Transformational value: preparing for a decade of radical change

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Transformational value exists at the nexus of scientific innovation, patient-centricity, regulatory and reimbursement reform, digital technology and affordability. Beyond COVID-19's, hopefully short-term, challenges, striving for a step change in value will remain the greatest challenge facing healthcare provision, and the pharmaceutical industry, over the next decade.

The concept refers, in part, to the extraordinary advances in science seen in recent years and the way they have produced some pioneering treatments that herald a period of radical change as they transform healthcare.

It also importantly incorporates the need to deliver recognisable and evidenced value to all stakeholders, so that these advances become affordable and sustainable therapeutic solutions for patients.

Early transformational advances in oncology and hepatitis C are just the beginning, but already they are changing how companies approach concepts of evidence, reimbursement and access. The longer-term implications will be broader still.

Consequently, the industry is faced with an inflection point, where ground-breaking innovation must be translated into transformational value for patients, healthcare professionals and society. It has an opportunity to take a big picture view of 'transformational value' and how to respond to it.

From development through to medical affairs, market access and commercialisation and beyond, the industry must prepare for a 'new tomorrow' that is quite different from today's reality.

Meeting this head-on needs new frameworks and a wide-ranging programme of internal transformations. It will require a new spirit of collaboration with all healthcare stakeholders and a commitment to respond at speed when making the case for a new therapy.

This white paper will look at the promise for the pharmaceutical industry as it strives for transformational value and examine the dynamic drivers that companies must address in order to maximise this opportunity.

The publication will also preview some of the themes that will be discussed at the next in Adelphi's long-running Renaissance Forum series, which provides a platform for senior decision makers to trade knowledge.

Introducing 'transformational value'

Pharmaceutical companies spend billions of dollars each year on research as part of their mission to advance healthcare, but it is hard for the outputs of such inherently risky spending, whether a medicine or a beyond-the-pill way of redirecting the patient journey, to be truly transformational.

Today, the pharmaceutical industry finds itself poised on the cusp of a decade of radical change. As companies strive to play meaningful roles in healthcare's ongoing metamorphosis, they need to be clear sighted about the implications and challenges of striving for transformational value.

> *"Transformational value is something that changes the standard of care, whatever therapeutic area it might be in, based on the unmet need that exists in the marketplace."*
> **Indranil Bagchi, Novartis Oncology**

The starting point for this is to examine what transformational value is, and why it is so very important to the pharmaceutical industry.

For Novartis Oncology's senior vice president and head of global value and access Indranil Bagchi, it's a broad picture with one central idea at its core. "Transformational value is something that changes the standard of care, whatever therapeutic area it might be in, based on the unmet need that exists in the marketplace today," he explains. "It might come from a new treatment that comes in and completely changes how different stakeholders look at a disease area, but medicine is just one piece of it. It could come from a different type of technology, a digital therapeutic or be something that changes practice patterns or compliance."

Excitingly, this presents a huge range of potential avenues for pharmaceutical companies to deliver huge and meaningful benefits to patients. Stuart Cooper, CEO at Adelphi Group, says: "Transformational value really is about 'leapfrog' improvements in the quality of medicine and treatment but, as an industry, we've got to get out of this mindset that it can only come from new drugs. Really, when you look into it, transformational value is about everything."

Although not every medical advance will transform patient care, medical history has plenty of examples that have- from antibiotics to vaccines, and beta blockers to angioplasty. What is different now is that during an unprecedented period of disruption multiple waves of medical innovation are arriving.

The promise of a more personalised approach to treatment from cell and gene therapies has at least started to be realised, within a range of therapeutic areas. These include major advances in oncology with, for example, CAR-T therapies that use cells from a patient’s own immune system against their cancer. The therapies have been heralded as being part of “a whole new scientific paradigm for the treatment of serious diseases” by the US Food and Drug Administration (FDA)[1]. Meanwhile, gene therapies are setting the innovation bar similarly high in vision loss[2], the rare muscle wasting disease spinal muscular atrophy (SMA)[3] and various types of cancer[4].

“Medical innovation that brings transformational value, must also address the issue of economic sustainability. What we must all strive for is to show how the implementation of new medicines or health technology, not only improve lives but does so at reduced cost to society.”
Mads Lennox Hvenekilde, Roche

Indranil says: “Transformational value is important to pharma because we have evolved into a state of healthcare where minor improvements do not receive the necessary reward for innovation. Today, policymakers, health technologists, assessment agencies and so on, do not place value on something that only makes very minor incremental change.

