



Pharma outlook 2030: From evolution to revolution

A shift in focus

Global Strategy Group

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Pharma 2030 outlook

The pharmaceutical sector is at a crossroads. In a heavily disrupted marketplace, characterized by shifting payer attitudes and patient empowerment, neither incremental adjustments nor steady evolution are likely to halt the decline of the traditional pharmaceutical business model.

This paper looks ahead to a 2030 scenario to examine the trends revolutionizing the sector; trends that we expect to have dramatic impacts.

We believe revenues will fall well short of forecasts as current projections, as well as business and operating models, do not reflect the turbulence in the marketplace. The continued upheaval will give rise to three distinct pharmaceutical archetypes. Executive teams need to carefully consider what type of company they want to be – and plot the optimal path towards this status.

By preparing for this future now, organizations not only reduce the risk of decreasing income, but can also open up new opportunities for growth. Over the coming months, we shall produce a series of thought-provoking articles that will examine more deeply specific topics outlined in this paper, which sets the scene for volatile times ahead.

Enjoy the read!



Roger van den Heuvel

Partner, Head of Life Sciences
Global Strategy Group



Chris Stirling

Partner
Global Chair, Life Sciences



Seismic shifts

Anyone taking a cursory glance at current pharmaceutical industry revenue forecasts could be forgiven for thinking that all is well. However, the assumptions behind these numbers do not adequately take into account two seismic shifts that are disturbing the industry status quo. The first shift is in the balance of power across the healthcare value chain, as governments and insurers take center stage, pressuring pharmaceutical companies to reduce prices and demonstrate greater value from their therapies. Secondly, we believe a swing from treatment to prevention, diagnostics and cure, will grow stronger in time, attracting a host of new entrants from within and outside of the sector.

Parallels with the automotive industry

Many of the developments in the pharmaceutical industry mirror those in the automotive sector. Like pharmaceuticals, the industry is relatively mature and made up of a few major players. And automakers also face intense pressure from regulators – in their case to cut emissions, accelerating the move toward electric and other non-polluting vehicles. The growing dependence upon technology, primarily software, is attracting the interest of new entrants such as Google, Uber and Tesla who are focusing on mobility, rather than on the automotive industry itself.

Shift 1: Downward pressure on pricing

With rising demand for healthcare and falling budgets, governments and payers are exerting pressure to drive down prices. One bold example involves the Netherlands. Not content with striking volume deals with the major pharmaceutical players, it is looking to utilize the power of the EU to create even greater economies of scale. At the moment, several member states are pooling together into a single procurement machine with much greater bargaining power.¹ This initiative, in its early stages, is also being looked at by other states seeking to cut their drug expenditure.

Additionally governments, insurers and patients are requiring greater transparency around drug pricing. The time-honored healthcare principle of fee-for-service is also under attack. Payers, insurers and hospitals are no longer willing to pay simply for a product push approach; they want fees to be dependent upon the success of the products and procedures through measurable outcomes.

In May 2016, US-based health insurer Cigna announced value-based contracts with Sanofi, Regeneron and Amgen for cholesterol lowering drugs, with the insurer receiving discounts if cholesterol levels are not sufficiently reduced following the therapy.² Another US system – Harvard Pilgrim Health Care – has signed a value-based contract with Lilly for its diabetes drug, Trulicity, with rebates for under-performance, and an incentive program for exceeding patient targets.³

Meanwhile, New York State's Delivery System Reform Incentive Payment has the ambitious aim of moving 80 – 90 percent of managed care payments to value-based methodologies by 2020 – a policy that will have a significant knock-on effect for drug companies.⁴ Also in the US, The Health Care Transformation Task Force made up of providers, insurers and employers has committed to shift 75 percent of its members' business into contracts with incentives for health outcomes, quality and cost management by January 2020.⁵

One of the challenges facing drug manufacturers is to build closer relationships with patients. This has many benefits – including better understanding of patient experience and improved adherence. However, the industry has some way to go to become a trusted part of the healthcare ecosystem.

