

Deloitte.



**Innovating to survive,
collaborating to thrive**
2017 Pharmaceutical R&D
leader survey

Deloitte Centre *for*
Health Solutions

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Deloitte Centre *for* Health Solutions

The Deloitte Centre for Health Solutions, part of Deloitte UK, generates insights and thought leadership based on the key trends, challenges and opportunities within the healthcare and life sciences industry. Working closely with other centres in the Deloitte network, including the US Center for Health Solutions, our team of researchers develop ideas, innovations and insights that encourage collaboration across the health value chain, connecting the public and private sectors, health providers and purchasers, and consumers and suppliers.

Foreword

Welcome to our first annual survey of pharmaceutical R&D leaders: Innovating to survive, collaborating to thrive. Our report is written against a background of rapid changes in the way that the pharmaceutical industry is operating; with regulatory, health system and political environments exerting unprecedented pressures on the returns that companies are achieving from pharmaceutical research and development (R&D).

This report examines how R&D leaders are guiding organisations to adapt to these changes, with insights derived from interviews with R&D leaders combined with observations from our work with the industry. These wide-ranging discussions touched on the key areas influencing pharmaceutical R&D, from long-standing issues in R&D productivity to the recent emergence of potentially disruptive forces from digital technologies, and the challenges presented by the political climates in the US and Europe.

We identify the priorities of R&D leaders and determine which operational and 'game changing' initiatives are being pursued in order to meet scientific, regulatory, cost and pricing pressures. We also explore the key factors driving operational excellence, including:

- forming productive and mutually beneficial partnerships and collaborations
- sourcing and deploying talent
- promoting a sustainable culture
- making best use of R&D IT
- embedding patient centricity across the R&D and commercial value chain
- how geopolitical challenges such as the new US presidency and Brexit are influencing executive decision making.

This is the first annual survey of R&D leaders conducted by Deloitte aimed at gauging their sentiment on current priorities, understanding the drivers behind their future investment plans and assessing portfolio risks. It has been our privilege to speak with leading R&D executives from seven companies which represent a combined \$30 billion annual R&D spend. Given the findings in our latest annual report *'Balancing the R&D equation: Measuring the return from pharmaceutical innovation 2016'*, which identified a continued decline in returns on R&D investment, we focussed our discussion on the most pressing issues facing the industry and their impact on the R&D function. We are looking forward to repeating this annual survey to monitor changes in the sentiments, priorities and factors influencing financial and operational decisions in the world's largest R&D organisations.

We hope this report helps stimulate rich dialogue within your own organisations and as always we welcome your feedback. If you would like to participate in the 2017 survey and contribute to the discussion, please let us know.

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Analysis of survey findings

Drivers influencing R&D priorities

R&D priorities are constantly evolving, driven by rapid shifts in regulatory and payer environments (particularly in the US), the arrival of new tangible insight on outcomes based on Real World Evidence (RWE), and pressures to reduce time to market. Priorities are also influenced by ongoing re-evaluation of the portfolio composition in light of competitor activities and therapeutic advances.

Regulatory and payer environments are demanding a renewed focus on innovation, with the emphasis and investment moving from life-cycle management (LCM) to developing new molecular entities (NMEs) in core therapeutic areas (TAs) likely to accelerate. The combination of higher development costs, increasing regulatory burden and pricing pressures means new assets will increasingly need to be able to show significant benefits over existing therapies in order to gain market access, let alone market share. Our survey respondents believe that there will be an ever-growing requirement for demonstrating meaningful value and significantly improved outcomes from new therapies against the standard of care usually used in Target Product Profiles.

Across companies of all sizes, earlier assessment of the portfolio by the risk and reward profiles of individual indications is being used to determine which assets to progress and which to terminate in order to balance the risk. Determining which R&D areas to accelerate, where to pause, and who to partner with, is now much higher on the agenda and is being reviewed more frequently. In some cases, the company's focus has been brought back to the core areas in which it has the strongest position. Becoming a TA leader is more critical than ever as pricing pressure and insurer consolidation weigh on the US market.

Other priorities include ongoing commitment to gaining experience in conducting real world studies, and leveraging insights for evidence generation. Harnessing the power of digital technologies is high on everyone's agenda. For example, one respondent discussed how their organisation is conducting wide scale experiments using remote biosensor data to provide real time information on product use. These data are providing new insights into patient compliance and valuable feedback on patient and physician experience.

