International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2024: 7.101

A Case Study on the Fiocruz and IBMP Partnership: Strengthening Biotechnology and Public Health in Brazil

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Abstract: ***Partnerships between public and private organizations are essential for advancing health innovation and improving national production capacity for medical solutions. This case study explores the long-term collaboration between Fiocruz and the Institute of Molecular Biology of Paraná (IBMP), which has played a pivotal role in enhancing Brazil's capacity to produce diagnostic kits and biotechnological products for the Unified Health System (Sistema Único de Saúde – SUS) Using qualitative methods, including interviews with key stakeholders and analysis of institutional records from 1999 to 2024, the study maps the evolution of this partnership, highlighting its strategic planning, implementation, and impact. Findings reveal that the success of this partnership is rooted in a culture of open innovation, functional entrepreneurship, and alignment with public health policies. Lessons learned from this experience offer valuable insights for similar initiatives seeking to strengthen national health systems and promote technological independence. This project demonstrated that the partnership model benefits Brazilian public health and can be replicated in other regions of the country. Understanding this partnership model offers valuable lessons for other countries seeking to strengthen their national health innovation systems through collaborative strategies.***

Keywords: public-private partnerships, health innovation, biotechnology development, IBMP, Fiocruz.

1. Introduction

Partnerships between companies and Institutions of Science, Technology, and Innovation (ICTIs), public or private, play a crucial role in advancing scientific and technological development, both in Brazil and globally, as they promote the exchange of knowledge, resources, and experiences, resulting in meaningful benefits for both partners and society as a whole (1,2). In the Brazilian context, partnerships between companies and ICTI have been increasingly valued and encouraged, given the growing need for innovation and competitiveness in the global market and, above all, Brazil's goal of achieving independence in the production of medicines, vaccines, diagnostic tests, and other health products (3). Such partnerships drive scientific and technological progress in health and contribute to the country's economic and social development. In Brazilian legislation, there are two types of partnerships provided for in the current regulatory framework: Public-Private Partnership (PPP), regulated by Law No. 11,079/2004 (4), and Partnership for Productive Development (PDP), established by Ordinance No. 837, of April 18, 2012 (5). PPPs are agreements between the public and private sectors for the joint performance of a service or work of interest to the population. PDPs are collaborations between public institutions that produce strategic health products and Science, Technology, and Innovation (ST&I) and private companies, in which the Ministry of Health (MoH) guarantees PDP partners a specific share of the public market for a specific drug, vaccine, or health product, for a defined period. The technology is then fully transferred to the public institution.

In a similar vein to the PPP and PDP, since 1999, there has been a relevant and prominent interinstitutional partnership in Brazil established between the Institute of Molecular Biology of Paraná (IBMP), a private company based in the state of Paraná, and the Carlos Chagas Institute of the Oswaldo Cruz Foundation (ICC/Fiocruz) that has delivered relevant biotechnological solutions for the Unified Health System (Sistema Único de Saúde – SUS), especially in diagnosis, which contributes substantially to improving health conditions and social well-being (6). These two institutions are a reference in biotechnology in Brazil and, over the last 25 years, this partnership has resulted in the development and production of high-quality diagnostic tests, essential for the fight against various diseases and epidemics due to the combination of scientific expertise and industrial production capacity.

Partnerships between companies and ICTI can generate a synergistic interaction with favorable results for both and represent a powerful tool to boost scientific, technological, and economic progress. Knowledge about the initial strategic planning carried out in the IBMP and ICC/Fiocruz partnership, the design process (implementation), and the *modus operandi* of the execution of the strategic actions planned over these years of partnership brings lessons learned that can contribute to the elaboration of future strategies for the aforementioned partnership – IBMP and Fiocruz – and contribute to and inspire other partnerships of similar format involving the actors of the research and innovation ecosystem of Brazil. The purpose of this study is to analyze the strategic development and operational dynamics of the IBMP-Fiocruz partnership and assess its contributions to advancing biotechnological solutions for Brazil's public health system.

2. Literature Survey

2.1 Institute of Molecular Biology of Paraná (IBMP)

IBMP is a non-profit private civil association located in Curitiba, in the state of Paraná, and endowed with administrative and financial autonomy. It was established in 1999 with the objective of developing education, applied research and technological development activities in the area of molecular biology, in partnership with and with the direct support of Fiocruz, the Paraná State Department of Health, the Paraná State Department of Science, Technology and Higher Education, the Paraná State Institute of Health, the Paraná Institute of Technology (Tecpar) and other entities in Paraná, other regions of Brazil and abroad that operate in this area of technology. Therefore, IBMP was born from a partnership between Fiocruz and the government of the state of Paraná, with the purpose of enabling the installation of Fiocruz in the state of Paraná. Throughout its history, IBMP has consolidated itself as a Scientific, Technological and Innovation Institution, collaborating with the development of science and technology in Brazil and providing quality health products for public health. Currently, IBMP has a portfolio of molecular tests and rapid diagnostic tests; its facilities are state-of-the-art and occupy an area of 2,200 m², in addition to an additional 1,500 m² dedicated to Research and Development and Innovation. The technical team is made up of more than 50 professionals with master's and doctoral degrees (7) (8).

2.2 Fiocruz (Oswaldo Cruz Foundation)

Fiocruz is a centennial Brazilian institution, linked to the Ministry of Health, created in 1900 by the renowned sanitary doctor Oswaldo Cruz. It is an institution focused on teaching, research, innovation, assistance, technological development and extension in the field of health and represents the most important complex of scientific research, technological development and innovation of the Brazilian public sector in the area of health (9) (10). Fiocruz has national coverage and operates in the five regions of Brazil - North, Northeast, Midwest, Southeast and South. Its headquarters are located in the city of Rio de Janeiro, but it has units in 10 other Brazilian states, relevant international units with offices in Maputo, Mozambique and the permanent research laboratory in Antarctica, Fioantar (11). The foundation has highly qualified employees and students; The number of employees registered in 2022 was more than nineteen thousand among servers, outsourced workers, service providers, scholarship holders, students, interns and others (12). Fiocruz Paraná was institutionalized in 2009 with the creation of the Carlos Chagas Institute (ICC) and represents a successful implementation experience.

3. Methodology / Approach

It is a case report research project at an exploratory, qualitative level, following Bourdieu's theoretical framework (13), including mapping of historical data and 17 semi-structured interviews with collaborators from diverse roles within the IBMP and Fiocruz institutions.

The objective of the research was to analyze the model adopted in the partnership between IBMP and Fiocruz to understand its planning, implementation, operation, management, and its scope in the promotion of technological innovations with a focus on biotechnology and in the development of diagnostic tests and biotechnological solutions. The project was executed from February 2022 (planning) to July 2024 (completion of the analysis of the results).

For the mapping of historical data, a bibliographic review using "state of the art" or "state of knowledge" approaches" was conducted to map and analyze relevant academic contributions across different periods and contexts (14). Different sources of information were used: (a) documents made available by the managers of these institutions, IBMP and ICC/Fiocruz; (b) books related to institutions; (c) public data available on the official IBMP website (https://www.ibmp.org.br/) and on the official website of Fiocruz (https://portal.fiocruz.br/); (d) documents, information obtained and websites accessed from internet search engines using the keywords "IBMP history", "IBMP foundation 1999", "ICC Fiocruz history", "Fiocruz Paraná", "IBMP Fiocruz Paraná", "IBMP inauguration", "Fiocruz Paraná inauguration". Information available on social networks was not considered. The time frame of the research comprises the period between 1999 and 2024. The interviews were conducted from August 2023 to January 2024 using a

semi-structured script for the interviews, prepared according to Bardin's qualitative research methodology (15). The type of sampling was 'intentional', since the team selected individuals to be interviewed. It was planned to invite 22 (twenty-two) professionals to the interview, all over 18 years of age, who participated in the history of the partnership between IBMP and ICC/Fiocruz-Paraná.

