CLOSING THE GAP:

INCREASING GLOBAL COMPETITION TO ATTRACT AND GROW THE BIOPHARMACEUTICAL SECTOR

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the nation's leading innovative pharmaceutical research and biotechnology companies, which are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new treatments and cures.

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EXECUTIVE SUMMARY

The biopharmaceutical industry stands out as a leading U.S. industry in which the United States has earned a position of global leadership through innovation. In turn, this global leadership is generating substantial economic benefits and health dividends for the United States. The biopharmaceutical industry's economic benefit in the United States is amplified by its large-scale supply chain for research and development (R&D), manufacturing, and distribution activities. Plus, it offers well-paying high-skilled and middle-skilled jobs, which provides for rising incomes and standard of living. The combined effects of the biopharmaceutical direct jobs, supply chain, and high wages result in $1.2 trillion in economic output and 4.4 million jobs. So, for every 1 new biopharmaceutical job created, another 4.21 jobs result from the broader impacts of its supply chain and the personal spending of its workforce.[1]

Still, like other R&D intensive industries, the biopharmaceutical industry is facing mounting competition. Today, a more intensive and globalized competition for the biopharmaceutical industry is taking root, with the developing world joining European and other competitors in seeking to challenge the U.S. global leadership in innovation. The United States is now facing increasing competition to attract and grow a biopharmaceutical presence not just from developed countries, but also from emerging nations such as Brazil, China, and Singapore that are laying the groundwork for future growth.

A 2012 assessment of international efforts to grow and attract the biopharmaceutical industry, prepared by the Battelle Technology Partnership Practice, found that, among 18 nations and the European Union identified for their efforts to advance innovation-driven biopharmaceutical clusters, "many of these countries are borrowing effective pro-innovation practices that have worked in the U.S. and building on them at the same time that the U.S., in some respects, is becoming less favorable to innovation."[2]

The purpose of this report is to provide insights into some of the pro-innovation initiatives other nations are focusing on in an effort to challenge U.S. global leadership. This report explicitly excludes a range of policies that are fundamental to fostering innovation including payment policies and intellectual property protections and their enforcement. As those policies have been

Nations Profiled*

- Australia
- Brazil
- Canada
- Chile
- China
- France
- Germany
- Ireland
- Israel
- Italy
- Japan
- Russia
- Saudi Arabia
- Singapore
- South Africa
- South Korea
- Sweden
- United Kingdom

**European Union as a whole also profiled*

addressed thoroughly in other reports, the intent of this report was to focus more broadly on policies aimed at supporting the building or expansion of industry R&D and supportive innovation infrastructure. This report serves as a companion to the report "Driving Innovation and Economic Growth for the 21st Century: State Efforts to Attract and Grow the Biopharmaceutical Sector," which similar to this report focused on the rise of state innovation policies focused on attracting, growing, and retaining an innovative biopharmaceutical presence. The review of policies and programs focused on innovation at the state and international levels highlights that states are not just competing with each other for the medical advances, high wages, and strong economic contributions offered by a biopharmaceutical presence but also with other countries.

This detailed examination of the efforts of the benchmark nations in pursuing the economic growth opportunities provided by the biopharmaceutical sector reinforces that U.S. global leadership in biopharmaceutical R&D cannot be taken for granted. In fact, the report finds that countries outside of the U.S. continue to implement new efforts to seek to grow the life sciences and biopharmaceutical presence as part of their economic development strategies, with many specifically stating that publicly-funded infrastructure investments are designed to create a competitive advantage to make them more attractive to biopharmaceutical industry investments.

Three areas that stand out as being areas of intensive new activity in recent years are as follows:

- **Building research and development excellence:** Nearly every nation examined has new initiatives or sustained major investments over the past five years focused on biopharmaceutical R&D. Three nations—Australia, Japan, and Russia—have established new funding mechanisms. But, the benchmark nations are not just pursuing research simply to advance basic science. There is a strong focus on the translation of research into innovative medical products, as exemplified by Canada's focus on human health therapeutics and China's focus on global health drug discovery in concert with the Bill and Melinda Gates Foundation. Perhaps the hallmark global effort of advancing multi-institutional, interdisciplinary

A LEADING EFFORT IN COLLABORATIVE PUBLIC-PRIVATE PARTNERSHIP FOR RESEARCH: THE EU'S INNOVATIVE MEDICINES INITIATIVE

The Innovative Medicines Initiative (IMI) was launched back in 2008 with a €2 billion budget shared equally between the European Union and the biopharmaceutical industry to support precompetitive research collaborations with a goal of speeding up the development of safer and more effective medicines. It has achieved a significant level of collaboration and data sharing among biopharmaceutical companies, academic teams, EU regulators, and patient advocates. Many significant results and shared datasets have been generated by IMI's first round of 40 consortia-based projects involving over 4,000 researchers from academia, industry, government, and patient advocate sectors, including in severe asthma, schizophrenia, depression, autism, and bacterial resistance.

The IMI entered its second major phase in 2014 with a budget of €3.3 billion through 2020, again shared between the European Union and biopharmaceutical companies, with three objectives: (1) 30 percent better success rate in clinical trials of medicines targeting the 12 priorities identified by the World Health Organization ; (2) clinical proofs of concept achieved in immunological, respiratory, neurological, and neurodegenerative diseases within five years; and (3) new and approved diagnostic markets for four of these diseases and at least two new medicines for Alzheimer's disease.

precompetitive, translational research bridging academia, industry, government regulators, and patient advocates is the EU's Innovative Medicines Initiative (see text box).

- **Improving access to innovation through regulatory reforms:** Along with continued reforms at the EU level with its 2015 new framework for its IMI and other reforms by the European Medicines Agency, eight of the other nations—China, France, Germany, Japan, Singapore, South Korea, Sweden, and the United Kingdom—have new initiatives that they state are focused on improved regulatory approaches to ensure that advances in cutting-edge science are not held back by outdated regulations for assessing their safety and efficacy. This suggests an increasing understanding by the benchmark nations of the elements needed to foster a favorable business environment for biopharmaceutical development.

- **Strengthening biopharmaceutical manufacturing capabilities:** An emerging area of focus for the benchmark nations is to develop in-country competencies in emerging technologies and specialized manufacturing. While Singapore has made this a focal point of its biopharmaceutical development strategy dating back to 2003, since 2012 other nations are beginning to follow in Singapore's footsteps with major new initiatives to enhance their capabilities to manufacture biopharmaceuticals, including Ireland, Saudi Arabia, South Africa, Sweden, and the United Kingdom.

Other policy areas of ongoing focus include the following:

- **Accelerating the commercialization of university research and new firm formation:** Eight of the nations examined—Australia, Canada, France, Ireland, Israel, Italy, Sweden, and the United Kingdom—have implemented new initiatives and major investments in accelerating commercialization and new firm formation since 2012, which logically flows from the significant investments in R&D infrastructure that the benchmark nations are making. Often these efforts are in collaboration with biopharmaceutical companies and focused on establishing a thriving innovation ecosystem that links large, established biopharmaceutical companies; new start-ups; and university researchers and graduates. Among the nations adding new initiatives or significantly augmenting existing efforts are Australia, Canada, France, Ireland, Israel, Italy, Saudi Arabia, Sweden, and the United Kingdom.

- **Increasing access to investment capital:** Five of the nations examined—Australia, Ireland, Italy, South Korea, and the United Kingdom—have established new initiatives to increase investment capital. A common approach of these new initiatives is to improve incentives to investors above and beyond what government funds are being invested.

- **Fostering industry R&D investment via tax and other incentives:** Nearly every nation is providing some form of R&D incentives to the private sector, whether in the form of tax credits, enhanced deductions, accelerated depreciation, grants, or reduced corporate tax rates on income generated from intellectual property. Since 2012, five nations—Ireland, Israel, Italy, Japan, and the United Kingdom—introduced substantial new initiatives in the form of major new incentives or overhauling existing incentives.

- **Building human capital:** Nearly all of the benchmark nations are actively involved in developing, attracting, and retaining talent through sustained initiatives. Since 2012, three nations—Australia, Canada, and the United Kingdom—have added new initiatives. Among those that stand out for sustaining major investments in biopharmaceutical-related talent efforts are Brazil, China, Germany, Saudi Arabia, Singapore, and Sweden.

To get a flavor of the importance and intensity of other nation's efforts, consider how they view biopharmaceutical industry development in their own words below.

China: "*The State Council … decided to innovate and upgrade the pharmaceutical industry, an industry not only crucial to public health, but also to the development of an innovative economy. The State Council called for enhancing research and development for drugs in urgent need and speeding up the industrialization of drugs for frequently occurring and rare diseases." State Council "Policy Watch" Statement of February 15, 2016.*[3]

France: "*These competitiveness clusters are a great success story.… Not only are they renowned ambassadors of French R&D in oncology, nutrition and genomics, to name but a few, but they are working closely together on the international stage, as we see it today. Second, the pharmaceutical and biotech sector is benefiting from tax incentives for innovation that are the most attractive in Europe."—Speech of Then-Ambassador Francois Delattre, June 18, 2012.* [4]

Ireland: "*The pharmaceutical and biopharma industries play a vital role in our economy. Eight of the top 10 pharmaceutical companies in the world have Irish facilities, and the country is one of the premier global locations for pharmaceutical and chemical product manufacture."*—Enda Kenny, Prime Minister, April 3, 2014.[5]

Russia: "*Developing the domestic production of medicines and medical devices is more than just an economic goal. It's a social project as well.… To do so, we need a modern research and educational base, because the modern pharmaceutical industry is a far cry from what it was like a hundred years ago, when medicines were prepared in pharmacies in front of customers. Today, it's a sophisticated high-tech industry.*" Prime Minister Dmitry Medvedev, May 16, 2014.[6]

Singapore: "*Singapore is home to a vibrant Biomedical Industry and Singapore will continue investing in key initiatives to stay at the forefront.… We are now looking beyond the immediate value-chain activities, to develop leadership in developing regulatory standards and to prototype new business models."*—Deputy Prime Minister Tharman Shanmugaratnam, 2015. [7]

South Korea: "*The biotech and biomedical industries, which include new drug development and medical devices, are full of potential, and capable of creating US $4 trillion added-value over the next 10 year … These industries create more jobs than regular manufacturing and have a higher ratio of R&D investment, and therefore attract highly educated scientists and engineers."*—Deputy Prime Minister Hyun, October 21, 2013[8]

Sweden: "*The future of life science in Sweden is of high priority for the government. There are many reasons: (1) The demands from the health sector are growing … (2) The life science industry is going through a change where … the industry is more and more dependent on collaborations with academia and health care providers. (3) Also, Life science is one of Sweden's largest export areas after wood and paper. So it is of high importance for creating jobs and growth for our economy."*—Minister for Higher Education and Research Helene Hellmark Knutsson, April 4, 2016.[9]

Although the United States continues to rank 1st in nearly all measures of innovation, the countries profiled continue to make significant efforts to try to close the gap with the United States. (Figure ES-1):

- For peer-reviewed publications, a key measure of academic scholarly activity, the United States is the world leader, but its growth is slightly off the pace of the benchmark nations. Saudi Arabia, with a small base, made the largest gains among the nations examined; and China also made strong gains.

- For national government-supported research funding, the United States declined from 2010 to 2014, while the benchmark nations rose rapidly, led by Germany and South Korea. Still, the U.S. level of national funding for biomedical research dwarfs that of the benchmark nations, but if trends continue, that may no longer be a key advantage for the United States.

- For industry R&D spending, the United States is the world leader and continues to grow, but at a much slower pace than the other nations examined.

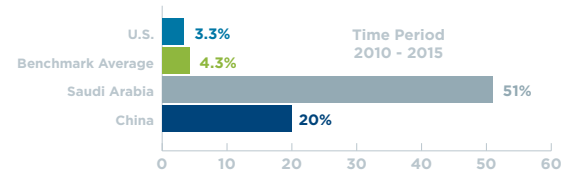
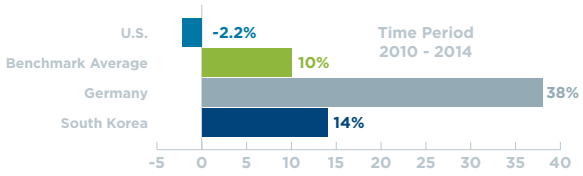
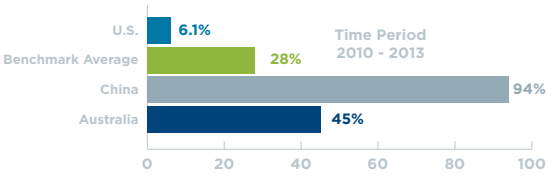
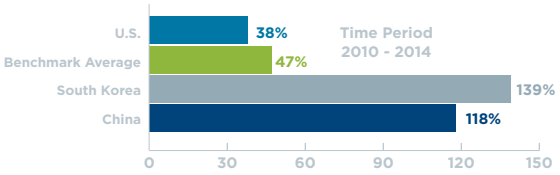
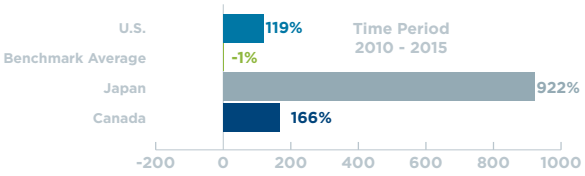
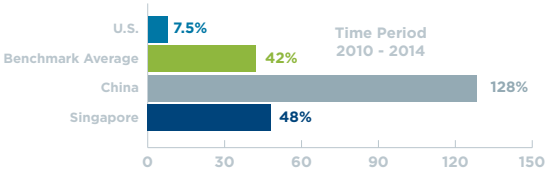
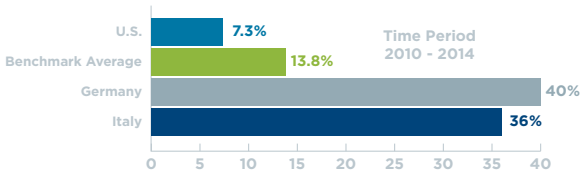
- For patents, the United States continues to grow at a healthy pace, but still slightly behind the growth of the other nations examined. China more than doubled the size of its patent activity and is closing in on the United States in absolute number of patents awarded. Of note, while China continues to increase its focus on seeking patents, the country continues to be one of the world leaders in terms of intellectual property violations. South Korea also more than doubled its patent filings between 2010 and 2014.

- For venture capital (VC), the United States dominates activity in this area with VC investments doubling between 2010 and 2015 from $3.7 billion to $8.2 billion. Japan's investments rose ninefold from $6 million to nearly $60 million.

- For biopharmaceutical exports, the United States is the leader among all the nations examined in the total value of its biopharmaceutical exports, though Germany is closing the gap with strong growth. Italy is also growing strongly among nations with a sizable export base.

- For value-added in biopharmaceutical production, the United States continues to grow, but China has edged out the United States in production capacity, which has more than doubled between 2010 and 2014. Singapore also made strong gains among other nations examined.

Figure ES-1 Benchmark Nations Closing the Gap on U.S. Leadership

Category	U.S. Share of Activity Among Nation's Examined and Ranking	Growth Rate
Peer-Reviewed Publications	35% Ranking: 1st	
National Government Biomedical Funding	74% Ranking: 1st	
Industry R&D Funding	55% Ranking: 1st	
Patent Innovation	33% Ranking: 1st	
Venture Capital Investment	82% Ranking: 1st	
Biopharmaceutical Exports	26% Ranking: 1st	
Value-Added in Biopharmaceutical Production	24% Ranking: 2nd	

Sources: i. Peer-Reviewed Publications: Thomson Reuters Web of Science; key fields analysis by TEConomy Partners; ii. National Government Biomedical Funding: OECD Main Science and Technology Indicators Database. Comparable data over the time period available only for Australia, France, Germany, Ireland, Israel, Italy, Japan, South Korea, Sweden and the United Kingdom. iii. Industry R&D Funding: OECD Main Science and Technology Indicators Database. Comparable data over the time period available only for Canada, China, France, Germany, Ireland, Italy, Israel, Japan, Singapore, South Korea, Sweden and the United Kingdom. iv. Patent Innovation: WIPO statistics database. Last updated: December 2015; v. Venture Capital Investment: Thomson Reuters Thomson One venture capital analysis database. No data available for Chile and South Africa

INTRODUCTION

While the United States is recognized as the world leader in biopharmaceutical R&D and the U.S. leads the world in the development of new medicines, other countries are increasingly recognizing the economic contributions of this industry. As these other countries seek to grow their economies, many are implementing pro-innovation policies and programs in an effort to attract and grow a biopharmaceutical sector presence. The new Administration has expressed heightened concerns about the need to ensure that the United States focuses on strong trade agreements and other policies to ensure that the U.S. continues to grow the biopharmaceutical and other high-wage, R&D-intensive industries. This report highlights some of the ways in which other countries are seeking to compete with the U.S. in efforts to attract innovative biopharmaceutical and other advanced manufacturing industries. While many of the countries included in this report have in place policies that impede innovation such as policies that do not sufficiently value medical innovation from an access and pricing perspective as well as policies that do not respect the intellectual property rights of U.S. companies, they are making progress in other policy areas that impact the environment for innovation.

In the U.S., the innovative biopharmaceutical industry stands out as a leading advanced industry where the United States has earned a position of global leadership. In turn, this global leadership is generating substantial economic benefits and health dividends for the United States. Still, like all advanced industries, which compete based on conducting a high level of research and development (R&D) and employing a highly skilled workforce, the biopharmaceutical industry is facing mounting competition. The purpose of this report is to review how other nations are competing and making in-roads in challenging U.S. global leadership and to reinforce the need to review and assess policies and regulations in the U.S. that impact innovation to ensure that the U.S. continues to attract and retain innovative biopharmaceutical companies and their R&D, manufacturing, and distribution jobs that sustain and grow the national as well as state economies.

Economic Benefits and Health Dividends from U.S. Leadership in Biopharmaceutical Industry

The biopharmaceutical industry's economic benefit in the United States is amplified by its large-scale supply chain for R&D, manufacturing, and distribution activities. Plus, it offers well-paying high-skilled and middle-skilled jobs, with the biopharmaceutical average annual wage standing at $123,108, roughly double the average manufacturing wage of $62,977. Middle-skilled production and technician jobs in the biopharmaceutical industry are roughly equal to the size of its scientific and engineering workforce. The combined effects of the biopharmaceutical direct jobs, supply chain, and high wages result in $1.2 trillion in economic output and 4.4 million jobs. So, for every 1 new biopharmaceutical job created, another

4.21 jobs result from the broader impacts of its supply chain and the personal spending of its workforce.[10]

But, biopharmaceutical manufacturing is not like traditional manufacturing. The U.S. competitive edge in biopharmaceutical manufacturing is based on its innovation capabilities. The Brookings Institution in its report on advanced industries, representing those leading industries that stand out in innovation and science, technology, engineering, and math (STEM) skills, found that the biopharmaceutical industry has the highest R&D spending per worker, far exceeding the next highest industry, communications equipment, by more than 57 percent, and well above other innovative manufacturing industries such as autos and aerospace.[11] And this R&D is critical for future success. By one estimate, 80 percent of the revenues for biopharmaceuticals and diagnostics in 2030 will be driven by advances in biological advances that were not on the market in 2010.[12]

This focus on innovation also drives significant health dividends for the United States. This includes not only having the United States be the world leader in developing new medicines, but in offering patients access to novel, improved, and often lifesaving medications in their clinical testing phases. The U.S. leadership in the introduction of novel medications through clinical research also supports its advantage in clinical excellence in the U.S. healthcare system and highly skilled public and private sector researchers. More than three-quarters of drug approvals in the United States in 2014 represented first approvals among leading national regulatory authorities.[13] Meanwhile, the biopharmaceutical industry sponsored 6,199 clinical trials of medicines in the United States in 2013, involving a total of 1.1 million participants and spending nearly $10 billion directly in the conduct of clinical trials at the site level across the United States.[14]

Growing Globalized Competition for the Biopharmaceutical Industry

International competition for biopharmaceutical innovation and related industry development is not a new phenomenon. The beginnings of the modern innovation-led biopharmaceutical industry took place in the late 19th century in Germany and Switzerland, with the rise of pharmaceutical chemistry and pharmacology as scientific fields.[15]

But, throughout the 20th century, the United States was emerging to compete with European domination of the biopharmaceutical industry, getting a substantial boost before and during World War II from the U.S. government's program to hasten the development of antibacterials, antimalarials, and anti-inflammatories. Then, with the advent of the molecular biology revolution that began in the 1970s, and a wide range of supportive policies in intellectual property (IP) protection, technology transfer, private equity investment, and regulatory oversight, the United States catapulted into a clear leadership position in the development of new and innovative medicines.[16]

Today, a more intensive and globalized competition for the biopharmaceutical industry is taking root, with the developing world joining European competitors in seeking to challenge U.S. global leadership in innovation. The United States is now facing increasing competition for biopharmaceutical industry development not just from developed countries, but also from emerging nations such as Brazil, China, and Singapore that are laying the groundwork for future growth.

