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THE BIOPHARMACEUTICAL COMPETITIVENESS & INVESTMENT (BCI) SURVEY 2025

Latin America Special Report

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Executive Summary

Biotechnology has become a cornerstone of economic growth. Emerging as a pillar of the Fourth Industrial Revolution, it involves the use of biology and biological tools to create everyday products and innovation. Among the web of industries making up the biotechnology sector, the biopharmaceutical industry stands out, with an estimated growth rate of over 8% until 2032. High-income economies tend to be global leaders in biopharmaceutical industries. Yet, policies they introduced over the last couple of years are decoupled from the importance of the bioindustry in these economies, while emerging actors have clearly signaled their intention to utilize their market size to attract investment. The changing international landscape can be an opportunity for Latin America to attract investment in the biopharmaceutical sector, leveraging its natural resources and capabilities.

Project rationale

FIFARMA, the Latin American Federation of Pharmaceutical Industry commissioned Pugatch Consilium to develop a 2025 Latin America edition of the Biopharmaceutical Competitiveness & Investment Survey. The Survey examines the entire ecosystem in which biomedical innovation takes place from scientific capabilities and infrastructure to the state of the clinical environment, the biomedical regulatory framework (including the protection of intellectual property), and healthcare financing.

The BCI adopts a "bottom-up" approach based on feedback from executives – country managers and their teams – to get a snapshot of the biomedical competitiveness of a given country. Their responses reflect a candid and often accurate understanding of the different aspects of their respective markets. The 2025 BCI Survey covers ten Latin American countries: Argentina, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Mexico, Panama and Peru. A statistical analysis ranked each country with a quantitative score (out of 100). The result benchmarks each country in relation to others in the region, revealing their relative attractiveness for biopharmaceutical investment.

Key findings

Key finding 1: As a region, Latin America lags behind leading emerging markets in biopharmaceutical competitiveness

Collectively, Latin America scores 59% of the total available score on the 2025 BCI survey. While this represents a slight improvement since the 2017 edition of the BCI Latin America survey, there is still much room for improvement before the region becomes a top competitor in biopharma.

For reference, the region ranks below the scores observed in the Asia Pacific and Middle-East and North Africa regions in the 2019 Emerging Markets BCI survey. Leading emerging markets, such as Israel, Taiwan and Singapore, score between 75 and 85% – well above the scores of Latin American top performers.

Key finding 2: Within the region, the biomedical pulse is fragmented with a handful of top performer leading the way

The gap between top performers and regional laggards has increased between 2017 and 2025. This is due to contrary trends between the majority of economies which have improved their policy landscape, and some markets which have deteriorated.

Overall, the region is led by Costa Rica, Chile and Mexico, the top performers in biopharmaceutical attractiveness in Latin America. They score between 65% and 70% of the possible score.

At the bottom of the scoreboard, Ecuador scores below 50% of available score, while Colombia achieves a score of 53%.

Key finding 3: Market access and IP protection face challenges that must be urgently addressed

Market access and financing and effective IP protections are the two areas facing the most challenges in the region. This is due to the implementation of policies by a majority of economies which hinder rather than encourage innovation, and harm their biopharmaceutical competitiveness in the process.

List of Abbreviations

ANVISA	Brazilian drug regulatory agency
BCI	Biopharmaceutical Competitiveness & Investment survey
COFEPRIS	Mexican drug regulatory agency
EFPIA	European Federation of Pharmaceutical Industries and Associations
EU	European Union
GDP	Gross domestic product
HIV	Human immunodeficiency virus
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
INVIMA	Colombian drug regulatory agency
IP, IPR	Intellectual property rights
LatAm	Latin America
NHS	National Health Service
P&R	Pricing and reimbursement
PAHO	Pan American Health Organization
PCT	Patent Cooperation Treaty
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
USTR	United States Trade Representative
WTO	World Trade Organization

Introduction – A look at biopharmaceutical attractivity and the current international landscape

Attracting investment in biopharmaceutical industries – Why does it matter?

Biotechnology has become a cornerstone of economic growth. Emerging as a pillar of the Fourth Industrial Revolution, it involves the use of biology and biological tools to create everyday products and innovation.[1] Among the web of industries making up the biotechnology sector, the biopharmaceutical industry stands out, with an estimated growth rate of over 8% until 2032.[2] In fact, spending on medicines created with biotechnology is estimated to grow from around $431 billion in 2022 to over $650 billion in 2027 – a 50% increase in 5 years.[3]

For example, the impact of the biopharmaceutical industry on the world economy was felt during the COVID-19 pandemic. Major pharmaceutical companies, such as Pfizer and Moderna,, produced vaccines to curb the spread of the virus in under a year – a result achieved through the application of mRNA technology. This impact is set to increase with biotech breakthroughs in gene and cell therapy, and in cures for rare diseases.

Shifting biopharmaceutical policy trends – Do as I say, not as I do

High-income economies tend to be global leaders in biopharmaceutical industries, and attract the most investments. For example, economies such as the United States, Singapore and Switzerland consistently rank at the top of previous editions of the BCI, in mature and emerging markets alike.[4] Similarly, in 2022, the United States and

[1] World Economic Forum, 'The Fourth Industrial Revolution: what it means, how to respond' (14 January 2016).
[2] Fortune Business Insights, March 2025.
[3] IQVIA, *The Global Use of Medicines 2023* (January 2023).
[4] See for example, BCI 2017 for emerging and mature markets.

Europe combined were responsible for more than 80% of all R&D expenditure in the pharmaceutical industry globally.[5] These economies have identified biopharma as a critical industry of growth, and claim to work towards increasing innovation and investments towards it.

Yet, policies introduced over the last couple of years in these leading biopharmaceutical markets are decoupled from the importance of the bioindustry in these economies. In the US, the 2022 Inflation Reduction Act differentiated between chemical and biological drugs for the purposes of drug price negotiation. This measure, commonly referred to as the pill penalty, disincentivizes innovation in small-molecule medicines. Since its introduction, early-stage funding for small-molecule development decreased by 70%,[6] and academic sources estimate that 188 fewer small molecule treatments could reach the market over 20 years as a result.[7]

In the United Kingdom, the government recently proposed to increase the payment rate that pharmaceutical companies must pay to the government for sales they make to the NHS. While it was previously set at 10.6% between 2019 and 2022, the government now proposes to increase this rate to 23.8% in 2025, with further increases in the next couple of years.[8] This has prompted major biopharmaceutical companies to alert that this increase would make the United Kingdom less attractive to biopharma investment.[9]

The European Union has also made proposals which would harm its biopharmaceutical environment. The proposed EU Pharmaceutical Legislation, commonly called the pharmaceutical package, would introduce measures undermining the IP framework that widely incentivizes innovation and R&D. On the one hand, the baseline period for regulatory data protection would be decreased, while adding complex conditions to increase this period on a case-by-case basis. This differentiation between new medicines arriving on the market, much like the pill penalty in the US,

[5] EFPIA.
[6] PhRMA.
[7] University of Chicago policy brief, *The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act*, 5 October 2023.
[8] ABPI, 'UK set to demand a third of pharmaceutical company revenue in second half of 2025' (14 March 2025).
[9] ABPI, 'Medicine levy makes the UK un-investable, say pharma leaders' (20 March 2025).

would discourage innovation in fields not covered by these narrow exceptions. On the other hand, the EU pharmaceutical package also includes measures to strengthen the compulsory licensing framework, including on an EU-wide level, further weakening effective IP protections in the life sciences sector. Together, these measures risk decreasing the attractiveness of Europe for biopharmaceutical investment, accelerating a decade-long trend of lagging behind other major actors.[10]

Meanwhile, emerging actors such as China and India have clearly signaled their intention to utilize their market size to attract investment and develop biopharmaceutical operations. China, particularly, has seen high growth of biopharmaceutical R&D. According to the EFPIA, China's annual growth rate of biopharmaceutical R&D was 16.3% between 2019 and 2022, more than double that of Europe and triple the US's R&D growth rate during the same period.[11] In addition, 34% of high-value licensing agreements in 2024 involved molecules sourced from China, up from only 6% in 2020.[12]

These contrary trends, coupled with the uncertainty created by the prospects of a tariff war between the United States and China,[13] suggest a shift in the power dynamics behind biopharma. Stronger economies are facing challenges to their attractiveness, while facing aggressive competition from emerging actors.

Where does Latin America fit within the global landscape?

In this context, a question arises: what about Latin America? Historically, the region has been confined to the margins of the biopharmaceutical industry. In 2022, Latin America accounted for only 1% of global pharmaceutical exports, down from 1.97% a decade earlier.[14] It is largely underrepresented, as the region houses over 8% of the world's population.[15]

[10] EFPIA, *Assessment of main provisions and key EFPIA recommendations on the revision of the pharmaceutical package* (October 2023).
[11] EFPIA.
[12] Stifel, 'Biopharma Market Update' (31 March 2025).
[13] At the time of writing this report, the American administration has repeatedly threatened the pharmaceutical industry with high levels of tariffs, despite this sector being historically exempt from such duties since the WTO's 1994 Pharma Agreement.
[14] Observatory of Economic Complexity, historical data for pharmaceutical products (HS30).
[15] World Bank.

The changing international landscape can be an opportunity for Latin America to attract investment in the biopharmaceutical sector, leveraging its natural resources and capabilities. However, this can only be achieved by understanding how to increase the region's attractiveness to biopharma investment. This requires understanding existing policies in place in the biopharmaceutical sector, and which policy areas to focus improvement on.

The Biopharmaceutical Competitiveness and Investment Survey 2025 – Rationale and methodology

Measuring the biopharmaceutical policy environment – The BCI in the statistical analysis toolbox

Various tools exist for mapping the biopharmaceutical policy ecosystem, including those that measure investment competitiveness more generally; those that focus on particular sectors; and those that measure specific policy areas.

Generally speaking, key measures of broad competitiveness and innovation rely on hard data and indices. Economies are ranked based on a set of quantitative and qualitative indicators such as number of hospital beds or physicians per capita, R&D expenditure in life sciences, or government spending on health. Statistical relationships are established between different indicators and the economy's performance in biopharma overall.

One aspect that, thus far, has been missing from the existing body of data is the on-the-ground perspective of the investment attractiveness of a given economy in Latin America specific to the biopharmaceutical sector – its biomedical "pulse". The BCI Survey, an executive opinion survey, aims to fill this gap.

Gauging the sentiment in biopharmaceutical executives

The BCI is an executive opinion survey that has been conducted globally and regionally since 2012. It examines the entire biopharmaceutical ecosystem, from the clinical and R&D environment to P&R, IP and the regulatory system.

The BCI seeks to capture the opinion of country- and region-level general managers and management teams, who serve as a focal point both inside their organization and

vis-à-vis the economy where they operate. The main focus of the survey is to collect experts' views about the prevailing market conditions in their respective economies. General managers and other industry leaders are responsible for making financing and investment decisions for their organizations. As such, their sentiment about the markets they operate in serves as an effective proxy for understanding the attractiveness of these economies.

By surveying relevant industry stakeholders, BCI results are representative of the perception of market conditions in ten major Latin American economies. This sentiment gives a snapshot of the biomedical pulse in each economy and in the region overall in real time. While executives' views only provide a perception of the market, they tend to be homogeneous among the surveyed population. Indeed, industry experts are well-informed, speak the same professional language and are able to provide an expert opinion on the subject matter. Their perception is critical to understanding the biopharmaceutical landscape in Latin America.

The sample of the BCI survey

The 2025 BCI LatAm Report covers ten countries in Latin America selected on the basis of their contribution to the regional GDP and trade and relative size of the biopharmaceutical market. As such, the 10 markets included in the BCI LatAm in 2025 capture many of the largest and most active biopharmaceutical markets region-wide.