The process of transcription of the interviews constituted, simultaneously, the process of pre-analysis and interpretation of data based on the available literature specific to interviews (16) (17) (18). Two types of transcriptions were used simultaneously: adapted transcription and standardized formal language transcription. The "adapted transcription" was chosen because the purpose of the interviews and their transcriptions was not to reproduce all aspects of speech, but to capture objective information for later data analysis; In addition, the "transcription into cultured or formal language" was chosen in order to correct any errors of agreement, including nominal, orthographic, and verbal. During the transcription process, the necessary grammatical changes were made in order to improve the text without losing the coherence and originality of what was said.

For the analysis of the data obtained in the bibliographic research, the main items to be addressed were categorized and, subsequently, a file was created for each category. Through the file, it was possible to organize and concentrate the main ideas of each document.

The project presented limitations inherent to qualitative content analysis research. Specifically, the subjectivity of the data obtained in the interviews was a constant concern, and the interpretations of the responses may have been influenced by the research team's perceptions and experiences, introducing bias into the results and conclusions.

This research project was approved by the ethics committees in accordance with current Brazilian regulations. Furthermore, it was registered in ReBEC (Brazilian Registry of Clinical Trials) under number RBR-4ng4kwf (Universal Trial Number [UTN]: U1111-1293-2608).

4. Results and Discussion

Twenty-one (21) employees were invited to the interview, with acceptance of seventeen (17) participants (IBMP = 11; Fiocruz = 6), among whom five participated directly in the planning, articulation, and implementation of the IBMP in 1999, and seven participated in the implementation of the ICC/Fiocruz in 2009. Chart 1 briefly describes the profiles of the participants.

Frame 1: Profile of the interviewees from IBMP and Fiocruz.

Age group	35-44 years old (n=4) 45-54 years old (n=4) Over 55 years old (n=9)
Self-reported gender	Male (n=11) Female (n=6)
Length of time (in years) working at the institution as of the interview date	Min = 0 Max = 38 Median = 16 years
Positions	Coordinator (n=3) Manager (n=6) Principal, vice-principal (n=2) President, Vice-President, Chief Executive Officer (n=3) Others (n=3)
Participation in the planning and implementation of the partnership	**Both periods = 4** Period 1999-2009 = 5 Period 2009-2010 = 7 No participation **in any period** = 5 (entry into the institution after 2009)

4.1 Planning and implementation of the IBMP and ICC/Fiocruz Paraná partnership

The IBMP was created in 1999 through the cooperation agreement between Fiocruz and the Government of the State of Paraná, through Tecpar, with the intention of starting the implementation of Fiocruz in the southern region and, ten years later (2009), the Carlos Chagas Institute (ICC/Fiocruz Paraná), a formal technical unit of Fiocruz based in Paraná, took place, and the IBMP maintained the same legal status, but under a different structure. This successful public-private initiative resulted from actions initiated by Fiocruz in Rio de Janeiro in the 1980s, in collaboration with the government of Paraná. In 1980, the Department of Public Health and Social Welfare of Paraná commissioned Fiocruz to develop a public health course aimed at preparing professionals with university-level education, following the model of the courses at the National School of Public Health/Fiocruz (ENSP). Another episode of collaboration between authorities in the state of Paraná and Fiocruz occurred in 1981 with the establishment of an agreement aimed at the implementation of a Toxicological Information Center in Paraná. Fiocruz contributed not only financial resources, but also technical and scientific expertise as coordinator of the National Toxico-Pharmacological Information System. It was in 1991 that a new agreement was signed between Fiocruz and authorities in Paraná, this time involving the Paraná Institute of Technology (Tecpar) with the objective of scientific and technological collaboration, mobilizing both human and material resources available in both entities, with the purpose of solving research and development problems (10). The creation of the IBMP itself took place on May 27, 1999 and was made official through the Minutes of the General Assembly of the Constitution of the IBMP with a legalization date of August 4, 1999, signed by the then governor of the state of Paraná and representative of the Ministry of Health of Brazil. According

to this document, the General Assembly established the "Institute of Molecular Biology of Paraná – IBMP" as a non-profit civil society under private law, the result of a partnership between Fiocruz and the government of the state of Paraná, with the purpose of enabling the installation of Fiocruz in this Brazilian state *and "strengthen the competence of the State in the area of Molecular Biology applied to Health"* (19). The minutes make it clear that the IBMP is endowed with administrative and financial autonomy, constituted with the objective of developing education, applied research and technological development activities, in the area of molecular biology, in partnership with and with the direct support of Fiocruz, the Paraná State Department of Health, the State Secretariat of Science, Technology and Higher Education of Paraná, the Institute of Health of the State of Paraná, the Institute of Technology of Paraná (Tecpar) and other entities in Paraná, other regions of Brazil and abroad that operate in this area of technology. The document also makes it clear that this partnership was conceived with the participation of the following actors: Paraná State Government, Federal Government, health institute (namely, Fiocruz), technology park (namely, TecPar).

At the aforementioned meeting, the IBMP Bylaws (1999 version) and the resolution on the acts resulting from it were approved, both included as annexes to the aforementioned minutes. The IBMP, at its creation, had in its organizational chart representatives of public power entities, civil society entities, individuals of notorious professional capacity and recognized moral suitability and the representative of the Associates on the Council. IBMP was qualified as a Civil Society Organization of Public Interest, according to Federal Law No. 9,790, of March 23, 1999 (20), which did did not aim to generate profit and whose main objectives were education, research and institutional development; this qualification made it able to enter into service contracts, agreements, management contracts or Partnership Terms with the Government or with other entities of direct or indirect administration, as it is framed in Federal Law No. 8,666 of 1993 (21), in force at the time. In addition, the organizational structure adopted and the unquestionable ethical-professional reputation of its founders and directors, allowed the IMBP to be eligible for tax exemption, in accordance with the Federal Constitution, Article 150 (22) and complementary requirements defined by the National Tax Code (23) and Federal Law No. 9,532 of 1997 (19,24).

The scientific group of the Department of Biochemistry and Molecular Biology of the Oswaldo Cruz Institute/Fiocruz (DBBM/IOC/Fiocruz) already had its lines of research consolidated, national and international recognition to obtain research funding, excellent articulation with other international groups and, above all, accumulated knowledge in Molecular Biology with great potential to be transformed into products and contributed greatly to the success of the implementation of IBMP in research, in education and production for the SUS. Although it was from the third sector, it had a structured graduate activity with the Federal University of Paraná and the graduate programs of Fiocruz, at the same time that he developed research, especially research on Chagas Disease based on molecular biology. It is important to mention that the motivations cited by the interviewees who participated directly in the creation of the IBMP in 1999 were: the opportunity for the group to occupy a larger physical space, allowing the group to grow in the number of researchers and students, a physical space that would have been difficult to obtain at the IOC/Fiocruz at the time (and still today); at that time, due to the physical limitation of the IOC/Fiocruz, the group was spread across the Fiocruz campus in Rio de Janeiro; professional motivations for the challenge of being pioneers in molecular biology in the southern region of Brazil on behalf of Fiocruz; personal motivations related to violence in the city of Rio de Janeiro. The transfer of the IBMP creator nucleus, from Rio de Janeiro to Curitiba, took place in 2011; the group was composed of 4 founding researchers and 2 non-civil researchers from Fiocruz.

The rapid and constant institutional development experienced by the IBMP from 2001 to 2007 was one of the main factors that led Fiocruz to decide, in 2007, to institutionalize the institute with Fiocruz. The IBMP was strengthened with the introduction of important technologies that were still being introduced in Brazil at that time, such as research with stem cells, functional genomic resources, virology and cytology, which were traditional areas of Fiocruz. Part of this development was a consequence of the decision to invest in molecular tests for the detection of HIV and HCV in the blood bags of the Brazilian blood bank. The project for the institutionalization of the institute with Fiocruz was approved and consisted of the installation of Fiocruz Paraná on the Tecpar campus, in the same facilities occupied by IBMP, with the agreement that IBMP's research and graduate activities would be the genesis of the new Fiocruz Paraná unit and IBMP would conduct the management of the plant for the production of molecular biology inputs for production in Bio-Manguinhos, molecular testing for the detection of HIV/HCV; in other words, Fiocruz would assume all the activities, assets and scientific legacy of IBMP and IBMP would be maintained as a company. The project was approved and a series of agreements were signed between Tecpar and Fiocruz, the Government of Paraná and the Ministry of Health (MS) to obtain the material and institutional conditions for the installation of this new unit. The Carlos Chagas/Fiocruz Paraná Institute was created by the Fiocruz Presidency Ordinance No. 103/2008-PR of March 24, 2008 and was inaugurated on August 4, 2009 (25,26). The name of the institute, Carlos Chagas Institute, was a tribute to the centenary of Carlos Chagas, since one of the main lines of research of the Paraná group, at that time, was Chagas disease.

