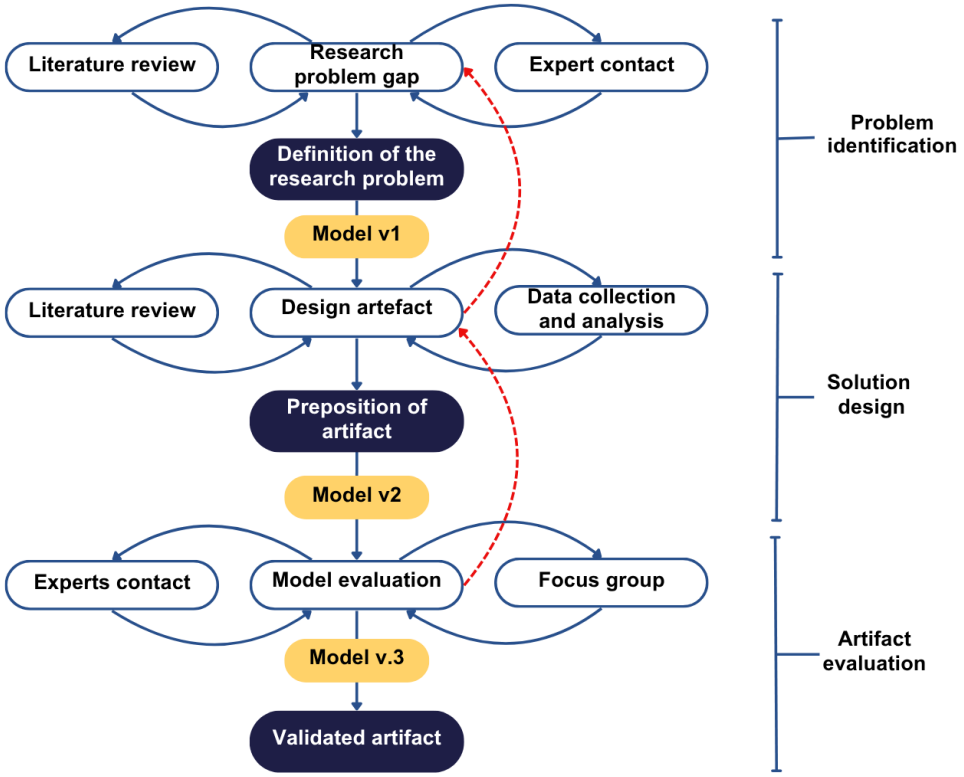
Based on integrating critical factors with risk management processes, this study proposes an NPD model structured around a hybridization approach to deepen the understanding of IVD development. Articulating these elements enhances the ability to anticipate challenges, guide decision-making, and direct efforts more effectively throughout the innovation cycle.

### 4.1.3 Methodological Procedures

Based on the above, this study aimed to propose and evaluate a NPD model focused on the development of IVD technologies, grounded in the Design Science Research (DSR) method. The primary purpose of DSR is to understand a problem and, based on this comprehension, to construct and evaluate artifacts that help bridge the gap between theory and practice (Dresch, Lacerda & Antunes, 2015). Within this context, the central artifact of the study is a model, defined as a set of propositions expressing relationships among constructs (March & Smith, 1995), that is, a set of elements and actions that guide the development of *in vitro* products.

The development of the proposed model was based on three main stages of DSR: (i) problem identification; (ii) solution design; and (iii) artifact evaluation, as guided by Dresch, Lacerda, & Antunes (2015) and Offermann *et al*. (2009). Figure 1 presents a description of these stages and their subdivisions, detailing the model development process, including the versions of the artifact generated throughout the study.

Figure 1 - Design Science Research process




Caption: The three stages are represented in the figure, indicating the phases and sub-phases, the milestones of each stage, as well as the versions of the artifact (the model). The three phases are supported by these sub-phases, and the dashed lines indicate possible transitions for iterations.

Source: elaborated by the author based on Offermann *et al*. (2009).

In the first stage, problem identification, the study's motivations were established and the research question was defined as: *How can critical success factors be translated into a model for new product development in the IVD sector?* (Further details are in Section 1). Additionally, a literature review (Section 3.1) was conducted to support the construction of the first version of the artifact. To further assist in delimiting the model's scope and structure, an expert in the field was consulted during this stage.

For the solution design, data collection was initially conducted with seven interviewees from different Brazilian companies in the IVD sector, selected through snowball sampling until theoretical saturation was reached (Rahimi & Khatooni, 2024). Participant information is presented in Table 2. Data collection occurred in two stages: (i) administration of a questionnaire containing scales to identify challenges in the development process, and (ii) conducting semi-structured online interviews, each

lasting approximately one hour. It is important to note that all participants provided informed consent by signing the Free and Informed Consent Form (ICF). Additional details regarding the data collection stage and supporting references can be found in Appendix E and F.

Table 2 - Interviewee profile of the study

| Interviewee (INT) | Academic level and professional field | Company profile | Company identification |
|---|---|---|---|
| INT1 | - Biomedical, MSc;<br>- Head of Research and Development; | Electrochemical point-of-care testing | Company A |
| INT2 | - Biologist, PhD;<br>- Production Manager in R&D; | Immunochromatographic test | Company B |
| INT3 | - Mechanical engineering, MSc;<br>- Co-Founder and CEO; | Immunochromatographic test | Company B |
| INT4 | - Doctor, MSc;<br>- Medical Director; | Point-of-care equipment and point-of-care testing: immunochromatographic, colorimetric, electrochemical, microscopy, molecular | Company C |
| INT5 | - Biomedical Engineering, MSc;<br>- Founder and CEO; | Point-of-care troponin measurement | Company D |
| INT6 | - Biomedical, MSc;<br>- Sales Executive | Sale of *in vitro* diagnostic solutions | Company E |
| INT7 | - Biologist, MSc;<br>- CEO | Electrochemical point-of-care testing | Company F |

Source: elaborated by the author (2025).

Subsequently, the data obtained from the interviews were analyzed. Initially, the data were tabulated using Atlas.ti software and organized based on six critical areas previously defined in this study for developing *in vitro* products: technology, human resources, management, market, regulation, and stakeholders. The compiled data from the collection are available in Appendix H.

Based on this tabulation, the data analysis stage was then carried out to identify the profile of interviewees and companies, their content analysis of

interviews, and the critical factors pointed out. Initially, a frequency analysis was conducted to quantify how often different stakeholders were mentioned during the interviews, enabling the mapping of their presence and relative relevance within the innovation process. Subsequently, all other data analyses were performed using RStudio (version 4.4.2). The full versions of the script used in R are available in Appendix N.

The first analysis involved generating alluvial diagrams to visualize the flow and relationships between the characteristics of the interviewed professionals and the companies to which they belong. The *ggplot2* and *ggaluvial* packages in RStudio were employed to construct these diagrams, allowing the identification of distributions and transitions between categorical variables. This approach provided a graphical representation of the respondents' and companies' profile data.

To explore in greater depth what the interviewees expressed regarding the product development process, these three main topics, "success," "learning curve," and "challenges", were selected for focused analysis. A qualitative analysis of the interview transcripts was then conducted to identify key aspects emphasized by the respondents within each topic. A text mining pipeline was implemented in R (version 4.4.2) using the *tm* and *dplyr* packages. The preprocessing steps included: (i) converting all text to lowercase to standardize the input, (ii) removing punctuation marks, numbers, and extra white spaces, (iii) eliminating stopwords in English as well as common non-informative words (e.g., "success", "also", "good") to focus on meaningful terms.

From the preprocessed text, a Document-Term Matrix (DTM) was constructed and sparse terms were removed (threshold: 95% sparsity). The remaining terms were subjected to Latent Dirichlet Allocation (LDA) topic modelling using the *topicmodels* package, with the number of topics set to 3, selected based on preliminary analyses to optimise interpretability of emergent themes. The number of words for each subject was defined as 4, trying to reduce redundancy. The document-topic distributions obtained from the LDA were visualized through Uniform Manifold Approximation and Projection (UMAP) using the *umap* package, with the number of neighbors set to 3 to capture local patterns in topic distribution.

To further illustrate the semantic structure of each topic, word clouds were generated using the *wordcloud* and *RColorBrewer* packages, displaying the 30 most frequent terms per topic. This methodological approach allowed the transformation of

unstructured textual responses into structured thematic categories, enabling both quantitative and qualitative interpretation of the interviewees' perceptions.

Additionally, the critical factor analysis was also conducted using the R software package *ggplot2*. The critical factors identified during the interviews were quantified based on the frequency with which each factor was mentioned as important by the respondents (n = 388). The frequencies were compiled into a data frame, and descriptive statistics, including mean and standard deviation, were calculated to characterize the distribution of factor occurrences. Visualization was performed through bar plots, where factors were ordered by their frequency to facilitate interpretation. A chi-square goodness-of-fit test was conducted on the frequency distribution to evaluate whether the observed pattern of mentions deviated significantly from a uniform distribution. This test assessed whether some factors were mentioned significantly more often than others, indicating their relative prominence among respondents.

To further explore patterns of similarity among critical factors based on their frequency of mention, hierarchical clustering was conducted on the frequency data. The resulting dendrogram and clusters were visualized using a heatmap generated by the *pheatmap* package, with a blue color gradient indicating frequency magnitude. The heatmap included frequency values for each factor, facilitating the identification of groups of factors with similar levels of importance as perceived by respondents. This approach applied the *pheatmap* and RColorBrewer R packages for *clstering* and color palletes, respectively.

It is worth noting that the questionnaire data were also analyzed by calculating the average score for each variable to identify the elements with the greatest impact on the analysis. These calculations were performed in RStudio, using the *dplyr* package, which allowed data manipulation and aggregation to obtain the average values for each variable.

Based on the results of the data analysis, it was possible to develop the second version of the model and proceed to the third stage of the methodology, corresponding to the evaluation phase, as proposed by Dresch, Lacerda, and Antunes (2015). The evaluation process was conducted on two fronts: (i) presentation of the model to six experts from different areas related to product development, and (ii) presentation of the model to a focus group composed of twelve employees from a company in the sector, to assess its applicability and acceptance.

The evaluation with experts was conducted through individual online interviews, guided by predefined topics according to each participant's area of expertise. The respective areas of expertise are detailed in Table 3. In the focus group, an adapted questionnaire, called the Technological Development Model Assessment Instrument (IAMDT), proposed by Salbego *et al*. (2023), was applied to assess the proposed model's acceptance level. Additional information and the results of the evaluation stage can be found in Appendix I.

Table 3 - Experts consulted for evaluation

| Expert | Domain | Academic background | Contribution |
|---|---|---|---|
| Expert 1 | NPD Specialist | Bs in Social Communication, Ms and PhD in Business Administration | Vice-coordinator of both the Innovation Management Lab and Engineering Education Lab. She combines academic leadership with a solid background in innovation and project management |
| Expert 2 | | Bs in Mechanical Engineer, Ms and PhD in Production engineering | Experience in product development management, Industry 4.0, and engineering education strengthens the research's technological and methodological foundation |
| Expert 3 | | Bs and Ms in Mechanical Engineer and PhD in Systematization of Production | Co-author of reference books widely used in academia and industry, including *Gestão de Desenvolvimento de Produtos* e *Gerenciamento de Processos de Negócio*. |
| Expert 4 | R&D Specialist | BS in Microbiology, MS in Biological Sciences, PhD in Biochemistry, MBA in Business Administration | Former Innovation Consultant at Biominas Brazil and co-founder/executive of biotech and deeptech startups, offering strategic insight into NPD and technology transfer |
| Expert 5 | ANVISA Specialist | BS in Chemistry and MBA in quality, management and process engineering | Over 13 years of experience as an auditor and consultant for ANVISA, specializing in medical devices |
| Expert 6 | DSR Specialist | BS in Production Engineering, MS in Production Engineering, and PhD in Production Engineering | One of the authors of the book "Design Science Research: a research method for advancing science and technology" |

Source: elaborated by the author (2025).

Subsequently, the evaluation stage was conducted, and the final modifications were incorporated into the model for developing an IVD. To quantitatively assess its relevance, the CVI was calculated in RStudio using the data obtained from the focus group through the IAMDT instrument. For each evaluated item, the mean and

standard deviation of the scores assigned by the participants were first calculated using the *dplyr* package. The CVI was then obtained by dividing the number of ratings equal to or above the defined agreement threshold by the total number of responses, with the mean representing the central tendency of evaluations and the standard deviation indicating the dispersion of agreement among participants. This approach follows the methodological guidelines proposed by Alexandre & Coluci (2011) and Grant & Davis (1997). The CVI measures the degree of agreement regarding the clarity, relevance, and representativeness of the model's components, with values equal to or greater than 0.80 indicating satisfactory content validity. The detailed results of this calculation are presented in Appendix I. The final version of the developed and evaluated artifact was thus established.

### 4.1.4 Results

The results of this study encompass the analysis of data collected through case studies, which included semi-structured interviews and questionnaires applied to companies involved in the development of IVDs. Based on this empirical foundation, combined with the theoretical framework previously discussed, a tailored NPD model for IVDs was developed.

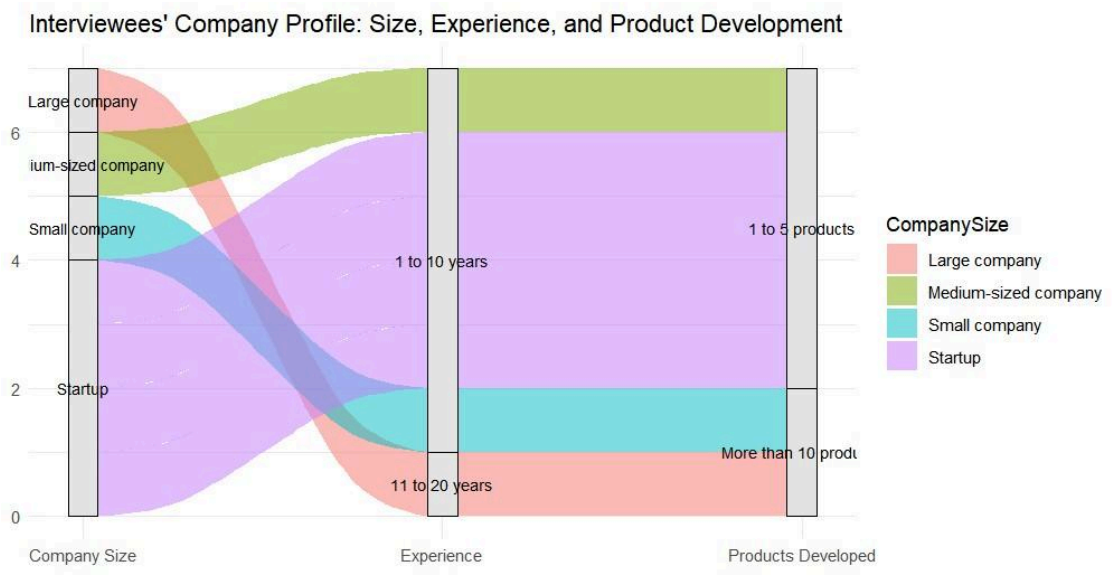
The presentation of results is structured into three parts. The first part outlines the profile of the case studies, focusing on the characteristics of the participating companies and the interviewed professionals. The second part explores the identification of key challenges and critical factors related to IVD development, as well as correlated aspects that influence the innovation process in this sector. Finally, the third part presents the proposed NPD model, integrating empirical findings and theoretical insights to offer a structured and applicable approach to new product development in the IVD context.

#### 4.1.4.1 Case Study Profile: Company and interviewee characteristics

A total of six distinct companies participated in the study, reflecting a diverse landscape in the development of IVDs. Notably, most participants (four out of six) were classified as startups, while the remaining included one small company, one medium-sized company, and one large company. Most companies (five) had

developed between one and five products, and only two reported having developed more than ten. In terms of experience, the majority reported operating for up to 10 years, with only one company indicating 11 to 20 years of activity. This distribution is summarized in Figure 2, which illustrates company size, experience, and number of products developed.

Figure 2 - Interviewees's company profile




Caption: Alluvial diagram representing the distribution and relationship between company size, years of experience, and number of products developed for the companies where the interviewees are employed.

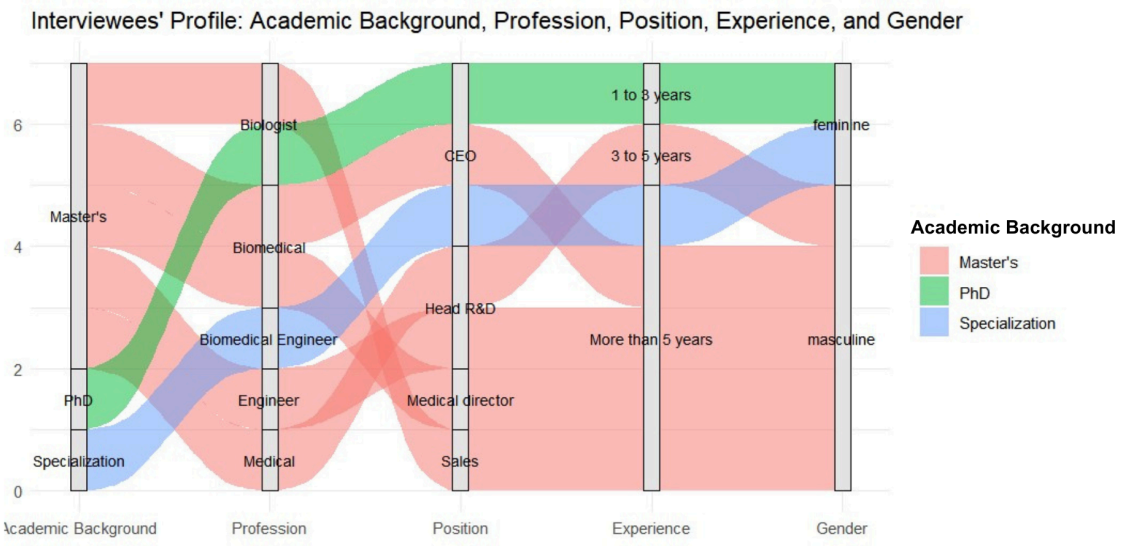
Source: elaborated by the author (2025).

This predominance of early-stage companies with a limited number of developed products may be associated with the inherent complexity, long development timelines, and high costs involved in the development and approval of IVDs. These characteristics underscore the structural challenges faced by emerging companies operating in a highly regulated and resource-intensive sector, such as the development of *in vitro* diagnostic devices.

In addition to the company profile, the interviews involved seven professionals with predominantly advanced academic qualifications and extensive experience in the sector. Most held leadership positions, such as CEO or head of R&D, and brought diverse technical expertise, including biology, biomedical sciences, medicine, and engineering backgrounds. Notably, only two participants were women, a disparity

that reflects the broader underrepresentation of women in leadership positions within the medical device sector. As summarized in Figure 3, this combination of strategic and technical perspectives provided valuable insights into the challenges and critical factors influencing the development of IVDs.

Figure 3 - Interviewees's profile




Caption: Alluvial diagram representing the distribution and relationship between academic background, profession, position, years of experience, and gender of the interviewees.

Source: elaborated by the author (2025).

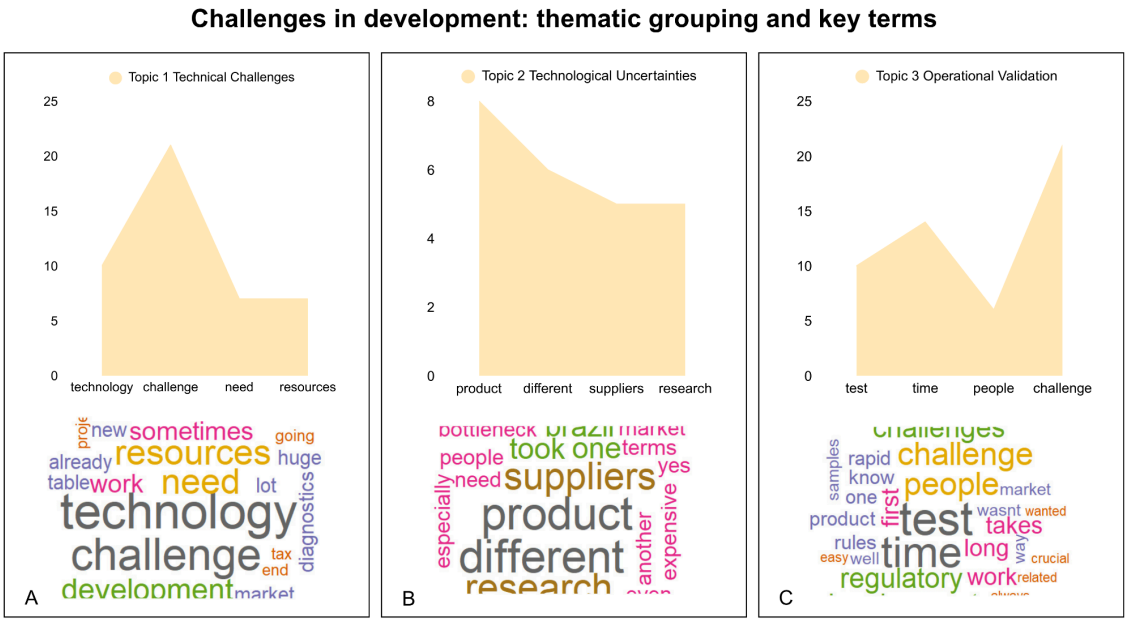
4.1.4.2 Challenges, critical factors, and influencing elements in the NPD

Considering the analysis of the collected narratives, the study sought to examine three central aspects in the development of *in vitro* products: (i) the main challenges faced, (ii) how the interviewees define success in this process, and (iii) whether the learning curve gained from one product is sufficient for the development of the next. To this end, the data were organized into these three categories, and within each category, a topic clustering technique was applied. Based on these clusters and the set of words comprising each topic, word clouds and term frequency analyses were generated to facilitate the visualization of the most relevant aspects.

In the "development challenges" category, 417 terms from seven narratives were analyzed (Figure 4). The analysis resulted in the categorization of three topics: Technical Challenges, which highlighted technological difficulties with terms such as

“technology,” “challenge,” and “resources”; Technological Uncertainties, which emphasized the inherent uncertainties of development, with terms such as “product,” “suppliers,” and “research”; and Operational Validation, which addressed the practical validation of the product, with terms such as “test,” “time,” and “people.” These findings indicate that the challenges reported in development involve overcoming technical difficulties, managing technological uncertainties, and ensuring operational validation through testing, adequate timelines, and collaboration among teams and suppliers.

Figure 4 - Challenges in development: thematic grouping and key terms



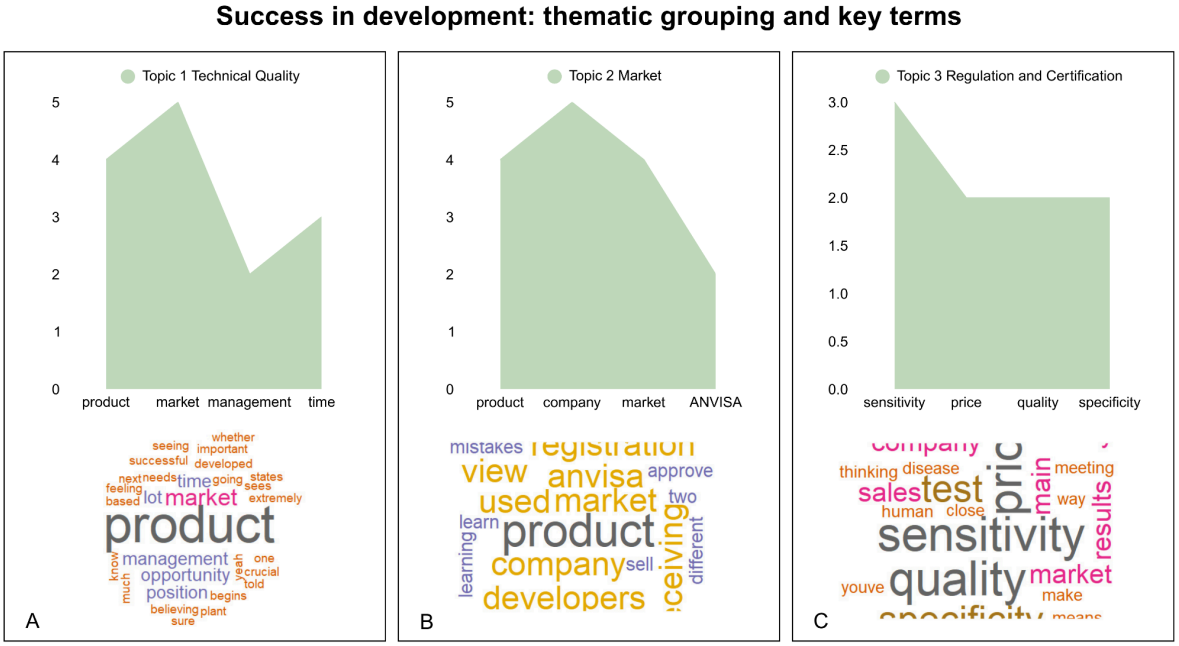

Caption: the identified terms were categorized into three main topics: (i) technical challenges; (ii) technological uncertainties; and (iii) operational validation. In each block, part A presents the frequency of the main terms, while part B shows the result of the word cloud associated with the respective topic.

Source: elaborated by the author (2025).

Understanding these obstacles makes identifying the elements contributing to project success possible. In the “development success” category, 145 terms were identified from the seven narratives, which were grouped into three main topics (Figure 5). The first topic, Technical Quality, encompassed terms related to product management and technical aspects, such as “product,” “management,” “market”, and “time.” The second topic, Market, highlighted terms such as “product,” “company,”

and “market,” underscoring the importance of commercial positioning and market acceptance. The third topic, Regulation and Certification, grouped terms such as “sensitivity,” “quality,” and “specificity,” demonstrating the relevance of regulatory aspects for product success. Thus, success in development can be defined as delivering a technically qualified product that is accepted by the market and compliant with regulatory requirements.

Figure 5 - Success in development: thematic grouping and key terms



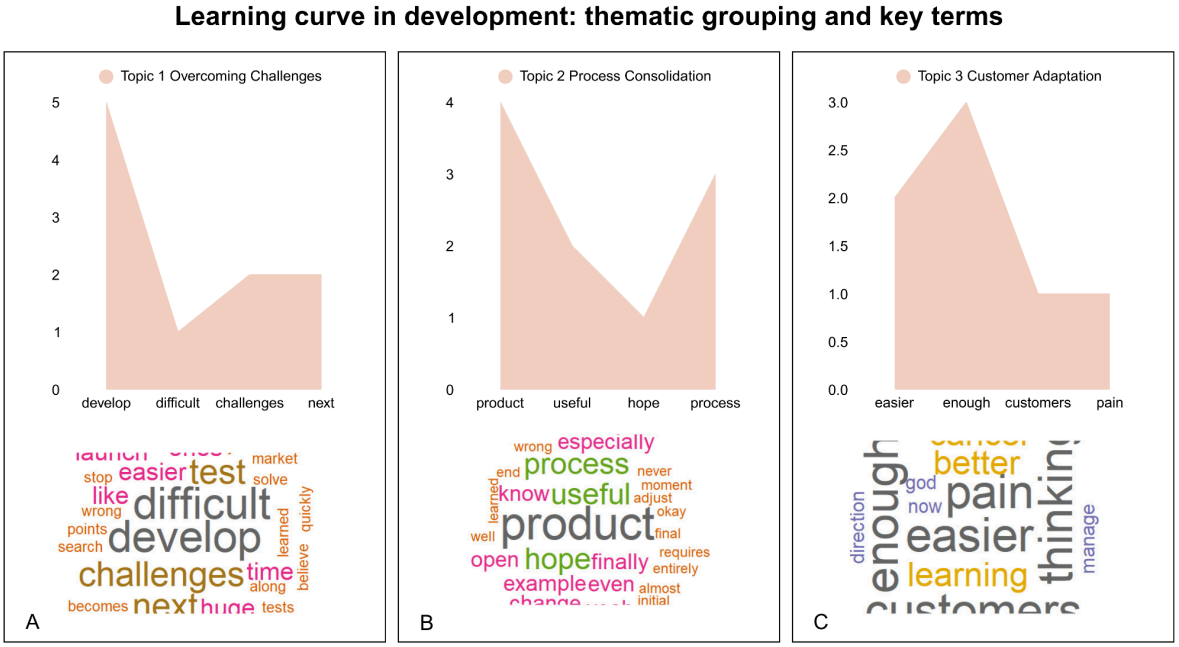

Caption: the identified terms were categorized into three main topics: (i) technical quality; (ii) market; and (iii) regulation and certification. In each block, part A presents the frequency of the main terms, while part B shows the result of the word cloud associated with the respective topic.

Source: elaborated by the author (2025).

Regarding the learning curve, the analysis of 218 terms (Figure 6) grouped the data into three topics. The first, Overcoming Challenges, highlighted the surmounting of obstacles in development, bringing together terms such as “develop,” “difficult,” and “challenges.” The second topic, Process Consolidation, suggested process maturity, with words such as “product,” “useful,” and “hope.” Finally, the third topic, Customer Adaptation, focused on tailoring the product to customer needs, as indicated by terms such as “easier,” “enough,” “customers,” and “pain.” In this context, it becomes clear that the learning curve in IVD development influences the

process but is not sufficient on its own; rather, it reflects a continuous cycle of overcoming challenges, consolidating processes, and adapting the product to customer needs, an essential foundation for enhancing future developments.

Figure 6 - Learning curve in development: thematic grouping and key terms

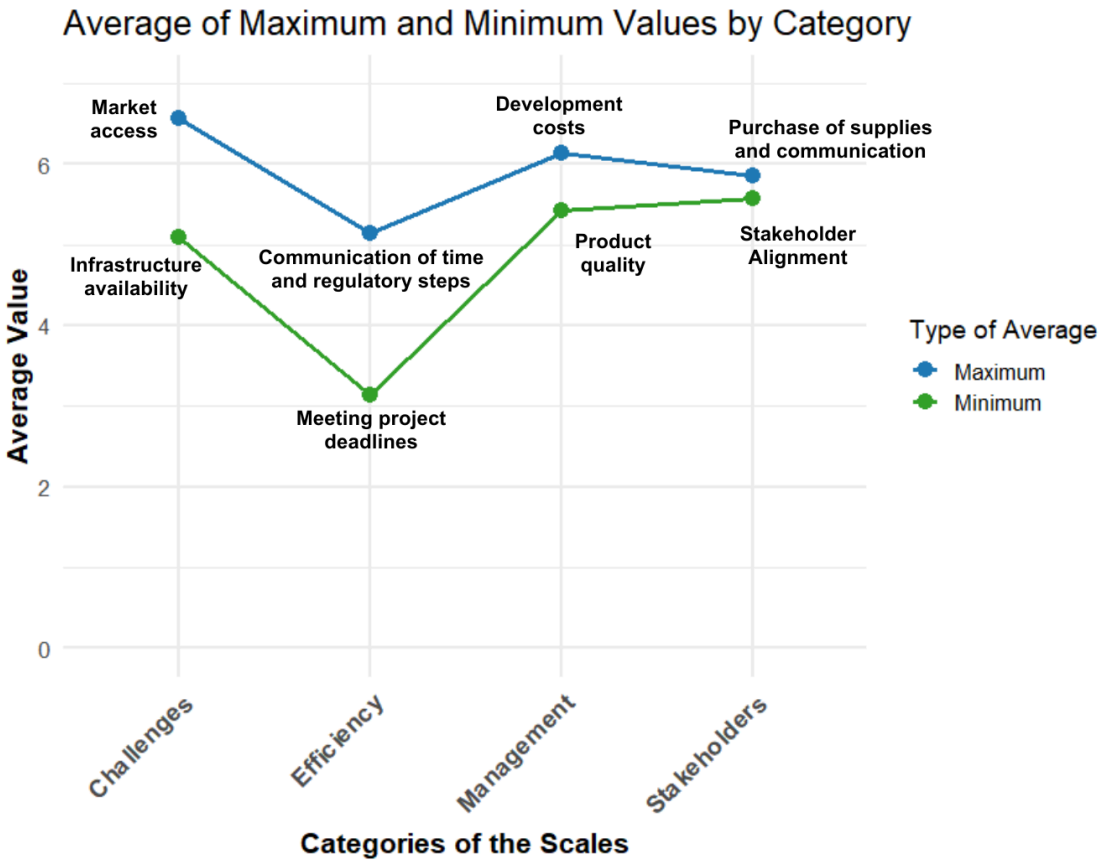



Caption: the identified terms were categorized into three main topics: (i) overcoming challenges; (ii) process consolidation; and (iii) customer adaptation In each block, part A presents the frequency of the main terms, while part B shows the result of the word cloud associated with the respective topic.

Source: elaborated by the author (2025).

To complement the discourse analysis, the applied scales were evaluated, enabling the quantification of development challenges, process efficiency, difficulties in stakeholder relationships, and the importance of innovation management for successful development (Figure 7). For each scale item, the mean of the responses was calculated, and the maximum and minimum values were identified, as these were considered most relevant for revealing the points of greatest and least perceived impact. This procedure allowed for comparison across the different dimensions assessed, and the raw data are provided in Appendix H.

Figure 7 - Average of maximum and minimum values from the applied scales by category




Caption: each block represents one area assessed in the applied scale. The chart displays the maximum mean value (in blue) and the minimum mean value (in green) for each category.

Source: elaborated by the author (2025).

It was possible to quantify that, in the context of the challenges faced in IVD development, market access emerges as the most significant difficulty, with a mean value of 6.57. In contrast, the least barrier relates to the availability of infrastructure (5.10). Regarding process efficiency, communication about timelines and regulatory stages has the greatest impact (5.14), in contrast to the lesser concern associated with meeting project deadlines (3.14). In the management domain, development cost, with a mean value of 6.14, stands out as the primary factor influencing managerial actions, followed by product quality (5.42). Finally, concerning stakeholders, the acquisition of inputs and communication were identified as the main challenges (5.85), while alignment among stakeholders showed lower relevance (5.57). The

slight difference between these values indicates that both aspects are important in the process.

When comparing the results across the different evaluated domains, it is observed that challenges related to development and management generally exhibit higher mean scores, indicating a greater perceived influence of these areas on the success of IVDs. The domains assessing process efficiency and stakeholder interaction show lower mean scores, although still relevant, suggesting that, in the respondents' perception, challenges directly linked to development stages and management exert a stronger influence on the successful development of IVDs.

These data corroborate the categories identified in the discourse analysis, reinforcing that technical and operational challenges are related to market, management, and communication issues, directly impacting the development process and product success. Thus, understanding these dimensions provides a more integrated perspective of the factors influencing the trajectory from overcoming challenges to consolidating the product in the market.

Complementing this perspective, the present study sought to identify critical success factors in developing IVDs. A total of 25 critical factors were identified, evaluated through 388 mentions made by the interviewees, and critically categorized according to six areas defined by this study, as presented in Table 4: management, market, regulation, technology, human resources, and stakeholders. This categorization enabled a clear organization of the critical factors, facilitating the identification of relevant aspects throughout the NPD process.

Table 4 - Categorization of critical success factors for IVD development

| **Critical factors defined** | **Critical elements identified** |
|---|---|
| Management | - Project Monitoring and Tools<br>- Decision Making<br>- Development Delays<br>- Documentation and Data Traceability<br>- Project Financing and Resources<br>- Risk Management<br>- Competitiveness and Financial Sustainability<br>- Intellectual Property |
| Market | - Product Incorporation and Acceptance<br>- Market Assessment<br>- Product Value<br>- Domestic Market |

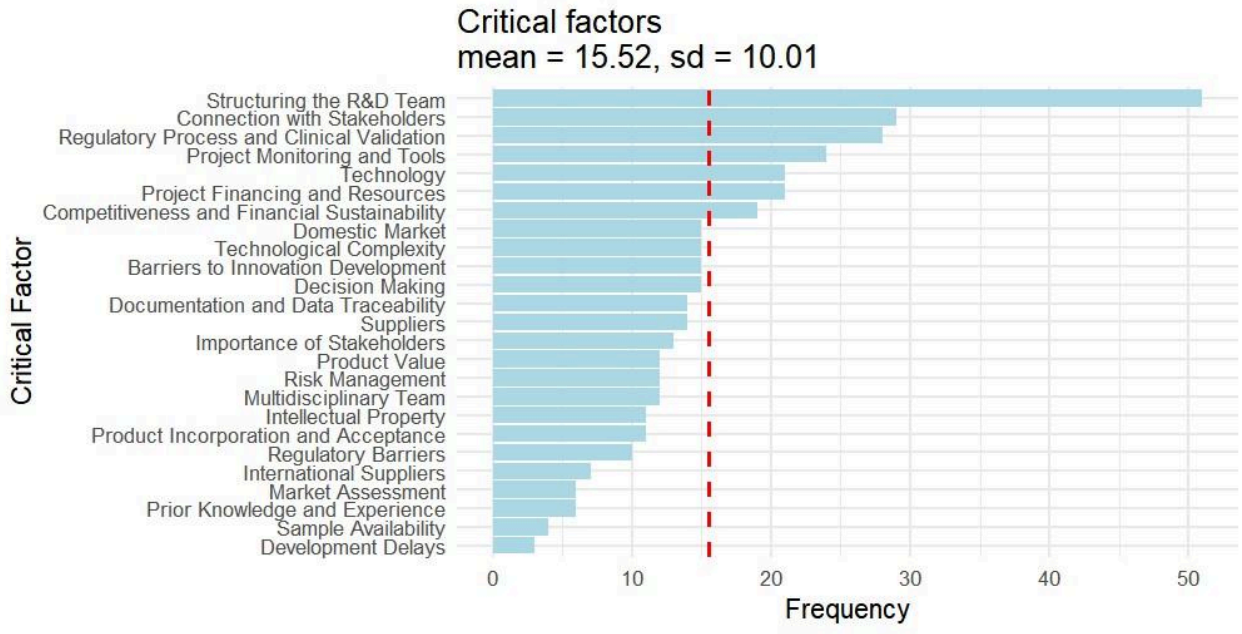
| | |
|---|---|
| Regulation | - Regulatory Barriers<br>- Regulatory Process and Clinical Validation |
| Technology | - Sample Availability<br>- Barriers to Innovation Development<br>- Technological Complexity<br>- Technology Development |
| Human resources | - Prior Knowledge and Experience<br>- Structuring the R&D Team<br>- Multidisciplinary Team |
| Stakeholders | - Define suppliers<br>- Connection with Stakeholders<br>- Importance of Stakeholders<br>- International Suppliers |

Source: elaborated by the author (2025).

