KPMG

R&D 2030

Reinvent innovation and become an R&D front-runner by 2030

Thriving on disruption series

R&D's risk profile is becoming unsustainable. With a history of declining productivity, the onset of personalized medicine and new entrants causing havoc, Life Sciences executives should fundamentally revisit their approach to R&D. By 2030, these companies will be adopting methods that focus on outsourcing, resource sharing and advanced technologies. Leading companies need to become familiar with these trends now, so they can be ready for the future.

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An evolving landscape

Unprecedented shifts are set to disrupt the R&D ecosystem.

Spiraling research & development (R&D) costs and shorter product lifecycles, combined with increased risks, are having a negative effect on the return on investment and productivity returns for Life Sciences companies. In addition, with the growing uptake of personalized medicine, focus on micro-populations including indication-slicing and rare and orphan diseases, and a reduction in eligible patient populations, the era of the 'one-size-fits-all' therapy, which was historically a cash cow for Life Sciences companies, is ending. Governments, insurers and patients are requiring greater transparency around drug pricing and with rising demand for healthcare and falling budgets, Life Sciences companies are being pressured to lower costs and prices. One way for companies to tackle this pricing pressure is by streamlining their R&D.

The R&D landscape has already fundamentally shifted and we expect it to look very different in 2030. KPMG Strategy professionals envision that the R&D ecosystem will move away from traditional stakeholders performing R&D. Instead, there will be an increased influence from technology players, clinical research organizations (CROs) and academia, and/or consolidation between these players. The R&D process will be largely externalized, shifting away from a predominantly in-house controlled process.[1] Virtual value chain orchestrators (VVCOs), an emerging pharmaceutical archetype that KPMG introduced in the paper Pharma Outlook 2030[2], will start offering core R&D services.

At the same time, CROs will become independent stakeholders within the R&D value chain. By 2030, we expect three major R&D company archetypes to emerge: technology players, tech-enabled CROs, and project-focused players.[3]

Future decentralization in R&D will also be driven by changes in funding models. By 2030, we anticipate R&D funding to be facilitated through cost and resource sharing practices among multiple healthcare stakeholders as a way to lower R&D costs. Equity partnerships between CROs and industry players will ease the R&D financial burden and drive innovation and cost effectiveness. In addition, crowdfunding for financing drug R&D will accelerate drug development and distribute the financial risk among various stakeholders, and perhaps even the wider public.

To remain successful in the market while developing an innovative and sustainable R&D capability, fundamental change is now a necessity and companies need to adapt to these new market dynamics.

Virtual value chain orchestrators

VVCOs are players that do not own anything physical, but offer 'virtual value' in the form of data and create various types of solutions 'virtually' – although their final delivered product or service is very real. They provide data capabilities and resources throughout the R&D process, owning data related to customer relationships, patient subsets, treatment decisions and resulting outcomes, and aggregating services from suppliers throughout the patient journey.

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Three major drivers will turn R&D upside down by 2030

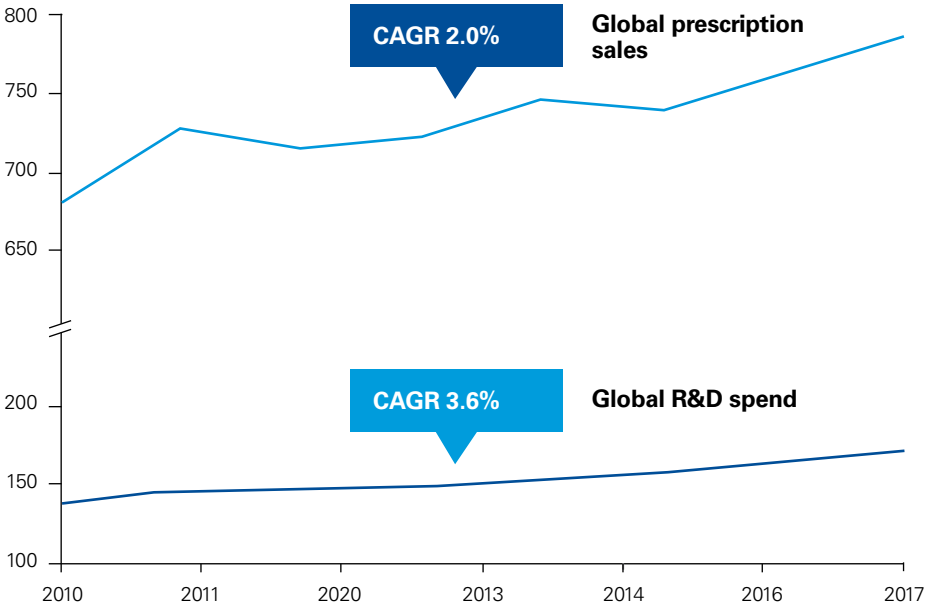
1

The pressure to make R&D much less risky

Life Sciences players face downward pressure on the return on investment they have made in R&D with spiraling R&D costs, lengthy R&D cycles and unpredictable success rates.

Companies need to continuously replenish their pipeline and develop innovative therapies, while also facing rising operational costs in R&D. Despite taking active measures – including restructuring global operations, divesting non-core parts of their portfolio and outsourcing certain processes – the industry continues to struggle. Given the high unmet demand to treat and cure diseases, the pressure in the mid-part of the last century was on government agencies to approve drugs, and as a result ~80 new drugs were approved in the 1950s per US$1 billion of inflation-adjusted R&D spending.[4] However, as healthcare has evolved, the burden to fill a gap in the market is shifting to Life Sciences players, with companies having to go the extra mile to demonstrate their value to their relevant stakeholders. A clear indication is the cost per approved new drug which has doubled approximately every 9 years between 1950 and 2010, and drug candidates are more likely to fail in clinical trials today relative to those in the 1970s. The compound annual growth rate (CAGR) in global spend on R&D was 3.6% between 2010 and 2017, outpacing global sales of prescription drugs, which grew at a CAGR of 2.0% during the same period.[5]

Figure 1: Declining R&D productivity, 2010-2017 (US$bn)[6,a]



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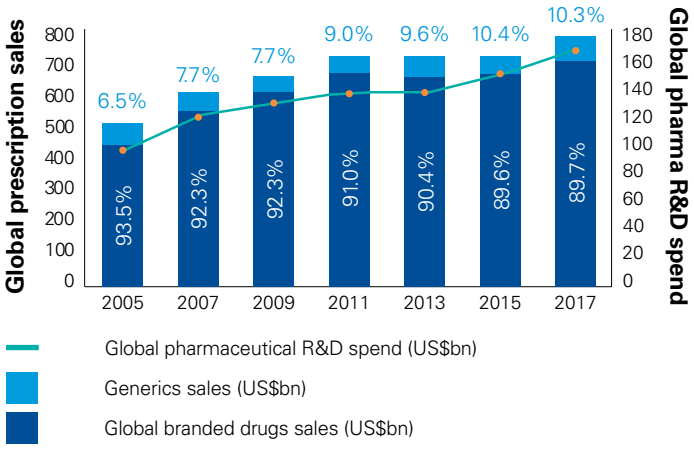
Additionally, global spend on R&D grew between 2005 and 2017, while the global sales of generics as a percentage of total pharma sales[b] increased from ~6% to ~10% during the same period.[7] This highlights the decline in R&D productivity and the course correction that needs to be undertaken by pharma companies.

