GOLD.

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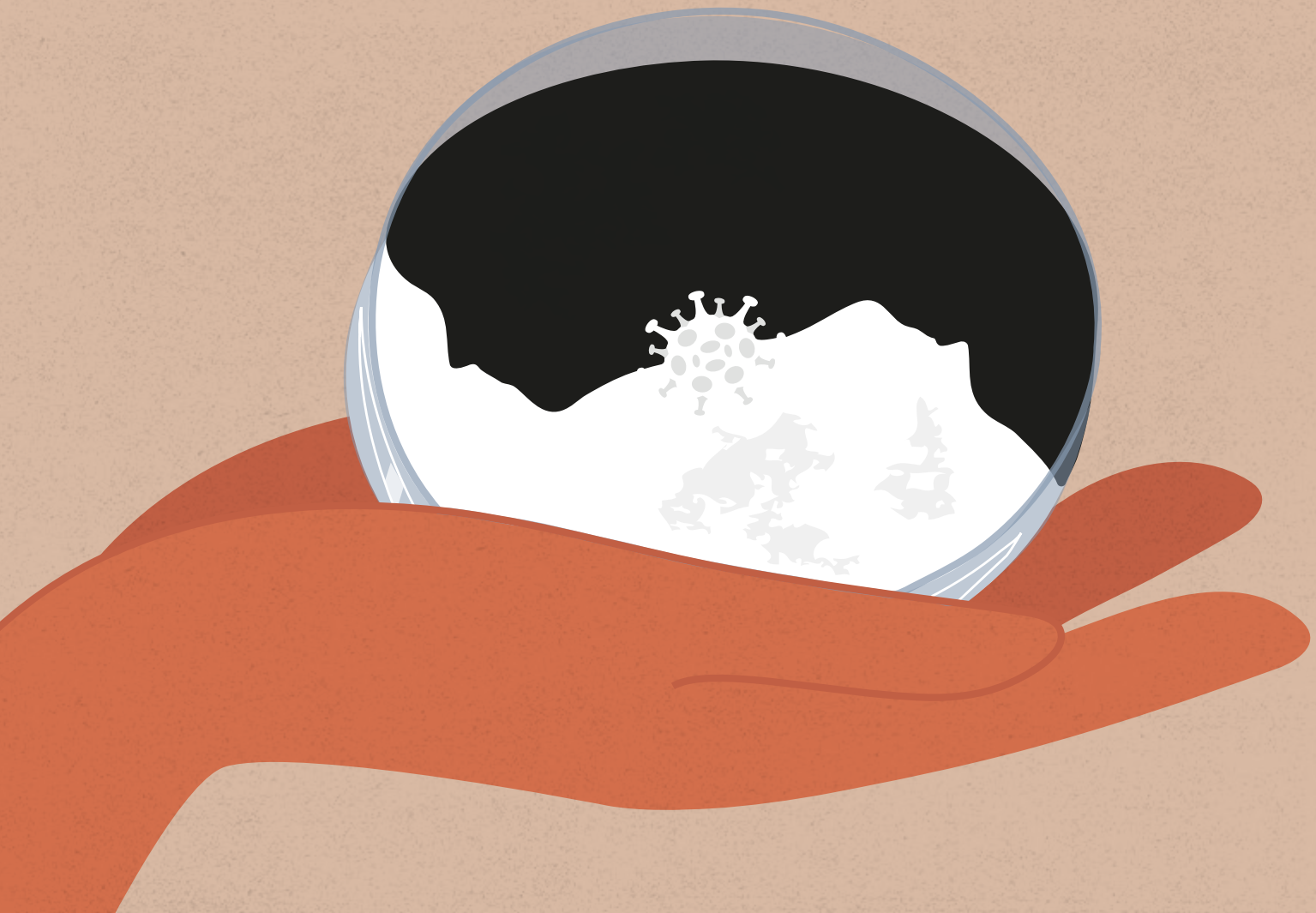
UNITING COMPETITORS, CREATING ALLIES



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CEO'S LETTER

2020 will be remembered as a year synonymous with extraordinary challenges, remarkable resilience, and unparalleled unity, as the world came together to fight the common enemy that is COVID-19. In the face of adversity, the pharmaceutical industry has acknowledged that this is bigger than any single company and requires the resources of all as we race against time to develop a vaccine.

We have seen some of the biggest pharma competitors come together, as companies recognise this is not the time for competition, but for alliance and collaboration. In our feature article, we delve into some of these partnerships and the truly ground-breaking impact they can have. In the spirit of working together, we also explore the industry's unique relationship with the NHS in the UK and how critical this partnership has been throughout the pandemic.

During challenging times, such as these, it is more imperative than ever for the industry to be driven by strong and trusted leaders. I'm excited to share with you the unique perspectives of three leaders from pharma, as we uncover the invaluable leadership lessons they have learnt during the pandemic in our inspiring roundtable discussion.

From the power of RWE for medical affairs to recruiting celebrity advocates for marketing campaigns, I hope you enjoy, and learn from, the themes we explore throughout this issue of GOLD. Now, more than ever, I am proud to see this industry choosing unity: pooling the immense knowledge and expertise within pharma to ensure we put our best foot forward.

Spencer Gore,
Chief Executive Officer

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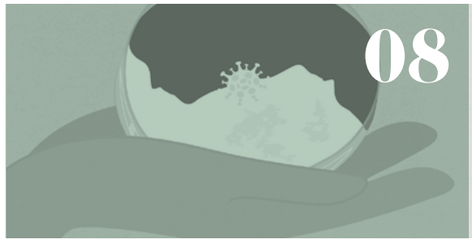
EMG HEALTH



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SPOTLIGHT

In this issue of GOLD, we shine a light on the top news stories from the pharmaceutical industry over the past few months. The COVID-19 pandemic continues to dominate news headlines, with vaccine trials gaining momentum and showing considerable promise. Alongside this progression, we are still seeing novel drug approvals, major acquisitions, and an increasing number of collaborations taking place.

17 AUGUST
Sanofi acquires Principia Biopharma Inc., solidifying their presence in allergy and autoimmune disease R&D

25 AUGUST
In a monumental milestone, Nigeria becomes the last country in Africa to eradicate wild polio

01 SEPTEMBER
BMS' oral tablet, Onureg®, gains US approval for adults with acute myeloid leukaemia

02 SEPTEMBER
Novo Nordisk launches the world's first oral GLP-1 receptor for treatment of type 2 diabetes

08 SEPTEMBER
MSD announce the success of Gefapixant in decreasing the frequency of persistent, unexplained, or treatment-resistant coughs

09 SEPTEMBER
Patrik Jonsson is named as new Chief Customer Officer, Senior Vice President, and President of Lilly USA

13 SEPTEMBER
AstraZeneca and Oxford University resume clinical trials for their COVID-19 vaccine candidate

14 SEPTEMBER
Gilead acquires Immunomedics for $21 billion, adding triple-negative breast cancer drug, Trodelvy, to its portfolio

18 SEPTEMBER
Sanofi and GSK commit with European Commission to provide 300 million COVID-19 vaccine doses to the EU

22 SEPTEMBER
Roche acquires Irish biotech firm Inflazome for $449 million in a bid to increase its offering of NLRP3 inhibitors

01 OCTOBER
NICE backs Sandoz's opioid-induced constipation drug, Rizmoic, which will be made available on the NHS in UK

06 OCTOBER
Merck enter agreement with Novartis to launch an osteoarthritis clinical-stage programme

JOINING FORCES WITH THE NHS

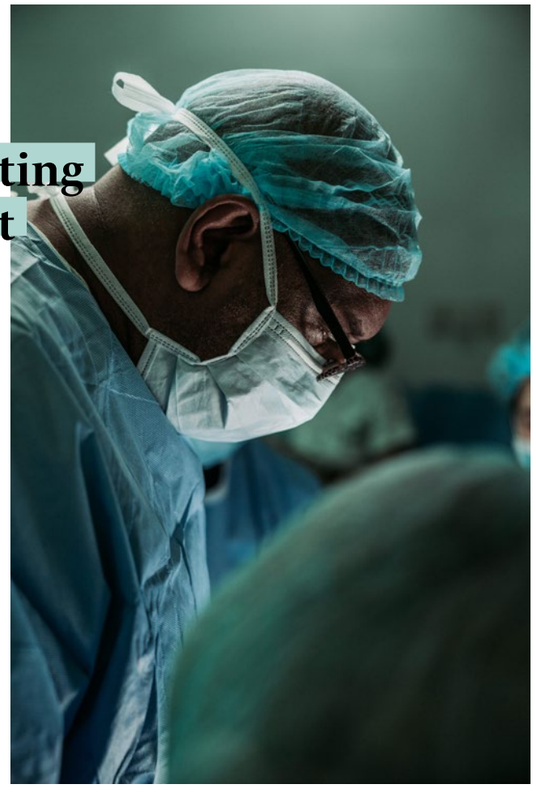
Words by **Kirstie Turner**

The zebras in Sub-Saharan Africa and the native oxpecker birds have one thing in common: an innate desire to survive. The pair have formed a symbiotic relationship, where the birds eat ticks inhabiting the zebra's skin and, in return, fly above the herds and let out warning calls when danger is near. The animals rely on one another to survive. The pharmaceutical industry's relationship with the NHS, while lacking in warning calls and ticks, shares the same principle: a common goal that is expedited by working in symbiosis. Just as for the fauna of Africa, there are ever-threatening challenges for the ecosystems of healthcare around the world, from ageing populations and rising costs to the COVID-19 pandemic. Can pharma further cultivate this partnership to create fruitful outcomes for all?

Benefits from collaborating with the NHS are almost boundless

The pharma industry is one of the most powerful entities in the world and it can have a considerable impact on advancing the capability and reach of the NHS in the UK. Ben Osborn, Managing Director, Pfizer UK, says: "For the NHS to deliver the scale and pace of change in the system, strong partnerships will be essential. Although industry is only one part of this combined effort, we have the tools and expertise to really help."

When forming any longstanding partnership, beginning with a common goal is critical for success. Blake Dark, Commercial Medicines Director, NHS England, makes the point: "Any collaboration should be based on a common goal to improve the lives of patients who rely on the NHS. So long as the shared objectives are in place, benefits from collaborating with the NHS are almost boundless."



