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Decisions, decisions

Permanent damage to the European medicines system. That was the EMA's damning verdict on eight of the 19 cities vying to host the regulator when it's forced to leave London in March 2019.

After counting the results from its staff survey (see page 6), the EMA didn't mince its words, saying it would be "unable to operate" should it be forced to move to places like Sofia or Warsaw. The consequences of this for the region would be a public health crisis as the EU single market for medicines unravels, it said.

And yet, looking over the bids, and given how politically-charged the competition is, it feels like the taking part really is more important to some than the winning.

How else to explain back-of-an-envelope thinking that offers 1,000 work stations when the EMA needs 1,300, or bids that plan on using 'Regus-type' offices while building work is completed.

And then there are the offers that want the EMA itself to help them manage the move - although it has no resources for this - or cities that don't actually have a firm plan for how to accomplish what will undoubtedly be an exceptionally tricky exercise for even the best prepared.

With the stakes so very high, for EU28 just as much as EU27, it's to be hoped that the competition's winner is a country that's up to the job. If not, we could all end up losing out.

Dominic

Dominic Tyer, director of editorial

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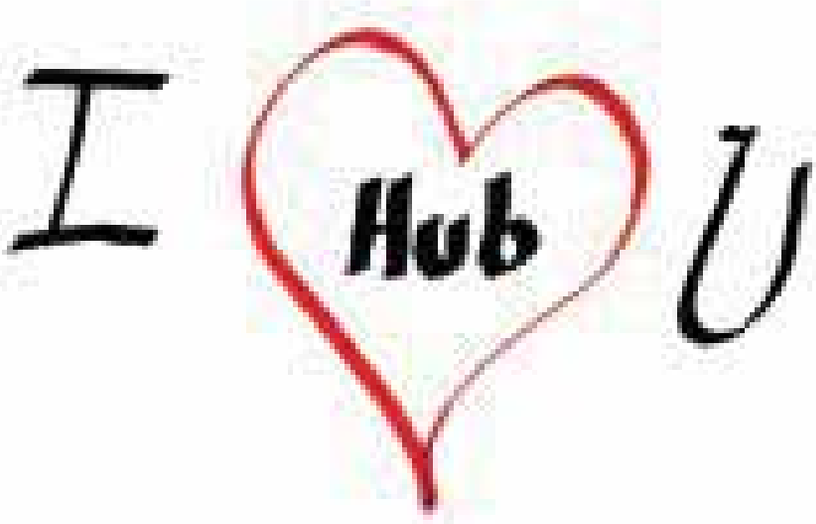

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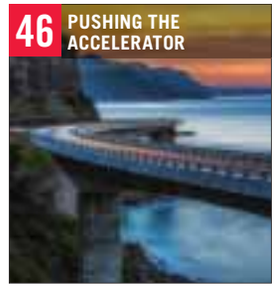

EMA faces 'permanent damage' if its move is mishandled

Picking a city such as Zagreb, Athens or Helsinki to host the regulator would cause a staff retention crisis

The European Medicines Agency has issued a dire warning should it be relocated to eight of the 19 cities currently vying to replace London as its host.

Picking any of those eight could lead to a public health crisis, with "permanent damage" to the drug regulation system and a need for emergency EU legislation, the regulator said.

A staff survey last month saw Athens, Bratislava, Bucharest, Helsinki, Malta, Sofia, Warsaw and Zagreb score the lowest in a new staff retention survey, with each on course to hold on to less than 30% of workers should one of them be selected as the Agency's post-Brexit home.

The EMA has only published ranked bands of the bids, rather than a league table, but these show the picture was particularly bad for three of the cities - just 10% or less of staff said they would move there.

The EMA's best-case scenario covers just five cities - Amsterdam,

Barcelona, Copenhagen, Milan and Vienna, each of which is expected to see it retain at least 65% of staff.

But any of those is still expected to presage an exodus of skilled workers that could cause drug approval delays and a wait of up to three years before EMA operations return to normal.

The agency said: "Some staff losses can be absorbed with EMA's business continuity plan, but beyond a critical threshold the Agency will no longer be able to fulfil its mandate to protect the health of European citizens."

The survey was sent to all the Agency's 880 or so employees, with 92% filling it out last month.

It asked them how likely they were to relocate to each of the 19 candidate host cities, based on the official member state offers and the extent to which they fulfil their (and their family's) needs and expectations to settle in a new location.

Additional results saw a further five cities - Bonn, Brussels, Dublin, Lille and Porto - expected to attract more than 50% of EMA staff. In those cases it would take up to five years to recover, while in Stockholm's case the move would likely see it retain 48% of workers with up to 10 years to recover.

Alongside the staff survey the EMA ran a scenario planning exercise that placed the cities into one of four groups, based on how staff retention levels would impact its existing workload.

This ranged from the approval of new medicines largely being maintained, for those five cities with the highest expected retention rates, to the "unravelling of the EU single market for medicines" at the opposite end of the scale.

The agency said: "The results of the survey emphasise the importance of the upcoming decision on the EMA's future seat as the retention of skilled and experienced staff is crucial for the Agency's continuity of operations."

The survey throws into sharp relief the difficult decision faced by the EU's General Affairs Council, which is due to make the final decision on the EMA's new location on 20 November.

AbbVie's deal with Amgen sets biosimilar Humira launch dates

Agreement will see European access come four years quicker than in the US

After months of legal wrangling, AbbVie has reached a deal with Amgen that will see the latter's biosimilar version of blockbuster drug Humira launched next in Europe, but not in the US until 2023.

The two companies have now ended their patent infringement litigation over Humira (adalimumab) - a TNF inhibitor used to treat rheumatoid arthritis and several other immunological diseases that is the world's biggest-selling pharmaceutical product.

As a result of the settlement, AbbVie has granted non-exclusive licences to Amgen that will allow it to launch its biosimilar from 16 October 2018 in Europe and from 31 January 2023 in the larger US market, which accounted for almost $6bn of the drug's $9bn turnover in the first six months of the year.

The drug still accounts for two-thirds of AbbVie's revenues, although it has made strenuous efforts to diversify into areas such as cancer and hepatitis C, and has high hopes for new launches such as blood cancer therapies Imbruvica (ibrutinib) and Venclexta (venetoclax).

Amgen has agreed to pay royalties on sales of its biosimilar, and AbbVie general counsel Laura Schumacher said in a statement that the deal "achieved the balance between protecting investment in innovation and providing access to biosimilars, which will play an important role in our healthcare system".

Amgen secured approval in Europe for its biosimilar under the Amgevita brand name in March and in the US as Amjevita a year ago, and said that the drug will be one of its first biosimilar launches.

"This agreement will allow us to secure a strong foothold in the $4bn European adalimumab market," said Scott Foraker, who heads the company's biosimilar unit. The settlement comes shortly after Amgen granted a licence to Simcere to co-develop and sell four of its biosimilar candidates in China.

Aside from Amgen, Samsung Bioepis' Imraldi Humira biosimilar has been approved in Europe, having been licensed by the European Commission at the end of August, and Novartis' Sandoz unit filed its own version with the EMA in May. Meanwhile, in the US, Boehringer Ingelheim is the second biosimilar developer to claim FDA approval after Amgen, getting clearance for Cyltezo (adalimumab-adbm), whose non-proprietary name follows FDA guidance requiring an additional suffix identifier.

Pfizer spins out SpringWorks Therapeutics biotech

What does a big pharma company do if it has a few promising but surplus drugs lying around? If you're Pfizer, you bundle them together into a new biotech along with a block of start-up cash.

The new company - called SpringWorks Therapeutics - debuts with four Pfizer candidates targeting an eclectic mix of indications outside the firm's target therapeutic categories, plus $103m in funding from the drugmaker plus venture capitalists Bain Capital and Orbimed and medical charity LifeArc.

The four drugs are nirogacestat for use in patients with desmoid tumours, the potential neurofibromatosis treatment PD-0325901, senicapoc for hereditary xerocytosis and PF-0445784 to treat post-traumatic stress disorder (PTSD) - all of which are ready for phase II or III testing.

According to Pfizer, what they have in common is that they "may hold significant promise for underserved patients".

Amgen pledges $1.5bn for preclinical drugs

Cancer deal with CytomX sees stellar immuno-oncology valuations continue

The stellar valuations for immuno-oncology candidates show no sign of coming back to earth, with Amgen offering $1.5bn for a T-cell-engaging antibody programme still in early-stage development at CytomX Therapeutics.

The deal includes upfront cash of $40m, with Amgen also paying $20m for a stake in the biotech and pledging another $455m in milestones for a licence to a double-headed (bispecific) antibody targeting the epidermal growth factor receptor (EGFR) and CD3 receptor that has come out of CytomX's Probody platform.

Amgen is also interested in three more undisclosed targets, which could generate another $950m in upfront and milestone payments, according to the terms of the deal.

In an unusual development, CytomX also gets a stake in an unnamed T-cell engaging bispecific developed at Amgen.

CytomX will handle the early stages of clinical development of the EGFR/CD3 Probody, with Amgen getting involved later in the process. The arrangement also gives the firm a chance to take a greater role in the development process and potentially split profits with Amgen, CEO Sean McCarthy said on a conference call today.

Amgen is already a player in the bispecific antigen space, winning approval for acute lymphoblastic leukaemia therapy Blincyto (blinatumomab) in the US in 2014, and is an ideal partner for these programmes, McCarthy said.

Amgen is not the first big biopharma company to be impressed by CytomX's Probody therapeutics, which are designed to direct immune T cells to cancer cells, while incorporating a masking peptide to reduce binding to healthy tissues and prevent side effects. That means it can target tumour-associated antigens that have been excluded from current therapeutic approaches because they are present on healthy cells.

Last year, AbbVie agreed a $500m deal with CytomX for CD71-targeted drugs and two undisclosed targets, while earlier this year Bristol-Myers Squibb (BMS) expanded a 2014 alliance with a $200m upfront payment for eight additional targets. Two lead candidates from the AbbVie and BMS programmes are due to start trials next year. Meanwhile, Pfizer also signed a $635m deal with the biotech in 2013.

ABPI's bid to overturn NICE's budget impact rules fails

One in five new medicines would have been affected by the rejected policy

The UK pharmaceutical trade body has failed in an attempt to force a judicial review of the new evaluation process introduced by the National Institute for Health and Care Excellence (NICE) earlier this year.

The Association of the British Pharmaceutical Industry (ABPI) has been fighting a legal action to try to overturn NICE's introduction of a £20m cost ceiling for new drugs that have already been assessed as cost-effective, a measure that could allow it to delay the introduction of new medicines for up to three years.

The High Court rejected the ABPI's application to have the changes to the evaluation process struck down, which the trade body claimed were "inappropriate and unworkable", would limit patient access to new treatments and lay outside the cost-effectiveness organisation's remit.

NHS England said in a statement that the High Court "has rejected ABPI's flawed legal manoeuvres which the judge said would 'produce an absurd result'".

"Rather than attempting to further frustrate NICE and the NHS' work to ensure patients and taxpayers get maximum value out of the £15bn being spent on drugs, it now makes sense to work together towards that shared goal," it continued.

In addition to the £20m budget cap, NICE introduced a fast-track approval mechanism for treatments that offer 'exceptional value for money', with Bayer's Eylea the first recipient (see page 11).

NICE has also put in place new rules on how it evaluates treatments for very rare conditions, raising the upper threshold limit to £300,000 from £100,000 for treatments considered to offer substantial clinical benefit.

Responding to the court's decision the ABPI said in a statement it would not appeal.

"Our concern has always been that patients should not miss out on medicines which are proven to be both clinically beneficial and cost-effective. Throughout this action the ABPI has maintained positive and constructive dialogue with NICE, the NHS and Government and we are encouraged that the issues are now better understood," the association said in a statement.

The ABPI had previously indicated that around one in five new medicines would be affected by NICE's new assessment policy.

In brief

Novartis' chief medical officer Vas Narasimhan will succeed Joe Jimenez as CEO next year. Jimenez will step down on 31 January 2018 but will stay on to assist the transition process until the end of August. He has been at the helm of Novartis since 2010.

Teva sold its women's health business assets, raising almost $2.5bn that will go towards paying off its debts. Its Paragard intrauterine contraceptive goes to CooperSurgical for $1.1bn and the rest of the business was sold to a private equity firm for $1.38bn.

Merck & Co has snapped up another early-stage immuno-oncology player, agreeing to buy German biotech Rigontec for up to €464m ($554m). The deal - which includes an upfront payment of €115m - gives Merck a position in another pathway that seems to be involved in the stimulation of immune responses against cancer cells.

A UK company has started trialling a new universal influenza vaccine that would avoid the annual scramble to guess the most likely strains circulating in the following flu season. The vaccine - developed by University of Oxford spin-out Vaccitech - will be tested in around 500 NHS patients.

Pharma's coral reef - how to compete has changed, **see p32**

Merck & Co pulls out of hepatitis C research

Discontinues its new-generation treatments as market shrinks

Merck & Co has decided to exit hepatitis C virus (HCV) drug development, making its $3.85bn deal to buy Idenix three years ago look like an expensive gamble.

At the time of the acquisition, the US pharma company insisted that there were so many HCV patents around the world needing treatment that there would be a fertile market for the new generation of directly-acting antiviral drugs for many years to come.

This turned out to be an over-confident prediction, with the HCV market already contracting as a result of pricing competition and a shrinking patient pool. And in the interim, the drugs used to treat HCV have largely been produced by Gilead Sciences, with AbbVie and Merck jostling for a distant second place. Now, with Gilead and AbbVie reporting shrinking sales and Johnson & Johnson (J&J) deciding it is time to get out of HCV R&D, Merck has decided it's time follow suit.

The company has discontinued two-drug and three-drug regimens that were intended to serve as new-generation treatments for the viral infection, cutting treatment times and expanding the range of HCV genotypes covered.

Cast aside are MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir), candidates which at one point were being held up as having the possibility to clear infections in as little as four to six weeks, compared to the 12-week and latterly eight-week courses needed for currently approved therapies.

The decision has been based on "a review of available phase II efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection", said Merck.

The decision leaves Merck with Zepatier (elbasvir/grazoprevir) as its only product in the HCV category, one which has made headway in the market with sales leaping ahead to $895m in the first six months of the year. The new decision comes after it already booked a $2.9bn impairment charge related to the HCV programme earlier this year.

In the same period, Gilead's HCV portfolio of Harvoni (sofosbuvir/ledipasvir), Epclusa (sofosbuvir/velpatasvir) and Sovaldi (sofosbuvir) brought in $5.44bn, down from around $8.3bn in the first half of 2016 due to pricing pressure and as the pool of patients available for treatment shrinks.

AbbVie meanwhile has seen its first-generation Viekira (ombitasvir/paritaprevir/ritonavir/dasabuvir) product hit by competition, with sales declining 40% to $488m in the first half. The company has just secured US approval for new combination Mavyret (glecaprevir/pibrentasvir), which needs to be administered for just eight weeks and has been launched at a discount to its rivals, and is expecting to claw back market share.

Lilly's abemaciclib data leaves potential uncertain

Needs to work hard to differentiate drug from Ibrance and Kisqali

One of Eli Lilly's most important pipeline prospects is breast cancer candidate abemaciclib, but new phase III data suggests the company could have its work cut out differentiating the drug from its rivals.

The MONARCH 3 trial was reported at the European Society of Medical Oncology (ESMO) conference in Madrid last month, and showed that the CDK4/6 inhibitor prolonged progression-free survival (PFS) by 46% when added to hormonal therapy as a first-line treatment for postmenopausal women with HR+/HER2 negative breast cancer.

That seems to be comparable to the benefit seen with two already-marketed drugs in the class - Pfizer's Ibrance (palbociclib) and Novartis' Kisqali (ribociclib). While there is no head-to-head data available for the three drugs, the finding is arguably a little disappointing as Lilly had pitched abemaciclib as being significantly more potent than its rivals, and amenable to continuous dosing rather than intermittent dosing, which had raised hopes of a more potent effect.

Lilly will hope that its drug will be preferred because of its side-effect profile, and in particular is hoping that what appears to be a reduced tendency to cause neutropenia could prove to be a big factor for prescribers and patients. It is associated with diarrhoea however, although Lilly says this can be managed with anti-diarrhoeal drugs such as loperamide.

If its safety profile is not a differentiating factor, Lilly will be forced to compete toe-to-toe with Ibrance, which is well-established in the marketplace, as well as new entrant Kisqali which was approved earlier this year. Ibrance saw sales almost triple to reach $2.1bn last year and has been tipped by EvaluatePharma to become a $6bn-plus product in 2022, with Kisqali and abemaciclib vying for second place in the market.

The trial also threw out some data that could have a bearing on all CDK4/6 inhibitors, namely that around one-third of women may not need a CDK 4/6 inhibitor as initial treatment because some patients - including those with bone metastases or indolent disease - may do well with endocrine therapy alone.

Meanwhile, Lilly is currently recruiting patients for a new phase 1 study of abemaciclib in combination with Merck & Co's Keytruda (pembrolizumab) to treat breast cancer.

Axovant joins ever-growing Alzheimer's failure club

Axovant's phase III trial of Alzheimer's disease (AD) candidate intepirdine has ended in failure, an outcome that wasn't unexpected but is still a big disappointment for patients and their carers.

Intepirdine - a serotonin 5-HT6 inhibitor - failed to achieve any of its main efficacy targets in the MINDSET study in mild-to-moderate AD patients, following in the footsteps of Lundbeck's idalopirdine, which suffered a similar late-stage failure a year ago.

In a statement, New York-based Axovant said intepirdine did not improve symptoms compared to placebo on two widely-used AD symptom measures - the ADAS-Cog and ADCS-ADL scales.

Axovant's parent company Roivant had this to say about the disappointing results: "Patients and physicians have witnessed an unrelenting series of failures in Alzheimer's disease trials over the past decade and a half. Regrettably this is one more to add to the list."

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GSK triple COPD therapy closes on EU approval

CHMP backs firm's combination of Telegy/Elebrato

GlaxoSmithKline has a lot riding on its new three-drug combination for Chronic Obstructive Pulmonary Disease (COPD), so will be celebrating a CHMP recommendation that could see the drug approved before the end of the year.

The EMA's advisory committee gave its blessing for Trelegy/Elebrato (fluticasone furoate, umeclidinium and vilanterol) as a maintenance therapy for COPD patients who do not respond to two-drug therapy with an inhaled corticosteroid (ICS) and a long-acting beta agonist (LABA).

The new product adds long-acting muscarinic receptor antagonist (LAMA) umeclidinium to the ICS/LABA combination, which has proved so successful in GSK's big-selling products Advair/Seretide (fluticasone propionate/salmeterol), which is facing a sales decline because of generic competition, and follow-up Breo (vilanterol/fluticasone furoate).

The benefits of Trelegy/Elebrato - delivered using the company's Ellipta dry powder inhaler - are its ability to improve lung function compared to AstraZeneca's ICS/LABA combination Symbicort (budesonide/formoterol) in uncontrolled patients with moderate-to-severe COPD, according to the CHMP.

GSK thinks it has a decent head start with the triple therapy in a market increasingly crowded with LAMA/LABA and LABA/ICS combinations, and has suggested it could dominate the market in the same way Advair did on launch, when monotherapies prevailed in COPD.

Analysts have suggested that the drug may find it difficult to gain traction, however, given the pricing pressure on respiratory medicines and the availability of cut price generic two-drug combinations.

The three-drug regimen could be a $1bn-2bn product by 2028, according to analysts, although that would still see it fall well short of the $7bn-a-year Advair brought in at its peak.

The triple version was recommended on the back of data from the FULFIL trial, but GSK has a second study - called IMPACT - due to report later this year that will compare the new product with both ICS/LABA and LAMA/LABA combinations. If positive, this could accelerate sales growth.

GSK said regulatory applications for the triple are under review in a number of other countries, including the US and Australia.

The CHMP also delivered more good news to GSK by recommending approval of its subcutaneous pen-injector of Benlysta (belimumab), providing a more patient-friendly alternative to the current infusion formulation. Benlysta is used as an add-on treatment for adults with active, autoantibody-positive systemic lupus erythematosus (SLE).

Janssen wins European approval for Symtuza

HIV drug wins licence, but firm's lymphoma treatment knocked back by NICE

The European Commission (EC) has approved Janssen's Symtuza (darunavir-STR) to treat adults with human immunodeficiency virus type 1 (HIV-1).

It's the first complete, single-tablet regimen (STR) based on its big-selling protease inhibitor Prezista (darunavir), which it combines with cobicistat, emtricitabine and tenofovir alafenamide (TAF).

Dr Frank Wiegand, medical director, Janssen UK, said: "The decision by the European Commission to approve the use of darunavir-STR validates our efforts to treat HIV more simply, addressing the issues of adherence and resistance.

"We are committed to developing effective and innovative treatments which address these issues, while helping all those living with HIV to achieve an undetectable viral load and ultimately enjoying an improved quality of life."

Results from a bioequivalence study that compared darunavir-STR with the combined administration of the separate agents darunavir, cobicistate and emtricitabine/tenofovir alafenamide paved the way for the decision from European regulators.

Janssen can now market Symtuza in all countries in the European Union and the European Economic Area, where it will be vying to compete with therapies from the GlaxoSmithKline, Pfizer and Shionogi venture ViiV.

But Imbruvica fails to win NICE backing

Meanwhile, Janssen's Imbruvica received a knock-back from NICE.

Draft guidance from the cost-effectiveness body doesn't back treating mantle cell lymphoma (MCL) - an incurable, rare type of B-cell lymphoma that affects approximately 500 people each year in the UK.

NICE said it would consider any proposal that included the MCL treatment via the new version of the Cancer Drugs Fund (CDF), but that more evidence would be needed for this.