Figure 1. Economies Covered in the 2025 BCI LatAm Special Report

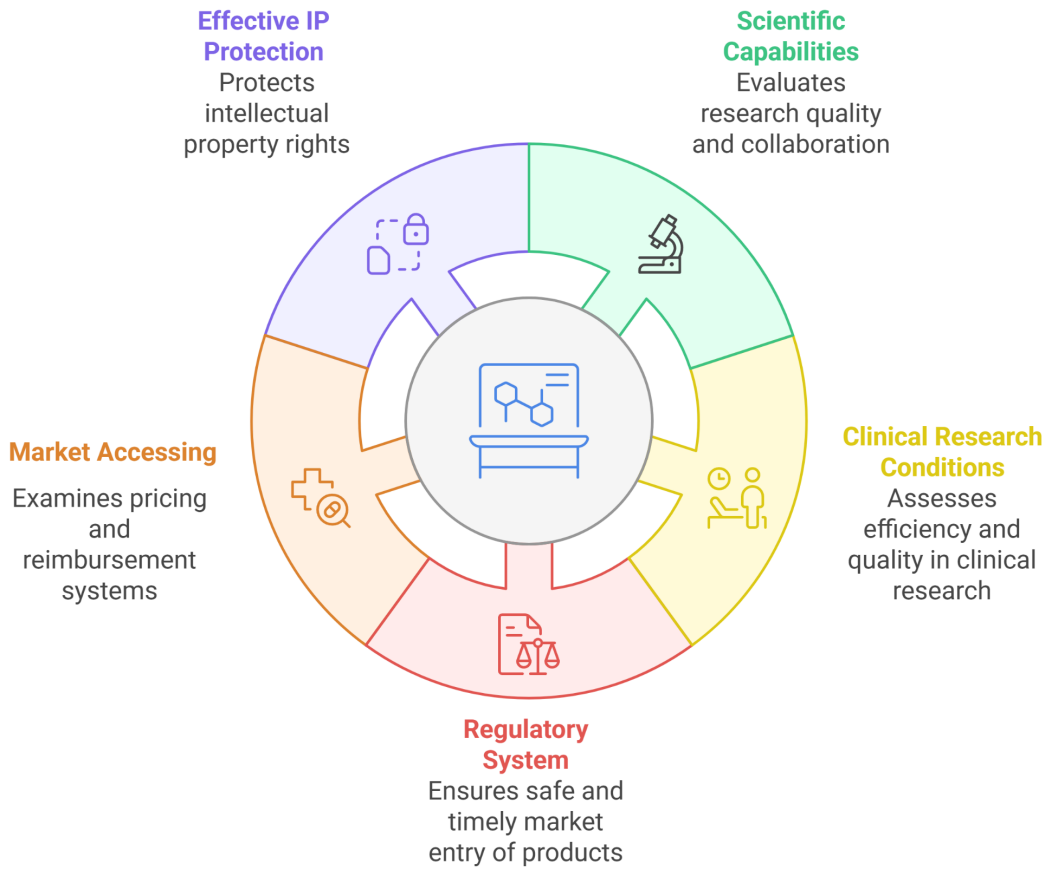
Argentina	Dominican Republic
Brazil	Ecuador
Chile	Mexico
Colombia	Panama
Costa Rica	Peru

These economies have all previously been included in earlier BCI Surveys, including the 2017 LatAm Special Report. Comparing their current results with previous scores reveals a number of important trends regarding the competitiveness of the respective economies and of the region as a whole. Has the environment improved or are executives on the ground in these countries still facing many of the same challenges they were eight years ago?

What factors does the BCI Survey measure?

Based on existing literature and experience, it is possible to piece together a set of principles and factors which - evidence suggests – are collectively enablers of biopharmaceutical innovation. These factors range from what might be termed "hardware" such as R&D infrastructure and human resources, and "software" such as public policies ranging from IPRs to regulatory capacity and standards to market and commercial incentives. These enabling factors are presented in figure 2.

Figure 2. Factors that Enable Biopharmaceutical Innovation



Scientific Capabilities and Infrastructure

Biopharmaceutical innovation is driven by an adequate environment in which biomedical research can take place. This includes a sustained supply of modern infrastructure and specialized human resources available and utilized for biopharmaceutical innovation. Notably, universities and public research institutions can play a key role in the process of fundamental biomedical research and discovery of new molecules and biologics.

As such, questions in this category assess the quality of personnel, technologies and facilities in biopharmaceutical research forums in the economy; the extent of collaboration between public and private research partners; and the ability to leverage these to translate discoveries into products.

Clinical Research Conditions & Framework

Clinical trials are the most significant part of the research and development of new medicines. It determines whether a chemical compound or biologic is safe and effective for treating a medical condition, helps determine optimum dosages and best ways of administration. It also can uncover new applications or tailor drugs to different populations. Investment in clinical research naturally flows where trials can be performed according to international scientific standards, by well-trained professionals, in well-equipped facilities, and with the ability to accurately and efficiently collect the required data.

Accordingly, questions in this category assess the ability of research institutions in the economy to conduct clinical research in a high quality and efficient manner.

The Regulatory System – Drug Approval, Quality Assurance and Pharmacovigilance

The regulatory environment in a given economy plays an important role in shaping incentives for investment and establishing adequate levels of quality and safety for biomedical products. Inadequate approval standards may promote the presence of substandard drugs in the market, which could affect demand for high quality drugs and discourage investment in new products. Conversely, a strong regulatory environment

creates the conditions for the production and sale of high quality products and technologies. High regulatory standards tend to refer to those which assess the quality, safety and efficacy of products in line with ICH. These standards also require systems for monitoring products once they are in the market (known as pharmacovigilance).

Accordingly, questions in this category assess the ability of the regulatory system in the economy to ensure that only high quality, safe biopharmaceutical products enter the market, yet do so in a timely manner.

Market Access & Financing

Most health care systems today have either direct or indirect mechanisms in place for regulating the pricing and reimbursement of medicines. While some countries maintain the traditional transactional approach searching for the lowest cost, others have adopted systems of pharmacoeconomic and cost-effectiveness analysis and comparisons, and aim for more sustainable value-based solutions. Academic research and modeling suggests that for biomedical products restrictive pricing and reimbursement policies limit and delay investment in a market, including new product launches.

Hence, the questions in this category assess the ability of new biopharmaceutical products to access the market via the pricing, reimbursement and procurement system in the economy in an efficient manner and at an acceptable price.

Effective Protection of Intellectual Property

Patents and other forms of exclusivity for biomedical products, such as regulatory data protection and special exclusivity incentives for the protection and production of orphan drugs, provide research-based companies with an incentive to invest vast sums in R&D and the discovery of new biomedical products and technologies. Hence, a strong legal basis for IP protection as well as its enforcement in a given market assures biomedical companies and other investors that their IP assets will be protected from infringement as they develop, test and launch products in that market.

Accordingly, questions in this category assess the ability to fully realize required terms of intellectual property protections for biopharmaceutical products.

Benchmark methodology

The full text of the survey can be viewed in the Annex to this report. For each question, respondents rate an economy's performance in relation to a certain benchmark.

Survey questions are based on an ordinal scale of four options. The four answer options for each question correspond to scores of 1, 2, 3 and 4 – ranging, in order, from the options reflecting the poorest to the highest performance. Based on the analysis of responses to all 25 questions, each economy receives a score for each category as well as an overall score, out of a maximum of 100.

Based on a statistical analysis of the responses, each market is assigned a quantitative score (out of 100). Since all sampled countries belong to the same Latin American region, economies are gauged in relation to other markets with similar levels of development, allowing for an even more fine-tuned snapshot of each market's attractiveness for biopharmaceutical investment.

Overall Findings of the BCI 2025

The BCI survey compares Latin American economies' capabilities in attracting investments for the biopharmaceutical sector in 2025. This section focuses on macro-level analysis of these results for the region as a whole, analyzing the overall trends that emerge. Further drill-down of the results for each economy individually is available in the corresponding section.

Latin America on the biopharmaceutical world stage – Playing catch-up with leading emerging markets

Taken as a whole, Latin America trails behind emerging markets in biopharmaceutical attractiveness. For context, three markets from the 2019 Emerging Markets BCI survey, Israel, Taiwan and Singapore are included as benchmarks. These markets score as top performers among the "newcomer" markets, competing with advanced mature economies on biopharmaceutical attractiveness.[16] Successive BCI editions have discussed at length these economies' capacity to adopt R&D centric policy approaches and innovative mindsets, leading the race for investment.

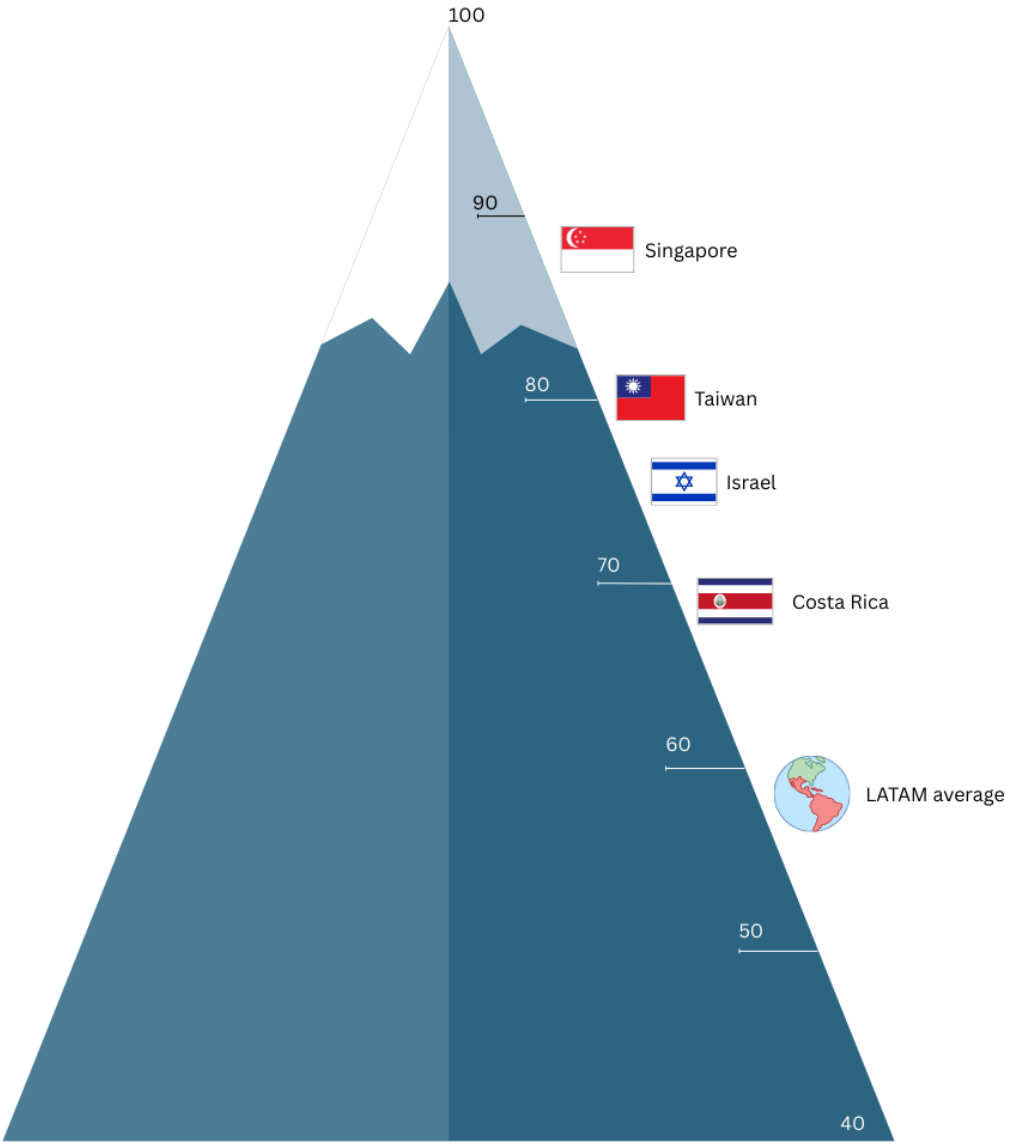
By comparison to these pace-setters, Latin American economies including the regional top performers still have room to grow. Chile and Costa Rica, leading the 2025 BCI LatAm survey with a score slightly below 70, have made progress in the last decade. Both have implemented national strategies aiming to strengthen the biopharmaceutical industry – the National Strategy for Science, Technology, Knowledge and Innovation in Chile, and the National Bioeconomy Strategy in Costa Rica. Focused on increasing scientific capabilities, increasing clinical trial activity and streamlining the regulatory process, these strategies constitute steps towards adopting the innovative mindset pioneered by leading emerging markets. However, the BCI results still show a gap with Taiwan, Israel and Singapore, signaling that more progress must be made in certain areas.