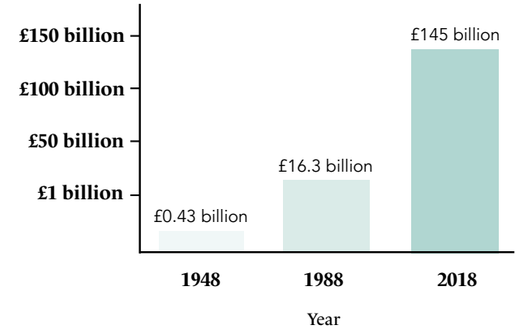
Colette Goldrick, Director, NHS Engagement Policy, ABPI, concurs: "Making partnerships work depends on agreeing a shared objective and committing the resources to make it happen, with both partners delivering what they promise." When this falls into place, the opportunities for success are vast.

Healthcare is, by nature, a highly regulated ecosystem, which can make collaboration seem more complex. However, Goldrick explains how this can actually boost the opportunity for success: "Prospective partners are often daunted by what they perceive to be regulatory constraints. There is a wealth of guidance and regulation on cross-sector working, like the ABPI Guide to Cross Sector-Working, the Code of Practice and NHS England's Conflict of Interest Guidance. However, it's designed to enable partnership, not to inhibit it. Transparent, well-governed partnerships not only have a greater chance of success, but also help build confidence across the system to replicate their success."

Earlier this year, when the COVID-19 pandemic hit, the need for successful and trusted collaboration grew inordinately. Dark says: "Over the past few months, the response to COVID-19 has shown how effective collaboration between the NHS and the pharma industry can be. Working closely with the NHS, companies have been ready to turn research efforts towards a potential vaccine and explore how established

Growth of the NHS budget since its inception

Source: Sky News, 2020



medicines may support patients with COVID-19." Without already having solid relationships built, it may have been more challenging to work cohesively during this challenging period.

But instead, the pair were able to pool their respective resources. Some pharma companies even sent their staff to help the NHS fight back in its most desperate hour. Goldrick says: "We have come together during this extraordinary period to tackle coronavirus, launching trials to investigate existing therapeutics and collaborating with NHS experts in the search for a potential vaccine. We've also seen doctors and scientists from industry volunteering to help out with the extra burden." This unique relationship has been nurtured, allowing the pair to rely on one another to best serve their patients, no matter the circumstances.

There is scope for progress in partnerships between the NHS and industry, not just in the launch of new drugs, but also in generics and biosimilars, as illuminated during the pandemic. "While securing access to new, branded medicines is often in the spotlight, the NHS Commercial Medicines Directorate is also responsible for generic and biosimilar medicines. Generic medicines make up three-quarters of all medicines used in the NHS and the use of some of these older generic drugs for the treatment of COVID-19 highlights just how vital they are," reiterates Dark.

Ultimately, cultivating pharma's relationship with the NHS should be a no-brainer, as the industry develops the drugs to help patients, and the health service uses these tools to provide the best care and outcomes possible. While the pandemic has highlighted the necessity of partnerships, we must learn from this time. "If anything, the pandemic has shown us how we can come out of this crisis stronger. Now we need to work hand-in-hand to not just get back to normal, but to make the most of what we have learnt about collaboration over the past 6 months and apply them more broadly across the health service," adds Goldrick.

With a flexible and engaging relationship that produces tangible value, pharma and the NHS have had a significant, positive influence on the lives of many patients. However, there is room for this partnership to blossom further. Dark advises: "Global companies that empower staff who hold the local knowledge – the UK General Managers and their teams – will find it far easier to collaborate with the NHS." With a focus on improved knowledge, open channels of communication, and a clear, defined goal, pharma and the NHS have the potential not just to survive, but to truly thrive.

The response to COVID-19 has shown how effective collaboration between the NHS and the pharmaceutical industry can be.

People

UNITING COMPETITORS, CREATING ALLIES

During 2020, there has been an augmented display of collaboration between big pharma companies, who have shifted from competitors to partners in the face of the coronavirus pandemic. Forming partnerships in such a highly regulated and competitive industry is a complex operation but the benefits are infinite.

Words by **Kirstie Turner**

The spirit of collaboration has gone a long way to advance science, which has reinforced trust in industry from stakeholders

People

From Lord of the Rings' elves and dwarves, to Toy Story's Woody and Buzz Lightyear, the competitors-turned-allies literary trope has been employed by storytellers for generations. But 2020 has shown that such alliances are more than just plot twists in pharma's narrative, as companies team up to face some of the toughest health challenges. During COVID-19, the relationships between many companies saw a momentous overhaul, from once unwavering competitors to now fierce allies. As a highly regulated, competitive industry, pharma partnerships are not simple affairs. But will they take us one chapter closer to the ultimate conclusion: improved outcomes for patients?

Cross-company collaboration in the pharmaceutical industry offers a plethora of benefits for all stakeholders. Rosalind Way, Head of Strategic Partnerships, Novartis Pharmaceuticals UK, explains: "We often look at how we can achieve a 'triple-win' – so that we see the benefits for pharma, the healthcare system, and patients. We have some really good examples of partnerships that achieve these aims. However, partnering between pharmaceutical companies, and other industries where relevant, can potentially add a further win when we start to see the benefits of shared expertise in addressing common challenges, thereby ensuring we are providing the best value and impact into the system for improved patient outcomes."

While rubbing shoulders with the competition may, at first, seem like a diminishing business choice, it could actually provide both parties with a newfound competitive edge. Thomas Huber, Head of Research, Almirall, explains: "Collaboration is a key catalyser and success driver for competitive drug discovery. Core expertise and resources of the two partners can optimally synergise." And to achieve this competitive edge, mutual trust and tangible benefits are critical to ensure high value. Huber continues: "Successful collaborations are excelled by clear separation of activities based on core competencies. They are built on an open and trustful relationship and have a common goal."

Along with high levels of trust, a common goal is an element of equal importance to Giles Platford, President, Europe and Canada, Takeda, says: "In any successful partnership, it is critical that all parties align on a set of goals, values, and principles by which to work. Equally, there must be an acknowledgement and respect for the value that each partner brings." Mutual respect and a shared vision are the key pillars upon which these alliances are built. Without a strong foundation, they are set up to fail.

For pharma, this year has seen one of the greatest challenges of the 21st century: the COVID-19 pandemic. This has been a catalyst for more partnerships between these powerful companies, as the need for a vaccine outweighed any initial hesitancies or concerns around losing their competitive edge. Speaking at the WIRED Health: Tech virtual event, Tal Zaks, Chief Medical Officer, Moderna Therapeutics, says: "I have only two competitors here: the virus and the clock."

Platford says: "It has been really inspiring to see industry come together and pool resources, data, and technology to accelerate efforts towards a vaccine that will combat the virus. The CoVIg-19 Plasma Alliance – of which Takeda is a member – is a great illustration of this new collective commitment." The alliance, which aims to drive the development of a COVID-19 therapy, is made up of a range of partners, including some big players in the pharma industry. Companies are recognising that this challenge is bigger than any individual, as Zaks adds: "The world needs much more than one company to succeed here."

By utilising partnerships for positive initiatives such as this, pharma can display to stakeholders that they are willing to work together and advance outcomes for patients. Platford adds: "The spirit of collaboration has gone a long way to advance science, which has reinforced trust in industry from stakeholders. I hope that with this positive trend, industry will be seen as a true and valued partner to health systems around the world."

We have seen partnerships blossom during the pandemic, as the industry races to find a vaccine, but successful pharma collaborations are by no means limited to COVID-19. Almirall's partnership with WuXi Biologics is a standout example in this realm, as Huber explains: "This strategic partnership aims to develop novel biotherapeutic drug candidates to help patients suffering from severe skin diseases." This alliance is elevating the companies' efforts to bring innovation to the field of dermatology.

These two partners bring their individual strengths to the table: "Almirall obtains access to WuXi's antibody discovery technology platform and can focus internal resources around its strong expertise in target biology and dermatology. Together, a strong team drives biotherapeutic projects," adds Huber. Almirall's position as a leader in skin healthcare and WuXi's development of first-in-class molecules in dermatology make for a winning formula.

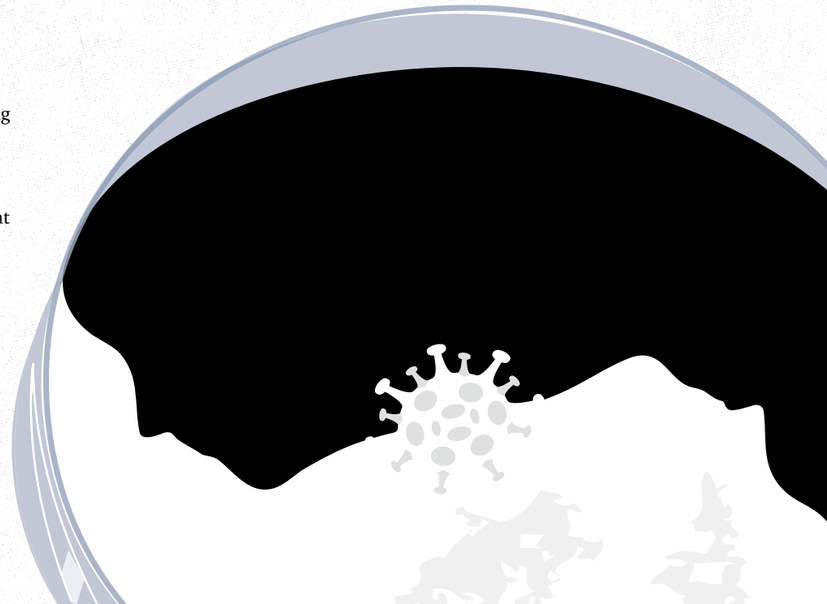
While partnerships are being created successfully, the challenges are still vast, notably the high levels of regulation in the industry. "We are rightly vigilant about ensuring our partnerships are transparent in their intention and meet with our compliance, medical, and legal regulations," says Way. From the beginning, these partnerships must be transparent and regulation-abiding, as the risks for non-compliance are high. Understandably, there is a reluctance to partner for many because of the associated regulatory concerns.

Additionally, companies must ensure they are partnering for the right reasons. Is the partnership truly adding value to patients and advancing science? Way explains: "We need to take our industry forward towards more transformative partnerships rather than merely transactional ones, and that means having a conversation about the potential for different types of partnerships." Again, transparency about the purpose of the partnership is critical in ensuring tangible value will be gained.

Collaboration is a key catalyser and success driver for competitive drug discovery

However, Platford believes that the various challenges that arise from aligning with competitors are far outweighed by the potential benefits: "Inevitably, there will be challenges along the way, but with open and constructive communication aimed at finding solutions, it is possible to build successful partnerships. After all, the potential of pharma industry partnerships to overcome the most pressing health issues of our time far outweigh any challenges when establishing them."

