CRA Charles River Associates

Value of IP for health and growth

The economic benefits of strengthening the environment for innovation in Colombia

SEPTEMBER 2021

CONTENTS

1. Project objectives and methodology

BACKGROUND AND OBJECTIVES

INTERPAT and AFIDRO asked Charles River Associates (CRA) to identify and quantify the economic benefits from strengthening the environment for innovation in Colombia.

The objective of the study is to:

1. Set out the **policy framework** for supporting innovation in Colombia and the current state of innovative activity.
2. Undertake a **case study analysis** on countries, outside the LATAM region, with potential lessons from other countries which may represent an opportunity for Colombia.
3. Develop **scenarios** as to how innovative activity could change in Colombia, if policies adopted in other countries were pursued.

The approach builds on a similar analysis applied to Argentina in 2018, Brazil in 2019 and Mexico in 2020.

THE PROJECT HAS FOUR STEPS

	1	2	3	4
	COLOMBIA IP POLICY FRAMEWORK	**STAKEHOLDER VIEW OF THE CURRENT IP ENVIRONMENT**	**COMPARISON TO OTHER MARKETS AND BEST PRACTISE**	**DEVELOPMENT OF PEER REVIEWED PAPER**
ACTIVITIES	• Review the current IP framework in Colombia, - The current rules and regulations. - Recent changes in the regime and changes to enforcement. - Academic, grey literature on how it works in practice. - The existing policy debate. • Discussion with local academics.	• Interviews with INTERPAT members on investment decisions in Latin America and current perception of Colombia. • Collection of statistics in terms: - R&D Investment - FDI - Clinical trials - Patent applications - Patents granted - Backlog and delays • Interviews with policymakers, academics, SMEs, CROs.	• Develop comparable country case studies. - Development of metrics and recent changes. • Development of scenarios. - Application to Colombia.	• Draft INTERPAT white paper. - Incorporate comments. • Develop peer-reviewed paper for publication. • Participate meeting to disseminate findings.
DELIVERABLES	• A description of the current regime including challenges and opportunities	• Deeper understanding of current challenges • Pressure test potential for change	• Setting out ranking in terms of Lat Am • Case studies on the potential speed of improvement • Scenarios	• White paper Report with policy implications • Published paper on metrics and potential benefits

WE REVIEWED BOTH THE LOCAL AND INTERNATIONAL LITERATURE ON COLOMBIA'S INNOVATION ENVIRONMENT

- We have reviewed more than 50 international and local publications on the current challenges in the IP regime and innovation policy environment in Colombia as well as its innovative performance, with a focus on the pharmaceutical industry:

ACADEMIC PUBLICATIONS

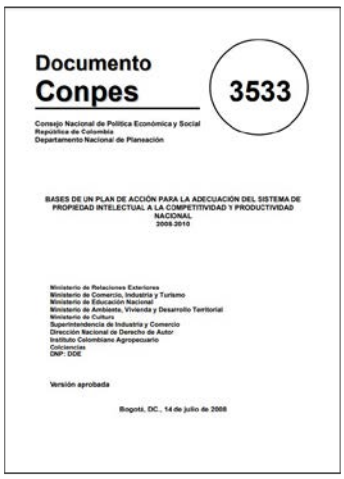
International and local academic literature including Crespi et al. and Busom et al.

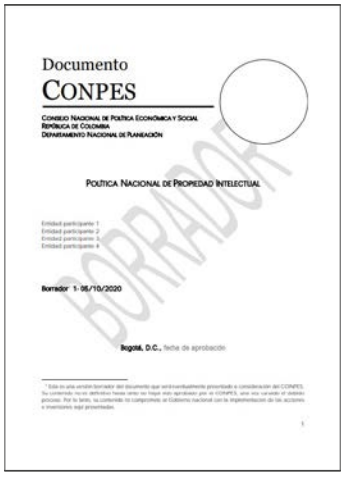
INSTITUTIONAL REPORTS

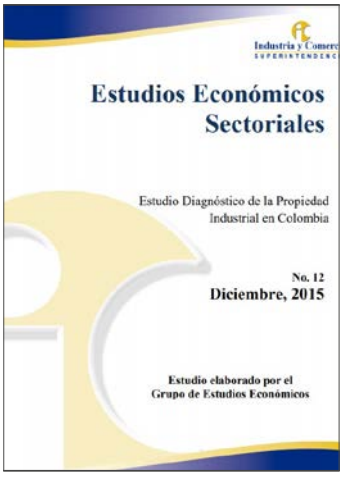
A review of institutional websites, including reports by PhRMA, SIC, CONPES, DANE, Colombia Productiva, OECD, Wilson Centre and WIPO.

GREY LITERATURE

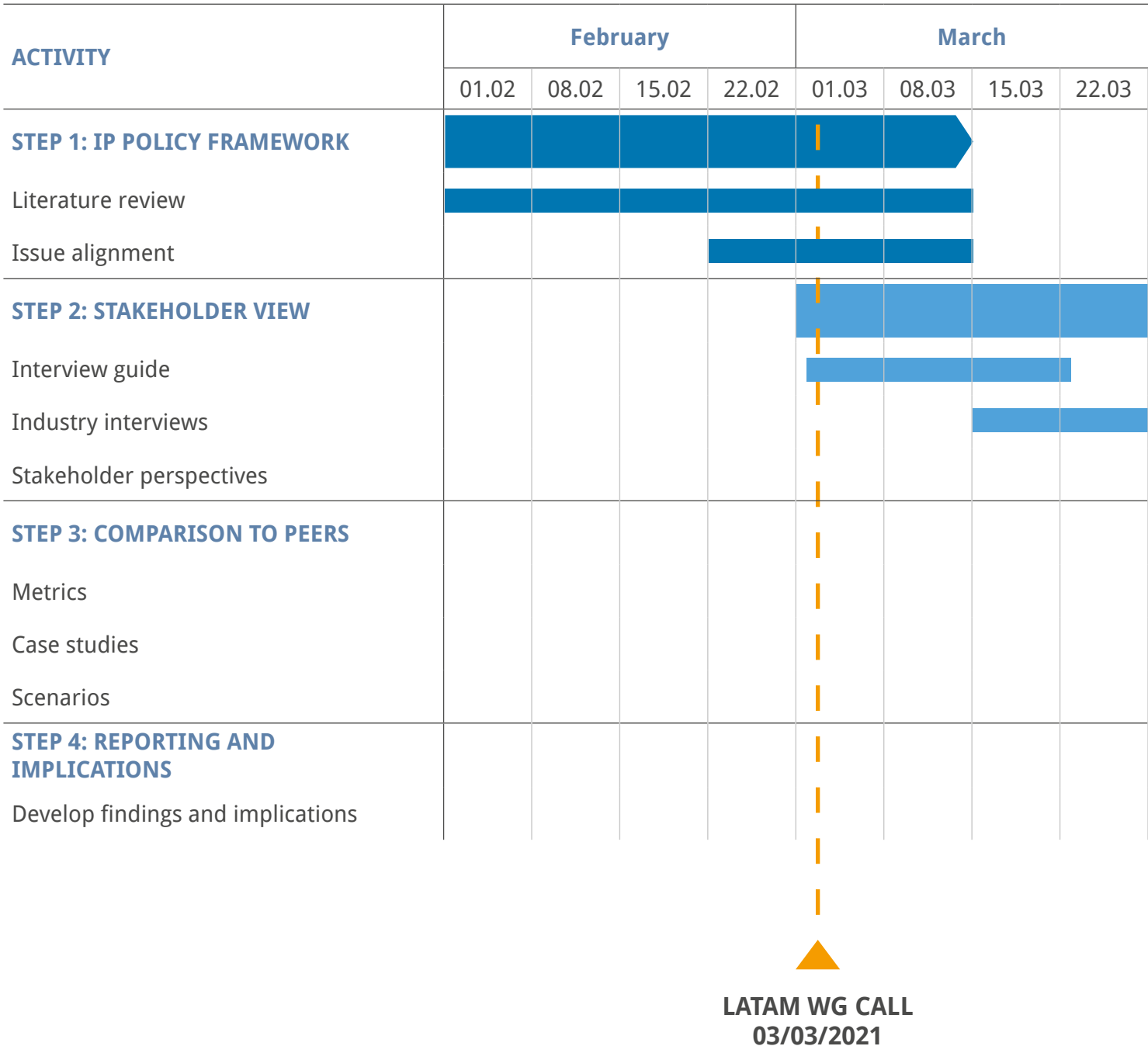
Sourced through targeted Google searches, including online media articles, reviews and op-eds, from local and international sources.



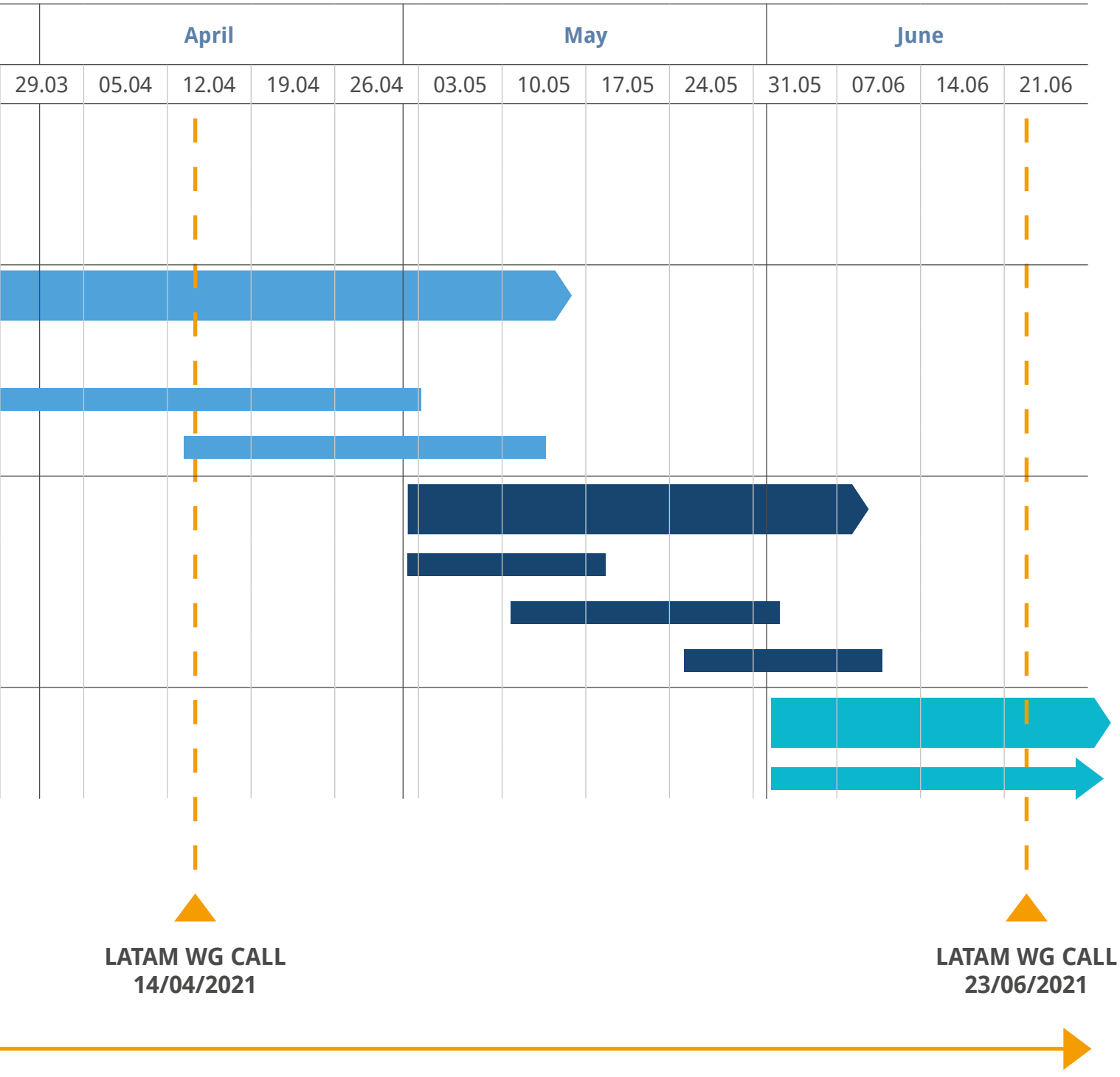




PROJECT TIMELINE



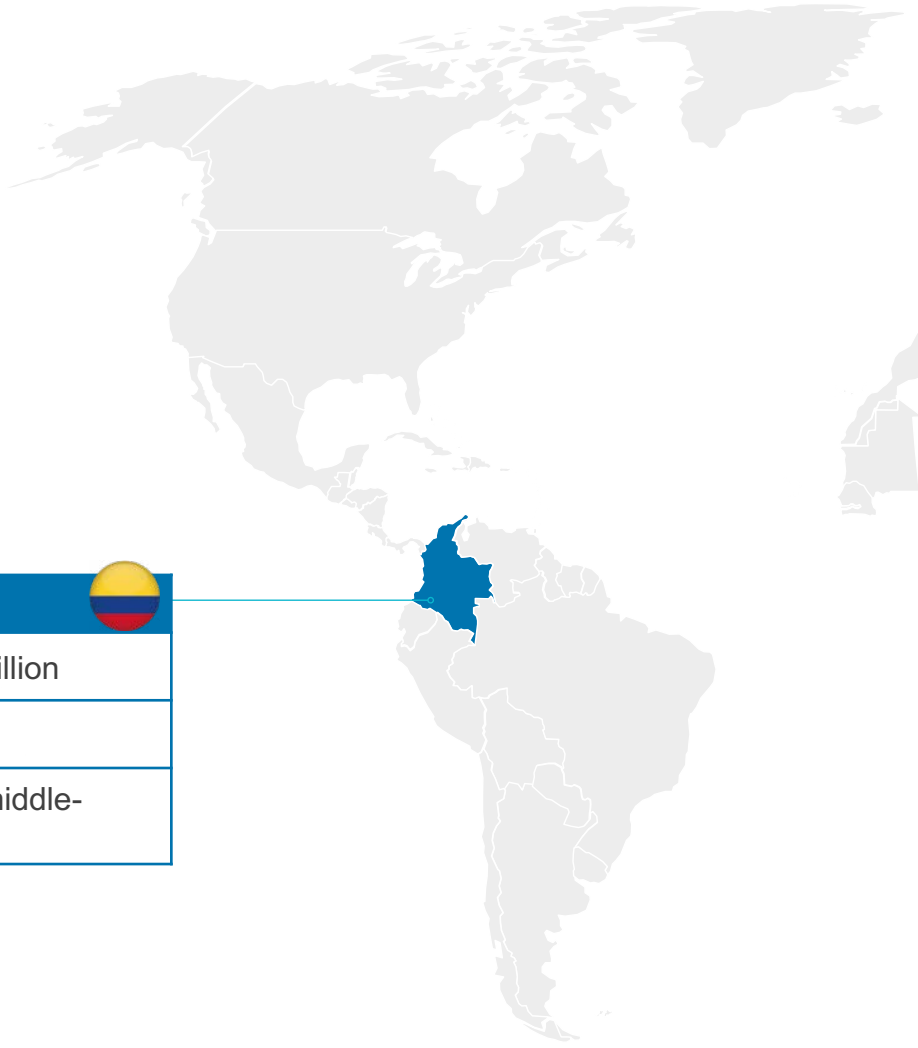
MONTHLY PROJECT UPDATES


April
May
June
29.03
05.04
12.04
19.04
26.04
03.05
10.05
17.05
24.05
31.05
07.06
14.06
21.06
LATAM WG CALL
14/04/2021
LATAM WG CALL
23/06/2021

CASE STUDY ANALYSIS AND SCENARIOS

THE OBJECTIVES OF A CASE STUDY APPROACH ARE TO:

- **Quantify the impact of policies** to strengthen innovation environment.
- Develop **understanding of the context**, to better understand the success of innovation policy change.
- To understand the **policy process to fostering pharmaceutical innovation** in an emerging economy.



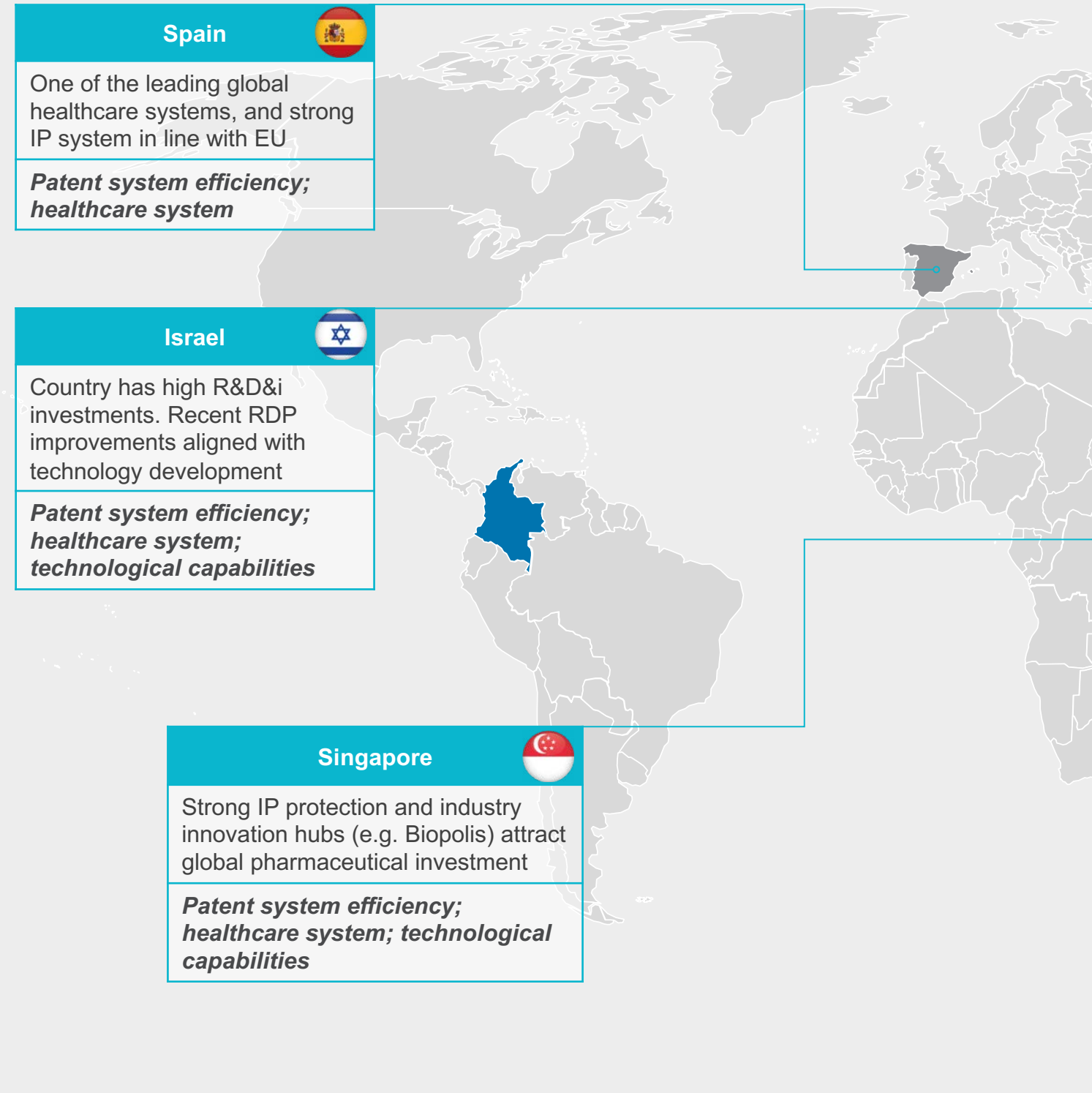
Colombia	
Population	50.34 million
GDP per capita	$6,429
Economy	Upper-middle-income

THE SELECTION CRITERIA FOR OUR CASE STUDY MARKETS SUGGESTS TWO MARKETS TO INVESTIGATE:

1. Have shown a **focus on strengthening innovative environment**, particularly the IP protection.
2. Placed **broadly in the same income, size and development category as Colombia** when started focusing on innovation.
3. Show an observable impact on **innovative activity.**

Tropic mountain forest during rain, Colombia, shutterstock.com/g/OndrejProsicky.

CASE STUDY ANALYSIS AND SCENARIOS: RATIONALE BEHIND SELECTED CASE STUDY MARKETS



Spain

One of the leading global healthcare systems, and strong IP system in line with EU

Patent system efficiency; healthcare system

Israel

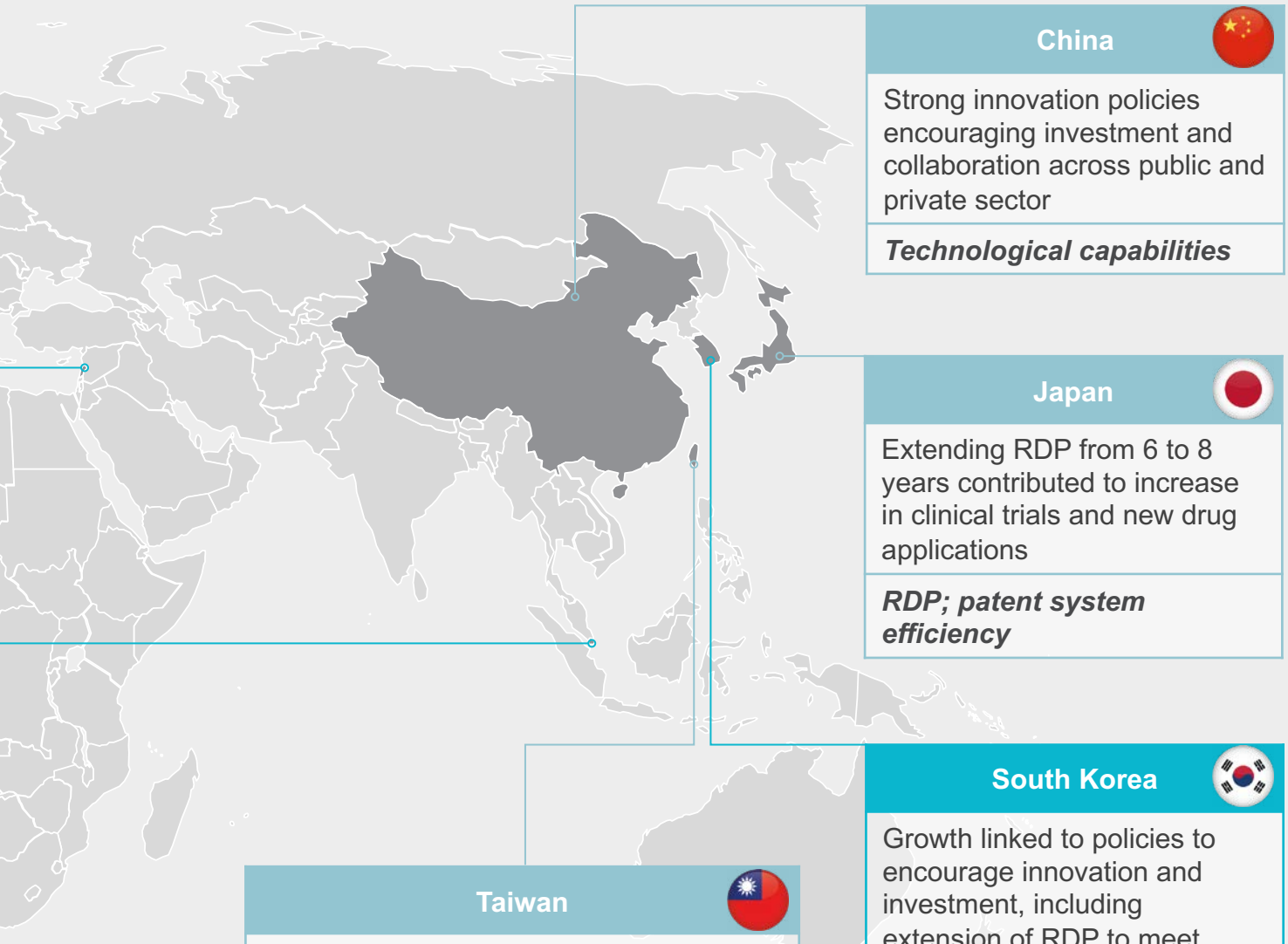
Country has high R&D&i investments. Recent RDP improvements aligned with technology development

Patent system efficiency; healthcare system; technological capabilities

Singapore

Strong IP protection and industry innovation hubs (e.g. Biopolis) attract global pharmaceutical investment

Patent system efficiency; healthcare system; technological capabilities



China

Strong innovation policies encouraging investment and collaboration across public and private sector

Technological capabilities

Japan

Extending RDP from 6 to 8 years contributed to increase in clinical trials and new drug applications

RDP; patent system efficiency

South Korea

Growth linked to policies to encourage innovation and investment, including extension of RDP to meet requests of US, EU and Japan

RDP; technological capabilities

Taiwan

Addressed gaps in IP regime in law passed in 2017 including extending RDP coverage for new indications and introducing a framework for patent linkage

RDP; patent system efficiency (especially linkage)

Key example market

Secondary example market

WE HAVE UNDERTAKEN A COMPREHENSIVE INTERVIEW PROGRAMME WITH 7 INDUSTRY INTERVIEWS

- Industry Interviews were used to provide industry view of Colombia IP policy and innovation environment and remaining key gaps and challenges.
- Local/regional teams provided context and validation of findings identified through literature.

14 EXTERNAL INTERVIEWS HAVE INCLUDED A RANGE OF GOVERNMENT MINISTRIES, ACADEMICS AND LOCAL INFLUENCERS

POLICYMAKERS, REGULATORY EXPERTS AND GOVERNMENT MINISTRIES

El futuro es de todos — DNP Departamento Nacional de Planeación

El conocimiento es de todos — Minciencias

La salud es de todos — Minsalud

MinCIT Ministerio de Comercio, Industria y Turismo

invima — Instituto Nacional de Vigilancia de Medicamentos y Alimentos.

Industria y Comercio — Superintendencia

OLARTEMOURE — Olarte Moure & Asociados — Abogados - Attorneys

LLOREDA · CAMACHO &CO

LOCAL INFLUENCERS IN THE CURRENT INNOVATION ENVIRONMENT

tecnnova — Conectamos Universidad Empresa Estado

Así Vamos en Salud

ISPOR — Improving healthcare decisions

THINK TANKS AND NGOS

WIPO — World Intellectual Property Organization

INNOS — Instituto de Prospectiva e Innovación en Salud

ACADEMICS

UNIVERSIDAD DE ANTIOQUIA

2.
The innovative environment in Colombia and comparison to other markets

THE FOLLOWING INDICATORS WERE ASSESSED TO UNDERSTAND THE OVERALL INNOVATIVE ENVIRONMENT

POLICY ENVIRONMENT → RESOURCES FOR INNOVATION

OVERALL INNOVATION SUPPORT

- National innovation plans.
- Targeted initiatives.

RULES FOR INNOVATION PROTECTION

- IP rules and patentability criteria.
- Patent filing and granting process.
- Regulatory data protection.
- Preliminary injunction process.
- Free Trade Agreements e.g. the CTPA/FTA.

INCENTIVES FOR INNOVATION

- R&D tax credits.

FUNDING FOR INNOVATION

- Public and private funding for research.
- Foreign Direct Investment.

EXPERTISE AND INFRASTRUCTURE

- University quality and education attainment.
- Care: Hospital infrastructure and physician availability.
- Collaboration and clusters.

HEALTH SYSTEM STRENGTH

- Care provision indicators.

INNOVATIVE ACTIVITIES → ECONOMIC ACTIVITIES

EARLY AND BASIC RESEARCH

- Publications.
- Public private collaborations.

PRODUCT DEVELOPMENT

- Clinical trials by phase, type and funder.

OUTPUTS OF INNOVATION

- Number of patents filed, granted both domestic and international.

EMPLOYMENT

- Researchers employed in pharma.
- Types (roles) of employees in pharma in the country.
- Compensation levels.

TRADE

- Imports vs exports in pharma and biotech.

RULES FOR PROTECTION AND OTHER INCENTIVES – ANDEAN LAW

DECISIONS 351: THE PROTECTION OF COPYRIGHT (ANDEAN COMMUNITY), 1993

- Through Decision 351, the Colombian government gave the Colombian Copyright Office the responsibility to oversee the registration of books, music, software, movies, architectural works, and other copyrightable works for the benefit of rights holders.[7]

DECISIONS 345: COMMON REGIME FOR THE PROTECTION OF THE RIGHTS OF BREEDERS OF NEW PLANT VARIETIES (ANDEAN COMMUNITY), 1993

- Decision 345 enabled the granting intellectual property rights over life forms and aimed to promoting research activities in the Andean area and promoting technology transfer activities within and outside the subregion.[8,9]
- Decision 391 builds on 345, aiming to strengthen integration and scientific, technical and cultural cooperation.[10]

DECISION 486: THE NEW INTELLECTUAL PROPERTY LAW OF THE ANDEAN COMMUNITY (ANDEAN COMMUNITY), 2000

- Decision 486 establishes the new legal framework for intellectual property applicable to members of the Andean Community. Decision 486 became effective on December 1, 2000, superceding Decision 344, which was enacted in 1993. The intention of Decision 486 is to strengthen patent protection, key changes vs Decision 344 are:[7,11]
  - New uses of a patented product or process may not be patented.
  - When a patent application is filed, any assignment by the inventor to the applicant as well as a copy of any foreign patent or patent application for the same invention shall be filed.
  - Patent license agreements cannot be registered if they do not meet Andean provisions on licenses or when they infringe provisions on restrictive commercial practices of the Andean Community.
  - The reasons for patent nullity are extended to include essential or procedural defects in the invention. Actions to nullify a patent must be filed within five years from the date the patent was granted or two years from the date the defects became known.

DECISION 689: ABOUT THE ADEQUATION OF DECISION 486 (ANDEAN COMMUNITY), 2008

- Decision 689 was proposed as an amendment to Decision 486, granting rights to each country member to develop and strengthen protection of Industrial Property rights through internal legislation. Said Decision 689 recommends introducing amendments aimed at the following aspects of Decision 486.[7,12]
  - Patents of invention
  - Re-establish the term for claiming international priority rights for a term not more than two months beyond the established initial period (Art. 9)
  - Demand of higher clearness in the description of the invention and higher sufficiency in said disclosure (Art. 28)
  - Accept the reporting of omissions contained in the initial application which priority is being claimed (Art. 34)
  - Except in the case of pharmaceutical patents, it grants rights to compensate the owner of a patent for undue delays in the grant of the patents, being those delays attributable to the Patent Office, restoring the patent term or patent rights. (Chapter V, Title II)
  - allowing the faculty of using the subject protected by a patent right to support the application for approval of commercialization of a product (Art. 53)

Sources:
[3] Insights from CRA external interview programme (Local IP Law Firms)

COLOMBIA'S RULES FOR PROTECTION AND OTHER INCENTIVES (1/2)

NATIONAL INTELLECTUAL PROPERTY POLICY (CONPES, 3533), 2008 (UPDATE EXPECTED 2021)

- This legislation aimed to protect intellectual property; promote the generation of patentable knowledge; strengthen public-private partnerships; and allocate greater public and private spending on science and technology.[13]

DECREE 733 OF 2012 (INVIMA), 2012

- Decree 733 establishes that the National Institute for Food and Drug Regulation (INVIMA) has to publish on its website the basic information related to a heath registration application within five days of the filing date.
  - It has been suggested that this database could be leveraged for patent linkage, however there is currently no indication of use for this purpose currently.[a]

PATENT PROSECUTION HIGHWAY, 2012

- Since 2012 the Colombia Patent Office has been implementing agreements with several Industrial Property Offices destined to achieve application of the Patent Prosecution Highway (PPH). Hence in 2012 it started the pilot program with the United States Patent and Trademark Office (USPTO); in 2013 with the Spanish Patent and Trademark Office (SPTO); and in 2014 it launched the pilot program with the Japan Patent Office (JPO).[14]

CIVIL PROCEDURE LAW REFORM, 2012

- The procedure implemented in July 2012 provided the Colombian Patent Office (CPO) with jurisdiction over infringement cases through an independent Judicial Division. Accordingly, civil actions may now be pursued before civil circuit judges or before the CPO. The CPO has become the principal venue to litigate infringements under civil jurisdiction since it has proven to be a very effective and reliable way to enforce patents.[15]

BOLAR EXEMPTION (DECREE NO. 729 OF 2012), 2012

- Member states of the Andean Community have the option of establishing a Bolar exemption in their national legislation (through Decision No. 689 on the adequacy of certain articles of decision 486 establishing the common regime on industrial property, allowing the development and deepening of the industrial property rights across the internal regulation of the members states).
- This Decree allows third parties to use the claimed subject matter to generate the information necessary to support an application for the marketing approval of a pharmaceutical or agrochemical product under the condition that it will not be made, used, sold, offered for sale or imported into the territory, other than for the purposes of meeting marketing approval requirements, before the patent expires.
- Despite an adequate Bolar exemption Law, Bolar exemption is often inaccurately implemented.[b]

Source:
[a] Insights from CRA external interview programme (Local Law Firms).
[b] Insights from CRA Internal interview programme.