Subsequently, each factor was assigned a frequency corresponding to the times it was mentioned as important during the interviews. To assess whether the distribution of these frequencies exhibited any significant pattern, a chi-square goodness-of-fit test was performed, yielding a p-value below 0.05. This indicates that the importance attributed to the factors is not random, with certain factors being significantly more prominent than others.

Figure 8 presents the described analysis, in which, considering the overall mean frequency (15.52) and standard deviation (10.01), factors with frequencies exceeding the mean plus one standard deviation (~25.53) were classified as high priority. Those with values above the mean (15.52) indicated relevant importance, while factors with frequencies below the mean minus one standard deviation (~5.51) were considered low priority.

Figure 8 - Critical factors based on frequency distribution



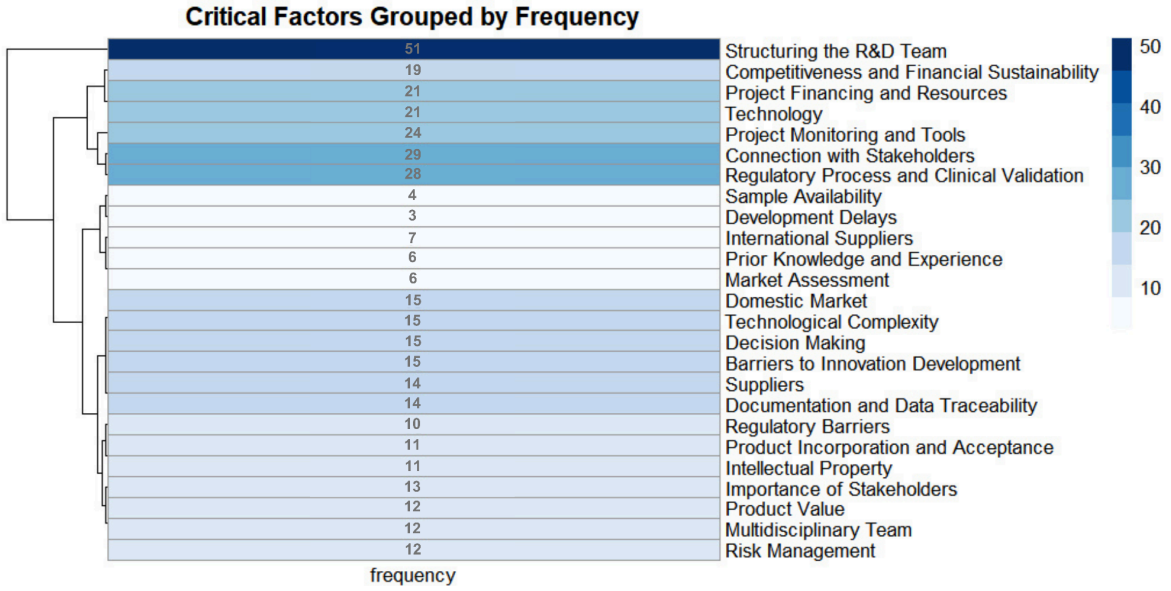

Caption: each variable represents an identified critical factor, and the dashed red line indicates the mean frequency across all factors

Source: elaborated by the author (2025).

Among the factors with frequencies above the mean, the following stand out: R&D team structuring, with 51 mentions; stakeholder engagement, with 29; regulatory process and clinical validation, with 28; project monitoring and tools, with 24; project funding and resources, with 21; and technology, also with 21 mentions. Thus, this classification enabled an objective assessment of each factor's relevance.

Subsequently, a hierarchical cluster analysis (HCA) was conducted based on the frequencies to identify groups of factors considered by the interviewees with similar relevance (Figure 9). The analysis revealed the formation of three main clusters, indicating sets of critical factors with comparable importance and highlighting priority areas in development.

Figure 9 - Critical success factors grouped by frequency



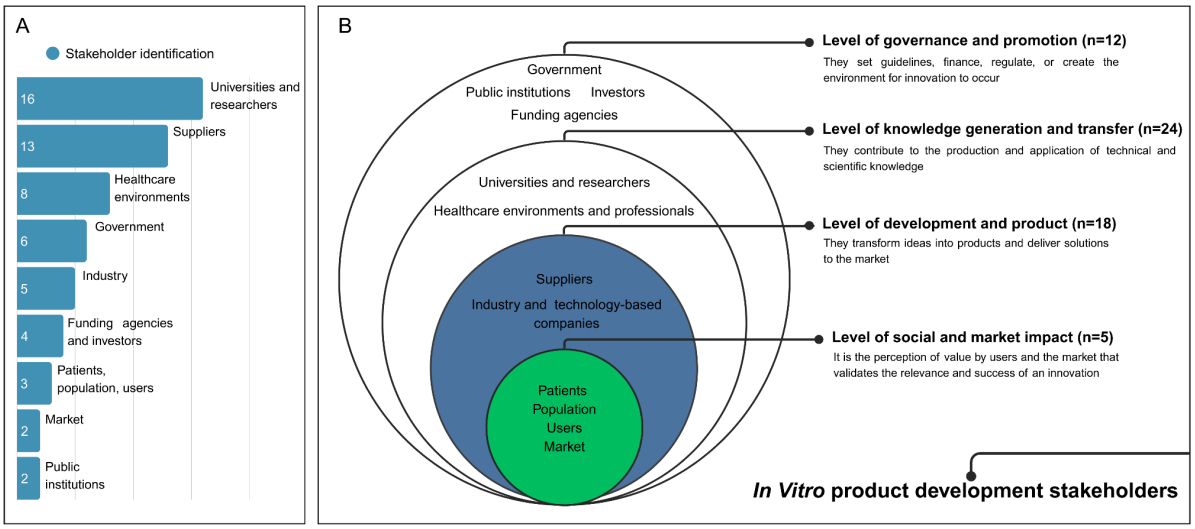

Caption: the figure presents the 25 critical factors identified in the study, displayed in a color gradient scale according to their observed frequency (the more intense the color, the higher the frequency, as indicated in the legend on the right side). On the left side, the groupings formed from the *Hierarchical Cluster Analysis* (HCA) are shown, highlighting the proximity relationships among the factors.

Source: elaborated by the author (2025).

Most of the critical factors (13/25), depicted in light blue tones, are grouped in the same branch, with frequencies ranging from 10 to 15, and are mainly related to the product development stage. The group with the least frequent critical factors, depicted in white, presents frequencies from 3 to 6 and includes only five elements. The third group is composed of six critical factors with higher frequencies (19 to 29), depicted in dark blue tones, and can be considered key points in the development process. However, the factor *"Structuring the R&D Team*" (navy blue) stood out for its remarkably high frequency (51 occurrences), reported in the interviews. This factor was not included in any of the three clusters, identified as the most critical factor among respondents. Considering the structuring factor of the team, this high-impact factor and the highest-frequency group, a pattern emerges that links these elements to the company's structuring related to the development and innovation process. Thus, it is believed that emphasizing these factors in an NPD model can increase the success of the development process.

Building on the identification of challenges and various critical factors in IVD development, it became necessary to understand the key stakeholders involved in this process. To this end, a frequency analysis was conducted on all parties mentioned in the interviews to map the actors actively participating in the development (Figure 10a). Subsequently, a diagram was created to illustrate the interrelationships among stakeholders, highlighting their connections and the role each plays in the NPD (Figure 10b).

Figure 10 - *In vitro* product development stakeholders




Caption: Block (A) displays all stakeholders mentioned during the interviews and their frequency analysis. Block (B) presents a diagram illustrating the different stakeholders and their interrelationships within the new product development process.

Source: elaborated by the author (2025).

This mapping is essential for understanding how the identified challenges are interconnected and how stakeholder interactions can be strategically leveraged to support the development of new national healthcare products. The analysis revealed strategic elements that should guide the design of an NPD model for IVDs, emphasizing that stakeholder interactions can shape an ecosystem that fosters collaboration, information sharing, and alignment among all actors involved.

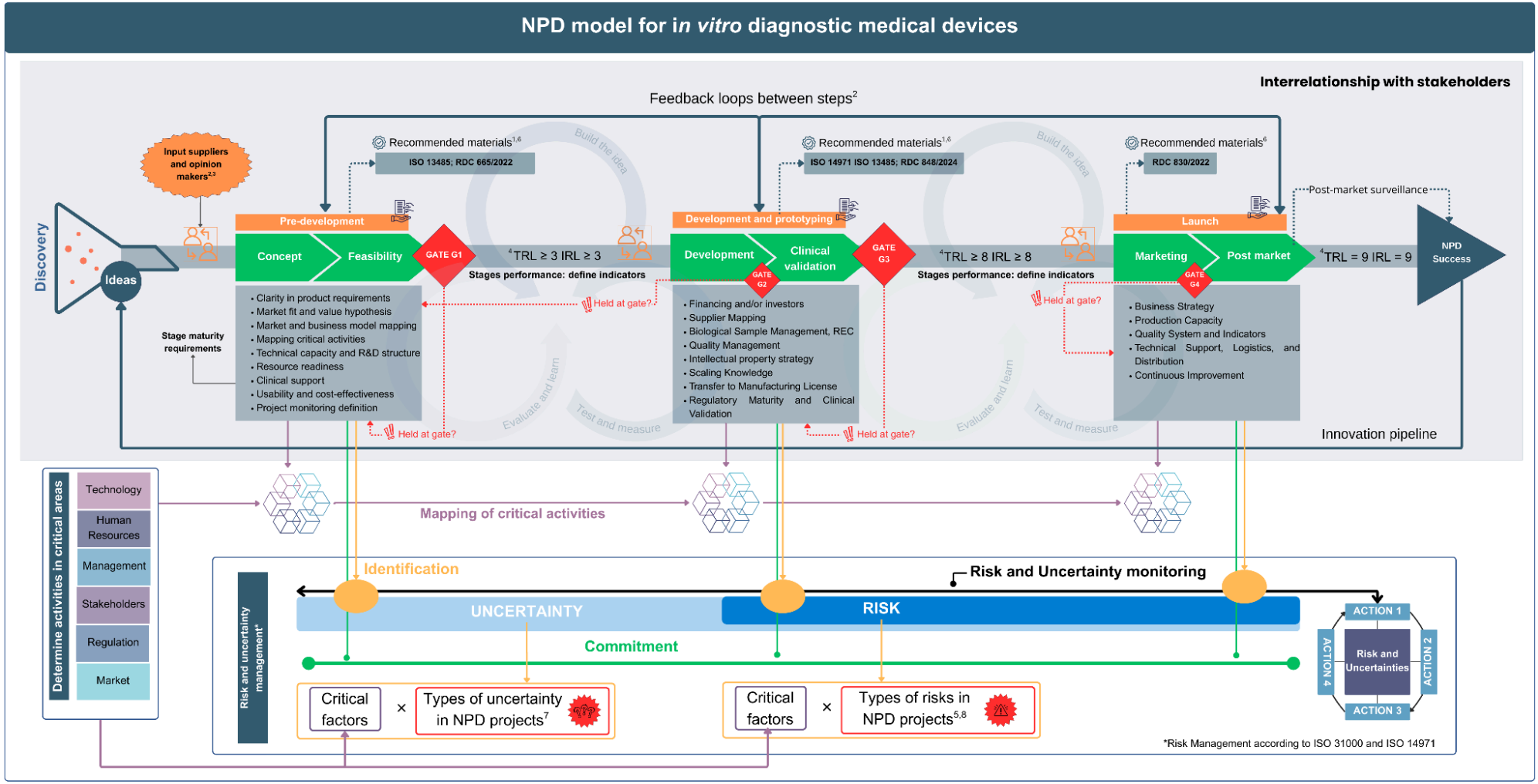
#### 4.1.4.3 Proposed NPD model for *In Vitro* diagnostic devices

The proposed NPD model for IVDs, as presented in Figure 11, was developed based on the results obtained during the data collection stage. In this stage, key challenges and critical factors, particularly those most frequently reported in the interview, were identified. These elements were treated as essential requirements and consequently incorporated into the model, with Figure 12 providing a caption of the symbols to facilitate interpretation. In addition, the model's design was supported by the literature through the evaluation of resources applicable to the medical device context and the analysis of consolidated approaches, such as the Stage-Gate (Cooper, 2015, 2008; 1994), DNA model (O'connor, 2008), Learning Plan (Rice; O'Connor; Pierantozzi, 2008), and the Development Funnel (Wheelwright; Clark, 2011). Thus, the model was developed in three versions: the first based on a literature review, the second incorporating insights from data collection, and the third refined through expert evaluation. To facilitate the interpretation of the model, Figure 12 presents a caption of the symbols used.

The model begins with the Discovery stage (O'connor, 2008), characterized by idea generation and an exploratory approach. At this phase, there is not yet a defined direction for a specific project; the focus is primarily on identifying opportunities and transforming initial ideas into potential initiatives. Multiple ideas or elements may be considered for product development, making it essential to understand customer needs and market demands. This stage functions as a development funnel, where numerous ideas, whether opportunities, challenges, or demands, enter and are progressively refined and prioritized (Wheelwright; Clark, 2011).

With the selection of ideas, the actual development cycle begins, organized into three main stages: pre-development, development and prototyping, and launch. Each of these stages encompasses specific steps, totalling six main steps: concept, feasibility, development, clinical validation, marketing, and post-market. The development cycle tracks the trajectory of an idea from its conception to market entry, representing the success of the NPD. Thus, the model's structure reflects the integration of stages and steps, enabling systematic monitoring of progress and ensuring that each phase is adequately addressed before transitioning to the next.

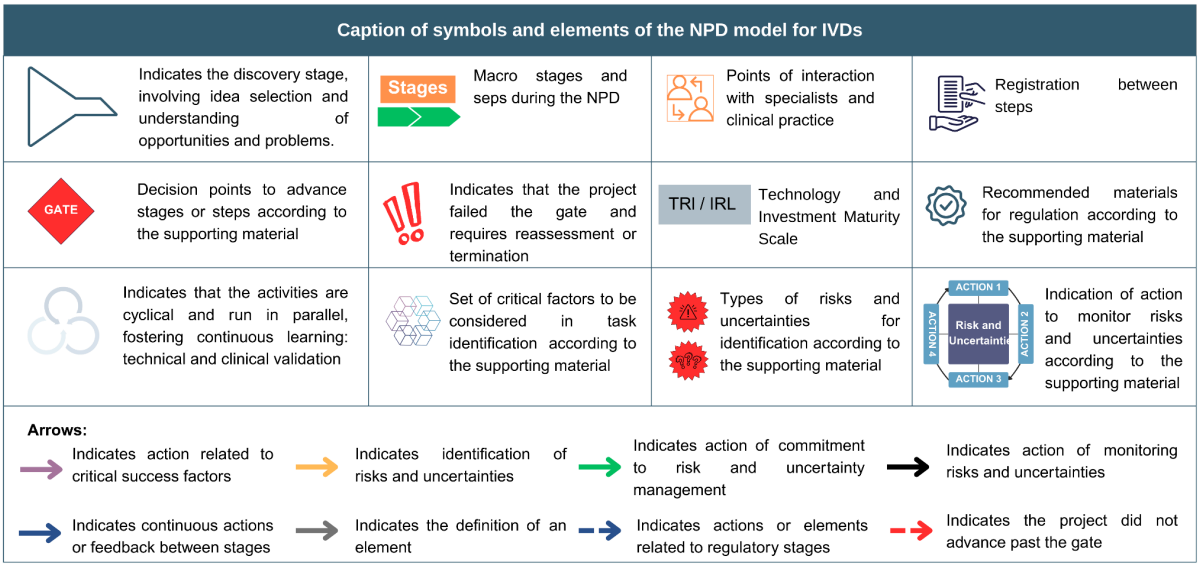
Figure 11 - NPD model for *in vitro* diagnostic medical devices




**References**: 1 - Lobato *et al.*, 2019; 2 - Busch *et al.*, 2021; 3 - Craig *et al.*, 2015; 4 - Kruachottikul *et al.*, 2023; 5 - PMI. Importance of project risk; 2019; 6 - GGREG; 2021; 7 - O'Connor, 2008; 8 - Ferreira de Araújo Lima; Marcelino-Sadaba; Verbano, 2021.

Source: elaborated by the author (2025).

Figure 12 - Caption of symbols and elements of the NPD models for IVDs




Source: elaborated by the author (2025).

In addition to the development stages, three fundamental practices were incorporated to support decision-making throughout the cycle. The first practice involves the definition of gates (Cooper, 2015), decision points distributed along the product development process, where projects are evaluated to determine whether they should continue (go) or be terminated (kill). Gates also provides an indication of the current value of the project and its future prospects, offering a strategic view of the potential success of innovations (Ocampo; Kaminski, 2019; Lobato *et al.*, 2019). To operationalize this practice, a support material was developed (Appendix O – Part 1), containing guiding questions and the gates to be achieved at each stage.

It is important to note that if a gate is not passed, a structured response is required, involving adjustments to the previously established plan. These modifications should be evaluated in light of the maturity requirements for each stage, which encompass essential technical, organizational, and regulatory aspects to ensure that the organization has the appropriate maturity to advance development. Thus, when a gate is not achieved, it is recommended to reassess organizational maturity at that specific stage and adopt an adaptive plan, allowing adjustments and revisions in previous steps before proceeding.

The second practice involves continuous interaction with experts from different areas, ensuring greater accuracy in information related to the product and its clinical

application (Busch *et al*., 2021; Vaquero Martín; Reinhardt; Gurtner, 2016). This practice consists of engaging strategic and clinical consultants who can provide insights on clinical needs, validation, usability, regulatory compliance, and practical applicability.

Finally, the third practice involves continuous project documentation, ensuring the traceability of data and decisions made throughout the development process (Marešová *et al*., 2020; Ocampo; Kaminski, 2019; Lobato *et al*., 2019). This practice not only ensures transparency and detailed recording of each stage but also supports the construction of the product's history, optimizing subsequent regulatory steps and contributing to the efficiency of future processes. Additionally, systematic documentation fosters organizational learning, allowing lessons learned from one project to inform subsequent initiatives and promote continuous improvement in NPD.

Among the model's stages is also an element representing the interactive process, emphasizing the cyclical and iterative nature of the activities involved in IVD development, including clinical and technical evaluation tests of the product. Within this cycle, ideas are continuously built, tested, evaluated, and refined, fostering constant learning throughout the process (Ries, 2011). This repetitive characteristic is particularly relevant during the prototyping stages, where multiple experiments are conducted to adapt the product to user needs and clinical requirements.

For clinical and technical product evaluation, monitoring technology maturity throughout development is essential. In the proposed model, this monitoring is performed using readiness scales, such as the Technology Readiness Level (TRL) and the Investment Readiness Level (IRL). The TRL allows for the assessment of a project's technological maturity, while the IRL provides information on the project's viability for attracting investment (Kruachottikul *et al*., 2023). These scales are central to the development cycle, providing indicators of project progress and facilitating strategic decisions (Salvador-Carulla *et al*., 2024; GAO, 2020). It is important to determine specific monitoring indicators aligned with the product's technical requirements, ensuring that maturity assessments adequately reflect reality.

The model also incorporates one of the essential dimensions of development: regulatory maturity, through the recommendation of materials and standards applicable to the Brazilian context. Considering these standards from the earliest stages helps prevent regulatory requirements from becoming barriers during clinical

validation. To support this application, Appendix O (Part 2) provides a categorized compilation of information on the regulatory process, facilitating alignment with legal requirements (ANVISA, 2025). Importantly, from a regulatory perspective, the product's lifecycle extends beyond clinical validation, requiring continuous post-market monitoring to ensure safety, efficacy, and compliance throughout its time on the market.

Although the model may appear linear, it is not characterized as a strictly sequential process. One piece of evidence for this is the incorporation of feedback loops between stages, which highlight the need for continuous interaction between different stages of development. These loops allow for return to previous stages to review information, validate decisions, or foster exchanges with other projects, in addition to reflecting the reality that many activities occur in parallel.

Furthermore, the model recognizes that NPD occurs within a dynamic innovation pipeline, in which multiple projects advance simultaneously through different stages. In this context, the completion of a project does not represent the end of activities, but rather the continuation of the innovation flow, ensuring that the R&D team remains constantly engaged. Even after a product enters the market, other projects remain ongoing, promoting continuous portfolio renewal. This approach ensures that the resources, learnings, and efforts gained from previous projects are leveraged and applied to future initiatives.

At the bottom of the model, two main contributions stand out: critical activity mapping and risk and uncertainty management. Critical activity mapping aims to identify and understand which actions are most relevant throughout the three stages of product development. For this purpose, the model considers the six critical factors described previously: technology, human resources, management, stakeholders, regulation, and market, allowing for the identification of essential activities within each group and guiding planning and execution. This mapping also strengthens the relationship with decision gates, as both complement each other in assessing progress and supporting informed decisions. Thus, the approach enables the identification and monitoring of bottlenecks and challenges throughout development and is also directly linked to risk and uncertainty management.

In this context, at the beginning of a project, uncertainties predominate, which, as more information is collected, transform into more concrete risks (Teece; Leih, 2016; Galli, 2017). This process highlights the need to identify and differentiate what

constitutes uncertainty or risk in a project. To address this, the study proposes an approach based on a comparison matrix, in which the previously identified critical factors are related to the types of risk (financial, schedule, quality, governance, technique, operational, market, regulatory, environmental and political), as defined by the Project Management Institute (PMI), (Hopkinson, 2006) and to the types of uncertainty (market, technical, resources and organizational), as categorized in the Learning Plan model (Rice; O'Connor; Pierantozzi, 2008).

After identification, the model proposes a continuous risk and uncertainty monitoring cycle, structured around four main actions performed periodically throughout development. These actions, inspired by the Learning Plan, include: i) identification and assessment of criticality; ii) testing of plans and alternatives; iii) execution of mitigation strategies; and iv) evaluation and learning. This practice broadens the coverage of identified risks and reduces human biases in the decision-making process, ensuring that risks and uncertainties are monitored and managed systematically, considering the specific characteristics of an *in vitro* product. Furthermore, the model includes a specific step focused on team commitment to effective risk management.

Finally, the model assumes that product development occurs within an ongoing relationship with various stakeholders, including academia, industry, suppliers, regulatory agencies, and healthcare professionals. This connection is essential, as it creates an innovation ecosystem in which product advancement depends not only on the internal team but also on interaction and collaboration with various external stakeholders. The active participation of these stakeholders, through partnerships with academic laboratories, hospitals, or research centers, helps overcome common barriers in healthcare product development, facilitates access to strategic resources and knowledge, and promotes more efficient integration of the NPD stages. This approach highlights that development success is not limited to the organization's internal capabilities but is also related to interactions established with the external environment.

Based on the above, it is important to emphasize that the proposed model followed the practice of hybridization, that is, the combination of two or more approaches to optimize the performance of the development process. This combination allows organizations to adjust methodologies according to their specific realities, promoting greater efficiency and alignment with their needs (Guérineau,

2024; Arandia; Garate; Mabe, 2023). Furthermore, the integration of already established elements, such as stage gates, facilitates communication between teams and process adaptation, as this is widely disseminated knowledge.

To verify the effectiveness of this proposal and its practical applicability, the model was evaluated by six experts and a focus group (n=12). These evaluations allowed the model design to be further tailored to the specificities of an *in vitro* product. Additionally, the adapted IAMDT was applied to the focus group to evaluate the model's applicability. The model achieved a score of 0.94, indicating a high level of acceptance (Appendix I). These results suggest that the proposed model is suitable for real-world implementation, supporting the verification of its benefits in the context of IVD product development.

### 4.1.5 Discussion

The findings identified during the data collection phase highlight aspects that reflect the barriers to IVD development and how these can be leveraged as inputs in an NPD model to mitigate such obstacles. Initially, the analysis of the mapped challenges revealed three main clusters: technical challenges, technological uncertainties, and operational validation. These results suggest that, in addition to the inherent difficulties of scientific and technological development, there is the further challenge of transforming technology into a viable product. This underscores that overcoming these challenges depends not only on technical expertise but, more importantly, on innovation management strategies (Garrido-Moreno; Martín-Rojas; García-Morales, 2024).

The observed challenges can be related to findings reported in the literature, such as in the study by Gbadegeshin *et al* (2022), which identified similar factors, including financial and market barriers, as well as the need for technical competencies, as potential causes of the "valley of death" for startups. This impact is particularly relevant, as this phenomenon tends to affect high-tech startups (predominantly represented in the data sample) more severely, especially those in the biological sciences.

On the other hand, when comparing the challenges identified in the scales with the terms associated with successful development, it is evident that elements cited as obstacles, technical challenges (technology, resources, suppliers), market

access, and regulatory compliance, also define NPD success. This indicates that success does not imply the absence of difficulties, but rather the ability to organize, manage, and mitigate existing obstacles. This finding aligns with Flessa and Huebner (2021), who emphasizes the importance of understanding the innovation process and adopting systematic management across all stages, as many projects fail precisely because they are unable to overcome the barriers they encounter.

By addressing NPD barriers, organizations also acquire knowledge on how to develop an IVD, resulting in a learning curve over the course of initial products. Analysis of this curve reinforces this perspective, as the identified terms reflect the overcoming of challenges, the consolidation of processes, and adaptation to the customer. However, although learning is fundamental, the interviewees did not report it as sufficient to guarantee NPD success.

However, in relation to the learning process, it is also acknowledged that companies' prior experience, combined with established technological development platforms, can significantly accelerate the development process (Rodriguez-Manzano *et al*., 2024). NPD models should ensure that lessons learned are systematically captured and documented, enabling continuous improvement and optimization of procedures. As observed during the COVID-19 pandemic, leveraging prior experience through these platforms allowed companies to streamline processes for new conditions (Kavruk *et al*., 2025). This integration highlights that a robust model, together with technological enablers and structured management, can substantially enhance efficiency, enabling faster and more reliable delivery of IVDs to the market.

The fact that the learning curve alone is not sufficient underscores the need for structured resources and systematic guidance to support companies' experience, facilitating decision-making and project monitoring. In this context, NPD models emerge as a viable alternative, helping organizations overcome the challenges inherent to IVD development. As reported in the literature, the use of a systematic framework can reduce development time and mitigate issues associated with rework, particularly in contexts characterized by high complexity and uncertainty (Florén *et al*., 2018).

In this regard, to propose a model capable of supporting both the overcoming of challenges and the learning curve, the developed model is directly aligned with the identified critical factors, clearly highlighting the aspects that need to be mitigated. For example, it encompasses data documentation and traceability, risk management

practices, provides regulatory guidelines to assist in overcoming compliance barriers, and indicates stakeholder engagement. Several other elements were also incorporated as maturity requirements, with particular emphasis on the critical factor most frequently mentioned by the interviewees: the structuring of the R&D team.

It is noteworthy that the developed risk management model adopts a comprehensive approach, particularly because it was observed that risk management was predominantly focused on regulatory stages rather than on continuous project monitoring in the companies evaluated. This highlights a limitation in the application of these practices, indicating the need to develop resources that facilitate the risk management process and clearly demonstrate its value and importance for development success.

Furthermore, the identification of stakeholders in IVD development is crucial, as it provides data to support the formation of a national ecosystem that fosters innovation in *in vitro* products, thereby increasing the availability of new devices to improve population quality of life. An example of this importance is a study describing a platform in Japan, which facilitated the development of 28 medical devices through collaborative efforts among academia, industry, and government (Ushimaru *et al*., 2025).

Thus, by identifying challenges, critical factors, stakeholders, and characteristics specific to IVDs within the developed model, the approach contributes to facilitating more accelerated development. In this context, recent studies by Cooper indicate that the pandemic has increased interest in accelerated development and highlighted factors that can promote it, such as improved team focus, an aspect also related to the primary critical factor identified in the present study. Consequently, research that supports accelerated innovation is particularly relevant, as this area is considered by Cooper to be a fertile field for academic investigation (Cooper, 2021).

### 4.1.6 Implications

The results of this study led to the development of an artifact, a model specifically designed to support the NPD of *in vitro* products. This model incorporates key dimensions for this type of product, including the specification of prototyping and clinical validation stages, an interactive cycle of experiments, context-specific

maturity requirements, guidance on applicable regulatory standards, and the integration of critical factors identified both in the literature and empirically. The application of DSR was fundamental in structuring and validating the model, ensuring scientific rigor and practical relevance, while also enabling the artifact to organize and systematize the key observed elements, aiming to increase the likelihood of success in IVD development and provide greater assurance throughout the process.

The model differs from those analyzed in the literature by having a specific focus on IVDs, an area still underexplored, and by integrating critical elements throughout the entire development cycle. It encompasses areas less addressed in other models, such as regulation, uncertainty management, and stakeholder engagement. Furthermore, the model was designed to be non-linear and intended to promote accelerated development, aligning with the demands of the medical device sector.

From a theoretical perspective, this study advances the debate on NPD by analyzing established models (Stage-Gate, DNA Model, Learning Plan, Development Funnel) and by integrating empirical evidence collected from professionals in the IVD industry. The research contributes a refined model that not only systematizes critical NPD factors in this context but also expands theory by adapting traditional approaches to a highly regulated and complex domain. In this way, the model engages with the literature while simultaneously addressing the practical needs of companies, constituting a strategic tool with practical contributions. Furthermore, it provides contributions to the literature on health innovation, medical product development, and complex project management, addressing a previously identified research gap due to the scarcity of materials focused on this area.

The study also contributes to the promotion of initiatives integrating universities, companies, and government, thereby strengthening the national medical device industry. Based on these findings, further research can be conducted, benefiting from the increased availability of resources for innovation management in the healthcare sector. Finally, considering the relevance of the IVD sector to public health, the model has the potential to impact early diagnosis, healthcare access, and responsible innovation, promoting technological advances with safety and regulatory compliance, contributing to the efficient development of medical devices and reinforcing public health.

### 4.1.7 Limitations and future research

Although this study provides valuable insights into IVD development, some limitations must be acknowledged. The number of interviews and case analyses was limited due to the inherent difficulty of accessing professionals and companies engaged in IVD innovation. In Brazil, the IVD industry is not yet highly consolidated, with relatively few companies dedicated to developing these technologies. Consequently, the perspectives captured may reflect mainly the practices of small and medium-sized enterprises, while larger or multinational companies with more advanced practices may not have been represented. Moreover, as the study focused exclusively on the Brazilian context, the findings may reflect specific regulatory, market, and institutional characteristics. It is worth noting, however, that the Brazilian Health Regulatory Agency (ANVISA) is widely recognized for its robust regulatory framework, which ensures the safety, efficacy, and quality of IVDs. This recognition reinforces the relevance of the study's findings within the national regulatory environment, even though it may introduce contextual limitations (ANVISA, 2020).

Despite these limitations, the proposed model provides a structured basis that can be expanded and refined. Future research could validate and enhance the model by applying it in different contexts and case studies, allowing for a broader assessment of its applicability and potential to support innovation in IVDs.

# 5 INTEGRATED DISCUSSION

The overall objective of this study was to propose a model that incorporates critical success factors and risk management practices to support the development of new products in the field of *in vitro* diagnostic technologies. To achieve this objective, the DSR (Design Science Research) method was adopted, enabling the integration of best practices identified in the literature with the development of an artifact applicable to real-world problem-solving. In this context, the developed artifact consisted of a model, understood as a set of propositions expressing relationships among constructs (March & Smith, 1995), serving as a structured representation capable of guiding and supporting decision-making.

Initially, a critical evaluation of NPD models for medical devices was conducted identifying gaps specific to the IVD sector. It was observed that most existing models focus on the development of medical devices in general, without addressing the technical, regulatory, and market-specific particularities of IVDs. This finding was obtained through a Systematic Literature Review, which also enabled the mapping and definition of six critical factors for IVD development: (i) human resources; (ii) technology; (iii) management; (iv) market; (v) stakeholders; and (vi) regulation. During this phase, the development stages were also determined, and a structured approach for risk management was proposed. This approach provided the basis for the conceptual-theoretical framework of the artifact, leading to the creation of its first version.

Subsequently, the data collection phase was conducted through interviews and questionnaires involving seven professionals from different companies in the IVD device sector. This stage presented considerable challenges, as the project focused on the national market, and many companies operating in this segment in Brazil primarily engage in product importation rather than local development. In total, more than 20 companies were contacted, but only six participated effectively.

Efforts were also made to include large multinational players, given their strategic relevance to the Brazilian IVD landscape and their influence on regulatory practices, technological trends, and supply chain dynamics. However, these companies proved difficult to access. Although their participation would have enriched the dataset by providing a broader perspective on global development practices adapted to the Brazilian context, the final sample still reflects professionals

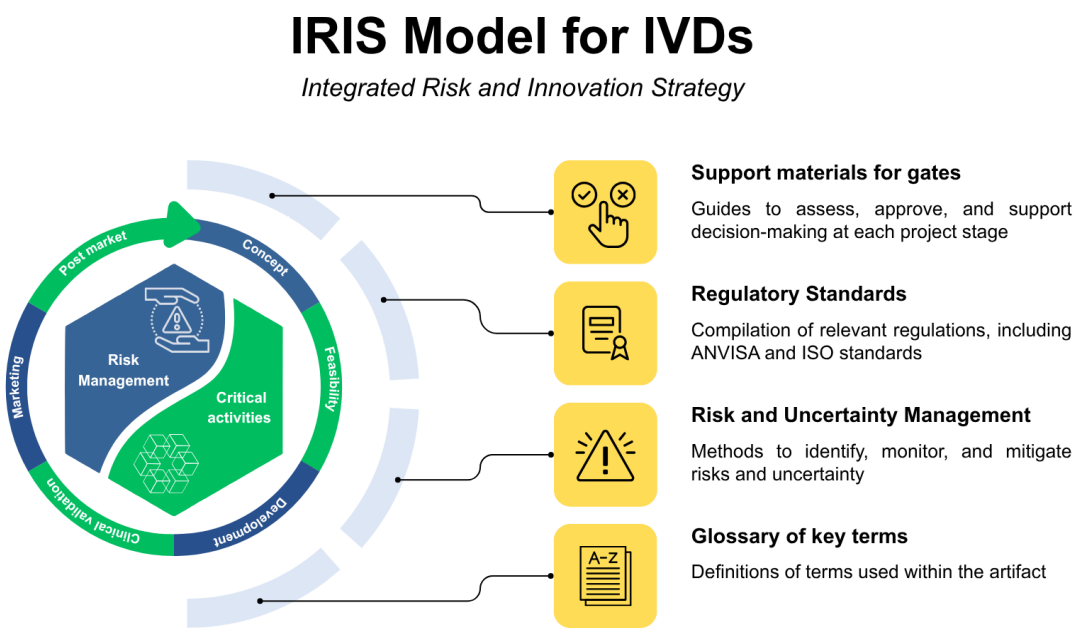
from companies that are active and experienced in the field of product development in health. Despite this, the data collection yielded substantial insights, enabling the identification of challenges and elements related to critical factors, thereby complementing the findings from the literature.

Based on the results of the literature review and the empirical analysis phase, the second version of the proposed model was developed using a hybridization approach, integrating elements from different models and perspectives in order to adapt them specifically for IVDs. This version of the model was evaluated through two fronts: (i) consultations with experts from various fields and (ii) a focus group discussion with employees from a company in the sector, which enabled refinements and verification of the artifact's practical applicability. Consequently, the third version of the model was elaborated with guidelines for identifying macro-stages in the NPD process for IVDs, integrating critical factors and managing risks and uncertainties, serving as a practical guide for companies in the *in vitro* diagnostics sector.

