



Facing the tidal wave

De-risking pharma and
creating value for patients

November 2016

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The Deloitte Centre for Health Solutions

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Foreword

The pharmaceutical (pharma) industry is a key player in a complex health ecosystem involving patients, health providers and payers, industry suppliers, researchers and government. This ecosystem is currently facing the healthcare equivalent of global warming, a 'tidal wave' of complex age and behaviour related diseases which are increasing healthcare costs and research risks and challenging delivery models.

Pharma has to manage an increasing number of contradictory demands. Patients, providers and payers are seeking better, more effective, medicines at affordable prices. At the same time, industry has to develop medicines at prices that justify the substantial risk and investment required to bring new drugs to market in an increasingly challenging regulatory environment.

This paper examines some of the underlying drivers of the 'tidal wave' of diseases, illustrates an alternative way of thinking about the demand challenges and suggests some emerging ways in which industry and the healthcare system can address them. Specifically, that pharma has to continue to innovate while focussing on de-risking its research, development and commercialisation models.

In examining the underlying drivers of the changing nature of disease and its implications for the pharma industry, we have been deliberately provocative in suggesting how the pharma company model needs to change. Our intention is to stimulate discussion and debate and as always we welcome your feedback.

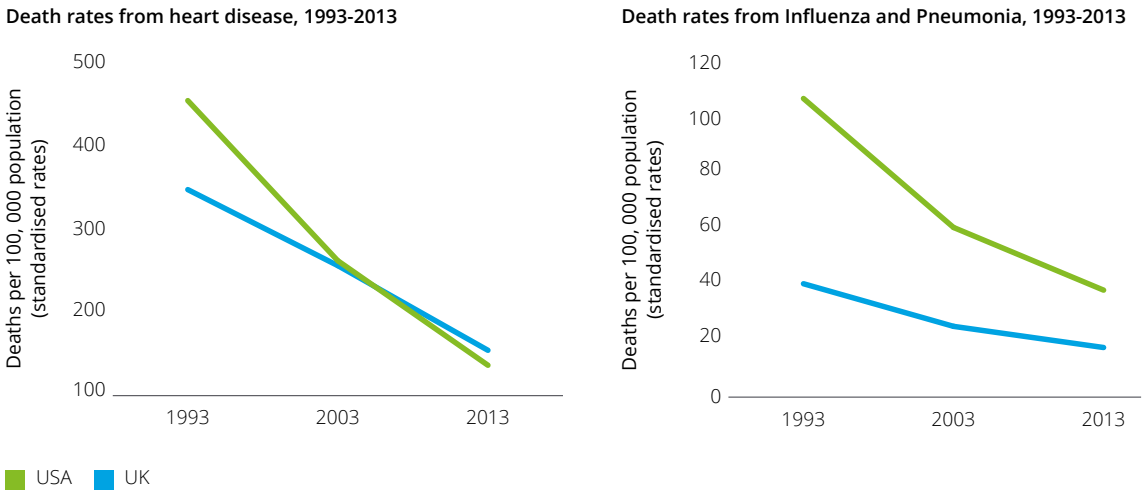
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Part 1. The tidal wave of diseases

Over the past 20 years, we have seen substantial improvements in health outcomes as a result of medical innovation most notably in infectious diseases, heart disease and stroke. For example, death rates from influenza and pneumonia and heart disease have steadily declined (Figure 1). The broad use of vaccines and antibiotics has transformed the prevalence of and outcomes for infectious diseases, while much of the improvement for people with heart disease is due to the widespread prescribing of 'blockbuster' drugs such as statins. Improvements in the consistency of treatment pathways have also played a part.

Figure 1. Reductions in death rates from heart disease, influenza and pneumonia 1993-2013



Source: Causes of Mortality, OECD, 2014

Note: Heart disease is inclusive of ischaemic heart disease and acute myocardial infarction

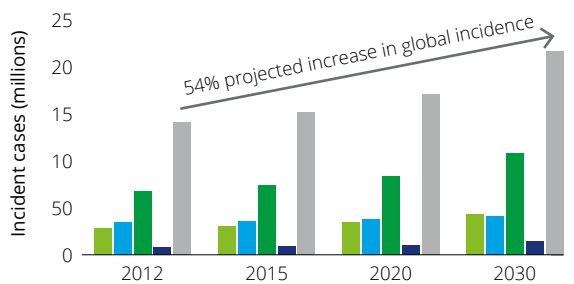
However, the improvements in life expectancy as a result of improved outcomes for chronic and infectious diseases have created their own challenges – namely, an increase in age related diseases such as cancer and dementia.

