GOLD.

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THE HEALTH AND HAPPINESS SYNERGY

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eyeforpharma
BY REUTERS EVENTS

CEO'S LETTER

It has been said that laughter is the best medicine, but in truth, the happiness of patients has not traditionally been a priority for the pharmaceutical industry. There are, however, signs that pharma is starting to appreciate the long-term benefits of patients living happier, more positive lives. How can the power of patient happiness be implemented more concretely into the industry?

In this issue of GOLD, we delve into the topic of pharma's role as a champion for patient happiness, as well as the potential for patient-made medicines and the challenge of medication adherence. A number of our articles are inspired by insights gained from expert speakers during this year's eyeforpharma Patient Summit Europe and Marketing and Customer Innovation Europe conferences; these include addressing the recruitment and retention crisis in clinical trials, as well as the vast potential of artificial intelligence in enabling pharma marketeers to target customers more effectively.

Medical affairs, as always, features substantially in this issue of GOLD. We present the history of the department in pharma, from its humble beginnings to the central position it holds in the industry today, and we also analyse the critical role it needs to play as pharma moves towards an era of precision medicine.

In keeping with the strong patient-centric theme of this issue, our catalyst interview is with Ipsen's Chief Patient Affairs Officer, Isabelle Bocher-Pianka: a proud champion for the patient voice. It has been another great year for GOLD, and to see the extent to which the pharma industry has evolved, even in that short space of time, has been awe-inspiring. Thanks for engaging with our magazine this year, and we will be back with more content to help you become a gold-medal winner in your company in 2020!

Spencer Gore,
Chief Executive Officer

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EMG HEALTH

CONTENTS

SPOTLIGHT

In this issue of GOLD, we're taking a look at the hottest news stories that have emerged during the last 3 months, which we believe are having the most profound impact on the pharmaceutical industry. As can be seen below, we have seen exciting digital advancements and collaborations, as well as some bold steps to tackle global health issues.

29 AUGUST

Merck, Novo Holdings, and other pharmaceutical companies partner with the Biotechnology Innovation Organisation trade group to form the 'Working to Fight AMR' awareness and lobbying campaign.

12 SEPTEMBER

Gilead's newly established TRANScend Community Impact Fund pledges $2 million to help transgender community groups across the USA.

24 SEPTEMBER

Evotec and Takeda enter into a collaboration, which will enable Takeda to utilise Evotec's drug discovery platform across oncology, gastroenterology, neuroscience, and rare diseases.

27 SEPTEMBER

Pfizer's chairman, Ian Read, announces he will leave the company at the end of 2019, with CEO Albert Bourla set to assume the position.

8 OCTOBER

Pre-Takeda buyout Shire CEO, Flemming Ornskov, is announced as Galderma's new CEO.

15 OCTOBER

Sanofi opens its first digitally-enabled, continuous manufacturing facility, signalling a new era of biotech manufacturing.

16 OCTOBER

Novo Nordisk builds a $40 million wastewater plant, then donates the facility to its host town Clayton, North Carolina, USA, as excess capacity will attract other drug makers to the area.

22 OCTOBER

Bayer launches LifeHub UK, which will focus on using AI to maximise data-led drug discovery and disease diagnoses.

24 OCTOBER

NHS England and Vertex agree on a price for ORKAMBI: the 'wonder drug' for cystic fibrosis, after 3 years of negotiation.

7 NOVEMBER

Europe launches its first national medical cannabis registry for patients with chronic conditions as a part of an initiative called Project TWENTY21.

11 NOVEMBER

Merck's Ebola vaccine, Ervebo, becomes a world first in achieving approval status.

13 NOVEMBER

Long-standing CEO of Abbott, Miles White, announces that he will leave the post in 2020, but will retain his position as Executive Chairman.

THE PATIENT WILL SEE YOU NOW

Words by **Michaila Byrne**

Not only does the very idea of a medicine being created by patients undermine our abiding belief in the traditional drug development process, but on first impression, it sounds pretty preposterous. Is such a knee-jerk reaction warranted? Typically, the timeline of drug development begins at discovery, moves into development, market access, commercialisation, and then, right at the very end of the line, sits the patient. It's an orthodox structure held at the very core of pharmaceutical practices for almost a century. But as our faith in data intensifies, these foundations start to erode and pharma must begin its preparations for a new template: one where this line bends, variations emerge, and patients are present from the onset. Consider the contrast between video content today and the film industry of the 1960s. Not only is video more easily accessible, but the number of people actually creating their own films has shot up exponentially. As the monopoly on information dissipated and trickled down to the everyman, people became empowered and subsequently, impatient. Information was democratised, triggering the advent of content being composed and distributed inhouse and by ordinary citizens. Industries across the board are restructuring and Paul Simms, Chairman, eyeforpharma, hypothesises that pharma is no exception: "Dataism and belief in the data is becoming stronger. That is the basis upon which we can develop our own drugs", he states.

Given the power an individual will hold in an increasingly data-centric society, realistically we should expect the early stages of drug formation to manifest at the ground level, commandeered by patients themselves. For evidence of this shift, look no further than last year's FDA approvals where, of the 59 drug approvals granted, 40% were to start-ups who had never had a drug released before and a record low of 26% were granted to big pharma. "You don't have to be a big pharma company to do research anymore. It's becoming something that smaller companies do. It's not at human scale yet, but it is certainly democratising", Simms continues.

Suppose you possessed all the tools to create your own medicines; you would undoubtedly alter processes to take matters into your own hands. Patient-led innovation groups emboldening this sentiment are galvanising and emerging support networks, including a community app, HealthUnlocked, on which patients connect and the forum 'patientinnovation.eu' wherein patient entrepreneurs hack solutions to their own problems. One diabetes patient-led innovation group aptly named 'We Are Not Waiting' have begun developing their own treatments, hacking glucose monitors, connecting smart watches to data systems in the cloud, publishing algorithms online, and sharing data on the cloud.

Paul Wicks, Vice President of Innovation, PatientsLikeMe, an online community for people living with medical conditions, explains: "Turning over some of the power to people living with conditions and non-profits is something that HealthUnlocked does. Equally I think there are great patient-led innovations... that really show you what can happen when systems themselves take back control."

One pharma company embracing this change is LEO Pharma, who have involved patients in the actual scientific creation of medications during R&D. As a result of patient engagement, LEO laboratories have already seen several dozen new compounds emerging and now entering clinical trials. Geraldine Murphy, Vice President, Cluster Europe North, Australia & New Zealand, LEO Pharma, stresses the importance of treating patients as equal collaborators. "We partner with patients on an equal level, we seek advice from them, and we give them advice... it takes active listening

52%

of patients engage with patient organisations monthly compared to 35% with pharma companies.

Source: Accenture, 2019

53

companies shared a total of 59 FDA drug approvals in 2018, with only six companies receiving multiple approvals.

Source: Forbes, 2019

to a new level when patients come into our organisation and sit with us. Our patients tell us what we are getting right - which is great - but they also tell us what we don't get right, which is just as important."

Simms continues: "Motivation eats regulation for breakfast. You don't care what the regulations say if you're a patient and you need your treatment." Citing peer-to-peer digital audio sharing platform Napster, Simms concludes: "Don't expect that the regulatory system will define or prevent patient-created medicine from becoming reality."

In times of poor health, people once collectively turned to religion, then they turned to the experts, and now they're looking inwards. As past doctrines are superseded by the guiding force of data, pharma must gear up as patient-made medicines are expected to make an appearance momentarily. Crucially, pharma can frame this change as an incentive for collaboration and a catalyst for uncharted innovation.

Dataism and belief in the data is becoming stronger. That is the basis upon which we can develop our own drugs

FEATURE ARTICLE

THE HEALTH AND HAPPINESS SYNERGY

Happiness has been shown to work in conjunction with medications to improve the road to recovery for patients. Despite this, the importance of patient happiness as a success measure still has some stigma surrounding it in the pharmaceutical industry.

Words by **Kirstie Turner**

We've all heard that laughter is the best medicine: if only the pharmaceutical industry could bottle happiness and that would suffice as a treatment for every condition. Pharmacies would be fully stocked with pills of positivity and lozenges to soothe the soul. In reality, the development of new drugs is still critical, but a sprinkling of happiness could be the missing ingredient in the recipe for recovery. It is time for pharma to recognise the importance of mental wellbeing in the treatment process and let the power of patient happiness work its magic.

Patient centricity is the buzzword on everyone's lips in the current climate of pharma, but maybe what we should be striving for is 'people centricity'. As Catalina Cernica, CEO, the Health & Happiness Research Foundation, says at the eyeforpharma Patient Summit Europe: "It is about seeing patients as people and not focussing on managing their disease, but understanding their lives and helping them live fulfilling and happy lives."

It is so easy to assume that symptom relief is the top priority for patients, but for many, happiness is a more important signifier of quality of life. Happiness is not as easily measured as physical symptoms, and therefore often overlooked or not considered to be as important. Cernica explains why: "Healthcare systems don't like subjective", continuing: "We want to challenge that and get inspired by happiness."

There is a plethora of research demonstrating the health benefits of a happier life. Participants in one study received the hepatitis

We are trying to redefine health through the lenses of happiness

B vaccine and showed a twice higher likelihood of having a high antibody response to the vaccine if they were classified as happier. Despite the evidence, there is still an overwhelming focus on physical symptom relief; but mental and physical health are deeply entwined and cannot be looked at as individual silos. Research by the World Health Survey suggests that people living with two or more long-term health conditions are seven times more likely to experience depression.

