HEALTH SCIENCES

! @ #

Total Value of Innovation

Choosing Metrics That Matter in Health Sciences

Total Value of Innovation

Choosing Metrics That Matter in Health Sciences

By Carolyn Buck Luce

Americas Pharmaceutical Sector, Ernst & Young LLP

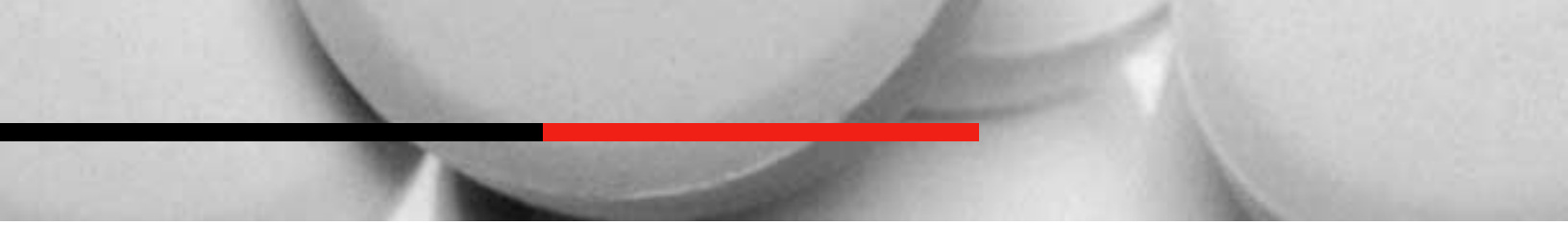
Society has long recognized the priceless benefits of health sciences innovation, including longer life span and improved health status. However, many forces driving our public policies equate the value of innovation to the current cost and rate of spending on prescription drugs. Often excluded from this discussion are short-term, intermediate, and longer-term benefits that both good health and a strong, intellectual capital-rich industry bring to the table. This discussion also ignores the many other values and variables—both direct and indirect, both realized and unrealized—that make up the rich, complex simultaneous equation that drives the Total Value of Innovation (TVI).

All stakeholders—industry, payers, governments, regulators and patients—need to truly and fully value the innovation that creates these life-saving and life-enhancing products. They ought to better understand the most relevant outcomes, how to measure them, and the impact that they have on each other. Indeed, a combination of variables—including macro-economic, competitiveness, and social value—is necessary to address innovation and the perceived imbalance in the current commitment to financing innovation in Europe and the U.S.

Long-term potential cost savings to governments and private payers committed to improving health outcomes have been well documented. This includes benefits such as care that enables elderly patients' independence, or trebled savings from the preventative use of prescription drugs that reduce the need for hospitalization. Yet, policymakers are challenged to appreciate most of the benefit from innovations without over-extending their budgets. The conversation among stakeholders is further complicated for three reasons:

- Each level of government—from local to global—faces different pressure points
- Time horizons differ—from immediate to infinite
- Public policies are exogenous variables—they change in response to shifts in other variables

The voices of all stakeholders need to be represented at the table to direct their collective energies into productive policies and initiatives. Incorporating additional measures of value and return on investment could address not only public and private payers' concerns over budgets—given the potential cost savings of innovative therapies—but also public concerns about access to care. Finding the optimal mix of policy initiatives requires a framework that captures the full range of variables that drive innovation. Ernst & Young, in working with a number of health sciences companies, created the Pillars of Innovation Framework (see page 3), which outlines the key variables of innovation and the components that drive or inhibit progress in improving health outcomes.



Thirty-eight percent of respondents feel that policies aimed at narrowing the time lag between the marketing approval and reimbursement approval would spur innovation.

The Many Faces of Success

Accomplished thought leaders recognize the importance of measuring a broader set of value metrics and other longer-term ROI indicators of innovation. Early attempts have been made to quantify, to the degree possible, the policy variables that achieve an optimal environment for innovation. These developments are occurring amid allegations that the current model for innovation in the health sciences industry is unsustainable, not to mention unfair.

The impact of Europe's pricing policies and the "Innovation Divide" are examined in Bain & Company's recent analysis, *Imbalanced Innovation: The High Cost of Europe's Free Ride in Pharmaceuticals*. As the paper points out, one of the major stumbling blocks to the current discussion is that "Success" is measured differently among stakeholders—and most of the conversation has revolved around cutting costs rather than increasing societal value. Using Germany as a case study, the analysis shows that the benefits gained by reducing drug spending are offset by the foregone benefits of wages, tax revenue, human capital creation, and positive health outcomes. Said another way, a country's achievement of a higher score in terms of the TVI requires solving a simultaneous equation comprising many measurements, only one of which is drug spending.

Prominent industry executives have called for specific policy actions: a free market for pharmaceuticals based on competition and choice; continued government support of basic biomedical research; effective intellectual property protection; efficient and effective regulatory and drug approval systems; and a global business environment conducive to free trade. Other leaders point to the current paradoxes of the pharmaceutical industry; for example, the all-time high levels of R&D investment and the record low levels of output.

Efforts to understand the perceptions of the key stakeholder groups are key to moving the discussion forward. Using a flexible and comprehensive framework for discussion, concrete actions can be taken to drive innovation that will contribute to all stakeholders.

What Drives Innovation?

Using the Pillars of Innovation as a framework, Ernst & Young conducted a high-level poll to capture the current perceptions of a key innovation stakeholder—industry executives. The objective of the survey was to have the respondents prioritize the Innovation Pillars and identify potential policies that could contribute the most to driving innovation and health outcomes. It represents a first step in a "work-in-progress" that aims to help articulate the ideas of the key stakeholders. (For more on the survey, see pages 6–32.)

Survey Details

- The survey included a wide range of senior-level executives whose roles relate to each of the Pillars.[1]
- Roughly 55% of targeted companies responded; 18% total response rate.
- Sixty-four individuals in six countries in Europe and North America responded.[2] Over half of the respondents were from the U.S.
- The majority (60%) of respondents were pharmaceutical executives; others represented medical device/diagnostic, biotech, biopharmaceutical, and diversified life sciences companies.

1. Business/Corporate Development (21%); R&D (16%); Chief Management Committee (14%); Legal/IP (11%); Regulatory Affairs/Compliance (10%); Human Resources (8%); Public Policy/Reimbursement/Health Economics (8%); Public Policy/Government Affairs (5%); Other (7%).
2. Countries included: U.S. (38), Germany (3), France (1), Switzerland (2) Canada (6), U.K. (4), unidentified (10).

The Pillars of Innovation Framework

Reimbursement/ Access	Intellectual Property	Regulatory Environment	Government Funding for R&D	Business Environment	Human Resources
· Price controls · Technology Assessment · Parallel imports	· Length of market exclusivity · Strength of patent enforcement · Global IP standards	· Registration and filing fees · Transparency · Global/regional harmonization	· Technology transfer · Government grants · Number of academic medical centers	· R&D tax credits · Corporate taxes · Capital markets	· Highly skilled workers · Risk-taking culture · Incentives for higher education

Twenty-six percent of respondents overall think extending patent exclusivity periods in countries with lower-than-average reimbursement would be most fruitful in addressing the Innovation Divide.

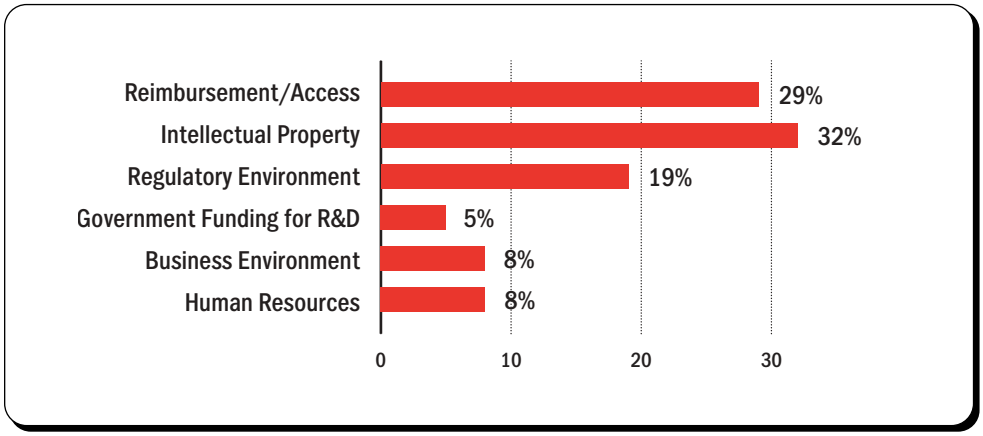
Key Survey Findings

1. Opinions in the U.S. and in Europe differ on the Innovation Divide and potential policy actions.
2. Highest scores received for three innovation policy priorities:
   - Determining the optimal length of patent exclusivity
   - Narrowing the time lag between marketing and reimbursement approval processes
   - Harmonizing regional and global regulations
3. European and U.S. executives agree on the top three indicators of the value that innovation creates for society and the top three leading indicators of long-term impact on innovation.