The predicted incidence of cancer and estimated prevalence of dementia is forecast to increase substantially over the next few decades. More specifically:

- Between 2012 and 2030, cancer incidence is expected to increase across all regions of the world (see Figure 2).¹ The global incidence of cancer is expected to increase by 54 per cent, Africa (69 per cent), Asia (60 per cent) and the Americas (56 per cent)
- From 2015 to 2050 the prevalence of dementia is forecast to increase in every region of the world (see Figure 3). In 2015, 46.8 million people worldwide were estimated to be living with dementia. This number is anticipated to double every 20 years, reaching 74.7 million in 2030 and 131.5 million in 2050. In Europe and the Americas peak incidence is among those aged 80-89 years, in Asia it is among those aged 75-84, and in Africa among those aged 65-74.²

While treatments and drug interventions for cancers are becoming more advanced, and survival rates have improved for many types of cancers, the emotional and financial burden of cancer in society remains high. The cost of treating cancer is also high and increasing. At the same time, the rise in dementia is placing a significant cost burden on society. Dementia also has a devastating personal impact on those diagnosed, their families and carers. The global costs of dementia have increased from \$604 billion in 2010 to \$818 billion in 2015, an increase of 35.4 per cent.³

Figure 2. Predicted increase in the incidence of cancer 2012-30



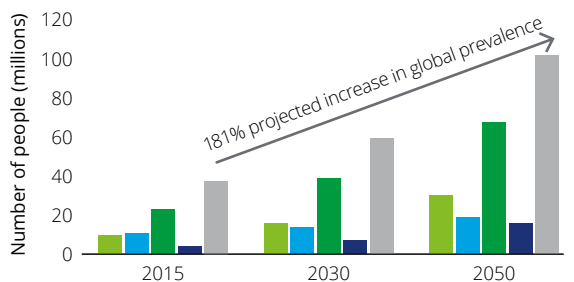
Percentage increase (2012-30): The Americas 56%, Europe 20%, Asia 60%, Africa 69%, World 54%

■ The Americas ■ Europe ■ Asia ■ Africa ■ World

Source: Estimated Cancer incidence, Mortality and Prevalence Worldwide in 2012, Globocan, 2012

Note: World totals for cancer will not sum to regionals due to the data presented in figure not covering all available regions

Figure 3. Predicted increase in the prevalence of dementia (in population aged over 60)



Percentage increase (2015-50): The Americas 216%, Europe 78%, Asia 194%, Africa 291%, World 181%

■ The Americas ■ Europe ■ Asia ■ Africa ■ World

Source: World Alzheimer Report 2015, The Global Impact of Dementia, Alzheimer's Disease International, 2015

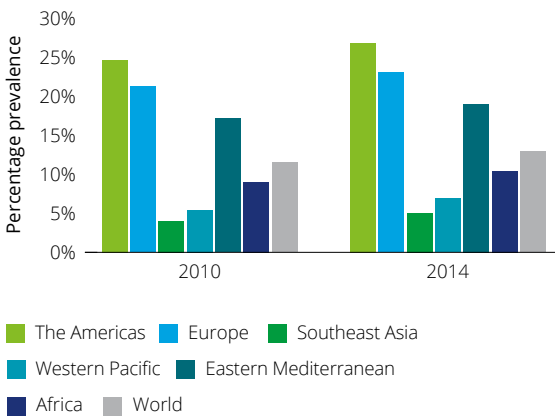
Over the past ten years there has also been a dramatic increase in the prevalence of lifestyle influenced or behaviour related chronic diseases, such as obesity and diabetes. In 2015, the International Diabetes Federation (IDF) estimated that the number of people with diabetes globally was some 415 million, and that, in 2015, five million people died from causes associated with having diabetes (one death every six seconds), more than all the deaths from malaria,

tuberculosis, and HIV combined. Complications from diabetes mean the global cost of treating diabetes is estimated at over \$670 billion a year.⁴

The growing prevalence of obesity and diabetes is placing healthcare systems in many countries under increasing strain. For example, Figures 4 and 5 illustrate the changing prevalence of obesity and diabetes worldwide.

Figure 4. The prevalence of adult obesity (BMI >= 30) across the world is high and increasing 2010-14

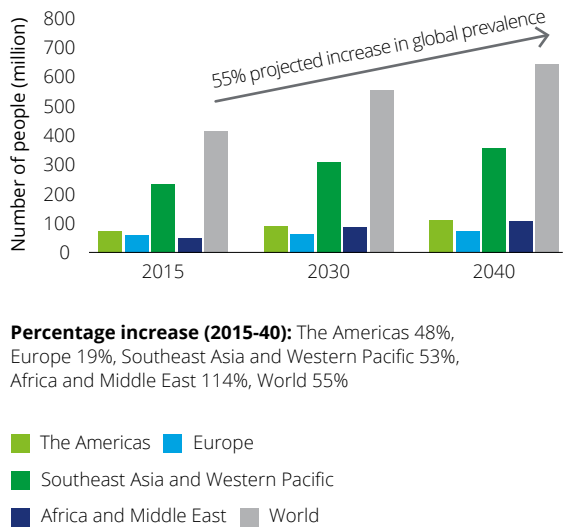
Estimated prevalence of adult obesity (BMI >= 30) worldwide, 2010-14



Source: Global Health Observatory, Obesity (body mass index >= 30) (age-standardized estimate), WHO, 2015.

