

# A BRAZILIAN OUTLOOK ON HEALTH AND MEDICAL INNOVATION

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This chapter looks at the challenges and opportunities for Brazil in the health sector—one of the most thriving sectors in the world. First, we consider global health trends in innovation and how Brazil is performing. Second, we outline the role of the National Confederation of Industry–Brazil (CNI), Social Service of Industry (SESI), National Service for Industrial Training (SENAI), Euvaldo Lodi Institute (IEL), and the Brazilian Micro and Small Business Support Service (SEBRAE) in shaping the future of health innovation in the country. Finally, we present recommendations for the Brazilian government to build a more innovative ecosystem in the country.

## Global health trends and the Brazilian outlook

### Global health trends

One of the main factors driving health innovations worldwide is an aging population. This has led to increased research into diseases that most commonly affect the elderly, such as neurodegenerative diseases like Parkinson's and Alzheimer's. Another effect of population aging is the increase in health costs. Health spending as a share of global GDP has steadily grown in recent years, from 8.6% to almost 10% between 2000 and 2015; in higher income economies it reaches up to 17% of GDP.<sup>1</sup>

However, the growing availability of health data may help mitigate rising health costs and increase the potential for using information and communication technologies (ICT), which can revolutionize health services.<sup>2</sup> The application of ICT to healthcare ranges from telemedicine to the use of artificial

intelligence (AI) as an auxiliary tool in diagnosing diseases and the development of medicines through the management of health systems. Several ICT-based technologies are among recent significant innovations in health.<sup>3</sup> Among them are telemedicine, artificial intelligence, the increased use of monitoring devices, virtual reality, and the use of social networks to improve health services. Specialists also mention immunotherapy—the activation or suppression of the immune system—as a tool to combat certain diseases and as one of the most promising new technologies for the treatment of cancer.<sup>4</sup>

A recent study by IEL, *2027 Industry: Risks and Opportunities for Brazil in the Face of Disruptive Innovations*, mentions several of these trends as relevant for Brazilian Industry.<sup>5</sup> The novelties are numerous, but the scope of these changes is still unclear. However, the conditions for the development of new technologies have not changed as much as the technologies themselves. In any field, innovating requires qualified people, adequate infrastructure for conducting research and product development, and a stimulating environment. In addition to this, innovation in healthcare and medicine has specific and more complex characteristics than any other sector.<sup>6</sup>

Creating new health products—especially medicine—requires more scientific research than practically any other sector of economic activity. Before developing medicine, medical equipment, or medical devices, it is necessary to understand the human body in relation to how diseases affect the individual—namely its mechanisms, causes, and effects. This is usually the purpose of scientific research conducted in universities and research institutions. Health innovations are also typically expensive and take time to reach patients. The development of a new drug, for example, can take about 10 years from the basic research stage to preclinical and clinical tests. Even

TABLE 14.1

## Participation (% of total scientific publications) of health-related scientific areas in Brazilian and worldwide scientific publications (2017)

Academic field	Health-related publications as a percent of Brazilian scientific publications	Health-related publications as a percent of worldwide scientific publications	Brazil's health-related publications as a percent of worldwide health-related publications
Biology and agriculture	11.6%	4.4%	6.5%
Biochemistry, genetics, and molecular biology	6.8%	6.4%	2.6%
Odontology	1.6%	0.3%	11.8%
Immunology and microbiology	2.5%	1.5%	4.0%
Medicine	17.9%	16.9%	2.6%
Neuroscience	1.6%	1.5%	2.6%
Nursing	1.3%	1.0%	3.1%
Pharmacology, toxicology, and pharmaceuticals	2.2%	1.8%	3.1%
<b>Total</b>	<b>45.3%</b>	<b>33.7%</b>	<b>2.4%</b>

Source: Ministry of Science, Technology, Innovation and Communications (MCTIC).

Notes: This table shows the participation of scientific areas related to health in Brazilian and world publications, as well as the participation of Brazilian science in the world. When the participation of the area in Brazilian publications is greater than its respective participation in world publications, it means that Brazil has advantages in these areas.

innovation in software, equipment, and devices take time to meet regulatory requirements before they are released to patients. Furthermore, the development of a new health product is a risky activity. Estimates indicate that the percent of drugs that reach the market after starting clinical trials vary between 6% and 13.8%.<sup>7</sup>

### Brazilian outlook

Brazil has over 200 million inhabitants and one of the largest public healthcare systems in the world, called the Unified Health System (SUS). The SUS provides healthcare, from basic treatments to complex transplants, to over 100 million people, free of charge. According to the Brazilian Institute of Geography and Statistics (IBGE), in 2015 the total costs of health-related goods and services in Brazil amounted to around 9.1% of GDP, approximately US\$180 billion today.<sup>8</sup> These numbers show that Brazil has a significant market for health. Rising health costs, together with the fiscal problems faced by the country, also make the SUS an excellent pilot to test technologies capable of reducing health costs, especially through ICTs.

