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BUILDING THE BIOECONOMY 4TH EDITION

National Biotechnology Industry Development Strategies Globally

This report was commissioned by the Biotechnology Industry Organization. The views represented here are those of the authors only.

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TABLES AND FIGURES

LIST OF ABBREVIATIONS

ANVISA	Brazilian National Health Surveillance Agency
FDA	US Food and Drug Administration
FDI	Foreign direct investment
GCP	Good Clinical Practices
GMP	Good Manufacturing Practices
GM	Genetically Modified
IP	Intellectual Property
IPRs	Intellectual Property Rights
IRP	International Reference Pricing
NGO	Non-Governmental Organization
OECD	Organisation for Economic Co-operation and Development
PCT	Patent Cooperation Treaty
PRO	Public Research Organization
RDP	Regulatory Data Protection
R&D	Research and Development
SME	Small and Medium Enterprises
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USTR	US Trade Representative
VC	Venture Capital
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

It is worth starting this edition of *Building the Bioeconomy* with what is not only the basic fact of globalization, but also its actual outcome. Today's global economy is inter-linked, inter-dependent and open for business in a way that it was impossible logistically, politically or financially a mere generation ago.

Much of the basis for current and future economic development and growth lies in those industries and sectors which are part of the knowledge-intensive economy. Industries and sectors that are defined by a need for constant and continuous innovation are also industries that can live and thrive anywhere in the world. Biotechnology is perhaps one of the best examples of this new reality. This year's edition of *Building the Bioeconomy* both confirms that this is the reality and shows how growing numbers of countries are responding and acting accordingly.

2017 marks the fourth edition of the *Building the Bioeconomy* series of papers examining national biotechnology industrial policies. The overriding purpose of this series has always been to examine international experiences and identify best practices and experiences: Which countries have been successful in developing their biotechnology sectors and how have they done it?

Within the context of globalization what is increasingly emerging is a real competition between the world's forward-thinking economies looking to build or increase their biotechnology capacity. Depending on their starting point more and more countries are asking themselves how they can improve their performance; catch up to the top-performers; or stay ahead of the competition.

Indeed, one of the revelations of this year's report – in large measure due to the substantial increase in the number of countries examined from 16 to 26 – is the fact that many countries are recognizing that globalization does allow them to change their economic model and basis for development and growth. For many biotechnology is a field identified as a strategic priority.

The below table lists the 26 countries included in this year's report. The mix of countries is both geographically and socio-economically diverse. *Building the Bioeconomy* includes economies from all major regions of the world and a broad spectrum of income groups as defined by the World Bank.

Building the Bioeconomy 2017 economies by World Bank income group

Lower-middle-income economies	Upper-middle-income economies	High-income economies	High-income OECD Members
India	Argentina	Saudi Arabia	Australia
Indonesia	Brazil	Singapore	Chile
	China	Taiwan	Denmark
	Colombia	UAE	Ireland
	Malaysia		Israel
	Mexico		Japan
	Russia		South Korea
	South Africa		Switzerland
	Thailand		UK
	Turkey		U.S.

Source: World Bank (2017)

Every country is different and has its own particular set of circumstances and starting points with regards to natural resources, socio-economic and demographic make-up as well as legal and cultural history. Yet as this edition of *Building the Bioeconomy* demonstrates again there are a set of universal principles and factors that heavily influence whether or not a given economy is likely to have success in stimulating the development of its biotechnology industries.

Measuring biotech policy performance

A key feature of the *Building the Bioeconomy* series has been the identification of those factors and public policies that enable biotechnology innovation. Based on the existing literature and experience of those economies that have been successful in building an advanced biotech capacity it is possible to piece together a set of principles and factors which, evidence suggests, are enablers of biotechnology innovation. What are these factors? Can they be measured? And how do they impact actual, real-world biotechnology outputs?

These are some of the key questions that the Biotech Policy Performance Measure (the "Measure") seeks to measure. First introduced in the 2015 edition of the report this tool provides readers a quick overview of a given economy's policy framework and performance in relation to the other economies sampled. This year the Measure has been expanded and now includes 28 indicators. These are evenly divided between 15 measures of policy inputs and 13 indicators of biotechnology outputs. Together these indicators provide a full and detailed measure of the complete biotechnology environment for a given economy.

The table on the following three pages shows the overall results for the Biotech Policy Performance Measure. Economies move from left to right in the tables from those economies that have the most challenging environments for both policy inputs and biotech outputs to those with the most attractive policy environments and accompanying high levels of biotechnology outputs.

Measuring Policy Inputs and Biotech Outputs: The Biotech Policy Performance Measure

Inputs	Indonesia	India	Mexico	Brazil	UAE	Colombia	Turkey	Saudi Arabia	Thailand
Factor 1: Human capital									
Number of researchers per million population	Challenging	Challenging	Challenging	Challenging	NA	Challenging	Mixed	NA	Challenging
Life sciences graduates (PhD & Masters), per million population	Challenging	NA	Challenging	Mixed	NA	Challenging	Challenging	NA	NA
Factor 2: Infrastructure for R&D									
R&D spending % of GDP	Challenging	Mixed	Challenging	Mixed	Challenging	Challenging	Mixed	Challenging	Challenging
BERD spending as a % of total	NA	NA	Challenging	NA	NA	NA	Mixed	NA	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA	NA	Challenging	NA	NA	NA	NA	NA	NA
Biotech R&D as a percentage of BERD	NA	NA	Challenging	NA	NA	NA	NA	NA	NA
Factor 3: Intellectual property protection	Challenging	Challenging	Mixed	Challenging	Challenging	Mixed	Mixed	Mixed	Challenging
Factor 4: The regulatory environment	Challenging	Challenging	Mixed	Challenging	Attractive	Mixed	Challenging	Mixed	Challenging
Factor 5: Technology transfer and commercialization frameworks									
University/PRO-industry tech transfer frameworks	Challenging	Challenging	Challenging	Mixed	Mixed	Challenging	Mixed	Mixed	Challenging
Private to private licensing and commercialization activity	Challenging	Challenging	Mixed	Mixed	Mixed	Challenging	Mixed	Attractive	Challenging
Factor 6: Market and commercial incentives									
Biopharmaceutical pricing and reimbursement policies	Mixed	Challenging	Challenging	Challenging	Mixed	Challenging	Challenging	Mixed	Challenging
R&D tax incentives	Challenging	Attractive	Mixed	Mixed	NA	Mixed	Attractive	Challenging	Mixed
Factor 7: Rule of law	Mixed	Challenging	Challenging	Mixed	Mixed	Challenging	Challenging	NA	Challenging
Outputs									
Scientific publications per million population	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete
Quality of academic publications	Mixed	Struggling to compete	Struggling to compete	Struggling to compete	NA	NA	Struggling to compete	NA	NA
Clinical trials per million population to date	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Mixed
Clinical trials for biologics per million population to date	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed
Early phase (Phase I and II) clinical trials for biologics, per million population to date	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed
Biotechnology triadic patenting, share of global total average 1999-2012	Struggling to compete	Mixed	Mixed	Mixed	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	Struggling to compete	Struggling to compete	Highly competitive	Mixed	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed
National % share total number of patents from top 50 PCT applicants: universities, 2015	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete
Biotechnology crops, hectares under cultivation, % of total 2016	Struggling to compete	Highly competitive	Mixed	Highly competitive	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Struggling to compete
BCI Survey Ranking 2016	Struggling to compete	Mixed	Mixed	Struggling to compete	Highly competitive	Struggling to compete	Struggling to compete	Highly competitive	Struggling to compete
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2016	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Mixed
No of Biotechnology firms, per million population	NA	NA	Struggling to compete	Mixed	NA	NA	NA	NA	NA
Biofuels production, % of global total, 2016	Highly competitive	Mixed	Mixed	Highly competitive	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Highly competitive

Measuring Policy Inputs and Biotech Outputs: The Biotech Policy Performance Measure (cont.)

Inputs	Russia	Argentina	South Africa	China	Chile	Malaysia	Taiwan	Australia
Factor 1: Human capital								
Number of researchers per million population	Mixed	Mixed	Challenging	Mixed	Challenging	Mixed	Attractive	Attractive
Life sciences graduates (PhD & Masters), per million population	Mixed	NA	NA	NA	Challenging	NA	Attractive	Mixed
Factor 2: Infrastructure for R&D								
R&D spending % of GDP	Mixed	Challenging	Mixed	Mixed	Challenging	Mixed	Attractive	Mixed
BERD spending as a % of total	Challenging	Challenging	Challenging	Attractive	Challenging	NA	Attractive	Mixed
Total biotechnology R&D expenditure, Millions USD PPP, per million population	Challenging	NA	Challenging	NA	NA	NA	NA	Challenging
Biotech R&D as a percentage of BERD	Challenging	NA	Mixed	NA	NA	NA	NA	Challenging
Factor 3: Intellectual property protection	Mixed	Challenging	Challenging	Challenging	Mixed	Mixed	Mixed	Attractive
Factor 4: The regulatory environment	Challenging	Mixed	Mixed	Challenging	Mixed	Mixed	Mixed	Attractive
Factor 5: Technology transfer and commercialization frameworks								
University/PRO-industry tech transfer frameworks	Challenging	Mixed	Mixed	Attractive	Mixed	Mixed	Attractive	Mixed
Private to private licensing and commercialization activity	Challenging	Mixed	Mixed	Challenging	Mixed	Mixed	Attractive	Attractive
Factor 6: Market and commercial incentives								
Biopharmaceutical pricing and reimbursement policies	Challenging	Challenging	Challenging	Challenging	Mixed	Challenging	Mixed	Challenging
R&D tax incentives	Mixed	Challenging	Mixed	Mixed	Mixed	Attractive	Mixed	Mixed
Factor 7: Rule of law	Challenging	Mixed	Mixed	Challenging	Mixed	Mixed	NA	Attractive
Outputs								
Scientific publications per million population	Mixed	Mixed	Struggling to compete	Mixed	Mixed	Mixed	Highly competitive	Highly competitive
Quality of academic publications	Struggling to compete	NA	Mixed	Struggling to compete	Mixed	NA	NA	Highly competitive
Clinical trials per million population to date	Struggling to compete	Mixed	Mixed	Struggling to compete	Mixed	Mixed	Highly competitive	Highly competitive
Clinical trials for biologics per million population to date	Mixed	Mixed	Mixed	Struggling to compete	Mixed	Mixed	Mixed	Highly competitive
Early phase (Phase I and II) clinical trials for biologics, per million population to date	Mixed	Mixed	Mixed	Struggling to compete	Mixed	Mixed	Mixed	Highly competitive
Biotechnology triadic patenting, share of global total average 1999-2012	Mixed	Mixed	Mixed	Mixed	Struggling to compete	Struggling to compete	Mixed	Highly competitive
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	Struggling to compete	Highly competitive	Mixed	NA	Mixed	Struggling to compete	Mixed	Mixed
National % share total number of patents from top 50 PCT applicants: universities, 2015	Struggling to compete	Struggling to compete	Struggling to compete	Highly competitive	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete
Biotechnology crops, hectares under cultivation, % of total 2016	Struggling to compete	Highly competitive	Mixed	Highly competitive	Mixed	Struggling to compete	Struggling to compete	Mixed
BCI Survey Ranking 2016	Mixed	Struggling to compete	Mixed	Mixed	NA	NA	Highly competitive	Struggling to compete
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2016	Struggling to compete	Struggling to compete	Mixed	Mixed	Mixed	Highly competitive	Mixed	Highly competitive
No of Biotechnology firms, per million population	NA	NA	Struggling to compete	NA	NA	NA	NA	NA
Biofuels production, % of global total, 2016	Struggling to compete	Highly competitive	Struggling to compete	Highly competitive	Struggling to compete	Struggling to compete	Struggling to compete	Mixed

Measuring Policy Inputs and Biotech Outputs: The Biotech Policy Performance Measure (cont.)

Inputs	Ireland	Japan	Korea	Israel	UK	Singapore	Denmark	Switzerland	US
Factor 1: Human capital									
Number of researchers per million population	Mixed	Attractive	Attractive	Attractive	Mixed	Attractive	Attractive	Attractive	Mixed
Life sciences graduates (PhD & Masters), per million population	Mixed	NA	Mixed	Attractive	Attractive	Attractive	Mixed	Attractive	Mixed
Factor 2: Infrastructure for R&D									
R&D spending % of GDP	Mixed	Attractive	Attractive	Attractive	Mixed	Attractive	Attractive	Attractive	Attractive
BERD spending as a % of total	Mixed	Attractive	Attractive	Challenging	Mixed	Mixed	Mixed	Attractive	Attractive
Total biotechnology R&D expenditure, Millions USD PPP, per million population	Mixed	Mixed	Mixed	Mixed	NA	NA	Attractive	Attractive	Attractive
Biotech R&D as a percentage of BERD	Attractive	Challenging	Mixed	Mixed	NA	NA	Attractive	Attractive	Mixed
Factor 3: Intellectual property protection	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive
Factor 4: The regulatory environment	Mixed	Attractive	Attractive	Mixed	Attractive	Attractive	Mixed	Mixed	Attractive
Factor 5: Technology transfer and commercialization frameworks									
University/PRO-industry tech transfer frameworks	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive
Private to private licensing and commercialization activity	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive
Factor 6: Market and commercial incentives									
Biopharmaceutical pricing and reimbursement policies	Mixed	Mixed	Challenging	Mixed	Mixed	Mixed	Mixed	Mixed	Attractive
R&D tax incentives	Attractive	Mixed	Mixed	Attractive	Attractive	Attractive	Attractive	Mixed	Mixed
Factor 7: Rule of law	NA	Attractive	Attractive	NA	Attractive	Attractive	Attractive	NA	Attractive
Outputs									
Scientific publications per million population	Mixed	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive
Quality of academic publications	Highly competitive	Mixed	Mixed	Mixed	Highly competitive	NA	Highly competitive	Highly competitive	Highly competitive
Clinical trials per million population to date	Highly competitive	Mixed	Mixed	Highly competitive	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive
Clinical trials for biologics per million population to date	Highly competitive	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive
Early phase (Phase I and II) clinical trials for biologics, per million population to date	Highly competitive	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive
Biotechnology triadic patenting, share of global total average 1999-2012	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Mixed	Highly competitive	Highly competitive	Highly competitive
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	Highly competitive	Mixed	Highly competitive	Struggling to compete	Highly competitive	Mixed	Highly competitive	Highly competitive	Highly competitive
National % share total number of patents from top 50 PCT applicants: universities, 2015	Struggling to compete	Highly competitive	Highly competitive	Mixed	Mixed	Highly competitive	Mixed	Mixed	Highly competitive
Biotechnology crops, hectares under cultivation, % of total 2016	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Highly competitive
BCI Survey Ranking 2016	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	NA	Highly competitive	Struggling to compete
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2016	Mixed	Highly competitive	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive
No of Biotechnology firms, per million population	Highly competitive	Struggling to compete	Mixed	Highly competitive	Mixed	NA	Mixed	Mixed	Highly competitive
Biofuels production, % of global total, 2016	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Struggling to compete	Highly competitive

Interpreting the Biotech Policy Performance Measure – Key findings

So what stands out from the 2017 results of the Measure?

Key finding 1: Measuring = managing

First, is the relative lack of concrete data for many of the countries added this year. Many of the new countries do not have data readily available on key indicators including number of researchers in R&D, life sciences graduates, business and enterprise expenditure on R&D and biotechnology specific R&D spending. For other countries – such as Singapore and Taiwan – the data is only available through national statistics offices and not international databases. The best possible comparable data is always what has been centrally collected or processed with any standardization methodology consistently applied by the collecting body.

Key finding 2: Newly added OECD economies should be more competitive

Second, of the new additions Australia and Chile stand out as two developed, high-income OECD economies whose policy environments are relatively weak. Although Australia has a number of strengths its main weaknesses compared to other OECD markets lay in its biopharmaceutical policy inputs and related outputs. In particular a stringent pricing and reimbursement environment on the input side is accompanied by relatively low levels of pharmaceutical product registration measured over close to a 20-year period as well as a low ranking by biopharmaceutical executives in Australia on the Biopharmaceutical Competitiveness Survey 2016. This is surprising given Australia's other intrinsic strengths as a high-income innovation driven economy with good levels of technical capacity. In this sense Australia could be more competitive than it currently is. Looking at Chile many of its policy inputs are

when compared to the other 25 countries not competitive. In fact looking at the raw numbers Chile is behind not only other OECD countries but even regional peers including Argentina and Brazil. For instance, as a percentage of its GDP Brazil spends three times as much on R&D as Chile; 1.23% versus 0.38%. This despite Brazil having an estimated 2015 per capita income at PPP close to 50% lower than Chile at USD15,473 versus USD23,366 for Chile. Equally, Argentina has rates of researchers in R&D almost three times as high as Chile at 1,202 per million population compared with Chile's 428. And looking at biotechnology specific expertise as measured by life sciences graduates, Chile again is far behind OECD countries with a per million population rate of 23.83 graduates (PhD and Masters) compared to 135.88 in Israel and over 200 in the UK; two of the top performers.

Key finding 3: Policy inputs still equal biotech outputs

Finally, and most importantly, just as with last year's edition what stands out most clearly from the results of the Biotech Policy Performance Measure is the link between policy inputs and biotech outputs.

Moving from left to right on the above tables it is clear that economies that tend to have in place policies that create an enabling environment tend also to be more competitive when it comes to biotechnology outputs. Few countries with challenging policy environments across the board are competitive on any of the 13 biotech outputs indicators measured.

In fact the addition of 10 new countries to the sample has only strengthened this claim and the evidence to support it.

Summing up: Lessons learned from four years of *Building the Bioeconomy*

The basic lesson of the fourth edition of *Building the Bioeconomy* – and indeed in some respects the most fundamental finding of the entire series – can be reduced to two basic principles.

First, to build a world-class biotechnology capacity it is not enough to focus on one or two areas of reform. Instead, reform efforts need to be comprehensive and include both the hardware side of innovation as well as the software, that is, the public policies that grease the wheels of biotech innovation.

Second, Rome was not built overnight.

Success in biotechnology is neither preordained nor guaranteed. Countries like Denmark, Singapore, Ireland and Israel are not intrinsically blessed with world-class biotechnology capabilities. They do not have sizeable markets that can on their own attract large-scale investment and R&D. Instead, these countries have had to focus on getting the policies right, making themselves attractive and competitive. And, instructively their efforts do not and have not stopped. This is a lesson all countries – big and small, advanced or just starting out – can take to heart.


8 ml
1.0 ml
2.0 ml

1 INTRODUCTION

When the world is flat, you can innovate without having to emigrate.
Thomas Friedman, 2005[1]

Today's global economy is inter-linked, inter-dependent and open for business in a way that it was impossible logistically, politically or financially a mere generation ago. Indeed, the sum of the technological, cultural, political and socio-economic changes of the last three decades amounts to what is truly a paradigm shift. In 1990 the internet was not a commercially or publicly available entity. The Soviet Union, although crumbling, was still the world's second most important geopolitical bloc and one of its largest economies. The value of world trade in goods in 1990 was an estimated USD 3.5trillion.[2] Today the value of global trade in goods is close to 5 time that amount at an estimated USD 16.6 trillion in 2016; and this is not counting trade in services which has grown exponentially over the last two decades.[3] In 1990 it cost a residential US AT&T customer USD 5.53 to place a three minute long distance telephone call to Japan and USD 4.61 for the same three minutes to Colombia.[4] Today those calls can be made for pennies or for free over the internet. Just in time manufacturing and the use of international supply chains was not industry standards and the basis for much of modern commerce. And biotechnology as a field was just in its infancy.

It is worth starting this edition of *Building the Bioeconomy* with what is not only the basic fact of globalization, but also its actual outcome. Much of the basis for current and future economic development and growth lies in those industries and sectors which are part of the knowledge-intensive economy. Industries and sectors that are defined by a need for constant and continuous innovation are also industries that can live and thrive anywhere in the world. As Thomas Friedman pointed out in 2005 the quintessence of globalization is that innovation and related economic activity is no longer limited by geographical constraints. Innovation can thrive and develop anywhere in the world where the right conditions and enabling factors are in place. Biotechnology is perhaps one of the best examples of this new reality.

This year's edition of *Building the Bioeconomy* both confirms that this is the reality and shows how growing numbers of countries are responding and acting accordingly.

1.1 From 16 to 26 the song remains the same…

2017 marks the fourth edition of the *Building the Bioeconomy* series of papers examining national biotechnology industrial policies. The overriding purpose of this series has always been to examine international experiences and identify best practices and experiences: Which countries have been successful in developing their biotechnology sectors and how have they done it?

Within the context of globalization what is increasingly emerging is a real competition between the world's forward-thinking economies looking to build or increase their biotechnology capacity. Depending on their starting point more and more countries are asking themselves how they can improve their performance; catch up to the top-performers; or stay ahead of the competition.

Indeed, one of the revelations of this year's report – in large measure due to the substantial increase in the number of countries examined from 16 to 26 – is the fact that many countries are recognizing that globalization does allow them to change their economic model and basis for development and growth. For many biotechnology is a field identified as a strategic priority. Below Table 1 lists the 26 countries included in this year's report. The mix of countries is both geographically and socio-economically diverse. *Building the Bioeconomy* includes economies from all major regions of the world and a broad spectrum of income groups as defined by the World Bank.

TABLE 1 *Building the Bioeconomy 2017* economies by World Bank income group[5]

Lower-middle-income economies	Upper-middle-income economies	High-income economies	High-income OECD Members
India	Argentina	Saudi Arabia	Australia
Indonesia	Brazil	Singapore	Chile
	China	Taiwan	Denmark
	Colombia	UAE	Ireland
	Malaysia		Israel
	Mexico		Japan
	Russia		South Korea
	South Africa		Switzerland
	Thailand		UK
	Turkey		U.S.

Source: World Bank (2017)

The expansion of the country sample included in this year's report from 16 to 26 of the world's major economies and aspiring biotech pioneers provide s additional depth and perspective on how no two countries biotechnology sectors or experiences are exactly the same. Every country is different and has its own particular set of circumstances and starting points with regards to natural resources, socio-economic and demographic make-up as well as legal and cultural history. Yet as this edition of *Building the Bioeconomy* demonstrates again there are a set of universal principles and factors that heavily influence whether or not a given economy is likely to have success in stimulating the development of its biotechnology industries.

1.2 Creating an enabling environment

A key feature of the *Building the Bioeconomy* series has been the identification of those factors and public policies that enable biotechnology innovation. Based on the existing literature and experience of those economies that have been successful in building an advanced biotech capacity it is possible to piece together a set of principles and factors which, evidence suggests, are enablers of biotechnology innovation. We call these the seven enabling factors for biotechnology innovation. Below Table 2 provides an overview of these factors and definitions for each. These factors range from what might be termed the "hardware" of biotechnology innovation such as R&D infrastructure and human resources to "software", that is, public policies ranging from IPRs to regulatory capacity and standards to market and commercial incentives. In addition to these seven enabling factors, it is also worth mentioning an added element which is public-private sector dialogue. Country experiences from all over the world is increasingly showing how critical public-private cooperation is. Without clear and transparent dialogue and partnership between government and industry it is almost impossible to achieve any degree of success in high-tech fields including biotechnology.

TABLE 2 Seven enabling factors for biotechnology innovation

Key enabling factors	Explanation
Human capital	A basic and fundamental building block for the biotech sector is the availability of high skilled and technically trained human capital. Without the right human capital it is virtually impossible to create the conditions in which biotech innovation can take place.
Infrastructure for R&D	Combined with having adequate, educated and technically proficient levels of human capital, R&D infrastructure and capacity is critical to successfully fostering innovation and activity in high tech sectors including biotechnology. Without the necessary laboratories and clinical research facilities biotechnology R&D would be next to impossible.
Intellectual property protection	IPRs (including patents and regulatory data protection) are historically of real importance to the biotech and biopharmaceutical innovation process. For biopharmaceutical as well as non-pharmaceutical biological products and technologies the evidence suggests that IPRs incentivise and support the research and development of new biological technologies and products.
Regulatory environment	The regulatory and clinical environment in a given country or region plays an important role in shaping incentives for innovation and establishing adequate levels of quality and safety for biotech products, particularly biopharmaceuticals. A strong regulatory environment creates the conditions for the production and sale of high quality products and technologies.
Technology transfer	Technology transfer is a critical mechanism for commercialising and transferring research from public and governmental bodies to private entities and private to private entities for the purpose of developing usable and commercially available technologies.
Market and commercial incentives	Market and commercial incentives range from general R&D incentives to specific policies aimed at biotech sectors such as pricing and reimbursement policies for biopharmaceuticals. For the biopharmaceutical sector incentives determined by pricing and reimbursement systems for medicines and health technologies can have a profound impact on commercial and market incentives for innovation in health and biotech R&D.
Rule of law	The general legal environment including as it relates to the rule of law and the rule of law within a business context is crucial to commercialization and business activities.