As renowned leadership and business expert, Ken Blanchard, once said: 'none of us is as smart as all of us.' Whether as a result of COVID-19, or facing up to more common challenges in healthcare, partnerships in this competitive industry are undoubtedly complex, but offer benefits worth pursuing, born from the specialities of each involved party. As we look to the future and consider our post-COVID world, it is more important than ever that we foster relationships, share knowledge and resources, and emerge on the other side of this pandemic as a united industry.



Standout Partnerships Formed in 2020

Sanofi and GSK

Amidst the pandemic, these pharma giants came together to develop a vaccine. Sanofi is contributing its S-protein COVID-19 antigen based on recombinant technology and GSK is bringing its pandemic adjuvant technology. The vaccine candidate is expected to enter Phase 3 trials later this year.

Source: GSK, 2020

The CoVIg-19 Plasma Alliance

Leading pharma and healthcare companies, including Takeda, CSL Behring, and Octapharma, have formed the CoVIg-19 Plasma Alliance. The alliance is accelerating the development of a treatment which utilises the plasma from recovered COVID-19 patients, which contains antibodies against the virus.

Source: CoVIg-19 Plasma Alliance, 2020

AstraZeneca and MiNA Therapeutics

AstraZeneca announced a collaboration with MiNA Therapeutics with the goal of evaluating small activating RNA molecules in metabolic diseases. The partnership utilises MiNA's saRNA expertise and AstraZeneca's ability to bring breakthrough treatments to patients who are living with metabolic diseases.

Source: Bloomberg, 2020

MSD, Taiho, and Astex Pharmaceuticals

Earlier this year, Taiho announced a worldwide research collaboration agreement with Astex Pharmaceuticals and MSD. This venture focusses on the development of small molecule inhibitors against drug targets, such as the KRAS oncogene, which are being studied for cancer treatment.

Source: Taiho, 2020

THE ROAD TO REPRESENTATIVE TRIAL RECRUITMENT

Words by **Michaila Byrne**

Achieving equal and accurate representation in clinical trials has long been a challenge for the pharmaceutical industry. We have made great progress towards the goal of patient inclusivity, but what more can be done to ensure that all patient groups are adequately represented and how can digital help to achieve this?

In this day and age, when you walk into a shop, you can rightly expect to browse through rails draped with clothes designed for all genders, sizes, ages, and shapes. As fashion and culture have become more inclusive, so has medical research, and in particular, clinical trial recruitment. Connectivity has improved on a mass scale, and as a result the pharmaceutical industry's access to more patient populations has improved. How can pharma build on its past progress to identify current gaps in clinical trial recruitment and utilise digital platforms in their pursuit to make clinical trials as representative and diverse as possible?

"Improved recruitment methodologies lead to a better selection of patients into the trial, which has a positive impact on trial quality and effectiveness," explains Zakia By, Vice President, Clinical, Medical and Regulatory, APAC, Novo Nordisk. A lack of representation in clinical trials is not simply an ethical concern, but a medical one too. Theresa Rohr-Kirchgraber, MD, Professor of Clinical Medicine and Paediatrics, Indiana University School of Medicine, reflects on past errors that have occurred as a result of underrepresentation in clinical trials: "When Ambien first came out, the majority of clinical trials were done in men so

there were multiple situations where patients were having problems and difficulty metabolising the medication. It was recommended as a 10mg dose. Now, if you are a woman, the recommendation is 5mg."

Thankfully, recruitment channels for clinical trials have moved from papers and radio, to online and social media, which has had a profound impact on the selection of recruits and ultimately the range of patients the industry can evenly serve. Camilla Krogh Lauritzen, Chief Patient Officer, LEO Pharma, views this evolution as: "Very much reflective of the general transition of paternalistic medicine to participatory medicine; the patient is now considered an important part of the solution in general, including a partner in both the design and delivery of clinical trials."

Improved recruitment methodologies lead to a better selection of patients into the trial

Clinical trials have marketing budgets to ultimately onboard larger and more appropriate numbers of patients and digital channels have the potential to facilitate this goal more than ever before. "Digital advertising makes patient outreach and the spread of trial information much simpler and progressive compared with conducting patient camps, searching physical patient databases and outpatient department cards, and letters to patients," says By. She reiterates that: "Continuous joint efforts are needed at industry level to endorse the new digitisation era in clinical trials in order to make it a success that benefits all involved parties."

The industry has made great progress and advancements in this realm, but what barriers in clinical trial recruitment remain that could be preventing 100% patient inclusivity?

Many make the argument that historical, language, and even trust barriers can prevent people from participating in clinical trials, and evidence indicates that research participation is lower for ethnic minorities and underrepresented groups like the elderly or pregnant women. To actively counteract this gap in medical research, marketing teams need to target the right communities and build a presence, online or offline, to recruit patients. To achieve this, Krogh Lauritzen advises pharma to partner with more patient organisations: "I am convinced that in the future, patient communities will play an even bigger role than they do today in the recruitment side of clinical trials… they are the experts in the disease at question and know the patient population better than anyone." Evidently, regular and active engagement with patient populations online is vital, otherwise, clinical trial outcomes are much more likely to be unrepresentative of patient outcomes in the real world.

Rohr-Kirchgraber identifies that much more needs to be done in the area of targeted recruitment, reminding us that: "Even though in 2010 we had mandates to increase the number of women in clinical trials; in 2018, 80% of the participants in clinical trials were men, even when factoring in disease specifics."

83%

of research participants in the US are Caucasian but only account for

67%

of the population

Source: Deloitte, 2019

Within Studies Utilising Traditional Recruitment

52%
meet enrolment quotas

11%
fail to enrol a single participant

37%
fail to meet enrolment quotas

Source: TrialFacts, 2020

For medicine to move forward and for the industry to fully eradicate medical research bias, marketing teams must harness the momentum we are seeing towards increased inclusion and channel it into clinical trial recruitment. More innovative methodologies could ensure that any potential gaps in the data are filled at these early, crucial stages and that our drugs are tailored to all patient populations, rather than just a select few.

Interview

Catalyst of Pharma

My whole career has been focussed on questioning how we can develop therapies that enable us to do better

Mace Rothenberg

Mace Rothenberg is the Chief Medical Officer at Pfizer. Mace spoke to us about his sustained passion for advancing the field of oncology, the importance of diverse representation in patient groups, and the challenges of balancing lifespan with health span.

I enjoy research and interacting with patients, and in clinical research and drug development, you get to combine both those elements

WHAT DREW YOU TO RESEARCH, THE FOCUS OF YOUR EARLY CAREER, AND HOW HAS YOUR PASSION FOR MEDICINE BEEN SUSTAINED OVER THE PAST 40 YEARS?

My attraction to research began during my specialty registrar training when I was assigned to the oncology in-patient unit. The patients were so sick and the therapies were so limited, but what really caught my attention was that we had access to new therapies that had not been available 5 years earlier. While some people viewed oncology as a depressing and hopeless area, that experience gave me a very different perspective. I saw it to be a hopeful and promising area with the potential for better outcomes with newer therapies.

My whole career has been focussed on questioning how we can develop therapies that enable us to do better. It just so happened that my career coincided with a time of dramatic advancement in our understanding of cancer and translation of those insights into highly effective treatments. When I began my career, the 5-year survival rate for people with cancer was less than 50%. Today, it's nearly 70%. Oncology is no longer an area that people view with pessimism, but one that they look to for hope, seeing how new technologies can vastly transform the outcome of a disease.

HAVING OVERSEEN THE DEVELOPMENT OF MANY ONCOLOGY DRUGS, HOW HAS THE EVOLUTION OF CLINICAL TRIALS CHANGED OVER THE COURSE OF YOUR CAREER?

I enjoy research and interacting with patients, and in clinical research and drug development, you get to combine both of those elements. Early in my career, clinical trials were designed to answer very specific clinical questions: Did a therapy cause the tumours to shrink and if so, in what proportion of patients? Did it allow patients to live longer, without the disease progressing? But one thing that we couldn't answer was 'why': Why did a drug work in some patients but not in others? Why did a drug that seemed to work for a period of time stop working? The answers to those questions lay in the laboratory. We recognised that these were in separate domains but that they could be linked through what is called "translational research". Questions from one domain could help inform the other. It goes in both directions; we learn as much from new insights into the disease, biology, and genetics and how we can apply them to patient selection and treatment, as we do from obtaining patient samples and analysing them in the laboratory. That's how my career evolved from clinical to more translational research and enabled richer insights and answers to those questions.

WHEN DEVELOPING CANCER TREATMENTS, IS IT CHALLENGING TO STRIKE A BALANCE BETWEEN HEALTH SPAN AND LIFESPAN?

This is an interesting question, especially since early on in my oncology training, the prevailing hypothesis was that we weren't giving patients high enough doses of chemotherapy to cure them. As a famous oncologist once said: 'We were killing patients with our kindness.' We weren't giving high enough doses of chemotherapy for our patients to get the full benefit possible. Unfortunately, the side effects from high-dose chemotherapy were daunting and we were bringing patients to the brink of what their bodies could sustain. While that approach was appropriate for a small segment of cancers, it was not the correct approach for many others and it forced us to evolve our thinking. I was never quite comfortable with pushing chemotherapy to its limits because if you achieve your goal and prolong survival at the cost of terrible toxicity, with much of that time spent in the hospital or feeling ill, what were you really gaining? What was the true benefit to the patient? It was important to measure not only what the new therapy was doing to the tumour, but what it was doing to the patient. Being able to examine that in a more systematic way and being aware of both elements ensures that the therapies that we are developing today truly have a positive benefit-risk relationship for the patient.

SINCE JOINING PFIZER LAST YEAR, WHAT HAVE YOU BEEN MOST SURPRISED BY AND WHICH ACCOMPLISHMENTS ARE YOU MOST PROUD OF?

Number one has been working with an incredibly talented and knowledgeable group of people. I have been very privileged to learn so much from them. My whole career prior to my current role was focussed on drug development; understanding what a new therapy could do to slow or halt the progression of a certain cancer. Now, my responsibility is to ensure that we have enough information on the impact of a medicine, both in terms of benefits and risks, to allow patients, physicians, and pharmacists to make informed decisions. My responsibilities include making sure that we have complete, accurate, and up-to-date information on all of Pfizer's medicines, whether they're just entering into clinical testing or they've been on the market for many years. It's been something that I've really enjoyed because it puts the patient at the centre of the decision-making process.

WHAT MORE CAN BE DONE TO ENCOURAGE PATIENTS TO TAKE OWNERSHIP OF THEIR HEALTH THROUGH SMARTER LIFESTYLE CHOICES, TO LOWER THE RISK OF OVERSTRETCHING OUR HEALTHCARE SYSTEMS?