On average, the region also lags behind other emerging biopharmaceutical regions. In the 2019 Emerging Markets BCI survey, both the Asia Pacific region and the Middle

[16] BCI 2016: The Race for Biopharmaceutical Innovation, Pugatch Consilium.

East and North Africa region scored above 60. Yet, even in 2025, Latin America still scores lower than 60 overall. While the region is not alone in facing challenges to attracting investment in biopharmaceutical industries, the BCI results suggest that these obstacles are particularly present in the LatAm region.

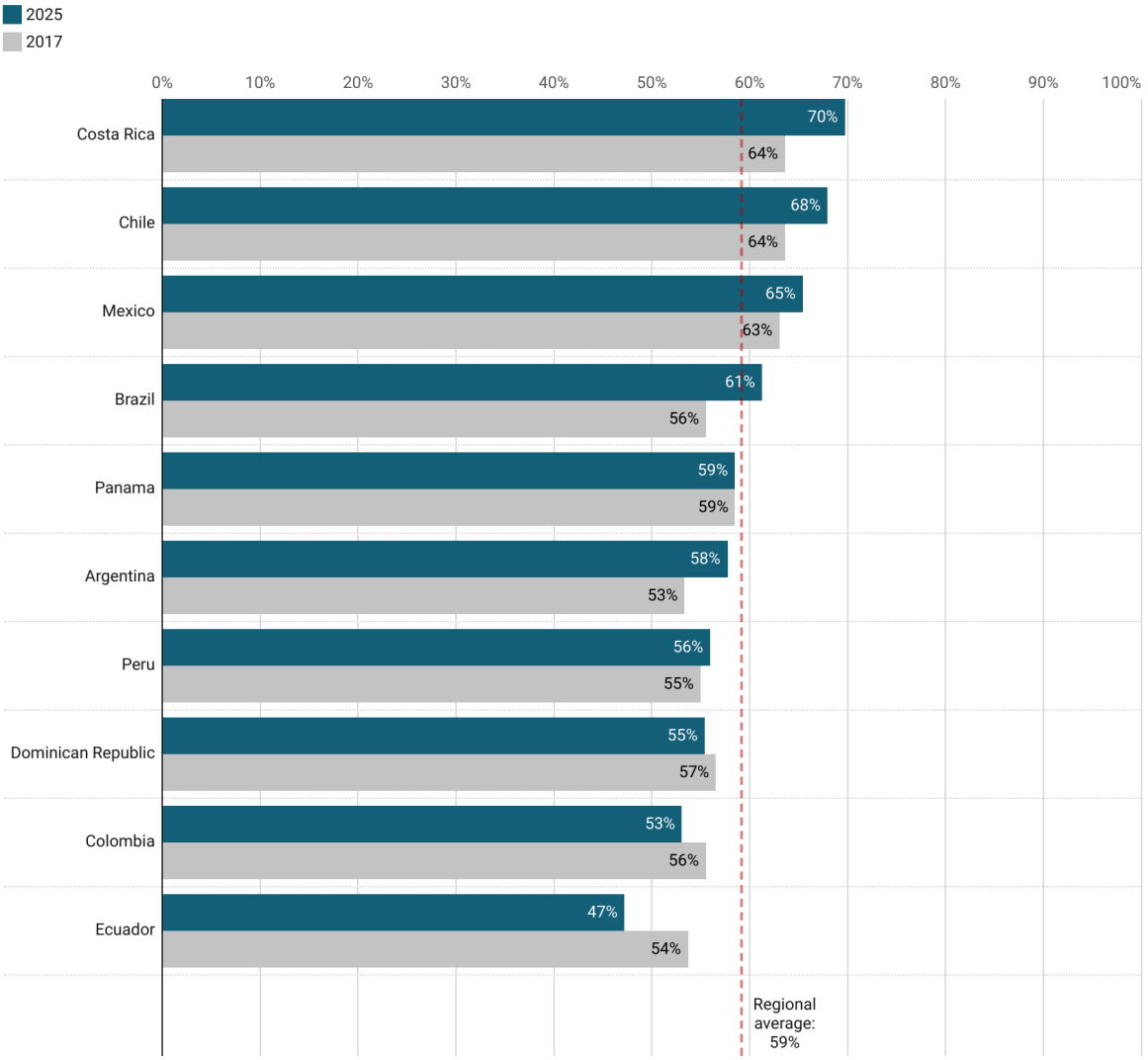
Figure 3. Latin America Biopharmaceutical Attractiveness in the Context of Emerging Markets



The regional biopharmaceutical stage – A handful of top performers

The key takeaway of the BCI 2025 Latin America survey is that the region has overall moved forward in biopharmaceutical attractiveness, but remains divided and with much room to grow. Figure 4 below shows the ranking of the 10 sample economies, compared to their score in the 2017 BCI LatAm report.

Figure 4. BCI Results, Latin America, 2025 vs 2017



The 2025 BCI Latin America survey is led by Mexico, Chile and Costa Rica. Scoring between 65 and 70, these three markets are more likely than their regional peers to attract foreign investments in biopharmaceutical industries. Yet, their results remain overall relatively low when compared to leading emerging markets. These regional top performers still face major challenges in some areas. For example, Mexico and Chile both perform significantly less well on market access. Meanwhile, Costa Rica does not score over 75% in any category. The region has also become more divided in biopharmaceutical competitiveness since the 2017 survey, with a gap of more than 20% between the top and bottom performers.

Below figure 5 presents the full performance of the sample economies for all categories. Their scores are specified in parentheses.

Figure 5. BCI Survey Detailed Results per Category, in Descending Order

Scientific capabilities	Clinical research	Regulatory System	Market Access	IP Protections
Costa Rica (73%)	Chile (78%)	Brazil (72%)	Costa Rica (68%)	Costa Rica (69%)
Mexico (70%)	Mexico (73%)	Chile (72%)	Brazil (59%)	Mexico (65%)
Chile (63%)	Costa Rica (73%)	Mexico (69%)	Argentina (59%)	Chile (65%)
Argentina (58%)	Brazil (69%)	Costa Rica (68%)	Chile (58%)	Panama (61%)
Brazil (55%)	Argentina (68%)	Panama (63%)	Panama (57%)	Dominican Republic (59%)
Peru (55%)	Colombia (63%)	Dominican Republic (61%)	Dominican Republic (54%)	Peru (56%)
Colombia (54%)	Panama (58%)	Peru (60%)	Colombia (54%)	Ecuador (48%)
Dominican Republic (50%)	Peru (55%)	Argentina (59%)	Peru (53%)	Brazil (46%)
Panama (49%)	Dominican Republic (51%)	Ecuador (53%)	Mexico (50%)	Colombia (44%)
Ecuador (46%)	Ecuador (41%)	Colombia (50%)	Ecuador (49%)	Argentina (43%)

Analysis of this table reveals two main insights. Firstly, the variance between countries remains significant. Since 2017, the gap between top percentages and bottom percentages in each category have deepened. In particular, Latin America does not evolve on a level playing field in the area of clinical research. Top regional economies lead lagging markets by over 35%. While gaps in other categories are less spectacular, they remain concerning: around 20% for all other areas.

Secondly, discrepancies exist between categories of the BCI survey. For example, Chile leads the area of clinical research with a score around 78%, while Costa Rica only leads market access and financing issues with 68%. Similarly, no economy scores 70% or higher on IP protection, a mark that tends to be crossed by regional top performers in scientific capabilities and the regulatory system. One should note that these categories remain vulnerable. Collectively, the top five economies in each area often do not score over 70%, and as low as 60% in market access and financing. The only exception is clinical research, where the leaders' average stands at 72%. Overall, these levels of biopharmaceutical competitiveness are relatively low, especially compared to front-runners such as Israel, Taiwan and Singapore, and remain not entirely satisfactory.

Gaps also exist inside of sample economies' scores. For certain economies, although they may get an overall relatively higher score in an area of the BCI, further analysis will reveal inequalities among issues. For example, in the context of regulatory approval timelines for orphan drugs, these gaps were pointed out in the W.A.I.T. indicator report published by FIFARMA.[17] Levels of public availability differed from market to market, but also between different types of molecules and therapeutic fields. These differences are also captured in the BCI Survey.

The overall rankings reveal a certain dynamic between biopharmaceutical attractiveness, market size and policy landscape. A common misconception is that market size is the sole determinant of foreign investments, due to the revenue potential generated by a larger population. Indeed, the largest pharmaceutical markets in Latin America tend to perform better on the BCI survey than smaller markets. However, the policy environment in biopharma also plays a role. On the one hand, economies which are unable to rely on market size to attract biopharmaceutical investments can compensate by presenting a positive and business-friendly policy landscape, fostering innovation and facilitating implementation of pharmaceutical companies. Most significantly, Costa Rica has a relatively small market size for pharmaceuticals estimated to reach roughly $400 million in 2025.[18] Yet it leads the region in the BCI with a score of close to 70 in biopharmaceutical attractiveness. This performance is the

[17] FIFARMA W.A.I.T. Indicator 2024.
[18] Statista, "Pharmaceuticals - Costa Rica", accessed 24 April 2025.

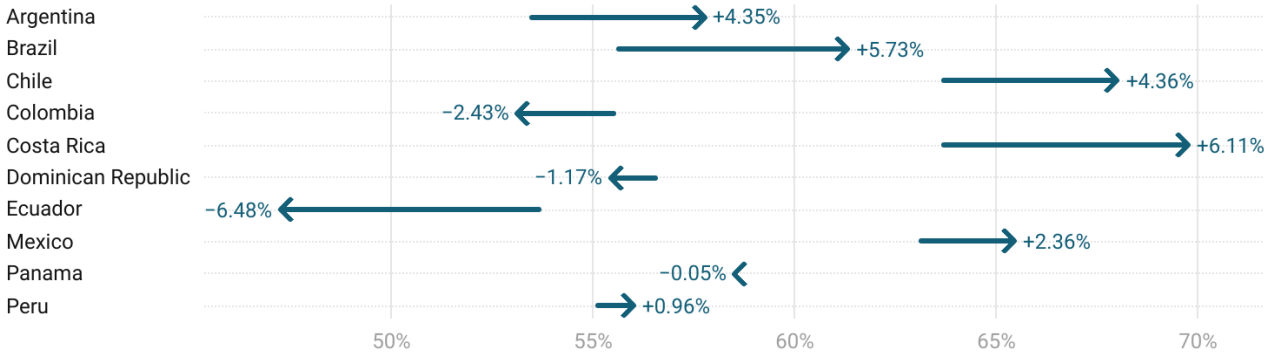
result of a national bioeconomy strategy which includes a focus on building a positive policy framework for the biopharmaceutical industry.

On the contrary, large pharmaceutical markets can harm their overall attractiveness for biopharmaceutical investments through negative policy decisions. For example, Colombia has a sizable pharmaceutical market, achieving $4.95 billion in sales in 2021.[19] Despite this, it trails other regional economies in the BCI 2025 Latin America survey, ranking second to last with a score just over 50. Experts have consistently flagged issues in policy-making over the past couple of years, including a deteriorating IP environment, and perceived hostility for innovative drugs in the regulatory authority.

A dynamic landscape in biopharma attractiveness

The gap between leading and lagging countries within the Latin American region has increased since 2017. This is due to contrary trends among LatAm economies. Figure 6 below shows the score shifts, positive or negative, of all 10 sample economies between the 2017 and 2025 editions of the BCI LatAm report.

