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A Systematic Review of Risk Sources in R&D Project Management: Implications for Proactive Mitigation Strategies

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Abstract

Through a systematic review, the study examines critical sources of risk affecting R&D initiatives. Out of an initial pool of 178 articles, 46 studies were selected for detailed analysis. Key risks identified include technological, financial, and management-related uncertainties. The review evaluates proactive mitigation strategies, such as agile methodologies and scenario planning, tailored to the distinct challenges of R&D environments. Findings highlight the significance of stakeholder engagement and the integration of advanced risk analysis tools in improving project outcomes. Additionally, this research proposes a comprehensive framework for understanding and managing risks in R&D, providing actionable recommendations to promote a culture of transparency and continuous learning. The study concludes with suggestions for future research aimed at refining risk management methodologies and enhancing collaboration among stakeholders to address the inherent complexities of R&D projects.

Keywords: Risk management; R&D projects and programmes; Stakeholder engagement; Project complexity; Proactive mitigation; Agile methodologies

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1. Introduction

Innovation is crucial for companies to maintain their competitive edge and create value, especially when compared to traditional methods of product and service development [1]. Therefore, it is essential to explore the elements that contribute to the effective advancement of innovation, focusing on risk management strategies and instruments applicable to innovation projects. According to the ISO 56000:2025 [2] standard, innovation is understood as an organisation's ability to adapt to change, explore new opportunities, and enhance performance through creative approaches.

In a global context marked by rapid technological transformations and intense competition, the ability to innovate and develop new technologies becomes a critical factor for organisational success. Research and Development (R&D) projects and programmes are essential for generating knowledge and creating new products and services; however, the complexity and uncertainty inherent in R&D projects require a robust and flexible project management approach, with risk management as a central component. Effective management of these projects is vital to ensure that investments in R&D yield tangible benefits [3]. Project management provides tools and methodologies for planning, organising, executing, and controlling initiatives, aiming to achieve established objectives [4]. In the context of R&D, project management is even more relevant due to its intrinsic characteristics: complexity, uncertainty, and often challenging deadlines. Risk management involves the identification and mitigation of events that may impact project success [5]. In R&D projects, risks can include technical failures, financial constraints, and collaboration challenges [6]. Effective risk management allows organisations to anticipate problems and increase the likelihood of achieving project objectives, given the potential impacts throughout the project duration [7]. In addition to these risks, it is crucial to bear in mind that the innovative and often uncertain nature of R&D projects can introduce additional variables that complicate the prediction of outcomes [8]. The increasing stakeholder demand for robust risk oversight further reinforces the critical role of risk management in ensuring project success, particularly in light of gaps in existing literature that result in financial losses and reputational damage [9].

This article presents a systematic review of the scientific literature published between 2020 and January 2025, with a focus on the principal sources of risk in research and development (R&D) projects and programmes, particularly within disruptive sectors such as aeronautics and medicine. Beyond these domains, sectors including energy, digital technologies, automotive, and civil construction are also subject to significant risks in their R&D endeavours, as evidenced by recent studies ([10], [11], [12], [13]). In the energy sector, several studies have highlighted regulatory risks associated with green transition initiatives, whereas ethical considerations related to artificial intelligence have emerged as a critical concern within digital technologies. For example, the energy sector faces regulatory and safety risks linked to environmental policies and green transition strategies, while the digital sector deals with ethical risks pertaining to privacy and artificial intelligence. These contexts demonstrate that the principles and strategic approaches outlined in this review are adaptable across multiple industrial landscapes, thereby reinforcing the cross-sector applicability of the proposed analytical framework. The study encompasses all phases of the project lifecycle, identifying risks such as technological uncertainties and planning failures, and evaluates proactive mitigation strategies, including portfolio diversification and agile project management methodologies. Furthermore, the article underscores existing gaps within the literature regarding risk management in R&D and advocates for the development of comprehensive, adaptable methodologies. It also offers practical recommendations for employing advanced risk analysis tools and fostering organisational cultures rooted in transparency.

The overarching objective of this review is to synthesise and categorise the primary sources of risk in R&D projects and to identify the most effective proactive mitigation strategies, thereby providing both a theoretical and practical foundation for enhancing risk management practices within innovation-driven environments.