While the size of the market is an important advantage for the development of new technologies in health and medicine, it is also important to note that Brazil has pertinent scientific competences in health-related areas as shown in Table 14.1.

Across all scientific areas, not just health-related areas, Brazil accounts for 1.8% of worldwide scientific publications. In the

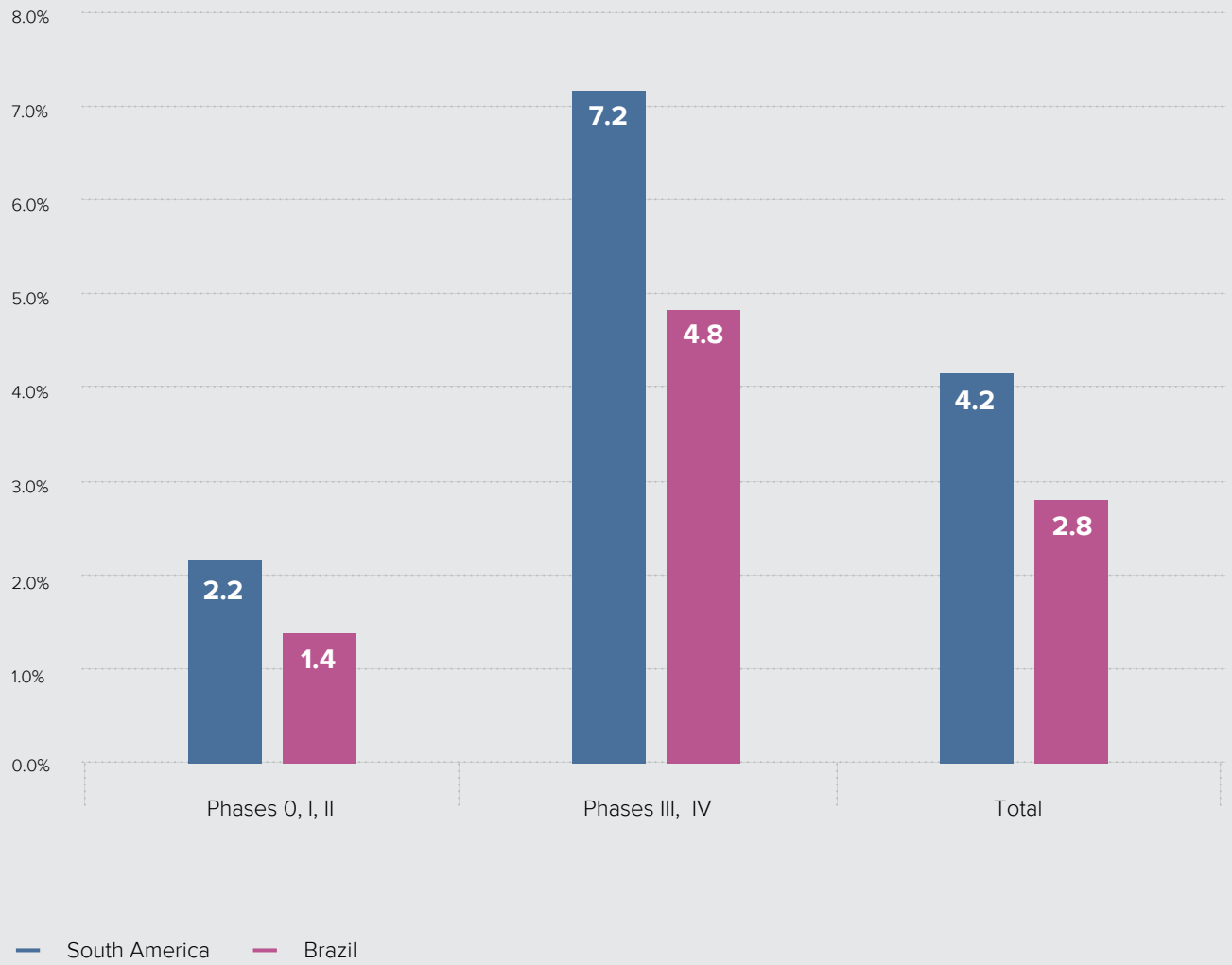
health-related scientific areas detailed in the table, Brazil's participation is 2.4% overall and much greater in specific areas. For example, Brazil accounts for almost 7% of worldwide scientific publications in biological and agrarian sciences, close to 12% in odontology, and precisely 4% in immunology and microbiology. This shows that Brazil has important scientific expertise in these areas (Figure 14.1).