While reducing cycle times remains a critical area of focus for late-stage development, early research is now returning as a priority for many companies. Here, some are aiming to identify and capitalise on lateral or external transformational opportunities (for example, one company has implemented a 'neural network' with their external partners, enabling immediate access to the latest advances in basic science), while others are launching initiatives to re-energise and 're-boot' internal research, based on the belief that external research has resulted in higher costs and more quality issues for some assets. Economic and practical challenges with scaling up innovative programmes and projects have led to some cutting-edge R&D activities being re-integrated into the main business.

Strong headwinds affecting peak sales

Changes in the payer and pricing environments in the US and Europe have meant that larger companies are re-balancing their portfolios to ensure that high price products are not over-represented, and that broad access to markets is maintained. A favoured course of action is to develop innovative programmes and bring new assets to market based on the volume of patients, rather than being focussed solely on achieving high prices in US and European markets serving small populations. However, activity in some areas of R&D activity serving the smaller markets – particularly rare diseases – remains important. The risks arising from the US election are also weighing on R&D investment decisions.

"Targeting diseases where no treatments are available, and developing truly transformational medicines which 'sell themselves' is key."

Global Development Leader

Strong partnerships with regulators are fundamental to creating sustainable innovation, ensuring new products progress efficiently through the pipeline. This can be achieved by generating the right evidence from the beginning and taking it through stepwise approaches, conditional approvals and subsequently expanding using RWE and digital clinical methods. The Accelerated Access Review (AAR) model launched in the UK at the end of 2016 gives an indication of the growing mutual understanding between governments, payers, patients, physicians and the pharmaceutical industry, providing access to new therapies up to four years earlier by using a defined path.

Time to peak sales remains a critical factor in facing down the challenge of declining peak sales, but this is being challenged by extended market access negotiations and post-marketing commitments. A focus on accelerating the time to filing has helped some companies increase the overall value assigned to their pipelines by bringing forward the peak sales period.

Companies focused on immunotherapy and oncology continue to face stiff competition and significant uncertainty over Phase III trial outcomes, and therefore are more often pursuing portfolio combinations of NMEs. Payers increasingly have choices, putting greater pressure on pricing through a mechanism of increasingly stringent approvals policies or in only reimbursing prescriptions in conjunction with other therapies.

Other companies have started to identify and pursue TAs and indications where competition is still low, understanding the trade-off that it is more challenging to develop assets but the competitive pressures may be lower or at least delayed for a longer period. Understanding the need for a good value proposition is vital – value in the eyes of patients and payers will increasingly drive pricing, not simply cover R&D expenses.

Indeed, companies focused on consistent TAs and few classes of high value products are seeing the highest returns in the industry. Balancing the value and volume parts of the business is key to a successful R&D portfolio strategy. A strong focus on optimising the US and high-priced markets is critical for the value-driven R&D areas, while the volume part is driven by international operations (tackling increasing diabetes prevalence in international markets for example).

In markets with pricing freedom, there remains a temptation to use historical comparators and models which are no longer valid, but without demonstrating the benefit to payers through the 'gold standard' of Randomised Controlled Trials (RCTs) it remains difficult to secure a good return on investment.

“Significant investment is going into data strategy. We are looking at harnessing huge amounts of data generated internally in R&D more effectively. These data were being held in different buckets previously, and can be made more accessible. We are setting out 6-8 pilot projects to demonstrate the value that could be had by being able to access and mine the data more effectively.”

Head of Business Development

Top three initiatives transforming the operating model

R&D leaders listed a broad range of strategies in the top three initiatives transforming the current operating model in their companies (Figure 1). The most frequently mentioned initiatives were those that were related to developing internal technical and data capabilities, with companies looking to grow their internal capabilities in order to harness growing volumes of data generated during development in order to improve efficiency of R&D. Companies are also upgrading internal systems in order to make better use of existing data. Other common initiatives were ones aimed at boosting operational efficiency, either through the modification or overhaul of existing operational processes and systems.

Ensuring effective decision making is clearly seen as a priority, and companies are changing governance models in order to improve both the speed and accuracy of decisions during the R&D process. Initiatives to utilise RWE were seen as an equal priority to governance and decision making initiatives. Still making the top three for some respondents, but less frequently selected, are initiatives relating to digital clinical, research productivity, patient centricity and market access.