Destigmatising the importance of patient happiness still has a way to go, but some companies, such as LEO Innovation Lab, are already recognising this critical aspect. Their initiative PsoHappy has the goal of improving the mental wellbeing of people living with psoriasis and truly is exemplary when it comes to championing patient happiness. The initiative has recently been span-out into an independent non-profit, the Health & Happiness Research Foundation, that will expand the success of PsoHappy in other disease areas. Cernica outlined the foundation's mission: "We are trying to redefine health through the lenses of happiness." By opening the conversation around patient happiness and making sure its importance is well known, Cernica urges the industry to: "Consider happiness measures in developing any healthcare solutions, treatments, and drugs."

Bridging the gaps between happiness and healthcare doesn't come without challenges, as Cernica explains: "Bringing social science methodologies developed by economists, behavioural specialists, or psychologists to clinical scientists is like trying to have a baby between a Vulcan and a Klingon", – arch nemeses if ever there were some. Considering the stigma around the importance of happiness, Cernica says: "People in pharma roll their eyes a lot because happiness is 'fluffy', but I think our work with PsoHappy has proved that there is a lot of value with these kinds of insights."

Another example of an initiative with patient quality of life at its heart, is Ensemble, by Novartis and Johns Hopkins, who won the eyeforpharma North American Most Valuable Collaboration award this year. For pharma, along with other healthcare professionals, the most critical element when dealing with cancer patients is treating the cancer; the patient's quality of life and mental wellbeing may take a backseat. The mission of Ensemble is 'easing the disease journey', with a focus on managing cancer at work. "[The initiative] plays directly into Novartis' mission, which is all about reimagining medicine to extend and improve people's lives", explains Steven Baert, Chief People and Organization Officer, Novartis. Having a platform to discuss the implications of cancer offers an extra support network for patients. Novartis are going the extra mile and considering the impact of a disease on quality of life, rather than focussing solely on disease treatment and symptom reduction.

For some patients, stigma surrounding their disease can play heavily on their mental health. Around 50% of inflammatory bowel disease patients have received abuse or discrimination

We are really thinking about empathy and how this can help to understand patients better and support them better

when using a disabled toilet, as their condition is not visible. Juliet Chambers, Communications Manager, Crohn's and Colitis UK, says: "It is an invisible condition; people cannot see that [the patients] have the condition and that can have a massive impact on their mental health."

To combat this, Takeda have partnered with Crohn's and Colitis UK to create 'In My Shoes', an app allowing users to live 24 hours in the life of an IBD patient and experience the challenges they face. Users receive tasks such as 'you have 3 minutes to find a toilet'. Audrey Liechti, Senior Communications Manager, Takeda says: "We are really thinking about empathy and how this can help to understand patients better and support them better." While this is not a treatment for the condition, this campaign is actively fighting stigma around the condition and raising awareness, working towards improved mental health for these patients.

NICE are ensuring that patient quality of life is given the attention it needs within their guidance and advice to the healthcare and life sciences industries. Mark Rasburn, Senior Public Involvement Adviser, NICE, explains how NICE measure success for patients: "We're able to say not just whether it has worked, but what the actual impact is on the patient: does it improve their quality of life?" Changing the metrics from what they assume the patient wants, to actually seeing what impact it has, gives clout to happiness as a measurement of success.

Happiness is subjective and what is important to one patient may not to be to another. Shared decision making between patients, pharma, and healthcare professionals must also be implemented to individualise treatment: "Doctors and patients must have a conversation together to understand what drug A does compared to drug B. They must discuss what the risks and benefits are, and then make an informed choice on which route they'd like to take. It's important because me taking a medication that results in severe side effects might be completely different to someone else's experience. My views on what a healthy lifestyle is may differ", explains Rasburn.

Change won't happen overnight. Opinions and stigma around the importance of happiness will be challenging to shift, but small steps on an aligned path towards a people-centric industry is a start. As Cernica says: "Start small, but always dream big." Every successful, new treatment that pharma develops brightens the future of healthcare, but they must also help patients to find the light: to seek out the stars, even on the darkest of days.

THE HEALTH AND HAPPINESS SYNERGY ACROSS HISTORY

1948 The World Health Organization (WHO) say: "Health is a state of complete mental, social, and physical well-being and not merely the absence of disease or infirmity."

1962 John Steinbeck writes that: "A sad soul can kill you quicker, far quicker, than a germ."

1969 A study of 4,486 widowers aged ≥55 years found that 213 widowers died during the first 6 months following the bereavement, 40% above the expected rate for married men of the same age.

1987 Research finds that immune system activity was linked to happiness: on days when participants were happier, they had higher presence of a protective antibody in their saliva.

1998 In his book 'The Art of Happiness', the 14th Dalai Lama says: "If you harbour hateful thoughts or intense anger deep within yourself, then it ruins your health; thus it destroys one of the factors for happiness."

2001 A paper studying the life expectancy of Catholic nuns finds that the happiest nuns lived 7–10 years longer than those in the unhappiest category.

2003 An experiment of 350 adults shows a link between positivity and a decrease in likelihood to develop a cold.

2005 Research finds a link between happiness and lower heart rate and blood pressure.

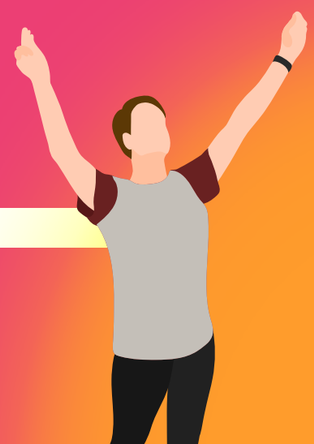
2006 Researchers find that students high in the positivity emotion are twice as likely to display a high antibody response to the hepatitis B vaccine.

2008 When studying 10,000 Australians, researchers find that participants who were happier were 1.5-times less likely to experience long-term health complications.

2010 A study finds that patients are 22% less likely to develop coronary heart disease for every 1-point increase in positivity they display.

2014 Oxford University publish findings that suggest serious mental illness can shorten life expectancy by 10–20 years.

2017 The World Psoriasis Happiness Report finds a -30% happiness gap for people living with severe psoriasis.



AN ANSWER TO THE ADHERENCE CRISIS

Low medication adherence brings with it a complex array of challenges for the pharmaceutical industry. Several companies are developing digital solutions to face the adherence crisis head on.

Words by **Kirstie Turner**

In the pharmaceutical industry's quest to provide drugs to treat, prevent, and cure all conditions, medication adherence is proving to be their Achilles heel. Poor adherence poses a myriad of challenges: it stops patients from getting better, costs healthcare systems vast amounts of money, and contributes to antimicrobial resistance, one of the greatest health threats of the modern age. There is a labyrinth of reasons behind low adherence that must be navigated. Can innovative, digital solutions stop adherence from becoming the chink in pharma's armour?

There were a record 59 drugs approved by the FDA last year, but new medications are only going to be successful if patients adhere to their treatment. It is critical to understand the wealth of possible reasons for poor adherence, such as the side effects of a treatment, as these will act as the catalyst for solutions. Completing antibiotic courses has long been a challenge because patients often stop taking antibiotics as soon as they feel better, instead of completing the course and ensuring eradication of the bacteria. In the USA, companies must disclose any risks when advertising drugs; this often-extensive list of side-effects can be off-putting for patients. The reason for some people may even be as simple as forgetting to take their medication.

Many of those working within the realm of healthcare are unaware of the presence of, and reasons for, poor drug adherence, as David Chandler, Lay Member, NICE, explains: "People with terminal cancer were stopping taking their medication during the course of the treatment. I was completely flabbergasted by that." He investigated further to find out why: "The treatment caused them severe side effects."

Pharma must work with healthcare professionals to outline to patients that, while side effects may be severe, the benefits will outweigh this, as well as educating them on the risks of not sticking to their treatment plan. The method in which this is done is key, as Chandler describes: "Be considerate around explaining the negatives ... [explain that] there is a negative, but the benefit is so much greater: weighing that risk and benefit is really important."

Vaccines are a prime area for focussing on improved medication adherence. At the eyeforpharma Patient Summit Europe, Philibert Goulet, Head of Patient Office, GSK Vaccines, outlines the drivers of hesitancy: "Confidence is the mistrust in the safety and efficacy of vaccines, and more broadly the mistrust of the health system generally... complacency is the underestimation of the impact of infectious diseases – it is quite frequent... and convenience is the fear of needles on one side and the effort of creating an appointment, when you aren't sick."

Once they had identified the reasons behind the poor adherence, GSK developed a solution: they created an online, double-blind community called HealthMakers, which enabled them to hear consumers' views and concerns surrounding vaccines. When educating patients on vaccine uptake, "it is important to provide the results of the science in a language that everyone can understand and not feel excluded", explains Goulet.

Pharma often have the issue of mistrust to contend with, or feelings that they are biased with their information on the success of vaccines. Goulet recognises that they may not be best placed to improve adherence, but could utilise their connection with HCPs: "We should increase our efforts collectively to provide HCPs with relevant and appropriate content for them and their patients."

Another approach to improving medication adherence comes from the innovative app Drug Stars. Users are rewarded for sticking to their medication plans: stars are earnt which can be used to donate money to one of their partner charities. A recent study of the app on a cohort of Danish patients with epilepsy showed that 33% of participants improved their ability to remember to take their medication and 28% were more motivated to do so.

At the eyeforpharma Patient Summit Europe, Claus Møldrup, CEO and Founder, Drug Stars, explains the reach of the app: "Any patient in the world can participate in our programme: it's completely free. Any patient charity can be a partner with us: it's also completely free for them." The more charities they collaborate with, the more direct lines of communications are opened with patients, as Møldrup continues: "Patient charities are giving us access to the patients who are then downloading the app."