Figure 6. BCI Survey Score Shifts, 2017 to 2025



The overall score of Latin American economies has slightly increased since 2017. Six of the sampled markets – a slight majority – have made progress in biopharmaceutical attractiveness. For example, Costa Rica's BCI score increased by 6.11% between 2017

[19] Tanner Pharma, *A Guide to the Key Pharma Markets in Latin America* (2022) <https://tannerpharma.com/wp-content/uploads/2022/10/LAC-A-Guide-to-the-Key-Pharma-Markets-in-LATAM.pdf>

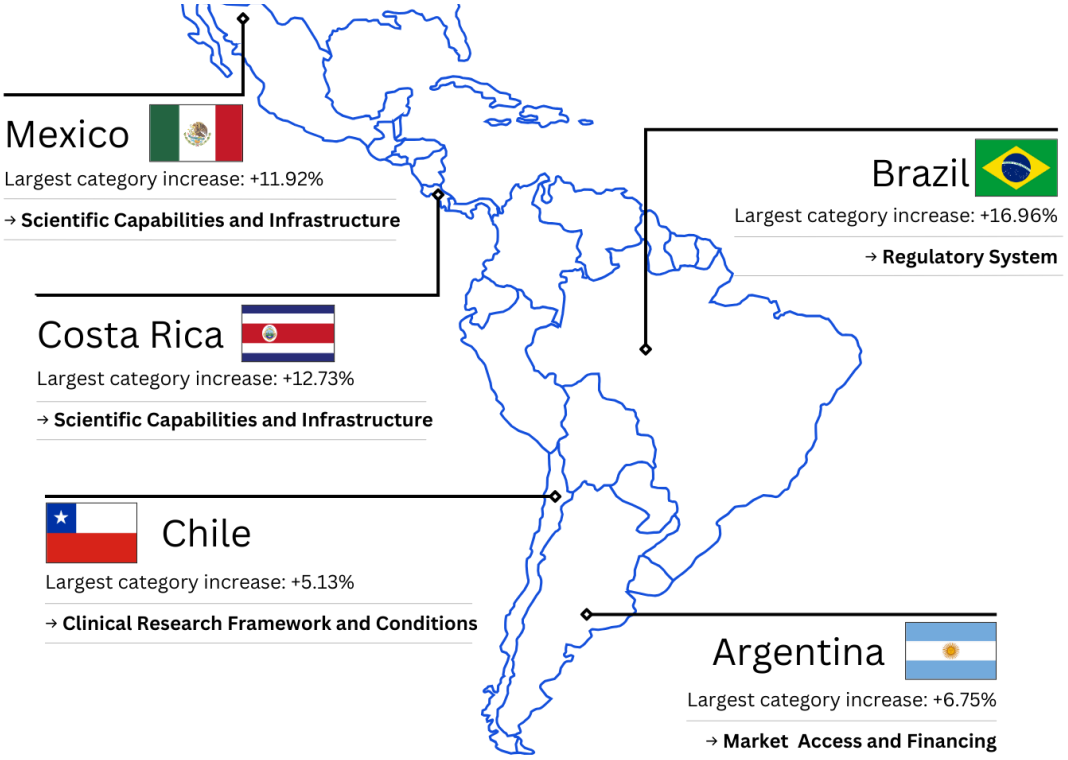
and 2025, while Brazil registered a 5.73% increase. Argentina, Chile, Mexico and Peru have also shown upward trends overall.

Generally speaking, progress in biopharmaceutical competitiveness tends to be particularly visible in certain areas. For example, Brazil has implemented policy changes in its regulatory system, with a 17% score increase since 2017. In Costa Rica and Mexico, scientific capabilities and infrastructure have been the main area of improvement, around 12% for both of these economies. More modestly, Argentina and Chile have improved their attractiveness in, respectively, market access (+6.75%) and clinical research (+5.13%).

It is important to note that generally speaking, these markets start from a low base. For example, Brazil had a score of 55% of the total available score on the regulatory system in the 2017 BCI survey. As such, despite its significant score increase in this area, it remains around 72%. While this is comparatively better than the score achieved by its peers in the region, it is far from the score required to become competitive internationally. Argentina, despite a score increase over 6% in market access, is still not competitive with a score below 60% and recent announcements, such as the intention to create a National Agency for the Financial Evaluation of Health Technologies – where the availability of new medicines would be subject to prior financial assessment, potentially taking precedence over safety, quality, and efficiency criteria – raise concerns about a possible step backward in this category. The same observation can be made for other sample economies: high score increases are in part due to a low starting point, which does not signify real leadership on any issue compared to leading emerging markets.

Figure 7 below summarizes these significant score increases in different categories.

Figure 7. BCI 2025 Significant Score Increases



Other markets have lost their attractiveness for biopharmaceutical investments. For example, Ecuador has seen its BCI score decrease by almost 6.5%, from 53.73 to 47.25. Another case is Colombia, which registers a 2.43% decrease since 2017. These examples are worrying as they signal a trend in certain Latin American economies of increasingly harmful policies.

For example, as pictured in figure 8, Ecuador is particularly vulnerable in its clinical research framework and conditions. In this area, Ecuador has registered a drop of almost 15% in its BCI score since 2017. Similarly, experts report a backward trend in protecting innovation in Colombia, with an 8.75% score decrease in effective IP protections. This trend is a direct consequence of the policies put in place in this market. For example, the willingness to issue a compulsory license in 2024 weakens the effectiveness of patents granted for pharmaceutical products and could disincentivize biopharmaceutical innovation in the country in the future.

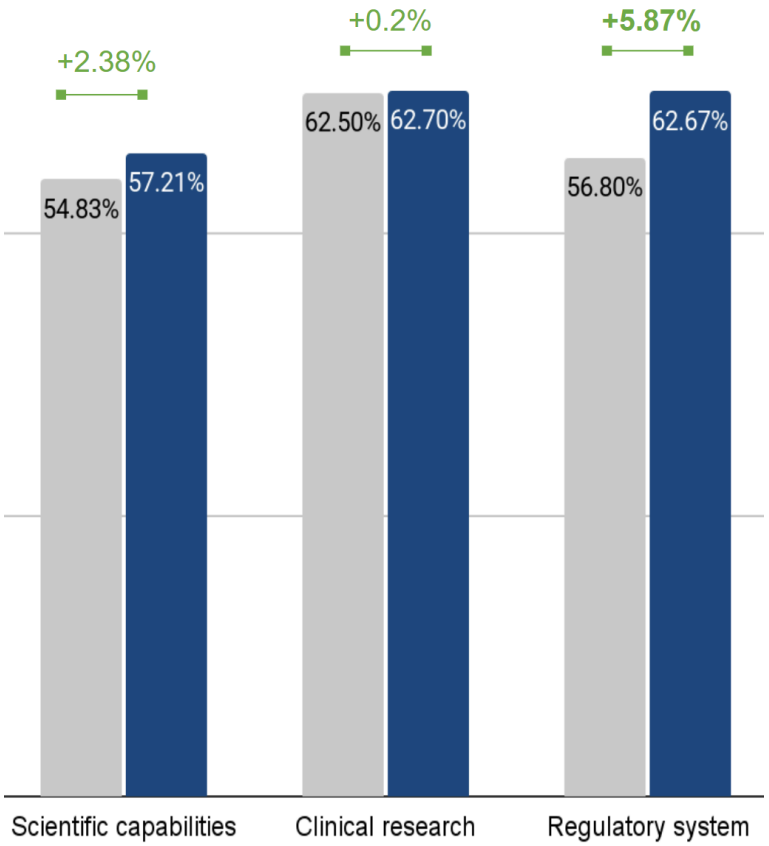
Figure 8. BCI 2025 Significant Score Decreases

Factor-specific findings

While virtually all Latin American countries in some way or another have stated a commitment to improve their biopharmaceutical competitiveness, relatively few actually recognize and execute a plan of comprehensive and long-lasting reforms. Most often countries tend to target one area such as streamlining clinical trials, improving patent backlog, investing in R&D infrastructure or the like. As essential as those efforts are, this is a relatively limited approach. The countries that have the best measurable performance are the ones that have the right policies simultaneously in place for all enabling factors.

Overall, the region has seen a positive shift in three of the areas measured by the BCI: scientific capabilities, clinical research, and most significantly, the regulatory system. This trend highlights an increased professionalism in how the biopharmaceutical industry is dealt with by policy makers. It also participates in building a more solid scientific base in the region, giving the industry more room to grow and develop.

Figure 9. 2025 BCI Survey, Positive Category Evolutions



On the other hand, the areas of market access and intellectual property protection have registered score decreases since 2017, highlighting the main challenges faced by Latin American economies. These legal and commercial incentives are critical to encouraging innovation and biopharmaceutical investment, by creating a structure according to which biopharmaceutical innovators can recoup their initial investment. Policies that negatively affect these incentives will necessarily bring down the attractiveness of the region.

Figure 10. Negative Category Evolutions

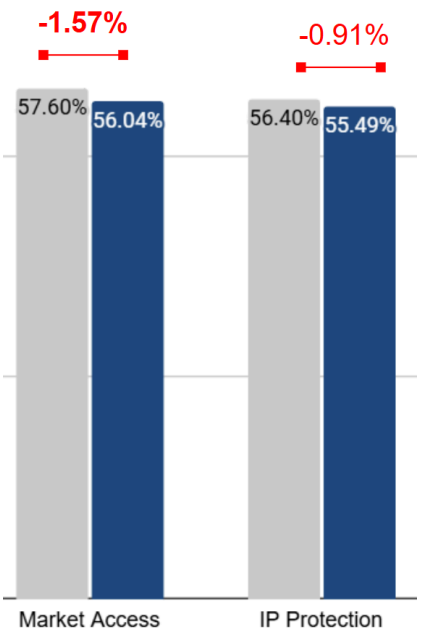
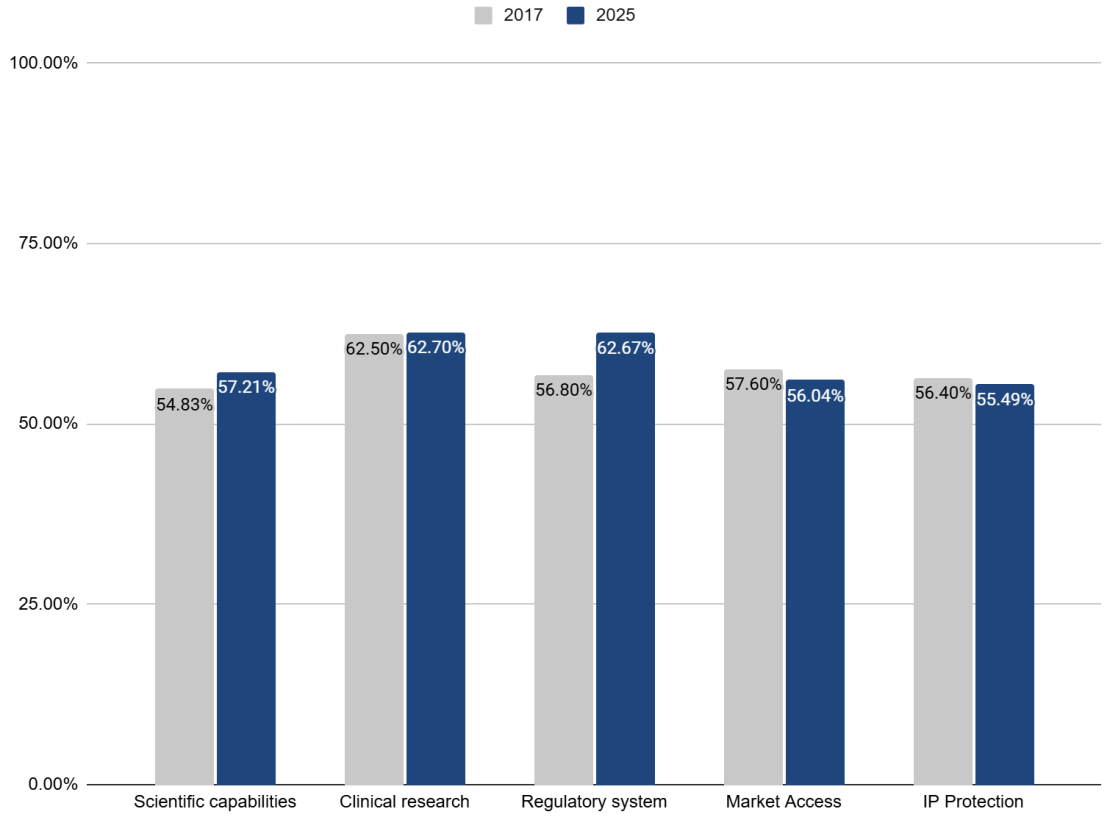


Figure 11 below provides a view of the factor-specific scores of the 2025 BCI survey, comparing them with the results in the 2017 Latin America edition.

