CRA Charles River Associates

Value of IP for health and growth

The economic benefits of strengthening the environment for innovation in Argentina

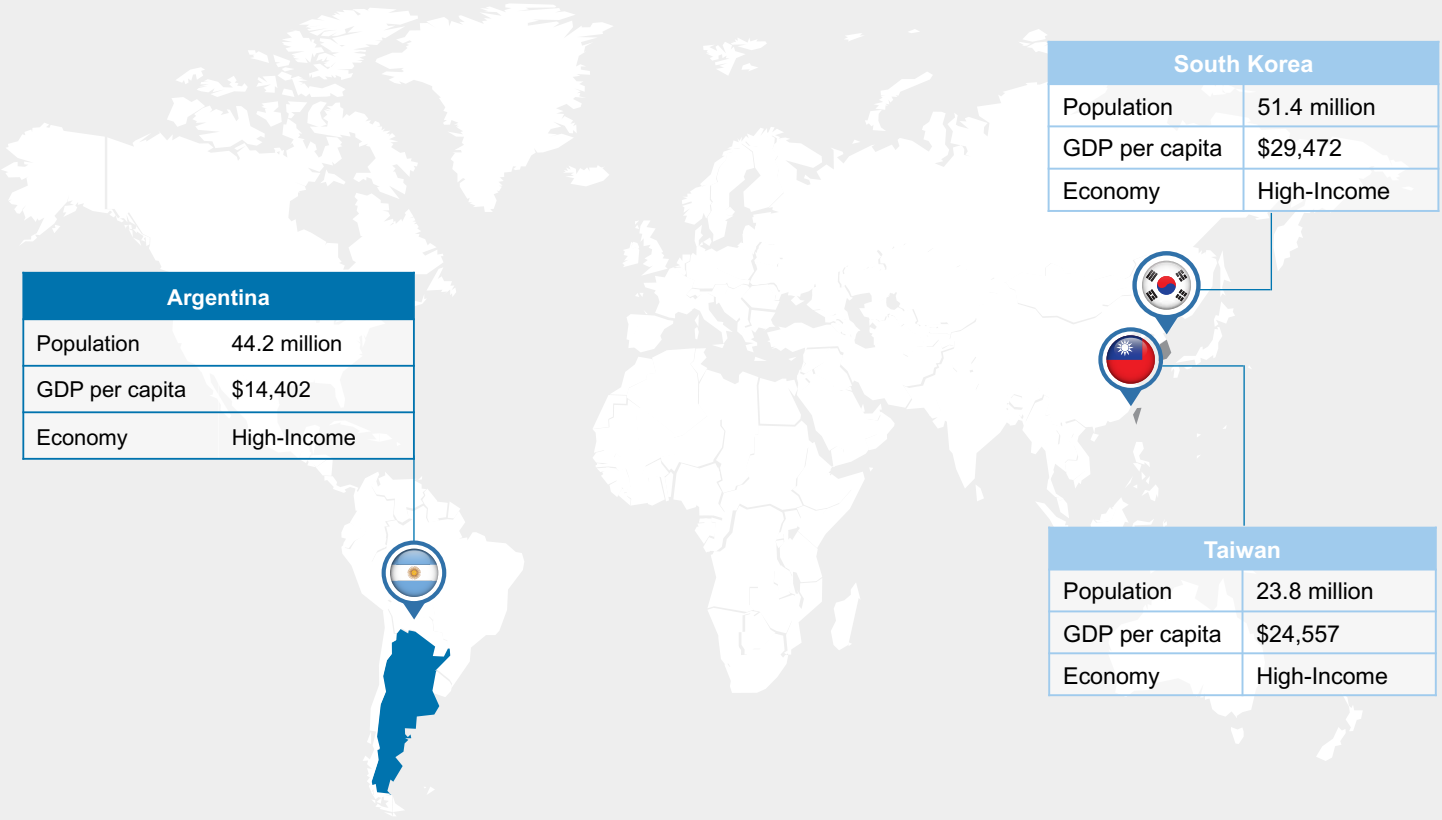
DECEMBER 2020

CONTENTS

1. Project objectives and methodology

PROJECT OBJECTIVES AND SCOPE

- INTERPAT asked Charles River Associates (CRA) to identify and quantify the economic benefits from strengthening the environment for innovation in Argentina.
- The objective of the study is to:
  - Set out the policy framework for supporting innovation in Argentina and the current state of innovative activity.
  - Undertake a case study analysis on countries with potential lessons for Argentina on how policies can improve innovation and related activities in countries.
  - Develop scenarios as to how innovative activity could change in Argentina, if policies adopted in other countries were pursued.



PROJECT STEPS

1

SET OUT INNOVATION IN ARGENTINA AND HOW IT COMPARES TO PEERS

- Review the current policy environment, resources and innovation and economic activity in Argentina and comparable markets.
- Undertake interviews with global and local experts on Argentina.

Stakeholder	Country
Industry Experts	Global
	Local
	SMEs
External (local policymakers/ experts)	IP expert
	Researcher/ Academic
	CRO
Total	17

2

ANALYSE CASE STUDY MARKETS AND SET OUT SCENARIOS

Choose case study markets that:

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

Analyse two case study markets:

- Changes in policies on innovation.
- Innovative environment and related economic activities pre and post policy changes.
- Any relationship between change in policy regime and innovative activity.

3

APPLY SCENARIOS TO ARGENTINA AND SET OUT FINDINGS IN A STUDY

- Statistical and impact analysis: Develop scenarios to assess potential gains in Argentina drawing on case studies and empirical analysis.
  - Innovative activity.
  - Economic activity.
- Reporting: Report out findings and implications for Argentina IP policy.
  - Draft results were presented at the LatAm conference and comments reflected.
  - *INTERPAT white paper for publication being developed.*

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

ASSESSING INDICATORS REFLECTING THE INNOVATIVE ENVIRONMENT

POLICY ENVIRONMENT → RESOURCES FOR INNOVATION

OVERALL INNOVATION SUPPORT

- National innovation plans.

RULES FOR INNOVATION PROTECTION

- IP rules and patentability criteria.
- Patent filing and granting process.
- Regulatory data protection.
- Preliminary injunction process.

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.

TAXES

- Tax revenues from pharma and biotech.

TRADE

- Imports vs exports in pharma and biotech.

INNOVATION POLICIES IN ARGENTINA

SCIENCE AND TECHNOLOGY PLAN 1997[1]

- Key focus: Adoption of a national innovation system, human capabilities development and investment in R&D.

"BICENTENNIAL" PLAN 2006-2010[2]

- Key focus: Improvement in productivity, competitiveness and exports through science and technology whilst promoting collaboration between private and public R&D institutions.
- Reducing national production vulnerabilities by diversifying national production and establishing conditions for sustainable development, particularly through an increase in R&D spending to 1% of GDP by 2015.

"INNOVATE ARGENTINA 2020" 2012-2015[3]

- Build human resource capabilities to meet the future demand for R&D and promote innovation.
- Key milestones include the increase in: 1) R&D investment as a percentage of GDP and 2) the number of researchers per 1,000 people in employment.
- Focus industries: agroindustry, environment and sustainable development, social development, energy, healthcare.
- The focus within human health lies with the development of biosimilars, infectious disease diagnostic kits and vaccines, development of treatments and diagnostic methods for chronic diseases, tissue repair, phytomedicines and drug deliver enabled by nanotechnology.

PLAN "INNOVATE ARGENTINA 2030", CURRENT AGENDA 2016-2020[4]

- Promote productive, inclusive and sustainable innovation, and expand and consolidate the scientific-technological capabilities for the achievement of a more complex and knowledge-intensive economy.
- Key milestones include developing an innovative culture, growth in the technology sector, financing of science and technology research, improvement in the tech-transfer ability from research to academia.
- Amongst the three prioritized sectors to develop further are the Industry and Health sectors.

THE NEW GOVERNMENT HIGHLIGHTED INNOVATION POLICY IN THE RECENT ELECTION CAMPAIGN, HOWEVER, RELATIVELY LITTLE POLICY CHANGE HAS OCCURRED TO DATE (WITH A PERCEIVED REDUCTION IN THE PROMINENCE OF SCIENCE MINISTRY)[5,6]

RULES FOR PROTECTION OF INNOVATION AND OTHER INCENTIVES

NO REGULATORY DATA PROTECTION[5,7]

- The lack of regulatory data protection (RDP) leads concerns about use of confidential clinical data.

WEAK IP ENFORCEMENT[5]

- The weak enforcement of the IP rules by the national agency has led to a burdensome and lengthy process of seeking preliminary injunction to prevent the sale of an infringing product during a litigation.

DELAYS IN PATENT PROTECTION[5]

- The substantial backlog of patent applications results in long delays to obtain protection and register rights, in the absence of provisional protection for pending patents.

R&D TAX INCENTIVES (LAW 26.270), 2007[8]

- As of 2007, specific to biotechnology companies, the law stipulates that a company may claim tax relief for multiple research projects as long as the sum of the costs of these projects does not exceed ARS 7 million.
- The Law also states the provision of seed capital and early-stage funding for young biotech companies through the Fund of Economic Stimulus for New Business Enterprises.

JOINT RESOLUTION 118/2012, 546/2012 AND 107/2012 (THE GUIDELINE ON PATENTABILITY), 2012[9]

- Introduced in May 2012 by the Argentinian government and followed by the Argentinian Patent Office the guideline restricts the patentability rules and methodology affecting innovation on existing molecules (e.g. new formulations, combinations, dosage) and the use of existing molecules such as in new indications.

RESOLUTION 283/2015, 2015[10]

- The resolution passed in 2015, leads to a more restrictive interpretation and application regarding the prohibition of patentability of every living matter pre-existing in nature (biologics) set forth in section 6 of the Argentine Patents Law.

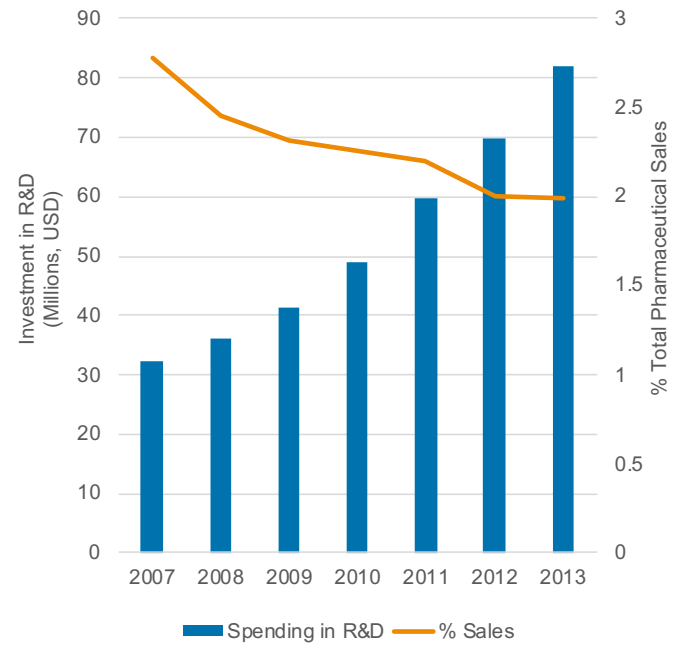
RESOLUTION P-56/2016 (2016)[11]

- Fast-track examination of patent applications with claims the same as for patents granted abroad, not applied in cases where granting of patent falls outside INPI's patentability criteria.

INVESTMENT IN INNOVATION AND R&D

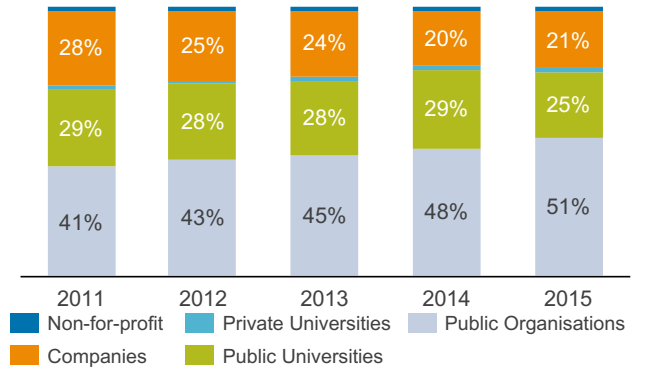
- Investment in R&D in Argentina is primarily driven by national public expenditure, whilst business enterprise investment in R&D remains low.
- Furthermore, the pharmaceutical industry invests only a small percentage of its overall sales in drug development.

Local Pharmaceutical Industry Investment in R&D[12]



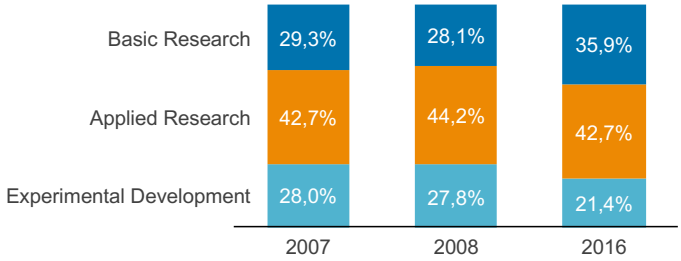
Sources: KPMG Report 2017

Distribution of R&D investment across time[13]



Source: Ministry of Science, Technology and Innovation Report 2017

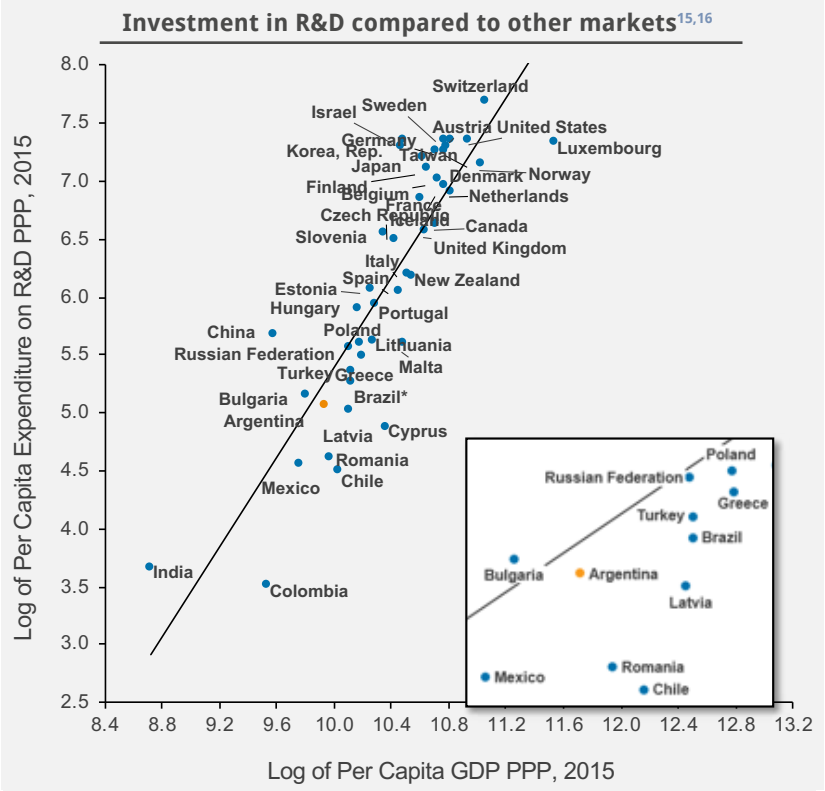
Spending by type of R&D activity[14]

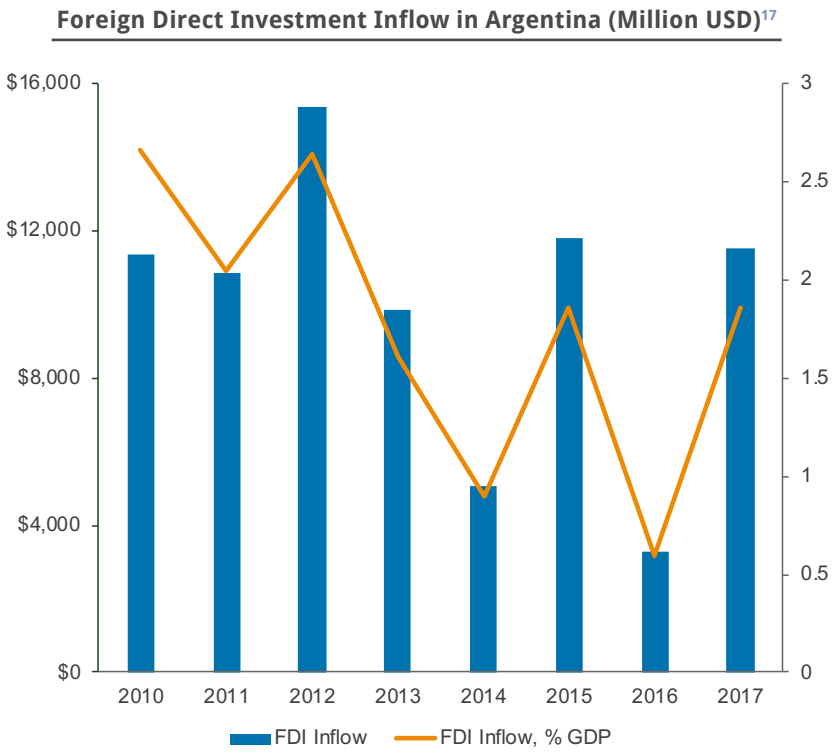


Source: Ibero-American Network, Science and Technology Indicators 2018

DOMESTIC R&D INVESTMENT AND FDI

- Despite the number of government plans and initiatives targeted at innovation, Argentina is falling behind on its investment into R&D relative to the GDP levels.
- Historically the most FDI has been invested in the manufacturing sector (42% of the total FDI in 2015).



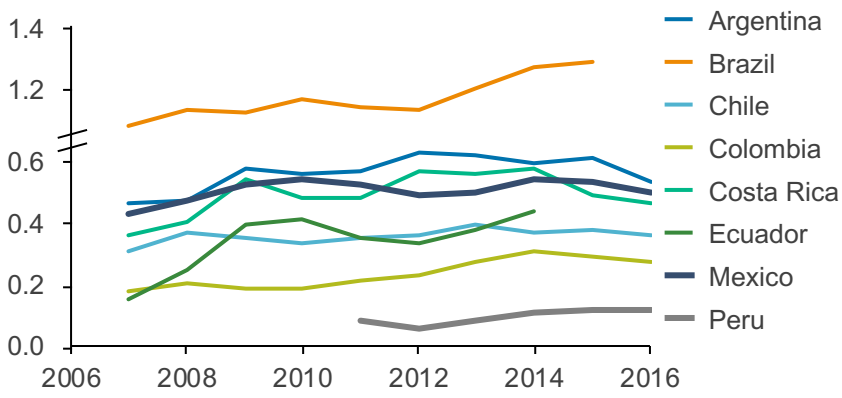


Note: *Brazil data on R&D investment is from 2014; Sources: World Bank Innovation Policy Platform; OECD Data for GDP per capita, PPP; OECD Data 2018; Argentina Central Bank 2016.

INVESTMENT IN R&D COMPARED TO LatAm PEERS

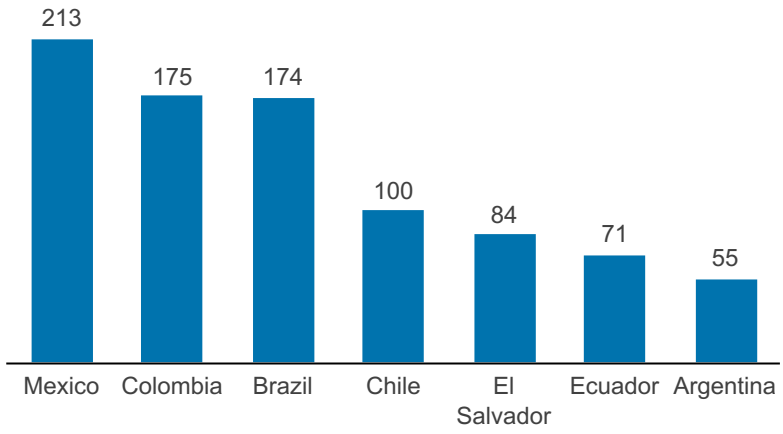
- Compared to other LatAm countries, investments in R&D, stands at good levels in the region.
- However, when investigating private investment as % of GDP and the level of spend and per researcher, Argentina falls behind other countries in the region.