They have coined the term 'Giving by Taking', which gives patients a stronger incentive by framing a consequence of adherence: by sticking to their treatment plan, they are helping other people living with the condition. And it seems to be working, as user numbers rise: "In the UK we have 37,000 users who are recording medications and they have done >60,000 reviews", says Møldrup.

With an onslaught of exciting developments across a range of therapy areas, it is critical that this progress is not hindered by the challenge of adherence. An open conversation with patients is sorely needed, along with the creation of innovative methods, such as Drug Stars and HealthMakers, to address the causes. Investing time and money into this realm will help to ensure that pharma do not become ensnared in the trap of low adherence on their mission to help patients.

Reasons for Poor Adherence

50%
of patients readmitted to hospital within 30 days have been non-adherent.
Source: Pillsy, 2018

125,000
deaths are caused by non-adherence each year.
Source: Catalyst, 2019

75%
of people living with a chronic condition, aged ≥40 years, say they have skipped or missed a dose in the last year.
Source: Catalyst, 2019

INTERVIEW

Catalyst of Pharma

Isabelle Bocher-Pianka

Isabelle Bocher-Pianka is Chief Patient Affairs Officer, Global Medical Affairs at Ipsen. We spoke to Isabelle about several topics, including the importance of the patient perspective, the biggest challenge for pharma in becoming a more trusted industry, and the most memorable moments from her impressive career.

We have a noble and unique mission to help improve patient lives

We have to know who we are working hard for every day

AS A CHAMPION FOR THE PATIENT VOICE, HOW IMPORTANT WAS IT FOR YOU TO ALIGN YOURSELF WITH A COMPANY, SUCH AS IPSEN, THAT SHARES YOUR DEDICATION TO IMPROVING PATIENT LIVES?

It was quite easy. Patient centricity was not a new venture for the company. Ipsen had some foundation from a cultural point of view. During my previous positions at Bristol Myers Squibb, or more recently at Ipsen as Senior Vice President of the Neurosciences franchise, I worked with many patients on numerous projects. My first mission as Chief Patient Affairs Officer was to design a global patient centricity strategy and engage the organisation to execute it! Alignment with Ipsen was easy thanks to the support of our CEO and Executive Leadership Team who want to make patient centricity a reality at our company. They supported the creation, as well, of the first Ipsen guidance for patients and patient organisation interactions based on the highest ethical principles. It starts from the top!

HOW DOES YOUR ROLE AS CHIEF PATIENT AFFAIRS OFFICER ALLOW YOU TO IMPLEMENT THE PATIENT PERSPECTIVE ACROSS OTHER DEPARTMENTS?

Ipsen has anchored this new role into the Global Medical Affairs (GMA) department. It offers huge opportunities to work cross functionally, across countries under an overarching common medical goal: to help improve patient outcomes and quality of life, whether they suffer from oncology, rare, or neuroscience-diseases. GMA colleagues are working with project teams all along the value chain. They help bring the patient voice into projects from the start and raise awareness of unmet medical needs.

Patient organisations expect a continuum of work from early development stages to post commercialisation. At Ipsen, patient centricity is approached pragmatically, through working with patients on concrete projects all along the value chain. I also serve as a member of the Global Leadership Team, which I find very valuable. It provides many opportunities to connect with senior cross functional and cross-country leaders. They, in turn, influence and spread both a 'patient centred' mindset and concrete actions. Their support and encouragement of their teams to listen to, work with, and embrace patient perspectives is vital to scale up my efforts.

WHAT IS THE MAIN CHALLENGE IN WORKING TOWARDS AN ENVIRONMENT WHERE PATIENTS CAN EDUCATE PHARMA TO IMPROVE PATIENT CENTRICITY?

Rather than a challenge, I see this as a great opportunity! The more educated pharma can be about patients, the better. I see the opportunity whenever we invite patients onto a project and seek their advice: we work hand-in-hand together, so they become like a colleague to us. They have a voice and can say, 'I was a really important part of this clinical development. With the knowledge I have from my disease, I contributed to this protocol.' We are working with patient organisations to support their initiatives and mission to help patients and caregivers.

DO YOU THINK THAT TO LEAD A SUCCESSFUL CAREER IN THE PHARMA INDUSTRY, YOU NEED TO BE PRIMARILY MOTIVATED BY THE DESIRE TO IMPROVE THE LIVES OF PATIENTS?

Yes – you absolutely need to be. This is a must for gaining an appreciation of what you're doing: we have to know who we are working hard for every day. To progress in a pharma career, it is also helpful to work with patients across different countries and different therapeutic areas. As Chief Patient Affairs Officer, I interact with different countries and very different functions including HR, marketing, finance, procurement, and manufacturing. I help make the link between their daily jobs and the patients they/we serve; this important link is at the heart of everything we do, however, it sometimes proves difficult for them to grasp. We are very motivated at Ipsen to serve patients as much as we possibly can.

WHAT WILL BE THE BIGGEST CHALLENGE IN PHARMA'S MISSION TO BECOME MORE TRUSTED BY PATIENTS, AS MORE COMPLEX TECHNOLOGY AND DATA COLLECTION SOFTWARE CONTINUES TO BE DEVELOPED?

The biggest challenge is to make our patient efforts transparent and simple while ensuring we protect privacy along the data collection process. To earn patient trust, we need to be transparent on our intent, clear in the language we use, and deploy safeguards to protect patient and caregiver privacy.

To become more trusted, pharma needs to open their doors and show how we use complex technologies in our research and development labs, in our manufacturing sites, etc. Complex technologies help advance the science needed to discover new treatments for unmet medical needs. You build trust when you show patients the quantum leap technology can help achieve to better serve them in the future.

HOW IMPORTANT IS IT FOR PHARMA EXECUTIVES TO CONTINUALLY SEEK OUT AND SHARE KNOWLEDGE, BOTH INTERNALLY, ACROSS FUNCTIONS, AND ACROSS INDUSTRIES?

It is critical. We operate in a complex and fast-changing environment. More than ever, we need to get a range of perspectives from different countries and different functions. This is the way to create value: through the sharing of knowledge, time, energy, and talent, we produce much more, at a higher value. When I joined the pharma industry, it was often told that 'we are different.' Why is that? We have a noble and unique mission to help improve patient lives that other industries don't have.

LOOKING BACK AT YOUR EXPERIENCE IN THE PHARMACEUTICAL INDUSTRY, IS THERE A DEFINING OR MEMORABLE MOMENT FOR YOU?

There are so many; it's hard to pick just one! I would probably say the day we gained a sense of urgency about patients suffering from rare diseases and the need to extend our mission to work for all patients. There should be no underserved patient populations.

I see the opportunity whenever we invite patients onto a project and seek their advice: we work hand-in-hand together

Also, I would say the day we started to see patients as individuals and started working directly with them and their healthcare professionals made a significant impression on me. There was also a turning point in the industry to better identify sub-populations of patients in our clinical development process. Finally, the time when we began to recognise the importance of caregivers. As an industry, we realised the importance, not only of being personal to patients, but in engaging and including caregivers in programmes to find out what was important to them. For example, developing education and coaching programmes for parents to support their sick children and contribute to improve health outcomes.

Catalyst of Pharma

1909 — 110 — 2019
YEARS OF ANTIBIOTICS

IT HAS BEEN 110 YEARS SINCE PAUL EHRLICH DISCOVERED THE FIRST MODERN ANTIBIOTIC. OVER THE PAST CENTURY, A WEALTH OF INFORMATION ON ANTIMICROBIAL RESISTANCE (AMR) HAS COME TO LIGHT.

HOW HAS AMR DEVELOPED OVER TIME AND WHAT ROLE HAS THE PHARMACETUICAL INDUSTRY PLAYED IN THE HISTORY OF ANTIBIOTICS?

TIMELINE

Paul Ehrlich

1909 — **Paul Ehrlich** discovers arsphenamine (syphilis treatment) - the first modern antibiotic

1928 — **Alexander Fleming** discovers penicillin, the first widely available antibiotic

1940 — First signs of resistance – E. coli strain inactivates penicillin by producing penicillinase

1945 — Alexander Fleming warns 'the public will demand [penicillin]...then will begin an era... of abuses'

1950 — Colistin is discovered to treat pneumonia

1952 — Erythromycin is introduced to treat chest and skin infections and STIs

1963 — Broad spectrum antibiotic gentamicin is introduced

1972 — Vancomycin is introduced to treat intestine infections and staph infections

1992 — GSK conducts the first antibiotic surveillance study 'The Alexander Project'

2000 — Linezolid is approved to treat MRSA

2003 — Daptomycin is introduced to treat systemic and life-threatening infections

2006 — EU bans use of antibiotics as growth promoters in animals reared for consumption

2009 — MRSA Infection Prevention and Patient Protection Act is introduced in the USA

2010 — Broad-spectrum antibiotic ceftaroline is introduced to treat complicated skin infections

2011/2 — The EU's Innovative Medicines Initiative (IMI) funds £180m into AMR, partnering with the pharma industry

2012 — Johnson & Johnson receives accelerated approval from the FDA for SIRTURO® (bedaquiline)

2014 — Abbott launches diagnostic platform IRIDICA, discouraging overprescription of antibiotics

2015 — The Global Antimicrobial Resistance Surveillance System launches, supported by WHO

2016 — Jim O'Neill's 10-point plan is recommended by the UK following review on AMR

