Health for All Now!
People´s Health Movement

GTPI
GRUPO DE TRABALHO SOBRE
PROPRIEDADE INTELECTUAL

ABIA
ASSOCIAÇÃO BRASILEIRA
INTERDISCIPLINAR DE AIDS

CASE STUDY:

BIO-MANGUINHOS/ FIOCRUZ MESSENGER RNA PLATFORM

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Commissioned by

The People's Health Movement (PHM), Brazil

and The Working Group on Intellectual Property (GTPI) of the Brazilian Interdisciplinary AIDS Association (ABIA)

2025

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INTRODUCTION

Vaccines are among the most effective interventions in the history of public health, responsible for the eradication and significant reduction of infectious diseases, as well as for increasing life expectancy and quality of life on a global scale. It is estimated that, over the past five decades, vaccination programs have saved at least 154 million lives, the vast majority (101 million) of whom were children under the age of. This number certainly increases if we consider not only the existence of vaccines for many more diseases than the 14 covered by this estimate, but also the fact that immunization programs contribute to other essential care in primary health care services[1].

From a biological standpoint, vaccines are preparations capable of stimulating and priming the immune system against an infection or disease, thereby generating a long-lasting and safe immune memory. Their main component is the antigen, which is derived from the pathogen of interest (the disease-causing agent) or produced using biotechnology[2] .

1 SHATTOCK, Andrew et al. Contribution of vaccination to improved survival and health: modelling 50 years of the Expanded Programme on Immunization. The Lancet, v. 403, n. 10441, p. 2307-2316, May 2024. Retrieved from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)00850-X/fulltext.

2 GHATTAS, Majed et al. Vaccine Technologies and Platforms for Infectious Diseases: Current Progress, Challenges, and Opportunities. Vaccines, v. 9, n. 12, Dec. 2021. Retrieved from: https://www.mdpi.com/2076-393X/9/12/1490.

Since Edward Jenner developed the smallpox vaccine in the late 18th century, there have been countless advances in the research and development (R&D) of vaccines against various diseases, leading to the vaccine platforms available today[3] .

Broadly speaking, a vaccine technology platform comprises a set of technologies that share the use of a basic "vector" or "carrier" (backbone), which can be adapted with different genes or sequences of interest to generate different vaccines based on the same technological foundation[4]. According to the World Health Organization (WHO), the use of the term "technology platform" would be appropriate in cases where (a) the manufacturing methods are essentially the same (but may be optimized for each specific vaccine candidate); (b) the testing methods (except for identity, potency, and stability) and acceptance criteria do not change; (c) the immunomodulatory compounds or elements do not change; and (d) compliance with Good Manufacturing Practices (GMP) is maintained[5]. Some examples of vaccine platforms include viral vector, toxoid, DNA, and messenger RNA (mRNA) platforms[6]. Vaccines are one of the categories[7] of biological medicines[8] . The biological route, which focuses on more complex molecules that are subject to greater structural variation, instability, and degradation, presents challenges in terms of standardization and predictability compared to the traditional chemical synthesis route[9,10,11].

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3 VERDECIA, Mark *et al.* COVID-19 vaccine platforms: Delivering on a promise? **Hum Vaccin Immunother**, v. 17, n. 9, May 2021. Retrieved from: https://www.tandfonline.com/doi/10.1080/21645515.2021.1911204?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

4 EMA – European Medicines Agency. **Guideline on data requirements for vaccine platform technology master files (vPTMF)**. EMA/CVMP/IWP/286631/2021, 28 Jan. 2022. Retrieved from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-data-requirements-vaccine-platform-technology-master-files-vptmf_en.pdf.

5 WHO – WORLD HEALTH ORGANIZATION. **WHO Expert Committee on Biological Standardization**: seventy-fouth report. Annex 3. WHO Technical Report Series 1039. Geneva: World Health Organization, 2022. Retrieved from: https://www.who.int/publications/i/item/9789240046870.

6 EMA – European Medicines Agency. **Guideline on data requirements for vaccine platform technology master files (vPTMF)**. EMA/CVMP/IWP/286631/2021, 28 Jan. 2022. Retrieved from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-data-requirements-vaccine-platform-technology-master-files-vptmf_en.pdf.

7 According to Article 4 of Collegiate Board Resolution (RDC) No. 55, dated December 16, 2010, in addition to vaccines, biological products are classified into hyperimmune sera, blood products, biopharmaceuticals, monoclonal antibodies, and products containing live, attenuated, or inactivated microorganisms (BRAZIL, 2010).

8 Biological medicines are complex, high-molecular-weight molecules derived from biological fluids, animal tissues, or biotechnological processes through the manipulation or insertion of other genetic material (recombinant DNA technology) or genetic changes caused by irradiation, chemicals, or artificial selection." (ZAIRE; HASENCLEVER; PARANHOS, 2016).

9 ZAIRE, Carla; HASENCLEVER, Lia; PARANHOS, Julia. Mudanças no marco regulatório brasileiro de pesquisa e produção de medicamentos entre 2003 e 2014: avanços e desafios. In: HASENCLEVER, Lia et al. (Org.). **Desafios de operação e desenvolvimento do complexo industrial da saúde**. Rio de Janeiro: E-Papers, 2016. [versão eletrônica]. Cap. 5. p. 167-203.

10 DE NEGRI, Fernanda; ARBIX, Glauco; PEREIRA, Larissa. S. O mercado de vacinas no Brasil. In: DE NEGRI, Fernanda *et al.* [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024. p. 109-129.

11 GUIMARÃES, Reinaldo. Vacinas: Da Saúde Pública ao Big Business. **Ciência & Saúde Coletiva**, v. 26, n. 5, p. 1847–1852, 2021.

From the supply side, uncertainties and challenges—such as high investment costs, complex production processes, a shortage of qualified human resources, and strict regulatory requirements—are some of the barriers to entry in this market[12].

Particularly since the 1980s, the intense wave of mergers and acquisitions of vaccine manufacturers by major pharmaceutical companies has been the primary strategy for overcoming their lack of expertise in the new production process[13]. This process has resulted in a highly oligopolistic global vaccine market, with high entry barriers and a small number of pharmaceutical companies controlling a large portion of the industry[14]. Regarding demand, the public sector is the world's leading purchaser of vaccines. International organizations, such as the United Nations Children's Fund (UNICEF) and the Pan American Health Organization (PAHO), also purchase large quantities of vaccines for low- and middle-income countries[15,16].

Specifically in Brazil, both the demand for and production of vaccines are essentially public, and the consolidation of this arrangement is directly linked to the history of the National Immunization Program (PNI). Created in 1973, in the context of the development of major national health programs, the PNI incorporated lessons learned from previous initiatives, such as the Smallpox Eradication Campaign and the National Polio Control Plan, while also introducing significant innovations, such as mass vaccination campaigns and the establishment of a unified national immunization schedule[17].

By centralizing coordination within the Ministry of Health and establishing vaccination as a universal and equitable policy, the PNI significantly expanded the population's access to vaccines, overcoming previous fragmentation and ensuring widespread coverage throughout the country[18].

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12 DE NEGRI, Fernanda; ARBIX, Glauco; PEREIRA, Larissa. S. O mercado de vacinas no Brasil. In: DE NEGRI, Fernanda *et al.* [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024. p. 109-129.

13 GUIMARÃES, Reinaldo. Vacinas: Da Saúde Pública ao Big Business. **Ciência & Saúde Coletiva**, v. 26, n. 5, p. 1847–1852, 2021.
Retrieved from: https://www.scielo.br/j/csc/a/DRnJ5VC6zb4pM9Jwprd9S3F/?format=html&lang=pt.

14 VARGAS, Marco Antonio. O mercado de biofármacos no Brasil e no mundo. In: DE NEGRI, Fernanda *et al*. [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024.

15 GADELHA, Carlos A. G. *et al.* Acesso a vacinas no Brasil no contexto da dinâmica global do Complexo Econômico-Industrial da Saúde. **Cadernos de Saúde Pública**, v. 36, supl. 2, Aug. 2020. Retrieved from: https://www.scielosp.org/article/csp/2020.v36suppl2/e00154519/pt/#.

16 DE NEGRI, Fernanda; ARBIX, Glauco; PEREIRA, Larissa. S. O mercado de vacinas no Brasil. In: DE NEGRI, Fernanda *et al.* [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024. p. 109-129.

17 TEMPORÃO, José Gomes. O Programa Nacional de Imunizações (PNI): origens e desenvolvimento. **História, Ciências, Saúde – Manguinhos**, v. 10 (suplemento 2), p. 601-17, 2003. Retrieved from: https://www.scielo.br/j/hcsm/a/XqLKLcj6NYjHdywSF6XPRZs/?format=pdf&lang=pt.

18 PINELLI, Natasha. PNI 50 anos: entenda por que o programa brasileiro de vacinação é referência internacional em saúde pública. **Instituto Butantan**, 13 Sep. 2023. Retrieved from: https://butantan.gov.br/noticias/pni-50-anos-entenda-por-que-o-programa-brasileiro-de-vacinacao-e-referencia-internacional-em-saude-publica

Ensuring a sufficient supply in terms of both quantity and quality thus became a strategic challenge, driving policies focused on local production, such as the National Self-Sufficiency Program for Immunobiologicals (PASNI) and the strengthening of public laboratories[19].

Public laboratories, also known as Official Pharmaceutical Laboratories (LFO), are public institutions that produce medicines, vaccines, serums, and other health-related products to meet the needs of the Unified Health System (SUS), as provided for in the Federal Constitution of 1988 (Article 200) and Law No. 8,080/1990 (Article 6)[20,21]. LFOs primarily use "technology transfer strategies to expand their portfolios and build capacity for the production of vaccines required by the PNI [National Immunization Program], particularly those at the cutting edge of technology"[22]. In this way, they meet the needs of the SUS by ensuring the effectiveness of the pharmaceutical care policy[23,24]. According to Tatsch, Botelho, and Koeller[25], "The success of this program can be assessed by the extremely high vaccination coverage rates over the past few decades, which have led to the eradication of several diseases, such as polio and measles, a decline in infant mortality, and an increase in life expectancy among Brazilians." Over the past two decades, it is estimated that the PNI has administered an average of more than 130 million vaccine doses per year[26].

Globally, the COVID-19 pandemic has had a significant impact on the biopharmaceutical market by accelerating the development and approval of new products, including groundbreaking technologies[27].

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19 TATSCH, Ana Lúcia; BOTELHO, Marisa dos Reis Azevedo; KOELLER, Priscila. **A resposta do sistema brasileiro de inovação em saúde à covid-19**: as políticas públicas e o papel da Fiocruz e do Butantan. Rio de Janeiro: Ipea, Feb. 2024. 38 p. (Texto para Discussão, n. 2959). Retrieved from: https://www.econstor.eu/bitstream/10419/285397/1/TD2959.pdf.

20 ALFOB – Associação dos Laboratórios Farmacêuticos Oficiais do Brasil. **Estratégias produtivas e tecnológicas para a Saúde do Brasil**. I Congresso dos Laboratórios Farmacêuticos Oficiais do Brasil: relatório final. Brasília: ALFOB, 2023. Retrieved from: https://alfob.org.br/wp-content/uploads/2023/11/Relatorio-Final-I-CLFOB-V-9-11-2023.pdf.

21 ALFOB – Associação dos Laboratórios Farmacêuticos Oficiais do Brasil; CFF – Conselho Federal de Farmácia. **Laboratórios Farmacêuticos Oficiais do Brasil**. 1ª ed. Brasília: ALFOB/CFF, 2019. Retrieved from: https://www.cff.org.br/userfiles/LFOBs%20Versao%20Digital.pdf.

22 GADELHA, Carlos A. G. *et al.* Acesso a vacinas no Brasil no contexto da dinâmica global do Complexo Econômico-Industrial da Saúde. **Cadernos de Saúde Pública**, v. 36, supl. 2, Aug. 2020. Retrieved from: https://www.scielosp.org/article/csp/2020.v36suppl2/e00154519/pt/#. p. 6.

23 VARGAS, Marco Antonio. O mercado de biofármacos no Brasil e no mundo. In: DE NEGRI *et al*. [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024. p. 53-107.

24 DE NEGRI, Fernanda; ARBIX, Glauco; PEREIRA, Larissa. S. O mercado de vacinas no Brasil. In: DE NEGRI, Fernanda *et al.* [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024. p. 109-129.

25 TATSCH, Ana Lúcia; BOTELHO, Marisa dos Reis Azevedo; KOELLER, Priscila. **A resposta do sistema brasileiro de inovação em saúde à covid-19**: as políticas públicas e o papel da Fiocruz e do Butantan. Rio de Janeiro: Ipea, Feb. 2024. 38 p. (Texto para Discussão, n. 2959). Retrieved from: https://www.econstor.eu/bitstream/10419/285397/1/TD2959.pdf. p. 15.

26 DE NEGRI, Fernanda; ARBIX, Glauco; PEREIRA, Larissa. S. O mercado de vacinas no Brasil. In: DE NEGRI, Fernanda *et al.* [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024. p. 109-129.

27 VARGAS, Marco Antonio. O mercado de biofármacos no Brasil e no mundo. In: DE NEGRI *et al*. [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024. p. 53-107.

On December 8, 2020, the first approved COVID-19 vaccine, Comirnaty, was administered to 90-year-old Margaret Keenan in the United Kingdom[28]. At the time, more than 200 vaccine candidates were in development around the world. Comirnaty, developed by Pfizer/BioNTech, demonstrated 95% efficacy against the disease and was the first mRNA-based vaccine used in humans. Shortly thereafter, in January 2021, the second mRNA-based vaccine, Spikevax from Moderna, also received emergency use authorization[29].

However, this unprecedented scientific breakthrough has been accompanied by a crisis in vaccine availability and unequal distribution, reflecting the contradiction between innovation and access. Access to vaccines, in varying quantities and at different times, varied according to the level of economic development of countries and regions. Reproducing structural inequalities, high- and upper-middle-income countries received larger quantities of doses faster than low- and middle-income countries[30,31]. In addition, the pandemic crisis has also led to shortages of medicines, personal protective equipment (PPE), diagnostic tests, ventilators, and other hospital care supplies, including vaccine active pharmaceutical ingredients (APIs), the production of which has historically been outsourced to lower-cost countries[32,33].

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28 BBC. **Covid-19 vaccine: First person receives Pfizer jab in UK**. BBC News, 8 Dec. 2020. Retrieved from: https://www.bbc.com/news/uk-55227325.

29 EMA – European Medicines Agency. **EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU**. EMA, News, 06 Jan. 2021. Retrieved from: https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu.

30 ABBOTT, Frederick. **Intellectual Property (IP) and Technology Transfer for COVID-19 Vaccines**: Assessment of the Record. Geneva: WIPO, 2023. Retrieved from: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf.

31 KAMEDA, Koichi; PIMENTA, Denise; MATTA, Gustavo. Affirming pharmaceutical sovereignty: Technology transfer agreements and vaccine geopolitics during a global health emergency. IN: QUET, Mathieu; KAMEDA, Koichi; POURRAZ, Jessica; RAULT-CHODANKAR, Yves-Marie. **Technoscientific Globalisation from Below**. Mattering Press, 2025. Retrieved from: https://shs.hal.science/halshs-05372744.

32 ALMEIDA, Celia. **Pandemia de Covid-19**: por que devemos olhar para o contexto internacional? Reflexões sobre a governança do setor Saúde. IN: PORTELA, M. C.; REIS, L. G. C.; LIMA, S. M. L. (eds). Covid-19: desafios para a organização e repercussões nos sistemas e serviços de saúde [online]. Rio de Janeiro: Observatório Covid-19 Fiocruz, Editora Fiocruz, 2022, 472 p. Retrieved from: https://books.scielo.org/id/kymhj/pdf/portela-9786557081587.pdf.

33 CHAVES, Luisa Arueira *et al.* **Desabastecimento, uma questão de saúde pública global**: sobram problemas, faltam medicamentos. IN: PORTELA, M. C.; REIS, L. G. C.; LIMA, S. M. L. (eds). Covid-19: desafios para a organização e repercussões nos sistemas e serviços de saúde [online]. Rio de Janeiro: Observatório Covid-19 Fiocruz, Editora Fiocruz, 2022, 472p. Retrieved from: https://books.scielo.org/id/kymhj/pdf/portela-9786557081587.pdf.

In Brazil, despite the denial of the severity of the pandemic and the political mismanagement of the public health response, both at the local and federal levels[34], The prior existence of a well-established public health infrastructure, based on a universal public health system, prevented the situation from becoming even more catastrophic[35]. Amid a global vaccine shortage, the country was only able to begin its vaccination campaign thanks to the efforts of its public science and technology institutions—particularly the Oswaldo Cruz Foundation (Fiocruz) and the Butantan Institute—and the National Health Surveillance Agency (Anvisa)[36]. Lessons learned from crises such as the COVID-19 pandemic underscore the importance of investing in research and development (R&D), public institutions, local innovation and production, and the ongoing strengthening of the supply chain to address future challenges[37,38].

In addition to technology transfer agreements aimed at making it possible to vaccinate the Brazilian population as quickly as possible—notably the partnerships established between the Butantan Institute and Sinovac Biotech, and between Fiocruz and Oxford/AstraZeneca—various initiatives to develop domestic vaccines have been launched. Among these initiatives, the development of a messenger RNA platform at the Institute of Immunobiological Technology (Bio-Manguinhos), a Fiocruz unit, stands out; this project had been initiated even before the pandemic. Due to the versatility and adaptability of messenger RNA technology[39,40], it was possible to redirect efforts toward tackling COVID-19.

34 ORTEGA, Francisco; ORSINI, Michael. Governing COVID-19 without government in Brazil: Ignorance, neoliberal authoritarianism, and the collapse of public health leadership. **Global Public Health**, v. 15, n. 9, p. 1257–1277, 2020. https://doi.org/10.1080/17441692.2020.1795223.
35 FONSECA, Eliza Massard da; NATTRASS, Nicoli; ARANTES, Luísa Bolaffi; BASTOS, Francisco Inácio. COVID-19 IN BRAZIL: Presidential Denialism and the Subnational Government's Response. In E. M. da Fonseca, S. L. Greer, E. J. King, & A. Peralta-Santos (Eds.), **Coronavirus Politics**: The Comparative Politics and Policy of COVID-19, p. 494–510, 2021. University of Michigan Press. http://www.jstor.org/stable/10.3998/mpub.11927713.29.
36 FIOCRUZ - Fundação Oswaldo Cruz. Ministério da Saúde. **Relatório de Balanço de gestão 2020/2022**: Atuação da Fiocruz na pandemia de Covid-19. Published 09 Sep. 2022. Retrieved from: https://fiocruz.br/documento/2022/09/balanco-de-gestao-atuacao-da-fiocruz-na-pandemia-de-covid-19.
37 LI, Xiaojing *et al.* Platform Technology in Global Vaccine Regulation: Development, Applications, and Regulatory Strategies with Insights from China. **Vaccines**, v. 12, n. 12, Dec. 2024. Retrieved from: https://www.mdpi.com/2076-393X/12/12/1436.
38 VERDECIA, Mark *et al.* COVID-19 vaccine platforms: Delivering on a promise? **Hum Vaccin Immunother**, v. 17, n. 9, May 2021. Retrieved from: https://www.tandfonline.com/doi/10.1080/21645515.2021.1911204?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.
39 BRANT, Jennifer; SCHULTZ, Mark F. **Unprecedented**: The Rapid Innovation Response to COVID-19 and the Role of Intellectual Property. Nov. 2021. Retrieved from: https://www.ifpma.org/publications/unprecedented-the-rapid-innovation-response-to-covid-19-and-the-role-of-intellectual-property/.
40 SZABÓ, G. T., Mahiny, A. J., & Vlatkovic, I. COVID-19 mRNA vaccines: Platforms and current developments. **Molecular therapy**: the journal of the American Society of Gene Therapy, v. 30, n. 5, p. 1850-1868, May 2022. Retrieved from: https://pmc.ncbi.nlm.nih.gov/articles/PMC8856755/.