GERD as a percentage of GDP (2007 – 2016)[18]



Source: Ibero-American Network, Science and Technology Indicators 2018

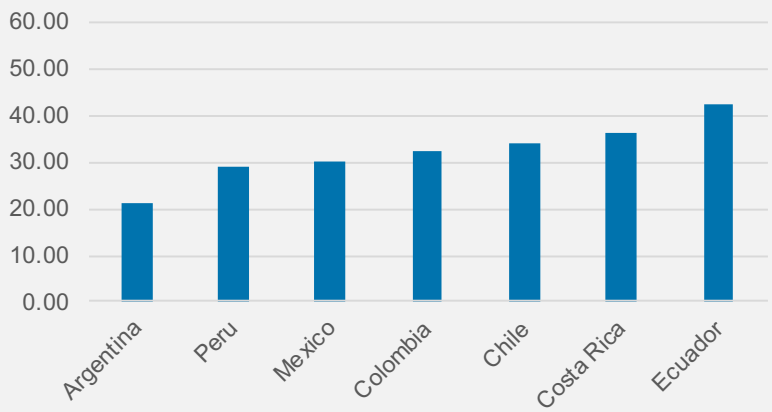
GERD per researcher in 2016* (US$000s)[18]



Sources: Ibero-American Network, Science and Technology Indicators 2018

Note: BR – 2014, EC – 2014; MX – 2014 Data

Private investment in R&D as % of total investment in R&D (Latest available year)[19]



- As we noted, private spend in Argentina is low and has decreased as a % of total R&D expenditure over the past 5 years
- In addition, this proportions are lower than other LatAm markets, reinforcing the observation that limited private investment is an issue for R&D in Argentina

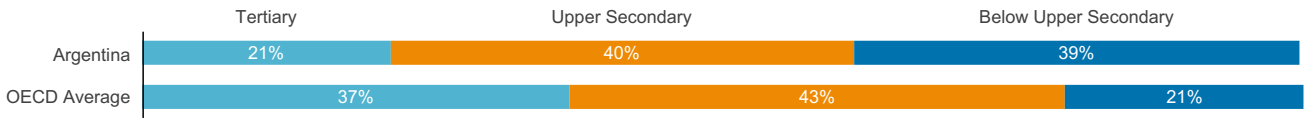
Source: World Bank Innovation Policy Platform 2018

Note: AR, MX, CO, CL – 2015; CR, EC - 2014

AVAILABILITY AND STRENGTH OF RESOURCES AND EDUCATION

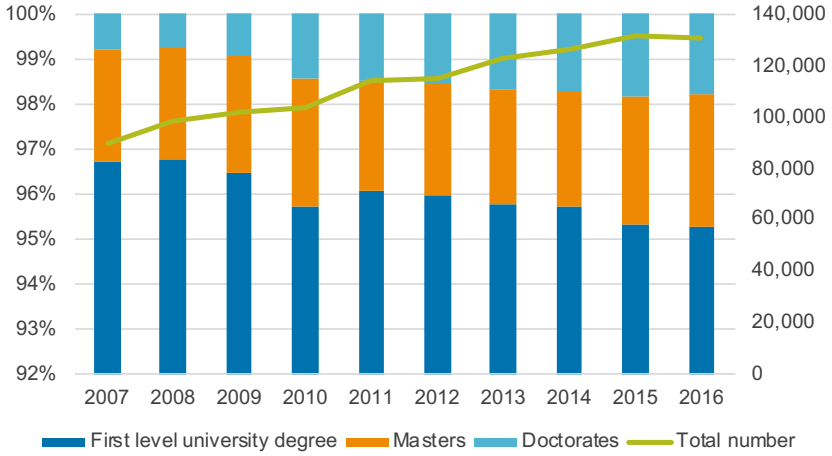
- Educational attainment in Argentina is high by regional standards. A relatively high percentage of the Argentine population has engaged in some secondary or tertiary education. Together with the strong base of graduates, these strengths place Argentina in a comparatively favourable position to embrace the knowledge economy.
- In terms of universities, despite LatAm not performing very strongly in top 500 universities with most cited Life Sciences research, out of the four universities that fit the criteria, one is located in Argentina.

Percentage of 25-64 year-olds (2017)[20]



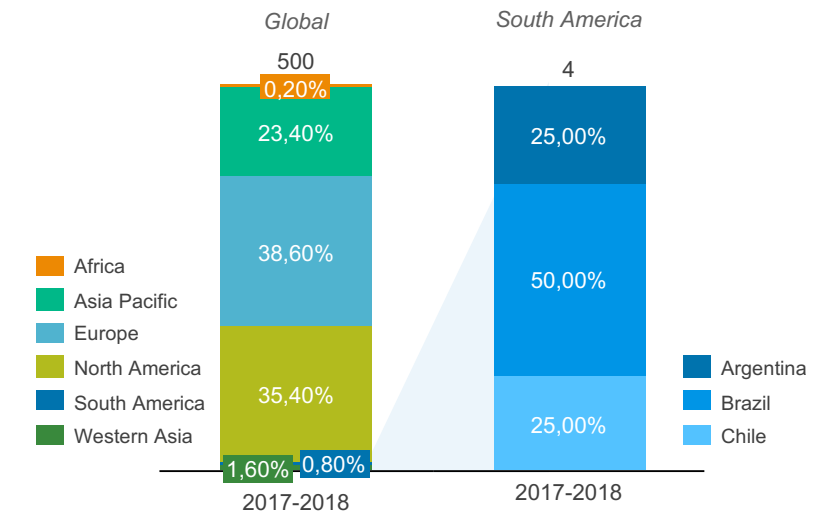
Source: OECD (2018)

Higher Education Graduates in Argentina[21]



Sources: Ministry of Science, Technology and Innovation and Ibero-American Network for Science and Technology

Proportion of top 500 Nature-ranked Universities in Life Sciences, 2017-2018[22]

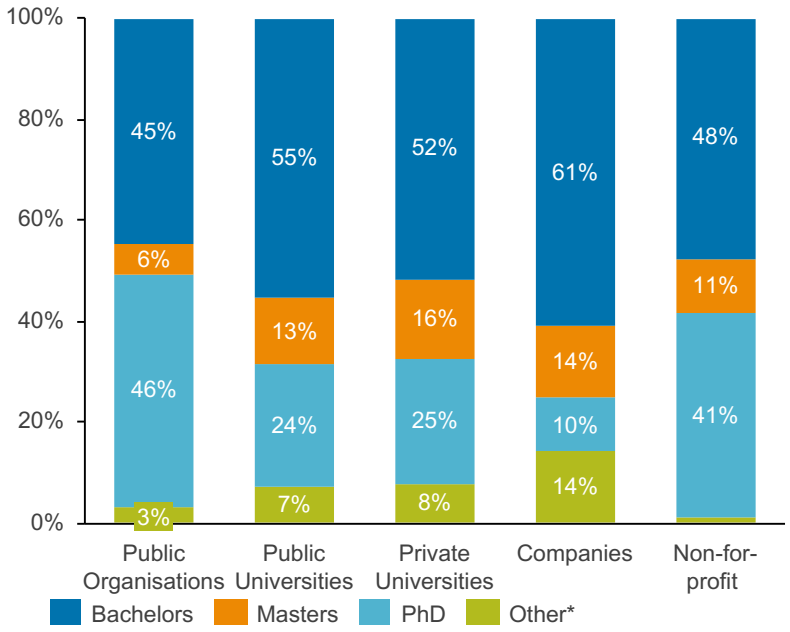


Source: Nature Publishing (2018)

AVAILABILITY AND STRENGTH OF RESEARCHERS

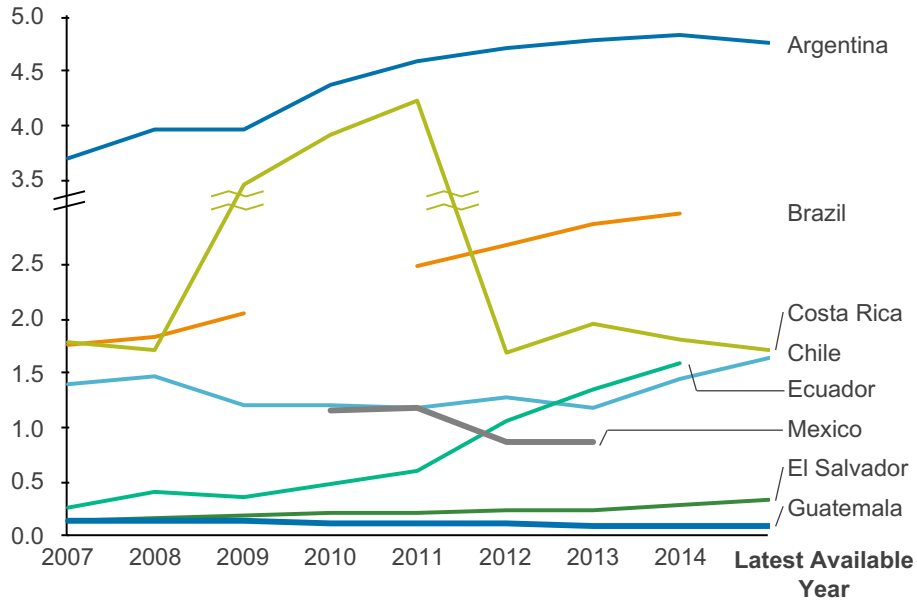
- Argentina has one of the highest number of researcher per thousand economically active in the region, although these are across all sectors.
- Prior research has indicated an increasing trend as the number of researchers doubled between 2003 and 2015 from 3,500 to 9,000.
- Interviews with experts from academia, clinical research and local and international pharma companies, agree that the level of education and expertise of researchers in Argentina is high and one of the most mature in the region.

Researchers by Academic Grade and Organization (2015)[21]



Sources: Ministry of Science, Technology and Innovation; Ibero-American Network for Science and Technology

Number of Researchers per 1,000 in Employment (2007 – Latest Available)[23]

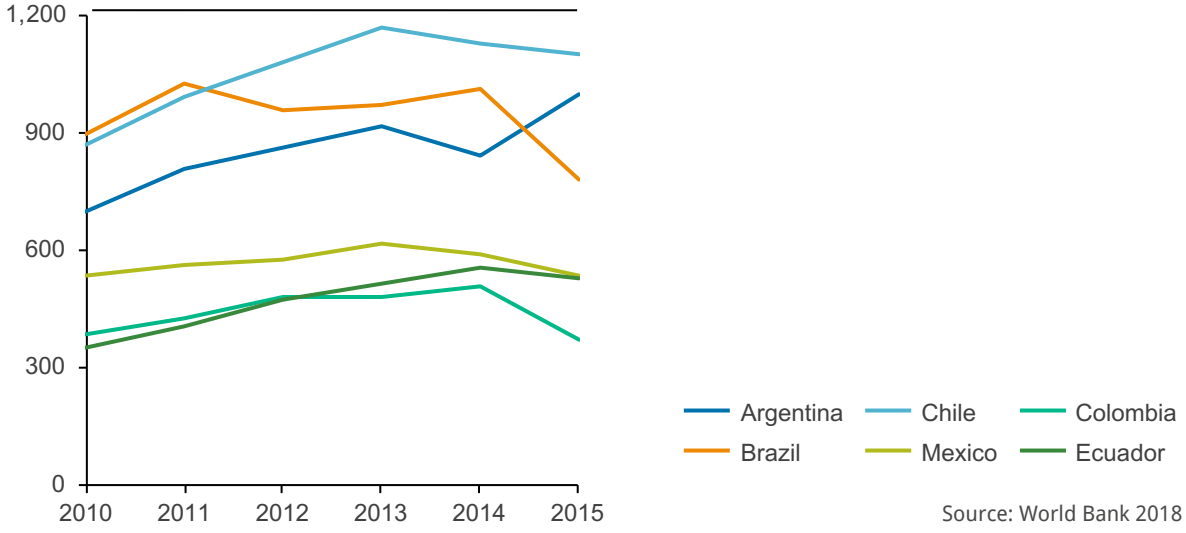


Sources: Ministry of Science, Technology and Innovation; Ibero-American Network for Science and Technology

HEALTH BUDGET AND INFRASTRUCTURE

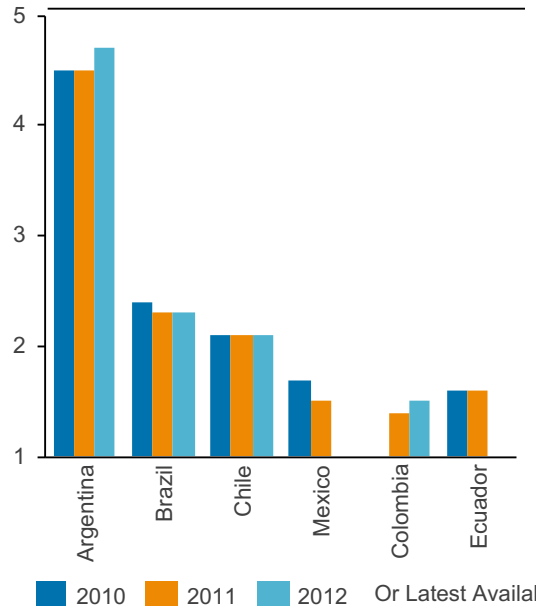
- Compared to other countries in the region, Argentina has high levels of healthcare spending per capita and has available infrastructure and sufficient medical personnel that has enabled the provision of high quality healthcare.
- Furthermore, as indicated in interviews with global companies, a key reason for Argentina being the preferred location for clinical trials is quality of hospitals and physicians. Another reason that was cited was the population being genetically similar to European populations.
- In terms of financing, the health system of Argentina is made up of three sectors that are not very integrated and fragmented within it: the public sector, the compulsory social insurance sector (Obras Sociales), 300 funds covering salaried workers and their families, and the private sector.[1] Private healthcare expenditure represent 30%.[82] Social security provides healthcare coverage to 60% of the population. This leaves another third (an estimated 16.5 million people) with no explicit coverage.[81,83]

Health expenditure per capita (current US$)[24]

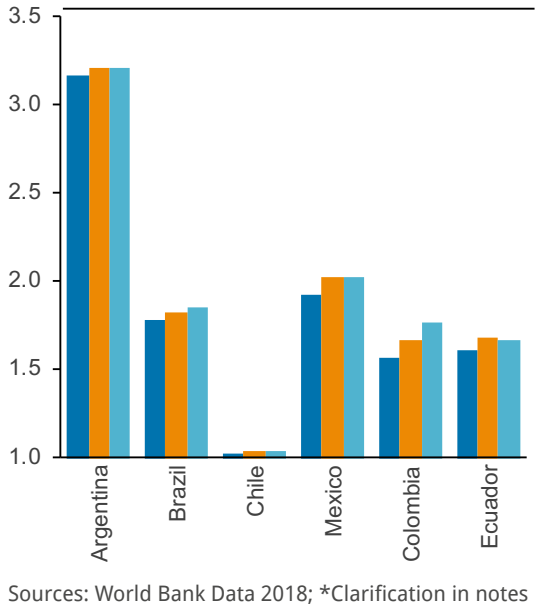


Source: World Bank 2018

Hospital beds (per 1,000 people)[25]



Physicians (per 1,000 people)[26]



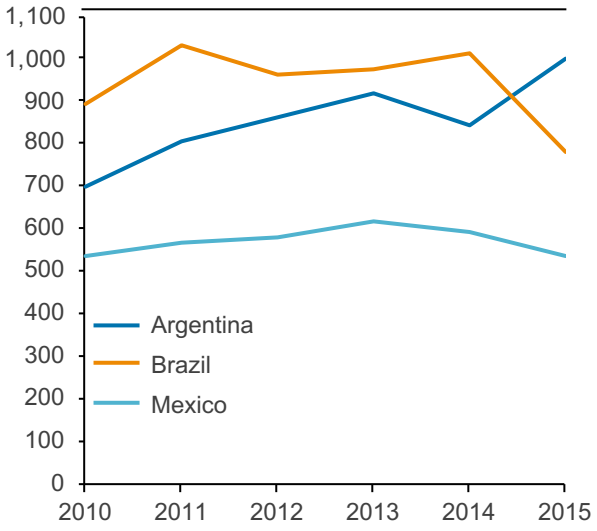
2010 2011 2012 Or Latest Available Data*

Sources: World Bank Data 2018; *Clarification in notes

HEALTHCARE SYSTEM AND CARE

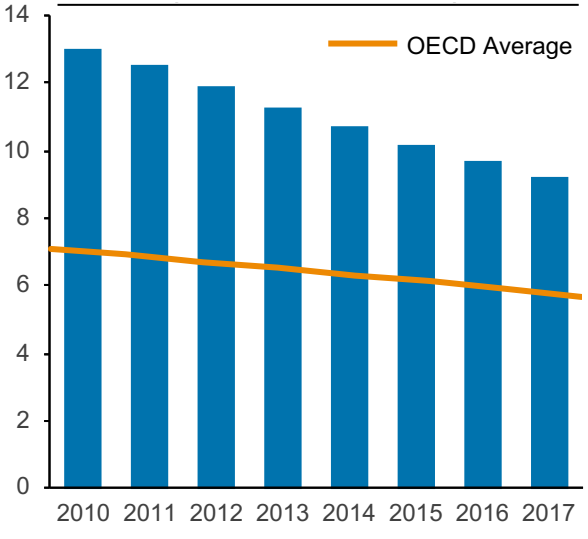
- Population health has improved markedly in the last 20 years. The epidemiological profile is characterized by a growing predominance of noncommunicable diseases – heart failure, cerebrovascular diseases, acute respiratory infections and ischemic heart diseases account for a third of total deaths.[81]
- The health system of Argentina is made up of three sectors that are not very integrated and fragmented within it: the public sector, the compulsory social insurance sector (Obras Sociales), 300 funds covering salaried workers and their families, and the private sector. [81] Private healthcare expenditure represent 30%.[82]
- Social security provides healthcare coverage to 60% of the population. The private sector covers approximately 6 million people, of which 4 million come from Obras Sociales. This leaves another third (an estimated 16.5 million people) with no explicit coverage. [81,83]

Health expenditure per capita (current US$)[24]



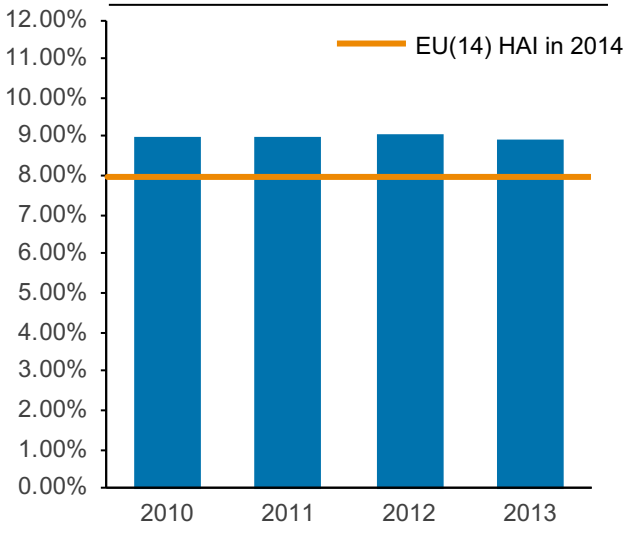
Source: World Bank 2018

Infant Mortality Rate (per 1,000 live births)[27]



Source: World Bank 2018

Prevalence of Healthcare Associated Infections[28]

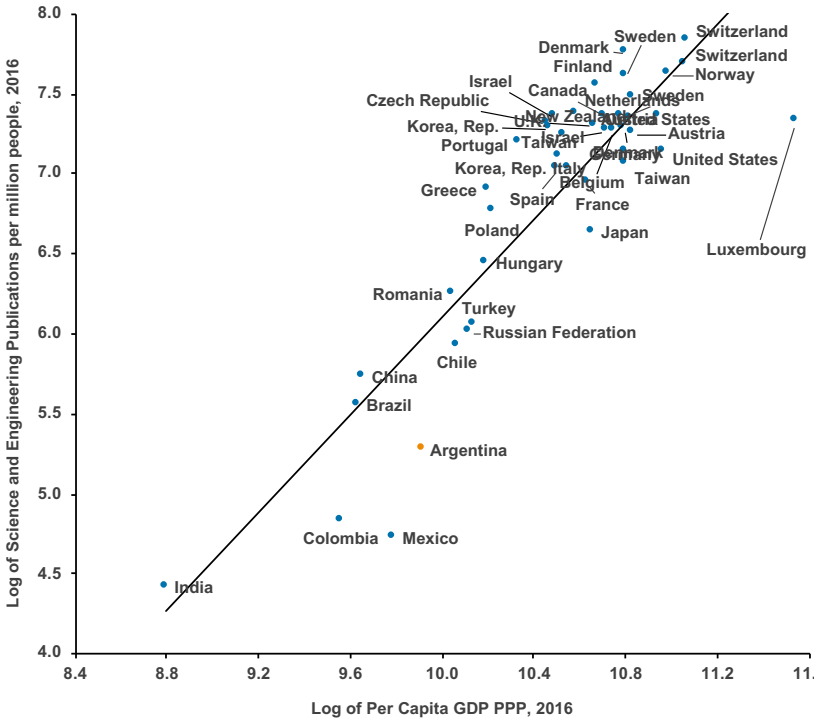


Source: Ministry of Health Argentina, VIHDA SisWEP

INNOVATIVE ACTIVITY: SCIENTIFIC PUBLICATIONS

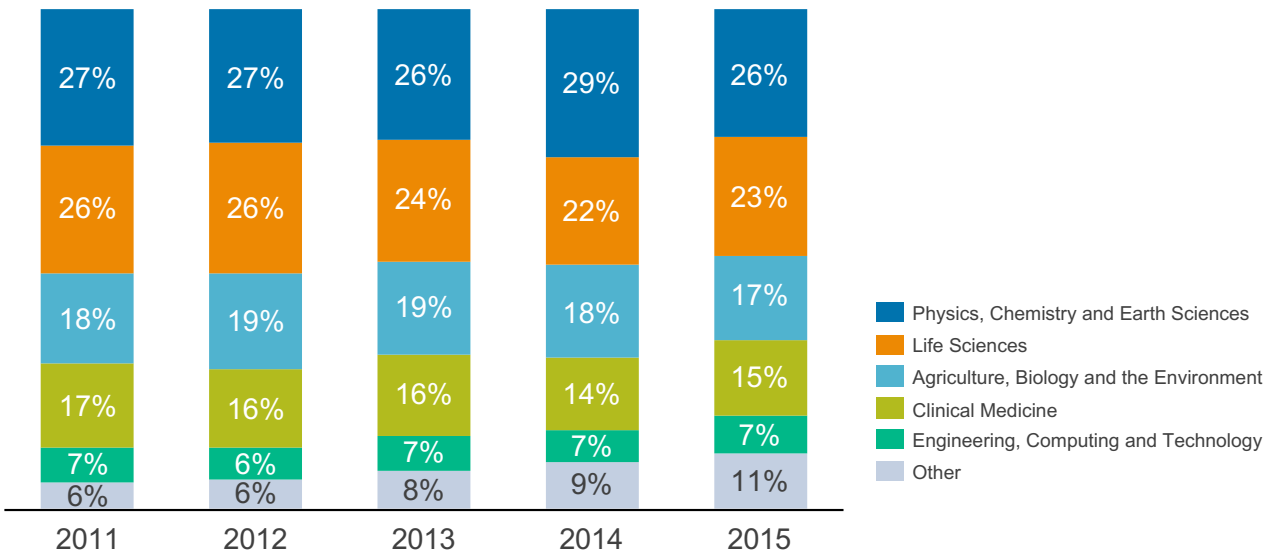
- Compared to other markets, the level of publications in Argentina is lower than expected (given level of income).
- Despite an increasing trend, Argentina has fewer internationally co-authored publications than LatAm and OECD.
- Also, this is falling with a decrease in the proportion of publications in life sciences being observable.

