Women leaders in UK healthcare

25 women leading by example

Maximising impact at congresses

What’s stopping change in clinical trials?

The $2.1m gene therapy  Europe looks ahead  Microbiome therapies  Lessons from Lartruvo
PMEA 2019
Recognising excellence in improving patient outcomes

OPEN FOR ENTRY

For further information contact Amy Watson on +44 (0)1372 414248 or awatson@pmlive.com

Full details and entry information at www.pmlive.com/pmea

For sponsorship opportunities please contact sales@pmlive.com

- Excellence in Patient Education and Support
- Excellence in Healthcare Professional Education and Support Programmes
- Excellence in Collaboration and Partnerships
- Award for Patient-Centricity
- Excellence in Engagement through Multiple Channels (Digital and Traditional)
- Excellence in Product Introductions
- Excellence in Managing Established Products
- Excellence in Rare Diseases and Orphan Drugs
- Excellence in Building Corporate Reputation and Trust
- Excellence in Innovation
- Excellence in Pharma Brand Management (new for 2019)
- Excellence in Capability Development
- PMEA Support Agency of the Year
- The Lucid Group Award for Company of the Year

ENTRY DEADLINE 29 AUGUST 2019
*EXTENDED ENTRY DEADLINE 5 SEPTEMBER 2019

SPONSORS
Our cover star this month is a plucky little bronze statue called Fearless Girl. She originally took up her defiant pose outside the New York Stock Exchange, but can currently be found in London outside London’s own stock exchange.

She represents, of course, a new sense of purpose and optimism around the promotion of women in work and society – a movement we return to in this issue’s special feature, 25 Women Leaders in UK Healthcare, starting on p16.

My heartfelt thanks to all the contributors to the feature, including those who featured in the list and those who kindly nominated others or who offered the deserving praise for these women leaders.

The UK pharma and biotech sectors, along with academic research leaders, continue to warn that a no-deal exit will be a very serious blow to the UK’s life sciences base, and must be avoided at all cost.

While there are dissenting voices within the Conservative party and Parliament there is hope it can be avoided, but the life sciences sector must continue to argue its case for the sake of its long-term health.

Read more about developments in Europe and Brexit on pages 12-13.
COMMUNIQUE
Awards 2019

CELEBRATE OUTSTANDING WORK IN HEALTHCARE COMMUNICATIONS ON 4 JULY!

Some of our 2018 winners

2018 Excellence in Social Media Strategy - 90TEN
2018 Healthcare Communications Leader - Kate Pogson
2018 Communiqué Communications Consultancy of the Year - Lucid Group

Book your tickets online www.pmlive.com/communiquetickets or contact Amy Watson on +44(0)1372 414 248 or email awatson@pmlive.com

Sponsors
JUNE 2019

NEWS
6-7. BioMarin in haemophilia lead; Lundbeck gets in on M&A act with Tourette’s buy; This year’s ASCO congress

8. Europe and the gene therapy challenge

10-11. Novartis secures US approval for new rare disease gene therapy Zolgensma

BREXIT NEWS
12-13. EU elections: Eurosceptics rise, but big parties hold on

DARWIN’S MEDICINE
14. Biology teaches business how to change

UNFRIENDED
15. Healthcare is the next frontier for fake online content

WOMEN LEADERS IN UK HEALTHCARE
16. 25 women trailblazers who are helping to shape the future of healthcare

LIZ HENDERSON
26. Merck UK & Ireland’s managing director on her ‘non-linear’ career path and the importance of mentoring

THE LARTRUVO WITHDRAWAL
28. The future of paying for conditional approval therapies

STREAMLINING CLINICAL TRIALS
30. Why better data use is key

A BUG’S LIFE
32. The power of microbiomes

THE SOCIAL DILEMMA: IS IT TIME FOR PHARMA TO JOIN THE PARTY?
36. Why social media still isn’t trending for pharma

PHARMA BRAND PLANNERS’ BLOG
40. Putting the moose on the table

BREAKING FROM TRADITION
41. How social media can improve doctors’ congress experience

WHAT PHARMA MARKETERS CAN LEARN FROM DISNEY
44. Why we need to continue to innovate, and surprise our audience

HEALTHCARE COMMS
46. Synergy Vision and Axon ranked among UK’s best workplaces

PEOPLE
50. Q&A with Raman Sehgal

APPOINTMENTS
47. Changes at Kintai Therapeutics, LEO Pharma and bluebird bio
THE BIG STORIES

Nine developments in the last month, and why they matter to biopharma and healthcare

1. Zolgensma approved with $2.1m price tag (see p10)

2. BioMarin in haemophilia lead

BioMarin has reported three-year data on its gene therapy for haemophilia A that sets up filings in Europe and the US, but also raises questions about its long-term value. BioMarin’s therapy, called valoctocogene roxaparvovec or ‘valrox’, improved levels of clotting Factor VIII sufficiently in eight of 20 adults with severe haemophilia A in the phase 3 GENER8-1 trial to meet the pre-specified criteria for regulatory review. What spooked investors – and sent BioMarin’s share price down 5% – was that Factor VIII levels seemed to fall off over the course of the study, leading to concerns about the durability of the response to what was originally intended as a one-shot therapy.

3. Lundbeck gets in on M&A act with Tourette’s buy

Danish drugmaker Lundbeck has moved to bolster its pipeline with a $400m deal to acquire Abide Therapeutics and its lead drug for Tourette’s syndrome and neuropathic pain.

The deal – which comes a few months after Lundbeck recruited new chief executive Deborah Dunsiere to orchestrate a turnaround of the business – includes an upfront payment of $250m and another $150m in development and sales milestones.

Neuroscience specialist Lundbeck has been facing declining sales of its older drugs and needs to reinvigorate its pipeline, a task made more difficult as developing neurology and psychiatry drugs is notoriously challenging. Efforts to bring forward its own drugs have been undermined by a couple of late-stage failures, including idalopirdine for Alzheimer’s disease and Lu AF35700 for treatment-resistant schizophrenia.

Under the deal, Lundbeck will gain access to the US biotech’s lead candidate ABX 1431, a potential first-in-class inhibitor of the serine hydrolase monoacylglycerol lipase (MGLL), as well as a discovery platform targeted at serine hydrolases based at a research unit in La Jolla, California.

4. Is this the EU’s next leader? (see p12)

5. Fish oil product close to approval

Amarin could be just a few months away from a lucrative cardiovascular outcomes claim on the label for its fish oil-derived product Vascepa, after the FDA agreed a priority review for the application.

The priority review sets up a possible approval of the additional indication for the drug in September, around four months earlier than expected.

Vascepa (icosapent ethyl) is already approved to treat elevated triglycerides, a risk factor for heart disease, but could see its usage rise markedly if it also gets the new cardiovascular risk reduction claim, with analysts forecasting anywhere between $1bn and $2bn. The filing is based on the stellar results of the REDUCE-IT trial in more than 8,000 statin-treated adults with elevated cardiovascular risk, reported last year. It achieved a reduction of 25% in major adverse cardiovascular events (MACE) and a 20% reduction in deaths.

6. ‘Landmark’ price transparency accord

A new resolution to demand greater transparency from the drug pricing has been called a landmark decision by many. The resolution, first put forward by Italy, was passed at the WHO’s World Health Assembly, despite opposition from the UK, Germany and Hungary.

It says nations should now ‘take appropriate measures to publicly share information on net prices’ and proposes structures to make this a reality.

The resolution originally called for the WHO to compel pharma to disclose information on drug pricing and allow it to analyse data on procurement prices and costs from clinical trials. However, the strongest measures were written out of the agreement.

Most remarkable was that the US voted in favour of the resolution – American government defence of the sector has been unwavering over the years, but the Trump administration’s ‘war’ on drug prices has changed the policy dramatically. The pharma industry argues that confidentiality allows it to set prices that are in line with each country’s ability to pay.

Many see the resolution as a big step forward. James Love of campaign group KEI said: “There is a big community that wants to pull back the curtain of secrecy and have more transparency...this resolution is a pretty good start.”
7. ASCO’s payload

This year’s ASCO congress has produced its annual payload of anti-cancer drug research across tumour types and drug modalities.

AstraZeneca and Merck & Co/MSD caused a stir at the congress with new data for their PARP inhibitor Lynparza in pancreatic cancer – a disease which is notoriously tough to treat.

The phase 3 POLO trial of Lynparza in advanced pancreatic cancer patients whose tumours carry BRCA mutations found that those on AZ’s drug had a progression-free survival of 7.4 months, almost twice the 3.8 months for a placebo group.

About 5-6% of pancreatic cancers are caused by mutations in one or both BRCA genes, more commonly associated with ovarian and breast cancer but observed in a range of tumour types. AZ’s head of oncology R&D José Baselga said it will submit the results to regulators “as quickly as possible”, potentially opening up a third indication for its fast-growing cancer drug, along with ovarian and breast cancer.

Amgen has achieved something that has eluded many other drugmakers by bringing a drug that inhibits the oncogene KRAS to the clinic and showing preliminary activity.

For three decades, mutations in the KRAS pathway have been recognised as an important factor in oncology, seen in around a third of all human cancers, but they became seen as ‘undruggable’ after repeated failures.

But now Amgen has reported good safety, tolerability and preliminary anti-tumour activity in a phase 1 trial of its AMG 510 candidate – which targets a KRAS mutation known as G12C.

The study in 35 patients found no dose-limiting toxicities at the tested dose levels, and revealed a 50% partial response rate among a subgroup of ten patients with KRAS-positive non-small cell lung cancer (NSCLC). Another four NSCLC patients had stabilised disease, giving the drug a disease control rate of 90%.

Amgen intends to move ahead quickly with additional studies of the drug, both alone and in combination with other targeted and immune therapies and in a broader range of tumour types.

Novartis and Merck KGaA have both reported phase 2 results from rival drugs designed to treat a rare form of non-small cell lung cancer (NSCLC), setting up a race to approval.

Novartis’ capmatinib and Merck’s tepotinib both target the MET-signalling pathway, which is mutated in 3-5% of NSCLC cases and tends to cause aggressive tumours with a poor prognosis for patients.

Direct comparisons between the two drugs are difficult at this stage, but both seem to have activity in a patient group that currently has no targeted therapeutic options.

Patient numbers in the studies are small, but both Novartis and Merck think their studies could be used as registration trials.

The data marks an inflection point for the well-known MET inhibitor class, which has been in search of a suitable indication to give it a clear path to regulatory approval.

8. Brexit. Trump. The Tory leadership contest, the NHS and pharma (see p13)

9. Verily unveils next-gen trials alliance with Novartis, Pfizer

Google’s healthcare spin-off Verily has unveiled a handful of big pharma companies as its first partners in a project to revolutionise clinical trials.

When it was launched by Google in 2015, Verily was seen as potentially a major disruptor of the current healthcare model, but the company has played its cards close to its chest for the past few years.

Now the company is teaming up with Novartis, Otsuka, Pfizer and Sanofi to transform clinical trials – which the industry, regulators, leading research and patient advocates all agree rely on outdated, cumbersome and inefficient systems that aren’t built around patient needs.

There’s no question that in recent years there have been many other initiatives to introduce digital tech and data initiatives to streamline trials, from incumbents and new entrants, so Verily is far from alone in the field.

Nevertheless, now it has invested heavily in setting up its ‘Project Baseline’ and relationships with key healthcare stakeholders, Verily clearly believes it can exploit its expertise in data management to become a leader in this multi-billion dollar field.

The partners say they aim to develop digitally innovative, patient-centred clinical research programmes using Verily’s Project Baseline’s evidence generation platform and tools.
Europe and the gene therapy challenge

Germany, Italy and England use outcomes-based deals, but progress is piecemeal

Europe is adapting to high-cost, specialised treatments reaching the market via accelerated access initiatives, including cell and gene therapies – but models are still in their infancy and a co-ordinated approach to value across the region would benefit all sides.

That was the message from a panel of industry leaders in the field at a conference in London in May, who shared the platform with payers to discuss how advanced therapy medicinal products (ATMPs) can gain market access.

Last year saw the launch of three groundbreaking products in Europe: the CAR-T competitors, Kymriah from Novartis and Gilead’s Yescarta and Spark’s rare eye disease gene therapy Luxturna.

Novartis and Gilead were successful in agreeing very rapid market access deals with NHS England in September and October last year respectively. The terms of those deals remain confidential, but are thought to include some outcomes-based components.

CAR-T market access in UK and Germany

Then in March, Novartis secured market access for Kymriah in Germany via an outcome-based deal, something which previously had been virtually unheard of in Germany. A coalition of health insurers, GWQ (Gesellschaft für Wirtschaftlichkeit und Qualität für Krankenkassen), has agreed to pay €320,000 for Kymriah, with payment based on overall survival in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL).

The Advanced Therapies & Regenerative Medicine congress, hosted by Terrapinn in May, brought together a panel of experts who discussed emerging reimbursement and financing models in the US and Europe. Tamir Singer, head of commercial development, specialised commissioning, NHS England, said his organisation was increasingly interested in integrating real-world evidence into reimbursement deals for ATMPs.

However, he said there were some clear limits to outcomes-based deals that NHS England would consider, and that the arrangements needed to be 'transactable'. This means the agreement needs to be based on clear and unambiguous clinical criteria, such as overall survival, or whether the treatment has prevented the need for the patient to have an organ transplant or not, for instance.

Sharing the platform was Carla Deakin, commercial and managed access, NICE, who underlined that her organisation and NHS England are now working much more closely together than before to provide a seamless market access route for industry.

That was illustrated last year when England became the first major European country to agree market access deals with both Gilead and Novartis for their CAR-T products – a contrast to recent history where England has often been a slow adopter of novel therapies.

Mr Singer indicated that dialogue now starts early with companies to shape expectations and make requirements for managed access agreements and real-world data clear.

"Part of my role is to educate companies about what this could look like when they are approaching a NICE appraisal. We work very closely together [with NICE] to make sure we can prepare companies and maximise the chances of faster access."

Chairing the session, Alexander Natz, secretary general of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), said Germany’s market access pathway was also changing.

He commented that Germany has always demanded high standards of evidence to support reimbursement decisions, and as such has not accepted that real-world evidence is robust enough. However, the changing dynamics of the pipeline and regulatory approaches mean the reimbursement field is also changing.

Germany’s GSAV legislation was introduced to the country’s parliament in November last year, and looks set to become law by June 2019. Among its provisions are plans for compulsory patient registries for all orphan products and medicines approved via conditional approval or exceptional circumstances.

The new law would give Germany’s G-BA (or Federal Joint Committee, the key market access decision-maker for the country) powers to dictate the data requirements for such products to the industry. This contrasts with the current situation, where this is determined through a dialogue between it and pharma companies.

Italy

Chiesi’s Holoclar is another groundbreaking ATMP, a stem cell replacement therapy for patients with the rare blindness condition limbal stem cell deficiency, which gained European approval in 2015. The company gained conditional approval for the treatment based on retrospective data and a value dossier, and has an ongoing international trial to support the conditional approval with confirmatory data. Giorgio lotti, head of programme leadership and special projects at Chiesi, told the conference that launch and market access was ‘complex’, with great variations across Europe.

“I think we have had a different situation in each European country…[which] is not good…I think we should at least have better organisation in how you evaluate the value of a product.”

He said that even while it might end up with different prices in the respective countries, there should nevertheless be a common understanding on what represents value across Europe. Italy is well known for being a pioneer of outcomes-based deals, and in Holoclar’s case, this involved a money-back guarantee if the product had failed to work after 12 months.

However, Mr Lotti indicated that the administration of this was more complicated than it needed to be: Chiesi was obliged by the EMA to set up a pan-European patient registry to monitor safety, but a second national-level registry was also set up in Italy and overseen by physicians, which collected the data to supply the pay-for-performance deal.

NHS England’s Tamir Singer says outcomes-based deals need to be ‘transactable’ – based on clear and unambiguous clinical criteria, such as overall survival

Mr Lotti called for "more collaboration, more harmonisation and better dialogue" between European systems to allow for smoother and faster uptake.

Extra notes of caution about the difficulty of gaining access for such therapies came from Axel Boehnke, director, market access, PTC Therapeutics, who stressed that the CAR-T deals could not be seen as templates for all other cell and gene therapies, which would be taken on their own merits, depending on data and needs within the specific therapy area.

Zynteglo ready for launch

Also addressing the conference separately was Doug Denison, head of global pricing and reimbursement at Bluebird Bio, who was explaining the company’s payment-by-instalment system it is proposing for its gene therapies, starting with its beta thalassemia therapy Zynteglo, which has just gained conditional marketing approval in Europe, its first anywhere in the world.

European healthcare systems may provide slightly more straightforward access to cell and gene therapy than the US, thanks to single payer systems and fewer for-profit players in healthcare delivery.
BRAND LAUNCHES

Powered up

BY FISHAWACK

Now with wider global reach and greater depth of services

HEALTHCIRCLE

A MEMBER OF THE FISHAWACK GROUP OF COMPANIES

BRAND LAUNCHES • PATIENT CAMPAIGNS • INNOVATIVE DIGITAL

Call: +44 (0)20 7038 0650 or visit: www.healthcircle-uk.com
Novartis secures US approval – and payer’s blessing for $2m gene therapy

Zolgensma is world’s most expensive drug – and trailblazer for sector

Novartis has gained FDA approval for its new rare disease gene therapy Zolgensma, unveiling a price of $2.12m per patient, making it the first US drug costing over one million dollars and the world’s most expensive medicine.

Cell and gene therapy is the biopharma sector’s current big innovation area, but the profitability of the first products, such as Novartis and Gilead’s rival CAR-T therapies, has so far failed to match their groundbreaking results in patients, which includes a potential cure.

Novartis hopes that one-time gene therapy Zolgensma (onasemnogene abeparvovec-xioi) can not only deliver a lasting cure for infants with spinal muscular atrophy (SMA), but also provide it with a new blockbuster product – via an entirely new model of outcomes-based instalment payments.

For the growing number of cell and gene therapies in the pipeline, Zolgensma will be a test of how commercially sustainable the field is.

Approved on 24 May, Novartis’ product is the first gene therapy for paediatric patients under two years of age with spinal muscular atrophy (SMA), a rare genetic disorder which until recently meant a death sentence within a few short years for these children.

Zolgensma now has Biogen’s existing biologic treatment for SMA, Spinraza, in its sights. Launched in December 2016, Spinraza has helped transform expectations for these children and people who develop SMA in later life – but Novartis is now arguing that its gene therapy is more clinically- and cost-effective than Biogen’s drug.

In the pivotal phase 3 STR1VE and the completed phase 1 START trials used by the FDA to make its decision, all 15 infants treated with Zolgensma were alive and off permanent breathing assistance at two years of age.

Follow-up results presented by Novartis last month showed the ten patients who continued with follow-up study maintained all motor function gains from treatment, such as sitting without support, and were alive at three to five years of age.

As well as clinching evidence of the drug’s effectiveness in clinical trials, Novartis has also been meticulous in laying the groundwork with payers in the US and beyond for many months ahead – having flagged that the drug would cost millions, but arguing that it would be worth it.

Novartis CEO Vas Narasimhan says his company is creating a new clinical and payment model for gene therapy, which is helping patients and also generating cost savings for healthcare systems.

After having argued last year that the drug could be priced in excess of $4m per patient, Novartis’ decision to price it at the much lower $2.12m per patient has been greeted warmly by US payers and ICER, the Boston-based independent medicines cost-effectiveness watchdog.

Novartis say this $2.12m cost will be payable via a series of five instalments of $425,000 – a level which it says represents a 50% cost reduction compared to the ten-year cost of Biogen’s Spinraza, which must be administered for life.

Spinraza is priced at $750,000 for the first year, and $350,000 afterwards.

“Zolgensma is a historic advance for the treatment of SMA and a landmark one-time gene therapy. Our goal is to ensure broad patient access to this transformational medicine and to share value with the healthcare system,” said Vas Narasimhan. “We have used value based pricing frameworks to price Zolgensma at around 50% less than multiple established benchmarks including the ten-year current cost of chronic SMA therapy.

As well as bringing transformative benefits, Novartis say this price is made possible by a potential cure. The drug has been shown to be so effective that it has transformed clinical outcomes for those treated, including the ability to sit up without assistance at two years of age.

