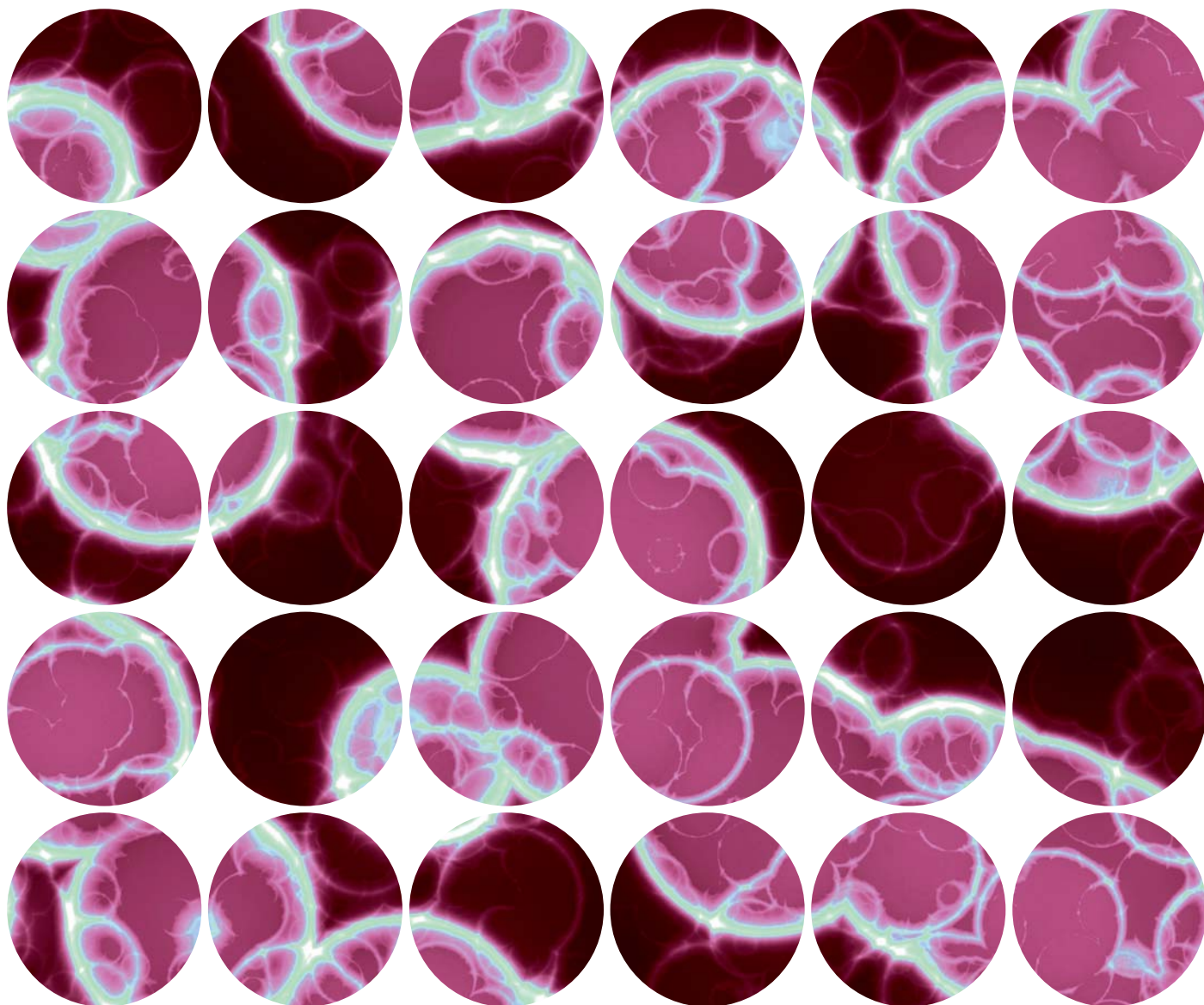
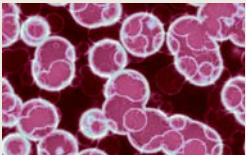


# Reinventing biopharma: Strategies for an evolving marketplace

## The value challenge

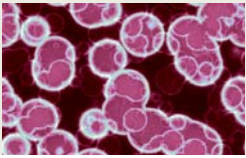
An Economist Intelligence Unit report  
Sponsored by Quintiles





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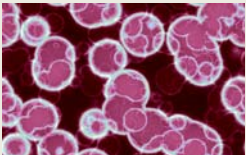


## Preface

*The value challenge* is the second in a series of four reports by the Economist Intelligence Unit. It is part of the *Reinventing biopharma: Strategies for an evolving marketplace* programme, sponsored by Quintiles. The Economist Intelligence Unit conducted the survey and analysis and wrote the report. The findings and views expressed in this report do not necessarily reflect the views of the sponsor.

The author was Dr Paul Kielstra. The editors were Diallo Hall and Rozina Ali, and Mike Kenny was responsible for layout.

January 2012



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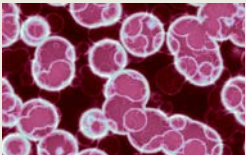
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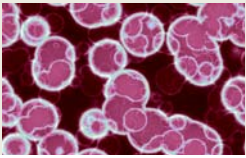


## Executive summary

**T**he biopharmaceutical industry today is facing a multifaceted “value challenge”. It is no longer enough for biopharma companies to create products that are simply safe and effective: they must also develop medications which provide results that are superior to those already on the market. At the same time, companies have to demonstrate this added value to a range of stakeholders if they wish to command prices that are higher than those of existing treatments. These tasks are further complicated by a shift in the balance of power among industry stakeholders, each of which may require different evidence to be convinced of a product’s value. Previously, doctors might have been satisfied with even marginal improvements in efficiency at any price; today, increasingly influential healthcare payers are no longer so easily convinced.

To understand the nature of the value challenge and how the industry is addressing it, this Economist Intelligence Unit study, sponsored by Quintiles, draws on a global survey of 399 senior executives in the life sciences industry and in-depth interviews with experts in the field, corporate leaders from biopharmaceutical companies and senior officials from prominent healthcare organisations. The report’s key findings are summarised below.

- **The value challenge is not just a temporary symptom of current economic conditions, but a long-term issue that is a leading concern for a majority of drug companies worldwide.** In our survey, 64% of respondents from biopharmaceutical companies, service providers and generics makers say that demonstrating value is a significant challenge facing their businesses. In every region of the world except the Middle East and Africa, a majority of survey respondents whose companies operate locally report that demonstrating value has become more important. Moreover, although deteriorating financial circumstances are prompting some payers—particularly governments—to focus more closely on reducing pharmaceutical spending, the demand for proof of value has been evolving for decades.
- **Many stakeholders, especially biopharmaceutical companies, lack confidence in the industry’s ability to respond to the value challenge.** Only about one-half of survey respondents (55%) say that the pharmaceutical sector is adjusting well to increasing demands for proof of value. Traditional biopharmaceutical companies—a group which excludes contract research organisations and generics manufacturers—are even less optimistic: just 36% say they are performing well. All respondents are



## Reinventing biopharma: Strategies for an evolving marketplace

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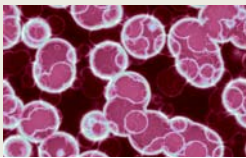
harsher about biopharmaceutical companies' ability to demonstrate value and, among payers and regulators, only 25% are confident about the broader claims of value made by biopharma firms.

- **Companies are actively experimenting with a range of ways to address the value challenge but have not converged in their choices.** According to 68% of life sciences respondents, the growing demand to provide value has had an important impact on their business models. More respondents have taken steps to demonstrate value better: 85% have made at least one change to their business model for this reason, 82% to their research and development (R&D) strategy, and 78% to their commercial strategy. A closer examination of the specific steps taken, however, shows that no single strategy to improve business, commercial or R&D models has been adopted by a majority of companies.
- **Leading companies are more active both in addressing the value challenge and in co-ordinating the response to it across the company.** Based on respondents' rankings of their company with regard to creating and demonstrating value and financial performance, we have classified top performers as "value leaders". These companies are more aggressive than their peers at pursuing strategies to respond to the value challenge. More important, rather than a scattergun collection of responses, these efforts involve extensive, integrated change across the company, particularly in how research and trials are carried out, and in how the R&D department interacts with the commercial function and outside stakeholders.
- **Biopharmaceutical companies see their market power decreasing, but others still regard them as dominant players.** Respondents from traditional biopharmaceutical firms are more than twice as likely to say their market influence over the last three years has decreased rather than increased. At the same time, they believe that the power of payers and regulators of formulary access has increased. Collectively, the other participants in the survey have a notably different perspective: although they observe some relative growth in the influence of payers, they see a much smaller shift. "Our influence has increased, but payers are still price takers for most medications," says Dr Ed Pezalla, the national medical director for pharmaceutical policy and strategy at Aetna.

### About the survey

The report is based on a survey of 399 senior executives from the life sciences industry, including biopharmaceutical companies (27%); service providers such as contract research organisations (11%); generics manufacturers (10%); private health insurers (21%); government payers (8%); and regulators (23%). Slightly under one-half of all respondents (45%) are C-level or above. Respondents

are distributed globally, with 32% based in western Europe, 31% in North America, 26% in the Asia-Pacific region and the balance in the rest of the world. Corporate respondents come from firms of all sizes: 47% represent companies with less than US\$500m in annual revenue, while 22% work for companies with revenue in excess of US\$5bn. To complement the survey findings, we conducted nine in-depth interviews with senior executives and experts, as well as extensive desk research.



## Introduction: Coming to terms with a global shift

Value is far from a new issue for the pharmaceutical, or any long-established, sector. As Anita Burrell, head of Sanofi's multiple sclerosis (MS) project unit, points out: "The concept has always been important when bringing anything to market. If it doesn't provide value, there is no basis for trade." Nevertheless, value is now among the biggest issues facing the pharmaceutical industry: 64% of survey respondents from life sciences companies—including biopharma, generics manufacturers and contract research organisations (CROs)—say that it is one of the most pressing issues, or the single leading challenge, for their firms.