Scientific output compared to other countries[29,15]



Source: 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

Distribution of science publication[21]

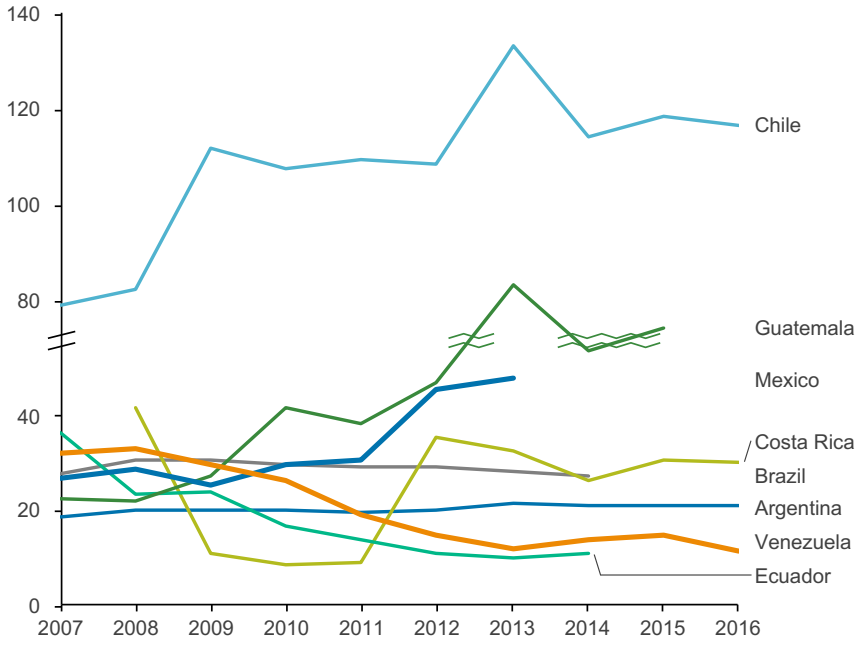


Source: Ministry of Science, Technology and Innovation Report

INNOVATIVE ACTIVITY:
SCIENTIFIC OUTPUT COMPARED TO LatAm

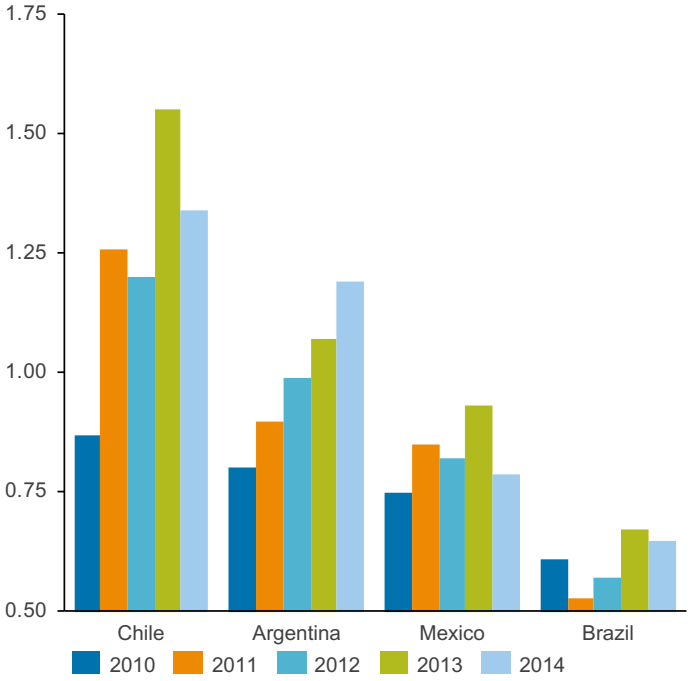
- Compared to markets in the region, in terms of researchers' productivity, the number of S&T publications per researcher in full-time equivalent is amongst the lowest in Argentina.
- Furthermore, Argentina falls behind Chile but is ahead of Mexico and Brazil, when it comes to the impact factor of its publication output as measured by the share of local publications out of the top 1% most cited articles in the Scopus database. However, the trend in recent years shows that Argentina is on an upward trajectory for this indicator.

Number of S&T publications per FTE Researcher[29]



Source: National Science Foundation Survey 2018

Share of top 1% most cited in Scopus*[30]



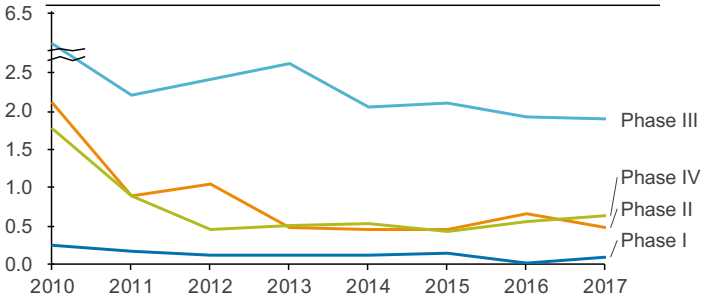
Sources: Ibero-American Network for Science and Technology

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

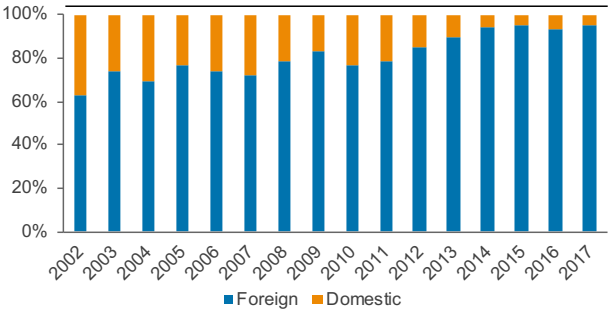
- Argentina underperforms in the total number of clinical trials per million of people compared to other low end high-income economies, but exceeds peers in the region, ahead of Brazil, Mexico, Colombia and Ecuador.
- The number of phase III clinical trials per million of people in Argentina experienced a drop after 2013, declining over the years. There are less phase 1 and 2 trials, indicating that early stage is less common in Argentina.

Number of clinical trials per million of people by phase[31]



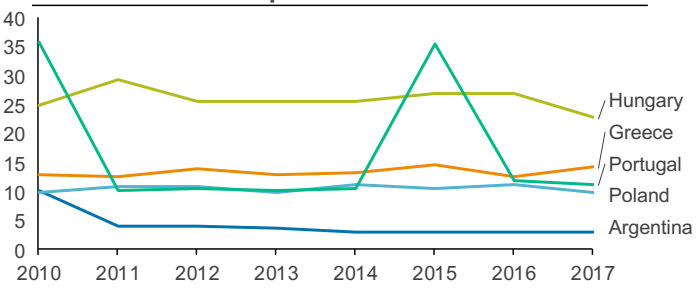
Source: CRA Analysis of Clinicaltrials.gov

Distribution of Phase I, II and II clinical trials[32]



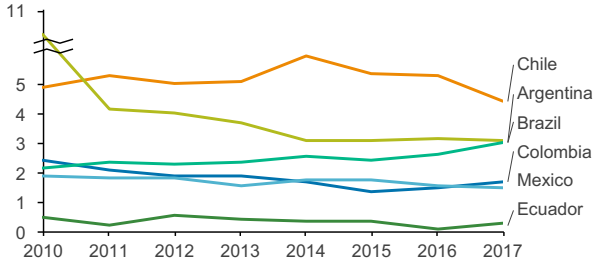
Source: ANMAT Database

Total number of clinical trials per million of people across comparable economies[31]



Source: CRA Analysis of Clinicaltrials.gov

Total number of clinical trials per million of people across LatAm countries [32]

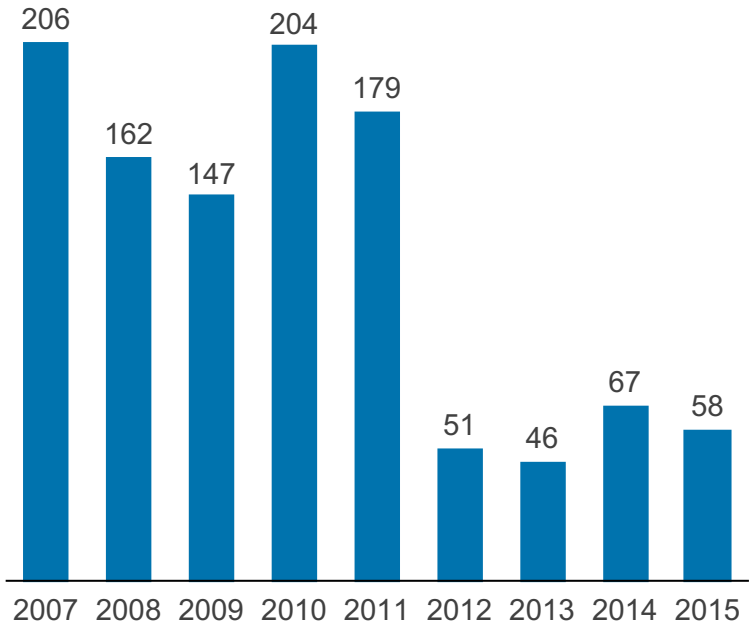


Source: CRA Analysis of Clinicaltrials.gov

INNOVATIVE ACTIVITY: PATENTS

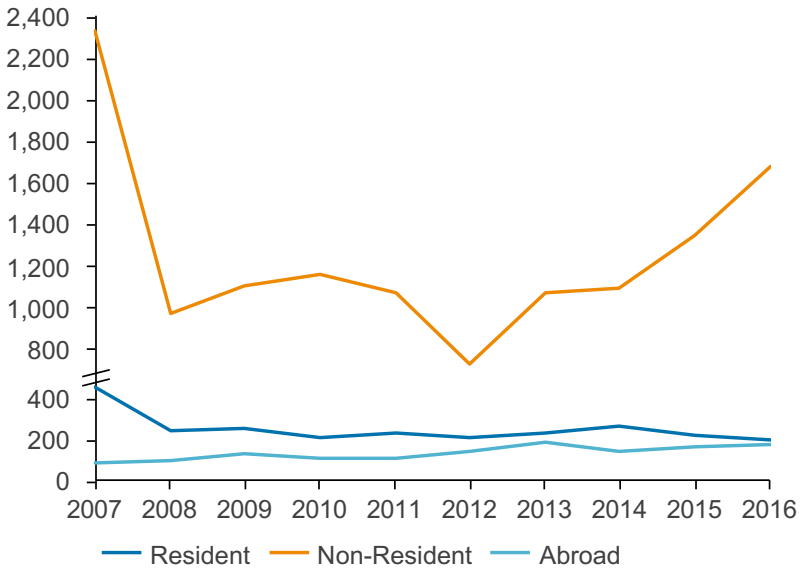
- In the case of the overall number of pharmaceutical patents granted by INPI in the past 10 years, there has been a sharp drop in the number in 2012 – 72% decrease compared to 2011. In the literature and according to interviewees this can largely be attributed to the adoption of the patentability guideline in 2012. Furthermore, the number has not recovered in recent years and remains low.
- The number of patents granted to nationals in and outside Argentina across all fields has remained constant. However, then number of those granted to Non-Residents experiences a drop in 2008, in line with the global financial crisis, and one around 2012, but this has steadily recovered in recent years, unlike the case of pharmaceutical only patents.

Number of patents for pharmaceuticals granted by INPI[12]



Sources: INPI 2017

Total number of patents granted according to WIPO[33]

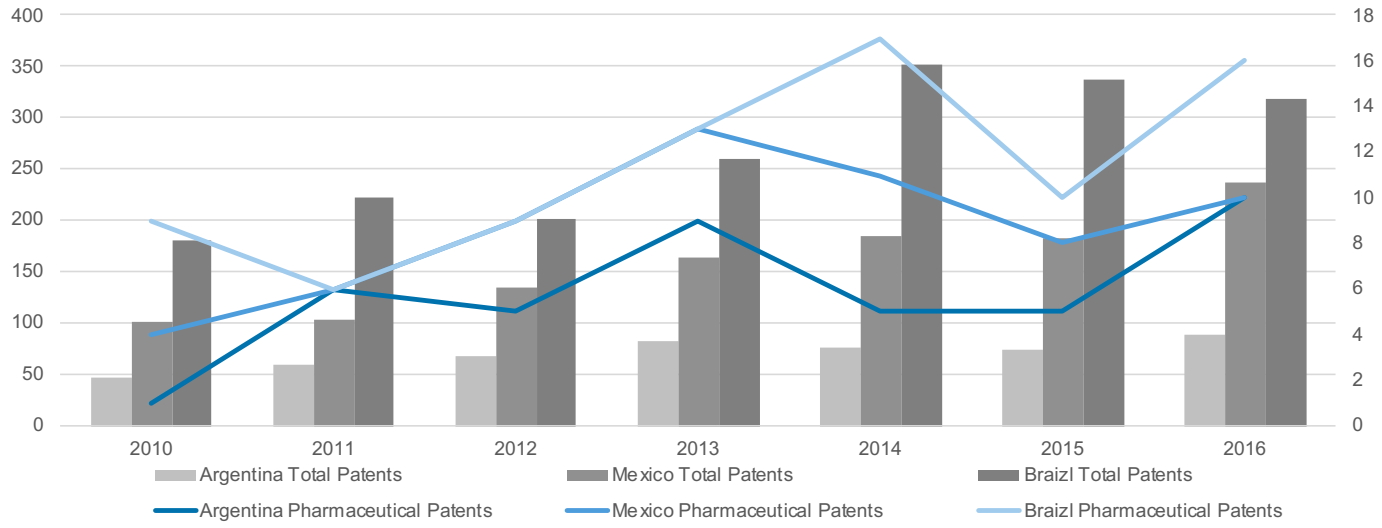


Sources: WIPO 2018

INNOVATIVE ACTIVITY:
PATENTS GRANTED COMPARED TO LatAm

- In terms of the number of patents across all fields granted to Argentine nationals by the U.S. Patent and Trademark Office (USPTO), Argentina is falling behind other countries in the LatAm region. Given that Argentina has the highest number of researchers of the three countries, the data shows that Argentina is facing a key problem in generating patents from basic research.
- Similarly Argentina is falling behind other countries in the comparison in terms of the number of pharmaceutical patents granted by USPTO to Argentine nationals, whereby the number has grown since 2010 but fluctuated across the years.
- According to interviewees, not sufficient role and prominence is given to technology transfer offices in universities, which in turn hampers the transfer and commercialisation of early stage research.

Number of USPTO patents granted to nationals[29]



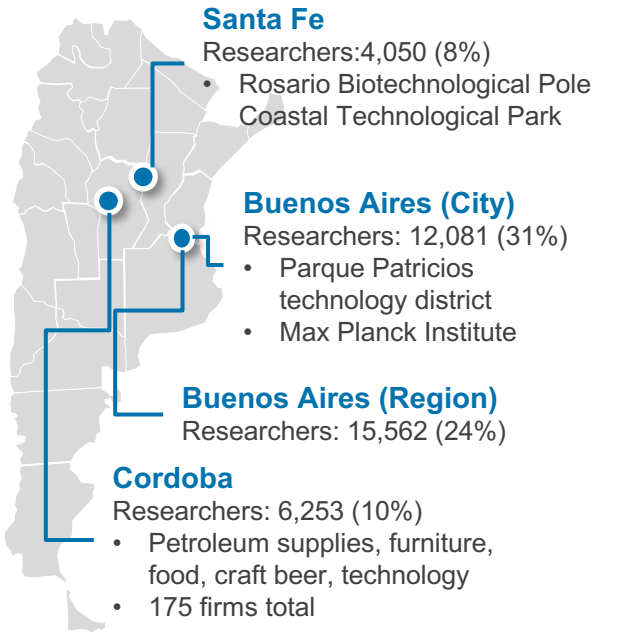
Sources: National Science Foundation Survey 2018

La Leona Petrified Forest, El Calafate, Patagonia, Argentina, shutterstock.com/Circumnavigation

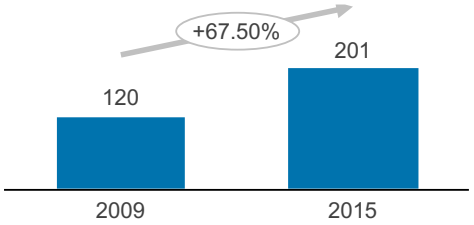
COLLABORATION AND ECONOMIC ACTIVITY

- Policy changes (such as the pharma and biotech plans) have primarily been aimed at expanding the biotech sector as well as stimulating integration between the private and public sectors for the formation of clusters for innovation and other spill-over effects. Positive results are evident:[34]
  - Over 200 biotech firms with earnings over $2 billion, across multiple sectors such as human health, animal health, food processing, and agriculture - most are small and medium-sized enterprises and employing 8,000+ workers.
  - More than half of these are involved in the development and commercialization of human healthcare products.
  - Geographically, these are concentrated to Buenos Aires, Santa Fe and Rosario.

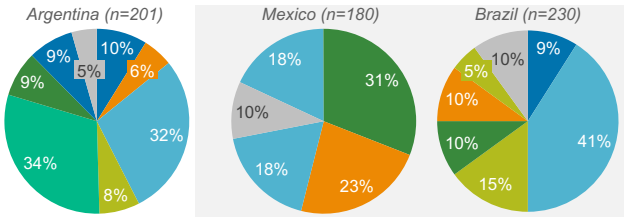
Key Science, Technology and Innovation Clusters



Number of Biotechnology Companies in Argentina[21]



Distribution of Biotechnology Companies by Sector[34]



Biotech Clusters in LatAm

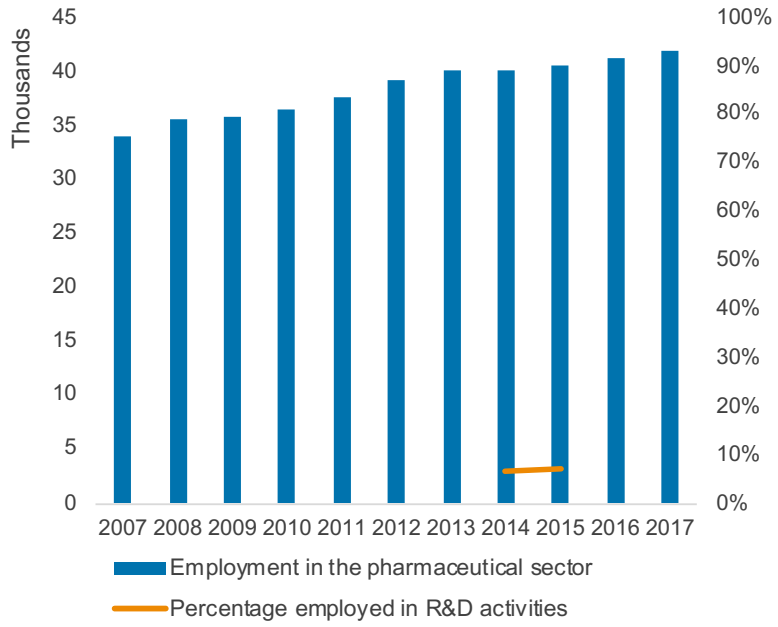
Brazil	13 clusters across in São Paulo, Minas Gerais, Rio de Janeiro
Mexico	Mexico City, Mexico, Queretaro, Coahuila de Zaragoza and Michoacan de Ocampo. A biotechnology science park is located in Baja California

Sources: Ministry of Science, Technology and Innovation; Haar, J., Wilson Center Latin American Program.

EMPLOYMENT IN THE PHARMA AND BIOTECH SECTORS

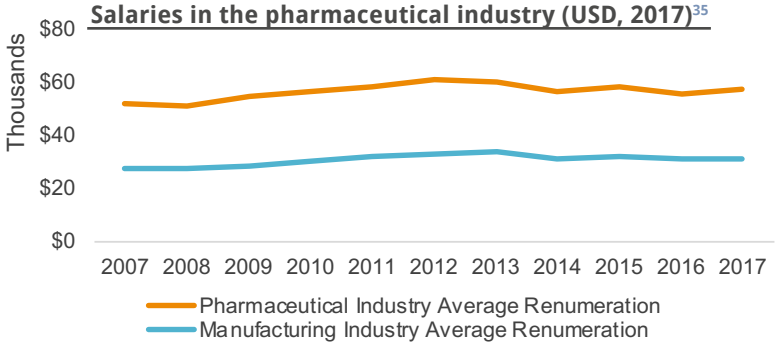
- In the past 10 years, small but consistent increases in number of employees in pharmaceutical sector is noted, although less than 10% are employed to undertake R&D activities.
- Interviewees report that cooperation between researchers and the domestic pharmaceutical industry is not common, as local manufacturers are focused on producing off-patent pharmaceuticals. In addition, whilst there has been a positive trend in the funding of research positions by multinational companies, this remains a rare practice.

