



Article

Navigating the Urgency: An Open Innovation Project of Protective Equipment Development from a Quadruple Helix Perspective

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Abstract: This study empirically explores the Quadruple Helix model's potential in facilitating an urgent open innovation project. By examining the life cycle of the project, developed during the COVID-19 pandemic crisis in Brazil, it reveals complex interactions among government, academia, industry, and civil society stakeholders, while also shedding light on the various risks arising from their dynamic collaboration. Employing an approach that combines case study analysis, risk assessment, and theoretical framework development, we unravel the project's evolution, highlighting pivotal elements such as trust, collaboration, communication, agile mindset, stakeholder partnerships, scale, and logistics. Additionally, the study underscores concerns related to finance, time, reputation, and health, which warrant consideration. Risk analysis uncovers internal and external risks and categorizes thirty-two risks, with one deemed unacceptable, thus revealing valuable insights into stakeholders' partnerships, institutional image, public equipment, manufacturing, project management, human resources, intellectual property, regulation, and sanitation risks. Building on these findings, we develop a new framework illustrating the management of the urgent open innovation project through the fast-paced Quadruple Helix formation. By exploring stakeholder collaboration and risk management, this research provides insights into the adaptability and speed required to successfully execute an emergency project, as well as presenting practical strategies for risk management and mitigation, significantly contributing to the domains of the Quadruple Helix and project management research.

Keywords: urgent projects; quadruple helix; risks; stakeholders; open innovation; pandemic; agile mindset; emergency project; agile project; project management



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1. Introduction

The concept of Open Innovation (OI) captures the efforts of organizational relationships to actively pursue external knowledge while also utilizing their internal knowledge externally [1]. To enable this process, establishing interorganizational relationships becomes crucial, as demonstrated by the Quadruple Helix (QH) theoretical model [2–4]. This model encapsulates the participation of firms, universities, governments, and user communities, who collectively engender a dynamic process [5]. The overlap of both OI and the QH model can represent a collaborative approach to generating value for society and organizations [6]. In this context, it is observed that such collaborative efforts in resource and knowledge sharing can lead to enduring advantages across economic, environmental, and social sectors, with a focus on sustainability [7].

Although early research [6–10] has investigated different aspects of Open Innovation with the Quadruple Helix model, normative empirical insights for specific contexts are still limited. Extant contributions in the literature include investigations on smart cities [11], payment system innovation [12], start-up ecosystems [13], knowledge transfer [10], business model and applications [14,15], as well as innovation and technology environments [8,16,17]. In this sense, the QH model appears as a manifestation of Open Innovation cooperating in the same sector [18].

Some authors [7] explore the role of Open Innovation in attaining sustainability amid the ongoing Fourth Industrial Revolution. The authors clearly emphasize the necessity for case studies to enrich the open innovation micro-dynamics model with quadric-helices as the way to achieve sustainability. More centrally, despite the extensive body of knowledge on healthcare and medical innovation as a response to the COVID-19 pandemic and the research conducted on risk management, there have been only a few studies so far that combine a QH model with risks, including explicitly analyzing natural and man-made disasters [3] and healthcare [4]. Moreover, adopting the Quadruple Helix framework in the context of urgent projects from the stakeholders' perspective remains unexplored in the literature, offering promising opportunities for investigation.

Urgent projects [19–21] encompass various scenarios, such as: (i) natural disasters, e.g., floods [21], earthquakes [22], forest fires [23], rock-fall protection [22], and ice disasters [24]; (ii) infectious diseases, such as a pandemics in the context of construction [25,26] or healthcare [27]; and (iii) infrastructure failure, e.g., power supply restoration [21], post-disaster reconstruction [28], or war situations [29]. Urgent projects are unique and critical initiatives that demand rapid action and collaboration among stakeholders. Within this context, emergency projects can be identified as a particular type of urgent projects, with the former occurring in an emergency, or in otherwise risky or disruptive contexts [30]. Some authors [27] reinforce this perspective on emergency situations.

Though the literature [19,27,31,32] addresses the subject of emergency projects, it fails to provide a clear definition. An emergency can be described as a sudden severe/dangerous event or situation that requires immediate action [33]. Moreover, an emergency situation refers to an extraordinary nonmilitary event that, by scale and intensity, poses a significant threat to the lives and health of the population, to the environment, to essential materials, and to cultural values [31]. Resolving such situations requires urgent measures and actions, allocating additional resources, and coordinating the management of forces and resources [31]. In extraordinary non-military events, the theory suggests that there is an urgent project subcategory, High Intensity and Time Sensitive Projects [20], that can occur in extreme contexts [30].

The emergence of the COVID-19 pandemic presented a fertile environment to explore the interactions among the QH's stakeholders while also shedding light on the risks of High Intensity and Time Sensitive Projects [20] that originated from their dynamic collaboration. This was particularly relevant because of the need for super-rapid innovation projects in the face of unknown effects on the disease's overall population mortality [34]. This led to the following research question: *How can urgent open innovation projects be executed in the context of the Quadruple Helix model considering stakeholder dynamics and the risk involved?*

This question is explored in the context of a case study involving the urgent development of Personal Protective Equipment (PPE) in Brazil during the COVID-19 pandemic. As the Quadruple Helix model includes stakeholders from government, academia, industry, and civil society, it is used to understand the collaborative dynamics and associated risks of executing an urgent open innovation project. This study aims to gain a deeper understanding of the micro-dynamics for knowledge sustainability [7] of the urgent Open Innovation project from the perspective of the helix leaders. This research highlights the importance of an agile mindset, stakeholder partnerships, scale, and logistics in managing an urgent project. It also emphasizes the various risks and impacts of this QH interaction during the pandemic, such as financial, temporal, reputational, and health issues. By categorizing thirty-two risks, one of which is considered unacceptable, internal and external risks to the

project in this context are revealed, in addition to risk categories regarding partnerships, institutional image, manufacturing of public equipment, project management, human resources, intellectual property, regulation, and sanitation. With this research question, we aim to develop a new framework for managing urgent open innovation projects in the accelerated context of the formation of the Quadruple Helix, with a focus on stakeholder collaboration and risk management and mitigation. To achieve this, this research combines qualitative case study analyses, risk assessment, and the development of a theoretical framework to explore an urgent open innovation project in times of crisis.

Analyzing the Brazilian response to the COVID-19 crisis holds significant academic and practical importance, especially in understanding institutional collaboration during disruptive events. Brazil, as the world's fifth-largest country, covering an area of approximately 8,515,767 square kilometers [35], and the sixth most populous nation, faced unique challenges in managing a vast health and humanitarian system during the pandemic. This included a range of urgent projects, from developing personal protective equipment (PPE) such as face shields [36,37] to constructing field hospitals [38–40]. The urgency and scale of these projects in Brazil are noteworthy. The country successfully produced and distributed 278,137 units of face shields across 8 states, covering 470 cities and benefiting 498 institutions and hospitals. This achievement is significant considering the typically prolonged timelines required for conventional Open Innovation (OI) projects of similar scale and complexity. Brazil's ability to rapidly conceive, develop, and execute such a massive project nationwide offers valuable insights into managing urgent, large-scale projects in times of national emergency [41,42]. Furthermore, the Brazilian case provides an essential contribution to the literature on disrupted contexts [30], which lacks sufficient discussion. This includes the transition from centralized to decentralized, ad hoc project management in such scenarios [43]. By examining how Brazil crossed these complexities, valuable lessons can be learned about managing large-scale, urgent projects under severe time constraints, an area that remains underexplored in current academic research.

By delving into stakeholders' collaboration and risk management in the context of a High Intensity and Time Sensitive Project, this paper gives valuable insights into the adaptability and speed required for the successful execution of such projects. The study analyzed stakeholder dynamics, understanding helices' connections and the interactions' characteristics. It also identified a relation of critical risks and discovered which risk is deemed unacceptable. Moreover, the research highlights the difference between risks in non-urgent projects (such as partnership and institutional risks) and High Intensity and Time Sensitive Projects (such as logistical risks), as well as the emergence of newly identified risks (e.g., regulation and sanitation). Overall, this study contributes to advancing the managerial aspect of the Quadruple Helix and project management research fields, particularly concerning urgent projects, stakeholders, and risk management.

2. Theoretical Background

In this section, we provide a review of the theoretical foundation pertinent to this research. It is grounded in the Quadruple Helix (QH) theoretical model [44], an established framework for understanding and examining the micro-dynamics of stakeholder collaboration within innovation ecosystems [7]. The QH model expands upon the traditional Triple Helix model by incorporating civil society as a fourth helix [45,46]. First, we explore Open Innovation [47–49] with the Quadruple Helix model. Additionally, we present an overview of emergency projects to establish the necessary context to explore the urgent Open Innovation project during the pandemic crisis. Finally, we present the risks associated with urgent projects in the context of the QH model. By utilizing the Quadruple Helix model as a theoretical lens, we seek to untangle the complexities of urgent open innovation projects, offering a perspective that facilitates a profound understanding of the interactions, roles, and contributions of each helix.

2.1. Open Innovation and the Quadruple Helix Model

Open Innovation (OI) is a collaborative approach [18] to innovation that involves the purposeful exchange of knowledge across organizational boundaries, utilizing both financial and non-financial mechanisms in accordance with the organization's business model [50]. The OI process overlaps the Quadruple Helix (QH) and encompasses the interconnectedness of the university, industry, government, and society, forming an innovation knowledge infrastructure [51]. Both frameworks emphasize the importance of collaboration and engagement among multiple stakeholders. Open Innovation promotes the idea of sharing and co-creating knowledge across organizational boundaries, while the Quadruple Helix model recognizes the interplay and interdependencies between the four sectors in driving innovation and societal development. The Open Innovation framework sits alongside the Quadruple Helix theory, identifying connections between the various stakeholders [7].