2017 — The Global Antibiotic Research and Development Partnership (GARDP) is established

2017 — Merck's ZINPLAVA® (bezlotoxumab) is approved by the FDA

2017 — Pfizer Inc. launches the Antimicrobial Testing Leadership and Surveillance website

2018 — AMR listed on the World Economic Forum's 'Global Risks Report' for the second time since 2013

2018 — Sanofi develops app Bact'Attack to educate children about appropriate use of antibiotics

2018 — UN Report is published, labelling AMR a global crisis

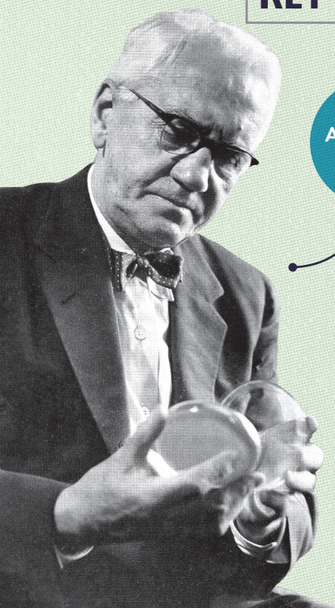
2018 — UK Department of Health and Social Care outline 20-year vision for AMR by 2040

2019 — FDA approves Merck's antibiotic Zerbaxa to treat hospital-acquired bacterial pneumonia

2019 — Novo Nordisk Holdings' REPAIR Impact Fund invests $165 million in three AMR start-ups

KEY

- Antibiotic discoveries
- Antibiotic approvals
- Antimicrobial resistance
- Efforts to combat AMR



Alexander Fleming

154 MILLION

PRESCRIPTIONS ARE ESTIMATED AS BEING WRITTEN FOR ANTIBIOTICS EACH YEAR IN THE USA

THE WONDER DRUG

- IN 1941, THE ADVENT OF WORLD WAR II PROMPTED THE LAUNCH OF 'THE PENICILLIN PROJECT'
- MERCK WORKED TO MASS PRODUCE THE DRUG, WHICH BY THE END OF THE WAR WAS NICKNAMED 'THE WONDER DRUG'
- PENICILLIN IS ESTIMATED TO HAVE SAVED 200 MILLION LIVES

700 000

DEATHS EACH YEAR ARE CAUSED BY AMR, A FIGURE EXPECTED TO RISE TO 10 MILLION BY 2050

THE HISTORY OF MEDICAL AFFAIRS

Words by **Kirstie Turner**

Once upon a time, there was an industry cursed with a negative reputation and a perceived lack of scientific integrity. Pharma's fairy godmother appeared in the form of a much-needed department: medical affairs. As the initial seeds of MA were sewn in the industry, no one could foretell just how integral its role would become. After years of nurturing, pruning, and nourishment, MA has truly blossomed, but what caused these changes and how will it continue to evolve?

Michal Konštacký, Global Medical Affairs Director, Shire, reminds us what the pharma industry was like before MA: "I remember meeting a marketing director from a big pharma company at a congress in Belgium. I asked him where his medical counterpart was, and he replied that medics in pharma companies should stay at home and read articles." Attitudes such as this led to a perception that pharma lacked scientific integrity: catastrophic for an industry at the forefront of scientific developments.

No tale is complete without conflict, and, with increasing negative publicity surrounding the industry, pharma were at risk of becoming the villain in their own story, as Ian Greenway, Medical Affairs Director, Complete HealthVizion, McCann Health Medical Communications, explains: "There was a trend towards negative publicity regarding the pharma industry and their influence over HCPs being linked to payments for conference attendance, entertaining, and gifts."

The industry was forced to reconsider the structure of commercial and medical organisations

Fast forward to 2019 and "the situation has dramatically changed. This is mostly visible in biotech and rare diseases where the interface between the company is on the side of MA. This requires medics with different personalities, who are more proactive, strategic, and better educated as the interactions are more scientific than commercial", says Konštacký.

But what has caused this evolution? "With an increasingly strict regulatory environment and a number of companies undergoing intense scrutiny over disguised promotion and unsubstantiated claims, the industry was forced to reconsider the structure of commercial and medical organisations. This led to the creation of separate MA organisations who had a clear reporting line through to medical leadership, rather than being linked to the commercial organisation", says Greenway.

The advent of MA organisations signals an important chapter in the story of pharma, moving away from being purely commercial to recognising the importance of medical integrity. Removing this heavily commercial influence was key, as Greenway continues: "The industry realised that it was essential to ensure a transparent relationship between their medically trained experts and HCPs so that medical communication and education regarding their clinical studies and products was conducted on a peer-to-peer basis, without commercial influence."

While there is no crystal ball to foresee what will become of MA in years to come, it is sure to remain an integral part of the industry, and indeed flourish further. Greenway believes that: "The MA role will become further integrated with the value demonstration function as pressure to demonstrate a medicine's value is increasingly important from the start of the development process. This requires early development of clear insight into future stakeholder needs, so that the medical strategy is developed to 'build in' these requirements from the early Phase I/II studies, rather than just considering these in Phase III trial design." Increased importance is being placed on medical strategy: an element of pharma that could once have been their downfall.

Going forward, MA must continue to collaborate with field medical professionals to provide insight and allow development of knowledge into the research and development process. With increasing regulation comes more restricted access to HCPs for pharma's sales departments and this channel of access must come from MA. Greenway continues: "MA will be the function that HCPs see as the face of the pharma company, which positions them in a unique position to transform the healthcare environment."

As we enter the age of the patient, with personalised treatments and patient centricity at the forefront of pharma, these elements must play into MA's plans for the future, as Greenway explains: "The advent of personalised medicine and tailored care packages for patients is transforming treatment algorithms and including a wider range of HCPs and the MA function should be ensuring that this transformation is built into their strategic medical plan early in the development phase."

While MA's function may grow and adapt even further in the coming years, the integral nature of the role is sure to remain constant, as Konštacký says: "I see MA as storytellers who help others to understand science with accuracy of their claims and help companies to maintain their scientific integrity." As MA continues to blossom and create fruitful return for the industry that has nurtured it, the department is in prime position to help pharma live happily ever after.

The Evolution of Medical Affairs

1 MEDICAL AFFAIRS DEVELOPS INTO A CREDIBLE ROLE: The role is formed, and the purpose identified as a new department, bridging the gap between pharma and patients.

2 INTEGRATION WITHIN COMPANIES: MA professionals are respected for the input and value they bring to pharma.

3 PARTNERSHIP: The role evolves further and is a co-leader on strategy within pharma.

4 FUTURE PROOFED: MA integrate insights to ensure they are benefiting all stakeholders.

Source: Kinapse, 2019

Medical Affairs

DESTINATION: THE PRECISION ERA

There has been an increasing focus on the development of precision medicine in the pharmaceutical industry over recent years. In this article, we analyse the critical role medical affairs needs to play in ushering in this new era of treatment.

Words by **James Coker**

MA teams must be able to transmit a complete understanding of the predictive marker and its power

Treating patients according to their personal genetic characteristics has long been thought of as a future phenomenon; this mindset must change. The recent growth and increasing sophistication of techniques such as gene sequencing, biomarkers, big data analytics, and companion diagnostics, provide the fuel the pharmaceutical industry needs to drive to this destination. They now need the specialist navigators who will steer them carefully through the complex, bumpy roads ahead. Medical affairs is well placed to pick up the A to Z and direct this journey due to their medical knowledge and experience in building collaborations.

"By gathering insights from the field and bringing them back in house, MA can help guide clinical development as to the most suitable, practical, and meaningful biomarkers around which to base precision medicine", declares Thomas Beveridge, Director, Medical Affairs Oncology, Ipsen.

MA is the beating heart of medical knowledge contained within the pharma industry, and such insights could not be more relevant when it comes to precision medicine. "In precision medicine, even more so than in conventional medicine, a complete understanding of the disease, including diagnostics and biomarkers, and not just simply of your medicine, is needed", explains Michael Zaiac, Head of Medical Affairs, Oncology Region Europe, Novartis.

Extensive insights into the mechanisms of disease is essential; but alone it is not a sufficient qualification for MA to start taking a lead role in this area. Utilising the novel techniques that have come to the forefront in recent years to identify complex genetic patterns and biomarkers should become a priority for this department.

"With the right data capturing and analytical experience, MA teams can generate insights into targeted treatments for post-marketing surveillance after early approval as well as highlighting the gaps for future developments", says Zaiac. "To make this happen we need to invest into the data and analytical skills of our medical teams and support them in co-creating data networks with primary suppliers."

When dealing with areas such as genetics, which are highly complex and specialised, tapping into the minds of others is a wise step to take. Firstly, much closer lines of communication must be established between MA and R&D departments internally within pharma companies, merging their respective expertise to work out the possible targets for future medicines. "Closer collaborations with R&D are essential in order to identify biomarkers and genetic mutations that may be key for precision medicine", states Beveridge. "The two-way communication between clinical development and MA, in general, needs to be much stronger. That would improve upon the access, and understanding, of internal data regarding biomarkers."