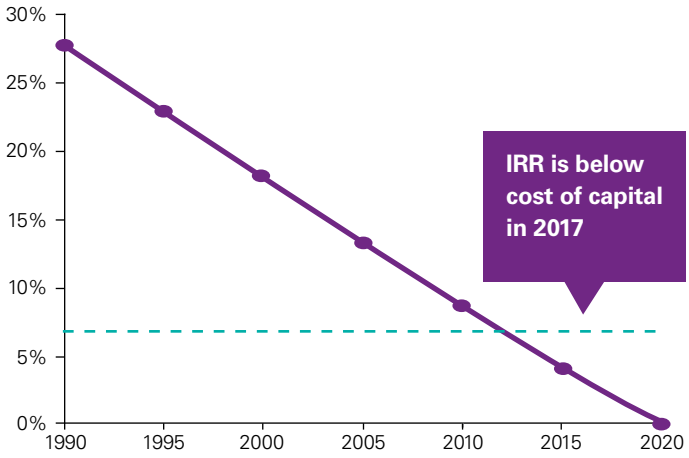
Figure 2: Declining share of prescription sales relative to growth in R&D spend, 2005-2017 (US$bn)[8]



Adding to this risk is the significant reduction in potential patient populations as innovative treatments are becoming increasingly stratified. The median patient population size served by a top 100 drug company decreased from 690,000 in 2010 to 146,000 in 2014.[9] This, in combination with intense competition and shorter time in-market, negatively impacts return on investment and profitability. The internal rate of return (IRR) in pharma R&D was below the cost of capital in 2017, and it is projected to hit zero over the next 2–3 years.[10] Over the past 40 years, the number of drugs commercialized per US$1 billion of R&D investment has decreased almost 30-fold, leaving the pharmaceutical industry with a current return on investment of only about 3.2%.[11]

All these elements are driving industry players to look for strategies that can lower their investment risks.

Figure 3: Return on investment in pharma R&D[12]



2

Shift towards personalized solutions

The healthcare industry is shifting away from a one-size-fits-all product goal that results in blockbuster medicines and is moving towards a more personalized approach to medicine. Historically, pharmaceutical companies have focused on blockbuster drugs, which are major sources of repeat revenues, with significant economies of scale. We are also on the verge of benefitting from "-omics" technology. Recent advances in proteomics, genomics and metabolomics, even radiomics, have enabled us to understand the molecular basis of disease at both the diagnostic and treatment levels. Equally important, a growing suite of biomarkers now provides predictive value for diagnosis, disease progression and cure/remission. Today, more of the R&D focus is on stratified medicine, targeting patient subgroups based on disease subtypes, demographics, risks, and biomarkers, among other types of individual needs. Manufacturers are increasingly developing customized products and personalized solutions.[13]

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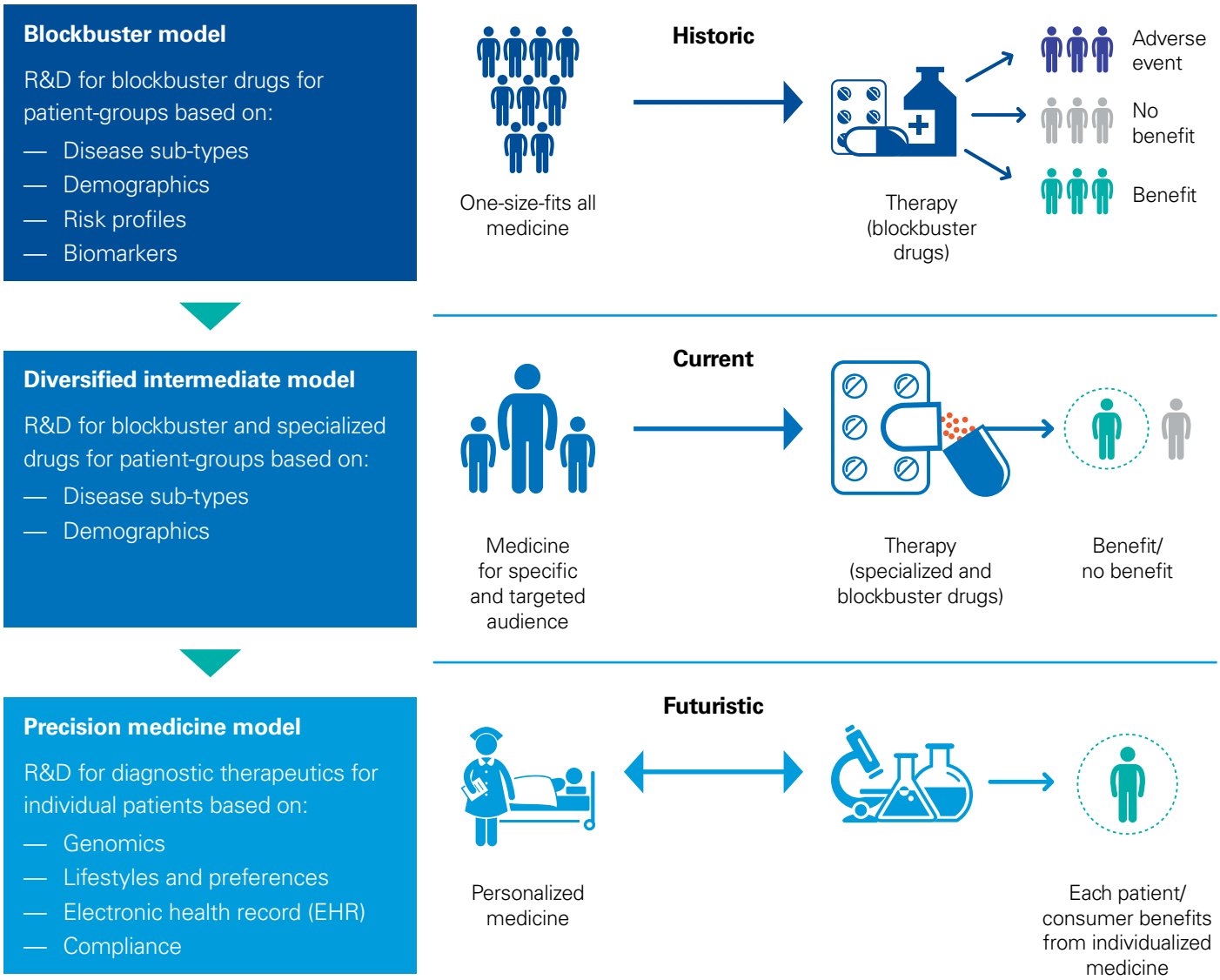
The access to real-world data, coming from electronic health records, mobile apps, diagnostics, genomics, as well as data analytic tools, will help to further support the development of these personalized treatment options. The value chain will subsequently shift from a push model to a mix of push and pull. Today's financial, business and operating models currently do not support a more personalized offering, economically and operationally, and will require a substantial reconfiguration going forward.