Is There an Innovation Divide? First and foremost, survey results indicate that executives based in Europe and the U.S. diverge somewhat in their thinking on the conventional wisdom that the U.S. is financing a disproportionate amount of global health sciences innovation. U.S.-based executives publicly express their frustration over the perceived imbalance. European executives, on the other hand, have been less vocal to date. The data suggests that, in acknowledging that a divide exists, there are opportunities for industry executives in Europe to work with their counterparts in the U.S. to address the growing concern.

How to Address the Situation? If progress is to be made, executives need to agree on the types of policies that best address the situation. U.S. respondents view policies on patent exclusivity as the best

Policy Priorities*



solution. European respondents, not surprisingly, are more focused on enhancing market-based pricing policies, given the tight controls in Europe. Ongoing work by the European Union Competitiveness Council to enhance the region's IP environment may, in part, explain why European executives rank IP lower than reimbursement.

Nevertheless, industry may increase its chances for influencing the policy debate if it speaks with one voice on both sides of the Atlantic. As industry considers the two issues, the importance of market exclusivity cannot be overstated—just observe the trajectory of Eli Lilly's Prozac, which shed nearly three-quarters of its market share in the first two months following patent expiry in the U.S. A longer period of market exclusivity could begin to offset, in part, the impact of price controls on innovation by allowing manufacturers to recoup the high cost of investment over a longer time period. If government is asked to look at the long-term cost savings of innovative therapies, perhaps industry could also consider a longer-term return on investment.

The respondents also focused on potential cost savings that can be realized through the reduction in duplicative regulations. The U.S. is actively involved in harmonization efforts on the global level. In Europe, where regional harmonization is a concern, regulatory agencies have made substantial progress, most notably in terms of harmonizing marketing approval under the auspices of the European Agency for the Evaluation of Medicinal Products (EMEA). Despite its progress, Europe's regulatory environment appears to pose a greater barrier to innovation than that in the U.S. Close to two-thirds of respondents selling mostly in Europe ranked the regulatory pillar as the most important, compared to fewer than one-third of companies focused on North American sales. An even greater challenge is now confronting companies seeking to enter the EU market: as of May 1, 2004, the EU is faced with ensuring the harmonization of regulations in ten new member countries.

Significant hurdles for innovators also remain in the area of reimbursement regulations. Although the EU G-10 Medicines Group has identified this issue as a key priority, progress has been slow in coming. Further harmonization may be possible for therapies neither purchased nor reimbursed by the government in European countries. One-quarter of respondents support greater market-based pricing for this category of products.

Prior to reaching the reimbursement and marketing approval stages, companies face significant costs performing clinical trials. Eighty percent of respondents in both the U.S. and Europe feel that policies on the extent of clinical trial requirements have a significant impact on their decision to pursue innovation. Harmonizing clinical trial and marketing approval processes between countries and regions was rated a top priority among executives on both sides of the Atlantic. The perceived failure of the U.S./EU Mutual

* Due to roundings percentages in this document may not always add up to 100%

Recognition Agreement (MRA) covering medical devices is a prime example of the setbacks and challenges on the harmonization front.

Industry on both sides of the Atlantic speaks with one voice as to the types of value measurements and metrics that are important and need to be included in the conversation around the TVI. The importance of incorporating these outcomes measures in the simultaneous equation is evidenced in the Bain & Company Case Study on Germany, which shows that poorer health outcomes resulting from less patient and physician access to innovative drugs resulted in a loss of an estimated $5 billion to Germany in 2002.

Stakeholders on each side of the Atlantic are currently at a crossroad. Framing the situation as an "innovation divide" likely will prove counter-productive in resolving the concerns being expressed. However, the results of our brief poll point to several clear areas where progress can be made and where consensus can be reached. Our aim in presenting the findings and analysis was not to answer the looming question over the divide, nor to prescribe solutions. Rather, we saw the opportunity to convey the opinions of a small sampling of industry executives as to fruitful areas for positive change. This snapshot clearly demonstrates that greater focus must be paid to the benefits gained by society from innovation as opposed to the costs incurred. The issues require a broader perspective and a complete chorus of stakeholders for a lasting consensus on the policy variables that will lead to greater value for society and to choose the measures that matter most.

Potential Areas for Further Discussion Regarding Innovation

1. Do industry's positions agree with those of other key stakeholders—the public and policymakers?
2. Where are the greatest gaps between the priorities of the public, policymakers, and industry?
3. What policies would make the greatest impact on closing those gaps?
4. How can we develop the metrics necessary to facilitate a broader discussion and actions that drive up the Total Value of Innovation (TVI) for society?

Top three leading indicators of long-term impact on health sciences innovation:

- Percentage of R&D expenditures allocated to enhancing the research infrastructure
- Number of collaborative relationships established with key centers of excellence and academic research centers
- Percentage of overall investments spent on tools used in the discovery process

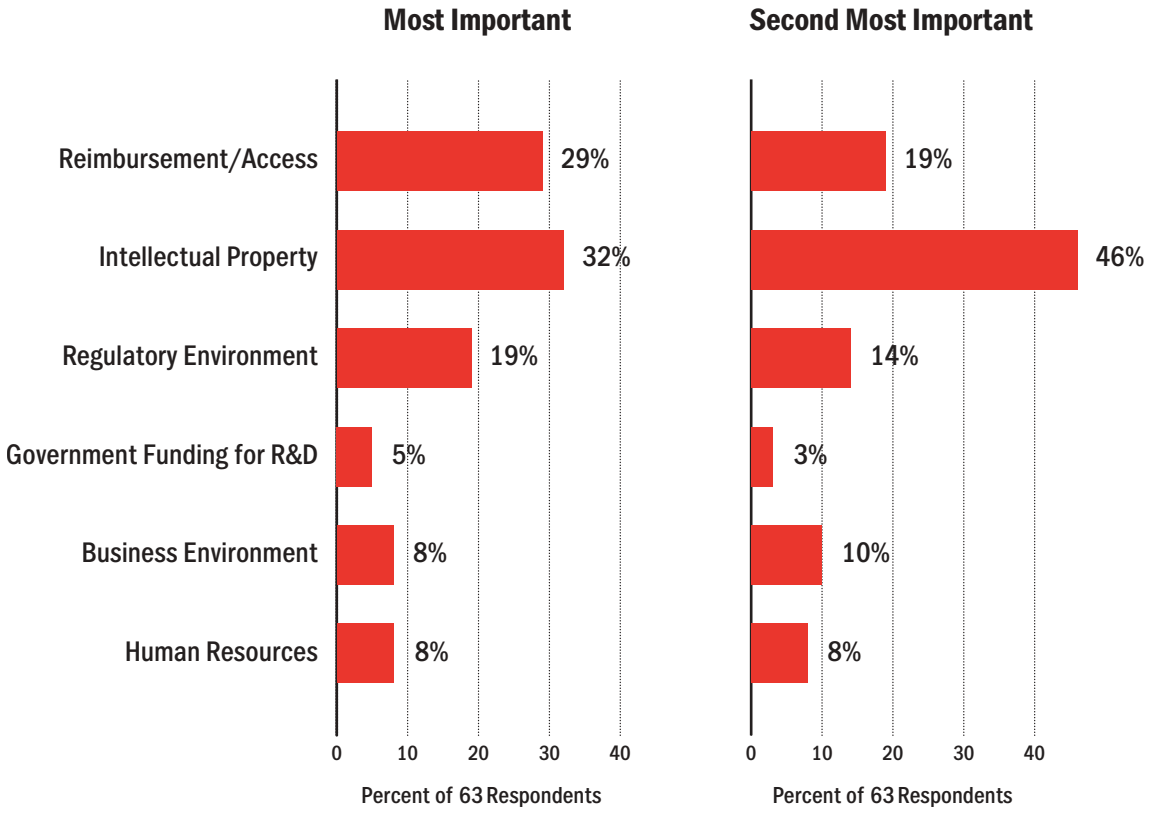
Forty-five percent of respondents think greater harmonization of clinical trial and marketing approval regulations among countries/regions would best facilitate patient access to innovations.