Figure 5. Behaviour related diseases like diabetes (adults aged 20-79) are anticipated to grow significantly from 2015-40

Estimated number of people with diabetes worldwide, 2015-40 (20-79 years)



Percentage increase (2015-40): The Americas 48%, Europe 19%, Southeast Asia and Western Pacific 53%, Africa and Middle East 114%, World 55%

Source: IDF Diabetes Atlas – 7th Edition, IDF, 2015; IDF Diabetes Atlas – 5th Edition, IDF, 2011

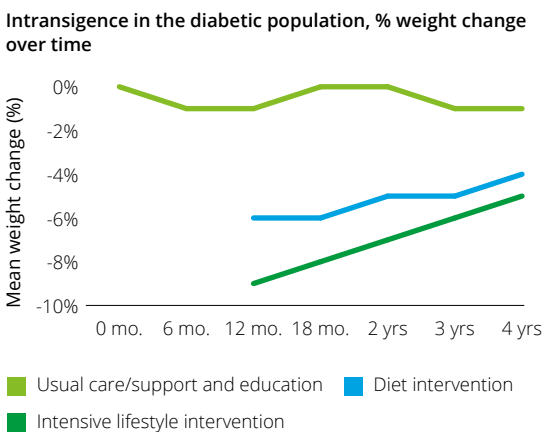
Behaviour related diseases like obesity and diabetes create two main challenges: preventing and treating them is very difficult; and the cost implications are significant. Part of the challenge lies in the intransigent behaviour of patients. Despite intensive efforts, the majority of patients gain weight after initial progress (see Figure 6). Furthermore, many diabetes patients fail to stop smoking or increase their exercise routines, despite evidence on outcomes, including the costs of treating the disease.

The cost implications of behaviour related diseases are profound, for example diabetes often leads to cardiovascular complications and is the main cause of adult blindness. Although long term chronic co-morbid patients typically make up only five per cent

of patients, they account for up to 30-45 per cent of costs in many hospitals (Figure 7).

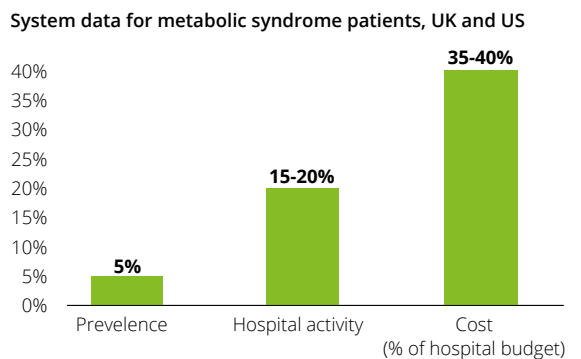
The changing nature and aetiology of diseases and the increasing costs of treating them is placing all health systems under significant demand and cost pressures. As a result all countries are considering how to contain costs while improving access to equitable care. Although workforce exerts the highest cost pressure, for most countries pharmaceuticals are the second highest category of expenditure. Accordingly providers and payers are scrutinising these costs more closely than ever and increasingly expect pharma companies to demonstrate evidence of improved outcomes and added value; often as part of a wider healthcare reform agenda.

Figure 6. The intransigence of the diabetic population as measured by weight gain following different interventions



Source: Lifestyle weight-loss intervention outcomes in overweight and obese adults with type 2 diabetes, Franz J, 2015

Figure 7. The impact of metabolic disease on hospital costs



Source: Quality and Outcomes Framework, Association on Public Health Observatory, Active People Study, Deloitte Analysis

Note: Metabolic syndrome is defined by at least three of the following conditions: insulin resistance, elevated blood pressure, abdominal obesity and cholesterol abnormalities

Part 2. Challenges for pharma

The pharmaceutical industry is at a juncture where companies are experiencing a period of significant change. They are confronted by increasing competition, shorter time-in-market, expiring patents, slowing sales growth, and declining profitability. The pressure is to maintain or reduce cost while the regulatory environment is becoming increasingly complex and R&D pipelines are harder to fill. There is also a need to embrace technological developments and respond to pricing pressures caused by healthcare reforms and government austerity measures. Science is also evolving at a rapid rate, with medical research accelerating accordingly, leading to the discovery of a wide range of treatments for many diseases that only a few years ago were unimaginable.

There are three main risks challenging the pharma industry:



Scientific risks – drug development takes time with new drugs taking, on average, 12 years to move from the research laboratory to the patient. Only five in 5,000, or 0.1 per cent of drugs, that begin preclinical testing ever make it to human testing. Only one of these five is ever approved for human usage.⁵ Increasing regulatory scrutiny is adding further layers of risk to the science of drug development.