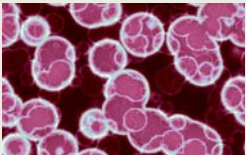
Part of the difficulty is finding new value in the many fields where treatments already exist. Dr Shari Ling, deputy chief medical officer at the US government's Centers for Medicare and Medicaid Services (CMS), explains that new treatments "face a tall order in many cases because new treatments are compared to existing drugs which have been proven to be effective. It gets harder over time to show that medical therapies are an improvement over what is already available." Patricia Danzon, Professor of Health Care Management at the Wharton School of the University of Pennsylvania, agrees: "For many disease classes we have effective, cheap generics. In that sense, the industry is a victim of its past success."

Delivering new products is not entirely new for any industry that relies on innovation. For the biopharma sector, however, it is only one aspect of today's value challenge. To begin with, payers have a greater role in deciding which products will be used. Previously this was left almost exclusively to medical professionals. Today, customers are unwilling to pay for products that are not sufficiently better than existing ones to justify the price premium charged. According to Dr Christopher-Paul Milne, the associate director of the Tufts Centre for the Study of Drug Development at Tufts University in Boston, Massachusetts, it is not enough to be "the 12th or 13th version of hypertensive drugs".

The type of evidence required has also changed. Adrian Thomas, vice president for Market Access at Janssen, says: "Payers are distributed across a variety of backgrounds—such as administrative, clinical or healthcare professionals, or healthcare economists—which can lead to different interactions. Market access functions [in biopharmaceutical companies] have to be able to communicate value messages to a diverse group of customers."

What is driving the value challenge? Recent and ongoing economic difficulties in the largest pharmaceutical markets and the need for governments to retrench accentuate the trend, but are not its root cause. The earliest government health technology assessment (HTA) bodies were established in the

"Sixty-four percent of survey respondents from life sciences companies say that value is one of the most pressing issues for their firm."



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late 1980s to examine the cost effectiveness of new treatments. By controlling access to which drugs are reimbursed, these organisations directly affect the biopharmaceutical market. For example, in the five years before Canada's Common Drug Review—which acts on behalf of all the provinces except Quebec—began making recommendations on formulary listings in 2003, participating drug plans listed between 47% and 66% of new drugs. In the following five years this dropped to between 12% and 40%.

While HTA bodies have been growing in number and influence, many governments have experimented with pricing mechanisms, such as direct controls, forced rebates or reference pricing. Now these two trends are coming together in value-based pricing. Germany, the world's third-biggest pharmaceutical market, recently changed its reimbursement system so that companies have one year to prove the value of a new drug compared with existing offerings. If they are successful, companies earn the right to charge a price premium compared with the competition; if not, a price is imposed based on similarly effective existing (and often generic) medications.

The UK also hopes to enact some form of value-based pricing by 2014. Already, its HTA arrangement is having an effect on prices. Its National Institute for Health and Clinical Excellence (NICE) does not negotiate with drug manufacturers on prices, but its recommendations can have an important, indirect impact in this area. Under the Pharmaceutical Price Regulation Scheme (PPRS), an initial rejection by NICE can lead pharmaceutical makers to offer Patient Access Schemes (PAS)—such as price discounts or pay-

### In search of value: Shire Pharmaceuticals changes its business model

A decade ago Shire Pharmaceuticals' business model centred on the improvement and reformulation of existing drugs. The value of these products resulted from marginal improvements to existing forms of the drug or improved compliance through greater ease of use.

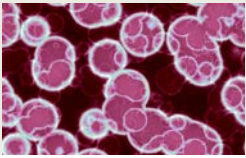
For some time the strategy worked reasonably well. "There were a lot of drugs that could be improved," says Angus Russell, the CEO of the company. "But about six years ago it was clear that there were two principal flaws [in the business model]." The first was that for the many generics manufacturers that were growing increasingly aggressive in attacking patents, the easiest targets were those granted around reformulations. Shire found itself beset by substantial litigation with its attendant expense and uncertainty.

The second problem went straight to the heart of the issues surrounding value. European governments, in particular, were reluctant to grant premium prices for reformulations. According to Mr Russell, authorities did not view them as innovative. "The reference prices for our reformulated drugs were generic prices. Most of our business was developed in the US because you could get superior pricing. We had become a company that was 90% dependent on

the US market, and we were struggling to get drugs that could go globally," he says.

The company decided that it needed a different approach that made the value of its output clearer. The company had previously focused on rare, specialist conditions, particularly those that were symptomatic (that is, displayed observable symptoms). "These became even more important because of the drive towards greater value," Mr Russell says. "With a symptomatic disease, it is easier to prove a drug is working because the changes are often physically observable." In addition, Shire wanted something with stronger intellectual property protection worldwide. It decided to pursue rare disease enzyme replacement, in which not many businesses were active. This field also provided orphan exclusivity, which can extend patents by 10-12 years, depending on the jurisdiction.

Since then, the company has not looked back. It has gone from one product, Adderall, providing about 45% of sales in 2006, to no single product providing more than 20% of revenue in 2010. Over the same time, the company's total revenue has nearly doubled from US\$1.8bn to US\$3.5bn. An active pursuit of international opportunities—made possible by the new strategy—has helped to drive this growth, with sales outside North America and the UK more than tripling to US\$900m. Shire's transformation shows that the value challenge need not be simply a problem. Addressing it properly can bring growth.



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**“As an industry we have continued to do the same old thing, putting out more me-too drugs and wanting premium pricing, while we’ve looked on payers almost as the enemy.”**

*Angus Russell, CEO of Shire Pharmaceuticals*

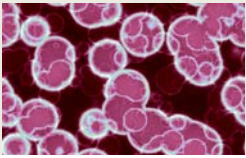
for-performance deals—which make their products more economically attractive. Johnson and Johnson, for example, in 2007 offered that the National Health Service (NHS) would pay for Velcade—a drug for the treatment of multiple myeloma—only when patients showed a full or partial response after four cycles of treatment. Given expected response rates, this represented a discount of about 15%, which led to the approval of the drug. In 2011, NICE rejected Tasigna, produced by Novartis, and Sprycel, produced by Bristol-Myers Squibb (BMS), both follow-on drugs for leukaemia that are considered to be about equally effective. However, it accepted Tasigna after Novartis submitted a PAS with an undisclosed price discount. BMS, in return, has chosen to appeal against NICE’s decision on Sprycel, showing one of the limits of voluntary, ad hoc pricing negotiations.

This history helps to explain why the issue of value is global. Angus Russell, the CEO of UK-based Shire Pharmaceuticals, explains that while Germany may have clearer regulations, tiering of reimbursement in the US has the same effect—customers only pay a price premium when a drug has demonstrably superior efficacy under given conditions.

The survey confirms the global challenge. In every region, with the exception of the Middle East and Africa, a majority of respondents whose companies operate locally report that demonstrating value is becoming more important. Fully 82% of respondents based in emerging Asia-Pacific markets—a growth area for the industry and among the world’s best-performing economies—express this concern. China has already tightened prices on essential medicines, and India plans to do the same. “You will see growth in the number of different countries that are looking at, and refining, the evidence they demand for reimbursement,” says Dr Thomas.

The sector has been very slow to respond positively to this trend, however. “As an industry we have continued to do the same old thing, putting out more me-too drugs and wanting premium pricing, while we’ve looked on payers almost as the enemy,” notes Mr Russell. Recent pushback by industry organisations against value-based pricing initiatives in the UK and Germany shows that this instinct is far from dead.

Nevertheless, the importance that survey respondents give to the value challenge indicates that the sector is starting to come to terms with these issues. “Everyone is talking the talk,” says Dr Milne. “There is some understanding of where we are going with value and some attempts to make sure [relevant stakeholders] are going in the same direction, but a lot of players are involved.” Similarly, Professor Carole Longson, the director of NICE’s Centre for Health Technology Evaluation, notes that when her organisation began 12 years ago, its role was very controversial. But things have changed. “Recognition that there needs to be a demonstration of added value, if not necessarily an accepted concept, certainly has become more mainstream in the industry,” she says. The question, of course, is whether the sector’s efforts are effective.



## The value challenge in a shifting marketplace

Industry stakeholders are ambivalent about their success so far—even though they have only just begun to address the value challenge. Biopharma companies tend to be the harshest in assessing their own performance. For example, more than one-half of respondents overall (55%) say that the sector is adjusting well to increasing demands for proof of value, but only 36% from traditional biopharmaceutical companies agree.

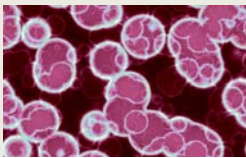
A look at particular aspects of the issue reveals a similar picture. Only 56% of all respondents are confident or very confident that the industry will introduce products with demonstrably more value than existing offerings in the next three years. Worse still, only 39% believe that the industry is more than just somewhat effective at creating such products. This falls to a meagre 24% among those working in clinical development at drug makers, who are at the sharp end of developing new treatments.

Respondents are also sceptical of biopharmaceutical companies' ability to demonstrate to others the value of their new products. Only 32% of respondents say that the industry is more than somewhat effective in this area. Moreover, only 25% of payers and regulators are confident or very confident about the broader claims of value made by biopharmaceutical companies.

At the heart of the sector's difficulties is the sheer breadth of change required. There is a significant gap between the appropriate evidence required to demonstrate value and the evidence needed to obtain regulatory approval. "It is only in very recent years or even months that meaningful conversations are beginning on how to address it. You need a fundamental shift in how clinical trial programmes are developed and a re-engineering in companies," says Professor Longson. Looking at the value challenge as a whole, Dr Milne adds: "Companies are all struggling with this. Nobody says it is easy."

Making matters worse is lack of clarity over the very basic question of what constitutes value. Actors in the pharmaceutical arena still start from very different positions. One evidently frustrated survey respondent from the industry explained: "Value' does not mean [for payers] what you think it means. It is the value to a bureaucrat, not economic value."