COLOMBIA'S RULES FOR PROTECTION AND OTHER INCENTIVES (2/2)

UPDATES TO THE PROCEDURES FOR THE EXAMINATION AND FILING OF PATENTS (RESOLUTION NO. 3719), 2016

- Through this resolution, the Colombian Patent Office has modified some procedures in relation to the conversion, division and merger of patent applications and the requirements for substantive examination. It is now possible to issue up to three patentability examinations during prosecution of an application, which provides the opportunity to applicant to consider different strategies and file further arguments before the issuance of a final decision. [16-19]

FURTHER EXPANSION OF THE PATENT PROSECUTION HIGHWAY, 2016

- The Colombia Patent Office has made additional PPH agreements with the Korean Intellectual Property Office (KIPO), the European Patent Office (EPO) and the Patent Offices from the member states of the Pacific Alliance (INAPI in Chile, IMPI in Mexico and INDECOPI in Peru).[16] Furthermore, Colombia has joined the Global Patent Prosecution Highway (GPPH) in 2017. [20-21]

COMMERCIAL COMPANIES FOR BENEFIT AND COLLECTIVE INTEREST (BIC) DECREE 2046/2019, 2019

- The regulation contains special provisions such as incentives related to: (i) preferential portfolio of services associated to industrial property; (ii) preferential access to lines of credit; and (iii) special tax treatment of profits distributed through shareholding to worker. [22]

NATIONAL INTELLECTUAL PROPERTY POLICY, 2020/1

- The National Council for Economic and Social Policy has published a draft document, containing the National Intellectual Property Policy that will govern the country. The policy on intellectual property would be governed by the following principles: (i) Encourage creativity and innovation, based on the effective use of intellectual property rights; (ii) Increase the effectiveness of the protection and enforcement of intellectual property rights, balancing the needs of owners and users; (iii) Consolidate intellectual property as a transversal tool for the generation and transfer of knowledge of any sector, through a consolidated and articulated institutional framework. [1,13]

INNOVATION POLICIES IN COLOMBIA (1/3)

COLOMBIA'S NATIONAL DEVELOPMENT PLAN (ARTICLE 71 OF LAW 1753/2015), 2015

- This Law authorises the Ministry of Health and Social Protection (MoH) to conduct centralised negotiations and directly purchase medicines, medical supplies and devices. This authorisation is part of a state policy aimed at guaranteeing access to medicines and healthcare services for all citizens. It also contributes to the financial sustainability of the General System of Social Security in Health.[23]

CONPES PRODUCTIVE DEVELOPMENT POLICY (CONPES 3866), 2016

- The main policy objectives are to develop instruments that aim to solve market, government or articulation failures at the level of the production unit, the production factors or the competitive environment, to increase productivity and diversify the Colombian productive sector towards more sophisticated goods and services.
- This policy describes key actions to improve innovation.[24]

SPIN-OFF LAW (LAW NO. 1838), 2017

- This law specifies that spin-offs must be articulated to the Regional Competitiveness Plans and to the Policies of the National System of Science, Technology and Innovation - SNCTi.
- Teachers and / or researchers who participate in the creation of spin-offs will be able to obtain economic benefits, without this constituting a salary factor or double assignment.
- Higher Education Institutes (HEIs) may also create a Fund to promote Science, Technology and Innovation Activities - ACTi. When the results that give rise to the spin-off come from public resources, the spin-off must revert to the Institution of Higher Education a percentage for reinvestment in ACTi. [a]

STRATEGY OF DIGITAL TRANSFORMATION, 2018 - 2022

- The Strategy of Digital Transformation of Companies and Productive Sectors aims to increase the degree of strategic adoption of technology and electronic commerce of the Colombian business sector, and promote its use for the sake of productivity and competitiveness. [25]

NATIONAL LABORATORY POLICY (CONPES 3957), 2019

- Objectives of this policy are to improve the measurement capabilities of laboratories, the development of the laboratory services market and the regulatory and institutional framework as a tool to promote the competitiveness and internationalization of the productive sectors and the protection of the consumer, health and environment. [a]

Source:
[a] Insights from CRA external interview programme (Government organisation).

INNOVATION POLICIES IN COLOMBIA (2/3)

DIGITAL TRANSFORMATION AND AI NATIONAL POLICY (CONPES 3975), 2019

- The main objective is to generate social and economic value through the transformation of the public and private sectors so that Colombia can take advantage of the opportunities and face the challenges related to the 4RI. [26]

INNOVA AWARD, 2019

- The Award – to which €50-100 million will be allocated yearly – is a strategy to promote innovation in Micro, Small and Medium Enterprises, with the intention of achieving greater productivity and competitiveness across economic sectors.[27-28]

KNOWLEDGE AND TECHNOLOGY TRANSFER - FÁBRICAS DE PRODUCTIVIDAD, 2019

- Program led by Colombia Productiva and the Ministry of Commerce with allies such as the Chambers of Commerce and SENA that seeks to increase the internal productivity of companies.[a]
- Aims to improve productivity and scale-up within companies, provide expert training and other support, e.g. financial.

LINKING KNOWLEDGE, 2019 - 2024

- Public call for programs and projects that generate knowledge along prioritized research lines through collaborations between research groups. The call also wants to support young researchers who are working in the obtaining or improvement of products, services, processes and their application.[29]

THE BUSINESS PLAN FOR THE PHARMACEUTICAL SECTOR, 2019 – 2032

- The vision for 2032 of the Business Plan for the Pharmaceutical sector is to be a specialist in the production and commercialization of high-quality chemical synthesis supplies and drugs and to enter the biotechnology market, being a solid drug marketer within the American continent.[2-4]

Source:
[a] Insights from CRA external interview programme (Government Ministry).

INNOVATION POLICIES IN COLOMBIA (3/3)

NATIONAL ENTREPRENEURSHIP POLICY (CONPES 4011), 2020

- The objective is to generate enabling conditions in the entrepreneurial ecosystem for the creation, sustainability and growth of start-ups that contribute to the generation of income, wealth and increases in productivity and internationalization of Colombian companies.[a]
- The policy establishes a regulatory framework supporting entrepreneurship and sustainability of companies.[a]
- Promotes the interests of SMEs, e.g. lowers INVIMA fees for SMEs; public procurement will promote micro and SMEs with different requirements (less competitive selection processes); provides tax benefit for regional registration for microenterprises.[a]
- Creates controlled environments (Sandbox model) for the government to assess the effect of new regulations on technologies or innovations.[a]

NATIONAL POLICY FOR SCIENCE TECHNOLOGY, AND INNOVATION, *UNDER DEVELOPMENT*

- This policy outlines actions to improve institutional coordination and update the institutional regulatory framework and to strengthen the scientific and technological infrastructure of the regions, in response to the particular needs of the country.[30]

RIGHT TO HEALTH POLICY (PROPOSAL 10/2020), *UNDER DEVELOPMENT*

- Through this law, adjustments are made to the Health System to guarantee the fundamental right to health outlined in Law 1751 of 2015. The key objective are to:
  - Guarantee the fundamental right to health, materializing the rule of law and centered on the person.
  - Redefine the essential functions of the health system, allowing the integration of public health, risk protection, and the provision of services that materialize the right to health.
  - Resume the real role of the insurer.
  - Establish territorialization for all actors.
  - Order the development of a public health policy, which includes a model of care and the promotion and prevention of health.

Source:
[a] Insights from CRA external interview programme (Government Ministry).

THE LITERATURE REVIEW IDENTIFIED FIVE MAIN WEAKNESSES IN COLOMBIA'S IP REGIME

COMPULSORY LICENSING

- Decision 486 of the Andean Community provides for compulsory licensing in the event of a Declaration of Public Interest (DPI) from Colombia's Ministry of Health and Social Protection (MOH).[31]
- In the past, there have been two compulsory license cases on public interest grounds, Abbott Kaletra and Novartis Glivec.[32] In both cases, the compulsory licenses were initiated by the same non-governmental organizations, namely, IFARMA Foundation, Mision Salud and CIMUN. In both cases, the compulsory licenses were rejected.[33]
- Most recently, in December 2017, Colombia's MOH accepted a Declaration of Public Interest (DPI) petition for review that could lead to the compulsory licensing of the entire class of innovative treatments for hepatitis C.[34]
- Additionally, in Article 57 of Proposed Bill 372 of 2020, Colombia proposes relaxed internal regulations to grant automatic compulsory licensing on all existing or future patents on essential public health technology goods.[35-36]

REGULATORY DATA PROTECTION FAILURES

- Colombia fails to respect existing legislation that would otherwise provide regulatory data protection upon approval of novel pharmaceutical products.[34]
  - The Colombian regulatory authority INVIMA recently has begun denying regulatory data protection upon approval of some new chemical entities, simply because they share a minor portion of their chemical structure with previously approved products.[34]

RESTRICTIVE PATENTABILITY CRITERIA

- Contrary to its obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Colombia does not grant patents for second uses because Andean IP Law does not allow for them.[34]
- Furthermore, INVIMA's potential role in patent examination are seen as greatly weakening the biopharmaceutical eco-system.[37]

WEAK PATENT ENFORCEMENT

- There is no mechanism in place to provide patent holders with the opportunity to resolve patent disputes prior to the launch of a follow-on product. This has led to the approval and marketing of follow-on products, despite the fact that a patent for the original drug is still in force.[34,37]

SUBSTANDARD BIOLOGICS REGULATION

- On September 18, 2014, Colombia issued Biological Medicine Decree 1782, which establishes marketing approval evaluation requirements for all biologic medicines. Decree 1782 established an unprecedented abbreviated pathway for the registration of non-comparable products, which does not require new or comparative clinical studies.[34]
- Some local stakeholders hold the view that this pathway aims to achieve cheaper biosimilars at the risk of patient health and safety. Moreover, there have been concerns raised about the decree internationally, including by the EU and the US. They have criticized the decree for the fact that it 'could put health and safety at risk', and lacks detail as to which biologicals the abbreviated pathway is intended for and how the pathway will be implemented.[37-38]

Source:
[a] Insights from CRA Internal interview programme.
[b] Insights from CRA External interview programme (Local Law Firm).

ADDITIONALLY, THERE IS A BILL THAT IS THREATENING COLOMBIA'S PROGRESS WITH ITS IP FRAMEWORK AND INNOVATION ECOSYSTEM

The "National Policy for Scientific Research, Technological Development and Innovation R&D&i for Pharmaceutical Safety and other provisions" Bill (Bill 372 of 2020) sets out to protect Colombia from a possible shortage of essential medicines and supplies for public health, in the context of COVID-19.[39] Colombia is heavily dependent on imports for medicines, but opposition to the bill argues that the goal of a self-sufficient pharmaceutical industry is not realistic and that other provisions in the bill would ultimately hinder the research, technological development and production needed to strengthen capacities in Colombia.

Chapter II of Bill 372 of 2020 covers Instruments related to Intellectual Property regarding Pharmaceutical Security:

- **ARTICLE 57. Automatic compulsory licenses:** Grant automatic compulsory licenses on all existing or future patents on essential public health technology goods.
- **ARTICLE 58. Exceptional suspension of the effects of intellectual property protection:** In the event of delay in granting compulsory licenses during any situation that compromises health or life, the impact of patents and any other figure that protects intellectual property in the national territory shall be exceptionally suspended.
- **ARTICLE 59. Exceptional discontinuation of intellectual property procedures:** In the event of a pandemic or public health emergency, discontinue the procedures for granting patents and any other form of IP protection in progress related to such pandemic or emergency.
- **ARTICLE 60. Open Science and Open Data:** In the event of a pandemic or public health emergency, declare all related technical and scientific data to be of public interest and provide public access to all such data within the framework of open science and open data policies.

There are additional concerns regarding:

- **The definition of essential public health technology goods:** The initiative defines this broadly, covering essential public health technology goods as all health technologies, including drugs, vaccines, instruments, equipment, among others, in this new category.
- **The creation of the Colombian Institute of Pharmaceutical Research and Manufacturing (ICIFF):** There are concerns that ICIFF may disregard the current institutional frameworks, as some of the responsibilities that are already covered by other institutions may be transferred to ICIFF.
- **The proposed tax instruments, freedom and promotion of innovation, tax control, import, and regulatory mechanisms to promote pharmaceutical safety:** These incentives are exclusive to the domestic industry and thus these incentives contravene the international treaties ratified by the country, especially regarding the basic principles of international trade.
- **An earlier version of the proposed bill included clauses to suspend adherence to TRIPS and the granting of patents during the COVID-19 pandemic.** These clauses were ultimately taken out of the proposal.[a]

This may result in IP rights, international standards, good practices, and norms in place to ensure safety and efficacy not being respected

Source:
[a] Insights from CRA External interview programme (local university think tank; local law firm).

INTERVIEWS WITH LOCAL STAKEHOLDERS CONFIRM AND HIGHLIGHT NEW CHALLENGES IN COLOMBIA'S **IP FRAMEWORK** (1/2)

LEVEL OF IMPORTANCE

	Trends and/or gaps:	Stakeholder perspectives:
REGULATORY DATA PROTECTION	• Regulatory data protection (RDP) is threatened by the regulatory authority, INVIMA, which reviews applications in the context of the ambiguous language in the data protection Decree 2085 of 2002 about new molecules. Recently, INVIMA rejects applications based on similarities to other molecules without a detailed explanation of the decision or the ability for companies to challenge the ruling.[a,b] • However, it should be noted that the CTPA/FTA (Article 16.10.2) provides an RDP obligation for Colombia.[a]	• RDP is one of the highest priority topics for enhancing the IP environment in Colombia according to local pharmaceutical trade association, AFIDRO and other industry stakeholders.[a] • There is also a desire to see greater capacity and training in INVIMA, and to address the challenges of the contract-based workforce turnover in the agency.[b]
EDUCATION ABOUT IP RIGHTS*	• Higher education in Colombian universities generally does not educate researchers or doctors in health sciences and medical fields about the role of IP.[b]	• Industry is partnering with universities to promote education about the importance of IPR in health sciences and medical fields to try to shift public opinion about the value of IP beyond just pharmaceutical interests.[a,b] • There are also efforts underway to educate Congressional staffers and the public abut IPR.[a]
COMPULSORY LICENSING	• Recent proposal from Congress to promote automatic compulsory licensing does not seem to have a balanced view of its impact on innovation, but the policy has gained political popularity from the Left.[a]	• AFIDRO is working to educate Congress and staffers on the link between IP rights and innovation.[a] • The renewed threat of compulsory licensing is dangerous, if passed, because of impacts beyond COVID-19. There is also a view, however, that past efforts to issue compulsory licenses have failed and serve as a threat to aid in negotiations.[b]

Source:
[a] Insights from CRA Internal interview programme.
[b] Insights from CRA External interview programme (university research thinktank; local health NGO; international IP organisation; local law firm).

Note: * challenge was first identified by CRA interview programme, rather than secondary research.

INTERVIEWS WITH LOCAL STAKEHOLDERS CONFIRM AND HIGHLIGHT NEW CHALLENGES IN COLOMBIA'S **IP FRAMEWORK** (2/2)

LEVEL OF IMPORTANCE (CONT.)

	Trends and/or gaps:	Stakeholder perspectives:
IP LAW ENFORCEMENT TIMELINES AND EFFICIENCY*	• The court system for patent enforcement is reliable and has improved in the last 5-10 years. However, litigation can take several years, similar to other countries in the region.[a,b]	• Stakeholders are divided on the efficiency of the court system. The specialised court for IP issues is fast compared to other courts, and preliminary injunctions are typically issued in a few months. Otherwise, cases brought to civil or criminal courts for enforcement may take several years.[a,b] • It is viewed favorably that companies have the reverse burden of proof in infringement cases for manufacturing patents.[1]
PATENT LINKAGE*	• There is no patent linkage framework or communication between the national regulatory authorities (INVIMA) and the Patent Office in Colombia (SIC). Companies and INVIMA are required publish information about patents under a transparency decree.[a,b,40] • This is despite the inclusion of wording in the CTPA/FTA (article 16.10.3) on the implementation of a system for patent linkage.[a]	• There is no interest in introducing a patent linkage framework nor to improve collaboration between INVIMA and SIC, coming from the agencies.[1,2] Patent linkage was discussed during negotiations for the US-Colombia FTA, but SIC and INVIMA asserted independence.[b] • According to industry and local law firm stakeholders, the patent database run by INVIMA created by the transparency decree is not viewed as being up to date or accurate.[a,b]
RESTRICTIVE PATENTABILITY CRITERIA	• *No trends identified. General acknowledgement of restrictive patentability criteria and framework which does not grant patents for second uses, differing from many other countries.*[a,b]	• Patentability criteria are generally accepted by industry, and although the current framework does not grant patents for second medical uses, overall, Colombia grants more patent types than other countries in LatAm.[a, b] • The issue of patents not currently available for second uses is a legal rather than policy topic that would need to be changed in the Andean Law.[b]

Source:

1 Insights from CRA Internal interview programme.

2 Insights from CRA External interview programme (university research thinktank; local health NGO; international IP organisation; local law firm; former employee of governmental agency).

Note: * challenge was first identified by CRA interview programme, rather than secondary research.

THE REGULATORY FRAMEWORK AND COST-CONTAINMENT MEASURES HINDER ACCESS TO INNOVATIVE PRODUCTS

SCIENTIFIC CAPABILITIES & INFRASTRUCTURE

- The current scientific research infrastructure could be improved. However, the government has introduced several policies to improve the country's scientific capabilities, including the Regional Networks of Entrepreneurship programme to encourage collaborations across different departments.[37]
- Multisectoral efforts are also underway to improve Colombian competitiveness in clinical research. Efforts include the Pact for Colombia, the Pact for Innovation and the Pact for growth and job creation in the pharmaceutical sector and inclusion of clinical research as a topic in the National Development Plan.[41,b] Increasing resources for tech transfer is another priority to increase local innovative activity.[b]

COST CONTAINMENT MEASURES

- Government measures to improve the sustainability of the Colombian health system have focused on the pharmaceutical industry, and have not addressed issues within the pharmaceutical supply chain or other health sectors.[42,43]
- Two policy efforts to reduce health expenditure included (i.) price caps, mostly used between 2010-2012, and (ii.) external reference pricing scheme, introduced in 2013, which covers the majority of public drug expenditure. Independent researchers found price controls did not decrease overall real pharmaceutical expenditures from 2011-2015.[43] The most recent price control regulations have been Circular 10 and 11 of 2020.[43]

REGULATORY SYSTEM BARRIERS

- INVIMA (Colombia's regulatory body) is under-staffed and utilises inefficient processes. Furthermore, the regulatory process is seen as lacking transparency,[42] and in need of greater modernization.[a]
- Article 72 of Colombia's National Development Plan (which was enacted as part of Law 1753 on May 7, 2015), is of particular concern to the industry as it inserts price and health technology assessment (HTA) criteria into the regulatory approval process.[37]
- Recent efforts to improve regulatory processes have helped to improve average clinical trial approval timelines which tend to take around 6 months. A new clinical trials platform (SiSEC) has also been adopted to assess and facilitate improvements to regulatory system barriers.[a]

Source:
[a] Insights from CRA Internal interview programme.
[b] Insights from CRA External interview programme (government agency stakeholders).

INTERVIEWS WITH LOCAL STAKEHOLDERS CONFIRM AND HIGHLIGHT NEW CHALLENGES IN COLOMBIA'S **INNOVATION ENVIRONMENT** (1/2)

LEVEL OF IMPORTANCE

	Trends and/or gaps:	Stakeholder perspectives:
UNEQUAL HEALTHCARE ACCESS	• Colombia has wide regional and socioeconomic disparities in healthcare access.[b]	• Improving national healthcare standards is a priority for policymakers and the public, and any report about the innovation environment should acknowledge this.[b]
TECHNOLOGY AND SCIENTIFIC CAPABILITIES*	• The technology available at manufacturing sites and level of innovation outputs in general have been improving but still lagging behind that of the region's leaders and this is attributed to lack of incentive policies.[a]	• Lagging capabilities contribute to innovative pharmaceutical companies investing in R&D elsewhere.[a] • No strong culture for R&D and entrepreneurship, resulting in a knowledge gap on bridging the two.[b]
COLLABORATION*	• Limited collaboration between industry and academia and lack of policies to encourage both sectors to partner.[a,b]	• Greater use of technology transfer as well as increased R&D by local industry seen as positive future direction for Colombian pharmaceutical innovation.[a] • Gaps in policies to promote and incentivize collaboration between companies and academia exist.[a]
DELAYS IN REGULATORY COMMUNICATION*	• Difficulties and delays communicating with regulatory and patent bodies.[a,b] • Apparent preference for local companies vs Pharma.[a]	• Low chance to clarify decisions made by INVIMA.[a] • Generics often gain approval within 6 months to 1 year by INVIMA, often resulting in launch prior to LOE of the branded product.[a,b]
PREVALENCE OF COUNTERFEIT MEDICINES*	• High prevalence of counterfeit medicines.[a,b]	• Counterfeit medicines pose a high risk to the public and damage reputation of Pharma companies.[a] • In addition, there is an apparent low level of preventative measures from government despite mention in most recent CONPES policy on IP protection.[a]

Source:
[a] Insights from CRA Internal interview programme.
[b] Insights from CRA External interview programme (university research thinktank; local health NGO; academics).

Note: * challenge was first identified by CRA interview programme, rather than secondary research.

INTERVIEWS WITH LOCAL STAKEHOLDERS CONFIRM AND HIGHLIGHT NEW CHALLENGES IN COLOMBIA'S **INNOVATION ENVIRONMENT** (2/2)

LEVEL OF IMPORTANCE

	Trends and/or gaps:	Stakeholder perspectives:
GOAL OF NATIONAL SELF-SUFFICIENCY*	• Arising from concerns of medicine supply shortages during COVID-19 pandemic, issues of supply security are politically salient.[b]	• Goals of national pharmaceutical self-sufficiency are unrealistic given the interconnected nature of the industry and can be detrimental to local capacity-building.[b]
POLITICAL BACKDROP*	• 2022 is an election year and there is uncertainty around whether the next national government will maintain current attitudes toward and initiatives supporting innovation.[b] • High frequency of 12-month employee contracts within INVIMA, SIC, and other stakeholder institutions results in a loss of time and short term thinking.[a,b]	• Current President Duque's "orange economy" platform supports economic growth and industry hubs, but the next president may be less industry or economy focused.[b] • Short term thinking has resulted in a lack of medium and long term solutions, which are essential for health and sciences.[b]
PRICING REGULATION*	• Inaccurate implementation of price controls due to similarity in molecule structure, despite difference in technology and indication.[a]	• Clarification of the regulations around molecule similarities and the level of restrictions and regulations imposed on companies is required to ensure no ambiguity.[a]

Source:
[a] Insights from CRA Internal interview programme.
[b] Insights from CRA External interview programme (university research thinktank; local health NGO; academics; former employee of governmental agency).

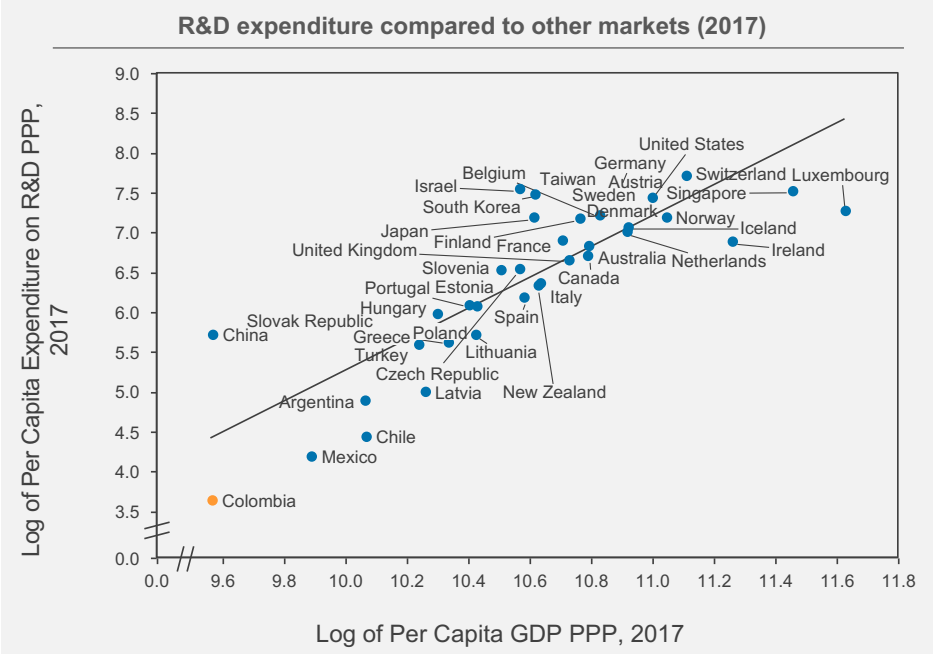
Note: * challenge was first identified by CRA interview programme, rather than secondary research.

Downtown Bogotá, Colombia, shutterstock.com/Henrry L Ramirez.

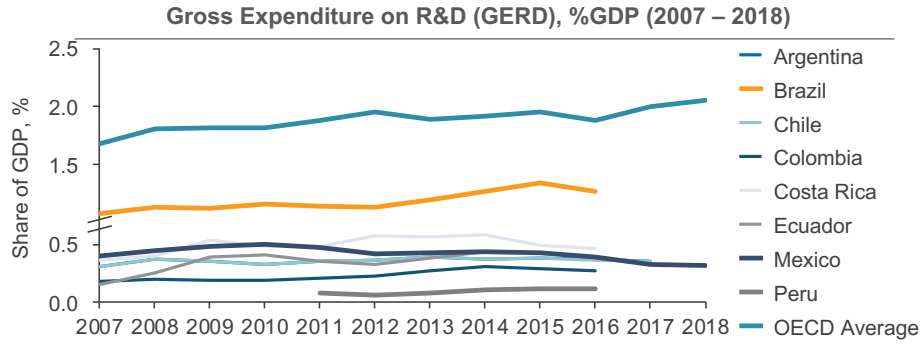
RESOURCES FOR INNOVATION:
INVESTMENT IN R&D COMPARED TO LATAM

- Colombia falls short of the OECD average in R&D investment relative to its GDP per capita by 1.6 percentage points (2016) and also versus other Latin America countries with comparable GDP per capita, including: Argentina, Brazil, Chile, Costa Rica, Ecuador and Mexico.
- However, Colombia has a higher R&D Expenditure per full-time equivalent (FTE) researcher than other Latin American markets.
- In addition, less than a quarter of companies can be considered innovative in Colombia, with the majority of companies focused on manufacturing, packaging and similar services.[a]

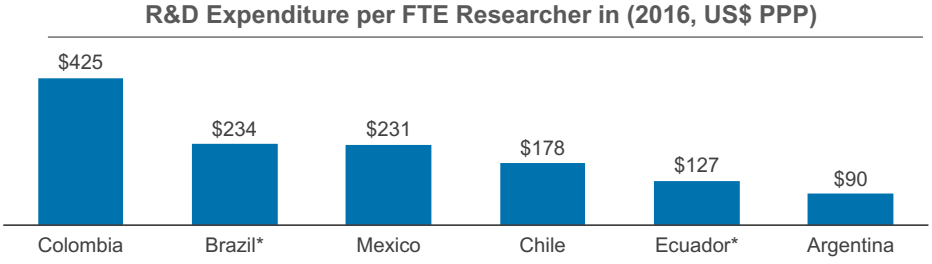
Source:
[a] Insights from CRA External interview programme (Government Ministry; Government organisation).



Sources: World Bank Data for GDP per capita, PPP; OECD Main Science and Technology Indicators (2021); Taiwan Population 1950-2021, Macrotrends; Taiwan GDP – per capita (PPP), Index Mundi.



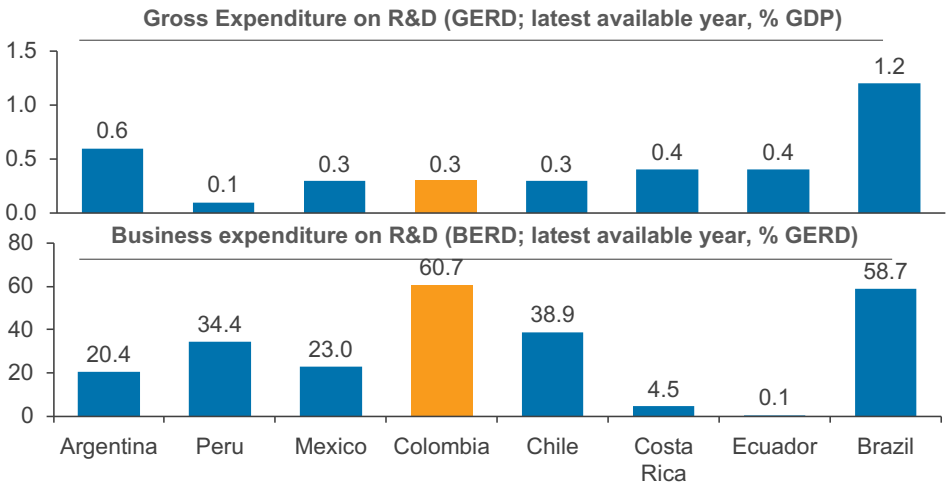
Source: Ibero-American Network, Science and Technology Indicators (2020); OECD Main Science and Technology Indicators (2020).



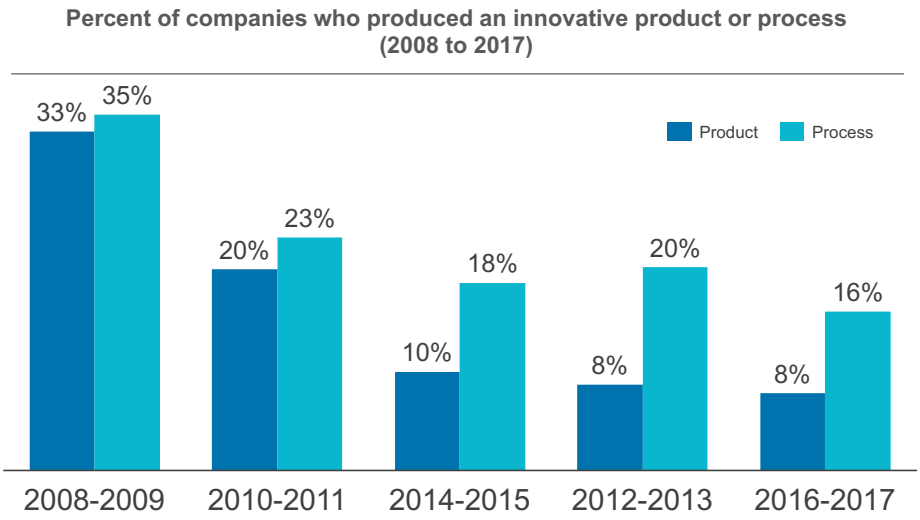
Ibero-American Network, Science and Technology Indicators 2018; OECD Main Science and Technology Indicators (2019). Note: * Latest data from 2014.

RESOURCES FOR INNOVATION:
INVESTMENT IN R&D COMPARED TO LATAM

- Gross expenditure on R&D in Colombia (0.3% of GDP) is comparable to other LatAm markets but lower than Brazil (1.2% of GDP).[44]
- In Colombia, private investment in R&D as a percentage of GERD is higher than other LatAm markets and in line with Brazil, which indicates a high rate of growth in business led innovation over the last few years from 30% in 2014 – private R&D investment is predominantly focused in the information technology, health and pharmaceutical, and chemicals and oils industry.[44,45]
- Government funded investment in R&D predominantly focusses on health sciences, with some dedicated to social sciences, energy and mining and agriculture.[46]
- In 2016-2017, 24% of companies have invested in an innovative project or process, or have developed at least one innovative product – this contrasts to 68% of companies' in 2008-2009.[46]
- This indicates that in 2016-2017 there were fewer companies investing in innovative products or processes, but level of expenditure has been increasing.



Source: Global Innovation Index 2021; Latest available year for all countries was 2020, except for Peru BERD, where the latest data was 2014).

