



Rethinking Life Sciences

July 2016

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Payers need big savings. R&D is costly. Time to shift from price-per-pill to charging for outcomes?

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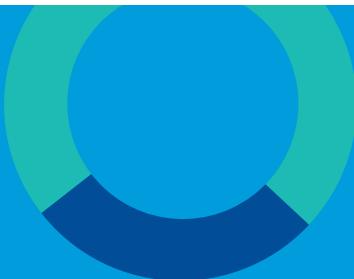
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Picture: Getty images

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Welcome

Welcome to *Rethinking Life Sciences*.

The highlight of this issue is our video interview with Clare Cutler, Vice President Oncology, Global Marketing at AbbVie. Clare shares her views on the challenges of combination treatments and the implications for therapy pricing.

We also uncover the key trends in pharmaceuticals with some of the leading lights in KPMG's Exceptional Women in Life Sciences programme. It's well known that pharma has struggled with a diversity deficit. Our campaign aims to highlight the work we're doing to support and encourage women in leadership roles – work we're also seeing our clients undertake.

Other articles in this issue include an updated breakdown of the implications of the OECD's Base Erosion and Profit Sharing (BEPS) action plan; and a look at the benefits of implementing a value-based pricing model in pharma.

As payers and providers all over the world struggle with the cost and complexity of the life sciences supply chain, there's a real opportunity to reshape the fundamental assumptions underpinning our industry. That means looking at pricing, contracts and "customer journeys" in new ways – and reshaping business models and market positioning around the value of lives, not the cost of pills.

No wonder patient-centric healthcare planning is a strong theme running through this issue.

KPMG takes a long view of these challenges and opportunities – and the topics in this edition of *Rethinking Life Sciences* are a useful reminder that, during periods of rapid change, sometimes a steady hand and a clear vision are the best routes to success.

We hope you enjoy this issue of *Rethinking Life Sciences* – and, as always, we welcome any feedback.

Chris Stirling

Partner and Global Head of Life Sciences at KPMG
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The espresso shot

A quick, concentrated look at the trends, topics and data that are shaping the life sciences sector.

Anticipate tomorrow...



Longer patient journeys

In 1900, the top three causes of mortality were all acute. By 2013, they were all chronic (heart disease, cancer, COPD). About 141 million people in the US had one or more chronic conditions in 2010; by 2030, it will be 171 million.



Real-time patient data

The world's 100 million wearable devices are generating 15 million gigabytes of monthly traffic. Forecast for 2019? 500 million wearables.

...deliver today



Invest in the platform. Life sciences firms need to be able to manage processes and interrogate data at huge scale to manage internal and external change. Legacy systems and siloed databases will soon create potentially fatal choke points. *See page 19*

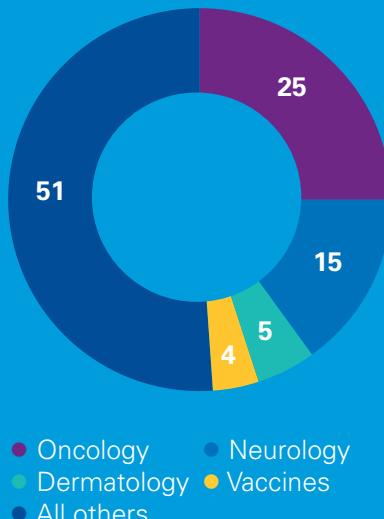


Cost pressure

NHS trusts in England overspent by £2.5bn in 2015; in the US, it is estimated that \$8.2bn a year is wasted due to duplicative testing in hospitals. Can the life sciences industry offer fast solutions? *See page 11*

Sources: *Nature*; RAND Health; BBC News; *Issues in Science and Technology*

Cancer in Focus: late-phase R&D pipeline (US drug tests)



More than 225 medicines will be introduced by 2020, with one-third focused on treating cancer. *See page 8*

Source: IMS Health



Women in life sciences: missing half the brains?

There remains a striking gender gap in terms of average remuneration and career progression in life sciences.

For example, women earned 39% of biomedical engineering degrees in the US in 2011. But Only 8% of board members at the top-ten biotech start-ups in 2014 were female. And only 20 of 112 senior management roles in the top-ten biomed companies in the US were held by women. *See page 14*

Source: *The Scientist Life Sciences Salary Survey*

Examining notions of value: health costs

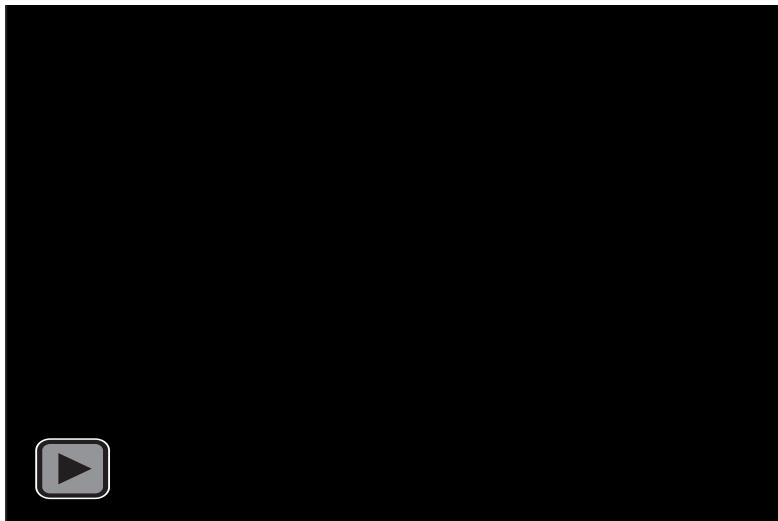
Health spending as percentage of GDP

	1973	1983	1993	2003	2013
OECD	5.0%	6.4%	7.1%	8.0%	9.0%
US	6.5%	9.3%	12.5%	14.5%	16.4%
Germany	6.8%	8.2%	9.0%	10.3%	11.0%
UK	4.0%	5.3%	6.0%	7.1%	8.5%

Healthcare spending has risen rapidly as a share of national income over the past 40 years – by 80% across the OECD, but 112% in the UK and a massive 152% in the US. Since 1973, the share of health spending on pharmaceuticals has grown from 14.9% (OECD average) to 17%.