- A 2013 study on the economic future of the U.S. biopharmaceutical industry that featured insights from senior-level strategic planning executives from biopharmaceutical companies found that, in head-to-head comparisons of the United States to seven other countries as a potential site for investments in expanded and new manufacturing, the United States trails behind other nations in its overall competitiveness, as these nations offer an increasingly higher-value operating environment.[17]

- More recently, a 2016 survey of 254 biopharmaceutical executives from around the world by the Economist Intelligence Unit found that biopharmaceutical companies are seeking to expand production and development capacity over the next five years. Those regions of the world in which the biopharmaceutical industry is most likely to add production and development capacity over the next five years include Latin America, with 28 percent of biopharmaceutical executives expecting to grow the current operations of their companies, and the Middle East and Africa (26 percent of companies). Still, the United States remains a competitive location for expansion, though not the dominant location for attracting expansion, with 25 percent of the biopharmaceutical executives expecting their companies to add production and development capacity in North America over the next five years.[18]

Nations across the world are stepping up to ensure their success in competing for advanced industries such as the biopharmaceutical industry. As the 2012 report by the National Research Council, Rising to the Challenge, notes: "*The global competitive environment is being shaped to an important degree by the national policies of our competitors … [foreign] national and regional governments are executing comprehensive strategies that seek to create innovation clusters in many of the same important, emerging industries. National and regional governments in Europe, Asia, and Latin America are backing up these strategies with heavy investment in universities, public-private research collaborations, workforce training, early-stage capital funds, and modern science parks.*"[19]

Changes since 2012 in International Efforts to Grow and Attract the Biopharmaceutical Industry

A 2012 assessment of international efforts to grow and attract the biopharmaceutical industry and individual companies, prepared by the Battelle Technology Partnership Practice, found that among 18 nations and the European Union—identified for their efforts to advance innovation-driven biopharmaceutical clusters—many of these countries are borrowing effective pro-innovation practices that have worked in the United States and building on them at the same time that the United States, in some respects, is becoming less favorable to innovation.[20]

This study updates the 2012 assessment and examines how nations are evolving their efforts in the global competition for biopharmaceutical industry development, including looking at whether nations have slowed down or are expanding their pro-innovation policies and programs, shedding light on trends in outcomes related to biopharmaceutical innovation, and gaining a sense as to whether other countries are closing the gap with the United States.

To consider these questions, the evolving policies and position of 18 nations and the European Union are considered. These nations were selected in 2012

Nations Profiled*

- Australia
- Brazil
- Canada
- Chile
- China
- France
- Germany
- Ireland
- Israel
- Italy
- Japan
- Russia
- Saudi Arabia
- Singapore
- South Africa
- South Korea
- Sweden
- United Kingdom

**European Union as a whole also profiled*

because of their interest in growing an innovation economy. They represent a mix of developed and emerging nations. Of the 18 nations, ten are developed nations that were selected because of the strength of their existing biopharmaceutical industry and geographic diversity representing regions of the world, including Australia, Canada, France, Germany, Ireland, Israel, Italy, Japan, Sweden, the United Kingdom, and the European Union as a whole. The eight emerging nations selected because of their interest in the biopharmaceutical industry for development include Brazil, Chile, China, Russia, Saudi Arabia, Singapore, South Africa, and South Korea.

The methodology involved analysis of key data trends on a wide range of measures to determine the changing position of the United States and benchmark nations, including measures of research, innovation, clinical trials activity, venture capital, talent, and industry growth. To assess changing policies and practices, an extensive search of national websites was undertaken, along with a literature search of key reports on national activities.

The next section reports the key findings on how these benchmark nations are closing the gap with their evolving policies and improving positions in competing for biopharmaceutical industry development.

Then, individual sections show the results of a more detailed examination of specific policies these nations are taking to advance their biopharmaceutical industry growth across specific policy areas.

The final section offers insights into the implications for U.S. policy and what lessons can be learned from other nations.

CLOSING THE GAP:

THE EVOLVING POLICIES AND POSITION OF SELECTED NATIONS IN COMPETING WITH THE UNITED STATES FOR BIOPHARMACEUTICAL DEVELOPMENT

Our analysis finds that other nations are continuing to focus on and make in-roads in their efforts to close the gap with the United States over the past five years. The 18 benchmark nations' focus on increasing their global competitiveness remains strong. Among the 18 benchmark nations, 12 nations have put in place new innovation strategies that target biopharmaceutical development. Another four nations have continued to follow through on previous innovation strategies and have sustained their efforts in targeting biopharmaceutical industry development. Only two of the benchmark nations stand as outliers—Israel, which is active in implementing an innovation strategy, though neutral in sector development; and Italy, which does not have a national innovation strategy, but is actively targeting biopharmaceutical industry development (Table 1).

The strong focus both on innovation polices and targeted efforts to advance biopharmaceutical industry development translates not only into a wide range of specific policy initiatives, but strong performance in measures related to biopharmaceutical development.

Table 1: Overview of Status of Innovation Strategies and Targeting of Biopharmaceutical Sector by Benchmark Nation

Country	Has a New or Ongoing Innovation Strategy	New or Updated Innovation Strategy since 2012	Ongoing Innovation Strategy	Biopharmaceutical/ biotechnology sector targeted
Australia	✔	*National Innovation Strategy, 2015*		Medical and Pharmaceuticals Growth Centre one of six targeted Industry Growth Centres of Australia's Department of Industry, Innovation and Science, for 2016–2020
Brazil	✔		*National Strategy for Science, Technology and Innovation (2012-2015)*	Health, involving biopharmaceuticals and medical devices, one of seven sectors targeted by Inova Empresa
Canada	✔	*Moving Forward in Science, Technology and Innovation 2014*		Health and related life-science technologies one of four broad areas targeted in innovation strategy; Plus supports innovation networks and clusters in biopharmaceuticals in concert with provincial governments
Chile	✔		*Innovation and Competitiveness Agenda 2010–2020*	Biotechnology
China	✔		*Medium and Long-term Plan for Science and Technology Development through 2020 remains in place, plus innovation one of five key tents of the 13th five-year plan covering 2016–2020*	Medicines and medical devices one of 10 industry clusters targeted for transformation in 2016–2020 five-year plan
European Union	✔	*Europe 2020 strategy targets innovation as one of seven flagship initiatives*		No specific targeting of industry development done by European Union (left to national governments), but biotechnology and health two key focal points for renewed framework agreement on academic-industrial collaborations
France	✔	*France 2020: A Strategic Agenda for Research, Technology Transfer and Innovation, 2013*		Strategic Council for Healthcare Industries; plus France supports six regional industry-cluster initiatives in biotechnology/health

Country	Has a New or Ongoing Innovation Strategy	New or Updated Innovation Strategy since 2012	Ongoing Innovation Strategy	Biopharmaceutical/ biotechnology sector targeted
Germany	✔	*High Tech Strategy (updated in 2014)*		Healthy Living is one of six designated priority areas of High Tech Strategy, plus Germany supports 36 geographically specific, biotechnology-focused clusters through Federal Ministry of Education and Research cluster competitions
Ireland	✔	*Innovation 2020 Strategy*		Biopharmaceuticals one of 11 industrial sectors targeted by IDA Ireland, the nation's business development agency, and Enterprise Ireland, the nation's innovation agency, has targeted Technology Centres in biopharmaceuticals
Israel	✔	Israel Innovation Authority Recommen-dations (2016)		No explicit targeting of biopharmaceutical development
Italy		No explicit innovation strategy		A national Advanced Life Sciences cluster funded by the Ministry of Education, Universities and Research, plus Ministry of Economic Development supporting biopharmaceutical industry clusters in 11 regions of Italy in conjunction with regional government efforts
Japan	✔	*Japan Revitalization Strategy, renewed in 2015, sets out science, technology and innovation as one of its pillars*		Life Sciences one of three sectors targeted by Japan External Trade Organization
Russia		No explicit innovation strategy		Pharma 2020 Initiative, adopted in 2009, is continuing to be pursued; Plus Medicine of the Future is set out as a high-priority "technology platform" supported jointly by Ministry of Education and Science, Ministry of Economic Development, and Russian Foundation for Technological Development

Country	Has a New or Ongoing Innovation Strategy	New or Updated Innovation Strategy since 2012	Ongoing Innovation Strategy	Biopharmaceutical/ biotechnology sector targeted
Saudi Arabia	✔	*Vision 2030 to diversify economy focuses on innovation; Second National Science, Technology and Innovation Plan (2015-2018)*		National Industry Cluster Development Program targets pharmaceutical and biotechnology cluster development
Singapore	✔	*Research, Innovation and Enterprise Plan updated*		Health and Biomedical Sciences one of four main strategic technology areas of updated national innovation strategy
South Africa	✔		*Innovation Towards a Knowledge-Based Economy: Ten-Year Plan for South Africa (2008–2018) still underway; plus, National Development Plan 2011–2030 targets innovation*	"Farmer to Pharma" Initiative leveraging biodiversity for pharmaceutical development still underway
South Korea	✔	*Creative Economy Blueprint (2013)*		Biotechnology and Technology Convergence of health and ICT components of Creative Economy Blueprint; Ministry of Health and Welfare has set goal of becoming one of the world's top 7 biohealth nations
Sweden	✔	Innovation Council, led by Prime Minister, guides policy, but no strategy issued		National Coordinator for Life Sciences established with a life-science advisory board
United Kingdom	✔	*Fixing the Foundations: Creating a More Prosperous Nation featured high quality science and innovation as one of 16 priorities*		National life-sciences strategy since 2011

Highlights of Major Initiatives to Advance the Biopharmaceutical Industry

The last five years has been an active period for the benchmark nations in advancing their policies and programs to advance biopharmaceutical development. Table 2 offers a quick snapshot of where the 18 benchmark nations have been undertaking new initiatives and major investments over this five-year period. Several important trends are apparent:

- **R&D is the most active area of new initiatives and major investment over the past five years to support biopharmaceutical development.** Only Brazil, Chile, and South Africa did not make significant shifts in R&D investment, which is likely due in part to deepening economic crises in those countries. This common focus by the benchmark nations recognizes that biopharmaceutical development is a highly research-driven effort and, in order to attract biopharmaceutical companies and spur their own innovation via new start-ups, there must be a strong foundation of research capabilities in place for biopharmaceutical development to take root.

  But, the benchmark nations are not just pursuing research simply to advance basic knowledge. There is a strong focus on the translation of research into innovative medical products as reflected below.

- **Accelerating commercialization and new firm formation,** in which eight of the nations examined—Australia, Canada, France, Ireland, Israel, Italy, Sweden, and the United Kingdom—have implemented new initiatives and/or major investments over the past five years. This focus on commercialization and new firm formation flows logically to seize the economic development potential from the significant investments in R&D infrastructure that the benchmark nations are making. Often governments are collaborating with biopharmaceutical companies and establishing a thriving innovation ecosystem that links large, established biopharmaceutical companies; new start-ups; and university researchers and college graduates. As leading economic observers, Antoine van Agtmael and Fred Bakker, document in The Smartest Places on Earth, the success of local innovation-led development efforts requires "collegial collaborations, open exchange of information, partnerships between the worlds of business and academia, multidisciplinary initiatives and ecosystems composed of an array of important players, all working closely together."[21]

- **Improving access to innovation through improved regulatory approaches and IP protections** was a focus of new initiatives by eight nations examined—China, France, Germany, Japan, Singapore, South Korea, Sweden, and the United Kingdom. The countries have positioned these efforts to directly create the operating environment that is critical to success for biopharmaceutical innovation, and suggest a more mature and sophisticated understanding by the benchmark nations on the critical business environment for success in biopharmaceutical development. As noted previously, at the same time some of these same countries have engaged in policies that undermine innovation. China for example was recently identified by the Commission on the Theft of American Intellectual Property for the massive theft of American IP which the Commission said "threatens our nation's security as well as vitality."[22] The Commission noted China's specific targeting of biotechnology and quantum communications technology. Two key attributes that positively impact companies' decisions related to R&D and manufacturing location are:

  - Ensuring a robust IP system that provides adequate patent rights and data protections

  - High level of certainty in regulatory review and approval processes.

These two attributes have been where the United States has been the gold standard. But emerging nations, as their regulatory systems evolve, increasingly have the potential to compete with the FDA. The role of IP protections cannot be overemphasized because they are directly linked to companies' ability to secure the substantial, long-term R&D investments needed to make up for the many R&D failures and to foster continued medical advances in the future."[23]

- **An up-and-coming area of focus by other nations is the strengthening of their capacity to manufacture biopharmaceuticals.** Five nations—Ireland, Saudi Arabia, South Africa, Sweden, and the United Kingdom—are pursuing new initiatives in this area. Singapore had already made its mark in this area with its 2003 formation of the Bioprocessing Technology Institute, one of its Agency for Science, Technology and Research (A*STAR) institutes that works in partnership with industry R&D labs and provides both core institutional support and competitive grants to participating scientific staff across partnering organizations. These nations are focusing on new areas of scientific opportunity, including cell and gene therapies, which will require new technologies and manufacturing competencies to increase their ability to compete. As the President of the International Society for Pharmaceutical Engineering explains: "The challenges facing pharmaceutical manufacturing have increased dramatically.… The advent of biologics, more widely distributed supply chains, and many other influences demand greater investment; better integration of product, quality and manufacturing design; and greater industry collaboration overall."[23]

- **Advancing STEM talent development remains a sustained focus across benchmark nations, with several undertaking new efforts.** Several benchmark nations have continued making major investments in their ongoing STEM programs, including Brazil, China, Singapore, and Germany, which are well known for their focused STEM talent development efforts. Three countries, Australia, the United Kingdom, and Canada have implemented new initiatives since 2012. Australia is establishing policies to recruit STEM graduate degree holders and provide incentives for STEM postgraduate career development. The United Kingdom is significantly ramping up its STEM education efforts, with a focus on the economically disadvantaged, while Canada is focusing on industrial internships and dedicated funding to attract and retain talent through the nation's research councils.

Table 2: Highlights of Major Initiatives of the Benchmark Nations to Advance the Biopharmaceutical Industry

Country	Building R&D excellence	Advancing regulatory reforms	Accelerating commercial-ization and new firm formation	Increasing access to investment capital	Fostering industry R&D investment via tax policies	Strength-ening the capabilities to manufacture biopharma-ceuticals	Building human capital
Australia	✔		✔	✔			✔
Brazil							✔
Canada	✔		✔				
Chile							✔
China	✔	✔					✔
European Union	✔	✔					
France	✔	✔	✔				
Germany	✔	✔					✔
Ireland	✔		✔	✔	✔	✔	
Israel	✔		✔		✔		
Italy	✔		✔	✔	✔		
Japan	✔	✔			✔		
Russia	✔						
Saudi Arabia	✔					✔	✔
Singapore	✔	✔					✔
South Africa						✔	
South Korea	✔	✔		✔			✔
Sweden	✔	✔	✔			✔	
United Kingdom	✔	✔	✔	✔	✔	✔	✔

Among the nations that have been very aggressive in advancing new initiatives and major investments for biopharmaceutical development have been Australia, Ireland, South Korea and the United Kingdom.

AUSTRALIA

Launching of Medical Technology and Pharmaceuticals Industry Growth Organization—In November 2015, Australia launched a new industry growth organization "to establish Australia as an Asian Pacific hub for medical technology and pharmaceutical companies." Known as MTPConnect (with MTP standing for medical technology and pharmaceuticals), it has established hubs at Monash, Sydney, and Flinders universities. Its goals include to advocate for a more streamlined regulatory system, to build a commercialization culture into skills creation, and to support industry initiatives aimed at SMEs (small- and mid-sized employers).[25]

A New Medical Research Futures Fund Established—Perhaps the most important commitment of Australia's efforts to advance biopharmaceutical development is the establishment of the Medical Research Future Fund.[26] This initiative is designed to "support the sustainability of the health system and drive medical innovation through transforming how health and medical research is conducted in Australia." The fund is intended eventually to reach AU$20 billion in fund balances and thereafter to disburse AU$1 billion annually to universities.

Commercialization Capacities Being Expanded—In 2015, the National Health and Medical Research Council established four regional Advanced Health Research and Translation Centres, hosted by universities and other nonprofits, and also funds smaller Translational Research Projects.[27] The National Innovation Strategy (NIS) and national budget propose augmenting the existing Medical Research Commercialization Fund[28] with AU$125 million in each of the next two years for a Biomedical Translation Fund that will invest in biomedical companies across the "valley of death" while sufficient proof of concept is developed to attract private capital.[29] In parallel, the NIS proposes AU$70 million toward a public-private Innovation Fund capitalized at AU$200 million in total, aimed at commercializing discoveries made within the governmental Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Tax Incentives for Early-Stage Investors Put in Place—In May 2016, Industry, Innovation and Science Minister announced[30] final passage of two new measures proposed in the NIS: (1) Tax Incentive for Early Stage Investors,[31] which provides a 20 percent nonrefundable tax credit for investments in qualified businesses along with 10 years of capital gains exemption, and (2) new Arrangements for Venture Capital Limited Partnerships, which provides a 10 percent nonrefundable credit and several areas of flexibility that had been requested by investors.[32]

IRELAND

Targeting Advanced Biomanufacturing Research Partnerships—A Research Prioritization Steering Group of Science Foundation Ireland (SFI) identified "Therapeutics: Synthesis, Formulation, Processing and Drug Delivery" as one of its specific research focus area targeted for its potential for attracting job-producing industrial interaction and investment. The Foundation seeks to fund industrial partnerships and facilitate contract research in any of the 14 areas.[33]

Enhanced Technology Transfer Advanced—Protocols for technology transfer from higher education institutes (such as the SFI Research Centres) have been developed and managed by one central office, known as Knowledge Transfer Ireland,[34] a unit of the Enterprise Ireland (EI) development agency, in collaboration with the association of universities. Through KTI, EI funds 75 percent of the cost of five Centres for Science, Engineering and Technology (CSET), major industry-university collaboratives aimed at technology transfer of which two are related to the biopharmaceutical sector—Systems Biology Ireland and the Biomedical Diagnostics Institute.[35]

Major New Pharmaceutical Manufacturing Technology Center Advanced—The Pharmaceutical Manufacturing Technology Centre (PMTC), hosted by the University of Limerick and funded at €1 million annually by EI and the Industrial Development Authority (IDA) Ireland inward investment authority.[36] This center is aimed explicitly at developing solutions that enhance the productivity of pharmaceutical manufacturing sites in Ireland. PMTC operates through a core research program to which all members hold rights, and the ability to take on single-sponsor projects additionally.

Four Dublin Universities Jointly Coordinate Workforce Training in Advanced Bioprocessing at an Industry-Friendly Pilot Plant—The IDA Ireland funded at €72 million the National Institute for Bioprocessing Research and Training (NIBRT),[37] a consortium of four Dublin universities that coordinates training curriculum in bioprocessing, while also offering industry access to a 6,500-square-meter pilot plant fully equipped to scale up mammalian cell-based cultures. The NIBRT claims to have trained 2,000 to date.