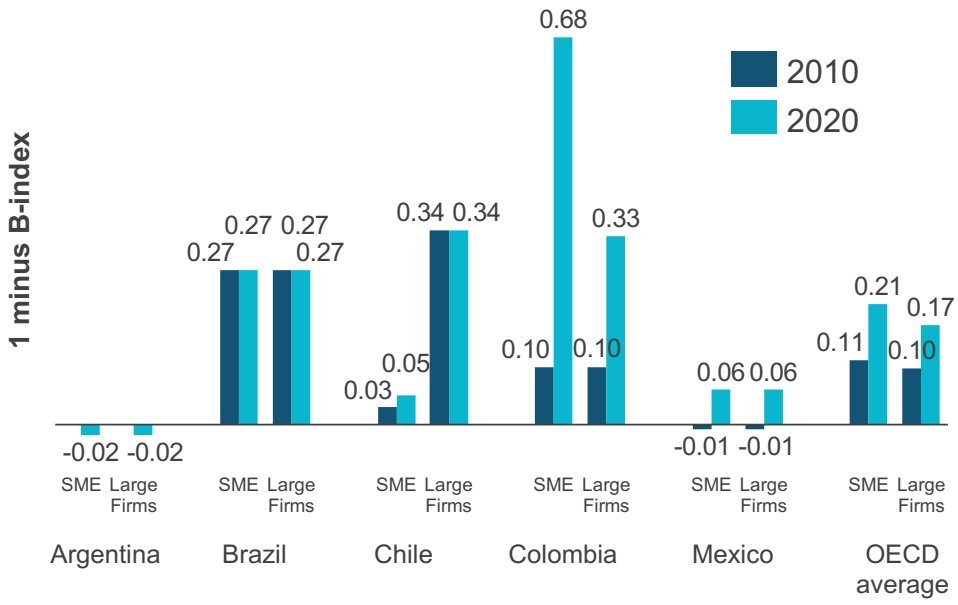


Source: Ocyt 2021

RESOURCES FOR INNOVATION:
R&D TAX INCENTIVES

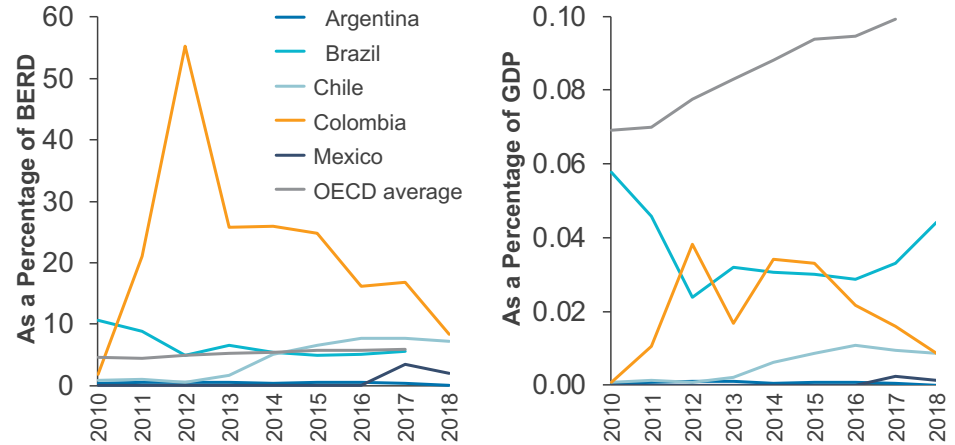
- Colombia provides R&D tax relief through a volume-based R&D tax credit for investment or donations in research and technology development:[47]
  - The headline rate of relief is 25%.
  - In the case of insufficient tax liability, unused credits can be carried-forward 4 years.
  - The R&D tax credit is limited to 25% of businesses' corporate tax liability.
- In 2020, the marginal tax subsidy rate for profit-making SMEs in Colombia is estimated 0.68, well above the OECD average of 0.21. The tax subsidy rate for large enterprises is 0.33 in the profit-making scenario and significantly larger than the OECD average of 0.17.
- However, Colombia is placed among the lower tier of OECD economies in terms of total government support to business R&D as a percentage of GDP,[47] equivalent to 0.0087 of GDP in 2018.

Implied tax subsidy rates on R&D expenditures (2010 and 2020)



OECD R&D tax subsidy (RDTAXSUB) dataset 2020.

Indirect government funding through R&D tax incentives (2010 – 2020)



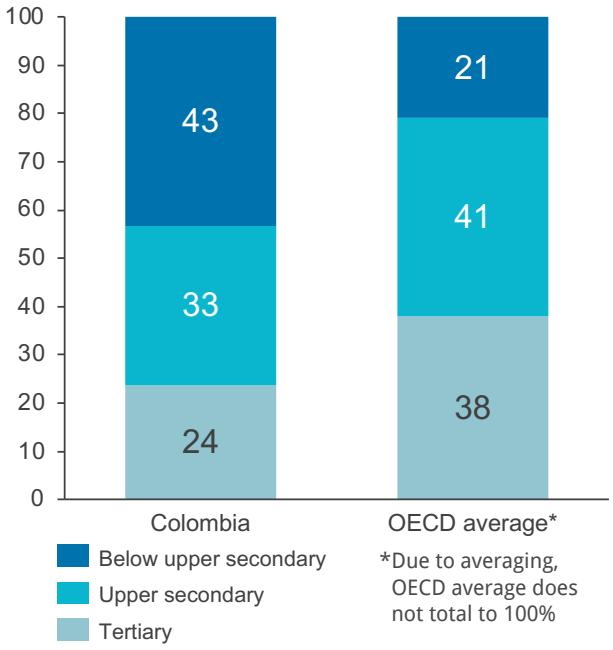
Source: OECD R&D tax subsidy (RDTAXSUB) dataset 2020.

RESOURCES FOR INNOVATION: AVAILABILITY AND STRENGTH OF RESOURCES AND EDUCATION

- In Colombia, the proportion of 25-64 year olds with tertiary education and Colombia's average PISA Science Score fall short of the OECD average.
- Furthermore, the percentage of biological and related sciences graduates across all science fields in Colombia (9%) is comparable to that in Mexico (9%) but lower than that of Chile (18%).
- However, Colombia has the third largest proportion of STEM graduates when compared to other LatAm countries, lagging behind Chile and Mexico.

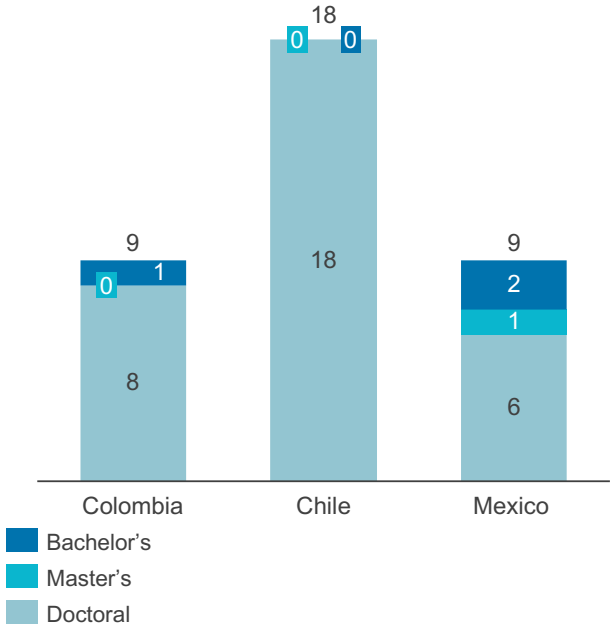
STEM - Science, Technology, Engineering and Mathematics.

Educational attainment of 25-64 year olds (2019, %)



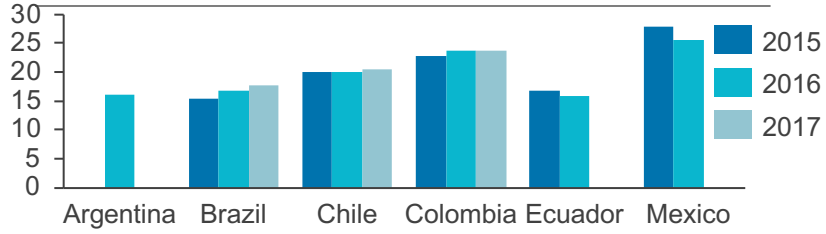
Source: OECD Data, 2019
STEM - Science, Technology, Engineering and Mathematics

Percentage of biological and related sciences graduates across all science fields by grade (2018)



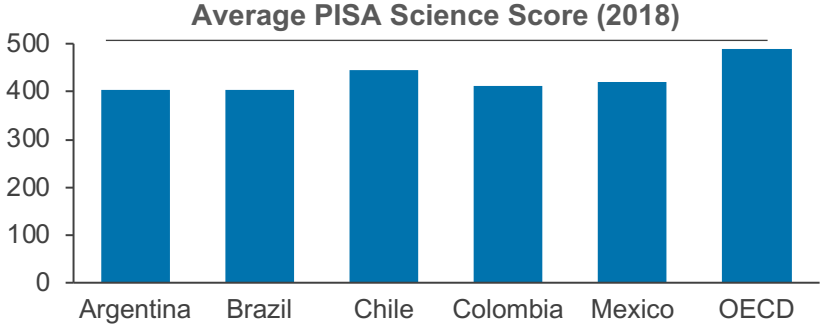
Source: OECD Data, 2020

Graduates from STEM degrees in tertiary education (%)



Source: UNESCO UIS.Stat, 2015-2017

Average PISA Science Score (2018)



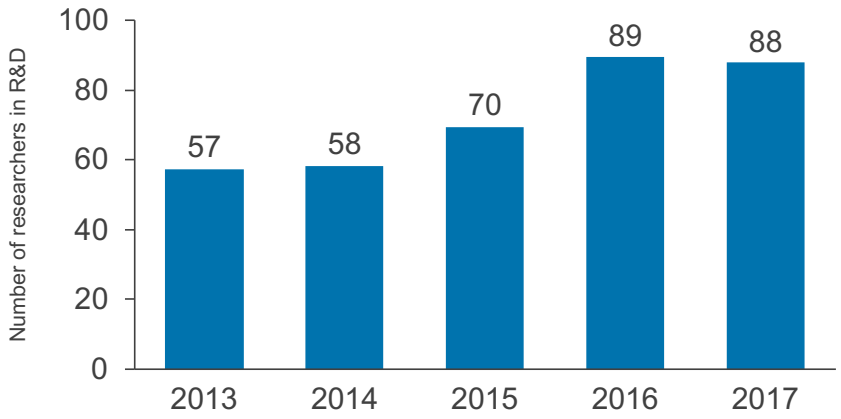
Source: OECD Data, 2018

RESOURCES FOR INNOVATION: AVAILABILITY AND STRENGTH OF RESEARCHERS

- Since 2013, the number of R&D researchers in Colombia has increased slowly but data suggests that funding in system which educates and employs scientists have been lacking for many years and has been cited as key barrier to growth in this area.[48]
- In addition, the brain drain is a major issue for Colombia's research and innovation environment. The government provides fellowships for PhDs outside of Colombia, however there are no efforts to attract this talent back to Colombia, resulting in many highly qualified researchers either not employed in the R&D initiatives in Colombia or finding employment elsewhere.[a]
- Colombia represents a sizeable proportion (17%) of the Latin American universities ranked in the top 500 universities for Life Sciences research namely Universidad Nacional de Colombia, Pontificia Universidad Javeriana and Universidad de Antioquia.

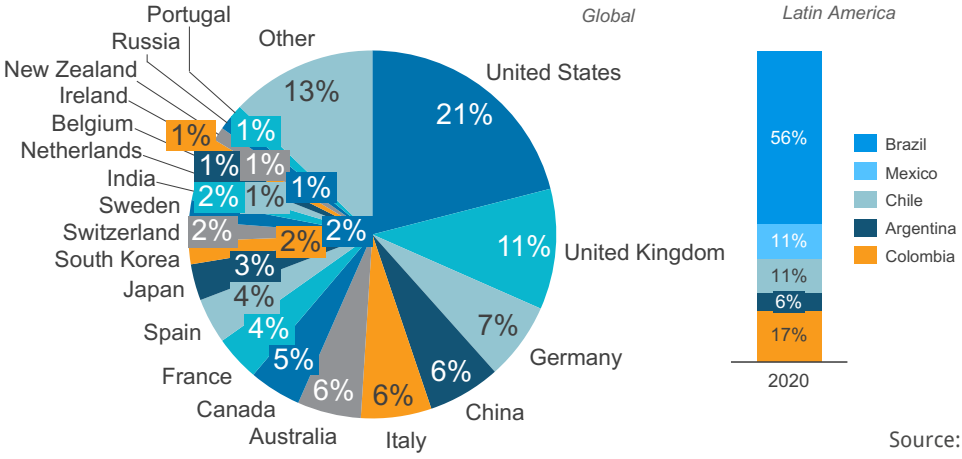
Source:
[a] Insights from CRA External interview programme (Academics).

Number of researchers in R&D (2013-2017, per million people)



Source: The World Bank (2020).

Proportion of top 500 The World University Rankings in Life Sciences research (2020, %)

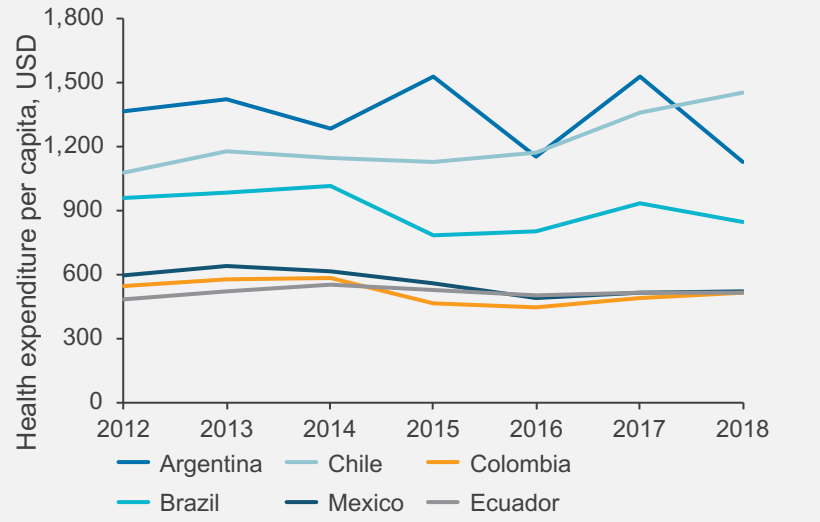


Source: Nature Publishing, 2018.

RESOURCES FOR INNOVATION: HEALTH BUDGET AND INFRASTRUCTURE

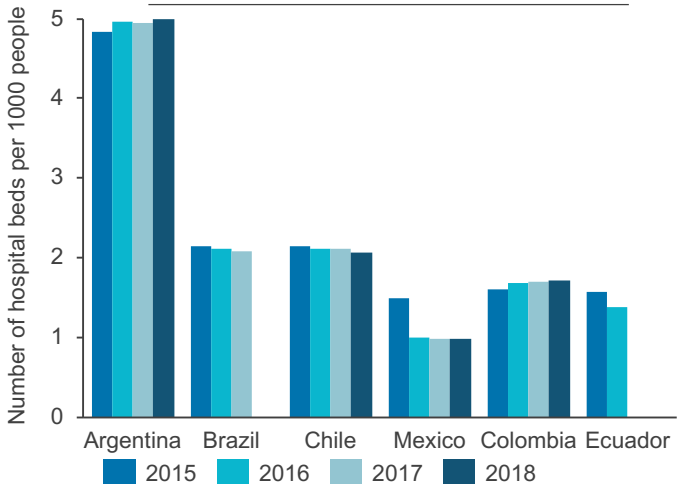
- Between 2012 and 2018, Colombia spent less on health expenditure per capita than Argentina, Brazil, Chile and Mexico, and a similar level of expenditure as Ecuador. Furthermore, after 2014, expenditure on healthcare declined, but has since started to increase again, although not yet back to pre-2014 levels.
- In terms of infrastructure, Colombia has a lower number of hospital beds per capita than Argentina, Brazil and Chile, a comparable number of hospital beds per capita to Ecuador and fewer than Mexico. Number of physicians per capita is comparable to other countries in LatAm and appears to be increasing year on year.

Health expenditure per capita (2012-2018, USD)



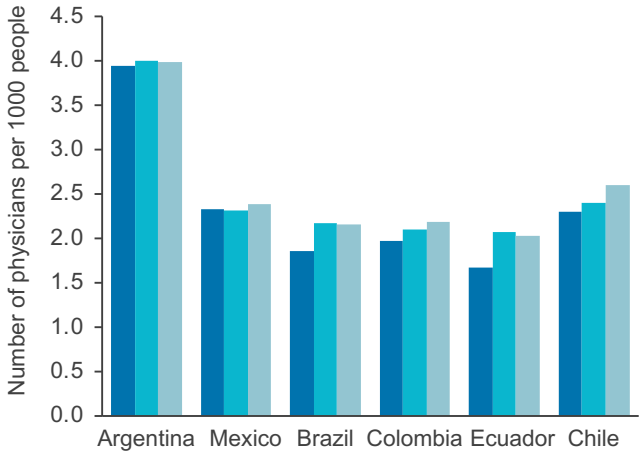
Source: World Bank, 2021.

Hospital beds per 1,000 people (2015-2018)



Sources: World Bank Data 2021.

Physicians per 1,000 people (most recent available data)



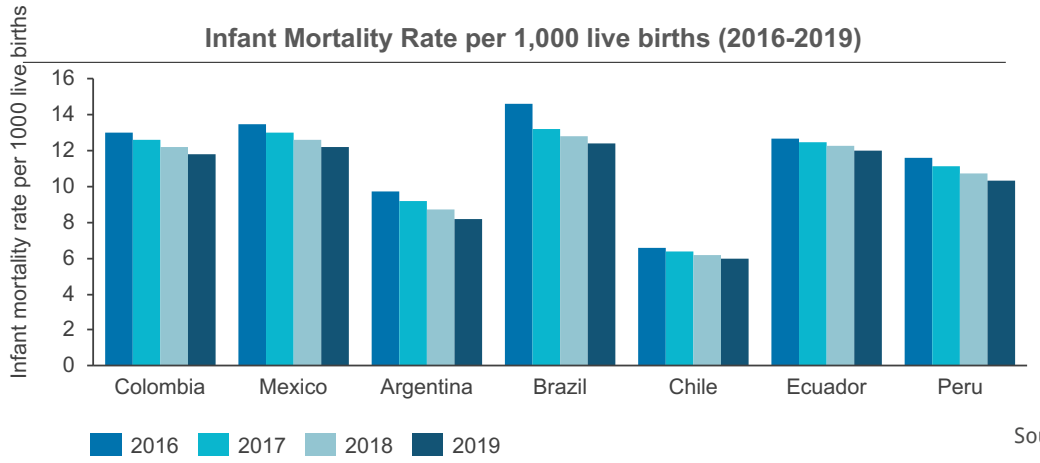
Sources: World Bank Data 2021;
*Most recent available data, clarification in notes.

Note the years for Physicians (per 1,000 people): Argentina: 2013, 2016, 2017; Brazil: 2011, 2017, 2018; Chile: 2016-2018; Mexico: 2015-2017; Colombia: 2016-2018; Ecuador: 2011, 2015, 2016.

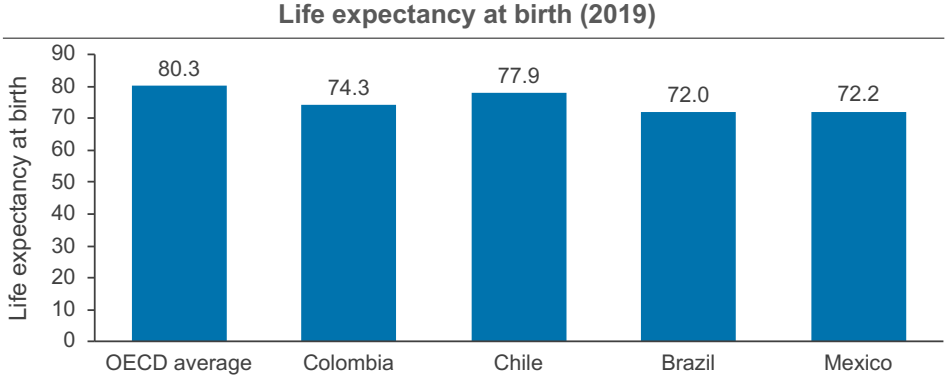
RESOURCES FOR INNOVATION:
HEALTHCARE SYSTEM AND CARE

- Since reforms in 1993, public healthcare is funded by the government, employer and employee contributions. It is managed by the Ministerio de Salud y Proteccion Social (MSPS or MOH) which manages the many health insurance agencies, made up of a mix of public and private agencies, and the healthcare provider agency (IPS).[49]
- Universal public health insurance now covers approximately 97% of the population and is compulsory in the national constitution.[a]
- However, actual access to health services is lacking and there are wide regional and socioeconomic disparities in the quality of services.[a]
- In 2019, Colombia spent 7.26% of GDP on health, less than the OECD average of 8.8%, which is equivalent to $ 1,212 PPP per capita per year (the OECD average is $ 4,223 PPP in 2019).[50]
- In 2018, out-of-pocket payments made up 15.1% of healthcare expenditure in Colombia.[51]
- In terms of provision of care, Colombia lags behind Argentina and Chile in terms of infant mortality rates per 1,000 live births. Moreover, Colombia performs moderately in the LatAm region when comparing life expectancy at birth and is under the OECD average.
- In terms of gaining access to new innovative medicines, Colombia falls behind OECD countries in the number of new molecules to be included on the drugs covered by the healthcare system and also in time to access to new drugs in a 2016 report.[52]

Source:
[a] Insights from CRA External interview programme (local health NGO).



Source: World Bank, 2021.

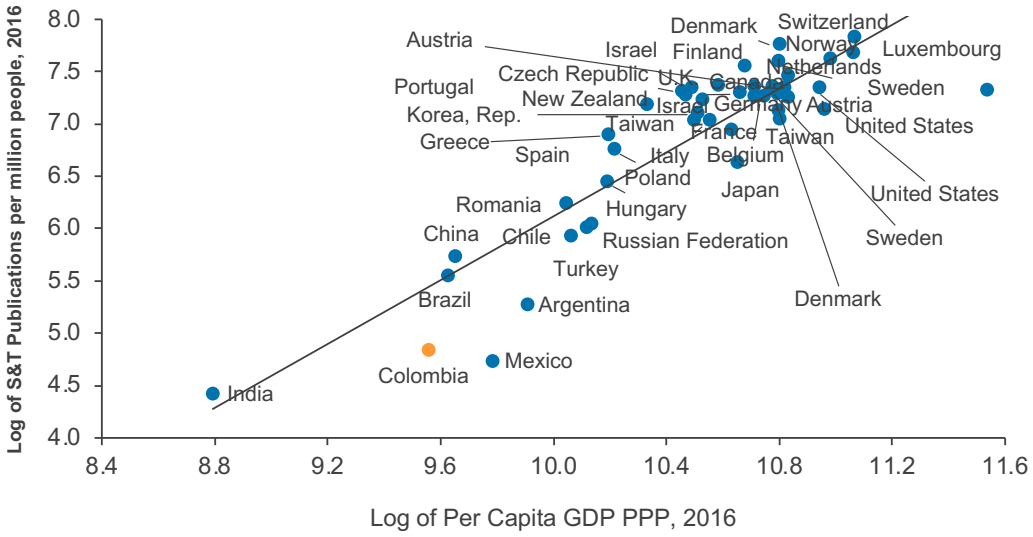


Source: OECD data, 2021.

RESOURCES FOR INNOVATION:
BASIC RESEARCH OUTPUT

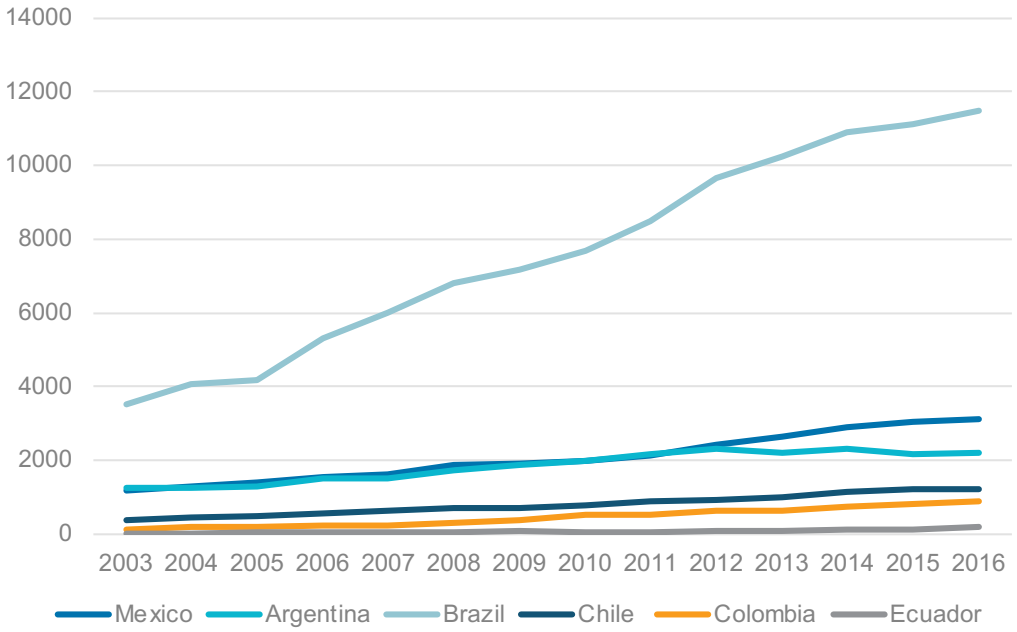
- In 2016, basic research output in Colombia (as measured by the number of scientific publications) was low relative to its economic size.
- This is reflected by absolute number of publications, which lags behind Argentina, Brazil, Chile and Mexico; and only exceeds the number of publications produced by Ecuador.
- Reasons for this have been suggested, such as disadvantages due to poor proficiency in English and high costs of translations for publication requirements, and lower funding vs other LatAm countries.[53,54]

Scientific output compared to other countries (2016)



National Foundation Survey for the number of publications in 2016. World Bank Data for population. World Bank Data for GDP per capita, PPP, except Taiwan sourced from the International Monetary Fund, World Economic Outlook Database, 2015.

Number of Science and Engineering articles in Biological Sciences (2003-2016)



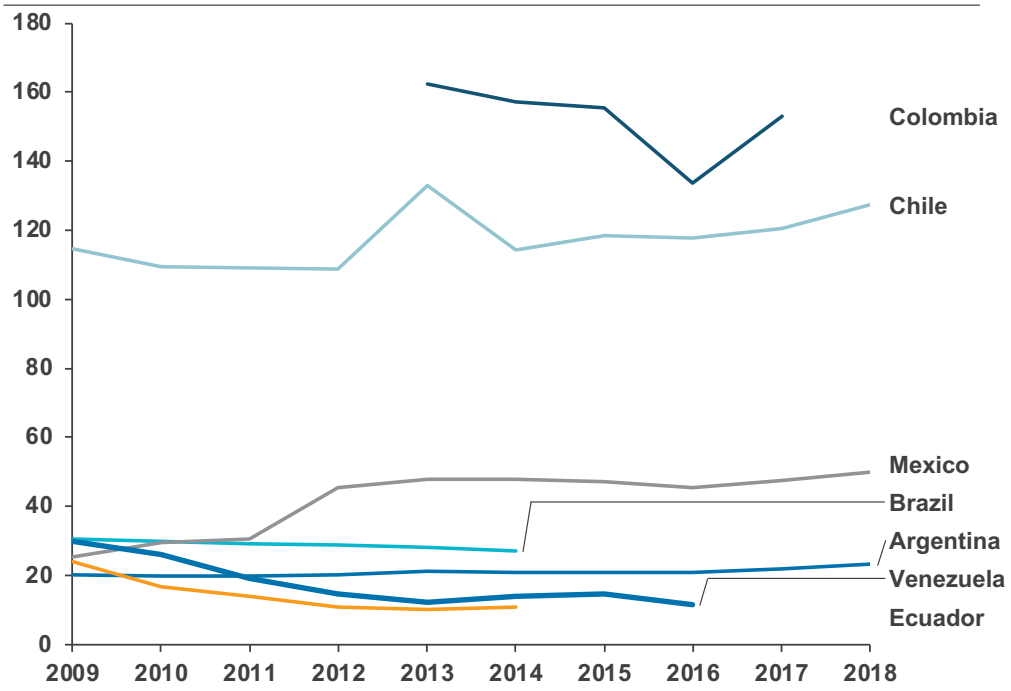
National Science Board, Science & Engineering Indicators 2018.

Note: Life Sciences includes the following areas listed by the Ministry of Science, Technology, Innovations and Communications – Biochemistry, genetics and molecular biology; Immunology and Microbiology; Medicine; Neuroscience and Pharmacology, toxicity and pharmaceuticals.

INNOVATIVE ACTIVITY:
RESEARCH PRODUCTIVITY COMPARED TO LATAM

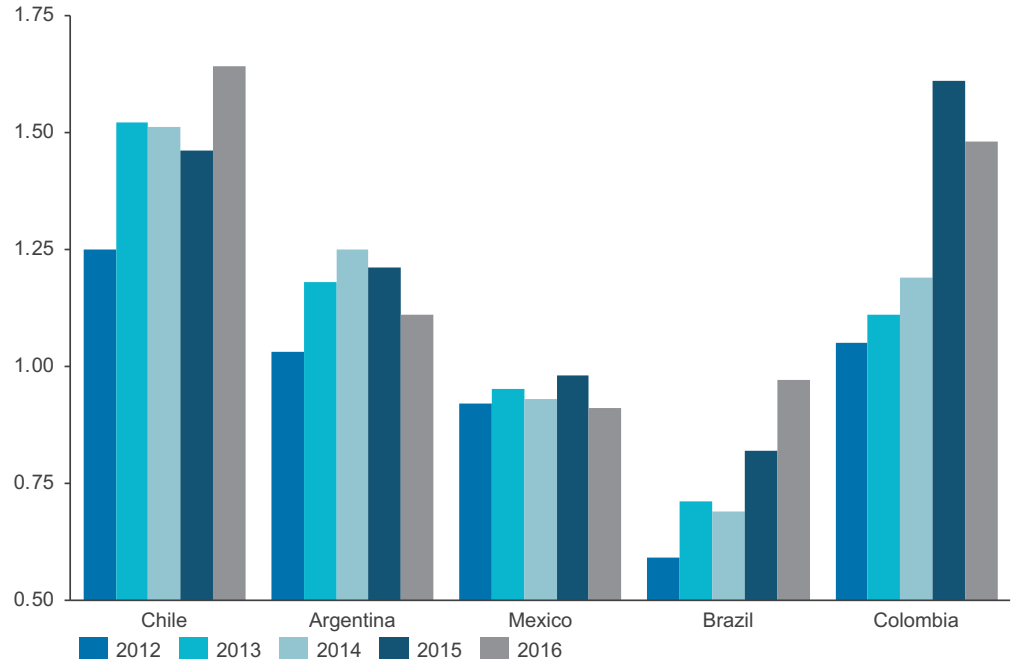
- Between 2009 – 2018, comparing the number of Science and Technology (S&T) publications per 100 FTE researchers, Colombia is the leading country in Latin America region in terms of research productivity.
- The impact of its scientific research, as measured by share of top 1% most cited articles in Scopus, is leading within the region (alongside Chile). Moreover, the impact has dramatically improved since 2015.

Number of S&T Publications per 100 FTE Researchers (2009 - 2018)



Ibero-American Network for Science and Technology.

Share of top 1% Most Cited Publications in Scopus* (2012 – 2016)



National Science Foundation Survey 2019.

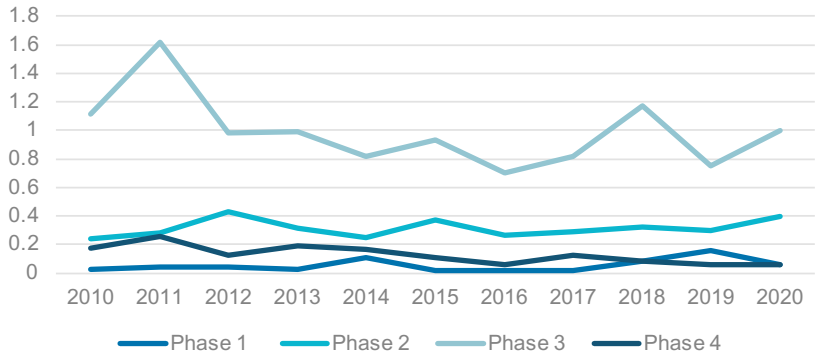
Notes: *Scopus is Elsevier's abstract and citation database launched in 2004. Scopus covers nearly 36,377 titles from approximately 11,678 publishers, of which 34,346 are peer-reviewed journals in top-level subject fields: life sciences, social sciences, physical sciences and health sciences.