There was some positive news for Janssen, as Imbruvica received a positive recommendation to treat Waldenström's Macroglobulinaemia (WM). The drug will be available for the first time in this indication via the CDF, but NICE concluded that further evidence would be needed before the treatment was recommended for routine use on the NHS.

Novartis gets EU nod for leukaemia drug Rydapt

Novartis has added EU approval to its US registration for FLT3 inhibitor Rydapt, bringing years of stagnation in the development of new drugs for acute myeloid leukaemia (AML) to an end.

The EC cleared Rydapt (midostaurin) for use with chemotherapy in adults with newly-diagnosed AML whose cancer cells carry the FLT3 genetic mutation.

The regulator also approved the drug for systemic mastocytosis (SM) and related conditions, such as mast cell leukaemia, making it the first EU-approved therapy for this group of rare and life-threatening diseases.

AML is the most common form of acute leukaemia in adults and has a low survival rate, with just one in four patients still alive five years after diagnosis.

"Novartis is proud that we can deliver Rydapt, a breakthrough medicine, to patients with serious and hard-to-treat diseases where there are few treatment options," said Bruno Strigini, chief executive of Novartis Oncology.

Sanofi claims EU approval for Dupixent

Analysts suggest sales of eczema drug could be worth €5bn at peak

Sanofi and its partner Regeneron have been granted EMA approval for Dupixent in atopic dermatitis, taking the product another step towards what some analysts predict will be blockbuster sales.

The EU approval is for the treatment of moderate-to severe atopic dermatitis (also known as eczema), a chronic skin condition characterised by skin blistering, cracking and often debilitating itching, and comes after the CHMP recommended the drug for approval in July.

Dupixent (dupilumab) is an interleukin-4 (IL-4) and IL-13 inhibitor that can be administered by a patient every other week via a subcutaneous injection after an initial loading dose, and in trials it has been shown to be effective at both clearing skin and helping patients avoid steroids and topical immunosuppressants such as cyclosporine and methotrexate, which can cause side effects with chronic use.

Sanofi said in its second-quarter results statement that Dupixent had got off to a good start in its first market, the US, making €26m in its first quarter on the market, but that is only a fraction of what analysts think the product is capable of achieving.

Analysts have previously suggested Dupixent could eventually become a €5bn product at peak, particularly if it can also find a role in additional indications, and there was some encouraging news for Sanofi and Regeneron on that front a couple of weeks ago.

A phase III trial of the antibody in persistent, uncontrolled asthma met its targets of reducing the frequency of severe asthma attacks in patients with high levels of eosinophilic cells, setting up a filing before the end of the year. Some analysts said the data fell short of expectations however - particularly in light of increased competition in the severe asthma category from IL-5 inhibitors such as GlaxoSmithKline's Nucala (mepolizumab) - and shares in the companies dipped as a result.

Dupixent is also being tested for its potential in nasal polyposis, another indication where it could see competition from Nucala.

CHMP backs maintenance use for Tesaro's Zejula

Swiss biotech's PARP inhibitor recommended for approval in ovarian cancer

Swiss biotech Tesaro has picked up a CHMP recommendation for its PARP inhibitor Zejula as a maintenance therapy for ovarian cancer, upping the ante in its rivalry with AstraZeneca and Clovis Oncology.

The EMA's advisory committee backed Zejula (niraparib) on the strength of data showing it improved progression-free survival (PFS) compared to placebo in ovarian cancer patients.

Once approval comes through Zejula will join AZ's Lynparza (olaparib) and Roche's Avastin (bevacizumab), currently the only two drugs approved for maintenance therapy of ovarian cancer in Europe.

Zejula's CHMP recommendation gives it one key advantage over the Merck & Co-partnered Lynparza - its closest rival - in that it has been backed for use in all patients, while for now AZ's drug is only approved in the EU for ovarian cancer patients with a BRCA mutation.

CHMP meeting round-up

The CHMP also backed GlaxoSmithKline's triple chronic obstructive pulmonary disease therapy Trelegy/Elebrato (see page 10), Janssen-Cilag's Tremfya (guselkumab) for plaque psoriasis and Steba Biotech's Tookad (padeliporfin) for prostate cancer.

Also given the nod were two drugs from Mundipharma intended to help people with opioid addiction - Nyxoid (naloxone) and Zubsolv (buprenorphine/naloxone), while Spanish drugmaker Grifols got the go-ahead for VeraSeal (human fibrinogen/human thrombin), a sealant for use during surgical procedures.

The CHMP recommended approval of two biosimilars, namely Samsung Bioepis' Ontruzant (trastuzumab) - the first biosimilar of Roche's Herceptin to be backed in the EU - and Boehringer Ingelheim's Cyltezo (adalimumab), a biosimilar of AbbVie's immune therapy Humira.

In brief

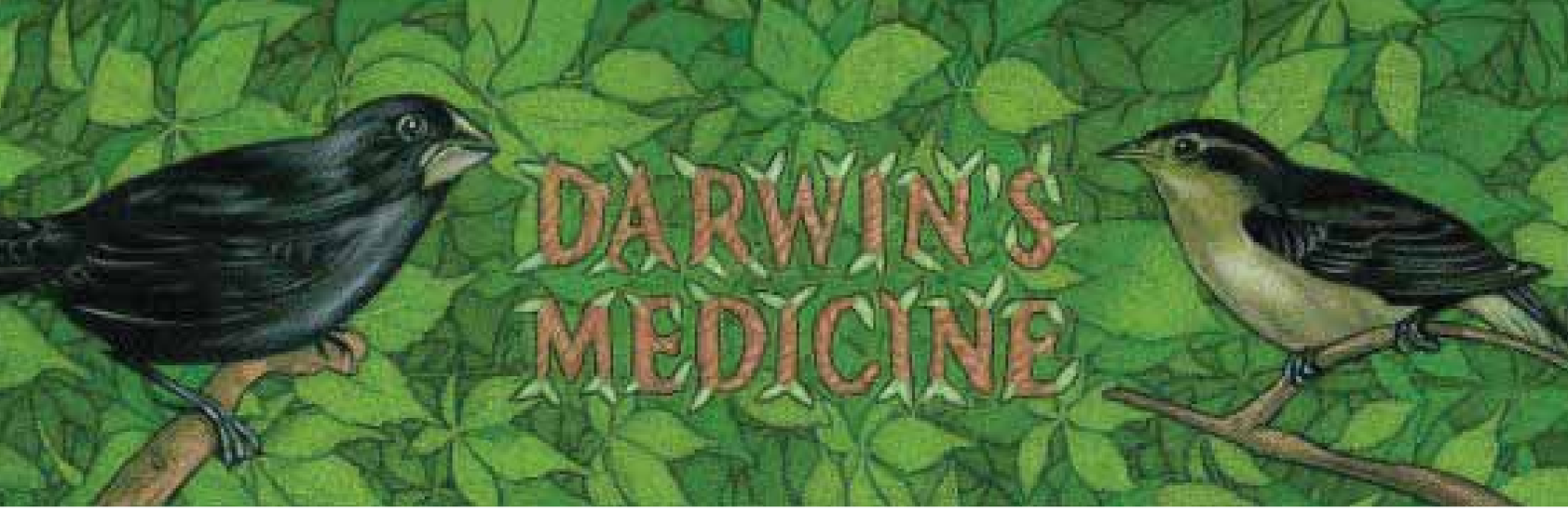
Merck Sharp and Dohme's monoclonal anti-PD-1 therapy Keytruda (pembrolizumab) has won a new indication in Europe for patients with locally advanced or metastatic urothelial carcinoma (mUC), the most common type of bladder cancer.

Patients in England and Wales will be able to get access to **Bristol-Myers** Squibb's Opdivo after it offered to reduce its price. NICE ruled Opdivo can be made available through the Cancer Drugs Fund as a second-line therapy for patients with advanced non-small cell lung cancer, after chemotherapy, having earlier turned down routine NHS use of the PD-1 inhibitor.

Roche's lung cancer drug Alecensa has been approved for early access in the UK under an MHRA scheme that allows it to reach patients prior to gaining a European licence. It means the country will be the first in Europe to access Alecensa, following the MHRA's positive scientific approval under its Early Access to Medicines scheme.

NICE has issued its first fast-track guidance, recommending Bayer's Eylea (aflibercep) in choroidal neovascularisation (CNV). The drug will consequently be made available to patients in England and Wales almost five months earlier than if it had gone through the usual NICE procedure.

Serious market access roadblocks for rare bleeding disorders, **see p18**



Breathing data

Novartis' new CEO-designate points to an evolutionary leap

BRIAN D SMITH

It's always interesting when several different news stories point in the same direction. For several months now, we've seen announcements and industry gossip about how information technology companies such as Apple and Google are planning to up-end the life science industry by their use of data. And just as I wrote this, Novartis's new CEO designate, Vas Narasimham, gave a *Financial Times* interview that stressed the use of AI and data to revolutionise research and development productivity.

For a geeky professor like me, this was music to my ears. Partly because it confirmed what I've been predicting in my various books and articles but also because it has strong parallels with evolutionary biology. As usual, let me delve into the science and then come back to the practical implications.

When Dr Narasimham said, "I really think of our future as a medicines and data science company", he was, in effect, signalling a shift in the basic functioning of Novartis and many other research-led life science companies. I don't think he would argue with me too much if I paraphrased it as "we're going to compete with our data geeks as much as with our biologists and chemists". This is a quite fundamental shift - one that I christened 'The Information Shift' in my book '*Darwin's Medicine*'. Such transitions are very rare in the history of industries and it is hard to find parallels in other businesses. But, as readers of my work will know, the life science industry is just an example of a complex adaptive system and we can therefore look for important parallels in other such systems, such as biological systems.

'In a world where data is pervasive, learning to use data at scale and in an integrated, bidirectional manner is essential for survival'

In particular, we can learn something from the way that life on earth changed at the end of the Ediacaran period, about 541 million years ago. Evolutionary biologists' latest thinking is that up until the end of the Ediacaran period, the earth was dominated by simple, single-celled organisms that thrived in the then oxygen-poor atmosphere. And then, it seems, atmospheric oxygen rose to near modern-day levels. Although the leading edge of this research argues over the detail of this change, it is agreed that it enabled an explosion of complex, multicellular species. It is a strong example of a change in the environment leading to a change in biological systems.

So how is this relevant to our understanding of present trends and the future of our industry? Well, shifting from anaerobic to aerobic metabolisms is a fundamental shift of the kind not seen often in complex adaptive systems. That's a parallel to what Dr Narasimham was saying about becoming a data science company. In our industry, the availability of data is triggering a change in a way that is directly analogous to the changes triggered by the availability of oxygen. Later in his interview, he also described the need to form working relationships with other companies with expertise in data science. It is not a stretch to draw analogies between the building of complex networks of firms and the emergence of complex life forms that followed the Ediacaran period. We are moving from an industry dominated by firms to one dominated by such networks, a phenomenon I describe in my work as the holobiont shift.

So, there are strong parallels between the two complex adaptive systems of Ediacaran earth and today's life science industry. Both show a changing environment, leading to a different way of competing and different forms and structures. But what are the practical implications of this? Can it tell us anything about how to thrive in our changing industry? I think there are three lessons to draw from this. The first is the most obvious. In a world where data is pervasive, learning to use data at scale and in an integrated, bidirectional manner is essential for survival. The second is that survival is likely to be within a holobiont, a network of symbiotic firms. Learning to do this will also be essential. The third lesson to be learned is less obvious but perhaps even more important. The Ediacaran period was followed by the Cambrian period, a time synonymous with the explosion of differentiated species that evolved to occupy every habitat and niche on earth. We should expect to observe the same explosive evolution in the life science industry as business models emerge to exploit every possible way of generating a good risk-adjusted return on capital. My work identifies no less than 26 such models, which I've described in earlier *PME* articles. The survival lesson to be drawn is that firms must work out which species they want to be and drive their evolution towards it. Undifferentiated, unspecialised business models will be outcompeted by new models.

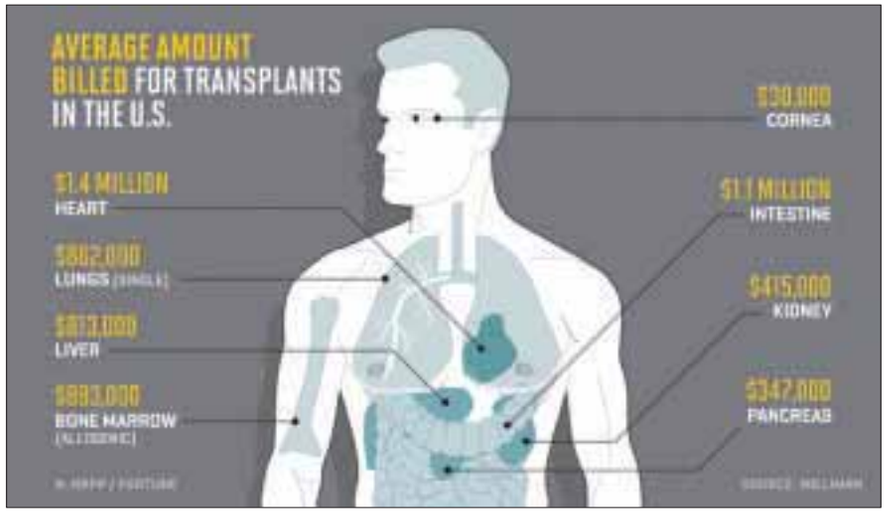
Novartis and our other leading companies are led by very smart people. They know they are leading a transition into a very different future. I wonder if they know the lessons that can be drawn from 541 million years ago?

Professor Brian D Smith is a world-recognised authority on the evolution of the life science industry. He welcomes comments and questions at brian.smith@pragmedic.com

ROHIT KHANNA

Price matters… but so does innovation

When it comes to organ transplants, with US costs that range from $415,000 for a mere kidney all the way up to $1,400,000 for a heart, price certainly does matter. But it also doesn't.



Let's conduct a social healthcare experiment: ask a thousand people if they would be willing to undergo a kidney transplant at 1960s prices - somewhere in the order of a 90% reduction versus today's prices depending on the country you live in - using today's medicines and technologies. And tell them that this is not a trick question. The answer would be a resounding 'yes'. And now ask them if they would be willing to undergo a kidney transplant at 1960s prices but using 1960s technology. This means 1960s surgeons and nurses. This means 1960s immunosuppressive drugs and instruments. And perhaps most importantly, this means 1960s surgical technique and know-how. And, by the way, tell the people that the mortality rates or complication rates are exactly the same between the two choices being offered. Go ahead. Ask. The number of people answering 'yes' is pretty low - isn't it? We learn many things from this simple question. We learn that if we were to invent an economic principle such as the 'price elasticity of innovation', it would demonstrate incredible elasticity. The rate of change of quantity demanded as a function of the state of innovation would be dramatically different for older medicines and surgical interventions as compared to newer ones (most of the time). We also glean from this question that technology matters to individuals at the micro level. At the macro level, policymakers and payers are motivated by different drivers and are forced to consider arcane concepts like the 'greater good' and 'budget impact'. But Individual patients are not. Individual patients want the 'best' and the 'latest and greatest' for themselves and their loved ones. Have you ever seen an individual patient's reaction to the choice between a brand name medication and a generic? It's priceless. Even when told that the generic medication is cheaper and works exactly the same way as the more expensive medication. In some regard, one could say that at the micro level, individual patients are willing to pay for innovation. And another (hidden) lesson from this social experiment of ours lies in the fact that healthcare is not a public good in the traditional sense. It is a private good. Even when its provision is delivered through the public system or it is financed by the public purse. It is only a public good when its consumption is non-rival and non-excludable. By non-rival, we mean that the consumption by one individual does not reduce someone else's consumption. And by non-excludable, we mean that a consumer cannot be excluded from consuming the goods either by having to pay for them, or by through some other mechanism[1]. When a patient 'consumes' a kidney, that patient reduces the consumption of a kidney and other ancillary healthcare services for another individual. And when patients cannot pay for their kidney transplants, or the waiting list for end-stage renal disease patients is so long that they die waiting for a transplant, they have most certainly been excluded from 'consumption' due to cost or some other means. But individuals don't think like that. They don't think about the effect their consumption has on others or what their inability to pay means in terms of the grand scheme of things. Why does this matter? Because we forget, or ignore the fact, that healthcare is vastly different at the individual level than it is at the population level. This 'micro' vs 'macro' difference doesn't just manifest itself in the form of kidney transplants. It's everywhere. Healthcare matters to actual people. When they need it and not at any other time. And innovation matters to people. And they are willing to pay for it. And so, in this brave new world of CAR-T and CRISPR and I/O therapies - to name a few - we continue to rely on governments to ensure that these therapies are safe and efficacious. We continue to look to regulators to ensure that access to these medications is available. But we also need to demand from governments and regulators that they not forget that healthcare at its core is about individual patients making decisions about care based on more than just price.

[1] The Economics of Health and Healthcare, 6th ed, Folland, Goodman, Stano, Chapter 19

Rohit Khanna is managing director of Catalytic Health, a healthcare communications, advertising and strategy agency. He can be reached at: rohit@catalytichealth.com

Redefining the real value within a good value proposition

Working at a marketing agency I use the words 'value proposition' perhaps a dozen times a day. It's part of our everyday language and we urge every one of our clients to have one.

As you know, a value proposition (let's call it VP) tells the world what your company or offering is about. It's a beacon; something every marketing and sales message should be working towards, making it easier for audiences to recognise why they should engage with your brand. It acknowledges where you are now and, importantly, where you want to be in the future.

A good VP is invaluable to your internal audiences too, like sales reps. It helps them talk about your brand with more clarity and conviction. This way they can make sure the key customer takeout is compelling, different and meaningful. So, job done? Well, not anymore…

Welcome to value proposition 2.0

For years, VPs have commonly been based on facts, figure and data. And that was just fine - it did the job well. But that only gets you so far.

With the healthcare sector developing faster than ever, we believe a VP has to be more than just stark clinical evidence and stats. The truth is, every product and service has evidence to back it up. Think about what makes you different. What's your unique hook? That's when you'll stand out from the marketplace.

Emotion first, data second

A VP needs to come from the heart of the product or service you're selling. And that, without exception, gives way to a more emotive proposition. At the end of the day, people buy from people. And people are not cold, fact-driven, decision-making machines. Actually, our emotions tend to come into play first, then we use the facts to post-rationalise our judgments. A purely fact-based play might make sense rationally, but it's unlikely to help build those emotional connections.

So what do we think makes a good value proposition?

Who are you? And what can you do for me? Two questions every VP needs to answer clearly and concisely. And from my experience that's the hardest part about creating an effective VP. Keeping things simple. It's often an exercise in what to leave out, than what to put in. Let's break those two questions down a bit more.

Who are you? This question is rarely looking for 'a leading manufacturer operating in 200 countries with 30,000 employees'. It's about the fact that 'people buy from people'. We care more about whether we trust the people talking than interrogating what they're saying. So even if you're working on a product-level VP, rather than a brand or corporate one, you can't 'divorce' the 'what are we selling' from the 'who's selling it'. Again, think about the emotional takeout that sets you apart.

> 'A value proposition should be about your audience, the issue they have and how you can solve it'

What can you do for me? It shouldn't be about you, what you make and what it does. It should be about your audience, the issue they have and how you can solve it.

This is a bit more complicated in health than for other industries, because that 'me' can vary based on which hat you have on. Especially if your audience is 'B2B', there are probably personal, organisational and patient challenges to consider. The important thing is to work out which problems your brand solves and which of these will to be the most compelling.

Don't throw the baby out…

That said, we shouldn't abandon the clinical evidence and results information that used to drive the VP. After all, this is useful information and reasons to buy. But it should be positioned as support for the main VP. These are why you should believe our VP.

Consistency, consistency, consistency…

So, let's say you have your perfect VP. It's based on a human/patient benefit or need and is backed up with solid evidence. Now you have to stick to it, throughout all the various mediums and situations when people may come into contact with your brand.

Sitting with the sales rep, reading your brochure, browsing your website, listening to your radio ad or standing in front of your conference stand. Repetition and consistency of message lead to familiarity and trust.

In short, a successful value proposition is usually:

1. Human and emotional
2. Focused on audience benefit (not company or product features)
3. Relevant to the audience
4. Single-minded
5. Distinctive - even if the product is similar to another, there's always room for it to 'be different' (or at least give the impression that it is).

Ed Hudson is managing director at Create Health, a specialist healthcare marketing agency

The patient's world is 'messy' - and therein lies the value for pharma

Over the last ten years, we have seen the status of the patient in healthcare research become more established. Yet often the insights about patients can still be considered 'nice to have' rather than a 'must have'. Their intrinsic value strategically and commercially is often not fully recognised. The real world of the patient is not valued as highly as the clinical world of the healthcare professional (HCP). The messiness of real life is edited down to a clean list of symptoms, outcomes and measurables. Science trumps human stories. However, science without the human stories falls short of reality. The patient world is multidimensional and what may seem irrelevant, clinically, may be crucial to managing and treating a disease optimally.

Mapping patients' journeys

Let's take patient journey research as an example. As a global healthcare market research agency we are asked regularly to map out patient journeys. Sometimes the language changes and clients have their own corporate template, but essentially the task is the same: to produce a pathway marking touchpoints with healthcare practitioners, timings, triggers and barriers to progress. The skill is to condense all we hear into a neat narrative and graphic that can be embedded in an organisation and used to improve clinical interventions and patient flow, and optimise prescriptions. Interestingly only around half of the patient journey projects we are commissioned for include patients themselves. Too often we need to put the case forward for the inclusion of patients, and this I believe is a clear demonstration that there remains a gap in the understanding of the real value of the patient perspective.

Directly engaging with patients

Only by engaging with the patients directly can the true patient journey be mapped and understood. If they are not included then vital information is lost and decisions are made based on the physicians' restricted perspective. HCPs cannot know in any detail what happens between appointments. Their hasty consultations cannot fill all of the gaps in their knowledge. Only patients can tell you how the late diagnosis came about.