Bio-Manguinhos's messenger RNA platform enables the entirely domestic and low-cost production of a COVID-19 vaccine, the transfer of this technology to other developing countries, and the acquisition of expertise that positions the country as a pioneer in the production of other vaccines and treatments for various diseases. The project was one of the factors that led to the institution being selected by the WHO as a center for the development and production of vaccines using this technology in Latin America[41,42].

In light of the above, the objective of this case study is to examine how Bio-Manguinhos has developed the messenger RNA platform, exploring the historical determinants, characteristics, potential, and challenges of this initiative. The central hypothesis is that it is possible to develop health technologies guided by the public interest, combining technical innovation with ethical principles that prioritize collective needs. Thus, public production and development constitute a concrete pathway to guarantee the right to health and overcome the systemic inequities produced by thetraditional logic operationalized by Big Pharma, which is driven by profit and the privatization of knowledge, among other problems[43].

In this regard, the discussion on public pharmaceutical companies serves as a theoretical framework for this study. According to the People's Health Movement[44]:

> One possible definition of Public Pharmaceutical Companies is a state-run infrastructure focused on the research, development, manufacturing, and/or distribution of pharmaceutical products and other health technologies. The state retains genuine decision-making authority and establishes governance based on public health needs. (...) In summary, this definition of Public Pharmaceutical Companies emphasizes key aspects: (1) state ownership; (2) effective social and state participation in decision-making and policy wformulation; (3) development of health technologies in the service of public health and the needs of the people.

Bio-Manguinhos' messenger RNA platform represents an unprecedented breakthrough not only for the SUS and the Brazilian population, but also for all of Latin America, as it helps strengthen regional capabilities to respond to public health emergencies. By placing Brazil among the group of countries that have mastered one of the most advanced technological platforms for vaccine development, this initiative signals an important step toward sovereignty and strategic autonomy in the health sector.

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41 FIOCRUZ - Fundação Oswaldo Cruz. Ministério da Saúde. **Relatório de Balanço de gestão 2020/2022**: Atuação da Fiocruz na pandemia de Covid-19. Published 09 Sep. 2022. Retrieved from: https://fiocruz.br/documento/2022/09/balanco-de-gestao-atuacao-da-fiocruz-na-pandemia-de-covid-19.
42 FIOCRUZ - Fundação Oswaldo Cruz. Ministério da Saúde. **Plataforma de RNA Mensageiro**. Apresentação Projeto-mRNA, Sep. 2023. Retrieved from: https://captacao.fiocruz.br/wp-content/uploads/2023/09/Projeto-mRNA.pdf.
43 MSP - Movimento pela Saúde dos Povos. **Farmacêuticas Públicas:** o que são e por que são importantes? Oct. 2024. Retrieved from: https://phmovement.org/sites/default/files/2025-02/PT%20BR%20-%20Public%20Pharma%20Policy%20Brief.pdf.
44 MSP - Movimento pela Saúde dos Povos. **Farmacêuticas Públicas:** o que são e por que são importantes? Oct. 2024. Retrieved from: https://phmovement.org/sites/default/files/2025-02/PT%20BR%20-%20Public%20Pharma%20Policy%20Brief.pdf. p.5.

Furthermore, it stands out for its public nature and its integration with health, productive development, and Innovation policies, serving as an example of a project oriented toward the public interest. Thus, this study seeks to tell a part of this story that is only just beginning, but which demonstrates the capacity of research and development conducted within the country and the indispensability of continuously strengthening the institutions that make up the Brazilian public health system.

02
METHODS

From a methodological standpoint, the case study approach (YIN, 2001) proved to be the most appropriate for this study. Bio-Manguinhos' messenger RNA platform exhibits key characteristics relevant to the debate on public pharmaceutical companies and health systems, thereby reinforcing the study's relevance. The starting point is the hypothesis that a model for the development of health technologies led by the government and centered on public health needs, as proposed by the People's Health Movement, can constitute an alternative to corporate hegemony, promoting health sovereignty and international solidarity, especially in the Global South. In this context, the case can be interpreted as a relevant empirical example—albeit one still in development—by demonstrating that cutting-edge technologies can be developed and produced in public institutions guided by the public interest.

Although the project originated before the COVID-19 pandemic, it was in this critical context that it achieved promising results, enabling Bio-Manguinhos to apply as an institution capable of transferring the technology to other producers in low- and middle-income countries (LMICs). It is also the first RNA platform in Latin America developed by a Brazilian public, non-profit institution. Finally, although it has already been covered in national and international media, particularly following its selection by the WHO, the platform's development history has not yet been the subject of more detailed research.

The preparation of this case study involved the collection and analysis of various types of evidence obtained from primary and secondary sources. Relevant material regarding the platform was obtained directly from the official Bio-Manguinhos/Fiocruz websites, but a bibliographic and documentary search was also conducted to gather articles, reports, and news stories to support the study. The study utilized information obtained from requests based on Law No. 12,527/2011, the Access to Information Act, which were answered by the institution in June and November 2025. The questions and answers are included in Annexes 1A and 1B. This information was used primarily to confirm and supplement that found in the bibliographic and documentary research.

A request to interview members of the platform's team was previously sent to the Office of Institutional and International Relations at Bio-Manguinhos/Fiocruz, which granted the request and organized a group interview[45]

45 FRASER, M. T. D.; GONDIM, S. M. G.. Da fala do outro ao texto negociado: discussões sobre a entrevista na pesquisa qualitativa. **Paidéia** (Ribeirão Preto), v. 14, n. 28, p. 139–152, May 2004. Retrieved from: https://www.scielo.br/j/paideia/a/MmkPXF5fCnqVP9MX75q6Rrd/?lang=pt.

with three researchers, including the two project leaders, as well as a representative from the aforementioned coordination office. Participants in the conversation included Ana Paula Ano Bom (AP), Hiago Albuquerque (HA), Patrícia Neves (PN), and Rafaele Loureiro (RL), as well as the author of this report and the Regional Coordinator for the Public Pharmacists Project of the Movement for People's Health, Sara Helena Gaspar (SG)[46].

The interview with the group took place in person on July 31, 2025, at Bio-Manguinhos, on Fiocruz's main campus. That day began with a police operation in Manguinhos, where the institution is located. There were shootouts and temporary traffic disruptions in the area[47,48]. Nevertheless, by following the safety guidelines, we were able to visit in person.

Text box 1 - Violence is also a public health issue

"The communities of Manguinhos are not located in the vicinity of the Oswaldo Cruz Foundation, as separate entities; rather, the Foundation is part of Manguinhos." (Dr. Nísia Trindade at the Second Conference on Health, Violence, and Drug Policy)[49]

Fiocruz's headquarters is located in the neighborhood[50] Manguinhos, The northern part of the city of Rio de Janeiro. This is a region historically marked by structural inequalities and high rates of violence[51]. Clashes between armed groups and police operations disrupt the daily lives of residents and workers, affecting a wide range of activities—including health and education services—and having a significant impact on the population's mental health[52].

In January 2025, for example, a projectile struck the window of a room at Bio-Manguinhos. A worker required medical attention due to shrapnel wounds, but there were no serious complications. Activities at the Fiocruz Museum of Life were suspended, and the workday ended early.

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46 Iniciais usadas no texto para identificação.
47 VOZ DAS COMUNIDADES. **Manguinhos amanhece com grande operação policial nesta quinta (31)**. Voz das Comunidades, Jul 31th. 2025. Retrieved from: https://vozdascomunidades.com.br/casos-de-policia/manguinhos-amanhece-com-grande-operacao-policial-nesta-quinta-31/.
48 ARAÚJO, Genilson *et al*. **Operação em Manguinhos tem um suspeito morto e 3 feridos; mais cedo, grupo correu na chegada da polícia**. G1, Rio de Janeiro, Jul 31th. 2025. Retrieved from: https://g1.globo.com/rj/rio-de-janeiro/noticia/2025/07/31/grupo-corre-na-chegada-da-policia-na-comunidade-do-mandela-na-zona-norte-do-rio.ghtml.
49 FIOCRUZ. **Cartilha de Prevenção à Violência Armada em Manguinhos**. Fiocruz: 2019. Retrieved from: https://fiocruz.br/sites/fiocruz.br/files/documentos/cartilha_grafica_-_22-11-2019_para_impressao_alta_compressed.pdf. p. 8
50 O MANGUINHO. **b**: favela, bairro ou comunidade? **Informativo Semanal do Intersetorial Manguinhos|Saúde, Educação e Assistência Social**, n. 20, 15 Dec. 2021. Retrieved from: https://informe.ensp.fiocruz.br/assets/anexos/be6024dc5b281011c050a4603258f66e.PDF.
51 LIMA, C. M. (org.). **Território, participação popular e saúde**: Manguinhos em debate. Rio de Janeiro: ENSP/Fiocruz, 2010. 104 p. Retrieved from: https://fiocruz.br/sites/fiocruz.br/files/documentos/territorio-popular-saude-manguinhos.pdf.
52 RIBEIRO, F. M. L.; ANDRADE, C. B.; DIAS, C. A. O.; MINAYO, M. C. S. Violência armada em Manguinhos/RJ, Brasil: saúde e cotidiano de trabalhadoras(es) de saúde e educação. **Ciência & Saúde Coletiva**, v. 29, n. 7, 2024. Retrieved from: https://www.scielo.br/j/csc/a/JqLwWgZnccWNK6yGYfqCLsh/?format=pdf&lang=pt.

Staff and visitors, including children, had to take shelter until they were escorted out of the building[53,54]. In late October 2025, more than 120 people were killed during a police operation carried out in the The Penha and Alemão slums. Most of the victims were found by family members and friends on a plot of land between the slums, showing signs of torture and decapitation. It was the deadliest police operation in the history of the city of Rio de Janeiro[55,56].

Fiocruz does not ignore the issue of violence and carries out various activities related to the subject, including those involving civil society[57,58]. In October 2024, the Federal Supreme Court (STF) admitted the organization as an amicus curiae in the proceedings regarding the Motion for Non-Compliance with a Fundamental Precept (ADPF 635), known as the "ADF das Favelas," which addresses lethality and human rights violations in police operations in Rio de Janeiro[59].

The evidence points to the need for strategies that prioritize the preservation of life and respect for human rights, since the indiscriminate use of force by state authorities has not reduced the territorial control exercised by armed criminal groups[60].

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53 AFN. Ação da Polícia Civil dentro da Fiocruz coloca trabalhadores em risco. **Agência Fiocruz de Notícias (AFN)**, Jan 08th, 2025. Retrieved from: https://agencia.fiocruz.br/acao-da-policia-civil-dentro-da-fiocruz-coloca-trabalhadores-em-risco.

54 SOUZA, R. Fiocruz tem protocolo de segurança para evitar ocorrência com bala perdida. **O GLOBO**, Jan 10th, 2025. Retrieved from: https://oglobo.globo.com/rio/noticia/2025/01/10/fiocruz-tem-protocolo-de-seguranca-para-evitar-ocorrencia-com-bala-perdida.ghtml.

55 FUNDAÇÃO OSWALDO CRUZ. Fiocruz e instituições divulgam Manifesto por uma Segurança Pública Cidadã para o Rio. **Agência Fiocruz de Notícias (AFN)**, 29 Oct 2025. Retrieved from: https://agencia.fiocruz.br/fiocruz-e-instituicoes-divulgam-manifesto-por-uma-seguranca-publica-cidada-para-o-rio.

56 FREIRE, F. MONTEIRO; J. LEITÃO; L.; MADUREIRA, L.; BOM DIA RIO. Megaoperação no Alemão e na Penha contra o CV tem 121 mortos e 113 presos; vias são fechadas em represália em todo o Grande Rio. **G1**, Rio de Janeiro, 28 Oct. 2025. Retrieved from: https://g1.globo.com/rj/rio-de-janeiro/noticia/2025/10/28/operacao-contencao-forcas-de-seguranca-tentam-cumprir-mandados-de-prisao.ghtml.

57 PIVS - Programa Institucional de Articulação Intersetorial em Violência e Saúde. **Relatórios Anuais**. Retrieved from: https://fiocruz.br/relatorios-anuais.

58 COOPERAÇÃO SOCIAL DA PRESIDÊNCIA. Boletim da Cooperação Social - 1º semestre/2025. **Fiocruz**, Notícias, 17 Jul. 2025. Retrieved from: https://fiocruz.br/noticia/2025/07/boletim-da-cooperacao-social-1deg-semestre-2025.

59 AFN. Fiocruz divulga nota sobre impactos da violência armada no Rio de Janeiro. **Agência Fiocruz de Notícias (AFN)**, 04 Feb. 2025. Retrieved from: https://agencia.fiocruz.br/fiocruz-divulga-nota-sobre-impactos-da-violencia-armada-no-rio-de-janeiro.

60 BUENO, Leonardo Brasil. **A favela (para)militarizada**: território contido e impacto da violência armada na saúde, na educação e no cotidiano de moradores de Manguinhos, Jacarezinho e Maré. Tese (doutorado) - Universidade Federal do Rio de Janeiro, Instituto de Pesquisa e Planejamento Urbano e Regional, Programa de Pós-Graduação em Planejamento Urbano e Regional, 2018.

Violence, including armed violence, goes beyond the realm of security and is also a public health issue[61], directly affecting the right to life and the collective well-being[62,63]. Therefore, there is an urgent need for a public safety policy that does not exacerbate the socioeconomic crisis or reinforce the stigmas historically directed at the local population.

The script used for the focus group interview is available in Appendix 2. It is, however, a flexible tool, since other questions emerged during the discussion, allowing access to additional insights and events. Furthermore, it is worth noting that the analysis conducted took into account both the content narrated by the interviewees and the references used to produce the report. This is because "(...) when analyzed, the interview must incorporate the context of its production and, whenever possible, be accompanied and supplemented by information derived from observation of the setting under study"[64] .

Considering the way in which the dialogue unfolded and the diversity of information gathered throughout the research, we chose not to concentrate the interview content in a specific section of this report. Instead, the statements were incorporated throughout the text, establishing connections with the various topics addressed. This choice sought to preserve the richness and spontaneity of the material, allowing for a fluid articulation of the interviewees' contributions on the topic under analysis.

Before addressing the topic of the messenger RNA platform in the discussion, an institutional presentation on Bio-Manguinhos/Fiocruz was given. To provide some additional context for the readers of this case study, we will now offer a brief overview of Bio-Manguinhos, highlighting some relevant facts and aspects of its history that paved the way for the emergence of an innovative project such as the messenger RNA platform.

61 MINAYO, M.C.S. **Violência e saúde** [online]. Rio de Janeiro: Editora FIOCRUZ, 2006. 132 p. Retrieved from: https://static.scielo.org/scielobooks/y9sxc/pdf/minayo-9788575413807.pdf.
62 CLAVES/ENSP/FIOCRUZ. **Violência armada e saúde - investigando os sentidos e os impactos da violência entre moradores e trabalhadores da saúde e da educação em Manguinhos/Rio de Janeiro/RJ - estudo de caso**. CLAVES/ENSP/Fiocruz: July, 2020. Retrieved from: https://api.arca.fiocruz.br/api/core/bitstreams/c0da4fa0-2f82-4a45-b7fd-74a4df337bc1/content.
63 BARBOSA, R. J. et al. Educação sob cerco: impactos do controle territorial do tráfico e da milícia sobre o desempenho escolar. **Estudos Avançados**, v. 39, n. 115, Sep.-Dec. 2025. Retrieved from: https://www.scielo.br/j/ea/a/SQw9DdXLFFmq6sZ4WgVrcRB/?format=pdf&lang=pt
64 MINAYO, M. C. DE S.; COSTA, A. P. Fundamentos Teóricos das Técnicas de Investigação Qualitativa. **Revista Lusófona de Educação**, v. 40, n. 40, 27 Aug. 2018. Retrieved from: https://revistas.ulusofona.pt/index.php/rleducacao/article/view/6439. p.142.

03

BIO-MANGUINHOS/FIOCRUZ

The Institute of Immunobiological Technology (Bio-Manguinhos) is a unit of the Oswaldo Cruz Foundation (Fiocruz) that conducts research, drives innovation, and engages in the technological development and production of vaccines, diagnostic kits, biopharmaceuticals, and advanced therapies, in addition to providing technological services[65,66]. Bio-Manguinhos was founded in 1976, during a decade marked by a major meningitis outbreak in Brazil. The goal was to incorporate and localize health technologies, and the first technology transfer agreement was signed with the Pasteur Mérieux Institute in France for the meningococcal AC vaccine, which is still produced today by Bio-Manguinhos[67].

The institution's mission is "to contribute to improving public health standards in Brazil through innovation, technological development, the production of immunobiologicals, and the provision of services designed primarily to meet the country's health needs."[68]. Commenting on Bio-Manguinhos's work, Hiago Albuquerque (HA) noted that the institution provides "solutions for public health needs, both routine and emergency." It produces the main vaccines for the Ministry of Health's National Immunization Program (PNI), in addition to "serving international agencies, specifically within the United Nations system, and Gavi [the Vaccine Alliance] as well" (HA).

65 Bio-Manguinhos/Fiocruz - Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Portfólio Bio-Manguinhos:** inovação e produção a serviço do SUS. Rio de Janeiro: Bio-Manguinhos. 2024a. Retrieved from: https://www.bio.fiocruz.br/images/portfolio-port-24.pdf.
66 Bio-Manguinhos/Fiocruz - Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Relatório de Atividades 2023 Bio-Manguinhos**. Rio de Janeiro: Bio-Manguinhos. 2024b. Retrieved from: https://www.bio.fiocruz.br/images/ra2023.pdf.
67 DANDARA, Luana. **Maior surto de meningite do país, na década de 1970, foi marcado pela desinformação**. Portal Fiocruz, 17 Nov. 2022. Retrieved from: https://fiocruz.br/noticia/2022/11/maior-surto-de-meningite-do-pais-na-decada-de-1970-foi-marcado-pela-desinformacao.
68 Bio-Manguinhos/Fiocruz - Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Portfólio Bio-Manguinhos:** inovação e produção a serviço do SUS. Rio de Janeiro: Bio-Manguinhos. 2024a. Retrieved from: https://www.bio.fiocruz.br/images/portfolio-port-24.pdf. p. 8.

Text box 2 - The Oswaldo Cruz Foundation (Fiocruz)

Founded as the Federal Serological Institute (ISF) on May 25, 1900, Fiocruz is one of the world's leading institutions for science, technology, and innovation in health. Affiliated with the Ministry of Health, Fiocruz's history is intertwined with efforts to address Brazil's most pressing health challenges. Through its 17 technical-scientific units, spread across Brazil's five regions, it carries out a wide range of activities: from research and production of pharmaceuticals and immunobiologicals to the preservation of the scientific, historical, and cultural heritage of health and the sciences. It is an institution of extreme importance to the SUS and to ensuring the right to health in the country[69,70].