INNOVATIVE ACTIVITY:
CLINICAL TRIALS

- In terms of total clinical trials, Colombia is comparable with Peru, Brazil and Mexico with around 2 trials per 1M people, but lags behind Argentina and Chile with nearly twice as many clinical trials per million people.
- Most research in Colombia is in late-stage research (Phase 3 trials) with limited early-stage research in Phase 1 trials.
  - Systemic inefficiencies and regulatory delays are referenced as barriers to greater industry investment in clinical trials.[a]
- One study found that there is a growing level of clinical research capabilities among hospitals and CROs.[37]
  - Furthermore, there has been adherence to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards and streamlined timeframes for clinical trial approval has already attracted several global CROs, though deterioration in other aspects of the biopharmaceutical environment could detract from this growth.[37]
- Within the past couple of years, the Colombian government has sought to attract more clinical trials.[b] Recent efforts to improve regulatory processes have helped to improve average clinical trial approval timelines which tend to take around 6 months. A new clinical trials platform (SiSEC) has also been adopted to assess and facilitate improvements to regulatory system barriers.[a]

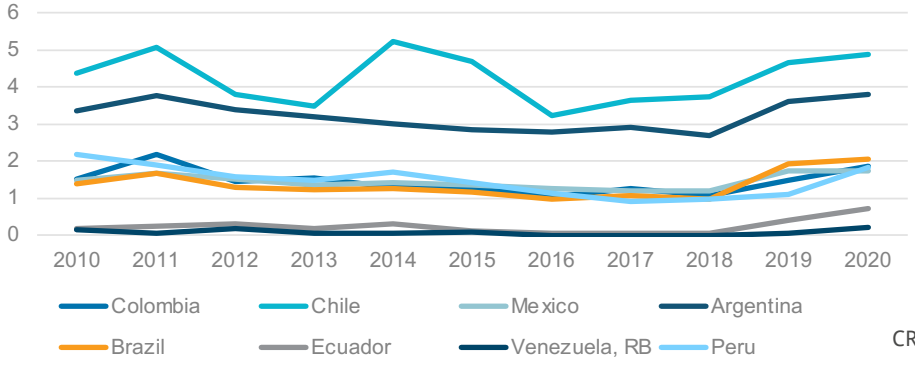
Sources:
[a] Insights from CRA Internal interview programme.
[b] Insights from CRA External interview programme (Government Ministry).

Number of Clinical Trials per 1M People by Phase in Colombia (2010 – 2020)



CRA Analysis of Clinicaltrials.gov.

Number of Clinical Trials per 1M People in LatAm Region (2010 – 2012)

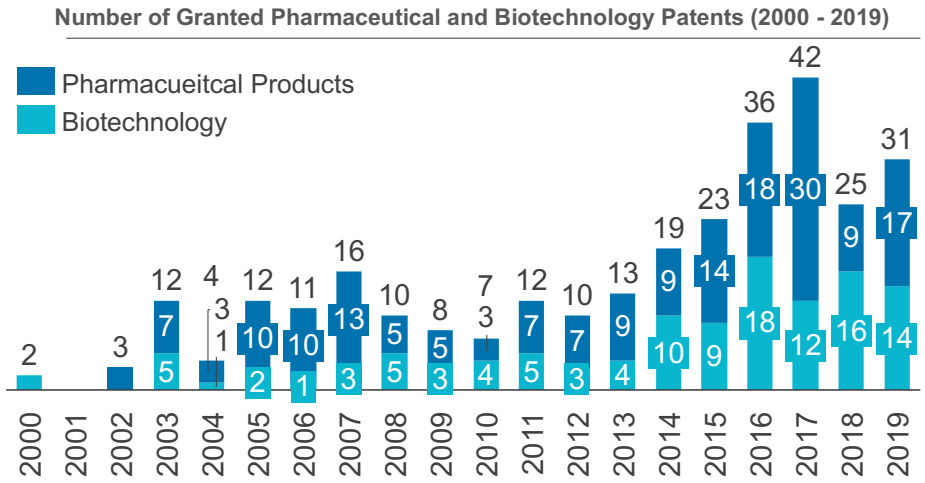


CRA Analysis of Clinicaltrials.gov.

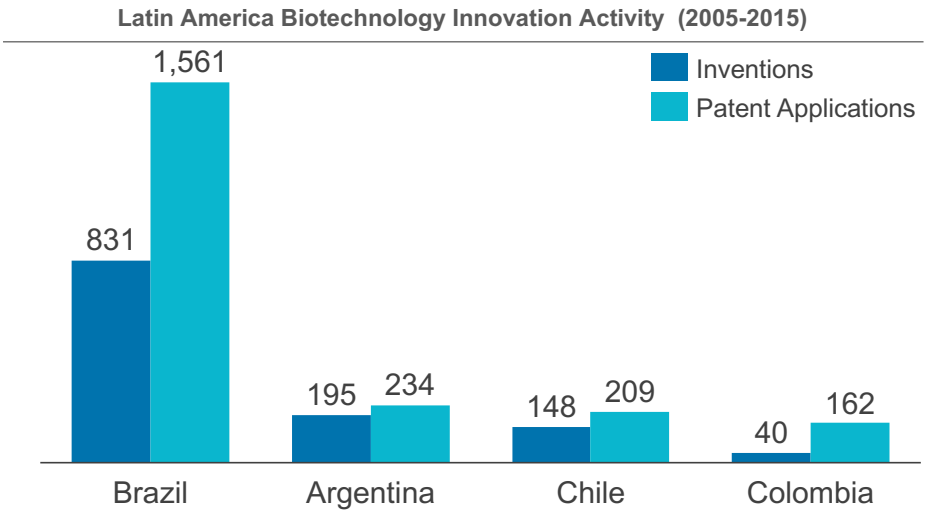
INNOVATIVE ACTIVITY: PATENTS

- The Industry and Commerce Superintendency (SIC), is the Colombian national authority that administers the National System of Intellectual Property.[55] The agency's jurisdiction also covers consumer complaints, antitrust issues, and the specialized court system. SIC has had judicial capabilities since 2012.[55,a]
- Measures have been taken to shorten decision timelines and reduce the initial application filing fee: [17,b]
  - In 2016, it was estimated that a patent application takes an average of 22 months, in contrast to an average of 62 months for the period 2000-2012.[2] SIC also moved the bigger portion of the total application fee to the substantive examination fee, encouraging more budget-limited inventors to file.[a]
  - These measures are also reflected in the increase in the increase in number of patents observed from 2016 onwards. For example, in 2016, 36 pharmaceutical and biotechnology patents were granted versus 23 in 2015.
- The National University of Colombia is the university with the most granted pharmaceutical and biotechnology patents (34), followed by University of Antioquia (14); Industrial University of Santander (14); and Pontifical Xavierian University (10) – resulting in academic institutions having more patents than the local industry.[a]

Source:
[a] Insights from CRA External interview programme (former employee of governmental agency; representatives from government agency).



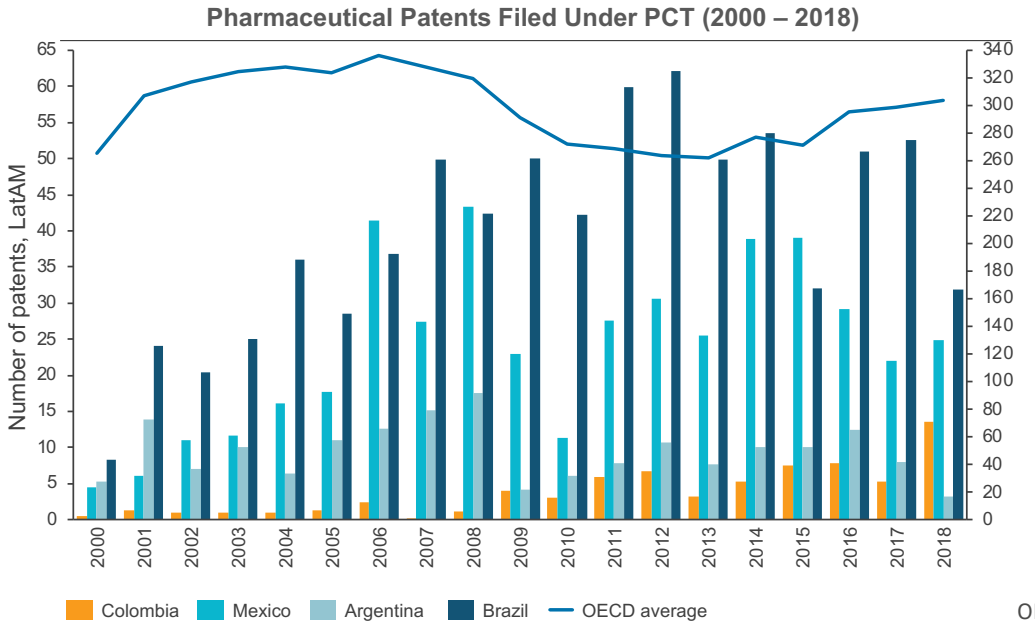
Source: https://www.sic.gov.co/estadisticas-propiedad-industrial / Patentes / Estadisticas Avanzadas / Patente en Colombia / Prouctos farmaceuticos & Biotecnologia (Via Presentacion = Nacional).



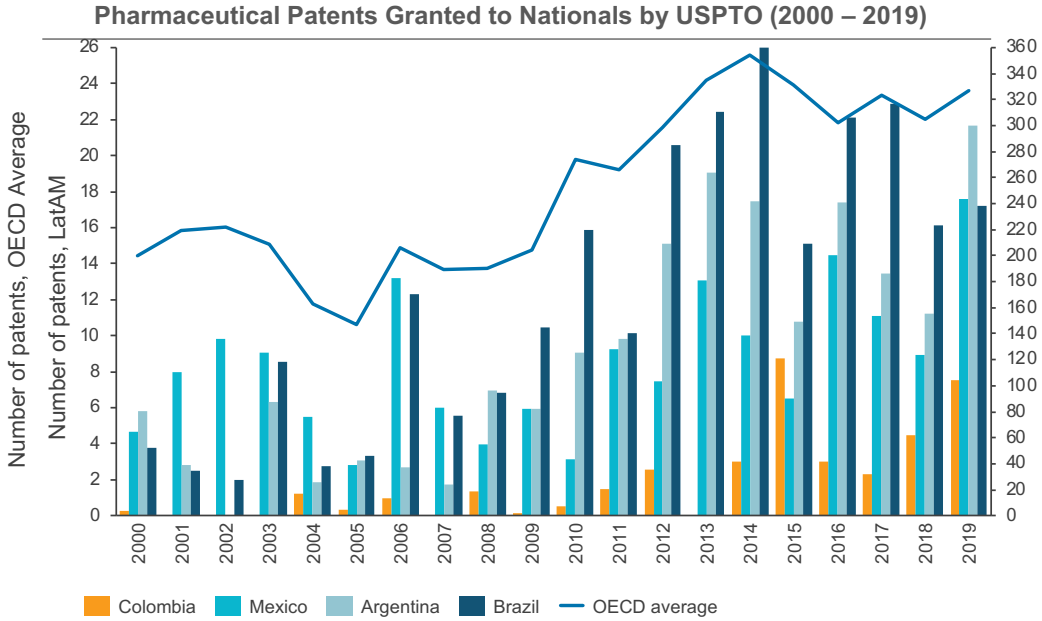
Source: https://www.sic.gov.co/sites/default/files/files/pdf/Biotecnolog%C3%ADa%20en%20el%20mundo%20Panorama%20gral%20Patentes%20%20Abril%202019%20(1).pdf

INNOVATIVE ACTIVITY:
PATENTS (PCT & USPTO) (1/2)

- In terms of the absolute number of pharmaceutical patent applications under the Patent Cooperation Treaty (PCT) and patents granted to Colombian nationals by the U.S. Patent and Trademark Office (USPTO), Colombia is lagging significantly behind other LatAm markets and the OECD Average.
- In Colombia, there are no specific incentives available for businesses or researchers to file patents. Tax benefits are available to those investing in R&D, including patent filing, however there is no requirement to file a patent to receive these benefits.[56] In addition, Colombia's local patent filing infrastructure and system are in need of further innovation and development to encourage patent filing.[57]



OECD Patents by Technology, 2020.

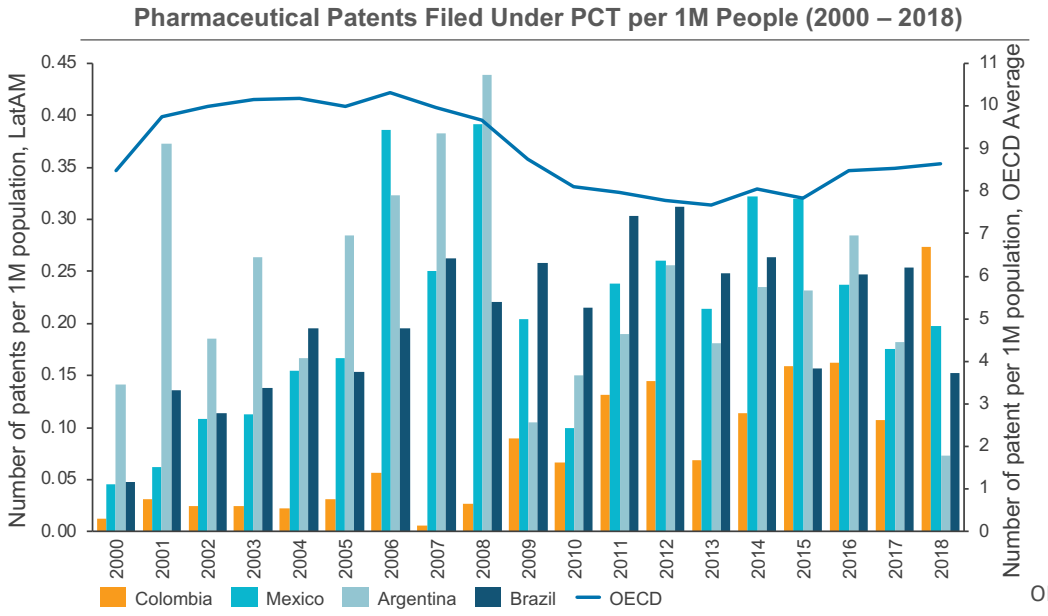


OECD Patents by Technology, 2020.

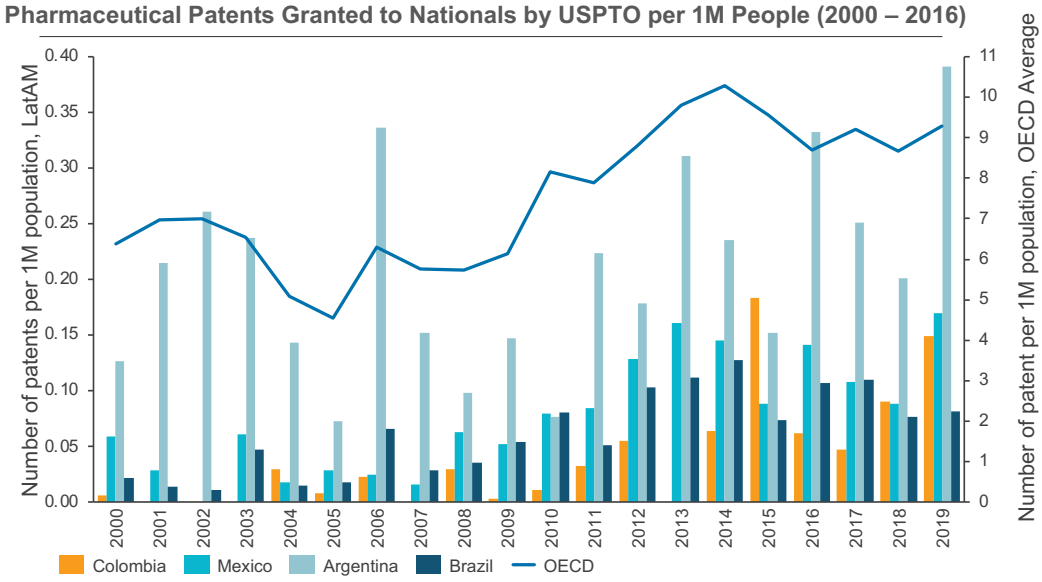
INNOVATIVE ACTIVITY:
PATENTS (PCT & USPTO) (2/2)

- In 2018, 0.27 pharmaceutical patents were filed under PCT per one million Colombian nationals, this has risen greatly over the past 10 years and now exceeds Mexico (0.20), Brazil (0.15) and Argentina (0.07) but remains below the OECD average (8.63) – however, Colombia has low tech transfer activities, resulting in low patent commercialization.[a]
- However 0.15 pharmaceutical patents were granted under USPTO per million Colombian nationals in 2019, lagging behind Argentina (0.39) and OECD average (9.29). Although there is still a large rise over the last 6 years vs >10 years ago.
- In light of this, in the period 2010-2019 21,273 patent applications were filed. Around 16% of all the patent applications came from Colombian applicants, which is similar to Brazil, where 18% of the applications in the country are filed by residents.[58]

Source:
[a] Insights from CRA External interview programme (Government Agency).



OECD Patents by Technology, 2021.



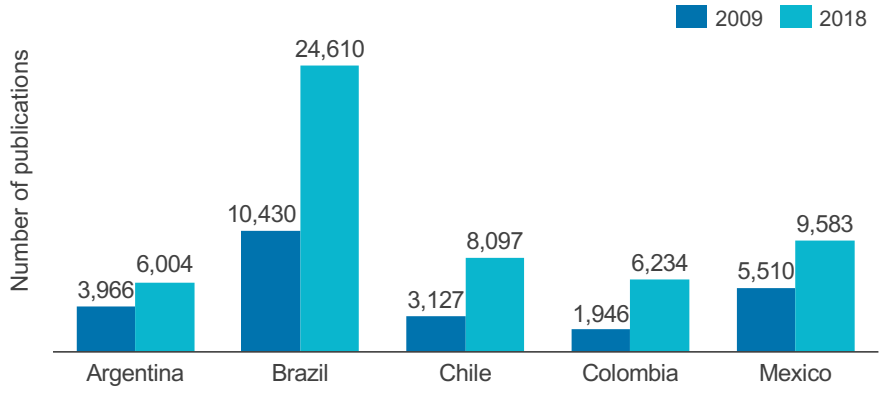
OECD Patents by Technology, 2021.

INNOVATIVE ACTIVITY:
CLUSTERS & COLLABORATIONS

- International collaboration as measured by co-authorship of publications in Colombia lags behind other countries in LatAm.
- In terms of collaboration between innovative SMEs and academic and government institutions, Colombia is in line with Mexico and the OECD average. Collaboration with large companies is ahead of other LatAm countries but behind the OECD.
- In Colombia, the Ministry of Science and Technology, and the National Planning Department (DNP) support several initiatives to encourage collaboration and technology transfer between public institutions and private industry, because currently most patents held by universities are not commercialized.[59,b] Ministry of Science and SIC also have a program to promote commercialization and tech transfer, and to increase innovator's Technological Readiness Level (TRL).[b]
  - A noted example of industry-university collaboration is between the local manufacturing and R&D company, Procaps and Universidad Del Norte.[a]
  - DNP also encourages PhD graduates from STEM fields to enter private sector through tax benefits to lower the cost to firms of hiring a PhD graduate.[b]
- Furthermore, for companies in the pharmaceutical sector to meet regulatory requirements, quality standards and to increase their competitiveness, Colombia Productiva and Bancóldex have launched a new specialized credit line for this industry.[60]

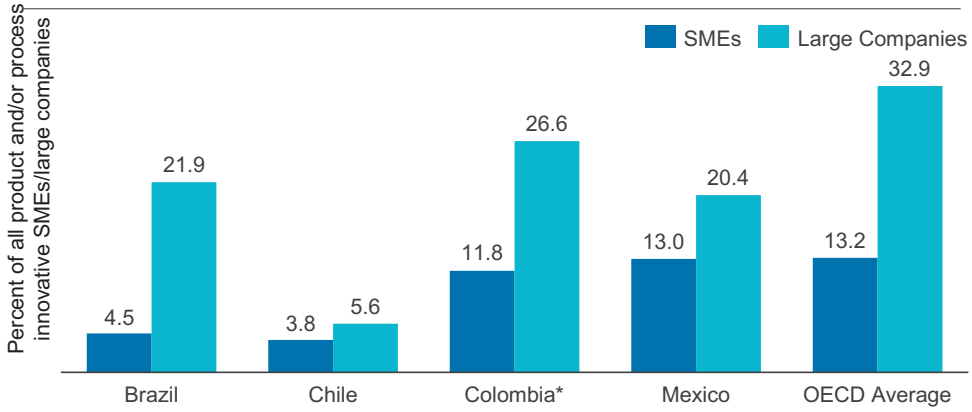
Sources:
[a] Insights from CRA Internal interview programme.
[b] Insights from CRA External interview programme (government agencies; local science, technology & innovation knowledge management firm).

Internationally co-authored science & engineering publications (2009, 2018)



National Science Foundation Survey 2019, OCYT 2021.

Firms collaborating with higher education or government institutions (2017)



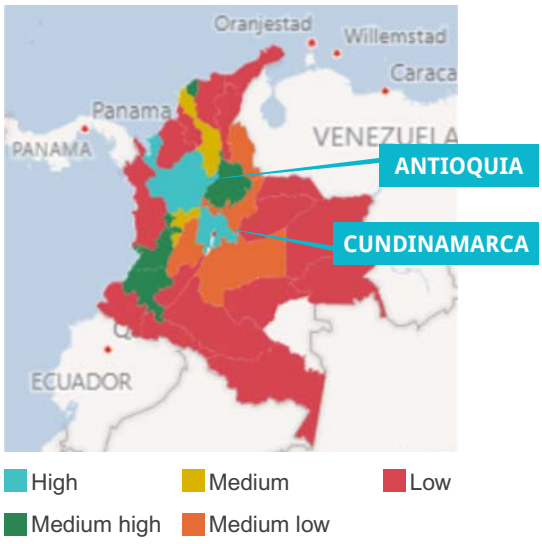
OECD Innovation Indicators 2017.

* For Colombia, this represents an average of the collaboration in the manufacturing and service sectors with higher education or government institutions.

ECONOMIC ACTIVITY:
CLUSTERS & COLLABORATIONS

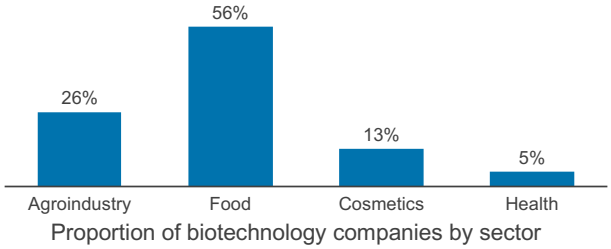
- In 2012, the Cluster Network Colombia was established to encourage collaboration within various industries including biotechnology.[61]
- Initiatives such as this and the Comités Universidad Empresa Estado (state enterprise university committees; CUEEs) have resulted in increasing productivity across industries, including biotechnology and health.[62]
- Bogota in the Cundinamarca region, is considered a biotechnology hub in Colombia and is home to ~40% of the country's biotechnology research groups, however Antioquia and Valle also have considerable activity in the biotechnology industry.[62,63]
- According to the commercial business registry in Colombia (RUES), of the 1,207 businesses registered under pharmaceuticals, 70% are micro businesses and only 4% are large companies, indicating a high level of growth and innovation.

Areas of knowledge and technology productivity (2018)

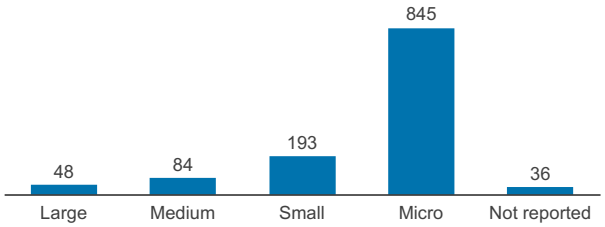


Source: OCYT, 2021.

Biotechnology companies by sector (2017)

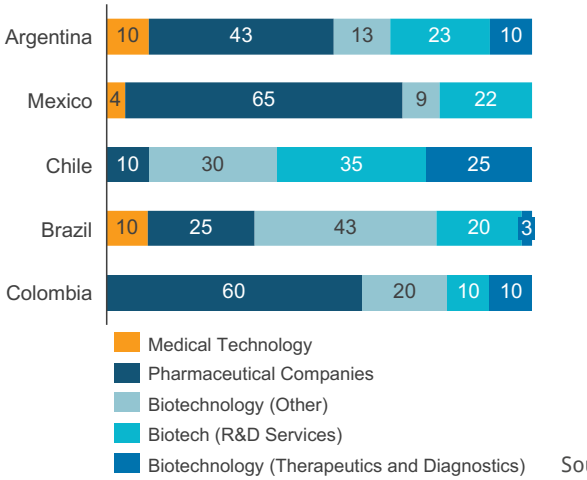


Pharmaceutical companies by size (2019)



Source: Bios, Colombia Productiva.

Proportion of life sciences companies by main activity type (2021)



Source: Biotechgate

INNOVATIVE ACTIVITY:
CLUSTERS & COLLABORATIONS

- The CEmprende National Network is the largest entrepreneurship and innovation ecosystem in Colombia.
  - It is part of the iNNpulsa Government initiative, the leading body implementing the Entrepreneurship Act, 2020, to strengthen innovation ecosystem in Colombia to make Colombia a leader in innovation and entrepreneurship with a goal to facilitate the collaboration between academia, private companies, the State and society with the aim to strengthen and stimulate entrepreneurship and innovation.[a]
  - iNNpulsa accompanies the acceleration of high-potential ventures and the innovative and financing processes that allow companies in the country to scale to generate more development economic, equity and opportunities for all Colombians.[a]
- The network of innovation hubs across Colombia each have developed their own specialized area, with the HUB-iEX at the Universidad El Bosque focusing mainly on health sciences, and other focusing on biotechnology and tourism amongst other industries.[a]
- In addition Bancóldex is an organization, which provides funding for entrepreneurs and innovation, including the pharma industry and is supported by the Ministry of Commerce and the Superintendency of Finance (SFC).[a]

CEMPRENDE NATIONAL NETWORK HUB OF HEADQUARTER OFFICES

BOGOTA
Bogotá Chamber of Commerce and El Bosque University

BUCARAMANGA
Bucaramanga Chamber of Commerce

CALI
Governorate of the Valley and University of the Valley

BARRANQUILLA
Atlanticonnect

PEREIRA
Technological University of Pereira

SATELLITE HEADQUARTERS

Chamber of Commerce (Manizales); Mayor's Office and University of Sinú (Montería); University of Sabana (Bogota); Socya Foundation (Medellín); Chamber of Commerce (Cali)

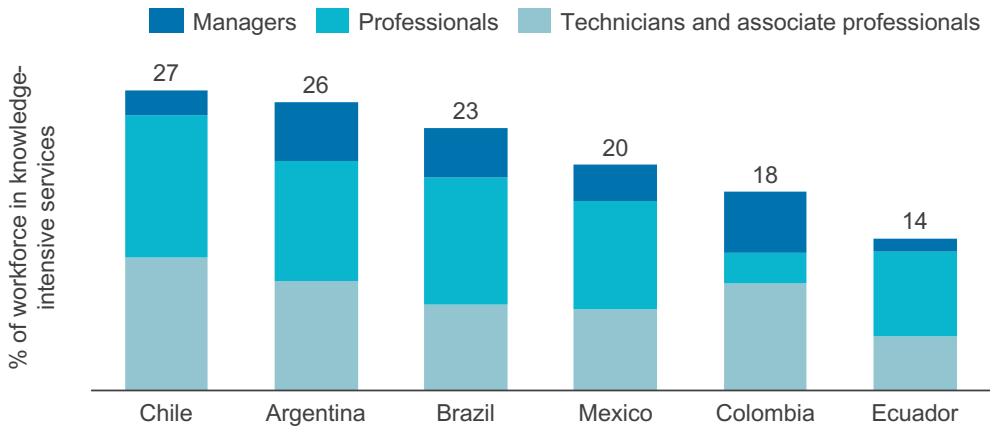
Source:
[a] Insights from CRA External interview programme (university research thinktank; Government Ministry).

ECONOMIC ACTIVITY: EMPLOYMENT

- In Colombia, in 2019, 18% of the workforce were employed in knowledge intensive services – lagging behind Chile (27%), Argentina (26%), Brazil (23%), and Mexico (20%) however, superior to Ecuador (14%).
- However, Colombia is leading other LatAm markets in terms of the number of inhabitants employed in the biopharmaceutical industry; approximately 973 people per million inhabitants are in employed in this sector in Colombia,[64] which is higher than Argentina (902 per million), Mexico (652 per million), and Brazil (464 per million).
  - The Business Plan for the pharmaceutical sector (2019) envisions Colombia expanding the employment in the biopharmaceutical industry to 98,084 by 2032 (an increase of more than 100% versus 2018).[2]
- In 2015, the average annual salary for a pharmaceutical chemist in industry in Colombia was 31,812,389 Colombian pesos (8,849 USD).[65]

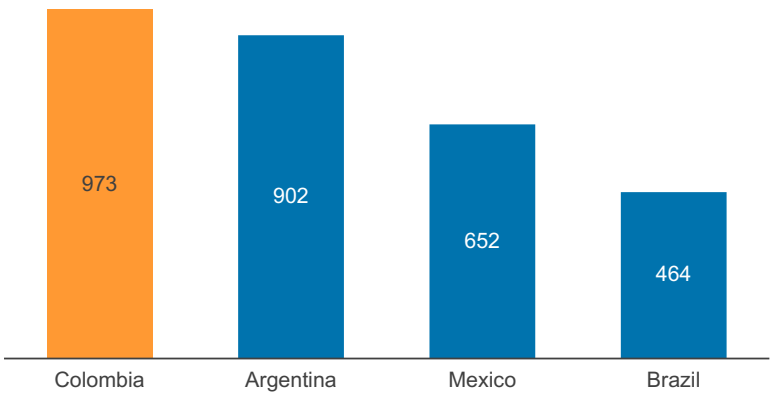
*2014 data for Argentina and Mexico, 2016 data for Brazil.

Employment in knowledge-intensive services (2019, % of workforce)



Source: International Labour Organisation, 2019.

Employment in the Biopharmaceutical Industry per million inhabitants (LatAm)

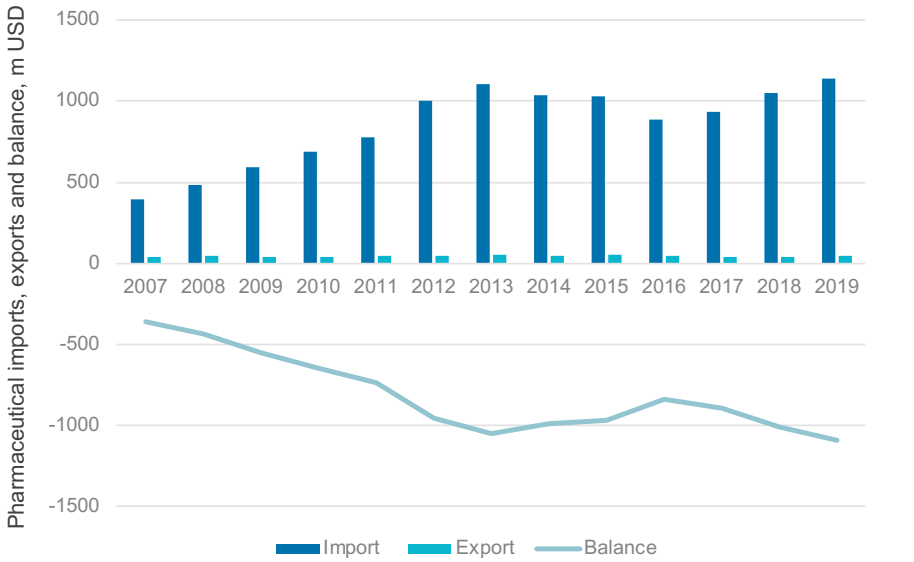


Sources: OEDE-MTEySS; INADEM Mexico; SINDUSFARMA; Colombia Productiva, latest data available.