> 'The combined journey will present more opportunity for intervention and greater insight into what is taking place'

Filling in the gaps

What happened between those hurried, irregular appointments? Why did they disappear off the radar for a year? Why did they give up taking their medication after only three months? Was it something the doctor said or did, or something they didn't say or didn't do? Sadly their HCPs know only a fragment of the picture.

One reason that the HCPs don't know the full story is that patients don't tell them very much. In fact, patients often give a poor account of what has happened to them between appointments. Partly this is because they feel hurried and are on 'foreign turf'. But it is also because they believe the doctor only wants to hear the edited clinical highlights. What has changed since they were last there? The consequences of the symptoms on their daily activities are often passed over as too irrelevant to mention. The background hum of symptoms is forgotten, 'normalised' and considered insignificant. The emotional and social impact of the disease is left out in order to try and speak the HCP's 'language'. So a patient journey solely based on what HCPs tell us will inevitably lack vital insight and overlook crucial decision moments.

Gaining a greater understanding

By conducting journey research with patients alongside the HCPs, we can not only understand what lies behind the patient's experience and behaviour, but we can identify additional decision moments for pharmaceutical companies, when intervention would be desirable and could lead to better clinical outcomes. If information is lacking or misunderstood by the HCPs, corrective measures can be taken. As well as working with the HCPs, pharma can also provide patient support to lift their knowledge of the disease or improve adherence.

A 'messier', more convoluted route

Yes, including patients in the overall journey will be 'messier'. It will introduce disconnects between what patients say and HCPs say. It may undermine the clinician's nice, linear view of the journey and present a more convoluted, less logical route. But the combined journey will be richer and more accurate. It will present more opportunity for intervention and greater insight into what is taking place.

JANE BARRETT

A richer and more accurate experience

The clinical perspective of the HCP of the patient journey is crucial but the human story telling the patient experience of the journey is equally important. Real life isn't just clinical. Diseases affect people - people who spend most of their lives out of hospital and not in surgery. Your drugs 'live' with them in a world which is messier than a laboratory but it is the real world and that is what needs to be taken into account.

CELLO HEALTH INSIGHT

Jane Barrett is director of patient insights at The Patient Centre, Cello Health Insight

Moving times

Continuity and stability are vital when it comes to the EMA's relocation when it leaves London

Following Brexit, Britain must pay to relocate the European Medicines Agency from London to a city within the EU and 19 European countries are placing their bids to be the next host. Indeed the EMA is favoured as being the most valuable of the Brexit spoils; its nature as one of the most prestigious European agencies bears both economic and political advantage for London's successor. Not only will it prove incredibly valuable for the victor of the fierce bidding war, its loss will be felt the British pharma industry.

Employing around 900 highly-skilled staff, the EMA has historically attracted around 36,000 experts per year to London, while also making the city an attractive location for pharmaceutical companies wishing to be positioned near the regulator while also having access to the EU market. Access to the EU market has always been a significant factor in a company's decision to invest and operate in Britain. It is likely then, that some of these workers, their families, the experts and the companies will move with the agency to whichever European city is selected or, with respect to the companies, move to an EU country (or move at least a substantial part of their employees to that country). This will contribute to the estimated €1bn economic uplift the EMA could generate for the new host.

There is the risk, then, that the British pharmaceutical industry may be negatively affected by the EMA relocation. Indeed, London may appear less attractive to international companies following the loss of the regulator; they might now prefer continental options. Similarly local London restaurants and hotels that have long benefited from EMA visitors could lose business.

In addition, many have noted that the relocation represents a double blow; indeed Britain will have to foot the bill for displacing the regulator. Furthermore, the agency's failure to negotiate a break clause in the lease for the Canary Wharf offices means that the move will now cost at least twice as much - up to around £520m pounds - as the agency is tied into a rental contract with the London offices until June 2039.

There are also fears that British patients may be confronted with drug shortages or delays due to the relocation. Drugs that are currently accessed by British patients as soon as they are registered for the EU market, as well as new treatments, will in future take longer to reach them; the UK may no longer be the centre of pharmaceutical innovation. It is critical therefore that, following Brexit, the UK pharmaceutical sector establishes itself in such a way that it does not find itself at the back of the queue regarding submissions for new medicines.

> 'The EMA employs around 900 workers and has historically attracted around 36,000 experts per year to London'

So what are the criteria for the relocation and where is it likely to move to? The principle question is one of business continuity; there are serious concerns that business may be disrupted, which could pose a significant threat to public health. Already there have been fewer applications for the EMA training programme, and the agency has provisionally suspended some work as it focuses on the transition plan. From a practical perspective, the new location will have to prove that it has sufficient IT capabilities, that will be up and running in time for the move, so as not to further hinder EMA performance.

A further key issue concerns the displacement of EMA staff and their families. A recent survey of agency staff (see page 6) highlighted that anywhere from 19% to 94% of employees said they would quit, depending on how unpopular the destination was regarded. This would significantly impact business continuity. The most popular locations incuded Amsterdam, Barcelona and Vienna, although following more recent, and violent, developments in Catalonia and the uncertainty of its European future, it is possible that Barcelona may be slip in the eyes of EMA staff.

Similarly, cultural considerations must also play a large role in the decision-making process. At the end of August, a group of LGBT EMA employees wrote an open letter to Guido Rasi (executive director of the EMA), Donald Tusk, Jean-Claude Juncker and Antonio Tajani expressing their anxieties: 'we are... concerned that our rights and freedoms, as legally guaranteed in the current hosting Member State and as enshrined in Union law, may be directly and adversely affected by the EMA relocation.' Naturally the letter does not cite any specific countries although is likely aimed at certain CEE countries that have not yet recognised same-sex marriages

or registered partnerships.

It is vital that the EMA does not lose too many staff during the relocation process; so concerns regarding policies on gay rights in some of the 19 candidate countries must be taken into serious consideration. From this it is clear that the decision is as much political as economic - the cultural divide between Western and Eastern Europe in the battle to win the EMA has not gone unnoticed.

Writing as Dutch nationals, we certainly understand why Amsterdam would be appealing to EMA staff. Indeed geographically, the city represents less of an 'uprooting', and it is believed that over 90% of the Dutch population speaks English. Employees relocating from Britain will likely find attractive international

'It is paramount the successful city can continue London's excellent work in this space'

opportunities, facilities and support. The Dutch bid to host the new regulator concentrates on the four Cs: 'commitment, continuity, connectivity and community', to highlight its position as a strong candidate in the bidding war. Furthermore, the video included in its proposal pushes for a smooth transition and jokingly underlines the important similarities between London and Amsterdam: 'We also have a very stylish queen and we enjoy fish and chips.' However, monarchy and diet aside, the significant point was made that the Dutch boast a 'first-class' medicines regulatory agency that will allow for a seamless transition and will assume the work currently undertaken by the MHRA.

The European Commission will come to a decision in November, and so far the 19 European cities have all demonstrated their most sophisticated campaign capabilities as part of their EMA bid. However, whichever city is successful in their bid, the European Commission must disregard both economic and political motivations when settling upon an appropriate candidate.

To echo the words of Edith Schippers, the resigning Dutch health minister, the fundamental goal of the relocation is to provide European citizens with safe and efficient medicines. Continuity and stability is vital here. It is paramount that the successful city (Amsterdam or another) is one that can best continue London's excellent work in this space.

Ellen Gielen is partner and **Willem Hoorneman** is managing partner at CMS Netherlands

Exploring serious market access roadblocks for rare bleeding disorders

Ensuring that sufferers get the treatment they require

Every single day, we are making medical advances that are taking the world by storm. New drugs are being created, procedures are being streamlined and robotics are being created to facilitate complex operations. Medically, we have taken great strides and, as each year goes by, new advances hit the headlines to demonstrate how far we have come. Unfortunately, however, there are still some areas that require much more attention, with certain diseases seemingly falling by the wayside.

One such area that requires a great deal more understanding and appreciation is that of rare bleeding disorders. Today, 7,000 diseases are listed as rare and 6-8% of the world's population is thought to be suffering from a rare disease, with rare bleeding disorders forming the largest group. In fact, as we will soon see, rare bleeding disorders pose a huge challenge to the healthcare sector and patient community. Due to certain roadblocks, it is increasingly clear that we are not providing sufferers of rare bleeding disorders with all the care and attention they need.

The key challenges for patients with rare bleeding disorders are awareness, cost of care, access to care, suboptimal treatment and, critically, a dearth of published data. A combination of these problems cause frequent problems for clinicians and result in market access concerns. Although efforts are now underway to develop and provide structured data at regional levels, the reality is that the data is not yet coordinated enough to answer unmet needs. This problem is particularly evident in emerging countries. We don't quite know the scope of the problem, but what is clear is that with conditions such as haemophilia, 75% of the patient population has little or no access to treatment. Even in some parts of Europe, like certain countries in the East and South, some individuals suffering from rare bleeding disorders are faced with a number of issues, including a lack of diagnosis and modern treatment, such as recombinant factors.

Below, we will cover the elements necessary to properly fight a disease, which obstacles are preventing patient access with regards to rare bleeding disorders, and how our biggest struggle in the healthcare sector is a lack of data and appropriate communication.

Fighting a disease

In order to fight a disease, an adequate action plan needs to be created. Healthcare policymakers and advocacy groups need to have consistent and structured patient data. On top of this, there is a need for established channels of communication between stakeholder groups. Such measures are critical when it comes to developing efficient and unified treatment guidelines.

'In emerging countries, 75% of the patient population with haemophilia has little or no access to treatment'

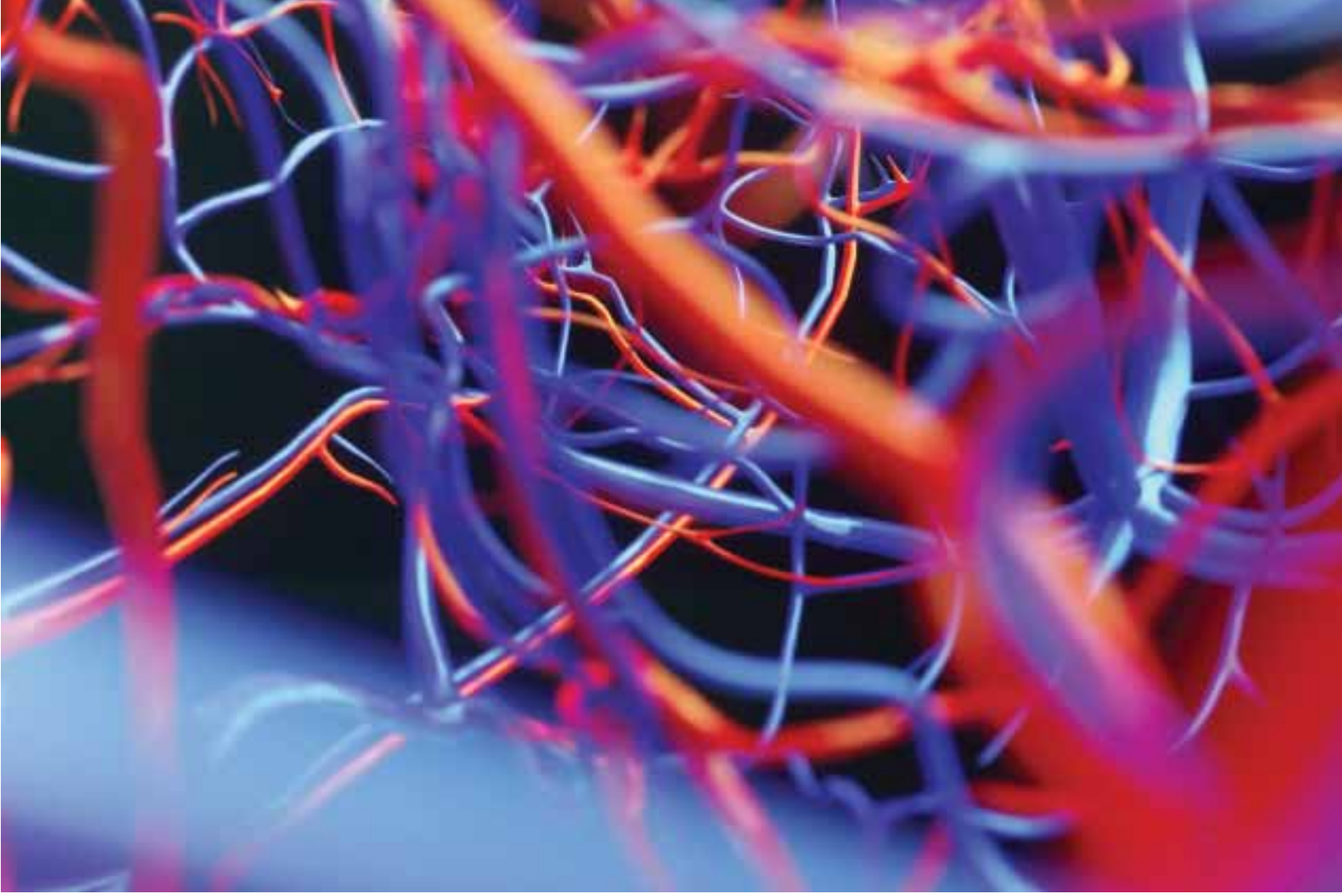
Structured data is so important to the pharmaceutical industry because if any deviation is observed, it means failures can be investigated, root causes identified and appropriate actions taken. Without such data, we're in the dark with regards to the safety, efficacy and quality of drugs, on top of the scope of a given disease.

A significant lack of data

Given the importance of data to the pharmaceutical industry, you would hope that we would have specific, structured data with regards to rare bleeding disorders. Unfortunately, this is not the case. In fact, there is a serious scarcity of data in this field and the data that is available is not organised or shared properly with stakeholders.

This is a well-known problem, and in the past there have been efforts to improve and enhance the understanding of rare bleeding disorders with regards to prevalence, diagnosis and treatment. In 2004, the Rare Bleeding Disorders Database (RBDD) was created in order to collect epidemiological information on 3,230 patients from 66 centres around the world. In addition, epidemiological data can be found from the World Federation of Haemophilia's annual survey. Unfortunately, the data is not homogenous and doesn't give an accurate reflection of the global distribution of rare bleeding disorders, as roughly 50% of the data only concerns European patients.

In fact, the true scope of patients affected by rare bleeding disorders is very limited, and this is particularly true of developing countries. This might be due to the limited number of reliable national registries. In less economically developed countries, political, economic and social situations can sometimes lead to patients not being diagnosed, which means their conditions are never managed.



Market access issues

Due to the fact that accurate data is such an issue for rare bleeding disorders, a number of market access issues arise that limit quality of life for hundreds of people around the world. Without appropriate data, we are unable to determine rates and severity of disease complications, engage stakeholders, identify unmet needs, develop systems, disseminate evidence, assess which health issues should be considered for further study and build awareness. Essentially, by collecting and managing vast amounts of data from a number of sources, pharmaceutical companies will be able to make more informed, strategic decisions.

In order to collect this data, we need to emphasise the importance of real-world data - a process which is useful in many phases of product development. Real-world research incorporates randomised controlled trials (RCTs) and 'more pragmatic research in real clinical practice'. Randomised controlled trials were once considered the gold standard among experimental methods, but due to their limitations, we now understand that more is needed. It has been said that real-world evidence is increasingly essential in order to ensure patient access and commercial success, as it is able to offer a bigger picture of the risks and benefits of a particular product, treatment or drug.

'Transparency of individual patient data is essential to personalise treatments and improve patient health'

One source points out how transparency of individual patient data is essential to personalise treatments and improve patient health, as it allows healthcare providers to monitor utilisation and forecast future needs. This same source suggests that part of the reason for this lack of data is that patients do not always track their own bleeds in a reliable and consistent way and, as such, an intuitive, easily accessible system should be provided to patients in order to easily report this data. This tracking system would provide transparent, visible data to all stakeholders, which would in turn 'facilitate benchmarking between centres and countries'. More complete data will also help pharmaceutical companies to justify drivers of treatment costs - a key element when it comes to ensuring market access.

Overcoming roadblocks

When it comes to overcoming market access roadblocks and improving quality of care for patients with rare bleeding disorders, we need to focus on collaboration and communication, through established, structured, scientific initiatives that engage clinical stakeholders.

In order to streamline communication, we need to assemble different groups of the health ecosystem (clinical leaders, patient organisations, developmental organisations, governments and healthcare industry partners) on a scientific communication and cooperation platform. Such a platform can then go on to generate evidence and insights to design, develop and deliver structured, scientific and sustainable initiatives, on a scale specific to disease areas.

It's critical for experts to convene, identify and formulate short-term and long-term activities to oversee their progress and provide course correction advice to manage rare bleeding disorders optimally. Such a network also facilitates the generation of relevant data on the issues, which can then be published in relevant scientific conferences or publications. The experts will be well-placed to participate in activities designed to aid patient access, as well as acting as advocates for rare bleeding disorder patients in their respective countries.

In time, with enough professional dedication and enthusiasm, we can work together to break down each and every roadblock that stands in the way of rare bleeding disorder sufferers getting the attention and care they deserve.

Sakshi Mittal is a senior clinical research associate at phamax

WARNING SIGNS

MAKING THE MOST OF MULTICHANNEL MARKETING

Pharma is making measured progress in its adoption of multichannel marketing, but can it actually measure success? And does it even know what good looks like?

It's fair to say that the European pharmaceutical industry's adoption of multichannel marketing (MCM) has been slow, cautious and variable. Compared to most other sectors, pharma is widely considered to be behind the play - held back by a combination of logical concerns, irrational fears and lazy excuses. However, change is apparently afoot.

For the first time in five years, pharma's digital spend has increased: Across Health's Multichannel Maturometer 2017 indicates that investment in digital has grown by 20% in the past 12 months. Alongside it, there are strong signs of an increase in executive buy-in for multichannel programmes. These upward trends are hugely encouraging, signalling the apparent dawn of a new phase of multichannel maturity. However, while the support of senior stakeholders is a welcome and indeed essential development, the concurrent growth in digital budgets is a double-edged sword. Multichannel progress requires much more than money. In fact, with channel mix and multichannel metrics widely recognised as areas of weakness, there's a risk that the additional investment could be squandered on the wrong activities - leading to suboptimal returns, increased dissatisfaction and a reversion to old approaches. So how can companies avoid the pitfalls and make the most of this new-found support for MCM?

Fonny Schenck, CEO, Across Health, believes that 2017 could prove to be the year when pharma's multichannel progress accelerates - but also points to potential concerns lurking in the shadows of the positive headlines. "There are indications that, despite senior executives finally exerting top-down leadership of multichannel programmes, there remains a poor understanding of what 'good' looks like. It's perhaps no great surprise. Our 2017 survey shows that companies still admit to having insufficient knowledge of the opportunities digital and multichannel present - with know-how actually declining since 2016. The only area where knowledge appears to be increasing is the multichannel rep - with analysis revealing that rep-focused channels are the only MCM tactics to grow consistently in the past five years. This could suggest the industry has a myopic focus on digitising the traditional sales model - an approach which both risks wasting the many opportunities of MCM and reinforces the view that companies do not yet have the wherewithal to leverage them."

Multiple channels is not multichannel

The field force is, perhaps, a natural place for pharma to start its multichannel evolution - it's familiar territory and optimising it has become a nagging operational headache that the industry is desperate to cure. The pursuit of a more effective commercial model is ongoing. "Senior leaders in pharmaceutical companies are looking for a better way to access their customer-base," says Paul Black, chief operating officer, OUTiCO. "The challenges around call rates, access and inefficiencies in the traditional representative model are well known. However, the alternative approaches that companies take can sometimes be too crude or simplistic. For example, we frequently hear of companies who think that they can engage their customers solely via digital channels, or who believe that telesales is the solution to the problem of gaining HCP access. Conversely, some go to the opposite extreme and try to leverage as many channels as they can. These tactics are symptomatic of a common silo mentality. There's often a degree of separation between sales and marketing where each party develops its own strategic view of how to engage customers and heads off in its own direction with isolated activities that reflect that view. Apart from being disjointed and inefficient, the approach is a long way from the utopia of integrated multichannel. Just because companies use multiple channels doesn't mean they're acting in a multichannel capacity.

'As the communications landscape becomes increasingly complex, the industry needs a framework for more effective multichannel metrics'

"True multichannel is about engaging the customer in their preferential style. This requires insight. The smartest companies are using intelligence and closed loop analytics to map channels, customers and preferences - and understand how they relate. They're

then using that intelligence to inform a genuine multichannel approach that combines appropriate human and digital engagement and allows them to optimise their commercial strategies. Fundamentally, if you're going to do multichannel, you need to make sure you're using the right channel for your end user - because if you're not, you're simply wasting time and money."

Measures for measures

The need to optimise resources is ever-critical. However, in a communications landscape that has become increasingly complex, the industry perhaps needs to establish a framework for more effective multichannel metrics - particularly if increases in budgets are to yield the desired outcomes. "Companies are becoming better at measuring ROI across channels - but there's a long way to go," says Paul Townley-Jones, senior consultant at Blue Latitude Health. "Return on Marketing Investment is the ultimate measure of financial efficiency - and it's essential to comparing campaigns and helping allocate budgets. However, effectiveness should in fact be a measurement of how much net profit campaigns deliver, rather than the incremental sales of every tactic. Again, other industries are further down the road with this - bringing in econometricians to measure true ROI. You'd be hard-pressed to find an econometrician in pharma. Marketers may therefore benefit from training to help understand the formulas and methods to calculate ROI. This would help ensure that campaigns are set up in the right way for effectiveness to be measured. This will be vital to driving the quality of multichannel engagement."