Source: OECD





"As well as working with patient groups and institutions treating patients, we need to collaborate with other industry players"

Oncology in concert

Modern oncology is all about treatments in combination – and working closely with patients. For AbbVie's Clare Cutler, that means finding ways to collaborate with health providers and rival pharma companies in pursuit of better patient outcomes.

Hilary Thomas

Partner and Chief Medical Adviser,
Life Sciences, KPMG
hilary.thomas@kpmg.co.uk

Clare Cutler CV

2003–2006 Business Unit Manager (Oncology & Haematology), Roche

2006–2010: Director of Oncology (UK), GlaxoSmithKline

2010–2011: Director & Head of Solid Tumour Commercial Development, GlaxoSmithKline Oncology Centre of Excellence

2011–2013: Global Commercial Lead (Oncology), GlaxoSmithKline

2013–2015: VP & Medicine Commercialisation Leader (Oncology), GlaxoSmithKline

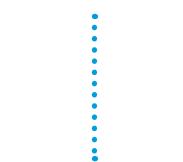
March 2015 August 2015: Vice President, Global Oncology, Novartis/GSK Integration Lead & Site Head, Novartis

Sept 2015–present: Vice President, Oncology, Global Marketing, AbbVie

AbbVie emerged from Abbott Laboratories in 2013 as a global biopharmaceutical company with focus and capabilities to address some of the world's greatest health challenges – including hepatitis C, cancer, immunology, neurological conditions, renal disease and endometriosis.

Out of the box

External challenges are forcing pharmaceutical companies to change business models from 'sales push' to a more value-based approach. Drug-makers need to prove efficacy to payers and regulators – but also that the price versus established products is justified by improved outcomes.



We know that constant innovation from pharma companies leads to a flow of new (often expensive) products – such as Glybera, one of the first gene therapy drugs released in Europe. But fiscally constrained Western economies have limited room to grow healthcare spending.

"Populations are ageing and medical advances offer more options for treating chronic diseases that a generation ago would have been hopeless cases," says Hilary Thomas, KPMG Partner and its Chief Medical Adviser in the UK. This led to public and political pressure on pharma companies and new consideration of alternative payment models such as value-based pricing. Based on our on-the-ground experience with payers, healthcare providers and pharma companies in many countries, we believe that value-based pricing models can be an adequate response to stakeholder concerns.

What do we mean by value?

Value-based healthcare is defined as the health gains (outcomes) created for patients per unit cost by healthcare interventions. Various outcome measures have been developed around the world, and outcomes data is collected and shared with clinicians and the public.

A good example is the Centers for Medicaid and Medicare (CMS) in the US, which reports hospital 30-day risk-standardised mortality, complication and readmission measures for acute myocardial infarction and heart failure. Combined with cost information for the pathway, this data can provide insight on the value provided for acute cardiovascular care.

"By opening up the entire clinical supply chain, from R&D to patient sign-off, it's possible to create value opportunities that life sciences businesses could use to fund innovation – and provide enhanced services in silos currently being neglected, such as post-operative care," says Hilary Thomas.

Value-based pricing considerations

A value-based pricing strategy is complex to design, however. Factors include product- and market-specific factors such as commoditisation and current revenue size; external circumstances such as the policy environment and reimbursement pressures; and the implementability of value-based pricing.

And not all products are suitable for value-based pricing. There needs to be measurable outcomes

of application of the product (otherwise it's impossible to measure the value to the patient); and no generic versions of the product are already, or will soon be, available in the market – other products can compete on costs or brand value rather than outcomes.

That means we need to evaluate products for value-based pricing depending on position in market, external challenges and feasibility. Consider the following aspects:

- Is there a need to differentiate from competitor products? If yes, value-based pricing could be ideal.
- Value-based pricing is resource-intensive – so does the product have a cost or level of sales big enough to justify the cost?
- A squeeze on the payer's ability to pay for the drug may be an indicator that it would be amenable to alternative pricing strategies.
- Value-based pricing may represent a politically more palatable solution for payers as it concentrates on improved outcomes for patients.
- Are there any insurmountable barriers to the decision – usually the availability and quality of the required outcomes data.

If yes, then how?

Our framework for value-based pricing comprises four main areas, each of which requires high-level and front-line decisions to be taken:

- 1.** The pricing strategy depends on the competitive market and on the chosen contract relationship. You might have a 100 percent value-based approach (outcomes fully drive payment) or a mixture between traditional market-based pricing and value-based, such as a bonus (or penalty) based on outcomes.
- 2.** Outcome measures that underpin the pricing scheme need to optimise the capture of value. Longer-term outcome measures are less useful when payments are made quarterly or annually.

3. Enforcement of the pricing scheme depends on the availability and accuracy of data and agreement on validity of outcomes by clinicians. Ideally, the infrastructure to measure and collect data will already be largely in place.

4. The pricing scheme has to be elaborated with the contractor, taking into account timing and legal possibilities.

Benefits to stakeholders

Patient

- Better access to treatments that otherwise would not be reimbursed
- Better outcomes of treatment
- More subgroup specified or personalised treatments

Medical doctor / hospital

- Potential for treatment of patients at lower cost
- Guarantees on the outcomes of treatment
- Improving evidence-based medicine by collecting real-world data

Society

- More and better health care for less costs
- Access to a wide range of treatments, including expensive treatments

Pharmaceutical company

- Approval for reimbursement and access to the market
- Larger volumes of sales (e.g. by improving adherence, incentivising clinicians to prescribe the drug)
- Improved position in the market and enlarging market share
- Real-world data collection that prove efficacy of products

Payer

- More health care for less costs
- More certainty on cost-effectiveness of treatment
- Guarantees on the outcomes of treatment
- A possible reduction of the costs of follow-up treatment due to better initial treatment

Translate value-based pricing schemes into practice

Making value-based pricing schemes a reality needs cooperation between pharmaceutical companies, hospitals and insurance companies. We have four recommendations:

- 1.** Be selective in using value-based pricing. Not all products are suitable for this approach.
- 2.** Close cooperation between hospitals, doctors and payers is essential – design the value-based pricing schemes on a product-by-product basis.
- 3.** Use pilot schemes involving smaller cohorts of patients to test value-based pricing; broaden the policy if it works.
- 4.** Include the necessary precautions in the contract, such as strict inclusion and exclusion criteria of the patient subgroups for value-based pricing.