There are two main factors driving this. One is understanding that the decisions we make today about our health, practices like not smoking or drinking too much and exercising, will have a big impact on our long-term health. Some people are able to follow these guidelines better than others; while some do things that feel good now and will worry about the future later, others are able to moderate things appropriately and will reap the long-term benefits in years from now. The other element is understanding the quality of the medical information that is available and putting it into its proper context. We see this especially around COVID-19, where we are being bombarded with information, numbers, and statistics on a daily basis. One of the things all of us in the medical profession can do is to try and make new medical information understandable and accessible to individuals who don't have a medical background and who aren't experts in epidemiology or medicine. I've tried to do that in the COVID-19 'Be Smart. Be Safe. Be Well' video series we have created, to add context and help the general public understand where we are in the course of this pandemic.

WHY IS DIVERSE REPRESENTATION OF PATIENT GROUPS SO IMPORTANT WHEN DEVELOPING AND BRINGING A NEW DRUG TO MARKET?

We have to acknowledge a paradox that exists in new drug development. When we are developing a new therapy, we try and isolate the effect of the agent on a particular disease and remove as many confounding or extraneous factors as possible. Basically, we're looking for people who are ill, or at risk, for a particular disease but are otherwise perfectly healthy. The thinking is that by doing so, we will get a more accurate assessment of the effects – both good and bad – of the new drug. But that is not the real world; most people don't have a single illness, they have several. When we bring our medicines to market based on clinical trials that were conducted on just a subset of patients, we may not have fully characterised that medicine. For instance, there may be side effects of the medicines that we didn't observe in these trials because the patients enrolled didn't fully reflect the population that would eventually receive our medicines. Government, sponsors, and academia are now embracing the idea that we should broaden the criteria and reduce some of these stringent requirements to allow people into the trials who better represent the general population. From concurrent illnesses, to age, ethnicity, and geographic location, it is important for us to get as broad an experience as early in the development of a new medicine as possible.

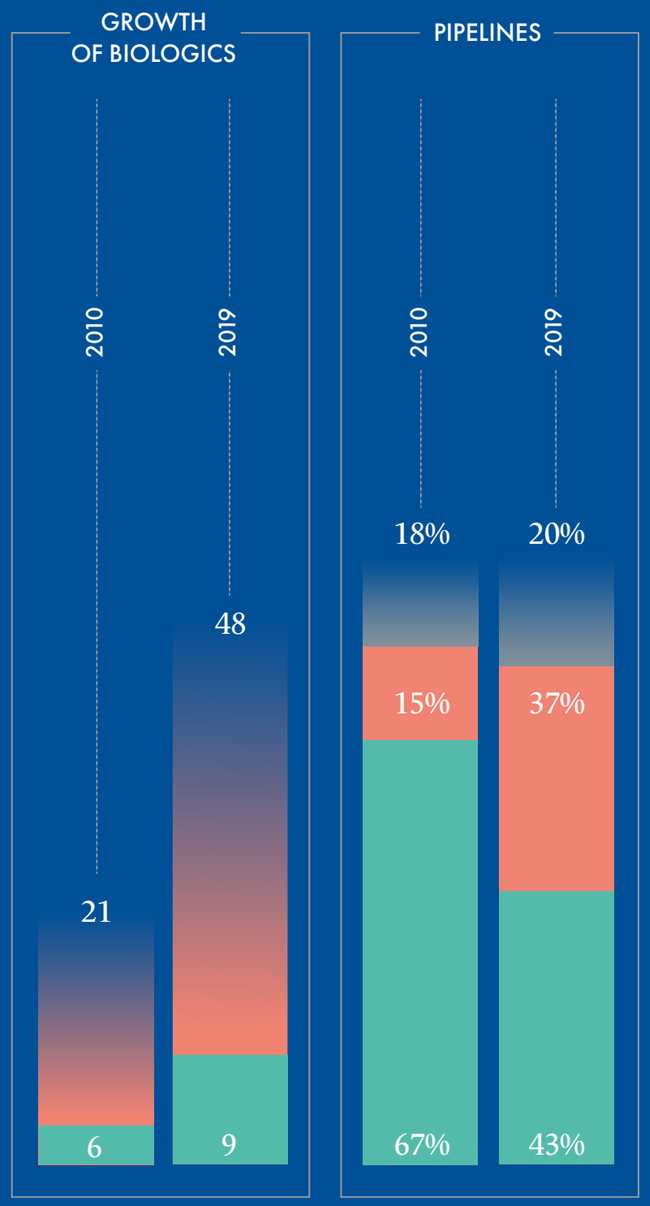
IF YOU WEREN'T WORKING IN THE HEALTHCARE INDUSTRY, WHAT CAREER PATH DO YOU THINK YOU WOULD HAVE TAKEN, ESPECIALLY CONSIDERING THAT YOU HOLD AN HONOURS DEGREE IN ART?

I have to admit that I'm not a very good artist. I am, however, an amateur mixologist and that's something that I quite enjoy doing in my leisure time! But if I wasn't in medicine, I think I would work in communications. When I was a student, it was such a delight to hear a lecture on a complex topic given by somebody who made the topic accessible, simple, and logical. There was a beauty to it and I left feeling uplifted. When that wasn't that case, I didn't learn as well and left feeling cheated and uninspired. Over the course of my career, I've had the privilege of working with a number of excellent communicators. I would not only listen to what they had to say, but how they were saying it. They helped me realise how important it is to know your audience, speak in a way that conveys information in context, and highlight the most important parts so that the audience leaves feeling not just informed, but inspired.

A DECADE OF INNOVATION

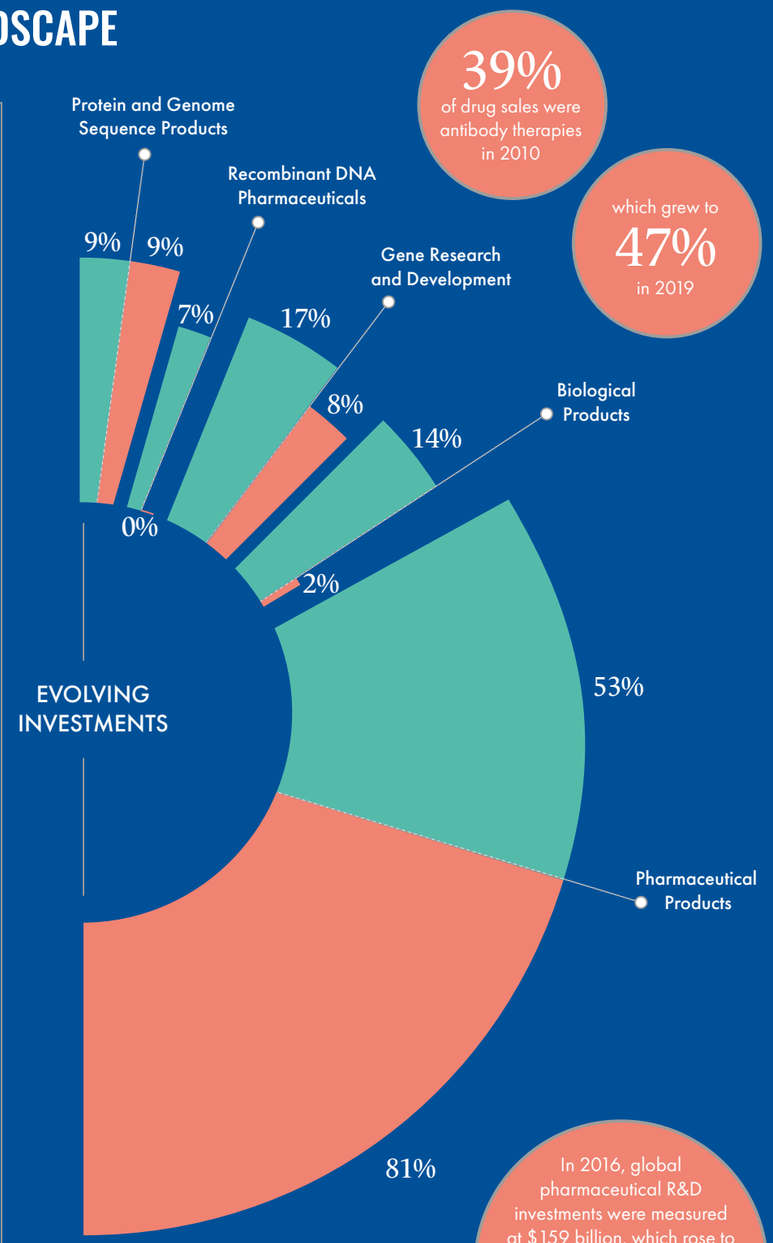
Over the past decade, innovative products have changed the landscape of the pharmaceutical industry. In this infographic, we highlight some of the biggest shifts, with increased investment and development of biologics, recombinant DNA, and gene research. We also explore the impact on resources; bringing biologics to market is more expensive, takes longer, and serves a smaller population of patients, lowering the opportunity for revenue. Looking forward, we showcase future innovation opportunities within the industry.

INNOVATION AND THE CHANGING LANDSCAPE



Source: Nature, 2020

Source: Deloitte, 2020



39% of drug sales were antibody therapies in 2010

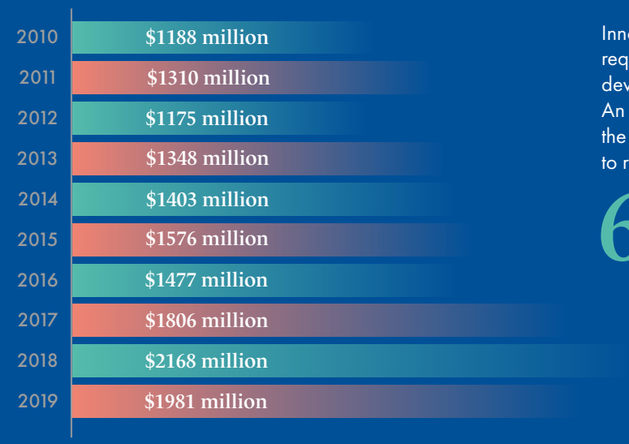
which grew to **47%** in 2019

In 2016, global pharmaceutical R&D investments were measured at $159 billion, which rose to $181 billion in 2018. This is predicted to continue rising in years to come, with 2026 figures predicted to hit $233 billion.