For more information about Fiocruz, visit: https://fiocruz.br/.

Fiocruz Castle, also known as Moorish Pavilion or Moorish Castle.

Image: Leonardo Oliveira | Fiocruz Image Collection

Bio-Manguinhos currently has in its portfolio "(...) 61 products, including 11 vaccines, 40 diagnostic kits, and 10 biopharmaceuticals. In its innovation portfolio, 17 projects involve technology transfer and 12 involve in-house technological development or co-development" (HA). Regarding intellectual property, "Bio-Manguinhos' portfolio of inventor patents, filed in the name of Fiocruz, totals 45 documents. Of this total, 35 patents have already been granted (4 in Brazil and 31 abroad) and 10 are in the application stage (4 in Brazil and 6 abroad)" [71].

Bio-Manguinhos' investment in R&D aims to "develop new products, therapies, services, or processes that, in some way, expand the population's access to healthcare through deliveries to the Ministry of Health"[72]. In 2024, the institution invested nearly R$150 million in R&D, about 28% more than in 2023. The chart below shows the amounts allocated to this area from 2019 to 2024.

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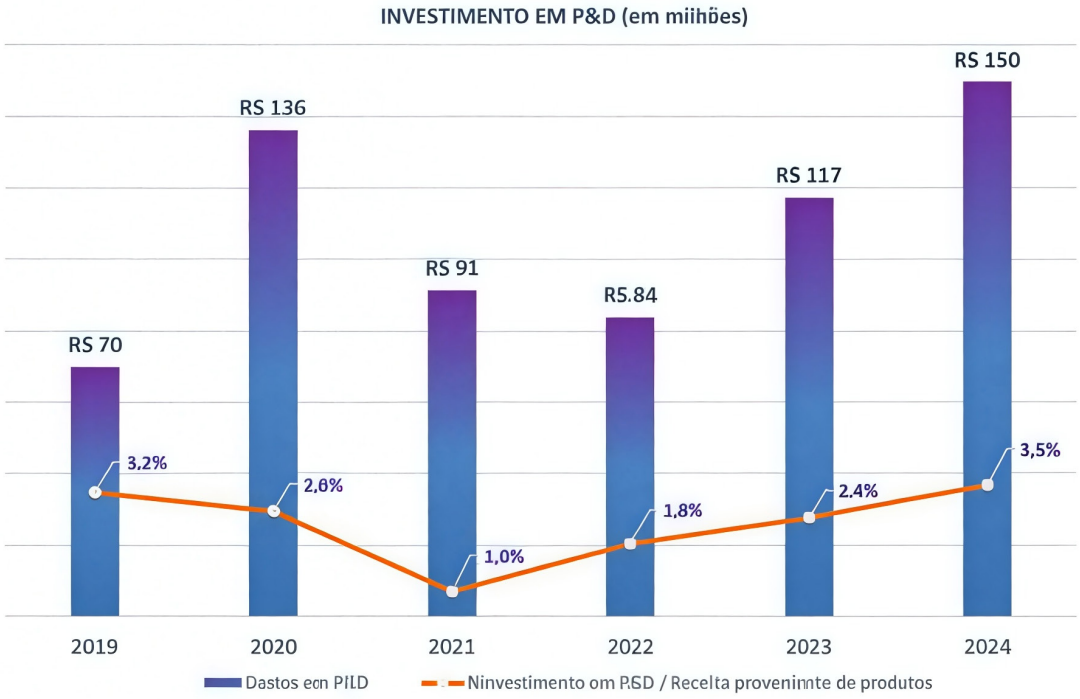
69 FIOCRUZ. **História**. Fundação Oswaldo Cruz, [s.d.]. Retrieved from: https://fiocruz.br/historia.
70 BIO-MANGUINHOS/FIOCRUZ. **Portfólio** - Bio-Manguinhos: inovação e produção a serviço do SUS. Bio-Manguinhos/Fiocruz: 2024. Retrieved from: https://www.bio.fiocruz.br/images/portfolio-port-24.pdf.
71 BIO-MANGUINHOS/FIOCRUZ- Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/ Fiocruz. Ministério da Saúde. **Resposta ao pedido de acesso à informação via Sistema Eletrônico de Informação ao Cidadão – e-SIC, integrado à Plataforma Fala.BR da CGU, protocolo 25072050437202538**. Rio de Janeiro, 07 Nov. 2025.
72 BIO-MANGUINHOS/FIOCRUZ- Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Relatório de Atividades 2023 Bio-Manguinhos**. Rio de Janeiro: Bio-Manguinhos. 2024b. Retrieved from: https://www.bio.fiocruz.br/images/ra2023.pdf. p. 40.

Figure 1 - Bio-Manguinhos/Fiocruz R&D Investment (2019–2024)



Source: Bio-Manguinhos/Fiocruz (2025).

Between 2019 and 2024, the institution "supplied more than 700 million doses of vaccines to the National Immunization Program (PNI) and to the WHO, more than 130 million diagnostic test kits, and more than 30 million biopharmaceuticals" (HA). In addition, it exported approximately 16.4 million doses of vaccines to more than 35 countries: 15.6 million doses of the Yellow Fever vaccine and 800,000 doses of the Meningococcal Polysaccharide AC/ACW vaccine, the latter in partnership with Cuba's Finlay Institute[73].

Bio-Manguinhos employs approximately 2,400 professionals across various departments. Growing demand has created a need to expand the institution's internal capacity, and a new facility, called the Industrial Complex for Health Biotechnology (Cibs), is currently under construction in Santa Cruz, in the West Zone of Rio de Janeiro. This will be the largest center for biological products in Latin America, with an estimated production capacity of 120 million vials of vaccines and biopharmaceuticals per year, in various formulations (number of doses per vial). A new campus, called the Strategic Inputs Technology Complex (CTIE), will also be built in Eusébio, Ceará, for the production of Active Pharmaceutical Ingredients (API)[74].

73 BIO-MANGUINHOS/FIOCRUZ- Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Relatório de Atividades 2023 Bio-Manguinhos**. Rio de Janeiro: Bio-Manguinhos. 2024b. Retrieved from: https://www.bio.fiocruz.br/images/ra2023.pdf.
74 BIO-MANGUINHOS/FIOCRUZ - Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Portfólio Bio-Manguinhos:** inovação e produção a serviço do SUS. Rio de Janeiro: Bio-Manguinhos. 2024a. Retrieved from: https://www.bio.fiocruz.br/images/portfolio-port-24.pdf.

The main business models are technology transfer and technological development, in addition to Partnerships for Productive Development (PDP)[75]. This approach enables the institution to incorporate new vaccine technologies into its portfolio, but it also "(...) can yield benefits that go beyond the development of a specific product, by establishing infrastructure and expertise that can subsequently benefit other technological projects"[76]. According to Moreira[77], There has been a significant increase in the institution's industrial capacity as a result of the technology transfer agreements, a strategy that "(...) has fostered the development of organizational capabilities critical to Bio-Manguinhos."

Guimarães[78] points out some issues related to technology transfer, such as "the possibility of transferring obsolete technologies whenever the contract does not provide for updates, and the failure to transfer all the technology, leaving the recipient in a state of permanent dependence on the seller and restricting markets and prices for the locally produced product." According to Tatsch, Botelho, and Koeller[79], "Although most laboratories have teams dedicated to R&D, their activities have focused on adapting and improving products developed in other countries; thus, these innovations can be characterized as incremental."

There are also positive references to agreements and partnerships as mechanisms that have contributed to the expansion of productive niches and the enhancement of LFOs' capacities[80].

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75 BIO-MANGUINHOS/FIOCRUZ - Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Inovação**. Bio-Manguinhos. Jul. 2022. Retrieved from: https://www.bio.fiocruz.br/index.php/br/home/inovacao-bio.

76 KAMEDA, Koichi; PIMENTA, Denise; MATTA, Gustavo. Affirming pharmaceutical sovereignty: Technology transfer agreements and vaccine geopolitics during a global health emergency. IN: QUET, Mathieu; KAMEDA, Koichi; POURRAZ, Jessica; RAULT-CHODANKAR, Yves-Marie. **Technoscwientific Globalisation from Below**. Mattering Press, 2025. Retrieved from: https://shs.hal.science/halshs-05372744. p.153.

77 MOREIRA, M. S. **As parcerias para o desenvolvimento produtivo (PDP) no setor da saúde**: o poder de compra do estado como política de indução à inovação e a capacitação tecnológica da Fiocruz no campo das biotecnologias. Tese (Doutorado) - Universidade Federal do Paraná, Setor de Ciências Sociais Aplicadas, Programa de Pós-Graduação em Políticas Públicas. Curitiba: 2018. Retrieved from: https://acervodigital.ufpr.br/xmlui/bitstream/handle/1884/58455/R%20-%20T%20-%20MARIO%20SANTOS%20MOREIRA.pdf?sequence=1&isAllowed=y. p.151.

78 GUIMARÃES, Reinaldo. Vacinas: Da Saúde Pública ao Big Business. **Ciência & Saúde Coletiva**, v. 26, n. 5, p. 1847–1852, 2021.
Retrieved from: https://www.scielo.br/j/csc/a/DRnJ5VC6zb4pM9Jwprd9S3F/?format=html&lang=pt. p.1850-1.

79 TATSCH, Ana Lúcia; BOTELHO, Marisa dos Reis Azevedo; KOELLER, Priscila. **A resposta do sistema brasileiro de inovação em saúde à covid-19**: as políticas públicas e o papel da Fiocruz e do Butantan. Rio de Janeiro: Ipea, fev. 2024. 38 p. (Texto para Discussão, n. 2959). Retrieved from: https://www.econstor.eu/bitstream/10419/285397/1/TD2959.pdf. p.26.

80 FERNANDES, D. R. A.; GADELHA, C. A. G.; MALDONADO, J. M. S. V. Estratégias de inovação em medicamentos e vacinas no âmbito do Ceis - modelos, mecanismos e expectativas. **Saúde Debate**, Rio de Janeiro, v. 47, n. 138, p. 377-392, Jul.-Sep. 2023. Retrieved from: https://www.scielo.br/j/sdeb/a/xsrgv5HYNppsGZD7TJpvSXp/?lang=pt.

Furthermore, although most of the agreements signed by Bio-Manguinhos are with transnational corporations, partnerships with institutions in the Global South also have the potential to provide productive capacity and decision-making power regarding which business deals to enter into[81].

Despite its limitations, the technology transfer agreement is considered strategic for the institution, as it allows it to "rapidly adopt new solutions (...), ensures selfsufficiency in domestic production and cost savings for the public coffers, and strengthens the health sector's economic and industrial complex" (HA). The most recent example was the partnership signed with AstraZeneca for the COVID-19 vaccine.

Bio-Manguinhos/Fiocruz's response to the COVID-19 pandemic

Despite the fact that the WHO did not declare COVID-19 a pandemic until March 11, 2020[82], Global efforts to understand the disease, its effects, and ways to protect the public began as early as late 2019, when the first cases emerged. In just 50 days, Fiocruz built and began operating the second-largest Intensive Care Unit (ICU) dedicated to COVID-19 in Brazil. Eight days after the first confirmed case in the country, the Foundation delivered the first RT-PCR molecular test to the Ministry of Health and, by March 2022, had produced more than 93 million tests of various types (rapid SARS-CoV-2 antigen tests/TR-Ag, RT-PCR molecular tests, and COVID-19 IgM and IgG tests)[83].

The institution coordinated the Solidarity study and conducted various academic research projects and outreach initiatives related to the disease. In addition, the epidemiological monitoring and communication efforts carried out through the COVID-19 Observatory were of great importance, especially amid the widespread dissemination of misinformation and health practices not based on scientific evidence[84].

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81 KAMEDA, Koichi; PIMENTA, Denise; MATTA, Gustavo. Affirming pharmaceutical sovereignty: Technology transfer agreements and vaccine geopolitics during a global health emergency. IN: QUET, Mathieu; KAMEDA, Koichi; POURRAZ, Jessica; RAULT-CHODANKAR, Yves-Marie. **Technoscientific Globalisation from Below**. Mattering Press, 2025. Retrieved from: https://shs.hal.science/halshs-05372744.

82 "WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020", Retrieved from: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

83 Fiocruz - Fundação Oswaldo Cruz. Ministério da Saúde. **Relatório de Balanço de gestão 2020/2022**: Atuação da Fiocruz na pandemia de Covid-19. Published 09 Sep. 2022. Retrieved from: https://fiocruz.br/documento/2022/09/balanco-de-gestao-atuacao-da-fiocruz-na-pandemia-de-covid-19.

84 More details about Fiocruz's activities related to the COVID-19 pandemic can be found at: FIOCRUZ - Fundação Oswaldo Cruz. Ministério da Saúde. **Relatório de Balanço de gestão 2020/2022**: Atuação da Fiocruz na pandemia de Covid-19. Published 09 Sep. 2022. Retrieved from: https://fiocruz.br/documento/2022/09/balanco-de-gestao-atuacao-da-fiocruz-na-pandemia-de-covid-19

In late January 2020, the Bio-Manguinhos Board of Directors requested a feasibility study to inform its decisions regarding strategic investments in treatments for the disease:

> One of the biggest challenges at the time was to simultaneously monitor the rapidly evolving technical and scientific development of vaccine candidates and the accumulation of knowledge about the mechanisms of the disease and viral transmission. (...) In addition, there were various technological platforms in use and under development, some of which had never been used before, making it difficult to predict the likelihood of technical success in R&D prior to the product's launch[85].

Schäferhoff et al.[86] They suggest that research on platforms such as messenger RNA, DNA, adenoviruses, and others may have benefited to some extent from the increased availability of funding over the past decade. In 2015, for example, the WHO established an action plan to accelerate R&D for diseases with epidemic and pandemic potential (WHO R&D Blueprint for Epidemics)[87]. In the same line of thought, Lima[88] states that the unprecedented speed with which the COVID-19 vaccine was developed stemmed from systematic investments in research and innovation made in previous years, although these were limited to certain laboratories, companies, and countries. Thus, the prior accumulation of knowledge and funding allowed technologies such as messenger RNA and viral vectors to advance more rapidly. Listed below are the different platforms corresponding to the main COVID-19 vaccines.

Table 1 - Categories of COVID-19 vaccine platforms

Conventional	
Protein-based	**Viral proteins or antigens used to stimulate an immune response. Examples: Novavax, Sanofi Pasteur/GSK, Dynavax, Vaxine Pty**
Virus-like particles (VLP)	**Protein structures that resemble viruses but are not infectious because they do not contain viral genetic material. Examples: Medicago Inc./GS**

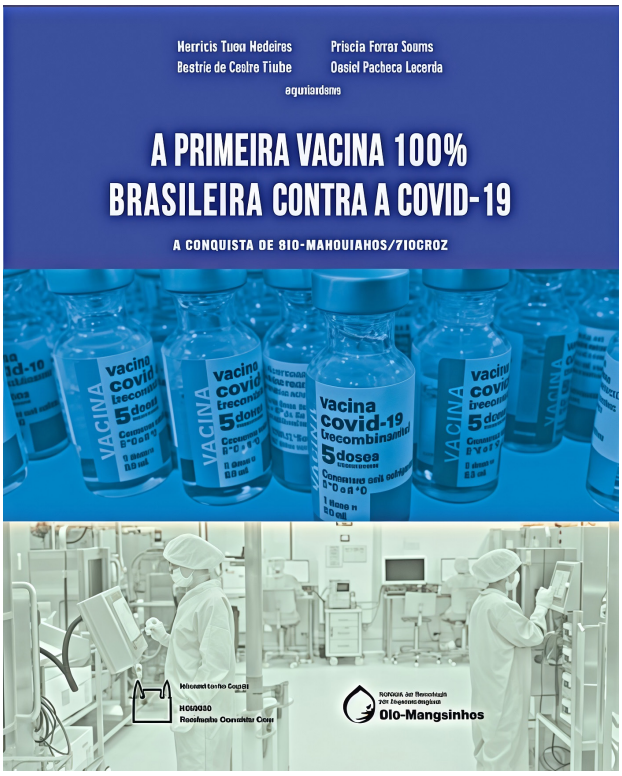
85 FIALHO, B. C. *et al.* Prospecção Tecnológica da Vacina contra Covid-19. In: MEDEIROS, M. Z.; FIALHO, B. C.; SOARES, P. F.; LACERDA, D. P. (org.). **A primeira vacina 100% brasileira contra a covid-19**: a conquista de Bio-Manguinhos/Fiocruz. Rio de Janeiro: Fundação Oswaldo Cruz, Bio-Manguinhos, 2022. p.57.
86 SCHÄFERHOFF, Marco et al. Reforming the research and development ecosystem for neglected diseases, emerging infectious diseases, and maternal health. The Center for Policy Impact in Global Health, 2024. Retrieved from: https://centerforpolicyimpact.org/wp-content/uploads/sites/18/2024/05/reforming-research-and-development-ecosystem-final.pdf
87 Mais detalhes em: https://www.who.int/teams/blueprint/who-r-and-d-blueprint-for-epidemics.
88 LIMA, N. T. Prefácio. In: MEDEIROS, M. Z.; FIALHO, B. C.; SOARES, P. F.; LACERDA, D. P. (org.). **A primeira vacina 100% brasileira contra a covid-19**: a conquista de Bio-Manguinhos/Fiocruz. Rio de Janeiro: Fundação Oswaldo Cruz, Bio-Manguinhos, 2022.

Deactivated	A vaccine consisting of pathogens (viral particles, bacteria) grown in culture and subsequently inactivated to eliminate their ability to cause disease. Examples: Sinovac, Sinopharm, Bharat Biotech
Diminished cheers	A vaccine composed of a pathogen with reduced virulence ("live"), rendered harmless or less virulent, that stimulates a strong, effective, and long-lasting immune response. Examples: Codagenix (Serum Institute of India)
Innovative	
Nucleic acids (DNA; RNA)	Fragments of DNA or mRNA that encode viral proteins or antigens and rely on host cells to produce the corresponding proteins in order to stimulate an immune response. Examples: Moderna, Pfizer/BioNTech, Zidus Cadila Healthcare, Inovio Pharmaceuticals
Viral vector (non-replicating; replicating	Like nucleic acid platforms, viral vectors encode proteins or antigens and rely on host cells to produce these proteins and thereby stimulate an immune response. They are generally based on a modified, harmless version of a different virus, such as adenovirus. Examples: AstraZeneca/University of Oxford, Johnson & Johnson, CanSino Biologics, Gamaleya Research Institute
Antigen-presenting cells (APC)	Immune system cells that mediate the immune response by presenting antigens for recognition by the host's lymphocytes.

Source: WIPO (2023, p. 24).

Considering the options in terms of stage of development, clinical trial results, and costs, Fiocruz has entered into a partnership with AstraZeneca to produce and incorporate the vaccine technology developed by the University of Oxford. As Lima points out[89], the decision was based on the pursuit of sustainability and autonomy for the SUS through the adoption of innovative technology with potential for application in other products, as well as the technical capacity and infrastructure already in place at Bio-Manguinhos, which resulted from previous investments. The sustainability of vaccination efforts and the licensing of the vaccine by the University of Oxford to AstraZeneca were also evaluated, guided by the principle of the vaccine as a public good. Finally, the need for a rapid response to the COVID-19 health emergency was taken into account.