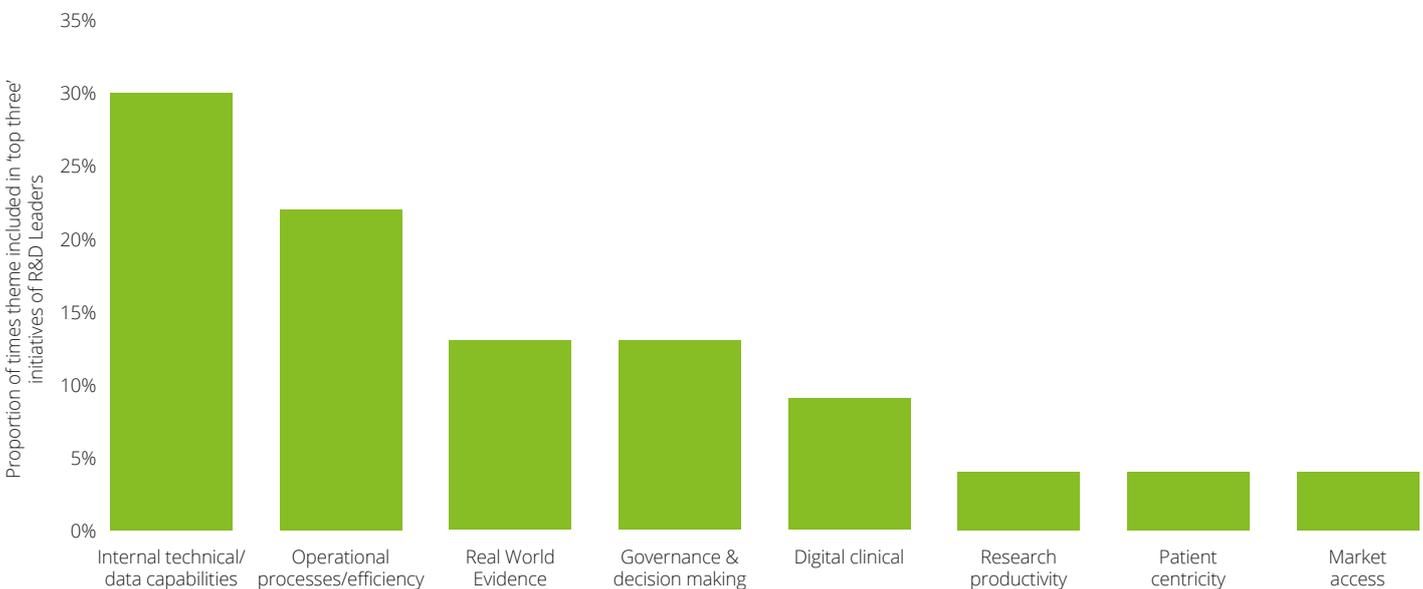
Game changing moves

Game changing moves are centred on:

- big data exploitation
- reduced time to launch
- better predictors for new treatments
- change in organisational set-up
- building technical capabilities
- efficient governance and decision making
- novel clinical trial models.

