

# Colombian Health Innovation Landscape: Building Bridges

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# Cover letter

This report is part of the broader “Research Collaboration on Technology, Equity, and the Right to Health”, between the Global Health Centre (GHC) at the Geneva Graduate Institute in Switzerland, the James P. Grant School of Public Health at BRAC University in Bangladesh, and the Universidad de los Andes (ANDES) in Colombia, supported by the Open Society University Network (OSUN). The larger research collaboration consists of two research projects – one on digital health and human rights, and the other on pharmaceutical research and development (R&D) in the Global South.

As part of the latter research project, three individual research reports present the findings on pharmaceutical R&D in the Global South: one report led by BRAC about pharmaceutical R&D in Bangladesh, another report led by ANDES about pharmaceutical R&D in Colombia, and finally, one report led by the GHC about pharmaceutical R&D in low-and middle income countries (LMICs).



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# 1. Introduction

In the Global South, health technology access is restricted, and Colombia is not an exemption. Historically, middle and low-income countries have been accessing medicines and technologies developed elsewhere, paying higher prices, and participating only in minor roles in some parts of the value chain. The COVID-19 pandemic explicitly highlighted access problems in supplies and medical technologies, as well as a lack of preparedness for emergency situations; for instance, like many other developing countries, Colombia faced shortages of mechanical ventilators, personal protective elements (EPPs), vaccines and some medicines. With the pandemic, a window of opportunity for addressing disparities in access to essential health technologies and the related knowledge production has opened; this report seeks to contribute to this agenda by analyzing the situation of R&D and product development in Colombia, a middle income country with interesting recent developments and an active role in global access to medicines' discussions.

Regarding the pharmaceutical industry in the Global South, part of the problem is that the diagnostic is not clear. A common denominator for Low and Middle Income Countries (LMIC) countries is having none or partial information about industrial capabilities, which in turn , limits the extent to which countries are able to introduce policies and actions to address innovation and access challenges. Since the pharmaceutical industry is complex, with different actors dispersed in a global ecosystem, keeping real-time information is a major challenge that needs continuous efforts. In the case of Colombia these challenges interact with a loose competitiveness public policy that privileges the coordination role of the state, facilitating connections amongst private actors in the value chain, over explicit industrial promotion policies. Despite the disperse and sometimes disconnected set of policies, an R&D ecosystem does exist in the country, both public and private basic and clinical research have increased, and new actors have emerged to facilitate the translation of basic research into product development. To provide a full picture of what is happening with health technologies' innovation in in Colombia in this report we analyze three aspects of the R&D scene. First, we review the literature and the public policies related with health technologies' R&D to describe the current R&D ecosystem; second, we zoom into one specific actor in this ecosystem, which we call "innovation accelerators" that have emerged to connect basic researchers with investors and product development opportunities; third, we analyze funding for R&D and clinical trials data to understand

how health technologies' R&D has changed over the past few years.

We decided to focus and interview innovation accelerators because they are actors that spontaneously emerged to solve one of the major problems raised by basic researchers in the many evaluations of the R&D ecosystem: the challenge of going beyond basic research and prototyping into clinical trials and product development.

Despite of having a clear competitiveness strategy and having created many public and private actors to foster science, technology and innovation in the country, one of the main conclusions of this report is that strengthening the biomedical and pharmaceutical industry in Colombia might require a more determined endeavor to orchestrate and articulate actors, policies and actions, and to analyze their impact in terms of innovation and access to health technologies.

## 2. Methodology

The research team followed three main approaches to carry out this research. First, we sought to identify relevant literature on R&D and the innovation ecosystem in Colombia. Second, we conducted interviews with innovation accelerators working on biomedical research. Third, we selected R&D funding and clinical trial databases that could be used to identify general trends in funding, the institutions and researchers active in pharmaceutical R&D in Colombia, and/or the products being developed. Hereinafter we described the specific methods used for our research. First, we conducted a policy and literature review on biomedical innovation in Colombia. Searches were conducted both in English and Spanish with keywords in major databases, especially PubMed, SciELO, ScienceDirect, Scielo, Wiley, from the earliest available literature until April 2022. Keywords include “pharmaceutical”, “drug”, “medicine”, “vaccine”, “health”, “innovation”, “research and development”, “product development”, “biomedical innovation”, “Colombia”. Reports from national government, international and regional organizations, comparative documents in which Colombia is a case study, and consulting firms, are also included. The literature review includes papers and reports in Spanish and English, therefore subject to limitations. The results allowed us to construct a general map of this ecosystem.

Second, we interviewed leaders from innovation accelerators to gather information on how the biomedical innovation ecosystem works in practice in Colombia. Given that prior research focuses mainly on the perspectives of policy-makers and/or researchers, we decided to focus on this new set of actors that act as brokers between research and production and that give a fresh perspective of how R&D investments can become actual accessible products. The interviewees were selected based on the internal knowledge of the research team and are from private and public organizations with extensive experience in knowledge transfer, pharmaceutical policy, access to medical devices and industry-researcher networking.

Third, we present the results of the analysis of some Ministry of Science, Technology and Innovation (MinCiencias) databases of funded biomedical R&D projects; our group had access to basic information on R&D projects presented in 14 different calls for proposals from 2010 to 2019 (1.534 projects in total). The variables taken into account for the analysis are: year, project title, principal investigator, research group, organization, program, thematic area, type of funding, department and city.

Additionally, we present the results of the analysis of clinical trials databases. We used a dataset created by the Global Health Centre (available at <https://zenodo.org/record/7801929>) based on datasets by Merson et al. (2022) that brings data extracted from the International Clinical Trials Registry Platform (ICTRP) of the WHO up to December 15, 2020 and adds a classification of sponsors and funders categorized as commercial and non-commercial, as well as additional information on health categories obtained from the WHO Global Observatory on Health Research and Development

# 3. Findings

In what follows we present the main results of our research. First, we present a policy and literature review on biomedical innovation in Colombia. Second, we present the results of scoping interviews with innovation accelerators. Third, we present the results from analyzing Minciencias databases. Fourth, we present the results of the analysis of clinical trials databases. Lastly, we conclude and discuss our findings.

## A. Policy and Literature review

The literature on biomedical innovation and research and development (R&D) in Colombia provides information mainly about funding, relevant actors, and different types of industries in the sector, as well as the role of the State and the public policies associated with the interest on science, technology, and innovation (STI). According to this, like other Latin American countries, Colombia began to build a science, technology, and innovation policy in the 1960s, which has gone through various stages marked by different theoretical approaches and governance models (Moncayo, 2018). Since the fiscal and administrative decentralization policies introduced in the 1990, by which subnational governments became the main providers of public services, STI investment policies have had an increasingly territorial focus. However, there is limited information at the state and municipal level on pharmaceutical and biomedical R&D, including where R&D activities are conducted, by whom, what products have been developed or are under development, and what policies or regulations are in place. To help fill this gap, we conducted a scoping literature review focused on the recent Colombian context.

The development of industrial policy on R&D in Colombia had its major shift in orientation since the 1990s. Prior to the 1990s the country followed the model of import substitution industrialization, with mixed results. Beginning in the 1990s after a constitutional reform there was a major shift in the country's economic model veering towards an export-led development approach (Moncayo, 2018). In that context, science and technology were supposed to drive industrial development. However, investment in general R&D and scientific, technological and innovation activities has been very low ever since, reaching a historical maximum of 0.84 % of PIB in 2020



(OCyT report of 2020, 2021); and access to undergraduate and graduate education restricted to a minority of students.

Before the 20th century, scientific projects were carried out without much external involvement or funding. This began to change after the creation of several non-governmental institutions and universities in the 20th century. In 1968, the National Financing Fund for Science, Technology and Innovation - Fund "Francisco José de Caldas" was created, attached to Colciencias - Administrative Department for Science, Technology and Innovation (Ospina Bozzi, 1998). Today, the Ministry of Science, Technology and Innovation (Colciencias until 2019, now MinCiencias) is responsible for the development of science and technology in Colombia and is the largest source of public funding for R&D in the country (OCyT report of 2020, 2021). To advise and create a better interaction between MinCiencias and the other instances of the government (i.e. Ministries of Commerce, Industry and Tourism, among others), the National Council for Science, Technology and Innovation (CSTIS) was founded in 2009 (Law 1286 of 2009). Legislation over the last two decades has made MinCiencias and CSTIS the main policy regulators of the Colombian Science, Technology, and Innovation (STI) system.

Literature on general R&D, not only focused on biomedical innovation, focuses on the public policy challenges, particularly related to funding. The question has been whether public funding for innovation reaches those who need it.

As a result of this type of critique, in the past decade, legislation was passed to reorganize the system and increase its budget. In 2009, the CONPES (Economical and Social Politics Council) issued a major STI policy program broadening the scope of Colciencias and increasing its autonomy. The policy focused on energy, natural resources, and biotechnology towards what was called Green Innovation, a program that focuses on topics such as biofuels, alternative energy, and biodiversity (Rodríguez-Fernández, 2013).

Other studies indicate that in Colombia, there is a growing awareness of the opportunity to improve productivity and competitiveness through general STI activities, as well as the need to develop articulated R&D dynamics, where the actors establish consensus and organize their actions according to development objectives that impact the entire region (Escobar and Herrera-Vargas, 2015). However, in the absence of a clear, regulated definition with continuity over time, the lack of actions for the development of coordinated processes between the productive sector and research production centers such as universities (Escobar and Herrera-Vargas, 2015), the difficulty of connecting the STI guidelines with productivity and competitiveness policies and with the instruments for the development of the STI policy, as well as the lack of a clear definition of the STI policy, which leads to an under-utilization of productive

capacities (Escobar and Herrera-Vargas, 2015).

Other literature has been concerned with tracking and characterizing innovation funding in Colombia. Currently, Minciencias is the main funder of R&D in the country; at the regional level, departmental governments (Colombian states) contribute to such funding through oil and mining royalty funds earmarked for STI activities (Bece-rra-Arévalo, 2015).

Historically, most of the R&D and scientific, technological and innovation funding has been public; but nowadays, a reconfiguration of funding has emerged. For instance, in 2015 public funding was 50.88% and private was 46.15%, whereas in 2020 public funding was 41.82% and private 55.82%. Meanwhile, international funding has been around 2% and 3% of the total investments (OCyT report of 2020, 2021).

The findings of Barona-Zuluaga et al (2015) identified that state resources have played a minor role in innovation funding in Colombia and that the relatively few resources do not appear to have been effectively allocated. According to the review, corporations, government, universities, and research centers used most of STI funding from 2000 till 2012 (Rodríguez-Fernández, 2013). This preliminary conclusion is consistent with that of Gómez and Mitchell (2014) about the country's misallocation of public resources for innovation.

However, the literature shows that there has been a recent phenomenon in which companies are committed to innovation as a central component of their competitive strategy and, in addition, operate in sectors that are intensive in health technology (Sierra-González et al, 2021). Juliao-Rossi et al (2019) note that a major constraint to (persistent) innovation generation appears to be access to financial resources; more specifically, it seems to be more important to be able to continuously invest in R&D with both external and internal funding than the amount that is actually invested. This finding is coherent with the results of the National Bureau of Statistics (DANE) Development and Technological Innovation survey conducted to manufacturing and services firms (OCyT, 2021).

Additionally, the literature shows that patents are not necessarily the main strategy to protect innovation by Colombian firms (Juliao-Rossi et al, 2013). Even an empirical study concluded that patent owning firms are less innovative in terms of new products, when compared to other small and medium companies (SMEs) (Forero, 2011). It is probable that Colombian companies that innovate seek alternatives to patents to protect their innovations. As one of the interviewees for this report told us, trade secrets may function as a simpler and faster alternative to lengthy and expensive patent processes. However, these results may also be since companies that patent are perceived to differ in the degree of technological development, absorptive capacity

and legitimacy from those that do not patent and that those that patent have developed the capacity to take advantage of ideas from clients and universities, while the others do not. Interestingly, some biomedical researchers seem to be disinterested in patenting their products and results and might not consider it a natural complement of their research. Therefore, researchers tend to delegate this initiative and task to the technology transfer offices of their organizations (Centro de pensamiento Medicamentos, información y poder (2019), which could generate a loss in potential products. This result contrasts with the fact that pharmaceutical and biotechnological products are among the areas with more patent applications in Colombia (OCyT, 2021).

Since 1992, tax incentives to science, R&D and innovation activities have been introduced in Colombian laws; in the last decades tax deductions were possible for firms that promote projects for investment in STI or equipment importation, among other activities. Nowadays, tax deduction was replaced by a 25% tax discount (EY, 2022). Life Sciences & Health Care are among the industries' most often affected by government incentives in the country (Deloitte, 2020).

## B. Industrial policies of the pharmaceutical sector and other health technologies

Pharmaceutical industry in Colombia had not a different evolution than other industrial sectors. In the 1990s the decentralization policies also came with a process of de-industrialization as many multinational firms transferred their production processes to other Latin American countries. As a result of this, in 2012, Colombia ranks 58th among 124 countries in the ranking that measures the technological complexity of the export basket of nations. This is because 48% of its exports correspond to goods of very low technological complexity (raw materials and minor manufactures). In contrast, the OECD countries occupy the top 30 places in the ranking. In Latin America, only Mexico (28) and Brazil (30) are among the first 30 positions in the ranking (Felipe, Kumar, Abdon y Bacate, 2012).

The pharmaceutical sector is no exception. Pharmaceutical imports in the country have grown exponentially in the last 20 years, generating large impacts on public spending on health. In 2001, the trade deficit in pharmaceuticals was 170.9 million dollars. In 2010, the deficit had become 1,110 million dollars and in 2021 it was 3,777 million dollars. The countries from which most medicines were imported in 2021 were the United States, China and Germany. The countries to which Colombia exported the most were Ecuador, Peru and Panama (DANE 2022).

The pharmaceutical market in the country has grown 44% in monetary value from 2008 to 2018, going from 1,8 billion dollars in 2008 to 2,7 billion dollars in 2018, in constant prices of 2008. 53% of the market in 2018 was sold through the commercial channel and 47% through the institutional channel<sup>1</sup>. Only 10 companies concentrate 40% of the total pharmaceutical market. 8 of them are multinational companies and 2 are local private producers (Lafrancol is the sixth and Tecnoquimicas the eighth) (SISMED 2019).

The literature shows that the pharmaceutical industry in Colombia has concentrated its R&D efforts on drug development, followed by vaccines and a few studies on diagnostics. Some of the identified literature provided information on the therapeutic areas being researched in the country, such as neglected diseases or tropical diseases. An example of this can be seen in the development of a topical cream (Anfoleish) for the control of non-complicated leishmaniasis. This product was developed by HUMAX (Colombian private pharmaceutical company) and the Program for the Study

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<sup>1</sup> The commercial channel includes private pharmacies where patients buy over the counter or prescribed medicines out-of-pocket, even if they are included in the basic healthcare plan, sometimes to avoid cues or because they prefer a particular brand. The institutional channel refers to medicines provided through hospital and pharmacies most of it paid with public resources.

and Control of Tropical Diseases (PECET) of the University of Antioquia, a public university, in order to provide an effective and accessible solution for people affected by this disease (López et al, 2018). Product development is based on basic research conducted by PECET and funded in part by Minciencias (Centro de pensamiento Medicamentos, información y poder, 2019).

Pharmaceutical public spending is concentrated in high cost imported pharmaceuticals with little competition in the market. Meanwhile, local production of generic products meets the demand of most medicines for the most prevalent pathologies. These production processes involve only packaging or fill and finish, but not the production of active pharmaceutical ingredients (API). Some estimate that domestic manufacturers contribute 80% of the units sold in the country but only 33% of the value, and that the average price of imported medicines is 8.1 times higher than that of those produced in the country (Sectorial 2022).

