

# Value of IP for health and growth

The economic benefits of  
strengthening the environment  
for innovation in Brazil

MARCH 2020



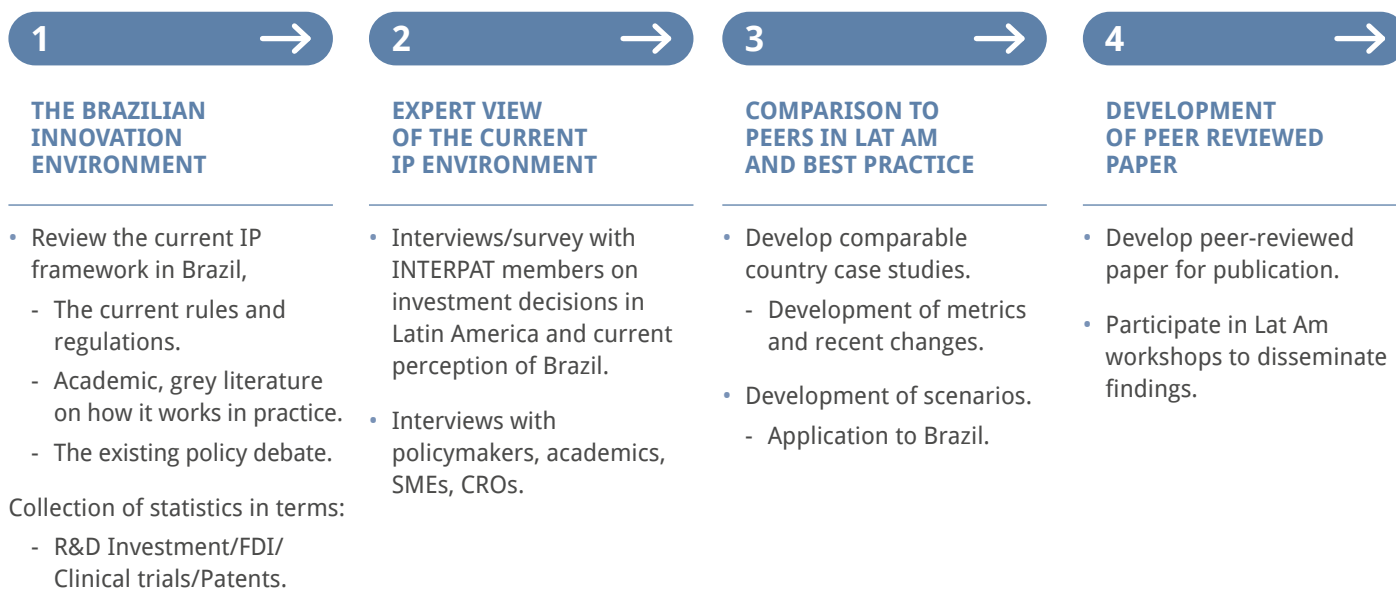
KEY  
FINDINGS



# PROJECT OBJECTIVES

- INTERPAT asked Charles River Associates (CRA) to identify and quantify the economic benefits from strengthening the environment for innovation in Brazil.
- The objective of the study is to:
  - Set out the policy framework for supporting innovation in Brazil and the current state of innovative activity.
  - Undertake a case study analysis on countries, outside the Lat Am region, with potential lessons for Brazil on how policies can improve innovation and related activities in countries.
  - Develop scenarios as to how innovative activity could change in Brazil, if policies adopted in other countries were pursued.
- The approach builds on a similar analysis applied to Argentina in 2018.

# RESEARCH STEPS



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

- We have reviewed more than 60 international and local publications on the current challenges in the IP regime and innovation policy environment in Brazil as well as its innovative performance, with a focus on the pharmaceutical industry:

## ACADEMIC PUBLICATIONS

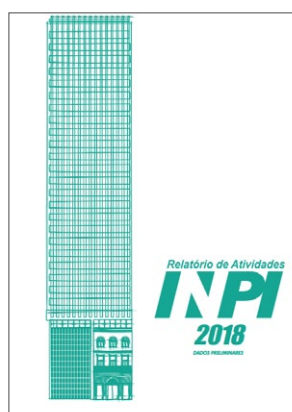
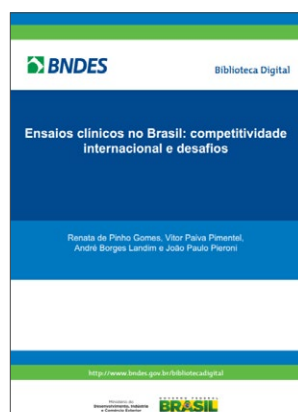
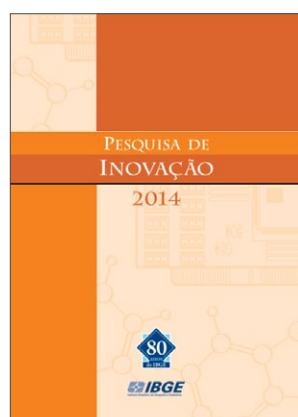
International and local academic literature including Vasconcelos & Silva (2019), De Negri & Rauen (2018), Vieira et al. 2017, Mazzucato & Penna (2016).

## INSTITUTIONAL REPORTS

A review of institutional websites, including reports by INPI, BNDES, IPEA, UNICAMP, Interfarma, OECD, Wilson Center Latin American Program and WIPO.

## GREY LITERATURE

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



# TO UNDERSTAND BRAZIL'S INNOVATION ENVIRONMENT, WE UNDERTOOK A COMPREHENSIVE INTERVIEW PROGRAMME

- **INTERVIEWS WITH 7 INTERNAL EXPERTS**

were used to provide industry view of Brazil's IP policy and innovation environment and remaining key gaps and challenges

- Pfizer; UCB; Novartis; Janssen; Grünenthal
- INTERFARMA

- Local/ regional teams could provide context and validation of findings identified through literature.

- **7 EXTERNAL INTERVIEWS**

with policymakers, academics, local CROs and bio-techs, and influencers of the current innovation environment were used to develop understanding of the broader innovation policy in Brazil

- INPI
- IPEA
- CIPD
- Aché

- Policy experts revealed plans for imminent reforms to innovation policy, while academics and local industry provided suggestions for additional improvements.
- Interviews with experts from other relevant stakeholders were also requested.

# THE FOLLOWING INDICATORS WERE ASSESSED TO UNDERSTAND THE OVERALL INNOVATIVE ENVIRONMENT

## POLICY ENVIRONMENT



## RESOURCES FOR INNOVATION

### OVERALL INNOVATION SUPPORT

- National innovation plans.
- Targeted initiatives e.g. the Brazilian Initiative on Precision Medicine (BIPMed).