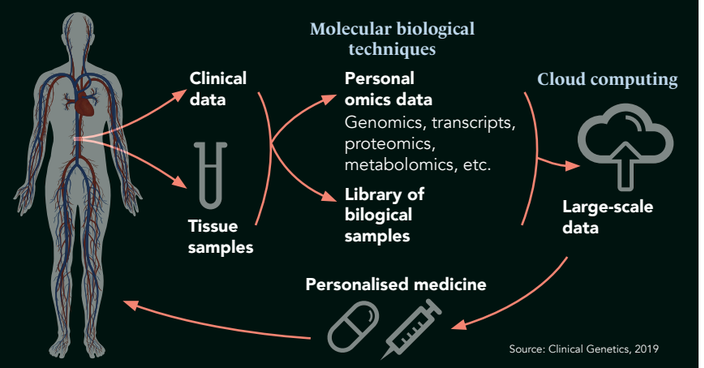
Reaching out externally to those particularly experienced in this area is likewise essential. "Internal data can be discussed under a confidential disclosure agreement (CDA) with expert external stakeholders during scientific exchange, allowing us to pressure test these data sets. Closer collaborations with our heath economics and outcomes research colleagues are also essential", adds Beveridge.

Even once biomarkers have been identified and agreed upon as a basis for clinical development, the job of MA is far from over. At this stage, their role arguably becomes even more crucial. Attention will then turn towards outlining the relevance and efficacy of the precision medicines to all stakeholders, which is a trickier prospect than with conventional medicines. This task requires all of MA's well-honed communication skills, and beyond that, deep understanding of the disease and its biomarkers are critical.

"Regulators and HCPs often look for very significant enrichments of positive outcomes using predictive markers/biomarkers, with the marker negative populations having <50% chance of response as the marker population or no chance of response. HTAs and payers can sometimes be satisfied with somewhat less acute differences when using precision medicines", notes Zaiac. "MA teams must be able to transmit a complete understanding of the predictive marker and its power, assuring all stakeholders that testing and marker guided use of medicines is useful for our patients."

MA has to become the driving force if pharma is to take full advantage of the huge promise that precision medicine offers to patients. Their deep medical insights should be combined with the expertise of R&D colleagues and external partners, enabling the discovery of workable clinical biomarkers. Demonstrating value of these medicines to the various stakeholders is another challenging task for MA in this area, which requires extensive understanding of the disease and the ability to explain the medicine's value according to different stakeholder expectations.

The Process of Developing Precision Medicines



Source: Clinical Genetics, 2019

MARKETING FORECAST: CLOUDY WITH A CHANCE OF AI

As artificial intelligence continues to prove itself an invaluable tool for pharma, this article explores how AI can streamline marketing budgets for optimal forecasting – showing marketers how to target consumers better, where to target, and at what times.

Words by **Michaila Byrne**

Few things are as infuriating as having consulted a weather forecast and dressed in accordance with it, only to later return home dripping wet in a pair of Bermuda shorts and a rain-soaked floppy sunhat. Marketing budgets are similarly unpredictable, fickle things, often disproportionately concentrated in areas where there is no demand. Case in point, it makes little sense to market cough and cold products during a July heatwave. More precise forecasting would unquestionably free up time and alleviate unnecessary spending. So, as marketers bid farewell to past tactics akin to stabbing in the dark, a collective sigh of relief can be heaved as we usher in the era of the AI weatherman – here to improve predictive forecasting and help marketers target consumers in a smarter way.

After all, true knowledge isn't general, it's specific. In the past, sales data has been an inadequate indicator around which to be centring media campaigns. "My ethos for data is that it has to be action driving. If not, it's actually just irrelevant. So, if you are just looking at data for data's sake, then you are actually just looking at superfluous data analysis", says Oliver Watherston, Head of Business Insight & Analytics, Novartis, speaking at the eyeforpharma Marketing and Customer Innovation Europe event. Alternatively, the key to spending optimisation is through obtaining a comprehensive understanding of the demand in question. Such insights are attained using AI analytics and predictive modelling techniques that generate independent level insights from collected data. So, what exactly does this mean for pharma marketers? This state-of-the-art optimisation supplies marketers with information that allows them to adjust campaign budgets accordingly as they begin the process of customising streamlined marketing strategies for specific regions.

A massive 90% of all data in the world has been collected in the last 2 years alone. With such an unprecedented level of information within reach, it can be tempting for marketers to blast audiences with content across all channels. But restraint is savvy, and in the words of Herbert Simon: 'A wealth of information creates a poverty of attention.' Marketers should aim resources towards the strongest demand and at the most appropriate time. AI achieves this goal as highly automated pipeline procedures extract signals and collects anything from social media to weather and sales data, updating the model and delivering forecasts to local teams. Depending on the model, marketers can track what signals are driving sales up and what signals are driving sales down.

As with weather forecasts, predictive tools in marketing are limited in the sense that they can only account for what has come before. Albert Pla Planas, Senior Data Scientist, Sanofi explains: "You can only work with the data that you have. In following the data science and traditional intelligence techniques, you get a forecast that only provides you with information that is similar to what happened before." Regions won't necessarily behave homogenously within themselves and predictions are largely dependent on external data with factors like climate change further exacerbating the unpredictability of seasons. To account for regional variations, a given country will generate a unique, personalised forecasting model based on different trends, data, and technologies. There is no reason to expect the North and South of Italy to behave in the same way. In Brazil, climate, pollution, dust, and humidity all contribute towards allergies whereas in Europe, allergies are driven primarily by pollen. The approach would work independently depending on the scenario and can be applied worldwide at more regular intervals.

"When people are sick, their online behaviour reflects this. They're searching for terms like cough, cold, sneeze... we realised we could use this information to really drill down and give local marketing teams immediate, actionable insights", says Darren Frey, Senior Data Scientist, Sanofi. Marketers can reuse this data to boost accuracy – and the proof is in the pudding. Upon implementing this, Sanofi discovered that the correlation between social media signals and demand was very high and observed an 88% accuracy in terms of long-term forecast. Anomalous seasons may not be forecast, but their potential impact can certainly be mitigated since they predict far more likely realities than traditional models. From there, it's a simple formula: "The approach we've taken is that media spend should be proportional to the likely demand. Demand goes up? You should be spending more. Demand goes down? You should be spending less. This applies at the smallest level possible", says Frey.

THE GLOBAL AI MARKET IS EXPECTED TO RISE FROM

$1.4 BILLION

IN 2016

TO ALMOST

$60 BILLION

IN 2025

Source: IQVIA, 2019

The ability to assemble mass data is surely in vain if not channelled and utilised for specificity. What is the point of accumulating data if the data is not actionable? Pharmaceutical marketers have an opportunity to wield AI to its full potential as they make sense of behavioural changes to create streamlined, precise, reliable marketing models rooted in state-of-the-art optimisation. Media spend should be proportional to the expected demand and with this newfound insight, marketers are fully equipped with the knowledge to weather any storm.

BUILD YOUR AD CAMPAIGN WITH BLOCKCHAIN

Words by **Isabel O'Brien**

Blockchain holds great potential for the pharmaceutical industry, particularly as a platform for programmatic advertising, which would allow marketers to seamlessly and safely target ads to healthcare professionals.

"The world is changing at a massively rapid pace", says Ryan Connolly, Vice President, Creative, Anthill Agency at the eyeforpharma Marketing and Customer Innovation Europe event. "The main thing changing this pace is technology… the different volatilities, uncertainties, complexities, and ambiguities."

Connolly is right to flag the challenges of technology. While it does deliver solutions and efficiency to the modern world, it also thrusts a sandstorm of abstract ideas, processes, and industry-specific buzzwords at us for comprehension.

A notorious zeitgeist term is blockchain. You may have heard of it in relation to the cryptocurrency Bitcoin, which enables users to store their money in a virtual wallet and perform transactions between each other outside the banking system. However, blockchain is much more far reaching.

"Bitcoin is not blockchain… there is confusion between the two", says Richard Springham, Deputy Managing Director, Four Health Media at Four Communications. "Blockchain is the platform on which Bitcoin sits, a bit like how the internet is the platform on which email sits, so they're very separate."

The benefits of the blockchain platform include transparency: all users in the network can see the data; immutability: no one in the network can alter that data; and security: the data is stored consecutively in different locations, so it cannot be hacked unless all locations are hacked at once. The system generates trust between all members of the chain.

"Everything we do in business and trade is about trust", comments Springham. "And when we were only trading with friends and family many years ago, there was trust, but as the world population grew, trust deteriorated."

For business and trade to continue and grow, a new system of middlemen was developed. Think of the Monopoly man – gesticulating in his top hat and tuxedo. These institutions facilitate transactions between buyers and sellers; imagine buying a house without a bank or estate agent, and while they create a secure channel for trade, there is also opportunity for exploitation – how can we be sure they are not abusing our trust?

This was an issue for Four Health when their client Johnson & Johnson expressed an interest in utilising programmatic advertising – a marketing system through which advertisers buy ad space for their products on publishers' websites – as a new innovative route to advertise to HCPs.

"Programmatic advertising is a bit like eBay; you have the product you want to buy… and you have a price you have set to buy that item at", explains Springham. "The product is a human being's interests and the price is the price that you're willing to pay to show that advert to that person."

The programmatic process takes place automatically, so advertisers and publishers are trading constantly, and consumers are receiving adverts based on their interests. According to Springham, the UK will spend £6 billion on programmatic advertising this year: 87% of the total digital display ad spend. In the USA, this figure could be as high as $59 billion. However, the ecosystem in which this takes place is convoluted and opaque; rather than advertisers trading directly with publishers, there are middlemen processing these transactions.

"There were issues", admits Springham. "Can we trust that all the middlemen were providing the services they needed to provide, at a cost that was relevant and fair? We had no vision – no view of that."

Blockchain enables transparency and total data security, making it the perfect platform to implement a pharmaceutical programmatic advertising campaign, in which better visibility and minimum risk is needed. Four Health, Johnson & Johnson, and their chosen blockchain partner teamed up to turn on the light and look inside the infrastructure.