SOUTH KOREA

Overall Government Spending on R&D to Increase 40 Percent between 2013 and 2017—The Creative Economy Blueprint calls for a 40 percent increase in government R&D by 2017, and continued reform efforts were announced in 2016.[38] Public research institutes included the Korean Research Institute of Bioscience and Biotechnology, which celebrated its 30th anniversary last year;[39] and the Biomedical Research Institute of the Korean Institute of Science and Technology.[40] In the university sector, support flows to the biotechnology activities of the Korean Advanced Institute of Science and Technology, an applied-sciences institute;[41] the BioMax Institute of the Seal National University;[42] and the Biotech Center of Pohang University of Science and Technology.[43]

Personalized Medicine to Get a Major Boost—Korea is rolling out measures to expand the growth of precision medicine, one of nine strategic projects announced earlier by the government aimed at securing the nation's new growth engines and enhancing the quality of life for the general populace. This includes plans to build a genome database from more than 100,000 participants and establish platforms for data sharing.[44]

Reinvented National Enterprise for Clinical Trials—The Korean National Enterprise for Clinical Trials (KONECT) was reinvented in 2014 as a foundation that acts as a one-stop shop for foreign sponsors of clinical trials, supports training of health workers in clinical trial techniques, and coordinates an Asia-wide network that seeks to leverage Korea's advanced IT infrastructure.[45] The Korean government also offers higher tax benefits and incentives for clinical trials of indigenous drugs and investment on R&D facilities.

UNITED KINGDOM

Large Public-Private Partnerships Advanced—Government support catalyzed a £150 million new Dementia Institute[46] and £1 billion toward a partnership[47] with the Bill and Melinda Gates Foundation for a global antimalaria initiative, including substantial shares for the development of new drugs. Private industry is leading a £40 million fund known as Apollo Therapeutics to speed translation of university research into medicines with three public research universities.[48]

New Commercialization Initiatives Underway—Innovate UK in 2015 established the Precision Medicine Catapult, designed to work with industry to develop business models, clinical-trial networks, and other necessary support for development of precision medicine.[49] Other relevant Catapult centers include the Cell and Gene Therapy Catapult.[50] Innovate UK joined with the medical research council to create a new Biomedical Catalyst proof-of-concept fund that in 2015 made £18 million in awards for innovation in both biopharmaceutical and devices topics.[51] Awards under this program may be made either to a university in partnership with business or directly to a business.

New Biologics Manufacturing Centre Launched—In October 2015, the Center for Process Innovation[52]—the process industry element of the government's "Catapult" high-value manufacturing initiative[53]—announced creation of a £38 million National Biologics Manufacturing Centre in Darlington,[54] in the North East of England. Funding is through the Department of Business, Innovation & Skills.

R&D Tax Incentives Enhanced—In 2013, the United Kingdom implemented a "patent innovation tax box," which applies a lower rate of corporate tax (10 percent) to net income attributable to qualifying commercial exploitation of patents (or certain other nonpatent rights in the case of medicinals owned or in-licensed).[55]

STEM Education Pursued—New initiatives are underway to increase the quantity and quality of STEM teachers, add apprenticeships, provide new loans for postgraduates; and match female STEM graduates to industry jobs.[56] Many of these initiatives are carried out through Cogent, an employer partnership sponsored by the UK Commission for Employment and Skills.[57]

U.S. Losing Market Share: Where the Benchmark Nations are Gaining Ground

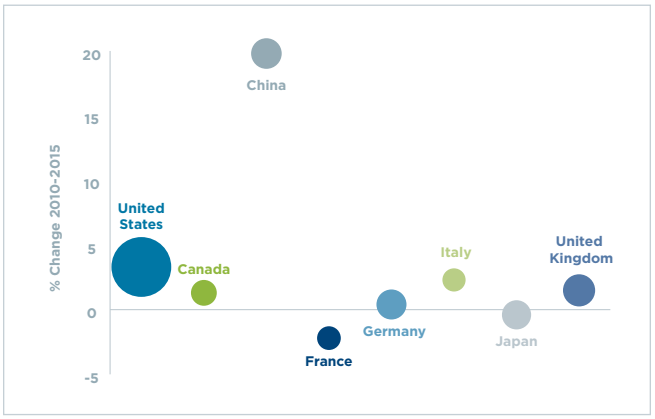
The active efforts by other nations are paying off in gaining market share on the United States. While the United States still remains the world's preeminent powerhouse in biopharmaceutical development, the trends over the past five years continue to suggest that, in all but a few areas, the United States is not keeping pace and so losing ground.

The starting data point for tracking the gains of the benchmark nations relative to the United States starts in 2010, which was the most recent year that data was available in the earlier 2012 report on international biopharmaceutical development efforts. In many cases, the most recent year for which data are available is 2015, but in some cases only updates through 2013 or 2014 are available.

R&D: U.S. Growth Falling Behind Growth, though U.S. Levels Still Lead the Benchmark Nations

For academic research, the United States is slightly off the pace of the benchmark nations. There is no comprehensive source of funding data for university research; but, through the use of peer-reviewed publications, it is possible to get a sense of scholarly activity. The United States grew its biomedical-related publications by 3.3 percent from 2010 to 2015, a full percentage point lower than the 4.3 percent growth among the other nations examined (Figure 1). Still, with 157,300 biomedical-related publications in 2015, the United States is well ahead of the other nations examined, with China having the second-highest level with 39,494 peer-reviewed publications. Several nations standing out in growth of peer-reviewed publications from 2010 to 2015 include China, with a 20 percent gain in biomedical publications.

Figure 1: United States and Leading Nations in Level of Peer-Reviewed Biomedical Publications, 2015, and Percentage Change, 2010–2015



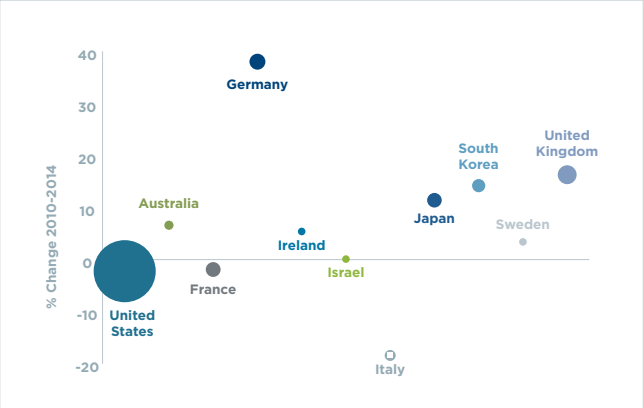
Source: Thomson Reuters Web of Science; key fields analysis by TEConomy Partners

Note: Leading Nations have over 20,000 biomedical publications in 2010

For national government-supported research funding, the United States declined from 2010 to 2014, while spending in the benchmark nations rose rapidly. The decline for the United States was 2.2 percent from 2010 to 2014—and 2015 was flat—reflecting the U.S. budget sequestration process in place to limit federal government spending (Figure 2). Among those benchmark nations tracked by the Organisation for Economic Co-operation and Development (OECD) from 2010 to 2014 (including Australia, France, Germany, Ireland, Israel, Italy, Japan, Korea, Sweden, and the United Kingdom), a 10.4 percent increase was generated. The biggest gains were made in Germany (38 percent), the United Kingdom (16.3 percent), and South Korea (14.2 percent).

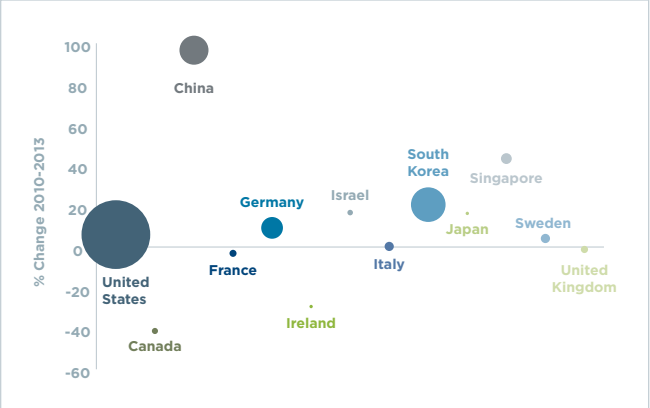
Still, the U.S. level of national funding for biomedical research dwarfs that of the benchmark nations. In 2014, the $33.5 billion spent by the U.S. government dwarfed that of all the benchmark nations, which stood at $10.4 billion in government spending for the nations where data were available.

Figure 2: United States and Leading Nations in Level of Government R&D Expenditures in Pharmaceuticals, 2014, and Percentage Change, 2010–2014



Source: OECD Main Science and Technology Indicators Database

Figure 3: United States and Leading Nations in Level of Business R&D Expenditures in Pharmaceuticals, 2013, and Percentage Change, 2010–2013



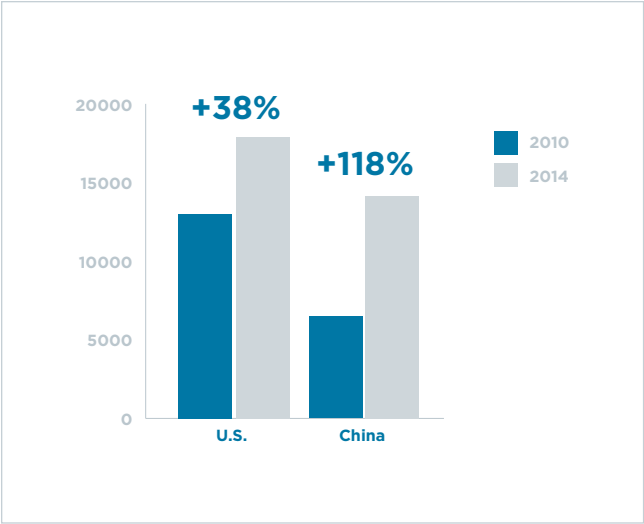
Source: OECD STAN R&D expenditures in Industry (ISIC Rev. 4)

For industry R&D spending, the United States continues to grow and has a large lead overall, but other nations are growing at a much faster pace. Over the years 2010 to 2013, U.S. industry biopharmaceutical R&D grew by 6.1 percent, reaching $52.4 billion (Figure 3). By comparison, among the 12 nations for which data are available (Canada, China, France, Germany, Ireland, Israel, Italy, Japan, Singapore, South Korea, Sweden, and the United Kingdom), the growth was a robust 28.4 percent from 2010 to 2013, reaching $34.2 billion.

It is important to note that, for both the United States and the other nations examined, the level of industry investment is considerably higher than national government funding, which reflects the extraordinary R&D costs associated with biopharmaceutical innovation from discovery to development to preclinical testing to clinical testing and manufacturing.

For patents, the United States continues to grow at a healthy pace, but China is making strong gains and nearing the size of the United States in total number of patents generated annually, though China's own continued violations of the IP rights of others suggests China is less interested in attracting R&D investments from outside the country and more focused on expanding domestic infrastructure. Patents represent the IP created for biopharmaceutical innovations, and the data analyzed draw upon the World Intellectual Property Organization's (WIPO's) filings of new patents by origin of the country of the inventor, which is a key step for protecting the worldwide rights to new biopharmaceutical innovations. From 2010 to 2014, the United States grew in its filings of biopharmaceutical patents by 38.7 percent, but China more than doubled in the size of its patent activity and is closing in on the United States in absolute number of patents awarded (Figure 4).

Figure 4: United States and China in Levels of Biopharmaceutical Patents, 2010 and 2014, and Percentage Change



Source: World Intellectual Property Organization Database

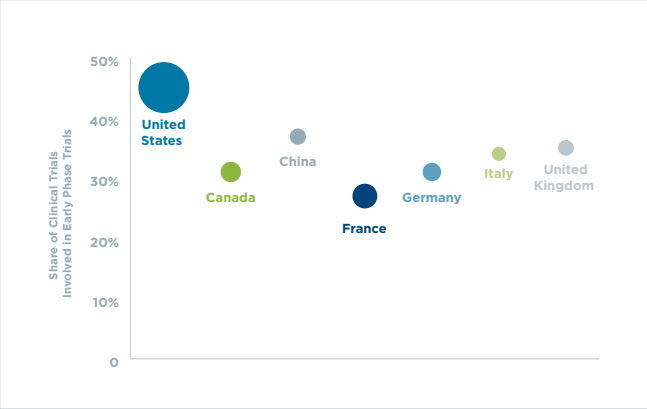
For venture capital, the United States has advanced its lead over the benchmark nations in this key measure of high-growth-potential new companies. Venture capital funding supports the efforts of high-growth-potential new biopharmaceutical companies seeking to advance innovations. The United States dominates with 74 percent of the worldwide total of venture capital investment in 2015. This strong showing by the United States suggests its key advantage in biopharmaceutical development continues to be its high-quality innovation ecosystem for commercializing biopharmaceutical innovations among new companies. It is not only the quality of the research advances, but also the ability to form proven management and scientific teams to lead these new companies that attracts venture capital investment.

From 2010 to 2015, the United States doubled its level of venture capital funding for biopharmaceutical new businesses, while the other nations examined declined by 1 percent. Still, the strongest showing was by Japan, which raised its level of venture capital investment from $6 million in 2010 to nearly $60 million in 2015.

For clinical trials, the United States is among the most active sites, especially for early-phase trials where new innovations are initially tested. The most comprehensive database on clinical trials activity is maintained by the U.S. FDA for new treatments being considered for drug approval in the United States that can be tested globally, but it is hard to get time series data on clinical trials given the improving coverage over time. In June 2016, among active sites for clinical trials registered with the U.S. FDA from across the globe, the United States stands out with 27,795 clinical trial sites (Figure 5). Several of the other nations examined had between 3,000 and 5,000 clinical trials, including France, Canada, Germany, United Kingdom, China, and Italy. So, while no other nation comes close to the U.S. total, the other nations examined overall have more clinical trial sites than the United States, with 37,150, reflecting the increasingly global nature of clinical trials.

The United States leads the benchmark nations in early-phase clinical trials where new innovations are initially tested and often refined in terms of target populations and protocols, with 45 percent of the clinical trial sites in the United States being involved in early-phase trials. Still, the gap is not wide, with China having 37 percent of its clinical trial sites involved in early-phase trials and other nations active in clinical trials having between 27 percent and 35 percent of their clinical trial sites involved in early-phase trials.

Figure 5: United States and Selected Countries in Number of Clinical Trial Sites and Percentage of Sites Involved in Early-Phase Trials as of June 2016

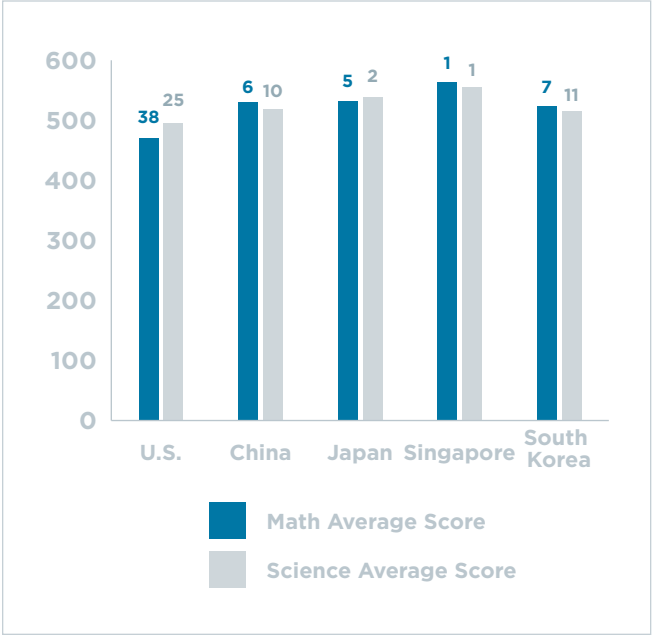


Source: ClinicalTrials.Gov as of June 30, 2016

Talent: United States Middling in K–12 Science and Math Performance, but Keeping Pace on Postsecondary Science Degrees

For K–12 education, the United States scored middling, but well off the leaders, in international assessments of 15-year-old students' math and science literacy. . The Program for International Student Assessment (PISA) is an international assessment of the functional skills that students have acquired as they near the end of compulsory K–12 schooling, including measures of mathematics and science literacy. It is administered to 15-year-old students every three years, with the latest results available for 2015 covering 72 nations. The United States ranked 25th in science and 38th in math (Figure 6). Among the benchmarks are leading nations, including Singapore (1st in both science and math), Japan (2nd in science and 5th in math), China (6th in math and 10th in science), and South Korea (7th in math and 11th in science).

Figure 6: U.S. Average Math and Science Scores and Rankings in 2015 PISA Compared with Leading Nations Considered

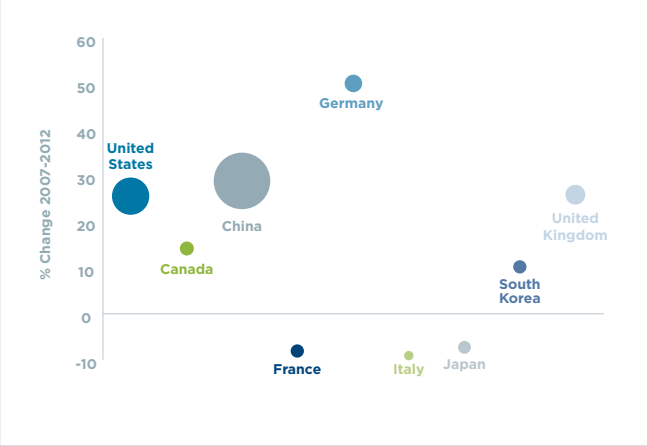


Source: OECD, 2015 PISA Results

For postsecondary graduates, the United States is holding its own in increasing the generation of undergraduate and doctoral degrees. The comparative data on postsecondary graduation are spotty and have long lag times, but the National Science Foundation (NSF) Science and Engineering Indicators suggest the United States continues to grow its base of undergraduate and doctoral degrees in the sciences (both physical and biological), rising 26 percent in undergraduate science degrees and 13 percent in doctoral degrees from 2007 to 2012.

In undergraduate degrees, the U.S. growth exceeds that for Canada, France, Italy, Japan, and South Korea. It is on par with the United Kingdom and exceeded by only Germany and China (Figure 7).

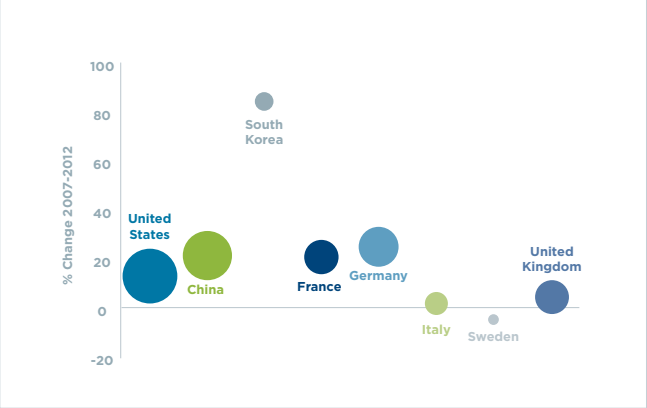
Figure 7: United States and Leading Nations in Level of Undergraduate Degrees Awarded in Physical and Biological Sciences, 2012, and Percentage Change, 2007–2012



SOURCES: OECD.StatExtracts, http://stats.oecd.org/Index

In doctoral degrees, the U.S. growth exceeds Italy, Sweden, and the United Kingdom. It is exceeded, though, by China, France, South Korea, and Germany (Figure 8).

Figure 8: United States and Leading Nations in Level of Doctoral Degrees Awarded in Physical and Biological Sciences, 2012, and Percentage Change, 2007–2012

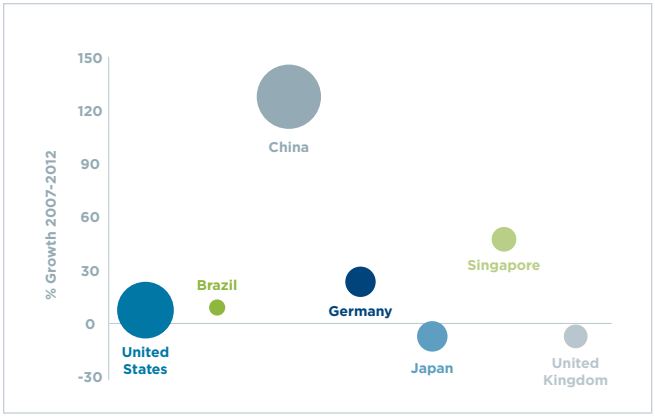


Source: OECD, StatExtracts, http://stats.oecd.org/Index

Production and Export: United States Overtaken by China in Production, but Not Exports. Still, Not Keeping Pace with Growth of Many Benchmark Nations.