### 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 (FDI).

### 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.

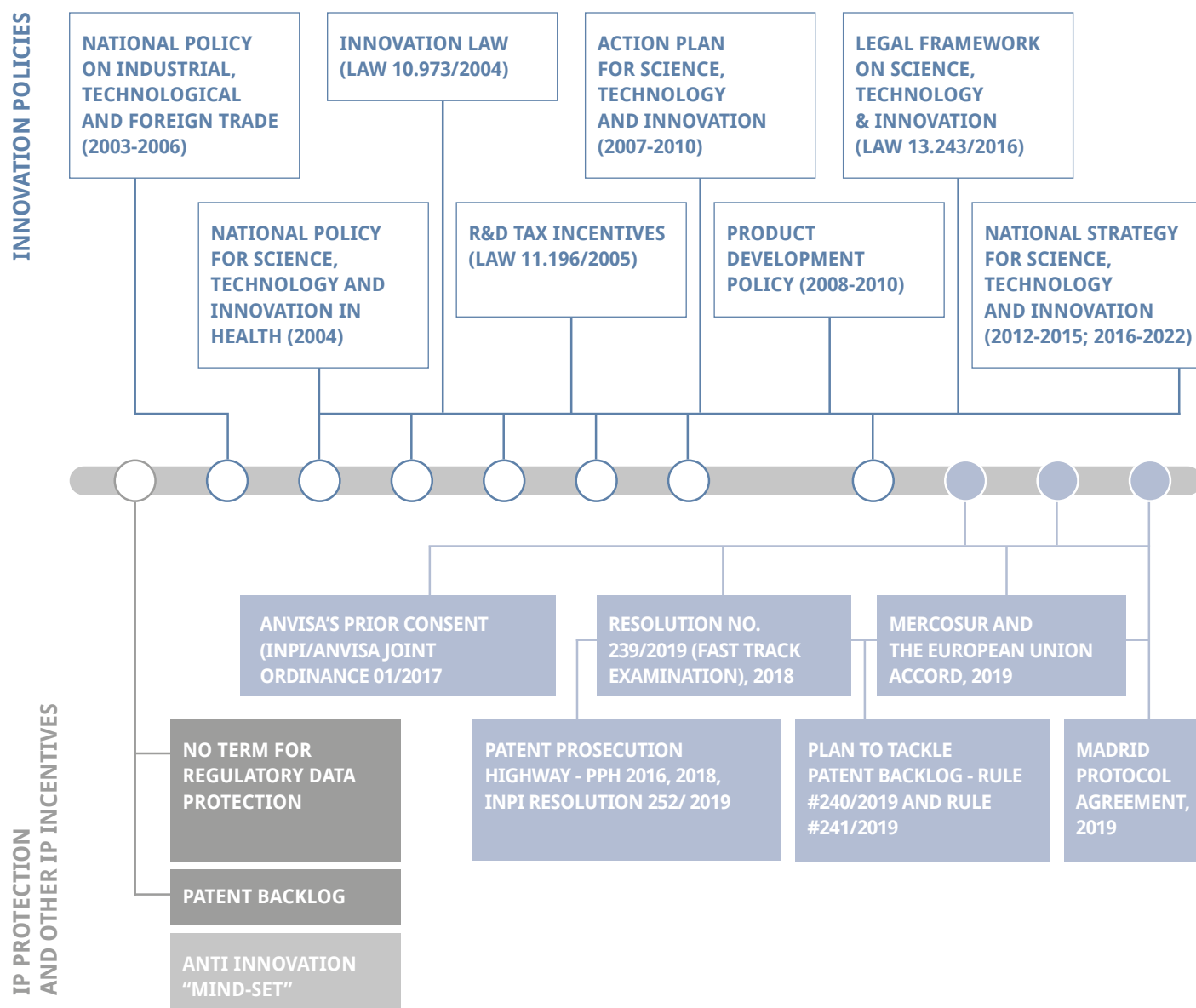
### TAXES

- Tax revenues from pharma and biotech.

### TRADE

- Imports vs exports in pharma and biotech.

# BRAZIL HAS IMPLEMENTED PRO-INNOVATION POLICIES BUT CAN STILL IMPROVE ON RDP AND ADDRESSING THE PATENT BACKLOG



**ALMOST 210 PATENT EXAMINERS HAVE BEEN HIRED TO ALSO ADDRESS THE PATENT BACKLOG.**

\* RDP – Regulatory Data Protection.

\* In relation to pharmaceutical products for human use, since Law n. 10,603/2002 establishes terms regulatory data protection for veterinary pharmaceutical products, fertilizers, pesticides, their components and the like.

\* Patent Backlog: Expression used for the patent applications, with requested examination and pending decision.



# BRAZIL: ASSESSMENT OF PERFORMANCE

- Brazil is an innovation leader in the LatAm region, with comparatively strong human resources, R&D investment and early stage innovative activity. However improvements are still welcomed in terms of healthcare infrastructure investment and patent system strength.
- Despite long-standing aspirations of economic growth, Brazil's innovation environment require changes to reach the same level of OECD counterparts. This suggests that Brazil should ensure an environment that supports the development of local human resources and investment in infrastructure to encourage R&D investment.
- Reforms to strengthen the IP environment could drive patent applications and pharma confidence to conduct local clinical trials and licensing partnerships.