The types of indicators industry deems important in measuring the value of innovation include:

- Improved quality of life
- Increased life expectancy
- Reduced volume length of in-patient hospital stay

Health Sciences Innovation Survey Results

What are the two most important pillars—in terms of external forces—that are accelerating the development of health sciences innovation in your company?



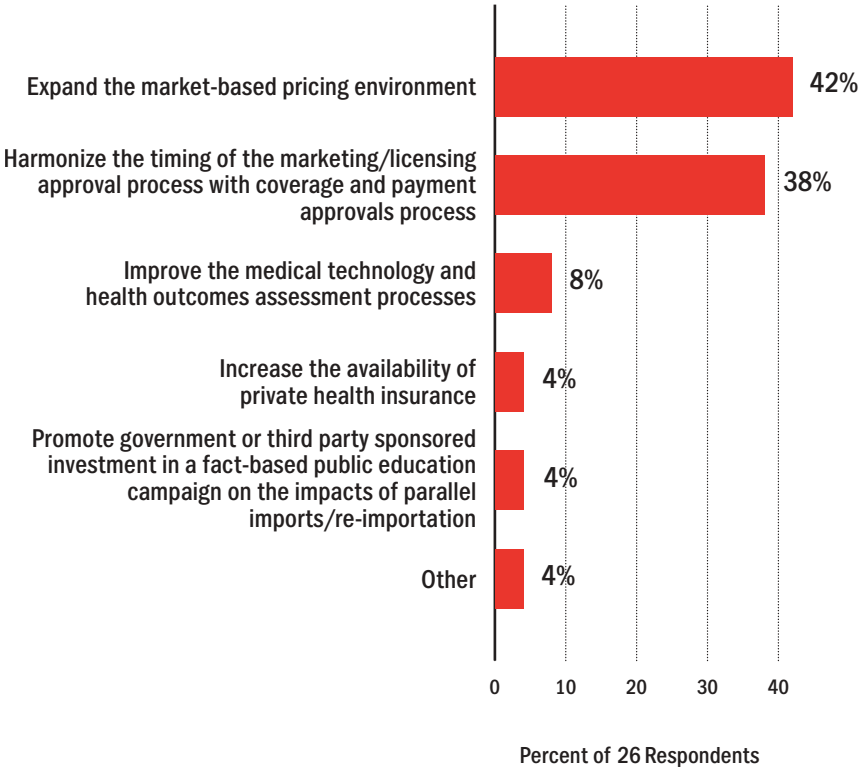
Reimbursement/Access

How important are the following components of this pillar in affecting your decisions on the development of health sciences innovation in your company?

Components	*N*	Percentage of *N* respondents for each component						Average component excluding "Don't know"				
			Not Important				*Very Important*	*Not Important*				*Very Important*
		Don't Know	1	2	3	4	5	1	2	3	4	5
Level of price/profit controls	30	0	0	3	3	10	83					ý
Level of payment/coverage by payers	30	0	0	3	10	50	37				ý	
Level of required medical technology assessment (cost effectiveness, quality outcomes)	29	3	0	3	7	55	31				ý	
Percent of the population covered by some form of health insurance	29	3	0	0	17	52	28				ý	
Level of parallel imports/re-importation	30	0	0	3	17	53	27				ý	
Other	3	Too few responses										

N Is the number who selected the Reimbursement/Access as the most or second most important pillar as well as the component.
ý Represents the average of all respondents sorted by overall average.

In your opinion, which of the following Reimbursement/Access policy actions would most benefit your company in the development of health sciences innovation?



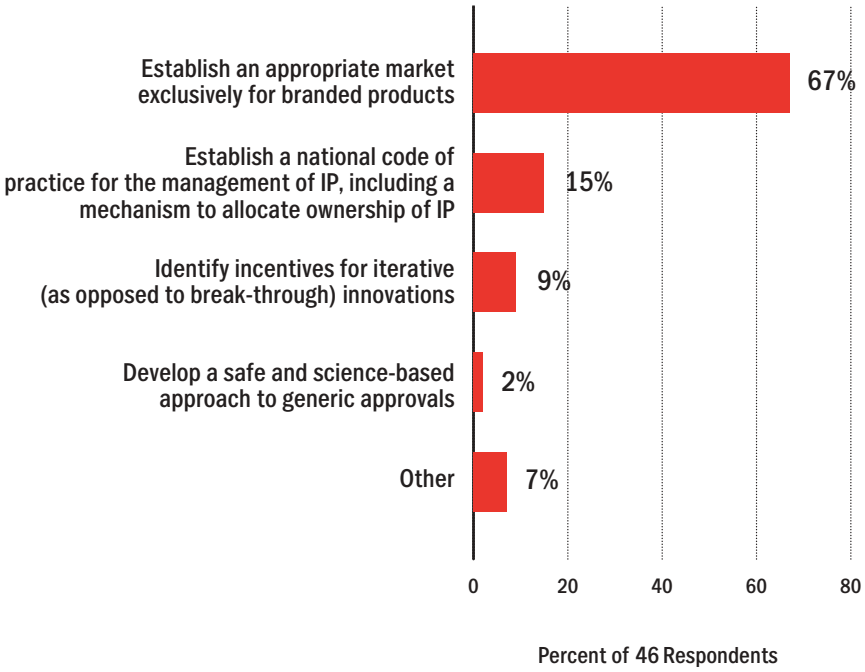
Intellectual Property

How important are the following components of this pillar in affecting your decisions on the development of health sciences innovation in your company?

Components	*N*	Percentage of *N* respondents for each component						Average component excluding "Don't know"				
			Not Important				*Very Important*	*Not Important*				*Very Important*
		Don't Know	1	2	3	4	5	1	2	3	4	5
Degree of patent enforcement	47	0	0	0	0	13	87					ý
Length of market exclusivity	47	0	2	0	0	21	77					ý
Requirements and cost to obtain a patent	45	2	2	7	33	33	22				ý	
Use of an abbreviated regulatory pathway for generics	45	2	13	11	13	24	36				ý	
Other	3	Too few responses										

N Is the number who selected the Reimbursement/Access as the most or second most important pillar as well as the component.
ý Represents the average of all respondents sorted by overall average.

In your opinion, which of the following Intellectual Property policy actions will most benefit your company in the development of health sciences innovation?



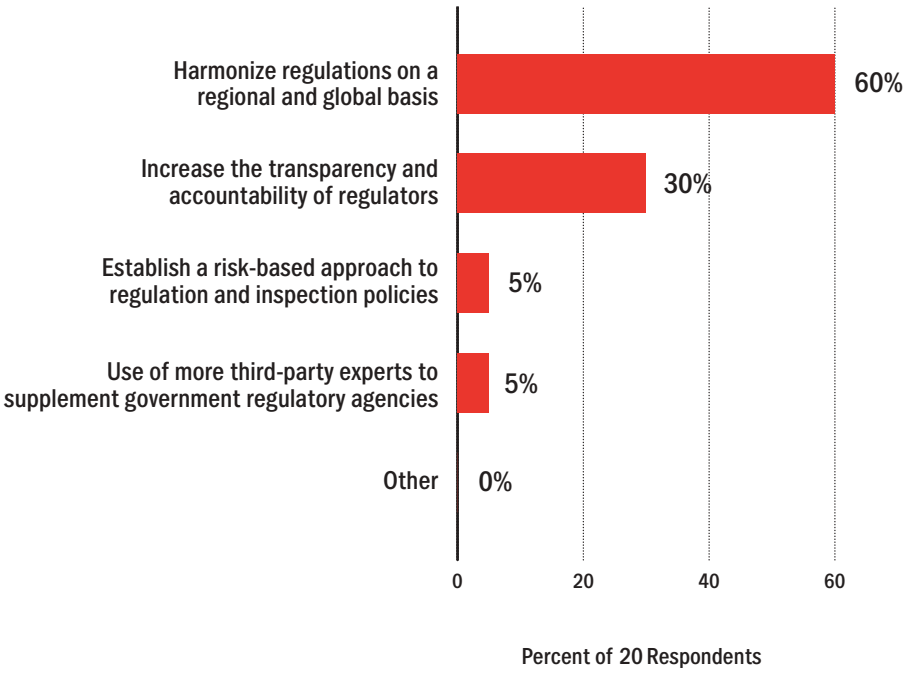
Regulatory Environment

How important are the following components of this pillar in affecting your decisions on the development of life sciences innovation in your company?