Source: Statista, 2020

Source: Deloitte, 2020

GROWING COST: BRINGING A PRODUCT TO MARKET



Innovative products, such as biologics, require more time and money to develop, test, and reach the market. An influx of such products has caused the cost of bringing an asset to market to rise over the last decade by

67%

Source: Deloitte, 2020

THE FUTURE OF BIOPHARMA INNOVATION

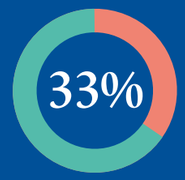
- Shift to small molecule research – accommodate emerging modalities to remain competitive
- Expedite pace of scientific breakthroughs – insight from interoperable data
- Move away from tradition – dataset-driven processes, intelligent computing, and cloud storage
- Advance analytics – end-to-end automation of R&D

Source: Deloitte, 2020

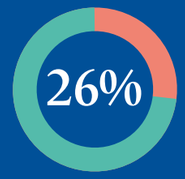
SOURCES OF INNOVATION

Mergers, acquisitions, and co-development are all being increasingly relied upon for innovation in large cap biopharma.

In 2019...



of forecast sales were attributed to acquisitions



of forecast sales were attributed to co-development

Source: Deloitte, 2020

Medical Affairs

MAXIMISING DRUG POTENTIAL WITH RWE

With data analytics enhancing opportunities to monitor drugs post-approval, the real-word evidence capabilities of medical affairs are growing. We look at how RWE can be used in conjunction with randomised control trials to influence healthcare decision-making.

Words by **Isabel O'Brien**

A new era of big data and patient-driven healthcare is pushing the boundaries of RWE

Every drug has a childhood: a time to fail and grow within the safety of the lab. Developers act as their parents, investing time and money to give their creation the strongest chance for success. This relationship is synergistic and must be maintained once the drug flies the nest. A strong real-world evidence strategy led by medical affairs keeps the family connected, measuring if potential is being reached and identifying further areas for success.

"MA teams possess the scientific and clinical expertise required to design RWE studies that can support both healthcare internal and external research goals and deliver cross-functional value," says Paul Berg, Senior Principal, Head of Real World Solutions, UK & Ireland, IQVIA.

Analytics tools enable fingers to remain on pulses: "A new era of big data and patient-driven healthcare is pushing the boundaries of RWE," says Berg. Once restricted to conundrums such as: "Does my child perform better than yours?" to decode how competing drugs performed in similar patient populations, tools can now predict how a drug will perform in a novel situation, gauging its potential beyond previously tested uses.

"Today, MA organisations realise that generating RWE offers many benefits over the conduct of randomised controlled trials, and if done properly, RWE can be applied to healthcare decision-making," says Scott Flanders, PhD, Vice President, Medical Affairs, Dendreon Pharmaceuticals LLC.

RWE allows MA to see how drugs perform beyond their childhood goals, which is particularly useful in the rare disease space, for reasons offered by Dr Maya Sharma, Global Medical Director, Modi-Mundipharma and Executive Board Member, ACMA Asia: "Because of the low patient pool, large scale and comparison studies are not possible, so a historical patient data pool has been used to extrapolate about efficacy of a new drug."

This benefit is corroborated by Flanders, who raises the specific example of male breast cancer: "One recent high impact case involving RWE was the expansion of an approved indication of a targeted therapy known as a CDK 4/6 inhibitor." The drug was conceived to treat female breast cancer, but RWE studies later showed it to be effective in male patients as well. Like a proud parent, the manufacturer presented these findings to the FDA in April 2019, offering "evidence from two Phase I safety studies, insurance claims data, and electronic health records," says Flanders, which led to a new use case approval.

Recent research by McKinsey has shown that pharmaceutical companies that adopt RWE across their whole value chain could unlock up to $300 million in the next 3–5 years, including a $100 million cost saving if used to complement RCTs. RWE is far from a nice-to-have, it is an increasingly vital stipulation of the drug lifecycle, with Berg advising that "Focussing on key therapeutic areas where RWE can be a differentiator and provide strong return on investment," will help to convince any sceptics of its necessity.

Generating RWE can be intricate and arduous work; therefore, MA teams must find ways to engage clinicians with their findings so as to ensure that new applications are known and are impacting healthcare decision-making. "To increase the understanding and communication of RWE, companies need to quickly expand their analytics capabilities 'in house' and hire medical writers who can turn data into peer-reviewed manuscripts," advises Flanders. After all, what point is there in checking in on your children if not to include their successes in the family newsletter?

Drugs must excel in adulthood and given the time, money, and hopes that are pinned upon them, it makes sense to deploy strategies that ensure they are achieving, and even exceeding, their potential. RWE is not simply a monitoring tool; it is a growing and innovative extension of RCTs, with MA leading the way in using this framework to impact healthcare decision-making and benefit underserved patient populations.

As Sharma concludes: "MA, with their thorough understanding of science and analytics, can strategically communicate and convince internal stakeholders on better return on investment of RWE in terms of evidence generation showing better patient outcomes, leading to change in disease management guidelines, and wide acceptance of therapy by clinicians."

$100 million could be saved in development spending through:

- The optimisation of RCT design with RWE
- The use of RWE studies rather than RCTs in some cases
- The implementation of synthetic trial arms

Source: McKinsey, 2020

LEADERSHIP IN A CRISIS

When crisis hits, it can be difficult to know exactly how to respond; in such times, we turn to our leaders for direction and guidance. For many pharmaceutical executives, the coronavirus pandemic presented a challenge unlike any in living memory, testing the industry but also paving the way for positive change. Here, three thought leaders share what they have learnt about leadership during this time, as they continue to care for their teams, patients, and themselves.

01 TO WHAT EXTENT CAN YOU PLAN AND PREPARE FOR A TIME OF UNEXPECTED CRISIS, LIKE THE COVID-19 PANDEMIC?

Baert: While you can never plan for every crisis, we have well-established emergency management systems and teams in place with clear roles and responsibilities. The response to a crisis depends very much on the company culture and the willingness and agility to support one another, as well as having the right experts in the right place. You need clear and honest communication – be open when you don't have all the answers. Start by creating clarity by listening and asking questions, then empower your teams to find the solutions and support them by removing obstacles

Banque: While none of us could have anticipated a global pandemic of this magnitude, we see countries and governments reacting differently, with more successful countries having had previous experience in dealing with disease outbreaks or robust protocols for crisis management. To boldly move forward during these times, we must learn to quickly adapt and be comfortable with the uncomfortable, not default to the role of victim. By working with teams to accept uncertainty, we will be in a much better position to pivot with agility.

Ali: A crisis management or business contingency plan is fundamental. In the case of COVID-19, the level of response required, the impact to business, and the length of the crisis have surpassed a lot of comprehensive business contingency plans. Government responses and restrictions put in place to contain COVID-19 have changed over time so businesses have had to stay agile, adapt, and re-group to deal with the changes.

STEVEN BAERT
Chief People and Organisation Officer, Novartis

ESTER BANQUE
Senior Vice President and Head Intercontinental Commercial, Bristol Myers Squibb

ASAD MOHSIN ALI
Managing Director, UK & Ireland Global Hub, Ipsen

02 HOW DO YOU SUSTAIN A CULTURE OF POSITIVITY, CARE, AND UNDERSTANDING WITHIN TEAMS AND TOWARDS EMPLOYEES DURING TIMES OF GLOBAL CRISIS?

Baert: When managing a crisis, it's important to set clear principles early on that serve as lighthouses. We agreed that two things truly mattered: the physical and mental wellbeing of our associates, and the continued supply of medicines to patients and customers. We know that people's potential is unlocked when they consistently experience an inclusive environment. In a remote environment, it's vital that all team members have an equal opportunity to be visible and contribute. To help our associates cope with the challenges presented by COVID-19, we rolled out a wide range of support tools from childcare and additional paid leave to learning solutions.

Banque: As one of my team members shared, "We're all in the same storm, but not in the same boat." It's imperative that we empathise with people's unique challenges. We must reinforce a culture of care and understand that issues and frustrations need to be addressed head on to co-create solutions. We also need to help people connect with their sense of purpose: ensuring that our medicines are available to patients, even when facing supply hurdles.

Ali: We clearly communicated our priorities: ensure employee safety and focus on business continuity. We recognised early that there is no 'one size fits all' way of working and have listened to employee feedback through 1:1s, team meetings, and pulse surveys. We provided wellbeing resources: virtual yoga, an online wellbeing hub, a network of Mental Health and Wellbeing Ambassadors, and our Employee Assistance Programme. We implemented a COVID-19 volunteering policy, enabling our employees to go back into the NHS or carry out volunteer work for local community groups one day per week fully paid.

03 HAVE YOU ADOPTED ANY PERMANENT CHANGES GOING FORWARD THAT WERE INITIALLY REACTIVE MEASURES TO COVID-19?

Baert: The pandemic has accelerated our ongoing digital and cultural transformation. It will have a lasting impact on how we travel and engage with each other, and the digital tools we use. It has also accelerated our exploration of future working models; we have begun to further 'unboss' associates by giving them greater choice to decide how, where, and when they work. This is a natural evolution of our culture transformation: the next step on our journey to unleash the power of our people to reimagine medicine.

Banque: Digital outreach has become a key component of how we engage internally and externally and is likely here to stay. Virtual can encourage greater frequency of contact, ease, and expanse of reach. Now more than ever, it's critical to lead with humanity and empathy, showing kindness and support. Although COVID-19 has been a disruptor, it is also an accelerator. Our ability to address change is grounded in our mission to serve patients and deliver medicines that help them prevail over serious diseases.

Ali: We already had the technology and capability to work flexibly and remotely; for many it was simply a case of replacing the 'corporate' office with the 'home' office We spent a significant amount of time and investment to engage with our customers remotely; this took many forms, from instant messaging to full video-based interactions with interactive e-materials. We have learnt that the way our customers interact with theirs (for HCPs, their patients) has also shifted significantly; they have an even bigger appetite for remote engagement than we imagined.

04 WHAT IS THE MOST VALUABLE LESSON YOU HAVE LEARNT ABOUT LEADERSHIP DURING THIS TIME?

Baert: The answer to most challenges is within the team. The leader's role is to frame problems and create psychological safety, listening to every voice in the team before agreeing on a solution. You need to ask: 'What can I do to best support my team so that they can do their job?' COVID-19 has taught us to be more aware of one another's humanity and as leaders, we should embrace this, practising our listening and coaching skills as we support our people in navigating the new normal.

Banque: I've been inspired by the resilience of our teams, overcoming hurdles to ensure patients receive medicines no matter how remote they are, while preserving the safety of our employees. I have also elevated my own resilience. COVID hit when the company was going through major organisational transformation and suddenly, I was working longer hours for extended periods of time. My desire to take care of everyone and lead effectively turned into a very demanding, intense experience. This taught me to manage my energy (meditation, exercise, healthy food, sleep) in order to take care of others.