When it comes to translating research into new drug production, however, there is room for the country to move forward. Evidence of this is Brazil's participation in clinical trials, the final stage of a long research and development (R&D) process that starts in the laboratory of a university or research center and ends with testing on humans. At this stage, fundamental research from universities and research institutions moves to the laboratories of large pharmaceutical companies, which are primarily responsible for conducting clinical trials. Brazil accounts for less than 3% of worldwide clinical trials, and this participation is lower in phases 0, I, and II, which are the most knowledge intensive. An increase in clinical trials will help establish the country within global networks of knowledge production in medicines and health products, especially in areas where Brazilian comparative advantages are relevant.

This is the case for biopharmaceuticals, an area that has grown the most in recent years and accounts for about 20% of the world's pharmaceutical market. A recent study conducted by researchers from the Massachusetts Institute of Technology (MIT), as part of a program sponsored by SENAI, argues

FIGURE 14.1

### South American and Brazilian share in worldwide clinical trials (phases 0 to IV) initiated between January 2000 and January 2018



Source: De Negri, 2018.

that Brazil has the conditions to be more than a follower in biopharmaceuticals because of its scientific competences and the potential of its biodiversity.<sup>9</sup> The 2027 Industry study conducted by IEL has reached the same conclusions.<sup>10</sup> However, biopharmaceuticals—which are more expensive than pharminochemicals—can burden health systems. For this reason, a resolution of the National Health Surveillance Agency (Anvisa) regulated the biosimilar market—drugs that are the equivalent to approved, but not patented, biopharmaceuticals—in 2010. By regulating this market, it is possible to increase patients' access to biological drugs without causing significant increases in drug costs. Nevertheless, according to the MIT study, by focusing solely on biosimilars, Brazil risks falling further behind the rapidly expanding science-based innovation frontier, meaning that the regulation of biosimilars is not enough to put Brazil on the path of innovative countries in biopharmaceuticals. By choosing the path of biosimilars and generics, Brazil has taken an important step towards facilitating access to cheaper medicines, but this is not enough for the country to be more than follower in this field. Pursuing a leadership strategy requires larger R&D investments from businesses in the health sector. Today, the Brazilian pharmaceutical industry invests around 2.4% of its revenues on R&D, according to the IBGE's Technological Innovation Survey (PINTEC).<sup>11</sup> This level of investment makes the sector one of the most R&D intensive in the country. However, this is far from worldwide R&D investment in the pharmaceutical sector, which is 10% to 15% of revenues.<sup>12</sup>

Yet, health innovation does not only relate to medicines. There is potential for Brazil to use ICT in health, since there is a significant ecosystem of start-ups and researchers in this area.<sup>13</sup> In addition, the SUS, one of the largest public health systems in the world, could improve management and efficiency using ICTs. A recent study has mapped out about 200 start-ups that offer solutions in ICTs applied to health, all of which are in operation and own proprietary technologies.<sup>14</sup> These companies are involved in telemedicine, wearables, internet of things (IoT), medical devices, electronic medical records management, AI, and big data. A significant Brazilian medical innovation is an application developed by researchers at the Federal University of Rio Grande de Norte who, through analysis of a user's speech, help in the diagnosis of patients with schizophrenia.<sup>15</sup>

Brazil is just beginning to participate in other technological trends, such as precision medicine. Nevertheless, important initiatives—such as the Brazilian Initiative on Precision Medicine (BIPMed), which brings together five research centers supported by the São Paulo Research Foundation (FAPESP)—facilitate the sharing of a genomic database. The Albert Einstein Hospital in São Paulo, in partnership with a genomics company, has created a center for personalized medicine. This center aims to use genetics to improve the diagnostic accuracy of serious and complex diseases while administering an assertive prevention plan and adopting an individualized approach for each patient.

## Prognosis and the role of the CNI, SESI, SENAI, IEL, and SEBRAE

Despite the challenges, the prospects for Brazil in terms of innovation in health and medicine are promising. SEBRAE, SENAI, SESI, IEL, and CNI all play a relevant role in the health area.

