

PharmaTimes

November 2022 @PharmaTimes

MAGAZINE

KICKSTARTING HEALTHCARE CONVERSATIONS



AIDS STORY

The ultimate journey
through health
inequality

People-watching: Industry must unite to help our country's carers

Age-old challenge: We're all getting older but who will look after us?

Priceless discovery: Innovation holds the key to rare disease solutions



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Mad world

We have all been doing a lot of squinting recently – trying to focus on the motley crew of politicians rolling across our screens, while attempting to identify a scintilla of humanity among them.

We wonder whether they know or care that playing the economy like its *Grand Theft Auto* has grave consequences way beyond a mind-boggling set of numbers. Socio-economic circumstances are so obviously linked to mental and physical health. But is it obvious to Truss, Kwarteng Hunt, Coffey, Rees-Mogg et al?

In contrast, as 'pharma people', we *do* understand that the fragility of the current situation has created a powder keg for health inequalities, the like of which we will have rarely seen.

But we have been here before. Four decades ago, Margaret Thatcher and Ronald Reagan closed their ears to the HIV/AIDS crisis. In those days, however, an already persecuted and marginalised group in society – gay men – would not accept the status quo. In a pre-internet age, they were able to mobilise, march and force people to listen.

Meanwhile, altruistic cohorts of this impacted community cast their fears aside and entered clinical trials, with so many knowing they would never see the results. It ignited action among governments, institutions and our industry, and was the first bold step which has, ultimately, enabled people with a positive status to live complete and fulfilling lives.

This issue of *PharmaTimes* pays homage to those early pioneers, at a time when the AIDS story has never been more relevant.

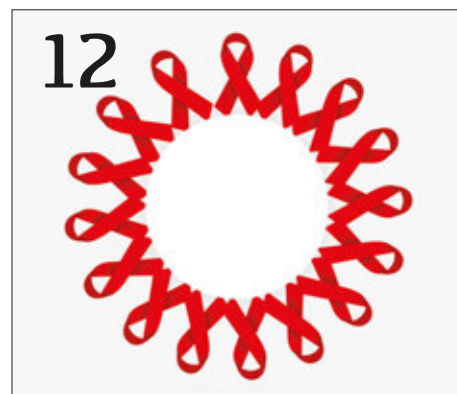
I hope you'll be inspired,

John Pinching
editor

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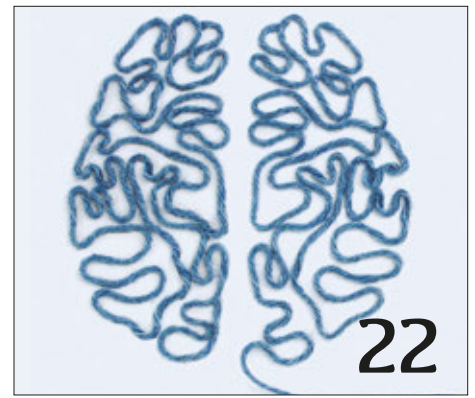
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NHS Confederation responds to the appointment of Jeremy Hunt

After a tumultuous week which culminated in Liz Truss sprinting out of a press conference, a new Chancellor was sent out to pick up the shards of a shattered economic policy.

Responding to the appointment of Hunt, alongside former health minister Ed Argar – who takes up the role of treasury chief secretary – NHS Confederation chief executive, Matthew Taylor, reflected:

“We congratulate both the Rt Hon Jeremy Hunt and the Rt Hon Ed Argar on their new appointments to Chancellor and treasury chief secretary respectively. The new Chancellor has been one of the most vocal politicians on the need for a new workforce plan for the NHS, recently admitting that the health service faces the ‘greatest workforce crisis’ in its history and shouldering partial responsibility for creating such a crisis as a former health secretary.

“He also understands well the gravity of the situation in the NHS as it approaches a perilous winter. Carrying 132,000 vacancies and with an exhausted workforce grappling the huge weight of patient need, this is Mr Hunt’s moment of truth.

“In recent months he has frequently called on the government to bring forward a now desperately needed, fully funded plan for an NHS workforce fit for the twenty-first century, so all eyes will now be on him to now deliver this, something he will know well.

“With 7 million people waiting for treatment, the new Chancellor is also in a unique position to provide some immediate

and urgent support to the NHS as it attempts to contend with a real-terms funding cut that could stretch to over £9bn this year alone as inflation rates take their toll on budgets. Health care leaders would urge both Mr Hunt and Mr Argar to be cognisant of the immense challenges also facing the social care sector, which is itself carrying 165,000 vacancies.”



3.2m UK birds culled as record avian flu cases increase

The UK is facing its largest-ever outbreak of avian flu, with 1,727 cases so far detected in the UK’s wild bird population. In addition, 161 captive birds have tested positive for the H5N1 strain. As a result, 3.2m birds have been culled across Britain in an urgent bid to stop its spread.

A leading testing expert has warned the British people that they must be extra vigilant. The UK is one of two western European countries where the potentially lethal H5N1 strain has already spread to humans.

The leading testing expert, Dr Quinton Fivelman, chief scientific officer at London Medical Laboratory, explained: “Obviously, this is a potential catastrophe for Britain’s bird breeders. This week alone, the Government has ordered that all poultry in Norfolk, Suffolk and parts of Essex must be kept indoors following the rapid spread of the virus. However, it could also represent a significant threat to humans.”

“It can be caught by touching infected birds, their droppings or bedding, or by killing or preparing infected poultry for cooking. It’s thought to be quite hard for humans to catch avian flu from birds but, when those cases do occur, there have been a number of fatalities,” he added.

Higher numbers of cases mean a greater chance of mutation which is possibly how the COVID-19 virus spread from bats to humans.

The main symptoms of bird flu can develop very quickly – within three to five days after infection – and include a cough or shortness of breath, a high temperature, aching muscles or a headache.



XBiotech enrolls first patient in Natrunix study

XBiotech has announced the enrolment of the first patient in a multicentre, randomised clinical study for Natrunix. The treatment will be analysed in combination with trifluridine and tipiracil for the treatment of colorectal cancer.

The clinical study for XBiotech's candidate cancer treatment is being funded by the French National Cancer Institute (INCA).

Subjects receiving the experimental

therapy have previously failed earlier treatment with oxaliplatin, irinotecan and fluoropyrimidine.

Meanwhile, participants are randomised to receive Natrunix plus chemotherapy or placebo and chemotherapy. The research is designed to seamlessly proceed through phase 3 development based on achievement of certain efficacy milestones in the phase 1 and phase 2 portions.

Colorectal cancer is one of the most common cancer in Europe and the US.



Patient recruitment completed in Tourette syndrome study

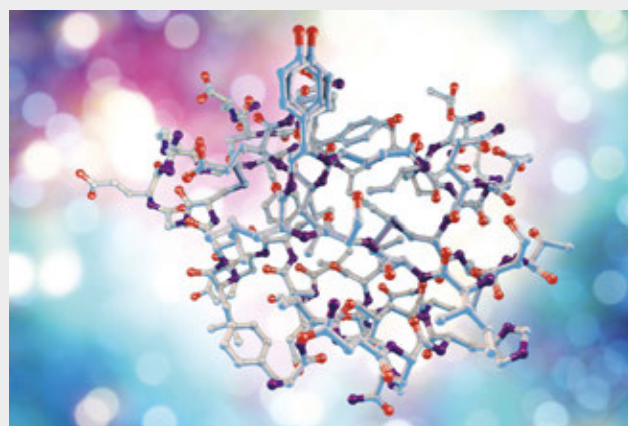
Asarina has completed the recruitment of patients to its phase 2a clinical study in Tourette syndrome with a total of 28 patients enrolled.

The study compound, Sepranolone, is an endogenous neurosteroid – an entirely new treatment modality for Tourette. It has demonstrated a strong safety profile in multiple previous clinical studies and reduced tics without inducing any of the motor side effects from previous preclinical studies.

Enrolment of adult patients started at the Bispebjerg University Hospital in Copenhagen in February 2022, while teenage patients have been enrolled at the Danish National Center for Tourette at Herlev University Hospital since summer 2022.

Until now, a total of 13 patients have completed the study. Last-patient-last-visit remains scheduled for January 2023 with top line results expected at the end of March 2023.

The study has had an unexpectedly low dropout rate with only two patients having departed the research. In most clinical studies, the highest dropout rates tend to come from the 'active dose' group rather than from the control group.



Positive results from trial of Arecor's insulin candidate

Arecor has announced headline results from the second phase 1 clinical trial of its ultra-rapid acting insulin, AT247, which supports the facilitation of a fully closed loop artificial pancreas.

AT247 is an ultra-rapid acting novel formulation of insulin that has been designed to accelerate the absorption of insulin post-injection. The superior pharmacokinetics (PK) and pharmacodynamics (PD) profile of a single AT247 dose, compared with gold standard insulins NovoLog and Fiasp, has been previously demonstrated in a phase 1 study.

This second clinical study further confirms that AT247 has a superior PK profile compared with NovoLog and Fiasp – showing a statistically significant difference when meeting the trial's co-primary endpoint.

AT247 also demonstrated a statistically superior early glucose lowering effect in the trial's second primary endpoint compared with NovoLog. The trial further demonstrated that AT247 can be safely and effectively delivered via continuous SC infusion using an insulin pump.

With a superior PK profile and promising PD results, this study supports the potential that AT247 can enable even more effective disease management for people with type 1 diabetes using fully automated delivery of insulin via a pump in closed loop mode.

PharmaLex seals merger with UK's NeoHealthHub



PharmaLex Group – the provider of specialised services for the pharma, biotech and medtech industries – has announced a merger with UK pharma services consultancy, NeoHealthHub (NHH).

The agreement will be an important step in building a pan-European market access practice covering major markets, including the UK, Germany, Italy, Spain, France and the Nordics.

Founded in 2013, NHH supports its customers by offering innovative and comprehensive market access, data and capability development solutions and healthcare brand life cycle through its four business units – NeoNavitas, NeoN, NeoSypher and NeoOptima.

NHH has its headquarters in Lutterworth, Leicestershire, employing individuals who provide their expertise through customised solutions and understanding differing processes across the entire UK healthcare system.

“The merger is a good strategic fit for NHH because we share similar values and corporate culture with PharmaLex, built on an entrepreneurial spirit,” reflected NHH chief executive officer, Simon Doyle. “Both our organisations support a model of thinking global but acting local, which for us means responding to the unique and complex needs of the pharmaceutical and healthcare marketplace.

“We have created an organisation and structure that allows us to operate in a truly agile way, maximising opportunities as they emerge. Through the merger, we will be able to build on those opportunities and offer extended services and expertise to our clients, while further expanding the client base,” he added.

Brainomix in collaboration with UK Government-funded NCIMI

Brainomix – the AI-powered medtech solutions company – has announced its collaboration with the National Consortium of Intelligent Medical Imaging (NCIMI) and three selected NHS sites on a project to optimise and validate its automated cancer tracking tool, e-ACT.

e-ACT measures the size of lung cancer tumours and detects changes in tumour size, indicating treatment response and disease progression. The collaboration will evaluate how automated assessment using e-ACT compares with the observations of medical specialists.

Preliminary data has shown that e-ACT is at least as good as specialist doctors in

measuring the size of lung cancer tumours at a single time point. This project will have NHS sites in Truro, Bath and Leeds, allowing Brainomix to develop e-ACT and demonstrate the potential impact that technology has to improve care of patients with cancer.

The 12-month study will include CT (CAT) scans and clinical data from 200 patients with confirmed lung cancer on systematic therapy.

The study team will then evaluate how automated assessment of disease progression and treatment response using e-ACT compares to radiologist analysis.



The research will also include descriptive analysis of tumour dynamics using e-ACT in a representative NHS cohort.

This new project also builds on a previous successful collaboration between NCIMI and Brainomix in the stroke space.

HOT & NOT

Growth Platform – Liverpool city region's growth company – and the Department for International Trade (DIT) have launched a new vaccines discovery, development and manufacturing 'high potential opportunity' (HPO) in recognition of the city's expertise.