Figure 4: Shift from traditional blockbuster to precision medicine model (KPMG analysis)



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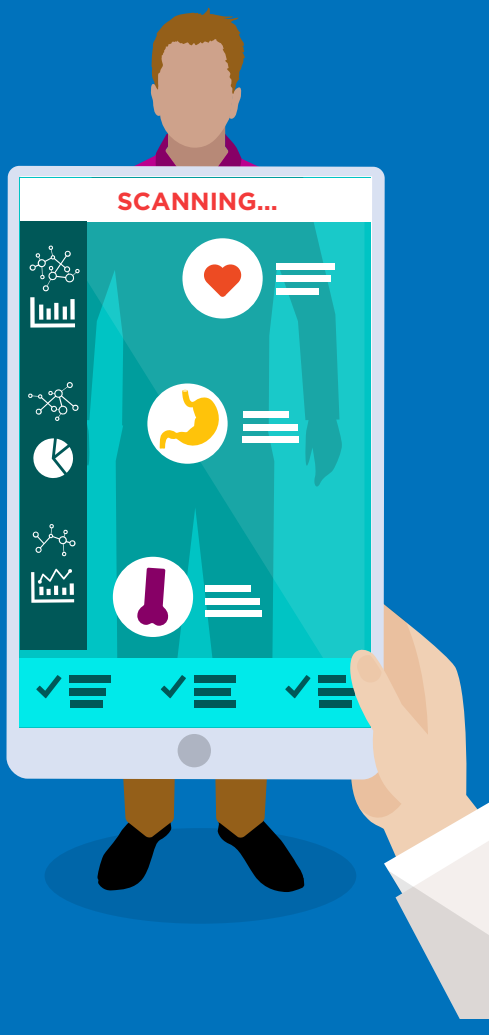

The long held holy grail of the randomized controlled trial will inevitably have to be disrupted as groups of patients become smaller, due to more precise treatment targets and greater personalization of medicines.

Hybrid trial models are already emerging which embrace technology to allow patients to participate with less disruption to their daily lives, under remote supervision. This enables more patients to be recruited across wider geographies and this trend is expected to continue.

The largest virtual clinical trial, the ADAPTABLE study with PCORI (the Patient Centered Outcomes Research Unit), was launched in 2014, and examines the impact of aspirin dosage levels on patients with heart disease. This recruited 15,000 patients through electronic health records at PCORnet and takes the approach of seeing patients as partners in clinical research, opening a new paradigm in this respect.[14] Going forward, virtual trial models will become the norm. CROs and data platforms will develop further to support these activities.

Clinical trials will become more specific as the patient populations they recruit will inevitably be smaller, but will have more accurate endpoints, enabled by progress in identifying better biomarkers.

3 The avalanche of scientific and technological innovations

A range of new capabilities and platform technologies are emerging, which will drive change along the entire R&D spectrum. New scientific technologies such as cellular, gene and tissue engineering will play an increasingly important role in the healthcare paradigm.[15] Research is ongoing to use stem cell therapies to reduce or even eliminate the need for surgery in areas such as cardiology and neurology. Genotyping helps to predict the propensity of a disease based on one person's genes. Coupled with gene editing technology, genomics is expected to play a significant role in transforming the R&D landscape, identifying both new therapies, as well as replacing existing treatments with curative therapies.

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Molecular biology continues to evolve exponentially which will enable more targets to be identified. Ex-vivo models are becoming increasingly more sophisticated and will not only speed up R&D, but will also make it more cost-effective and increase precision. For example, Midbrains (stem-cell based 'brains in a dish') show great potential for the replacement of animal brains for preclinical testing.[16]

At the same time, technological innovations are vastly expanding the realm of what is possible. For example, 3D printing can be applied in multiple contexts that range from organ printing for clinical trials (thereby reducing the need for animal models to perform preclinical tests) to supporting simulation models for precision surgery, to full organ replacement and thus, a cure. Big pharma has already seen the potential and is investing significantly in its additive manufacturing capability, in addition to partnering to attain needed assets. Artificial organs work both as R&D aids and can also have therapeutic benefits. Merck & Co., for example, has struck a deal with Organovo to use a 3D printed human liver system for toxicology testing as a supplement to in-vitro and preclinical animal testing.[17]

Digital solutions to augment clinical trials are rapidly gaining ground. Parexel launched a patient sensor solution powered by the Perceptive MyTrials analytics platform that enables the remote collection of study subject data via medical devices and reduces onsite visits during clinical trials, which decreases trial costs.[18]

In order to successfully reconfigure R&D in the future, companies will need to understand which technologies will become tomorrow's disruptors and enablers, and develop bespoke technology strategies and roadmaps.

There is an increasing acceptance of innovative technologies; new pathways exist for accelerated approval and there is an internationalization of regulatory processes. Examples include the changes in clinical trial approval methods, including adaptive trials and open-label enrolments. These changes suggest that the regulatory mind-set is shifting with more balance between regulatory evidentiary requirements versus post-approval follow-up.

The 21st Century Cures Act provides numerous provisions aimed at improving data sharing, accelerated approval for RMx and advance the science of patient input through rigorous approaches that better reflect real-world care and outcomes.[19]

The largest regulator, the Food and Drug Administration (FDA), has allowed data from non-US studies to become the basis of approval, supporting a trend for most agencies to converge on a set of common standards such as study design, use of statistical techniques, prioritization of 'breakthrough' indications and technologies.

Although regulatory risk posture is moving in the right direction, it is still moving much more slowly than the speed at which new technologies are emerging.