There are bound to be political complications, too. "As compelling as it might sound to offer a service or an outcome rather than sell a pill-in-a-box, it is those considerations that might define success or failure of value-based approaches," says Hilary Thomas. "In the UK, in particular, the NHS is considered by many to be tainted when it uses private sector contracts that see front-line health provision outsourced to commercial enterprises.

"But we need to establish sustainable models that improve patient outcomes, generate savings and create the financial and operational headroom for life sciences businesses to invest in innovative ways to improve KPIs across the board," she concludes. "That should build a compelling case for value-based pricing in healthcare – and offer some solutions to the coming healthcare crisis."

Based on the KPMG paper, Pharma shifts towards value, by Dr David Ikkersheim, Dr Annemarie Oosterwaal and Dr Thishi Surendranathan.

Value-based pricing in action

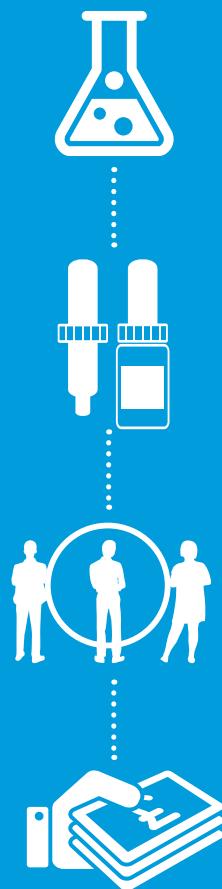
In 2012, ZINL, the HTA body in the Netherlands, agreed to reimburse Novartis for Xolair, a treatment for severe asthma on a “pay-for-performance” basis.

During evaluation of Xolair for reimbursement, ZINL had concerns on the cost-effectiveness of Xolair for severe persisting allergic asthma. Approximately 30% of patients were unresponsive. Cost per patient was €16,000. Ruling out Xolair for reimbursement was not an option because clinicians saw response in a good proportion of patients. So a “no cure, no pay” arrangement was implemented. If there was no response in six months, the cost of treatment was reclaimed by the hospital from Novartis. The success of this arrangement would depend in large part on the appropriate use of the drug by clinicians. It is in the patients', clinician's, payer's and manufacturer's interests to ensure as many people

who would benefit from the drug are prescribed it.

Even earlier, in 2009, Merck contracted with insurer Cigna in the US to discount diabetes products Januvia and Janumet if a key intermediate outcome – blood sugar control – was achieved for members with Type 2 diabetes, in return for a more favourable position for Januvia and Janumet on the Cigna formulary (meaning lower co-payments for members, driving higher volumes for Merck's products).

Cigna concentrated on improved treatment adherence in all diabetes patients to achieve these outcomes improving volumes for all diabetes drug manufacturers. It reported an improvement in blood sugar control of more than 5 percent on average, and improved medical adherence across all diabetes drugs – peaking at 87 percent for those taking Januvia and Janumet.



Patient capital

KPMG's Exceptional Women in Life Sciences explain why focus on patients, not interventions, is key – and investments in R&D and M&A must be geared to better end-user outcomes if they're to deliver sustainable returns.

We've asked some of the firm's global leaders from the Exceptional Women in Life Sciences programme about the key trends in life sciences. The consensus is clear: **it's all about the patients**. Delivering clear beneficial outcomes over a well-defined patient journey looks set to be the defining model for primary health providers, drug and medtech companies, as driven by three factors.

First, **commissioning agencies** – insurers in the US or state health services such as the NHS in Europe – are unrelenting in their drive for cost efficiency. There are limits to margin squeezes and volume discounts. Value-based models are sure to come to the fore.

Second, **regulatory pressures** in both business practices and treatment approvals. Compliance for each part of the patient supply chain in isolation is going to become very costly. Meanwhile regulations – from IP rights to drug approvals – are becoming globalised.

Third, **data**. Diagnostics of all kinds are improving and getting cheaper, and that's reshaping the landscape for preventative health and early intervention. But the data collected by primary care providers, life sciences businesses and, above all, patients themselves is changing the way we look at end-user interactions. From wearable tech and the internet of things, to sophisticated analytics and open data, bits and bytes look set to continue their sector-defining role.



Hilary Thomas

Chief Medical Adviser and Partner at KPMG in the UK

The industry is starting to see the real value it brings to patients. We strive to help companies understand how they can maximise that, whether it's by changing their business model; the way they engage with patients and with healthcare systems; or exploring the total value chain for a drug. It's about how we make sure that patients are engaged in their healthcare and how taking their health seriously adds value.

The digital age is driving another transformation. To keep one step ahead of the likes of Google and Apple, this sector will need to be really innovative.

▲ **"The life sciences industry will need to think about the breadth of the services it can offer and how it can be an important stakeholder in the healthcare ecosystem, and not just sitting on the sidelines"**



Anna-Marie Deter

Director in People and Change at KPMG in the UK

I'm really excited about the sales and commercial models in life sciences. For example, technology like wearables and virtual reality means we can influence people to take medicines in a more proactive way. Companies that can design an experience around the patient to help them self-diagnose, take preventative action and self-treat will do well. We need payers, patients and the industry to work together to help people take more ownership of their care. KPMG works across the patient pathway to help deliver this vision. Even in acute care, we're going to see more specialisation and a better dynamic between the public sector and private hospitals without having to go through so many stages to deliver patient outcomes.