Therefore, it is not appropriate to speak of IBMP and ICC/Fiocruz cooperation or partnership, or even IBMP and Fiocruz partnership, in 1999 because from that year until 2009, there were not two parties, since IBMP was the entity that operated Fiocruz in its relationship with Tecpar and the government of Paraná, in Curitiba. It was only later, in August 2009, with the creation of ICC/Fiocruz Paraná as a technical unit of Fiocruz, that two independent legal personalities came into existence, namely, IBMP and ICC/Fiocruz, and, therefore, the possibility of partnership between these entities. The history of IBMP and Fiocruz Paraná is divided into two distinct moments, 1999-2009 and 2009 onwards, a point highlighted by most interviewees.

The configuration of *Biotech* mentioned by some interviewees, currently assumed by the IBMP differs from the IBMP planned in 1999. The initial planning foresaw the sowing of seeds for Paraná to have an area of excellence in research and graduate studies in the field of molecular biology through Fiocruz from the creation of IBMP, which would later become a unit of Fiocruz. However, the internal and external opportunities combined with the competent management and visionary look of the managers involved at that time with IBMP and Fiocruz are what allowed IBMP to be maintained as a company and for Fiocruz Paraná (ICC) to develop as a technical unit of Fiocruz characterized by outstanding knowledge in molecular biology, technological platform, maturity in the area of innovation and entrepreneurship. One of the interviewees highlighted the functional entrepreneurship component coordinated by one of the Fiocruz managers at the time. This type of entrepreneurship was taken to IBMP and was one of the factors for the successful development of IBMP, culminating in the creation of Fiocruz Paraná, in the development of both entities after 2009. In this type of entrepreneurship, employees are free to share ideas and develop projects, with benefits including increased productivity and greater employee commitment, as well as a more collaborative organizational climate. Functional entrepreneurship leads to "corporate entrepreneurship or intrapreneurship", in which a company's employees are the drivers of change and innovation, that is, it is an internal entrepreneurship (27).

In addition, other factors that contributed to the success of the creation of IBMP, the creation of Fiocruz Paraná and the strengthening of the IBMP and Fiocruz partnership to the present day were:

a) Participatory management - in the interviews conducted, the participatory management of IBMP managers, the result of functional entrepreneurship, was mentioned several times as a positive and motivating factor in the development of IBMP in its 2 phases, both from 1999 to 2009, and after 2009 when it was remodeled.
b) Culture of innovation that values innovation and experimentation and that allows employees to experiment with new ideas and think critically.
c) It is important to highlight that these factors were pointed out by most respondents as relevant to feel motivated and engaged.
d) Intellectual capital of IBMP's founding core in molecular biology.
e) Accumulated knowledge that allows IBMP and Fiocruz institutions to respond quickly to demands, especially for molecular tests.
f) Strategy of establishing partnerships with other companies, *startups* and universities to explore new ideas and technologies and insert their operations in a broader ecosystem with more opportunities.
g) IBMP received, and still receives, a demand from Bio-Manguinhos, which, as a Fiocruz manufacturing unit, expressed/expresses a demand from the SUS, ensuring sufficient revenue to maintain the structure and develop new products, including non-diagnostic ones, thanks to its expertise in molecular biology; cited as 'virtuous flow'.

To adapt to the changes in their governance, IBMP and Fiocruz needed to reorganize their organizational charts over time. IBMP amended its Bylaws and, on March 18, 2020, during the Annual and Extraordinary General Meeting, a new version of IBMP's Bylaws was approved (28) which recognizes IBMP as an Institution of Science, Technology and Innovation (ICT), according to Law No. 10,973/2004 (29) and Paraná State Law 17,314/2012 (30) and designates the IBMP as a Non-Profit Civil Association of Private Law ('Society' has been replaced by 'Association'). IBMP's Bylaws version 2020 describe, in the Second Paragraph of Article 2, new activities of IBMP that reflect a strategic plan of the company different from the plan of its creation, in light of the current Brazilian regulations related to P&DI. Among these new activities, "associating with other companies, entities, public or private institutions. as well as to constitute specific legal arrangements, in favor of the development of its activities, including participating in business companies in Brazil and abroad". In 2023, IBMP approved a new version of its bylaws, but without considerable adjustment of the organizational structure (31). The ICC/Fiocruz Paraná has been using the current Internal Regulations, a document approved on June 28, 2018 (25). This document, in ARTICLE 1, designates it as a specific singular body of Fiocruz and, therefore, governed by the aforementioned regulation and by the Fiocruz Statute. The continuity of the partnership between IBMP and ICC/Fiocruz is guaranteed by the provision of ARTICLE 2, which provides that, in order to fulfill its mission, ICC may enter into agreements, contracts, agreements, and arrangements with national and international entities, public, philanthropic or private; establish partnership relationships with public and private entities, national and foreign.

4.2 Impact of Public Policies on the establishment of the IBMP and Fiocruz partnership

During the interviews, the managers' statement that P&DI needs government incentives at all three government levels — in the deliberation of public policies and in financial incentives, through promotion policies and tax incentives, was unanimous.

Since 1999, the year IBMP was created, several Brazilian political actions - federal, state and municipal - have favored the success of the IBMP and ICC/Fiocruz partnership. In line with national public policies aimed at RD&I, the states of Paraná (IBMP's location) and Rio de Janeiro (where Fiocruz's main unit is located) sanctioned important regulations and carried out important actions to stimulate RD&I and partnerships between companies and ICTI through economic subsidies. Despite Brazil's progress in the field of public policies for R&D in the health area, it was pointed out that some conditioning factors still hinder this process. According to the report and opinion of one of the interviewees, the main one is the financial resource for innovation, because innovation requires medium and long-term investment and maturation; others include legal and cultural restrictions.

During one of the interviews, the limitation of legal possibilities was discussed. Currently, IBMP has a "strategic alliance" with Fiocruz, which is another practice allowed by the Legal Framework and the current innovation law between

a private entity and a public entity, between the public ICT ICC and the private ICT IBMP, but several IBMP initiatives, which are operated in strategic political alignment with Fiocruz, there is no legal framework in place to formalize the collaboration between Fiocruz and IBMP. One of the interviewees mentioned that they thought the R&D legal system was sufficient, but ratified that Fiocruz's legal model has limited the process of internationalization of our S&T innovation activity. Although the innovation framework provides this, Fiocruz does not have an adequate legal model to deal with the dynamics of the biotechnology sector because it is a very tough autarchic foundation. This is a legal challenge that Fiocruz is currently trying to solve.

The managers interviewed expressed confidence in the improvement of policies to foster innovation from the relaunch of the CEIS. On September 26, 2023, the "National Strategy for the Development of the Economic and Industrial Health Complex" was officially launched by the Federal Government in Brasília-DF, with an investment of 42.1 billion by 2026 (32). The strategy launched has six structuring programs and aims to expand the national production of priority items for the SUS and reduce Brazil's dependence on foreign inputs, medicines, vaccines and other health products. This seeks to give the country greater autonomy in order to reduce the vulnerability of the health sector, strengthen the local production of goods and services, reduce judicialization in health and stimulate job creation in the sector (33). The launch of the strategy is the result of the work of the Executive Group of the Health Economic-Industrial Complex (Geceis), recreated in April 2023, through Decree No. 11,464/2023 (34).