Economic risks – the scientific risks lead to significant economic risks for pharma. The cost per successful drug launch is increasing and for the big pharma companies the average cost is now over £1.58 billion per asset. High failure rates are contributing to the lower returns from investment in research and development, requiring higher prices for those drugs that succeed, which in turn leads to payer resistance to approve new products, further increasing the 'failure' rate.⁶



Delivery risks – getting drugs to patients, and creating market access is becoming more difficult. Cost pressures and the need to demonstrate that drugs add promised value is higher than ever. In addition, the need to add infrastructure to track and measure outcomes in countries across the world like the UK, France, and Italy and in selected parts of the US system, adds further cost and delivery risks. Even if drugs are successfully developed and have market access, patients and the healthcare system do not always get the full benefit. Often patients themselves do not comply with medicines for their chronic diseases, making the promise of good outcomes elusive. As value pricing increases and pharma companies are more involved with the delivery; a new set of risks will emerge.

The disease areas discussed in Part 2 present different risk profiles to pharma, for example, chronic diseases such as diabetes drive both economic and delivery risks (see Figure 8).

Figure 8. Different diseases present different risk profiles for pharma

	 Scientific risks	 Economic risks	 Delivery risks
Alzheimer's	✓	✓	
Cancer	✓	✓	
Diabetes		✓	✓

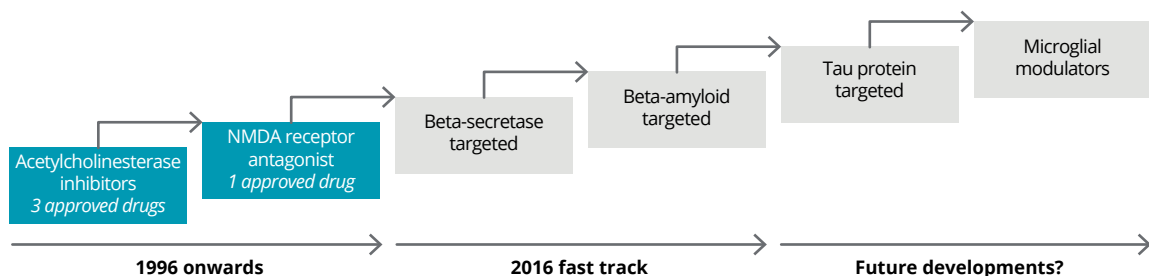
Source: Deloitte research and analysis

The pharma industry is responding in different ways to the above risks, examples of these responses are detailed below.

 **Scientific risks - the search for breakthrough innovation**

The pharma industry has spent decades trying to find drug therapies to treat, cure or, as a minimum, delay progression of diseases such as Alzheimer's, however, to date the progress has been very limited (Figure 9).⁷ While some drugs can slow deterioration for some people with Alzheimer's, there have not, as yet, been any scientific breakthroughs that can significantly modify the disease. Indeed, the search for an effective cure or treatment for Alzheimer's, more than for any other disease, highlights the significant scientific risk facing pharma and its reliance on finding new treatments. Unlike cancer, there is a poor understanding of the underlying causes of Alzheimer's, with previous notions of amyloid plaque build within the brain being the underlying cause of the disease, now seen as being more complicated. This, coupled with a lack of identifiable biomarkers and diagnostic tests makes the condition difficult for pharma companies to mitigate the economic risks of developing drugs for the disease.⁸

Figure 9. Progress developing new Alzheimer's treatments has been very limited illustrating the challenges facing the industry



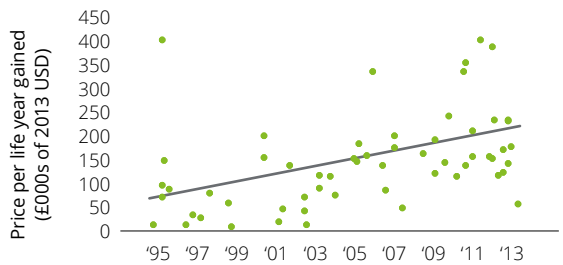
■ Drugs approved for use in Alzheimer's (first drug receiving FDA approval was in 1996, three others followed in 2000, 2001 and 2003)
 ■ Drugs awaiting approval for treatment

Source: Deloitte research and analysis

The search for breakthrough innovations has been particularly important in the development of cancer therapies. Cancer has moved from being a disease that in the 1960s gave patients a very short life expectancy, to being regarded, at least for some cancers, as a potentially chronic disease. Advancements in early diagnosis and treatments, for example for skin or breast cancers, have had a significant impact on cancer survival. However, other cancers remain more challenging with treatments for renal and brain cancers, for example, able to increase longevity by only a few weeks or months. New drugs, such as the new generation of immuno-oncology drugs, are facing similar challenges in that many may only have a limited impact on life expectancy.

Scientific progress has been accompanied by sharply rising costs. Costs of oncology drugs reached \$107 billion globally in 2015, an increase of 11.5 per cent over 2014 and up from \$84 billion in 2010. These costs are expected to reach \$150 billion globally by 2020.⁹ The rising cost of cancer drugs to health systems is putting significant pressure on provider and payer budgets, with cancer drug costs increasing from an average of \$50,000 per life year gained in the mid-1990s to more than \$200,000 per life year gained in 2015 (Figure 10).¹⁰

Figure 10. Increasing cost per life year gained for cancer treatments in the US (1995-2013)



Source: Pricing In The Market For Anticancer Drugs, National Bureau of Economic Research, 2015

Note: Research studied the trends in the launch prices for 58 anticancer drugs approved between 1995 and 2013 in the US. The study included drugs who included survival time as a primary outcome measure (overall and progression free)

Part of the reason for the increased cost of new drugs is the challenge inherent in innovation and the high risk of failure of new drugs in the research and development (R&D) phase. At the same time, our increasing knowledge of science and genomics and an understanding of the differences in patients' genetic response to treatment, means that 'one size fits all' treatments are difficult to justify leading to the need for more precision therapies.