Although the country has not issued an explicit industrial policy for pharmaceuticals, Law 1438 of 2011 recognized the importance of competition in drug production, and the Statutory Health Law 1751 of 2015 orders the adoption of a pharmaceutical policy that includes strategies, priorities, and mechanisms for drug production<sup>2</sup> (Ochoa, 2017).

Similarly, in the National Pharmaceutical Policy (Conpes 155 of 2012), one of the ten strategies to guarantee the access to effective and safe pharmaceutical products is to “encourage the research, development and production of strategic medicines; the promotion of (generic) drug competition and the national availability of medicines for diseases prioritized by the Minister of Health”. Since 2018, a particular interest on bioeconomy arose, identifying opportunities in pharmaceutical (biologics), tissue engineering, personalized healthcare, genomics, among others (Biointropic, 2018). The National Policy on Science, Technology, and Innovation (STI) was recently approved through Conpes 4069 of 2021, which will be implemented over a 10-year horizon with enabling and management actions. While the Conpes allocates additional financial resources to the national STI policy, these resources are very limited (257 million US\$ for 10 years) and will unlikely be sufficient to accomplish the task.

According to domestic producers, the country should incentivize local production of low complexity over-the counter medicines (OTCs), given that it would lower the pressure over public health spending if people who can afford it move toward that

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<sup>2</sup> Article 90 of the Law 1438 of 2011 says “ARTICLE 90. GUARANTEE OF COMPETITION. The National Government must guarantee effective competition for the production, sale, marketing and distribution of medicines, supplies and medical devices.” Article 23 of the Law 1751 of 2015 says “The National Government will establish a national, programmatic and comprehensive Pharmaceutical Policy in which the strategies, priorities, financing mechanisms, acquisition, storage, production, purchase and distribution of supplies, technologies and medicines are identified, as well as the mechanisms for regulating drug prices. This policy will be based on criteria of need, quality, cost effectiveness, sufficiency and opportunity”.

market for low complexity medicines. The industry also finds the regulatory standards adopted by the country to be unnecessarily stringent limiting the possibilities for domestic production (ASINFAR 2018).

### *Sparse policies to promote local biomedical R&D, production, and access to medicines*

In Colombia, there is no specific industrial legislation that favors the installation of pharmaceutical and health technology industries. Instead, what exists is a collection of scattered public policies to foster science, technology, and innovation, to promote industrial production, and to encourage entrepreneurship. As Figure 1 illustrates, if one had to map all the policy and regulatory instruments that create the environment to increase production capacity of health technologies, there are both instruments that explicitly refer to or that are devoted to pharmaceuticals (marked in red), whereas there are more generic instruments that could apply to any sector (marked in black).

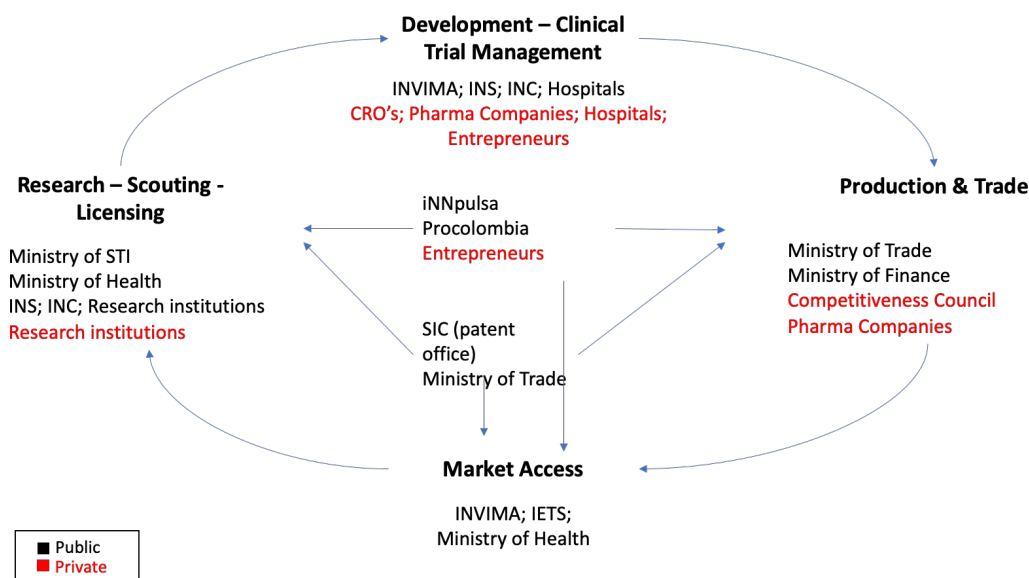
Similarly, this set of policies involve different kinds of actors, both public and private, intersectoral and sectoral. One could say that pharmaceutical industrial policy in Colombia, although not explicitly stated or drafted, is thought to be part of a broader R&D, entrepreneurship, production, and competitiveness policy environment that involves all kinds of actors, some of them belonging to the pharmaceutical sector, and some of them to broader innovation or competitiveness platforms. Each of the fields of policy described in Figure 1 involves different sets of actors. These actors include state agencies, public research institutions, private competitiveness think tanks, public and private innovation accelerators, pharmaceutical companies, entrepreneurs, etc. Figure 2 is an attempt to list and classify the actors who participate either directly or indirectly in the promotion of domestic pharmaceutical industrial production.

Figure 1. Policy and regulatory instruments to increase production capacity of health technologies



The different policies and actors will be described in detail in the chapters to come, but below is a brief outline of the content and actors included in each policy realm. Many of the policies outlined here are what in Colombia is known as “Conpes documents”. Conpes documents are general and intersectoral policy documents signed by all the ministries of state, who in turn belong to the National Social and Economic Policy Council, created in 1958. The council is the highest national planning authority and acts as an advisory body to the government in all aspects related to the economic and social development of the country. However, as it will become clear, some of these Conpes documents have been turned into law.

Figure 2. Actors involved in the production of health technologies environment



## Research - Scouting - Licensing

The national policy of science, technology, and innovation (STI) issued in 2020 was, in part, the result of an expert taskforce that began two years before and resulted in a report with 9 thematic areas in which the country should implement different strategies to advance science, technology and innovation to foster the competitiveness and development. The taskforce was called “Misión de Sabios” (Mission of Sages) and it took over a year to come up with strategic policy recommendations for all 9 areas. Sciences of life and health was one of those 9 areas.

Parallel to the development of the Misión de Sabios, the National Planning Department (DNP) set out to develop a Conpes document on the national policy of STI. This Conpes is organized along seven strategic axes that are believed to be transversal to the emblematic missions and strategic focuses recommended by the Misión: (i) the promotion of vocations and employment in STI; (ii) the generation of knowledge;

(iii) the use of knowledge, (iv) the appropriation of knowledge, (v) regional, social, and international potentialities, (vi) dynamic factors of the National STI System and (vii) financial resources.

The Conpes is set to make Colombia one of the three STI leading countries in Latin America by 2031. In 2021 Colombia ranked 67th among the 132 evaluated in the Global Innovation Index (GII), ranking below Mexico, Chile, Costa Rica, Brazil, and Uruguay (WIPO, 2021). The country's investment in this area was only 0.29% of the gross domestic product (GDP) as of 2020. While the Conpes allocates additional financial resources to the national STI policy, these resources are very limited (257 million US\$ for 10 years) and will unlikely be sufficient to accomplish the task.

Financial resources available to fund STI activities beyond the national budget include some tax exemptions, a portion of the revenue from extractive industry activities (estimated at 6.7 billion US\$ for 10 years), and, for the case of health-related innovation activities, 7% of the taxes collected for gambling and other games. The latter taxes go to a fund called the Fund for Health Innovation (FIS for its Spanish name), which is administered jointly by the Minister of Health and the Minister of Science and Technology. The total amount of resources the fund receives varies year to year but based on Minciencias data for years 2010 to 2017 it used to fluctuate around 10 million US\$.

Therefore, Colombia's publicly funded health innovation system revolves mainly around the FIS. It was established by Law 643 of 2001 and it provides a steady source of income to the National Program of Science, Technology, and Innovation in Health, which is an advantageous resource in comparison to the other government's programs of STI.

Regarding its governance, the fund is managed jointly by the Ministry of Science and the Ministry of Health through a committee composed by two head officials of each ministry and a technical manager from the Ministry of Science. This committee convenes twice a year to prioritize lines for research and development according to epidemiological and financial criteria. Administratively, the Health Research Fund is based in the Ministry of Science's National Program of STI in Health, where technical and financial staff evaluate project proposals from research groups across the country according to the prioritization previously established by the committee.

## ***Production***

The construction of the Productive Development Policy began in 2015 and it was a public-private effort. The general objective of this policy was to articulate different governmental efforts to increase the productivity and diversification of Colombian productive sectors towards producing and exporting more diversified and sophisticated goods and services.



According to the policy, the country had historically concentrated exports on low value-added goods, decreasing its productivity. In this context, the policy adopts a Productive Development Policy (PDP) framework that argues that productivity is hampered by a combination of market, government, and coordination failures (Crespi, Fernandez-Arias and Stein 2014). The policy proposed three strategies to address such failures and increase domestic production, particularly in high value-added goods: to invest in innovation; to invest in human capital; and to facilitate companies' access to financial resources, including those necessary to comply with quality standards.

This policy had a 10-year term, due to end in 2025 and it can be viewed as the umbrella to other policies that were later developed, such as the national entrepreneurship policy, the entrepreneurship law and public institutions that were created such as iNNpulsa, supporting entrepreneurship to promote high-impact innovation, or refurbished such as Procolombia, promoting Colombian non-traditional exports, international tourism and foreign investment. The policy also developed a methodology to prioritize certain sectors to support in different regions. This was supposed to foster diversification of production and to take advantage of the productive vocation of each region.

The Ministry of Trade and the entities involved worked on the execution of the Policy beginning in 2016. The work included 90 actions framed in 7 axes. i) Transfer of knowledge and technology, ii) Innovation and entrepreneurship, iii) Human capital, iv) Financing, v) Productive chains, vi) Quality and vi) Foreign trade.

Although the policy has been implemented accordingly, and although it recognized that the national industry needed to catch up in terms of productivity and technology in order to be competitive in international and local markets, the pharmaceutical sector has not been prioritized in any of its interventions.

## *Entrepreneurship*

The objective of this policy strategy is to generate high value-added entrepreneurship, that is, one that has innovative content and that responds to the needs of the consumer in a differentiated way. Likewise, it seeks that these new companies grow and become sustainable over time.

Up to 2018 only 6.7% of the young companies in all sectors that exported did so with technology intensive products such as medical devices, pharmaceuticals, and diagnostics. In 2020, the Law of entrepreneurship was passed (Law 2069 of 2020). Among other things, the law states that the National Institute for Food and Drug Surveillance (Invima) will establish differentiated fees for obtaining regulatory approval

taking into account the classification of companies' size. Based on the method and system defined in this law, Invima will define the percentage of the rate that small and medium-sized companies must pay.

### *Pandemic or health emergency response*

During the Covid pandemic, due to the shortage of diagnostic tests, ventilators and other supplies, a public debate arose around the lack of productive capacity of the country<sup>3</sup>. In response, the government worked on a new framework for health sovereignty and the promotion of production capacity. They drafted a decree outlining the main components of the strategy, which include measures to overcome the fragmentation of public policies to promote domestic production, the lack of industrial capacity and the shortage of human talent. The decree was on public consultation at the end of President Ivan Duque's government, and it was signed only a couple of days before the government transition took place on August 5 2022<sup>4</sup>. (Decree 1411 of 2022). As of April 2023, and although the new government of President Gustavo Petro has spoken of prioritizing reindustrialization policies, it is unclear how much of prior analysis and institutions will be preserved.

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3 <https://www.elespectador.com/salud/colombia-fabrico-y-exporto-vacunas-podra-volver-a-hacerlo-article/>

4 <https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/resolucion-1411-de-2022.pdf>

## C. Scoping interviews

Probably due to the lack of cohesiveness of the innovation ecosystem in the country, in the last few years a series of Innovation Accelerators have emerged as facilitators for R&D and public-private collaborations for product development in different technological sectors. Innovation accelerators or facilitators are public, private, or mixed organizations that seek to advance, improve, or shape the R&D process, but do not directly perform or fund R&D (e.g., policy makers, intergovernmental organizations, data sharing platforms, patent pools, product development partnerships, partner search efforts and analysts). Exceptionally they can conduct some aspects of R&D but at a very late stage, for example for clinical trials. Some of them emerged spontaneously and individually specially in Medellín and Antioquia, and one of them, Innpulsa, as a concerted national effort. In this context and as a complementary approach to the database analysis presented in the next section, we conducted a set of interviews with some of these Innovation Accelerators to gather information on how the biomedical innovation ecosystem works in practice in Colombia and to get a sense of who are the main actors involved, what are the incentives to innovate and what are the main challenges researchers, entrepreneurs and investors face.

The interviewees were selected based on the internal knowledge of the research team and followed up by snowballing. Similarly, the selected individuals are from private and public organizations with extensive experience in knowledge transfer, pharmaceutical policy, access to medical devices and industry-researcher networking. These are the innovation accelerators interviewed:

1. **Ruta N:** Innovation and Business Center of the city of Medellín. This public corporation was created by the local government, and Public Enterprises of Medellín (EPM) a state-owned organization, in order to promote the development of technology-based businesses to increase competitiveness in the city. We find this initiative interesting because it has three specific focuses, health technologies being one of the most relevant areas.
2. **Tech Innovation Group (TIG):** Organization focused on the development of companies dedicated to technologies that contribute to human, animal, and environmental health. The organization seeks to solve unmet needs under the principles of conscious capitalism, economic development, and sustainability. We are particularly interested in this organization's diverse approach to health that includes animals, humans, and the environment.
3. **PECET - Programa de estudio y control de enfermedades tropicales:** Universidad de Antioquia's multidisciplinary research group in tropical diseases. Foun-

ded in 1986 by Ivan Darío Vélez, it started by researching Leishmaniasis and has further expanded its scope and capacity. With over 250 research projects and 340 articles, PECET has developed their work in Colombia, Central America, Africa, The Mediterranean, and Asia. PECET has received significant funding from MinCiencias and has partnered with domestic and multinational industries and pharmaceutical companies.

On top of the innovation accelerators we interviewed there are two additional innovation accelerators we were unable to interview because of the transition between governments at the time of the research and the difficulty contacting leaders of these institutions. These are:

4. **Fastrack Institute:** Medellin-based Fastrack Institute (FTI) is a non-profit organization co-founded with Salim Ismail, former Innovation Director at Yahoo, co-founder of Singularity University and with Maurice R. Ferré MD, co-founder, and former CEO of Mako Surgical, current CEO of Insightech. According to their webpage, they are a “non-profit organization that accelerates technology into society by finding holistic approaches to solving problems, with a focus on large urban centers.” Also, according to them, to achieve their objectives they use mobility, health, financial inclusion, and air quality as their key areas of focus.
5. **Innpulsa:** Public agency for entrepreneurship and innovation of the Colombian government. It is aimed at ventures throughout the national territory, with projects of high social sense and innovative ideas in a wide variety of topics related to productive sectors relevant to the country. This initiative is one of the largest in the country. They are interested in understanding how a national public organization supports entrepreneurship and research in health and its relationship with public and private organizations.