The concept of Open Innovation, as explored in existing papers [6,50,52], involves the utilization of external networks by organizations to facilitate the development of innovation and knowledge [53]. This approach serves as a complementary option to traditional in-house research and development (R&D) practices [54]. Analyzing the timeline of the overlap between OI and QH frameworks, data from the Scopus database until July 2023 (Figure 1) illustrate that, since 2006, the focus of research on innovation and technology environments has shifted from technology transfer to the exploration of diverse methods and forms of innovation [8]. This shift seems to increase positive impacts while reducing the risks and uncertainties [55] associated with open innovation and technology.

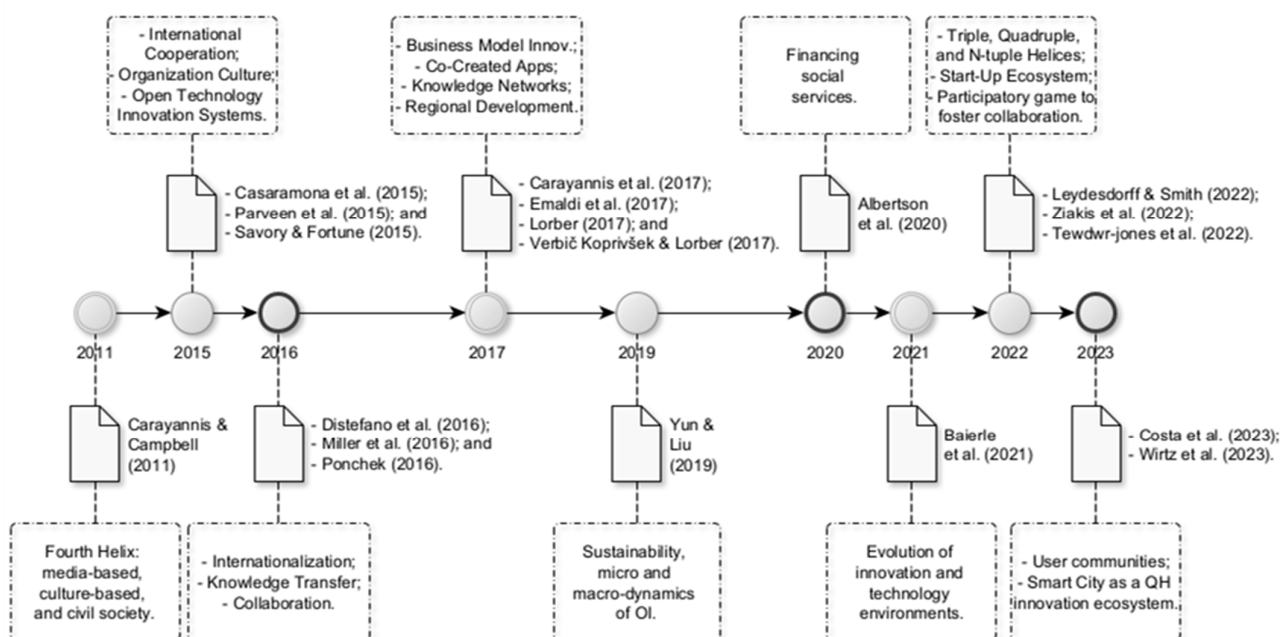


Figure 1. Timeline of Open Innovation in the context of the QH theoretical model. Sources: [6–11,13–17,46,47,56–61].

Recent research indicates a growing interest in economic factors [12,13,62] and technology environments [8,11,56,62]. After 2019, the literature discusses various studies such as user communities driving firms' innovation [62], financial inclusion and payment system innovation [12], smart cities as collaborative ecosystems [11], start-up ecosystems [13], co-designing urban innovation [56], multiple helices models [46], and micro- and macro-dynamics of open innovation with a Quadruple Helix Model as the way to achieve sustainability [7].

However, the analysis of the existing literature on Open Innovation with the Quadruple Helix model reveals an incomplete examination of all the QH dimensions. As presented

by Yun and Liu [7], there is a need to enrich the “open innovation micro-dynamics model with quadric-helices”, as corroborated by recent studies mentioned here; this indicates a lack of exploration of the interplay and collaboration among the four dimensions. Therefore, a deeper examination of the Quadruple Helix model is necessary to fully understand its implications for Open Innovation. Furthermore, despite the recent importance of innovation as a result of the COVID-19 pandemic, there is no explicit mention of urgent Open Innovation projects in the QH model.

2.2. Urgent Project Risks within the Context of the QH Model

Risk is the probability of an adverse event occurring in a given time frame or the probability of a variation of an expected result [57]. Within the context of the Quadruple Helix model, urgent project risks involve multiple stakeholders, each contributing their own set of risks. Government actors may face risks related to cost factors [63] as well as reputation concerns [64], for example, which are particularly pertinent to the dimension of anticipation within the responsible innovation framework [65]. Academic institutions may encounter risks pertaining to the reputation of their faculty members [66,67] and scientific production [68]. Industry stakeholders, on the other hand, may be exposed to risks associated with production and innovation [69,70], potential loss of technological competitive advantage [71,72], and supply chain vulnerabilities [73]. Finally, civil society actors may face, for instance, risks related to public perception [74].

The literature analysis shows studies that fit the current research on Quadruple Helix and risks, despite risk management increasingly relying on collaboration [7] and the relevance of anticipation related to responsible innovation [65]. Concerning the risk types, the risks identified in the literature are related to (i) socio-ethical risks [4] in areas such as privacy and data property, disruption of existing societal structures, inequality, and injustice; and (ii) natural risks [3]. The specific application cases were related to (i) healthcare and responsible innovation [4] in the context of digital twins (combining emerging technologies such as Artificial Intelligence, Internet of Things, big data, and robotics) and (ii) natural and man-made disasters in the context of the resilience of a city (the ability of an urban system to adapt to an external event and quickly return to normality [3]). Therefore, only one [4] is related to healthcare in traditional projects or operations, and none of them to urgent projects.

When reviewing the relevant literature, risks in the context of QH can be classified into two categories: internal or external. Internal risks include misaligned technology strategy, inadequate internal capabilities, and process inefficiency [63], inefficient Technology Transfer Offices (TTO) processes, insufficient faculty involvement, cultural barriers and misaligned incentives [64], financial loss, relational issues, institutional impact [66], ethical conflicts and academic integrity, conflicts of interest, compromising research autonomy, internal governance challenges [67], conflicting R&D spending priorities, reduced university-industry collaboration, inadequate in-house R&D, and internal organizational conflicts [68]. External risks include market dynamics impacting product development, insufficient external collaboration [63], adverse environmental and institutional factors, inadequate industry engagement, market dynamics and legal environment [64], policy changes and government regulations, market dynamics and competition [66], sponsor pressure and influence, public perception and trust issues, legal and contractual challenges, reputational damage and altered research agendas [67], economic cycles impacting trust and collaboration, policy and funding changes, changes in external economic conditions, and fluctuating public and government support [68].

Finally, the risk assessment and analysis of potential risks associated with the development of an urgent OI project under the QH framework shed light on the complexities and challenges that arise from the interaction among the four helices (government, academia, industry, and civil society) in an urgent scenario. By incorporating viewpoints from stakeholders within each helix, the risk analysis offers multiple perspectives on the involved risks, from operational to strategic, and from internal to external risks [63,64]. This approach

captures a broad spectrum of potential risks and aids in understanding how different stakeholders perceive these risks. By integrating risk assessment into the QH model, the research expands this theoretical framework and adds a layer of potential challenges and uncertainties related to the Quadruple Helix model. This combination is relevant for developing risk mitigation strategies, especially in the context of superfast interactions among the helices in future extremely urgent projects.

3. Materials and Methods

This research employs three distinct approaches: (i) Case Study Analysis, (ii) Risk Assessment and Analysis, and (iii) Theoretical Framework Development. The Case Study Analysis involves an empirical case study approach to gain insights into the stakeholders' dynamics, key characteristics, and life cycle of the urgent agile project (presented in Sections 3.1 and 4.1). The chosen case study serves as the descriptive phase of the investigation and is used to understand the contemporary event and then to analyze it from the risk perspective. Regarding the Risk Assessment and Analysis, the urgent project is analyzed from a risk management perspective. This part of the research focuses on identifying and analyzing potential risks, considering the viewpoints of stakeholders from each helix (outlined in Sections 3.2 and 4.2). Finally, the Theoretical Framework Development was built advancing on the theoretical framework presented by Pirlone et al. [3]. It combines risk assessment techniques with the principles of the Quadruple Helix (QH) framework (presented in Sections 3.3 and 4.3).

Figure 2 presents the conceptual framework for the research and visually summarizes the integration of Case Study and Risk Analysis. The starting point is a case study of an urgent innovation project, moving through the assessment of the project's characteristics and phases, identifying the impact dimensions or consequences, and then proceeding to the risk analysis and categorization. The flowchart outlines this structured approach formed by two sections labeled "Case Study", on the left, and "Risk Analysis", on the right, indicating the sequential stages of the research and the logical progression between the distinct phases.

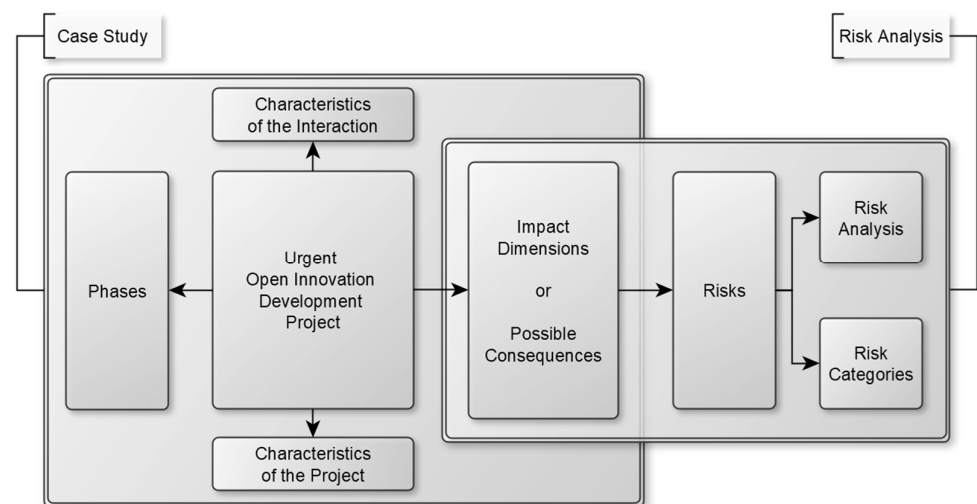


Figure 2. The conceptual framework for the study combining the case study and the risk analysis.

