



cutting through complexity

Growing the pipeline, growing the bottom line

**Shifts in pharmaceutical
R&D innovation**

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CONTENTS



Page
4

The great
research challenge



Page
8

Organizational
barriers to
innovation



Page
6

A new era in R&D?



Page
12

Five ways to
enhance R&D
innovation



Page
15

About the survey



Page
14

How KPMG
can help

The great research challenge

As spending on pharmaceutical research and development (R&D) continues to soar, executives, shareholders, and analysts alike are entitled to ask: what value are we getting for our investment?

The pharma sector invests more money in research than any other industry, with five of the world's 10 highest R&D budgets belonging to drug companies¹. Between 2004 and 2013 the total industry expenditure on R&D rose from USD88 billion to USD135 billion, and is forecast to reach USD149 billion by 2018².

Yet in the same time period, the estimated cost of bringing a new chemical or biological product to market has more than trebled from USD451 million to USD1.5 billion³. Meanwhile, the average number of annual US Food and Drug Administration (FDA) approvals for new molecular entities (NMEs) – a good directional indicator of innovation – fell from 31.5 in 1990 to an average of just 22.9 from 2001-2010⁴.

Nevertheless, there are signs of an upturn in approval rates, with the average annual NME figures for the years 2011-2013 rising to 32⁵. But is this enough evidence to suggest that pharmaceutical players are starting to turn the corner on innovation in drug development?

To explore this question further, KPMG sought the perspective of senior executives from the R&D departments and R&D support functions of some of the world's leading pharmaceutical companies. Their responses cover a range of critical issues such as productivity, attitudes to risk, organizational structure, and governance, and offer some valuable ideas for increasing innovation to feed the pipeline of new products.

I would like to thank all those that gave their valuable time to assist with this paper. As always, we look forward to supporting you as you adapt your own approach to innovation in our sector.

Chris Stirling

Global Chair, Life Sciences
KPMG International

Exchange rate and margin adjusted data on R&D spend from 2003-2013



Source: KPMG estimates, 2014

¹EU R&D Scoreboard, The 2013 EU industrial R&D investment scoreboard, Brussels: European Commission, Joint Research Centre, 2013.

²World Preview 2013 Outlook to 2018, EvaluatePharma, June 2013.

³The R&D cost of a new medicine, J. Mestre-Ferrandiz, J. Sussex and A. Towse, Office of Health Economics, December 2012 (Hansen, 1979; Wiggins, 1987; DiMasi et al, 1991; OTA, 1993; DiMasi et al, 2003; Mestre-Ferrandiz et al, 2012).

⁴FDA official figures, FDA website, accessed 14 March 2014.

⁵IBID.



Our survey results tell us that...

- ...innovation is on the rise in companies after a decade of decline
- ...the trend toward increased outsourcing and collaboration is set to continue, with a shift in emphasis from pure cost-saving to accelerated innovation
- ...administration and organizational complexity is preventing scientists from devoting time to research and is holding back progress in R&D
- ...companies are still struggling to determine their appetite for risk; some research decisions are made too subjectively, while others struggle from excessive caution and over-analysis.

A new era in R&D?

Pharma executives believe their companies are enjoying a resurgence in innovation

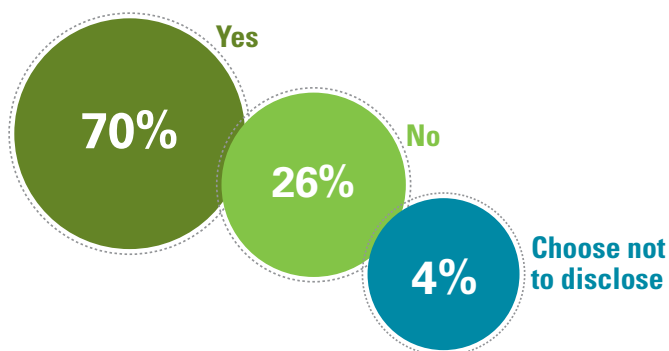
Although many established blockbusters have fallen off the 'patent cliff,' there is still an urgent need for fresh sources of revenue. The rise in FDA and EMA new molecular entity approvals in the past few years has sparked renewed hope in the industry's ability to come up with exciting, novel drugs – optimism echoed in the responses to our questions. The majority of executives surveyed by KPMG member firms are confident that innovation is on the rise in their organizations, and over half say they are satisfied with their portfolio's ability to address unmet medical needs.