For value-added in biopharmaceutical production, the United States continues to grow, but is being well outpaced by the benchmark nations. Value-added measures the contributions a nation makes in the production of biopharmaceutical goods above the cost of imported materials and inputs, and so is a higher standard in measuring the manufacturing capacity of a nation. The United States grew its value-added in biopharmaceutical production by 7.5 percent from 2010 to 2014 (Figure 9). By comparison, the benchmark nations' value-added rose by 42 percent, led by China's gain of 128 percent. Among developed nations, Germany stood out among leading nations with a 24 percent gain. So, the competitive issue for the United States is not simply the growing markets of developing nations driving where production is located, but also the rising competitiveness in manufacturing capacity in other nations.

Figure 9: United States and Leading Nations in Level of Value-Added of Pharmaceutical Industry, 2014, and Percentage Change, 2010–2014

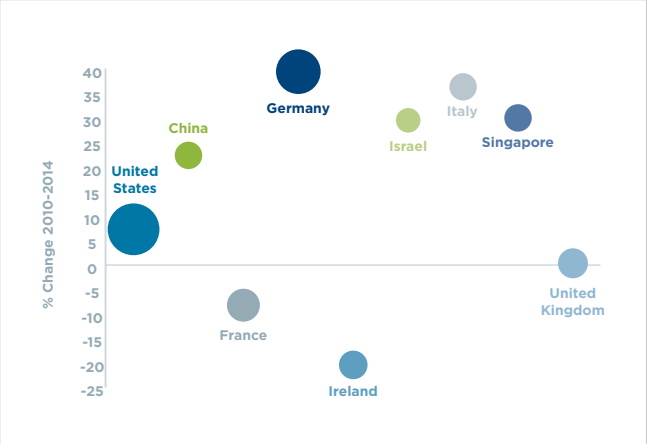


Source: Science and Engineering Indicators, 2016 - IHS Global Insight, special tabulations (2015) of the World Industry Service database.

Note: Leading Nations have more than $10 billion in value-added for pharmaceutical industry

For biopharmaceutical exports, the United States continues to grow and is the leader among benchmark nations in the total value of its biopharmaceutical exports. The U.S. growth in total biopharmaceutical exports reached 7.3 percent from 2010 to 2014 (Figure 10). While this growth is below the benchmark nations' growth of 13.8 percent, the United States is the leader in total value of its biopharmaceutical exports with $47.7 billion compared with $33.9 billion for Germany and $14.9 billion for China and Singapore. Still, the growth of competitors like Germany, China, and Singapore, among others, is well above the United States and, if this higher pace continues, they will challenge the U.S. leadership.

Figure 10: United States and Leading Nations in Level of Exports, 2014, and Percentage Change, 2010–2014



Source: Science and Engineering Indicators, 2016 - IHS Global Insight, special tabulations (2015) of the World Trade Service database

Note: Leading Nations have more than $10 billion in exports

2016 UPDATE:

BIOPHARMACEUTICAL DEVELOPMENT STRATEGIES AND POLICIES AROUND THE WORLD

The biopharmaceutical industry is among the most highly regulated industries across the globe. Combined with the complexities related to scientific and technological advances and sophisticated manufacturing and delivery systems, this industry is unique in how it advances innovation. The following are included among its other distinctive features:

- A higher reliance on lengthy R&D investments calling for large academic and industry R&D efforts.
- Close and needed interface between research, clinical care, and new product development, often referred to as “bench to bedside” translation for successful biopharmaceutical innovation.
- A significantly longer, more uncertain, and far more expensive development process for bio-pharmaceutical products compared with products developed by other advanced industries.

Other nations are bringing an increasingly sophisticated approach to advancing their biopharmaceutical industry that recognizes the unique innovation requirements to bring new medicines to patients.

Seven specific policy areas highlight the efforts on the part of the benchmark nations to advance their leadership:

- Building in-country R&D excellence
- Accelerating the commercialization of university research and new firm formation
- Increasing access to investment capital
- Fostering industry R&D investment via tax policies
- Accelerating access to innovation through regulatory and IP protection policies
- Strengthening the capabilities to manufacture biopharmaceuticals
- Building human capital

In the sections that follow, an updated examination of the policies and programs underway by the benchmark nations in these seven areas is provided in the context of changing demands and emerging challenges for biopharmaceutical industry development.

2016 International Report Update: R&D Practices

As a science- and discovery-driven industry, the biopharmaceutical industry is dependent upon robust national R&D infrastructure. Investment in advanced bioscience research is the foundation upon which many nations are building their capacities for competing in biopharmaceutical industry development. Such efforts build on the model that has enabled the United States to become a world leader based on a biopharmaceutical innovation.

While the United States continues to be the world leader in both industry and government investment in biomedical research, the U.S. government has not been able to sustain its past commitment to growing biomedical research due to federal budget constraints and a lack of a strategic investment framework.

In sharp contrast to the U.S., other nations are sustaining their focus on innovation strategies that target the biopharmaceutical sector as a growth opportunity as noted earlier, including strong investments in public research. While the United States declined in federal research funding by 2.2 percent from 2010 to 2014, available data from the OECD on selective nations find growth occurring over this time period in Australia (+6.6 percent), Germany (+38 percent), Ireland (+5.4 percent), Japan (+11.4 percent), South Korea (+14.2 percent), Sweden (+3.4 percent), and the United Kingdom (+16.3 percent).

A more comprehensive measure available for all of the benchmark nations, though less specific to just biopharmaceutical research, is the research intensity of a nation. Research intensity considers total public and private domestic R&D expenditures as a share of total economic activity (i.e., gross domestic product or GDP). Overall, the average for benchmark nations went up by 0.07 percentage points from 2 percent in 2010 to 2.07 percent in 2014, while the United States declined by 0.05 percentage points from 2.83 percent in 2010 to 2.78 percent in 2014 (Table 3). Eleven of the 18 benchmark nations increased their level of research intensity, with Brazil, China, Russia, South Korea, Saudi Arabia, and Singapore each growing their R&D activities by more than one-tenth of a percentage point of overall GDP from 2010 to 2014. Other benchmark nations making smaller advances in their research intensity include Australia, Brazil, Chile, France, Germany, and South Africa

Table 3: Public and Private R&D Expenditures as a Percent of GDP, 2010 and 2014, for the United States and Benchmark Nations

Country	2010 R&D as a %GDP	2014 R&D as a %GDP	Difference in R&D as a %GDP, 2010-2014
United States	2.83%	2.78%	-0.05%
Australia	2.21%	2.25%	0.04%
Brazil	1.10%	1.21%	0.11%
Canada	1.95%	1.90%	-0.05%
Chile*	0.33%	0.38%	0.05%
China	1.48%	1.95%	0.47%
France	2.21%	2.25%	0.04%
Germany	2.82%	2.85%	0.03%
Ireland*	1.60%	1.48%	-0.12%
Israel	4.27%	4.15%	-0.12%
Italy	1.27%	1.20%	-0.07%
Japan	3.44%	3.40%	-0.04%
Russia	1.03%	1.50%	0.47%
Saudi Arabia	0.10%	0.32%	0.22%
Singapore	2.52%	2.65%	0.13%
South Africa	0.93%	0.95%	0.02%
South Korea	3.36%	3.60%	0.24%
Sweden	3.62%	3.40%	-0.22%
United Kingdom	1.81%	1.81%	0.00%
Benchmark Average	**2.00%**	**2.07%**	**0.07%**

Source: R&D Magazine reports on Global R&D Funding from publications in December 2011 and Winter 2016, using actual 2010 and actual 2014, except for Chile and Ireland which were not reported.

*OECD statistics to calculate Chile and Ireland.

THE STATED COMMITMENTS OF OTHER NATIONS TO FOSTERING INNOVATION

Japan—"The Japan Agency for Medical Research and Development (AMED) has been established to serve as an institution dedicated to improving medicine through research and development in Japan. Our goal is to fast-track medical R&D that directly benefits people, not only by extending lifespans, but also by improving quality of life."—Makoto Suematsu, MD, PhD, president of the Japan AMED (see http://www.amed.go.jp/en/aboutus/aisatsu.html).

France—"France is making an unprecedented effort for innovation through what we call the investment in the future program. Overall we are investing 60 billion dollars of private and public money in the key sectors of research and in higher education. The healthcare and biotechnology sector, which should receive more that 10 percent of the investment, is one of the program's priorities."—Speech of Then-Ambassador Francois Delattre, Boston, June 18, 2012 (see http://franceintheus.org/spip.php?article3603).

South Africa—"By establishing networks of centres of excellence in health innovation in Africa, the African Network for Drugs and Diagnostics Innovation (ANDI) is playing a critical role in helping to ensure better coordination of and efficiency in investments harnessing STI to fight disease in Africa. The centres of excellence focus on drug and vaccine development, diagnostics, and medical devices and technologies. With targeted interventions across the full innovation value chain, the goal is also to boost Africa's indigenous pharmaceutical capacity for optimal impact on society."—Minister Naledi Pandor on science, technology and innovation in Africa, November 23, 2015 (see http://www.gov.za/speeches/minister-naldei-pandor-science-technology-and-innovation-africa-23-nov-2015-0000).

Emerging Practices in R&D

An examination of R&D investment programs and initiatives conducted five years ago revealed a number of commonalities among the countries studied, including the following:

- Increasing public investment in R&D
- Enhancing the quality of their R&D enterprise by attracting world-class researchers and engaging in international partnerships
- Funding multidisciplinary, multi-institutional R&D
- Focusing on translational research.

A leading example of these key features is the EU's Innovative Medicines Initiative (IMI), one of the most significant public-private partnerships in biopharmaceutical innovation. IMI was launched back in 2008 with a €2 billion budget shared equally between the European Union and biopharmaceutical industry to support precompetitive research collaborations with a goal of speeding up the development of safer and more effective medicines. It has achieved a significant level of collaboration and data sharing among biopharmaceutical companies, academic teams, EU regulators, and patient advocates. Many significant results and shared datasets have been generated by IMI's first round of 40 consortia-based projects involving over 4,000 researchers from academia, industry, government, and patient advocate sectors, including in severe asthma, schizophrenia, depression, autism, and bacterial resistance.

The IMI entered its second major phase in 2014 with a budget of €3.3 billion through 2020, again shared between the European Union and biopharmaceutical companies, with three objectives: (1) 30 percent better success rate in clinical trials of medicines targeting the 12 priorities identified by World Health Organization (WHO);[58] (2) clinical proofs of concept achieved in immunological, respiratory, neurological, and neurodegenerative diseases within five years; and (3) new and approved diagnostic markets for four of these diseases and at least two new medicines for Alzheimer's disease. Some 50 projects are being supported,[59] including, for

example, the European Lead Factory, offering industry-level high-throughput screening tools to researchers in academia and small- and medium-sized biopharmaceutical companies.[60]

The focus on increased public research funding focused on multidisciplinary, multi-institutional, translational research efforts still appears to be in place, but the following additional approaches have emerged.

Benchmark Nations are Revitalizing Academic Research:

A wide range of nations are creating entirely new funding mechanisms for biomedical research, including the following:

- **Australia** has established a Medical Research Future Fund,[61] an initiative run directly by the Department of Health (not the Medical Research Council). It is designed to "support the sustainability of the health system and drive medical innovation through transforming how health and medical research is conducted in Australia." The fund is intended eventually to reach AU$20 billion in fund balances and thereafter to disburse AU$1 billion annually.

- **Japan** has created the Japan Agency for Medical Research and Development (AMED),[62] conceived as an analogue to the U.S. National Institutes of Health (NIH). Funded relatively modestly, AMED consolidates certain government budgets that had formerly been managed by four separate ministries to take an integrated approach to research funding through a series of competitive calls that span basic to applied research, including clinical studies.

- **Russia** has been revamping its biomedical research funding to create a new competitive framework that supports the development of research capacity at universities either directly in the state budget (Moscow State University and St. Petersburg State University), and through supplements aimed at R&D excellence, or through competitive grants from the Russian Foundation for Basic Research. It should be noted though that Russia is primarily focused on forced localization of biopharmaceutical manufacturing.

Other Nations are Defining their R&D Goals in Terms of Human Health Needs and Outcomes:

A number of the benchmark nations are recognizing the need to establish research excellence in areas where human health needs are critical and/or indicate potential for new markets. Often these efforts involve collaboration with universities and foundations, many of which are based in the United States.

- **Canada** through its National Research Council has identified "human health therapeutics" as a targeted area of focus and seeks to "de-risk critical steps in the development of biologics,[63] vaccines[64] and delivery of large molecules to the brain.[65]"[66] In connection with the latter priority, the Canadian government includes C$20 million over three years for the Brain Research Fund at Brain Canada Foundation.[67] Plus, the 2016 budget provides C$237 million, a substantial increment, to Genome Canada.[68] Genome Canada[69] was established in 2000 specifically to develop and implement a national strategy for large-scale genomics and proteomics research projects with a focus on translation to personalized medicine.[70]

- **China** through Tsinghua University has partnered with the Bill and Melinda Gates Foundation in 2016 to develop a new Global Health Drug Discovery Institute in Beijing, focused on cures for diseases faced by developing nations, with an active partnership with the California Institute for Biomedical Research.[71]

Other Nations are Incentivizing Academic -Industrial Partnerships:

New organizational approaches are being implemented to better meet private sector needs:

- **Singapore** continues to support non-university research institutes[72] as they work with the biopharmaceutical and medical technology sectors. The institutes most directly relevant to the biopharmaceutical sector include the Bioprocessing Technology Institute, the Experimental Therapeutics Centre, the Genome institute of Singapore, the Institute of Bioengineering and Nanotechnology, the Institute of Medical Biology, the Institute of Molecular and Cell Biology, and the Singapore Institute for Clinical Sciences.

- **Germany** has a "Clusters of Excellence" competition, which encourages German universities to expand into fundamental and applied research. Among new multi-institutional clusters approved in the latest round are efforts involved in systems neurology, cellular systems, and neurological cures.[73] Earlier-selected clusters of excellence also remain in operation. These clusters typically involve several universities, occasionally transnational EU "infrastructure" resources, and/or one or more independent research institutes.

- **Ireland** through the Science Foundation Ireland (SFI) has established research centres,[74] based at universities with industry support. Three have direct relevance to biopharmaceutical innovation focusing on synthesis and solid state pharmaceuticals (located at University of Limerick);[75] the microbiome, advanced materials, and bioengineering (located at Trinity College);[76] and fetal and neonatal translational research (located at Cork University Hospital)[77].

- **The United Kingdom's** government supported Medical Research Council (MRC) launched in 2016 a new Dementia Institute[78] in partnership with key charities that will bring together leading scientists to advance research into the mechanisms underlying the development and progression of the dementias,[79]

- **Canada's** Network Centres of Excellence are a cross-research-council collaboration designed to fund five-year research and translational projects involving universities, federal labs, and industry that break institutional and disciplinary silos and create forums for collaboration among researchers in allied programs in federal and university settings. There are currently 26 funded network centres in the health and life sciences area.[80] C$800 million was designated in the 2016 budget over four years to support existing and new networks and clusters.[81] Among these will be five new networks for patient-oriented research in chronic diseases.[82]

- **France** continues to support a series of 34 "Carnot Institutes"[83] (inspired by the German Fraunhofer Institutes) that manage applied research collaborations, typically between a university, grand école, or state research organization and private industry. Life science remains a key focus area of the Carnot Institutes, with several focusing on specific diseases. The network claims a 50 percent increase in contract-research revenues between 2010 and 2014.

2016 Update: Accelerating the Commercialization of University Research and New Firm Formation

Research investments alone are not sufficient to generate new biopharmaceutical innovations. A lengthy, uncertain, and costly process must be undertaken to build upon research insights into the mechanisms of disease to identify and validate potential therapeutic approaches. This method of going from research insight to biopharmaceutical inventions is at the heart of the commercialization process.

One key indicator of biopharmaceutical innovation being advanced through commercialization efforts is patents, which provide the legal protection for new IP for biopharmaceuticals necessary to ensure private investment. To gain an understanding of the level of innovation taking place across competitor nations, it is useful to consider the number of biopharmaceutical-related patents filed with the WIPO, which goes beyond narrow country patent filings and is the basis upon which patents can gain worldwide protection.

This data analysis reveals that the United States remains the nation generating the largest number of biopharmaceutical patents, though its growth rate is behind many of the other nations examined as set out in Table 4. The fast growth of China in biopharmaceutical patents filed with WIPO stands out and suggests that it may soon overtake the United States in total number of biopharmaceutical-related patents generated each year.

But, for biopharmaceutical patents, number is not the same as quality. A recent study examined the first inventors of key patents for 3,229 U.S. FDA-approved drugs over the past 25 years by country of origin. The study found that the United States led the world in first inventors of new drugs with 61.8 percent, followed by the EU5[84] with 22.6 percent (the 28 EU countries accounted for 28.7 percent), and Japan with 5.2 percent.[85] The continuation of U.S. domination in the generation of high-quality IP into the future is not guaranteed, and some of the countries included in this report appear to be focused on growing their domestic capacities in part by violating the IP rights of companies that are not based in that country. Of note, potentially contributing to the high level of patent filings in the U.S. is the favorability of U.S. regulatory and payment and access policies which leads many companies to want to launch their products first in the United States.

Table 4: Pharmaceutical and Biotechnology Patents Awarded by the WIPO by Origin Nation of Inventor, for the United States and Benchmark Nations, 2014, and Percentage Change, 2010–2014

Country	2014 Patent Awards	Percentage Change, 2010-2014
United States	17,893	37.6%
Australia	577	36.4%
Brazil	75	44.2%
Canada	809	13.8%
Chile	28	180%
China	14,126	118%
France	2,400	14.2%
Germany	3,483	0.5%
Ireland	289	13.3%
Israel	462	34.3%
Italy	938	8.8%
Japan	5,955	20.3%
Russia	1,462	8.3%
Saudi Arabia	14	1300%
Singapore	108	92.9%
South Africa	38	5.6%
South Korea	3,790	139.3%
Sweden	606	-13.6%
United Kingdom	1,701	-4.4%

Source: WIPO Statistics Database, 2010-2014.

An important contributor to the commercialization of university research advancements in the age of molecular biology and the major new scientific breakthroughs it has unleashed is the rise of start-up biopharmaceutical firms. These new biopharmaceutical firms often focus on novel areas of science. The formation of these start-up biopharmaceutical companies complements the significant internal R&D efforts in novel drug science technologies found at major existing biopharmaceutical companies by offering a broader means for commercializing university research discoveries. Often partnerships and collaborations between major and start-up biopharmaceutical companies take place to jointly pursue promising new biopharmaceutical innovations.