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Importance of data security

Will data security be your Achilles' heel?

Core to the effectiveness of R&D are data integrity, confidentiality and reliability. Personalized medicine means that the medicine is specific for an individual and that the data for that medicine must be specific to an individual patient. Any changes to the integrity of that data will mean that treatments and medicines will be incorrectly made and directly impact patients' health and wellbeing. This is why manufacturers of personalized therapies such as T-cells require highly honed and secure processes used by companies together with their health providers, incorporating highly secure techniques such as retinal scans to match the correct physical medicine to the individual.

Machine learning techniques in the research process will significantly reduce the time to evaluate potential molecules, perhaps by years. However, this requires algorithms to remain secure. Due to their very nature, it is virtually impossible to evaluate whether algorithms have been tampered with from reviewing their output, and so the security around the algorithmic 'black box' must remain robust with unauthorized access monitored and acted upon. Algorithms are only half of the machine learning process, with the artificial intelligence (AI) acting upon specific data flows into the 'black box' – security over these data flows is also essential.

Companies such as GlaxoSmithKline (GSK) are exploring automation of laboratories.[20] Molecules will be automatically made to order with operations being directed autonomously through third and fourth parties. The operational technology systems used to run these laboratories are vastly different to enterprise IT systems and require specialist engineering to design and architect security in all aspects including contracts, laboratory hardware and the processing chips.

The security required to protect patient data, along with the technology that identifies and produces medicine must be robust to protect companies against attack from malware. Many pharmaceutical companies are building sophisticated security covering technology, process and people, and incorporating AI as part of their defenses.

Most of the huge research advances expected over the next ten years are likely to come from data science, much of it using personal clinical data. Successful research organizations, such as tech-enabled CROs, must comply with data privacy laws, such as the GDPR in Europe and the Californian privacy law in the US, which protect individuals' rights over their data with significant fines in place for data breaches. One CRO, for example, has a patented approach to anonymize patient data which aims to retain the value of the data whilst protecting the individual involved. Balancing the effective management of personal data and complying with privacy regulations, whilst obtaining insights from the clinical data, will be absolutely core to success.

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Blockchain in Life Sciences

Will blockchain be the next Bitcoin?

Interest and investment in blockchain has grown exponentially across a large number of sectors, but particularly within both Life Sciences and Healthcare. This is not surprising given its potential to transform existing business and operational models, creating operational efficiencies, as well as new revenue opportunities.

Pharmaceutical companies have been exploring blockchain use cases in:

- Patients, focusing on consent and permission within business processes such as managing the patient journey; clinical trials; electronic health records; and recall management.
- Regulatory/compliance, focusing on data integrity, audit trail and traceability in business processes including laboratory instrumental data; preventing counterfeit drugs; and employment of cross-border healthcare professionals.
- Interoperability, focusing on provenance and data sharing in business processes such as supply chain; contract management; and the cool chain.

Blockchain development and implementation is still moving from proof of concept and minimum viable product stages through to live pilots. However, there are some use cases that are front-runners in this sector and have moved to more wide-scale implementation within supply chain and electronic health records. One of the most successful vendors is Guardtime, who have worked with the Estonian government to implement a blockchain-enabled health record solution which covers the full population of 2 million people.[21]

As with any technology, and especially emerging technologies, this requires effective planning, design and implementation and, despite its inherent security benefits, it is not immune to security issues. KPMG's paper on 'Securing the Chain'[22] explores two particular security incidents; one with insecure and vulnerable code and the other poor cryptographic key management. KPMG has also supplemented this analysis with a paper 'Realizing blockchain's potential'[23], which outlines a possible risk assessment solution to assist businesses establish or review their risk framework for blockchain.

The key is to get the implementation right the first time, in order to establish confidence in the technology within your organization.

> **Engage regulators early on in the process and make sure they're fully supportive and in line with the goals of deploying blockchain.**
>
> – Mike Gault, CEO of Guardtime

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What could the results look like?

Three key R&D operating model archetypes are likely to emerge.

The need for lower risks, more personalized demand and the opportunities and challenges provided by new technologies will have a huge impact on the R&D landscape. The ecosystem will move away from traditional stakeholders performing R&D to diverse partnerships with a range of players and multiple partnership structures. By 2030, R&D will be largely externalized. A partly new breed of stakeholders will manage the majority of the R&D processes, from early stage discovery to R&D completion and commercial distribution. In this changing landscape, we envision the rise of three major archetypes: technology players, tech-enabled CROs and project-focused players.

1 Technology players will play a pivotal role in drug discovery and the R&D value chain

Technology firms continue to show their desire and competence to enter the Life Sciences space. In 2030, technology companies will be key players and provide crucial input by leveraging new technologies such as AI, cloud-based platforms, machine learning, cognitive technology and wearables.

Technology will enable personalization and increasing diagnostic accuracy

Capturing real-time clinical trial patient data through cloud-based platforms will provide a holistic view of the trial patient's health status and assist in creating a more comprehensive database of biomarkers. This data can be used in general drug discovery and target molecule identification, as well as in the development of personalized medication and the improvement of diagnostic accuracy.

For example, IBM launched a cloud-based platform for drug discovery in December 2016. The platform uses deep learning, natural language processing and cognitive technology to support researchers in new drug discovery. Pfizer is using the platform in immuno-oncology research and also in recruiting patients for clinical trials.[24] Microsoft launched Project Hanover in September 2016, which uses AI to create a genome-scale database to treat cancer. The database uses machine learning to personalize the drugs to be utilized on a patient-by-patient basis.[25] Verily Life Sciences launched a wristwatch called Study Watch in 2017, which will help gather health data during clinical studies. The data captured will be used to identify patterns in the progression of Parkinson's disease and research for possible solutions.[26]

Technology will play a key role in the virtualization of clinical trials and facilitation of patient enrollment

With patient data readily accessible in real-time, it will be much easier for researchers to accurately identify new drug targets and indications. This will help resolve one of the biggest bottlenecks in the drug development process and expedite the corresponding timeline. Furthermore, patients' dependency on doctors for suitable trials will be reduced through virtual consultations made possible as tech players build platforms for telemedicine. In March 2015, Apple introduced the ResearchKit, a software medical platform for developers to create apps thereby bringing more focus to various medical matters. The platform will allow developers to create many possible medical solutions. Pharmaceutical companies will appreciate further technological development in an effort to reduce the high costs of clinical trial enrollment and data gathering.[27]

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2 Tech-enabled CROs will be able to escape commoditization through innovation

Tech-enabled CROs will be well-equipped to offer broad portfolio services in the R&D value chain, rather than merely outsourced clinical trials.