Components	*N*	Percentage of *N* respondents for each component						Average component excluding "Don't know"				
			Not Important				*Very Important*	*Not Important*				*Very Important*
		Don't Know	1	2	3	4	5	1	2	3	4	5
Extent of clinical trial requirements	20	0	0	0	5	15	80					ý
Extent of post-marketing compliance requirements (manufacturing, sales and marketing)	20	0	0	0	10	55	35				ý	
Level of cultural or ethical restrictions on specific biomedical innovation	20	0	0	20	25	45	10			ý		
Investment in registration and filing fees for marketing/licensing approval	18	0	6	28	28	39	0			ý		
Other	5	20	0	0	0	0	80					ý

N Is the number who selected the Reimbursement/Access as the most or second most important pillar as well as the component.
ý Represents the average of all respondents sorted by overall average.

In your opinion, which of the following Regulatory Environment policy actions will most benefit your company in the development of health sciences innovation?



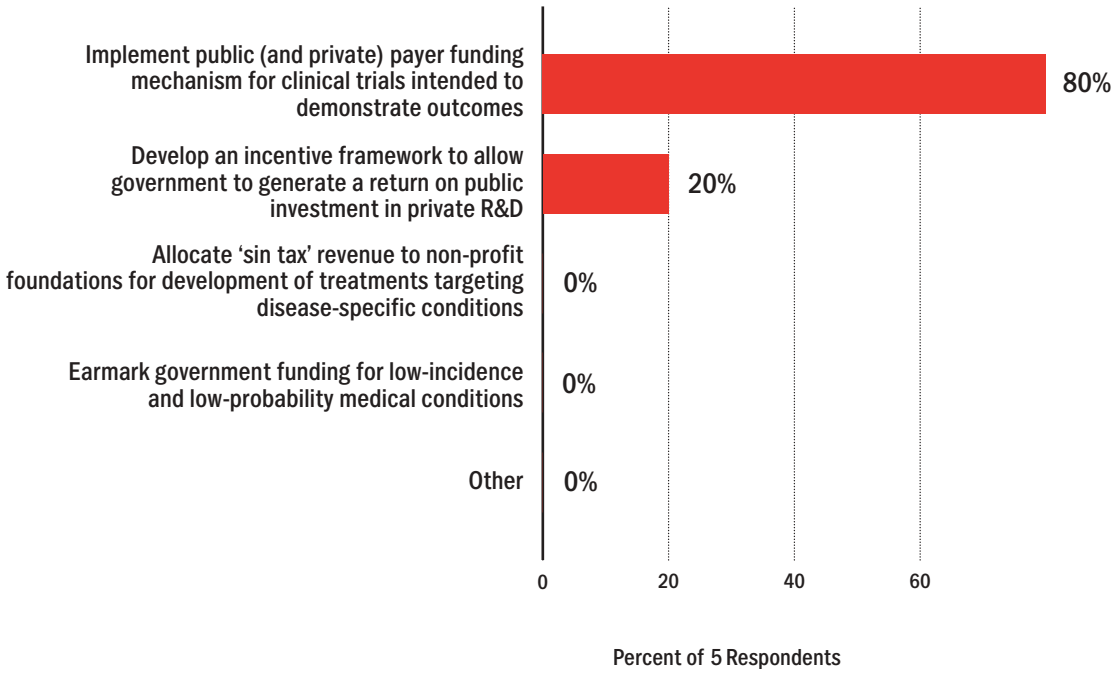
Government Funding for R&D

How important are the following components of this pillar in affecting your decisions on the development of health sciences innovation in your company?

Components	*N*	Percentage of *N* respondents for each component						Average component excluding "Don't know"				
			Not Important				*Very Important*	*Not Important*				*Very Important*
		Don't Know	1	2	3	4	5	1	2	3	4	5
Amount of government funding available (e.g. grants)	5	0	0	0	20	20	60				ý	
Number of academic medical centers	5	0	0	0	40	20	40				ý	
Presence of a statutory technology transfer framework	5	0	0	20	20	40	20			ý		
Abundance of non-profit foundations	5	0	0	20	40	40	0			ý		
Other	1	Too few responses										

N Is the number who selected the Reimbursement/Access as the most or second most important pillar as well as the component.
ý Represents the average of all respondents sorted by overall average.

In your opinion, which of the following Government Funding for R&D policy actions will most benefit your company in the development of health sciences innovation?



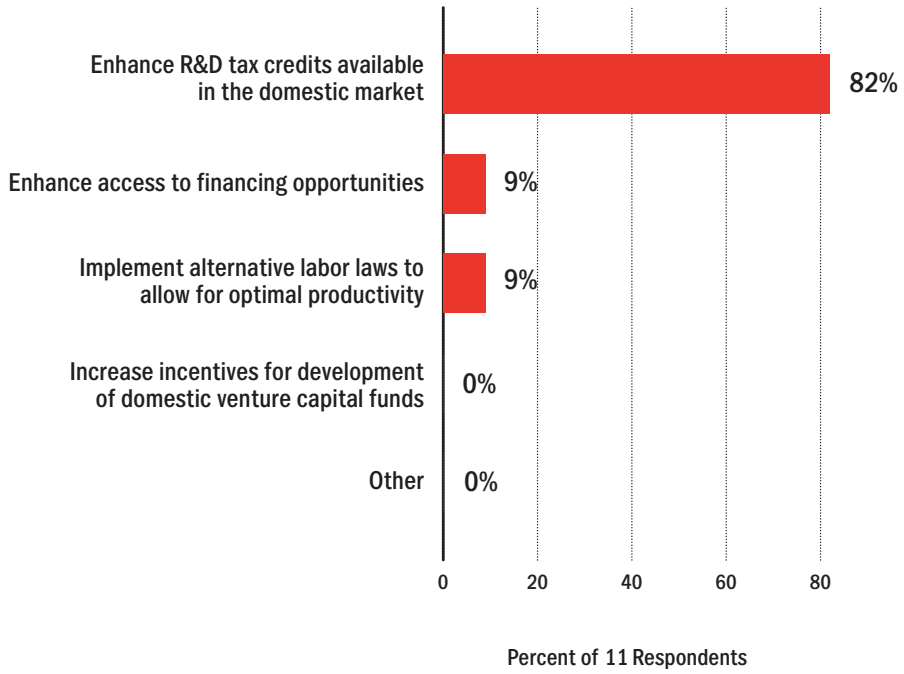
Business Environment

How important are the following components of this pillar in affecting your decisions on the development of health sciences innovation in your company?

Components	*N*	Percentage of *N* respondents for each component						Average component excluding "Don't know"				
			Not Important				*Very Important*	*Not Important*				*Very Important*
		Don't Know	1	2	3	4	5	1	2	3	4	5
Amount of available R&D tax credits	11	0	0	0	9	36	55				ý	
Access to public markets or private financing	11	0	0	9	27	9	55				ý	
Level of corporate tax requirements	11	0	0	0	18	64	18				ý	
Labor law requirements	11	0	9	0	55	27	9			ý		
Other	0	Too few responses										

N Is the number who selected the Reimbursement/Access as the most or second most important pillar as well as the component.
ý Represents the average of all respondents sorted by overall average.

In your opinion, which of the following Business Environment policy actions will most benefit your company in the development of health sciences innovation?