Employment in the pharmaceutical industry in Argentina[35]

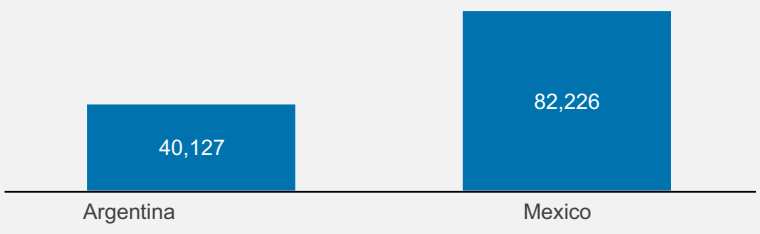


Source: Ministry of Science, Technology and Innovation; INDEC, OEDE-MTEySS

Salaries in the pharmaceutical industry (USD, 2017)[35]



Employment in the Biopharmaceutical Industry 2014 [36]

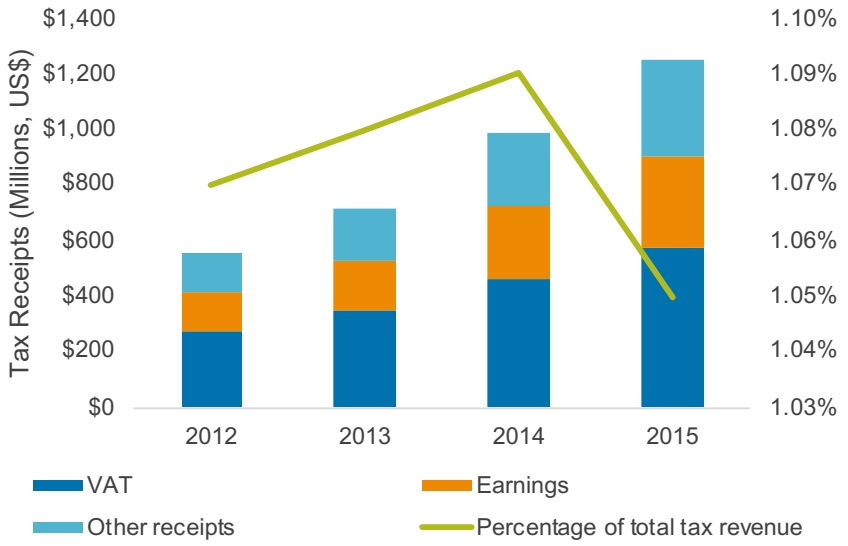


Source: INDEC, OEDE-MTEySS; INADEM Mexico

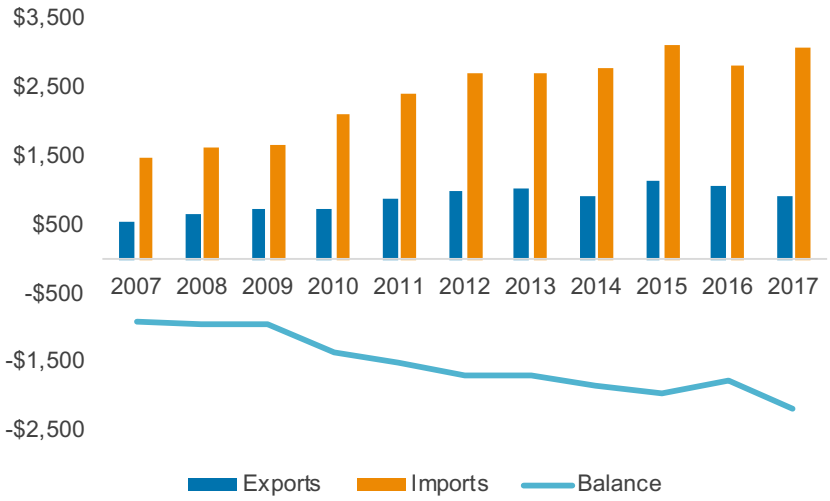
OTHER ECONOMIC ACTIVITY LINKED TO THE PHARMA SECTOR

- Despite growth in some economic activities related to the pharmaceutical sector, in real terms Argentina does not enjoy increasing benefits in the form of tax gains and trade surplus.
  - **Taxes:** Since the early 2010s, pharmaceutical tax receipts have increased but in latest years these constitute a smaller proportion of overall tax revenue suggesting a significantly higher increase in tax collection in other industries.
  - **Trade:** Although there is some growth in the level of exports over the past ten years, this has been offset by a larger increase in imports leading to consistent trade deficits in the sector in Argentina.

Evolution of pharmaceutical tax receipts (m, USD)[12]



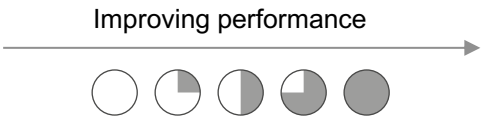
Evolution of pharmaceutical imports and exports (m, USD)[35]



Source: INDEC, KPMG Report 2017

ARGENTINA: ASSESSMENT OF PERFORMANCE

	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		
	Taxes		
	Trade		



3.

Lessons from other regions

LESSONS FROM COMPARABLE MARKETS

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

Choice of case studies: We chose to focus on two markets that:

1. **Have shown a focus on strengthening innovative environment, particularly the IP protection.**
   - Through strong and clear patentability rules.
   - Implementation of regulatory data protection.
   - Other support and incentives for innovation in pharma and bio.

2. **Placed in the same income and development category as Argentina when started focusing on innovation.**
   - Classified as upper middle income to high income country.
   - Opting for membership in key international groups and organisations e.g. OECD.

3. **Show an observable impact on innovative activity.**
   - Demonstrate good data availability.

APPROACH OF ANALYSIS ON STEP 2

The 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 control for other factors.

CASE STUDY ANALYSIS AND SCENARIOS: FOCUS ON SOUTH KOREA AND TAIWAN

Argentina	
Population	44.2 million
GDP per capita	$14,402
Economy	High-Income

South Korea	
Population	51.4 million
GDP per capita	$29,472
Economy	High-Income

Taiwan	
Population	23.8 million
GDP per capita	$24,557
Economy	High-Income

INNOVATION AND IP POLICIES

CHANGES IN THE IP REGIME

SCIENCE AND TECHNOLOGY PLAN 1997[37]

- Amendment to the 1961 Patent Law to introduce substance patents

PATENT LAW STANDARDISATION 2001[38]

- The Government changed their 'Patent Law' and worked with the World Trade Organisation (WTO) to bring Korea's patent regime in line with international standards. This started in the '80s with the substance patent amendment which opened the government's eyes to R&D

★ PHARMACEUTICAL AFFAIRS ACT 2007[39]

- 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 four to six years

DOSAGE PATENT DECISION 2015[40]

- The South Korean Supreme Court allowed patenting of dosage regime

ORPHAN DISEASE MANAGEMENT ACT 2016[41]

- The Orphan Disease Management Act (ODMA) allowed orphan drugs to benefit from a 10 year re-examination period if the indicated disease does not have therapeutic alternatives

CHANGES IN INNOVATION POLICY

"BIOTECH 2000" PLAN 1994[42]

- National Science and Technology Plan "Biotech 2000" recognising the importance of biotechnology as an emerging sector and shifting national attention to work in that area

KOREAN HEALTH INDUSTRY DEVELOPMENT INSTITUTE 1999[43]

- Establishment of the Korean health Industry Development Institute to improve the national health industry by providing support for programs and strengthen the global competitiveness of the national health industry

★ "BIO-VISION 2016" PLAN 2007[44]

- National science and technology plan with the intention of expanding Korean R&D infrastructure, globalize the bio industry and raise awareness among the general public

★ "577 INITIATIVE" 2008[45]

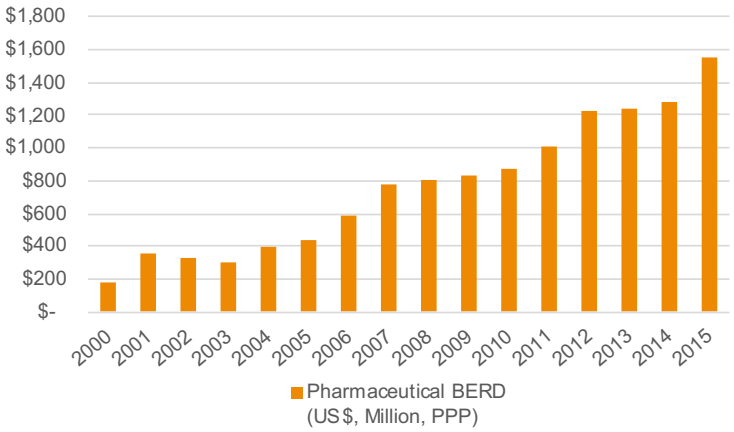
- A science and technology plan that aimed to invest 5% of GDP on R&D, focus on 7 key S&T area and become of the major global S&T powers

Note: Regulation market with a star will be used as proxy for change in estimating growth differences

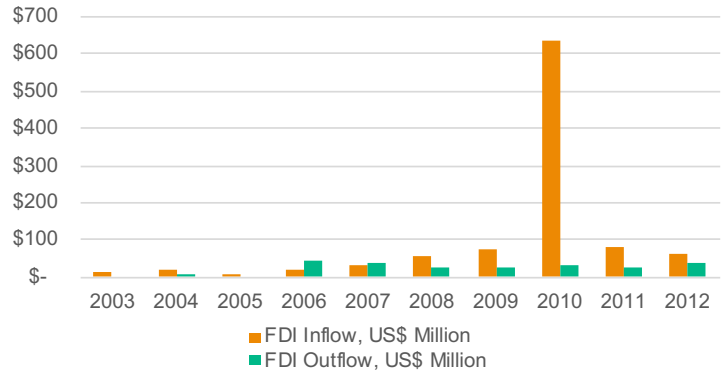
INVESTMENT IN R&D AND FDI

- With a national focus on biopharma, South Korea has seen a rapid increase in government and private R&D investments and a focus on the pharmaceutical industry.
- Korea has enjoyed increasing FDI inflows for pharmaceuticals, demonstrating it's ability to attract foreign investment by raising awareness of the strength of the national industry.

Pharmaceutical BERD performed in South Korea[46]

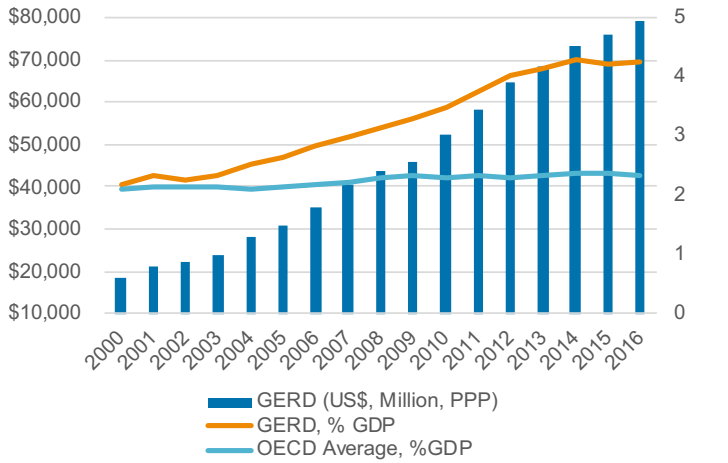


South Korean FDI flows for Pharmaceutical, Medicinal Chemical and Botanical Products[47]



Note: *outflow data for 2003 and 2005 unavailable

South Korean Investment in R&D[47]



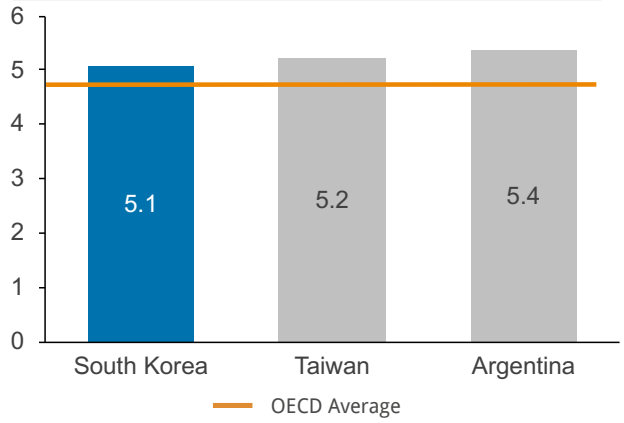
GERD = gross expenditure on R&D, BERD = business expenditure on R&D, FDI = foreign direct investment,
OECD = organisation for economic cooperation and development, KOTRA = Korean Trade-Investment Promotion Agency

Sources: OECD Statistics, KOTRA 'Invest Korea Annual Report 2010'

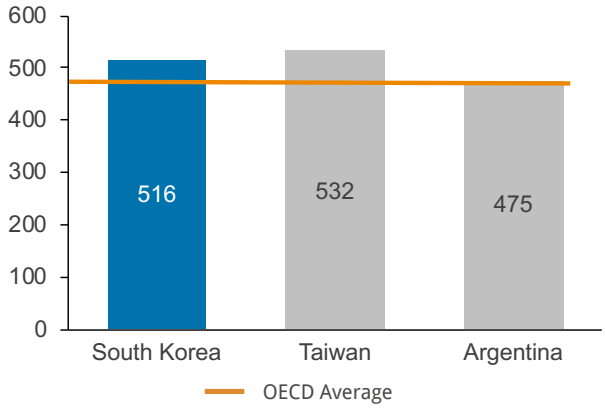
UNIVERSITIES AND QUALITY OF EDUCATION

- Korea's shift in national mentality to focus on becoming a leading biotechnology powerhouse has also been seen by the spill over effects in higher education.
- Korean universities regularly appear in top 200 universities in the world for a variety of biomedical subjects and the general trend of focus on science and technology have put Korea as the 2nd largest Asian nation (on par with China) to be represented in the best universities in the world.

Public Spending on Education (2014), %GDP[48]

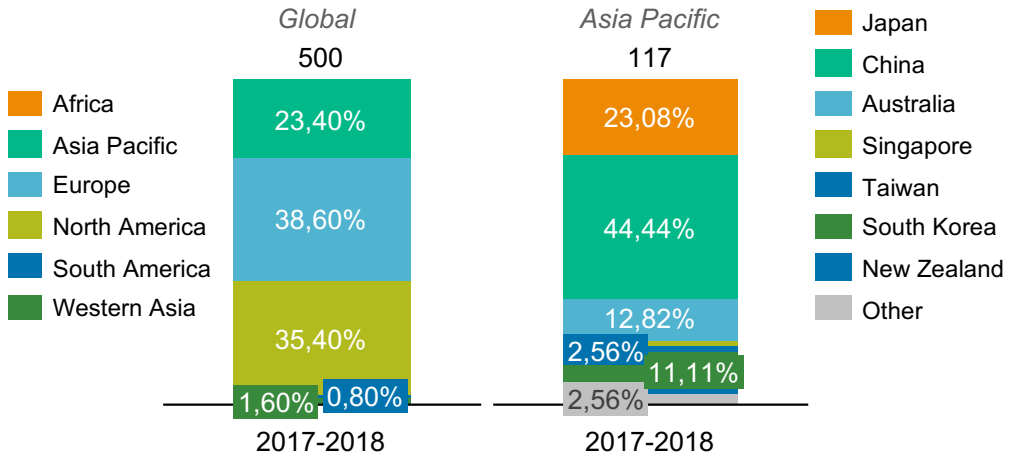


Mean PISA Score in Science (2015)[22]



Sources: OECD Statistics, Top Universities (QS Rankings) 2018/2019

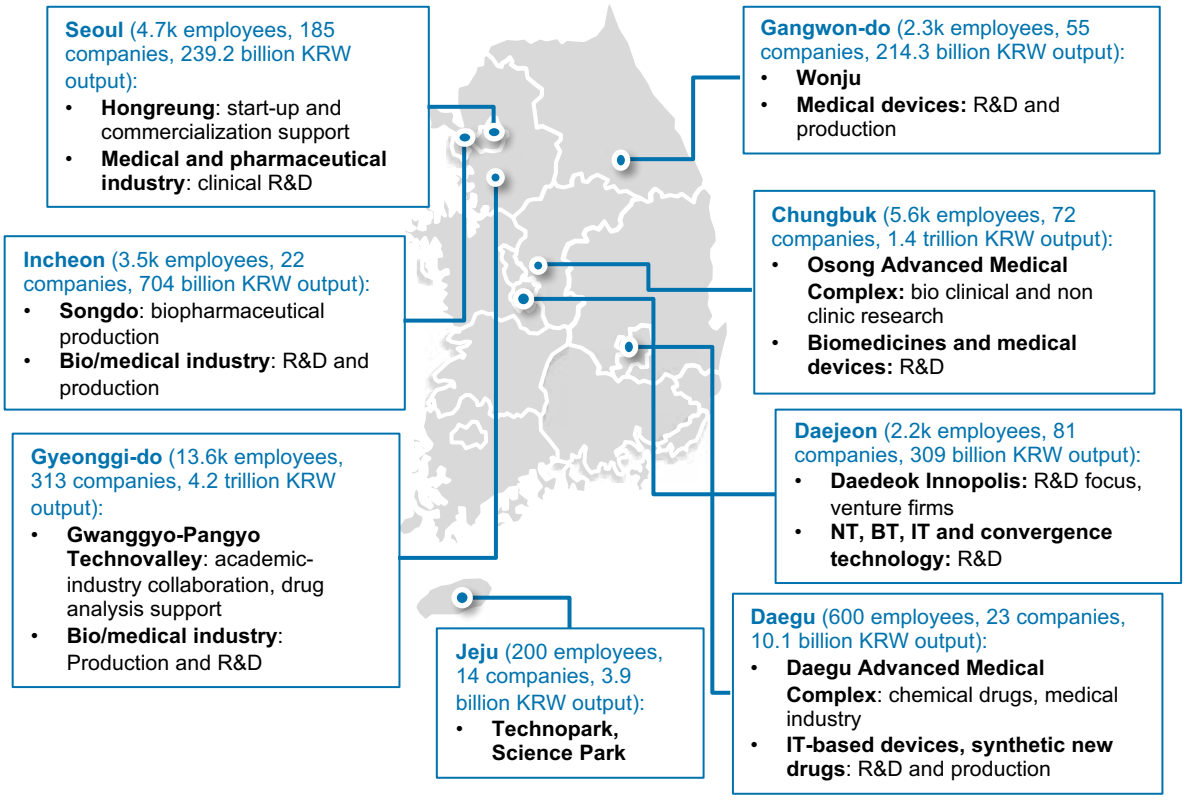
Proportion of top 500 Nature-ranked Universities in Life Sciences, 2017-2018[49]

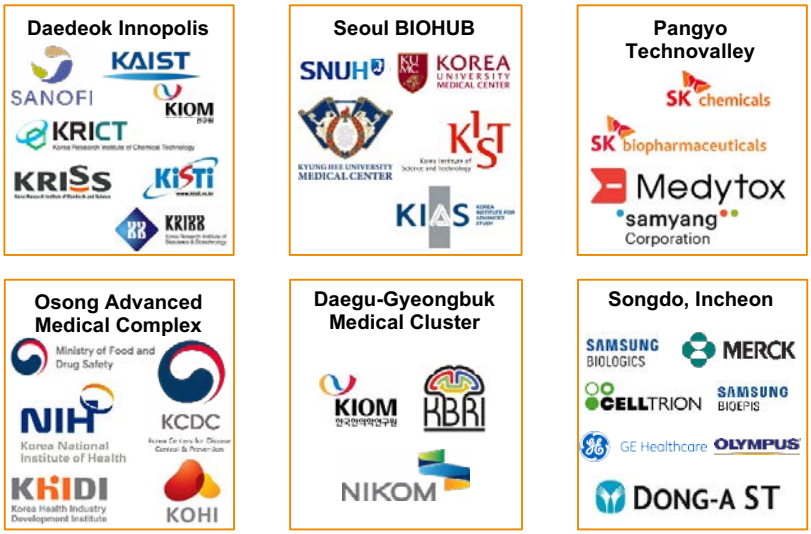


Source: Nature Publishing (2018)

COLLABORATION AND INFRASTRUCTURE FOR RESEARCH

- Korea has spurred the creation of bio clusters that vary in activity (from R&D to production) and industry (from pharmaceuticals to medical devices) aiming to gain both vertical and horizontal integration opportunities.
- This push towards an innovative environment throughout the nation has attracted numerous international companies, government-funded research centres and universities of upmost academic excellence. By being in close proximity to each other, the simplification of process is possible with companies able to seek regulatory and government help by having agencies near them or being able to hire the brightest academic talents.