Technology has the potential to eliminate the gap between clinical strategy and execution

New technologies will be able to support optimization of clinical trial design, including exclusion and inclusion criteria, patient recruitment and execution. Services are already offered in this space. PRA Health Sciences acquired Symphony Health Solutions to provide data-driven insights to optimize global clinical studies and drug commercialization.[28]

Tech-enabled CROs will own the platforms and toolkits to fundamentally optimize clinical trial operations

Apart from improving clinical trial design, tech-enabled CROs will also be able to reduce patient dropouts during clinical trials, due to real-time support through digital and social platforms. This in turn will lead to an increase in patient engagement and compliance, having a positive effect on both time and cost of clinical trials. In November 2017, ICON's innovation team developed a proof-of-concept application that operates on a smart speaker platform.[29] The application leverages a voice assistant to deliver a patient-reported outcome and collect patient responses. Certain areas where these applications could be used include patient training, information and consent, patient engagement and retention, as well as the collection of patient-reported outcome data and other trial-related information directly from the patient.

Tech-based CROs will have access to technologies leading to low infrastructure costs for clinical trials. These technologies will eliminate or reduce the need for clinical trial sites by using mobile-based platforms and medical devices such as wearables and sensors. In October 2017, Science 37 announced the completion of a clinical study conducted entirely through a mobile application, which was done on the firm's mobile Network Oriented Research Assistant (NORA) platform, which allows for real-time video chat, customized self-photography models, data collection and electronic consent.[30]

Technology will decrease the clinical development timelines and resulting costs

A decrease in development times and costs will be made possible by increasing operational efficiencies and trial status visibility, by tracking and managing investigational contracts, activities on the critical path of trials, budgets and regulatory submissions, while minimizing clinical trial data anomalies. In March 2017, INC Research implemented an end-to-end study startup platform provided by goBalto, Inc., a cloud-based clinical study startup solutions provider to accelerate the different phases of clinical trials.[31]

The company also expanded their technology partnership with Medidata by leveraging Medidata's machine learning capabilities to identify clinical trial data anomalies within a study and for better prioritization of resources around patient data.[32]

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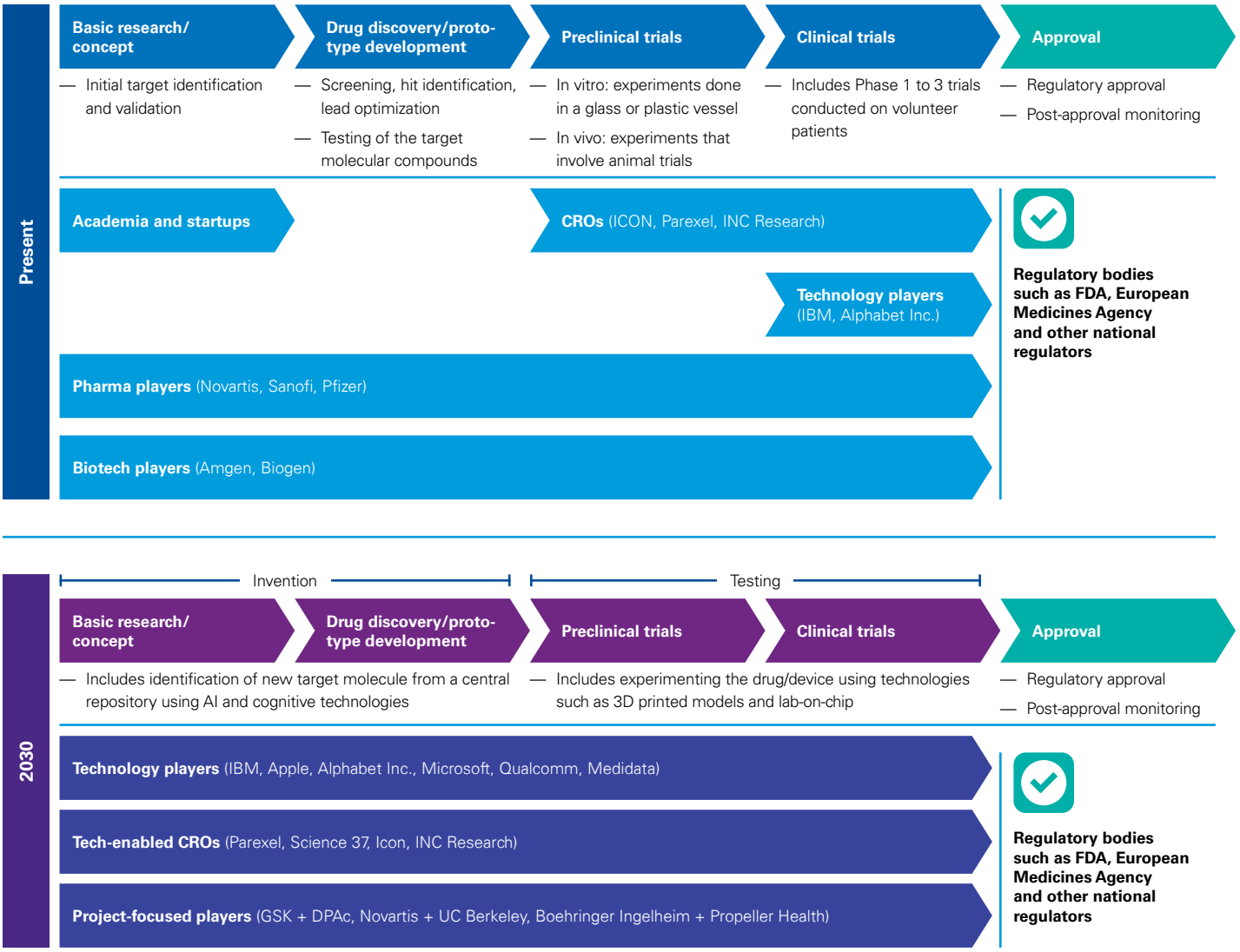
Figure 5: Stages of the R&D value chain (KPMG analysis)



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3

Project-focused players will manage the R&D value chain end-to-end

Project-focused players are teams of various stakeholders brought together for a common purpose. These teams will be able to manage the entire continuum of the R&D value chain from early stage discovery to late-stage development of drugs, and then disband once their R&D goal is achieved. They could comprise of a consortium of pharma and biotech players, members of academia and healthcare startups. This archetype moves away from the traditional model where academia and startups were only involved in early-stage discovery. To be successful, a project player will need to be lean and flexible throughout its organization, from research-focused project teams, integration and adoption of new tools, decision-making processes around go/no-go decisions and governance.