The United States has led the world in the formation of biopharmaceutical start-ups. Much of the credit for driving new formation of biopharmaceutical start-ups in the United States is due to the passage of the Bayh-Dole Act of 1980, which allowed universities and other government-funded research organizations to retain title over their inventions and heralded a new era to move medical discoveries beyond the walls of academia so that they can effectively benefit patients. The Economist explains: "The idea was not to enrich universities, but to give them a reason to propagate the fruits of research which had been moldering unexploited. And it has worked… Scores of medical advances and technical innovations have resulted."[86] The Association of University Technology Managers (AUTM) reports that, since 1980, American universities have spun off more than 4,000 companies. In fiscal year 2012 alone, $36.8 billion of net product sales were generated and start-up companies started by 70 academic institutions employed 15,741 full-time employees.[87]

To nurture and accelerate the formation of biopharmaceutical-related new start-ups, U.S. states have been at the forefront of advancing initiatives to realize the potential of their academic medical institutions for biopharmaceutical-related economic development. This includes various forms of commercialization assistance and dedicated biopharmaceutical incubators and entrepreneurial development programs. An important

COMPETITIVE NATIONS SPEAK:

Accelerating Commercialization and New Firm Formation

United Kingdom—"As part of our successful Catapult network, the Centre will bridge the gap between business and academia and help to turn great ideas into commercial reality."—Jo Johnson, MP, Minister of State for Universities and Science, October 1, 2015.[88]

Canada—"In Budget 2016 the Government is defining a new vision for Canada's economy: to build Canada as a centre of global innovation. Canada will be propelled by its creative and entrepreneurial citizens; its leading science and technology; its excellent innovation infrastructure; and its globally competitive companies offering high-quality products and services, thriving within a business environment that supports commercialization and growth. Through 2016 and 2017, the Government will define a bold new plan, its Innovation Agenda, to achieve this vision."—Budget 2016.[89]

Singapore—"As the commercialisation arm of the Agency for Science, Technology and Research (A*STAR), we have supported A*STAR in transforming the economy by driving innovation and commercializing R&D. In the last decade, we have provided a full suite of technology transfer services catered to the needs of our industry partners and the research community … Our commercialization efforts have also seen tangible outcomes. We are now managing a portfolio of more than 3,400 active patents and applications, has granted more than 800 licenses for A*STAR technologies and have created a portfolio of more than 50 start-up companies." Philip Lim, CEO, Singapore's Exploit Technologies Pte Ltd.[90]

federal initiative has been the Small Business Innovation Research grant program in which 2.5 percent of each federal agency's extramural research budget is targeted to supporting technology commercialization for small businesses through a competitive awards process—with the funding provided as research grants to further the commercial viability in Phase I and developing prototypes in Phase II. A National Research Council review showed about 25 percent of the top 200 NIH Phase II award winners from 1992 to 2005 went on to attract private venture-capital investment.[91]

Emerging Practices in Accelerating University Commercialization and New Firm Formation

The last five years has witnessed a steady rise in efforts across the benchmark nations to accelerate university commercialization and new firm formation. These efforts span a broad range of activities from enhancing the capacities of university's in technology transfer, to offering proof-of-concept support mechanisms to address the commercial viability of research discoveries, to supporting incubators and accelerators.

Singapore's long-standing efforts in commercialization and new firm formation are perhaps one of the best known and well accomplished. In 2002 A*STAR established a dedicated technology transfer and commercialization arm called Exploit Technologies Pte Ltd. (EPTL)[92] to serve the Research Institutes. In addition to its centrally managed IP licensing operations, EPTL offers the proof-of-concept funding in an incubator-like environment. Plus, there are a number of proof-of-concept support mechanisms, including grants offered by SPRING, the start-up unit of the Economic Development Board, to newly formed businesses covering 85 percent of the cost of proof-of-concept projects, up to a maximum of S$500,000.[93]

Over the last five years, many nations have been adding new initiatives or significantly augmented ones to accelerate commercialization and new firm formation:

- Australia proposes to augment the existing Medical Research Commercialisation Fund[94] with AU$125 million in each of the next two years for a Biomedical Translation Fund that will invest in biomedical companies across the "valley of death" while sufficient proof of concept is developed to attract private capital.[95]

- France's Investments for the Future fund have provided €900 million toward creation of a large number of "technology transfer acceleration companies" (these might be called state-funded proof-of-concept centers that hold an exclusive license to institutional IP) at a number of institutions.[96] Most of these companies are focused in biotechnology.

- Ireland has put in place new protocols for technology transfer from higher education institutes (such as the SFI Research Centres) that are managed by one central office, known as Knowledge Transfer Ireland,[97] a unit of the Enterprise Ireland (EI) development agency, in collaboration with the association of universities.

- Saudi Arabia's King Abdul Aziz City for Science and Technology (KACST) has funded the creation of a national Innovation and Industrial Development Institute, bringing together many stand-alone efforts into a more integrated "technical innovation cycle" for the Kingdom. This includes the IP and inventors support unit and the technical innovation centers program found at numerous universities and national research centers. The institute is fully equipped with technology incubators and accelerators, and seeks to encourage viable and sustainable businesses in technical fields.

- The United Kingdom announced £18 million in awards in 2015 for innovation in both biopharmaceutical and devices topics made through the eight rounds of Biomedical Catalyst,[98] a proof-of-concept fund run jointly by the medical Research

Council and Innovate UK.[99] Awards under this program may be made either to a university in partnership with business or directly to a business.

PROOF-OF-CONCEPT SUPPORT TO ACCELERATE BIOPHARMACEUTICAL COMMERCIALIZATION IS BECOMING A MORE COMMON TOOL BY BENCHMARK NATIONS.

Many promising biomedical research discoveries have unanswered questions concerning their commercial value that need to be addressed before an existing biopharmaceutical company is willing to license the technology or a private investor is willing to help invest in the formation of a new company. This requires "proof-of-concept" studies, such as how well the research discovery works in live animals or whether it can be replicated under different conditions. Without this proof-of-concept stage, many significant research discoveries with commercial value may go untapped. Now, a wide number of the benchmark nations are offering such funding, including the following:

- Australia
- Canada
- European Union
- France
- Ireland
- Singapore
- South Africa
- United Kingdom.

Major New Development – Formation of New Industry-University Partnerships to Drive Commercialization Centers.

Over the past five years, there has been growth in the number of partnerships between universities and biopharmaceutical companies. Several new initiatives have been launched in recent years:

- In Canada, the 2016 budget provides C$32 million over two years starting in 2017 targeted specifically to the Centre for Drug Research and Development,[100] a nonprofit commercialization entity supported through the Network Centres of Excellence Program, located on the campus of the University of British Columbia. The Centre attracts partnership commitments from multinational pharmaceutical firms. Likewise, the budget targets C$12 million over two years to the Ottawa-based Stem Cell Network,[101] to support clinical-translational research.

- In Ireland, through Knowledge Transfer Ireland, two biopharmaceutical-related Centres for Science, Engineering and Technology—Systems Biology Ireland and the Biomedical Diagnostics Institute—have been formed as major industry-university collaboratives aimed at technology transfer, with the government funding 75 percent of the cost.[102] Each has large industrial partners from the respective sectors that pay the required 25 percent cost share.

- In Israel, the Office of the Chief Scientist incubator program (now part of the Israel Innovation Authority) established a new $2 million accelerator for novel drug development, in partnership with several biopharmaceutical companies.[103] Its charge is to lead biotech start-ups toward clinical trials and A Round investments. The incubator is 85 percent funded by OCS and 15 percent by its private partners. Its first two start-ups are in Alzheimer's disease and cancer therapy.[104]

- In the United Kingdom, three global biopharmaceutical firms and the technology transfer offices of Imperial College, University College, and Cambridge created a £40 million fund known as Apollo Therapeutics to speed translation of university research into medicines.[105] Each industry partner will contribute $15 million and each university partner $5 million. Funding will be used to support ex-industry scientists to advance preclinical studies to the stage where a technology can be taken up by one of the partners by internal bid or out-licensed.[106] The program is based at Stevenage Bioscience Catalyst, a research campus built on a public-private partnership.[107]

These industry-university partnerships in commercialization centers among the benchmark nations are consis-

tent with the growing emphasis on broader corporate innovation centers collocated near major academic centers in the United States. An excellent example is the California Institute for Quantitative Biosciences or QB3 in San Francisco, which represents a partnership between the University of California system, state government, and industry with strategic collaborations across each entity. The Institute has developed a range of support for entrepreneurs including a network of incubators, a venture capital fund, a "startup in a box" program, Small Business Innovation Research grant workshops, and Bridging-the-Gap Awards. QB3 also has a strong track record in advancing strategic research alliances with private biopharmaceutical companies.

2016 Update: *Increasing Access to Investment Capital*

The lifeblood for start-up biopharmaceutical firms is access to private venture-capital investment. It is well recognized that attracting venture capital investment for biopharmaceutical development is more challenging than investments in software or Internet companies. It is not just the higher costs of developing new therapeutics that makes venture investing more challenging. There is significant uncertainty about how long clinical trials testing and regulatory approval will take, and a significant probability of failure for novel therapeutics even once at the clinical trials stage.

The private venture-capital industry has its roots in the United States, which continues to lead the world in venture capital investment. In 2015, PricewaterhouseCoopers (PwC) reports that venture capital investment in life sciences and biotechnology reached its highest level in the United States since it began measuring venture investment trends back in 1995.[108] From 2010 to 2015, the global level of biopharmaceutical-related venture investment rose from $6 billion in 2010 to $11 billion in 2015, a gain of $5 billion. Of this gain, $4.4 billion was invested in the United States.

Many other nations are turning to local mechanisms to ensure that there are pools of available capital to invest in start-up and emerging biopharmaceutical ventures though it is unclear the degree to which these policies are aimed at attracting investments outside of the country versus growing domestic capacity.

COMPETITIVE NATIONS SPEAK:

Accelerating Commercialization and New Firm Formation

Australia — "Our Medical Research Future Fund is a major initiative to deliver increased funding for health and medical research, but it won't invest in the late stage transition of that research to market. So we've created a new $250 million biomedical translation fund that will increase the capital available for commercialising medical research sooner without affecting the Medical Research Future Fund's ability to reach its target of a balance of $20 billion by 2019."—Speech by Christopher Pyne, MP, Minister for Industry, Innovation and Science, December 8, 2015.[109]

Russia — "We have launched a programme that cost about 150 billion [rubles] to develop our own pharmaceutical industry.… The federal funding is only designed to create conditions, to give an impetus to the development of this business."—President Vladimir Putin, Address to the Russian Popular Front for Quality and Affordable Medicine, September 7, 2015.[110]

Emerging Practices in Increasing Access to Investment Capital

The last five years have not been particularly active in advancing new initiatives for access to private capital. Still, the benchmark nations are continuing to stay active through existing program efforts, whether involving direct investment or investment in privately managed venture funds through what is referred to as fund-of-funds approaches, including in Brazil, Canada, France, Germany, Israel, Japan, Russia, Saudi Arabia, Singapore, South Africa and Sweden (see Table 5 below).

Table 5: Overview of Investment Capital Initiatives Underway in Benchmark Nations

Nation	Investment Capital Initiative
Brazil	The Program to Support the Development of Industrial Complex of Health (Profarma) is expected to make $2.56 billion available from 2013 to 2017 through credit and venture-capital equity investments in the private sector aimed at improving national capacity to develop biotechnology products and processes.[111]
Canada	The Venture Capital Action Plan through the Business Development Bank of Canada is investing C$400 million of government funds in different venture capital funds, including one that focuses on life sciences.[112]
France	Bpifrance, the state-chartered bank in France, provides a range of loan and grant instruments and acts as a fund-of-funds manager in private equity markets and occasionally as a direct investor through funds such as InnoBio,[113] a €173 million fund in which it co-invests with several biopharmaceutical companies.
Germany	The public development bank in Germany (KFW) offers equity and near-equity investment vehicles for start-up entrepreneurs.[114]
Israel	A life-science venture-capital fund managed by general partner Orbimed Partners has received government funding.[115] Total investment in the fund including private-sector LPs is $220 million and the fund lifetime will be at least 10 years.
Japan	A government fund co-invests with the biopharmaceutical sector in new-drug start-ups among other sectors.[116]
Russia	A government-run fund of funds[117] has a Biofund focused on investing in laboratory, analytical, and consulting contractors who in turn will serve biopharma developers as well as new Seed Fund for life sciences.[118]
Saudi Arabia	The technology unit of the Saudi public investment fund,[119] TAQNIA, invests in six sectors including life sciences and health both directly and through partnerships.
Singapore	The strategic-investment affiliate of the Economic Development Board[120] targets the biomedicine sector for direct equity investments. Plus, the start-up unit of the Economic Development Board operates its own direct investment fund called SPRING SEEDS Capital that can invest up to S$1 million[121] and will match investment in angel groups dollar-for-dollar up to S$2 million.[122]
South Africa	The Industrial Development Corporation funds industrial infrastructure in a dozen sectors including “chemical products and pharmaceuticals” both through standard debt instruments and a unit that provides equity risk capital targeting SMEs.[123]
Sweden	Industrifonden, a foundation established by the government in 1979, invests directly in SMEs in three areas including life sciences and also owns stakes in private venture-capital funds.[124] ALMI Invest, a subsidiary of the state-owned regional-development fund ALMI Företagspartner AB, uses EU “structural funds” to take minority investments in life sciences and other start-ups, matched by private investors in the respective targeted regions.[125] [126]

Still, a number of benchmark nations have taken on new initiatives that reflect the importance of increasing investment capital. Interestingly, many of these newer efforts also address incentives for investors beyond direct government funding. Among the new initiatives are the following:

- Australia, which enacted several investment incentives, including: (1) Tax Incentive for Early Stage Investors,[127] which provides a 20 percent nonrefundable tax credit for investments in qualified businesses along with 10 years of capital gains exemption, and (2) new Arrangements for Venture Capital Limited Partnerships, which provides a 10 percent nonrefundable credit and several areas of flexibility that had been requested by investors.[128] In parallel, the National Innovation Strategy proposes AU$70 million toward a public-private Innovation Fund capitalized at AU$200 million in total, aimed at commercializing discoveries made within the governmental CSIRO. An additional AU$20 million would be set aside for CSIRO to help other publicly funded research organizations prepare faster for commercializing discovery.[129]

- EI's Seed and Venture Capital Scheme[130] has committed €175 million during 2013 to 2018, to be matched by at least EUR525 million in private investment. In addition, Ireland is offering the Start-up Refunds for Entrepreneurs program to provide a 41 percent capital investment credit against income taxes, for investments in qualifying start-ups held for specified periods, including investors in the seed and venture start-up scheme.[131]

- Italy, through its Startup Act of 2012, offers innovation-led start-ups simplified, no-fee, fast-track access to a government fund that may provide 80 percent bank loan guarantees up to EUR2.5 million.

- South Korea exempts smaller bioventures from minimum requirements and allows them listing on the South Korean stock exchange for a maximum of five years.[132]

- In the United Kingdom, all quasi-public venture-capital initiatives have been consolidated into the British Business Bank (BBB),[133] a state-owned development bank. The BBB's Venture Capital Catalyst Fund,[134] a fund-of-funds program, has invested in eight venture-capital funds, including in the life sciences. The Local Enterprise Partnerships (LEPs) Network the announced launch of a £45 million life-science investment fund targeting SMEs in the North West of England.[135]

All of this suggests that increasing the availability of investment capital is a concern of nearly all of the benchmark nations, though typically they are staying the course with specific targeted initiatives.

2016 Update: *Fostering Industry R&D Investment Via Tax Policies*

Biopharmaceutical innovation depends heavily upon industry investment in R&D. Research!America reports that industry R&D investment is nearly three times larger than the federal government and represents two-thirds of total medical and health R&D in the United States.[136] Similarly, analysis of available OECD data for the benchmark nations finds that industry investment in biomedical research is also nearly three times the level of national government investment.[137]

Still, without incentives, it is likely that industry will underinvest in R&D because it is hard for an individual company to capture all of the economic benefits from their investment in R&D activities—what economists refer to as knowledge spillovers. Plus, R&D is a risky activity for companies, with an uncertain return, which limits access to capital for industry R&D investments, especially for young innovative companies.

For the biopharmaceutical industry sector, R&D incentives are particularly important. The long and costly process to advance biopharmaceutical innovation and the significant uncertainty of success—with only 12 percent of investigative medicines entering clinical trials

being ultimately approved by the U.S. FDA—makes it particularly important to encourage R&D activities.[138]

The evidence bears out the importance of economic incentives for R&D (see text box below). Most industrialized nations currently provide incentives for the conduct of private-sector R&D. The reasons are straightforward: (1) to ensure that companies perform more than they would otherwise and (2) to ensure that they do so in one's own jurisdiction rather than somewhere else.

TAX INCENTIVES BOOST R&D

R&D tax incentive schemes are widely adopted in advanced economies.… The vast majority of studies surveyed in this report conclude that R&D tax credits are effective in stimulating investment in R&D.… In some countries analyzed, small- and mid-sized enterprises tend to respond more strongly to the support for R&D.… Recent evidence suggests that knowledge spillovers of large firms exceed those of small firms.

European Commission, A Study on R&D Tax Incentives, November 2014.

An extensive 2014 European Commission *Study on R&D Tax Incentives* covering nations involved in the European Union explains the complexity and variety of approaches in R&D incentives across nations: "Countries have introduced the R&D tax incentives at different points in time and have shaped them in various ways. Even for such a generic policy instrument, the specific design, type and number of R&D tax incentives differ substantially across countries.… Different approaches co-exist in the countries shape R&D tax incentives."[139]

The European Commission study notes that four broad approaches are typically used:

- Tax credits—which offset taxes by the level of R&D investment made by a company
- Super or enhanced allowances—which inflate the level of R&D investments as a cost that reduces the base of taxable income
- Accelerated depreciation—which allows for fixed assets, such as equipment and buildings, used for R&D to be depreciated at higher rates in the first years of the asset's life
- Reduced corporate tax rates on IP—which lowers the corporate rate on income generated from sales of products associated with a company's own IP.

COMPETITIVE NATIONS SPEAK:

Accelerating Commercialization and New Firm Formation

United Kingdom — "Here in the UK we have already created a Patent Box—which means that if a company creates intellectual property in the UK, it will pay a corporation tax rate of just 10 percent on any profits generated by those patents. But I want us to go further, including by looking at extending the length of patents so that companies which successfully invest in a new drug may have a longer period of exclusivity in reaping the rewards for that investment. I think these new incentives will be critical in overcoming the market failure that perilously undermines research and drug development." Then Prime Minister David Cameron, speech on dementia initiative, June 19, 2014.[140]

France — "[T]he pharmaceutical and biotech sector is benefiting from tax incentives for innovation that are the most attractive in Europe." Speech of Then-Ambassador Francois Delattre, Boston, June 18, 2012.[141]

Table 6 summarizes the variety of efforts underway drawing heavily upon Deloitte's *2015 Global Survey of R&D Incentives*, which provides one of the most comprehensive reviews of what different nations are doing and for the benchmark nations covered, and additional information from the European Commission study.