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

Improving performance →



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

# CASE STUDY ANALYSIS AND SCENARIOS: FOCUSING ON JAPAN, SOUTH KOREA, CHINA AND TAIWAN

## CASE STUDY SELECTION:

**Our research and interview insights reveal that Brazil's key innovation policy gaps are:**

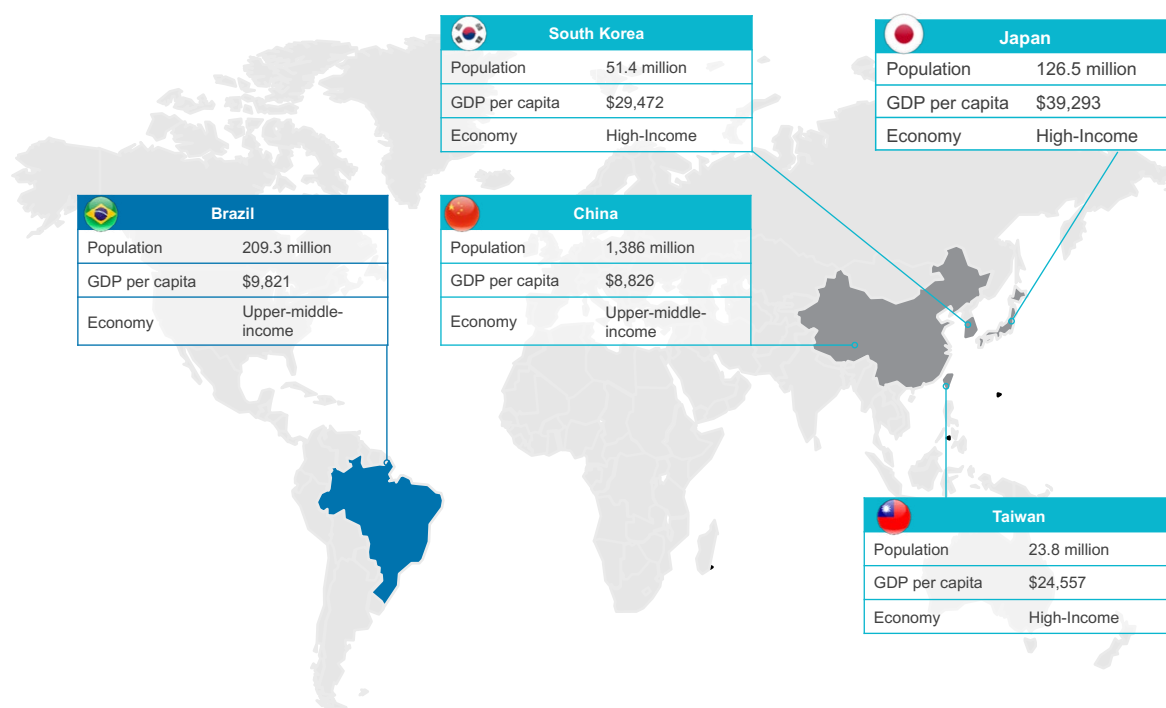
- Lack of term for RDP.
- Patent backlog.
- Prior focus on pro “manufacturing” rather than “innovation” by some academics and local companies\*.

**Our criteria suggests four countries that Brazil could learn from**

- Lessons from South Korea and Taiwan were applicable to Argentina. However, they remain relevant for Brazil. In addition, we examine two new countries: China and Japan.
- **Implementation of RDP:** Japan; South Korea.
- **Reduction of patent backlog:** Taiwan; Japan.

We note that Brazil's economic size and therefore potential for innovation capacity is much larger than South Korea and Taiwan.

- **Comparable economy, increasingly pro-innovation:** China.



\* CRA External Interview Program.

RDP – Regulatory Data Protection.