1.3 Inputs still equal outputs

A key innovation in the *Building the Bioeconomy* series has been the development of the Biotech Policy Performance Measure (the "Measure"). First introduced in the 2015 edition of the report this tool provides readers a quick overview of a given economy's policy framework and performance in relation to the other economies sampled.

This year the Measure has been expanded and now includes 28 indicators. These are evenly divided between 15 measures of policy inputs (related to the seven enabling factors listed above) and 13 indicators of biotechnology outputs. Together these indicators provide a full and detailed measure of the complete biotechnology environment for a given economy.

What is exciting about this year's edition of the report is that more and more countries are actively embracing the policy factors and principles identified in *Building the Bioeconomy* when they are embarking on their own economic and biotech reform efforts. From the Middle East to Asia and Latin America countries are indeed embracing many of the essential components of building and environment that enables biotech innovation and success.

Yet what is also clear – and a recurring theme from previous editions of the report – is while embracing many of these enabling factors, many economies are still clinging to ideas that are actually counter-productive; whether it be mandating the use of local content, manufacturing, hiring requirements or loosening standards for the protection of intellectual property.

If there is one thing the Biotech Policy Performance Measure seeks to demonstrate is the clear link between the types of policies that countries have in place and real biotechnology

outputs. And is discussed below, when it comes to achieving real world desired biotechnology outputs, having the policy fundamentals in place is not an option but an absolute necessity.

1.4 Report overview

In addition to this Introduction this year's *Building the Bioeconomy* consists of three main sections.

Section 2 provides a thematic analysis and overview of the past year in biotechnology. What were the major developments internationally and what stands out as the key challenges and opportunities as we move further along into 2017 and beyond? The section focuses on policy developments in the 26 countries sampled and in particular the ten new economies added to this year's report. It is organized around the seven enabling factors for biotechnology innovation.

Section 3 describes the Biotech Policy Performance Measure, explains the 28 indicators included and provides an overview of all the underlying data the feeds into the Measure. It seeks to answer the question of what the results of the Measure actually mean for countries. What can government officials and policymakers take from the results of the Measure both in aggregate and on an individual indicator by indicator level? What are the results of the Measure and what do they tell us about best practices for enabling biotech innovation? What can the countries included in the Measure learn from it and what does it mean for other countries not included but are aspiring to develop their biotech capacity?

Section 4 provides concluding thoughts and ties together the data, information and performance review of the preceding sections.

2 NATIONAL INNOVATION STRATEGIES, BIOTECH SECTOR SPECIFIC POLICIES AND THE SEVEN ENABLING FACTORS – KEY POLICY DEVELOPMENTS AND TRENDS

Global politics has over the course of the last year been characterized by deep uncertainty. Whether through Brexit, the election of Donald J. Trump as 45th President of the United States, the impeachment of President Dilma Rousseff and subsequent transition of power in Brazil or the collapse of the Trans-Pacific Partnership, the global economy faces deeply uncertain times.

Political leadership in many key countries is new and there remains a great deal yet to be learned about key global macroeconomic policies affecting trade, investment and multi-lateral relations.

The world of biotechnology is naturally not immune from this political uncertainty and change. Political uncertainty breeds policy uncertainty across the spectrum of the seven enabling factors for biotechnology innovation. For example, looking at one critical policy area, Enabling factor 3: Intellectual property protection, the fact that the TPP is no longer moving forward creates a level of uncertainty for global IPRs standards. As the largest pluri-lateral trade agreement signed since the completion of the Uruguay Round covering some 40% of global GDP, including some of the most dynamic emerging economies in the world, the TPP had the potential to truly set a new 21st century standard for the protection of IP. Signed in February 2016, the agreement was heralded as a significant break-through for international trade and establishing a new post-TRIPS international standard for the protection of IP. Yet barely one year later the future of these standards remain uncertain.

This section will describe and discuss the major biotechnology and innovation policy developments over the course of the last year across the 26 countries sampled for *Building the Bioeconomy 2017.* Particular attention is paid to developments and the policies in place in the ten new countries added this year.

2.1 National innovation and biotechnology strategies

National innovation strategies are a set of policies and initiatives aimed at encouraging innovation on or at a macro or micro level. They can be coherent, synergistic plans for interconnected action or a laundry list of disparate initiatives that on their own promote innovation. They can consist of both generic policies (those that generally address factors of innovation) and specific policies (those that address components specific to innovation in the targeted field, say biotechnology). The type of policy pursued and the prospective effect (negative or positive) is largely a result of what type of innovation infrastructure and factors are already in place.

National innovation strategies are increasingly popular among many countries as a way of identifying and targeting a specific national goal. Often these strategies either form the basis for industrial and economic policy or are part of a larger policy initiative to reform a given economy.

Of the 26 countries sampled for *Building the Bioeconomy* the majority have in place national innovation policies. Indeed, of the 10 new countries included this year it's striking how many have developed national innovation plans or equivalent strategies and the import they have for overall industrial and economic policy. What is more, ever more countries are including a real emphasis on how to develop their biotechnology capacity either through dedicated sections in their

national strategies or through separate policy documents and efforts.

For example, in 2016 **Saudi Arabia** released Vision 2030 an ambitious long-term vision aimed at diversifying the Saudi economy by: opening up even further to investment; encouraging innovation, competition and public-private-partnerships; privatizing government services including healthcare; and supporting national enterprise. The vision includes some specific targets of economic development:

- Entering the world top 15 economies (currently 19th)
- Ranking among the top 10 countries in the Global Innovation Index (currently 25th)
- Increasing FDI from 3.8% of GDP to 5.7%
- Increasing the private sector's contribution from 40% to 65% of GDP

The Vision was accompanied by the document *National Transformation Program 2020* which helps translates the Vision into more detailed programs for all Saudi ministries and agencies. The main themes of this document are job creation, digitalization and industrial localization. A number of specific targets with regard to innovation policy are also set:[6]

- Increasing the number of tech-companies emerging from incubators and universities to 600 and 800 respectively
- Creating over 7,000 jobs in start-ups
- Raising the number of patents issued by the country to 5,000 (up from current 700)
- Publishing 20,000 peer-reviewed articles per year (up from 16,000 currently)
- Achieving 125 localized and developed technologies in targeted sectors

The **UAE** in 2015 introduced a similar set of documents in 2014 and 2015: *National Innovation Strategy and Vision 2021*, respectively.[7] Both documents aim to transform the Emirates into a leading knowledge-intensive economy built on innovation. A number of key targets are part of both documents including ranking among the top 20 countries in the Global Innovation Index; raising R&D expenditures to 1.5% (0.87% in 2015); and seeing non-oil real GDP growth at 5% year-on-year.

Significantly, both the Saudi Arabian vision and the UAE's transformation plan identified biotechnology and the life sciences as central elements of their reform initiatives. In Saudi Arabia the overhaul of the healthcare market will involve the biopharmaceutical sector. And in the UAE the Vision aims to establish world-class healthcare services, by achieving full accreditation of health infrastructure according to international standards, reducing the burden of chronic diseases and "developing pharmaceutical industries and biotechnology".[8] As is detailed below, the UAE has impressively already carried out a number of these reform efforts, particularly with regards to cutting regulatory approval times for new biopharmaceutical products and technologies. Saudi Arabia is also in the midst of such a reform effort.

Other countries too are following a similar trajectory.

For example, **Taiwan** (also a new country included this year) is a known success story in the ICT sector, not least due to its efforts to build a competitive science base, R&D clusters and strong links between public research institutions and the private sector and incentives like tax credits. However, much of these efforts lent towards creation of follow-on technologies instead of pioneering ones. Over the past decade, Taiwan has attempted to replicate similar strategies for other high-tech sectors, including biotech, but this time with greater emphasis on R&D from the ground-up. One of the major platforms of the new administration under Tsai Ing-Wen and the Democratic Progressive Party is to boost Taiwan's innovation system. Taiwan's National Development Plan 2017-2020 and plan for 2017 issued by the National Development Council (an inter-ministerial committee) in early 2017 aims to definitively shift the national economic model

from high-tech manufacturing to R&D through promoting investment in innovation and carrying out structural reforms. Biotechnology is among the key sectors prioritized for investment in the plan. Looking for example at biopharmaceuticals though the sector in Taiwan is relatively small it has grown substantially over the past 15 years in part due to the government's emphasis on creating supportive framework conditions including introducing robust IP protection for life sciences, an international-standard regulatory framework and various incentives and funding for R&D, as well as building on a traditionally strong science base. As of 2015 the biomedical sector was valued at USD9,360million (which was at least a tripling over the previous decade), with around 1,900 companies.[9] Policies aimed at supporting the development of this sector in Taiwan go back over a decade, initially focusing on incentives and public funding for R&D. The Biotech and New Pharmaceutical Development Act 2007 introduced tax credits and other incentives to stimulate growth of the biomedical industry. Efforts today have shifted towards cluster development and technology transfer support. For instance, a newly opened National Biotechnology Research Park focuses on R&D and product development, providing particular incentives and support for SMEs in pre-clinical and clinical development. New drug development is focused on a number of areas including biologics, cancer, rare diseases and other diseases thought to be incurable.[10] Biomedicine is one of the seven innovative industries targeted in the National Development Plan 2017-2020, with a view to becoming an "Asia-Pacific Biomedical R&D Industrial Center". The Plan identifies areas such as human and physical capital, FDI and growth of biomedical clusters as key areas for strengthening. In November 2016 the Executive Yuan approved a Biomedical Industry Innovation Program, which includes a recently launched Center of Biomedical Industry Innovation focused on promoting FDI and integrating funding.[11] In addition to biopharmaceuticals, agricultural biotechnology is also one of the sectors prioritized in the National Development Plan 2017-2020. Small-scale commercial farming has traditionally played a significant role in the

economy and over the past two decades Taiwan has sought to develop the ag-bio sector to provide a competitive edge, improve productivity and overcome land limitations. A number of national ag-bio plans and initiatives have been introduced in the past 10-15 years. For instance in 2007 the Council of Agriculture of the Executive Yuan invested NTD10 billion over 6 years to support, among other elements, the development of the ag-bio sector in Taiwan. In 2008 a 5-year cross-agency Development Program for Industrialization for Agricultural Biotechnology was introduced involving education, science, health and agriculture bodies, specifically aimed at creating a platform for commercialization of ag-bio R&D. In turn, there is a growing focus at universities on ag-bio particularly plant biotechnology and genetic modification of seeds as well as spin-offs and incubators for SMEs.[12] The Council of Agriculture has created a number of ag-bio parks aimed at R&D and tech transfer particularly in the Ping-tung region in southern Taiwan (established in 2003), including in the areas of biotech fertilizer and pesticides, seed development, marine and animal biotechnology and bio-cosmetics.[13] As of 2016 there were over 100 R&D companies and nearly USD300 million invested in the Ping-tung Ag-Bio Park, with another USD100 million+ in public funding committed through 2020.[14] In addition, the Council of Agriculture reports over 100 cases of technology transfer and licensing per year from public research institutions and labs, which has grown rapidly over the past 15 years (with tech transfer valued at just NTD1 million in 2002 and rising to around NTD80 million (about USD3 million) by 2013.[15] Established in 2014, the National Institute of Agricultural Science and Technology supports these efforts by capacity building and partnership platforms, particularly with foreign investors.[16]

Yet – just as was pointed out in previous editions of *Building the Bioeconomy* – it is also clear that while on the one hand many countries are putting in significant resources and efforts in building a strong innovation capacity and focusing on biotechnology, countries are at the same time embracing sometimes contradictory sets of policies. Encouraging innovation on the one hand, but also erecting barriers or mandatory requirements that make investment and R&D more, not less, difficult. This is particularly the case for the continued use and rise of so-called localization and local content requirements which, despite the evidence, many countries continue to believe will help accelerate their development. For example, the above discussed positive reform efforts in Saudi Arabia contain a high degree of localization and local content requirements. With regards to biopharmaceuticals the Saudi Transformation Plan includes a goal of doubling the value of local pharmaceutical manufacturing to 40% by 2020.[17] Manufacturing is a decreasing share of the global biopharmaceutical value chain with R&D accounting for the largest share of investment and expenditure by the world's leading biopharmaceutical manufacturers.

Other countries, such as **Turkey** and **Russia**, with longstanding localization policies in place are intensifying these efforts despite the fact that over the course of the past half-decade or more they have not produced tangible results. For example, in Turkey import substitution policies and procurement preferences have been strengthened over the last year for biopharmaceuticals. The Turkish Medicines and Medical Devices Agency has drawn up plans to require drugs that face at least one local generic or therapeutic equivalent to localize production by 2018 or be excluded from reimbursement list.[18] Implementation of this import substitution plan has been recently completed for drugs with a 50% market share and 3 local equivalents, and is reportedly ongoing for 99 drugs with at least 2 local equivalents.[19] As of March 2017, 54 drugs had been identified for de-listing from reimbursement.[20] Similarly the Turkish Government's 2016 Action Plan promised to introduce purchase guarantees for local "upper middle and high tech products" (as done in the IT sector).[21] The model was tested for pharmaceuticals in January 2016 with the announcement of a 7-year purchase commitment for a firm that launches a Hepatitis A vaccine manufacturing facility in Turkey.[22] And in Russia the trend to forced localization of biopharmaceutical products continued at full speed in 2016, with the addition of further discriminatory rules for foreign products in public procurement[23] the use of sole local supplier for public needs,[24] and the increasing of subsidies for local manufacturing and clinical trials.[25]

Indeed, stepping back and looking at big-picture trends for all 26 countries included in *Building the Bioeconomy* it is clear that while the vast majority of countries have clearly stated their goals of becoming leading innovators in the field of biotechnology, only a minority are actually pursuing reforms under all seven enabling factors. In fact, while most countries have recognized the necessity of the hardware side of the biotech innovation equation – that is, highly trained and skilled human resources and R&D infrastructure – and are targeting these enabling factors with resources, with few exceptions much less attention has been placed on positive reform efforts in other areas including regulatory standards, technology transfer and the protection of IPRs.

2.2 Getting the hardware right – Enabling factors 1 and 2: Human capital and Infrastructure for R&D

Although many countries still exhibit real weaknesses when it comes to their technical capacity in respect of both human capital and R&D infrastructure, the vast majority of both emerging and developed markets aspiring to develop their biotech sectors recognize the need to invest and develop this hardware capacity. Below Figures 1 and 2 compare relative capacity looking at researchers in R&D per million population and R&D spending as a percentage of GDP.

Indeed both the UAE and Saudi Arabia in their new economic development and innovation plans have recognized the need for increasing expenditure on R&D and improving technical capacity and education levels of its population.

Perhaps the best example of a country which has – and continues – to invest in the building of its human capital and R&D infrastructure is China. Over the past fifteen years China has seen tremendous growth in the number of university graduates particularly in science and engineering. The total number of natural science and engineering graduates has jumped from just under 240,000 in 1998 to over 1.1million in 2010 and China produces by far the greatest absolute number of these graduates in the world.[27] China also produces a very high number of doctoral degrees in science and engineering. In 2010 this was close to 31,000 degrees with only the US, at

FIGURE 1 Number of researchers in R&D per million population, 26 countries *Building the Bioeconomy 2017*

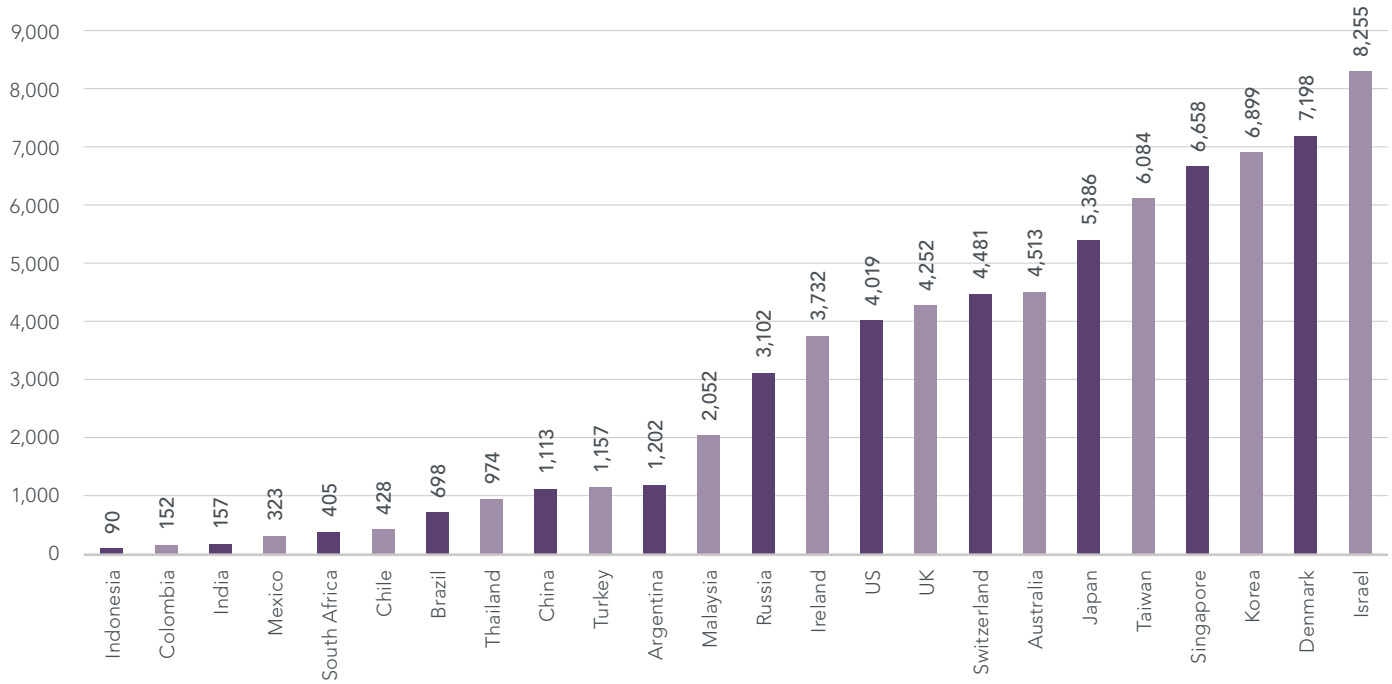
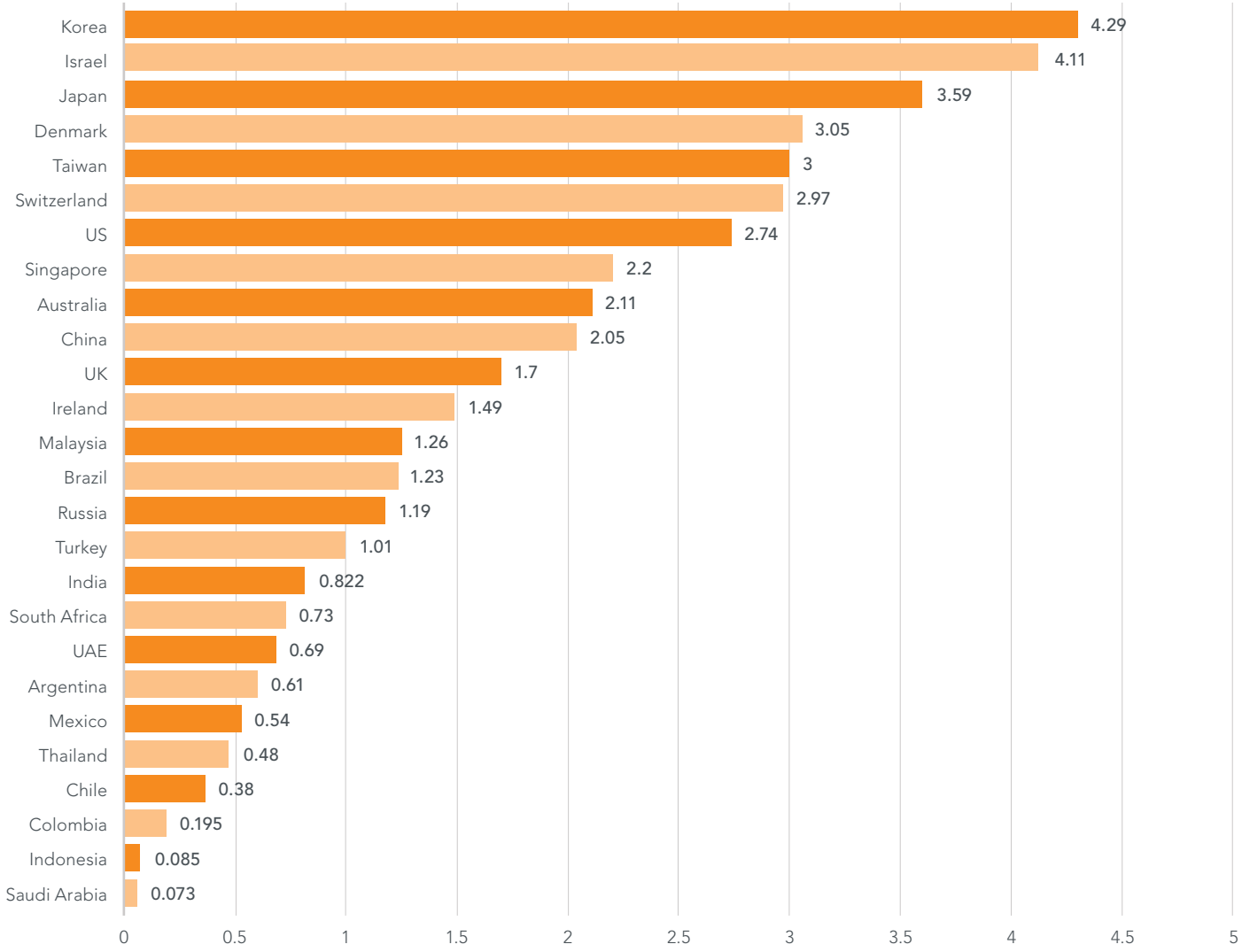


Figure 2 Expenditure on R&D, percentage of GDP, 26 countries *Building the Bioeconomy 2017*, 2014 or latest available year[26]



just over 33,000, having a higher rate.[28] Similarly, a growing share of China's workforce consists of researchers. Looking at the number of researchers in the population the latest (2014) data from the World Bank shows that China had 1,113 researchers per million people.[29] This is an increase of over 100% since 2000 when the equivalent figure per million population was 547. Similarly, rates of Chinese R&D spending is in both absolute terms and as a percentage of Chinese GDP is world leading. The Chinese Ministry of Science and Technology announced on April 24, 2017 that China will increase by 35% annual spending on R&D to RMB 500,000 per capita ($72,800 per cap) by 2020 from RMB 370,000 in 2014. R&D spending reached 1.42 trillion yuan (~$208.38 billion) in 2015 (at 2.05% of GDP) an 8.9% increase from 2014 (and up from 2.02% of GDP). Public spending accounted for 15.1% of total, Academic institutions accounted for 7%, and private spending on R&D accounted for 76.8% of total with remaining from other sources.[30]

Even countries which already have high levels of R&D infrastructure spending are not standing still. For example, the Government of **Korea**

announced in September 2016 the creation by 2018 of a biomedical cluster outside Seoul along the model of the Boston Bio Cluster as part of a strategy to foster bio and healthcare industry.[31] This will add to a network of 25 bio-clusters already set up in the country.[32] And Korea remains the world leader in R&D spending allocating 4.29% of GDP on R&D expenditure and with the vast majority of this (75.3%) made up of business and enterprise spending.

And although actual results at times does not keep pace with stated aspirations overall most of the sampled countries have defined improving their human capital, technical capacity and investment in R&D as a national priority. For instance, **Mexico** under President Enrique Peña Nieto has long had a stated policy goal of increasing R&D spending to 1% of GDP.[33] The latest data from the World Bank from 2014 (included above) shows Mexican R&D expenditure at 0.54% of GDP; only marginally higher than the 0.4% spent a decade ago in 2005.

Indeed, if one trend is relatively clear it is that most countries recognize the need for allocating resources to human capital and R&D infrastructure. Less focus is on other equally critical policy areas including the protection of intellectual property, the regulatory environment, technology transfer and market and commercial incentives.