Table 6: Overview of R&D Incentives Offered to Companies by the United States and the Benchmark Nations

Country	Nature of Benefit Available	Details of Tax Benefit Generally Available	Specific Preapproval Required from Government	Refundable/ Carryforward	Cap/ Limitations on Benefits	R&D Activities Must Occur in Country
United States						
Australia	Tax Credit	• Refundable tax volume-based credit of 45% below for small companies • Nonrefundable tax credit of 40% for all other companies	Application required within 10 months of tax year end	Yes, for small companies	No	Up to 50% of total project costs can be performed outside of Australia
Brazil	Super Deductions Accelerated Depreciation Excise Tax Exemptions	• Super deductions of 160%–200%	Must have tax certificate for super deduction	Carried Forward Permitted	No	Yes
Canada	Tax Credit	• Small companies earn refundable tax credits at a rate of 35% on first $3 million	No	Yes, for small companies	No	Up to 10% of eligible wages can occur outside of Canada
Chile*						
China	Super Deduction Tax Exemption	• 150% super deduction • Exemptions offered for selective companies and activities impacting value-added tax, corporate income tax and on import duties	Government approval required	Carried Forward Permitted	No	Up to 40% of activities can occur outside of China
France	Tax Credits Cash Grants Accelerated Depreciation Patent Box	• Patent box reduces corporate tax to 17%	No	All unused credits refunded over time	Yes, for level of subcontracted research and on credits	100% must take place within EU/ European Economic Area (EEA)
Germany	Nonrepayable Cash Grants	• Grants average about 50% of eligible project costs	Large projects need notification	n/a	No	Yes

Country	Nature of Benefit Available	Details of Tax Benefit Generally Available	Specific Preapproval Required from Government	Refundable/ Carryforward	Cap/ Limitations on Benefits	R&D Activities Must Occur in Country
Ireland	Tax Credits Cash Grants Employee Tax Benefits	• Credits can be used to offset R&D employees' personal income tax liabilities	No	Refunds permitted up to total tax paid for previous ten years or payroll tax liabilities of past year	No	100% within EU/EEA
Israel	Tax Rate Reductions Cash Grants	• Companies must apply for grant programs and tax rate reductions	Yes	n/a	n/a	Yes
Italy	Tax Credits Patent Box Investment Incentives Grants	• 35% tax credit for amounts paid to qualified researchers in addition to incremental R&D tax credit • 20% deduction permitted for company investments in small R&D-intensive companies • Patent box allows for a 50% exemption of income earned from IP over a 3-year period • Cash grants available on a regional basis	Generally no, except for credit for qualified researchers	No	Caps on tax credit for qualified researchers and investments in small research-intensive companies	Yes
Japan	Tax Credits	• Both volume-based and incremental tax credits available	No	No	Yes	No
Russia	Super Deduction Reduced Tax Rates Value-Added Tax Exemptions	• 150% super deduction • Reduced tax credits for companies in special economic zones	Yes	Carried Forward Allowed	No	No
Saudi Arabia						
Singapore	Super Deduction	• Additional 250%–300% super deductions on first S$400k–S$600k of R&D expenditures, depending on size of company	Yes	Can convert unused deductions to cash grant of 60% or can be carried forward	Yes	Yes

Country	Nature of Benefit Available	Details of Tax Benefit Generally Available	Specific Preapproval Required from Government	Refundable/ Carryforward	Cap/ Limitations on Benefits	R&D Activities Must Occur in Country
South Africa	Super Deduction Accelerated Depreciation	• 150% super deduction	Yes	Carried Forward Allowed if Company is Not Generating Income	No	Yes
South Korea	Tax Credits Investment Tax Credit IP Transfer Tax Credit	• Both volume-based and incremental R&D tax credit • IP transfer tax credit for small- and mid-sized companies	No	Carried Forward Allowed	Yes, for large companies	No
Sweden						
United Kingdom	Super Deduction Tax Credits	• 130% super deduction for large companies and 230% for small- and mid-sized companies	No	Yes, for small- and mid-sized companies	Yes	Yes, if supervised by UK company

Source: Based on summary country tables provided in Deloitte's 2015 Global Survey of R&D Incentives, October 2015, except for Chile, Saudi Arabia, and Sweden that were based on TEConomy web searches.

Emerging Practices in Fostering Industry R&D Investment

As the Deloitte *2015 Global Survey of R&D Incentives* explains: "Many of the countries reviewed have changed their laws or policies since the last edition in March 2014. There is no consistent global trend reflecting a movement toward curtailing or expanding R&D incentives… A brief review of the changes since March 2014 demonstrates that many governments are continuing to search for the right mix of incentives to encourage the growth of R&D in their countries."[142]

Typically, nations are making small refinements in their R&D incentives from year to year, focusing on narrow and often technical changes in the definitions of R&D, the application of their incentives, or the level of tax benefit.

Keeping the focus on major new changes in creating new incentives or overhauling existing incentives—with the understanding as expressed by Deloitte that there is not a major shift to curtailing or expanding R&D incentives overall—below are some of the key new initiatives since 2012:

- **Ireland**—Converted its R&D tax credit to apply to all R&D expenditures, not just to the incremental increase in R&D activity by companies.

- **Israel**—Established an "approved enterprises" program[143] under which enhanced tax privileges are available to companies in targeted sectors such as high-tech or R&D, especially those opening facilities in designated areas of the country.

- **Italy**—Enacted a "patent tax box" in which steadily higher percentages (30 percent in 2015, 40 percent in 2016, and 50 percent thereafter) of income derived from IP may be excluded from taxation, resulting in an effective tax rate on this kind of income of 15.7 percent instead of the standard 31.4 percent. Under the same law, the R&D tax credit has been advanced to 25 percent of the incremental amount over the average of the three preceding years, or 50 percent in the case of R&D conducted in collaboration with universities or with highly qualified staff.

- **Japan**—Increased the rate and scope on its R&D tax credit, with credit given for license fees paid to SMEs and start-ups.[144]

- **United Kingdom**—Implemented its plans for a "patent tax box," which applies a lower rate of corporate tax (10 percent) to net income attributable to qualifying commercial exploitation of patents (or certain other nonpatent rights in the case of medicinals) owned or in-licensed.[145]

More important than the details of R&D tax incentives is to consider their overall level of generosity and novel trends in their focus of activities.

R&D Tax Generosity of Benchmark Nations Generally Exceeds the United States

The United States was a trailblazer in recognizing the importance of offering incentives for research and development by being the first nation to offer such an incentive in 1981. But, now the United States is falling behind other nations in the generosity of its tax incentives for research and development. Even though, the United States recently took an important step to strengthen its research and development incentive by making it a permanent feature of the tax system, the United States is not keeping pace with other countries.

A study by the Information Technology and Innovation Foundation (ITIF) across the mix of tax incentives for R&D offered by different nations found that, out of 42 nations, the United States ranked 27th, and 14th among the benchmark nations (all of which were studied except Saudi Arabia). Among the benchmark nations, several offer steeper R&D tax incentives for small- and mid-sized enterprises, including Australia, Canada, France, South Korea, and United Kingdom.

Table 7 summarizes the findings by ITIF on the level of generosity. Nations such as Chile, Germany, Israel, and Sweden, despite offering some R&D incentives to targeted companies in the form of rate reductions or

grants for undertaking R&D activities, do not have broad-based R&D tax incentives and so, across the base of their biopharmaceutical industry conducting R&D, offer no level of incentive.

Table 7: United States and Benchmark Nations in Level of R&D Tax Incentives for SMEs and Large Firms, 2012

Country	SMEs		Large Firms	
	Level of R&D Tax Subsidy	Rank	Level of R&D Tax Subsidy	Rank
United States	0.06	14	0.06	14
Australia	0.17	7	0.11	9
Brazil	0.26	4	0.26	2
Canada	0.33	2	0.18	4
Chile*	0	15	0	15
China	0.14	9	0.14	5
France	0.43	1	0.34	1
Germany	0	15	0	15
Ireland*	0.13	10	0.13	6
Israel	0	15	0	15
Italy	0.12	11	0.12	8
Japan	0.16	8	0.13	6
Russia	0.10	12	0.10	11
Saudi Arabia	n/a	–	n/a	n/a
Singapore	0.09	13	0.09	13
South Africa	0.22	6	0.22	3
South Korea	0.26	4	0.10	11
Sweden	0	15	0	15
United Kingdom	0.28	3	0.11	9

Source: Stewart, Warda, and Atkinson, "We're #27!: The United States Lags Far Behind in R&D Tax Incentive Generosity," ITIF Research Paper, July 2012.

Innovative Practices from Benchmark Nations Help Distinguish them from the United States

Across the range of R&D tax incentives, there are two approaches being pursued by the benchmark nations that stand out for biopharmaceutical R&D and distinguish them from the traditional R&D tax credit that the United States pursues.

One is the growing use of a "patent innovation box" that applies a lower rate of corporate tax to income generated from IP (patents and other nonpatent rights) owned by the company. Since 2012, both Italy and the United Kingdom added this approach to their mix of R&D tax incentives (Table 8). The value of a patent innovation box is that it provides an incentive for companies who are undertaking R&D to manufacture within their home countries. The economic research suggests that patent innovation boxes are encouraging more patent activity and industry R&D, but the European Commission in A *Study of R&D Incentives* warns that, if not tightly focused on lowering tax rates for income generated from in-country R&D, they may not be effective.[146]

Table 8: Patent Innovation Box Approaches across Benchmark Nations

Nation	Effective Corporate Tax Rate on Income from Qualifying IP	Types of IP that Qualify
China	0–12.5%	Registered patents and know-how
France	15%	Patents and supplementary protection certificates
Ireland	<10%	Most IP
Italy	15.7%	Patents and other IP considered functionally equivalent
United Kingdom	10%	Patents, supplementary protection certificates, regulatory data protection

Source: ITIF, Contributors and Detractors: Ranking Countries' Impact on Global Innovation, January 2016.

A number of the nations examined are also pursuing more generous R&D incentives to industry when they pursue collaborative R&D activities. Recently, Italy joined the ranks of Chile, France, Japan, and the United Kingdom in offering more generous R&D incentives for industry research conducted collaboratively with universities and research institutions (Table 9).

For biopharmaceutical innovation, collaborative R&D approaches between industry and universities is well recognized as an important driver for advancing new cures. A detailed analysis by the Tufts Center for the Study of Drug Development provides a vivid picture of the role of collaboration in the research ecosystem—by highlighting partnerships with academic medical centers. It found that nearly 80 percent of the most transformative new drug innovations over the last 25 years were the result of at least some collaboration among industry and academia, with industry dominating the discovery, development, and manufacturing phases of the R&D process.[147] The report confirms that collaborations between biopharmaceutical companies and academic medical centers are an increasingly common, "naturally complementary" approach to harness the full potential of new scientific discoveries. Creating incentives can reinforce broader national investments in R&D capacity and improve the translation of new scientific and technological advances to develop treatments to improve the health and lives of patients.

Table 9: Selected Enhanced R&D Incentives for Industry-University Collaborations across Benchmark Nations

Nation	Type of Incentive	Details
Chile	46% flat tax credit	For companies collaborating with a university or research institute and certified by the Chilean Economic Development Agency
France	60% flat tax credit	For companies collaborating with research institutes or federal laboratories
Italy	50% flat tax credit	For industry-funded R&D collaborations with a university or research institution
Japan	12% flat tax credit for large companies 30% flat tax credit for small companies	For companies collaborating with a university or research institute
United Kingdom	175% (small companies) or 130% (large companies) super/enhanced deduction for R&D expenses	Contracted R&D with external organizations is eligible

Source: ITIF, Contributors and Detractors: Ranking Countries' Impact on Global Innovation, January 2016.

2016 Update: *Access to Innovation through Regulatory and IP Protection Policies*

To attract and advance biopharmaceutical innovation, there also must be in place a policy and regulatory environment that encourages innovation in order for biopharmaceutical companies to undertake the lengthy, rigorous, costly, and uncertain R&D process. Reflecting the importance of these regulatory and IP protection policies, a survey of senior-level strategic-planning executives from major biopharmaceutical companies, who are directly involved in making real-world decisions about where to locate biopharmaceutical operations across the world, found that the following were among the most critical policies driving future biopharmaceutical industry growth:[148]

- A well-functioning, science-based regulatory system; and
- Strong IP protections.

Bioscience inventions advanced through technology development are protected as IP through patents, which provide the predictable legal protection necessary to ensure private investment for technology development. Also of increasing importance is data exclusivity of valuable clinical data of the safety and efficacy of novel pharmaceutical and biologic drugs generated by inventors to obtain U.S. FDA approval, which runs concurrently with patent protections for a fixed number of years. As *Scientific American* explains in its *2014 Worldview Scorecard: A Global Biotechnology Perspective:* "Biotechnology innovation—like that of many other businesses—relies on strong IP protection. In short, fewer innovators would take the risk of time and investment without some hope of capturing a return."[149]

Keeping regulatory policies up-to-date with the fast pace of scientific advances is also a significant challenge. As the U.S. FDA report on the *Challenge and Opportunity on the Critical Path to New Medical Products* (commonly referred to as the Critical Path Report) explained: "at a time when basic biomedical knowledge is increasing exponentially, the gap between bench discovery and bedside application appears to be expanding.… There is currently an urgent need for additional work on applying technologies such as genomics, proteomics, bioinformatics systems and new imaging technologies to the science of medical product development."[150]

COMPETITIVE NATIONS SPEAK:

Importance of Regulatory and IP Policies for Encouraging Medical Innovation

European Union—"We have been assessing regulatory barriers to innovation. We will soon pilot a new approach called 'Innovation Deals.' We will invite innovators to come forward with specific regulatory hurdles they face, and sit down with them to find ways they can bring their innovations to market within the flexibility of existing regulations."—Carlos Moedas, Commissioner for Research, Science and Innovation, March 10, 2016, at the Lisbon Council, presenting the report "Science, Research and Innovation Performance of the EU 2016." (see http://ec.europa.eu/commission/2014-2019/moedas/announcements/science-research-and-innovation-performance-eu-2016_en).

Singapore—"And overall we have created an ecosystem that supports the pharma industry in Singapore, with a sound regulatory and ethical framework, for example in terms of intellectual property protection and in terms of clinical trials, and also animal trials, and also close partnerships with industry and with our international counterparts."—Prime Minister Lee Hsien Loong, speech at the 30th/40th anniversary of GSK's manufacturing plants, 2012. (see http://www.pmo.gov.sg/mediacentre/speech-prime-minister-lee-hsien-loong-30th40th-anniversary-gsks-pharmaceutical).

Together, IP and regulatory policies and enforcement, while often complex and unique to biopharmaceutical innovation, represent a critical underpinning upon which innovative biopharmaceutical development can be advanced.

Emerging Practices in Regulatory and IP Policies

In both IP and regulatory policies and enforcement, other nations have been actively engaged and are demonstrating a more sophisticated understanding of the issues involved and importance of creating a more predictable, streamlined, and science-driven environment.

Competitor Nations are Actively Reforming Regulatory Agencies, Speeding up their Work, and Bringing In-House New Scientific Capacity to Deal with Innovative Therapies

Today, the drug review process in the United States—involving a rigorous evaluation of safety, quality, and effectiveness before new biopharmaceuticals can be approved for general patient use—is recognized worldwide as the gold standard.[151] But, even as the U.S. FDA has earned its reputation, there continues to be competition from other nations.

A report by the Centre for Innovation in Regulatory Science found that the significant advantages enjoyed by the U.S. FDA are being challenged by the current two main competing medical-approval agencies in the world, the Japanese Pharmaceuticals and Medical Devices Agency (JPMDA) and the European Medicines Agency (EMA). For instance, the faster median-approval times that the U.S. FDA enjoyed in 2005 compared with the JPMDA and EMA converged from 2005 to 2014 with the JPMDA now slightly faster than the U.S. FDA; average approval time for JPMDA was 306 days in 2014 compared with 343 days for the U.S. FDA (the EMA reached 418 days). Part of the reason is that the JPMDA caught up to the U.S. FDA in advancing expedited approvals. Still, the U.S. FDA continues to lead in having the highest percentage of first approvals in new active substances at 78 percent of all approvals. It is important to note that while review times are important for providing timely market entry of new medicines, many of the other countries discussed, while making progress on review times, subsequently subject new medicines to additional lengthy reviews that impact pricing and access to new medicines. While it is beyond the scope of this report to delve into payment and coverage polices in various countries, the U.S. is well recognized as being more favorable to new medical advances and thus U.S. patients generally have access to the latest medical advances in a more timely manner than patients in other countries.

Looking forward, many nations now have the advantage of upgrading their regulatory capacities. Major improvements in the regulatory environment are now shared broadly through organizations such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which allows benchmark nations to close the gap on regulatory quality with the United States as well as Japan and Europe. So, now the United States must be aware that improving its regulatory environment is a competitive issue with other nations.

The **European Union** has been a worldwide leader in regulatory reform dating back to its adoption of the Innovative Medicines Initiative, noted earlier. The EMA announced in 2015 a new framework for interaction with the pharmaceutical industry stressing exchange of views, improved and more timely communication; and cooperation with established networks and alliances.[152] Consistent with this framework, the EMA created an Innovation Task Force that holds regular briefing meetings with applicants covering issues arising from development of innovative medicines.[153]

Outside the European Union, other nations are stepping up their own efforts in regulatory sciences to ensure that advances in cutting-edge science are not held back by outdated approaches to assessing their safety and efficacy.

- In Japan, the JPMDA has been aggressively promoting its effort to reduce the lag in approval of new drugs for clinical use. By allowing for reg-

ulatory consultation (both free and fee-based) as early as the applied-research stage, the agency claims to have shrunk the lag from as long as four years to closer to the U.S. median approval time of one year.[154]

- In Korea, the Institute of Drug Safety and Risk Management, a nonprofit affiliated with the drug regulator, was created to develop a system "that systematically evaluates domestic and foreign drug safety information."[155] Plus, KONECT was reinvented in 2014 as a foundation that acts as a one-stop shop for foreign sponsors of clinical trials, supports training of health workers in clinical trial techniques, and coordinates an Asia-wide network that seeks to leverage Korea's advanced IT infrastructure.[156]

- In Singapore, a new Centre of Regulatory Excellence (CoRE)[157] was set up in 2014 at the Duke University–National University of Singapore Graduate Medical School Singapore (Duke-NUS). According to the Deputy Prime Minister, "It will promote regulatory leadership and policy innovation in regulatory science. The centre will bring together industry players and regulators, as well as build a pipeline of regulatory talent to support Asia's rapidly growing healthcare sector."[158]

- In Sweden, the Medical Products Agency (MPA), that nation's drug regulator, created an Innovation Office. While MPA already provided regulatory and scientific advice to industry on a fee basis, the Innovation Office provides free assistance to innovators in academia and SMEs.[159] Plus, the Swedish Research Council now provides national coordination of all clinical trials, with the goal of increasing collaboration between industry, university, and clinical health centers.[160]

- In China, the State Council announced in 2015 that it would reform the regulatory process for pharmaceuticals and medical devices,[161] attempting to clear a backlog of applications, mostly in generics, so that attention can be turned to new drugs, reducing the burden on innovative biotech firms. Earlier, the China Food & Drug Administration (CFDA) announced that it will accept applications from drug discovery firms rather than only from drug manufacturers.[162] It should be noted that implementation of these reforms has been slow and it remains to be seen when and if these stated reforms will be fully implemented.

Among European Union nations, there have been strong in-nation activities to complement the efforts of the EMA and IMI, including the following:

- In France, under the Health Act introduced by the government in 2014,[163] the time frames for approval of clinical trials would be reduced from 18 months to two months, and a standard protocol used.

- In Germany, the Federal Institute for Drugs and Medical Devices, the main regulatory agency for authorization of new medical products, advances the regulatory expertise of its scientific staff by maintaining its own intramural research program with components on pharmacogenomics, pharmacoepidemiology, neuropsychopharmacology, and other areas.

- In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency supports a National Institute for Biological Standards and Control,[164] which provides scientific advice and applied research to manufacturers of biologics and regulatory authorities in the United Kingdom and beyond.

U.S. Sets the World Standard, but many Benchmark Nations Working to Keep Pace

Given the unique aspects of the biopharmaceutical life cycle and the length, complexities, and costs related to the development of new medicines, adequate IP incentives and protections are critical to fostering the substantial long-term investments needed to bring new medicines to patients. Nevertheless, ensuring adequate IP rights and their enforcement remains a challenge in the United States and other nations. New threats to the strength and enforceability of patents, as well as repeated calls to undermine long-standing patent, data, and regulatory incentives contributes to business uncertainty for established and emerging biopharmaceutical companies, negatively impacting their ability to make long-term R&D investment decisions.

In IP protection, studies examining the strength of IP protection place the United States as a leader although Europe provides more favorable incentives for small molecule drugs versus the U.S. Among international competitors, the favorability of incentives is variable. Table 10 presents the findings from the comprehensive 2016 International IP Index prepared by the Global Intellectual Property Center.

Each nation is scored based on whether or not it complies with 30 indicators of policies, legal rights, and enforcement regimes in IP encompassing six categories: (1) Patents; (2) Copyrights; (3) Trademarks; (4) Trade Secrets; (5) Enforcement; and (6) International Treaties. The top score possible is 30, meaning that a nation meets all indicators.