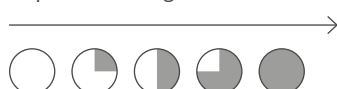
# IMPACT ATTRIBUTABLE TO THE CHANGE IN REGULATION IN A 5-YEAR PERIOD: SUMMARY

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

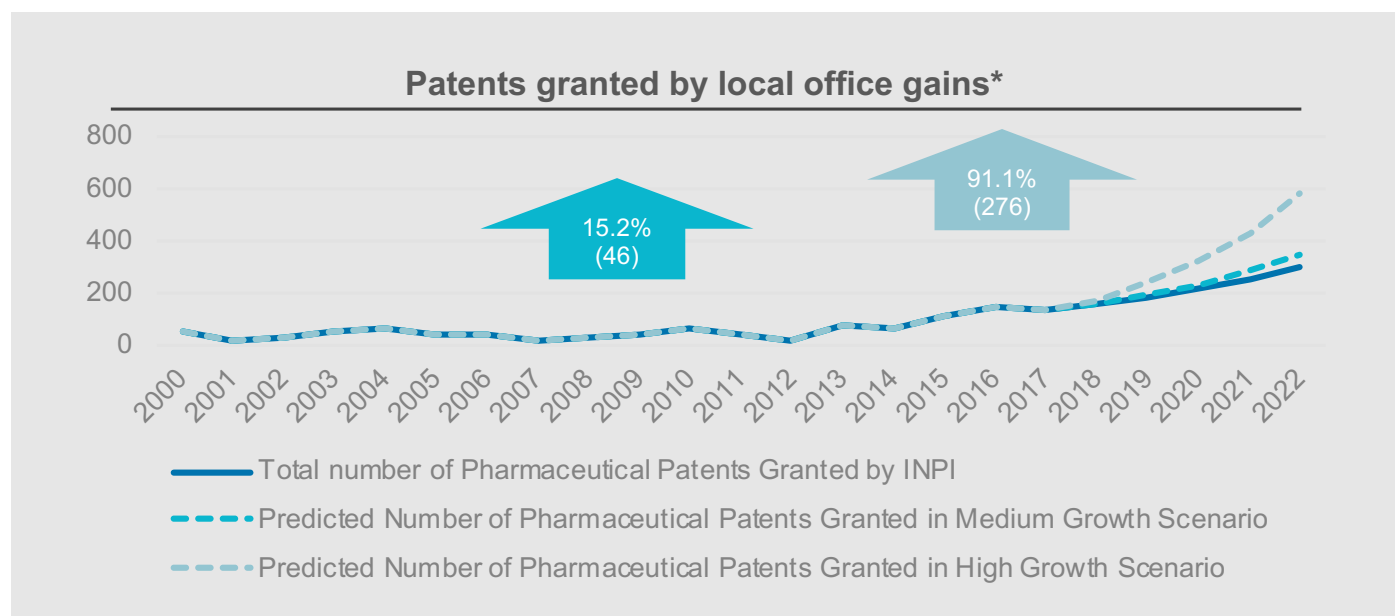
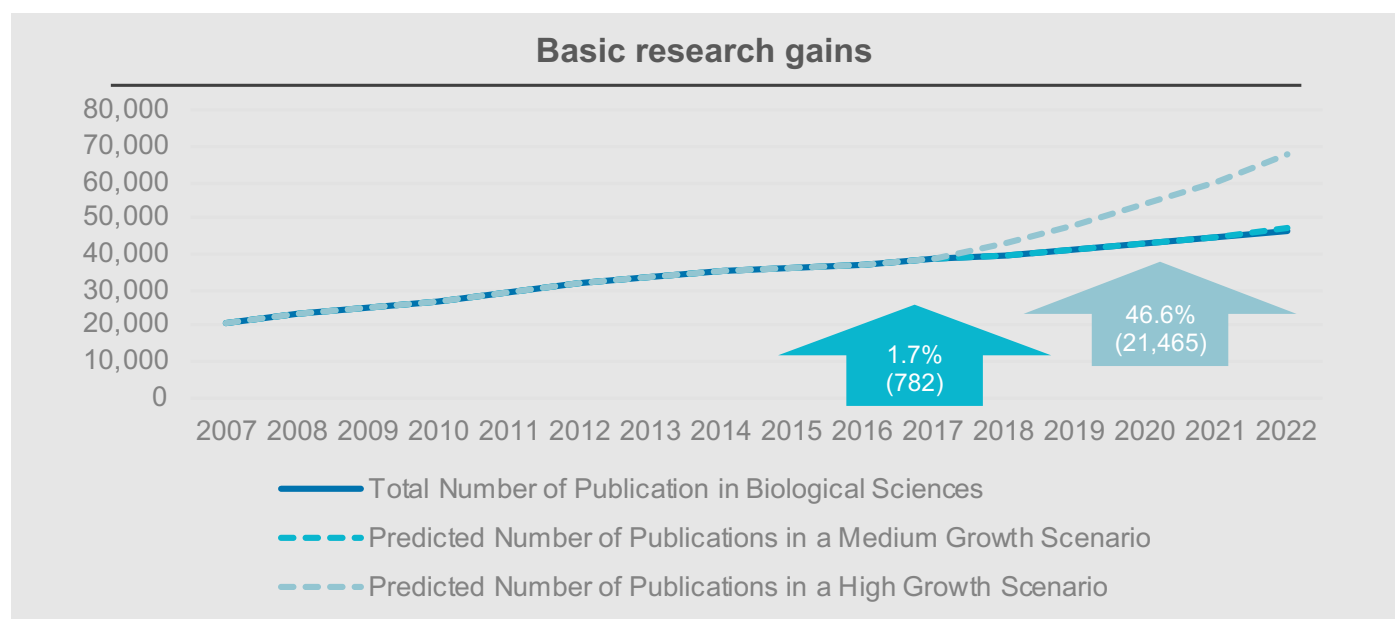
		Growth	Attributable to regulation	Growth	Attributable to regulation	Growth	Attributable to regulation	Growth	Attributable to regulation
<b>Innovative Activity</b>	BERD	11%		14%		26%		4%	
	Early research (publications)	4%		4%		12%		-1%	N/A
	Clinical trials (All)	7%		17%		16%		-3%	N/A
	Patents (local residents)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