The ten patients who continued in Novartis’ pivotal phase 3 and phase 1 trials were all alive at three to five years of age, compared to Biogen’s Spinraza, which only has evidence of effectiveness up to two years of age.

Novartis say this has allowed them to price Zolgensma at $2.12m, a level which they believe is affordable for payers, given the potential cure.

Significantly, ICER has confirmed that it believes Zolgensma’s price just sneaks into the range it considers value for money.

ICER’s Steven Pearson

Steven D Pearson, MD, MSc, president of ICER, said: “Zolgensma is dramatically transforming the lives of families affected by this devastating disease... the price falls within the upper bound of ICER’s value-based price benchmark range.”

Given the severity of the condition, and Zolgensma’s early results, Pearson said insurers would go “cover Zolgensma no matter the price” even when Novartis has publicly floated the idea of a price approaching $5m.

He added: “It is a positive outcome for patients and the entire health system that Novartis instead chose to price Zolgensma at a level that more fairly aligns with the benefits for these children and their families.”

Waiting in the wings

Zolgensma looks set to be just the first in a new generation of $1bn+ gene therapies.

Bluebird’s beta thalassemia therapy Zynteglo

William Blair (WB) analyst price forecast: $1bn in the US, $900,000 in Europe

BioMarin’s Valrox factor for haemophilia A

WB forecast: near Zolgensma price, $2.12m

Sarepta’s SRP-9001 for Duchenne muscular dystrophy (DMD)

WB forecast: near Zolgensma price, $2.12m

Audentes’ AT132 for rare disease XLMTM

WB forecast: $3m
The company is offering this ‘pay-over-time model’, which it says fits with the US healthcare system, and has already established outcomes-based agreements in principle with as many as 15 payers.

The drug has been developed by gene therapy specialist AveXis, which Novartis acquired in April last year. It has established a partnership with finance lender Accredo to offer credit to healthcare payers via the five-yearly instalment option. Novartis says this will ease any short-term budget constraints, especially for US states, small payers and self-insured employers who wouldn’t be able to pay these sums upfront.

Among these payers is Harvard Pilgrim Health Care, which has made a name for itself in pioneering outcomes-based deals with the industry.

“We are thrilled to be able to offer our members access to this groundbreaking gene therapy, particularly in light of AveXis agreeing to place a portion of the cost at risk, contingent upon demonstrating continued performance over a five-year period,” said Michael Sherman, MD, MBA, chief medical officer of Harvard Pilgrim Health Care.

Analysts forecast the gene therapy could hit peak annual sales of between $1.8bn-$2.6bn.

A few key questions remain for Novartis and the success of Zolgensma. Chief among these is the long-term efficacy of the treatment – whether or not patients who respond initially to the gene therapy will see it maintained over years is yet to be seen.

The treatment hasn’t been without some safety concerns, either: an infection-related death in one patient in the STR1VE EU study is currently being investigated.

Another unknown is just how many patients Novartis can treat over the longer term, after an initial surge of patients came forward in the US.

According to David Lennon of AveXis, there are currently around 1,100 patients eligible for treatment with Zolgensma in the US. In addition to that, around 400 children are newly diagnosed with the condition in the US every year.

Novartis will need to treat all of these patients, and a similar amount in the rest of the world every year, in order to reach those peak sales forecasts.

Zolgensma could hit a sweet spot in the market, with a relatively small number of patients being treated and partially replacing an older drug (Spinraza) with a more cost-effective option.

Novartis isn’t expected to wipe out Spinraza, however – and it will also see competition from PTC Therapeutics/Roche’s late-stage SMA candidate risdiplam.

Analysts at Jefferies recently forecast the three therapies will split the market into roughly equal thirds, with Zolgensma claiming newly diagnosed patients who stand to gain the most from early intervention, driving sales of the therapy to $2.6bn at its peak.

Zolgensma is expected to gain approval in the EU and Japan in the coming months, where similar financing deals are being discussed.

Another gene therapy pioneer, with a similar payment model, has beaten Novartis to the European market, however – Bluebird Bio and its beta thalassemia treatment Zynteglo.

---

**Zolgensma in figures**

| Children newly diagnosed with SMA type 1 in the US every year | $8.7bn Amount Novartis paid to acquire AveXis last year |
| Proposed instalments in which US payers can pay for treatment | 18 months Average life expectancy of children with SMA type 1 without treatment |
| $425,000 x 5 | $1.8bn-$2.6bn Analysts peak sales forecast range for Zolgensma |
| $2.12m Total US price of the one-time therapy | 50% Novartis says Zolgensma works out 50% less expensive than Spinraza over ten years |
EU elections: Eurosceptics rise, but big parties hold on

Member states now haggling over choices for top Commission roles

After predictions that the EU’s political map could be hit by an earthquake, results from the European Parliamentary elections show the centre-ground parties have survived with a medium-sized tremor.

That was the picture when results from across the EU’s 28 member states were collated and put into the groupings which sit in the Parliament in Brussels. Country by country, the picture differs, however. The UK remains paralysed and fixated by Brexit, and the UK’s two biggest parties, the Conservatives and Labour, have been humiliated by two opposing tribes of voters who are angry about their policies. Both lost many seats to Nigel Farage’s newly minted Brexit Party, which is focused on seeing through the UK’s departure from the EU, and the resurgent Liberal Democrats, which have been buoyed by voters seeking to stop Brexit.

“Industry will be wary of the influx of Green party MEPs, traditionally suspicious of pharma lobbying and its profit motive”

Across Europe, Green parties and Liberal groups have made gains, as well as the right-wing nationalist and populist groups, who saw the biggest rise in the share of the vote, up 8.7%.

These largely Eurosceptic parties have a figurehead in Italy’s Matteo Salvini, leader of the Northern League which took pole position in the country with around a third of the total vote. Despite this surge, it’s easy to overlay the gains of the smaller parties.

Interim results from across the 28 EU member states show the two big groups, the centre-right European People’s Party (down 4.7%) and the centre-left Socialists and Democrats (-7%) remaining in a dominant position, despite both blocs having lost over 40 MEPs each.

They remain the two largest groups in a parliament of 751 MEPs, but have lost their traditional majority and will now have to turn to other parties to form coalitions. This will mean that the liberal ALDE group or the Greens will now have a decisive role in decision-making over the five-year parliamentary term.

Choosing new leaders

Attention now turns to the task of choosing candidates for a number of key roles, replacing current president of the European Commission Jean Claude Juncker, plus 28 EU Commissioners, and a new president of the European Council, currently Donald Tusk.

Manfred Weber, from the EPP bloc, has been the favourite to take over from Jean Claude Juncker, but the group’s poor showing at the elections means this is no certainty. The decision will be subject to much negotiation and horsetrading among the member states’ leaders, with France’s Emmanuel Macron believed to favour the current competition commissioner, Denmark’s Margrethe Vestager, over the Angela Merkel-backed Weber.

Pharma’s perspective

While Europe’s pharma lobby group the EFPIA has been as careful as ever to stay away from endorsing candidates, its leaders did urge Europeans to take part in the elections and engage with a pan-European vision. The sector is keen to see Europe deliver a pro-business and pro-innovation agenda, and this makes it fearful of the kind of disruption and breakdown in pan-European co-operation that is threatened by the nationalist parties.

An even clearer threat to public health and pharma has been the anti-vax movement, which has gained a voice among Italy’s populist eruptions in particular.

When the elections kicked-off on 23 May, EFPIA’s Director General Nathalie Moll said the health of EU citizens depended on “policy-makers, healthcare professionals, civil society and industry” to pool resources and expertise.

EFPIA developed its own manifesto for the elections, a nine-point plan which included driving an “evolution towards outcomes-focused healthcare systems”, fostering new clinical trial design supported by digital tools and a new “strategic dialogue on healthcare and life sciences” in the EU. Probably the biggest outstanding issue is the future of plans to introduce EU-wide health technology assessment regulations, which ran out of time to be finalised under the current Commission.

The industry will be wary of the new influx of Green party MEPs, who have traditionally been strongly suspicious of pharma lobbying and its profit motive. Moves to form a coalition against pharma and high prices for specialist medicines is also growing, with Italy and other EU nations backing a new resolution for drug price transparency at the recent World Health Assembly.

Nevertheless, the new Commission is likely to continue its predecessor’s focus on supporting economic growth in Europe, where stagnation has helped foment the political unrest.
Deal or no deal? Brexit battlelines drawn in Tory leadership bids

UK pharmaceutical industry warns again on no-deal impact

Theresa May steps down from her roles as prime minister and Conservative party leader on 7 June, with the contest to succeed her now in full swing.

The leadership battle is clearly divided along Brexit lines between those still pushing for an orderly Brexit at all costs, and those on a no-deal ticket.

Former foreign secretary and Brexit hardliner Boris Johnson is currently considered the favourite, despite facing legal proceedings related to his claims of a £350m weekly dividend from Brexit he made in the 2016 referendum campaign, as well as doubts among his parliamentary colleagues about his abilities to hold high office.

Johnson and others, such as former work and pensions secretary Esther McVey, who either want to threaten no-deal in a new round of negotiations with the EU – or indeed aim for that outcome outright – are loosely gathered in one camp.

In the other camp are the likes of foreign secretary Jeremy Hunt and health secretary Matt Hancock, who want a deal to a smooth exit process that would be preferable to industry.

Johnson, remembered for his claims of a £350m weekly dividend related to Brexit he made in the 2016 referendum, is considered the favourite, despite facing legal proceedings and a number of key life sciences research professions be among those added to the list.

Jobs listed on the SOL are exempt from many of the current immigration restrictions, which include a cap on visas granted to many professions, including those working in life sciences research. The committee has recommended broadening the SOL to include all roles in several other occupations such as medical practitioners, nurses, programmers and software development professionals.

The MAC’s review comes as the UK government prepares to leave the EU, but another comprehensive review will be needed again when post-Brexit immigration rules are decided.

Fears about a strict post-Brexit immigration policy have been hampering life sciences recruitment since the referendum result three years ago, and they show no sign of being resolved soon.

Provisions included on the SOL list can ‘jump the queue’ as they don’t have to be above the £35,800 salary threshold, and employers don’t have to first advertise within the UK.

Biological scientists and biochemists were among those the MAC recommended to be added to the list.

UK pharma’s hard-to-recruit posts need foreign recruitment boost

A review of high-skilled and in-demand jobs has recommended ‘queue-jumping’ measures to attract extra workers from outside the European Economic Area (EEA).

The Migration Advisory Committee (MAC) has published its full review of the shortage occupation list (SOL) and recommended that a number of key life sciences research professions be among those added to the list.

Bioinformatics, clinical pharmacology and immunology were among the roles it highlighted as having shortages.

“The UK needs a highly-skilled workforce so we can maintain high-quality research, create the advanced treatments people need and secure better outcomes for patients,” said Andrew Croydon, Director of Skills and Education at the ABPI.

“I want to create advanced treatments, increasingly we need our scientists to study the immune system and harness the power of genetics – hence all these disciplines are vital. Putting these fields on the shortage occupation list will help us as we look to address the evolving shortages we face.”

New post-Brexit rules have not been finalised and much depends on who becomes the next prime minister (the leadership contest is now underway) and how Brexit itself plays out.

Vaccine vulnerability

Meanwhile, Sanofi UK managing director Hugo Fry has warned that a no-deal Brexit would cause major disruption of the UK’s flu vaccination programme, leading to a rise in hospitalisations and “huge” financial costs to the NHS.

Speaking to The Times, he said that seasonal flu vaccines are particularly vulnerable to supply chain disruption as they cannot be stockpiled, and need to be produced in the months before the flu vaccination season.
Biology teaches business how to change

In a transforming market, the term ‘change management’ is tautological because management is rarely about anything but change. It follows that an understanding of the mechanics of change – how it happens and why it often does not – is among the most valuable knowledge a manager can acquire. So what can evolutionary science teach us about change in life sciences companies? Quite a lot and, if you can bear with me for a few minutes, I’ll get there.

Pharma and medtech companies are built on a body of knowledge that is both deep and wide. If you wrote down everything your company knows about how to invent, develop, make and market its products, it would be a huge, multi-volume work. And while that expertise is the rock on which your competitiveness is built, it is also the rock to which your company is tethered. Knowledge-based companies can’t suddenly transform into something based on very different knowledge. But nor can they afford to ignore their changing environment. They need to maintain that knowledge asset while changing how that asset fits with the market environment. How can they do this? The answer lies in their biological analogues.

Knowledge-based companies are like plants that must respond to, for example, climate change but can neither move to another environment nor rewrite their genome. How organisms adapt to changing environments has useful lessons for life sciences companies. When a plant changes its appearance or physiology without changing its genome, it is called phenotypic plasticity. There appear to be two, not mutually exclusive, mechanisms by which this happens. The first is exemplified by the way many wetland plants respond to drought and involves two capabilities: sensing when a specific environmental change reaches a threshold level and then initiating a specific, necessary change. This first and relatively simple mechanism, in which a given level of specific environmental change leads to pre-determined phenotype change, is ‘baked in’ to the organism’s genome. The second mechanism is more sophisticated. It involves gene regulation mechanisms, triggered by the numerous environmental changes, that enable a wider and more variable amount of change in the phenotype. We see this mechanism in many plants but also in some butterflies, which change colour, and Rockhopper penguins, who adapt their behaviour in response to changing conditions. In this second, more complex mechanism, what is baked in to the genome is not just a single, specific response but a more generalised ability to change.

How this applies to companies

We see the first change management mechanism in most life science companies. For example, when competition suddenly intensifies at the loss of exclusivity, firms are often hardwired to cut marketing costs in response. My work traces this response to a specific organisational routine that works backwards from profit targets to define what marketing costs can be. This is widespread in pharma and medtech companies. It may be effective, but it is rigid and inflexible. More interesting is the less-commonly observed second mechanism, which biologists call adaptive plasticity. This involves a more complex set of organisational routines for sensing and understanding market change and then selecting and implementing a range of changes.

We see this in, for example, companies that adapt to maturing, segmenting markets by creating a series of segment-specific value propositions that involve products, pricing and beyond-the-product value. In my work, this sophisticated adaptive capability can be traced to a complementary set of organisational routines that sense change, develop insights, target resources, design propositions and shape the organisation to deliver them.

The net outcomes of this set of routines are called dynamic capabilities; those which change things inside the company so that it may better fit with its external environment. Looked at in this way, we can see that the first, simple mechanism of change is a narrow, rigid version of the second mechanism.

What does all this mean in practice? Biology implies that it is simple to install the first (single routine) mechanism into a company but much harder to install the second (multi-routine) mechanism. That explains why so many change initiatives fail: firms install a simple mechanism of the first type when what is needed is a complex mechanism of the second type. It’s a case of doing what is easy instead of what is right. This mistake is particularly disappointing given that we now have a good understanding of the organisational routines needed in the second mechanism. The result of this mistake is a lack of phenotypic plasticity and a failure to adapt to a rapidly changing world.

The recent UN publication about one million species facing extinction was evidence of this in the natural world. In the life sciences market, lack of phenotypic plasticity is shown in worse commercial outcomes and shorter, worse lives for patients. We should take a lesson from the species that thrive, not those that are disappearing.

Professor Brian D Smith is an expert on the evolution of the life sciences industry. He welcomes comments and questions at brian.smith@pragmedic.com
A few weeks ago, an obviously doctored video of American Speaker of the House Nancy Pelosi appeared online. The video attempted to show her in a less-than-flattering light by slowing down her voice so as to give the impression that she was impaired, incoherent or possibly inebriated. Almost contemporaneously, information that discourages people to get their children vaccinated has gone viral on social media platforms and may have contributed to the recent surge in the measles outbreak in the US.

When questioned on CNN about the Nancy Pelosi video, Facebook VP for Product Policy and Counterterrorism, Monika Bickert, stated that viewers and users are “being alerted that this video is false”. That’s a nice sound bite, but it’s hollow. Providing people with a message that the content they are viewing, or reading, has been flagged and directing them to fact-checking links is a dubious strategy at best. At a behavioural level, this requires the users to do some work on their own. And at a practical level, in a time-constrained world, this rarely happens with any degree of critical mass.

In response to the anti-vaccine content, Facebook said: “It is exploring additional measures to best combat the problem.” That might include “reducing or removing this type of content from recommendations, including Groups You Should Join, and demoting it in search results, while also ensuring that higher quality and more authoritative information is available”.

Bickert went on to affirm that Facebook’s policy is to work with independent fact-checking organisations that drive the decisions about fake vs real content and that Facebook itself does not make these decisions. While this is a necessary check-and-balance on the system, it only works if you address the fake content quickly and remove it. It does not work if you take days to verify your fact-checkers’ claims and then decide that you’re going to keep the content online but ‘flag it’ for viewers, which is a toothless end run around the issue.

Here’s the rub: if social media platforms are going to continue to establish rules of engagement that do not include the truthful and accurate reporting or posting of content, then it’s just a matter of time before this problem becomes more widespread than it already is. I have advocated long and hard about this issue. The fact that patients have difficulty distinguishing between high and low value healthcare information. And how high health literacy is strongly associated with better health outcomes as compared to low(er) health literacy, and how we need to have a better system to adjudicate, authenticate and validate online health information.

But these recent and ongoing examples of shameless deceit paint an increasingly urgent picture of this situation. With their staggering reach, social media platforms and search engines are being weaponised to deliver false information (see Figure 1). This is not the case of some lunatic fringe group or ‘lone wolf’ individual that posts a single, benign piece of content in the far-flung corners of the internet.

For healthcare, this dangerous trend has implications that touch on all aspects of our industry. And this is problematic. Because today it’s about vaccinations and the impact on measles. Tomorrow it’s about adverse events for a particular drug therapy that potentially drives people to avoid complying with their medication. And next week, it’s about a fake post showing that Indian and Chinese manufacturers are using dangerous APIs for manufacturing drug therapies. And the week after, it’s about a local hospital’s emergency room being overcrowded so that patients are directed elsewhere. And in an election year, it’s about a presidential candidate’s health status (see Hillary Clinton circa 2016).¹

The solution is not obvious. And even if it was, it would be tremendously complicated. But healthcare is in the crosshairs of this growing and disturbing trend. We must, collectively, find a way to lead the way on this issue. This does not mean trying to control every piece of content on the internet. Or even trying to correct every snippet of misinformation. But it does mean that we must get our heads out of the sand. It means that we cannot rely on these massive social media conglomerates to fix the issue themselves in a silo. At a time when our industry continues to lose the public’s trust and when our industry’s reputation is in freefall, this may be an opportunity to demonstrate what we have always said is our raison d’etre: patients. If that is true, then this issue must be one that we prioritise and address immediately. Because the people who suffer the most from this are the patients.

Rohit Khanna is the Managing Director of Catalytic Health, a healthcare communication, advertising & strategy agency. He can be reached at: rohit@catalytichealth.com

Welcome to Pharmaceutical Market Europe’s special feature on 25 Women Leaders in UK Healthcare. This is our second annual list and this time we’ve followed the same formula as last year, albeit focusing on 25 outstanding individuals rather than 30 as we did last year, helping us to examine what makes these women leaders exceptional a little more closely.

There is no doubt that the last few years have seen some encouraging progress towards promoting women in society and the workplace, including it becoming increasingly commonplace for women to occupy the most senior positions in life sciences. However, there is little room for complacency as there remain many systemic and often invisible barriers.

One clear example of ‘unconscious biases’ at work is in health tech funding, which Ada’s Claire Novorol (number 7 on our list) says must be addressed if women are ever to have a level playing field. Let’s not overlook, also, the matter of ethnic diversity, where pharma and biotech most definitely still have a problem.

Meanwhile, the rolling back of access to abortion in some states in America – and its continuing illegal status in Northern Ireland – illustrates that rights need to be continually defended and campaigned for. Included in our list here is Sarah Ewart, the woman who has shown enormous courage in challenging Northern Ireland’s absolute ban on abortion in the courts.

This year, we’ve picked out some key themes which women say are particularly relevant to helping overcome obstacles. The first of these is mentorship and women ‘sending the lift down’ for other women. To back up this concept, we asked several of the women included in last year’s list to nominate other women who they thought were particularly deserving of praise. My thanks to everyone who contributed these suggestions, as well as those who volunteered the much-deserved praise for these 25 women.