Following this consolidation, the final artifact (fourth version) was structured in a single document (Appendix O), containing: support materials for the determination of gates (project advancement points); references to regulatory standards; guidelines for risk and uncertainty management, whose approach was enhanced to more systematically address the identification; monitoring of uncertainties, and a glossary of key terms. It is still planned, in the future, to incorporate a critical activities matrix, as presented in the first article of the dissertation (section 3.1.4.4).

Based on this structure, the model was designated IRIS – Integrate Risk and Innovation Strategy, reflecting its purpose of aligning risk management with innovation strategies. Figure 8 presents the main elements considered in the model. In addition to representing a conceptual and academic contribution, IRIS was developed as a practical tool with application guidelines, allowing its adoption by companies and professionals in the sector. Consolidating the model into a functional artifact was an essential step, as it transforms theoretical principles into operational guidelines, enabling its effective use in real development processes.

Figure 8 - Structural Overview of the IRIS Model




Source: elaborated by the author (2025).

Furthermore, to understand the generalization of the class of problems addressed by the artifact, it is noteworthy that it was designed with a focus on the macro-stage development process and the specificities of an IVD. The model aims to address the lack of resources dedicated to this context, since developing an effective model requires considering and understanding the product's particularities. Accordingly, it can be applied for educational purposes, contributing to the training of professionals and students in innovation management, as well as promoting best practices in NPD and management within technological environments.

Another aspect related to the generalization of the model concerns its development within the regulatory scope of ANVISA. However, this does not represent a limitation to its applicability. ANVISA is internationally recognized for its regulatory rigor and alignment with global health authorities (ANVISA, 2020). As a result, companies from other countries can adopt the guidelines referenced in the artifact as a basis for structuring their development processes, even when operating under different jurisdictions. Furthermore, products approved by ANVISA may obtain facilitated recognition in other regulatory systems through mutual agreements, which reinforces the suitability of the proposed framework. Therefore, rather than restricting

generalization, the model's regulatory foundation strengthens its potential for adoption in diverse contexts.

Thus, this study's theoretical and practical contributions include offering an original perspective on a NPD model specifically for IVDs, consolidating best practices for successful development with a focus on critical factors and the management of risks and uncertainties. The proposed model not only reflects real challenges faced by companies, bridging theory and practice, but also provides a structured and functional tool capable of supporting accelerated development in this highly regulated sector. Additionally, these contributions have led to the preparation of two academic articles, further promoting scientific dissemination and reinforcing the study's impact on both research and practice, including its potential to improve healthcare outcomes through more efficient development of diagnostic technologies. To explicitly demonstrate how the dissertation's objectives were translated into results, Table 7 presents the alignment between each research objective and its corresponding contribution.

Table 7 – Theoretical and practical contributions of the dissertation

| Contribution field | Contribution | Dissertation objectives | Location in the dissertation |
|---|---|---|---|
| Theoretical | Integration of theoretical and empirical evidence for the development of an NPD model focused on IVD technologies | General objective and Specific objective C | Section 3.1.4 and 4.1.4.2 |
| | Application of the hybridization approach (theoretical and empirical) for the development of an integrative model that incorporates Critical Success Factors and risk management | General objective and specific objective C | Section 4.1.4.3 |
| | Identification of six critical areas that influence the success of IVD development (human resources, management, technology, market, stakeholders, and regulation) | Specific objective B | Section 3.1.4.2 |
| | Analytical categorization of the stages of the IVD development cycle | Specific objective B | Section 3.1.4.1 |
| | Expanded understanding of the regulatory, technological, and organizational specificities of the medical device sector | Specific objectives A and B | Section 3.1.4 |

| | | | |
|---|---|---|---|
| | Theoretical synthesis of the main barriers, challenges, and facilitators for medical device innovation | Specific objectives A and B | Section 3.1 |
| | Application of the DSR method in a healthcare innovation context still underexplored in Brazil, demonstrating its suitability for the development of applied models | General objective and Specific objective C | Section 2.2.1 and 2.2.2 |
| | Production of scientific materials aimed at disseminating knowledge on healthcare development and innovation | General objective | Section 3.1 and 4.1 |
| | Contribution to the development of resources specifically geared towards the healthcare sector | General objective | Section 4.1 and Appendix O |
| Practical | Development of a model structured in macro-steps, focused on the development process of *in vitro* diagnostic technologies | General objective and Specific objective C | Section 4.1.4.3 |
| | Development of a practical guide for applying the proposed model, offering operational guidance for organizations | General objective and Specific objective C | Appendix O |
| | Mapping of the main stakeholders involved in the healthcare innovation ecosystem | General objective and Specific objective C | Section 4.1.4.2 |
| | Identification of critical factors observed in Brazilian companies, providing support for improving management practices based on the identified challenges | Specific objective B | Section 4.1.4.2 |
| | Proposal of guidelines for mitigating risks and uncertainties throughout the different phases of the IVD development cycle | Specific objective C | Section 4.1.4.2 and Appendix O |

Source: elaborated by the author (2025).

This alignment shows how the research objectives were translated into concrete results, supporting the development of a practical and applicable model. In summary, the IRIS model advances the discussion on product development for IVDs by proposing a solution that is not only theoretically consistent but also compatible with the real world. Its strength lies in providing a structured yet adaptable framework to guide more systematic and evidence-based decision-making, helping to reduce the gap between early development and market access. Thus, it serves not only as a

reference for NPD practices but also as a catalyst for innovation processes, fostering the development and adoption of new ways of innovating in Brazil, maturely and safely within the diagnostic technology sector.

# 6 FINAL CONSIDERATIONS

The advancement of health technologies, particularly in diagnostics, plays a crucial role in expanding access to early detection, strengthening surveillance control, improving clinical decision-making, and ultimately reducing healthcare costs. However, innovation in this field only becomes truly meaningful when it translates into real availability for patients. In this regard, the model developed in this dissertation serves as an instrument to support faster and safer development of new IVDs. Its value lies not only in organizing internal processes but also in helping to bridge the gap in studies on NPD within this context, thereby facilitating the arrival of innovations to the population.

As a limitation, it is worth noting that the study focused on the national context, which may introduce bias due to the exclusive participation of Brazilian companies. The small number of interviewees and the predominance of startups and small enterprises may also affect the generalizability of the findings, as larger or multinational companies, often adopting more mature development models, were not represented due to difficulties in establishing contact. Furthermore, the artifact may not yet encompass all specific requirements of IVDs, reflecting both the limited availability of specialized firms and the scarcity of consolidated literature in this domain.

Nevertheless, these limitations create promising opportunities for future research. Expanding the investigation to include not only professionals involved in IVD development but also those engaged in adoption and use, such as healthcare practitioners, laboratory managers, and even end users, could deepen the understanding of real-world implementation challenges. Practical application of the model in development projects would enable the assessment of its feasibility, adaptability, and actual impact on process efficiency. Additionally, engaging with larger or multinational companies could enable benchmarking of practices and comparison across different maturity levels and strategic approaches to product development. Moreover, continuous refinement of the artifact is essential, incorporating new tools, validation metrics, and user feedback to ensure that the model evolves and continues to meet the needs of companies.

Based on the results and discussion presented throughout this dissertation, the central outcome was the developed model, which stands out for both its

theoretical contribution and its practical relevance to public health. It offers a structured tool for companies in the sector, supporting innovation in technological environments and contributing to the development of IVDs that can positively impact health. By facilitating the creation of more efficient, safe, and accessible diagnostic products, the model directly contributes to improving the population's quality of life, promoting progress in early disease detection and comprehensive healthcare.

## REFERENCES

ABERNETHY, A. *et al.* The Promise of Digital Health: Then, Now, and the Future. **NAM Perspectives**, [*s. l.*], v. 6, n. 22, 2022.

ABPMP (2013). CBOK v3.0 – **Guide to the Business Process Management Common Body of Knowledge**. 3. ed. Indiana: Association of Business Process Management Professionals. Available at: www.abpmp.org.

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (ANVISA). **Manual para regularização de equipamentos médicos na ANVISA**. Brasília, DF: ANVISA, 2021. Available at: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/produtos-para-a-saude/manuais/manual-para-regularizacao-de-equipamentos-medicos-na-anvisa.pdf.

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. **Biblioteca de Produtos para a Saúde. Brasília: Coordenação de Processos Regulatórios – CPROR**; Assessoria de Melhoria da Qualidade Regulatória – ASREG; Gabinete do Diretor-Presidente, 2025. Available at: <https://anvisalegis.datalegis.net/action/ActionDatalegis.php?acao=recuperarTematicasCollapse&cod_modulo=135&cod_menu=8453>. Access at: 19 Aug. 2025.

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (ANVISA). Cooperação Internacional. Brasília, 21 set. 2020. Updated on October 3, 2025. Avaliable at: https://www.gov.br/anvisa/pt-br/assuntos/relacoes-internacionais/cooperacao. Access at: 15 Out. 2025.

ALAGUMALAI, Vijayarajan; KADAMBI, Pooja; APPAJI, Abhishek. Interdisciplinarity in New Product Development in an Indian MedTech Perspective: Gap and the Solution. **Health and Technology**, [*s. l.*], v. 9, n. 5, p. 817–827, 2019.

ALEXANDRE, Neusa Maria Costa; COLUCI, Marina Zambon Orpinelli. Validade de conteúdo nos processos de construção e adaptação de instrumentos de medidas. **Ciência & Saúde Coletiva**, [*s. l.*], v. 16, n. 7, p. 3061–3068, 2011.

ALLEN, James Albert. **Scientific Innovation and Industrial Prosperity**. 1ºed. [*S. l.*]: Elsevier, 1967.

AMARAL, Carolina et al. Global Regulatory Challenges for Medical Devices: Impact on Innovation and Market Access. **Applied Sciences**, [s. l.], v. 14, n. 20, p. 9304, 2024.

AMIR-ASLANI, Arsia; NEGASSI, Syoum. Is technology integration the solution to biotechnology's low research and development productivity? **Technovation**, [*s. l.*], v. 26, n. 5–6, p. 573–582, 2006.

ARANDIA, Nerea; GARATE, Jose Ignacio; MABE, Jon. Medical Devices with Embedded Sensor Systems: Design and Development Methodology for Start-Ups. **Sensors**, [*s. l.*], v. 23, n. 5, p. 1–30, 2023.

ARENA, Marika; ARNABOLDI, Michela. Risk and performance management: are they easy partners?. **Management Research Review**, [*s. l.*], v. 37, n. 2, p. 152–166, 2014.

ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS. **ABNT NBR ISO 14971: Dispositivos médicos – Aplicação da gestão de risco a dispositivos médicos.** Rio de Janeiro, 2009.

ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS. **ABNT NBR ISO 31000: Gestão de riscos – Diretrizes.** Rio de Janeiro, 2009

BABU, Dr Koppala Ravi. Challenges faced by healthcare start-ups. **Archives of Business Research**, [*s. l.*], v. 9, n. 8, 2021.

BAGNO, Raoni Barros; SALERNO, Mario Sergio; DA SILVA, Débora Oliveira. Models with graphical representation for innovation management: a literature review. **R&D Management**, [*s. l.*], v. 47, n. 4, p. 637–653, 2017.

BAGNO, Raoni Barros; SALERNO, Mario Sergio; DA SILVA, Débora Oliveira. Models with graphical representation for innovation management: a literature review. **R&D Management**, [*s. l.*], v. 47, n. 4, p. 637–653, 2017.

BARKAOUI, Houssem *et al.* Multi-Criteria Decision Making for Medical Device Development. **EMJ - Engineering Management Journal**, [*s. l.*], v. 35, n. 2, p. 102–119, 2023.

BARNES, D. Research methods for the empirical investigation of the process of formation of operations strategy. **International Journal of Operations & Production Management**, [*s. l.*], v. 21, n. 8, p. 1076–1095, 2001.

BARRATT, M.; CHOI, T. Y.; LI, M. Qualitative case studies in operations management: Trends, research outcomes, and future research implications. **Journal of Operations Management**, [*s. l.*], v. 29, n. 4, p. 329–342, 2011.

BAYLOR, Norman W. **Regulatory Approval and Compliances for Biotechnology Products**. [*S. l.*]: Elsevier, 2014.

BERGSLAND, J.; ELLE, O. J.; FOSSE, E. Barriers to medical device innovation. **Medical Devices: Evidence and Research**, [*s. l.*], p. 205, 2014.

BERS, John A. *et al.* Extending the Stage-Gate Model to Radical Innovation - the Accelerated Radical Innovation Model. **Journal of the Knowledge Economy**, [*s. l.*], v. 5, n. 4, p. 706–734, 2014.

BERWICK, Donald M. Disseminating Innovations in Health Care. **JAMA**, [*s. l.*], v. 289, n. 15, p. 1969, 2003.

BIANCHI, Mattia; MARZI, Giacomo; GUERINI, Massimiliano. Agile, Stage-Gate and their combination: Exploring how they relate to performance in software development. **Journal of Business Research**, [*s. l.*], v. 110, p. 538–553, 2020.

BRASIL. Agência Nacional de Vigilância Sanitária (ANVISA). **Resolução RDC nº 36,** de 25 de julho de 2015. Dispõe sobre medidas de prevenção e controle de infecções relacionadas à assistência à saúde. Diário Oficial da União: seção 1, Brasília, DF, n. 141, p. 43-44, 26 jul. 2015.

BRASIL. **Classificação de produtos para Diagnóstico *in vitro***. [*S. l.*], 2020. Available at: https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/produtos-para-saude/conceitos-e-definicoes/classificacao-diagnostico-in-vitro. Access at: 10 jan 10. 2025.

BRASIL. **Conselho Nacional de Saúde. Resolução no 588, de 12 de julho de 2018. Institui a Política Nacional de Vigilância em Saúde (PNVS).** Diário Oficial da União: Seção 1, Brasília, DF, p. 87, 13 ago. 2018. Available at: https://www.gov.br/saude/pt-br/composicao/svsa/pnvs. Access at: 20 jun. 2025.

BRASIL. **Ministério da Saúde. Política Nacional de Ciência, Tecnologia e Inovação em Saúde** [recurso eletrônico]. Brasília: Ministério da Saúde, 2009. Available at: https://bvsms.saude.gov.br/bvs/publicacoes/Politica_Portugues.pdf. Access at: 20 jun. 2025.

BRASIL. **Testes rápidos no SUS permitem diagnósticos em até 30 minutos**. [*S. l.*], 2022. Available at: https://www.gov.br/pt-br/noticias/saude-e-vigilancia-sanitaria/2022/10/testes-rapidos-no-sus-permitem-diagnosticos-em-ate-30-minutos. Access at: 17 feb. 2025.

BRASIL. **Estratégia Nacional para o Desenvolvimento do Complexo Econômico-Industrial da Saúde (CEIS)**. Brasília, DF: Presidência da República, 2023. Available at: https://www.gov.br/saude/pt-br/assuntos/noticias/2023/setembro/governo-federal-lanca-estrategia-nacional-para-o-desenvolvimento-do-complexo-economico-industrial-da-saude-com-investimento-de-r-42-bilhoes-ate-2026.

BROOKS, Steven S. Regulation and Device Development: Tips for Optimizing Your Experience With the Food and Drug Administration. **Techniques in Vascular and Interventional Radiology**, [*s. l.*], v. 20, n. 2, p. 109–115, 2017.

BROWNE, Ikennah L.; SUTTON, Andrew J.; ZHANG, Wei. Perceptions and Attitudes Regarding Medical Device Development in Canada Among Canadian Innovators: A Qualitative Study. **PharmacoEconomics - Open**, [*s. l.*], v. 7, n. 5, p. 793–809, 2023.

BRYANT, Antony; CHARMAZ, Kathy. **The SAGE Handbook of Grounded Theory**. [*S. l.*]: SAGE Publications Ltd, 2007.

BURNARD, K. J. Developing a robust case study protocol. **Management Research Review**, [*s. l.*], v. 47, n. 2, p. 204–225, 2024.

BUSCH, Erik *et al.* Optimizing the innovation and development process of medical devices - a study based on angiographic equipment. **Health and Technology**, [*s. l.*], v. 11, n. 3, p. 563–574, 2021.

BYRNE, Mark. **The Development and Commercialization of Medical Devices**. [*S. l.*]: INC, 2020.

CÂMARA BRASILEIRA DE DIAGNÓSTICO LABORATORIAL (CBDL). Laboratory Diagnostics White Book 2021. [Internet]. [*s. l.*], 2022.

CARLS, Tommy. **The growing role of clinical Influencers in product development. Healthcare Business Today**, s.l., 3 jun. 2023. Available at: <https://www.healthcarebusinesstoday.com/the-growing-role-of-clinical-influencers-in-product-development/?utm_source=chatgpt.com>. Access at: 19 Aug. 2025.

CARVALHO, J. V.; ROCHA, Á.; ABREU, A. Maturity Models of Healthcare Information Systems and Technologies: a Literature Review. **Journal of Medical Systems**, [*s. l.*], v. 40, n. 6, p. 1–10, 2016.

CAUCHICK-MIGUEL, P. A. Estudo de caso na engenharia de produção: estruturação e recomendações para sua condução. **Production**, [*s. l.*], v. 17, n. 1, p. 216–229, 2007.

CHAISIRIN, Wansiri *et al.* Role of Point-of-Care Testing in Reducing Time to Treatment Decision-Making in Urgency Patients: A Randomized Controlled Trial. **Western Journal of Emergency Medicine**, [*s. l.*], v. 21, n. 2, p. 404–410, 2020.

CHAKRAVARTY, S. Resource constrained innovation in a technology intensive sector: Frugal medical devices from manufacturing firms in South Africa. **Technovation**, [*s. l.*], v. 112, n. October 2021, p. 102397, 2022.

CHATTERJEE, S. *et al.* The consequences of innovation failure: An innovation capabilities and dynamic capabilities perspective. **Technovation**, [*s. l.*], v. 128, n. July, p. 102858, 2023.

CHETTRI, Bijaya; RAVI, Ramya. A comparative study of medical device regulation between countries based on their economies. **Expert Review of Medical Devices**, [*s. l.*], v. 21, n. 6, p. 467–478, 2024.

CHIKU, Charles et al. Navigating regulatory landscape: A qualitative exploration of medical devices and in vitro diagnostic medical devices oversight in Zimbabwe

through key stakeholder perspectives. **PLOS ONE**, [s. l.], v. 19, n. 5, p. e0287415, 2024.

COOPER, R. G. Expected Commercial Value for New-Product Project Valuation When High Uncertainty Exists. **IEEE Engineering Management Review**, [*s. l.*], v. 51, n. 2, p. 75–87, 2023.

COOPER, Robert G.; EDGETT, Scott J.; KLEINSCHMIDT, Elko J. Optimizing the Stage-Gate Process: What Best-Practice Companies Do—II. **Research-Technology Management**, [*s. l.*], v. 45, n. 6, p. 43–49, 2002.

COOPER, Robert G.; SOMMER, Anita F. The Agile–Stage‐Gate Hybrid Model: A Promising New Approach and a New Research Opportunity. **Journal of Product Innovation Management**, [*s. l.*], v. 33, n. 5, p. 513–526, 2016.

COOPER, Robert G. Accelerating innovation: Some lessons from the pandemic. **Journal of Product Innovation Management**, [*s. l.*], v. 38, n. 2, p. 221–232, 2021.

COOPER, Robert G. Perspective: The Stage-Gate. [*s. l.*], p. 213–232, 2008.

COOPER, Robert G. The Stage-Gate® Product Innovation System: from Idea to Launch. *In*: WILEY ENCYCLOPEDIA OF MANAGEMENT. [*S. l.*]: Wiley, 2015. p. 1–13.

COOPER, Robert G. **Winning At New Products: Accelerating The Process From Idea To Launch, Second Edition**. 2ªed. [*S. l.*]: Basic Books, 1993.

DAS, S.; DUNBAR, S. The COVID-19 Pandemic – A Diagnostic Industry Perspective. **Frontiers in Cellular and Infection Microbiology**, [*s. l.*], v. 12, n. March, p. 1–5, 2022.

DA SILVA, Débora Oliveira. **PROPOSTA PARA ANÁLISE DA GESTÃO DA INOVAÇÃO EM SERVIÇOS HOSPITALARES: UM ESTUDO NO HOSPITAL MÃE DE DEUS – PORTO ALEGRE, RS**. 2011. - Universidade do Vale do Rio dos Sinos (UNISINOS), [*s. l.*], 2011.

DAVID, Y.; JUDD, T. Evidence-based impact by clinical engineers on global patients outcomes. **Health and Technology**, [*s. l.*], v. 10, n. 2, p. 517–535, 2020.

DE CARVALHO, Marly Monteiro; RABECHINI JUNIOR, Roque. Impact of risk management on project performance: The importance of soft skills. **International Journal of Production Research**, [*s. l.*], v. 53, n. 2, p. 321–340, 2015.

DEGERLI, Mustafa; OZKAN YILDIRIM, Sevgi. Identifying critical success factors for wearable medical devices: a comprehensive exploration. **Universal Access in the Information Society**, [s. l.], v. 21, n. 1, p. 121–143, 2022.

DE LA TORRE, K. *et al.* The Application of Preventive Medicine in the Future Digital Health Era. **Journal of Medical Internet Research**, [*s. l.*], v. 27, p. e59165, 2025.

DE SOUZA NETO, Rômulo Andrade *et al.* Effects of Qualitative Data Analysis Softwares in the Quality of Researches. **Revista de Administracao Contemporanea**, [*s. l.*], v. 23, n. 3, p. 373–394, 2019.

DOCHERTY, M. Primer on 'Open Innovation': Principles and Practice. **Vision**, [*s. l.*], v. XXX, n. 2, p. 13–17, 2006.

DRESCH, Aline; LACERDA, Daniel; ANTUNES, José Antonio Valle Júnior. **Design Science Research: Método de Pesquisa para Avanço da Ciência e Tecnologia**. 1ºed. [*S. l.*]: Bookman, 2015.

DUBÉ, L.; PARÉ, G. Rigor in Information System Positivist Case Research. **MIS Quarterly**, [*s. l.*], v. 27, n. 4, p. 597–635, 2003.

DURFEE, William K.; IAIZZO, Paul A. **The medical device innovation process**. [*S. l.*]: Elsevier Inc., 2019.

DUTTA, Neelarnab; DHAR, Debayan. **Understanding Medical Technology Innovation in Low- and Middle-Income Countries: Factors, Impact, and a Model Proposal**. [*S. l.*]: Elsevier, 2024-. ISSN 24058718.v. 10

EISENHARDT, K. M. Agency Theory : An Assessment and Review Linked references are available on JSTOR. **Agency Theory : An Assessment and Review**, [*s. l.*], v. 14(1), n. 1, p. 57–74, 1989.

ELDAR, Reuben. Health technology: Challenge to public health. **Croatian Medical Journal**, [*s. l.*], v. 43, n. 4, p. 470–474, 2002.

ENG, T. R. Population health technologies: Emerging innovations for the health of the public. **American Journal of Preventive Medicine**, [*s. l.*], v. 26, n. 3, p. 237–242, 2004.

ERMEL, Ana Paula Cardoso; LACERDA, Daniel Pacheco; MORANDI, MARIA ISABEL W GAUSS, Leandro. **Revisões da literatura: um método para a geração de conhecimento científico e tecnológico**. 1ªed. [*S. l.*]: Folio Digital, 2022.

ERNST, H. Success Factors of New Product Development: A Review of the Empirical Literature. **International Journal of Management Reviews**, [*s. l.*], v. 4, n. 1, p. 1–40, 2002.

FALAHAT, Mohammad; CHONG, Shyue Chuan; LIEW, Cindy. Navigating new product development: Uncovering factors and overcoming challenges for success. **Heliyon**, [*s. l.*], v. 10, n. 1, p. e23763, 2024.

FDA. ***In Vitro*** **Diagnostics**. [*S. l.*], 2024. Available at: https://www.fda.gov/medical-devices/products-and-medical-procedures/in-vitro-diagnostics. Access at: 17 feb. 2025.

FEARIS, Kristy; PETRIE, Aidan. Best practices in early phase medical device development: Engineering, prototyping, and the beginnings of a quality management system. **Surgery (United States)**, [*s. l.*], v. 161, n. 3, p. 571–575, 2017.

FELDMAN, Maryann P. **The Geography of Innovation**. Dordrecht: Springer Netherlands, 1994. (Economics of Science, Technology and Innovation). v. 2

FERREIRA DE ARAÚJO LIMA, Priscila; MARCELINO-SADABA, Sara; VERBANO, Chiara. Successful implementation of project risk management in small and medium enterprises: a cross-case analysis. **International Journal of Managing Projects in Business**, [*s. l.*], v. 14, n. 4, p. 1023–1045, 2021.

FERRUSI, I. L. *et al.* Health Technology Assessment From a Canadian Device Industry Perspective. **Journal of the American College of Radiology**, [*s. l.*], v. 6, n. 5, p. 353–359, 2009.

FIGUEIREDO, Paulo Soares; LOIOLA, Elisabeth. Enhancing new product development (NPD) portfolio performance by shaping the development funnel. **Journal of Technology Management and Innovation**, [*s. l.*], v. 7, n. 4, p. 20–35, 2012.

FINK, Matthias; AKRA, Bassil. Comparison of the international regulations for medical devices–USA versus Europe. **Injury**, [*s. l.*], v. 54, p. 110908, 2023.

FIRDAUSI, Novandina Izzatillah. The Influence of the COVID-19 Pandemic on Technology. **Kaos GL Dergisi**, [*s. l.*], v. 8, n. 75, p. 147–154, 2020.

FLESSA, Steffen; HUEBNER, Claudia. Innovations in Health Care—A Conceptual Framework. **International Journal of Environmental Research and Public Health**, [*s. l.*], v. 18, n. 19, p. 10026, 2021.

FLORÉN, Henrik et al. Critical success factors in early new product development: a review and a conceptual model. **International Entrepreneurship and Management Journal**, [s. l.], v. 14, n. 2, p. 411–427, 2018.

FONTAINE, Mike. Project Risk Management. *In*: ENTERPRISE RISK MANAGEMENT: A COMMON FRAMEWORK FOR THE ENTIRE ORGANIZATION. [*S. l.*]: Elsevier, 2016.

FOO, Jong Yong Abdiel; TAN, Xin Ji Alan. Limited Awareness of the Essences of Certification or Compliance Markings on Medical Devices. **Science and Engineering Ethics**, [*s. l.*], v. 23, n. 3, p. 653–661, 2017.

FOX, Nick J. Personal health technologies, micropolitics and resistance: A new materialist analysis. **Health (United Kingdom)**, [*s. l.*], v. 21, n. 2, p. 136–153, 2017.

FRANZ, Colin K. *et al.* Impact of traumatic brain injury on amyotrophic lateral sclerosis: From bedside to bench. **Journal of Neurophysiology**, [*s. l.*], v. 122, n. 3, p. 1174–1185, 2019.

FRIEBE, M. H. *et al.* The PLH - Purpose Launchpad Health - Meta-Methodology to Explore Problems and Evaluate Solutions for Biomedical Engineering Impact Creation. **Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS**, [*s. l.*], v. 2022-July, p. 3299–3302, 2022.

GAGLIARDI, Anna R. *et al.* Factors influencing the reporting of adverse medical device events: Qualitative interviews with physicians about higher risk implantable devices. **BMJ Quality and Safety**, [*s. l.*], v. 27, n. 3, p. 190–198, 2018.

GALLI, Brian J. The Effective Approach of Managing Risk in New Product Development (NPD). **International Journal of Applied Management Sciences and Engineering**, [*s. l.*], v. 4, n. 2, p. 27–40, 2017.

GARRIDO-MORENO, Aurora; MARTÍN-ROJAS, Rodrigo; GARCÍA-MORALES, Víctor J. The key role of innovation and organizational resilience in improving business performance: A mixed-methods approach. **International Journal of Information Management**, [*s. l.*], v. 77, p. 102777, 2024.

GBADEGESHIN, Saheed A. *et al.* Overcoming the Valley of Death: A New Model for High Technology Startups. **Sustainable Futures**, [*s. l.*], v. 4, p. 100077, 2022.

GIL, A. C. **Como Elaborar Projetos de Pesquisa**. 6ªed. [*S. l.*]: Atlas, 2017.

GIRLING, Alan *et al.* Early-stage valuation of medical devices: the role of developmental uncertainty. **Value in Health**, [*s. l.*], v. 13, n. 5, p. 585–591, 2010.

GLASER, Barney G.; STRAUSS, Anselm L. **The Discovery of Grounded Theory**. [*S. l.*]: Routledge, 2017.

GOECKS, Lucas Schmidt et al. Design Science Research in practice: review of applications in Industrial Engineering. **Gestão & Produção**, [s. l.], v. 28, n. 4, 2021.

GOFFIN, Keith; MITCHELL, Rick. **Innovation Management: Strategy And Implementation Using The Pentathlon Framework**. 1ªed. [*S. l.*]: Palgrave Macmillan, 2005.

GOLDENBERG, Seth J.; GRAVAGNA, Jeff. A real-world perspective: Building and executing an integrated customer engagement roadmap that bridges the gaps in

traditional medical device development processes. **Journal of Medical Marketing**, [*s. l.*], v. 16, n. 2, p. 41–49, 2017.

GRANT, Joan S.; DAVIS, Linda L. Selection and use of content experts for instrument development. **Research in Nursing & Health**, [*s. l.*], v. 20, n. 3, p. 269–274, 1997.

GRAZIADIO, Sara *et al.* How to ease the pain of taking a diagnostic point of care test to the market: A framework for evidence development. **Micromachines**, [*s. l.*], v. 11, n. 3, 2020.

GUÉRINEAU, Julia. Organizing the fragmented landscape of multidisciplinary product development: a mapping of approaches, processes, methods and tools from the scientific literature. [*s. l.*], n. August, p. 12–14, 2024.

HANSEN, Morten T.; BIRKINSHAW, Julian. The innovation value chain. **Harvard Business Review**, [*s. l.*], v. 85, n. 6, p. 1–9, 2007.

HARKIN, Kathleen R.; SORENSEN, Jan; THOMAS, Steve. Lifecycle evaluation of medical devices: supporting or jeopardizing patient outcomes? A comparative analysis of evaluation models. **International Journal of Technology Assessment in Health Care**, [*s. l.*], v. 40, n. 1, 2024.

HARPALDAS, Harshit *et al.* Point-of-care diagnostics: recent developments in a pandemic age. **Lab on a Chip**, [*s. l.*], v. 21, n. 23, p. 4517–4548, 2021.

HOKKANEN, Laura; LEPPÄNEN, Marko. Three patterns for user involvement in startups. **ACM International Conference Proceeding Series**, [*s. l.*], v. 08-12-July, p. 1–8, 2015.

HOOD, Colin; WIEDEMANN, Simon; FICHTINGER, Stefan; PAUTZ, Urte. Requirements Management: The Interface Between Requirements Development and All Other Systems Engineering Processes. Berlin; Heidelberg: **Springer-Verlag**, 2008. DOI: 10.1007/978-3-540-68476-3.

HOPKINSON, M. **Categorizing risks for effective project risk management.** *Project Management Institute (PMI)*, 2006. Available at: https://www.pmi.org/learning/library/categorizing-risks-project-risk-management-684 Access at: 30 January, 2025.

HOVELING, Tamara *et al.* Circular economy for medical devices: Barriers, opportunities and best practices from a design perspective. **Resources, Conservation and Recycling**, [*s. l.*], v. 208, p. 107719, 2024.

HULETT, D. T. (1996). **Schedule risk analysis simplified**. PM Network, 10(7), 23–30.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. ISO 9000:2015 – **Quality management systems — Fundamentals and vocabulary**. Geneva: ISO, 2015.

JAVANMARDI, Ehsan *et al.* Exploring business models for managing uncertainty in healthcare, medical devices, and biotechnology industries. **Heliyon**, [*s. l.*], v. 10, n. 4, p. e25962, 2024.

KAGAN, Evgeny; LEIDER, Stephen; LOVEJOY, William S. Ideation–Execution Transition in Product Development: An Experimental Analysis. **Management Science**, [*s. l.*], v. 64, n. 5, p. 2238–2262, 2018.

KALINOWSKA-BESZCZYŃSKA, Olga; PRĘDKIEWICZ, Katarzyna. MedTech start-ups: A comprehensive scoping review of current research trends and future directions. **PLoS ONE**, [*s. l.*], v. 19, n. 8 August, p. 1–24, 2024.

KAVRUK, Murat *et al.* Biotechnological Preparedness for Novel Pandemics: Diagnostic Performance of IVDS Against SARS‐CoV‐2. **MicrobiologyOpen**, [*s. l.*], v. 14, n. 4, 2025.

KHAN, Aliya A. *et al.* An Enhanced Agile V-Model: Conformance to regulatory bodies and experiences from model's adoption to medical device development. **Heliyon**, [*s. l.*], v. 10, n. 6, p. e26928, 2024.

KHEIR, Omar; JACOBY, Alexis; VERWULGEN, Stijn. Risk Identification and Analysis in the Development of Medical Devices Among Start-Ups: Towards a Broader Risk Management Framework. **Medical Devices: Evidence and Research**, [*s. l.*], v. 15, n. August, p. 349–363, 2022.

KIM, Y.-H.; PARK, S.-W.; SAWNG, Y.-W. Improving new product development (NPD) process by analyzing failure cases. **Asia Pacific Journal of Innovation and Entrepreneurship**, [*s. l.*], v. 10, n. 1, p. 134–150, 2016.

KIMURA, H.; ASANO, R. Strategies to simplify operation procedures for applying labeled antibody-based immunosensors to point-of-care testing. **Analytical Biochemistry**, [*s. l.*], v. 654, n. February, p. 114806, 2022.

KIRKIRE, Milind Shrikant; RANE, Santosh B.; ABHYANKAR, Gayatri Jayant. Structural equation modelling – FTOPSIS approach for modelling barriers to product development in medical device manufacturing industries. **Journal of Modelling in Management**, [*s. l.*], v. 15, n. 3, p. 967–993, 2020.

KNUDSEN, Mette Praest *et al.* Best practices in new product development and innovation: Results from PDMA's 2021 global survey. **Journal of Product Innovation Management**, [*s. l.*], v. 40, n. 3, p. 257–275, 2023.

KORLEY, Frederick K. *et al.* Emergency Department Evaluation of Traumatic Brain Injury in the United States, 2009–2010. **Journal of Head Trauma Rehabilitation**, [*s. l.*], v. 31, n. 6, p. 379–387, 2016.

KRUACHOTTIKUL, Pravee *et al.* MediGate: a MedTech product innovation development process from university research to successful commercialization within emerging markets. **Journal of Innovation and Entrepreneurship**, [*s. l.*], v. 13, n. 1, p. 71, 2024.

KRUACHOTTIKUL, Pravee *et al.* New product development process and case studies for deep-tech academic research to commercialization. **Journal of Innovation and Entrepreneurship**, [*s. l.*], v. 12, n. 1, p. 1–26, 2023.

LAGUMALAI, Vijayarajan; KADAMBI, Pooja; APPAJI, Abhishek. Interdisciplinarity in New Product Development in an Indian MedTech Perspective: Gap and the Solution. **Health and Technology**, [s. l.], v. 9, n. 5, p. 817–827, 2019.

LEE, Munjae; PARK, Sewon; LEE, Kyu Sung. What are the features of successful medical device start-ups? Evidence from KOREA. **Sustainability (Switzerland)**, [*s. l.*], v. 11, n. 7, p. 1–17, 2019.

LEE, Munjae *et al.* Innovative distribution priorities for the medical devices industry in the fourth industrial revolution. **International Neurourology Journal**, [*s. l.*], v. 22, n. Suppl 2, p. S83–S90, 2018.

LI, Chen-zhong. Special Topic: Point-of-Care Testing (POCT) and In Vitro Diagnostics (IVDs). **Journal of Analysis and Testing**, [*s. l.*], v. 3, n. 1, p. 1–2, 2019.

LIMA; OLIVEIRA; COELHO. **Regulação e Regulamentação na Perspectiva da Contabilidad**e. In: CONGRESSO USP DE CONTROLADORIA E CONTABILIDADE, 14., 2014, São Paulo. Anais... São Paulo: FIPECAFI, 2014. Available at: <https://congressousp.fipecafi.org/anais/artigos142014/156.pdf>. Access at: 19 Aug. 2025.

LISTER, C. *et al.* The public health innovation model: Merging private sector processes with public health strengths. **Frontiers in Public Health**, [*s. l.*], v. 5, n. AUG, p. 1–9, 2017.

LITTEL, J. **Systematic Reviews and Meta-Analysis (Pocket Guides to Social Work Research Methods)**. 1ªed. [*S. l.*]: Oxford University Press, 2008.

LOBATO, Kelly C.D. *et al.* Good practices systematization for medical equipment development and certification process: A Brazilian case study. **Health Policy and Technology**, [*s. l.*], v. 8, n. 3, p. 268–277, 2019.