Arguably, regulatory authorities have helped this revival by cutting back on red tape to simplify and speed up the approval process, particularly where therapies for serious diseases are concerned. The higher figures may also reflect the industry's concerted effort to improve productivity and gain a better return on investment.

“According to a senior executive at a global pharma company, his organization's approach for enhancing innovation involves:

“...successfully selecting and translating scientific breakthroughs to address unmet medical needs.”

My company is enjoying a resurgence in innovation



Source: KPMG's Global Life Sciences Research & Development Survey, 2013

Technology at the heart of change:

The use of data and technology is crucial to capturing and interpreting product information as it passes through the development process. An innovative technology company, already working with one of the top pharmaceutical companies, has been using a new platform to do exactly this.

It helps companies define and quantify value metrics for treatments - at the beginning of the R&D process, and enables the company to continuously assess a product against these metrics, throughout its development.

Partnerships and outsourcing are leading the way in change

One notable trend is the move to forge stronger alliances with universities, with some companies moving their R&D headquarters closer to university sites to promote collaboration and enhance the scientific dialogue.

The most notable recent partnerships include⁶:

Partnership	Description
Sanofi and the University of California, San Francisco	In January 2012, UCSF and Sanofi announced they would work together in a USD3.1 million pilot project to identify drug targets for both type 1 and type 2 diabetes.
Johnson & Johnson (J&J) and the University of Queensland	In February 2012, the Australian University and the Queensland's Institute for Molecular Bioscience (IMB) entered a collaborative research agreement with J&J to develop components of spider venom that may be effective as a pain treatment.
Pfizer, Lilly and Merck with the University of Hong Kong and the National University of Singapore	In 2010, Eli Lilly, Merck and Pfizer announced their commitment to launch a research group in Asia focusing on new therapies and diagnostics for Asia's most common forms of cancer. The Asian Cancer Research Group (ACRG) is currently focusing on lung, gastric and liver cancers.
AstraZeneca and the University of Cambridge	In July 2013, AstraZeneca signed an agreement with the University of Cambridge and Cancer Research UK for a 2 year collaboration on three pre-clinical and clinical oncology projects. The collaboration follows AstraZeneca's announcement that by 2016, its new UK-based global research and development centre and corporate headquarters will be located at the Cambridge Biomedical Campus.
Novo Nordisk and the University of Oxford	In April 2012, Novo Nordisk and Oxford University teamed up to develop novel treatments for rheumatoid arthritis and other inflammatory diseases.

In addition to partnerships, KPMG member firms are seeing the trend toward asset swaps, carve outs, and transaction collaborations across the industry in an effort to spread risk and reduce R&D investment. There is also a rise in R&D licensing, as well as outsourcing to Contract Research Organizations (CROs).

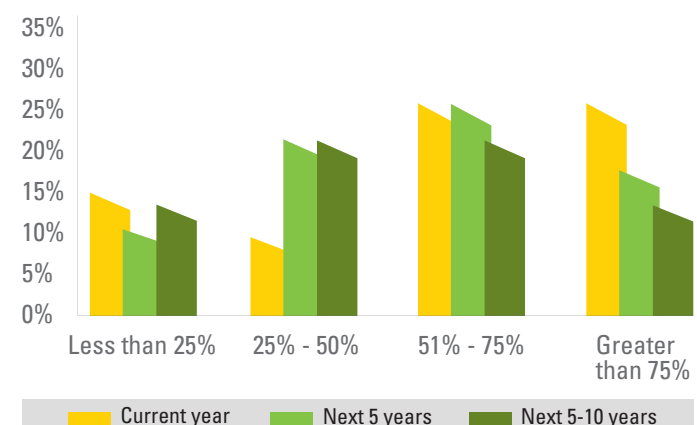
Although preclinical and clinical trial activity has been outsourced for some time, companies are now starting to contract drug research and registration work. The global drug discovery outsourcing market (including early stage R&D) has been growing at an annual rate of about 10 percent between 2008 and 2013. Currently, outsourcing accounts for around USD13 billion per year, close to 10 percent of total global pharmaceutical R&D spend. This figure is forecast to double to USD25 billion by 2018⁶. Close to 40 percent of the estimated USD51 billion spent on clinical development in 2013 was outsourced⁷.