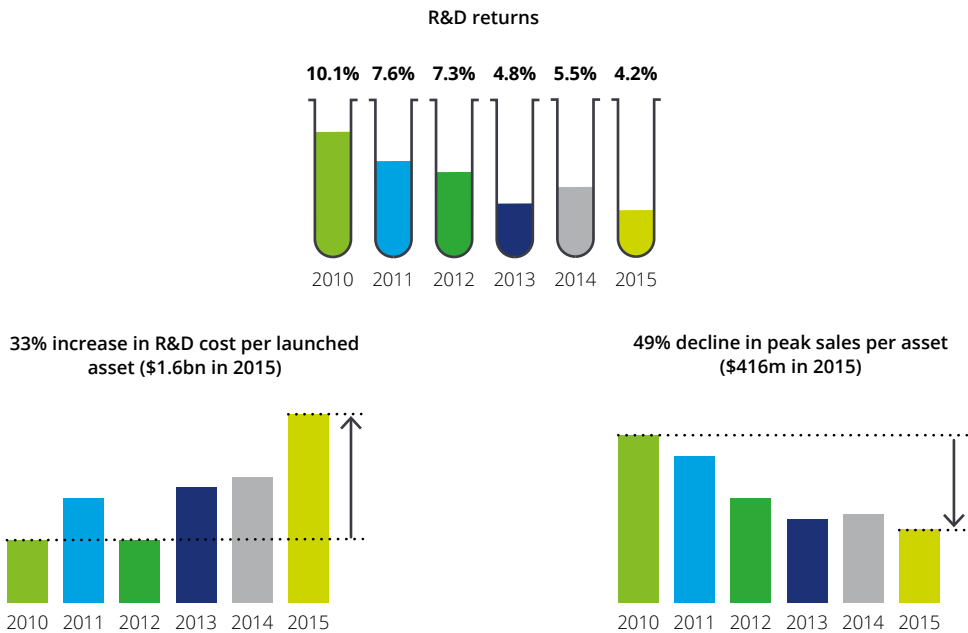


Economic risks – the increasing costs and reducing returns from pharma R&D

The emergence of smaller groups of patients who are more likely to benefit from a new drug means that the increasingly high R&D costs associated with drug discovery have to be recovered from ever fewer numbers of potential patients, challenging the established pharma business model. In response, regulators have begun actively reviewing approval processes for precision therapies. As a result the percentage of precision medicine drug approvals in the US, for example, increased from 22 per cent in 2014 to 29 per cent in 2015^{11,12}, and the number of products available on the market increased from 13 in 2006 to 113 in 2014.¹³

Despite the increasing cost of drugs the economics of pharma companies remain challenging. Deloitte's annual report *Measuring the return from pharmaceutical innovation 2015*, found that the rate of return for a cohort of 12 leading pharma companies halved from 10.1 per cent in 2010 to 4.2 per cent in 2015. This was largely due to the growing imbalance between declining forecast peak sales and growing asset development costs (Figure 11). Consequently, those products that make it to approval require a price that reflects the cost of their innovation, while addressing payer demand for demonstrating value.¹⁴

Figure 11. R&D returns have declined to the lowest point in five years



Source: Measuring the return from pharmaceutical innovation: Transforming R&D returns in uncertain times. Deloitte Centre for Health Solutions, December 2015



Delivery risks – the challenges in moving to a new pharma operating model

The number of new pharmaceuticals approved per billion US dollars spent on R&D has halved roughly every nine years.¹⁵ Some pharma companies are repositioning themselves in response to the increasing cost of drug development, improved efficacy of next generation drugs and the emergence of value for money and cost containment strategies by payers. They are focusing on demonstrating increased value for money through a combination of new pricing models, improved benefit tracking and increased downstream intervention.

The move to improve long-term profitability however creates new challenges. Repositioning a pharma company from a product to a service delivery model is difficult, potentially diluting margins, increasing liabilities and adding complexity. Attempts to reduce the economic risk of high prices could result in a new set of risks associated with service delivery. The 'tidal wave' of diseases however means that the industry is facing an increasingly risky operating environment.

To reduce the delivery risk in successfully launching products, pharma companies are trying to understand how to:

- more precisely comprehend what drives the value of their products in the real world in terms of outcomes and impact on the healthcare system
- measure this value more accurately
- develop different pricing models (for example, indication based pricing) to reflect the value
- ensure that through service design and other interventions the value is delivered to patients.¹⁶

The most difficult challenge will be the transition to a new service delivery model: repositioning organisations from in many cases a product model, to a product and service delivery model. This transition has specific challenges – different economics of providing services over selling drugs, new management structures, new competences and potentially increased liabilities (e.g. from direct service provision). It will also require the healthcare system to be open to new types of partnerships.