Increasing access to data and core development capabilities will make the technology players and tech-enabled CROs key contributors to the R&D value chain.

In March 2018, a new international project consortium called CARAMBA was launched. It will research an innovative immunotherapy for the treatment of multiple myeloma, known as Chimeric Antigen Receptor T-cell (CAR-T) therapy. Through strategic collaboration with a wide range of stakeholders, the consortium aims to ensure the streamlined transition of CAR-T from the laboratory through to multiple myeloma patients in the clinic.[33]

In September 2017, Novartis partnered with the University of California, Berkeley, to create the Novartis-Berkeley Center for Proteomics and Chemistry Technologies. The partnership will work on covalent chemoproteomics technology to swiftly map locations on protein targets, including areas that were previously not drug accessible.[34]

In February 2018, Merck partnered with Avillion, a co-developer and financier of late-stage pharmaceutical product candidates, to collaborate in the development of anti IL-17 A/F Nanobody from Phase II through Phase III. Avillion will also finance the clinical program through to regulatory submission.[35]

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Emerging funding models

By 2030, alternative R&D funding strategies will be in place.

A reconfiguration of the R&D landscape will not be enough to de-risk R&D investments. Current funding models will also have to change and our expectation is that R&D costs and resources will most likely be distributed among the various stakeholders in three different ways: through a sharing economy model; through equity partnerships with CROs; and through crowdfunding.

The new sharing economy model

The sharing economy model will lower costs as physical assets will be shared, instead of owned. Companies across the R&D ecosystem will work together to optimize their assets, human, capital and intellectual resources, and take advantage of technological capacity to improve costs and services.[36] Service providers will rent out their technologies, talent and services to resource labs and innovation studios.

These resource labs will be dedicated, open-sourced, project-focused and well-equipped R&D sites and centers that will be used to perform research and development by the requestors. The requestors, identified as any of the pharmaceutical and biotech players, startups, government agencies, independent scientists and researchers from academia, will no longer perform in-house R&D for drugs. Data sharing – including patient data and clinical data – will take place between the service providers, resource labs, requestors and healthcare providers, and can also be sourced directly from patients using digital tools and platforms. Funding in the form of pooled funds from many research projects will allow resource labs and innovation studios to buy better and faster equipment and continue to provide R&D services. Project teams will be formed, and once the project is over, the project team will dissolve and move on to another research project.

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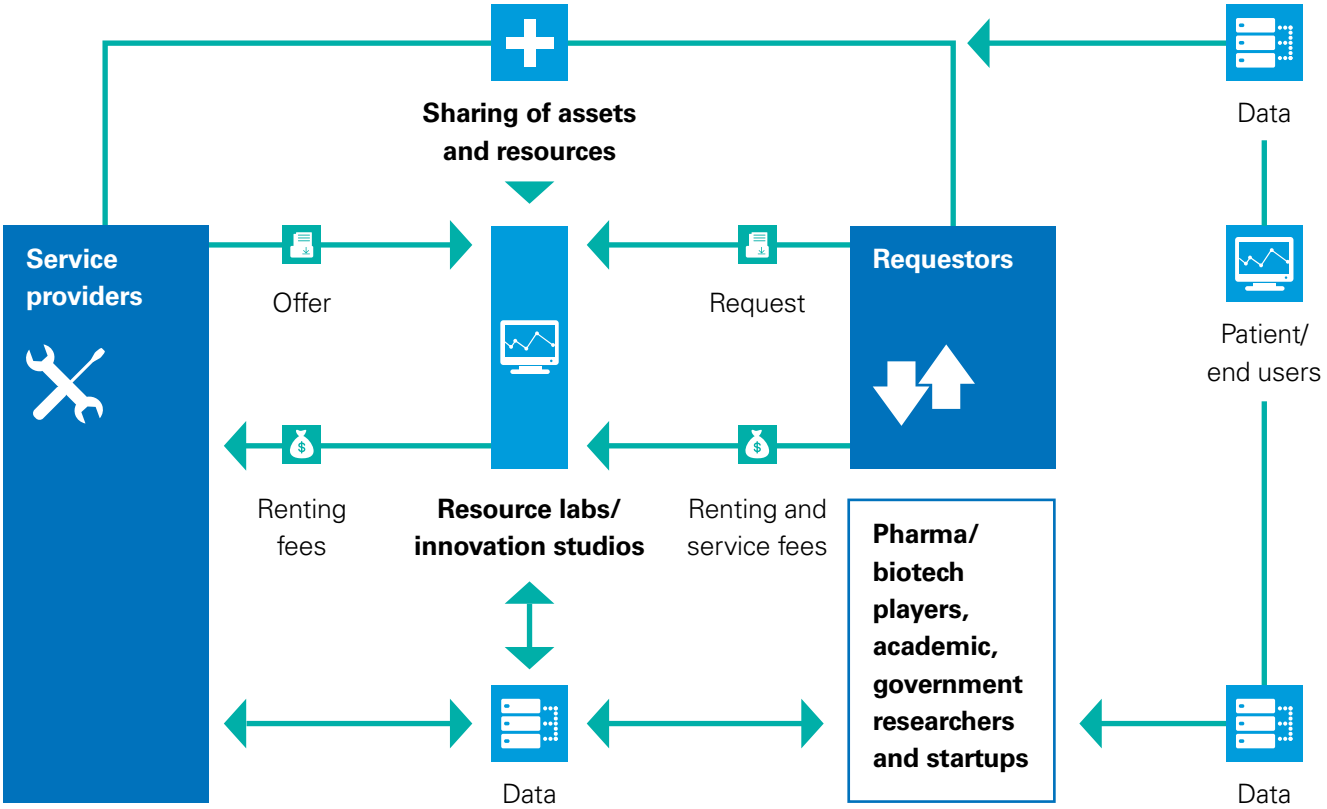
Figure 6: Potential sharing economy model for the pharmaceutical industry (KPMG analysis)



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A broader introduction of platform providers, such as Science Exchange, will further accelerate the sharing economy model and make it the default model going forward.[37] Science Exchange, a US-based startup, is an online marketplace where researchers can arrange to outsource some of their experiments to contract service providers that have the equipment or expertise in place. In 2016, the number of projects handled through the Science Exchange increased by 350% and its clients included big pharma players such as Merck, Amgen and Gilead. In June 2017, the company secured US$28 million in a Series C funding round led by new investor Norwest Venture Partners with US$58 million raised in total.[38] The company has been expanding its scope to areas of research other than drug development, and it has also partnered on research projects for medical devices and cosmetics. We anticipate that this model – which has been successfully implemented in other industries by players such as Uber and Airbnb – will create a fundamentally different resourcing platform for R&D in the Life Sciences sector.