The second theme, continued from last year, is a focus on women leaders who are helping to break down barriers between the different disciplines in healthcare – across the NHS, industry and academia, and digital health. Special thanks goes once again to the Healthcare Businesswomen’s Association (HBA) London chapter, who last year provided the initial inspiration for this feature, and who continue to further the cause of gender parity in our sector with great energy, and a generous and inclusive spirit.

Finally, the logic behind our list remains unchanged: this is not a ‘power list’; indeed there is no hierarchy (the numbering is there simply to make it easier to navigate), and it doesn’t strive to be definitive. Rather, these women have been identified for their leadership in their chosen field, often breaking out of the mould and taking a new approach to an old problem, even if they’re not in an ‘entrepreneurial’ role. We also wanted to illustrate the diversity of talent working across healthcare and emphasise how seeing UK healthcare as one ecosystem, and breaking down organisation barriers, is the best way forward for patients and society.
Melanie Lee
Research leader

Melanie Lee is one of the most respected leaders in UK life sciences, having excelled in roles across the spectrum, from her early work in academic genetic research through to drug development in pharma, and into leadership of several successful UK biotech firms. Today Melanie is chief executive of the medical research charity LifeArc, which she joined late last year, and which is about to transformed by a $1.29bn royalty deal based on its role in developing immunoncology blockbuster Keytruda. LifeArc already has a stake in a broad range of translational research, from investments in small-scale academic research to major drug development alliances with pharma, but now plans a significant expansion of its mission. She said each phase of her career has given her “new insights and unique challenges along the complex process of enhancing patient quality of life”, experience which she intends to put to good use at LifeArc. Lee joined LifeArc from her previous role as chief scientific officer at specialist pharma company BTG, and said one key attraction was the chance to accelerate translational research and catalyse convergence across currently very distinct life sciences disciplines. “The new wave of healthcare has to start to bring diagnostics, devices and therapeutics together.

If we’re really aiming for disruptive change in health treatment and in pathways, we’ve got to start to integrate those three. I left the industry to be able to facilitate that, and that’s what LifeArc can do.”

Lee is now reviewing LifeArc’s portfolio of projects, but sees scope for in-house research on pain, plus networked ‘open innovation’ style collaborative research on underserved areas such as neurology, dementia and antimicrobials.

Now Prof Hill and colleagues are taking the project into its next phase, steps which include the creation of 13 NHS Genomic Medicine Centres (GMCs), a state-of-the-art sequencing centre run by Illumina, and an automated analytics platform to return whole genome analyses to the NHS.

This means the UK has become the first nation in the world to apply whole genome sequencing at scale in direct healthcare, and is providing access to high quality de-identified clinical and genomic data for research.

The project has laid the foundations for an NHS Genomic Medicine Service to provide genomic testing to patients across the NHS from 2019.

Prof Hill is also an active advocate for more women in key STEM professions, including being patron of the WISE Fellowship scheme.

The coming Keytruda windfall will also allow the charity to set up a stand-alone venture capital division, with which it could seed funding and help promote research in key areas. She says she is delighted to see more women making progress into senior roles in the sector. This is thanks in part to the demise of the Old Boys network which she said was “very inhibitory to women” – but added that greater ethnic diversity in the sector will take many more years to bring about.

In January Lee was awarded the BIA’s Lifetime Achievement Award, and in her acceptance speech she laid out some thoughts on leadership. Among her biggest tips was to build a trusted professional network, which she says should span all age groups, thereby providing you with not only support, but also a natural talent pool and network when scouting for future leaders.

Sue Hill
Genomics Pioneer

Chief scientific officer for England, Professor Dame Sue Hill is the leader of no fewer than 50,000 healthcare scientists who work in the NHS and associated bodies.

She is also senior responsible officer (SRO) for the NHS Genomics Programme and has played a crucial role in enabling the groundbreaking 100,000 Genomes Project by ensuring these healthcare scientists were engaged in the programme.

The 100,000 Genomes Project, led by Genomics England, reached its goal of sequencing 100,000 whole genomes from NHS patients late last year, making it a world leader in the field.

It has already produced some life-changing outcomes, giving one in four participants in the project with a rare disease a diagnosis for the first time, and providing potentially actionable findings in up to half of cancer patients.

"The new wave of healthcare has to start to bring diagnostics, devices and therapeutics together. If we’re really aiming for disruptive change in health treatment and in pathways, we’ve got to start to integrate those three. I left the industry to be able to facilitate that, and that’s what LifeArc can do.”

Lee is now reviewing LifeArc’s portfolio of projects, but sees scope for in-house research on pain, plus networked ‘open innovation’ style collaborative research on underserved areas such as neurology, dementia and antimicrobials.

Ruth is the chief nursing officer for England and an executive/national director at NHS England and NHS Improvement.

She took on the role in early 2019, and is best known for the hugely successful ‘Stop the Pressure’ campaign, which nearly halved the number of pressure ulcers in one NHS region, improving care for patients, and delivering cost savings.

Nurses and midwives are the backbone of the health service, accounting for around 320,000 of its 1.5 million staff. However, hospitals have been struggling to retain and recruit sufficient numbers in recent years, with cuts to nursing bursaries identified among the major factors. NHS England is now aiming to recruit an extra 40,000 nurses over the next five years.

Key to May’s mission is ensuring that nurses, midwives and allied health professions (AHPs) can develop their careers and become leaders as she did, having served as chief executive of two NHS Trusts in her time. Also important is nurturing a happy working environment, including supporting improved mental health awareness in the workplace, and increased diversity across the NHS.
4 Jayne Spink  
**Rare disease patient champion**

Medical research is expanding our understanding of genetics and genetically inherited rare diseases daily, but this progress is agonisingly slow if you are living with a rare condition for which there is no diagnosis, or no treatment, or where there is no access to new therapies on the NHS.

Of equal importance is support for patients and families, especially in reaching a correct diagnosis as early as possible.

Jayne has more than a decade’s experience in the third sector, after earning a BSc and PhD in genetics, with postdoctoral research experience.

This insight into genetics is matched with experience in the Department of Health and NICE – the perfect combination to help rare disease communities navigate their way through the system and gain greater access to diagnosis and treatment.

Jayne has led Genetic Alliance UK for two years, a UK charity and umbrella group comprised of 200 third-sector organisations that variously provide support, information and funding for research.

Genetic Alliance UK is home to Rare Diseases UK that campaigns on behalf of all those affected by rare conditions, and SWAN UK, that provides support to families affected by ‘syndromes without a name’ which are likely of genetic origin.

Driven by a desire to ensure that no-one is denied care, treatment or support because of the rarity of their condition, Jayne strives for a future in which terms like ‘diagnostic odyssey’ are consigned to the history books.

At the heart of her work is a drive to help create strong and cohesive healthcare structures and resources in the UK to deliver the most up-to-date and effective options for patients with rare, genetic and undiagnosed conditions.

She works to empower patients, families and their communities in the corridors of power and ensure that their voices are heard in the decision-making processes that will affect their lives.

Jayne’s team added: “Jayne is a woman of action and confidence, unafraid to speak on behalf of the community she represents to those in power; she is equally empowering to her team, valuing our insights and expertise, supporting us in our work and development, and fostering a great workplace atmosphere of shared responsibility for the work of the charity.”

5 Professor Clare Gerada  
**Doctor campaigner**

Having qualified as a GP more than 25 years ago, Professor Gerada has a special interest in treating and raising awareness around mental health and substance misuse.

In recent years she has also been outspoken about the pressures on doctors, highlighting the high levels of burnout, depression and suicide in the profession. She has launched an award-winning programme to help GPs return to work after mental health issues, and set up a support group for those left bereaved after a death or suicide of a doctor.

A self-described ‘general agitator’, Professor Gerada is nonetheless respected by her peers (having served as RCGP chair) and NHS and government leaders.

In February she was appointed co-chair of a new forum set up to oversee the delivery of the NHS Long Term Plan.

The NHS Assembly will bring together front-line clinical leaders, staff, patients, and voluntary and community sector leaders to advise NHS senior leaders on implementation of the improvements it outlined.

6 Joanna Holbrook  
**AI drug discovery**

Professor Joanna Holbrook is director, translational biology at BenevolentAI, pioneers of AI-based drug discovery and development.

Joanna’s entire career has been dedicated to the study of genetics and she has moved seamlessly from the academic environment into a commercial one several times.

The firm has just signed a long-term collaboration with AZ for the discovery of new drugs for chronic kidney disease and idiopathic pulmonary fibrosis (IPF). The firms will work together to combine AZ’s genomics, chemistry and clinical data with BenevolentAI’s target identification platform and biomedical knowledge graph – a network of contextualised scientific data (genes, proteins, diseases and compounds).

7 Dr Claire Novorol  
**Digital health pioneer**

Dr Claire Novorol initially trained as a paediatrician in London before moving to Cambridge to work in genetics. She had a eureka moment when she understood the potential of technology to support medical diagnosis and decision-making.

Interested in an entrepreneurship role, she was introduced to Daniel Nathrah and Dr Martin Hirsch in Berlin, and co-founded Ada Health, an AI-based service. Ada Health is a decision-support service for doctors, while Ada is for consumers.

Ada is an artificial intelligence (AI) app that helps patients navigate quickly and accurately to the right health service and, ultimately, the right diagnosis.

A chatbot poses questions to the users and helps them to understand their symptoms, suggesting what a condition might be and how to seek further help.

Novorol and her colleagues don’t see Ada as being a replacement for interaction with healthcare professionals, but do see it as a major leap forward compared to ‘Dr Google’, where using a standard search engine to research health worries can do more harm than good.

Because of the nature of AI, the service is continually improving, with the team’s doctors training the software to fine-tune its answers.

So far, Ada has performed eight million assessments around the globe, and every three seconds a new Ada assessment is completed.

Claire is also a champion of promoting women leaders in the field. In a recent article for Forbes, she cited research by Rock Health which found that just one in seven health tech start-ups that received investment in 2018 had a female CEO – that’s just 13%.

She pointed to a number of factors, including unconscious biases in the overwhelmingly male leaders of VCs who select which entrepreneurs to back.

She continued that it’s not just gender diversity lacking in the field, but also ethnic diversity.

“We are going to need some fundamental changes if we are to ever properly redress the imbalance that exists in funding within healthtech,” she said.
You have big ideas for your business. You want to grow and expand, innovate and transform, and to do all this you want a partner that is like-minded. Side by side, we can shine. We’ve expanded our global footprint with offices spanning the UK and US, each with a team of talented star performers covering multiple disciplines, making us a seamless business with a true local attitude.

Together we can excel. Learn more at openhealthgroup.com
Dr Sam Roberts
Innovation translator

The UK life sciences sector has always lacked a single leader who could bring the NHS and industry together to work on promoting research and uptake of innovation to the benefit of business, patients and taxpayers alike.

In the last 12-18 months, Dr Sam Roberts has shown that this is possible.

Originally trained as a doctor, Sam practised medicine in her native Australia, South Africa and the UK before joining McKinsey and eventually specialising in healthcare. After McKinsey she moved into the NHS as a senior manager at a large teaching hospital in London (UCLH) and a director in an Academic Health Sciences Centre and Network (UCLPartners).

She was made NHS England’s director for innovation and life sciences in January 2018 – at a time when fears about the impact of Brexit on the sector were creating a new imperative for real collaboration between government and industry.

Within a year, Sam had led the development and implementation of a policy designed to attract more R&D investment from pharma and to protect the UK from the worst of Brexit and benefit patients by unlocking the NHS’ potential.

Working with the National Institute for Health Research (NIHR), the HRA and NHS Improvement, she led the introduction of new measures to eliminate variation and delays in setting up commercial contract research.

Accelerated Access Collaborative (AAC). This is a dedicated fund aimed at helping innovation that has been given the seal of approval by NICE and NHS England to fast-track uptake into the NHS. Pharma has been sceptical about the AAC’s value until now, but Dr Roberts’ leadership will give it a far better chance of making a real impact.

Speaking about innovation, Dr Roberts said: “This is one of the best times to be involved in innovation, because the need is so clear. We know funding is tight for healthcare, we know the needs of the population are changing, and that people are running their lives in completely new ways beyond healthcare. So it feels like a perfect storm for the transformative power of innovation to be unleashed.”

Technology has completely changed the power dynamic between individuals, organisations and power structures. I am really excited to see how, over the coming decades, people will become much more empowered about the kind of health information they want and the decisions they feel they can participate in.”

Ruth Marsh
Precision medicine leader

Precision medicine and the use of companion diagnostics now plays a fully integrated role in many successful new cancer therapies. But how do you deliver these companion diagnostics to healthcare systems and patients so that they reach the market with the medicines and keep innovating to maximise targeted therapy and patient benefits?

Ruth Marsh knows the answers to these questions, because over the last few years she has emerged as one of the industry’s leaders in the field and has played a key role in helping AstraZeneca’s renaissance in oncology.

Commenting on her colleague, Susan Galbraith, head of oncology at AstraZeneca’s IMED Biotech unit (and herself one of our listed leaders last year), said: “Ruth has helped transform AstraZeneca into an industry leader in precision medicine, with four launched drugs (Iressa, Tagrisso, Lynparza, Imfinzi) linked to companion diagnostics, 440 scientific papers and more than 90% of AstraZeneca’s clinical pipeline following a precision medicine approach.”

Key to her role is partnerships with diagnostic companies, and through these Ruth has delivered 28 approved diagnostic tests in three major markets. These include 11 industry firsts, including the world’s first use of circulating tumour DNA to guide therapy, which decreases clinical risks associated with solid tumour biopsy, and increasing patient access to targeted therapies.

Building on expertise in population genomics, Ruth initiated and provides science input to AstraZeneca’s genomics initiative, which aims to analyse 2 million human genomes, identifying rare variants that underlie common disease and applying machine learning, artificial intelligence and collapsing analysis to pinpoint genes that contribute to disease and drug response.

Ruth has more than 80 publications to her name, and led the first genome-wide FDA submission of a hepatic adverse event and the first tumour-based analysis of an AstraZeneca clinical trial. She serves on seven boards and advisory bodies and provides insight to global health authorities and government initiatives.
10 Theodora Harold
Biotech leader

While big pharma is making some significant strides in having women as their top leaders (most notably GSK’s CEO Emma Walmsley), the biotech sector, particularly in Europe, is not making the same progress.

It’s long been recognised that one of the biggest factors holding back UK and European biotech success has been a paucity of leaders, and that’s why efforts are being made to help promote women in these roles.

That’s why Theodora Hall taking on the top job at emerging UK biotech Crescendo Biologics is worth noting, as she represents a new generation of leaders in the sector.

Somewhat atypically, Theodora doesn’t come from a life sciences background, but qualified as a chartered accountant with PricewaterhouseCoopers and read Classics at Trinity College, Cambridge before moving into biotech management.

Before she joined Crescendo, she held industry and corporate finance roles with private and listed SMEs, including PsiOxus Therapeutics, MISSION Therapeutics, OrthoMimetics and Cytomx. She played a key role in Crescendo's recent $70m fundraising project, has overseen finances and operations and, more recently, business development.

11 Alice Choi
Northern powerhouse

They say if you want to get an important job done, give it to a busy person. And that person is more often than not a woman, juggling many responsibilities and roles while keeping the show on the road.

McCann Healthcare’s Alice Choi exemplifies this spirit, able to take on a wide range of roles while keeping her sense of fun and down-to-earth nature remarkably intact.

Alice is chief operating officer, McCann Health Medical Communications, and executive director of McCann Health’s Global Scientific Council.

She is also a Women of Influence Mentor for Cancer Research UK and a public governor for The Christie NHS Foundation Trust in Manchester and recently took on the voluntary role of chairing the Healthcare Communications Association (HCA).

Alice says she’s looking forward to helping lead the HCA as it moves ahead with its evolution, further consolidating its position as a leading UK healthcare communications organisation championing the specialty. Alice will work closely with HCA’s chief executive Mike Dixon to deliver the HCA’s long-term strategy.

A proud native of England’s north west, another significant voluntary role for Alice is as a ‘role model’ for Northern Power Women. The group engages women and men in the north of England across sectors and industries to act as ‘agents of change’ and advocates for gender balance.

“I am a big believer in mentorship. I think it comes in lots of different forms,” said Alice. “I think diversity is very important as well, and also having cross-sector mentorship, because you get exposed to a lot more diversity of thinking and experiences.”

Keeping a balanced view between the ‘big picture’ thinking, professional pressures and her personal life is important to her.

“I am really proud of what I’ve achieve professionally, but I am equally proud of being the mother of three daughters. So it’s all about that juggling,” she added.

“I’m proud of what I’ve achieved professionally but I’m equally proud of being a mother to three girls”

Julie Adrian
Health comms leader

Julie Adrian is one of the best known and influential leaders in the world of European healthcare communications, and as president of Syneos Health Communications Europe, leads with creativity, warmth and wit.

Julie has more than 25 years’ experience in the development and execution of healthcare marketing communications. As well as overseeing the European communications group for Syneos Health, she also provides strategic counsel for integrated communications for pharma, biotech and device clients.

Also a great contributor to the HBA at both the EU and UK level, Julie supports its mission through its events, including the annual EU Summit.

She also advises teams and individuals, and hosts regular HBA events at the Syneos offices in London.

Her HBA colleagues commented: “Julie’s enthusiasm and tireless support seem to have no end!”

13 Soraya Bekkali
Gene therapy pioneer

Cell and gene therapy is definitely the most exciting development in biopharma research, promising breakthroughs and even cures for previously untreatable diseases. Pioneers in the field include some notable women – such as CRISPR’s co-developers Jennifer Doudna and Emmanuelle Charpentier – although women remain in the minority in both the R&D and business functions of firms in the area.

One notable exception to that is Soraya Bekkali, president, head of R&D at Gyroscope, a UK firm developing gene therapies for eye diseases. One of Europe’s most experienced drug development leaders in the field, Soraya and her colleagues could have one of the most transformative gene therapies in the industry’s pipeline on their hands.

Eye diseases are at the forefront of the gene therapy revolution because delivery into the eye is much easier than systemic dosing, and it is also easier to gauge the outcome of the therapy.

Between 2017 and March 2019 Soraya served as CEO and CMO of Gyroscope and led the company successfully to clinical stage. After a merger with fellow Syncona stablemate Orbit, Soraya has taken on the R&D lead role, charged with developing and eventually gaining approval for its lead investigational gene therapy, QT005 for advanced dry Age-related Macular Degeneration (AMD).

Prior to joining Gyroscope, Soraya served as EVP Chief Medical Officer of Lysogene, a clinical stage biotech developing gene therapy products in rare central nervous system diseases, serving in global gene therapy development at Sanofi before that.

Building on the research of its scientific founders, the Gyroscope team has been working relentlessly over the last two years, and earlier this year took its lead candidate into the clinic.
14 Andreea Apostol president, HBA, London chapter

Andreea is president of the London chapter of the Healthcare Businesswomen’s Association (HBA), a voluntary role she combines with her career at Pfizer where she is currently artwork implementation manager. The last few years have seen a new surge of energy behind advancing women in society and in the workplace, where there remain serious disparities with men, including a pay gap and representation at the most senior levels.

The HBA is helping to advance this cause in the world of life sciences, which despite encouraging signs of change, also still has some way to go to reach gender parity. There is ample evidence that greater diversity (in gender, ethnicity and socio-economic background) helps to create more successful businesses, but these cultural shifts take time and determination to bring about.

Andreea exemplifies this determination. Her disarming charm and commitment to the cause is helping the HBA build its profile in the UK, and spread its message. Her colleagues at the HBA praised her ‘tireless energy and relentless pursuit of the organisation’s mission’. They added: “Through her leadership she has driven impressive membership gains and an increasingly strong community of like-minded women and men eager to be a positive force for change. Andreea explained: “Being able to help others achieve their goals is a motivator for me. As a child, I was inspired by my parents who are both leaders in their own way. “My mother was the leader in our family, ensuring the household was run with precision and integrity. My father had his own company which required his leadership to navigate many challenges. Growing up with two strong leaders has made me who I am. It has helped frame my ambitions and made me want to strive to lead and motivate others the way my parents motivated me.”