3.1. Case Study Analysis

Providing a case study overview [75], the study addressed the research question related to the urgent Open Innovation (OI) project outlined during COVID-19. The case study adopted an inductive approach [76] to explore the High Intensity and Time Sensitive Project development process timeline [20] and recognize the critical dimensions of the QH model. Its analysis was conducted by focusing on the emergency initiatives implemented in the Brazilian project to address the escalating demand for Personal Protective Equipment

(PPE) during the crisis. This step focuses on the project that exemplifies and explains the fast Quadruple Helix formation and describes the fast product development from its initial conception to final delivery.

Regarding data collection and selection criteria, the data collection was conducted through an interview process involving the four connections in leadership positions of each Helix: (i) a university professor and manager representing the academic helix; (ii) an agent of society directly engaged in the project; (iii) an Army colonel representing the government helix; and (iv) a spokesperson of one of the companies involved representing the industry helix. By including the representatives from each helix, it was possible to collect data from different points of view about the project from the perspective of individual actors in leadership roles, in line with the insights offered by Hoffmann [77]. All these leaders possessed decision-making authority and were responsible for driving changes within their respective helix.

Concerning the interview process, the questionnaire script for data collection is presented in Appendix A. It focused on explanatory questions such as “how” and “what” to deal with the tracing of operational processes over time [75]. The questionnaire was designed to extract data to form an understanding of the Open Innovation development process. The interviews were conducted via video calls, recorded in audio format, and subsequently transcribed. Each participant completed three rounds of interviews, ranging from 34 min to 1 h and 3 min.

The leader of each helix was selected for their ability to provide a complete, top-down management perspective crucial to understand the dynamics, interactions, and actors involved in the PPE development project. Furthermore, as the project life cycle was extremely short (11 days), but with high daily intensity, and as each leader was dedicated exclusively to that project during the period because of the pandemic, each leader was able to report in detail the events and iterations that occurred each day. Our approach sought to capture a diverse range of knowledge and experiences relating to the project, thus reflecting the complexity and urgency of the situation.

The first round aimed to obtain daily empirical information from the project regarding the entry of each actor, their respective actions, and the distinct roles on each day of the rapid formation of the QH. On Day 1, University researchers, society members, and volunteers started the project, focusing on developing face shields, data collection, and initiating fundraising and donation efforts. Industry started collaborating from Day 2, the same day as donations began. Until Day 8, the focus was on partnering between companies and the university for large-scale production, as well as technical specifications and local logistics. Society was involved in mobilizing financial support and donations. The government, especially the Brazilian Army, came together with greater protagonism on the 9th Day to assemble, sanitize, and distribute products. This initial round of interviews was conducted shortly after the project was completed, which allowed us to gather empirical information from each day of the project. This timely data collection was crucial as Brazil was experiencing a total lockdown at the time, and these leaders were the only ones within their respective institutions with the autonomy to make decisions and coordinate this unexpected urgent project. The empirical data obtained from the respondents, detailing each day of the project, were essential for the development of the visual structure that illustrates the detailed timeline of the project development process, as presented in Appendix B (Figure A1), depicting the rapid formation of the Helix Quadruple and extremely fast project execution, which are central to our research.

Pertaining to the data analysis, the collaborative nature of the urgent open innovation project was analyzed through the lens of the QH model. The research team began by coding the interview data into days to obtain a clear and accurate picture of how the QH formed. Next, the data were analyzed to identify patterns related to the daily challenges and actions faced by the project. We identified the emergent key dimensions while examining the interactions among government, academia, industry, and civil society stakeholders. After that, to better understand the distinct roles of each helix, the project life cycle was classified

into three phases (I, II, and III), brought together based on helix patterns observed over time. Utilizing an inductive approach, the researchers examined the data to generate the key dimensions pertinent to the Quadruple Helix model, which, in the next step, was represented in a framework. By analyzing the actions, inputs, and roles of different stakeholders of each Helix, with the urgent project divided into phases, the relevance of each stakeholder during the project life cycle was identified.

In relation to visual framework development, based on the inductive analysis, a visual framework was developed to illustrate the QH model, as presented in Appendix B (Figure A1). The detailed timeline of the development process for the urgent project was structured in a vertical format with events from the first to the last day, indicating the stages in the project's development. The timeline is organized into two columns, with icons indicating specific activities or components associated with each stage. Icons are used to visually represent different aspects of the project timeline. The left column lists activities and the right column lists stakeholders involved at each stage. The framework illustrated the interactions among the helices and strengths offered by each helix. The visual framework outlines the different levels of participation by the stakeholders, with categories such as "Listening", "Creating", and "Implementing". By visualizing the complexity of the innovation ecosystem, the framework highlights the collaborative efforts required for the project's successful outcome. The interpretation of the results sheds light on stakeholders' partnership and the agile mindset in achieving the project's objectives.

The second round (first part of the risk assessment process) aimed to obtain the list of risks related to the urgent project. The list was identified with 32 risks and classified into 10 categories, including Image of the Institutions Involved, Logistics, and Stakeholders' Partnership. The third round (second part of the risk assessment process) aimed to ask about the perception of probability and impact of each risk. We detail these steps in Section 3.2 (Risk Assessment and Analysis).

3.2. Risk Assessment and Analysis

With respect to the Risk Assessment and Analysis Overview, in the context of the urgent Open Innovation (OI) project developed during the COVID-19 crisis, the second part of the study is a risk assessment and analysis conducted to map the potential challenges and uncertainties. This subsection systematically identifies and evaluates the risks in the rapid development of Personal Protective Equipment (PPE) in Brazil. Emphasizing the project's High Intensity and Time Sensitive nature, the assessment was fundamental in recognizing and categorizing the risks in line with the Quadruple Helix (QH) model.

In terms of the data collection and risk identification, the first part of the risk assessment process contemplates the data collection through semi-structured interviews with project stakeholders, as detailed in Appendix A. Leaders from each helix—academic, society, government, and industry sectors—identify the risks involved in the process based on their own perceptions [78,79], thus facilitating the identification of risks associated with the project [80]. These identified risks were then classified into categories that were later integrated into the theoretical framework and support the narrative findings.

In a second round of interviews, the interviewees were again asked about the perception of probability and impact for each risk [81], according to the scale presented in Table 1. This scale is defined by qualitative or semi-qualitative methods. Qualitative methods of risk analysis define levels of judgment for the probability of occurrence (e.g., from "very rare" to "very probable", or from "improbable" to "frequent") and the severity of impact (e.g., from "too low" to "very high", or from "minor" to "severe") [82]. The semi-quantitative risk analysis methods use a numerical scale for probability and impact [82,83]. The analysis considered four dimensions of potential consequences: financial, reputational, health-related, and temporal impacts on the project. These dimensions were defined from the first round of interviews.

As for the Risk Index Calculation, each risk was evaluated and assigned a risk index (RI) [83], calculated by multiplying its impact and likelihood. This index allowed for priori-

tizing risks based on their criticality. The final impact and probability were calculated using the average of the impact and probability estimated by each interviewee (Figure 3). We calculated the local risk index for each group, along with a global risk index (Appendix C).

Table 1. Probability and impact scale. Source: [84].

Scale	Probability	Impact
1	Improbable	Minor
2	Remote	Medium
3	Rare	Significant
4	Probable	Major
5	Frequent	Severe

The risk matrix [83,84], also known as the risk assessment matrix, depicted as a two-dimensional plot, was constructed to visualize each risk's probability and impact [85] to estimate the degree of risk [82]. It included additional dimensions such as risk names and categories (Table A2). The risk categories were chosen using the existing literature (e.g., partnership and institutional image) and the new groups were discovered. In this matrix, each risk is represented by a symbol with an "R" followed by a number (for example, R1, R2, etc.), indicating the different risks identified. The symbols represent the risk categories. The risk matrix is shaded in gray levels from light to dark, indicating zones of severity, with darker areas representing higher combinations of impact and probability. For example, risk R29 is in the darker area in the upper right corner, indicating that it is perceived as having a high probability of occurrence and a high impact. On the other hand, risk R10 is in the lower left corner, indicating lower probability and impact.

The multiplication formula [83] is used for the risk index for prioritizing risks [84,86]. This research utilizes the criterion of 30% more significant to identify the critical risk set. The criterion used is, thus, $RI > 12.25$, where $P = 3.5$ and $I = 3.5$. Furthermore, a criterion of 20% more significant is applied to select the unacceptable risk set, thus, $RI > 16$, where $P = 4$ and $I = 4$. In the face of unacceptable risks, regardless of the cost, mandatory safety measurements should be carried out to diminish the risk level to a critical level [87]. Then, we use the symbol " \succ ", indicating the ordinal scale of the relative importance of the risk. Therefore, it denotes that the risk on the left has a higher priority than the risk on the right. For example: $R29 \succ R27$. This scale is derived from the utility indifference curves [85,87], which are based on economic utility theory [88,89].

Regarding the Risk Classification Procedure [90] as 'Internal' (originating within the project) and/or 'External' (originating outside the project), we follow the steps below. First, we define the two categories. Internal Risks are defined as those originating from within the project's scope, such as team dynamics, decision-making, and resource management, as well as operational, safety, and security risks [91]. As we are analyzing the project within the Quadruple Helix context, the project encompasses the four helices. External risks are those influenced by factors outside the project's immediate control, such as political, economic, social-cultural, and environmental risks [91], as well as media, public perception, and regulatory bodies. A new column, titled "Risk Origin", was added to Table A2. We then individually reviewed and analyzed each risk to verify whether its origin was internal or external to the project. Two different researchers assigned the rating to each risk. As the classification of some risks can be subjective and depend on the project context and the expert's perspective, when researchers disagreed, a third researcher was called in to decide on a definitive categorization. We present the discussions separating the risks into these two broad categories. The division of risk into external and internal introduces the possibility of distinguishing the main risks in these two areas related to the QH model.