Ali: The importance of communication and maximising virtual channels to retain engagement, while recognising that people's appetite for this new way of working will vary and some will take more time to adjust than others. Listening to colleagues to understand how to properly support individual challenges, particularly around psychological health and well-being, as we adapt to the new world. Prioritise deliverables, cutting out non-value-adding activities more than ever, and use a flexible working approach to allow employees space to balance changing personal circumstances.

PHARMA'S RECESSION RESILIENCE

Words by **Isabel O'Brien**

Recession resilience is coveted across all industries, and the pharmaceutical industry is in a stronger position than most to weather economic turbulence. Whether the world is being tested by a housing market crash or a global pandemic, diseases will always exist and patients will always need treatment. But how 'recession-proof' is pharma, and what challenges has COVID-19 posed to this famously robust industry?

"Pharma companies might be generally more resilient to this crisis than other businesses, as they are less exposed to the macro economic environment," says Anthony Bruce, Pharmaceutical and Life Sciences Leader, PwC UK. "Looking back at previous recessions, revisions in earnings for the industry are half of what you see for the rest of the market."

Since the industry is not affected by typical recession triggers, including changes in gross domestic product (GDP), inflation, employment, spending, and monetary and fiscal policy, pharma often avoids having to perform the same cutbacks as other industries in times of economic downturn.

The pharmaceutical industry is less dependent on typical economic cycles and fluctuations than most sectors

"The pharmaceutical industry is less dependent on typical economic cycles and fluctuations than most sectors because we are serving high, unmet patient needs – a mission to be proud of," corroborates Andrius Varanavičius, Chief Financial Officer Canada and Europe, Takeda. Although companies may not be at the mercy of the changing whims of external forces, "Instead, the performance of pharma companies tends to be driven by product lifecycles and the breadth and quality of innovation," says Varanavičius.

Innovation is particularly relevant in the downturn caused by COVID-19, with companies failing to innovate in-house or through partnerships, at risk of being left behind. "Innovation will be particularly key to success. Larger life sciences companies have to be proactive early on in the development cycle, in order to ensure that they're in a position to support highly innovative companies to maintain the productivity of the industry pipeline," says Bruce.

Digital health solutions are key to any profitable strategy: "Digital health solutions such as telemedicine, patient-centric apps, and innovative payer solutions will come into their own," says Varanavičius. If pharma can compete with large technology companies who are rapidly developing these solutions, this could bolster both their short-term and long-term durability.

Beyond increasing capabilities to create the technology itself, the industry will have to make digital solutions work two-fold. "The evolution and innovation of the digital ecosystem provides a unique opportunity to collect real-world evidence to substantiate the value our products bring to patients. This also provides a feedback loop into our R&D engine, which allows us to focus on the future so that we can continue to bring solutions to patients that go beyond treatments," continues Varanavičius. The value of data insights should not be underestimated, as these will help pharma prosper during these uncertain times and beyond.

While global recessions may provoke survival of the fittest across industries, pharma is often relatively unharmed by wider economic downturns. As Bruce concludes: "The industry still has its issues, but companies have increased resilience through future-proofing and are in a much better place. Regardless, they continue to be attractive for investors, not least because whatever the economy is doing, the demand for medicines does not decline." Recession resilience is in pharma's favour, but adaption and innovation are needed to uphold this resilience for the sake of patient populations worldwide.

THE PLASTIC PANDEMIC EMERGENCY

Words by **Michaila Byrne**

As the public reaches for their blue face masks and frontline workers pull on their hazmat suits, there is a united sense that safety and protection are, at present, our most pressing and top priority – but at what cost? Until we find a vaccine, facemasks and PPE may be our only defence against the COVID-19 virus, but healthcare industries must remain mindful and vigilant about the increased consumption of plastic and the environmental consequences. How can the pharmaceutical industry assist and leverage their influence so that we do not regress on all the positive progress we have made when it comes to sustainability?

"The whole focus of the world has been on the elimination of plastics, then came COVID-19 and put the whammy on everything that we were doing right," states Janet Carlson, CEO and Creative Director for Copy, One Eleven Group. Take a stroll through any major city, town, or even the countryside, and you will likely stumble across scenes of single-use face masks blighting outdoor landscapes. Dr Dorota Napierska, Chemicals Policy & Projects Officer, Health Care Without Harm Europe, warns against what is likely to evolve into a major environmental issue: "The COVID-19 pandemic has obviously had a tremendous impact on the waste sector. The volume of medical waste is rising steadily and this is linked to growing populations and an increase in patients, but crucially, the healthcare sector has also become more and more reliant on single-use items and products with a lot of packaging."

129
billion
face masks and 65 billion plastic gloves have been used every month since the start of the pandemic

Source: GreenMatters, 2020

29
million tonnes
of plastic per year may end up in the ocean if greater action is not taken by 2040

Source: SystemIQ, 2020

It is imperative that we do not revert to bad habits and we must keep reminding ourselves of the incredible strides we have taken in adopting innovative and sustainable alternatives over the past few years. Our reliance on and addiction to plastic is by no means an incurable disease. Sian Sutherland, Co-Founder, A Plastic Planet, urges pharma to "turn off the plastic tap and embrace ingenious alternatives". She goes on to say: "The pandemic has also brought out the best in some of the world's most innovative companies. We were proud this year to work with packaging designers, Reelbrands and Tams Packaging, to develop plastic-free visors to protect frontline workers without adding to plastic pollution." Although pharmaceutical companies might not be manufacturers of PPE, Napierska reminds us that "[they] are users of PPE and can demand manufacturers to provide them with more durable, reusable, and sustainable products, and encourage them to innovate and pilot safer and more environmentally friendly solutions, free from hazardous chemicals." Every challenge brings with it the chance for innovation as well as real, quantifiable change. This is especially true for juggernaut industries like pharma, with Carlson advising that corporations "find a company to partner with who can take your waste and make something great out of it. We all have to look for opportunities to not only be responsible but to help grow the economy and support entrepreneurs too."

The healthcare sector has become more and more reliant on single-use items and products with a lot of packaging

As is the case with any collective effort, clarity and consistency of information cannot be understated. By now we are all aware of the dangers of plastic, but education around the proper disposal of PPE can certainly be improved, emphasising the relationship between human and planetary health more explicitly. Sutherland emphasises that PPE "needs to be treated as waste as it is not recyclable or biodegradable, but this has not been properly communicated and it has led to disastrous consequences. If 1% of masks are disposed of incorrectly, approximately 10 million will end up in the natural environment every month." Pharma can assume a greater role in encouraging hospitals, patients, physicians, and the general public to opt for more sustainable and environmentally conscious decisions when it comes to PPE. "Whilst PPE is essential for the protection of health workers and patients, the general population can consider alternative solutions such as reusable face masks and avoiding using gloves in public spaces to limit the burden on Earth's resources and environment," suggests Napierska.

In times of crisis when priorities are understandably being reshuffled, it is easy to fall off the wagon and back into old habitual behaviours, but the industry cannot afford to throw to waste all the progressive work we have set in motion. Through embracing innovative, sustainable alternatives at every level and by engaging in this conversation publicly and honestly, we can all pause, correct our behaviours, and put sustainability back in the front seat. If we can strike a balance between protecting ourselves and the planet, we will all reap the rewards in the years to come.

Medical Affairs

THE FIGHT AGAINST THE SUPERBUGS

Words by **Michaila Byrne**

700,000
people die annually as a result of drug-resistant diseases

Source: WHO, 2019

> 30
years have passed since the most recent class of antibiotics was discovered

Source: CFR, 2019

A viable economic environment is important as well as more partnering opportunities and policy reform

In the century since Alexander Fleming's eureka moment, antibiotics have reigned as one of mankind's proudest achievements: a wonder drug that fights infection, saves lives, and even wins wars. But as we navigate the present 'era of abuses' with the threat of superbugs looming and few new antibiotics on the horizon, how can the pharmaceutical industry and, in particular, medical affairs teams, take heed of Fleming's warnings and urgently action optimistic, pragmatic approaches to combat and curb antimicrobial resistance (AMR)?

Historically, pharma has shone as a formidable force in antibiotic development, playing a key role in the recovery and survival of millions. But as the years have passed, the industry has become less active in this arena causing an extreme drought in new antibiotics, which combined with poor adherence and habitual over-dependence, has culminated in a perfect storm: "Despite the growing threat of AMR and widespread recognition of the need for new antibiotics, the number of companies conducting antibiotic R&D has significantly declined due to scientific, regulatory, and economic challenges," explains Dr Elizabeth Hermsen, Head of Global Antimicrobial Stewardship, MSD (known as Merck & Co., Inc. in the US and Canada. Despite how indomitable the challenge may first appear, the industry must take note of the disruptive impact of COVID-19 and adopt this experience as a cautionary tale. "The next pandemic could be caused by a drug-resistant pathogen and it is far too costly on all accounts to develop a treatment on short notice," warns Fatema Rafiqi, Research Programme Manager, Access to Medicine Foundation.

MA have a leading part to play in raising the alarm and communicating the need for strong education, awareness, and stewardship programmes. AMR is a complicated topic, too often poorly understood; however, with their foundational training in science and medicine, MA can prioritise not only patient needs, but also uphold public health interests. Hermsen corroborates: "MA professionals have a large network to facilitate best practice sharing and, as such, they understand different perspectives from various geographies, providers, and/or practice settings. With their expertise and capabilities in infectious diseases, MA professionals can clearly complement other stakeholders in efforts to address AMR." MA can compensate for knowledge gaps and build bridges between multiple stakeholders who all have their own unique part to play. "MA serve as trusted communicators with external stakeholders, such as key opinion leaders, healthcare professionals, policy makers, government officials, and patients," says Bruce Altevogt, Vice President and Head of External Medical Engagement, Hospital Business Unit, Pfizer.

Plainly put, the current financial ecosystem is unsustainable, and the antibiotic pipeline is not accelerating at the rate necessary for innovation to flourish. Rafiqi explains that support and funding are essential: "A viable economic environment is important as well as more partnering opportunities and policy reform." Pharma must create better incentives and a viable economic environment for antibiotics to not only survive but prosper. Altevogt attributes additional reasons for a lack of innovation to the "steep costs of antibiotic development, high risk of failure, long lead times, and growing awareness of the need to limit their use," explaining that "there are few incentives for venture capital or pharmaceutical companies to invest in antibiotic R&D since it will be extremely difficult to realise a return."