The model will drive collaboration, along with benefits such as[39]:

Access to new ideas, technology, talent and expertise

Historically, drug development was a relatively simple process as pharma companies developed drugs primarily using small molecules. As drug development has evolved and become more complex and specialized (for example, with the use of biological compounds), there is a greater need for access to newer technologies and expertise, which is facilitated by the sharing economy.

Decentralization of the R&D process control

In a sharing model, pharma companies and researchers can choose to contract out specific parts of the research without disclosing their entire drug idea. This ensures flexibility in the process, lessens bias, and limits intellectual property (IP) risks.

Lower cost of R&D

With the investment required to set up labs, buy new equipment and technology, as well as hire specialized resources, the sharing economy provides companies with an option to rent assets or outsource elements of the process, thereby not committing to big investments.

More effective use of underutilized resources

There are instances where a company's resources (assets or people) are underutilized. Renting these resources out during such downtime enables these resources to be utilized more effectively and is cost-effective for both parties involved.

Drive R&D projects that lack funding

The sharing model can also push projects that might have fallen through the cracks due to lack of funding as researchers can now tap into a common pool of funds or raise funds through crowdfunding platforms.

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Equity partnerships

Current outsourcing models have evolved from simple transactional-based models to services which are outcome-based, with more emphasis on collaborations with industry players. With cost pressures and technological innovations continuing to gain ground, the relationship between traditional players and CROs is changing. Increasing numbers of non-traditional collaborations and strategic alliances are developing.

Traditionally, there have been three basic types of relationships between CROs and established pharma companies[40]:

— The **transactional outsourcing model** with the organizations paying for non-core activities with a focus on cost efficiency, as a basic provider, approved provider or preferred provider.

— The **relational outsourcing model,** which is performance-based with key performance indicators such as quality, consistency and reliability to be met with a risk and reward element involved.

— The **outcomes-based outsourcing model,** which focuses on the end result or the outcome of the service, thus emphasizing the collaborations between all the stakeholders and their investments.

KPMG professionals foresee that by 2030, equity partnerships will be the major type of relationship between CROs and traditional players, with CROs acquiring ownership interests in the drug development process. Such equity partnerships will help to[41]:

— De-risk R&D by distributing the financial burden;

— Share knowledge and expertise between CROs and pharma players, which is likely to boost innovation and enhance cost effectiveness;

— Stimulate growth as equity partnership funds fuel new product launches, facilities and capabilities.

Crowdfunding

The third funding model for the future will be crowdfunding. Crowdfunding is a collaborative effort by individuals to support an idea, a cause or a company by pooling their resources and funds through web-based platforms or portals.[42] We can distinguish between two types of crowdfunding models: the donation model where projects are posted on portals such as Kickstarter and individuals donate funds to gain access to discounts or an opportunity to buy products pre-production; or the equity-based model, where crowdfunding members receive an ownership interest in the company. Crowdfunding has been gaining popularity in the R&D space and is moving towards a viable way of 'micro-financing' parts of a company's pipeline.[43]

In June 2016, Indiegogo, a global crowdfunding platform, partnered with Pfizer to launch Project Get Old.[44] The focus of this initiative is on innovation projects that aim to change the future of aging. The projects will be shared on the platform, with the chance for one creator to win extra funding and mentor support from the Pfizer team. In September 2017, Capital Cell, a crowdfunding platform dedicated to Life Sciences, had officially opened to investors working with early stage companies that need investments to develop new ideas.[45]

We believe crowdfunding will become the default means of raising capital along with angel investors, venture capitalists, grants, foundations and support funds to cover all aspects and stages of the drug development process. With US$150 billion generated globally in in 2015, crowdfunding is expected to overtake venture capital funding by 2020[46]. Crowdfunding may also be a very welcome side-effect, allowing individuals to provide pipeline funding, perhaps even at a new molecular entity (NME) level. The broader public will gain a more in-depth understanding and ownership of the risks involved in the development of treatments and the corresponding costs. So perhaps one day, 'Big Bad Pharma' will become 'Our Pharma.'

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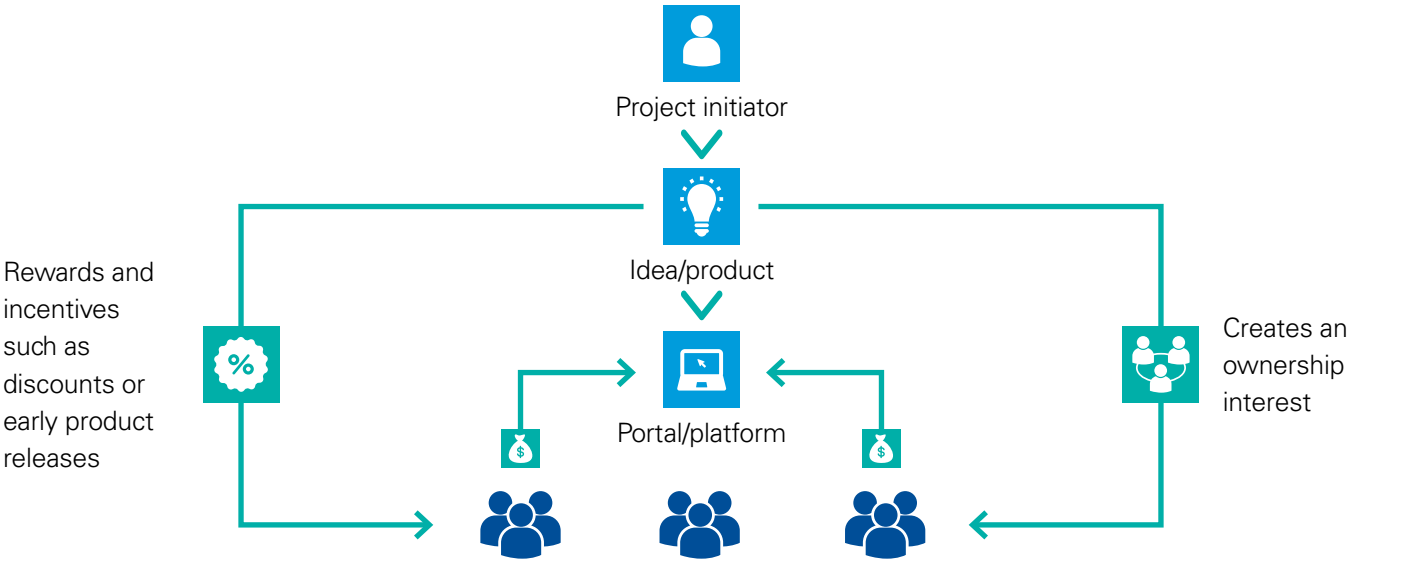
Figure 7: Crowdfunding in the pharma industry (KPMG analysis)