She said her professional ambition is to become an experienced and trusted business leader, and added her role as HBA president mirrors the kind of general manager role she is aiming for in the near future. “Working in Pfizer has offered me some great opportunities to develop my career from development plans to coaching, mentorship and sponsorship. If I’m honest, I consider myself a sum of all the mentors I’ve benefited from – this role allows me to pass on their learnings and show them my appreciation.”

16 Sarah-Jane Marsh NHS leader

A force of nature and an inspirational leader in the highly pressured world of NHS managers, Sarah-Jane Marsh began her health service career via the graduate Management Scheme, where her ability was soon spotted. She became Britain’s youngest hospital leader when she was appointed chief executive of Birmingham Children’s Hospital in 2007 at the age of 32, subsequently helping it win Provider Trust of the Year in the Health Service Journal awards.

She then led the creation of the first integrated Women’s and Children’s Trust, with the merger of Birmingham Women’s with Birmingham Children’s Hospital in 2017. Under her leadership, the Children’s Trust also became the first stand-alone hospital in the UK to receive an ‘Outstanding’ rating by the Care Quality Commission (CQC). Renowned for her innovative approach to improving NHS services, Sarah leads by example by putting patients and staff at the heart of her work.

Talking about leadership earlier this year, she said it was about having clear vision and values, and articulating those every day. “Rolling your sleeves up and getting your hands dirty, that’s really the best way to learn. But having role models is also really important, and sometimes doing courses and taking time out can be really helpful for reflection.”

On the new challenge of delivering integrated care, she said: “It’s less about leading for organisations, and more about leading for systems, and the way our patients and service users move between our organisations. That requires helping people through change, doing even more communication and thinking about even more improvement.”

15 Liz Henderson Pharma leader

“Mentors can and should be both senior and junior people who you look to for advice, guidance and support”

Read the full interview on p26

17 Yvonne Coghill Diversity champion

Yvonne Coghill is one of the NHS’ most senior nurses, and one of her roles is in promoting race equality within the health service. She is director of Workforce Race Equality Standard Implementation for NHS England and deputy president of the Royal College of Nursing. For International Women’s Day this year, she wrote: “Women in the 21st century are told they can do and be anything, yet we know that for some women it is truer than for others, and for women it isn’t as true as it is for some men.”

She added: “We cannot as women achieve equity with men unless they act as our advocates and supporters; we need our male allies. We need men to speak up for the unfairness and inequality in this gap and at the same time we need white women to speak up for their black and minority ethnic (BME) sisters, because across the board BME people earn less than their white counterparts; this is the race equality pay gap.”
For trials without tribulations we must improve patient experience

By Mark Evans

‘Clinical trials are broken and only patients can help us fix them – if we let them’

Specialist patient recruitment agency Havas Lynx Faze, from the leading global healthcare communications agency Havas Lynx Group, has spent months speaking to patients and leaders across the pharmaceutical industry to better understand what’s working – and what’s not – in clinical trials. The result of this consultation is Havas Lynx Group’s latest white paper ‘Patient Centricity on Trial’. Faze’s Mark Evans explains the simple but transformative insight that runs through the white paper.

Charles Darwin famously talked about survival of the fittest. The idea that those that have better adapted to their environment are more likely to succeed than those who don’t.

The environment for clinical trials is unrecognisable from the turn of the century. Just looking at the numbers is staggering – over 13,000% more trials were registered in 2018 than in the year 2000. And this massive growth in competition for clinical trials has coincided with the advent of the web and the digital age, which have forever changed the rules of engagement.

Yet the well-worn statistics on the dire state of clinical trials are ample evidence that we’ve failed to evolve with this changing environment. Almost half of clinical trials (46%) fail due to poor recruitment; 50% of sites enrol one or no study participants; 80% of trials are delayed by at least one month... The result? Pharma is haemorrhaging money and patients aren’t seeing the benefits they need.

The old clinical trial model was well adapted to the blockbuster era of drug discovery and delivery. But the simpler ‘find patients, test drug’ era has well and truly passed.

So we must adapt to survive. And yes – you’ve guessed it – that means involving patients.

Beyond the buzzwords
True evolution, however, doesn’t come from merely paying lip service to ‘patient-centricity’ and ‘co-production’, or whatever preferred buzzword is doing the rounds. To survive and stand out from the ever-expanding crowd, we need to embed an understanding of patient experience into the very DNA of our businesses.

Our latest white paper is an exploration of how some of the world’s most innovative companies are bringing the patient experience front and centre in clinical trials, and reaping the benefits of doing so. From the way they speak to and seek out patients in recruitment ads, to protocol design and end-of-trial communications, we show that those who are taking the time to understand and respond to a patient’s experience at every clinical trial touchpoint are those who are building successful clinical trials. Who wants five blood tests when they could have two, for instance? This kind of simple, practical question can be the difference between success and failure of a clinical trial, and is usually only raised by patients.

Tailored experiences
We’ve heard individual patient stories of why one particular trial experience was better than another, and we’ve explored case studies and evidence of how the patient voice has helped companies and clinical trials succeed where others have failed. Time and again we’ve seen that genuinely successful patient-centricity is fundamentally about understanding the everyday experiences that people (not abstracted ‘patients’) have – and the practicalities they face – and better tailoring trials as a result of that understanding.

Look beyond the confines of the pharmaceutical industry to consumer-land and you’ll soon find that, actually, a focus on experience isn’t new news. It’s just that Pharma is late to the party. The Apples, the Amazons, the Nikes of the world have long adapted their businesses to centring around and optimising customer experience. In doing so, they’ve not only succeeded where others have failed, but they’ve changed expectations of consumers. Our patients live in the world of Amazon and Nike. They are consumers too, albeit with often life-changing conditions.

Experience mindset
We compete not simply with other clinical trials, but the world of distraction that is modern life. The average person, for instance, is thought to see as many as 3,000 advertising messages a day across all media.

The ‘product’ we’re selling isn’t as trivial as an iPad or new trainers – it’s the very life-blood of modern medicine – yet if we continue to use the tools of old and fail to adapt, we’re condemned to continue a trajectory of poor recruitment and retention, and of rising costs.

Survival comes from adaptation. In clinical trials, that means adapting our mindset, our trials, our very businesses to look at patients as our ultimate customer, and improving their experience at every step.

Clinical trials are broken and only patients can help us fix them – if we let them.

To find out more, sign up to read our white paper and supporting insights at: www.patientcentricityontrial.com

Mark Evans is Managing Director of Havas Lynx Faze
18 Sarah Price
Population health leader
Greater Manchester is the pioneer that is leading England’s health and social care into the future, away from the old siloed, disjointed services towards integrated care. It’s also looking to switch the focus from ‘picking up the pieces’ towards population health and preventative care, a radical switch that is needed to help people manage their health and keep healthcare sustainable.

Greater Manchester’s Health and Social Care Partnership, formed in 2016, has pooled resources from local authorities, hospitals and Clinical Commissioning Groups (CCGs) to create a single £6bn budget to provide integrated service, and focus on long-term drivers of ill health and sickness.

One of the region’s leaders is Sarah Price, executive lead for population health and commissioning at the partnership.

Price has to make a relatively small slice of that budget – £30m – go a long way in population health initiatives, but it’s an exciting venture for the region, as it looks to improve on many metrics compared to the rest of England.

Price’s projects include incentivising behaviour change through a mobile app-tracked points system, aiming to influence wider determinants.

Another major problem being tackled is unemployment due to health problems, with 240,000 people out of work in Greater Manchester, 150,000 of those for health reasons. A small fund has been set up to provide an early help scheme to help prevent people from dropping out of employment when they fall ill.

Another major programme involves joined-up health commissioning with police – diverting people out of the criminal justice system, especially in mental health – something that is simply not possible when systems are siloed.

Sarah says the region is seeing early signs of this joined-up approach working, with smoking rates declining and the gap between Greater Manchester and the rest of England narrowing.

She told a recent King’s Fund meeting: “Moving from picking up the pieces to a preventative approach – if we can achieve that in Greater Manchester, I think we’ll be doing a fantastic job.”

19 Tara Donnelly
NHS digital leader
Tara Donnelly is the chief digital officer at NHS England and oversees a portfolio of citizen-facing digital services which aim to help people engage with the NHS online and also nurture a culture of self-care among the public and patients.

That’s a big cultural shift, but can’t happen until the NHS has developed robust and user-friendly digital services.

The NHS app is seen as particularly important in providing the public with a digital ‘front door’ to the NHS, helping users to access their own records and NHS services. All GP practices in England will be connected to the NHS app by 1 July.

The hope is that it becomes a trusted and user-friendly hub, and that it will help nurture an environment in which other commercially developed apps can also thrive.

There are plenty of challenges – IT budgets in the NHS are under new pressure and a new stand-alone organisation, NHSX, is taking over many strategic aspects of the digital agenda.

Nevertheless, the NHS needs leaders who know how to make big strategic projects work at a local level: Tara has this frontline experience, having previously served as chief executive of London NHS’ pioneering digital hub, Health Innovation Network.

She also has decades of experience in leading change in the health service, rising rapidly into senior roles over her 30 years in the NHS, where she started as a ward housekeeper when she was just 18 years old.

20 Sarah Ewart
Abortion rights campaigner
Sarah Ewart is a woman of enormous personal courage who is trying to change the rules on abortion in Northern Ireland, where it remains illegal in almost all cases.

She is mounting a legal challenge in the UK High Court, basing the case on her own experience.

In 2013 Sarah was in her early 20s, married and pregnant with her first child, when she was told a fatal foetal abnormality (FFA) meant the baby would not survive after birth.

However, she was denied an abortion in her native Northern Ireland, and was forced to travel to England for a termination – necessary because the province’s laws weren’t updated in line with the rest of the UK when abortions were legalised in 1967. The procedure is only permitted if a woman’s life is at risk or if there is risk of permanent and serious damage to her mental or physical health.

Rape, incest or diagnoses of fatal foetal abnormality (FFA) are not grounds for a legal abortion in Northern Ireland.

Sarah has now taken the High Court case in her own name, after a previous Supreme Court appeal, led by the Northern Ireland Human Rights Commission, failed last year.

She has spoken of the huge emotional distress and financial burden of having to make the trip to England for the abortion.

She and abortion rights campaigners hope her testimony can bring about a change in the law, granting women in Northern Ireland the same rights as those in the rest of the UK.

21 Natasha Devon
Mental health campaigner
Natasha Devon is a writer and activist, an independent voice championing issues such as mental health in young people.

She tours schools and colleges across the UK, delivering talks and conducting research on mental health, body image, gender and social equality.

She is also a passionate advocate of gender equality rights, campaigning in the media and fighting resolutely against misogynist social media trolls.

Devon is a fiercely independent champion of her causes and was sacked from her role as the government’s children’s mental health tsar in 2015, after she spoke out against inaction on mental health issues in schools.

She campaigns both on and offline to make the world a fairer place. Her current projects are the Mental Health Media Charter and Where’s Your Head At? which aims to change the law to protect the mental health of UK workers.
Dr Harietta Eleftherochorinou
AI pioneer

After a wave of hype, AI is now starting to show its value across the life sciences sector, harnessing big data and real-world evidence (RWE) to derive new insights for the ultimate benefit of patients.

Dr Harietta Eleftherochorinou, IQVIA's senior principal RWE AI and ML, is a leading light in applying the techniques to pharma's commercial challenges, including creating personalising medical treatment.

Highlights of her work include the integrated analytics roadmap on Personalised Healthcare for over 20 healthcare organisations across Europe, USA and Africa, large-scale big data lake implementations for ML-led applications in pharma and real-world ML/AI platforms for scalable disease diagnostics, progression and treatment.

Dr Larissa Kerecuk
Rare disease leader

England's groundbreaking 100,000 Genomes Project hasn't been a scientific endeavour achieved exclusively through lab technology – it has required thousands of rare disease patients to volunteer, as well as a handful of clinical leaders across the country to translate the cutting edge science into meaningful benefits for those patients.

Dr Larissa Kerecuk is a doctor who has made an outstanding contribution to the project and to the bigger cause of helping advance treatment of children with rare diseases. A consultant paediatric nephrologist at Birmingham Children's Hospital, Larissa led the development of the UK and indeed the world's first dedicated paediatric rare disease centre in Birmingham, which opened in 2018.

Dr Kerecuk is the lead for the 100K Genome Project for her hospital and helped make it the top recruiting hospital for the region. Indeed, the hospital is among the most active clinical trial centres in the UK, attracting inward investment and addressing unmet need in patients. Above all else, it is Larissa’s compassion for her patients that shines through, and she has been dubbed 'Wonder Woman' for her determination to improve care.

This includes setting up a support group for families, called the Marvellous Superstar Club, which Larissa raised money for by absailing down a local Birmingham landmark.

Dr Nikki Kani
GP leader

Dr Nikki Kani is director of primary care for England, charged with helping general practice thrive and adapt, and still retain its place as the trusted gateway to the 21st century NHS.

However, general practice is struggling under growing demand and a huge recruitment and retention problem among GPs. As a generation of older primary care doctors retire, the NHS is struggling to find new recruits, and much of this is due to the high workload and non-family-friendly long hours.

Dr Kani is a GP herself, and has two young children, so she knows first-hand the kind of pressures the job comes with.

Nikki’s career path has shown her long-term vision for science and for promoting women. She co-founded STEMmsisters with her sister, a social enterprise supporting young people to study science, technology, engineering, maths and medicine.

She has brought that energy to her leadership role since she was appointed last year. She played a key role in persuading the government to commit £4.5bn of its recent £20.5bn uplift for the NHS to primary and community care – a far larger proportion than in recent years.

She has just negotiated the most substantial changes to the GP contract in 15 years, producing a deal that incentivises practices to join new networks covering 30,000-50,000 patients in exchange for access to new funding streams.

The extra funding and the NHS Long Term Plan mean primary care is set for major change over the next five to ten years. There are some positive signs on GP recruitment, with numbers hitting their highest ever recorded level, but this must also be matched by retaining experienced mid-career GPs in order to sustain the service. She said: “Ultimately, we need to make things more enjoyable and sustainable in primary care and out of that will come a better offer for patients.”

Hilary Hutton-Squire
Healthcare partnerships, cures for patients

Gilead is leading a remarkable transformation in pharma – moving from long-term treatments to cures. It has brought to market not one but two groundbreaking drugs in hepatitis C, Harvoni, and in diffuse large B cell lymphoma, Yescarta, one of the first CAR-T therapies to reach the market.

The high cost of these treatments, and the need for entirely new healthcare infrastructures to ensure they reach patients is an enormous challenge for Gilead and for the NHS.

Charged with leading this mission in the UK and Ireland is Hilary Hutton-Squire.

Appointed general manager in early 2018, Hilary has had a big impact in improving the dialogue between the NHS, government and industry. This is demonstrated in Gilead securing two truly groundbreaking partnerships with NHS England in CAR-T therapy and hep C last year and this year respectively.

In April, NHS England unveiled a deal with several pharma companies working in hep C, confirming they would work in partnership to eliminate the disease in England well ahead of the WHO goal of 2030.

NHS England judged Gilead’s offer to be the best, giving it a ‘Gold’ partner status.

Hilary commented: “What made it happen was openness on both sides to have a constructive dialogue. That’s required the breaking down of quite a lot of cultural barriers.”

The challenge of hep C elimination is not so much in achieving successful treatment but more about finding and treating people with the disease, who often don’t know they have it.

Gilead has been working with drug treatment services, prisons and building expertise since 2013. After all this time, Hilary said she has to remind her team how remarkable the hep C elimination programme is. “We’re going to work with the NHS to eliminate this disease in the UK. Wow. I see people’s faces light up when we talk about it. It’s a really inspiring and engaging thing to be working on.”

“[NHS partnership] requires the breaking down of a lot of cultural barriers”
Liz Henderson
Merck UK & Ireland’s managing director on her ‘non-linear’ career path and the importance of mentoring

What led you to a career in the pharma industry?
I have always loved science and after I did a chemistry degree at university, it was a natural progression to start my career in the pharmaceutical industry, starting my career at Pfizer and Amgen, before moving to Merck. It’s an exciting industry to work in – I love seeing how science is translated into patient benefit and it is so rewarding to work with inspirational people who can turn ideas into life-changing therapies.

Your career hasn’t been very ‘linear’ – you’ve moved between lots of different companies and functions. Is that something you’d recommend? How does that come about?
Yes, I would definitely recommend trying lots of different jobs, especially early in your career. The skills you pick up along the way are invaluable and I have always taken a role because it will help me develop my portfolio of experiences, not because it was a linear progression – sideways and even backwards moves can be just as rewarding. I believe thinking only in the linear can really curtail your career aspirations, so I have always taken opportunities when they have come my way and have never regretted taking roles outside my comfort zone. Women are sometimes inclined to think they are not ready for the next challenge, so I always encourage my colleagues not to be risk averse and to be comfortable with perhaps not being the ‘expert’ – so many skills are transferable, and the toughest part is often taking the decision to jump forward to the next challenge. Once there – and with the right mentoring and training – people are often surprised by how quickly they can shine.

How far have things advanced in terms of women in leadership roles in pharma, in your view? What are the big issues which remain as obstacles?
Fields like pharmaceutical manufacturing have been male-dominated until recently. What advice can you give to women in those environments? I would say that authentic leadership is crucial in any role – it’s important to be who you are and lead with integrity and honesty. I don’t believe anyone should have to change their leadership style to ‘fit in’ – in fact, we need to champion the fact that women have different skills and capabilities to offer than men. An inclusive and collaborative approach to leadership is also important to inspire people to achieve.

Merck is proud of the fact that currently already 30% of its leadership roles are held by women. This percentage has been growing over the years and we anticipate a further evolution in the number of women leading our company soon.

“**We need to champion the fact that women have different skills and capabilities to offer than men...an inclusive approach is important to inspire people to achieve**”

Do you think women need to exhibit the more ‘masculine’ traits of ambition and self-confidence as Sheryl Sandberg advises in her book Lean In, or should women look to champion a different, more ‘feminine’ approach to management?
In my experience, management style is not influenced by gender – your own personal leadership style is much more important whether you are male or female. Again, being authentic to yourself and accepting that different people have different leadership qualities is vital. In our business, we have a variety of leadership styles and this leads to a healthy level of debate and challenge which I believe is essential to a successful business environment. I also agree with Sheryl Sandberg that mentors can and should be both senior and junior people who you look to for advice, guidance and support. Sometimes, by only looking upwards for mentors, you can easily overlook the unique viewpoints and experiences that the younger generation can bring to a leadership role.

One of the themes in PME Women leaders in UK healthcare is how healthcare stakeholders – especially the pharma industry and the NHS – can better align themselves to advance patient outcomes. What is Merck doing in the UK on that front? What’s your personal view on how this can work?
Merck has evolved from a mid-sized chemicals and pharma company to become the pioneering science and technology company with specialisations in biopharma, life sciences and high-tech materials that it is today.

We make a positive difference to millions of peoples’ lives every day. Our constant curiosity and specialist approach drive our partnerships and bring new ideas to life. We pride ourselves on being a solutions-focused partner to patients and the NHS.

For example, in our Endocrinology franchise, we are using digital technologies to help healthcare professionals manage and improve patient adherence and, as a result, help our patients achieve the maximum potential of our treatments. In Fertility, we have developed services for fertility clinics to support patients – on average, it can take three rounds of IVF to achieve a clinical pregnancy and our services are designed to help clinics support their patients throughout the fertility journey.

We are now playing an active role in supporting trusts in their communication with the new genomic hubs to ensure that there are no delays or limitations in the new testing environment. We are also working with a number of patient groups across the business to help build alliances across therapy areas.

Another major theme in advancing women in leadership roles is mentorship. What is your experience of mentorship? Is it especially crucial for women?
Yes, mentorship is really crucial – I have been fortunate to have had some amazing mentors in my career, both men and women. I do feel that women perhaps need this more than men. In my experience, women are less likely to push themselves forward for a new role – especially early in their careers – and may need the extra support a great mentor can provide in giving them the confidence to apply for a new role or ask for that promotion.