But the industry is showing signs of heading in the right direction. Earlier this year, the AMR Action Fund was formed, with pharma companies collectively donating £1 billion in a push for innovation in late-stage development. Furthermore, 'push and pull' incentives have been introduced to support younger companies, who have the ideas but lack the funding to develop new antibiotic drugs. In this way, big pharma can support the creation of antibiotics by partnering with these ambitious biotech companies through covering the operational and commercialisation costs. This two-pronged solution helps to stop more prominent drug makers from retreating, prevents smaller biotechs from going bankrupt, and saves the lives of patients: a collective win by all accounts.

It is easy to forget that until very recently, patients routinely succumbed to common but treatable infections. We cannot regress and undermine the incredible progress that has been made; pharma needs to reclaim its position and become part of the solution. As the COVID-19 pandemic has proven, mobilisation is possible and political willingness for acceleration is here. AMR is humanity's slower-moving pandemic, so combatting it is a medical imperative as well as an ethical one and MA has the chance to take the reins for real change.

SPOONFUL OF COLLABORATIONS

We delve into the most engaging collaborations from the pharmaceutical industry that have taken place in the last few months, specifically those that have featured non-traditional healthcare players and those that are set to have a positive impact on patients.

GSK AND THE GAY TIMES GROUP

GSK is on a mission to boost diversity and inclusivity across its marketing channels, particularly in their consumer campaigns, and have partnered with the Gay Times Group to achieve this for the UK market. The pair are collaborating on two OTC campaigns for toothpaste brand Sensodyne, and pain relief gel Voltarol, aiming to amplify LGBTQ+ voices in two original television adverts featuring famous faces such as TV personality and cabaret star, Gingzilla.

SANOFI BELIEVES THAT MENTAL HEALTH MATTERS

Sanofi Genzyme has assumed the role of hot-shot movie investor in its collaboration with Mental Health Matters and production company Believe Limited. The company financed "Let's Talk", a 40-minute documentary highlighting the mental health issues associated with blood disorders. The film features five patients discussing their experiences, and debuted at the National Haemophilia Foundation annual conference.

BAYER AND FOGSI 'ASK TANU'

Bayer Zydus Pharma has partnered with the Federation of Obstetric & Gynaecological Societies of India (FOGSI) to drive adoption of their chatbot 'Ask Tanu'. The AI has been designed to combat misinformation around women's health in India by providing 24/7 instant access to endometriosis and contraception information. The pair hope that wider adoption will improve rates of diagnosis and counteract a troubling reduction in health visits due to COVID-19 fears.

AN ADVANCO AND SYNTEGON PACKAGE

Packaging manufacturers, Advanco and Syntegon, are partnering to tackle the growing and dangerous problem of counterfeit medications. The collaboration will harness Advanco's advanced serialisation capabilities and pair them with Syntegon's top-of-the-range packaging manufacturing, to ensure that packaging can be verified and traced at all stages of the supply chain. Action of this kind is particularly urgent as pharma companies prepare to circulate potential treatments and vaccines for COVID-19.

'THE NEW NORMAL' FOR KPIS

Words by **Isabel O'Brien**

In the middle part of this year, it was near impossible to brew your morning coffee before encountering talk of 'the new normal'. The phrase polluted televisions, radios, and newspapers. Zoom was alight with strategy meetings to decipher how this new state of affairs would be navigated. What was less talked about was KPIs and how the new normal would impact both their structure and usage.

This absence from thought was best encapsulated during an interview at Cannes Lions Live 2020 with Bozoma Saint John, who was, at that time, CMO, Endeavor. When asked about what success metrics her company were using amidst the pandemic, she laughs: "Success is still being alive. Success is still having a business at the end of this thing."

However, now that the shockwaves have plateaued and businesses have had to time adjust, a refocus has taken place. Talk of the new normal has waned into acceptance, and industries, including the pharmaceutical industry, are taking active steps to develop fresh success metrics for the new era.

"Measuring KPIs is about measuring progress towards goals. Irrespective of circumstances and changing environments, our ability to define what we are trying to accomplish and have a way of moving closer to that is critical," says Nikos Georgiades, Senior Vice President, Global Head of Digital Commercial Execution, Novartis.

For pharma's commercial arm, revisions have been particularly important. Restrictions on travel and reduced clinician availability have called for new, digital methods of engagement and identifying KPIs to track these interactions has been key for healthy business continuation.

"When digital interactions were seen as a mere support act to the main business of speaking face-to-face with customers, the focus was perhaps more on 'reach' metrics for all interactions… But with little or no face-to-face interaction, we must use digital KPIs to track our conversion rate. Such as, has visiting our website changed the customer's view about our product? Did our webinar have an impact on prescribing habits, whether they attended or viewed on-demand?" says Kay Wesley, CEO, Kanga Health. "In addition, to understand our conversion-rate we must also track engagement – how interesting was this content? How relevant was that interaction to the customer? Furthermore, to achieve the required number of conversions, we must still reach enough customers in the first place. So, to succeed, we must now track KPIs for reach, engagement, and conversion," she continues.

Whilst the COVID-19 pandemic has invalidated many of the monthly targets and 5-year plans that were in place for commercial teams, it has also acted as a catalyst for developing new and more thorough KPIs, which align more closely with pharma's digital future.

"No one knows when this pandemic will end, or what our industry will look like at the end of it. Positives can be taken from how we have adapted our business practices (as an industry) over the previous 6 months and we will have to show similar flexibility in setting KPIs in the future," says Chris Lawson, Managing Partner, Orientation Agency.

Georgiades shares an aligned future outlook: "We will certainly not revert back to the fully traditional measures and KPIs, but instead we expect that a combination of old and new KPIs will measure progress, efficiency, and effectiveness of our efforts."

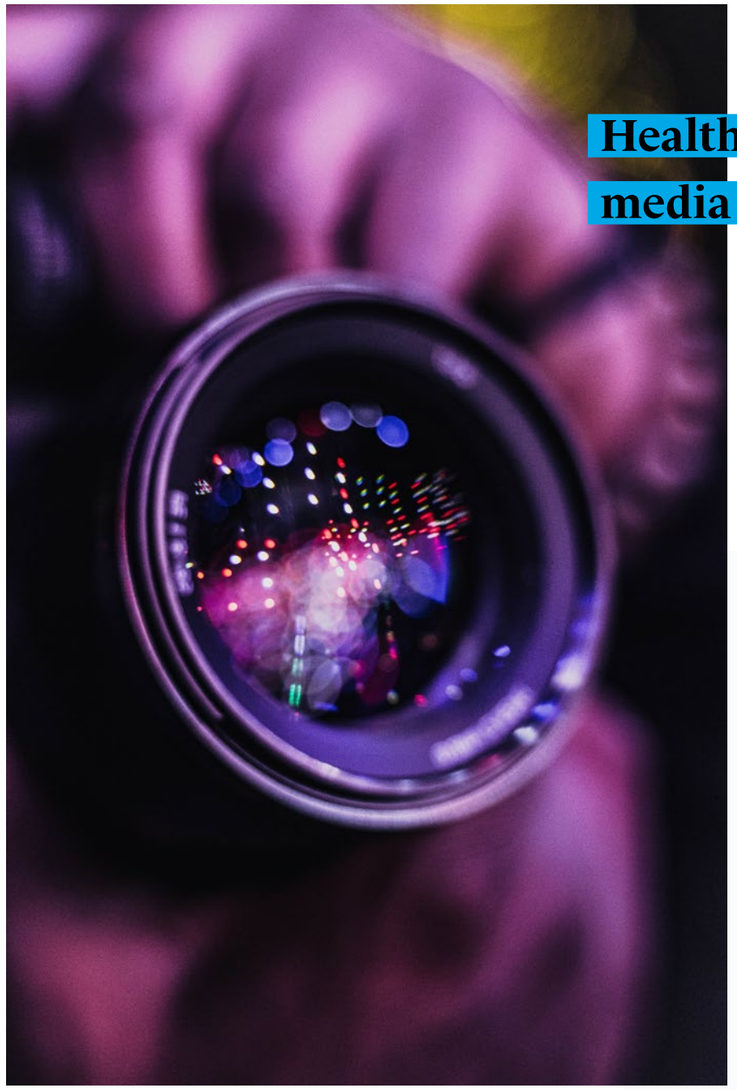
We expect that a combination of old and new KPIs will measure progress, efficiency, and effectiveness of our efforts

We may be so deeply engrossed in the new normal that it no longer feels like an adjustment, but the industry has undergone a transformation and KPIs have proved to be the dial on the compass that is keeping commercial teams on track for their goals. As Wesley concludes: "Only by tracking the right KPIs can we work in this nimble yet effective way to build a business fit for the future."

PICKING THE PERFECT CAMPAIGN STAR

Words by **Isabel O'Brien**

Celebrity endorsements can transform a mediocre campaign into a pitch-perfect hit, but choosing the right spokesperson is crucial. We explore the practice of attaching famous faces to campaigns and how to ensure a representative strikes the right chord.



The best campaigns incite action. The worst trigger international scandals, leading to product boycotts and campaigns being pulled. Getting the tone of a campaign right is critical. When choosing a celebrity figurehead to represent a cause, the pharmaceutical industry must think like a hit record producer and pick a voice that will positively resonate with their target audience.

In Europe, industry campaigns are restricted to over-the-counter (OTC) health products and disease awareness. Health holds universal appeal, it is not a divisive genre, but marketing and communications teams still face challenges in engaging the public with their causes.

Celebrity endorsements can help a product to stand out in a bustling space. The supplement market is valued at a huge $133.15 billion and a common difficulty for manufacturers is gaining attention for their products. While prescription medications have competitors, with HCPs able to choose from multiple treatment options, an OTC probiotic may be in competition with hundreds of similar offerings. "When you operate in a crowded market with many products competing for 'share of voice,' we have to come up with strategies to boost brand visibility and reach," says Arpita Pani, Senior Commercial Governance, Digital Transformation and e-Commerce Lead, Ferring Pharmaceuticals. This stands to be an increasingly prominent challenge, with the market set to grow to $245.62 billion by 2027, due to rising interests in health, changing lifestyles, and evolving dietary habits.

of OTC product adverts are endorsed by a celebrity

Source: International Journal of Management and Social Science Research Review, 2019

Celebrity endorsements in disease awareness have a strikingly similar function; data shows there to be >10,000 known diseases, each with their own stories, needs, and patient populations. Communication teams must sing out about the diseases in their portfolio, with collaborations allowing impact to be amplified in public discourse.