Outsourcing is clearly on the agenda for the executives canvassed by KPMG. Although 52 percent say they currently spend over half their total R&D budget in-house, this proportion is expected to fall to 35 percent in the next 5-10 years.

A physician at a leading global pharma company was recently

quoted at a conference saying: "Good science is more important than the specific source of R&D," implying that pharmaceutical companies should not worry about losing complete 'ownership' of the research process.

Share of R&D allocated in-house



Source: KPMG's Global Life Sciences Research & Development Survey, 2013

⁶The New Trends of Global Drug Discovery Outsourcing 2013, Research and Markets report, September 2013.

⁷Quintiles talks R&D spend and outsourcing trend in Second Public Offering, Outsourcing – pharma.com, 10 March 2014.



Despite the resurgence
in innovation, there are
still organizational
**barriers to
innovation**

Executives believe excessive administrative duties for scientists are hindering R&D potential

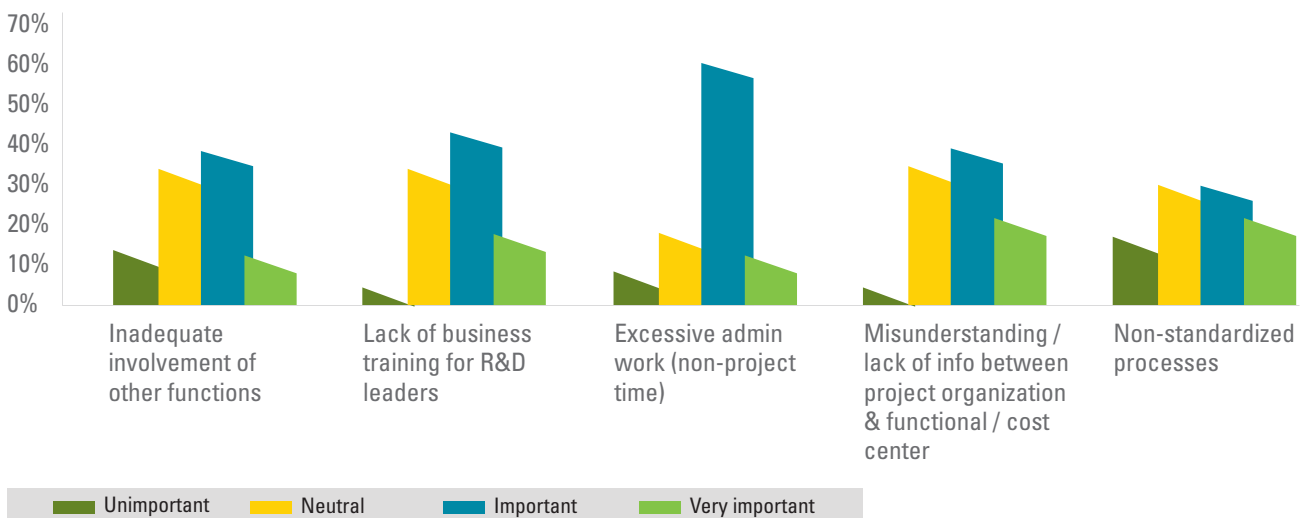
Given the tremendous budgets and human resources allocated to R&D activities, pharmaceutical companies are understandably keen to monitor their expenditure through strong governance and controls. There is, however, a danger of over-managing the process and stifling creativity.

KPMG findings suggest that scientists are being sidetracked by bureaucracy in the form of project management, scheduling, and other non-research duties. Seventy-two percent of those taking part in our study claim that excessive administrative work is a major challenge to the effectiveness

of R&D. As pharmaceutical businesses grow more complex to keep pace with rapid changes in the global healthcare landscape, this problem is likely to be exacerbated in the years ahead.

Other aspects of organizational life are also proving a handicap. Less than two out of 10 respondents are satisfied with the speed of decision making, indicative of an over-complicated approval process, with decisions often made by layers of management and committees.