One of the priorities is supporting the production of inputs for the prevention, diagnosis and treatment of socially determined diseases, such as tuberculosis, Chagas disease, viral hepatitis, HIV, as well as diseases relevant to public health, such as chronic diseases (such as cancer, cardiovascular, diabetes, and immunological conditions), dengue, health emergencies, and orthopedic trauma. The managers of IBMP and Fiocruz reaffirmed the importance of the concept brought by CEIS that health is an investment. In 2023, the health sector accounted for 10% of the Gross Domestic Product (GDP) and accounted for a third of scientific research in the country. However, Brazil's dependence on health inputs makes the SUS vulnerable to the foreign market, that is, more than 90% of the raw material used in Brazil for the production of vaccine and medicine inputs is imported. In the area of medical equipment, the national production meets 50%; in medicines, about 60% and, in vaccines, a little higher. The goal, with the investment foreseen in the strategy launched, is to reach an average of 70% of national production in the health sector (33).

The resumption of the CEIS was widely discussed during the 17th National Health Conference, held in July 2023, and was mentioned in eighteen different moments of the conference's Final Report (35). On this occasion, the programs and instruments of the National Strategy for the Development of the CEIS, presented at the 17th National Health Conference/MS among which the "Program for the Expansion and Modernization of Infrastructure of the Economic-Industrial Health Complex" stands out. The programs and instruments of this strategy have been corroborated by the approval of regulations of the Department of the Economic-Industrial Complex of Health and Innovation for the SUS, which strengthens the CEIS program and brings legal support to the strategic planning of Brazilian ICT (36–40).

One of the strengths of the IBMP-Fiocruz partnership is the fact that managers are directly involved in public policy discussions at the national level; the participation of the president of Fiocruz, Mário Moreira, in Geceis stands out.

It is important to note that the National Strategy for the Development of the CEIS is integrated into the effort to implement the New Policy for the Development of the Brazilian Industrial Sector, presented by the federal government in January 2024, whose guidelines are aimed at the economic, social, and sustainable development of Brazil. The new policy was created with the meaningful collaboration of the National Council for Industrial Development (CNDI) and provides for regulatory actions, intellectual property and incentives for local production, through new fundraising instruments, such as the "Development Credit Line" (LCD), and a framework of new policies. Among the areas targeted by the proposals, the CEIS stands out, in addition to agribusiness, the transport sector, civil construction and the energy sector. The new policy has the following measures: creation of special credit lines; Grants; regulatory actions; intellectual property actions; policy of public works and purchases, with incentives for local content, to stimulate the productive sector. The goals are grouped into six missions that guide efforts until 2033, among which mission 2 stands out, which refers to CEIS (41,42): "***Mission 2****: Resilient CEIS to reduce SUS vulnerabilities and expand access to health. Its goal is to increase the share of production in the country from 42% to 70%, in the context of the acquisition of medicines, vaccines, equipment and medical devices, among others, in addition to strengthening actions in the SUS*."

Along with the policy, the CNDI delivered the action plan for the period 2024-2026, indicating the priority strategic areas for the application of resources over the next two years.

4.3 Partnerships established and strengthened by the institutions IBMP and Fiocruz

Before 2009, the relationship between IBMP and Fiocruz was conventional, since it had a base strongly determined by the institute's focus on research and training. However, the Federal Court of Auditors guided the establishment of contracts instead of agreements through agreements, since the IBMP, although not a for-profit unit, is a private institution. Since then, the partnership between IBMP and Fiocruz has been established through contracts, facilitated in 2009 by the new phase of IBMP, which became a supplier of inputs and no longer an institution focused on training and research. Currently, IBMP and Fiocruz have also established a strategic alliance that allows for a more open and organized dialogue on strategic planning, market, demand, and production.

The establishment of partnerships with public and private entities has been the trademark of IBMP and Fiocruz, both in

strengthening the existing partnership between IBMP and Fiocruz, with the expansion of common scientific projects, as well as in the establishment of partnerships with other national and international entities, which reinforces and evidences that open innovation is part of the strategic plan of both institutions, as strongly corroborated by the interviewees. During the interviews, it was asked if the interviewees recognized the partnership between IBMP and Fiocruz as PDP and all answered no, since there is no technology transfer of a product, as is the objective of PDP, but rather product development in a joint, complementary way; a collaboration between ICTs that combines technological capabilities and complementary strengths, Fiocruz with molecular biology on the one hand and IBMP with the ability to transform this into a product on the other. The interviewees were unanimous in stating that the IBMP-Fiocruz partnership is an organizational innovation that has allowed the acceleration of innovation.

The innovation ecosystem in which IBMP and Fiocruz Paraná operate supports the strengthening of existing partnerships and the formation of new ones. Some actors in the innovation ecosystem of which IBMP and Fiocruz Paraná are part are: Tecpar, Secretariat of Science, Technology and Higher Education (SETI), Tecpar Technological Incubator (Intec), Paraná State Secretariat of Health (SESA), Evandro Chagas Institute (IEC), Lacen Paraná, FIEP System, universities.

Below are some outstanding actions to strengthen the IBMP-Fiocruz partnership, strengthen IBMP and Fiocruz partnerships with other public and private entities, as well as the establishment of new partnerships that have been relevant to both institutions and to public health:

- Partnership between IBMP, Fiocruz, Hemobras, Tecpar: signing of the Technical-Scientific Cooperation Agreement in December 2006 for the implementation of the NAT HIV/HCV molecular test in the Brazilian blood cell for the detection of HIV and hepatitis C viruses in blood bags destined for transfusion in Brazilian blood centers. This product applied in the screening of blood banks represented a great advance for the entire Brazilian blood bank, reducing the risk of HIV and hepatitis C virus transmission. The first registration of this kit, at Anvisa, was in 2011. In 2014, the Ministry of Health demanded the incorporation of another molecular target in the NAT HIV/HCV Kit, HBV; therefore, IBMP now produces two amplification modules: HIV/HCV amplification module - HIV/HCV/HBV NAT Kit and HBV amplification module - HIV/HCV/HBV NAT Kit. In 2016, the kit was revalidated by Bio-Manguinhos. In 2019, the molecular target for malaria detection, called NAT PLUS, was incorporated into the NAT Kit, the new version is presented in a single product: HIV/HCV/HBV/MAL Amplification Module (26,43).
- Partnership between IBMP, Fiocruz (Flavivirus Laboratory of the Oswaldo Cruz Institute) and the Ezequiel Dias Foundation (Funed/MG): partnership established in 2018 for the development of the General Yellow Fever Kit. Product registered with Anvisa in August 2020, making it possible to sell it in private laboratories in Brazil and Latin America that are able to perform molecular tests using real-time PCR (polymerase chain reaction) technology (44).
- Partnership between ICC-Fiocruz Paraná, IBMP and the Paraná State Health Department (SESA): on April 16, 2019, the Memorandum of Understanding was signed between the entities initiating the partnership (45).
- Partnership between IBMP, Fiocruz, Tecpar and the Center for Production and Research of Immunobiologicals (CPPI – Paraná): in 2019 a partnership was established to produce the production of Immunobiologicals and Immunobiologicals (CPPI – Paraná). (46).
- Partnership between IBMP, Fiocruz (ICC and IOC), Instituto Pasteur de Montevideo, Universidade de la Republica – UdelaR: in October 2019, an important partnership was signed for joint work in both technological development and production and with commercial perspectives in both countries, Uruguay and Brazil (47)
- Partnership between IBMP, Tecpar, ICC-Fiocruz Paraná and the Bio-Manguinhos/Fiocruz Institute of Technology in Immunobiologicals: at the beginning of the COVID-19 pandemic, in April 2020, the Covid-19 Diagnostic Support Unit was inaugurated on an emergency basis to meet the high demand for RT-PCR molecular tests for the diagnosis of the Sars-CoV-2 virus (48).
- Partnership between IBMP, ICC-Fiocruz Paraná and the State Department of Health, through the Worker's Hospital Complex: in December 2020, the research phase for the Rapid Test for COVID-19 Ag began, which culminated in registration with Anvisa in April 2021 (49).
- Partnership between IBMP and Tecpar, 2021, to modernize the IBMP Technological Development Center and the Health and Environmental Technology and Materials Technology centers It was in this space that the Biomol OneStep Covid-19 Kit and the rapid antigenic Covid test were developed to meet the demand in the COVID-19 pandemic. Both are registered with Anvisa and are used by the Unified Health System (SUS) to expand testing capacity in Brazil (50).
- IBMP and Tecpar partnership: in 2022 strengthen the partnership by signing an agreement for the licensing of all IBMP products to Tecpar, since this is a public company, which will be able to offer these products to SUS through decentralized purchases by state and municipal secretariats. The agreement signed in 2022 also provided for interaction between the teams of the two institutes, with the purpose of transferring knowledge of storage and distribution processes and technical-scientific support in the technovigilance stage (51).
- Partnership between ICC/Fiocruz Paraná, IBMP and Tecpar: in December 2022, the Precision Public Health Center was inaugurated, aimed at conducting studies on individuals with rare diseases and cancers, through next-generation genetic sequencing and genomic research. The unit is installed at Tecpar and, under the coordination of Fiocruz Paraná, uses Next Generation Sequencing (NGS) DNA sequencing technology, in addition to other additional molecular tests, for precision diagnosis in health. This was the first genomic diagnosis initiative using high-performance sequencers aimed entirely at the SUS and, through the diagnostic results, the SUS will be able to inform the acquisition of specific treatments for the diseases surveyed and plan actions, allowing the optimization of costs (52).