Although value-based pricing (VBP) comes with its fair share of risks and challenges, as evidenced by Novartis' Entresto drug, there is large potential to create a win-win situation for multiple healthcare stakeholders if structured and implemented correctly.⁶

In KPMG's white paper, *Value-based pricing in pharmaceuticals: Hype or hope?*⁷ we explore in greater detail some of the challenges of introducing a value-based pricing approach.

Shift 2: From treatment to prevention ... and beyond

Catalyzed by an exciting range of new, disruptive technologies, the pharmaceutical industry needs to reimagine its future. By 2030, we should not simply expect more targeted therapies, practitioners will also be able to predict the likelihood of a patient being diagnosed with a disease or health condition, and shift from treatment of symptoms to prevention measures and complete cures, rather than providing temporary respite. In this new world, some conditions may well become a thing of the past. For example, it is now possible to cure hepatitis C, which was previously regarded as incurable and afflicts 180 million people worldwide.⁸ This has created a paradigm shift that has taken healthcare professionals, patients and payers by surprise.

This shift is driven by three underlying developments:

- groundbreaking new therapies
- advances in technology
- the consumerization of health through increased access to data by patients.

The latter enables patients to better understand and get more involved in managing their conditions, which in turn will raise expectations.

The effects of these changes, and the speed with which some historical treatment methods are replaced, will inevitably differ by therapeutic area.