“However, healthcare innovation, by definition, is incremental. Treatments that totally change the paradigm only come once in a while. The balance to strike is between the completely transformative and those minor improvements that are still needed.”

As part of this the budgetary considerations cannot be overlooked, says Mads Lennox Hvenekilde, global product strategy and lifecycle leader for Roche. “Medical innovation that brings transformational value, aside from delivering verifiable real-world outcome improvements, must also address the issue of economic sustainability. What we must all strive for is to show how the implementation of new medicines or health technology, not only improves lives but does so at reduced cost to society.”

This means reliable systems must be created to capture both health outcomes data, resources utilisation and societal cost, he explains, in order to verify that transformational value is achieved in this broad sense. It’s a point that speaks to the sheer scale of the challenge and the issues that surround it.

As the head of scientific content development at DIA, Inka Heikkinen notes: “It’s a very difficult but very exciting topic, in the sense that the whole healthcare industry is going through a transformation. This includes the way we understand pharmaceutical treatments and new technology, which is all being applied in a more holistic way, instead of just focusing on the chemical molecules. When you talk about the concept of achieving transformational value, and it’s a big question currently with the new policymakers in office, you’re also talking about whether the system itself is geared towards producing and generating value for society.”

Pharma disruption

Underpinning and relentlessly driving transformational value is the current period of unprecedented disruption in healthcare which is having a major impact within the pharmaceutical industry.

A major role has been played by the convergence of health and technology. The rise of artificial intelligence has found applications in therapy areas such as diabetic eye disease, pneumonia and dermatology providing many new applications that could transform healthcare.

“Because of the promise of digital health and the integration with personalised medicine, the opportunity today is greater than ever before, to deliver transformational value in a much more targeted way.”
Mads Lennox Hvenekilde, Roche

Mads explains: “Because of the promise of digital health and the integration with personalised medicine, the opportunity today is greater than ever before, to deliver transformational value in a much more targeted way. For example, by applying molecular companion diagnostics to identify responders to cancer immunotherapies, while also improving health care delivery efficiencies via digital health technologies across the patient journey.”

The healthcare industry also faces a number of emerging external threats from new entrants that could massively disrupt the industry, such as Haven, the joint venture from Amazon, JPMorgan Chase and Berkshire Hathaway. Though as yet unproven, Haven is emblematic of consumers’ rising expectation for a more technologically savvy approach to health innovation.

Inka says: “A big change is actually the access to public research, enabled by digitalisation. Sharing of science has become much faster, and policy is constantly one step behind. The time at hand to shape a good policy is very short - that’s why the regulators and policymakers have chosen an iterative, flexible process and frequent touch points with developers for the COVID treatments and vaccines. We hope to see the learnings carried forward to create a regulatory framework that enables the type of innovation that creates transformational value.

"One aspect of these developments which is under consideration currently is how quickly can authorities access the data from trials- could it be instant? And if so, who will analyse the data and decide on the narrative - will it be the developers or the authorities, especially if they deploy more advanced technologies, like AI. There are developments in some European countries, and it is a potential challenge for pharma companies."

> *"Although hugely disruptive in the short term, the COVID-19 pandemic may in the longer-term herald opportunities to re-design care in both a more efficient and more effective way."*
> **Mads Lennox Hvenekilde, Roche**

One thing that the industry, and society in general, has had to get used to in 2020 has been the unprecedented COVID-19 pandemic. The pharmaceutical industry's race to research treatments and potential vaccines for the disease, has had to come while it grapples with the very visible disruption of reduced patient access to clinical trials and supply chain delays, not to mention a major part of its workforce adjusting to homeworking.

It has also brought about some benefits, in terms of digital health innovation and uptake, with COVID-19 "acting as gasoline on the digitalisation fire", according to Mads. "Although hugely disruptive in the short term, the pandemic may in the longer-term herald opportunities to re-design care in both a more efficient and more effective way, not just because of necessity but also because healthcare was already trending in that direction before COVID-19," he says.

Consequently, he expects to see an acceleration in this shift toward 'consumerism'. "Patients will take on a much greater responsibility for both self-care and prevention, and chronic diseases will be managed outside the hospital setting to a much greater extent, all the way from diagnosis to treatment monitoring. This is the new world we are facing on the other side of the COVID-19 pandemic, and so in a perverse way you can almost think of COVID-19 as an enabler of transformational value, by laying the tracks for acceleration of digitalisation and health care sustainability."