2.3 Protecting IP – A fundamental component to encouraging biotechnology innovation

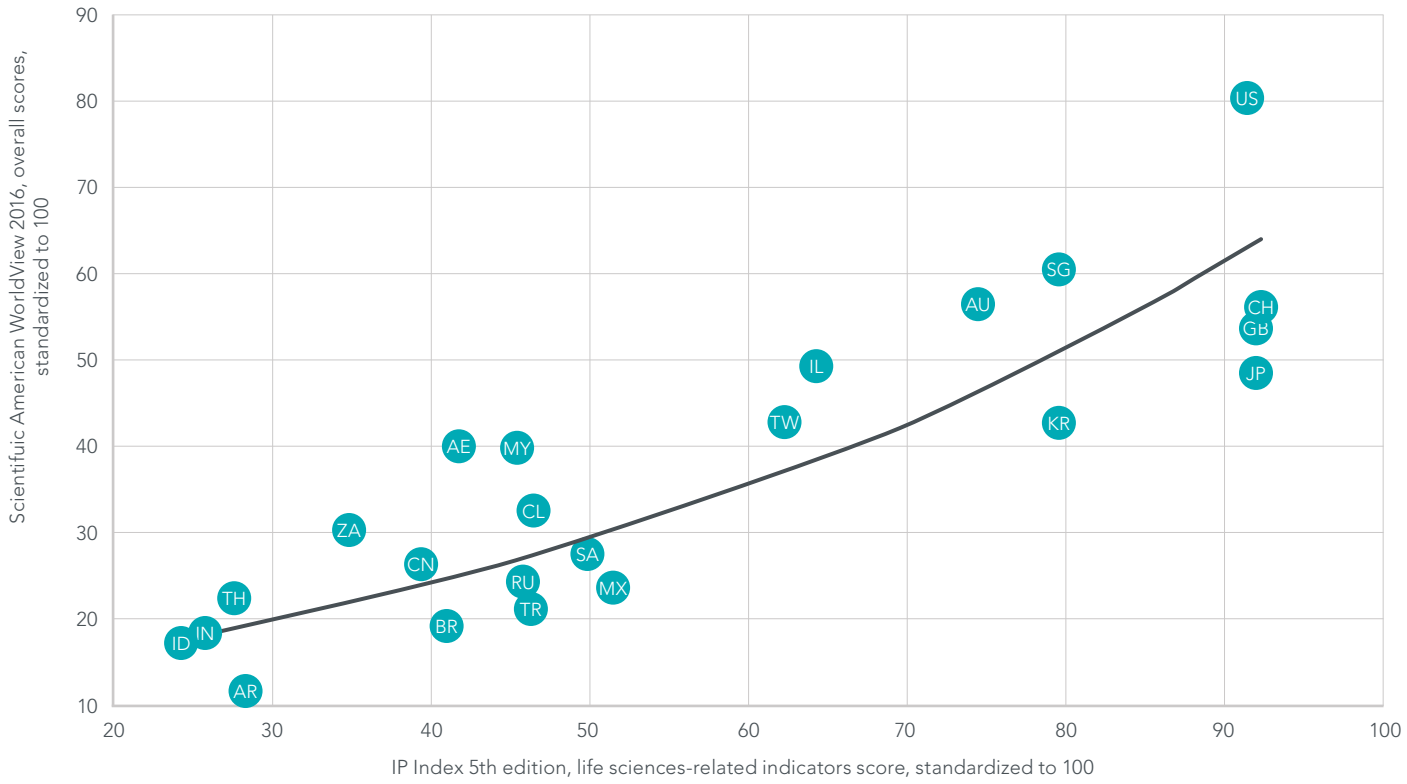
Always a controversial field (particularly in relation to biopharmaceutical innovation) yet the economic and empirical evidence built up over the last few decades suggests strongly that overall IPRs tend to have a positive impact on economic activity, especially for high-tech industries like biotechnology and for attracting FDI.[34] In fact, IPRs are historically of real importance to the biotech and biopharmaceutical innovation process. For biopharmaceutical as well as non-pharmaceutical biological products and technologies the evidence suggests that IPRs incentivise and support the research and development of new biological technologies and products.[35] In particular patents and other forms of exclusivity for biopharmaceuticals such as regulatory data protection and special exclusivity incentives for the protection and production of orphan drugs provide research-based companies with an incentive to invest vast sums in R&D and the discovery of new biotech drugs, products and therapies. Given the research process for biopharmaceuticals (and many other biotech products) is unique in its time, cost and high rate of failure the market exclusivity period provided by IPRs give firms the protection and incentive needed to recoup R&D investments made. Evidence suggests that many drugs and therapies would not have been discovered had it not been for the incentive and protection provided by these IPRs. Indeed, there is a strong relationship between strong IP protection and high levels of biotechnology innovation. As part of its broader analysis of the economic impact IPRs have, the US Chamber's annual International IP Index includes statistical correlation analysis of the relationship between IPRs and various forms of economic activity. One correlation the IP Index measures is the relationship between biotechnology innovation (as measured by Scientific American's WorldView Score 2016) and IP protection. The strength of this correlation was quite high; measured at 0.77 for the 45 economies included in the 2017 International IP Index.[36]

On the next page Figure 3 shows the relationship between IP protection and Scientific American WorldView Scores for 24 of the 26 countries included in *Building the Bioeconomy* (Denmark and Ireland are not included in the IP Index).

As Figure 3 illustrates countries that protect biotechnology specific IP rights tend also to see higher levels of biotechnology innovation. Indeed of the 24 countries from *Building the Bioeconomy 2017* included in the IP Index, no country with a weak IP environment (scoring under 50% of the IP Index life sciences indicators) scores highly on the WorldView. Unfortunately, many countries are not recognizing this fundamental lesson and learning from the reform efforts and experiences of other countries.

As noted last year an instructive example is **Israel**. Since the mid-2000s Israel has made significant changes to its biopharmaceutical

Figure 3 Biotechnology innovation and IP protection



policy environment and in turn experienced substantial benefits. Through strengthening key components of its biopharmaceutical policy environment (including root and branch reform of its IP framework) Israel has managed to build up its own innovative biopharmaceutical sector and create strong incentives for future investment, growth and development. Following a 2010 Memorandum of Understanding with the US, Israel carried out significant improvements in key areas of biopharmaceutical IP protection, including in relation to regulatory data protection, patent term restoration and legal remedies for infringement. And the positive results can be seen today. 20 years ago the innovative research-based biopharmaceutical sector consisted mainly of research organizations and early stage companies focused on licensing out technologies, with little development and commercialization of biopharmaceuticals and biomedical technologies in Israel. But today according to the Office of the Chief Scientist's 2015 Innovation Report, the number of life sciences companies in Israel has increased by more than five times in the past 15 years (from 200 in the late 1990s to around 1,100 in 2015) and the sector represents around 18% of total exports.[37] Today at least 40% of the total biopharmaceutical sector includes companies involved in biopharmaceutical discovery, development and delivery (with 22% engaged in drug discovery).[38] Despite the small size of the Israel domestic market, Israel hosts 19 local subsidiaries of research-based multinational biopharmaceutical companies. Besides being traditionally involved in importing and marketing of their products, multinational research-based companies are active in R&D activities and play a critical role in cooperating with local firms and creating a vibrant innovation start-up platform. Israel attracts a high level of R&D investment from PhRMA member companies; they invested USD8.8 million per million population in 2012 – a level comparable with Japan and leading EU markets. The Israeli innovative sector not only continues to play a role in many new biopharmaceuticals (with contributions from Israeli-developed

technologies to a number of recent "blockbuster" biopharmaceuticals estimated at around 25%), but is also leading the development and marketing of cutting edge treatments, such as the Israeli company Protalix's BioTherapeutics plant cell-based enzyme replacement therapy for Gaucher disease.[39]

Similarly, **Singapore** remains a shining example of a how a country can essentially from a very low base over the medium-term establish itself as a global leader in both biopharmaceutical R&D and manufacturing. Singapore has developed world-class R&D and manufacturing capabilities and has seen tremendous growth in investment by multinational research-based companies. Manufacturing today alone is estimated at SGD23 billion, a value close to 5 times higher than in 2000.[40] In relation to FDI, Singapore has made huge strides in attracting investment in both R&D and advanced manufacturing over the past 10-15 years. Around USD500 million in R&D spending (close to half of the total amount spent on biomedical R&D) was provided by foreign biomedical companies in 2013, more than a tenfold increase compared to their R&D investment in 2003.[41] Today, around 50 biopharmaceutical companies carry out R&D activities in the country, including more than 30 top global biomedical companies.[42] In addition, at least 40 corporate research laboratories are based in Biopolis together with A*STAR research institutes.[43] Looking at R&D investment from the angle of clinical research, Singapore has a high rate of clinical trials per capita, among the highest globally.[44] Nearly half of clinical trials in Singapore are for the more complex and cutting edge Phase I and II trials.[45] Indeed, many of the top global research-based companies have also established their regional clinical trial center in there.[46] Moreover, of the top ten research-based biopharmaceutical companies worldwide, seven manufacture a portion of their products in Singapore and eight have regional headquarters in Singapore.[47] Some of them have chosen Singapore as a global manufacturing base.[48] The availability of a skilled workforce, supportive business environment and a local biomedical presence are cited as decisive factors of investment for a number of these companies.[49] In turn, Singapore now sees a very high presence of innovative drugs in the market; the innovative segment is substantial, at around 60% of the market, while generics represent just a fraction of that figure.[50] Some of these products are ones developed in Singapore itself.[51] The Health Sciences Authority continues to approve innovator products at a higher rate than generics; for instance in 2014-15, 115 Western Pharmaceutical Product Licenses of innovator drugs were approved, compared to 88 generics, bringing the number of Western Pharmaceutical Products registered to 5,493.[52] Singapore also increasingly supplies international markets. It was the third fastest growing nation globally in the export of pharmaceutical goods from 2000 to 2010,[53] with a growth rate of 503% over the decade.[54] Exports in 2014 were worth USD1.39 billion per million population, i.e. around USD7.5 billion.[55] This is nine times more than the size of its internal market.[56] Expansion of pharmaceutical exports continued in 2015, with a 7.5% growth year-on-year registered in April 2015.[57] Significantly, a key turning point in Singapore's development and a critical part of its overall reform efforts was the US-FTA in the late 1990s which ushered in the modernization of Singapore's IP environment, including the introduction of regulatory data protection and patent term restoration.

Unfortunately, many of today's aspiring biotechnology nations are not emulating the experiences of Israel and Singapore. Instead, countries like **Colombia**, **Russia**, **India** and others including OECD markets like **Chile**, are instead weakening standards of IP protection in the hope that this will stimulate R&D and innovation.

For instance, over the last 2 years the IP policy environment in Colombia has become much more challenging. In 2016 the Ministry of Health and Colombian Government actively considered the issuing of a compulsory license on the oncology drug Glivec on grounds of high prices. Subsequently the Colombian Government issued a "Declaration of Public Interest" via Resolution 2475 and committed to unilaterally reducing the price of Glivec by about 45%. On November 22, 2016 the National Commission of Prices of Medicines and Medical Devices (*Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos*) issued Circular 03 of 2016, which defines the general

pricing methodology applicable to all drugs under a public interest declaration. In contrast to the existing price setting methodology – whereby the average price is calculated from a basket of 17 countries – public interest medicines are subjected to the lowest price available, including prices of follow-on products.[58] In effect, this practice all but nullifies any existing IP protection and is highly questionable under Colombia's obligations under TRIPS and the US-Colombia Trade Promotion Agreement.[59] Shortly after the issuance of Circular No. 3, in December 2016 the National Pricing Commission issued Circular No. 4 of 2016 which sets the price of Glivec at ~44% of its former price.[60] Following pressures from different stakeholders the Colombian Government on April 25 2017 issued Decree No. 670, which regulates the use of the public interest measure. This requires that any declaration of public interest will be issued by an inter-institutional technical committee composed of representatives from the Ministry of Commerce, Industry and Tourism and from the National Planning Department in addition to representatives from the Ministry of Health.[61] The bottom-line is that instead of improving the IP and policy environment in Colombia remains highly uncertain with the negative trajectory still in place.

Similar to Colombia's policy direction, **Chile** has seen the introduction of new measures that would undermine the protection of IP. In January 2017 the Chamber of Deputies (*Cámara de Diputados*) of the Chilean Congress voted in favor of Resolution 798 which calls for expediting the utilization of compulsory licensing of patented drugs. The text of the Resolution extends beyond the measures applicable under TRIPS, namely for public health crises. The Resolution calls for the Minister of Health to utilize compulsory licenses: *"for reasons of Public Health and non-commercial government use, to facilitate its acquisition at* ***competitive prices****"*, noting particularly the Hepatitis C drug *sofosbuvir* (Sovaldi).[62] During March 2017 representatives of the Chilean Congress and patient groups submitted to the health ministry a proposal urging the government to use compulsory licenses for drugs treating Hepatitis C and prostate cancer.[63] It remains to be seen whether the Chilean Government will move on this issue.

And in other countries the weakening of biotechnology IP rights continues. In **Brazil** the Brazilian National Health Surveillance Agency ANVISA continues to have the right to provide prior consent to pharmaceutical patents that are being examined by the Brazilian Patent Office, INPI. Consequently, decisions on whether to grant a pharmaceutical patent are based on examination not solely by patent specialists and officials at INPI, but also by ANVISA. The exact meaning and nature of ANVISA's right to prior consent has been questioned in a court of law and based on some of these decisions in the past few years there was a feeling that perhaps this policy would be revised. However, recent developments suggest that on the contrary the policy has been strengthened with ANVISA's role solidified. In April 2017 Interagency Ordinance 1 was published clarifying the relationship between ANVISA and the INPI with regards to pharmaceutical patent applications.[64] Local legal analysis suggests that the Ordinance will restrict patentability of pharmaceutical products through the establishment of an "Interagency Policy Group" between ANVISA and the INPI.[65] IN effect the Ordinance not only acknowledges the status quo but even strengthens and institutionalizes ANVISA's role in evaluating biopharmaceutical patent application.

2.4 The regulatory environment

The regulatory and clinical environment in a given country or region plays an important role in shaping incentives for innovation and establishing adequate levels of quality and safety for biotech products, particularly biopharmaceuticals. Procedures, standards and conditions are to a large extent dependent on the regulatory framework and regulations in place. Different biotech sectors have different needs and regulatory structures in place. The regulation of GM crops, for example, may be carried out by a separate entity from that which regulates biopharmaceuticals. Overall the most advanced and innovative biotech markets in the world are also those which have the highest levels of clinical and regulatory standards. Looking at biopharmaceuticals this is achieved through setting and imposing high clinical and manufacturing standards through GCPs and GMPs

as well as post-marketing surveillance through pharmacovigilance programs.[66]

While regulatory frameworks and decisions in many countries are actually inhibiting innovation and the development of biotechnologies – this is particularly the case for agricultural biotechnology where many countries have in place a restrictive non-sciences based regulatory framework – a number of aspiring biotech countries have actively sought to reform their regulatory structures in order to encourage the development of their biotech sectors.

For example, **Argentina** has for many years been a leader when it comes to agricultural biotechnology. Argentina has taken a science based approach to ag-bio regulation and is one of the global leaders in biotechnology crops. The Argentine National Advisory Committee on Agricultural Biotechnology (*CONABIA*) is well established and highly regarded internationally.[67] 2015 saw the introduction of "New Breeding Techniques" regulation for innovative biotech use in plants which makes Argentina a global leader in introducing this. These efforts can be contrasted with Argentina's relative reluctance to reform its biopharmaceutical regulatory environment and harmonize to international standards. For example, Argentina continues to have three separate regulatory drug classifications: i) innovative or original, ii) generics, iii) similars. Category one drugs are used as reference drugs for both generics and similars. The crucial difference between similars and generics is that the latter undergo bioequivalence testing and the former do not. They simply need to contain the same active ingredient, concentration, pharmaceutical form and dosage, but can differ in size, shape, packaging and period of activity. The use of similars is encouraged by the Argentine government with many health officials drawing little distinction between the similars and bioequivalent tested generics. Argentina is only just beginning to introduce/implement regulations requiring bioequivalence testing for similares. The intention is to improve quality and safety of medicines, and align with international standards. The focus is first on certain therapeutic groups with "high health risk" including ARVs, immunosuppressants, antipsychotics, etc. Nevertheless, the large majority of biopharmaceuticals on the Argentine market are not bioequivalence tested and generics and similares are frequently referred to as being interchangeably. Consequently,

there is a great risk for substandard medicines penetrating the supply chain. Further illustrating the regulatory gaps and challenges in Argentina, when asked on the regulatory environment for clinical trials executives pointed to long delays and excessive amounts of red tape in the 2016 Biopharmaceutical Competitiveness Survey.[68]

Other world leaders when it comes to regulatory infrastructure include several smaller countries that have managed to build up real world-leading biotechnology sectors. Which goes to show that to become and maintain a position of leadership in biotechnology it is absolutely essential to have in place an internationally recognized and leading regulatory infrastructure and framework.

For instance, **Denmark** has taken several steps to create a supportive clinical trial environment and regulatory framework for biopharmaceuticals. In 2011 the Clinical Trials Office Denmark (DKMA) was established as a joint project of Denmark's five regional healthcare authorities and the pharmaceutical industry, with the intention of creating a simple and efficient communication channel for planning clinical trials and recruiting subjects in Denmark. The Clinical Trials Office Denmark acts as a mediator for clinical trials' sponsors, offering a nationally-standardized service in recruitment of subjects, advising on the best ways to conduct clinical trials in Denmark, and assisting in concluding contracts and agreements.[69] The Danish MoH has also launched a website which informs citizens on new and on-going clinical trials in order to assist in the recruitment process.[70] Additionally, since 2012 Denmark offers a fast-track approval pathway for clinical trials on investigational drugs which are: authorized for use in the EU or the EEA, tested under a licensed indication, and not involving an additional risk to the subjects beyond the existing treatment. Clinical trials which satisfy these criteria are assessed in a period of only 14 days.[71] While pursuant to the Danish law the DKMA has an assessment timeframe of 60 days, most trials are authorized within a significantly shorter period. In 2015, over 80% of all clinical trial applications were reviewed within a period of 43 days.[72] Furthermore, in 2014 the DKMA has launched the DKMAnet, a designated portal which enables companies to submit (using a digital certificate and signature) clinical trial applications, amendments, notifications and other safety-related material electronically and directly to both the DKMA and the Scientific Ethical Committees.[73] The shared

platform relies on available data from the pan-European EudraCT database, and automatically selects the relevant information for the DKMA and the Scientific Ethical Committees.[74] This initiative essentially renders clinical trials' regulatory approval process into an optimized, efficient and attractive 'one-stop shop' for sponsors. In addition, under the Danish government's INNO+ initiative which aims to place Denmark as a preferred location for conducting riskier, early-phase trials the National Experimental Therapeutic partnership was formed in November 2014. This public-private partnership joins the Capital region of Denmark, public hospitals and pharmaceutical companies in order to invest in the establishment of cutting-edge national research centers.[75]

Similarly, **Singapore** over the past decade reformed its clinical trials regulatory infrastructure to make itself more attractive for clinical research. Legislation governing clinical trials in Singapore requires the separate authorization of both the Health Sciences Authority and of an Institutional Review Board, which provides the ethical approval. Since 2006 applications can be made in parallel to these bodies, thus decreasing the timeframe of the regulatory approval process.[76] Indeed, clinical trial applications are usually processed within a timeframe of 30 days, and small-scale clinical trials (such as for the assessment of bioequivalence or food-drug/drug-drug interactions) are processed within a timeframe of only 15 days.[77] Additionally, clinical trials that test drugs (or a drug indication) which are already approved for marketing are exempt from the process and must only submit a notification to the Health Sciences Authority.[78] Like the Danish authorities to better optimize the regulatory approval process, the Authority has implemented a Pharmaceutical Regulatory Information System – an electronic system which enables clinical trials' sponsors to submit applications and other supporting documents online, using a secured electronic authentication system. The system validates the submissions, provides guidance on the regulatory approval process, and has an online payment and tracking options.[79] In 2012 the Health Sciences Authority also launched a local Clinical Trials Register, which enables access to ongoing clinical trials by therapeutic areas and the trial's drug, sponsor and site.[80]

Colombia is also looking to improve its attractiveness to clinical trials. During recent years the Government have dedicated efforts in improving the clinical research environment to international standards and enhancing its relative attractiveness. In 2008, Resolution 2,378 established the roles and responsibilities of actors involved in clinical research (sponsors, investigators, regulators and medical facilities), covering site accreditation, GCP inspection in accordance to ICH standards, trial protocol evaluation, and approval of the trial's agreement by the a review board.[81] The regulatory framework was further expanded with additional definitions and responsibilities, revised timelines and more.[82] Today there are 63 GCP-certified institutional ethics committees and over 120 medical facilities approved by INVIMA for clinical research. A clinical trial application must be reviewed by both bodies, except for phase 4 trials which only require an IRB approval. Colombia's medical facilities rank highly in regional comparison, and a pool of nearly 50 million people with adequate health coverage is accessible.[83] In addition, a number of global and local CROs operate in Colombia and maintain an open communication with INVIMA,[84] and a US-based clinical development company entered into an agreement with the Government of Colombia to position Colombia as a preferred destination for conducting clinical trials by US-based sponsors.[85] However, despite the efforts taken to enhance Colombia's attractiveness in the global clinical research arena, some challenges still exist in several aspects. First, approval times for clinical research are marred by significant delays. Trial approval times-frames in Colombia are currently very long. According to 2016 research conducted by the local biopharmaceutical trade association AFIDRO (*Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollo*) the regulatory approval of a clinical trial in Colombia takes no less than 225 days: some 50-60 days for an approval by the Ethics Committee, and an additional 165 days for the approval by the regulatory agency.[86] As a response to this in April 2016 Colombia's DRA INVIMA announced significant changes to the regulatory approval process of clinical trials.[87] Most significantly, the timeframe for approval would be reduced to only 2 calendar months, or 60 days. In May 2016 INVIMA released guidelines for evaluation of clinical

research protocols which limits the maximum evaluation time to 2 months.[88] In addition, the *Sala Especializada de Medicamentos y Productos Biológicos al Grupo de Investigación Clínica de la Dirección de Medicamentos y Productos Biológicos* began operating in February 2017.[89] Yet as discussed in the preceding sub-section, while these are positive steps to improve the attractiveness of Colombia in one enabling area, the lack of certainty in the IP space risks potentially crowding out these positive reforms.

Other countries are also seeking to reform their regulatory institutions and procedures, in particular for biopharmaceutical product registration.

For instance, the **UAE** in 2015 introduced a new fast track procedure for innovative medicines already approved by a stringent DRA including the US FDA and EMA.[90] This has already led to a number of innovative and ground-breaking products being registered in the UAE within months of US or EU approval and made available to patients in the Emirates.

Mexico too introduced a similar fast-track system in 2012, which among other elements recognizes existing approvals from leading drug regulatory agencies, including the FDA and EMA. Approval delays for new medicines have been reduced from 360 to 60 days.[91] In 2014 COFEPRIS also cut the pre-approval time for clinical trials from 3 months to 1 month, in an effort to attract more biopharmaceutical R&D investment and clinical research.[92] Yet just as in Colombia, Mexico's positive efforts in one area risks being crowded out by challenges in another, specifically in the area of pricing and reimbursement policies for biopharmaceuticals. In comparison to other countries Mexico's current pricing and reimbursement system in many ways limits and slows down access to new medicines and technologies. Mexico has strict price controls in place with maximum retail prices for patented medicines capped by the *Secretaría de Economía* (mainly for the private sector). Mexico uses an international reference pricing system calculated on the basis of the average ex-factory price of the previous quarter in the six largest markets for a given product globally. In addition to the pricing system Mexico's public reimbursement of pharmaceuticals is quite strict and there are often long time lags between product registration and listing for public reimbursement. All public institutions and insurance schemes are governed by a National Formulary (*Cuadro Básico y Catálogo de Medicamientos*) which is set by the *Comisión Interinstitucional del Cuadro Básico de Insumos del Sector Salud of the Consejo de Salubridad General*. This institute sets first, second and third lines of treatment for all publicly reimbursed medicines. Most of the medicines are off-patent and there generally are very few new products added every year. Authorized products are then evaluated for reimbursement by the *Consejo de Salubridad General* based on cost-effectiveness analysis. Products are then reviewed a second time within each of the six insurance bodies, which maintain different drug formularies and standards of care.[93] While coverage of many basic medicines and technologies is in place, public reimbursement for newer, innovative technologies is not common. Indeed, data published by IMS Health in 2014 comparing the availability of new molecules in a sample of markets found that Mexico had one of the lowest rates of the economies sampled.[94] Out of a total of 154 new NMEs introduced between 2008-12, only 45 were on the Mexican market by 2013.[95] This in comparison to 104 in the US.