Present situation – Crowdfunding:

- Used as a means of raising additional funds and cannot be used alone to meet the entire capital demands
- Generates enough funds to cover small preclinical experiments and trials (early stage developments)
- Helps attract big pharma/ biotech players as a strategy for de-risking, in which they purchase drug patents once they have been pre-validated by other stakeholders in early clinical research

By 2030 – Crowdfunding:

- Could be used as a traditional means of raising capital along with angel investors, venture capitalists, grants and foundations
- Provides funds to cover all aspects/stages of drug development

Potential impact

- Acceleration of drug development as less time will be spent on raising funds and more on R&D
- Diversification of the financial risk across all the stakeholders
- Opening up of possibilities of hybrid funding models such as Angelcrowds

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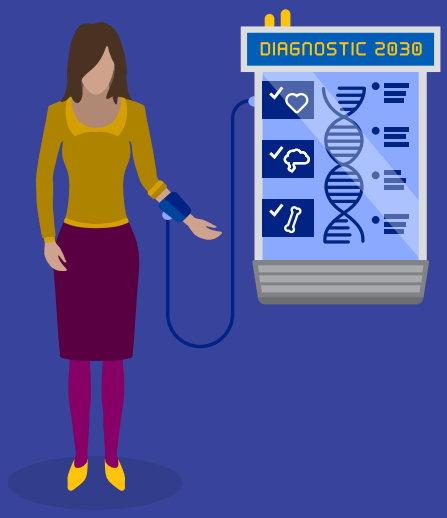
R&D ownership in 2030?

Given the 2030 outlook of a highly externalized and decentralized R&D landscape with an increasing amount of different stakeholders, we may wonder who will effectively own R&D in the future and what implications this distributed ownership could have on intellectual property, target product profiles, and pricing strategies, among other topics.

Let us imagine, for example, that academic institutions - funded by the government and payer agencies - are involved across the R&D value chain, including late-stage clinical development. How will this impact pricing and reimbursement? And what about drugs developed by crowdfunding? Will the crowd want to fund at any condition or will people want to have their say on the accessibility of the drug, the profile of the drug and target population, and therefore pricing and reimbursement? Will the large consortia, with their multitude of players involved in late-stage development, have potential pricing effects through minimal price levels agreed upon in the contract? Will payer agencies exert sufficient influence to reduce R&D programs for ultra-orphan diseases?

In short, will current price levels defended by the industry's high development cost and risky returns still be defendable in a landscape of distributed funding and ownership? Perhaps the distribution of funding and ownership of R&D can be a crucial building block on the road towards more sustainable healthcare costs.



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Being an R&D front-runner by 2030

So what does this mean for your R&D function?

How will these major changes affect your R&D organization? What can you do to prepare your R&D organization for the fundamental changes the R&D landscape will experience? For R&D leaders, it is not enough to simply recognize the emerging changes in R&D. In order to participate and benefit from these anticipated structural shifts, they should look to the three archetypes for guidance and tailor their own business and operating models accordingly. Given the rapid pace of evolution and technological innovation in this space, change will need to be initiated in an iterative manner to ensure that the model implemented is capable of delivering the 2030 vision and desired role within the future R&D ecosystem.

In order to create an R&D capability that is innovative and sustainable, we suggest you embrace the following recommendations:

Broaden your R&D scope

Develop toolkits and digital culture for success

Variabilize strategically

1

Broaden your R&D scope

R&D teams will have to rethink their remit and move towards becoming fully patient/consumer-centric rather than product-centric. Their scope will have to expand to providing holistic and personalized solutions rather than product-based treatments, and do this across prevention, disease interception, treatment and real cure. Solutions such as personalized clinical trials, targeted therapies and companion diagnostics will evolve from being buzzwords to becoming the norm.

A redefinition of the R&D scope will also require a redefinition of the required R&D capabilities and even the culture at Life Sciences companies. Companies will need to imbibe a culture where they are adaptable to incorporate new clinical advancements, flexible to cater to individual consumers and agile to integrate new technologies in a seamless manner. Becoming more patient-centric can only follow a thorough understanding of patient health pathways or even prospective patients' pain points. You may well need to create a 'health consumer office', to make the consumer more central and an active part of the world of science. The 'health consumer office' will work with consumers to offer personalized services, from selecting molecules for development and designing clinical trials, all the way to redefining end points based on what is important to the consumer.

Although the patient is at the core, the payer's perspective cannot lag behind. Comprehensive solutions should include the understanding of pricing and reimbursement, along with a clear strategy for both. Reimbursement and pricing strategies need to address not just for treatment, but also for preventive alternatives and real cures.

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2 Develop toolkits and digital culture for success

Upgrading your technological and scientific toolkit, with components such as midbrains, lab-on-chip technology and 3D printing, and committing to deep-rooted cultural change will be crucial for becoming an R&D front-runner. Therefore, you will need to craft your scientific and digital technology roadmaps in a flexible way to be able to benefit from the fast-moving world of scientific and technological advances. The roadmaps should be augmented with proper planning of required capabilities, through in-house workforce planning or new resourcing approaches, such as the shared economy model, tested through targeted pilots. While moving towards an increasingly digital and virtual R&D landscape, cybersecurity issues need to be considered and companies need to proactively engage in potential regulatory discussions to tackle possible road blocks.

Review your operational models and prepare your teams to function in a flexible environment where there are no hard lines between R&D stages and there is a seamless two-way information flow from the market to R&D and back. Teams should also be able to move and work horizontally, not just vertically. Embed your commercial teams within the R&D culture – innovation, flexibility and creativity should be emphasized across all teams end-to-end.

3 Variabilize strategically

KPMG Strategy professionals consider that the current R&D model, and its costs, are simply unsustainable. The blockbuster model is unlikely to exist in the future. Leading R&D organizations are increasingly externalizing and experimenting with partnerships, with academia, technology players and startups, but not always in the most effective way. While pilots can be very useful, you may well be overwhelmed with the level of experimentation within your organization, or simply unaware of leading practices. Make sure your company has a clear strategy concerning where it wants to be in the R&D value chain and that it is developing the matching capabilities, either in-house or through partnering, to avoid wasting resources through uncoordinated and disconnected experiments. And while conducting these experiments, try to share the risks and benefits, with technology players, CROs, and perhaps even with the public.

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a. Prescription sales includes sale of generics
b. Does not include OTC sales

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