Text box 3 - Recommended reading



THE FIRST 100% BRAZILIAN COVID-19 VACCINE - A milestone achieved by Bio-Manguinhos/Fiocruz

Available at:https://portolivre.fiocruz.br/primeira-vacina-100-brasileira-contra-covid-19-conquista-de-bio-manguinhosfiocruz

The contract was entered under two instruments[90] in two separate phases, given that the Oxford/AstraZeneca vaccine, like all the other candidates, was not yet fully ready and approved by health authorities[91]. The Technology Transfer Agreement was entered into in September 2020, ensuring the Brazilian institution's access to and capacity for vaccine production, as well as the provision of the technology necessary for the final

89 LIMA, N. T. Prefácio. In: MEDEIROS, M. Z.; FIALHO, B. C.; SOARES, P. F.; LACERDA, D. P. (org.). **A primeira vacina 100% brasileira contra a covid-19**: a conquista de Bio-Manguinhos/Fiocruz. Rio de Janeiro: Fundação Oswaldo Cruz, Bio-Manguinhos, 2022.
90 Os documentos de contratação estão disponíveis para acesso em: https://fiocruz.br/vacina-covid19-contratos-e-documentos.
91 Fiocruz - Fundação Oswaldo Cruz. Ministério da Saúde. **Relatório de Balanço de gestão 2020/2022**: Atuação da Fiocruz na pandemia de Covid-19. Published 09 Sep. 2022. Retrieved from: https://fiocruz.br/documento/2022/09/balanco-de-gestao-atuacao-da-fiocruz-na-pandemia-de-covid-19.

processing steps adapted to Fiocruz's production facilities. In June 2021, the Technology Transfer Agreement was signed, formalizing the transfer of technology for the Active Pharmaceutical Ingredient (API) to enable fully domestic production of the COVID-19 vaccine[92].

In January 2021, Bio-Manguinhos initially provided the Ministry of Health with 2 million doses of the vaccine, imported from India. By March of that same year, an additional 4.2 million doses had been produced in Brazil using imported inactivated vaccine (IFA). Starting in February 2022, the first batches of vaccines produced entirely in Brazil, including the IFA, were delivered to the Ministry of Health[93,94] .

Among the factors that contributed positively to the negotiation and production process, Rosenberg and Antunes[95] note that AstraZeneca provided technical information even before negotiations began, which allowed Bio-Manguinhos to assess scientific and technological aspects more accurately. Furthermore, despite the legal complexities surrounding the drafting of the contractual instruments—particularly with regard to Brazilian law and the constraints faced by the public institution—transparency and communication between the institutions were key to the agreement's success. The entire technology transfer process, which under the circumstances would have taken 10 years or more, was completed in record time, enabling the national laboratory to meet the Ministry of Health's demand and ensure the Brazilian population's access to the vaccine[96].

It is worth noting that the agreement with AstraZeneca did not impose any restrictions on Bio-Manguinhos/Fiocruz's in-house development of vaccines and treatments. As mentioned in the interview, "we couldn't transfer COVID vaccine technology from another company, but we could develop our own." (PN) Thus, in parallel with the Oxford/AstraZeneca vaccine, the institution can proceed with its own messenger RNA platform project, as detailed on the following pages.

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92 Bio-Manguinhos/Fiocruz - Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Fiocruz assina contrato de Transferência de Tecnologia da vacina Covid-19**. Fiocruz - Notícias, 01 Jun. 2021. Retrieved from: https://fiocruz.br/noticia/2021/06/fiocruz-assina-contrato-de-transferencia-de-tecnologia-da-vacina-covid-19.

93MEDEIROS, M. Z.; FIALHO, B. C.; SOARES, P. F.; LACERDA, D. P. Modelo de Análise das Inovações no Desenvolvimento e Transferência de Tecnologia Vacinal em Situações Emergenciais. In: MEDEIROS, M. Z.; FIALHO, B. C.; SOARES, P. F.; LACERDA, D. P. (org.). **A primeira vacina 100% brasileira contra a covid-19**: a conquista de Bio-Manguinhos/Fiocruz. Rio de Janeiro: Fundação Oswaldo Cruz, Bio-Manguinhos, 2022.

94 SOARES, P. F. *et al.* **Iniciativas e Mecanismos que possibilitaram a Transferência da Vacina contra a Covid-19 para o Brasil**: um estudo de caso em Bio-Manguinhos/Fiocruz. In: Encontro Nacional de Engenharia de Produção, XLIII ENEGEP, 17 a 20 de outubro de 2023. Ceará, 2023. Retrieved from: https://encurtador.com.br/zQgo.

95 ROSENBERG, V. Z.; ANTUNES, A. M. S. Transferência de tecnologia para vacina contra COVID-19 no Instituto de Tecnologia em Imunobiológicos (Bio-Manguinhos), Fundação Oswaldo Cruz. **Cadernos de Saúde Pública**, v. 24, n.4, 2024. Retrieved from: https://www.scielo.br/j/csp/a/DqgphkgtGvnKrpMt7XmqJfR/?format=pdf&lang=pt.

96 Fiocruz - Fundação Oswaldo Cruz. Ministério da Saúde. **Relatório de Balanço de gestão 2020/2022**: Atuação da Fiocruz na pandemia de Covid-19. Published 09 Sep. 2022. Retrieved from: https://fiocruz.br/documento/2022/09/balanco-de-gestao-atuacao-da-fiocruz-na-pandemia-de-covid-19.

04

THE BIO-MANGUINHOS/FIOCRUZ MESSENGER RNA PLATFORM

A dose of friendship: a boost for innovation

The selection of Bio-Manguinhos as a hub for the development and production of mRNA vaccines in Latin America is the result of an innovation built on solid foundations, both personally and institutionally. Patrícia Neves (PN) and Ana Paula Ano Bom (AP), the researchers leading the initiative, have a long-standing friendship and complementary backgrounds in areas critical to the project's success.

Even before the COVID-19 pandemic, the collaboration stemmed from the recognition that the researchers' complementary knowledge and experience constituted a strategic asset: Ana Paula, with a strong background in biochemistry, was conducting research in her laboratory on RNA interference and nanoformulations; and Patrícia, with extensive experience in vaccine development, was also leading a laboratory focused on monoclonal antibodies at the time. The research, focused on breast cancer therapies, began in 2018[97][98].

> The innovation process isn't linear. Ana was working on one thing, and I was working on another. We've been friends since college, but in graduate school we went our separate ways, so our backgrounds complement each other. (...) And then we started talking (...). (PN)

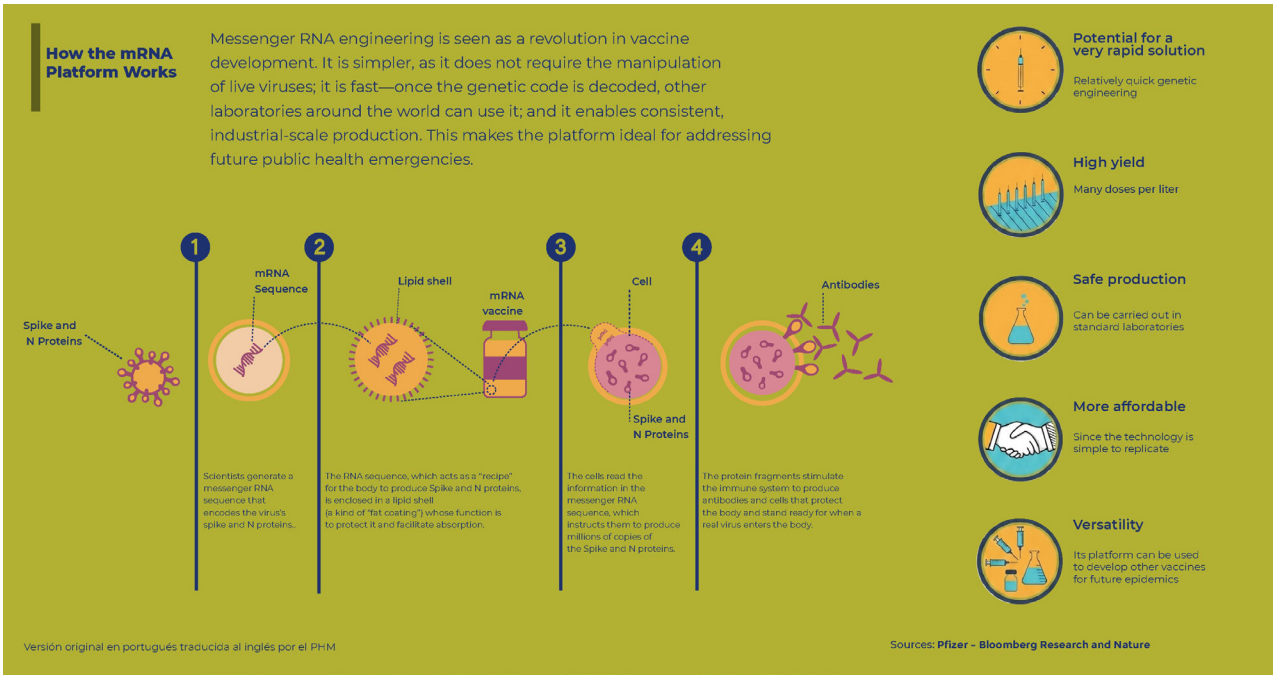
Both were advising doctoral student Thiago Chaves on a messenger RNA vaccine project for cancer. With the onset of the pandemic, Patrícia suggested redirecting their research efforts toward COVID-19. According to Ana Paula, "(...) the idea really came from within. It wasn't something that came from above. (...) And we're very proud of that because we know there are many ideas that, sometimes, don't move forward."

97The response received via the LAI (Appendix 1A) lists 2019 as the year when RNA product development began at Bio-Manguinhos. However, considering the interview transcript, the cited news article (Dobarro, 2025), and older information about the project recorded in the lead researchers' Lattes CVs, research focused on cancer began in 2018.

98 DOBARRO, Marcela. **Fiocruz avança com plataforma nacional de vacinas de RNA mensageiro**. Agência Fiocruz de Notícias, Aug 22. 2025. Retrieved from: https://agencia.fiocruz.br/fiocruz-avanca-com-plataforma-nacional-de-vacinas-de-rna-mensageiro.

Text Box 4 - How do mRNA vaccines work?

mRNA vaccines work by harnessing our cells' own ability to produce proteins. mRNA is a natural molecule found in all cells and is responsible for carrying the instructions for protein production. Vaccines use a synthetic version of messenger RNA, created in a laboratory, that contains the code necessary for the cell to produce the virus's proteins, such as the spike and N proteins. Because of its fragility, the RNA sequence must be protected by a lipid shell so that it does not break down before reaching its target. When the messenger RNA enters the cell, it induces the production of viral proteins which, once produced, are recognized by the immune system as foreign to the body and trigger an immune response. Then, helper T cells stimulate B cells to produce antibodies, while cytotoxic T cells learn to identify and destroy cells that express this protein. Thus, the body develops immune memory, becoming prepared to respond quickly and effectively should it come into actual contact with the virus. It is important to note that the messenger RNA does not alter human DNA and is naturally degraded after fulfilling its function[99].



Infographic: Fiocruz (2023), based on data from Pfizer, Bloomberg Research, and Nature.

For more on the history of messenger RNA vaccines, see: The tangled history of mRNA vaccines.

99 Prepared by the author based on Corum and Zimmer (2021), Gaviria and Kilic (2021), and Fiocruz (2023).

The underlying idea behind the use of a vaccine platform is the same: it leverages accumulated knowledge (production processes, product stability, method validation, nonclinical and clinical data, etc.) to accelerate the development of new biological candidates[100]. By maintaining a product's basic structure and modifying only the target, when necessary, the platform serves as a central tool for streamlining regulatory processes and responding quickly to emerging global health threats[101,1012]. Although no mRNA vaccine was ready or approved for human use before the pandemic, the versatility of this technology allowed institutions that were already conducting research in this field to quickly adapt their efforts to develop a COVID-19 vaccine[103].

The infrastructure and expertise available at Bio-Manguinhos enabled a swift and successful adaptation aimed at developing its own mRNA vaccine for COVID-19:

> We started out working separately in our own labs, but we were already building a team—something we'd been talking about a lot among ourselves. (...) And so, we really achieved a lot in a short time. But that was all because we already had a background. I'm bringing all this up in the context of innovation—how important it is to strengthen these technological foundations for what you'll want to achieve down the road. (AP)

This highlights the importance of investing in R&D and in internal capabilities to capitalize on opportunities. One of Bio-Manguinhos's unique strengths is its ability to bring together expertise ranging from laboratory research to product registration—something rarely found within a single institution, especially a public one. Being able to draw on the necessary internal expertise—such as knowledge of documentation, final processing, quality control, and other areas—to move the project forward was crucial, as highlighted in the interview:

> To actually develop a product, if we weren't part of an institution that possesses all this other expertise, we wouldn't be able to move forward. We could get as far as the candidate compound and the patent, but from there on, we need the significant industrial expertise that Bio-Manguinhos possesses. And it possesses that expertise because of technology transfers. These are skills we've acquired through those transfers. (PN)

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100 LI, Xiaojing *et al.* Platform Technology in Global Vaccine Regulation: Development, Applications, and Regulatory Strategies with Insights from China. **Vaccines**, v. 12, n. 12, Dec. 2024. Retrieved from: https://www.mdpi.com/2076-393X/12/12/1436

101 LI, Xiaojing *et al.* Platform Technology in Global Vaccine Regulation: Development, Applications, and Regulatory Strategies with Insights from China. **Vaccines**, v. 12, n. 12, Dec. 2024. Retrieved from: https://www.mdpi.com/2076-393X/12/12/1436.

102 WHO – WORLD HEALTH ORGANIZATION. **WHO Expert Committee on Biological Standardization**: seventy-fouth report. Annex 3. WHO Technical Report Series 1039. Geneva: World Health Organization, 2022. Retrieved from: https://www.who.int/publications/i/item/9789240046870.

103 BRANT, Jennifer; SCHULTZ, Mark F. **Unprecedented**: The Rapid Innovation Response to COVID-19 and the Role of Intellectual Property. Nov. 2021. Retrieved from: https://www.ifpma.org/publications/unprecedented-the-rapid-innovation-response-to-covid-19-and-the-role-of-intellectual-property/.

Bio-Manguinhos' engagement with the graduate school ecosystem contributes to these opportunities. In addition to offering the Professional Master's Degree in Immunobiological Technology (MPTI)[104], The institution also participates in other programs, such as the Graduate Program in Nanobiosystems[105], where Thiago was a doctoral student when the project began. In that sense:

> Bio-Manguinhos is an institution that places a strong emphasis on applied science, but if we don't have these kinds of initiatives at an early stage—or at least make a genuine effort, as we did with the ones that gave rise to the platform—we sometimes can't achieve something more effective on our own without an external partner. (PN)

The availability of qualified personnel in vaccine production is a key distinguishing feature of countries such as Brazil, India, and China, which have developed this expertise over time[106]. The shortage of skilled professionals in vaccine production—a problem faced worldwide—tends to worsen when it comes to innovative vaccine technologies, such as messenger RNA vaccines[107].

In addition to the technical aspects, the empathetic and motivating dynamic of the leadership and the team emerged as a positive factor in this journey. As Rafaele Loureiro (RL) recalled: "(...) I was also part of LATIM [Immunological Technology Laboratory] and recently left to join the Project Office; it's a group that really supports one another (...) and without good people management, that wouldn't exist." In the same vein, the unconditional support of the Vice-Directorate of Technological Development—later renamed Innovation—headed at the time by Sotiris Missailidis, was highlighted. Confidence in the ability to execute proposals and institutional mobilization can be interpreted as manifestations of the dynamic capacities to identify opportunities and reconfigure resources to enable innovation[108], reaffirming the importance of interpersonal relationships as a key factor in maximizing the results achieved.

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104 https://www.bio.fiocruz.br/index.php/br/sobre-o-mestrado.
105 https://nanobio.caxias.ufrj.br/.
106 PLOTKIN, S. *et al.* The complexity and cost of vaccine manufacturing - An overview. **Vaccine**, v. 35, n. 33, Jul. 2017, p. 4064-4071.
Retrieved from: https://www.sciencedirect.com/science/article/pii/S0264410X17307703?via%3Dihub.
107 DE NEGRI, Fernanda; ARBIX, Glauco; PEREIRA, Larissa. S. O mercado de vacinas no Brasil. In: DE NEGRI, Fernanda *et al.* [org.]. **Tecnologias e preços no mercado de medicamentos**. Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea), 2024. p. 109-129.
108 TEECE, D.J.; PISANO, G.; SHUEN, A. Dynamic Capabilities and Strategic Management. **Strategic Management Journal**, v. 18, n. 7, p.509-533, 1997. Retrieved from: https://sms.onlinelibrary.wiley.com/doi/epdf/10.1002/%28SICI%291097-0266%28199708%2918%3A7%3C509%3A%3AAID-SMJ882%3E3.0.CO%3B2-Z

The public and nonprofit nature of Bio-Manguinhos is a strategic advantage for the platform's development, which is guided by the collective interest. The link to the SUS provides a clear purpose for the research, given that there is still domestic demand for the COVID-19 vaccine: "(...) other partners, for example from the WHO initiative, will halt their efforts at the proof-of-concept stage, in Phase I, because there is no longer global demand for the vaccine in general." (PN). This condition favors a long-term approach and provides the freedom to establish agreements and partnerships aligned with the public interest, including prioritizing South-South relations.

Another highlight was the joint improvement of internal processes, some of which were unprecedented for Bio-Manguinhos in its role as a developer of proprietary technology. On certain occasions, the only possible answer to questions that arose was "we don't know; actually, we're going to have to figure it out together because the product is ours—it didn't come ready-made." (PN) This scenario fostered a collective learning environment with positive repercussions on organizational culture and the strengthening of internal capabilities.

At the same time, this paradigm shift—combined with the development of groundbreaking technology and the need to establish processes that had not existed before—posed a challenge for the team. As the research progressed, the documentation required for the new phase was developed collaboratively, in a collective effort to ensure compliance with technical and regulatory requirements. At these moments, the knowledge accumulated through technology transfers was mobilized as a practical reference for structuring the team's own strategies; with the support of specialists from different sectors of the institution, the team arrived at the answers needed to move forward. This is how it happened, for example, when there was a need to move the research from the laboratory environment to the pilot plant. With each new stage, new questions arise, shaping a continuous process of organizational learning.

mRNA TT Program and its selection as a hub in Latin America

During the COVID-19 pandemic, the WHO launched various initiatives to promote R&D for vaccines and medicines and to ensure more equitable access to these technologies, particularly in low- and middle-income countries. Among these initiatives, the Access to COVID-19 Tools Accelerator (ACT-A) and the COVID-19 Technology Access Pool (C-TAP) stand out[109].

109 SILVA, Luiza P. A.; RAPINI, Márcia Siqueira. Suitability of two WHO research and development initiatives for COVID-19 to promote equitable innovation: the Access to COVID-19 Tools Accelerator and COVID-19 Technology Access Pool. **Rev Panam Salud Publica**, v. 46, May 2022. Retrieved from: https://www.scielosp.org/article/rpsp/2022.v46/e194/en/#.