Impact of the regulation

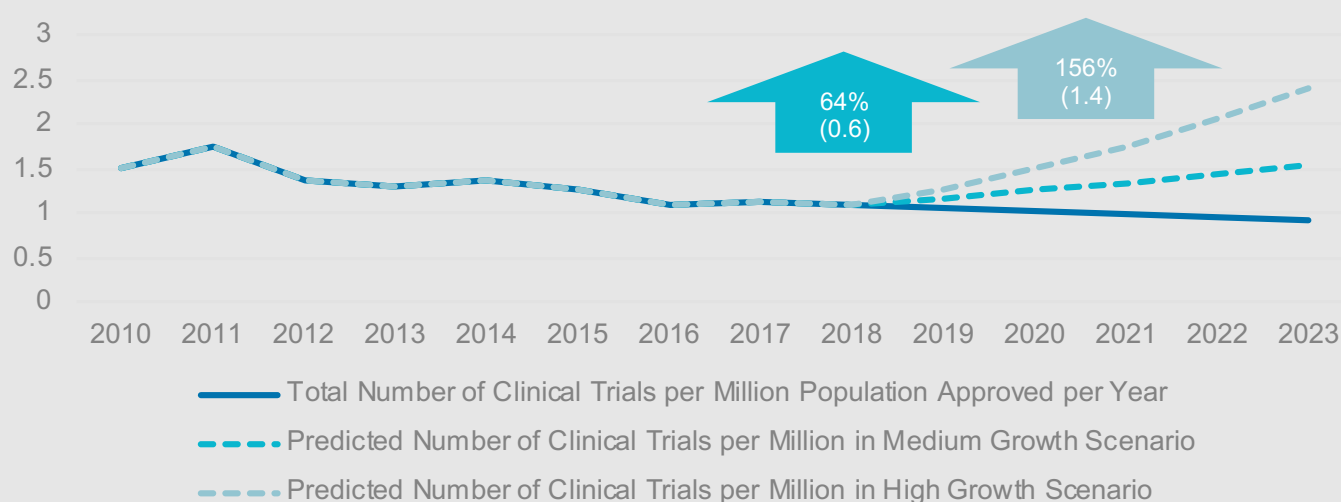
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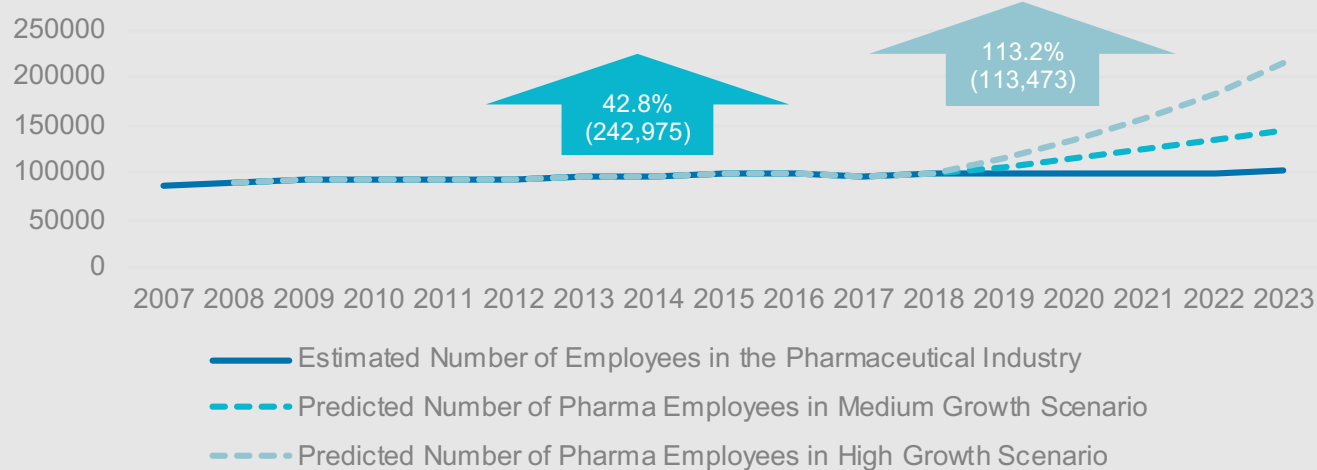
# SCENARIO ANALYSIS ACROSS INNOVATIVE AND ECONOMIC ACTIVITY IN BRAZIL: ABSOLUTE GAINS AND GROWTH POTENTIAL (ON AVERAGE)