2. Theoretical background

This section presents the theoretical foundation supporting the systematic review on risk sources and mitigation strategies in R&D. It outlines key concepts in project and risk management, alongside the specific challenges of innovation-driven environments, and provides a framework for analysing the review's findings. Establishing this foundation involves assessing the relevance of robust risk management approaches tailored to the complexities of R&D initiatives. The work of Fortes [9] reinforces both theoretical and practical perspectives, offering valuable insights — particularly for the health and aerospace sectors. Risk management in projects is constantly evolving, benefiting from the integration of diverse theories that enhance the identification, analysis, and mitigation of risks.

Among these theories, Contingency Theory and Stakeholder Theory stand out as fundamental for contextualising the complexities and dynamics involved in risk management. The ideal application of these theories provides managers with a broader foundation to address contemporary challenges in project management.

Contingency Theory suggests that best management practices depend on the situation, indicating that there is no one-size-fits-all approach to risk management; instead, strategies should be adapted to the project's context, environment, and organisational structure [14]. Recent studies, such as that by Mahmud et al. [15], have examined how this theory can be applied to improve the effectiveness of risk management practices, demonstrating that environmental management practices within companies should be customised according to their specific circumstances.

Stakeholder Theory highlights the importance of addressing the needs and expectations of stakeholders in the risk management process. Engaging stakeholders can reveal overlooked risks and create a collaborative environment for effective mitigation. Eyieyien et al. [16] illustrate how stakeholder management impacts the identification and response to risks in large-scale projects. In summary, effective stakeholder management is crucial in large international projects, promoting early engagement, understanding of expectations, improved communication, trust-building, use of local knowledge, and collaborative scenario planning, thereby enhancing flexibility and project success.

A systematic and integrated approach to risk management—comprising identification, assessment, mitigation, and continuous monitoring—is fundamental to ensuring project success across various sectors. Tools such as SWOT analysis and Monte Carlo simulations are instrumental in facilitating comprehensive risk evaluation, while agile methodologies and artificial intelligence (AI) integration further enhance responsiveness throughout the project lifecycle. In healthcare, particularly within R&D projects, risk management assumes heightened importance due to stringent regulations and substantial uncertainties that threaten patient safety and public health [17]. Both the healthcare and other sectors necessitate a proactive, structured approach to effectively manage uncertainties, thereby increasing the likelihood of achieving desired outcomes. The standardisation of project risk management practices is evidenced by frameworks such as ISO 56000:2025 [2], which defines project risk as the probability and impact of not attaining specified objectives, with methodologies like the Plan, Do, Check, Act (PDCA) cycle and Risk Management Plans (RMP) providing structured guidance [19].

Key risk management models include risk identification tools such as Risk Breakdown Structure (RBS) and Failure Mode and Effect Analysis (FMEA) [20], risk assessment techniques like the Risk Assessment Matrix [21], and risk response planning through mitigation strategies [22]. Despite the availability of these techniques, their effective implementation remains a challenge, often due to inadequate stakeholder involvement and infrequent monitoring, which are essential for proactively addressing emerging risks [23]. The success of risk management efforts hinges on integrating activities across the project lifecycle and engaging stakeholders, forming the basis of the holistic approach known as Integrated Risk Management (IRM) [24]. A range of analytical tools—including brainstorming, checklists, probability/impact matrices, event trees, decision trees, and portfolio management—is utilised to assist with risk identification, analysis, response planning, and evaluation. Software solutions such as @Risk, Crystal Ball, and Bayesian networks further enhance risk management and decision-making processes.

3. Method

A systematic literature review was conducted, comprising three phases: search, selection and screening, and detailed content analysis. The methodology followed Pollock and Berge's [25] guidelines to ensure consistency and reliability, with clear scope definition, source identification, critical evaluation, and synthesis. The review focused on publications from 2020 to 2025 to capture recent research, reflecting a period of rapid technological change, market shifts, and socio-economic impacts from events like COVID-19, which influence innovation project management amidst inherent uncertainty and complexity. Limiting the timeframe enhances relevance and reduces methodological variability, facilitating clearer analysis of risks. The study aims to answer: "What are the most significant sources of risk impacting the success of R&D projects and programmes?"