The first initiative, ACT-A, was launched in April 2020 as a public-private partnership with three main pillars (diagnostics, treatments, and vaccines), in addition to a pillar focused on strengthening health systems[110]. COVID-19 Vaccines Global Access (COVAX)[111], the official responsible for vaccine issues within the ACT-A initiative, which was designed to be a fair global mechanism for vaccine procurement but did not achieve the expected success[112]. First, the failure was attributed to the program's alignment with an approach that leaned more toward charity. Second, it was attributed to the fact that wealthy countries were given priority to purchase vaccines for their own populations directly from manufacturers, before the vaccination of vulnerable groups around the world could take place, as had been proposed by COVAX[113].

The other initiative, C-TAP, was launched in May 2020 by the WHO, the Costa Rican government, and other member states. Its main objective was the voluntary licensing of intellectual property rights for various technologies to meet the needs of low- and middle-income countries, a move that was well received by civil society but heavily criticized by the industry, its partners, and the Gates Foundation[114]. According to Silva and Rapini[115], Compared to ACT-A, C-TAP proposed the best mechanisms for financing, strengthening production capacity, and promoting access to COVID-19-related technologies. In 2024, C-TAP was replaced by the Health Technology Access Programme (HTAP), which seeks to expand equitable global access to health technologies by expanding regional innovation and manufacturing capacity. HTAP selects priority technologies and mobilizes partners to support their development, transfer, and sustainable production, in order to make them available to the communities that need them[116].

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110 SILVA, Luiza P. A.; RAPINI, Márcia Siqueira. Suitability of two WHO research and development initiatives for COVID-19 to promote equitable innovation: the Access to COVID-19 Tools Accelerator and COVID-19 Technology Access Pool. **Rev Panam Salud Publica**, v. 46, May 2022. Retrieved from: https://www.scielosp.org/article/rpsp/2022.v46/e194/en/#.

111 Jointly managed by Gavi, the Vaccine Alliance, CEPI, the Coalition for Epidemic Preparedness Innovations, and the WHO.

112 DSILVA, Luiza P. A.; RAPINI, Márcia Siqueira. Suitability of two WHO research and development initiatives for COVID-19 to promote equitable innovation: the Access to COVID-19 Tools Accelerator and COVID-19 Technology Access Pool. **Rev Panam Salud Publica**, v. 46, May 2022. Retrieved from: https://www.scielosp.org/article/rpsp/2022.v46/e194/en/#.

113 HERDER, Matthew; BENAVIDES, Ximena. 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. **PLOS Global Public Health** [Internet], v. 4, n. 9, set. 2024. Retrieved from: https://journals.plos.org/globalpublichealth/article/metrics?id=10.1371/journal.pgph.0003173#citedHeader

114HERDER, Matthew; BENAVIDES, Ximena. 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. **PLOS Global Public Health** [Internet], v. 4, n. 9, Sep. 2024. Retrieved from: https://journals.plos.org/globalpublichealth/article/metrics?id=10.1371/journal.pgph.0003173#citedHeader.

115 SILVA, Luiza P. A.; RAPINI, Márcia Siqueira. Suitability of two WHO research and development initiatives for COVID-19 to promote equitable innovation: the Access to COVID-19 Tools Accelerator and COVID-19 Technology Access Pool. **Rev Panam Salud Publica**, v. 46, May 2022. Retrieved from: https://www.scielosp.org/article/rpsp/2022.v46/e194/en/#.

116 WHO - WORLD HEALTH ORGANIZATION. **Health Technology Access Programme**. s.d. Retrieved from: https://www.who.int/initiatives/who-health-technology-access-programme

Another project was conceived by internal and external stakeholders at the WHO. Focused on building capacity for vaccine production, this proposal involved establishing one or more centers, based on the "hub-and-spoke model," to transfer knowledge and provide appropriate training to vaccine manufacturers in low- and middle-income countries. It was the embryonic stage of what later became known as the mRNA Technology Transfer (mRNA TT) Program[117]. Currently, this program is linked to HTAP, which replaced C-TAP.

On June 16, 2021, the WHO published a call on its official website[118] *for those interested in the mRNA TT Program*[119]. According to the organization itself, this was "(...) a valid strategy for increasing the production capacity of messenger RNA vaccines in underserved regions and thereby promoting regional public health"[120]. The decision to use messenger RNA technology was justified by the following reasons: (i) its high efficacy against COVID-19 and its variants; (ii) its relatively rapid flexibility and adaptability; (iii) the possibility of production not only by vaccine manufacturers but also by drug and active ingredient producers; and (iv) the relative absence of intellectual property barriers in various jurisdictions[121].

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117 WHO - WORLD HEALTH ORGANIZATION. **Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub**. 16 Apr 2021a. Retrieved from: https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub.

118 Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub. It is interesting to note that a text that is practically identical, but with a different title, was published on the same date by the Organization; visit: Establishment of a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing.

119 WHO - WORLD HEALTH ORGANIZATION. **Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub**. 16 Apr. 2021a. Retrieved from: https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub

120 "While WHO continuously advocated for equitable sharing of vaccines through the COVAX Facility, and for sharing of technology through bilateral and multilateral agreements (i.e. through the COVID-19 Technology Access Pool), the initiative of establishing an mRNA technology transfer hub surfaced as a valid strategy to increase mRNA vaccine production capacity in under-served regions, and thus promote regional health security." WHO - WORLD HEALTH ORGANIZATION. **Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub**. 16 Apr. 2021a. Retrieved from: https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub.

121 WHO - WORLD HEALTH ORGANIZATION. **Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub**. 16 Apr. 2021a. Retrieved from: https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub.

This call for proposals sought submissions of:

> 1. Small and medium-sized manufacturers (public or private) of medical products (drugs, vaccines, or active pharmaceutical ingredients), preferably but not exclusively in LMICs, that can host a COVID-19 mRNA hub and:
> Scale up the technology to GMP-grade (Good Manufacturing Practices) pilot batches for clinical trials;
> Transfer the appropriate know-how and technology to existing or new manufacturers in LMICs, in order to enable them to develop and produce mRNA vaccines against COVID-19.
> 2. Holders (public or private) of technology and/or intellectual property (IP) rights. These may include academic institutions, pharmaceutical companies, nongovernmental organizations, or any other entity willing to contribute these technologies to a transfer hub coordinated by WHO, enabling the production of mRNA-based COVID-19 vaccines in LMICs[122]

It was expected that a specific call for producers in PBMR regions interested in receiving the technology developed by the hub(s) would be issued in the coming weeks. However, this announcement was not found on the official WHO website, nor was any news item with the same content. An update to the call for centers, dated May 31, 2021, indicated that the call had closed, but left open the possibility of contact from donors or those interested in receiving technology transfer[123].

On June 21, 2021, the WHO announced the selection of the South African consortium comprising Afrigen Biologics, the South African Medical Research Council (SAMRC), and Biovac as the first technology transfer hub[124,125].

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122 "To support this activity, we are seeking expressions of interest from: 1. Small/middle-size (public or private) manufacturers of medical products (drugs, vaccines or drug substances) preferably, but not exclusively in LMICs, which could host a COVID-19 mRNA hub and: Assemble the technology up to GMP-grade pilot lots for clinical trials; Transfer the appropriate know-how and technology to existing or new manufacturers in LMICs to enable these to develop and produce COVID-19 mRNA vaccines. 2. Owners (public or private) of technology and/or Intellectual Property Rights (IPR). These may be academic institutions, pharmaceutical companies, non-governmental organizations or any other entity willing to contribute these to a technology transfer hub, under the auspices of WHO, to enable production of mRNA-based COVID-19 vaccines in LMICs." WHO - WORLD HEALTH ORGANIZATION. **Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub**. 16 Apr. 2021a. Retrieved from: https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub.
123 WHO - WORLD HEALTH ORGANIZATION. **Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub**. 16 Apr. 2021a. Retrieved from: https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub.
124 WHO - WORLD HEALTH ORGANIZATION. **WHO supporting South African consortium to establish first COVID mRNA vaccine technology transfer hub**. 21 Jun. 2021b. Retrieved from: https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub.
125 MPP - Medicines Patent Pool. **MPP welcomes WHO announcement of the first COVID-19 mRNA vaccine technology transfer hub to be established in South Africa**. Geneva, 22 Jun. 2021. Retrieved from: https://medicinespatentpool.org/news-publications-post/who-covid-19-mrna-vaccine-tech-transfer-hub-sa.

Herder and Benavides[126] thoroughly analyzed this consortium, highlighting the critical aspects of its structure and the decisions made regarding the development of the project in South Africa, while comparing it to traditional biopharmaceutical production. Despite the emphasis on cooperation and knowledge sharing, the authors noted that the South African hub was implemented based on dynamics typical of the biopharmaceutical industry's production model, with limited pricing commitments, inconsistent licensing agreements, and a centralized governance structure.

The discrepancy between the hub's initial design and its actual implementation demonstrated that, even in the face of a global health crisis, efforts to promote greater self-sufficiency and productive capacity in regions historically neglected by the pharmaceutical industry were co-opted by market-driven dynamics. Ultimately, access to health goods for the most vulnerable populations was once again sidelined, exposing a critical gap between the rhetoric of equity promoted by the project's mission and the program's implementation.

As noted by Dutt, Mazzucato, and Torreele[127], the economic sustainability of the hub was initially conceived according to market logic, with the individual financial viability of partner companies taking precedence over the collective goal of protecting and ensuring public health. Intellectual property and governance dynamics, dependent on hegemonic structures, were replicated in its implementation. This meant that the messenger RNA platform was not an asset to be collectively managed. Instead, there was a set of fragile and limited agreements among the partners, dependent on market fluctuations and each partner's own objectives.

In addition to the South African consortium, other applications were submitted to the WHO. In total, the call for proposals resulted in 28 proposals to provide the technology and/or host a hub and 25 expressions of interest from PBMRs to receive the technology[128]. Incidentally, the fact that these latest submissions were received during the same period as the call for proposals to the centers may explain why no specific publications were found, as mentioned earlier.

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126 HERDER, Matthew; BENAVIDES, Ximena. 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. **PLOS Global Public Health** [Internet], v. 4, n. 9, set. 2024. Retrieved from: https://journals.plos.org/globalpublichealth/article/metrics?id=10.1371/journal.pgph.0003173#citedHeader.

127 DUTT, Devika; MAZZUCATO, Mariana; TORREELE, Els. An mRNA technology transfer programme and economic sustainability in health care. **Bulletin of the World Health Organization**, n. 102, Mar. 2024, p. 344-351. Retrieved from: https://pmc.ncbi.nlm.nih.gov/articles/PMC11046156/.

128 WHO - WORLD HEALTH ORGANIZATION. **WHO supporting South African consortium to establish first COVID mRNA vaccine technology transfer hub**. 21 Jun. 2021b. Retrieved from: https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub.

In light of the progress made in developing its own mRNA platform against COVID-19, Bio-Manguinhos submitted an end-to-end proposal for the mRNA TT Program—that is, covering everything from antigen design to the final formulation. Sotiris Missailidis, then Director of Innovation at Bio-Manguinhos, told Herder and Benavides[129] that the initial understanding was that there would be multiple hubs and their associated spokes. When South Africa's selection was announced, the WHO stated that it would continue to evaluate projects to select new hubs as needed, in order to ensure equity across all regions[130]. The announcement itself in April[131] mentioned the possibility of establishing "one or more" technology transfer centers.

In fact, on September 21, 2021, Bio-Manguinhos and the Argentine company Sinergium Biotech were specifically designated as hubs by the Pan American Health Organization (PAHO)[132]. However, during a visit to *Afrigen* in April 2022, representatives from Bio-Manguinhos were informed that their role within the initiative had been unilaterally redefined by the WHO as a *spoke*[133]. The situation was recalled in the interview:

> In June, they had announced Afrigen in South Africa. And we were already in the selection process here—so much so that the application we filled out was for a Latin American hub. They announced us in September and were then going to announce one in Asia. So, there was supposed to be a hub in each region. (...) But then they changed the rules in the middle of the game: 'now there will be just one hub, and everyone else will receive the technology from that hub that will be developed.' (PN)

In light of the progress made in developing its own mRNA platform against COVID-19, Bio-Manguinhos submitted an end-to-end proposal for the mRNA TT Program—that The decision to concentrate the entire program in central South Africa and to treat the other institutions as spokes was not explicitly justified, but it may be linked to the political and financial pressures faced by the WHO and to the functioning of the Medicines Patent Pool (MPP), which tends to rely on contractual arrangements more in line with market practices.

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129 HERDER, Matthew; BENAVIDES, Ximena. 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. **PLOS Global Public Health** [Internet], v. 4, n. 9, Sep. 2024. Retrieved from: https://journals.plos.org/globalpublichealth/article/metrics?id=10.1371/journal.pgph.0003173#citedHeader.

130 HERDER, Matthew; BENAVIDES, Ximena. 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. **PLOS Global Public Health** [Internet], v. 4, n. 9, Sep. 2024. Retrieved from: https://journals.plos.org/globalpublichealth/article/metrics?id=10.1371/journal.pgph.0003173#citedHeader.

131 WHO - WORLD HEALTH ORGANIZATION. **Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub**. 16 Apr. 2021a. Retrieved from: https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub

132 PAHO - Pan American Health Organization. **PAHO selects centers in Argentina, Brazil to develop COVID-19 mRNA vaccines**. 21 Sep. 2021. Retrieved from: https://www.paho.org/en/news/21-9-2021-paho-selects-centers-argentina-brazil-develop-covid-19-mrna-vaccines.

133 HERDER, Matthew; BENAVIDES, Ximena. 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. **PLOS Global Public Health** [Internet], v. 4, n. 9, Sep. 2024. Retrieved from: https://journals.plos.org/globalpublichealth/article/metrics?id=10.1371/journal.pgph.0003173#citedHeader.

It is also possible that the choice is associated with "the very logic of official foreign aid, of international cooperation in the broadest sense (...)" (HA), since "(...) when you look at the map of 'vaccine apartheid,' as they call it, Africa was in terrible shape, much worse off than we were." (PN)

Regardless of the reason, the disagreement between the parties led to an impasse regarding the signing of any agreement that would place Bio-Manguinhos in the position of a spoke or restrict its operational freedom, potentially conflicting with its commitment to public health and the principles associated with it. Bio-Manguinhos submitted its application as a hub precisely because it is developing its own technology, the patent ownership of which allows it to apply it to different projects and transfer the technology to third parties.

Furthermore, Bio-Manguinhos could not "(...) due to the AstraZeneca contract, receive a technology transfer from another company for the COVID-19 vaccine" (PN). Initially, the MPP's priority was to obtain a voluntary license for an mRNA vaccine already available on the market to use in the mRNA TT Program. However, in light of refusals from Moderna and Pfizer/BioNTech, the WHO decided that Afrigen should attempt to replicate Moderna's vaccine, since more information about it was publicly available compared to the Pfizer/BioNTech vaccine. Moderna had also committed to not enforcing its patent rights during the pandemic[134].

Some pharmaceutical companies authorize manufacturers in low- and middle-income countries, particularly in Africa, to produce generic versions of medicines and vaccines. The MPP, in fact, acts as a mediator in this process. However, the licenses have geographical limitations, and Brazil is generally excluded from the territories covered by the agreements, since it is considered a significant commercial market rather than a recipient of humanitarian aid. There are also restrictions regarding the use of the transferred technology, which in most cases cannot be applied for purposes other than those specified in the granted license.

In short, this whole situation ultimately led to a change in how the institutions involved in the mRNA TT Program are referred to; whereas they were previously called spokes, they are now explicitly referred to as partners. However, it is still possible to find some inconsistent references in official materials regarding the initiative. On the "Frequently Asked Questions" page (Figure 1), for example, it is stated that there are no plans for new hubs and that Bio-Manguinhos and Sinergium Biotech are spokes in the Latin American region[135]. On another

134 MAXMEN, A. South African scientists copy Moderna covid vaccine. **Nature**, 03 Feb. 2022. Retrieved from: https://www.nature.com/articles/d41586-022-00293-2.
135 WHO - WORLD HEALTH ORGANIZATION. **FAQ - The mRNA vaccine technology transfer hub**. s.d. Retrieved from: https://www.who.int/initiatives/mrna-technology-transfer-(mrna-tt)-programme/faq.
136 WHO - WORLD HEALTH ORGANIZATION. **Recipients of mRNA technology from the WHO mRNA technology transfer hub**. s.d. Retrieved from: https://www.who.int/initiatives/mrna-technology-transfer-(mrna-tt)-programme/recipients-of-mrna-technology-from-the-who-mrna-technology-transfer-hub.

Figura 1 - FAQ - The mRNA vaccine technology transfer hub[137]

3. Have any mRNA hubs been established, and how many are planned?

In April 2021, WHO issued a call for expressions of interest to companies wishing to host an mRNA technology transfer hub. In June 2021, WHO announced that it had selected a South African consortium to run the hub, which will serve all low- and middle-income countries. No additional mRNA technology transfer hubs are planned.

The selected consortium comprises Afrigen Biologics, the South African Medical Research Council (SAMRC) and Biovac, a South African vaccine producer. Within this consortium, Afrigen is the entity mandated to establish mRNA vaccine production technology, SAMRC is providing the research and Biovac is the first manufacturing "spoke".

The hub has already established mRNA vaccine production at laboratory scale and is currently scaling up and validating production at commercial scale.

Training of the recipients (the spokes) will begin in March 2022.

4. How many spokes will there be?

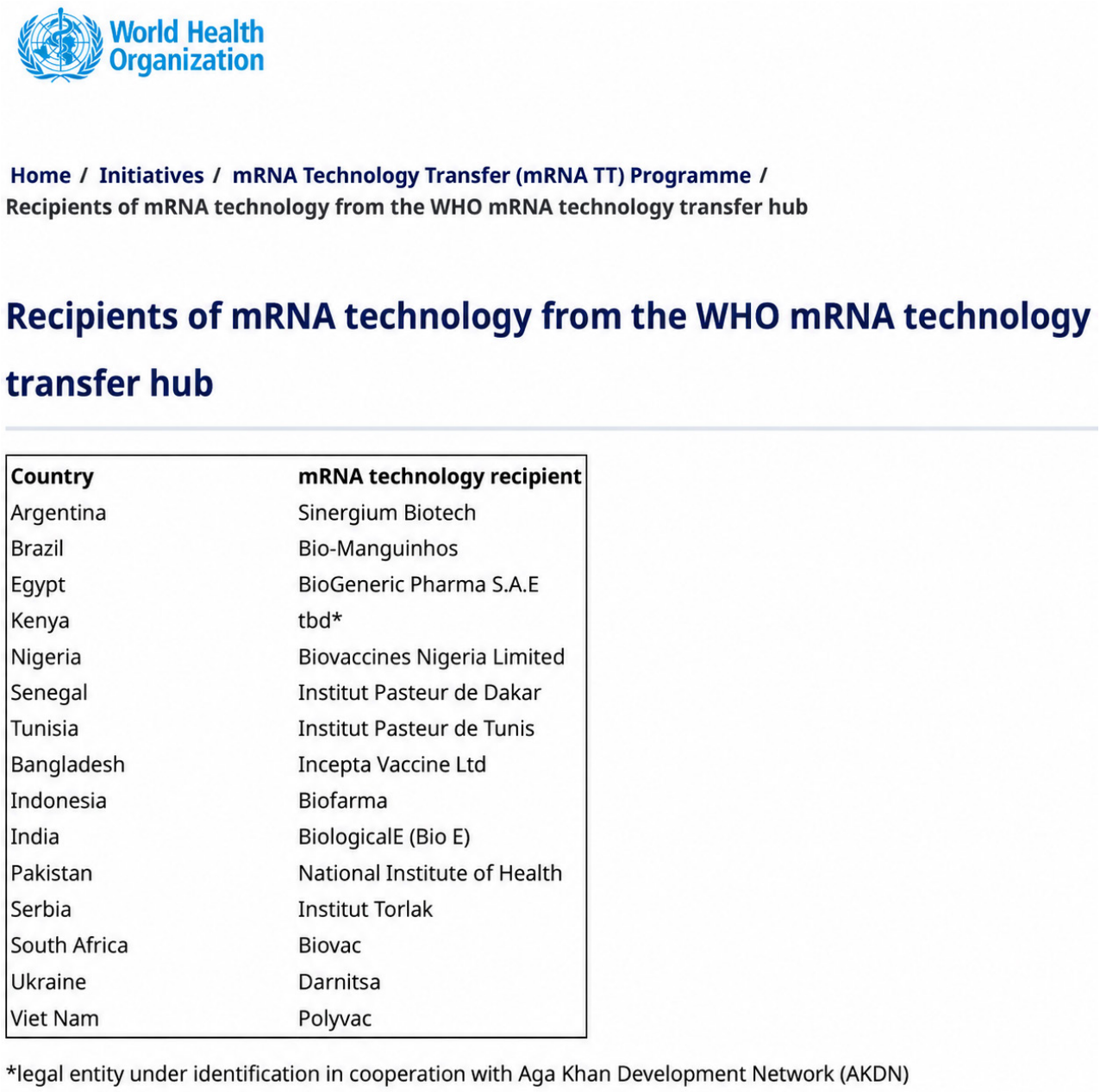
In September 2021, the Pan-American Health Organization (PAHO) announced agreements with two centres to establish regional mRNA manufacturer spokes - in Brazil, with the Bio-Manguinhos Institute of Technology on Immunobiologicals at the Oswaldo Cruz Foundation, and in Argentina with Sinergium Biotech.