- Public-Private Partnership between Fiocruz, IBMP, and the World Mosquito Program (WMP): in March 2023, a new partnership was announced that will expand access in Brazil to mosquitoes with Wolbachia, a method that has already been proven effective in reducing the incidence of arboviruses, such as dengue, chikungunya, and zika (53).

During the interviews, it was encouraged that the innovation is one of IBMP's priorities and that the partnership with Fiocruz has taught, above all, that the best way to do innovation is through partnerships. Since its creation in 1999, IBMP has strengthened its partnerships with Fiocruz (Fiocruz Paraná and other Fiocruz units, especially Bio-Manguinhos) and with Tecpar, in addition to having expanded its portfolio of partnerships with other entities, allowing the expansion of its manufacturing area, expanding its production capacity and expanding its product portfolio. Over the past few years, IBMP has developed partnerships with strategic companies to improve internal processes and has expanded its presence to other continents to increase global reach. The outstanding partnerships and companies of IBMP and Fiocruz are highlighted in Figure 1 (54):

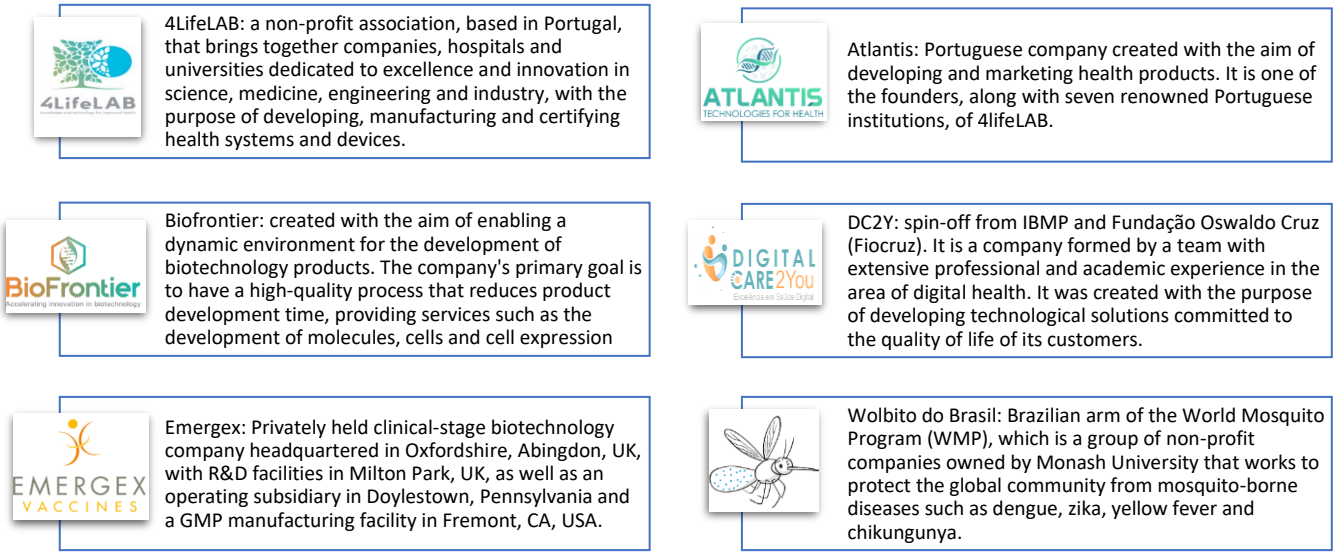

Figure 1: IBMP strategic partners (54).

companies based in the United States and Portugal, branches of IBMP, which also interact with Fiocruz, stand out. This movement of internationalization of the IBMP, with structures in favor and fully available to Fiocruz to carry out innovation, constitutes a favorable model for the process of leveraging the innovation system of both institutions.

Since its foundation, Fiocruz has established R&DI and education partnerships with national and international entities, which together with its strategic plan for nationalization and internationalization has allowed its expansion to eleven Brazilian states, to Africa and Europe (Portugal). During the interviews, the importance of doing innovation through partnership was strongly mentioned; Among the speeches, the belief that both internal and external partnerships are key to innovation stands out. The recent partnership with the Federal University of Rio de Janeiro (UFRJ) reinforces this futuristic vision. In February 2024, Fiocruz and UFRJ signed an agreement for the installation of a Research Center in the UFRJ Technology Park, which will constitute an environment that promotes innovation, structured as a technological platform in health, with the objective of developing products, services, and technologies to meet the demands of the SUS. The new research center will be in a building with a total built area of 4,849.40 m² and a private free area of 1,870.00 m², on a plot of 7,071.28 m² (55,56).

In addition to the partnerships described above, Fiocruz participates in scientific cooperation with hundreds of universities from all continents and dozens of networks, such as the Pasteur Network and IANPHI (in Portuguese: International Association of National Institutes of Public Health) with which there is a forecast for launch of a call for open innovation within this network. It is important to mention that Fiocruz, as the largest National Institute of Public Health in Brazil, collaborates with various organizations through the Network of Laboratories for Epidemiological Surveillance, in order to identify and treat public health problems, which contributes to market forecasting, strategic planning, and portfolio definition. A recent example of the importance of Fiocruz in this network combined with the IBMP-Fiocruz partnership was the characterization of the geographic patterns of the dengue virus subtypes in the 2006-7 epidemic at the national level, which constituted one of the signs of demand for the development of the ZDC molecular test (zika, dengue 1, 2, 3 or 4 and chikungunya) by the IBMP and, later, through Bio-Manguinhos/Fiocruz, through understandings with the Ministry of Health, this product reached the Unified Health System (SUS).

4.4 Principal products of the IBMP and ICC-Fiocruz/IBMP and Fiocruz partnership

As a result of the IBMP and Fiocruz partnership, as some highlighted in the previous item, several products were developed and registered with Anvisa. Chart 2 lists some highlights in chronological order.