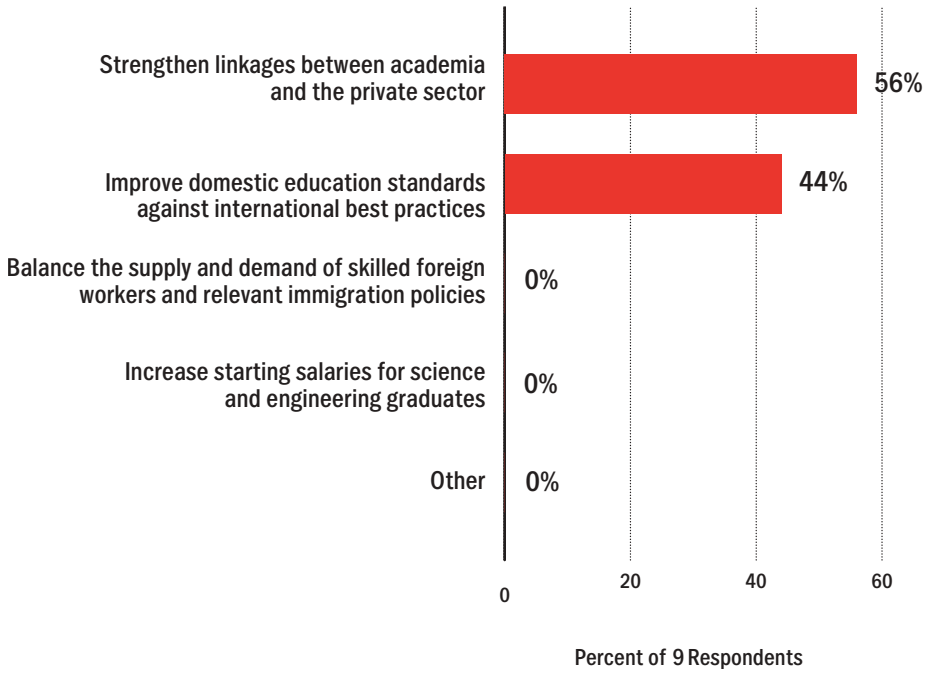
Human Resources

How important are the following components of this pillar in affecting your decisions on the development of health sciences innovation in your company?

Components	*N*	Percentage of *N* respondents for each component						Average component excluding "Don't know"				
			Not Important				*Very Important*	*Not Important*				*Very Important*
		Don't Know	1	2	3	4	5	1	2	3	4	5
Level of existing skilled workforce	9	0	0	0	0	22	78					ý
Degree of entrepreneurial spirit in domestic/regional work culture (e.g. number of new start-up companies annually)	9	0	0	0	11	33	56					ý
Availability of local incentives and funding available for higher education	9	0	0	22	22	44	11				ý	
Measurable productivity of the domestic/regional workforce	9	11	11	11	22	22	22				ý	
Regulations and quotas on work VIsas/Permits for highly skilled workers	9	0	0	22	22	56	0				ý	
Other	2	Too few responses										

N Is the number who selected the Reimbursement/Access as the most or second most important pillar as well as the component.
ý Represents the average of all respondents sorted by overall average.

In your opinion, which of the following Human Resources policy actions will most benefit your company in the development of health sciences innovation?

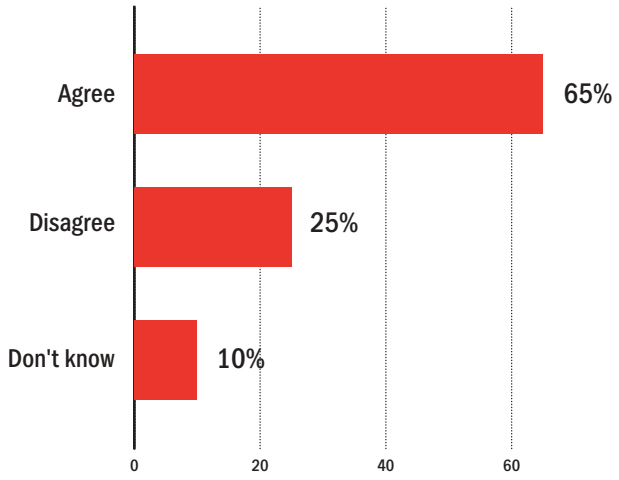


Certain innovative therapies that reduce medical costs over the long run may not pay off quickly enough for public or private payers to recognize their value. How helpful would the following potential policy actions be in easing the budget concerns of health sciences innovation development?

Potential Policy Actions	*N*	Percentage of *N* respondents for each component						Average component excluding "Don't know"				
			Not Important				*Very Important*	*Not Important*				*Very Important*
		Don't Know	1	2	3	4	5	1	2	3	4	5
Tax credit for conducting quality outcomes studies	54	6	2	0	15	50	28				ý	
Increased government rebates on innovative products	55	9	0	4	18	44	25				ý	
Increased transparency of reimbursement process	55	4	0	2	27	40	27				ý	
Government mandates for therapies with enormous clinical value but negative short-term economic returns	56	9	4	9	14	25	39				ý	
Government supported public education campaign to demonstrate innovation value	54	0	0	9	20	46	24				ý	
Other	4	Too few responses										

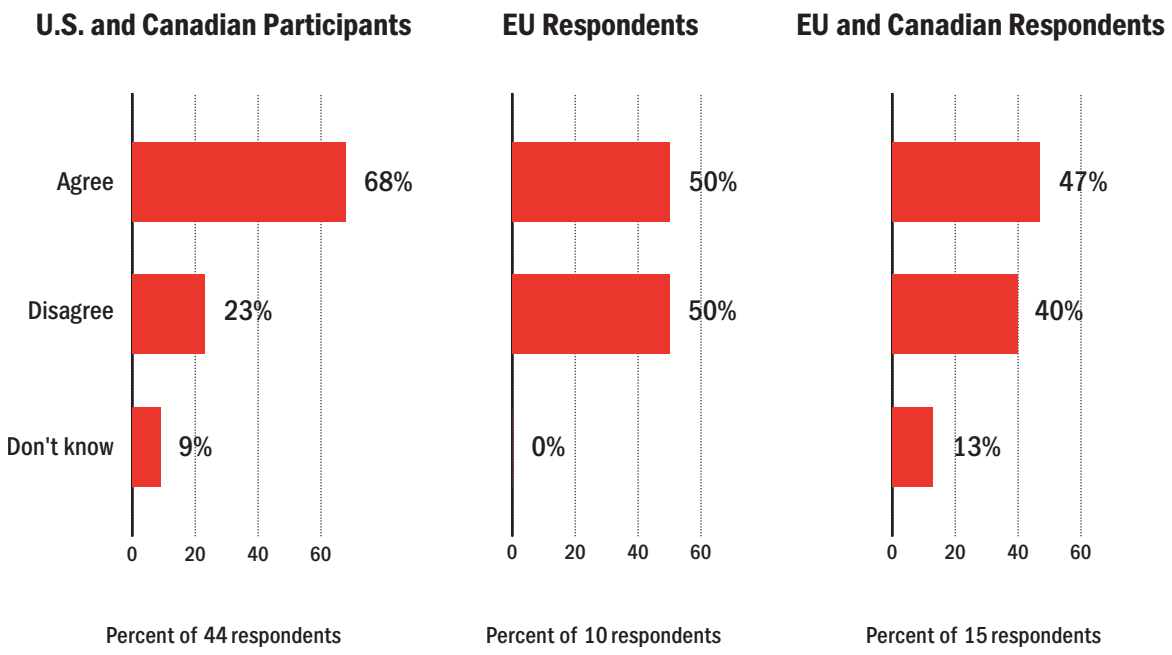
N Is the number of people who responded to the survey question.
ý Represents the average of all respondents sorted by overall average.

Do you agree with the conventional wisdom that governments and citizens in the U.S. are currently financing a disproportionate amount of state and federal health sciences innovation relative to those in Europe?