In November 2021, WHO had an open call for Expressions of Interest from other potential manufacturing spokes. Announcements of these are expected in February.

Source: FAQ - The mRNA vaccine technology transfer hub.

137 Translation from the author: "3. Has any mRNA hub been established, and how many are planned? In April 2021, the WHO issued a call for expressions of interest from companies interested in hosting an mRNA technology transfer hub. In June 2021, the WHO announced that it had selected a South African consortium to serve as the hub that will serve all low- and middle-income countries. No other mRNA technology transfer hubs are planned at this time. The selected consortium consists of Afrigen Biologics, the South African Medical Research Council (SAMRC), and Biovac, a South African vaccine manufacturer. Within this consortium, Afrigen is responsible for establishing the technology for producing messenger RNA vaccines; SAMRC provides research support; and Biovac acts as the first spoke. The hub has already established mRNA vaccine production at the laboratory scale and is currently scaling up and validating production at the commercial scale. Training for the recipients (the spokes) is scheduled to begin in March 2022. 4. How many spokes will there be? In September 2021, the Pan American Health Organization (PAHO) announced agreements with two centers to establish regional mRNA manufacturing hubs (spokes): in Brazil, with the Institute of Immunobiological Technology (Bio-Manguinhos) of the Oswaldo Cruz Foundation (Fiocruz); and in Argentina, with Sinergium Biotech. In November 2021, the WHO issued a new call for expressions of interest from other potential manufacturing hubs (spokes). Announcements regarding them are expected in February."

Figure 2 - Recipients of mRNA technology from the WHO mRNA Technology Transfer Hub[138]



World Health Organization

Home / Initiatives / mRNA Technology Transfer (mRNA TT) Programme /
Recipients of mRNA technology from the WHO mRNA technology transfer hub

Recipients of mRNA technology from the WHO mRNA technology transfer hub

Country	mRNA technology recipient
Argentina	Sinergium Biotech
Brazil	Bio-Manguinhos
Egypt	BioGeneric Pharma S.A.E
Kenya	tbd*
Nigeria	Biovaccines Nigeria Limited
Senegal	Institut Pasteur de Dakar
Tunisia	Institut Pasteur de Tunis
Bangladesh	Incepta Vaccine Ltd
Indonesia	Biofarma
India	BiologicalE (Bio E)
Pakistan	National Institute of Health
Serbia	Institut Torlak
South Africa	Biovac
Ukraine	Darnitsa
Viet Nam	Polyvac

*legal entity under identification in cooperation with Aga Khan Development Network (AKDN)

Source: Recipients of mRNA technology from the WHO mRNA technology transfer hub.

138 Tradução nossa: “Receptores da tecnologia de RNA mensageiro do *hub* de transferência de tecnologia da OMS [país - receptor]: Argentina - Sinergium Biotech; Brasil - Bio-Manguinhos; Egypt - BioGeneric Pharma S.A.E.; Quênia - tbd*; Nigéria - Biovaccines Nigeria Limited; Senegal - Instituto Translation from the author: “Recipients of messenger RNA technology from the WHO technology transfer hub [country - recipient]: Argentina - Sinergium Biotech; Brazil - Bio-Manguinhos; Egypt - BioGeneric Pharma S.A.E.; Kenya - tbd*; Nigeria - Biovaccines Nigeria Limited; Senegal - Pasteur Institute of Dakar; Tunisia - Pasteur Institute of Tunis; Bangladesh - Incepta Vaccine Ltd; Indonesia - Biofarma; India - BiologicalE (Bio E); Pakistan - National Institute of Health; Serbia - Institut Torlak; South Africa - Biovac; Ukraine - Darnitsa; Vietnam - Polyvac. *Legal entity in cooperation with the Aga Khan Development Network (AKDN).”

More recently, it is evident that MPP has been approaching the mRNA TT Program as an even broader initiative, highlighting collaboration among partners on a global scale. In this regard, the organization highlighted three pillars of the initiative in its latest report: the South African consortium, partnerships for the manufacture of messenger RNA-based products in low- and middle-income countries, and R&D consortia focused on diseases of local epidemiological relevance[139]. The document, published in June 2025, highlights some of the South African consortium's achievements in 2024, such as the demonstration of efficacy and safety in preclinical trials of the AfriVac2121 vaccine candidate, comparable to those of the Moderna and Pfizer vaccines.

In addition, it highlights the facility's progress regarding Good Manufacturing Practices, including an automated filling line, which is scheduled to be certified by the South African Health Products Regulatory Authority (SAHPRA) in 2025. In-person training and procurement of the equipment and supplies necessary for Biovac to scale up production. And the SAMRC-led initiative synthesized about 90 and evaluated approximately 50 new cationic lipids to replace SM-102 in the formulation of lipid nanoparticles (LNPs), aiming to reduce costs, ensure operational flexibility, and improve the immune response[140].

For all these reasons, the framework established by the mRNA TT Program proved completely unworkable for Bio-Manguinhos, which continued to develop its own messenger RNA platform. The Brazilian institution did not sign any contracts nor receive any funding. According to what was discussed in the interview, contact between Bio-Manguinhos and MPP is still ongoing with the aim of facilitating other agreements and partnerships different from the model adopted for South Africa. Thus, the expectation is to secure funding to advance the platform, but without compromising the fundamental values and principles of the SUS, which is Bio-Manguinhos' priority.

139 MPP - Medicines Patent Pool. **Breaking New Ground - Annual Report 2024**. Geneva, 26 jun. 2025. Retrieved from: https://medicinespatentpool.org/news-publications-post/breaking-new-ground-mpps-2024-annual-report-demonstrates-sustained-innovation-and-impact.
140 MPP - Medicines Patent Pool. **Breaking New Ground - Annual Report 2024**. Geneva, 26 jun. 2025. Retrieved from: https://medicinespatentpool.org/news-publications-post/breaking-new-ground-mpps-2024-annual-report-demonstrates-sustained-innovation-and-impact.

The structure of the mRNA TT Program brings to mind long-standing issues with the solidarity model or charitable welfare. There are also contradictions inherent in these mechanisms themselves. In discussing C-TAP and ACT-A, Almeida[141] points out that "(...) in reality, they are at odds with one another, as they reflect different policy choices and highlight underlying conflicts: distinct approaches to resolving problems involving global public goods that are, in reality, treated as private goods." Not even relations among countries in the Global South are entirely immune to market tensions: for example, when the Brazilian government was unable to procure doses of the COVID-19 vaccine from the U.S. and the U.K., the Serum Institute of India (SII) agreed to supply 2 million doses, but at a price nearly twice as high as the one previously negotiated with AstraZeneca[142].

The search for alternative ways to decentralize productive capacities, strengthen local production, and expand the autonomy of countries historically disadvantaged by colonial logic does not take place in a depoliticized space. The proposed initiatives face obstacles in overcoming historical imbalances that keep low- and middle-income countries subordinate to those with greater economic and scientific power[143]. Confronting these structures requires political decisions that safeguard the public interest, promote innovation, and ensure access. Achieving this, however, is no trivial matter. And in certain circumstances, the decision will be to mobilize the very instruments that once threatened these objectives, strategically appropriating them to prevent new forms of subordination and to assert a vision of autonomy for the Global South.

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141 ALMEIDA, Celia. **Pandemia de Covid-19**: por que devemos olhar para o contexto internacional? Reflexões sobre a governança do setor Saúde. IN: PORTELA, M. C.; REIS, L. G. C.; LIMA, S. M. L. (eds). Covid-19: desafios para a organização e repercussões nos sistemas e serviços de saúde [online]. Rio de Janeiro: Observatório Covid-19 Fiocruz, Editora Fiocruz, 2022, 472 p. Retrieved from: https://books.scielo.org/id/kymhj/pdf/portela-9786557081587.pdf. p.53-54.

142 KAMEDA, Koichi; PIMENTA, Denise; MATTA, Gustavo. Affirming pharmaceutical sovereignty: Technology transfer agreements and vaccine geopolitics during a global health emergency. IN: QUET, Mathieu; KAMEDA, Koichi; POURRAZ, Jessica; RAULT-CHODANKAR, Yves-Marie. **Technoscientific Globalisation from Below**. Mattering Press, 2025. Retrieved from: https://shs.hal.science/halshs-05372744.

143 ALMEIDA, Celia. **Pandemia de Covid-19**: por que devemos olhar para o contexto internacional? Reflexões sobre a governança do setor Saúde. IN: PORTELA, M. C.; REIS, L. G. C.; LIMA, S. M. L. (eds). Covid-19: desafios para a organização e repercussões nos sistemas e serviços de saúde [online]. Rio de Janeiro: Observatório Covid-19 Fiocruz, Editora Fiocruz, 2022, 472 p. Retrieved from: https://books.scielo.org/id/kymhj/pdf/portela-9786557081587.pdf.

The patent for the Brazilian messenger RNA platform and its implications for the Global South

The intellectual property protection regime established with the signing of the TRIPS Agreement was one of the main obstacles to the development and progress of emerging economies in the last century. Countries in the Global South were prevented from climbing the "ladder" [144] and to rely on imitation as a means of learning and accumulating technology—a practice widely used by more developed countries in the past. From that point on, inequalities in the production of and access to pharmaceutical products became increasingly pronounced.

During the COVID-19 pandemic, companies holding mRNA technologies refused to share proprietary information and license their patents, thwarting the South African hub's initial plans and even requests from the U.S. government[145, 146, 147, 148].

Without access to know-how and information protected by intellectual property rights, not even low- and middle-income countries with manufacturing capacity were able to produce mRNA vaccines. Moderna, which received thousands of dollars in public funding to develop its vaccine, like other companies in the sector, sued Pfizer and BioNTech for patent infringement, demonstrating its willingness to aggressively protect its intellectual property and seek financial compensation. Pfizer responded with a counterclaim, reiterating the strategic and contested nature of this technology .

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144 CHANG, Ha-Joon. **Kicking away the ladder**: development strategy in historical perspective. London: Anthen Press, 2002.
NOLEN, Stephanie; STOLBERG, Sheryl Gay. Pressure Grows on U.S. Companies to Share Covid Vaccine Technology. **The New York Times**, 22 set. 2021. Retrieved from: https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html.
145 HERDER, Matthew; BENAVIDES, Ximena. 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. **PLOS Global Public Health** [Internet], v. 4, n. 9, set. 2024. Retrieved from: https://journals.plos.org/globalpublichealth/article/metrics?id=10.1371/journal.pgph.0003173#citedHeader.
146 KOLAWOLE, Omowamiwa; NCUBE, Caroline; DE BEER, Jeremy. Challenges implementing technology transfer as a viable pathway for equitable vaccine production and access: A case study of the mRNA vaccine hub in South Africa. **Global Public Health**, v. 20, n.1, May 2025. Retrieved from: https://www.tandfonline.com/doi/full/10.1080/17441692.2025.2504698.
147 Mulumba, M., Oga, J., Koomson, N. *et al.* Decolonizing global health: Africa's pursuit of pharmaceutical sovereignty. **BMC Health Serv Res**, v. 25, n 1015, 2025. Retrieved from: https://link.springer.com/article/10.1186/s12913-025-13211-9#citeas.
148 Mulumba, M., Oga, J., Koomson, N. *et al.* Decolonizing global health: Africa's pursuit of pharmaceutical sovereignty. **BMC Health Serv Res**, v. 25, n 1015, 2025. Retrieved from: https://link.springer.com/article/10.1186/s12913-025-13211-9#citeas.

In this context, it has become abundantly clear that we cannot rely on the goodwill of large corporations or the voluntary efforts of countries in the Global North to ensure equitable access to health technologies. Thus, the decision by Bio-Manguinhos/Fiocruz to patent its messenger RNA platform can be understood as a defensive measure to protect this public good and, ultimately, all the people who will benefit from the technology[149].

Application No. BR 10 2024 026208 5 was filed with the National Institute of Industrial Property (INPI) on December 13, 2024, in the name of Fiocruz, and is still under confidentiality (Appendix X). As mentioned in the interview:

> I think the strategy behind patenting is, first and foremost, to give us the freedom to use it. So that no one could take that knowledge and, I don't know, add a little something to it and patent it in a way that would later prevent us from using the very knowledge we generated. And the second thing is that the Brazilian government is making a financial investment in the project, and we are a public, non-profit institution, but it's obvious that if we can generate transfers with a minimal financial return for Brazil, that's important for Brazilian development as well—for the development of the innovation ecosystem. My dream is that we get to the products and those royalties come back to us to reinvest in the platform. Because when we talk about the RNA platform, we're not just talking about preventive vaccines. Quite the contrary, the trend is that we'll now start seeing other RNA-based products enter the market—replacement of heterologous proteins in rare diseases, CAR-T technology itself. About three weeks or a month ago, news broke about a gene therapy for that baby who was cured, which used RNA to express the CRISPR-Cas protein and make the genetic alteration in vivo. We're going to see a lot of convergence between advanced therapies and the RNA platform. So, having this knowledge in Brazil will allow us to make progress in many other areas—things that were previously unimaginable within the therapeutic field. (PN).

149 Baker, B. K.; Hassan, F. **Covid-19's silver lining? The WHO mRNA Technology Transfer Programme for the Global South Overcoming IP Barriers is central to the South-South Innovation and Access Goals of the WHO mRNA Technology Transfer Programme**. In: Health Justice Initiative. Pandemics and the illumination of "hidden things" – Lessons from South Africa on the global response to Covid-19. Edited Volume. Jun. 2023.

As mentioned earlier, a technology platform can be adapted for the development of products in different categories or therapeutic areas[150]. This is an innovation with significant implications for the discovery of new products and the improvement of existing ones[151]. One of the benefits of adopting this type of technology is that the experience and knowledge gained, the data generated (related to manufacturing, quality control, stability, and nonclinical studies), and the validation of methods that remain unchanged can be used as supporting data to accelerate the evaluation and development of a new vaccine or treatment candidate[152] (WHO, 2022).

Table 2 - Advantages of a messenger RNA platform

Speed	**The speed of product development accelerates the start of clinical trials, optimizing these stages. The first batches of Moderna's vaccine (mRNA-1273), for example, were delivered in just 42 days, whereas with traditional methods, lead times range from 18 months to two years.**
Versatility	**The platforms can be reused for different products and pathogens, eliminating the need for new toxicity studies, for example, and thus reducing time and costs.**
Faster production	**Compared to the traditional model, manufacturing based on messenger RNA platforms may require fewer steps, more compact and cheaper facilities, and yield higher output. Operating multifunctional plants can produce vaccines for different targets sequentially and quickly.**
Responsiveness	**It offers the ability to respond proactively to new pathogens, unlike purely reactive approaches.**

150 Baker, B. K.; Hassan, F. Covid-19's silver lining? The WHO mRNA Technology Transfer Programme for the Global South Overcoming IP Barriers is central to the South-South Innovation and Access Goals of the WHO mRNA Technology Transfer Programme. In: **Health Justice Initiative**. Pandemics and the illumination of "hidden things" – Lessons from South Africa on the global response to Covid-19. Edited Volume. Jun. 2023.

151 WHO - WORLD HEALTH ORGANIZATION. **Potential benefits and limitations of mRNA technology for vaccine research and development for infectious diseases and virus-induced cancers**: Report of the WHO Science Council. Geneva: World Health Organization, 2023. Retrieved from: https://www.who.int/publications/i/item/9789240084551.

152 WHO - WORLD HEALTH ORGANIZATION. **Evaluation of the quality, safety and efficacy of messenger RNA vaccines for the prevention of infectious diseases**: regulatory considerations. Technical Document, 07 Dec. 2021. Retrieved from: https://www.who.int/publications/m/item/evaluation-of-the-quality-safety-and-efficacy-of-messenger-rna-vaccines-for-the-prevention-of-infectious-diseases-regulatory-considerations.

Potential to overcome logistical and application barriers	**With investment, it is expected that vaccines could be thermostable, single-dose, or administered nasally, which significantly facilitates their use in areas with limited infrastructure.**

Source: Prepared by the author based on Schäferhoff et al. (2024) and an interview.

By ensuring control over the use and even the development of the technology itself, as well as adaptations and updates, patent protection also enables patent holders to profit economically from their innovations[153]. Currently, the intellectual property landscape for messenger RNA technologies is characterized by a network of thousands of patents filed around the world covering integrated platforms and technology-related components[154]. Various (sub)licensing agreements between different stakeholders (educational and research institutions, industry, and biotechnology startups) also contribute to a complex web of relationships that is difficult to unravel and to assess its impact on vaccine production[155] (GAVIRIA; KILIC, 2021).

The mRNA TT Programme, for example, monitors[156] patents related to mRNA vaccine technologies, focusing on: delivery systems and formulations; modifications to the mRNA (nucleotide, encapsulation, etc.) to improve expression; and mRNA vaccines for various diseases, including HIV, respiratory syncytial virus (RSV), influenza, HPV, and tuberculosis, in addition to COVID-19. The latest update to the database, which took place on October 14, 2025, compiles data from 2,656 patents published through the end of June. As in other similar references, ModernaTX, CureVac, and BioNTech are among the leading applicants[157].

There is a growing effort to analyze patent data using a wide variety of sources and methods. According to Li et al.[158] , Starting in 2021, there has been an exponential increase in patents, establishing mRNA platforms as a foundational infrastructure for new therapies in the form of vaccines or other treatments.