"More than one-half of respondents overall (55%) say that the sector is adjusting well to increasing demands for proof of value, but only 36% from traditional biopharmaceutical companies agree."



## Reinventing biopharma: Strategies for an evolving marketplace

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#### 1 Perceptions of value differ throughout healthcare industry

Which of these factors have the greatest influence on how your organisation currently assesses the value of a new drug?

	Biopharmaceutical company	Biopharmaceutical services provider	Generic pharmaceutical company	Health insurance company	Government payer	Regulatory agency
Degree of improved efficacy over existing products	63%	50%	44%	31%	26%	36%
Total patient outcomes	41%	39%	29%	34%	26%	29%
Whether it addresses an unmet medical need	54%	36%	27%	15%	39%	32%
Potential number of patients who could use the drug	23%	31%	54%	33%	10%	25%
Costs compared with competing products	14%	8%	37%	38%	29%	21%
Improved longevity of patient	14%	11%	20%	31%	36%	44%
Improved quality of life of patient	25%	31%	34%	65%	52%	52%

● 50% and over ● 40–49% ● 30–39% ● 20–29% ● 19% and under

Source: Economist Intelligence Unit survey, September 2011

#### 2 Perception of value remains divergent in future

In the next three years, which, if any, of these attributes will become significantly more important in your assessment of value of a new drug?

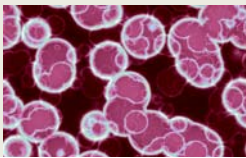
	Biopharmaceutical company	Biopharmaceutical services provider	Generic pharmaceutical company	Health insurance company	Government payer	Regulatory agency
Degree of improved efficacy over existing products	49%	28%	34%	27%	19%	26%
Total patient outcomes	55%	58%	27%	32%	26%	23%
Whether it addresses an unmet medical need	36%	31%	34%	21%	29%	24%
Potential number of patients who could use the drug	14%	14%	56%	31%	29%	19%
Costs compared to competing products	29%	36%	32%	26%	23%	25%
Improved longevity of patient	17%	11%	17%	29%	42%	25%
Improved quality of life of patient	26%	28%	34%	58%	52%	70%

● 50% and over ● 40–49% ● 30–39% ● 20–29% ● 19% and under

Source: Economist Intelligence Unit survey, September 2011

The survey results highlight this split (see charts 1 and 2). Respondents from life sciences companies consider value to consist of attributes such as the degree of improved efficacy over existing products or the cost/benefit implications of a new drug for overall treatment. Payers, on the other hand, tend to look more towards improved longevity and quality of life. For example, Dr Ling says: “When we [at CMS] talk about value, we are talking about the ‘three-part aim’ of better health outcomes for patients, better health of populations, and lower costs through quality improvement. That is a general concept that translates across all conditions and care settings.” Looking forward, the survey indicates that these differences will persist.

This comes as no surprise to Janssen’s Dr Thomas: “A significant gap in understanding between payers and the industry still exists. I don’t think it will close. To some extent it is natural and healthy, but it is also a consequence of being in a fundamentally different business with different incentives.”



## Value and oncology: a different definition?

Oncology is the therapeutic area in which the value challenge is most acute. According to 41% of survey respondents and 50% of those from drug companies, it is the most difficult area in which to demonstrate value.

A major part of the problem is the high cost of many new medications in this field which, “from the payer perspective, have somewhat limited clinical benefits in that they extend life by three or six months,” says Dr Christopher-Paul Milne, associate director of the Tufts Centre for the Study of Drug Development at Tufts University in Boston, Massachusetts. This problem has been growing steadily: a 2009 study in the *New England Journal of Medicine* found that the median cost of cancer medication had increased more than 4.5 times in the preceding decade.<sup>1</sup> Payers understandably sometimes balk at the expense: in 2011 alone the National Institute for Health and Clinical Excellence (NICE) in the UK recommended that health authorities not reimburse for Bristol-Myers Squibb’s Yervoy for late-stage metastatic melanoma and Sanofi’s Jevtana for hormone refractory metastatic prostate cancer.

Value for money, however, is only part of the issue. Patricia Danzon, Professor of Health Care Management at the Wharton School of the University of Pennsylvania, explains that “there is a public

perception that cancer is different, not necessarily from all other diseases, but from run-of-the-mill ones. That makes it harder to say ‘no’ [to new treatments], which gets people into a discussion of how much clinical benefit new treatments need to demonstrate to justify reimbursement. This is a tough choice, because paying more for cancer care means less spending on other things.” The rejection of given treatments because of cost, however, opens up those who regulate formularies to accusations of passing death sentences.

Regulators are not unaffected by the higher value which societies seem to give to cancer treatments. Hervé Hoppenot, the president of Novartis Oncology, notes that “the acute nature of cancer for many patients—a disease that can kill them relatively quickly—makes the entire discussion with health authorities very different.” He adds that many accelerated approvals by drug regulators are in oncology.

Nevertheless, those in charge of health budgets are caught in a bind. Science may provide a solution where cost-benefit analysis leaves only painful dilemmas, says Mr Hoppenot. “There is a significant technological revolution happening in the way we understand cancer,” he explains that will help in gaining greater value from medications. The Economist Intelligence Unit article, “Cancer treatment and the search for value”, will look into how changing the way in which research on cancer is done can help with the value challenge in oncology.

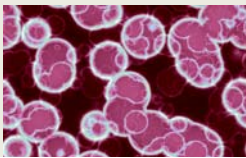
The split between providers and payers is only the beginning. Other studies point to differences in value perception among other groups, such as physicians, pharmacists and patients.<sup>2</sup> Nor is any one group a monolith. HTA bodies, for example, differ markedly in the information they require and in their behaviour.<sup>3</sup> Indeed, for drug companies, the biggest barriers in demonstrating value are the differences in the understanding of the term by stakeholder group (56%), medical condition (36%) and geography (33%).

Despite the inherent difficulties in improving how they address the notions of value of other businesses, traditional biopharmaceutical companies feel under pressure to do so, especially as they see payers and regulators of formulary access and approval gaining influence. Meanwhile, more biopharma respondents say their own market power has decreased in the last three years (41%, compared with 17% who say it increased).

1. Peter B Bach, “Limits on Medicare’s Ability to Control Rising Spending on Cancer Drugs”. *New England Journal of Medicine* (2009); 360:626-633.

2. Wertheimer A, Radican L, Jacobs MR, “Assessing different perspectives on the value of a pharmaceutical innovation”. *Southern Med Review* (2010) 3; 1:24-28.

3. O’Donnell JC, Pham SV, Pashos CL, Miller DW, Smith MD, “Health technology assessment: lessons learned from around the world—an overview”. *Value in Health* (2009 Jun); 12 Suppl 2:S1-5.

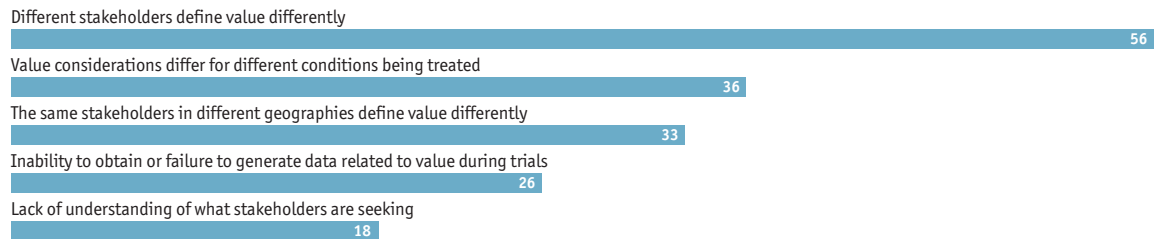


## Reinventing biopharma: Strategies for an evolving marketplace

The value challenge

### 3 Lack of clear definition of value is significant challenge for biopharma companies

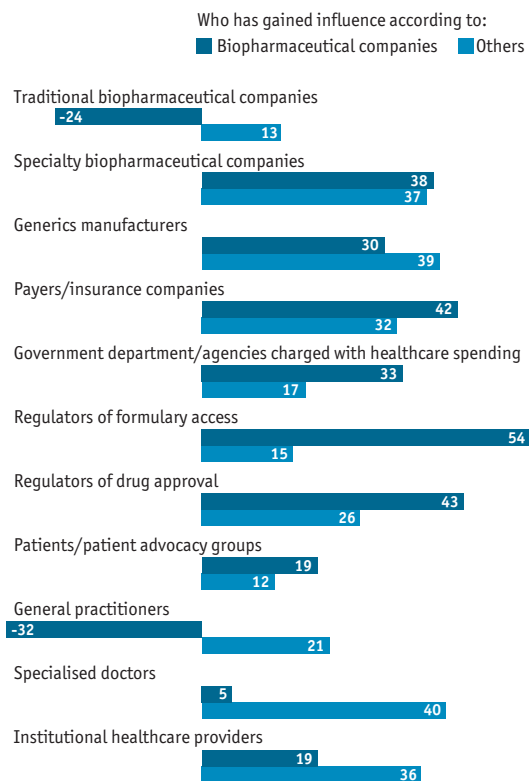
What are the biggest barriers to your company's efforts to demonstrate the value of its products?  
(% respondents)



Source: Economist Intelligence Unit survey, September 2011

### 4 Balance of power shifts in healthcare market\*

In your opinion, how has the influence of the following stakeholders on the type and price of products brought to market changed in the biopharmaceutical market in the past three years?  
(% respondents)



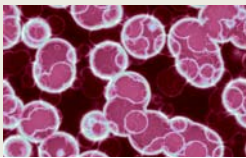
\* Percentages show the difference between the positive and negative responses for each group. For example, 41% of respondents from biopharmaceutical companies say their segment has lost influence and only 17% say it has gained influence, for a net negative 24%.

Source: Economist Intelligence Unit survey, September 2011

This is not the whole story, however. Other respondents may agree that a shift is occurring, but they do not see a marked decline in the power of biopharmaceutical companies (see chart 4). Dr Ed Pezalla, the national medical director for pharmaceutical policy and strategy at Aetna, explains: "The industry is still making decisions about what drugs come to market and what they can charge. It is just beginning to pay attention to payer sensitivity."