Figure 11. BCI Results, Category Scores, 2017 vs 2025



Scientific Capabilities and Infrastructure

Policymakers throughout the region agree that creating scientific capabilities and infrastructure should be a national priority. Realities on the ground, however, tell a different story. Collectively, the BCI ranks Latin America at just 57% of the total possible score. Costa Rica ranks highest, with Mexico as a close second. Ecuador and Panama score on the lower end.

BCI results compared to R&D expenditures as a percentage of GDP reveal the importance of a holistic approach to creating an ecosystem with a focus on equally critical policy areas including the protection of intellectual property, the regulatory environment, technology transfer and market and commercial incentives. R&D expenditure compared to GDP has not significantly increased in any sample economy since 2017 and has, in fact, tended to decrease.[20] Yet, countries having implemented national plans to improve R&D capacities and clinical trial activity, such as Mexico and Costa Rica, have registered big increases in BCI scores. Thus, it is not a matter of how much you spend, but how well you spend it.

Among the factors measured in this area of biopharmaceutical competitiveness, the level and quality of scientific education and training are the main driving factors of scientific capability. For example, Costa Rica scores 87.5% of the possible score on this question. Meanwhile, policy makers should encourage collaboration between research institutions and the biopharmaceutical industry, through public private partnerships and technology transfer platforms. Collectively, the region scores 51% on this indicator, indicating low levels of collaboration.

Clinical Research Conditions and Framework

As a region, Latin America does slightly better in this category compared to other categories in the BCI. Chile ranks the highest. Mexico ranks second, with Costa Rica as a close second. Ecuador still has significant room for improvement, currently scoring over 20% below the regional average.

[20] World Bank data, R&D expenditure (% of GDP), 2017 vs latest available data.

While the area of clinical trials fares somewhat better than other areas measured in the BCI, the region still falls short to effectively compete with biopharmaceutical leaders elsewhere in the world. Although the bulk of clinical research activity takes place in developed countries – which host on average around three times more clinical trials when compared to emerging markets - some emerging markets manage to attract more clinical trials than others.

As discussed, as a region Latin America has not matched the pace of development of other regions such as Asia Pacific. Indeed, despite strong per capita income growth and investment levels over the last decade, clinical research levels for the top performers in Latin America have little to show for it. For example, Korea, Israel (another global leader outside the region) and Taiwan have become attractive hubs for global clinical research. When adjusting for population size, these countries are placed at the top of the list with 300-400 clinical trials per million population in Korea and Taiwan, and over 1000 clinical trials per million population in Israel. By contrast, Latin American economies only have 1 to 30 clinical trials per million population.[21]

The Regulatory System – Drug Approval, Quality Assurance and Pharmacovigilance

The regulatory landscape in LatAm looks uneven, with Chile, Costa Rica, Brazil, and Mexico performing better than the rest. These regulatory gaps and challenges are negatively affecting the biopharmaceutical ecosystem of low-scoring countries, and in turn, discouraging foreign investment.

Long delays and excessive amounts of red tape is a main concern raised by many executives surveyed and reflected in the BCI scores. Primarily affected by these concerns is Mexico, which despite an overall positive score on the regulatory system has caused concerns among experts due to the relatively long timelines from clinical trials and drug approval. This trend signals a deterioration in the investment environment of this economy compared to the 2017 BCI LatAm survey, which had flagged investor sentiment around decreasing timelines.

Conversely, executive sentiment around Brazil's regulatory system has drastically improved since 2017. While ANVISA's performance and long delays were previously

[21] Pugatch Consilium analysis based on data from clinicaltrials.gov and World Bank population figures.

seen as a major setback for investors, Brazil now lists among the leading regulatory frameworks in Latin America. Despite regulatory delays still considered relatively long by executives, it is seen as a leading market in its capacity to review applications for drug approval in biopharmaceutical products, generic and biosimilar drugs.

Market Access and Financing

Market access and financing is the area of the BCI with the largest score decrease since the 2017 Latin America survey. Costa Rica and Brazil take the lead, with Ecuador and Mexico trailing their peers in the region.

These results echo previous discussions in Latin America around pricing and reimbursement policies. As a region, Latin America has heavily focused on the traditional transactional approach of lowest bid and price controls. There are no meaningful efforts to look beyond the pill in value-based models.

For example, Mexico's pricing and reimbursement policies for biopharmaceuticals, while meant to contain rising healthcare spending, instead historically limited and slowed down access to new medicines and technologies.

Such displays of hostile policies on price controls have severely hampered incentives to invest in the Latin American bio-economy.

Effective IP Protections

As a whole, the Latin American region faces significant challenges in providing effective protection for intellectual property. It scores 55.5% of available score, the lowest performance across the five categories. Again, the exceptions are Costa Rica, along with Mexico and Chile – all three performing relatively better.

Evidence suggests that the harder it is to get patent protection in a given country, the less attractive the country becomes for foreign investment. Historically, intellectual property protection in Latin America for biopharmaceutical innovations has been lukewarm at best, and non-existent at worst. Implementation of international intellectual property standards have been notoriously slow, patent examination backlogs are unreasonably long and infringers do not receive proper deterrent judgments. Virtually all countries sampled in the 2017 BCI LatAm were listed in the

USTR's 2017 Special 301 Report. This situation has not evolved. Still in 2025, four Latin American economies were listed on the Watch List, in addition to Argentina, Chile, and Mexico on the Priority Watch List.

Another example of the poor performance of the region in IP is observed in the International IP Index. Collectively, Latin American economies score below 50% of available score in life sciences, with particular vulnerabilities in Argentina and Ecuador. Specifically, Argentina has long-standing issues with its 2012 *Guidelines for the Patentability Examination of Patent Applications for Chemical and Pharmaceutical Inventions.* Industry and IP experts worry that these guidelines are not in line with the requirements of the TRIPS agreement at the WTO level, overly restricting patentable subject matter for pharmaceutical products. Argentina has yet to address these concerns, as well as the lack of regulatory data protection and non-ratification of the PCT.

Colombia is another example of an economy having deteriorated its IP environment since 2017. Specifically, it has been done through the implementation of policies directly weakening intellectual property protections. For example, the Colombian government issued its first-ever compulsory license in 2024, targeting the HIV treatment dolutegravir. This mechanism effectively undermines the platform for protecting innovation in the biopharmaceutical industry, disincentivizing future innovation. Colombia's status as a trailing economy in the region breaks with its history as a regional leader in IP rights, including pioneering regulatory data protection as early as 2002. It is a case study of the importance of policy in participating in a friendly environment for biopharmaceutical investments.

Economy-Specific Findings and Profiles

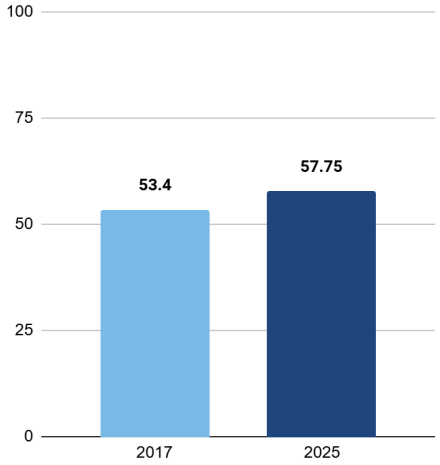
This section presents a summary and analysis of each individual economy's overall and category scores.

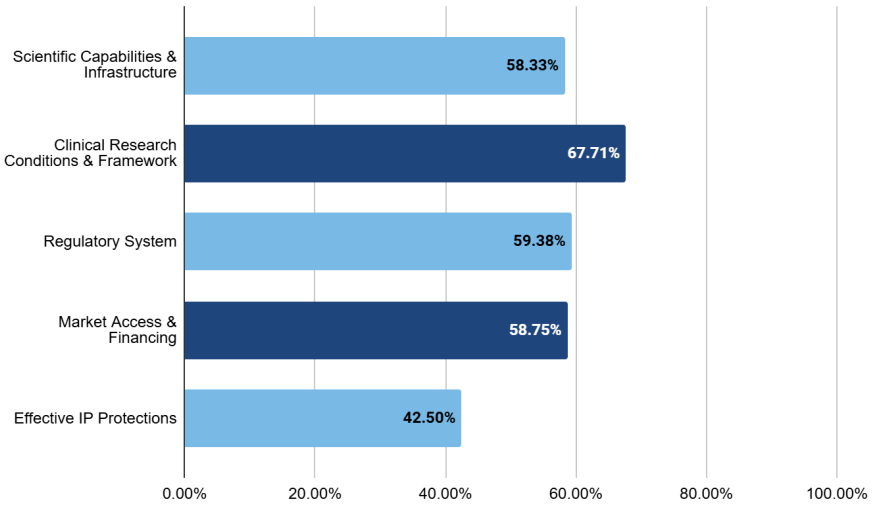
Each profile first displays the overall BCI score in 2025 compared to its BCI score in the 2017 Latin America report. The profiles also provide a comparative analysis of the economy's score and performance by category (in terms of share of the total possible score).

Drawing on BCI responses and comments, a more in-depth analysis and explanation of the economy's BCI scores is provided. This section includes the key strengths, weaknesses, and trends identified by executives. A policy spotlight on a selection of economies aims to provide a discussion of key policies implemented since 2017 which contextualize the economy's performance.

Argentina (57.75%)

BCI scores





BCI Results In-Depth: What helps and what hinders Argentina's biopharmaceutical competitiveness?

Clinical research conditions and framework are Argentina's clearest strengths, in line with its history as a regional hub for clinical trial activity. **Market access and financing** is another area where Argentina has a comparative advantage despite room to improve, as it registered the highest growth among the sampled economies since 2017, increasing its score by 6.75%. However, recent announcements, such as the intention to create a National Agency for the Financial Evaluation of Health Technologies—where the availability of new medicines would be subject to prior financial assessment, potentially taking precedence over safety, quality, and efficacy criteria—raise concerns about a possible step backward in this category.

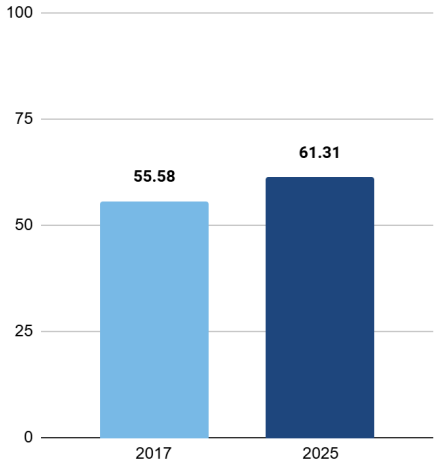
Effective IP protections require urgent attention in Argentina, with both its lowest category score and the only area where Argentina's score decreased since 2017.