In an ever-competitive business environment where share price is all important, making the most of multichannel is a strategic imperative for pharmaceutical organisations. The challenge is at last occupying the c-suite, as companies transition from sporadic, bottom-up innovation to structured, top-down leadership. But the bottom line is clearly the bottom line, and the need for commercial efficiencies has become the catalyst for frank and sober assessment of a failing model. "Senior stakeholders are increasingly buying into the multichannel concept," says Paul Black. "Many have recognised it's become too expensive to put a traditional field force on the road and that they need to do something fundamentally different to drive shareholder value. It's an uncomfortable thought and one where the alternative approaches take them into areas where there's traditionally been fears around governance and compliance. However, necessity is the mother of invention. If a salesforce is costing more than it's yielding over the 12-year life cycle of a brand, it's not sustainable. Sustainable customer engagement dictates the need to communicate across multiple channels - so long as they're the right channels - and to a broader, more diverse customer-base than simply HCPs. Companies also need the agility to adapt their approach over the product life cycle. The keys to success are courage and intelligence. The future is without doubt multichannel. If you cannot see it - and do it well - you're going to be in trouble."

The customer is king

One area that will be key to 'doing it well' is customer insight - the lifeblood of MCM. Without deep and responsive customer intelligence, communications will neither resonate nor cut-through. It's a message that's finally hitting home. "Pharma has at last recognised that multichannel is not about pushing content across multiple different channels, it's about personalising the experience and delivering content across the correct channel with respect to the context in which the person is accessing the information," says Paul Townley-Jones. "The industry has generally become smarter in how it distributes its budget, cross channel. However, there's still work to be done in the shift towards true customer-centricity that will fuel multichannel excellence. Progressive companies are focusing on customer experience - they're developing detailed customer journeys that show a greater understanding of the context in which their customers live and the channels they use. This deeper appreciation is being supported by an improvement in customer insight that's informing multichannel strategies. But in some companies, brand plans remain too insular - focusing on what the organisation wants rather than what their customers want.

"To be successful, companies need to build their long-term vision around identifiable customer needs. If they do that properly, they'll naturally become multichannel organisations. Ultimately, making the transition from a brand-focused to a customer-focused company is crucial to multichannel excellence. This requires setting out your vision and identifying the critical success factors that are going to help you reach it. From there, you can develop the roadmap and workstreams that will help you transform into a customer-centric - and therefore multichannel - corporation. In other sectors, companies are leading the charge with the introduction of roles like chief customer officer. We are not yet seeing that in pharma. We ought to be."

New segments, new opportunities

The argument for better customer insight is universally accepted. However, one of pharma's biggest challenges has always been the breadth of its customer-base, which extends far beyond traditional HCPs. This breadth has not only created obvious regulatory concerns around how industry communicates with stakeholders, it's also brought added complexities to multichannel thinking. Consequently, the road to multichannel excellence has become paved with old habits - not least an apparent fixation on targeting doctors.

"The industry talks a lot about patient-centricity, but if you look at what it actually does, it still largely focuses on physicians," says Fonny Schenck. "In the longer run, companies won't be able to sustain competitive differentiation simply by sending out reps equipped with digital tools - just think of the high hopes for tablets initially and how fast commoditisation set in.

"Although the move to the multichannel rep is important, it should not be the only focus. A recent MIT Sloan management review concluded that successful organisations are those that don't just move first, they use digital to enter different segments. The business case for omnichannel customer engagement in other segments - referrers, no-see HCPs, caregivers, patients, nurses, payers - as well as new growth opportunities like health technology, is hardly ever made. At the same time, other players - like Google, Apple, other tech giants, as well as VC-backed start-ups - are hugely consumer-centric and are beginning to enter the space. If pharma continues its myopic focus on a prescriber-led business model it will end up being too late to a party where Apple and the likes already own the right data on consumers and patients. These entrants aim to help consumers stay healthy longer, and, when they do get ill, navigate them and their providers through all treatment options (ie, beyond pharmaceuticals) in an evidence- and value-based way, and then maximise adherence and optimise outcomes. You can see some of these dynamics already playing in the diabetes area - but much more is coming."

And so the message is clear: the pharmaceutical industry's future business model will look very different from that which we see today. Pharma needs to get in front of this before disruptive innovation from outside the sector overtakes it. As the Canadian ice hockey player Wayne Gretzky once famously said: "I skate to where the puck is going to be, not where it has been." It's a powerful metaphor. Multichannel can help us get there - but we'd better get our skates on.

Chris Ross is a freelance writer specialising in the pharmaceutical industry

Multichannel in pharma: get ready for the perfect storm

Exactly 20 years ago, I launched my first HCP website. On the surface, not a lot seems to have changed since then. While many other industries have moved ahead, pharma continues to see digital as a 'shiny object' and an 'afterthought'. Our Across Health Maturometer, which measures the 'temperature' of digital transformation, has confirmed this picture year after year for almost the past decade:

- Digital marketing budgets remain small and basically flat
- Pharma's satisfaction with its own digital efforts remains low
- Digital knowledge is not increasing.

But in our 2017 Maturometer, we see clear signs of change: budgets are up 20% and senior support grew significantly. Is this the second coming of digital, finally?

The HCP landscape is changing

The needs and digital footprint of our HCP customers are certainly evolving. Firstly, by 2020, close to 70% will be 'digital natives'. Secondly, the once dominant rep-friendly 'relationship seekers' have sunk to rank third (25%); 'independents' and 'knowledge seekers' now constitute over 65%. As a result, channel habits are changing, with:

- A substantial drop in the reach of reps (from 60% in 2011 to 40% in 2015 for US oncologists)
- A strong growth in online pharma channel reach (pharma websites have jumped from 25% to 45% reach).

Also, in any market where pharma's digital 'supply' grows, physicians are becoming more satisfied. In Europe, for instance, 34% of HCPs were (very) satisfied in 2017 - against 29% in 2015.

The pharma landscape is changing too

Pharma is changing rapidly, too. As mentioned, both digital budgets and board support are up - strongly - this year. Several companies have undertaken massive efforts to roll-out state-of-the-art platforms and digital capabilities, as well as to hire digital staff. And on the ground, the multichannel rep has become 'the new normal'. The focus is now shifting to execution at scale and well-designed impact measurement, supported by sophisticated business cases.

In short, the surround sound for digital in pharma is distinctly up again - as is FOMO (the fear of missing out).

Fast forward to 2020

As both the 'demand' (HCP) and 'supply' (pharma) sides are accelerating, a virtuous cycle for digital transformation in the life science sector should be emerging.

Is the following scenario for 2020 far-fetched? Pharma increases its digital investment significantly, pressured by competition and customers alike, and within a few years the early movers become digital leaders. Digital native HCPs (70% by 2020!) appreciate these much-improved offerings, and further shift their focus to digital - leading to a further drop in rep access and higher reach and impact for online pharma channels. At the same time, medical departments start offering robust 'anytime, anywhere' med-ed and meeting services, to complement or substitute the high-cost, time-intensive traditional meetings and congresses.

Some of the savings realised by redefining the go-to-market model for target HCPs are then redeployed towards digital engagement with other stakeholders, like referrers, non-target HCPs, patients and payers. In addition, controlled experiments with fast-emerging and promising health tech solutions and platforms are carried out, allowing ever deeper customer engagement. The result for the fast movers is a virtuous cycle, with stakeholder engagement, revenue, market share and margins… up.

In this 'perfect storm', companies who myopically focus on maximising salesforce efficiency will lose out, and proactive leaders will reap the reward of digital transformation by developing a new competitive edge.

What should you do now?

Whether the above scenario will be reality in 2020 is not certain. Its timing will depend on the intensity of customer and pharma dynamics, but it is clearly possible. Just think of the speed with which the industry adopted tablets…

So what should be done now? Let's look at pharma's three self-declared key weaknesses first (Maturometer 2017):

1. Marketing automation
2. Channel affinity and mix
3. Training.

To overcome these, we recommend these five actions:

1. Revisit your MCM strategy - and make it tangible and measurable (develop a 3-5-year roadmap)
2. Go beyond multichannel rep myopia: include stakeholders beyond target HCPs
3. Invest in marketing technology and high-quality data
4. Bring in actionable training across the board: from the CEO down to the rep and MSL
5. Invest in channel mix methodology and channel affinity.

Across Health engages with its customers in all these areas, with unique offerings like the Navigator (channel mix and beyond), Maturometer (digital maturity), Excellerator (capability building), as well as strategy formulation, integrated execution and impact measurement services.

The tipping point has been reached… we hope you are well-prepared for the perfect storm!

Fonny Schenck is
CEO of Across Health
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Journal sponsorship

A multichannel marketing solution

Communicating and connecting with your target audience are key to successful marketing campaigns. For a healthcare company about to launch a new product or wishing to actively engage with a therapy area, one opportunity that needs to be considered is journal sponsorship.

Read on to discover how sponsoring a journal could benefit your corporate reputation and relationship with HCPs, while also underpinning your marketing and market-access objectives.

The benefits of sponsorship?

As a healthcare company, sponsoring a medical journal allows you to:

- Engage with a ready-made target audience
- Build trust through association with a quality publication led by an independent specialist Editorial Board
- Educate the readership and facilitate advances in patient care and outcomes
- Promote disease awareness and understanding
- Raise company/brand/product awareness.

How does sponsorship differ from advertising?

While traditional page advertising communicates directly to a target audience through an interruptive process, *sponsorship* succeeds in more subtle ways. Some of the benefits include:

- *Building trust* – The association with high-quality, practical, educative content helps fortify the sponsor's image and reputation.
- *Engaging with the audience* – The front cover declaration of the partnership, with an acknowledgement that the sponsor has no editorial input or control, enables readers to continue their educative journey without interruption.
- *Promoting disease awareness and disseminating medical education* – Raising the profile of a therapy area through publication of articles targeted to a tailored distribution list is an effective way of bringing content of direct relevance to exactly the audience a healthcare company wants to reach.
- *Boosting brand and product awareness* – A sponsor's association with a high-quality journal enables the sponsor to become progressively more associated with that clinical field.

Sponsorship options

An alternative to outright sponsorship is the sponsorship of a supplement to an established journal; a one-off publication, providing the opportunity to be affiliated with high-quality scientific and clinical content independently commissioned around a key theme. The presentation and delivery of content can be tailored to company-specific needs, distributed alongside the parent journal or independently to a specific, targeted list of readers.

Final thought

Prudent sponsorship of a targeted healthcare journal can help to cut through the noise generated by the marketing avalanche, providing clinically relevant and engaging content, while reinforcing the audience's perception that the sponsoring company is committed to a disease area.

■ *Hayward has been helping healthcare companies reach their target audiences for over 26 years. To find out how one of our existing titles or developing a bespoke publication could meet your needs, please contact Martin Griffiths (martin.griffiths@hayward.co.uk). Martin is publications manager at Hayward Medical Communications.*

Embracing multi-channel in the digital age

Access to HCPs is in decline, but with mounting pressure to maintain sales delivery, how can pharma use digital channels to up its game?

The NHS, and the healthcare industry as a whole, has changed rapidly in recent years. Decreasing budgets and tighter time restraints mean that accessing NHS customers in the traditional way is a growing challenge.

However, the digital age has presented us with an opportunity. It has reshaped the way we live and work in general, improving our productivity and aiding communication. From social media through to managing money, digital interaction is well and truly integrated into our daily lives. And now, digital channels have become a viable alternative to accessing HCPs.

The pharmaceutical industry has been a little slow in adapting to the digital revolution. We are seeing companies experimenting with different modes of communication, from e-detailing to email, but what they have a tendency to forget is that, ultimately, effective communication is about individual preferences, over and above a company's digital strategy.

Consider HCPs as individuals

As consumers we all have our own preferences in how we are approached by brands, so it should come as no surprise that the HCPs we're targeting have individual preferences too. Not all HCPs will respond well to the telephone, some simply prefer emails, and this medium shouldn't be underestimated. They're developing different ways of working, and they're also getting younger and more adept at mastering technology.

OUTiCO has seen some superb results with our multichannel approach over the last few years. The response of HCPs to new technology has been extremely positive, and we routinely receive feedback that a flexible approach which considers their time and preference is refreshing.

Digital communication still has a long way to go, but every time we successfully and professionally engage with an HCP, we increase the understanding of the benefits this can offer busy clinicians who need to stay up to date with pharmaceutical developments.

What is multichannel account mangement?

Multichannel account management is an alternative to the traditional, key account management sales model. It combines the skills of qualified sales professionals with new tools and techniques that optimise their engagement with customers, and it lets them develop channels that are tailored to the individual preference of their customers.

> 'For commercial success, the pharma industry needs to adopt new and innovative ways to access their customer base'

We've seen superb results using a combination of channels.

- Video conferencing/screen sharing is a simple interface for fast, online meetings. It's very effective and our customers have commented on how easy it is to use, and how valuable they've found the meetings. We can engage with HCPs without wasting time on the road or waiting for a clinician to become available.
- Email is fast and flexible. Once we have permission to use email, many HCPs prefer this method of communication because it doesn't involve a lengthy conversation, and they can review the content at their own pace.
- Telephone calls work for those HCPs who want to have a conversation with a trusted adviser. A phone call can save so much time, and it's a really cost-efficient way to build relationships.
- Face-to-face meetings can still be facilitated by multichannel account managers if this is the HCP's preference. It allows the reps to build relationships and have a personal interaction. However, unlike the traditional sales model, we don't make cold calls. All our meetings are 'warmed-up' first, so that both parties support the objectives and value of the meetings.

What makes a future-proof rep?

Strong business acumen and excellent negotiation skills will, of course, remain important, but to keep pace with the HCPs of today, sales reps need to engage successfully across all available channels and treat people as individuals.

Once a preferred channel has been established, sales professionals should adapt their style to suit their customer, build a relationship, share expertise and hold high-level conversations, demonstrating their vast knowledge of the industry.

What lies ahead?

We all have a part to play in the digital revolution of healthcare and the NHS. It's no longer an option to stand still in an environment where everything else is changing.

PAUL BLACK

The next generation of pharma sales reps will be multichannel communicators who put their customer's preference at the heart of every sales interaction.

For commercial success, the pharma industry needs to adopt new and innovative ways to access their customer base, which will deliver a broader channel mix. It's this sustainable method that will ensure a bright future for any company that embraces change.

Paul Black is COO at OUTiCO


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Patient disengagement

Patient engagement, patient centricity, patient focus… Understand what these mean, apply them to our work and we'll be able to positively impact on patients' lives, right? It's not so simple.

It's easy to achieve patient engagement if you actually have an engaged patient to start with. But what if you don't? Instead we should look at those disengaged patients and ask 'why?'. Why are they not adhering to their treatment? Why are they less interested in their health? Why are they not empowered to follow what the doctor has advised?

There are many barriers to engagement.

But at the heart of them are typically three key things:

- They lack knowledge or skills – a classic pharma default to overcome this: 'we must educate, educate, educate'
- The environment that they live and work in does not facilitate an optimal health experience
- And the big one – they don't have the motivation, the driver to actually do something at different points in time.

Designing an informed solution is vital.

If we are to drive engagement, we need to understand which of these, or which combination of these, is making patients disengaged. Let's look at an example.

Around 30% of us don't seek medical help because its not convenient[1] – we can't book appointments online or simply don't have the time.

I am one of them. I have worked in healthcare for over ten years. I therefore feel that I am fairly knowledgeable about health and the importance of wellness, and empowered to be the master of my healthcare.

Knowledge and motivation are not the problem.

But, give me a reason to actually go and see a doctor, and that's a different story. Case in point: after recently signing up to a new GP surgery, I asked if I could set up online appointment booking. "Oh no," she said, "you have to wait at least two weeks until you're on the system, then you can come back in and do it." The environment wasn't working in my favour. I left the surgery pretty sure I would be going there only if absolutely required.

What I need is the option to take care of my health in a way that suits my lifestyle.

So three weeks later, when I actually needed a doctor, I came across and tried Push Doctor – one of the recent examples of online doctor consultation services. Within seven minutes I had registered, booked an appointment and was video-calling a GP.

Within four more minutes, she had given me a diagnosis, prescribed medication, and emailed the prescription through to my nearest open pharmacy. An hour later I received an email to let me know that I could go and pick up my medication.

I was genuinely amazed. Here was eHealth in all its glory. And although this type of efficiency and convenience does not come for free, it is a beautiful example of how technology can remove the environmental barriers that I, and others like me, face when trying to stay on top of our health.

So, the next time you set about a new patient engagement initiative, or begin planning for that next patient support tool, ask yourself 'why are my patients disengaged in the first place?' Understand that, and you can then develop the best solution for them. Or call us. Patient engagement is what we do best.

1. Future Health Index (2016) Connected care: where the fault lines lie. Available at https://www.futurehealthindex.com/report/2016/chapter/412/connected-care-where-the-fault-lines-lie/?lang=en [accessed September 2017].

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Gene therapy - when will it deliver?

The concept of gene therapy has been around for decades; with over a quarter of a million peer-reviewed publications generated, careers made and retired from, and hundreds of biotech companies coming and going in that time. However, this vast investment in time, human resources and money has yet to deliver significant direct patient benefit and still remains more of a promise for the future, rather than a medicine of today.

This raises the following questions:

1. Why hasn't the research translated to mainstream patient benefit?
2. How are these limitations impacting current gene therapy programmes?
3. What is the roadblock to gene therapy?
4. Will gene therapy ever fulfil its promised potential?

The early years

The brief answer to question number one is: a combination of over-ambition and naivety about the target, accompanied by a lack of resources and enthusiasm for understanding and overcoming the major hurdle of delivery.

In the early nineties, as the concept of gene therapy was taking hold, scientists and pharmaceutical companies could only see the upside of how gene therapy would offer a precision medicine option for all diseases. These early pioneers were largely focused on DNA-based gene delivery or the use of DNA anti-sense technologies to specifically inhibit mRNA translation.

In oncology, there was already a plethora of seemingly obvious targets, as our knowledge of oncogenes driving different cancers expanded. However, with hindsight, many basic questions were ignored, such as what percentage of cancer cells would have to be transfected for the therapy to work? Would there be off-target effects? Or challenges of tumour heterogeneity? And how easily would resistance to such an overtly targeted therapy arise? While these questions are applicable to all types of therapy, when combined with the experimental delivery vectors and the associated lack of pharmacokinetic/toxicology knowledge of these vectors, they ensured that the promise of gene therapy in the early nineties could not be remotely met.

'There is a lack of resources and enthusiasm for understanding and overcoming the major hurdle of delivery'

The over-simplification of gene therapy, personal ambition and a rush to clinic and commercial competition had tragic consequences, with the death of Jesse Gelsinger in 1999 being attributed to the viral vectors used in the trial. Because of his death, 652 previously unreported, serious adverse events, including deaths, were reported to the US National Institute of Health. As many of these trials were performed on very sick patients, it is unclear how many of these events can be attributed to the gene therapy itself. However, the culture of secrecy, corner-cutting and late reporting further undermined this dawning technology.

These tragic outcomes, coupled with the realisation that gene therapy was not a 'quick-fix' for all diseases, led to a downturn in the enthusiasm for gene therapy trials and research, which has only started to recover over the last decade.

Renaissance

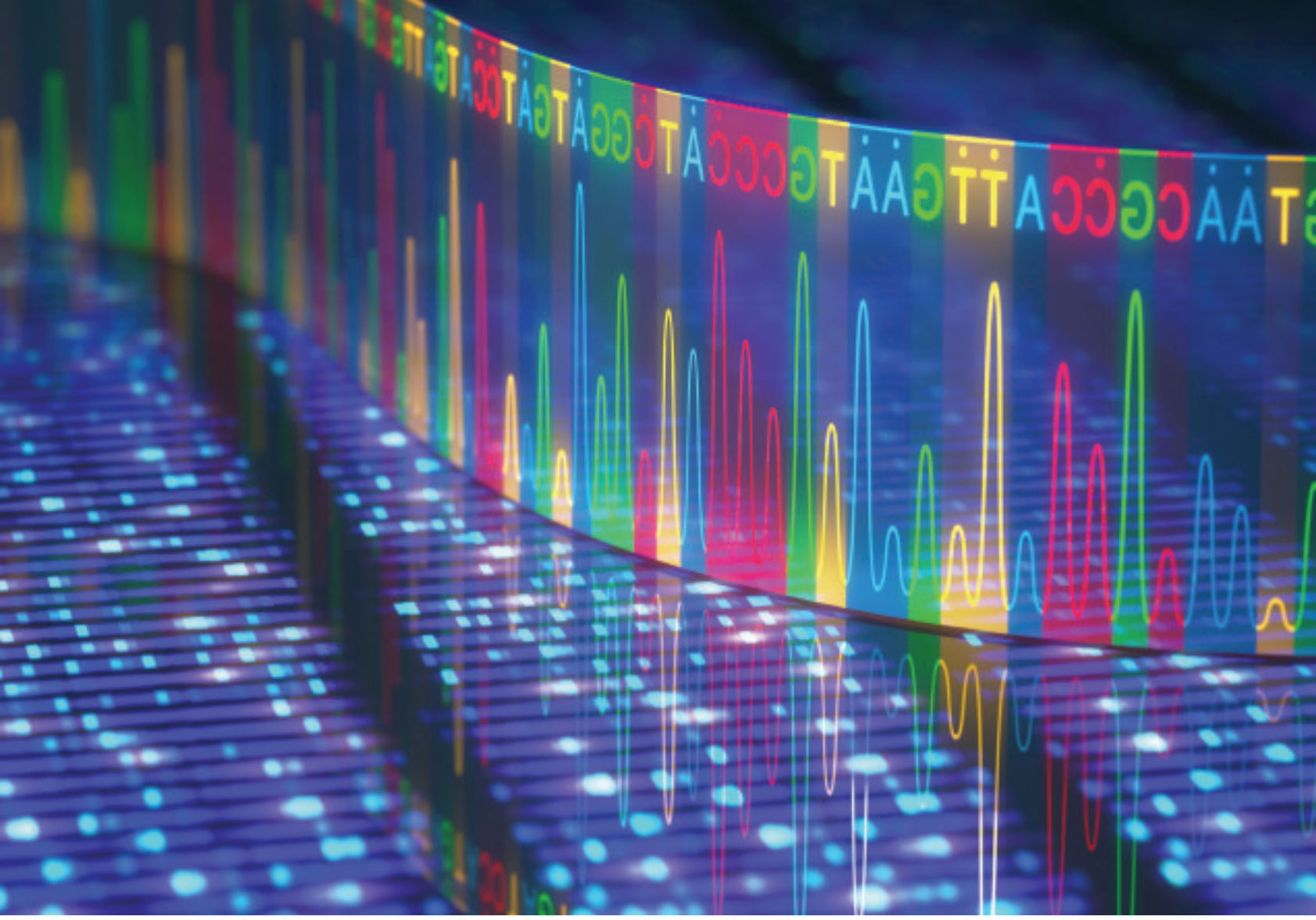
Renewed interest in gene therapy in recent years has been driven by new, basic biology discoveries. From a payload perspective, these include new technologies such as siRNA, Sleeping Beauty transposases, CRISPR-Cas9 gene editing, ARCUS gene editing, nucleic acid vaccines, oncolytic viruses and chemically modified mRNA. These new capabilities, together with improved delivery vehicles, offer fresh hope to fulfilling at least some of the early promise of gene therapy.