MACCORMACK, Alan; VERGANTI, Roberto. Managing the Sources of Uncertainty: Matching Process and Context in Software Development. **Journal of Product Innovation Management**, [*s. l.*], v. 20, n. 3, p. 217–232, 2003.

MAHARA, G. *et al.* Revolutionising health care: Exploring the latest advances in medical sciences. **Journal of Global Health**, [*s. l.*], v. 13, p. 1–8, 2023.

MALLET, Lethícia; SALERNO, Mario Sergio. Managing ambidexterity tensions in transferring innovation projects to mainstream units. **European Journal of Innovation Management**, [*s. l.*], 2025.

MANETTI, S.; LETTIERI, E.; NI, M. Z. Development and validation of Medical Device Key Evidence Tool ('MeDKET'): An evidence-based framework to explain success in selected European and US companies. **PLOS ONE**, [*s. l.*], v. 18, n. 7, p. e0288126, 2023.

MANKINS, John C. **Technology Readiness Levels – A White Paper**. Washington, DC: NASA, Office of Space Access and Technology, Advanced Concepts Office, 6 abr. 1995; atualizado em 22 dez. 2004. Available at: http://www.artemisinnovation.com/images/TRL_White_Paper_2004-Edited.pdf. Access at: 21 jun. 2025.

MARCH, Salvatore T.; SMITH, Gerald F. Design and natural science research on information technology. **Decision Support Systems**, [*s. l.*], v. 15, n. 4, p. 251–266, 1995.

MARCH, Salvatore T.; SMITH, Gerald F. Design and natural science research on information technology. **Decision Support Systems**, [s. l.], v. 15, n. 4, p. 251–266, 1995.

MAREŠOVÁ, Petra *et al.* Complexity stage model of the medical device development based on economic evaluation-MedDee. **Sustainability (Switzerland)**, [*s. l.*], v. 12, n. 5, p. 1–27, 2020.

MAREŠOVÁ, Petra *et al.* Medical Device Development Process, and Associated Risks and Legislative Aspects-Systematic Review. **Frontiers in Public Health**, [*s. l.*], v. 8, n. July, p. 1–13, 2020.

MARTIN, Jennifer L; BARNETT, Julie. Integrating the results of user research into medical device development: insights from a case study. **BMC Medical Informatics and Decision Making**, [*s. l.*], v. 12, n. 1, p. 74, 2012.

MARTINS, Micaela; E SILVA, Cláudia Sousa; MAGANO, José. Project management maturity in the biotechnology industry. **Procedia Computer Science**, [*s. l.*], v. 196, p. 748–755, 2022.

MAYRINK, Nadja N. V. *et al.* Competency gaps and institutional challenges for translational research in medical devices: insights from Brazilian researchers. **BMC Medical Education**, [*s. l.*], v. 25, n. 1, p. 571, 2025.

MEDINA, Lourdes A.; KREMER, Gül E.Okudan; WYSK, Richard A. Supporting medical device development: A standard product design process model. **Journal of Engineering Design**, [*s. l.*], v. 24, n. 2, p. 83–119, 2013.

MEDINA, Lourdes A. *et al.* An investigation of critical factors in medical device development through Bayesian networks. **Expert Systems with Applications**, [*s. l.*], v. 40, n. 17, p. 7034–7045, 2013.

MENSHENIN, Yaroslav; PINQUIÉ, Romain; CHEVRIER, Pierre. New Product Development Process for Medtech Combination Products. **Proceedings of the Design Society**, [*s. l.*], v. 3, p. 2795–2804, 2023.

MISHRA, Soumya Ranjan; BEHDINAN, Kamran. Multidisciplinary Design Analysis and Optimization Framework for Regulatory Driven Medical Device Development. **Proceedings of the Design Society**, [*s. l.*], v. 3, n. JULY, p. 2735–2743, 2023.

MOBEY, Alison; PARKER, David. Risk evaluation and its importance to project implementation. **Work Study**, [*s. l.*], v. 51, n. 4, p. 202–208, 2002.

MOHER, David *et al.* Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. **PLoS Medicine**, [*s. l.*], v. 6, n. 7, 2009.

MOORMAN, C. *et al.* Marketing in the Health Care Sector: Disrupted Exchanges and New Research Directions. **Journal of Marketing**, [*s. l.*], v. 88, n. 1, p. 1–14, 2024.

MUGAMBI, Melissa Latigo *et al.* How to implement new diagnostic products in low-resource settings: an end-to-end framework. **BMJ Global Health**, [*s. l.*], v. 3, n. 6, p. 1–9, 2018.

NAMATI, Eman. Rapid product development and commercialization in a regulated industry, the path to success. (Conference Presentation). *In*: , 2019. (Anita Mahadevan-Jansen, Org.)**Advanced Biomedical and Clinical Diagnostic and Surgical Guidance Systems XVII**. [*S. l.*]: SPIE, 2019. p. 166.

NICHOLS, James H. Point-of-care testing. *In*: CONTEMPORARY PRACTICE IN CLINICAL CHEMISTRY. [*S. l.*]: Elsevier, 2020. p. 323–336.

NIRALI P SHAH. Navigating challenges in new product development: Strategies for reducing failure rates in the medical device industry. **World Journal of Advanced Research and Reviews**, [*s. l.*], v. 22, n. 3, p. 786–795, 2024.

NIROUMAND, Marjan *et al.* Frugal innovation enablers, critical success factors and barriers: A systematic review. **Creativity and Innovation Management**, [*s. l.*], v. 30, n. 2, p. 348–367, 2021.

O.NYUMBA, Tobias *et al.* The use of focus group discussion methodology: Insights from two decades of application in conservation. **Methods in Ecology and Evolution**, [*s. l.*], v. 9, n. 1, p. 20–32, 2018.

OCAMPO, Jovany Uribe; KAMINSKI, Paulo Carlos. Medical device development, from technical design to integrated product development. **Journal of Medical Engineering and Technology**, [*s. l.*], v. 43, n. 5, p. 287–304, 2019.

OFFERMANN, Philipp *et al.* Outline of a design science research process. *In*: , 2009, New York, New York, USA. **Proceedings of the 4th International Conference on Design Science Research in Information Systems and Technology - DESRIST '09**. New York, New York, USA: ACM Press, 2009. p. 1.

OLIVEIRA, A. de A. *et al.* **Tratado Brasileiro de BioTecnologia em Saúde: Da Bancada ao Leito**. [*S. l.: s. n.*], 2024.

**ORGANIZAÇÃO DAS NAÇÕES UNIDAS (ONU).** Objetivos de Desenvolvimento Sustentável (ODS). Available at: https://brasil.un.org/pt-br/sdgs. Access at: 2 apr. 2025.

**ORGANIZAÇÃO DAS NAÇÕES UNIDAS (ONU).** ONU prevê que população idosa dobrará até 2050, com mais de 2 bilhões de pessoas acima de 60 anos. 2023. Available at: https://news.un.org/pt/story/2023/10/1821122. Access at: 2 apr. 2025.

OYEWOLE, Anne O. *et al.* Covid-19 impact on diagnostic innovations: Emerging trends and implications. **Diagnostics**, [*s. l.*], v. 11, n. 2, 2021.

O'CONNOR, Gina Colarelli. Major Innovation as a Dynamic Capability: A Systems Approach *. **Journal of Product Innovation Management**, [*s. l.*], v. 25, n. 4, p. 313–330, 2008.

O'DWYER, Clare; CORMICAN, Kathryn. Regulation - Do or die: An analysis of factors critical to new product development in a regulatory context. **Journal of Technology Management and Innovation**, [*s. l.*], v. 12, n. 1, p. 26–38, 2017.

PANDA, Swati; DASH, Shridhar. Constraints faced by entrepreneurs in developing countries: a review and assessment. **World Review of Entrepreneurship, Management and Sustainable Development**, [*s. l.*], v. 10, n. 4, p. 405, 2014.

PANESCU, D. Medical device development. *In*: , 2009. **2009 Annual International Conference of the IEEE Engineering in Medicine and Biology Society**. [*S. l.*]: IEEE, 2009. p. 5591–5594.

PAUL, Steven M. *et al.* How to improve RD productivity: The pharmaceutical industry's grand challenge. **Nature Reviews Drug Discovery**, [*s. l.*], v. 9, n. 3, p. 203–214, 2010.

PELJHAN, Darja; MARC, Mojca. Risk management and strategy alignment: influence on new product development performance. **Technology Analysis & Strategic Management**, [*s. l.*], v. 35, n. 12, p. 1547–1559, 2023.

PETER, Lukas *et al.* (30) Regulation, risk classification, and open.pdf. [*s. l.*], n. Mdi, 2020.

PETKOVIC, Jennifer *et al.* Key issues for stakeholder engagement in the development of health and healthcare guidelines. **Research Involvement and Engagement**, [*s. l.*], v. 9, n. 1, p. 27, 2023.

PICH, Michael T.; LOCH, Christoph H.; DE MEYER, Arnoud. On uncertainty, ambiguity, and complexity in project management. **Management Science**, [*s. l.*], v. 48, n. 8, p. 1008–1023, 2002.

PIETZSCH, Jan B. *et al.* Stage-gate process for the development of medical devices. **Journal of Medical Devices, Transactions of the ASME**, [*s. l.*], v. 3, n. 2, 2009.

PISONI, Alessia; MICHELINI, Laura; MARTIGNONI, Gloria. Frugal approach to innovation: State of the art and future perspectives. **Journal of Cleaner Production**, [*s. l.*], v. 171, p. 107–126, 2018.

PIUZZI, Nicolas S. *et al.* Consolidation and maturation of the orthopaedic medical device market between 1999 and 2015. **European Journal of Orthopaedic Surgery and Traumatology**, [*s. l.*], v. 29, n. 4, p. 759–766, 2019.

POPE, C. Qualitative research in health care: Analysing qualitative data. **BMJ**, [*s. l.*], v. 320, n. 7227, p. 114–116, 2000.

POST, J. E., Preston, L. E., & Sauter-Sachs, S. (2002). **Redefining the corporation: Stakeholder management and organizational wealth**. Stanford University Press. https://www.sup.org/books/title/?id=1967

PRASAD, Vinay; MAILANKODY, Sham. Research and development spending to bring a single cancer drug to market and revenues after approval. **JAMA Internal Medicine**, [*s. l.*], v. 177, n. 11, p. 1569–1575, 2017.

PROENÇA, Adriano *et al.* **Gestão da Inovação e Competitividade no Brasil: Da Teoria para a Prática**. 1ªed. [*S. l.*]: Bookman, 2015.

RAHIMI, Sara; KHATOONI, Marzieh. Saturation in qualitative research: An evolutionary concept analysis. **International Journal of Nursing Studies Advances**, [*s. l.*], v. 6, p. 100174, 2024.

RAKIC, K. Breakthrough and disruptive innovation: A theoretical reflection. **Journal of Technology Management and Innovation**, [*s. l.*], v. 15, n. 4, p. 93–104, 2020.

RICE, Mark P.; O'CONNOR, Gina Colarelli; PIERANTOZZI, Ronald. Implementing a Learning Plan to Counter Project Uncertainty. **IEEE Engineering Management Review**, [*s. l.*], v. 36, n. 2, p. 92–102, 2008.

RIES, E. (2011). **The lean startup.** New York: Crown Business.

ROBERT G.COOPER. **Third generation of NPD processes**. [*S. l.: s. n.*], 1994.

ROBERTS, Deborah. L.; PALMER, Roger; HUGHES, Mathew. Innovating the product innovation process to enable co‐creation. **R&D Management**, [*s. l.*], v. 52, n. 3, p. 484–497, 2022.

ROBSON, Matthew J. *et al.* New Product Development Process Execution, Integration Mechanisms, Capabilities and Outcomes: Evidence from Chinese High‐Technology Ventures. **British Journal of Management**, [*s. l.*], v. 34, n. 4, p. 2036–2056, 2023.

ROCKART, J F. Chief executives define their own data needs. **Harvard business review**, [*s. l.*], v. 57, n. 2, p. 81–93, 1979.

RODRIGUEZ-MANZANO, Jesus *et al.* Innovative diagnostic technologies: navigating regulatory frameworks through advances, challenges, and future prospects. **The Lancet Digital Health**, [*s. l.*], v. 6, n. 12, p. e934–e943, 2024.

ROHR, Ulrich-Peter *et al.* The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report. **PLOS ONE**, [*s. l.*], v. 11, n. 3, p. e0149856, 2016.

ROWLEY, J. Using Case Studies in Research Hill College of Higher. **Management research news**, [*s. l.*], v. 25, p. 16–27, 2002.

ROZENFELD, Henrique. **Gestão de desenvolvimento de produtos: uma referência para a melhoria do processo**. 1st ed. São Paulo: Saraiva, 2006.

RUBERA, Gaia; CHANDRASEKARAN, Deepa; ORDANINI, Andrea. Open innovation, product portfolio innovativeness and firm performance: the dual role of new product development capabilities. **Journal of the Academy of Marketing Science**, [*s. l.*], v. 44, n. 2, p. 166–184, 2016.

RUSSELL, Richard K.; TIPPETT, Donald D. Critical Success Factors for the Fuzzy Front End of Innovation in the Medical Device Industry. **Engineering Management Journal**, [*s. l.*], v. 20, n. 3, p. 36–43, 2008.

RYAN, Bridget L. *et al.* Beyond the grey tsunami: a cross-sectional population-based study of multimorbidity in Ontario. **Canadian Journal of Public Health**, [*s. l.*], v. 109, n. 5–6, p. 845–854, 2018.

SAIDI, Trust; DOUGLAS, Tania S. Critical elements in the design, development and use of medical devices. A systemic perspective of orthopedic devices landscape in low- and middle-income countries. **Health Policy and Technology**, [*s. l.*], v. 11, n. 1, p. 100593, 2022.

SALBEGO, Cléton *et al.* Elaboração e validação do Instrumento para Avaliação de Modelos metodológicos voltados ao Desenvolvimento de Tecnologias. **Revista Brasileira de Enfermagem**, [*s. l.*], v. 76, n. suppl 4, 2023.

SALERNO, Mario Sergio *et al.* Innovation processes: Which process for which project?. **Technovation**, [*s. l.*], v. 35, p. 59–70, 2015.

SALGADO, Eduardo Gomes *et al.* Critical Success Factors for New Product Development in Biotechnology Companies. **EMJ - Engineering Management Journal**, [*s. l.*], v. 29, n. 3, p. 140–153, 2017.

SALVADOR-CARULLA, Luis *et al.* Adaptation of the technology readiness levels for impact assessment in implementation sciences: The TRL-IS checklist. **Heliyon**, [*s. l.*], v. 10, n. 9, p. e29930, 2024.

SANTOS, Carolina *et al.* Project Management in Public Health: A Systematic Literature Review on Success Criteria and Factors. **Portuguese Journal of Public Health**, [*s. l.*], v. 38, n. 1, p. 37–48, 2020.

SAUNDERS, M. **Design Science Research: Research Methods for Business Students Paperback**. 6ªed. [*S. l.*]: Pearson Custom Publishing, 2012.

SCHROEDER, Lee F. *et al.* Time for a Model List of Essential Diagnostics. **New England Journal of Medicine**, [*s. l.*], v. 374, n. 26, p. 2511–2514, 2016.

SCHUMPETER, Joseph Alois. **Business Cycles: A Theoretical, Historical, And Statistical Analysis of the Capitalist Process.** 1ªed. [*S. l.*]: Martino Pub, 2014.

SENGE, Peter M.; ZIDE NETO, Gabriel. **A quinta disciplina: arte e prática da organização que aprende**. 38. ed. São Paulo: Best Seller, 6 set. 2013. 644 p. ISBN 8576847140

SHAH, Komal; ARORA, Manish. Considerations in theShah, K., & Arora, M. (2024). Considerations in the testing of a minimum viable product in healthcare. Proceedings of the Design Society, 4, 1677–1686. https://doi.org/10.1017/pds.2024.170 testing of a minimum viable product in health. **Proceedings of the Design Society**, [*s. l.*], v. 4, p. 1677–1686, 2024.

SHIN, Jaeho *et al.* Is There a Difference in Innovation Performance Depending on the Investment in Each Stage of Development Process? Evidence From Medical Device Industry. **IEEE Access**, [*s. l.*], v. 11, n. August, p. 92092–92099, 2023.

SIM, Julius; WATERFIELD, Jackie. Focus group methodology: some ethical challenges. **Quality & Quantity**, [*s. l.*], v. 53, n. 6, p. 3003–3022, 2019.

SINGER, Michael E.; HACK, Dallas C.; HANLEY, Daniel F. The power of public-private partnership in medical technology innovation: Lessons from the development of FDA-cleared medical devices for assessment of concussion. **Journal of Clinical and Translational Science**, [*s. l.*], v. 6, n. 1, 2022.

SINHA, R. The role and impact of new technologies on healthcare systems. **Discover Health Systems**, [*s. l.*], n. November, 2024.

SLATTERY, Owen *et al.* A Review of Lean Methodology Application and Its Integration in Medical Device New Product Introduction Processes. **Processes**, [*s. l.*], v. 10, n. 10, 2022.

SOARES, A. de S. Pesquisa em ciências sociais aplicadas: métodos e técnicas. **Revista de Administração Contemporânea**, [*s. l.*], v. 10, n. 3, p. 185–185, 2006.

SOENKSEN, Luis R.; YAZDI, Youseph. Stage-gate process for life sciences and medical innovation investment. **Technovation**, [*s. l.*], v. 62–63, n. April, p. 14–21, 2017.

SONGKAJORN, Yaninee; THAWESAENGSKULTHAI, Natcha. Medical device innovation development process. **International Journal of Innovation and Technology Management**, [*s. l.*], v. 11, n. 4, p. 1–24, 2014.

SONY, Michael; ANTONY, Jiju; TORTORELLA, Guilherme L. Critical Success Factors for Successful Implementation of Healthcare 4.0: A Literature Review and Future Research Agenda. **International Journal of Environmental Research and Public Health**, [*s. l.*], v. 20, n. 5, p. 4669, 2023.

SOUZA, M. K. *et al.* Termo de consentimento livre e esclarecido (TCLE): fatores que interferem na adesão. **ABCD. Arquivos Brasileiros de Cirurgia Digestiva (São Paulo)**, [*s. l.*], v. 26, n. 3, p. 200–205, 2013.

STEWART, David W.; SHAMDASANI, Prem N. **Focus Groups: Theory and Practice**. Volume 20 of Applied Social Research Methods. 1. ed. Newbury Park, CA: Sage Publications, 1990. 160 p. ISBN 0803933894 .

STUART, I. *et al.* Effective case research in operations management: A process perspective. **Journal of Operations Management**, [*s. l.*], v. 20, n. 5, p. 419–433, 2002.

SULLIVAN, Diane M.; MARVEL, Matthew R. Knowledge Acquisition, Network Reliance, and Early‐Stage Technology Venture Outcomes. **Journal of Management Studies**, [*s. l.*], v. 48, n. 6, p. 1169–1193, 2011.

TALLARICO, Salvatore *et al.* Health Technology Assessment of medical devices. Overcoming the critical issues of current assessment. **Journal of Multi-Criteria Decision Analysis**, [*s. l.*], v. 29, n. 1–2, p. 150–172, 2022.

TASE, Arkeliana *et al.* Usability challenges in the use of medical devices in the home environment: A systematic review of literature. **Applied Ergonomics**, [*s. l.*], v. 103, p. 103769, 2022.

TEECE, David; LEIH, Sohvi. Uncertainty, Innovation, and Dynamic Capabilities: An Introduction. **California Management Review**, [*s. l.*], v. 58, n. 4, p. 5–12, 2016.

TEZA, Pierry *et al.* Modelos de front end da inovação: similaridades, diferenças e perspectivas de pesquisa. **Production**, [*s. l.*], v. 25, n. 4, p. 851–863, 2015.

THAKUR, Ramendra; HSU, Sonya H.Y.; FONTENOT, Gwen. Innovation in healthcare: Issues and future trends. **Journal of Business Research**, [*s. l.*], v. 65, n. 4, p. 562–569, 2012.

THIJSSEN, Salina V. *et al.* The barriers and facilitators of radical innovation implementation in secondary healthcare: a systematic review. **Journal of Health Organization and Management**, [*s. l.*], v. 37, n. 3, p. 289–312, 2023.

TIEDEMANN, Fredrik; JOHANSSON, Eva; GOSLING, Jonathan. Structuring a new product development process portfolio using decoupling thinking. **Production Planning and Control**, [*s. l.*], v. 31, n. 1, p. 38–59, 2020.

TOLEDO, J. C. de *et al.* Fatores críticos de sucesso no gerenciamento de projetos de desenvolvimento de produto em empresas de base tecnológica de pequeno e médio porte. **Gestão & Produção**, [*s. l.*], v. 15, n. 1, p. 117–134, 2008.

TROTT, Paul *et al.* The changing context of innovation management: A critique of the relevance of the stage-gate approach to current organizations. **Prometheus: Critical Studies in Innovation**, [*s. l.*], v. 38, n. 2, p. 207–227, 2022.

TSAI, I. C.; WANG, C. Da; CHEN, P. T. Strategies for Medical Device Development: User and Stakeholder Perceptions. **Journal of Healthcare Engineering**, [*s. l.*], v. 2023, 2023.

TSAI, I. Ching; WANG, Ching Da; CHEN, Peng Ting. Strategies for Medical Device Development: User and Stakeholder Perceptions. **Journal of Healthcare Engineering**, [*s. l.*], v. 2023, 2023.

TUMELERO, Cleonir *et al.* The role of networks in technological capability: a technology-based companies perspective. **Journal of Global Entrepreneurship Research**, [*s. l.*], v. 8, n. 1, p. 7, 2018.

U.S. GOVERNMENT ACCOUNTABILITY OFFICE. **GAO schedule assessment guide: best practices for project schedules.** Washington, D.C.: GAO, 2020. Available at: https://www.gao.gov/assets/gao-20-48g.pdf. Access at: 15 january , 2025.

UCTU, Ramazan; EKSTEEN, Karen. The Covid-19 Pandemic and the Importance of Financing the Biotechnology Industry in South Africa. **The Journal of Entrepreneurial Finance**, [*s. l.*], v. 24, n. 1, 2022.

USHIMARU, Yuki *et al.* Development of medical devices driven by academia-industry collaboration: An internal audit. **Surgery**, [*s. l.*], v. 181, p. 109289, 2025.

VAN AKEN, Joan; CHANDRASEKARAN, Aravind; HALMAN, Joop. Conducting and publishing design science research. **Journal of Operations Management**, [*s. l.*], v. 47–48, n. 1, p. 1–8, 2016.

VAN OORSCHOT, Kim; ELING, Katrin; LANGERAK, Fred. Measuring the Knowns to Manage the Unknown: How to Choose the Gate Timing Strategy in NPD Projects. **Journal of Product Innovation Management**, [*s. l.*], v. 35, n. 2, p. 164–183, 2018.

VAQUERO MARTÍN, María; REINHARDT, Ronny; GURTNER, Sebastian. Stakeholder integration in new product development: a systematic analysis of drivers and firm capabilities. **R and D Management**, [*s. l.*], v. 46, p. 1095–1112, 2016.

VARGAS, Sandra Martins Lohn *et al.* Práticas organizacionais requeridas para inovação: um estudo em empresa de tecnologia da informação. **Gestão & Produção**, [*s. l.*], v. 24, n. 2, p. 221–235, 2017.

WANG, L. *et al.* Methods and Advances in the Design, Testing and Development of *In Vitro* Diagnostic Instruments. **Processes**, [*s. l.*], v. 11, n. 2, p. 1–19, 2023.

WANG, Taige; CHEN, Han Mei. Integration of building information modeling and project management in construction project life cycle. **Automation in Construction**, [*s. l.*], v. 150, n. August 2022, p. 104832, 2023.

WARTY, R. R. *et al.* Barriers to the Diffusion of Medical Technologies Within Healthcare: A Systematic Review. **IEEE Access**, [*s. l.*], v. 9, p. 139043–139058, 2021.

WHEELWRIGHT, Steven C.; CLARK, Kim B. **Revolutionizing Product Development: Quantum Leaps in Speed, Efficiency and Quality**. 1ªed. [*S. l.*]: Free Press, 2011.

WILKE, Michael H; SCHENKER, Mike; HOFFMANN, George. Detection and documentation of DRG-relevant comorbidities using laboratory tests. **Australian Health Review**, [*s. l.*], v. 25, n. 3, p. 152, 2002.

WILSON, Michael L. *et al.* Access to pathology and laboratory medicine services: a crucial gap. **The Lancet**, [*s. l.*], v. 391, n. 10133, p. 1927–1938, 2018.

YEOM, Kyungtae *et al.* What is important for the growth of latecomers in the medical device industry?. **Journal of Open Innovation: Technology, Market, and Complexity**, [*s. l.*], v. 7, n. 1, p. 1–15, 2021.

YIN, R. **Estudo de Caso: Planejamento e Métodos**. 5ºed. [*S. l.*]: Bookman, 2014.

YU, Fei; LIU, Chuanrui; SHARMIN, Selina. Performance, Usability, and User Experience of Rayyan for Systematic Reviews. **Proceedings of the Association for Information Science and Technology**, [*s. l.*], v. 59, n. 1, p. 843–844, 2022.

ZAMZAM, Aizat Hilmi *et al.* A Systematic Review of Medical Equipment Reliability Assessment in Improving the Quality of Healthcare Services. **Frontiers in Public Health**, [*s. l.*], v. 9, n. September, p. 1–12, 2021.

ZHANG, J. J.; LAN, T.; LU, Y. Translating *in vitro* diagnostics from centralized laboratories to point-of-care locations using commercially-available handheld meters. **TrAC - Trends in Analytical Chemistry**, [*s. l.*], v. 124, 2020.

ZHANG, X.; THOMSON, V. The impact and mitigation of complexity during product design. **International Journal of Design and Nature and Ecodynamics**, [*s. l.*], v. 11, n. 4, p. 553–562, 2016.

# APPENDIX A – DESIGN SCIENCE RESEARCH PROTOCOL

For the execution of the study and the development of the artifact, a Design Science Research (DSR) protocol was followed, designed to guide the process in accordance with the principles of this methodology, ensuring data reliability, procedural standardization, and result replicability. The protocol was developed based on Dresch, Lacerda, and Antunes (2015), and is presented in Table 1.

Table 1 - DSR Protocol

| | |
|---|---|
| **Problem identification** | **Origin of the problem:**<br>☑ Solution to a given class of problem<br><br>**Problem Description:** The development of new products in the *in vitro* diagnostic (IVD) sector faces complex challenges, such as strict regulatory requirements, rapid technological advancements, and specific clinical demands. However, there is a noticeable gap in the availability of NPD (New Product Development) models tailored to this type of product that integrate elements capable of contributing to a more systematic and efficient innovation process. |
| **Awareness of the problem** | - **Key Information:** The development of *in vitro* diagnostic products involves specific complexities, such as compliance with international regulatory standards, short technological innovation cycles, and the need for rigorous clinical validation. Despite the strategic importance of these products, companies often face challenges in structuring their development processes in a systematic and context-specific manner.<br>- **Main Causes:** The absence of NPD models specifically designed for the IVD sector, along with the lack of clear guidelines that integrate the various dimensions of product development.<br>- **Expected artifact functionalities:**<br>a. Guide the NPD process with a focus on the specificities of IVDs;<br>b. Integrate risk management and critical elements identified in the literature and organizational practice;<br>c. Serve as a tool to support decision-making throughout the development phases.<br>- **Expected artifact performance:**<br>a. Better organization and structuring of the NPD process for IVDs;<br>b. Greater alignment between strategy, operations and regulatory compliance;<br>c. Reduction of failures and rework through a more systematic process adapted to the sector.<br>- **Artifact operating requirements:**<br>a. Conceptual basis based on literature and practical cases on NPD;<br>b. Flexibility to adapt according to the company's reality and type of IVD product;<br>c. Empirical validation of the model.<br>- **Contingency heuristics of the problem:** |

<table>
<tr><td></td><td>a. The model must consider the degree of complexity of the product and its diagnostic purpose;<br>b. The regulatory and market environment may vary between regions, requiring contextual adjustments;<br>c. The structure and maturity of the organization's innovation process affect the applicability of the model.</td></tr>
<tr><td>Systematic Literature Review</td><td>Followed “Appendix B - Research Protocol”: It is based on the Literature Grounded Theory (LGT) method proposed by Ermel et al (2022).</td></tr>
<tr><td>Identifying artifacts and configuring problem classes</td><td>
<table>
<tr><th>Problem class</th><th>Problem</th><th>Artifact</th></tr>
<tr><td rowspan="2">Challenges in structuring the NPD process in highly technological sectors such as healthcare</td><td rowspan="2">Absence of specific NPD models aimed at the IVD sector</td><td>NPD Models for Medical Devices</td></tr>
<tr><td>Methods to support NPD</td></tr>
</table>
</td></tr>
<tr><td>Preposition of artifacts to solve the specific problem</td><td>
<table>
<tr><td>Proposed Artifact</td><td>NPD Model for In Vitro Medical Devices</td></tr>
<tr><td>Justification</td><td>Presented in section 1.3</td></tr>
<tr><td>Pros</td><td>Provides a structured and systematic approach to NPD; Tailored to the unique challenges of the IVD sector; Supports decision-making throughout the product development cycle.</td></tr>
<tr><td>Cons</td><td>Evaluation was limited to Brazilian companies, which may affect generalizability; The model was applied to the entire IVD sector, but IVDs encompass diverse product types with distinct development requirements; Adaptation may be required depending on company size, structure, or innovation maturity; Implementation may require training and organizational alignment.</td></tr>
</table>
</td></tr>
<tr><td>Design of the selected artifact</td><td>Selected artifact: NPD model aimed at the in vitro diagnostics sector.<br>- Solutions required for the artifact to function: it must be applied in organizational contexts interested in structuring or improving their NPD processes. In addition, stakeholder involvement is essential.<br>- Procedures:<br>a. Artifact construction: (i) literature review, which mapped practices and elements relevant to NPD in medical devices; (ii) conducting case studies in companies in the sector, in order to incorporate empirical evidence; and (iii) validation with experts<br>b. Artifact evaluation: analysis of its practical applicability according to experts</td></tr>
</table>

| | |
|---|---|
| | - **Expected results:** The model is expected to contribute to improving the structuring of NPD processes in IVD companies, promoting greater efficiency, strategic alignment, regulatory compliance and risk reduction throughout the product development cycle. |
| **Artifact development** | For the development of the artifact, the protocol established in "Appendix E – Data Collection Protocol" and "Appendix F – Structure for Interviews and Questionnaire" was followed. |
| **Artifact evaluation** | The proposed NPD model was expected to integrate critical success factors and risk management practices in a hybrid structure suitable for developing IVDs devices. The artifact also needed to demonstrate conceptual clarity, practical applicability, and alignment with the healthcare sector's specific challenges.<br><br>Assessment result: found in Appendix I |
| **Explanation of learning** | A key success was the ability to synthesize complex factors into a single framework that supports strategic decision-making. However, there are opportunities to improve the artifact's adaptability to different company sizes or stages of technological maturity, as well as to refine its application through testing in real industry settings. |
| **Conclusions** | The model contributes by offering a structured and adaptable framework that supports strategic decision-making and reduces uncertainty in early-stage innovation. However, as a conceptual proposal, it has not yet been tested in real-world applications, which limits the assessment of its practical effectiveness. Future work should focus on validating the model in different organizational contexts, refining it based on stakeholder feedback, and exploring the integration of digital tools to enhance its applicability and scalability. |
| **Generalization to a class of problems** | **Classes of problems that the artifact could contribute to:**<br>- Development of new products in technology-based healthcare companies;<br>- Structuring NPD *in vitro* medical device companies;<br>- Application of the model in NPD focused on *in vitro* diagnostic products;<br>- Use of the model for educational purposes, aiming to train professionals and students in innovation management;<br>- Promotion of best practices in new product development and innovation management in technological environments. |
| **Communication of results** | **Communication of research results:**<br>☑ Dissertation<br>☑ Dissertation Scientific article for journal. Journal of Medical Engineering & Technology and Journal of Product Innovation Management (JPIM) |

Source: Prepared by the authors (2025)

## APPENDIX B - SYSTEMATIC LITERATURE REVIEW RESEARCH PROTOCOL

This appendix presents the research protocol (Table 1) designed to guide the methodological steps of the Systematic Literature Review. It is based on the model suggested by the Literature Grounded Theory (LGT) method proposed by Ermel *et al* (2022).

Table 1 - Systematic Literature Review Research Protocol

| **Research Protocol** | | |
|---|---|---|
| **Research title:** Process of developing new products for *in vitro* diagnostics | | |
| **Research Team:** Giovana Dalpiaz | | |
| **Stakeholders:** Researchers and teachers | | |
| **Review:** 4 | **Date:** 20240917 | **Reviewed by:** Omitted for blind review purposes |
| **1. Research Question(s):** | | |
| 1.1 How can the new product development process be optimized for in vitro diagnostic medical device innovations?<br><br>1.2 How can the integration of risk management with new product development models benefit the development of *in vitro* diagnostic medical devices?<br><br>1.3 What are the main criteria for the success of *in vitro* diagnostic medical device innovations? | | |
| **2. Review question(s):** | | |
| 2.1 What are the main new product development models applied to the area of diagnostic medical devices?<br><br>2.2 How is risk management incorporated into new product development models to ensure the success of innovations in diagnostic technologies?<br><br>2.3 What are the main critical elements for the development of new products in the area of diagnostic medical devices?<br><br>2.4 How do companies in the diagnostic medical device sector evaluate the success of a new product development process? | | |
| **3. Purpose(s) of the review** | | |
| Identify and analyze the main product development process models applied in the | | |

| | | |
|---|---|---|
| diagnostic technology industry, including traditional and innovative approaches | | |
| **4. Scope of review** | | |
| 4.1 Breadth | ☐ Narrow | ☑ Ampla |
| 4.2 Depth | ☐ Superficial | ☑ Profunda |
| 4.3 Type of review | ☐ Agregativa | ☑ Configurativa |
| **5. Conceptual framework** | | |
| New product development process models aim to ensure the success of these products by organizing the process of creating and launching innovations, integrating best project management practices. These models are essential for establishing structured processes that promote innovation in the healthcare area, ensuring that new products are developed safely and efficiently, meeting both market demands and regulatory requirements for safety and efficacy. | | |
| **6. Time horizon** | | |
| Publications between 2004 and 2024 were considered to aggregate studies covering the state of the art of the research topic. This timeframe ensured the inclusion of recent and relevant evidence, while also capturing seminal articles that laid the foundation for new product development in the healthcare and medical device sectors. | | |
| **7. Search string** | | |
| TITLE-ABS-KEY (("product development process" OR "PDP" OR "new product development" OR "product development" OR "development cycle" OR "process model" OR "process innovation") AND ("Medical Equipment" OR "medtech" OR "medical biotechnology" OR "healthcare" OR "medical device development" OR "technology diagnostic") AND ("risk management" OR "good practices" OR "regulatory" OR "innovation" OR "life cycle") AND (PUB YEAR > 2003 AND PUB YEAR < 2025) AND (LIMIT-TO (LANGUAGE,"English")) | | |
| **8. Research sources** | | |
| Scopus, Web of Science and Pubmed | | |
| **9. Search approach** | | |
| Database Search | Snowballing | |
| **10. Eligibility criteria** | | |
| 10.1 Inclusion criteria | 10.1.1 Articles that specifically deal with the development of technologies for diagnosis, or related areas, addressing the development cycle, innovation processes, critical | |

| | |
|---|---|
| | development factors and risk management.<br><br>10.1.2 Studies that, although not directly related to diagnostic technologies, present robust methodological procedures that can be adapted or applied to the process of developing new products.<br><br>10.1.3 Prioritize articles published in peer-reviewed journals to ensure the scientific quality of the reviewed information and that it is available in full. |
| 10.2 Exclusion criteria | 10.2.1 Articles that do not apply to the context of diagnostic technologies and that do not bring relevant methodological contributions to the topic of new product development.<br><br>10.2.2 Studies that focus solely on sustainability, commercialization, design, or marketing strategies of diagnostic products, without a clear connection to the technical or regulatory development of the product.<br><br>10.2.3 Studies focused exclusively on the development of pharmaceutical targets, vaccines or pathology treatment bias.<br><br>10.2.4 Studies on areas of medicine or that address clinical trials of diagnostic technologies.<br><br>10.2.5 Studies that address as their main theme the process of new technologies for hospitals or service provision.<br><br>10.2.6 Studies that address only the development of software, applications or artificial intelligence for technologies.<br><br>10.2.7 Studies that address the |

| | | |
|---|---|---|
| | | presentation of the technology involved and not the development process<br><br>10.2.8 Studies evaluated with low methodological rigor according to indicators such as CiteScore and impact factor |
| **11. Data analysis** | | |
| 11.1 Scientometric analysis | | Scientific development |
| 11.2 Bibliometric analysis | ☐ Scientific performance | ☑ Scientific mapping |
| 11.3 Content analysis | ☐ Aggregative | ☑ Thematic and structural analysis |
| **12. Data synthesis** | | |
| 12.1 Aggregative synthesis | ☐ Quantitative meta-analysis | |
| 11.2 Configurative synthesis | ☑ Meta-synthesis | ☐ Others |

Source: Prepared by the authors and adapted from Ermel *et al* (2022).