OTHER ECONOMIC ACTIVITY
LINKED TO THE PHARMA SECTOR

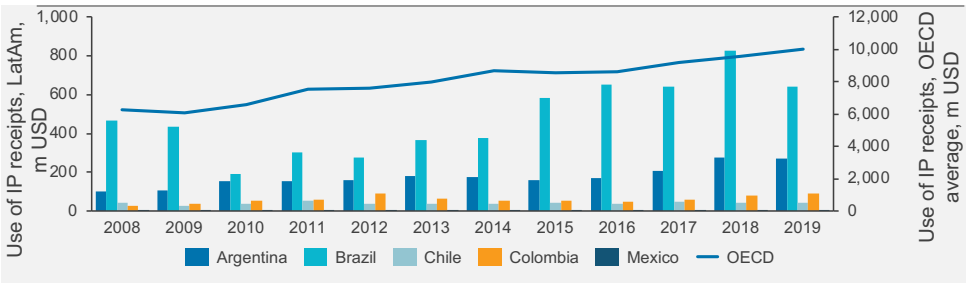
- Between 2007 and 2019, pharmaceutical exports from Colombia have remained steady. However, imports increased between 2007-2013 and have remained similar since indicating that the pharmaceutical industry is not significantly important in Colombia.
  - However, through the National Business Plan for the Pharmaceutical Sector, Colombia is aiming to increase its pharmaceutical exports by 5 times by 2032 (versus 2018 levels).[66]
- Between 2009 to 2019, the FDI inflow into Colombia was on average USD 14,314 million – which is approximately 4.5 times the level of FDI outflow (which was on average USD 3,219 million over the same period).
- However, Colombia is lagging behind Brazil, Argentina, and average OECD in the levels of payments from licensing intellectual property.

Evolution of pharmaceutical imports and exports (2007-2019, m USD)



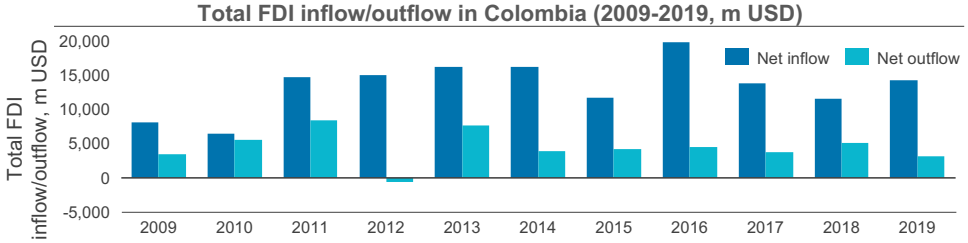
Source: UNCTADstat, 2007-2019 – Medicinal and pharmaceutical products, excluding 542.

Receipts for the use of intellectual property (licensing payments) (2008-2019, m USD)



Source: World Bank, 2008-2018.

Total FDI inflow/outflow in Colombia (2009-2019, m USD)



Source: World Bank, 2009-2019.

COLOMBIA:
STRAWMAN ASSESSMENT OF PERFORMANCE

- Compared to the LatAm region, Colombia comparatively has a strong university and education system, with strong human resources and a fairly strong healthcare system. Colombia also appears to be investing in innovation in R&D. There is moderate investment in early stage research and clinical trials.
- On the other hand, in Colombia there is limited implementation of IP legislation and inconsistent regulatory data protection, which dis-incentivises FDI.

	INDICATORS	COMPARED TO LATAM	COMPARED TO OECD*
HUMAN RESOURCES	Universities		
	Education attainment		
	Collaboration		
	Researchers		
HEALTHCARE SYSTEM STRENGTH	Infrastructure		
	Effective and safe care		
INVESTMENT IN INNOVATION	R&D investment		
	FDI		
INNOVATIVE ACTIVITY	Early research (publications)		
	Clinical trials		
	Patents		
ECONOMIC ACTIVITY	Employment		
	Trade		

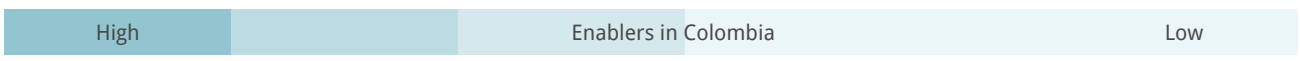
Improving performance

*Where OECD average not available, comparison was made against World: higher income countries average.

ENABLERS OF INNOVATIVE ACTIVITY AND CHALLENGES IN COLOMBIA

- Drawing from the Colombia analysis on its IP framework and policies to foster innovation, together with the analysis of the key economic metrics and activities, Colombia exhibits:
  - Good human capital and expertise particularly in basic research and local innovation hubs, and moderate investment in R&D and tech transfer, but
  - Lags behind on IP legislation, patent linkage, international collaborations and leveraging its diverse population for clinical trials.

	AREAS	DESCRIPTION IN COLOMBIA
ENABLERS	**Human capital and expertise**	Good availability of top universities and education attainment to higher degrees and good standards.
	Private investment in R&D	The government has introduced tax incentives to attract private R&D investments.
	Size of population	Being highly populated, Colombia represents an attractive market for foreign manufacturers and could be an attractive location for clinical trials if the regulations were to be simplified.
	Technology transfer and industry collaboration	The government is active in initiatives to promote collaboration between academia and businesses and government funded regional technology transfer offices exist to facilitate this.
	IP legislation	The IP framework can be improved, particularly in regards to regulatory data protection and the patentability criteria.
	Patent linkage	There is no patent linkage framework or communication between the national regulatory authority and the Patent Office in Colombia.
	International collaboration	International collaboration, in terms of co-authored publications, in Colombia is low.



3.
The benefits of an improved environment for innovation

LESSONS FROM COMPARABLE MARKETS

The second step of the project aims to investigate the performance of "similar" markets to Colombia (drawing from regions outside of Latin America).

Choice of case studies: We created a list of potential case study markets that:

1. **Have shown a focus on strengthening the innovative environment through policies that improve regulatory data protection; patent enforcement efficiency (speed and linkage); local technology and scientific capabilities; and the overall healthcare system.**
   - Introduced policies to protect or extend regulatory data protection period.
   - Improved IP law enforcement timelines and efficiency, including implementation of patent linkage frameworks.
   - Improved awareness on IP through educational programmes and dissemination activities.
   - Incentivized improvements in innovative capabilities.
   - Developed an efficient, equitable, and sustainable healthcare system.
2. **Placed broadly in the same income, size and development category as Colombia when started focusing on innovation.**
   - Drawing on case studies developed for Argentina, Brazil and Mexico studies.
   - Opting for membership in key international organisations e.g. OECD, and have trade relationships in common with Colombia.
3. **Show an observable impact on innovative activity.**
   - Demonstrate good data availability.

WE USE CASE STUDIES TO DRAW LESSONS FROM COMPARABLE MARKETS

Using case studies, our aim is to investigate

1. The changes in the policy regime supporting innovation.
2. The innovative environment and economic activities related to innovation across a range of areas.
3. Whether there is any relationship from changes in the policy regime to innovation activity by analysing the growth changes in indicators before and after key policy changes.

It is important to note that this is a challenging approach, due to:

- Many factors affect innovative activity.
- Factors work together and need to be considered as package rather than in isolation.
- Changes in innovative activity can only be observed over time and may occur in anticipation of a change – making causation difficult to interpret.
- Certain indicators take a longer time to experience the impact from policy changes – making the determination of impact more difficult.
- We need to test results are robust to differences between markets (role of off-patent sector).

We use key dates of significant policy changes and examine whether there is a reflected change in the innovative environment through a:

- Change in growth rates.
- Change in average level (where an apparent step change).
- A statistical analysis to try to identify a causal link.

CASE STUDY ANALYSIS AND SCENARIOS: FOCUSING ON SPAIN AND ISRAEL

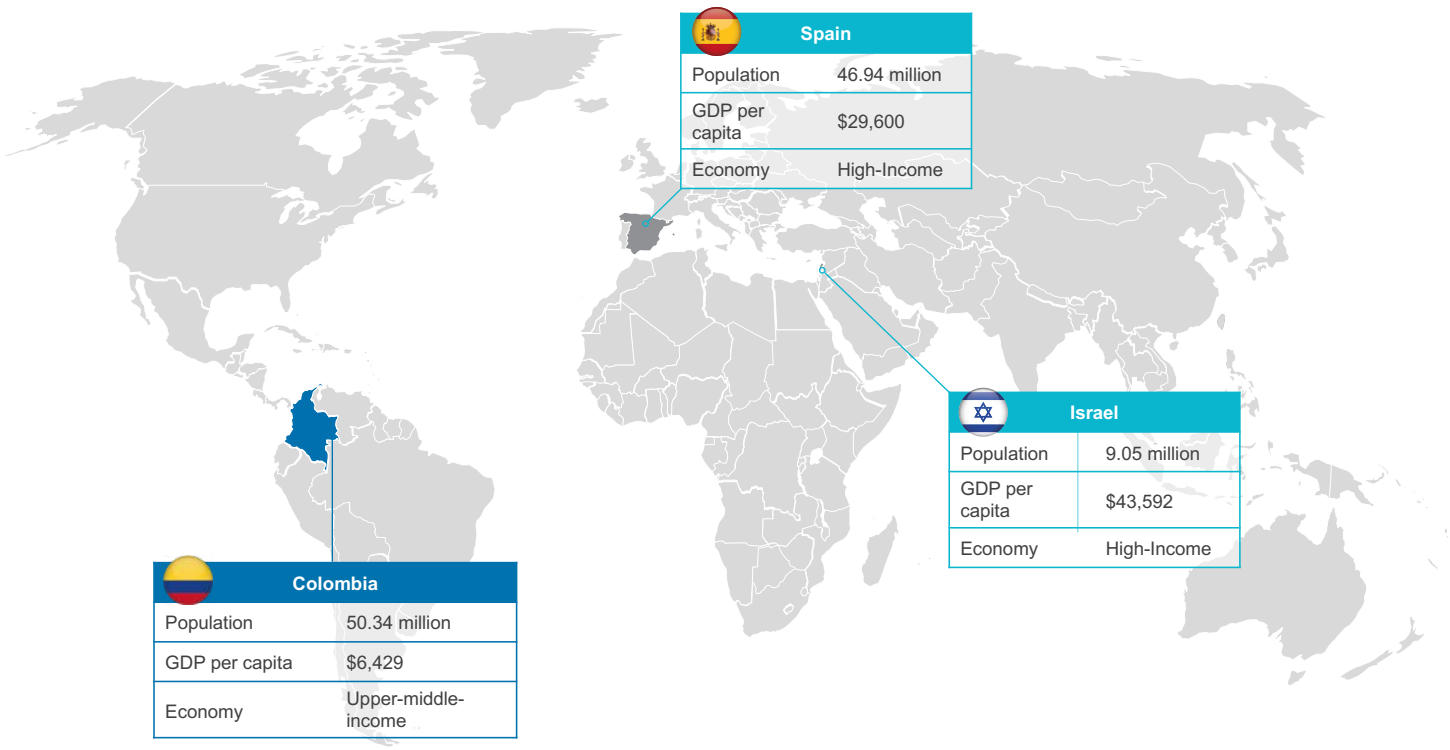
The objectives of a case study approach are to:

- **Quantify the impact of policies** to strengthen innovation environment.
- Develop **understanding of the context**, to better understand the success of innovation policy change.
- To understand the **policy process to fostering pharmaceutical innovation** in an emerging economy.

The selection criteria for our case study markets suggests two markets to investigate:

1. Have shown a **focus on strengthening innovative environment**, particularly the IP protection.
2. Placed **broadly in the same income, size and development category as Colombia** when started focusing on innovation.
3. Show an observable impact on **innovative activity**.

We also on lessons from China, Japan, Singapore, South Korea and Taiwan (studied in previous reports).



RDP – Regulatory Data Protection.

CASE STUDY: ISRAEL

CHANGES IN THE IP REGIME OF ISRAEL

BINATIONAL INDUSTRIAL RESEARCH AND DEVELOPMENT (BIRD) FOUNDATION, 1977, PHARMA MODEL CREATED 2007

The BIRD Foundation between Israel and the US has approved over 950 project grants with leading companies in the US, including pharmaceutical companies (e.g. Bayer).[67] It created a specific Pharma Model in 2007 applicable to Biotech or Pharma projects, which may include funding clinical trials, especially at early stages (up to $1M).[68]

PATENT COOPERATION TREATY (PCT), 1996

The PCT deals with submitting international patent applications and the International Search & Examination procedures. The decision to join the treaty was made to help Israeli applicants and promote local industry.[69]

AMENDED ISRAELI PATENT LAW 5727-1967, 1998, 2006, 2021 ET AL.

Israel amended its Patent Law in 1998 to provide for Patent Term Extensions, and updated this amendment in 2006, and later years. 2006 amendment limited patent term extension to the period of protection in a set of recognized countries, i.e. United States, EU-15, Switzerland, Norway, Iceland, Japan and Australia. The patent extension period covers the license application submission date to the date the license was granted, subject to the five-year limit.[75-77] There is currently a proposed amendment for 2021 which would include reducing regulatory burden aligned with 2014 government resolution.[78]

MANAGEMENT OF KNOWLEDGE PRODUCTS DIRECTIVE, 2010

Directive to regulate research conducted in government hospitals and manage IPR. It describes that governmental knowledge products are owned by the state and health entities (hospitals) can use them for research or commercialization with permission and other conditions.[79]

LAW FOR THE ENCOURAGEMENT OF CAPITAL INVESTMENT REVISION, 2011

The Law aims to strengthen industrial capabilities. The 2011 revisions removed benefits for foreign owned companies. Companies may qualify for cash and tax benefits as a Preferred Enterprise (PFE), if it is registered in Israel, internationally competitive (>25% turnover exported), or most of its activities are in biotech or nanotech. There is also a Preferred Technology Enterprise Regime and R&D incentives.[70,71]

ISRAEL INNOVATION AUTHORITY, 2015

The Innovation Authority's was launched in 2015 with the aim to establish Israel as a world leader in innovation and entrepreneurship that frequently grows innovation-driven companies that provide extensive, highly productive employment for all population groups and all regions of the country.[67]

NATIONAL DIGITAL HEALTH PROGRAM, 2018

The Israeli Ministry for Social Equality, Health Ministry, and Innovation Authority launched a program to be carried out in healthcare organizations to support R&D proposals and pilots in digital health. It invests $264 million over 5 years to improve health sector collaboration and infrastructure. In 2021, it provides financial support of between 20%-50% of the approved R&D expenditure for participating companies.[72-24]

HUMAN CAPITAL FUND AND THE EMERGENCY TRAINING PROGRAM, 2020

The Israel Innovation Authority (IIA) launched two new programs in the Covid-19 pandemic, the Human Capital Fund and the Emergency Training Program, to help unemployed citizens enter the Israeli tech ecosystem. It is aimed at strengthening human capital during times of national crises while helping job seekers. In total, the IIA will contribute NIS 139 million ($43 million) to both programs, awarded to 62 organizations.[80]

Key

○ Changes to the IP regime.

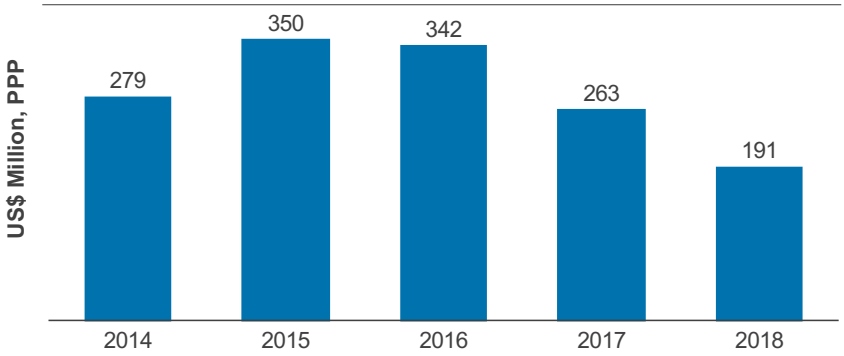
○ Changes to the Innovation Policy Landscape.

★ NOTE – Regulation market with a star will be used as proxy for change in estimating growth differences.

INVESTMENT IN R&D AND FDI

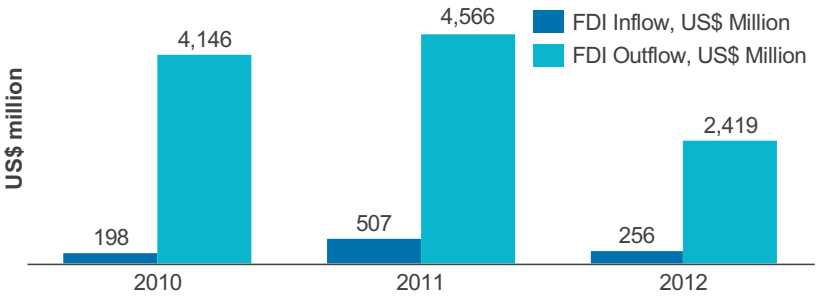
- Based on most recent available data, Israel is ranked 1st in the world for R&D spending, investing approximately double vs average OECD as a % of GDP, linked to their strong policies encouraging innovation and supporting commercialisation of publicly funded research.[81]
- Israel has a highly developed Public and Private Sector research infrastructure. 69% of Israel's GERD is contributed by the Private Sector, who at the same time is the most important performer of research (3.6% of GDP).[82]
- FDI Outflow have generated a significantly higher rate of return than the return on FDI Inflow.[83]

Pharmaceutical BERD (2014 – 2018, US$ Million, PPP)



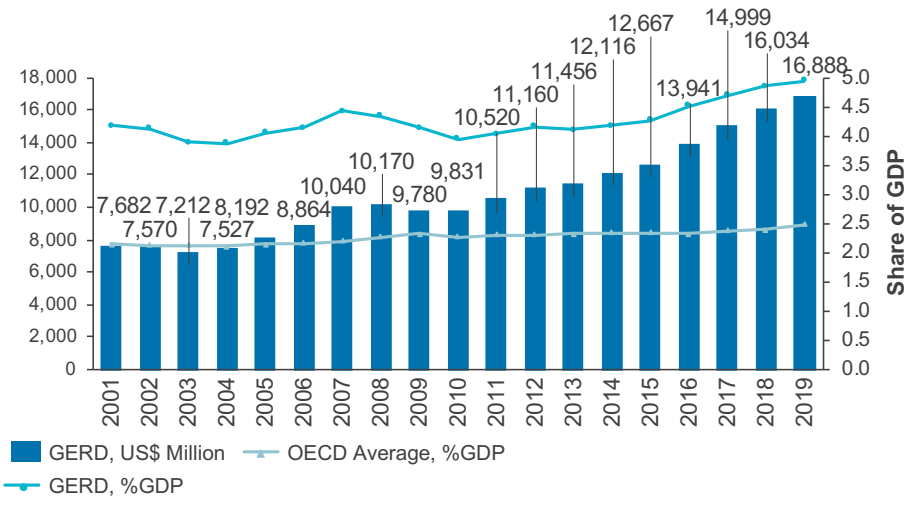
Source: https://read.oecd-ilibrary.org/science-and-technology/main-science-and-technology-indicators/volume-2020/issue-2_0bd49050-en#page50

FDI flows for Pharmaceutical, Medicinal Chemical and Botanical Products (2010 – 2012, US$ Million)



Source: https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm

Investment in R&D (2001 – 2019)



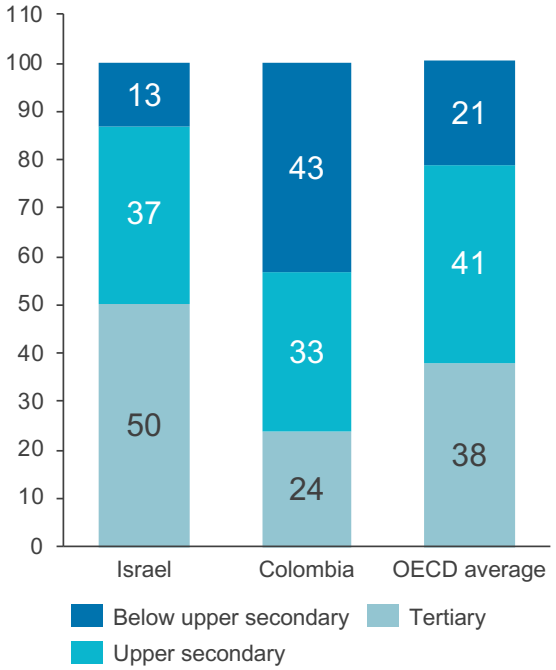
Source: https://stats.oecd.org/Index.aspx?DataSetCode=FDI_FLOW_INDUSTRY

*Spending on R&D is defined as the total expenditure (current and capital) on R&D carried out by all resident companies, research institutes, university and government laboratories, etc., in a country and includes R&D expenditure across sectors

UNIVERSITIES AND QUALITY OF EDUCATION

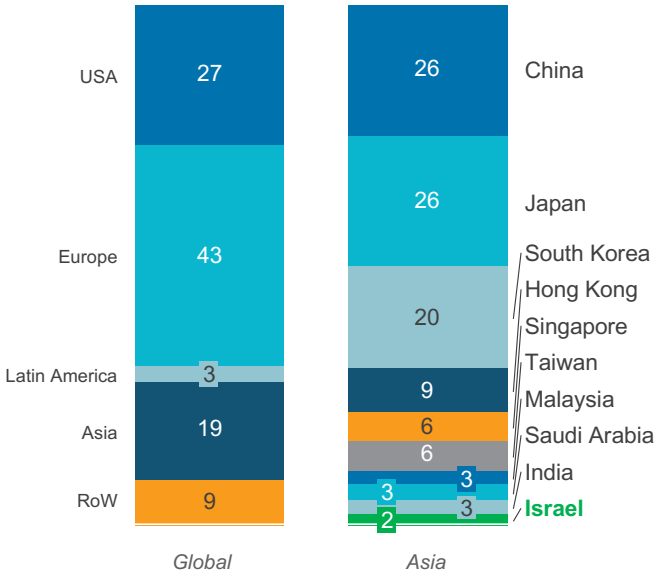
- Half of the Israeli population has attained tertiary level education and just over a third have at most, upper secondary education.[84]
- Israel makes up just under 2% of the Asian universities to be ranked in the top 200 for biological sciences in the world, with 2 universities in the top 200 for biological sciences: Weizmann Institute of Science and The Hebrew University of Jerusalem.[85]
- Israel ranks 27 points below the OECD average PISA scores in science at 462 versus 489 for the OECD average.[86]

Educational attainment of 25-64 year olds, (2019, %)



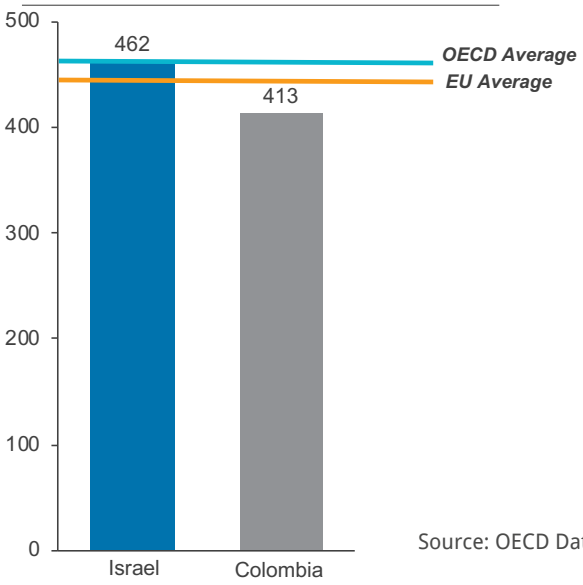
Source: OECD Data, 2018.

Universities in Top 200 Universities for Biological Sciences (2020, %)



Source: QS Top Universities, 2020.

Average PISA Score in Science (2018)

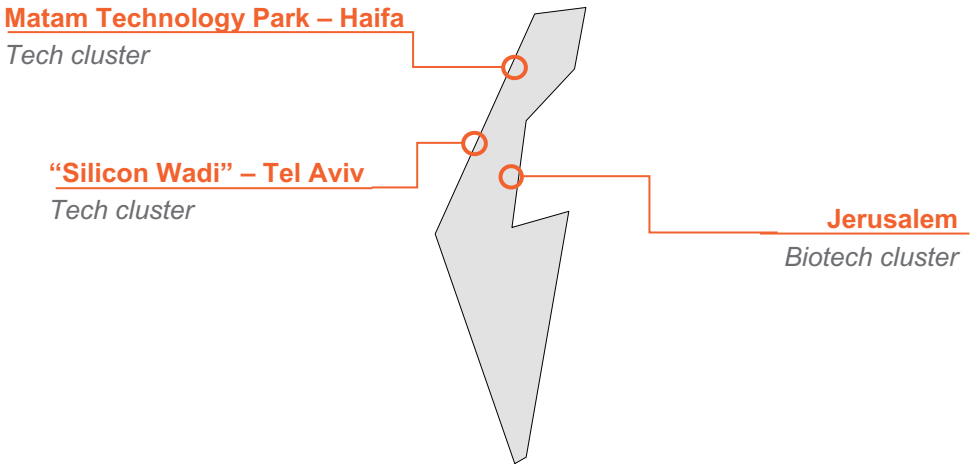


Source: OECD Data, 2018.

COLLABORATION AND INFRASTRUCTURE FOR RESEARCH

- In Israel, Jerusalem hosts a major biotech cluster. Many blockbuster treatments have been developed by Israel's academic institutes and marketed by global Pharma, such as: Azilect, a Parkinson's Disease therapy, was developed by Teva based on research at the Technion in Haifa; Rebif, a MS treatment, was developed by the Weizmann Institute in conjunction with Serono's subsidiary InterPharm; Exelon, a drug for the treatment of Alzheimer's originated at the Hebrew University and was developed and marketed by Novartis.[87]
- The BIRD policy has also resulted in collaborations across Pharma and Israel's Biotechs and Universities, e.g. a collaboration between Bayer and Omni Laboratories in Israel.[88]
- In addition, the Management of Knowledge Products Directive, 2010 and associated programmes has resulted in additional grants for the commercialization of academic research. As of 2019 12% of these grants had been provided to healthcare innovations.[89]
- In 2011, Merck Serono set up a bioincubator in Tel Aviv to stimulate innovation by bridging the gap between academic research and biotech. €10M was initially committed to help fund innovative start-up companies. An example is Metabomed founded by researchers from the Tel Aviv University and the Technion Israel Institute of Technology, and is funded by the Merck Serono and other sources.[90]

Map of biotech/biomedical clusters



Source: The Royal Society: Research and Innovation Clusters Report 2020

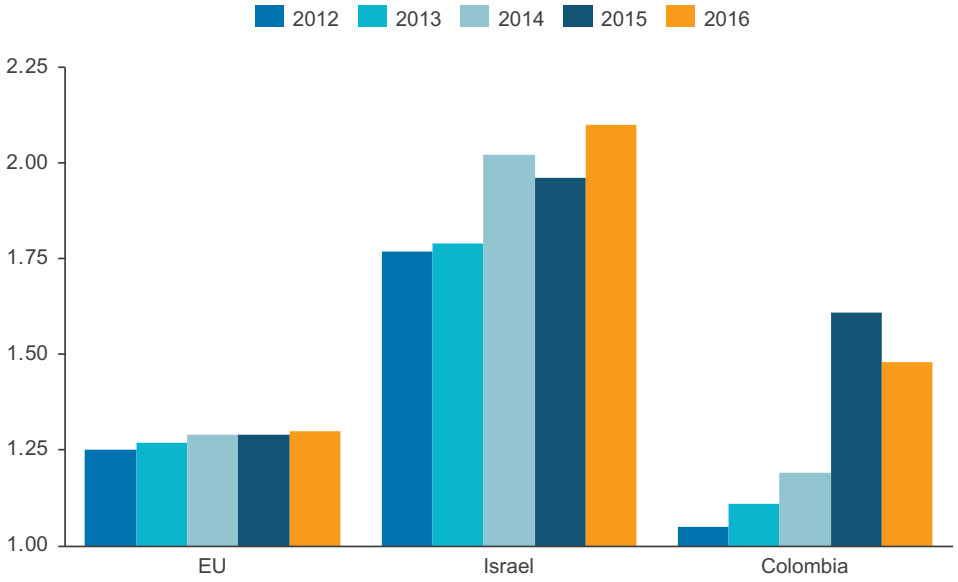
Pharmaceutical and biotech companies within Israel

teva NOVARTIS Takeda CellCure NeuroSciences Ltd. MERCK

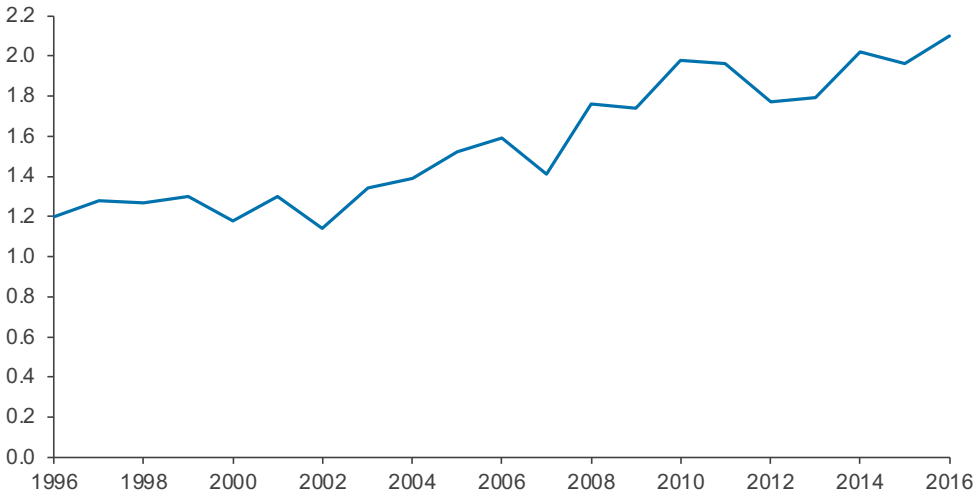
INNOVATIVE ACTIVITY: PUBLICATIONS

- The strength and influence of Israeli publications have been relatively high vs the EU and have grown steadily, Israel has outperformed the EU by 1.5 times between 2014-2016.[91]
- The share of Israel science and engineering publications in the top 1% most cited in the Scopus databased has almost doubled between 1996-2016.[91]

Share of top 1% Most Cited S&E Publications in Scopus* (2012 – 2016)



Share of Israel S&E publications in the top 1% most-cited in the Scopus database (1996 – 2016)

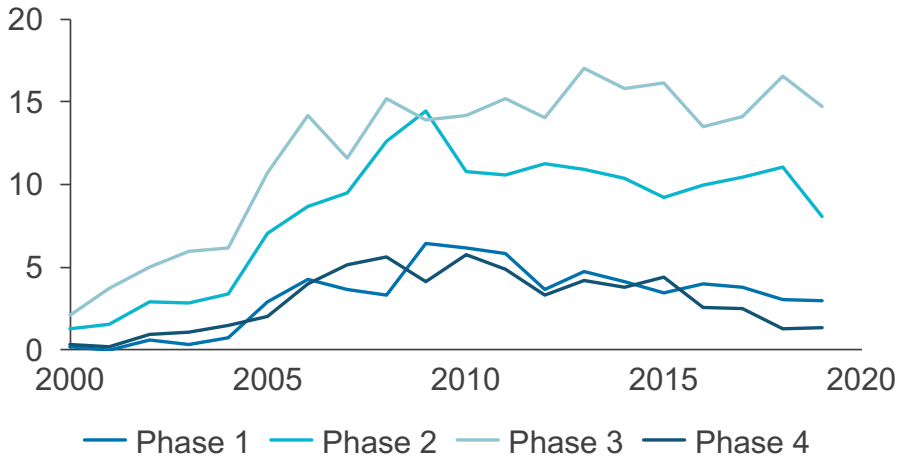


Sources: Scopus database; National Science Foundation Survey 2020.