Chart 2: Main products of the IBMP and ICC-Fiocruz/IBMP and Fiocruz partnership

Diagnostic kits and registration data in Anvisa
HIV/HCV/HBV NAT Kit: kit offered since 2011, expands the country's transfusion safety, reducing the immunological window period. This molecular test is used in blood centers across the country, in the screening of blood bags and uses an automated platform with great processing capacity, in a reliable traceability system, allowing simultaneous analysis of up to 552 samples per routine. The registration of this kit had a great impact on Brazilian public health, preventing the transmission of diseases through blood donation, which were previously undetectable.
IBMP Biomol ZDC Kit: for diagnosing Zika, dengue (the four dengue serotypes: DENV-1, DENV-2, DENV-3 and DENV-4) and chikungunya; registered as a medical device at Anvisa in October/2019.
IBMP Biomol Yellow Fever Kit, for diagnosis of yellow fever: registered as a medical device at Anvisa in August/2020.
IBMP Biomol Trachoma Kit, for the diagnosis of trachoma: registered as a medical device at Anvisa in November/2020.
Biomol OneStep/COVID-19 Kit: registered as a medical device at Anvisa in January/2021.
IBMP Biomol Malaria Kit, for molecular diagnosis of malaria: registered as a medical device at Anvisa in March/2021.
IBMP TR COVID Ag Kit: registered as a medical device at Anvisa in April/2021.
IBMP Biomol Leprosy Kit, for diagnosis of leprosy: registered as a medical device at Anvisa in May/2021.
Bio-Manguinhos Discriminatory Yellow Fever Kit, to distinguish between the wild virus and the vaccine strain: registered as a medical device at Anvisa in April/2022.
IBMP Biomol Flu A, B, COVID Kit, for diagnosis of influenza A, B, and COVID-19: registered as a medical device at Anvisa in June/2022.
IBMP Biomol Chagas Kit, for diagnosis of Chagas disease: NAT Chagas kit, from English *Nucleic Acid Test for Chagas Disease*; was the first kit for molecular diagnosis of Chagas disease approved in Brazil **(57)**; registered as a medical device at Anvisa in June 2022.
IBMP COVID AG SELF-TEST Kit: registered as a medical device at Anvisa in 2022.
IBMP TR Ag Flu A, B and COVID Kit: registered as a medical device with Anvisa in 2022.
IBMP Biomol Rickettsiosis Kit, for diagnosis of spotted fever: registered as a medical device at Anvisa in 2023.
IBMP Biomol AdV, RSV, hRV/EV Kit: for diagnosis of Adenovirus, respiratory syncytial virus and Rhinovirus: registered as a medical device at Anvisa in 2023.
IBMP TR ABO Rh Kit: registered as a medical device at Anvisa in 2022.
IBMP Biomol HPV High Risk Kit: for diagnosis of Human Papillomavirus: registered as a medical device at Anvisa in 2023.
IBMP TR Duo Cardio Kit: registered as a medical device with Anvisa in 2023.
IBMP TR Dengue NS1 Kit: registered as a medical device at Anvisa in 2023.

IBMP, in the field of diagnosis, has surpassed the PCR barrier and, nowadays, produces rapid tests, produces or develops devices for reading both rapid and molecular tests and, in addition, has entered the field of molecules of biotechnological origin, biomolecules and other biotechnology-based products. As pointed out in the interviews, it has a development portfolio also focused on vaccines and, it is expected that in the next 2-3 years it will already have products in the clinical phase with the objective of registration with Anvisa and introduction into the SUS. Thus, in addition to the product portfolio, IBMP has a technological portfolio in terms of molecular biology, diagnostics, and in vitro obtaining and applying therapeutic molecules in areas of chronic-degenerative diseases, tissue regeneration, and aesthetics, as listed below (58):

1) Immunoassay diagnostic tests: diagnostic tests that detect the immune response, using platforms that allow the delivery of the result in less than 20 minutes and facilitate the immediate start of treatment, or monitoring of infectious diseases, such as HIV, HBV, HCV, syphilis and Chagas disease, among others.
2) Molecular diagnostic tests: the real-time PCR platform serves as a basis to promote the development of high-precision and sensitivity diagnostics, detecting DNA or RNA from the selected targets. This platform is complementary to the detection of the immune response, since it is also suitable as a possibility for the detection of pathogens before the host has antibodies responding to the pathogenic organism.
3) Therapeutic solutions (Biomolecules): IBMP has as one of its objectives mastering technological competence in the area of development of molecules and processes used for the treatment of diseases. Examples of these molecules are proteins and antibodies. Through this new competence, it is sought to reduce the cost and increase the accessibility to several therapeutic proteins of paramount importance for public health.
4) Likewise, ICC/Fiocruz Paraná offers a highly qualified technological portfolio (59):
5) Recombinant protein for diagnosis of bovine fasciololosis: development of proteins to improve diagnosis, seeking the most effective, accessible, and affordable targets to produce.
6) VisualXL – Computational methodology for protein interaction analysis: development of protocols that, when applied to protein mixtures and subsequent analysis by mass spectrometry, allows the characterization of protein complexes.
7) DiagnoProt - Mass spectrometry diagnosis: development of a methodology that includes a differentiated form of mass spectrometry analysis in conjunction with an artificial intelligence platform.
8) Biomarkers for pancreatic cancer: technology to identify genes that have an influence on the onset of pancreatic cancer and associated biomarkers for early identification and follow-up of the disease.
9) Production process of *activated polymeric microbeads: creation, in partnership with the Institute of Molecular Biology of Paraná, of a new technological route that allows the production of polymeric* microbeads.
10) PatternLab – *Software* for proteomics: development of a computational environment, the *PatternLab for Proteomics*, which enables the analysis of spectra for proteomic experiments.
11) Alternative method to using animals for cytotoxicity testing: *in vitro* method for predicting the toxicity of a test substance through the use of human adult stem cells.
12) Formulation for the treatment of chronic wounds: a pro-regenerative hydrogel was developed to enable the cell growth necessary for wound closure, stimulating

vascularization, reducing fibrosis, inflammation and pain at the site of injury.

13) Experimental system for screening new antifungal drugs: development of technology to search for therapeutic alternatives for fungal diseases, which kill 1.6 million people annually worldwide.
14) BioterC – Software for management control of vivariums: *software* to manage all the information of a vivarium in an organized and systemic way, and in accordance with the best academic practices.
15) Stem cell-associated 3D printing devices for the treatment of joint injuries: development of biocompatible and bioresorbable 3D printed devices for use as tissue substitutes in orthopedic surgical procedures.
16) Method of surface activation of polymeric materials: the use of polymeric *microbeads* allows for greater efficiency of bioseparation processes and greater specificity and sensitivity of diagnostics.
17) Complete technological solution for the diagnosis of Communicable Diseases at the Point of Care (Leprosy; Tuberculosis; Malaria): it is a portable and complete kit with all the reagents and equipment necessary to perform molecular tests to aid in the diagnosis of neglected communicable diseases (malaria, leprosy or tuberculosis) directly at the point of care.

In addition, ICC/Fiocruz Paraná has development competencies that ratify the recognition as one of the references in health technology in the world, namely, pre-clinical evaluation of the efficacy of new vaccines and drugs against malaria and toxoplasmosis; development of rapid diagnostic devices (*point-of-care*); identification of molecules with antifungal activity; search for new targets for malaria vaccine; molecular characterization of proteins with potential for diagnosis and treatment of toxoplasmosis; tissue engineering; genotyping by large-scale sequencing for the study and diagnosis of human diseases; drug tests for tegumentary and visceral leishmaniasis; development of immunosensors for early diagnosis of infections; development of electrotherapy bandage; Detection of antibiotic metabolites in monitoring their efficiency in clinical practice in severe infections (60).