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153 SCHILLING, Melissa A. **Strategic Management of Techonological Innovation**. 6 ed. McGraw-Hill: Nova Iorque, 2020.

154 Baker, B. K.; Hassan, F. Covid-19's silver lining? The WHO mRNA Technology Transfer Programme for the Global South Overcoming IP Barriers is central to the South-South Innovation and Access Goals of the WHO mRNA Technology Transfer Programme. In: **Health Justice Initiative**. Pandemics and the illumination of "hidden things" – Lessons from South Africa on the global response to Covid-19. Edited Volume. Jun. 2023.

155 GAVIRIA, Mario; KILIC, Burcu. A network analysis of COVID-19 mRNA vaccine patents. **Nature Biotechnology**, v. 39, p. 546-549, May 2021. Retrieved from: https://www.nature.com/articles/s41587-021-00912-9#citeas.

156 IP monitoring in the mRNA Technology Transfer Programme.

157 MPP - Medicines Patent Pool. **MedsPaL and other patent status information tools**. Update on initiatives on publicly accessible databases of patent status information concerning medicines and vaccines. WIPO 37th SCP, Geneva, 04 Nov. 2025. Retrieved from: https://www.wipo.int/edocs/mdocs/scp/en/scp_37/scp_37_c4_health.pdf.

158 OH, Kyungdae; CHOI, YOUNGBO; HONG, Surin. Patent landscape and innovation trajectories of mRNA vaccine technologies. **World Patent Information**, v. 82, Sep. 2025. Retrieved from: https://www.sciencedirect.com/science/article/pii/S0172219025000493#tbl3.

Patents related to lipid nanoparticles (LNPs) are particularly prevalent. As for the origin of these filings, most patent families come from North America, Europe, and East Asia.

When looking at the evolution of mRNA vaccine patents over the past 25 years, Oh, Choi, and Hong[159] highlight the maturation of the technology and the contrasts between the R&D strategies of the leading institutions active in the sector. In addition to pharmaceutical companies, universities and public institutions have also filed patents. According to the authors, ModernaTX and Translate Bio tend to primarily protect vertically integrated platforms. CureVac, on the other hand, emphasizes antigen design and RNA stability, while the Massachusetts Institute of Technology (MIT) focuses primarily on mRNA delivery systems. These different innovation strategies help explain the rapid and diverse evolution of this technology.

With regard to existing patents, the researchers at Bio-Manguinhos took care to seek alternatives so as not to infringe on the rights of third parties or rely on future authorizations to explore the invention.

> When developing our product, we adopted a strategy of circumventing existing patents to avoid legal issues. This ultimately allowed us to patent our own platform because we circumvented the lipid, the sequence, and the use of regulatory elements... And so we ended up doing something different that enabled us to file our own patent. But it was a strategy to move away from what had already been filed (PN).

Patenting the platform is also a way to preserve decision-making autonomy and strengthen negotiating power in the interest of public health:

> The fact that we develop this knowledge in-house also gives us bargaining power. (...) We can operate as a public entity—even when filing patents—so that this serves to promote equity and ensure fair distribution (PN).

A very current concept that has emerged in this debate is that of sovereignty, the application of which in the field of health involves different meanings. For example, Kameda, Pimenta, and Matta[160] use the term “pharmaceutical sovereignty,” asserting that

159 OH, Kyungdae; CHOI, Youngbo; HONG, Surin. Patent landscape and innovation trajectories of mRNA vaccine Technologies. **World Patent Information**, v. 82, Sep. 2025. Retrieved from: https://www.sciencedirect.com/science/article/pii/S0172219025000493.

160 KAMEDA, Koichi; PIMENTA, Denise; MATTA, Gustavo. Affirming pharmaceutical sovereignty: Technology transfer agreements and vaccine geopolitics during a global health emergency. IN: QUET, Mathieu; KAMEDA, Koichi; POURRAZ, Jessica; RAULT-CHODANKAR, Yves-Marie. **Technoscientific Globalisation from Below**. Mattering Press, 2025. Retrieved from: https://shs.hal.science/halshs-05372744.

it encompasses both the state's ability to implement national health policies aimed at promoting access to essential technologies and the existence of domestic technological and industrial capacity to meet local health needs[161].

To Guimarães[162], In the context of public health, sovereignty is enshrined in Article 196 et seq. of the Federal Constitution as a right of all and a duty of the State, without any gradation.

> However, in the specific context of the Health Industrial Complex (CIS), the situation is different: the challenges it currently faces relate more to the concept of self-sufficiency than to sovereignty. More specifically, they concern reducing external dependence in this area[163].

During the interview, the link between patents and sovereignty also came up. Although it is not a sufficient condition for addressing the problem of external dependence, the strategic use of intellectual property rights can be part of the formula that gives Brazil leverage in critical negotiations, for example.

> I think patents are closely tied to the issue of sovereignty. It's great that the world has them. But we have them too. It's great that the United States has them. But Brazil has them too. So, you're not going to tell me what I can and can't use. Because if the mechanism for asserting sovereignty is the patent, then naturally it should be the patent itself. (...) [And] since we created it, we have that sovereignty, we're in a position to share it—why not receive something to reinvest? Not to make a profit and become millionaires. But to reinvest in the system; after all, we need money to buy supplies for the SUS itself. (RL)

Note that this perspective has a structural limitation typical of the global health innovation system, as discussed by Dutt, Mazzucato, and Torreele [164]. The logic of private value capture—in which R&D priorities are determined by market opportunities rather than health needs—still drives this system. As a result, circumventing existing patents and securing one's own patents protects operational freedom, but does not resolve all the challenges involved in achieving self-sufficiency in production. In this same vein, the People's Health Movement[165]

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161 "One key concept is pharmaceutical sovereignty, which involves the state's ability to implement national health policies with regards to promoting access to essential health technologies, from medicines to vaccines and diagnostics. Pharmaceutical sovereignty also comprises the existence of domestic technological and industrial capacity to address local health needs. (KAMEDA; PIMENTA; MATTA, 2025, p. 143)

162 GUIMARÃES, Reinaldo. sobre a Soberania Sanitária no Complexo Industrial da Saúde. **Ciência & Saúde Coletiva**, v. 28, n. 11, Nov. 2023. Retrieved from: https://www.scielo.br/j/csc/a/LjGrN4HvNrmgz3zzXYLtQmS/?format=html&lang=pt.

163 GUIMARÃES, Reinaldo. sobre a Soberania Sanitária no Complexo Industrial da Saúde. **Ciência & Saúde Coletiva**, v. 28, n. 11, Nov. 2023. Retrieved from: https://www.scielo.br/j/csc/a/LjGrN4HvNrmgz3zzXYLtQmS/?format=html&lang=pt. p.3094.

164 DUTT, Devika; MAZZUCATO, Mariana; TORREELE, Els. An mRNA technology transfer programme and economic sustainability in health care. **Bulletin of the World Health Organization**, n. 102, Mar. 2024, p. 344-351. Retrieved from: https://pmc.ncbi.nlm.nih.gov/articles/PMC11046156/.

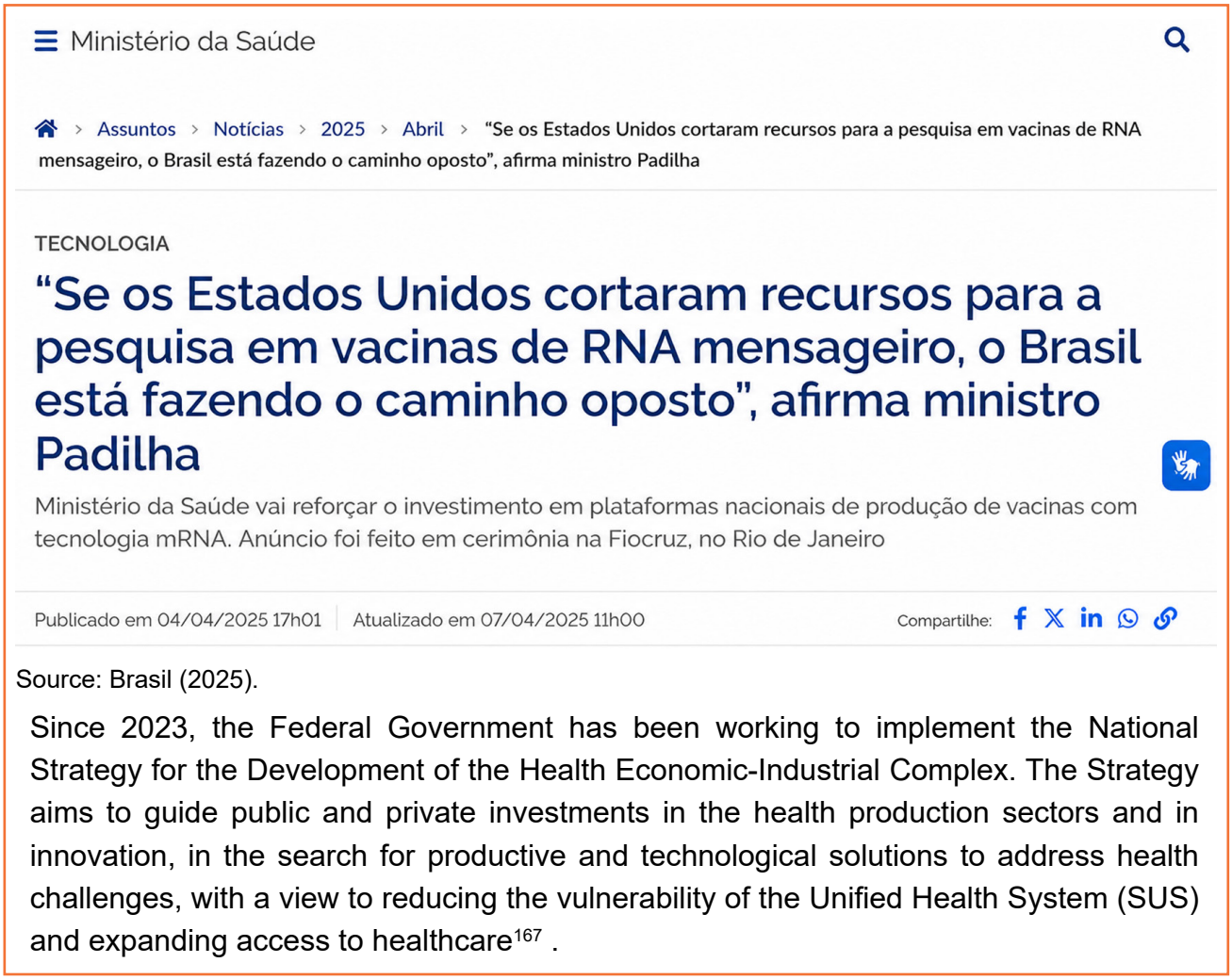
165

He expands on this critique by arguing that true health sovereignty requires going beyond simply correcting “market failures” to ensure legal ownership. This tension becomes more evident in the recent geopolitical context.

Segundo Cipollone[166]:

> Technological sovereignty in the field of health is a critical issue for the Global South, and Brazil finds itself at the center of this struggle. Although it has a well-established universal healthcare system and centers of excellence in science and technology, the country remains dependent on imports of strategic supplies, particularly immunobiologicals and vaccines.

Text Box 5 - The Return of CEIS to the Forefront



Source: Brasil (2025).

Since 2023, the Federal Government has been working to implement the National Strategy for the Development of the Health Economic-Industrial Complex. The Strategy aims to guide public and private investments in the health production sectors and in innovation, in the search for productive and technological solutions to address health challenges, with a view to reducing the vulnerability of the Unified Health System (SUS) and expanding access to healthcare[167] .

166 CIPOLLONE, Giulia Amadio. **Governança Global em Saúde e Colonialidade:** Vacinas e Soberania Sanitária no Sul Global. Dissertação (Mestrado) – Pontifícia Universidade Católica de São Paulo. Mestrado em Governança Global e Formulação de Políticas Internacionais. São Paulo: 2025. Retrieved from: https://sapientia.pucsp.br/bitstream/handle/46531/1/Giulia%20Amadio%20Cipollone.pdf.

167 BRASIL. **Decreto nº 11.715, de 26 de setembro de 2023**. Institui a Estratégia Nacional para o Desenvolvimento do Complexo Econômico-Industrial da Saúde. Brasília, DF: Presidência da República, 2023.
Retrieved from: https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2023/decreto/d11715.htm.

Six key programs[168] are intended to increase access to healthcare, expand domestic production of priority items for the SUS, and reduce Brazil's dependence in the healthcare sector. The development of Bio-Manguinhos' messenger RNA platform was awarded funding under the new policy[169].

In 2025, Brazil faced trade retaliation from the United States, including the deliberate imposition of tariffs on various Brazilian products and its inclusion on the Special 301 Watch List as a country with shortcomings in intellectual property protection. Civil society organizations presented proposals on how the country could respond to U.S. "external shocks," combining active industrial policy instruments, flexibilities provided for in intellectual property legislation, and a prioritization of South-South relations[170].

In light of this, the strategic use of the intellectual property regime by institutions in the Global South takes on a different meaning than that observed in the North, insofar as it serves as one of the tools capable of preserving a minimum degree of health sovereignty. Metaphorically, a patent would function as an umbrella that, by sheltering the holder, protects them against external restrictions on their own creations and guarantees them autonomy to decide on the exploitation of the technology. In the Brazilian case, this use is primarily oriented toward meeting local health demands, in accordance with the principles and values of the SUS.

One concrete result of this move to patent the platform was the opportunity to secure funding, such as the grant proposed by the Gates Foundation for the development and transfer of knowledge packages related to messenger RNA technology to institutions in Senegal, South Africa, and Indonesia, as reported in the interview. This stands in contrast to the traditional approach, which ultimately privatizes prior public investment in R&D[171], Patent ownership by an institution such as Bio-Manguinhos/Fiocruz serves as a prerequisite for accessing international funding streams that enable knowledge sharing and the operation of partners who would otherwise struggle to access technologies controlled by Big Pharma.

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168 Programa de Parceria para o Desenvolvimento Produtivo (PDP); Programa de Desenvolvimento e Inovação Local (PDIL); Programa para Preparação em Vacinas, Soros e Hemoderivados (PPVACSH); Programa para Populações e Doenças Negligenciadas (PPDN); Programa de Modernização e Inovação na Assistência (PMIA); e Programa para Ampliação e Modernização da Infraestrutura do CEIS (PDCEIS).

169 BRITO, Gabriel. Indústria da saúde leva soberania à realidade? **Outra Saúde**, 22 Sep. 2025. Retrieved from: https://outraspalavras.net/outrasaude/industria-da-saude-tira-soberania-do-discurso-para-realidade/. Retrieved from: https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2023/decreto/d11715.htm.

170 LEITÃO, Carmem; PINHEIRO, Eloan. Soberania farmacêutica: virada necessária no SUS. **Outra Saúde**, 27 Aug. 2025. Retrieved from: https://outraspalavras.net/outrasaude/soberania-farmaceutica-virada-necessaria-no-sus/.

171 MSP - Movimento pela Saúde dos Povos. **Farmacêuticas Públicas:** o que são e por que são importantes? Oct. 2024. Retrieved from: https://phmovement.org/sites/default/files/2025-02/PT%20BR%20-%20Public%20Pharma%20Policy%20Brief.pdf.

Kameda, Pimenta, and Matta[172] explain that "while technology transfer instruments can contribute to the implementation of national vaccination plans, their provisions may allow for greater or lesser flexibility, and their negotiation has decisive implications for long-term pharmaceutical sovereignty in the Global South"[173]. This is a crucial aspect of this dynamic: even when the rhetoric emphasizes solidarity, in practice there are significant constraints on the full development of research and production capabilities, especially when technology remains subject to patents and trade secrets held by large corporations.

In fact, depending on the target disease, history shows that pharmaceutical companies do not—and will not—make an effort to meet patients' needs. It is therefore up to Bio-Manguinhos and its partners in the South to respond to these demands.

> And it is also part of our role to address these diseases that large pharmaceutical companies overlook. In fact, the story of Professor Chetan—who is involved with us in the Dakar initiative—as well as the Pasteur Institute of Tunisia, which is also interested in developing a leishmaniasis initiative with us, is that they placed their antigens on Moderna's platform. Moderna claims that its platform is open and that researchers can test it however they wish. Both groups used the platform and achieved successful results in their studies. However, Moderna was not interested in moving forward. They basically said, 'That's great, great, excellent results, but we are not interested in continuing the development.'" (PN)

This statement clearly illustrates the contradiction and the limitations imposed by the commercial interests of pharmaceutical companies. It also underscores the need for public institutions in the Global South to build their own innovation capabilities.

In addition to leishmaniasis and COVID-19, for which research is more advanced, other diseases were mentioned as subjects of research, with national and international partners, within the scope of the messenger RNA platform. Some of the targets cited are: Oropouche fever, tuberculosis, African swine fever, and malaria. This demonstrates that the platform is not only useful for international emergency situations but can also inform the development of industrial and health policies to address local needs. The vast research network forming around the platform involves collaborators working in Brazil—in the states of Rio de Janeiro, Minas Gerais, and Mato Grosso, for example—as well as in South Africa, Cuba, Ghana, Indonesia, Panama, Kenya, and Senegal, among others.

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172 KAMEDA, Koichi; PIMENTA, Denise; MATTA, Gustavo. Affirming pharmaceutical sovereignty: Technology transfer agreements and vaccine geopolitics during a global health emergency. IN: QUET, Mathieu; KAMEDA, Koichi; POURRAZ, Jessica; RAULT-CHODANKAR, Yves-Marie. **Technoscientific Globalisation from Below**. Mattering Press, 2025. Retrieved from: https://shs.hal.science/halshs-05372744. p.158.

173 "In this sense, whereas technology transfer instruments may contribute to the implementation of national vaccination plans, their clauses might establish more or less freedom, and their negotiation has decisive implications for long-term pharmaceutical sovereignty in the South." (KAMEDA; PIMENTA; MATTA, 2025, p. 158)

These connections have strong potential to consolidate a more equitable ecosystem for the Global South, focused on the equitable production and circulation of health knowledge and technologies.

Impact of the innovation movement: contributions to the market, costs, and future prospects

According to the WHO, experts have high hopes for messenger RNA platforms. In addition to enabling the development of new vaccines and therapies for various diseases, the technology's inherent versatility could also lead to related innovations, such as improvements in vaccine shelf life, production costs, and the raw materials used in manufacturing[174]. The Bio-Manguinhos project has already made significant contributions to helping other stakeholders enhance their innovative and production capabilities.

> For example, we adopted Quantoom's technology to produce the RNA. It is a small Belgian company—not a major pharmaceutical firm—but a process development technology company. They received funding from the Bill & Melinda Gates Foundation to develop equipment that would be affordable not only financially but also in terms of infrastructure for low- and middle-income countries. It's equipment with a lot of embedded technology—it has robotic arms and such—but it doesn't require any utilities to be installed. It's a self-contained unit, so it can operate in a less stringent manufacturing classification area because, effectively, it achieves a higher classification level internally. And it just needs to be plugged in. We were the first to adopt this technology, and they still talk about that today. We had a visit from the Princess of Belgium here, and they gave their presentation. And the company's CEO himself—we ended up having a great relationship, obviously, because we were the first to believe in his technology—he said, "You were the first to visit us in Belgium and believe that we could develop viable technology; it took you half an hour to tell us: 'we trust you, and we don't have a Plan B, so please make it work...'." (PN)

This episode underscores the importance of Bio-Manguinhos's internal capabilities, particularly the qualifications and experience of the professionals working at the institution. The decision to invest in a technology that had not yet been fully validated reflects the understanding that risk is an inherent part of innovative processes. It also demonstrates how public institutions can play strategic roles in building technological autonomy through decisions that involve risk.