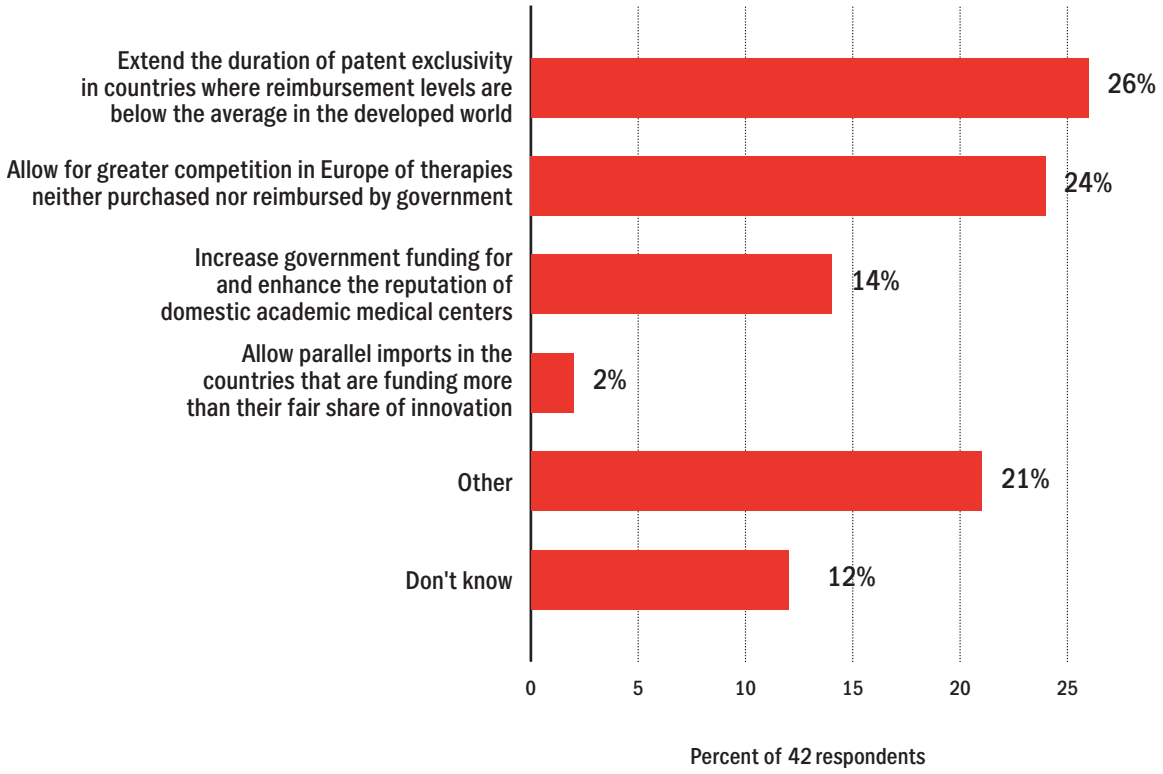


Percent of 63 respondents

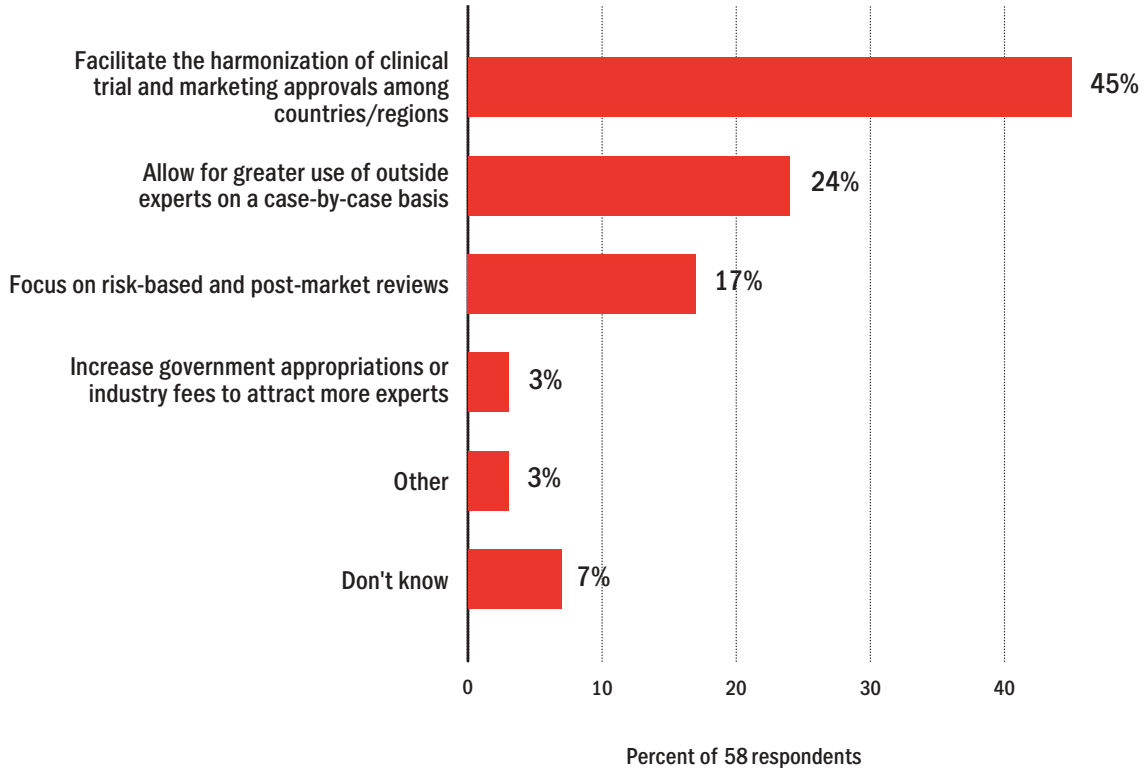
Do you agree with the conventional wisdom that governments and citizens in the U.S. are currently financing a disproportionate amount of health sciences innovation relative to those in Europe?

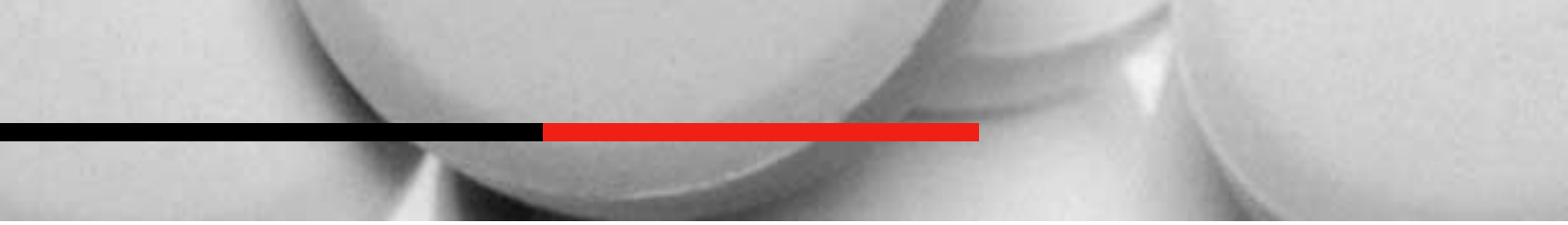


In your opinion what would be the most effective approach to address this disparity?



In your opinion, which is the most effective action that industry and governments could take to ensure that regulators are equipped to review any novel ideas in a timely manner, while still maintaining safety and quality standards?





How important are the following innovation metrics in validating the return on investment from public and private research and development?

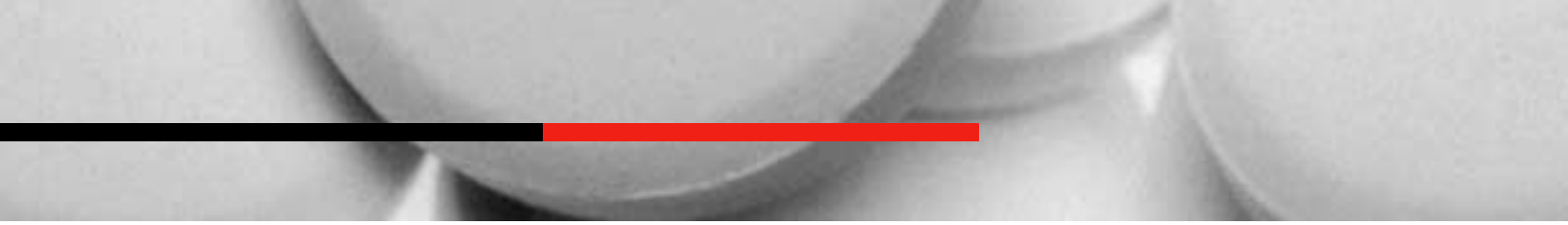
Innovation Metrics	*N*	Percentage of *N* respondents for each component: Don't Know	1 *Not Important*	2	3	4	5 *Very Important*	Average component excluding "Don't know": 1 *Not Important*	2	3	4	5 *Very Important*
Amount of time it takes for a new therapy to reach the market	54	6	2	0	15	50	28				ý	
Number of new therapies reaching the market targeting previously untreatable conitions	55	9	0	4	18	44	25				ý	
Ratio of R&D investment in infrastructure and discovery tools versus number of new products	55	4	0	2	27	40	27				ý	
Amount of iterative enhancements to existing therapies	56	9	4	9	14	25	39				ý	
Number of new life sciences patents issued	54	0	0	9	20	46	24				ý	
Company market capitalization	54	0	0	9	20	46	24			ý		
Other	4	Too few responses										

N Is the number of people who responded to the survey question.
ý Represents the average of all respondents sorted by overall average.

How important are the following indicators of the value that innovation creates for society?