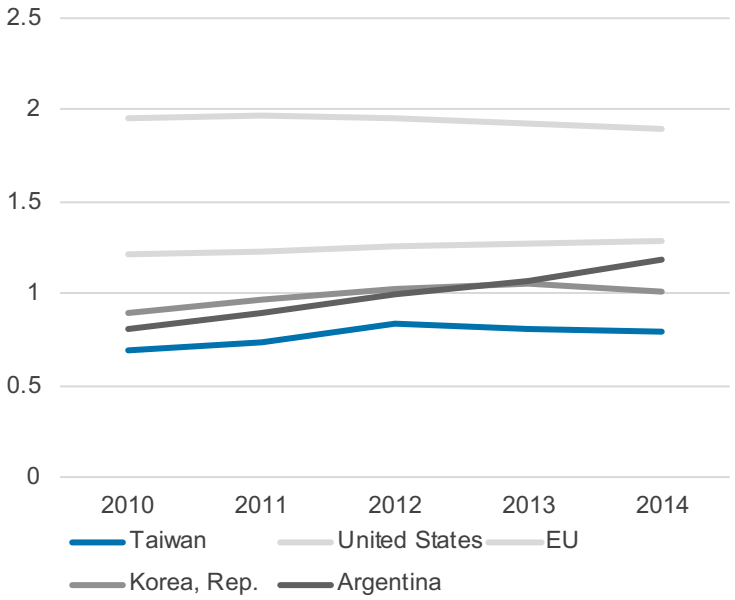


Sources: Biotechnology in Korea 2018 Report (https://www.kribb.re.kr/eng/file/2018_BIK.pdf)[50]

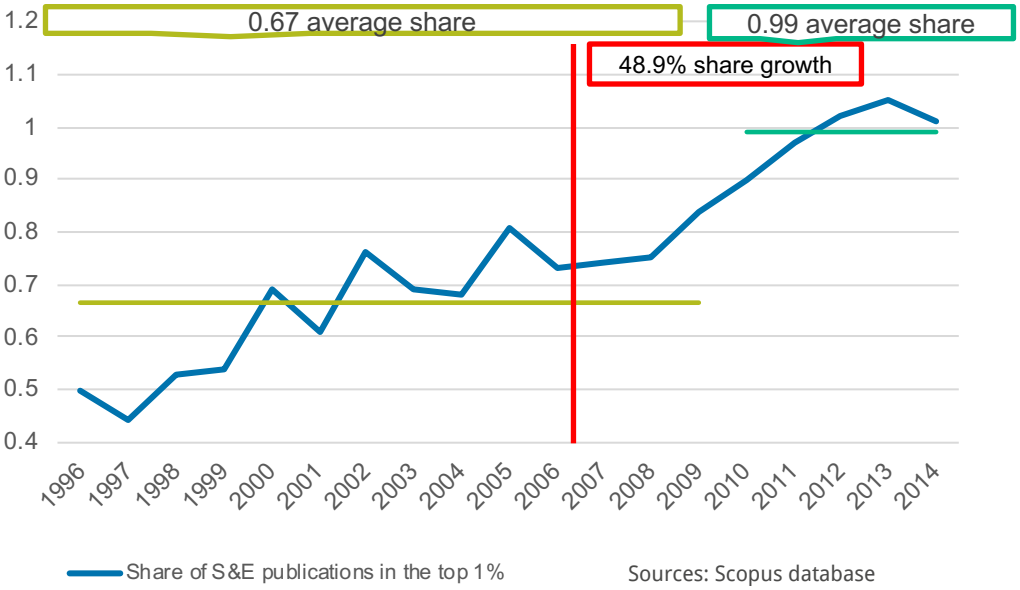
INNOVATIVE ACTIVITY: PUBLICATIONS

- Korean publications have grown significantly in impact factor over between 1996 and 2014 as shown by the rapid growth in share of the top 1% of most-cited S&E publications, having more than doubled in those 18 years.
- Whilst lagging behind the US and EU, the share of publications has increased in comparison to other Asian neighbours such as Taiwan.

Share of S&E publications in the top 1% most-cited in the Scopus database[29]



Share of S&E publications in the top 1% most-cited in the Scopus database[29]

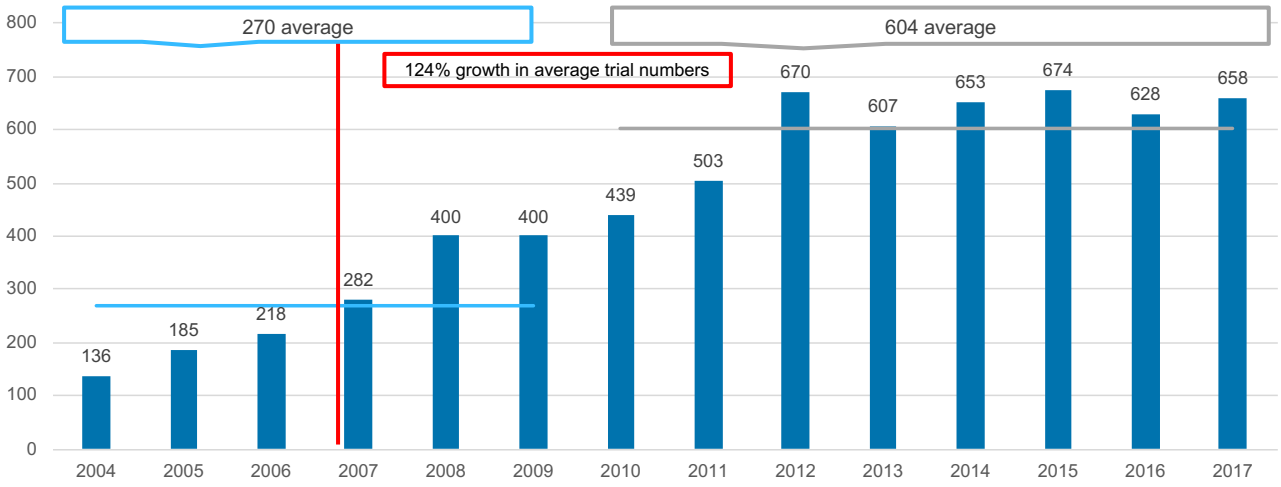


Sources: Scopus database

INNOVATIVE ACTIVITY: CLINICAL TRIALS

- Korea has experienced a rapid increase in the number of clinical trials over the last 14 years with the largest jump being between 2011-2012 where an additional 167 trials were conducted.
- The period between 2012-2017 has been relatively stable with only minor occasional decreases in trial numbers but the continual trend of 600+ trials for 5 consecutive years speaks to the reliability of Korea as a clinical study powerhouse.

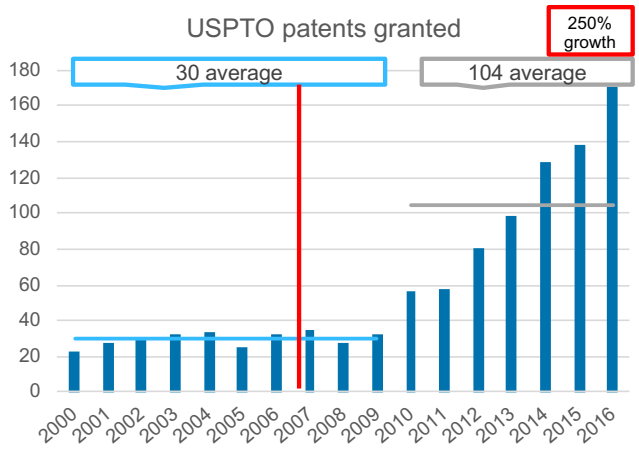
Clinical trials in South Korea[50]

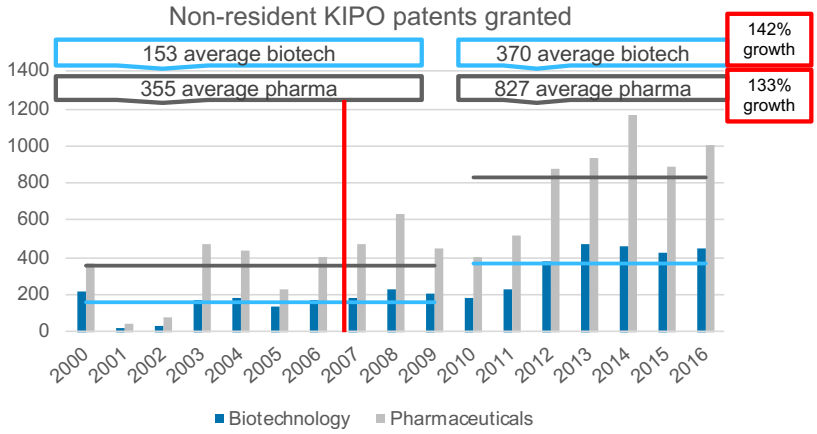


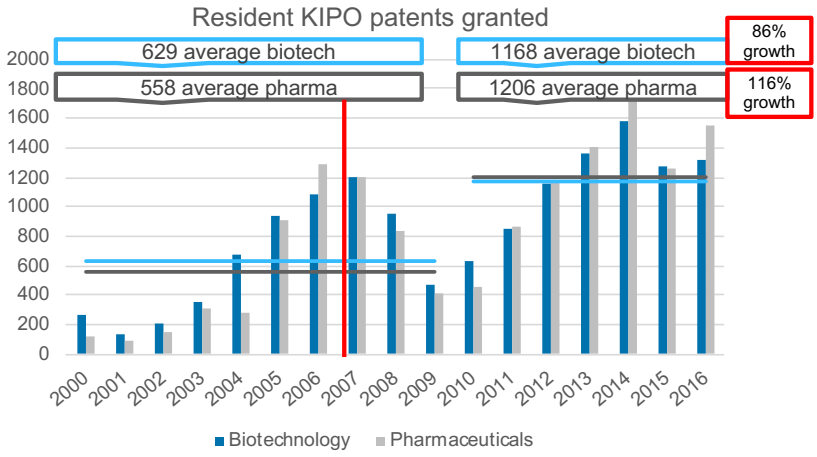
Sources: https://www.kribb.re.kr/eng/file/2018_BIK.pdf

INNOVATIVE ACTIVITY: PATENTS

- There has been a sharp growth in USPTO patents granted from 2009 potentially showing the globalisation elements of the '577 Initiative' as more Korean companies expand internationally and seek to patent in the US.[51]
- Additionally, the number of KIPO patents for residents and non-residents has been growing with the largest increase observed for pharmaceutical patents post-2010 for non-residents and post-2004 for residents.[51]
- Resident patents suffered from a decrease between 2008 and 2010 (in line with the 2008 mortgage crisis) but rapidly recovered from 2011 testifying to the resilience of the Korean economy.[51]



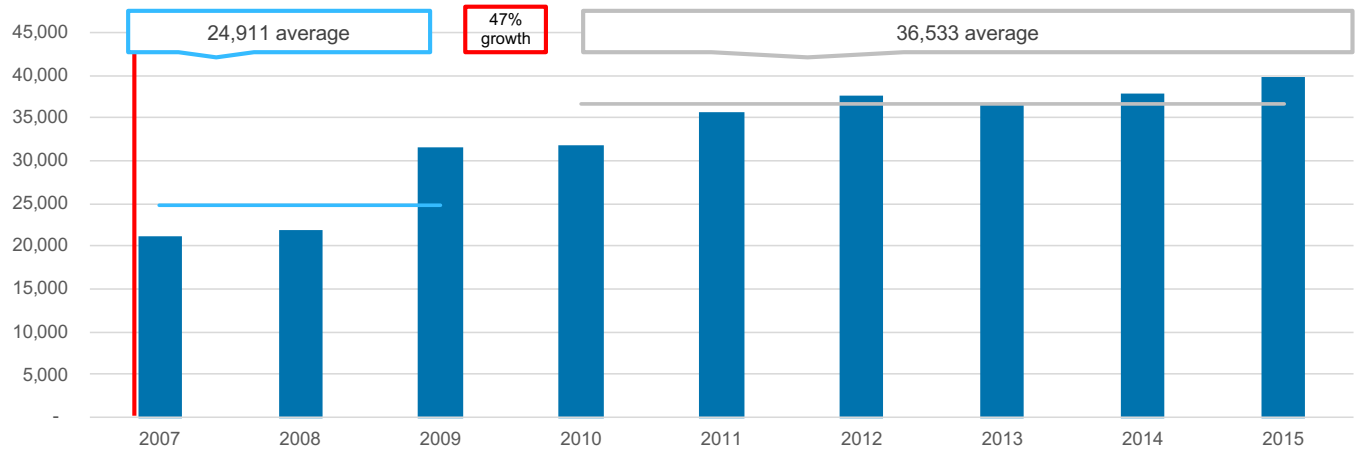




EMPLOYMENT IN THE BIOTECH SECTOR

- In line with the implementation of ambitious biotechnology and science & technology plans from 2007 (notably the 2007 'Bio-Vision 2016' initiative and the 2008 '577 Initiative') the number of individuals hired in biotechnology has steadily increased since 2007 (with a minor dip in 2013).
- This increase in employees may also testify to the strength and prowess of Korean universities for biological sciences as they produce talented individuals who have the skills and tools to go on and innovate.

Clinical trials in South Korea[50]



IMPACT OF IMPROVED IP REGIME ON INNOVATIVE ACTIVITY

- Innovation policy has long been debated in South Korea and there may be challenges in unpicking the causal factors underlying growth rates in innovation, advances in innovative initiatives or the general progression of the science and technology economy.
- Prior studies have observed the following:
  - Jae-Hong Baek (2008) notes how strong IP increases market competitiveness. This can be incentivised through government initiatives such as KIPO IP consultations for companies in an effort to nurture high-growth entities.[52]
    - With close to 1000 domestic biotech companies,[50] the Korean industry has embraced the culture of nurturing their companies with a focus on IP as shown by the number of USPTO and KIPO patents granted.
    - The size of capable workforce, number of world-renowned universities and creation of numerous bio clusters emphasises the national desire to embrace an entrepreneurial spirit – the ability to do this in a strong and reliable IP environment enables long-term growth and global competitiveness.
  - Kyle et al (2015) observe that changes to this national focus on IP started well before the new millennium.[53]
    - "Once the Korean government began to recognize and grant patents on substances in 1987, pharmaceutical companies could no longer produce active substances without patent permissions. This situation led them to realize that the key to survival was the development of new drugs, which in turn opened their eyes to the central importance of R&D investment."
    - This departure from a 'copy-cat' economy launched Korea into an innovation spree with 1 national science and technology plan being completed by the turn of the millennium and 2 additional ones planned (1 launched) by 2008.
  - Government support for pharmaceutical R&D has also been a significant contributing factor with investments increasing from 154 billion KRW in 2006 to 294 billion KRW and a commitment to pledge 5% of the GDP towards science and technology R&D (part of the '577 Initiative')[54]
    - This significant increase in R&D expenditure has mainly been concentrated in universities and companies with the former benefiting more. In the United States, government funding indirectly contributed to at least half of new drug approvals (Lichtenberg, 2011) emphasising the role of government funding in bio-pharmaceutical innovation.

INNOVATION AND IP POLICIES

CHANGES IN THE IP REGIME

EXTENSION OF PATENT TERM (1992)[55]

- The patent term extended to 20 years (WTO rules).

PATENT EXTENSION (SPC) PROVISION 1997[56]

- Amendment to the Patent Act was introduced to allow for the possibility to extend patent by 2-5 years to a maximum of 14-year protection period following the marketing authorisation of the product, with the aim to compensate for regulatory delays.

★ REGULATORY DATA PROTECTION PROVISION (2005)[57]

- Taiwan effectively implemented Article 39.3 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and introduced exclusivity for 5 years*.
- In addition, the basic framework for patent linkage was introduced – registration of patent owners upon marketing authorisation similar to Orange Book.

RDP AND PATENT LINKAGE PROVISION (2017)[57-60]

- RDP was expanded to include new indications though lasting for 3 years, which can be extended to 5 years if clinical trials are conducted in Taiwan.
- The Patent Linkage Provision requires generic manufacturers to demonstrate evidence that no patents would be infringed upon grant of marketing authorisation.

CHANGES IN INNOVATION POLICY

★ BIOTECH AND PHARMACEUTICAL TECHNOLOGY ISLAND PLAN (2005)[61]

- With an aim to build Taiwan's Biobank database and establish a clinical trial and research system.

★ BIOTECH AND NEW PHARMACEUTICAL DEVELOPMENT ACT (2007)[62]

- Incentivised academia-industry collaborations and tech transfer by allowing for publicly-funded researchers to help private companies with R&D & serve as biotech company executives. Introduced R&D tax incentives.

ACTION PLAN FOR BIOTECH TAKE-OFF (2009 & 2013)[63]

- Key actions included to strengthen Taiwan's technology acquisition capabilities, establish the industry's venture capital, promote the country's incubation system.
- Promote the development of legal, commercialisation and technical services in Taiwan to improve world-wide perception.

LATER PLANS IN 2015 ONWARDS[64]

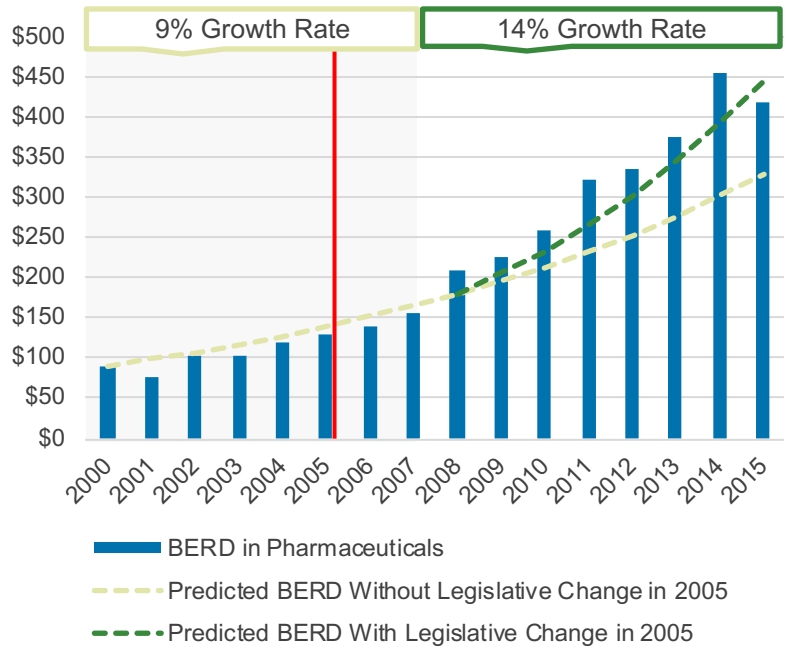
- Bio-economy Development Plan 2015.
- Five plus Two Innovative Industries for Priority Development, with a specific Biomedical Industry Innovation Program in 2016.

Note: *Data exclusivity did not apply to new dosages, formulations, indications and combinations; Regulation market with a star will be used as proxy for change in estimating growth differences

INVESTMENT IN R&D AND FDI

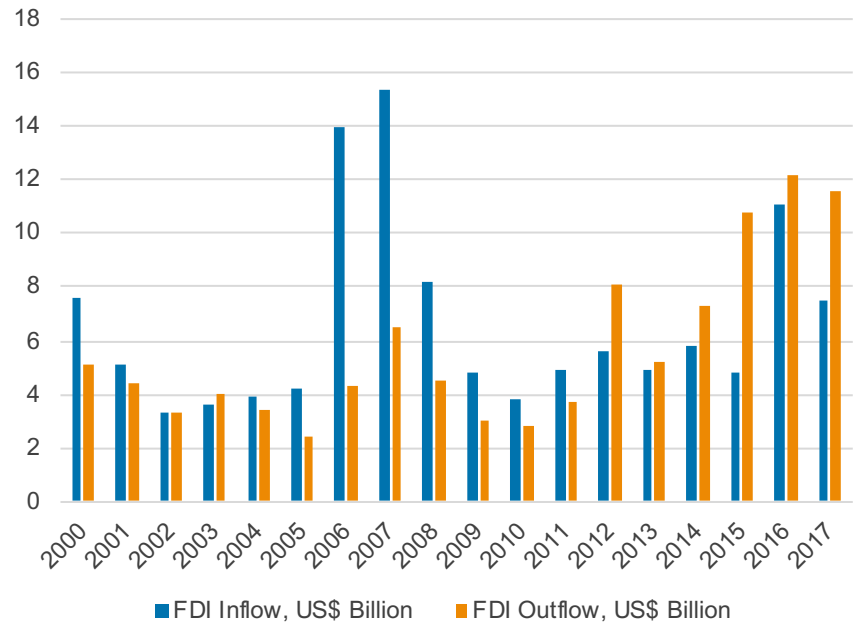
- With its increasing focus on the innovative knowledge based economy, companies have increased their R&D spending on pharmaceuticals in Taiwan, as both local and multi-national companies have increased their local footprint.
- Taiwan has historically focused on attracting FDI based on its highly educated and productive labour force, which more recently has evolved to attracting FDI in the technology-intensive areas in order to encourage and promote domestic spill over effects.

Business Enterprise Spending on R&D (US$, million)[46]



Source: OECD Indicators 2018

Foreign Direct Investment Flows (US$, billion)[17]



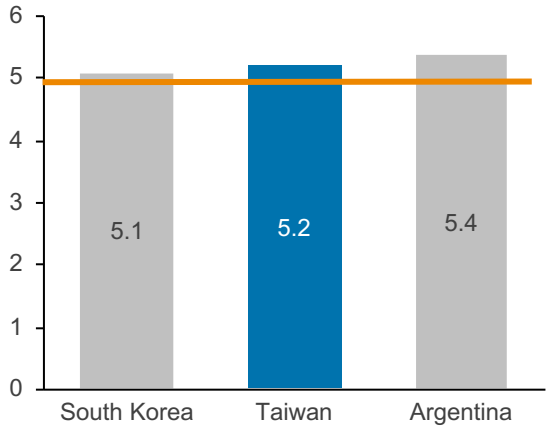
Note: According to Chen 2013 the peaks in FDI Inflows in 2006 and 2007 we due to "several large investments by foreign multinational enterprises (MNEs) such as Phillips, and private equity firms, including the Carlyle Group, Macquarie Bank, MBK Partners, and Newbridge Asia", whilst the drop 2008-2010 is attributed to the global financial crisis.