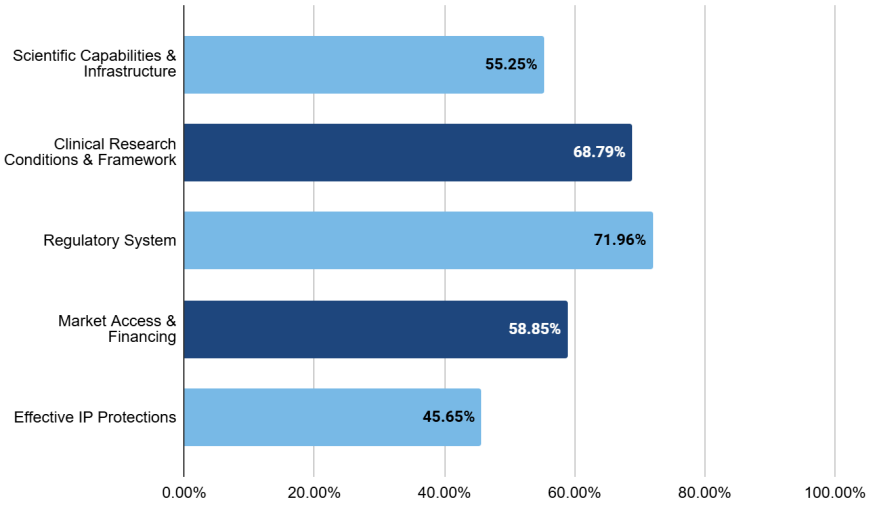
Policy spotlight

Argentina's biopharmaceutical competitiveness has deteriorated over the last decade, despite progress since 2017. Its BCI score in 2015 was 60.07%, roughly 2.5% higher than in this edition. This year, experts have flagged Argentina's long-standing issues on IP protection. Since 2012, concerns remain that the Guidelines for Patentability of Pharmaceutical Products are not in line with TRIPS standards. Argentina could also strengthen its protection of innovation by adhering to the PCT which it has not ratified.

Brazil (61.31%)

BCI scores



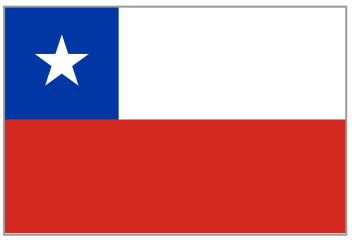


BCI Results In-Depth: What helps and what hinders Brazil's biopharmaceutical competitiveness?

The regulatory system is Brazil's greatest strength, with the highest score among the sampled economies at 71.96%. It is also the area where Brazil progressed the most.
Effective IP protections are a major issue in Brazil for biopharmaceutical competitiveness, with a score of 45.65%. This represents the third lowest score in this category among sample economies.

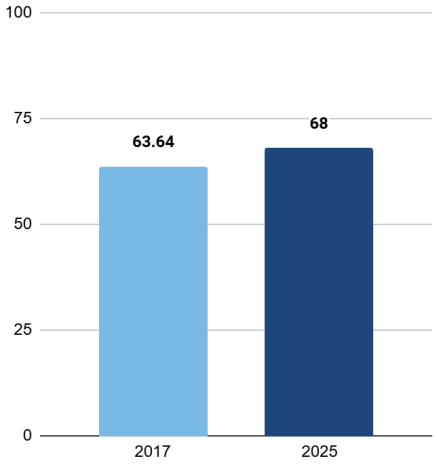
Policy spotlight

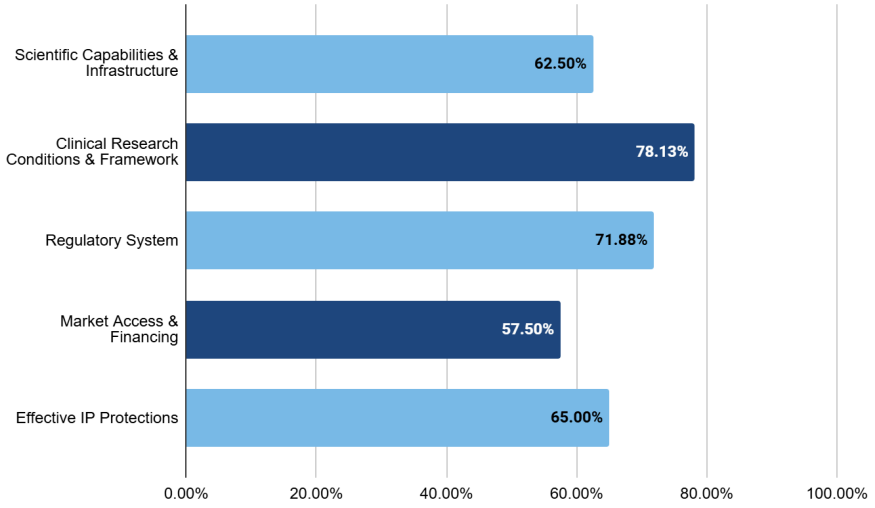
Executive sentiment has improved around Brazil's regulatory system, previously seen as a main weakness. ANVISA is widely recognized as a leader of this improvement, implementing policies to address the long approval timelines for clinical trials and market authorization.
Despite this, IP remains a contention point for experts. The main outstanding issues concern the absence of regulatory data protection, an essential IP mechanism in the pharmaceutical industry, and a large patent backlog hampering patent grant timelines. Most significantly, a 2021 Supreme Court decision has invalidated the mechanism providing for automatic adjustment of patent term when the grant term exceeds 10 years, largely targeting the biopharmaceutical industry.



Chile (68%)

BCI scores





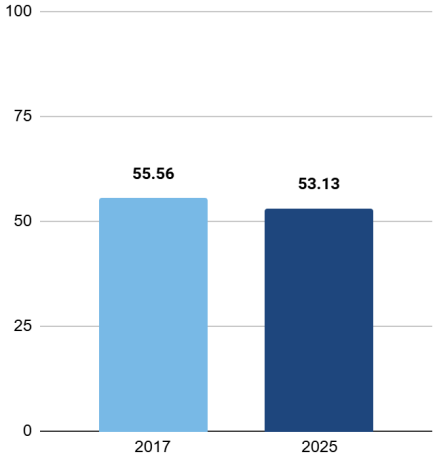
BCI Results In-Depth: What helps and what hinders Chile's biopharmaceutical competitiveness?

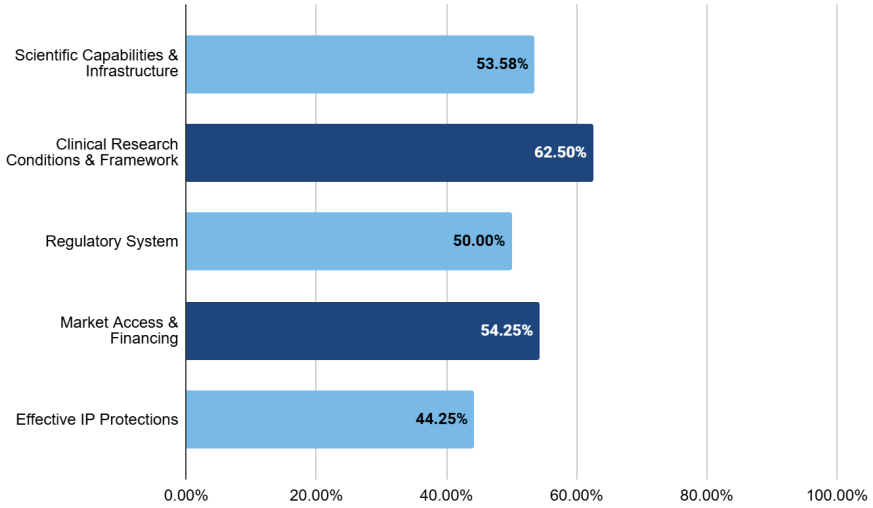
Biopharmaceutical competitiveness in Chile is mainly supported by its **clinical research conditions and framework**. With a score of 78.13%, clinical research is also Chile's greatest increase since 2017. Chile's score on clinical research is the highest score obtained in the BCI survey for any country across all categories. This confirms its standing as the main market in Latin America for clinical trial intensity.

On the other hand, attention must be paid to **market access and financing**, the lowest category score for Chile. With 57.5%, it must focus on issues of public procurement, pricing and reimbursement. Similarly, despite a relatively good performance in **scientific capabilities and infrastructure** in comparison with other sample economies, Chile registered a 9.5% decrease in this area, its highest decrease since 2017.

Colombia (53.13%)

BCI scores





BCI Results In-Depth: What helps and what hinders Colombia's biopharmaceutical competitiveness?

Colombia's results on the 2025 Latin America BCI survey are worrying. No category stands out as a relative strength for the market. In **clinical research conditions and framework**, Colombia's relative best performance, Colombia remains in the middle of the pack. It has also registered score decreases in all areas since 2017.

Effective IP protections stand out as a particular weakness, with a score of 44.25% and a decrease of almost 9% since 2017.

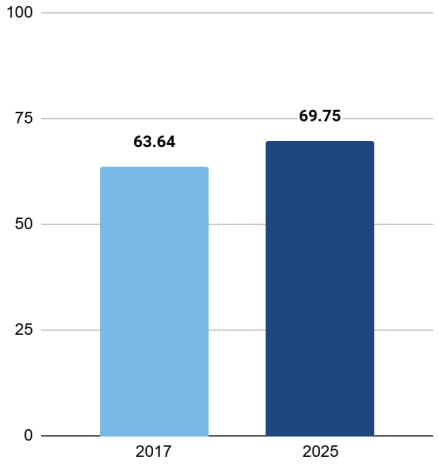
Policy spotlight

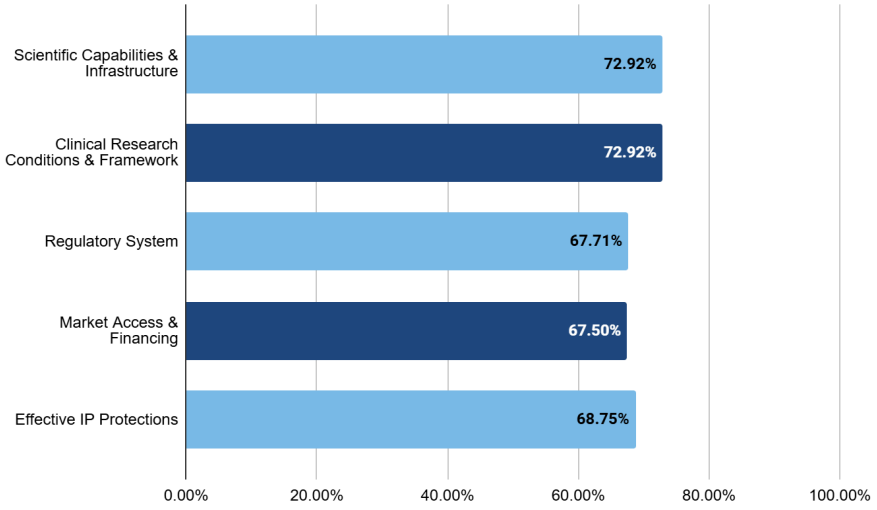
Surveyed executives have expressed serious concern around the policy trajectory adopted by Colombia since 2017. Over the past two years, efforts put in place by previous administrations to improve the clinical trial process by cutting approval timeframes and increasing efficiency have been put on hold.

In addition, pharmaceutical innovation has faced challenges on many fronts. From an IP perspective, the issuance of a first-ever compulsory license in 2024 against dolutegravir, an HIV treatment, weakens the efficiency of the system. From a regulatory perspective, experts have reported instances of institutional opposition to innovative drugs from INVIMA.

Costa Rica (69.75%)

BCI scores





BCI Results In-Depth: What helps and what hinders Costa Rica's biopharmaceutical competitiveness?

Costa Rica has performed well in all areas measured by the 2025 BCI survey, increasing its score in all categories. **Scientific capabilities and infrastructure** stand out as a particular strength with **clinical research conditions and framework**, both tied at 72.92%. Costa Rica also registers the best score among sample economies in **effective IP protections**.