## APPENDIX C - ELIGIBILITY CRITERIA FOR SYSTEMATIC LITERATURE REVIEW

This appendix presents the justifications for the inclusion and exclusion criteria, with the number of exclusions (Table 1) of the Systematic Literature Review (SLR), based on the definition of the research protocol.

Table 1 - SLR eligibility criteria

| Inclusion criteria | Exclusion criteria |
|---|---|
| Articles that specifically deal with the development of technologies for diagnosis, or related areas, addressing the development cycle, innovation processes, critical development factors and risk management. | Application, software and artificial intelligence development (n=51) |
| | Treatment, vaccine, drugs or biomarkers (n=100) |
| | Prosthesis development (n=5) |
| | Products for the food or agricultural industry (n=12) |
| | Technology and Health Technology Assessment (n=6) |
| Studies that, although not directly related to diagnostic technologies, present robust methodological procedures that can be adapted or applied to the process of developing new products. | Clinical medicine, clinical trials and epidemiology (n=146) |
| | Hospitals and health services (n=63) |
| | Commercialization, market and marketing (n=13) |
| | Product design (n=6) |
| | No innovation process and models (n=28) |
| | Sustainable Development Goals (n=4) |
| Prioritize articles published in peer-reviewed journals, with full versions available and assessment of indicators such as CiteScore and impact factor | Level of evidence (n=14) |
| | Unrelated to health (n=32) |
| | Unrelated to diagnosis (n=180) |
| | No full version available (n=36) |

Source: Prepared by the authors (2025)

## APPENDIX D - *CORPUS* OF ANALYSIS OF THE SYSTEMATIC LITERATURE REVIEW

Table 1 presents the evidence included in the Systematic Literature Review (SLR), along with their respective years of publication.

Table 1 - SLR *Corpus*

| | Selected evidence | | Year of publication |
|---|---|---|---|
| 1. | An Enhanced Agile V-Model: Conformance to Regulatory Bodies and Experiences from Model's Adoption to Medical Device Development. | Khan *et al.*, 2024 | 2024 |
| 2. | Considerations in the testing of a minimum viable product in healthcare | Shah; Arora, 2024 | 2024 |
| 3. | Organizing the fragmented landscape of multidisciplinary product development: a mapping of approaches, processes, methods and tools from the scientific literature | Guerineau, 2024 | 2024 |
| 4. | A systematic review of the literature on the evaluation of medical device lifecycle | Harkin; Sorensen; Thomas, 2024 | 2024 |
| 5. | Strategies for Medical Device Development: User and Stakeholder Perceptions | Tsai; Wang; Chen, 2023 | 2023 |
| 6. | Perceptions and Attitudes Regarding Medical Device Development in Canada | Browne; Sutton; Zhang, 2023 | 2023 |
| 7. | Multidisciplinary Design Analysis and Optimization Framework for Regulatory Driven Medical Device Development | Mishra; Behdinan, 2023 | 2023 |
| 8. | Multi-Criteria Decision Making for Medical Device Development | Barkaoui *et al.*, 2023 | 2023 |
| 9. | Is There a Difference in Innovation Performance Depending on the Investment | Shin *et al.*, 2023 | 2023 |
| 10. | A New Product Development Framework for Deep-Tech Academic Research: A Case Study Approach | Kruachottikul *et al.*, 2023 | 2023 |

| | | | |
|---|---|---|---|
| 11. | Risk Management in Medical Device Development: A Qualitative Study of Start-ups | Kheir; Jacoby; Verwulgen, 2022 | 2022 |
| 12. | A Review of Lean Methodology Application and Its Integration in Medical Device New Product Introduction Processes | Slattery *et al.*, 2022 | 2022 |
| 13. | Optimizing the innovation and development process of medical devices - a study based on angiographic equipment | Busch *et al.*, 2021 | 2021 |
| 14. | How to ease the pain of taking a diagnostic point of care test to the market: A framework for evidence development | Graziadio *et al.*, 2020 | 2020 |
| 15. | Integrated SEM-FTOPSIS framework for modeling and prioritization of risk sources in medical device development process | Kirkire; Rane; Abhyankar, 2020 | 2020 |
| 16. | Complexity Stage Model of the Medical Device Development Based on Economic Evaluation—MedDee | Marešová *et al.*, 2020 | 2020 |
| 17. | Medical Device Development Process | Marešová *et al.*, 2020b | 2020 |
| 18. | Medical Device Development | Byrne, 2020 | 2020 |
| 19. | Medical Devices: Regulation, Risk Classification, and Open Innovation | Peter *et al.*, 2020 | 2020 |
| 20. | Interdisciplinary Collaboration in Medical Device Development: A Case Study from India | Alagumalai; Kadambi; Appaji, 2019 | 2019 |
| 21. | Good practices systematization for medical equipment development and certification process: A Brazilian case study | Lobato *et al.*, 2019 | 2019 |
| 22. | Medical device development, from technical design to integrated product development | Ocampo; Kaminski, 2019 | 2019 |
| 23. | The Medical Device Innovation Process | Durfee; Iaizzo, 2019 | 2019 |
| 24. | How to implement new diagnostic products in low-resource settings: an end-to-end framework | Mugambi *et al.*, 2018 | 2018 |

| | | | |
|---|---|---|---|
| 25. | A real-world perspective: Building and executing an integrated customer engagement roadmap that bridges the gaps in traditional medical device development processes | Goldenberg; Gravagna, 2018 | 2018 |
| 26. | Regulation and device development | Brooks, 2017 | 2017 |
| 27. | Regulation – Do or Die | O'Dwyer; Cormican, 2017 | 2017 |
| 28. | Limited Awareness of the Essences of Certification or Compliance Markings on Medical Devices | Foo; Tan, 2017 | 2017 |
| 29. | Best Practices in Early Phase Medical Device Development | Fearis; Petrie, 2017 | 2017 |
| 30. | Stage-gate process for life sciences and medical innovation investment | Soenksen; Yazdi, 2017 | 2017 |
| 31. | Critical Success Factors for New Product Development in Biotechnology Companies | Salgado *et al.*, 2017 | 2017 |
| 32. | Stakeholder integration in new product development: a conceptual model | Vaquero Martín; Reinhardt; Gurtner, 2016 | 2016 |
| 33. | Death Helped Write the Biologics Law | Baylor, 2014 | 2014 |
| 34. | Medical Device Innovation Development Process | Songkajorn; Thawesaengskulthai, 2014 | 2014 |
| 35. | Supporting Medical Device Development: A Standard Product Design Process Model | Medina; Kremer; Wysk, 2013 | 2013 |
| 36. | Stage-Gate Process for the Development of Medical Devices | Pietzsch *et al.*, 2009 | 2009 |
| 37. | Critical Success Factors for the Fuzzy Front End of Innovation in the Medical Device Industry | Russell; Tippett, 2008 | 2008 |

Source: Prepared by the authors (2025).

## APPENDIX E – DATA COLLECTION PROTOCOL

The data collection protocol (Table 1) was developed based on Burnard's study (2024). It aims to provide a structure for conducting the research, ensuring the reliability of the data obtained, promoting the standardization of procedures, and replicability of results.

Table 1 - Data collection protocol

| Steps | Required activities |
|---|---|
| Section 1: Scope and objectives of the case study (means through which data will be collected) | - Objectives: To identify the main critical factors for the success of medical device development.<br>- Requirements for participation: companies in the market, with years of experience and having a research and development (R&D) sector for medical devices.<br>- Initial contact: e-mail<br>- Informed consent form (ICF): participants will be informed of the objectives of the study through the form, and their signature is required to ensure ethical issues (Appendix G) |
| Section 2: Case study structure | - Focus Areas: R&D of *in vitro* diagnostic medical devices<br>- Research Proposals: The literature identified a lack of clarity and standardization in the process of developing new products for health technologies, in addition to being generalist in the criticality of some stages, focusing too much on the regulatory period. It is understood that for NPD to be successful, a systematic structuring that encompasses several elements of development is necessary, so we seek to understand how this is done in practice and whether there is no standardization in this process.<br>- Research stages:<br>a. Initial contact with participants<br>b. Signing of the informed consent form and application of the questionnaire<br>c. Scheduling of interviews<br>d. Preliminary dialogue: gathering general information about the company and the interviewee<br>e. Semi-structured interviews in 6 blocks<br>☐ Company: 1. What is the name and size of your company? (Micro, Small, Medium, Large); 2. How long has the company been operating in the medical diagnostic device market?; 3. What type of i*n vitro* medical device does the company develop?; 4. How many products have been launched by the company? |

<table>
<tr><td></td><td colspan="2">☐ Interviewee: 1. What is your role in the company?; 2. How many years of experience do you have in product development? How long have you worked at the company?; 3. What is your academic background?; 4. How many product development projects have you participated in?</td></tr>
<tr><td>Section 3: Template for data collection</td><td colspan="2">- Estimated total time: 60 to 95 minutes for the interview and 10 minutes for the questionnaire<br>- Primary data: semi-structured script and questionnaire available in Appendix F<br>- Supplementary data: documentary analysis according to the company's availability, and direct observations<br>- Intended results: identify factors that were relevant to contributing to the success of NPD for medical devices.</td></tr>
<tr><td>Section 4: Analytical Procedures</td><td colspan="2">- Analytical methods and procedures to be followed: coding and triangulation of raw data for qualitative and quantitative analyses.</td></tr>
<tr><td rowspan="5">Section 5: Research Schedule</td><td>Activities</td><td>Planned period</td></tr>
<tr><td>Selection and contact with cases</td><td>Until April 2025</td></tr>
<tr><td>Finalization of the model for collection and pilot testing</td><td>Until April 2025</td></tr>
<tr><td>Interview and analysis period</td><td>May - June 2025</td></tr>
<tr><td>Generate final report:</td><td>July - August 2025</td></tr>
<tr><td>Section 6: Database</td><td colspan="2">Data organization: using Atlas.ti software<br>Data Analysis: RStudio</td></tr>
</table>

Source: Prepared by the authors (2025)

## APPENDIX F – STRUCTURE FOR INTERVIEWS AND QUESTIONNAIRE

The structure for the semi-structured interviews (Table 1) and the questionnaire (Tables 2) was developed based on the studies Lobato *et al*. (2019), O'Dwyer; Cormican (2017), and Toledo *et al*. (2008). The materials will be applied in the study data collection.

Table 1 - Script for semi-structured interviews

| **Area of interest and coding** | **Interview script** | **Checkpoints of topics to be covered** |
|---|---|---|
| Product technology and features<br><br>References: Kirkire; Rane; Abhyankar, 2020; Guerineau, 2024; ; Medina; Kremer; Wysk, 2013; Kruachottikul *et al*., 2023; Browne; Sutton; Zhang, 2023. | Could you tell us, in retrospect, what were the main challenges in developing a new product? Can you use a specific example to illustrate?<br><br>During the process, did specific bottlenecks arise that hindered progress? Especially in the context of the technology developed.<br><br>How long did it take on average for product development to take place in the company?<br><br>Have there been any significant delays? How do you mitigate this? | ☐ Product technological challenges<br>☐ Main bottlenecks in technology development<br>☐ Development time |
| Human Resources<br><br>References: Alagumalai; Kadambi; Appaji, 2019. | What was the team involved in this project like? Number and skills; academic level;<br><br>Was it a challenge to find qualified human resources?<br><br>During the project, what technical skills were most required of the team?<br><br>How did these difficulties involving HR influence the progress or final success of the project? | ☐ Team size<br>☐ Academic level<br>☐ Technical skills |
| Stakeholders<br><br>References: Medina; Kremer; Wysk, 2013; Kirkire; Rane; Abhyankar, 2020; Craig *et al*., 2015; Goldenberg; Gravagna, 2018; Busch *et al*., 2021 | In practice, who do you see as the main stakeholders involved in the development of a new medical device in the company?<br><br>During the project you mentioned earlier, were there any specific challenges in dealing with any of these stakeholders? | ☐ Who are the main stakeholders<br>☐ Challenges involving stakeholders |

| | | |
|---|---|---|
| Management<br><br>References: Russell; Tippett, 2008; Marešová *et al*., 2020b; Ttsai; Wang; Chen, 2023; O'Dwyer; Cormican, 2017; Lobato *et al*., 2019; Peter *et al*., 2020; Pietzsch *et al*., 2009; | How do you typically start a new medical device development project in your company? Is there a process or environment within the company that encourages the emergence of these ideas?<br><br>How are strategic decisions made? Who participates?<br><br>Does the company use a specific model or methodology for project management (e.g., Stage-Gate, SCRUM)?<br><br>What methods or tools do you believe could improve project management, especially in meeting deadlines and goals?<br><br>Is risk and uncertainty management part of the project from the beginning? How is this applied in practice?<br><br>How is the documentation process carried out during the project? Is there a standard or tool used?<br><br>How does the company deal with issues related to intellectual property, such as patents? Is the path clear and known by the technical team?<br><br>How are development projects financed in your company? (e.g.: internal resources, partnerships, investors, funding)<br><br>In your view, what is considered success in a new medical device development project? | ☐ Project start milestone<br>☐ Strategic decision makers<br>☐ NPD model used<br>☐ Methods and tools that could be used<br>☐ Risk management<br>☐ Product documentation and registration<br>☐ Intellectual property<br>☐ Project financing and investment<br>☐ Defining successful development |
| Regulatory requirements<br><br>References: Brooks, 2017; Medina; Kremer; Wysk, 2013; Pietzsch *et al*., 2009; | What is the regulatory process adopted by your company for submitting a new product to ANVISA? (Ex: consultancies)<br><br>Have there been cases in which the submission of a product to ANVISA did not receive a response or had to be resubmitted several times? Or was it returned due to requirements related to the documentation presented?<br>- No no: What do you understand that, in the development process, may have led to this non-approval?<br>- No yes: And what do you believe contributed to this positive history in submissions? Are there practices or strategies that make a difference in | ☐ Regulatory process adopted by the company |

| | | |
|---|---|---|
| | this process? | |
| Market<br><br>References: Brooks, 2017; Russell; Tippett, 2008; Barkaoui *et al*., 2023; Lobato *et al*., 2019; Shin *et al*., 2023; Ocampo; Kaminski, 2019. | How is the product market mapped?<br><br>How was the financial performance of a new medical device launched by the company (or as you expect it to be)? How was it/it will be evaluated?<br><br>If the product is already on the market: Did the financial return achieved meet expectations? If not: How did the company address these issues? What measures were taken to adjust or improve the product's performance in the market? | ☐ Financial return<br>☐ Evaluation strategies |
| End of the interview | Do you believe that the learning curve acquired during the development of a new product is sufficient to make the next product less challenging?<br><br>If you had to choose, what would be the biggest challenge in the process of developing new medical devices in your company? And why? | Free response |

Source: Prepared by the authors (2025)

Table 2 - Questionnaire to assess NPD

| **Stage** | **Questionnaire organization** |
|---|---|
| Stage 1 | - Presentation of the research and its objectives<br>- Informed Consent Form (ICF) |
| | |

| **Stage** | **Questioning** | **Aspects to be evaluated** |
|---|---|---|
| Stage 2 | Company profile | 1. What is the name of the company you work for? *Free answer*.<br>2. How big is the company you work for?<br>☐ a) Startup<br>☐ b) Microenterprise<br>☐ c) Small enterprise<br>☐ d) Medium enterprise<br>☐ e) Large enterprise<br>☐ f) I don't know<br>3. How long has the company you work for been in the diagnostic medical devices market?<br>☐ a) Less than a year<br>☐ b) 1 to 10 years<br>☐ c) 11 to 20 years<br>☐ d) More than 20 years |

| | | |
|---|---|---|
| | | ☐ e) I don't know<br>4. How many *in vitro* diagnostic products has the company you work for launched on the market?<br>☐ a) 1 to 5 products<br>☐ b) 6 to 10 products<br>☐ c) More than 10 products<br>☐ d) I don't know |
| | General information | 5. Completed academic training:<br>☐ a) Basic Level (Elementary and High School)<br>☐ b) Technical<br>☐ c) Graduation<br>☐ d) Postgraduate (Specialization)<br>☐ e) Master's and PhD<br>☐ Other ____<br>6. What is your area of expertise? *(Example: engineer, biomedical engineer, administrator, researcher, etc.) Free answer.*<br>7. What is your role or function in the company? *(Example: R&D, Quality Analyst, Project Manager) Free answer.*<br>8. Have you ever participated in the development of a medical device?<br>☐ a) Yes, from the initial ideation phase to commercialization *(when selecting this option, you go to question 9)*<br>☐ b) Yes, I participated in one or more intermediate phases of the process *(when selecting this option, you go to question 8.1)*<br>☐ c) No, but I am interested in the area *(when selecting this option, the questionnaire is completed)*<br>☐ d) No *(when selecting this option, the questionnaire is completed)*<br>8.1 What phases or steps of the medical device development process did you participate in?<br>☐ a) Pre-development stage (concept and feasibility)<br>☐ b) Development (Technological development and validation)<br>☐ c) Launch (Commercialization and post-market)<br>☐ Others: ____ |
| | Experience and Perceptions about NPD | 9. How many product development projects have you been involved in?<br>☐ a) 1 to 2 projects<br>☐ b) 3 to 5 projects<br>☐ c) 6 to 10 projects<br>☐ d) More than 10 projects<br>10. How long have you been involved in medical device development?<br>☐ a) Less than 1 year<br>☐ b) From 1 to 3 years<br>☐ c) From 3 to 5 years<br>☐ d) More than 5 years |

| | | |
|---|---|---|
| | | 11. What type of *in vitro* medical device does the company develop? *(Ex: immunochromatographic, point-of-care, electrochemical test) Free answer.*<br>12. *What are the 5 ASPECTS that you consider to be most essential in a product development model for medical devices? (Select exactly five options from those listed below):*<br>☐ Risk and uncertainty management during development<br>☐ Gates to support decision-making (Decision points to assess project progress)<br>☐ Access to supporting regulatory standards (e.g. ISO standards)<br>☐ Systematic recording during development stages<br>☐ Identify and prioritize critical development activities<br>☐ Use of scales to assess development maturity<br>☐ Indication of methods or tools for evaluating development<br>☐ Identification of market needs<br>☐ Structuring the technological research and development stage<br>☐ Identifying the profile of the technical team<br>☐ Feedback cycles between stages for the executing team<br>☐ Planning of laboratory tests and preclinical validations<br>☐ Planning of product prototyping<br>☐ Clinical validation strategy<br>☐ Product regulatory strategy<br>☐ Marketing and launch strategy<br>☐ Post-market monitoring strategies<br>☐ Other: ____ |
| Stage 3 | Assessment of challenges in NPD | 13. In this stage of the questionnaire, the objective is to assess the main challenges faced in the product development process in your company. You will be asked to assign a score from 1 (not very relevant) to 7 (highly relevant) for each item listed, according to your perception of the relevance of each challenge in the context of your organization.<br><br>13.1 Challenges in human resources management<br>13.2 Challenges in regulatory stages<br>13.3 Challenges in market access<br>13.4 Challenges in technological development<br>13.5 Challenges in identifying and selecting suppliers and strategic partners<br>13.6 Challenges in acceptance of the product by the end customer<br>13.7 Challenges in the availability of adequate physical spaces for development |
| | Efficiency assessment in NPD | 14. In this part of the questionnaire, we seek to understand your perception of the efficiency of the product development process in your company. You should evaluate each item using a scale from 1 (very inefficient) to 7 (very efficient), based on your experience and the performance observed in your organization. |

| | | |
|---|---|---|
| | | 14.1 Initial project planning: *Consider your initial planning efficient if it was well structured, with clear objectives and defined deadlines. Consider it inefficient if the planning was poorly defined, with a lack of clarity or an inadequate schedule.*<br>14.2 Allocation of financial resources: *Consider the allocation of financial resources efficiently if investments were made strategically, meeting the needs of the project and within the established budget. Consider it inefficient if resources were poorly distributed, resulting in shortages in essential areas or excessive spending in less critical phases.*<br>14.3 Integration and communication between teams: *Consider integration and communication between teams efficient if there was effective collaboration, with continuous exchange of information and alignment of objectives at all phases of the project. Consider inefficient if communication was faulty, with a lack of alignment between teams, resulting in misunderstandings or delays in the process.*<br>14.4 Response to changes in project requirements: *Consider the response to changes in project requirements to be efficient if the changes were quickly identified, evaluated and implemented without compromising the schedule or budget. Consider inefficient if the changes caused significant delays, cost increases or problems in the execution of the project due to lack of adaptation or adequate planning.*<br>14.5Meeting deadlines and project objectives: *Consider the fulfillment of deadlines and project objectives to be efficient if the goals were achieved within the established deadlines, without compromising the quality of the work. Consider inefficient if there were frequent delays or non-compliance with objectives, resulting in a negative impact on the progress of the project and the expected results.* |
| | Assessment of the importance of management in NPD | 15. In this section, the focus is on evaluating the impact of management within the product development process. You should indicate the level of impact perceived in each item, using a scale from 1 (no impact) to 7 (significant impact), based on your professional experience.<br><br>15.1 What is the effect of management on reducing development costs?<br>15.2 What is the effect of management on reducing development time?<br>15.3 What is the effect of management on the technical quality of the final product?<br>15.4 What is the effect of management on regulatory compliance during product development?<br>15.5 What is the effect of management on the traceability of design documents throughout development? |
| | Assessment of stakeholder challenges | 16. In this part of the questionnaire, we seek to assess the challenges related to interacting with stakeholders during product development. You should rate the current level of each item using a scale from 1 (not very relevant) to 7 (highly |

| | | |
|---|---|---|
| | | relevant), according to the reality observed in your company.<br><br>16.1 Challenges in alignment and communication between the development team<br>16.2 Challenges in communicating with suppliers during the project<br>16.3 Challenges with stakeholder involvement in initial planning<br>16.4 Challenges in purchasing inputs needed during product development? |
| Stage 4 | Space for Comments and Observations | 17. Would you like to leave a tip, suggestion or learning that can help other professionals involved in product development? *(Feel free to direct your contribution specifically to the pre-development, development or commercialization phases.) Free and non-obligatory response.* |

Source: Prepared by the authors (2025)

## APPENDIX G – FREE AND INFORMED CONSENT FORM

The document entitled Free and Informed Consent Form (ICF) was developed with the purpose of obtaining participants' permission for the information collected during data collection to be used and published anonymously in scientific outlets. All procedures in this study were designed to ensure the privacy and confidentiality of the information provided by participants. The identity of the interviewees will be protected through the anonymization of names. This condition was previously explained by the interviewer, and the signing of the ICF served to formalize the participants' agreement with the terms of the study.

To facilitate completion, the consent form was made available online at the beginning of the questionnaire, which was presented in Portuguese, the language in which the data collection was conducted. The full version of the TCLE can be read below.

*Título do estudo: Do desenvolvimento ao sucesso: avaliação de fatores críticos para o desenvolvimento de novos produtos para tecnologias de diagnóstico in vitro*
*Nome da pesquisadora responsável: Giovana Dalpiaz*

*Você está sendo convidado(a) a participar de uma pesquisa acadêmica vinculada ao Programa de Pós-Graduação em Engenharia de Produção e Sistemas da Universidade do Vale do Rio dos Sinos (UNISINOS). Esta pesquisa faz parte de uma dissertação de mestrado e tem como objetivo identificar e analisar os principais fatores críticos que impactam o processo de desenvolvimento de novos produtos (NPD) em empresas do setor de dispositivos médicos, com o objetivo de desenvolver um modelo que incorpore esses elementos e contribua para o desenvolvimento de recursos aplicáveis à área da saúde.*

*Caso você concorde em participar do estudo, inicialmente a coleta de dados será feita por meio deste questionário online. Sua participação é voluntária e você poderá se retirar a qualquer momento, sem qualquer prejuízo. Posteriormente, uma entrevista será agendada previamente, com sua ciência e a dos gestores. As entrevistas serão conduzidas por meio de reuniões online utilizando o Microsoft Teams. Essa ferramenta permite ao pesquisador gravar áudio e vídeo dos entrevistados, possibilitando a coleta detalhada das informações e a revisão das*

*gravações, o que contribui para a precisão e a eficiência no processo de transcrição do conteúdo da entrevista.*

*Os potenciais riscos associados a esta pesquisa incluem cansaço ou aborrecimento durante o preenchimento dos questionários; desconforto, constrangimento ou alterações de comportamento durante as gravações de áudio e vídeo; além de receios por parte do entrevistado, como não saber responder adequadamente às perguntas ou temer ser identificado, mesmo com a garantia de anonimização dos dados.*

*Todos os procedimentos deste estudo serão realizados com o objetivo de assegurar o direito à privacidade e a proteção da confidencialidade dos dados dos participantes. Para resguardar a identidade dos entrevistados e garantir que se sintam confortáveis para discutir abertamente o tema abordado, os nomes serão anonimizados.*

*Ao marcar a opção de aceite no formulário, você declara estar ciente dos objetivos da pesquisa e concorda em participar de forma livre e esclarecida. Em caso de dúvidas sobre este estudo, podem entrar em contato com a pesquisadora responsável Giovana Dalpiaz, por meio do telefone (51) 99219-5693 ou por e-mail giovana.dalpiaz@gmail.com.*

## APPENDIX H – DATA FROM THE CASE STUDY

Data collection was carried out through a multiple case study, as detailed in Appendix F. Table 1, Table 2 and Table 3 presents the results obtained from the questionnaire, while Table 4 compiles the data gathered from the semi-structured interviews, organized into six thematic categories: technology, stakeholders, management, market, regulation, and human resources.

Table 1 - Compiled results: Qualitative questionnaire

| **Questions** | | **Interviewees (INT)** | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | INT1 | INT2 | INT3 | INT4 | INT5 | INT6 | INT7 |
| 1 | Company identification | Company A | Company B | Company B | Company C | Company D | Company E | Company F |
| 2 | Company size | Small company | Startup | Startup | Medium-sized company | Startup | Large company | Startup |
| 3 | Time in the company | 1 to 10 years | 1 to 10 years | 1 to 10 years | 11 to 20 years old | 1 to 10 years | 1 to 10 years | 1 to 10 years |
| 4 | Products already launched | In ANVISA validation | 1 to 5 products | 1 to 5 products | More than 10 products | 1 to 5 products | More than 10 products | 1 to 5 products |
| 5 | Academic background | Master's degree | PhD | Specialization | Master's degree | Master's degree | Master's degree | Master's degree |
| 6 | Area of activity | Biomedical | Biologist | Engineer | Doctor | Biomedical engineer | Biomedical | Biologist |
| 7 | Role in the | Head of R&D | Production | CEO | Medical director | CEO | Sales | CEO |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | company | | Manager | | | | Executive | |
| 8 | NPD Participation | Yes, at some stage | Yes, at all stages | Yes, at all stages | Yes, at all stages | Yes, at all stages | Yes, at some stage | Yes, at some stage |
| 8.1 | Stages | Pre-development, development, | Pre-developm ent, development, launch | Pre-developmen tdevelopment, launch | Pre-development development, launch | Pre-developme ntdevelopment, launch | Launch | Pre-developme nt, development, |
| 9 | Number of projects involved | 3 to 5 projects | 3 to 5 projects | More than 10 projects | 3 to 5 projects | More than 10 projects | 1 to 2 projects | 3 to 5 projects |
| 10 | Time of operation | More than 5 years | 3 to 5 years | More than 5 years | More than 5 years | More than 5 years | 1 to 3 years | More than 5 years |
| 11 | Product Type | Point-of-care electrochemical | Point-of-care | Point-of-care | Point-of-care different types | Point-of-care | Point-of-care | Point-of-care electrochemical |

Source: Prepared by the authors (2025)

Table 2 - Qualitative questionnaire: result of essential aspects for an NPD model

| **Interviewees (INT)** | **Aspect 1** | **Aspect 2** | **Aspect 3** | **Aspect 4** | **Aspect 5** |
|---|---|---|---|---|---|
| INT 1 | Systematic recording during the development stages | Identify and prioritize critical development activities | Identifying market needs | Laboratory testing and preclinical validation planning | Clinical validation strategy |
| INT 2 | Indication of methods or tools for evaluating development | Identification of market needs | Structuring the technological research and development stage | Clinical validation strategy | Product regulatory strategy |

| | | | | | |
|---|---|---|---|---|---|
| INT 3 | Gates to support decision making | Identifying market needs | Planning of laboratory tests and preclinical validations | Product regulatory strategy | Marketing and launch strategy |
| INT 4 | Managing risks and uncertainties during development | Access to supporting regulatory standards | Identifying market needs | Clinical validation strategy | Product regulatory strategy |
| INT 5 | Access to supporting regulatory standards | Identifying market needs | Product prototyping planning | Clinical validation strategy | Product regulatory strategy |
| INT 6 | Managing risks and uncertainties during development | Identifying market needs | Product prototyping planning | Clinical validation strategy | Marketing and launch strategy |
| INT7 | Access to supporting regulatory standards | Systematic recording during the development stages | Identify and prioritize critical development activities | Using scales to assess developmental maturity | Identifying market needs |

Source: Prepared by the authors (2025)

Table 3 - Compiled results: Quantitative questionnaire

| **Questions** | | **Interviewees (INT)** | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | INT1 Company A | INT2 Company B | INT3 Company B | INT4 Company C | INT5 Company D | INT6 Company E | INT7 Company F |
| 13 Challenges<br><br>1 (not very relevant) to 7 (highly relevant) | 13.1 - human resource | 6 | 6 | 6 | 5 | 7 | 7 | 7 |
| | 13.2 - regulatory steps | 7 | 6 | 7 | 6 | 7 | 6 | 7 |
| | 13.3 - market | 7 | 6 | 7 | 7 | 6 | 7 | 6 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | access | | | | | | | |
| | 13.4 - development | 7 | 6 | 6 | 6 | 6 | 7 | 7 |
| | 13.5 - suppliers | 6 | 7 | 5 | 6 | 6 | 5 | 5 |
| | 13.6 - end customer | 6 | 6 | 7 | 7 | 5 | 6 | 7 |
| | 13.7 - infrastructure | 7 | 6 | 4 | 5 | 6 | 3 | 5 |
| 14 Efficiency<br><br>1 (not very relevant) to 7 (highly relevant) | 14.1 - planning | 4 | 6 | 3 | 4 | 5 | 7 | 3 |
| | 14.2 - financial | 6 | 6 | 4 | 4 | 4 | 6 | 5 |
| | 14.3 - communication | 6 | 6 | 6 | 5 | 5 | 5 | 3 |
| | 14.4 - requirements | 6 | 7 | 6 | 5 | 5 | 3 | 4 |
| | 14.5 - deadlines | 3 | 5 | 2 | 3 | 4 | 3 | 2 |
| 15 Development management<br><br>1 (no impact) to 7 (significant impact) | 15.1 - costs | 7 | 7 | 6 | 6 | 5 | 7 | 6 |
| | 15.2 - time | 7 | 6 | 6 | 6 | 3 | 7 | 5 |
| | 15.3 - technical quality | 5 | 7 | 4 | 7 | 6 | 5 | 5 |
| | 15.4 - regulation | 5 | 7 | 5 | 7 | 6 | 6 | 7 |
| | 15.5 - traceability | 7 | 7 | 3 | 7 | 6 | 7 | 7 |
| 16 Stakeholders<br><br>1 (not very relevant) to 7 (highly | 16.1 - Technical team | 6 | 7 | 4 | 6 | 5 | 7 | 6 |
| | 16.2 - Suppliers | 5 | 7 | 5 | 6 | 5 | 4 | 7 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| relevant) | 16.3 - in initial planning | 6 | 7 | 4 | 6 | 6 | 4 | 6 |
| | 16.4 - Purchase of supplies | 6 | 7 | 5 | 5 | 7 | 5 | 6 |

Caption: The numbers presented in the table correspond to the scores assigned by each participant on a 7-point Likert scale. In each section of the questionnaire, participants rated the listed items according to their perception.