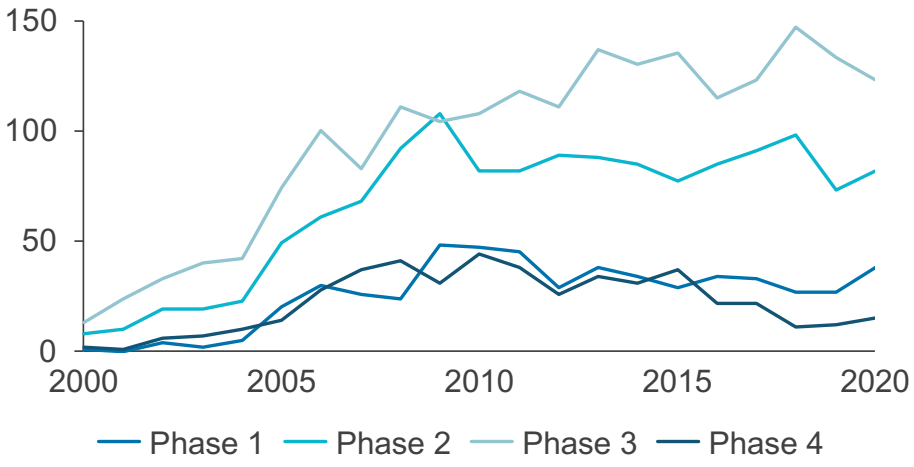
INNOVATIVE ACTIVITY: CLINICAL TRIALS

- The level of clinical trial activity has been fairly constant in Israel since 2006. A significant growth in Phase 2 and 3 trials occurred between 2004 and 2006, while phase 1 and 4 trials experienced more gradual growth.
- More clinical trials are conducted in Israel than in many other countries outside of Western Europe and the United States, and it is regarded as having a familiar regulatory environment, high-quality health care system, and strong patient enrolment rates.[92]
  - Israel's attractive clinical trial environment is also attributed to its innovative ecosystem and the area's ethnic diversity.[93]
- The Israeli government issued Government Resolution No. 2118 of 22 October 2014, followed by stricter rules and guidance in 2016 to reduce regulatory burdens across all agencies and ministries. While these weren't specific to promoting innovation or a particular industry, they may have further benefitted the innovation environment for clinical trials.[94,95]

Number of New Clinical Trials per 1M Population (2000 – 2019)



Absolute Number of New Clinical Trials (2000 – 2020)

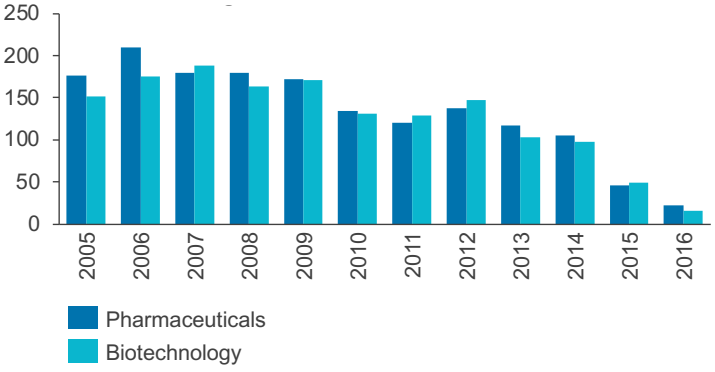


Source: Clinicaltrials.gov

INNOVATIVE ACTIVITY: PATENTS

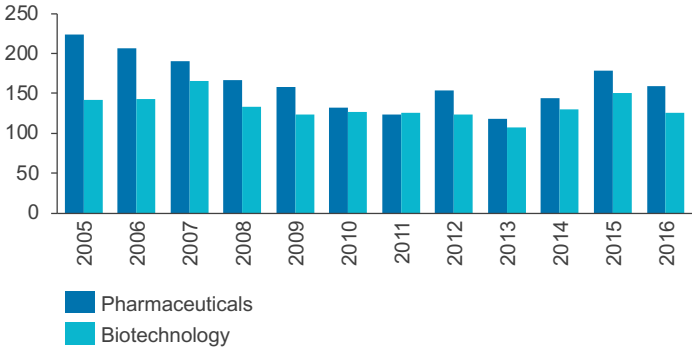
- The Israel Patent Office filing process is regarded as relatively simple compared to other countries. Applications can be expedited but are usually examined about 3 years after filing.[96]
- Israel is among the top 20 origins for resident patent applications per population based on WIPO indicators from 2019.[97]
- Patent applications filed abroad made up 90.3% of the total patent applications originating from Israel in 2018 and 91.5% of the total in 2019.[97,98]
- International patent applications originating from Israel filed via the PCT grew by over 5.7% in 2019.[97]
- Israel is a leading country for medical device patents per capita.[5]

USPTO Pharmaceutical and Biotech patents granted to Israel residents



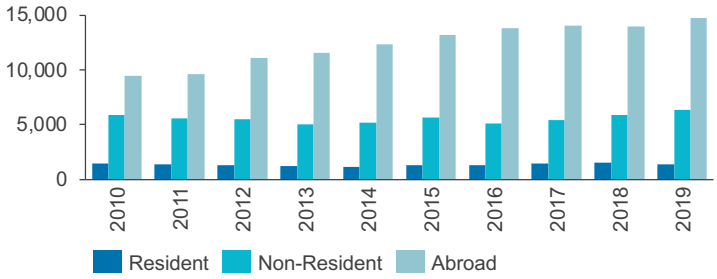
Source: OECD

EPO Pharmaceutical and Biotech patents granted to Israel residents



Source: OECD

Filed patent applications at Israel Patent Office

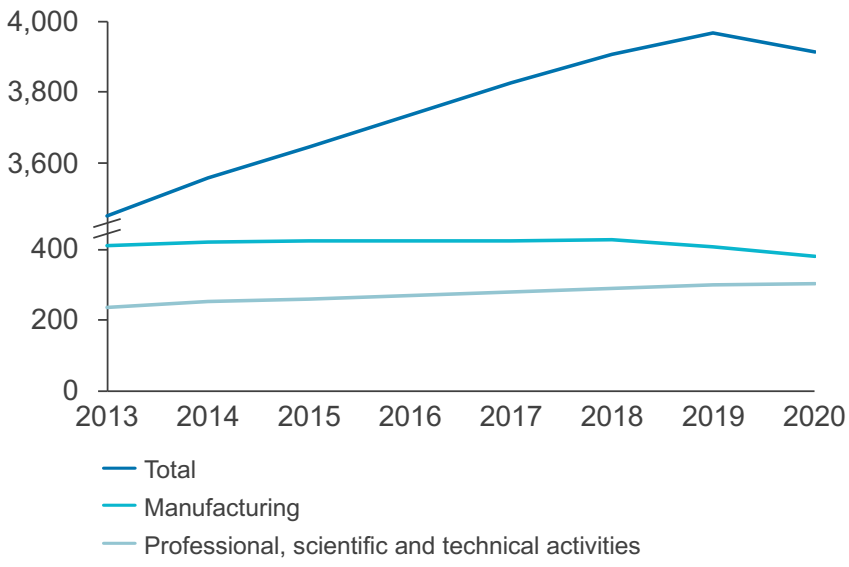


Source: WIPO

EMPLOYMENT IN THE PHARMACEUTICAL AND BIOTECH SECTORS

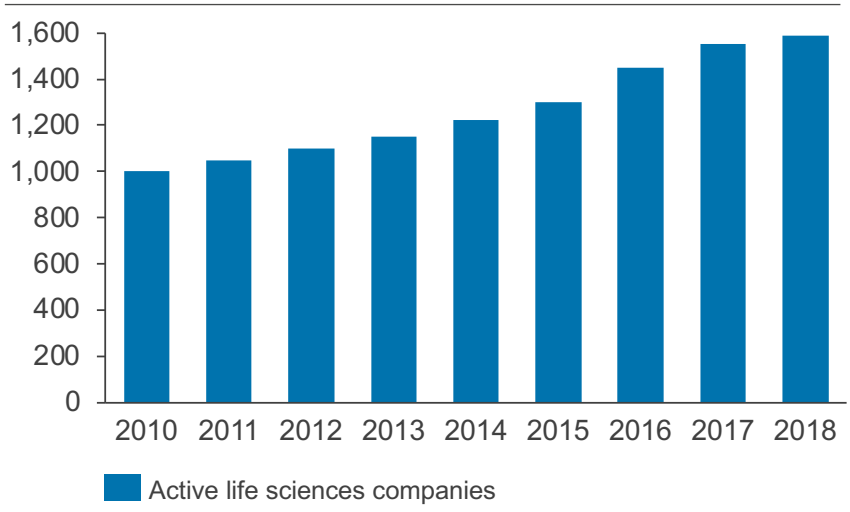
- The percentage of employees in Israel's high-tech sector (including pharmaceutical industry) rose to 8.7% by the end of 2018 from 8.3% in 2017. In the last decade the rate of workers employed in the high-tech sector has been stable around 8%.[99] The restructuring of Teva Pharmaceuticals reduced pharmaceutical industry employment by 3,000 employees from 2017 to 2018, with layoffs through 2019.[99,101]
- Before 1996 Israel had 186 life sciences companies and by 2010 it had over 1,100. The majority of these life sciences companies are in MedTech or healthcare IT.[102]
- Israel's Technological Incubators Program launched in 1991, is now the primary sponsor of start-ups in the country, supporting 60-70 new start-ups in biotech and tech each year. The Israeli government's National Program for Digital Health launched in 2018 invests $264 million for a 5-year plan to foster collaboration between sectors and improve infrastructure.[102]

Number of Israeli Employees in Principal Industries (2013-2020, thousands)[1]



Source: Bank of Israel.

Cumulative number of active life science companies in Israel (2010-2018)[6]



Source: Israel Advanced Technology Industries Report.

Tel Aviv, Israel, shutterstock.com/Dmitry Pistrov.

CASE STUDY: ISRAEL

APPLYING LESSONS FROM ISRAEL TO COLOMBIA

Changes in the policy regime to support innovation

A long-term plan investment plan for the innovation ecosystem.

- The **Israeli Innovation Authority** has a **long-term plan** in establishing Israel as a world leader in innovation and entrepreneurship that frequently grows innovation-driven companies, in order to provide extensive, highly productive employment for all population groups and all regions of the country.[103]
  - In its **2018-2022 Strategic Plan**, four strategic goals and ten strategic objectives have been identified. Two of these objectives were increasing the economic impact of multinational corporations' R&D centers and supporting competitiveness via R&D in the manufacturing industry.[103]

Prioritisation on local and international collaboration.

- Since 1977, Israel and the US have been collaborating through the **Binational Industrial Research and Development (BIRD) Foundation**.[104]
  - Since its inception in 1977, BIRD has approved over 950 projects with leading companies in the US, including pharmaceutical companies (e.g. Bayer).[104]
  - The Foundation also created a **Pharma Model** in 2007 applicable to Biotech or Pharma projects, and this may include the funding of clinical trials.[105]
- The **Israeli Innovation Authority** has an **International Collaboration Division** with separate resources for Europe, the Americas, Asia-Pacific and Africa, as well as a desk responsible for multinational corporation collaboration.[106]
  - For example, the authority organizes events such as the **Israel-US - Health Innovation Dialogue** to bring together leaders from American and Israeli government, business, and research institutions.[107]
- In addition, the **Management of Knowledge Products Directive, 2010** and associated programmes has resulted in additional grants for the commercialization of academic research. As of 2019 12% of these grants had been provided to healthcare innovations.[108]

An efficient universal healthcare system.

- Israel provides **universal coverage to citizens and permanent residents** as part of its national health insurance law.[103]
  - An OECD report found that Israel's healthcare system achieves a higher life expectancy and better healthcare metrics versus the OECD average, with significantly fewer financial resources compared to the other OECD countries, which shows the especially **high efficiency of the health system**.[109]

Dialogue to extend Regulatory Data Protection for biologics.

- In 2018, Israel has established an **inter-governmental committee to consider providing RDP for biologics** and the Ministry of Health has invited individuals, organizations and stakeholders to participate in the examination process for the need to amend Section 47D of the Pharmacists Ordinance with regard to biological preparations and the appropriate scope of the proposed amendment.[34,110]
  - However, the process **has not yet yielded a policy recommendation** for providing adequate protection.[34]
  - At the moment, Israel has legislation affording RDP to small molecule drugs for either six years from the registration date of the original drug in Israel or six-and-a-half years from the registration date of the original drug in another jurisdiction – whichever is earliest.[34,110]

Impact of changes in policies on innovation activity

- The innovative ecosystem in Israel has attracted investment to Israel: there are more than **430 investors with a permanent presence in Israel**, of which 23% are non-Israeli, with the most prominent late-stage investors are from the US, then Israel, followed by China, the UK, and Japan – resulting in Israel having **1,500 active life sciences companies**.[111,112]
  - Investments in Israeli companies have increased from around USD 2 billion to USD 8 billion over 2004-2019.[113]
  - This investment has resulted in about **65% of goods and services exported from Israel** have been manufactured by companies with a high level of innovation (mainly from the hi-tech, pharmaceutical and chemical industries), with the pharmaceutical exports amounting to USD1.66 billion in 2020.[104,114]
- Due to its innovative ecosystem and the country's ethnic diversity and genetic makeup, Israel is **increasingly being considered as a go-to market for conducting clinical trials**.[92,93]

Main expected effects of policy change

- The proposed **regulatory data protection amendment for biologics** is expected to have significant implication on the biologic market; with an increased protection it is expected that pharmaceutical companies would increase their R&D activity and to launch more biologics in the market.[110]
- The strong policies enhancing and encouraging c**ommercialization of academic research** have attracted investment from many Venture Capitalist funds and continually attracts national and international investment.[115]

CASE STUDY: SPAIN

IP SYSTEM CHANGES AND INNOVATION POLICIES

LAW 14/2011, ON SCIENCE, TECHNOLOGY AND INNOVATION, 2011

- The section II of the new Science, Technology and Innovation Act prompts the adoption of new schemes concerning human resources in S&T working in public research organisations (PROs) and universities. The implementation of a new and harmonised promotion scheme in the development of scientific careers forces research organisations to adapt their rules of procedure in the management of human resources towards higher levels of flexibility and to increase researchers mobility among public institutions and between public and private organisations.[121]

SPANISH STRATEGY FOR SCIENCE AND TECHNOLOGY AND INNOVATION, 2013-2020

- The Spanish Strategy for Science, Technology and Innovation addresses the challenges and needs of the Spanish Science, Technology and Innovation System, leveraging its capacities, strengthening the agents and their relations, boosting levels of business participation in RDI activities and increasing the social and economic returns from the public investment.[116]
- The strategy is structured according to four strategic goals acting as drivers of RDI policies and actions aimed at promoting: 1. talent and its employability. 2. scientific and technical research of excellence. 3. business leadership in RDI. 4. RDI solutions to global societal challenges.[116]

ROYAL LEGISLATIVE DECREE 1/2015, 2015

- This decree brings Spanish Law in line with European legislation and amongst other regulations, specifies that a generic medicine cannot be effectively placed on the market until the period of data exclusivity protection has elapsed (10 years after approval of the medicine of reference or 11 years if new indications have been authorised for the medicine during the first eight years).
- This provides incentive for innovation as exclusivity for a defined period is guaranteed.

ROYAL DECREE 1090/2015 (REGULATING CLINICAL TRIALS WITH MEDICINAL PRODUCTS), 2015

- This Royal Decree aims, to adapt Spanish legislation to make feasible the current and future application of Regulation (EU) No 536/2014, and to develop those aspects that the Regulation leaves to national legislation.[122]
- Intended to promote and facilitate clinical research with medicinal products in Spain, the generation of knowledge, transparency, the safety of participants and the usefulness of the results or, in summary, to consolidate the confidence of society in research and to foster its progress.[122]

LAW 24/2015 ON PATENTS (THE NEW PATENTS ACT), IN EFFECT FROM 2017

- The new law intends to update Spanish patent law to adapt it to international standards and, in particular to bring it further into line with European legislation.[117,118]
- Among the main changes incorporated in this new Law, the most notable aspect is the establishment of a single grant procedure for patent applications, which requires a substantive examination to be carried out to assess novelty and inventive step.[118]
- This law included improved definition of the process for Supplementary Protection Certificates (SPCs) for the period during regulatory approval, which may delay full patent protection.[119]
- This law includes the Bolar exemption and the subsequent practical requirements, including the preparation, production and use of the active ingredients for those purposes.[120]

SPANISH STRATEGY ON SCIENCE, TECHNOLOGY AND INNOVATION 2021-2027

- The EECTI is the necessary instrument to strengthen the SECTI in an integrated way and to respond to the current national and European crisis. The EECTI is conceived as the multiannual reference framework that will make it possible to reach a set of targets shared by all the Public Administrations with competences in the field of promotion of scientific and technical research and innovation.[123]

STRATEGIC FRAMEWORK FOR SME POLICY 2030, 2019

- A Policy framework for small and medium-size enterprises (SME). The framework is based on seven pillars in line with EU SME policy (Small Business Act for Europe, SBA), from which it derives 50 line of actions or recommendations.[124]
- The objective is to establish a set of measures to improve the SME competitiveness, as well as helping to create the framework to promote their growth.[124]

Key

○ Changes to the IP regime

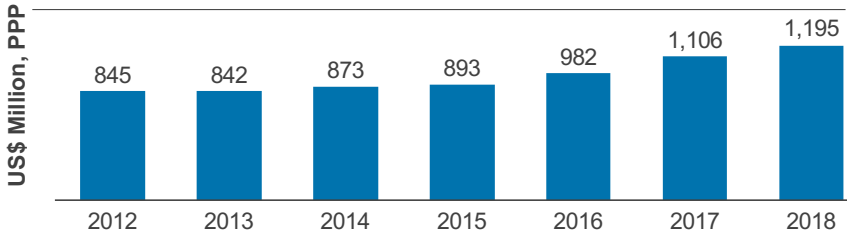
○ Changes to the Innovation Policy Landscape

★ NOTE – Regulation market with a star will be used as proxy for change in estimating growth differences

INVESTMENT IN R&D AND FDI

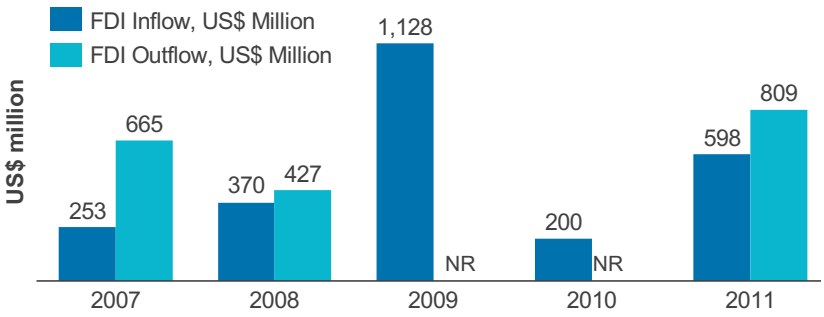
- Based on most recent available data, Spain is ranked 16th in the world for R&D spending. Additionally, in 2019 Spain invested about half of the OECD average for investment in R&D as a % of GDP.[125]
- Reports show that organisations that continued with R&D despite the economic recession after 2008 were more likely to have access to public funding and were more likely to have patents granted, demonstrating the need for public research policies at the national and regional level.[126]
- In addition, under the Strategy for Science and Technology and Innovation 2013-2020 policy, the Ministry of Science & Innovation set out their budget for direct investment each year. For the year 2021, the Ministry have confirmed the largest direct investment in R&D&I in absolute terms in Spanish history.[127]
- In 2016, public and private investment in R&D accounted for 0.55% and 0.64% of GDP.[128]
- FDI Outflow have consistently generated a higher rate of return than the return on FDI Inflow. In 2015, Spain was cited as being Europe's 3rd economy for outward FDI as a share of GDP and second for inward FDI.[128]

Pharmaceutical BERD (2012 – 2018, US$ Million, PPP)



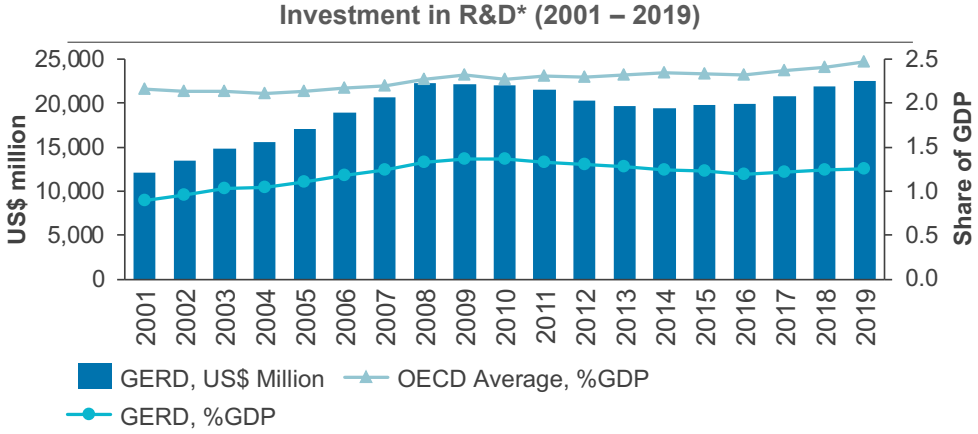
Source: OECD Data, 2020.

FDI flows for Pharmaceutical, Medicinal Chemical and Botanical Products (2010 – 2012, US$ Million)



Source: OECD Data, 2021.

Investment in R&D* (2001 – 2019)



Source: OECD Data, 2021.

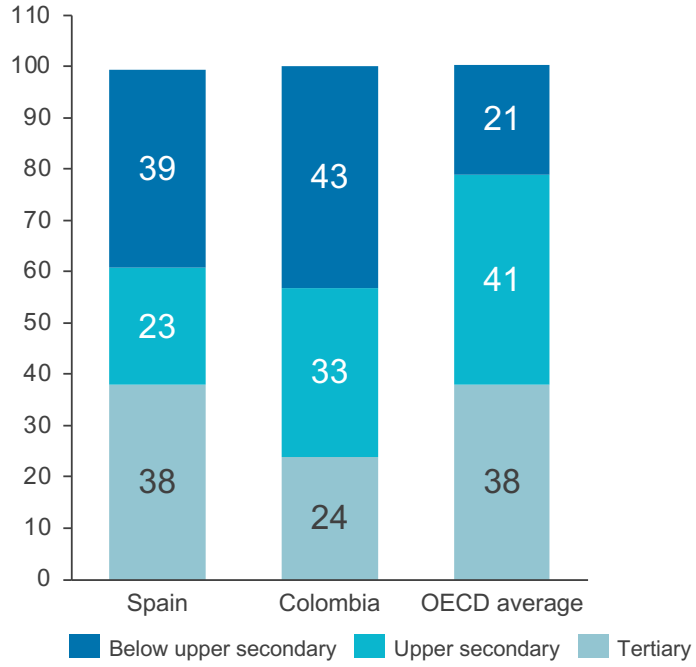
NR = Not reported

*Spending on R&D is defined as the total expenditure (current and capital) on R&D carried out by all resident companies, research institutes, university and government laboratories, etc., in a country and includes R&D expenditure across sectors.

UNIVERSITIES AND QUALITY OF EDUCATION

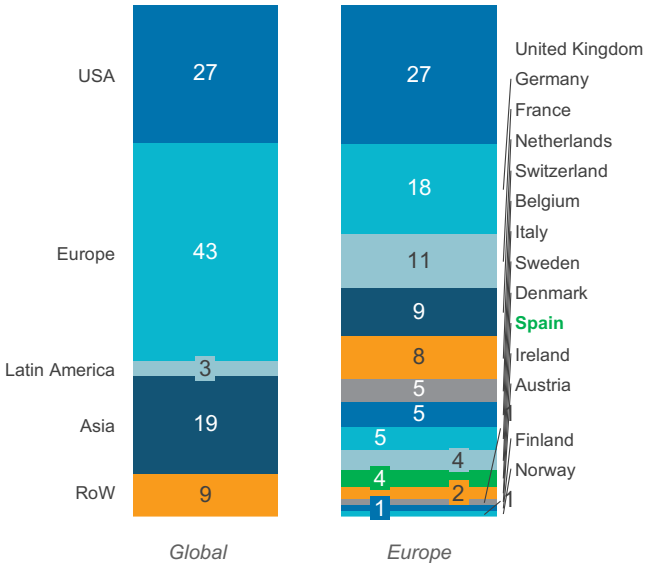
- The level of educational attainment in Spain is somewhat higher than Colombia, with 38% of adults greater than 25 years having Tertiary level education. Spain has a similar proportion of Tertiary education as the OECD average, but also has higher proportion with only below upper secondary education than the OECD average.[84]
- However, the average PISA score in Science is also on par with the OECD average, at just 6 points below.[86]
- Spain represents ~4% of the European universities in the top 200 for biological sciences and falls in the bottom half of the European universities in terms of contribution.[85]

Educational attainment of 25-64 year olds, (2019, %)



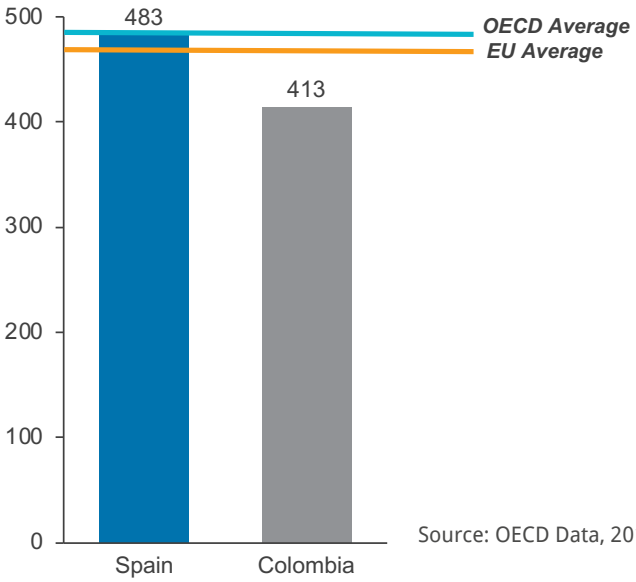
Source: OECD Data, 2019.

Universities in Top 200 Universities for Biological Sciences (2020, %)



Source: QS Top Universities, 2020.

Average PISA Score in Science (2018)

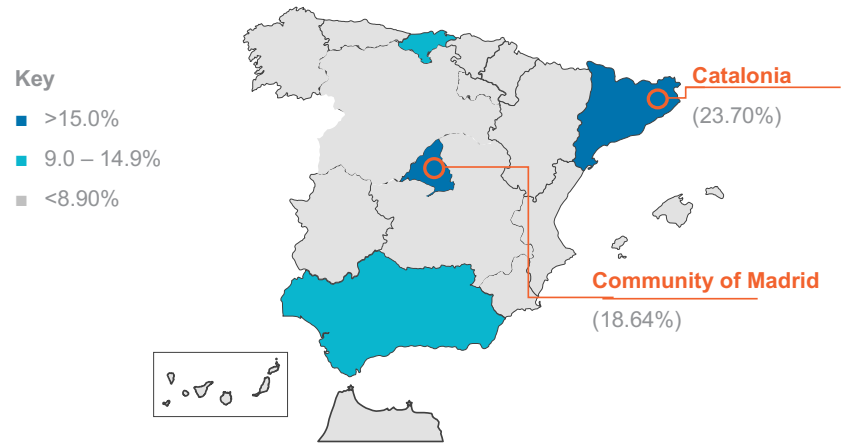


Source: OECD Data, 2018.

COLLABORATION AND INFRASTRUCTURE FOR RESEARCH

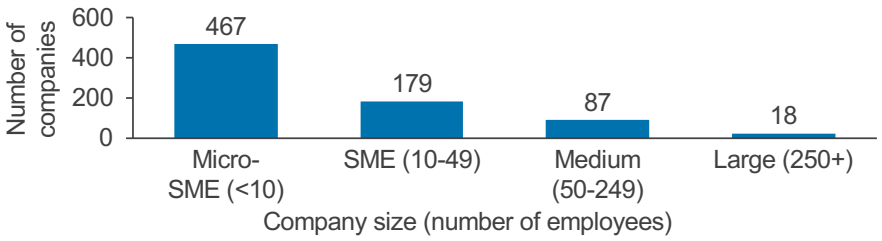
- The Spanish biotech sector is ranked as being in Europe's top 4 biotech clusters based on the number of patents, jobs, companies and level of funding.[129]
  - Catalonia, with nearly 24% of all biotech companies, is the main hub of biotechnology activity in Spain, both in number of biotech companies and in turnover, with over 50% of the joint turnover in 2018. It is followed by the Community of Madrid and Andalusia.[130]
  - Just under 55% of these are micro-SMEs with fewer than 10 employees and 28.4% have fewer than 50 workers. Nevertheless, in terms of total turnover, over 86% of the total is created by the 87 medium sized companies and 18 large corporations identified.[130]
- Asebio also highlight the high level of collaboration between Pharma with local biotech companies and with universities in Spain, e.g. collaborations between GSK and the university of Granada, and Nostrum Biodiscovery established collaborations with IRB Barcelona, University of Santiago de Compostela and Vall d'Hebron.[130]

Territorial breakdown of biotech firms and biotechnology-related facilities



Source: ASEBIO, 2020.

Number of Pharma and biotech companies within Spain



Source: ASEBIO, 2021.

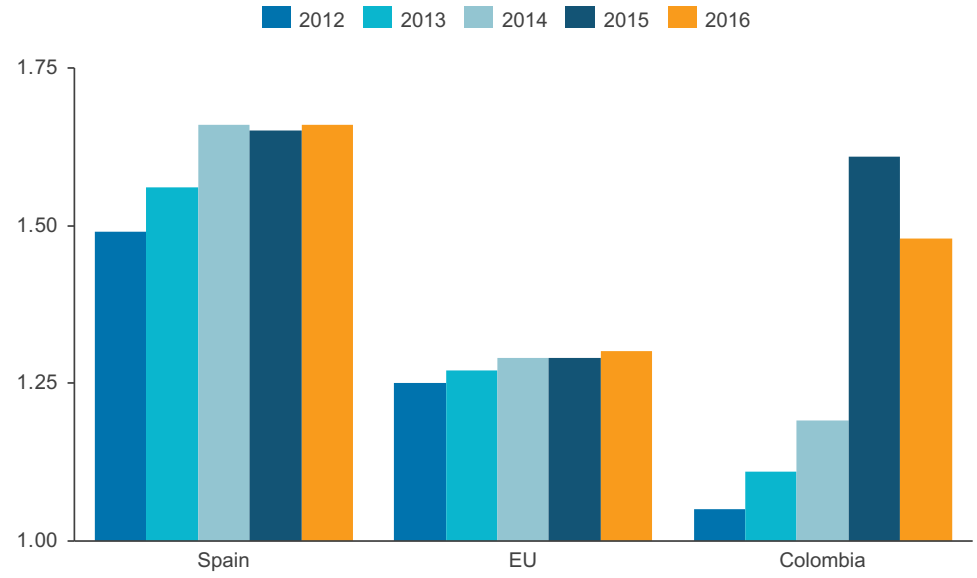
Pharma and biotech companies within Catalonia

Source: catelonia.com, 2021.

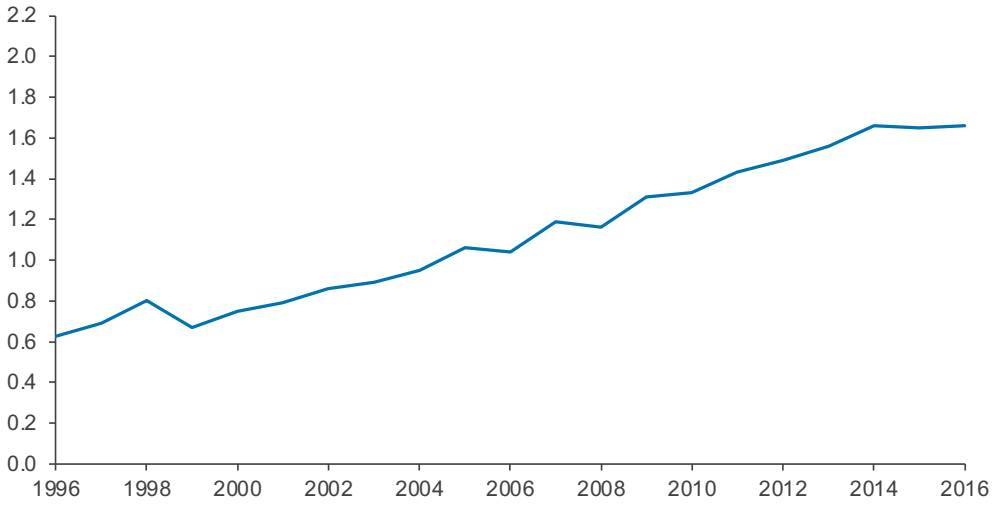
INNOVATIVE ACTIVITY: PUBLICATIONS

- The strength and influence of Spanish publications have grown significantly and steadily, its share of Science & Engineering publications in the top 1% most-cited articles tin the Scopus database has multiplied by 2.6 times from 1996 to 2016.[91]
- To compare within the region, Spain outperforms the European average by approximately two times between years 2012-2016.