Part 3. Reducing risks and creating value

The challenges identified in Parts 1 and 2 are forcing companies to review their current research models, development processes, and commercialisation approach in order to stay relevant. Strategies such as simply outsourcing a range of business functions including R&D and marketing or just tweaking the commercial model are not enough to succeed. The many stakeholders in the health ecosystem have different expectations of pharma (Figure 12). These expectations cannot be reconciled by marginal changes to how pharma operates. The scientific, economic and delivery risks facing pharma are just too great. Instead, we believe a new paradigm focusing on innovation and de-risking pharma is required if pharma is to succeed in the 21st Century.

Figure 12. Significant pharma challenges and opportunities are shaped by the different stakeholders in the health ecosystem



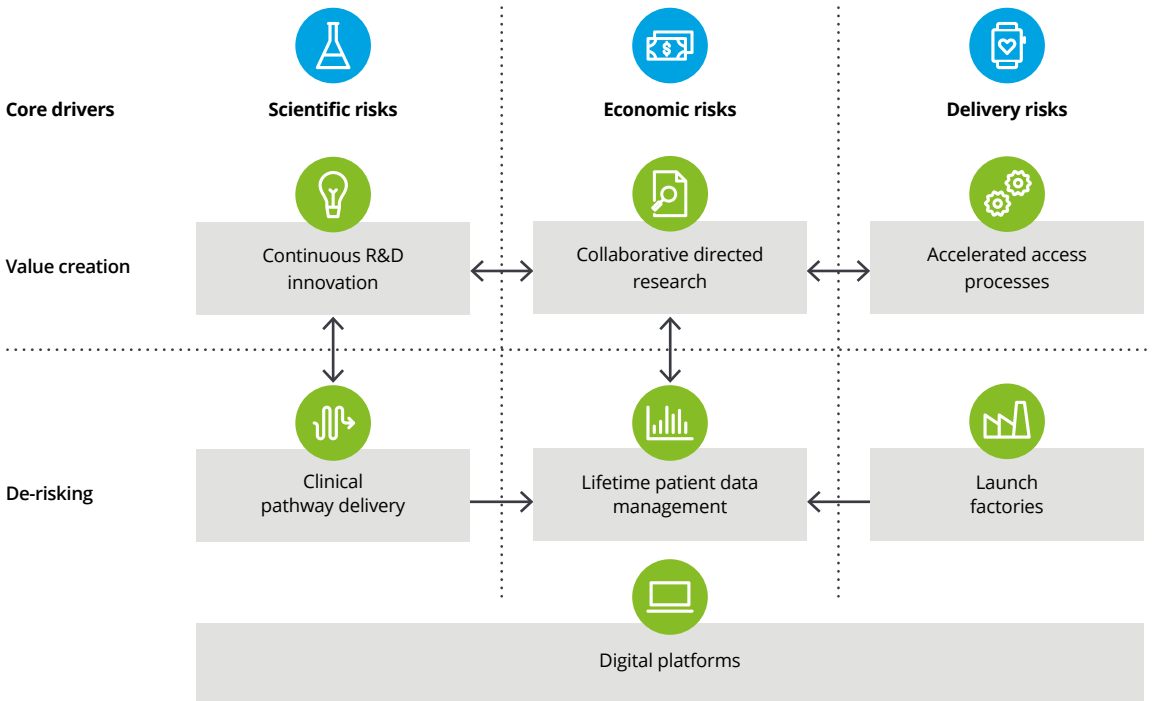
Source: Deloitte research and analysis

Reducing risks and creating value

Pharma companies can build a new paradigm to minimise the scientific, economic and delivery

risks by developing incremental and breakthrough strategies that de-risk the business model and create value (Figure 13).

Figure 13. Seven options for developing the pharma business model



Source: Deloitte research and analysis

Note: The different options can also mitigate more than one risk, as illustrated by the arrows