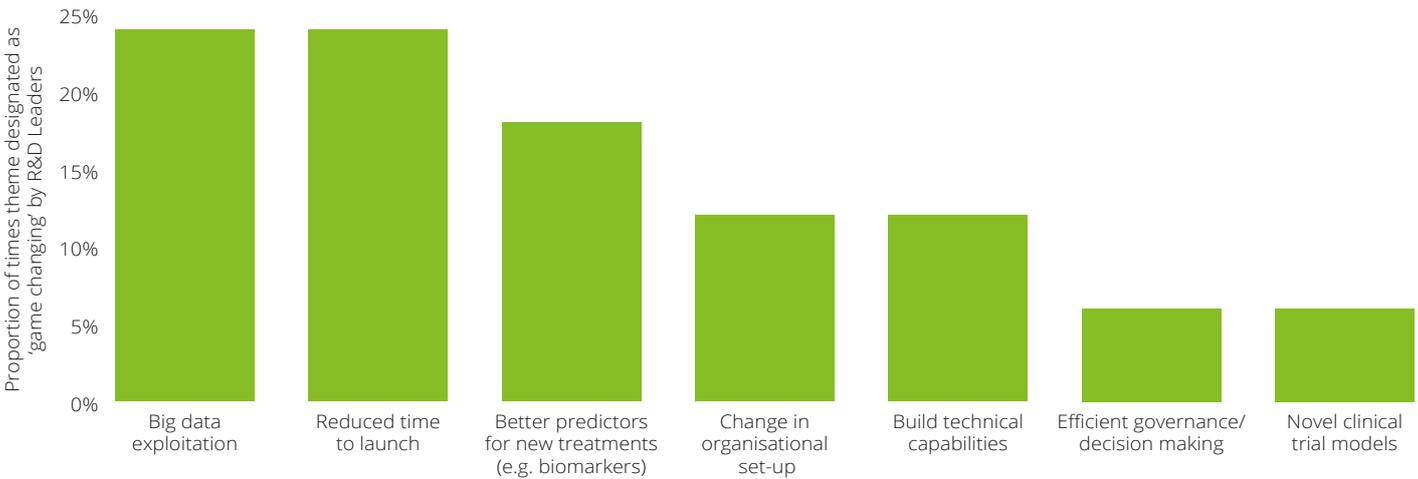
The two leading game changing moves for R&D leaders are being able to significantly reduce the time to market and to exploit big data for insights which can drive value-based pricing and market access (See Figure 2). In terms of reducing launch timelines, faster approval from the Food and Drug Administration (FDA) and European Medicines Agency (EMA) are becoming possible based on new forms of evidence, and approaches are changing from simply moving the molecule through the R&D pipeline in a shorter time frame.

Figure 1. Top three initiatives transforming the operating model



Source: Deloitte Research

Figure 2. Game changing moves



Source: Deloitte Research

Experiments are underway using digital biomarkers backed up by more objective clinical measures to give more confidence in early read outs and allow larger trials to be designed more effectively from the very first protocol design.

The joint leading game changing move, exploiting big data, requires the application of big data mining and robotics, cognitive and analytics (including machine learning). The use of big data for evidence generation is expected to contribute to improving the speed and outcomes of clinical development. This could be conducted via a 'virtual control room' from which data-driven R&D operations are led and continuously improved upon. However, a paperless R&D world remains a distant prospect.

While these two themes are not entirely new, the priority for leaders in 2017 is making them a reality through the use of technology and redesigned capabilities. The imperative of halting or reversing the decline in returns from late-stage R&D will renew CEO and Board scrutiny of R&D spend as well as the timelines to deliver the portfolio.

Better predictors for new treatments is also seen as a game changing prospect, particularly given the sizeable cost of failure for late-stage assets in R&D operations. Implementing precision medicine to support products being used in the right settings, on the right patients, as part of the right therapy is one way of reducing the failure rate. Earlier understanding of what the right dose is for patients is important, and knowing which patients do or do not benefit from the therapy is beneficial in gaining faster approval from payers.

Increasingly, decisions are being based on Phase IIb data – understanding how to select patients for combination therapy, and gaining a better understanding of how early read outs translate into meaningful Phase III success are critical. This can be enabled by using pre-clinical models to drive decisions for pursuing combinations.

A major challenge facing accelerated development is that it takes on average five years from lead candidate selection to proof of concept. Completing Phase I and Phase II faster is possible using smarter implementation of insights into personalised medicine and patient stratification from big data and biomarkers. This would drive reductions in the timelines and costs of R&D programmes though shorter development timelines as well as reducing the impact of attrition.

Other game changing activities identified by R&D leaders include:

- a change in organisational design and operations, with a stronger interface between Commercial and R&D, could enable them to succeed in areas where their presence is emerging (i.e. in TAs where they have a limited or no commercial infrastructure)
- innovative scientific programmes could soon yield convincing data and enable franchises to be built around one medicine
- efficient governance and decision making, in building technical capabilities and novel clinical trial models.

In one company, half of their R&D spend occurs within the platform organisation supporting the pipeline for all TAs. They are currently developing a more structured, robust framework to align internally on prioritisation of resources. This framework allows decisions around resource allocation to the portfolio to happen more seamlessly – enabling simpler prioritisation of R&D initiatives.

In drug development, novel design of trials (including open protocols and virtual placebos) and shifts in the FDA's capability to accommodate 'model-informed drug development' are also being adopted and are beginning to have an impact. These have the potential to help sponsors avoid some of the mistakes that most commonly lead to rejections of first-time drug applications, especially uncertainties related to dose selection, the choice of endpoints that do not reflect clinical benefit, and improper dosing for specific populations.