"Even within companies things are not changing as much as you might think," notes Dr Milne. "Some R&D people still say they don't consider what the marketing people are saying. On the payer side, they feel somewhat powerless to influence what is being produced or invented. That is a serious disconnect." The change, he feels, has been that biopharmaceutical companies are seeing some diminution in the extent to which they dominate the market. "They have trepidation about products earning return on investment because more things are out of their control."

It is a sign of the depth of the value challenge that biopharmaceutical companies are left worrying both about their ability to respond and their declining market power.



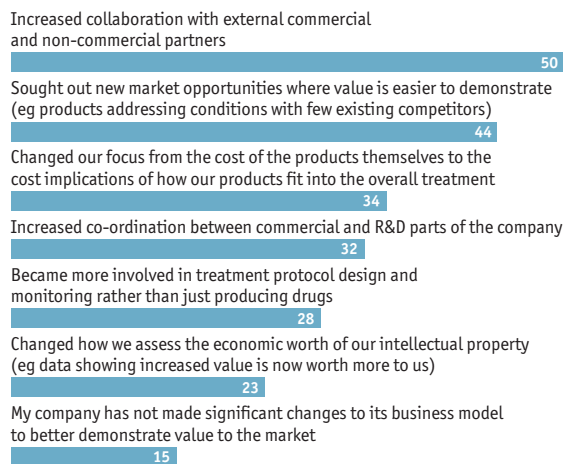
## Activity vs evolution: developing strategies for success

**F**aced with such uncertainty, life sciences companies are not sitting back: 85% have made at least one change to their business model, 78% to their commercial strategy, and 82% to their R&D strategy to improve their ability to demonstrate value. Similarly, over one-half report that the growing demand to provide value has had an important or significant impact on their business model (68%), as well as their strategies for drug discovery (58%), drug development (68%), trials (63%) and commercialisation (66%).

A closer look, however, suggests that many biopharmaceutical companies are searching for solutions in different parts of the company rather than converging on a new set of best practices. None of the numerous business model, commercial strategy or R&D changes covered in the survey is being pursued

### 5 Business model changes are under way, but there is no single winning strategy

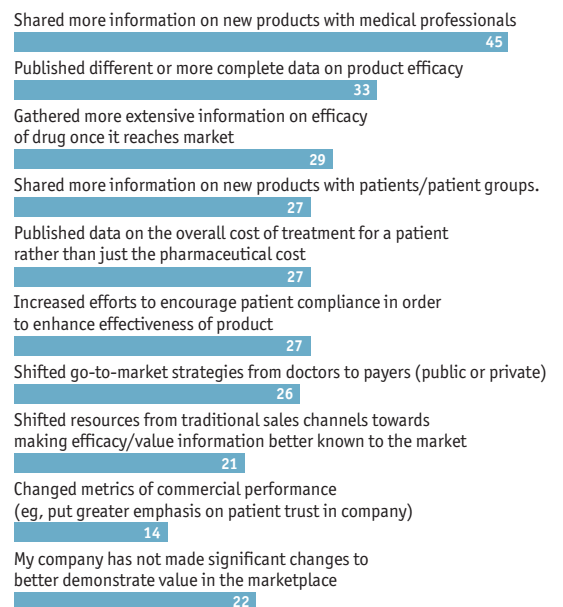
Regarding its go-to-market strategy, which of the following has your organisation done in the last three years in order to better demonstrate value to the market? (% respondents)



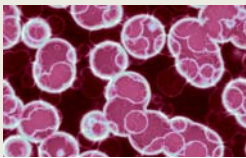
Source: Economist Intelligence Unit survey, September 2011

### 6 No clear path emerges for marketing strategies to prove value

Regarding its go-to-market strategy, which of the following has your organisation done in the last three years in order to better demonstrate value to the market? (% respondents)



Source: Economist Intelligence Unit survey, September 2011



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at a majority of companies. Moreover, the more popular strategies, such as greater collaboration with outside organisations, are already being pursued for other reasons, such as improved innovation.

This reflects an industry engaged in experimentation rather than thorough reform. Observing from the outside, Dr Pezalla notes that, while drug makers overall are getting better at providing value-related data: “It is not consistent across the industry, or even within a given company. It may depend on the particular marketing or R&D team.” More generally, Mr Russell believes that current efforts are insufficient. “Many players are aware [of the value challenge], but they haven’t evolved. Substantial change still has to take place,” he says.

“Many players are aware [of the value challenge], but they haven’t evolved. Substantial change has to take place.”

Angus Russell, Shire

**The value leaders**

If broad experimentation still leaves companies lacking confidence in their ability to address the issue, how do they need to evolve? Adapting to demands to produce and demonstrate value is a complex process and “involves changes on many different levels”, according to Dr Milne.

The survey shows that successful companies are moving in this direction: 17% of life sciences respondents benchmark their companies as above average at creating value in products, demonstrating value, and in overall financial performance.

These “value leaders” stand out in two ways. First, they work harder across the board on value issues. Fully 91% of this group report that the demand to provide value has had an important or significant impact on their overall business model, compared with 64% of the rest of the survey. This group is also more likely to have changed many elements of commercial and drug development and trial strategies to better demonstrate value (see charts 8, 9 and 10).

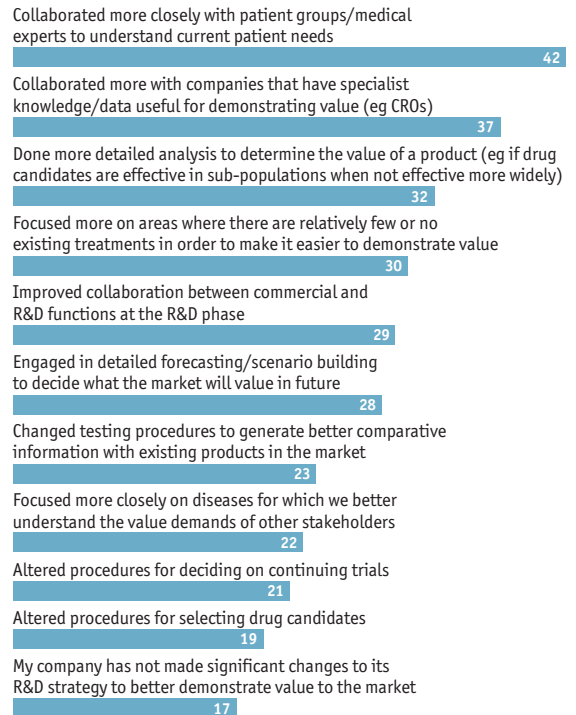
The second difference is that these changes are affecting the entire company, in particular R&D. In that function, value leaders are much more likely to be working to understand patient need, to analyse the potential value of a product and to change testing procedures to generate comparative information with existing products.

This is not merely more of the same—the whole trial process is being re-envisioned. Ms Burrell, who is overseeing the launch of Sanofi’s new MS drug, Teriflunomide, notes that “[in the last five years] the depth and breadth of evidence we feel we need to provide and the number of questions which we seek

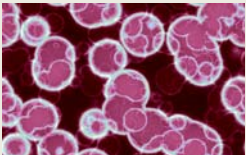
**7 R&D strategies become more collaborative in push to demonstrate value**

Regarding its R&D strategy, which of the following has your organisation done in the last three years to better demonstrate value to the market?

(% respondents)



Source: Economist Intelligence Unit survey, September 2011



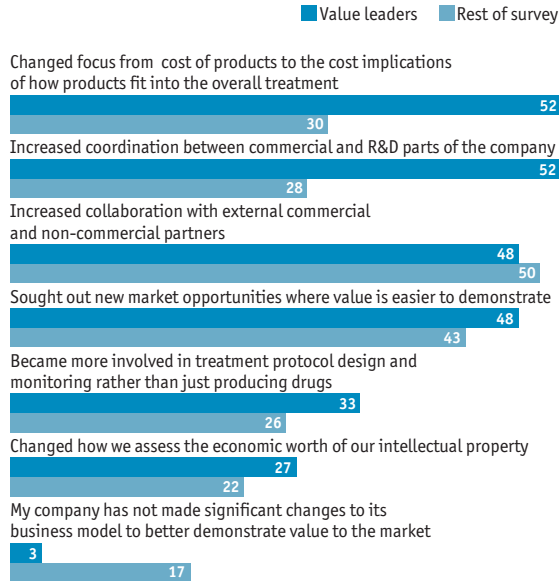
## Reinventing biopharma: Strategies for an evolving marketplace

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### 8 Value leaders change business models to better demonstrate value

Regarding its business model, which of the following has your organisation done in the last three years to better demonstrate value to the market?

(% respondents)

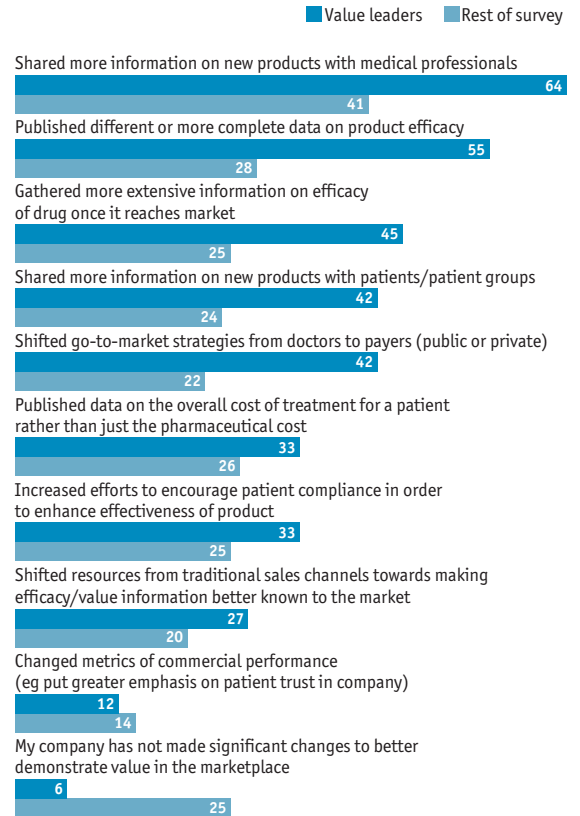


Source: Economist Intelligence Unit survey, September 2011

### 9 Value leaders change marketing strategies to better demonstrate value

Regarding its go-to-market strategy, which of the following has your organisation done in the last three years to better demonstrate value to the market?