The HPO programme aims to help accelerate the growth of business and industry, boost local job creation and prosperity, and strengthen the UK's sectorial advantage. The region's vaccines capabilities will also be promoted to targeted DIT teams.

Researchers from the **University of Aberdeen** have been awarded almost £1m to fund research into how pregnant women can be supported to plan their birth.

The National Institute of Health and Care Research awarded more than £973,000 to the team of scientists, clinicians and members of the public. Over the next two and a half years, the group will develop an aid that can be used to guide discussion between pregnant women and health professionals.

A team from the **University of Lincoln** and the **University of Sheffield** identified how oxidative breaks in so-called 'junk' DNA are formed and repaired, exploring how the repairing of these breaks could protect us from neurological diseases in the future.

The discovery unlocks the potential for pioneering new research into this 'junk' DNA, which makes up 98% of our total cellular DNA.

LEO Pharma launches 'AD Days Around the World'

LEO Pharma, a leader in medical dermatology, today launched 'AD Days Around the World', a global disease awareness campaign that highlights the experiences of people living with atopic dermatitis (AD), the most common form of eczema.

AD is a chronic, inflammatory skin disease characterised by intense itch and eczematous lesions. The condition is the result of skin barrier dysfunction and immune dysregulation, leading to chronic inflammation.

In collaboration with patient advocacy organisations in France, Italy, Germany and Spain, the campaign shares real patient stories to educate and inform people living with AD that, regardless of nationality or culture, there is hope, despite common everyday challenges.

The campaign features global patient advocate Ashley Ann Lora, who travels from the US to France, Italy, Germany and Spain to meet with and document the emotionally compelling stories of four women – Marjolaine, Laura, Julia and África – who are living with AD, each at a different stage in their lives.

Through in-depth interviews, the documentary-style videos show audiences what it is like to live with and navigate the challenges associated with AD.



LifeArc and MRC launch toolkit to navigate medicines repurposing

Medical research charity LifeArc and the Medical Research Council (MRC) have launched a toolkit that aims to navigate the complex journey of medicines repurposing.

The toolkit will help researchers and charities to prepare for the key activities, potential challenges and important questions at each development stage on the repurposing journey, with the ultimate ambition of ensuring that patients get access to life-changing treatments faster.

Medicines repurposing offers new avenues for treating a range of common and

rare diseases – it can reduce the costs and time frames, and is potentially a source of treatments. This journey of exploring other diseases, however, can be challenging.

Developed in consultation with scientific, industrial and regulatory experts, the toolkit signposts users to a wealth of existing information. It includes advice on the key issues for medicines repurposing at each development stage, such as research steps for demonstrating efficacy, the regulatory environment, patient engagement and accessing medicines.



Professor Patrick Chinnery, MRC's clinical director, explained: "Having learned the challenges of repurposing first hand, I think this toolkit is enormously practical and valuable. The major opportunities presented by repurposing are speed, so medicines can reach patients faster, and lower costs, which is needed both within the NHS and lower-income countries."

In a boost to the UK's life sciences sector, **Mission Street** and **BentallGreenOak** will deliver a science and innovation campus in Cambridge, following the acquisition of a 23-acre site on the city's Coldham's Lane. It represents the fifth and largest acquisition by the specialist science and innovation development venture since the partnership formed in January 2021. Furthermore, the platform now has a development pipeline of over 1m square foot of lab and office space in UK locations.

For some European myeloma patients, their diagnosis can take over five months, require four medical consultations and involve visits to at least three different medical specialists.

These are the findings of pan-European research conducted by **Myeloma Patients Europe** with the aim of exploring patient and doctor experiences of myeloma diagnosis. It ran a survey and focus groups in which more than 600 myeloma patients and 80 haematologists across Europe participated.

MEAction UK held a #MillionsMissing demonstration in Parliament Square in October calling for the 'millions' missing from myalgic encephalomyelitis (ME) research. Numerous MPs took part, while Lord Bethell and Fleur Anderson MP made speeches. Researchers also discussed their work and the intersection between ME and long COVID. Preliminary studies show that one-third to nearly half of people with long COVID meet the criteria for the complex, chronic disease of ME.



Listen without prejudice

The UK is making progress towards the zero HIV transmissions milestone

As the UK pushes towards the goal of zero new HIV transmissions by 2030, Gilead is striving to challenge inequity, bring forward innovation and eliminate prejudice to end the HIV epidemic for everyone, everywhere.

In the early days of the HIV epidemic, the race was on to find any treatment that could potentially help the thousands of people who were testing positive for the virus. In 1987, a landmark approval of azidothymidine (AZT) marked the start of the journey that we have been on over the last 35 years and the multiple revolutions in treatment that have followed.

There have been ups and downs along the road. Over the years many different treatments that have been able to suppress the virus within the blood to undetectable levels have become available.

While working as a pharmacist in the NHS, I witnessed the introduction of a wave of combination and triple therapies that become available for people living with HIV. Until that point, people had relied on taking multiple treatments, often multiple times a day.

These treatment regimens would often come with side effects and, unfortunately, some would work less effectively over time. With the introduction of combination therapies, treatments could be considered that were not only effective but could also improve the quality of life for many people.

Lightening the load

Progress with HIV/AIDS has continued anew – recently we have seen innovation continue in the care of HIV with the introduction of treatments that can be delivered by injection.

This innovation has the potential to be an important change in how we are able to manage HIV. Stigma is still persistent for many who live with the virus, and for some of those individuals, daily oral treatment reinforces both external and internal stigma.

While there may now be a multitude of different options available to support managing HIV, each and every new development – with their different modes of administration,

mechanisms of action and dosing schedules – are all of huge importance. Namely because they offer choice.

Ultimately, this could be one of the key opportunities in meeting the UK government's ambition in getting towards zero HIV transmissions by 2030.

Although traditionally some populations, such as men who have sex with men (MSM), have been more actively engaged in their HIV care, the prevailing stigma among certain communities can mean higher proportions of these groups becoming 'lost to follow-up'.

Recent HIV surveillance figures found that at least one in seven people with HIV in England, and possibly as many as one in five, has a detectable and transmissible HIV viral load. An estimated doubling since before the COVID-19 pandemic, when this was estimated to be less than one in ten.

March of time

One of the shared priorities across the HIV community, and something that is of utmost importance to us at Gilead, is being able to understand the rationale for these patterns and properly support individuals to re-engage in care.

'It does not matter if we have an effective treatment – if it does not suit the individual, they are not going to take it'

As a community, we understand the collective responsibility to support these individuals, and so rather than considering this group as 'lost to follow-up' we now think of them as those we 'need to find'.

The knowledge and expertise of patient support groups and healthcare professionals who work with groups that are more likely to disengage with care is immeasurable. Working alongside them, we are delivering and supporting various programmes that aim to broaden support, break down barriers between communities, reduce stigma and improve education around HIV.

Nevertheless, once we have found these individuals, we have only taken the first step. At that point, it is critical that we remember that every person living with the virus is individual, and every treatment plan should be considered on a personalised basis.

Working in the NHS and directly among people living with HIV, this was one of my own biggest learnings. It does not matter if we have an effective treatment – if it does not suit the individual, they are not going to take it.

Here's where the story ends?

View from PharmaTimes Editor, John Pinching:

The HIV/AIDS story is unique. Its initial narrative involved the astonishing bravery of mainly gay men in 1980's California, and then in London, who were suffering demonisation from wider society, but found the resolve to protest on the streets until their situation came into sharp focus.

Of course, this illness affects us all. The first person in the UK diagnosed with HIV was a female suburban housewife – as far from any caricature as you could possibly imagine.

Nevertheless, HIV and AIDS has still carried its toxic stigma, in spite of the knowledge, awareness and incredible leaps in life-transforming therapy. Indeed, it is only through popular culture – notably the feature film *Dallas Buyers Club* and the recent TV series *It's a Sin* – that people who are HIV positive felt 'normalised' and empowered.

High profile people are now feeling comfortable enough to announce their status in the knowledge most will understand that this is only part of who they are. Contrast this with Freddie Mercury, over 30 years ago, announcing his condition only the day before he died.

Mercifully, people who are HIV positive now have the chance to realise their dreams without the all-encompassing fear of previous decades. It is not, however, all about the promised land of single-pill therapies – employers, communities and healthcare institutions still have much to learn about what it is like to live with HIV.

The only way this can happen is – not through academic pondering – but by tapping into the knowledge, humour and realities of people living with HIV/AIDS. This isn't where the AIDS story ends, but we are embarking on a new route where hope, opportunity and decency prevail.

That is why with every new development that comes – and any of those that may come in the future – ensuring the patient voice is heard and fully involved in care decisions helps to make sure that no individual is left behind.

Continuing the current momentum in HIV care over the next few years will be critical in reaching the goal of zero new HIV transmissions by 2030 and it will take a collective effort to do so.

Ultimately, we have a passionate belief that together we can end the HIV epidemic for everyone, everywhere. ▲

Chris Robinson is Medical Director for HIV at Gilead Sciences UK & Ireland. Go to gilead.co.uk



We've come a long way

People with HIV are living long and fulfilled lives but what is the future of HIV care?

The treatment and management of HIV has a long history, not without its turbulence. In the early years of the HIV and AIDS epidemic, an HIV diagnosis was almost always met with fear and terror, and the belief that it was a death sentence. For many people it was.

Effective treatment, which began to emerge in the mid-1990s, helped some people diagnosed in those early years to survive. In the years since, and with the development of novel treatments, more and more people are showing they can live long and fulfilling lives while also being HIV positive.

Most recently, the advent of U=U (undetectable = untransmittable) now means that people who are on effective treatment and have an undetectable viral load cannot pass the virus on to their sexual partners.

Today, 40 years on, thanks to decades of clinical research, innovation, advocacy and cross-sector collaboration, HIV has largely become a chronic condition in the UK. The UK has led the way and in 2020 – for the first time – the UK achieved the UNAIDS 95-95-95 targets of 95% of people living with HIV being diagnosed, 95% of those diagnosed being on treatment, and 95% of those on treatment having an undetectable viral load.

Growing older with HIV

The progress which has been made through improvements in testing and treatment has been remarkable, and pleasingly new diagnoses of HIV, and deaths, due to the virus continue to decrease in the UK.

Following these successes, we have seen an increase in the numbers of people accessing HIV care who are aged 50 or older. In 2018, 40% of people accessing HIV care in England were aged 50+, a figure which rose to 48% in 2021 and is on a trajectory to pass half of all people accessing HIV care in England within the next couple of years.

‘We have seen an increase in the numbers of people accessing HIV care who are aged 50 or older’

This brings with it a host of new challenges – like the management of other long-term conditions in addition to HIV, access to adequate social care, the impact on mental health and a higher likelihood to experience loneliness. Or continued stigma or self-stigma and specific impacts on women with HIV, such as menopause and heart and bone issues.

Many uncertainties remain about how HIV interacts with the ageing process – there is no blueprint for growing older with HIV. This generation that is ageing with HIV is the first to do so, and no generation has before had to face the myriad challenges of ageing with this backstory behind them.

So, we asked ourselves what needs to happen next? We need to celebrate the achievements in the fight against HIV and AIDS without perceiving the challenge to be over. We need to recognise and embrace the changing landscape of HIV care which is in front of us. And more than anything else we need to stop speculating and listen to people living with HIV themselves.

Providing a platform to listen

Fifty Over 50 is a unique listening exercise. Its vision was not to conduct scientific research but to seek meaningful, qualitative accounts of experience to add to the body of evidence and existing insights on HIV and ageing.

To do this, it was critical we worked in partnership to shape the approach. The Whole Person Care (WPC) Partnership, a coalition between MSD UK and several HIV community and professional organisations, worked to form a framework sympathetic to the diverse nature of those impacted by HIV and their stories.