Alongside this, the pandemic has also brought an appreciation for - and acceleration in - vaccines research, and there may be more positive changes to come as society adjusts its expectations in areas such as the sharing of health data.

"A lot of success has come from tracing the people that have tested positive and then informing people that have been exposed to that person. If people are changing their minds about sharing their health data to protect themselves and others, perhaps that same behaviour could spill over to elsewhere in the healthcare system."

An obligation for constant change

Interest in transformative therapies has never been higher. For some, the changes that these will require might be uncomfortable, but it's a central tenet of the pharmaceutical industry, which is by its very nature innovation-driven, and one that underpins the opportunities that are becoming available.

> *"It behooves us to change constantly – we have to be on the cutting edge of innovation."*
> **Indranil Bagchi, Novartis Oncology**

Commenting on this, Indranil says: "It behooves us to change constantly – we have to be on the cutting edge of innovation. When you look at new projects, you have to be aware of new treatment modalities, new pathways, new ways of administration and new payment models. We are an industry that thrives on innovation, and we continue to change as the environment changes, and work on our mission to bring life-changing therapies to society."

Everyone in healthcare needs to rise to this challenge. The new, modernised approach that is required is beginning to emerge, as the FDA noted[5] in its 2018 strategic policy roadmap: "When it comes to new areas like regenerative medicine, gene therapy and digital health … it is going to require us to modernise our traditional approach to regulation to make sure that our policies are suited to novel challenges."

> *"Regulatory authorities, health technology assessment authorities, payers, they all have to be agile in the way they judge things, and we in the pharmaceutical industry although we are big organisations have to be agile as well."*
> **Stuart Cooper, Adelphi Group**

The scale of those challenges is only just becoming clear in gene therapy, where the director of the FDA's Center for Biologics Evaluation and Research Peter Marks says scientific development is "fast-paced, complex and poses many unique questions during a product review"[6]. The FDA may have approved only four gene therapy products to date, but it is preparing for many more, with over 900 investigational new drug applications having been made for ongoing clinical studies.

Commenting on developments in these new areas of medicine Stuart says: "I can't put it better than our former and extremely valued colleague, who very sadly passed away earlier this year, Jo Sollano who was the co-chair of our Renaissance meeting in Basel. She talked about the fact that the science has shot past us in a way that we did not anticipate, and that going forward, all authorities need to be agile. Regulatory authorities, health technology assessment authorities, payers, they all have to be agile in the way they judge things, and we in the pharmaceutical industry although we are big organisations have to be agile as well. I take that as read- if we're not being agile, well, we don't deserve to be around."

Transforming pharma's outlook

For all of the future benefits that transformational value can offer to pharmaceutical organisations, it is already visibly impacting organisations and their priorities.

This is clearly the century of biotech and the sector plays a vital role for the pharmaceutical industry in bringing its nimbler approach to drug development to swell pharmaceutical companies' product pipelines. The last decade has seen many of those companies realise the fruits of their billion-dollar biotech acquisitions and strike further deals with the biotech sector.

> *"Developing, demonstrating and communicating the value proposition of our medicines is truly a cross-functional effort."*
> **Indranil Bagchi, Novartis Oncology**

Roche has been something of an industry leader for these activities. In addition to its merger with Genentech[7], the pharmaceutical company has more recently made strategically important investments in health records tech start-up Flatiron Health[8], genomic profiling company Foundation Medicine[9] and Spark Therapeutics[10], a leading gene therapy biotech company.

Another strategic approach to allow greater focus on transformational projects has been to review and divest large proportions of company pipelines. GSK and Novartis were among those pursuing this approach[11,12] , they have stated that streamlining in this way allows them to concentrate resource on ground-breaking transformation, including investment in specialist gene therapy acquisitions.

However, there are a rather different set of issues for smaller biotech companies, for whom the burden of proof for transformational interventions is likely to be even riskier. The science is often so far ahead of the regulation and reimbursement, that the new value endpoints needed do not yet exist and will need to be based on measurements that will have to be taken over a long time period.

While large industry M&A deals can only be directed by CEOs and a company's board of directors, those outside the C-suite's upper echelons can still have an important impact on the wider transformational value agenda.

Indranil says: "Developing, demonstrating and communicating the value proposition of our medicines is truly a cross-functional effort. Development owns and drives drug development, but they need contributions from medical affairs, market access and patient advocates, in ensuring the product profile meets the needs of all stakeholders including not just the regulator, but physicians, payers and most importantly the patients."