Kelly Dane

Director, KPMG Global Life Sciences

We're applying the right talent to the biggest challenges for our clients. We're one of the few firms bringing together our Healthcare and Life Sciences practices: we know their challenges have to be overcome through partnership. And we want to encourage more women to extend themselves in the industry. Its issues will only become more challenging unless we bring in the best talent from every background and apply diversity of thought to its problems.



Women earned 39 percent of biomedical engineering degrees in the US in 2011...

◀ "You have to be passionate about what life sciences can do for the world. But internally, it's about tenacity. You have to have a vision"



Jennifer Lospinoso

**Director in Life Sciences
Compliance at KPMG in the US**

Scrutiny on drug pricing is sharper than ever. Payers and providers are looking for new types of – and steeper – discounts. It's leading life science companies into increasingly complex contracting arrangements. Now we're starting to see contracts based on patient outcomes – and data has an impact, because that's where the proof is on key metrics like quality of life. But we still have reference pricing in some countries in Europe; in the US, we have different government programs with statutory pricing. Companies really need to start looking at things from a global perspective, instead of having these fragmented business approaches.



Allison Little

Life Science Advisory Leader for KPMG in the US

Companies are really trying to figure out how they're going to create value in the future. Specialise in a particular therapeutic area and differentiate on the science? Or diversify to capitalise on market reach with a larger portfolio? It's a tremendous opportunity for transformation. Even the specialists are focused on the patient journey, trying to provide supporting services or devices that make it more manageable.

There will also be breakthroughs in science that will make some conditions that people struggle with curable, or at least more manageable. People will live a longer, healthier, happier life. But there will still be care needed and end of life management. We have an opportunity to see quality of life improve significantly.



Lynn Buhl

**Director in Life Sciences Advisory
at KPMG in the US**

Compliance does drive better business practices. You need better data, better systems, better processes on the compliance side. But we can also recommend new systems or data analytics that benefit the business as a whole. When clients are facing potential lawsuits, the big risk is that practices are not well documented. Robust and complete documentation doesn't just help prove they were trying to do the right thing. It's valuable across the board.

8% 

...but only 8 percent of board members at the top-10 fund-raising biotech start-ups in 2014 were female...



Jennifer Shimek

**Partner and principal in Forensic
Advisory Services at KPMG in the US**

Enforcement actions and due diligence on third-party intermediaries has become a big part of the M&A and divestiture activity – knowing what you're buying and making sure that you have a perspective on any [operational or regulatory] risk. Pharma companies not domiciled in the US but with a large presence here are forced to live under these rules. Data analytics is critical. Using data well helps us identify what people are doing wrong or how well a drug is working for the patient population or make sure we're reporting any adverse events. Government is really focused on going after this data, too.



Patricia Wylie

**Forensic Manager in enforcement
and compliance for KPMG in the US**

More companies are looking to M&A and joint ventures to grow their capabilities and extend their global reach. However, they're also opening themselves up to some increased risks, particularly in regulatory and compliance. We're seeing a lot of emerging markets replicate many of the regulations in the US, too. And there's an increased regulatory focus on how we're meeting patients' needs and bringing them services in a more efficient way – providing a holistic solution.

◀ “We need to be aware of the emerging risks as we open up to big data and analytics – and new transparency in how we're interacting with patients”



Kelli Brooks

**Partner in Forensic Technology Services
at KPMG in the US and Global Leader
for eDiscovery**

As companies are acquired or merge, there's a proliferation of data. Dealing with legacy systems and maybe cultural issues gives clients pause to understand what to do with their data. Also how they deal with regulatory obligations in different countries – and what that means around data privacy. Embracing technology can really help you to get at your information much more quickly, more efficiently, and certainly more cost-effectively.



Carol Streicher

Partner, Deal Advisory, at KPMG US

Slow FDA approvals and limited pipeline are causing a lot of concern in the industry. These challenges are creating significant M&A activity. The lines between big pharma, generics and specialty are getting blurred. A perfect example is Pfizer acquiring Hospira last year.



Christine Kachinsky

**Partner at KPMG in the US and
Global Head of Sustainability Tax**

We have tax accountants and attorneys on our team, but also scientists and engineers who can speak the language of our clients. That's vital if we're to get the information that we need to comply with the tax law and optimise tax benefits – and to increase the level of sustainability of these tax benefits upon examination. We also use our technology to streamline information gathering through to reporting – which also increases efficiency.

▲ As companies talk to each other to streamline patient care, I'm hoping that technology helps them both comply with privacy laws as well as become quicker and more efficient.

“Every time there's a discussion about an opportunity, I make sure we bring the right team to my client and do the right thing for them” ▶



Vicky Phelan

**Leads on Life Sciences for the
Shared Services and Outsourcing
Advisory group at KPMG in the US**

We're going to see more convergence – of payers, providers, pharma, medical devices. At the same time, people will take more accountability for their own health, the way they monitor their bodies and make sure that they're doing preventative things as opposed to being treated by medicines. It's important that we have the medicines. But if you can avoid using those drugs [simply to treat acute symptoms rather than as part of a patient journey], all society benefits.

◀ “Acquiring companies need to make sure they're doing a really deep assessment on their compliance programme – and once the deal closes, make sure that extends to integration efforts”



Regina Cavaliere

**Principal in Advisory, Regulatory Enforcement &
Compliance at KPMG in the US**

Consolidation right now means we'll see some very large organisations, and then a lot of smaller ones, focused on clinical innovation. They can be more nimble – but they still have to work within the compliance and regulatory framework.

Clients are looking for a holistic, innovative approach that connects them to the patient, but also takes into account the legal and regulatory framework. For example, the European Court of Justice struck down the Safe Harbor provision that allowed for data sharing between the European Union and the US. But how we use data is central to creating more coherent patient journeys, so it must be tackled.

**Jaime Marks Corvino****Associate Director of Account Management, KPMG in the US**

Companies are really focused on how they're going to invest to bring the most value to customers. The science to individualise therapies and treatments is here now, for example. But the policies and payment approaches haven't caught up. Many life sciences companies are waiting to get that figured out to see if the investment is worth it.