Fifty Over 50 set out to speak with 50 people living with HIV aged 50+ willing to collaborate and share their first-hand accounts. Resulting contributors ranged from aged 50 to 80, were diagnosed at a range of times, from the 1980s through to the last decade, and as much as possible represented a balance of genders and backgrounds.

It would be easy to fall into the trap of talking about older people with HIV as one group, but even a cursory glance at the experiences in *Fifty Over 50* will highlight the folly in that approach. Not only are the contributors diverse in demographic, but also in their outlook on life. While there are some commonalities of experience, *Fifty Over 50* doesn't provide any easy answers via consensus.

Fifty Over 50 has, however, helped us signpost some of the key issues that clearly need more consideration from policymakers and those who can influence the commissioning and delivery of services for people living with HIV, as well as those who provide support services for older people.

In 2019, the Government announced its goal to end HIV transmissions in England by 2030, through 'better prevention, detection, and treatment'. Alongside these important pillars, to achieve this goal sufficient focus must also be provided to the over 90,000 people currently living with HIV in England.

Policy and healthcare services must listen and adapt to reflect the changing needs of people with HIV, where areas such as quality of life are becoming increasingly important for an ageing population.

Living well for life

The project brings into focus how for many in the HIV community being well is about more than just viral suppression, it's also about living well. By taking a person-centred approach people living with HIV can be encouraged to remain active in their care throughout their whole life, and in doing so remain well, remain undetectable and remain untransmissible.

MSD and the WPC partners are committed to supporting people who are growing older while living with HIV. We are united in our belief that more needs to be done in this area, and that the voices of people with lived experience should be central to this. We will continue to partner together on the priorities identified through *Fifty Over 50*, with a commitment to deliver meaningful work as a result.

‘Many uncertainties remain about how HIV interacts with the ageing process – there is no blueprint for growing older with HIV’

Thank you to the WPC partners and all our contributors, without whom *Fifty Over 50* would not have been possible.

Published in the form of both an e-book and hard-copy version, *Fifty Over 50* has provided a platform for people to share their own personal experiences, bringing to light the range of issues that exist for people living and growing older with HIV. ▲

Nipur Siani is Head of HIV Medical Affairs at MSD UK.
Go to hivworkingtogether.co.uk

Society's ties

Delivering true value for people living with rare diseases comes from partnership and innovation

We need to get closer to patients' needs to achieve the right solutions for them.

When we talk about patient value in rare disease what do we mean? The long-term question can't be about how we get every single patient to try one particular medicine in a broad-sweeping approach.

That won't deliver the right answers. As an industry, we need to ask how we can be more precise in the way we engage with these communities to meet their needs. What insights can we learn, what are the lived experiences patients face every day, what are the improvements that could tangibly improve their lives. It's about understanding that each person living with the disease is an individual and our job is to help them get to the right medicine or solution, quickly.

Achieving true value for the community with our solutions is only possible with a strong foundation of partnership. Across the pharma and healthcare sector, it is common to talk about patient-centricity and partnership – indeed, this is a basis for all our interactions. To generate meaningful change, however, this needs to be more than just words on paper.

This is especially true in rare diseases where, in some cases, levels of support, funding and research lag behind better understood medical conditions.

Partnering with patients, advocacy groups and physicians over the long term enables us to get closer to patient needs, so that we can develop the right technologies, medicines and solutions.

It helps our scientists develop more precise, targeted therapies and it enables us to design clinical studies and generate evidence with end points that we know will be relevant to these communities.

For this reason, gaining knowledge and insight from genuine collaboration is one of the most important steps on our development journey.

Lived experiences

There are many tools we, as an industry, can use to amplify insights – supporting patients and facilitating improved knowledge and understanding among clinicians, payers, policymakers and the public at large.

We've pioneered this approach across multiple projects, for example, a recent co-authored and peer-reviewed paper we worked on in partnership with Nancy Law – a former President of the Myasthenia Gravis Foundation (MGFA) and an expert patient – focused on the lived experience of myasthenia gravis (MG), where the gaps are and where we might be able to improve care for the MG community.

Everything we learned from Nancy and working with other groups that also have a great need for medicine and support, motivates us and should motivate the industry to do its best on every level for them. Our confidence in the importance of these types of initiatives is reinforced as we see the community citing this paper as being transformational in conveying the lived experience of MG.



Other groups that also have a great need for support and medicines are those living with rare genetic conditions – many of which manifest themselves in early childhood. Take, for example, thymidine kinase 2 deficiency (TK2d).

This is an ultra-rare, debilitating and life-threatening genetic mitochondrial disorder that causes progressive and severe muscle weakness, predominantly in a paediatric population. Here, the impact of success for patients can be measured in very tangible human terms – a reminder we keep at the forefront of our minds all the time to ensure that, in everything we do, we're striving to help patients and their families.

By working with these communities, engaging with them from the beginning of research, through every stage from trials to outcomes, we can ensure we're taking the right steps to help improve their diagnosis rates and education around the ultra-rare diseases they're living with. In parallel we will be striving to deliver medicines that we hope will make a significant impact on their lives and those of their families.

Creating the space

Providing a space for an exchange of ideas and giving the medical community an avenue for conversations is important to change what the future looks like in rare disease. At UCB we've listened to the community and founded the Rare Disease Connect Network (RDCN), a forum for this very purpose, which will hopefully help lead to better care for myasthenia gravis and other rare neurological conditions. We are committed to being a partner in the conversation.

We are also committed to investing in digital technology and innovation in rare disease. We know there's no magic moment to 'turn on' the future, rather it's a trial-and-error evolution to meaningful results. There is great promise for digital as a more integrated part of care, taking the voice of the physician and the needs of the patient and connecting them outside of the clinic.

We're investing in technologies that, in the future, could produce clinically meaningful algorithms to help detect and even predict the future health status of patients using a smartphone camera and microphone to observe their face and listen to their voice. The possible benefits of helping patients predict oncoming symptoms earlier and taking appropriate actions could be substantial and potentially lead to tangible improvements in care.

Until now, data to support these tools has eluded us. But with the rapid developments in smartphone and wearable technology seen in the last decade and combined with our dialogue with patients to understand the role technology plays in their lives, we can start to harness innovations to potentially transform outcomes and experiences for patients.

We often hear about 'future-proofing the industry' – perhaps the better discussion is about how we bring industry into line with the needs of society as a whole. It is vital that our goals and our approach are relevant to the community and the people we serve; hardwiring an innovation and collaboration mentality can yield a multitude of benefits.

We aspire to lead and be recognised as genuine partners in each of the communities we work with; as such, we attract individuals who are equally committed to this approach, and who are not afraid to embrace new and innovative activities.

It's also imperative we illustrate the value of our innovations. The more articulately we can talk about the value we deliver into the marketplace, the more sustainable our business model will be. By demonstrating to our partners – patients, clinicians, researchers and payers – the value of our efforts, we help grow their understanding and confidence in what this partnership can potentially achieve.

Through our proximity to the communities, listening to their lived experience, participating in open learning, working on digital innovations and articulating clear translations of value, we can be best placed to deliver solutions to people living with rare diseases. ▲

Chris Clark is Global Head of Asset and Commercial Strategy, Rare Diseases at UCB. Go to ucb.com



The price of love

An unpaid care crisis was emphasised by the pandemic but now the pharma industry must unite to support carers

The social care system needs a serious shake-up to improve the lives of the 10.58 million unpaid carers. After all, these are the people who form the de facto backbone of the wider UK health system. How we treat, perceive and support these heroic individuals must be a high priority for the wider healthcare ecosystem.

An ageing population has created a staggering increase in unpaid carers, with the figure almost doubling in the last ten years according to the Office of National Statistics. The pandemic has seen this number rise further, with many finding themselves caring for the first time, with little or no understanding or training to apply to their new role.

Carers faced mental health challenges long before COVID-19, but the pandemic just exacerbated those issues. Today, 70% of UK unpaid carers report struggling with their mental health, which is completely unacceptable.

Care continues to be a top health priority for the new Secretary of State for Health and Social Care, Thérèse Coffey, but as the health service recovers from the pandemic, the pharmaceutical industry is in a unique position to also help unpaid carers. With cross-industry expertise in areas like oncology and neurology, we understand the health conditions that often go hand in hand with unpaid care, and what it means to provide meaningful support.

Changing the culture

At Merck, we've been looking at the evolving needs of unpaid carers around the world for several years. Our latest Carer Well Being Index highlighted the significant toll and drain on mental and physical health, as well as the financial well-being of unpaid carers. In the UK alone, 77% of unpaid carers reported burnout.

Not only that, but the nation's unpaid carers said they felt undervalued, despite the fact that without their vital support, our health system would be completely unsustainable. As healthcare leaders, we have a shared responsibility to improve conditions for carers as well as patients and we are committed to better meeting their needs and to push for tangible solutions and action.

As a family-run company, the well-being of carers is ingrained in our company culture. Because two of our key therapeutic areas, MS and oncology, have a high carer need, we have spearheaded the Embracing Carers Initiative – a global movement dedicated to better understanding and supporting unpaid carers.

Alongside our partners, Embracing Carers looks to make a measurable difference to the lives of carers by creating connections and providing much-needed resources, support and information.

This includes materials aligned to what carers tell us are their greatest needs and concerns, and guides to facilitate healthcare professional conversations, because having a network of people – including a strong link between unpaid carers and HCPs – can make all the difference. By partnering with HCPs, the pharmaceutical industry can play a key role in helping to build further awareness among HCPs about how the lives of unpaid carers are upended by taking on a carer role.

Showing we care

Across the pharma industry, we need to provide support for carers so they can make important decisions about the person for whom they are caring. That support comes in the form of educational resources and expert advice, but also advocacy.

It's also important to look internally at ways we can advocate for unpaid carers within the pharmaceutical industry and within our own organisations. You may not realise someone in your workplace is a carer. Indeed, many of these carers don't realise they are either – but anyone in your working life could be looking after parents, siblings, friends or neighbours in addition to their normal working duties.

This will also likely take its toll on their career – a particular problem for women in the workplace. We found that 60% of employed female UK carers reporting that the pandemic has negatively affected their career, compared to 48% of male carers in the UK.

'With cross-industry expertise in areas like oncology and neurology, we understand the health conditions that often go hand in hand with unpaid care'

Flexible working is one key avenue where the pharma industry can provide essential support. We know that employees have many responsibilities and duties outside the workplace, and for those taking on informal care, we have a responsibility to provide greater flexible working. Taking learnings from the pandemic, we can ensure that we create cultures and working environments in which employees can thrive and continue their caring duties.

Another opportunity for our industry is to provide internal training, helping staff to understand more about the challenges that their colleagues might be facing. This will allow them to learn more about what it's like to be a carer and how to actively support those colleagues who may have caring responsibilities outside of the workplace.

As we work together across the industry to bolster support and care for our nation's unpaid carers, we need to work collaboratively alongside the Government, private and public sectors. Pivotal, we must ensure that these caring duties – performed willingly by loved ones on a daily basis – are recognised and appropriately supported now and in the future. ▲

Doina Ionescu, General Manager UK and Ireland at Merck.
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Cold comfort?

Decision intelligence can help to ease winter pressures on the NHS

The long tail effects of the pandemic have hit healthcare services hard and winter is set to compound matters further. Huge backlogs in elective care – with over 6.8m now waiting for treatment – combined with increases in flu admissions, COVID-19 surges, other respiratory infections and patients requiring immediate care – have created a ‘perfect storm’.

Never before have medical professionals had a greater need for new tools and technologies to help.

A connected, whole pathway view from primary care to community care and discharge is required – and this is where AI can help. It can help drive operational performance, potentially allowing staff to prioritise care and ensure the right patients are accessing the right care at the right time, despite the intense pressures.

Landscape change

Winter pressures are nothing new, but this year they come against intense efforts to tackle huge treatment backlogs that grew during the pandemic. The Institute for Public Policy Research (IPPR) predicts the backlog could take over a decade to clear and estimate there have been around 20,000 missed cancer diagnoses.