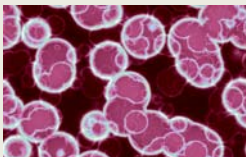
(% respondents)



Source: Economist Intelligence Unit survey, September 2011

to answer has increased exponentially". The Teriflunomide trials, for example, started by exploring implications from the client perspective. Understanding patients' needs required building up a greater understanding of what it is like to live with MS, how patients differ and how they interact with the healthcare system. The trials therefore have examined both clinical and other outcomes, such as the effect on time spent in hospital, emergency room visits and overall fatigue levels, as well as the tendency to continue medication—which is particularly relevant since, unlike most MS treatments, Teriflunomide is an oral drug (injectables are often abandoned by patients within a year). "We put in the clinical study the standard things," adds Ms Burrell, "but we also wanted to put in the things [about quality of life] that would make sense to the physician and the payer."

Interaction with outside stakeholders is also undergoing change. Shire, which has restructured its entire business model around the need to create and demonstrate value [see box], seeks to consult holistically with what it calls the "circle of value": physicians, patients, payers and policymakers. According to Mr Russell, the industry needs to increase discussions with the latter two in particular. To do so, his company has begun to establish formal advisory boards of payers to help assess potential value.



## Reinventing biopharma: Strategies for an evolving marketplace

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Perhaps the biggest internal change, though, is the removal of silos within the company so that value considerations can feed through consistently. Better co-ordination between the R&D and commercial functions sets value leaders apart from other companies. The market demand to produce goods of greater value has had an important or significant effect on this co-operation for 82% of value leaders, compared with 61% among other respondents. More striking, over one-half of value leaders (52%) have adjusted their business models to improve such co-ordination, compared with just 28% of others.

Dr Thomas describes how Janssen is doing this. The company has restructured its market access function, giving it responsibility for pricing, health economics and monitoring patient-reported outcomes. At the regional level, many of Janssen's operating companies have merged the regulatory and reimbursement functions. Both changes were designed to improve co-ordination in order to demonstrate value better. Just as important, Dr Thomas says that his department now has "tight linkages with R&D to make sure our compound market access leaders have a visible presence on all the decision-making bodies that prioritise product strategy".

"[This has] dramatically changed R&D over a fairly short period of time," he adds. "Our R&D organisation has developed a fairly solid understanding of payer value. Clinical evidence and regulatory hurdles are still crucial, but equally important are commercial considerations that products will meet other thresholds of acceptability. Our target profiles have a clear section on what the required evidence for payers will be. We have the value question as a critical piece of decision-making. That is a huge departure from three to five years ago."

As companies learn to meet the value challenge, the actions of value leaders illustrate that success will require scrutiny of operations across the entire organisation.

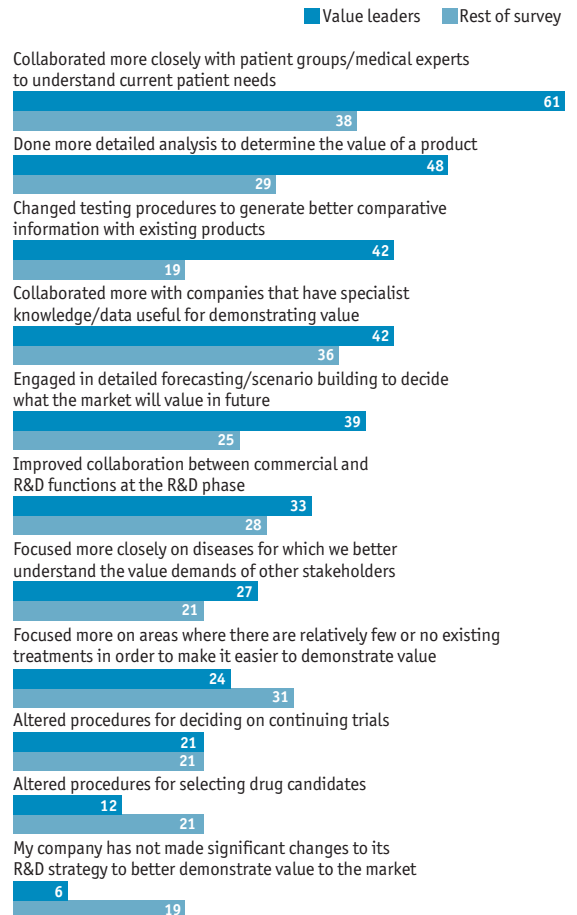
"We have the value question as a critical piece of decision-making. That is a huge departure from three to five years ago."

*Adrian Thomas, Janssen*

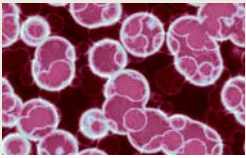
### 10 Value leaders have more aggressively adapted their R&D strategies to demonstrate value

Regarding its R&D strategy, which of the following has your organisation done in the last three years to better demonstrate value to the market?

(% respondents)



Source: Economist Intelligence Unit survey, September 2011



## Conclusion: Meeting the value challenge

**B**iopharmaceutical companies know that they have to change how they find, measure and demonstrate value. They lack confidence in their ability to do so, however. Without a single definition of value to guide their strategies, and conscious of detrimental shifts in market power, companies have not yet identified best practices in facing the value challenge.

One-off measures are insufficient. Companies should make comprehensive changes across the organisation that will allow them to:

- **Understand what the market wants and needs.** Payers, patients, regulators and drug makers define value differently. Determining what is of value to the patient, and to the payer, is the first step to successfully meeting the value challenge. Dialogue and collaboration with outsiders, however, is not enough. Internal structures and processes must be changed to use this information as valuable input for R&D and commercialisation decisions.
- **Pursue a value-based R&D strategy.** The biggest qualitative differences between value leaders and other companies are greater co-ordination between the R&D and commercial functions, and a greater focus in the former on understanding patient needs. This in turn changes the R&D process dramatically, from the nature of trials to decisions on which leads to pursue.
- **Then shape your go-to-market strategy.** Addressing the value challenge is not simply about proving that a company's products have clinical benefits that other stakeholders just do not see. It is about using data generated from a value-conscious R&D process that shows how these products will meet the needs of patients and payers. As with any industry, the consumers may not be aware of those needs ahead of time, but they will recognise innovative solutions when they see them.

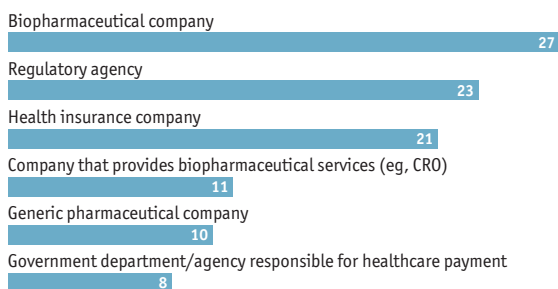
Such measures may entail significant change, but the advantages are substantial. Simply being above average at value creation and demonstration correlates with above-average financial performance, the survey shows. Moreover, these changes may help restore the shaken self-confidence of the sector. Value leaders not only deliver better results, they are also more confident that the biopharmaceutical industry as a whole is doing well in adjusting to increasing demands for proof of value (67% to 44%). By facing the value challenge head-on, the life sciences industry can regain its momentum.

## Appendix: Survey results

Percentages may not add to 100% owing to rounding or the ability of respondents to choose multiple responses.

### Which of the following best describes your organisation?

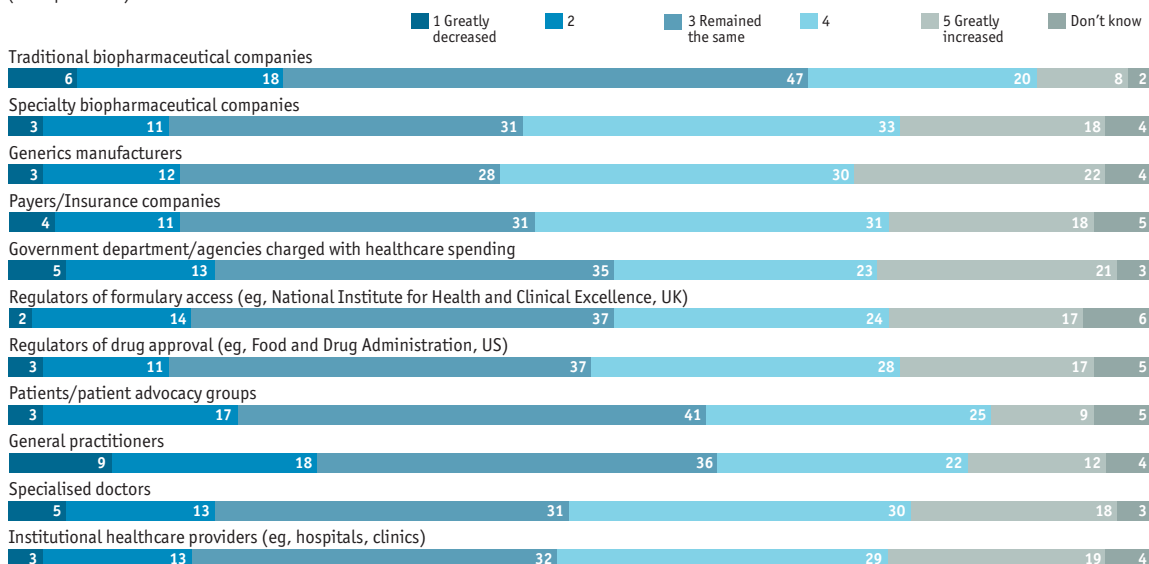
(% respondents)



### In your opinion, how has the influence of the following stakeholders on the type and price of products brought to market changed in the biopharmaceutical market in the past three years?