Colombia is one of the prominent cases to explore biomedical R&D because it has an evolving research ecosystem fed by the needs of a context in which there is no public production of medicines. Unlike countries like Brazil, that have public research institutes such as Fiocruz or Butantan that work all across the innovation process, from basic research to product development, testing, and production, the majority of Colombia’s R&D is done at public and private universities which have difficulties bringing their innovations into the market. Moreover, although the domestic pharmaceutical in the country is strong, it has mainly focused on the fill and finish of generics and branded generics rather than investing in R&D activities. In this context, the interviews conducted by the team with key actors in the Colombian ecosystem, known as innovation accelerators, are a valuable input to describe the R&D system that is currently being proposed and implemented at the national level.

We conducted three interviews with the leaders of three innovation accelerators

in Colombia: Carlos Castro from Ruta N, Juan José Zuluaga from Tech Innovation Group, and Ivan Dario Agudelo from PECET. In the following, we will describe the findings derived from these conversations to answer the question of how the R&D process in the country works with regards to financing, project prioritization, sustainability and public policy.

Without underestimating public funding, which is key to finance basic research and the early stages of product development, the interviewees highlight the proactive role that innovation accelerators play in seeking external funding, both national and international, to support biomedical research. In this sense, innovation accelerators not only provide seed funding to develop products, but they also make products visible, which helps researchers and entrepreneurs find additional national and international investors. The development of new biomedical products in Colombia depends on local innovation led by both public and private research institutions or individual university researchers who, with mostly public funding, drive the development of new drugs and/or medical devices with an emphasis on technologies that would address local needs.

In other words, innovation accelerators, both public and private, have helped bridge the funding gap that exists between basic research and the prototype development, clinical trials, and production phases. Innovation accelerators select projects and allocate funding to them depending on their promise, the stage of development at which they are and the funding pre-invested by the technology's owners. Whilst the Tech Innovation Group follows up on research projects that are in the final stages, Ruta N and PECET support multiple health projects and technologies which are at different stages of development.

About the financing and sustainability of the accelerators, the interviewees reveal that their main objective is to boost the biomedical innovation market, to guarantee research independence. In Colombia and in the region, funding efforts have focused mostly on prevalent diseases and on drug discovery from natural products. However, this has not limited research to tropical diseases, and it is possible to find researchers developing products for a wide variety of other diseases. The interviewees refer to this characteristic of biomedical innovation as a "potential for entrepreneurship in innovation" and seek through this to create businesses that can be competitively inserted into the global market. As Tech Innovation Group's founder said: "This is the knowledge era. Colombia will not change at the tip of avocado, flowers, and bananas."

Indeed, Tech Innovation Group has created 17 private companies with self-managed resources and free to seek funding from other sources. This particular case shows how the accelerator not only provides funding to investigator-led start-ups to drive innovation, but also provides expertise in translating research to production. They

believe that to foster local health innovation companies it is necessary to link them with universities.

Likewise, variability in the availability of funds and in installed capacities create differences in the development of innovation and investment models. This encourages accelerators to participate in a constant search for other local and international investors, through regional articulation networks with research centers, universities, NGOs, private investors, and philanthropy. Although Ruta N's funding comes largely from public resources, it seeks to attract private donors and investors. The model proposed by Ruta N consists of investors either contributing to a pool of resources that supports several projects or supporting the projects they decide by mutual agreement with Ruta N. Additionally, Ruta N has included a clause in which a percentage of the profits from the products returns to Ruta N, and these resources are reinvested in the development of new products.

Similarly, Tech Innovation Group recently initiated conversations with the Universidad de Antioquia's Foundation to create a similar fund that would invest in promising start-ups and reinvest revenues to support future research and/or product development.

Regarding intellectual property, Ruta N indicated that this is managed individually for each project. However, as an organization they do not require any kind of participation in the patents derived from the projects they support. Instead, they have sought to create strategies to protect the intellectual property of the projects it promotes, such as the Patent Fund, in association with the Ministry of Science. The Patent Fund provides technical assistance and funding for patent applications and sustenance.

By contrast, although PECET owns several patents, given that their interests lie in tropical diseases, they have found patents to be mere signs of recognition, rather than an avenue for licenses and product development. For those purposes PECET has partnered with Ruta N and with private companies willing to invest in their prototypes. In the case of Tech Innovation Group they have not applied to patents yet due to their high cost. Instead, they have relied on trade secrets to protect the intellectual property of the innovations they sponsor. However, they acknowledge that patents may provide an added value when seeking international investment.

According to the interviewees, the R&D ecosystem could benefit from a more organized public investment strategy. In their view there is unnecessary competition and jealousy amongst researchers, furthered by MinCiencias' lack of follow up on the results of the project they fund. In their view, articulating research groups and fostering collaborations and partnerships could deeply benefit the innovation ecosystem.

Finally, the interviews underlined that the lack of a formal industrial policy is one of the major challenges for biomedical R&D in Colombia. They point out that the government has not

been the main facilitator of product development processes. In addition, at the central government level, there is no record of the innovation taking place in the country or how this innovation could be used to address local needs.

## D. Indicators of pharmaceutical R&D capacities and activities

To map pharmaceutical R&D activities in Colombia, the research team identified different databases that could be used to provide information on different stages of product development. These databases provide information about different aspects of the R&D cycle, from public investment to clinical trials. Additionally, we analyzed global clinical trials databases to understand how close to introducing a product or a medical device are domestic innovation efforts when compared to transnational ones.

### I. Funding flows for health R&D

Taking as a main source the Ministry of Science's (MinCiencias) database of funded projects we seek to analyze biomedical production through a series of descriptive variables, which are directly related with the project objectives. This database compiles information about publicly funded R&D projects in Colombia. Specifically, our research group has access to information on R&D projects related to health, presented in 14 different calls for proposals ranging from 2010 to 2019. In total, information is available for 1.534 projects.

The criteria we use to include or discard projects for this review focuses on the potentiality of developing a product at the end of the research process. In this sense, the variables we take into account for the analysis are: year, project title, principal investigator, research group, entity, program, thematic area, type of funding, department and city. We believe these categories allow us to broadly determine which projects may potentially lead to product development(s).

For this preliminary report we complemented MinCiencias' data with two other sources: These are: i) the open-access World Report NIH database on global research investments in Colombia; and ii) the open-access G-FINDER survey by Policy Cures for R&D investments in Colombia. The three databases provide different information, but together they give a relatively good account of the biomedical research activity in the country. Table 1 summarizes and compares each database' characteristics.



Table 1. Databases' characteristics

	Ministry of Science (MinCiencias)	NIH World Report	Policy Cures
Number of projects	1534	468	304
Years	2010-2019	2016-2020	2008-2020
Type of funding	Local	External	Local (177 projects) and external (126 projects).
Information available	<p>Geographical: 1239 projects</p> <p>R&amp;D area and type: information available for 295 projects (2018 &amp; 2019)</p> <p>Recipient organization, researcher, eligibility criteria</p> <p>Funding amounts: In review.</p>	<p>Geographical: All projects (468).</p> <p>R&amp;D area: 439 projects. Manually assigned.</p> <p>Funder &amp; recipient organizations, researcher</p> <p>Funding amounts: 87 projects</p>	<p>Geographical: 0 projects. (No geographical information available).</p> <p>R&amp;D area: All projects (304). Original from database.</p> <p>Funder &amp; recipient organizations, R&amp;D stage</p> <p>Funding amounts: All projects (304).</p>

In order to make the databases comparable we had to clean and transform the data to homogenize some of the common fields like names of cities and organizations, currencies and health areas. We worked particularly hard on health areas given that the MinCiencias database provides information about diseases while the other two databases provide information about types of diseases -e.g. tropical, non-communicable, and so on.

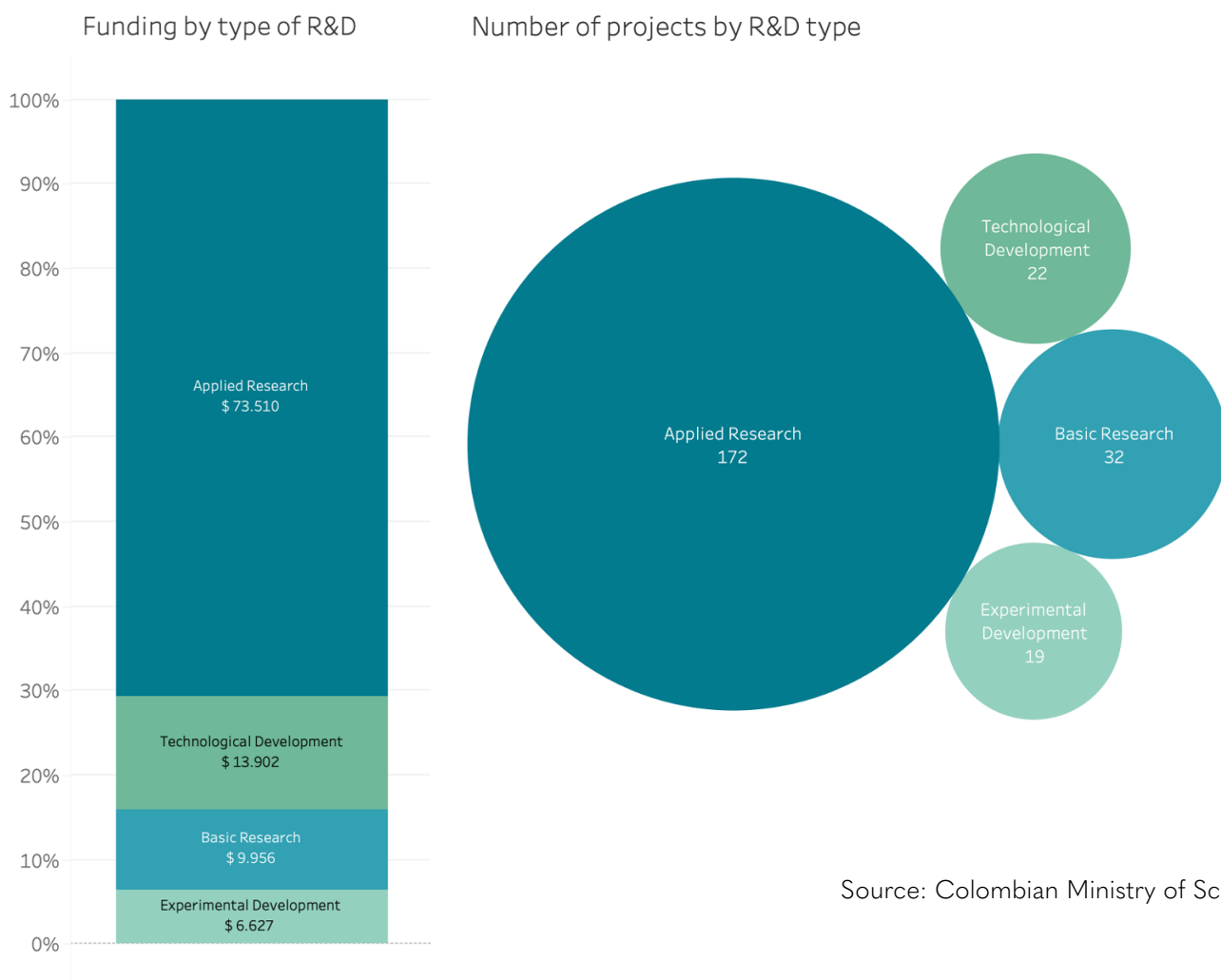
Once we unified key fields across databases we conducted an analysis mapping geographical areas according to their amount of projects and we identified organizations and biomedical researchers with strong funding. Among the biomedical researchers with strong funding we also looked at the health areas they work on and whether they received direct funding or through international collaborations.

Based on our previous research in 2019 with policymakers involved in the Health

Research Fund, we were able to gain access to data about projects presented to this fund (Mejia et al., 2019). Although the data was not standardized due to limitations in the Ministry of Science's information centers, we were able to establish some trends in the publicly funded health promotion environment. Below we present a characterization for what type of R&D is mostly promoted, how projects fall into the different stages of R&D, which are the main health and disease areas funded, and how biomedical innovation is geographically distributed within the country.

As a first finding, we observe that public funding from the Health Research Fund recently has been directed mostly towards applied research. This type of research involves applying existing knowledge to a specific biomedical problem which may be purely research-oriented or also focused on the development of a new drug, therapy, or surgical procedure. Applied research is still research only that it is not basic research, but it uses existing basic research to solve new problems. It is different from technological development as per the definitions used by Minciencias, which happens at a later stage and seeks to develop a new product prototype before it reaches industrial production level<sup>5</sup>. As seen in Figure 3, more than 70% of funding during 2018 and 2019 was for projects in applied research. This data suggests that R&D promotion during this period is risk-averse, as only 10% of total funding is directed towards basic research. In terms of project amounts, only 32 projects in basic research were promoted. This amounts to around 13% of all funded projects.

**Figure 3. Local funding and total number of funded projects by type of R&D, 2018-2019**



Source: Colombian Ministry of Science

The fact that applied research, technological development, and experimental development surpass basic research is coherent with the testimonies we have previously collected from researchers and policymakers. These tend to stress this new tendency in the local biomedical promotion environment towards a more practical, goal-oriented type of research.

According to the interviews conducted for this report, this is a point of tension within both researchers and policy makers alike. On the one hand, researchers that are involved in basic or “pure” science are critical towards the current allocation. Similarly, some policy makers recognize the need of supporting the early steps of the innovation chain. Nevertheless, others celebrate the current way funds are allocated given how this has changed over time. For example, an experienced official that worked both in the Ministry of Health and the Ministry of Science since the creation of the Health Research Fund highlights that since the beginning of the Fund, promotion of basic research was dominant. To policymakers with this point of view, epidemiological criteria tend to be favored over scientific and technical perspectives. For example, since chronic diseases are the leading cause of mortality, R&D should be oriented towards this type of research.

Regarding these tensions, an important point to bear in mind is the average duration of the Health Research Fund’s grants. Due to limitations in Colombia’s policy framework, long-term promotion of R&D projects is on paper inexistent. Grants are legally constrained to a short period of time. Despite this, researchers have adapted “Trojan horse” strategies in which they present their previous projects through new, differentiated research proposals. These types of strategies have allowed some research groups to add certain continuity to their R&D projects. Since a significant amount of biomedical innovation processes require mid- or long-term development processes to advance to the next stages in the innovation chain, these strategies are a make-do solution to the government’s policy restrictions.

To this date public funding has been insufficient to guarantee the advancement of biomedical research into later stages of development. The low institutional capacity is directly reflected in the difficulty of the researchers to obtain funding until the end of their projects. This weak installed capacity opens the way for innovation accelerators to play an important role, as discussed above. They not only finance and support early-stage projects, but also seek to ensure they will continue to advance until their products find a place in the market.