Companies are having to look first at their talent pool. There are a lot of opportunities to create roles to answer these really difficult questions. New partnerships, too – looking outside the industry and getting creative about what they can do, whether it's technology or patient advocacy. Twenty years from now, we're going to see a very different set of companies doing lots of different things for patients. We'll be surprised at where we were today.

**Dana McFerran****Partner in the Forensic practice for KPMG in the US**

Many companies focus on improving outcomes. At the same time, there's increased government scrutiny. Robust compliance is key, but we need to ensure we're not overburdening businesses. We can identify the roles and risks that they need to deal with from a regulatory perspective.



... and only 20 of 112 senior management roles in the top 10 biomed companies in the US were held by women

“We have a passion for the patients and a passion to see those organisations [working for better outcomes] become successful”



Diversity deficit under attack

What can the life sciences industry do to address its diversity issues? According to Catalyst, a New York-based research and advocacy group, women earned 39% of biomedical engineering degrees and 38% of doctorates in the US in 2011. Yet in the 10 highest-value biomed companies there, only 20 of 112 senior management roles were held by women. Only 8% of board members at the top-10 fund-raising biotech startups in 2014 were female, according to science journal *Nature*.

KPMG's Exceptional Women in Life Sciences project is just one way the firm is attempting to address that diversity deficit. “For example, the KPMG Network of Women (KNOW) is a global programme to give women coming up through the firm the chance to network, see role models and understand how people made it work for them,” says UK Chief Medical Adviser Hilary Thomas.

Hilary, like many of her peers in the global life sciences community, is also a member of the Healthcare Businesswomen's Association (HBA). “It's a really powerful opportunity for women to come together,” she says of an organisation with more than 40,000 members in the US alone. “There isn't a global big pharma company yet that has a female CEO. That has to be the next crack in the glass ceiling.”

Anna-Marie Detert, director in People and Change in London, thinks for firms like KPMG, diversity is an out-and-out commercial issue. “Our female clients in life sciences are starting to really take on some senior roles,” she says. “KPMG is moving at pace with them – we're bolstering our capability and our diversity as our clients are doing the same thing. It's creating new relationships.”

There's still a long way to go. But as the balance in young women studying science, technology, engineering and maths (STEM) subjects shifts, companies and firms with an open and inclusive approach will be significant beneficiaries in terms of people, talent and creativity.

Big data, big insights

From deep research to driving changes in patient behaviour, the opportunities for smart use of data science and analytics in the life sciences industry are almost limitless.

Today opportunities for innovation frequently lie in the analysis of data beyond the primary use for which it was generated. New technologies and policies are beginning to improve access to, and analysis of, this data while ensuring protection of individual privacy.

Big data has potential applications across the whole value chain, from drug discovery to provision of front-line healthcare. With so many opportunities – and issues – the challenge is to know where to begin. Not only do opportunities differ in intrinsic value across individual organisations and the pharmaceutical industry as a whole, but practical realisation of big data opportunities relies on a wider data ecosystem of assets and services.

It is a common mistake to assume that value of big data lies in the data itself – its volume, accuracy, accessibility, linkability and so on. In reality the ‘bigger’ the data, the less this holds true. Even with high-quality data, it is not possible to leap straight to business value.

In theory, the chain is simple: data generates insight that creates value. This means capturing the data; transforming it into more

easily usable formats; analysing it; generating knowledge; and applying the knowledge to produce valuable insight. But each step requires a different investment in skills, technology, tools and techniques that broadly reflects the complexity of the data and of the question at stake.

Key client issues

Life sciences companies typically understand what interventions work for which patients at what cost. Internal and externally generated data must now support more complex applications.

There are a number of challenges that make it difficult to fuse vast heterogeneous data sets together to improve patient outcomes. Healthcare data typically resides in silos (see box). By making use of all of these disparate and siloed datasets, the Life Sciences industry can greatly improve patient outcomes analysis.

Another challenge is using data for secondary and tertiary analysis. For instance, administrative data is collated primarily to account for services rendered and collect payment; Electronic Health Record (EHR) data helps track patient

Three big challenges for big data

To realise its true value, big data needs to be integrated into organisational design and a wider ecosystem supportive of good data management, analytics, as well as new business and investment models. Other sectors such as retail and financial services offer examples of how this might be achieved.

1 Understand the risks and regulations around data sharing. Data protection laws, such as the Health Insurance Portability and Accountability Act in the US or the Data Protection Act in the UK, are stringent on patient information. Researchers may have to anchor data to a baseline date and use de-identification measures. Attempts to de-identify data can restrict moving or sharing data.

2 Recognise obstacles such as data silos.

Administrative – claims, reimbursement, cost information.

Clinical – such as patient history, vital signs, progress notes, and diagnostic test results, usually stored in Electronic Health Record (EHR) systems.

Patient reported – often overlooked because it does not neatly fit traditional data systems.

3 Overcome the challenge of unstructured data. Roughly 80 to 90 percent of business information is unstructured data. In healthcare, that can be clinician notes, scanned documents, patient diaries, images and even test results. A UCLA study has posited the use of social media to track HIV incidence and drug-related behaviours to detect and perhaps prevent outbreaks.

progress, treatment and clinical status. When these data are used to measure quality, outcomes, and for real-world evidence (comparative effectiveness, cost reimbursements, behavioural analysis and so on) the original use of the data must be acknowledged as a potential limitation and may compromise the reliability and validity of any resulting parallel conclusions.

This secondary and tertiary analysis is often performed in a data warehouse where all contextual analysis is removed. Thus the results are degraded and correlations are highly suspect. Unstructured content is neither stored nor searchable against the structured information, creating an inability to link and correlate information.

But the most significant challenge in aggregating and analysing healthcare data is that much of it is unstructured poorly stored, retrieved, queried and viewed. The content is spread across multiple data models, systems and data marts.

Increase awareness

Accelerating awareness and understanding of big data is critical to increase public and private investment in the short-term. The pharmaceutical industry has a wealth of experience and insight that will be key to realising its potential. Initiatives to grow awareness across the ecosystem will help different organisations find ways to engage around big data for mutual benefit.