The backlog means capacity challenges within hospitals are already acute, and will likely worsen as increased infections drive higher bed demand throughout winter. So, what can be done? The IPPR highlighted three investments – a larger workforce, more diagnostic equipment and more physical space to provide care. The limiting factor, however, is investment, with at least £8 billion needed to tackle waiting lists.

Regardless of investment, new ways to help the NHS optimise resources are needed, and use technology to do more within the constraints it faces – whether they be staffing, equipment or buildings.

Currently, AI is most commonly known within diagnostics or to augment clinical decision-making. It also has a huge impact on optimising patient services, however, and therefore needs rolling out further to support operational decision-making and help teams handle winter pressures. By doing so, the NHS could realise the following benefits:

1. Improving access to care

On the frontline, operational AI means using local and national data to accurately predict where equipment and resources will be needed. At the height of the pandemic, AI helped forecast patient demand for ventilators and other equipment through using real-time data.

The same technology was also used in the allocation of beds, using thousands of 111 calls and other data to accurately predict how the pandemic was spreading, and how this would impact hospital admissions up to three weeks in advance.

Beyond the pandemic, AI still plays a pivotal role in optimising resources. Where availability appears, AI can predict who needs treatment first, as well as where and when. It can even look at the likelihood of treatments going ahead, and identify those at risk of not attending and tailor communication strategies to improve access.

2. Preventing harm for those waiting for care

Operational AI can also help in prioritising patients needing care most and minimise unnecessary harm. For example, AI can help prioritise waiting lists both for those needing urgent treatment and those with a longer management plan to continually monitor a patient's condition and risk score, helping determine changes in treatment.

‘At the height of the pandemic, AI helped forecast patient demand for ventilators and other equipment through using real-time data’

Similar applications are powerful in remote patient monitoring and virtual wards when used to create early warning systems and prioritise intervention – be that accelerating access to care, or incentivising self-administration of care.

3. ‘Right-sizing’ clinical services

Using AI-driven demand forecasting and scenario planning, healthcare services can better predict and supply ‘right-sized’ services. Decision-makers can also use AI for scenario planning, helping to optimise resources in critical areas such as real estate and staffing.

4. Evaluating the impact of new models of care

In the face of continually changing pathways (e.g. remote monitoring and virtual clinics) AI can play a crucial role in the ongoing monitoring and evaluation of models of care. Sophisticated AI techniques can be used to provide near-real-time understanding of outcomes with a view to supporting timely onward decision-making – challenging the long-standing audit approach.

5. Having embedded decision intelligence

Developing this whole pathway view takes time, yet NHS staff need immediate solutions to help them handle winter pressures. Early access to AI tools in advance of the winter peak is an important step to embedding machine learning within the delivery team's operational decision-making.

Maintaining efficiency

Operational planning in healthcare is a game of chess. What's important is not just the next move, but confidently predicting the next four or five. It is especially crucial now to look ahead as we move into an intense winter period. That is where operational AI comes in – by ensuring the next moves are calculated with greater precision, and taking in a range of complex factors a human cannot digest alone.

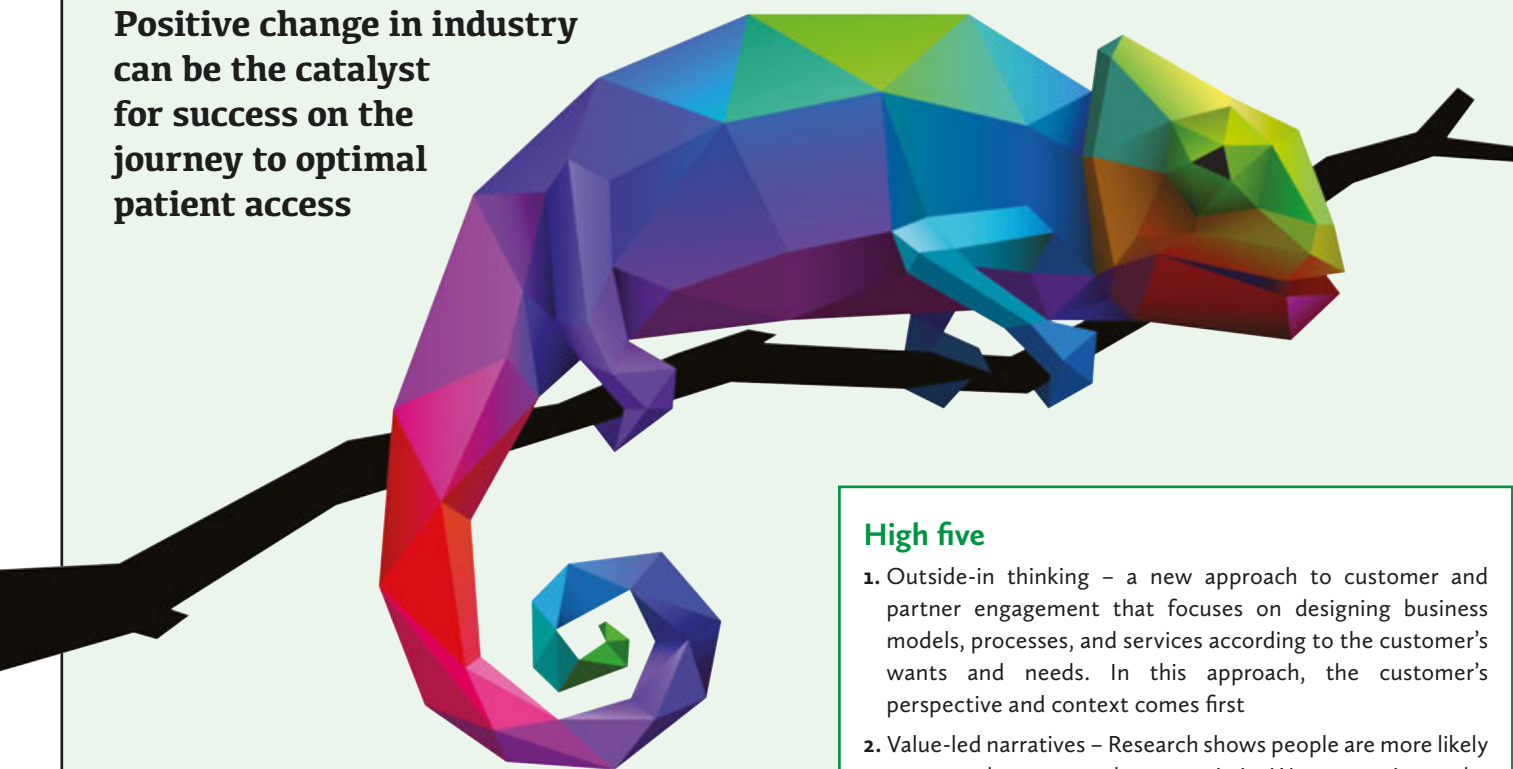
The NHS is a complicated supply chain that can become more efficient. It needs to be as agile as possible, like 'just-in-time' production where manufacturers make exactly the right amount at exactly the time customers need it. This agility bolsters resilience, and will help the NHS adapt as winter pressures place operational teams under intense strain.

While staff are extremely busy and are set to become even busier, none should be waiting around in under-utilised screening facilities while elsewhere patients wait for procedures. The beauty of a national health service is in the potential to optimise resources right across the country, despite peaks and troughs in demand. ▲

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Pharma chameleon

Positive change in industry can be the catalyst for success on the journey to optimal patient access



The nzyme proposition to optimise patient access was developed with deep, forensic research and co-created with key NHS stakeholders, on the understanding that in a post-COVID world the need for traditional pharma models to change and at pace, is not an aspiration but an imperative.

Our Mind the Gap white paper was an output of the questions we posed to our NHS contacts and while there is a lot that pharma is doing right, there is still a lot of disconnect between what HCPs desire and what the industry is delivering.

The ability to delve quickly into the minds of NHS leaders and gather insights in almost real time around any number of prescient challenges became such an attractive and powerful proposition that it necessitated the formation of the nzyme Brains Trust.

Our Brains Trust is an expert panel comprising over twenty KOLs and senior NHS stakeholders across a range of disease areas and specialties.

Not as proscribed as a traditional Advisory Board, more a collective intelligence and anathema to the echo chambers that have informed conventional thinking for too long.

They work closely with the nzyme group because of a shared belief system that pharma still has a huge role to play in NHS and industry engagement, but on the understanding that without value underpinning every HCP interaction there is only a finite number of opportunities to engage.

They have helped us co-create our own value proposition that we share with clients to help optimise NHS interactions and patient access, and key to this is our success catalysts – five embedded principles that are the lifeblood of our organisation.

High five

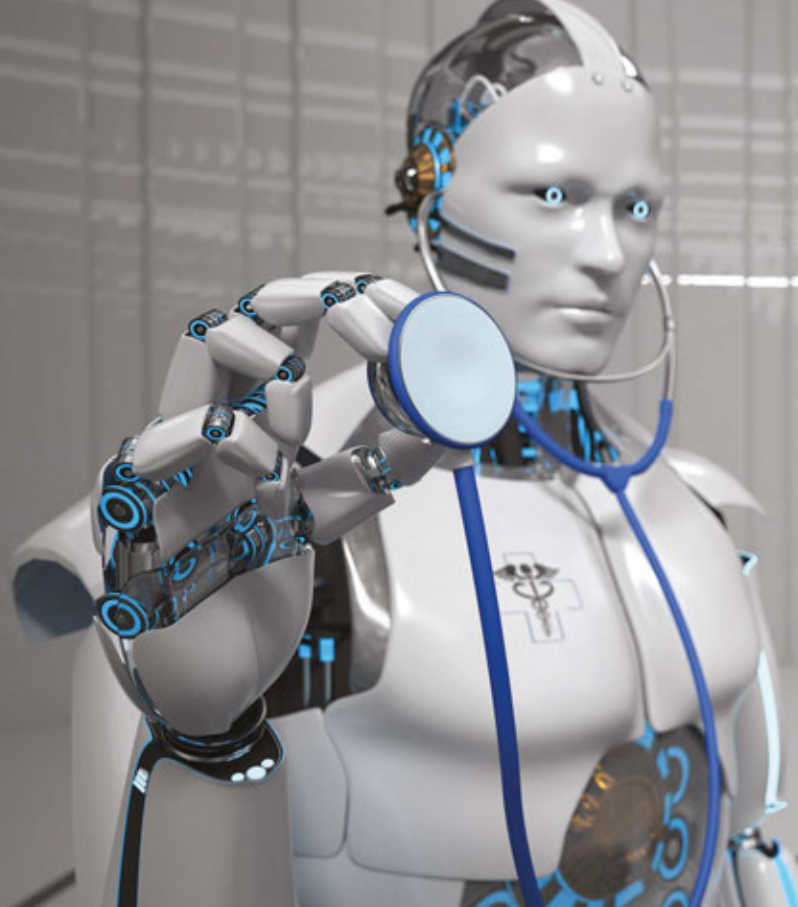
1. Outside-in thinking – a new approach to customer and partner engagement that focuses on designing business models, processes, and services according to the customer's wants and needs. In this approach, the customer's perspective and context comes first
2. Value-led narratives – Research shows people are more likely to remember a story than a statistic. We put stories at the heart of all our programmes and develop them with the needs of patients and clinicians at the centre
3. Digitally enabled and powered by AI – We create resilience and agility through applying learning. We design with metrics to understand, learn and optimise and use technology to make it easier
4. Innovative hybrid engagement – Designed to deliver the right message at the right time in the right channel: On demand, remote, in-person or hybrid
5. Test, Learn & Iterate – We hack the usual programme approach and implement programmes step by step so build in ways to learn as you go, iterate and optimise.

In this disrupted, uncertain post-COVID era, organisations live and die by their ability to adapt, embrace and manage change.

nzyme believes that there is an imperative for change and that the future of healthcare will be fundamentally different. Our company mantra is that we are customer-centric, insight driven, digitally resilient and value-obsessed.