Regarding diseases addressed, the Ministry of Science data for 2018 and 2019 show that non-communicable, chronic diseases, cancer, and rare diseases combined near-

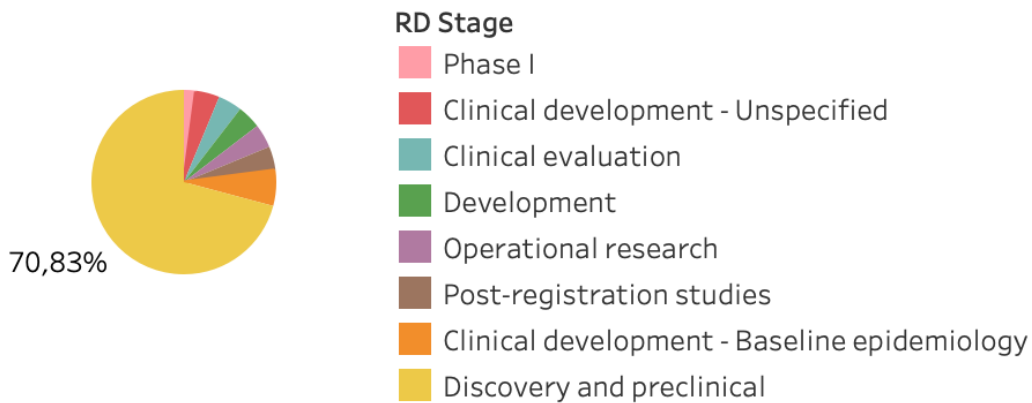
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5 The most recent version of this typology is available here: [https://minciencias.gov.co/sites/default/files/upload/paginas/documento\\_de\\_tipologias\\_-\\_version\\_5.pdf](https://minciencias.gov.co/sites/default/files/upload/paginas/documento_de_tipologias_-_version_5.pdf)

ly doubles the funding for infectious diseases (Figure 4). As noted previously in our first finding, this is coherent with the turn in recent years towards applied research. Therefore, if previously basic research in communicable diseases was the main object of public investment, this appears to have been displaced recently by applied research in non-communicable diseases.

Figure 4. Local R&D funding by health area, 2018-2019

### Distribution by R&D Stage

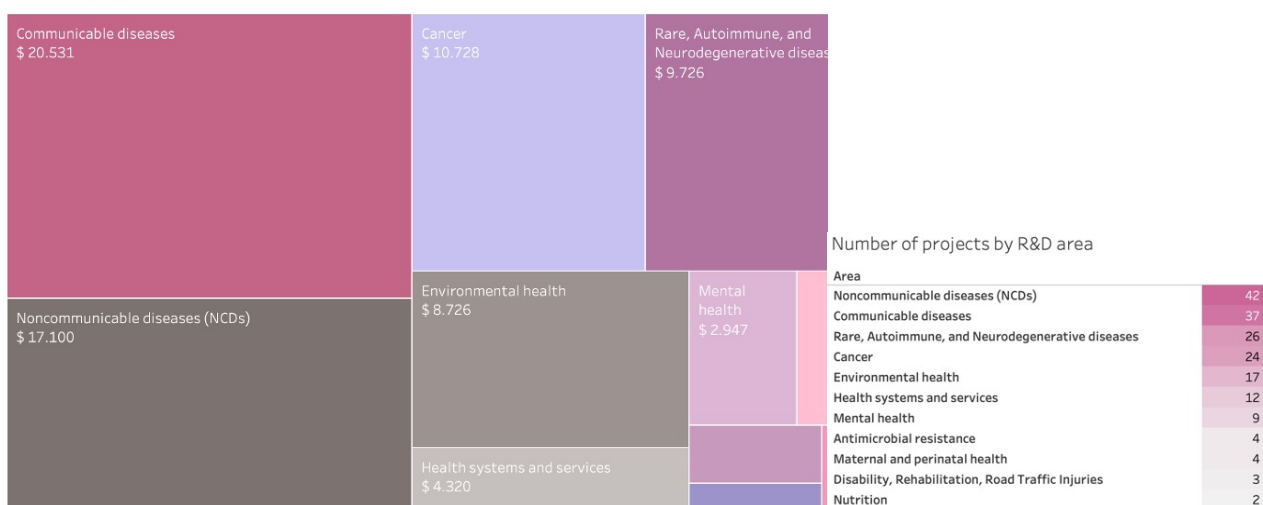


Source: G-FINDER survey, Policy Cures

Looking at a different source of data, only for neglected diseases, we identify that in Colombia the state of biomedical research and development is still weak. As seen in Figure 5, more than two thirds of projects have not progressed from the preclinical stages of R&D.

Figure 5. Locally-funded distribution of projects by R&D stage, 2008-2020

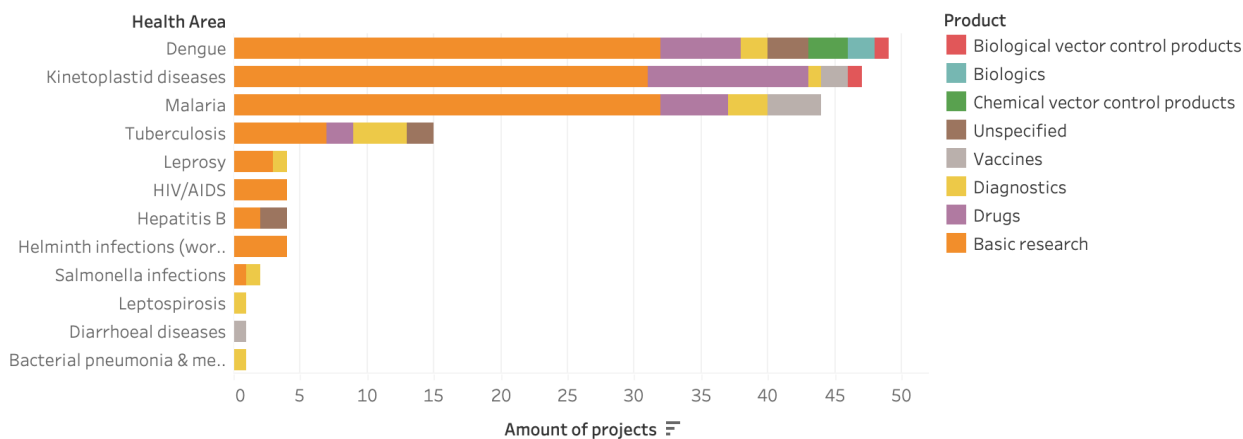
### Funding by area



Source: Colombian Ministry of Science

As for the distribution of funding for neglected diseases over time, we find that from 2008 to 2020 basic research has been predominant and that Dengue, Kinetoplastid diseases and Malaria concentrate the most research (Figure 6).

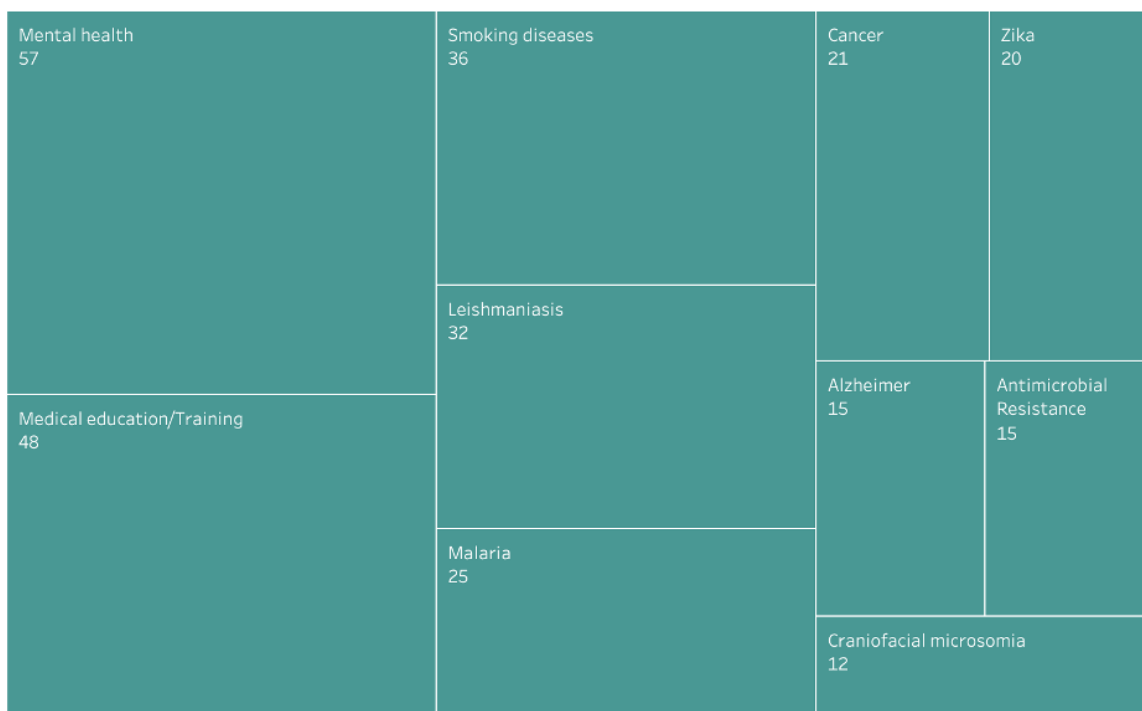
Figure 6. Amount of locally-funded projects per Health Area distributed by type of product developed, 2008-2020



Source: G-FINDER survey, Policy Cures

Although we don't have comprehensive data, the information of the NIH World Report suggests that international funding has been a complementary source of funding for R&D in Colombia. Although the focus remains on communicable diseases, mainly Leishmaniasis, Malaria, and Zika, there is still a relevant participation of non-communicable diseases such as smoking diseases, cancer, and congenital diseases like craniofacial microsomia (Figure 7).

Figure 7. External R&D promotion by health area, 2016-2020



Source: World Report NIH

## International funding

Below we present a characterization for who have been the main external funders, who are the research organizations and researchers that have received most external funding, and lastly how these are geographically distributed within the country.

In the NIH World Report, and once again considering the limited number of funders that are included here, the main international funder, with a total of 364 projects financed between 2016 and 2020, was the US National Institute of Health (NIH). The Canadian Institute of Health Research and the Global Alliance of Chronic Diseases occupy a far second and third place with 35 and 23 projects funded respectively (Figure 8).

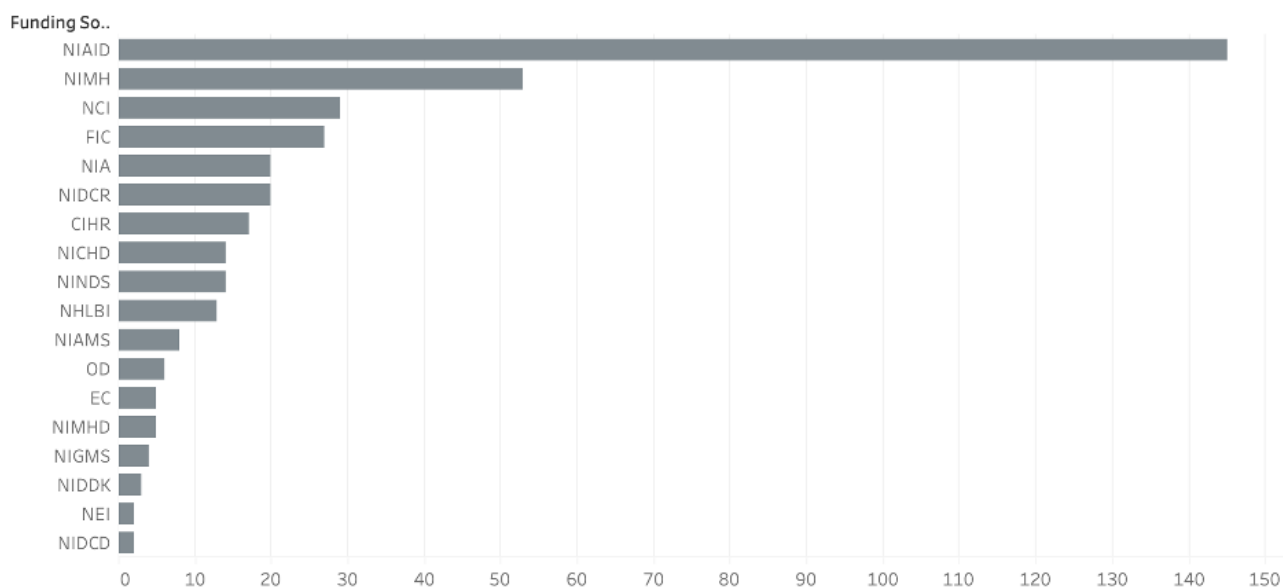
Figure 8. Amount of externally-funded projects by funder, 2016-2020



Source: World Report NIH

In addition, we wanted to see how the leading international funders were disaggregated to identify some of the areas of interest of these organizations (Figure 9). For instance, like it happens with national funding, the NIH seems to be prioritizing research on communicable diseases. As shown in Figure 9, circa 40% of the projects funded by NIH (145) are funded through the National Institute of Allergy and Infectious Diseases (NIAID). It is interesting to note that the second funding source is the National Institute of Mental Health, which sponsored more than 50 projects during the observed period.

Figure 9. Amount of externally funded projects by funding source, 2016-2020



Source: World Report NIH

Major recipients of international funding include public and private universities and research centers. The leading recipient organization is the Universidad de Antioquia, one of the best public universities located in the city of Medellin, with 58 projects funded between 2016 and 2020, followed by the CIDEIM, a private research center located in the city of Cali, and the Universidad de los Andes, a private university located in the capital, Bogota (Figure 10).

The quest for international funding is led by a handful of researchers. Fifteen researchers lead almost half of the projects funded by international organizations, three of them with more than 20 projects granted during this four-year period: Carlos Gómez, a leading psychiatrist from Universidad Javeriana; Francisco Lopera, an Alzheimer disease researcher based at Universidad de Antioquia; and Nancy Saravia, the director of CIDEIM and one of the most recognized researchers on Leishmaniasis (Figure 11).