However, despite the improvement in both viral and non-viral (primarily liposomal) delivery vectors, the recurring delivery roadblock for gene therapy remains, imposing constraints on its widespread use. However, this time, these constraints are largely self-imposed, with companies limiting their pre-clinical programmes to targets currently accessible to existing vectors.

This is reflected in the large number of companies focusing on liver disease, as liposomal delivery vehicles tend to accumulate in the liver, or where the mode of delivery offers targeting capabilities for viruses, such as ocular and ex vivo therapies. While this more realistic approach is favourable compared to the early 'gold-rush' days of gene therapy, it potentially confines gene therapy to the rare disease sector and not mainstream therapeutics. This is reflected in the attitude of some blue-chip pharma companies. One company, for example, is not seeking new delivery vectors as it is happy with viral delivery for its rare disease programme - the implication being that this is the only space the company sees for gene therapy. In order to move gene therapy back to the mainstream, the roadblock of delivery must be faced head on.

Delivery

Liposomes remain the backbone of non-viral delivery. There are many valuable biotech companies out there with brilliant science and great targets, but which are essentially in the clinic with ancient, simplistic liposomal delivery vehicles, often traceable to generic formulations that are over 10 years old. Liver accumulation, lipid-mediated toxicity and lack of targeting remain hurdles that liposomes are yet to fully clear. In contrast, viruses still seem to be the obvious choice, as delivering nucleic acids into cells is what they do. However, the pathogenic origins of viral vectors and associated immune response mounted against them is their biggest limiting factor as it precludes regular or even repeat dosing. This exacerbates the challenges of gene therapy



further, as therapies/payloads must be designed to largely work as a one-hit treatment. Additionally, despite decades of complex viral molecular biology research, toxicity, payload limitations, inability to target different cell types, manufacturing and regulatory complexities further stymie their use beyond ex vivo and niche targets.

The overt focus on liver disease has led to one new system for delivering siRNA to the liver, called GalNAc. GalNAc uses a specific sugar group attached to chemically-modified siRNA to target liver cells. GalNAc technology does hold potential, but has limited utility, and a recent trial suspension using this technology has not yet been fully resolved.

Therefore, the use of sub-optimal delivery vectors may continue to result in disappointing trial data and further hinder gene therapy. Despite Jesse Gelsinger's death being over 18 years ago, unexplained deaths have occurred in recent gene therapy trials and a decade of progress could still be hampered by using ill-conceived or poorly-understood delivery vectors. Delivery remains the biggest barrier to gene therapy.

Future prospects

To ensure that the promise of gene therapy can be fulfilled, investment in new gene therapy delivery technologies needs to be raised. As do their profiles, to escape the negative connotations of 'standard' drug delivery/platform companies. Cracking gene therapy delivery is very different from marginally improving the pharmacokinetics profile of an existing drug with a new delivery platform.

Looking to the future, there is exciting progress being made with nucleic acid vaccines, where the bar of efficiency of transfection and targeting may be lower. Yet there is still room for improvement. Some companies are investing in liposome development, but this needs to become far more systematic, along the lines of big pharma's small-molecule programmes, in order to identify new lipid combinations that are capable of matching the best viral platforms and that are safe and simple to manufacture.

'Cracking gene therapy delivery is very different from marginally improving the pharmacokinetics profile of an existing drug'

Finally, looking beyond liposome versus viral delivery, alternative technologies such as new polymers, conjugates, vesicles, dendrimers and peptide nanoparticles, such as LipTide (an 'artificial virus'), urgently need investment and further evaluation. A safe, simple-to-manufacture, non-immunogenic and targetable vector with payload flexibility remains the holy grail for gene therapy delivery. In the meantime, a more flexible 'mix-and-match' approach using existing and newly developed technologies optimised for specific targets remains the best way forward.

In summary, if expectations are managed and investment made in the fundamentals of delivery, gene therapy can emerge as far more than just a niche player, but rather as a mainstay of therapeutic approaches for a wide variety of common diseases.

Dr Simon Newman is director of pre-clinical research at Nanogenic Solutions

Effective sales performance - the role of targeting

A sales force is the most expensive and long-term of the options that we have to market our product. This is therefore the most important activity to get right. Yet most sales forces deliver considerably less than optimum performance. Almost invariably this is because of one of two reasons.

Either the effort is too widely dissipated across non-responsive customers who lack the inclination or influence to affect prescription, or promotion is rarely aligned to the local market.

The first of these is due to poor targeting, where there are four common problems: target overlap, target creep, target gaps and/or failure to measure.

Target overlap occurs when your choice of targets matches and overlays those of your competitor. The net result is an excessive calling pattern applied to specific doctors who either switch their allegiance regularly or switch off. In either case leading to lower sales and rapid target wear-out.

Target creep is when you allow your representatives to change a proportion of their targets. Over time your targeting efforts get watered-down in favour of 'convenience doctors', ie easier access and nearby location.

Target gaps occur when you fail to address the hidden 'iceberg' of potentially productive doctors whom you have not called upon this year, last year and perhaps for a considerable number of years.

Failure to accurately measure your promotion thus ensuring that you deliver the right message at the right frequency delivered by the right promotional instrument. Here an assumption that digital calls are equivalent to face-to-face contact is rarely tested yet evidence suggests that in many circumstances these two forms of promotion are in no way equivalent and a carefully managed blended approach is the solution.

The traditional approach is based mainly on simple economics.

a) At a macro level select the bricks or practices with the largest therapy area sales and divide by the number of doctors. With limited resources this indicates 'where' to concentrate your efforts.

b) Purchase a list of doctors from an external vendor. Here individual doctors are often ranked by their prescribing potential perhaps tempered by a known 'interest' in a given therapy area or additional roles/activities undertaken.

Both of these approaches are essentially based on the same information, as leaving aside single-handed practices we cannot be sure of an individual's true prescribing behaviour. In both cases competing companies target precisely the same individuals - due to purchase of a common list and following similar logical procedures. In effect our target list will overlap precisely with that of our competitors. This is the first and most common targeting error.

The net result - no competitive advantage is gained. Targets are subject to considerably higher call pressure while non-targets may effectively be ignored. This means that targets wear out more quickly, are subject to higher 'switch pressure' and may become more reluctant to see representatives. Under these circumstances non-targets may often be more productive to call upon. In effect the expected economic benefit of greater return per call is not achieved.

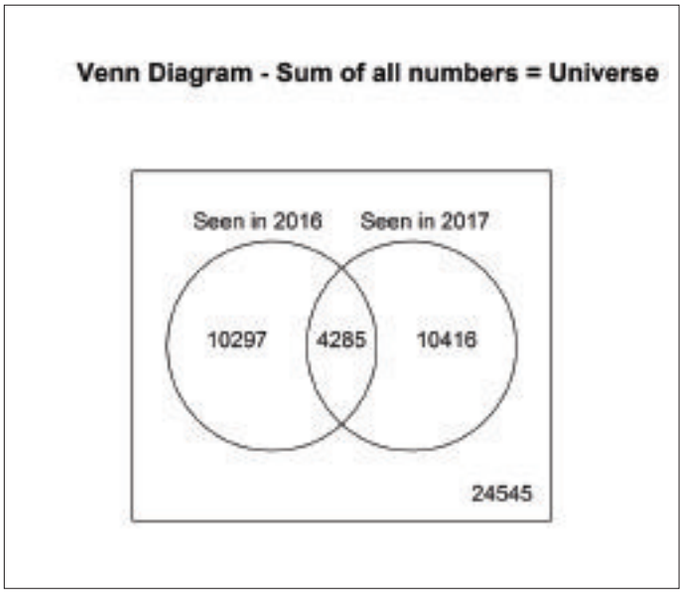
Commonly a further decision is made allowing the local representative to change up to 10% of the target list to reflect local knowledge and relationships. The net result is that difficult-to-see and geographically distant customers are excluded in favour of easier-to-see, more 'convenient' targets.

I recently carried out an analysis that looked at representative call patterns in relation to their geographic territory and home location. The results were fascinating, particularly when we took the day of the week into account. Good targeting chooses customers based on sound criteria. These criteria should be common across the sales and marketing divide so there should not be any difference of opinion. Once the target list is issued representatives should have their say but unless a sound validated business case is put forward the target list should remain unchanged. Target creep, for whatever reason should be avoided.

Effective targeting also manages the customer base significantly without unintended gaps. A good procedure is to take your customer universe and draw a Venn diagram comparing the customers seen this year versus those seen last year. The most telling statistic is the percentage of customers not seen in either year. This hidden iceberg is frequently very considerable and may represent a massive untapped opportunity for your brand. An interesting question to ask is: how small is your consistently managed doctor population and where are those doctors located geographically compared to your representative's home? This is another very productive area to apply strong analytics.

Targeting is critical to managing an effective sales force. The key is to make informed sound choices driven by good analytic procedures. In short to take advantage of the depth and richness of pharmaceutical data to pinpoint who the right customers to call upon are and at what effective frequency. Here a common problem is to confuse optimal call frequency with effective call frequency. For a given product the range of call frequencies over which a call is effective will vary by type of customer and local conditions. Often this effective call frequency is a good deal lower than expected and certainly lower than that invariably advocated by contract team providers. In most field forces up to 50% of calls are wasted.

A common cause of this wastage is that either the customer has been seen at too low a frequency (below



the effective call frequency corridor ECFC) or at too high a frequency (above the ECFC). Identifying the right call frequency is critical but this should not be applied at National level. When presenting these results to Regional Managers a common objection is that Oxford is different from Birmingham for example. This is quite true and call frequencies should be calculated locally. Promotion does not occur in a vacuum. In some areas the ECFC is much lower than in others.

Yet the biggest cause of wastage, in my experience, is failure to identify and target profitable customers. Non-responsive customers act as a major cost and time drain that saps the energy and resources of your representatives. This is a very common problem with specialist hospital products where often a large amount of time and effort is expended on non-productive roles or specialties that often divert attention to little benefit.

We should also ask ourselves at what level should we be targeting?

There are three key targeting levels; individual doctor, GP practice or hospital department and CCG or hospital group

Which of these is apposite for your brand depends upon the life cycle stage of your product and the aim of the promotion. To take two extremes:

1. New products are evaluated first by an individual trying a product. If the product performs as expected, trial may lead to adoption. Finally the individual may act as an advocate whereby colleagues are made aware and try the product themselves - a process of contagion. In short: Trial -> Adoption -> Contagion

It is when this third stage is reached that a new product is likely to be proposed and successfully adopted into the practice 'preferred list', departmental formulary or CCG 'green list'.

2. The second extreme is a drug about to come off patent in one or two years. Research has shown that most elements of product marketing fail to have little significant effect after a product has plateaued within the market. Despite this most companies continue to plough significant promotional resources into their established brands without considering that many elements could be withdrawn with little or no impact on sales. The key is identifying which customers still need support and which elements of the marketing mix are necessary. If properly analysed and the results acted upon these savings will drop right to the bottom line.

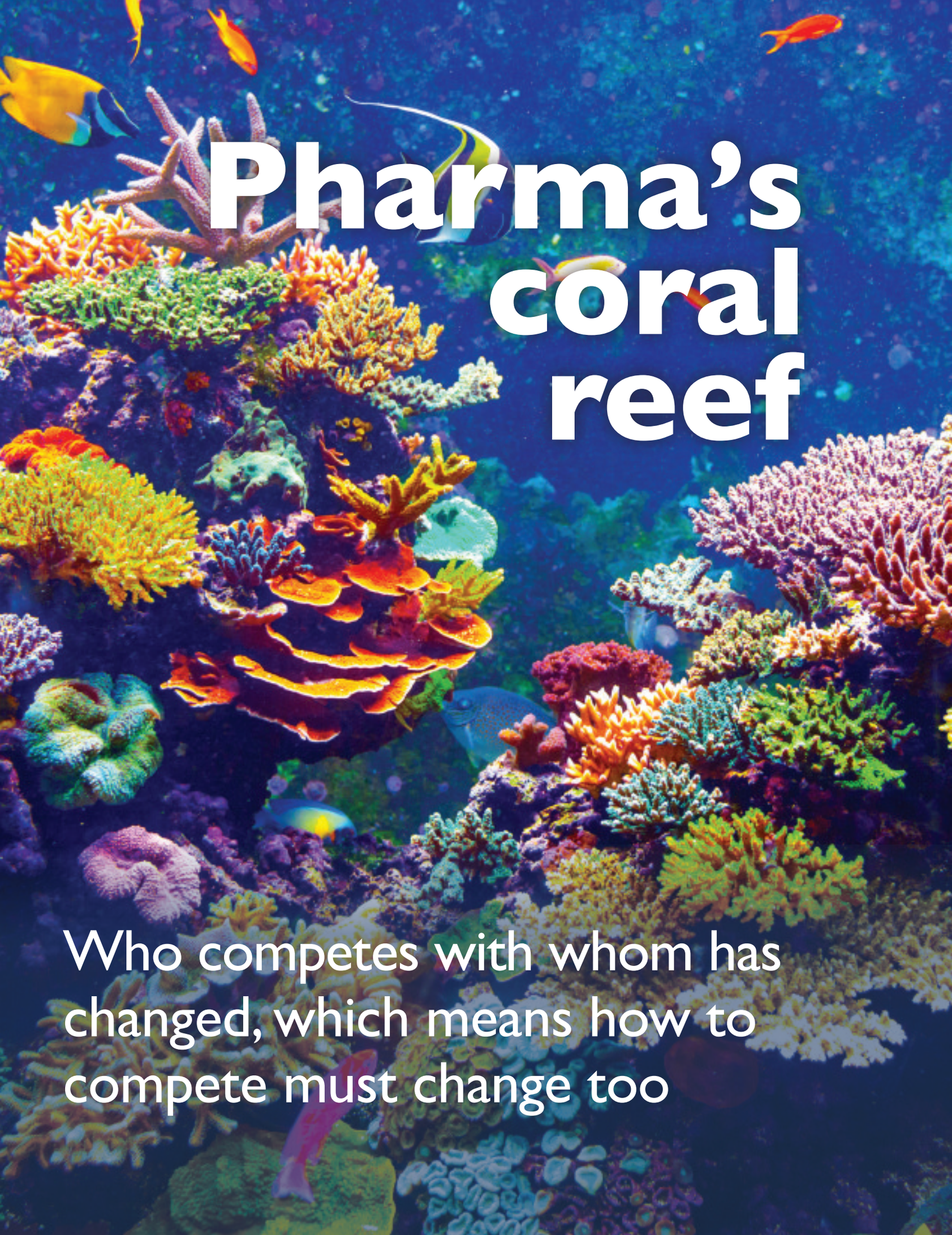
In either case the key is to get your targeting right - yet this is rarely implemented to maximum effect.

Good targeting aligns activity to the most productive targets and adjusts to local conditions. We are able to plot every surgery on Everett Roger's diffusion curve by identifying which practices are most likely to accept a new product at that stage of the product's life cycle. Sound analytics pinpoints every practice or department and can place them on this adoption continuum. In short it is of no value to pursue laggard practices when you launch a new product, your targets should match the promotional focus at that stage of the life cycle.

Another thing to consider is how you intend to treat individual practices or hospital departments? The key question here is do you believe the locus of the prescribing decision to be the individual doctor or via a consensus - at practice or departmental level? If the former, individual targeting is key while for the latter, identifying key practices or departments may be the key to success. This latter point is particularly important when separating those practices that are promotion responders from non-responders when pinpointing where to safely cut back promotion in the two years prior to product expiry.

Bruce Henderson, founder of the Boston Consulting Group, once said: "Any competitor with less than one quarter the share of the largest competitor cannot be an effective competitor." What this means in practice is that many pharmaceutical products are net users of cash and will contribute little to their companies' net profits. Our aim should be to achieve a relative market share above 0.6 in any GP practice or department. This will ensure that you are either market leader or second choice (the two most profitable positions). If your relative share languishes below 0.3 evaluate whether you can change the status quo or are best advised to place effort elsewhere. Good targeting strategy is about making effective choices that drive profits.

Dr Graham Leask is an academic, consultant and writer for the pharmaceutical and healthcare industries, grahamleask5@gmail.com



Pharma's coral reef

Who competes with whom has changed, which means how to compete must change too

If you are more than a newcomer to the life science industry, I invite you to try a comparison. At the start of your career, who invented and developed your company's products? Who made and distributed them? And who sold them? Now ask the same question of your company today. Where are those things done now?

It's a fair guess that this rumination on the past will reveal one of the biggest shifts in our industry's structure. Traditionally, most of these value-chain processes used to be done by people who were employed by your company. But today many of them are done by other companies, working in partnership with yours. In short, competition in pharma, medtech and the life science industry generally used to be between companies but now it is between networked alliances of companies. This phenomenon, which in my academic research I refer to as the holobiont shift, is very important. It means that who your competitors are is different and, as a result, the capabilities you need in order to compete are different. In this article, I explain what the holobiont shift is and why it came about. Then I'll describe what my research suggests about how you should adapt to this changed industry environment.

Let me begin with the explanation. A holobiont is a term coined by the evolutionary biologist Lynn Margulis, who realised that one source of evolutionary innovation was for species to work together symbiotically. It was first applied to coral and the single-celled zooxanthellae, which are mutually dependent on each other for survival. But since the term was coined, we've come to realise that many life forms are assemblages of symbiotic species, which is the definition of holobiont. If you need another example, look in the mirror and consider that a large part of the creature facing you is made of other organisms, such as those in your microbiome.

More recently, the term holobiont has been used to describe networks of companies that work together to compete in the market place. They are common in many sectors, but the life science industry is the prime example. When a concept from an academic lab is turned into a therapy by a biotech, that works with big pharma to bring it to market, and then contracts out its manufacture and work with another big pharma to market it across the globe, that is a holobiont. It is different from the more traditional hub and spoke model of a big company with myriad contractors and suppliers. In a holobiont, the relationships between partners is both more balanced and more complex. As your comparison of past and present will have reminded you, holobionts are the principal form of competitor in today's life science market place. Its ancestor, the fully integrated, self-sufficient company, is becoming a rarity.

'If company vs company competition is being replaced... what new capabilities do we need to compete?'

Why did this happen? The short answer is that it is an evolutionary adaptation to a changing world. The 20th century, ancestral environment of life science companies was very different from that of today. In the past, the expertise needed to develop, make and market a new product was complex but simple enough that a single company could encompass all the necessary know-how. That historical environment was also restricted to developed western economies that were, by today's standards, spendthrift. And importantly, information flow and communications between companies were costly and difficult. In that earlier world, the most effective and efficient organisational structure was the fully-integrated pharma or medtech company, doing everything but the most trivial tasks within its organisational boundaries. By contrast, today's life science market is very different from that ancestral environment. The expertise required to compete is both much deeper and much wider. Firms must now apply that expertise globally to markets where success depends primarily on health economic value. And crucially, we now operate in a world where communication and information flow are much easier, faster and cheaper than ever before. Given these fundamental changes in the market environment, it would be surprising, from an evolutionary perspective, if the optimal organisational structure for the old world - the integrated company - was well suited to the new one. And of course it isn't. We have seen how the environment selects against the old model, as the holobiont model - far better adapted to the present - emerges to take its place in most parts of the market. The great shift you have seen over your career happened because it made evolutionary sense. Our new market environment favours holobionts over integrated companies.

My description and explanation of the holobiont shift comes from years of my academic research into the evolution of our industry. It's well founded and robust. But it is not enough for practicing industry executives, who not only need to understand their market but to adapt to it. If company vs company competition is being replaced by a contest between holobionts, what new capabilities do we need to compete in this very different world? My research suggests four vital considerations.

The first of these is strategic lucidity, the capability to understand and articulate where and how to compete. Without this clarity, it is impossible to know how the holobiont should create value and for whom. And without that knowledge, there is no basis on which to design and build the optimal holobiont. Surprisingly, I find many firms lack strategic lucidity, settling instead for a product-oriented, unfocused statement of intent.

The second essential factor is the capability to design a holobiont. In essence, this means deciding which value-adding activities should be done in-house, which should be done by strategic partners and which by mere transactional suppliers. Such decisions are a function of their risk-adjusted cost and their strategic criticality, but many firms lack the ability to assess these factors and make these decisions. Instead, their holobionts are often the result of opportunistic whims or strategic inertia, disguised with grandiose strategic bluster.