### The role of SENAI

SENAI has contributed significantly to innovation in Brazil, through training and the provision of technical services. To address innovation challenges, SENAI has created a network of innovation centers called the SENAI Innovation Institutes (ISI), equipped to develop innovative projects in several transversal areas, including health and medicine. To date, 10 of the 26 ISIs have developed over 43 R&D projects related to health, in partnership with companies and other research institutions. Some examples are:

1. The ISI for Microelectronics, in Manaus, Brazil, is leading R&D of medical devices, in partnership with the Oswaldo Cruz Research Foundation (Fiocruz) based in Rio de Janeiro, Brazil. The first project aimed to design and produce a low-cost device capable of conducting isothermal reactions to assist in the diagnosis of infections such as tuberculosis, leprosy, malaria, and dengue.
2. In Pernambuco, Brazil, the ISI for Information and Communication Technologies is focusing R&D on a radiology imaging transmission system, a virtual reality solution to train Paralympic athletes, and portable equipment to use for retinal diagnosis.
3. The ISI specializing in polymer engineering, in Rio Grande do Sul, Brazil, tests materials, orthoses, and breast prostheses, in addition to developing health instruments.

Several additional SENAI Innovation Institutes undertake R&D in health and medicine, such as the ISIs for Advanced Materials and Nanocomposites, Advanced Manufacturing in São Paulo, Microfabrication in São Paulo, Byosynthetics in Rio de Janeiro, and Automation of Production in Bahia. Before the end of 2019, SENAI expects to launch the ISI for Biotechnology in São Paulo, whose R&D efforts will focus on the development and optimization of bioprocesses and biomolecules, engineering genetics, and the development of intelligent products with a biological basis.

### The role of SEBRAE

SEBRAE aims to foster development and to support micro and small companies in areas such as technological prospection, intellectual property consulting, business modeling, market positioning, investor relations, consulting, and business and financial management. One SEBRAE initiative, for example, is to promote events where inventors and investors present market trends and business opportunities to small companies.

In the health sector, SEBRAE initiates participation from innovation professionals in areas such as biotechnology, nanotechnology, bioinformatics, and artificial intelligence. For example, through SEBRAE, start-ups and innovators have the opportunity to present their solutions to solve specific health challenges to investors.

## The role of SESI

SESI focuses on, and promotes innovation in, health and safety at work. This contributes to business competitiveness by reducing costs, reducing work-related accidents, and improving workers' well-being. To face the challenges of safety and health at work, SESI has implemented nine innovation centers aimed at identifying challenges and developing solutions in several areas: prevention of disability, health and safety economics, ergonomics, lifestyle and health, longevity and productivity, health and safety management systems, psychosocial factors, occupational hygiene, and healthcare technologies.

For example, the SESI Innovation Center for Health Care Technologies developed a gamification solution to encourage users to adopt healthy habits. The solution facilitates monitoring and data visualization of personal habits that need to change for a healthier lifestyle. This and other examples of innovations developed by the SESI Innovation Centers are publicly available on the web in the National Platform of Innovations.<sup>16</sup>

## The role of CNI and IEL

CNI manages SENAI, SESI, and IEL. Together, state federations and employers' trade unions form the Industry System, a national private network responsible for initiatives to support the Brazilian industrial sector.

From the demands identified in the companies by the industrial federations and unions, the System offers basic education, professional training, business training, and technical and technological solutions to industries. It also develops socio-educational programs that contribute in an effective way to improve safety and health conditions in the workplace.

The Innovation Directory of CNI/IEL also supports innovative companies in the health and medical sector through management consulting and training. The program Inova Talentos, in partnership with the National Council for Scientific and Technological Development (CNPq), encourages fellows to participate in innovation projects, such as validating biomarkers discovered through metabolomics and development, or validating tools to aid molecular diagnosis in precision oncology.

Finally, CNI hosts the Entrepreneurial Mobilization for Innovation (MEI) in Brazil. One of MEI's initiatives—carried out through an agreement between CNI, SESI, SENAI, and SEBRAE—is the publication *Business Innovation Cases*, which aims to inspire companies to innovate.

These are just a few examples of how the CNI, SENAI, SESI, IEL, and SEBRAE can collaborate in the development of new technologies in health and medicine in Brazil. Brazil has enormous opportunities ahead, and the research and business support infrastructures provided by the aforementioned institutions will play an essential role in realizing these opportunities.

## Key challenges and recommendations for health innovation in Brazil

Despite the country's scientific expertise and potential in some aspects of healthcare and medicine, developing more technologies in these areas requires us to overcome regulatory, financial, and institutional constraints.