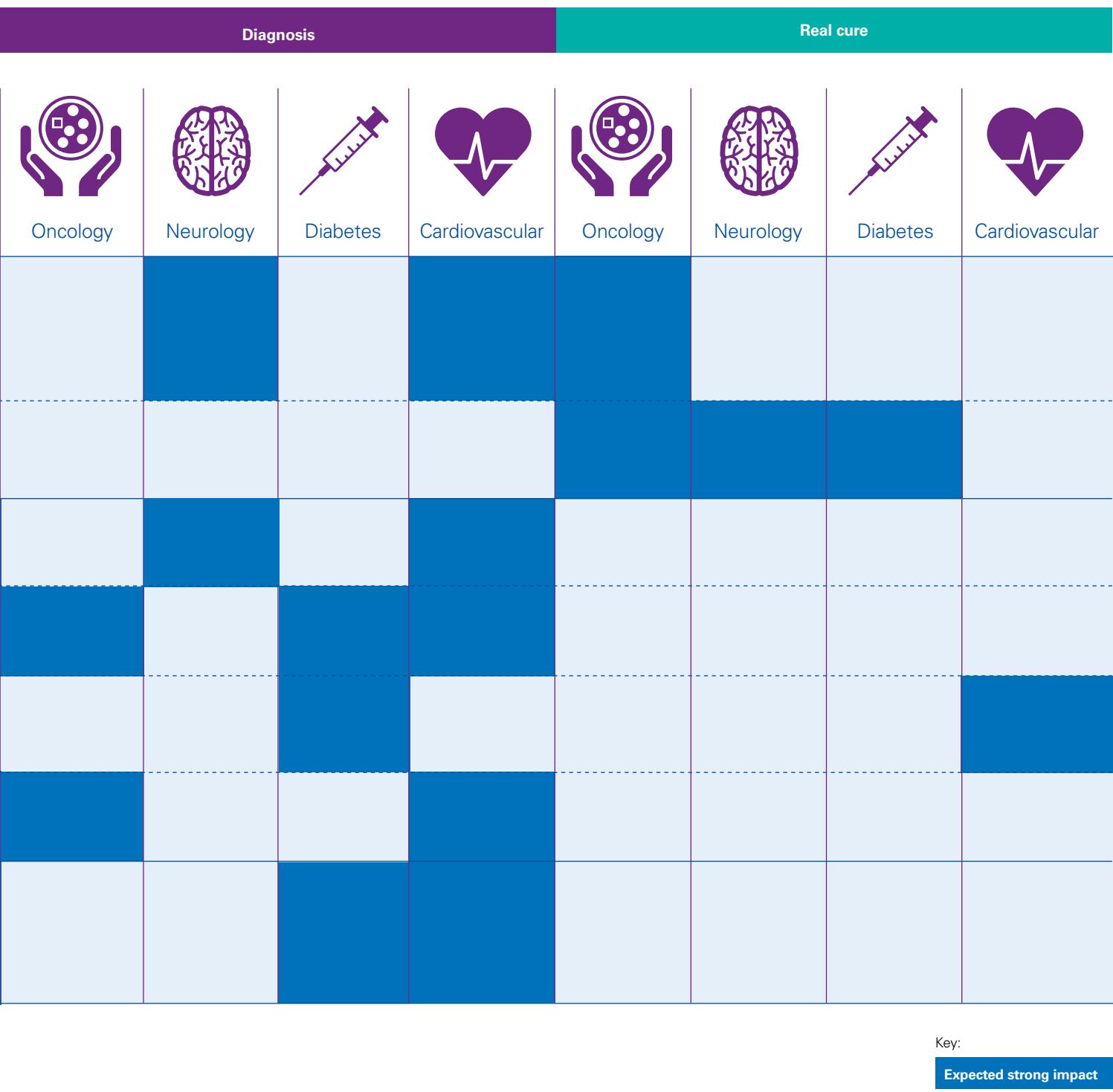
Key trends impact

The table evaluates the potential impact of selected trends across four therapeutic areas: oncology, neurology, diabetes and cardiovascular.

| | | Prevention | | | | |
|-----------------------------------|--|--|----------|-----------|----------|----------------|
| | | Enablers | Oncology | Neurology | Diabetes | Cardiovascular |
| New therapies (selected examples) | | Genetics Gene editing, genotyping, genetic profiling and mapping, gene therapy | | | | |
| | | Cellular programming Stem cell therapies | | | | |
| Advances in technology | | 3D printing 3D printed models, organs, cells | | | | |
| | | Nanotechnology Nanobots, nanoparticles, nanochips | | | | |
| | | Bionics Artificial organs, implants, prosthetics, assistive devices, exoskeletons | | | | |
| | | Predictive analytics Artificial intelligence, big data analytics | | | | |
| Consumerization of health | | Patient access to data and technology Wearable monitoring devices, apps, gamification and digital medicine | | | | |

Source: KPMG Analysis, 2016.

Note: These examples are not exhaustive. They are selected to demonstrate the underlying key developments behind the second shift.

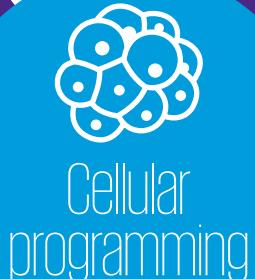


Key trends examples



The National Heart and Lung Institute at Imperial College London, has developed a blood test to detect 174 different genes leading to 17 inherited heart conditions.⁹ And, since March 2015, diagnostic information services provider Quest Diagnostics has been offering Neurome, which helps to diagnose rare neurological disorders in children. Researchers at Sichuan University's West China Hospital have also started using gene editing to test blood cells in lung cancer patients.¹⁰

Harvard researchers have developed an automated cancer diagnostic method based on artificial intelligence, which is able to determine the presence of breast cancer by examining lymph node cells.²⁰



In February 2016, ViaCye and Janssen Biotech agreed to consolidate the assets of the Janssen BetaLogics group into ViaCye to find a Type 1 diabetes cure through stem cell treatment.¹¹

Kiadis Pharma is developing stem cell transplant based immunotherapies to treat – and potentially cure – blood cancers with its product 'ATIR101,'TM currently enrolled for Phase 2 clinical trials. Meanwhile, the International Stem Cell Corporation (ISCO) is working towards developing a potential cure for Parkinson's disease using stem cell therapy, with patients enrolled in Phase 1 trials.¹²