Key culture and talent challenges

A major source of cultural challenge is seen at the interface between TAs and platforms. Companies are attempting to break down silos between functions by forming cross-functional groups - changing the perspective from individuals acting as representatives of their respective function, to becoming members of a high performing team. In addition, initiatives are underway to promote the importance of sharing knowledge between departments and TAs, and to embed guiding principles to help the organisation understand what the key operational priorities are.

“We are aiming to create a collaborative rather than competitive culture within our organisation.”

SVP R&D Strategy and Portfolio

In terms of talent, some companies continue to wrestle with the out-sourced model where the role of the project manager has changed from managing internal resources to managing a complex budget and vendor model.

Elsewhere, different approaches to trial management are being piloted. In a large TA division of one large company, two models were compared in an internal 'accidental' experiment. In one model, clinical leads managed both the design and execution of studies; in the other, pharma leads were split across both design and execution. The results were inconclusive, with no clear option being superior in terms of cost or outcomes. This points to the importance of talent in these key roles responsible for driving multi-million dollar programs.

“We want to get everyone involved in the science and operations; the science of operations.”

Global Head of Drug Development

Smaller companies are seeking greater access to internal and external talent, using a shift towards a higher level of globalisation to achieve this. Adopting elements of off-shoring and out-sourcing capabilities ensures competitive pricing while allowing flexibility in the operational model.

In the research area, systematic programmes aimed at building relationships with academia through supporting doctoral and post-doctoral research at leading universities worldwide give opportunities to access new talent. Significant investment is being made in these areas to drive recruitment of core scientific, bioinformatic and analytical talent.

Changes in the product development strategy, moving from skilled formulation research on well-established molecules towards discovering NMEs is also driving the talent agenda. Increased scientific risk and subsequent risk from entering new indications and TAs requires better integration of the research groups involved in taking a product from discovery to launch. Now, once research groups come up with a new molecule, they immediately think about what the company has to overcome at all stages of the R&D process in tandem with skilled chemistry, manufacturing, and controls (CMC) teams. This process was previously run sequentially leading to sub-optimal solutions, affecting profitability and potentially delaying the product from reaching patients.

Further R&D talent initiatives include hiring new talent in CMC, growing research groups comprising people with broader experience from relevant technology and biological areas, and establishing dedicated translational medicine groups. Better integration of research, translational medicine and full scale regulatory development organisations is a key focus area. Objectives are to use higher quality data and make well-considered lead selections when taking products to market. This approach sees a dedicated translational function owning the molecule until it's ready to progress to full scale development. This means that once the molecule is ready for development, technical aspects are already known (i.e. how it behaves, its administration, the device solution that would be the product on the market), enabling a 'military operation' to execute a set plan for full development straight away. This approach of making earlier decisions between development Phases is delivering cost savings.

Transforming collaborative working with stakeholders across the value chain

Deloitte's R&D research¹ suggests that a strong TA focus can result in higher returns than pursuing a broad commercialisation strategy. Ensuring a stronger TA focus is enabled by leveraging established relationships with stakeholders along the development process and enabling the R&D organisation to make better decisions throughout.

This research finding is supported by our respondents, who confirmed that establishing collaborative working is high on their agenda. In order to leverage cross-functional expertise early during the R&D process, they recognise that silos between teams need to be broken down. Several companies have established cross-functional steering committees in their R&D function to increase focus on what needs to occur at each development stage. Functions to be integrated with R&D are mainly drawn from commercial, medical affairs, clinical, market access and also key areas of external partners. In addition, a global product strategy is central to the effort and all relevant functions along the development path need to understand the key drivers for the value of newly developed products.

"We are piloting a new approach where a very small (cross-functional) group of top-notch people (no more than five) decide on moving a molecule from lead optimisation to Phase I. This leads to very fast and effective decision making."

Head of Clinical Pharmacology Unit

"Stakeholders with whom relationships and interfaces are changing: Clinical platforms, digital support and biostatistics. The interface between the R&D and commercial organisations is a major focus over the next year."

SVP R&D Strategy and Portfolio

For companies focusing on relatively few TAs, R&D leaders confirmed that greater cross-functional interaction has been built over recent years which supports efficient decision making. Those established cross-functional teams now have to broaden their collaborations and build on the growing availability of RWE to meet increasing market access challenges.