Figure 10. Amount of externally funded projects by recipient organization, 2016-2020

Universidad de Antioquia 58	Universidad del Rosario 25	Universidad del Valle 23	Pontifical Xavierian University 18	
Centro Internacional de Entrenamiento e Investigaciones Médicas 38	MISC COLOMBIA 12	Pontifical Xavierian University; Hospital Universitario San Ignacio 11	Caucaseco Scientific Research Center 9	Industrial University of Santander 9
	National Cancer Institute (Colombia) 12	El Bosque University 10	Fundación Clínica Noel 7	Malaria Vaccine Development Center 7
Universidad de los Andes 37	National University of Colombia 12	Icesi University 10	Centro Médico Imbanaco 6	Universidad del Norte 6

Source: World Report NIH

Figure 11. Amount of externally funded projects by director, 2016-2020

Gomez Restrepo, Carlos 27 Universidad Javeriana	Herrera, Socrates 14	Sarmiento, Olga Lucia 12	Rodas, Juan David 10	Gaviria Garces, Carlos 9
Lopera, Francisco 21 Universidad de Antioquia	Lopez, Carlos 8	Velez, Ivan Dario 7		Castillo, Jesus Oswaldo 6
	Gomez, Maria Adelaida 7	Anaya, Juan Manuel 6		Gallego, Juan 6
Saravia, Nancy Gore 21 CIDEIM	Valencia Ramirez, Luz Consuelo 7	Arevalo Herrera, Myriam 6		

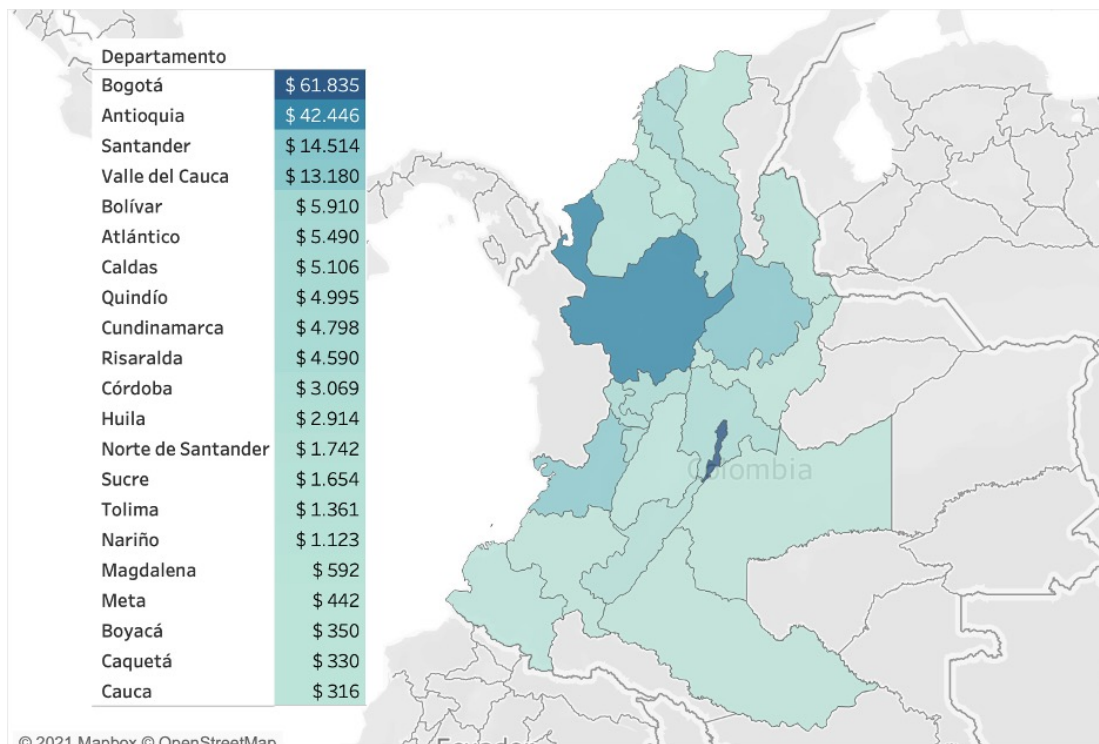
Source: World Report NIH



## Local and external funding at the national level

The graphs below show the geographic distribution of both local and external funding in the country. As Figure 12 illustrates, local funding is distributed across 19 of the country's 32 departments. It is mainly concentrated in Bogotá, the capital, Antioquia, Santander, and Valle del Cauca which are hosts to some of the country's principal cities such as Medellín, Bucaramanga, and Cali, respectively. In these four cities we can find research centers and universities mentioned above such as Universidad de Antioquia (Medellín), CIDEIM (Cali), and Universidad de los Andes (Bogotá). Other relevant organizations are Universidad Nacional and Universidad Javeriana (Bogotá), Universidad del Valle (Cali), and Universidad Industrial de Santander (Bucaramanga).

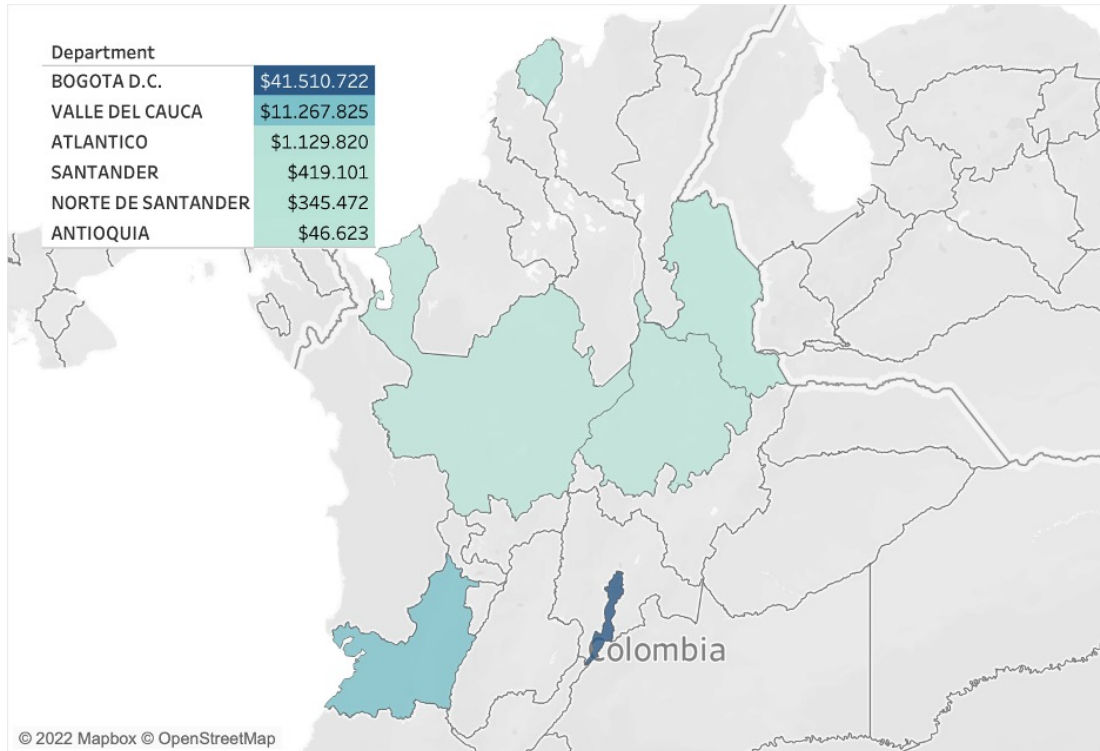
Figure 12. Geographical distribution of local funding (millions of \$COP), 2010-2016



Source: Colombian Ministry of Science

In Figure 13 it might seem evident that the distribution of external funding is much more concentrated in fewer departments. Nonetheless, this conclusion cannot be done given the limited availability of funding data in the World Report NIH database (87 observations). Furthermore, a clean comparison cannot be made due to the differences in time periods for each database. Due to this scarcity in funding data, significant conclusions cannot be made regarding external funding with Figure 13.

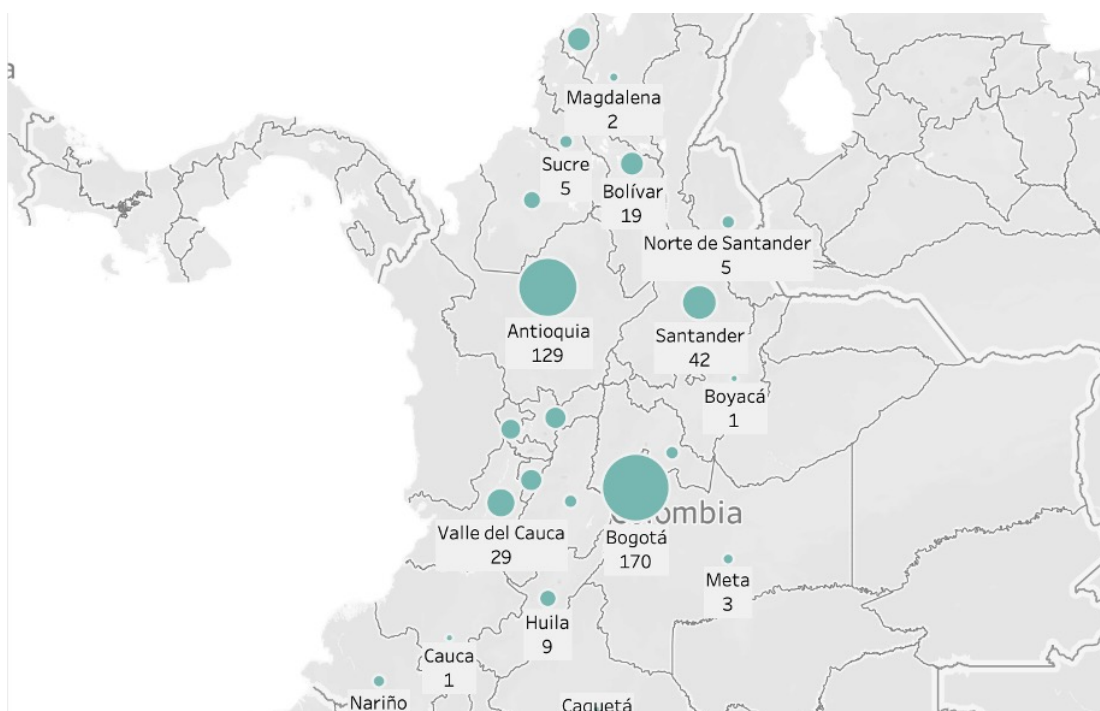
Figure 13. Geographical distribution of external funding (\$USD), 2016-2020



Source: Colombian Ministry of Science

However, when looking at the total number of funded projects, we see that local funding also concentrates in Bogota, Antioquia, Santander, and Valle del Cauca (Figure 14). Bogota and Antioquia comprise more than 55% of the total number of projects. In the case of externally funded projects, Bogota, Antioquia, and Valle del Cauca amount to 74% of the total number of projects (Figure 15).

Figure 14. Geographical distribution of locally funded projects, 2010-2016



Source: World Report NIH, Note: Data available only for 87 projects.

Figure 15. Geographical distribution of externally funded projects, 2016-2020



Source: World Report NIH

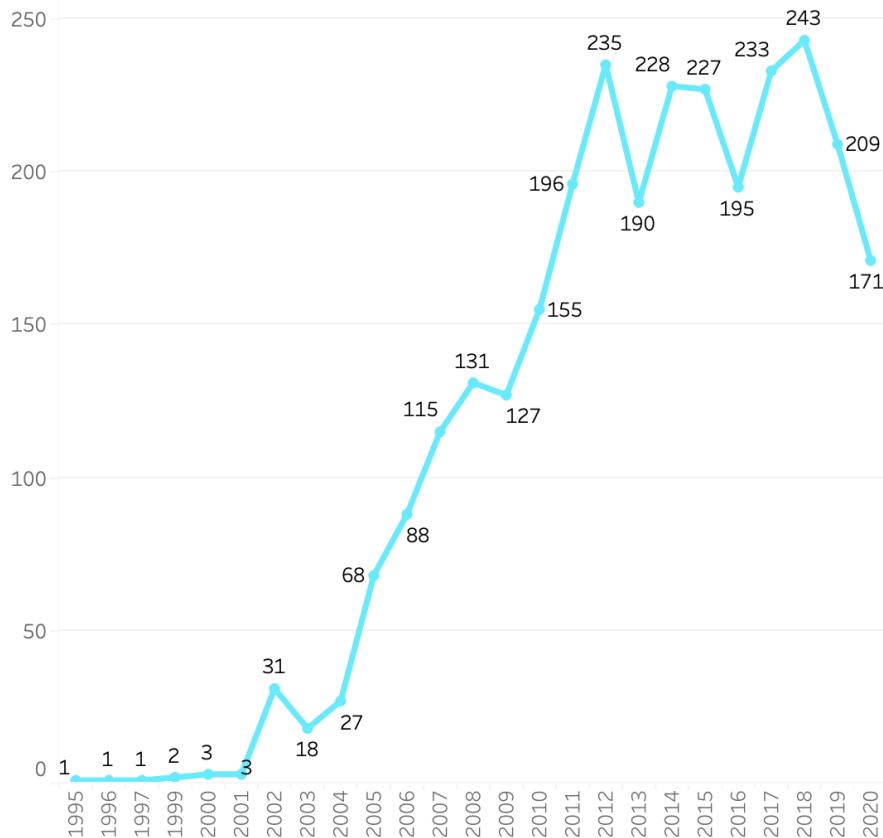
## II. Clinical trials analysis - overview of clinical trials conducted in Colombia

Part of the limits of health technologies' R&D in Colombia, as expressed by researchers in prior research and by innovation accelerators for this report, is linked to the development of clinical trials. There is limited funding for clinical trials of domestic prototypes and possibly regulatory barriers to register local clinical trials. For this reason, we wanted to analyze this aspect for the country and analyze issues such as the diseases to be treated, the actors involved, their characteristics, the number of clinical trials per year, sponsors, among others. As noted in the methodology, for this analysis we used a dataset created by the Global Health Centre based on a cleaned datasets by Merson et al. (2022), that brings data extracted from the International Clinical Trials Registry Platform (ICTRP) of the WHO up to December 15, 2020 and adds a classification of sponsors and funders categorized as commercial and non-commercial, as well as additional information on health categories obtained from the WHO Global Observatory on Health Research and Development. Supplementary data supporting the analysis presented below is available at <https://zenodo.org/record/7802113>.

### *Total number of trials*

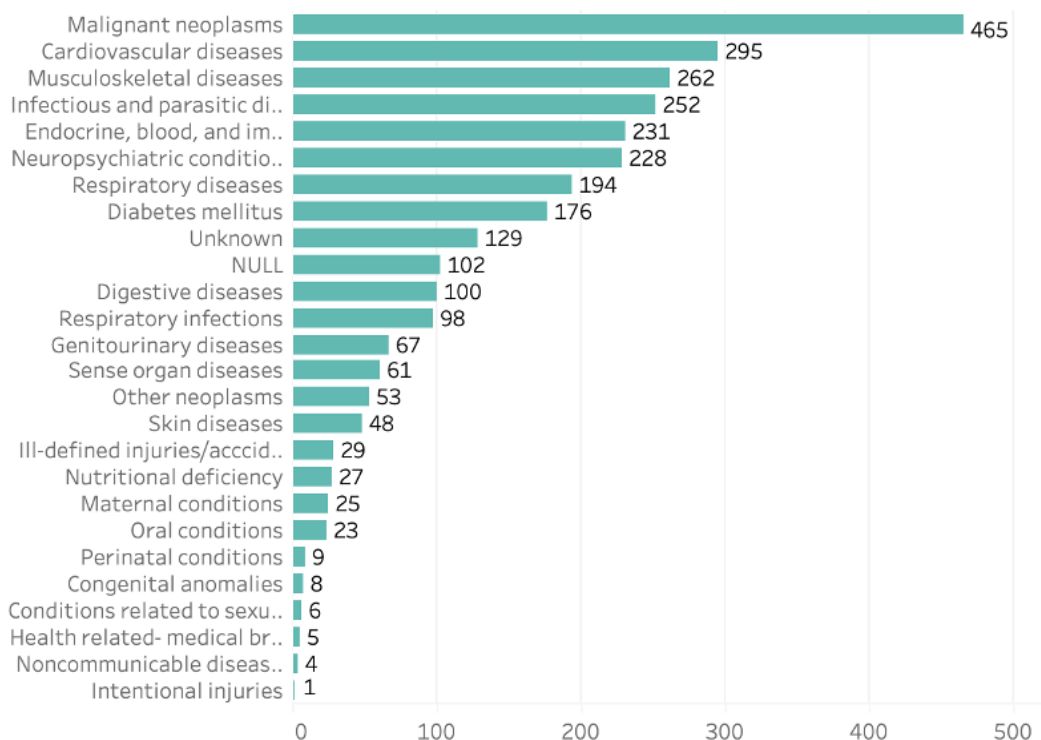
Figure 16 shows the total number of clinical trials developed in Colombia during the period from 1995 to 2020 (period with available records). There is a sharp increase beginning in the late 2000s with the country conducting between 170 and 243 yearly trials since 2010. In total 2898 clinical trials in Colombia were registered in this database.

Figure 16. Clinical trials by year in Colombia (1995-2020)



Besides the distribution by year of the number of clinical trials conducted in the country, we also analyzed how the clinical trials are divided according to their health category. Malignant neoplasms, cardiovascular diseases, musculoskeletal diseases, and infectious and parasitic diseases are the health categories with the highest participation in the country (Figure 17).