Once the broad risk categories (internal or external) and subcategories (e.g., partnership, equipment, production) have been identified, to present suggestions and recommendations for similar projects in the future, we revisit the analysis of stakeholder dynamics

and review the cycle life of the project; based on this, we formulate possible risk mitigation strategies. First, we review the interactions and roles of different stakeholders in the QH model to understand how these dynamics contribute to or mitigate risks. We then examine the project lifecycle to identify the most relevant suggestions for each risk classification. Finally, based on this analysis, we suggest strategies for each aspect of risk classification.

3.3. Theoretical Framework Development

This research aims to refine the theoretical framework initially proposed by Pirlone et al. [3] by integrating risk management into the QH model based on a deep understanding of how this project emerged and the crucial characteristics of this formation. It expands the understanding of the micro-dynamics of open innovation with the Quadruple Helix framework as the way to achieve sustainability. This profound understanding helps us see new possibilities and ideas for organizational studies that are often in the background or invisible in the foreground [52]. To gather empirical evidence, this work used qualitative research methods, as per de Ven [92] and Yin [75], to observe, examine, and develop a model that is a partial representation of theories [92].

With regard to the case study and risk analysis synthesis, this step summarizes the findings of the narrative case study with the risk analysis during the execution of the urgent Open Innovation project with the Quadruple Helix model. To build the model, the researchers confront the participants' perceptions concerning the urgent OI project [92]. By considering the points of contact and interaction among the stakeholders, the framework enables a detailed perspective on the project from this point of view. Consequently, it combines the "how" aspect, as emphasized by Yin [75], with the incorporation of the risk assessment approach from the participants' point of view.

Based on the theoretical framework presented by Pirlone et al. [3] in the context of the Quadruple Helix model, this approach provides an enriched understanding of how the urgent Open Innovation process happens. By examining the project phases, crucial aspects of the interaction, project-related factors, extracting impact dimensions, and possible consequences emerge for the risk analysis (Figure 2). The research extends these results by integrating risk and their categories, resulting in a novel map of the micro-dynamics of OI with the QH model. The final framework summarizing the findings is presented in Figure 4.

4. Results

The findings offer valuable insights into the understanding of urgent Open Innovation (OI) projects with the Quadruple Helix (QH) model, with a particular emphasis on stakeholders' interactions and risk assessment. As a consequence, it reveals the perspective of an agile mindset in an urgent project.

4.1. Case Study Analysis

To address the research question, we analyzed an emergency project, called GRU, established to meet the high Brazilian demand for the face shield product during the pandemic. A total of 278,137 units were produced and donated to thousands of health professionals working on the front lines in eight different Brazilian States: São Paulo, Rio Grande do Sul, Amapá, Amazonas, Alagoas, Goiás, Paraná, and Rondônia. The project involved more than 60 people, with a budget of over BRL 220,000.00. It covered 498 institutions and hospitals in 470 cities. The GRU project's primary objective was to develop, manufacture, and supply face shields. Assessment of the empirical data allows a complete examination of the collaboration among all Quadruple Helix Dimensions in the urgent OI ecosystem.

The project started with a group of volunteers at the beginning of the pandemic. In the initial stage, different face shield prototypes were manufactured using 3D printing technology. To ensure their usability and efficacy, extensive tests were conducted within hospitals. With users' feedback collected and analyzed, it was possible to refine the

design, optimized with a particular attention to comfort and virus protection, required for the situation.

The final design of the GRU face shield model comprised three main components: a forehead piece, a clip/strap mechanism, and a visor. To facilitate large-scale production, the final design and manufacture of the GRU model was transitioned to the injection process by partner companies, which allowed for much faster and more efficient production to satisfy the exponential demand for visors at the beginning of the pandemic. The project's design was recognized with the Bornancini Design Award 2020 [93] in the COVID Professional Category and the Petzold Professional Award for Outstanding COVID Action. These prizes highlight the significant contribution of the GRU initiative in the scientific, technological, and design domains.

In the detailed calendar of urgent project development process (Appendix B), one can observe the entry of each actor, represented by the image of the helical formation to which they are related, and their respective actions on each day of the rapid formation of the QH. Figure A1 provides a high-level overview of the project lifecycle, illustrating the complexities of product development and the collaboration interfaces and review required to deliver the product to healthcare professionals. The university's Engineering Department developed the project, using the agile mindset [94,95] to drive the project, achieving a lifecycle of only 11 days. Stakeholders' actions and inputs throughout the process are illustrated in a vertical timeline from day 1 (D1) up to day 11 (D11). To better understand the daily actions of the urgent agile project and the distinct roles of each Helix, the project was separated into three phases (I, II, and III), determined based on empirical patterns of the helices over time.

Phase I of the project's development started on a Saturday (D1). It was driven by research professors motivated by the immediate need to protect healthcare professionals who had difficulties acquiring Personal Protective Equipment (PPE) in their hospitals due to the exponential increase in local and global demand. On that day, a team of researchers collaborated with members of the university's research laboratories and connected with a society player through a group on the WhatsApp instant messaging application. D1 marked the beginning of data collection for the face shield product development, forming partnerships with stakeholders, and the production study. This phase was characterized by the university and society's leading role. The university launched a campaign to encourage the population to contribute to this initiative, while society played a leading role in finding donors, foundations, and equity fund resources for gathering capital investments. Society actors involved healthcare professionals and a group of volunteers made up of professors, employees, and university scholarship holders, aligned with the collective group Brothers in Arms. One of the interviewees pointed out that *"There was a need to expand the manufacturing scale. Even due to the limitation of existing equipment at the university and, ideally, through partnerships. . . using the machinery of a company that volunteered, more materials were also purchased or donated"*. Therefore, expanding manufacturing required partnerships for equipment and material acquisition and use due to the limitations at the university.

In phase II (from D3 to D8), digital communication resources were utilized to search for, reach, and establish connections with companies interested in collaborating with the university to form immediate partnerships to scale up the product's manufacture. The exchange of information with companies made it possible, through the application of Open Innovation, to develop a face shield model for large-scale production by industries possessing compatible production lines and local logistics capabilities. Digital communication resources were also employed to disseminate information about the project to society, given the need to integrate it, collect donations, and enhance collaborations essential for the project's development and adaptability, as well as to manufacture the product at the university and deliver it to the target audience. This phase was characterized by the connection of the third Helix: industry. This collaboration with industry partners enabled the first manufacturing at scale to be achieved. Thus, this phase involved using digital communication

resources to partner with industry for large-scale production while engaging civil society for support.

As to how industry leaders collaborated closely with the university, “Companies T, S, C” are mentioned at various stages, indicating that specific industry participants were involved throughout the urgent project. Collaboration between industry and university helices was focused on activities such as “Data Collection” (D3), “Technical Specifications” (D4), “Preparation for Production” (D5), “Production Standardization” (D5), “Logistics” (D5), and “Definition of Model for Production” (D6 and D7). Furthermore, the presence of a “Graduated Startup” alongside university and companies at various stages highlights the bridge between academic research and practical industrial application of the urgent project.

Industry leaders collaborated with society through the following interactions: donations, the Brothers in Arms collective, and Equity Fund. From D2 onwards, donations started, and these continued until the end of the project. This indicates that industry both received and provided donations and contributed to societal efforts, pointing to a financial and resource-based collaboration with the community. Company T, for example, donated at least 50,000 complete face shields plus straps out of a total of 140,000 produced. Another company donated around 90,000 forehead pieces. The Brothers in Arms group helped mobilize community financial support. This shows that industry leaders worked alongside volunteers to implement the project. The mention of an “Equity Fund” (D3, D4, D5, D6 and D7, D8, D9, D11) points towards investments made by societal actors into the PPE development project, once again reflecting a financial collaboration between industry and society.

Concerning industry interaction with the government, the involvement of both industry and university in the “Regulatory Agency” (D4, D5, D6 and D7, D9) suggests that industry leaders worked within the guidelines set by the government to ensure standard compliance.

In phase III (D9 to D11), a connection was made on Sunday with the government through a messaging application to a figure of the Brazilian Army. It was necessary to count on the support of the military for the assembly and cleaning/sanitizing of the products manufactured by the partner companies and for distribution in Brazil due to its logistical presence throughout the national territory. The formation of this new helix connection made it possible to achieve the second product scale. One of the interviewees highlighted that: *“the project wouldn’t have gained the scale that it gained if it hadn’t been for that contact . . . on Sunday”*. The establishment of this helix connection made it possible to further increase the scale and reach of the product, as well as logistical and distribution support for deliveries over continental distances in Brazil, which has an area of approximately 8,515,767 km² [35].

Concerning how the government interacted with other sectors of society, the “Government” is represented by the involvement of “Regulatory Agency” (D2 to D8), “Military Forces” (D9), and “State Civil Defense” and “State Secretary of Health” (D11). However, the government figures took a much greater role in the latter stages, beginning with “Assembling” (D9) and “First Delivery” (D11).

On the university’s interaction with the government, the university’s engagement with regulatory agencies at various stages indicates close interaction to ensure that the development of PPE met government standards and regulations. The presence of the State Secretary of Health and State Civil Defense at the final stage indicates that the university interacted with these bodies to start the first delivery of the urgent project outcomes, which involved coordination with health and emergency services.

Analyzing these three phases, it is noted that these achievements were made possible by using an instant messaging app, an agile mindset, and the imminent necessity to safeguard the lives of healthcare professionals. This approach allowed for time to be gained by moving beyond the formal steps that a project of this nature would have required under normal circumstances. Moreover, instant digital communication enabled the helices to perform as a network system where each actor could access any other instantaneously.

The extremely high speed of collaboration in the project also brought associated risks (Appendix C). Respondents revealed concerns about potential financial, time, reputation, and health consequences. The absence of barriers between institutions is also noteworthy because the managers were already acquainted and had mutual professional trust from previous work, projects, and partnerships. One of the participants stated that “*it was a practical test for the institutional relationship, that worked*”. Trust emerged as a critical element, facilitating stakeholder collaboration, knowledge sharing, and mutual understanding.