4.5 Internal challenges, external challenges, and lessons learned

During the interviews, discussions of successful planning/actions that were internalized by the institutions were addressed, the main internal and external challenges faced since 1999 were questioned and how, from the point of view of the interviewed managers, these challenges were overcome, were discussed. Below are listed the lessons learned cited by the interviewees in these discussions:

1) **The technological development environment has to be separate from the research environment.** The IBMP, because it was initiated by researchers from Fiocruz, carried for a long time the perspective of research and generation of knowledge with academic attributions (master's, doctorate, internships, etc.) in the same production environment. As mentioned by the interviewees, one of the most striking actions throughout the history of IBMP was the separation of research and technological development, and this was one of the biggest internal challenges. A rearrangement was made in the team, its attributions and priorities, so that everyone had an employment relationship focused on product. A new management model was adopted; the entry of projects into the portfolio is analyzed from the point of view of the market, demand of the SUS/MS and decided jointly by the managers and no longer by the researchers, who had their lines of research; knowledge management has been redesigned to ensure that the knowledge generated is institutionalized; tangible elements of planning, of singular portfolio management were introduced.
2) **It is important to have a good integration between project management and technological development management.** One of the challenges faced by IBMP after 2009 was the organization chart in order to adjust it to market demands and the planned strategic plan. This integration took time to be established at IBMP; After internal adjustments, there was a fine synchronization of the processes in the areas of technological development, quality and production, which reflected in a leap in deliveries and quality.
3) **Adopt aggressive *commercial marketing*.** Even for companies strongly inserted in an ecosystem mostly composed of public entities, it is important to adopt aggressive *commercial marketing*, which is a useful strategy to increase your sales and gain a larger market share. The IBMP management team from Fiocruz, a public environment, has a public environment culture that is not very focused on aggressive commercial marketing; This point was identified by the management as a point of improvement and was implemented.
4) **Intellectual Capital is an important asset for institutions and companies to innovate, remain in constant development, and respond quickly to health demands.** It is important to include a knowledge management plan within the company/institution's strategic plan. The COVD-19 pandemic showed that the institution that has accumulated knowledge, competence and flexibility to reorganize itself according to market demand responds quickly and with quality.
5) **The strategic plan must include the forecast of reinvestment of part of the profit in national technological development.**
6) **It is necessary to constantly seek funding through induction notices, but to make a commitment to sustainability in its strategic plan from the sale of its production.**
7) **Establish integration between the scientific agendas of the parties to the partnerships.** A relevant factor mentioned by the interviewees is that the institutional insertion of IBMP in Fiocruz was not mainly due to the ICC/Fiocruz, based on the initially planned model, but rather to the relations with Bio-Manguinhos; one of the challenges faced, and present to this day, was the integration of the scientific agenda of ICC/Fiocruz with the technological agenda of IBMP, which, although it has positive results and some projects, it does not flow naturally. From the point of view of a broader partnership between IBMP and Fiocruz (including all units and offices), the absence of alignment of the

agenda in a complementary, synergistic way was addressed as an internal challenge; what exists is an implicit pact.

8) **The innovation agendas of the parties to the strategic partnership or alliance need to be discussed internally and independently**. In addition, a partnership innovation agenda is important and effective for assertive decision-making, but always respecting the strategic plan of each institution.
9) **A government development plan is needed in the medium and long term to maintain and improve the facilities, invest in human resources and good quality inputs.** Lack of market development to make the production chain viable can negatively impact or prevent the implementation of good innovation management. It was mentioned by several managers that innovation cannot be done without government financial support.
10) **From the point of view of public policies, it is necessary to establish an agenda of the Ministry of Health that clearly signals the demands for delivery of the SUS.**
11) **The establishment of participatory management aligned with good innovation and knowledge management has proven to be an effective strategy in the R&D of efficient solutions to public health demands.** Fiocruz, within the scope of the Brazilian public administration, adopts a unique governance system model that allows it to choose its own managers, periodically, allowing long-term planning to be continued throughout the administrations. It is structured with participatory and democratic principles, structures and practices incorporated into corporate decision-making processes, resulting in collegiate deliberations at all organizational levels. The governance structure is made up of institutional collegiates: Internal Congress, Superior Council and the Ombudsman's Office, Collective of Managers, self-control bodies (Audit and Attorney's Office) and Chambers and Technical Forums (61). IBMP, for having part of its senior management composed of founding collaborators (Fiocruz and Tecpar), shares this organizational chart advantage.
12) **The adoption of open innovation is a primary condition for the establishment and strengthening of partnerships.** The Fiocruz Technological Platforms Network (RPT) stands out as an action of excellence in open innovation, with the support and cooperation of FINEP. The RPT is structured as a technological support for research, technological development, and health surveillance with the objective of optimizing the infrastructure, maintenance, and operation resources of more complex equipment at Fiocruz. This network is accessible beyond institutional boundaries, that is, to scientists from other institutions and companies, both public and private (62).
13) It is necessary to encourage national industries, especially those in the health sector. Instead of verticalizing the production of demands (especially inputs), it is more strategic to engage and support producers and national industries through the establishment of partnerships or alliances.
14) Innovation is a collaborative process. It is important to establish partnerships, make non-academic alliances, participate in national and international scientific and technological cooperation networks.

The history of IBMP and ICC/Fiocruz Paraná, from the creation of these institutions through the establishment of the partnership and extending to its strengthening over the last few years, shows that the participants knew how to integrate and align, with extreme competence, two apparently distinct and sequential universes: research and development. It is common in the literature from high-income countries to treat research and development as a single process. Authors in the field of economics such as Rosenberg (1982), management and marketing such as Cooper (1994) see R&D as a single process, but research and development are two distinct processes, with different management and organization logics. While research projects are more linked to science, of a more experimental nature, development projects have a greater connection with the market and are more tangible. In addition, the degree of uncertainty and complexity in science-oriented projects tends to be greater than in development projects. Therefore, P&E requires different management models (63). The inIt should be noted that the lessons learned above, based on the experience and practice of the interviewees, align with the CEIS proposals and can guide managers planning to establish similar partnerships in their regions.

5. Conclusion

The IBMP was created in 1999 through the cooperation agreement between Fiocruz and the Government of the State of Paraná, through Tecpar, with the intention of starting the implementation of Fiocruz in the southern region and, ten years later (2009), it became official as a formal technical unit with the inauguration of the Carlos Chagas Institute (ICC/Fiocruz Paraná) and the IBMP remained with the same legal status, but under a different framework. Therefore, it is not appropriate to speak of IBMP and ICC/Fiocruz cooperation or partnership, or even IBMP and Fiocruz partnership, in 1999 because from that year until 2009, there were not two parties, since IBMP was the entity that operated Fiocruz in its relationship with Tecpar and the government of Paraná, in Curitiba. It was only later, in August 2009, with the creation of ICC/Fiocruz Paraná as a technical unit of Fiocruz, that two independent legal entities came into existence, namely, IBMP and ICC/Fiocruz, and, therefore, the possibility of partnership between these entities. The history of IBMP and Fiocruz Paraná is divided into two distinct moments, 1999-2009 and 2009 onwards, a fact considered by most of the interviewees and considered during the description of the results and discussion. As of 2009, the IBMP-ICC/Fiocruz partnership was initiated, not restricted to the ICC, but to the entire Fiocruz, especially Bio-Manguinhos.

The results of this project reinforce the history of the creation of IBMP (1999), ICC/Fiocruz Paraná (2009) and subsequent "IBMP-Fiocruz" partnership as a *successful case*. The mapping of this history, from 1999 to June 2024, showed that this implementation format, although different from the one initially planned, consists of an excellent example of

organizational innovation and corporate management that can be replicated by Fiocruz itself in its nationalization and internationalization policy and could inspire ICTI managers to replicate this format in other regions of Brazil, while respecting regional specificities.

The analysis of the IBMP and Fiocruz partnership also reveals that this partnership is intended to meet the specific demands of the Unified Health System (SUS) and to give the Brazilian State sufficient bargaining power to reduce national technological dependence in the health sector, which aligns with recent Brazilian federal policies, such as CEIS and the New Industrialization Policy.

This partnership model offers a blueprint that can inspire other countries seeking to bridge scientific research with practical health solutions through institutional collaboration.

6. Future Scope

The results present lessons learned that can support other ICTI managers and organizations. The project presented limitations inherent to qualitative content analysis research. First, the subjectivity of interview data was a constant concern, and the interpretation of responses may have been influenced by the researcher's perspectives and experiences, potentially introducing bias into the results and conclusions.