Saudi Arabia has also introduced similar measures looking to fast-track the registration of medicines that have already been approved by a stringent regulatory authority. The Saudi FDA is reportedly currently working on implementing this system and simplifying registration procedures.[96]

2.5 Technology transfer

Technology transfer is a critical mechanism for commercialising and transferring research from public and governmental bodies to private entities and private to private entities for the purpose of developing usable and commercially available technologies. Technology transfer activities that are based on academic-industry and public-private sector collaborations provide a significant and distinct contribution to the economic strength and well-being of countries in which such activities take place.[97] The process enables public research institutions to obtain access to commercial

research funds, state-of-the-art equipment and leading-edge technologies, while allowing industry to benefit from the extensive knowledge and ingenuity of academic researchers.[98]

Increasingly countries are recognizing how critical technology transfer is – particularly in the biotechnology field – and the need for introducing the right incentives and frameworks to maximize the transfer of know-how and development of new products and technologies.

The **US** Bayh-Dole model has long been cited as a success story and was described by *The Economist* in 2002 as "Possibly the most inspired piece of legislation to be enacted in America in the last half-century".[99] The latest data from the Association of University Technology Managers survey shows the sustained and significant impact Bayh Dole has had on the American economy. This includes over 100,000 total licenses executed; nearly 11,000 start-ups formed; and more than USD37 billion in licensing income.[100] Indeed, Bayh Dole stands as a shining example of what can be done over time with positive changes and clear incentives in place for technology transfer. And while all countries are different and have to adapt their policies and reform efforts to the particular characteristics of their innovation ecosystem, many other countries are too recognizing the importance of technology transfer.

For example, **Singapore** has been, and continues to be, at the forefront of seeking to stimulate public-private partnerships between higher education institutions and industry, particularly in the biopharmaceutical space. Singapore has created a specific body to liaise between universities, public research institutes and industry needs, called the Biomedical Sciences Industry Partnership Office. This body seeks to catalyze and promote partnerships between industry and public sector research, linking upstream public sector research with downstream commercialization partners.[101] Building up a high quality biomedical research base has allowed Singapore to attract a number of multinational pharmaceutical companies, which are now supporting the further development of a domestic biomedical industry, particularly in fields of biologics and translational and clinical research.[102]

Similarly both **Denmark** and **Ireland** have in place long-standing technology transfer arrangements and policies – both biotech specific and general – to help incentivize cooperation and work between publicly funded universities/PROs and industry. Denmark was one of the first EU countries to put in place technology transfer legislation supporting university commercialization of publicly funded research[103]. Denmark also provides a number of funding measures to help young and innovative biotechnology companies thrive. In 2014, Innovation Fund Denmark had a budget of DKK5.3 billion (~€710 million) to provide funding to research-based companies that focused on innovative, technical-based solutions to solve societal problems in the country; DKK1.6 billion (~€215 million) of the total funding went to companies focused on diseases.[104] Separately, The Danish Growth Fund is a state-run fund that collaborates with private sector partners to provide funding for small and medium sized companies. The fund is particularly active in the biotechnology space, directly and indirectly facilitating DKK 5 billion (~€670 million) of investment in the sector since 2000. As of 2014, these biotechnology companies employed 1,000+ people with revenues of DKK 4 billion (~€540 million).[105] A third government funding mechanism is allocated through the Danish Council for Strategic Research. The Council places a particular emphasis on international pharmaceutical research collaboration and in the past two years has provided funding for collaboration on biotechnology projects with European partners, India and China.[106] This cooperative environment is furthered through the government's creation of biotech clusters. Cooperation is particularly active at the Medicon Valley Biotech Cluster where over 300 life science companies, 12 universities, and 32 hospitals (together employing 40,000 people) operate.[107] Further, the Danish Health and Medicines Authority has gained a reputation for rapidly approving products from successful trials,[108] ensuring that companies taking advantage of these collaborative mechanisms will be able to bring products to market in a timely manner. In the same vein, Ireland places a high value on collaboration and offers corporations generous incentives for working with local businesses or universities. The National IP Protocol (first drafted in 2012) was updated in 2016 following a consultation process led by Enterprise Ireland and Knowledge Transfer Ireland. The protocol – drafted by the Department of Jobs, Enterprise and Innovation[109] – provides a framework for companies and Research Performing Organizations on norms for research-related IP agreements. The Protocol clearly spells out IP arrangements for research projects funded publicly, privately or funded jointly by private and public entities.[110] The tech transfer system is well developed with public-private initiatives taking place at different levels, such as technological centers,[111] larger collaborations such as the Health Innovation Ireland,[112] and support programs such as the Innovation Vouchers[113] the Technology Gateway Program[114] and the Technology Transfer Strengthening Initiative. The latter has seen a total of €52 million invested from 2012 to 2016 to support translating Government-funded research into new spin-out companies and licenses to companies.[115] 2016 reportedly saw a record number of collaborative innovations between industry and Higher Education Institutions.[116] And looking at the EU Innovation Union Scoreboard, Ireland has advanced from tenth in 2013 to sixth in 2016.[117] There are also other Government led initiatives aimed to stimulate cooperation between industry and publicly funded research. One program aimed at pharmaceutical companies conducting novel research is the Industry-led Research Networks Programme. This program is designed to mitigate the risk of companies conducting cutting edge research by allowing a consortium of companies working in similar areas to contract the research out to publicly-funded institutions.[118] Pharmaceutical companies may also access the Technology Gateway Program and "Gateways" located around the country,[119] such as the Shannon Applied Biotechnology Centre, the Pharmaceutical & Molecular Biotechnology Research Centre, and the Microsensors for Clinical Research and Analysis Gateway.[120]

Looking at the Middle East technology transfer has been a key part of **Saudi Arabia**'s science and technology framework since the early 2000s and the 2002 National Policy for Science and Technology. There are several key initiatives most notably the government-owned Technology Development and Investment Company which is tasked with developing and launching

industrial opportunities aligned with the national research center priorities as Joint Ventures with international technology companies.[121] There is also the 2014 Saudi Arabia Advanced Research Alliance a public-private collaboration among the main entities working on innovation (KACST, TAQNIA, KAUST KFUPM and RTI International) aimed at supporting commercialization of new technologies. This Alliance created Technovia, a venture dedicated to building a pipeline of commercialization opportunities (screen ideas, conduct IP and market assessment, test prototypes and prepare technologies for commercial launch).[122] The King Abdulaziz City for Science and Technology is the main government research institution charged with managing public research funding and runs a network of national research centers that include the Joint Center of Integrated bio-nanotechnology (carrying out basic research)[123] and the National Center for Biotechnology (officially established in 2011) that performs applied research in molecular biology, microbiology, tissue culture, cancer research, pharmaceutical industries and Bioinformatics labs. Within KACST, various entities and programs deal with tech transfer including the KACST Industrial Innovation and Development Institute which is tasked with linking research output and industry and leading technology transfer activities and infrastructure.[124] The institute specifically provides legal and financial support to domestic inventors in registering their patents both locally and internationally. Saudi inventors also receive funding to transfer their technology, manufacture prototypes, conduct laboratory experiments, and commercial investment. There is also the BADIR Program.[125] Under this framework, seven technology incubators have been launched to support early-stage technology projects with commercial potential, including one for biotechnology in 2010.[126] More broadly, all main universities in Saudi Arabia have tech transfer office and clear IP policies in place that grant IP ownership to the research entity.[127] KAUST has been particularly successful in developing their tech transfer capacity including running: astart-up accelerator;[128] a Proof-of-Concept Funding Program to test and prototype new technologies; and a scale-up facility for pharmaceutical active ingredients and organic products.[129] The relative success of Saudi Arabia's efforts can be seen in the Biotech Policy Performance Measure where Saudi Arabia is one of the few emerging markets whose universities are among the top-50 globally in terms of PCT patent applications.

An interesting case is **China** which on the one hand has a very positive record when it comes to encouraging technology transfer and commercialization for research produced by PROs and at universities. Chinese universities have been encouraged since the mid-1980s to manage and commercialize inventions produced by their researchers, although formal ownership was retained by the state. This was changed through a number of reform initiatives culminating in the 2002 "Opinion on Exerting the Role of Universities in Science and Technological Innovation".[130] Combined with the overall growth and development of the Chinese economy, the results of this relative freedom for universities and researchers to pursue commercial ventures has been a sharp increase in university patenting, patent and technology transfers and number of spin-offs. Looking at university and PRO patenting rates these have increased dramatically and been a major contributor to China's rise as one of the world's top patenting nations. On the other hand there are a number of barriers in place for licensing agreements and entry into the new market that

both directly and indirectly requires localization in order to access the market. Examples of such policies include joint ventures and technology transfer deals, whereby technology intensive industries trade technology for market access or government entities must favor foreign suppliers that provide training services or transfer of know-how, have been common practice in China for several years, despite being prohibited by the WTO.[131] One illustration of this is the specially reduced corporation tax of 15% (compared to 25%) for high-tech companies, foreign entities must transfer ownership of their IP to a local entity in order to qualify.[132] In addition, licensing of foreign IP to local entities is subject to wide flexibilities on the local entities' part, including the ability to make improvements or reverse engineer the licensed asset without any ownership on the part of the foreign rights holder.[133] In the context of standard setting, there is also a trend toward greater administrative involvement in determining patent licensing terms and ability to secure relief from infringement. Draft patent amendments would allow for automatic licensing of Standard Essential Patents where a patent was not disclosed as part of participation in a national standard setting process (though royalties would be negotiated separately).

2017 saw a positive change of direction in **Brazil**. Traditionally, significant regulatory and formal requirements were in place limiting the attractiveness of licensing and widespread technology transfer. For example, to become effective and binding on third parties licensing agreements were required to be published in the INPI's *Official Gazette*.[134] Agreements were also required to be approved by INPI with limitations on fees and payments between the contracting parties.[135] Exclusive licensing agreements were subject to more onerous publication requirements than non-exclusive licenses making this process more time-consuming.[136] This changed in 2017 with the INPI announcing through Rule 70 that INPI will no longer take an active role in the framing and approval of licensing agreements.[137] Instead, the new Rule suggests that the agency will merely operate as an agency of recordal. If this is implemented and, in fact, the net effect of the rule it would represent a significant improvement in the technology transfer environment in Brazil.

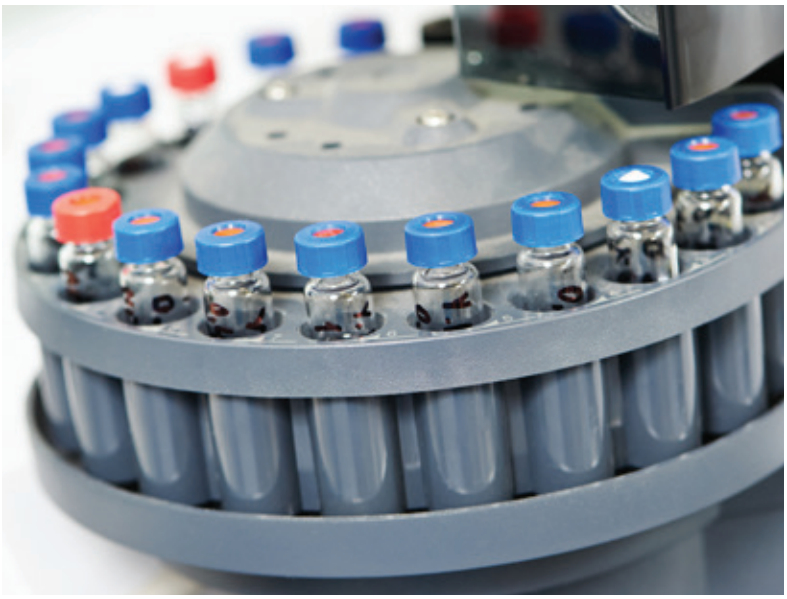
2.6 Market and commercial incentives

Market and commercial incentives for innovation and biotechnology R&D can come through a number of different forms. These can include general R&D tax incentives as well as biotech sector specific incentives.

Of the 26 countries included in *Building the Bioeconomy 2017* the majority have in place some form of R&D tax incentive. Surprisingly some of the most generous incentives in place are in countries that tend to struggle in other policy areas. For example, **India** has long-standing R&D tax incentives. There are general R&D deductions (up to 100%) as well as super deductions for contracted out research to Indian entities. And there are also targeted incentives for the biotech sector. Other countries including the **UK**, **Ireland**, **Singapore**, **Turkey** and **Malaysia** also have in place generous R&D tax incentives. Many mature, developed markets including the **US**, **Australia** and **Chile** have relatively paltry R&D incentives in place. For example, in Australia the effective tax incentive rate is relatively low ranging from 8.5-15% depending on the size of the enterprise.[138] There are also no specific incentives in place for biotechnology.

Looking more specifically at individual biotech sectors it is clear that most countries do not have in place particularly generous incentives. As mentioned above, most health care systems have in place either direct or indirect mechanisms for regulating and adjusting the pricing and reimbursement of medicines. In Europe this is frequently done directly through pricing and reimbursement negotiations between health ministries or government agencies and biopharmaceutical manufacturers. Prices are often determined through complicated formulas of internal and external reference pricing that compare the cost of medicines in a number of economies. Many health systems have also adopted advanced systems of pharmaco-economic and cost-effectiveness analysis and comparisons. The UK's national HTA body (NICE) for example, has been criticised repeatedly for denying reimbursement on several new and innovative products.

Somewhat contradictorily many countries that have very robust biotechnology innovation agendas simultaneously adopt stringent pricing and reimbursement policies. For instance, **Korea** has in place a strict system applicable primarily to innovative products.[139] Mandatory price cuts have been instituted through a therapeutic reference price system that places innovative and generic drugs in the same baskets, with prices set based on the average price in the basket.[140] The innovative or therapeutic value of a given product is not factored into the price. This system is complemented by other measures including rebates associated with price-volume agreements.[141] Moreover, inclusion for reimbursement is dually determined by a ruling of cost-effectiveness by the Health Insurance Review and Assessment Service and price negotiations with the National Health Insurance Corporation. Most recently Korea has introduced a number of changes to its pricing and reimbursement policies that favor local manufacturers and penalize foreign companies. The "Reform Plan for Reimbursement Prices of Biopharmaceuticals and Global Innovative Pharmaceuticals", presented in June 2016, grants price preference to locally developed innovative drugs. The Plan increases by 10% the prices of biosimilars tested in local trials and developed by companies designated as innovative (mostly Korean) or jointly developed with a Korean firm.[142] Only 2 out of the 47 biopharmaceutical drugs designated as innovative are by foreign companies, although many more invest in local clinical trials.[143] Companies designated as innovative receive special tax benefits, preferential governmental research funding and postponement of drug price discounts.[144] As a result of such punitive measures the price of new drugs in Korea is 45% of the OECD average of 2014, and it is predicted that the price will decrease further in the future.[145] In particular, over the past four years, Korea's patent prices have fallen by an average of 17%, which is two times lower than the average OECD countries average drug price cut rate of 9%.[146] The long term risk of such policies to Korea is to effectively undermine all the other incentives and hard work put in place to encourage innovation and investment.



2.7 Summing up

What perhaps is the most striking theme from the preceding discussion is how varied approaches to the biotechnology field and innovation are. While virtually all countries in some way or another have a clearly stated goal of building or maintaining their competitiveness in biotechnology relatively few actually recognize and execute a plan of holistic reforms. Most often countries tend to target education, improving technical capacity and physical R&D infrastructure including building research centres, techno parks, hospitals and the like. And as essential as those efforts are, as the next section describing the results of the 2017 Biotech Policy Performance Measure shows, this is a relatively limited route.

The countries that have the best measureable biotechnology related outputs – whether it be levels of clinical research, ag-bio crops, biotechnology patent applications or number of biotech firms – are the ones that have the right policies in place for all enabling factors. Indeed, if there's one thing which is abundantly clear form the results of this year's Biotech Policy Performance Measure it is that inputs still very much equal outputs.

3 MEASURING POLICY IMPACT AND REAL-WORLD BIOTECHNOLOGY RESULTS – THE BIOTECH POLICY PERFORMANCE MEASURE

First featured in 2015 the Biotech Policy Performance Measure (the "Measure") is at essence a way of illustrating the interaction between public policy and actual, real-world biotechnology outputs. Originally the Measure was solely intended to provide readers a quick overview of a given economy's policy framework and performance in relation to the other economies included in the report.

It consisted of some of the most important elements for each of the seven enabling factors delineated in the *Building the Bioeconomy* series. Last year the Measure was fundamentally revamped and significantly expanded to also take into account biotech outcomes. Indicators on biotechnology outputs measured covered a broad spectrum ranging from levels of total clinical trial activity, biologics clinical trials, scientific output, GM crops under cultivation, venture capital attractiveness, biotechnology patenting, rates of university patenting, biopharma product launches and so forth.

This year builds on the work of previous editions. Again, the Measure has been expanded with seven new indicators added bringing the total number of indicators examined to 28. These indicators are evenly divided between 15 measures of policy inputs (as before related to the seven enabling factors) and 13 indicators of biotechnology outputs. Together these indicators provide a full and detailed measure of the complete biotechnology environment for a given economy.

As with previous editions the purpose of the Biotech Policy Performance Measure is not to benchmark individual countries to a pre-determined set of criteria; this is not a computational index Rather, the purpose is to give readers (and the economies mapped) an idea of how a sample of their policy inputs (for each enabling factor), firstly, compares with the same policy inputs for the other economies sampled and, secondly, what type of actual biotech outcomes these policy inputs translate into.

3.1 Policy inputs

The Biotech Policy Performance Measure consists of two distinct halves: policy inputs and biotech outputs. Policy input indicators are drawn from the seven enabling factors. These are indicators that provide a sense of a given economy's policies and direction under each of the enabling factors.

In addition to the indicators included last year, five new indicators have been added bringing the total number of policy input indicators measured to 15. The new indicators are:

1. Life sciences graduates (PhD & Masters) per million population
2. Business and Enterprise R&D (BERD) spending as a % of total R&D spending
3. Total biotechnology R&D expenditure, Millions USD PPP, per million population
4. Biotech R&D as a percentage of BERD
5. Private to private entity licensing and commercialization activity

On the following page Table 3 shows the 15 indicators for each of the 7 enabling factors.

TABLE 3 Biotech Policy Performance Measure, policy input indicators

Key enabling factors	Indicators
Human capital	• Number of researchers per million population • Life sciences graduates (PhD & Masters), per million population
Infrastructure for R&D	• R&D spending % of GDP • BERD spending as a % of total R&D spending • Total biotechnology R&D expenditure, millions USD PPP, per million population • Biotech R&D as a percentage of BERD
Intellectual property protection	• Availability of regulatory data protection for submitted clinical data during the regulatory approval process • Availability of Patent Term Restoration for biopharmaceuticals • US Chamber of Commerce International IP Index 2017 life sciences score, standardized to %
Regulatory environment	• Existence of regulatory framework and efficiency
Technology transfer	• University/PRO-industry technology transfer frameworks in place • Private to private licensing and commercialization activity
Market and commercial incentives	• Biopharmaceutical pricing and reimbursement policies • R&D tax incentives
Rule of law	• World Justice Project *Rule of Law Index* country ranking

Factor 1: Human capital

Number of researchers per million population

This indicator estimates the level of technical capacity and human resources available within a given country by measuring the number of researchers in R&D activities standardized per million population. This indicator is not biotechnology specific but covers all major forms of scientific and technical fields.[147] The data is collected by the World Bank and forms part of the Bank's World Development Indicators.

This data set includes all of the economies sampled in *Building the Bioeconomy 2017* except Saudi Arabia, Taiwan and the UAE. Equivalent data for Taiwan was collected from the Ministry of Science and Technology's 2016 *International Comparison of S&T Activities* available on the Ministry's website.

Life sciences graduates (PhD & Masters), per million population

This indicator compares the number of post-graduate graduates in the life sciences for each of the sampled economies. This data provides an indication of a given economy's overall technical capacity for advanced R&D activities in the life sciences. This information is collected by the OECD and forms part of the OECD.Stat databank.

The number of life sciences graduates has been standardized for population to provide a more accurate reflection of intensity in a given economy regardless of population size.

This OECD dataset includes all of the economies sampled in *Building the Bioeconomy 2017* except Argentina, China, India, Japan, Malaysia, Saudi Arabia, Singapore, South Africa, Taiwan, Thailand and the UAE. Data for Singapore was collected from the *Yearbook of Statistics Singapore 2015* published by the Department of Statistics Singapore. Data for Taiwan was collected from the Ministry of Science and Technology's 2016 *International Comparison of S&T Activities* available on the Ministry's website.

Factor 2: Infrastructure for R&D

R&D spending % of GDP

This indicator measures the investment into R&D taking place in each economy as a percentage of that economy's GDP. This indicator is not

biotechnology specific but covers all major forms of scientific and technical fields.[148] The data is collected from the World Bank World Development Indicators and OECD.Stat.

This dataset includes all of the economies sampled in *Building the Bioeconomy 2017.*

BERD spending as a % of total R&D spending
This indicator measures the investment into R&D taking place by business and private sector enterprise in each economy as a percentage of the total expenditure on R&D. High levels of BERD suggests a higher propensity for private sector investment and commitment to innovation and creating new processes, products and technologies for commercialization. This indicator is not biotechnology specific but covers all major forms of scientific and technical fields. The data is collected from the OECD.Stat databank.

This data set includes all of the economies sampled in *Building the Bioeconomy 2017* except Brazil, Colombia, India, Indonesia, Malaysia, Saudi Arabia, Thailand and the UAE.

Total biotechnology R&D expenditure, millions USD PPP, per million population

This indicator measures R&D expenditure that is specific to the biotechnology field. The amount of R&D investment has been standardized for population to provide a more accurate reflection of intensity in a given economy regardless of population size. The data is collected from the OECD.Stat databank and forms part of its "Key Biotech Indicators" measure.

This data set includes all of the economies sampled in *Building the Bioeconomy 2017* except Argentina, Brazil, Chile, China, Colombia, India, Indonesia, Malaysia, Saudi Arabia, Singapore, Taiwan, Thailand, Turkey, UAE and the UK. Data for Taiwan was collected from the Ministry of Science and Technology's 2016 *International Comparison of S&T Activities* available on the Ministry's website. The data for Taiwan was not standardized for purchasing power parity but is in current USD at current exchange rates.

Biotech R&D as a percentage of BERD
This indicator measures R&D expenditure specific to the biotechnology field as a percentage of overall business enterprise R&D spending. The data is collected from the OECD.Stat databank and forms part of its "Key Biotech Indicators" measure.

This data set includes all of the economies sampled in *Building the Bioeconomy 2017* except Argentina, Brazil, Chile, China, Colombia, India, Indonesia, Malaysia, Saudi Arabia, Singapore, Taiwan, Thailand, Turkey, UAE and the UK.

Factor 3: Intellectual property protection

Availability of regulatory data protection for submitted clinical data during the regulatory approval process
This indicator measures the availability of regulatory data protection for submitted clinical data during the regulatory approval process.

Availability of patent term restoration for biopharmaceuticals
This indicator measures the availability of a term of patent restoration for biopharmaceuticals due to delays caused during the sanitary regulatory review process.

US Chamber of Commerce International IP Index 2017 life sciences score, standardized to %
This indicator measures the availability and enforcement of IPRs related to the life sciences sector. This is a composite measure based on an aggregation of 12 indicators included in the International IP Index 2017.

All three above indicators are drawn from the U.S. Chamber of Commerce International IP Index 2017.

The International IP Index includes all of the economies sampled in *Building the Bioeconomy 2017* except Denmark and Ireland. Information for the first two indicators relating to RDP and PTE are drawn from public legal sources for both countries.

Factor 4: Regulatory environment

Existence of regulatory framework and efficiency
This indicator seeks to measure all aspects of the regulatory framework in place for all biotech sectors from product approval and manufacturing standards to clinical standards for biopharmaceutical R&D. This incudes, for instance, the speed of market authorization for biotechnology products; patent office backlogs; the existence and efficiency of an ag-bio framework; and the existence of a biosimilars pathway in line with international standards. Each economy sampled in *Building the Bioeconomy 2017* is evaluated individually on a qualitative basis.

Factor 5: Technology transfer

University/PRO-industry technology transfer frameworks in place
This indicator examines the existence and extent of technology transfer frameworks and operational arrangements in a given economy that aim to facilitate the development and commercialization of technologies developed within public sector entities. Each economy sampled in *Building the Bioeconomy 2017* is evaluated individually on a qualitative basis. This indicator is not biotechnology specific.

Private to private licensing and commercialization activity
This indicator measures the existence of barriers to private entity licensing and commercialization activities in a given economy. The data is collected from "Indicator 24: Regulatory and administrative barriers to the commercialization of IP assets" in the U.S. Chamber of Commerce International IP Index 2017. This indicator is not biotechnology specific.