● = Prevention redefined

● = Cure redefined

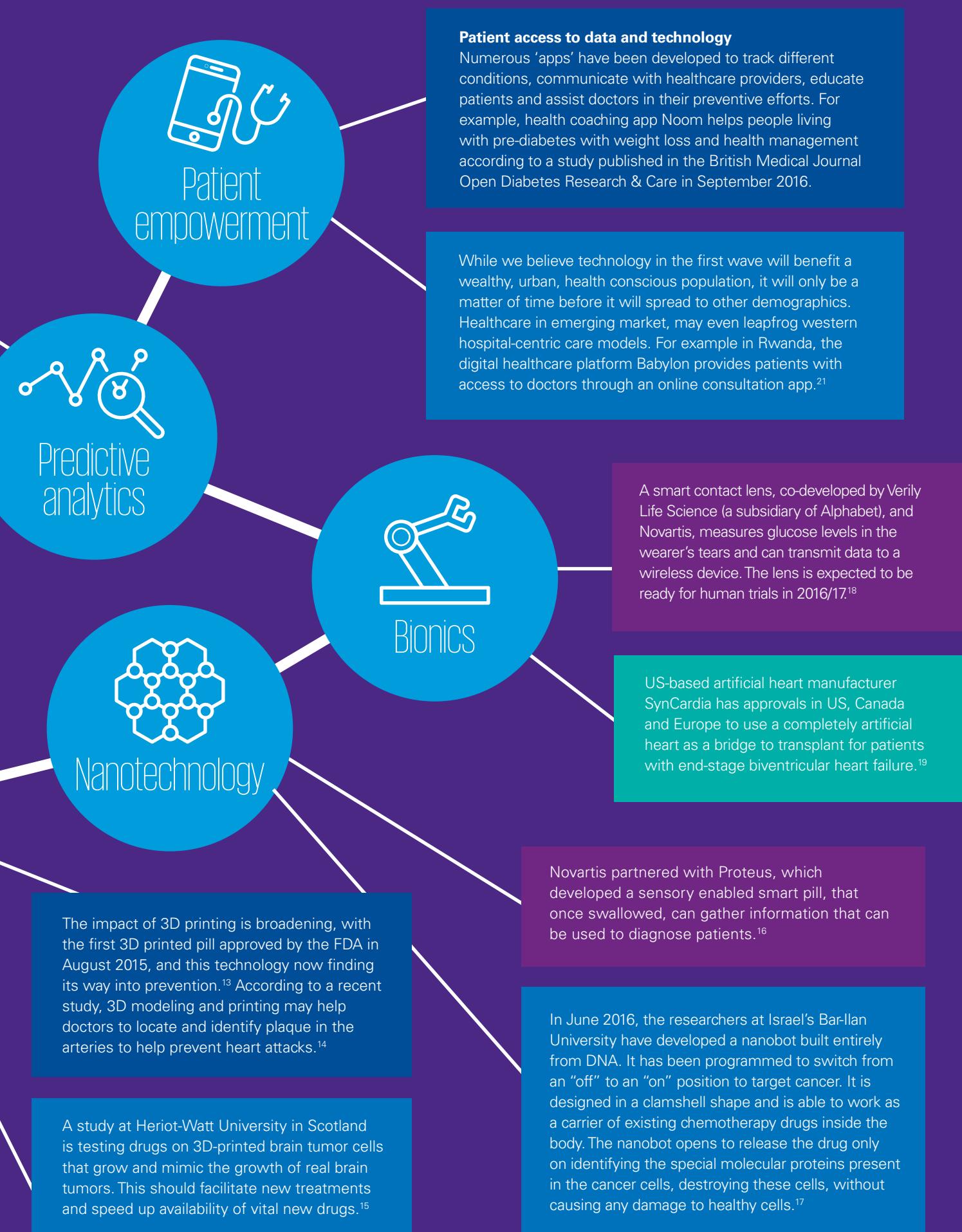
● = Diagnoses redefined

● = Treatment redefined

Source: KPMG Analysis, 2016.

Note: These examples are not exhaustive. They are selected to demonstrate the underlying key developments behind the second shift.

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The new pharmaceutical playing fields

It is apparent that some pharmaceutical companies are starting to recognize the impact of the two major shifts: downward pressure on pricing and the move towards prevention, diagnosis and real cures. These changes are upsetting the established order, opening the door to new competition, and forcing companies to rethink where they play – and who they play with, requiring a growing emphasis on collaboration and partnership. Among others, we see three new 'playing fields' emerging in response to disruption: pharma tech, genetics and immunotherapy.

Pharma tech

An increasing number of pharmaceutical firms – and, indeed, medical device companies – are partnering and integrating with technology businesses.