Distilled down, we are the perfect partner and collaborator to help pharma navigate the potentially treacherous waters ahead. "The greatest danger in times of turbulence is not the turbulence – it is to act with yesterday's logic" – Peter Drucker. ▲

Dom Knights is Director of Customer Engagement at nzyme.
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We are the robots

‘Robotic’ ELRIG Drug Discovery 2022 conference captures our sustainability guru’s imagination

Recently, I had the opportunity to attend the European Laboratory Research & Innovation Group (ELRIG) Drug Discovery Conference 2022.

A meeting of more than 1,500 delegates over two days with a raft of scientific and technology talks and posters. It was reassuring to see that sustainability struck a consistent chord amongst the topics. My sustainability highlights are discussed in this article.

Sanofi described how it managed to replace single-use plastic pipette tips with reusable steel nozzles in a high-throughput nanobody screening set-up. The move was initially driven by an acute shortage of pipette tips during COVID. Lowered costs and reduced plastic waste, however, meant that the reusable tips stayed the course.

Meanwhile, AstraZeneca Open Innovation launched their inaugural CoSolve sustainability challenges: ‘ways to enable filter tip re-use or recycling’ and ‘ways to improve recycling or circularity of chemical solvents’.

After entries close in December 2022, a shortlist will be selected to pitch ideas in March 2023 and the winners could get the opportunity to develop their proposals in partnership with AstraZeneca.

Takara Bio showcased improved models of human disease using 3D organoids. These produce more ‘human-like’ data early on in drug development and reduce reliance on resource intensive and ethically challenging animal models. The overarching aim being to improve the predictability of clinical results and prevent surprise clinical trial failures.

The robots cometh

GSK explained how investment in understanding the environmental impact of various commonly used chemical reagents and solvents is paying dividends by helping to make greener choices in chemical development.

It was a talk from Arctoris CEO Martin-Immanuel Bittner, however, that really captured my imagination. The company’s USP is the automation of research using robots. Robots are already utilised in pharma, but Arctoris’ concept goes further.

Its robots run more experiments and record more complete data. The robotic precision removes human error and improves certainty. This results in a rich and organised data which feeds beautifully into the burgeoning field of AI enabled drug discovery.

Just a few years ago, remote labs were a hard sell. In the wake of enforced homeworking during the COVID-19 pandemic, however, attitudes towards remote working have softened in the research industry. More to the point, many researchers are realising that externally run labs offers improved business continuity.

Martin likened the shift towards centralised labs to the tech boom that came on the back of cloud technology. Just as tech companies no longer need to build and maintain their own servers, grassroots biotech and pharma companies will soon be able to get themselves off the ground without even needing their own lab.

Moreover, this kind of remote robotic lab paradigm comes with a plethora of potential sustainability advantages. Better decision-making early in drug development based on high quality data can reduce late-stage attrition of drug candidates, preventing resources being poured into projects that eventually fail. Centralisation also means that scientific equipment can be run at higher levels of utilisation, reducing the resource burden of building, servicing and maintaining equipment.

In addition, scientists can implement their protocols from anywhere in the world. This brings the two-fold benefit of slashing carbon emissions from commuting and making access to top-class equipment more equitable.

Right now, it seems a brave new world, but the vision of companies like Arctoris could give researchers more time to spend pondering results and deciding how to progress projects, with sustainability benefits to boot. Surely that’s a good thing. ▲

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Hearts and minds

Making mental health and well-being for all a priority

As a nation, we have never been more aware of the importance of mental health. Yet, despite an increasing understanding of the interconnectedness between mental and physical well-being, it is also fair to say that discussing issues around day-to-day mental well-being remains an uphill struggle.

With individuals – such as frontline NHS workers, students, the elderly and socially disadvantaged – under arguably greater pressure than ever before, the onus is very much on business leaders to drive improvements within their own organisations, on a micro level.

There is a raft of strategies that leaders can embrace. These include initiatives to

help individuals better understand and manage their own mental well-being, forums for teams to come together and discuss issues and broader social activities.

They also include digital platforms that can track health in a more holistic way, provide access to self-learning coping techniques and – critically – provide us with data that will help inform future mental healthcare innovation.

Changing mindsets

In the last seventy years, mental health has been transformed. From the closure of old asylums, to moving care into the community; new methodologies for studying mental

health outside of a hospital setting, and the use of talking therapies, the impact on patients and mental health care has been hugely positive.

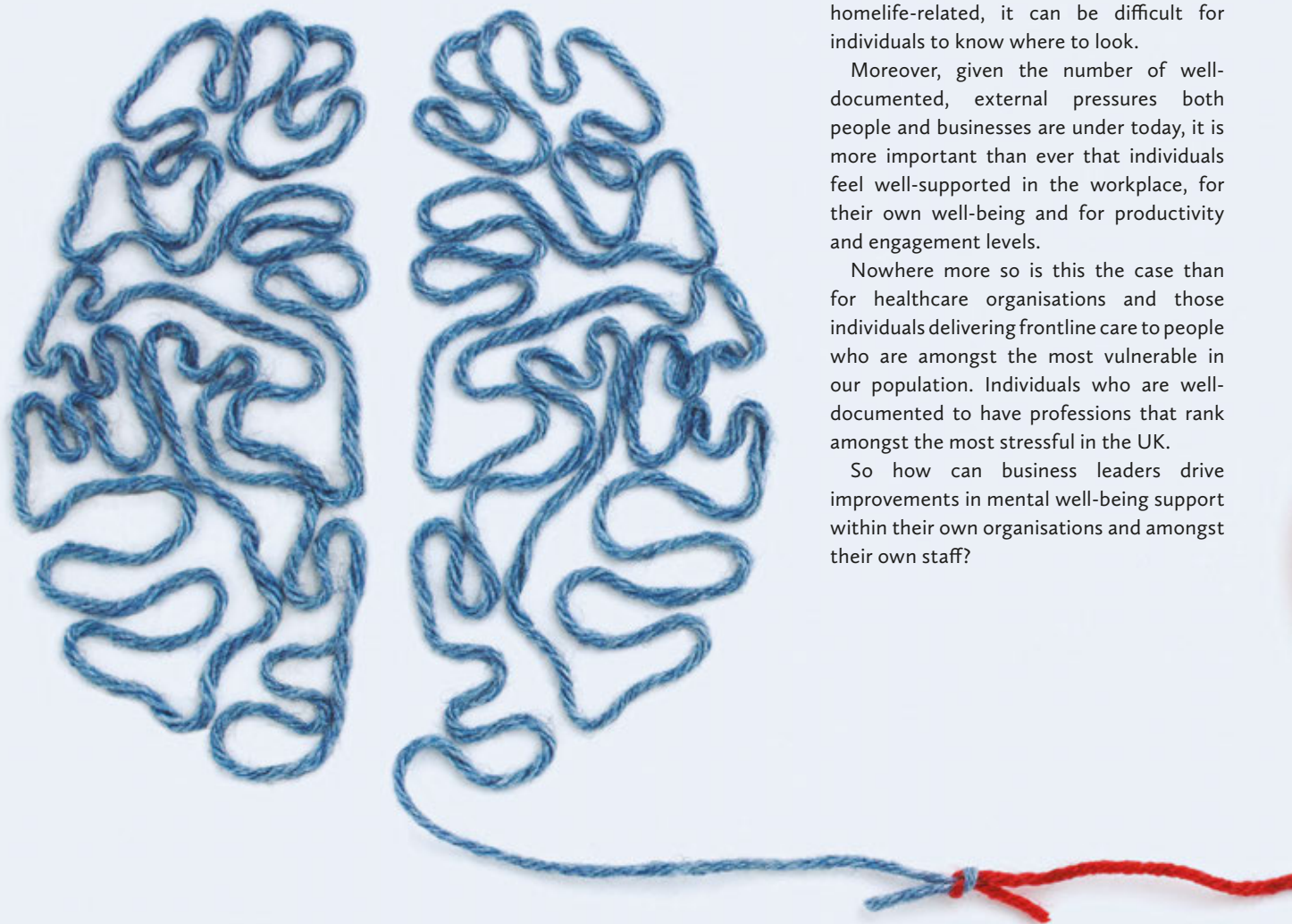
Arguably, the biggest positive change has been a shift in societal attitude. People and businesses are becoming more accepting of mental health issues and more aware of the need to support individuals with their mental well-being as well as their physical well-being.

Yet, despite the huge increase in support for mental health through the likes of high profile initiatives and charities such as Heads Together, Anna Freud Centre and Every Mind Matters, when it comes to discussing and helping people cope with everyday stresses, whether they are workplace- or homelife-related, it can be difficult for individuals to know where to look.

Moreover, given the number of well-documented, external pressures both people and businesses are under today, it is more important than ever that individuals feel well-supported in the workplace, for their own well-being and for productivity and engagement levels.

Nowhere more so is this the case than for healthcare organisations and those individuals delivering frontline care to people who are amongst the most vulnerable in our population. Individuals who are well-documented to have professions that rank amongst the most stressful in the UK.

So how can business leaders drive improvements in mental well-being support within their own organisations and amongst their own staff?



Openness and kindness

One of the easiest ways to foster mental well-being in a workforce is through establishing a sense of community and inclusiveness.

Mental ill health can be aggravated through feelings of isolation. According to researchers from King's College London, people with mental health conditions are disproportionately affected by loneliness, with one in five patients diagnosed with a psychiatric disorder or reporting feelings of loneliness.

According to the Campaign to end loneliness, the group most likely to report feeling lonely are over the age of 65 with around 10% saying they feel lonely 'all or most of the time'. In particular, people who had been widowed or had long-term illness or disability reported feeling lonely. Young people are also at risk. A recent survey by the Carers Trust found that 33% of young carers felt 'usually' or 'always' lonely.

Feelings of loneliness can be readily alleviated through social inclusivity, which has a key role in the workplace. Establish forums or workshops – be they in person or through communication platforms – where people can be encouraged to share their thoughts and feelings about work pressures, and take solace in each other. Encourage staff to undertake little acts of kindness and take regular walks together, taking a pause from the screen or work environment.

Host social get-togethers – coffee mornings, for example that can, to add even greater cause, be fundraising exercises for a charity of the team's choice – or off-site team building. You may even want to consider getting in external advisors to offer pensions advice or tips on 'how to eat well for less'. With a little imagination, the list is endless.

Individual understanding

Perhaps more challenging, but of equal importance, is to help individuals to understand their own mental well-being and patterns that might be associated with feelings of either negativity or positivity, as well as how their physical and mental health are connected.

This might be something associated with their role, for example: have they got all the tools and training they need to feel comfortable in every aspect of their job? Is there an aspect of their role that might be causing anxiety? Are they happy with their interpersonal relationships at work?

app, logging behaviours and trigger points can be crystallised in the moment, with little more than a touch of a button.

Moreover, these digital tools have the benefit of algorithms that make it far easier to spot physical trends and correlate data to identify the root cause of a potential mental well-being issue.

In addition, the most advanced of these digital platforms will also come with access to tutorials or self-help videos on a vast range of issues, from how to stop smoking to even basic Cognitive Behaviour Therapy (CBT).

Future of innovation

That said, one of the biggest technological challenges we face in mental health at the moment is lack of data. Despite the increase in focus on it, mental health is still not blessed with large research budgets. If we can advance studies by looking at ever-bigger comparative data sets, however, then we can jump forwards in our understanding of mental health.

'One of the easiest ways to foster mental well-being in a workforce is through establishing a sense of community and inclusiveness'

Equally, there might be a correlation between work and home-life that is causing imbalance. Is shift work causing poor diet and/or sleeping patterns that are affecting an individual's overall well-being? Or indeed, are pressures at home spilling over into the working environment?

A basic understanding of what might be triggering mental unrest is the first step on the road to taking action to rectify it. But how?

Digital tools

This is where the latest generation of digital platforms and apps can help. Very few people have the time or inclination these days to keep a diary of their emotions on a day-by-day basis. With a mobile or wearable

Through the use of these digital platforms, we will gain access to data sets that bring mental health into sharp focus. This would have the potential to revolutionise how we view and treat mental health – indeed, holistic health – in the future.