What are the main barriers to successful R&D?



Source: KPMG's Global Life Sciences Research & Development Survey, 2013

Eli Lilly's Chorus: An alternative approach to traditional R&D sourcing

In an effort to transform the drug development process through a lean approach, Eli Lilly and Company have created Chorus, an early phase drug development group that operates as an autonomous division, supported by a 100 percent outsourcing model.

Chorus has a small in-house team of drug development experts that are empowered with their own budgets, with no reporting lines to functional groups. Clinical trials and functional operations use a streamlined set of standard operating procedures and business processes.

Over time, Chorus has significantly reduced the time and cost of drug development, increasing R&D productivity. The division is used by Eli Lilly as an alternative way to move molecules through the early phase pipeline – from discovery to proof of concept – and now manages a significant portion of the company's R&D portfolio.

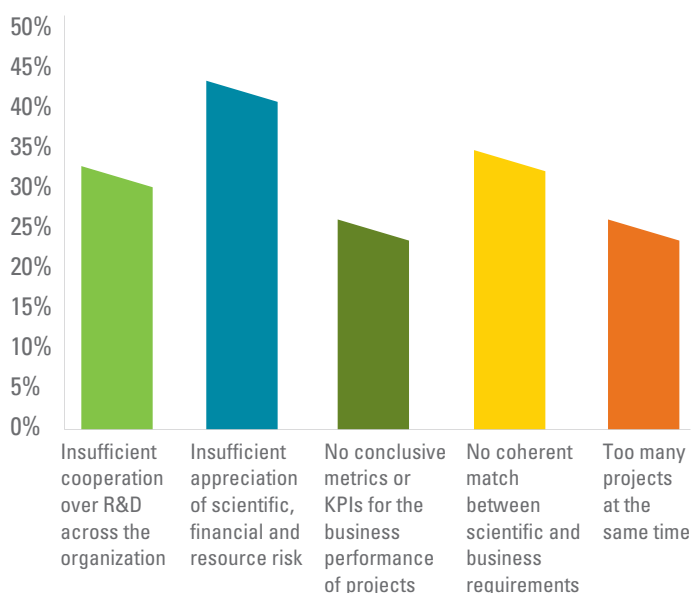
Source: <http://www.choruspharma.com/about-us.html>

One of the main challenges to productivity is managing risk without restricting innovation

As the price of failure places more and more at risk, there is a strong temptation to make more conservative research choices that may limit the prospects of discovering genuine 'breakthrough' compounds. Research decisions are driven from the top down, by defined therapeutic areas, which may limit the capacity for new drug discoveries. Similar motivations may also drive project teams to conduct additional testing on molecules that have only demonstrated marginal benefits. Both of these drivers increase the time and cost of R&D.

Despite a perceived increase in checks and balances, more than four in 10 of the respondents surveyed feel their organizations still lack a sufficient appreciation of the scientific, financial, and personnel resource risks they face. This can negatively impact productivity by reducing the accuracy of forecasts for investment capital and cash, resources, and ultimately, sales volumes. Indeed, only 34 percent of the executives in our survey feel satisfied with the accuracy of scientific planning and forecasting.

What are the main challenges to productivity?



Source: KPMG's Global Life Sciences Research & Development Survey, 2013

“When asked what else was influencing R&D productivity, one senior R&D executive said: **“The core challenge of R&D is about attracting and retaining scientific talent.”**”





Perhaps more worrying is the additional time frequently devoted to assessing and testing, which does not necessarily result in better informed choices. Of the executives polled, just over half say that one of the main obstacles to R&D transparency is subjectivity in project decision making. In the absence of definitive data from reliable modeling tools, the opinions of the most powerful and influential project leaders, rather than a systematic approach to a variety of scientific and commercial factors, may impact project choice.

The growth of value-based pricing – where payers and pharma companies agree to link payment for a medicine to value achieved for the patient – could help focus research more sharply on the genuine clinical and commercial potential of new compounds.

By involving regulators at an earlier stage in the R&D decision-making process, companies can better demonstrate how their research will satisfy unmet medical needs (where patients may have no medical alternatives). Such evidence could help speed up the approval process without compromising high standards of safety and efficacy.