4. Data collection

The literature search, initiated by keyword generation from the scoping review, yielded 178 articles (Fig. 1). These chosen publications are evaluated in accordance with the inclusion-exclusion criteria given in Table1. Following assessment of relevance and quality, 46 were selected for in-depth analysis. Scopus and Web of Science databases were used, employing specific search strings and criteria for peer-reviewed articles, including keywords such as "risk factors", "risk sources", "uncertainty", and "technology".

The string used was (ALL ("risk factors" OR "risk sources" OR "uncertainty" OR "technological risk" OR "financial risk" OR "market risk" OR "regulatory risk" OR "strategic risk" OR "operational risk" OR "project failure") AND TITLE-ABS-KEY ("research and development" OR "R&D projects" OR "innovation projects" OR "technology development" OR "scientific projects") AND TITLE-ABS-KEY ("risk mitigation" OR "risk management" OR "proactive strategies" OR "risk response" OR "uncertainty management" OR "resilience strategies")) AND PUBYEAR > 2019 AND PUBYEAR < 2026 AND (LIMIT-TO (LANGUAGE , "English")) AND (LIMIT-TO (DOCTYPE , "ar")).

Table 1 – Inclusion and exclusion criteria for article.

Articles' Inclusion Criteria	Justification
• Publication year = 2020-2025; • Publication Language = English; • Peer-reviewed journals; • Focus: Risk categories in R&D projects	• To ensure relevance and methodological rigour, only recent, peer-reviewed studies in English were selected. The focus on R&D-specific risks maintains thematic consistency.
Articles' Exclusion Criteria	**Justification**
• No abstract; • Duplicates; • Non-empirical/theoretical studies; • Studies with poorly documented methods.	• Studies lacking abstracts or robust methodologies were excluded to uphold reliability. Non-empirical works (e.g., editorials) were omitted to prioritise actionable insights.
• Non-English publications; • Outdated (pre-2020).	• Non-English texts and outdated studies were excluded to maintain linguistic consistency and contemporary relevance.

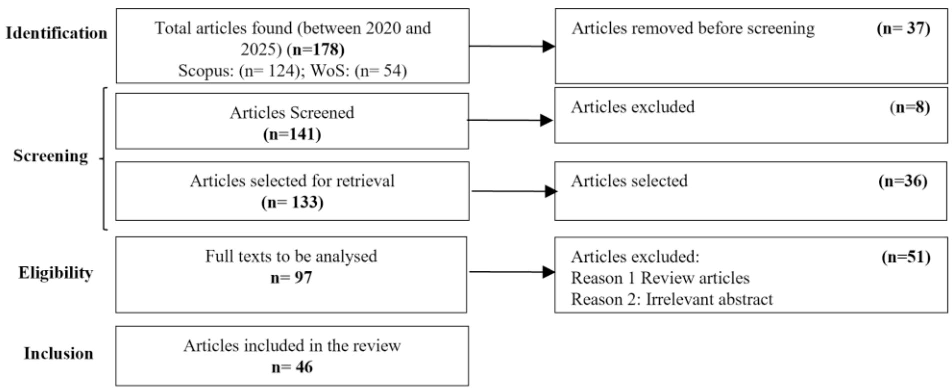

Fig. 1. PRISMA flowchart of article selection. Initial search yielded 178 articles; 46 met final inclusion criteria.

The search was limited to articles published in English-language journals, excluding other publication types such as conference proceedings and books. This process resulted in six separate search queries, yielding 54 documents from Web of Science (WoS) and 124 from Scopus, for a total of 178 documents (see Figure 1). All retrieved records were imported into Mendeley for deduplication. A total of 37 duplicates were removed, leaving 141 documents for review. These were subsequently screened, and a further 8 documents were excluded due to missing abstracts or titles, incorrect classification as journal articles (when they were reports or news items), or because they were duplicates with minor variations in titles or author names. Non-article formats were excluded to ensure that the review was based solely on rigorous, peer-reviewed academic sources. This refinement resulted in 133 documents for screening based on titles and abstracts. During abstract screening, all articles explicitly or implicitly referring to project management or risk were retained. When relevance could not be clearly determined from the abstract or title, the full text was reviewed to confirm suitability. Of these, 36 articles were excluded for not meeting the inclusion criteria, leaving 97 articles for full-text review. After examining the full texts, an additional 51 articles were excluded due to limited relevance to the research objectives, resulting in a final selection of 46 articles for inclusion in the systematic review, as illustrated in Figure 1. This final body of literature provides a comprehensive foundation for the review and offers diverse perspectives on risk and project management in R&D contexts—particularly in health and aerospace. Together, these sources form a robust evidence base for understanding the complexities of risk in R&D projects.