Rate on a scale of 1 to 5, where 1=Greatly decreased and 5=Greatly increased

(% respondents)

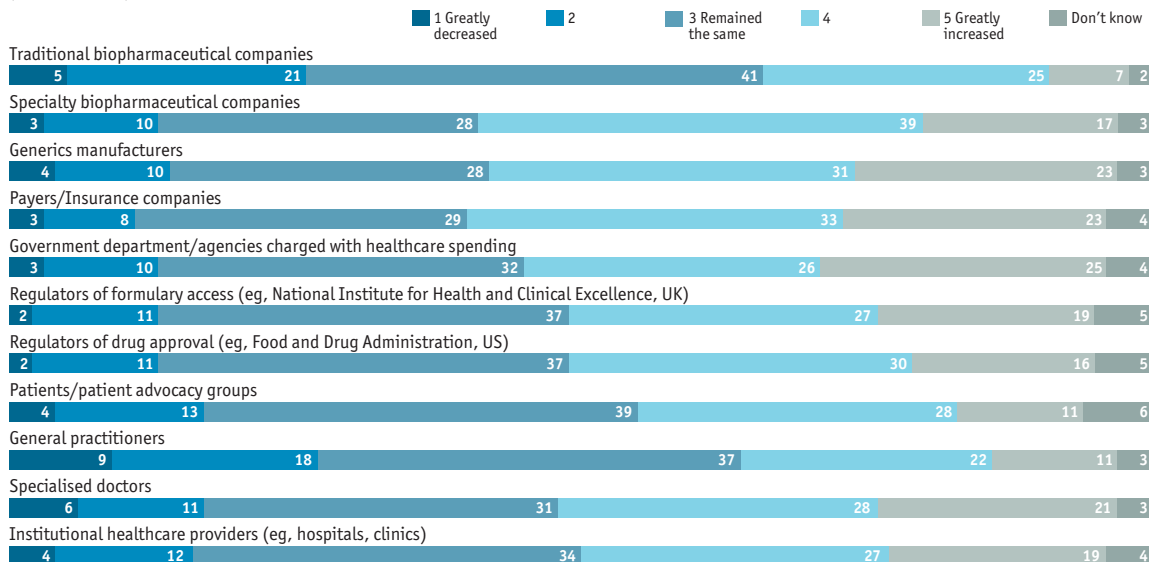


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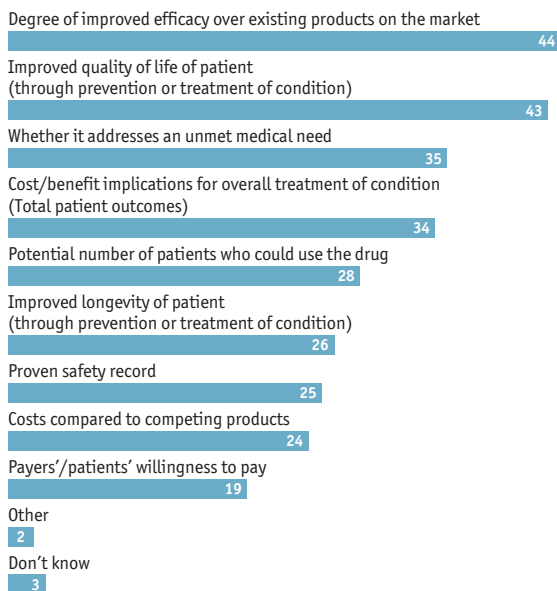
**In your opinion, how will the influence of the following stakeholders on the type and price of products brought to market change in the biopharmaceutical market in the next three years?**

Rate on a scale of 1 to 5, where 1=Greatly decreased and 5=Greatly increased  
(% respondents)



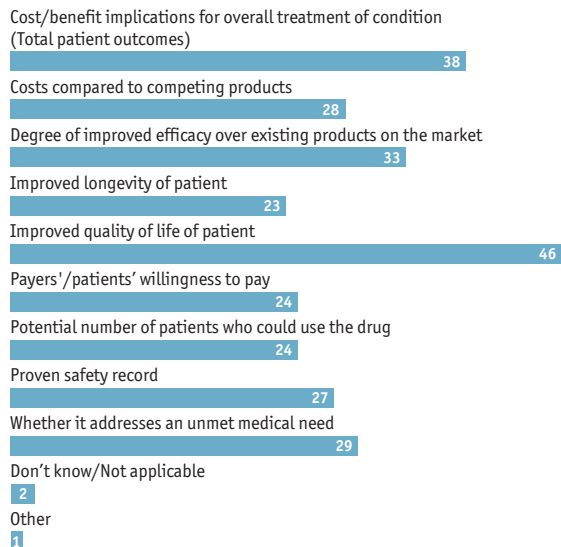
**Which of these factors have the greatest influence on how your organisation currently assesses the value of a new drug?**  
Select top three.

(% respondents)



**In the next three years, which, if any, of these attributes will become significantly more important in your assessment of value of a new drug?**  
Select top three.

(% respondents)



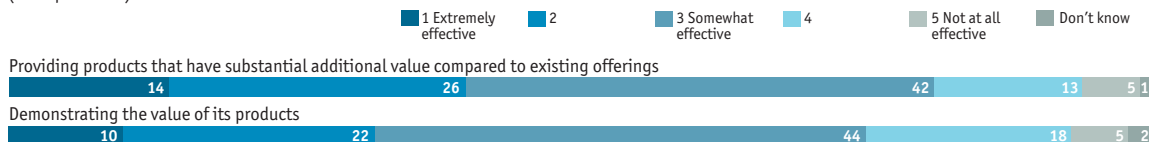
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**How effective is the biopharmaceutical industry today in the following:**

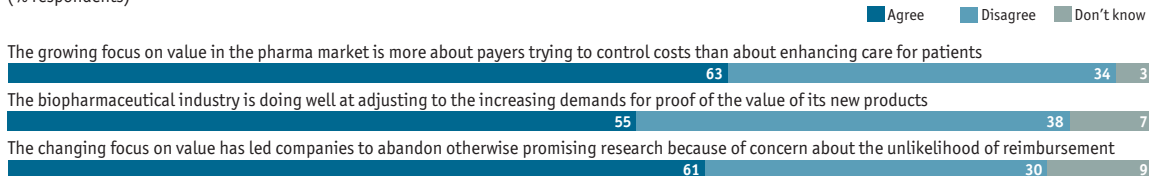
Rate on a scale of 1 to 5, where 1=Extremely effective and 5=Not at all effective

(% respondents)



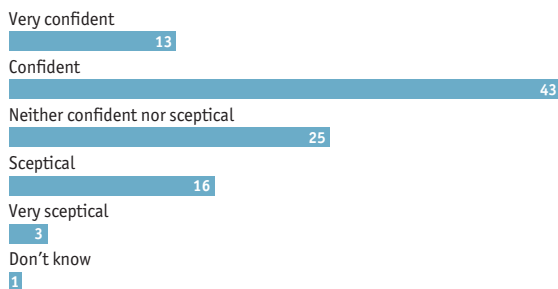
**Do you agree or disagree with the following statements?**

(% respondents)



**How confident are you that the biopharma industry will bring to market products with demonstrably more value than existing ones in the next three years?**

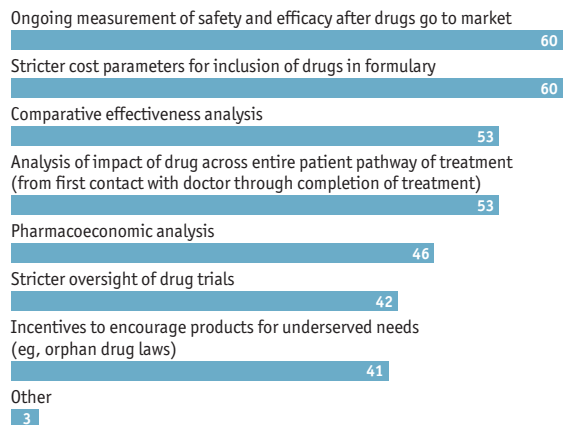
(% respondents)



**Which measures/policies does your organisation consider a priority to improve the value of drugs being brought to market?**

Select all that apply.

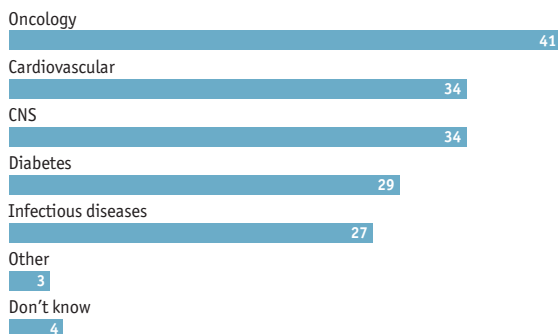
(% respondents)



**For which of the following therapeutic areas is it most challenging to demonstrate value?**

Select top two.