Factor 6: Market and commercial incentives

Biopharmaceutical pricing and reimbursement policies
This indicator examines the commercial incentives provided through existing biopharmaceutical pricing and reimbursement policies. For the biopharmaceutical sector market and commercial incentives are primarily determined by the existing pricing and reimbursement systems for medicines and health technologies. The manner and extent to which these policies are put in place can have a profound impact on the commercial and market incentives for innovation more broadly in the health sector as well as for biotechnology R&D. Each economy sampled in *Building the Bioeconomy 2017* is evaluated individually on a qualitative basis.

R&D tax incentives
This indicator examines the tax incentives available and provided in a given economy as a means of encouraging R&D. R&D incentives can be various tax incentives, credits, deductions, lower rates of taxation for specific forms of income (e.g. income derived from IP assets such as patent box schemes) and/or direct support mechanisms such as grants and subsidies for R&D activities. In some countries R&D tax incentives are in place that target biotechnologies and/or biopharmaceutical innovation. Each economy sampled in *Building the Bioeconomy 2017* is evaluated individually on a qualitative basis.

Factor 7: Rule of law

World Justice Project Rule of Law Index country ranking
This indicator examines the legal certainty in a given economy as measured by the World Justice Project's *Rule of Law Index*. This indicator is not biotechnology specific.

3.2 Biotech outputs

As mentioned, the second half of the Biotech Policy Performance Measure relates to biotechnology outputs. Just as with assessing inputs, measuring biotechnology outputs is a difficult task. There are challenges with both defining what constitutes an actual biotech output as well as finding empirical evidence that is comparable for all the economies sampled.

As with the policy inputs this half of the Measure has been expanded this year with an additional two indicators to now include 13 indicators in total. The two new indicators measure the number of biotechnology firms in a given economy and a country's percentage share of global biofuels production. Table 4 shows the 13 indicators measuring biotechnology outputs.

TABLE 4 Biotech Policy Performance Measure, biotech outputs

- Scientific publications per million population
- Quality of academic publications
- Clinical trials per million population to date
- Clinical trials for biologics per million population to date
- Early phase (Phase I and II) clinical trials for biologics, per million population to date
- Biotechnology triadic patenting, share of global total average 1999-2013
- Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000
- National % share, total number of patents from top 50 PCT applicants: universities, 2015
- Biotechnology crops, hectares under cultivation, % of total 2016
- Biopharmaceutical Competitiveness Index (BCI) Survey 2016 Ranking
- Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2016
- No of Biotechnology firms, per million population
- Biofuels production, % of global total, 2016

As can be seen many of these indicators relate directly to a given form of biotechnology. These include, for example, rates of clinical research on biologic medicines or number of hectares of biotechnology crops under cultivation. Other indicators are more general and not biotechnology specific. For example, the data for rates of university patenting is not biotech specific. Still, this measure provides a good indication of the propensity of higher education institutions in a given economy to seek to patent their technologies. Each of the 13 indicators is described below together with its source and the number of *Building the Bioeconomy* countries which the data set covers.

Indicator 1: Scientific publications standardized for population

This indicator measures the number of scientific and technical journal articles published from a given economy.[149] This data provides an indication of a given economy's overall level of scientific and academic proficiency and output. This indicator is not biotechnology specific but covers all major forms of scientific and technical fields.[150] The data is collected by the World Bank and forms part of its World Development Indicators. The number of scientific publications has been standardized for population to provide a more accurate reflection of scientific publishing intensity in a given economy regardless of population size. The data has also been aggregated and a calculated average has been used for the period 2000-2013.

This data set includes all of the economies sampled in *Building the Bioeconomy 2016* except Taiwan. Equivalent data for Taiwan was collected from the Ministry of Science and Technology's 2016 *International Comparison of S&T Activities* available on the Ministry's website. This data measures annual papers and rank by nationality in the SCI ranking.

Indicator 2: Quality of academic publications

This indicator examines the quality of scientific publications. This data is collected by the OECD and measures the percentage of scientific publications among the world's 10% most cited.[151]

This data set includes all of the economies sampled in *Building the Bioeconomy 2017* except Argentina, Colombia, Malaysia, Saudi Arabia, Taiwan, Thailand, Singapore and the UAE.

Indicator 3: Clinical trials per million population to date

This indicator provides an overview of the biopharmaceutical clinical research environment in a given economy. Specifically, it provides the absolute number of clinical trials taking place (or having taken place) in a given economy as collated and registered on the website ClinicalTrials.gov; a website maintained by the National Library of Medicine at the National Institutes of Health in the US. As with other indicators the total number of trials has been standardised to population to provide a more accurate reflection of levels of clinical research intensity in a given economy regardless of population size.

This data set includes all of the economies sampled in *Building the Bioeconomy 2017.*

Indicator 4: Clinical trials for biologics per million population to date

This indicator examines the amount of recent clinical research focusing on biologic medicines. Specifically, it provides the number of clinical trials on biologic medicines taking place (or having taken place) in a given economy as collated and registered on the website *ClinicalTrials.gov* to date. Examining rates of clinical research specific to biologics is a good indicator of a given economy's technical capacity and proficiency in complex biotech innovation. Given the size, complexity and inherent instability of a biologic, the R&D process requires a considerable level of stability and technical capacity. The testing of a biologic drug candidate's safety and efficacy within a clinical trial necessitate a highly-controlled environment where the transportation and storage of the drug are controlled, the trial protocols are strictly adhered to and patients are monitored carefully. As with other indicators the total number of biologic trials has been standardised to population to provide a more accurate reflection of levels of biologics clinical research intensity in a given economy regardless of population size.

This dataset includes all of the economies sampled in *Building the Bioeconomy 2017*.

Indicator 5: Early phase (Phase I and II) clinical trials for biologics, per million population to date

This indicator focuses on early phase clinical research on biologic medicines to date. Early phase trials are the most scientifically advanced and represent the most innovative and riskiest phases of the clinical development process. As with other indicators the total number of trials has been standardised to population to provide a more accurate reflection of levels of early phase biologics clinical research intensity in a given economy regardless of population size.

This dataset includes all of the economies sampled in *Building the Bioeconomy 2017*.

Indicator 6: Biotechnology triadic patenting, share of global total average 1999-2013

This indicator examines levels of triadic patenting and an economy's share of the global number of biotechnology patents between 1999-2013. Triadic patenting is generally considered to be the best indicator of the perceived overall value and quality of a patent. The patent application is filed in three separate locations and filing costs are quite high. The three major patenting offices in which protection is sought are: the European Patent Office, the US Patent Office and the Japanese Patent Office.

This data is collected from the OECD.[152] This dataset includes all of the economies sampled in *Building the Bioeconomy 2017*.

Indicator 7: Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000

This indicator compares relative levels of biopharmaceutical product penetration in the sampled economies. Specifically, it looks at the percentage of products available in a given economy within five years of first global launch. The data is drawn from a 2014 National Bureau of Economic Research working paper and is in turn based on national product approval rates in 76 individual economies including all of the economies sampled in *Building the Bioeconomy* except China.[153]

Indicator 8: National % share total number of patents from top 50 PCT applicants: universities, 2015

This indicator examines rates of university PCT patenting as collected and published by WIPO.[154] Specifically, it looks at in which countries the world's 50 most prolific PCT patenting universities were based. To obtain a weighted share for each economy included in *Building the Bioeconomy 2017* the total number of PCT patents applied for by universities from each economy included in the top-50 was divided by the total number of patents applied for in 2015 by all 50 universities.

The underlying data includes all of the economies sampled in *Building the Bioeconomy 2017*.

Indicator 9: Biotechnology crops, hectares under cultivation, % of total 2016

This indicator compares levels of biotechnology derived crops in the sampled economies.[155] Data on hectares of biotechnology crops under cultivation are collected by the International Service for the Acquisition of Agri-biotech Applications and published annually. The number of hectares of biotech crops under cultivation is a good indicator of the level of biotechnology derived agricultural products in a given economy.

This data set includes all of the economies sampled in *Building the Bioeconomy 2017*.

Indicator 10: Biopharmaceutical Competitiveness Index (BCI) Survey, 2016 Ranking

This indicator compares economy's relative attractiveness to biopharmaceutical investment and innovation as viewed by executives on the ground in a given economy and captured in the BCI survey.[156] The BCI Survey examines the entire ecosystem in which biomedical innovation takes place from scientific capabilities and infrastructure; to state of the clinical environment; quality and efficiency of biomedical manufacturing and logistics operations; the biomedical regulatory framework (including the protection of intellectual property); healthcare financing; and overall market and business conditions. Using statistical analysis respondents' answers are translated into a quantitative score, which is used to benchmark economies' performance and overall attractiveness for investment. The BCI Survey is conducted by Pugatch Consilium, an international research consultancy and commissioned by PhRMA.

The 2016 BCI Survey has been developed into two separate surveys, one targeting "mature" markets and the other "newcomer" markets. This division is based on sophistication of the health and biopharmaceutical system as well as extent of historical biopharmaceutical R&D and manufacturing capabilities. The two surveys have been collected, scored and analyzed separately. For the purposes of country ranking on the Biotech Policy Performance Measure each country is compared within its respective country group.

This data set includes all of the economies sampled in *Building the Bioeconomy 2016* except Chile, Denmark and Malaysia.

Indicator 11: Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking

This indicator compares economies relative attractiveness to venture capital and private equity.[157] The *Venture Capital & Private Equity Country Attractiveness Index* is compiled by the IESE and EMLYON business schools and examines factors from general rates of economic activity to the taxation environment, investor protection mechanisms, size and liquidity of existing capital markets and other relevant factors.

Availability of venture capital and private equity funding is of considerable importance to biotechnology innovation and commercialization as many biotechnologies begin as nascent ideas within a start-up, smaller company or university. Figures from the National Association of Venture Capital suggests that in the US (the largest venture capital market in the world) biotechnology investments accounted for 11% of the USD69 billion total invested in 2016.[158]

This dataset includes all of the economies sampled in *Building the Bioeconomy 2017*.

Indicator 12: No of Biotechnology firms, per million population

This indicator measures the number of biotechnology firms present in a given economy. The data is collected from the OECD.Stat databank and forms part of its "Key Biotech Indicators" measure.

This data set includes all of the economies sampled in *Building the Bioeconomy 2017* except Argentina, Australia, Chile, China, Colombia, India, Indonesia, Malaysia, Russia, Saudi Arabia, Singapore, Taiwan, Thailand, Turkey, and the UAE.

Indicator 13: Biofuels production, % of global total, 2016

This indicator measures each country's percentage share of the total amount of biofuels produced globally in 2016. This data is collected from BP's Statistical Review of World Energy published in June 2016.

This data set includes all of the economies sampled in *Building the Bioeconomy 2017.*

3.3 Green, yellow and red – Traffic light classification system

Each economy's performance is classified according to three categories of classification for both indicators relating to policy inputs and biotech outputs:

1. Attractive (Policy inputs)/Highly Competitive (Biotech outputs)

2. Mixed

3. Challenging (Policy inputs)/Struggling to compete (Biotech outputs)

Quantitative indicators for both policy inputs and biotech outputs compare economies to one another based on relative performance. The top third of the economy sample is classified as "Attractive" or "Highly Competitive". The middle third of the economy sample is classified as "Mixed". And, finally, the lower third of the economy sample is classified as "Challenging" or "Struggling to Compete".

Based on the discussions in previous sections on the desirability and necessity of each of the seven enabling factors to stimulate innovation in the biotechnology sector economies with higher levels of the measured indicators (for instance, R&D spending) translates into a higher classification.

Qualitative indicators are based on a normative assessment of the desirability of the remaining enabling factors. For example, for Enabling Factor 3: Intellectual Property Protection, the availability of such IPRs as regulatory data protection and patent term restoration are viewed as attractive. Similarly, the indicator included in Enabling Factor 4: The Regulatory Environment examines the existence and efficiency of the regulatory structure in a given country. As mentioned above this incudes, for instance, the speed of market authorization for biotechnology products; patent office backlogs; the existence and efficiency of an ag-bio framework; and the existence of a biosimilars pathway in line with international standards.

As is explored in more detail in the following sub-section the relationship between policy inputs and biotech outputs is strong; economies that tend to have stronger environments with all enabling factors in place tend also to see higher levels of biotechnology outputs. This was a key finding in last year's *Building the Bioeconomy* and it has only been strengthened this year with the addition of 10 new countries.

3.4 The Biotech Policy Performance Measure – Overall results

On the following three pages Table 5 shows the overall results for the Biotech Policy Performance Measure. Economies move from left to right in the tables from those economies that have the most challenging environments for both policy inputs and biotech outputs to those with the most attractive policy environments and accompanying high levels of biotechnology outputs.

TABLE 5 Biotech Policy Performance Measure – Overall results

Inputs	Indonesia	India	Mexico	Brazil	UAE	Colombia	Turkey	Saudi Arabia	Thailand
Factor 1: Human capital									
Number of researchers per million population	Challenging	Challenging	Challenging	Challenging	NA	Challenging	Mixed	NA	Challenging
Life sciences graduates (PhD & Masters), per million population	Challenging	NA	Challenging	Mixed	NA	Challenging	Challenging	NA	NA
Factor 2: Infrastructure for R&D									
R&D spending % of GDP	Challenging	Mixed	Challenging	Mixed	Challenging	Challenging	Mixed	Challenging	Challenging
BERD spending as a % of total	NA	NA	Challenging	NA	NA	NA	Mixed	NA	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA	NA	Challenging	NA	NA	NA	NA	NA	NA
Biotech R&D as a percentage of BERD	NA	NA	Challenging	NA	NA	NA	NA	NA	NA
Factor 3: Intellectual property protection	Challenging	Challenging	Mixed	Challenging	Challenging	Mixed	Mixed	Mixed	Challenging
Factor 4: The regulatory environment	Challenging	Challenging	Mixed	Challenging	Attractive	Mixed	Challenging	Mixed	Challenging
Factor 5: Technology transfer and commercialization frameworks									
University/PRO-industry tech transfer frameworks	Challenging	Challenging	Challenging	Mixed	Mixed	Challenging	Mixed	Mixed	Challenging
Private to private licensing and commercialization activity	Challenging	Challenging	Mixed	Mixed	Mixed	Challenging	Mixed	Attractive	Challenging
Factor 6: Market and commercial incentives									
Biopharmaceutical pricing and reimbursement policies	Mixed	Challenging	Challenging	Challenging	Mixed	Challenging	Challenging	Mixed	Challenging
R&D tax incentives	Challenging	Attractive	Mixed	Mixed	NA	Mixed	Attractive	Challenging	Mixed
Factor 7: Rule of law	Mixed	Challenging	Challenging	Mixed	Mixed	Challenging	Challenging	NA	Challenging
Outputs									
Scientific publications per million population	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete
Quality of academic publications	Mixed	Struggling to compete	Struggling to compete	Struggling to compete	NA	NA	Struggling to compete	NA	NA
Clinical trials per million population to date	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Mixed
Clinical trials for biologics per million population to date	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed
Early phase (Phase I and II) clinical trials for biologics, per million population to date	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed
Biotechnology triadic patenting, share of global total average 1999-2012	Struggling to compete	Mixed	Mixed	Mixed	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	Struggling to compete	Struggling to compete	Highly competitive	Mixed	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Mixed
National % share total number of patents from top 50 PCT applicants: universities, 2015	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete
Biotechnology crops, hectares under cultivation, % of total 2016	Struggling to compete	Highly competitive	Mixed	Highly competitive	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Struggling to compete
BCI Survey Ranking 2016	Struggling to compete	Mixed	Mixed	Struggling to compete	Highly competitive	Struggling to compete	Struggling to compete	Highly competitive	Struggling to compete
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2016	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Mixed
No of Biotechnology firms, per million population	NA	NA	Struggling to compete	Mixed	NA	NA	NA	NA	NA
Biofuels production, % of global total, 2016	Highly competitive	Mixed	Mixed	Highly competitive	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Highly competitive

TABLE 5 Biotech Policy Performance Measure – Overall results (cont.)

Inputs	Russia	Argentina	South Africa	China	Chile	Malaysia	Taiwan	Australia
Factor 1: Human capital								
Number of researchers per million population	Mixed	Mixed	Challenging	Mixed	Challenging	Mixed	Attractive	Attractive
Life sciences graduates (PhD & Masters), per million population	Mixed	NA	NA	NA	Challenging	NA	Attractive	Mixed
Factor 2: Infrastructure for R&D								
R&D spending % of GDP	Mixed	Challenging	Mixed	Mixed	Challenging	Mixed	Attractive	Mixed
BERD spending as a % of total	Challenging	Challenging	Challenging	Attractive	Challenging	NA	Attractive	Mixed
Total biotechnology R&D expenditure, Millions USD PPP, per million population	Challenging	NA	Challenging	NA	NA	NA	NA	Challenging
Biotech R&D as a percentage of BERD	Challenging	NA	Mixed	NA	NA	NA	NA	Challenging
Factor 3: Intellectual property protection	Mixed	Challenging	Challenging	Challenging	Mixed	Mixed	Mixed	Attractive
Factor 4: The regulatory environment	Challenging	Mixed	Mixed	Challenging	Mixed	Mixed	Mixed	Attractive
Factor 5: Technology transfer and commercialization frameworks								
University/PRO-industry tech transfer frameworks	Challenging	Mixed	Mixed	Attractive	Mixed	Mixed	Attractive	Mixed
Private to private licensing and commercialization activity	Challenging	Mixed	Mixed	Challenging	Mixed	Mixed	Attractive	Attractive
Factor 6: Market and commercial incentives								
Biopharmaceutical pricing and reimbursement policies	Challenging	Challenging	Challenging	Challenging	Mixed	Challenging	Mixed	Challenging
R&D tax incentives	Mixed	Challenging	Mixed	Mixed	Mixed	Attractive	Mixed	Mixed
Factor 7: Rule of law	Challenging	Mixed	Mixed	Challenging	Mixed	Mixed	NA	Attractive
Outputs								
Scientific publications per million population	Mixed	Mixed	Struggling to compete	Mixed	Mixed	Mixed	Highly competitive	Highly competitive
Quality of academic publications	Struggling to compete	NA	Mixed	Struggling to compete	Mixed	NA	NA	Highly competitive
Clinical trials per million population to date	Struggling to compete	Mixed	Mixed	Struggling to compete	Mixed	Mixed	Highly competitive	Highly competitive
Clinical trials for biologics per million population to date	Mixed	Mixed	Mixed	Struggling to compete	Mixed	Mixed	Mixed	Highly competitive
Early phase (Phase I and II) clinical trials for biologics, per million population to date	Mixed	Mixed	Mixed	Struggling to compete	Mixed	Mixed	Mixed	Highly competitive
Biotechnology triadic patenting, share of global total average 1999-2012	Mixed	Mixed	Mixed	Mixed	Struggling to compete	Struggling to compete	Mixed	Highly competitive
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	Struggling to compete	Highly competitive	Mixed	NA	Mixed	Struggling to compete	Mixed	Mixed
National % share total number of patents from top 50 PCT applicants: universities, 2015	Struggling to compete	Struggling to compete	Struggling to compete	Highly competitive	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete
Biotechnology crops, hectares under cultivation, % of total 2016	Struggling to compete	Highly competitive	Mixed	Highly competitive	Mixed	Struggling to compete	Struggling to compete	Mixed
BCI Survey Ranking 2016	Mixed	Struggling to compete	Mixed	Mixed	NA	NA	Highly competitive	Struggling to compete
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2016	Struggling to compete	Struggling to compete	Mixed	Mixed	Mixed	Highly competitive	Mixed	Highly competitive
No of Biotechnology firms, per million population	NA	NA	Struggling to compete	NA	NA	NA	NA	NA
Biofuels production, % of global total, 2016	Struggling to compete	Highly competitive	Struggling to compete	Highly competitive	Struggling to compete	Struggling to compete	Struggling to compete	Mixed

TABLE 5 Biotech Policy Performance Measure – Overall results (cont.)

Inputs	Ireland	Japan	Korea	Israel	UK	Singapore	Denmark	Switzerland	US
Factor 1: Human capital									
Number of researchers per million population	Mixed	Attractive	Attractive	Attractive	Mixed	Attractive	Attractive	Attractive	Mixed
Life sciences graduates (PhD & Masters), per million population	Mixed	NA	Mixed	Attractive	Attractive	Attractive	Mixed	Attractive	Mixed
Factor 2: Infrastructure for R&D									
R&D spending % of GDP	Mixed	Attractive	Attractive	Attractive	Mixed	Attractive	Attractive	Attractive	Attractive
BERD spending as a % of total	Mixed	Attractive	Attractive	Challenging	Mixed	Mixed	Mixed	Attractive	Attractive
Total biotechnology R&D expenditure, Millions USD PPP, per million population	Mixed	Mixed	Mixed	Mixed	NA	NA	Attractive	Attractive	Attractive
Biotech R&D as a percentage of BERD	Attractive	Challenging	Mixed	Mixed	NA	NA	Attractive	Attractive	Mixed
Factor 3: Intellectual property protection	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive
Factor 4: The regulatory environment	Mixed	Attractive	Attractive	Mixed	Attractive	Attractive	Mixed	Mixed	Attractive
Factor 5: Technology transfer and commercialization frameworks									
University/PRO-industry tech transfer frameworks	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive
Private to private licensing and commercialization activity	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive	Attractive
Factor 6: Market and commercial incentives									
Biopharmaceutical pricing and reimbursement policies	Mixed	Mixed	Challenging	Mixed	Mixed	Mixed	Mixed	Mixed	Attractive
R&D tax incentives	Attractive	Mixed	Mixed	Attractive	Attractive	Attractive	Attractive	Mixed	Mixed
Factor 7: Rule of law	NA	Attractive	Attractive	NA	Attractive	Attractive	Attractive	NA	Attractive
Outputs									
Scientific publications per million population	Mixed	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive
Quality of academic publications	Highly competitive	Mixed	Mixed	Mixed	Highly competitive	NA	Highly competitive	Highly competitive	Highly competitive
Clinical trials per million population to date	Highly competitive	Mixed	Mixed	Highly competitive	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive
Clinical trials for biologics per million population to date	Highly competitive	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive
Early phase (Phase I and II) clinical trials for biologics, per million population to date	Highly competitive	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive
Biotechnology triadic patenting, share of global total average 1999-2012	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Mixed	Highly competitive	Highly competitive	Highly competitive
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	Highly competitive	Mixed	Highly competitive	Struggling to compete	Highly competitive	Mixed	Highly competitive	Highly competitive	Highly competitive
National % share total number of patents from top 50 PCT applicants: universities, 2015	Struggling to compete	Highly competitive	Highly competitive	Mixed	Mixed	Highly competitive	Mixed	Mixed	Highly competitive
Biotechnology crops, hectares under cultivation, % of total 2016	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Struggling to compete	Highly competitive
BCI Survey Ranking 2016	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	NA	Highly competitive	Struggling to compete
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2016	Mixed	Highly competitive	Mixed	Mixed	Highly competitive	Highly competitive	Highly competitive	Highly competitive	Highly competitive
No of Biotechnology firms, per million population	Highly competitive	Struggling to compete	Mixed	Highly competitive	Mixed	NA	Mixed	Mixed	Highly competitive
Biofuels production, % of global total, 2016	Struggling to compete	Struggling to compete	Mixed	Struggling to compete	Mixed	Struggling to compete	Struggling to compete	Struggling to compete	Highly competitive

3.5 The Biotech Policy Performance Measure – Discussion

So what stands out from the 2017 results of the Measure?

First, is the relative lack of concrete data for many of the countries added this year. Many of the new countries do not have data readily available on key indicators including number of researchers in R&D, life sciences graduates, business and enterprise expenditure on R&D and biotechnology specific R&D spending. For other countries – such as Singapore and Taiwan – the data is only available through national statistics offices and not international databases. The best possible comparable data is always what has been centrally collected or processed with any standardization methodology consistently applied by the collecting body.

Second, of the new additions Chile and Australia stand out as two developed, high-income OECD economies whose policy environments are relatively weak. Although Australia has a number of strengths its main weaknesses compared to other OECD markets lay in its biopharmaceutical policy inputs and related outputs. In particular a stringent pricing and reimbursement environment on the input side is accompanied by relatively low levels of pharmaceutical product registration measured over close to a 20-year period as well as a low ranking by biopharmaceutical executives in Australia on the Biopharmaceutical Competitiveness Survey 2016. This is surprising given Australia's other intrinsic strengths as a high-income innovation driven economy with good levels of technical capacity. In this sense Australia could be more competitive than it currently is. Looking at Chile many of its policy inputs are when compared to the other 25 countries not competitive. In fact looking at the raw numbers Chile is behind not only other OECD countries but even regional peers including Argentina and Brazil. For instance, as a percentage of its GDP Brazil spends three times as much on R&D as Chile; 1.23% versus 0.38%. This despite Brazil having an estimated 2015 per capita income at PPP two-thirds that of Chile at USD15,473 versus USD23,366 for Chile.[159] Equally, Argentina has rates of researchers in R&D almost three times as high as Chile at 1,202 per million population compared with Chile's 428. And looking at biotechnology specific expertise as measured by life sciences graduates, Chile again is far behind OECD countries with a per million population rate of 23.83 graduates (PhD and Masters) compared to 135.88 in Israel and over 200 in the UK; two of the top performers.