The third factor essential to competing as a holobiont is the capability to find symbiotic partners, persuade them to join forces with you and manage the relationship. This is especially important for so-called keystone alliances with those sought-after partners who have distinctive capabilities, such as unique technology or distinctive customer relationships. Many such partners, such as academic centres of excellence, report that large life science companies work through their lawyers and procurement departments, making what should be a trusting relationship into a distrustful transaction.

The final indispensable factor to working as a holobiont is conflict resolution and relationship termination. When each firm has many relationships and when technological and commercial uncertainty is unavoidable, both disagreements and terminations are inevitable. What matters then is the ability to resolve issues or exit the relationship with minimal trauma while preserving future options. Frequently, human nature hinders this capability, personalising business

issues, damaging the present relationship and making future association much more difficult.

Strategic lucidity and holobiont design, building and maintenance are all necessary to compete in our changed industry, but they are all common gaps in the competitive capability set of many life science companies. While it may surprise some that great, successful global firms in pharma and medtech have these gaps, it is not unanticipated from an evolutionary perspective. The market changes that favour and require holobiont structures are relatively new, so even our best firms have not needed to respond to them until quite recently. And since new capabilities take time to evolve, it is anything but surprising, when looked at through the lens of Darwin's great idea, that these holobiont management capabilities are not yet fully formed. For most firms, they are a work in process.

Evolutionary lag explains why these capabilities are not yet universal. But this leaves the question of the actions executives might take to accelerate their firm's evolution of these four essential capabilities. Here, the Darwinian parallels helps us still further. Just as proteins are the workhorses within organisms, capabilities are the things that do the work within organisations. And, just as proteins are expressed by complex combinations of genes, capabilities are the expression of complex combinations of organisational routines. Genes, of course, are built from the four nucleotides of ACGT. In the same way, there are four microfoundations of organisational routines. These are the attributes of individuals, the structuring of teams, the processes linking groups and the methods used to manage intra-organisational conflict. To develop new capabilities quickly and effectively, executives have to deliberately engineer these four factors just as geneticists purposefully modify DNA sequences. It is beyond the scope of this short article to describe the detail of how that is done but this manipulation of a firm's 'capabileome' is given a detailed treatment in my book *Darwin's Medicine*.

So what is the take-home from this research? There are three important things that executives, when tasked with adapting their organisations to a different world, ought to reflect upon. Firstly, it's time to stop obsessing about how your firm competes with other firms. Instead, you should consider how your holobiont will vie with others. Secondly, this is an evolutionary race. The winners will be those who build their holobionts faster and better than the others. Finally, evolution needn't be the blind, wasteful process it is in nature. Thoughtful executives can elucidate their strategy clearly and then use it to design their optimal holobiont. That design can guide how it is built and managed. Such a deliberate approach has the same advantages of speed and efficiency over opportunistic organisational development as genetic engineering has over randomly driven biological evolution. In the race to compete, thought will always win over chance.

Professor Brian D Smith is a world-recognised authority on the evolution of the life science industry. He welcomes comments and questions at brian.smith@pragmedic.com

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So, you think you can multitask?

Mel is having a busy day. Mel is on the marketing team of a large pharmaceutical company and she's already analysed data from over 1,000 unique journeys on an online patient support programme, written and published 10 approved and compliant social media posts for various platforms, placed online advertising for a disease awareness campaign and made technical adjustments to a company website to ensure it's optimised for search visibility.

There's nothing particularly unusual about any of that, except for the fact that Mel has done all of this in the last six and a half minutes and hasn't even had a coffee this morning. That's because Mel is a machine. Not the kind of hard-working, driven and career-focused person you might figuratively describe as a machine - Mel is an actual machine, made up of a complex combination of machine-learning algorithms that could also be described as artificial intelligence.

While this may seem like a far-off fantasy environment, some studies suggest that nearly half of all jobs could be automated within the next 20 years - and that figure includes a number of highly skilled and often well-paid consultancy and marketing roles.

Artificial intelligence is starting to become commonplace in many industries and marketers have already started taking advantage of the benefits that high-quality automation and machine learning can bring. Google has been using an AI system called RankBrain to interpret complex search queries that require natural language processing and a deep understanding of context since as early as 2015. A number of companies have also started using AI to prevent security breaches of marketing data by tracking and analysing vast data sets to identify suspicious activity.

Although some of the early forays into chatbots and AI in social media haven't been regarded as the most successful marketing exercises, AI and machine learning do offer significant potential benefits to online platforms. Companies like Facebook are investing huge amounts in AI research, not just to serve up the best content or most relevant advertising using the huge volume of data they have, but also to interpret and describe images so that, for example, visually impaired people can use its services.

'Pharma has the potential capital and innovation-focused environment to spark massive change'

ROB STONE

Naturally the tech industry, with its fast-moving culture, huge budgets and foundations in technical innovation, will lead the way with AI and machine learning - but pharma, too, has the potential capital and innovation-focused environment to spark massive change. Pharma and, more broadly, healthcare industries are already utilising early AI experiments in a number of fields, from drug discovery to the detection of certain types of symptoms. In an old world where doctors would need to read up to 160 hours of new medical research produced every week just to keep up, computers can scan, index and understand vast amounts of content in a matter of seconds.

IBM has been working with healthcare companies in the US with the aim of using its AI technology, Watson, to improve diagnosis and reduce costs at the same time. Watson has absorbed more than 600,000 pieces of medical evidence and more than two million pages from a wide range of medical journals, and has the ability to search through over a million patient records, giving it an obvious advantage over a human doctor - in certain respects, of course.

The next big step is likely to be in marketing because the applications are practically endless and the potential gains so large. The pharma industry offers exactly the kind of complex, large volume data that allows deep learning to offer huge value. Machines and algorithms also follow rules exceptionally well - something of huge importance in such a detail-focused and highly-regulated industry. In a few decades' time, an AI marketer might undertake the types of large-scale tasks in one morning that would be impossible for a human to accomplish in an entire career.

Marketers shouldn't feel that AI and machine learning are out of reach in 2017, however. Much of the recent work completed in these areas is open-source or available online, even from big companies like IBM. At Pegasus we have a team already looking at how AI can help solve some of our clients' challenges - for example, building prototypes for complex data analysis, or chatbots to interact with people and engage in dialogue based on their understanding of a user's personality and emotions.

The potential ethical and socioeconomic concerns presented by the inevitable growth of AI are the topic of numerous further articles. Here, I'd simply encourage anyone with an interest in the subject to begin playing around with a few of the examples already available online. None of us could ever be quite as efficient as Mel, so it's vital we all start to understand how the power of this fast-developing technology might be harnessed to positively benefit ourselves - and the future of our industry.

Pegasus inspiring healthy decisions.

Rob Stone is head of digital at Pegasus

The cultural construction of illness

Why understanding this concept is essential for pharmaceutical marketers

There are two realities to any illness. One is a medically observed event that happens to the human body, the other a mass of culturally relative assumptions that affect how we make sense of that event. On the one hand, for example, is the metastasising of cells and the various treatments used to halt cancer, on the other the stories of bravery and the status of 'survivor' that our culture readily attaches to people recovering from the condition.

These latter stories are culturally and historically constructed, although we frequently mistake them for being natural or 'just the way things are'. For example, in the 21st century TB is seen exclusively as an appalling condition linked with poverty, whereas in the early 19th century, fashionable metropolitans tried to cultivate a pleasingly pale and 'consumptive' appearance, driven by the perception of a link between tuberculosis and creativity.

We may think that we're too smart to fall for this kind of thing today, but in fact it's hard for anyone to avoid interpreting illness according to the norms of their culture. Those norms are different today than they were in the 19th century, but can obscure the experience of having or treating many kinds of illness just the same.

Why is this important? Put simply, not seeing beyond the dominant constructions can prevent us from developing messaging that is sufficiently credible, salient and distinctive. Here's a characteristic example of how this can work.

Cultural bias cannot be avoided

Some years ago, we were asked to advise on marketing a cure for migraines in the UK. As we analysed communications by brands in the sector, it was remarkable how consistently migraines was represented as something which overtook women, rendering them helpless, even hysterical, until brought back into normative living by whatever treatment was being promoted. Perhaps unsurprisingly, the treatments themselves were represented as sober, male and commanding.

Two things became clear. Firstly, that most brands in the category were - probably unconsciously - conforming to the cultural idea of migraines as a woman's problem and to an increasingly outmoded understanding of what that might mean. In this world, migraines were associated with ideas of the overly sensitive, or even hysterical woman, requiring rational male intervention to bring her back to her senses. There was even a sense that migraines weren't a particularly serious condition - its role in popular comedy as an excuse given for refusing sex and its roots as a term used to describe a whim or a fancy ('megrim') all contributed to this.

Secondly, it was clear there was an opportunity for a brand to construct a different understanding of migraines, based on more self-determining ideas of womanhood, while representing the misery of the condition more respectfully. The brand communications developed as a result of these recommendations were highly successful and helped to evolve the way in which the condition is now marketed.

This was a case of a category unable to see beyond a certain cultural construction of the condition it was in the business of treating, something it took for granted that many of our clients weren't even aware of.

Pharma is stuck in a rut

Although this project happened a few years ago, it's telling that as we continue to work with pharmaceutical brands, many stories and ideas of illness recur across conditions. Some of these can be positive and lead to very effective communications, but many are habits that marketers can fall into and that prevent new and compelling ways of communicating from being developed.

Here are some examples:

We can be heroes

It's an obvious option to portray people with a serious condition as heroes confronting a formidable enemy; serious illness tends to be experienced as a catastrophe and we see plenty of messaging that plays on this using imagery of warfare ('my battle against…', 'overcoming the challenge of…', 'I won't give up fighting…'). It also presents the person with the condition as having individual agency and independence, all of which are highly valued by our culture.

This can be impactful - particularly for younger people - but it's interesting how much this taps into a general cultural narrative of heroism which doesn't have that much to do with illness. The result can be dramatic or even exciting, but also disconnected from the reality of illness as experienced by patients, carers and medical professionals.

In our work we've observed that, just as our culture is increasingly sceptical about medical products having heroic properties, so it's starting to question the representation of people facing serious illness as heroes.

How does this account for the day-to-day experience of having a disease? Doesn't it place an unrealistic expectation on the person with the condition?

To really connect with patients and professionals, brands need to find ways of avoiding both the negative associations of the victim and the overly positive associations of the hero.

Health always means harmony

Because illness is so strongly associated with disharmony in our culture, there's a tendency to construct the return to health as always harmonious and calm. While this might be what many people aspire to, it can also inhibit strong depictions of how pharma products work to return people to health.

We've lost count of the times we've seen 'recovery' depicted as someone doing yoga on a beach or as the metaphor of a butterfly

or a flower. These are clichés of course, but they also represent the deep-rooted cultural need to see the return to health as a kind of calm resolution.

It's interesting to see the success you can have when you break these cultural conventions. Health can also be credibly constructed as messy and chaotic, joyful and engaged or even angry and defiant.

We once worked with a team marketing a product for people with HIV. Their advertising was failing to cut through and it became clear to us that one of the reasons for this was its depiction of happy, calm people living with HIV, but always depicted on their own. When the advertising was evolved to depict these people spontaneously playing with their children in messy, realistic homes or at the heart of social occasions, the uplift was substantial.

Moving away from the idea of the calm and settled individual as the signifier of health was the breakthrough here - finding an alternative but equally salient cultural construction helped move the brand on.

The necessity of taboos

We live in a culture that increasingly prides itself on being liberal and not squeamish when it comes to describing the workings of the body. It's surprising, then, how we still use the constructions of taboos and euphemisms to represent certain conditions that are viewed as particularly sensitive or shaming.

Of course, it's essential to show respect, sensitivity and compassion in marketing communications - but it's also true that openness and black humour can create common currency between pharmaceutical brands and those purchasing them, just as it unites many people in patient support groups.

Work we conducted on COPD (Chronic obstructive pulmonary disease) in the US demonstrated this. There was an assumption among many people working in the category that the nature of COPD needed to be played down. It was too unpleasant and, since it tended to be linked to lifestyle, there was a perceived element of guilt and shame.

Through analysis of the language used by people with the condition when discussing it online, or by celebrities who lived with it, another picture emerged. Black comic imagery of 'the elephant that jumps on my chest' and a 'you only live once, no regrets' approach to past lifestyle choices were common. When this kind of language was incorporated carefully into advertising, the response was very positive from those with the condition and physicians alike.

The sense that the experience of having the condition was being more authentically portrayed was seen as empowering. The previous assumption that it needed to be talked about in terms of euphemism and that realistically representing it was too much, possibly reflected the cultural assumptions of the marketers more than the patients.

Embedding in culture to empower

Understanding how particular illnesses are culturally constructed is essential work for anyone in pharmaceutical marketing. It both reveals some of the assumptions getting in the way of developing better messaging and helps create better, more humane constructions that in turn can drive more effective campaigns that can help consumers cope more easily with their illnesses.

Those pharmaceutical marketers that frame communications around particular drugs and illnesses when selling to healthcare professionals can do more than improve sales of their drugs. Indeed, if done properly, this approach helps pharma companies to demonstrate their commitment to transforming people's lives. Talking in terms of cultural constructs helps pharma reps educate healthcare professionals on the best way to talk to patients, their families and the wider public. In turn, this helps consumers to better understand how to deal with their condition and use the available drugs more effectively, which can significantly improve the length and quality of their lives which, ultimately, is what every pharma company is aiming for.

Al Deakin is a director at Space Doctors

Asthma: beyond the blue and the brown

To breathe is a fundamental human right. Yet every day 235 million people around the world struggle to do just this. Asthma is one of the most significant non-communicable diseases of the 21st century. Combine asthma with other respiratory diseases, including chronic obstructive pulmonary disease (COPD), and it contributes to more than 4 million deaths every single year, a stagnated figure that has seen no decline since 2006. Although most asthma-related deaths occur in low- to middle-income countries, asthma is very much a First World problem. We in the UK have the highest rates in Europe, taking three lives every day. This is a shocking statistic.

The mayor of London, Sadiq Khan, revealed last year that he had recently begun suffering from asthma. He has since initiated plans to battle air pollution in the city, which he holds accountable for his disease. With asthma affecting 1 in 3 children in every classroom in the UK, Khan decided to launch his 50 'air quality' audits for primary schools in the worst polluted areas in London; his goal: to 'protect pupils from toxic air'. London has come under increasingly intense scrutiny in the media for its appalling levels of air pollution, a significant cause of which is road traffic. Labelled the Mayor Air Quality Audit, the recommendations include moving school entrances away from busy roads and improving walking initiatives. Khan's audits, which were started in September, will be completed by the end of 2017 and the report will be available by March 2018.

Earlier this year, a PhD student who had just started at Imperial College London wrote an article in *The Guardian* in which she described how moving to London and cycling to her campus had triggered her first asthma attack in 10 years. She attributed her trigger to the air pollution. Feeling unsupported by the university's reaction to her concerns, she decided that her health was not worth compromising for her degree. Imperial College London is ranked as the number one UK university in the respiratory, cardiovascular and gastroenterology fields, so it is sad and startling to discover such a huge disconnect between the teaching university support services and the academic research ethos.

> 'For innovation in respiratory medicine to be meaningful in the real world, a more fundamental shift is needed'

The National Heart & Lung Institute (NHLI) at Imperial College is one of the largest heart and lung departments in the world and is the highest-ranking medical department of the university. The NHLI's affiliation with the Royal Brompton and Harefield NHS Trust puts the NHLI in a unique position to carry out research in respiratory-related diseases. The research includes those diseases that are rare and neglected such as cystic fibrosis, a condition that has a devastating effect on patients, families and carers. One of Imperial College's research ventures has culminated in the development of Circassia Pharmaceuticals, a spin-out biotech whose co-founders were at the time testing a prototype vaccine technology for prevention of cat and ragweed allergies. This year, Circassia established a commercial collaboration with AstraZeneca in the US for COPD.

SAIRA SILIE

For innovation in respiratory medicine to be meaningful in the real world, a more fundamental shift is needed. Andrew Bush, professor of paediatric respirology at Imperial College, and Ian Pavord, professor of respiratory medicine at Oxford, have called for a radical rethink around asthma. The two professors led *The Lancet Clinical Commission*, 'After asthma: redefining airways diseases' in 2015. In this, they set out the need to break asthma down into its individual components - definition, basic concepts, diagnosis, monitoring approaches, drug development, treatment, guideline development, life-course approach and current inadequate approaches to serious disease and severe attacks. The Commission conveyed a strong and urgent message that progress in this disease has been slow and unacceptable. Having convened a panel of 23 international asthma experts, the group published a paper on 11 September 2017 in *The Lancet*. It calls for a deconstruction of asthma in its current abstract terminology, moving towards true functional, pathological and molecular understanding and descriptions that can lead to individualised and effective treatment. Indeed, it challenges the validity of the term 'asthma' in the modern day medical lexicon at all.

To make progress in chronic airway diseases, we need to activate at a grass-roots level, and that includes patients who must challenge their 'asthma' diagnosis and demand more from their healthcare practitioners with regards to treatment and management. The medical communications industry is the linchpin that brings patients, clinicians, researchers and the pharmaceutical industry together. Working collaboratively, the future could look brighter and beyond the blue and brown.

VirgoHealth
HEALTH WITH A HUMAN TOUCH

Saira Silie is executive director of strategy and science at Virgo Health

Janssen's 'Interceptors' and the quest to prevent diseases taking hold

The Corpus Museum takes visitors on a beguiling journey through the human body, unlocking the complexities of anatomy along the way. It is a head-to-toe immersion in the physical wonders of life and its striking architectural design - half the building is a rust-coloured seated figure - can be seen for miles around.

It is a beacon to advances in medical knowledge but it also stands as a reminder of how the quest to comprehend and tame viruses, diseases and conditions is still a work in progress.

While tour parties were navigating the museum's centre-piece of interactive intestinal and reproductive systems, Johnson & Johnson's (J&J) senior scientific leaders were outlining a bold shift away from purely treating diseases to intercepting them before they take hold.

The company's vision is a 'World Without Disease' by 2030 - a radical goal that requires a deep dive into the darkest recesses of biology.

"People live longer but they are not healthier. They have more diseases and, to cope with that phenomenon and to have a sustainable system, you really need to go beyond treatment and that is where prevention is important," says Johan van Hoof, general manager of Janssen Vaccines & Prevention, who was part of a J&J panel showcasing the company's future plans at a media day at the Corpus museum, near to its base in Leiden, The Netherlands, earlier this year.

"We will still focus on cures, of course, but we also want to be able to identify those patients who have high risks of becoming ill and treat them before they have symptoms, and ahead of that going into prevention which is where our vaccines come into play.

"Recalibrating public understanding and shifting behaviour will not happen overnight but we are going in that direction."

Forest fires

The need to open up a different attack front is compelled by ageing populations afflicted by chronic and complex combinations of diseases that are sending healthcare systems into meltdown. As proof, van Hoof points to recent analysis from PwC's *Pharma 2020, The Vision*, report which stated: 'As the global population grows and ages, and demand for better healthcare management increases, the emphasis on treatment rather than prevention will become increasingly unsustainable.'

Identifying diseases at incubation stage - a volatile period of a disease evolution - will take a huge genetic decoding effort but van Hoof believes that a new range of biomarkers can be developed. "It will take time," he adds. "But we can already identify children with a high risk of type 1 diabetes from certain antibodies, and there are extremely predictive biomarkers moving into cognitive problems such as Alzheimer's, so the first wave of treatments will be in those areas. The clear vision is to have affordable tests.

"Prevention is more and more what the future is all about because of the malignant diseases we are seeing. If you apply interception principles in oncology for pre-malignant states, it's like putting out little, almost invisible fires. If you pick up the right biomarkers we can deal with them before they become forest fires."

Go faster

Vaccines will play a huge role in prevention, he adds, and many companies are pushing the boundaries of science to crack the codes of infectious and non-communicable diseases and to prompt powerful immune responses for early interventions.

The visionary thinking almost suggests that medical science and healthcare systems have maxed out their credit levels on blockbuster drugs and sharper business models to the point where only small gains are left. Van Hoof and

JOHAN VAN HOOF

J&J are insistent that the company remains committed to cures and transformational medicines - it is currently enjoying a rich run of form with major molecular breakthroughs - but that fresh insight is essential.

"Others are working on prevention but we are the ones who have crystallised it clearly. Governments and payers know that it makes sense to talk about this," he adds. "How you do that is the challenge and new business models will be needed. EFPIA (the European Federation of Pharmaceutical Industries and Associations) is talking about performance-related schemes. I think we will get there because I don't see many other options. I don't know exactly how we will get there and maybe it will be a painful process and some countries might go faster than others.

"There will be small steps as the evidence builds up."

Janssen, which has a bustling campus at Leiden incorporating Janssen Biologics, Janssen Vaccines, Mentor medical systems and the Janssen Prevention Centre, has been reshaping its structure to best serve its quest for greater biological insights and the mechanics to conquer diseases swiftly and efficiently.

"We want to be in fewer areas but focusing on the areas with huge need where we can make a difference," says van Hoof, who has an illustrious R&D track record. "If you want to be transformational then you need to have a deep understanding of a disease and find the best size for it, internal or external, and combine it with operational excellence."

Janssen's acquisition of Crucell in 2011 brought it a suite of promising platforms covering HIV, a universal flu vaccine, respiratory syncytial virus (RSV), which is an infection of the lungs and respiratory tract that affects children and the elderly, and pathogens such as Ebola. It has the added bonus of being able to test vaccine candidates through its high-yield human cell line, which it can combine with its technology to create gene carriers that can be engineered for specific diseases to kick-start immunity.

This potent test bed has helped with development of its promising mosaic-based vaccine regimen for HIV which was reported at the 9th International Aids Society Conference on HIV Science in Paris in July this year.