(% respondents)



**To what extent is the way your organisation thinks about value affected by attitudes or measures adopted by regulators/payers in other countries?**

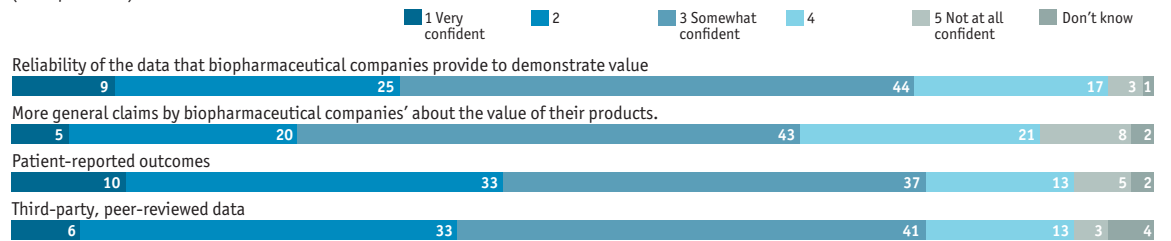
(% respondents)



**How confident are you about the following?**

Rate on a scale of 1 to 5, where 1 = Very confident and 5 = Not at all confident

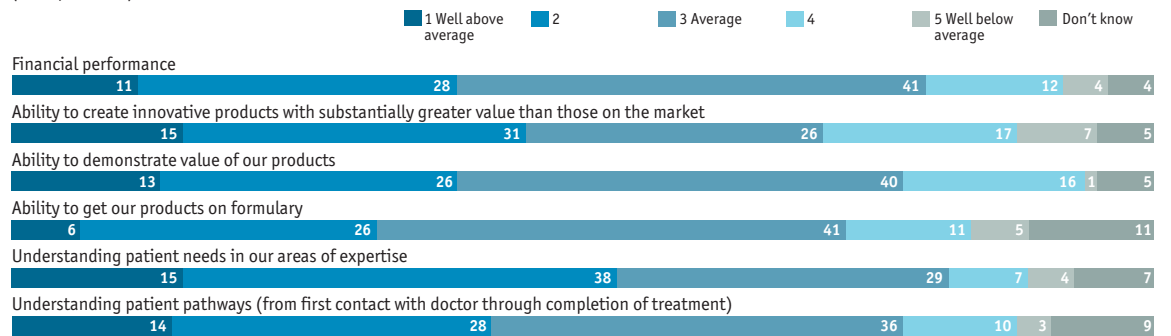
(% respondents)



**Compared with other biopharma companies, how does your company perform in the following areas?**

Rate on a scale of 1 to 5, where 1=Well above average, 3=Average, and 5=Well below average

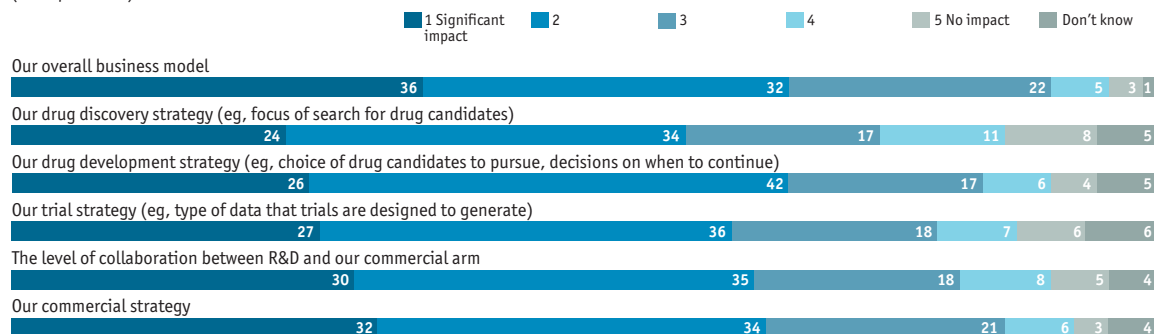
(% respondents)



**To what degree have growing demands to provide value in the pharmaceutical market affected the following:**

Rate on a scale of 1 to 5, where 1=Significant impact, and 5=No impact

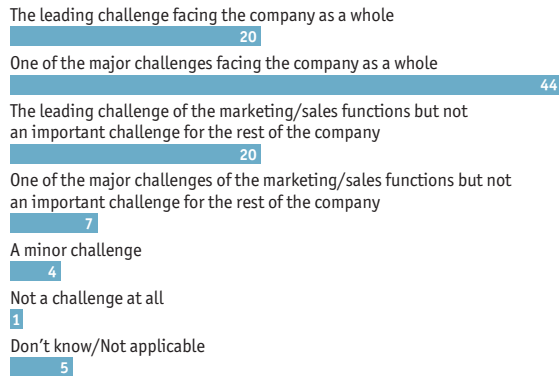
(% respondents)



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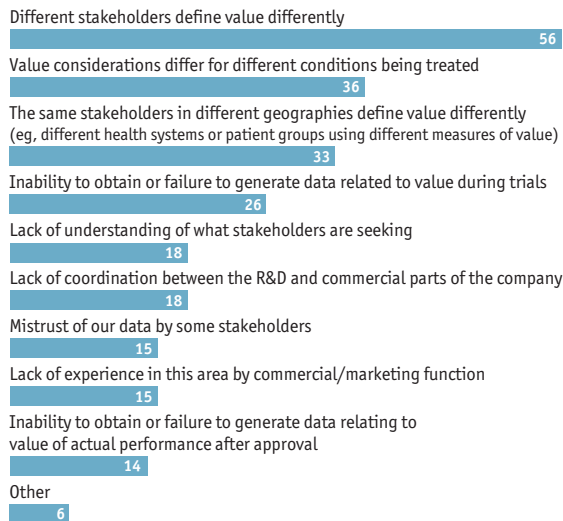
The value challenge

**Which of the following best describes the challenge of demonstrating the value of your products in current markets? The challenge of demonstrating the value of our products is ...**  
(% respondents)



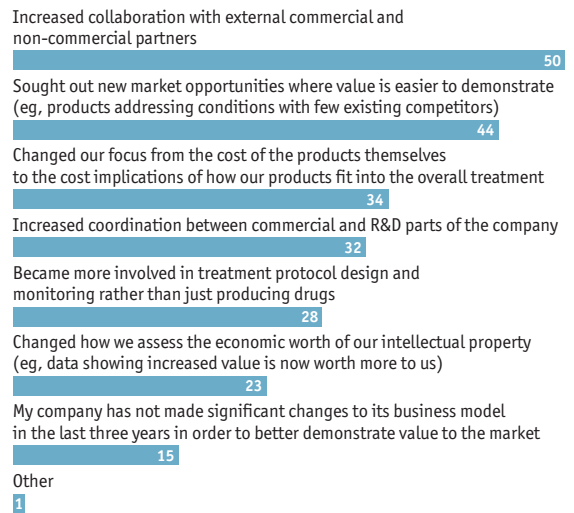
**What are the biggest barriers to your company's efforts to demonstrate the value of its products?**

Select up to three.  
(% respondents)



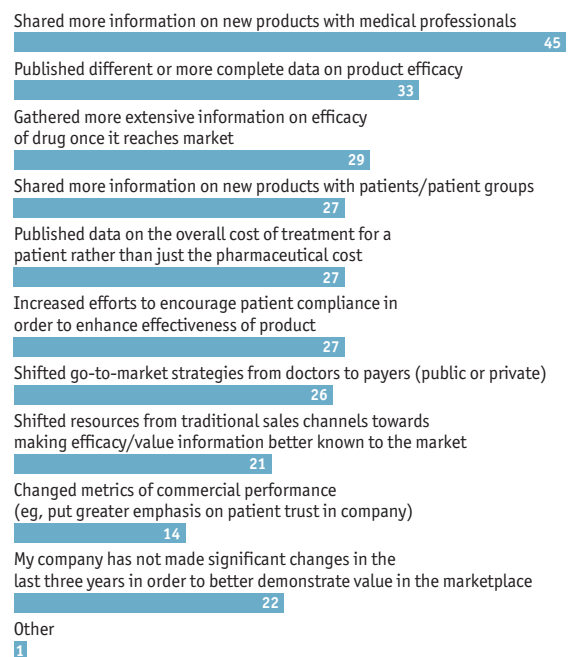
**Regarding its business model, which of the following has your organisation done in the last three years in order to better demonstrate value to the market?**

Select all that apply.  
(% respondents)



**Regarding its go-to-market strategy, which of the following has your organisation done in the last three years in order to better demonstrate value to the market?**

Select all that apply.  
(% respondents)

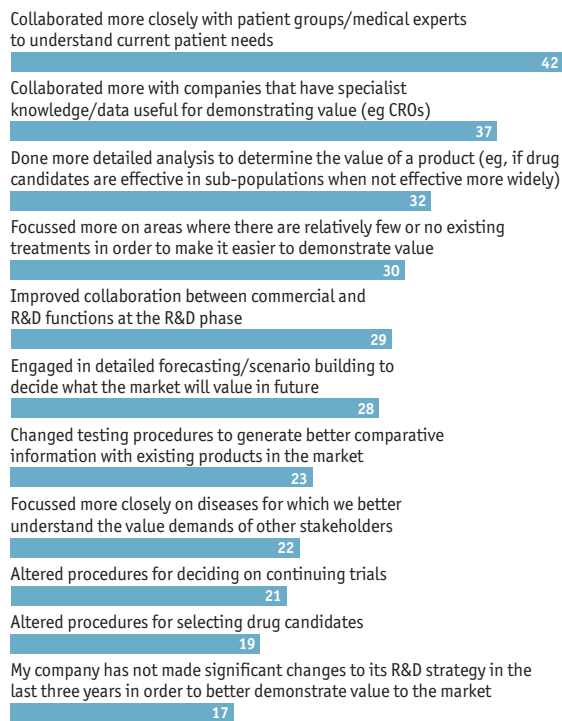


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The value challenge

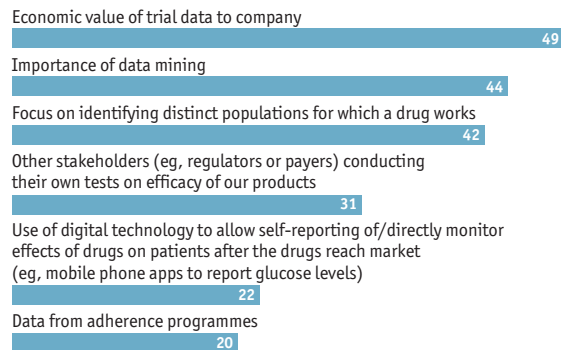
**Regarding its R&D strategy, which of the following has your organisation done in the last three years to better demonstrate value to the market?**

Select all that apply.  
(% respondents)