What are the best and worst things about working in pharma industry leadership?
The best things are working in a fast-paced environment, seeing science and innovation changing patients’ lives and working with a bunch of inspirational, sharp and fun people.
Like any industry, the challenges are around bureaucracy and slow systems which can impede our ability to progress – which is especially frustrating when it means that patients are not getting the medicines they need as quickly as we would like.

**How do you relax and re-focus away from work?**
I have a young son, so I love spending time with him. He’s at a great age, with so many questions so life is never boring! I also like to get outside and exercise, both walking and running – and I have recently discovered yoga which is a great way to relax after a busy day in the office.

**Who’s your pharma/healthcare/all-time hero/heroine?**
There are so many it’s difficult to pin it down to one individual, but I would say Rosalind Franklin, who was a groundbreaking scientist, instrumental in the research of DNA. She only received the recognition she deserved in recent years – and was famously overlooked for the Nobel Prize – so it’s fantastic to see a resurgence in support for Franklin’s work now and the belated recognition that she deserves. I hope it will inspire a new generation of female scientists in our industry.

Liz Henderson is Managing Director and General Manager of Merck UK & Republic of Ireland, a post that she has held since September 2018.

Prior to this, Liz was Executive Vice President, Head of Global Manufacturing & Supply for the Biopharma business of Merck.

Liz’s career spans more than 20 years in manufacturing and supply in the healthcare and life sciences industries. She joined Merck in 2009, initially as European Environmental Health & Safety Director for the company’s life sciences business sector and subsequently became Site Director for Merck’s manufacturing plant in Cork, Ireland. Before moving to Merck’s Healthcare business sector, Liz was leading the Separations Technology Cluster of manufacturing sites across the US and Europe. Prior to Merck, Liz worked at Pfizer and Amgen for over ten years in a variety of manufacturing leadership roles.

Liz holds a Bachelor of Science degree in Analytical Chemistry from Dublin City University, Ireland.

“I always encourage my colleagues not to be risk averse... the toughest part is often taking the decision to jump forward to the next challenge”
The Lartruvo withdrawal: a question of how to pay for hope?

What Lartruvo means for the future of paying for conditional approval therapies

The story of Eli Lilly’s cancer treatment
Lartruvo represents a significant development in the world of novel oncology drugs, where conditional marketing approvals have become commonplace.

Approved in 2016 via accelerated approval in the US and a conditional marketing authorisation in Europe for patients with advanced soft tissue sarcoma, the drug has now failed to confirm its benefits to patients and is being withdrawn from the market by Eli Lilly.

While Lartruvo isn’t the first drug to fail to demonstrate its value following conditional approval, it is the first of its kind where the EMA and FDA have acted decisively on the negative data. Both agencies were swift to limit its use and now the EMA’s CHMP committee has called for its licence to be formally revoked.

So what does this mean for the industry and regulators? And what does it mean when healthcare systems have already paid for drugs which then subsequently fail to prove their value?

It’s a fair question, and some US doctors have claimed the results mean healthcare payers are entitled to a refund.

In England, the question is very real, as Lartruvo had been given interim funding via the Cancer Drugs Fund (CDF). This is a time-limited fund which provides market access while further data is collected.

Should we ‘pay for hope’ that a novel drug might help patients, and how might we develop better systems for sharing the risk?

Lartruvo
Lartruvo (olaratumab), in combination with doxorubicin, was given conditional approval by the European Medicines Agency (EMA) on 9 November 2016. The US Food and Drugs Administration (FDA) approved Lartruvo just a few weeks earlier on 19 October 2016. Lartruvo was approved to treat adults with advanced soft tissue sarcoma. Lartruvo’s approved use was for those patients who cannot have surgery or radiotherapy and who hadn’t yet had doxorubicin.

The number of patients who have advanced soft tissue sarcoma is small; just under 3,000 patients were diagnosed with soft tissue sarcomas in England in 2010, for example. The rarity of soft tissue sarcoma translated to an orphan drug designation.

‘Should we ‘pay for hope’ that a novel drug might help patients, and how might we develop better systems for sharing the risk?’

Patients diagnosed with soft tissue sarcoma are often diagnosed late, and it is clear that sarcoma has a profound effect on them and their families. Lartruvo was seen by clinicians as the first effective treatment for this cancer for 25 years, particularly given the standard treatment for those who could not have surgery or who didn’t respond to radiotherapy, with doxorubicin, only had a response rate of between 10-36%

Cancer Research UK statistics suggest that almost 60 out of 100 people with soft tissue sarcoma survive their cancer for five years of more after diagnosis. It’s likely that everyone thought Lartruvo offered hope for more time, in a rare cancer where patients only faced a slightly better than 50/50 chance of making it for more than five years.

The EMA’s conditional approval was based on one main phase 2 study; JGDG. This included 133 patients in the US. The study found that those patients who had Lartruvo and doxorubicin lived an average of 6.6 months without their disease progressing and in total lived for 26.5 months. Those patients who did not have Lartruvo added to doxorubicin lived for an average 4.1 months before their disease progressed and in total lived for 14.7 months. In recognition of the small sample size EMA gave Lartruvo a conditional approval; this signals that there are some remaining questions about a drug. It also requires the company to generate and submit new evidence to the EMA.

In the US, Lartruvo was granted fast track and breakthrough therapy designation, priority review and accelerated approval. Accelerated approval required Lilly to conduct a confirmatory trial.

A conditional approval also followed for Lartruvo from NICE by recommending use by the Cancer Drugs Fund (CDF). The CDF has been operating since 2016 with its ‘managed access fund’ version.

This allows drugs which still have uncertainties around their key data to be made available on the NHS for a limited time (two years or more), after which time they must have generated data to confirm their clinical and cost-effectiveness.

If it is clinically- and/or cost-effective, it will be paid for using the usual routes within the NHS. If it isn’t, it will no longer be funded.

NICE’s recommendation reflected the impressive survival gain – increasing survival by 11.8 months on a median basis. NICE described this as unprecedented, potentially showing a step-change in the treatment of a rare cancer. This was achieved with what was seen as a higher, yet manageable, incidence of side effects compared to standard care.

This decision was taken while a confirmatory phase 3 trial – ANNOUNCE – was still ongoing. ANNOUNCE was a multicentre, randomised, double-blind, placebo-controlled trial, and did not allow cross-over. It enrolled some 460 patients and was therefore a very different type of trial from JGDG, which was an open-label multicentre study.

All told, ANNOUNCE would give a more reliable understanding of efficacy, particularly survival, as well as in some other areas such as the number of treatment cycles, as well as data that was not collected in the JGDG trial, such as quality of life.

Reflecting the uncertainties in the data, the cost-effectiveness estimates produced for the NICE appraisal varied from a cost of £46,000 to £60,000 per Quality Adjusted Life Year (QALY).

In NICE’s view the most likely cost was at the higher end, and that would push the limits of what NICE usually accepts, even allowing for a higher threshold for end-of-life treatments. End-of-life treatments are generally accepted around a cost of £50,000 per QALY.

www.pmlive.com
The managed access agreement needed to help secure the CDF funding included a confidential discount and provided estimates of the number of patients who were likely to be eligible: 451 a year. The list price is £1,000 for one 500mg/50ml vial, but patients need repeat doses – how many is uncertain – making the cost of treatment per patient far higher.

Fast forward to 19 January 2019 and Lilly announced that the ANNOUNCE trial did not confirm the benefit shown in the phase 2 trial. There was no difference in survival with LARTRUVO compared to standard care. The EMA’s CHMP decided on 26 April that the EMA authorisation for LARTRUVO should be revoked. There are naturally questions about the regulatory implications of this first withdrawal under accelerated access and the failure to show the hoped for benefit also raises a question about the value for money of LARTRUVO.

**Should we pay for hope?**

There is a general theme that underlies the LARTRUVO example – there is great pressure from patients, clinicians (and indeed pharma) to provide access to drugs when they show great promise, even if evidence is still immature. It might sound trite (and is not meant to be dismissive), but in essence that in case healthcare systems are being asked to pay for hope.

The challenge comes when hope disappears and the drug doesn’t work, just as in the LARTRUVO case. That means that the NHS has paid for a drug – and patients have faced side effects – that, despite all early signs, according to better evidence now available, won’t have resulted in any improvement in survival.

It’s true, we don’t know exactly how much was spent on LARTRUVO since there was a discount on its list price and estimates of patients eligible for treatment are just that: estimates. Whatever the real spend, it’s likely to be a drop in the ocean when it comes to the £1.7bn the NHS spends on systemic anticancer therapy in England, according to NHSE. Yet at the same time, every little helps.

While the LARTRUVO case may be unique so far, the level of uncertainty of increased survival for cancer drugs being appraised by NICE is not. Analysis of past NICE decisions has found that immature survival data was the number one uncertainty across cancer drugs looked at by NICE during 2014 to 2016 (figure 1). This analysis also makes it very clear that there are a host of other uncertainties too.

As more drugs are approved earlier, this issue of immature data – and greater uncertainty – applies to more medicines.

‘There’s an appeal in sharing the risks regarding drugs that don’t quite work as well as we all want them to – we want to pay for what matters’

So what should we do, if we want to nurture hope? Hope must surely be a major driver of resources invested in research and development, and other activities, yet it is vital to avoid wasting resources on drugs that don’t work.

**Outcome-based contracts**

Whether we call them outcome-based contracts or any other name, there is an appeal in sharing the risks regarding drugs that don’t quite work as well as we all want them to. We want to pay for what matters.

The idea of only paying when a drug works is not new, but is very difficult to achieve. The reasons for this range from the willingness of companies and payers to enter into negotiations regarding these drugs, through to practical issues of what and how to collect outcomes.

Yet despite the difficulties there are still calls to implement this system in the NHS. For example, outcome-based contracts were covered most recently in a February 2019 report commissioned by the Greater Manchester Combined Authority, NHS in Greater Manchester and Cancer Research UK, with research from the Office of Health Economics, Rand Europe and King’s College London.

In the LARTRUVO case, however, the deal could have simply been linked to the results of the clinical trial – which avoids issues of bias that come with real-world evidence – that was happening in any case and crucially, using an objective and well accepted, practical, single measure. It would have been an evolution of the managed access agreement that had been agreed and signed up to, assuming that all parties would have agreed to it (a big unknown).

But the real reason to ask if an outcomes-based approach would have been better than CDF funding as it was given, is simply that a rebate – even if not 100% of the costs of LARTRUVO could have meant that the NHS could recoup (some of) the money spent when it became clear the benefits weren’t realised, and reinvest that money elsewhere.

That could be compelling for the NHS to manage short-term financial challenges; yet to play devil’s advocate, there is a need to consider whether there could be a dynamic effect too. Could outcome-based contracts, especially ‘pay for performance’ deals, affect incentives for companies, and change decisions on whether and when to bring drugs to launch in the UK, as well as incentives for research and development?

Whatever your view on outcomes-based contracts or the CDF, the LARTRUVO story should prompt further debate on the way to pay for hope.

Leela Barham is an independent health economist and policy expert who has worked with stakeholders across the healthcare system, both in the UK and internationally.
WHAT IS AVAXHOME?
Unlimited satisfaction one low price
Cheap constant access to piping hot media
Protect your downloadings from Big brother
Safer, than torrent-trackers
18 years of seamless operation and our users' satisfaction

All languages
Brand new content
One site

We have everything for all of your needs. Just open https://avxlive.icu
Streamlining clinical trials – why better data use is key

Big data, blockchain technology and artificial intelligence have given industry the chance to streamline drug trials, say experts, who agree with recent FDA calls for more efficient clinical research models.

Dr Scott Gottlieb’s brief, energetic tenure as US FDA Commissioner is likely to shape agency oversight of the pharmaceutical industry for years to come, particularly in relation to clinical development.

In April, shortly before stepping down, he suggested industry’s complicated and costly approach to trials stymied drug research.

Gottlieb blamed “legacy business models that discourage collaboration and data sharing”. He also warned that unless industry finds ways to streamline trials, therapeutic opportunities made possible by advances in genomics and precision medicine would be missed.

“Without a more agile clinical research enterprise capable of testing more therapies or combinations of therapies against an expanding array of targets more efficiently and at lower total cost, important therapeutic opportunities may be delayed or discarded because we can’t afford to run trials needed to validate them.”

R&D inefficiency

The criticism is not without foundation, says Patrick Pilch, managing director and national leader of the BDO Center for Healthcare Excellence & Innovation.

“I would agree with Dr Gottlieb – as the health and life sciences sectors continue to converge and the ecosystem overall shifts towards value-based models that reward positive patient outcomes, inefficiencies in clinical trials can’t be ignored.”

The argument is supported by the fact that increased R&D spending has not resulted in more approvals. According to a PhRMA survey, industry invested $71.4bn in R&D in 2017, up from $29.8bn in 2001. While the number of approvals grew over the period, the increase was nowhere near proportional.

Pilch told us the disparity “makes the need to improve clinical trials’ speed and efficiency more urgent than ever”, adding that “if we want to continue to incentivise spending on finding treatments for rare diseases, clinical trial speed and efficiency need to be addressed”.

Challenging trials

Gen Li, founder and president of data-driven drug development contractor Phesi, acknowledged that industry’s approach to clinical research could be improved by making better use of data and technology.

“Over the years, our industry has been generating and has accumulated an unbelievable amount of data. The opportunities to pool, understand and utilise these dynamic and ever increasing data are tremendous, as Dr Gottlieb suggested.

“Specifically, to his point, our industry has collected and accumulated a large amount of data from placebo and comparator arms. It is absolutely possible to utilise this ‘useless’ data to reduce the sample size and potentially eliminate the placebo and comparator arms. The implications are huge: reduced costs, shortened cycle times and better and more ethical patient care,” Li said.

The caveat is that the sources of this data need to be taken into consideration. Li continued: “Without objective and quantitative understanding of the steps leading to the generation of data in the placebo and comparator arm, it will be risky to accurately and reliably utilise the data. With analytics tools, however, this is now possible and the opportunities this presents are significant.”

‘As the ecosystem shifts towards value-based models, inefficiencies in clinical trials can’t be ignored’

Blockchain

Better data use will only help industry streamline clinical development if maintenance and exchange technologies are effective, according to Pistoia Alliance President Steve Arlingon.

“While data has huge potential to greatly increase trial efficiency, the challenge is in making it interoperable and shareable across the industry – so it can be used to inform how trials are designed and executed, to improve the accuracy of conclusions drawn from results and accelerate the approvals process.

“Today, organisations are harvesting information in many different formats without any standardisation and with few protocols for sharing. Greater use and adoption of data standards will be essential if the industry is to overcome barriers to efficiency in the clinical trial process.”

Blockchain is one possible trial data management solution. The technology creates a digital record of products or information as it is exchanged. Each transaction is a ‘block’ and these are chained together to create a record that all parties involved can access, but not edit.

Arlington said blockchain could be used to build trust levels and assure regulators that data from a trial is ‘true’. Each block in a chain can be linked to show that methodology has been followed, keeping the trial transparent, showing the data’s provenance and providing an audit trail.

“This would enable regulators to see the entire clinical package with all documents traceable back through the blockchain to give confidence in the trial’s history and outcomes – and could significantly decrease the time and money necessary to develop a drug.”

To implement a clinical trial blockchain, all parties would need to agree on privacy protocols and data formats, as well as decide who holds which access keys and this, Arlington said, would take considerable negotiation.

“To embrace innovations like blockchain, as Gottlieb asks, all relevant stakeholders need to be ‘in the same room’. This would require technology vendors and device manufacturers, pharma and biotech companies, and global regulators to all work on the same problem. No single organisation will be able to go it alone, and collaboration will be critical in ensuring the industry can realise the potential of technology in making trials more efficient, more productive and safer.”

Trial training

Patrick Pilch from BDO also sees collaboration and the establishment of common standards as key to streamlining trial data management.

“Increasing standardisation and improving user-friendliness of data collection technology is one of the greatest opportunities to improve the speed and efficiency of clinical trials.”

He explained that many clinical trials are outsourced by pharma companies to physician practices, which may be simultaneously conducting multiple trials for different companies using differing data collection technologies.

“Reducing the time spent learning and operating multiple different data collection technologies would reduce the administrative burden placed on investigators at clinical trial sites and speed-up the overall process. Technologies like artificial intelligence and robotics may be able to help as well,” Pilch said.

However, while automating some administrative tasks may speed-up research, sponsors will need to ensure their systems are robust. Pilch continued: “While digital transformation offers much promise, technology is not infallible. Organisations that are keen to automate their administrative work need to rigorously vet and test the technologies they plan to incorporate.”
“Additionally, they’ll need to have secure systems in place to monitor technology for any errors and protect against cyberattacks.”

**Patients are a virtue**

Recruitment is another area in which trials could be streamlined. According to research by the Tufts Center for the Study of Drug Development (TUFTS), most clinical studies do not meet their patient recruitment goals.

Gen Li from Phesi commented that “challenges in patient recruitment are only the symptom of underlying clinical trial dysfunction”, citing the inability to find successful investigators and the lack of effective methods of finding patients as the major hurdles.

A more systemic approach could help streamline recruitment according to Li, who continued: “A seamless synthesis of the most efficient and validated approach to strategy, design, execution and monitoring is preferable.”

Patrick Pilch also commented that industry needs to get better at planning and executing recruitment strategies.

“Investment in patient enrolment and fulfilling compliance requirements are likely to remain staples of clinical drug trials – and for good reason. Compliance requirements are in place to ensure patient safety when a drug ultimately comes to market.”

“Performing due diligence when determining patient eligibility for a trial is important for the safety of patients participating in the trials and those that will ultimately receive the treatment after commercialisation.”

Here again data and technology can help. Pilch continued: “There are several innovative approaches that we’re monitoring right now. For instance, there’s a health tech start-up focused on connecting experimenters with qualified patients to improve clinical trial efficiency.”

The organisation – Elligo Health Research – provides a platform to connect physicians with qualified patients. The aim is to reduce the administrative burden associated with scheduling and collecting data from trials.

Pilch said: “This [Elligo] platform, and ones like it, are examples of innovative approaches that are working to tackle the most significant barriers to efficiency in clinical trials.”

**Research QbD**

Pamela Tenaerts, executive director of the Clinical Trials Transformation Initiative (CTTI), also sees opportunities for patient recruitment to be streamlined. She told us sponsors should apply QbD manufacturing principles in a clinical setting.

“The benefits of thinking differently with QbD as an approach to protocol design can be significant – essentially, you should focus resources on errors that matter to decision-making primary endpoints and patient safety, which can lead to better data, faster enrolment and reduced patient burdens.”

She continued that survey results from CTTI’s recruitment work indicate that identifying patients who meet eligibility criteria is the primary barrier to meeting recruitment goals.

“Participant recruitment must be considered at the initial outset of trial planning. Evidence-based trial feasibility, site selection and communication strategies must also be taken into account,” Tenaerts added.

Industry’s approach to trial patient safety – specifically the work carried out by Institutional Review Boards – could also be streamlined, according to Tenaerts, who continued: “For nearly a decade, CTTI has championed the adoption of single IRBs for multicentre clinical trials.” She added that an sIRB for such studies can improve quality and efficacy.

“We have developed a number of recommendations and other resources for sIRB implementation. Today, CTTI is building on this work by collaborating with an NIH workgroup to develop a comprehensive plan for assessing the NIH’s sIRB policy, and by developing resources to assist researchers and institutions in implementing the sIRB model.”

Gareth Macdonald is a journalist specialising in the life sciences industry.
The human microbiome – the microorganisms that normally live within our bodies – has until recently been largely ignored by the pharma industry, but is now emerging as an important therapeutic target for a wide range of diseases.

It’s been recognised for decades that maintaining a healthy balance in the 1 to 2 kilos of microbes that populate our gastrointestinal tract can provide health benefits, for example helping us to break down the food we eat, producing essential amino acids, hormones and vitamins, and protecting us from pathogens.

That has spawned a big industry selling ‘live’ or probiotic foods and supplements designed to encourage healthy bacteria and discourage pathogens. Those products – indirectly due to marketing restrictions – claim a list of health benefits as long as your arm, from GI health to obesity, cancer and even neurological conditions like anxiety.