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Author Profile

Karla Gram holds a degree in Pharmacy from the Federal University of Rio de Janeiro/UFRJ (2003) with a specialization in Biochemistry-Clinical Analysis (2006) at the same institution, a Specialization in Clinical Laboratory Sciences from UFRJ (2006), a Master's degree in Medical Sciences from UFRJ (2007), an MBA in Project Management from Fundação Getúlio Vargas (FGV) (2014) and a Specialization in Clinical Research from Hospital Alemão Oswaldo Cruz (2016). She is a PhD student in the Postgraduate Program of Clinical Medicine at UFRJ, expected to complete the program in 2025.. Karla Gram has been active in research in the health area since 1999, specifically in Clinical Research since 2002, with additional experience in Project Management. Professionally, she worked in Bioequivalence and Relative Bioavailability studies at the LabFarma laboratory/Biopharmacy and Pharmacometrics Program/UFRJ, accredited by ANVISA (2003-2005); at ORPC (Representative Organization for Clinical Research), from 2006 to 2013, acting as Clinical Monitor of Clinical Research Projects, Manager of Project Assistants for Latin America, Regulatory Manager for Brazil, and Start-Up Manager for Brazil and Latin America; Research Project Manager and Executive Director at Limulus, a clinical research consulting company. In January 2015, Karla Gram joined the Vice Presidency of Research and Biological Collections of Fiocruz (VPPCB/Fiocruz), where she has since served as Project Manager of the Clinical Research Platform of VPPCB/Fiocruz. She also served as an advisor to VPPCB/Fiocruz and as deputy coordinator of the VPPCB/Fiocruz Clinical Research Platform from 2016 to 2019. Since September 2018, she has worked as a consultant in tuberculosis clinical research projects coordinated by the Faculty of Medicine/UFRJ and funded by DECIT/Brazilian Ministry of Health (DECIT/MS) and by the National Tuberculosis Control Program/Brazilian Ministry of Health (PNCT/MS). Cofounder and CEO of the consulting firm Limulus, where she has served as executive director since 2020. Since 2022, she has worked as a professor of a postgraduate course at Hospital Alemão Oswaldo Cruz (HAOC) in partnership with the Ministry of Health through PROADI-SUS. Co-founder of EnPeC (Meeting of Clinical Research Professionals) since July 2023. Judicial expert in legal proceedings related to patents for pharmaceuticals and cosmetics.

Afrânio Lineu Kritski has a degree in Medicine from the Faculdade Evangélica do Paraná (1980), a master's degree in Pulmonology and Phthisiology from the Universidade Federal do Rio de Janeiro (1990), a PhD in Infectious and Parasitic Diseases from the Universidade Federal de São Paulo (1995), and a postdoctoral degree from the Royal Tropical Institute of the Netherlands (2006). He held the following positions: a) Head of the Department of Clinical Medicine from August 2006 to May 2010; b) Vice Dean of the Faculty of Medicine (FM) from May 2010 to December 2015; c) Coordinator of the Diagnostic Area of the Brazilian TB Research Network (REDE TB) from 2001 to 2014; d) Coordinator of the Advisory Committee - Medicine of the CNPq from August 2010 to August 2012; e) Deputy Editor of the International Journal of Tuberculosis and Lung Disease (1027-3719) from 2001 to 2011; f) Elected representative of the full professors of the Center for Health Science on the University Council of UFRJ from September 2011 to 2015; g) Deputy Editor of the Brazilian Journal of Pulmonology from 2004 to 2018; h) Member of the Task Force for TB Research of the World Health Organization from 2009 to 2019; i) President of REDE TB 2014-2018; j) Consultant of the CAPES/MEC Evaluation Committee from 2014 to 2019; k) Representative of Academia in the BRICS TB Research Network from September 2017 to September 2019; l) Member of the Advisory Committee - Medicine of CNPq from August 2020 to June 2023; m) Member of the Technical Chamber of the Regional Council of Medicine - Rio de Janeiro, 2019-2023. Currently holds the following functions: a) coordinator of the Tuberculosis Academic Program of the UFRJ School of Medicine since August 2006; b) Vice coordinator of the National Institute of Science and Technology - Tuberculosis (INCT-TB), since 2008; c) Member of the Technical Advisory Committee of the Ministry of Health on TB since 2007; d) Full Professor of Phthisiology and Pulmonology at the UFRJ School of Medicine since 2010; e) Member of the International Editorial Board of the Brazilian Society of Tropical Medicine since 2019; f) Member of the Scientific Advisory Board of the Global Center for Health and Tropical Medicine of the Institute of Hygiene and Tropical Medicine of NOVA University Lisbon-Portugal, for the period 2020–2024; g) Member of the MCTIC Virus NETWORK in the fight against COVID-19 since April 2020; h) Technical consultant in TB at the Directorate of Strategic Affairs for Health Surveillance (DAEVS) of the Secretariat for Health and Environmental Surveillance (SVSA) of the Ministry of Health since March 2023. He has experience in medicine, with an emphasis on phthisiology, infectious diseases, and pulmonology, working on the following topics: tuberculosis/HIV, diagnosis, immunopathogenesis, molecular biology, molecular epidemiology, treatment, clinical trials, operational studies, biosafety, cost-effectiveness, and the impact of technological incorporation.

Martha Oliveira holds an Executive MBA in Health Management from FVG (2022). She has been working in the coordination of clinical and laboratory research studies since 2006. PhD in Sciences - Clinical Medicine from the Federal University of Rio de Janeiro (2004, CAPES concept 7) and Post-Doctorate (via CAPES) at the Federal University of Rio de Janeiro (2013). Master's in Parasite Biology from the Oswaldo Cruz Foundation (2000). She graduated in biomedicine from the State University of Rio de Janeiro (1996). Since 2004, she has been a researcher at the Tuberculosis Academic Program/Faculty of Medicine of the Federal University of Rio de Janeiro and coordinated the Laboratory of Molecular Mycobacteriology. From 2009 to 2014, she was president of the Brazilian Tuberculosis Research Network/TB REDE, and since 2014, she has been the coordinator of the quality management and technology transfer area of the TB Network. Since 2009, she has been a member of the Executive Secretariat of the Brazilian Partnership against TB (affiliated with the Stop TB Partnership). From 2007 to 2009, she was a member of the Technical Group (GT) in Laboratories for the National Technical Committee of the Ministry of Health on TB. Since 2014, she has been a Specialist in Science, Technology, Production, and Innovation in Public Health at the Center for Technological Development in Health - CDTS Fiocruz. He has experience in the area of Molecular Biology and Immunogenetics, with an emphasis on Molecular Diagnosis, mainly in the following topics: tuberculosis/HIV, diagnosis, immunopathogenesis, molecular biology, molecular epidemiology, immunogenetics, molecular mechanisms of the innate immune response, and genetic polymorphisms. Martha Oliveira coordinated multicenter clinical studies. In 2007, she specialized in laboratory quality and research, having been certified by the WHO, the Brazilian Society of Clinical Pathology (SBPC), and Inmetro. She worked from 2006 to 2017 as an auditor for the Clinical Laboratory Accreditation Program (PALC) of the SBPC and since 2015 as a specialist evaluator for INMETRO.

Fabricio Marchini is a biologist with a master's degree in Cellular and Molecular Biology from the Federal University of Paraná (2004) and a PhD in Cellular and Molecular Biology from the Oswaldo Cruz Institute of the Oswaldo Cruz Foundation (2010). He has been a researcher at the Carlos Chagas Institute/Fiocruz since 2008, having published 42 scientific articles and two book chapters. Fabricio was the coordinator of the Mass Spectrometry Platform of the Carlos Chagas

Institute/Fiocruz between 2010 and 2017, when he installed and put into operation the first mass spectrometer at this institute. He has been a permanent professor in the Postgraduate Program in Biosciences and Biotechnology of the Carlos Chagas Institute/Fiocruz since 2010, supervising four master's and six doctoral students. Since 2017, he has been the Technological Development Manager at IBMP, dedicating himself to the area of management and technological development of diagnostic kits, equipment, and therapeutic proteins, directing and improving the biotechnological development process of strategic health products, delivering solutions and products registered with ANVISA (13 diagnostic kits and two pieces of equipment) and available to the Brazilian health system.