Biomarkers

"The vaccine has been 10 years in the making and the regimen gives 94% protection if challenged once and up to 66% if challenged six times consecutively - a challenge deemed to be 200 times higher than human perspective," adds van Hoof. "Many trials have failed, and the Thailand trial which was deemed a great step forward gave 34% protection, which is why there is such excitement. It looks like a paradigm shift for HIV as people with the right biomarkers can be taken off antivirals.

"We can all have disappointments but we are cautiously optimistic."

The returns in terms of public health are immense: an estimated 37 million people around the world are living with HIV-1 and almost two million people become newly infected every year.

Its continuing work on Ebola has seen laboratory results that suppress the virus over 18 months and increased promise of an effective vaccine. And it drew praise for its rapid production of two million regimens in response to the outbreak in West Africa from 2014 to 2016.

The atmosphere of discovery at the Corpus museum is a catalyst for bold vision.

The J&J panel warmed to the theme and the concept of 'immorbidity' coined by the founder of the Janssen Prevention Centre, Jaap Goudsmit, to signify a state where people can enjoy their extended life expectancy free from the chronic illnesses that are currently shackled to the later years of many people. More than 50% of elderly people live with two chronic diseases and die with three or more but reversing that tide will clearly take more than visionary thinking, as healthcare systems have their viewfinders full of day-to-day adversaries swarming towards their creaking defences.

Although bolting together pharmaceutical, political and economic components can be frustratingly difficult and ponderous, there is more than just free thinking behind the new era of prevention, says van Hoof.

"I am optimistic about its progress," he adds. "There is a feeling that many stakeholders think it is going in the right direction and the conditions are there to make it happen. I'm not so optimistic about the speed of change. There will be pilots that will fail and some people will be against it like with any change but I think the data will prevail and I am convinced this is the best way forward.

"We are not moving away from cures and it won't happen in two or three years' time. But it can be done and many people realise that it needs to be done."

One of the panel demonstrates J&J's light therapy acne mask

Danny Buckland is a health journalist

Bayer picks digital firms for open innovation support

Four new start-ups enter its Grants4Apps Accelerator programme

A New York company designing a non-invasive endometriosis test, and a start-up from Seoul developing a ring that can diagnose and manage atrial fibrillation, are among the firms picked for Bayer's digital health accelerator.

Now in its fifth year the German firm's Grants4Apps programme offered 'open innovation' support to four digital health start-ups, each of which moves into premises within Bayer's Berlin pharma headquarters.

There they will receive €50,000 in financial support and mentoring over the next month or so from senior Bayer managers and external experts to further develop their business models and products.

Reinhard Franzen, head of Bayer Pharmaceuticals Commercial Operations Europe, Middle East and Africa, said: "We recognise the huge creative potential outside Bayer and we believe that combining expertise is key to innovation and success.

"The Grants4Apps Accelerator offers new partnership opportunities in the digital

health area with its vibrant development in the past years. We are very excited to welcome the four new start-ups for 2017!"

The four firms selected this year were aparito, Oratel Diagnostics, Sky Labs and ThinkSono.

London-based aparito aims to transform the way clinical trials are conducted. It wants to focus on improving the trial experience for patients by collecting objective, meaningful patient data at home and in real-time, using wearables and disease-specific smart phone apps.

Oratel Diagnostics is a New York-based company designing a non-invasive test for endometriosis to decrease healthcare costs and improve the health and well-being of girls and women with the disease. The firm is working on technology that can reduce the time to diagnosis - currently this can take up to seven years.

Seoul's Sky Labs is developing a ring-type device for accurate diagnosis and customised management of atrial fibrillation that can be worn on the user's finger and then offer continuous AF detection and personalised care guides.

Finally, ThinkSono from London creates software to diagnose deep vein thrombosis. It uses deep neural networks and portable ultrasound scanners, allowing any healthcare professional to diagnose DVT at the point of care.

Bayer received more than 450 digital health-related applications from 61 countries for its programme this year, with extremely strong bids from the US, Germany, Brazil and UK.

Roche and J&J picked for 'revolutionary' digital health pilot

Firms will line up alongside Apple, Fitbit, Samsung and Verily in FDA pre-certification programme

Roche and Johnson & Johnson will join the likes of Apple, Fitbit and Samsung in a US digital health pilot programme.

The FDA wants to put in place a new, more pragmatic way of evaluating digital health products that could speed up their approval by scrapping the need for a pre-market submission and allow lower levels of submission content.

To help it test this the US regulator has picked a range of pharma and tech giants to participate in the first-of-its-kind pilot, which it hopes will 'revolutionise' digital health.

The scheme would allow the FDA to 'pre-certify' digital health technology, by focusing more on the company behind it rather than primarily focusing on the product itself.

FDA Commissioner Scott Gottlieb said: "Our method for regulating digital health products must recognise the unique and iterative characteristics of these products.

"We need to modernise our regulatory framework so that it matches the kind of innovation we're being asked to evaluate, and helps foster beneficial technology

while ensuring that consumers have access to high-quality, safe and effective digital health devices. These pilot participants will help the agency shape a better and more agile approach toward digital health technology that focuses on the software developer rather than an individual product."

Just nine firms were picked for the pilot: Apple, Fitbit, J&J, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool and Verily. But the FDA said it had received interest from more than 100 companies.

The regulator said its selection process saw it look to include a range of different perspectives and unique approaches to digital health technology development.

Bakul Patel, associate director for digital health at the FDA's Center for Devices and Radiological Health, said: "We are extremely appreciative of the tremendous interest in participating in the FDA Pre-cert pilot programme. The number of applicants speaks to the significant impact this approach could have on facilitating the timely advancement of software that has the potential to benefit health.

"The diversity of the Pre-cert pilot programme participants means that we will receive a variety of input on how the industry defines organisational excellence and other key performance indicators."

As part of the pilot participants will provide the FDA with access to the measures they currently use to develop, test and maintain their software products, including ways they collect post-market data. The firms have also agreed to be available for site visits from FDA staff and provide information about their quality management systems.

Almirall looks to crowdsource new skin treatments

Launches open innovation platform AlmirallShare

Spanish pharma company Almirall has set up an online open innovation platform through which it hopes to find skin health solutions.

Focusing on speeding up the development of new treatments for skin conditions, Almirall is looking to dermatology researchers around the world to post their solutions to challenges posted in sharedinnovation.almirall.com.

The site is underpinned by crowdsourcing technology company Innocentive, whose clients also include AstraZeneca and Boehringer Ingelheim, and current research calls cover preclinical models and high throughput systems for topical drug delivery.

Chief scientific officer Dr Bhushan Hardas said: "Our R&D strategy is based on three important aspects: science, innovation, and partnerships. We are convinced that there are plenty of breakthrough ideas and innovation outside our walls.

"With this in mind, we have created AlmirallShare, our open innovation platform, to help us identify and progress innovative solutions for skin health."

The Barcelona-headquartered company is looking to work with scientists from universities, public or private research institutions, hospitals and biotechnology companies.

Maribel Crespo, AlmirallShare leader, said: "AlmirallShare is about shared innovation. With this platform, we want to share our passion for science with experts worldwide to start a journey where cooperation will result in better solutions for skin health. We want to help move science forward."

Almirall's first call for research proposals concerns skin pathology in diseases such as psoriasis, atopic dermatitis, acne and rosacea. After proposals are submitted, Almirall said its team would review them and then suggest the best way for the selected proposals to progress.

The firm recently revamped its corporate identy in an exercise that placed greater emphasis on its skin health focus. The last few years have seen the company strengthen its R&D efforts in the area as it takes aim at a leadership position in the therapy area, having moved away from respiratory research.

Merck to co-lead new oncology big data alliance

Will work with Project Data Sphere to improve cancer care

Germany's Merck is to jointly lead a big data alliance that aims to accelerate the discovery, development and delivery of new approaches in cancer care.

Alongside the not-for-profit Project Data Sphere, Merck will take the helm of the Global Oncology Big Data Alliance (GOBDA), a three-year project that hopes to better define personalised treatment options and help improve the way that treatment outcomes can be predicted.

Belén Garijo, Merck's healthcare CEO, said: "The ultimate goal of our alliance with Project Data Sphere is to unleash the power of big data to bring value to cancer patients.

"Merck is deeply committed to investing in initiatives that push the boundaries of cancer research, that we hope will accelerate the discovery, development and delivery of innovative treatments to all who need it."

Its partner, Project Data Sphere, is an initiative of the CEO Roundtable on Cancer, a non-profit corporation founded by former US president George HW Bush in 2001 that supports oncology research.

Through the GOBDA initiative the two will work on expanding access to de-identified patient data sets in order to improve analytical capabilities and build a registry of data.

Dr Martin Murphy, CEO of Project Data Sphere, said: "Big data is changing the face of healthcare as we know it, and advances in our ability to collect data, share and analyse it has already led to groundbreaking work.

"The joint force of Merck and Project Data Sphere will aim to connect and empower a truly global oncology community with these big data and analytical capabilities."

Project Data Sphere's existing digital platform already contains clinical trial data from almost 100,000 patients.

The GOBDA will expand this platform to include rare tumour trial, experimental arm and real-world patient data, looking to combine it with big data analytics in order to optimise clinical trials.

In brief

Genentech has worked with 23andMe to identify 17 new genetic variants associated with Parkinson's disease, almost doubling the total number of known risk variants for the condition, in the largest meta-analysis of Parkinson's disease to date.

Medtronic has launched a pain management implant in the US that can be remotely controlled by a Samsung tablet. The Intellis system treats chronic pain via neurostimulation, the level of which can be adjusted wirelessly by the Samsung Galaxy Tab S2.

Biogen Purdue Pharma has enrolled the first patient into a clinical trial that will assess the effects of wearable technology on the treatment of those with chronic pain.The study pairs an Apple Watch, which will measure physical activity, patient-reported pain, disability, sleep quality, depression, medication use and heart rate, with a bespoke pain app. Purdue is partnering with health organisation Geisinger on the project.

US regulators have approved the first mobile medical application for substance use disorders involving alcohol, cocaine, marijuana and stimulants. Pear Therapeutics' Reset app offers cognitive behavioural therapy and is designed to be used alongside outpatient therapy and a widely-used SUD contingency management programme.

Sanofi has teamed up with US tech firm Evidation Health to tap into its Real Life Study behavioural data analysis platform for work that will be powered with data collected from wearables and mobile applications. The three-year partnership aims to increase Sanofi's understanding of disease burden and develop solutions from the data that will improve therapeutic outcomes.

Positive disruption in business intelligence - a drug launch strategy

We live in an exciting time of opportunity for pharmaceutical business intelligence professionals. The environment in which we operate has been disrupted by the evolving market, and customer behaviours are changing. This creates a challenge for pharmaceutical planning which can be addressed with business intelligence. But even the business intelligence function must adapt to new customer behaviours if it is to solve today's challenges.

A significant influence on customers has been the digital age: the Internet and social media have transformed the way health stakeholders learn and interact with each other. Healthcare professionals (HCPs) are learning about innovations faster than ever before, thanks to online networks. Specialist-themed Twitter hashtags - global, open, online conversations among people with a common interest - are being used by HCPs to connect peers all over the world with common interests from rare diseases to community nursing.

While the way HCP customers learn has been being transformed by social media, the pharmaceutical business model has also been evolving. Let's take a look at the drug launch process, for example. Over the past decade, many of the largest pharmaceutical companies have moved into an era of more targeted launches. Where ten years ago, most large pharmaceutical companies launched a few blockbuster drugs each year, recent years have been characterised by a higher number of smaller launches, often focused on rare diseases, specialised medicine and highly-targeted customers with special interests.

So with changing customer behaviours and business demands for highly targeted insights, what role does business intelligence play in supporting effective drug launches? The ability to distil and analyse conversations among HCPs on social media gives business intelligence teams new tools to inform pharmaceutical launch strategy. Three areas where insights-led tactics are emerging are in pre-launch awareness and advocacy; product differentiation; and market access.

Pre-launch awareness and advocacy

Business intelligence can support business goals to raise awareness, position a drug candidate's advantages and develop advocates well before the launch. During the years before a product launches, HCP 'digital opinion leaders' - online HCP influencers in a particular therapy area - may be identified who are advocating for a new product in development.

Earlier this year when Boehringer Ingelheim started a trial on its biosimilar candidate to Abbvie's Humira, it announced the study in a press release and tweeted: 'We start a clinical study on interchangeability between a biosimilar candidate and its reference product.' The company has started to raise awareness of its drug candidate well before the product comes close to being launched.

Research into HCP conversations about products shows that they are highly interested in the results of clinical trials. In an analysis of 47,000 UK HCP posts about type 2 diabetes, 58% of mentions of named drugs were about drug trial data. While some high-profile clinical trials were mentioned by name during congress meetings, HCP mentions of drug trials in type 2 diabetes took place virtually every day throughout 2016 (see Figure 1).

Differentiation

When it comes to product differentiation, the online conversations of HCP customers provide powerful insights for business intelligence. Since new drugs need to demonstrate what additional benefit they bring to the market, knowing how HCPs feel about current treatment approaches is essential for developing launch messaging for a product (see Figure 2).

Positioning a drug launch for differentiation might be about its use for a currently untreated disease; its improved efficacy or safety when compared with existing treatments; its low price; or a combination of factors. The key thing is to develop a credible message that resonates with customers, and then to build the positioning of the product around that message.

Ask yourself - and listen to HCPs' online conversations to develop evidence - what customers in your therapy area care about. Is it pricing?

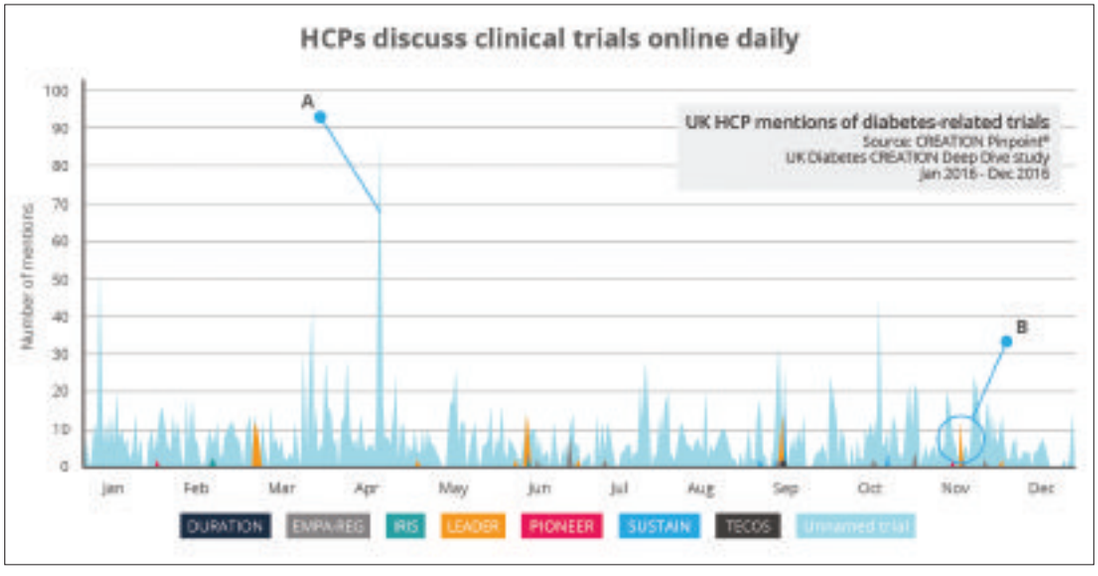


Figure 1

Are they concerned about safety? Is medicine administration a problem, or is there a patient concern? Then you can test messaging and language among the online customer community, before your product is launched and without even mentioning the drug (see Figure 3).

Market access

Online HCPs are passionately engaged with policymakers, patient advocacy groups and the public around market access. Take the recent recommendation by NICE, the UK's drug-spending policymaker, of Kadcyla, the breast cancer treatment launched by Roche.

In December 2016, NICE issued draft guidance indicating Kadcyla was too expensive for routine funding on the NHS. Among the widespread disappointment expressed by patients, caregivers and HCPs, some took to social media to challenge the manufacturer.

Angela Gilchrist, a consultant clinical psychologist pointed out that the NHS is quick to be blamed when a new drug treatment is not funded, but asked by tweet: 'Why aren't we asking why Roche charges so much for it?'

The following day, HCPs encouraged members of the public to take action by signing an online petition. 'Women could be denied access to a drug for incurable breast cancer,' tweeted an oncology nurse. 'Sign the petition to #KeepKadcyla available.'

As the online movement grew and HCPs continued to encourage action, even NICE joined in the conversation, tweeting that its decision was not final and it was still working with Roche.

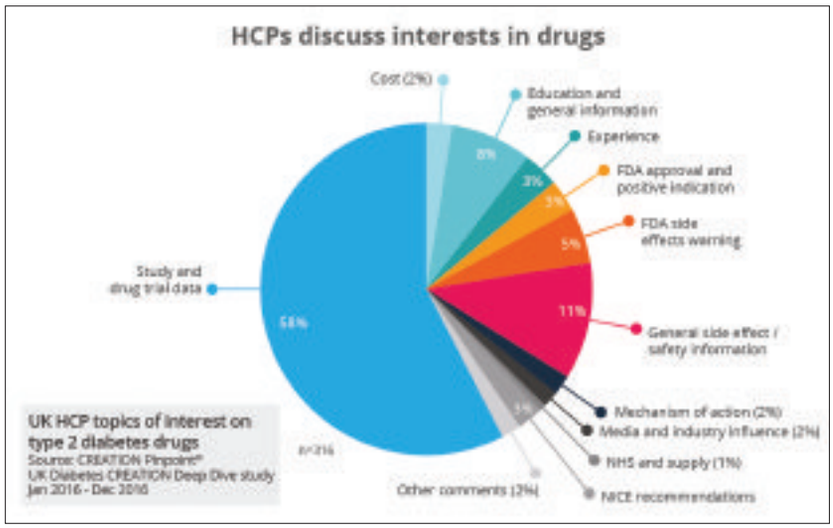
Finally, in June, NICE reached a decision that Kadcyla would be made available on the NHS to breast cancer patients after negotiations with Roche. Oncology HCPs expressed their delight online, but some were still sceptical. Ben Merriman, a clinical community pharmacist with a role in local commissioning, tweeted asking: 'How much were Roche wanting to make on ill patients over and above what they needed to?'

While it may be difficult for a pharmaceutical company to engage in open public debate with HCPs via social media during market access negotiations, listening to customers can provide an immediate picture of their emerging ideas and priorities.

Tactical opportunities

Listening to HCPs' online conversations allows business intelligence to inform new tactical opportunities for pharmaceutical product launches. Starting years before the launch, through to the early years post-launch, pharmaceutical companies are using new kinds of customer insight gained through social media to strengthen their launch planning.

Figure 2



One pharmaceutical company, for example, studied the online conversations of nurses and pharmacists during its launch campaign for a vaccine product. Through this exercise it learned about specific needs among nurses including some areas of confusion about the administration of the vaccine. The company responded by providing a training programme for nurses, addressing their areas of greatest need. Shortly afterwards, nurses' online conversations indicated enthusiastic endorsement of the training courses.

The first years immediately after a drug launch can set the course for the product's success over the following decade. Business intelligence has the opportunity to develop timely insights that can inform how a pharmaceutical company responds to HCP customer needs with tailored support programmes and relevant messaging. To be effective, the company must adopt an agile approach to messaging and tactics.

When a pharmaceutical company launched a new drug into the competitive type 2 diabetes market, it listened to HCP online conversations during the first year after the launch in order to identify specific areas of need and measure the effectiveness of marketing campaigns. From the conversations taking place among HCP peers, the company discovered that the messaging it had developed in its materials for doctors was not getting through to all customers. It was then able to review its digital and traditional communications channels, as well as informing its field force across launch markets, in order to make sure that the right messages reached doctors who needed help. The product went on to become a top performer in its class.

Start listening

When your HCP customers' behaviours are changing, positive disruption in business intelligence can make all the difference to drug launches. Whatever stage in the launch process your drug is at, listening to HCPs' online conversations may bring you closer to customers than ever before. Their openly shared views, hopes and concerns can inform and empower the drug launch process - from candidate selection, to differentiation, developing and refining messaging, to tactical planning. There's no better time than now to start listening.

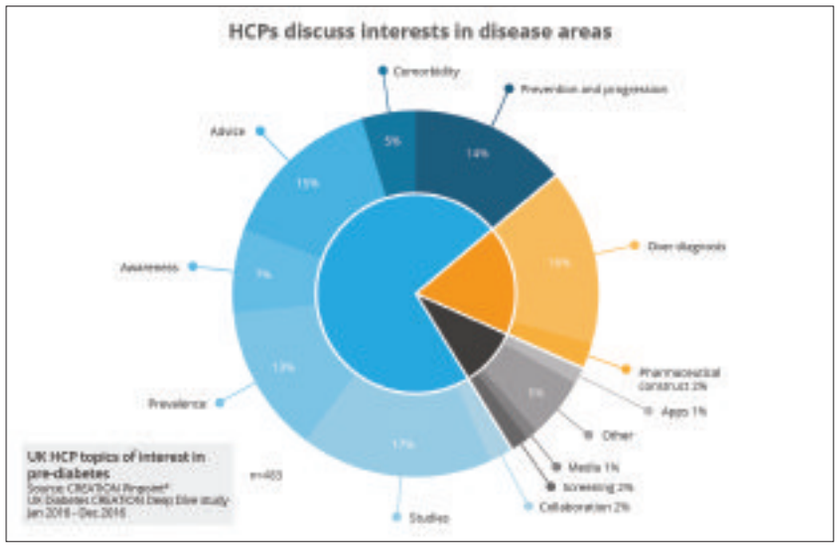


Figure 3

Daniel Ghinn is founder and CEO of Creation

Pushing the accelerator

How eClinical technologies can speed up the drug development process

Though our understanding of human biology and medicine has increased tremendously over the past decade, the pace at which drugs are brought to market has remained remarkably slow, and the process very expensive. It still takes an average of 12 years for a drug to go from lab bench to bedside, and while costs vary greatly the Association of the British Pharmaceutical Industry has estimated the average to be £2bn.