The findings of this review are aimed at both academic discourse and practical guidance, supporting project managers and researchers in addressing the unique challenges associated with executing R&D projects. The next section presents a detailed analysis of the specific literature, highlighting key themes and insights.

5. Study results and findings

In the development of new products, R&D project managers strive to complete projects as quickly as possible while also considering other dimensions of project management, such as cost, quality, and risk.

As highlighted by Azevedo-Sa et al. [26], risks can be categorised into two main types: internal and external. External risks are beyond a company's control and are influenced by external factors in the environment. Understanding these distinctions can help businesses better navigate the challenges they face. On the other hand, internal risks are those that arise within a company and can be addressed through internal management. These risks can be actively managed and mitigated through internal processes.

The study presents a systematic review of the main risks affecting research and development (R&D) projects and programmes, categorising them into external and internal risks (Fig. 2).

External risks, which are inherently difficult to control, can nonetheless be anticipated and managed contingently. Four main subcategories are identified: economic and regulatory, technological disruption, socio-environmental, and geopolitical. Economic and regulatory risks include volatile funding and policy shifts, such as changes in public R&D grants or carbon emission mandates. Technological disruption involves rapid obsolescence of legacy systems, exemplified by semiconductor shortages or patent conflicts. Socio-environmental risks cover public resistance and climate-related delays, while geopolitical risks involve trade restrictions and intellectual property gaps. Internal risks stem from organisational decisions, offering mitigation opportunities through addressing strategic misalignment—such as prioritising blockbuster drugs over niche therapies—operational inefficiencies like resource misallocation, ethical issues including data handling violations, and technical debt, exemplified by reliance on unvalidated methodologies in aerospace software projects.

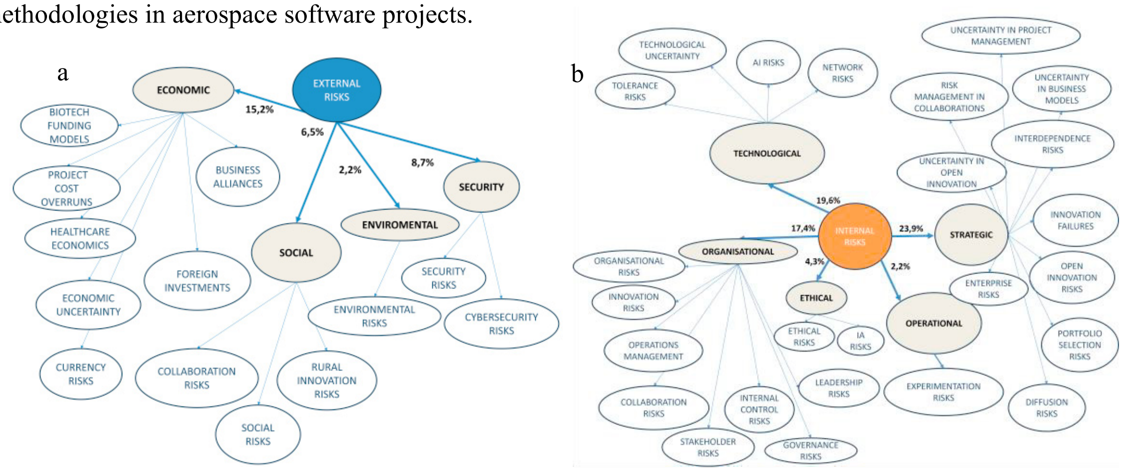

Fig.2. Taxonomy of R&D risks: (a) external risks; (b) internal risks.