Source: Prepared by the authors (2025)

Table 4 - Compiled results: Interviews

| Interview blocks | Compiled from interviewees |
|---|---|
| Product technology and features | **INT1:** Requirements and challenges: An initial lack of clarity regarding the technology's requirements creates unexpected challenges and obstacles, which can delay development. During the process, unforeseen needs often arise, requiring adjustments and restarts. Development timeline: The actual development of the current version began in 2021, meaning it has been underway for approximately five years (until 2025). The technology transfer to a facility with good manufacturing practices (GMP) approved by Anvisa has not yet occurred, but is scheduled for this year. Only after this transfer will clinical validation of the product be possible. Uncertainties in the regulatory and bureaucratic process: There is no clear estimate for the time required to prepare the regulatory documentation, transfer the technology, and undergo Anvisa's review. Anvisa may request additional information, which adds uncertainty to the certification timeline. Continuous learning: Many steps need to be repeated during development because procedures were not well defined. Prior knowledge and experience facilitate the process, making subsequent projects smoother.<br><br>**INT2:** Product characteristics: 100% sensitivity has been reported for both the ELISA and the rapid test, but in practice, rapid tests generally have slightly lower sensitivity. Development time: The project has been in development for approximately 2.5 to 3 years. Initial challenges: Developing a functional method and protocol required adapting and combining different protocols, as there was no standardized protocol to follow. Standardizing the technique and ensuring the availability of inputs were the main initial bottlenecks. Validation and inputs: It is essential to obtain sufficient patient samples to perform tests that guarantee reproducibility, repeatability, and test quality. Problems encountered included low-quality inputs or inputs degraded during transport, lack of characterization services, and import delays (customs, expensive freight). Reproducibility and technical complexity: Many tested protocols did not produce consistent results; reproducibility was one of the biggest |

| | |
|---|---|
| | challenges, requiring significant expertise. Development was done practically from scratch, including the in-house production of colloidal gold and impregnation of the nitrocellulose membrane. Specific technical aspects: Adapting proteins validated using other techniques for rapid testing was challenging due to differences in methodologies, especially when combined with colloidal gold. Costs and logistics: Difficulties are not limited to purchasing inputs, but also to the import process and high costs, exacerbated by the fact that the company is a startup. Suppliers often handle the purchasing and delivery, and there is no direct option for purchasing in large volumes, making planning usage difficult.<br><br>**INT3:** Partnership and stakeholders: Product development is a joint effort between a private company, a university, and the government, all of which act as stakeholders in bringing the technology to the public. Factors driving development: The combination of three elements: internal expertise, desire/idea of what to develop, and market demands. Technology Development: This begins with sample collection. It verifies whether the necessary antibody or antigen is already commercially available for use in the rapid test impregnation. If suitable inputs are not available on the market, they are developed internally, using bioinformatics or animal immunization to generate antibodies. A constant pursuit of quality ensures a competitive edge. Assessing the test's sensitivity and specificity is important, and for class 3 and 4 tests, INCQS (National Institute of Quality of Life) assessment is required before release. Development Time: The average development time can be about a year, but it varies considerably, especially if samples are required, which can take up to a year at this stage alone. Each innovative product has a unique journey with its own challenges; it is never a simple process. Obtaining well-characterized samples is identified as the company's greatest internal challenge and obstacle. Other challenges arise throughout the process, such as bioinformatics failures or animal immunization. Technical complexity: In-house production of colloidal gold for conjugation was a complex and time-consuming process, requiring expertise in biochemistry. Care in preparing the diluent solution and membrane is also crucial. The ability to understand the details of conjugation and know what works and what doesn't is essential for optimization. Importance of experience: With more experience accumulated, the time to optimize the test decreases, reducing risks and delays in development.<br><br>**INT4:** Importance of IVD: Based on the decentralization of sample collection and centralization of analytical processing. Company history and evolution: Founded in 2004, initially as a software company for hospital data integration, it evolved into hardware development, launching its first medical devices. The first uses established methodologies (chromatography, fluorescence, dry chemistry). The innovation lies in the network structure for sectorization and remote laboratory analysis, not in the biochemistry itself. Development time: The first product took about 1.5 to 2 years from idea to launch, a relatively quick process. Development was smoother due to financial stability, a lean organizational structure, and less complex team. Currently, the company works on multiple products simultaneously, increasing process complexity.<br><br>**INT5:** Development time: The product development cycle took about five years, although ideally it could have been three years. Factors influencing development time: Simple processes that don't require clinical validation can be faster. If a clinical |

| | |
|---|---|
| | study is required, development time increases significantly. The entire development journey is long and complex. Main challenges faced: Bringing together people and financial resources, and navigating the regulatory environment. Vulnerability to staff turnover (e.g., scholarship holders leaving), which affects continuity. Serious problems with suppliers and services in Brazil, including a lack of specialized analysis. Supplies are often of low quality or degrade during transportation. Technical difficulties inherent to the project, such as ensuring long-term stability and reproducibility. Opening a medical device company is an extremely complex task, especially without prior experience. Experience: Worked for seven years in the surgical equipment industry, starting as a developer and then as R&D manager and technical manager of the factory. Knowledge of regulatory processes and metrology was essential for his development. Team strategy: He recruited a large part of the team from the previous company, a common practice to maintain know-how and continuity.<br><br>**INT6:** Importance of IVD: Inequality in healthcare access in Brazil: In Rio Grande do Sul, approximately 70% to 80% of the population has health insurance or dual coverage (health insurance + SUS). In the North and Northeast regions, a large portion of the population has no access to health insurance or, often, to the SUS. Therefore, solutions such as remote testing are essential to serve these regions with less access. Technology: It is difficult to find technologies that cause significant disruption; evolution occurs more through gradual improvements to existing technologies. Most devices are still based on basic concepts taught in microbiology and biochemistry. Innovation challenge: Innovating with a truly disruptive technology is difficult, but those who succeed can grow significantly in the market. The big challenge is identifying and developing this innovative technology.<br><br>**INT7:** Technology: Blood test to detect breast cancer by biomarkers, using an electrochemical method. Innovation challenges: Integration of the different areas involved (biology, biomedicine, engineering); electrochemistry and blood sample handling are technical areas unfamiliar to the team initially. Regulatory process: Intended to submit the dossier to Anvisa by mid-2026 for official approval, possibility of early commercialization via a paused model, with well-defined internal controls. Challenges faced: Need to establish relationships with hospitals; bureaucratic process for ethics committee approval; bottleneck in regular sample receipt, even with established partnerships; and demand for an adequate volume of samples to advance analyses. |
| Human resources | **INT1:** Team Size: Internal team of approximately 7 people, divided into specific roles according to company needs, including external suppliers, a consultant specializing in regulatory affairs (Anvisa), and a partner company for technology development; Academic Level: 2 doctoral students, 2 master's students, 1 master's degree student, and 3 undergraduate students; Salary: Work is primarily carried out with research grants, which requires training new researchers for projects; limited resources prevent the hiring of more experienced professionals. Team Expansion: The company is in the process of reformulating standard documents related to quality; Challenges for Technology Development: Financial and structural resources are required, but these are not always fully available. Interns need to be hired and trained to become technology developers. During the four years of development, many employees were in academic training, balancing academic life and |

| | |
|---|---|
| | work, at different stages of undergraduate and graduate studies; Profile: It is important to balance the profiles of people at different academic levels (undergraduate and graduate). Technical knowledge, especially the clear definition of product specifications, was essential in guiding the development of diagnostic tests.<br><br>**INT2:** Team Size: The current team is small, with about 6 permanent employees. For production, they hire freelancers or temporary assistants. The company is 5 years old, starting with the CEO who combines administrative and operational functions. They have three researchers, all PhDs. HR Challenges: There were significant challenges related to people: despite the potential, there was a lack of genuine curiosity and critical commitment to identify and correct problems during the work. Techniques and experimental organization were deficient, impacting development. The main problem was a lack of curiosity and engagement, more than a lack of knowledge, as technical training was provided. Confidence in delegating critical tasks was low due to insufficient commitment. Team Expansion: Initially, there was no quality management system; it was necessary to implement a manual and documentation, under formalized and rigorously documented technical responsibility.<br><br>**INT3:** Team Size: The number of people on the team has varied significantly over time; at times, there have been seven people working on the development of a single product. The team is predominantly from the healthcare field, composed mostly of biologists and biomedical scientists. Recruitment was facilitated by close contact with UFMG, which eliminated the need for an HR department to directly participate in this process. Compensation: Project planning is structured around available research grants, with management assigned to a specific team member (research leader). Grants have specific rules, some requiring a master's or doctoral degree; the research leader has a postdoctoral degree. Academic Level: The team is composed primarily of postdoctoral fellows, but also includes graduates and master's students with completed or ongoing master's degrees. Currently, there are people with grants working on development, including doctoral and master's students.<br><br>**INT4:** Team Size: The R&D team is the core and strength of the company, participating from conception to implementation of innovations, with strong involvement from the founders. The company has between 40 and 50 R&D staff, divided into departments responsible for specific devices or methodologies, with overlapping responsibilities. Profile: The team is multidisciplinary, composed of computer engineers, biomedical engineers, medical professionals, and other specialties, with the R&D team as the main pillar. The commercial team brings demands directly to R&D, enabling rapid detection and adaptation of products or services according to market needs. Academic Level: The leadership is mostly master's students; the teams include postgraduate degrees, but the majority of professionals have undergraduate degrees, many pursuing MBAs or postgraduate degrees. The company attracts academic talent at different stages of training, especially in engineering and biomedicine, giving it a competitive advantage in legal negotiations with the private sector. Talent retention: The company's backbone is made up of leaders with more than five years of experience and authority, but it faces |

| | |
|---|---|
| | challenges with professionals at the beginning of their careers. There is high competition for professionals, especially programmers, who have remote and international work options; the company strives to be the first choice, but faces high turnover. HR challenges: In the artificial intelligence field, turnover is even higher due to competitiveness and the high demand for qualified professionals. Quality team: This team is involved from the beginning of projects, maintaining alignment with regulatory requirements to ensure compliance and product quality.<br><br>**INT5:** Team size: Composed of 6 hired people, in addition to the 4 founders. Profile: In the biochemical development field, the team includes chemists, biologists, pharmacists, physicists, and biomedical scientists, forming a multidisciplinary scientific team. The startup began with four founders: two mechatronics engineers (one with a master's degree in biomedical engineering), an electronics engineer with a master's degree in biomedical engineering, and a cardiologist. Having a physician on the team is essential for validating and convincing other physicians, especially for products of this type. Academic level: 4 PhDs and 2 master's degrees; Team expansion: The commercial team is in the initial assembly and hiring phase, while the research structure remains as described. HR challenges: Qualifying and gaining experience in the field is a challenge, as there are few people with specific experience in medical device development, especially for *in vitro* diagnostics. Finding specialized professionals was difficult; in the absence of these, the company trained people, preferably those with experience in surgical equipment, who are easier to adapt to. The biggest challenge is that many candidates come from academia, an environment that doesn't encourage efficiency and the delivery of practical results. Soft skills training is necessary to change the mindset and professional attitude of academics, which is a difficult process. Many people have technical and scientific knowledge, but lack practical experience and commitment to delivering effective results. The shortage of qualified labor combined with limited financial resources makes development very difficult. Quality team: The company has quality management systems with standardized records. Team development: Professional qualifications are encouraged both through internal training and through the promotion of postgraduate, master's, doctoral, and postdoctoral programs, directing development toward the market and not just academic research.<br><br>**INT6:** Sales team: participates directly, providing market feedback, especially when the product generates value and impact for the patient, receiving positive feedback. This feedback is reported to the marketing department, as multinationals have highly segregated structures (sales, marketing, quality, supplies). There is strong integration between the sales and marketing departments, which provides significant support to the sales process. Distribution channel strategy: is essential to provide capillarity; multinationals adopt specific strategies to reach markets where direct operations are not feasible (e.g., in the interior of the state due to financial and logistical issues). The clinical staff model was inspired by the pharmaceutical industry, which has proven effective.<br><br>**INT7:** Technical team and team size: Recently added a biomedical engineer, who added technical expertise to the team. Initially, engineering and development roles were performed by biomedical scientists who had to learn on the job. There are |

| | |
|---|---|
| | two founders: the interviewee and the advisor, and five people working directly on the project through the PED. Profile definition: Clear definition of the desired profile, including technical functions and personal characteristics. Academic level: Desire to have professionals with more advanced degrees (PhDs, post-doctorates), but financial constraints prevent hiring, requiring greater operational support. Currently, there are two recent graduates working on the bench with experiments, a postgraduate student responsible for quality control and the quality assurance system, a postgraduate biologist who manages clinical research, hospital relations, and the ethics committee, and a PhD in biology responsible for internal control, management, purchasing, and various functions. HR challenges: onboarding and training challenges, a difficult onboarding and training process, many hires coming from basic research backgrounds, struggling to understand product development, frequent frustration, especially among young and junior professionals, requiring maturity and resilience to handle the process. Quality team: the importance of hiring the first person dedicated to quality assurance, in recognition of the importance of good production practices and compliance for diagnostic projects. |
| Stakeholders | **INT1:** International suppliers: Much of the inputs and equipment are imported, which created difficulties with validation, delivery times, and communication, especially initially due to the language barrier. Strategic suppliers: Initially, the company tried to internalize all stages (electronics, manufacturing, and validation), believing it needed dedicated teams for each phase. Over time, it realized that outsourcing parts of the process to specialized suppliers was more efficient. There are still no validated alternative suppliers for some strategic components, which poses a risk. On the other hand, for general inputs, there are already approved secondary suppliers. One of the biggest challenges was finding partners capable of supplying inputs quickly, especially considering that i*n vitro* diagnostic materials are highly specific and, for the most part, come from abroad.<br><br>**INT2:** University: They maintain frequent contact with professors from other universities who have specific needs, especially those related to proteins. They rely on partners in areas such as bioinformatics, who are called upon according to the project's needs. Many studies are conducted in master's and doctoral programs, generating public results, but these results are not always continued after this stage. They have established partnerships with universities, where developments are already included in theses, dissertations, or doctoral programs, leveraging results such as sensitivity and specificity for comparisons with other tests. There is ongoing integration with academia, which uses the results of the company's products, strengthening the bridge between academic research and technological development.<br><br>**INT3:** Suppliers: Using commercially available antibodies helps mitigate risks by avoiding developing something from scratch. Having multiple suppliers allows you to evaluate and select the most suitable product. Triple Helix: During COVID, there was synergy between government, academia, and companies: an interested government, a university with expertise, a company focused on development and the market. The ultimate focus is the population, seeking to improve quality of life through access to effective products. Success also depends on the relationship with the government, especially when incorporating solutions into the Unified Health System (SUS). Calls for proposals such as Fapemig's "Triple Helix" encourage |

| | |
|---|---|
| | partnerships between government, academia, and the private sector for innovation and technological development.<br><br>**INT4:** International suppliers: Equipment and tests depend on external suppliers, many of them international (USA, China, India, Europe), which creates complexity in the logistics chain, inventory, and vulnerability, as there are no alternative options in the event of failures. Development aims to meet real market demands, with continuous engagement to ensure alignment with needs. Universities and healthcare settings: There is strong synergy between companies and academia (Unicamp, USP, local hospitals), with validations and collaborations essential for project advancement. Funding sources involve multiple stakeholders, requiring integration between the financial department and investors to sustain the RDP (Research, Education, and Development), whose return is long-term. Funding sources: Partnerships with science institutes, such as Embrapii, are important to make fundable projects viable. The involvement of different stakeholders must occur from conception to proof of concept, ensuring that future market demand is met.<br><br>**INT5:** Suppliers: Many suppliers and inputs are imported, generating high costs, long lead times, and logistical complexity. There are few qualified options in Brazil, especially in the biochemical sector; local suppliers offer inferior quality and agility. The lack of specialized local suppliers forces companies to import and even relocate part of their operations to Europe. The absence of a qualified supplier network limits the sector's growth and increases technical and financial difficulties. Funding sources: Agencies such as INPI, Finep, Fapesp, and CNPq are important for fostering the industry, which requires more specific support lines. Strengthening the patenting industry helps implement innovation in practice and drives industrial modernization. Government and public policies: The government is interested in reducing technological dependence and imports to increase Brazil's sovereignty. There are economic, political, and commercial interests behind the promotion of domestic production. Incentives and policies must improve to stimulate investment and domestic development. Academia and industry: It is important to end the tension between universities and industry; in the US, industry funds research, and universities deliver applicable results. In Brazil, academia still resists focusing beyond basic research, hindering the delivery of commercial solutions. Universities provide infrastructure, specialized equipment, and talent, making them essential partners in development. Triple helix: The interaction of the triple helix (industry, academia, and government) is fundamental to innovation and technological development. Market and investment: Investors, especially venture capitalists, seek high returns in biotechnology, but the Brazilian market is still in its infancy. Brazil is not seen as a hub for hardware and biotechnology development, with a greater focus on software and fintech. Building a strong local supply chain and improving the country's technological branding are challenges that require continuous effort.<br><br>**INT6:** Healthcare professionals: Physicians are key players in the chain, both influencing and being influenced by the adoption of diagnostic technologies. They can question the absence of a test in the laboratory and advocate for its adoption based on clinical justifications. In the hospital, different stakeholders have distinct perspectives: Laboratory management focuses on technical aspects (accuracy, speed, control). Hospital management prioritizes financial viability (costs, margins, |

| | |
|---|---|
| | reimbursement). Physicians have a broad clinical vision, connecting the impact of the device on patient conduct and safety. Physicians act as a link between the laboratory and management, reinforcing the product's cost-effectiveness. Mapping all stakeholders involved is essential for planning communication and adoption strategies. Hospitals as opinion leaders: Physicians who are opinion leaders in leading institutions (e.g., Santa Casa de Porto Alegre, Clínicas, Conceição) are essential for guiding and promoting the product's market. Physicians' influence is strategic for the final decision to purchase and implement the device, and can mobilize managers, directors, and technical teams.<br><br>**INT7:** Public institutions and government: Fiocruz has a strong product development focus, more so than many public universities. This is because Fiocruz is affiliated with the Ministry of Health, not the Ministry of Education, creating a greater incentive for researchers to move beyond basic research and develop patents and solutions for the healthcare system. This approach was a reality check for those coming from basic research backgrounds, as was the case with the interviewee. Fiocruz Paraná is reorganizing its Innovation and Technology Center (NIT) to create a portfolio of developed technologies. The goal is to make these technologies more commercial and facilitate contact with companies interested in licensing or patent transfers. Suppliers: The equipment used is imported, which creates significant delays—in some cases, up to six months to receive them. Healthcare environment: The relationship with hospitals to obtain samples is complex due to the bureaucracy involved, such as submission and approval by the ethics committee. Despite partnerships with two hospitals, the difficulty in receiving samples regularly impacts the project's progress. Industry: Industry shows interest, but the researcher needs to be able to demonstrate the value of the technology to engage these companies. Government: The government is also interested, but requires proof that the product will be cost-effective and capable of replacing current alternatives, which requires cost-effectiveness studies. Both government and industry do not adopt technologies they do not fully understand, making it essential for the researcher to clearly explain their technology. Opinion leaders: Partner physicians, hospitals, and experienced professionals participated in the market survey. The feedback was positive, especially regarding the financial aspect. The test developed has an affordable production cost, which may facilitate its adoption. |
| Management | **INT1:** Decision-making: Development decisions are made by technical leaders and CEOs. They avoid starting projects from scratch; they prefer to incorporate external demands into ongoing projects to leverage existing structures. Funding: The biggest challenge identified is securing financial and human resources. Public resources are important, but bureaucratic procedures and approval phases lengthen the process. The entry of strategic investors who become partners is seen as positive, as they align interests and strengthen the commitment to the company's results. Project initiation: Two main paths for new developments: (i) Market demand: identification of markers with potential clinical impact; (ii) Public calls: calls often guide project themes through funding. Project monitoring: There is no formal established method for monitoring development. Previous attempts to use these methods were abandoned because they did not adapt to the team's routine. Currently, they use ClickUp software for organizing and tracking tasks. Planning follows schedules, and delays are managed reactively, without in-depth methodological considerations. Risk management: Risk management was not part of the initial |

| | |
|---|---|
| | development process. It was only considered later, during preparation for technology transfer and compliance with Anvisa requirements. The lack of risk management from the outset made it difficult to go back and map previous risks. Documentation: The arrival of a specialized consultancy (not limited to Anvisa) significantly improved the company's documentation processes. The consultancy also helps with structuring for registration and regulatory compliance. Intellectual property: Internal knowledge of IP is still superficial, based on courses and scattered experiences. Today, they have specialized legal support to guide the patenting process.<br><br>**INT2:** Decision-making: There is an internal evaluation committee responsible for analyzing the technical and structural feasibility of projects before moving forward with development. The company's strategy is to leverage existing structures, avoiding starting projects entirely from scratch. Funding: Raising financial and human resources is seen as the main management challenge. The company receives funding from agencies such as Fapemig and Finep, as well as resources from private investors and partnerships with artists, especially for specific projects. Partnerships with universities or independent researchers are common, usually involving shared responsibilities and joint fundraising. Project monitoring: There is no specific project management methodology consistently adopted. Tools and methods have been tried but ultimately abandoned. Activities follow practical schedules, and when delays occur, specific justifications are sought. Risk management. Risk management is implemented late, usually after risks are identified or as the regulatory phase approaches. Risk management is carried out jointly by the research and quality teams and is improved as the project progresses. Documentation: The company has not yet computerized this stage—all of it The risk and documentation process is paper-based, with plans for future digitization. The Product History Record (RHP), master record, warehouse control, and other data are kept updated manually. The organization is traditional, but there are plans to automate processes to improve efficiency and traceability. Intellectual Property:Internal control over intellectual property is limited, but the company has specialized legal support and institutional partnerships. In joint projects, inputs (such as proteins) may come with pre-established IP, making it difficult to register as co-inventors. When the company develops inputs from the ground up (e.g., via bioinformatics), it has greater autonomy over intellectual property. Patents resulting from internal projects are registered with the support of the UFMG National Institute of Technology (CTIT), ensuring protection of innovations.<br><br>**INT3:** Decision-making: manages production, leads research and development, participates in strategic meetings, and organizes documentation. Whenever possible, efforts are made to leverage ongoing projects and align expectations with partners from the outset. Planning is done with clear estimates of stages and deadlines, but there is an awareness that unforeseen events can arise at any time. To minimize frustration, regular meetings with partners are held for continuous alignment and transparent communication. The impact of delays is significant, especially for startups with high fixed costs—a 10-month delay also represents 10 months of expenses. Funding: Funding comes from public notices (such as Fapemig and Finep), private investors, and partnerships with artists and universities. During the pandemic, investments were made that enabled, for example, the construction of the laboratory and the certification of the factory by Anvisa. Strategic partnerships: |

| | |
|---|---|
| | Partnerships with universities such as UFMG are essential, especially for access to inputs, technical support, and joint development. Contact with researchers and monitoring news help identify technological development opportunities aligned with emerging demands. Project monitoring: The company does not systematically use a specific project management tool. Monitoring is done through informal schedules, but with task traceability. They are familiar with tools such as ClickUp, Trello, and Pipefy, and recognize the future need for systematized adoption as project complexity grows. Risk management: Risk management is performed reactively and adaptively, typically initiated when a risk is already identified. When closing contracts, specific risks (e.g., supply, time, technical failures) are analyzed, but schedule risks are more difficult to predict. Research and quality are integrated to improve risk management over time. Documentation: All processes are manually recorded, including product history, tested variations, and results obtained. Even with records not digitally systematized, traceability is carefully maintained to avoid loss of experimental data. There is a desire to computerize control to increase efficiency. Intellectual property: This may be wholly owned by the company when development is in-house, or shared when there is a partnership with other institutions. Some inputs arrive with already defined IP (e.g., licensed proteins), while others are developed internally (e.g., via bioinformatics). The company relies on support from UFMG's CTIT for patent filings. There is an understanding that technical distance can guarantee a competitive advantage even without a patent, but this is not always understood by investors, leading to misalignment.<br><br>**INT4:** Decision-making: Development begins with executives and technical leaders, who validate the idea based on criteria of economic feasibility, sustainability, and alignment with the strategic plan. Projects are evaluated from the outset for technical and regulatory specifications, required at the time of product registration. Management considers the short, medium, and long term, articulating revenue targets, R&D, and operational structure. Financing: Raising funds is considered essential, with various sources: Public: Embrapii, Finep, Fapemig, Lei do Bem (Information Technology Law), Ministry of Health, among others. Private: investors and funds focused on technology and innovation. International: calls for proposals from the WHO, PAHO, Gates Foundation, and Pewing. The lack of economic incentives for biotechnology is an obstacle to the creation of new companies in the sector. The main focus is on incremental innovations based on existing products, and calls for proposals guide this focus, especially when they involve incorporation into the SUS (Unified Health System). Radical innovation is rare and, when it occurs, involves a careful assessment of technical and regulatory feasibility. Project monitoring: The company currently does not use specific management software. They used to, but abandoned it due to the bureaucracy it entailed. Management is conducted through quick and frequent meetings, which ensure fluid communication between teams and executives. The shared physical environment also favors this direct and agile interaction between those involved. Risk management: A quality team is involved from the beginning of projects, working in sync with regulatory requirements and risk management. This integrated approach aims to ensure that Anvisa's requirements are met throughout the development process, especially for registration and certifications. This reinforces the importance of alignment among stakeholders regarding development objectives and deadlines. Intellectual property: IP ownership is not formalized through a documented process, but rather occurs based on common-sense agreements, recognizing the technical contributions of |

| | |
|---|---|
| | those involved. The company already holds about seven or eight patents, but not all of them are disruptive. In some cases, it chooses not to patent, especially when the innovations are merely technical adaptations to the existing platform, avoiding the cost of processes that don't add significant strategic value. When the innovation is substantial, IP registration is strategic and crucial to increasing the asset's value.<br><br>**INT5:** Decision-making: Key decisions are made by the company's founders, with investor input depending on the project's phase and financial impact. There is a focus on avoiding excessive verticalization, focusing on core business and seeking strategic partnerships for complementary areas. Financing: The main initial challenge was raising capital to make the first project viable. Brazil still lacks the maturity for private investment in R&D in the medical device sector. The company leveraged both private investors and public funding, structuring itself with legal and accounting advice from the outset—a crucial factor in organizing contracts, intellectual property, and partnerships. Technology: The ideal process involves: market need, applied research, proof of concept, patent, and final product. Innovation stems from real bottlenecks identified in the market, ensuring applicability and commercial direction. They work with continuous and incremental innovation, including device miniaturization and new biomarker test panels. Project monitoring: They use an agile methodology adapted (based on Scrum) for the hardware and biotechnology context. Risk management: implemented from the beginning of the project, complying with Anvisa's RDC 82/2023, with reviews whenever there are significant changes to the project. A robust traceability and quality management system is in place, including: Project history records; Batch and input control; and detailed documentation in accordance with regulatory requirements. Intellectual property: the company has international patent protection (BR, US, Canada, Mexico, EU, UK, Israel, India). Specialized legal counsel advises on: patent filings; NDAs (nondisclosure agreements); and co-ownership agreements with universities and partners. IP protection is strategic, with a vision of internationalizing technology and ensuring legal certainty in collaborations. Challenges: Reports significant difficulties with deadlines and efficiency in the Brazilian supply chain, especially with inputs such as antibodies. Delays of up to two weeks are common and hinder development. The interviewee emphasizes that this scenario is inefficient and unacceptable, directly impacting the schedule.<br><br>**INT6:** Strategic market management: involves internally evaluating the company's capabilities (technology, know-how, resources) and aligning them with market demands, always focusing on financial return and commercial viability. Product management comes into play when testing market hypotheses. A technically viable idea doesn't always translate into commercial success, and anticipating this risk is essential. Measuring return on investment (ROI) is a critical component for project prioritization. Market intelligence as a priority: The first area to be structured should be market intelligence. It's not enough to know how to develop technically; it's necessary to understand the applicability, competition, costs, and clinical/commercial impact of the proposed solution. This includes evaluating: Cost-effectiveness; Real user impact; Technical, regulatory, and market feasibility. Decision-making: Modern healthcare management needs to be based on evidence and structured data. No large company today makes development decisions without: Market analysis; Risk |

| | |
|---|---|
| | management; SWOT (strengths, weaknesses, opportunities, and threats) matrices. Financing: The use of data analysis and artificial intelligence (AI) tools to guide product development is highlighted as essential. The biggest obstacle remains the availability of financial resources, especially in mature markets where well-established solutions already exist. The entry of new products into this scenario requires significant investment and robust validation to realistically compete.<br><br>**INT7:** Financing: Technology development is very expensive, requiring continuous investment, constant submission of projects and public funding requests. Passage through the "valley of death" until commercialization begins. Private investors offer little investment and expect high returns; they prefer projects with more advanced TRL. Strategy of prioritizing public resources whenever possible. Challenges: Scarce resources create pressure to avoid errors and delays. Growing experience in project development and fundraising, delays in the transfer of public funds. Time-consuming purchases, especially imported equipment, which can take up to six months to arrive. Bureaucracy and difficulties in relationships with hospitals to obtain samples. Project monitoring: The advisor's previous experience with project management facilitated learning, recognition of the need to invest in market research, and initial planning. Use of various management tools (OKR, Kaysan, SWOT matrix, Monday platform). Team resistance to meetings focused on strategy, metrics, and improvements. Agile methodologies incorporated into the process. Participation in the Fiocruz Entrepreneurship Program, which offers acceleration, mentoring, and resource acquisition. Networking is important, as is the active pursuit of specialized knowledge and support. Risk management and documentation: Creation of a risk management matrix and spreadsheet covering all areas and stages. Periodic review of risks and mitigation measures. Advance preparation of SOPs, work instructions, forms, and protocols for compliance with Anvisa (Brazilian Health Regulatory Agency). Strict document control, with signed reports and monthly monitoring of team activities. Intellectual property: Intellectual property is split 50/50 between the startup and Fiocruz. Patent not yet submitted, awaiting a strategic moment for protection. |
| Regulatory requirements | **INT1:** Regulatory standards: There is a lack of well-defined Brazilian regulations for the development of new diagnostic technologies, especially for specific diseases. Companies end up using international legislation as a reference, which creates uncertainty and confusion, as not all requirements apply to the Brazilian context. Technical specifications provided for in foreign regulations are not always compatible with Brazil's regulatory system or infrastructure. Regulatory process: There is still a lack of clear understanding of the exact steps a development must follow to meet the requirements of national regulations.<br><br>**INT2:** Regulatory Standards: There is a lack of clear Brazilian standards to guide the development of diagnostic technologies, especially in newer areas. The company must rely on international legislation, which doesn't always apply to the Brazilian reality, creating confusion in the development process. Regulatory Process: They have already lost their registration once due to delays and flaws in the process. So far, only one product has been submitted for registration to Anvisa. Delays were caused by the complexity of the research and the need to structure documentation from scratch. After submission, the company faces long waits without clear feedback from Anvisa. The lack of transparency and agility in the |

| | |
|---|---|
| | system makes it difficult to plan the next steps. The regulatory process was initially challenging, as there was no ready documentation. The company relied on specialized consulting at the beginning, which helped organize and prepare the regulatory documentation.<br><br>**INT3:** Regulatory Process: Regulation is not part of the test's technical development, but it is essential for its market entry. The biggest challenge is the long time and high cost of the regulatory process, especially for startups. After factory certification, products are submitted for registration, but: It takes an average of a year, with sample submissions, analyses, and questions. The product category (3 or 4) further increases the complexity and timeframe. More innovative tests face more bureaucracy. Initially, the company relied on specialized consultants, who helped with: Document preparation and organization. Internal training of the team to deal with Anvisa's requirements. Later, they internalized the process, taking on the regulatory steps with greater autonomy. Traceability: Anvisa requires complete traceability of all inputs and processes. Meticulous records must be kept, from development to manufacturing. There is also a requirement for reverse traceability: if a problem occurs in the field, the origin can be traced (e.g., expired input). Barriers: Slowness and regulatory complexity negatively impact the innovation and competitiveness of Brazilian companies. A more agile process would allow: More innovations to enter the market. Direct benefits to patients with faster and more accessible diagnoses.<br>A better environment for startups and technology-based companies.<br><br>**INT4:** Standards: Brazilian regulations were vague regarding the environments authorized to perform tests with the company's devices, which hindered market incorporation. This regulatory vacuum created uncertainty for customers, professionals, and patients, compromising the use and adoption of the product. For new diagnostics, the company still needs to rely on international standards, which don't always apply to the Brazilian reality. This lack of alignment leads to confusion and rework in regulated development. Regulatory Process: Initially, the company used external consultants to structure the initial submissions and technical descriptions. As the company grew, it began to internalize the process, now with a dedicated regulatory team. The regulations involve extensive documentation, required both by Anvisa and for certification audits (ISO, internal and external). The company has faced delays of up to six months, even without pending issues. After the COVID-19 pandemic, there was a backlog of submissions at Anvisa, which impacted response and analysis times. Risk class 1 or 2 (low risk) products still face delays, despite their lower complexity. Barriers: Regulations don't impede development per se, but they directly impact market entry, potentially jeopardizing all prior investment. Regulatory uncertainty is common in innovative products, where the regulations haven't yet been adapted to the new product.<br><br>**INT5:** Barriers: Anvisa is recognized as crucial, as it acts as a safety tool for both patients and healthcare professionals. However, the goal should not be to impede the market, but to ensure that products are safe and of high quality. Regulations: Anvisa's regulations contain many loopholes and ambiguities, which leave room for subjective interpretations by auditors. Attempts to seek clarification directly from Anvisa rarely yield conclusive answers, and technicians avoid taking firm |

| | |
|---|---|
| | positions, which creates legal uncertainty. The regulations were designed for large foreign companies, but the current scenario includes Brazilian startups, which face significant barriers. There is a "chicken-or-egg dilemma": to obtain guidance from Anvisa, the company must already be formalized as a medical device manufacturer (with CNAE, permits, etc.), which requires a high initial investment without guarantees. This discourages domestic entrepreneurship and leads companies to prefer to operate outside Brazil. Regulatory Process: The regulatory environment is highly bureaucratic and lacks institutional support. He recommends specialized consultancies to handle the requirements, even though he has handled the process internally. The lack of clarity and standardization in interpretations is seen as an obstacle to the sector's advancement.<br><br>**INT6:** Barriers: Its rigidity is positive in the public health context, as it protects patients and the system. However, this same rigidity leads to high bureaucracy, which can delay important processes. Anvisa (Brazilian Health Regulatory Agency) hinders the incorporation of new technologies, not because it rejects innovation, but because of a lack of clarity and specific guidelines, especially for new products. Companies often need to follow international regulations, which are not always compatible with the Brazilian reality. Regulatory Process: The document validation process with Anvisa can take months or even years, depending on the complexity of the product. It requires extensive documentation, continuous reviews and submissions, with requirements for traceability and technical detail. Bureaucracy is cited as a barrier, especially for smaller companies or those with less infrastructure. Initially, the company relied on external consultants to deal with Anvisa's requirements. Standards: Innovative products face regulatory uncertainty: there are no regulations adapted to the new, which generates rework and delays. Anvisa's standards have loopholes that leave room for individual interpretation by auditors. This makes planning difficult and increases regulatory risk. This discourages entrepreneurship and may lead companies to abandon operations in Brazil.<br><br>**INT7:** Regulatory Challenges: The regulatory area is one of the main current challenges, although it is a stage they are close to overcoming. They lack practical experience in direct contact with Anvisa (Brazilian Health Regulatory Agency) and knowledge of the specific requirements for the product. Regulatory Process: Ensuring good manufacturing practices is still a distant process for the team, which has had to seek external consultants for guidance. The biomedical scientist responsible for quality assurance has limited experience, only sufficient to assist with the initial development of the regulatory dossier. They need to hire specialized consultants to validate the correctness of the entire process and obtain direct guidance from Anvisa. After about five years, the team already knows the path to follow to structure regulatory approval. Standards: There is still no specific standard (RDC) for the type of test developed, which makes initial alignment with the regulatory agency difficult. Keeping documentation organized avoids complications with personnel changes and facilitates quick access to the necessary information. |
| Market | **INT1:** Limitations in Brazil: It was difficult to find national references, which required searching for similar technologies in other countries. This created an additional challenge due to the different realities between markets and the need to adapt solutions to the local market. Market assessment: The company began to consider not only the technical aspect, but also the |

| | |
|---|---|
| | economic and systemic impact of the technologies developed. The criterion for choosing new markers: those that allow early diagnosis and expedite treatment, with the potential to reduce costs and improve clinical outcomes.<br><br>**INT2:** Market Entry: It's difficult to compete with established brands, especially in markets dominated by established tests. The company assesses the market scenario in advance, but the lack of its own products in the market still limits the practical validation of these analyses. There is concern about the acceptance of innovations, especially in pioneering projects, where the company would be the first to offer a given solution. Market Assessment: Before launching a product, the company analyzes whether there is real market demand, considering: Whether the product will be innovative or incremental; How the market will react to this innovation; and whether entry is viable given the existing competition. Limitations in Brazil: The lack of local solutions forced the company to seek international references, which increased the complexity of development due to the need to adapt to the Brazilian context. Strategic Positioning: Biomarker selection considers not only technical aspects but also clinical and economic impact. The focus is on early diagnosis, which can accelerate medical decision-making and reduce healthcare costs.<br><br>**INT3:** Market Assessment: The decision to develop or register a test is based on market demand analysis, even if the product is not innovative (e.g., dengue, Zika, chikungunya). The company prioritizes real market gaps and avoids developments based solely on academic motivation. Preliminary market studies are conducted, but since there are no widely marketed products yet, some decisions are made based on estimates and calculated risk. There is an awareness that a technically sound test can fail commercially if market acceptance is poor. Strategic Positioning: The company focuses on products that are not yet available on the market, seeking solutions that add real value and replace traditional methods with clinical, logistical, or economic advantages. The company also recognizes that, in markets already saturated with similar solutions, it needs to offer superior quality to stand out. Because it is a new company, the market often does not perceive it with confidence, hindering the adoption of its products. The company's reputation and track record are recognized as important factors in gaining commercial market share. Market Challenges: It recognizes the risk of investing years in a test. that the market may not adopt, even if it offers quality and competitive pricing. Market analysis errors or rapid changes in the landscape (e.g., the COVID-19 pandemic) can lead to low acceptance or excessive competition. The COVID-19 experience highlighted the risks of a chaotic, saturated, and unstable market, with: Excessive testing (both good and bad), Price fluctuations, and Difficulty in penetrating new brands. The company lacks control over the distribution chain, which hinders its ability to generate consistent business results. Partnerships with distributors and manufacturers are the primary market entry channel. The lack of control over distribution was a critical factor during the pandemic and is seen as a strategic vulnerability.<br><br>**INT4:** Market assessment: Product development is guided by real market needs, not just academic interest. The company conducts preliminary studies, but acknowledges that there are uncertainties until the product is accepted by the market. In some cases, even with good technical quality, the product may not gain public acceptance, demonstrating the importance of |

| | |
|---|---|
| | accurate market analysis. Market challenges: It is difficult to enter markets already dominated by other established brands. During the COVID-19 pandemic, the company faced unfair competition and saturation, with tests of questionable quality flooding the market. Brand trust is a challenge for new companies. The company lacks control over the distribution chain, which negatively impacts results. It establishes partnerships with manufacturers and distributors to enter the market. Distribution failures have limited the commercial success of promising products. Strategic positioning: Products must be accessible and sustainable, both for the company and the healthcare system. Pricing considers social impact, cost, and expected return. Intangible gains such as portfolio diversification are also considered. There is a system of Integrated data that allows monitoring post-market usage, performance, and economic viability. Limitations: Brazil: The domestic market is fragile, with a shortage of local suppliers and high costs. Even with import costs, purchasing from abroad is often cheaper than acquiring inputs in Brazil. Brazil faces disadvantages compared to countries like the US, China, and Israel, which have more robust innovation and financing ecosystems. Post-market: The company conducts continuous post-market evaluations, identifying product improvement needs and adjusting prices. User feedback and actual performance are essential to identify unseen flaws in the development stage. Usability and acceptance are monitored in different niches (pharmacies, SUS, occupational health, etc.).<br><br>**INT5:** Limitations: Brazil is not prepared to invest in hardware and biotechnology development within a solid business framework. The venture capital environment is heavily focused on software (fintechs, B2C solutions), leaving the biotechnology and hardware niche quite small. Poor infrastructure and image: Brazil lacks adequate infrastructure for high-tech companies and has a weak image as a technology and science supplier. This causes the country to miss opportunities for technological development and depend on the localization of products designed abroad. Operating in Brazil poses constant challenges, such as the need for in-depth knowledge of the market, hospitals, and clinical teams to identify real opportunities and apply research in a targeted manner. Market assessment: The company bases its analyses on concrete data such as DATASUS and TUSS, as well as information on amounts paid by the SUS (Unified Health System) and health plans, to develop realistic and up-to-date projections of market potential in Brazil, with the potential for expansion abroad. Strategic positioning: Investors in the biotechnology sector are willing to take long-term risks, unlike the software market, which has faster cycles. Biotechnology is beginning to gain prominence in the financial market, reflected in high multiples and appreciation on stock exchanges, although the Brazilian market is lagging behind in realizing this potential.<br><br>**INT6:** Limitations: Brazil is a continental country with a huge market, but it faces significant economic instability, exchange rate fluctuations, a high tax burden, and a SUS (Unified Health System) system (SIGTAP) that has been outdated for almost 30 years, hindering business operations and profitability. The diagnostics sector is dominated by multinationals; there are no large national companies producing large-scale laboratory equipment, which represents a bottleneck for local development. Market assessment: Success depends on knowing the region in depth, validating products with key opinion leaders and reference centers (such as Einstein and Sírio-Libanês hospitals), which influence product acceptance and adoption. |

| | |
|---|---|
| | Companies invest in market intelligence and use sources such as the Brazilian Chamber of Laboratory Diagnostics (CBDL) and ANAP reports to inform decisions and understand the diagnostics landscape in Brazil, facilitating positioning and segmentation. Market penetration: Product acceptance is related to market share, presence in hospitals and potential customers, and the ability to generate continued demand, often driven by prescribing physicians, following models similar to the pharmaceutical industry. Products must be of the highest quality to compete, and there is risk in entering already established markets. Furthermore, control of the distribution chain is crucial to sales success. Clinical value and cost-effectiveness: Product value is linked to its impact on patient clinical outcomes and the financial sustainability of healthcare institutions. Demonstrating that a product, even with a higher initial cost, reduces hospital stays and improves treatment is essential for adoption. The future of the market depends on valuing cost-effectiveness and a deep understanding of the clinical and economic benefits of devices, aligning innovation with sustainability and access.<br><br>**INT7:** Market assessment: Initially, it took a while to conduct market research to understand whether the product would be adopted and what users really want. After talking to doctors and the general public, they discovered that 99% of women prefer blood tests to mammograms. Doctors are still resistant, as they rely more on imaging and need additional validation to trust biomarkers. Research outside the laboratory is crucial for the product's market entry. It took a while to define the market; initially, they considered all women interested in breast cancer screening. Women over 40 interested in prevention are the main focus, but there is also attention to younger women (under 35) with family history, who are not adequately mapped. Technical and Economic Feasibility Study: The technical and economic feasibility study (OIBTE) stage was difficult and involved learning how to calculate expenses and plan costs. Market insertion: Many technologies remain merely filed patents, never being brought to market. Researchers wait for large companies to contact them, which rarely happens. Most technologies are not explored by Lack of interest or initiative from large corporations. Strategic positioning: Focus on diagnostic laboratories, not imaging laboratories, since the product works with blood. Cost-effectiveness: Fiocruz offers cost-effectiveness validation for tests. Incorporation by the SUS, via Conitec, depends on proof of clear benefit and economic advantage. Without this validation, the technology will not be officially incorporated. |

Source: Prepared by the authors (2025)

# APPENDIX I – ARTIFACT VALIDATION

The evaluation process, including individual interviews with experts and focus group discussions, was structured based on the study by Salbego *et al*. (2023) and other references cited in section 2.2.2. Table 1 presents the feedback obtained from each expert. Furthermore, the IAMDT tool was applied in the focus group, as shown in Table 2 and the results in Table 3.