### Clinical trials gains



### Employment in pharma gains



**Note:** the number of employees in the pharmaceutical industry was estimated based on ILO data for the number of employees in knowledge intensive industries and the number of pharmaceutical industry employees in 2016. The employment ratio of pharmaceutical to total knowledge intensive industries is assumed constant throughout the years.

# KEY FINDINGS

## 1. BRAZIL'S CURRENT INNOVATION CAPACITY AND POTENTIAL

**Brazil leads the LatAm region in many innovation activities, but still trails OECD and Asia markets in many innovation activities**

- These include businesses expenditure on R&D, the strong educational attainment of the population, growing number of patent filings and international S&T collaborative activities. Compared to the OECD and Asian markets, R&D investment and spending on healthcare infrastructure remain low, leading to lower scientific publications and clinical trials in Brazil.

**The result was a less dynamic industry but with opportunity to increase innovative and economic activity**

A decline in growth and overall low levels of innovative activity lead to losses in employment, trade and taxes.

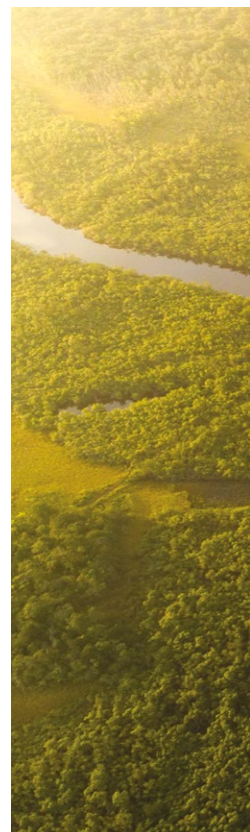
## 2. LESSONS FROM STATISTICAL ANALYSIS AND CASE STUDIES

**Statistical analysis shows that IP protection leads to a positive impact across innovative and related economic activities**

- This in turn, incentivises more overall spend on research activities. Indeed, applying updated data illustrates an even stronger statistical association between IPR and innovative activities such as R&D.