Share of top 1% Most Cited S&E Publications in Scopus* (2012 – 2016)



Share of Spain S&E publications in the top 1% most-cited in the Scopus database (1996 – 2016)

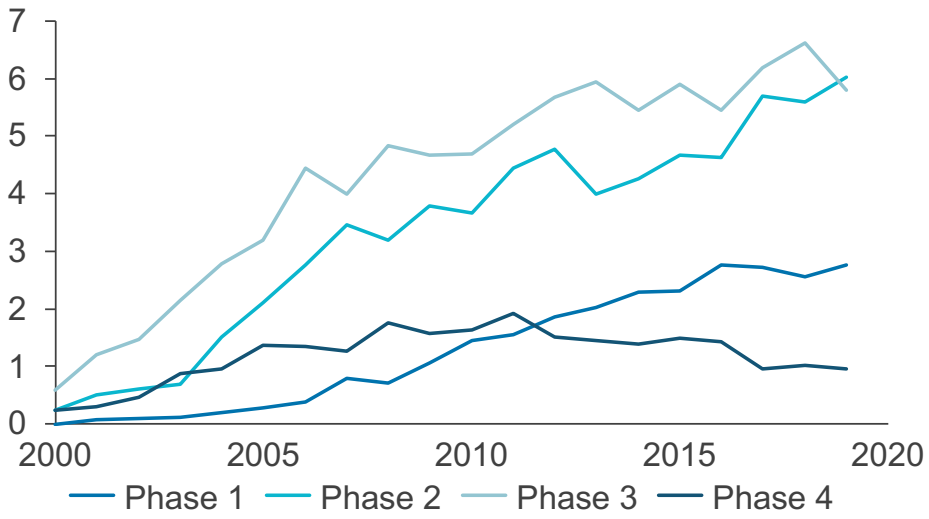


Sources: Scopus database; National Science Foundation Survey 2020.

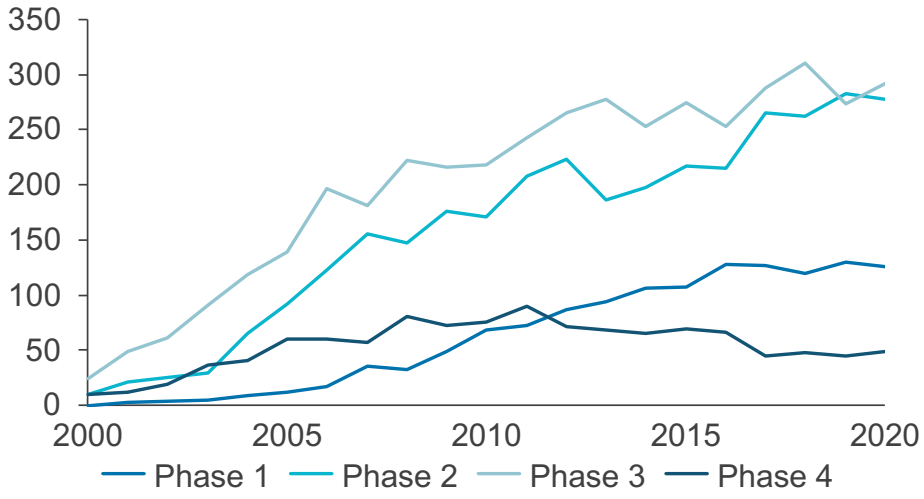
INNOVATIVE ACTIVITY: CLINICAL TRIALS

- The level of clinical trial activity has increased overall in Spain since the early 2000s across all stages of clinical trials.
- The largest growth was observed between the years 2003-2006 with largest growth Phase 2 and 3 trials. Absolute numbers increased from 29 to 156 between 2004-2006.
  - Consistent growth in Phase 1 trials per 1M population from before 2010 to 2014 was followed by steeper growth from 2015 to 2016, around the time of the "New" Regulation on Clinical Trials (Royal Decree 1090/2015) which simplified procedures and created other favorable conditions for clinical trials in Spain.[131,132]
- As of data from 2018, Spain collaborates in nearly 20% of international clinical trials. Clinical trials represent 45% of pharma investment in Spain.[133]

Number of New Clinical Trials per 1M Population (2000 – 2019)



Absolute Number of New Clinical Trials (2000 – 2020)

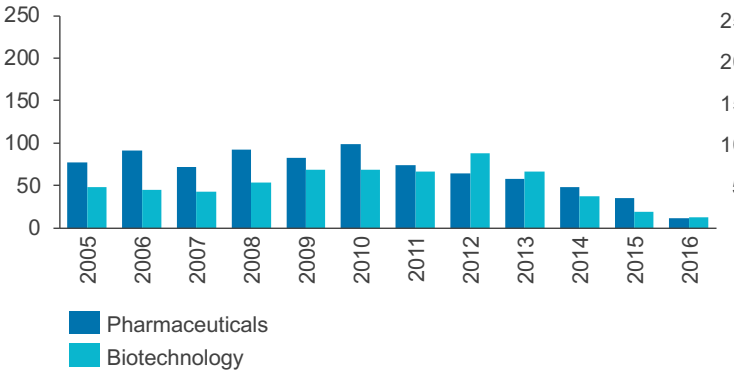


Source: Clinicaltrials.gov.

INNOVATIVE ACTIVITY: PATENTS

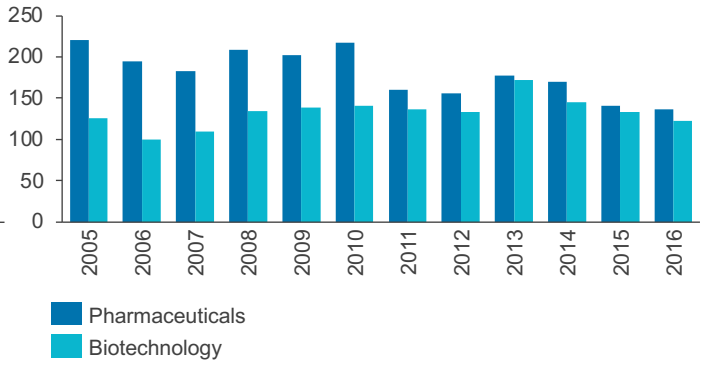
- According to WIPO indicators, in 2018, Spain ranked 15th in total (resident and abroad) IP filing activity by origin and 14th in resident IP filing by origin.[98] In 2019, Spain ranked 16th and 15th respectively for the same categories.[97]
- Between 2005-2016, annual filed patent applications with a Spanish applicant has remained relatively stable for both pharmaceuticals and biotechnology with the EPO, although declined for both with the USPTO.
- Spanish international patent applications filed via the PCT grew by over 8% in 2019.[97]
  - Growth from 2017 on may be attributable to Law 24/2015 on Patents which helped to make Spanish patenting more in line with international, and especially European standards.[118]

USPTO Pharmaceutical and Biotech patents granted to Spain residents



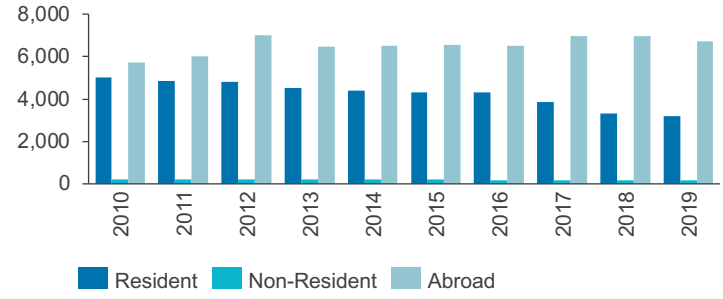
Source: OECD.

EPO Pharmaceutical and Biotech patents granted to Spain residents



Source: OECD.

Filed patent applications at Spanish Patent and Trademark Office

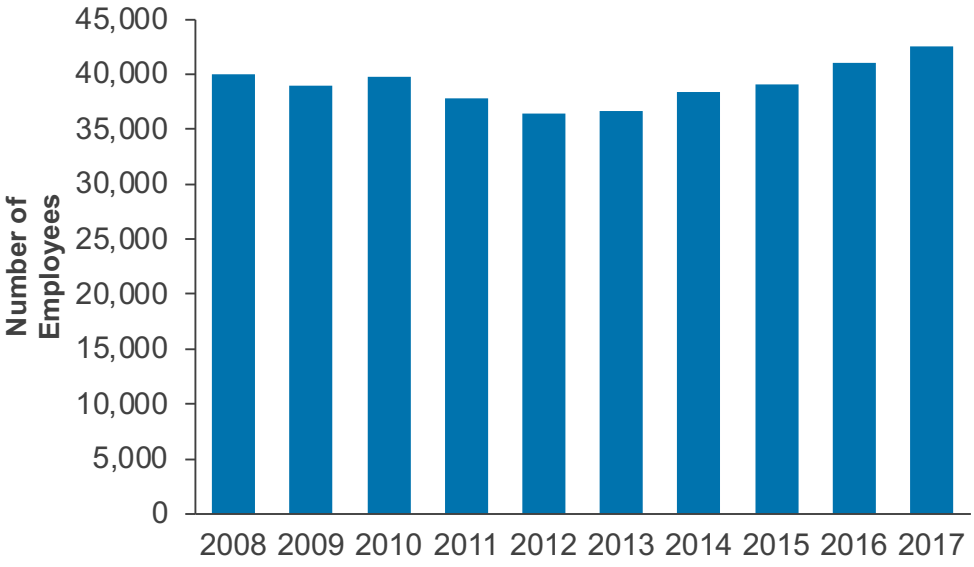


Source: WIPO country profile statistics.

EMPLOYMENT IN THE PHARMACEUTICAL AND BIOTECH SECTORS

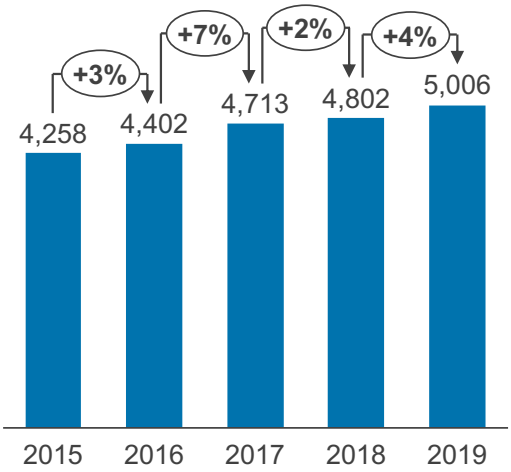
- Spain had the second highest number of biotech firms out of European countries in 2018 (Spain is placed between France, first, and Germany, third.)[134] There are around 3,000 companies involved in biotechnology and 1,000 involved in healthcare technology.[135]
- There are over 425 pharmaceutical companies in Spain employing over 40,000 people.[135,137] Around 60% are foreign companies.[135]
- The majority, 62%, of those employed by the pharmaceutical industry have university degrees, compared to 42% of the Spanish economy overall.[136]

Workers in pharmaceutical manufacturing companies in Spain (2008-2017)



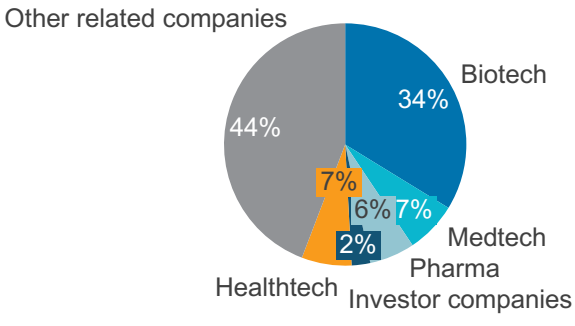
Source: Statista.

Growth of professionals graduating with R&D education in Spain (2015-2019)



Source: FarmaIndustria.

Spanish life sciences industry composition (2017)



Source: C5 Life Sciences Trend Analysis.

Valencia, Spain, shutterstock.com/ESB Professional.

CASE STUDY: SPAIN

APPLYING LESSONS FROM SPAIN TO COLOMBIA

Changes in the policy regime to support innovation

The New Regulation on Clinical Trials made Spain a more attractive place to conduct clinical trials.

- The **"New" Regulation on Clinical Trials** (Royal Decree 1090/2015) was created with the aim to simplify procedures for clinical trials, increase transparency and protect patients' rights, and foster public research to cover non-priority areas for the pharmaceutical industry[131,132]
  - Through this Regulation, the Spanish Clinical Trials Registry was created to increase to the transparency, one can consult all the clinical trials authorized in Spain and the sites where they are being conducted.[131]
  - This resulted in Spain being the **first to apply the most recent European regulations** on clinical trials which went into force in May 2016.[132]
- Furthermore, Spain's **healthcare system**, the **public funding** into Spain's healthcare system, together with its skilled workforce contributes in making the country an attractive place to conduct clinical trials.[133]

A long-term National Plan to increase R&D and Innovation activities.

- Since 1988, the government has launched **consecutive National Plans to improve the R&D** and Innovation activities in the country, the last being the State's Plan for Scientific and Technical Research and Innovation 2017-2020.
  - As a result, the Ministry of Science and Technology have confirmed the largest direct investment in R&D&I in absolute terms in Spanish history for 2021.[127]
  - Recent studies have highlighted the importance of **public funding** in resilience of companies through economic downturns, with companies in Spain continuing R&D after the 2008 crash being more likely to have a source of public funding and be granted more patents.[126]

A more comprehensive Intellectual Property Law.

- The Law 24/2015 on Patents was introduced in order to update the Spanish Patent Law (11/1986) more in line with international standards and, in particular, to bring it further in line with European legislation.[118] Some of the changes incorporated through the new Law include:
  - The new Law requires that **all patents are examined** (which was option under the old Patent Law[5]
  - The new Law incorporates the **patentability of substances or compositions already known** for use as a medicament or for new therapeutic indications - which is in line with the amendments adopted in the Revision of the European Patent Convention made in 2000 (and which entered into force in 2007).[118]
  - The new Law included improved definition of the process for Supplementary Protection Certificates (SPCs) for the period during regulatory approval, which may delay full patent protection.[118]
  - Additionally, through the new Law only those **Commercial Courts that have been assigned exclusive jurisdiction to hear patent cases** will be competent to hear patent cases (such Courts are now also referred to Patent Courts).[139]

- The Spanish Patent and Trademark **Office publishes an Official Intellectual Property Gazette** (referred to BOPI) which includes information on the granted patents, patent applications that meet certain requirements and the associated search reports, and which is published on a daily basis.[140,141]
  - Third parties can **oppose to the granting of the patent post-grant**, up to six months from the publication of the grant of the patent.[139]
  - In cases where the validity of the patent is disputed, one can r**equest the Spanish Patent and Trade Mark Office to issue a report** on the aspects on which the parties' experts contradict one another.[139]

Impact of changes in policies on innovation activity

- The **"New" Regulation on Clinical Trials** has contributed to an increase in the **total R&D investment** from the pharmaceutical industry – the total pharmaceutical R&D increased by 17.8% between 2013-2019, from €921.6 million to €1,085 million, resulting in the pharmaceutical industry being the leading industry in the terms of R&D investment in Spain.[132]
  - 51% of this investment is allocated to clinical trials, 14% to basic research, and the rest to post-authorization studies and Galenic research.[132]
  - Between 1997 and 2016, the number of clinical studies conducted in Spain increased by 48.1%.[132]
- As the new Patent Law (Law 24/2015) made it obligatory to substantive examine all patents, there has been a **dramatic change in the patents being examined** (and it is estimated that less than 10% were previously examined – this has resulted in an increase the quality of Spanish patents.[138]

Main expected effects of policy change

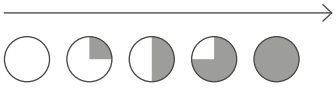
- The revised **Patent Law** makes Spain an attractive place to invest in R&D and innovation activities
- Furthermore, given that **specific Commercial Courts** have been assigned exclusive jurisdiction to hear patent cases, this will lead to increased efficiency in patent litigation.
- Analysts have highlighted the **maturing biotechnology community** and strong infrastructure that has developed over recent years in Spain, noting that clusters in other areas of the country such as the Basque region are growing.
  - As a result, Spain's biotech community is expected to equal those of Northern European countries in the coming years.[142]

IMPACT ATTRIBUTABLE TO THE CHANGE IN REGULATION IN A 5-YEAR PERIOD: SUMMARY

	ISRAEL	SPAIN
KEY INNOVATION POLICY CHANGES	The Pharma Model created by the Binational Industrial Research and Development (BIRD) Foundation, 2007.	Royal Decree 1090/2015 (regulating clinical trials with medicinal products), 2015.
KEY IP REGULATION CHANGES	Amended Israeli Patent Law 5727, 2006.	Royal Legislative Decree 1/2015, 2015.
OTHER KEY REGULATION CHANGES		Law 24/2015 on Patents (the new Patents Act), In effect from 2017.

		Growth	Attributable to regulation	Growth	Attributable to regulation
Innovative Activity	BERD / GERD	6%		3%	
	Early research (publications)	43%		52%	
	Clinical trials (All)	158%		78%	
	Patents	38%		Negative	
	Patents (USPTO/EPO)	Negative		Negative	
Economic Activity	Employment in biopharmaceuticals	51%		9%	

Impact of the regulation



El Torcal de Antequera, Málaga, Spain, shutterstock.com/Deep Pixel.

IMPACTS ON INNOVATION FROM POLICY CHANGE IN ADDITIONAL ASIAN MARKETS: CHINA, JAPAN, SINGAPORE, SOUTH KOREA AND TAIWAN

CASE STUDY: CHINA

Changes in the policy regime to support innovation

Pro-innovation policies to encourage development of technological capabilities.

- The **National Medium- and Long-Term Program for Science and Technology Development (2006–2020)** established the framework for Chinese research and technology policy up to 2020.[143]
  - Specific targets involved an increase in R&D expenditure to at least 2.5% of GDP and raise the R&D contribution to economic growth to at least 60% of GDP.[143]
- In 2008, the Chinese State Council issued "National Intellectual Property Strategy Compendium", asserting that China would be transformed into a country with **high level of domestic technological capabilities; creating, utilizing, protecting and administrating intellectual properties** by 2020.[144]
  - This strategy provided a comprehensive plan to **improve the efficiency of the protection and enforcement of intellectual property rights** while emphasising the need for **active development of domestic or independent intellectual property.**[145]
  - Literature notes that the National IP Strategy was significant in increasing the priority of national development of IP.[146]
- The China Pharmaceutical Innovation and Research Development Association find that Chinese companies have recently been **building up R&D capabilities to develop and improve clinical trials for innovative drugs.**[147]
  - From 1949 to 2008, less than five domestically developed drugs were approved by Chinese authorities, while from 2008 to 2018, the number increased by about 10 times to about 40.

Impact of changes in the policy regime on innovation activity

Partnerships and collaboration to increase local innovation and IP.

- Zhang et al. (2018) link the strengthening of IP in China to the **rise of manufacturers' R&D capabilities in China**. In addition, the authors find that the manufacturers in China are moving from coordinating global R&D projects to increasingly focusing on **national public and private sector partnerships** to increase **localized innovation and product development.**[148]
- Hu and Jefferson (2009) find that China's growth in patent applications from the late 1990s was in part driven by **amendments to national Patent Law** that include mechanisms to **improve the efficiency of the enforcement of patent rights.**[149]

Strengthening IP protection increases R&D Investment and FDI.

- Fang et al. (2015) also find that **strengthening IP protection in China has led to increased private R&D investment.**[150]
- Awokuse and Yin (2008) study the relationship of IPR protection in China to FDI inflows, and conclude that IPR reforms in China have had a positive and significant effect on inbound FDI, and this effect is more pronounced in knowledge-intensive sectors such as pharmaceuticals.[151] The authors find that **pharmaceutical market expansion in China was more significant** in the early 1990s as China began to **strengthen it's patent laws and efficiency of enforcement.**

Main expected effects of policy change

- Pro-innovation policies and strengthening enforcement of patent rights are expected to lead to increased domestic technological and R&D capabilities and partnerships leading to increasing patent applications.

CASE STUDY: SINGAPORE

Changes in the policy regime to support innovation

Strong long-term commitment to innovation activity.

- The **Biomedical Sciences Initiative** which was launched in 2000, was established with the intention of strengthening the Pharmaceutical, Biotechnology, Medical Engineering and Technology and Healthcare Services industries in order for Singapore to become a leading drug discovery centre and a leader in the Asia.[152]
  - In the first phase of the initiative (2000–2005) Singapore focused on establishing **core capabilities in biomedical research, and introducing important human capital and industrial capital development initiatives**, whereas in the second phase (2006–2010), Singapore focused on **strengthening its capabilities in translational and clinical research to bring discoveries from the bench to the bedside and the marketplace**, and ultimately improve human healthcare.[152]
- Through the **Research, Innovation and Enterprise Plan** 2020 plan, the Singapore Government has committed to invest nearly US$2.4 billion over 5 years to advanced pharmaceutical development. The plan focused on areas where Singapore **has the potential to be internationally competitive**, and to align R&D efforts with national healthcare strengths and needs to deliver on health and economic outcomes.[152-154]

Policies encouraging collaboration across different institutions.

- The Agency for Science, Technology and Research (A*STAR) was established in 2002 and is Singapore's lead public sector R&D agency and it aims to **bridge the gap between academia and industry.**[155]
  - In fact, A*STAR working with **30 leading pharmaceutical companies** from around the world, including Chugai Pharmaceutical Co., Ltd and Novartis International AG.[156]

Measures to achieve more efficient patent resolutions.

- Singapore passed the **IP Dispute Resolution Act** to introduce new provisions to facilitate more efficient patent resolutions. This included the implementation of a specialist IP litigation system enabling the High Court to handle all litigation disputes as a fast track option.[157]

Impact of changes in the policy regime on innovation activity

Introducing policies to strengthen innovation creates employment and research activity.

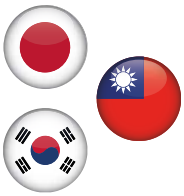
- Between 2011 and 2007, **the number of pharmaceutical and biological manufacturing establishments** increased by 23%, from 44 to 54 and more than 6,000 people in the skilled workforce employed in the biopharmaceutical sector, more than double since the early 2000s.[158-159]
- As the regional headquarters for many global pharmaceutical companies, between 2004-2013, **pharmaceutical applications made up the largest proportion of patent applications in Singapore.**[160]
  - This is reflected in the number of patent publications in the field of pharmaceuticals, biotechnology and medical technology has increased significantly from 4.8% of publications in 2005 to 19.9% in 2015.[160]
  - Almost 90% of the patent applications filed in Singapore are through foreign applicants. The majority of patents filed between 2009-2013 and the majority were in arthritis disease and cancer contributed by major pharmaceutical companies such as Merck, Novartis, Roche.[160]

Introducing measures to achieve more efficient patent resolutions strengthens the country's position as a global IP leader.

- With the reform to the IP Dispute Resolution Act in 2019, it has reinforced Singapore's role as an **international hub for arbitration**[161] with Singapore consistently ranking highly on global IP rankings including World Economic Forum's Global Competitiveness Report 2019 (2nd in the world).[162]

Main expected effects of policy change

- The implemented policies **provided multinational companies assurance** to choose Singapore as a location to develop local manufacturing and research centres and developments have been observed in the increase in the number of patents and clinical trials as well as recognition as a global hub for IP arbitration.[160]



CASE STUDY:
JAPAN, SOUTH KOREA AND TAIWAN

Changes in the policy regime to support innovation

RDP for pharmaceuticals in Japan.

- Japan provides d**e facto RDP through PMS**. Originally introduced in 1979 with only 2 years, **data exclusivity was most recently extended to 8 years for new medicines** in 2007 by the Pharmaceutical and Food Safety Bureau (PFSB) at the Ministry of Health, Labour and Welfare (MHLW).[163]
- When a novel drug is approved, it is subject to re-examination. This **re-examination period or PMS period of 8 years prevents any applicant of a generic product from relying on the originator's clinical trial data** and applying to marketing authorisation, until the re-examination period for the original (innovator) drug expires. This has an equivalent effect to RDP.[163]

RDP for pharmaceuticals in South Korea.

- The Korean Pharmaceutical Affairs Act was amended in 1995 to provide a **de-facto 4 or 6 year data protection for new drugs and certain prescription drugs.**[164]
- Although not officially RDP, this Amendment provides data exclusivity through Post-Marketing Surveillance (PMS). Before the expiry of the PMS period, **no generic applicant can rely on the clinical trial data of the reference product** unless data is significantly different or exceeds the scope of data submitted first approval.[164]
- This was to meet the requests from the United States, EU, and Japan to extend the patent for 'pipeline' products.[164]

RDP for pharmaceuticals in Taiwan.

- The Pharmaceutical Affairs Act was amended in 2017 to harmonise the generic approval process with international norms including data exclusivity and patent linkage. The system is very similar to the Hatch-Watchman Act governing US generic approvals[165] Taiwan recognised that.
  - **5 years of data exclusivity for drug approvals** containing new ingredients and 3 years for drug approvals of new indications was enacted in 2018.[166]
  - A patent linkage system was established in 2019 for resolving disputes related to listed patents between the generic applicant and original marketing approval holder.[165]

Impact of changes in the policy regime on innovation activity

Impact of RDP provisions.

- Between 2007 and 2017, the Korean pharmaceutical industry developed and **successfully launched 17 innovative drugs**. In addition, South Korea demonstrated a **14% increase in the number of clinical trials over the second time period (2011–2012)** while exhibiting a decline in site numbers, suggesting an **improvement in efficiency, as new medicines were increasingly trialled.**[167]
- In Japan, **when RDP was introduced in 2007**, the number of **new drug approvals grew by 37% between 2009-2018.**[168]
- RDP provides an incentive for the introduction of new innovations and once period exclusivity ends.
- Analysis of OECD data from Japan (and Canada) find that **pharmaceutical spending as a share of GDP did not increase** following extensions to local RDP provisions.
- Examination of orphan drug clinical trials highlights a **significant increase in trials after the extension of de facto RDP in Japan in 2007.**
- In Taiwan, **the number of clinical trials and also biopharma companies have steadily increased**. The sector grew from US$6 billion in 2009 to 22 billion in 2015.[169]

Main expected effects of policy change

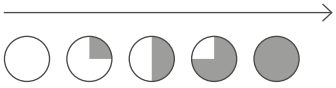
- Implementation of **RDP leads to increased clinical trials and product development** since innovators feel secure that their **R&D efforts are protected without increasing pharmaceutical spending** and hindering efforts towards universal access to medicines.

IMPACT ATTRIBUTABLE TO THE CHANGE IN REGULATION IN A 5-YEAR PERIOD: SUMMARY

	CHINA	JAPAN	SINGAPORE	SOUTH KOREA	TAIWAN
KEY INNOVATION POLICY CHANGES	Program for Science and Technology Development (2006).	Science & Technology Basic Plan (1996 – 2016).	Biomedical Sciences Initiative, 2000.	"Bio-Vision 2016" Plan of 2007 "577 Initiative" of 2008	Biotech and New Pharmaceutical Development Act (2007).
KEY IP REGULATION CHANGES	Regulatory Data Protection (RDP) (2001).	Notice extending the RDP term (2007).	Singapore-US Free Trade agreement, 2004 .	Pharmaceutical Affairs Act of 2007: Grant of RDP.	Revision of Pharmaceutical Affairs Law (2005): Grant of RDP.
OTHER KEY REGULATION CHANGES	National Intellectual Property Strategy (2008).	Policies targeted at the patent backlog (2004 – 2007).			Backlog Reduction Program, 2010 – 2017.

		Growth	Attributable to regulation	Growth	Attributable to regulation	Growth	Attributable to regulation	Growth	Attributable to regulation	Growth	Attributable to regulation
Innovative Activity	BERD	26%		4%		70%		11%		14%	
	Early research (publications)	12%		-1%	N/A	4%		4%		4%	
	Clinical trials (All)	16%		-3%	N/A	7%		7%		17%	
	Patents (local residents)	35%		0.6%		4%		25%		23%	
	Patents (local non-residents)							16%		11%	
	Patents (USPTO)	-2%	N/A	-31%	N/A	22%		29%		20%	
Economic Activity	Employment in biopharma-ceuticals	17%		-1%	N/A	6%		7%		8%	

Impact of the regulation



RDP – Regulatory Data Protection.

Seoul City Skyline, South Korea, shutterstock.com/CJ Nattanai.

4.

Innovation policy implications for Colombia

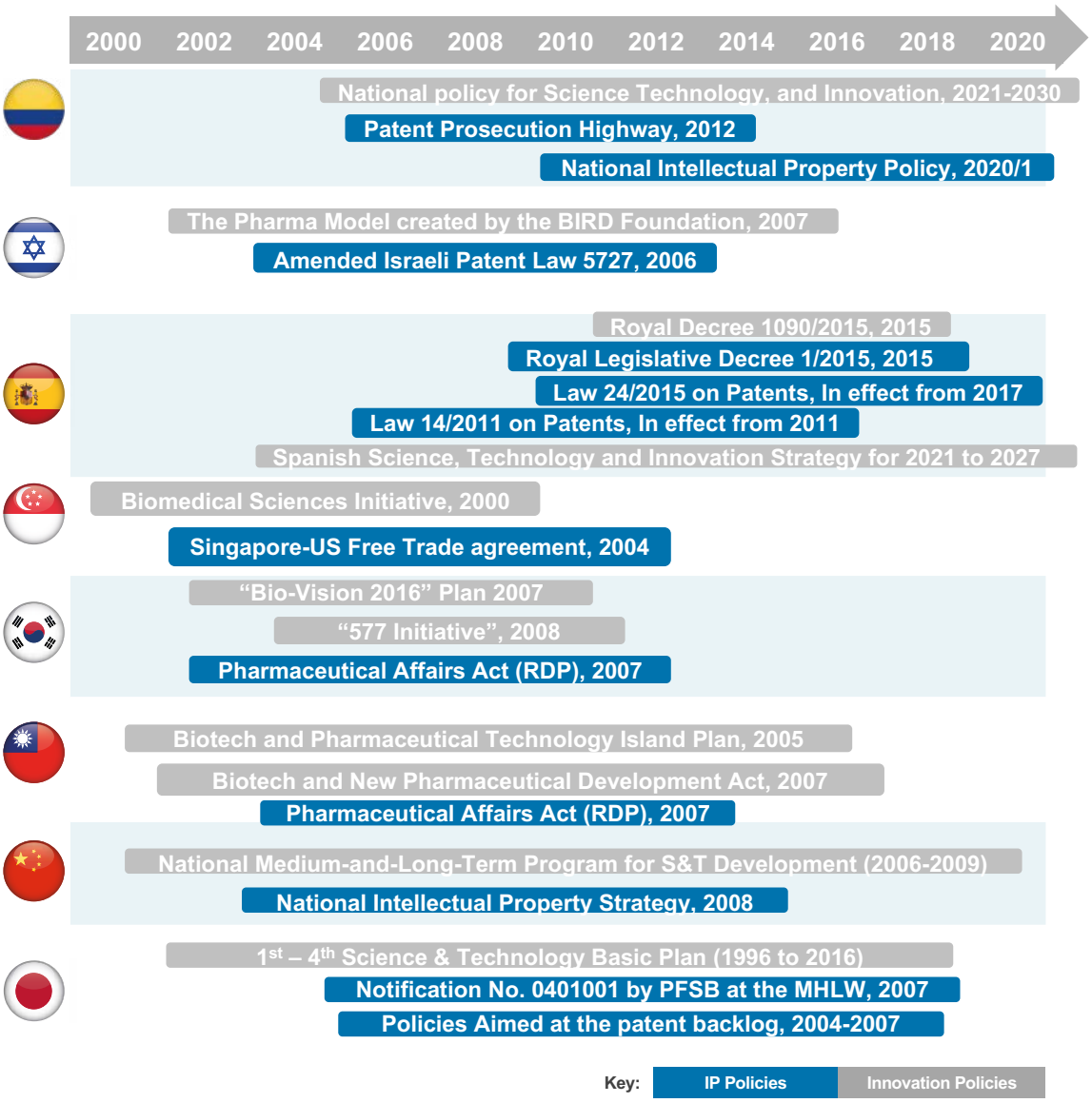
WHAT IF COLOMBIA CONTINUES ON A POSITIVE TRAJECTORY OF INNOVATION FRIENDLY ENVIRONMENT?

1. Support for IP and innovation in biopharma:

- Colombia has recently instituted policies that are more favourable to the growth of the local biopharmaceutical industry, particularly the development of the new National Intellectual Property Policy, 2020/2021, it aims to:
  - Generate enabling conditions for the creation and management of economically valuable intangible assets;
  - Strengthen and expand the instruments for the protection of intellectual property;
  - Promote the effective defense of intellectual property rights;
  - Establish dissemination, awareness and training mechanisms on intellectual property rights;
  - Strengthen the institutional architecture of intellectual property and coordinate government interventions on the matter.

Additional support for IP:

- However, compared to other case study markets, Colombia lags behind on granting regulatory data protection consistently and in fostering private-public partnerships.