“We focus on few TAs so have built deep relationships with the medical community and people involved in market access in those areas for many years. Market access is being transformed as there is greater access to RWE and large databases.”

Head of Global Research

Partnerships and alliances shaping R&D

Companies that took part in major M&A activities in the late 2000s have now commercialised many of the externally innovated products and are seeking to refresh and maintain the value of their late-stage pipeline. Further collaborations and acquisitions are now required to maintain the advantages realised from external innovation and to replenish late-stage portfolios.

Our respondents share a strong belief that alliances and partnerships will become more important over the coming years for accessing external expertise and technology to enhance product innovation and development success rates. Strategic alliances enable companies to acquire new knowledge about technologies, processes, products and business models.

However, the considerations and focus areas for external collaborations differ amongst companies depending on their size and product portfolio:

Scientific partnerships and alliances

Collaboration with academia will remain important to gain access to talent and technologies, including developing centres of expertise to generate new ideas.

Collaboration amongst pharmaceutical companies is expected to lead to consolidation in certain areas of the industry, thereby protecting companies better against cost of attrition and providing some risk sharing.

Digital, IT or data analysis collaborations

To develop new forms of competitive advantage, collaborations with technology partners will become increasingly important. Pharmaceutical companies need to increase their technical capabilities for the development of innovative products and devices which will enable optimised patient treatment regimens, management and analysis of increasing amounts of data as well as improving internal data accessibility to drive better informed decision making.

“We will start to explore partnerships in bioelectronics and related areas, and expect to see more activities at the interface between pharmaceutical, electronics, IT and data analysis companies.”

SVP and Head of TA R&D

Clinical partnerships and alliances

Some R&D leaders acknowledged that gaining and maintaining expertise in designing clinical trials is becoming increasingly important as a knowledge base for future value creation. Becoming less dependent on Contract Research Organisations (CROs) for the design and conduct of clinical trials is believed to support a more patient centric trial design and subsequent value creation.

“We are changing to become more extroverted in early stage research, while development will become more introverted by harnessing internal knowledge to use as a competitive edge and to become less dependent on CROs who have little to lose from failing.”

Chief Scientific Officer

R&D leaders emphasised that their proprietary expertise in focus TAs will remain at the centre and that collaborations will be used to complement and extend their knowledge. Strong emphasis is placed on striking a good balance between being open and accessing to new ideas and being ‘introverted’ where internal expertise must be built up or protected.

Geographical focus of partnerships

Scope for collaborations and partnerships remains global, but with a heavy focus on the US and Europe. New collaborations and partnerships are not intended to build up geographical presence but will tend to be established where the best scientific or technological fit can be achieved.

“We invested heavily in R&D in China in the late 1990s – we were proactive in seeking to establish close collaborations with local academia and to build our access to talent locally. We lately realised that there is a major challenge in delivering cost effective innovation in this space.”

Head of Global Research

Patient centricity

The increasing pressure to provide value for money requires R&D organisations to revisit their operating models. New approaches will see a shift from mostly focusing on delivering a commercially successful product towards delivering a patient centred service rewarded on outcomes. Under the new model, the patient moves from being a passive recipient of treatment to becoming a central part of the R&D process for new therapies. Successful adoption of this approach is expected to deliver products that better meet patient needs, satisfy payer and provider expectations and are commercially rewarding.

Research and development

Systematic interactions with patients and patient organisations will facilitate the identification of new areas of unmet need, and also the use of this knowledge to improve the design and conduct of clinical trials. Focusing on the patient is increasingly seen as essential to enhance speed of patient recruitment, improve patient resilience, reduce patient burden and raise awareness of patient issues. One respondent reported that their company sets targets for a certain percentage of new clinical trials to include patient representatives in the development program. This approach of actively involving patients during the design of clinical trials aims to increase acceptance by payers and providers through improved demonstration of value directly to patient groups.

“We have a very systematic approach within different TAs by working directly with patient organisations and individual patients in workshops and symposia to bring scientists together to understand future unmet needs.”

Head of Global Research

“We set ourselves objectives to, e.g. have a certain percentage of clinical trials where patients get identified during the development programme with the ambition that at the Phase IIb decision they have provided their input.”