In a bid to tackle the huge and rising blight of diabetes, Sanofi and Verily, the life sciences unit of Google parent Alphabet, announced in September 2016 that they would invest approximately US\$500 million in a joint venture to combine devices, software and medicine.²²

We believe medical device companies are leading the cooperation with tech companies. For example, in the diabetes space, one interesting partnership involves device giant Medtronic teaming up with tech firm Qualcomm, to develop a continuous glucose monitoring system that will also provide actionable insights to patients and providers.²³

"We see new 'playing fields' emerging in response to disruption: pharma tech, genetics and immunotherapy."

Software is becoming more and more important in our lives, and healthcare is no exception. Another pharma tech alliance between Varian Medical Systems and Flatiron Health aims to develop cloud-based, electronic health records, data analytics and decision support software geared toward oncology patients.²⁴

In our recent article, *Blurring the Lines: Preparing for Convergence in Health and Life Sciences*²⁵, we explore the opportunities that will transform the global healthcare marketplace, as well as pose five key questions that any player needs to address to take advantage of the convergence opportunity.



Genetics

Genetics has moved forward with real pace in recent years, with gene editing fueling a new wave of potential applications to aid both prevention (via early detection) and real cures. The leading genomics firms are essentially biotech players, acting either independently or through collaboration.

In the coming decades, gene editing could revolutionize the treatment of different diseases such as neurological disorders or cancers. This approach enables healthcare providers to alter/replace the problematic gene, to produce a new therapeutic protein or 'silence' mutant cells. A number of neurological disorders are benefiting from these advances, like Alzheimer's, Parkinson's, Huntington's, Amyotrophic Lateral Sclerosis and strokes.

The University of Florida Health, US, has created a genotype testing process to help physicians tailor treatment based on patients' genetic information. Genetic information is used to understand whether a drug for preventing blood clots (Clopidogrel) will be effective in patients after a specific heart procedure, or whether an alternate procedure should be prescribed.²⁶