Figure 17. Number of clinical trials by health categories in Colombia



## *Types of sponsors and phases of clinical trials*

Furthermore, we reviewed and classified the main sponsors of clinical trials, for this purpose we made a division between national and international primary sponsors. We classified them manually searching for their information on the web. It is possible, however analyzing both the primary and secondary sponsors would deepen our understanding of private-public and national-international collaborations. Clinical trials sponsored mainly by international organizations had most of the participation with about 90% (2597 records), while national sponsors had a participation of around 10% (301 records).

Figure 18 shows the participation of international primary sponsors in clinical trials conducted in Colombia. We observe a very similar distribution to the total number of clinical trials conducted in the country, being the period from 1996 to 2000 the one with the lowest number of clinical trials registered in the country. The following years were mostly dominated by international primary sponsors, but it is from 2010 onwards when the number of clinical trials conducted by national sponsors has been growing continuously. In addition, international trials have had significant fluctuations since 2012, reaching the year 2018, where there is a significant decrease in the number of clinical trials per year until 2020.

Thus, yearly, clinical trials with international primary sponsors represent more than 70% of the total clinical trials. This suggests that the increasing trend in the number of clinical trials conducted in Colombia is explained by global pharmaceutical markets and transnational companies rather than by local R&D processes. This is also consistent with our qualitative findings, which suggest that trials are difficult to fund, and with the analysis of the funding data, which suggests that funding is concentrated in early stages of R&D, both basic and applied, rather than on prototyping (technological development) and production.

Figure 18. Clinical trials per year in Colombia with international primary sponsors (1995-2020)

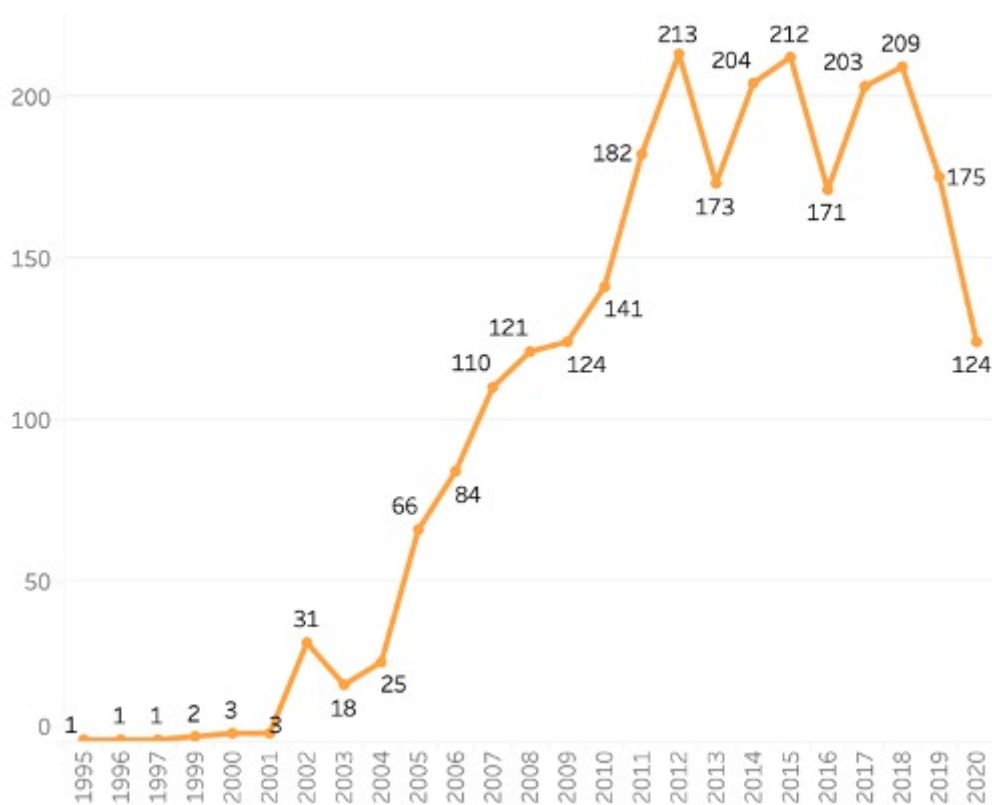
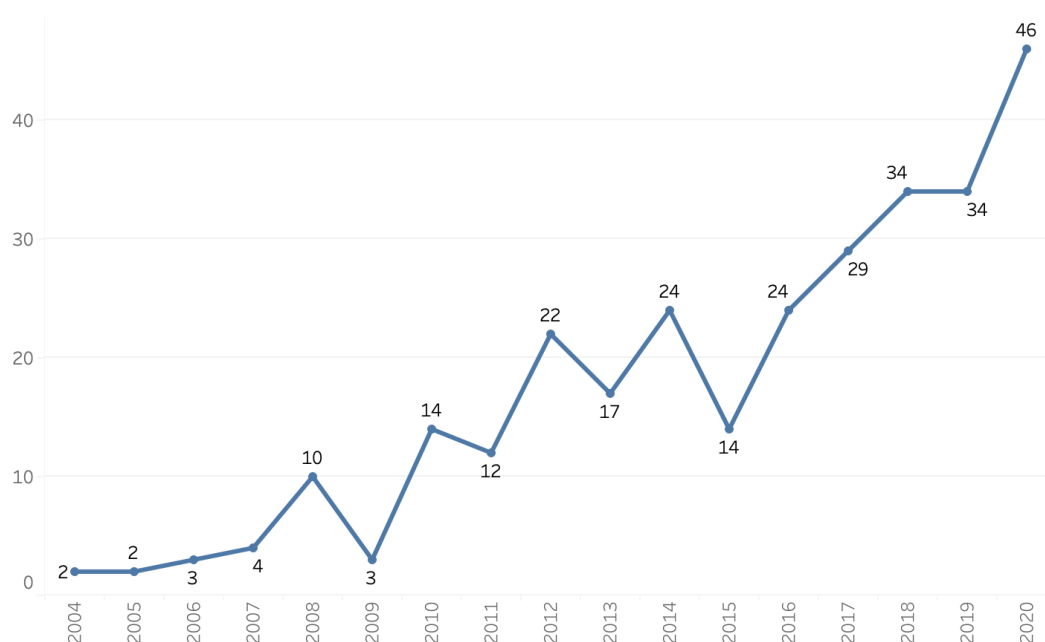


Figure 19 shows the number of clinical trials by year in which the primary sponsor was national, in total 294 clinical trials were conducted in which the primary sponsor was national in the country between 2004 to 2020 (period with available records). There are few clinical trials with domestic sponsors, but still, there has been a general upward trend with periods of fluctuations from year to year.

Figure 19. Clinical trials per year in Colombia with national primary sponsors (2004-2020)



With an outlook of the number of clinical trials, we analyzed how they were distributed in the different phases. For international sponsors, the most common phase was phase 3 with 1590 registrations, followed by phase 2 with 364 registrations and phase 4 with 141 registrations. It is important to note that there is a large amount (387 records) of data where no phase is recorded (Figure 20). For national sponsors, phase 3 is also the most com important, with a total of 44 clinical trials registered, followed by phase 4 with 32 registrations (Figure 21). The remaining phases have a lower participation; however, it is important to note that there are many records in the database in which no reference is made to the phase of the clinical trial.

Figure 20. Distribution of clinical trials by phase (International primary sponsors)

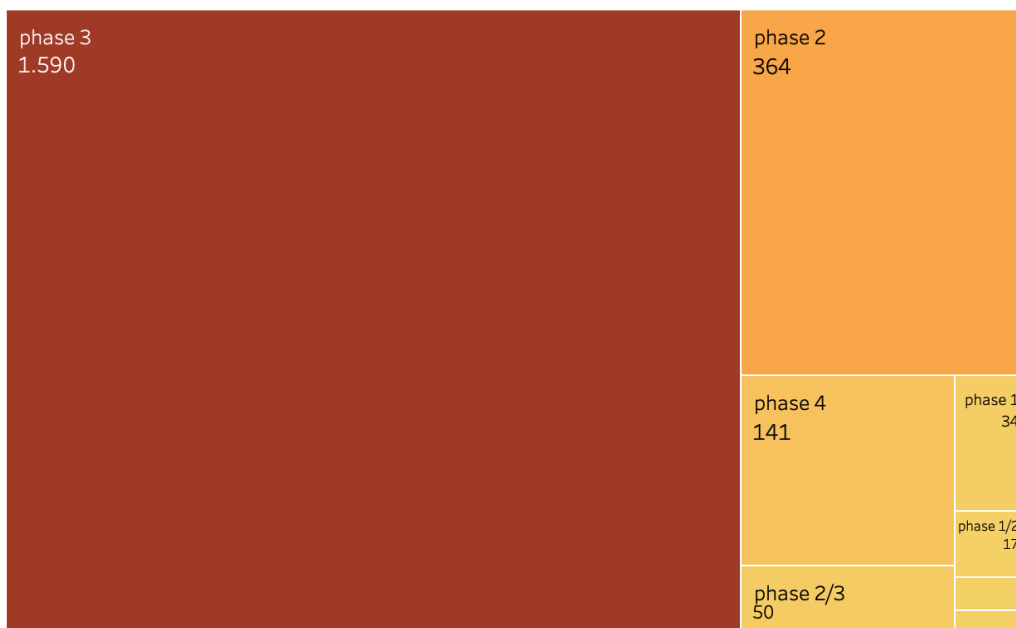
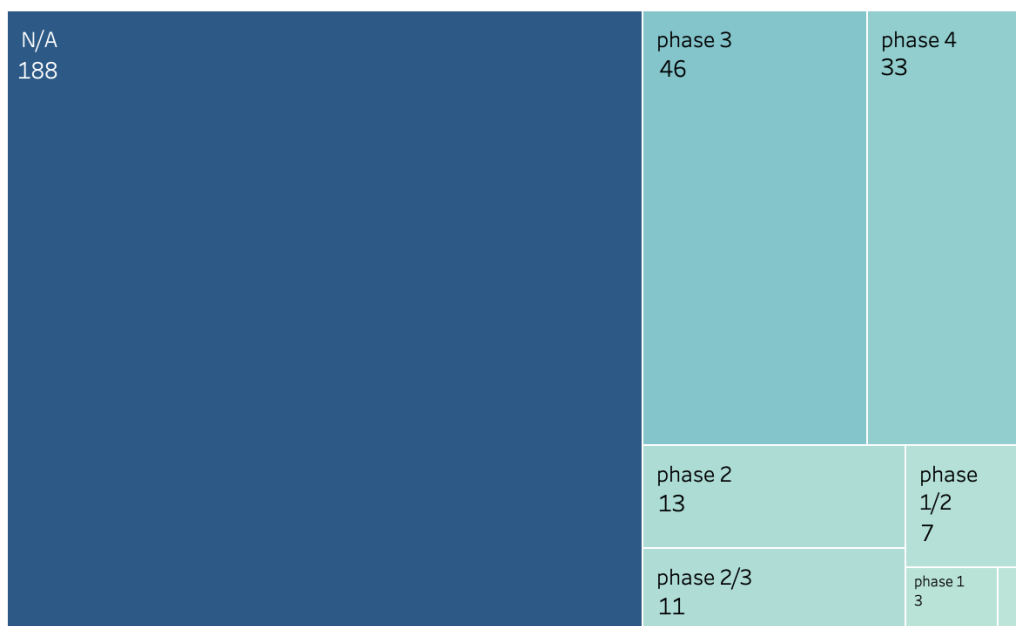


Figure 21. Distribution of clinical trials by phase (National primary sponsors)





Regarding the commercial vs. non-commercial character of primary sponsors on clinical trials, we found that about 91% of the international sponsors are commercial, while less than 9% are non-commercial (Figure 22). By contrast, domestic sponsors are mostly non-commercial (96%), with only 4% of the domestic sponsors being commercial (Figure 23).

Figure 22. Distribution of commercial and non-commercial international primary sponsors

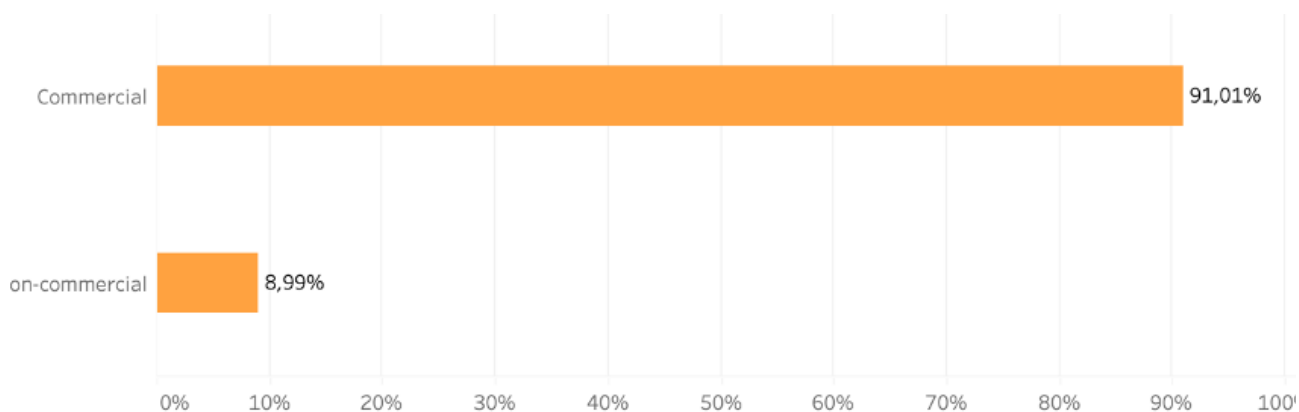
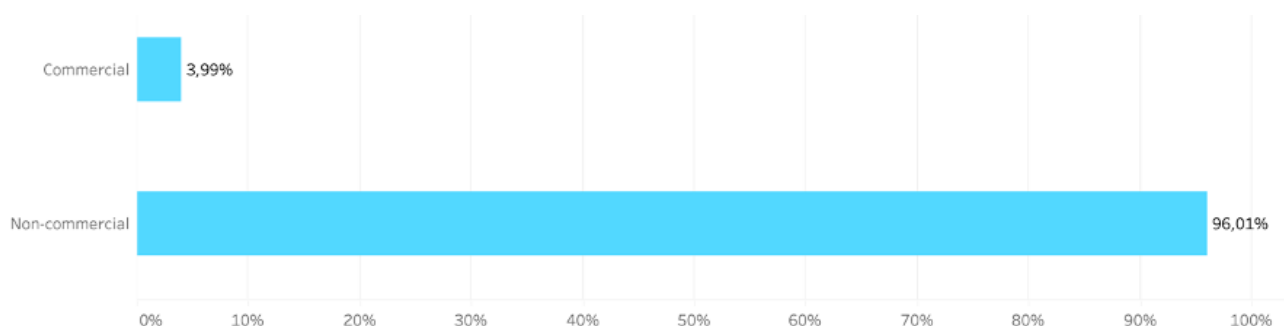


Figure 23. Distribution of commercial and non-commercial national primary sponsors



Now, combining the information of the distribution of the health categories for each type of sponsors with the information regarding the trial phase, we found that for international sponsors the main health categories are malignant neoplasms (457 records), cardiovascular diseases (262 records), and musculoskeletal diseases (251 records) with an emphasis on phase 3 and beyond trials (Figure 24). The information of domestic sponsors is very incomplete with many records (68) having no information available. From the records with information, the main health categories were cardiovascular diseases (33 records), infectious and parasitic diseases (30 records), and neuropsychiatric conditions (24 records) (Figure 25).