This comprehensive analysis of the urgent OI project with the QH model showed that the project developed during the COVID-19 pandemic required rapid and well-coordinated actions and collaboration among stakeholders from government, academia, industry, and civil society. Even with a superfast but relatively straightforward product, the Quadruple Helix framework shows the complexity of this innovation ecosystem, identifying strengths offered by each helix, as illustrated in the framework (Figure 4). Effective and instant communication ensured a continuous and intense flow of information, enabling coordination and alignment of extremely time-sensitive goals. The extremely agile mindset adopted in the urgent OI project allowed for adaptive responses to rapidly changing circumstances. Finally, the stakeholders’ partnerships played a vital role, leveraging the strengths of each helix to ensure the successful outcome of the project.

4.2. Risk Assessment and Analysis

Thirty-two (32) risks were identified and classified into ten (10) categories (Appendix C). These categories are related to (i) the stakeholders’ partnership (PA); (ii) the image of the institutions involved (IM); (iii) the public equipment (EQ) used for project development, involving laboratories and materials in general; (iv) the production (PR), specifically concerning tools and assembly; (v) the project (PJ), related to decision making and the proposed model; (vi) the people (PE) participating directly or indirectly; (vii) the patents and intellectual property (IP); (viii) the logistics (LO); (ix) the Health Surveillance Agency (AN) in Brazil (Agência Nacional de Vigilância Sanitária—ANVISA), responsible for the products’ technical and sanitary specifications; and (x) the cleaning/sanitization (SA) of laboratories, materials, and products.

The risk index, *RI* [83], as presented graphically (Figure 3), provides a comprehensive assessment of risks associated with this urgent OI project. Critical risks provide a better understanding of the emergency. The risk index result indicates that risks R28 (12.4), R17 (13.2), R5 (14.3), R14 (14.6), R6 (14.8), R27 (15.1), and R29 (17.3) are the most critical (Appendix C). Among these, the logistical risk of delaying the personal protective equipment (PPE) delivery and losing the task force’s effectiveness (R29) appears as the most critical or unacceptable [87]. Qazi and Akhtar [85] define unacceptable as a risk zone where it is essential to reduce the risks to a critical level at any cost.

Based on the risk index (*RI*), the risks were prioritized from highest to lowest: R29 > R27 > R6 > R14 > R5 > R17 > R28 > R8 > R12 > R22 > R19 > R26 > R13 > R32 > R9 > R18 > R25 > R11 > R20 > R3 > R2 > R24 > R1 > R31 > R23 > R7 > R30 > R21 > R4 > R10 > R16 > R15. The local risk index was also analyzed within each group (Appendix C), resulting in the following priority:

$$SA > LO > AN > PA > IM > PE > EQ > PR > PJ > IP$$

This shows that equipment, production, project, and intellectual property appear with less criticality. Sanitation (SA) appears as a critical group. Furthermore, critical risks appear in six categories.

Regarding the classification of risks into internal and external, as presented in Table A2, we consider the nature of each risk and whether it originates within the project or from external factors.

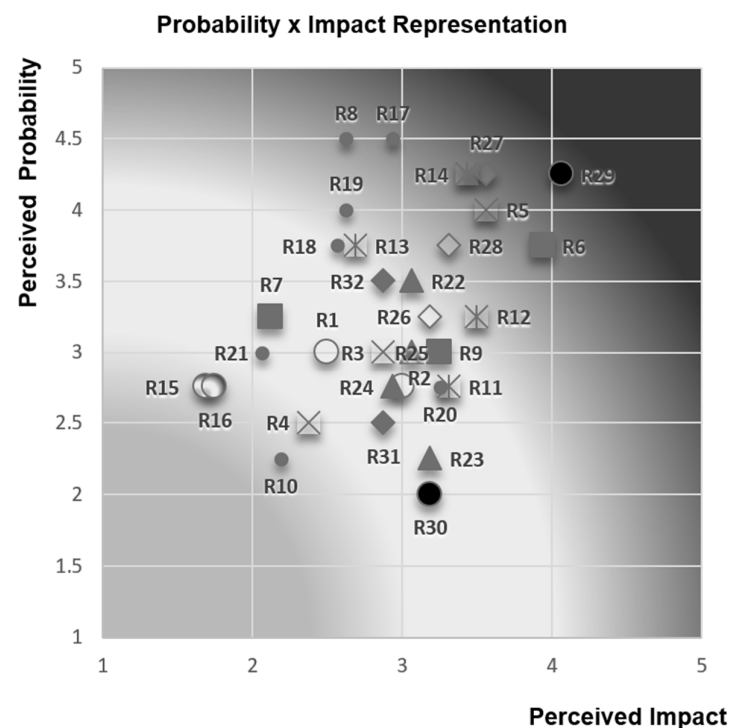


Figure 3. Spatial representation of the probability-impact relationship for each of the 32 identified risks and the categorization of risks.

In relation to internal risks, those are intrinsic to the project operation and involve aspects that are directly under the control and influence of the project team within the QH model. They include equipment management (EQ), production processes (PR), project management (PJ), team dynamics and participation (PE), intellectual property handling (IP), health and safety practices (SA), partnership dynamics within the project (PA), and logistics concerns (LO). Risks related to equipment (R22, R23, R24, R25) are internal, as they pertain to the management, usage, and functionality of the project's own equipment and resources. Production (PR) risks (R31, R32) are internal, as they are associated with the project's internal production activities and processes. Project-related risks (R1, R2) are internal, originating from the project's internal decision-making and project management processes. The researchers disagreed on R2 (Risk of the product not serving its purpose), requiring a third researcher to decide. Risks involving people (R3, R4, R5) are internal, because they are related to the dynamics, management, and participation of the project team and volunteers. Intellectual property (IP) risks (R15, R16) are internal. Sanitation (SA) risks (R26, R27, R28) are internal, as they focus on the project's internal health, safety, and sanitary protocols practices.

The classification of some risks, particularly those related to partnerships (PA) and logistics (LO), may vary based on the context and specific project model. Because of the QH model framework and the interaction between the helices, these were defined as internal due to their dependence on the dynamics and management internal to the theoretical model. Partnership (PA) risks (R6, R7, R9) are typically internal as they are related to internal dynamics and agreements within the project team or between project partners within the QH model. A third researcher resolved disagreements on partnership-related risks R6 (Risk of breaking the partnership), R7 (Risk of not signing a Protocol of Intent between the institutions involved), and R9 (Risk of not reaching consensus on joint product development). In an isolated project they could be considered external risks, but in the context of the QH model they were considered internal risks. The same logic applies to Logistics (LO) risks (R29, R30).

External risks that involve compliance with guidelines and requirements set by external authorities, which are not under the direct influence or control of the project team within the theoretical model, include aspects such as institutional image (IM) and compliance with regulatory standards (AN). Institutional Image (IM) risks (R17, R18, R19, R20, R21, R10, R8) are considered external, as they involve factors such as media representation, public perception, and external stakeholder reactions. This dispute was solved in R21 (Risk of improper use of the product). ANVISA (AN) risks (R11, R12, R13, R14) are related to compliance with external regulatory standards and approvals from regulatory bodies such as ANVISA. This dispute was solved in R14 (Risk of lack of inputs).

4.3. Theoretical Framework Development

The present paper presents a unified theoretical framework as a finding summary, as illustrated in Figure 4. It helps understand the complete development of the urgent OI project. Summarizing the findings elucidates the relationship between the fast and dynamic nature of innovation with the Quadruple Helix theoretical model and risk management during a crisis. Therefore, based on the empirical research findings, the conceptual framework (Figure 4) contributes to advancing the theory by gathering previous research from Pirlone et al. [3] and Popa et al. [4].

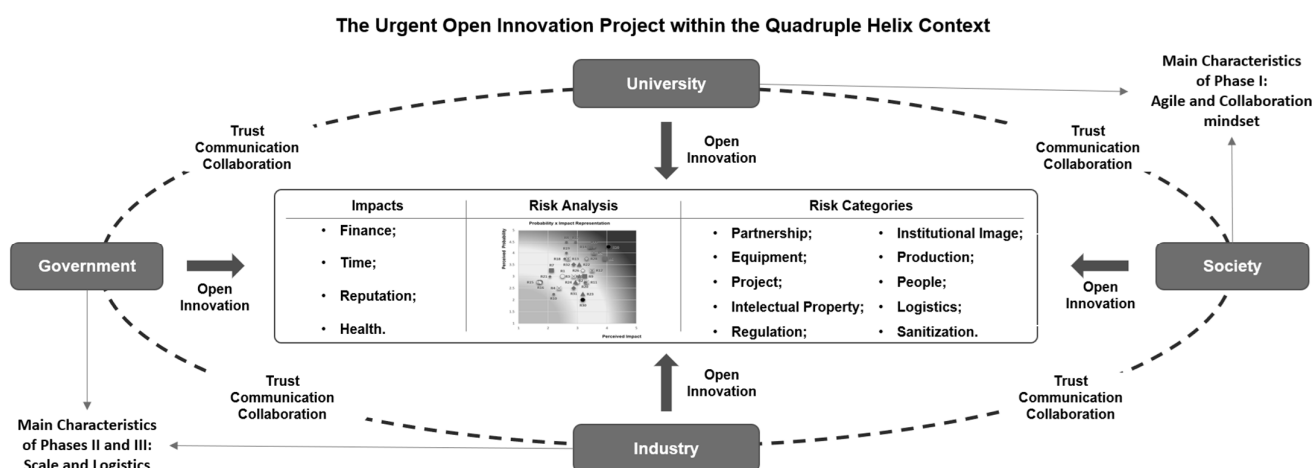


Figure 4. Conceptual framework of the urgent open innovation in the fast Quadruple Helix formation context.