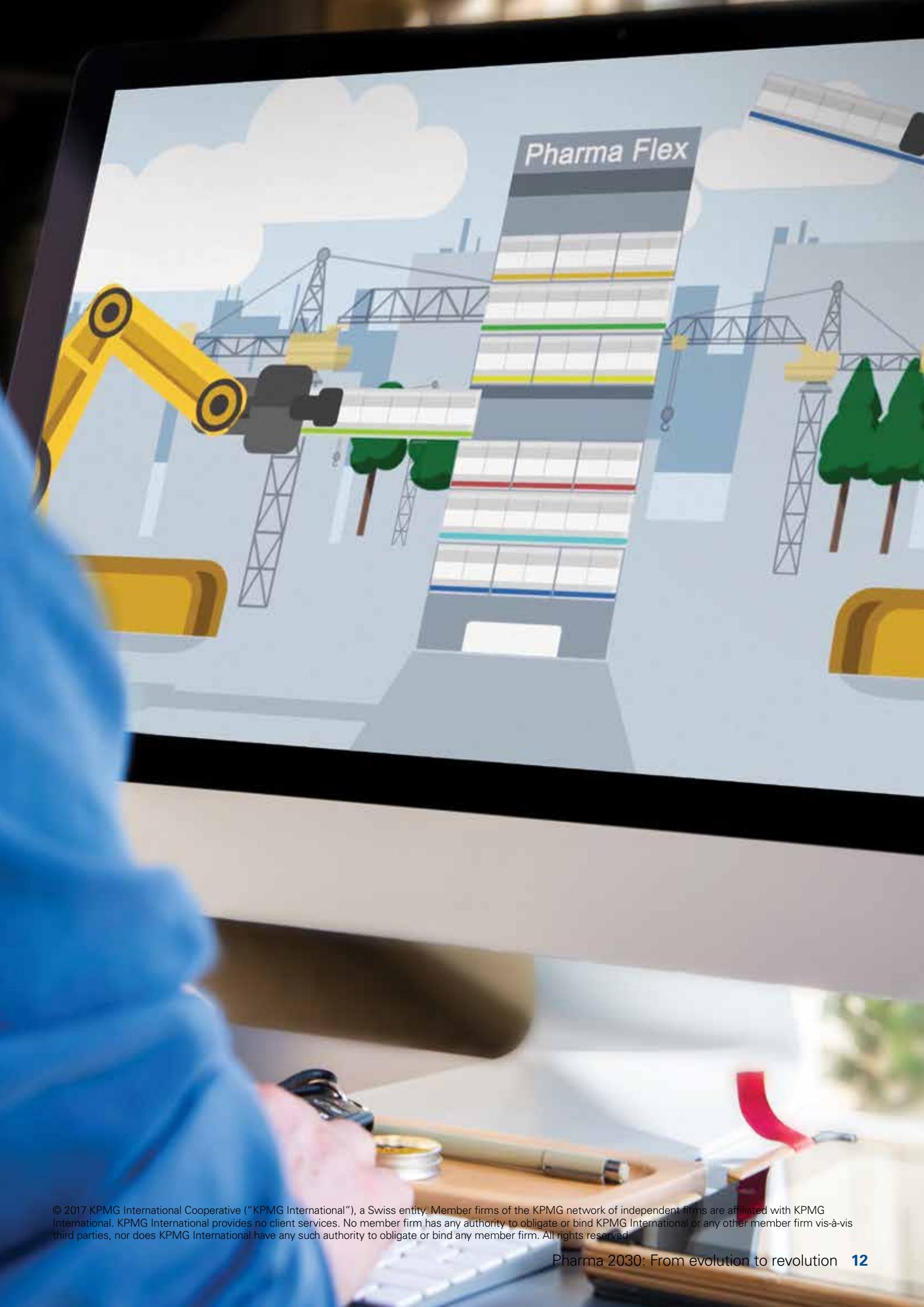
Immunotherapy

Technology is also boosting another, more established field of play: immunotherapy.

Many companies are focusing on developing immunotherapies, either independently or in collaboration with big pharma players, to treat and, ultimately, to prevent diseases.

Immunotherapy based drugs are increasingly being used for treatment of various cancers, but companies are also exploring their use in the treatment and prevention of other chronic conditions like diabetes, cardiovascular diseases, Parkinson's and Multiple Sclerosis. For example, Cardiovax, a US based biotech company, is developing immunotherapies to treat and prevent cardiovascular diseases such as atherosclerosis. These therapies may potentially be used to predict the risk of cardiac attacks.²⁷

Meanwhile, Prothena and Roche are jointly developing immunotherapies to help delay progression of Parkinson's disease, by targeting a protein which is potentially involved in the onset and progression of this condition.²⁸



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The emergence of three pharmaceutical archetypes

Shifts in the business model, and a refocus on new fields of play, can help pharmaceutical firms to adapt to disruption. But even these changes are unlikely to generate the kinds of growth and revenue that shareholders demand.

Only through a complete organizational transformation can today's leading companies maintain influence and earnings. This means rethinking how to play, which throws up three types of 'archetype' that we believe will prevail in the future industry:

The active portfolio company

An active portfolio company is typically active in several therapeutic areas within its portfolio. For example, those operating in pharma tech, genetics and immunotherapy are constantly looking for new forms of therapy, while simultaneously reappraising their product mix to match unmet needs. Active product lifecycle management in pharmaceuticals is becoming ever more critical, as the number of blockbuster drugs protected by patents continues to decrease.

Recent asset swaps – like those involving GlaxoSmithKline and Novartis on vaccines, oncology and consumer health interests²⁹ – are just one example of active portfolio management; a trend that is likely to accelerate and will therefore require new, internal capabilities.

The ultimate manifestation of a portfolio player is a modular organization, with an enterprise layer equipped to acquire and divest parts of its portfolio in a 'plug-and-play' fashion. For these companies, it's all about being flexible and agile, to move quickly to take advantage of opportunities. Our analysis of the life sciences deal landscape confirms the increasing trend towards specialization, which manifests in the acquisition of a complementary portfolio to the existing business. We will be exploring this and other aspects of active portfolio company archetype in more detail in our next article in the Pharma 2030 series.

"Only through a complete organizational transformation can today's leading companies maintain influence and earnings."

The virtual value chain orchestrator

Companies offering 'virtual value' do not own anything physical, but create various types of solutions 'virtually' – although their final delivered product or service is very real. What they do own is data – and lots of it – on therapies, patients and research. Whereas data used to be almost exclusively in the hands of the main life sciences companies, it has now been liberated – and put to use to drive major change.