Figure 24. Distribution of health categories by phase (International primary sponsors)

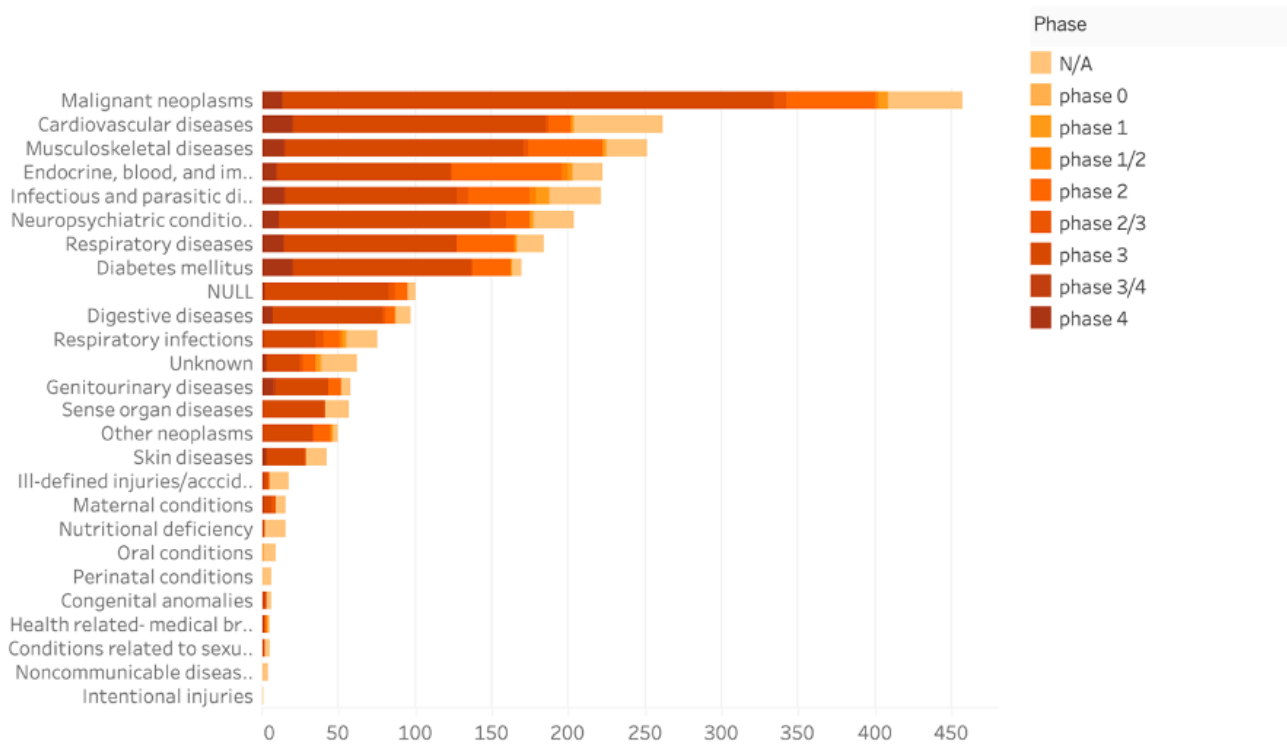
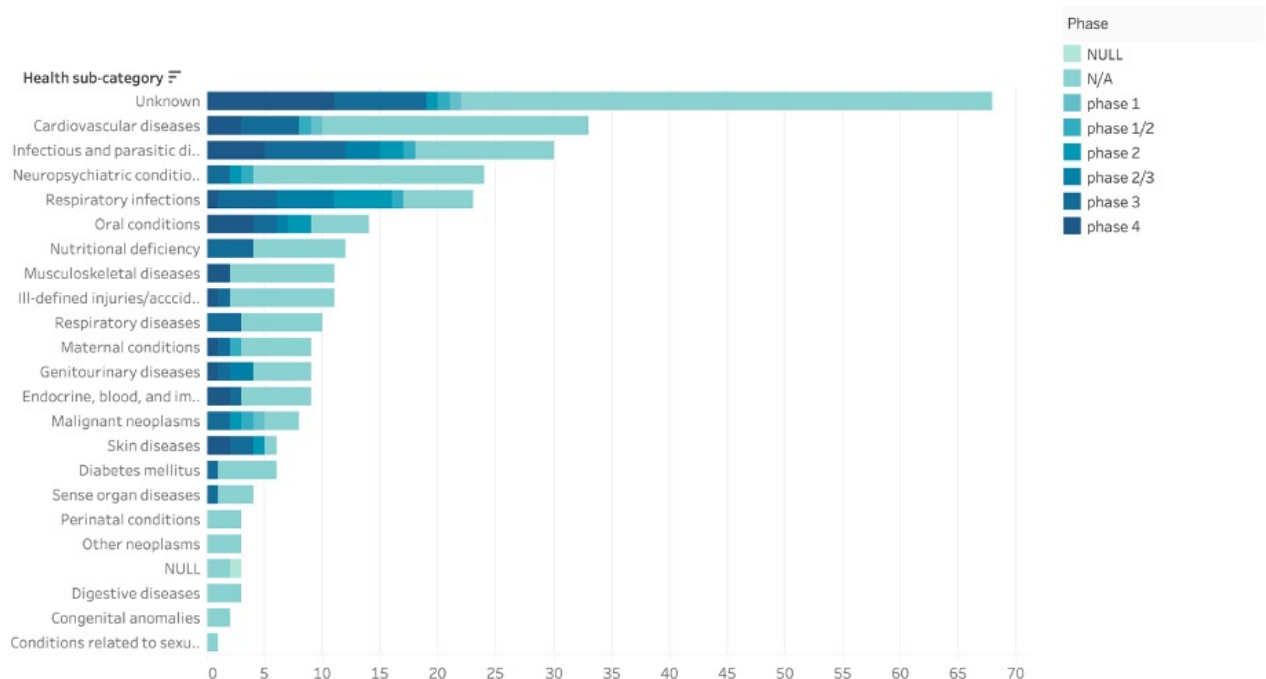


Figure 25. Distribution of health categories by phase (National primary sponsors)

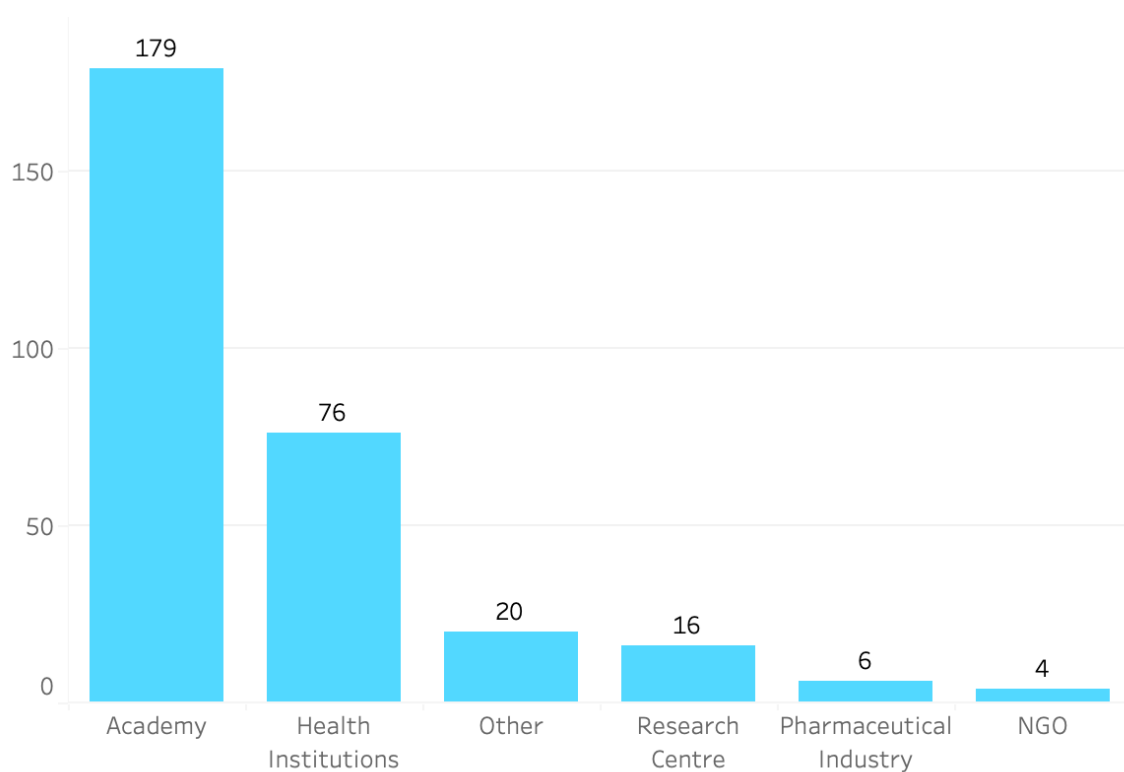


## National sponsor trends

After looking at the previous data of clinical trials in the country, we wanted to do a zoom-in on the participation of national organizations. We analyzed this participation based on the sponsors of clinical trials, specifically the primary ones. This classification was made by checking one by one the different sponsors and separating the organizations that only develop their operations in the Colombian territory.

Furthermore, we categorized the national sponsors depending on their characteristics, looking at their web pages or available information to understand whether they are academic institutions, research centers, health institutions, NGOs, pharmaceutical companies, or other types of institutions (Figure 26).

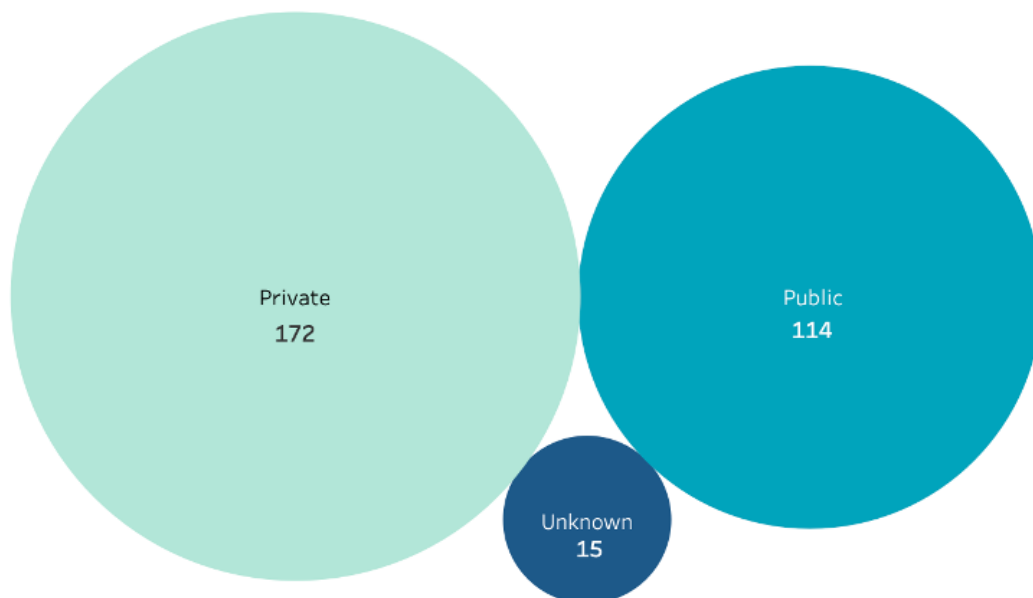
Figure 26. Categories of national organizations that are primary sponsors



According to the data analyzed, the main group of primary national sponsors belong to academia (public and private universities). Among these academic institutions the ones with the greatest participation are the University of Antioquia with 53 trials, the CES university with 20 trials and the National University with 19 trials. Following academic institutions come health institutions where the Cardiovascular Foundation stands out with 12 trials, followed by the Fundación Santa Fe de Bogotá with 11 trials and the Fundación Clínica Valle de Lili with 8 trials. Among the research centers, the Intensive Care and Obstetrics Research Group and the Colombian Neonatal Research Network are the most important. Among the pharmaceutical industry the main organizations involved as primary sponsors are Tecnoquímicas, Lafrancol and Procaps –all of them domestic manufacturers. Finally, for the NGOs the only one with more than one trial is the Corporation for the Fight Against AIDS.

Having this division of stakeholders, we wanted to know how they were divided between those of a public and those of a private nature (Figure 27). For this classification, the websites of the organizations were reviewed, in most cases specifying whether they are private or state-owned. While trials conducted by private primary sponsors are more than those conducted by public ones, the difference is not so significant. This may be the result of alliances between private transnational pharmaceutical companies that act as secondary sponsors and ally with public universities or research centers that act as primary sponsors.

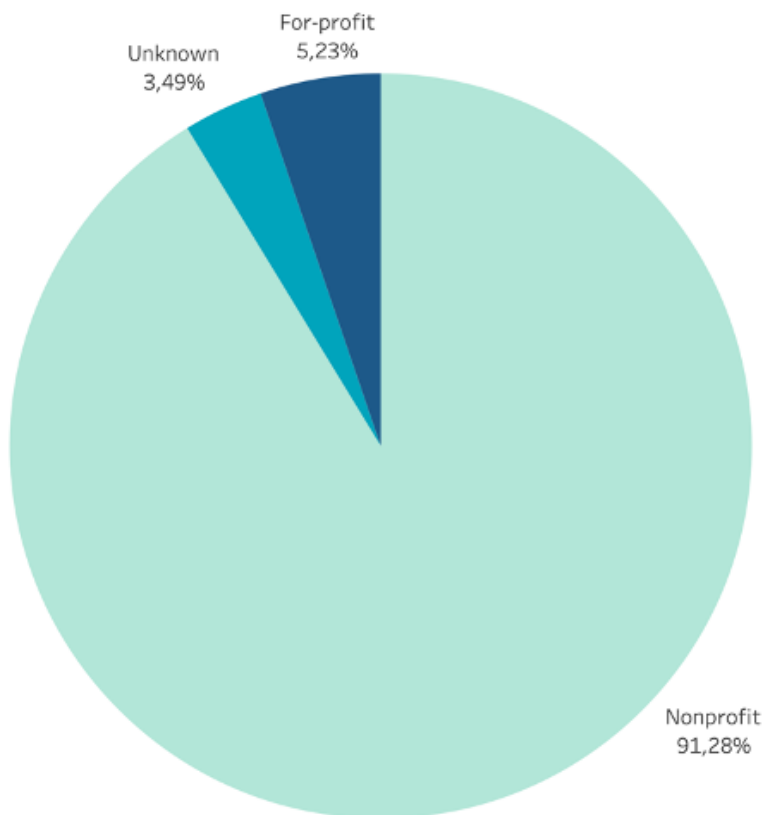
Figure 27. Private and public national primary sponsors involved in clinical trials



Likewise, we examined how private primary sponsors were divided between for-profit and not for-profit (Figure 28). We were particularly struck to see that the largest proportion of actors that were primary sponsors of national clinical trials were nonprofit organizations, with a very low percentage of organizations recognized as for-profit. Among the nonprofit organizations there are many private universities from different regions of the country, as well as hospitals and foundations dedicated to specific areas of health, while in the for-profit organizations there are mostly national pharmaceutical companies. There are also a considerable number of records in which individuals are registered as primary sponsors, but we were unable to determine the nature of their sponsorship.

The classification of the information that we did for the primary sponsor was also intended to be done for the secondary sponsor, but it was not possible because more than half of the registries did not have available data. Similarly, the clinical trials that did have records showed more than one organization involved as secondary sponsor and these oscillated between national and international.

Figure 28. For-profit and nonprofit national primary sponsor organizations



## Colombian clinical trials in regional perspective

After studying the clinical trials in detail for Colombia, we analyzed the country's position in the region. When comparing Colombia with other Latin American countries that have national regulatory agencies of reference –i.e. Argentina, Brazil, Mexico and Chile– we found that although clinical trials have increased in Colombia (2898), the total number of trials is lower than those conducted in Brazil (15471), Mexico (6360), Argentina (5428) and Chile (3199).