Areas of possible improvement include **market access and financing** and the **regulatory system**, both scoring around 67.5%

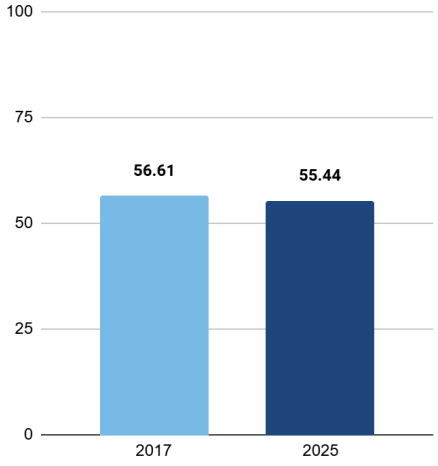
Policy spotlight

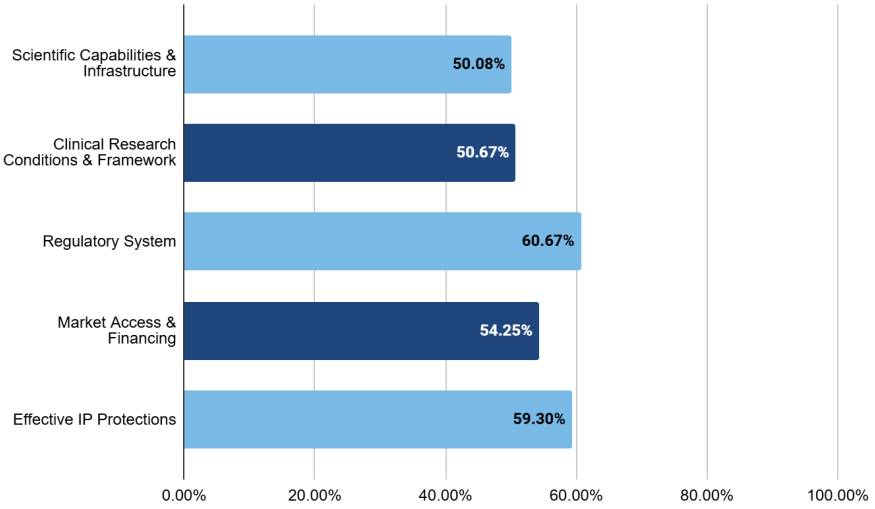
Costa Rica stands out due to its national bioeconomy strategy. Political leadership has accurately captured Costa Rica's role as a regional leader in protection of innovation and R&D infrastructure.

However, the national bioeconomy strategy lacks a clear path towards improving the regulatory system and market access and financing issues, despite relatively weaker performances in the BCI. IP challenges also remain.

Dominican Republic (55.44%)

BCI scores





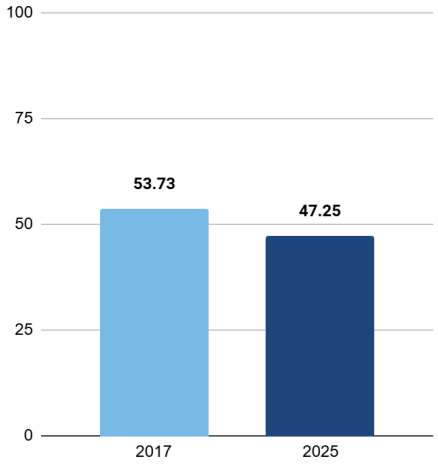
BCI Results In-Depth: What helps and what hinders the Dominican Republic's biopharmaceutical competitiveness?

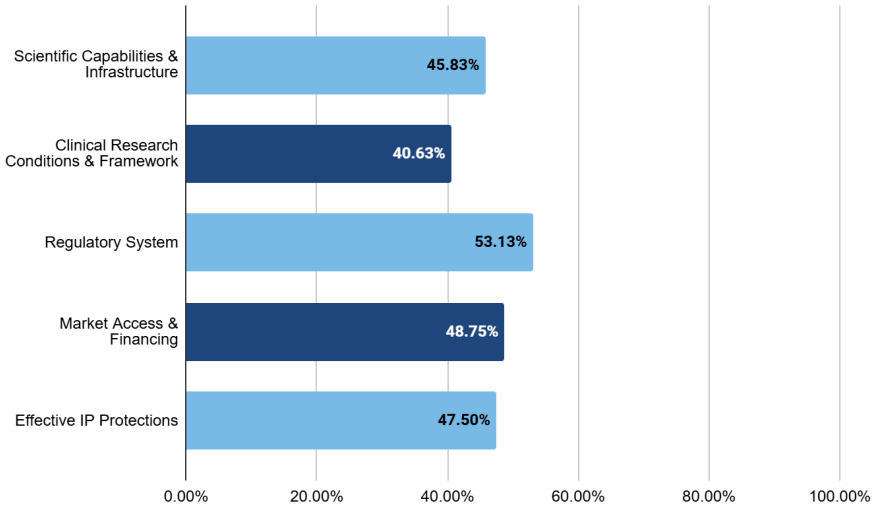
Scientific capabilities and infrastructure as well as **clinical research conditions and framework** are the two areas which most hinder the Dominican Republic's biopharmaceutical competitiveness. Scoring just over 50% in both these areas, the Dominican Republic seems to struggle to put in place a framework in which research and development can really take place, harming the pharmaceutical innovation process. **Market access and financing** is another area of weakness, with a score of 54.25%. This is the largest score decrease in the Dominican Republic since 2017.

Relatively speaking, the **regulatory system** is the area where the Dominican Republic performs best with a score of 60.67%. This is the area where it registered its highest increase since 2017. In addition, the Dominican Republic is in the upper bracket of sample economies when it comes to **effective IP protections**, ranking fourth in this category.

Ecuador (47.25%)

BCI scores





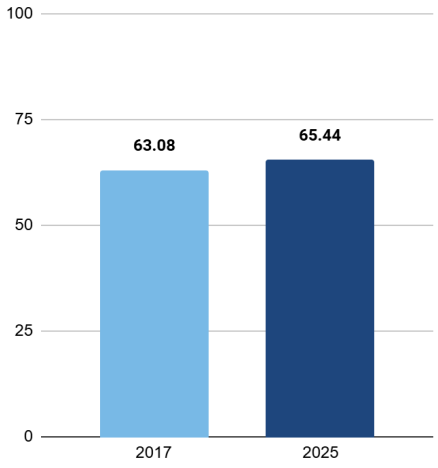
BCI Results In-Depth: What helps and what hinders Ecuador's biopharmaceutical competitiveness?

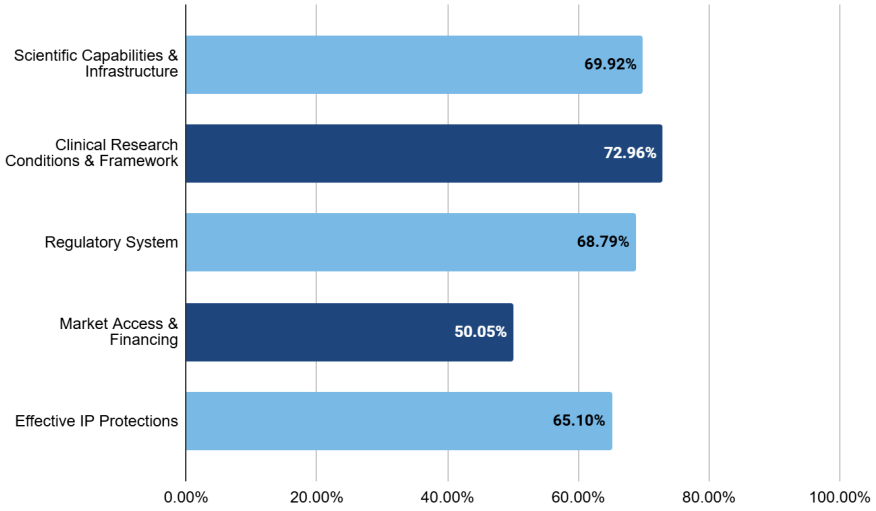
Ecuador is the lowest scoring economy in the 2025 BCI survey. Analysis of its results reveals a valuable opportunity to implement reforms across key policy areas that could significantly enhance its biopharmaceutical competitiveness.

Ecuador's highest performing area is the **regulatory system**. The greatest area of concern in Ecuador is the **clinical research conditions and framework** with a score of 40.63%. Ecuador's clinical research score has declined by nearly 15% since 2017, signaling a valuable opportunity to revamp its R&D environment. With the right focus and significant investment, the country can still turn the tide and position itself as a real player in biopharmaceutical innovation.

Mexico (65.44%)

BCI scores





BCI Results In-Depth: What helps and what hinders Mexico's biopharmaceutical competitiveness?

Clinical research conditions and framework are Mexico's greatest strength for biopharmaceutical competitiveness, with a score of 72.96%. Since 2017, Mexico has also improved its policy and performance in **scientific capabilities and infrastructure**, increasing its score by almost 12%.

Market access and financing matters hinder Mexico's attractiveness, with a low score barely over 50% and a decrease of almost 6% since 2017.

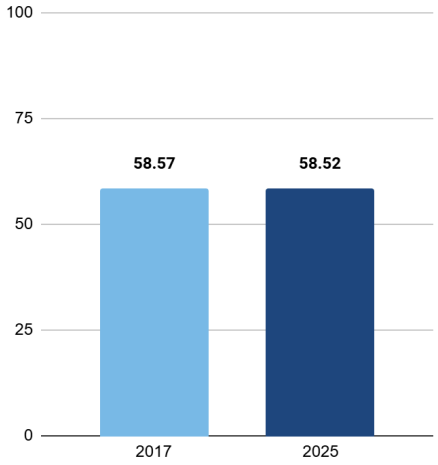
Policy spotlight

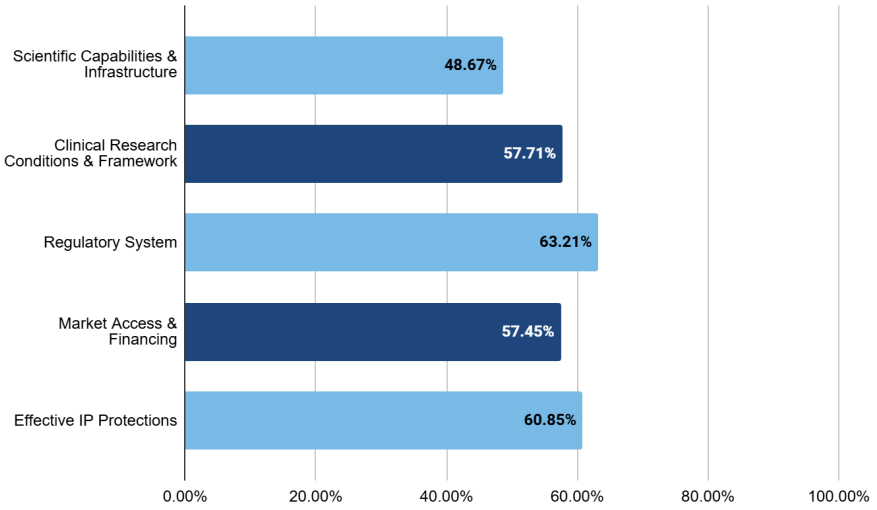
Mexico has positioned itself as a regional hub for biopharma, laying out its ambitions of being the regional hub for clinical trial activity in its national development plan. Its scores on scientific infrastructure and clinical research framework capture these ambitions.

Experts have expressed contradictions in Mexico's regulatory performance. On the one hand, executives are convinced by Mexico's capacity to review data for approval of biopharmaceutical products, generics and biosimilars. The sentiment around GMP and pharmacovigilance in the market are also very positive. However, serious concerns exist around regulatory approval timelines at COFEPRIS, widely perceived as being relatively long compared to other sample economies.

Panama (58.52%)

BCI scores





BCI Results In-Depth: What helps and what hinders Panama's biopharmaceutical competitiveness?

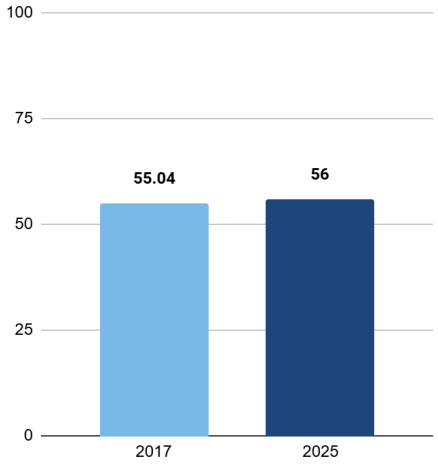
Panama's performance in the 2025 Latin America BCI Survey is middle of the pack in most categories.