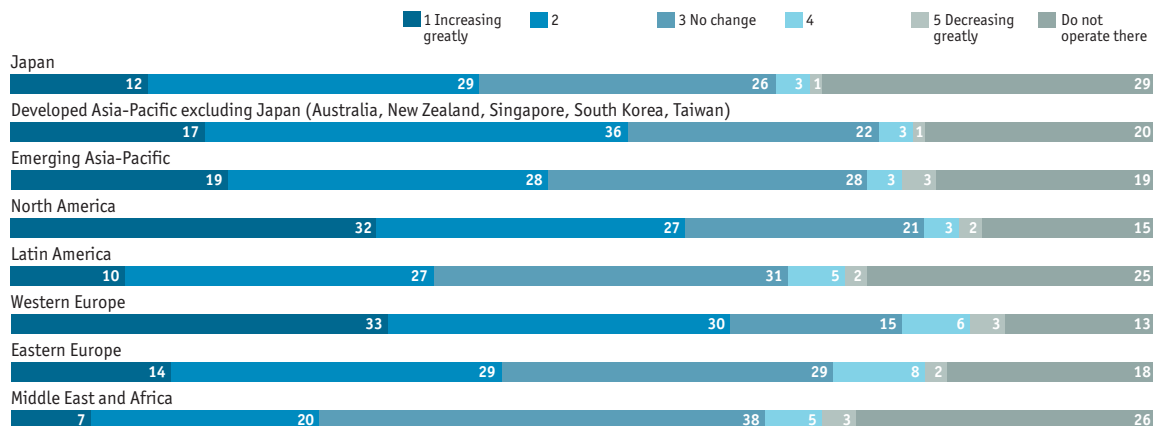
**Has growing demand for demonstrable value made any of the following significantly more important for your organisation?**

Select all that apply.  
(% respondents)



**In the markets in which your company operates, how is the importance of demonstrating value changing?**

Rate on a scale of 1 to 5, where 1=Increasing greatly and 5=Decreasing greatly  
(% respondents)



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**Do you agree or disagree with the following statements?**

(% respondents)

Agree Disagree Don't know

Given my company's ability to demonstrate value, value-based pricing is more of an opportunity than a threat for us	55	34	11
Whatever other changes the growing focus on value may have brought about, it has not fundamentally altered the way we develop our products	42	28	29
Whatever other changes the growing focus on value may have brought about, it has not led us to fundamentally change our business model	37	35	28
The growing focus on value has led us to focus more on the cost implications of how our products fit into overall treatment, rather than the costs of the products themselves	53	35	12
The need to demonstrate value of new products has led my organisation to stop development of drugs whose value might only appear in the long term, such as by changing treatment practices	29	42	29

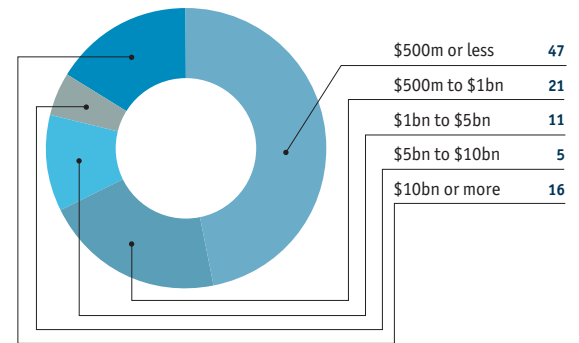
**In which country are you personally located?**

(% respondents)

United States of America	28
Germany, India	7
United Kingdom	6
Spain	5
Switzerland	4
Philippines, Australia, Canada, Sri Lanka, United Arab Emirates, Malaysia	3
Denmark, France, Singapore, China, Hong Kong, Hungary	2
Japan, Mexico, Norway, Brazil, Finland, Italy, Belgium, Colombia, Egypt, New Zealand, South Africa, Argentina, Austria, Indonesia, Netherlands, Sweden	1

**What are your company's annual global revenues in US dollars?**

(% respondents)



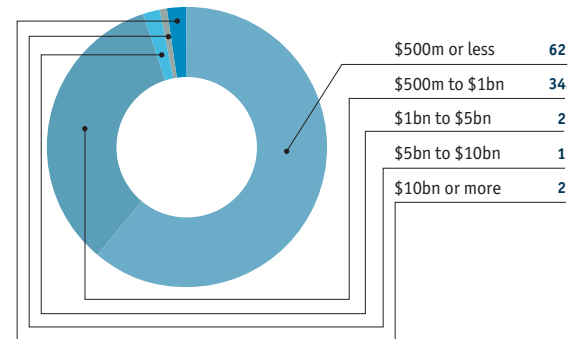
**In which region are you personally based?**

(% respondents)

Western Europe	32
North America	31
Emerging Asia-Pacific	19
Developed Asia-Pacific excluding Japan (Australia, New Zealand, Singapore, South Korea, Taiwan)	6
Middle-East and Africa	5
Latin America	4
Eastern Europe	2
Japan	1

**What was the size of your organisation's budget in US dollars for the last fiscal year?**

(% respondents)

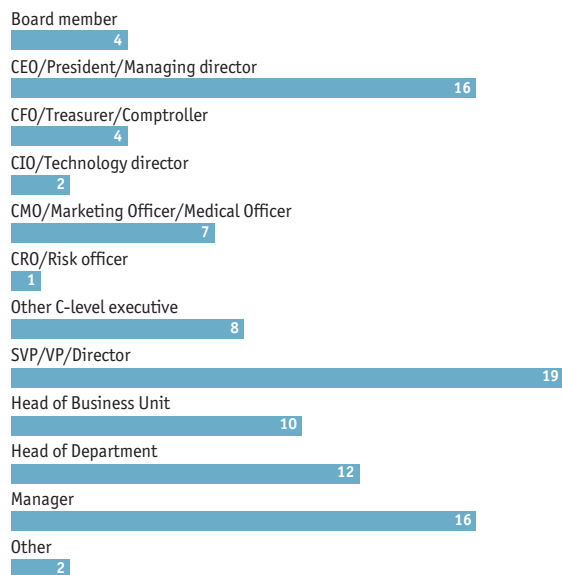


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**Which of the following best describes your title?**

(% respondents)



**Which of the following best describes your title?**

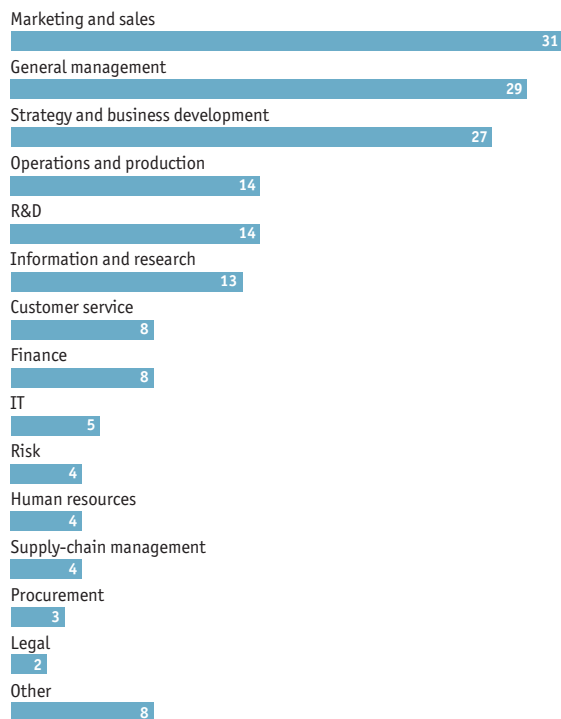
(% respondents)



**What are your main functional roles?**

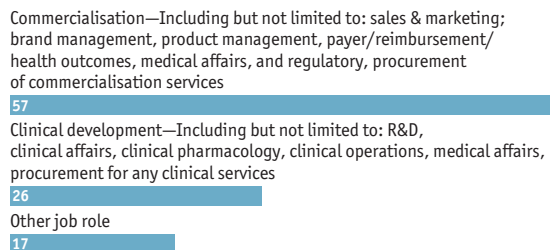
Select up to three.

(% respondents)



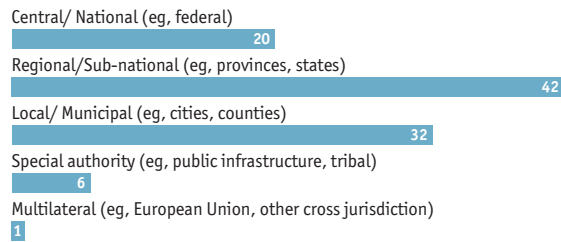
**Which of the following best describes your primary job role?**

(% respondents)



**What is the scope of your authority (jurisdiction)?**

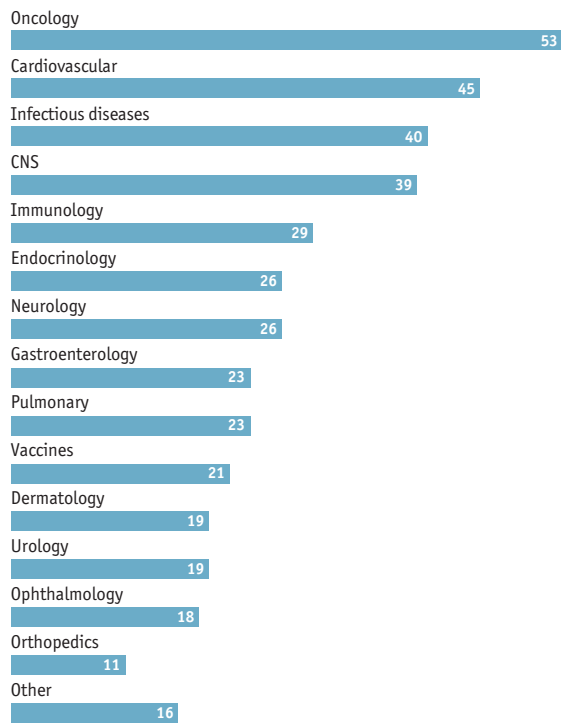
(% respondents)



**Which therapeutic areas is your organisation active in?**

Select all that apply.

(% respondents)



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