Finally, and most importantly, just as with last year's edition what stands out most clearly from the results of the Biotech Policy Performance Measure is the link between policy inputs and biotech outputs. Moving from left to right on the above tables it is clear that economies that tend to have in place policies that create an enabling environment as captured by the seven enabling factors tend also to be more competitive when it comes to biotechnology outputs. Few countries with challenging policy environments across the board are competitive on any of the 13 biotech outputs indicators measured. In fact the addition of 10 new countries to the sample has only strengthened this claim and the evidence to support it.

4 CONCLUDING THOUGHTS

How can aspiring countries successfully build their biotech capacity? After four years of *Building the Bioeconomy* we take a look at some of the key lessons.

In the first edition of *Building the Bioeconomy* we made six recommendations that countries should take for advancing their biotechnology sectors:

1. Identify the biotechnology sector as an area of strategic importance

Identifying the biotechnology sector as an area of strategic importance is the first step in successfully building a national biotechnology policy.

2. Create a national blueprint

The existence and creation of a blueprint of national biotechnology strategy can be a powerful tool in creating a vision and setting a goal for national aspirations.

3. Measure performance

The measuring of performance of the biotechnology sector in a transparent and systematic fashion is of real importance to understanding progress made and challenges remaining in order to allow for mid-course corrections that may be necessary.

4. Recognize and use existing best practices

Although no two countries are the same and all face different circumstances, countries can learn from the experiences of each other. International best practices should be shared and repositories of information and resource sharing are all positive and worthwhile undertakings.

5. Leverage national capabilities

Understanding and focusing on one's comparative and competitive advantage can lead to the most effective allocation of resources. Country size, scientific and research strengths, geography and biodiversity are all important attributes. Some countries have natural strengths in some biotech sectors whereas others can compete and develop across the board.

6. Enhance local and international cooperation

Cooperation and partnerships between public and private, national and international stakeholders can be key in attracting investment and building up a world-class biotech industry.

While these recommendations remain as relevant today as they were four years ago, what is interesting is that, just as with the seven enabling factors, countries are focusing on s subset of these recommendations rather than the entire six.

For example, as detailed in section 2, more and more countries are in fact identifying biotechnology and its core industries as strategic sectors and putting in place national innovation plans as well as biotechnology specific strategies or visions. Yet in key areas – including recognizing and using existing best practices and deepening international cooperation – there is less of an emphasis. It is instructive in this respect that many of the smallest global leaders in biotechnology are not resting on their laurels but actively seeking out new ways to enhance and improve their competitiveness. Singapore, again, is leading the way both in respect of taking a holistic approach but also focusing on the details and what matters to the case of improving its own competitiveness. The Committee on the Future of the Economy, an ad-hoc entity helmed by the Ministry of Finance tasked with developing pro-innovation economic strategies, issued its report in February 2017.[160] Among others, the report recommended: Singapore's universities and companies should link up with overseas partners in major innovation hubs through a Global Innovation Alliance; introduce new and technology-focused skills training; and simplify the regulatory framework for venture capital to encourage more investment in start-ups and young companies.[161] Despite the fact that on most metrics – including all 28 indicators included

in the Biotechnology Policy Performance Measure – Singapore is a world leader in innovation and biotechnology the Government is moving ahead with an ambitious agenda as if the country were again starting from scratch.

The lesson for other countries is simple and can be reduced to two basic principles. One, to build a world-class biotechnology capacity it is not enough to focus on one or two areas of reform. Instead, reform efforts need to be comprehensive and include both the hardware side of innovation as well as the software, that is, the public policies that grease the wheels of biotech innovation. And two, Rome was not built over night. Success in biotechnology is neither preordained nor guaranteed. Countries like Denmark, Singapore and Israel are not intrinsically blessed with world-class biotechnology capacity. They do not have sizeable markets that can on their own attract large-scale investment and R&D. Instead, these countries have had to focus on getting the policies right, making themselves attractive and competitive. And, instructively their efforts do not and have not stopped. This is a lesson all countries – big and small, advanced or just starting out – can take to heart.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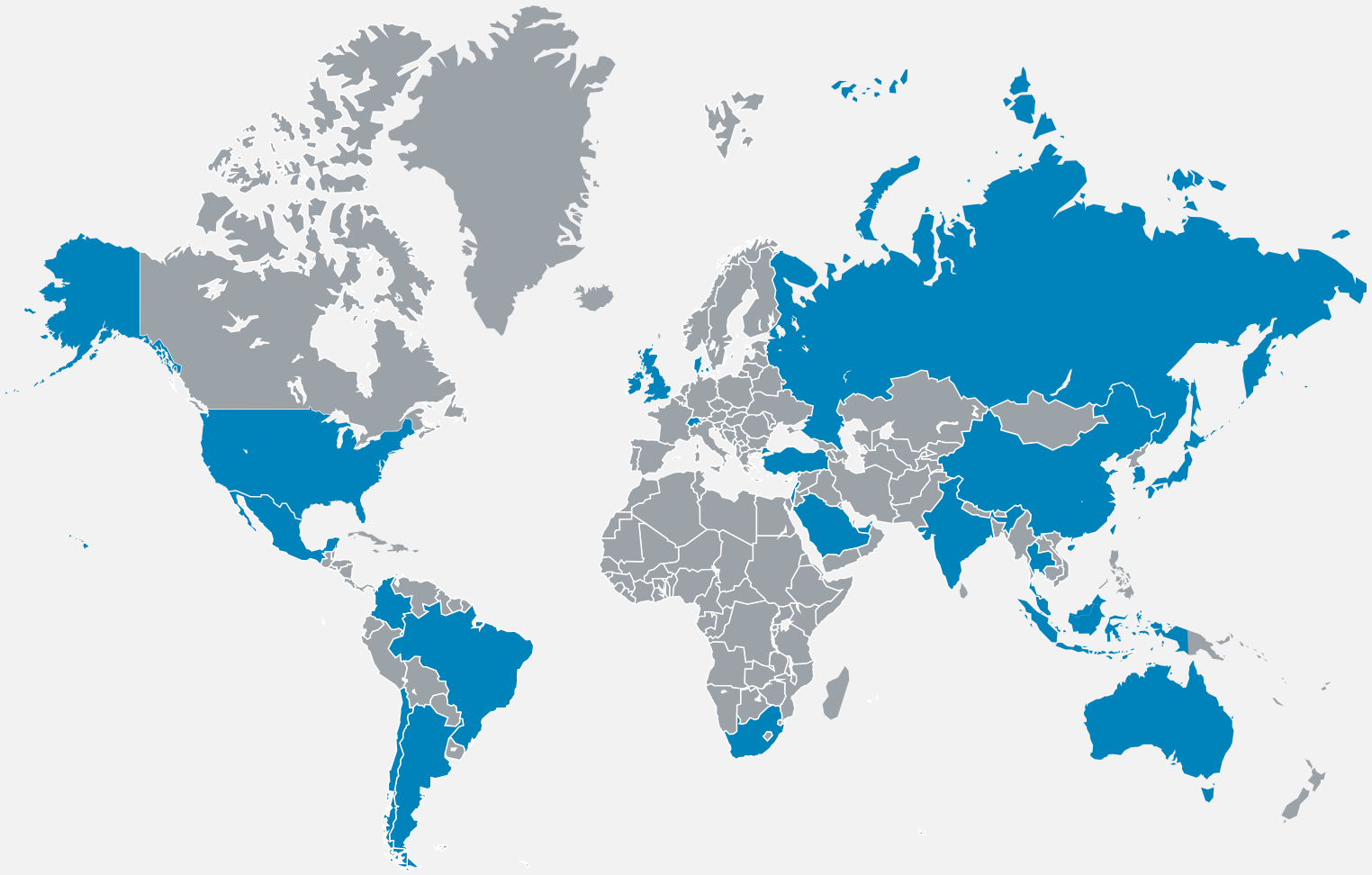
ANNEX – INDIVIDUAL COUNTRY OVERVIEWS AND STATISTICS

As detailed in preceding sections each country included in the Biotechnology Policy Performance Measure has been compared on each of the 28 indicators and categorized for each one according to the traffic-light classification system discussed above.

The data used as a basis for classifying and categorizing each country has been collected from international and national sources and databases. Below is a full individual country overview for each of the 26 countries included in *Building the Bioeconomy 2017* including all relevant statistics and information on which each country has been assessed.



ARGENTINA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	1,202 (World Bank 2014)
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.61% (OECD 2014)
BERD spending as a % of total	20.1% (OECD 2013)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	Neither RDP nor PTE available. Achieved a score of 28.31% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Strong regulatory authority and science based regulations for ag-bio: global leader with US, Brazil. 2015 saw introduction of "New Breeding Techniques" regulation for innovative biotech use in plants. Argentina a global leader in introducing this. For biopharma sanitary regulations are lacking: i) no bioequivalence requirement for generics; ii) poor pharmacovigilance; iii) long CTs delays/approval times (180 days).
Factor 5: Technology transfer and commercialization frameworks	No direct barriers in place for licensing between private and private entities (including foreign entities). Registration with INPI is not required but can result in tax benefits. No framework in place for universities; CONICET (National Scientific and Technical Research Council) automatically owns 50% of any invention developed by public universities. Some high profile examples of success stories in public-private tech transfer include National University of Litoral/ CONICET discovery and isolation of a gene that makes plants resistant to drought and saline soil. CONICET has relatively well developed tech transfer platforms and frameworks in place.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Generally challenging P&R environment. Caps on price growth introduced in recent years together with increased focus on cuts to reimbursement and preferential treatment for lower cost, locally manufactured medicines. Non-bioequivalence tested generics drugs (*similares*) a pervasive part of the market.
R&D tax incentives	General R&D tax incentive scheme in place is limited; for 2014/15 was capped at US$15million total budget. Additional incentives target software and biotechnology. Incentives for biotech range from VAT accelerated payments and 50% tax credit on social security contributions.
Factor 7: Rule of law	Ranked 51 out of 113 countries

OUTPUTS	
Scientific publications per million population	143
Quality of academic publications	NA
Clinical trials per million population to date	49.20
Clinical trials for biologics per million population to date	4.15
Early phase (Phase I and II) clinical trials for biologics, per million population to date	1.08
Biotechnology triadic patenting, share of global total average 1999-2013	0.05%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	45.30%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	12.86%
BCI Survey Ranking 2016	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	54
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	2.60%

AUSTRALIA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	4,530 (2010 World Bank)
Life sciences graduates (PhD & Masters), per million population	66.78 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	2.11 % (OECD 2013)
BERD spending as a % of total	47.9 (OECD 2000)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	5.24 (OECD 2015)
Biotech R&D as a percentage of BERD	1% (OECD 2015)
Factor 3: Intellectual property protection	Both RDP and PTE are available. Some uncertainty relating to the future of PTE through the Productivity Commission's recommendations. Achieved a score of 74.58% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Generally high standard of regulatory approval for biopharmaceuticals although unlike other stringent DRAs Australia has not had fast track approval in place. Reform plans underway following Expert Panel Review. Regulatory hurdles in place for ag-bio cultivation: AUS federal government is generally supportive however significant restrictions have historically been in place at a state level e.g. the 2003 GM Free Areas Bill in Western Australia which was not repealed until Oct 2016.
Factor 5: Technology transfer and commercialization frameworks	University/PRO cooperation has traditionally not been as strong as in leading high-income economies. In 2016 OECD STI Outlook Australia's tech transfer was ranked around the OECD average. On a positive note Australia does not have any significant barriers in place for private-private licensing and commercialization arrangements.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Generally challenging P&R environment. Number of product registrations relatively low and number of products included for reimbursement on PBS is low compared the high-income developed world averages.
R&D tax incentives	Relatively low effective rate ranging from 8.5-15% depending on size of the enterprise. No biotech specific R&D incentives
Factor 7: Rule of law	Ranked 11 out of 113 countries

OUTPUTS	
Scientific publications per million population	1,425
Quality of academic publications	15.4%
Clinical trials per million population to date	226.82
Clinical trials for biologics per million population to date	27.03
Early phase (Phase I and II) clinical trials for biologics, per million population to date	12.26
Biotechnology triadic patenting, share of global total average 1999-2013	1.67%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	27.30%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	0.49%
BCI Survey Ranking 2016	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	91.9
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	0.30%

BRAZIL

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	698 (2010 World Bank)
Life sciences graduates (PhD & Masters), per million population	24.24 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	1.23 % (World Bank 2013)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	Both RDP and PTE for biopharmaceuticals unavailable; RDP available for agricultural and veterinary products. Achieved a score of 40.65% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Regulatory system in place for biotechnology through ANVISA and CTNBio. Ag-bio framework generally regarded as science-based and world-leading. Biosimilars pathway in place. Dual examination requirement for biopharmaceutical patent applications outside international standards. Long delays (10+ years) for patent applications reduces effective exclusivity period. On a positive note unlike Argentina and other LatAm countries Brazil introduced bioequivalence testing requirements for all similares in 2003.
Factor 5: Technology transfer and commercialization frameworks	2017 saw removal of INPI as regulator of licensing agreements. Registration requirements remains but INPI has no oversight or inclination to amend commercial terms. If fully implemented would represent a significant improvement in tech transfer environment.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Generally challenging P&R environment. Prices regulated by the Câmara de Regulação do Mercado de Medicamentos (CMED) founded in 2003. Drugs are priced based on relative innovativeness compared to comparators – HTA process included in decision. IRP used extensively and calculated on lowest average ex-manufacturing price of the product in a basket of countries. Separate IRP calculation for "exceptional medicines" to which a "Coefficient Adequacy Price" (Coeficiente de Adequação de Preço) or CAP is applied. Reimbursement decisions by CONITEC, SUS and MoH; largely based on cost analysis.
R&D tax incentives	R&D tax credits and super deductions in place for qualifying expenditure. However, super deductions for patents are contingent on registration; long patent delays mean tax credit in effect is unavailable.
Factor 7: Rule of law	Ranked 52 out of 113 countries

OUTPUTS	
Scientific publications per million population	140
Quality of academic publications	6.7%
Clinical trials per million population to date	25.54
Clinical trials for biologics per million population to date	1.43
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.47
Biotechnology triadic patenting, share of global total average 1999-2013	0.11%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	31.60%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	26.52%
BCI Survey Ranking 2016	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	58.3
No of Biotechnology firms, per million population	4.38
Biofuels production, % of global total (Rule of Law Index 2016)	23.60%

CHILE

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	427 (2014 World Bank)
Life sciences graduates (PhD & Masters), per million population	23.83 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.38 % (OECD 2014)
BERD spending as a % of total	32% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	5-yr RDP term available. PTE calculations limit actual 5-yr availability and heightened uncertainty through new recommendations by FNE committee in 2016. Achieved a score of 46.46% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Generally high regulatory standards relating to biopharmaceuticals, in particular Chile is seeking to become a Level 4 PAHO/WHO accredited regional authority. However, *similares* still on the market in Chile. "Ricarte Soto" Law introduced greater ambiguity and potential costs for companies around clinical trials. Specifically, clinical trial sponsors face greater liability for adverse effects, including those that were not predictable with available scientific knowledge at the start of the trial and for a period of ten years following the trial (as opposed to the 5 years previously required). Has led to a drop in trials. Chile does not allow for the cultivation of ag-bio products. Only production of seeds is allowed for export purposes. No biotechnology framework in place.
Factor 5: Technology transfer and commercialization frameworks	CORFO has in place a number of tech transfer initiatives including Technology Transfer Hubs and Start-Up Chile. Some examples of success stories e.g. *Fundación Chile*, a well-established not-for-profit NGO, has had several successful biotech collaborations in the past including R&D collaborations in fruit and forestry biotechnology with US and Canadian biotech firms. Overall Chile ranks low on OECD 2015 STI Scoreboard for technology transfer activities.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	No central price control with public sector prices negotiated via public tenders through CENABAST or directly with public institutions. Minimum 30% discount for CENABAST-negotiated medicines. Reimbursement policies vary but long-standing insecurity of reimbursement for high-cost treatments resulted in "Ricarte Soto" Law (Ley 20,850) which aims to increase the level and scope of funding for high-cost treatments with an initial budget of around USD35 million in 2015 that increased to nearly USD150 million in 2017, providing full reimbursement to expensive drugs treating 14 health conditions.
R&D tax incentives	Tax credits (35%) and tax deductions are available. However the credit is capped at $US1.2million and there are no specific biotech incentives.
Factor 7: Rule of law	Ranked 26 out of 113 countries

OUTPUTS	
Scientific publications per million population	185
Quality of academic publications	9.3%
Clinical trials per million population to date	66.64
Clinical trials for biologics per million population to date	6.02
Early phase (Phase I and II) clinical trials for biologics, per million population to date	2.06
Biotechnology triadic patenting, share of global total average 1999-2013	0.03%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	28.80%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	0.01%
BCI Survey Ranking 2016	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	73
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

CHINA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	1,113 (2014 World Bank)
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	2.05 % (OECD 2014)
BERD spending as a % of total	75.4% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	6-yr RDP term available but limited protection for biopharmaceuticals; only applies to NCEs. No PTE available. Achieved a score of 39.42% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	CFDA is increasing its capabilities but regulatory hurdles for biopharmaceuticals persist including substantial delays in product and clinical trial registration and major gaps in pharmacovigilance policies and enforcement. Over 18,000 drugs applications are awaiting market authorization as of 2015. Positively, 2015 biosimilar pathway broadly reflects the approach taken in the EU and US. For ag-bio a number of regulatory related barriers to market entry persists. They include: the requirement that a product must be registered and approved in the country of export prior to an application for approval can be made in China; and a requirement that import applications include viable seeds.
Factor 5: Technology transfer and commercialization frameworks	Tech transfer framework in place encouraging high levels of commercialization. Relative freedom for universities and researchers to pursue commercial ventures has seen a sharp increase in university patenting, patent and technology transfers and number of spin-offs where Chinese academics are world-leaders. More serious barriers are in place for private to private licensing and commercialization activity. China has for several years pursued an overarching approach to investment and innovation that both directly and indirectly requires localization in order to access the market.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Cost containment measures designed to make medicines more accessible for patients have largely hindered innovative drugs from entering the Chinese market. Prices are increasingly contained by reimbursement and tendering procedures, as well as price limits on certain types of drugs. For instance, the public Essential Drug List restricts the number of "high-cost" drugs that can be prescribed in local hospitals and clinics. A strict and limited reimbursement procedure also exists e.g. the National Reimbursement Drug List does not include major types of biologics, including monoclonal antibodies.
R&D tax incentives	Generous R&D tax credits in place and target high-tech industries (including biotech) but local ownership requirements/partnerships in place.
Factor 7: Rule of law	Ranked 80 out of 113 countries

OUTPUTS	
Scientific publications per million population	149
Quality of academic publications	6.7%
Clinical trials per million population to date	6.29
Clinical trials for biologics per million population to date	0.55
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.34
Biotechnology triadic patenting, share of global total average 1999-2013	0.99%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	NA
National % share total number of patents from top 50 PCT applicants: universities, 2015	8.11%
Biotechnology crops, hectares under cultivation, % of total 2016	1.51%
BCI Survey Ranking 2016	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	77.1
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	3.20%

COLOMBIA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	152 (2013 World Bank)
Life sciences graduates (PhD & Masters), per million population	7.91 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.195 % (World Bank 2014)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	5-yr RDP term available but uncertainty over protection for biologics. No PTE available. CLs threats used as a means of price negotiation. Achieved a score of 43.77% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Recent 2016 reforms to biopharma CTs environment should improve CT approvals dramatically. Biosimilar pathway in place but outside international standards. Ag-bio regulations science-based but time consuming.
Factor 5: Technology transfer and commercialization frameworks	Colombian public sector researchers and university faculty are not allowed a second salaried income which essentially means that the incentives to set up new businesses through spin-offs or start-ups is limited. Looking at outputs there is limited evidence but relatively few universities derive significant forms of income from commercialization and commercial research services. Colombian law prohibits any non-profit organization, including private universities, from engaging in commercial activities. Andean Community legislation also adds significant restrictions on agreements with foreign licensors, requiring registration and evaluation of licenses by national authorities on the basis of subjective criteria regarding the so-called value of imported technologies.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The pricing and reimbursement environment for biopharmaceuticals in Colombia is relatively challenging. Maximum sales prices for all medicines is since the signing into law of the 2015 health reform package (Ley Estatutaria de Salud, 1751) vested within the Ministry of Health and not with the now defunct Comisión Nacional de Precios de Medicamentos. Drug prices set by the Ministry of Health are applicable to both private and public markets based on a system of international reference pricing. Prices are set according to wholesale levels with margins monitored by the Ministry of Health. With regards to the reimbursement environment this remains uncertain with question marks as to the effect on access to innovative medicines with the difficult budgetary environment. Significant price cuts and reimbursement limits have been introduced and the Colombian Government has introduced more extreme price control measures including the threat of using compulsory licensing with the latest being the new public interest declaration route outlined in 2016/17.
R&D tax incentives	Limited range of R&D tax incentives; capital investment allowance available but capped with universal budget allowance. Availability of allowance contingent on local content requirements.
Factor 7: Rule of law	Ranked 71 out of 113 countries

OUTPUTS	
Scientific publications per million population	40
Quality of academic publications	NA
Clinical trials per million population to date	20.03
Clinical trials for biologics per million population to date	2.51
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.73
Biotechnology triadic patenting, share of global total average 1999-2013	0.01%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	31.50%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	0.05%
BCI Survey Ranking 2016	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	66.3
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	0.90%

DENMARK

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	7,198 (2014 World Bank)
Life sciences graduates (PhD & Masters), per million population	92.18 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	3.05 % (OECD 2014)
BERD spending as a % of total	57.9% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	196.6
Biotech R&D as a percentage of BERD	22%
Factor 3: Intellectual property protection	Both 10-yr RDP term available and 5-yr SPC available under EU law. Not included in IP Index.
Factor 4: The regulatory environment	High regulatory standards for biopharmaceuticals (both EMA and national agency, *Laegemiddelstyrelsen*). But Denmark has banned GMO cultivation and is one of 19 EU Member States to opt out from Commission approved cultivation of a GM crop.
Factor 5: Technology transfer and commercialization frameworks	Denmark was one of the first EU countries to put in place technology transfer legislation supporting university commercialization of publicly funded research. Denmark also provides a number of funding measures to help young and innovative biotechnology companies thrive. Cooperation is particularly active at the Medicon Valley Biotech Cluster where over 300 life science companies, 12 universities, and 32 hospitals (together employing 40,000 people) operate.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	By European standards the pricing and reimbursement environment for biopharmaceuticals is less stringent than other countries. Price controls are only indirectly in place with agreements between the Danish pharmaceutical industry and MoH. Reference pricing system in place and heavy use of generic substitution and promotion policies.
R&D tax incentives	Tax credits and deductions are available as R&D incentives. The R&D tax credit is up to 25% with a maximum cap of 25 million Danish Crowns.
Factor 7: Rule of law	Ranked 1 out of 113 countries

OUTPUTS	
Scientific publications per million population	1,621
Quality of academic publications	18.6%
Clinical trials per million population to date	1,085
Clinical trials for biologics per million population to date	56.66
Early phase (Phase I and II) clinical trials for biologics, per million population to date	22.36
Biotechnology triadic patenting, share of global total average 1999-2013	1.71%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	44.90%
National % share total number of patents from top 50 PCT applicants: universities, 2015	1.91%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Not included
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	85.4
No of Biotechnology firms, per million population	24.36
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

INDIA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	157 (2010 World Bank)
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.822 % (2011 World Bank)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	No RDP term or PTE available. Generally a very challenging IP environment with heightened patentability standards (section 3D) and use of CLs. Achieved a score of 25.42% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Under-developed biopharmaceutical regulatory framework; high levels of substandard and counterfeit medicines. No ag-bio applications approved since 2011. Biosimilars pathway in place.
Factor 5: Technology transfer and commercialization frameworks	Technology transfer and commercialization of public funded research remains relatively limited. Identified as a key priority in the *National Biotechnology Development Strategy and National Intellectual Property Rights Policy*. Yet very few Indian universities have functioning TTOs and outputs relatively sparse.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Relatively strict price controls are in place for drugs and pharmaceuticals available through the National List of Essential Medicines. Over the last few years price restrictions have been extended to increasing numbers of drugs, including anti-diabetic, cardiovascular and oncology treatments.
R&D tax incentives	Significant R&D tax incentives are available for qualifying expenditure. Limited localization requirements
Factor 7: Rule of law	Ranked 66 out of 113 countries