Clinical evidence ranges from reasonably robust to very limited, as one might expect, but now an expanding group of biopharma companies – already numbering in the dozens – is applying pharma-grade development practices to put microbiome-targeting drugs through their paces, with a number of read-outs due in the coming months and years.

What is immediately clear from looking at the range of companies operating in this area is that microbiome-based therapies are not just for gastrointestinal diseases. Research suggests the microbiome may also play a role in suppressing an overactive immune system in inflammatory diseases, boosting a suppressed immune system in other diseases including cancers, and maintaining metabolic balance to tackle obesity and diabetes.

The dollars being spent in the area are also evidence of the potential of the human microbiome market, which Transparency Market Research has predicted will reach almost $1.9bn by 2026, driven by advancing capabilities in next-generation sequencing and metagenomics.

Novartis-backed venture capital group Seventure Partners said it spotted the potential of the sector more than a decade ago, and has already raised hundreds of millions of dollars to invest in microbiome start-ups.

Meanwhile, food giant Nestlé is also getting involved, with a $1.9bn partnership with one of the more established microbiome specialists – Seres Therapeutics – which became the poster child for the field when its initial public offering (IPO) raised $135m in 2015. Johnson & Johnson’s Janssen unit is also investing in this area, and has even set up a research institute dedicated to microbiome studies.

Players in this area are mainly developing bacterial cultures based on the organisms that naturally live in the human body, but some are also working on compounds that stimulate microbial growth, or microbiome-derived compounds rather than microbes themselves, as therapeutic vehicles.

GI disease
When it comes to GI disease, the most popular target among microbiome drug developers is a group of pathogens that can cause serious infections in vulnerable patients, such as those with compromised immune systems because of a concomitant condition or advancing age.
The results of these trials will be crucial in using microbiome platforms as a new generation for drug discovery.

‘The next decade will see’ strong integration between microbiome experts and experts in pure therapeutic disciplines such as cancer and neurology’

Last year, Vedanta reported preclinical results suggesting that VE800, both alone and in combination with a checkpoint inhibitor, showed anti-tumour effects, including cytotoxic T cell infiltration into the cancer, suppression of tumour growth and extended survival.

Enterome meanwhile is once again taking a slightly different approach to cancer. It is working on a potential microbiome-derived therapeutic vaccine for glioblastoma, an aggressive form of brain cancer, which draws on the interaction between the immune system and the microbiome to render tumours visible to immune surveillance.

Central nervous system disorders and more

While still in the early stages, some groups are exploring how manipulating the microbiome may have an impact on central nervous system (CNS) disorders through what is known as the gut-brain axis, a complex biochemical signalling system that includes hormonal, immune and neuronal linkages.

One biotech – Axial Biotherapeutics – is developing gut-selective therapies to try to tackle CNS disorders including Parkinson’s disease and autism, and raised $25m in a second round of financing in February to help accelerate its programmes into the clinic. Another – AOBiome – has a microbiome-based intranasal spray in testing as a preventive treatment for migraine.

Another possible use of microbiome-targeting drugs is obesity, where it has been hypothesised that disruption to a healthy bacterial population in the GI tract can both increase susceptibility to becoming overweight and may make it more likely that weight is put on again after dieting.

To explore that link further, Pfizer signed a deal with Second Genome in 2014 to try to understand the link between obesity and the microbiome, although its other programmes in areas like non-alcoholic steatohepatitis (NASH) and inflammatory bowel disease are further forward, having started clinical trials. Another gut-brain axis specialist – Kallyope – is working with Novo Nordisk to discover peptide treatments for both obesity and diabetes.

In a report published last year, Senventure chief executive Isabelle de Cremoux predicted that the next decade will see “strong integration between microbiome experts and experts in pure therapeutic disciplines such as cancer and neurology”.

Much will depend on the first phase 2 and phase 3 microbiome trials due to read out in the next couple of years.

Phil Taylor is a journalist specialising in the healthcare industry.

Top of that hit list is Clostridium difficile or C. diff, a pathogen that while causing unpleasant symptoms is generally not life-threatening and can usually be treated effectively with antibiotics. In vulnerable patients, however, it can cause repeated infections, leading to damage to the bowel and serious dehydration.

The Centres for Disease Control and Prevention (CDC) classes C. diff as an urgent public health threat, causing around 29,000 deaths in the US each year from approximately half a million cases. It is hoped that rather than using antibiotics to kill C. diff – along with other beneficial bacteria in the gut – they can be used to restore the balance of the microbiome.

There’s a fiercely fought race to market for microbiota-based therapies for C. diff. Finch Therapeutics, Seres and Ferring/Rebiotix both have breakthrough designations (BTD) from the FDA for their phase 3 candidates – respectively CP101, SER-109 and RX2660 – with data read-outs due this year.

Takeda has partnered CP101 as well as another candidate in development at biotech NuBiota, which seems to have dropped off the radar somewhat after signing the deal in 2017.

Staying in the GI area, microbiome therapeutics are also being targeted towards inflammatory bowel disease – building on the premise that in patients with conditions like ulcerative colitis and Crohn’s disease there is a reduced abundance and diversity of the microbiome, with greater levels of some species thought to be linked to inflammation.

Seres’ SER-287 is a donor-derived microbiome therapy designed to improve the signs and symptoms associated with ulcerative colitis. It’s in a phase 2b trial, building on a phase 1b study that found clinical improvements as well as engraftment of the probiotic bacteria in the GI tract.

Meanwhile, Roche/Genentech is working with Cambridge, UK-based Microbiota on a $534m project that will use precision metagenomics to analyse patient samples from clinical trials of its inflammatory bowel disease (IBD) medicines. The aim is to identify microbiome biomarker signatures of drug response, novel IBD drug targets as well as probiotic therapeutics.

Last year, serial microbiome partner Takeda signed a $640m-plus deal with Enterome to license the latter’s lead therapy EB8018 for Crohn’s disease, although unlike most of its microbiome competitors this candidate doesn’t rely on administering bacterial probiotics. Instead, it is a small-molecule agent designed to treat Crohn’s by inhibiting the ability of a specific type of enterobacteria to cause inflammation.

Last November, a three-year collaboration between J&J and Vedanta resulted in a first clinical trial of VE202, a bacterial ‘consortium’ aimed at IBD, sparking a $12m milestone payment for Vedanta. VE202 is based on the idea that IBD patients are deficient in certain Clostridia species in the gut, and as a result lack the T-regulatory cell component necessary for controlling inflammation.

Cancer

Oncology is another popular target for microbiome companies, with particular interest in how this approach could lie in cancer immunotherapies, which are currently transforming the treatment of a number of different blood cancers and solid tumours.

Seres is active in this area too, and in March the company received a $20m payment from AstraZeneca to kick off a collaboration that will explore whether microbiome therapeutics can increase the efficacy of cancer immunotherapies. The programme builds on research carried out at MD Anderson Cancer Center and the Parker Institute for Cancer Immunotherapy that suggested the gut microbiome influences the response to checkpoint inhibitors.

AZ is working with Seres to see if it is possible to use the microbiome to predict how well a patient will respond to checkpoint inhibitor therapy, and also to explore using therapies to alter the microbiome in order to make patients more likely to respond.

Merck & Co/MSD has taken a similar approach with UK biotech 4D Pharma, testing its Keytruda (pembrolizumab) drug and 4D’s live biotherapeutic candidate MRX0518 in patients with solid tumours, and Bristol-Myers Squibb is also joining the fray via a collaboration with Vedanta to test its VE800 probiotic alongside checkpoint inhibitor Opdivo (nivolumab).

Last year, Vedanta reported preclinical results suggesting that VE800, both alone and in combination with a checkpoint inhibitor, showed anti-tumour effects, including cytotoxic T cell infiltration into the cancer, suppression of tumour growth and extended survival.

Enterome meanwhile is once again taking a slightly different approach to cancer. It is working on a potential microbiome-derived therapeutic vaccine for glioblastoma, an aggressive form of brain cancer, which draws on the interaction between the immune system and the microbiome to render tumours visible to immune surveillance.

Central nervous system disorders and more

While still in the early stages, some groups are exploring how manipulating the microbiome may have an impact on central nervous system (CNS) disorders through what is known as the gut-brain axis, a complex biochemical signalling system that includes hormonal, immune and neuronal linkages.

The next decade will see strong integration between microbiome experts and experts in pure therapeutic disciplines such as cancer and neurology’

One biotech – Axial Biotherapeutics – is developing gut-selective therapies to try to tackle CNS disorders including Parkinson’s disease and autism, and raised $25m in a second round of financing in February to help accelerate its programmes into the clinic. Another – AOBiome – has a microbiome-based intranasal spray in testing as a preventive treatment for migraine.

Another possible use of microbiome-targeting drugs is obesity, where it has been hypothesised that disruption to a healthy bacterial population in the GI tract can both increase susceptibility to becoming overweight and may make it more likely that weight is put on again after dieting.

To explore that link further, Pfizer signed a deal with Second Genome in 2014 to try to understand the link between obesity and the microbiome, although its other programmes in areas like non-alcoholic steatohepatitis (NASH) and inflammatory bowel disease are further forward, having started clinical trials. Another gut-brain axis specialist – Kallyope – is working with Novo Nordisk to discover peptide treatments for both obesity and diabetes.

In a report published last year, Senventure chief executive Isabelle de Cremoux predicted that the next decade will see “strong integration between microbiome experts and experts in pure therapeutic disciplines such as cancer and neurology”.

Much will depend on the first phase 2 and phase 3 microbiome trials due to read out in the next couple of years.

Phil Taylor is a journalist specialising in the healthcare industry.

Gut bacteria, microbiome: bacteria inside the large intestine
Good data is nothing without advocacy

By Jon Hallows

‘Effective advocacy will make your brand stand out from the crowd and influence change’

In a world focused on improved outcomes, the days when drugs sold themselves on data alone are long gone. While the need for good data is indisputable, it is important to take this data and clearly communicate what it really means.

Additionally, the healthcare market is an increasingly ‘noisy’ and restricted environment, with drug developments often being only incremental. Therefore, how data is communicated and by whom is important to influence the target audience.

As such, advocacy development is an important strategic imperative for sustaining and leveraging successful product life cycles, from launch to maturity.

What is effective advocacy in the pharmaceutical sector and what can it do for you?

Having a network of recognised industry experts (usually doctors) who act as spokespeople for a product or brand is key to increasing brand awareness and acceptance among healthcare professionals (HCPs). These respected key opinion leaders (KOLs) can provide invaluable advice to HCPs at meetings, congresses and advisory boards and are crucial in gaining traction with doctors and pharmacies for your brand.

Additionally, changes in the way that people access information today mean that advocates can act as influencers on social media. Peer opinions are often highly regarded and online media has the potential for highly targeted messages with an infinite reach. Consequently, advocates with a strong social media presence are becoming increasingly important in the advocacy mix.

Advocacy is particularly beneficial at the launch stage of a product life cycle, as it can provide favourable independent voices when it comes to funding decisions and can be seen as ‘investing in intelligence’, therefore facilitating market access for your product.

Building a successful advocacy development programme

First, consider these parameters to build an advocacy development plan:

1. Recognition and relationships:
   - Brand/company recognition
   - Overall opinion of your brand/company
   - Quality and quantity of relationships within the therapy area.

2. Willingness to engage:
   - Agreement to participate in programme activities
   - Provision of useful feedback in meetings
   - Help with study enrolment/publications/congresses, etc
   - Sales and market research
   - Recommendation of peers.

3. Mix of advocates:
   - Advocates who are keen to engage and educate their peers
   - Credible advocates to promote your brand and align your brand with overall strategy
   - Variety within the cohort to ensure broader reach and longevity of relationships.

Second, consider your brand focus:

- What is your current brand situation?
- Who are your core consumers and how do you want them to perceive your brand?
- What barriers are there to increasing the market share of your brand?

Third, build the advocacy development programme: define your objective, apply a robust strategy and plan carefully.

Possible options:

- Award panels
- Rising star academies
- CME
- Debating societies
- Educational faculties
- Policy steering committees.

Also consider making a strategic and tactical plan for each advocate, mapped out with an advocacy matrix grid.

Recruitment

Consider what motivation a potential advocate has for being involved. Can you have a true symbiotic relationship? Does your contracting process ensure transparency and compliance with relevant codes of practice?

Plan ahead: long-term development

Managing roles

Ensure that no single advocate is overused or forgotten. Outline the activities within your programme to ensure that advocates are aware of their expected participation and align advocates by their interests and abilities.

Developing charters

Charters can be used to define the role and responsibilities of each advocate as well as the limitations on the terms and length of service. It also provides an exit strategy, as participants know the proposed longevity of their involvement with the programme.

Measurement

At the outset of the programme, develop a set of key performance indicators (KPIs) to measure the impact of a given educational intervention. These could range from simple in scope, for example, the number and quality of publications, to complex, for example, the impact on social media.

Getting it right

If you get it right, effective advocacy will give your data credibility and increase its reach, make your brand stand out from the crowd and influence change. This doesn’t have to be tackled alone – experienced med comms agencies have the capabilities and resources to access the best advocates and achieve the best outcomes for your brand.

Jon Hallows is Joint Managing Director at Porterhouse Medical Group
THE SOCIAL DILEMMA: IS IT TIME FOR PHARMA TO JOIN THE PARTY?
Chris Ross explores why social media still isn’t trending for pharma – and asks what needs to be done to join in the fun.

WHAT PHARMA MARKETERS CAN LEARN FROM DISNEY
Why we need to continue to innovate, and surprise our audience.

PEOPLE
Q&A with Raman Sehgal
The social dilemma: is it time for pharma to join the party?

Chris Ross explores why social media still isn’t trending for pharma – and asks what needs to be done to join in the fun

“There’s a party going on next door, but our industry is too scared to go in. We’re worried that, if we do, we won’t know what to say, how to say it or what we should do with the information we hear. So we ultimately conclude that we’re better off keeping the door shut.”

Welcome to the world of social media in pharma, 2019-style. The words of Dennis O’Brien, CEO at Lucid Group, provide a mischievous metaphor to which we can all relate: on a global scale, there’s a health conversation happening online, but pharma has yet to join the party. If it’s waiting for the invite it should think again: it won’t arrive. The industry must be brave and turn up on its own, bringing something of value to excite the crowd. That’s within its gift – but if it doesn’t rock up soon, it won’t be long before disruptors from outside pharma swagger in and take over the dance floor.

Pharma’s widespread absence from social media continues to defy modern logic. At the consumer level, use of social media continues to grow; the number of active social media users, worldwide, reached almost 3.5 billion in January 2019 – that’s 45% of the global population. And many are using it a lot. The average user spends around 2 hours and 22 minutes every day on social networking and messaging platforms, with millennials spending even more. It’s fair to say that social media has, for the majority of consumers, become the default mode of communication. And guess what? HCPs are consumers too – and they’re using social channels just as much as the rest of us.

The digital doctor

Research shows that HCPs are spending an increasing amount of time online. For example, research into HCPs’ online engagement reported over 30,000 mentions directly relating to ASCO during 2017, while more than 2,000 posts from ESMO 2016 linked to HCP authors at the congress. Clearly, just as in wider society, HCP use of social media is growing.

In fact, medical congress trends are a good indicator of HCPs’ growing comfort with digital media. International congresses are still regarded – by both the medical community and pharma – as a valuable source of education and engagement. However, as the demands on doctors’ time intensify, HCP attendances are falling, forcing medics to seek alternative means of accessing clinical and scientific information.

‘Digital gives HCPs the opportunity to ‘be there’ at congresses virtually and provides a bridge to education that they may otherwise miss’

“Time and budgetary constraints have meant that physicians are becoming less able to attend international congresses, but digital is giving them the opportunity to ‘be there’ virtually and provide a bridge to education that they may otherwise miss,” said Houda Kamoun Folot, Chief Strategy and Marketing Officer at Aptus Health. “What’s more, for busy HCPs, online media is a gateway not only to valuable ‘snackable’ content that they can easily consume and share, but also to comment streams and social channels that enable peer-to-peer conversation and help them put clinical information in a real-world context.”

However, although HCPs’ use of digital channels has grown considerably in recent years, there’s evidence that pharma is not keeping pace with customer expectations. “There’s a delta between what physicians want from pharma and the communications they actually receive,” said Houda.

“Recent research from DT Associates and Aptus Health revealed a wide variation in content and channel preferences among HCPs, depending on their country and specialism. However, our data also showed that pharma companies don’t always address those variations, leading to suboptimal customer experiences and communications. One key finding was that, while physicians prefer a mix of communications, pharma companies typically underutilise digital channels and rely too much on face-to-face engagement. It also showed that while HCPs generally are most interested in medical education, patient support materials or content that informs clinical practice, pharma communications are too often tactical or promotional, focusing predominantly on drug-related information.”
The 2019 report – The State of Customer Experience in the Pharmaceutical Industry, 2018: HCP Interactions – listed 17 interaction types that pharma companies typically deploy. These cover a wide range from face-to-face rep meetings and congress booths to direct mail, email, mobile apps and eNewsletters. Significantly, less than 0.5% of industry interactions during the survey period occurred via social channels. In a world where health is increasingly debated over social media, pharma’s voice is absent from the conversation. The question is: why?

Pay to party

“Pharma isn’t yet configured to embrace social media or fully exploit the new digital world,” said Dennis O’Brien. “Companies know they need to think ‘mobile first’ and that paid digital channels are becoming increasingly valuable, but the structures they work within are the same today as they were 15 years ago. Unfortunately, in the real world, the way the world communicates is now radically different; what worked for pharma in the past just isn’t going to cut it in the future.

“When it comes to engaging customers, HCPs are normal human beings – and they connect with the world in the same ways as everyone else. But our industry isn’t yet designed to do that. Other industries have got Social Media Directors, social strategies and planning to leverage what’s become an enormous channel – yet pharma’s still reliant on traditional routes. We’re concerned about the regulations and the level of investment it might take to safely contribute to the social conversation. We’re scared to go to the party. We must move from being scared to being real.”
The number of active social media users, worldwide, reached almost 3.5 billion in January 2019 – that’s 45% of the global population.

Physicians spend on average 180 minutes a week watching online video content for educational purposes, while two-thirds of doctors with mobile devices use them to source and share information more than ten times every working day.

The average user spends around 2 hours and 22 minutes every day on social networking and messaging platforms, with millennials spending even more.

Research into HCPs’ online engagement reported over 30,000 mentions directly relating to ASCO during 2017, while more than 2,000 posts from ESMO 2016 linked to HCP authors at the congress.

So how can they do that? “Companies have got to be confident,” said Dennis. “They must be prepared and empowered to communicate in this whole new world of communication. That requires infrastructure and investment to ensure the conversations they have are ethical, professional and productive. It’s an organisational shift. In the past decade, medical affairs has evolved into a proactive, customer-facing resource that’s transformed the nature of HCP engagement. We need a similar evolution in communication. Tomorrow’s leaders will likely be those that invest in a similar level of infrastructure for communications as they historically did in the salesforce. Certainly, current levels of spending on traditional activities are unsustainable when there’s this enormous digital powerhouse that companies are barely touching. Reconfiguration will undoubtedly take time. Getting there may require a ‘whole industry’ approach to work out how organisations can evolve to play in a brave new world. If we don’t, disruptors who aren’t weighed down by legacy will, at some point, gate-crash the party and find a way of connecting that leaves pharma behind.”

Reframing KOLs
Pharma’s communications challenges are far broader than a failure to trend on social media; there’s an argument that the industry needs to think differently right across the board and rethink old ways of working. One potential area is Key Opinion Leader (KOL) development. Pharma builds much of its engagement model around KOLs. It’s a tried-and-tested, successful and – ultimately – sensible approach; innovation always needs a champion, and who better than an eminent expert? But is the industry’s emphasis on KOLs dictating – and perhaps even restricting – modern HCP engagement? It might be time to change tack. “Pharma places great weight on finding KOLs to champion innovation and science – and it’s completely understandable,” said Tapas Mukherjee, Associate Medical Director, Havas Lynx.