The Content Validity Index (CVI) was calculated for each item, and the scale was divided into two blocks: items 1 to 14 and items 15 to 20 (Figure 1). The mean CVI was computed for each block separately, with a value above 0.8 considered necessary for approval. Both blocks achieved mean CVI values exceeding this threshold, indicating satisfactory content validity.

Tabela 1 - Evaluation process

| Expert | Domain | Feedback |
|---|---|---|
| Expert 1 | NPD | It may be beneficial to incorporate the 'Learning Plan' perspective into the model, especially to make it more applicable in contexts of radical innovation; to state in the supporting text that the model is not linear; to highlight the importance of concurrent engineering and present ways to accelerate development, such as what was done during the COVID-19 pandemic; to clarify that the ecosystem can support accelerated development and emphasize this role; to better highlight the model's main contribution and place greater emphasis on the lower part of the model, as it is its main differentiator; to state the primary application of the model, such as the use of a stage-gate-like approach to facilitate communication, while aiming for development under uncertainty; to focus on uncertainties, as companies do not have a model tailored to them; and, in the risk typology, to clearly define each type of risk. |
| Expert 2 | NPD | Suggested subjects, highlighted the complexity of developing a model, validated the visual logic of the artifact, and questioned specific characteristics of an IVD, emphasizing that I should clearly state what these characteristics are and why my model is applicable in this context. It was also suggested to include more aspects related to prototyping and validation, reflect on the use of the word "ecosystem" in the model, incorporate all the concepts used, add clinical components in the gates, and consider that developing an IVD requires distinct competencies. |
| Expert 3 | NPD | Review the initial stages of development and how I am naming each of them, in order to ensure greater conceptual accuracy; incorporate the concepts of development funnel, lean startup, and design thinking; reorganize the order of the MVP; adjust the activities according to the actions defined in the gates; conceptually define the stages and terms used, possibly using a glossary; include the optimization, stability, and reproducibility phase as a cyclical stage; determine the level of abstraction of the model; make it clear that product development occurs in parallel with technology development, and that TRL scales support |

| | | |
|---|---|---|
| | | technology development and require technological maturity to enable development. |
| Expert 4 | R&D | Importance of contact with experts throughout development; make it clear in the model that we cannot be afraid of "killing" a project; clarify the need to establish partnerships with ICTs and which types of contracts are most beneficial; adapt the TRL scales so they are not generic in healthcare projects; determine the productive capacity and/or productive partner; include the legal team as stakeholders; the model helps map bottlenecks and is a potential material for consultancies. |
| Expert 5 | ANVISA | Explain that the model also contributes to the safety and efficiency of product development through to market; add guiding questions to the gates that indicate risk and uncertainty analysis; replace the term "approved" with "approved by the regulatory agency" to facilitate understanding; include information about production volume; verify the stages of the added ISO standards; define the incorporated market tools; include that, from a regulatory perspective, the product cycle does not end post-market; and clarify that there are differences between project risk management and product risk management. |
| Expert 6 | DSR | Agreed with the definition of the artifact as a model; validated the way the DSR stages were conducted; indicated the need to clearly state when the focus group was conducted and to include, in the appendices, all versions of the model to date, highlighting the changes made; confirm whether the problem class is appropriate; emphasized the importance of the textual explanation of the model; correct actions that are described in the explanation but not clearly represented in the model, such as what happens if the project is blocked at the gates due to immature requirements; include all elements of the model in the legend. |

Source: Prepared by the authors (2025)

Table 2 - The IAMDT tool

**Evaluation of methodological models aimed at the development of technologies - IAMDT**

| 1<br>I totally disagree | 2<br>Disagree | 3<br>Partially disagree | 4<br>Agree | 5<br>Totally agree |
|---|---|---|---|---|

| Mark with an X the question that best represents your answer. | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| **DOMAIN 1 - CONTENT VALIDATION** | | | | | |
| 1 Does the title of the template represent your goals? (Q1) | | | | | |
| 2 Is the supporting text used relevant and applicable to the proposal? (Q2) | | | | | |
| 3 Do the elements used in the model adequately represent the problem it seeks to solve? (Q3) | | | | | |
| 4 Does the model systematically present its steps/stages? (Q4) | | | | | |
| 5 Does the model clearly describe the steps/stages? (Q5) | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 6 Does the name of each step/stage of the model match the content presented? (Q6) | | | | | |
| 7 Are the operational steps sufficiently detailed to allow practical application of the model in healthcare NPD projects? (Q7) | | | | | |
| 8 Are the phases of the model articulated in a logical way, reflecting the realistic flow of *in vitro* medical device development? (Q8) | | | | | |
| 9 Does the model contribute to the construction of knowledge in the area? (Q9) | | | | | |
| 10 Does the model encourage engagement between those involved (researcher, process actors and organizational context) throughout product development? (Q10) | | | | | |
| 11 Does the model offer methodological support and visual/conceptual representation appropriate to the technological development process in health? (Q11) | | | | | |
| 12 Do the language and structure of the model encourage participatory involvement between researchers and other actors in the process? (Q12) | | | | | |
| 13 Does the model provide a systematic rationale for the *in vitro* medical device development process? (Q13) | | | | | |
| 14 Does the model favor the identification and mitigation of critical elements for the development of new products in the area of *in vitro* diagnostics? (Q14) | | | | | |
| **DOMAIN 2 - APPEARANCE VALIDATION** | | | | | |
| 15 Are the illustrations of the model clear and understandable? (legend, symbols or colors used in the model) (Q15) | | | | | |
| 16 Are the visual elements used in the model (shapes, arrows, groupings, flows) appropriate for the purpose and do they facilitate understanding of the proposal? (Q16) | | | | | |
| 17 Is the visual organization of the model consistent with the supporting text, facilitating its interpretation? (Q17) | | | | | |
| 18 Is the visual hierarchy clear (e.g. beginning, middle and end of the process)? (Q18) | | | | | |
| 19 Can the model be easily understood even without additional oral explanation or supporting text? (Q19) | | | | | |
| 20 Is the structure and size of the model suitable for presentation, publication or internal training purposes? (Q20) | | | | | |

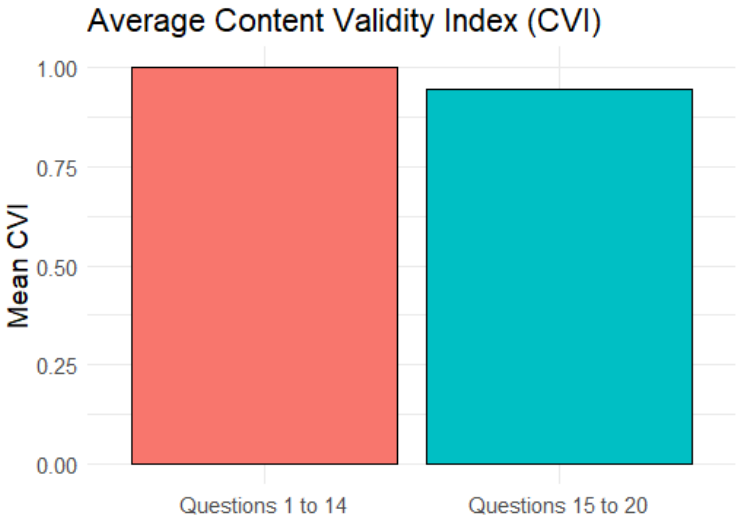
Source: Adapted from Salbego *et al*. (2023)

Table 3 - The IAMDT tool: results

| Question | Mean | Standard Deviation | Content Validity Index (CVI) |
|---|---|---|---|
| Q1 | 4,67 | 0,492 | 1 |
| Q2 | 4,92 | 0,289 | 1 |
| Q3 | 4,67 | 0,492 | 1 |
| Q4 | 4,83 | 0,389 | 1 |
| Q5 | 4,67 | 0,492 | 1 |
| Q6 | 4,83 | 0,577 | 1 |
| Q7 | 4,50 | 0,674 | 1 |
| Q8 | 4,75 | 0,622 | 1 |
| Q9 | 4,92 | 0,289 | 1 |
| Q10 | 4,92 | 0,289 | 1 |
| Q11 | 4,83 | 0,389 | 1 |
| Q12 | 4,50 | 0,522 | 1 |
| Q13 | 4,75 | 0,622 | 1 |
| Q14 | 4,67 | 0,651 | 1 |
| Q15 | 4,25 | 0,965 | 1 |
| Q16 | 4,33 | 0,778 | 1 |
| Q17 | 4,75 | 0,452 | 1 |
| Q18 | 4,75 | 0,452 | 1 |
| Q19 | 3,42 | 0,793 | 0,667 |
| Q20 | 4,50 | 0,522 | 1 |

Source: Prepared by the authors (2025)

Figure 1 - Average Content Validity Index (CVI) Scores by Scale Sections

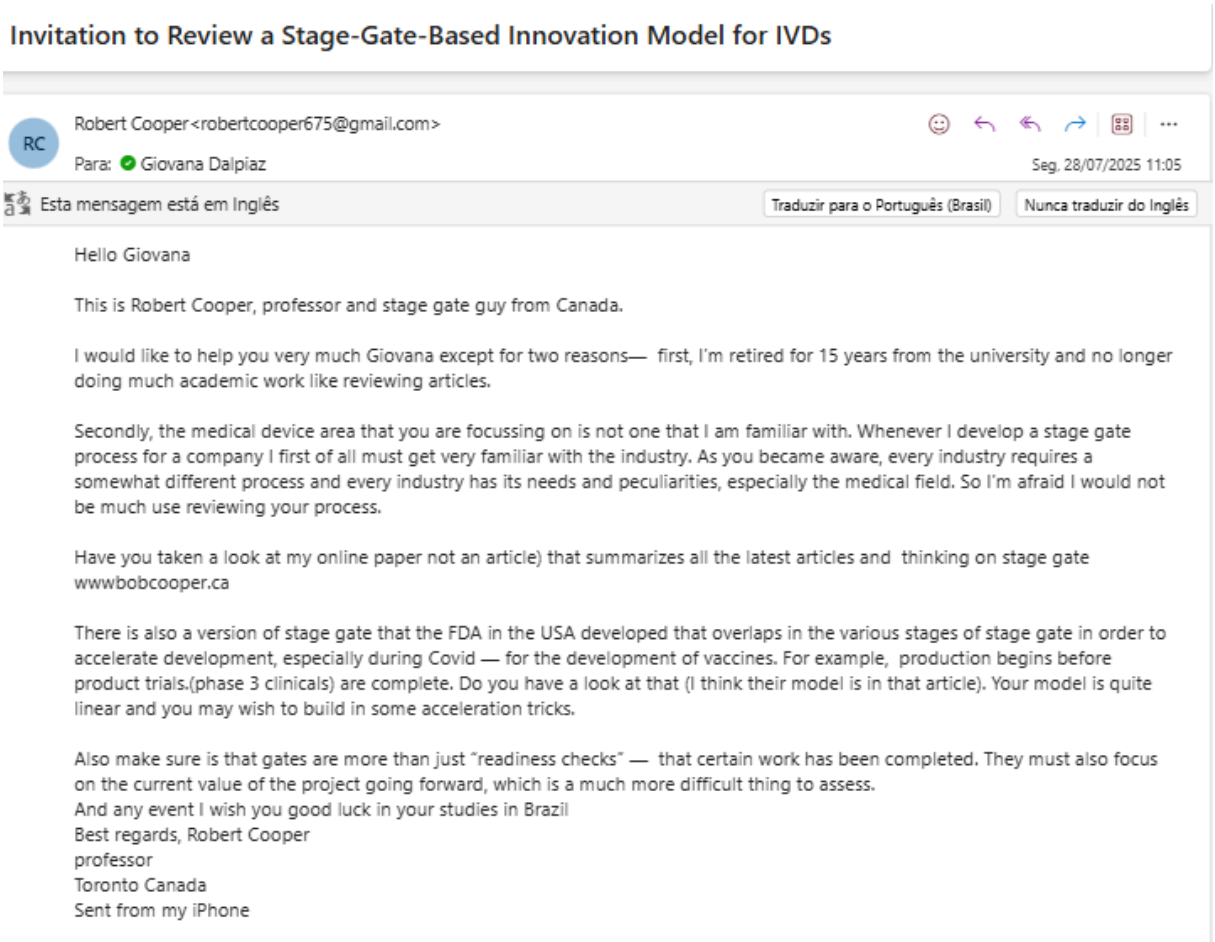



Source: Prepared by the authors (2025)

# APPENDIX J – EXPERT FEEDBACK: ROBERT COOPER (CREATOR OF THE STAGE-GATE MODEL)

The contact with Robert Cooper was made via email, presenting the developed model (version 2) and requesting his expert opinion. Below is the feedback received, which contributed to the critical reflection and validation of the proposed approach (Figure 1).

Figure 1 - Email feedback from Robert Cooper



**Invitation to Review a Stage-Gate-Based Innovation Model for IVDs**

RC Robert Cooper<robertcooper675@gmail.com>

Para: Giovana Dalpiaz — Seg, 28/07/2025 11:05

Esta mensagem está em Inglês — Traduzir para o Português (Brasil) — Nunca traduzir do Inglês

Hello Giovana

This is Robert Cooper, professor and stage gate guy from Canada.

I would like to help you very much Giovana except for two reasons— first, I'm retired for 15 years from the university and no longer doing much academic work like reviewing articles.

Secondly, the medical device area that you are focussing on is not one that I am familiar with. Whenever I develop a stage gate process for a company I first of all must get very familiar with the industry. As you became aware, every industry requires a somewhat different process and every industry has its needs and peculiarities, especially the medical field. So I'm afraid I would not be much use reviewing your process.

Have you taken a look at my online paper not an article) that summarizes all the latest articles and thinking on stage gate wwwbobcooper.ca

There is also a version of stage gate that the FDA in the USA developed that overlaps in the various stages of stage gate in order to accelerate development, especially during Covid — for the development of vaccines. For example, production begins before product trials.(phase 3 clinicals) are complete. Do you have a look at that (I think their model is in that article). Your model is quite linear and you may wish to build in some acceleration tricks.

Also make sure is that gates are more than just "readiness checks" — that certain work has been completed. They must also focus on the current value of the project going forward, which is a much more difficult thing to assess.
And any event I wish you good luck in your studies in Brazil
Best regards, Robert Cooper
professor
Toronto Canada
Sent from my iPhone

Source: Prepared by the authors (2025)

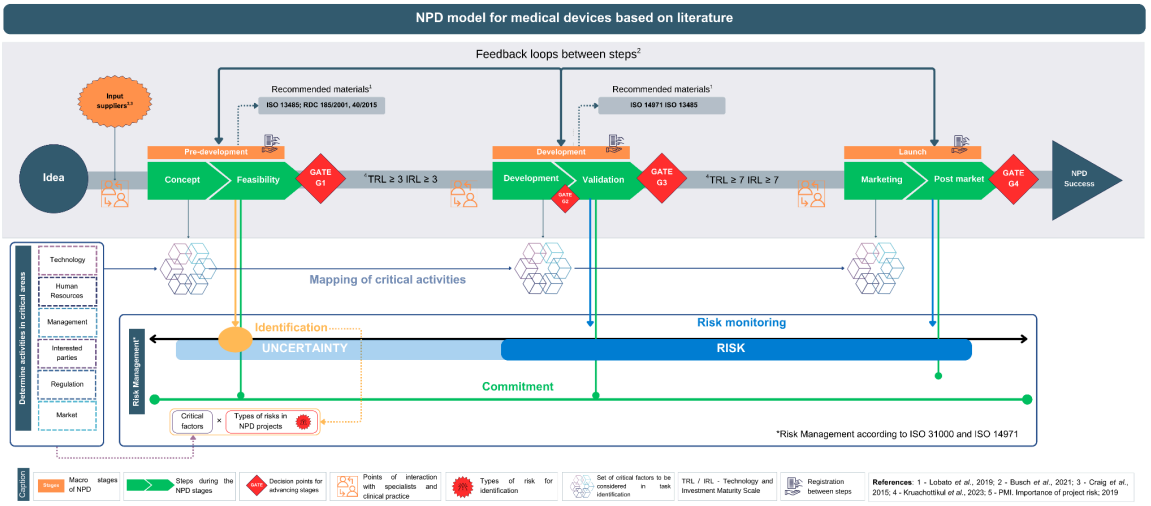
# APPENDIX K – DOCUMENTATION OF ARTIFACT EVOLUTION

The figures below show the artifact's version history, accompanied by a brief description of the modifications made in each version.

- **Version 1: Literature-Based Model**

Figure 1 shows the first version of the model, which served as a preliminary version for further adjustments and refinements.

Figure 1 - Model version 1

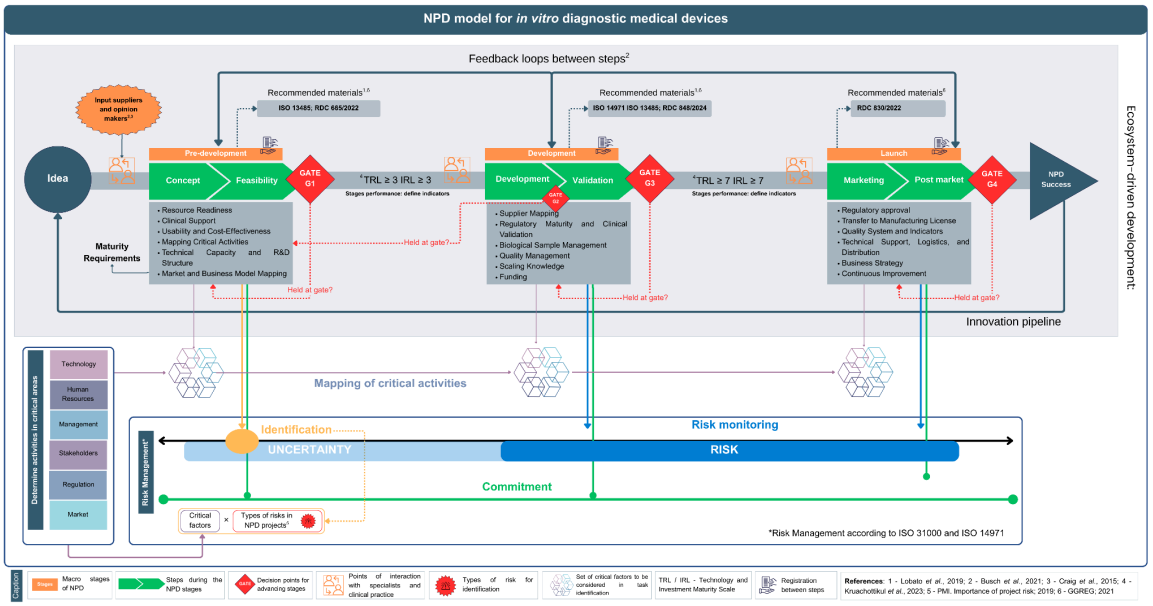



Source: Developed by the authors (2025).

- **Version 2: Literature-Based Model and Data Collection**

In the second version (Figure 2), several improvements were made, including the inclusion of maturity requirements and the reassessment of gates, the introduction of the innovation pipeline concept, the establishment of interactions between stakeholders, and the need to define indicators.,

Figure 2 - Model version 2

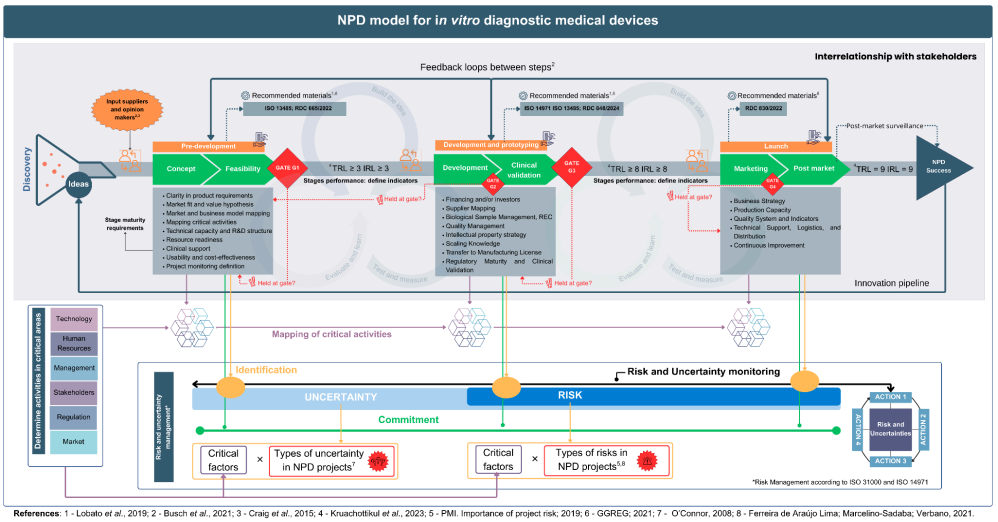



Source: Developed by the authors (2025).

- **Version 3: Model Evaluated by Experts and Focus Group**

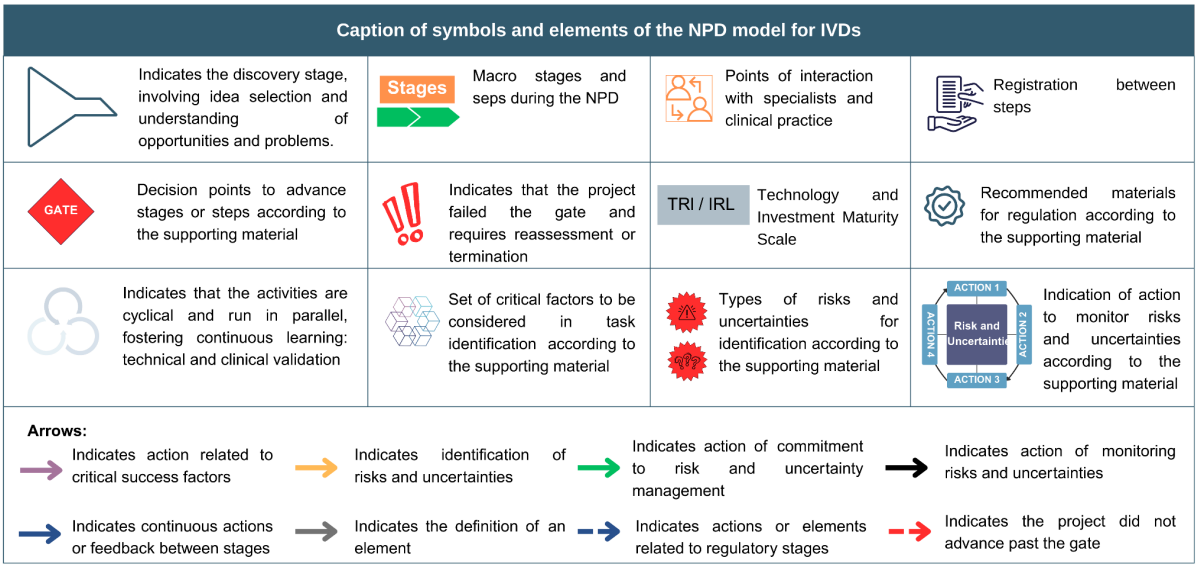
The third version (Figure 3 and Figure 4) of the model represented the last structural modification, including interactive cycles, improvements in risk and uncertainty management, the inclusion of post-market regulatory monitoring, the introduction of a Discovery stage and the prototyping stage along with the development, and a clearer presentation of captions.

Figure 3 - Model version 3




Source: Developed by the authors (2025)

Figure 4 - Model version 3: captions




Source: Developed by the authors (2025)

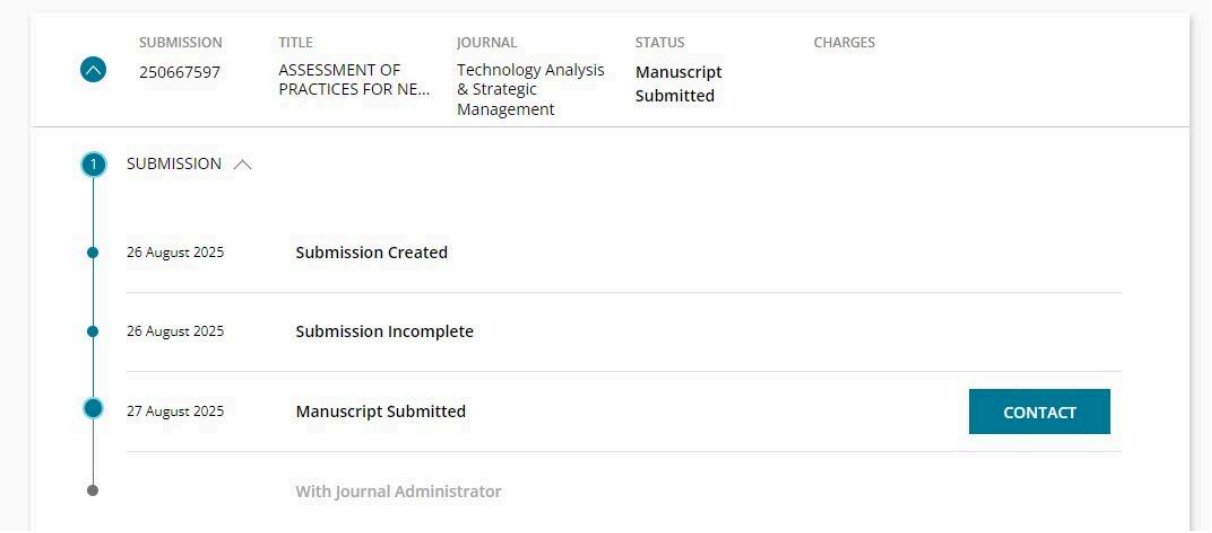
- **Version 4: Model Developed with Supporting Material**

The fourth and final version of the model included the inclusion and development of supporting materials, focusing on the application of the artifact in real-world contexts, as well as the creation of a glossary to facilitate understanding of the terms used. The final version of the artifact is available in Appendix O.

## APPENDIX L – PROOF OF SUBMISSION OF ARTICLE 1

The first article of this dissertation was submitted to journal Technology Analysis & Strategic Management in August 2025 and is currently under review. The submission receipt is presented in Figure 1.

Figure 1 - Proof of submission of Article 1




Source: Prepared by the authors (2025)

## APPENDIX M – CRITICAL EVALUATION OF NPD MODELS FOR MEDICAL DEVICE

This appendix presents a critical evaluation of New Product Development (NPD) models applied to the medical device sector. The analysis was carried out as part of the theoretical framework for the second article of this dissertation. Table 1 provides a structured comparison of selected models based on several dimensions, including their purpose and application, NPD stages, development and contributions, and the presence of critical elements such as regulatory considerations, risk management, market focus, and stakeholder involvement.

Table 1 - Comparison of NPDs models aimed at the medical device sector

| Reference | Purpose and application | NPD Stages | Development and contribution | Presence of elements | | | |
|---|---|---|---|---|---|---|---|
| | | | | Regulation | Risk | Market | Stakeholders |
| Guérineau, 2024 | Explore and propose an approach for the development of smart medical technologies, combining engineering systems and agile methods | Ideation, development, validation, launch | Based on the literature, the model proposes a hybrid approach that integrates systems engineering with Scrum's flexibility and iterativity | Not | Yes | Yes | Not |
| Marešová *et al*., 2020 | Provide a model that supports economic evaluation during development, using economic methods to facilitate decision-making and optimize resources. | Concept, design and development, verification and validation, production and market device deployment | Combining literature and expert input, the model streamlines financial management and standardizes cost assessment from conception to market entry | Not | Yes | Yes | Not |
| Busch *et al*., 2021 | A model to optimize and accelerate medical device development through agile, efficient innovation processes that quickly respond to technological advances, clinical | Problem definition, solution finding, development, design, validation, pre-commercializatio | Based on literature review, empirical data, and model validation, the main contribution is a framework that integrates technical, organizational, and managerial factors to identify critical | Not | Not | Yes | Yes |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | trends, and regulatory demands | n, launch and monitoring | points. | | | | |
| Lobato *et al*., 2019 | Systematizes best practices for medical equipment development in Brazil, organized by phases and functions to ensure compliance, risk management, and efficiency | Opportunity, concept, design, verification and validation, design transfer and product launch | Based on standards and case studies, the model structures development into phases, functions, and tools, streamlining certification and reducing rework | Yes | Yes | Yes | Not |
| Ocampo; Kaminski, 2019 | Provide a structured approach tailored to the specific needs of companies, facilitating the integration of multidisciplinary knowledge, ensuring regulatory compliance and increasing the chances of technical and commercial success of the product | Concept, development and launch | The model was developed through a literature review and analysis of existing medical device development practices. Its contribution lies in adapting to the needs of small and medium-sized companies, considering the sector's regulatory and technical complexity | Not | Yes | Not | Yes |
| Craig *et al*., 2015 | Provide a framework that enables companies to effectively identify, interact with, and integrate relevant stakeholders throughout the development process | Identify, interact and integrate | Developed from a literature review, this study proposes a conceptual model that explains the drivers of stakeholder integration in NPD and the key capabilities required for effective implementation | Not | Not | Not | Yes |
| Songkajorn; Thawesaengskulthai, 2014 | Provide a systematic framework for the development of medical devices and conduct technological innovation in a structured and sustainable manner, promoting value creation and the transfer of multidisciplinary knowledge | Preliminary systematic analysis, risk management, conceptualization, clinical development, production and marketing | Developed from case studies and literature, the MDI model provides a practical framework for medical device development, integrating internal and external factors. | Yes | Yes | Not | Not |
| Medina; Kremer; Wysk, 2013 | Develop and validate a conceptual model for the medical device development process, integrating the development phases and regulatory requirements | Pre-development, development and launch | It combined theoretical elements with case study validation, providing a global view of the development cycle | Yes | Yes | Yes | Not |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Pietzsch *et al*., 2009 | Provides a structured view of the medical device development process, from design to post-market evaluation, serving as a reference for best practices, standard procedures, and strategic decisions across the product lifecycle. | Opportunity, concept and feasibility, design and development, product launch preparation, launch and post-launch | Built and validated with empirical data, the model emphasizes the importance of regulatory frameworks and the product lifecycle, enabling early integration of regulatory, clinical, and commercial aspects. | Yes | Not | Yes | Not |

Source: Developed by the authors (2025).

## APPENDIX N – RSTUDIO SCRIPTS FOR DATA PROCESSING AND ANALYSIS

Table 1 provides the R scripts used for data analysis in this study. All analyses were conducted in RStudio version 4.4.2 and include procedures for profiling companies and interviewees, analyzing challenges and success factors in new product development, exploring learning curves, generating word clouds, identifying critical factors, performing scale analysis, and assessing content validity using the Content Validity Index (CVI). These scripts support the reproducibility and transparency of the research findings.