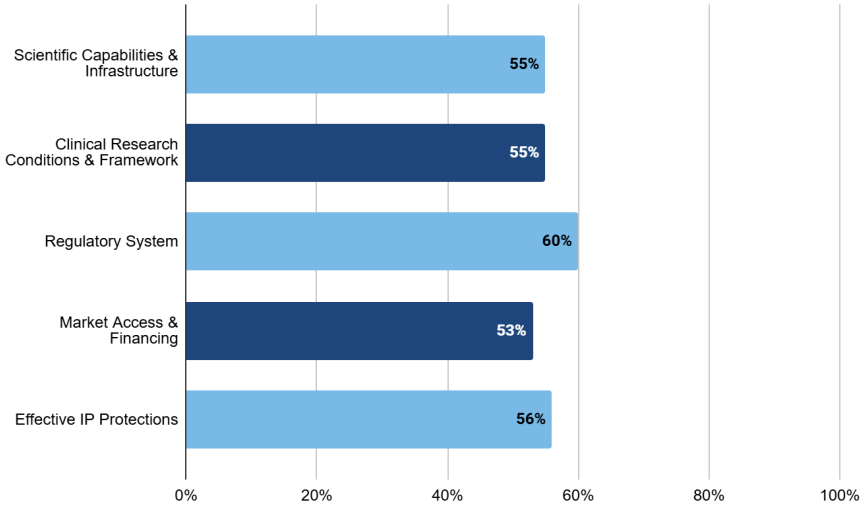
Among its strongest performances, Panama scores 63.21% in the **regulatory system**. This also represents Panama's largest progress since 2017, increasing the score by 9.21%. There remains room for improvement in this category.

On the other hand, **scientific capabilities and infrastructure** are lacking in Panama. It receives a score of 48.67% from experts in this area, a roughly 4% drop since 2017. Similar drops are registered in **clinical research conditions and framework** and **market access and financing**. These categories effectively balance out the progress made by the economy on the regulatory system.

Peru (56%)

BCI scores





BCI Results In-Depth: What helps and what hinders Peru's biopharmaceutical competitiveness?

Executives surveyed for the 2025 BCI report feel that the economy's biopharmaceutical competitiveness is middle of the pack and even across the board. Peru's score has virtually stagnated since 2017, only increasing by less than 1%.

The **regulatory system** is an area of relative strength, with a score of 60%. This represents an increase of almost 9% since 2017. However, Peru remains lagging behind other sample economies, below the regional average score on the regulatory system. Similarly, Peru registers a 7% increase in **scientific capabilities and infrastructure**. Yet, with a score of 55%, it is relatively middle of the pack and still falls behind the regional average.

On the other hand, particular attention must be paid to **market access and financing**. With a score of 53%, it is Peru's greatest weakness, and a 5% decrease since 2017. Similarly, it registers a 6% decrease in **clinical research conditions and framework**, effectively erasing the progress on the regulatory system and scientific infrastructure.

Annex. BCI Survey

Scientific Capabilities & Infrastructure

Question 1

How would you describe the overall level of your country in terms of its capabilities to engage in biopharmaceutical research and development?

Low (seriously behind other countries) ☐	Basic ☐	Significant (more than other countries, but still lacking in some areas) ☐	Excellent (top of the curve) ☐

Question 2

In your view, the level of scientific education and training in your country is:

Low (very basic and incomplete knowledge base) ☐	Basic (not sufficiently advanced to meet modern developments) ☐	Significant (more than other countries, but still lacking in some areas) ☐	Excellent (of the highest caliber across the board) ☐

Question 3

How strong and effective is the level of collaboration in your country between research institutions and the biopharmaceutical industry?

Almost no collaboration ☐	Limited collaboration ☐	Occurs frequently and is relatively effective ☐	Occurs daily (is of a strategic interest) ☐

Clinical Research Conditions and Framework

Question 4

How would you describe the readiness and capabilities of hospitals in your country to carry out clinical trials of different phases?

Low (limited capacity for conducting clinical trials) ☐	Basic (focusing mostly on post-clinical phases) ☐	High (strong capabilities for conducting clinical trials of different phases, but mostly final phase trials, i.e. phase III, are taking place) ☐	Excellent (of the highest caliber across the board; hospitals conduct and lead clinical trials in all phases and their standards are harmonized with global GCP standards) ☐

Question 5

How easy is it to recruit and maintain volunteers for participating in clinical trials in your country?

Very difficult (greatly lacking in volunteers; adverse public perception) ☐	Relatively difficult (volunteers are available but in insufficient numbers; officials anxious about public perception) ☐	Relatively easy (some limitations in the ability to secure long term participation; public perception generally positive or not a factor) ☐	Easy (high level of success in recruiting and maintaining candidates; positive public perception) ☐

Question 6

Compared to mature markets, how costly is it to conduct clinical trials in your country?

Financially unattractive (facilities and manpower are relatively expensive and difficult to access) ☐	Relatively costly ☐	Relatively less costly ☐	Financially attractive (infrastructure and manpower of adequate quality are relatively inexpensive to secure) ☐

Question 7

In your view, what is the typical timeframe for obtaining approval for a clinical trial by the Health Authority in your country?

More than 180 days or unpredictable ☐	90-180 days ☐	60-90 days ☐	30-60 days or less ☐

Question 8

How compliant are organizations participating in clinical trials in your country with global clinical standards (GCP) and procedures?

Compliance is lacking ☐	Compliance varies ☐	Relatively compliant (with exceptions) ☐	Very compliant (across the board) ☐

Question 9

How developed is the clinical research management (CRM) industry in your country?

Undeveloped ☐	Limited (in terms of presence and capacity) ☐	Fairly developed (with room for improvement) ☐	Highly developed (of the highest standard across the board) ☐

The Regulatory System – Drug Approval, Quality Assurance and Pharmacovigilance

Question 10

How would you describe the capacity of the health regulator in your country to review the data submitted to it for the approval of new biopharmaceutical products?

Very low (low capacity for independent review) ☐	Basic (most reviews based on prior approval in other countries; lacks significant capacity for independent review) ☐	Good (review based on prior approval in other countries as well as on independent review) ☐	Excellent (full capacity to conduct independent review) ☐

Question 11

In your view, how long are delays in the registration of an innovative drug that has already been approved by a major drug agency in a mature market (such as the FDA or EMA)?

Very long (takes 24 months or more, despite having data from prior approval in other countries) ☐	Relatively long (takes 12 months or more) ☐	Fairy short (takes 6-12 months) ☐	Very short (takes no more than 6 months) ☐

Question 12

How would you describe the capacity of the health regulator in your country to review and approve generic drugs (based on small molecules/chemical entities)?

No capacity (approval is automatic or not necessary) ☐	Limited (only bioequivalence tests are required) ☐	Reasonable (quality, safety and efficacy data is also required, but gaps remain in terms of phasing out substandard drugs) ☐	Excellent (regulatory framework requires approval according to the highest acceptable scientific standards) ☐

Question 13

How would you describe the capacity of the health regulator in your country to review and approve biosimilars (based on large molecules/biologics)?

No capacity (approval is automatic or not necessary, or only requires bioequivalence tests) ☐	Limited (preclinical and/or clinical testing is required for approval but only a minimal amount) ☐	Present, with some limitations (adequate preclinical and clinical testing is required and clearly defined in most cases) ☐	Satisfactory (regulatory framework fully in line with international best practices) ☐

Question 14

In your view, to what extent are locally manufactured products in your country compliant with GMP rules that conform to international standards?

Compliance is lacking and/or GMP rules are below international standards ☐	Compliance varies ☐	Relatively compliant (with exceptions) vis-à-vis international GMP standards ☐	Very compliant (across the board) and GMP rules are in line with international standards ☐

Question 15

How would you describe the pharmacovigilance system in your country?

Non-existent ☐	Basic (rudimentary reporting system, frequent delays, inadequate response) ☐	Relatively effective (adequate reporting system and response in most cases, with some exceptions) ☐	High-level (effective reporting system; rapid and comprehensive response) ☐

Market Access and Financing

Question 16

How comprehensive is the public reimbursement framework in your country?

Non-existent (there is no national or public reimbursement of pharmaceutical products) ☐	Lacking (reimbursement is usually given to less costly and domestically manufactured products, i.e. focus is on generics) ☐	Partial (most medicines are reimbursed, but severe limitations are imposed on drugs which are considered relatively more costly) ☐	Comprehensive (reimbursement is given across the board, including the possibility of reimbursing costlier, innovative medicines) ☐

Question 17

How would you describe the transparency of the public pricing and reimbursement

framework in your country?

Completely non transparent (decisions take place behind fully closed doors; industry has little influence on or knowledge of the actual decision making process) ☐	Limited transparency (industry participates in negotiations but has only limited access to the basis of final pricing decisions) ☐	Quite transparent (industry routinely participates in decisions but is not privy to all aspects of the process) ☐	Fully transparent (rationale, data and personnel involved in decisions are entirely public information and are developed in collaboration with industry and key stakeholders, e.g. patients) ☐

Question 18

How stringent are price controls on publicly reimbursed products in your country? *If biopharmaceutical products are not publicly reimbursed in your country please select the first option.

Not applicable ☐	Highly stringent (prices are determined by the state and are highly restrictive) ☐	Relatively stringent (price controls are imposed but to a limited extent) ☐	Moderate (companies are allowed to set their own prices, subject to structural limitations, such as profit margins and negotiations) ☐	Relatively free pricing (there are almost no limitations on how prices are set at the national level) ☐

Question 19

In the absence of public reimbursement (or serious delays), to what extent are private or supplementary channels that allow patients to access biopharmaceutical products available in your country?

Not available (such channels do not exist in my country) ☐	Sporadically (mainly through out of-pocket spending on individual drugs) ☐	Partially (supplementary coverage schemes are available, but mainly for certain income levels or disease areas) ☐	Frequently (the population can choose from various supplementary and commercial coverage schemes that allow access to a significant number of treatments) ☐

Question 20

To what extent does the public procurement system in your country allow your organization to effectively compete to provide patients access to your products?

Hardly at all (the process is heavily biased and/or providers/payers have all the negotiating power) ☐	To a limited extent (only in cases in which the product is very strong) ☐	To a reasonable extent (providers or other bid participants have an advantage some of the time) ☐	To a great extent (we are able to compete with other bids and/or negotiate with providers on an equal footing) ☐

<u>Effective IP Protections</u>

Question 21

How effective are the IP protections associated with proprietary pharmaceutical products in your country?

Non-existent (high risk environment in which products are immediately deprived of protection) ☐	Ineffective (both in terms of the length and the scope) ☐	Relatively effective (reasonable length, yet the scope of protection is frequently challenged and disputed) ☐	Highly effective (both in terms of the length and scope of protection) ☐

Question 22

How effective is the process of patenting in your country?

Highly ineffective (complex and slow, with a very poor degree of professional examination capacity) ☐	Somewhat ineffective (a bureaucratic process with a fairly low level of expertise in the examination process) ☐	Fairly effective (professional, but with some exceptions) ☐	Highly effective (in line with current international standards; streamlined process for both domestic and international patents) ☐

Question 23

How effective are mechanisms in your country aimed at safeguarding clinical trial data (i.e. regulatory data protection)?

Non-existent (no such framework exists) ☐	Little effectiveness (the framework is very limited both in relation to term of exclusivity and scope) ☐	Partially effective (a framework exists but is mainly applicable only to new chemical entities and does not cover biologic products) ☐	Very effective (the framework generally applies to all types of innovative medicines, including biologics and new indications) ☐

Question 24

In your view, how effective are civil and criminal remedies for infringement of intellectual property rights and battling counterfeit medicines in your country?

Highly ineffective (framework for litigation and penalties does not exist) ☐	Fairly ineffective (framework exists but is generally not implemented or enforced) ☐	Fairly effective (framework is generally implemented and enforced but with key exceptions) ☐	Very effective (including compensation, injunctions, seizures and penalties; ability to challenge validity of a patent) ☐

Question 25

To what extent does your country have in place a regulatory patent enforcement mechanism for biopharmaceuticals that allows for patent dispute resolution prior to the marketing of a potentially infringing product?

Non-existent (no patent linkage framework exists and judicial remedies are ineffective) ☐	On a limited basis (a partial mechanism is in place but is applied inconsistently or is restricted to certain types of patents ☐	To a reasonable extent (a formal mechanism is in place that effectively enables timely dispute resolution, with some exceptions) ☐	To a great extent (a strong mechanism is in place and allows for timely and effective biopharmaceutical patent enforcement across the board ☐