APPROACH TO DEVELOPING GAINS IN FOUR INDICATORS

- In order to assess potential gains from an improvement in the enablers of innovation we apply the following approach:
  - ***Step 1,*** we take as baseline the level of innovative activity per indicator Colombia for the latest available year, assuming Colombia remained on the positive path and improved IP and innovation policy changes.
  - ***Step 2,*** we apply the average growth rates for the 5 year period prior to the baseline year assuming constant growth.
  - ***Step 3,*** finally, we apply growth scenarios from case study countries, where positive changes in the IP and innovation regime were introduced.
- We apply the methodology to four indicators of innovative and economic activity including: publications, clinical trials, patents, employment in the biopharmaceutical sector.

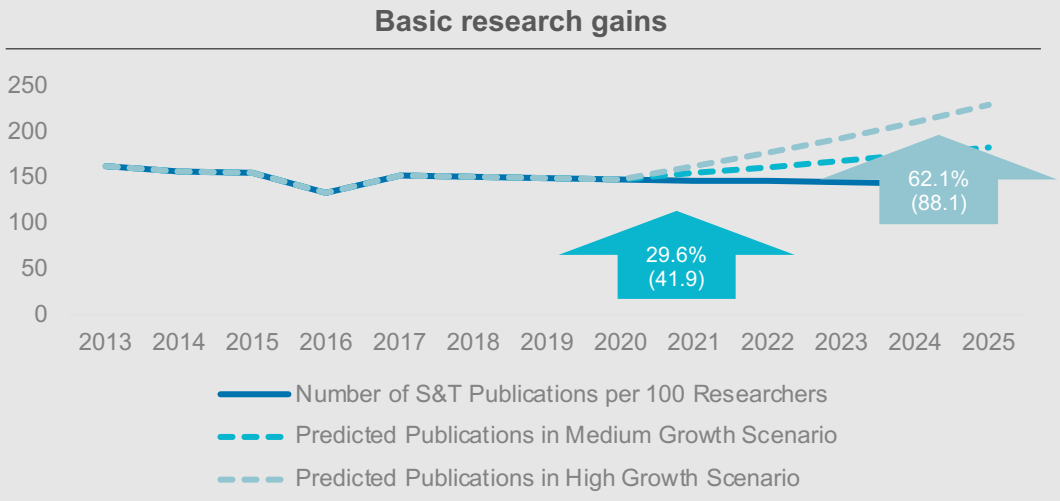
SCENARIOS: DEVELOPING SCENARIOS ON IMPACT ON STRENGTHENING IP REGIME AND INNOVATION POLICY

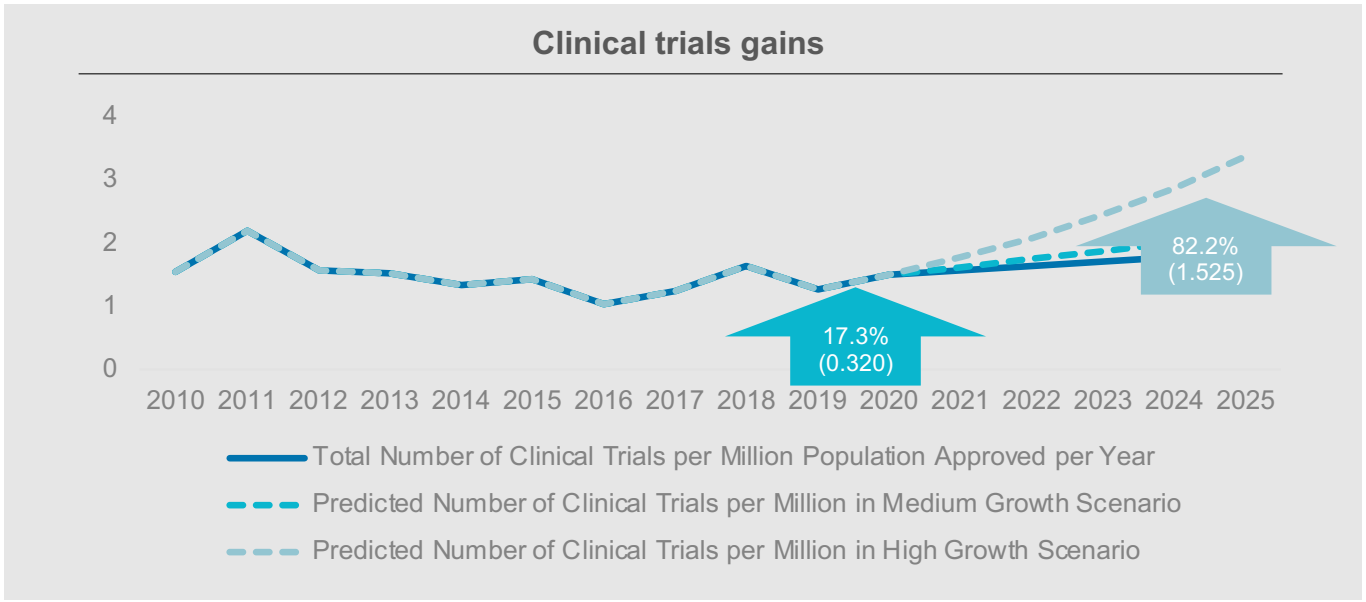
Drawing from the case study analysis and the statistical analysis, we establish two scenarios:

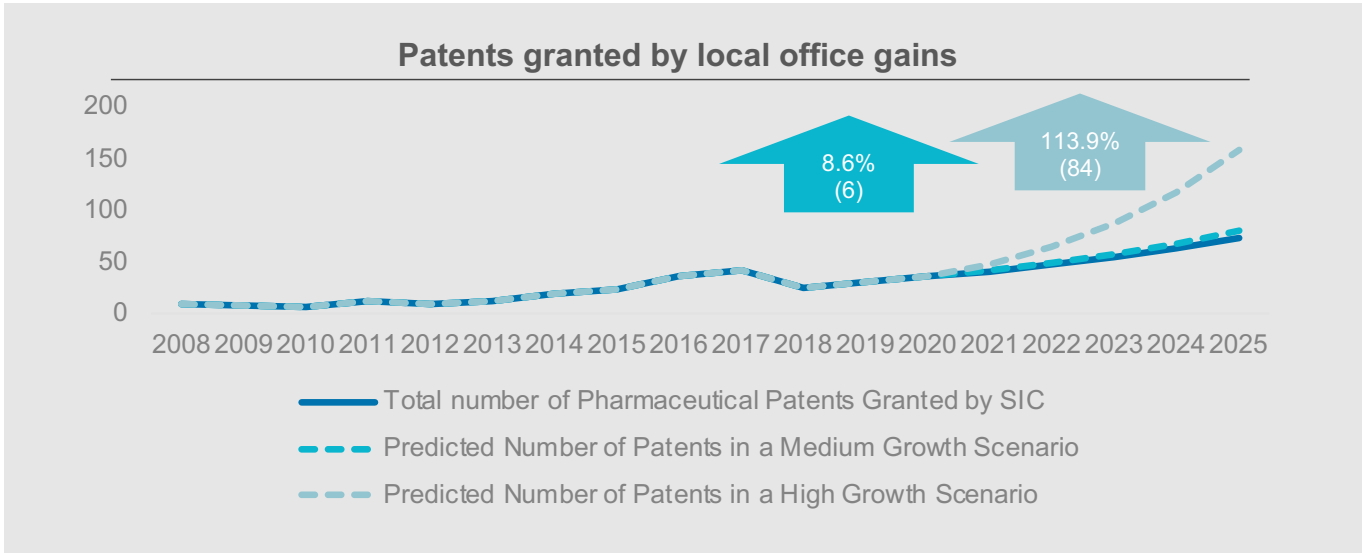
- A scenario assuming an IP regime change in conjunction with other innovation policies (medium growth due to limited implementation).
- A scenario assuming an IP regime change in conjunction with other innovation policies (high growth with good policy implementation).

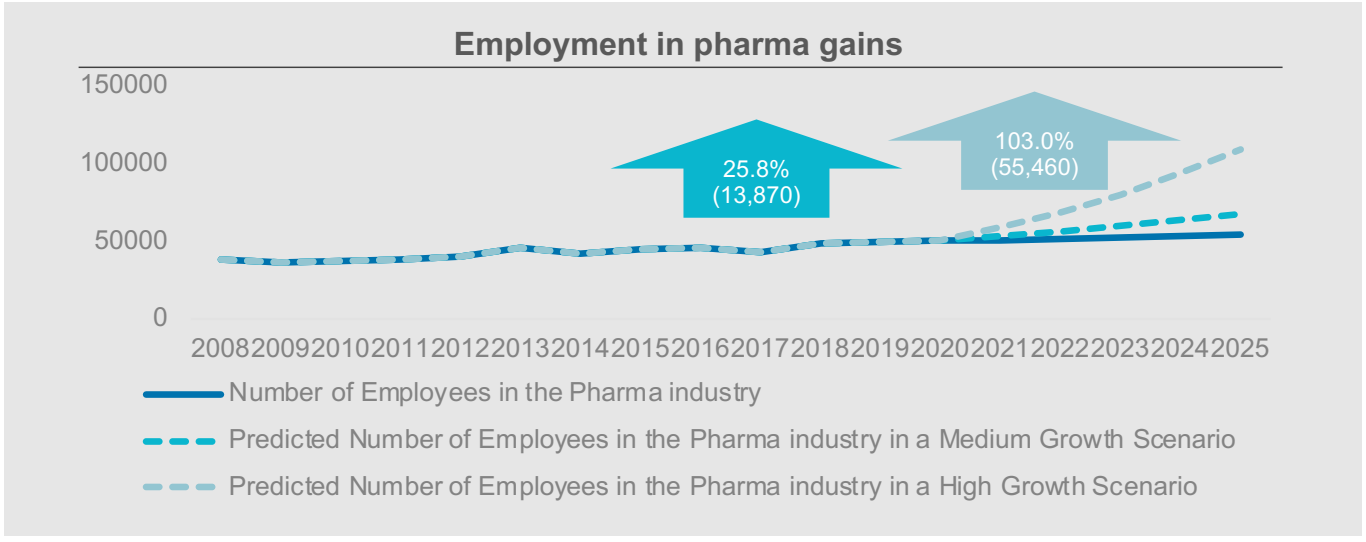
	SCENARIO DETAILS	BASIC RESEARCH	CLINICAL TRIALS	PATENTS	EMPLOYMENT
IP REGIME AND INNOVATION POLICY – MID GROWTH	Paced growth scenario based on an improvement of the IP regime (for example, by improving RDP and patent linkage) and other innovation incentives but with limitations in implementation (based on case study markets analysis).	Average annual year on year growth of S&E publications in the top 1% most-cited in the Scopus database of 4%.	Average annual number of clinical trials of 8%.	Average annual year on year growth in pharmaceutical patents of 17%.	Average annual year on year growth in employment in the biopharmaceutical industry 6%.
IP REGIME AND INNOVATION POLICY – HIGH GROWTH	Escalated growth scenario based on an improvement of the IP regime (for example, by improving RDP and patent linkage) and other innovation incentives with good implementation (based on case study markets analysis).	Average annual year on year growth of S&E publications in the top 1% most-cited in the Scopus database of 9%.	Average annual number of clinical trials of 17%.	Average annual year on year growth in pharmaceutical patents of 35%.	Average annual year on year growth in employment in the biopharmaceutical industry 17%.

SCENARIO ANALYSIS ACROSS INNOVATIVE AND ECONOMIC ACTIVITY IN COLOMBIA: ABSOLUTE GAINS AND GROWTH POTENTIAL (ON AVERAGE)




Clinical trials gains
4
3
2
1
0
2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
17.3%
(0.320)
82.2%
(1.525)
Total Number of Clinical Trials per Million Population Approved per Year
Predicted Number of Clinical Trials per Million in Medium Growth Scenario
Predicted Number of Clinical Trials per Million in High Growth Scenario

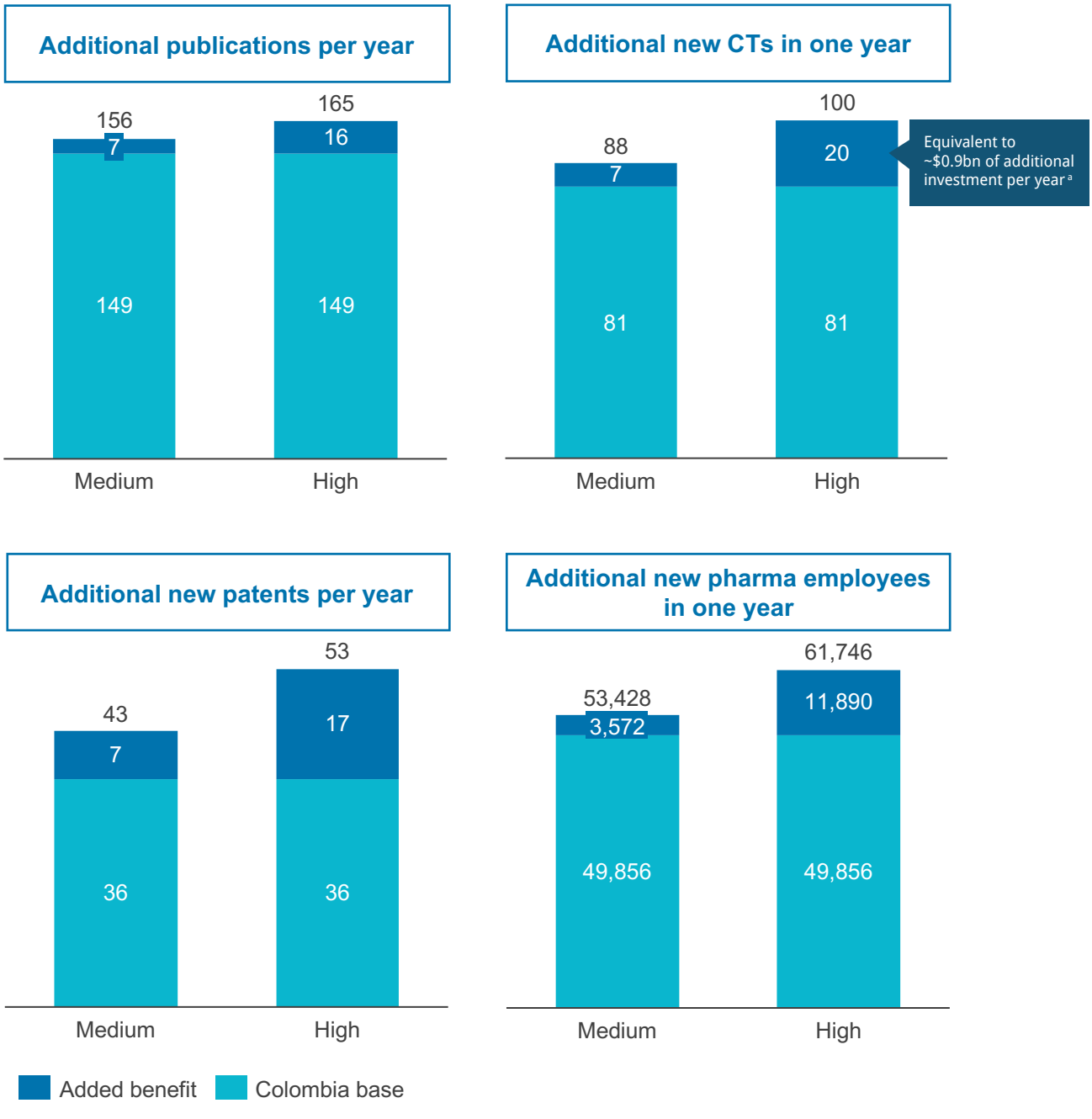

Patents granted by local office gains
200
150
100
50
0
2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
8.6%
(6)
113.9%
(84)
Total number of Pharmaceutical Patents Granted by SIC
Predicted Number of Patents in a Medium Growth Scenario
Predicted Number of Patents in a High Growth Scenario


Employment in pharma gains
150000
100000
50000
0
2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
25.8%
(13,870)
103.0%
(55,460)
Number of Employees in the Pharma industry
Predicted Number of Employees in the Pharma industry in a Medium Growth Scenario
Predicted Number of Employees in the Pharma industry in a High Growth Scenario

QUANTIFYING THE POTENTIAL BENEFIT – DELIVERING REAL GAINS

Drawing from the findings in the analysis, strengthening the IP environment in Colombia would lead to:

- **Significant gains** in areas such as patents granted (with the most direct impact from IP rules) and employment (with most direct impact from improvement in innovation policies).
- **Moderate gains** in areas such as biological publications (are expected to be indirectly impacted by IP and Innovation regime changes) and in clinical trials (that are strongly impacted by the level of protection of data generated).



[a] Note: The cost of CT development in Colombia is estimated to be 10-35% lower than the costs in the US.

FINDINGS

1. Colombia's current innovation capacity and potential

Colombia has many of the factors required for innovation.

- Colombia has many of the factors required to develop a strong innovation environment. Colombia benefits from several unique advantages: a strong university and education system, with strong human resources, and several policies were implemented or are currently being developed, to ensure a strong innovative eco-system.
- The market has also developed a relatively comprehensive IPR framework, a strong healthcare system foundation and several regional innovation clusters.

Indicators show there is room for improvement when compared to OECD and Asia markets in many innovation activities.

- Several weaknesses in Colombia's innovation framework remain a barrier to effective innovation.
- Despite the number of innovative policies in place, there is limited private and public R&D investment, limited innovative activities by private companies, and limited opportunities for private-public partnerships resulting in poor commercialisation potential of granted patents.
- Lack of long-term commitments on improving the IP environment, including ambiguous implementation of Regulatory Data Protectioncreate uncertainties for the innovative industry.
- Shortcomings in education about Intellectual Property rights amongst graduates and other actors such as the members of the Congress.
- Furthermore, Colombia has wide regional and socioeconomic disparities in healthcare access and does not properly leverage its treatment naïve population for clinical trials.
- Gaps in Colombia's innovation framework have constrained innovative activity in Colombia, especially in terms of lower basic research, clinical trial activity, patent filings and employment.

2. On-going debate on how to improve innovation policy

Colombia has recently published a draft version of the National Intellectual Property Policy and various key innovation policies, such as the Business Plan for the Pharmaceutical Sector. However, these fail to address certain gaps in the innovation environment.

- The Draft National Intellectual Property Policy published in 2021 focuses on supporting the effective use and protection of IP rights to encourage innovation and balance the interests of IP owners and users.[1]
- The Business Plan for the Pharmaceutical Sector for 2019-2032 includes objectives to position Colombia to specialize in the production and commercialization of high-quality chemical synthesis supplies and drugs and to enter the biotechnology market, to be competitive within the American continent.[2-4]
- *Our analysis suggests the potential for further mechanisms to unlock the potential value of strong resources in Colombia and incentivise increased economic activity (summarized on next two pages).*

3. Implications for Colombia's innovation and economic policy

Developing a long-term plan to strengthen the country's innovation ecosystem.

- The Colombian government has implemented various policies to encourage growth in the innovation ecosystem – including the **Business Plan for the Pharmaceutical Sector** (2019 – 2032) and the **National Policy for Science, Technology and Innovation**, which is under development. However, the Colombian government lacks a long-term vision which prioritises innovation. Another weakness reflecting shorter-term planning is that institutions such as INVIMA rely on a contract labor force with high turnover.
- The Israeli, Spanish, Singapore and Chinese governments have been prioritising innovation as a way to achieve long-term growth and productivity; for example, the Israeli Innovation Authority has a long-term plan in establishing Israel as a world leader in innovation and entrepreneurship whereas the Spanish government, since 1988, has launched consecutive National Plans to improve the R&D and Innovation activities in the country.
- In Singapore, an IP steering committee has been set up. Key roles include development of long-term action plans, such as Singapore's IP Hub Master Plan to advise the government and maintain continuity in IP innovation policies and activities across governments.

Developing a culture which fosters collaboration.

- Through the **2020 Entrepreneurship Act**, the CEmprende National Network has been established. This is the largest entrepreneurship and innovation network in Colombia. It aims to facilitate the collaboration between academia, private companies and the State to stimulate entrepreneurship and innovation.
- The development and financial support for initiatives to enhance collaboration between academia with the business sector in innovative projects over the short and long term is important for stimulating and sustaining an innovative environment. Short term initiatives such as Colombia Cientifica and Pact for Innovation and Pact for growth and job creation in the pharmaceutical sector have begun to address this, however further medium and long term initiatives are needed. There could be opportunities for the National Department for Planning to develop and engage in initiatives supporting greater academic and industry collaboration.
- Singapore opened Biopolis, a cluster for biomedical sciences researchers in academia and private industry in 2003 to foster innovation and collaboration across sectors and it has consistently grown in terms of size and number of affiliated organizations.
- In China, an increased focus on national technological capabilities has resulted in increased public and private sector collaboration to develop innovative products, which has in turn increased the level of private investment in China.

A universal healthcare system that is efficient and can serve as the backbone of clinical trials.

- Colombia aims to improve the national healthcare standards by reducing healthcare inequalities across regions and patient sub-populations. Despite significant improvements in Colombia's healthcare system infrastructure over the past two decades, it is estimated that 15% of the population remains uninsured; benefit plans under the contributory regime and the subsidized regime still differ and there are deficiencies in the quality of care as not all public hospitals are modernized.[5]
- Ensuring consistent access to healthcare and clinical trials may result in Colombia being a more attractive place to conduct clinical trials. In addition, reducing existing regulatory barriers to conducting clinical trials will be important in attracting investment and research to Colombia.
- Both Israel and Spain provide a universal healthcare system and achieve high health standards outcomes when compared to other OECD countries. Additionally, Spain has enacted a new Regulation on Clinical Trials (Royal Decree 1090/2015) to simplify procedures for companies to conduct clinical trials.

Long term commitment to strengthening the IP regime.

- Overall, implementing medium and long term plans to ensure consistency in IP procedures, processes and interpretations of the legislation will strengthen and improve Colombia's IP regime.
- Development of educational programs to strengthen understanding of the benefits of and consistent interpretation of IP legislation across public institutes, regulatory and governmental bodies is likely to lead to long term benefits for the IP and innovation environment in Colombia, such as improving the rate of filing of domestic patent applications by local innovators and researchers, in turn further strengthening Colombia's innovation environment and local economy.
- At the moment, the communication between INVIMA, the Patent Office and industry is not encouraged, and past efforts to increase communication between INVIMA and the Patent Office were unsuccessful as the agencies asserted independence. If such communication is encouraged, the IP regime would be strengthened, and Colombia would benefit from greater innovation activity.
- Colombia's IP regime can be strengthened further by improving the communication between the regulatory authority (INVIMA) and the Patent Office to develop and implement strong patent linkage mechanisms, whilst ensuring that the timelines for litigation are kept to a minimum through an efficient patent enforcement process.
- In addition, providing RDP consistently is also likely to strengthen the IP system and attract further innovation and investment.
- Successful IP educational programs have been implemented by Singapore and Israel, e.g. the extremely comprehensive IP academy run by the Intellectual Property Office of Singapore (IPOS). In Israel, the Israel Patent Office collaborates with WIPO to host a two week practical training course as a follow up to the WIPO training course on IP.
- An example of enhanced RDP is in the case of Japan, which provides de facto RDP through Post-Marketing Surveillance (PMS). Originally introduced in 1979 with only 2 years, data exclusivity was most recently extended to 8 years for new medicines in 2007 by the Pharmaceutical and Food Safety Bureau at the Ministry of Health, Labour and Welfare. This policy results in an increase in clinical trials and a 37% increase in new drugs approved in Japan between 2008-2018.
- Additionally, more dialogue regarding RDP can be achieved if Colombia follows Israel; in 2018, Israel has established an inter-governmental committee to consider providing RDP for biologics and the Ministry of Health has invited individuals, organizations and stakeholders to participate in the examination process for the need to amend the Regulation accordingly.
- Regarding patent linkage, there are potential learnings from South Korea: The South Korean Patent-Approval Linkage System was introduced and implemented between 2012 and 2015, in response to Article 18.9 of Korea-US Free Trade Agreement.
- Another learning on transparency of granted patents could be taken from Spain: The Spanish Patent and Trademark Office publishes an Official Intellectual Property Gazette (referred to BOPI) which includes information on the granted patents, patent applications that meet certain requirements and the associated search reports, and which is published on a daily basis.
- Regarding second uses of patents, the issue of patents not currently available for second uses is a legal rather than policy topic that would need to be changed in the Andean Law, and therefore this would require a long term commitment to pursue the process for change.

5.

Appendix: Detailed analysis of case study markets

WE DEVELOPED A LIST OF POTENTIAL CASE STUDY MARKETS BASED ON SECONDARY RESEARCH AND RECOMMENDATIONS FROM INTERVIEWS

Methodology

- Learnings from stakeholder interviews and past INTERPAT projects in LatAm directed our search for comparator countries for Colombia such as Asian markets Singapore, South Korea, Taiwan and Japan
- We conducted a targeted search for countries based on the following areas of comparison:

– OECD membership

Given Colombia's recent accession to the OECD, we looked at other countries that joined since 2010 which may have developed innovation policies related to or after joining

– Trade relationships

Countries with similar trading partners or bilateral trade relationships with Colombia may offer insights into link between strong IP environment/ innovation policies and the economy

– Historical comparisons

We looked into countries which have been compared to Colombia in the past two decades in terms of level of economic development, trends in industry growth, or other areas that may inform on points of divergence.

– GDP similarity

Countries that are close to Colombia in terms of total or per capita GDP that perform better across measures of health system efficacy or efficiency may appeal to policymakers.[a]

Sources: [a] Insights from CRA External interview programme (INNOS).

SPAIN, ISRAEL AND PREVIOUSLY ANALYSED ASIAN MARKETS HAVE BEEN IDENTIFIED AS KEY MARKETS WHICH COLOMBIA CAN DRAW LEARNINGS FROM TO IMPROVE THEIR IP ENVIRONMENT

	Market	Rationale	Improvements to RDP	Efficient IPR enforcement	Improvements to technology/ local capabilities	Sustainable healthcare system	Secondary comparison quality: Regional comparison	Secondary comparison quality: Joined OECD within last 20 years	Recommend as a case study market
Asia	China	Improvements in policies incentivising industry R&D&I and encouraging patent applications.		✓	✓				✓
Asia	South Korea	Significant improvements to IPR since 1990s, now considered one of the strongest IPR in Asia.	✓	✓	✓	✓			✓
Asia	Japan	Extended RDP to 8 years in 2007; has policies incentivising industry R&D&i.	✓	✓	✓	✓			✓
Asia	Indonesia	Uses a sector-based and industry-targeted incentive scheme to support R&D&i.			✓				
Asia	Taiwan	Amended gaps in RDP and created patent linkage framework in the last decade.	✓	✓	✓	✓			✓
Asia	Singapore	FTA with the US strengthened IPR; seen as hub in Asia for pharmaceutical industry.	✓	✓	✓	✓			✓
Europe & Middle East	Spain	One of the leading healthcare systems in the world; strong IP enforcement system consistent with EU; cultural/historical ties.	✓	✓	✓	✓			✓
Europe & Middle East	Israel	Advanced local industry attracts global investment; recently improving RDP to align with new technologies; FTA with Colombia in 2020.	✓	✓	✓	✓		✓	✓
North and South America	Canada	Often regarded as a model country for robust IP systems; long RDP period.	✓	✓	✓				
North and South America	Chile	Former member of Andean Community and has had an incentive program for tech transfers since 2014; recent unfavorable IPR changes.			✓		✓	✓	
North and South America	Peru	Current member of Andean Community, country with strong regional ties to Colombia.					✓		

POTENTIAL COMPARATOR COUNTRIES FOR COLOMBIA

	Country:	Relevant policy topic:	Example healthcare, IP, and/or innovation ecosystem strengths:	Qualities for comparison:
Asia	**South Korea**	1. RDP; 2. Technology and scientific capabilities	• The Pharmaceutical Affairs Act (PAA), initially amended in 2007, includes a provision that new drugs and certain prescription drugs benefit from de facto data protection of 4-6 years.	• Rapid growth linked to government commitment to encouraging and attracting innovation and investment.
	Japan	1. RDP 2. Patent enforcement	• Following the extension of RDP to 8 years in 2007, new drug approvals grew by 37% between 2009-2018, and same with the amount of orphan drug clinical trials.	• Government policies incentivising innovation and industry investment in R&D.
	Indonesia	1. Technology and scientific capabilities	• Uses budgetary allocations to S&T programs, and sector-based and industry-targeted incentive scheme to support R&D&i in industries including health.	• Seeking increased trade connectivity with Colombia (2020), and has common trading partners, e.g. US. • Slightly lower GDP per capita.
	Taiwan	1. RDP 2. Patent enforcement (and linkage)	• Adheres to TRIPS RDP of 5 years, amended gaps in 2017. • Framework for patent linkage was introduced by registering patent owners upon market authorisation.	• Rapid growth linked to government commitment to encouraging and attracting innovation and investment.
	Singapore	1. Patent enforcement; 2. Technology and scientific capabilities; 3. Healthcare system	• Strong IPR attracts global investment and the IP system is highly ranked. • Cluster for biomedical sciences, Biopolis, opened in 2003. • Local environment is technologically advanced and attracts industry investment.	• Trade with the US, a common trade partner, impacted Singapore's IP laws beginning around 2004. • Historic trend of rapid growth and industry development, and innovation clusters can be compared to Colombia.
Europe & Middle East	**Spain**	1. Patent enforcement; 2. Healthcare system	• One of the leading healthcare systems in the world. • Strong IP law enforcement system consistent with EU.	• Relatively close, higher total GDP (higher GDP per capita). • Trades with US and other countries in common with Colombia via US-EU agreement.
	Israel	1. Technology and scientific capabilities 2. Healthcare system	• High GDP growth and high GERD, 4% of GDP spent on R&D. • Local industry and innovation environment is technologically advanced and attracts industry investment. • Universal healthcare system ranked highly for efficiency.	• Joined OECD 2010. • Entered Free Trade Agreement with Colombia Aug. 2020.
North and South America	**Canada**	1. RDP	• Long RDP period of 8 years. • Investment of $4bn into innovation ecosystem in 2018 to improve R&i and healthcare system.	• Historically prioritized commodity sector for economic development, similar to Colombia. • Canada-Colombia Free Trade Agreement. • Relatively close total GDP to Colombia.
	Chile	1. Historical patent enforcement	• Historically viewed favorably among LatAm for IPR, but negative recent trends. • Created voucher system to encourage tech transfers in 2014.	• Regional comparison. • Joined OECD in 2010. • Pacific Alliance trading bloc (Chile, Colombia, Mexico, Peru) est. 2011.
	Peru	n/a	• Similarly working to support and incentivize innovative activities.	• Regional and GDP comparison. • Member of Andean Community.

* Note:
Countries with similar GDP per capita in most recent year are:[1]
– lower: Brazil, China, South Africa, Indonesia
– higher: North Macedonia, Mexico, Costa Rica, Argentina, Bulgaria

Countries with similar total GDP are: [1]
– lower: South Africa, Romania, Switzerland, Belgium
– higher: Netherlands, Argentina, Poland, Australia, Saudi Arabia, Spain, Canada

[1] https://data.oecd.org/gdp/gross-domestic-product-gdp.htm

Sources:

• US – Colombia trade agreement: https://ustr.gov/trade-agreements/free-trade-agreements/colombia-tpa

South Korea:

• From CRA analysis in INTERPAT Brazil case study

Japan:

• From CRA analysis in INTERPAT Brazil case study

Taiwan:

• From CRA analysis in INTERPAT Brazil case study

Canada:

• http://yourcandidatesyourhealth.ca/resources-for-candidates/information-on-health-research-and-innovation-in-canada/
• https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/colombia-colombie/fta-ale/background-contexte.aspx?lang=eng
• https://www.mckinsey.com/featured-insights/americas/colombias-lesson-in-economic-development

Israel:

• FTA feasibility 2011: http://www.tlc.gov.co/getattachment/acuerdos/vigente/israel/contenido/herramientas/analisis-y-estudios/israel-colombia-joint-study-on-the-feasibility-of/israel-colombia-joint-study-on-the-feasibility-of-an-fta.pdf.aspx
• Article about FTA 2020: https://www.lexology.com/library/detail.aspx?g=b197d8a6-4df8-494f-9a37-c0426fd8c9e3
• https://www.innovationpolicyplatform.org/www.innovationpolicyplatform.org/content/israel/index.html
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• https://www.commonwealthfund.org/international-health-policy-center/countries/israel

Singapore:

• https://thelawreviews.co.uk/edition/the-intellectual-property-review-edition-9/1226912/Singapore

Spain:

• Biotech collaboration with Colombia: https://bitfinance.news/en/spain-and-colombia-will-work-on-biotechnology-projects/
• healthcare ranking: https://www.thisistherealspain.com/en/spain-in-the-world/healthcare/spanish-healthcare-once-again-leading-world-rankings
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