For Mads, transformational value responsibility sits with each employee within a pharma company. "This means each employee feeling both energised by the promise to innovate and empowered to take action no matter what that role is," he explains.

Patient-centricity, a subject of past Renaissance meetings, can be seen as a precursor to transformational value.

"Patient-centricity is incredibly important," says Stuart, "but if you're not careful, it can become just a mission statement rather than truly being the core of the strategy. The pharmaceutical industry invests heavily in understanding patients' needs - and it's clearly in its interest to do so."

A patient-centric approach involves listening to, and partnering with, the patient, understanding their perspective as a starting point, rather than simply inserting patient views into an established process. In the case of transformational medicines, there is a need to identify an often new and very different set of endpoints that are meaningful and valuable to patients, society, payers and HCPs. Identifying and developing these novel endpoints requires insights gleaned from patients and carers, as well as an understanding of what is truly important to them.

Embracing the authentic ideals behind 'patient-centricity' is a vital pillar in delivering transformational value. Another key element is ensuring that drug development processes are fit-for-purpose, and that requires both an internal transformation and a recognition that the environment is changing.

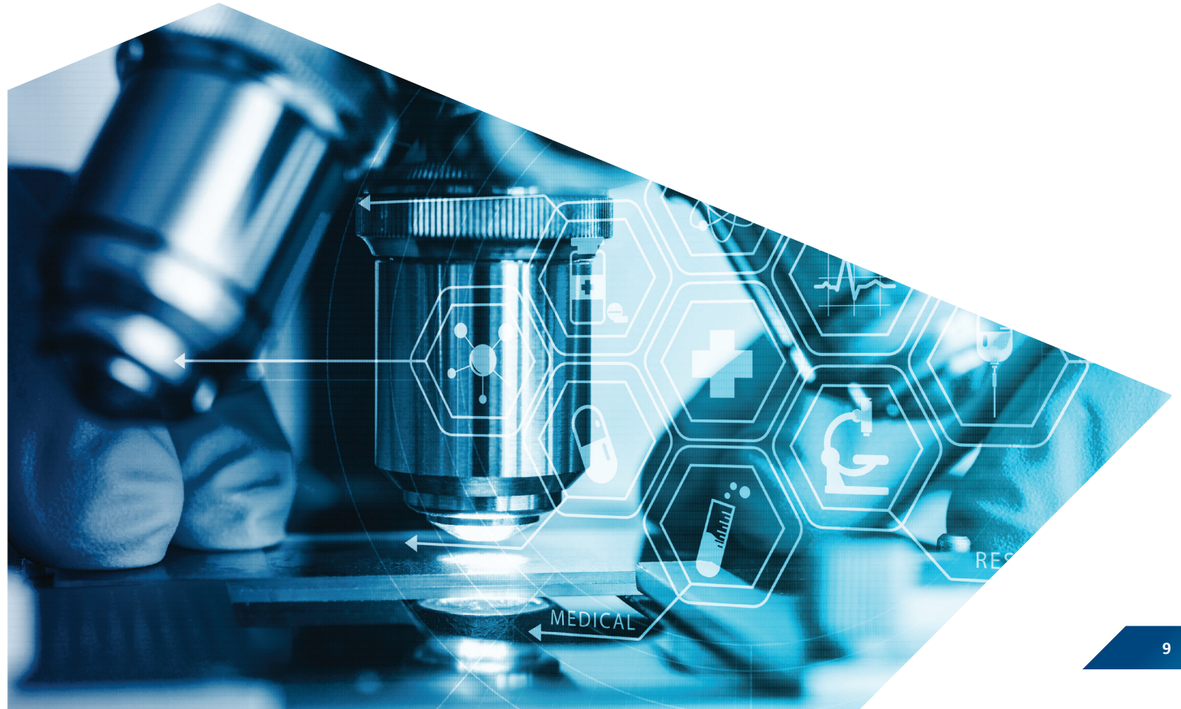
Indranil explains: "That means making sure the right voices are at the table in terms of addressing patients, payers, policymakers and all the other stakeholders. We then need to look at drug development - in terms of trial length, endpoints, comparators, treatment sequencing and governance for which molecules go forward, and how we shepherd candidates through to launch. We need to take a look at all of this in a more cross-functional way, ensuring both internal and external voices around the table are represented."