OUTPUTS	
Scientific publications per million population	37
Quality of academic publications	6.8%
Clinical trials per million population to date	2.26
Clinical trials for biologics per million population to date	0.19
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.09
Biotechnology triadic patenting, share of global total average 1999-2013	0.57%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	8.20%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	5.83%
BCI Survey Ranking 2016	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	69.9
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	0.50%

INDONESIA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	90 (2009 World Bank)
Life sciences graduates (PhD & Masters), per million population	0.1 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.085 % (2013 World Bank)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	No RDP term or PTE available. Generally a very challenging IP environment with heightened patentability standards introduced in 2016 and active use of CLs. Achieved a score of 23.88% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Wide-spread presence of counterfeit and substandard medicines and weak pharmacovigilance system undermines the integrity of Indonesia's drug supply chain. There are also strong mandatory localization efforts in place. Indonesia also does not allow the commercial cultivation of biotechnology agricultural products. The Government supports research efforts but not commercial cultivation.
Factor 5: Technology transfer and commercialization frameworks	Technology transfer and commercialization of public funded research remains relatively limited. Draft Bill on a National System of Science and Technology (Sinas IPTEK) should bring greater clarity to STI regulations including technology transfer.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Limited public reimbursement for innovative products. Procurement and tendering favors generics and locally produced products. Multiple challenges exist for innovative products that are included in the formulary and marketed in Indonesia. No clear methodology exists for their addition to the list or how long they will remain listed. Once listed, they cannot be sold for more than a 50% margin. Under the 2009 Health Law, generic prescription is compulsory within the public health system and packaging must include the generic name.
R&D tax incentives	Limited R&D tax incentives; main incentive is accelerated depreciation and carry-forward of qualifying expenditure.
Factor 7: Rule of law	Ranked 61 out of 113 countries

OUTPUTS	
Scientific publications per million population	4
Quality of academic publications	8.8%
Clinical trials per million population to date	1.17
Clinical trials for biologics per million population to date	0.09
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.04
Biotechnology triadic patenting, share of global total average 1999-2013	0.001%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	19.50%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	64.9
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	1.80%

IRELAND

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	3,732 (2014 World Bank)
Life sciences graduates (PhD & Masters), per million population	103.11 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	1.49% (OECD 2014)
BERD spending as a % of total	53.6% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	84.64
Biotech R&D as a percentage of BERD	17.2%
Factor 3: Intellectual property protection	Both 10-yr RDP term available and 5-yr SPC available under EU law. Not included in IP Index.
Factor 4: The regulatory environment	Like Denmark high drug regulatory standards through EMA and local Health Products Regulatory Authority. Ireland is not one of the countries that opted out of the EU Commission approved cultivation in 2015. However, there is currently no biotechnology cultivation in Ireland with only research taking place.
Factor 5: Technology transfer and commercialization frameworks	The National IP Protocol (firstly drafted in 2012) was updated in 2016 and provides a framework for companies and Research Performing Organizations on norms for research-related IP agreements. Overall, the Irish tech transfer system is well developed with public-private initiatives taking place at different levels, such as technological centers, larger collaborations such as the Health Innovation Ireland, and support programs such as the Innovation Vouchers, the Technology Gateway Program and the Technology Transfer Strengthening Initiative.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Traditionally a generally attractive pricing and reimbursement environment for biopharmaceutical companies, with, for instance, the public health system fully reimbursing a large proportion of cutting edge, high cost medicines with patients contributing a co-payment; although coverage has tightened somewhat over the last few years. 2013 Health (Pricing and Supply of Medical Goods) Act introduced a system of therapeutic reference pricing that applies to around 1,500 products (although prices are still competitive relative to other European markets). The 2013 Health Act also initiated automatic generic substitution where interchangeability between the generic and reference product has been formally established by the HPRA. Various accompanying initiatives have also been piloted, such as the Medicines Management Program, which identifies a single "preferred drug" within a therapeutic drug class, and accompanies it with prescribing tips for patients and guidelines for doctors.
R&D tax incentives	Tax credits and deductions available for qualifying R&D expenditure; up to 25% of expenditure. Patent box incentives reduce corporate tax by 50% IP derived income.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population	1092
Quality of academic publications	15.1%
Clinical trials per million population to date	275.00
Clinical trials for biologics per million population to date	24.12
Early phase (Phase I and II) clinical trials for biologics, per million population to date	5.56
Biotechnology triadic patenting, share of global total average 1999-2013	0.20%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	38.50%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	82.2
No of Biotechnology firms, per million population	52.67
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

ISRAEL

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	8,255 (2012 World Bank)
Life sciences graduates (PhD & Masters), per million population	135.88 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	4.11% (OECD 2014)
BERD spending as a % of total	36.5% (OECD 2013)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	50.07
Biotech R&D as a percentage of BERD	5.7%
Factor 3: Intellectual property protection	6-yr RDP term available but only for NCEs not biologics; 5-yr PTE available. Achieved a score of 64.15% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	High standard biopharma regulatory environment. Israeli MoH relies on the prior approval by a select number of drug regulatory authorities for innovative products, primarily the FDA and EMA. The stated maximum time for approval of innovative products is 270 days (although in practice, challenges remain surrounding registration delays). In 2006 a fast-track registration process was introduced for innovative drugs, setting a 45-day registration deadline for new drugs that are included in the Essential Drug List. Ag-bio not allowed for commercial production.
Factor 5: Technology transfer and commercialization frameworks	Technology transfer is well established in Israel, with over 10 tech transfer offices and companies present at the major universities and research institutions for over 50 years. Tech transfer model is similar to the US' Bayh-Dole framework but based on largely independent and corporate-style offices heavily focused on generating royalties and creation of new companies, and has been widely successful. Indeed, two technology transfer offices in Israel, Yissum from Hebrew University and Yeda from the Weizmann Institute, are ranked among the top tech transfer offices worldwide. TTOs are active, with by some estimates an average of 150 new licensing deals, 15 start-ups and NIS1.5 billion (USD400 million) in royalties per year.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The pricing and reimbursement environment remains mixed, in some ways rewarding biopharmaceutical innovation and in other ways putting significant price pressure and eroding reimbursement for cutting edge treatments. For example within Israel's "basic basket" of health services that are reimbursed within the national health system is a fixed annual budget dedicated specifically to innovative products with a special committee determining regular additions to the basket. Yet at the same time, for other drugs the MoH uses an external reference pricing system to set pharmaceutical prices and price cuts are frequently imposed.
R&D tax incentives	Significant R&D incentives in place for biotech, start-ups and targeted R&D. Under the 2017-2018 national budget Israel launched its "Innovation Box" aiming to attract MNCs' operations. Incentives include: a lowered corporate income tax of 6% to companies with global turnover of 2.5 billion USD, and 7.5%-12% for companies with lower turnover; a 4% tax on dividends; a capital gains / exit tax for sale of IP of 6% / 12% for companies with over/under 2.5 billion USD.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population	1289
Quality of academic publications	14.6%
Clinical trials per million population to date	703.43
Clinical trials for biologics per million population to date	42.48
Early phase (Phase I and II) clinical trials for biologics, per million population to date	18.25
Biotechnology triadic patenting, share of global total average 1999-2013	1.13%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	24.00%
National % share total number of patents from top 50 PCT applicants: universities, 2015	3.28%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	81.3
No of Biotechnology firms, per million population	29.13
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

JAPAN

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	5,386 (2014 World Bank)
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	3.59% (OECD 2014)
BERD spending as a % of total	77.3% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	9.69
Biotech R&D as a percentage of BERD	1.2%
Factor 3: Intellectual property protection	8-yr RDP equivalent term available and 5-yr PTE available. Achieved a score of 92.08% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	High standard biopharma regulatory environment. Recent reform efforts have focused on reducing approval times for innovative products and incentivizing new R&D and clinical trials. The Sakigaki Strategy launched in 2014 provides support for pre-clinical and clinical research targeting cancer and orphan drug treatments through public-private coalitions and networks, improvements to infrastructure and fast-track review.
Factor 5: Technology transfer and commercialization frameworks	Japan introduced a Bayh-Dole framework in 1999 under the Industrial Revitalization Special Law. It covers a range of IP rights, including patents, utility models and seed and seedling registration rights, and similar to the US Bayh-Dole framework allows universities and public research institutions to own IP rights associated with publicly funded R&D.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Japan has a highly regulated pricing environment with the Government setting prices and determining whether a drug will be reimbursed in the national health system based on the recommendation of the Central Social Insurance Medical Council. Starting from 2018 price reviews will be conducted every year and would extend to all prescription drugs. This followed the decision, in November 2016, to halve the price of cancer drug Opdivo ahead of the next review scheduled in April 2018 on fears that a rapid uptake of the drug would excessively burden the healthcare budget. Drugs rapidly adopted after approval for new indications would be reviewed four times per year. MHLW has announced that it intends to incorporate HTA findings in repricing decisions, starting from the seven currently trialed HTA products (HCV antiviral therapies, Opdivo and Kadcyla). From 2018 onwards, a broader HTA system should be introduced for other drugs. These actions risk undoing innovation-based Sakigake Strategy which included rewarding brand new drugs as well as biosimilars, vis-à-vis existing equivalent treatments.
R&D tax incentives	Japan offers R&D tax incentives to both small and large companies. SMEs can qualify for a credit of 12% of total R&D spending and large companies for an 8-10% credit (which for both should be equal or lower than 25% of the company's corporate tax rate). For SMEs the credit rises to 30% for R&D taking place in partnership with a university or PRO.
Factor 7: Rule of law	Ranked 15 out of 113 countries

OUTPUTS	
Scientific publications per million population	773
Quality of academic publications	8.8%
Clinical trials per million population to date	34.00
Clinical trials for biologics per million population to date	3.02
Early phase (Phase I and II) clinical trials for biologics, per million population to date	1.51
Biotechnology triadic patenting, share of global total average 1999-2013	14.69%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	31.90%
National % share total number of patents from top 50 PCT applicants: universities, 2015	9.35%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	91.8
No of Biotechnology firms, per million population	4.35
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

KOREA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	6,899 (2014 World Bank)
Life sciences graduates (PhD & Masters), per million population	58.08 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	4.29% (OECD 2014)
BERD spending as a % of total	75.3% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	28.29
Biotech R&D as a percentage of BERD	2.5%
Factor 3: Intellectual property protection	5-yr RDP term available and 5-yr PTE available. Achieved a score of 79.5% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Korea has a relatively strong clinical and regulatory environment. For biopharmaceuticals the Ministry of Food and Drug Safety (formerly the Korean Food and Drug Administration) is responsible for the authorization and safety supervision of pharmaceuticals. The agency is highly regarded internationally and has been praised by the FDA. Korea introduced a biosimilar pathway in 2009. Plans announced to enhance regulatory management of biopharmaceuticals in 2017 (e.g. guidelines for clinical trials of gene therapy products, guidelines for cell therapy products etc.)
Factor 5: Technology transfer and commercialization frameworks	Korea early on recognized the importance of closer working relations between universities and businesses and encouraging the commercialization of publicly funded research. Since the early 2000s and the initial interest in developing technology transfer Korea has seen a steady growth in university licensing income and patent rates. Korean biotechnology industry has benefited directly from government-backed tech transfer initiatives through the Law for the Creation and Promotion of the Government Research Institutes enacted in 1999. This program sought to promote technology transfer and the commercialization of biotechnology through start-ups, venture capital partnerships and spin-offs.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Korea has in place a strict P&R system applicable primarily to innovative products. Mandatory price cuts have been instituted through a therapeutic reference price system that places innovative and generic drugs in the same baskets, with prices set based on the average price in the basket. The innovative or therapeutic value of a given product is not factored into the price. This system is complemented by other measures including rebates associated with price-volume agreements. Moreover, inclusion for reimbursement is dually determined by a ruling of cost-effectiveness by the Health Insurance Review and Assessment Service and price negotiations with the National Health Insurance Corporation. Most recently Korea has introduced a number of changes to its P&R policies that favor local manufacturers and penalize foreign companies.
R&D tax incentives	Korea offers R&D tax incentives for both large and SMEs. The incentives are based around incremental and volume-based deductions ranging from 40-50% for qualifying expenditure.
Factor 7: Rule of law	Ranked 19 out of 113 countries

OUTPUTS	
Scientific publications per million population	733
Quality of academic publications	10
Clinical trials per million population to date	149.91
Clinical trials for biologics per million population to date	9.56
Early phase (Phase I and II) clinical trials for biologics, per million population to date	4.08
Biotechnology triadic patenting, share of global total average 1999-2013	2.34%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	42.60%
National % share total number of patents from top 50 PCT applicants: universities, 2015	10.38%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2017	80.8
No of Biotechnology firms, per million population	18.8
Biofuels production, % of global total (Rule of Law Index 2016)	0.50%

MALAYSIA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	2,052 (2014 World Bank)
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	1.26% (World Bank 2014)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	5-yr RDP term available de jure but de facto exclusivity term much less and limited to global launch; no PTE available. Achieved a score of 44.96% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	DRA marked by long processing times for market authorization applications for biopharmaceuticals. While the agency and Ministry of Health have a target of 210 days for market approval industry reports suggest that lengthy delays are not uncommon. Malaysia introduced biosimilar guidelines in 2008 broadly in line with international standards.
Factor 5: Technology transfer and commercialization frameworks	Technology transfer at universities and public research institutions are guided by internal guidelines (often developed together with the main funder of the program, the Malaysian Government) and two Government regulations: the 1999 Government Circular and the 2009 Intellectual Property Policy. Data on transfer activities is relatively limited; WIPO patent statistics shows Malaysian activity is relatively low.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Biopharmaceutical P&R environment is challenging. Reimbursement decisions are often delayed with industry reports suggesting delays of up to five years after regulatory approval. Moreover, there is, for example, no automatic inclusion of products onto the national formulary even if they were developed in Malaysia including through local clinical trials involving local patients. Only drugs included in the National Essential Medicine List are exempted from the 6% Good and Services Tax in force since April 2015.
R&D tax incentives	Generous and relatively non-discriminatory tax incentives available, both biotech specific and general. The Investment Tax Allowance can take several forms including a 50% tax allowance on capital expenditures for ten years for companies performing in-house R&D and 100% tax allowance on capital expenditures for ten years for R&D service providers. A 200% super deduction on non-capital expenditures is available for companies conducting in-house R&D, donations to research institutes and on the registration of patents, trademarks and licenses overseas if it promotes an exported product. Domestic companies can achieve "Pioneer Status". Companies receiving this designation pay no income tax on statutory income for five years and this benefit can be extended for an additional five years. BioNexus status is available to biotech companies and companies that derive a substantial amount of their final product from biotechnology. Qualifying entities receive a tax exemption on 100% of relevant income for a period of five-ten years (depending on the age of the entity) and a 20% tax exemption after the initial period has expired.
Factor 7: Rule of law	Ranked 56 out of 113 countries

OUTPUTS	
Scientific publications per million population	216
Quality of academic publications	NA
Clinical trials per million population to date	29.01
Clinical trials for biologics per million population to date	2.14
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.53
Biotechnology triadic patenting, share of global total average 1999-2013	0.04%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	20.20%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	85.6
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

MEXICO

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	323 (2011 World Bank)
Life sciences graduates (PhD & Masters), per million population	13.11 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.54% (OECD 2014)
BERD spending as a % of total	23.8% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	0.29
Biotech R&D as a percentage of BERD	1.1%
Factor 3: Intellectual property protection	5-yr RDP term available but uncertainty over applicability to biologics; no PTE available. Achieved a score of 51.35% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	COFEPRIS has introduced a number of reforms and committed to cutting market authorization times. The agency has been commended for quickly approving medicines that meet urgent local needs, reducing the approval time for drugs already approved in the US, Canada, and EU from 360 days to 60 days. COFERIS approved medications are also approved with less scrutiny in many other South American countries. In 2014 the agency also cut the pre-approval time for clinical trials from 3 months to 1 month reflecting a desire to attract more biopharmaceutical investment and trial activity. For ag-bio Mexico has had a framework in place for over a decade. In 2005, the government passed the Biosafety Law that clarified regulatory issues relating to the research, production and marketing of biotech foods. The Inter-Ministerial Commission on Biosecurity and Genetically Modified Organisms and its subsidiary bodies oversees food related biotech activities. The biotechnology regulations enforced by the Commission are not considered burdensome.
Factor 5: Technology transfer and commercialization frameworks	Existing Mexican technology framework is ad hoc and is based largely on the policies in place at the institution receiving the public funding. Some initiatives in place to boost tech transfer activities (e.g. National Council of Science and Technology programs) but overall the environment is weak. OECD STI Outlook 2016 assessment of tech transfer Mexico was at the bottom of OECD economies.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Mexico has strict price controls in place with maximum retail prices for patented medicines capped by Secretaría de Economía (mainly for private sector). Mexico uses an international reference pricing system calculated on the basis of the average ex-factory price of the previous quarter in the six largest markets for a given product globally. Public reimbursement of medicines in Mexico is primarily focused on cost and there are long delays with inclusion. Drug formularies under the major public schemes – Cuadro Básico y Catálogo de Medicamentos, Seguro Popular and the IMSS drug list – all contain relatively low levels of new, innovative drugs. The majority of products included are generic.
R&D tax incentives	Mexico eliminated R&D tax credits and incentives in its 2010 tax reform replacing them with grants. New 30% federal R&D tax credit introduced in 2017.
Factor 7: Rule of law	Ranked 88 out of 113 countries

OUTPUTS	
Scientific publications per million population	72
Quality of academic publications	7.1
Clinical trials per million population to date	21.04
Clinical trials for biologics per million population to date	1.76
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.48
Biotechnology triadic patenting, share of global total average 1999-2013	0.04%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	37.40%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	0.05%
BCI Survey Ranking 2016	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	64.6
No of Biotechnology firms, per million population	1.23
Biofuels production, % of global total (Rule of Law Index 2016)	0.10%

RUSSIA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	3,102 (2014 World Bank)
Life sciences graduates (PhD & Masters), per million population	67.08 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	1.19% (OECD 2014)
BERD spending as a % of total	27.1% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	1.55
Biotech R&D as a percentage of BERD	0.9%
Factor 3: Intellectual property protection	6-yr RDP term available but uncertainty over actual availability e.g. 2016 IP Court ruling; 5-yr PTE available. Achieved a score of 45.81% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	For biopharmaceuticals key challenges include lack of GMP enforcement, quality control (e.g. presence of counterfeit and substandard medicines) and localization requirements. Pharma 2020 includes clear targets for local production, including 50-70% of domestic drugs on the total pharmaceutical market (in 2012 the share was about 20%), 60% of patented medicine market in terms of value by local companies and 85-90% of the medicines on Russia's Essential Drug List (EDL). Since 2010 there is also a local clinical trial requirement in place. For ag-bio commercial cultivation is outlawed.
Factor 5: Technology transfer and commercialization frameworks	Central legislative framework for technology transfer focuses on enterprise partnerships as opposed to patenting and licensing agreements. Federal Law 217-FZ on the Commercialization of University Research (2009) provides universities with the exclusive right to market their research through launching their own SMEs or obtaining stock in companies that rely on their research. Specifically, Law N. 217 requires that universities have at least a 25-33% share in spin-offs, depending on the type of company, in exchange for the right to use the university invention. Looking at outputs patenting by Russian institutions is relatively low as is tech transfer activities at universities.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	P&R environment is challenging. Prices of medicines included in the EDL are subject to control on three levels (manufacturer, wholesaler and pharmacy prices) and by a process of registration of maximum manufacturer price and by wholesaler and pharmacy markup limitations (varying by region). The EDL, which is the basis for reimbursement in the hospital segment and the reference for regional formularies, is updated infrequently limiting reimbursement for medicines recently approved for market. Resolution 979 "On amendments to Resolution N.865" adopted in September 2015 introduced a step-down pricing system establishing that maximum selling prices for generics and biosimilars cannot exceed, respectively, 80% and 90% of the reference drug.
R&D tax incentives	Russia offers a generous 150% R&D tax deduction on qualifying expenses. This is available generally as well as for targeted industries. In addition, entities operating in Special Economic Zones (such as the Skolkovo Innovation Centre) may qualify for additional tax credits and benefits.
Factor 7: Rule of law	Ranked 92 out of 113 countries

OUTPUTS	
Scientific publications per million population	203
Quality of academic publications	4.1
Clinical trials per million population to date	24.14
Clinical trials for biologics per million population to date	2.47
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.80
Biotechnology triadic patenting, share of global total average 1999-2013	0.26%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	14.30%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	63.5
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

SAUDI ARABIA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	NA
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.073% (World Bank 2009)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	Clear 5-yr RDP term in place. Some reports indicate follow-on products have been approved through indirect reliance. No PTE offered. Achieved a score of 49.77% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Saudi FDA viewed as being a high standard DRA comparable to Singapore, Canada etc. New fast-track verification route for product approval being implemented in 2017. Ag-bio regulatory framework in place. Strict labelling requirements in place. There is currently no commercial cultivation of ag-bio products.
Factor 5: Technology transfer and commercialization frameworks	Technology transfer has been a key part of Saudi Arabia's science and technology framework since the early 2000s and the 2002 National Policy for Science and Technology. There are several key initiatives most notably the government-owned Technology Development and Investment Company which is tasked with developing and launching industrial opportunities aligned with the national research center priorities as Joint Ventures with international technology companies. There is also the 2014 Saudi Arabia Advanced Research Alliance a public-private collaboration among the main entities working on innovation (KACST, TAQNIA, KAUST KFUPM and RTI International) aimed at supporting commercialization of new technologies. Saudi Arabia is one of the few emerging markets whose universities are among the top-50 globally in terms of PCT patent applications.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Pricing environment based on IRP. Basket of countries frequently include low-income economies with substantially lower per capita income than Saudi Arabia. Maximum prices based on lowest price in basket of comparable countries. BCI Survey results 2016 suggest that pricing policy lacks transparency and predictability.
R&D tax incentives	No statutory R&D tax incentives in place. Some R&D grants made directly by KAUST.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population	102
Quality of academic publications	NA
Clinical trials per million population to date	14.24
Clinical trials for biologics per million population to date	0.63
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.14
Biotechnology triadic patenting, share of global total average 1999-2013	0.01%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	13.70%
National % share total number of patents from top 50 PCT applicants: universities, 2015	1.03%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	66.8
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total, 2016	Negligible

SINGAPORE

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	6,658 (World Bank 2014)
Life sciences graduates (PhD & Masters), per million population	146 (Singapore Statistics 2015)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	2.2% (OECD 2014)
BERD spending as a % of total	52.7% (OECD 2013)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	Clear 5-yr RDP and PTE term in place. Achieved a score of 79.54% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Health Sciences Authority is highly regarded and is involved in the regulation of Western medicinal products as well as Chinese proprietary medicines and cosmetic products. Circa 80% of marketing applications approved through an abridged route relying on evaluations from leading drug regulatory agencies in other countries. Under this route the approval time is on average just 60-180 days (depending on the number of external evaluations available). An additional priority review path is also available for certain life-threatening conditions with limited treatment options, which further reduces approval time to 60 days. GM foods are regulated by the Genetic Modification Advisory Committee. Singapore's regulations are science-based and the registration process is generally viewed as efficient.
Factor 5: Technology transfer and commercialization frameworks	Singapore has a strong tradition of technology transfer with governmental bodies as well as academic institutions being closely involved in transfer activities. Biotech/pharm specific transfer activities include the Biomedical Sciences Industry Partnership Office which liaises between universities, public research institutes and industry. Singapore's main bioclusters host domestic and international firms, biomedical research institutions and are also integrating governmental R&D bodies. Technology transfer is also being promoted and is made accessible by the close proximity of these bioclusters to the Singapore Science Park and the National University of Singapore.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The biopharmaceutical market is relatively free with government subsidies in place only for pharmaceuticals included on the Standard Drug List (though this covers the majority of drugs prescribed). Products may be added to the list on an annual basis. Under the scheme, "essential" or first-line drugs are the most heavily subsidized, with patients covering just SGD1.40 per item per week. For relatively more expensive essential drugs patients pay 50% of the sales price. Drugs not included on the list are priced based on the market. Additional concerns over access are addressed through financial assistance schemes, such as the special chronic disease insurance program.
R&D tax incentives	Singapore offers an R&D tax credit of up to 400% on qualifying R&D expenditure, but subject to a cap of SGD400,000 or SGD600,000 (approximately USD292,000 or USD437,000, respectively). The majority of this relief is available on R&D performed in Singapore. Singapore also has an "angel investors tax deduction" program that provides a tax deduction for 50% of the investment amount, up to a cap of SGD500,000.
Factor 7: Rule of law	Ranked 9 out of 113 countries