Think about the opportunity a virtual value chain orchestrator possesses, e.g. guiding patients effectively through a complex healthcare value chain, from cradle to grave, supporting healthcare practitioners to provide tailored care each time, or even allowing pharma companies to receive outcomes-based payments.

Like every other industry, tech businesses such as Google (and other smaller players that may not even exist yet) could transform the sector, and 'own' the customer by creating one-stop healthcare platforms. 'Health' could become just another area of consumer choice, where the platform owner offers everything a patient needs, from advice on diet and lifestyle, monitoring of conditions via wearables, and access to physicians, drugs, devices and possibly even replacement organs.

Looking ahead, platforms are the new way to link supply with demand, and it is highly likely that we will see a healthcare version of Uber, evolving beyond the current delivery of flu vaccines to entirely disrupt the market.³⁰ As with the automotive industry, pharmaceutical firms are at risk of becoming just another provider to the platform.

The niche specialist

These companies tend to be smaller, and are organized in a very different way from traditional players. They are focused on a single therapeutic area or disease, and look at the entire patient pathway from prevention to real cure. A prominent example is a company like Novo Nordisk, which focuses on diabetes with the objective of ridding the world of this disease.³¹

The niche players typically specialize in a more complete sense than simply providing a single treatment. For instance, a specialist in arthritis would treat the symptoms, but also provide a range of outcomes that together create a better lifestyle for an arthritis sufferer. This could mean extending the business to include comfortable shoes for painful joints, as part of a one-stop shop for arthritis. A niche specialist may eventually become part of a portfolio company, to gain greater access to funding, to enable the provision of combined therapies, and/or to collaborate with a virtual value chain orchestrator to connect with a broader client population.





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Preparing for the future

"Pharmaceutical companies that manage to embrace the most appropriate archetypes, and master disruption, have the greatest chance to deliver real value."

For pharmaceutical CEOs, it is not enough to simply recognize the emerging changes facing the industry. Their biggest challenge is to translate the impact of these changes on business and operating models in a holistic way, to adapt swiftly and decisively to disruption.

The lesson from other disrupted industries is loud and clear. Pharmaceutical companies cannot just partially adjust existing business and operating models, when the fundamental rules of engagement are changing so dramatically. One way CEOs can prepare for the future is to set up fully independent, integrated Pharma 2030 experimental laboratories that report directly to them. These labs can:

- test new archetypes that align with the company's financial ambition, to generate more realistic forecasts that take account of the sector's disruption
- evaluate how different archetypes could impact the way the business is organized, and, equally importantly, determine which new organizational capabilities are needed
- develop a balanced transition map that addresses the multiple and significant risks facing the business.

Those pharmaceutical companies that manage to embrace the most appropriate archetypes, and master disruption, have the greatest chance to deliver real value to patients, which should in turn drive their success.