Indicators	N	Percentage of N respondents for each component						Average component excluding "Don't know"				
			Not Important				Very Important	Not Important				Very Important
		Don't Know	1	2	3	4	5	1	2	3	4	5
Improved quality of life	63	0	0	0	0	22	78					ý
Increased life expectancy	62	0	0	2	8	29	61				ý	
Reduced length of in-patient hospital stay	61	0	0	3	2	46	49				ý	
Increased worker productivity (less time absent from work)	62	0	0	2	8	48	42				ý	
Number of individuals treated by an innovative therapy	61	0	0	5	20	48	28				ý	
Quality-adjusted price for medical services	62	3	0	3	26	45	23				ý	
Number of therapies for orphan conditions	62	0	0	6	27	50	16				ý	
Other	1	Too few responses										

N Is the number of people who responded to the survey question.
ý Represents the average of all respondents sorted by overall average.

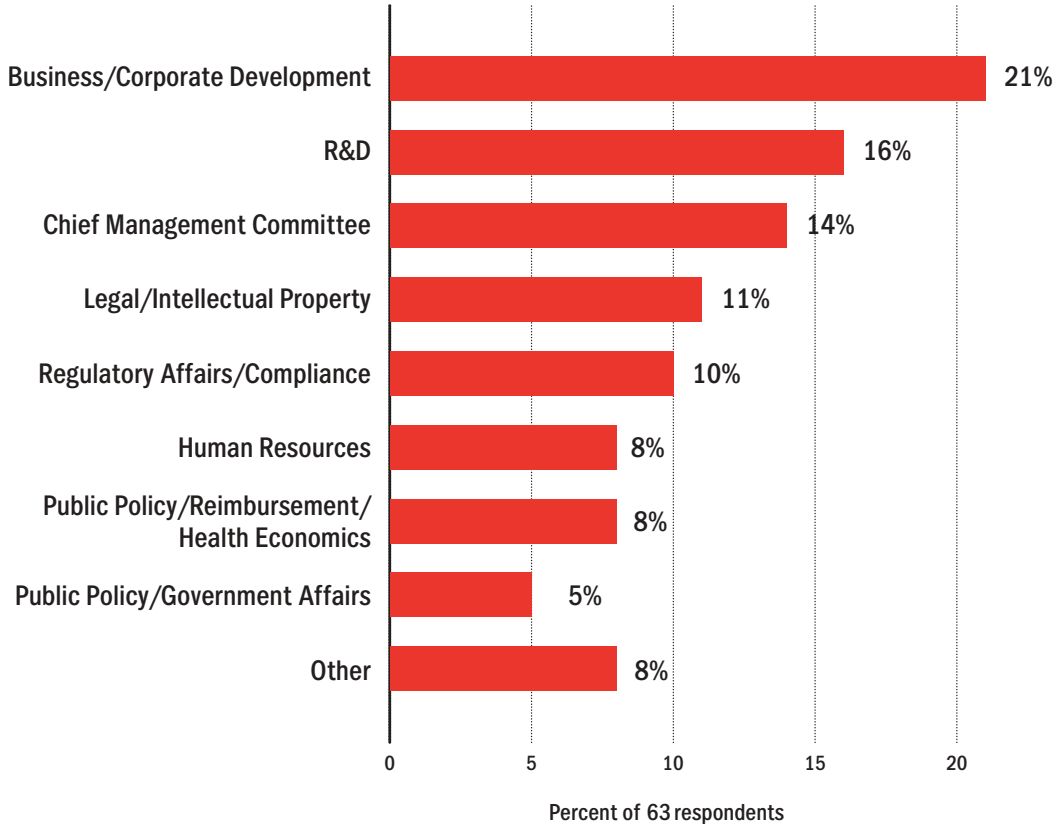


How important are the following indicators with regard to positive long-term impact on life sciences innovation?

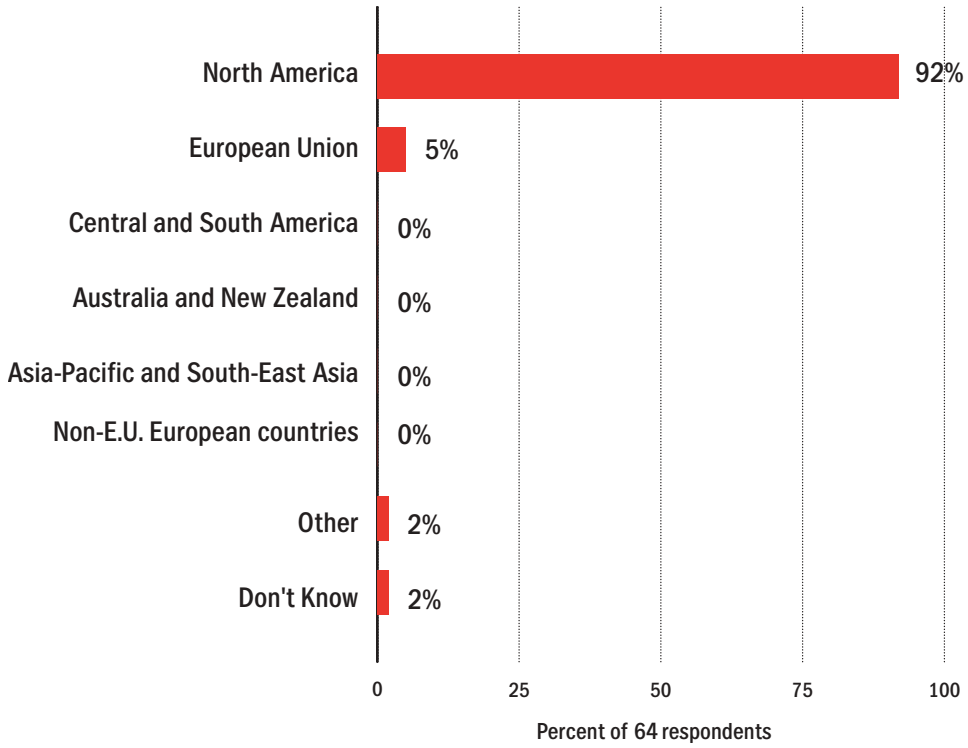
Leading Indicators	*N*	Percentage of *N* respondents for each component						Average component excluding "Don't know"				
			Not Important				*Very Important*	*Not Important*				*Very Important*
		Don't Know	1	2	3	4	5	1	2	3	4	5
Percentage of R&D expenditures allocated to enhancing the research infrastructure	63	0	0	5	14	52	29				ý	
Number of collaborative relationships established with key centers of excellence and academic research centers	62	0	0	8	15	53	24				ý	
Percentage of overall investments spent on tools used in the discovery process	62	2	0	5	19	60	15				ý	
Number of public-private alliances formed to address a specific disease or condition	62	2	2	15	27	44	11				ý	
Resources spent on benchmarking global best practices to innovation	61	3	0	10	49	31	7			ý		
Number of companies operating in the industry	62	0	2	16	42	34	6			ý		
Other	0	Too few responses										

N Is the number of people who responded to the survey question.
ý Represents the average of all respondents sorted by overall average.

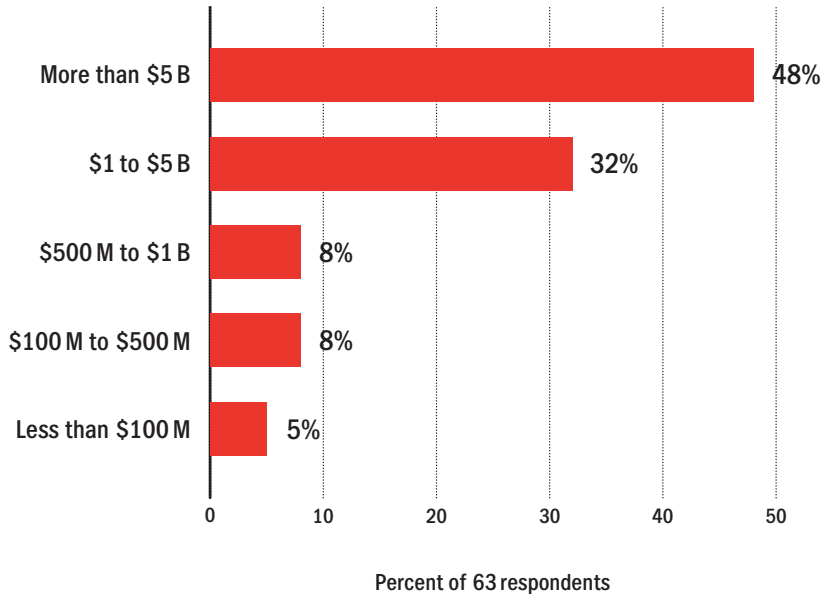
With which category would you most closely associate your role in your organization?