Recruiting and retaining talent

At the heart of ‘good science’ are ‘good researchers’. Recruiting world-class scientists to work in the pharmaceutical industry is an ongoing challenge for R&D leads. Retaining them once recruited is even harder. This sentiment resonated throughout the comments made by executives who completed our R&D survey.

As we have seen, traditional R&D facilities can stifle innovation through excessive administration and risk aversion. These environments are unattractive to scientists who want the freedom to explore research opportunities without commercial pressures. Going forward, pharmaceutical companies will need to develop and maintain research environments that attract scientists and engage them for the duration of their career.

How should companies enhance R&D innovation?



Strategy

1 Balance governance and administrative burdens with the size and complexity of the project

Scientists want to practice science, so companies need to provide adequate space to engage in genuine research with minimal bureaucratic obligation. Designing a lean governance and project management function, where the scrutiny of projects is aligned to the cost and return on investment, can help to alleviate the unnecessary strain of a 'one-size-fits-all' approach, improve decision making, and support scientists to focus on the discovery of breakthrough innovations.

2 Strengthen collaboration and adapt the R&D model to support innovation across networks

Many pharmaceutical companies have already embraced the need to collaborate with external partners. Getting the most out of a collaborative partnership will require proper joint development that will lead to licensing agreements earlier in the product development process.

The ongoing opportunity is to deepen collaborations, harness the variety of skills across the network, and enhance the understanding of unmet medical needs. This requires companies to continue to promote an 'open' culture that encourages scientific dialogue and sharing findings.

3 Bring commercial, finance and R&D closer together

To preserve scientific innovation, pharmaceutical companies need to foster the right balance of power between their commercial and research executives. This is essential to ensure that decision making reflects both clinical and financial drivers within the business.

One way of achieving this would be to bring the teams closer together or provide training which enables both sets of incentives to be understood by colleagues.

This type of integration can introduce more rigorous challenges to R&D departments, and help forecast expected returns on investment, ensuring compounds with the highest potential receive the most funding and are brought to market as rapidly as possible.

4 Bring the customer and patient to the heart of the R&D process

Adapting to the changing healthcare ecosystem requires that companies start assessing the 'value' of a project from a patient perspective as early as possible in the R&D process.

Decisions should be made based on the ability to meet an unmet medical need, a realistic assessment of scientific output, and an approximation of the impact that an effective treatment will have on a patients' health and wellbeing.

Traditionally, companies have put shareholder return at the heart of the R&D process and 'risk' is assessed predominantly by financial metrics. Companies need to rebalance this assessment incorporating a wider range of metrics which look at data on clinical efficacy and impact on patient outcomes as well as financial data.

Technology platforms should be designed which can synthesize this range of data and track the 'value' of a product along the development pathway, from initiation to phase IV. This will allow companies to make project decisions which are more aligned to what patients and regulators are looking for, namely treatments that have, and can demonstrate, a marked impact on patients quality of life.

5 Develop an environment that attracts and retains world-class scientists

Scientists are motivated by scientific discovery and the publication of their research in peer reviewed journals. Pharmaceutical companies need to foster this environment for scientists if they intend to recruit and retain top talent. The co-location of facilities to top academic institutions is also increasingly important as it not only allows for cross-pollination of ideas through a broader network, but also encourages collaboration, which is vital to successful innovation.