"Every single part of the chosen ecosystem had to implement a bit of code that was going to open their doors in order to share information across that network", explains Springham. "Some were not happy."

Future-proofing is how big business cures its own anxieties over change

The alliance could now access data about the intermediaries. "One middleman was consistently three times more expensive and half as effective as their peers", reveals Springham. Not only did blockchain grant insight into the inner workings of the ecosystem, but it also released information that could guide Four Health to make smart business choices on behalf of their client.

"The outcome was that if we tweaked one thing in scenario one… we saw a 25% performance improvement. If we did two things in scenario two it was a 36% through to 50% performance uplift", discloses Springham, demonstrating the commercial value blockchain can deliver when used in this context.

"Future-proofing is how big business cures its own anxieties over change", concludes Connolly. "And within pharma, particularly in my experience, we need to flip that on its head and try and look at different strategies that relinquish some of the controls."

The exciting reality of blockchain is that, while it is an alien and complex technology, it does not require relinquishing too much control. Blockchain is new, but not laden with risk, and for the industry, a police escort into the seamless trading that programmatic advertising has to offer.

Did you know?

50%
of a brand's programmatic advertising spend goes into the pockets of middlemen.

Source: IBM, 2018

1/3
of ad views in the current programmatic system are fraudulent.

Source: IBM, 2018

PHARMA: THE SOCIAL BUTTERFLY

Words by **Kirstie Turner**

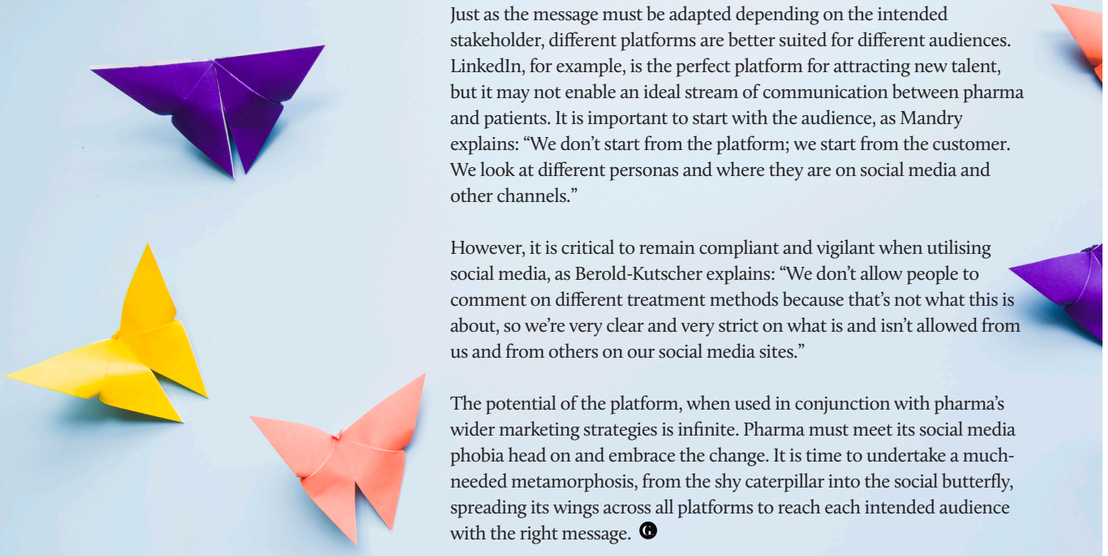
The internet is a jungle, tangled and overgrown, dense with information overload. Among the unkempt chaos lies social media: a treasure trove of possibilities. For the pharmaceutical industry, the potential of social media remains, on the whole, untapped. At the eyeforpharma Marketing and Customer Innovation Europe event, Cyril Mandry, Senior Marketing Director, MSD, goes as far as to say that pharma has a "social media phobia". The industry needs to face its fears and navigate the digital ecosystem to reap the benefits of social media.

Mandry explains the multi-faceted opportunities for pharma within this realm: "You can reach everyone on social media, all your audiences: healthcare professionals, patients, policy makers – they are all on social media." The reach is incomparable, with an active audience of 3.5 billion users. "No other channel offers this opportunity", reiterates Mandry.

Stacey Berold-Kutscher, Senior Digital Marketing Manager and Brand Lead, Ferring Pharmaceuticals, explains how publishing the right content on the right channel is creating fruitful returns for Ferring Pharmaceuticals: "We've been able to find a process that allows us, through our digital channels, to actually engage, and we respond to comments that come through our social media channels." It's important to remember that social media should not be used in isolation. As Mandry says, it should be used "in an integrated way: social media is not a separate channel, it is part of an omni-channel approach."

One industry example comes from Sanofi Pasteur, CABA Association, and Horizon Marketing Solutions. They were commended by eyeforpharma for their initiative 'Householder Health Ambassadors', which uses a chat show form, supported by social media, to improve vaccine education and uptake by household decision-makers. The initiative, which employed social media campaigns, had a reach of 14 million people and resulted in a 95% positive change in perception of vaccines, highlighting the power and potential of social media as a platform.

A blanket message, however, will not suffice. When implementing social media marketing, adaptability and alignment are key components: content must be altered to speak the language of the intended audience. "It is about knowing your audiences and building a presence", explains Mandry, continuing: "They have different goals and different needs, so the content needs to be relevant: make sure your content is aligned with what matters to your audience."



Just as the message must be adapted depending on the intended stakeholder, different platforms are better suited for different audiences. LinkedIn, for example, is the perfect platform for attracting new talent, but it may not enable an ideal stream of communication between pharma and patients. It is important to start with the audience, as Mandry explains: "We don't start from the platform; we start from the customer. We look at different personas and where they are on social media and other channels."

However, it is critical to remain compliant and vigilant when utilising social media, as Berold-Kutscher explains: "We don't allow people to comment on different treatment methods because that's not what this is about, so we're very clear and very strict on what is and isn't allowed from us and from others on our social media sites."

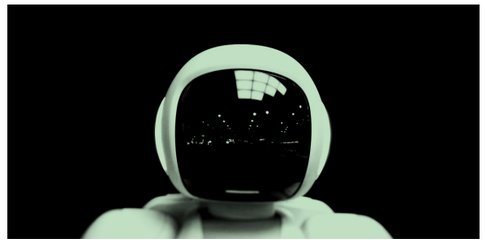
The potential of the platform, when used in conjunction with pharma's wider marketing strategies is infinite. Pharma must meet its social media phobia head on and embrace the change. It is time to undertake a much-needed metamorphosis, from the shy caterpillar into the social butterfly, spreading its wings across all platforms to reach each intended audience with the right message.

SPOONFUL OF COLLABORATIONS

We delve into the most compelling collaborations in the pharmaceutical industry that have taken place in recent months, particularly those that have featured non-traditional healthcare players – a theme becoming more commonplace as pharma pushes for more patient-informed strategies. There is a particular emphasis on partnerships that explore disease detection, technology, and the arts.

PFIZER AND BMS RUN WITH FITBIT

BMS and Pfizer have announced a partnership with Fitbit with the mission of improving early detection of individuals with an increased risk of stroke. Plans are in place to collaborate on the development of educational content and guidance to support those at increased risk of atrial fibrillation as the alliance seeks FDA approval.



GILEAD AND ELTON JOHN AIDS FOUNDATION LAUNCH

Gilead have partnered with the Elton John AIDS Foundation to meaningfully combat new HIV infections and death from AIDS-related illnesses in parts of Eastern Europe and Central Asia (EECA). The RADIAN initiative builds on their already existing collaboration in the EECA Key Populations fund and aims to provide support and funding in the hopes of reversing damaging trends and reaching the most vulnerable people disproportionately affected by HIV.