**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 BRAZIL'S INNOVATION AND ECONOMIC POLICY

#### **Regulatory Data Protection**

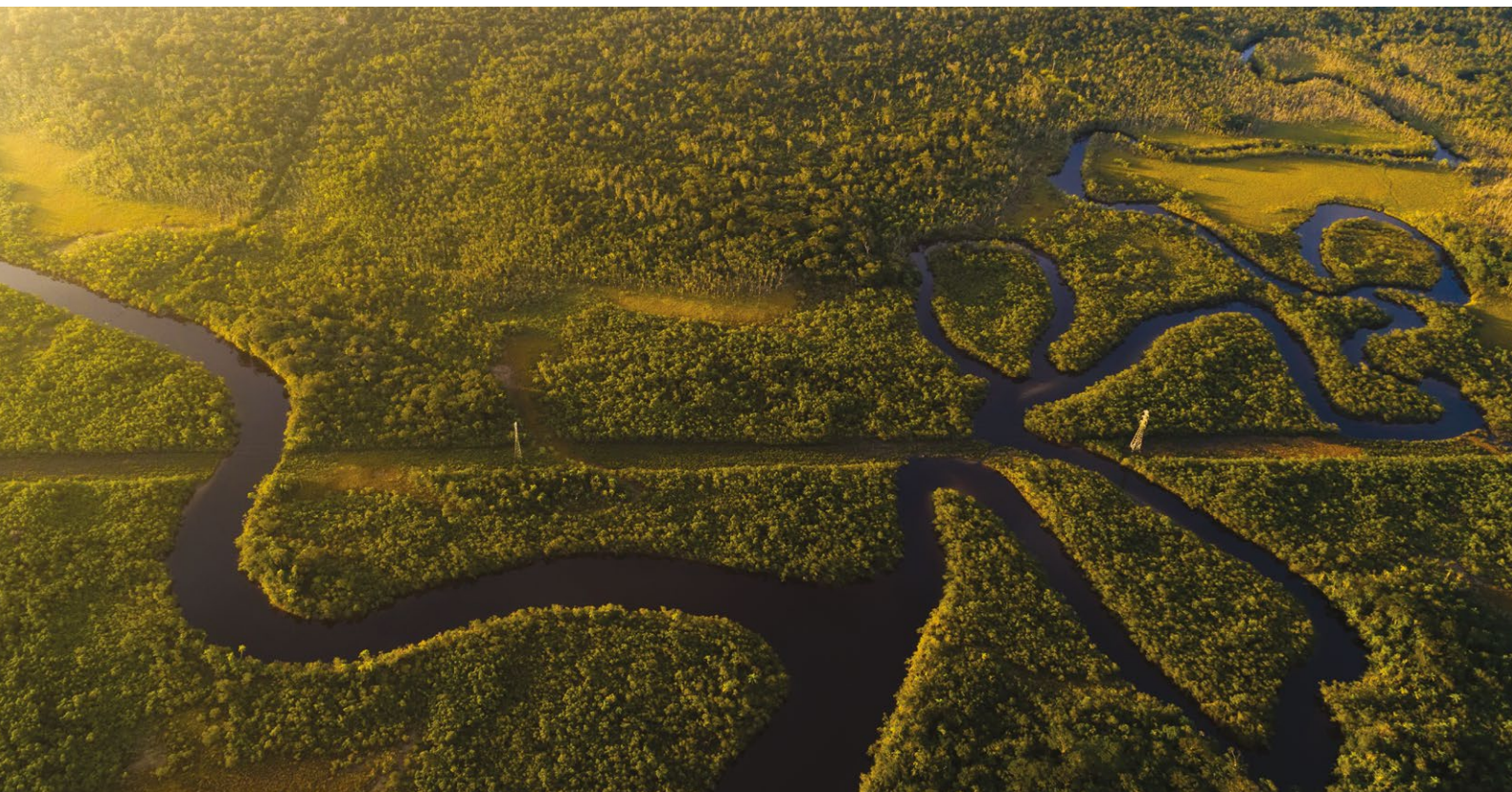
- Innovators would be able to invest in clinical trials and manufacturing with security that their innovation would be protected. RDP can also support local investment in clinical research.

#### **Direct support for research**

- Lessons from China highlight the value of targeted programs of investment in the science and technology sector. 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**

- Increase incentives for academics in biomedical sciences to stay or return to Brazil and engage in research activities in order to leverage their strong academic potential.



Amazon Rainforest in Brazil, shutterstock.com/Gustavo Frazao



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