Table 10: Scores of the United States and the Benchmark Nations according to the 2016 International IP Index

	International IP Index, 2016				
Country	Overall Score (out of 30 indicators)	Patents, Related Rights and Limitations (score out of 7 indicators)	Enforcement (score out of 6 indicators)	Membership and Ratification of International Treaties (score out of 4 indicators)	Data Exclusivity Period for Biologic Medicines (years)
United States	28.61	6.50	5.36	4.00	12.00
Australia	24.79	6.00	4.66	4.00	5.00
Brazil	10.41	1.25	2.28	0.50	0.00
Canada	18.17	4.30	3.24	1.50	8.00
Chile	13.05	3.35	2.32	2.00	5.00
China	12.64	4.10	1.26	1.50	6.00
France	12.00	6.50	5.48	4.00	10.00
Germany	27.36	6.50	5.48	4.00	10.00
Ireland	n/a	n/a	n/a	n/a	10.00
Israel	20.06	5.80	4.38	1.00	5.00
Italy	22.69	6.25	3.78	3.50	10.00
Japan	23.34	6.30	5.26	1.00	8.00
Russia (Russian Federation)	13.06	3.10	1.97	3.00	0.00
Saudi Arabia	n/a	n/a	n/a	n/a	n/a
Singapore	25.63	6.50	4.89	3.00	5.00
South Africa	11.74	1.00	2.96	0.50	0.00
South Korea (Republic of Korea)	23.32	5.85	4.73	2.00	6.00
Sweden	27.12	6.50	5.52	4.00	10.00
United Kingdom	27.53	6.50	5.65	4.00	10.00

Source: Global Intellectual Property Center, U.S. Chamber International IP Index, Infinite Possibilities, February 2016.

2016 Update: *Strengthening the Capabilities to Manufacture Biopharmaceuticals*

While the importance of translating novel medical discoveries into new cures and treatments is well understood as a cornerstone of biopharmaceutical industry growth worldwide, often overlooked is the importance of advancing manufacturing technologies associated with making these novel medical products. As McKinsey & Company explains: "biopharmaceuticals are among the most sophisticated and elegant achievements of modern science.… Yet there are operational and technological challenges. Reproducing large molecules reliability at an industrial scale requires manufacturing capabilities of a previously unknown sophistication."[165]

The consequences of falling behind in biomanufacturing capabilities may be key determinants in whether nations win or lose in their efforts to stay competitive in biopharmaceutical industry development. As McKinsey explains: "The prize [for] mastering these operational challenges is far more significant than just short-term competitive advantage. Many of the next major opportunities for biotech will require companies to develop new and different technologies.… Today's actions will shape companies' readiness to grasp these opportunities as they come to fruition."[166]

COMPETITIVE NATIONS SPEAK:

Strengthening the Capabilities to Manufacture Biopharmaceuticals

Singapore — Today, Singapore is a leading global manufacturing site for active pharmaceutical ingredients (APIs) and solid dosage and is well placed to ride on the growth of Asia. We have also diversified successfully into new modalities like biologics and cell therapy which hold tremendous potential for the future of medicine. We have achieved considerable success within a short span of five years since our first biologics manufacturing investment in 2007." Mr. Yeoh Keat Chuan, Managing Director, Singapore Economic Development Board, at groundbreaking for Novartis manufacturing facility, February 6, 2013.[167]

Sweden — "The Government has identified that with Sweden's skills in protein research and development it is time to make an effort to make Sweden one of the leading regions for bio-production.… By this new program the Swedish government wishes to enhance the collaboration between the different sectors and make Sweden a stronger international player in the Life Science area."—Helene Hellmark Knutsson, Minister for Higher Education and Research, remarks given at BIO-Europe, April 4, 2016.[168]

United Kingdom — "CPI is supporting the commercialisation of research by promoting collaboration with industry across the supply chain, from research through to manufacture and clinic. Utilising the new Centre we will help companies to commercialise ideas and take them to market faster and with less risk. We are already underway with a number of projects which are helping UK companies prove their technologies in an industrially relevant environment."—Chris Dowle, Director of Biologics at the Centre for Process Innovation, at the announcement of the National Biologics Manufacturing Centre, October 1, 2015.[169]

Emerging Practices in Strengthening Biopharmaceutical Manufacturing Capabilities

The potential for creating a competitive advantage through advancing biomanufacturing is an up-and-coming area of strategic focus by the benchmark nations. Singapore had already made its mark in this area with its 2003 formation of the Bioprocessing Technology Institute, one of its A*STAR institutes that works in partnership with industry R&D labs and provides both core institutional support and competitive grants to participating scientific staff across partnering organizations.

Now, a growing number of other nations are recognizing the potential competitive benefits of expanding their knowledge and application of new technologies and manufacturing competencies.

- **Ireland**—To support the needs of the large biopharmaceutical sector, the Industrial Development Authority (IDA) Ireland funded at €72 million the National Institute for Bioprocessing Research and Training (NIBRT),[170] a consortium of four Dublin universities that coordinates training curriculum in bioprocessing, while also offering industry access to a 6,500-square-meter pilot plant fully equipped to scale up mammalian cell-based cultures. The NIBRT reports having trained 2,000 technicians to date.

- **South Africa**—The Biomanufacturing Industrial Development Centre is a three-year project designed as a hub for open innovation in biomanufacturing, incubating small- and medium-sized enterprises. Funded by the Development Bank of Southern Africa and the Department of Science and Technology's Industry Innovation Support Fund, the program provides incubated small- and medium-sized enterprises with access to ready-to-use facilities and supporting laboratories for process development and scale-up.[171] South Africa is also advancing Ketlaphela, initially conceived as a joint venture with Switzerland's Lonza but now restructured as an entirely state-owned pharmaceutical company. It is intended to produce the APIs for at least half the required national supply of retroviral drugs for treatment of HIV/AIDS.[172] The effort, which includes a number of biopharmaceutical company partners, ensures supply from a domestic source of 25 million doses of nine different vaccines required for the national childhood vaccination program.[173]

- **Sweden**—The government has announced a national program for protein research, method development, and biologics production in partnership with a private foundation, a biopharmaceutical company, and several Swedish universities.

- **United Kingdom**—In October 2015, the government's Center for Process Innovation[174] announced creation of a £38 million, 5,000-square-meter National Biologics Manufacturing Centre in Darlington,[175] in the North East of England. Funding is through the Department of Business, Skills & Innovation.

In the future, other benchmark nations can be expected to address the advancement of biomanufacturing capabilities in their nations. It is expected that these approaches will not only involve advancing technologies and building out complex and costly shared-use facilities, but also addressing workforce and standards that can support a broad-based supply chain.

2016 Update: *Building Human Capital*

Talent is a key driver for biopharmaceutical industry competitiveness. Virtually all elements of the biopharmaceutical enterprise from discovery, development, and manufacturing require educated and skilled workers in the STEM fields. These skill needs for the biopharmaceutical industry translate into a broad range of skilled occupations from laboratory technicians and advanced production workers to PhD-level scientists, engineers, bioinformaticists, and other researchers.

Biopharmaceutical executives have consistently reinforced the importance of finding talented STEM workers to the sustainability and growth of the innovative biopharmaceutical industry and its ability to bring new treatments to patients and to continue to grow local and state economies across the United States. PwC's *Global Innovation Survey* finds talent tops the list of innovation challenges for pharmaceutical executives, ahead of other critical areas such as speed to market of innovative ideas, establishing an innovative culture, and finding the right partners for collaboration.[176] Nearly three in five biopharmaceutical executives say "finding and retaining the best talent to make innovation happen" is a challenge for their company, higher than the average for respondents across all industries (53 percent).

Increasingly, talent is becoming a significant vulnerability in U.S. competitiveness for biopharmaceutical industry development. Like other advanced manufacturing industries in the United States, biopharmaceutical industry development is facing a significant "skills gap." In their third assessment of the skills gap in U.S. manufacturing, the Manufacturing Institute and Deloitte find the skills gap is widening.[177] For 2015 to 2025, the authors estimate that U.S. manufacturers will need to hire 3.4 million workers; and they find that an estimated 60 percent of those positions, or 2 million jobs, will likely go unfilled due to shortages in talent. Among other factors expected to contribute to this gap is a lack of STEM-related skills in the U.S. workforce. Executives agree, with a large majority (84 percent) in the Deloitte-Manufacturing Institute study agreeing there is a talent shortage.

At the same time that the United States is struggling with its ability to generate a STEM workforce, other nations are actively building their competitive advantage on access to talent. A key building block for competing on talent is focusing on K–12 STEM education. While the United States is middling, emerging Asian nations are creating a clear advantage in the preparation of their K–12 students. Based on scores from PISA, an international assessment of the functional skills that students have acquired as they near the end of compulsory K–12 schooling, China, Singapore, Japan, and South Korea, are world leaders (Table 11).

Table 11: Rankings of the United States and Benchmark Nations in Math and Science for 2015 PISA

	2015 Program for International Student Assessment	
Country	**Math Ranking**	**Science Ranking**
United States	38	25
Australia	22	14
Brazil	67	65
Canada	10	7
Chile*	49	46
China	6	10
France	25	26
Germany	16	15
Ireland*	16	19
Israel	38	41
Italy	25	34
Japan	5	2
Russia	22	32
Saudi Arabia	n/a	n/a
Singapore	1	1
South Africa	n/a	n/a
South Korea	7	11
Sweden	22	28
United Kingdom	26	15

Source: OECD PISA 2015 Database

The U.S. advantage in higher education is also appearing to be challenged not only by Asian nations, but also by key developed-world competitors, such as Germany and the United Kingdom. The comparative data on postsecondary graduation is spotty and has long lag times, but the NSF's Science and Engineering Indicators suggest that the United States is making gains, but is vulnerable. Despite strong growth in undergraduate science and engineering degrees, the United States is behind many key competitors in the share of total first degrees found in science and engineering. In doctoral degrees, where many U.S. graduates come from abroad, the U.S. gains of 12.9 percent from 2007 to 2012 are being outpaced by a number of benchmark nations, including China, South Korea, Germany, and France (Table 12).

Table 12: Postsecondary Degree Performance, United States and Selected Benchmark Nations

Country	Growth in Science & Engineering First University Degrees, 2007–2011/2012	Share of Science and Engineering Degrees among All First University Degrees, 2012	% Change in Doctoral Degrees in Sciences, 2007–2012
United States	25.6%	7.0%	12.9%
Australia	1.4%	5.9%	n/a
Canada	14.2%	9.6%	n/a
China	28.9%	9.7%	21.3%
France	-8.1%	5.3%	20.7%
Germany	50.1%	7.7%	24.9%
Italy	-9.1%	5.1%	1.5%
Japan	-7.3%	3.2%	-14.8%
South Korea	10.2%	4.9%	84.4%
United Kingdom	25.9%	9.4%	4.3%

Source: U.S. NSF, 2016 Science and Engineering Indicators.

COMPETITIVE NATIONS SPEAK:

Building Human Capital

Singapore — "We have built up our S&T capabilities by making science and math compulsory in school."—Prime Minister Lee Hsien Loong, speech at the 30th/40th anniversary of GSK's manufacturing plants, 2012.[178]

Sweden — Another thing that is necessary for our success is gender equality. If not all our talents are given the possibility to develop, we lose valuable competence. Therefore, the government wants to promote gender equality in science in general and at universities in colleges in particular."—Minister Helene Hellmark Knutsson, remarks given at Nordic Life Science Days 2015.[179]

Emerging Practices in Building Human Capital

As the benchmark nations seek to generate a competitive advantage in talent, they continue to focus on a mix of approaches to both develop talent from within as well as to attract talent from abroad (Table 12). Policies and programs range from among the following:

- Offering scholarships and fellowships to attract students to study science, math, and engineering
- Subsidizing doctoral wages
- Recruiting world-class talent by offering incentives targeting both foreign and native scientists and researchers to relocate
- Making it easier for skilled workers to immigrate
- Subsidizing overseas study.

Table 13: Select Initiatives to Develop, Attract, and Retain Talent

Country	Fellowships/ Scholarships/ Upgrading Universities	Incentives to Attract Researchers, Faculty, and Students	Eased Immigration Policies for Skilled Workers	Overseas Study for Residents
Australia	X		X	
Brazil	X			X
Canada	X	X	X	
Chile				X
China	X	X		
France		X		
Germany		X	X	
Ireland	X			
Israel		X	X	
Italy			X	
Japan	X	X	X	
Russia	X	X		
Saudi Arabia	X			X
Singapore	X	X	X	X
South Africa				X
South Korea		X		
Sweden	X	X	X	
United Kingdom	X	X		

While, for the most part, the benchmark nations have sustained their efforts, a number have taken on new initiatives.

Among the benchmark nations, the following are notable for sustained efforts:

- **Brazil**—Under the Science Without Borders[180] program, some 100,000 university students and researchers will receive scholarship support from 2015 to 2018 to study abroad. Reciprocal provisions are also made to support visiting researchers from abroad in Brazil.[181] Companies inside Brazil have access to a database of students who have been through the program and, under the Human Resources in Strategic Areas Program (RHAE), may receive subsidies for employing postdoctoral students or sending existing workers for master's degrees.[182]

- **China**—China continues to execute on its Thousand Talents Plan,[183] a multifaceted recruitment program designed to incentivize return to China on long- or short-term assignments diverse

"overseas Chinese" who are prestigious academics, entrepreneurs, or other experts. The program website claims that 4,180 recruitments have been accomplished as of 2014.[184]

- **Germany**—There is an extensive effort under way to improve graduate education and better integrate foreign professionals into the workforce.[185] Germany is also seeking to attract foreign scientists through research fellowships.[186] [187]

- **Singapore**—Through its Graduate Academy,[188] A*STAR also offers a very broad array of scholarships and fellowships. Many of the advanced-degree programs are aimed either at attracting foreign students or providing graduates of Singapore's universities with significant, multiyear doctoral or postdoctoral experiences at major universities abroad and then re-integrating them into the research institutes as scientific staff. Other fellowships assure that those on a traditional academic career track in Singapore also gain experience in the more targeted environment of the research institutes. A strong theme of Singapore's talent programs is development of physician-scientists. Singapore's flagship workforce program in this area is the Duke-NUS Graduate Medical School[189] (established in 2005). Many of the programs also stress international exchange: bringing international scientists to Singapore or allowing Singapore scientists to complete part of their training overseas.

- **Sweden**—Three grant programs are aimed at talent development: grants to allow personal mobility between academia and industry; the Ingvar Carlsson Award to support postdocs returning to Sweden from abroad to establish and independent research career; and a program to support doctoral students who remain 80 percent employed by industry during the course of their programs.[190] Sweden's Research Council offers the well-known Marie Skłodowska Curie fellowship, a career development fellowship that supports movement either from Sweden abroad or inward bound to Sweden.[191] Sweden's Innovation Agency supports several programs aimed at postdoctoral students, including supporting the placement of young researchers in industrial settings.[192]

Among the benchmark nations, the following are pursuing new initiatives in talent

- **Australia**—The National Innovation Strategy calls for (1) a new entrepreneur visa and pathways to permanent residence for graduate degree-holders with STEM qualifications;[193] (2) expansion of women in STEM;[194] and (3) a new Innovations Connection initiative that would also support postgraduate student placements in businesses, or business researchers in publicly funded research organizations.[195]

- **Canada**—Budget 2016 includes C$14 million over two years to Mitacs, a national nonprofit that supports industrial internships. Some 15 percent of Mitacs projects are in the life sciences.[196] Canadian Research Chairs,[197] a joint venture of the three research councils, invests C$265 million annually to attract and retain talent across a range of fields including health sciences. The program is supplemented by investments in associated infrastructure by the Canada Foundation for Innovation.[198]

- **United Kingdom**—The 2014 innovation strategy aims to increase the quantity and quality of STEM teachers; add higher apprenticeships, provide new loans for postgraduate qualifications, and provide a platform to match female STEM graduates to industry.[199] Many of these initiatives are carried out through Cogent, an employer partnership sponsored by the UK Commission for Employment and Skills.[200]

An important element of nearly every nation's efforts is a focus on the internationalization of talent and finding ways to connect their own residents to international education opportunities or recruiting talent to their nation.

Another theme that is also beginning to become more apparent is a focus on broadening the reach of STEM to the disadvantaged and women. This is being emphasized in the new efforts underway in Australia and the United Kingdom, plus is an important focus in Sweden.

Summary and Implications for the U.S. Efforts in Biopharmaceutical Development

Innovation is the key driver of competitiveness, wage and job growth, and long-term economic growth. Recognizing that building a robust medical innovation infrastructure is important to a nation's long-term economic security, countries around the world are implementing a range of economic and other policies to encourage innovative companies to shift or to increase R&D and manufacturing investment within their borders. In recent years, various studies of global competitiveness show that the U.S. business climate for R&D and manufacturing investment is lagging behind other countries on many key indicators. The U.S. is currently the leader in biopharmaceutical R&D with new medicines often introduced in the U.S. first, addressing the unique needs of U.S. patients. This report finds that a number of countries recognize the role that biomedical innovation can play in driving economic growth. Fostering a predictable policy and regulatory framework is critical to continuing to incentivize companies to make the long, costly, and risky investments in biopharmaceutical R&D. Our analysis focused not on all of the policies that impact the ability to innovate but rather focused more narrowly on pro-innovation policies and programs primarily focused on building a well-functioning R&D infrastructure as a way to attract biopharmaceutical investments.

The report highlights three key areas of focus across countries where there has been new activity and new investments since the 2012 review and assessment:

- **A majority of countries are focused on building R&D excellence in biopharmaceutical innovation through expanded government funding in an effort to develop competitive advantage versus other countries.** While private sector biopharmaceutical R&D investment continues to grow year over year, public sector investments have declined dramatically. The U.S. is the global leader in biopharmaceutical R&D in part due to the complementary roles and investments made by both the public and private sector in advancing scientific and technological advances key to bringing new medicines to patients. The U.S. needs to continue to foster public and private sector partnerships and ensure robust funding needed to fund the next generation of new treatments and cures to benefit U.S. patients and continue to grow the U.S. economy.

- **More than half of the nation's examined have stated their intention to or have launched new initiatives focused on improving the timeliness and efficiency of the review and approval process for new medicines.** To stay competitive with other countries, public policies in the U.S. must continue to focus on fostering a predictable policy and regulatory framework that is critical to continuing to incentivize companies to make the long, costly, and risky investments in biopharmaceutical R&D.

- **Recognizing the influence of manufacturing capacity on job creation and economic growth, other countries are strengthening their biopharmaceutical manufacturing capabilities.** Other countries recognize that a strong manufacturing capacity plays an important role in stimulating economic prosperity and are seeking to develop advanced manufacturing capacity through a number of means including through investments in infrastructure and STEM education to grow the next generation of high-wage workers. Policymakers need to ensure that we are creating an environment for American manufacturing

innovation that will advance U.S. manufacturing competitiveness and drive export growth.

This report confirms that the U.S. competitive advantage in a number of areas is shrinking and should serve as a call to action for a national dialogue about how the U.S. can maintain its global leadership position in the area of biopharmaceutical R&D and continue to grow the industry's economic footprint in the U.S. through a favorable policy and regulatory environment. The United States must continue to build upon its competitive advantage of offering the most vibrant biopharmaceutical innovation ecosystem—involving commercialization, new firm formation, and private investment. The report documents that U.S. leadership as the gold standard for bringing new biopharmaceuticals to market should not be taken for granted. Importantly, the overall business environment in the U.S. is becoming less favorable in part due to other countries closing the gap in key areas, including the development of a STEM workforce, R&D and manufacturing infrastructure investments, and the development of new tax and other policies specifically focused on enticing R&D investment. The central message of this report is that the United States cannot be complacent and that meaningful steps can be taken, learning from international competitors to improve U.S. competitiveness for biopharmaceutical development.

ENDNOTES

1 TEConomy Partners, The Economic Impact of the U.S. Biopharmaceutical Industry, Prepared for PhRMA, May 2016.

2 Battelle Technology Partnership Practice, The Biopharmaceutical Research and Development Enterprise: Growth Platform for Economies Around the World, Prepared for PhRMA, May 2012.

3 See http://english.gov.cn/policies/policy_watch/2016/02/15/content_281475290364118.htm.

4 See http://franceintheus.org/spip.php?article3603.

5 See http://www.taoiseach.gov.ie/eng/News/Taoiseach's_Speeches/Speech_by_the_Taoiseach_Mr_Enda_Kenny_TD_Alexion_Pharmaceutical's_Investment_Jobs_Announcement_April_3rd_2014.html.