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174 WHO - WORLD HEALTH ORGANIZATION. **Potential benefits and limitations of mRNA technology for vaccine research and development for infectious diseases and virus-induced cancers**: Report of the WHO Science Council. Geneva: World Health Organization, 2023. Retrieved from: https://www.who.int/publications/i/item/9789240084551.

More on evolution and collaborative learning:

> Back in the beginning, we didn't even have that many suppliers. Many suppliers learned from us. We learned from them, and they learned from us. (...) We were also among the first to adopt nanoencapsulation equipment. And they started asking, 'Wait, does this cassette actually work or not?' 'Let's see…' We were the ones who tested it to find out, and we became the showcase: 'Oh, Fiocruz is using it…' Today we already have quite a few suppliers involved; the big ones, the major players, already have plenty of products. But in the beginning, many suppliers sat down with us to understand what we were doing so they could start thinking about the products or what to bring. There were some products available, but the local representatives sat down with us to try to understand what they needed to import for the domestic companies. (...) We also helped, in a way, to train the technical representatives. (AP)

Another consequence of the development of the messenger RNA platform relates to regulation. As mentioned earlier, the adoption of platforms such as messenger RNA has the potential to accelerate responses to health emergencies and the identification of treatments. However, the lack of a global definition and standardized procedures can be a significant barrier to realizing this potential[175]. When asked about the regulatory aspects of the RNA platform, specifically its relationship with Anvisa, the team emphasized that communication is good and that "there are no obstacles" (AP).

Leaders from the research team and a representative from Bio-Manguinhos' Quality Department are directly participating in the Coalition for Epidemic Preparedness Innovations (CEPI) working group focused on preparing regulatory documents for emergency situations. Together with members from other public and private institutions in various countries, documentation templates were developed to support the work of regulatory agencies, and Anvisa also received the final draft. In addition to discussing specifics of the COVID-19 vaccine—which is currently the most advanced product—the team has also been working with Anvisa to improve processes to avoid rework with each new product developed.

175 LI, Xiaojing *et al.* Platform Technology in Global Vaccine Regulation: Development, Applications, and Regulatory Strategies with Insights from China. **Vaccines**, v. 12, n. 12, Dec. 2024. Retrieved from: https://www.mdpi.com/2076-393X/12/12/1436.

With regard to the investments made in the project, inquiries submitted via the LAI sought to obtain the figures from the institution. However, the responses received were inconclusive. The first response (Appendix 1 A) merely listed the sources of funding by name, including international organizations and the Ministry of Health, as well as the private sector, whose contact is facilitated by Fiocruz's Fundraising Office. According to the institution, the figures could not be disclosed because they are protected by industrial/commercial confidentiality.

In another attempt to obtain the information, the institution provided a more detailed explanation as to why it would not disclose the exact amount invested at the current stage of the project, but assured that an accounting of the funds would be provided in due course (Appendix 1 B). According to Bio-Manguinhos/Fiocruz, due to the nature and specific characteristics of the research, which "(...) involves both the development of a product and the establishment of a platform (...)", it is difficult to identify expenses separately, and disclosure in this regard could lead to misinterpretations. Furthermore, to protect competitiveness and institutional negotiating capacity, complete information will remain restricted for the time being, with only the statement of direct investment from the Ministry of Health being disclosed[176].

Figure 3 - Direct investment (LOA) by the Ministry of Health in the Covid-RNA project

FONTE	2023 RECEBIDO	2024 RECEBIDO	2025 RECEBIDO	TOTAL RECEBIDO
LOA	R$ 13.770.287,59	R$ 6.153.500,00	R$ 42.446.000,00	R$ 62.369.787,59

Source: Bio-Manguinhos/Fiocruz (2025).

Listed below are the figures obtained from searches on the official websites of the organizations cited by Bio-Manguinhos/Fiocruz in its initial response via the LAI. It should be noted, however, that this information should be read and interpreted with caution, since, as the institution itself has explained, it is not possible to distinguish or determine exactly what the funds were actually allocated for. Without an official response, any inference on the matter is fragile. In any case, it remains clear that the largest portion of the funds allocated to the project comes from public sources and that external funding sources are supplementary.

176 Bio-Manguinhos/Fiocruz - Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos/Fiocruz. Ministério da Saúde. **Resposta ao pedido de acesso à informação via Sistema Eletrônico de Informação ao Cidadão – e-SIC, integrado à Plataforma Fala.BR da CGU, protocolo 25072050437202538**. Rio de Janeiro, 07 Nov. 2025.

Table 3 - Investments in the Covid-RNA project (unofficial)

Institution	Amount	Source
Brazilian Development Bank (BNDES)	R$30 million	Brazil is developing a COVID-19 vaccine using messenger RNA technology Contract Document 23.2.0344.1
Coalition for Epidemic Preparedness Innovations (CEPI)	$17.9 million (approx. R$92 million)	Mobilising Brazil's manufacturing might to support vaccine production in the Global South | CEPI
Gates Foundation	US$1.208.626	Gates Foundation Committed Grants Database[177]
Novo PAC Saúde	R$77.393.775,87	Healthcare Industrial Complex — Office of the Chief of Staff

Source: Prepared by the author based on the information consulted.

With regard to the project's medium- to long-term plans, the expectation is to eventually reach a point, as the literature indicates[178], in advanced therapies. In addition to the targets already mentioned—particularly infectious and neglected diseases—the idea is to focus efforts on cancer treatment, immunotherapies, and perhaps rare diseases. "We're now focusing a bit more on this aspect of immunotherapies, which is a front that demands a bit more, and in the case of nanoparticles, we need to attach targeting agents to specific targets, so there are other technical issues we've been working on." (AP)

Some plans, however, require careful consideration of the institution's own logistics, as a public laboratory focused on producing large batches of products.

According to the researchers, there are ways to make certain therapies—even personalized ones—feasible, and this is expected to be the future of messenger RNA technology. However, "we still have a long way to go." (AP).

177 "To provide African institutions access to advanced RNA technologies and data, enabling them to independently develop RNA vaccines and research capacity."

178 VAN RIEL, D.; DE WIT, E. Next-generation vaccine platforms for COVID-19. **Nat. Mater.**, v. 19, p. 810-812, 2020. Retrieved from: https://www.nature.com/articles/s41563-020-0746-0.

05

OVERCOMING OLD CHALLENGES TO REACH NEW HORIZONS

When looking to the future, we cannot ignore the present, much less forget the past. Moving forward with Bio-Manguinhos' messenger RNA platform project requires overcoming long-standing obstacles: the issue of in-house production and self-sufficiency at the IFAs, and the vulnerability of the SUS budget. During the interview, when discussing the challenges faced by the project, the responses inevitably touched on these points.

Regarding funding, the unequivocal statement was that "(...) this is the biggest bottleneck at the moment" (AP), highlighting the long-standing vulnerability faced by the country's public institutions. "Funding is always a challenge because of these inconsistencies. We, as public institutions, face this vulnerability: depending on who is in government, we receive more or less support" (PN).

Although the pharmaceutical industry and CEIS were identified as priorities in the industrial policies launched in the early 2000s, beginning in 2016–2017, a process of dismantling the instruments created by those policies significantly undermined the sector's performance[179]. The situation was exacerbated by the passage of Constitutional Amendment No. 95/2016, which imposed a spending cap on the federal government and led to a "free fall" in health care revenues in the following years[180,181]. This amendment, the constitutionality of which was challenged in the Federal Supreme Court[182], was partially repealed and replaced by a new fiscal framework, which, according to experts, still limits the expansion of funding for the SUS and leaves it vulnerable to economic instability[183].

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179 PARANHOS, J. *et al.* As prioridades de saúde e a articulação com as políticas de indústria e CT&I no Brasil entre 2003 e 2017. **Novos Estudos CEBRAP**, São Paulo, v. 41, n. 2, p. 315-332, May-Aug. 2022. Retrieved from: https://novosestudos.com.br/wp-content/uploads/2022/09/07_artigo_paranhos_123_p314-333.pdf.
180 CNS - CONSELHO NACIONAL DE SAÚDE. **Saúde perdeu R$ 20 bilhões em 2019 por causa da EC 95/2016**. 28 Feb. 2020. Retrieved from: https://www.gov.br/conselho-nacional-de-saude/pt-br/assuntos/noticias/2020/fevereiro/saude-perdeu-r-20-bilhoes-em-2019-por-causa-da-ec-95-2016.
181 Ocké-Reis, C. Não basta o SUS ser eficiente economicamente; precisa atender as necessidades da população. **CEE**, 07 fev. 2023. Retrieved from: https://cee.fiocruz.br/?q=Ocke-reis-Nao-basta-o-SUS-ser-eficiente-economicamente-precisa-atender-as-necessidades-da-populacao.
182 SANTOS, L.; FUNCIA, F. Emenda Constitucional 95 fere o núcleo do direito à saúde. **CEE - Centro de Estudos Estratégicos da Fiocruz Antonio Ivo de Carvalho**, 24 Jan. 2019. Retrieved from: https://cee.fiocruz.br/?q=Emenda-Constitucional-95-fere-o-nucleo-essencial-do-direito-a-saude.
183 OBSERVATÓRIO DO SUS. Novo arcabouço fiscal sob a perspectiva de especialistas. **Observatório do SUS - Notícias**, 29 Jul. 2024. Retrieved from: https://observatoriodosus.ensp.fiocruz.br/noticias/novo-arcabouco-fiscal-sob-a-perspectiva-de-especialistas/.

Since 2023, with the announcement of the resumption of policies to strengthen the CEIS through the National Strategy for the Development of the Health Economic-Industrial Complex, the Federal Government has sought to reduce the country's vulnerability by ensuring that the SUS produces pharmaceutical inputs, medicines, vaccines, medical devices, and other health technologies in a sustainable manner. The adoption of various policy instruments and the announcement of direct and indirect investments in health projects aim to position the CEIS as a key driver of national development[184].

Budgetary instability, however, significantly undermines the institution's performance and the implementation of its plans. Fiocruz's 2024 Management Report shows that, just as in 2023—when actual investments were 44% lower than in 2022—execution in 2024 also fell significantly, to 37% below the previous year's level. Most of the funds were allocated to maintaining current activities, such as paying for services, supplies, and contracts, at the expense of expanding production capacity, modernizing infrastructure, and acquiring equipment—all of which require capital investments. In addition to internal decisions, this occurred as a result of two external factors: first, the resource constraints imposed by Decree No. 12,120/2024; second, the return of part of the funds originally allocated under the New PAC, redirected by the Ministry of Health for direct execution in other projects considered a priority[185].

Innovative initiatives such as the mRNA platform depend, among other things, on resources to invest promptly in opportunities that arise within the institutions. A key challenge facing innovation at Bio-Manguinhos relates to what the interviewees referred to as the "funding-time balance":

> So, I think another challenge we face is this balance between funding and time, and that ties in a bit with risk management—we have to weigh whether to take the risk to move faster. (...) Because if we move too slowly, we'll miss the boat and people will lose interest. We've seen that happen with several products here at Bio-Manguinhos. I've been at Bio-Manguinhos for 19 years, so we saw the meningitis vaccine that took a long time, and then when it was ready, ours was the meningitis C vaccine, and the government already wanted the CWY, so it was over, it died. Meningitis B was the same thing—I don't know what happened there, it didn't match the strain here, blah blah blah, it died. The pegylated interferon, which was also a collaboration of ours with Cuba, blah blah blah—when it arrived, protease inhibitors came along and it died. (PN)

184 NASCIMENTO, T. Ministro da Saúde anuncia fortalecimento de parcerias para produção nacional de vacinas com RNA mensageiro. **Ministério da Saúde**, 30 May 2025. Retrieved from: https://www.gov.br/saude/pt-br/assuntos/noticias/2025/maio/ministro-da-saude-anuncia-fortalecimento-de-parcerias-para-producao-nacional-de-vacinas-com-rna-mensageiro.
185 Fiocruz - Fundação Oswaldo Cruz. Ministério da Saúde. **Relatório de Gestão 2024**. Retrieved from: https://fiocruz.br/sites/fiocruz.br/files/documentos_2/relatorio_de_gestao_fiocruz_2024_vf.pdf

This reinforces external dependence and undermines health sovereignty, insofar as it limits the institutional capacity for continuous innovation, making successful initiatives even more exceptional than the uncertain and risky nature of innovation itself would suggest. In this scenario, the losses are not only technological, but also economic and social. As Hasenclever et al. point out[186]:

> Public investment in research and development and in sectors that enable the faster diffusion of cutting-edge technologies drives productivity growth, creates higher-paying jobs, and has greater multiplier effects than other forms of government spending.

Another chronic problem mentioned in the interview concerns supplies. According to Vasconcelos *et al*.[187], "While approximately 80% of the medicines consumed in Brazil are produced domestically, less than 5% of active pharmaceutical ingredients (APIs) are supplied by domestic pharmaceutical companies, which highlights the fragility of the local pharmaceutical industry." Guimarães[188] explains that,

> In the 1980s, we imported about 50% (other estimates put the figure at 20%). The change was due to the trade liberalization that took place in the 1990s. This liberalization led to the closure of many IFAS production facilities in the country, which were unable to compete with Indian and Chinese manufacturers, supported by stricter industrial policies aimed at stimulating local production.

In 2020, the chemical and biotechnology subsector played a central role in the CEIS complex's deficit, and the degree of dependence on more sophisticated inputs approached 90% of domestic demand for certain items[189]. This high dependence on imported active pharmaceutical ingredients (APIs) is a structural weakness that undermines pharmaceutical production and the ability to respond quickly to health emergencies, such as COVID-19.

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186 HASENCLEVER, Lia *et al.* Política industrial e tecnológica para o setor de saúde: o instrumento de parcerias para o desenvolvimento produtivo e os desafios de sua operação. In: KON, A.; BORELLI, E. (org.). **Quatro faces da economia brasileira**: uma abordagem crítica [livro eletrônico]. São Paulo: Blucher, 2017. 256 p.

187 VASCONCELOS, Daniela M. M. de *et al.* **Panorama da produção local de medicamentos no Brasil:** desafios e vulnerabilidades. Brasília: Fundação Oswaldo Cruz; Organização Pan-Americana da Saúde/Organização Mundial da Saúde, 2023. Retrieved from: https://naf.ensp.fiocruz.br/sites/default/files/panorama_da_producao_local_de_medicamentos_no_brasil_desafios_e_vulnerabilidades.pdf.

188 GUIMARÃES, Reinaldo. sobre a Soberania Sanitária no Complexo Industrial da Saúde. **Ciência & Saúde Coletiva**, v. 28, n. 11, Nov. 2023. Retrieved from: https://www.scielo.br/j/csc/a/LjGrN4HvNrmgz3zzXYLtQmS/?format=html&lang=pt. p.3095.

189 GADELHA, C. A. G. Complexo Econômico-Industrial da Saúde: a base econômica e material do Sistema Único de Saúde. **Cadernos De Saúde Pública**, v. 38, sup.2, 2022. Retrieved from: https://www.scielo.br/j/csp/a/v5ytyHYJjj3tpZn9DYFLzWv/?lang=pt.

The geographic concentration of raw material production also affects innovation capacity. The messenger RNA project at Bio-Manguinhos itself experienced this situation. Regarding this, one of the interviewees reports: “(...) sometimes we even have the budget, we’re ready to start, but the raw materials don’t arrive. We don’t have local suppliers in the supply chain.” (AP)

Given the above, planning for the future of health technology research and production—including the messenger RNA platform at Bio-Manguinhos—requires addressing the structural problems of the local industry with a view to achieving, above all, health sovereignty. The consolidation of a robust national capacity for the production of critical inputs and innovative health technologies thus requires a coordinated set of recommendations involving the government, the productive sector, educational, scientific, and technological institutions, and civil society. A systemic strategy is therefore needed that aligns industrial policy, health policy, stable funding, and innovation management with a focus on health sovereignty. Thus, it is essential to: guarantee continuous, long-term public funding for R&D activities; ensure that industrial and technological policy is consistent with the needs of the population; invest in integrated innovation ecosystems, fostering connections between teaching, basic and applied research, and domestically owned industry; promote fair regulatory harmonization, without compromising the safety and efficacy of products and enabling the rapid provision of health technologies demanded by the population; prioritize access to knowledge and promote decentralized pharmaceutical and pharmaceutical-chemical production; stimulate the development of innovative projects at the forefront of knowledge, such as the messenger RNA platform; defend and preserve, now and always, the right to health and to a free and universal public system.

06
CONCLUSION

The development trajectory of the messenger RNA platform at Bio-Manguinhos/Fiocruz represents a fundamental milestone in the reshaping of health policies in the Global South, demonstrating that it is possible to innovate based on a public infrastructure guided by the population's health priorities. This complex process is grounded primarily in the treatment of health as a public good rather than a commodity.

As discussed in this study, the capacity to develop, adapt, and produce health technologies constitutes a strategic attribute directly related to countries' health sovereignty and autonomy. The historical concentration of these capabilities among a few private actors in Big Pharma, located mainly in the Global North, has reinforced historical asymmetries, limiting the possibility of autonomously defining health priorities and subordinating local epidemiological needs to global market opportunities. The Bio-Manguinhos experience thus emerges as a counterpoint to traditional models of innovation and technology transfer.

From the perspective of Public Pharmaceutical Companies, the Brazilian experience exemplifies the integration of research, development, and production within a state entity whose priority is meeting local public health needs. This case suggests that true technological autonomy lies not merely in the possession of equipment or transferred know-how, but in the construction of a public innovation ecosystem that prioritizes equity and internal and external cooperation over market logic.

However, the consolidation of this model faces structural challenges that cannot be ignored. The budgetary vulnerability of the SUS, the reliance on imported medical devices, and the lack of continuity in industrial policies pose real risks to the sustainability of state-led innovation in health care. The "funding-time balance" reported by the research team highlights that, without continuous, long-term public funding, the capacity to innovate is compromised and opportunities to respond to emergencies may be lost. Dependence on strategic inputs, especially in the chemical and biotechnology sectors, remains a bottleneck that limits the full realization of health sovereignty. Therefore, the completion of this case study should also serve as a warning regarding the need for a systemic strategy that aligns industrial policy, health policy, stable funding, and innovation management.

In short, Bio-Manguinhos' messenger RNA platform proves that it is possible to develop health technologies guided by the public interest, combining technical innovation with ethical principles that prioritize collective needs.

The project demonstrates that public production and development constitute a concrete path toward guaranteeing the right to health and overcoming the systemic inequities produced by the traditional logic operated by Big Pharma. For this model to remain active, it is essential that the Brazilian government and civil society maintain pressure for policies that guarantee funding, domestic production of inputs, protection of the decision-making autonomy of public institutions, and the strengthening of South-South cooperation networks. Only in this way will it be possible to transform the promise of health sovereignty into a tangible reality, where health ceases to be a commodity and becomes, in fact, a universal right guaranteed by the productive and innovative capacity of the people themselves. The case of the Bio Manguinhos platform is merely the beginning of a broader movement toward a more just, equitable, and sovereign global health system.

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