Many see medical affairs' role as critical to taking a longer, cross-functional view of the broader value of medicines to patients and the need to go beyond short-term regulatory and reimbursement requirements. Certainly, medical affairs has a central role in ensuring the full, long-term value of transformational medicine is assessed effectively and then communicated to everyone who has a role to play in achieving better patient outcomes.

According to Roche's CEO Severin Schwan "the new business dynamics require us to act in a fast and more flexible manner". That recognition within Roche means that any internal transformation needs to be on a cultural/philosophical level as well as a structural/operational one, and has led to the implementation of a pioneering restructure and new ecosystem that's based on empowered, agile and enabled teams that deliver more and faster to stakeholders.

As Mads points out: "It's really very simple, what we have done in Roche is to push more empowerment down to the teams who sit with the expertise, removed a lot of governance layers and allowed smaller self-governing teams the space to drive patient-centric co-creation of new development programmes to deliver transformational value, guided by an overall company vision to do now, what patients need next."

However, across the industry, agile transformation remains something of a challenge.



Identifying and building the concept of value

The rapid evolution of science, and the revolutionary treatments that are being developed, have important implications for value evidence beyond the current expectations and requirements for market access.

Unless a case for value including health economics can be made for ground-breaking new treatments, they will ultimately fail to break new ground for patient outcomes, but making the case for new medical advances is particularly challenging. New types of evidence and different ways of evaluating medicines are needed, including in a post-approval setting.

Current HEOR does not capture the full impact and benefit of these interventions, especially over the longer term, partly because the meaningful endpoints that are needed to demonstrate often life-changing value, are either not yet captured or don't yet exist.

Transformational medicine also brings with it an enhanced need for proactive safety monitoring in the post-approval phase. Ongoing pharmacovigilance has been a requirement for some time in Europe, but particularly for gene editing it raises a number of new challenges in relation to value – will these interventions be the cure that they promised to be, or might they have effects that were not anticipated.

> *"If we were to design the framework today, what would the process look like? Who would be involved and where? How do you communicate to the patient, what about the public?"*
> **Inka Heikkinen, formerly at DIA**

There may also be a need for an entirely new way of looking at health technology assessment (HTA) bodies.

Inka says: "There have even been discussions about whether the HTAs, while still in their infancy, will become redundant in the future, because ultimately it's the payers who decide whether they have the capacity to pay for specialty medicines. Just as new models and frameworks have been put in place to make sense of it all, the speed of innovation in medicine has already overtaken them."

New concepts of value within market access are needed, she says. "If you were to speak with academics and researchers, they say that even though there is a lot of discussion about the cost-effectiveness methods, they are so artificial. Also, most companies still look at FDA evidence first and evidence for HTA bodies is not even the second priority. Real world evidence and health outcomes standardisation are key for value discussions."

Inka adds: "I don't think that the way things are currently done really benefits anyone. There are delays to access, prices are high because development costs are high and operational costs are higher still. If it were up to me, I would ask: if we were to design the framework today, what would the process look like? Who would be involved and where? How do you communicate to the patient, what about the public? What data should be submitted to whom and when? EMA has started this process but others in power or impacted need to jump on the bandwagon too."

One of the difficulties facing pharmaceutical companies is the 'efficacy to effectiveness' gap[13] and the way it challenges confidence in decisions made for drugs when based on randomised controlled trials (RCT) alone. There are disagreements on the evidence needed to fill the gap, but it's clear that real-world evidence will continue to grow in importance.

2019 marked the first time the FDA approved a drug[14] based on RWE, with the US regulator drawing on its newly-developed RWE guidance[15].

But it has been a long time coming, with more than a decade elapsing since Professor Sir Michael Rawlins, then chair of NICE, called[16] for a new approach to analysing clinical evidence that doesn't just rely on RCTs and, though greater efforts are needed to fully realise this, change has been coming.

Alongside this, traditional healthcare concerns persist, as Inka notes. One such example, pertinent to transformational value, is affordability. "The population is getting older, so societies are, at least in Europe, looking more and more at how they can afford healthcare. You can see this in delegating national competence to the EU level for leverage - you see headlines about joint procurement, joint evaluation of value, other ways of seeking efficiency gains."

> *"There are a lot of issues where pharma should take a greater role in public engagement."*
> **Inka Heikkinen, formerly at DIA**

"The pandemic demonstrated a huge lesson from other parts of the sector - while there is public discussion about prices for treatments, many European countries had major challenges in supplying medical equipment and millions of euros were wasted.
It's easy to pick on pharma, but the bigger wins are elsewhere in the system. Yet, the industry needs to do a better job in managing reputation and trust. COVID-19 treatments and vaccines also provide an opportunity to regain some of it."