Mental health and well-being is a huge challenge to address and it may feel like a challenge we each face in isolation. That could not be further from the truth, however.

Taking steps towards a culture of openness in the workplace – aiding individuals in managing their own mental well-being, appreciating how mental and physical well-being correlate and embracing digital tools – can ensure that businesses can advance wider understanding. Now that is worth making it a priority. ▲

Alison Meadows is CEO at Priority Digital Health. Go to prioritydigitalhealth.com



We can see clearly now

The ABPI has brought pharma transparency into the broader healthcare mix and HCP relationships are at its heart

The 7th annual publication of Disclosure UK data by the Association of the British Pharmaceutical Industry (ABPI) was an important event overlooked, ignored and missed by many.

This, in itself, serves as a reminder that, while disclosure and transparency around financial arrangements between pharma companies, HCPs and healthcare organisations is a good thing, the disclosure process is still not good enough to be properly meaningful for its stakeholders – the industry, HCP peers, HCOs or the general public. But it could be.

Within Government, it is a legal requirement for MPs to disclose financial benefits made to them outside their salaries. Similarly, under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, the pharmaceutical industry has a requirement to disclose payments and transfers of value (ToVs) made to healthcare professionals and organisations.

With disclosure in the UK being a voluntary act, however, and not a legislative requirement, data protection rules must be applied, which means that, while all HCO data is disclosed, pharma companies must still gain consent from the HCPs they pay in order to disclose their data and name them. The annual Disclosure, therefore, contains some named HCPs – but, if an HCP doesn't consent, the data goes into an aggregated number.

About 29% of the payments to HCPs is aggregated and, for me, this has always been somewhat at odds with the principles and philosophy of a transparency initiative. The aggregated amount tells you how many HCPs have been paid but nothing more than that.

Joint working initiative

Disclosure reporting within the European Union first began in 2015 as an initiative around improving the industry's reputation and as a direct response to the US healthcare law, the 2010 [Physician Payments] Sunshine Act. This made it a legal requirement for US pharmaceutical and medical device manufacturers to publicly disclose any payments or ToVs made to healthcare professionals and providers.

The Act itself came into force as a result of the industry wanting to address criticisms made against it following well-publicised bad practice and a resulting scepticism around the pharma/healthcare industry.

Five years later, the EFPIA implemented a voluntary disclosure programme into its guidelines and framework for any country where there was no legislative requirement, and the individual European member states applied these to their own markets.

Countries such as Belgium, Denmark, France, Portugal and Slovakia have made varied forms of disclosure of payments to HCPs mandatory through legislation – whilst, in the UK, this is still a voluntary requirement, although there are increasing calls for this to become a blanket legal requirement.

Collaboration between industry and HCPs is a relationship that has delivered many improvements in the provision of care and equality of knowledge across the health profession, changing the way diseases can impact on our lives.

Full transparency, therefore, must be required. However, it is vital that we first improve the rules and requirements for disclosure reporting – to allow greater detail to be recorded for each payment or ToV. This would provide much-needed context for such vast amounts of money changing hands and enable us to properly understand both the nature of the relationship and the transaction without guesswork or artistic licence.

There are, after all, several ways that HCPs can be paid.

They can be paid directly as is often the case with speaker fees, consultancy work and advisory boards. But they can also be paid indirectly, as in ToVs, which are like a benefit in kind, and where a company may pay, for example, the registration fees directly to the congress or cover travel and accommodation expenses in relation to such an event, and where the HCP would be a recipient.

Currently, there is no scope for providing such context such as a description of the services or even allowing HCPs to record if they have declined payment or what they





have done with the payment e.g., donated it to charity or research fund. And so, a consultant recorded as receiving £100,000 from a pharmaceutical company could be easily misconstrued.

The pharma industry's total Disclosure for 2021 was revealed to be £557.1m, up £70.6m (14.5%) on 2020. Of that, some £405.1m was categorised as Research & Development (R&D), up £57.4 (16.5%) on last year. And the remainder, £152m, was categorised as non-R&D spend – split between HCOs (77%) and HCPs (23%).

As a further breakdown, £35.4m was spent on Cost of Events (up £7.6m / 27.4%); £44m on Donations & Grants (down £8.8m / 16.6%); £65.5m on Fees & Service (up £11.3m / 20.8%); and £7.1m on Collaborative Working (up 3.2m / 80.8%).

Full disclosure?

Unsurprisingly, the greatest part of the spend was on R&D, for planning and conducting clinical studies for HCPs and HCOs. This is, however, what I would call a 'vanity number' for an industry that likes to showcase the amount it's pumped into the UK for this. It's just a total number, no breakdowns, and so you can't do a lot with this figure, and it has no place within a transparency initiative.

'For an HCP, Disclosure UK is a bit like *The Times* Rich List. There's a measure of 'who gets more than me'? Who else is considered by industry to be a thought leader'

There is a lot of the information within Disclosure UK that could be of enormous value to the industry in helping it to understand itself and its competitors better, and how the individual companies relate to their peers and different promotional strategies. And, of course, there's the relativity to where they were last year, who else engages with our key opinion leaders and how much are they paying them.

For an HCP, Disclosure UK is a bit like *The Times* Rich List. There's a measure of 'who gets more than me'? Who else is considered by industry to be a thought leader in my therapy area, and which companies are they working with? Of course, such assessments are limited to the value received and number of companies engaged with, which are primarily geared towards validation and ego-driven rankings.

Even so, the data set could provide even greater value by digging deeper to deliver a richer assessment of what is being shared. Then it has the potential to provide real insight and greater understanding, with a platform for individuals to advance their knowledge even further – and this approach could be a game changer.

From the general public's understanding and perspective, these are astonishing figures in terms of the sheer size of the transactions and it is clear that more detail and context is necessary.

If you were to run the information as a headline: 'UK pharma industry paid £543million to UK HCPs and HCOs in 2021' – providing the facts but not the context (way beyond the definitions and typical practices) leaves this open to interpretation based on the personal bias of the person receiving the information.

And, while I could look up my consultant and see how much he/she has received, without any context, so what? What's the value? OK, it's there and it's publicly available – but it's nothing more than a big data dump and, in the spirit of transparency, it's not really shining a light on anything.

On the one hand, someone who has been paid £113k, mostly by a single company (and the previous year, and the year before that), you could ask: Is this someone in the industry's pocket, and do I really value his opinion? But, without an explanation, there is no way of knowing if this is indeed the case or if, conversely, this person has been paid for giving an invaluable talk to share leading clinical practices in regard to a killer or debilitating disease and has donated the money he or she received to a research fund to advance treatment options for rare diseases. Both highly commendable actions.

Healthy relationships

You could also think that, because an HCP has been transparent and disclosed payments, that's a good thing because, effectively, it looks like he or she has got nothing to hide. But an HCP can agree to disclose that he or she made £1k with one company and decline consent to disclose that he or she made £50k with another. The data is open to manipulation and can create smoke and mirrors. So there needs to be caution when trying to interpret the data.

Best of all, I would like to see HCPs taking control of their own data. The industry might gather, collate and publish the data – but there must be scope for HCPs to provide the context and add information around these payments. Otherwise, there's a danger of these disclosures taking on the dark angle of people solely looking at who's being paid the most amount of money - interpreting the figures through a negative lens.

The real and most important focus should be this very important relationship between the HCP/HCO and the pharma company, which is at the heart of enabling healthcare to grow, evolve and be innovative.

The industry has taken some action to increase the visibility of payments, with an increasing number of companies using 'legitimate interest' as a legal basis for disclosure, where all ToVs made are publicly disclosed on a named basis without consent. Or, alternatively, 'legitimate interest with the right to object', where all ToVs made are publicly disclosed on a named basis unless an HCP explicitly requests to opt out.

It is great that more and more HCPs are choosing to disclose the payments made to them but more needs to be done to provide context and explanation – and to include the missing 29% of HCP payments to bring them in line with HCO disclosures. In the final

David Bloomfield, CEO & Founder at PAYCE Portal. Go to payceportal.com



The human condition

Our AI guru looks at how decision-making can go to the next level with hyperautomation

Interest in hyperautomation has been growing ever since Gartner first coined the term in 2019.

Applied to vast amounts of data, this technique – which involves the simultaneous use of digital operating systems, workflow, robotic process automation and artificial intelligence – can augment decision-making in a way never seen before.

Despite being relatively new, hyperautomation is expected to have far-reaching benefits in sectors such as banking, insurance, retail and telecoms. It promises to dramatically increase efficiency and productivity of businesses, enabling them to deliver seamless customer experiences while enhancing employee engagement and controlling costs.

While the term might not be so widely known in life sciences, hyperautomation could also radically change clinical trials, healthcare and patient outcomes for the better. In a clinical context, it is important to note that hyperautomation could mean the automated delivery of information to augment clinical decision-making – not automate the clinical decision-making.

The increasing use of wearables in clinical trials, for instance, allows researchers to collect more data from a more diverse set of participants. Safety and efficacy of drugs in patients can be monitored on a continuous basis. This removes some of the mechanical constraints imposed in clinical trials and enables a more representative set of patients to participate – not just those that can get to the study sites.

Reality show

As data flows from patients' real-life experience, clinicians will be able to see in much more detail, and much more continuously, how people are responding to the drugs. Importantly, they also gain insights into the social factors that determine the likelihood of patients sticking to their treatment plan so alerts can be sent to ensure better adherence to the protocol.

By applying artificial intelligence and machine learning – the key components of hyperautomation – data can be interpreted at speed to support real-time and effective decision-making. Greater efficiency reduces the time-to-market for new drugs, making innovative treatments available sooner.

The ability to access, interpret and share more data expands clinicians' horizons. No matter how distinguished or dedicated medical professionals are, they've always been constrained by their own experience, knowledge and time. If they can aggregate data at a national or global level, however, they extend their view beyond what any one individual alone can know – paving the way for better and faster diagnoses, particularly when it comes to new or rare diseases.

A large part of medicine, and indeed our civilisation, has been based on human experience. Think of family doctors in the past who seemed to know their patients' history when they walked through the door of the consulting room, rarely needing to look at their notes.

Now those days are largely gone. As our understanding of conditions improves, and treatments become more sophisticated, clinicians need insights that go beyond the scope of their experience. Whereas drugs were once something of a blunt instrument, they're now highly targeted. Yet how could anyone know the distinct characteristics of every patient and how they're likely to respond, especially in the limited time available to them?

New and ethical data models are being developed and refined at a rapid rate as the mass digitalisation of organisations continues – so it's only a matter of time before advanced technologies like hyperautomation become more widely available to researchers and clinicians, enabling them to drive better health for more people. ▲

Simon Tilley is Global Lead for Healthcare and Life Science at SAS.
Go to sas.com



True voices

Inclusive approaches to diversity and inclusion. How can we move from awareness to action?

In meeting rooms around the world, discussions are taking place that examine what can be done at strategic, protocol, trial site and patient levels to ensure accelerated clinical trials yield successful drug development in rare diseases. Historically, these conversations have not included the patient voice, particularly representative and diverse voices.

ICON is committed to advancing diversity and inclusion in clinical trials in partnership with sponsors and other clinical research stakeholders. We believe that when done well, patient advocacy and Diversity, Equity and Inclusion (DEI) are similar in that they focus on moving people with expertise borne from lived experiences from the margins of partnership and decision-making to the centre.

Patients advocate for, take and benefit from the therapies being developed. They are the end user, and therefore should be considered a key stakeholder in the drug development process. This is best expressed by the patient advocacy community itself in the slogan: 'Nothing for us without us.'

Moving the dial

At ICON, we see a number of key actions that can help when it comes to increasing diversity in clinical trials.

Be accountable. Measurement is the alpha and the omega in drug development. What gets measured, gets done. If companies want to demonstrate an authentic commitment to DEI, there needs to be a measurable system for accountability.