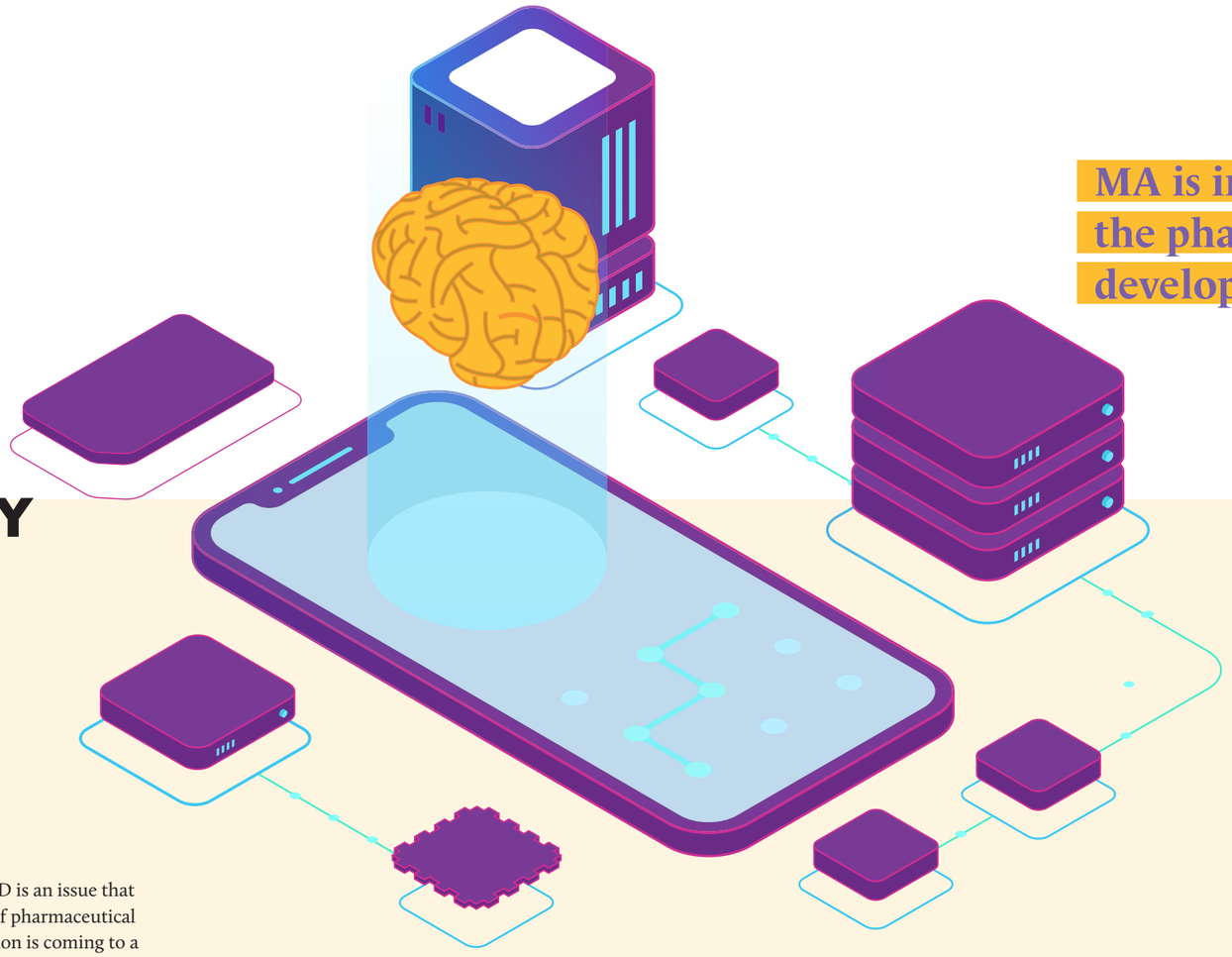
NOVARTIS AND MICROSOFT AI COLLABORATION

Novartis and Microsoft have committed to a multi-year R&D effort focussing on artificial intelligence empowerment and exploration to address some of the most difficult computational challenges within the life sciences industry. The aim is to strengthen Novartis' AI capabilities, from research through to commercialisation, to propel the discovery and development of transformative medicines across the world.

BIOMARIN LOOK TO THE ARTS

BioMarin are currently in the process of developing a haemophilia gene therapy and have embraced the therapeutic value of the arts. BioMarin have teamed up with non-profit group 'The Moth' for the off-Broadway show 'Hemophilia: The Musical', in which patients collaborated to accurately inform and represent the patient experience. The company are also sponsoring the podcast series 'BloodStream Journeys', which features people living with blood disorders telling their stories.

Medical Affairs



BUILDING A R&D STRATEGY FOR THE MODERN AGE

Words by **James Coker**

Low levels of return on investment in R&D is an issue that has been bubbling beneath the surface of pharmaceutical companies for some time and the situation is coming to a head, threatening the industry's future. Medical intelligence is a concept increasingly being pointed to as a means of addressing this challenge, but first and foremost, it must be clearly defined. "When you think of intelligence you envision military intelligence", outlines Isma Benattia, Vice President, Europe Medical Affairs, Amgen. "This critical discipline is constructed on information collection and analysis to guide and assist commanders in their decisions. Medical intelligence is no different. We need to apply the same discipline in data collection and interpretation of clinical, biotechnology, and environmental information to guide R&D strategies and resource planning."

This highly methodical approach described by Benattia is no mere fad for pharma to try, nor is it the latest buzzword to be echoed around the industry's walls; it is the bricks and mortar upon which future R&D strategies should be constructed, with MA playing the role of chief architect. "As MA is well positioned to understand, engage, and support both the patient and provider journey, it becomes all the more essential for MA to steward the trusted, valid, and reliable 'source of truth' and relationships associated", notes Jennifer Wong, Senior Director, Real World Evidence Strategy & Alliances, Global Medical Affairs, AstraZeneca.

Using this intelligence-led approach is critical for enabling R&D teams to focus on areas that can have the most profound impact for patients and consequently, improve return on investment. "A disciplined approach to medical intelligence will allow an early detection of unmet needs", explains Benattia. "The close contact with data collection and analysis of the healthcare ecosystem, which is in constant evolution, will allow the detection of early signals of changes in healthcare."

A disciplined approach to medical intelligence will allow an early detection of unmet needs

Real-world evidence, in particular, provides a seemingly bottomless pit of health information that can identify the best opportunities for pharma, and MA are now required to dig deep beneath the surface to discover as many golden nuggets of information as possible. "MA is in a unique position within the pharma industry to impact drug development from bench to bedside. When utilised properly, patient registries, claims databases, and medical records are rich sources of real-world data that can inform R&D strategies", says Wendell Valdecantos, Director, Immunology Clinical Development and Medical Affairs, Boehringer Ingelheim.

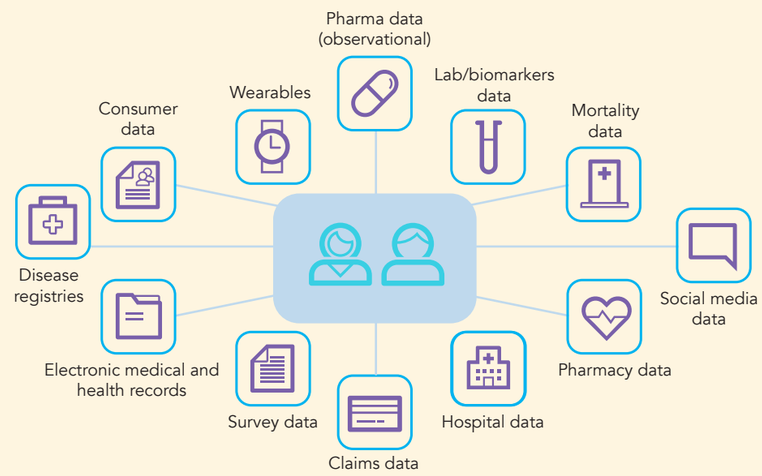
Access to vast swathes of data is one thing; obtaining relevant insights from this data is an entirely different affair. Firstly, heavy investment in state-of-the-art digital technologies in data analytics is necessary to ensure MA can perform this function properly. "We are undergoing a technical and cultural transformation", comments Wong. "Keeping up with the latest advanced technologies is both exciting and daunting due to the size and scale of the options available. Most importantly, we all need to be empowered and well-equipped to learn, assess, adapt, and take action quickly and intelligently and cut through the noise to identify, curate, and act on 'actionable information' to drive real-world decisions and outcomes."

MA is in a unique position within the pharma industry to impact drug development from bench to bedside

Once the technology is in hand, MA must then become adept at using it, which is no mean feat. It requires new skills that go beyond their traditional requisite of medical knowledge and good communication. "We need to consider diversifying MA's conventional talent pool", says Benattia. "We have to augment the scientific expertise with digital and analytical ones and add these threads to the MA fabric. It encompasses digital skill and monitoring solutions for big data mining. The aim is to detect early new trends in patients' care and turn them into insights to guide research activities. These investments in the development of the MA staff will allow the use of the new technologies to their maximum effect."

The vast availability of data, coupled with sophisticated data-mining technologies, gives pharma a unique chance to revolve R&D strategies around unmet needs which provide the best opportunities to improve return on investment. This also offers a long-term solution to the recent decline in productivity observed throughout the industry in the last decade. MA should be at the heart of this methodical, intelligence-based approach, and be afforded the data analytic technology and technical skills required to accurately present this information to R&D colleagues.

Sources of Real-World Data



Source: ERGOMED, 2019

COMPLIANCE: THE UNDERDOGS

Words by **James Coker**

Successfully co-creating services and products with patients has felt like drinking from the holy grail for the pharmaceutical industry in recent years. But ensuring this aspiration ultimately develops into something more concrete than a Monty Python film requires a new type of relationship to be built with a department that is not always viewed in the most favourable of lights: compliance.

"I think compliance is the elephant in the room; it's the issue that has to be addressed for an organisation to feel comfortable in going out and working with patients", comments Geraldine Murphy, Vice President, Cluster Europe North, Australia & New Zealand, LEO Pharma, during the eyeforpharma Patient Summit Europe.

It can be tempting to compare compliance officers to a pompous bank manager, taking delight in denying loan applications based on spurious technicalities. Hearing 'compliance says no', or words to that effect, is a major source of frustration when exciting new initiatives are stopped dead in their tracks.

Far from being deliberately obstinate, however, compliance personnel are driven by the desire to protect their company's interests. Additionally, the consequences of making the wrong call can even have legal implications for individual compliance officers. "Very often, we find ourselves having to make decisions on very little information and worst case, there are no regulations, and so we have to think about the risk we are covering and then make a decision. And even with the best intentions, the decision can be a roadblock", explains Manuela Bruegger, Compliance Officer, Novartis.

Have us as part of the discussion and not at the very end when we have to say no

To add to this picture, numerous new regulations affecting pharma companies at a global level, particularly when collaborating with patients, have come into force over recent years. "We all know that the regulatory environment is becoming increasingly tough", notes Paul Simms, Chairman, eyeforpharma.

A regular scenario is one of great ideas being delayed or even failing to see the light of day due to tedious bureaucratic red tape. To overcome this frustrating situation, a fundamental rethink is required regarding the input compliance currently has, to become heavily involved from project conception; this is the polar opposite to being forced into making a binary yes or no decision based on information passed to them at the end of the process. "One of the biggest challenges for patient organisations is the bureaucracy and the never-ending list of details that we need to have", acknowledges Bruegger.