Table 1 - Summary of R Scripts Used for Data Analysis

| Data Analysis Topic | Script |
|---|---|
| Company profile | # Sample dataset creation<br>dados <- data.frame(<br>  CompanySize = c(rep("Startup", 4),<br>  rep("Medium-sized company", 1),<br>  rep("Small company", 1),<br>  rep("Large company", 1)),<br><br>  Experience = c(rep("1 to 10 years", 6),<br>  rep("11 to 20 years", 1)),<br><br>  Products = c(rep("1 to 5 products", 5),<br>  rep("More than 10 products", 2))<br>)<br><br># Alluvial plot generation<br>ggplot(dados, aes(axis1 = CompanySize, axis2 = Experience, axis3 = Products)) +<br>  geom_alluvium(aes(fill = CompanySize), width = 1/12) +<br>  geom_stratum(width = 1/12, fill = "gray90", color = "black") +<br>  geom_text(stat = "stratum", aes(label = after_stat(stratum)), size = 3) +<br>  scale_x_discrete(limits = c("Company Size", "Experience", "Products Developed"), expand = c(.05, .05)) +<br>  theme_minimal() +<br>  labs(title = "Interviewees' Company Profile: Size, Experience, and Product Development") |
| Interviewee profile | # Load necessary libraries<br>library(ggplot2)<br>library(ggalluvial)<br><br># Manually expanded dataset for 7 interviewees<br>dados_expandido <- data.frame(<br>  Formacao = c("PhD", rep("Master's", 5), "Specialization"), |

| | |
|---|---|
| | Profissao = c("Biologist", "Medical", "Biomedical", "Biomedical", "Biologist", "Engineer", "Biomedical Engineer"),<br>Cargo = c("CEO", "Head R&D", "CEO", "Medical director", "Sales", "Head R&D", "CEO"),<br>Experiencia = c("1 to 3 years", "3 to 5 years", "More than 5 years", "More than 5 years",<br>"More than 5 years", "More than 5 years", "More than 5 years"),<br>Genero = c("feminine", "masculine", "masculine", "masculine", "masculine", "masculine", "feminine")<br>)<br><br># Verify if the data is in alluvial form<br>is_alluvia_form(dados_expandido, axes = 1:5)<br><br># Generate the alluvial plot with five axes<br>ggplot(dados_expandido, aes(axis1 = Formacao, axis2 = Profissao, axis3 = Cargo, axis4 = Experiencia, axis5 = Genero)) +<br>geom_alluvium(aes(fill = Formacao), width = 1/12) +<br>geom_stratum(width = 1/12, fill = "gray90", color = "black") +<br>geom_text(stat = "stratum", aes(label = after_stat(stratum)), size = 3) +<br>scale_x_discrete(limits = c("Academic Background", "Profession", "Position", "Experience", "Gender"), expand = c(.05, .05)) +<br>theme_minimal() +<br>labs(title = "Interviewees' Profile: Academic Background, Profession, Position, Experience, and Gender") |
| Analysis of challenges in NPD | desafios$`interviewee's speech`# para verificar a coluna que será utilizada na primeira análise<br>library(tm) #chamar o pacote que deve ser utilizado<br>library(dplyr)<br>corpus <- Corpus(VectorSource(curva$`interviewee's speech`))<br>corpus <- corpus %>%<br>tm_map(content_transformer(tolower)) %>% # tudo minúsculo para a análise<br>tm_map(removePunctuation) %>% # remove pontuação<br>tm_map(removeNumbers) %>% # remove números<br>tm_map(removeWords, c("development","things", "new","already","today","first","much", "today", "one", "always","also","doesnt", "truly", "able","good", "thats","can", "think", "will", "dont", "life", "thing","right", stopwords("english"))) %>% # remove stopwords e |

```
palavras comuns demais
  tm_map(stripWhitespace)                    # remove
espaços extras
dtm <- DocumentTermMatrix(corpus) #criar a matriz de
termos
dtm <- removeSparseTerms(dtm, 0.95) #remover os termos
esparços
dim(dtm) # aponta numero de documentos/discursos e
termos na análise

library(topicmodels) #pacote para que seja possivel dividir
em tópicos os termos

k <- 3  # número de tópicos (ajuste conforme necessidade)
set.seed(1234)
lda_model <- LDA(dtm, k = k)
terms(lda_model, 4) #aqui define-se quantas palavras
devem ser trazidas em cada tópico

theta <- posterior(lda_model)$topics

dominant_topic <- apply(theta, 1, which.max)
dados$Topic <- dominant_topic

topic_names <- c(
  "Qualidade Técnica",
  "Mercado",
  "Regulação e Certificação"
)

dados$Topic_Name <- topic_names[dados$Topic]


library(umap)
library(ggplot2)
umap_config <- umap.defaults
umap_config$n_neighbors <- 3  # precisa ser < 7

umap_result <- umap(theta, config = umap_config)
plot_df <- data.frame(UMAP1 = umap_result$layout[,1],
                      UMAP2 = umap_result$layout[,2],
                      Tópico = dados$Topic_Name)

ggplot(plot_df, aes(x = UMAP1, y = UMAP2, color =
Tópico)) +
  geom_point(size = 4) +
  theme_minimal() +
  labs(title = "Distribuição dos Discursos por Tópico
(UMAP)",
```

| | |
|---|---|
| | x = "UMAP 1",<br>y = "UMAP 2") |
| NPD success analysis | library(tm)<br>library(dplyr)<br>library(topicmodels)<br>library(umap)<br>library(ggplot2)<br><br># Prepare corpus from interviewees' speech on "success"<br>corpus <- Corpus(VectorSource(sucesso$`interviewee's speech`))<br>%>%<br>tm_map(content_transformer(tolower)) %>%<br>tm_map(removePunctuation) %>%<br>tm_map(removeNumbers) %>%<br>tm_map(removeWords, c("success","also","doesnt", "truly", "able","good", "thats","can",<br>"think", "will", "dont", "life", "thing","right", stopwords("english"))) %>%<br>tm_map(stripWhitespace)<br><br># Create Document-Term Matrix and remove sparse terms<br>dtm <- DocumentTermMatrix(corpus)<br>dtm <- removeSparseTerms(dtm, 0.95)<br><br># Fit LDA model with 3 topics<br>set.seed(1234)<br>k <- 3<br>lda_model <- LDA(dtm, k = k)<br><br># Extract top terms per topic<br>terms(lda_model, 4)<br><br># Extract topic distributions and assign dominant topic<br>theta <- posterior(lda_model)$topics<br>dominant_topic <- apply(theta, 1, which.max)<br>dados$Topic <- dominant_topic<br>topic_names <- c("Technical Quality", "Market", "Regulation and Certification")<br>dados$Topic_Name <- topic_names[dados$Topic]<br><br># Apply UMAP for visualization<br>umap_config <- umap.defaults<br>umap_config$n_neighbors <- 3<br>umap_result <- umap(theta, config = umap_config)<br><br>plot_df <- data.frame(UMAP1 = umap_result$layout[,1],<br>UMAP2 = umap_result$layout[,2],<br>Topic = dados$Topic_Name)<br><br># Plot UMAP results colored by topic<br>ggplot(plot_df, aes(x = UMAP1, y = UMAP2, color = Topic)) +<br>geom_point(size = 4) +<br>theme_minimal() + |

| | |
|---|---|
| | labs(title = "Distribution of Speeches by Topic (UMAP)",<br>x = "UMAP 1",<br>y = "UMAP 2") |
| Learning curve analysis | library(tm)<br>library(dplyr)<br>library(topicmodels)<br>library(umap)<br>library(ggplot2)<br><br># Prepare corpus from interviewees' speech on challenges<br>corpus <- Corpus(VectorSource(desafios$`interviewee's speech`)) %>%<br>tm_map(content_transformer(tolower)) %>%<br>tm_map(removePunctuation) %>%<br>tm_map(removeNumbers) %>%<br>tm_map(removeWords, c("development","things", "new","already","today","first","much", "today", "one", "always","also",<br>"doesnt", "truly", "able","good", "thats","can", "think", "will", "dont", "life", "thing","right",<br>stopwords("english"))) %>%<br>tm_map(stripWhitespace)<br><br># Create Document-Term Matrix and remove sparse terms<br>dtm <- DocumentTermMatrix(corpus)<br>dtm <- removeSparseTerms(dtm, 0.95)<br><br># LDA topic modeling with k=3<br>set.seed(1234)<br>k <- 3<br>lda_model <- LDA(dtm, k = k)<br><br># Extract top 4 terms per topic<br>terms(lda_model, 4)<br><br># Posterior topic probabilities and dominant topic assignment<br>theta <- posterior(lda_model)$topics<br>dominant_topic <- apply(theta, 1, which.max)<br>dados$Topic <- dominant_topic<br><br># Assign topic names<br>topic_names <- c("Technical Quality", "Market", "Regulation and Certification")<br>dados$Topic_Name <- topic_names[dados$Topic]<br><br># UMAP dimensionality reduction for visualization<br>umap_config <- umap.defaults<br>umap_config$n_neighbors <- 3<br>umap_result <- umap(theta, config = umap_config)<br><br>plot_df <- data.frame(UMAP1 = umap_result$layout[,1],<br>UMAP2 = umap_result$layout[,2],<br>Topic = dados$Topic_Name) |

| | |
|---|---|
| | # Plot UMAP result colored by topic<br>ggplot(plot_df, aes(x = UMAP1, y = UMAP2, color = Topic)) +<br>  geom_point(size = 4) +<br>  theme_minimal() +<br>  labs(title = "Distribution of Speeches by Topic (UMAP)",<br>  x = "UMAP 1",<br>  y = "UMAP 2") |
| Word cloud by topic | library(wordcloud)<br>library(RColorBrewer)<br><br>beta <- posterior(lda_model)$terms<br>terms <- colnames(beta)<br>k <- nrow(beta)<br><br>for (i in 1:k) {<br>  cat("Topic", i, "\n")<br>  wordcloud(words = terms,<br>  freq = beta[i, ],<br>  max.words = 30,<br>  colors = brewer.pal(8, "Dark2"),<br>  random.order = FALSE)} |
| Identification of critical factors | library(ggplot2)<br>library(dplyr)<br>library(pheatmap)<br>library(RColorBrewer)<br><br># Data frame of critical factors and their frequencies<br>df_fatores <- data.frame(<br>  fator = c("Product Incorporation and Acceptance", "Project Monitoring and Tools", "Decision Making",<br>  "Sample Availability", "Development Delays", "Regulatory Barriers", "Barriers to Innovation Development",<br>  "Technological Complexity", "Suppliers", "Connection with Stakeholders", "Importance of Stakeholders",<br>  "Prior Knowledge and Experience", "Market Assessment", "Structuring the R&D Team",<br>  "Documentation and Data Traceability", "Multidisciplinary Team", "Project Financing and Resources",<br>  "International Suppliers", "Risk Management", "Product Value", "Technology",<br>  "Domestic Market", "Competitiveness and Financial Sustainability", "Regulatory Process and Clinical Validation",<br>  "Intellectual Property"),<br>  frequencia = c(11, 24, 15, 4, 3, 10, 15, 15, 14, 29, 13, 6, 6, 51, 14, 12, 21, 7, 12, 12, 21, 15, 19, 28, 11)<br>)<br><br># Order factors by frequency for plotting<br>df_fatores$fator <- factor(df_fatores$fator, levels = df_fatores$fator[order(df_fatores$frequencia)]) |

| | |
|---|---|
| | # Bar plot with highlighted factors above mean frequency<br>df_fatores <- df_fatores %>%<br>  mutate(above_mean = frequencia > mean(frequencia))<br><br>mean_freq <- mean(df_fatores$frequencia)<br>sd_freq <- sd(df_fatores$frequencia)<br><br>ggplot(df_fatores, aes(x = fator, y = frequencia, fill = above_mean)) +<br>  geom_col() +<br>  scale_fill_manual(values = c("lightblue", "steelblue"), guide = FALSE) +<br>  geom_hline(yintercept = mean_freq, color = "red", linetype = "dashed", size = 1) +<br>  coord_flip() +<br>  labs(title = sprintf("Critical Factors - Frequency Analysis (mean = %.2f, sd = %.2f)", mean_freq, sd_freq),<br>  x = "Critical Factor",<br>  y = "Frequency") +<br>  theme_minimal()<br><br># Chi-square goodness-of-fit test<br>teste_chi <- chisq.test(df_fatores$frequencia)<br>print(teste_chi)<br><br># Prepare data for clustering heatmap<br>rownames(df_fatores) <- df_fatores$fator<br>mat_cluster <- as.matrix(df_fatores["frequencia"])<br><br># Heatmap with hierarchical clustering of factors by frequency<br>pheatmap(<br>  mat_cluster,<br>  cluster_rows = TRUE,<br>  cluster_cols = FALSE,<br>  color = colorRampPalette(brewer.pal(9, "Blues"))(100),<br>  fontsize_row = 10,<br>  main = "Critical Factors Grouped by Frequency",<br>  display_numbers = TRUE,<br>  number_format = "%.0f",<br>  fontsize_number = 10,<br>  border_color = "grey60"<br>) |
| Scale analysis | library(ggplot2)<br>library(dplyr)<br><br>escalas <- data.frame(<br>  Category = rep(c("Challenges", "Efficiency", "Management", "Stakeholders"), each = 2),<br>  Type = rep(c("Maximum", "Minimum"), times = 4),<br>  Value = c(6.57, 5.10, 5.14, 3.14, 6.14, 5.42, 5.85, 5.57),<br>  Description = c(<br>  "Market", "Infrastructure", |

| | |
|---|---|
| | "Communication and Regulation", "Deadlines",<br>"Cost", "Product Quality",<br>"Communication and Suppliers", "Stakeholders at Start"<br>),<br>stringsAsFactors = FALSE<br>)<br><br>escalas$Category <- factor(escalas$Category, levels = c("Challenges", "Efficiency", "Management", "Stakeholders"))<br>escalas$Value <- as.numeric(escalas$Value)<br><br># Calcular média de Value por Category<br>media_por_categoria <- escalas %>%<br>group_by(Category) %>%<br>summarise(Media = mean(Value))<br><br>print(media_por_categoria) # Exibe a média calculada<br><br>ggplot(escalas, aes(x = Category, y = Value, group = Type, color = Type)) +<br>geom_line(linewidth = 1.2) +<br>geom_point(size = 4) +<br>ylim(0, 7) +<br>labs(title = "Average of Maximum and Minimum Values by Category",<br>x = "Categories of the Scales",<br>y = "Average Value",<br>color = "Type of Average") +<br>scale_color_manual(values = c("Maximum" = "#1f78b4", "Minimum" = "#33a02c")) +<br>theme_minimal(base_size = 16) +<br>theme(<br>axis.text.x = element_text(angle = 45, hjust = 1, size = 14, face = "bold"),<br>axis.title = element_text(size = 16, face = "bold"),<br>legend.title = element_text(size = 14),<br>legend.text = element_text(size = 13)<br>) |
| CVI Assessment | # Content Validity Index (CVI) Calculation<br># ----------<br># Required packages<br>library(dplyr)<br>library(tidyr)<br><br># ----------<br># Parameters<br># ----------<br># Define the agreement threshold (e.g., ≥ 3 on a 1–4 scale)<br>agreement_threshold <- 3<br><br># ----------<br># Item-level calculation: mean, standard deviation, and CVI |

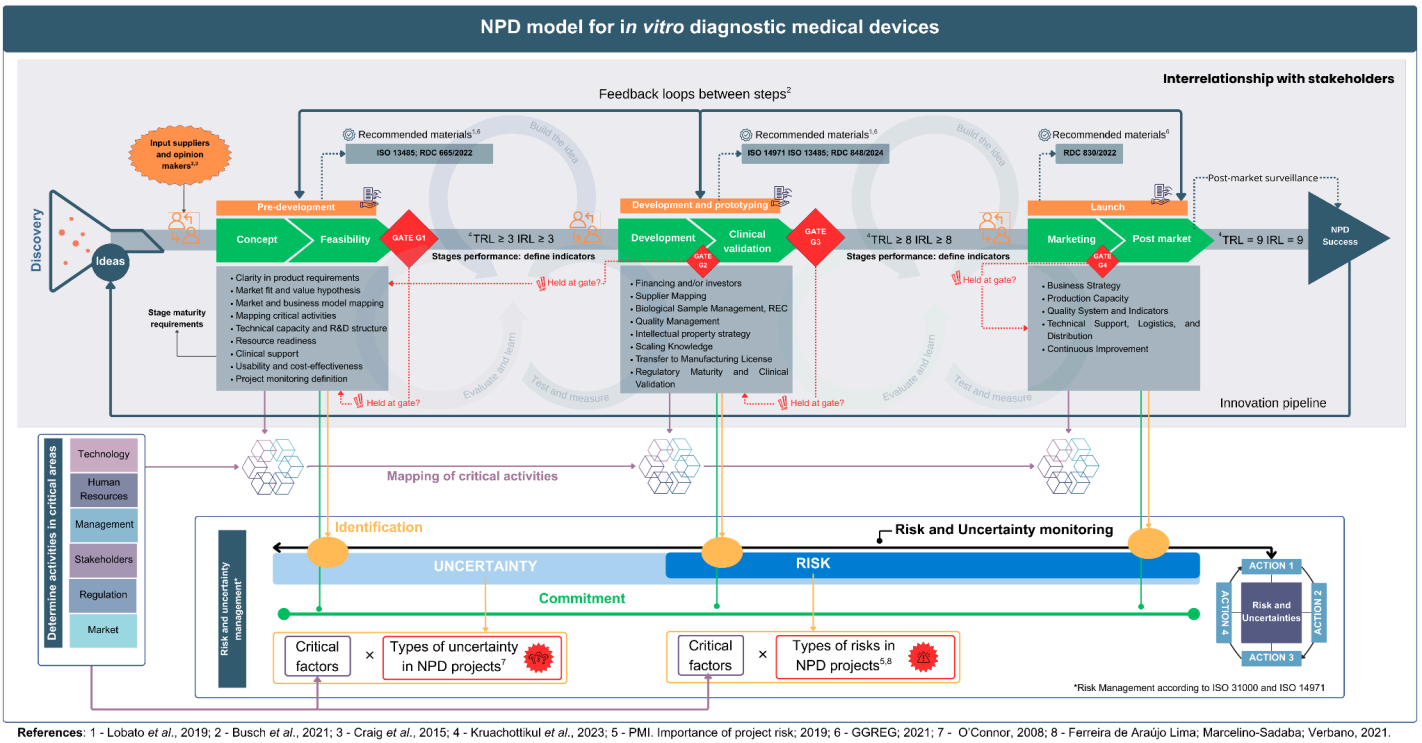
```
# ------------------------------------------
cvi_results <- CVI %>%
  summarise(across(everything(),
                   list(
                     mean = ~ mean(.),
                     sd   = ~ sd(.),
                     cvi  = ~ sum(. >= agreement_threshold) /
length(.)
                   ),
                   .names = "{.col}_{.fn}"
  )) %>%
  pivot_longer(cols = everything(),
               names_to = c("Item", ".value"),
               names_sep = "_")

# ------------------------------------------
# Global CVI calculation (average of item CVIs)
# ------------------------------------------
global_cvi <- mean(cvi_results$cvi)

# ------------------------------------------
# Display results
# ------------------------------------------
print(cvi_results)
cat("\nGlobal CVI:", round(global_cvi, 2), "\n")

# ------------------------------------------
# Interpretation:
# CVI values ≥ 0.80 indicate satisfactory content validity
# ------------------------------------------
```

Source: Developed by the authors (2025).

# APPENDIX O – FINAL ARTIFACT

The final version of the model includes the development of materials applicable in practice for the development of *in vitro* products. Thus, in addition to providing the NPD model (Figure 1), the following resources and supporting materials were developed: caption of symbols and elements of the model. guiding questions and gates for each stage of development, a compilation of regulatory standards, an approach for risk and uncertainty management, and a glossary with definitions of key terms used. It is worth noting that data from Article 1 of the dissertation, such as the list of critical activities, can also be used as a resource, and these materials may be further enhanced in the future.

Figure 1 - Final version of the artifact



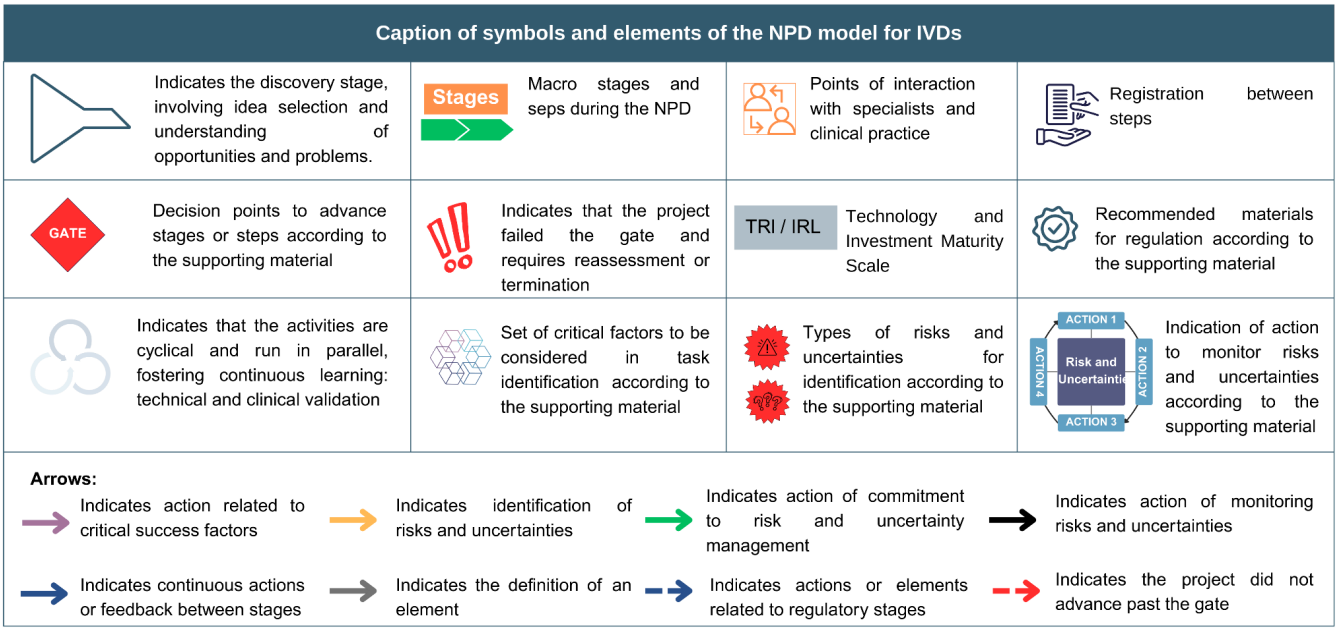

**References**: 1 - Lobato *et al.*, 2019; 2 - Busch *et al.*, 2021; 3 - Craig *et al.*, 2015; 4 - Kruachottikul *et al.*, 2023; 5 - PMI. Importance of project risk; 2019; 6 - GGREG; 2021; 7 - O'Connor, 2008; 8 - Ferreira de Araújo Lima; Marcelino-Sadaba; Verbano, 2021.

Source: Developed by the authors (2025).

- **Part 1 - Caption of symbols and elements of the NPD models for IVDs:**

Figure 2 presents the caption of symbols and elements employed in the proposed NPD model for IVDs. This caption serves as a guide to support the interpretation of the model, clarifying the meaning of each symbol and facilitating its understanding.

Figure 2 - Caption of symbols and elements of the NPD models for IVDs

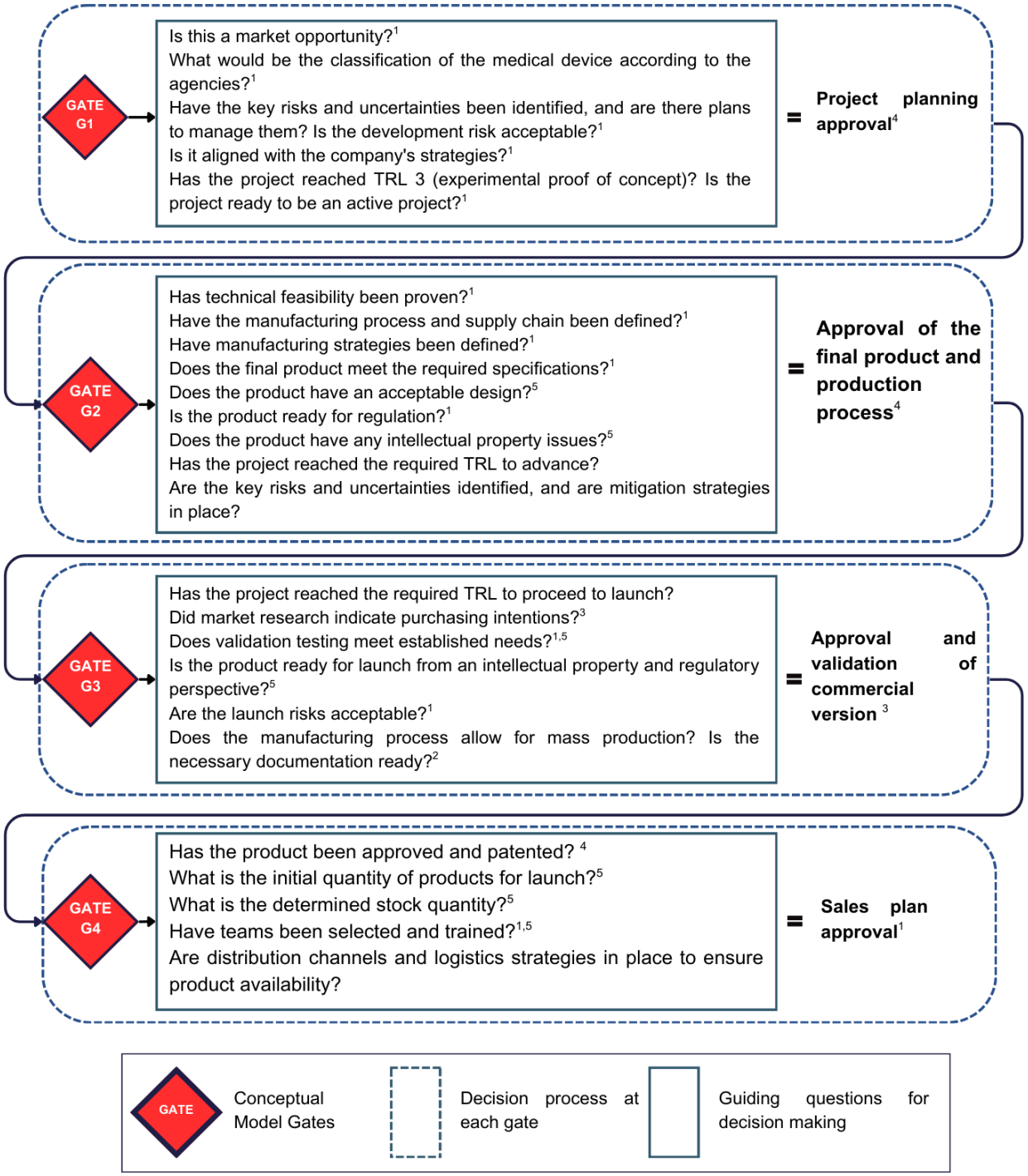



Source: elaborated by the author (2025).

- **Part 2 - Guiding questions and gates for the stages of development:**

In Figure 3 each block indicates the guiding questions for each gate defined in the model and specifies the milestone that must be achieved.

Figure 3 - Gates for the stage of development




Source: Developed by the authors (2025).

- **Part 3 - Regulatory standards:**

Table 1 presents a compilation of laws and standards that should be consulted during the corresponding stage indicated in the table.

Table 1 - Regulatory standards

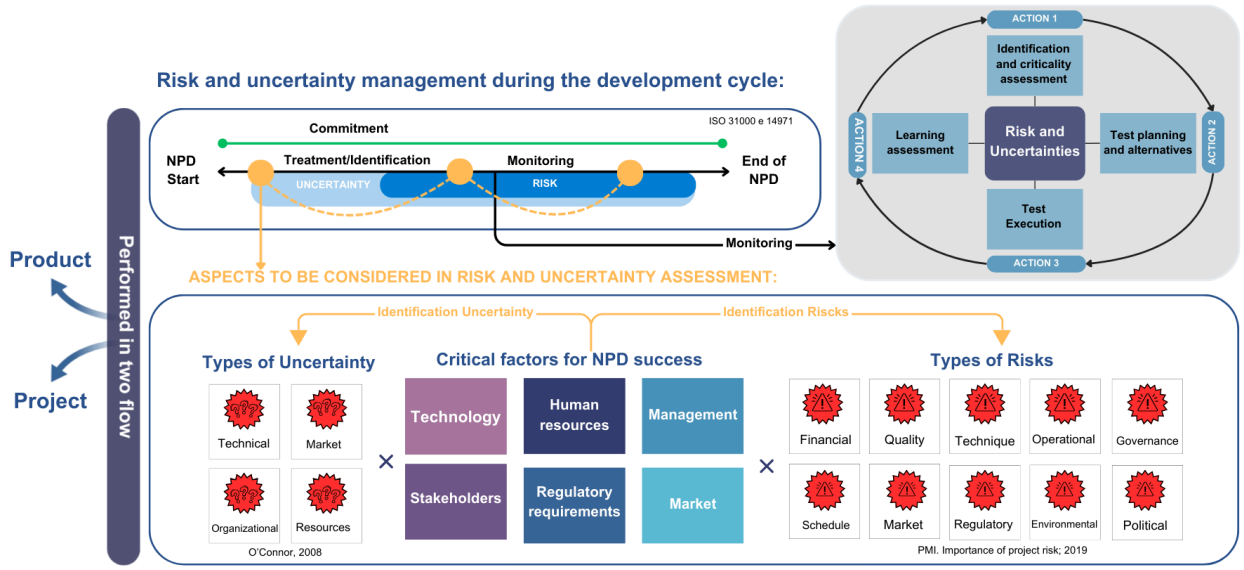
| Standard | Application | Related stage |
|---|---|---|
| Law 9782/1999 | Law that establishes ANVISA aiming to protect the health of the population through the inspection and control of products and services | Pre-development and development |
| RDC 665/2022 | Strengthens quality and safety control throughout the lifecycle of medical and IVD products | Pre-development, development and launch |
| RDC 830/2023 | Defines specific rules for the risk classification of IVDs | Pre-development and development |
| RDC 848/2024 | Establishes essential safety and performance requirements for all medical devices and IVDs | Pre-development, development and launch |
| ISO 14971:2020 | Establishes procedures for risk management in medical devices | Pre-development, development and launch |
| IEC 62366 | International standard that establishes the usability engineering process for medical devices, focusing on user safety and risk mitigation | Development |
| ISO 23640:2011 | Stability assessment of IVD reagents | Development |
| ISO 13485:2016 | Establishes the requirements for a quality management system (optional) | Development |
| IEC 61010-1:2010 | International standard that establishes safety requirements for electrical equipment for measurement, control and laboratory use. | Development |
| ISO 15223-1:2022 | Establishes general requirements for the use of symbols on medical devices, with the aim of providing clear and understandable information to users | Development |

Source: Collected based on ANVISA material (ANVISA; 2025).

- **Part 4 - Risk and uncertainty management:**

Figure 4 provides a detailed view of the model's risk and uncertainty management, presenting the approach for identification, monitoring, and commitment to managing these elements. This approach is based on a confrontation matrix, designed to enhance the coverage of identified risks and uncertainties by cross-referencing their typologies with the critical factors, both shown in the figure. In addition, it proposes a monitoring process structured into four actions: i) identification and assessment of criticality; ii) testing of plans and alternatives; iii) execution of mitigation strategies; and iv) evaluation, learning, and periodic repetition of the cycle.

Figure 4 - Risk and uncertainty management




Source: Prepared based on Kheir; Jacoby; Verwulgen (2022) and Ferreira de Araújo Lima; Marcelino-Sadaba; Verbano, 2021

- **Part 5 - Glossary:**

Table 2 presents a glossary prepared based on the "flexmethod4innovation" tool and metabook, bringing together the main terms used in the developed model.

Table 2 - Glossary

| Category | Element | Definition | Reference |
|---|---|---|---|
| Stages, stages of development | Discovery | Set of activities organized with the aim of deeply understanding users' needs and desires, identifying problems and opportunities, and generating valuable insights that will guide the development of innovative solutions. | O'Connor, 2008 |
| | Idea | Related to the central concept of innovation as a process that starts from specific opportunities, challenges or demands of the current situation or the vision of a future situation. | FlexM4i, 2024 |
| | Pre-development | This refers to the initial activities of the innovation and product development process, often referred to as the "fuzzy front-end," and includes activities to further define the opportunities and market for the product. | Pietzsch *et al*., 2009 |
| | Concept | It has a well-defined form, including a written and/or visual description, which includes the main features and benefits for the customer combined with a broad understanding of the required technology. | Teza *et al*., 2015 |
| | Feasibility | It refers to assessing the technical feasibility of the product, as it requires demonstrating that the idea is functional through an initial prototype. | Durfee; Iaizzo, 2019 |
| | Development | It refers to the core phase of product creation, characterized by iterative cycles of prototyping, testing, validation, and refinement. This phase integrates technical, regulatory, and market requirements, preparing the product for production and launch. | Alagumalai; Kadambi; Appaji, 2019; Shin *et al*., 2023 |
| | Prototyping | The stage of product development in which functional models or samples are built to test concepts, refine features, and optimize performance before formal validation. | FlexM4i, 2024 |

| | | | |
|---|---|---|---|
| | Clinical validation | The stage where the product undergoes clinical trials to demonstrate safety and efficacy, starting with a pilot phase and followed by a pivotal phase that confirms results for regulatory and market approval. | Lobato *et al*., 2019 |
| | Launch | The stage where, after development and validations, the product is introduced to the market to make the product available to end users, promoting its adoption and competitive positioning. | Kruachottikul *et al*., 2023 |
| | Marketing | The phase that supports and follows product launch. It encompasses preparation for large-scale production, strategic management of market introduction, and continuous monitoring of performance. | Marešová *et al*., 2020; |
| | Post-market | The phase after launch focused on continuous monitoring of safety, performance, and market acceptance, including user feedback, economic analysis, adverse event reporting, and decisions on improvement, continuation, or withdrawal. | Songkajorn; Thawesaengskulthai, 2014 |
| | Post-market surveillance | It is the regulatory phase that begins after market entry. It is focused on continuous monitoring of safety and efficacy in real-world use. It involves gathering evidence, meeting legal obligations, and ensuring sustained product performance. | O'Dwyer; Cormican, 2017 |
| Model symbols | Success | Refers to the introduction of a regulated product into the product that meets clinical needs and contributes to a health problem. | Based on data collection |
| | Maturity requirements | This refers to whether the organizational conditions and capabilities that ensure innovation and requirements management are effective, consistent, and sustainable, favouring the success of product development. | Hood *et al*., 2007 |
| | Interrelationship with stakeholders | Are the individuals and groups who contribute, voluntarily or involuntarily, to its wealth-creating capacity and activities and who are, therefore, the people who potentially receive the benefits and/or run the risks. | Post *et al*., 2002 |

| | | | |
|---|---|---|---|
| | Gates | Decision points incorporated throughout the product development process, where projects are evaluated to determine whether to continue (go) or not (kill). | Cooper, 2018 |
| | TRL / IRL | Technology Readiness Levels (TRL) assess the maturity of a specific technology, ranging from TRL 1 (lowest) to TRL 9 (highest), tracking its development from initial research to full market application. Innovation Readiness Levels (IRL), in contrast, evaluate the broader maturity of an innovation, considering not only technological factors but also organizational, market, and other critical aspects for the success of a solution. | Manning, C, 2023; Kruachottikul *et al*., 2023 |
| | Opinion makers | This involves engaging strategic and clinical consultants to provide insights on clinical needs, usability, regulatory compliance, and practical applicability, supporting the definition of product scope, design, validation, and dissemination. | Carls, 2023 |
| Risks and uncertainties | Risks | Risk can be quantified using probability conditions. That is, we don't know what will happen, but we can establish a distribution of possible outcomes . | Teece & Leih, 2016 |
| | Uncertainties | Uncertainty cannot be quantified since the unknowns are unknown. In other words, we don't know what will happen, nor do we know the possible distribution of possible outcomes. | Teece & Leih, 2016 |
| | Technical or Technique | Completeness and correctness of the underlying scientific knowledge, and the extent to where the technical specifications of the product can be implemented. | O'Connor, 2008 |
| | Organizational | Challenges and unpredictability that arise due to the organization's own dynamics and structure throughout the life cycle of a disruptive innovation. | O'Connor, 2008 |
| | Resources | Related to the availability and stability of resources needed for the project, including funding and core competencies. | O'Connor, 2008 |
| | Market | Related to the market's reaction to innovation, such as understanding | O'Connor, 2008 |

| | | | |
|---|---|---|---|
| | | customer needs, adapting interaction channels and sales models, and positioning the product in relation to the competition. | |
| | Financial | Interest rate fluctuations, financial problems or lack of resources, and any other type of change in the financial situation of the stakeholders. | Ferreira de Araújo Lima; Marcelino-Sadaba; Verbano, 2021 |
| | Quality | Refers to the ability to satisfy customers and the intended or unintended impact on stakeholders. It encompasses not only the function and performance of products and services but also their perceived value and benefit to the customer. | ISO 9000:2015 |
| | Operational | Related changes in technology selection, risks related to materials and equipment, risks related to change requests and their implementation, design risks. | Ferreira de Araújo Lima; Marcelino-Sadaba; Verbano, 2021 |
| | Governance | It is a structured approach to decision-making to define the means by which decisions will be implemented. | ABPMP, 2013 |
| | Political | Related changes in environmental authorizations or governmental authorizations. | Ferreira de Araújo Lima; Marcelino-Sadaba; Verbano, 2021 |
| | Regulatory | Refers to the impact of standards and rules established by the State (at municipal, state, or federal levels) on the population and society as a whole. | Lima, Oliveira & Coelho, 2014 |
| | Environmental | Related changes in environmental authorizations or governmental authorizations. | Ferreira de Araújo Lima; Marcelino-Sadaba; Verbano, 2021 |
| | Schedule | Time-related events occur that affect the project schedule. Time risk often causes the project to take longer than initially anticipated. | Hulett, 1996 |
| Critical factors for success | Critical factors for success | These are strategic decisions, skills, attitudes, and conditions that, when prioritized and optimized, increase the chances of success in innovation projects and deliver real value to the business. | Rockart, 1979 |

| | | | |
|---|---|---|---|
| | Technology | Technical and scientific foundation refers to the essential knowledge and capabilities for medical device development, including technical complexity, technology assessment, clinical trials, and collaboration between academia and industry. | Kirkire; Rane; Abhyankar, 2020; Guerineau, 2024; ; Medina; Kremer; Wysk, 2013; Kruachottikul et al., 2023; |
| | Human Resources | This refers to the technical capabilities needed for R&D teams to operate effectively in innovative environments, where skilled and well-prepared teams are essential to managing uncertainties and the specific demands of the medical device sector. | Alagumalai; Kadambi; Appaji, 2019 |
| | Stakeholders | Stakeholder engagement refers to interaction, communication, and collaboration with all parties involved in product development (healthcare professionals, users, government, and investors). | Medina; Kremer; Wysk, 2013; Kirkire; Rane; Abhyankar, 2020; Busch et al., 2021; |
| | Management | Refers to the planning, execution, and control of development projects. It encompasses time, cost, short product life cycles, process optimization, and risk management to ensure strategic focus, efficient resource use, and a greater likelihood of success. | Russell; Tippett, 2008; Marešová et al., 2020b; Tsai; Wang; Chen, 2023; O'Dwyer; Cormican, 2017; Lobato et al., 2019; |
| | Market | Refers to the external conditions affecting product success, including market size, customer expectations, investment capacity, and competitiveness. These conditions guide product positioning and alignment with real sector demands. | Brooks, 2017; Russell; Tippett, 2008; Barkaoui et al., 2023; Lobato et al., 2019; Shin et al., 2023; Ocampo; Kaminski, 2019. |
| | Regulation | Encompasses the legal and regulatory requirements for the approval, safety, and commercialization of medical devices, essential for ensuring compliance and minimizing the risk of rejection. | Brooks, 2017; Medina; Kremer; Wysk, 2013; Pietzsch et al., 2009; |

Source: Developed by the authors (2025).