Source: OECD Indicators 2018

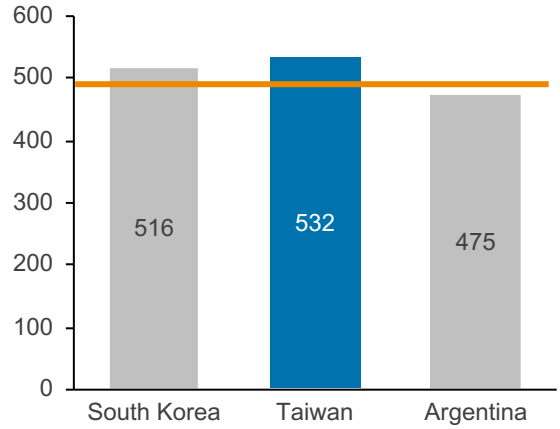
UNIVERSITIES AND EDUCATION QUALITY AND ATTAINMENT

- Higher education has gradually evolved to universal since the 1990s to meet the demands of economic transformation from manufacturing based to an innovation based knowledge economy.

Public Spending on Education (2014), %GDP[49]

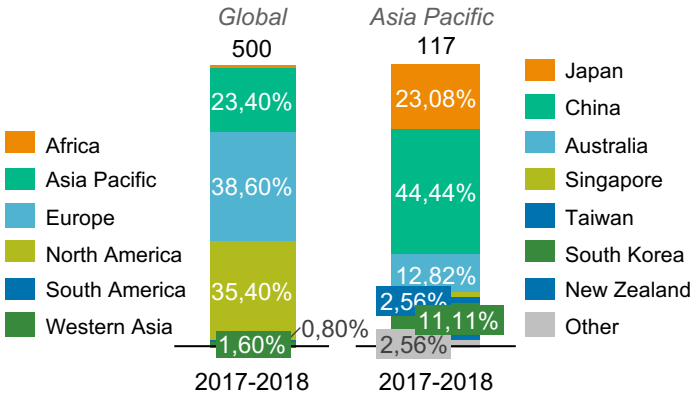


Mean PISA Score in Science (2015)[58]



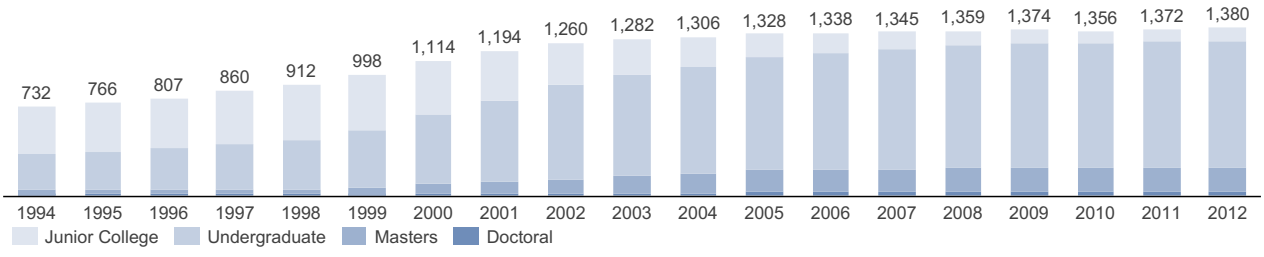
Source: OECD Indicators 2018

Proportion of top 500 Nature-ranked Universities in Life Sciences, 2017-2018[22]



Source: Nature Publishing (2018)

Number of Students in Higher Education by Level (in thousands)[66]



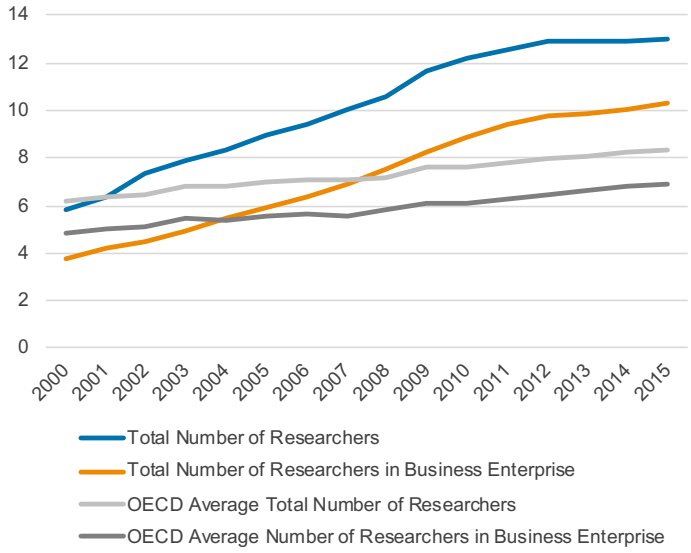
Source: Ministry of Education 2014

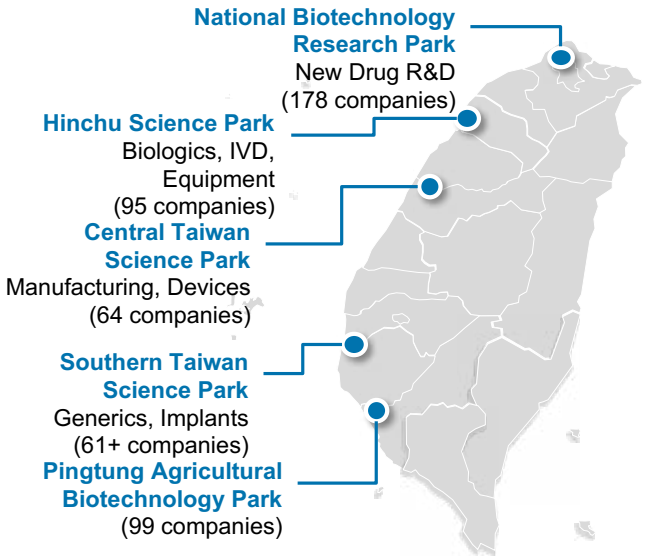
Other sources: Chan and Lin, "Massification of Higher Education in Taiwan: Shifting Pressure from Admission to Employment" 2015

COLLABORATION AND INFRASTRUCTURE FOR RESEARCH

- To build highly skilled base of researchers, with its Bio-Pharmaceutical Innovation Plans, Taiwan has historically focused on encouraging collaboration between the private and public sectors.
- Science clusters are a key element of this.

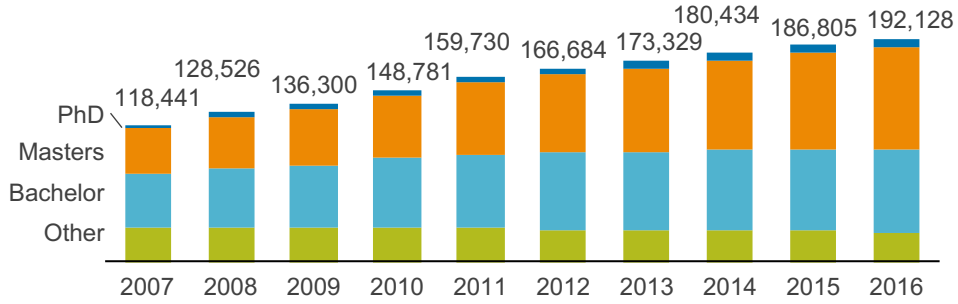
Researchers per 1,000 in Employment[67]





Source: OECD Indicators 2018

Business Enterprise R&D Personnel (FTE)[68]

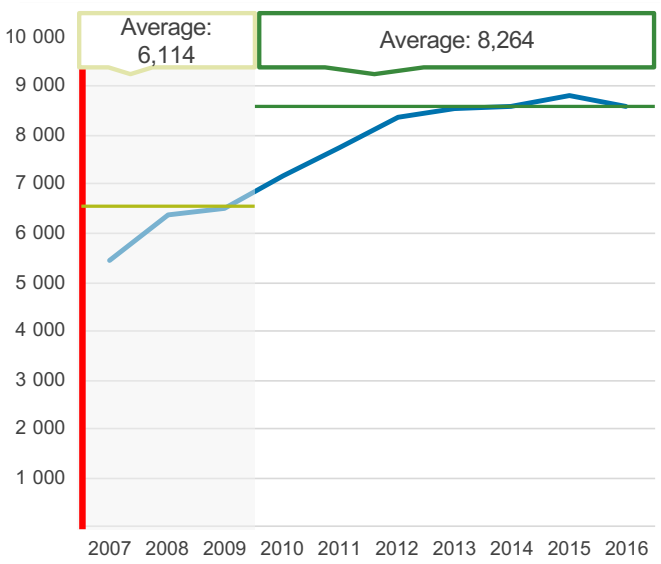


Source: Ministry of Science and Technology Indicators

INNOVATIVE ACTIVITY: PUBLICATIONS

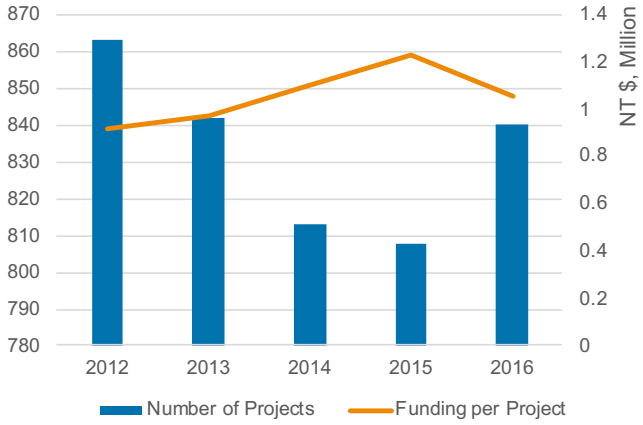
- The number of Biological Sciences publications has more than tripled in recent years. However, Taiwan underperforms in terms of impact of its publications in comparison to peers.
- Funding per collaborative project has grown, offset by a decrease in the number of projects.

Publications in the Biological Sciences [68]



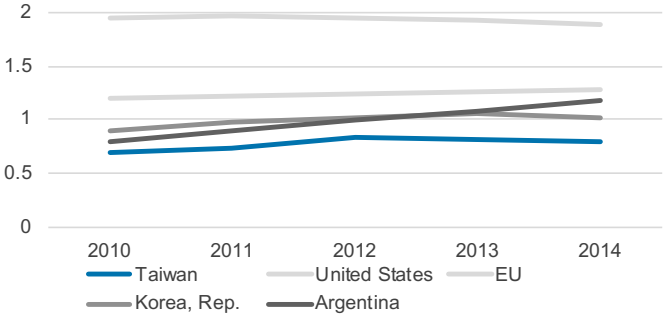
Source: Ministry of Science and Technology

Industry-Academia Collaborations[68]



Sources: Ministry of Science and Technology

Share of S&E publications in the top 1% most-cited in the Scopus database[22]

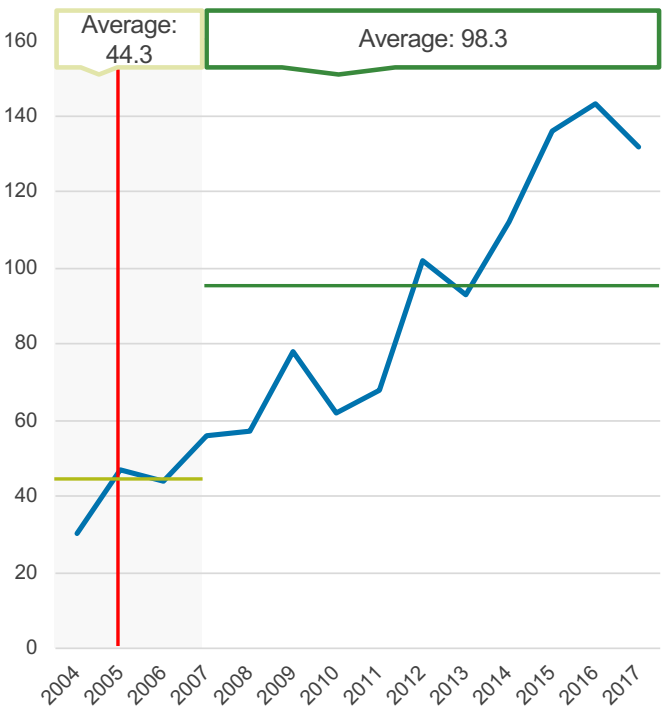


Sources: National Science Foundation Report 2018

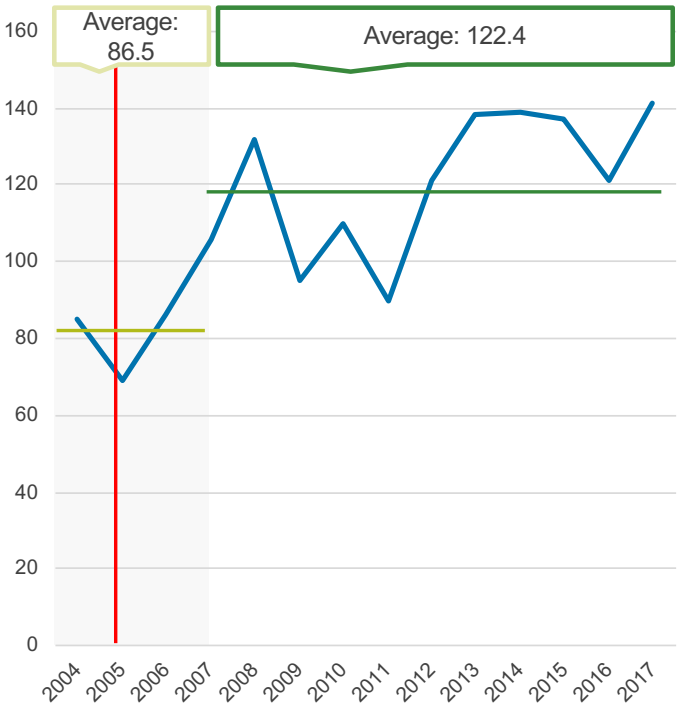
INNOVATIVE ACTIVITY: CLINICAL TRIALS

- There has been a steady growth in the number of phase 1, 2 and 3 clinical trials in Taiwan with a significant jump in 2008 and later in 2012, potentially reflecting the strengthening of RDP from 2005 and the effects of the earlier Bio-Pharmaceutical Innovation plans.

Number of FTE Researcher Employees in the Pharmaceutical Industry[69]



Number of Approved Phase 3 Trials[69]

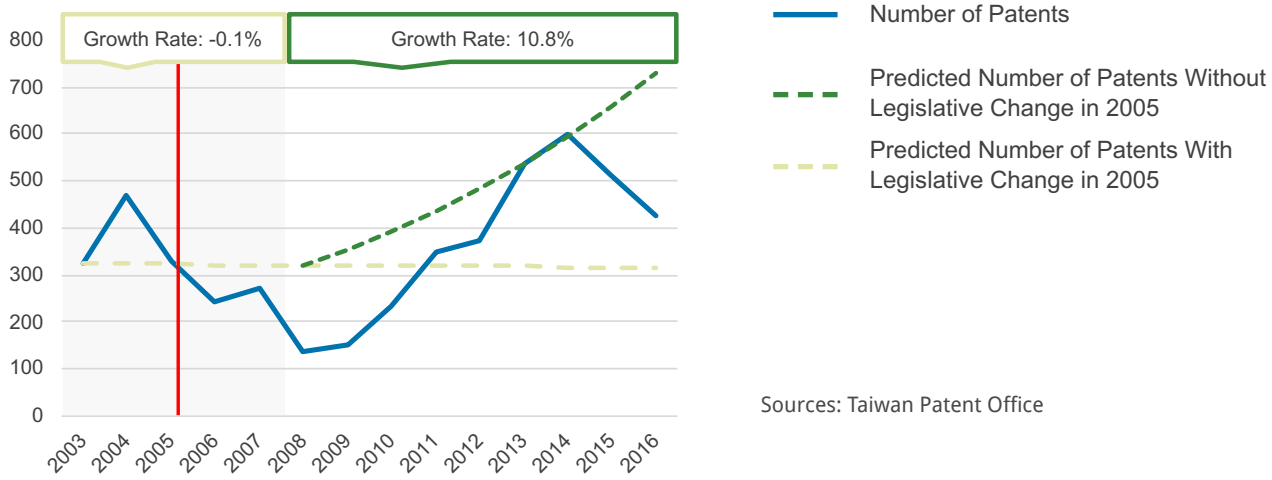


Source: TFDA

INNOVATIVE ACTIVITY: PATENTS

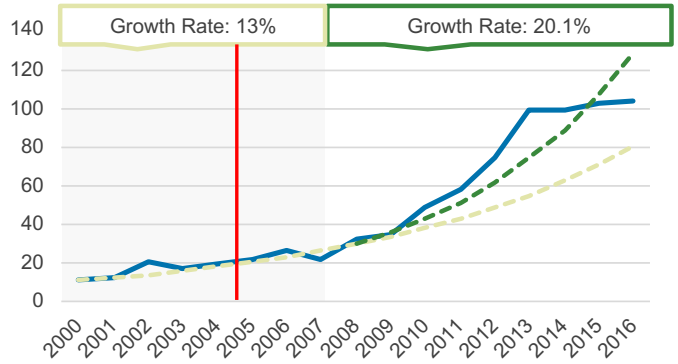
- Innovation patent indicators that experienced significant growth in recent years include the patents granted to Taiwanese nationals by USPTO, as well as the patents granted by TIPO to Non-Residents in the pharmaceutical and biotechnology industries.
- Whilst the number of TIPO patents to residents has grown over time, the change growth rate is less pronounced.

Pharmaceutical Patents Granted to Non-Residents by TIPO[70]



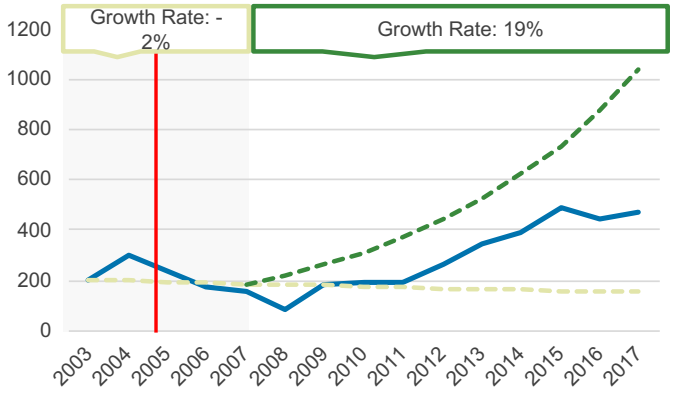
Sources: Taiwan Patent Office

Pharmaceutical Patents Granted to Taiwanese Nationals by USPTO[51]



Sources: National Science Foundation Report 2018

Biotechnological Patents Granted to Non-Residents by TIPO[70]

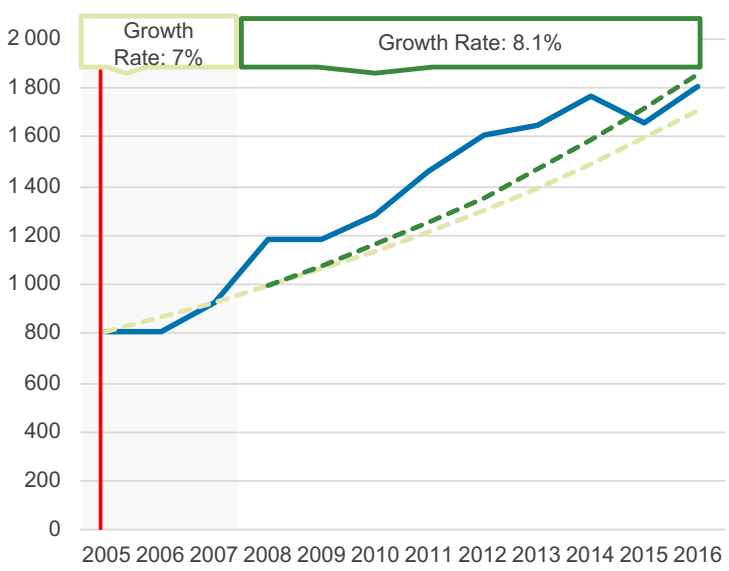


Sources: Taiwan Patent Office

EMPLOYMENT IN RESEARCH IN PHARMA AND BIOTECH

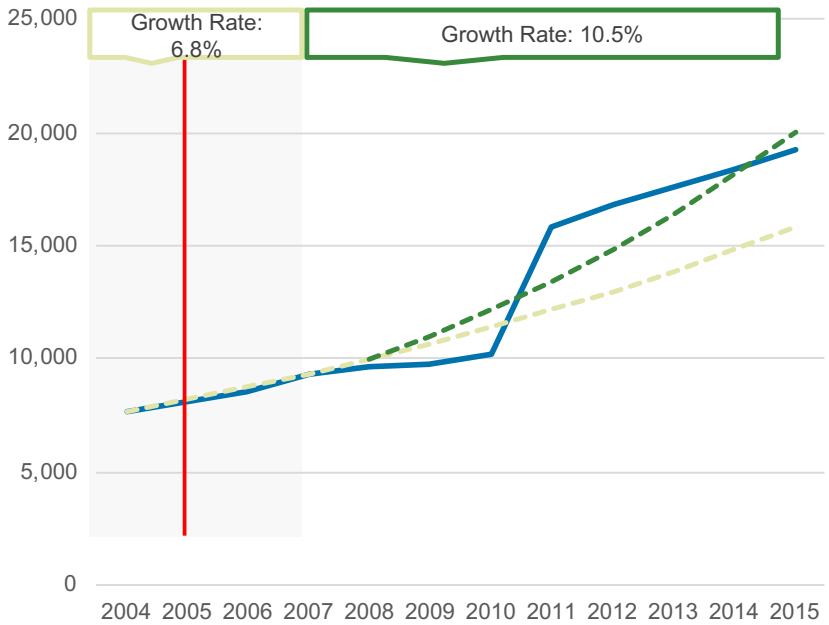
- The number of researchers employed in the pharmaceutical industry and the overall number of employees in the biotechnology has grown significantly compared to growth prior to the 2005 change.
  - The biotechnology has benefited more than the pharmaceutical industry in terms of revenue and workforce size.