There are good reasons for this pragmatism. A great deal of time must be dedicated to background research, not to mention rigorous clinical trials and due diligence throughout the drug testing phases. However, the process is still rife with inefficiencies. It takes between three and five months for a pharmaceutical company to set up a trial, and considering that some drugs require as many as 70 trials before receiving regulatory approval, these months can eventually add up to years spent on preparation instead of progress.

What is the limiting factor?

While software can't speed up the research to develop the molecule or biologic, it can have a significant impact on speeding up the process. Most of the process inefficiencies in today's drug development environment stem from longstanding operational silos between internal stakeholders. With each department working in relative isolation and using only their own data sets to inform their decisions, pharmaceutical companies have yet to make use of all the information at their disposal in a cohesive, advantageous way.

Progress has been made of course. Over the last 10 years the industry has started to move from clunky, manual processes to eClinical technologies such as Electronic Data Capture (EDC), Clinical Trial Management Systems (CTMS) and Clinical Data Management Systems (CDMS). These have improved the way data is used at individual points in the drug development chain and sped up distinct pockets of analysis, but they are still point solutions that work independently of each other and are prone to the same redundancy and data entry errors as manual processes.

A catalyst for faster, safer trials

eClinical technology has only fulfilled part of the promise of an all-digital ecosystem, but the emergence of cloud-based eClinical software is paving the way for significant improvements. Cloud-based systems are ideally suited to unifying disparate systems, and can allow pharmaceutical companies to link every element of their drug development cycle to each other and to a single central database. As a result, they help to eliminate duplicate processes, allow all teams to work off a single and complete set of data that is only entered once, and most importantly speed up trials so drugs can be tested more quickly.

Improved visibility into data will drive faster and better decision-making across the organisation. For instance, teams will be able to more quickly prepare submissions for biostatistical analyses and share their learnings. Quintiles, the world's largest contract research organisation, has differentiated itself by providing its customers with a real-time view of clinical trial data so they monitor their progress and quickly adjust their approach when required.

There are also efficiencies to be gained from a regulatory perspective. With a transparent view of where data is stored and how it flows between teams, companies can access compliance reports and respond to health authority requests more quickly. By some estimates, an integrated eClinical platform has the potential to cut set-up time for clinical studies by 50-80%.

Discovering new patterns in the data

In addition to working more quickly, a more universal approach to data will allow researchers to uncover hidden relationships in their data sets that might provoke new, potentially life-saving discoveries.

Take the case of a pharmaceutical company that worked with PwC to find out why a promising cancer drug kept failing in some phase III trials and to pinpoint suitable patient groups for future testing. An analysis of clinical and biomarker data from phase II and phase III trials allowed the company to divide patients based on specific gene expressions and mutation signatures that demonstrated drastically different survival rates, and ultimately attributed the drug's failures to a genetic imbalance in a portion of patients afflicted with a rapidly progressing disease. This discovery led to the identification of several valuable biomarkers and helped the organisation determine

‘Intelligent algorithms will enable pharmaceutical companies to predict potential supply and demand for new drugs’

which patient groups to target in future trials and which to exclude.

The potential of machine learning

The ability to collect, analyse and process all of a company’s data in a centralised way will also form the foundation for success for new innovations like machine learning and artificial intelligence (AI), which allow researchers to augment their analyses even further with new algorithmic techniques. While we are still in the early days of AI, the technology will increasingly help research teams to identify the best candidates for particular drug trials.

Machine learning will help deliver operational cost savings as well. Intelligent algorithms will enable pharmaceutical companies to predict potential supply and demand for new drugs based on a range of historical and market data, or to automatically reallocate manufacturing capacity to avoid product shortages.

Machine learning and AI also lend themselves to more careful candidate selection for clinical trials, which will result in safer testing. Historical data collected over thousands of trials will reveal a range of flags indicating a potential safety risk for patients. As this data set grows the level of insight it reveals will increase, which means the risk of choosing at-risk candidates will drop. Pharmaceutical companies are under enormous pressure to develop drugs faster while still ensuring patient safety, and advances like this will be crucial to helping them achieve this.

New technology requires new culture

The ultimate aim of clinical trials is to provide the public with life-saving or disease-curing drugs as quickly and safely as possible. This is not a goal that can be realised by technology alone, and it will take a cultural shift across the pharmaceutical development industry if companies are to make the most of eClinical platforms.

Researchers have been conditioned for years to work in isolation, both by the organisational structure in which they operate and the limited technologies at their disposal. This is why the shift from manual processes to fully digital ones, and the subsequent shift from on-premise solutions to cloud platforms, will not happen overnight. Even today, pharmaceutical companies are still adjusting their way of working as they move to digital data management systems and begin to experiment with cloud-based capabilities.

The step-change promised by fully cloud-based eClinical platforms will demand a significant change in approach and more collaborative research methods, but these are both advantageous in their own right. With the right people, processes and roadmap in place pharmaceutical companies may finally be in a position to speed up and improve drug development by significant margins.

Jim Streeter is global vice president of Life Sciences Product Strategy at Oracle

Neovii Pharmaceuticals

JUERGEN POHLE

Swiss biopharmaceutical company Neovii Pharmaceuticals has promoted its chief commercial officer **Juergen Pohle** to managing director and chief executive officer. He will assume the new role in January, when he takes over from outgoing chief executive officer Alexandre Sudarskis, who will continue at the firm as an executive director and member of its board. Pohle has served as Neovii's chief commercial officer of Pharmaceuticals since 2016 and has over 25 years of experience in the pharmaceutical industry, having previously worked at the likes of Bayer HealthCare and Novartis. Prior to joining Neovii he headed Novartis' emerging growth markets and institutional customers businesses, such as UNICEF for Novartis' Vaccines and Diagnostics unit. Before that he served at Bayer HealthCare in Germany as head of marketing and sales consulting and then head of business strategy and intelligence.

Merck

PAOLO CARLI

Germany's Merck has appointed **Paolo Carli** as its new head of healthcare business, taking the helm of its commercial operations for the Middle East, Africa and Turkey (MEA) region. Carli joined Merck in 2009 as a member of the mergers and acquisitions team in Darmstadt, Germany, where he participated in the execution of transactions for the group. Prior to that he served at Deutsche Bank in a business development role.

Bayer

WOLFGANG NICKL

Bayer has appointed a new chief financial officer in the form of **Wolfgang Nickl** who will take over from Johannes Dietsch on June 1, 2018. Nickl has already been the CFO of several companies in the United States and the Netherlands, and is currently executive VP and CFO at Dutch lithography firm ASML. Outgoing CFO Dietsch announced that he would be leaving Bayer at his own request.

Ipsen

IAN WEATHERHEAD

Ipsen has appointed **Ian Weatherhead** as vice president, corporate external communications. He brings 20 years of corporate communications experience within the life science sector, most recently at Teva UK and Ireland where he led its corporate communications and government affairs team. Prior to that he has held global, regional and affiliated roles with AstraZeneca, Syngenta, UCB and Sanofi.

Voyager Therapeutics

MATTHEW OTTMER

Voyager Therapeutics has appointed **Matthew Ottmer** as its new chief operating officer. Ottmer has 18 years' experience in biotechnology, including leadership of business operations, product development, and commercialisation across multiple therapeutic areas. He joins Voyager most recently from Momenta Pharmaceuticals, where he was chief operating officer. Prior to Momenta, Ottmer spent 16 years at Biogen.

Bayer

DR SHARON JAMES

Bayer has appointed **Dr Sharon James** as head of global innovation and development for consumer health, following the retirement of her predecessor Dr John O'Mullane. Dr James joins from Reckitt Benckiser, where she mostly recently held the position of senior vice president, head of global research and development at the company's global headquarters in Slough, UK. She has also previously held various senior roles for PepsiCo and GSK.

Bristol-Myers Squibb

KAREN VOUSDEN

Cancer Research UK's **Karen Vousden** is set to join Bristol-Myers Squibb's board of directors in January. Vousden is currently chief scientist at research charity and patient group Cancer Research UK, as well as serving as group leader at the Francis Crick Institute in London, and will also sit on the pharma firm's Science and Technology Committee. She has more than 30 years' experience in cancer research.

Rubius Therapeutics

CHRIS CARPENTER AND JOANNE PROTANO

Former GlaxoSmithKline senior vice president and head of cancer epigenetics, **Chris Carpenter** has taken up the chief medical officer position at Cambridge, Massachusetts-based Rubius Therapeutics. **Joanne Protano** also moves from her previous role as senior vice president of finance from Flagship Pioneering to take up the role of vice president of finance at Rubius.

Bicycle Therapeutics

MARIA KOEHLER

Bicycle Therapeutics has appointed **Maria Koehler** as its chief medical officer, a role that will see her lead clinical strategy and oversee operational functions for the biotech's clinical development team. Koehler has two decades of industry experience and joins from Pfizer, where she was VP of strategy, innovation and collaborations for its oncology business unit. She has also worked at GlaxoSmithKline and AstraZeneca.

Synthego

SIR ANDREW WITTY

Genome engineering solutions provider Synthego has appointed former GlaxoSmithKline chief executive **Sir Andrew Witty** to its advisory board. Witty led GSK from 2008-2017, when he was succeeded by Emma Walmsley. Witty brings more than 30 years' experience to Synthego - all of it accrued at GSK. He has also recently taken up a role as a venture partner at biotech venture capital firm Hatteras Venture Partners.

Medicxi

MONCEF SLAOUI

Medicxi has appointed former GSK chairman of pharmaceutical R&D, vaccines **Dr Moncef Slaoui** as its new partner. Dr Slaoui takes on the role alongside his other board positions, which see him serve at companies such as Galvani Bioelectronics, Moderna Therapeutics and Sutovax. His experience includes medical and scientific leadership gained during his 28 years at GSK, from where he retired in 2017.

Turnstone Biologics

KRIS ELVERUM AND JOSÉ OTERO

Canadian immuno-oncology company Turnstone Biologics has appointed **Kris Elverum** as its chief business officer. He has over 12 years' pharma and biotech experience. The company has also appointed **José Otero** as its vice president, manufacturing and CMC following his 15 years experience in the industry. He has previously worked for Merck & Co and Seres Therapeutics.

Vertex

TOM GRANEY

Tom Graney has moved from Ironwood Pharmaceuticals to Vertex to become its chief financial officer. His responsiblities at the Boston-based biotechnology firm will include the development and execution of its financial strategy and operations. Graney spent three years at Ironwood Pharmaceuticals as its chief financial officer and prior to that he served at Johnson & Johnson, where he was CFO for its Ethicon business.

TiGenix

DR GREGORY GORDON AND ANNETTE VALLES-SUKKAR

TiGenix has appointed **Dr Gregory Gordon** (pictured) to head its US medical department. The group has also appointed **Annette Valles-Sukkar** as associate director, clinical projects. Dr Gordon joins from Nestlé Health Science, where he was global clinical affairs lead, gastrointestinal health. Meanwhile, Valles-Sukkar arrives from Alexion, where she was responsible for clinical trial development.

NDA

DR PAULA SALMIKANGAS

UK-headquartered regulatory affairs consultancy the NDA Group has appointed **Dr Paula Salmikangas** as a director. She is the former chair of the EMA's Committee for Advanced Therapies and comes to NDA from the Finnish Medicines Agency, where she served as a research professor. She has also served as an adjunct professor of biochemistry for the University of Helsinki since 2006.

Envigo

LIZANNE MULLER

Contract research organisation Envigo has appointed **Lizanne Muller** as president of its EMEA operations. She brings 18 years' experience working within a multinational pharmaceutical manufacturing company, with 16 years spent at the Dishman Group serving in a variety of roles. Muller will be accountable for Envigo's contract research services and research services models operations across Europe and Asia.

Incisive Health

PROFESSOR SIR MIKE RICHARDS

UK health policy consultancy Incisive Health has recruited the UK's former chief inspector of hospitals **Professor Sir Mike Richards** as senior counsel to bolster its advisory team. Sir Mike led the development and implementation of the NHS Cancer Plan in 2000, the Cancer Reform Strategy in 2008 and Improving Outcomes: A Strategy for Cancer in 2011. At the group, he will work alongside Richard Douglas.

Oxford BioDynamics

PAUL STOCKDALE

Paul Stockdale has joined Oxford BioDynamics as its new chief financial officer and as an executive director on the UK biotech's board. He takes over from Katie Long, who has returned to her role within Tessera Investment Management having previously established and led Oxford BioDynamics' finance function. Stockdale arrives at the company from e-Therapeutics, where he had been financial controller since 2012.

Nektar Therapeutics

JEFF AJER

Nektar Therapeutics has appointed **Jeff Ajer** as its independent director to the company's board of directors. Ajer's expertise includes driving commercial operations within rare diseases and speciality medicines and he joins the group from BioMarin, where he served as an executive vice president and chief commercial officer. There he worked on establishing BioMarin's global footprint and commercial infrastructure.

Teckro

DANA POFF

Life science technology group Teckro has appointed **Dana Poff** as its new chief operating officer. She brings 28 years of experience in healthcare and clinical research to the role and joins the Limerick, Ireland-based group from ICON. During her time at the clinical research organisation Poff held leadership roles in clinical operations, project management and alliance management, most recently as its chief of staff.

Rubius Therapeutics

MARK BOSHAR AND THEO PROUKOU

Mark Boshar has joined R**ubius Therapeutics** as its new VP of regulatory affairs. His experience includes establishing the legal department at Millennium Pharmaceuticals - now Takeda Oncology. **Theo Proukou** also joins Rubius as VP of human resources, bringing nearly 20 years of pharma and biotech experience to the group, during which he spent 16 years at Novartis.

Appointments

Tonic Life

ANN BARTLING

Tonic Life Communications has appointed **Ann Bartling** as managing director, EU, based at the healthcare public relations and communications agency's European headquarters in London. She brings more than 25 years of experience to her new role, most recently gained at Edelman, where she led that agency's UK and European health practice. She will lead Tonic's European offering and provide strategic counsel.

Medmeme

FRANCO BARBALINARDO

Medmeme has appointed **Franco Barbalinardo** as its senior VP for sales and business, following more than 20 years' healthcare experience. Barbalinardo's expertise spans across the commercial, analytics, medical affairs, R&D and life science functions. He joins the group from Carson Analytics, where he was senior vice president of sales and marketing, responsible for rebranding and relaunching the company.

Wilmington Healthcare

GARETH THURSTON

Wilmington Healthcare has appointed **Gareth Thurston** as an account director to oversee a number of key accounts across its portfolio. Thurston moves to the UK healthcare intelligence firm from Cello Health Consulting, where he was a consultant. He has nearly 30 years of experience in the healthcare industry, and prior to his time with Cello he spent almost 10 years with Novartis in the UK.

Healthcare Research Worldwide

PAUL BOYCE, LISA LOGAN AND YULIYA FONTANETTI

Healthcare Research Worldwide has strengthened its global management team with the addition of new hires. **Paul Boyce** joins as its vice president for the US team following his previous roles at GfK Healthcare and Ipsos Healthcare. **Lisa Logan** also joins the US office as its associate vice president and **Yuliya Fontanetti (above)** joins its London office in a newly created role as head of operations.

Conversis

JAMIE NEWALL

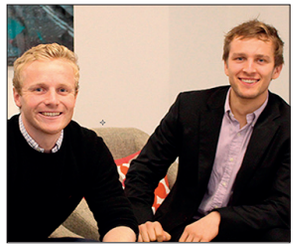
Oxfordshire, UK-based translation company Conversis has appointed **Jamie Newall** as joint chief executive officer as it seeks to enhance its executive team. Newall previously held a number of senior global executive roles in the private equity, finance and natural resources sectors. In his new role Newall will join the board of directors and will work alongside Conversis' founder and current CEO Gary Muddyman.

Hive Health

MIKE WALKER

Hive Health has appointed **Mike Walker** as director of brand development. He brings over 25 years of global and local brand development expertise, most recently from BBH London, where he served as a creative director working on global healthcare business. Prior to his time at BBH Walker served at the likes of Saatchi & Saatchi Healthcare, Grey Healthcare and McCann Erickson Healthcare.

Emotive



ROB MACKICHAN AND NICK GREENWAY

Communications agency Emotive has strengthened its client services team with the addition of two new hires. Biology graduate **Rob Mackichan** joins the agency as an account manager after experience working with infectious diseases, rare diseases and medical devices. **Nick Greenway** joins the team as a senior account executive, bringing experience in healthcare comms, med ed and PR.

NDA

DR WERNER VAN DEN EYNDE

Regulatory affairs consultancy group NDA has appointed **Dr Werner Van den Eynde** as its new vice president to head its advisory board providing strategic advice to pharmaceutical clients during its drug development life cycle. Eynde comes to the Swiss group with international pharmaceutical experience, having held senior positions for the likes of GE Healthcare, Abbott and Solvay Pharmaceuticals.

Ascom

LJUBISAV MATEJEVIC

Healthcare ICT solutions provider Ascom has appointed **Ljubisav Matejevic** as vice president, global ecosystem of central and eastern Europe. His new role will see him take the helm of the group's sales team, market development and business strategy. Matejevic comes to the group from Healthcare and Life, Science and Public Health where he managed Global E-Health Forum to generate cooperation across IBM's strategic partners and stakeholders.

Adelphi Research UK

MIKE PICKERING, SEB NEWTON, HANNAH STEVENSON

Adelphi Research hires six new starters. **Mike Pickering** joins as its associate director from Harris Interactive and arrives with 15 years' experience in the sector. Research executive **Seb Newton** joins following a research role in the education sector. **Hannah Stevenson** joins the team from Adelphi Communications where she was working as an associate client services manager.

Makara Health

HELENA WRIGHT AND GINA DOOTSON

Makara Health has appointed **Helena Wright** as its associate director, client relations. Wright joins from Havas Life Medicom, where she was associate director for its PR team. She has previously held roles with GSK and Alliance Healthcare. Also joining the team is **Gina Dootson**, who takes up a senior medical writer role following eight years of medical writing experience.

Akari Therapeutics

DAVID HORN SOLOMON

Akari Therapeutics has appointed **David Horn Solomon** as its CEO, a role that will see him take the helm of the biopharma as it focuses on the development and commercialisation of orphan autoimmune and inflammatory disease treatments. His other roles have included CEO of Bionor Pharma and most recently he was at Nordic healthcare investment group Sund Capital as its managing partner.

Top job this month

Exciting Senior Product Manager - Cardiovascular

Full-time • London • Competitive Salary & Bonus

This award-winning pharmaceutical organisation was recently voted as one of the best companies to work for thanks to their very open, people-focused culture and flexible working environment. Their medicines are diverse and their best-in-class therapy areas include oncology, HIV, psychiatry, diabetes, hepatitis and transplantation.
An exciting opportunity is now available for a strong pharmaceutical marketing professional to work as a senior product manager in their Cardiovascular business unit.
Based in their west London offices, you will be providing strategic and tactical leadership, developing an annual brand plan and maximising digital channels and platforms.

October highlights*

Brand Lead - Respiratory
Full time • South East England
An exciting role exists for a brand lead to work on a highly successful respiratory brand. You will support the development of brand strategy and lead the implementation of tactics through the account teams.

Scientific Director
London, Europe • Neg salary
If you have a strong strategic and scientific background and are able to translate complex scientific concepts into something the average Joe can understand, this is the role for you.

Freelance or permanent Senior Director - Healthcare PR
London • £65,000 to £90,000 per annum
Fantastic new opportunity exists for a seasoned healthcare PR professional to take on a senior director role which will be heavily focussed on new business development.

Senior Manager - External Communications
London • £70,000 to £80,000 per annum
A large pharmaceutical company based in the London area is currently looking for a senior manager to join their communications team.

Business Unit Director, Creative Healthcare Communications Agency
London • £70,000 to £80,000 + Bonus+ Benefits
Are you an associate director looking for early promotion or a business unit director in a healthcare communications agency who wants a new challenge?

Editorial Director, Medical Communications
London
Excellent package
Excellent career advancement managing the editorial team in this expanding, respected agency.

Managing Director - Healthcare Market Research
London • Neg salary
This is a truly exciting opportunity to join a business that offers their clients the opportunity to gain a truly unique insight into building strong brands.

Medical Writer, Healthcare Advertising Agency
London • £30,000 to £35,000 + benefits
This ever-evolving, innovative healthcare advertising agency is seeking a talented senior medical writer to bolster their successful team.

Senior Medical Writer, Medical Communications
London
Excellent package
Successful, expanding agency with excellent career opportunities.

Account Director
London • £40,000 to £45,000 per annum
It is an exciting time for this agency as recent pitch wins mean that their team is expanding, which is the reason why they are in need of an established account director to join their ranks.

Interim Client Services Director
London • £80,000 to £90,000 per annum
The opening will involve heading an integrated healthcare communications team which offers a range of services across medical education and digital. This is a 6-9-month maternity contract from January 2018.

Product Marketing Specialist
Cambridge • Competitive Salary & Package
Based in their global HQ in Cambridge, this new role will support the company's US-based in-vivo research model product and service activities, as well as other cross-category campaigns.

*100's of live vacancies with more added daily

- **152** Medical communications
- **110** Healthcare PR
- **81** Medical writing
- **36** Healthcare market research
- **51** Pharmaceutical
- **14** Market access
- **125** Medical education
- **85** Healthcare advertising
- **44** Healthcare consultancy

Pharma marketing, sales & communications jobs

jobs.pmlive.com

*Job numbers were correct as of 4/10/17

*Featured jobs were live as of 4/10/17

CSOh!

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