Health consumers in the age of social media are savvier than ever

The ignition of conversation is most needed in conquering stigma. In a recent report by ViiV Healthcare, 61% of people said that if they found out a potential partner was HIV-positive, they would or might end the relationship, with 81% identifying the reason as fear of contracting HIV themselves. In reaction, ViiV launched a campaign with rugby star Gareth Thomas, who himself is living with HIV: "The Tackle HIV campaign is an initiative aimed at improving public understanding of HIV, dispelling the myths and breaking the stigma around it," says Helen McDowell, Head of Government Affairs and Global Public Health, ViiV Healthcare. Collaborations can be used to drive more than just awareness; they have the potential to tackle deeply ingrained public prejudice.

While the upshots are plentiful, it is important to approach these collaborations with a precision akin to a composer arranging harmonies. "Health consumers in the age of social media are savvier than ever. Diligent research is critically important to ensure that the talent can passionately and authentically communicate the key messages. Pharma should align with a celebrity in a way that conveys trustworthiness and integrity, and a clear connection to the cause will often be the anchor of the campaign," says Amy Doner, Founder and President, Amy Doner Group, a talent procurement agency that matches celebrity talent with pharmaceutical causes.

For products where marketers are hoping to influence behaviour, authenticity is integral to reaping results. "It is important to understand if your product needs a celebrity endorsement and match that to the product personality," says Pani. "For VSL#3, a poly-biotic, multi-strain product that I lead, I have worked with many influencers who have approached me directly due to the value of the product, and we have then assessed the impact they can have to enhance brand visibility due to their love for the product." Onboarding existing brand ambassadors cultivates authenticity, as their audiences can recognise how closely the product aligns with the influencer's values.

For disease awareness, where communication teams aim to change opinions, any shifts will be linked to whether the celebrity's connection is a believable one. As a person with HIV who is passionate about eradicating stigma, Gareth Thomas is an example of a perfect choice. "The real difference is that having Gareth Thomas at the centre of it as a public figure helps bring it to life in a very passionate and involved way, and gives it more traction with the general public," says McDowell. "The launch media campaign results include widespread prime-time news coverage, more than a dozen radio interviews, along with newspaper articles in most of the national papers and more than 160 local and regional online news outlets." Stigma can only be dismantled if a campaign reaches a high percentage of the target population, and a celebrity spokesperson generating a buzz can bring about positive change.

With a considered choice, a celebrity endorsement can carry a campaign to chart-topping success, with reach and engagement far exceeding a campaign without a famous representative. As Doner concludes: "A strong, targeted celebrity endorsement campaign can grow into a profitable long-term partnership, strengthening your brand and enhancing visibility and understanding."

Did you know?

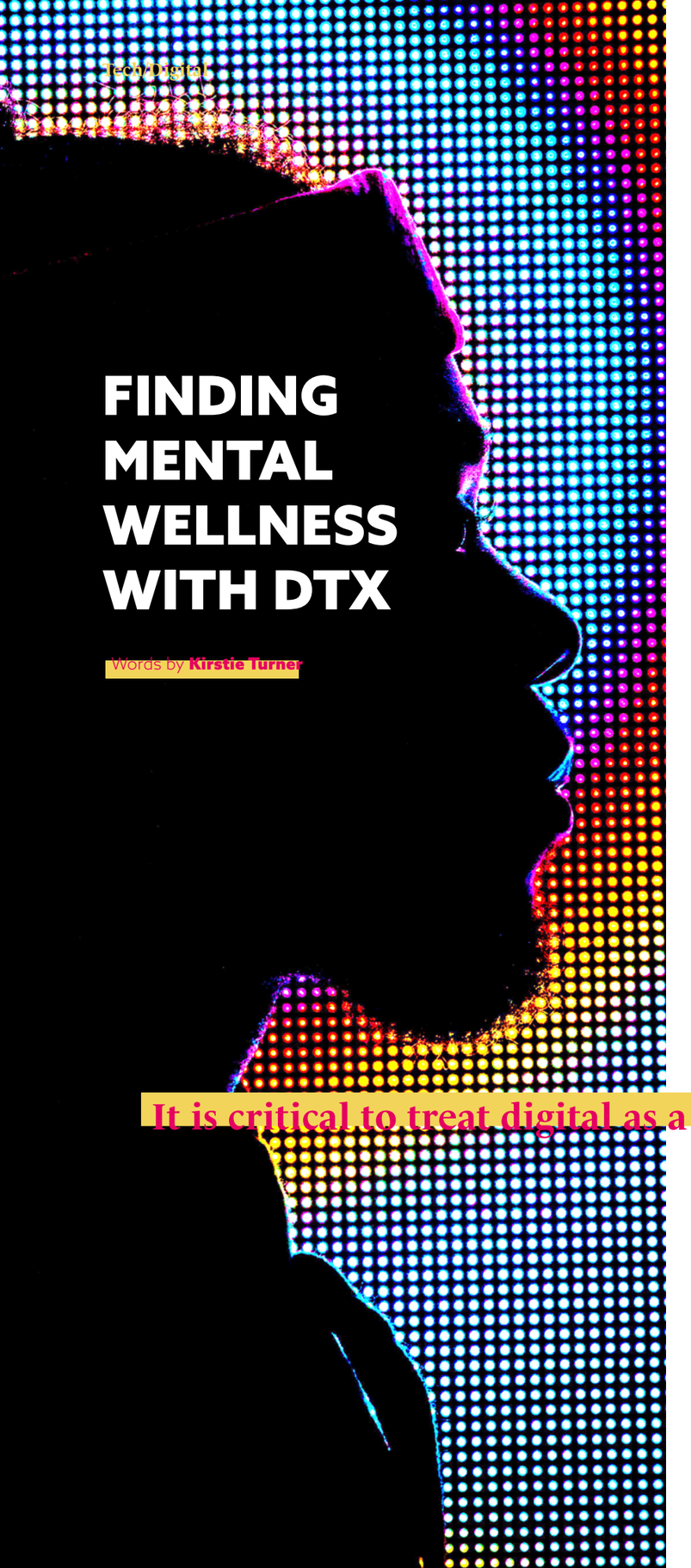
When a celebrity is involved, public health messages reach increases by

72%

79%

of this effect comes from the celebrity authoring the message themselves

Source: MIT, 2020



FINDING MENTAL WELLNESS WITH DTX

Words by **Kirstie Turner**

In recent years, mental health awareness has increased exponentially, but the hard fact remains that, globally, 800,000 people still die from suicide each year. For the pharmaceutical industry, the cost and intricacies of drug research into psychological disorders mean that new solutions are rare and complex; more widely, the drug versus behavioural therapy argument remains steadfast. The answer may lie in digital therapeutics, which can be harnessed for both treating mental health and as an aid to more traditional drug-based therapies. Will digital create the foundation for the next phase of psychiatric pharmacology?

Speaking at the WIRED Health: Tech virtual event, Pravene Nath, Global Head for Digital Health Strategy, Roche, discusses digital health tools: "Most digital health tools take the same three-part form. First, a wearable device or mobile app that captures patient data. Second, algorithms, including artificial intelligence, that generate insight from the data. And third, a portal for the healthcare provider to visualise the insight at the point of care." These tools can be utilised for a large, varied range of uses in healthcare.

While we have seen an explosion of innovative technology in recent years, digital health tools are still relatively new for pharma. Nath explains: "We have all heard the stories about the explosive growth in tele-health. But, at one of the places I worked, it took us 10 years to get to 4% virtual visits." The uptake may be slow, but future predictions for this market are huge: "It is thought that the potential market size for virtual care could reach around $250 billion," adds Nath.

It is critical to treat digital as a true therapeutic

Despite slow uptake, digital therapeutics have made great leaps in improving treatments, prevention, and adherence for many conditions. However, there is still much to be explored in the realm of mental health. Joris Van Dam, Head of Digital Therapeutics, Novartis Institutes for BioMedical Research, discusses the potential: "Digital therapeutics offer unprecedented opportunities to promote access to care, improve engagement, and reduce stigma. At the same time, you can apply quality control processes that are common to pharmacotherapy, yet impossible to enforce during in-person therapy."

As the treatment of mental health using digital therapeutics is still relatively new and unexplored, Van Dam believes that trust must be developed in these products if they are to succeed as viable treatment options: "It is critical to treat digital as a true therapeutic and to garner the evidence that deserves the trust of patients, the buy-in of healthcare professionals, the clearance of regulators, and the reimbursement of payers." These products must not be viewed as gimmicks or fads, but as legitimate tools for improving outcomes for patients living with poor mental health.

If stakeholders are to build trust in these products and treat them with equal importance to drugs in the treatment of mental health, they must be passed through the same rigorous standards of regulation and labelling. Van Dam adds: "We must provide transparency as to what the product does and doesn't do through accurate product labelling, just like all the other healthcare products we have come to trust."

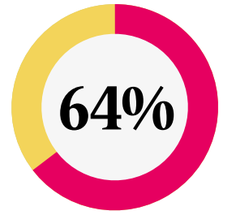
As challenges remain, from risky investments and strict regulations to complex trials, partnering with digital tech companies could be the answer in improving digital health tools. IntroSpect Digital Therapeutics, an ATAI Life Sciences Company, is one such example of a potential partner for pharma companies. Their mission is to extend the potential of psychedelic-assisted psychotherapy to change patient lives and bring innovation to the healthcare system. David Keene, CEO, IntroSpect Digital Therapeutics, outlines their goals: "Using the flexibility and power of digital technology allows us to be more capable than ever of meeting patients on their own terms." They also focus on offering individualised therapies to patients through the power of digital, as mental health is personal and manifests differently in every patient.

While digital therapeutics are being used to treat mental health conditions, tools are also being developed to be used in conjunction with traditional therapies, to better inform their use. Van Dam continues: "These digital devices can provide accurate insights into personal behaviours that can be effectively used to target therapeutic content." In many cases, digital therapeutics are not removing the need for treatment, but are designed to work hand-in-hand with them, elevating their impact with better informed insights.

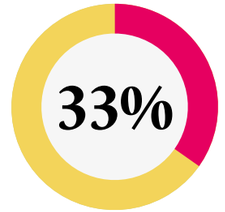
Despite perceived challenges with high costs and regulatory pressures, the opportunities to improve outcomes for mental health patients are too valuable to ignore. Digital will continue to dominate in all areas of the health sphere and psychiatric treatment cannot be left behind: it is time for pharma to fully embrace mental health treatment developments driven by digital solutions.

264
million
people worldwide are impacted by depression

Source: WHO, 2019



of patients with depression do not respond to the first drug they are prescribed



of patients do not achieve remission of symptoms after taking 5 different antidepressants

Source: ADAA, 2019

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