DEI and patient engagement must not be relegated to token objectives that are arbitrary or optional. Incorporate DEI and patient engagement into company objectives with performance metrics tied to those objectives. Until there is an incentive to make DEI actionable, it will be hard to deliver real progress.

Be aware of and challenge presumptions and assumptions. Test the validity of assertions about barriers around clinical trial participation by engaging a variety of patients and advocacy leaders who can verify or dispel potential misunderstandings.

For example, in some patient communities there may be hesitancy to participate in clinical research because of Tuskegee and Henrietta

Lacks, but there are also many people who want to participate in clinical research who are never given the opportunity, or because of various barriers – language, cultural, geographic, financial etc.

One direction

If the presumption is that one voice or one experience is all experiences, and this is not challenged, the industry has done a disservice to the entire community. Therefore, it is incumbent to include diverse and representative voices into discussions to ensure assumptions are not heralded as fact until they are validated as such with patients.

Access existing talent and resources. Build well-resourced patient advocacy teams that can connect to diverse patient voices and insights. Partner with health equity advocates to ensure historically underserved communities are engaged in culturally competent and impactful ways. Invest in clinical trials sites located in traditionally underserved areas or innovate to decentralise trials and make them more accessible to participants.

Tap into myriad webinars, seminars, panels, podcast and platforms created by leaders in the DEI space. There is no lack of resources instructing individuals and companies on how to effectively engage diverse and representative patient voices.

Among these offerings is ICON's Patient-Centric Drug Development Toolkit that includes DEI considerations to encourage and promote representation in clinical research. ICON's Centre for Rare Disease also hosted Beyond Buzzwords, an interdisciplinary panel of experts who provided insight on systemic and individual barriers to DEI in clinical research and how to solve for those barriers.

Despite myriad resources available, there is no action without acting. Ultimately, moving from awareness to action in DEI begins as simply as just doing the work. ▲

Devra Densmore is Senior Lead, Patient Advocacy Strategy, Centre for Rare Diseases at ICON. Visit [ICONplc.com/rare-disease-insights](https://iconplc.com/rare-disease-insights) to access the resources mentioned in this article.



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Mind craft

Analysing the worsening mental health landscape across Europe

Poor mental health is on the rise. Economic challenges, geopolitical crises and a changing environment are all negatively impacting mental health. Healthcare systems, however, are still struggling to tackle this crisis and public awareness often remains insufficient – this needs to change.

Since 2017, Angelini Pharma has partnered with The European House, Ambrosetti, to map mental health, its contributing factors and its potential management solutions through the 'Headway' initiative, with the annual report and index as outcomes. This year's results are more alarming than ever.

For our latest report, we examined 28 countries using 55 key performance indicators to explore the status of mental health, its external factors and how countries need to individually adapt and react to growing issues. We've also been able to analyse, in detail, the causes of poor mental health, from the conflict in Ukraine to climate change.

This report has given us insights into a broad range of contributing factors to the worsening mental health landscape in Europe that have so far been unanalysed. In this article series, we will be exploring the different facets of that research over the coming months.

From the environmental determinants of mental health to the responsiveness of healthcare systems, numerous factors play into our collective mental well-being and never has it been more important to develop a roadmap to improve this scenario.

Brains trust

To understand how to build a roadmap first, we must understand mental health status.

Over 100 million people in Europe alone are living with a mental disorder. 200,000 deaths are attributed to it annually, of which 140,000 are suicides. This is equal to 4% of all registered deaths, making it one of the deadliest non-communicable diseases (NCDs) affecting European and British populations. Not only is it deadly, but it is also disabling – ranked the second most disabling of all NCDs.

The prevalence of mental disorders in Europe has also been increasing. Since the start of the COVID-19 pandemic, there has been a 25% increase in the prevalence of anxiety and depressive disorders, and based on the outlook, environmentally and geopolitically, we anticipate that this number could continue to grow.

The costs alone to treat this are astronomical. Mental health conditions cost around 600 billion euros, or roughly 4% of the Europe's collective GDP, annually. This is despite the fact that for people living with a mental health condition, the poor quality of their health and lack of adequate treatment is responsible for more than 16.9 million years lived with disabilities.

With mental health conditions on the rise, more needs to be done to support those living with a condition – especially as mental and physical health are inextricably linked.

The Headway Report clearly shows that only a united community will be able to change the unacceptable status quo of mental health and build a roadmap to shift treatment in the direction of those that need it most. ▲

Rafal Kaminski, Chief Scientific Officer at Angelini Pharma. Go to angelinipharma.com

Do we focus enough on the well-being of members of promotional review teams?

Anyone who has worked in or around commercial teams in the life sciences industry will have seen the ups and downs of team members involved in promotional review.

My own ten+ years in the pharmaceutical industry, working as a reviewer, approver and content creator, has led me to believe that it is one of the most emotionally challenging roles in the industry. It's this experience working in the promotional review teams that made one result from our annual Pepper Flow benchmarks report stand out from the others: users satisfaction correlates with faster and fewer review cycles. But is this a correlation or a causation?

Firstly, a little more about the report; it provides the life sciences industry with an overview of promotional material review metrics from different sectors. The data is based on anonymised records from users of Pepper Flow – Vodori's material review software for promotional and non-promotional content.

It represents life sciences industries of all sizes, from emerging companies all the way to household-name multinationals. It also covers the following life sciences industries – diagnostics, medical devices, nutrition, biotechnology and pharmaceuticals.

Trending now

The headline numbers show some interesting trends: small to medium companies (100-500 employees) perform the best, taking just under 7 days to review and approve material, while large companies (>500 employees) take 7.5 days on average, and also require more circulations before jobs are approved. Medical reviewers have the fastest average review time at 2 days, similar to marketing, but significantly faster than legal, who typically take 4.1 days per cycle.

The most thought-provoking area of the data though comes from the user satisfaction statistics. Companies with the highest degree of user satisfaction took 5.7 days to review and approve materials, vs nearly 8 days for companies with the lowest satisfaction.

User satisfaction is dependent on many things: how easy the software is to use; how closely the software configuration matches the business needs; effectiveness of the overall business review process. For me, having worked for my whole career in review teams, the data made me question whether life sciences companies spend enough time focused on the well-being of members of the review teams.

Data day

The data is not strong enough yet to demonstrate a causation, but for me, it probably doesn't matter. Whether a focus on reviewer well-being leads to improved satisfaction, and then faster review times, or a focus on review processes leads to faster review times and better satisfaction, I know they are an interlinked network of relationships.



At Vodori, as a software provider, it is our responsibility to make sure that the tool (in this case Pepper Flow) is easy to use, intuitive and configured to your business needs. The user well-being, however, is definitely much more of a shared responsibility; we will continue to explore the relationship between user satisfaction and faster review. The more we can demonstrate the link to hard business metrics (i.e. faster release of materials), the easier it will be for team leaders to dedicate time to improving well-being of teams performing the difficult task of material review.

Ultimately though, does a focus on well-being have to be proven to improve hard business metrics before we give it the importance it deserves? I know my view on this but encourage you all to discover your own answer. ▲

Dr Joe DiCapite is Director of Strategy UK/EU at Vodori. Download your report at vodori.com and search: 'benchmarks report' or contact the team on hello-london@vodori.com
Vodori is a Chicago-based software company, creators of the next generation material review software Pepper Flow with customers across the globe.

Life cycle

How can pharma help the NHS to support older people better?



With social care in crisis and hospital wards at breaking point, redesigning health and care services for older people has never been more important for the sustainability of the NHS. But how is the health service responding to the challenge, and how will it affect the way pharma works with NHS in the future? Wilmington Healthcare's Oli Hudson explores an age-old issue.

It is no secret that caring for older people is the mainstay of NHS business. Before the pandemic, around two-thirds of all hospital beds were occupied by people over 65, many with multiple and complex health conditions, aggravated by frailty. Treating these age groups accounted for more than two-fifths of all NHS spending back then. It is likely to be higher still today.

Wilmington Healthcare's recent *State of the Nation* report, meanwhile, shows that older age groups bore the brunt of the closure of hospital services during the pandemic: adult patients in the 55 and over age bands experienced 2.5 million fewer spells of inpatient care in 2020-21 compared to the previous year, with over 85s seeing over a million fewer episodes alone.

COVID-19, in other words, had a massive, cratering impact on the continuity of care provided to hundreds of thousands of elderly people, who now make up a considerable proportion of the record waiting lists we are now seeing. It is a situation further compounded by long-standing shortages in social care provision and widespread workforce and capacity challenges across pathways.

Unsurprisingly, on a macro level, population age also plays a key role in determining how a particular system fares on health indicators, including access and waiting times, as well as the prevalence of cancer, respiratory conditions, diabetes, cardiovascular disease and dementia.

New models of care

For all of these reasons, older patients now have a vital strategic importance for new integrated care systems (ICSs).

This is reflected, either implicitly or explicitly, in many of the five-year plans being developed by these systems. The Suffolk and North East Essex plan is a case in point: its 'higher level ambitions' include 'the best quality of life as we grow older' and 'the care and support we need at the end of our life'.

On the ground, these commitments are manifested in the work that health and care organisations are doing to improve support for older populations. These include:

- The introduction of technology-enabled care, such as virtual wards and other remote-monitoring solutions, which can enable more patients to be cared for safely in their own home (or in a care home)
- The expansion of preventative health services, such as frailty clinics or falls assessment services, the presence of social prescribing professionals in GP surgeries, and greater join-up with social services and mental health teams, to help identify and support those at risk
- Investment in multidisciplinary community health support, such as improved out-of-hours crisis response services and a more proactive approach to supporting care homes through the Enhanced Health in Care Home programme
- Changes in the way hospital-based services work, such as the introduction of same day Emergency Care services, patient-initiated follow up (PIFUs) for outpatient care, and the continuing expansion of virtual clinics to support patients and primary care teams.

‘Every system and locality will be different, so take time to gather evidence to inform your approaches’

Gilt-edged opportunities

All these developments have practical implications for the way pharma works with the NHS – while also offering some gilt-edged opportunities to join forces with health professionals to deliver higher quality care for older patients.

For many conditions, there will be significant changes to the care pathway, involving different points of entry and taking in a much wider range of health and care professionals with a direct involvement in the patient’s ongoing care.

For example, there will be extended roles for nurses, allied health professionals, pharmacists and advanced practitioners, and more overlap between acute/specialist and community teams as more care is pushed outside of hospital settings. Pharma will need to reflect this broader perspective in its stakeholder mapping.

The new approaches also carry with them the need to manage risks and work closely with older people and their carers to educate and inform them about the changes in their care – which pharmaceutical companies can support by forging new strategic partnerships with NHS customers.

A case in point is ‘patient initiated follow ups’, which all Trusts are being encouraged to introduce where appropriate. Patients will need information and advice to help them understand their

condition and when they may need to come forward for additional clinical care. Similarly, digital transformation creates the potential for digital exclusion of older age groups who may find it more difficult to transact with the NHS online or virtually.

Challenges emerge too when it comes to decisions about how drugs are administered for older patients. While the pandemic prioritised oral or subcutaneous methods over hospital-based infusion for practical, there is evidence that this creates issues with adherence among some patient cohorts.

How these risks might be mitigated – either by upskilling and supporting frailty teams and community-based health professionals, or by reverting to more traditional hospital-based infusion methods – needs to be part of the conversation pharma has with its NHS customers.

Industry’s response must also reflect the headwinds that many health organisations will be facing. Inadequate access to diagnostics, delays in hospital discharge due to lack of social care packages and skills shortages across the pathway may limit what the NHS can do for its older patients.

So how should pharma respond? Firstly, it is important to understand local realities. This may include looking at current diagnosis and referral patterns, waiting times, workforce capacity challenges, development plans, relevant patient surveys and any corporate commitments being made to improve service delivery. Every system and locality will be different, so take time to gather evidence to inform your approaches.