6 See http://government.ru/en/news/12433/.

7 See http://www.mof.gov.sg/news-reader/articleid/1475/parentId/59/year/2015?category=Speeches.

8 See http://english.mosf.go.kr/eco/view.do?bcd=E0001&vbcd=N0001&seq=3414&bPage=1.

9 See http://www.government.se/speeches/2016/04/speech-by-helene-hellmark-knutsson-at-bio-europe-spring-2016/.

10 TEConomy Partners, The Economic Impact of the U.S. Biopharmaceutical Industry, Prepared for PhRMA, May 2016.

11 Brookings Institution, America's Advanced Industries.

12 Organisation for Economic Co-operation and Development (OECD), The Bioeconomy to 2030, 2009, page 199.

13 Centre for Innovation in Regulatory Sciences, New Drug Approvals in ICH Countries, 2005–2014, July 2015.

14 Battelle, Biopharmaceutical Industry-Sponsored Clinical Trials, March 2015.

15 National Research Council, Rising to the Challenge: U.S. Innovation Policy for Global Economy, 2012, page 405.

16 See a number of studies and news articles that explain the rise of U.S. leadership in biopharmaceutical industry development including: Daemmrich and Bowden, "Rising Drug Industry," Chemical & Engineering News, June 20, 2005, Volume 83, Number 25; and Alfred Chandler, Shaping the Industrial Century: The Remarkable Story of the Evolution of the Model Chemical and Pharmaceutical Industries, Harvard University Press, 2005.

17 Battelle, The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It, commissioned by PhRMA, 2013.

18 "The Changing Biopharma Risk Equation," The Economist Intelligence Unit, 2016

19 Charles W. Wessner and Alan Wm. Wolff, Eds. Rising to the Challenge: U.S. Innovation Policy for the Global Economy, 2012, The National Academies Press, Washington, DC, page 431.

20 Battelle Technology Partnership Practice, The Biopharmaceutical Research and Development Enterprise: Growth Platform for Economies Around the World, Prepared for PhRMA, May 2012.

21 Antoine van Agtmael and Fred Bakker, The Smartest Places on Earth: Why Rustbelts are the Emerging Hotspots of Global Innovation, Public Affairs, 2016, page 8.

22 http://ipcommission.org/report/IP_Commission_Report_Update_2017.pdf; http://www.sciencemag.org/news/2017/02/china-s-theft-us-trade-secrets-under-scrutiny

23 Battelle, The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It, commissioned by PhRMA, 2013, page 21.

24 Nancy Berg, "Today's Pharma: Big Challenges, Big Expectations," Pharmaceutical Manufacturing, May 22, 2012, http://www.pharmamanufacturing.com/articles/2012/084/.

25 See http://www.mtpconnect.org.au/content/about.

26 See http://www.health.gov.au/internet/main/publishing.nsf/Content/mrff.

27 See http://www.nhmrc.gov.au/research/nhmrc-advanced-health-research-and-translation-centres.

28 See http://www.mrcf.com.au.

29 See http://www.innovation.gov.au/page/biomedical-translation-fund.

30 See http://www.minister.industry.gov.au/ministers/pyne/media-releases/start-tax-breaks-passes-senate.

31 See http://www.treasury.gov.au/Policy-Topics/Taxation/NISA/Tax-incentives-for-early-stage-investors.

32 See http://www.treasury.gov.au/Policy-Topics/Taxation/NISA/New-arrangements-for-venture-capital-investment.

33 See http://www.sfi.ie/funding/funding-calls/open-calls/sfi-partnerships.html.

34 See http://www.knowledgetransferireland.com/About_KTI/.

35 See http://www.knowledgetransferireland.com/Research_in_Ireland/Find-a-Research-Partner/CSET/

36 See http://www.pmtc.ie .

37 See http://www.nibrt.ie.

38 See http://www.investkorea.org/en/news/ivest.do?mode=view&articleNo=464654.

39 See http://www.kribb.re.kr/eng/.

40 See http://eng.kist.re.kr/kist_eng/?sub_num=468.

41 See http://www.kaist.ac.kr/html/en/research/research_0402.html.

42 See http://www.nbiosnu.org.

43 See http://www.biotechcenter.org/english/people/faculty.asp.

44 See http://english.yonhapnews.co.kr/business/2016/09/08/0504000000AEN20160908004000320.html

45 See http://en.konect.or.kr/KoNECT/Overview.htm.

46 See https://www.gov.uk/government/news/charities-historic-pledge-sees-funding-for-landmark-dementia-research-institute-soar-to-250-million.

47 See https://www.gov.uk/government/publications/spending-review-and-autumn-statement-2015-documents/spending-review-and-autumn-statement-2015

48 See http://cen.acs.org/articles/94/web/2016/01/Industry-Academia-Join-UK-Drug.html?type=paidArticleContent .

49 See https://pm.catapult.org.uk/about-us/ or full presentation at https://pm.catapult.org.uk/wp-content/uploads/2016/03/Latest-Precision-Medicine-Catapult-presentation.pdf.

50 See https://ct.catapult.org.uk/about-us/who-we-are/.

51 For the award list see https://www.gov.uk/government/news/medical-innovations-backed-by-18-million-fund.

52 See https://www.uk-cpi.com.

53 See https://hvm.catapult.org.uk/about-us/.

54 See https://www.uk-cpi.com/biologics/facilities/ or full brochure at https://www.uk-cpi.com/wp-content/uploads/2011/09/cpi-biologics-brochure.pdf.

55 See https://www.gov.uk/guidance/corporation-tax-the-patent-box.

56 See https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/387780/PU1719_HMT_Science_.pdf.

57 See http://dev.cogent-lifescience.co.uk/about-cogent/.

58 See http://www.imi.europa.eu/content/research-agenda.

59 See http://www.imi.europa.eu/content/ongoing-projects.

60 See http://www.imi.europa.eu/content/european-lead-factory.

61 See http://www.health.gov.au/internet/main/publishing.nsf/Content/mrff.

62 See http://www.amed.go.jp/en/.

63 See http://www.nrc-cnrc.gc.ca/eng/solutions/collaborative/biologics_index.html.

64 See http://www.nrc-cnrc.gc.ca/eng/solutions/collaborative/vaccines_index.html.

65 See http://www.nrc-cnrc.gc.ca/eng/solutions/collaborative/tbbb_index.html.

66 See http://www.nrc-cnrc.gc.ca/eng/rd/hht/index.html.

67 See http://braincanada.ca/en/About.

68 See http://www.genomecanada.ca/en/news-and-events/news-releases/genome-canada-applauds-federal-leadership-genomics.

69 See http://www.genomecanada.ca/en/about-us.

70 See http://www.genomecanada.ca/en/news-and-events/news-releases/minister-duncan-announces-new-network-strengthen-personalized-medicine.

71 See http://english.gov.cn/news/international_exchanges/2016/01/23/content_281475277011606.htm.

72 See http://www.a-star.edu.sg/About-A-STAR/Biomedical-Research-Council/Biomedical-Research-Institutes-Consortia.aspx.

73 See http://www.dfg.de/en/research_funding/programmes/list/index.jsp?id=EXC&prg=EXC&sort=beginn_desc.

74 See http://www.sfi.ie/investments-achievements/sfi-research-centres/.

75 See http://sspc.ie/about_sspc.

76 See http://ambercentre.ie.

77 See http://www.infantcentre.ie.

78 See https://www.gov.uk/government/news/charities-historic-pledge-sees-funding-for-landmark-dementia-research-institute-soar-to-250-million.

79 See http://www.dementiasplatform.uk/about/.

80 See http://www.nce-rce.gc.ca/NetworksCentres-CentresReseaux/BySector-ParSecteur_eng.asp.

81 See http://www.budget.gc.ca/2016/docs/plan/ch2-en.html#_Toc446106698.

82 See http://news.gc.ca/web/article-en.do?mthd=index&crtr.page=1&nid=1044399.

83 See http://www.instituts-carnot.eu/en.

84 The EU5 includes the top five European countries in terms of biopharmaceutical industry size: the United Kingdom, Germany, France, Switzerland, and Italy.

85 Tang, X., and Du, J. (2016). "The performance of China's biomedical innovation: a scientometric analysis." Science China: Life Sciences doi:10.1007/s11427-016-5078-6.

86 The Economist, "Bayhing for blood or Doling out cash?" December 20, 2005.

87 See AUTM website—https://www.autm.net/AUTMMain/media/Advocacy/Documents/BayhDoleTalkingPointsFINAL.pdf.

88 See http://www.lepnetwork.net/news/2015/national-biologics-manufacturing-centre-launched/.

89 See http://www.budget.gc.ca/2016/docs/plan/ch2-en.html#_Toc446106698.

90 See https://www.etpl.sg/introduction/from-the-ce-office.

91 National Research Council, An Assessment of the SBIR Program at the National Institutes of Health, Charles W. Wessner, ed., Washington, DC: The National Academies Press, 2009.

92 See https://www.etpl.sg.

93 See http://www.spring.gov.sg/Nurturing-Startups/Pages/technology-enterprise-commercialisation-scheme.aspx.

94 See http://www.mrcf.com.au.

95 See http://www.innovation.gov.au/page/biomedical-translation-fund.

96 See http://www.satt.fr/wordpress/ or third-party coverage in English at http://www.nce-rce.gc.ca/AnnualMeeting-ReunionAnnuelle/2014/Presentations-Presentations/CE-CRBLNCE-CECRRCEE/05-04-FrancoisDupoteau.pdf.

97 See http://www.knowledgetransferireland.com/About_KTI/.

98 See http://www.mrc.ac.uk/funding/science-areas/translation/biomedical-catalyst/.

99 For the award list see https://www.gov.uk/government/news/medical-innovations-backed-by-18-million-fund.

100 See http://www.cdrd.ca.

101 See http://www.stemcellnetwork.ca/index.php/about-scn/.

102 See http://www.knowledgetransferireland.com/Research_in_Ireland/Find-a-Research-Partner/CSET/.

103 See http://www.incubators.org.il/incubator.aspx?id=36408&catid=576 or specifically http://www.futurx.co.il.

104 See http://www.globes.co.il/en/article-new-biotech-incubator-selects-first-two-projects-1001000994.

105 See http://www.apollotherapeutics.com.

106 See http://cen.acs.org/articles/94/web/2016/01/Industry-Academia-Join-UK-Drug.html?type=paidArticleContent.

107 See http://www.stevenagecatalyst.com.

108 PWC, Life Sciences Funding Reaches Record High, MoneyTree Report, 2015.

109 See http://www.minister.industry.gov.au/ministers/pyne/speeches/national-press-club-address-national-innovation-and-science-agenda.

110 See http://en.kremlin.ru/events/president/news/50249.

111 See http://www.innovateinbrasil.com/sectorial-information/healthcare.

112 See See https://www.fin.gc.ca/vcap-pacr/index-eng.asp.

113 See http://www.bpifrance.fr/Bpifrance/Nos-metiers/Fonds-propres/Fonds-directs-Bpifrance/Capital-Innovation/Pole-Sciences-de-la-vie/InnoBio (French only).

114 See https://www.kfw.de/inlandsfoerderung/Unternehmen/index-3.html.

115 See http://www.orbimed.com/en.

116 See http://www.dbj-cap.jp/english/ and also http://cen.acs.org/articles/91/i31/Japan-Retools-Drug-Research.html?type=paidArticleContent.

117 See http://www.rusventure.ru/en/investments/investments.php.

118 See http://www.rusventure.ru/en/investments/biofund/index.php.

119 See http://www.taqnia.com/2014/EN/industry.html.

120 See https://www.edbi.com.

121 See http://www.spring.gov.sg/Nurturing-Startups/SEEDS/Pages/spring-start-up-enterprise-development-scheme.aspx.

122 See http://www.spring.gov.sg/Nurturing-Startups/Pages/business-angel-scheme.aspx.

123 See http://www.idc.co.za/home/idc-products/special-schemes/risk-capital-facility-programme.html.

124 See http://industrifonden.com/news/industrifonden-appoints-new-investment-directorhead-of-business-unit-life-science/.

125 See http://www.almi.se/Almi-Invest/About-Almi-Invest/.

126 See http://www.almi.se/Almi-Invest/Portfoljbolag/?it=Life%20Science.

127 See http://www.treasury.gov.au/Policy-Topics/Taxation/NISA/Tax-incentives-for-early-stage-investors.

128 See http://www.treasury.gov.au/Policy-Topics/Taxation/NISA/New-arrangements-for-venture-capital-investment.

129 See http://www.innovation.gov.au/page/csiro-innovation-fund.

130 See https://www.enterprise-ireland.com/en/Invest-in-Emerging-Companies/Seed-and-Venture-Capital-Scheme/.

131 See http://www.revenue.ie/en/tax/it/leaflets/it15.html#section1.

132 See http://english.mosf.go.kr/pre/view.do?bcd=N0001&seq=4024.

133 See http://british-business-bank.co.uk.

134 See http://bbbinv.co.uk/work-with-us/venture-capital-analyst-fund/.

135 See http://www.lepnetwork.net/news/2015/cheshire-warrington-lep-secures-45m-lifeline-for-life-sciences/.

136 Research!America, U.S. Investments in Medical and Health Research and Development: 2013–2015, Fall 2016, pages 3–4.

137 TEConomy analysis of OECD STAN R&D Expenditures in Industry and Government Health R&D Expenditures.

138 DiMasi JA, Grabowski HG, Hansen RA. "Innovation in the pharmaceutical industry: new estimates of R&D costs," Journal of Health Economics, 2016, 47:20-33.

139 European Commission, A Study on R&D Tax Incentives, November 2014, page 51.

140 See https://www.gov.uk/government/speeches/global-dementia-legacy-event-david-camerons-speech.

141 See http://franceintheus.org/spip.php?article3603.

142 Deloitte, 2015 Global Survey of R&D Incentives, October 2015, page 2.

143 See http://www.israelbusiness.org.il/financialassistance/investmentincentives.

144 See https://www.jetro.go.jp/ext_images/_Invest/pdf/support/RandD_tax_incentives_.pdf and also http://www.meti.go.jp/english/aboutmeti/policy/fy2016/pdf/151216tax.pdf.

145 See https://www.gov.uk/guidance/corporation-tax-the-patent-box.

146 See Rachel Griffith, Helen Miller, and Martin O'Connell, "Corporate Taxes and the Location of Intellectual Property" (working paper, Center for Economic and Policy Research, June 2011), which simulated impact of patent innovation box schemes and found it would increase patent activity; and ITIF Report "Patent Boxes: Innovation in Tax Policy and Tax Policy for Innovation," October 2011, which found industry R&D grew higher in European nations with patent innovation boxes than without.

147 Tufts Center for the Study of Drug Development, "Public and Private Contributions to the R&D of the Most Transformational Drugs of the Last 25 Years," January 2015.

148 Battelle, The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It, Commissioned by PhRMA, 2013.

149 Scientific American, Worldview Scorecard: A Global Biotechnology Perspective, Special Report, 2014, page 36.

150 U.S. FDA, Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products, March 2004, pages 3 and 15.

151 See http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/ for more details on the history of the U.S. FDA.

152 See http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000224.jsp&mid=WC0b01ac058003791c.

153 See http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000334.jsp&mid=WC0b01ac05800ba1d9.

154 See http://www.pmda.go.jp/files/000211767.pdf and http://www.pmda.go.jp/files/000211768.pdf.

155 See http://www.drugsafe.or.kr/iwt/ds/en/introduction/EgovGreeting.do.

156 See http://en.konect.or.kr/KoNECT/Overview.htm.

157 See https://www.duke-nus.edu.sg/research/centers/centre-regulatory-excellence-core.

158 See http://www.mof.gov.sg/news-reader/articleid/1475/parentId/59/year/2015?category=Speeches.

159 See https://lakemedelsverket.se/english/product/Welcome-to-the-Innovation-Office/More-about-the-Innovation-Office/.

160 See http://www.government.se/speeches/2015/09/speech-at-nordic-life-science-days-2015/ or http://www.vr.se/inenglish/shortcuts/clinicaltherapyre-search.4.58307f8b1465661b088659d7.html.

161 See http://cen.acs.org/articles/94/i6/China-Improving-Drug-Approval-Process.html?type=paidArticleContent which in turn cites State Council document https://translate.google.com/translate?hl=en&sl=zh-CN&tl=en&u=http%3A%2F%2Fwww.sfda.gov.cn%2FWS01%2FCL0103%2F126861.html (Google Translate).

162 See http://cen.acs.org/articles/93/i45/Chinas-Drug-Discovery-Firms-Soon.html.

163 See http://www.gouvernement.fr/en/the-guidelines-of-the-health-act.

164 See http://www.nibsc.org/about_us.aspx.

165 Ralf Otto et al., "Rapid Growth in Biopharma: Challenges and Opportunities," McKinsey & Company, December 2014, published online at http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/rapid-growth-in-biopharma.

166 Ralf Otto et al., op. cit.

167 See https://www.edb.gov.sg/content/dam/edb/en/news%20and%20events/News/2013/Downloads/Speech-by-EDB-MD-Novartis-Groundbreaking.pdf.

168 See http://www.government.se/speeches/2016/04/speech-by-helene-hellmark-knutsson-at-bio-europe-spring-2016/.

169 See http://www.lepnetwork.net/news/2015/national-biologics-manufacturing-centre-launched/.

170 See http://www.nibrt.ie.

171 See http://biomanufacturing.csir.co.za/.

172 See http://www.sanews.gov.za/south-africa/government-establishes-pharmaceutical-company.

173 See http://www.biovac.co.za/about-biovac/.

174 See https://www.uk-cpi.com.

175 See https://www.uk-cpi.com/biologics/facilities/ or full brochure at https://www.uk-cpi.com/wp-content/uploads/2011/09/cpi-biologics-brochure.pdf.

176 PwC, Managing Innovation in Pharma, see: http://www.pwc.com/gx/en/pharma-life-sciences/assets/pwc-managing-innovation-pharma.pdf. Includes results and analysis from the PwC Global Innovation Survey.

177 The Manufacturing Institute and Deloitte, The Skills Gap in U.S. Manufacturing 2015 and Beyond, 2015.

178 See http://www.pmo.gov.sg/mediacentre/speech-prime-minister-lee-hsien-loong-30th40th-anniversary-gsks-pharmaceutical.

179 See http://www.government.se/speeches/2015/09/speech-at-nordic-life-science-days-2015/.

180 See http://www.cienciasemfronteiras.gov.br/web/csf-eng/home.

181 See http://www.cienciasemfronteiras.gov.br/web/csf-eng/opportunities-for-individuals-from-abroad.

182 See http://www.innovateinbrasil.com/innovation-in-brazil#.

183 See http://www.innofund.gov.cn/english2/index.shtml.

184 See http://www.sciencemag.org/news/2015/01/china-dangles-green-cards-entice-foreign-science-talent.

185 See https://www.bmbf.de/en/recognition-of-foreign-professional-qualifications-1413.html.

186 See http://www.germaninnovation.info.

187 See https://www.humboldt-foundation.de/web/about-us.html.

188 See https://www.a-star.edu.sg/About-A-STAR/A-STAR-Graduate-Academy.aspx.

189 See https://www.duke-nus.edu.sg.

190 See http://stratresearch.se/en/call-for-proposals/.

191 See http://www.vr.se/inenglish/researchfunding/applyforgrants/callforproposals/closedgrants/marieskodowskacurieactionsinternationalcareergrant.5.7c02767a14a5b51525b5f82f.html.

192 See http://www.vinnova.se/en/Our-acitivities/Cross-borde-co-operation/Cooperation-Programmes/SAMPOST/.

193 See http://www.innovation.gov.au/page/supporting-innovation-through-visas.

194 See http://www.innovation.gov.au/page/opportunities-women-stem.

195 See http://www.innovation.gov.au/page/innovation-connections.

196 See https://www.mitacs.ca/en/about-mitacs/.

197 See http://www.chairs-chaires.gc.ca/about_us-a_notre_sujet/index-eng.aspx.

198 See http://www.chairs-chaires.gc.ca/media-medias/releases-communiques/2016/february-fevrier-eng.aspx.

199 See https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/387780/PU1719_HMT_Science_.pdf.

200 See http://dev.cogent-lifescience.co.uk/about-cogent/.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