Figure 2(a) demonstrates that external risks, accounting for 32.6% of all identified risks, hold a strategic influence over the oversight and success of research and development (R&D) projects. These external risks are categorised into four principal groups: economic risks (15.2%), social risks (6.5%), environmental risks (2.2%), and security risks (8.7%). Economic risks, the most prevalent among external categories, encompass macroeconomic uncertainties, currency fluctuations, funding models—particularly notable in biotechnology—project cost overruns, and risks associated with foreign investments and commercial alliances. Such volatility can directly affect cash flow, financial sustainability, and investment capacity; hence, continuous monitoring of economic indicators and the application of hedging strategies are critical to risk mitigation. Social risks involve issues related to institutional collaboration, strategic alliances, societal concerns, and health economics impacts, which, although less frequent, can substantially influence the accessibility and realisation of innovations, especially within regulated environments or those heavily dependent on external partnerships. The limited research in this domain highlights the necessity for further investigation into how social and collaborative factors impact project outcomes. Environmental risks, including traditional environmental hazards and those linked to rural innovation, constitute a smaller percentage but can cause significant disruptions—particularly in sectors such as agriculture, energy, and biotechnology—when extreme environmental events or regulatory changes occur. The paucity of literature addressing environmental risks in R&D underlines the importance of integrating sustainability practices and environmental impact assessments into comprehensive risk management frameworks. Finally, security risks encompass both physical threats and cyber threats; in an increasingly digitalised landscape, cyber threats pose substantial risks to sensitive data, intellectual property, and project continuity. Implementing robust security policies and regularly updating protocols are essential strategies for effective risk mitigation.

Figure 2(b) provides a detailed taxonomy of internal risks, which constitute 67.4% of the total and have direct, immediate impacts on project outcomes. Five primary categories are identified: strategic risks (23.9%), technological risks (19.6%), organisational risks (17.4%), ethical risks (4.3%), and operational risks (2.2%). Strategic risks, the most significant category, include uncertainties in project management, business models, organisational interdependencies, innovation failures, and risks associated with portfolio selection and open innovation. These risks are multifaceted and require integrated mitigation approaches, such as project scoping, probabilistic modelling, and fuzzy logic, to support decision-making under uncertainty. Technological risks encompass uncertainties related to emerging technologies, AI-related challenges, network vulnerabilities, and fault tolerance issues. The rapid pace of technological advancement and the emergence of new platforms increase complexity, highlighting the need for continuous upskilling and incremental R&D investments. Organisational risks relate to operational management, collaboration, leadership, internal controls, governance, and stakeholder engagement. Ensuring process efficiency, clear communication, and updated governance structures are essential measures to reduce these risks. Ethical risks, although less frequent, are gaining prominence due to heightened concerns over social responsibility, privacy, transparency, and regulatory compliance. Implementing strong ethical codes and conducting regular audits are recommended to mitigate reputational damage.

Operational risks involve challenges in experimentation, dissemination of results, and portfolio management. While less prevalent, these risks can impair project efficiency, especially within highly experimental innovation environments. An integrated analysis confirms that while internal risks are more frequent and manageable, external risks—particularly economic and security-related—can determine R&D project success or failure. Gaps in the literature on environmental and social risks highlight opportunities for future research and the development of more comprehensive risk management frameworks aligned with contemporary demands for sustainability and social responsibility.

6. Discussion

The findings of this review contribute significantly to the theoretical understanding of risk management in R&D projects. By systematically categorising risks into organisational, economic, technological, strategic, ethical, hazardous, and social dimensions, this study offers a comprehensive framework for understanding the complexities involved. However, limitations exist, such as the review's focus on articles published between 2020 and January 2025, which may restrict the generalisability of the findings. Additionally, the predominance of studies from specific sectors like aeronautics and healthcare may not fully represent the diversity of risks encountered across different industries.

To enhance the generalisability of the presented framework, it is recommended that future research incorporate empirical data from a broader range of sectors. Notably, the energy sector presents significant relevance, particularly concerning risks associated with green transition projects, such as policy shifts and grid integration challenges. The digital technologies sector also warrants attention, especially regarding ethical considerations in artificial intelligence and vulnerabilities in cybersecurity within Internet of Things (IoT) systems. The automotive industry, with a focus on research and development risks related to autonomous vehicle technology and battery innovations, constitutes another important area. Additionally, the construction sector, where compliance with sustainability standards in smart infrastructure projects is increasingly critical, offers valuable insights. Incorporating these sectors would serve to validate the framework's cross-sector applicability and facilitate the identification of industry-specific risk mitigation paradigms.