An area that is also the subject of much discussion, but far less resolved, is the impact of the public as a voice, and the way it perhaps creates another 'hurdle' for the pharmaceutical industry to overcome when proving the value of transformational, and therefore more costly, interventions.

There is an increasing need to convince the public of the value of new healthcare interventions, within an often-hostile environment that tends to be driven by populist media outlets whose audience may not have a full understanding of the healthcare funding picture. Elements of the press can have a tendency to thrive on this sort of public reaction, and shared negativity on social media can turn it into a disaster.

This can be compounded by the pharmaceutical industry's poor public perception, a long-standing issue that has been fuelled by the opioid crisis and price gouging accusations.

Such media perceptions don't play in pharma's favour, but the industry has an opportunity to undo a lot of that damage, says Inka. "There are a lot of issues where pharma should take a greater role in public engagement. There has been a lot of focus in talking to the KOLs and medical societies, but there is a need to also engage with the public, patients and caregivers way more than there has been in the past."

A solution may lie with medical affairs, starting with the building of more meaningful value endpoints and gathering evidence for these. It also goes back to limited understanding of, and miscommunication about, what pharma companies really do. Media reports will often focus on 'the manufacturers of X drug', rather than acknowledging the true extent of a company's role in a new medicine's discovery, development and ongoing monitoring.

An additional challenge for high cost transformational value therapies is working out what payment and contracting models are

required for the new era. Cell and gene therapies, for example, present the pharmaceutical industry with an evolving scenario of 'one-time' treatments for chronic diseases that can effectively cure patients for life. But they're coming to market with very high price tags and often limited clinical data.

For the promise of these types of therapies for a very long-term efficacy and effectiveness to be economically viable, new data collection methods are needed to track these patients for their lifetime and assess whether a therapy's effectiveness aligns with the efficacy that has been generated.

As Indranil notes: "These two effectiveness and efficacy parameters need to come together or coincide for the patient's entire life. That's where, as we talk about value capture and how we look at rewarding value for this new innovation, significant progress still needs to be made."

Within this, payment structures are starting to change, such as to outcomes-based contracts or risk-sharing models. "We see these new models coming into place, and the industry is also actively approaching these different payment models, recognising the new wave of innovation will need to be funded," Indranil says.

Discussions about affordability need to happen. If payers do not have money to fund treatment today, different financing models must be developed, and work on this is ongoing with, for example assessment of risk sharing/shifting agreements or the so-called 'Netflix' approach implemented in Louisiana that saw hepatitis C treatment funded via an annual subscription fee[17].

Transformational value is equally about innovation in healthcare and building value – it's only by following this twin path that it will be sustainable and affordable.

Future needs for transformational value

As steps are taken towards realising the opportunities for pharmaceutical companies of providing transformational value, a multi-stakeholder, collaborative approach is vital.

> *"Collaborations are very, very important. It is particularly true today with the high number of revolutionary new companies and approaches coming through."*
> **Stuart Cooper, Adelphi Group**

Stuart explains: "Collaborations are very, very important. It is particularly true today with the high number of revolutionary new companies and approaches coming through as well as an ongoing need for closer work with regulators and academic institutions."

If better use of data can improve clinical trials, as regulators like the FDA acknowledge it will, the tech companies entering healthcare will accelerate this. The change can already be seen in the advances made with mobile and wearable devices, and data generation and collection.

However, for Mads, developing new medicines with transformational value, will require the pharma industry to co-create solutions with the entire ecosystem of stakeholders from patients, to regulators, payers, clinicians and other technology providers.

"We need to look at both how we drive innovation faster by empowering cross-functional development teams (including external partners) to streamline decision-making with a patient-centric mindset, while also further integrating technology to deliver the innovation to patients.

"An example of integrating technology in drug development to increase likelihood of success can be found within the area of neurodegeneration. For example, within Parkinson's disease, companies are now working with patients, clinicians and regulators to build digital endpoints into their clinical trials relying on wearable sensors that capture continuous efficacy measures – both active and passive, and thus improving likelihood of trial success due to greater endpoint reliability than patient or physician-based questionnaires."

Although a higher degree of collaboration is a change for the industry, there is a need to make the effort to learn together with regulators and payers. Leading the way in multi-stakeholder solutions within is the Innovative Medicines Initiative (IMI), the world's largest life science public-private partnership, with its RWE project GET REAL[18], the Adapt-Smart[19] initiative for accelerating the development of appropriate patient therapies and Harmony[20] alliance for blood cancer medicines.