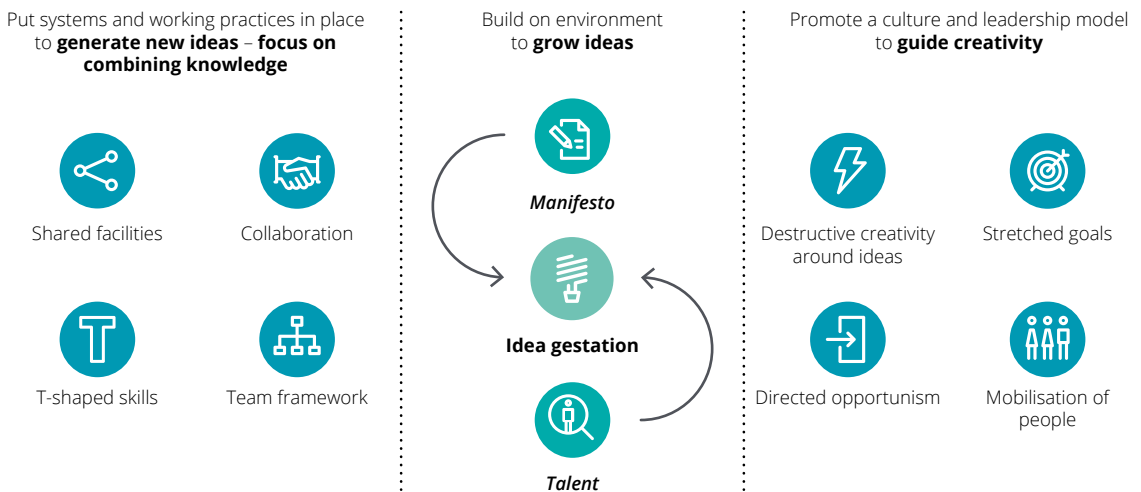
Continuous R&D innovation

While there is no recipe for guaranteeing successful R&D there are emerging models for improving the operational effectiveness of research organisations. Figure 14 below illustrates the success factors for new innovation models in R&D.

The continuous R&D innovation model below includes:

- **Balance of T-Shaped skills** – R&D centres which develops talent with broad and deep expertise and with the ability to identify and manage links across the different specialties are more likely to succeed
- **Collaboration and team work** – collaboration within the R&D unit across all stages of development focused around a common goal based on scientific excellence rather than management of tasks
- **A manifesto** – a way of articulating the principles of how R&D is conducted that unifies and mobilises the team and creates a common platform for working
- **Collaboration and partnerships** – a willingness to embrace partnerships with traditional partners such as universities and small biotechnology companies as well as new, non-traditional partners, such as technology companies
- **Destructive creativity** – a way of inventing and destroying ideas and concepts before rebuilding something better
- **Multidisciplinary staff** – covering a wider range of disciplines and capabilities within the research function including biostatisticians, artificial intelligence (AI), robotics, crowdsourcing and behavioural scientists.

Figure 14. Success factors for innovation



Source: Deloitte research and analysis



Lifetime patient data management

Lifetime datasets represent the collection, on a consented basis, of data of each patient's medical history and even lifestyle. They help develop an integrated understanding of patients, beyond the randomised clinical trial setting, and help de-risk the process of discovery through a better focus on unmet needs, improve selection of biomarkers/ sub-populations and earlier/faster identification of trial patients. A patient engagement strategy can reduce delivery risk by improving companies' understanding of how co-morbid patients actually live and consume medications, enabling them to develop improved clinical and lifestyle services that deliver better health outcomes. Lifetime data will help smooth the transition from drug development to launch and will enable companies to implement agile development models more effectively.



Clinical pathway delivery

The clinical pathway delivery approach follows what happens to patients as the disease and treatments develop, allowing pharma companies to offer treatments and services that improve success for the patient. It requires a greater focus on designing, delivering and pricing new drugs and services for the entire clinical pathway in collaboration with health systems, as opposed to concentrating on product innovation alone, aimed at lowering both economic and delivery risks. Clinical pathway delivery combines new drugs, devices, processes and digital platforms and

increases the probability of both improved outcomes and increased productivity (Deloitte research found that of 22 new medical interventions which improved outcomes and productivity 18 involved pathway redesign). Joint development of clinical pathways, particularly when based on real world evidence also offers the opportunity to reduce delivery risks by improving pathway design and optimising the division of work between pharma companies and the healthcare system. Adding services to the patient pathway will ensure better outcomes while potentially reducing costs. Services could range from preventative services, for example pre-diabetes, to wellness and weight loss programmes, from pre-surgery physiotherapy and fitness regimes to interventions to aid post treatment recovery, including drug adherence programmes.



Digital platforms

Digital platforms can create a step change in the cost of engaging with patients and physicians, both delivering significant new value and helping to lower costs. Emerging consent architectures, clearer definitions of Information Governance (IG) regulations, new security frameworks and the experience gathered from the first generation platforms is opening the possibility of the wider scale rollout of primary/secondary care data platforms. These digital platforms will help with patient engagement, improved reimbursement, accelerated development/launch and lower cost development and supply chain.



Collaborative, directed research

Collaborative, directed research is a way to shift the balance of economic and scientific risk radically, and involves governments or funders of the research, directing the research. This approach was used successfully in the development of vaccines for Zika and Ebola for example. The Center for Disease Control and Prevention (CDC) in the US and the National Institute for Health Research in the UK are putting funding into public and private research based on their views of the disease threat and extent of unmet need. In the defence industry this is already the dominant model – where government funds a consortia of defence companies to conduct research, paying the consortia for the development with no commitment to ‘buy’ the results of the research afterwards.



Accelerated access processes

Working with governments and regulators to redesign access processes offers the opportunity to accelerate the availability of new drugs, increase adoption rates and redesign reimbursement and contracting models. These opportunities are emerging in a number of countries including the US, China, Japan and the UK. For example, the UK's Accelerated Access Review was published in October 2016.¹⁷ They offer the prospect of reduced risks to both pharma companies and healthcare systems.