As a rough estimate we weighted the two decade total number of clinical trials in each country over their population in 2022. With that estimate the ranking changes considerably: Chile is the country with the highest rate of clinical trials per million inhabitants (163,2), followed by Argentina (119,3), Brazil (71,9), Colombia (55,9), and Mexico (49,9).

Figure 29. Clinical trials done by year in Latin America (1990-2020).

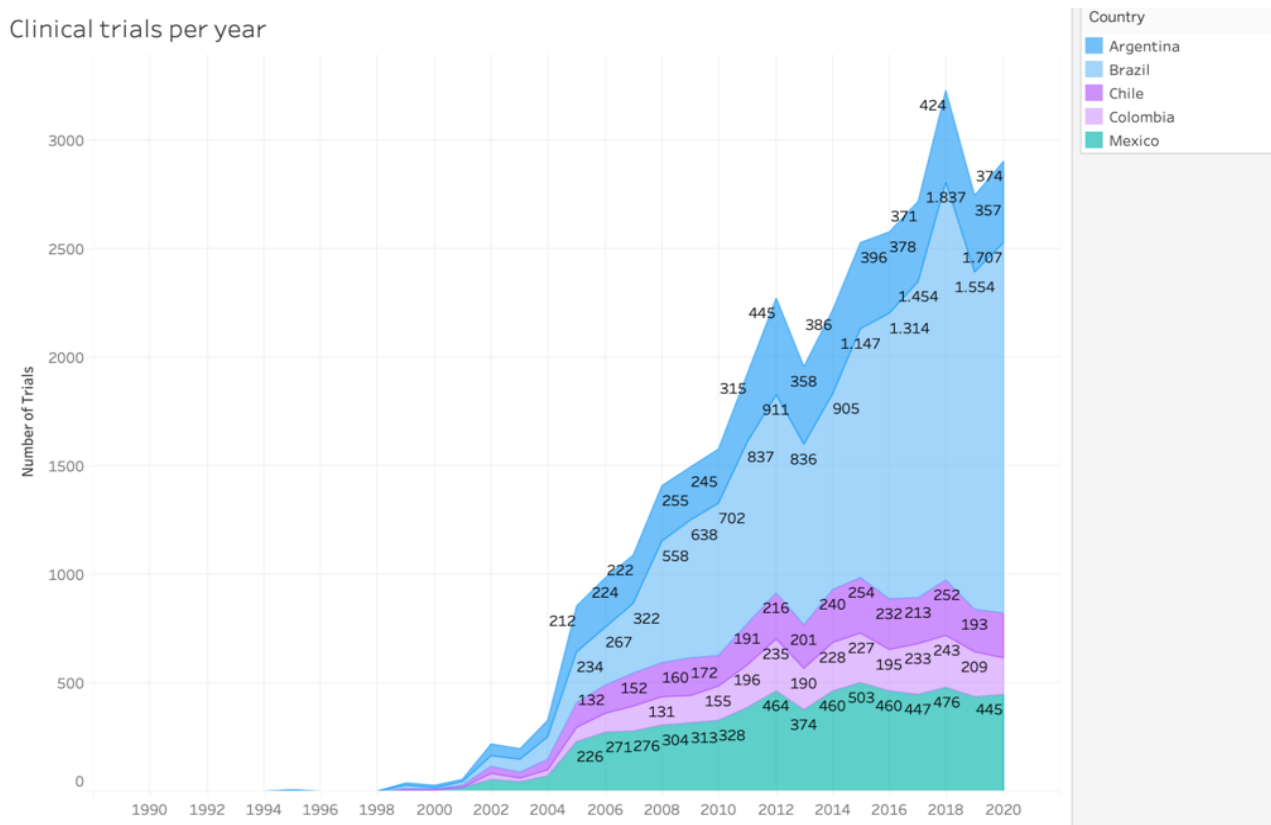
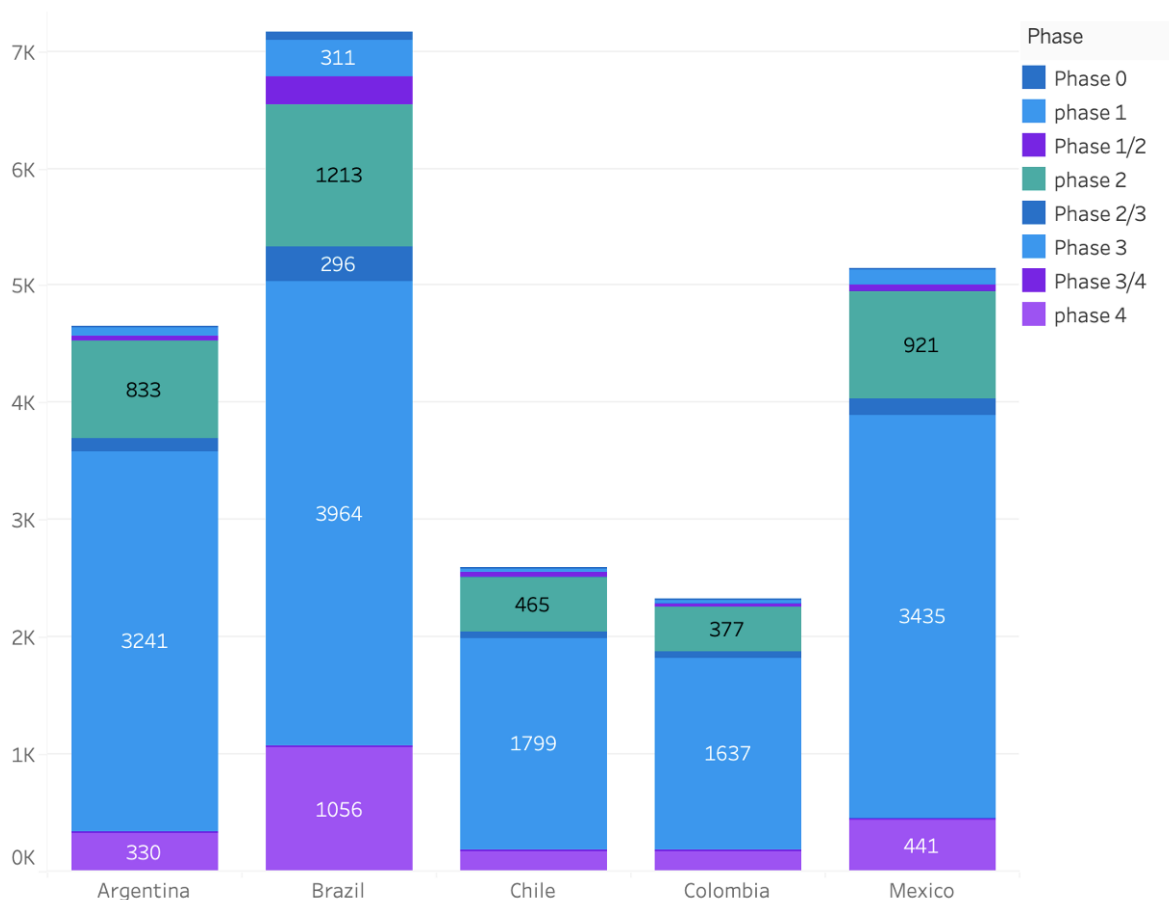


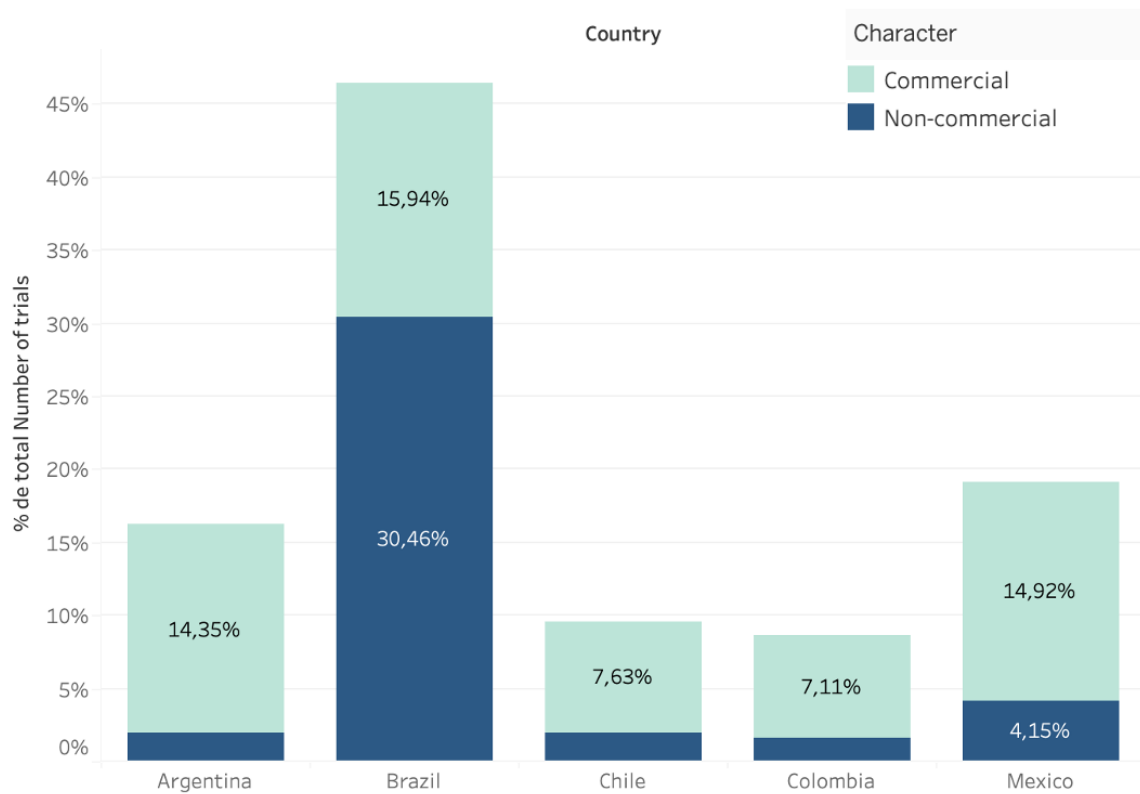
Figure 30. Clinical trials phase in Latin America (1990-2020)



We also analyzed the phases and their distribution for each country (Figure 30). In general terms, the phase with the highest number of clinical trials for all countries is phase 3, with very similar proportions between countries for this phase. The second most common phase for the different countries is phase 2, followed by phase 4, where a considerable increase is seen for Brazil. We were particularly struck by the fact that, although the number of clinical trials varies from country to country, the proportions are very similar for all.

Finally, we were able to observe how the primary sponsors of the Latin American countries analyzed are divided between commercial and non-commercial actors (Figure 31). Based on the data, we found that 4 of the 5 countries studied have similar proportions, where non-commercial primary sponsors have a low participation compared to commercial ones. The only case that is different from the other countries is Brazil, where the majority (30.46%) of the primary sponsors do not necessarily have commercial interests, while (15.94%) do have commercial interests when sponsoring clinical trials.

Figure 31. Commercial and Noncommercial primary sponsors Latin America (1990-2020)



Colombia is thus similar to Chile in the sense that it has had an increasing trend in total clinical trials over the past few years, with a similar proportion of clinical trials within the region, but with mostly commercially sponsored trials, and mostly focused on phase 3. By contrast, a country like Brazil has more non-commercial than commercial sponsors, although proportionally also focusing more on phase 3 trials.



## 4. Discussion of the results, limitations and conclusions

Colombia is the most recent member State of the OECD and it barely invests 0.25% of GDP in science, technology and innovation (STI). While public spending on STI activities recently reached 30% of total funding, private actors contribute the remaining 70%; firms contribute 53% of the total spending, and higher education entities, non-governmental organizations, research centres and government entities contribute the remaining 47%, jointly. Likewise, Minciencias –the Ministry of Science, which is the hub of the national innovation system– is the main financier of seed capital in the country; at a regional level, the departmental (Colombian states) governments contribute to such financing through oil and mining royalty funds allocated to STI activities. However, there are few companies that bet on innovation as a central component of their competitive strategy and, in addition, there are even fewer that operate in technology-intensive sectors.

As stated in the introduction, the pandemic revealed the gaps in access to vital healthcare technologies globally. Considering this, many LMIC countries, including Colombia, have stressed the need to develop a sanitary sovereignty strategy that includes fostering domestic production and R&D. While desirable, such strategies will need more than political will. For the case of Colombia and given the findings of this report, there are three sets of recommendations that we consider indispensable if the country were to embark on a serious R&D and industrial policy strategy for the health sector.

First, there must be a concerted effort to strengthen domestic production and R&D with major participation from the state. A national government that aims at enabling their firms to persistently generate new products will have to lend a hand for these firms to continuously have access to funding. Indeed, government programs that enable a “one-shot” investment should be replaced by government programs that motivate continuous R&D investments. Moreover, public funding should be targeted to enhance the translation of basic and applied R&D into actual prototypes and products when R&D proves promising and is targeted to solving strategic health priorities for the country. As illustrated in our literature and policy review section, all of this

will only be possible with increased investment and coordination across government agencies.

Second, the government should foster public-private partnerships to encourage technology transfer to increase domestic production capacities, once again prioritizing strategic health technologies such as vaccines. As revealed in the analysis of clinical trials' data, the country is participating in phase 3 and phase 4 trials for international sponsors, but the production of such products occurs elsewhere. A public-private technology transfer policy could work similarly to the one developed in Brazil under the productive development partnerships (parcerias para o desenvolvimento) -PDPs program. Colombia publicly finances most health technologies so it could use its purchasing power through centralized negotiations to incentivize private partners to transfer their technology.

Third, these efforts need some type of regional coordination mechanism, so that countries in the Latin American region won't end up developing redundant capacities and producing inefficiently and/or expensively the same health technologies.

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# 6. Annex

## Scoping interviews - sample interview questions

1. **Introduction and short explanation of the research objectives**
2. **Context and Prioritization of R&D activities**
  - a. Can you describe the work of the organization to which you belong and your work in it? (Probe: designation/position, prime role and responsibilities, link to R&D)
  - b. How do you see your organization's role in the R&D ecosystem?
  - c. How does your organization decide on its priority areas of focus (e.g., therapeutic, technology, policy areas)?
3. **Resources and Sustainability**
  - a. What is your organization's financing strategy? What are the main challenges you face in sustaining the organization financially?
  - b. Can you quantify your institution's contribution in financial terms?
  - c. For organizations that provide (non-financial) resources to R&D initiatives: What requirements or conditions are expected to be met by R&D organizations to whom you provide resources? How do you decide on these conditions and how do you ascertain whether they have been met?
  - d. Can you name and explain the type of projects you have funded or contributed to?
4. **IP and Data**
  - a. Can you tell us about your organization's approach to information- and data-sharing, whether internally or externally? (e.g., contracts, data, clinical trial results, publication)?
  - b. What is your organization's approach to IP management (e.g., patenting, in- or out-licensing, march-in rights, geographical coverage, enforcement)?
5. **Industrial Policy**
  - a. How can you describe the industrial policy on medicines, R&D and biomedical innovation in Colombia?
  - b. What are the most important challenges and obstacles to achieve better R&D results?

**6. Closing questions.**

- a.** Are you aware of any other public or philanthropic contributions to the discovery or development of biomedical technologies in Colombia?
- b.** Who else, within or outside your organization, would you recommend we try to speak with?