Secondly, it is helpful to leverage relevant policy in making your case for change. For example, it is worth looking at the growing collection of Getting It Right First Time (GIRFT) reports, which outline best practice case studies and expose variations in clinical practice across a range of disease areas and specialties (including geriatric medicine). NICE guidelines are also influential in shaping clinical decision-making. Make sure your value proposition is shown to be ‘going with the grain’ of national policy.

Thirdly, it remains vital to engage directly with the clinical community to raise awareness of disease and facilitate best practice across a given pathway. Pharma is often in a unique position to be able to describe and share what works, by drawing on a wealth of national and international experiences. Remember that this is invaluable evidence to help influence local decision-makers’ thinking.

In short, the unerring maths of demographic change tell us the challenge of supporting increasing numbers of older patients is not going away any time soon – indeed, the number of over-85s living in England is expected to double within the next 25 years.

By engaging intelligently with ICSs, pharma can make a significant difference to many older cohorts of patients today, while also playing a key role in making the healthcare system more resilient for the future. ▲

Oli Hudson is a consultant at Wilmington Healthcare.
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■ ValiRx – a company focused on early-stage cancer therapeutics and women's health – has bolstered its drug discovery and therapeutic expertise with the appointment of **Dr Cathy Tralau-Stewart** as its interim Chief Scientific Officer (CSO).

With more than 20 years' senior academic and industry leadership experience, Cathy joins ValiRx from drug discovery company C4X Discovery, where she was CSO and managed the project portfolio and research and development strategy. Prior to this, she was Senior Director of Alliances for Takeda Pharmaceuticals where she was responsible strategic development and management of academic alliances for the US, Australia, Japan and Europe.

Cathy started her career at GSK in various roles, before moving into academia where she built drug discovery portfolios.

■ **Matthew Skinner** is Care City's new Chief Executive Officer. Matthew will lead the company in its mission to secure a happier, healthier older age for East Londoners, through research, innovation and workforce development.

Other responsibilities will include securing future investments for the business, leading relationships with key partners and continuing to raise the profile of Care City through generating a positive image of the contribution the work makes to the community it serves.

As Care City takes possession of its long-term office in Barking next Spring, Matthew will also be responsible for making a success of this home, using it to bring benefit to the local community and as a platform to showcase Care City's work and mission. Matthew joins the team from TPXimpact where, as Managing Director, he oversaw the delivery of complex and innovative organisational change projects for public sector clients.



■ UPS has appointed **Cathy O'Brien** as UPS Healthcare's Vice President for International Sales.

Based in Ireland, Cathy will be responsible for driving growth across Europe, AMEA and Latin America for the end-to-end supply chain service dedicated to supporting pharma, medical device, lab and dental segments. Cathy joined UPS in July 2016 as a Managing Director for UPS Healthcare's European business and took on further responsibility for the ISMEA region in 2020.

UPS Healthcare is growing its global footprint and has recently announced plans to acquire the Bomi Group, which has temperature-controlled facilities in 14 countries across Europe and Latin America. The acquisition will add nearly 3,000 team members to UPS.

■ Myeloma UK, the national charity for the incurable blood cancer myeloma, has appointed **Shelagh McKinlay** as its new Director of Research & Advocacy.

The position is a new role for Myeloma UK, consolidating the full portfolio of the charity's clinical and health services research alongside its policy, drug access and clinical practice focus.

Shelagh holds 25 years' experience in high profile policy roles, with over eight years of experience specialising in policy and treatment access in blood cancer. Recently, she served on a task and finish group as part of the NICE Methods Review as well as taking up membership of a working group looking at NICE processes.

She also led the team that earlier this year produced the report, *A Life Worth Living*, which focused on the importance of quality-of-life outcomes to patients with the incurable blood cancer myeloma; benchmarks that the charity is currently pressing to be recognised in the English and Scottish cancer strategies.



Mover of the Month

■ Envision is pleased to announce the appointment of **Meg Heim** as its new Chief Executive Officer. Meg is an accomplished business leader with strong leadership experience, and an established reputation within pharmaceutical, medical device and health technology markets. Throughout her career she has championed the professionalism of medical affairs and the innovations that improve patient experience. Working closely with a strong and experienced executive leadership team, Meg will be responsible for delivering an ambitious five-year plan that will reinforce Envision as a global leader in scientific and commercialisation strategy and solutions, medical affairs, and life cycle planning enabled by leading technology solutions and world-class people. Meg joins Envision at a pivotal moment, with Group performance accelerating as it continues to deliver a compelling combination of technology and services to clients.



■ Onyx has announced the appointment of **Trevor Pill** as its new Managing Director. He will be taking over the day-to-day running of the agency from owner and founder Karen Winterhalter, who originally set up the agency in 2003.

Trevor's key priority in his new role will be driving forward the agency's international growth plans and establishing a commercial presence in the United States. Onyx Health already has several major national and international clients in the pharmaceutical industry, including Bayer, Clinigen, Nova Laboratories and Foot Science International.

Trevor plans to expand Onyx Health's existing service offer by developing omnichannel campaigns to establish it as a leading independent healthcare agency.

■ Optibrium – a developer of software and artificial intelligence solutions for drug discovery – has announced three appointments: **Michelle Harrison** as Head of Strategic Marketing, **Chris Khoury** as Associate Director of Business Development and **Imran Ghauri** as Business Development Manager.

The appointments bring extensive AI and life sciences expertise and will align global business development and marketing strategies to further develop and commercialise the company's computer-aided drug discovery technologies.

Michelle joins Optibrium as Head of Strategic Marketing with eight years' marketing experience, delivering high-impact strategy and effective marketing campaigns for scale-ups in the drug discovery and digital health space to successfully target global pharma, biotech, academic and investor audiences. Michelle was previously Senior Marketing Manager at Healx, where she gained significant expertise in the AI drug discovery space, as well as cultivating the brand.



■ Cherwell Laboratories, supplier of environmental monitoring and process validation solutions for the pharmaceutical industry, has expanded its cleanroom microbiology sales specialist team to create additional support for customers in the north of the UK. **Eleanor Corbett** has been appointed as Cherwell's Business Development Manager across the north.

An experienced microbiologist with over 25 years of laboratory practice, Eleanor is well placed to work closely with Cherwell's customers to fully understand and help them meet their specific environmental monitoring and validation needs.

Her microbiology experience is extensive, transitioning from technician to lab management, plus quality and site management roles, predominantly in the food and water industries. More recently Eleanor has evolved to business development in the life sciences sector.

■ Osivax, a company developing vaccines to provide broad-spectrum protection against highly mutating infectious viruses and diseases, has announced the expansion of its leadership team with the appointment of **Dr Vincent Bille** as Chief Manufacturing Officer.

His years of experience and in-depth knowledge of Chemistry, Manufacturing and Control (CMC) will be instrumental for the scale-up of the manufacturing process for its lead programme, OVX836, a broad-spectrum influenza vaccine candidate currently in phase 2 clinical evaluation.

Vincent has already contributed to Osivax' manufacturing strategy through the certification of his quality control lab, located at the heart of the Liège Science Park, that will enable the release of OVX836 batches for use in clinical trials.

Before joining Osivax, Vincent spent 15 years as an independent consultant for biotech and pharmaceutical companies.



■ Pharma digital consultancy, Kanga Health has created two new leadership roles within its management team. The roles will help the agency support a string of new clients.

Audrey Gent, Client Services Director, will be responsible for leading the 25+ team of digital strategists, and the development of strategic services across the agency. She will ensure that Kanga processes – internally dubbed the 'Kanga Way' – is echoed in all that the agency does for its clients and the healthcare and pharma industry.

She is also the senior point of contact for the day-to-day management of key clients, to integrate new ideas, strategies, and solutions; leads client programs; and projects from a strategic business perspective.



Helen Harrison, Client Strategy Director, is Kanga's senior authority on the agency's strategic customer and patient-centric approach. Helen is responsible for ensuring internal strategic methodologies are current, effective and tailored appropriately to each client's individual needs, and are being implemented accordingly. As well as providing strategic direction to Kanga's client-facing business and to client projects.

Helen and Audrey bring immense pharma and consumer experience, spanning over 23 years. This includes senior roles at AstraZeneca, Pfizer, Veeva and Eli Lilly, alongside a decade of combined years at Kanga Health.

Unbelievable site

PharmaTimes Awards 'Clinical Site' category winners, Surrey & Sussex Healthcare (SASH) NHS Trust talk about why getting recognised will have a lasting impact



PharmaTimes Editor John Pinching talks to SASH's victorious trio – Samantha Clueit, Louise Nimako and Sarah Davies – about what lifting this prestigious award means to them.

What has been the most satisfying aspect of your victory in the site category?

Louise: Being able to showcase our site's experience and being recognised for it.

Sarah: To feel that our hard work has been recognised, especially during a particularly challenging year.

Samantha: Having what I already know – that our site is a winner – confirmed!

What aspects of your clinical research sets you apart?

Sarah: Collaborative team working! We have great working relationships with our support services and engagement from clinical colleagues.

Samantha: Our great teamwork, feasibility and set-up processes consistently delivers on time and target. Most importantly it reflects

our relationships with, and our dedication to, our research participants and patients.

Louise: We are a cohesive team who collaborate well, embedding our SASH values and putting patient experience at the forefront of what we do. We have also developed excellent experience in planning, implementation, delivery and problem-solving.

How has your approach to engagement with patients enabled you to be successful?

Samantha: Know your patients and patient groups – what works for some won't for others.

Louise: We consider research as part of a patient's journey of care. Close collaboration with, and integration within, clinical teams enable us to understand the needs of our

patients.

Sarah: Being as flexible as possible to participant needs has resulted in important relationships and ultimately supports retention, particularly in long-term follow-up studies.

'The pandemic was a catalyst for change in research delivery. We had to adjust quickly to some new ways of working'

How did the international pandemic change how you conduct clinical trials?

Louise: The pandemic was a catalyst for change in research delivery. We had to adjust quickly to some new ways of working, such as remote consent. In the long term, this has introduced some flexibility into protocols and trial activities enabling greater choice and opportunities for patients to participate.

Sarah: This led to significant changes in consent processes and how we facilitated our visits. Putting mechanisms in place to ensure direct-to-patient shipment of study medication has enabled our participants to continue their involvement with no break in study treatment.

Samantha: We adapted to ensure our research participants continued to get the treatments and care they needed. It was good to see sponsors keeping certain processes post-pandemic, such as changing in-person visits to virtual.

How much has better communication and the digital era ignited your operation?

Sarah: Electronic health records makes retrieval of medical data a lot more accessible. Smartphone apps have also revolutionised the collecting of patient reported outcome measures and using social media for study promotion has increased research awareness and participation.

Samantha: Ignited? We've always been on fire!



Our Clinical Site award winners are joined by Jennifer Harris of the ABPI, NIHR's Sine Littlewood and host Dr Sarah Jarvis

Louise: We recognise the benefits in relation to clinical research but also some of the challenges associated with the increase in digital platforms and solutions.

Are patients more likely to get involved in clinical research these days?

Louise: I think it's about the same although there does seem to be more awareness of research, post-pandemic. Patient motivation is still about what, where, how and who presents the research opportunity to them.

Sarah: Patients surprise you all the time. Their generosity and thinking about the future. There's certainly a sense of wanting to give something back.

How do you see the patient/provider dynamic changing over the next few years?

Samantha: I foresee patients being more active in their care and asking HCPs about treatment options, which includes research.

Sarah: Patients being more involved in their care with research being introduced from the beginning as an option in the patient's care pathway

Louise: A focus on cost and efficiency will cause changes to the provider landscape, which may impact on a site's ability to deliver certain types of research activity. Platforms such as NIHR's #BePartofResearch are enabling patients to identify research opportunities themselves and this may influence their provider choice.



What advice would you give future entrants into this category?

Louise: Team selection is key – the three of us all brought something slightly different to the table by virtue of our experience and skill sets, as well as a shared passion for clinical research.

Sarah: Apply! I thoroughly enjoyed the whole experience with my team and winning gold at the end was just the cherry on top.

Samantha: Go for it, showcase your talents and relish the challenge! ▲

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