“However, there’s always a risk that KOLs talk among themselves. It’s not easy to determine quite how many ‘real-world’ HCPs – the ones at the front line of clinical practice – actually engage with this elite circle of KOLs. When you’re a doctor working in a hospital, you don’t see a ‘KOL’, you see your boss; the person that you go to when there’s a real-world problem or you need practical advice. Pharma’s reliance on KOLs is a worthwhile bridge to academia, but does it connect them to the ‘shop-floor’ clinicians or the diverse community of medical professionals who engage patients every day? Possibly not. Social media can be a gateway to the younger generation of doctors, or demographics that are rarely represented in KOL communities.”

In fact, said Tapas, pharma’s reliance on KOLs inevitably hugely influences the style and nature of their communications. “Materials are often data-rich, scientific and academic, but this doesn’t translate well into social media or use language that captures the broader audience. If industry wants to engage a new cohort of customers across social channels, it may make sense to reframe the approach around ‘influencers’ rather than simply KOLs. The real influencers may not be elite academics but millennial doctors. How do they connect? They use WhatsApp, Instagram and social media. If we’re to capture the full range of today’s influencers, that’s where we need to go. We have to meet our customers where they live.”

The landmark moment?
Pharma companies will undoubtedly continue using traditional routes – not least the major medical congresses – but they may need to step out of their comfort zones in terms of channel and tone if they’re to connect with tomorrow’s medical workforce. “There’s no doubt that pharma is an evidence-based industry where trust and credibility relies on science and data,” said Tapas. “However, the health industry as a whole needs to recognise that there are things of value that aren’t always presented in an academic way.

Education and information need to be compelling, engaging or (at times) entertaining if they are to connect with their target audience. It’s all about storytelling – it’s rarely data that captures the heart and soul. Pharma needs to recognise that there are ways of communicating beyond a medical poster or journal article – and explore new routes to customers that engage and excite. Fundamentally, those ‘new’ routes must include social media. The prospect raises an interesting question: pharma companies can often tell you when a landmark paper came out or when breakthrough science transformed the treatment of a particular disease… but what’s going to be the landmark tweet that changes the course of pharma engagement? And when will that moment arise when pharma can say ‘we’ve cracked it’ and begin communicating with people in ways that befit the new normal?”

Personalisation driving the future
The future of HCP engagement will ultimately depend on pharma harnessing the opportunity of digital channels, not least social media. “It’s all about personalisation, relevance and value,” said Houda Kamoun Foliot. “Medical communications is moving from face-to-face engagement and large-scale international congresses to being able to offer value at the individual level through a wide variety of content formats and channels.

‘Medical affairs has evolved into a proactive, customer-facing resource that’s transformed the nature of HCP engagement – we need a similar evolution in communication’

Education is becoming more personal, matching learning needs with individual preferences to deliver the right content for the right person at the right time. Digital and data is helping us to get that right. It’s creating powerful opportunities for personalised engagement and giving industry the chance to become part of an ongoing conversation. Fundamentally, these opportunities have the potential to create better experiences and better relationships with HCPs.”

As communications becomes increasingly personalised, the industry’s use of digital channels will need to flex in line with customer preferences. Social media won’t always be the best option. But as 3.5 billion people – including a whole wave of millennial doctors – use social media as their routine channel of communication, it won’t be long before pharma’s absence from the conversation has more damaging commercial repercussions. It’s time to join the party.

Chris Ross is a freelance writer specialising in the pharmaceutical and healthcare industry.
Adding value ‘beyond the pill’

By Houda Kamoun Follot

‘Physicians see value in digital coverage of live events – 76% express interest in receiving email recaps of conferences they were unable to attend’

Pharma companies provide some of the most important products an HCP can have – the therapies that help the patients they serve. But simply offering those products is not enough.

In a competitive landscape, pharma companies need to offer added value ‘beyond the pill’. These are the elements that will attract physicians, engage them with content that is trustworthy and valuable, and build these relationships over time through personalised content that supports better practice.

That content includes the clinical news, data and breakthroughs that are often discussed at some of the industry’s most popular medical congresses, like ASCO, Society of Medical Oncology and more. Many pharma marketers invest in a presence at these congresses to get valuable face-time with HCP audiences and distribute their messages to a rapt audience.

Savvy marketers are finding ways to extend their investment through digital congress coverage that engages target HCPs well beyond the event itself, while offering valuable insights into target audiences’ attitudes and behaviours. It’s a powerful way for pharma brands to keep the conversation going throughout the year and stay at the top of key audiences’ minds.

Bring the congress to them

Physicians see value in digital coverage of live events – in fact, 76% of physicians express interest in receiving email recaps of conferences they were unable to attend. For over a decade, we’ve been engaging digitally with HCPs around the world through our clinical news and education site, Univadis. Congress coverage is an especially popular topic for our members in the EU5, yielding higher-than-average engagement rates compared to other topics:

• 13.9% increase in article views for coverage of a key cardiology congress
• 145% increase in article views for coverage of a key oncology congress
• A nearly 400% increase in article views for coverage of a key infectious disease congress.

Digital channels also help understand which topics an audience is most interested in, as well as which formats and which channels, that can help inform an overall multichannel marketing strategy.

Provide ongoing engagement and value

Recent data from a survey we did of our global HCP members on Univadis shows that the vast majority have three key expectations of the interactions they have with pharma: trustworthiness, relevance and simplicity, in that order of importance.

In terms of content, there is a gap between what HCPs want from pharma and what they receive. For example, our report shows that HCPs are receiving an overwhelming amount of prescription drug information from pharma, and not enough about medical news, education and patient materials they want.

In addition, we found that while a relatively small percentage of HCPs say they prefer to engage with pharma through in-person symposiums or a company’s congress booth, the top-ranked channel for these interactions is an online or virtual meeting like a webinar, webcast or congress.

Insights like these demonstrate that while HCPs still value personal channels, there is a clear role for digital to complement these face-to-face interactions as part of an effective HCP engagement strategy.

A real-world example

Digital experiences can enhance the live experience of congresses – allowing HCPs to spend more time with the content while offering pharma companies the opportunity to position their messages in the context of the latest news and breakthroughs in their therapeutic area.

For example, pharma-sponsored digital coverage of a well-respected congress held earlier this year included ten reports covering key congress content, as well as five customised video interviews (which typically yield double the amount of engagement of other channels) with clinical experts in the field.

This exclusive content was hosted and promoted through our Univadis platform, which attracts over three million HCPs around the world, localised for each geographic market. This ‘globcal’ approach allows for cost-effective deployment of these digital assets in different markets. In this particular case, the content was published in five languages across eight markets and promoted to HCPs in four key specialties through a mix of custom newsletters, banners, mobile push notifications, social media and more.

In addition to helping keep HCPs up-to-date with the latest advances in their area, the pharma client that sponsored this content was able to position itself as delivering high-value clinical content in formats that appeal to HCPs – content they can return to time and time again.

For more information on how pharma companies can take advantage of digital to extend their congress investment, go to http://info-intl.aptushalth.com/econgresscoverage-aptushalth-int

Houda Kamoun Follot is Chief Strategy and Marketing Officer at Aptus Health
### Part 2: Putting the moose on the table

This month’s blog is focused on local brand planners – leaders and cross-functional team contributors who have an important job to do in translating global and/or regional strategic guidance and plans at a local level.

There are inherent tensions in this endeavour: on one side, the global team wants to ensure its carefully researched strategies and global programmes achieve global reach and deliver a consistent brand and customer experience. From the local team’s perspective, it has to grapple with local market/access/customer/competitor differences, a complex picture which often doesn’t closely resemble that global vision.

So how do you get started on local brand planning for a pharma or biotech brand?

**Step 1: Plan the plan**
- Check you know your company’s brand and financial brand planning timeline, process, frameworks and expectations – some companies have a very structured process and others are less structured.
- Assemble your cross-functional team and plan contributors including your trusted agency partners who can input to strategy and can therefore create better solutions for your team and brand. Engage professional training or facilitation help for your brand planning working sessions if needed – they (we!) can provide invaluable help in tackling the big strategic challenges, gaining team alignment and support for the overall process.
- Create a ‘Brand Plan Plan’ – define a series of working sessions, assign roles and mini-deadlines to get you and your team to where you need to be at the right time. You may need to deprioritise some operational activities or delegate them.

In my work with client teams across the industry, I am often asked for brand planning hacks, quick tricks and shortcuts to creating a great local brand plan. This is a tough ask, but here are a few tips:

1. Invest in your cross-functional brand team so that it is skilled in the company brand planning framework and process, and fully commit to its role in delivering a strong brand plan.
2. Allocate short time slots for uninterrupted time to tackle key questions such as the big strategic questions and collate creative ideas.

3. Write up your brand plan ‘story’ on one page – intuitively what is the story you want to tell about your local market, your brand, the challenges you face and how you will tackle them. It doesn’t matter if this isn’t perfect – this will give you a compass and a starting point. If you had to, how would you create your brand plan on one page – it can be done.

**Step 2: Gather your analysis and insights**
- The first question to ask is what has changed since your last plan – what’s different about what you know about the environment, competitors, customers and your brand performance?
- Next, what are the implications for this year’s brand plan? Be honest; if you’re doing well, could you be doing better? If you’re not doing well, how could you do better? As one pharma company says: ‘Put the moose on the table.’ This is the time to ask tough questions.
- As a team, work through your latest performance data, market research and observational data to form the latest view of the market. This is the time to list any information gaps and fill in as many as you can.
- Now start to ask the question ‘why’ again and again as you review your analysis and create a map of the key insights by patient/physician/payer. Don’t rely on global research and insights – these need to resonate at the heart of local patients/physicians/payers and be better than the competition. Create an insight map for each key customer and add to your collective team knowledge.

**Step 3: Create a robust situational analysis and SWOT**
- The best tip here is not to ‘wallow in analysis’. What are the top 10 charts and pieces of analysis of your market that you’ll use in your brand plan? Multiple slide decks of research or performance data are not needed here.
- A SWOT working session is a great cross-functional team activity but it’s worth engaging a strong facilitator to ensure the integrity of the SWOT is adhered to. It’s easy to create a mediocre SWOT by committee.
- This is the platform for your whole brand plan, so ensure the points are prioritised, specifically articulated and are a true picture of your market position – your SWOT may be imbalanced in one or more quadrants.
- Having created your SWOT, it’s worth moving forward with the three or four key implications that need to be addressed in your strategies. Consider this as a funnel: what are the most important SWOT issues that can act as the logic backbone to your whole brand plan?

Need a break? Taking a break as the next phase of your brand plan is even more important to your future brand plan performance.

With a strong SWOT and resulting key issues and strategic implications, the ‘so what’s’, you should now be ready to tackle the objectives, strategic mix and segmentation, targeting and positioning. Tune in next time to Part 3: Creating bold not bland strategies.

Stephanie Hall is MD of the award-winning brand planning healthcare consultancy Uptake Strategies.

---

**PHARMA BRAND PLANNERS’ BLOG**

**Part 3: Creating bold not bland strategies**

**MARKETING**
Breaking from tradition
How social media can improve doctors’ congress experience

By Suzanna Gamwell

In doctors’ increasingly pressured professional lives, medical congress can provide a welcome space for physicians, away from front-line responsibilities, to connect with colleagues, discuss ideas and in the words of one physician ‘to push the next line of reasoning with the latest treatments’.

Pharmaceutical brand teams have long recognised congress as an important opportunity to get face-time with customers. More recently, these same teams are beginning to consider the role that social media can play in extending the reach and impact of their traditional, onsite congress activities, and seeing social media as a channel to better understand the priorities of their healthcare professional customers at congresses.

At CREATION, we have been studying the online conversation of healthcare professionals for many years. During this time, we have observed the digital behaviours of HCPs in diverse global markets, across a huge range of therapy areas – and in every scenario, we have consistently seen HCP online conversation spike during medical congresses.

Why do HCPs flock to social media during congresses?
Social media provides HCPs with a means of connection, both with other peers in relevant roles, and with information. Platforms like Twitter offer HCPs a highly accessible, familiar and free tool for sharing and commenting on data as it is released, whether with the colleague sitting next to them in the lecture theatre or (and perhaps more importantly) with peers across the globe who are following updates and taking part in conversations remotely. In this sense, social platforms can and do optimise the experience of the congress environment, enabling HCPs to follow, in real time, not only what is happening in their workstream, but what is happening across the entire congress, and to have access not only to other experts within the room, but with experts across the world.

Further to this, many online doctors are passionate about educating other HCPs regarding their specialism, and throughout the year use social media to share developments from, and...
develop knowledge within, their chosen therapy area (see, for example, hashtags such as #meded, #foamed and #hcsm). The plethora of data released at congresses fuels this sharing of information and resources, with HCPs around the world following congress-specific hashtags and ‘significant’ voices within the online conversation to keep abreast of news and discussions as they unfold.

From the physicians’ perspective, it is also worth considering the potential kudos of being seen as one of the first to share or sign-post a significant finding, or a useful reflection from a speaker at congress – or indeed profile their own research beyond the confines of the conference centre.

What does this mean for pharmaceutical marketers?
Although interest in using social channels alongside more traditional tactics has increased in recent years, we sometimes find that brand teams are reticent to take the first steps towards integrating social media into their congress strategy, often citing resource or compliance issues.

In reality, when considering the role that social channels could play for your brand during congresses, it can be helpful to start by considering the similarities between your online presence and your real life presence on the ground.

Yes, you can be confident of seeing familiar faces at the conference centre; you can also be confident that prescribers will be gathered online to discuss the key findings shared in those sessions – and potentially the role of your product in light of those findings. Likewise, you know that HCPs participating in congresses have carved out time to further their understanding, gather resources and build their networks, and that consequently, this is a prime time to engage your customers, who will be actively seeking and sharing information, and looking to make new connections. The same is true in the online space.

There is little doubt that congresses present some great opportunities for pharmaceutical companies to connect with customers online. However, just as offline it can be difficult to be heard amid the noise of the exhibition hall, online there is a danger that your ‘voice’ will be drowned out by the noise generated in response to congresses. In this situation, remembering to put the basics in place can increase your chances of engaging your customers.

1. Listen. Start by listening. Just as face-to-face conversations can give you a great insight into the views of your customers, observing the online interactions of HCPs during congresses can give you an unbiased view of their hopes and concerns for new treatments, as well as highlighting what HCPs perceive to be the current ‘gaps’ in treatment. Congresses can be a great time to gather competitive intelligence; how are HCPs responding to competitor data and announcements? Taking the opportunity to listen will also give you a sense of the tone of the online conversation, and very practically, the language, lexicon and hashtags that HCPs are using to discuss and group certain topics.

2. Add value. It goes without saying that adding value to customers is the cornerstone of a good customer experience. Offline, congress stands are stacked with useful educational resources, but all too often, online we see pharmaceutical companies using congresses as a time to ‘shout’ about their latest corporate accomplishment; in reality, these posts tend to garner little engagement from HCPs. Plan instead to offer HCPs something that will both enrich their research.

How will you measure the success of your conference presence?

Use Conference Live to collect in-the-moment feedback and insights from leading specialists before, during and after the event.

We will provide you with all of the tools you need to understand how your presence at conferences has been perceived by your target customers and what this means for your brand or franchise.

Visit our website to find out how Conference Live can offer you a competitive advantage.

researchpartnership.com/conferencelive
experience of congresses, and prove useful beyond the event. In the online space, this could mean anything from sharable educational resources, through to designing a Twitter poll that connects HCP peers (and perhaps patients) in a meaningful dialogue.

3. Collaborate. You don’t have to go it alone; in fact, having listened to your customers, you may well find that your corporate voice is not the most effective vehicle for sharing your message. Consider the role of partners, whether Digital Opinion Leaders (those HCPs who are actively influencing the conversation within a therapy area), research organisations, advocacy groups or, where appropriate, expert patients, for collaboration around voicing a message online.

4. Provide a platform for others. Could you tick both the value-added and partnership boxes by helping your Key Opinion Leaders (KOLs) to develop their profile using your corporate social media platforms? Increasingly, as well as planning offline symposia and speaking opportunities for KOLs during congresses, pharmaceutical companies are working with their KOLs to develop corporately branded video resources ahead of congresses, which can then be shared during congresses in concert with KOL speaker slots.

5. Broader needs. Whether on or offline, consider the broader needs of your HCPs at congresses. In recent months, we have been struck by the number of posts from HCPs at medical congresses that have been ‘non-clinical’ in focus, and yet have received a high level of engagement from other HCPs. This has included conversation about the need for more professional networking opportunities at congresses, the provision of childcare at several high profile congress meetings, and using congresses as a time for peer support and encouragement in the face of the pressures of working as an HCP. Treating your customers as real people tells HCPs something about your values and will influence how comfortable HCPs feel interacting with your brand online.

6. Tracking. Tracking the online conversation pre, during and post congresses can both give you an indication of how HCPs respond to new data during congresses, and also how this data then goes on to influence the nature and tone of the evolving conversation beyond congresses. Yes, HCPs may be excited about a particular paper or announcement, but in the weeks after congresses, what are their concerns? What are the questions they asking one another? Do they anticipate changing, or have they changed, their practice in response to this? Tracking these online conversations also allows you to see the extent to which your own content has resonated, and how HCPs are responding to competitor content.

Conferences are the stages on which pharmaceutical, biotech and medical device companies demonstrate leadership and their commitment to a specific field of medicine. Increasingly, senior management wants to keep a closer eye on how the company is perceived by key prescribers and whether the dollar spend on conference presence has been justified in terms of enhancing this perception. With full control over sample and the ability to compose a sufficient basis for simple quantitative comparisons, mobile conference research perfectly meets both requirements.

We are now witnessing a further evolution of conference research. In addition to looking at single-conference ‘issues’ piecemeal, there is an increased demand for an ongoing evaluation of company performance and perceptions over time. Major conferences are being used as marker points on the continual pathway to pre-eminence and provide the perfect juncture for both an inward- and outward-looking self-evaluation: What is our position in the minds of our customers? Can we defend our leadership position in the face of new treatment approaches? Of what value is our heritage versus the impact of a new revolutionary product?

These are some of the questions that conference research is now helping to address and it is why pharmaceutical companies are increasingly looking to track KPIs across numerous conferences and throughout the year as well as subsequent years. The comparative evaluation of US versus European meetings/prescribers is of interest, as is the year-on-year measurement of change at a single major meeting. By building conference-specific questions around a core of repeated KPIs, we can simultaneously understand the buzz of an individual meeting, while also contributing insights on the trends in the bigger picture.

John Branston is a Director at Research Partnership

**Conducting effective conference research to measure your performance over time**

By John Branston

‘Major conferences are being used as marker points on the continual pathway to pre-eminence’
The principles of multichannel marketing are well established, but as the evolution of new technologies continues to allow for greater connectivity and integration between channels, does pharma need to embrace crosschannel or omnichannel strategies to keep up with stakeholders’ expectations?

In pharma, ‘channel’ is often used broadly to refer to the routes for communicating with customers. Multichannel relates to relaying a single communication objective using more than one channel. Multichannel marketing first became familiar terminology when the internet became part of the marketing mix. At first, the different channels were completely separate. Crosschannel marketing has the subtle difference that the channels are connected together. A typical example of crosschannel marketing is running an integrated campaign that involves using email and social media channels to reach your target audience and drive it to a website via calls to action. Omnichannel marketing not only uses multiple channels that communicate back and forth, but these channels also work seamlessly together, in parallel, to provide customers with a cohesive experience across all channels.

Disney is the master of omnichannel marketing and the de facto leader in the field. It has a stunning mobile-responsive website where users can buy Disney-branded merchandise, purchase Disney movie tickets and subscriptions, and most importantly, book holidays to one of the Disney theme parks.

After booking a holiday on the website, users can download the ‘My Disney Experience’ app to plan every detail of their trip, from accessing real-time wait times and parade showtimes, to using the GPS-enabled map to explore the resort and locate restaurants and other attractions. Furthermore, they can use the app to purchase theme park tickets, browse restaurant menus, make dining reservations and even start the hotel check-in process.

Disney’s brilliantly thought-through omnichannel experience shines at every step of the user journey, which continues with the use of its most unique tool, MagicBand – a secure, all-in-one device resembling a watch or a bracelet that works seamlessly with the My Disney Experience app and allows users to unlock their hotel door, check in at the entrances, charge food and merchandise purchases to their hotel room and even unlock special personalised experiences.