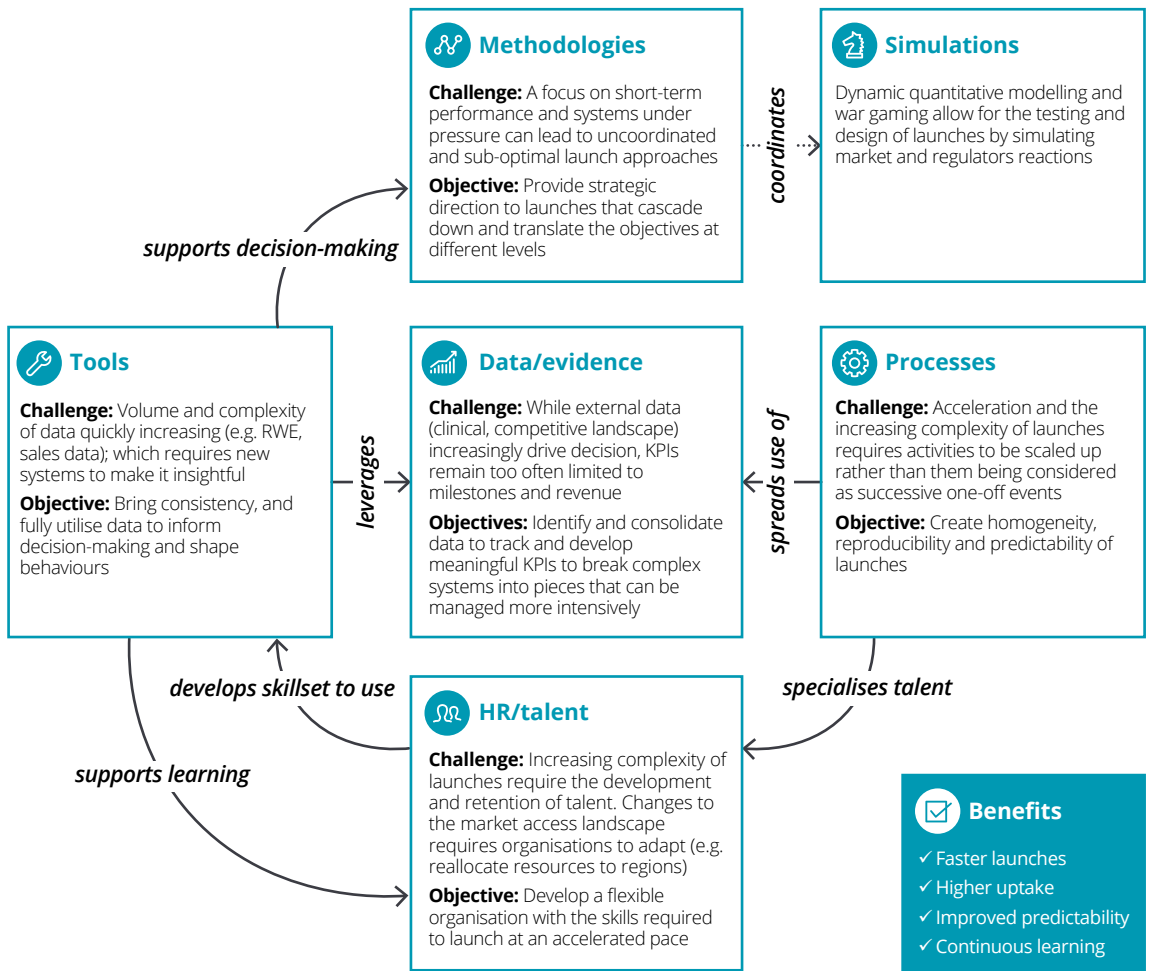


Launch factories

Launch factories help improve the efficiency of launching drugs successfully – particularly in an environment where pharma can launch more indications for smaller patient populations based on the same molecule. The essence here is to improve efficiency, reliability and compliance of launches by modularising and standardising the core elements for launch. This makes them deliverable across different countries and products over time. A ‘launch factory’ industrialises tools, methodologies, data sources, people/talent and processes as outlined in Figure 15 overleaf.

Innovate, address inefficiencies in the current business model and deliver better health outcomes for patients.

Figure 15. The key components of a pharma launch factory



Source: Deloitte research and analysis

Conclusion

The seven strategies in Figure 13 and discussed in this section will be critical in de-risking the drug discovery model and finding new, incremental sources of value for reimbursement and pathway delivery.

The ‘tidal wave’ of diseases combined with scientific uncertainty and variations in patient behaviour make these important strategic choices for the pharma sector to ensure continued growth and profitability.

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Acknowledgements

Amen Sanghera, Sarah Botbol and Surbhi Mehta, Deloitte Centre for Health Solutions and Nicole Malouf.

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Designed and produced by The Creative Studio at Deloitte, London. J10090