Build capability and capacity

We need new capabilities to exploit big data analytics and manage the diverse data available across the pharmaceutical industry, academia and healthcare services. The complex analyses inherent in big data applications demand technical skills – but these skills alone are not enough. A new generation of informatics/business analysts is needed to translate that analysis into real value – data scientists who are able to extract and analyse information from large data sets and then present value-added knowledge and insight to non-technical experts.

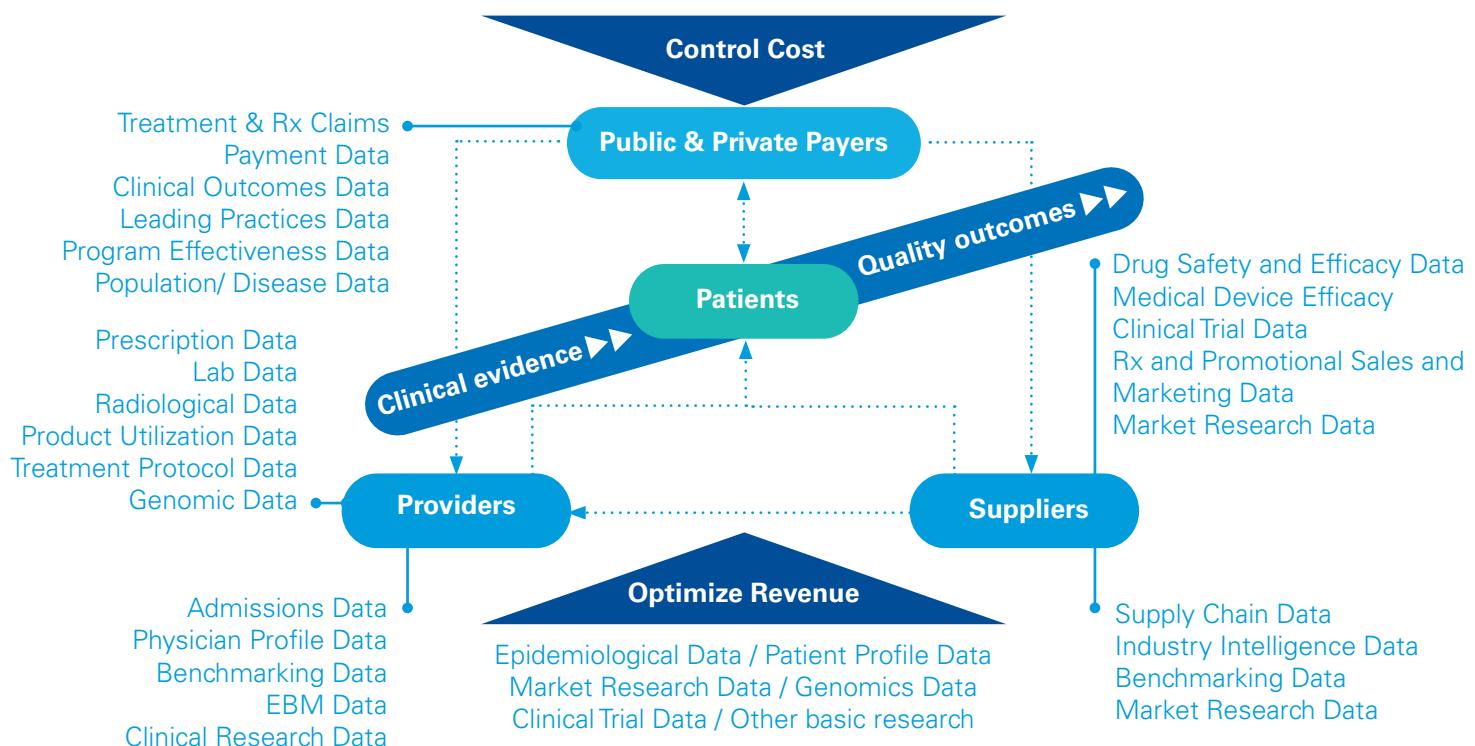
Make a sustainable data ecosystem

The multitude of new information sources remains an underutilised asset. We need accessible and interoperable data to generate economic value and realise applications such as personalised medicine. A collective of NHS data and service providers, and a wider data service market, is fast emerging in the UK to address these challenges – all within a robust governance framework to protect patient privacy. There is an opportunity for the industry to become a more strategically engaged customer of NHS data services and to help build a stronger collaborative culture – one that involves stakeholders aligning around the common aim of delivering better value for patients.