This theoretical framework captures the Quadruple Helix perspective on stakeholders, risks, and an agile mindset during the analyzed High Intensity and Time Sensitive Open Innovation project, thereby consolidating the empirical evidence of a project with a high degree of urgency, extremely short duration and very high speed [20]. The model also suggests crucial components such as trust, collaboration, communication, agility, stakeholder partnerships, scale, and logistics. Considering these elements, the framework provides a view of urgent project management within the fast-paced Quadruple Helix formation. Moreover, the theoretical model delineates the interdependencies and interactions between the Armed Forces (government), industry, university, and citizens helices, illustrating how each of these elements contributed to delivering successful outcomes.

5. Discussion

This section discusses the findings of the case study and the risk analysis. It addresses the main characteristics emphasized in the case study. Additionally, it explores the ten risk categories and their respective risks identified in the Open Innovation literature. This comparative analysis enables us to compare the risks and categories found in the literature and the novel identified risks associated with an urgent project conducted during a pandemic.

5.1. Open Innovation, Agility, Key Aspects and Gaps

The use of digital communication resources emerged as a crucial factor in enabling information exchange and coordination among the stakeholders. These results align with the existing literature, which emphasizes the importance of communication technologies in facilitating innovation processes, as highlighted by Dodgson et al. [96] and Huizingh [49], and on effective Open Innovation [97]. Instant digital communication worked as a network to instantaneously connect all project levels; Papa et al. [18] explored knowledge exchange in complex collaborative networks. This phenomenon bolstered the intra-organizational level of analysis, as presented by Bogers et al. [98]. However, it also extended beyond the organizational boundaries, encompassing the stakeholders' perspectives. The indispensability of this connectivity is evident; it would not otherwise have been possible to start and execute the project because of the physical distancing imposed by the pandemic crisis. Thus, the findings are consistent with prior research conducted on Open Innovation [47–49].

The findings show that adopting an agile mindset in the project's development is also noteworthy, as it enables adaptive responses to rapidly changing circumstances. This observation is consistent with prior contributions that have acknowledged the value of agile methodologies in Open Innovation initiatives, as presented by Pellizzoni et al. [99], Vesci et al. [100], and Zare Khafri et al. [101]. The project's three-phase approach exemplifies the fast nature of the OI process, where collaboration and partnerships rapidly evolve over time to achieve larger-scale production and logistical support. Therefore, this aligns with previous studies emphasizing the dynamic nature of OI processes and the need for continuous collaboration and adaptation.

The literature sheds light on several key aspects within the QH model. The importance of necessity has been emphasized [13,19], along with the crucial role of communication and knowledge exchange [102,103], collaboration [104,105], agility [58], partnership [106], and scale [107]. Furthermore, the literature also puts light on trust dynamics as a major risk in innovation [66] and discusses the role of necessity as a potential driving force [71]. Despite an extensive literature search, no specific research articles were found addressing logistics within the context of the Quadruple Helix model. Such a gap presents an opportunity for future research in this area.

The evidence reinforces the individual actors' aspects [71] as motives for collaboration engagement at the organizational level [108]. Additionally, the research evidence also reinforces the belief that trust is essential in initiating and sustaining collaboration [71]. Moreover, the benefits of the partnerships have been found to outweigh the associated risks [67], supporting the notion of trust as a critical element in such contexts [109,110]. Due to existing professional relationships and mutual trust, the absence of barriers between institutions in this project highlights the importance of established networks and previous collaborations in fostering effective OI practices.

When analyzing the impacts of the urgent OI project from a non-commercial perspective, the study has shown the importance of the financial consequences, as emphasized by the participants in the case study. This empirical evidence aligns with the literature as a risk category, as pointed out by some authors [66,71]. However, the participants did not view financial impacts as a risk to the execution of the urgent project. The literature shows that urgent projects often necessitate the allocation of resources in an uneconomical manner [21], and that the speed of execution takes precedence over cost considerations [42,111]. Additionally, due to being a High-Intensity Time-Sensitive Project, characterized by tight deadlines and a high level of urgency, managers seemed to opt for "near maximum speed," increasing the total cost of the project [20]. This contradiction in the existing literature calls for further exploration into the factors influencing participant's perspective.

5.2. Global Perspectives vs. Brazil's GRU Project

The comparison of Brazil's PPE development process with those of other nations reveals diverse approaches. While other initiatives also adopted collaborative design and production [112,113], rapid prototyping and agile approach [114,115], use of 3D printing

technology [116–118], and user feedback in iterative design [119], each project employed distinct approaches to design and production. Furthermore, Brazil’s project differed notably in other aspects. Initially employing 3D printing, the GRU project moved within days to injection molding for mass production, a unique strategy compared to other countries. Furthermore, the project was much larger in scale and speed, producing more than 278,000 units, distributing them across several states in Brazil, and involving significant financial and human resources, while other studies were more localized and less rapid, as shown in Table 2.

Table 2. Comparative Analysis of PPE Development Processes: Global Perspectives vs. Brazil’s GRU Project.

Source	Country	Key Focus of Development Process	Comparison with GRU Project (Brazil)
[112]	France	Collaborative design and production using 3D printing, local logistics.	Collaborative design and local production. Smaller scale and local reach compared to GRU’s large-scale production and wide geographic distribution. Less agility compared to GRU.
[114]	Australia	Rapid design and manufacture of standard and ENT-specific face shields, compliance with standards, local manufacturing.	Rapid design approach. GRU’s transition to injection molding for scale surpasses this project’s scope.
[120]	Multi-country	Ad hoc supply chains, rapid product development, supply chain agility.	Rapid response and supply chain agility. GRU’s integration of different stakeholders is more comprehensive. Multi-country focus but specific production numbers not provided.
[116]	United Kingdom	Development of a one-size-fits-all face shield, ergonomic considerations, user evaluation.	Focus on usability and comfort. GRU’s larger scale and societal involvement are additional aspects.
[113]	Ireland	Rapid prototyping and production, local manufacturing.	Rapid production and local production. Produced 12,000 units, significantly less than GRU’s 278,137 units; limited to regional distribution. GRU project’s scale and multi-stakeholder collaboration are broader.
[118]	Greece	FDM 3D printing equipment to produce 800 protective face shields.	3D printing, much smaller scale compared to the GRU project, producing 800 face shields. The financial aspects of the project show a detailed cost analysis, which is a unique aspect compared to the GRU project.

Table 2 provides a comparative analysis of Personal Protective Equipment (PPE) development processes, as detailed in various academic papers, in relation to the GRU project in Brazil during the COVID-19 pandemic. The Key Focus of Development Process column describes the primary approach and methods employed in each country’s PPE development process. The Comparison with GRU Project (Brazil) column provides a comparative analysis of each country’s initiative against the GRU project in Brazil. The comparison considers factors such as the scale of production, collaborative efforts, technology used (such as 3D printing and injection molding), agility of response, stakeholder involvement, and focus on usability and comfort.

5.3. Internal Risks

Internal risks [91] in the project are identified as those originating from within the project’s scope, encompassing aspects such as team dynamics, decision-making, resource management, and other internal processes. They include Stakeholders’ Partnership, Public Equipment, Manufacturing and Project, Human Resources, Intellectual Property, Logistics and Distribution, and Sanitation Risks.

5.3.1. Stakeholders’ Partnership Risks

The trust dynamics among partners [66,67] and open communication [97] seems to impact the beginning of the partnership, helping to minimize the partnership dissolution risk (R6). Also, the trust aspect of the interaction seems to exclude the opportunistic behavior described by Al-Tabbaa and Ankrah [121], even without a formal Protocol or Memorandum of Understanding (R7) that would precisely determine the obligations of each actor involved. Results show that the high incentive of protection during a pandemic can surpass collaboration problems when it involves complex or novel ventures, such as

R&D projects [66], rapidly solving conflicts supported by the effective and open communication channel [97] and reaching on joint product development (R6) based on the dynamic of confidence [121]. The risk of opportunistic behavior and the need for effective communication are consistent with the concerns about conflicts of interest and the importance of open innovation strategies [66,97]. The partnership-related risks associated with the urgent project remain consistent with those in traditional projects. However, what changes is the underlying motivation that enables actors to establish and continue the partnership despite the risks, thereby overcoming conflicting priorities even without contractual formalization.

5.3.2. Public Equipment Risks

The management of public equipment involves four risks, as presented in Appendix C. However, the existing literature highlights the value of equipment, laboratories, and industrial sectors [63] in various contexts, such as technology transfer projects [122] and cooperation factors between university and industry [123,124]. Thus, this research offers a novel perspective by analyzing the risks associated with equipment beyond its monetary value. Specifically, the evidence acknowledges the risk of non-utilization (R22) and equipment misuse (R24 and R23).

5.3.3. Manufacturing and Project Risks

The findings highlight two potential risks associated with the manufacturing process: the manufacturer's lack of a suitable tool for the project execution (R31) and the possibility of incorrect assembly between the visor and forehead (R32). As far as we searched, the specific literature reveals that neither of these risks has been directly or indirectly addressed. In this case, the main point in the literature regard innovation implementation [69,70] and scientific production [68], for example.

There is no reference to design/project-related risks about the project model (R1) and purpose (R2) in the existing literature. Previous studies are related to technology transfer projects [63], for example, and the risk of non-performance of the technology or losing its innovative edge [71,72]. Project-related risks are consistent with each other (7.5 and 8.3). However, risks associated with projects are extensively discussed in the broader literature, as indicated by Ball and Watt [125], the Project Management Institute—PMI [126], and Ruan et al. [87]. Like production-related risks, risks related to the project have not received attention in the specific literature since they are at a research level beyond the organizational level, which traditionally remains in the sphere of technology transfer [63].

5.3.4. Human Resources Risks

In another context, citations associated with the people category can be found in the literature [121]. The extant literature covers research on people seeking opportunities for collaborative knowledge generation [127], of people and knowledge in the context of global university partnerships [128], or in organizational change [129], for example. Al-Tabbaa and Ankrah [121] pointed out risks referred to as underpinning challenges, such as misinterpretation, expected responsibility of members, different and contradicting priorities, and trust. Notice that characteristics of the interaction, such as trust and collaboration, were also commented on by Al-Tabbaa and Ankrah [121]; these when combined, could explain the Open Innovation. However, the findings show psychological/emotional (R3 and R5) and legal aspects of the interaction (R4). In general, the managers and participants who worked on this project learned how to overcome risks and difficulties, ultimately saving time in addressing potential risk scenarios.