Work by the IMI and others is welcome, but there remain many other future needs in transformational value, from inpatient payment system reform to indication-based pricing to novel financing approaches.

As Indranil explains: "In terms of value for innovation or value for transformation, the overall notion of value-based healthcare is not very widely understood by all the stakeholders that are involved. Dialogue is needed to increase that understanding and essentially to bring everybody on the same page, to ensure the pace of breakthrough advances continues and is sustained by appropriate reward for innovation.

Transformational Value: now ask yourself

- What are the unexpected challenges for me in delivering transformational value?
- How does our internal thinking and operating need to change?
- What new types of collaboration will be necessary for me?
- What role will medical affairs play in the new reality?
- How do I plan to capture transformative value, when impact is long-term?
- Is the pharmaceutical industry really ready to play our part ?

Conclusion

These are disruptive times for healthcare and the pharmaceutical industry has an opportunity, and an obligation, to 'think bigger' about the opportunities to provide transformational value.

Science and technology are advancing and combining to provide previously unthinkable 'science fiction' innovations, but for new medicines, technologies and healthcare practices to positively impact patient outcomes a broader definition of 'value' is needed.

As Indranil notes: "Patient-reported outcomes are gaining traction, but in terms of taking a comprehensive approach towards value and looking at multiple different criteria, there are many elements of value today that are still not well recognised by many different stakeholders.

"As an industry, we need to improve our definitions of value, in a multi-stakeholder way, and bring in the new components: the value of hope or the value of a new therapy that might just let you live long enough to benefit from the next wave of innovation. There are a number of elements of value that are not yet being captured systematically in the current system."

Furthermore, pharmaceutical companies need to make a broad commitment to the delivery of transformational value, as Mads notes: "Being successful with delivering transformational value will require broad partnerships across both pharma and tech industries working with patient groups, academia and policy-makers. The goal of such broad collaborations must be to not only deliver on outcomes via integrated solutions, but also to drive health care reforms that enable integrated health solutions that ultimately will drive transformational value to both patients and society.

Alongside this pharmaceutical companies need to be more nimble, fluid and agile, particularly when it comes to the speed in which the case for transformational value is made.

Inka says: "The biggest transformational value will come from how fast we can treat our patients - how fast we can take an idea and working concept into the clinic. The pharmaceutical industry and all healthcare stakeholders need to rethink how we work and ask ourselves: can we serve our patients faster?"

Where do we go next?

- What would you like to be on the agenda for debate at our next Transformational Value Renaissance forum?
- What areas of Transformational Value do you personally think should be addressed?

Email us with your thoughts and suggestions:
transformationalvalue@adelphigroup.com

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16 Royal College of Physicians: Sir Michael Rawlins attacks traditional ways of assessing evidence
https://www.politics.co.uk/opinion-formers/royal-college-of-physicians/article/royal-college-of-physicians-sir-michael-rawlins-attacks-trad

17 CMS approves 'Netflix' model for hepatitis C drugs in Louisiana's Medicaid program
https://www.fiercehealthcare.com/payer/cms-approves-netflix-model-for-heptitis-c-drugs-louisiana-s-medicaid-program

18 IMI GetReal
https://www.imi-getreal.eu

19 ADAPT-SMART
https://www.imi.europa.eu/projects-results/project-factsheets/adapt-smart

20 HARMONY
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About the contributors

Indranil Bagchi

PhD SVP Global Value and Access, Novartis

Dr Indranil Bagchi is senior vice president and head of global value and access at Novartis Oncology. In this role, he drives the overall strategy on value demonstration, market access and stakeholder engagement through appropriate pricing strategies, health economic modelling, outcomes research, real world evidence and innovative mechanisms that increase access to its cancer medicines.

Indranil has more than two decades of experience in pricing and reimbursement, health economics and outcomes research, and market access across several major companies in the pharmaceutical industry. In 2010, Indranil was recognised in Pharmaceutical Executive magazine's annual roster of emerging leaders, The New Breed of Leadership, and in 2014, he received the Outstanding 50 Asian Americans in Business award from the Asian American Business Development Center. Indranil is a frequent speaker and contributor to forums, articles and conferences addressing issues related to access to medicines.