The review emphasises the critical importance of integrating risk management throughout the entire project lifecycle, aligning with contingency theory which advocates for strategies tailored to specific organisational contexts. Stakeholder engagement, supported by Stakeholder Theory, plays a vital role in identifying overlooked risks and fostering collaboration, while advanced analytical tools such as Bayesian networks, Monte Carlo simulations, and quantitative risk analysis are presented as effective methods for assessing and mitigating risks in complex R&D environments. These approaches enable project managers to make informed decisions, develop contingency plans, and increase the likelihood of project success through proactive risk management.

Practically, the findings underscore the need for organisations involved in R&D to adopt structured, proactive risk identification processes supported by mitigation strategies like agile methodologies and continuous monitoring. Cultivating a culture of transparency and integrating risk management into organisational routines are also deemed essential. However, the review highlights limitations regarding its applicability to SMEs, given the focus on larger organisations and methodological diversity, suggesting that further research is needed to develop flexible, context-specific risk management frameworks suitable for various industries and organisational sizes. Future studies should aim to address these gaps, particularly focusing on embedding comprehensive risk practices within the unique challenges of SMEs in complex R&D settings.

To meet this need, a visual model is proposed that synthesizes the main risk categories and tools into a dynamic and adaptable framework for project managers. Fig. 3 illustrates the integrated risk management framework derived from this review.

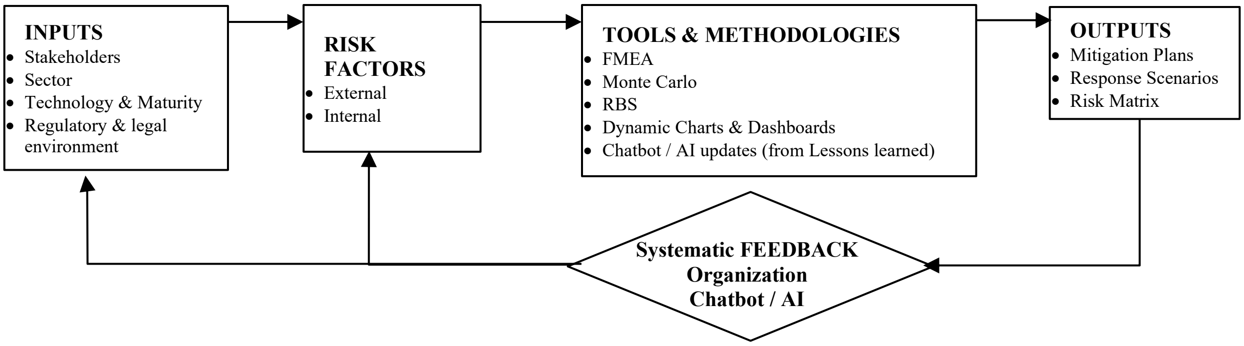

Fig. 3. Integrated framework for proactive risk management in R&D projects.

The integrated model (Fig. 3) links inputs (e.g., stakeholders) to tools (e.g., Monte Carlo) and outputs (e.g., mitigation plans). Its feedback loop enables adaptation to emerging risks, particularly for SMEs. Although the predominant focus of existing literature has been on large organisations, the importance of risk management within SMEs is increasingly recognised, particularly in emerging economies where resource constraints and institutional uncertainties are more pronounced. Studies such as Turgay and Aydin [6] emphasise the necessity for simplified and adaptable frameworks that incorporate agile practices and collaborative mitigation strategies to bolster the resilience of SME-led R&D projects. Empirical research in sectors like Latin American agricultural biotechnology, as illustrated by Bruszies [27], demonstrates that the success of innovative ventures often hinges on agile risk mitigation approaches, including strategic partnerships and stakeholder engagement, which are vital for navigating technological, regulatory, and socio-environmental risks. Furthermore, the integration of digital technologies within risk management frameworks has shown to significantly enhance project success rates in emerging economies such as South Africa, as noted by Sibiya et al. [28]. The adoption of hybrid models combining traditional, agile, lean, and Six Sigma principles has contributed to a reduction in project failures, underscoring the need for flexible and modular risk management approaches tailored to the operational and institutional contexts of SMEs. These insights suggest that future frameworks should foster SME participation in innovation ecosystems by aligning risk mitigation practices with their specific limitations and opportunities, thereby improving their capacity for sustainable growth and competitiveness.

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