5.3.5. Intellectual Property Risks

The relevance of the intellectual property cluster in risk analysis was found to be relatively low (R15, 4.6; R16, 4.8), with the smallest variation between them. This indicates that competitors' concerns, as pointed out by Ankrah et al. [71], were not a priority in this particular project because it did not intend to proceed to commercialization. Previous

studies [67,130,131] provide examples supporting this notion. They point to problems that can be encountered in the release of research information of a sponsor or product, confidentiality problems for researchers, and the possible consequences of fractured relationships between sponsors and researchers. Furthermore, Ankrah et al. [71] highlighted the risks associated with the diminished control or leakage of proprietary information and the dilemma of withholding the publishing of their results until patenting has taken place and the knowledge becomes obsolete [59]. Thus, these findings reinforce the importance of intellectual property in interactions, even in non-commercial projects, as the existing literature corroborates. During the peak of the pandemic, several companies released their patents, as occurred with the regulation of the National Health Surveillance Agency (ANVISA). This helps explain this category's relevance.

5.3.6. Logistics and Distribution Risks

Previous studies have already acknowledged the risks of cooperation within the supply chain context [73] and within the context of the goal of collaboration with the university [60], for example. However, this article emphasizes the importance of saving time in this urgent cooperation, with findings revealing the risk of delay (R29) and displacement (R30). Also, it is noteworthy that the risk of delay (R29) is the only unacceptable risk [87], and it is therefore essential to reduce it at any cost. It helps to explain and reinforce the perspective of a high intensity and time sensitive sector within the analysis of urgent projects [20].

5.3.7. Sanitation Risks

The analysis of urgent Open Innovation projects, particularly during the COVID-19 pandemic, highlights a significant yet underrepresented aspect in existing literature: the risks associated with sanitation practices. Despite being well characterized as internal risks [91], this study underscores their critical nature, especially in environments such as university laboratories, where the project development took place. Our findings reveal that risk perception in High-Intensity Time-Sensitive Projects in a pandemic context, such as the one under study, markedly differs from those encountered in less time-critical initiatives. Sanitation risks, particularly those related to maintaining sterile conditions (R26) and avoiding contamination during the production and handling process (R27), emerged as paramount. Moreover, the risk of failing to properly sanitize materials and products (R28) was identified as a higher priority, appearing in a critical group. These findings amplify the importance of robust sanitation protocols in pandemic-responsive projects, where the risks of contamination and inadequate sanitization processes carry potentially more severe consequences.

5.4. External Risks

External risks [91] are those influenced by factors outside the project's immediate control. They include Institutional Image (IM) Risks and ANVISA (AN) Risks.

5.4.1. Institutional Image and Reputation Risks

The literature has already highlighted institutional risks faced by universities and their research staff, particularly concerning their reputation [66,67]. The findings revealed the existence of seven risks associated with the image of the institutions (Appendix C). Notice that the image risk category was the biggest risk group. This emphasizes the concern perceived by the interviewees about this cluster. It is noteworthy that previous authors have already recognized the relevance of the image issue, e.g., enhancement of corporate image [74] and reputation by associating with a prominent institution [64]. However, these authors did not address the risks involved. Furthermore, in a different direction, Harman and Sherwell [67] pointed out that in an urgent project, senior management did appear to be fully aware of the possible dangers before the case became highly publicized, thus avoiding any controversy. The evidence reinforces the importance of institutional

image and reputation, contributing to a list of risks that had not been discussed in the specific literature.

5.4.2. Regulation Risks

Risks associated with compliance and interaction with regulatory bodies, in this case the Brazilian National Health Surveillance Agency (ANVISA), are external, stemming from the need to align with established regulatory standards and obtaining necessary approvals from ANVISA. These results are in line with the external risks of government regulations [66] and indirectly affect public perception and trust issues [67] already highlighted in the Institutional Image and Reputation category. The findings highlight the role of ensuring product specifications (R11), adherence to regulatory frameworks (R12), and managing inputs (R13 and R14). These elements identified as the third most critical risk category in the context of the pandemic.

6. Risks Mitigation Strategies within the Context of the QH Model

Based on the analysis and discussion of the urgent Open Innovation project carried out under the Quadruple Helix (QH) model, this experience can be valuable for other urgent projects regarding the application of risk management techniques. By studying the identified risks and their respective categories, researchers were able to present recommendations and suggestions that aim to assist managers in developing and implementing risk mitigation strategies in similar contexts.

Table 3 summarizes the main suggestions for risk mitigation strategies for urgent projects within the QH model. Risk mitigation involves trust and open communication, equipment, and project management, cultivating a team environment, attention to intellectual property, sanitation practices, supply chain planning, distribution and logistics, proactive management of image and reputation, and regulatory compliance. Each aspect must be adapted to the specific needs and dynamics of the project and its stakeholders.

Table 3. Risk mitigation strategies within the context of the QH model.

Risk Origin	Classification	Suggestions for Risk Management in Similar Projects
Internal	Partnership (PA)	Foster trust and open communication among project partners to manage expectations and reduce partnership dissolution risks.
	Equipment (EQ)	Implement equipment management practices including monitoring, maintenance, and training for proper handling.
	Production (PR) and Project (PJ)	Develop a fast, comprehensive, and time-sensitive project management plan with agile methodologies for flexibility. Ensure ongoing oversight to maintain alignment with objectives.
	People (PE)	Cultivate a collaborative work environment. Address emotional and legal aspects to enhance team dynamics and efficiency.
	Intellectual Property (IP)	Manage intellectual property, including protecting proprietary information and balancing the timely dissemination of research.
	Sanitation (SA)	Use strict sanitation practices, especially on health-sensitive projects, to mitigate contamination risks.
	Logistics (LO)	Establish strategic relationships with supply chain, distribution, and logistics partners, for clear communication and shared objectives. Optimize internal coordination and logistics processes to prevent delays and bottlenecks.
External	Institutional Image (IM)	Implement a proactive communication strategy to manage institutional image and reputation, engaging actively with media and external stakeholders.
	ANVISA * (AN)	Develop compliance processes, continuously monitor regulatory changes, and establish open communication with regulatory bodies.

* National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária—ANVISA).

7. Conclusions

This research on an emergency Open Innovation (OI) project during the COVID-19 pandemic within the context of the Quadruple Helix (QH) model yielded significant insights into the management of urgent innovation projects. The application of the QH theoretical model was essential for understanding the complex interactions between government,

academia, industry, and civil society. Furthermore, it facilitated a detailed understanding of the project lifecycle, highlighting the vital role of stakeholder collaboration in the face of a crisis.

Key findings include the agility and adaptability in managing high-intensity, time-sensitive projects. The crisis context demanded agile actions, collaboration, and fast communication among stakeholders. The key elements of trust, collaboration, communication, agility, partnerships with stakeholders, scale, and logistics emerged as critical factors in successfully delivering the urgent OI project. These elements interplay to create an enabling environment for innovation and successful implementation of the project. By providing an in-depth urgent OI project management description, this paper offers an understanding on how the risk context was created while unveiling a deeper meaning and details of such projects.

In the Quadruple Helix model context, risks can manifest in various dimensions. This study identified thirty-two risks and ten categories inherent to urgent OI projects contributing to a comprehensive risk management framework. Understanding these risks is essential to developing proactive mitigation strategies like those presented in this study, promoting collaboration, and improving high-intensity time-sensitive project outcomes. Interestingly, risk categories known in the literature from a non-urgent perspective, such as socio-ethical and natural risks, were not of the participant's concerns. Traditional risks, such as equipment, production, project, and intellectual property, are deemed less critical. Less prominent categories in literature appear with more criticality. Ultimately, the temporal aspect is the most critical one in this extremely urgent project.

The framework proposed offers a representation of the urgent Open Innovation project, specifically related to risks, with the context of the fast Quadruple Helix formation. It expands the framework of Pirlone et al. [3] about the relationship between risk and the Quadruple Helix model, expanded here similarly to Popa et al. [4] in the healthcare domain, and extended in this research on extremely urgent projects. Furthermore, it expands the traditional QH theory by incorporating Risk Analysis to investigate urgent projects with an Open Innovation development process.

Finally, this research contributes to the literature on the Quadruple Helix model by providing valuable insights into managing urgent OI projects during crises. The findings underscore the significance of stakeholder collaboration and risk management in such projects. It also expands the urgent project literature by explaining precisely how the OI project is formed from the leadership perspective, overcoming the challenges such as rapid development, material sourcing, funding constraints, scaling manufacturing, usability and efficacy, logistical complexity, communication and coordination, risk management, trust building, technological constraints, and adaptability. The main contribution was to explore the challenges presented by an extremely urgent Open Innovation Project during the COVID-19 pandemic, shedding light on the fast and dynamic nature of innovation in times of crisis. The case study validates the effectiveness of the QH model in extremely urgent, complex ecosystems requiring extremely rapid innovation in an extremely short duration. By focusing on the risks of interaction in an urgent project related to the QH model, this paper contributes to a list of risks that can be improved in future research. We hope this study proves beneficial to researchers, policymakers, and practitioners engaged in high intensity Open Innovation time-sensitive projects in times of urgency and emergency.

We acknowledge the limitations of our research. The total number of interviewees was restricted. However, because each participant completed different rounds of interviews, the initial round of interviews was conducted right after the completion of the project, and we were able to access the highest management of each institution with decision-making and management authority and knowledge of the entire project process during the pandemic crisis; this allowed us to gather very recent and detailed information about the extremely urgent project. Future research could expand the number of participants or include individuals from different levels within each helix to gain a more comprehensive

understanding. We were unable to carry out this approach due to the complete lockdown imposed during the pandemic.

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Appendix A

Table A1 presents the set of questions designed to gather detailed data into the initiation, execution, and risk factors associated with the project. It presents the method divided into two parts: the case study focuses on the developmental process and stakeholder engagement, while the risk identification aims to capture the perceived risks involved in the collaboration.