Head of Business Development

Personalised treatment optimisation

Patients who are about to receive, or are already under treatment will benefit from an increased focus on patient centricity, for example through companion diagnostics or supporting digital technologies which help patients and providers determine the best treatment and correct dosing. One R&D leader mentioned the lessons gleaned from a workshop on gamification and recounted how the marketing organisation has input the findings into the development of web based services which collect patient data and allow for translation into personalised regimens to remind or inspire patients to take an active role in managing their treatment.

An increasing level of engagement with patients, patient organisations and advocacy groups is seen as necessary not only to support the development of products that meet patient needs and improve treatment regimens, but also improve acceptance of new products or service by payers and regulators.

“Patient centricity for us is a set of mutually aligned goals where engaging the patient brings wider benefits for them as well as for our company.”

Global Head Clinical IT

Digital and technology transformation

The R&D data landscape is becoming increasingly complex. Efficient data management with regards to data accessibility, security and costs, is becoming crucial for companies. Respondents distinguished between different ‘classes’ of data that need to be managed and exploited. In particular:

- genomic data collection and analyses are growing in importance for target discovery in early R&D
- ever-increasing volumes of patient data will fundamentally change the way clinical trials are run by supporting stratification and hypothesis generation
- management of multiple disparate data sources is becoming more important for the development and use of insights derived from patient interfaces and digital health sources
- legacy data requires continuous maintenance to ensure accessibility through new systems.

“We work with ‘big data’ for opportunities such as hypothesis generation for future clinical trials – conducting large-scale analyses to generate hypotheses for future programmes that might become combination therapies.”

Head of Global Research

Digital and big data management are consistently seen amongst all respondents to support more informed decision making, improved hypothesis generation and greater confidence in decision making.

Geopolitical upheaval

The UK referendum on EU membership, the US election and pending elections in other leading European countries have contributed to an era of geopolitical uncertainty. The impact of these decisions on pharmaceutical companies, including their R&D activities, is still being assessed. There is therefore, as yet, limited information or understanding as to what changes might be necessary. Our 2017 survey will explore in more detail the impact of both Brexit and the US presidential elections, and will benefit from nearly a full year of experience of the new administration in the US.

At the time of the interviews, and based on the outcome of the referendum, the UK had announced its decision to leave the EU but other political outcomes were still subject to speculation. Respondents were therefore invited to comment on what they thought Brexit might mean for their operations. Their responses indicate that the effect of Brexit on R&D operations will depend to an extent on the detailed terms and conditions of the Brexit negotiations, the scale of the companies' presence in the UK and the extent of their collaborations with UK academia and external partners. The issues highlighted by respondents as having the greatest amount of uncertainty and potential impact are:

- flexibility of the workforce – R&D leaders highlighted their concerns regarding the free movement of people and its implications for the current and future workforce based in the UK, many of whom are not UK nationals
- regulatory and market access – the biggest perceived challenge was around the increasing uncertainty and tension between the UK and EU with regards to the future location of the EMA. Other issues that were highlighted were IP management, clinical trials, application of regulatory rules, registration processes and market access
- academic collaboration – the UK is seen an important source of talent and innovation for research-based organisations given their collaborations with UK universities. Leaders confirmed that these collaborations may experience some uncertainty following Brexit. If the UK leaving the EU results in greater barriers to hiring international talent or makes the UK a less attractive place to live and work in, there may be a significant impact on R&D organisations based there.

“There is a level of uncertainty around funding for ongoing and new university collaborations.”

SVP R&D Strategy and Portfolio

While the British Prime Minister has confirmed that the UK intends to leave the EU single market, the implications for the pharmaceutical industry remain uncertain given the global nature of leading pharmaceutical companies. The potential consequences are profound and depend on a number of interconnected industry dynamics, including trade relationships, the free movement of people, and the future of the regulatory landscape. In order to help life sciences companies consider the implications of Brexit, the Deloitte Life Sciences Industry Team and The Centre for Health Solutions have recently published a 'Brexit playbook' based on the views of subject matter experts across the life sciences value chain. The views were developed in a series of scenario planning workshops aimed at helping life sciences companies accelerate their understanding of the impact Brexit might have. Recognising that the road ahead will remain uncertain for some time, the playbook is not a solution in itself but suggests some clear 'do now' actions that companies use to combat uncertainty and prepare for Brexit.

We will continue to monitor the impact of other geopolitical changes as they emerge.

Endnotes

1. Deloitte (2016). Measuring the return from pharmaceutical innovation 2016. See also: <https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/measuring-return-from-pharmaceutical-innovation.html>

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