OUTPUTS	
Scientific publications per million population	1541
Quality of academic publications	NA
Clinical trials per million population to date	307.14
Clinical trials for biologics per million population to date	20.78
Early phase (Phase I and II) clinical trials for biologics, per million population to date	10.20
Biotechnology triadic patenting, share of global total average 1999-2013	0.41%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	25.50%
National % share total number of patents from top 50 PCT applicants: universities, 2015	3.41%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	93.3
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

SOUTH AFRICA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	405 (World Bank 2012)
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.73% (World Bank 2012)
BERD spending as a % of total	38.3% (OECD 2012)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	1.31
Biotech R&D as a percentage of BERD	3%
Factor 3: Intellectual property protection	Neither RDP term of protection nor PTE term in place. Achieved a score of 34.62% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Primary challenge has been long approval delays for biopharmaceuticals. New DRA (South African Health Products Regulatory Agency) has yet to start functioning one year after being approved. South Africa is a global leader and major producer of ag-bio crops with a clear regulatory framework in place. The 1997 GMO Act and the 2011 Consumer Protection Bill regulate the production and consumption of GE food.
Factor 5: Technology transfer and commercialization frameworks	South Africa introduced a modern technology transfer framework in 2008. The "Intellectual Property Rights from Publicly Financed Research and Development Act" established the parameters by which publicly funded research can be commercialized and, crucially, where ownership over the generated IP resides. The stated purpose of the Act has been to stimulate research and the commercialization of publicly funded research. Broadly speaking the Act and its accompanying regulations establish the principle that the recipient will retain IP generated through publicly funded research.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	P&R system both directly and indirectly prioritizes generic drugs, primarily through a new external referencing pricing system that favors low cost drugs and generic substitution policies. Since 2005 biopharmaceutical prices have been capped at a rate in line with inflation, which for imported medicines is typically considered to be under value in relation to the exchange rate. On top of this, in 2015 a de facto external referencing price mechanism was introduced for innovative drugs. Under the new regulation innovative manufacturers will have to provide the price of their drugs in Australia, New Zealand, Spain and Canada (or, if not present in these markets, in all the countries they are sold) and the DoH will reportedly request companies to forego the yearly price increases if the price applied in South Africa is higher than these reference prices.
R&D tax incentives	South Africa offers relatively generous R&D tax benefits including a 150% super deduction for R&D expenditures and accelerated depreciation for capital expenditures incurred to develop or construct assets used in R&D activities (40% for the first year and 20% in the three years after for infrastructure built after 2012).
Factor 7: Rule of law	Ranked 43 out of 113 countries

OUTPUTS	
Scientific publications per million population	111
Quality of academic publications	10.7
Clinical trials per million population to date	40.70
Clinical trials for biologics per million population to date	4.40
Early phase (Phase I and II) clinical trials for biologics, per million population to date	1.98
Biotechnology triadic patenting, share of global total average 1999-2013	0.06%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	28.80%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	1.46%
BCI Survey Ranking 2016	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	67.5
No of Biotechnology firms, per million population	0.56
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

SWITZERLAND

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	4,481 (World Bank 2012)
Life sciences graduates (PhD & Masters), per million population	144.75 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	2.97% (OECD 2012)
BERD spending as a % of total	60.8% (OECD 2012)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	320
Biotech R&D as a percentage of BERD	27.8%
Factor 3: Intellectual property protection	10-yr RDP term of protection in place and 5-yr PTE term in place. Achieved a score of 92.15% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Stringent DRA and high quality biopharmaceutical regulations including biosimilars pathway. No regulatory framework for ag-bio; national ban on GM foods.
Factor 5: Technology transfer and commercialization frameworks	Switzerland has a strong tradition of technology transfer with governmental bodies as well as academic institutions being closely involved in transfer activities. The Commission for Technology and Innovation has as one of its core goals to promote technology transfer between universities and industry including the Swiss Biotech association. It does so through innovation mentors providing support in drawing up project applications as well as interactive and physical platforms. Academic institutions and professionals have their own technology transfer association through swiTT (Swiss Technology Transfer Association). Swiss institutions have a high rate of patenting intensity and activity.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Relatively strict pricing policies are in place for drugs and pharmaceuticals available through basic insurance. There are consequently a limited number of market incentives for these products, which total over 2,500 medicines. However, for both supplementary insurance and all medicines not listed on the public reimbursement list there is free pricing and a relative free market.
R&D tax incentives	New tax reform package passed in June 2016 includes significant changes to R&D incentive structures. Package includes a "cantonal patent box" according to which IP-generated income would be exempted up to 90% on cantonal and communal taxes. Package also includes a potential 150% R&D super deduction.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population	2001
Quality of academic publications	19.4
Clinical trials per million population to date	575.84
Clinical trials for biologics per million population to date	45.64
Early phase (Phase I and II) clinical trials for biologics, per million population to date	20.00
Biotechnology triadic patenting, share of global total average 1999-2013	2.04%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	44.40%
National % share total number of patents from top 50 PCT applicants: universities, 2015	2.07%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	85.7
No of Biotechnology firms, per million population	29.13
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

TAIWAN

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	6,084 (Taiwan Ministry of Science and Technology 2014)
Life sciences graduates (PhD & Masters), per million population	123.4 (Taiwan Ministry of Science and Technology 2015)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	3% (OECD 2014)
BERD spending as a % of total	77.2% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	33.8
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	5-yr RDP term of protection in place and 5-yr PTE term in place. Achieved a score of 62.19% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Taiwan's DRA is viewed as quite strong adhering to international regulatory standards; however, there have been long delays in product approvals. With regards to ag-bio there is no commercial cultivation of biotechnology products. Taiwan is a significant importer of GM corn, cotton and soybeans from the US and Brazil. Labelling is required on some products but generally the regulatory framework is science based.
Factor 5: Technology transfer and commercialization frameworks	The Basic Law on Science and Technology introduced in 1999 establishes a Bayh-Dole style framework for tech transfer such that publicly funded IP rights and technologies are fully owned by public institutions. At the same time, the government promoted patenting and licensing as a means of university and PRI income by reducing other types of funding for universities or by matching any revenue gained from the private sector. Significant resources are dedicated to training IP management and commercialization for universities and SMEs. Taiwanese universities and research institutes are known for strong patenting rates as well as generating substantial income from royalties and license fees. Rates of patents registered by the Industrial Technology Research Institute (IRTI, the largest public research institute) with the USPTO and co-owned by either a university or firm rising more than eight times between 2002 and 2012.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	National Health Insurance pricing is considered a significant challenge, involving annual drug price and spending targets and delays in approval of reimbursement, especially for innovative products.
R&D tax incentives	Business tax rate is 17% (fell from 25% under 2010 amendments to the Income Tax Act); plus a 15% tax credit for R&D-directed business expenditures as well as R&D investment off-sets for SMEs under the SME Development Regulations
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population	1183
Quality of academic publications	NA
Clinical trials per million population to date	195.90
Clinical trials for biologics per million population to date	11.33
Early phase (Phase I and II) clinical trials for biologics, per million population to date	3.83
Biotechnology triadic patenting, share of global total average 1999-2013	0.38%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	28.30%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	79.4
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

THAILAND

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	974 (World Bank 2014)
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.48% (World Bank 2014)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	No RDP term of protection or PTE term in place. Achieved a score of 27.65% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Real quality concerns and lack of regulatory resources. Lack of enforcement of cGMP requirements and self-regulation of GPO entity. De facto ban in place on GM crop cultivation with no field trials allowed and no commercial sale of GE products. Ag-bio regulatory framework in limbo.
Factor 5: Technology transfer and commercialization frameworks	Thailand's innovation infrastructure fundamentally being reformed in 2017. New Law on Competitiveness in Targeted Industries (BE 2560) adopted in February 2017. Seeks to encourage investments in fields that are new to the country or use new technology or advanced production in core industries such as Biotechnology, Nanotechnology, Advanced Materials technology and Digital technology, as well as enabling technology support services. Reform efforts include technology transfer policies. Existing technology and commercialization efforts are primarily based in the National Science and Technology Development Agency, the main national PRO. The Agency has a relatively extensive patent portfolio and partners with both industry, universities and other research institutes in Thailand.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Traditionally for the biopharmaceutical sector the key challenge has baeen the favored status of local state supplier GPO. GPO is the dominant local pharmaceutical producer and supplier, and has long been given preferential treatment in the public procurement system, both on the basis of procurement rules which require public hospitals to make 60% of purchases from the GPO as well as the government's "Median Price" scheme in which prices are arbitrarily determined in favor of the GPO price or lowest local generic price. Under a new public procurement law GPO is reportedly to lose its favorable status vis-à-vis other local producers and foreign companies. Uncertainty remains as to whether this will happen practice. Regarding reimbursement in order to obtain reimbursement within the public health system it is necessary to be listed on the NLED. However, the NLED is structured such that it is impossible to achieve listing if a generic or therapeutic equivalent is available. The list includes around 1,400 products, of which only 16 belong to the E2 subcategory for innovative ("high-cost") drugs. Even for products included on the NLED price negotiation is the norm.
R&D tax incentives	200% deduction available on R&D expenses carried out by qualifying Thai R&D service providers. Accelerated depreciation for qualifying expenditure also available.
Factor 7: Rule of law	Ranked 64 out of 113 countries

OUTPUTS	
Scientific publications per million population	70
Quality of academic publications	NA
Clinical trials per million population to date	29.74
Clinical trials for biologics per million population to date	2.74
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.82
Biotechnology triadic patenting, share of global total average 1999-2013	0.02%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	30.40%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	71.5
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	2.00%

TURKEY

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	1,157 (World Bank 2014)
Life sciences graduates (PhD & Masters), per million population	20.35 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	1.01% (OECD 2014)
BERD spending as a % of total	50.9% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	6-yr RDP term of protection in place but based on EU product entry not domestic market entry. No PTE term in place. Achieved a score of 45.73% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	Localization drive continues and was strengthened in 2016. The Turkish Medicines and Medical Devices Agency has drawn up plans to require drugs that face at least one local generic or therapeutic equivalent to localize production by 2018 or be excluded from reimbursement list. Implementation of this import substitution plan has been recently completed for drugs with a 50% market share and 3 local equivalents, and is reportedly ongoing for 99 drugs with at least 2 local equivalents. As of March 2017, 54 drugs had been identified for de-listing from reimbursement. Similarly the Turkish Government's 2016 Action Plan promised to introduce purchase guarantees for local "upper middle and high tech products" (as done in the IT sector). The model was tested for pharmaceuticals in January 2016 with the announcement of a 7-year purchase commitment for a firm that launches a Hepatitis A vaccine manufacturing facility in Turkey. Since 2009 not only domestic companies but also foreign ones must include a GMP certificate from the MoH and produced by its inspectors with the registration dossier for all pharmaceutical products including those manufactured abroad. However, the MoH does not possess sufficient technical expertise and capacity (including adequate number of staff) and resources to carry out on-site checks in a timely manner, particularly for foreign manufacturing sites. The result is significant delays in market approval.
Factor 5: Technology transfer and commercialization frameworks	Turkey has been working to improve technology transfer with local and regional partners. In conjunction with the European Union, the Turkish Government created the "Technology Transfer Accelerator Turkey". The primary objectives of the program are to set up a fund to assist in the commercialization of technologies developed at Turkish universities and research centres, and to promote local transfers especially in less developed regions. Impact so far in terms of outputs has been limited but Government action through TUBITAK and others is nevertheless positive.

INPUTS CONTINUED	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	In recent years drug pricing has been one of the most problematic issues for innovators and generics alike. Within the public reference price system in place, prices are set for both innovative drugs and generics at 60% of the lowest price for the same product in a basket of five European countries. Moreover, until recently the reference price was calculated on the basis of a fixed and outdated euro-lira exchange rate (in terms of 2009 levels), despite the fact that the Turkish lira has devalued by more than 50% as compared to the Euro since 2009. A new system in place since July 2015, which mandates a conversation rate of 70% of the previous year's average exchange, is expected to raise products slightly (by around 4%), though overall limits on spending on pharmaceuticals continue to be quite blunt.
R&D tax incentives	A number of generous R&D incentive programs and tax benefits are in place for both biotech and generally. There is a general 100-150% deduction for qualifying expenditure depending on the size of the company; smaller companies qualify for the larger deduction. There is also an 80-90% reduced rate of tax withholding for personnel involved in R&D activity. Special incentives are in place for domestic manufacturing of biopharmaceuticals.
Factor 7: Rule of law	Ranked 99 out of 113 countries

OUTPUTS	
Scientific publications per million population	258
Quality of academic publications	6.9
Clinical trials per million population to date	29.19
Clinical trials for biologics per million population to date	1.70
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.35
Biotechnology triadic patenting, share of global total average 1999-2013	0.02%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	25.10%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	67.2
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

UAE

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	NA
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.69% (World Bank 2014)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	No RDP term of protection or PTE term in place. Achieved a score of 41.54% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	DRA generally viewed as highly capable with new fast-track approval initiative introduced in 2015. No biotechnology regulatory framework in place (limited agricultural production/cultivation in general). Some unenforced regulations requiring labelling in place.
Factor 5: Technology transfer and commercialization frameworks	Growing emphasis on technology transfer and public-private partnerships in R&D. Key part of both Vision 2021 and National Innovation Strategy. Main universities (including Abu Dhabi University and UAE University) have in place tech transfer frameworks. The first biotechnology innovation incubator in the region was launched in Abu Dhabi University in 2012. Dubai Science Park is a free zone that provides a platform to Life Sciences, New Energy and Environment communities. Over 230 business partners out of 280 operate in the life sciences, including global industry players Pfizer, Amgen, Bristol-Myers Squibb, Maquet, Firmenich and IFF. Other examples include the Khalifa Center for Genetic Engineering & Biotechnology (created in 2014 from the United Arab Emirates University and the Ministry of Presidential Affairs) where scientists apply biotechnology and genetics to desert plants to make them better able to endure and prosper in dry, hot and salty conditions. And the Reproductive Biotechnology Centre in Dubai, an R&D center focusing on animal biotechnology. There is also the Masdar company, a strategic government initiative tasked with investing, incubating and advancing the establishment of a clean energy industry which includes the Masdar Institute of Science and Technology.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Price and profit controls in place. System of reference based pricing in place. References include other GCC countries, wholesale and retail prices in country of origin etc. Tendency for UAE price to be determined based solely on cost.
R&D tax incentives	Not applicable. Corporation tax applied at the emirate level but only to oil and gas companies.
Factor 7: Rule of law	Ranked 33 out of 113 countries

OUTPUTS	
Scientific publications per million population	90
Quality of academic publications	NA
Clinical trials per million population to date	15.62
Clinical trials for biologics per million population to date	0.87
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0.21
Biotechnology triadic patenting, share of global total average 1999-2013	0.01%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	21.10%
National % share total number of patents from top 50 PCT applicants: universities, 2015	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	65.2
No of Biotechnology firms, per million population	NA
Biofuels production, % of global total (Rule of Law Index 2016)	Negligible

UK

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	4,252 (World Bank 2014)
Life sciences graduates (PhD & Masters), per million population	225.73 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	1.7% (OECD 2014)
BERD spending as a % of total	46.5% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	10-yr RDP term of protection and 5-yr SPC term in place. Achieved a score of 92.23% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	The UK has a strong clinical and regulatory environment. For biopharmaceuticals the MHRA is responsible for the authorization and safety supervision of pharmaceuticals. The Agency works hand-in-hand with the EMA to ensure the proper dissemination of drugs approved at the EU-wide level. With regards to the UK leaving the EU and the EMA, there is a clear risk that this could lead to delays in approval and product launches with products needing to be re-registered. While the UK embraces GM food products the current list of genetically modified seeds approved for planting by the EU are not suitable to the UK's growing environment, so there is limited commercial biotech crop cultivation. This is likely to change after Brexit. Growing Government policy emphasis on ag-bio through 2013 Agri-tech initiative.
Factor 5: Technology transfer and commercialization frameworks	The UK maintains a sophisticated and active technology transfer environment. Universities such as Oxford, Cambridge and Imperial College are active participants in transferring and commercializing research and technology. In terms of direct central government support for technology transfer Innovate UK maintains a web portal that allows members of industry, academia, potential funders and entrepreneurs to collaborate on ideas. In 2016 the Government issued a new Industrial Strategy. The strategy is aimed at better leveraging key assets of the UK and addressing remaining structural barriers to the UK's global competitiveness through promoting supportive conditions, including an additional GBP 2 billion invested per year. One challenge identified is to not only develop but also commercialize new technologies in UK (rather than selling them off to non-British firms). As part of this the government established a new Industrial Strategy Challenge Fund (ISCF) specifically targeting priority technologies – with biotech one of the top priorities. In the first announcement of funds, over GBP 1 billion is committed over 4 years focusing on 6 areas, which include healthcare and medicines. Tax relief aimed at encouraging pension and investment funds to make long term capital investments in university spin-offs and biotech firms are also under consideration.

INPUTS CONTINUED	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The UK has a highly regulated pricing environment with the NHS negotiating prices with the pharmaceutical industry through the PPRS. Companies that do not participate in the voluntary PPRS are subject to the statutory scheme that imposes a list price cut of 15% on products. Discussions on reforming the PPRS have been ongoing with the Government tabling a Bill in Parliament in late 2016 increasing price regulations to also cover generic medicines. This was followed by the Competition and Markets Authority levelling a fine of a major manufacturer of over USD100million for alleged excessive pricing. New Cancer Drugs Fund (launched in July 2016) has been fundamentally revamped with a fixed budget introduced and all decisions for reimbursement to be made by NICE.
R&D tax incentives	The UK offers R&D tax incentives to both small and large companies. SMEs can qualify for a super-deduction on qualifying R&D activities of 230% and SMEs that post a yearly loss can additionally qualify for up to 33.3% cash back on R&D related spending. A patent box regime offering a 10% rate of corporation tax to profits generated from patents is in place.
Factor 7: Rule of law	Ranked 10 out of 113 countries

OUTPUTS	
Scientific publications per million population	1280
Quality of academic publications	16.1
Clinical trials per million population to date	194.16
Clinical trials for biologics per million population to date	17.41
Early phase (Phase I and II) clinical trials for biologics, per million population to date	8.38
Biotechnology triadic patenting, share of global total average 1999-2013	5.24%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	50.60%
National % share total number of patents from top 50 PCT applicants: universities, 2015	3.05%
Biotechnology crops, hectares under cultivation, % of total 2016	NA
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	95.5
No of Biotechnology firms, per million population	7.23
Biofuels production, % of global total (Rule of Law Index 2016)	0.50%

USA

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	4,019 (World Bank 2012)
Life sciences graduates (PhD & Masters), per million population	69.95 (OECD 2014)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	2.74% (OECD 2013)
BERD spending as a % of total	60.9% (OECD 2014)
Total biotechnology R&D expenditure, Millions USD PPP, per million population	120.89
Biotech R&D as a percentage of BERD	12%
Factor 3: Intellectual property protection	12-yr RDP term of protection for biologics in place, 5-yr term for NCEs and 5-yr PTE term in place. Achieved a score of 91.5% on the IP Index life sciences indicators. Remaining uncertainty as to PTO and courts' standard for patenting of biotech inventions, continued low rate of life sciences patents found to be eligible by PTO, and ongoing feeling from innovators and legal analysts that the US' patentability standard has diverged (fallen behind) from other developed countries and from its long-standing pro-innovation approach. Guidance issued over the past year is limited in utility and has not provided adequate clarity, and the Supreme Court decided in late 2016 to decline to review a number of Federal Circuit cases that held biotech and other inventions were not patentable.
Factor 4: The regulatory environment	With regards to the regulation of products and technologies developed using modern biotechnology, the Coordinated Framework for Regulation of Biotechnology is generally viewed as being one of the key building blocks and drivers of American biotech innovation. Since its announcement in 1986 the policy and subsequent sector-specific regulations are seen as having been instrumental in promoting the development of the American biotechnology industry and bringing a wide array of biotechnology products and technologies to consumers. With regards to biopharmaceuticals the FDA sets and enforces rigorous standards. The FDA plays a leading role in efforts to harmonize regulatory standards through the International Conference on Harmonisation. Moreover, the regulatory standards of the FDA are frequently emulated and recognized as a gold standard amongst clinicians, health economists and the academic community. In response to criticism of long approval times new expedited pathways have been introduced. Major new legislation in 2016 21st Century Cures Act which allows for: • Draft guidance on interchangeability of biosimilars released in Jan 2017 • FDA final guidance on naming biologics and biosimilars issued in Jan 2017 allows for all biologic products to be distinguished from one another instead of generic naming: in addition to the INN it requires an FDA-designated suffix to distinguish product by product. • As a result of the proposed (re)authorization of user fees for biosimilars (specifically under the Biosimilars User Fee Act) FDA also commits to faster timelines for originator biologics review (within 10 months); communication and guidance for biologics sponsors in advance of the review as well as during the review in order to anticipate needed changes and avoid delays in approval; and devoting greater resources for biologics review. • Act also widens scope of permissible clinical trial data for approval of new biopharma products including observational studies, anecdotal data, and other informal types of data in additional to formal clinical trial results

INPUTS CONTINUED	
Factor 5: Technology transfer and commercialization frameworks	One of the key drivers of American biotech innovation and commercialization has been the success of technology transfer in the US. The Patent and Trademark Law Amendments Act of 1984 and 1986 (commonly referred to as the Bayh-Dole Act) and the Stevenson-Wydler Technology Innovation Act, which was later amended by the Federal Technology Transfer Act of 1986 and the Technology Transfer Commercialization Act in 2003 have all been instrumental in incentivizing technology transfer. These laws gave institutions that received federal support (such as American universities, small businesses and non-profits) control and the rights to any resulting intellectual property of their inventions or research.
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The US has a relatively free market in the purchase and sale of biopharmaceutical products. There are no national price regulations or national reimbursement agencies. Instead, private health insurers and public payers (such as Medicare, the VHA and Medicaid) negotiate prices with manufacturers and only indirectly set reimbursement limits and influence prescribing and patient usage through the use of formularies. Drug formularies (which often include therapeutic interchange or so-called switching mechanisms) and differential cost-sharing (such as tiered co-payments) are two of the more commonly used techniques to influence prescribing practices. Arguably, one of the strongest drivers of biopharmaceutical innovation in the US has been the existence of this relatively free market in the pricing of pharmaceuticals.
R&D tax incentives	The US provides only limited R&D tax credits, both at the federal and state level. The federal Research and Experimentation Tax Credit allows companies to claim a tax credit of between 14-20% of qualifying amounts. In addition, 39 US states offer R&D tax credits at varying rates.
Factor 7: Rule of law	Ranked 18 out of 113 countries

OUTPUTS	
Scientific publications per million population	1123
Quality of academic publications	16.4
Clinical trials per million population to date	302.44
Clinical trials for biologics per million population to date	25.70
Early phase (Phase I and II) clinical trials for biologics, per million population to date	18.68
Biotechnology triadic patenting, share of global total average 1999-2013	41.92%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	53.10%
National % share total number of patents from top 50 PCT applicants: universities, 2015	57.42%
Biotechnology crops, hectares under cultivation, % of total 2016	39.38%
BCI Survey Ranking 2016	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy score, 0-100	100
No of Biotechnology firms, per million population	36.33
Biofuels production, % of global total (Rule of Law Index 2016)	41.40%

NOTES

1 T Friedman (2005) "It's a Flat World, After All", New York Times Magazine, April 3 2005

2 World Bank Data Bank, Trade, Merchandise exports (current US$) (Accessed April 2017)

3 Ibid.

4 FCC (1998) TRENDS IN THE U.S. INTERNATIONAL TELECOMMUNICATIONS INDUSTRY, Industry Analysis Division, Common Carrier Bureau Federal Communications Commission, August 1998

5 Note that the World Bank does not include Taiwan in its classification or its databank. However, based on current per capita income levels Taiwan would be classified as a high-income economy. World Bank (2017), "Country and Lending Groups", http://data.worldbank.org/about/country-and-lending-groups

6 National Transformation Program (2016), p.72.

7 Vision 2021 website, www.vision2021.ae/sites/default/files/uae-vision2021-brochure-english.pdf and UAE National Innovation Strategy, http://www.uaeinnovates.gov.ae/docs/default-source/pdfs/national-innovation-strategy-en.pdf?sfvrsn=2

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