Table A1. Case study and risk analysis question script.

Method	Question Script
Case Study	(i) Explain, in your own words, how you started the process of developing the Face Protector. (ii) What was the interest in participating in this project? What was the first contact made with the university? (iii) In your opinion, where did this demand come from at the university/company/army/society? (iv) How many people from the institution participated in the process? What are the roles/positions of those involved in this work? (v) In addition to the university/company/army/society, were other companies or institutions involved? Please quote which ones. (vi) Describe, objectively, the stages of the development process. (vii) What were the barriers and advantages that occurred during the process?
Risk Identification	What are the risks perceived by you in this interaction process?

Appendix B

Figure A1 illustrates a detailed timeline for the GRU project's development cycle. It begins with initiating partnerships and progresses through data collection, various stages of prototyping, comprehensive testing, and preparation for production. The visual narrative underscores the project's iterative essence, marked by continuous testing and feedback loops with the involved stakeholders. This reiterative process signifies the adaptive and responsive nature of the development to ensure efficacy and compliance. The diverse roles and contributions of stakeholders are symbolized by distinct icons, which provide a quick visual reference to their involvement and influence at various stages of the urgent project development.

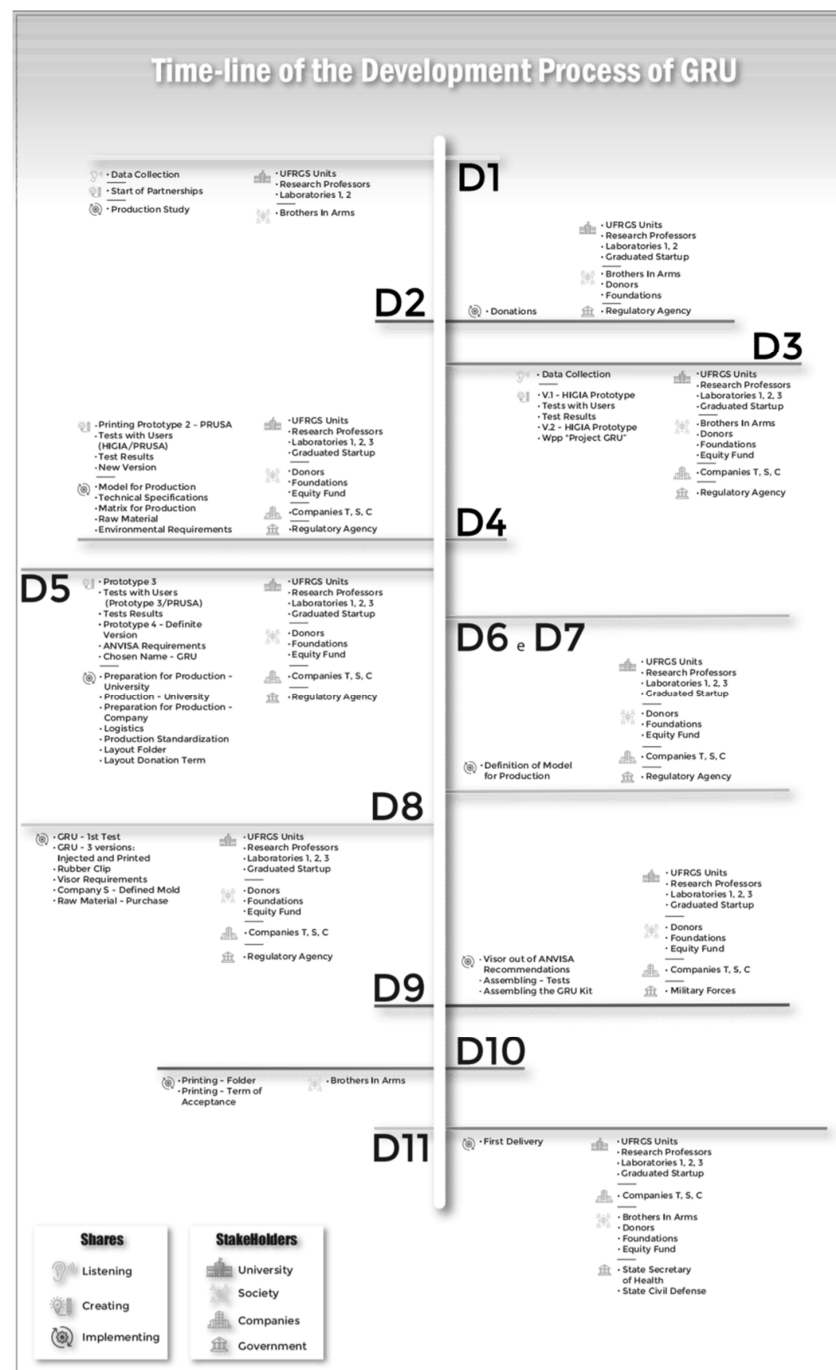


Figure A1. Characterization of the helices, their actors, and the time-line in which each actor joins the project.

Appendix C

Table A2 systematically provides and categorizes risks associated with the execution of the rapid Open Innovation project during the COVID-19 pandemic, offering a quantified evaluation of each risk in terms of its impact, probability, individual Risk Index (RI), and average risk index for grouped risks, spanning multiple categories such as Partnership, Institutional Image, Equipment, Production, Project, People, Intellectual Property, Logistics, ANVISA compliance, and Sanitation.

Table A2. Classification and quantitative assessment of risks in rapid Open Innovation Project amid the COVID-19 pandemic: impact, probability, and group averages for Risk Index.

Classification	Risk	Risk Name	Risk Origin	Impact	<i>I</i>	Probability	<i>P</i>	<i>RI</i> <i>P</i> × <i>I</i>	Group Average
Partnership (PA)	R6	Risk of breaking the partnership.	Internal	Major	3.94	Probable	3.75	14.8	10.5
	R7	Risk of not signing a Protocol of Intent between the institutions involved.	Internal	Medium	2.13	Rare	3.25	6.9	
	R9	Risk of not reaching consensus on joint product development.	Internal	Significant	3.25	Rare	3	9.8	
Institutional Image (IM)	R17	Risk of the media not highlighting the contribution of each of the entities involved.	External	Significant	2.94	Frequent	4.5 **	13.2	9.53
	R18	Risk of receiving the press without the consent of the university dean.	External	Significant	2.56	Probable	3.75	9.6	
	R19	Risk of disclosure of company names without the consent of the parent company.	External	Significant	2.63	Probable	4	10.5	
	R20	Risk of poor evaluation of the product by society or by health workers.	External	Significant	2.63	Probable	4	10.5	
	R21	Risk of improper use of the product.	External	Medium	2.06	Rare	3	6.2	
	R10	Risk of image association between the Armed Forces and one of the participating companies.	External	Medium	2.19	Remote	2.25	4.9	
	R8	Risk of misrepresentation of the purpose of the face shield development project by the press.	External	Significant	2.63	Frequent	4.5 **	11.8	
Equipment (EQ)	R22	Risk of not being able to open the 3D printing lab.	Internal	Significant	3.06	Probable	3.5 **	10.7	8.8
	R23	Risk of misuse of public equipment.	Internal	Significant	3.19	Remote	2.25	7.2	
	R24	Risk of using equipment from other university professors.	Internal	Significant	2.94	Rare	2.75	8.1	
	R25	Risk of using material from the warehouse stock of the School of Engineering and the central warehouse of the university.	Internal	Significant	3.06	Rare	3	9.2	
Production (PR)	R31	Risk of the manufacturer not having a tool to carry out the project.	Internal	Significant	2.88	Rare	2.5 **	7.2	8.65
	R32	Risk of incorrect assembly between visor and forehead.	Internal	Significant	2.88	Probable	3.5 **	10.1	
Project (PJ)	R1	Risk of error in decision-making about the project model.	Internal	Significant	2.5 **	Rare	3	7.5	7.9
	R2	Risk of the product not serving its purpose.	Internal	Significant	3	Rare	2.75	8.3	
People (PE)	R3	Risk of lack of appreciation of the people involved.	Internal	Significant	3	Rare	2.75	8.3	9.5
	R4	Risk of the participation of volunteer employees.	Internal	Medium	2.38	Rare	2.5 **	5.9	
	R5	Risk of conflict between project participants.	Internal	Major	3.56	Probable	4	14.3	
Intellectual Property (IP)	R15	Risk of not depositing intellectual property.	Internal	Medium	1.69	Rare	2.75	4.6	4.7
	R16	Risk of breaking patents.	Internal	Medium	1.75	Rare	2.75	4.8	

Table A2. Cont.

Classification	Risk	Risk Name	Risk Origin	Impact	<i>I</i>	Probability	<i>P</i>	<i>RI</i> <i>P</i> × <i>I</i>	Group Average
Logistics (LO)	R29	Risk of delay in the delivery of personal protective equipment (PPE), losing the effectiveness of the task force.	Internal	Major	4.06	Probable	4.25	17.3	11.85
	R30	Risk of a problem occurring in the displacement of the material.	Internal	Significant	3.19	Remote	2	6.4	
ANVISA * (AN)	R11	Risk of having technical product specifications denied.	External	Significant	3.31	Rare	2.75	9.1	11.3
	R12	Risk of not having a product regulated by ANVISA.	External	Major	3.5 **	Rare	3.25	11.4	
	R13	Risk of using inputs other than the DRC of ANVISA, due to lack of supply.	External	Significant	2.69	Probable	3.75	10.1	
	R14	Risk of lack of input.	External	Significant	3.44	Probable	4.25	14.6	
Sanitation (SA)	R26	Risk of inadequate cleaning/sanitization of laboratories.	Internal	Significant	3.19	Rare	3.25	10.4	12.63
	R27	Risk of contamination of the team.	Internal	Major	3.56	Probable	4.25	15.1	
	R28	Risk of improper cleaning of the product after manufacture.	Internal	Significant	3.31	Probable	3.75	12.4	

* National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária—ANVISA); ** The rounding scans were made for more for the qualitative classification, e.g., 3.5 ≅ 4.

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