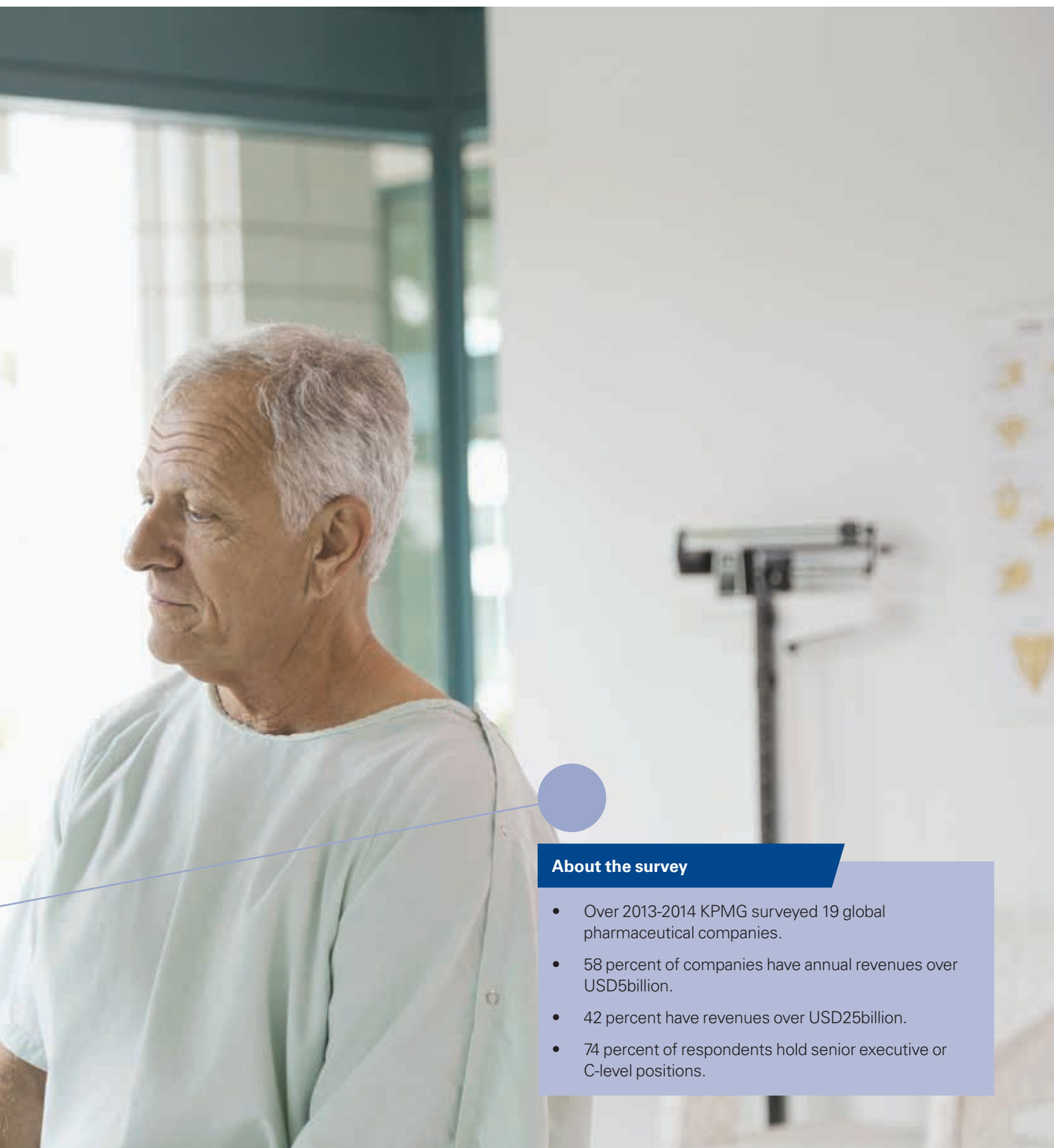
How KPMG can help

With extensive life sciences experience, KPMG's network of professionals are in touch with trends and issues, providing established insights and advice to help companies overcome their unique business challenges. Our Life Sciences network works with all top 20 global pharmaceutical companies, the top 10 medical technology companies, and almost half of the top 50 biotech firms.

KPMG member firms can help clients increase the efficiency of their R&D functions, through professional project management, cost-efficient organizational structures, and streamlined reporting and approval processes. With our combination of pharma and financial expertise, we can introduce a sound scientific and business rationale to portfolio management, enabling companies to make informed decisions that can improve return on investment in R&D.

With outsourcing, partnerships and alliances on the rise, member firms assist clients in establishing reliable and risk-optimized outsourcing agreements, as well as models for innovation, collaboration and partnership.

Our global network shares knowledge, so you get access to our worldwide resources, wherever you are located.



About the survey

- Over 2013-2014 KPMG surveyed 19 global pharmaceutical companies.
- 58 percent of companies have annual revenues over USD5billion.
- 42 percent have revenues over USD25billion.
- 74 percent of respondents hold senior executive or C-level positions.

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