Inka Heikkinen

Formerly Head of Scientific Content Development, EMEA at DIA

At the time of contributing to this paper, Inka Heikkinen was head of scientific content development at DIA, a not-for-profit organisation connecting top leaders from all sectors in health care. This included working with key opinion leaders from the EMA, CHMP, HMA, EUnetHTA and payer organisations, facilitating discussions about challenges that they face. Inka is currently focusing on the debates that are taking place between payer organisations and regulators as they face the challenge of streamlining the system to prepare for a vast influx of high value interventions. Before her role at DIA, Inka worked in life science policy and regulatory roles in London, Brussels and Finland, liaising closely with European Commission officials and health authorities.

Mads Lennox Hvenekilde

Lifecycle Leader, Global Product Strategy, F Hoffmann-La Roche

Mads is responsible for full lifecycle strategy for prasinezumab, an investigational monoclonal antibody that targets α-synuclein in phase 2 development in patients with early Parkinson's Disease. The position is accountable for all development, manufacturing and commercialisation aspects of the molecule including value maximisation through early lifecycle planning.

During his 8+ years at Roche, Mads has held a variety of lifecycle Leadership positions across Alzheimer's disease, oncology, and CV/metabolism, as well as leading change management programs and global cross-functional issues in management teams. Prior to Roche, Mads held senior commercial positions within US brand leadership and global pipeline commercialization within areas of obesity and diabetes at Novo Nordisk.

Mads holds a Bachelor's degree in international Business and an MBA from Middlebury Institute of International Studies, California, USA and is an external lecturer on Copenhagen Business School's (CBS) Pharma Marketing Module.

Stuart Cooper

CEO, Adelphi Group

Stuart is the CEO of the Adelphi Group, which comprises ten businesses across Europe, the USA and Asia. Specialising in the healthcare sector, Adelphi provides services across the strategic development and lifecycle of healthcare interventions. Stuart's own professional focus for over 30 years has been global pharmaceuticals and the changing requirements for successful development and launch, including evidence and outcomes, but always with special interest in improving the life of the patient.

In addition to CEO responsibilities, Stuart chairs a number of the individual Adelphi businesses and remains a consultant to clients. He also frequently participates in debates at conferences and industry workshops, with regular involvement in publications. Most recently, Stuart has been a contributor to the 2019/20 Parliamentary Review on Best Practice in Business, and he has also been a member of the local industry panel for the Bio Science Park for start-up companies on the former Astra Zeneca research site. Stuart has a BSc in Economics and Politics from the University of London.

A tribute to a great friend and respected late colleague

We would like pay tribute to our late colleague Jo Sollano, Senior Vice President, Adelphi Values.

Jo was instrumental in driving our Transformational Value Renaissance topic, both in development of programme content and bringing on board members of our expert speaker panel.

Well-known and respected across the industry, Jo was a highly accomplished health outcomes, real world evidence, market access and reimbursement senior executive with an acclaimed track record in both academia and the biopharmaceutical arenas. With a long history of leadership positions across major pharmaceutical companies, Jo had oversight of more than 15 product launches over her career, including reimbursement submissions and mock payer negotiations across Europe, the US, and Asia Pacific.

At Pfizer, she was responsible for end-to-end global and US outcomes research across a portfolio of products. She also led a large global team of outcomes researchers and medical communications teams in supporting clinical development and commercialisation of the Oncology Business Unit pipeline and portfolio.

She leaves behind many people who benefited greatly from her expertise and generous support. We all miss her very much.

About Adelphi Group

Adelphi was founded in 1986. A leading healthcare marketing services group, Adelphi offers services across Strategic Marketing, Marketing and Business Intelligence, Real-world Observational Research and Disease Specific Programmes, Health and Economic Outcomes, Market Access, Pricing and Reimbursement, Value Insight, Multi-channel Health Communications, Scientific Services, Medical Education and Strategic Product Development Consultancy.

For over thirty years it has successfully supported the development, launch and marketing of pharmaceutical brands in most therapeutic areas. A global organisation, Adelphi has a network of offices across the US, Europe and Asia and employs over 700 staff worldwide.

About Renaissance

Adelphi's Renaissance events have, over the years, become established as unique, one-day invitation-only forums, at which senior pharma leaders have the opportunity for discussion of the most dynamic drivers of major and disruptive change in pharma in an intimate setting.

Global Headquarters
Adelphi Mill, Bollington
Cheshire, SK10 5JB, UK
Tel: +44 (0) 1625 577233

US Headquarters
437 Madison Avenue (20th Floor)
New York, NY 10022, USA
Tel: +1 212 515 8174

www.adelphigroup.com