Footnotes

1. *Austria joins Benelux in pharma coalition*, Dutch Government website as accessed on 2 December 2016:
<https://www.rijksoverheid.nl/actueel/nieuws/2016/06/17/oostenrijk-sluit-zich-aan-bij-geneesmiddelencoalitie-benelux>
2. *Health Insurers Push to Tie Drug Prices to Outcomes*, Wall Street Journal, 11 May 2016.
3. *Lilly's Trulicity joins pay-for-performance trend with Harvard Pilgrim deal*, Fierce Pharma, 28 June 2016.
4. *A Path toward Value Based Payment: Annual Update*, Department of Health, June 2016.
5. *Where healthcare is now on march to value-based pay*, Modern Healthcare, 28 January 2015.
6. *Value-based pricing in pharmaceuticals: Hype or hope?*, KPMG International, 2016.
7. IBID.
8. *Global distribution and prevalence of hepatitis C virus genotypes*, Hepatology, 2015.
9. *Blood test detects all known genes for inherited heart conditions*, Medical News today, 19 February 2016.
10. *Chinese scientists to pioneer first human CRISPR trial*, Nature, 21 July 2016.
11. *ViaCyte Acquires Rights to BetaLogics Assets, Expanding and Extending Industry-Leading Portfolio for Stem Cell-Derived Approaches to Type 1 Diabetes* Preliminary data of STEP ONE clinical trial are promising, Viacyte press release, 4 February 2016.
12. *Kiadis Pharma's Orphan Drug Designation for ATIR101™ further expanded to include treatment in a hematopoietic stem cell transplantation*, Kiadis Pharma press release, 30 June 2016.
13. *First 3D-printed drug approved by FDA*, CNN Tech, 4 August 2015.
14. *3D Printed Arteries Could Help Cardiologists Better Predict and Treat Heart Disease*, 3DPrinting.com, 25 February 2016.
15. *3D printing brain tumours to improve treatment*, Heriot-Watt University website, 25 May 2016.
16. *The Smart Pill That Was Worth \$104 Billion*, Wyatt Investment Research, 10 February 2015.
17. *Nanobots are waiting in the wings to cure cancer and clean up ocean pollution*, Market Watch, 9 June 2016.
18. *Google and Novartis to develop 'smart' contact lens for diabetics*, Financial Times, 15 July 2014.
19. *Regulatory Approvals, 70cc SynCardia temporary Total Artificial Heart*, SynCardia website accessed 24 November 2016:
<http://www.syncardia.com/>
20. *Artificial Intelligence May Help Improve Accuracy of Cancer Diagnoses*, Cancer Therapy Advisor, 15 July 2016.
21. *Rwanda: Digital Healthcare Scheme to Be Launched in June*, The East African, 13 Feb 2016.
22. *Sanofi, Google parent form \$500 million diabetes joint venture*, Reuters, 12 Sept 2016.
23. *It's Medtronic & Qualcomm Vs. Google & Dexcom in Race to Develop Next-Gen CGM*, Medical Device and Diagnostic Industry, 26 May 2016.
24. *Varian Medical Systems and Flatiron Health to Develop Next Generation of Cloud-based Oncology Software*, PR Newswire, 26 May 2015.
25. *Blurring the lines: Preparing for convergence in health and life science*, Rotman Magazine, Fall 2016.
26. *Personalized medicine' drives better outcomes for certain heart patients*, University of Florida news, 9 November 2015.
27. *Our Products: CardioVax's Products in the Pipeline, Mucosal Vaccine*, CardioVax website, accessed 24 November 2016:
<http://www.cardiovax.com/our-products.php>
28. *Prothena Reports Results from Phase 1b Study of PRX002 Demonstrating Robust Antibody CNS Penetration and Significant Reduction of Free Serum Alpha-synuclein in Patients with Parkinson's Disease*, Prothena press release, 9 November 2016.
29. *GSK-Novartis deal 'a model' for industry*, Financial Times, 2 March 2015.
30. *Uber will deliver up to 5 free flu shots and a free care pack to users*, TechCrunch, 24 October 2016.
31. Novo Nordisk website accessed 9 January 2017:
<http://www.novonordisk.co.uk/>

About KPMG Global Strategy Group

KPMG Global Strategy Group works with private, public and not-for-profit organizations to develop and implement strategy from 'Innovation to Results' helping clients achieve their goals and objectives. KPMG Global Strategy professionals develop insights and ideas to help address organizational challenges such as growth, operating strategy, cost, deals and transformation.

Contacts

Chris Stirling

Partner

Global Chair, Life Sciences
KPMG in the UK
T: +44 20 73118512
E: christopher.stirling@kpmg.co.uk

Roger van den Heuvel

Partner

Global Strategy Group
Head of Life Sciences
KPMG in the Netherlands
T: +31206 567044
E: vandenheuvel.roger@kpmg.nl

Peter Gilmore

Principal

Global Strategy Group
KPMG in the US
T: +1 703 343 2392
E: pgilmore@kpmg.com

Dr. Christoph A. Zinke

Partner

Head of Global Strategy Group in
China and Asia Pacific
KPMG in China
T: +85221402808
E: christoph.zinke@kpmg.com

Professor Hilary Thomas

Partner

Global Life Sciences Sector Team
Chief Medical Adviser
KPMG in the UK
T: +44 20 73114154
E: hilary.thomas@kpmg.co.uk

Dr. Adrienne Rivlin

Director

Global Strategy Group
KPMG in the UK
T: +44 20 76941992
E: adrienne.rivlin@kpmg.co.uk

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