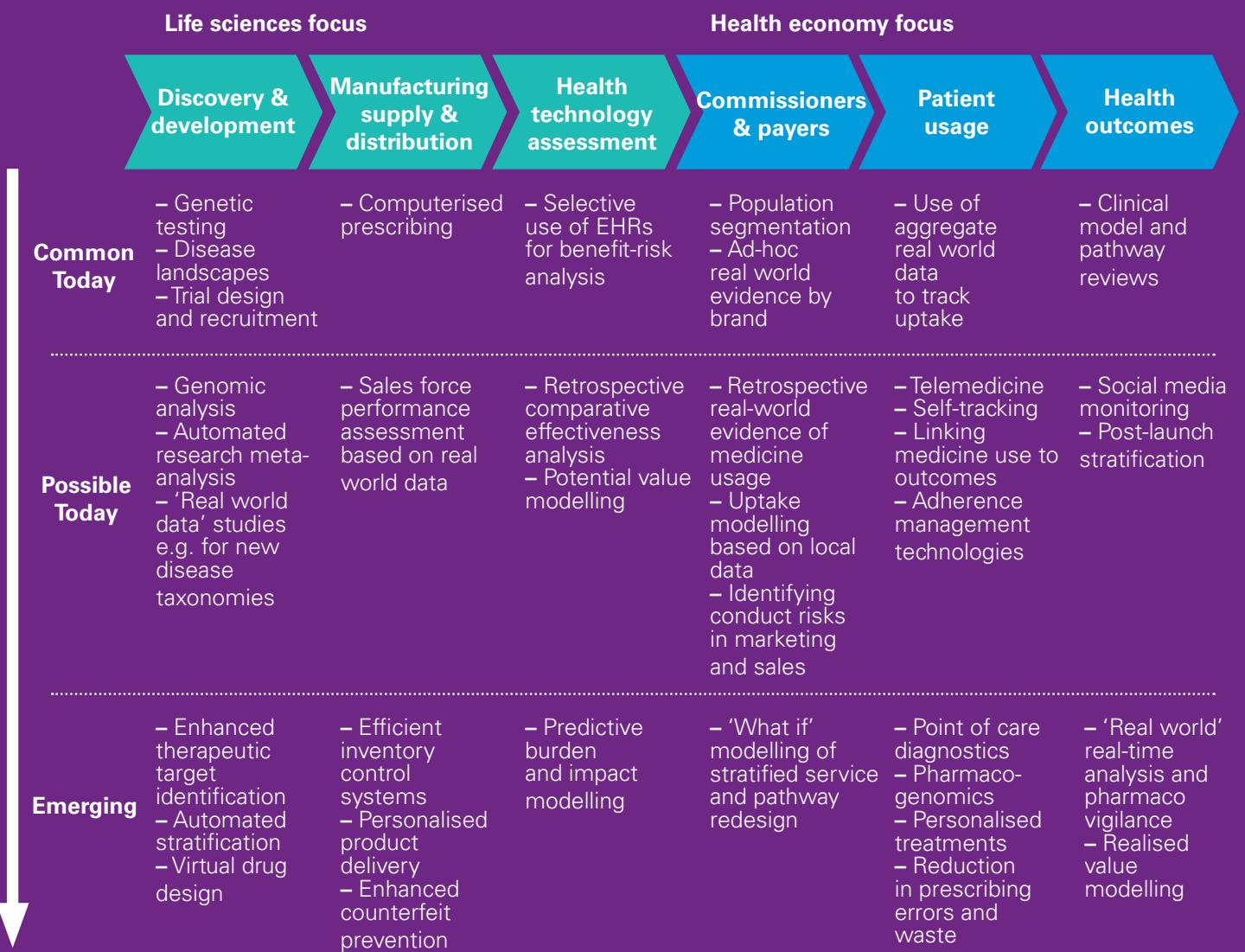
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Big data What does it look like?



The roadmap to big data



Common base of real world data



Your BEPS check-up

The OECD's 15 point action plan on Base Erosion and Profit Shifting (BEPS) will fundamentally change how and where life science companies are taxed – and have a material impact on their competitiveness and market valuation.

The Organisation for Economic Co-operation and Development (OECD) Action Plan on Base Erosion and Profit Shifting (BEPS) is designed to prevent multinational businesses from achieving non-taxation on profits or artificially shifting profits across borders to exploit lower corporate income tax rates.

There is a 27.5% difference between the lowest and highest corporate income tax rates across OECD countries. It is estimated that there is a 24% spread in the tax rates paid across the top 20 companies in the life sciences sector. BEPS will therefore potentially increase the tax burden of many companies currently structured to take advantage of lower-tax jurisdictions.

The final BEPS reports were issued in October 2015 and set out the recommended actions for individual countries. If implemented as outlined, some of the proposals are likely to significantly impact the post-tax profitability of life sciences companies, which may alter funds available to invest in essential R&D.

We are starting to understand how individual countries will adopt the recommendations – especially jurisdictions that seek to lead the pack such as the UK, Australia and certain other European states.

Businesses that appropriately adapt their business model in line with the OECD's recommendations should be able to minimise the impact of inevitable inefficiencies in the system caused by a lack of certainty. In the medium term, this should give them the best chance to maximise R&D funds to gain innovation leadership.

The potential impact of BEPS

BEPS will impact life sciences companies in various ways, affecting the tax deductions available and the risks of double taxation. For example:

- Groups that rely heavily on interest deductions to manage their current year tax charge may suffer a material impact, as will those who have financing arrangements which rely on hybrid mismatches
- BEPS Actions 8 to 10 stress 'value creation' and 'key decision making' in determining where profit should be taxed. Yet there is no consensus on what these terms mean in practice. Does a decision to fund or undertake a clinical trial drive value? Or is it the local management of the trial? Life sciences companies will need to provide tax authorities with a clear and consistent message on what drives value across their portfolio.

The proposals, then, might significantly impact the bottom line by increasing the overall effective corporate income tax rate. Or

they might merely achieve a concentration of 'substance' in jurisdictions offering the most competitive effective corporate income tax regime.

We recommend multinational life sciences companies review their organisational, legal and funding structures and perform scenario planning to assess the likely impacts of the BEPS work-streams. Consider, too, how existing structures would be viewed should information regarding the supply chain and taxes paid in-country be made available to the public.

Corporate income tax post-BEPS

If companies want more visibility over future tax liabilities and to maintain a flow of funds for essential R&D, they need to reconsider their organisational, legal and funding structures; and to quantify the value of intellectual property and intangible expenditure such as R&D and marketing.

In order to reduce uncertainty over transfer prices, companies can make better use of advanced pricing agreements, which establish an agreed pricing formula for a set period of time and minimise the prospect of costly legal challenges.

Businesses should start to model the effect of BEPS on their forecasts and future tax profile to quantify the impact; and prioritise areas for review and restructuring

Life sciences companies should also embrace the move to greater transparency, as this creates better relationships with tax authorities and enables more dialogue on tax planning.

Financing in a post-BEPS world is expected to undergo comprehensive changes, especially in those countries that need to make radical changes to their interest deductibility regime to align to the OECD's recommendations. Groups that have significant debt funding and/or use financing structures that benefit from hybrid mismatches are likely to need to undertake substantial restructuring in order to minimise the impact (and cost) of BEPS compliance.