Early clarification for all parties as to regulatory and legal requirements on a given project could make all the difference. "This is a call from me as a compliance officer to have us as part of the discussion and not at the very end when we have to say no; have us at the very beginning because we truly can make a difference. We can be there, we can help you find a solution", says Bruegger.

It is time for compliance to step out of their silo and engage with internal and external colleagues in a much more overarching way than is currently the case, beginning from the initial discussions of an idea with patient organisations. It is incumbent on both compliance departments and other areas of pharma, be it R&D or marketing, to cross the floor of the house and enter a permanent state of coalition to make this happen.

CREATING THE PATIENT-CENTRED TRIAL

Words by **James Coker**

"Patient recruitment and retention remain the biggest challenges in clinical studies", comments Gail Adinamis, CEO, GlobalCare Clinical Trials, during the eyeforpharma Patient Summit Europe. "It is not a sustainable model; we know that <5% of patients actually participate in studies and this is primarily because it's not convenient or comfortable for them to do so. We also know that 20% of sites that are initiated never see a single patient, while 15–40% of patients are going to drop out before the end of the study." When concerns over a lack of geographic and ethnic diversity are mixed into Adinamis' sobering analysis, it is surely time for the pharmaceutical industry to trial a new approach to clinical studies.

Patient recruitment and retention remain the biggest challenges in clinical studies

As always, diagnosis is the first step to finding an effective cure. In the traditional clinical trial model that remains prevalent throughout the life sciences sector, participants are obliged to travel back and forth from investigator sites to contribute. Such a model, unsurprisingly, presents difficulties for those with heavy work and family commitments, notwithstanding the physical limitations that their condition may place upon them. "If a patient is very far away, has a debilitating disease, doesn't have transportation, and has family obligations, they may want as many home visits as possible", points out Adinamis.

90%
of worldwide clinical trials are delayed due to under-performing patient recruitment.
Source: TrialFacts, 2019

>40
million patients need to be recruited for around 300,000 clinical trials worldwide every year.
Source: Havas Lynx Group, 2019

85%
of trials discontinue because of patient retention.
Source: Havas Lynx Group, 2019

50%
of trials are delayed due to patient recruitment.
Source: Havas Lynx Group, 2019

While patient-centric approaches are increasingly being woven into the fabric of pharma's clothing, the set-up of clinical trials in R&D have, to date, remained steadfastly rigid, perhaps the equivalent of medieval chainmail. Adopting a flexible prose, centred around the needs of patients, must become a priority of R&D teams at the initiation of clinical studies. Anna Cederberg, Co-Founder, Melio, considers the perverse quandary that while Justin Bieber can sell 40,000 seats for a concert twice in 30 seconds, a clinical trial of an Alzheimer's treatment has yet failed to reach its target of 800 volunteers after 2 years. Just like any other service or product, in Cederberg's view, user experience is fundamental to improving the recruitment issue. "This requires you to be creative and to have a product or a service that people actually want", she says.

This is a principle Servier have adopted for a large, multinational, ongoing Phase III trial of an autism treatment for children and adolescents. To account for the varying needs of children and multiple caregivers, as well as cultural nuances at play with this condition, the traditional clinical trial paradigm was abandoned in favour of pragmatism. "We decided to explore and build an environment around autistic children", notes Marta Garcia, Director of Patient Service, R&D Clinical Development, Servier. She added: "We had to challenge our existing practice and explore resolutions to be flexible with each country, so we thought out of the box and learned by experience."

Decentralised trials present a more general concept pharma can explore within clinical studies. "A decentralised trial includes studies at locations that are remote to the investigator site; it could be in patients' homes, their workplace, or travel destination. And these are visits that are conducted through the use of mobile or local healthcare providers", explains Adinamis.

These providers are able to remotely conduct services, such as blood draws and drug administration, in the presence of a qualified healthcare professional; several hundred have now been undertaken in recent years, to great effect. In a Phase I trial in which patients were administered a drug three-times a week, incredibly not a single participant dropped out. In another, in which homecare services were offered following study initiation, a mere 3% of those who used homecare services dropped out, compared with 67% of those who did not use this option.

A decentralised trial includes studies at locations that are remote to the investigator site

"Families, patients, and caregivers all appreciate the convenience and comfort of having these services done at a location and time that's convenient for them", says Adinamis. "Investigators are able to recruit patients from a much broader geographic area, have better compliance, and ensure geographic and ethnic diversity. And for sponsors, the development timeline is shorter; if they have faster recruitment and better retention, fewer patients have to be enrolled because there's fewer dropouts. And most importantly, consumers get access to new therapies faster."

In the words of Sir Winston Churchill, 'to improve is to change; to be perfect is to change often'. In general terms, pharma has, to date, failed to amend the traditional structure of clinical trials, and the consequences of poor recruitment and retention rates are there for all to see. The evidence from decentralised trials underlines that people are far more willing to engage in these studies than current evidence suggests; pharma must demonstrate to patients that it's capable of flexible and innovative practices, and acknowledge that it cannot continue with a one-size-fits-all approach to clinical trials.

Average Drop-out at Each Recruitment Stage

	Pass	Drop-out
Online Prescreen	39%	61%
Site Phone Contract	72%	28%
Interested	76%	24%
Phone Screen	42%	58%
Attend Visit 1	91%	9%
Clinic Screen	68%	32%
Overall	8%	92%

Source: TrialFacts, 2019

AGILITY TO STAY RELEVANT

The digital world has accelerated out of the starting blocks and it is time for the pharmaceutical industry to sign up to the race. We look at how pharma marketers can inspire internal agility and convince colleagues to bet on a new digital approach.

Words by **Isabel O'Brien**

When video gaming became less popular, Nintendo had to re-strategise in order to stay relevant. They came up with Pokémon Go: the iconic mobile game that earned >$200 million in its first month and achieved a daily peak of >45 million users. It captivated the globe by transposing a classic product into a new digital dimension.

This model of agility is introduced by Ryan Connolly, Vice President, Creative, Anthill Agency, at the eyeforpharma Marketing and Innovation Europe event. "This is a non-pharma brand", he says. "But it's crucial to have a holistic view of how different companies are having to adapt and adopt to different mindsets."

Healthcare is not a transient commodity, but it must still evolve and grow with the culture of its consumers. Pharmaceutical marketers are leading this transformation, but often face resistance when proposing innovative new ways to engage healthcare providers and patients with their products.

"We need to understand the world we are in now", says Erasmus Holm, CMO and Digital Transformation Lead, Nordics and Baltics, MSD. "We are not moving into a digital era – we are already there... it's really thinking about digital as electricity, when we first got electricity that was a fundamental change."

Ferring Pharmaceuticals is one company that is pioneering digital. They launched the new generation of their bed wetting drug, Minirin, without a sales force, instead using a tracking app, interactive web resources, and social media.

"The big challenge was to deliver sales and reach the required targets in a declining market", says Stacey Berold-Kutscher, Senior Digital Marketing Manager and Brand Lead, Ferring Pharmaceuticals. "Not the easiest thing to do with a sales team, not the easiest thing to do without."

Yet it was a success: the digital strategy engaged children and their families with the condition, freed up the sales force to focus on other products, and improved awareness of the medical significance of bed wetting in HCPs. The return may not have been financially measurable from the outset, but it was rapidly quantifiable in terms of patient centricity, internal workload reduction, and brand visibility.

65%
of HCPs are active on some form of digital media for professional purposes.

>60%
of HCPs say their use of digital media for digital purposes has increased over the last few years.

Source: IQVIA, 2018

How then, in an industry that often lags behind due to heightened processes and regulation, do you convince colleagues of the potential of digital transformation and communicate its necessity?

"The way to get there for us has been to give very specific examples of what you need to change", says Holm. "Because if someone just says: 'well you just need to be agile and proactive and do blockchain and 5G', no one understands what that means."

If someone just says: 'well you just need to be agile and proactive and do blockchain and 5G', no one understands what that means

Decoding digital can also be done through the creation of storytelling tools. When presenting a substantial change that will lead to upheaval, it is important to show colleagues the journey of the transformation – to pitch it, in a medium that works hard to engage them.

"The world is moving towards an era of experience culture", says Connolly. "When we experience something, we understand it in a very different way, it does different things to our brain, creates different connections."

LEO Pharma are in the process of developing personalised advertising to HCPs, and during his talk at the eyeforpharma event, Christian Scheuer, Vice President of Global Strategy & Commercial Excellence, LEO Pharma, shared an internal video created to show how this would work and the benefits it would deliver.

"We developed this to show what it actually means to go on the journey", Scheuer says.

The short film invited colleagues to consider their family Netflix account and how the algorithms can alter suggestions based on watch history. Watch Mad Men? Get recommended The West Wing. Go away for the weekend – come back to Stranger Things. Personalisation adapts in real time, and while it can cause frustrations at home, the video analogised how it could revolutionise marketing to HCPs in the future.

Still, we must be pragmatic. "When I watch Netflix at home, there is a whole machinery designed and deployed for basically one purpose and that is to generate data to continuously improve my experience", says Scheuer. "However, Netflix started out in a different way to how we did in pharma."

Whilst we can champion the importance of digital transformation and look to companies such as Nintendo and Netflix for inspiration, we must also be aware of the rigid and entrenched infrastructure of our industry. We cannot force agility; it must be gradually worked towards. Pharma can't dive straight off the top board, we must build up to it, with marketing departments poolside as the enthusiastic coach.

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