Number of FTE Researcher Employees in the Pharmaceutical Industry[71]



Sources: Ministry of Economic Affairs

Total Number of Employees in the Biotechnology Industry (headcount)[71]



Sources: Ministry of Economic Affairs

IMPACT OF IMPROVED IP REGIME ON INNOVATIVE ACTIVITY

- Taiwan has incrementally improved the IP regime for pharmaceuticals in line with WTO standards and deficiencies set out in the 2013-2015 PhRMA 301 Special Reports. To date there are no studies that have tried to examine the impact of the introduced changes in the IP regulatory as a result. However, past studies exist measuring effects on innovation across developed countries and past regulatory changes:
  - For example, Lo (2011) found that the introduction of longer lasting patent rights in 1986 led to a long-lasting increase in innovation measured in terms of R&D spending and patents filed in the U.S. [72]
- **Domestic innovation:** Taiwan is widely recognised to have taken long-term strategic steps to the improve the IP regime more widely and reinvented itself as focusing on IP and innovation. As a result, in 2014 Taiwan had the highest number of patents per population, and per R&D expenditure in the world according to Bloomberg, additional contribution was the availability of the strong skills base of the population.
- In terms of wider innovation studies, there is lack of clear consensus in the literature as to whether stronger domestic IP regime leads to improved local innovation (measured by the number of pharmaceutical patents granted by USPTO):
  - Some studies (Allred and Park 2007) find a "U" shaped relationship between patent protection and foreign patent filings. Similar relationship has been found in other studies (Chen and Puttitanun 2005) between IP rights and the economic development of a country. [73,74]
  - Gamba finds a positive correlation between local Pharmaceutical Patent Index strength and the innovative activity of a country as measured by patent applications to EPO. Furthermore, similar to Taiwan's approach, it is concluded that gradual implementation of reforms that slightly increase the level of protection rather than rare reforms that greatly alter it will render the strongest effect. [75]
- **Clinical trial activity:** Berndt, Cockburn, and Thiers (2006) find the rising trend of clinical trials in emerging economies at the beginning of the century to be due to changes in the strength of patent protection for biomedical inventions. This activity is primarily driven by Phase III clinical trials. [76]
- **Number of employees:** Kumar 1995 finds that whilst the available infrastructure and local capabilities influence the probability of attracting R&D investments from multi-national companies (MNCs), the overall strength of the intellectual property protection also contributes to attracting foreign R&D investments in a sample of industrialised countries including Taiwan. [77,84]

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

	SOUTH KOREA	TAIWAN
KEY INNOVATION POLICY CHANGES	"Bio-Vision 2016" Plan of 2007 "577 Initiative" of 2008	Biotech and New Pharmaceutical Development Act (2007)
KEY IP REGULATION CHANGES	Pharmaceutical Affairs Act of 2007: Grant of RDP	Revision of Pharmaceutical Affairs Law (2005): Grant of RDP
OTHER KEY REGULATION CHANGES		Biotech and Pharmaceutical Technology Island Plan (2005): Clinical trials database

		Change	Attributable to IP Regulation	Growth	Attributable to IP Regulation
Investment	BERD			5% increase*	
Innovative Activity	Early research (publications)	49% increase**		35% increase*	
	Clinical trials	124% increase		61.2% increase	
	Patents (local residents)	101% increase		249% increase	
	Patents (local non-residents)	138% increase		23% increase*	
	Patents (USPTO)	250% increase		7.1% increase*	
Economic Activity	Employment in biotechnology and pharmaceuticals	47% increase		2.4% increase*	

Impact of the regulation →

Notes:
*Indicated increase in average YoY growth rate;
**Indicates an increase in the impact factor of publications rather than absolute number

HOWEVER, THERE ARE REMAINING GAPS IN THE IP REGIME

Taiwan

Some gaps were addressed with the amendment of the Pharmaceutical Act in 2017:

- RDP did not cover additional new indications.
- RDP is limited to registrations filed within three years from the first approval granted anywhere in the world for a product based on that new chemical entity.
- Lack of systems to effectively prevent marketing of patent-infringing pharmaceutical products (in 2012 at least 58 patent-infringing drugs were approved in Taiwan, and most of them were included on the reimbursement lists).

The remaining gaps in the IP regime are mainly around enforcement:

Enforcement of the Patent Linkage System:

Particularly, when applying for market approval, the Abbreviated New Drug Application (ANDA) filer is allowed to reference the data of the approved originator. On the day following the 5-year RDP period, the generic manufacturer can launch its product. However, when applying for marketing authorisation, the ANDA filer is obligated to declare that the generic drug does not infringe any IPRs of the reference drug. Despite this the TFDA may approve it for the market regardless of whether the declaration is correct or false, and whether or not the reference drug is protected by patents.[78,77]

Enforcement of Preliminary Injunction:

The ANDA filer is not required to notify the branded manufacturer, who will only become aware once the generic is launched on the market and be in a position to file a lawsuit. Due to Taiwan's double-track system of administrative law and civil law, civil action and has no influence on the grant of market approval, which is an administrative matter. Thus, a preliminary injunction ordered by a civil court neither prevents the TFDA from granting market approval nor does it prevent the National Health Insurance Administration (NHIA) from including the infringing pharmaceuticals on reimbursement lists.[78,77]

South Korea

Although Korea's IP system is strong, there have been instances where challenges stemming from IP have arisen. When the US urged developing countries to introduce laws to allow patents on chemical and pharmaceutical products in 1985 (at the time Korea was considered a developing country), the result was not what people expected. A study by La Croix and Kawaura (1996) showed that the legislative change did not increase the expected market value of domestic firms, By analysing the performance of the Korean pharmaceutical stock portfolio to that of the market portfolio, they found that the former suffered a decline of 74% compared to the former.[37]

The patent-approval linkage system in Korea also brought some challenges to the Korean market. When the Hatch-Waxman Act was enacted in 1984, patent holders would often misuse the patent-approval linkage system for instances such as overusing patent litigations or unfair agreements including reverse payment between the patent holder and first applicants for generic drug approval.[79]

UNDERSTANDING SPECIFIC IMPACT OF THE IP REGIME: APPROACH

AIM: In order to establish useful lessons on potential gains from an improved environment, we first need to:

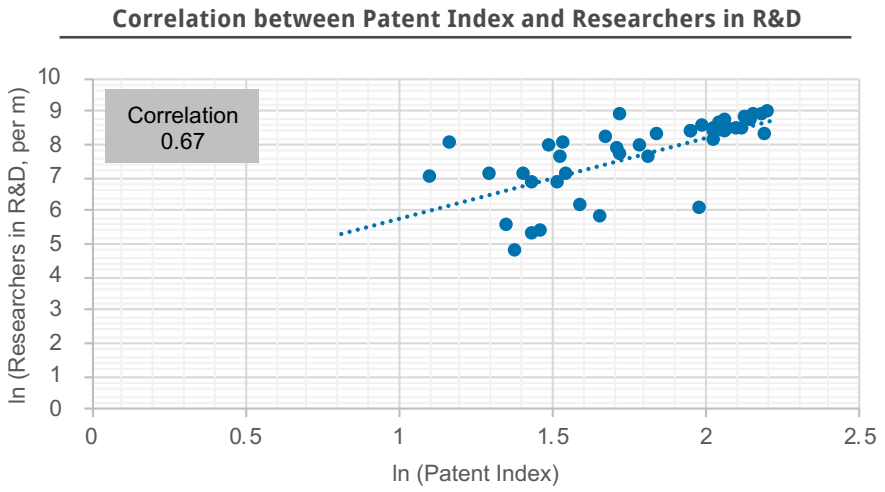
1. Determine relationship and causality between policy and regulation change and impact in innovative activities.
2. Understand the overall magnitude of impact of the IP regime on innovative activities
3. Create alternative scenarios of impact of broader policy approach including IP regime and other innovation incentives based on the experience of case study markets.

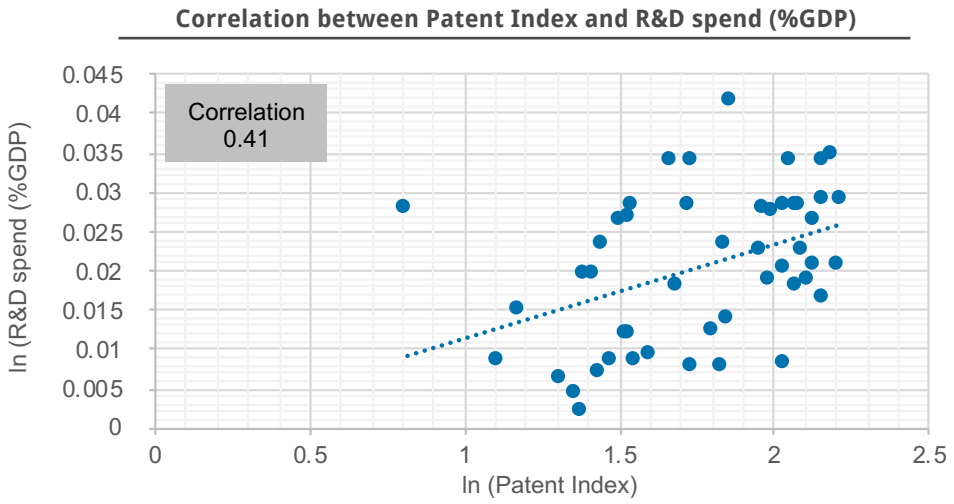
- **Literature on causality and impact of IP:**
  - Prior research has shown that patents and other forms of exclusivity for pharma and bio products such as RDP, provide companies with an incentive to invest in innovative activity to deliver new medicines.
  - These studies have found that a 1% change in the strength of a national IP environment (based on a statistical index) is associated with:[80]
    - a 2.8% increase in FDI in-flows.
    - a 2% increase in service imports.
    - a 0.7% increase in domestic R&D.

- **Determining causality and magnitude of impact.** To assess potential impact and magnitude of gains from an improvement in the IP regime, we apply the following approach:
  - **Step 1:** we construct a database including the following data:
    - **IP protection** using patent index (by US Chamber of Commerce (n=50)) as a proxy – countries are rated on a scale from 0 (lowest-weakest) to 8 (highest-strongest).
    - **Innovative and economic activity variables:**
      - R&D spending (as % of GDP).
      - Clinical trials (adjusted per population).
      - Patent numbers (adjusted per population).
      - Number of researchers (adjusted per population).
  - **Step 2:** we determine whether there is a correlation between each innovative activity variable and IP protection.
  - **Step 3:** we run regressions to analyse if there is a significant impact (causality) of IP protection on innovative activity. The coefficient for each variable will also dictate the direction and magnitude of impact (reported in appendix).

CORRELATION BETWEEN PATENT PROTECTION STRENGTH AND INNOVATIVE ACTIVITY (1/2)

- There is a positive correlation between IP protection and variables on innovative activity, i.e. the stronger the IP protection, the more innovative activity we note in each area.
- **R&D spend**, the correlation shows medium strength which can be attributed to the fact that R&D decision particularly in early stages are determined by multiple factors and internal managerial decisions.
- **Researchers employed in R&D**, the correlation shows medium to high strength which can be attributed to the increased incentives for activity in clinical research which in turn increases the demand for researchers.

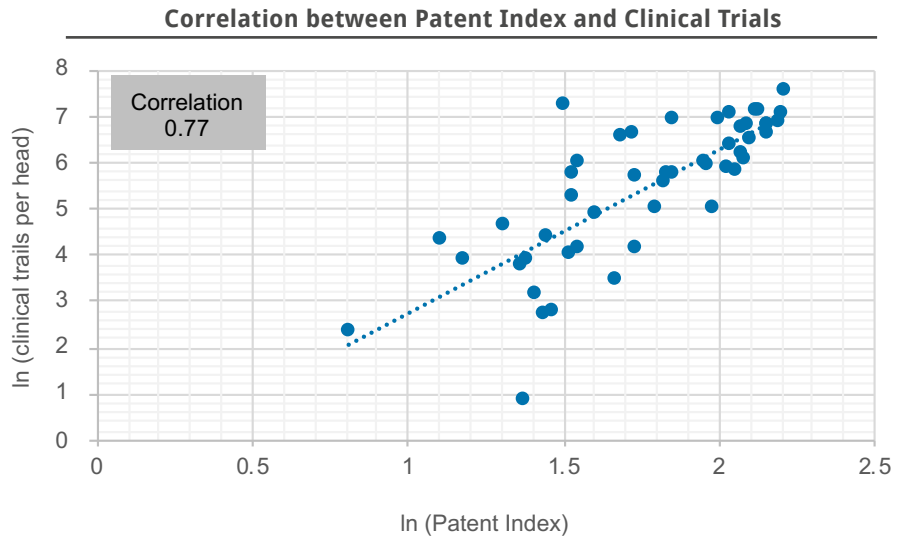


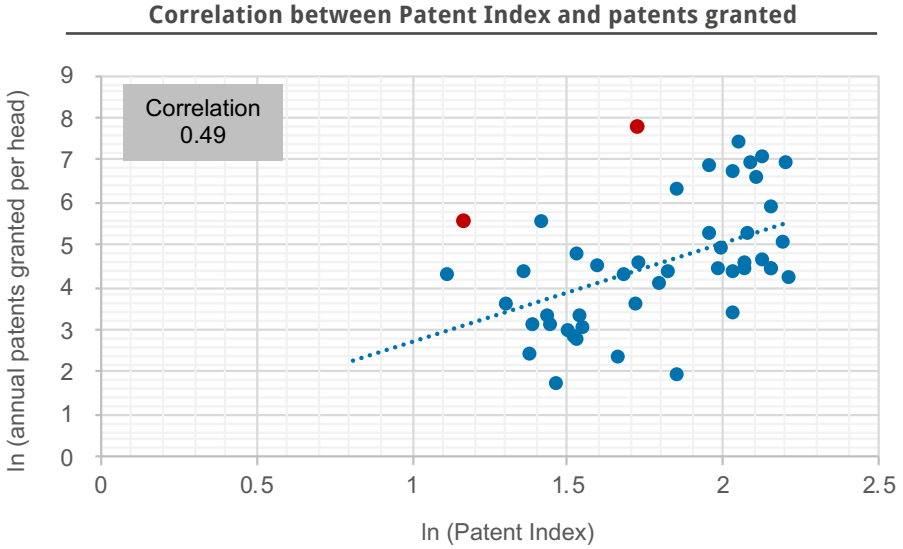


Source: CRA analysis

CORRELATION BETWEEN PATENT PROTECTION STRENGTH AND INNOVATIVE ACTIVITY (2/2)

- There is a positive correlation between IP protection and variables on innovative activity, i.e. the stronger the IP protection, the more innovative activity we note in each area.
- **Clinical trials**, the correlation shows high strength which is in line with evidence that this is one of the areas most commonly impacted by the strength of the IP protection.
- **Patents granted**, the correlation shows medium strength which can be in part attributed to significant outliers (some countries with particularly high number of patents for their size a nd IP strength – see examples in red).





Source: CRA analysis

SCENARIOS: DEVELOPING THREE 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	R&D SPEND	CLINICAL TRIALS	PATENTS	EMPLOYMENT
IP REGIME AND INNOVATION POLICY – MID GROWTH	Paced growth scenario based on an improvement of the IP regime and other innovation incentives but with limitations in implementation (based on case study markets analysis)	Annual publications growth rate (of S&T publications) at 4.10%	Annual clinical trials approved growth rate at 4.40%	Annual patents granted growth rate (by local patent office to both pharma and biotech) at 14.9%	Annual employment growth rate in pharma at 3.97%
IP REGIME AND INNOVATION POLICY – HIGH GROWTH	Escalated growth scenario based on an improvement of the IP regime and other innovation incentives with good implementation (based on case study markets analysis)	Annual publications growth rate (of S&T publications) at 4.81%	Annual clinical trials approved growth rate at 7.40%	Annual patents granted growth rate (by local patent office to both pharma and biotech) at 17.9%	Annual employment growth rate in pharma at 8.10%

Perito Moreno Glacier, Patagonia, Argentina, shutterstock.com/Circumnavigation

4.

Policy implications for Argentina

ENABLERS OF INNOVATIVE ACTIVITY AND CHALLENGES IN ARGENTINA

- Drawing from the analysis on policies, innovation base and resulting activities and discussions with global and local experts in IP, research, academia, clinical research and industry, Argentina shows:
  - A good development in education base, infrastructure and market opportunity for innovations, but
  - Lags behind in investment in research, regulatory process, system predictability and strength of IP protection
- The rest of the analysis focuses on potential gains from improving the underdeveloped enablers and particularly the strength of the IP regime.

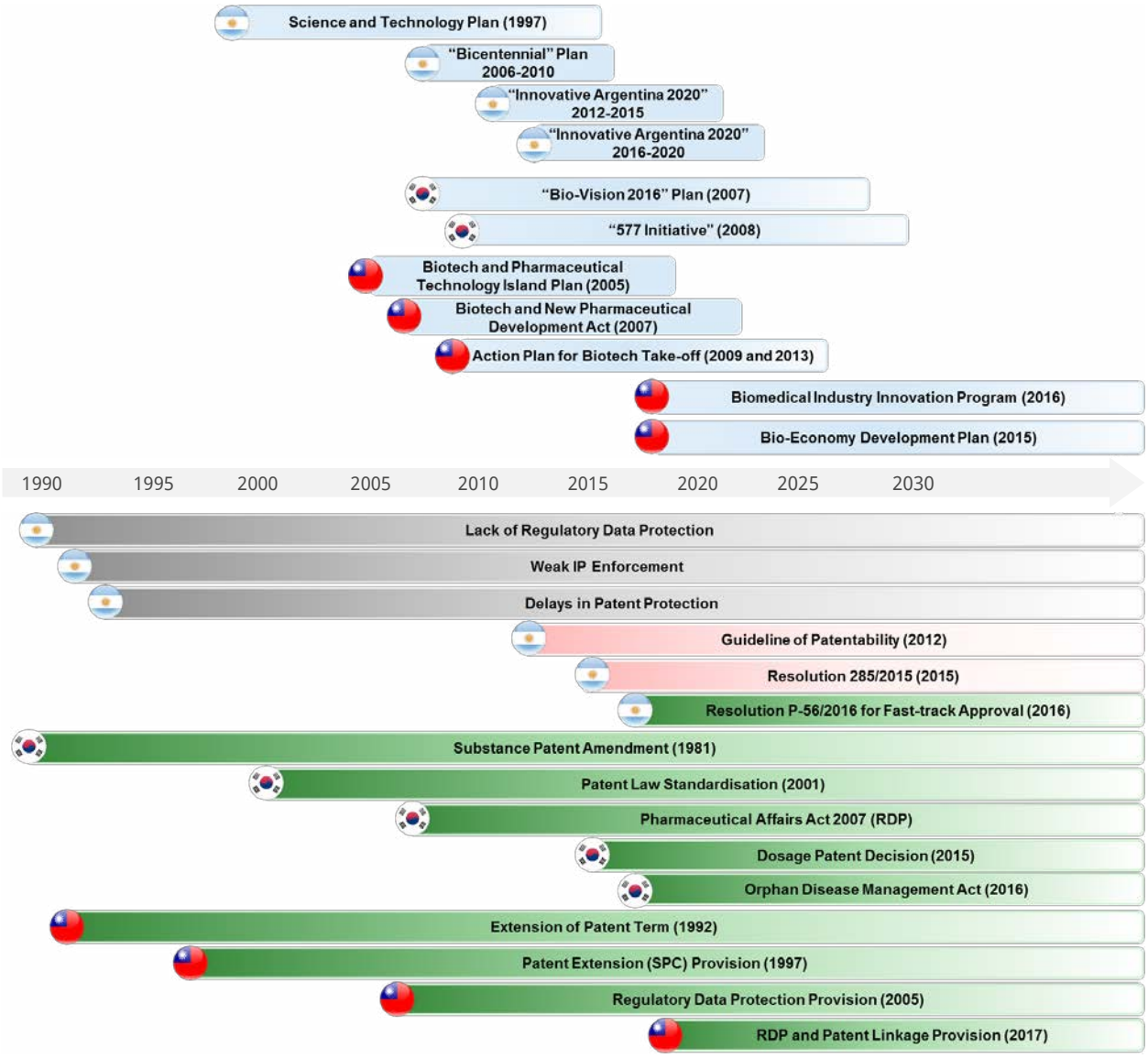
High	Enablers in Argentina	Low

	AREAS	DESCRIPTION IN ARGENTINA
ENABLERS	**Human capital and expertise**	Good availability of top universities and education attainment to higher degrees and good standards
	Infrastructure to undertake research	Good hospital infrastructure and collaboration for research
	Market opportunity for innovations	Strong healthcare system with good coverage and generally good levels of access to innovation
	Investment in research	Direct R&D spend and FDI are lagging behind case study countries but also leaders in LatAm
	Regulatory methods and process	The regulatory process is regarded by local experts and researchers as a key flaw as agencies have not developed in line with LatAm peers (Invima vs ANVISA differences)[5]
	Predictability of the system	Regarded highly unpredictable as the agenda on innovation and support for pharma and bio has had large shifts with government changes[5]
	IP protection	Weakened protection due to recent rules and methodology changes, lack of RDP and slow and inefficient processes

WHAT IF ARGENTINA HAD INSTITUTED A MORE INNOVATIVE FRIENDLY ENVIRONMENT?