One significant constraint is the discontinuity in public policies and research funding, which undermines the country's scientific infrastructure and expertise. Although companies account for a significant portion of R&D investment in health, public investment is still the primary source of scientific research in the area worldwide. In Brazil, discontinuities in public funding for science and technology (S&T) lead to *brain drain*—training gaps for qualified staff—and obsolescence of equipment and laboratories, which need to be continuously updated if the country wishes to produce relevant scientific knowledge in this area.

Therefore, one of the most important recommendations for Brazilian government is to set up a transparent and stable strategy for innovation in healthcare and medicine, which should consist of long-term investments in infrastructure and research. This strategic plan should also address institutional constraints that hamper innovation in the country.

Regulation is one constraint that partially explains the low participation of the country in world clinical trials. According to companies, the time required by ANVISA to approve clinical trials is one of the regulatory problems, and a study by the Brazilian Development Bank (BNDES) showed that these time requirements are higher than the world average.<sup>17</sup> Since many studies are conducted concomitantly in several countries, delays in the approval process may limit Brazilian participation in those studies.

One reason for this delay may be the existence of multiple requests for approval for clinical trials. Each research institution has its own research ethics committee, which is not always expeditious in analyzing tests. In some cases, this approval still needs to go to the National Ethics Research Council, where the process can take up to six months to complete.<sup>18</sup>

In addition, entrepreneurs and studies point out that the cost of clinical research in Brazil is an impediment to growth.<sup>19</sup> This cost comes, in part, from regulatory standards, such as the need to supply medicine to trial participants after the study ends.

One possible solution to these issues lies in a bill currently under discussion in the Congress. This bill establishes standards for clinical research in human beings and creates a national system of ethics and research, which will improve and give consistency to the regulation of clinical research in the country.

Intellectual property is also a major challenge for innovation in Brazilian industry. Specifically, in the health sector, intellectual property rights are the main tool to reward the innovator for the risk incurred in innovating. In Brazil, the registration of a patent

can take up to 11 years, which hampers innovation in the country. Therefore, one important recommendation of CNI is to increase the efficiency of the National Patent Office (INPI) in evaluating patents, which requires more evaluators, better management, and the use of international collaborative schemes.

An example of a good international collaborative scheme is the Budapest treaty, aimed at advancing the protection of microorganisms, which allows deposits of microorganisms at an international depositary authority for patent procedure. CNI considers that Brazil becoming a member of the Budapest treaty would be an important step for the development of the biopharma industry in the country.

With regard to advancing the use of ICT in health, there are some relevant bottlenecks related to legislation and the availability of information. One example is the adoption of the electronic medical record in the Unified Health System network. For this to be feasible, it is necessary to provide basic infrastructure for public health units across the country and to establish interoperability protocols among several health service providers. Government and regulatory agencies need to develop standards and protocols for medical records to widen its use, which could benefit both the public and private health system and its patients.

The recently passed General Data Protection Act, due to come into force in 2020, introduces a new element to this scenario. From this, any use of personal data—especially sensitive information such as health—will require the consent of the owner. Two factors requiring clarification are whether the law is expected to protect people and their personal information from indiscriminate and unauthorized use, and if the Act will impact health research, especially using big data and AI. Therefore, the CNI will follow the developments of this law and its impact on innovation in health in Brazil.

Brazil has immense potential to innovate in health and medicine. These are merely a few recommendations that could help the country overcome challenges and build a more dynamic health innovation ecosystem, thus benefiting Brazilian society with improved and more affordable healthcare. The Brazilian industry is committed to these ideas and to the goal of transforming the country into a hub of innovation in health.

#### Notes:

- 1 The World Bank, 2019.
- 2 The Economist, 2018.
- 3 Deloitte, 2016.
- 4 Deloitte, 2016.
- 5 Instituto Evaldo Lodi, 2018.
- 6 De Negri, 2018.
- 7 Cross, 2018

- 8 IBGE, 2017.
- 9 Reynolds et al., 2016.
- 10 Instituto Euvaldo Lodi, 2018.
- 11 IBGE, 2016.
- 12 OECD, 2015.
- 13 Revista Exame, 2018.
- 14 Distrito, 2018.
- 15 Prêmio Abril Dasa de Inovação Médica, 2018.
- 16 Plataforma Nacional de Soluções SESI, 2019.
- 17 Gomes et al., 2012.
- 18 Gomes et al., 2012.
- 19 Reynolds et al., 2016.

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