All multinationals, regardless of sector, should be acting now to:

- Identify the BEPS Actions and key countries of most relevance to the group and operating model.
- Understand the detail of the proposals and how they are to be implemented on a local level.
- Quantify the impact of BEPS on the group.

They should also be establishing a robust transfer pricing and documentation system to minimise their exposure to tax audit and transparency demands.

The three major impacts on life sciences companies:

1. Reduced availability of interest deductions. BEPS Action 4 is likely to restrict the ability to take interest deductions even on third party debt.

Advice: assess existing financing flows to minimise the impact of these new restrictions.

2. More subjective transfer pricing rules increase likelihood of disputes over where profit should be taxed. 'Value creation' and 'key decision making' will determine taxable location.

Advice: provide tax authorities with a clear and consistent message on what drives value across the portfolio of products.

3. Increased risk of creating a taxable presence. Life sciences companies that rely on the use of representative offices or third parties as their in-country presence may be at increased risk of creating a permanent establishment in the location of the representative office.

Advice: Review organisational structures and supply chains to evaluate optimum approach for tax purposes.

The four actions life sciences companies should consider taking

1. Understand precisely **how the group is funded** and what flexibility there is to refinance to minimise the impact and cost of BEPS compliance.

2. Review **the use of representative offices** within global business operations, quantify the impact that a change in the definition of a permanent establishment may have and consider restructuring to reduce the potential impact on post-tax revenues.

3. Assess the relationship between **the owners of all intangibles** across the business and the related business activities, ensuring that activities are commensurate to the revenues generated in the place of ownership.

4. Develop a system which is able to **measure the value of data** that is collected through business activities, enabling you to predict the potential of a data asset to become taxable and the amount of taxable profit that would be generated.



Nutraceutical update

What are the key consumer trends driving the nutraceuticals and supplements industry forward in 2016? Katrina Lytton has the answers.

2015 saw consumers taking control of their own health and weight management and recognising that health is intrinsically linked to individual food and lifestyle choices. I see the increasing demand for a personalised approach to wellness driving innovation in the fields of sports nutrition, weight management and healthy snacking.

The trend for 2016 continues to be very much around naturally functional products, healthy snacks, 'clean', plant-based products and an emphasis on healthy fats and proteins.

'Free from' (particularly gluten-free) is likely to remain a key factor in product development. It has contributed to the recognition of the role of gut health in weight management. There will be greater demand for 'gut friendly' products such as fermented foods, unrefined carbohydrates as well as prebiotic and probiotic products and supplements.

Ingredients, advice and claims: what's next?

Naturally functional foods will continue to dominate, particularly those that claim benefits for sports performance and weight management – such as complex carbohydrates, particularly seeds and grains, and 'healthy fats'. The use of protein products, such as whey, will become more mainstream.

The trend in 'free-from' ingredients looks set to stay. Products that claim to promote digestive benefits – such as 'alternative' flours, dairy free milks and ancient grains, as well as prebiotic and probiotic supplements – are likely to proliferate.

Sugar replaced fat and salt to become one of the most vilified ingredients in 2015 – and will contribute to further growth of the 'free-from' market and the demand for unrefined, natural ingredients. Products made with plant-based superfoods and containing powerful antioxidants, such as raw cacao and matcha, will further boost claims of the medicinal properties of natural ingredients.

What is the future for personalised nutrition?

Personalised nutrition is at the heart of trends in health and wellbeing. The recognition that each individual has their own nutritional profile and responds to ingredients in a different way is transforming the role technology can play in this sector.

There is a strong appetite for consolidation amongst pharmaceutical, food and technology companies, as technology plays an increasingly crucial role in the management of individuals' behaviour. The trend in digital health and prevalence of apps and wearable devices to track movement and diet give individuals a perceived sense of control over their own wellbeing by providing them with measurable facts and statistics. This in turn provides companies with the ability to analyse consumer behaviour more effectively and use this data to tailor products to individuals and market them in such a way that is motivating and empowering.

The trend for 2016 continues to be very much around naturally functional products

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Sports nutrition has gone mainstream. What does it mean for nutraceuticals?

Sports nutrition is no longer the domain of athletes; it continues to move to the mainstream, largely driven by the focus on protein for both sports performance and weight management. Protein supplements, such as whey, are increasingly in demand. They are often used in combination with fruit and vegetables as part of a balanced diet and go hand in hand with an active lifestyle.

The past year has seen an increase in the appeal of protein supplements for women thanks to the prevalence of the 'strong not skinny' trend and growing popularity of women's resistance training. The use of supplements as part of daily nutrition is likely to generate an increase in innovation around proteins that contain a wide range of amino acids and that target specific goals such as weight loss, energy, satiety and muscle repair.

What about opportunities among the senior population?

The number of adults over the age of 60 is expected to double by 2050. As incidence of chronic disease – notably obesity, diabetes and cancer – continues to increase, a shift towards prevention rather than treatment is needed to match quality of health to the rise in longevity.

The current trends in personalised nutrition and technology are going some way to ensuring individuals take a more proactive part in addressing their own health needs. But a number of today's chronic conditions are lifestyle diseases. So further changes in behaviour are critical to ensuring a healthier ageing population.

Consumers have access to increasing amounts of data, enabling them to make rational choices. However, as non-rational beings, there needs to be a greater understanding of how to incentivise people to make decisions that will benefit them in the long term. Some progress is being made. For example, health devices can track activity, make recommendations and reward good behaviours. Published advice emphasises the importance of making small, sustainable lifestyle changes that have a lasting impact.



How do 'clean label' and 'free-from' trends drive innovation in supplements?

Consumers increasingly want to know the provenance of their food; clean labelling is fast becoming the norm. The demand for products containing only a few, more recognisable, ingredients – and without additives or preservatives – is likely to contribute to an increase in products that are natural and unprocessed.

The requirement for information about both the contents and origins of products will necessitate greater transparency within the wellness industry on supplement development and formulation. The normalisation of dietary supplements should lead to an increase in innovation, with a particular emphasis on vitamins, minerals and amino acids found in plant compounds, reflecting the overarching trend for natural, clean ingredients.

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