Applying Disney principles to pharma – we couldn’t, could we?

It is evident that Disney knows its audience very well and is an expert in refining the user experience, making sure the latter is personalised and totally integrated across physical devices and channels. It’s not an often-asked question, but can we learn anything from Disney and apply those learnings to pharma?

‘There is an almost limitless amount of metrics that can be derived from digital channels. But is pharma utilising them to their full potential?’

- Map the journey of the target audience. Whether they are patients or HCPs, we need to understand what kind of information your audience is looking for, and when and where.
- Tell a story and meet audience needs at every stage in the journey. It is important to bring the audience along its journey to prescribing or, in the case of patients, to perhaps asking their physician the right questions, by telling a compelling and cohesive story and overcoming barriers along the way.
- Develop content in a format your audience wants to consume. Modern life exposes us to vast amounts of information, and audiences are overwhelmed and distracted. We need to make it easy for audiences to consume our content using language and lexicon they are familiar with, and provide information in short relevant bites that is actionable in their daily lives.
- Link all content to communication goals. For maximum impact, all content needs to have a red thread linking it back to your communication objectives. Everything leads in one direction… towards your goal!
- Measure success and adapt. You probably won’t get it right the first time, and even if you do, fine-tuning will optimise success. Using metrics to measure performance against KPIs is key. And there is an almost limitless amount of metrics that can be derived from digital channels. But is pharma utilising them to their full potential? Should we be analysing customer experience metrics such as net promoter score, customer satisfaction, churn rate, retention rate, customer lifetime value and customer effort scores in finer detail?

But after all, pharma is not Disney…

Due to the regulatory environment, pharma is unique in that what is communicated to HCPs changes dramatically as an asset moves from bench to brand. From publications in phase 2, to unbranded awareness campaigns in phase 3, through to promotional campaigns at launch, there is a need for content to evolve and to continuously optimise both the messages and channel selection to meet the changing communication priorities. This constant need for reinvention is at odds with the increasing pressure on budgets as a result of pharma companies investing more and more of their spend in R&D.

There is a clear need to select priority channels, and to do this we need to truly understand our customers and how their habits are changing. To optimise content development spend, a COPE (Create Once Publish Everywhere) approach makes sense, where content and assets are developed and reused across the channels.

Our audience is also distinct in that it demands credible, accurate information. No matter what the channel, content needs to have scientific integrity, empathy and impact. Our audience, whether it’s HCPs or patients, demands content that has its origins firmly rooted in science, as empathy can mean different things, from supporting patients and carers, to understanding the needs of time-
challenged HCPs and how to provide them with the actionable information they are looking for.

Rising above the noise is an exponential challenge. As products enter increasingly crowded marketplaces, differentiation is key; not only communicating insightful messages that resonate with the audience, but also in terms of transmitting the message in novel and impactful ways through insightful channel selection.

Becoming more agile is one way. Oreo capitalised on the massive power outage inside of the Mercedes-Benz Superdome in New Orleans by tweeting: ‘Power out? No problem, you can still dunk in the dark.’ For those who think this is not a possibility in the pharma industry given the lengthy approval process, just consider the response to US comedienne Roseanne Barr blaming the sleep aid product Ambien for a racist post she made. Sanofi US tweeted: ‘People of all religions and nationalities work at Sanofi every day to improve the lives of people around the world. While all pharmaceutical treatments have side effects, racism is not a known side effect of any Sanofi medication.’ These agile responses caught the eyes of millions and, when well executed, can certainly get you noticed.

The power of impactful design, whatever the channel, should also never be underestimated. But most of all we need to continue to innovate, and surprise our audience. Despite increasing usage and demand amongst HCPs globally, digital channels are still under-represented in the pharma marketing mix. Channels such as YouTube, while immensely popular among both HCPs and patients, are considered off-limits by many companies, while patient advocacy groups capitalise on them for disease awareness.

Our audience expects to be able to access information on pharma products in the way it does any other information in daily life, and there are lots of technologies with huge potential waiting to be adopted by pharma. Yes, there are hurdles to overcome, but these are not unsurmountable. These are exciting times for digital strategists, and Nucleus Global looks forward to determining how we can find the place of new technologies in the multichannel marketing mix!

New technologies that are ripe for adoption

- How can we use new technology, such as voice?
- How can we capitalise on social media?
- Is there a place for online communities?
- How can we unify data from different channels and use it to build seamless and personalised experiences?
- How can we utilise AI to optimise our digital strategies?

Karen Isherwood, Director Client Services, MediTech Media Ltd;
Harry Politis, Digital Product Director, SynaptikDigital;
Viorica Gheorghita, Senior Digital Product Manager, SynaptikDigital
Synergy Vision and Axon ranked among UK’s best workplaces

Medical communications specialist Synergy Vision has been placed 2nd overall in the UK’s Best Workplaces 2019, in the small business category.

The ranking is a leap up of nine places from its position last year, and the agency attributes this to its “ongoing commitment to putting the team first”.

In total, 132 organisations qualified as the UK’s Best Workplaces this year, which is ranked by combining the Trust Index Survey findings.

This is found by an employee survey, which sees all employees answer questions about their respective workplace, with answers accounting for two-thirds of the overall criteria.

The remaining third is made up of an in-depth review of leadership and people practices through the Culture Audit.

Eileen Gallagher, MD, commented: “We have built our success by putting the team first, with trust at the heart of everything we do. Clients have long recognised that our culture transcends physical boundaries and helps our people to deliver the difference in partnership and with integrity, while keeping a good work-life balance. This external recognition is the icing on the cake”

Synergy Vision was also recently recognised for Excellence in Wellbeing by Great Place to Work, which was announced just ahead of its launch of its first senior development programme, designed to augment personal development plans already in place and catapult mid-level managers to senior positions.

The company also recently implemented a four-day working week, which launched in December and allows staff to work a 36-hour week compared to their previous 40-hour requirement.

Healthcare communications group Axon was also recognised in the Great Place to Work UK in the medium-sized category, ranking 21st.

It’s the fifth consecutive year that the agency has been recognised, and the award is the latest in a series of wins for the healthcare communications agency group, including Best Workplaces for Women in the UK and Excellence in Wellbeing.

“At AXON, the secret to our success is our people. We aim to build a culture where our employees feel empowered and nurtured, and we’re extremely proud of the environment we have created together,” said Miranda Dini, Managing Partner of AXON London.

“We have grown substantially over the past five years, while maintaining that family feel, which is critical to ensuring our expanding team continues to flourish. By living our values every day, we’ve been able to achieve this and are pleased to be recognised for these efforts again this year by Great Place to Work.”

Valid Insight receives Queen’s Awards for Enterprise

Valid Insight has received a Queen’s Award for Enterprise, an accolade presented to companies demonstrating outstanding results in their field.

Valid Insight, a company first established in 2016, provides consultancy services to pharma, biotech and the medical device industry on global market access issues.

The recognition for Valid Insight follows its work with client firms across Europe, Switzerland, the USA and Japan involved in the development and commercialisation of medical treatments, diagnostics and devices across multiple therapy areas.

“We are honoured to receive the Queen’s Award for Enterprise in International Trade. We compete against a strong set of consultancy firms on a global level and to win this award means that what we are doing is world class,” said Steve Bradshaw, founder and managing director, Valid Insight.

“From the outset, our strategy was to create a competitive, truly differentiated, global strategy consulting firm with a virtual working model to attract the best talent irrespective of geography. We provide world-class expertise and strategic consulting solutions and tools to give the highest level of certainty around our clients’ most critical business decisions, wherever they are based.

“To win the Queen’s Award strengthens our reputation as a leader in the field and we look forward to an exciting future.”

Porterhouse Medical launch medical advisory group

Porterhouse Medical has introduced a new team to its services, launching its first medical advisory group (MAG) to advise on clinical matters.

The agency is already well-versed in scientific expertise with its PhD-level medical writers and in-house doctors, but says it “recognises the value of having an intimate understanding of client challenges from a clinical perspective”.

Brian Parsons, joint managing director and co-founder of Porterhouse Medical, commented, “The MAG is an exciting opportunity to take the Porterhouse vision forward. We are committed to the concept of adding value to communications through tailored insights, and the MAG is another outstanding example of this.”

The move follows a similar one made by McCann Health last year, when the agency launched a scientific council to further assist its employees and clients.
Paul-Peter Tak has been named president and chief executive officer of newly formed Kintai Therapeutics, a company that aims to deliver a range of precision therapeutics based on enteric signalling networks in the human body. With a career spanning more than 25 years in life sciences, Tak was most recently senior vice president and global head of R&D for immuno-inflammation, oncology and infectious disease, as well as chief immunology officer, at GlaxoSmithKline (GSK) before he joined Flagship Pioneering as a venture partner in October 2018. Tak transitioned to industry, co-founding Arthrogen in 2005, where he was chief scientific officer until 2011. He was CEO and board member of Tempus Pharmaceuticals from 2012 until 2015, at which point he facilitated the company’s acquisition by GSK. Under his leadership, the immuno-inflammation unit brought more than ten new mechanisms of action into the clinic and filed Benlysta for systemic lupus erythematosus.

LEO Pharma Innovation Lab has appointed Justin Ko to its governing advisory board. Ko has a background in melanoma and early cancer detection. At Stanford Health Care, he led research initiatives around the application of machine learning and artificial intelligence to improve diagnosis and care delivery for melanoma patients. He has also developed a teledermatology care programme that provides virtual visits.

bluebird bio has appointed Joanne Smith-Farrell as chief business officer. She will lead corporate development and strategy, and will continue to serve as its oncology franchise leader, which she has done for the past two years. Previously, Smith-Farrell was vice president, business development transactions at Merck, where she led the team that executed business development transactions supporting Merck Research Labs.

Silence Therapeutics has named Rob Quinn as its new chief financial officer, a role in which he served ad interim from January 2019. Before this, Quinn served as head of financial planning and analysis at the company for two years. He has a wealth of financial and scientific experience and before joining Silence he held a senior role at GSK, as area finance director for Africa and developing countries.

GW Pharmaceuticals has appointed Darren Cline as its new chief commercial officer. Cline’s new role will see him lead cannabidiol medicine Epidiolex. He succeeds Julian Gangolli who is retiring but will help Cline transition into the organisation. Cline has over 25 years’ commercial experience and was previously executive vice president, commercial and a member of the executive committee at Seattle Genetics.

Giles Campion has joined Silence Therapeutics as its head of R&D and chief medical officer. Campion has over 20 years’ experience within the biotech and pharmaceutical industries, most notably serving as chief medical officer and senior vice president of R&D from 2009-2016 at European biotech Prosensa. He also held senior R&D roles with Novartis and Alumbex and co-founded rare disease-focused PepGen.

LEO Pharma’s Innovation Lab has announced that Joel Dudley will join its governing advisory board. Dudley is founding director of the Institute for Next Generation Healthcare and Associate Professor of Genetics and Genomic Sciences at Mount Sinai hospital, where he ran the Precision Health Enterprise. His guidance will enable LEO’s Innovation Lab to pioneer more disruptive developments in digital health technology.

Crescendo Biologics has announced that Theodora Harold, the current chief finance officer, will be appointed as the company’s new chief executive officer. She succeeds Peter Pack who stepped down from the role last month. Harold joined Crescendo in 2016, and was central to its recent $70m series B financing round. Before joining the Company, she held both industry and corporate finance roles in biotech.
Aduro Biotech, a clinical stage biopharmaceutical company developing therapies in the Stimulator of Interferon Genes and A Proliferation Inducing Ligand pathways, has appointed Dimitry Nuyten as its chief medical officer. Nuyten will join Aduro from Pfizer where he most recently served as vice president and immuno-oncology clinical development leader and oversaw the clinical strategy for Bavencio.

Novartis’ Haseeb Ahmad has been appointed as the new president of the ABPI. Managing director, UK, Ireland & Nordics at Novartis Pharmaceuticals, and also country president of Novartis UK, Ahmad formally took on the role at the association’s annual conference. Haseeb takes over from Pfizer’s Erik Nordkamp, who will lead on overseeing the ABPI, the ABPI Board and the ABPI’s Code of Practice.

Sanofi’s UK managing director Hugo Fry has been appointed as the ABPI’s vice president, which will involve serving pharma company heads taking on leadership roles for the ABPI, alongside its full-time chief executive, Mike Thompson. As Sanofi’s UK managing director, Fry leads commercial, industrial and R&D units. During his career, Fry has served in various positions for Sanofi Pasteur and Sanofi Aventis.

Eisai has hired Harald Hampel as its vice president, global medical affairs, Alzheimer’s Disease. Hampel will be responsible for creating and overseeing the company’s global AD/dementia medical strategies. He will also oversee investigator-initiated trials. Hampel, who has 25 years clinical trial experience in AD and related neurodegenerative diseases, has published over 600 scientific publications.
Hall & Partners has announced the creation of a new role, global head of people and culture, and has appointed Sue Klinck to the position. Klinck will support the group’s continued transformation into a strategic brand consultancy while growing Hall & Partners’ talent. Klinck, who first joined the company back in 2005, will work closely with its chief transformation officer Richard Owen.

Also expanding the ranks at Red Consultancy, Grace Wardley joins the company as its new senior account executive. Wardley’s previous role was at Burson-Marsteller, where she served as a client executive, specialising in healthcare. Her experience spans urology, oncology, diabetes, dermatology, above brand corporate campaigns and international work. Previously, she worked for Diabetes UK.

Deborah Blain has joined Lucid Group’s Vivid Medical Communications as an account manager. Blain has over ten years’ experience in medical communications, working in anticoagulation and neurology. Ugo Battaglia joins Vivid as a medical writer in its Macclesfield office. Ugo has two years’ medical writing experience with expertise in diabetes and obesity.

Kate Wagstaff has joined UK, London-based emotive as its senior account executive in the client services team. Wagstaff joins the company from a background in healthcare PR, where she fostered an understanding of healthcare communications for a range of key stakeholder groups. She has previously worked for Instinctif Partners as an account executive and has a degree in biomedical science.

emotive has strengthened its medical writing team, appointing Dorothy Overington as a senior medical writer. Overington started her career with an internship at imc before finishing her PhD in Neuroscience at UCL in 2013. Upon graduation, she moved into a medical writing role at imc and was responsible for delivering a range of medical education initiatives, from scientific exchange meetings to digital assets.
What gets you out of bed in the morning?
Coffee and my journal! I use the five-minute journal technique that focuses on gratitude and visualising how you will make your day great. Some people might be a tad sceptical about this kind of thing, but I find the process of reflection enables you to learn a great deal about yourself. For example, what motivates you, good and bad habits, concerns, what makes you happy, etc. Through this you can grow on both a personal and professional level.

What’s the best thing about working in healthcare comms?
Being able to communicate technological advances, business growth and interesting content that helps drive the drug development sector forward.

What’s the worst thing about working in healthcare comms?
Confidentiality! We often see and hear some amazing things going on with clients that we simply can’t bring to the market. It’s a real shame but is commercially sensible.

What’s your favourite bar or eatery?
Café 21 and Broad Chare in Newcastle. I love Parish Café in Boston – the beer selection is incredible and the food is excellent.

What buzzwords/office-jargon get on your nerves?
Having just moved to the US, people here love to use the phrase ‘struggling with bandwidth’, when they are struggling for time/resource. It’ll make its way to the UK soon, no doubt.

Which person, living or dead, do you admire the most and why?
I really admire elite athletes who reach the top of their game yet continue to work tirelessly to stay there. Roger Federer is the best example of this. And even though I’m very much in the Messi camp, I have to admit Ronaldo ticks this box too.

Who’s your healthcare comms hero/heroine?
I can’t say I really have one, to be honest, but I do admire Lisa Bradley who founded Pegasus.

What has been your career highlight to date?
We recently won a global account for one of the biggest names in the pharma sector against nine other agencies. That was pretty great and felt like the culmination of ten years’ worth of blood, sweat and tears.

What buzzwords/office-jargon get on your nerves?
Having just moved to the US, people here love to use the phrase ‘struggling with bandwidth’, when they are struggling for time/resource. It’ll make its way to the UK soon, no doubt.

Which person, living or dead, do you admire the most and why?
I really admire elite athletes who reach the top of their game yet continue to work tirelessly to stay there. Roger Federer is the best example of this. And even though I’m very much in the Messi camp, I have to admit Ronaldo ticks this box too.

Raman Sehgal
Raman Sehgal is Founder and MD of ramarketing

Which book/film would you recommend above all others and why?
Two books I would recommend are *Eat That Frog!* by Brian Tracy and/or *The One Thing* by Gary Keller. Learning how to focus on the important stuff (not your social notifications) and work on a single task at a time will propel you ahead of your counterparts.

A film I would recommend that I saw recently is Bohemian Rhapsody – I thought it was amazing. Among the emotion and music, it also shows the value of thinking big and teamwork.
Client Partner, Healthcare Brand Communications
London, Highly competitive package

Our client’s culture is entrepreneurial and they love what they do. With healthcare brand comms agency experience you will develop strategic direction, proactively and regularly creating ideas that deliver on the client’s business objectives. You will be curious and eager to learn about clients, the industry and the organisation. You will continue to build your expertise in healthcare brand communications, leading teams to deliver unique solutions to clients. Call Anthony on 07968 181759 or email anthony@adeptoconsulting.com for more information.

Top job this month

June highlights

Scientific Editor/Content Submission Specialist
London, Competitive salary
Previous experience as an editor in healthcare/science publishing and a BSc, along with experience in managing Veeva or a similar system are essential. Call Anthony on 07968 181759 or email anthony@adeptoconsulting.com.

Medical Writer/Senior Medical Writer
Macclesfield, Manchester, London or Basel
Competitive salary and benefits package
Applicants need a degree in the life sciences, ideally with an MSc or PhD, and experience in agency or pharmaceutical writing. Call Jon Gawley on 01932 797996 for more information.

Account Director, Med Comms
Manchester/Cheshire, Excellent salary and benefits
Applicants should have a life sciences degree, as well as relevant account management and operational experience within a pharma or med comms agency environment. Call Jon Gawley on 01932 797996 for more information.

Account Director, Disease Awareness and Brand
London, circa £60,000 with benefits
Applicants must have existing healthcare PR agency experience at least Senior Account Manager level. Call Richard on 0208 866 2418 or email richard@chemistrysearch.co.uk for more information.

Account Manager, Oncology
London, circa £35,000 with benefits
This role, working on a high profile oncology account, will see you building upon your scientific knowledge as well as your experience of working in brand comms. Call Richard on 0208 866 2418 or email richard@chemistrysearch.co.uk.

Account Manager, Senior Account
Manager, Med comms
London/Cheshire, Excellent salary and benefits
Applicants need a life sciences degree, and previous experience of account management. Call Jon Gawley on 01932 797996 for more information.

Medical Writer
London, £55,000 to £59,000 with benefits
This PR healthcare med comms agency is looking for a hybrid writer with account handling experience to work on a variety of therapy areas. Call Steve on 020 7359 8244 or email steve@media-contacts.co.uk for more information.

Senior Account Executive/Account Manager
London, £32,000 to £43,000 with bonus
Applicants need to have a degree, ideally with a background in science, and a minimum of 18 months experience working in a healthcare advertising agency. Call Chris on 07713358677 or email chris.french@clrrecruitment.co.uk for more information.

Account Director
London, £50,000 to £55,000
You will be an account director in a healthcare PR agency with a passion for high science, excellent at writing for different audiences and digitally savvy. Call Julia on 020 7359 8244 or email julia.walton@media-contacts.co.uk for more information.

J100s of live vacancys with more added daily

68 Medical communications
40 Healthcare PR
32 Medical writing
8 Healthcare market research
25 Pharmaceutical
4 Market access
34 Medical education
33 Healthcare advertising
16 Healthcare consultancy

Pharma marketing, sales and communications jobs
jobs.pmlive.com

*Job numbers were correct as of 04/06/19
*Featured jobs were live as of 04/06/19
OUR CREATIVE MAGIC

IS THE DOG’S

BLUEDOG
Transforming lives. Always.
A LUCID GROUP COMPANY