- **Support for innovation in biopharma:**
  - A similar trend is noted across three markets as these have actively issues a number of plans to support innovation in the sectors.
  - Bio/pharma specific agendas were launched at similar times across countries fin the years spanning 2005 to 2007.
- **Additional support for IP:**
  - Argentina lags significantly behind in support for IP compared to South Korea and Taiwan as
    - Whereas in other markets patentability rules have been reinforced in Argentina these have weakened as a result of the guideline and resolution.
    - There is a lack of support for regulatory data protection.
    - IP related processes are slower and less efficient.

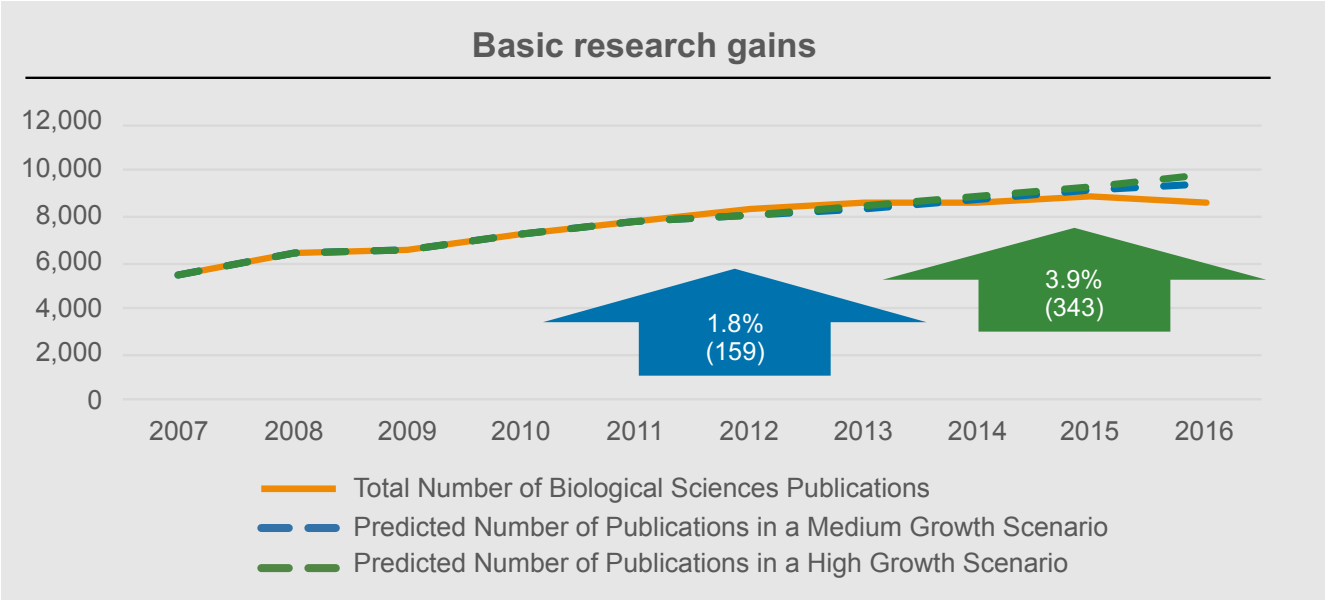
IP and innovation policies in Argentina, South Korea and Taiwan

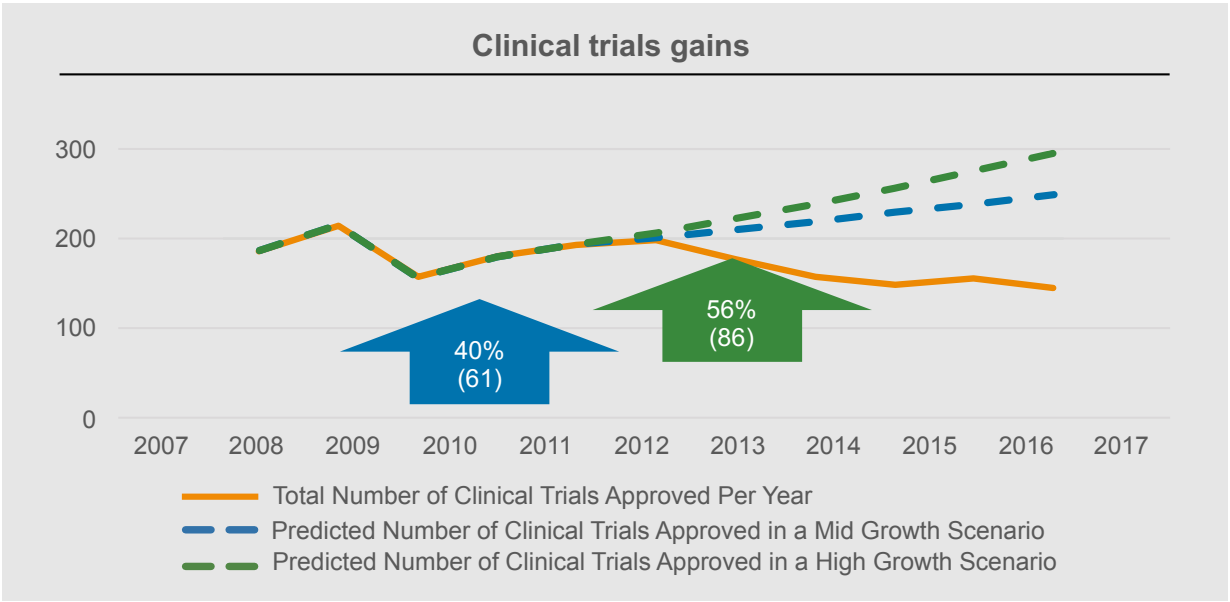


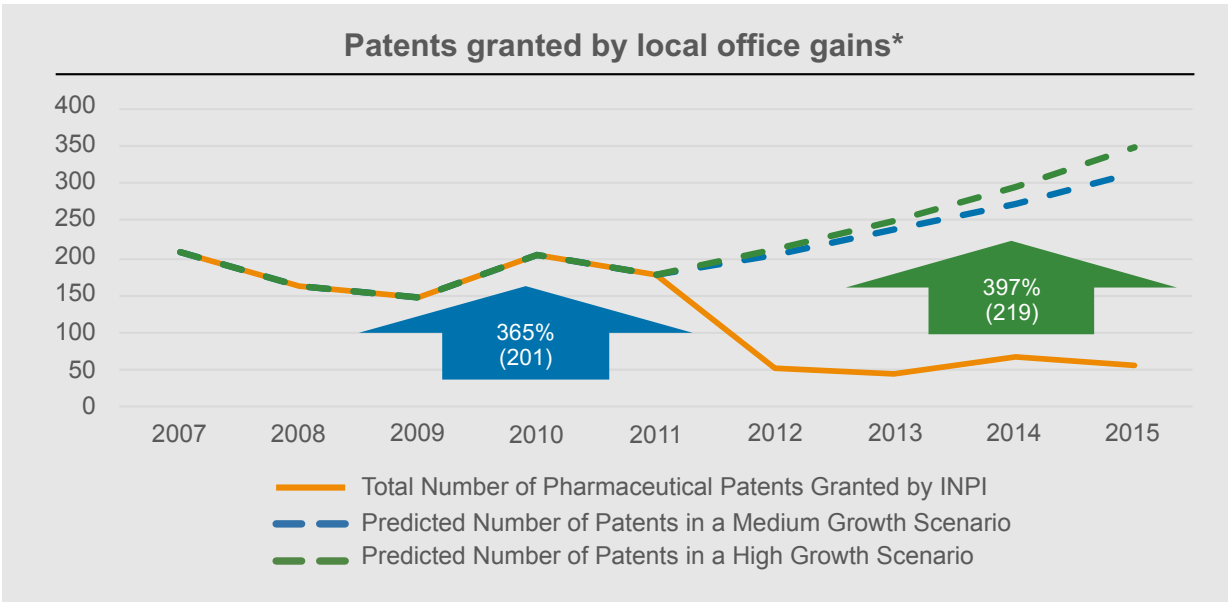
APPROACH TO DEVELOPING GAINS IN THE THREE SCENARIOS

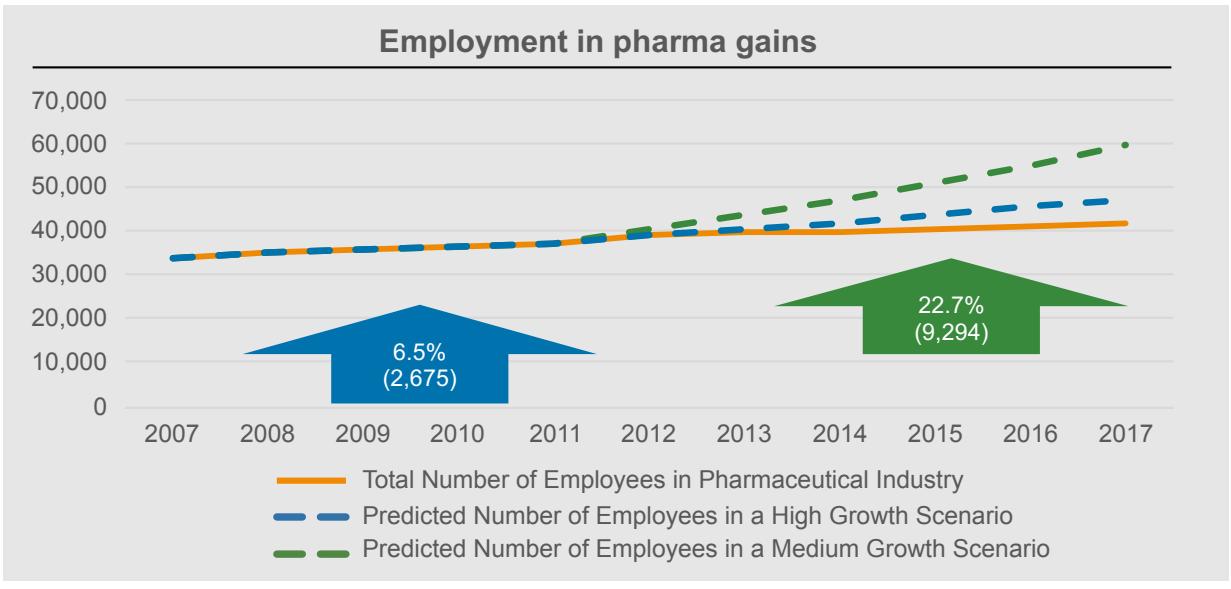
- In order to assess potential gains from an improvement in the enablers of innovation we apply the following approach:
  - ***Step 1:*** we take as baseline the level of innovative activity per indicator Argentina in 2011, which is the year prior to the first key change in IP rules (i.e. patentability guideline).
  - ***Step 2:*** we apply the average growth rates from the baseline year to last year available assuming constant growth.
  - ***Step 3:*** finally, we calculate two scenarios of gains in the difference between growth potential and absolute gains.
- We apply the methodology to four indicators of innovative and economic activity including: R&D spend, clinical trials, patents, employment in the sector.

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







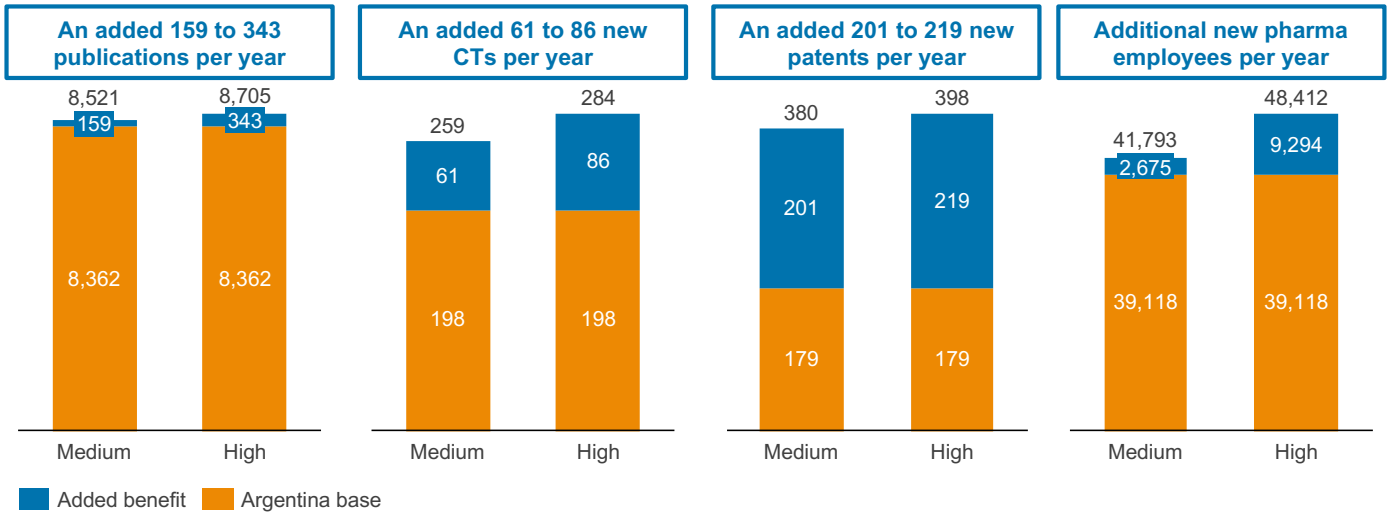


*Note: From 2011 calculations

ILLUSTRATION OF GAINS FOR ARGENTINA (GROWTH RATE GAINS)

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

- ***Significant gains*** in areas such as clinical trials (that are strongly impacted by the level of protection of data generated) and patents granted (with the most direct impact from IP rules).
- ***Moderate gains*** in employment in pharma (as these are not only research-related employees) and publications (which are also S&T and would expect less impact).



FINDINGS

1. ARGENTINA'S CURRENT INNOVATION AND POTENTIAL

Argentina lags behind LatAm and comparable OECD and Asia markets in innovation activities.

- This is noted both in the levels of activity and growth rates during the past 5 – 10 years.
- Particularly, Argentina performs below peers the clinical research outputs and patents issued locally.

However, in comparison it is a leading country in education, infrastructure and healthcare strength.

- This shows potential to unlock further value from existing resources in undertaking research activities and increasing the levels of investment, which remain suboptimal comparatively to other countries in LatAm.
- Also, the degree of development in capacity is similar to that of case study markets at the times of positive changes in innovation policy demonstrating a potential to drive a comparable growth.

An underdeveloped environment has led to a less dynamic industry with low and decreasing economic outputs.

- A decrease in growth and overall low levels of innovative activity lead to losses in employment, trade and taxes requiring a broader consideration in policy.

2. LESSONS FROM STATISTICAL ANALYSIS AND CASE STUDIES

The statistical analysis shows that a strong IP protection and patent regime leads to a positive impact across innovative and related economic activities.

- This in turn, incentivises more overall spend on research activities.

However, case studies show that a broader approach to support innovation is beneficial across activities and particularly clinical trials, patents issued and employees in research.

- This entails innovation plans in addition to strong rules on IP protection and economic incentives.

3. IMPLICATIONS FOR ARGENTINA INNOVATION AND ECONOMIC POLICY

Apply a suite of support mechanisms to unlock potential value of strong resources in Argentina and incentivise increased economic activity, that include:

Innovation plans.

- Issue *updated follow-on innovation plans* that include broad considerations on appropriate incentives for innovation activity including IP protection.
- Implement *monitoring mechanism on innovation plans* to improve accountability on implementation.

IP regime.

- Ensure the application of strong *IP rights* that allow appropriate rewards for innovation specific to pharmaceuticals and biotech.
- *Provide regulatory data protection* in line with countries of similar healthcare development and aspiration for innovation to support clinical research – an area with significant potential gains.

Direct support for research.

- Increase levels of public spending on R&D activities in general and in pharma to provide support to early research and signal an enhanced focus in the sector.
- Encourage collaboration between public and private entities in conducting research.

Support for resources.

- Increase incentives for academics in biomedical sciences to stay or return to Argentina and engage in research activities.

Macro stability.

- Increase government accountability for support for innovation to create a more predictable and supportive environment for investment in innovation.

5. Appendix

INTERVIEW PROGRAMME:
STAKEHOLDER LIST

INTERNAL/EXTERNAL	ORGANISATION	FOCUS
INTERNAL	**PhRMA**	Global
	EFPIA (x2)	Global
	J&J	Global
	Pfizer	Global
	Sanofi	Global
	Novartis	Global
	BI	Global
	Astellas	Global
	Novartis	Local
	J&J	Local
EXTERNAL	**Universidad San Andres**	IP
	Universidad Nacional de Cordoba	Researcher
	Universidad Nacional del Litoral	Researcher
	CONICET	Researcher
	Paraxel	CRO
	Abel Santos & Asociados	CRO
	Eriochem	SME

DETERMINING CAUSALITY AND MAGNITUDE OF IMPACT FROM PATENT INDEX STRENGTH ON INNOVATIVE AND ECONOMIC ACTIVITY (1/2)

R&D SPENDING (AS % GDP)

Regression output

```
. reg ln_rd_gdp ln_patent_index
```

Source	SS	df	MS	Number of obs	=	49
				F(1, 47)	=	9.51
Model	.000745666	1	.000745666	Prob > F	=	0.0034
Residual	.003684234	47	.000078388	R-squared	=	0.1683
				Adj R-squared	=	0.1506
Total	.0044299	48	.00009229	Root MSE	=	.00885

ln_rd_gdp	Coef.	Std. Err.	t	P>|t|	[95% Conf.	Interval]
ln_patent_index	.0116821	.0037877	3.08	0.003	.0040623	.0193019
_cons	-.0001486	.0068179	-0.02	0.983	-.0138644	.0135672

- **Causality:** There is a *significant* impact of IP protection (patent index) on R&D spending (as % of GDP)
- **Impact:** There is a *positive* impact of IP protection (patent index) on R&D spending (as % of GDP)

For every one percent increase in patent index score, there is a 0.012% increase in R&D spending (% of GDP)

RESEARCHERS IN R&D (PER M)

Regression output

```
. reg ln_researchers_m ln_patent_index
```

Source	SS	df	MS	Number of obs	=	42
				F(1, 40)	=	33.28
Model	23.778193	1	23.778193	Prob > F	=	0.0000
Residual	28.5757667	40	.714394167	R-squared	=	0.4542
				Adj R-squared	=	0.4405
Total	52.3539597	41	1.27692585	Root MSE	=	.84522

ln_researcher~m	Coef.	Std. Err.	t	P>|t|	[95% Conf.	Interval]
ln_patent_index	2.422147	.4198363	5.77	0.000	1.573626	3.270668
_cons	3.322734	.7610812	4.37	0.000	1.784532	4.860937

- **Causality:** There is a *significant* impact of IP protection (patent index) on the number of researchers employed in R&D.
- **Impact:** There is a *positive* impact of IP protection (patent index) on the number of researchers employed in R&D.

For every one percent increase in patent index score, there is a 2.42% increase in the number of researchers in R&D

DETERMINING CAUSALITY AND MAGNITUDE OF IMPACT FROM PATENT INDEX STRENGTH ON INNOVATIVE AND ECONOMIC ACTIVITY (2/2)

CLINICAL TRIALS TOTAL (PER POPULATION)

Regression output

```
. reg ln_ct_pop ln_patent_index
```

Source	SS	df	MS	Number of obs	=	49
				F(1, 47)	=	71.21
Model	67.4303643	1	67.4303643	Prob > F	=	0.0000
Residual	44.5076632	47	.946971557	R-squared	=	0.6024
				Adj R-squared	=	0.5939
Total	111.938028	48	2.33204224	Root MSE	=	.97312

ln_ct_pop	Coef.	Std. Err.	t	P>|t|	[95% Conf.	Interval]
ln_patent_index	3.512977	.4163092	8.44	0.000	2.675471	4.350483
_cons	-.7658544	.7493641	-1.02	0.312	-2.27338	.7416716

- **Causality:** There is a *significant* impact of IP protection (patent index) on the number of clinical trials approved.
- **Impact:** There is a *positive* impact of IP protection (patent index) on the number of clinical trials approved.

For every one percent increase in patent index score, there is a 3.52% increase in the number of clinical trials approved

PATENTS GRANTED (PER YEAR)

Regression output

```
. reg ln_researchers_m ln_patent_index
```

Source	SS	df	MS	Number of obs	=	42
				F(1, 40)	=	33.28
Model	23.778193	1	23.778193	Prob > F	=	0.0000
Residual	28.5757667	40	.714394167	R-squared	=	0.4542
				Adj R-squared	=	0.4405
Total	52.3539597	41	1.27692585	Root MSE	=	.84522

ln_researcher~m	Coef.	Std. Err.	t	P>|t|	[95% Conf.	Interval]
ln_patent_index	2.422147	.4198363	5.77	0.000	1.573626	3.270668
_cons	3.322734	.7610812	4.37	0.000	1.784532	4.860937

- **Causality:** There is a *significant* impact of IP protection (patent index) on the number of patents granted each year.
- **Impact:** There is a *positive* impact of IP protection (patent index) on the number of annual patents granted.

For every one percent increase in patent index score, there is a 2.33% increase in the number of patents granted

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