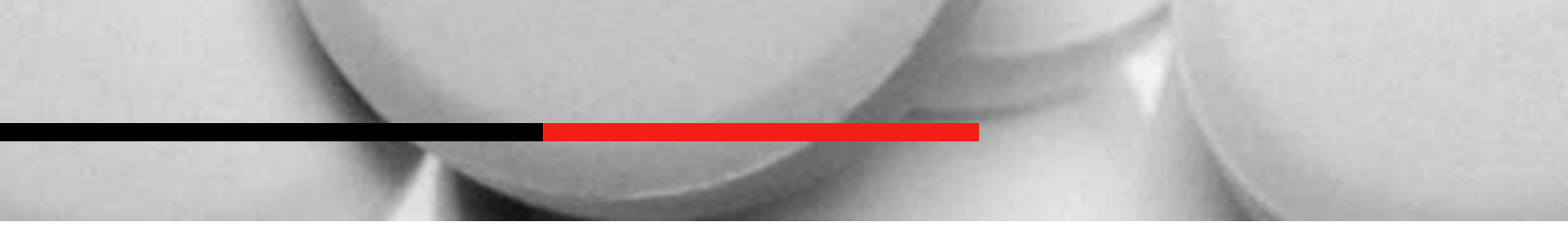


What is the top revenue-generating geographic region for your company?

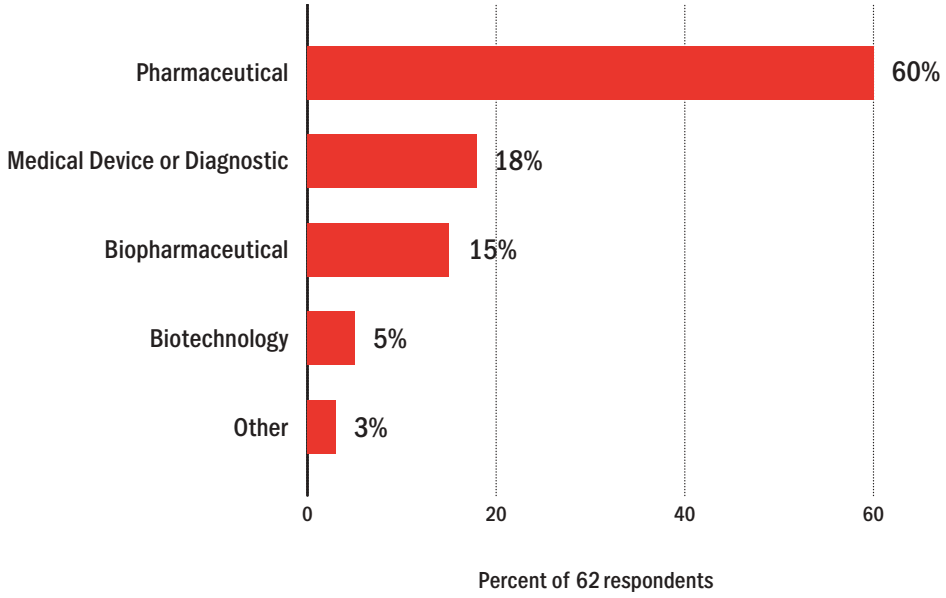


What is the size of your company? (in revenue $ U.S.)

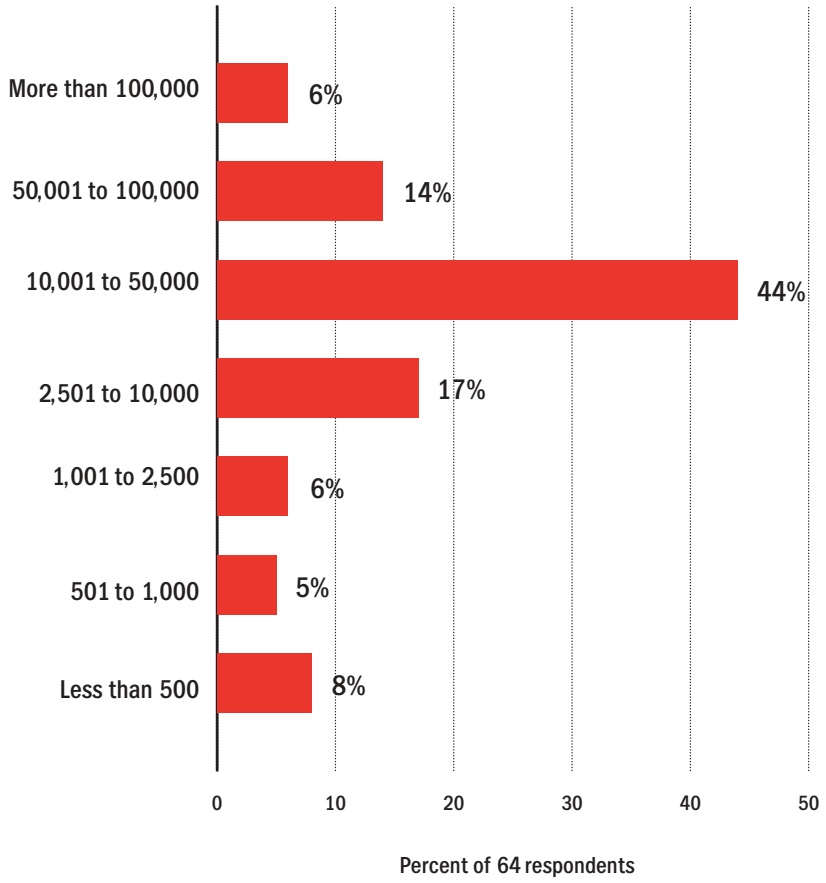


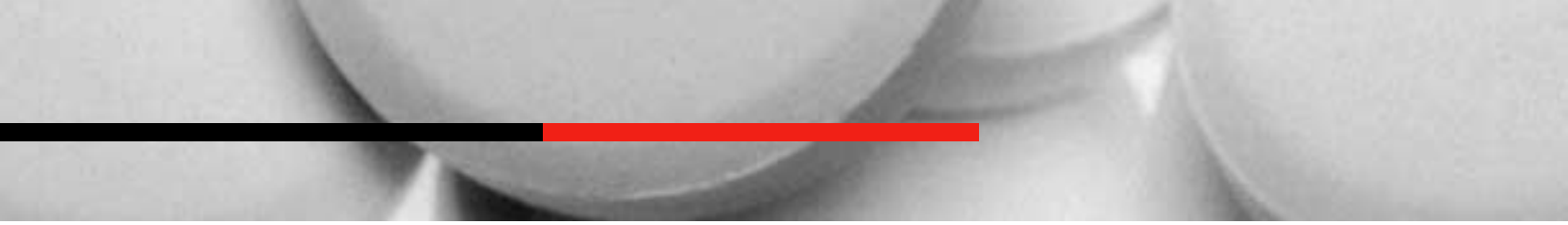


Which of the following best describes your organization?



How many employees are in your entire organization?





By: Carolyn Buck Luce
Ernst & Young LLP
(212) 773-6450
carolyn.Buck Luce@ey.com

For questions regarding Ernst & Young's Pharmaceutical practice:

Blake Devitt
Americas Pharmaceutical Sector Leader
(212) 773-2099
blake.devitt@ey.com

Please refer questions directly related to this article to:

Chris Gray
(212) 773-5471
christopher.gray@ey.com

Ernst & Young, a global leader in professional services, has over 10,000 professionals located in over 130 countries dedicated to serving clients in the converged health sciences marketplace. Our goal is to pursue the highest levels of integrity, quality, and professionalism to provide clients in the provider care, biotechnology, and pharmaceutical sectors with solutions based on financial, transactional, and risk-management knowledge in Ernst & Young's core services of audit, tax, and transaction advisory services. We have dedicated our Global Health Sciences Center for Industry Change to developing thought leadership and other tools to assist clients anticipate and respond to the opportunities and challenges emerging market changes, government forces, and technological innovation present. Ernst & Young also provides legal services in those parts of the world where permitted. For more information about the content of this document and the firm's Health Sciences practice, visit **www.ey.com/health**.

ERNST & YOUNG www.ey.com

SCORE Retrieval File
EYG No. OO0376
NYC CSG: 0402-0508764